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1. INTRODUCTION

Thank you for purchasing the DynoSense Vital Sign Measuring System. Please read the manual carefully before you use the unit, and keep the manual after use.

2. INDICATIONS FOR USE

The DynoSense Vital Sign Measuring System is intended to record, transfer, store and display of single lead electrocardiography (ECG), heart rate (HR), functional oxygen saturation of arterial hemoglobin (SpO₂), pulse rate (PR), respiration rate (RR), and oral body temperature (TEMP). The device comes in contact with the patient for approximately 60 seconds at each use. This system is for spot checking and does not have continuous monitoring capability or any alarm features.

This system is intended for patients **18 years and older** in the home environment. It is intended for use with patients who are well perfused and during no motion condition.

This system makes no specific diagnosis. The device is for single patient use. Users with implanted pacemaker and/or implanted cardio-defibrillators (ICD) are not recommended to use the device.

3. PRODUCT DESCRIPTION

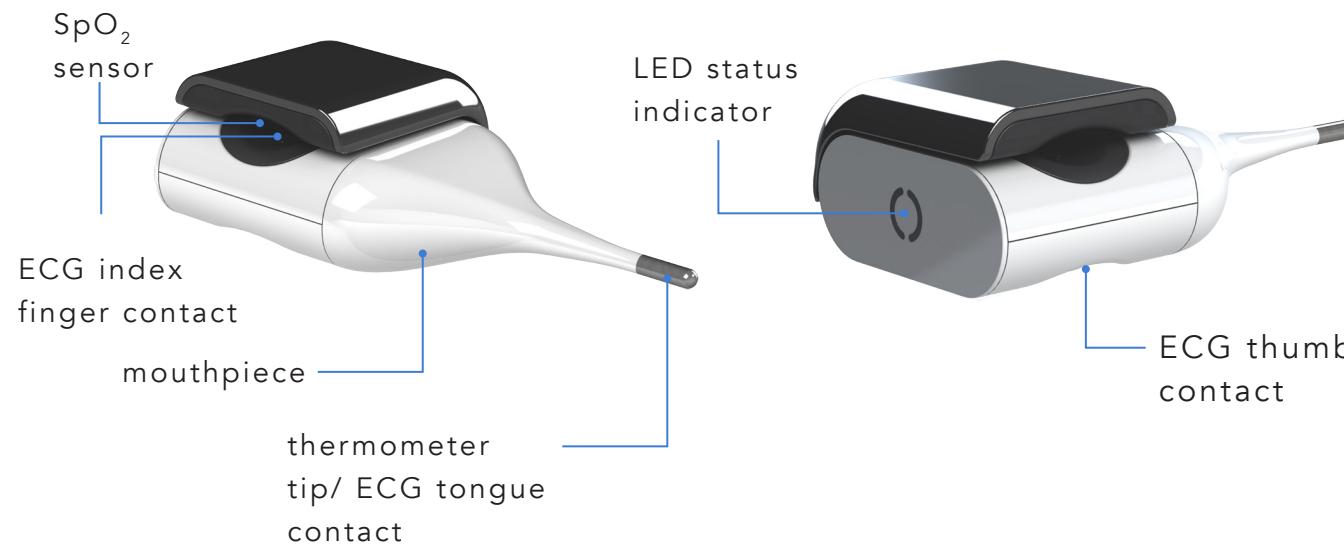
System Components

The DynoSense Vital Sign Measuring "System" comprises of following components;

- Device
- Software (Mobile and Cloud Application)
- Accessories

Device

The operation is based on capturing vital signs in response to a single action from you. The device receives your thumb on the metallic contact electrode, index finger inserted into the opening, tongue above the thermometer tip, and mouth over the mouthpiece, the vital signs data is captured and communicated to a mobile device for forwarding to cloud for processing.



The device is a battery powered, handheld, personalized, single patient use vital sign measuring device. The device captures and transfers;

- Single-lead electrocardiography (ECG) and heart rate (HR),
- Non-invasive measuring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR),
- Respiration rate (RR),
- Oral body temperature (TEMP).

