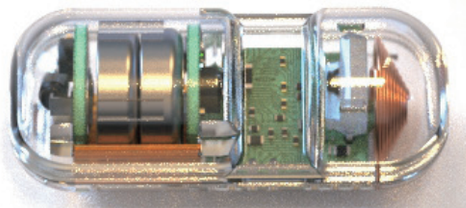
PILLSENSE™
GI BLEED DETECTION SYSTEM

PillSense™ System
INSTRUCTION FOR USE



CONTENTS

PILLSENSE™
GI BLEED DETECTION SYSTEM

INDICATION FOR USE

The PillSense™ System is a prescription only device consisting of a reusable receiver and single-use ingestible capsule, intended to be used for the detection of blood in the upper gastrointestinal tract in hemodynamically stable adults suspected of having upper gastrointestinal bleeding (UGIB).

PillSense™ is not a standalone diagnostic device, but an adjunct for clinical decision making. A negative or normal result obtained by the PillSense™ System does not exclude presence of pathology, if symptoms persist, further evaluation should be performed.

DEVICE DESCRIPTION

The PillSense™ System is an accurate and non-invasive device designed to detect blood for evaluating the presence of upper gastrointestinal bleeding (UGIB). The PillSense™ System consists of a PillSense™ Capsule, an atraumatic, ingestible and disposable capsule, and PillSense™ Receiver, an external real-time receiver and associated software.

The **PillSense™ Capsule** (11x27mm) is a single-patient use device which features an optical sensor which detects blood and wirelessly transmits data to the battery-powered PillSense™ Receiver. The optical sensor contained in the PillSense™ Capsule detects the presence of liquid blood and/or hematin by analyzing the absorption of multiple wavelengths of light of the environment in which it is immersed. The data are then processed by an algorithm to determine if blood is present. The PillSense™ System has been validated to detect clinically relevant amounts of blood to as low as 5% blood in gastric contents. The capsule is designed to withstand the mechanical forces and the chemical environment of the digestive system. After ingestion, the PillSense™ Capsule travels through the GI tract and is then passed naturally from the body.

The **PillSense™ Receiver** collects and displays real-time information gathered by the PillSense™ Capsule. The PillSense™ Receiver interprets the data and displays a result message “Blood detected” or “No blood detected”. From the time of PillSense™ Capsule activation and ingestion until the result message is displayed takes less than 10 minutes.

The system does not require any special patient preparation and provides results almost immediately. The PillSense™ System is used to supplement clinical scoring systems and other clinical parameters to decrease uncertainty when screening patients for active UGIB to help inform the care pathway.

The PillSense™ Capsule is for single-use only and is provided non-sterile. The PillSense™ Receiver is a reusable component also provided non-sterile. The receiver should be cleaned between uses (see Cleaning Instructions below).

CONTRAINDICATIONS

The device is contraindicated in patients with the following conditions:

- Hemodynamic shock
- Cardiac pacemakers or other implanted electronic devices
- Known or suspected gastrointestinal obstructions, strictures or fistula
- Chron's Disease (CD) and/or other inflammatory bowel disorders
- Gastroparesis
- Swallowing disorder or difficulties in swallowing the capsule

ADVERSE EVENTS

Potential adverse events associated with the use of this device may include:

1. capsule retention, capsule aspiration. In some instances, intervention is required to remove the capsule.
2. Obstruction, perforation, mucosal bleeding.
3. Abdominal pain, vomiting, nausea.

NOTE: Any adverse event that has occurred in relation to the device should be reported to Cook Medical (see contact information at the end of this document) and any appropriate government entity.

DEVICE SUMMARY AND PROCEDURE RELATED COMPLICATIONS

Following commencement of monitoring, if the receiver display continues to display a flat line at zero you should terminate the procedure and proceed with the standard patient care procedures.

CAUTIONS

1. Thorough understanding of technical principles, clinical applications and risks associated with the PillSense™ System is necessary before using this product. Read the entire manual before using the system for the first time.
2. A negative or normal result obtained by the PillSense™ System does not exclude the presence of pathology and if symptoms persist, further evaluation should be performed.
3. To prevent the patient from being exposed to unforeseen risks during passage of the PillSense™ Capsule, ensure that the patient thoroughly understands the procedure and provide the patient with a copy of the Patient Leaflet and Patient Card.
4. If capsule excretion is not seen after 15 days, the patient should contact their physician for consideration of an X ray.

