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Certification Exhibit

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IC: 10060A-FAS1511**

**FCC Rule Part: 15.209, 15.231, 15.249
IC Radio Standards Specification: RSS-210**

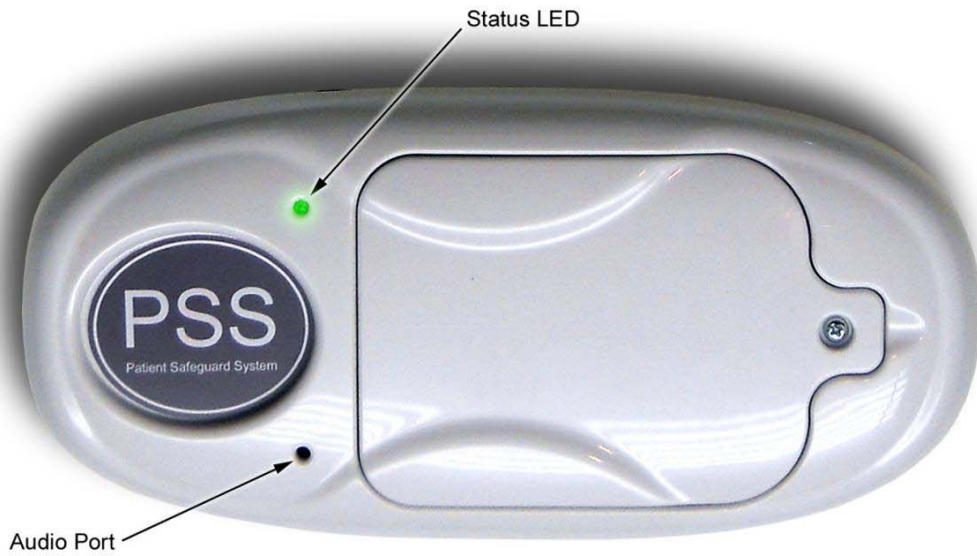
ACS Project: 11-2104

Manufacturer: UltraClenz, LLC
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User Manual

Patient Safeguard System (PSS) Bed Beacon User's Guide

DOC1048 Revision 1



UltraClenz, LLC

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Revision History

Revision	Date	By	Description
0	03/14/12	MES	Initial Release
1	08/09/12	DLS	Corrected TOC and replaced FCC class A statement with class B statement

1.0 Introduction to the System

The Patient Safeguard System (PSS) was designed to help Healthcare Workers (HCW) protect their patients from the unintentional spread of pathogens. This is achieved by providing a tool to remind HCWs to perform hand hygiene when the opportunities are presented. Hand hygiene opportunities, in a patient care environment, are defined as instances when hand hygiene should be performed to reduce or eliminate a patient’s exposure to harmful or even deadly pathogens carried on the HCW’s hands. These patient care hand hygiene opportunities are described in detail by the World Health Organization’s (WHO) “**Your 5 Moments for Hand Hygiene**”.

PSS software provides HCWs with real-time feedback when hand hygiene opportunities occur and will also provide a warning when hand hygiene opportunities are missed or ignored. The real-time data can be viewed at a designated computer terminal or a tablet running the PSS application software. PSS may also be configured to monitor and assess the hand hygiene performance of HCWs on either a group or individual basis. By assessing how well a HCW recognizes and engages in hand hygiene opportunities, the HCW will receive feedback that lets them know how well they’re doing. This feedback can then be used to establish performance benchmarks and goals. HCW performance can then be tracked over time, measured against these benchmarks and goals to assess overall compliance to identify specific areas where improvement is needed. Ultimately, the purpose of PSS is to provide HCWs with a tool that allows them to improve upon, and then maintain, high levels of hand hygiene performance, thus providing a safer environment for their patients and themselves.

