“VITOM Plus” Multi-function Physiological Monitoring Device

Model name:VITOM3 Plus
APP: VITOM Plus APP iOS v1.0.0 / VITOM Plus APP Android v1.0.0

* Please read all of the information in the instruction manual before operating the product.
* This product involves the collection, processing and utilization of personal data, which shall comply with the Personal Data Protection Act.

【Product description and Intended Use】

This product is a portable device for the simultaneous recording of physiological signals, in particular electrocardiogram (ECG), photoplethysmogram (PPG) and oxygen saturation. With these signals the pulse transit time be determined to obtain real-time, spot-checking and cuffless blood pressure. The physiological signals are intended to track the physiological parameters of adults at home or in medical institutions and assist in the diagnosis of cardiovascular diseases. This product has no diagnostic and warning functions.

The measurement results are recorded in the mobile application via device and mobile phone Bluetooth transmission, which can be used to track the physiological parameters changes and provide as reference for medical personnel.

【Principle of measurement】

Through collection of electric signal and PPG signal of the fingers, utilize 2 signals to calculate pulse wave transit time, further use calibration data from blood pressure measurement in the beginning together with algorithm analysis, to convert PWTT to a correct blood pressure value.

【Indication】

This product is intended to measure and monitor heart rate, heart rhythm regularity, blood oxygen and blood pressure changes, and record electrocardiogram (ECG) at the same time. It is suitable for adults over 20 years old.

【Side effect or complication】

None.

【⚠Contra-indications】

1. Do not use the device on infant under 10 kg or person under 20 years old.
2. Need to have consultations with doctors such as may be present in patient with arrhythmia and heart disease.
3. The VITOM3 Plus ability to detect Blood Pressure may be limited or difficult in some patients who, such as: Young children, Pregnant woman, Bedridden patients, arrhythmia, atrial fibrillation, the patients taking cardiovascular drugs.

【⚠Safety Information】

1. Any user who uses this device must carry out calibration. Calibration process is suggested to follow under medical personnel instruction, to make sure correctness of the calibration and validity of measurement data.
2. Due to the difference of each person, do not use data other than your own to process the measurement.
3. This product is not for self-diagnosis, rather it only provide a measurement data for reference. Do not use it for self-diagnosis, treatment, judge to use/ or not to use a certain medicine or change dose of medication without consultation of the clinical staff.
4. This product is mainly used as a health management tool, regardless of the data and warning message, depend on one's physical condition, users still need to consult with physician and carry out health examination periodically.
5. This product does not contain alarm, only used to do measurement and to keep the record.
6. Do not use this product for measurement when there is wound on skin of the finger.
7. Please stop using this product and consult to a physician, during the period of usage when there is red or swollen, severe itching, and allergic symptom.
8. This product is easy to be affected by certain environment, misuse or patient conditions. If one can't confirm the correctness of measurement data, please use other methods of confirmation.
9. Do not use together with AED, MRI, or Neurostimulator.
10. Users need to eliminate interference, when you detect abnormal behavior due to Electromagnetic interference. Please re-position the facility accordingly and execute APP all over again.
11. Fingernail polish or false fingernails may cause inaccurate SpO2 readings.
12. If the transducer is damaged (such as the shell is damaged), please stop using it immediately.
13. Please keep the electrodes clean and do not touch other metals or any power sources.
14. Uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the user with microcirculation disorder. It is recommended that the product should not be applied to the same finger for over 30 minutes.

