BewellConnect Logo

Picture cover

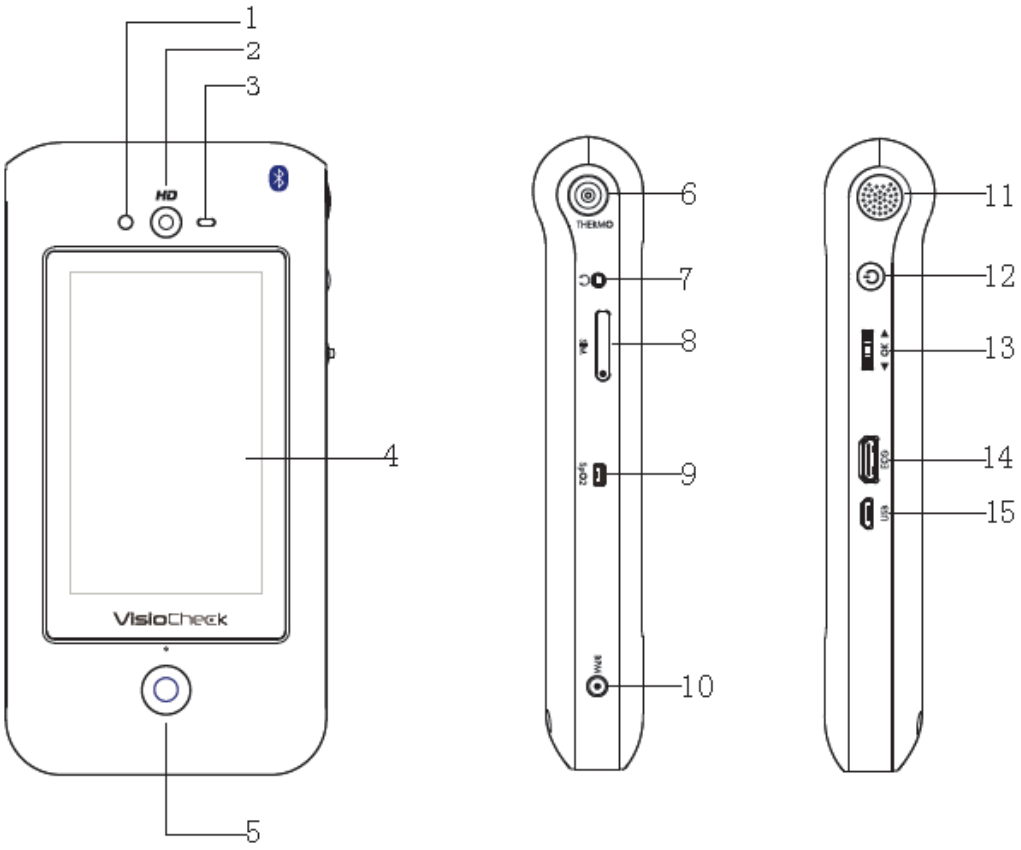
REF PRODUCT+CE+pictos

VisioCheck

By Visiomed

DIAGRAMS

Diagram A



1) **LED (Flash)**
2) **HD Camera**
3) **Indicating light**
4) **Display screen**
5) **Home button**
6) **Infrared probe**
7) **Earphone port**
8) **SIM card tray**
9) **SpO2 port**
10) **BPM port**

11) Speaker
12) On/Off button
13) Up/down wheel (OK Button)
14) ECG port
15) USB port

Diagram B

Accessories picture

Diagram C **Diagram D** **Diagram E**

Diagram F

ECG Connexion Diagram

Thermometer Diagram

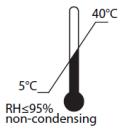
SpO2 Connexion Diagram

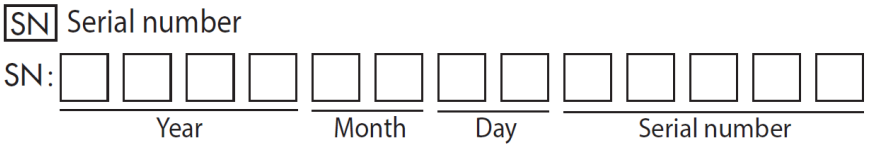
BPM Connexion Diagram

+ rating label

SYMBOLS DEFINITION

CE	CE marking
	Caution
	Refer to instruction manual. Note on the equipment "Follow instructions for use".
	Type BF applied part
	The device, accessories, and the packaging have to be disposed of correctly at the end of usage. Please follow local ordinances and regulations for disposal.
	Pulse frequency
PRbpm	Pulse Rate (BPM=beats per minute) - Heart rate monitoring
SpO_2	Checking oxygen saturation in blood
	No SpO_2 alarm
	Continuous readings
	Mesure automatique
	Direct current
	Protected against sold foreign objects of 12,5mm and greater; Protected against falling water drops (≤15° tilted).
	Authorized representative in the European community
	Manufacturer
	Device conforms to RoHS requirements
	Low battery
	Do not reuse
SN	Serial number

	Type CF applied part
	Power - Back button
	Storage temperature and relative humidity



TECHNICAL DEFINITIONS

ECG or EKG : Electrocardiogram

SpO2: Blood oxygen saturation

MRI: Magnetic resonance imaging

RF: Radio Frequency

EMC: Electromagnetic Compatibility

PVC: Polyvinyl chloride

ABS: Acrylonitrile Butadiene Styrene

TPU: Thermoplastic Polyurethane

ISM device: Industrial, scientific and medical device

CISPR 11: International Standard for electromagnetic emissions (disturbances) from industrial, scientific and medical (ISM) equipment

MAM: Mean Arterial Measurement

MAP: Mean arterial pressure

SBP: Systolic Blood Pressure

DBP: Diastolic Blood Pressure

PI : Perfusion index

Language

Logo BewellConnect COVER

VisioCheck

Picture of product

CE + Pictos + Ref product

By Visiomed

This product is a medical device, class IIa, compliant with European directive and part 15 of the FCC rules.

TABLE OF CONTENTS

Log onto our website to find out how to use VisioCheck

www.bewell-connect.com/install

The manufacturer reserves the right to change the product's technical specifications without prior notice.

Dear customer,

Thank you for purchasing the HandHeld VitalSigns Monitoring System VisioCheck. Please read this guide prior to device use.

This device is not intended for use as a conventional diagnostic tool, but it is a healthcare tool which can provide a doctor the recorded data as a reference to help evaluate the patient's health. It must be used in conjunction with other devices to evaluate symptoms and clinical signs.

For further information about the health or specific measurements, PLEASE CONTACT A DOCTOR.

1. Notes on safety

- The equipment must be used per the requirements of this manual. Failure to properly use the equipment may result in degraded performance, loss of functionality, measurement abnormalities and equipment damage. The manufacturer assumes no responsibility for personal injury or device damage sustained by or through the use of this product.
- This device is intended to monitor patient's physical index at home, hospital, hospital facility or other outdoor situation. Do not use for any other purpose.
- This product should not encourage self-medication or adaptation of the treatment.
- Always consult the doctor if the patient has any questions or he believes he has abnormal measurements. The measurement results are given for information
- Do not take measurements in a moving vehicle.
- Stop use of the device in case of anomalies or malfunction.

Visiomed and Bewell Connect Corp are not held liable for any problems resulting from failure to observe the installation and operating rules stated in these directions for use.
Visiomed and Bewell Connect Corp are not held liable of the use with incompatible components which can result in degraded performance.

Warning

- This device must always be placed in a clean and dry place.
- This device is not designed for use by people (including children) with reduced physical, emotional or mental abilities or those lacking experience or knowledge unless used in the presence of someone responsible for their security, under supervision or following instructions about how to use the device.
- Do not use the ECG function while charging the device because of the risk of electric shock.
- Do not use the ECG with a cardiac pacemaker or defibrillator.
- The protective glass over the lens is the most fragile part of the thermometer. Do not touch the glass of the infrared lens with your fingers.
- Do not insert other objects into any holes.
- Do not use accessories, detachable parts and materials not described in the instructions for use
- Do not use sharp tools to operate any of the buttons.
- Do not interconnect this device with other equipment not described in the instructions for use
- Do not open, disassemble, repair or modify the device. In case of problems, contact customer service.
- Do not expose the device to static electricity. Disperse static electricity from your body before handling the device.
- Do not use near flammable anesthetics, or near pressurized oxygen such as in a hyperbaric chamber, ultraviolet sterilizer or oxygen tent.
- Do not expose the device to strong shocks, vibrations, electric shocks, sunlight or water. Never drop the device.
- Do not operate the device if it has been immersed in liquid
- Follow the maintenance instructions specified in this manual.

- This electrical medical equipment requires specific precautions regarding electromagnetic compatibility. It must be installed and used in accordance with EMC (Electromagnetic Compatibility) Information.
- Mobile and portable RF communications equipment may affect the equipment. The equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment as recommended below, according to the maximum output power of the communications equipment.
- The received signal may be interfered/disrupted by other equipment operating in this frequency band (i.e. Bluetooth, other non-associated access points, microwave ovens, ISM devices, etc) even if the other equipment complies with its applicable regulations such as CISPR 11.

- Use this device in an ambient temperature range of 5 to 40°C / 41 to 104°F.
- Avoid using the device immediately after a significant change in temperature or humidity.
- Do not expose this device to extreme temperature conditions > 50°C (122°F) or < -10°C (14°F).
- Do not use this device at a relative humidity of more than 95%.
- Do not use the device out of the required condition to avoid inaccurate measurement.
- The values displayed by the device are the ones obtained at the time of measurement. Medical conditions can change suddenly. If you notice any change in your condition, consult a doctor, regardless of the measured results.
- Do not use the device for measurements when the battery power is lower than 15% or 3.5V.
- Be careful about the small parts broken off the device, as children may swallow and it could lead to suffocation.
- When the screen displays the battery symbol  , this indicates that the battery is low and you should charge the product through our adapter as soon as possible.

1.1. ECG cable/lead-wires and SpO2 adapter cable

- As with all medical equipment, carefully place cables to reduce the possibility of patient entanglement or strangulation.
- Do not use the cables during MRI scanning. Conducted current could cause burns.
- Do not use the ECG function during charge of the device. Risk of electric shock
- Do not use the ECG with a cardiac pacemaker or defibrillator.
- Do not use lotion or oil prior to the test. Skin must be clean and dry.
- This product is not suitable for PVC, TPU and ABS plastic allergy patients and users.
- The ECG cable/lead-wires and SpO2 adapter cable are designed for use with VisioCheck
- Do not use the ECG cable/lead-wires and SpO2 adapter cable if the cable, wires and connector are broken or damaged.

