pregnancy coach®

pregnancy coach® system

USER MANUAL

October 22, 2018.

SMART HUMAN DYNAMICS

UMANEN-1/1

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BACKGROUND AND INTRODUCTION

Certain body positions are thought to be dangerous to pregnant women and their fetuses because they cause significant obstruction of blood flow in the abdomen.

The Pregnancy Coach Sensor monitors the user's position at all times. If the user spends too long in certain positions that are likely to restrict abdominal blood flow, the sensor vibrates gently. These are called *vibrational alerts*. They alert the user that she may benefit from changing body positions.

EXAMPLES OF SAFE BODY POSITIONS FOR DIFFERENT SCENARIOS:

- While sitting on a couch or lounge chair
  - Don't recline straight back
  - Instead, tilt slightly to the left or right side while reclining
- While Sleeping or laying on a bed
  - Don't sleep on your back (*supine* position)
  - Instead, try to sleep on your left side. The right side is the 2nd best option but not as good as the left side.
- While standing up
  - Don't stand still in one place
  - Instead, take breaks from standing or occasionally walk around slowly.
- While exercising
  - Don't exercise vigorously (intense running or weight lifting) in the 2nd half of pregnancy (20 to 40 weeks of gestation)
  - Instead, stick to low impact, light aerobic exercise for 30 min or less.
- While sitting at a desk or table eating or doing work
  - Don't sit motionless for long periods of time
  - Instead, occasionally shift positions so that your pregnant abdomen shifts slightly.

INDICATIONS FOR USE

The Pregnancy Coach System is indicated to reduce supine sleep in pregnant women.

There are no known contraindications for the Pregnancy Coach System, although care should be taken when considering using the device according to the warnings and precautions in this manual.

CAUTIONS

DO NOT drop or bump with excessive force.

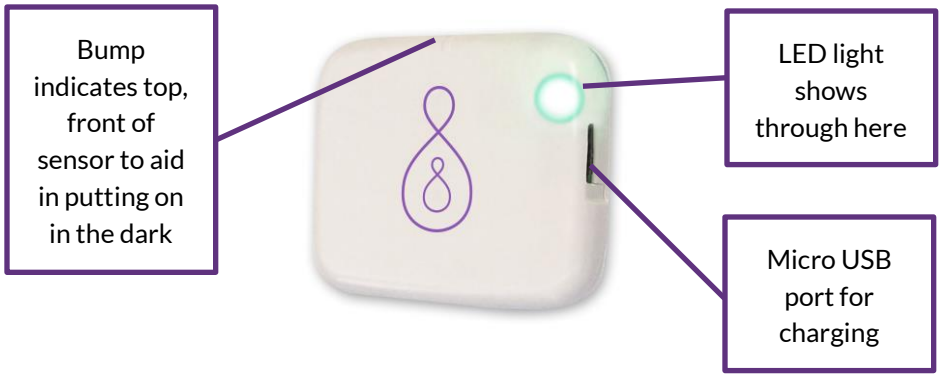
DO NOT wear the sensor if it or the magnetic clip is damaged.

DO NOT wear the sensor on broken skin.

DO NOT continue to use until further instructed by a physician if your skin is irritated or inflamed around the sensor.

PREGNANCY COACH SYSTEM COMPONENTS

PREGNANCY COACH SENSOR



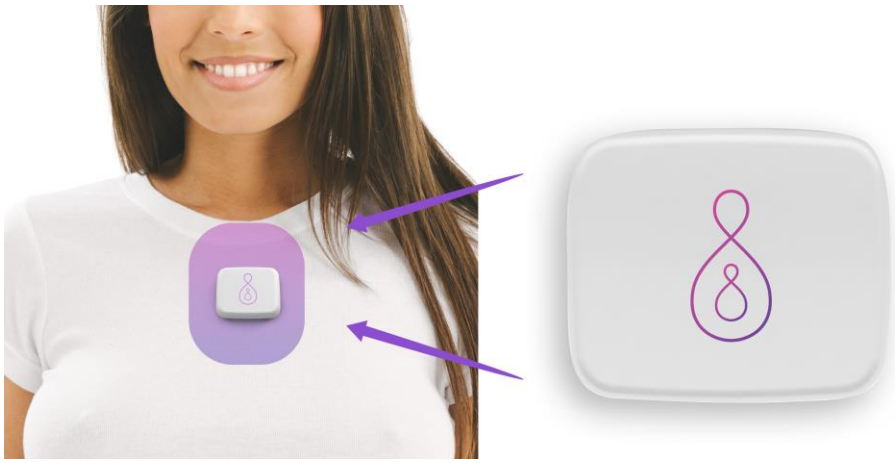
PREGNANCY COACH MAGNETIC SHIRT CLIP

USB CABLE AND CHARGER

WEARING THE SENSOR

The Pregnancy Coach Sensor should be worn as much as possible during the night. It can also be worn during the day for users who spend a lot of time in bed or couches where they might frequently recline.

