casana

The Heart Seat™
Instructions for Use

Casana Care, Inc.
150 Metro Park Drive, Suite A, Rochester, NY 14623
Phone: 1.585.944.6549 www.casanacare.com
eIFU available at: https://www.casanacare.com/eifu

casana

Table of Contents

Contact Information

Casana Support is available during normal business hours. Please call this number for all questions to Casana:

Country	Phone Number	Email	Address
USA	+1-585-944-6549	support@casanacare.com	150 Metro Park Drive, Suite A Rochester, NY 14623

Important Safety Information

This document provides you with important information about the Heart Seat. To ensure the safe and proper use of the Heart Seat, READ and UNDERSTAND all of these instructions.

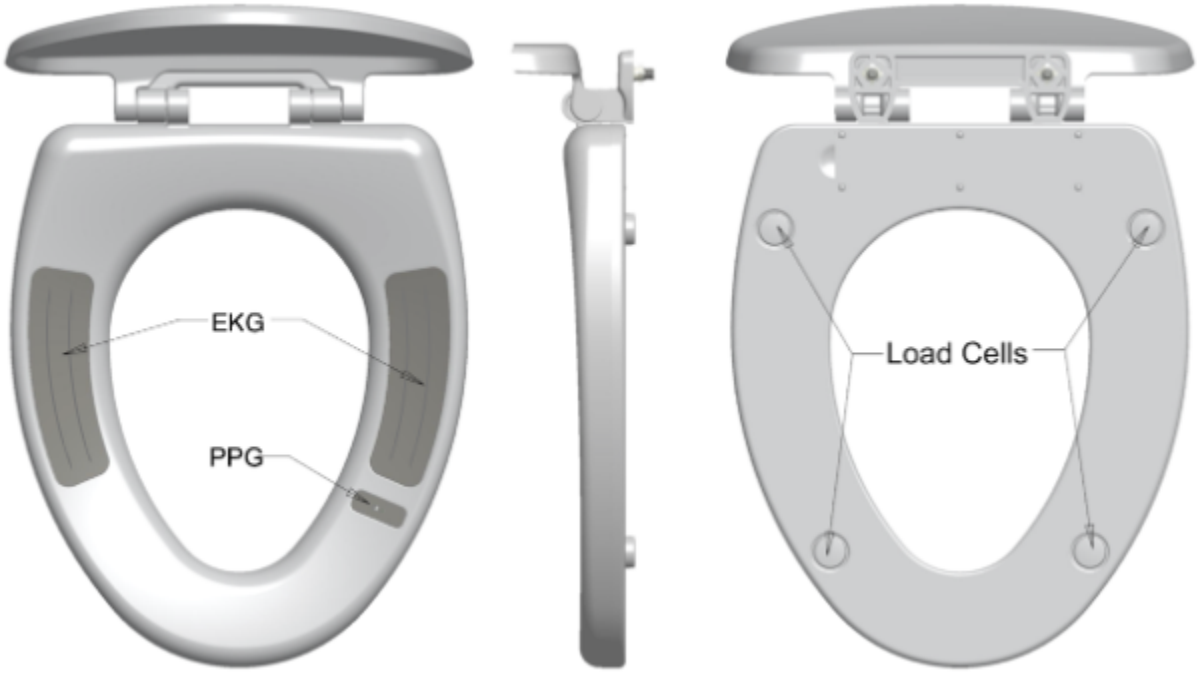
If you do not understand these instructions or have any questions, contact 1-585-944-6549 before using the Heart Seat. For specific information about your health data, consult with your prescribing clinician.

- **The Heart Seat is intended for use by adult individuals who are able to sit on a toilet seat without assistance and make full skin contact with the sensors.**
- **The Heart Seat is intended for physiological monitoring in home settings.**
- **The Heart Seat is not intended to replace regular office visits with a clinician.**
- **The Heart Seat is intended for use by individuals who weigh between 90 and 350lbs.**
- **The home health environment does not unacceptably affect basic safety or essential performance of the Heart Seat.**
- **The Heart Seat does not have the capability to detect an SpO2 or pulse rate physiological alarm condition.**

CAUTIONS & WARNINGS:

- **Caution: Federal law restricts this device to sale by or on the order of a clinician.**
- **DO NOT use the Heart Seat in oxygen-rich environments or near flammable gas.**
- **The Heart Seat must be installed and set up by a trained individual.**
- **WARNING: No modification of this equipment is allowed.**
- **The Heart Seat is strictly a monitoring device. Patients with concerning data from the Heart Seat should be evaluated by their prescribing clinician prior to treatment decisions.**
- **Stop using the Heart Seat and consult with your prescribing clinician if you experience skin irritation from using the Heart Seat.**
- **Tattoos on the thighs or buttocks that make contact with the sensors may inhibit the Heart Seat from gathering data.**
- **Failure to follow warnings and directions may lead to no data or inaccurate data collected.**
- **DO NOT open the Heart Seat or battery compartment. If you suspect a dead battery or a broken seat, please contact Casana.**
- **DO NOT use any toilet accessories with the Heart Seat that are not approved for use by Casana.**

Heart Seat Overview



Top View **Side View** **Bottom View**

The Heart Seat incorporates a single-lead electrocardiogram (ECG) for measuring the electrical activity of the heart, a photoplethysmogram (PPG) for measuring blood oxygenation and volumetric changes associated with the peripheral pressure waveform, and load cells for the measurement of seated weight and the ballistocardiogram (BCG) for measuring mechanical forces associated with the cardiac cycle. These instruments are used to positively identify the monitored user and calculate the Heart Seat parameters including non-invasive blood pressure, blood oxygenation, and heart rate.

Indications for Use

The Heart Seat is a replacement for a standard toilet seat that is indicated for use in home and home healthcare environments. The Heart Seat is intended to be used for measuring, displaying, reviewing and storing non-invasive functional oxygen saturation of arterial hemoglobin (SpO2), heart rate (HR), and non-invasive blood pressure (systolic and diastolic) in adults of at least 22 years of age with weight ranging from 90 to 350 pounds. Data from the Heart Seat are collected whenever the Heart Seat is used and are automatically uploaded to the Casana Cloud where they can be viewed by the healthcare provider. The Heart Seat is not intended for continuous monitoring.

CONTRAINDICATIONS:

- **The Heart Seat is NOT intended for use by anyone who utilizes a left-ventricular assist device or other mechanical circulatory support.**
- **The Heart Seat is NOT intended for individuals with known arrhythmias and/or irregular rhythms as the accuracy in individuals with any significant irregularity of the heart rate is unknown.**
- **The Heart Seat has NOT been tested to confirm tall T-wave rejection.**
- **The Heart Seat is NOT intended, and should NOT be used, in the presence of implantable cardiac electrical devices (e.g., pacemakers) since performance of The Heart Seat has NOT been verified in the presence of such devices.**
- **DO NOT use the Heart Seat if you have a known titanium or polypropylene allergy or sensitivity.**
- **DO NOT use the Heart Seat if you have any open wounds that may contact the Seat.**

What to Expect

Once your clinician prescribes your Heart Seat, Casana will contact you to confirm that the seat will fit on your toilet and schedule an installation and onboarding visit. The Heart Seat will be installed in your home and connected to your home wifi by a trained installer. The installer will also conduct a setup process with you, which will include measuring your blood pressure with a cuff and programming the seat to identify you.

Use the Heart Seat as you would a normal toilet seat. The Heart Seat will gather data on your health when you sit on it. The data will be automatically uploaded to the secure Casana Cloud.

SpO2 (Blood Oxygenation)
The pulse oximeter sensor uses both red and infrared light to detect your blood oxygen level. The light shines on your thigh while you are seated, and is reflected back to the pulse oximeter sensor. Based on the amount of light returned through the tissue of your thigh, your blood oxygenation is calculated.

Heart Rate
The Heart Seat's ECG sensors detect heartbeats and Casana's algorithms calculate your heart rate. The heart rate displayed to your health care team is a median value over the duration of your sit. The Heart Seat will not provide a heart rate measurement if the value is less than 40 beats per minute.

Blood Pressure
Your Heart Seat is calibrated using blood pressure values collected during the setup process. After successful calibration, the Heart Seat's blood pressure algorithms will calculate changes in your blood pressure using data gathered from the Heart Seat's sensors and report those blood pressure values to your health care team. The Heart Seat will not provide a blood pressure measurement if the systolic pressure is outside the range of 60 - 299 mmHg or the diastolic pressure is outside the range of 40 - 299 mmHg.