The device uses Bluetooth Low Energy as the wireless link to enable data transmission and communication to a mobile device. All the acquired data by the device is encrypted with AES128 GCM. Acquired data is wirelessly transmitted to the cloud using the mobile device. Analyzed and archived data is available for remote monitoring by authorized user(s).

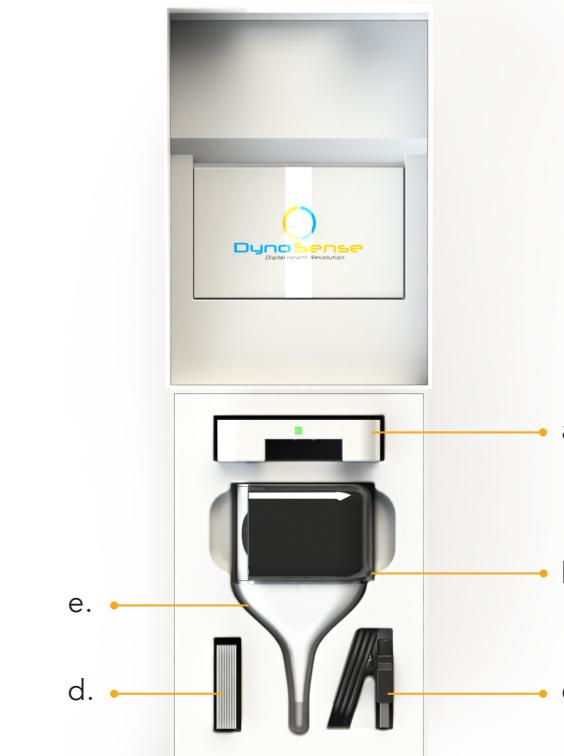
Software (Mobile and Cloud Applications)

To use the device, you will install an app (DynoLife) on your mobile device. This app will initiate data collection for measurements, show you a status during data collection, and tell you when data collection is complete. The data collected by the DynoLife app will be transferred to the cloud for analysis and storage, and will then be returned to your mobile device for viewing.

Accessories

The device accessories are;

- Charging Base - is used to charge the device via contact with device.
- USB Cable - is used to connect the charging base to a USB power source.
- Alcohol Wipes - is used to sanitize the device prior and after each use.
- Glass Cover - is used to protect the mouthpiece from dirts and to turn off the device.



No.	Part Number	Name
a.	900-01113-01	Charging Base
b.	900-01100-01	Device
c.	360-01001-01	USB Cable
d.	300-01382-01	Alcohol Wipes
e.	900-01107-01	Glass Cover

4. CONTRAINDICATIONS

- Do not use this device if you have a pacemaker and/or implanted cardio-defibrillators (ICD).
- Do not use the device if your left hand index finger or thumb or tongue has cuts or open wounds.
- Do not use the device if you have trouble breathing normally.
- Do not use the device if you are under 18 years of age.
- Do not use the device if you are sensitive to Polycarbonate, UPS Class VI material. This material has been tested for biocompatibility and has been confirmed to be safe when it comes in contact with human tissue but some individuals maybe hypersensitive to this material when they become in contact.
- Do not share your device with others to avoid potential risk of contamination.

5. SAFETY WARNINGS AND CAUTIONS

Carefully read the following safety warnings and cautions before using the system.



Warnings

- No modification to the System is permitted. PLEASE DO NOT DISASSEMBLE.
- All components of the System should be kept out of the reach of children, pets, or anyone who may be at risk of being harmed by components.
- This device is prescription use only.
- The device makes no diagnosis interpretation or treatment.
- Device is not provided sterile. Clean with alcohol wipe before each use.
- Product has not been tested for compatibility with exposure to Magnetic Resonance Imaging (MRI) environment. Therefore it is not recommended to use the device in Magnetic Resonance (MR) environment.
- When choosing a third party USB charging devices, select one that complies with IEC 60950.
- The device is intended for single patient use, and is recommended to be cleaned and sanitized with alcohol wipe between uses.
- Please ensure that 20 minutes has passed since last food/drink consumption or strenuous activity prior to use.

