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Compilation of Emission Safety Reports on the L3 Communications, Inc. ProVision 100 Active Millimeter Wave Advanced Imaging Technology (AIT) System

Version 2

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U.S. Department of Homeland Security
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16. Abstract
This document is a compilation of reports describing investigations into the safety of the L-3 Communications, Inc. ProVision 100 active millimeter wave advanced imaging technology (AIT) system. L-3 Communications submitted test reports and certifications from independent organizations (CKC Laboratories and EMC International Services) in response to solicitations issued by the Transportation Security Administration. Under Department of Homeland Security sponsorship, the Food and Drug Administration's Center for Devices and Radiological Health independently repeated selected emissions measurements and assessed the risk of these emissions to a sample of prevalent, ambulatory personal medical electronic devices.

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EXECUTIVE SUMMARY

This document contains reports describing investigations into the emissions safety of the L-3 ProVision Advanced Imaging Technology (AIT) system, which uses non-ionizing millimeter waves. L-3 Communications submitted test reports and certifications from independent organizations (CKC Laboratories and EMC International Services) in response to solicitations issued by the Transportation Security Administration (TSA). Under Department of Homeland Security sponsorship, the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA) independently repeated selected emissions measurements and assessed the risk of these emissions to a sample of prevalent, ambulatory personal medical electronic devices (PMEDs).

The FDA CDRH report first estimates the exposure time based on emissions testing and power density calculations provided by EMC International Services (at the request of L-3 Communications and required by TSA). The pulse exposure measurements were used by FDA in the medical devices study (described below). The CDRH also repeated the emissions measurements for human exposure assessment made by CKC Laboratories (done at the request of L-3 Communications and required by TSA) and corroborated those findings, concluding that the electromagnetic energy levels emitted by the L-3 AIT system were 1000 times less than the safety limits determined by international standards (IEEE C95.1 and ICNIRP guidelines).

In addition, CDRH studied the risks of both spurious emissions and electromagnetic interference (EMI) on several types of PMEDs exposed to the emissions from an AIT screening system. Using a millimeter wave exposure simulator and an L-3 ProVision system, CDRH performed a risk assessment for potential EMI effects on a range of PMEDs (including pacemakers, neurostimulators, implantable cardio defibrillators, insulin pumps and blood glucose monitors). No effects were observed for any PMEDs exposed to the MMW AIT, and the CDRH concluded that the risks for the non-ionizing, millimeter wave and out of band emissions to disrupt the function of the selected PMEDs is very low.

This compilation includes the FDA CDRH report, including all methods and measurements, as well as certificates and test results by CKC Laboratories, Inc. and EMC International Services.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION: Report of Measurements and Assessment for Potential Electromagnetic Interference Effects on Personal Medical Electronic Devices from Exposure to Emissions from the L3 Provision Millimeter Wave Advanced Imaging Technology (AIT) Security System

April 4, 2011

1. Summary

This report presents the findings of the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) performed for the Department of Homeland Security (DHS), Science and Technology Directorate. The findings cover CDRH research, measurements, and testing that examined the risks of electromagnetic interference (EMI) of active medical devices (hereafter called personal electronic medical devices or PMEDs) exposed to the emissions from a first generation Advanced Imaging Technology (AIT-1) security screening system utilizing non-ionizing, millimeter wave (MMW) emissions. This report presents the methods and materials used in the project, a summary of the tests and findings, and an assessment of the risk for users of certain PMEDs exposed to the emissions from the L3 ProVision security system. The PMEDS were selected based on FDA concerns for EMI risks. For the purposes of this report the security screening system under test will be referred to as the MMW AIT-1. The information is organized into the body of the report with a brief introduction, information about measurements of human exposure levels, test methods, and findings for sample PMED exposures using the novel CDRH simulation system, and the actual AIT-1 system description, test methods, and findings for exposure with the L3 system, a brief risk assessment, and summary for the project. Detailed information about analysis, simulations, test set-up and methods and findings are located in appendices.

A qualitative assessment of the public exposure was performed per a DHS request to examine the exposure of security screening subjects to the non-ionizing electromagnetic energy emitted by the MMW AIT-1 using both CDRH measurements and other information. Peak electric field levels at worst-case locations inside the AIT security system were measured to be on the order of 0.01 V/m in the intended (in-band) MMW frequency range. Taking into consideration the short duration of exposure, and the very low levels of emissions from the MMW AIT-1, the electromagnetic energy levels were determined to be 1000 times less than the limits in the IEEE C95.1 [1] standards and guidelines from International Commission on Non-ionizing Radiation Protection (ICNIRP). [2]

A novel millimeter wave (MMW) simulator system was developed by engineers in the CDRH EMC-Wireless laboratory to mimic the emissions from the MMW AIT-1. The simulator allowed for a controlled testing environment for the PMEDs enabling careful study with predictable E-field strengths and exposure duration that were designed to be well above the expected worst-case exposure scenario. Methods were developed for each PMED type, tailored to its configuration, accessories, and programming. For the simulator, the PMED exposure was performed at a fixed distance and was set to produce an exposure several times greater than the expected exposure received by the MMW AIT-1 so that any effects on the PMED could be studied. Monitoring of the PMEDs was based on consensus standards for electromagnetic compatibility (EMC) testing for active medical devices intended to minimize perturbations of the exposure and spurious signals or artifacts. For the AIT, testing methods were developed to map the emissions, devise exposure locations, elevations, and orientations that span the possibilities for subjects and the sample PMEDs.

The laboratory testing performed with the MMW simulator and the MMW AIT-1 showed no effects on the sample PMEDs. Those PMED samples consisted of five implantable pacemakers, six implantable cardioverter defibrillators (ICDs), six implantable neurostimulators, and 12 insulin pumps and glucose sensors. The risks for active medical devices when exposed to emissions from the MMW AIT-1 were analyzed using the methods in the ISO: 14971:2009 standard [5]. Following the steps given in this standard, the probability of EMI occurrence and severity of harm were analyzed. Based on the test observations and findings, the likelihood of effects on PMED and the risk of EMI when exposed to this particular MMW AIT-1 appears to be very low. Thus, from the findings to date, the potential for EMI would appear to be rare for the PMEDs tested. Caution should be taken in understanding the scope of these findings. While the expected likelihood of PMED effects from exposure to the MMW AIT-1 appears to be rare, these findings might not be applicable for every model and type of PMEDs that could be exposed to the MMW AIT-1. However, the low level of exposure from the AIT-1 suggests it would likely not cause effects on the vast majority of PMEDs.

2. Introduction

Under the Interagency Agreement HSHDQC-10-x-00495 with the Department of Homeland Security, research and testing was performed by the Center for Devices and Radiological Health (CDRH) Food and Drug Administration (FDA) to examine the risks for possible electromagnetic interference (EMI) on personal medical electronic devices (PMEDs) from exposure to the L3 ProVision Advanced Imaging Technology (AIT) security screening system that emits non-ionizing, millimeter wave (MMW) energy.

High priority ambulatory, active medical devices (PMEDs) were selected for study based on history of electromagnetic compatibility (EMC) concerns and risks, priority of device function, and concerns for potential EMI. The medical devices under study included implantable pacemakers, implantable cardioverter defibrillators (ICDs), implantable neurostimulators, insulin pumps and glucose sensors. Arrangements were made with several medical device manufactures to borrow selected devices and provide expertise in their function and testing. The medical device manufacturers' representatives visited the test site at one or more during testing providing PMED programming and set-up expertise and guidance. It should be noted that the medical devices used in this study cover a limited portion of the entire device population and extrapolation of the findings to the vast range of devices and users could be misleading.

The engineers in the CDRH EMC-Wireless laboratory developed a novel simulator system that mimicked the MMW emissions of the MMW AIT-1. In parallel, the engineers performed computer modeling on a modified standard human torso simulator and determined that it was suitable for testing in the MMW frequencies. This report presents information about the EMC testing of active PMEDs exposed to simulated emissions and to an actual MMW AIT-1. The body of this report will briefly present the public considerations, mmw simulator system, torso simulator, MMW simulator and

MMW AIT-1 testing, findings from the testing, and the risk analysis. Detailed information about exposures, MMW AIT-1 emissions, torso simulator system, MMW simulator, test locations around the MMW AIT-1 and test procedures, PMED settings, and test data are located in the respective appendix.

3. Pulse Exposure Consideration

The estimated exposure time of a PMED occupying a 10cm x 10cm area at the closest distance from the MMW AIT-1 antenna was estimated in order to aid in determining the risks for EMI. Based on the emissions characteristics and dimensions of the MMW AIT-1, it was calculated that an active medical device will be exposed to 520 pulses out of a possible 138,008 pulses over the duration of a single MMW AIT-1 spatial scan and the total direct exposure time of the 100 cm^2 area was determined to be 161 ms. This is considered the worst-case for the longest exposure time. Appendix A provides more details about pulse exposure assessment.

4. Human Exposure Assessment

Measurements were made of the MMW in-band emissions from the antenna array within the MMW AIT-1 to analyze the levels of E-field exposures of personnel and body worn medical devices. The exposure of an object (person, receiving antenna, or body-worn medical device) is for only a brief period as the MMW AIT-1 transmitting antennas sweep their designed volume. Measurements were made of the maximum peak electric field strength (E-field) during a selected worst-case individual pulse emitted by the scanner using an envelope detector system configured by CDRH. Figure 1 illustrates this envelope detector system. Details about the measurements and instrumentation are in appendix B.

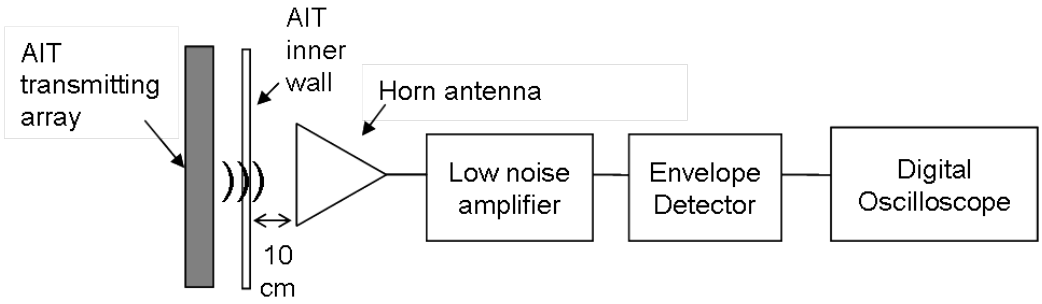

Figure 1: Envelope detector system for measuring emissions from MMW AIT-1.