Your health care team will monitor your health data and contact you as appropriate.

General Use Information

To Increase the Likelihood of Obtaining a Clinical Value:

- Sit upright on the Heart Seat such that the skin on your buttocks and thighs make direct contact with the two titanium sensors and plastic window of the pulse oximeter sensor.
- Do not lean back against the Heart Seat lid.
- Sit on the Heart Seat for at least 90 seconds.
- Sit calmly on the Heart Seat without excessive movement (e.g. fidgeting, bouncing legs, or shifting position).

Suggested Cleaning and Care:

- Clean the Heart Seat on a weekly basis. Apply a non-abrasive bathroom cleaner (e.g. Lysol Power Bathroom Cleaner) to the seat and then thoroughly clean the Heart Seat with a soft sponge or cloth. After cleaning, wipe the Heart Seat with a clean, water-dampened cloth.
- Do not use abrasive cleaners or tools to clean the Heart Seat (e.g. powdered cleaners, scouring pads, cleaners containing bleach).
- The Heart Seat should not be immersed fully in water or put into a dishwasher to be cleaned.
- The top of the Heart Seat should be clear of grime and dirt to ensure the sensors make good contact with the skin.
- The Heart Seat has slow-close hinges. Do not slam the Heart Seat shut.
- Ensure the ambient temperature of the bathroom where the Heart Seat is installed is between +41^{o}F to +104^{o}F (+5^{o}C to +40^{o}C).

Disposal:

- If you no longer need the Heart Seat, please return it to Casana.
    - Clean the seat, then place it back inside the Heart Seat box.
    - Contact Casana support for a return label and address (see Contact Information section).

Cybersecurity Information

The following cybersecurity risks have been identified as associated with the Heart Seat use: Personal identity loss or identity sharing; Identity spoofing; Identity theft and misuse; Insecure Protocol Negotiation / Website XSS Vulnerabilities; Zero-Day / Unknown-unknowns; Physical System Compromise; Physical System Compromise / Local Interface Compromise; Man-In-The-Middle Attacks; Unauthorized Data Access from an employee; Unauthorized Data Deletion or Modification; (Distributed) Denial of Service Attacks; Unauthorized User Privacy Breach from an employee; Website XSS Vulnerabilities Leak User Data; Website XSS Vulnerabilities Leak User Data; Unauthorized Data Access from an employee; Data Compromise and Exfiltration.

Use of the Heart Seat in the monitored user's home environment requires an internet network interface (wifi) capable of forming secure HTTPS connections. Any modern internet connection is capable of supporting such connections without modification.

The following requirements have been implemented to protect the user from cybersecurity risks and to operate in a secure manner:

- When connecting to a seat via bluetooth, the System shall require the user to enter a seat PIN before connecting, unless the user is authorized to connect using the Setup App
- The cloud shall not accept requests from seats that are not able to prove they are genuine Casana Seats;
- The cloud shall expose an API to the seats over TLS 1.2 or higher;
- The cloud shall always communicate over TLS 1.2 or higher when transmitting data on a network;
- The seat shall authenticate to the cloud using a TLS trust chain;
- The seat shall not execute commands from an unauthorized BLE connection;
- The seat shall gracefully reject invalid commands issued over BLE

The following requirements have been implemented to protect from cybersecurity risks and to operate in a secure manner:

- The clinical user must use a modern web browser with all relevant security updates installed;
- Email addresses used in Casana Cloud shall be required to be unique;
- Casana Cloud shall require passwords to be at least 10 characters long with at least one special character, one uppercase letter and one lowercase letter;
- Casana cloud shall support two-factor authentication;
- Upon updating their email, users shall receive an email with a link to click to verify the new email is under their control prior to the system updating their login email;
- When changing their password, users must successfully enter their original password before entering a new password.

Casana Cloud implements audit trail logging for all actions taken by clinical users while logged into the Casana Cloud. As such, security breaches and future anomalies may be investigated, the root cause determined, and any necessary remedial action taken.