SpO₂,

- Pulse oximetry performance is adversely affected by excessive ambient light, excessive motion, poor patient perfusion, fingernail polish on the left hand index finger, anemia or low hemoglobin concentrations.
- Do not use if device optical sensor or LED is damaged or a sensor with exposed electrical or optical components.
- If the index finger surface skin is damaged or discolored, pulse rate reading may not be accurate.
- Tissue damage can be caused by incorrect application or long duration of use of an SpO₂ sensor.
- A functional tester cannot be used to assess SpO₂ accuracy of the device.

ECG,

- Do not use this device during defibrillation.
- Interference from a non-grounded instrument near the patient can cause problem with the waveform.

Temperature,

- Direct contact of the patient's tongue with the thermometer tip is required.
- Do not move the thermometer tip under the tongue during the measurement. The thermometer tip should be placed under the tongue at or close to sublingual pockets for accurate measurements.

Respiration,

- Do not use the device if you have problem breathing normally.
- The device should not be used as an apnea monitor.



Cautions

- Keep System (device and case) away from excessive heat exposure, as this may cause damage. Use the device in the recommended operating conditions in the specification.
- If any component of System fails to operate after attempting all suggested troubleshooting methods, contact your product provider or distributor immediately.
- Do not dispose system parts in a household trash bin. Return parts to DynoSense for disposal.
- Always store your device in the charging case when not in use.
- Do not drop the device.
- Do not immerse in water.
- Do not use while in bathtub or shower.
- Do not use soap or chemicals to clean the device.
- Do not turn power off during firmware update.
- The service life of the battery will depend on the conditions of use.
- The maximum range specified for bluetooth technology is about 10 meters.

6. SETUP INSTRUCTIONS

What you need to get started

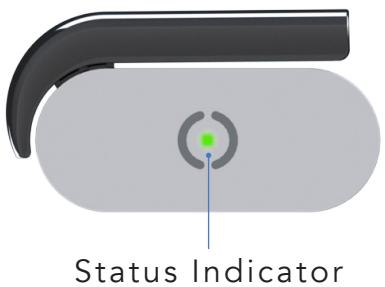
- Device
- A smart mobile device with Bluetooth Low Energy capability and internet connectivity
- Access to the computer USB port or USB power supply

Unpack

1. Open the packaging box.
2. Ensure the following is included in the box:
 - a. Device
 - b. USB Cable
 - c. Alcohol Wipes
 - d. Glass Cover
 - e. Charging Base

7. HOW-TO-USE INSTRUCTIONS

Device Status Indicator



Status Indicator

Status Indicator	Description
no light	Battery off
	Device is ready for use
	Device is in firmware update mode
	Device is connected
	Device Fault. Please contact support team

Proper device use

1. Hold the device and insert LEFT hand index finger under the flap until you feel the ridge at the end.
2. Place LEFT thumb on the bottom metallic contact.
3. Insert the thermometer tip under your tongue.
4. Close mouth around the mouthpiece.
5. Breathe naturally through your nose for about 60 seconds or until the device vibrates. (Follow mobile app on-screen instructions)

6. Remove the device, rinse with water (see Section 9), shake for a few seconds to allow any water in the device to come out.
7. Clean the device with alcohol wipe, and place it back into the charging case.
8. PLACE THE GLASS COVER AND RETURN THE DEVICE TO CHARGING BASE TO TURN OFF THE DEVICE.



Download and Install the App

Download and install DynoLife from the App Store or Google Play. Sign up and follow the instructions on the app to complete the process and log in.



Complete Profile

- a. If you already have an account, continue the process by clicking "Login".
- b. If you do not have an account, click "Join DynoSense" to set up a new account. Follow the instruction to complete the profile.

