V1000 System

Instructions for Use

PRQ-00100-01

Table of Contents

Preface

V1000 System (also known as Dyno 100) which includes:

- Device: model # Dyno101, P/N 999-00101-01
- Case: Model # Dyno102, P/N 999-00102-01

Part Number: 999-00100-01

IEC 60601

CE Mark Complies with the Council Directive 93/42/EEC Manufactured by:

DynoSense Corp.
100 Century Center Court, Suite 650
Sam Jose, CA 95112
Phone: 650-397-6103
Fax: 650-397-6105

Distributed in the USA by:
DynoSense Corp.
100 Century Center Court, Suite 650
Sam Jose, CA 95112
Phone: 650-397-6103
Fax: 650-397-6105

Copyright Notice

Warranty

NOTICE: Manufacturer's Specifications and Policies Subject to Change. DynoSense Corp. reserves the right to make changes in the products described in this manual in order to improve design or performance. Reproduction or distribution of any portion of this manual without the prior written consent DynoSense Corp is prohibited.

Limited Warranty

Subject to the conditions and limitations on liability stated herein, the System as so delivered, shall materially conform DynoSense's then current specifications for the System (from here on known as 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., IMPRACTICAL, TO REFUND OF THE PRICE PAID FOR THE SYSTEM. EXCEPT FOR THE FOREGOING, THE SYSTEM IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND, EXPRESS OR IMPLIED,

Additionally, this warranty does not apply if:

1) The System is operated in other than a manner prescribed by DynoSense Corp.
2) The System is operated in a manner that is not in conformance with purchase specifications and specifications contained in the System.
3) The System is not maintained in accordance with procedures and processes defined in this Instruction for Use, the System Instructions for Use.
4) 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.

System parts or components repaired or replaced under warranty bear the same warranty expiration date as the original equipment. 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 replacement parts may void the warranty. In all cases, DynoSense Corp. will be the sole judge as to what constitutes warrantable damage.

Purpose of this Manual

This instruction manual is designed for use by the end users (patient) and health care professionals to provide clinical and technical information about the safe use of the System V1000 System family. This manual should be read and understood prior to the use of V1000 System.

Safety

Carefully read and review this entire the following instruction safety warning and caution before operating the system.

Warnings

	No modification to the System is permitted. DO NOT DISASSEMBLE
	Do not use, without the consent of your healthcare provider.
	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. Seek emergency medical attention immediately.
	Do not share your Sensor with others to avoid potential risk of contamination.
	Do not use with a defibrillator.
	Do not use soap or chemicals to clean the Dyno sensor.
	Do not immerse in water.
	Do not use while in bathtub or shower
	To be used only by adults over age 18

Caution

	No modification to the System is permitted. DO NOT DISASSEMBLE.
	If any component of System fails to operate after attempting all suggested troubleshooting methods, contact your product provider immediately.
	Do not dispose system parts (sensor and scale) in a household trash bin. Return parts to DynoSense for disposal.
	Keep System (sensor/device and case) away from excessive heat exposure, as this may cause damage. Recommended operating temperature range: 10 - 40 degrees C. Recommended operating relative humidity range: 10 – 95% RH
	Always store your Dyno in the case when not in use.
	Place the Dyno case on a firm surface near a wall outlet.
	Do not drop, especially onto hard surfaces.
	To be inserted only into the MOUTH.

General

The System has been tested by UL for electrical safety test, and complies with the applicable requirements.
The System has been tested by UL for FCC compatibility in accordance with ANSI C63.10-2013, FCC CFR 47 Part 2, FCC CFR 47 Part 15, RSS-GEN Issue 4, and RSS-247 issue 1, and it meets the applicable requirements.
The System is RoHS compliant.
The System software failure, firmware failure or battery failure has no adverse effect on the end-user. The failure would disable vital data collection and transmission.
The System has been tested for ingress protection, and it meets IPX4 protection.
No installation or maintained is required for using the System. Follow Set-Up procedure described in this document.
No cable is required for operation. Follow Set-Up procedure described in this document.
If the unit is dropped onto a hard surface from a height of approximately 3', more than 3 times OR dropped onto a soft surface from a height of approximately 5', more than 3 times, the sensor may sustain physical and functional damage. If this occurs please contact DynoSense Corp for assistance.