Place the sensor on form fitting shirt on the front of the chest in the area shown below. Note, the side of the sensor with the logo faces *away* from the body and the logo is pointed *up* towards the head.



⚠ WARNING

For safe and effective operation:

- **Always place the sensor on the body in the correct orientation. It will not function properly facing towards body or upside down!**
- **Always put the sensor on a tight fitting garment in the area shown. If it's loose or placed elsewhere, the sensor may not identify your body position correctly.**
- **Do not wear the sensor on broken skin.**
- **Do not wear the sensor if it or the magnetic clip is damaged.**

If the sensor is accidentally placed on the body upside down (logo pointing towards feet), the sensor's LED will turn on and it may vibrate once. This lets you know the sensor was placed on the body incorrectly.

NOTICE **Before putting on the sensor, turn it upside down to confirm it is on.**

Whenever the sensor is not being worn, plug it into the charger.

OPERATING THE SENSOR

TURN THE SENSOR ON

To turn on the Pregnancy Coach Sensor, plug the sensor into the charger – it will automatically turn on if it is not already on.

QUIET MODE

You can place the sensor into a temporary "*quiet mode*" for 2 hours. During this time, all vibrations and LED signals are disabled and the sensor turns off its Bluetooth radio.

To enter or exit "*quiet mode*":

1. rest the sensor in the palm of one hand
2. repeatedly tap it quickly 8 times or more with a finger of your other hand.

After 2 hours in "*quiet mode*", the sensor will exit "*quiet mode*" automatically unless you are wearing it and are actively moving around. In this case it will wait for movement to stop. Once it exits "*quiet mode*", Bluetooth radio, vibrations and LED signals will be re-enabled.

LOW POWER MODE

The sensor will automatically go into low power mode if it is placed *flat* on a table or other surface for a few minutes. All vibrations and LED signals are disabled in this mode and the sensor turns off its Bluetooth radio. You can wake the sensor up simply by picking it up. Turn the sensor upside down to check if it's now on – its LED should turn on. If it does not wake up, it may be too low on battery and should be plugged into a charger.

CHARGING THE SENSOR

You should try to charge the sensor for at least 30 minutes every day.

You may charge the sensor with any standard 5V Micro USB mobile phone charger as well as the one included with the Pregnancy Coach Sensor.

There is no danger in over-charging the sensor so it may be left connected to a charger when not in use. Whenever the sensor is not being worn, it is best to leave it plugged into the charger.

LED SIGNALS

The LED light should only come on when the sensor is charging or the sensor is positioned upside down (logo pointing towards ground). In normal use, if the sensor is being worn properly by the user, the LED light should never come on.

- **Solid green**: sensor is fully charged
- **Solid orange**: medium battery (or charging battery if plugged in)
- **Solid red**: low battery
- **Flashing red**: very low battery
- **Blinking blue:** the sensor is currently connected to the mobile app
- **Flashing a sequence of red then orange then green in quick succession repeatedly**: this is a warning that the internal clock needs to be reset. It is important that you immediately sync the sensor with the mobile app which will automatically reset the clock.

SPECIAL LED BEHAVIOR WHEN YOU ARE IN LIVE DATA SCREEN IN THE MOBILE APP

When you go to the Live Data screen in the Pregnancy Coach app, the sensor LED will turn on. It will then change its color from green to red depending on the relative health of your body position.

This behavior is not enabled in the "*clinical trial observation mode*".

MOBILE APP

For help deciding which smartphone or tablet to use, please consult the latest list of compatible devices which can be found at http://www.pregnancycoach.com/support/

You must have a 64-bit Apple iPhone or iPad or an Android phone with Bluetooth Low Energy (BLE) capability:

APPLE (IOS):

- iPhone 5s (iOS 10.3.2 or 11.1)
- iPhone 6/6 Plus (iOS 11.1)

ANDROID:

- Samsung Galaxy S4 (Android 5.0.1)
- Samsung Galaxy S5 (Android 6.0.1)
- Samsung Galaxy S7/S7 edge (Android 7.0)

IPHONE/IPAD INSTALLATION:

Go to the App Store and search for "pregnancy coach app" (it may not come up without the word "app"). Install the Pregnancy Coach app by Smart Human Dynamics.