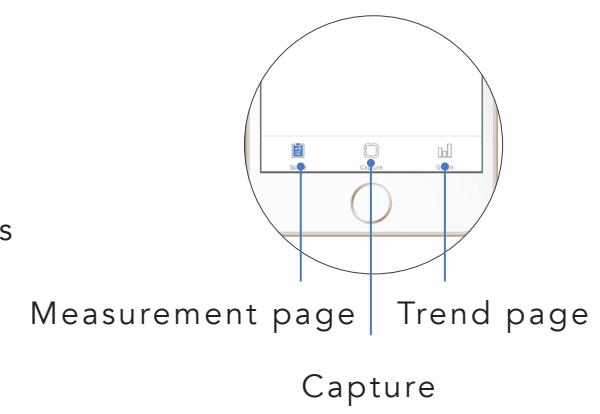
Pairing the Devices

Follow the on-screen instructions to add a new device.



Capture Process

1. Press "Capture" and follow on-screen instructions to start a new measurement.
2. Follow on-screen instructions in case of an invalid capture.

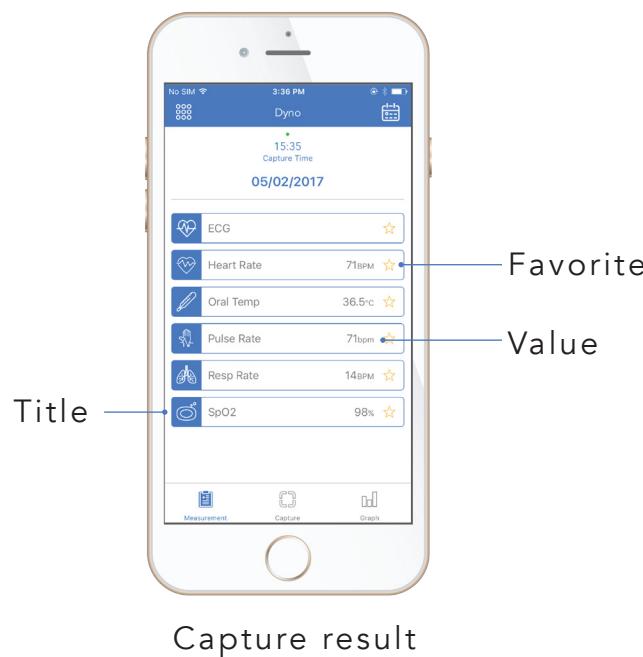


8. DYNOLIFE DESCRIPTION

Measurement Page

The measurement page shows all the health metrics. Each block has:

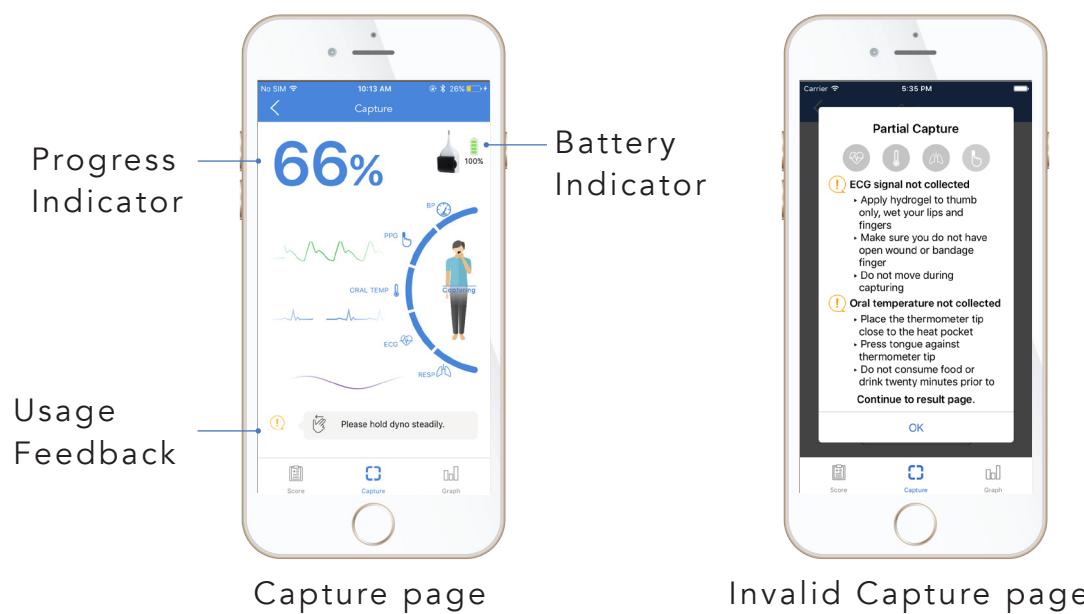
1. Title - Symbol and name of the metric
2. Value - Captured result value for the metric
3. Favorite - Allow user to prioritize the metric