The captured pulse was analyzed by applying correction factors for distance from the emitting antennas, receive antenna near field gain characteristics, input power in vs. output voltage out characteristics of the envelope detector, equations relating received power to power density, and E-field to power density. This allowed calculation of the power density and E-field vs. frequency. The peak values for transmitted in-band MMW emissions were calculated to be 0.01 V/m or approximately 0.027 W/m^2 in the 24.5 –

24.6 GHz frequency range. For the frequency range of the MMW AIT-1, the IEEE C95.1-2005 [1] standard for the general public is 10 W/m^2 averaged over a 5 minute period. Occupational exposure limits are 100 W/m^2 averaged over a period of approximately 40 seconds. A MMW AIT-1 scan lasts only X[1] seconds. Appendix B provides more detailed information about the MMW AIT-1 primary emissions field measurements.

The IEEE C95.1 limits are also defined for exposures averaged over the entire body. The exposure a person receives during one scan at a worst-case distance of 10 cm from the inner wall of the unit is on the order of 1000 times less than the IEEE standard's limit for the public exposure. In addition, the International Commission on Non-Ionizing Radiation Protection (ICNIRP) Guidelines published in 1998 [2], and endorsed by the European Union, are very similar to the IEEE C95.1. These Guidelines also limit exposures of the general public to 10 W/m^2 and average exposures over a period of time similar to the IEEE standard that depends on the frequency of the E-field.

5. Lower Frequency Band Emission Measurements

Measurements were performed to investigate MMW AIT-1 for any non-primary emissions or out of band (unintended) spurious emission in the frequency range between 5 Hz and 6 GHz. This was done because PMEDs can be susceptible to electromagnetic emission in these lower frequency ranges and for the most part EMC testing for PMEDs is conducted in this lower frequency range. Electric and magnetic field survey instrumentation were used to measure the emitted field strengths at several locations inside and around AIT-1 at a distance of 1 m from the surface of AIT-1. This separation distance was chosen as a reasonable estimate for the location of personnel and checkpoint subjects that are outside the AIT-1, and limitations on the survey instrumentation. Our measurements seem to agree reasonably well with those performed by the AIT-1 manufacturer to certify compliance with FCC rules. However their measurements were done at greater distances from the AIT-1 and direct comparisons are very difficult to make.

Findings from our measurements indicate the peak E-field measured from 100 kHz to 6 GHz was less than 1 V/m, which was the lower limit sensitivity of our instrumentation. The peak H-field measured from 5 Hz to 30 MHz was less than 5 mA/m. Other variables can include AC power line quality or other sources of electromagnetic emissions located in proximity. Thus, while these measurements represent reasonable findings at a point in time and space for the AIT-1 system, there are environmental factors around a deployment outside the emissions from the AIT-1 that could alter PMED exposure in the security checkpoint area.

[1] Proprietary value removed.

As a point of reference, the international standard for most non-implanted medical electrical equipment IEC 60601-1-2 [3] includes radiated immunity testing between 80 MHz and 2.5 GHz at the 3 V/m level with specified modulations. At lower frequencies immunity testing is performed via direct injection of voltages into the medical device from 150 kHz to 80 MHz using 3 V rms. Testing for immunity to magnetic fields is limited in these standards to the AC power line frequencies of 50/60 Hz at 3 A/m. However, certain particular implantable active medical device standards recommend testing up to 30 MHz with up to 150 A/m, though this is not a requirement and varies by the device type. Implantable medical devices are tested for EMC at various levels and for specific emitters such as external defibrillators. Such testing is done at generally more intense exposures in these frequency ranges. None of the present standards include testing in the range of the MMW AIT-1 primary frequency range between 25 and 30 GHz. These measurements may not reflect the highest level emitted by the AIT-1 because of temporal changes to the emissions. These measurements indicate the tested MMW AIT-1 does not seem to emit very large spurious electric or magnetic fields. Further details about the instrumentation and measurements performed are found in appendix C.

6. Medical Device Testing

In addition to measuring and analyzing the exposure a two prong approach was taken to perform PMED testing that involved development and use of a novel simulation system and testing in the MMW AIT-1 system. The simulation system was developed to create an alternative to performing tests with the MMW AIT-1 that is repeatable and reproducible for a wide range of PMEDs. In addition, a simulation of the human body called the torso simulator was created based on previous work as a platform on which to expose the PMEDs or devices under test (DUTs) with minimum effects on the exposure and device function. The torso simulator and MMW AIT-1 simulator system are described briefly below followed by findings from the PMED testing.

6.1 Torso Simulator

A torso simulator was developed and used for the implantable and body worn PMEDs. Because of the shallow penetration in the body resulting from exposures to the MMW AIT-1 emissions, computational simulations of penetration depth and attenuation were performed on two models. These assessed the MMW attenuation and energy penetration depth in the human torso. Simulations were performed with a torso model using electrical characteristics of human skin and fat tissues. Results were compared with a torso model with electrical properties of the saline filled torso simulator described in the ANSI PC69:2007 standard for implantable cardiac pacemakers and implantable cardioverter defibrillators [4]. The PC69 torso simulator is used for EMI testing of implanted cardiac devices. These models were used to compare the electromagnetic energy penetration and reflection in the 20 to 30 GHz frequency range. The findings indicate that in this frequency range saline attenuates the E-field deposition significantly more than typical for human tissues. These findings suggested that use of the ANSI

based saline filled torso simulator would under-expose implanted PMEDs and thus under-test such devices. Therefore, testing was done with a worst-case exposure where the DUT was placed 'in air' in front of a sheet of commercially available millimeter wave absorbing material (see Figure D-2 and D-3). Appendix D provides more details about torso simulator and analysis for use in the MMW AIT-1 measurements and testing.

6.2 MMW AIT-1 Simulation System

In order to create a more controlled, less costly yet reproducible exposure system in pursuit of evaluating potential worst-case PMED effects, a novel MMW simulator was created in the CDRH laboratory to mimic the exposure of emissions from the MMW AIT-1 system. The MMW simulator consists of a signal generator to produce the baseband frequency that is then modulated and feed into a waveguide horn antenna to expose the device under test. This system allows exposure above the levels expected in the MMW AIT-1 to allow for worst-case testing. The DUT was placed on MMW absorbing material covering the torso simulator at a separation distance of 70 cm from the transmitting horn of the MMW simulator. For most of the sample PMEDs, the electrical output of the DUT was monitored during exposure for indications of malfunction, degradation of performance, or deviation beyond the tolerances indicated in the individual device specifications. The monitoring circuitry for implantable devices was designed and arranged to minimize perturbations of the exposure E-fields or influence testing. A conductive path between the outer case of the device (reference electrode) and the saline was maintained via a wire to the back of the medical device with conductive tape (see Figure D-2). The other end of the wire was submerged in saline to complete the electrical circuit for DUT operation. A novel approach was used to monitor the function of the insulin pump device because these devices deliver insulin rather than electrical stimulation as pacemakers do. For the insulin pump devices their output activity was monitored using a 5 turn, 10 cm diameter pickup loop behind the MMW absorbing material. Appendix E provides more details about simulation system.

6.3 MMW Exposure Simulation System Test Procedure

The following steps comprise the general testing procedure for individual PMED tests in the series of testing for each sample DUT.

1. Verify simulator equipment setup and operation.
2. Program the DUT to applicable settings.
3. Place the DUT and leads at the proper location and orientation.
4. Initiate test sequence.
5. Record the DUT output and observe for any changes or effects during exposure.
6. Analyze DUT recordings.

The MMW AIT-1 exposure simulations used the following output parameters:

- Carrier frequency: 26.5 GHz - 30 GHz
- Primary Modulation: ranging from 100 Hz – 500 Hz, and ranging from 100 Hz – 300 kHz

- Additional Modulation: 1 Hz, 3 Hz, 200 Hz, 1.1 kHz , 76.8 KHz, 100 KHz, 178 kHz
- Exposure time: 20 seconds
- Antenna field polarization: separately horizontal and vertical.
- Peak exposure E-field strength: 12 V/m

6.4 Methods and Materials Testing PMEDs with the MMW AIT-1

The DUT was placed on MMW absorbing material of the torso simulator at locations inside and outside the MMW AIT-1 (Figure F-1). Based on the human anthropomorphic data, implantable devices were tested at two different heights above the floor (1m and 1.4m) corresponding to typical implantation locations in the human body. The insulin pumps were tested at three different heights above the floor (0.25m, 1m and 1.4m). Appendix F provides more detailed explanation of test locations. The electrical output of the DUT was monitored before, during, and after exposure for changes to the output while exposed. Observations were focused to look for any effects particularly indications of malfunction, degradation of performance, or deviation beyond the tolerances indicated in the individual device specifications. The monitoring circuitry for implantable devices was designed and arranged to minimize influence on testing such as perturbations of the exposure E-fields or pick-up of spurious emissions. Where needed by the PMED, a conductive path between the DUT and the saline within the torso simulator was maintained via a wire to the back of the medical device with conductive tape with the other end of the wire submerged in saline (See Figure D-3). The lead configurations for the pacemaker and ICD were based on the ANSI/AAMI PC69:2007 [4]. The lead configurations for the neurostimulators, shown in Figure 2, were based on ANSI 14708-3:2008 [5]. The output of insulin pumps was observed using a 5 turn, 10 cm diameter pickup loop behind the MMW absorber.

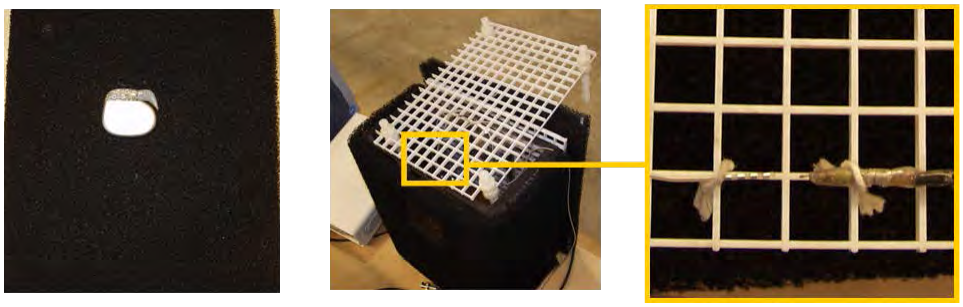

Figure 2: Torso simulator with neurostimulation device and associated lead configuration

6.5 Test Procedure using the MMW AIT-1

The following steps comprise the testing procedure for each individual test in the series of testing for each DUT. Appendix G provides more detailed test protocol for each device category.

1. Power and calibrate MMW AIT-1.

2. Program and activate the DUT.
3. Place the DUT on the torso simulator and place these at the test location.
4. Conduct five MMW AIT-1 scans (or emission depends on the test mode) of the DUT over 30 seconds time period.
5. Record the DUT output and observe for any changes or effects during exposure.
6. Analyze DUT recordings.
7. Repeat the test for new test location and height.

