PHYSICIAN GUIDE

ActaStim-S Spine Fusion Stimulator

ActaStim·S

Theragen

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1. PRESCRIBING INFORMATION

Description

ActaStim-S passes a specific current between the electrodes in order to promote healing by inducing a therapeutic, low level electrical current at the fusion site. Federal law restricts this device to sale by or on the order of a physician, prescription (Rx) only. This device is not intended for re-sale.

Indications for Use

The ActaStim-S Spine Fusion Stimulator is a noninvasive bone growth stimulator indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels. The device is Rx only, and intended for single patient use in adult patients only.

Contraindications

There are no known contraindications.

Warnings

Cardiac pacemakers or cardioverters may be adversely affected by ActaStim-S. The concomitant use of ActaStim-S and a pacemaker or cardioverter must be assessed on an individual basis, such as with an electrocardiogram, prior to use. The patient should be referred to a cardiologist for monitoring of pacemaker function while wearing the active stimulator device. If there are any observable adverse changes in the pacemaker rhythm or output, ActaStim-S should not be used.

The safety and effectiveness of ActaStim-S in pregnant women have not been studied, and the effects of ActaStim-S on the mother or the developing fetus are unknown. A patient who is either pregnant or is intending to become pregnant should be referred to her doctor prior to treatment with ActaStim-S.

Precautions

The safety and effectiveness of ActaStim-S in individuals with the following conditions have not been studied, and therefore the safety and effectiveness of ActaStim-S in these individuals are unknown:

- spondylitis, infection, Paget's disease
- cancer, diabetes mellitus, renal disease
- trauma of the lumbar spine
- osteoporosis

Apply the electrodes after the skin has been cleaned and dried. If erythema develops at the electrode sites, the electrodes should be relocated adjacent to the original sites. If the reaction does not resolve after 48 hours after relocating the electrodes, the patient should be instructed to consult with the physician.

Do not submerge or expose ActaStim-S to water. The patient must be instructed to remove ActaStim-S during bathing, showering or swimming.

Compliance with the treatment schedule, daily battery pack changes, and replacing the electrodes (1 to 7 days) as needed are essential for proper device function. This system should only be used with components and replacement parts supplied by Theragen. Other components, parts and accessories may not be compatible, and may damage ActaStim-S. If any component does not function properly, contact **Customer Support at 1-800-901-5667**. No attempt should be made to modify or repair ActaStim-S.

Patients should be able to use ActaStim-S in accordance with the instructions for use. **If a patient cannot comply with these instructions for any reason, use of ActaStim-S is not recommended.**

Adverse Events

During a multi-center clinical study of 349 patients treated with a device delivering the same output parameters as ActaStim-S for the indication listed above, skin irritation was the most common adverse effect associated with the use of the device. It occurred in 9 patients (2.6% of the trial population): 4 patients treated with the active device and 5 patients treated with the placebo device.

Recommended Usage

ActaStim-S is designed to deliver 270 days of continuous therapeutic treatment for 24 hours per day. The recommended daily therapeutic treatment is continuous for 24 hours.

2. DIRECTIONS FOR USE

General

The stimulator and all of the following instructions have been specifically designed for safe, comfortable and easy use by a patient. They include the required assembly, operation, troubleshooting and maintenance (battery charging and cleaning) activities.

Begin using the stimulator immediately after reading the instructions for use and having received instructions from the prescribing physician.

The device is intended for use 24 hours per day until treatment is determined to be complete by the prescribing physician. Compliance with the instructions provided by the prescribing physician are critical to achieving effective treatment. Proper care of ActaStim-S is also required for the proper function of ActaStim-S.

The system has been designed to give 24 hours of treatment from a fully charged battery and routine charging and swapping of the 2 batteries every 24 hours will help ensure no inadvertent gaps in treatment. Indicators are provided to demonstrate the latest point at which a fully discharged battery will need recharging if treatment is to avoid being interrupted.

Examine the skin for signs of irritation when replacing the electrodes. If irritation is present, relocate the electrodes to a place adjacent to that site but still within the guidance. Disconnect the ActaStim-S generator during bathing, showering or swimming, and reconnect as soon as practical following these activities. Either remove the electrodes or cover the electrodes with the electrode covers during showering.

Placement of Electrodes

There are 2 types of electrodes provided. Both types are designed to work effectively. One or other type may be preferred based on how well they stick to the skin and how easily they can be removed.