Chapter 1 – General Information

DynoSense V1000 system consisting of Dyno100 (Device+Case+Charging Cable, Hydrogel and Sanitizing Wipe) is a vital monitoring system intended to measure Electrocardiograph (ECG), functional oxygen saturation of arterial hemoglobin (SPO2), photoplethysmography (PPG), Respiration Rate (RR), Oral Body Temperature (TEMP), and Breath Alcohol Content (Ethanol) percentage.

Wireless Technology

DynoSense System uses wireless techniques to transmit data. The wireless link uses the Bluetooth BLE V4.1, transmitting at 2.4GHz. As with any wireless system, it is possible to disrupt communications if there is a high amount of RF interference or if the maximum wireless link range has been exceeded. The maximum range specified for this technology is about 10 feet, line of sight. If too much interference is detected or if the user has gone out of range, the link between the sensor and iPhone will be suspended.

Patient data and configuration are transmitted through a secure, encrypted link in order to protect the user from unauthorized access.

iOs Device is compatible and is version V5.0 or higher. Wireless internet connection provide by a router is compatible with Wi-Fi IEEE 802.11 b/g standard and supports WEP WPA and WPA2 personal security modes.

Indications for Use

DynoSense system consisting of multi-functional scanner and cradle is intended for monitoring physiological data within inpatient, outpatient or home settings. This includes: Electrocardiograph (ECG), functional oxygen saturation of arterial hemoglobin (SPO2), photoplethysmography (PPG), Respiration Rate (RR), Oral Body Temperature (TEMP), and Volatile Organic Compounds (VOC) level.

The system is intended for use on general care patients (including home use) who are at least 18 years of age. It is not intended for use on critical care patients.

System Set-up Instruction:

What you need to get started:

1. An iPhone is required in order to use the Dyno 100 for the DynoLife app.
2. Charging cable wall to connect case to the computer or charging block.
    a. Charging block is not included in the box and should be provided by the user.

Unpack:

1. Remove the protective outer sleeve from the Dyno 100 box by gently sliding it off.
2. Save the protective outer sleeve, as it contains important information that you may need later for reference.
3. Open the protective box and remove the plastic case.
4. Ensure the following is included in the box:
    a. Dyno sensor
    b. Charging Cable
    c. Hydrogel
    d. Sanitizing Wipes

Prepare Dyno 100 Sensor for use:

1. Plug the small end of the charging cable into the plastic case, and then plug the other end of the cable into a charging block or plug into laptop computer USB port.
2. The Dyno sensor is automatically charged and sanitized when it's placed in the case. Note: sanitization begins when the case top is closed, and cable is plugged into a USB charger that is plugged into wall outlet or a computer USB port.
    a. Flashing light on the back of the case indicates that the Dyno is being sanitized. Case must be closed for sanitization
3. Continue charging until the green LED indicator light is on.
    a. Charger LED indication is: red = need charge, amber = charging, green = charged).
    b. Battery is charged through inductive charging and is compatible with Qi (inductive power standard).
4. Additional sanitization can be achieved by wiping the tip and mouthpiece with a sanitizing wipe. Sanitizing wipes are intended for single use only.

Download and Install the App:

a. From the iPhone, click on the "App Store" (Figure-1).
b. Go to "Search", type in "DynoLife"
c. When DynoSense" app appears on the screen, select "Get" (Figure-3) to download the App.
d. When the download is successfully complete, "DynoSense" App will be added to the iPhone, and instruction video opens (Figure-3).