1.2. Reusable Blood Pressure Cuff for adults

- When the cuff is not connected to monitor, always fit cap to tubing to prevent accidental entry of liquid.
- Periodically inspect and replace damaged or deteriorated cuffs.

- Only use the appropriate size cuff when the artery index marker falls within the printed range, Otherwise erroneous readings may result.

Principle of operation

This device adopts the oscillometric technology with Fuzzy Algorithm to measure the arterial blood pressure and pulse rate. The cuff is wrapped around the arm and automatically inflated by the air pump. The sensor of the device catches weak fluctuation of the arm in response to each heartbeat. The amplitude of the pressure waves is measured, converted in millimeters of the mercury column, and is displayed by digital value.

1.3. Finger Clip SpO2 Sensor for Adult

- Probes are designed for use with VisioCheck. Do not use them with other device.
- Using the sensor in the presence of direct sunlight may result in inaccurate measurements. In such cases, put the receiving surface of the sensor back to ambient light sources (such as fluorescent lamps) or cover the sensor with a black cloth after removing the sensor from the patient's body in order for the monitor to displaySpO2 value, pulse rate value and their waveforms.
- Reusable sensors must be moved to a new site on the patient at least every 4 hours. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients. If skin integrity changes, move the sensor to another site.
- Intravascular dyes may lead to inaccurate measurements.
- The performance of the sensor is compromised by motion.
- Do not apply tape to secure the sensor in place or to tape it shut; venous pulsations may lead to inaccurate saturation measurements.
- As with all medical equipment, carefully place cables to reduce the possibility of patient entanglement or strangulation.
- Do not use the sensor or other oximeter sensors during MRI scanning. Conducted current may cause burns. Also, the sensor may affect the MRI image, and the MRI unit may affect the accuracy of oximeter measurements.
- Do not alter or modify the sensor. Alterations or modifications may affect the performance or accuracy.
- Do not use if the wire or the shell of connector is broken or damaged.
- Sterilize using ethylene oxide only.
- The MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided at the end of this user manual.
- Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.
- The equipment is without a manual sensitivity adjustment. The minimum amplitude or value of patient physiological signal is 70% SpO2. Operation of the EQUIPMENT or SYSTEM below this amplitude or value may cause inaccurate results.
- The use of accessories, transducer and cables other than those specified, with the exception of those sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased EMISSION or decreased IMMUNITY of the EQUIPMENT or SYSTEM.

- Be aware that following removal of the sensor from the patient, it is possible that environmental light may cause the monitor to continue to display a waveform or data values but these are not a basis for a clinical diagnosis.
- Make sure the application site for the sensor is not deeply pigmented, or deeply colored. For example, nail polish, artificial nails, dye or pigmented cream may cause inaccurate measurements. In any of these cases reposition the sensor or choose an alternative sensor for use at a different site.
- Protect the sensor and connector from becoming soaked with any liquid. Do not immerse the sensor or connector in any cleaning solution, disinfectant, or other liquid (the sensor and connector may be wiped with cleaner and disinfectant but never immersed).
- Where possible, the application site for the sensor should be an extremity free of arterial catheters, blood pressure cuffs, or intra-vascular infusion lines.
- At elevated ambient temperatures, patient skin could become severely burned after prolonged sensor application on sites with poor blood circulation. To prevent this condition, be sure to check patient application sites frequently. All listed sensors operate without risk of exceeding 41℃ /105.8°F on the skin if the initial skin temperature does not exceed 35℃/95°F.
- The waste of the pulse oximeter probe must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative for information concerning the disposal of your equipment
- A warning to the effect that misapplication of a pulse oximeter probe with excessive pressure for prolonged periods can induce pressure injury.

1.4. FCC statement

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

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.

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 con nected.

– Consult the dealer or an experienced radio/TV technician for help.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End user must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

The device is designed to meet the requirements for exposure to radio waves established by the Federal Communications Commission (USA). These requirements set a SAR limit of 1.6 W/kg averaged over one gram of tissue. The highest SAR value reported under this standard during product certification for use when properly worn on the body is 1.250W/kg.

For body operation, this device has been tested and meets FCC RF exposure guidelines when used with any accessory that contains no metal and that positions a minimum of 5mm from the body. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

2. Information

VisioCheck® is a four in one handheld, smart and connected medical device, designed for the remote monitoring of vitalsigns and telemedicine, by health professionals and patients. The product combines a blood pressure monitor, a pulse oximeter, an electrocardiograph (5 electrodes, 7 leads), and a non-contact infrared thermometer.

VisioCheck software is an embedded software which provides multiple services. It is applicable for home care, hospital and other remote and mobile situations. The software can be used by healthcare professional providers or patients, to monitor vitals. Medical data can be stored locally and a reports can be sent through WiFi, 3G or 4G.
It is designed to be easy to use to take measurements and share results accross long distances.
VisioCheck allows the user to communicate with their health professional through an HD video conferencing system but cannot be used as a phone (no voice-only IP connection, only M2M sim cards)

3. Features

The devices used with the application include:

-> Non-Contact Thermometer based on a miniature version of Visiomed's ThermoFlash® technology
-> Blood Pressure Monitor (and pulse rate)
-> 5 electrodes and 7 leads ECG (and pulse rate)
-> Pulse Oximeter (and pulse rate)

4. Description

View diagram A page 2

Accessories

View diagram B page 2

1) BPM Cuff *1
2) SpO2 Adapter Cable *1

3) SpO2 universal sensor connector *1
4) ECG 5-Electrode Cable*1
5) Infrared Probe Cover*1
6) USB Cable*1
7) Adapter*1

5. Precautions before use

Before using the VisioCheck,

- Do not confuse self-monitoring with self-diagnosis. Measurement should only be interpreted by a health professional who is familiar with your medical history.
- If you are taking medication, consult with your physician to determine the most appropriate time to measure your vital signs.
- This device should not encourage self-medication or adaptation of your treatment. NEVER change a prescribed medication without first consulting with your physician
- This device is designed for use by adults only. If using the device on a child, toddler or elderly patient, please consult with your physician first.
- Check that the accessories are intact and clean.
- Always consult your doctor with any medical questions.

Adhere to the temperature ranges and humidity levels shown in the specifications.

5.1. Precaution before use ECG

- Low battery may affect the accuracy of heart rate measurements.
- Do not use this device near an Electrosurgical Unit (ESU), since it may function incorrectly as a result.
- Do not use the ECG while charging VisioCheck because of the risk of electric shock.
- The electrodes pads are disposable and for single use only

Duration of use: it is recommended to replace the ECG cable every 6 months. If it is necessary to use, please evaluate the period of use, it should be regularly inspected.

5.2. Precaution before use Oximeter

- Do not use this device near an Electrosurgical Unit (ESU), since it may function incorrectly as a result.
- The pulse oximeter must be placed so that the pulse can be recorded correctly and the main objective is to evaluate the oxygen saturation (SpO2) level. Check that nothing is interfering with the readings.
- Do not use the device in an MRI (Magnetic Resonance Imaging).
- Do not use the device in an explosive atmosphere.
- Frequently check (every 30 minutes) on the application zone of the device sensor (checking for signs of skin sensitivity, change in position, etc.).
- The device must not be used near or on top of another device.
- Inaccurate readings may result from:

-> Nail-polish (colorimetric interference) or artificial nails
-> High levels of dysfunctional hemoglobin (carboxyhemoglobin or methemoglobin)
-> Intravascular dyes (indocyanine green or methylene blue)
-> Bright light. If necessary, protect the sensor positioning area
-> Excessive movement of the patient
-> Defibrillators and interference from high-frequency electrosurgical devices
-> Venous pulse
-> Placing the sensor on a patient with a blood-pressure cuff, an arterial or intravascular catheter
-> High blood pressure, severe vasoconstriction, acute anemia or hypothermia
-> Heart failure or stress
-> Poor pulse quality (low blood flow)
-> Low levels of hemoglobin.

Duration of use: It is recommended to replace the SpO2 adapter cable every 6 months. If it is necessary to use, please evaluate, and the period of use should be thoroughly inspected.

5.3. Precaution before use Blood pressure monitor

Blood pressure measurements determined by this monitor are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard Institute, electronic or automated sphygmomanometers.
Reference: Association for the Advancement of Medical Instrumentation. American National Standard. Manual, electronic or automated sphygmomanometers ANSI/AAMI SP10-2002.

The followings texts are adapted for a personal use of the VisioCheck

Choice of the arm for the blood pressure measurement:

For the first use, it's recommended to take the measurement in both arms. If one arm consistently has higher blood pressure than the other (> 10 mmHg in US or > 20mmHg in Europe), that arm should be used to measure your blood pressure except in the event of contraindications (e.g. fistula, ganglion) in this arm. If there is no difference in readings, the readings are often more easily taken in the non-dominant arm (left for right-handed, right for left-handed).
Reference: American Heart Association. How to Monitor and Record Your Blood Pressure.
Haute Autorité de Santé. « Prise en charge des patients adultes atteints d'hypertension artérielle essentielle » - Recommandations pour la pratique clinique - juillet 2005

Self-measurement of blood pressure

-Repetition is essential in self-monitoring blood pressure as single measurements are often unreliable for a number of reasons due to huge variations in blood pressure and its susceptibility to factors such as: recent activity, stress and even breathing. Taking 3 consecutive measurements in a row and averaging them provides a more reliable home measurement by a non-professional.
This method comes recommended by the American Heart Association and the European Society of Hypertension.

- The rule of three: 3 measurements recommended while seated, at rest, 3 days in a row:

In the morning before taking medications, 3 consecutives measurements in a row (MAM); In the evening after taking medications, 3 measurements in a row (MAM). A single measurement may not be significant especially in terms of blood pressure self-monitoring.

- Blood pressure self-measurement: the ideal targets for a person with high blood pressure when self-measuring at home are different and lower than those of the American Heart Association (AHA) or European Society of Hypertension (ESH)). These targets depend on age and can vary depending on your health.

General case: SBP* < 135 mmHg and DBP* < 85 mmHg

* *SBP: Systolic Blood Pressure - DBP: Diastolic Blood Pressure*

The aforementioned targets are provided for reference only and need to be rechecked by a doctor.

It is important to check your targets in the event of serious disease or pregnancy.

Before taking measurements,
- Avoid eating, smoking or exercising for 30 minutes prior. Relax for 15 minutes before taking blood pressure.
- Stress increases blood pressure. Avoid taking measurements during a stressful period
- You must take a blood pressure measurement in a calm environment and you must be relaxed and seated with your arm on a table.
- Remain stationary and do not speak while taking your measurement.