Clean and dry the skin where the electrodes are to be placed. Trimming (not shaving) body hair from the electrode application area is often helpful. Choose one of the 2 electrode types provided with the system.

Remove the electrode from the pouch and remove the plastic backing material from the electrode. **Place one electrode on the back, two to three inches to the left of the area of the spinal fusion and the second electrode two to three inches to the right of the area of the spinal fusion so that the electrodes are on the back, four to six inches apart.**

Depending on the ability to move after surgery, it may be helpful to ask another person to assist in placing these electrodes. The patient should consult their prescribing physician if they have any questions or concerns regarding proper electrode placement.

If the skin becomes abnormally red at the electrode sites, the electrodes should be moved adjacent to the original sites. If the redness does not go away after 48 hours with the electrodes removed, the patient should contact their prescribing physician.

If there are issues with the electrodes remaining in place, try the alternative electrode type and/or consider applying an electrode cover over the top of the electrode.

3. PATIENT COUNSELING INFORMATION

Compliance - Compliance with device use and care is critical to assure the proper function of ActaStim-S and to ensure effective treatment.

Battery - Change the battery approximately every 24 hours or as indicated by ActaStim-S. Charge the spare battery immediately on removal or at least when indicated by ActaStim-S (orange light).

Electrodes - Replace the electrodes when needed and clean the electrode application sites thoroughly with soap and water, and dry the site before applying the electrodes.

Skin Irritation - Examine the skin for irritation when replacing the electrodes. If irritation is present, relocate the electrodes adjacent to the original sites. The patient should be evaluated periodically to assess the skin for sensitivity.

Bathing - Disconnect ActaStim-S during bathing, showering or swimming. It should be reconnected as soon as practical following these activities. Either remove the electrodes, or cover the electrodes with the protective retainer patches, during showering.

4. CLINICAL INFORMATION

A. Study Design

The capacitively coupled (CC) BGS device clinical study was a concurrent, multi-center, randomized, double-blinded, prospective study. The objective of the study was to determine whether the CC BGS device increased the frequency of overall success when compared to placebo (inactive) units, after primary (first-time) one-level or two-level fusions within L3 to S1

Subjects were eligible if they had degenerative disc disease and had undergone one-level or two- level between L3 and S1. The surgical procedures qualifying for inclusion were: an interbody fusion, including either a posterior lumbar interbody fusion (PLIF) or anterior lumbar interbody fusion (ALIF); a bilateral posterolateral fusion; or a combination of both procedures. Subjects could also receive either autograft or allograft graft material. Subjects could also receive internal fixation. Subjects were randomized to receive either an active or placebo device within three weeks of surgery.

The study was constructed to demonstrate superiority. Study success was determined by making a comparison between fusions of the lumbar spine the percentage of active patients in the core group considered to be overall successes (radiographic success and clinical success) and the percentage of placebo patients in the core group considered to be overall successes. The study was to be considered successful if the comparison between the active and placebo core patients considered to be overall successes yielded a statistically significant result (p-value less than or equal to 0.05), in favor of the active device.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the study was limited to patients who met the following inclusion criteria:

- degenerative disc disease
- spine segments: L3/I4, L4/I5, L5/S1, L3/I5, L4/S1
- interbody fusion, either posterior lumbar interbody fusion (PLIF) or anterior lumbar interbody fusion (ALIF), or bilateral posterolateral fusion (with or without fixation hardware)
- primary fusion, within three weeks of enrollment
- one-level or two-level fusion
- autograft or allograft graft material
- closed epiphyses

Patients were not permitted to enroll in the study if they met any of the following exclusion criteria:

- pathologic process at spine level - spondylosis, infection, Paget's disease
- systemic disease that may affect fusion - cancer, diabetes mellitus, renal disease
- osseous trauma of the lumbar spine
- pregnancy
- cardiac pacemaker
- inability of patient to understand or comply with study instructions
- osteoporosis

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at three, six, nine and 12 months after the initial use of the device. The subjects were instructed to use the device continuously, except for periods of personal hygiene, until a physician had assessed overall success or for a period of nine months (the period of time allocated for this study).

Preoperatively, the Patient Self-Assessment Form (PSAF). Postoperatively, the objective parameters measured during the study included the following items.

During this trial, assessments of radiographic (x-ray) and clinical status (pain and function) were made.