【⚠Transducer Precautions】

1. Sensor has no water resist function, please avoid any liquid spread, keep dry, avoid touching by wet finger, and keep away from high temperature, fire or any corrosive liquid.
2. This is a precision measurement equipment, please avoid strong collision, fall over, etc.. Sensor damage would affect signal and measurement result, please do not rubbing surface with sharp or rough objects, or scrub the product.
3. Do not try to change battery on your own, please do not disassemble or break outer casing.
4. The function might be affected by strong electro-magnetic environment, do not use together with other electronic products.
5. Strong light environment might affect function measurement, it is suggested to use in indoor to avoid under the strong sunshine.
6. To ensure the product functionality and safety, the products should also not be used or storage under following circumstances:
   -.High temperature and high humidity environment.
   -.Near fire or any place where the spark might be induced.
   -.The room full of dust.
   -.The room full of Oxygen, Nitrous Oxide, or any mixture of combustion gases.
7. Please use this product in accordance with the operating environment indicated in the "Product Specifications" section of this manual. If the product is found to have any defects or faults during normal use after unpacking, the original factory will provide a free replacement. If the product is not used or kept in accordance with the requirements of this manual, any abnormal phenomenon or damage to the human body or machine will be caused. The original factory will not be responsible for the safety function, and will not provide free maintenance for such faults.
8. Please keep away from child, pets, avoid swallow by mistake, or endanger by winding cable.
9. Please use IEC60950 complied USB charger (DC5V, 1A)) for the transducer recharging.
10. The device should be charged every 3 months, to keep Li-polymer battery in good condition.
11. Do not use charging cable or accessory which was not granted approval by manufacturer, to avoid electro-magnetic negative effect to measuring data.
12. Cleaning:
    -Please use clean soft cloth or cotton buds adding proper amount of medical alcohol for cleaning. It is only apply to normal cleaning process. It is not applicable to infectious prevention. Please contact expert for infection procedure.
    -Please do not use benzene, gasoline, high concentration alcohol or other volatile detergent for cleaning of transducer and its electrode spot.
    -Please do not execute cleaning procedure when product in use.
13. Disposal: Transducer is composed of metal and plastic components, and it must be handled separately from household waste.
14. The applicable operating environment is between 15%~85% relative humidity, 10~40°C, and non-condensing environment. DO NOT use the product while the user showering or swimming.

15. According to NCC LP0002 Low power radio frequency equipment technology regulation_Section3.8.2 Low power radio frequency equipment which received qualification approval, should not change the frequency, enlarge the power, or change the characteristics and functions of the original design, by companies, shops, or users without permission. It is not allowed to affect the aviation safety and interfere legal radio communication when utilizing low power radio frequency equipment. It should be stopped using and improved until no interference can be detected when interference phenomenon occurs. Above mentioned legal radio communication, is applied to wireless communication which comply telecommunication regulation law. Low power radio frequency equipment should bare the interference of legal communication, industry, science, and medical radio wave radiation of electrical equipment.
16. This product is portable radio frequency communication equipment, it might affect medical electric facilities. We suggest keeping a safety distance of no less than 30cm (12 inch) from any portion. The safety distance is at least 1m for sensitive facilities.
17. This device is intend to receive the RF frequency includes: 2402-2480MHz, and this device's radio frequency transmitting portion includes the transmission frequency range of 2402-2480MHz .
18. 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.
19. You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.
20. 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.
21. 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.
22. FCC RF Radiation Exposure Statement:
    1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
    2. For body worn operation, this device has been tested and meets FCC RF exposure guidelines. When used with an accessory that contains metal may not ensure compliance with FCC RF exposure guidelines.

【Product description】

This product includes a transducer and APP software. Physiological signals are collected through the transducer, and used in conjunction with the APP software through Bluetooth transmission, the physiological signal information is obtained from the APP, and the changes in the user's physiological parameters are recorded. For Bluetooth and software specifications and requirements, please refer to the [Product Specifications] of this product.

【Download APP and preparation】

Download mobile APP (Name: VITOM Plus)

This device should not be used in adjacent to, or stacked up on to other devices. You can choose to do pairing again if there are more than 2 devices. It is suggested to use one device at a time to avoid confusion.