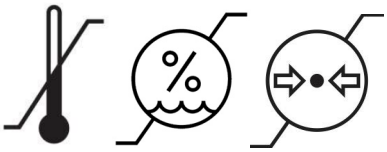
The Casana Heart Seat is a secure connected medical device that utilizes wifi and Bluetooth connectivity. To safeguard data collected, The Heart Seat is installed, securely configured, and updated only by Casana-trained individuals. Casana recommends that the user not alter any wifi security settings on the local wifi network after the Casana-trained individual configures the Heart Seat for use.

The Heart Seat should not be used on public, open, or unsecured wifi networks. If you suspect or confirm a cybersecurity incident on your wifi network, including the presence of an unauthorized connected device, unauthorized access, or a device on the network becoming infected with a malware or a computer virus, please contact Casana Support.

Frequently Asked Questions

Can I urinate and defecate while using the Heart Seat?	Yes. You can use the Heart Seat as you would a normal toilet seat.
How will the Heart Seat know that it's me? Will it get confused if other people use the Heart Seat?	The Heart Seat will use a combination of factors from the set up session to identify the prescribed patient. This means that the Heart Seat dashboard will report data when the system identifies that it is you who sat on the seat.
Can more than one person be set up on the same Heart Seat?	Not at this time.
Who will have access to my health data? What should I do if I suspect unauthorized access?	Your care team will have a dashboard with the ability to review your physiological data. If you suspect unauthorized access to your account or data, **contact Casana immediately at 1-585-944-6549**.
Can I see my data from the Heart Seat?	No. At this time, only your prescribing clinician and care team will have access to your data.
Do I have to turn the Heart Seat on or off?	No. The Heart Seat detects when someone sits and immediately begins recording data. You do not need to turn it on or off.
What is the red light on the Heart Seat?	Each time you use the Heart Seat, the red LED light on the pulse oximeter sensor turns on. This light is what allows the Heart Seat to capture your blood oxygenation level. Sometimes, opening the lid or motion around the Heart Seat may activate the light. That’s normal. The light will turn off automatically after a few seconds.
Is there a camera in the Heart Seat? Is there a microphone in the Heart Seat?	No.
How long does the battery last? How do I know the batteries are still working? What do I do if the batteries are dead?	Battery lifetime is dependent on device usage. Casana monitors each Heart Seat’s battery level and will schedule an installer to replace the batteries as needed. Used batteries are sent to a specialized battery recycler for proper disposal.

Symbols/Markings

Symbol/Marking	Meaning
 https://www.casanacare.com/eifu	Caution, consult accompanying documents: Instructions For Use (IFU). The IFU is available at this web address https://www.casanacare.com/eifu
	Type BF Applied Part
	Temperature, humidity, and atmospheric pressure limits
IP52	Device is dust-protected and protected against vertically falling water drops per IEC 60529
	Device is prescription-only
	Serial number
	Manufacturer
 (01)11111111111110	QR code with Unique Device Identifier

Specifications

Model[1, 2]	HS2
User Weight Range	90lbs to 350lbs
Transmission Method	Wifi
Wireless Communication	**Wifi Frequency Range:** 2.412 GHz – 2.484 GHz, 4.9 GHz – 5.975 GHz **Bluetooth Frequency Range:** 2.402 GHz – 2.480 GHz **Modulation:** IEEE 802.11 a/b/g/n (OFDM, DQPSK, DBPSK, CCK, 64-QAM, 16-QAM, QPSK, or BPSK) **Effective Radiated Power:** <20 dBm **Operating Distance to Access Point:** <150 m **Security Protocol:** WPA/WPA2/WPA3
Accuracy[3, 4]	**SpO2:** A_{RMS} less than or equal to 3.5% over the range 70 to 100% **Heart Rate:** ±10% or ±5 bpm, whichever is greater over the range of 40 to 200 bpm **Blood Pressure:** 0.4 ± 8.2 mmHg over the range of 40-299 mmHg for diastolic pressure and 0.7 ± 10.1 mmHg over the range of 60-299 mmHg systolic pressure
LED Wavelengths	**Red:** 624 nm **IR:** 860 nm
LED Maximum Output Power	**Red:** 190 mW **IR:** 35 mW
Operation Mode	Continuous Operation
IP Classification[5]	IP52
Power Source	ER26500H 1S3P 3.6V 25.5Ah Lithium Thionyl Chloride Primary Battery Pack
Battery Life	One year operating life based on Expected Use Case
Use Life	5 Years
Operating Conditions	+41°F to +104°F (+5°C to +40°C) / 15 to 95% RH (non-condensing)
Storage/Transport Conditions	**Storage:** +14°F to +131°F(-10°C to +55°C) / 10 to 95% RH (non-condensing) **Transport:** -27.4°F to 159.8°F (-33°C to +71°C) / 10 to 95% RH (non-condensing)
Weight	5.5 lbs
Dimensions	18.16” (l) x 14.40 (w) x 3” (h) with lid closed
Compatible Toilet Bowl Length	18.5” in length from the mounting holes to the front edge
Internal Memory	Stores at least one week of recorded Patient data based on the Expected Use Case
Applied Part	Type BF
Protection Against Electric Shock	Internally Powered ME Equipment
Max. Temperature of Applied Part	Lower than +118.4°F (+48°C)
Contents	Heart Seat, 2 Sta-Tite Nuts, Instructions for Use
Materials	Polypropylene (PP), Grade 2 CP Titanium, Polymethylmethacrylate (PMMA)