WARNINGS

PROCEDURE RELATED

1. Patient must swallow only the capsule, ensure that it is free from the magnet or the retainer lid, and only after confirmation that no other PillSense™ Capsule or other ingestible diagnostic devices remain in the patient's body.
2. Capsule must be paired with the receiver before swallowing. Do not give to patient to swallow otherwise.
3. The capsule should not be swallowed by patients for whom this device is contraindicated.
4. Prior to using this device, consider performing a contrasted x-ray series in patients with suspected strictures or fistulas.
5. Instruct the patient to contact the physician immediately if, after ingesting PillSense™ Capsule, there is any abdominal pain, nausea, or vomiting.
6. The capsule should not be swallowed if it has been dropped on the floor or appears damaged in any way, including by forceful biting.
7. If the patient has accidentally swallowed any unpaired or a non functional PillSense™ Capsule, or embedded package magnets, seek immediate medical attention.
8. The patient should swallow capsule with 150ml (5 oz) water only (e.g., no lubricants, no other liquids, fluorescent fluid).
9. The patient should drink the recommended volume of water and at a normal pace.
10. The patient should be in the left lateral decubitus position prior to initiating the data acquisition.
11. The patient should remain in the left lateral decubitus position until the PillSense™ System test results are finalized to ensure that the capsule and the stomach contents accumulate in the fundus.

12. Patient should not have an MRI exam performed until the PillSense™ Capsule has been excreted. Possible patient injury and medical condition could occur.
13. When swallowing the capsule, there is a possibility of choking on the capsule. The capsule shall be ingested under the supervision of authorized medical personnel.
14. If the patient has not positively verified the excretion of the capsule from his/her body, he/she should contact the physician for evaluation and possible abdominal X-ray before undergoing an MRI evaluation.
15. Store the device in a secure location for access to authorized personnel only.
16. Do not leave the PillSense™ Receiver unattended during data acquisition to avoid use by non-authorized personnel.

PRODUCT RELATED

1. The PillSense™ Capsule is designed for single-use only. Attempts to re-process and/or reuse may lead to device failure or transmission of disease. This may also increase the risk of contamination.
2. Do not use PillSense™ Capsule after its expiration date.
3. Do not to open the capsule tray until just before use.
4. Never attempt to disassemble and or modify the product yourself.
5. Do not use PillSense™ Receiver or PillSense™ Capsule if either the packaging or products appears damaged.
6. PillSense™ Receiver must be wiped after every use. If it is not visibly clean, repeat cleaning steps or safely dispose of the device.
7. Patient should avoid biting the PillSense™ Capsule prior to swallowing.
8. The capsule does not function properly if other light sources are in the upper GI tract, for example a scope light.
9. **Keep package, including embedded magnet, at least 5cm (1.9685 inches) away from other active-implanted medical devices.**
10. To ensure reliable communication do not use the PillSense™ Receiver while it is plugged into a wall outlet.
11. The use of power supplies and cables other than those provided with the PillSense™ System is not recommended. Check regularly.
12. Portable and mobile RF communications equipment may affect PillSense™ System.
13. PillSense™ System should not be used adjacent to or stacked with other equipment, if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation.
14. Safety and performance of the PillSense™ System has not been evaluated in pregnant women or patients who have undergone an upper GI series within the previous 24 hours.

PATIENT PREPARATION

1. Verify that no contraindications apply to the patient and that all warnings, cautions and risks have been considered.
2. The patient should not take any drug which affects gastrointestinal motility (prokinetic agents, laxative, etc.) prior to PillSense™ Capsule ingestion.
3. Provide the patient with the PillSense™ System Patient Leaflet and PillSense™ System Patient Card. Talk them through the information provided paying particular attention to the following:
    - After ingesting the PillSense™ Capsule, and until it is excreted, patients should not be near any source of powerful electromagnetic fields, such as one created by an MRI device.
    - Patient should not have an MRI exam performed until the PillSense™ Capsule has been excreted.
    - If the patient experiences any abdominal pain, nausea, or vomiting after ingesting the PillSense™ Capsule they should consult their physician.
    - Inform the patient that they will drink up to 150 ml (5 oz) of water at the time of capsule ingestion and then that they will remain in the left lateral decubitus position for a short time until capsule test results are finalized.
    - When the results are finalized, the patient can resume oral intake upon instruction and will have no physical activity restrictions.
    - The patient should inform the doctor if the capsule has not been excreted prior to any further surgery.