Once the app is installed, **plug the Pregnancy Coach Sensor into the charger**, open the app and follow the onscreen instructions.

ANDROID INSTALLATION:

Open the Android Play store and search for "pregnancy coach". Install the Pregnancy Coach app by Smart Human Dynamics.

Once the app is installed, **plug the Pregnancy Coach Sensor into the charger**, open the app and follow the onscreen instructions.

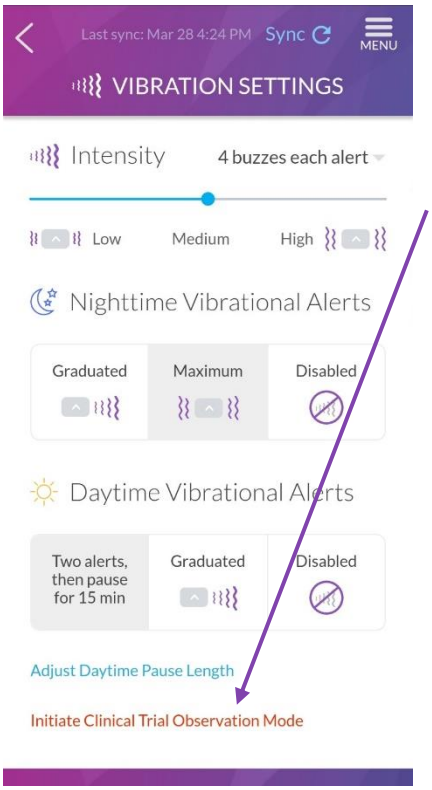
The Pregnancy Coach Sensor has enough internal non-volatile memory to store sleep position and activity data for up to eight weeks of typical use. However, you should make sure your app *syncs* with the sensor frequently.

NOTICE

Check your nightly summary in the app on a daily basis for:

- **any warning messages**
- **to verify it is successfully syncing with the sensor**

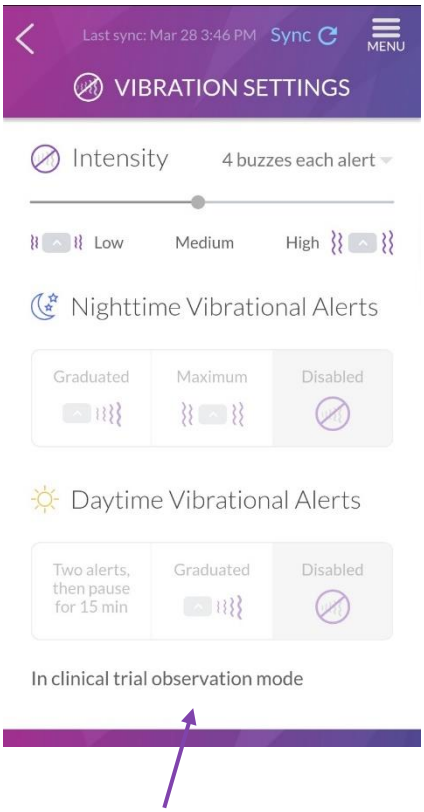
ENTERING CLINICAL TRIAL OBSERVATION MODE (OPTIONAL – ONLY IF PART OF TRIAL!)



If you are part of a trial, you can initiate the "*clinical trial observation mode*" by tapping on the red link in the Vibration Settings screen.

In this mode, the sensor will not vibrate if you spend time on your back. In addition, in the mobile app, it will not display nightly summaries on the dashboard screen.

Note: the sensor may still occasionally vibrate when turning on/off. However, it will not vibrate if you have spent too much time on your back.



TROUBLESHOOTING

For assistance in setting up or using the product or to report unexpected operation or event, please visit: http://www.pregnancycoach.com/support/

Contact technical support for a printed copy of this manual.

PREGNANCY COACH SENSOR ISN'T VIBRATING AT ALL

Test the sensor to see if it is on. Turn the sensor upside down (as if patient is on their head). The sensor should turn on its LED. If sensor is off, turn it on by plugging the sensor into the charger.

Check to make sure the sensor is charged, then unplug it. Sensor will not vibrate when plugged in.