Figure-1

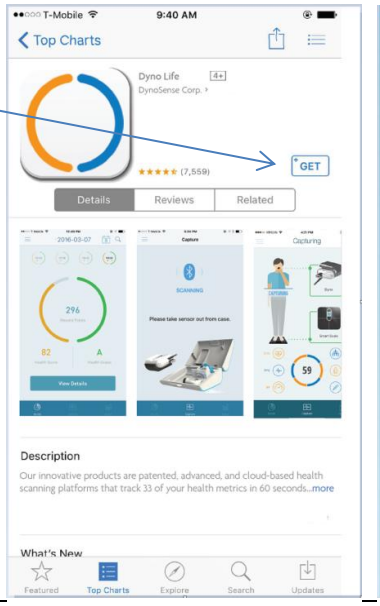


Figure-2

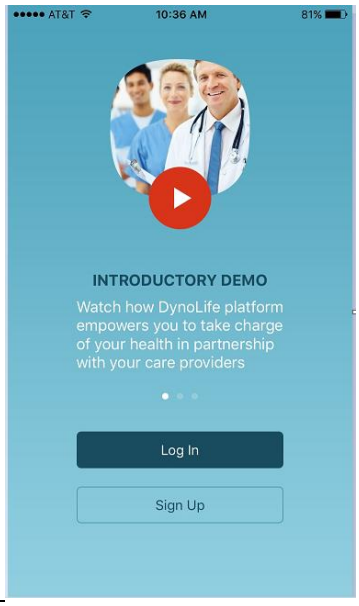


Figure-3

Watch Instruction Video:

a. Tap on the red play button  (Figure-3) to watch a 30-45 seconds video covering the following topics: following topics:
    1. Trouble shooting
    2. Sign up and complete profile
    3. Pairing the device with iPhone

Sign up and Complete Profile:

a. Tap on "Create Account" to sign up a new account. If you already have an account set up with DynoSense, tap on "Login" to continue (Figure-4).

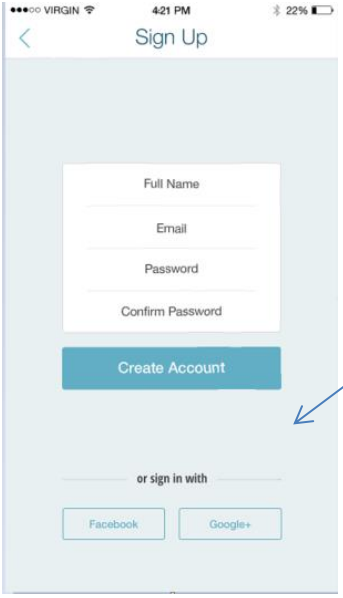
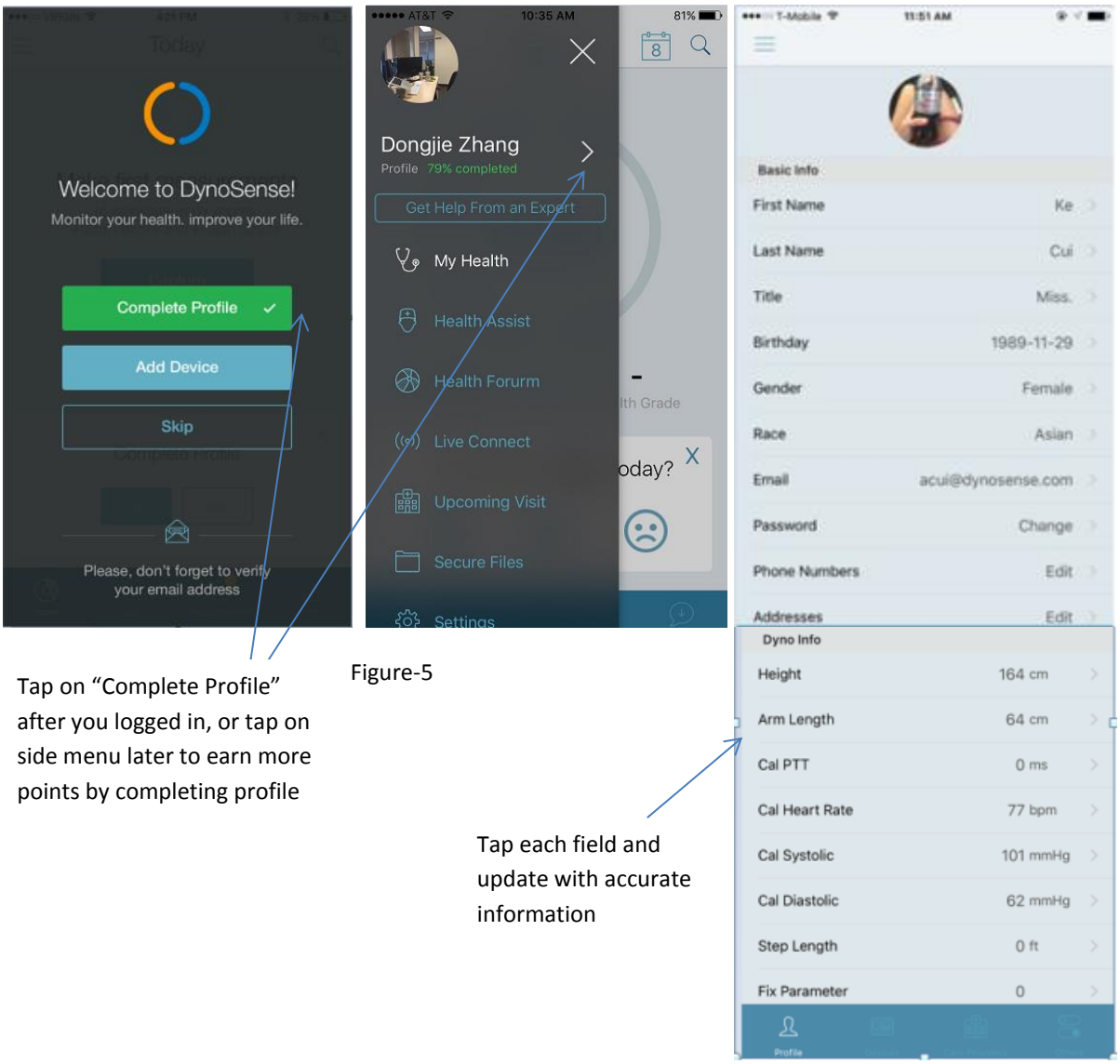