DIRECTIONS FOR USE

1. Setup the PillSense™ System by selecting a PillSense™ Receiver
    - Remove receiver from packaging box and using the push button switch on the righthand side to turn the receiver on.
    - Using the stylus provided configure the time and date to your location by clicking the ‘Settings’ icon. You will only need to perform this operation upon initial setup.

2. Select ‘Start new monitoring’ to proceed with a new monitoring process.
   - If it is desired to view results from previous procedures press ‘Review previous records’ and select the wished monitoring session from the list on the PillSense™ Receiver screen.
3. Use the provided stylus to enter the patient ID (assigned by the hospital/clinician) and select ‘ok’ on the screen. To proceed select ‘continue’. If an incorrect ID was entered press ‘back’ button.
4. Select a new PillSense™ Capsule.
   Warning: Do not open the capsule tray until just before use.
5. Add PillSense™ Capsule address, taken from the capsule packaging, to the patient record and the Patient Card. To re-enter patient ID select ‘back’ (repeat and proceed from step 3).
6. Open the capsule packaging. Do not use if packaged seal is damaged or opened.
7. Remove the PillSense™ Capsule from its tray. Intermittent blinking lights will be visible in the cavity of the capsule once it has been removed from the packaging. Use your hand to shield the light from the room entering the cavity for better visibility. To continue select ‘ok’.
   Warning:
   - Inspect the capsule for any visible crack or damage.
   - Do not use a damaged capsule.
   - Do not drop the capsule. Place dropped capsules in the bin. Ensure the magnet remains in the tray.
8. Pair the desired capsule by selecting the corresponding address from the list on the PillSense™ Receiver screen. If an incorrect capsule address is selected, wait until ‘Unpair’ button appears and select ‘Unpair’.
9. Wait for ‘capsule Battery Check’ to be completed successfully. If any of the checks fail, select ‘unpair’ and restart procedure with a different capsule. To continue select ‘Start’.
10. Prepare a container of water, minimum 150 ml (5 oz).
11. Instruct the patient to swallow the paired capsule with the water.
    Warning:
    - Ensure patient does not swallow a capsule that has not been paired successfully.
    - The patient should avoid biting the capsule.
    - Ensure patient drinks the recommended volume of water and at a normal pace.
12. Instruct the patient to remain in the left lateral decubitus position until the PillSense™ System test results are finalized.
    Warning:
    - If the patient does not remain in the left lateral position, PillSense™ Capsule may not function as expected.
13. Confirm that the PillSense™ Capsule has been swallowed and that the patient is on their left-hand side and click ‘Start’ to commence the monitoring process for a minimum of 5 minutes.
14. If there is blood in the upper GI tract, ‘**Blood Detected**’ will appear on the screen almost immediately even if the monitoring period is less than 5 minutes and the message remains displayed.
15. Once the 5 minutes ‘Monitoring Time’ has passed (as indicated on the bottom of the screen) and the user stops the monitoring session the message ‘**No Blood Detected**’ will appear on the screen if no blood has been found in the upper GI tract. Note: This message will also appear on the screen at the end of the monitoring period if no blood has been found.
    Note: During use, ensure there is no obstruction (such as another person or objects) between patient and the receiver. If communication is lost during monitoring, a crossed-out gray signal will appear. 
    Move the receiver closer to the patient. If communication successfully reconnects a blue signal will appear on the screen . 
    If communication persists to fail, a communication warning page will appear. Ensure receiver is close to the patient and select ‘retry’ which resumes the monitoring session. If communication still fails, up to 5 times, select ‘unpair’ and terminate the procedure.
16. Monitoring can be stopped by holding the ‘**Stop**’ button for 2 seconds. It can be restarted by clicking the ‘**Re-Start**’ button.
17. If monitoring is stopped before 5 minutes has elapsed a warning will appear ‘**Minimum 5 minutes required. Continue monitoring**.’
18. After 10 minutes, the following warning will appear: ‘Warning: 10 min passed since ingestion.’ The monitoring period automatically stops after 10 minutes but can be restarted for up to 40 minutes.
19. To terminate the procedure when monitoring has finished, press and hold the ‘Stop’ button to enable the ‘Terminate’ button. Select ‘Terminate’.