Note: For more reliable results, take measurements on the same arm.
Speak to your doctor if you have any questions about using the blood pressure monitor

Duration of use: The Blood pressure cuff is reusable for 1 year.

5.4. Precaution before using of Thermometer

This device is pre-set at the factory. It is not necessary to calibrate it when starting it up.
- In order to obtain reliable and stable results: Each time there is a significant change in the ambient temperature (due to a change in environment), you are advised to allow the VisioCheck thermometer to acclimate to this ambient temperature for 15 to 20 minutes before using it. It is important to allow a one-minute interval between two measurements.

Practical considerations when taking a temperature:
- In order to ensure that precise and accurate temperature measurements are obtained, it is essential that each user has received adequate information and training in the temperature measurement technique when using such a device.
- It is essential to remember that although procedures such as taking a temperature may be simple, they must be followd correctly.
- The patient must not have undertaken vigorous physical activity prior to taking his/her temperature and the room temperature must be moderate.

- Be aware of physiological variations in temperature which must be taken into consideration when evaluating the results: temperature increases by 0.5C° /1.6°F between 6am and 3pm. Women have a temperature that is higher, on average, by around 0.2C°/ 0.4°F. Their temperature also varies in accordance with their ovarian cycle. It rises by 0.5C°/ 1.6°F in the second half of the cycle and at the early stages of pregnancy.
- When sitting, temperature is lower by about 0.3° to 0.4°C/ 0.5 to 0.7 °F than when standing.

Reference: Haut Conseil de Santé Publique : Recommandations sanitaires du Plan national canicule 2014. P123 (French Public Health Council: Sanitary recommendations of the National Heatwave Plan 2014)

6. User guide

6.1. General functions

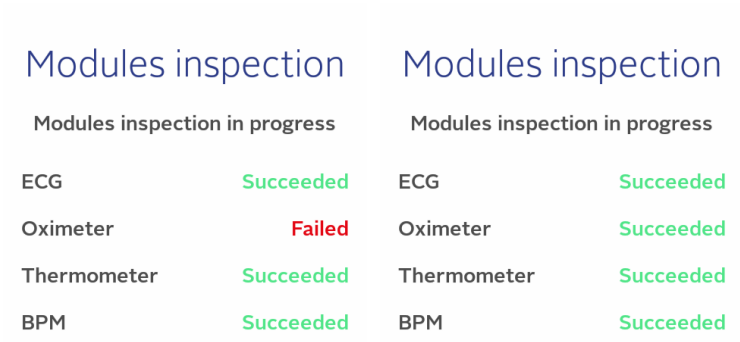
6.1.1. *Start/Shutdown the Device*:

Start: Long press the On/Off button until the display screen is on.
Shutdown: Long press the On/Off button until the display screen is off

6.1.2. Modules inspection

After turning on the device, it performs a module inspection which allow to verify each module functioning before launching the application.

- The status *Failed* means that the module doesn't functions properly, you should not use it. Please contact the customer service.
- The status *Succeeded* means that the module functions properly, it can be used.

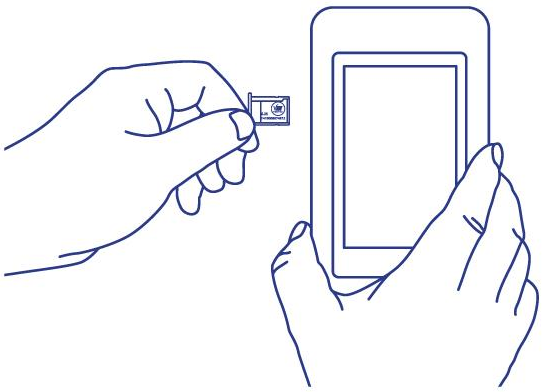


1.1.1. Connect the device to internet

You can connect the device to the internet using a M2M sim card or a WiFi connection.

Note: Connect the device to internet is required for data sharing (see page 20)

1.1.1.1. Sim card Installation

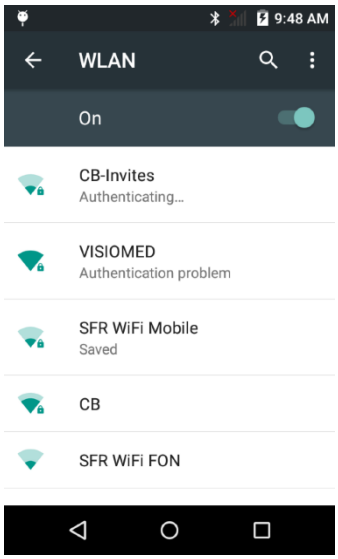


Insert a small paper clip or the sim card eject tool provided into the opening of the SIM tray, located on the side of VisioCheck®. See Diagram A, page 2.
Press lightly to bring out the SIM tray and place the sim card as indicated.
Close carefully.

Note: M2M sim card provided by your retailer.

6.1.2.2 Wifi Connection

Go to the settings parameters of the system. In wireless and networks > WLAN, turn the button ON. The list of available networks will be displayed. Select your secured network and enter the password. Go back to the Application, the device is now connected.

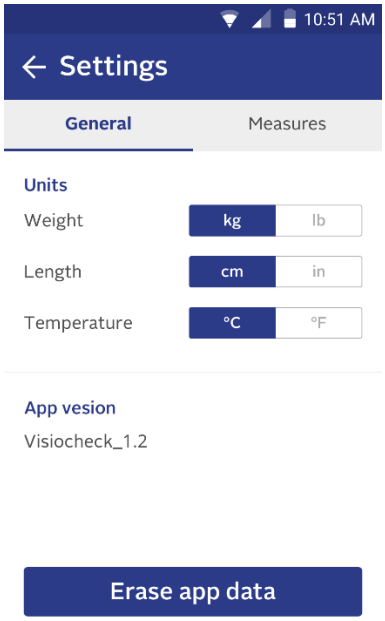


6.1.3. VisioCheck Settings

The VisioCheck settings are defined for all accounts (admin, user)

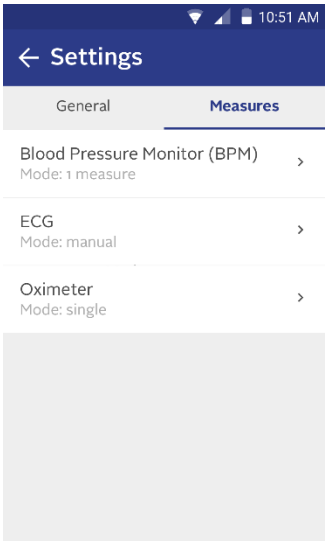
6.1.3.1. General

In the general settings, you can choose the units in which you want to display your measurements.
The Admin can also erase all the previous data saved in the application by clicking on “Erase app data button”.

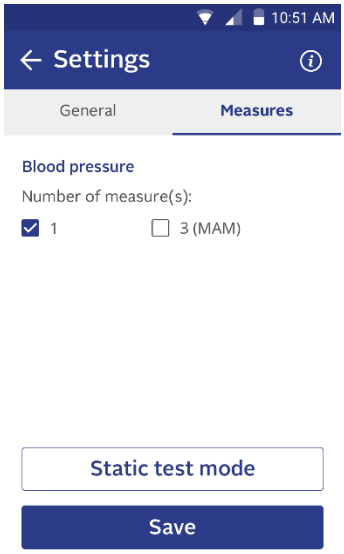


6.1.3.2. *Measures*

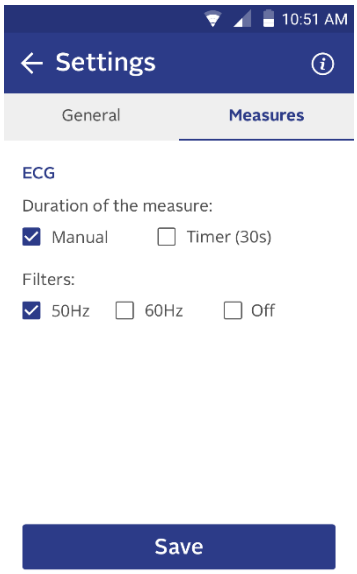
In the Measures setting, you can select the mode you want to use for the measurements. For personal use, we advise you to consult your physician prior choosing the measurements modes.



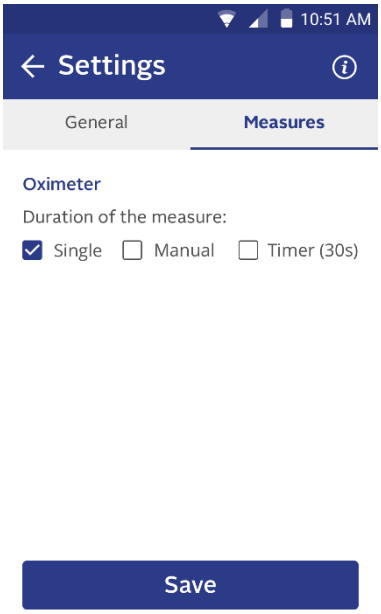
- **For the Blood Pressure Monitor**, you can choose between a simple standard measurement or a triple measurement (Mean Arterial Measurement).
  You can also set a ***static mode*** to simulate a range of normal, hypertensive and hypotensive dynamic noninvasive BP in order to verify if the VisioCheck's blood pressure monitor functions correctly and that the blood pressures values measured are reliable. You'll need a blood pressure simulator and tester for that (not provided).



- **For the ECG,** you can select the duration of the measurement by choosing manual (control the recording time is controlled during the measurement) or timer mode (the recording time is preset for 30 seconds).
  You can also set the filters in three different positions to control the interference of electric current during the tracing ECG: Off, 50Hz (mostly for France and Europe) or 60Hz (mostly for US)



- **For the Oximeter**, you can choose between three different modes: Single (the measurement is instantaneous), Manual (you can control the recording time during the measurement) or Timer (the recording time is preset for 30 seconds).