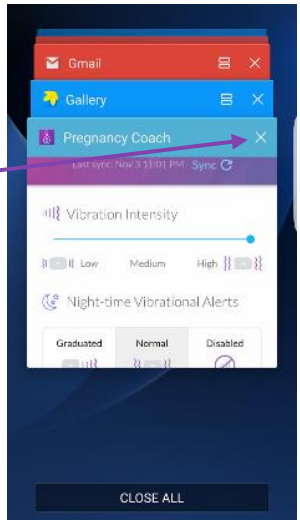
It is possible the sensor is temporarily silencing the vibrations due to logic in the algorithms. If the sensor LED is on when the sensor is plugged in, it is very likely the sensor is functioning properly.

THE SENSOR AND APP DON'T SEEM TO BE PAIRING OR CONNECTING

Reset Bluetooth radio in the Pregnancy Coach Sensor by entering and exiting *Quiet Mode* using the continuous tapping method described under Operating the Sensor.

Close the app on the phone. Make sure you don't just exit the app but that the app is actually closed:

On Android, tap on the Tasks hardware button (typically to the left of the Home button) and close the app by tapping the X (or by swiping the app to the side of the screen).



On iPhone, double-press the Home button and swipe the app up to the top of the screen.

Launch the app again.

Reboot the phone if still not pairing/connecting and launch the app again.

CLEANING AND CARE

⚠ CAUTION The sensor contains sensitive electronics and should never be rinsed or submerged in water.

Cleaning is not required, but a damp towel may be used to clean the surface of the case while being careful not to allow water into the USB port. **Do not use abrasive cleaning agents.**

The sensor, similar to a cell phone, may be damaged if it is dropped too many times or placed under a heavy object. Always treat it with care. **Do not wear the sensor if it or the magnetic clip is damaged.**

PREGNANCY COACH SENSOR SPECIFICATIONS

Dimensions: 43mm x 36mm x 10mm (1.75" x 1.5" x 0.38")
Weight: 28g (1oz) (35g (1.25oz) with magnetic clip)

Operating Temperature: +5°C to +40°C (41°F – 104°F)
Relative humidity: 10% to 95% (non-condensing)
Atmospheric pressure: 700 hPA to 1060 hPA

Storage Temperature (Sensor): -25°C to +70°C (-13°F – 158°F)
Storage Temperature (Adhesives patches): +10°C to +27°C (50°F – 80°F)
Relative humidity: 10% to 95% (non-condensing)
Atmospheric pressure: 700 hPA to 1060 hPA

Ingress Protection Rating: IP22 (Protected from touch by fingers and objects greater than 12 millimeters and protected from water spray less than 15 degrees from vertical.)

Compliant with standard IEC60601-1-11:2015.

Radio: Bluetooth® Low Energy (2402-2480 Mhz <+10 dBm)

Battery: 1 Rechargeable (up to 500 times or for 1000 days of typical use before reduction in capacity) 3.7V Li-ion (non-removable). 5 days of typical use on a single charge. 1-2 hours charging time with a 5V 5W USB charger.

In conformity with Directive 2012/19/EU-WEEE, this marking on the product or its package indicates that it should not be disposed of with other waste at the end of its useful life.

To prevent possible harm to the environment or human health, please separate this product from other types of waste and recycle it responsibly to promote the sustainable reuse of material resources.

Outside the US, please contact the retailer where you purchased this product or your local government office for details of where and how you can return this item for environmentally safe recycling.

In the US, a free return shipping label can be found inside the product box. You can also contact our support at http://www.pregnancycoach.com/support/ for a free return shipping label.

CONTACT INFORMATION

Made in USA by:

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+1 (707) 579-7697

www.pregnancycoach.com
(844) 9-MONTHS

European Authorized Representative:
Mftcr Rep, Inc
Street Address,
City, Region, Postal Code, Country

Australia / New Zealand Authorized Representative:
Mftcr Rep, Inc
Street Address,
City, Region, Postal Code, Country

ELECTROMAGNETIC & OTHER INTERFERENCES STATEMENTS

WARNING. Any changes or modifications to the device could void the user's authority to operate the equipment.

The Pregnancy Coach System has been tested and deemed in conformance with the relevant requirements in IEC60601-1-2:2014 Class BF for EMC (*Electromagnetic Compatibility*).

This portable transmitter with its antenna complies with FCC/IC RF exposure limits for general population / uncontrolled exposure.