20. Select ‘Yes’ on the next page to proceed with termination of procedure.
    - If it is desired to view the results of the procedure press ‘review previous records’ on page 1 and select the monitoring session from the list on the PillSense™Receiver screen.
21. To turn off the receiver press the power switch.

BENEFITS

1. Atraumatic and non-invasive procedure with no sedation: PillSense™Capsule is safe to ingest. The atraumatic capsule will travel through the GI tract before being excreted. No other interventions are required, and sedation is not required.
2. Faster turn-around diagnosis: PillSense™will acquire data as soon as the capsule has been ingested. The real-time blood detection enables a faster diagnosis which will inform the care path treatment. Clinical papers have shown that a fast diagnosis and immediate intervention is associated with lower in-hospital mortality, morbidity, shorter length of stay and lower total hospital costs[1,2,3]. PillSense™System can be administered in any clinical setting, therefore, PillSense™System offers a readily available solution.
3. Accurate detection of blood: PillSense™System contains a sensor specifically designed to detect blood in the upper gastrointestinal tract. The result “Blood/No Blood” is clearly communicated at the end of the procedure on the receiver display requiring no interpretation.
4. Ease of use. The system does not require any special patient preparation and provides results immediatly, therefore the product can be used in a multitude of settings including both the Emergency Room and ICU, and step-down units if rebleed after initial treatment is suspected. The device can be dispensed by personnel other than a gastroenterologist and provides a reading that requires no interpretation. This will allow more highly qualified clinical staff to attend to more demanding tasks.

RISKS

1. A normal ‘No blood’ detected capsule result does not exclude the possibility of any other conditions being present.
2. After ingesting the PillSense™ Capsule, and until it is excreted, patients should not be near any source of powerful electromagnetic fields, such as one created by an MRI device.
3. The risks of PillSense™ include Capsule retention, Capsule aspiration, obstruction, perforation, mucosal bleeding, abdominal pain, nausea, and vomiting.
4. There is an extremely rare risk of Capsule aspiration while patients are attempting to swallow a PillSense™ Capsule. Capsule aspiration occurs in 1 out of 800-1000 procedures[4], mostly in elderly male patients with co-morbidities and/or swallowing disorders. Repeated attempts required for ingesting the Capsule can predict Capsule aspiration.
5. There is a risk due to possible poor communication that the user may get an ‘inconclusive result’ warning displayed if they stop the monitoring. If this occurs, an extended monitoring period is required by restarting the monitoring on the receiver. This is due to insufficient data packets gathered during acquisition caused by poor communication.
6. The risks of Capsule leakage, allergic reaction, biological contamination, and infection have been addressed and mitigated as far as possible. There is a possibility that these can occur if care is not taken in handling the product according to these instructions for use and hospital procedures, but the probability of occurrence is very low.
7. Capsule retention has been reported in less than 2% [5] of all Capsule endoscopy procedures. It is particularly prevalent in patients with inflammatory strictures due to Crohn’s disease or who have gastrointestinal obstructions, strictures, or fistula.
8. Although each risk has been addressed and mitigated as far as possible, there is a possibility that the PillSense™ System can fail due to components, hardware, software, and packaging issues which may cause delay of diagnosis, incomplete exam, or data corruption.
9. Medical, endoscopic, or surgical intervention may be necessary to address any of these complications, should they occur.

1. https://www.ncbi.nlm.nih.gov/pubmed?term=10320114
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5432117/
3. https://www.hcup-us.ahrq.gov/nisoverview.jsp
4. https://www.ncbi.nlm.nih.gov/pubmed/21409372
5. https://www.ncbi.nlm.nih.gov/pubmed/17963875

CLINICAL RESULTS

PIVOTAL STUDY (DETECT-1 Study)

The PillSense™ System was evaluated in a prospective single-center, single-arm comparative study to determine the sensitivity, specificity, and accuracy of the device for detection of blood in hemodynamically stable adults suspected of an upper gastrointestinal bleed (DETECT-1 Study -NCT05385224). Patients were recruited from a high-volume metropolitan hospital with patients evaluated in the gastroenterology endoscopy clinic. PillSense™ System performance was compared with esophagogastroduodenoscopy (EGD). Capsule transit and safety were also documented. Patients were first administered the PillSense™ Capsule followed by EGD performed within 4 hours by a gastroenterologist blinded to the PillSense™ System result.