7. Summary of Findings for MMW AIT-1 Simulator Testing

The following section presents results of testing conducted on the following PMEDs: implantable pacemakers (A1-A5), ICDs (B1-B6) implantable neurostimulators (C1-C6) and insulin pumps and blood glucose monitors (D1-D12). While all PMEDs (except for certain insulin pumps and blood glucose monitors) were tested in the actual MMW AIT-1, not all PMEDs were tested using the MMW simulator. This was because the MMW AIT-1 unit was made available for only a limited period of time in the FDA labs, and testing with this source was given priority over testing with the simulated source. Appendix H provides table of DUT settings.

Table. 1 Summary of MMW AIT-1 simulator testing of implantable pacemakers.

Device	Device Mode	Lead Configuration	Observed Reactions
A1	AAI VVI	Bipolar Unipolar	None
A2	VVI	Bipolar Unipolar	None
A3	VVI	Bipolar Unipolar	None

Table. 2 Summary of MMW AIT-1 simulator testing of ICDs.

Device	Device Mode	Lead Configuration	Observed Reactions
B1	AAI VVI	Bipolar	None
B2	VVI	Bipolar	None
B3	AAI VVI	Bipolar	None

Table. 3 Summary of MMW AIT-1 simulator testing of implantable neurostimulators.

Device	Device Mode	Observed Reactions
C1	Electrical Periodic	None
C2	Electrical Periodic Magnetically Induced	None
C3	Cycling On	None

C4	Cycling On	None
C5	Cycling On	None

Table. 4 Summary of MMW AIT-1 simulator testing of insulin pumps and glucose sensors.

Device	Device Mode	Observed Reactions
D1	Bolus Delivery	None
D2	Data Transmission	None
D3	Data Transmission	None
D4	Data Transmission	None
D5	Data Collection	None
D6	Data Collection	None
D10	Bolus Delivery	None

During stimulated exposure conditions for the DUT settings mentioned above no changes were observed in the output, settings, data packets or programming of the DUTs.

8. Summary of Findings for the MMW AIT-1 Exposure Tests

The following section reports results of testing conducted on the sample PMEDs. Observations are based on exposures with the PMEDs at location 1 and 2 shown in Figure F-1. The DUTs A1-A5, B1-B6 and C1-C6 were tested at 1m and 1.4m above the floor of the MMW AIT-1. DUTs D1-D12 were tested at the 0.25m, 1m and 1.4m above the floor of the MMW AIT-1. Note that not all insulin pumps and glucose sensors were available for testing in the MMW AIT-1. This is because some prototypes were brought into the FDA labs and then taken back by manufacturers' representatives during the time when FDA did not have the actual MMW AIT-1. Selected DUTs (A1, A3, A5, B1, B3, B4, C1, C4, C6, D12) were tested at position 3 through 6 at all heights in addition to the testing done at position 1 and 2. Maximum PMED sensitivity modes (if available) were tested for all devices only in position 2 at the 1.4 m height. Appendix H provides a table of DUT settings and Appendix I provides more detailed test data at each location.

Table. 5 Summary of MMW AIT-1 exposure testing for sample implantable pacemakers

Device	Device Mode	Lead Configuration	Observed Reactions
A1*	AAI VVI AAI (Max Sensitivity) VVI (Max Sensitivity)	Bipolar Unipolar	None
A2	VVI VVI (maximum sensitivity)	Bipolar Unipolar	None
A3*	VVI VVI (maximum sensitivity)	Bipolar Unipolar	None

A4	DDDR	Bipolar Unipolar	None
A5*	DDDR	Bipolar	None

* These DUTs were tested at position 3-6 in addition to position 1 and 2.

Table. 6 Summary of MMW AIT-1 exposure testing for sample ICDs.

Device	Device Mode	Lead Configuration	Observed Reactions
B1*	AAI VVI AAI (Max Sensitivity) VVI (Max Sensitivity)	Bipolar	None
B2	VVI VVI (Max Sensitivity)	Bipolar	None
B3*	AAI VVI AAI (Max Sensitivity) VVI (Max Sensitivity)	Bipolar	None
B4*	DDDR	Bipolar	None
B5	DDD	Bipolar	None
B6	VVIR	Bipolar	None

* These DUTs were tested at position 3-6 in addition to position 1 and 2.

Table. 7 Summary of MMW AIT-1 exposure testing for sample implantable neurostimulator.

Device	Device Mode	Observed Reactions
C1*	Electrical Periodic Magnetically Induced Off	None
C2	Electrical Periodic Magnetically Induced Off	None
C3	Cycling On Cycling Off	None
C4*	Continuous On Continuous Off	None
C5	Cycling On Cycling Off	None
C6*	Cycling On Cycling Off	None

* These DUTs were tested at position 3-6 in addition to position 1 and 2.

Table. 8 Summary of MMW AIT-1 exposure testing for sample insulin pumps and blood glucose monitors.

Device	Device Mode	Observed Reactions

Device	Device Mode	Observed Reactions
D1	Bolus Delivery Alarm Idle	None
D3	Data Transmission	None
D7	Data Collection	Defective Device
D8	Data Collection	Defective Device
D9	Data Collection	None
D10	Bolus delivery alarm idle	
D11	Bolus delivery alarm idle	None
D12*	Bolus delivery alarm idle	None

* These DUTs were tested at position 3-6 in addition to position 1 and 2.

During exposures conditions for the DUT settings mentioned above, no changes were observed in the output, settings or programming of the DUTs. However, two of the DUTs (D7, D8) malfunctioned at a time when they were not being tested in the MMW AIT-1. Further evaluation is being done to examine and resolve the device malfunctions. These malfunctions are not related to exposure to emissions from the MMW AIT-1.

9. Risk Analysis

A key task under the IAA is to assess the risks for users of the high priority PMEDs for exposure to the emissions from the MMW AIT-1. The process called out in the ISO 14971:2009 [6] standard was used to analyze these risks. This standard entails a risk analysis process for medical devices which includes: determining the device intended use and identification of characteristics related to the safety of the medical device, identification of the hazards, and estimation of the risks for each hazardous situation. If it is determined that the risks are unacceptable then risk control measures must be implemented.

Samples of medical devices most likely to be exposed to electromagnetic fields from the MMW AIT-1 were analyzed using this process. Table 9 speaks to the sample devices used in this study and their intended use.

Table 9: Device category and intended use.

Device Category	Number of Devices Tested	Major Category of Intended use
Pacemakers	5	Life supporting
Implantable cardioverter defibrillators	6	Life supporting

(ICDs)		
Neurostimulator	6	Therapeutic
Insulin Pump and Glucose sensor	12	Life supporting

The hazards for pacemakers, ICD and neurostimulators include pulse inhibition, pulse rate change, programming change, and false shock (for ICDs). For insulin pumps, the hazards include failure of insulin delivery, false alarm, and program change. Based on work by Hayes et al. [7] with implantable cardiac pacemakers and ICDs, the hazards were categorized into three different classes based on the severity of harm: clinically significant (Class I), probably clinically significant (Class II), and probably not clinically significant (Class III). The risks of the hazards associated with each device category were estimated based on their probability of occurrence and severity of harm. Because there were no effects observed with exposure to the MMW AIT-1 emissions, the general risks for the sample devices were categorized as very low. This finding applies to the sample medical devices that were tested. Extrapolation of these findings to other medical device types might be misleading.

10. Summary

CDRH performed laboratory testing using several sample PMEDs with the MMW exposure simulator and L3 ProVision (MMW AIT-1), and performed a risk assessment for potential electromagnetic interference (EMI) effects. No effects were observed for any PMEDs exposed to the MMW AIT-1. Based on the work performed it appears the risks for the non-ionizing, millimeter wave and out of band emissions from a MMW AIT-1 to disrupt the function of the selected PMEDs is very low. While the testing and analysis are limited to the relatively small sample size of devices, the device types that were tested comprise a significant portion of PMEDs of historical concern for EMI that are in use today.

Most concerns about EMI that are associated with active medical devices tend to focus on exposure to radio frequency emissions below a few gigahertz (GHz) which are more common in the environment (e.g., broadcast commercial radio and TV, cellular telephones). Generally, medical devices tend to be more susceptible to emissions that contain carrier frequencies or modulations within the band pass of the medical device. For example, a cardiac pacemaker generally senses the cardiac electrical activity between 0.5 Hz up to perhaps several Hz and in some cases sensing capabilities may go to a few kilohertz (kHz) to effectively capture the rhythm of the heart. Other types of devices such as insulin pumps have different characteristics and functions that change the potential susceptibilities.

The work described in this report is applicable only to those devices tested and analyzed for EMC from exposure to the MMW AIT-1. These results should not be applied to other active medical devices or AIT systems.

Human exposures to millimeter wave emissions from the MMW AIT-1 were also evaluated. Taking into considering the short duration of exposure, and the very low

levels of emissions from the MMW AIT-1, the electromagnetic energy levels were determined to be 1000 times less than the limits in the IEEE C95.1 standards and guidelines from International Commission on Non-Ionizing Radiation Protection (ICNIRP).

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12. Appendix A: Exposure Pulse Considerations

The L3ProVision MMW AIT-1utilizes the frequency bandwidth of 5.75 GHz from 24.25 to 30 GHz using a pulsed signal which also incorporates linear frequency sweeping (chirp) technique to acquire a cylindrical image of individuals who pass through security checkpoints. The total system scan time is X^2 seconds. During that time, two vertical antenna arrays rotate partially around the body. Each antenna array consists of X^3 transmit and receive elements that are activated sequentially down the array to capture a vertical image line. Each vertical scan takes 3.1 milliseconds and repeated every X^4cm of the antenna array's traveling the arc length with a total of 362 vertical scan lines. Each individual element transmits for 5.59 microseconds during an 8.08 microsecond pulse period. The timing diagram is shown in Figure A-1.

The estimated exposure time of a 10cm x 10cm area, which for the present analysis is the assumed area of an implantable or wearable medical device, on a person is estimated below to help quantify the EMI risks. If an assumed radius of 64 cm from the center of the MMW AIT-1 to the antenna array and a medical device is located 25 cm from the center of the MMW AIT-1 then we can find the exposure time of a 10 cm arc length. This is illustrated in Figure A-2.