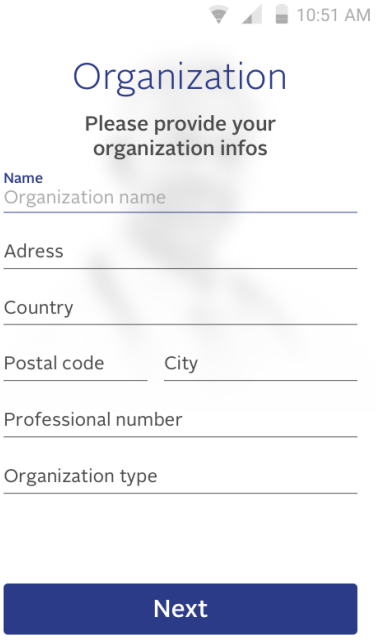


6.1.4. Accounts

The professional use allows you to create and manage several accounts (organization, admin and users accounts)

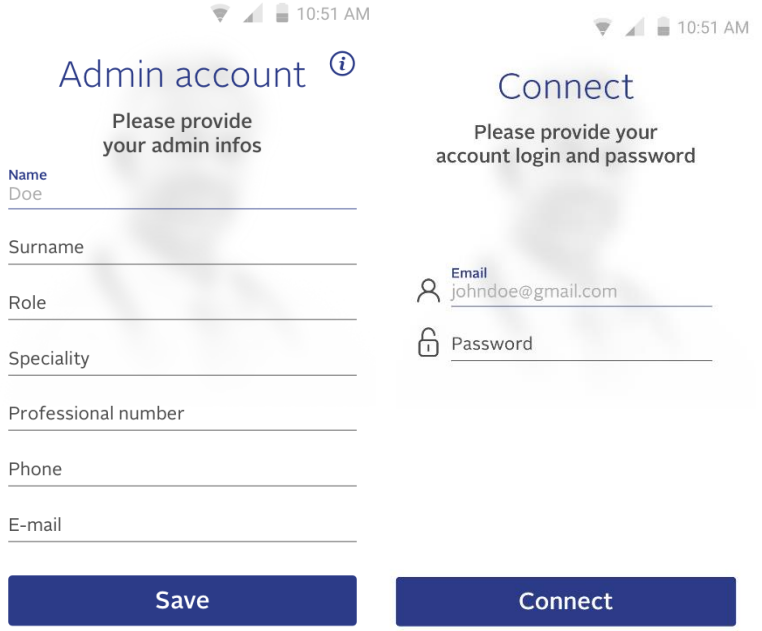
6.1.4.1. Organization

At the first use you need to provide your organization's informations.



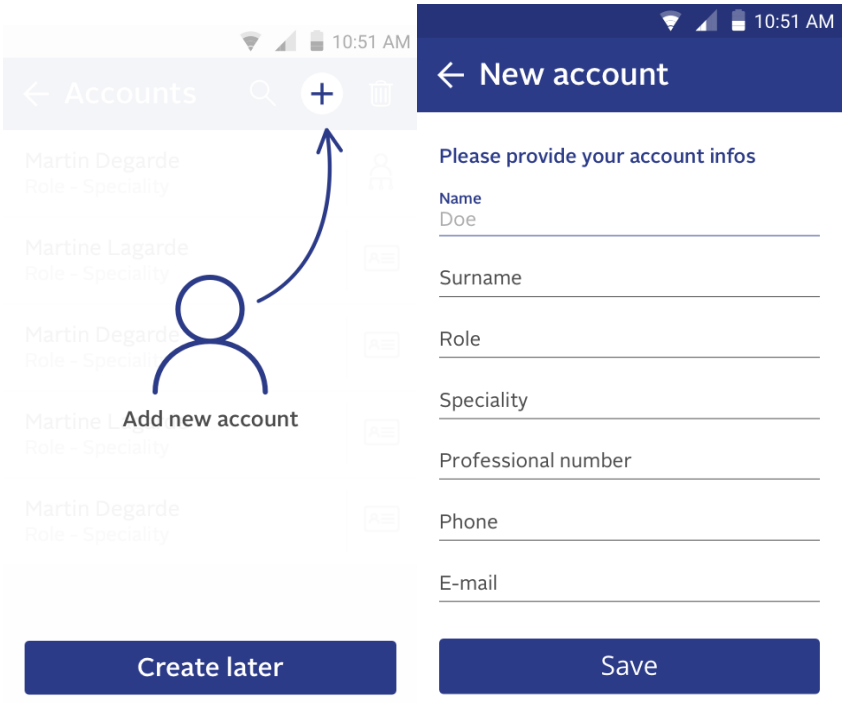
6.1.4.2. Admin account

You need to create an admin account which allow you to create, modify or delete other user accounts. To be connected to your admin account, you will need to provide your email and password.



6.1.4.3. User accounts

As Admin, you can add new user accounts



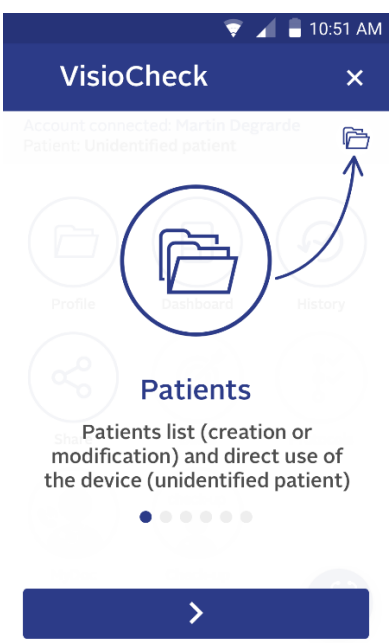
To connect to his account, the user will need his login and password.

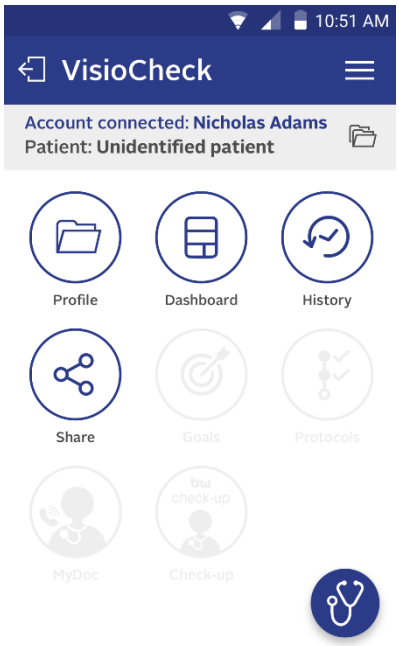
As admin, you can also modify or delete patient's files related to other user accounts.

6.1.5. Patient's file and patient's profile

The Admin or any user account can create a patient's file.

The patient's file include profile, dashboard, history and share options.

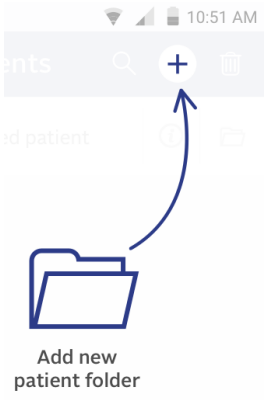




You can also have an unidentified patient file, allowing the user to make measurement without assigning the result to a specified profile. It allows to use the medical device directly and simply.

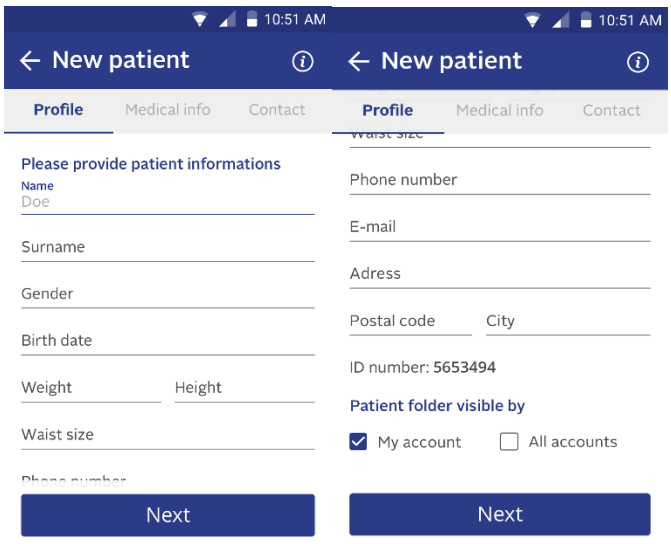
To switch to unidentified patient or another patient's file you can click on the top bar.

6.1.5.1. Patient's profile



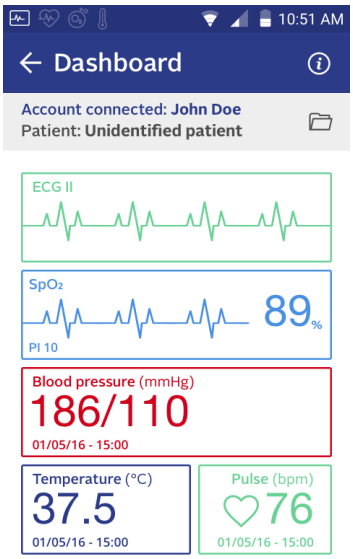
Before starting to monitor a patient, you can create his patient file, and complete his profile with his personal data (medical history, allergy, contact) and choose the visibility of the file. Don't forget to save all the information to have a complete file.

Thereby all the measurements can be saved in the patient's file.



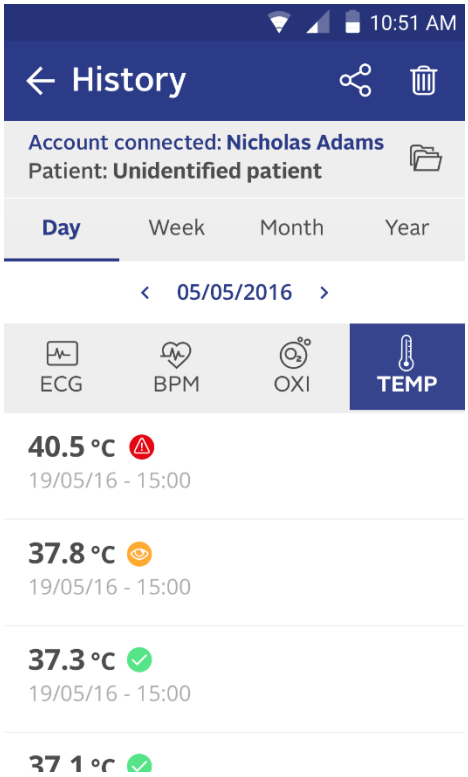
6.1.5.2. Dashboard

The dashboard is the last measurements, done for the patient.
It also allows to view oximeter and ECG recordings simultaneously



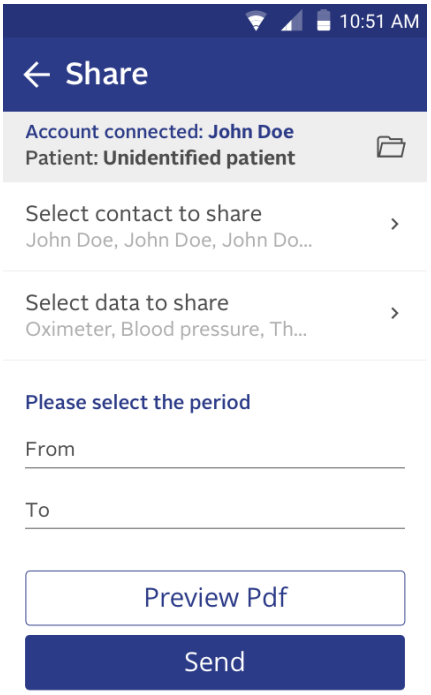
6.1.5.3. View history

The data history can be viewed by day, week, month or year, by selecting the specific date and the specific device (ECG, BPM, OXI or TEMP)



6.1.5.4. Data sharing

You can share the data of a patient with another health professional, a family member, caregiver. For that, the contact information should be pre-saved in the patient profile.