Figure-4

b. Complete Profile

After you signed up or logged in, you can either “Complete Profile” to fill in your detail information for a better health result or complete it later (Figure-5).



Tap on “Complete Profile” after you logged in, or tap on side menu later to earn more points by completing profile

Figure-5

Tap each field and update with accurate information

Figure-6

Pairing the Devices:

a. Tap on “Capture” before pairing the device with iPhone (Figure-7)
b. Turn on “Bluetooth” on your iPhone
    1. Go to Setting
    2. Select Bluetooth
    3. Tap on the Bluetooth radio button to turn green
c. Tap on Settings to go back to the main screen

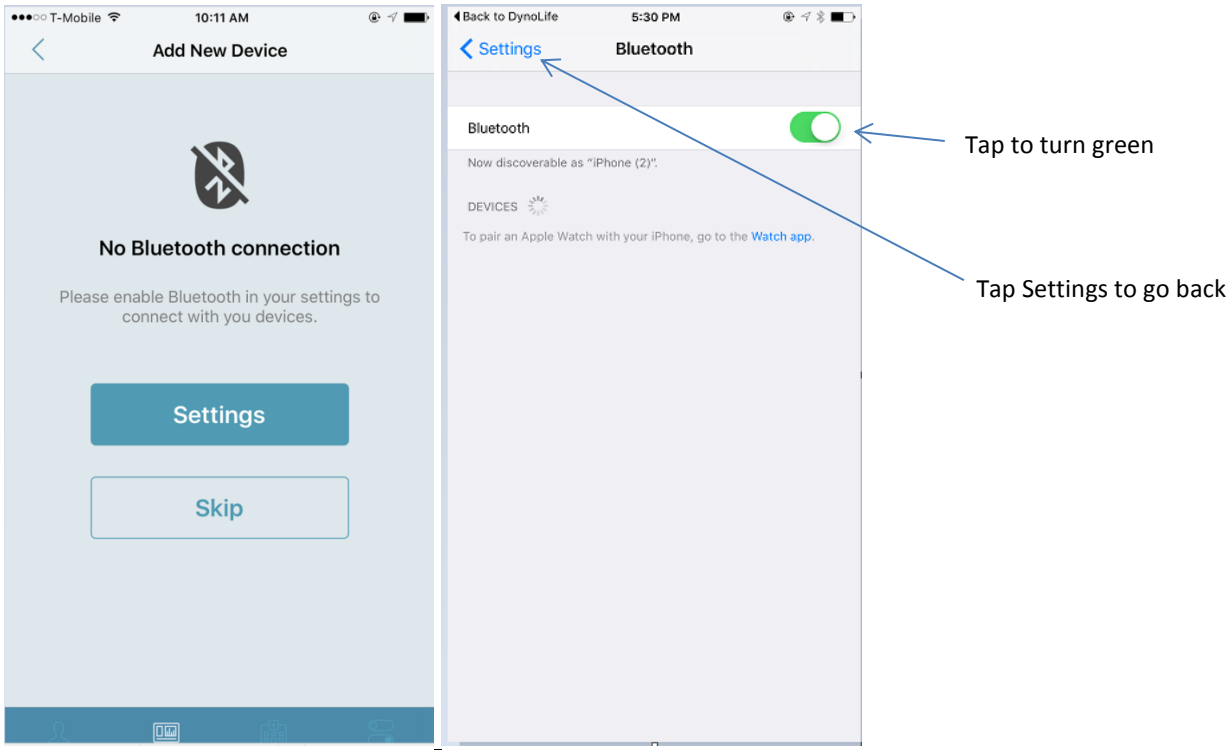


Figure-7

d. Complete paring the device and get ready to start capturing data (Figure 8)

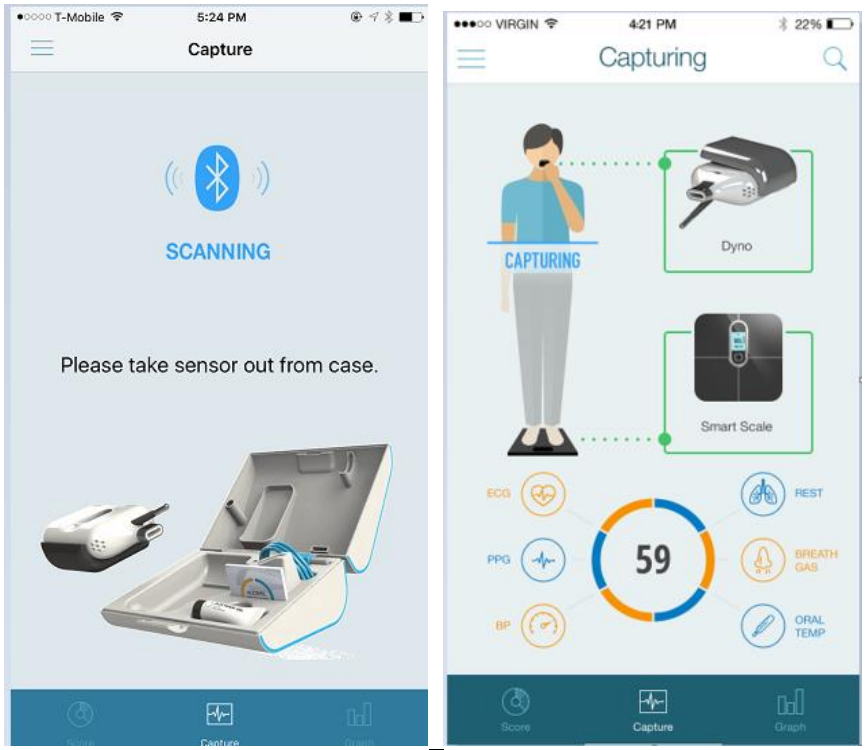


Figure-8

How to use Dyno 100:

1. Make sure your iPhone is turned on.
2. Make sure the Dyno sensor has been charged (green light will indicate fully charged) and sanitized prior to use.
3. For best results, remove the hydrogel from the case and gently squirt a tiny, thin dot of gel on left THUMB (if you run out of hydrogel, you can still use the sensor).
4. While sitting down, place your left arm on a table for stability.
5. Hold the Dyno sensor in your LEFT hand. (Figure-9)
6. Insert your FOREFINGER underneath the moveable cover and place THUMB on the sensor located underneath. Your left hand fingers should not rest on top of Dyno cover. Rest your elbow comfortably on a firm surface.
7. Insert the sensor tip under your tongue, and make sure that the opening of the sensor is above the tongue, so you can breathe into the opening.
8. BREATHE normally into the opening (do not blow) until completion beep is heard (in less than 60 seconds).
9. Remove the Dyno from your mouth, remove your forefinger and thumb from the sensor, wipe the mouthpiece and underneath sensor clean with sanitizing wipe, and replace the Dyno into the case, positioning it correctly, so the LED light will change color.