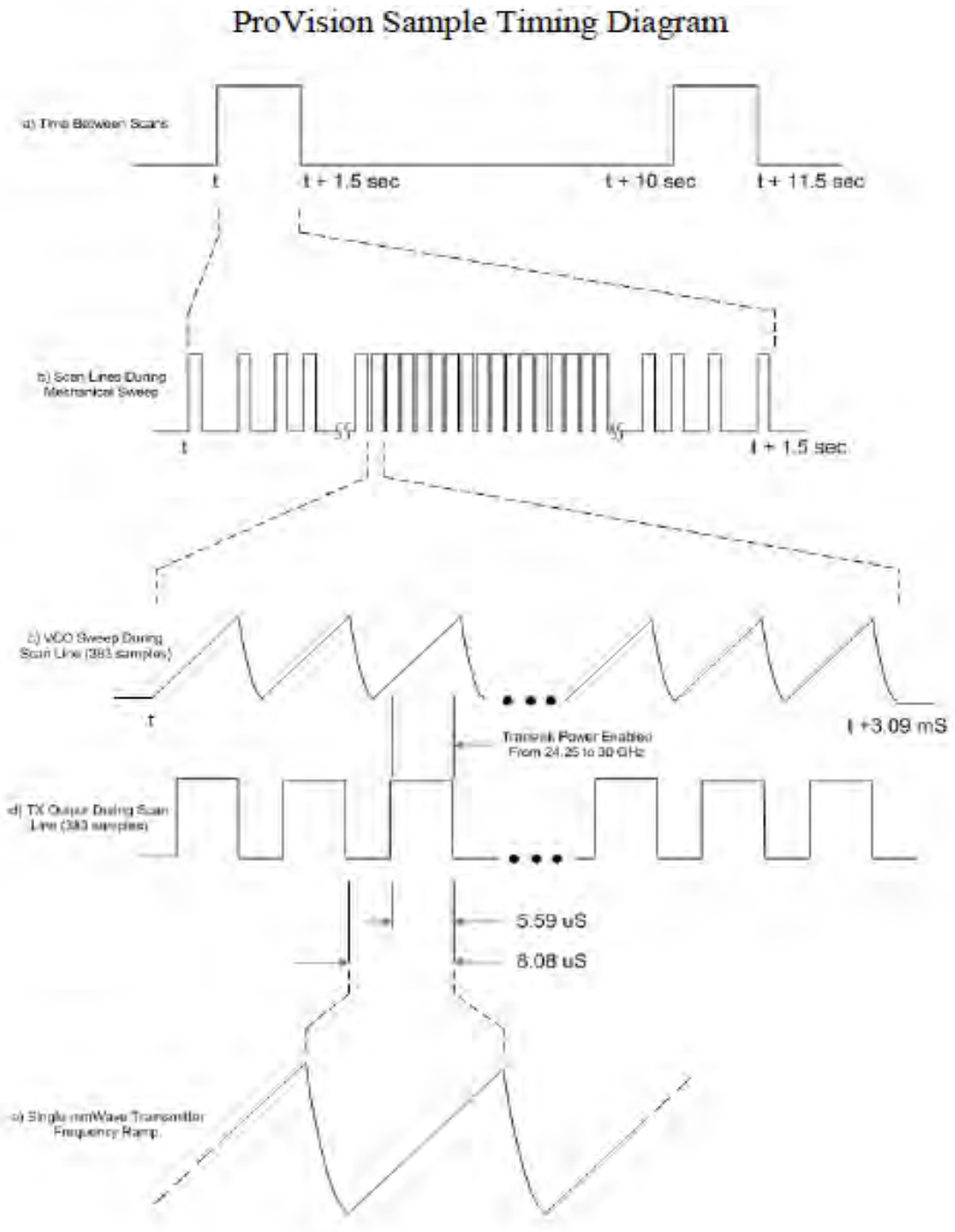


Figure A-1 MMW AIT-1 Timing Diagram.

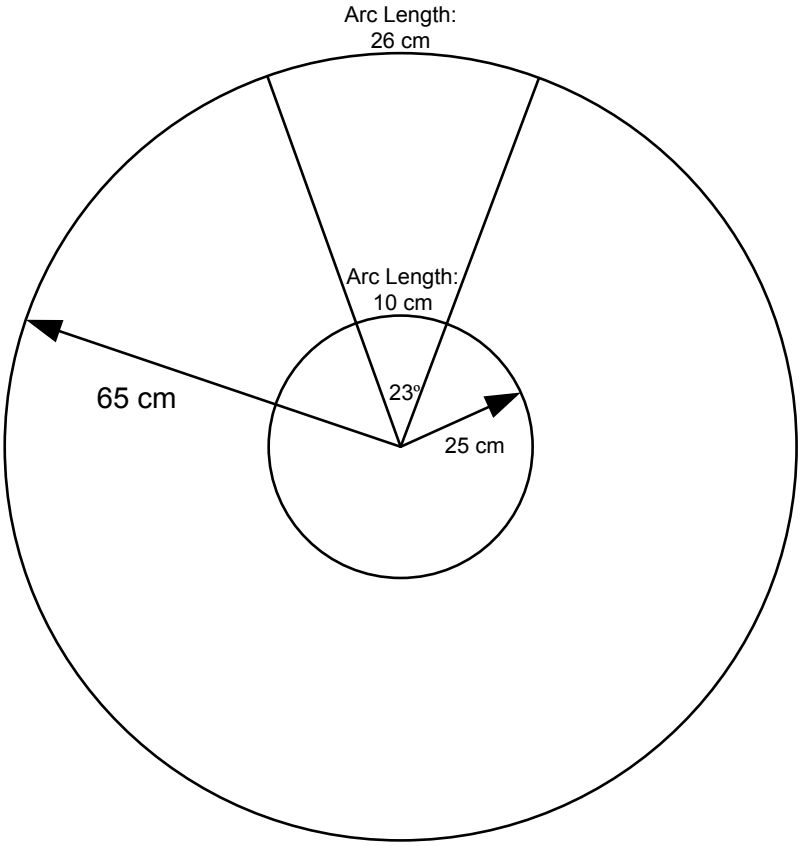


Figure A-2: Horizontal exposure of the AIT-1 scanner for maximum time exposure.

Calculations for the antenna array travel distance of 26 cm with a vertical scan at every X[6] cm yields 52 vertical scans within a horizontal distance of 10 cm on a person's body. Then with an antenna array height of 2 m, with X[7] arrays, there is an element every 1.04 cm, or 10 elements over a 10 cm height. It is then estimated that a 10 cm x 10 cm area is exposed to 520 pulses out of a possible 138,008 pulses from the AIT screening unit.

If one is observing from a single point in the prescribed area, then one would see two different frequency repetitions of the pulse. First a pulse every 8.08 μS, which translates into 123.762 kHz with a 70% duty cycle. In addition, a medical device within the prescribed area also observes a pulse shown in Figure A-3, with a repetition rate of 3.1 mS that translate into 322 Hz with a 20% duty cycle. This 3.1 mS delay is caused as the system scans the X[8] elements in the two antenna arrays. The frequency of 322 Hz is close to the biological frequency of the heart as compared to the 123 kHz and 24.25 to 30 GHz unit carrier frequencies. Depending upon the design of the low pass filter or digital filter at the front end of an active implantable medical device, 322 Hz could be detected by the medical device sensing circuitry. The total direct exposure time of the 100 cm^2

[6] Proprietary value removed.
[7] Proprietary information removed.
[8] Proprietary information removed.

area is 161 mS, which is considered in this case as the worst-case for the longest exposure time.

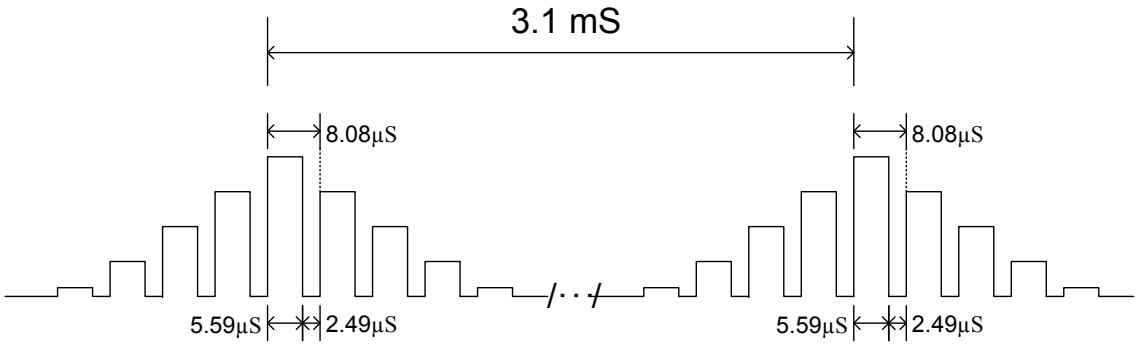


Figure A-3: Perceived exposure at a single point on the human body when exposed to the AIT screening system.

Let us turn our attention to the worst-case scenario in which the medical device is exposed to the maximum power. In this case, if an assumed radius of 65 cm from the center of the unit to the antenna array and a medical device is located 15 cm from the antenna array, then we can find the exposure time of a 10 cm arc length. This is illustrated in Figure A-4. A minimum distance of 5 cm is kept from the antenna array and the individual being scanned at all times by a protective barrier. Then taking into account that a vertical scan is performed every 0.5 cm of the antenna array's trajectory, we find the distance travelled by the antenna array for 23º. In this case assume a 31 cm radius circle and the 65 cm radius of the MMW AIT-1 will have approximately the same arc length for small angles and this simplifies the calculation.

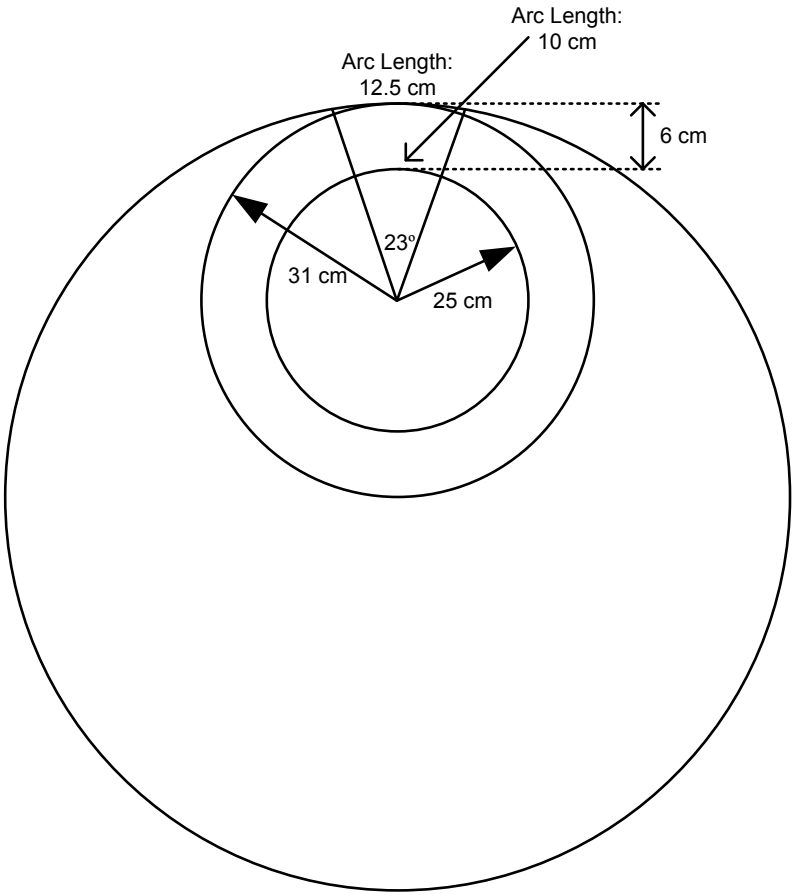


Figure A-4: Horizontal exposure of the AIT-1 unit for maximum power exposure.