Radiographic Assessment: Radiographic assessments were gathered in 2 formats:

- Interim Assessments (Follow-Up Case Report Form at 6 weeks and, at three, six, nine and 12 months after the initial use of the device)

  Radiographic assessments on the Follow-Up Case Report Forms consisted of checking the appropriate description of the patient's radiographic condition from the following list: Complete; Incomplete - progressing; Incomplete - not progressing; and No Fusion Evident. No additional definitions were provided of these descriptive terms.

  Interim assessments were not used as a determinant of overall success within the approved Investigational Protocol.

- Final Evaluation (Final Success Evaluation Form at the final office visit)
  Radiographic assessments on the Final Success Evaluation Case Report Form were made in the following fashion:
  The following definitions (Table 1) were used in evaluating the interbody fusion (ALIF and PLIF) and the bilateral posterolateral fusion.

Table 1. Radiographic Evaluation - Final Success Evaluation

ALIF/PLIF	
a. > 75% assimilation of graft and vertebrae	Success
b. 50-75% assimilation of graft and vertebrae	Success
c. 25-50% assimilation of graft and vertebrae	Failure
d. < 25% assimilation of graft and vertebrae	Failure
Bilateral Posterolateral	
a. Fusion	Success
b. Incomplete fusion	Failure
c. Absence of fusion mass	Failure

When a subject completed the study and received a radiographic assessment of "success" from the investigator, a series of the subject's radiographs were forwarded to a blinded, independent radiologist for a second opinion. If the independent radiologist agreed with the investigator's evaluation of "success", the investigator's assessment remained as the radiographic outcome. If the independent radiologist disagreed with the investigator, the radiographs were to be sent to a second blinded, independent reviewer. The opinion of this reviewer served as the radiographic outcome. Any subject receiving a negative radiographic assessment from the investigator at the completion of the study was automatically classified as a study failure.

Clinical Rating: Clinical assessments were gathered in 3 formats:

- Interim Assessments (Follow-Up Case Report Forms completed by the attending physician (at 6 weeks and, at three, six, nine and 12 months after the initial use of the device)

  Clinical assessments on the Follow-Up Case Report Forms consisted of checking the appropriate description of the patient's clinical condition from the following list: Excellent, Good, Fair, and Poor. No additional definitions were provided for these descriptive terms.

  Interim assessments were not used as a determinant of overall success within the approved Investigational Protocol.

- Final Evaluation (Final Success Evaluation Form completed by the attending physician at the final office visit)

  Clinical assessments on the Final Success Evaluation Case Report Form were made in the following fashion (Table 2):

Table 2. Clinical Assessment - Final Success Evaluation.

Excellent	Resumption of normal activities; no pain	Success
Good	Resumption of normal or modified activites; Occasional episodes of back or leg pain; Occasional pain medication	Success
Fair	Resumption of activities on a limited basis; Daily back and/or leg pain; Requires frequent pain medication	Failure
Poor	Unable to resume normal or modified activites; Severe back and/or leg pain; Requires daily pain medication	Failure

- Patient Self-Assessment Form (PSAF) - completed by the patient at baseline, 6 weeks, and, at three, six, nine and 12 months after the initial use of the device.

  The patient self-assessment questionnaire consists of 14-questions which describe a patient's perception of their pain and their ability to function. The patient answered each question, by providing the degree of their symptom. To analyze the results of the questionnaire, each answer was given a numeric score and the sum of the results was used as an indicator of outcome. The highest score, i.e., the worst possible pain and function score, would be 57 while the best score would be 0.

  The PSAF was not used as a determinant of success within the approved Investigational Protocol.

3. Clinical Endpoints

With regards to safety, every subject entered into the study was analyzed for adverse events.

Patient Success

With regards to effectiveness, patient was considered to be a success in this study if he/she was considered both clinically and radiographically successful at the time of the final evaluation. Patient progress at the interim (follow-up) visits was not taken into consideration in making the final evaluation.

A radiographic success at the final evaluation was:

For ALIF/PLIF

- 75% assimilation of graft and vertebrae, or
- 50-75% assimilation of graft and vertebrae

For Bilateral Posterolateral:

- "Fusion"

A clinical success at the final evaluation was a determination by the physician of either:

- Excellent: Resumption of normal activities; no pain;
  or
- Good: Resumption of normal or modified activities; occasional episodes of back or leg pain; occasional pain medication.