2.0 System Components

PSS consists of 4 basic components; a HCW badge, a soap/sanitizer dispenser beacon, a patient bed beacon and a patient bed antenna. These components work together to form a system that will alert HCWs when hand hygiene needs to occur or alarm them when hand hygiene failed to occur.



1. Healthcare Worker (HCW) Badge
FAS1509



2. Soap/Sanitizer Dispenser Beacon
FAS1510

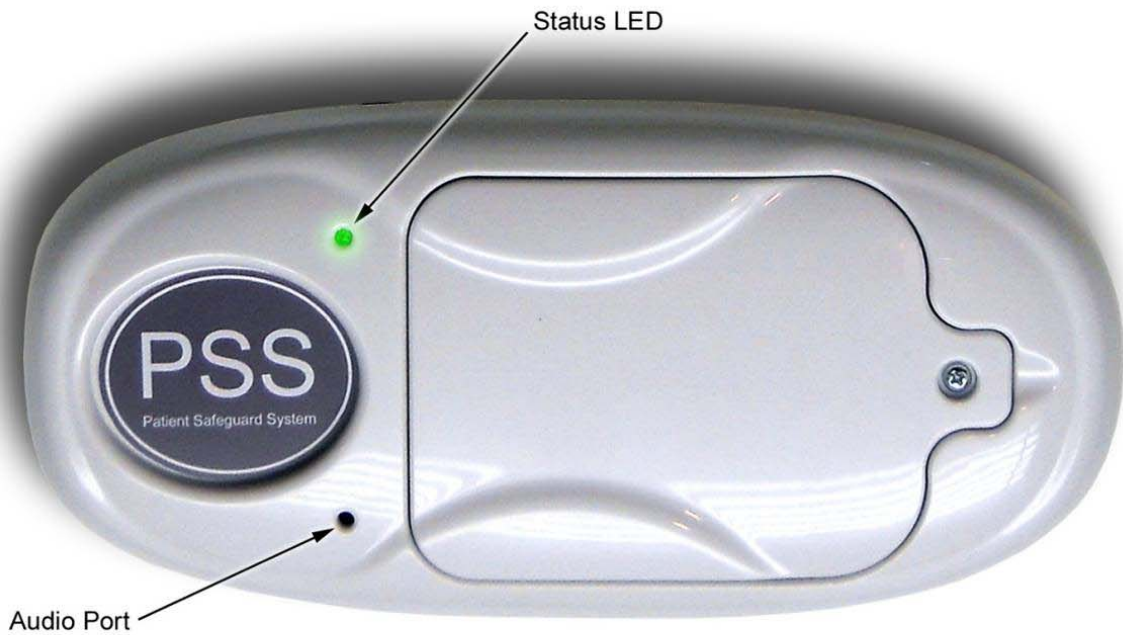


3. Patient Bed Beacon
FAS1511

3.0 Patient Bed Beacon

The bed beacon, via its detachable patient bed antenna, creates an invisible boundary around the patient’s bed. This boundary defines the patient’s “space” and is called the patient zone. When a HCW crosses this boundary and enters the patient zone, the HCW is now considered to be in contact with the patient. The HCW’s badge will then communicate with the bed beacon. The bed beacon will then reply and the badge will immediately change its hand hygiene state. For example, if the HCW’s badge is in the sanitary state (green flashing LED) it will then change to a cautionary state (yellow flashing LED) to indicate that a compliant patient contact event has occurred. A thorough explanation of badge states and state changes is provided later in this document.

The bed beacon provides both audio and visual alerts to indicate that it has successfully communicated with a HCW’s badge. Upon successful communication, the status LED will flash green one time followed by a two tone chime (see *Figure 5*).