A travel distance of 12.5cm with a vertical scan at every X[9] cm yields 25 vertical scans within a horizontal distance of 10cm on a person's body. Again, with an antenna array height of 2 m, with X[10] arrays, there is an element every 1.04 cm or 10 elements over a 10 cm height. It is then estimated that a 10cm x 10cm area is exposed to 250 pulses out of a possible 138,008 pulses from the MMW AIT-1. In this case, the total direct exposure time of the 100cm^2 area is 77.5mS, which is considered the worst-case for the highest exposure power.

[9] Proprietary value removed.
[10] Proprietary information removed.

13. Appendix B: MMW AIT-1 Primary Frequency Band Emission Measurements

13.1 Background of MMW AIT-1 System

Figure B-1 illustrates the two radiating antenna masts that are located inside acrylic shields on opposite sides of the area to be scanned for imaging. When a scan is initiated, the masts are physically rotated in a 120º arc in approximately 1.5 sec. Each mast consists of a vertical array of X[11] radiating elements that are activated (MMW RF turned on) sequentially vertically with one of the X[11] radiating elements fires every 8.08 μsec, a rate of 123.762 kHz. This vertical sequential cycling on and off of one of the X[11] radiating elements continues while the masts are rotating. During each activation of a radiating element the transmit MMW signals are swept rapidly from 24.25 to 30 GHz (a 5.75GHz sweep) in 5.6 μsecs.

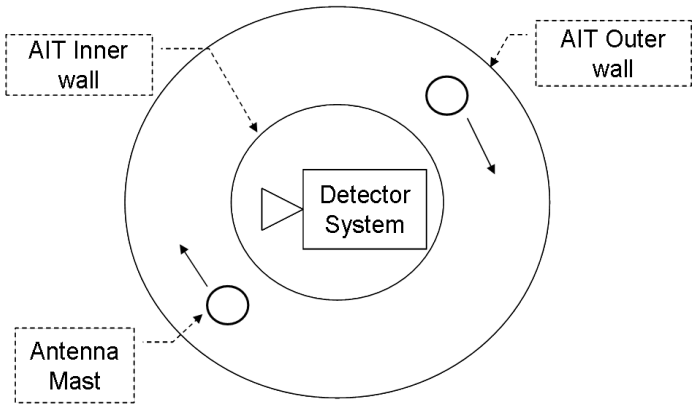
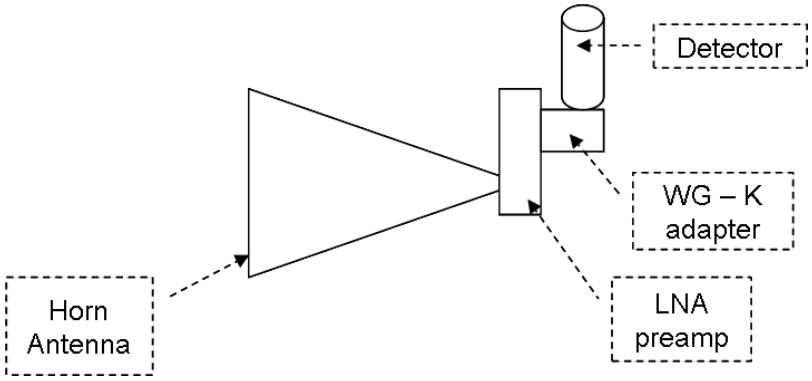


Figure B-1: Top view of scan area with detector system showing direction of the antenna mast movement in one pass.

To detect this burst of MMW emissions, a simple broadband detector shown in Figure B-2 was assembled using the equipment listed in Table B-1.



[11] Proprietary information removed.

Figure B-2: MMW detector system.

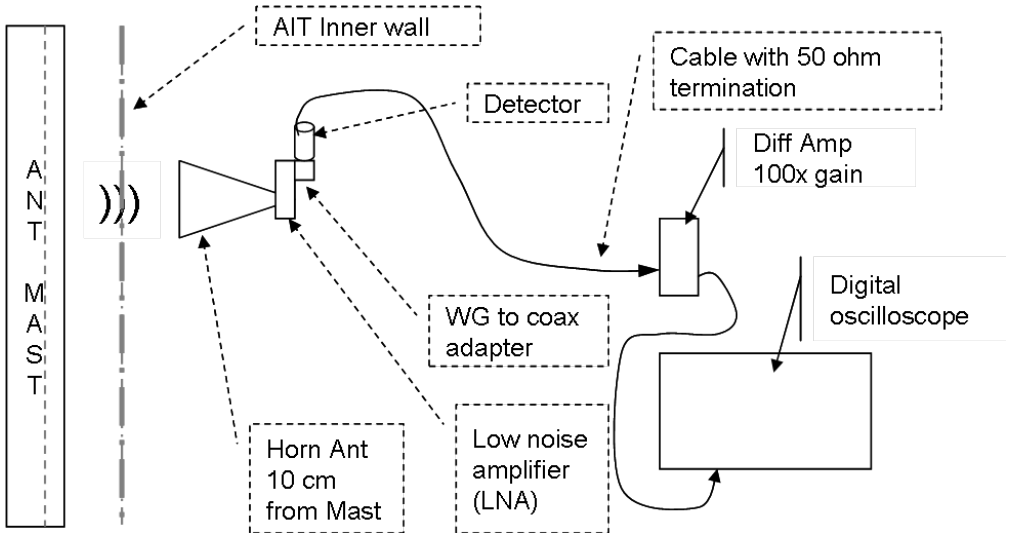


Figure B-3: MMW detector system diagram.

Table B-1: List of components of MMW detector system.

Component	Brand/model#	Purpose	Settings
Pyramid horn antenna (standard horn)	QuinStar QWH-APRS00	Capture radiated signals from masts	Oriented for vertical polarization
Low noise amplifier (LNA)	Spacek Labs SL266-20-3W	Amplify weak signal pickup by antenna	DC voltage power to pins = 12VDC
Waveguide to K connector adapter	Spacek Labs T28-K	Convert signal in waveguide to coaxial transmission	Attached to output of LNA
Schottky zero bias diode detector, 0.01 – 40GHz	Krytar 203BK, sn: 00256	Convert MMW RF power to DC voltage as a function of input power	Attached to K connector of WG-K adapter. BNC => mV output
50 ohm feed through termination	HP 11048C	Provide 50 ohm load to detector for best frequency response for pulsed responses	Mounted at +input of Tektronix AM502
Post detection amplifier	Tektronix AM502 differential amplifier	Amplify the mV output of the detector to levels measureable by an oscilloscope	Gain: 100x HF = 1MHz LF = DC
Digital oscilloscope	LeCroy LT264	Display and store detected pulses in spreadsheet format	Input Z = 1MΩ

WR-28 waveguide was used throughout because it covers the frequency range (lower frequency cutoff is 21.08GHz even though it is listed as 26.5 – 40GHz) and components are readily available from many sources.

The receive antenna (horn) was placed inside the scan area at a distance 10 cm from the AIT inner wall. This was selected as the worst-case distance for estimating personnel exposure. As the emitter order moves vertically along the mast, the receive antenna sees

MMW pulses increasing in amplitude vs. time, reaching a peak, and followed by a decreasing amplitude (Figure B-4, top trace). The maximum amplitude occurred when the radiator that is transmitting is immediately in line with the receiving horn antenna's boresight, and is closest to the horn, as shown in Figure B-5. The detected pulse amplitude at the maximum position in the received signal (Figure B-4, bottom trace) is the amplitude that was used to determine the peak received power and field strength.

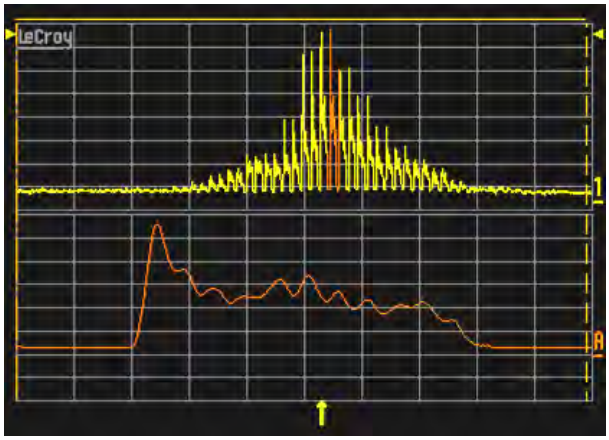


Figure B-4: Detected pulses captured at 60 cm height, 10 cm from AIT inner wall with MMW detector system. The top trace (channel 1, yellow) shows all pulses during a vertical transmit sequence of the transmitting array. The bottom trace (channel A, orange) shows expanded view of the selected pulse (highlighted in channel 1) with maximum amplitude when the individual radiating element that is in line with the receiving antenna's boresight is transmitting.

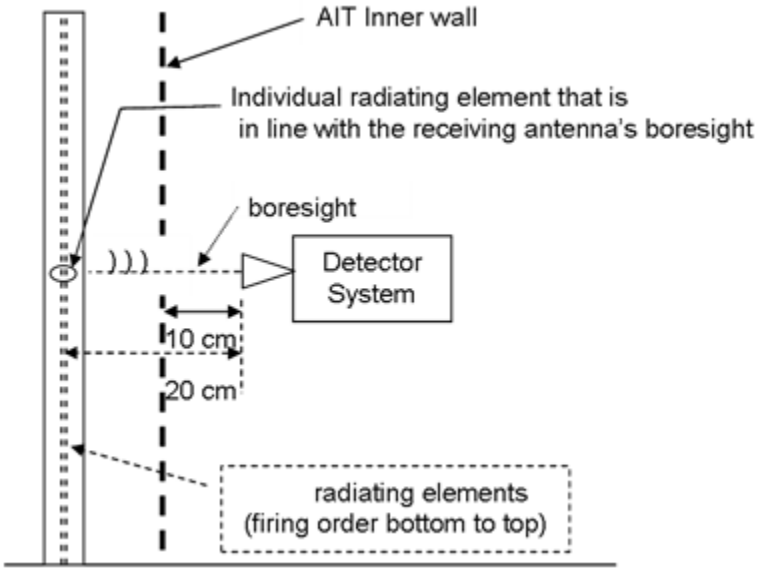


Figure B-5: Position of Detector system antenna relative to radiating elements in the antenna mast.