Two patients were unable to swallow the capsule. These patients were excluded from the effectiveness analysis. Among the 124 patients included in the effectiveness analysis population (28 with bleeds and 96 without bleeds based on EGD evaluation), the PillSense™ System detected blood with 92.9% sensitivity (95% Confidence interval-CI, 76.5%, 99.1%) and 90.6% specificity (95%CI, 82.9%, 95.6%). The positive and negative predictive values were 74.3% and 97.8% respectively. Among the Safety Population of 126 patients, there were no adverse events related to the device. The capsules passed in 125/126 (99.2%) patients who ingested the capsule, with the device clearing the GI tract within a mean of 3.6 days (median 3 days; range 0-9). In one patient with a history of gastric bypass, the capsule was removed during the EGD. In two other patients with a history of gastric bypass the capsule passed naturally.

The DETECT-1 study established that the PillSense™ System is a safe and effective tool for detecting blood in patients being screened for UGIB.

FEASIBILITY STUDY

A feasibility study evaluated the PillSense™ System in a prospective multi-center, single-arm comparative study in the Czech Republic. Thirty patients were evaluated having first received the PillSense™ Capsule and then an EGD within 2 hours of ingestion. EGD confirmed UGIB in 11 patients. The sensitivity and specificity were 91.0% and 89% respectively. It was observed that the PillSense™ Capsule was well tolerated by all patients. The capsule passed naturally in 28/30 (93.3%) of the patients. The capsule was removed early in one patient during the confirmatory EGD as the EGD detected a large malignancy which was later confirmed to be gastric adenocarcinoma. In a second patient, the capsule was retained due to the unknown presence of a large colon tumor. As the patient was already scheduled for colon removal, the investigator decided to remove the capsule during that procedure. The surgeon removed the capsule without any complications. This observation shows that it is necessary to exclude small-bowel obstruction as carefully as possible before capsule ingestion.

RATINGS

The PillSense™ Capsule (P00050-01FP) and PillSense™ Receiver (P00167-01FP): See Table 01 Below

OPERATING RANGE

PillSense™ Capsule operates in-vivo.

- Atmospheric Pressure: 59kPa – 100kPa

PillSense™ Receiver operates under normal indoor environmental conditions:

- Temperature: 5 ºC – 40 ºC
- Humidity: 5% - 95%

OPERATING ENVIRONMENT

PillSense™ System is used in a clinical setting. The device shall be used away from an active MRI machine and particular precautions shall be used in presence of other machines that could cause electromagnetic (EMC) interference and loss of data. Consult the EMC information provided in this manual.

Do not use in oxygen-rich environment. There are no other known characteristics within the hospital setting (e.g., glare, vibration, ambient noise, high levels of activity) that could adversely affect user interactions with the device.

CAPSULE (P00050-01FP)	RECEIVER (P00167-01FP)
IP67	IP20
Rating: 3.8 VDC – 20mA	For use with power supply: GSM40B05-P1J • Input: 80 ~ 264VAC; 47~63Hz; 1A/115VAC 0.5A/230VAC; • Output: 5 V d.c. 5A For use Battery Pack: 1/LPP 503759 8HH PCM W • Rating: 3.7 V d.c. 2,400 mAh nominal; 8.9 Wh
Type BF applied part	Type BF applied part
Class II device	Class II device

Table 01 - Ratings of both Capsule & Receiver

RECEIVER ICONS

DESCRIPTION	ICON
EnteraSense Logo	
Battery icon	
Charging icon	
Low battery icon	
Poor RF communication signal icon	

DESCRIPTION	ICON
Strong RF communication signal icon	
System check pass icon	
System check fail icon	
Waiting icon during system check	

Table 02: Receiver Icon Definitions

STORAGE

If a PillSense™ System is broken, damaged, or the receiver is in need of repair or any other assistance please contact the Cook Medical customer service at customersupport@cookmedical.com

CAPSULE

1. Store PillSense™ Capsule under normal indoor environmental conditions.
2. Do not remove PillSense™ Capsule from the packaging until just prior to use.

RECEIVER

1. Store PillSense™ Receiver under normal indoor environmental conditions.
2. Store the product away from humidity and do not use under water.
3. The PillSense™ Receiver can be re-used for multiple procedures. Switch off prior to storage between procedures and ensure battery is maintained in a full condition.

RECEIVER SERVICE LIFE

The PillSense™ Receiver has a recommended service life of 2 years.

