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Sensifirm

Instructions for Use - US

Authorization				
	Name	Title	Signature	Date issued
Updated by:	Veronika Kravtsov	RA/ QA Associate		Dec 28 th , 2017
Approved by:	Yael Liebes-Peer, PhD	RA/ QA Manager		Dec 28 th , 2017

List of Revisions

Revision	Paragraph	Change Description	Date	Issued by
A0	All	Initial release according to discussions with Prof. Avner Shemer	February 21 st , 2016	Veronika Kravtsov
B0	All	Sections re-organization, Wording and re-phrasing	December 13 th , 2016	Veronika Kravtsov
	Contraindications, warnings and cautions	Re-organized		
	Electromagnetic compatibility (EMC) and Specifications	Section was added		
B1	Electromagnetic compatibility (EMC) and Specifications	Updating information according to external lab certification	Jan 26 th , 2017	Veronika Kravtsov
	All	Correction of typos (removal of "touch" from "touch button" and replacing "treatment fingers" with "electrodes")		
C0	All	According to FDA comments (K170637): Addition of indication for use statement, clearer language, removal of "unique" sensor description	May 7 th , 2016	Veronika Kravtsov
D0	All	According to FDA comments (K170637/S001)	July 13 th , 2017	Veronika Kravtsov
D1	All	Typos correction and editing by "copy"	Nov 20 th , 2017	Veronika Kravtsov
	Labeling	Updating symbols		
E0	FCC	Section was added	Dec 28 th , 2017	Veronika Kravtsov
E1	FCC	According to FCC COMMENTS regarding the Bluetooth Module, added in the FCC section: "Device contain FCC ID: 2ACCRMC10"	July 19 th 2018	Eitan Blaich

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Indications for Use

The Sensifirm device is intended to achieve the following result, using non-thermal radiofrequency combined with massage: temporary reduction in the appearance of cellulite.

What is Sensifirm?

Sensifirm is a home-use device used for the temporary reduction in the appearance of cellulite.

The treatment is applicable to areas of the body where cellulite occurs: the buttocks and thighs.

Sensifirm brings a completely new approach to non-invasive and non-ablative treatment, featuring Sensica LIPO RF™ (Radio Frequency) technology, commonly used by professional medical practitioners worldwide.

How does it work?

Introducing LIPO RF™ technology

The Sensifirm device combines the advantages of localized heating produced by radiofrequency energy, together with a massage achieved by a vibration motor and manual manipulation.

The massage. Massage therapy is known to be useful for various applications, including improving cellulite appearance. The Sensifirm houses a vibration motor, which causes a gentle massage sensation as you move the device over your skin.

RF technology. Radio Frequency (RF) is a form of electromagnetic energy that has been used for a long time in aesthetic medicine. The spacing between Sensifirm's four RF electrodes enables great treatment volume and allows multiple RF waves to reach deep into the skin layers, heating the dermis, hypodermis (inner skin layers) and subcutaneous fat layers, without damaging the epidermis (outer skin layer).

The deep thermal effect of the combined RF currents and massage activates several biological mechanisms, among which are collagen and elastin remodeling and later production, improvement in microcirculation and in lymphatic drainage. Together, these effects lead to improvement in cellulite appearance, with the best possible visible results, that last for 3 months.



Please carefully read these Instructions for Use before you start your Sensifirm treatment. This guide, as well as an instructional video, can also be found at www.sensica.com

Intended use of Sensifirm

- ***Sensifirm*** is intended for use by women who want to improve cellulite appearance in the treatment area.
- ***Sensifirm*** is especially designed for use on the buttocks and thighs, where cellulite tends to appear.

Note: Sensifirm is especially designed for your own personal treatment, and is intended for a single user.

Safety

Sensifirm is designed to protect your skin. The device has two built-in sensors, which constantly measure your skin temperature. When the temperature rises to the maximal level (41°C/ 106.7°F), the RF energy (heat) will automatically stop. When the temperature has decreased again, the RF energy (heat) will be automatically re-activated.