13.2 Calculations

The basis of calculating the E-field levels is contained in the formulas that relate power density, E-field, near field antenna gain, effective aperture, and received power at the antenna. Starting with the numerical gain G of the antenna, effective aperture A_e of the receive antenna can be derived from:

(B.1) $A_e = G \lambda^2/4\pi$

Where the antenna gain G is calculated [8] from dimensions and wavelength.
Power density P_d is related to effective aperture A_e and power received P_r in Watts from:

(B.2) Power density $P_d = P_r/A_e$

Then from power density, the E-field can be determined from:

(B.3) E-Field = $\sqrt{(120\pi \bullet P_d)}$

The known values are:

- Frequency (wavelength λ)
- Antenna dimensions for calculating near field antenna gain
- Detector factor (mW/mV ratio of power in to mV out) is measured with calibrated coupler, power meters, and a digital multimeter
- Low noise amplifier (LNA) gain: measured with calibrated coupler, and two MMW power sensors (includes output through waveguide to K connector adapter)
- Near field antenna gain G_{near} is calculated from dimensions, wavelength, and distance from the radiating source
- Distance from radiating source
- Effective aperture $A_e = G_{near} \lambda^2/4\pi$ is calculated for each frequency

13.2.1 Near Field Gain of Horn

In order to have sufficient signal to noise ratio to detect the MMW unit's signal, it was determined experimentally that the detector system antenna needed to be around 10 cm from the AIT inner wall. This placed the horn antenna at about 20 cm from the transmit antenna mast and for the frequency range 24.2 – 30GHz, D^2/λ is ≈ 0.8 – 1.0 meters. This means that the measurement is being made in the near field of receiving antenna ($r << D^2/\lambda$). For this reason, far-field antenna gain could not be used without introducing an error. Therefore, near-field gain G_n was calculated from formulas (B.14) and (B.15) in a paper [8] on 'Near Field Gain of a Horn' by Kanda and Orr and used to determine the antenna's effective aperture from formula (B.1) mentioned above $A_e = G_n\lambda^2/4\pi$. At the frequency of maximum emission, 24.565GHz, the far field gain of the horn antenna is

241.63 and the near field gain is 79.4 (numerical). The distance from the radiating elements was estimated to be 10 cm from the mast to the AIT inner wall plus another measured 10 cm from the AIT inner wall to the receive antenna totaling 20 cm from radiators inside the mast to the receive horn antenna. This distance was used for calculations of near field gain of the receiving antenna.

The distance from the antennas inside the mast and the AIT inner wall could not be measured because they are enclosed between two acrylic shields and the mast is also enclosed inside a cylindrical tube making it impossible to visualize where the emitters physically are. The best estimate was that the distance is about 10 cm. This is a source of uncertainty in the measurements and calculations since the distance was used to calculate the near field gain which was used to ultimately calculate the received power density. The distance uncertainty is estimated to be ±1 cm leading to an uncertainty of ±0.17 dB. At the frequency of maximum emission used above, the near field gain at 19 cm was 76.15 and 82.45 at 21 cm.

Another source of uncertainty was the detected amplitude at different heights within the AIT screening unit. It was noted during measurements that slight variations of the angle of the horn antenna as it was aligned perpendicular to the vertical mast resulted in noticeable differences in peak amplitude detected. No data was recorded until the angle was adjusted for maximum amplitude. This large variation may be due to a narrow beam-width of the radiating elements on the masts. However, the characteristics of these elements were not known at the time of this study. We also have not ruled out the possibility that there is a variance of emission levels at different heights along the masts. This could account for variation in detected amplitude when the receive antenna boresight is focused on a different radiating element than one at a perpendicular from it as is illustrated in Figure B-5. Also, the near field beam-width of the horn antenna might be narrow enough to exhibit sharp roll-off with small angular changes.

13.2.2 Calibration

Calibration was performed separately on the coupler, the low noise amplifier (LNA), and the detector, using a computer controlled signal generator, a frequency doubler, variable waveguide attenuator, power meter, digital oscilloscope, post detection amplifier, and digital multimeter.

The coupler was calibrated by automatically stepping the frequency of a MMW source from 24.1 GHz to 30 GHz in 0.1 GHz steps while measuring power at the forward coupling port and at the output of the coupler with a calibrated power meter, Agilent 4419B. The results were stored in a table in the controlling computer along with the difference that represented the coupling factor as a function of frequency. This table was then used to provide data lookup table to establish the power out of the MMW signal source delivered to the LNA, during calibration of the LNA vs. frequency. Using the coupler data, a program written in MatLab stepped through the frequencies in the coupler calibration table while measuring power out of the LNA to provide a table of gain vs. frequency.

The data captured by the detector system's digital oscilloscope generates a much larger array of data points due to the required sampling rate for digitizing the MMW pulses. The greater number of points made it necessary to interpolate the gain vs. frequency table of the LNA to match the points acquired by the detection system. To accomplish this, a curve fitting function in Matlab was applied to the LNA gain table to generate a 4th degree polynomial (see Figure B-6). This was used in calculations to approximate the LNA gain at any frequency. The maximum gain uncertainty (measured vs. polynomial) using this method was < 1.4 dB.

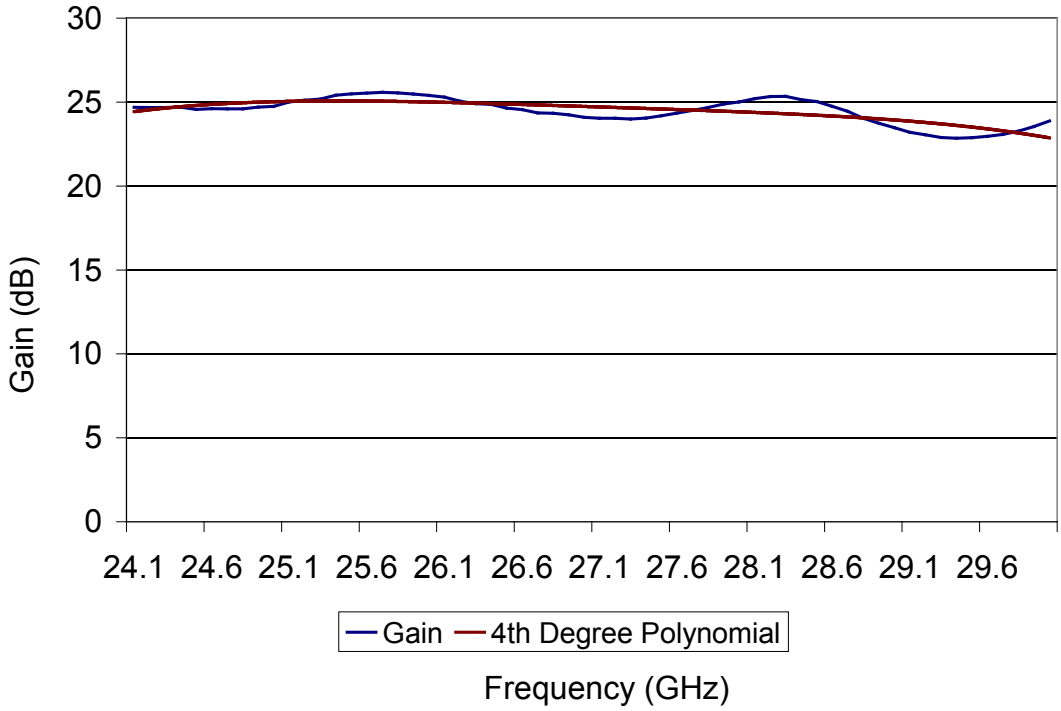


Figure B-6: LNA measured gain and 4th degree polynomial vs. frequency.

13.2.3 Detector Factor

Earlier the term 'detector factor' was introduced as the ratio of power (in mW) at the input of the detector to the voltage out of the detector amplifier (in mV). This was measured by adjusting the power at the input of the detector that would produce 100 mV output through the 100x differential amplifier (see Figure B-3) at frequencies from 24.1 to 30 GHz in 0.1 GHz increments, and recording that power level in dBm. A 100mV detector output was selected because it was in the amplitude range of most of the detected pulses from the unit at the distance of 10 cm from the AIT inner wall (20 cm from the radiators on the mast). The power to the detector was then converted to mW and the ratio mW/mV was calculated at each frequency to be the detector factor (DF). The detector and post detection 100x amplifier were treated as a unit at all times to minimize confusion whether measuring pulses or DC.

(B.4) $DF = mW_{in}/mV_{out}$

Detector factor is analogous to the antenna factor defined for EMC antennas used in measuring E-field. For the Krytar 203BK detector, the measured detector factor values for 60 frequency data points from 24.1 – 30 GHz were statistically:

- Mean: 5.7742E-4 mW/mV (0.00057742 mW/mV)
- Standard deviation: 5.74229E-06 or 0.00000574229
- Range (minimum to maximum): 0.000553 to 0.000586 mW/mV

Because of the narrow range of values measured, the mean value of 0.00057742 mW/mV was used as the detector factor for s/n: 00256 at all frequencies.

13.3 Testing

13.3.1 Measuring the MMW Field

The detection system illustrated in Figures B-2 and B-3 was positioned with the aperture of the horn antenna 10 cm from the AIT inner wall resulting in a distance of approximately 20 cm between the receiving horn antenna and the antennas within a mast. The horn antenna was facing the mid-point of travel of a mast antenna and at specified heights above the floor. The detection system was mounted on Styrofoam blocks in order to minimize reflections of the MMW signals. The LNA was powered through a shielded coax cable with BNC to clip lead adapters at the end to connect to the VDC pins. The output of the detector was connected through another shielded coax cable to a 50 ohm feed-through adapter to a differential amplifier. The output of the differential amplifier connected to an input of the digital oscilloscope (Figure B-3) set for 1MΩ input impedance.

When a scan was initiated, the oscilloscope was triggered on a burst of pulses resulting from a vertical sequential cycling ON & OFF of radiating elements in the mast. Figure B-4 shows a typical oscilloscope display of a burst of pulses. The zoom trace (bottom trace A) selected the maximum amplitude pulse from the burst using a sweep time of 1 μsec/div for best detail of the 5.6 μsec pulse from a single MMW sweep. The image and traces were saved in a test computer to provide data for the analysis that follows.

13.3.2 Analysis of Detected Pulse

The zoomed pulse waveform was opened in a spreadsheet to display two columns of data: time and voltage from the oscilloscope trace recording of a detected pulse. The graph in Figure B-7 is the detected pulse with the x axis for time and the y axis for voltage from the digital oscilloscope. Where the voltage increased above the noise floor at the leading edge was the beginning of the MMW RF sweep at about 24.2GHz. And where the detected voltage decreases to the noise floor (about 5.5 – 5.6 μsec later) is the end of the MMW sweep or 30GHz. Using these start and stop frequencies, a column was created in the spreadsheet for frequency in GHz to fill in incremental frequencies for each data point in the detected pulse. This converts the time domain graph in Figure B-7 to a frequency domain graph in Figure B-8 as graphed in the spreadsheet. The data now is analyzed as amplitude vs. frequency.

This process has a degree of uncertainty that has not been fully analyzed at the time of this report. To accurately match points in time captured by the oscilloscope to a specific frequency of a sweeping signal that has a delta from start to stop frequency of 5.75GHz in 5.6µS is not an easy task. It assumes linearity of the sweep and accurate measurement of start and stop frequencies.