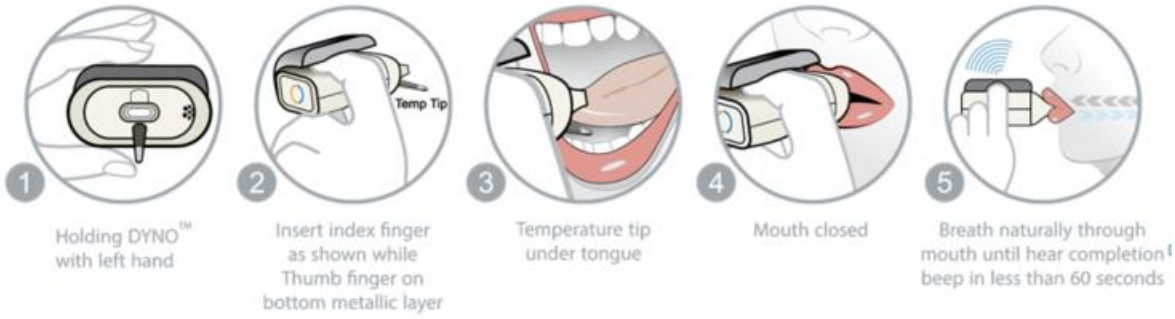


Figure-9, Dyno Sensor use instruction

Cleaning and Sanitizing

Cleaning

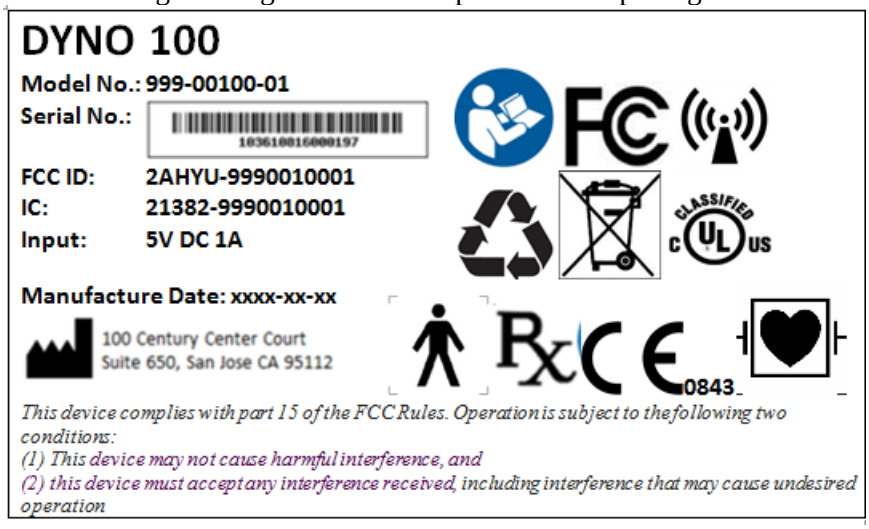
Alcohol wipes are used to clean the surface of the Dyno Sensor, case, and cable. IPA (80-20 Isopropyl alcohol) based alcohol wipe packets for surface cleaning are provided initially, and can be purchased from commercially available stores (CVS pharmacy, Rite Aid, target, Walmart, etc.).

Sanitizing

Dyno Sensor is automatically sanitized by a UV light inside the Case, when Dyno Sensor is placed in the case and the lid is closed. An indicating light on the back of the case indicates UV sanitizing operation. The UV light is UVC (254 nm) standard wavelength for sanitization.

The following marking information is placed on the Sensor:

The following marking information is placed on the package:



Additional information not on the marking:

Underwriters Laboratories

MEDICAL — PATIENT MONITORING EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH

ANSI/AAMI ES60601-1 (2005), "Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance; CAN/CSA-C22.2 No. 60601-1:08; ANSI/AAMI/IEC 60601-2-25,

"Medical Electrical Equipment - Part 2-25: Particular Requirements for the Basic Safety and Essential Performance of Electrocardiographs"

Clinical Restrictions:

SpO2

1. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to influence.
2. For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicycle hemoglobin, and some with icterus problem, the SpO2 determination by this monitor may be inaccurate.
3. The drug like domamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO2 measure.
4. As the SpO2 value serves as a reference value for judgement of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO2 measurement.

General Information

This section provides general information on the System.