Notes:

[1]These specifications are subject to change without notice.

[2]The Heart Seat complies with the requirements of ISO 80601-2-61:2017, IEC 60601-1:2005, IEC 60601-1-2:2020, and IEC 60601-1-11:2010.

[3]Because SpO2 measurements are statistically distributed, only about two-thirds of SpO2 measurements can be expected to fall within ±2.7% A_{RMS} of the value measured by a co-oximeter.

[4]A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor.

[5]IP classification is the degree of protection provided by enclosures in accordance with IEC 60529:2013. The Heart Seat is dust-protected and protected against vertically falling water drops.

Clinical Data Summary

SpO2 Clinical Data Summary

The following data was obtained from a controlled, induced hypoxia validation study in healthy adult volunteers.

Study methods: The study was conducted under normal office environment conditions. The participant sat on the Heart Seat with left and right thighs covering the embedded sensing pad. A Control Pulse Oximetry system was placed on the participant to evaluate the stability of the blood draws. The participant was connected to a breathing circuit, for administering medical grade oxygen and nitrogen to induce hypoxia resulting in stable oxygen saturation plateaus between 100% and 70% SaO2. Arterial blood samples were drawn during simultaneous data collection from the control pulse oximeter and the test oximeter.

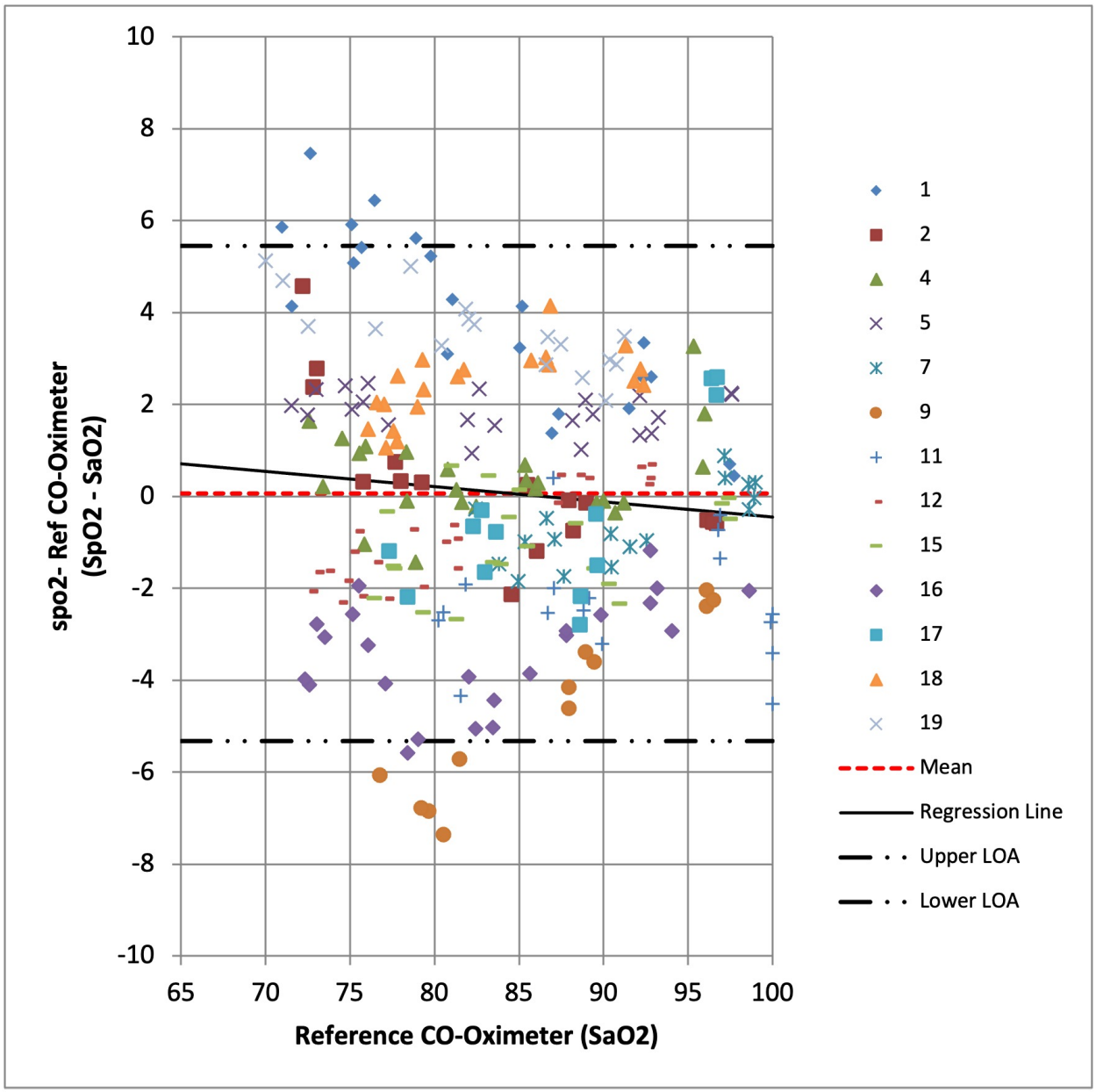
Study population: The study population included 16 subjects between the ages of 18 and 50 (46% male and 54% female; 23% of the subjects had Dark skin tone as defined by Fitzpatrick scale V & VI).

Study Results: The results included below demonstrate that the Heart Seat meets the acceptance criteria of A_{RMS} < 3.5%.

SpO2 Observed Study Results

SpO2 Range	70-100%	70-80%	80-90%	90-100%
A_{RMS}	2.7%	3.3%	2.5%	2.0%

Modified Bland-Altman Error Plot: Casana Heart Seat