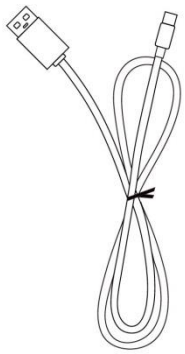
【Measurement】

1. For the preciseness of the measurement, each user should use “Medical Approved” electronic or mercury type blood pressure monitor to carry out calibration before using this measuring device, due to the variation of each human body. Later on please do calibration every 3 months, or do calibration after big change on body weight, operation, and critical diseases, or according to personal needs to pull in calibration (you can delete previous calibration data to re-calibrate within user data). It is suggested to do calibration under the instruction of medical personnel, and to keep calibration data be more reliable.
2. The user information and measurement records in the product are only saved in the APP software used by the user for personal tracking and change use. If the mobile phone or device is replaced, it must be re-calibrated. In addition, this product APP will not transmit or store personal data and measurement records in any database, please keep relevant records properly.
3. Please follow the instructions in the APP for how to use the device. The time for a measurement is 40 seconds. The heart rate and blood oxygen value will appear in about 8 seconds, and the blood pressure value will appear after about 16 seconds. It is updated every second, and these measurement values is displayed and recorded after a measurement is completed.
4. If there is no value during the measurement, or if there is a poor signal prompt after the measurement, you can refer to the **[Troubleshooting]** chapter or click the **[Help]** in the APP to correct the measurement.

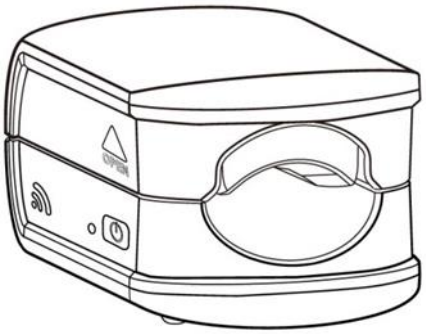
【Contents in product package】

- USB charging cable
- Transducer
- User manual

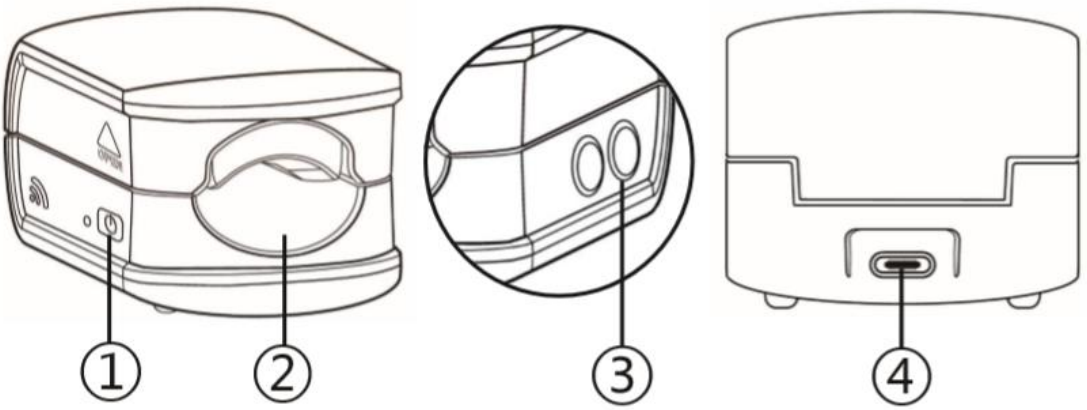
Type C charging cable



Transducer



【Product host introduction (transducer)】



	transducer portion	functions description
①	on/off switch & indicator light.	apparatus on/off & status reminder.
②	electric sensor A & photo sensor.	electric & photo signal measured on finger
③	electric sensor B	electric signal measured on another finger
④	charger port	connection to Type C cable.