Life of the Device:

- Recommend life of Sensor is 2 years
- Recommended shelf life of the Sensor is 18 months

Recommendations:

- Recommend gently wiping the sensor module with a sanitizing alcohol wipe after every use
- Recommended operating temperature range: 10 - 40 deg C
- Recommended shipping and storage temperature range: 0 – 40 deg C
- Recommended shipping and storage relative humidity range: 10 – 95% RH
- Recommended operating relative humidity range: 10 – 95% RH
- Recommended operating altitude: < 2000 m
- Recommended barometric pressure: 80 kPa

FCC:
FCC ID: 2AHYU-9990010001
IC: 21382-9990010001

FCC part15.19(3):
All other devices shall bear the following statement in a conspicuous location on the device:

- 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 part15.21:
The user's manual or instruction manual for an intentional or unintentional radiator shall caution the user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

IC RSS-Gen section 8.4

English
This device complies with Industry Canada's licence-exempt RSSs. Operation is subject to the following two conditions:
(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.

French
Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :
(1) l'appareil ne doit pas produire de brouillage;
(2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

- 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 Title 47, Subpart A, Part 15.19(3)).
- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment (FCC Title 47, Subpart A, Part 15.21)

Electromagnetic Compatibility (EMC):

- The System may need special precautions regarding EMC and should be used according to the EMC information provided in the "Warning" and "Caution" sections of this document.
- Portable and mobile RF communications equipment can affect the sensor, cradle or scale. See Medical Electrical Equipment user manual for RF communication precautions.
- Type of radio modulation, frequency and antenna power is follows:
  - Radio modulation: FSK (frequency shift keying)
  - Frequency: 2.4 – 2.5GHz
  - Antenna power: 4dbm

Electromagnetic Emission Declaration		
The system is intended for use in the electromagnetic environment specified below. The end user should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment**
RF emissions CISPR 11	Group 1	The cradle 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 sensor 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.

Guidance and declaration – electromagnetic immunity (For ME equipment ME system that are not life-supporting)			
The System is intended for use in the electromagnetic environment specified below. The end user of should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment- guidance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the System than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1,2\sqrt{p}$ 80 MHz to 800 MHz $d = 2,3\sqrt{p}$ 800 MHz to 2.5 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 meters (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: 

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

[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.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between
Portable and mobile RF communications equipment and the Sensor (Dyno 100)

Dyno 100 sensor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Dyno 100 sensor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Dyno 100 sensor 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 2.5 GHz** $d = 2{,}3\sqrt{p}$
0.01	NA	0,12	0,23
0.1	NA	0,38	0,73
1	NA	1,2	2,3
10	NA	3,8	7,3
100	NA	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.

Guidance and declaration – electromagnetic immunity
(For ME equipment ME system that are not life-supporting)

The System is intended for use in the electromagnetic environment specified below. The end user should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment- guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	0.3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T *is* the a.c. mains voltage prior to application of the test level.

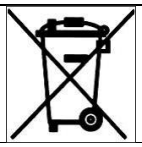
Trouble Shooting:

For complete troubleshooting watch the instructional video downloaded on your iPhone (after DynoSense App is downloaded), see table below or go to Visit www.dynosense.com.

Problem	Solution
Dynolife can't find the sensor when trying to add new sensor.	Make sure you take the sensor out from case and the sensor is power on. (Sensor bottom light is green). If still can't find the sensor, put the sensor back to the case and reset it
Bluetooth connection failed.	1. Make sure you take the sensor out from case and the sensor is power on. (Sensor bottom light is green or blue). If still failed, put the sensor back to the case and reset it. 2. If Step 1 didn't work, turn off and turn on the Bluetooth of your iOS device. 3. If Step 1 and 2 didn't work, restart your iOS device.
No Cloud Error.	1. Make sure you are connected to internet. 2. If internet connection is not good, please try again.

For DYNO technical support, or call 1-xxx-xxx-xxxx

General symbols

Symbol	Title
IPX4	Protected against splashing water
	Operating instruction
	Follow operating instruction
	Non-ionizing radiation
	Defibrillation proof type CF applied part
	Type B applied part
	Manufacturer
	Do not dispose in household trash
	Recycle
	Underwriters Laboratories **MEDICAL — PATIENT MONITORING EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH** ANSI/AAMI ES60601-1 (2005), "Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance; CAN/CSA-C22.2 No. 60601-1:08; ANSI/AAMI/IEC 60601-2-25, "Medical Electrical Equipment - Part 2-25: Particular Requirements for the Basic Safety and Essential Performance of Electrocardiographs" E358758
	CE Marking conformity