4.0 Adjusting the Patient Bed Beacon Communication Range

The patient bed beacon range of communication is adjusted during installation to maximize communication with the Healthcare Worker (HCW) badge. To adjust the communication range, remove the battery cover located on the front of the beacon using a #2 Phillips screwdriver (see *Figure 3*). Note: the battery cover has a retaining ring to prevent the screw from being detached. After the cover has been removed, the beacon communication range is adjusted by repeatedly pushing either the “+” *increment* or the “-” *decrement* range buttons (see *Figure 4*) to achieve the desired range. The total adjustable range of each beacon is 1 to 32 increments between the lowest and the highest setting. Each push of either the “+” or “-” button will produce an audible beep indicating one increment up or down. When the lowest or the highest setting is reached, four audible beeps will be heard. To reset a beacon’s range back to the factory default setting, push and hold both the “+” and the “-” buttons down, at the same time, until four audible beeps are heard. The factory default range setting for the Bed beacon is 24. Replace the battery cover when the adjustment is complete.

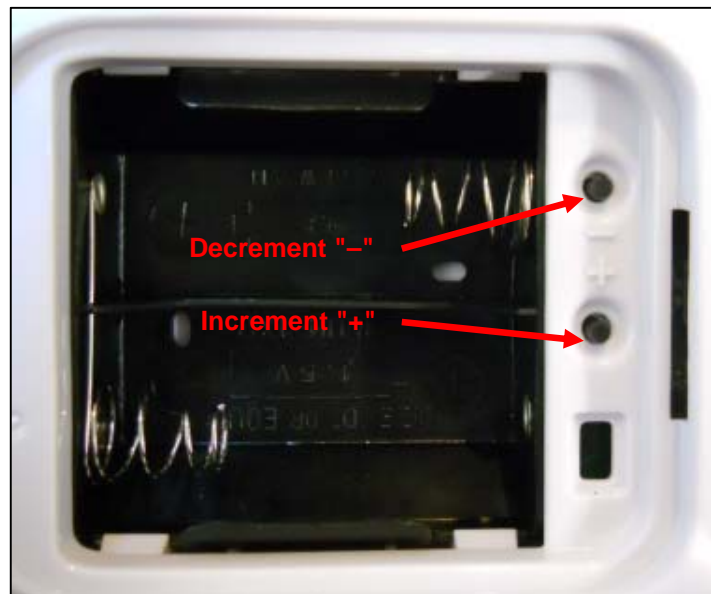


Figure 6 - Patient Bed Beacon Increment “+” and Decrement “-” Communication Range Buttons

There may be circumstances which require a beacon’s range to be adjusted, after the initial installation, to properly communicate with a badge. Examples of why bed beacon’s range may need to be adjusted are explained below.

Case for Bed Beacon Range Adjustment

1. Two beds with bed beacons in one room.
2. Two beds with bed beacons in separate but adjacent rooms separated by a wall.

In both cases, the range of communication of a given bed beacon may overlap or interfere with a nearby bed beacon. If this occurs, the HCW’s badge may communicate with a nearby bed beacon instead of the intended bed beacon. This miscommunication will result in the system reporting contact with the wrong patient. To eliminate the possibility of miscommunication, the range of bed beacons in close proximity may be decreased, at any time, to insure that a HCW’s badge will communicate with the intended bed beacon. This is accomplished by removing the beacon’s battery cover and pressing the “-” button to shorten the range. Continue pressing the “-” button until the desired range and thus proper communication is achieved.

5.0 How the System Works

When a Healthcare Worker (HCW) begins their shift, they will attach an assigned badge to their clothing in a location above the waist that is clearly visible to HCW as well as others. The badge will be dormant with no blinking LED visible. This is normal because the badge will go into a “sleep” state to conserve battery power when not in use for a period of 30 minutes or more.

The first thing the HCW will do, after attaching their badge, is wash or sanitize their hands. The dispenser beacon attached to the soap/sanitizer dispenser will communicate with the badge when the dispenser is activated. Even though the badge is in a sleep state, it is always listening and the dispenser beacon’s communication will wake it up. The badge will produce 3 quick beep tones with the second tone being lower in pitch than the first or third tones. This indicates successful communications between the badge and the dispenser beacon. The badge will then be set to the sanitary or clean state with the green LED blinking about once every 1.5 seconds. The HCW is now ready to begin their normal work routine.