【Product Specification】

Specification	
Dimensions and weight	62.5(L) x 40.7(W) x 34.2(H) mm/45 g
Data transmission	Bluetooth 5.0
Storage Display	Inside mobile device Mobile device APP
Storage Display	Inside mobile device Mobile device APP
Operation system	Above Android 8, download from Google play Above iOS13, download from Apple store System Space Requirements : above 100Mb
Battery	Li-polymer battery
charging cable	Type C to USB
Electrocardiograph Specification	
Lead	1 Lead
sampling rate	250 Hz
resolution	21 bit
Frequency response	0.67-40 Hz
Dynamic range	± 5 mV
Input impedance	>10 M
CMRR	>60 dB
AFib detection	regular /Atrial Fibrillation (AFib)
Pulse Parameter and The Pulse Oxygen Saturation(SpO2) Specification	
Pulse display range	40-200 bpm
Pulse measuring range	40-200 bpm
Pulse accuracy	≤±10% or 5 bpm select larger
SpO2 display range	0%-100%
SpO2 measuring range	0%-100%
SpO2 accuracy	±2%@70-100%; 0-69% unspecified
LED	660nm/ <1mW 940nm/ <1mW
Toxicity	The thumb sensor is made of silicone with no known toxic reactions.
Abnormal alarm	None
Blood pressure Specification	
Calibration	Yes, use electronic or mercury sphygmomanometer
Blood pressure range	Systolic 60-260mmHg，Diastolic 40-200mmHg
Blood pressure accuracy	Static condition ≤±5mmH
Operating and Storage	
Waterproof level	IP21 (Dripping water (vertically falling drops) shall have no harmfull effect.)
Operating Environment	Temperature: 10~40 ℃ / Relative humidity :15%~85% ，Altitude:0~1000m
Transportation/Storage environment	Temperature :-20~55 ℃ /Relative humidity :10%~99% ，Altitude:0~1000m

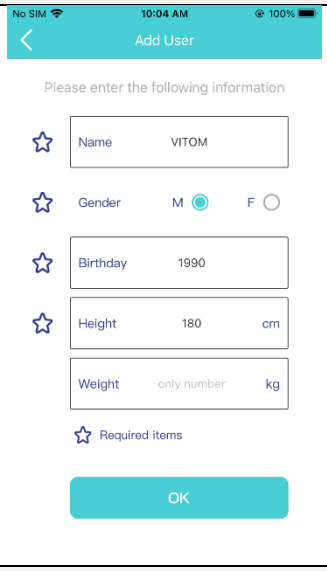
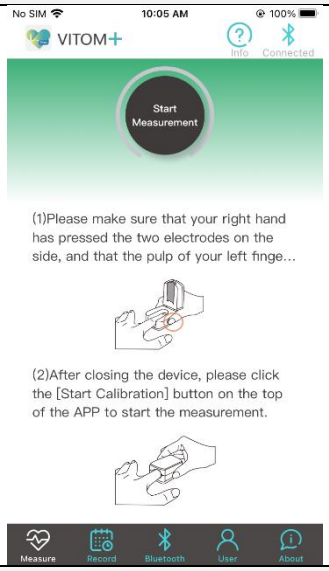
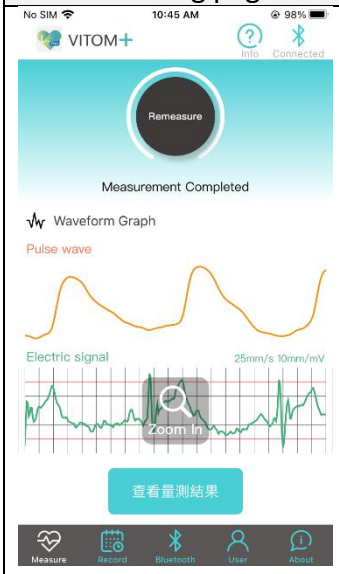
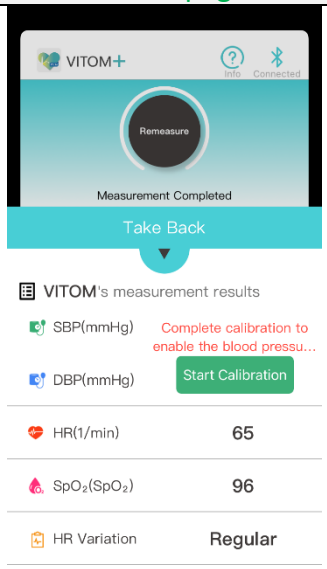
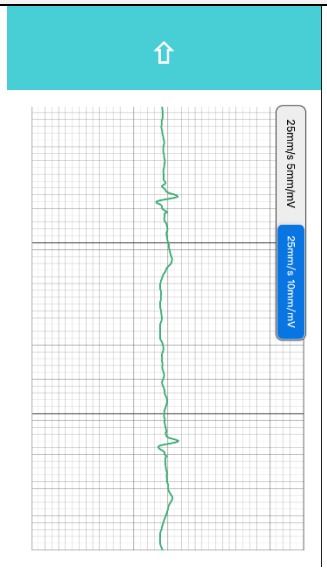
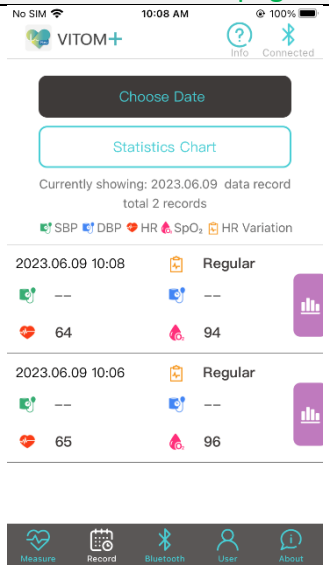
* Additional instructions