WIRELESS CHARACTERISTICS

Radio Transmission:

Table 03 - Radio Transmission

Frequency	Transmission power	Transfer rate	Modulation	Duty Cycle
433.92 MHz	15 dbm (30 mW)	50 kbit/s	GFSK-2	4 ms every 2 seconds

Quality of Service Requirements:

Table 04 - Quality of service requirements

Required bit rate	Latency	RSSI	Packet lost
50 kbit/s	No impact	> -100 dbm	<50%

CLEANING

CAPSULE
Capsule is a single use only device and should not be cleaned or reused.

RECEIVER
Wipe the PillSense™ Receiver with IPA wipes. The device should be wiped after every use and if the device is not visibly clean, the user should either repeat the cleaning process or safely dispose of the device, so that a visibly soiled device is not used.

DISPOSAL
Dispose of PillSense™ Capsule and Receiver device and packaging as per local ordinances.

WARRANTY
EnteraSense warrants that the PillSense™ System is free from defects in both material and workmanship. Suitability for use of the capsule functionality for any procedure shall be determined by the user. EnteraSense shall not be liable for incidental or consequential damages of any kind.

GUIDANCE AND MANUFACTURER DECLARATIONS

PILLSENSE CAPSULE

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS		
The PillSense™ Capsule is intended for use in the electromagnetic environment specified below. The customer or the user of the PillSense™Capsule should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF Emissions Conducted and Radiated CISPR 11 EN 55011	Group 1	The PillSense™ Capsule 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.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The PillSense™ Capsule is intended for use in the electromagnetic environment specified below. The customer or the user of the PillSense™ System should assure that it is used in such an environment.			
Immunity tests	EN 60601 Test level	Compliance	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2 EN 61000-4-2	+/- 15 kV contact +/- 8 kV air	±2, 4, 6 & 8 kV contact ±2, 4,6 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 %.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8 EN 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: UT is the AC mains voltage prior to application of the test level			
Radiated RF IEC 61000-4-3 EN 61000-4-3	3 V/m 80 MHz to 2.7 GHz 27 V/m, 18 Hz PM 385 MHz 28 V/m, 50 %18 Hz PM 450 MHz 9 V/m, 217 Hz PM 710 MHz 9 V/m, 217 Hz PM 745 MHz 9 V/m, 217 Hz PM 780 MHz 28V/m, 18 Hz PM 810 MHz 28 V/m, 18 Hz PM 870 MHz 28 V/m, 18 Hz PM 930 MHz 28V/m, 217 Hz PM 1720 MHz	3 V/m 80 MHz to 2.7 GHz 27 V/m, 18 Hz PM 385 MHz 28 V/m, 50 %18 Hz PM 450 MHz 9 V/m, 217 Hz PM 710 MHz 9 V/m, 217 Hz PM 745 MHz 9 V/m, 217 Hz PM 780 MHz 28V/m, 18 Hz PM 810 MHz 28 V/m, 18 Hz PM 870 MHz 28 V/m, 18 Hz PM 930 MHz 28V/m, 217 Hz PM 1720 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the PillSense™Capsule, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = [1.17] √P ...80MHz to 800 MHz d = [2.33] √P ...800 MHz to 2.7GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, * should be less than the compliance level in each frequency range. **

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
Immunity tests	EN 60601 Test level	Compliance	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3 EN 61000-4-3	28 V/m, 217 Hz PM 1845 MHz 28 V/m, 217 Hz PM 1970 MHz 27 V/m, 217 Hz PM 2450 MHz 9V/m, 217 Hz PM 5240 MHz 9 V/m, 217 Hz PM 5500 MHz 9 V/m, 217 Hz PM 5785 MHz	28 V/m, 217 Hz PM 1845 MHz 28 V/m, 217 Hz PM 1970 MHz 27 V/m, 217 Hz PM 2450 MHz 9V/m, 217 Hz PM 5240 MHz 9 V/m, 217 Hz PM 5500 MHz 9 V/m, 217 Hz PM 5785 MHz	Interference may occur in the vicinity of equipment marked with the following symbol: 
IEC 61000-4-39	8 A/m 30 kHz 65 A/m, 2.1 kHz modulation 134.5 kHz 7.5 A/m, 50 kHz modulation 13.56 MHz	8 A/m 30 kHz 65 A/m, 2.1 kHz modulation 134.5 kHz 7.5 A/m, 50 kHz modulation 13.56 MHz	

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.