This device complies with part 15 of the FCC Rules and Industry Canada's license-exempt RSS. Operation is subject to the following two conditions: (1) This device may not cause interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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 Class B digital apparatus complies with Canadian ICES-003.

Cet appareil numerique de la classe B est conforme a la norme NMB-003 du Canada.

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 and 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.

Hereby, Smart Human Dynamics, Inc. declares that the RE type non-specific SRD is in compliance with RED 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address:

http://www.pregnancycoach.com/support/

EQUIPMENT SYMBOLS

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	EN 980, Clause 5.12	Symbols for use in the labelling of medical devices.	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1, Clause 5.1.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-3082	Graphical symbols for use on equipment.		
	EN 980, Clause 5.6	Symbols for use in the labelling of medical devices.	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1, Clause 5.1.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-2497	Graphical symbols for use on equipment.		
	EN 980, Clause 5.13	Symbols for use in the labelling of medical devices.	Authorized European representative	Indicates the Authorized representative in the European Community.
	ISO 15223-1, Clause 5.1.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		

REF	EN 980, Clause 5.10	Symbols for use in the labelling of medical devices.	Catalogue or model number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1, Clause 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-2493	Graphical symbols for use on equipment.		
SN	EN 980, Clause 5.5	Symbols for use in the labelling of medical devices.	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 15223-1, Clause 5.1.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-2498	Graphical symbols for use on equipment.		
LOT	EN 980, Clause 5.4	Symbols for use in the labelling of medical devices.	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1, Clause 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-2492	Graphical symbols for use on equipment.		
	EN 980, Clause 5.3	Symbols for use in the labelling of medical devices.	Use by	Indicates the date after which the

	ISO 15223-1, Clause 5.1.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		medical device is not to be used.
	ISO 7000-2607	Graphical symbols for use on equipment.		
	IEC 60601-1, Table D.2, Symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Follow instructions for use	Refer to instruction manual/booklet.
	IEC 60601-1-2:2007, Clause 5.1.1	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests	Non-ionizing electromagnetic radiation	Includes RF transmitter
	IEC 60417-5140	Graphical symbols for use on equipment.		
	IEC 60878-5140	Graphical symbols for electrical equipment in medical practice.		
	ISO 15223-1, Clause 5.3.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Storage humidity range	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 7000-2620	Graphical symbols for use on equipment.		

	EN 980, Clause 5.17.3	Symbols for use in the labelling of medical devices.	Storage temperature range	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1, Clause 5.3.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-0632	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.3.9	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Atmospheric Pressure	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	ISO 7000-2621	Graphical symbols on equipment		
	EN 980, Clause 5.21	Symbols for use in the labelling of medical devices.	Keep dry	Indicates a medical device that needs to be protected from moisture.
	ISO 15223-1, Clause 5.3.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	ISO 7000-0626	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.3.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	ISO 7000-0621	Graphical symbols for use on equipment.		

	IEC 60601-1, Table D.1, Symbol 20	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1.
	IEC 60417-5333	Part 1: General requirements for basic safety and essential performance.		
IP22	IEC 60601-1, Table D.3, Symbol 2 IEC 60529	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance. Degrees of Protection Provided by Enclosures (IP Code).	Degree of Ingress Protection Provided by Enclosure	Protected from touch by fingers and objects greater than 12 millimeters and protected from water spray less than 15 degrees from vertical.
	EN 50419	Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).	Recycle: Electronic Equipment	DO NOT THROW IN TRASH.

SYMBOLS NOT FROM STANDARDS

SYMBOL	REFERENCE	TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	21 CFR 801.15(c)(1)(i)F	Labeling-Medical devices; prominence of required label statements.	Prescription only	Requires prescription in the United States.
	21 CFR 801.109	Labeling-Prescription devices.		
	765/2008/EC 768/2008/EC MDD 93/42/EEC Articles 4,11,12,17, Annex II)	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive.	CE marking	Signifies European technical conformity. 4 digits under the symbol identify the Notified Body organization.
FCC ID: 2AREE02E	(47 CFR Part 15)	Radio Frequency Devices (US).	Federal Communication Commission Number (FCC ID #)	Complies with United States Radio communication requirements.
IC: 24379-02E	(RSS-102)	Radio Standards Specifications (CA).	Industry Canada Radio Communications License (IC:#)	Complies with Industry Canada Radio communication requirements.
	(AS/NZS 4417.1:2012)	Australian Radio Communications Requirements.	Australian Radio Communications License	Complies with Australian Radio communications requirements.