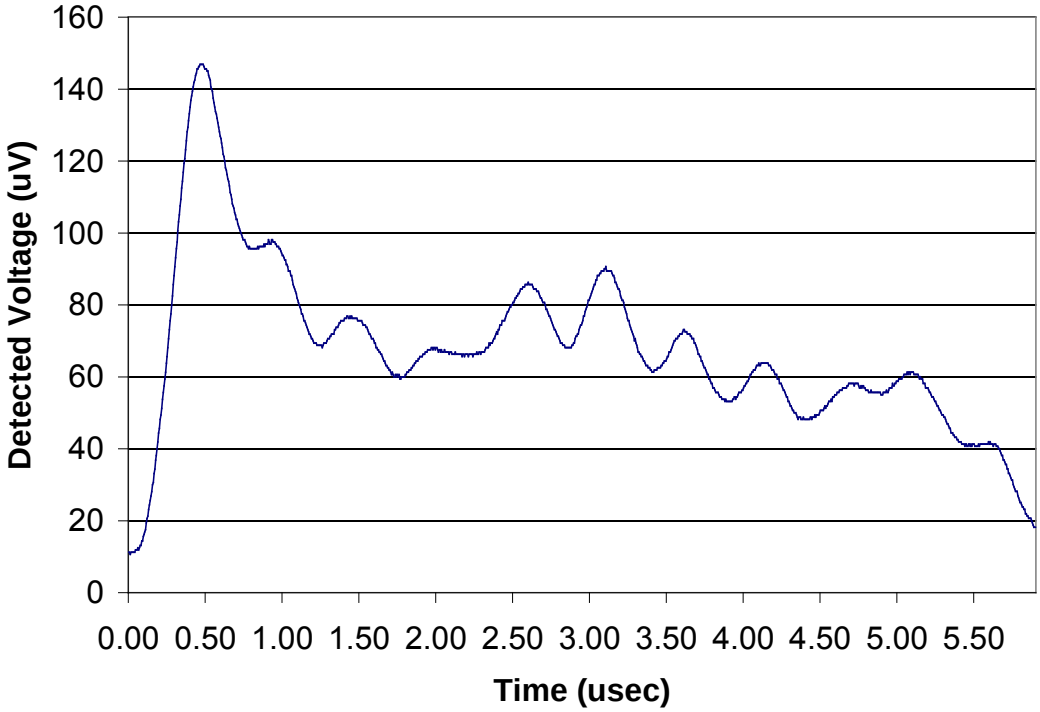


Figure B-7: Detected voltage vs. time from digital oscilloscope at 60 cm height and10 cm from AIT inner wall (Peak detected level at this location = 146.9 mV).

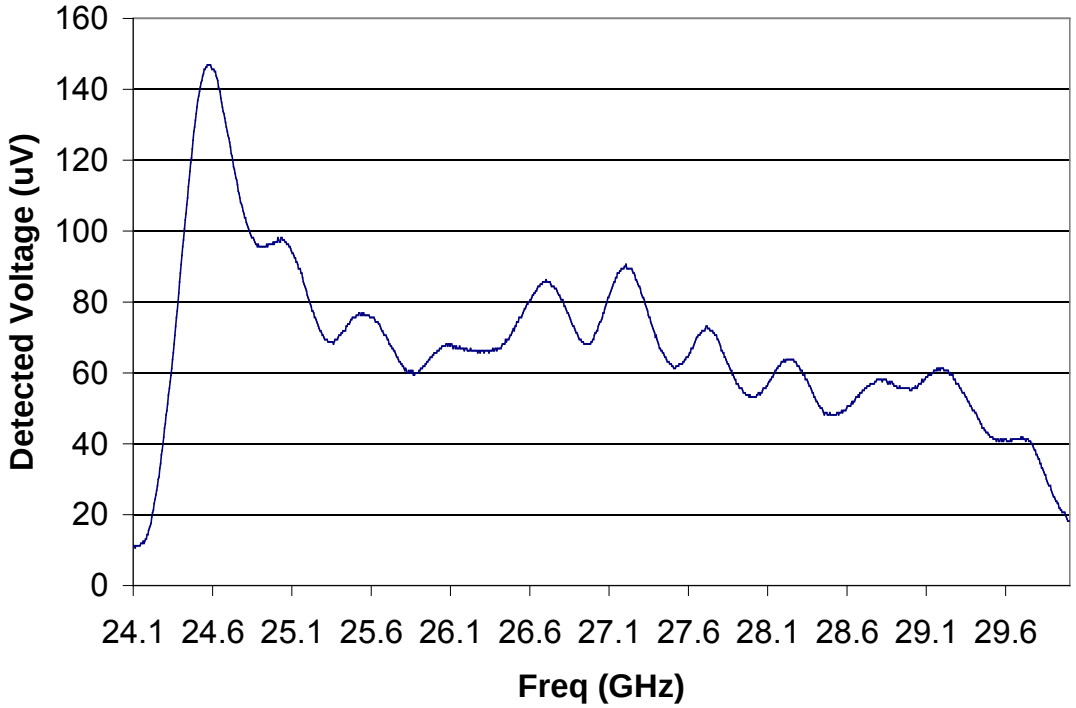


Figure B-8: Detected voltage vs. frequency in GHz from digital oscilloscope at 60 cm height and10 cm from AIT inner wall. Time converted to frequency in GHz. Peak detected level 146.9 mV occurred at 24.5GHz.

Using the modified spreadsheet containing detected voltage vs. frequency (data from Figure B-8) from the digital oscilloscope, the detector factor (DF) equation (B.4) discussed earlier can now be used to calculate detected power (DP) using the following formula:

(B.6) DP = DVA x DF, Detector voltage out x Detector factor = Power detected, mW

Power detected in mW is then converted to dBm in order to subtract the LNA gain to calculate power received $P_{r\text{-}dbm}$ by the antenna in dBm.

(B.7) P_{dbm} = 10Log (mW)

(B.8) $P_{r\text{-}dbm} = P_{dbm}$ – LNA gain, Power received in dBm, by the antenna

The power received in Watts, P_r is calculated from

(B.9) $10^{(Pr\text{-}dBm/10)}$ /1000.

From formulas discussed earlier (B.1), (B.2) and (B.3), we have a relationship between frequency (from wavelength λ), near field gain of the receiving horn antenna G_n discussed in detail in [8], power received P_r watts (B.9), and power density P_d W/m^2.

Solving for effective aperture:

(B.10) $A_e = G_n\lambda^2/4\pi = P_r/P_d$

For power density yields:

(B.11) $P_d = 4\pi P_r/ G_n\lambda^2$ in W/m^2

And from power density P_d, E-field level in V/m can be determined from

(B.12) $E = \sqrt{(120\pi \bullet P_d)}$ in V/m

By calculating these parameters for every frequency data point in the amplitude vs. frequency spreadsheet using frequency dependent calculations where appropriate, the original pulse from the detector, trace A in Figure B-4, and Figure B-7 and B-8 yield power density vs. frequency in Figure B-9 and E-field vs. frequency in Figure B-10.

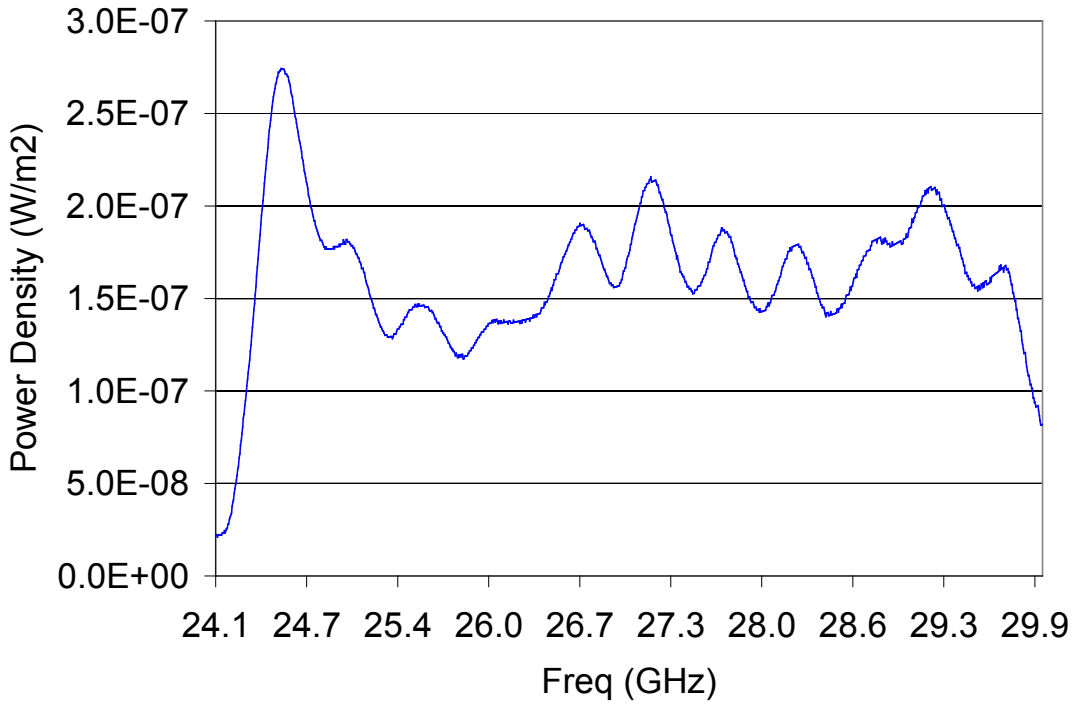


Figure B-9: Calculated power density in W/m^2 vs. swept frequency at 60 cm height and 10 cm from AIT inner wall.