Study Success

With regard to success/failure criteria, study success was determined by making a comparison between the percentage of active patients in the core group considered to be overall successes (as defined above) and the percentage of placebo patients in the core group considered to be overall successes (as defined above). The study was to be considered successful if the comparison between the active and placebo core patients considered to be overall successes yielded a statistically significant result (p-value less than or equal to 0.05), in favor of the active device.

B. Accountability of PMA Cohort

Table 3 summarizes subject accountability, by "active" and "placebo" group as of a data-cut-off point.

Table 3. Summary of Subject Accountability - All Subjects Enrolled as of 12/31/1997.

	All Subjects	Active	Placebo
Enrolled (does not include 4 who received ID No. but not entered)	349	177	172
Not Reached Twelve Months Post Surgery, or Fused	-6	-3	-3
Twelve Months Post Surgery, Potentially Eligible for Evaluation	343	174	169
Withdrawals	-83	-43	-40
Reasons Unknown	(59)	(32)	(27)
Adverse Reactions	(12)	(5)	(7)
Compelled (jail, secondary surgery)	(7)	(4)	(3)
Requested (violated entry criteria)	(5)	(2)	(3)
Twelve Months Post Surgery, Eligible for Evaluation (Intent to Treat Population)	260	131	129
Protocol Deviations (Censored Population)	-45	-21	-24
Twelve Months Post Surgery, Meet Protocol (Core Population)	**215**	**110**	**105**

As Table 3 shows, 349 subjects were initially enrolled in the study and randomized to receive either an active or inactive (placebo) unit. Eighty-three subjects (24%) withdrew from the study and six had not yet completed the study as of the data cutoff date, leaving 260 subjects who completed the study and were available for analysis.

Of the 260 subjects who completed the study (Intent-To-Treat Population), 45 did not meet the entry criteria, had an intervening surgical/medical event that precluded an unbiased evaluation of overall success, or did not have an independent assessment of their radiographs (Censored Population). This left a total of 215 subjects who met all the protocol criteria and completed the study (Core Population).

Different groups of subjects were analyzed to demonstrate the safety and effectiveness of the CC BGS device. The safety analyses included all subjects who used the device at least once and had the potential to experience an adverse event (n=349). The effectiveness analyses focused on the findings from the core group (n=215).

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a noninvasive bone growth stimulator for use as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels study performed in the US.

Clinical Characteristics of Core Subjects (n=215)

The demographic and clinical characteristics of the active and placebo subjects in the core group are comparable. The mean age for the active and placebo groups was 46.54 years and 44.75 years, respectively. The active and placebo groups included an approximately equal number of men and women (active female = 46.4%, active male = 53.6%, placebo female= 51.4%, placebo male= 48.6%). Of the active subjects, 24.5% smoked; 21.0% of the placebo subjects smoked.

A number of subjects had prior (pre-operative) surgeries; 29.1 % of the actives, and 36.2% of the placebos. 67% of the actives and 59.1 % of the controls had a posterolateral fusion. The remaining subjects had some type of interbody fusion, including a posterior interbody fusion, an anterior interbody fusion, or a combination of an interbody and posterolateral fusion. Approximately, one half of the subjects in both groups had a one-level fusion. Almost all subjects had a graft material; and 26.4% of the actives and 20.0% of the placebos had fusions with internal fixation (hardware). The 99 active core subjects had a baseline summed mean pain and dysfunction score of 31.44 from their 14-question self-assessment form; the 99 placebo subjects had a summed mean of 33.35 at baseline.

D. Safety & Effectiveness Results

1. Safety Results

The analysis of safety was based on both the active and placebo cohorts of 349 total patients.

Adverse effects that occurred in the PMA clinical study:

Every subject entered into the study was analyzed for adverse events. Of the 349 subjects enrolled in the clinical study and who used the device at least once, nine experienced skin and cited this as a reason to withdraw from the study (2.6%). Of the nine subjects, four were in the active group and five were in the placebo group.

Three other subjects withdrew from the study because of adverse events: one placebo had a wound infection (non-device related); one placebo had back spasms; and, one active was "not progressing." (While lack of progression is normally not considered an adverse event, the investigator reported it that way.)

Eight subjects who completed the study experienced adverse events: (1) leg pain (placebo); (2) recurrent pain due to over-activity (placebo); (3) post-surgical wound seroma (active); (4) superficial wound disruption from a staple reaction {placebo); (5) pedicle fracture - screw removed (placebo); (6) a pedicle screw placement (active); (7) an aneurysm clipping (placebo); and (8) a cluneal nerve neuroma at the graft site (active). These eight subjects continued in the study, and were included in the effectiveness analyses.