Non-Motion Conditions, 13 Subjects



Guidance and Manufacturer's Declaration

Important information regarding lithium metal batteries

The batteries used in the Heart Seat conform to IEC 60086-4 and UN 38.3. The Heart Seat is shipped in accordance with the requirements of DOT CFR Title 49.

Important information regarding Electromagnetic Compatibility (EMC)

This Heart Seat, manufactured by Casana Care, Inc., conforms to IEC 60601-1-2:2020 Electromagnetic Compatibility (EMC) standard. Nevertheless, special precautions need to be observed:

- The use of accessories other than those specified or provided by Casana could result in increased electromagnetic emission or decreased electromagnetic immunity of the monitor and result in improper operation.
- During a recording, the use of the Heart Seat adjacent to another device should be avoided because it could result in improper operation. In case such use is necessary, the Heart Seat should be observed to verify that it is operating normally.
- The Heart Seat has not been tested for use with diathermic, electrocautery or wireless power transfer (WPT) devices. During Heart Seat use, diathermic, electrocautery or wireless power transfer (WPT) devices should not be used because it could result in improper operation.
- During Heart Seat use, portable RF communications devices (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the Heart Seat. Otherwise, degradation of the performance of the Heart Seat could result.
- Refer to further guidance below regarding the EMC environment in which the Heart Seat should be used.

Table 1 - EMISSION Limits and Compliance

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Class A Class B	The Heart Seat uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment
NOTE: EMISSION tests for Harmonic distortion, Voltage fluctuations, Conducted emissions, and flicker are not applicable.		