6.2. Taking a measurement

To take a measurement, go to the main screen of your account and click on the stethoscope icon. Then select the icon of the device you want to use.

6.2.1. ECG

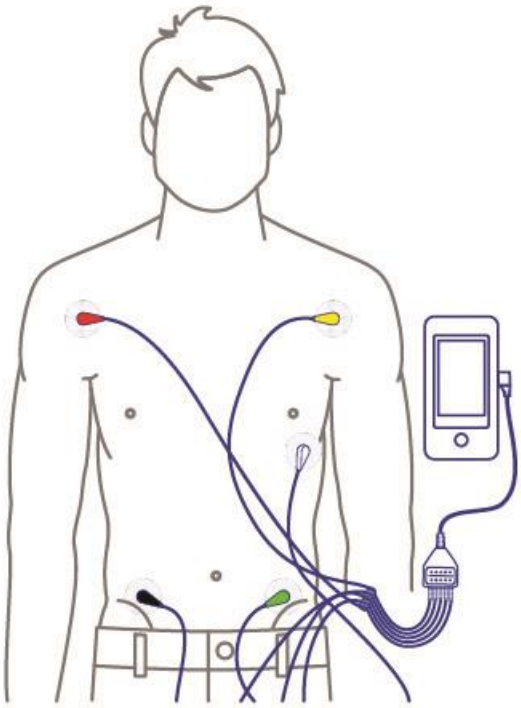
See diagram C page 2

<u>Before taking a measurement</u>

It is recommended to be in a comfortable position (lying flat or sitting), your back straight and in a relaxed position for the full duration of the measurement. Make sure that your chest is free of tension.
Prepare the skin by cleansing and drying the areas where the electrodes will be placed. Typically, 70% alcohol is used for this purpose. Be sure to dry the skin.
If necessary, shave the skin before placing the electrodes.
Avoid skin with scars, wounds, lesions, folds or swelling.
It is recommended placing the electrodes facing a visible bone structure.
The electrodes pads are disposable and for single use only

WARNING: It is strictly prohibited to attach the lead cable electrodes on the patient's body if the lead cable is not connected with the device.
Before you begin a measurement, first connect the lead cable with the device, next attach the lead cable electrodes to your body. After taking a measurement, first remove the lead cable electrode from the body, second disconnect the lead cable from the device.

1) Connect the ECG cable to VisioCheck
2) Stick the electrodes pads to the correct positions (see picture below).
3) Connect the lead-wires set to the electrodes pads.



-> **Red electrode**: Right shoulder or right wrist
-> **Yellow electrode:** Left shoulder or left wrist
-> **Green electrode**: Left ankle or left spine iliac
-> **White electrode**: Two fingers under the nipple (for the woman, if the breast is voluminous, under the fold of the breast opposite the left nipple)
-> **Black electrode:** right ankle or right spine iliac

Taking a Measurement

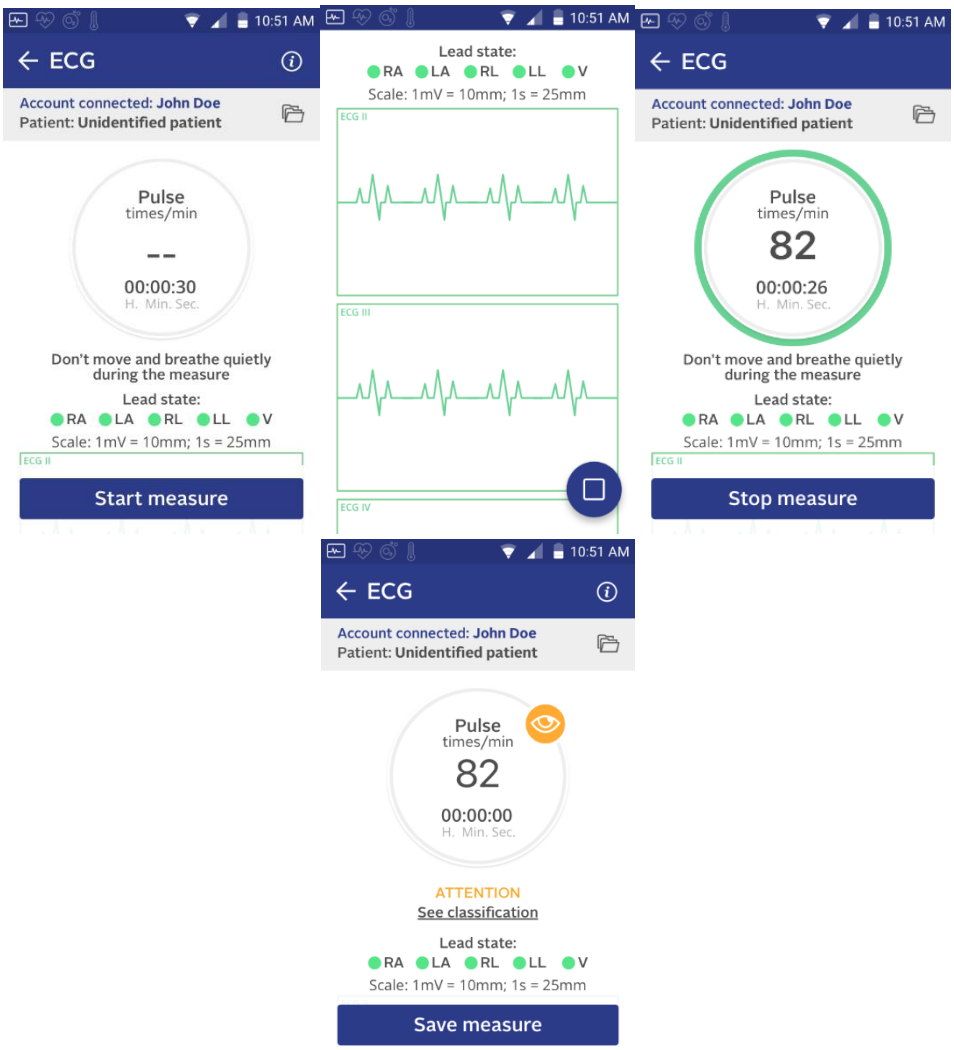
Follow the steps to properly measure and record your data

1) Press “start measure” on the screen of VisioCheck to launch the measurement
2) Click on “stop measure” to stop the measurement and then “save measure”, to save the measurement.

Remain still, and do not flex or move until the recording is complete. If the device senses poor contact or the measurement is interrupted by a hand adjustment, you will need to repeat the recording.

After a measurement, you should first remove the lead-wires from the body, second the cable should be disconnected to the device.

You can take ECG and SpO2 measurements simultaneously, and view them in real-time from the Dashboard.



WARNING: When disconnecting the cable, pull on the plug itself not on the cable.

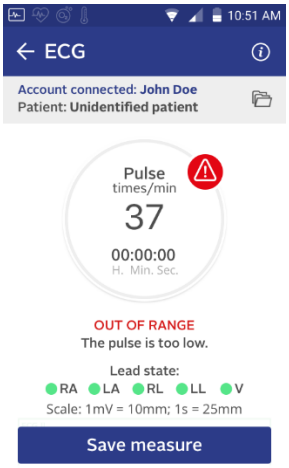
Scale:

Calibration of ECG Signal: 1 mV=10 mm ± 1.0 (in ordinates)

Graph paper unwinding speed: 1s = 25 mm (in abscissas)

Notes about the results

The values for Pulse given by VisioCheck are between 40-180mmHg. Outside this interval, the device display OUT OF RANGE and the measurement should be retake.



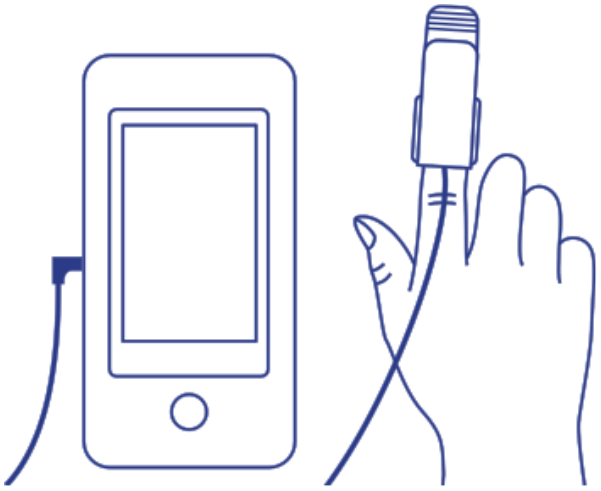
6.2.2. SpO2

See diagram D page 2

<u>Before taking a measurement</u>

Avoid eating, smoking or exercising for 30 minutes before measuring your oxygen saturation.
Remain calm for 15 minutes before the measurement

1) Plug the adapter cable into VisioCheck SpO2 port
2) Connect the SpO2 adapter cable to the SpO2 Sensor connector.
3) Insert an index finger over the sensor window with the fingernail facing upwards and the fingertip against the end.
4) Spread open the rear tabs of the sensor to provide even force over the length of the pads.
5) Check the position of the sensor. If an index finger cannot be positioned correctly or is not available, a smaller finger can be used. Do not use on the thumb, toe, or across a child's hand or foot.
Note: When selecting a sensor site, priority should be given to an extremity free of an arterial catheter, blood pressure cuff, or intravascular infusion line.
The sensor should be oriented in such a way that the cable is positioned along the top of the hand. See picture below.