The temperature sensors prevent local over-heating. Follow these Instructions for Use for a comfortable and pleasant treatment experience.

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Sensifirm device description

The Sensifirm kit includes the following components:

- External power supply.
- Sensifirm hand-held device:
 - Four treatment electrodes for applying RF.
 - Two safety temperature sensors, one positioned between each pair of electrodes.
 - RF energy selection button and LED indicators for RF intensity selection.
 - LED to indicate the device status (ON/OFF).

- Base Gel:

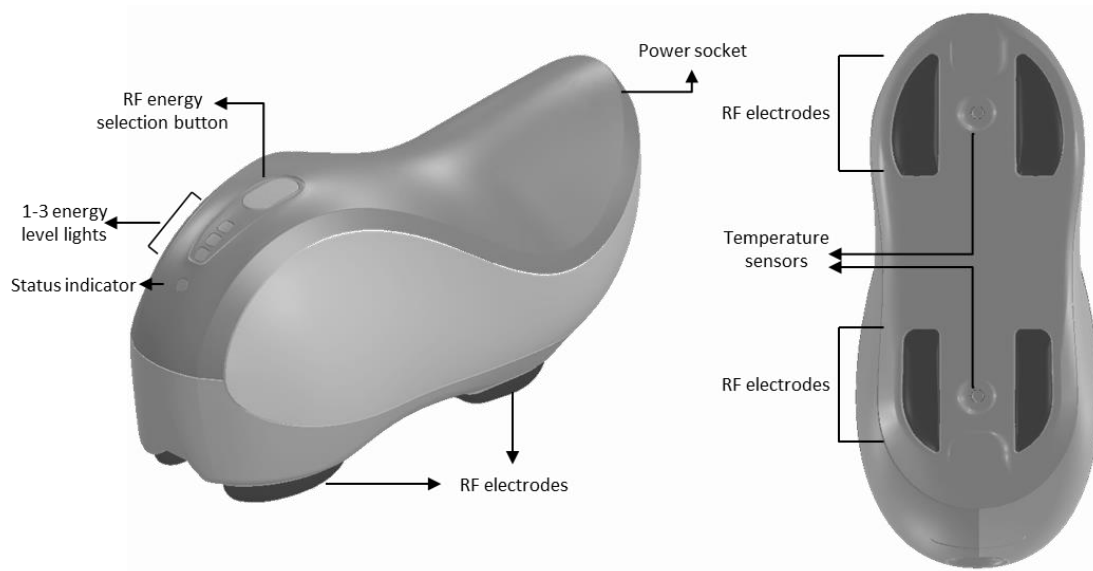
Designed specifically to improve contact between the device and the skin, and to improve skin conductivity, to ensure proper delivery of RF energy and best possible results.

DO NOT use Sensifirm without first applying the Base Gel, as this will compromise your safety and treatment efficacy.

Base Gel ingredients: Glycerin, Aqua, Phenoxyethanol, Ethylhexylglycerin, Triethanolamine and Carbomer.

- This Sensifirm Instructions for Use booklet.

Hand-held description



User interface description

Status indicator	Transient (for ~5 sec) orange light followed by transient (for ~1 sec) green light	Sensifirm is in standby mode and ready to work.
	Steady green light	Sensifirm is in treatment mode . RF is activated, skin contact is detected and the treatment is underway*.
	Alternating red and orange lights	Sensifirm is in error mode . The device has detected a malfunction and has blocked the activation of the RF function.
RF energy level selection button	1-3 energy levels lights	The green light indicates which RF energy level has been activated. Press the RF energy level selection button repeatedly until you reach the desired level: 1, 2, 3, or off.

Note: RF energy is delivered only when proper contact with your skin is detected. When proper treatment is underway, the status indicator will have a steady green light and you will feel vibration.

* Upon contacting the treatment area, the massage function is automatically turned on.