1. The blood oxygen accuracy is evaluated by comparing it with a commercially available products.
2. Product functions are finally confirmed by using the signal simulator (Whaleteq AECG100 with PPG-2R-940).

[Troubleshooting]

Issues	Causes	Solutions
Sensor can't turn on.	Low battery so that can't turn on.	To recharge the device, till continuous light on.
Sensor can't connect w/ APP.	Too far between Device and Mobile.	The distance need to keep within 8 meters.
Sensor can't connect mobile	1. Device Bluetooth didn't turn on. 2. Mobile do not support over BLE5.0. 3. Android ver. is not over 8.0 ver. or iOS ver. is not over 13.0 ver.	1. Make sure the Bluetooth is on. 2. Make sure Mobile system and BLE ver. meet Spec.
Bad pulse wave signal	1. Poor contact. 2. Press too hard. 3. Finger too cold. 4. Body moving during measurement.	1. Make sure the position of both hands are correct. 2. If the finger is too cold, rub your fingers until it gets warm.
Bad electric signal	1. Poor contact. 2. Body moving during measurement. 3. Abnormal signal from the finger. 4. Effect from other electronic facility around the environment.	1. Make sure the position of both hands are correct. Silicon rubber covers finger. Right hand thumb covers the metal plate. The body holds steady. 2. Far from electronic facility to avoid EMI. 3. To wet metal plate with little water, to increase contact stability.
Big difference between measurement & calibration.	Large deviation might cause from: 1. Moving during measurement. 2. Left/right hand or fingers might be Different during measurement and Calibration. 3. Body parameter changed.	1. Refer to "Bad signal" problem solving. 2. Left/right hand position and finger used should be identical during calibration and measurement. 3. We suggest to calibrate every 3 months, and after drastic change in body weight, surgical operation , recover from critical illness. 4. Measure a few more time, and suggest to recalibrate if keeps on getting this message.