2. Effectiveness Results

The analysis of effectiveness was based on the active and placebo 215 evaluable patients of the core group (n=215) at the 12-month time point.

Table 4 compares success in the active and placebo subjects of the core group (n=215). An overall success requires an independent confirmation of radiographic successful outcome on the Final Assessment Case Report Form and also a successful clinical outcome on the Final Assessment Case Report. For each group the number of successes is shown. The p-value presented for "Overall Success" indicates statistical significance (a p-value of less than or equal to 0.05 denotes significance). The data were analyzed using a two-tail Fisher exact test.

Table 4. Frequency of Success the Core Group, by Treatment (n=215).

	Overall Success (Clinical AND Radiographic Success)	Clinical Success	Radiographic Success	Average PSAF Score Baseline/12 months
Active (N=110)	87 (79%)	95 (85%)	94 (85%)	31.44/23.03
Placebo (N=105)	64 (61%)	79 (75%)	82 (78%)	33.35/23.44
P-value	0.0018			

Note: A patient was considered to be a success in this study if he/she was considered both clinically and radiographically successful at the time of the final evaluation. Patient progress at the interim (follow-up) visits was not taken into consideration in making the final evaluation

In the 215-subject core group, 87 active subjects (79%) achieved an overall success (defined as a combination of both physician described clinical success and also a radiographic success at the time of final evaluation) whereas 64 placebo subjects (61 %) achieved overall success at the time of final evaluation. This difference in the rates of overall success (18.1 %) was statistically significant (p=0.0018).

This trial was not designed to look at either clinical success or radiographic success independently. However, in the 215 core group, 94 of 110 active subjects (85%) were reported by the treating physician as being radiographically successful at the time of final evaluation; whereas 82 of 105 placebo subjects (78%) were reported by the treating physician as being radiographically successful at the time of final evaluation This difference in the rates of success (7%) was not statistically significant (p=0.0535). In the 215-subject core group, 95 active subjects (85%) achieved clinical success at the time of final evaluation; whereas 79 placebo subjects (75%) achieved a clinical success at the time of final evaluation. This difference in the rates of success (10%) was statistically significant (p=0.0163). However, these values were not adjusted for multiplicity and were also not adjusted for additional confounding factors (e.g., prior surgery, posterolateral fusion, or smoking).

As presented previously, the PSAF was also used to compare treatment groups. At baseline, the active and placebo core treatment groups were similar, with the active core subjects having a summed mean score of 31.44 and the placebos having a mean summed score of 33.35. The 1.91 point difference between core active and placebo mean patient self-assessment scores is not statistically significant (Z= -1.62426). At the time of final evaluation, active core subjects have a mean summed score of 23.03 and placebo core subjects have a mean summed score of 25.44. The point difference between core active and placebo mean patient self-assessment scores is not statistically significant (Z = -0.2675).

Logistic Regression Analysis

A number of subject characteristics and demographics may affect the probability of an overall successful outcome. A logistic regression analysis was conducted to determine if any variable(s) may have affected overall success. A logistic regression analysis tests whether any variable is statistically associated with success after controlling for the other variables, and provides an odds ratio to indicate the nature and strength of the relationship. A logistic regression was conducted using the following 13 variables that may have had an effect on the likelihood of an overall successful outcome:

1. the active device;
2. history of prior surgery (treatment);
3. gender;
4. age;
5. overweight;
6. smoking;
7. use of pre-operative medications, including steroids and NSAIDS
8. a secondary diagnosis of herniated disc pulposus;
9. a secondary diagnosis of spondylolisthesis;
10. occupational type, such as sedentary employment or moderate/heavy labor;
11. type of fusion, such as posterolateral or interbody;
12. level of fusion (single or multiple); and
13. the use of fixation hardware.

The following four variables were associated with overall success and were statistically significant: the active device, a history of prior surgery, fusion type, and smoking. The other variables, including the use of fixation hardware, were not significantly associated with overall success after controlling for the other variables. An analysis was then conducted with only the four identified variables, and is shown below in Table 5.

Table 5. Logistic Regression Analysis for the Core Group (n=215).