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When Sensifirm should not be used

Sensifirm is designed especially for you, to allow safe and effective treatment. However, Sensifirm may not be appropriate for everyone. Please read the information below before use. If you still have any doubts, and you are unsure whether Sensifirm is safe for your use, please consult your physician.

CONTRAINDICATIONS

Do NOT use the Sensifirm device if any of the following conditions apply:

- If you have an active implant, such as a pacemaker or insulin pump, or if you have any known severe heart disorder, such as arrhythmias.
- If you are pregnant or breastfeeding.
- If you suffer from severe or uncontrolled endocrine or metabolic conditions, such as diabetes or uncontrolled thyroid disease.
- If you have a damaged immune system or autoimmune disorder, such as AIDS or Lupus, or if you use drugs that influence the immune system.
- If you suffer from blood clotting disorders, excessive bleeding or bruising, damaged wound healing or if you routinely take blood-thinning medications.
- If you suffer from a history of deep vein thrombosis.
- If you have a history of collagen disorders, or suffer from keloid scarring (growth of extra scar tissue where the skin has healed after an injury).
- If you have a general extreme illness, such as hepatitis, liver disease or epilepsy.
- If you suffer from sensitive or damaged skin such as in cases of frequent redness or rash, inflammations, breakouts (such as psoriasis), blisters, sores, infections, acne or extra dry skin.
- If you have diminished or exaggerated perception of temperature change.
- If you have taken Accutane in the past 6 months.
- If you have a heat-induced disease or an active skin disease, such as herpes, eczema, rashes etc., in the treatment area.

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- If you have skin cancer, areas at risk of malignancy, or if you have received radiation therapy or chemotherapy within the past 3 months.

WARNINGS

There are some scenarios in which Sensifirm's safety and effectiveness has not yet been tested or established. Therefore, if any of the following conditions apply, it is NOT advised that you use the device:

- If you have any permanent implants in the designated treatment area, including but not limited to: silicon or injected chemical materials, metal plates or other metal materials.
- If in the past 3 months you have had surgery, including plastic surgery, or you have undergone any esthetic procedure, such as skin resurfacing, liposuction, deep peeling, cryolipolysis (fat freezing), or have had esthetic injections of fillers, such as hyaluronic acid, collagen, fat or Botox, in the treatment area.
- If you have any metal items, such as jewelry or piercings, or tattoos or permanent make up on the designated treatment areas.
- If you have sunburn, or dark brown or black spots such as freckles, birth marks, moles or blisters in the treatment area.
- If you are allergic or sensitive to chrome or nickel or any component of the Base Gel.
- If you are male.
- If you are under the age of 18.
- If you have reduced physical, sensory or mental capabilities.
- Do not use Sensifirm over breasts, genitals or areas not recommended in Instructions for Use guide.
- Do not use Sensifirm over hairy areas of the body, as this may result in the hairs being burnt.

Note: If you have undergone any other aesthetic procedure in the designated treatment area, or if you have treated the skin with a prescribed drug within the past 3 months, or if you have any concerns regarding potential side effects, please consult your physician before using Sensifirm.


CAUTIONS

In order to avoid serious harm from using the Sensifirm device:

- Never use flammable liquids, such as alcohol (including perfumes, sanitizers, or other applications containing alcohol) or acetone to clean the skin in the hour before using Sensifirm as it may cause burning of the skin.
- Do not open or repair the device, as it may expose you to dangerous electrical components.
- Do not place, store or use Sensifirm near bathtubs, showers, basins or other vessels containing water, as this may cause severe electrocution.
- Do not leave Sensifirm unattended while plugged into the electricity supply, as it may lead to electrocution.
- Keep out of reach of children and pets.
- Use the Sensifirm only in accordance with these Instructions for Use and for the intended use.
- Do not use the device if any part of the device is missing, damaged or loose, if the device is not working properly, if you see or smell smoke, or if the device becomes damp or wet.
- Make sure the device is clean, dry and intact before each use. Cleaning instructions are detailed in the **Cleaning** section below
- Do not use the Sensifirm device without first applying the Base Gel.
- Do not use the Base Gel after its expiration date.