Table 2 - IMMUNITY TEST LEVELS

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV,±4 kV,±8 kV,±15 kV air
Radiated RF electromagnetic fields	IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Proximity magnetic fields	IEC 61000-4-39	See table 4
NOTE: IMMUNITY tests for Electrical fast transients / bursts, Surges Line-to-line, Surges Line-to-ground, Conducted disturbances induced by RF fields, Voltage dips and Voltage interruptions are not applicable.		

Table 3 - Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications device

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM +/- 5 kHz deviation 1 kHz sine	2	0.3	28
740	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE BAND 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 to 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

Table 4 - Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

Test Frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz	CW	8
134.2 kHz	Pulse modulation 2.1 kHz	65
13.56 MHz	Pulse modulation 50 kHz	7.5

Additional Wireless Instructions

- The Heart Seat incorporates wireless technology in order to transfer data collected on the Heart Seat to the Casana Cloud where it can be viewed by the healthcare provider. The Heart Seat utilizes an internal WiFi radio to establish this connection. As part of the setup process, a technician will assist in the configuration of the Heart Seat in order to establish connectivity to the Casana Cloud.
- The Heart Seat operates as a store and forward device meaning that the data collected is written to internal storage while the Heart Seat is in use. During typical operation, once the user gets off the Heart Seat, the device will attempt to connect to the Casana Cloud to upload the data. Once the data has been successfully transferred to the Casana Cloud, the data collected is then erased from internal storage.
- Because of the small size of the data as well as the store and forward nature of the Heart Seat, the wireless connection is not sensitive to latency nor utilizes high amounts of bandwidth. As such, the wireless connection for the Heart Seat does not have any specific Quality of Service (QoS) requirements.
- In the event that a connection to the Casana Cloud cannot be established, the Heart Seat continues to store the collected data in the internal storage. The Heart Seat will then automatically retry to connect to the Casana Cloud at predetermined intervals in order to upload all user recordings still stored in the Heart Seat. If the Heart Seat has not connected to the Casana Cloud for over 24 hours, the Heart Seat is considered “offline” and the clinician is instructed to reach out to Casana for assistance.
- As with any wireless device there exists the possibility of interference with the intended communication between the Heart Seat and the Casana Cloud. For other wifi devices sharing the same access point in the home, these should be used no closer than 15 inches (38 cm) to any part of the Heart Seat. In order to improve poor wifi radio performance, moving the access point closer to the Heart Seat or installing additional access points in the home should improve radio performance. In addition, where saturation of the default wifi channel is the cause of degraded performance, the instruction manual for the particular access point should contain instructions on how to change the default channel for the wifi network. The Heart Seat will automatically adjust to using a new channel.
- Allocations and technical parameters of RF technology may be different outside the United States, which could affect the functioning of the Heart Seat.

FCC Statement

FCC Caution

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.

Contains FCC ID: 2A93F-M7DB7

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines. This equipment has been evaluated in accordance with part 47 CFR § 2.1093 "Radiofrequency radiation exposure evaluation: portable devices" and has been found to be compliant with the exposure limits in § 1.1310.

The language below is required by the FCC; however, some of the suggested actions are not applicable to the Heart Seat. The Heart Seat power source should only be accessed by trained installers, as specified within the Instructions for Use. The Heart Seat cannot be connected to an AC outlet. Please contact Casana Support in the event of device malfunction or with any questions at (1-585-944-6549).

Note: 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 connected.
- Consult the dealer or an experienced radio/TV technician for help.

PDPROJ-1-IFU (DOC-608) Ver. 1

Approved By:

(CO-116) Update to PDPROJ-1-IFU

Description

Changes to PDPROJ-1-IFU Instructions for Use: - Frequently Asked Questions: Added row for urination/defecation. / - Symbols/Markings: Added atmospheric pressure symbol. / - FCC Statement: Added the last two paragraphs and 4 bullet points to address SAR testing and FCC requirements.

Justification

FAQs updated to address a new potential question. Symbols/Markings updated to address 60601-1 documentation review. FCC Statement updated to address requirements for FCC filing for SAR testing.

Assigned To:	Initiated By:	Priority:	Impact:
Lauren Iuranich	Lauren Iuranich	Urgent	Major

Version History:

Author	Effective Date	CO#	Ver.	Status
Lauren Iuranich	July 7, 2023 8:55 AM EDT	CO-116	1	Published
Lauren Iuranich	June 12, 2023 8:23 AM EDT	Not Available	0	Superseded