Capture Page

The capture page shows the progress of a measurement with usage feedback to you to ensure optimal signal is captured. You will receive invalid capture page whenever there is an error during the capture process.

1. Progress Indicator - Progress of each measurement
2. Usage Feedback - Feedback for you to correct the usage that could potentially lead to incorrect measurements

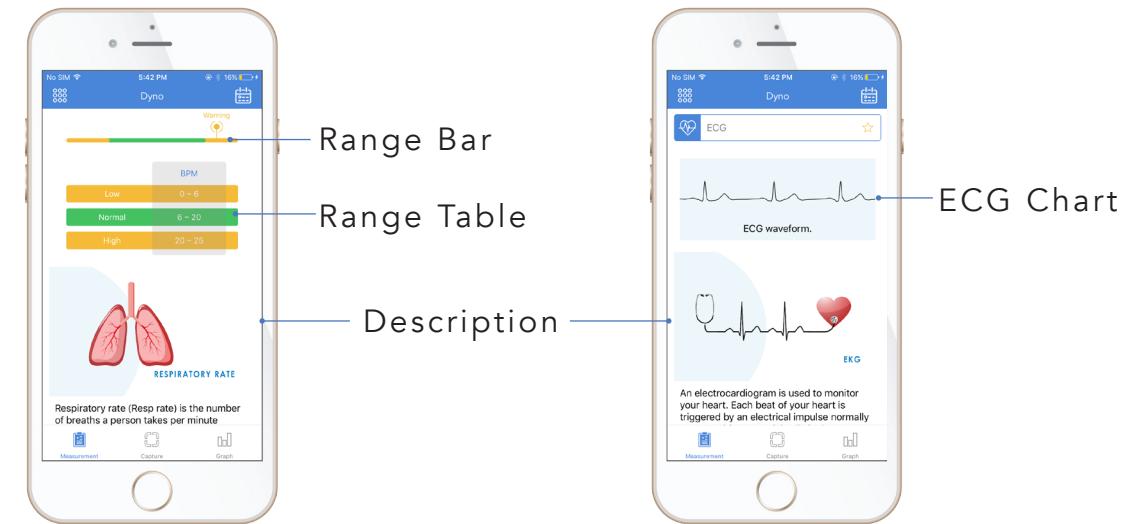


Data Interpretation (Heart Rate, Oral Temperature, Pulse Rate, Respiration Rate, SpO₂)

You can view your measured result in detail by clicking the block.

Data Interpretation (ECG Waveform)

You can view your measured ECG in detail by clicking the ECG chart.