Note: the Base Gel is for external use only - avoid direct contact with eyes. In the event that such contact does occur, wash the eyes immediately with water.

Note: Sensifirm is designed to be used by a single user.

 Use Sensifirm only with the original power supply. For your safety, never use DC adapters which are not approved by the manufacturer.

Possible side effects

When using the Sensifirm device according to these Instructions for Use, side effects are rare. However, every esthetic procedure, including the use of home-use devices, may cause side effects. Therefore, it is important that you understand and accept the risks and complications that can occur when using an RF cellulite appearance reduction device:

Degree of side effects	Side effects
Minor	Local pain Skin irritation Skin redness Minor swelling Skin sensitivity Allergies or sensitivity to Base Gel
Rare	Mild skin burns Pigment changes Excessive redness, rash, swelling Subcutaneous bleeding
Extremely rare	Severe burns Infection Bruising Blistering

If necessary, please consult with your physician if any of these side effects occur.

What to expect when using Sensifirm

The use of the Sensifirm device is simple and quick, as detailed in the **User Instructions** section below.

The Sensifirm treatment session, may cause:

- Sensations of warmth, created by the RF energy and the massage.
- Some mild red or pink color on the skin, during and just after the treatment session.

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User instructions

Sensifirm is intended for use on buttocks and thighs.

Device set-up

1. Remove all components from the box (the Sensifirm device, power supply and Base Gel).
2. Check the expiration date of the Base Gel.
3. Before beginning the treatment, make sure that the electrodes are clean, dry and intact.
4. Insert the plug end into an electrical outlet, and insert the cord end into the device socket.

Your Sensifirm device is now ready for use.

1. Prepare the treatment area. Make sure your skin is dry, clean and free of topical products, such as moisturizers and lotions.

Caution: Never use flammable liquids, such as alcohol (including perfumes, sanitizers, or other applications containing alcohol or acetone) to clean the skin in the hour before using Sensifirm, as it may cause burning of the skin.

2. Remove all jewelry from the treatment area.
3. Remove excessive or long hair from the treatment area.
4. Perform a preliminary test on a small patch of skin in the intended treatment area, 48 hours before the first use of Sensifirm. In the preliminary test, you can determine the energy level settings that best suit you (see **Preliminary test** section below).

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Preliminary test

The preliminary test is intended to determine how your skin will react to the Sensifirm treatment, and to help you to find the most comfortable setting for you, for each treatment area.

Perform a preliminary test on each area you intend to treat 48 hours before the first full treatment.

1. Apply a thin, even layer of Base Gel, included in your kit, on the treatment area.
2. Plug in the Sensifirm device and select RF energy level 3.
3. Place the Sensifirm device on the desired treatment area and move it in a circular motion, for 3 minutes.
4. The treatment will create a warm sensation on your skin. However, if you feel your skin is heating up too fast, reduce the RF energy level, adjusting it to suit your own comfort.
5. Stop the test immediately if you do not feel comfortable, or if you see adverse effects such as severe redness or blistering.
6. Wait 48 hours and examine the tested area.
7. If the skin in the test area seems normal (no adverse effects) you can proceed with a full treatment at the highest comfortable energy level.

*Note: The RF energy level indicates the rate at which the temperature rises when in heating mode. A high RF energy level will enable you faster and more even heating.

We recommend performing all treatments at energy level 3 (highest). However, you can achieve maximum results at all RF energy levels: at lower levels, it will just take longer to reach the effective temperature.

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How to use the Sensifirm device

*Note: A preliminary test should be conducted before proceeding to a full treatment. (See **Preliminary test** section above.)

See treatment areas, treatment time and treatments schedule in the **Recommended treatment protocol** section below.