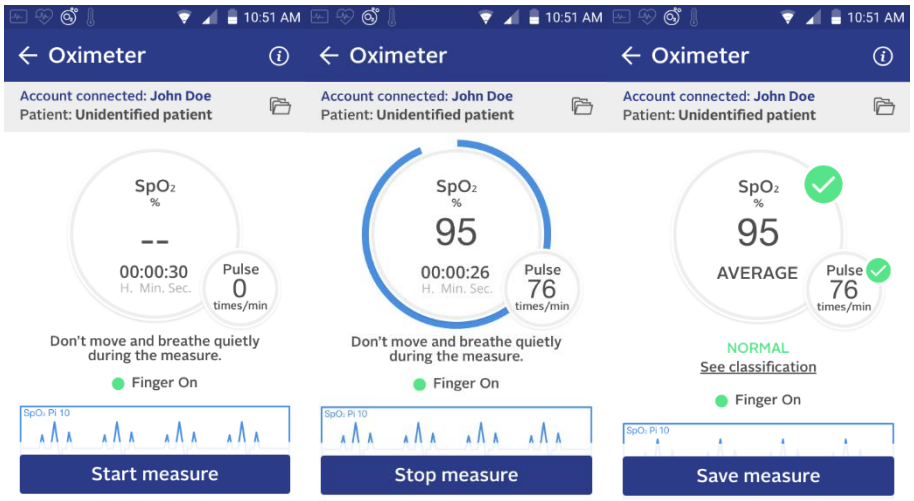


Taking a Measurement

Follow the steps to properly measure and record your data

1) Press “start measure” on the screen of VisioCheck to launch the measurement.
2) Click on “stop measure” to stop the measurement and then on “save measure”, to save the measurement.
Remain still, and do not speak, flex or move until the recording is complete. If the device senses poor contact or the measurement is interrupted by a hand adjustment, you will need to repeat the recording.
For the value to be reliable, the blood supply index (signal strength of the arterial pulse) must be superior to 0.3%.

You can take ECG and SpO2 measurements simultaneously, and view them in real-time from the Dashboard.



WARNING: When disconnecting the cable, pull on the plug itself not on the cable.

Note: If the sensor does not track the pulse reliably, the blood flow may be too thick, thin, or deeply pigmented to permit appropriate light transmission. If any of these situations occur, reposition the sensor or choose an alternate sensor.

Notes about results:

Many factors can modify hemoglobin's affinity for oxygen and reduce oxygen saturation in the blood. Measuring oxygen saturation is vital for individuals who may be at risk of desaturation, a condition that could result in the need for medical treatment to address the deficiency.

Warning: This table DOES NOT apply to individuals already suffering from certain illnesses (e.g. asthma, heart disease, respiratory diseases) or who are at altitudes above 1500 meters. If you are already suffering from a disease, always consult your doctor to analyze your results.

ANALYSIS OF RESULTS	
***Warning** : This table DOES NOT apply to individuals already suffering from certain illnesses (e.g. asthma, heart disease, respiratory diseases) or who are at altitudes above 4921 feet / 1500 meters. If you are already suffering from a disease, always consult your doctor to analyze your results. If you have any doubts about your results, contact your doctor.*	
SpO_2 (peripheral capillary oxygen saturation) result as a %	**Diagnosis**
99 - 95	Normal level
94 - 90	Reduced level (medical visit recommended)
< 90	Critical level : consult a doctor immediately or call for emergency help

Reference: World Health Organization (WHO): Pulse Oximetry Training Manual, 2011.

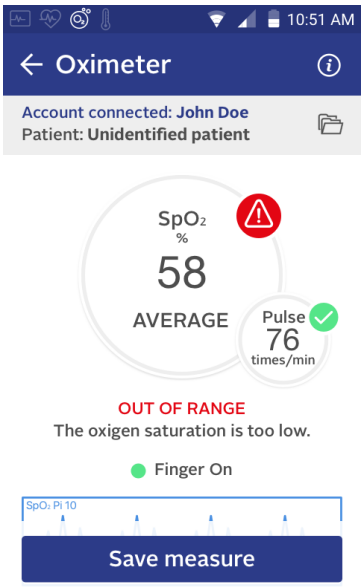
Warning: the results below show the average for a person in good health whose measurements are taken in a calm environment.
An individual may have a higher or lower pulse rate as a result of numerous factors (illness, regular exercise, medical treatment, etc.).
In the event of irregularities in your results (lower or higher pulse rate than normal), we advise you to consult your physician.

ASSESSMENT OF RESULTS			
Normal pulse rate result (in beats per minute)	**High pulse rate result (in beats per minute)**	**Low pulse rate result (in beats per minute)**	**Age range**
120 - 150	**> 150**	**< 120**	Infant
80 - 150	**> 150**	**< 80**	Child aged 1 - 5
60 - 120	**> 120**	**< 60**	Child aged 5 - 12
60 - 105	**> 105**	**< 60**	Adolescent
60 - 80	**> 100**	**< 50**	Adult
90	**-**	**-**	Elderly person

Reference: Mistovich, Joseph J., Brent Q. Hafen, and Keith J. Karren. Prehospital emergency care. Prentice-Hall, Inc., 2007

The values for oxygen saturation given by VisioCheck are between 70-99 mmHg. Outside this interval, the device display OUT OF RANGE and the measurement should be retake.

The values for Pulse given by VisioCheck are between 40-180mmHg. Outside this interval, the device display OUT OF RANGE and the measurement should be retake.

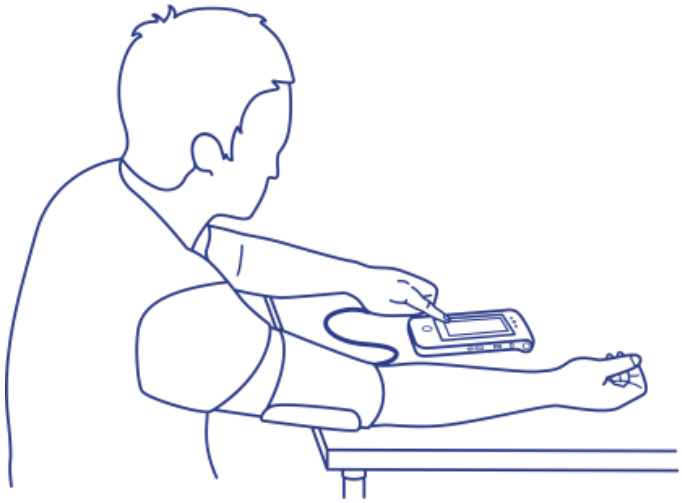


6.2.3. Blood pressure

See diagram E page 2

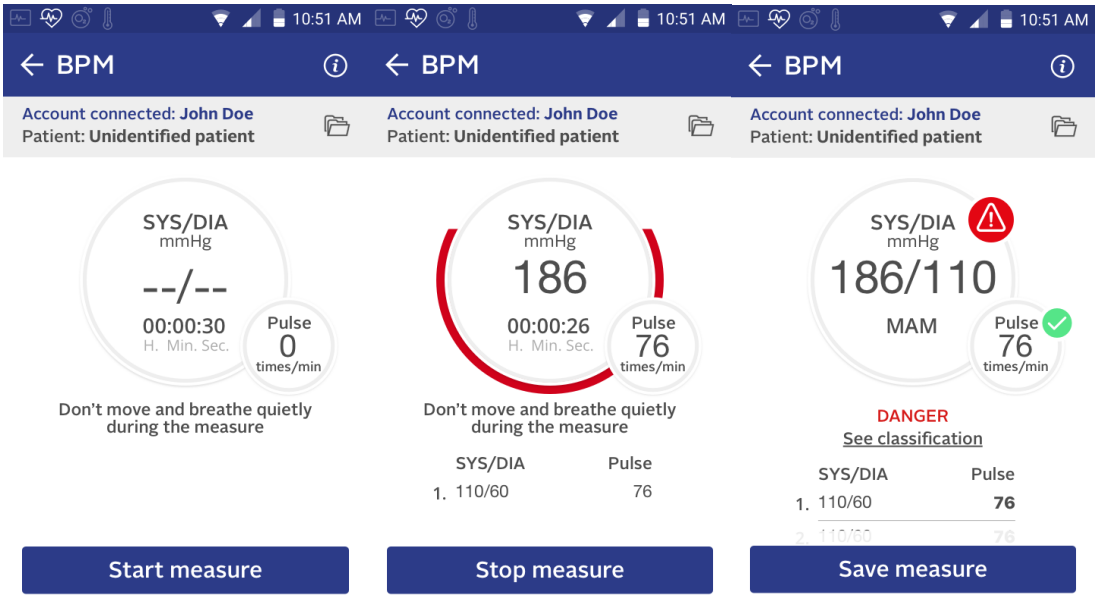
Before taking a measurement

- Sit down on a chair with your feet flat on the floor (do not cross your legs).
- Apply cuff to arm so that the orange mark on the cuff is over branchial artery. The cuff must be 0.4 – 0.8 inches / 1-2 cm from elbow crease.
- Wrap cuff around arm. Make sure the white side line folds within the arrow box, if it does not, change to a bigger or smaller cuff that fits better.
- Close the cuff with the Velcro (not too tight).
- Put your arm on the table, palm up so that the blood pressure cuff is level with the heart.
- Remain seated and calm for 5 to 15 minutes before taking measurement
- Do not take measurements over clothing. Remove jewelry from the arm you are measuring before taking measurement (watch, ring, bracelet etc.).
- Avoid eating, smoking or exercising 30 minutes before taking measurements. Relax for 15 minutes before taking blood pressure



Taking a Measurement in real time

1) Press “start measure” on the screen of VisioCheck to launch the measurement.
The armband inflates automatically. Do not remove the armband before the end of the measurement.
2) At the end of the measurement, click on “save measure”, to save the measurement.



Notes:
- For more reliable results, always take measurements on the same arm for the same patient
- Only use the appropriate size cuff when the artery index marker falls within the printed range. Otherwise erroneous readings may result
-The measurement will be too low if the armband is higher than the heart or too high if it is lower than the heart.

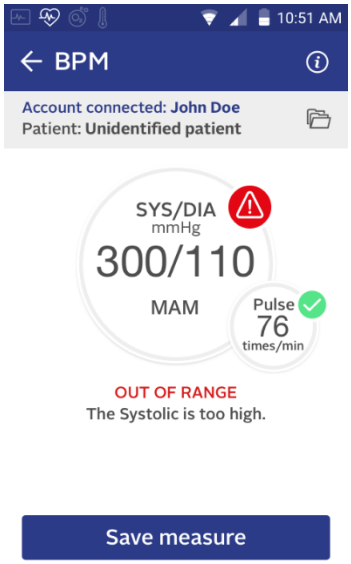
Notes about results:

In 2013, the American Heart Association (AHA) defined a blood pressure classification shown in the table below. Nevertheless, this classification is just a general guide, as blood pressure varies from one person to another, based on age, weight, and health.
This blood pressure chart reflects categories defined by the American Heart Association

TABLE FOR CLASSIFYING BLOOD PRESSURE VALUES (MMHG)			
Blood Pressure Category	Systolic (upper)		Diastolic (lower)
Normal	less than 120	and	less than 80
Prehypertension	120 - 139	or	80 - 89
High Blood Pressure (Hypertension) Stage I	140 - 159	or	90 - 99
High Blood Pressure (Hypertension) Stage II	160 or higher	or	100 or higher
Hypertensive crisis (emercency care needed)	higher than 180	or	higher than 110

The values for Blood Pressure given by VisioCheck are between 0-297 mmHg. Outside this interval, the device display OUT OF RANGE and the measurement should be retake.