When the badge is set to the sanitary state, the badge starts an internal timer. If there is no interaction between the HCW and a dispenser or patient bed, the timer will continue to increment. If the timer reaches 20 minutes, the badge will automatically change from the sanitary state to the cautionary state. When this transition occurs, the badge will produce 2 quick beep tones with both having the same pitch. This indicates to the HCW that the badge has automatically changed state. The badge’s yellow LED will then blink about once every 1.5 seconds. The cautionary state does not imply a violation of hand hygiene protocol. In this case, it is indicating to the HCW and anyone else able to see the badge’s yellow LED that the HCW has not washed or sanitized their hands for at least 20 minutes and that they may not approach a patient until doing so.

If the HCW does approach a patient while in the cautionary state, this event will be considered a violation of hand hygiene protocol and the badge will change from the cautionary state to the warning state. The badge will produce 3 quick beep tones with the second tone being lower in pitch than the first or third tones. This indicates successful communications between the badge and the bed beacon located within the patient zone. The badge’s red LED will then blink about once every 1.5 seconds. Immediately after changing to the warning state, the badge will produce a rapid burst of 4 tones with each having a different pitch. This will be repeated 4 more times over the next 20 seconds and will indicate to the HCW that they must wash/sanitize their hands immediately.

If the HCW approaches a patient while in the sanitary state, the badge will change to the cautionary state. The badge will produce 3 quick beep tones with the second tone being lower in pitch than the first or third tones. This indicates successful communications between the badge and the bed beacon located within the patient zone. The badge’s yellow LED will then blink about once every 1.5 seconds. The cautionary state does not imply a violation of hand hygiene protocol. In this case, it is indicating to the HCW and anyone else able to see the badge’s yellow LED that the HCW is currently in contact with a patient or has had contact with a patient within the last 5 minutes.

While the HCW is inside the patient zone, their badge will remain in the cautionary state. When the HCW leaves the patient zone, the badge starts an internal timer. If there is no interaction between the HCW and a dispenser, after leaving the patient zone, the timer will continue to increment. If the timer reaches 5 minutes, the badge will automatically change from the cautionary state to the warning state. When this transition occurs, the badge will produce 2 quick beep tones with both having the same pitch. This indicates to the HCW that the badge has automatically changed state. Immediately after changing to the warning state, the badge will produce a rapid burst of 4 tones with each having a different pitch. This will be repeated 4 more times over the next 20 seconds and will indicate to the HCW that they must wash/sanitize their hands immediately.

A HCW may contact a patient, leave the patient zone briefly and then re-contact the same patient without washing/sanitizing their hands. However, the HCW may not re-contact the patient without first using a soap/sanitizer dispenser if they are outside of the patient zone for more than 1 minute. As long as the HCW remains inside the patient zone, their badge will remain in the cautionary state. When the HCW leaves the patient zone, the badge starts an internal timer. If there is no interaction between the HCW and a dispenser, after leaving the patient zone, the timer will continue to increment. If the HCW then reenters the patient zone and the internal timer has not reached 1 minute, the badge will remain in the cautionary state and the internal timer will be reset. However, if the HCW reenters the patient zone and the internal timer has reached or passed 1 minute, the badge

will change to the warning state. The badge will produce 3 quick beep tones with the second tone being lower in pitch than the first or third tones. This indicates successful communications between the badge and the bed beacon located within the patient zone. The badge’s red LED will then blink about once every 1.5 seconds. Immediately after changing to the warning state, the badge will produce a rapid burst of 4 tones with each having a different pitch. This will be repeated 4 more times over the next 20 seconds and will indicate to the HCW that they must wash/sanitize their hands immediately.