1. Apply a thin, even layer of the Base Gel included in your kit, on the area that is intended for treatment.
2. Set the RF energy level to the level you found most comfortable when you carried out the preliminary test. Press the RF energy level selection button repeatedly until you reach the desired level: 1, 2, or 3.
3. Place the devices on the intended treatment area, ensuring full contact of all 4 electrodes with your skin throughout the entire treatment. If the device is not properly placed, the RF energy and massage will not be delivered. When the device is working, you will feel and hear a gentle vibration, and the indicator will be lit up in green.
4. Move the device over the treatment area in slow circular motions, while maintaining constant, firm contact with the skin.
5. If you do not feel a sensation of warmth after approximately 30 seconds, try moving the Sensifirm over a smaller treatment area, and/or increasing the RF energy.
6. At the end of each treatment session, turn off the device by pressing on the energy selection button. An orange indicator light will light up while the device is shutting down. After the light has turned off, unplug the device from the electrical outlet.
7. After completing the treatment, wipe off any remaining Base Gel from the treated area.
8. Clean the device with a soft damp cloth or paper towel, according to the cleaning instructions in the **Cleaning** section below.

Recommended treatment protocol

For long-lasting results, use Sensifirm once a week on each treatment area, for a period of 8 weeks.

To sustain optimal results, you can repeat the Sensifirm treatment protocol as needed.

- You can use the Sensifirm device on buttocks and thighs. A typical treatment session takes about 20 minutes for a body area that is 15cmX30cm (6inX12in) in size - about the size of your two palms.
- We recommend performing all treatments at energy level 3 (the highest). However, you can achieve maximum results at all RF energy levels: at lower levels, it will just take longer to reach the effective temperature. Therefore, select your RF energy level according to your own level of comfort, as determined by you during the preliminary test.

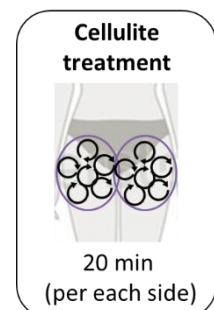
Note: The way the body responds to the Sensifirm treatment differs between individuals, depending on environmental and biological factors, heredity and age.

Treatment areas

Do not treat full areas with energy levels you have not tested before (as detailed in the Preliminary test section above).

Buttocks and thighs (cellulite treatment)

- Place the treatment electrodes on the treatment area, as indicated in the diagram.
- Move the Sensifirm in continuous circular motions around the area, as indicated by the arrows in the diagram.
- The recommended treatment time for this area is 20 minutes for each side.



Note: For your own comfort, it is recommended to perform the treatments of all areas while lying down.

Post-treatment care

- After completing the treatment, wipe off the remaining Base Gel from the treated area.
- Do not expose the treatment area to direct sun light without applying a high-factor sunscreen (at least 30 SPF). Uncontrolled sun exposure might cause your skin to be sensitive
- For 2 days after treatment, avoid the use of extremely hot water and do not use abrasive or harsh products.
- In cases where superficial crusting or scabbing occurs, do not rub, scratch or remove the scab. Cleanse the area gently and pat dry.
- Since skin cellulite formation is an ongoing process, you may repeat the Sensifirm treatment according to your needs.

Cleaning

1. Make sure to turn off and unplug the device before cleaning.
2. It is recommended to use a soft damp cloth, paper towel or pre-moistened wipe to clean any residual Base Gel from the Sensifirm. Make sure the entire underside of the device, including the electrodes area, temperature sensors and plastic cover, is cleaned thoroughly.



Do not rinse the Sensifirm device under running water, as this may cause device malfunction.

3. Keep the Sensifirm device dry. Never place, store or use your Sensifirm near bathtubs, showers, basins or other vessels containing water, as this may cause electrocution.
4. If you do not plan on using your Sensifirm device for a long period of time, it is recommended to keep it clean and stored in its original box.

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5. If you plan to travel and take your Sensifirm with you, you should store it in the original box and follow the maintenance instructions.