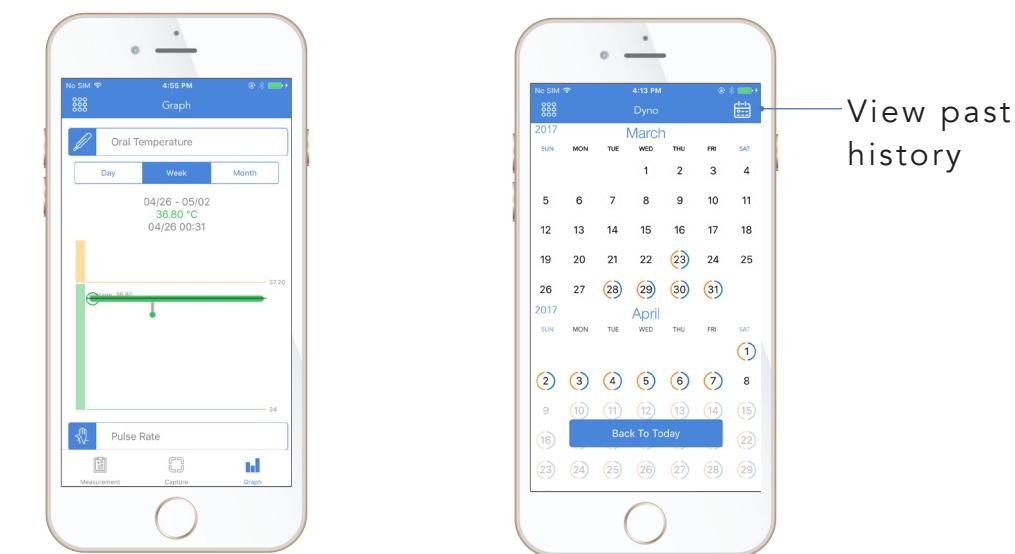


Trend Page

You can monitor your daily, weekly or monthly health trend by viewing the trend history.

Past History Result

View past history of your health metrics.



9. CLEANING INSTRUCTIONS

Alcohol Wipe

Use alcohol wipe to clean the surface of the device. IPA (70% isopropyl alcohol) based alcohol wipe packets should be used for cleaning.

Rinsing

Rinse ONLY the mouthpiece with warm water before and after every use. Do not submerge in water. After rinsing, be sure to shake the device for a few seconds for any water trapped in the mouthpiece to drip out. Wipe the device with alcohol wipe afterward and before place the glass cover.

10. CHARGING INSTRUCTIONS

1. Plug the small end of the charging cable into the charging base, and then plug the other end of the cable into a USB power supply or a computer USB port.

	Device is powered and fully charged
	Device is charging



11. STORAGE INSTRUCTIONS

Make sure to place glass cover on device to keep the device off. The device battery will gradually drain if the device is not covered.

The device with the glass cover should be stored in room temperature and not exposed to excess heat.

12. SAFE DISPOSAL INSTRUCTION

Do not dispose the device in unsorted municipal waste. This device should be returned to the distributor in case of damage.

13. TROUBLESHOOTING

Problem	Possible Cause	Solution
Device does not turn on, no status indicator	Low Battery	Charge the battery and try again. If the problem persists contact the distributor.
No valid heart rate/ECG on result screen (HR ----/ECG---)	No valid ECG data collected	Try a new data collection/capture by wetting your lips. Pay attention to the on-screen data collection progress indicator.
No valid respiration rate on result screen (Resp Rate ----)	No valid respiration data collected	Breathe normally through the nose.
No valid SpO ₂ data on results screen (SpO ₂ ---)	No valid pulse oximetry data collected	Reinsert the left index finger under the flap. Hold the device steadily and gently without too much pressure. Repeat the measurement. Warm your finger prior to use.
Temperature reading too low	Thermometer tip is not making a good contact or too much movement	Repeat the measurement by pressing tongue against the thermometer tip. Do not move the thermometer tip during the measurement.
The App can't find the device when trying to add new device	Device is not on	Make sure the device is taken out from the charging base and is on. Device status indicator should be blinking green.
Bluetooth connection failed	Mobile device Bluetooth problem	Turn off and turn on the Bluetooth of your mobile device.
"Can't connect to Cloud"	No server/No internet connection	1. Make sure you are connected to the internet. 2. If the internet connection is not good, please try again.

14. MAINTENANCE

There are no repairable parts in this device. If the device is inoperable after exhausting all the cases in the troubleshooting table without resolution, contact the distributor using the information provided in the "user assistance information" section of this manual. Make sure the device is cleaned properly after each use according to the guidelines outlined in the cleaning section of this manual.