A HCW may not go from one patient zone to another without washing/sanitizing in-between. While a HCW is in a patient zone, their badge will be in the cautionary state. When they leave the patient zone, their badge will remain in the cautionary state for up to 5 minutes beyond which time their badge will automatically change to the warning state or until they wash/sanitize at which time their badge will then change to the sanitary state. If the HCW leaves a patient zone and then enters a different patient zone without first interacting with a soap/sanitizer dispenser, the badge will change from the cautionary state to the warning state. The badge will produce 3 quick beep tones with the second tone being lower in pitch than the first or third tones. This indicates successful communications between the badge and the bed beacon located within the patient zone. The badge’s red LED will then blink about once every 1.5 seconds. Immediately after changing to the warning state, the badge will produce a rapid burst of 4 tones with each having a different pitch. This will be repeated 4 more times over the next 20 seconds and will indicate to the HCW that they must wash/sanitize their hands immediately.

6.0 Installing the System

6.1 Patient Bed Beacon Installation

The patient bed beacon can be mounted on the wall near the head of the patient’s bed or directly to the frame of the bed itself. It is also possible to mount the bed beacon to a gurney, wheelchair or other transportable device that may be occupied by a patient. In the case of a patient bed located in a patient room, it may be best to mount the bed beacon to the wall so that if the bed is removed and replaced, the bed beacon will remain and will always be associated with the same patient room regardless of what bed is currently present (see *Figure 6*).

6.1.1 Mount Using Tape

To mount the bed beacon on a metal surface or a transportable device, double sided tape or Velcro tape may be the best choice. Double sided tape and Velcro tape may also be used for wall mounting if desired. Velcro tape will have the advantage of making the bed beacon removable from the mounting surface. For both double sided tape and Velcro tape, a minimum of a single strip, at least 3 inches long, should be used.

To insure the best adhesion of the tape, make sure that the mounting surface of both the bed beacon and the object the bed beacon will be mounted to is clean and free of dirt and oil. A soft cloth dampened with isopropyl alcohol will work well to clean both surfaces. Most tape adhesives require about 24 hours of curing. Avoid installing batteries into the bed beacon until the tape’s adhesive has had a chance to cure. Otherwise, the extra weight may cause the bed beacon to detach from the surface it has been mounted to.