Troubleshooting

If you experience any problems with your Sensifirm, please refer to the information below:

- If Sensifirm does not turn on:
 - a. Make sure that the power cord is plugged in properly to the electrical outlet and into the device socket.
 - b. Make sure that the power outlet has power.
- If Sensifirm does not deliver RF signal energy and massage (i.e. you cannot feel the warm sensation or hear/ feel the gentle vibration):
 - a. Make sure there is full contact of the electrodes with the skin
 - b. Make sure that the Base Gel has been applied properly over the treatment area.
 - c. The RF signal will be activated only when all 4 electrodes are in full contact with the skin. (See indicator details set out in the **User interface description** section above.
- General error:
 - a. If dirt or debris get stuck on the electrodes, you should clean them in accordance with the **Cleaning** section above. If you cannot get the area clean, contact our customer service.
 - b. In case of a general error, reset the device – unplug the power cord from the electrical outlet on the wall, wait 10 seconds and then reconnect it.
 - c. If you still have problems with your device, please contact our customer service.

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Customer service

- For more information about Sensifirm, if your Sensifirm is broken or stops working, if you need assistance or if you would like to order more Base Gel (for additional treatments or if your Base Gel has expired), please contact us:
- Tel: XXXXXXXX
- Email: support@sensica.com

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Device specifications

The RF handheld device is powered by multipolar RF at 10±1 Watt

Frequency: 1±0.05 MHz

Selectable output power level: 3 levels

Temperature sensors: RF heating is automatically deactivated when skin temperature reaches 41 °C (106.7°F). The heating is reactivated when temperature decreases.

Treatment area: ~20cm² (~3.25 in²)

External power supply:

Input 100-240VAC, 50-60Hz, 0.5A

Output 12VDC, 1.8A

Device size:

146mm X 74mm X 63mm (LxHxW)

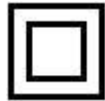
5.75in X 2.91in X 2.48in (LxHxW)

Weight:

192g (6.77oz)

Storage Instructions:

Storage and transport conditions	
Temperature	-10 °C to 70 °C (14°F to 158°F)
Humidity	10% to 90% RH at 55°C (131°F)
Pressure	Non-condensing
Operational conditions	
Temperature	10°C to 40°C (50°F to 104°F)
Humidity	30% to 70% RH
Max operating altitude	3,000 m.

Labeling**Model:** CEL100US, add GUDID number**Power:** 9V, 1.5A, 100-240VAC, 50-60Hz

Double insulation



Type BF equipment



Consult Instructions for Use



Do not dispose




Please read all warnings and safety precautions prior to use



Do not use the Sensifirm device on sensitive tanned skin or after sun exposure



Keep dry

 Use Sensifirm only with original power supply. For your safety, never use DC adapters which are not approved by the manufacturer.

The FCC Wants You to Know:

This equipment has been tested and found to comply with the limits of ISM device, pursuant to Part 18 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 according to the instructions, may cause harmful interference to radio communication. 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:

- a. Reorient or relocate the receiving antenna.
- b. Increase the separation between the equipment and receiver.
- c. Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- d. Consult the dealer or an experienced radio/TV technician.

FCC WARNING

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC Rules.

Electromagnetic compatibility (EMC) and Specifications

- The Sensifirm requires that special precautions are taken regarding EMC, and must be installed and put into service according to the EMC information provided.
- Portable and mobile RF communications equipment can affect Sensifirm.
- Portable RF communications equipment, including antennas (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the Sensifirm, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result
- The use of accessories or replacement parts, other than those sold/specified by Sensica International, may result in increased emissions or decreased immunity of the Sensifirm.
- The Sensifirm should not be used adjacent to or stacked with other equipment. If this is unavoidable, the Sensifirm should be observed to verify normal operation in the configuration in which it will be used.
- Device Contains FCC ID: 2ACCRM10

EMC Information

IEC 60601-1-2: 2014 4 th Edition		
The Sensifirm is intended for use in the electromagnetic environment specified below. The customer or the user of the Sensifirm should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Sensifirm emits electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	The Sensifirm 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.