15. LIMITED WARRANTY

Subject to the conditions and limitations on liability stated herein, the System as so delivered, shall materially conform DynoSense's current specifications for the System, for a period of one year from the date of delivery. ANY LIABILITY OF DynoSense Corp. WITH RESPECT TO THE SYSTEM OR THE PERFORMANCE THEREOF UNDER ANY WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER THEORY WILL BE LIMITED EXCLUSIVELY TO SYSTEM REPAIR, REPLACEMENT OR, IF REPLACEMENT IS INADEQUATE AS A REMEDY OR, IN THE OPINION OF DynoSense Corp.

Additionally, this warranty does not apply if:

- 2) The System is operated in a manner other than prescribed by DynoSense Corp.
- 3) The System is operated in a manner that is not in conformance with purchase specifications and specifications contained in the System.
- 4) The System is not maintained in accordance with procedures and processes defined in this Instruction for Use.
- 5) The System is repaired, altered, or modified in any way by other than DynoSense Corp. authorized personnel, or without DynoSense Corp. authorization. Contact DynoSense Corp. for instructions and issuance of a Return Material Authorization if claims under this warranty become necessary and if the System or components of the System are to be returned. The System or components will not be accepted for warranty purposes unless the return has been authorized by DynoSense Corp.

The System or accessories purchased outside the original warranty period are warranted for a period of 90 days, subject to all of

the restrictions contained in this Limited Warranty. Use of unauthorized accessories may void the warranty. In all cases, DynoSense Corp. will be the sole judge as to what constitutes warrantable damage.

16. USER ASSISTANCE INFORMATION

Please make sure you have reviewed the material in this user manual in general and the troubleshooting section specifically. In case you need further help please contact your local distributor or DynoSense at +1-650-397-6103 or visit www.dynosense.com.

17. GENERAL SAFETY INFORMATION

This section provides general information on the System.

Life of the Device:

- Service life of the device is based on battery: 18 months
- Shelf life of the device: 18 months

Recommendations:

- Frequency of device use shall be determined by your physician.
- Recommend periodic recharges the rechargeable battery, even during storage, so that the battery will not discharge to an unacceptably low voltage level, resulting in permanent damage.

18. SPECIFICATIONS

Classifications		
Degree protection against electrical shock		Type BF Applied Part
Bluetooth 4.1 Wireless Technology Information		
Modulation Type	GFSK	
Max. Output Power	+4 dBm dBm	
Frequency Range	2402-2480 MHz	
Antenna Peak Gain	0 dBi	
Recommended Range	<10 meters, line-of-sight	
Environment		
Item	Operating	Storage
Temperature	10° to 40° C	10° to 40° C

Relative humidity (non-condensing)	10% to 95%	10% to 95%
Barometric	800 to 1060 hPa	800 to 1060 hPa
Ingress rating	IPX4	
Drop test	1.0 m	
Physical		
Size Device	65.13mm X 42.35mm X 97.08mm	
Charge/Case	106.69mm X 126.98mm X 68.39mm	
Packing size	152mm X 89mm X 132mm	
Total Weight (Device+Case+Package)	~600 g	
Connector	Micro USB Connector	
Power Supply		
Battery type	Rechargeable Lithium-Polymer battery 210 mAh	
Battery run time (full charge)	Device usage twice daily: ~1 month Standby Mode: ~2 weeks In-case Mode: ~3 months	
Charge time	<3 hrs. to 90%	
Cycle life	>300 times	
ECG		
Lead type	Single Lead, 3 Contacts	
Lead set	Lead I	
Sampling rate	500 Hz	
Sampling accuracy	24 bit	
Display Gain	10 mm/mV	
Bandwidth	0.67 to 40 Hz	
Electrode offset potential tolerance	±300mV	
HR measurement range	30 to 250 bpm	
HR accuracy	±2 bpm or ± 2% (of reading), whichever is greater	
Measurement summary	Heart Rate	