Variable	Odds Ratio	95% Confidence Interval	p-value
Prior Surgery	0.48	0.25 - 0.92	0.0276
Posterolateral Fusion	2.40	1.26 - 4.55	0.0073
Smoker	0.33	0.16 - 0.68	0.0024
Active Device	2.33	1.21 - 4.48	0.0110

This analysis showed that subjects with a history of prior surgery were less likely to achieve success, regardless of other factors (odds ratio = 0.48; p=0.0276). Subjects who had a posterolateral fusion were more likely to be overall successes, regardless of the other variables (odds ratio = 2.40, p=0.0073). Subjects who smoked were also less likely to achieve overall success (odds ratio= 0.33, p=0.0024). The subjects in the active group were more likely (odds ratio = 2.33) to achieve overall success regardless of their type of fusion, their prior history of surgery, or smoking. This odds ratio was statistically significant (p=0.0110).

5. TECHNICAL INFORMATION

Equipment Classification

Classification: Charger - Class II, Generator – Internally Powered
Type Applied Parts: Type BF (Electrodes, Generator Cable)
IP Rating of the System (Generator, battery, generator lead, electrodes): IP22 where:
The first characteristic numeral of 2 means both:

- Protected against access to hazardous parts with a finger
- Protected against solid foreign objects of 12,5 mm ⌀ and greater

The second characteristic numeral of 2 means:

- Protected against vertically falling water drops when enclosure tilted up to 15°

Mode of operation: Continuous

Output Waveform

60 KHz (plus or minus 10%) sinusoidal
5 to 10 mA (r.m.s.) at impedances between 100 and 450 Ohms
Greater than 3mA (r.m.s.) at impedances between 450 Ohms and 750 Ohms

Transport and Storage Conditions

-25°C to +5°C
+5°C to +35°C at a relative humidity up to 90%, non-condensing;
> 35°C to 70°C at a water vapor pressure up to 50 hPa

Operating Conditions

+5°C to +40°C
15 to 90% humidity
700 to 1060 hPa

Battery

Theragen p/n: 1101-0002
Voltage, nominal: 3.7 V
Capacity, nominal: 1,590 mAh

Power Supply

Manufacturer: CUI Inc
P/N: SWM6-5-NH-138
AC Input: 100-240 Vac, 0.6-3.0A, 50-60Hz
DC Output: 5V, 1.2A

6. ELECTROMAGNETIC COMPATIBILITY

ActaStim-S is intended for use in the Home Healthcare Environment (Restaurants, cafes, shops, stores, markets, schools, churches, libraries, outdoors (streets, sidewalks, parks), domiciles (permanent or temporary), vehicles, stations, airports, museums and theaters.

In these environments there is no identified risk of loss in essential performance of the ActaStim-S device due to EM disturbances.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories and cables other than those specified or provided by Theragen of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Do not use unapproved components. Only use system components provided with the system or obtained from the company as supplies or replacements.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ActaStim-S system including cables specified by Theragen. Otherwise, degradation of the performance of this equipment could result.

Emissions Test	Standard	Compliance
RF Emissions	CISPR 11	Group 1, Class B
Harmonic Emissions	IEC 61000-3-2	Class A
Voltage Fluctuations / Flicker Emissions	IEC 61000-3-3	Yes

Immunity Test	Standard	Test Levels
Electrostatic Discharge (ESD)	IEC 61000-4-2	+/- 8 kV contact +/- 15kV air
Electrical Fast Transient / Burst	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surge	IEC 61000-4-5	± 2 kV
Voltage Dips and Interruptions	IEC 61000-4-11	Voltage dips: 1) 0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 2) 0 % UT; 1 cycle and 70 % UT; 25/30 Single phase: at 0° Voltage interruptions: 0 % UT; 250/300 cycle
Power Frequency H-Field	IEC 61000-4-8	30 A/m

Conducted RF	IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF	IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz 27 V/m 385 MHz Pulse Modulation 18 Hz 28 V/m 450 MHz FM +/-5 kHz deviation 1 kHz sine 9 V/m 710/745/780 MHz Pulse Modulation 217 Hz 28 V/m 810/870/930 MHz Pulse Modulation 18 Hz

Radiated RF (cont.)		28 V/m 1,720/1,845/1,970 MHz Pulse Modulation 217 Hz 28 V/m 2,450 MHz Pulse Modulation 217 Hz 9 V/m 5,240/5,500/5,785 MHz Pulse Modulation 217 Hz

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