IEC 60601-1-2: 2014 4th Edition

The Sensifirm is intended for use in the electromagnetic environment specified below. The customer or the user of the Sensifirm 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	± 8 kV contact ± 2, 4, 8, 15 kV air	± 8 kV contact ± 2, 4, 8, 15 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%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	± 1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips Voltage Interruptions IEC 61000-4-11	0 % U_T , 0,5 cycle 0 % U_T , 5 cycles 70 % U_T , 30 cycles 0 % U_T '300 cyles	0 % U_T , 0,5 cycle 0 % U_T , 5 cycles 70 % U_T , 30 cycles 0 % U_T '300 cyles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Sensifirm requires continued operation during power mains interruptions, it is recommended that the Sensifirm be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 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 AC mains voltage prior to application of the test level.

IEC 60601-1-2: 2014 4th Edition

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

Immunity Test	IEC 60601 Test Level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC61000-4-6	3Vrms 0.15 MHz to 80 MHz 6Vrms in ISM and amateur radio bands between 0.15 MHz to 80 MHz 80% AM at 1kHz	3Vrms 0.15 MHz to 80 MHz 6Vrms in ISM and amateur radio bands between 0.15 MHz to 80 MHz 80% AM at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Sensifirm, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \frac{3.5}{3} \sqrt{P} = 1.17 \sqrt{P}$ $d = \frac{3.5}{6} \sqrt{P} = 0.58 \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	80% AM at 1kHz 10 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	 $d = \frac{3.5}{10} \sqrt{P}$ $= 0.35 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \frac{7}{10} \sqrt{P} = 0.7 \sqrt{P} \quad 800 \text{ MHz to } 2.7 \text{ GHz}$ 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).

			<p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following</p>  <p>symbol:</p>
<p>NOTE 1 At 80 MHz and 800 MHz, 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 Sensifirm is used exceeds the applicable RF compliance level above, the Sensifirm should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Sensifirm.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

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Recommended separation distances between portable and mobile RF communications equipment and the Sensifirm

The Sensifirm is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Sensifirm can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sensifirm 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)			
	0.15 MHz to 80 MHz $d = \frac{3.5}{3} \sqrt{P} = 1.17 \sqrt{P}$	80 MHz to 800 MHz $d = \frac{3.5}{6} \sqrt{P}$ $= 0.58 \sqrt{P}$	80 MHz to 800 MHz $d = \frac{3.5}{10} \sqrt{P}$ $= 0.35 \sqrt{P}$	800 MHz to 2,7 GHz $d = \frac{7}{10} \sqrt{P}$ $= 0.7 \sqrt{P}$
0.01	0.12	0.058	0.035	0.07
0.1	0.37	0.18	0.11	0.22
1	1.17	0.58	0.35	0.7
10	3.70	1.83	1.11	2.21
100	11.67	5.8	3.5	7

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 affected by absorption and reflection from structures, objects and people.

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Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment							
Test Frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{a)}	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)	Compliance Level (V/m)
385	380-390	TETRA 400	Pulse modulation ^{b)} 18Hz	1.8	0.3	27	27
450	430-470	GMRS 460 FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704-787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9	9
745							
780							
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28	28
870							
930							
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28	28
1845							
1970							
2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9	9
5500							
5785							
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1m. The 1m test distance is permitted by IEC 61000-4-3.							
^{a)} For some services, only the uplink frequencies are included.							
^{b)} The carrier shall be modulated using a 50% duty cycle square wave signal.							
^{c)} As an alternative to FM modulation, 50% pulse modulation at 18Hz may be used because, while it does not represent actual modulation, it would be worst case.							

Treatment log

<i>Treatment date</i>	<i>Treated area</i>	<i>Comments</i>
	