The values for Pulse given by VisioCheck are between 40-180mmHg. Outside this interval, the device display OUT OF RANGE and the measurement should be retake.



6.2.4. Body temperature

See diagram F page 2

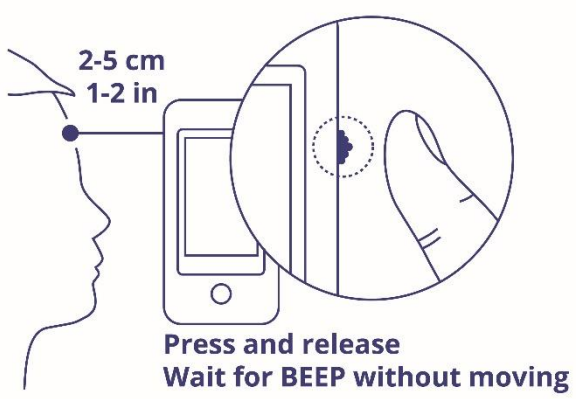
<u>Before taking a measurement</u>

Please take the following precautions before any measurement to ensure a stable and reliable result:

- Push back hair from the forehead.
- Wipe away any perspiration from the forehead.
- Avoid any drafts (e.g. from nasal specs, air conditioning, etc.).
- Each time there is a significant change in the ambient temperature due to a change in environment, allow the thermometer to acclimate to this ambient temperature for at least 15 minutes before using it.
- Do not put the thermometer in contact with an open wound
- Do not drink hot or cold drinks, or exercise while taking a temperature measurement

Taking a Measurement

1) Aim at the forehead, over the region center, from a distance of about 2-5cm / 1-2 inches, see picture below
2) Press and release the "OK" button on the right side of VisioCheck.
3) Wait for the BEEP sonore without moving. The temperature is instantly displayed on the screen.
4) Click on "save measure" to save the measurement.



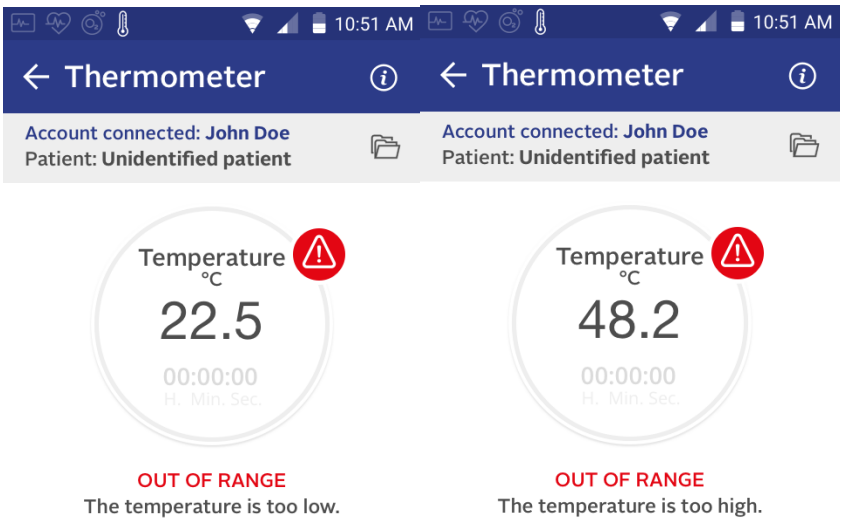
The reliability of the measurement cannot be guaranteed if the temperature is measured over another part of the body (e.g. arm, torso…).

Note about results

Diagnostic of temperature readings

●	<95°F <35°C	Hypothermia / Hipotermia / Hypothermie
●	95°F - 97.2°F 35°C - 36.2°C	Temp. to watch / Temp. para vigilar / Temp. à surveiller
●	97.3°F - 99.1°F 36.3°C - 37.3°C	Normal temp / Temp. normal / Temp. normale
●	99.3°F - 100.2°F 37.4°C - 37.9°C	Temp. to watch / Temp. para vigilar / Temp. à surveiller
●	≥ 100.4°F ≥ 38°C	Fever / Fiebre / Fièvre

The values for temperature given by VisioCheck are between 32°-43°C /89.6 -109.4 °F. Outside this interval, the device display OUT OF RANGE and the measurement should be retake.



7. HD Camera

To be defined

8. Storage and maintenance

Do not pour or spray any liquid on the surface of the device or its accessories; Make sure that liquid does not come into contact with any of the device openings.

Do not sterilize the device or its accessories in an autoclave, with ethylene oxide, by radiation, by steam, by high pressure or by immersing it in a liquid. The device or its accessories must not be sterilized.

Protect the device or its accessories from UV radiation

WARNING: Never immerse the device or its accessories in any liquid.

VisioCheck

- Avoid extreme changes in temperature and humidity. Do not use this device in locations subject to high or low temperatures or humidity.
- Do not store the device in ambient conditions such as exposed to direct sunlight, with high temperatures and/or high humidity, that are wet or damp or where water may get on the device, that are dusty near fires or open flames or exposed to strong vibration, or strong electromagnetic fields.

- Dispose of the device in accordance with applicable local regulations.
- This device is designed to be compliant with the rules and regulations in locations which it is sold and will be labeled as required.
- Any changes or modifications to this device, not expressly approved by the manufacturer, will void the user’ s authority to operate the equipment

Storage Conditions -10° C~+50°C (14°F ~122°F), 10～95%RH, 50kPa～106kPa（Non condensing)

Working conditions 5° C~+40° C (41°F~104°F), 15%～95%, 70kPa～106kPa（Non condensing）

- Clean the device using a medical disinfectant wipe only.
- Do not use water, or substances such as benzene, gasoline, paint thinner, concentrated alcohol, or detergents. Do not clean other parts of the device with any liquid.
- Do not drop or hit this device.
- Do not disassemble the device.

ECG cable/lead-wires, SpO2 adapter cable

Cleaning

1) Disconnect the cables from the monitoring device.

WARNING: When disconnecting pull on the plug itself not on the cable.

2) Dampen a clean cloth or gauze pad with an appropriate cleaning solution and wipe all exposed surfaces.
3) Dampen a clean cloth or gauze pad with sterile or distilled water and again wipe all exposed surfaces.
4) Dry all exposed surfaces with a clean, dry cloth or gauze pad.

NOTES: Do not treat the cables with oils (e.g. household or lubricating) or aggressive fluids or solvents (e.g. acetone). The cable is not made with natural rubber latex.

Disinfection

Disinfect with a chemical disinfectant, such as ethanol, propanol, phenolic disinfectant.

Pulse oximeter probe

Cleaning

The sensor may be surface cleaned by wiping it with a solution such as 70% isopropyl alcohol.

To clean or care for the sensor:

1) Disconnect the pulse oximeter probe from the SpO2 adapter cable
2) Soak a clean, dry gauze pad with the cleaning solution. Wipe all surfaces of the sensor and cable with this gauze pad.
3) Soak another clean, dry gauze pad with the sterile or distilled water. Wipe all surfaces of the sensor and cable with this gauze pad.
4) Dry the sensor and cable by wiping all surfaces with a clean, dry gauze pad

Disinfecting

If low level disinfection is required, use a 1:10 bleach solution. Do not use undiluted bleach (5%-5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the sensor could occur.

Blood Pressure cuff

Cleaning

1) Disconnect the BP cuff from the monitoring device
2) Clean the cuff by wiping a damp cloth with mild soapy and water

Warnings:

Do not sterilize cuffs. Do not use bleach.

Wash and rinse; temperatures should not exceed 104 F/ 40°C

Disinfecting

The cuff can be disinfected by 70% isopropyl alcohol. After disinfection, the cuff cover should be left out to air dry.

Warnings:

1) When cuff is not connected to monitor, always fit the cap to the tubing to prevent accidental entry of liquid.

2) Periodically inspect and replace damaged or deteriorated cuffs.

Thermometer

Cleaning

- Clean the surface of the glass over the lens with a cotton ball lightly moistened with 70% isopropyl alcohol.

9. Specifications

1.1. Technical specifications		
Vital Signs	Temperature (Non-contact), SpO2 (Probe type-internal), BP (Inflation), ECG (5 leads-internal)	
Model	BW-XO7HD	
Brand	Bewell Connect	
Classification	Class IIa (for Europe) / Class II (for US)	
CPU	Chipset	Qualcomm MSM8909
	Type	Cortex A7
	Number of cores	Quad Core
	Frequency	1.1GHz
GPU	Chipset	Adreno 304
	Number of cores	Quad Core
	Frequency	400MHz

RAM	Capacity	1GB
ROM	Capacity	8GB
Operating system	OS Version	Android 5.1
	Language	Multi-language
LCD	Type	HFFS
	Screen size	10“/ 3.97inch
	Color	16M
	Brightness	400cd/m²
	Screen resolution	480*800
Touch panel	Type	5 Points capacitive touch screen
	Material	G+F+F
Camera	Front Camera	5.0MP AF
	Rear Camera	No
	Flash light	Yes
Speaker	Built-in	8Ω/0.5W×1
MIC	Built-in	Yes
Receiver	Built-in	No
G-sensor	Built-in	Yes
Gyro-Sensor	Built-in	No
Light-Sensor	Built-in	No
Proximity Sensor	Built-in	No
Grade of Waterproofing	IP22	
1.2. Blood Pressure		
Measuring Mode	Upper arm type	
Measuring Method	Inflation+MAP (Mean arterial pressure)	
Measurement Range	Pressure: 0-295mmHg (0-39.3kPa)	
	Pulse Rate: 40-180 times/min	
Measurement Accuracy	Pressure: ±3mmHg (±0.4kPa)	
	Pulse Rate: ±5%	
1.3. SpO2		
Measuring Mode	Finger type (Internal)	
Measuring Method	Infrared & Absorption Spectrometry	
Measurement Range	Oxygen Saturation: 0%～100%	
	Pulse Rate:25～250 times/min	
	PI: 0.05%～20%	
Measurement Accuracy	Oxygen Saturation: 70%-100%: ±2% 0%-69%: Accuracy is not defined	
	Pulse Rate: ±3 times/min	
	PI: Accuracy is not defined	
1.4. ECG		
Measuring Mode	5 Electrodes,7-Lead ECG	
ECG Lead	Ⅰ、Ⅱ、Ⅲ、 aVR、aVL、aVF、V	
DC offset Voltage Range	±300mV	
Differential Voltage Measurement Range	±5mV	
Voltage Measurement Accuracy	±5%	