* 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 access 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 PillSense™Capsule is used exceeds the applicable RF compliance level above, the PillSense™Capsule should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PillSense™System.
**Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1]V/m.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE PILLSENSE CAPSULE

The PillSense™ Capsule is intended for use in an electromagnetic environment specified in Table below. The customer or the user of the PillSense™Capsule can help prevent electromagnet interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PillSense™Capsule as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (P)	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz d= 1.17 x √P	80 MHz to 800 MHz d= 1.17 x √P	800 MHz to 2.7 GHz d = 2.33 x √P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.75
1	1.17	1.17	2.33
10	3.70	3.70	7.36
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be calculated using the equation applicable to the frequency of the transmitter. P is the maximum output power rating of the transmitter in watts (W) as declared by 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.

PILLSENSE RECEIVER

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF Emissions Conducted and Radiated CISPR 11 EN 55011	Group 1	The PillSense™Receiver 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 Conducted and Radiated CISPR 11 EN 55011	Class B	The PillSense™Receiver is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2 EN 61000-3-2	Compliant	
Voltage fluctuations/flicker emissions IEC 61000-3-3 EN 61000-3-3	Compliant	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The PillSense™ Receiver is intended for use in the electromagnetic environment specified below. The customer or the user of the PillSense™ Receiver should assure that it is used in such an environment.			
Immunity tests	EN 60601 Test level	Compliance	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2 EN 61000-4-2	+/- 8 kV contact +/- 15 kV air	±2, 4, 6 & 8 kV contact ±2, 4,6 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 EN 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	+/- 2 kV for power supply lines +/- 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5 EN 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	+/- 0.5, 1 kV differen-tial mode +/- 0.5, 1, 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11 EN 61000-4-11	<5 % Ut (>95 % dip in Ut) for 0.5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 70 % Ut (30 % dip in Ut) for 25 cycles <5 % Ut (>95 % dip in Ut) for 5 sec	<5 % Ut (>95 % dip in Ut) for 0.5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 70 % Ut (30 % dip in Ut) for 25 cycles <5 % Ut (>95 % dip in Ut) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the PillSense™ Receiver requires continued operation during power mains interruptions, it is recommended that the PillSense™ Receiver be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8 EN 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.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
Immunity tests	EN 60601 Test level	Compliance	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 EN 61000-4-6	3 Vrms outside industrial, scientific and medical (ISM) and amateur radio bands. 6 Vrms in ISM and amateur radio bands 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the PillSense™Receiver, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = [1.17] √P ...80MHz to 800 MHz d = [2.33] √P ...800 MHz to 2.7GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, * should be less than the compliance level in each frequency range. ** Interference may occur in the vicinity of equipment marked with the following symbol: 
	3 V/m	3 V/m	
Radiated RF IEC 61000-4-3 EN 61000-4-3	80 MHz to 2.7 GHz 27 V/m, 18 Hz PM 385 MHz 28 V/m, 50 %18 Hz PM 450 MHz 9 V/m, 217 Hz PM 710 MHz 9 V/m, 217 Hz PM 745 MHz 9 V/m, 217 Hz PM 780 MHz 28V/m, 18 Hz PM 810 MHz 28 V/m, 18 Hz PM 870 MHz 28 V/m, 18 Hz PM 930 MHz 28V/m, 217 Hz PM 1720 MHz 28 V/m, 217 Hz PM 1845 MHz	80 MHz to 2.7 GHz 27 V/m, 18 Hz PM 385 MHz 28 V/m, 50 %18 Hz PM 450 MHz 9 V/m, 217 Hz PM 710 MHz 9 V/m, 217 Hz PM 745 MHz 9 V/m, 217 Hz PM 780 MHz 28V/m, 18 Hz PM 810 MHz 28 V/m, 18 Hz PM 870 MHz 28 V/m, 18 Hz PM 930 MHz 28V/m, 217 Hz PM 1720 MHz 28 V/m, 217 Hz PM 1845 MHz	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
Immunity tests	EN 60601 Test level	Compliance	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 EN 61000-4-6 Radiated RF IEC 61000-4-3 EN 61000-4-3 IEC 61000-4-39	28 V/m, 217 Hz PM 1970 MHz 27 V/m, 217 Hz PM 2450 MHz 9V/m, 217 Hz PM 5240 MHz 9 V/m, 217 Hz PM 5500 MHz 9 V/m, 217 Hz PM 5785 MHz 8 A/m 30 kHz 65 A/m, 2.1 kHz modulation 134.5 kHz 7.5 A/m, 50 kHz modulation 13.56 MHz	28 V/m, 217 Hz PM 1970 MHz 27 V/m, 217 Hz PM 2450 MHz 9V/m, 217 Hz PM 5240 MHz 9 V/m, 217 Hz PM 5500 MHz 9 V/m, 217 Hz PM 5785 MHz 8 A/m 30 kHz 65 A/m, 2.1 kHz modulation 134.5 kHz 7.5 A/m, 50 kHz modulation 13.56 MHz	
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.			
* Fixed 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 access the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the PillSense™Receiver is used exceeds the applicable RF compliance level above, the PillSense™Receiver should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PillSense™System. ** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 [V1]V/m.			