Figure 6. *Bed Beacon Mounted on Patient Bed*

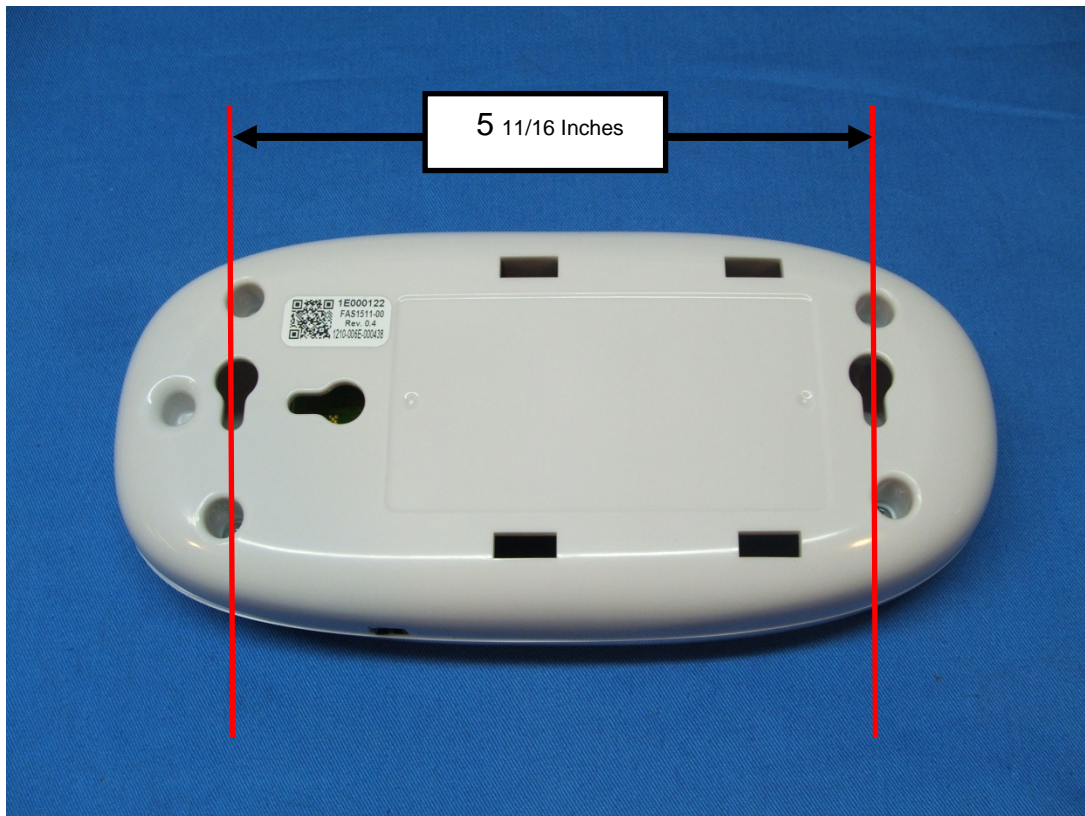
6.1.2 Mount Using Screws

The rear surface of the bed beacon has two keyhole shaped openings that are $5 \frac{11}{16}$ inches on center. Locate the position and height on the wall where the bed beacon will be mounted. Mark the location for the first mounting screw. Then, measure left or right $5 \frac{11}{16}$ inches and mark the location of the second mounting screw. Use a level to verify that the screw locations lineup parallel to the floor.

The keyhole openings will accept #6 or #8 screws and it is advisable to use properly sized wall anchors. Using a correctly sized drill bit, drill a hole in the wall for each mounting screw at the locations marked. Be aware that the wall at the head of a patient bed may contain gas lines. Insert the wall anchors into the wall and then install the screws. Both screws will need a gap between the base of the screw’s head and the surface of the wall. Start with about 1/8 of an inch.

Attach the bed beacon to the wall by lining up the large portion of the keyhole openings with the mounting screw heads and push the bed beacon flush against the wall. Then, gently slide the bed beacon towards the floor until the smaller portion of the keyhole openings make contact with the shaft of both mounting screws.

If the bed beacon is not in tight contact with the wall, remove the bed beacon and tighten both mounting screws a little more to reduce the gap between the screw’s head and the surface of the wall.



6.2 Patient Bed Antenna

The bed antenna is placed on the patient’s bed either under the mattress pad or under the mattress. It is made from a thin sheet of Tyvek® with the antenna screen printed on its surface. The antenna is cleanable, disposable or recyclable. It may be replaced and discarded whenever the patient’s bed linens are changed.

The bed beacon uses the bed antenna to create the barrier that defines the patient zone around the patient’s bed.

The bed antenna is attached to the bed beacon via a small cable and breakaway connector. The breakaway connector will allow the bed antenna to disconnect from the bed beacon when the bed is moved without damage to the bed beacon. However, it is best to manually disconnect the connector before moving the patient bed.



Figure 7. Bed Antenna shown on top of bed for illustration purposes.