Anti-electrosurgical Capability	No	
Defibrillation Protection	No	
PACE	No	
1.5. Temperature		
Measurement range	Body temperature：32.0°C~43.0° C / 89°F ~109.4°F Room temperature： 0°C~50° C / 32°F~122°F Surface temperature： 0°C~90° C / 32°F~194°F	
Measurement speed	1s-2s	
Measurement site	Forehead	
Measurement distance	2-5 cm / 1-2 inches	
Display resolution	0.1°C / 0.1°F	
Measurement Accuracy	+/- 0.2°C (35°C-42°C) / +/- 0.2°F (95°F-107.6°F) in body temperature +/-0.3°C (32°C-34.9°C, 42.1°C-43°C) / +/- 0.3°F (89.6°F-93.2°F, 107.6°F-109.4°F) in body temperature. +/- 0.2°C (22°C-40°C) / +/- 0.2°F (71,6°F-104°F); others +/-2°C / +/-2°F in surface temperature.	
Unit	°C/°F	
1.6. Wireless Communication		
Wi-Fi	Built-in	Yes
	Cryptographic algorithms	WFA, WPA/WPA2
	Version	802.11b/g/n
Bluetooth	Built-in	Yes
	Version	4.0
GPS	Built-in	Yes
	A-GPS	Yes
3G(WCDMA)	Frequency band	B1, B2
LTE-FDD	Frequency band	B1, B2, B3, B4, B7, B12, B20
Data transmission speed	Upload	50Mbps (4G mode)
	Download	150Mbps (4G mode)
Phone feature	Phone calls & message	No
FM Radio	No	
NFC	No	
1.7. Key and Interface		
Earphone	3.5mm CTIA standard headphone jack	
Buttons	Home Key; Power key; Up/Down Wheel (Up/Down, one click confirm)	
Micro USB	Charge	
BP port	Yes	

SpO2 probe port	Yes		
ECG cable port	Yes		
Non-contact temperature sensor	Yes		
Micro Sim Card	Yes		
Micro SD	No		
1.8. Power Parameter			
Battery	Type	Li-ion battery	
	Capacity	3.7V/2500mAh	
	Time on stand by	3 days	
	Performance capacity	4 hours	
Charge lamp	Blue/Green		
Adapter Information	Temperature	Operating: The adapter is capable to operate from 32° to 104° Fahrenheit / 0°C to 40°C. Non- Operating: The adapter is capable to store from -4° F - 140°F / -20°C to 60°C	
	Humidity	Operating: The adapter is capable to operate from 10% to 90% RH. Non- Operating: The adapter is capable to store from 5% to 90% RH.	
	INPUT: 100-240V~50/60Hz,500mA OUTPUT: 5.0V 2.0A		
1.9. Appearance			
Body Material	PC+ABS		
Color	White		
Size	172*87*30 mm (length*width*height) About 6.77in*3.43in*1.16 inches		
Weight	298g / 10.5oz (without accessories)		
1.10. Life time			
Life time of button	50 000 times pressed		
Life time of BPM Bump and Valve	30 000 times		
Battery life	500 times of full Charging (The capacity will decrease 10% each year)		
Continuous usage	With Battery 100% Charged, BPM: 50 times; SPO2: 5 hours; ECG: 5.5 housrs.		
Period of	5 years		
1.11. Accessories included			
- Carrying pouch, including: o VisioCheck BW-XO7HD o Cable and cuff for BPM (22~42 cm / 8.5~16.5 in) o Pulse oximeter SpO2 probe o SpO2 adapter cable (50cm / 20 inches) o ECG cable 5 electrodes / 7 leads			

- AC Adaptor 5V 2A with EU/US/UK plug, USB cable 1 m / 3.3 ft

- Pouch of 10 disposable adhesive electrodes for ECG
- PP bag including:
  - Quickstep
  - User manual
  - Warranty card with serial number
  - Sim card removal tool
  - Earphone with microphone

1.12. Other Accessories (not included)

Item NO.	DESIGNATION
BW-XA8-13	cuff for BPM-infant (8cm-13cm)
BW-XA12-19	cuff for BPM- Children (12cm-19cm)
BW-XA17-25	cuff for BPM-Medium (17cm-25cm)
BW-XA22-36	cuff for BPM-standard(22cm-36cm)
BW-XA22-42	cuff for BPM-large(22-42cm)
BW-XA32-52	cuff for BPM-X-large(32cm-52cm)
BW-XSPOP	Pediatric Pulse oxymeter SpO2 probe with extension cable (50cm / 20 inches)
BW-XSPOS	Pulse oxymeter SpO2 probe
BW-XSPOC	SpO2 adapter cable (50cm / 20 inches)
BW-XDC2A	AC Adaptor 5V 2A with EU/US/UK plug, USB cable 1 m
BW-ECG5/7	ECG cable 5 electrodes / 7 leads
BW-XTM1	Professionnal table stand for VisioCheck
BW-XCASE	Silicone Protection holster with lanyard and cart stand
BW-XTP1	Table stand for VisioCheck

BW-XTCART	VisioCheck professional cart with wheel
BW-XT001	Telescopic mobil stand with 2 International AC adaptor, 1 USB - power cord 2 m, wheel with security lock
BW-XT002	Basket for cart
BW-XT003	Handle for cart
BW-XT004	Tray for cart
BW-XT005	Cart stand for VisioCheck

2. Troubleshooting

Main device			
1.	Device can't be turned on.	System is abnormal. Battery has low power. Device is damaged.	Restart the device. Charge the device. Contact customer service.
2.	Module Inspection Failed	The module concerned has a problem Device malfunction	Restart the device If restarting can't solve the problem, contact customer service.
3.	After turning on the device, 4G/Wi-Fi signal is abnormal.	Network signal is weak. Wi-Fi hotspot is configured incorrectly. Device malfunction.	Be patient and wait. If there is still no signal, try to restart the device. If restarting can't solve the problem, contact customer service. If the communication mode is Wi-Fi, check whether the Wi-Fi hotspot (router) is configured correctly.
4.	Device crash	Device malfunction	Stop measuring and unplug the BPM cuff, SpO2 cable and ECG cable. Long press the on/off button to shut down. If the device can't be shutdown normally, try to press the on/off button for 15s to force restart. Contact customer service.
5.	Device doesn't recognize SIM card.	SIM card is connected poorly. Device malfunction.	Check if SIM card is plugged in correctly Take out the SIM card and plug in again. Contact customer service.
6.	Speaker has no sound.	The setting of volume is too low. Device malfunction.	Reset the volume in system setting. Contact customer service.
7.	Earphone is abnormal (no	Earphone has a poor connection	Plug the earphone correctly.

	sound/ with noise/ abnormal recording)	Using earphones that are not in match with the device.	Use the earphone matching to the device. Contact customer service.
Oximeter module			
8.	SpO2 probe malfunction	Probe is not entirely plug in the device. Probe has a problem. Device malfunction	Take out the probe and plug in again, then re-measure. Change with a new probe and re-measure If the problem persists, restart the device. If problem can't be solved, contact customer service.
9.	No pulse rate found	The measured site has novital signs. Measuring in wrong operation. Device malfunction	Re-measure according to the user manual If still no vital signs after several tries, contact customer service.
10.	Weak perfusion index	PI of the measured site is low, lower than 0.3% may cause inaccuracy.	Change measuring site, and re-measure according to the user manual.
11.	Light interference	The test environment has strong light	Re-measuring in weak light environment.
12.	Oximeter module fails to start.	Firmware malfunction.	Restart the device. If the problem persists, contact customer service
BPM module			
13.	Measure overtime	cuff being worn the wrong way. Device malfunction.	Remeasure according to the user manual. If the problem persists, contact customer service
14.	Measured result is low	Device malfunction	Remeasuring according to the user manual. If the problem persists, contact customer service
15.	Pressurize overtime	Cuff dropping, loose or deflating	Restart the device If the problem persists, contact customer service
16.	Deflate overtime	Valve damage	Restart the device If the problem persists, contact customer service
17.	Pulse detecting overtime	Wearing the cuff the wrong way. The measured person is wearing thick clothing. Device malfunction.	Wear the cuff according to the user manual. Undress the thick clothes and do the measure a second time. If the problem persists, contact

			customer service
18.	Interference in measuring process	The measured person moves or talks.	Do again the measuring according to the user manual.
19.	BPM module fails to start	Firmware malfunction	Restart the device If the problem persists, contact customer service
ECG monitor			
20.	ECG malfunction	Hardware malfunction (chip does not respond for 5s) Chip error of ECG Data frames lost	Restart the device If the problem persists, contact customer service
21.	Weak ECG signal	Electrodes stuck in the wrong position.	Re-connect the cable with device according to the user manual, and restart the device for measurement.
22.	Measuring result of heart over the limit	Measuring result of heart over the limit	To measure again according to user manual If still not normal, please contact your doctor.
23.	ECG interference	Interference signal exist.	Be quite and breath smoothly during measurement. Check and remove the interference signal around the cable and electrodes. Re-connect the cable with device and measure again.
24.	ECG fails to start	Hardware malfunction	Restart the device If the problem persists, contact customer service
Body temperature module			
25.	Temperature module malfunction	Open circuit or bad connect on the cable of infrared sensor. Infrared sensor is abnormal. Battery voltage lower than 3.2V. Communication protocol is wrong. Reading data overtime	Restart the device Please charge the device and restart. If the problem persists, contact customer service
26.	Abnormal body temperature measurement.	Big temperature difference between room temperature and device temperature. Room temperature beyond the range of 41 – 104 Fahrenheit / 5℃-40℃	Please allow the device to acclimatize the room temperature for at least 30min before using it. Please measure the body temperature within 41-104

		during body temperature measuring,	Fahrenheit / 5℃- 40℃ of room temperature.
27.	Temperature module fails to start	Hardware malfunction	Restart the device If the problem persists, contact customer service

CARTE DE GARANTIE - GUARANTEE CARD
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Marché Européen /
European Market
Visiomed Group SA
Service clients / Customers service
112, avenue Kléber
75116 Paris - France
Tel : +33 8 92 350 366 (0,34€/mn)
Fax : +33 1 44 17 93 10
contact@visiomed-lab.fr

Made in China.
Nexmed Technology Co., LTD.
2nd Floor of N°.1 building, Jia An
Technological Industrial Park
67 District, Bao An
518101 Shenzhen - China