SpO₂		
Standard Conformance	Meet standards of ISO 80601-2-61	
SpO ₂ display range	0% to 100%	
SpO ₂ Accuracy (A _{rms})	Range	Accuracy
	70% to 100 %	±2 %
Sampling Rate	250Hz	
PR display range	30 to 250 bpm	
PR accuracy	±2 bpm or ±2% of the reading, whichever is greater	
Measurement summary	SpO ₂ , PR	
Wavelength / Max emission power	660 nm/905 nm, 1.96 mW/1.10 mW	
Thermometer		
Technique	Thermo-resistive	
Environment temperature	10.0°C to 40.0 °C	
Measurement site	Oral, under tongue	
Measurement range	30.0 °C to 43.0 °C	
Accuracy	± 0.2 °C	
Respiration Rate		
Technique	HRV based	
Measurement range	8 bpm – 30 bpm	
Accuracy	± 2bpm or ± 2% of the reading, whichever is greater	

19. GUIDANCE AND MANUFACTURERS DECLARATION

FCC:

FCC ID: 2AHYU-9990005001
IC: 21382-9990005001

FCC Part 15.19(a):

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.

FCC Part 15.21:

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

FCC Part 15.105(b):

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 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.

ISED RSS-Gen Notice:

(1) This device may not cause interference; and (2) This device must accept any interference, including interference that may cause undesired operation of the device.

1) l'appareil ne doit pas produire de brouillage; 2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Electromagnetic Emissions

The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device 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.
RF emissions CISPR 11	Class B	The device 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Radiated emissions limits and results:

EN/IEC 60601-1-2 Class B Limits below 1GHz

Frequency range MHz	10m measuring distance	3m measuring distance ^a
	Quasi-peak dB(µV/m)	Quasi-peak dB(µV/m)
30 to 230	30	40
230 to 1000	37	47

On a test site, class B equipment can be measured at a nominal distance of 3m or 10m. A measuring distance less than 10m is allowed only for equipment which complies with the definition given in 3.10.

At the transition frequency, the more stringent limit shall apply.

^aThe limits specified for the 3m separation distance apply only to small equipment meeting the size criterion defined in 3.10.

Electromagnetic Immunity

<p>The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.</p>			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±8kV contact ±15kV air	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 ±1kV for input/output lines	Mains power quality should be that of a typical commercial hospital environment
Surge IEC 61000-4-5	±1kV differential mode	±1kV differential mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95% dip for 0,5 cycle 60% dip for 5 cycles 30% dip for 25 cycles >95% dip for 5 sec	>95% dip for 0,5 cycle 60% dip for 5 cycles 30% dip for 25 cycles >95% dip for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

NOTE UT is the a.c. mains voltage prior to application of the test level.

Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80MHz	3Vrms 150 kHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2,5 GHz	10V/m 80MHz to 2,5 GHz	$d=1.2 \sqrt{P}$ 80MHz to 800MHz $d=2.3 \sqrt{P}$ 800MHz to 2.5GHz 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a) should be less than the compliance level in each frequency range. b) Interference may occur in the vicinity of equipment marked with the following symbol (())
<p>NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.</p>			
<p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceed the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary such as reorienting or relocating the device.</p> <p>b. Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.</p>			

Recommended separation distances between Portable and mobile RF communications equipment and device			
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 2.5 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.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is effected by absorption and reflection from structures, objects and people.

Symbol	Title
IPX4	Protected against splashing water
	Operating, storage and transport temperature limit
	Operating, storage and transport atmospheric pressure limitation
	Operating, storage and transport humidity limitation
	Operating instruction
	Follow operating instruction
	Non-ionizing radiation
	Type BF applied part
	No Alarms
	Manufacturer
	Do not dispose this product as unsorted municipal waste
	Recycle
	Underwriters Laboratories MEDICAL — PATIENT MONITORING EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH IEC 60601-1 (2012), "Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance; CAN/ CSA-C22.2 No. 60601-1:08
	CE Marking
	MR unsafe, presents hazards in all MR environments as device contains strongly ferromagnetic materials.
	Prescription ONLY.

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DynoSense Corp.
100 Century Center Court, #650
San Jose, CA 95112, USA



European Authorized
Representative
Emergo Europe
Molenstraat 15
2513 BH The Hague
The Netherlands

Tel: (31) (0) 70 345-8570
Fax: (31) (0) 70 346-7299

DynoSense