Appendix A - System Component Care and Maintenance

Cleaning the Components

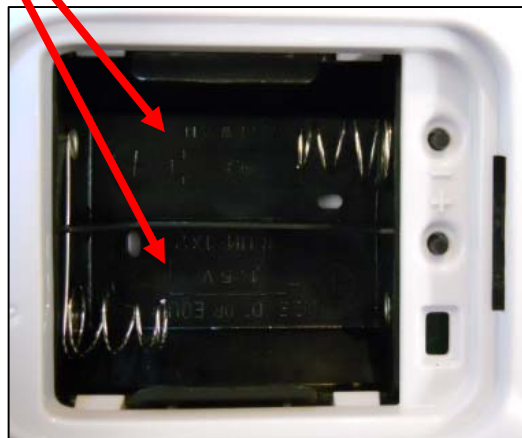
The bed beacon should be cleaned by wiping with a soft cloth. A mixture of 90% water and 10% chlorine (bleach) or water and mild detergent (dish soap) may be used. The cloth should be damp but not wet. Only the exterior of the component may be cleaned. Do not attempt to clean any interior surface of this component as this will damage the component’s circuitry. Do not use abrasive cleaners or cleaning products in aerosol cans as they will damage the component’s finish.

Handling the Bed Beacon

The bed beacon is an electronic device and should be handled with care. Like other electronic devices such as cell phones, the bed beacon must be protected from extreme heat, cold and moisture. Avoid handling the bed beacon with wet hands or exposing it to rain. Avoid dropping or tossing the bed beacon. The shock can damage the beacon’s sensitive internal electronics.

Battery Replacement

Bed Beacon is powered by 2 “D” Cell Batteries



Appendix B - Certification and Safety Approvals

FCC

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:

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

WARNING: Changes or modifications not expressly approved by UltraClenz, LLC could void the user's authority to operate the equipment.

Industry Canada

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada. Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

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

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, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

This radio transmitter (IC: 10060A-FAS1511) has been approved by Industry Canada to operate with the antenna types listed below with the maximum permissible gain and required antenna impedance for each antenna type indicated. Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

Le présent émetteur radio (IC: 10060A-FAS1511) a été approuvé par Industrie Canada pour fonctionner avec les types d'antenne énumérés ci-dessous et ayant un gain admissible maximal et l'impédance requise pour chaque type d'antenne. Les types d'antenne non inclus dans cette liste, ou dont le gain est supérieur au gain maximal indiqué, sont strictement interdits pour l'exploitation de l'émetteur.

Magnetic Loop Antenna
Printed-F antenna, 6.3 dBi
Wire monopole antenna, -2.3 dBi

Warranty

This device is warranted against defective materials and workmanship for one year from the date of delivery.

Equipment covered by this warranty will be repaired or replaced in the United States and Canada, WITHOUT CHARGE, except for shipping and handling, by our Factory Service Center.

When returning equipment for warranty service, you must first call your distributor's **Warranty Service Department** for your Return Merchandise Authorization Number (RMA), the RMA must be on your return label, also the shipping charges must be pre-paid and a copy of your receipt must be enclosed.

This warranty covers all defects incurred from normal use of the equipment and does not apply in the following cases:

- a. Loss or damage to the equipment due to abuse, mishandling, accident or failure to follow mounting instructions.
- b. If the equipment is defective as a result of leaking batteries.
- c. If the equipment has been serviced or modified by someone other than our authorized agents.

THE AFOREMENTIONED IS IN LIEU OF ALL WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE. IN NO EVENT SHALL THE VENDOR BE LIABLE FOR CONSEQUENTIAL, INCIDENTAL, INDIRECT OR SPECIAL DAMAGES OR LIABILITY, TRANSPORTATION, INSTALLATION OR SUBSTITUTION COSTS, DELAYS, OR FOR ANY OTHER DAMAGES, COSTS, OR EXPENSES INCURRED, IRRESPECTIVE OF HOW THEY OCCUR. THIS WARRANTY SHALL NOT EXTEND TO ANY OTHER PERSON OTHER THAN THE ORIGINAL PURCHASER OF THIS EQUIPMENT OR THE PERSON FOR WHOM IT WAS PURCHASED AS A GIFT.

This warranty gives you specific legal rights, and you may also have other rights, which may vary from state to state. This warranty is given with respect to equipment purchased in the United States.

Patent Pending