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE PILLSENSE SYSTEM RECEIVER.

The PillSense™ Receiver is intended for use in an electromagnetic environment specified in Table below. The customer or the user of the PillSense™ Receiver can help prevent electromagnet interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PillSense™ Receiver as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (P) W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.17 \times \sqrt{P}$	80 MHz to 800 MHz $d = 1.17 \times \sqrt{P}$	800 MHz to 2.7 GHz $d = 2.33 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.75
1	1.17	1.17	2.33
10	3.70	3.70	7.36
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be calculated using the equation applicable to the frequency of the transmitter. P is the maximum output power rating of the transmitter in watts (W) as declared by 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.

SYSTEM LABELLING

Symbol	Title of Symbol	Description as Per FDA Recognized Consensus Standards
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself (Ref # 5.4.4 ISO 15223-1)
	Consult Instructions for use	Indicates the need for the user to consult the instructions for use (Ref # 5.4.3 ISO 15223-1)
	Manufacturer	Indicates the medical device manufacturer (Ref # 5.1.1 ISO 15223-1)

SYSTEM LABELLING		
Symbol	Title of Symbol	Description as Per FDA Recognized Consensus Standards
	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process (Ref # 5.2.7 ISO 15223-1)
	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure (Ref# 5.4.2 ISO 15223-1)
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified (Ref # 5.1.6 ISO 15223-1)
	Batch code (Lot number)	Indicates the manufacturer's batch code so that the batch or lot can be identified (Ref # 5.1.5 ISO 15223-1)
	Use by date	Indicates the date after which the medical device is not to be used (Ref# 5.1.4 ISO 15223-1)
	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.	N/A
	MR unsafe	Keep away from magnetic resonance imaging (MRI) equipment.
	Storage humidity range	Indicates the range of humidity to which the medical device can be safely exposed. (Ref# 5.3.8 ISO 15223-1).
	Storage temperature range	Indicates the temperature limits to which the medical device can be safely exposed. (Ref# 5.3.7 ISO 15223-1).
	Non-ionizing radiation	To indicate generally elevated, potentially hazardous, levels of nonionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.

SYSTEM LABELLING		
Symbol	Title of Symbol	Description as Per FDA Recognized Consensus Standards
IPN$_1$N$_2$	Degree of Ingress Protection Provided by Enclosure	IEC 60529: Manufacturer-determined degree of particle and water ingress protection, where... N1= degree of protection from particulates (scale of 0-6); and N2 = degree of protection from water (scale of 0-8) NOTE When a characteristic numeral is not required to be specified, it is replaced by the letter ÕXÓ.
	Applied part: Type 'BF' IEC 60601 series electrical safety classification	IEC 60417-5333 Type BF applied in Part
	Keep Dry	Indicates a medical device that needs to be protected from moisture (Ref# 5.3.4 ISO 15223-1)
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened (Ref# 5.2.8 ISO 15223-1)
	Separate collection for waste of electrical and electronic equipment.	Do not throw in the trash.
	Medical Device	Indicates the item is a medical device.
	Keep away from sunlight	Indicates a medical device that needs protection from light source.

ENTERA SENSE

CONTACT DETAILS

For assistance please contact **Cook Medical** customer service at customersupport@cookmedical.com or +1 812.339.2235, 800.457.4500.

COOK® MEDICAL

Distributed By:
Cook Medical LLC
400 N Daniels Way
Bloomington, IN 47404 USA

Manufacturer
EnteraSense Ltd
Block 4
Ballybrit Business Park
Galway, H91 A4XW
Ireland

P00049-07IFU Rev 1.0