【Operation interface】

APP icon	Initial page (Bluetooth connection)	User information	Calibration
			
Measuring page	**Result page**	**ECG waveform record**	**Result record page**
			

【**Manufacturer's declaration**】

<table>
<tr><th colspan="3">Manufacturer's declaration-electromagnetic emissions</th></tr>
<tr><td colspan="3">The VITOM3 Plus is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.
The customer or the user of the VITOM3 Plus should assure that it is used in such an environment.</td></tr>
<tr><td>Emission test</td><td>Compliance</td><td>Electromagnetic environment-guidance
(for home and professional healthcare environment)</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The VITOM3 Plus uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class B</td><td rowspan="3">The VITOM3 Plus is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations /flicker emissions
IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

Manufacturer's declaration-electromagnetic immunity

The VITOM3 Plus is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the VITOM3 Plus should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home and professional healthcare environment)**
Electrostatic discharge(ESD) IEC 61000-4-2	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines Not applicable	Mains power quality should be that of a typical home and professional healthcare environment.
Surge IEC 61000-4-5	± 0.5kV, ±1kV line(s) to line(s) ± 0.5kV, ±1kV,± 2kV line(s) to earth	± 0.5kV, ±1kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical home and professional healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % *U*T; 0,5 cycle 0 % *U*T; 1 cycle 70 % *U*T; 25/30 cycles Voltage interruptions: 0 % *U*T; 250/300 cycle	Voltage dips: 0 % *U*T; 0,5 cycle 0 % *U*T; 1 cycle 70 % *U*T; 30 cycles Voltage interruptions: 0 % *U*T; 300 cycle	Mains power quality should be that of a typical home and professional healthcare environment. If the user of the VITOM3 Plus requires continued operation during power mains interruptions, it is recommended that the VITOM3 Plus be powered from an uninterruptible power supply or a battery.
Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	The VITOM3 Plus power frequency magnetic fields should be at levels characteristic of a typical location in a typical home and professional healthcare environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Manufacturer's declaration-electromagnetic immunity			
The VITOM3 Plus is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the VITOM3 Plus should assure that it is used in such and environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home and professional healthcare environment)**
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	**Portable and mobile RF communications equipment should be used no closer to any part of the** VITOM3 Plus including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80MHz to 800 MHz $d = 2,3\sqrt{P}$ 800MHz to 2,7 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meterzes (m).
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended separation distance between portable and mobile RF communications equipment and the VITOM3 Plus

The VITOM3 Plus is intended for use in an electromagnetic environment (for home and professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the VITOM3 Plus can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VITOM3 Plus as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,7 GHz** $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The VITOM3 Plus is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the VITOM3 Plus should assure that it is used in such an environment.

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)	**Compliance LEVEL** (V/m) (for home and professional
385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
1 845							
1 970							
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5 500							
5 785							

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used

【Battery life and power recharge】

1. This device uses rechargeable Li-polymer battery.
2. Please make sure to carry out battery charging before initial use.
3. When light signal is constant on while complete charging, it means the power is sufficient.
4. A fully charged battery will continuously connect for 5 hours, if measure 6 times per day, it would last for about 100days.
5. The battery can be repeat charging for about 500 times. It needs about 3 hours to be fully charged.
6. Charging time takes about 3 hours.

【Internet safety and privacy statement】

Please note, when you install VITOM APP which means that you will agree to our privacy policy. We will not collect your personal information and measurement data, and will not spread to other persons. Detailed privacy policy please refer to URL : http://www.focaltech-sensors.com/privacy_vitom.html.

For the safety of your data, we suggest to use your apparatus and APP as follows::

- To download APP through a safe internet.
- Use compatible smartphone to install and to use APP.
- Do not use a manufacturer modified rooted or jailbroken cell phone.
- Do not use cell phone system simulator.
- Please turn off Bluetooth connection or device power when the device is not in use.

【Notification in case of defects】

Please report according to competent authority when there is incident or defect as follows: Home page of Taiwan Food and Drug Administration(TFDA) website > Report and Safe security zone > Report entrance(I want to report) > Medical Equipment Incident Report, or download and fill out “Medical Equipment Defect Report Table” then post or e-mail to National Medication Side Effect Center.

【Information contact】

FocalTech Smart Sensors Co., Ltd.
Manufacturer Address:
8F-1,-2 No.32, Gaotie 2ND Rd. Zhubei City, Hsinchu 30274, Taiwan ver.1.1