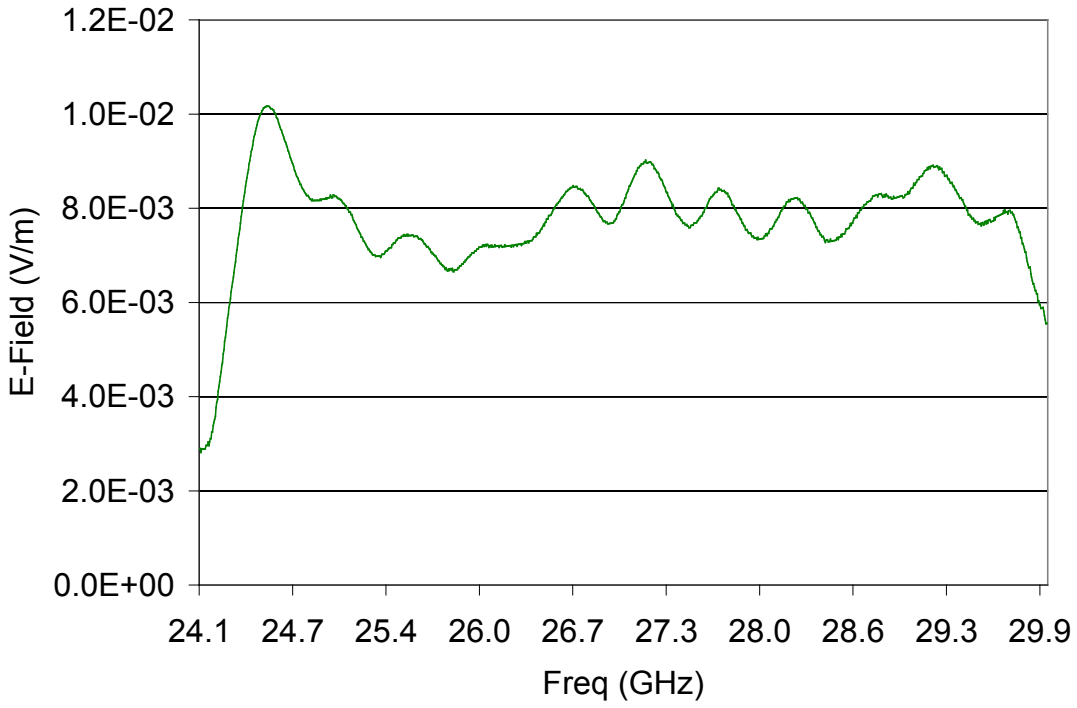


Figure B-10: Calculated E-Field V/m vs. Swept Frequency at 60 cm height and 10 cm from AIT-1 inner wall.

13.3.3 Peak Value Calculation

Table B-2 illustrates a calculation of power density and E-field at only one data point representing the worst-case pulse amplitude detected at 60 cm height. These same calculations were performed at every data point and graphed in Figures B-9 and B-10.

Table B-2: Sample calculations of Power density and E-field.

Explanation	Worst-case at 24.565GHz (based on near field gain calculated at 10 cm)
Multiply the detected level from oscilloscope data by the detector factor to achieve power in mW at the input of the detector: Detected mV x $^{mW}/_{mV}$ = mW at the detector.	0.146875 mV (detected mV) X 0.000578 $^{mW}/_{mV}$ (detector factor) 8.48312E-05 mW (power at detector, mW)
Convert mW at the detector to dBm: 10Log (mW)	-40.7144 dBm (power at detector, dBm)
Subtract LNA gain from detector input power in dBm to yield received power from the horn antenna in dBm. (LNA gain is derived from the 4th degree polynomial computed in Matlab from measured data).	-25.16 dB LNA gain -65.876 dBm (received power from Horn, dBm)
Convert the received power in dBm to Watts P_r = $10^{(dBm/10)}$ /1000 Watts	2.5847E-10 Watts (received power from Horn, Watts)

Explanation	Worst-case at 24.565GHz (based on near field gain calculated at 10 cm)
Calculate effective aperture $A_e = G_n\lambda^2/4\pi = P_r/P_d$ (near field gain at 10 cm, 24.565GHz)	33.116 x $(0.01221^2)/4\pi$ 0.000943 m^2
Calculate power density P_d by dividing power received P_r by effective aperture A_e $P_d = P_r/A_e$ W/m^2	2.5847E-10 W / 0.000943 m^2 **2.742E-07 W/m^2**
Calculate-E-field level (E) by taking the square root of (120π x P_d), E = $\sqrt{(120\pi \bullet P_d)}$ V/m	$\sqrt{(120\pi \bullet 2.742E-07)}$ **0.0101 V/m**

14. Appendix C: MMW AIT-1 Lower Frequency Band Emission Measurements

Radiated spurious emissions from the MMW AIT-1 were measured from 5Hz – 6GHz. These emissions are generally emitted by the electrical and electronics components of a product and are expected to meet applicable regulatory requirements such as Federal Communication Commission (FCC) Part 15 for emissions. While the MMW AIT-1 appears to have undergone thorough testing for these types of emissions and passed, the potential for some of the emitted fields to affect medical devices in and around the AIT unit was examined via measurements and comparisons to applicable medical device EMC standards.

Table C-1 lists the instruments and equipment used in making the lower frequency radiated emissions from the MMW AIT-1. The emissions measurements were made at locations 3, 4, and 5 around the AIT-1 as shown in figure C-1. These locations were chosen to represent where a medical device user might be located.

Table C-1: Test equipment for lower frequency radiated emissions.

Instrument make and model number	EM Field Type	Frequency Range
Narda SRM-3000 (with isotropic antenna p/n 3501)	Electric Field	50MHz – 3 GHz
ETS-Lindgren HI-6105 Probe	Electric Field	100kHz – 6 GHz
Wandel and Goltermann EFA-2 EM Field Analyzer	Magnetic Field	5Hz – 30kHz
61 mm diameter - 3 loop Antenna (designed and calibrated in-house)*	Magnetic Field	10kHz – 30MHz
HI-3637 very low frequency (VLF) probe	Magnetic Field	2kHz – 400 kHz
Com-Power AL-130 Loop**	Magnetic Field	9kHz - 30MHz

* This instrument was used in testing at positions 1 and 2 shown in figure C-1.
**This instrument was used in testing at positions 3, 4 and 5 shown in figure C-1

Prior to these AIT-1 measurements, baseline environmental measurements were made with the AIT-1 system and UPS turned off. The emission levels from baseline measurements were used to compare the E-field strengths of AIT-1 emission with other electromagnetic sources in the immediate environment of the AIT-1. The baseline measurements were necessary because the AIT-1 system was not located in an anechoic chamber. Emissions measurements were performed with the AIT-1 system with the MMW emitters active and moving through the same operation cycle used in the PMED testing.

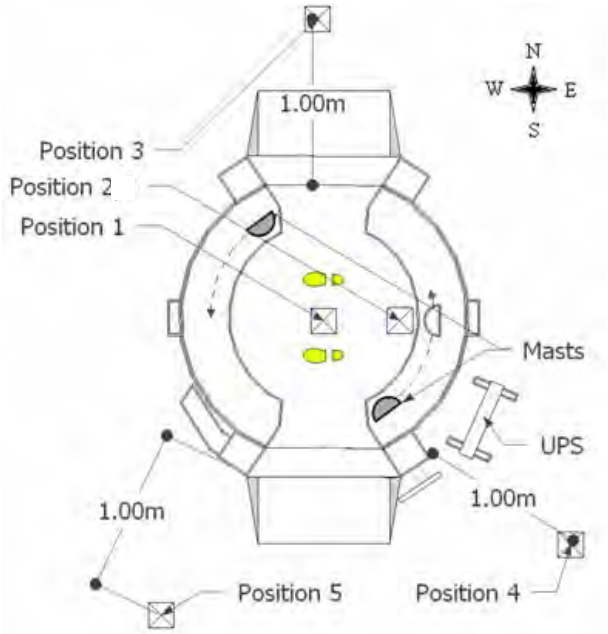


Figure C-1: The lower frequency spurious radiated emission measurement locations.

Tables C-2 and C-3 below report the highest emission field strength levels measured from the AIT-1 system at the frequency range given. These measurements may not reflect the highest level emitted by the AIT-1 because of temporal changes to the emissions. In general, most non-implantable active medical devices are tested for immunity to field strengths of 3 V/m or more depending upon the essential function of the device [3]. Implantable PMEDs can be tested to even higher levels. Non-implantable PMED immunity testing is typically done at power line frequencies with 3 A/m field strength in present standards. Present standards for implantable PMEDs check immunity to magnetic fields generally below 450 MHz at various field strengths up to 150 A/m. These measurements indicate the tested MMW AIT-1 does not seem to emit very large spurious electric or magnetic fields.

Table C-2: Peak Electric Field measurements.

Frequency Range	Position	Peak AIT-1 E-Field Strength (V/m)
100 kHz – 6 GHz*	1	0.861
	2	0.826
	3	0.831
	4	0.827
	5	0.845
50 MHz – 1.5 GHz	1	0.0151
	2	0.0045
	3	0.0423
	4	0.0148

Frequency Range	Position	Peak AIT-1 E-Field Strength (V/m)
	5	0.0204
1.5 GHz – 3 GHz	1	0.0254
	2	0.0278
	3	0.031
	4	0.0344
	5	0.0273

*The peak E-field measurements in this frequency range were with in 0.6 dB of the peak ambient measurement. The measurement was limited by the sensitivity of the probe.

Table C-3: Peak Magnetic Field measurements.

Frequency Range	Position	Peak AIT-1 H-Field Strength (A/m)
5 Hz – 30 kHz*	1	0.0021
	2	0.0020
	3	0.0022
	4	0.0022
	5	0.0021
2 kHz – 400 kHz*	1	0.0032
	2	0.0032
	3	0.0032
	4	0.0032
	5	0.0032
300 kHz - 30MHz*	1	0.00464
	2	0.00488
9 kHz - 30 MHz	3	3.60E-06
	4	4.05E-06
	5	3.90E-05

*The peak H-field measurements in this frequency range were within 0.35 dB of the peak ambient measurement at these locations. The measurement was limited by the sensitivity of the probe.

15. Appendix D: Torso Simulator

Engineers in the CDRH EMC-Wireless laboratory designed torso simulators (phantoms) for EMC testing of active, implantable medical devices such as pacemakers and neurostimulators in conjunction with the MMW AIT-1 units operating at 24 to 30 GHz. Because of the much higher frequencies used in this AIT system an analysis was performed of the exposure energy deposition for the standardized saline based torso simulator that uses 0.18% salt water (saline) that was developed for work at much lower frequencies. This torso simulator approach is specified in the ANSI/AAMI PC69:2007: active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators [4] presently used for EMC testing of these types of medical device. The basis of the analysis in this case was computational modeling using SEMCAD-X finite difference time domain (FDTD) software. We compared the MMW attenuating properties of saline with those of skin, fat, and muscle. This indicated how much MMW electric field strength (E-field) would exist at the top surface of a medical device implanted under 5 mm of saline that is typical for implantations of these type devices. The electric field strength was also computed at the surface of an implant under a combination of 2 mm skin [9] and 5 mm fat [10], while the implant was above a layer of muscle 12.5 mm deep (Figure D-1). The dimensions for all models of phantoms were chosen to correspond to nominal values for human anatomy, and to provide sufficient attenuation to ensure minimal reflections from the sides and bottom. The goal of this work was to develop a torso simulator that would not under-estimate the worst-case E-field (and the potential EMI) induced by a MMW unit compared to the real-world situation. This real world (clinical) situation involves a medical device implanted under the skin and fat, and above the muscle of a patient.

Results of modeling at all the MMW frequencies used in AIT-1 show a large under-estimation of the E-field at the device surface (closest to the MMW unit antenna) exists for submersion under 5 mm of saline (table D-1) as specified in the EMC standard [4]. This under-estimation is relative to implantation under human skin and fat.

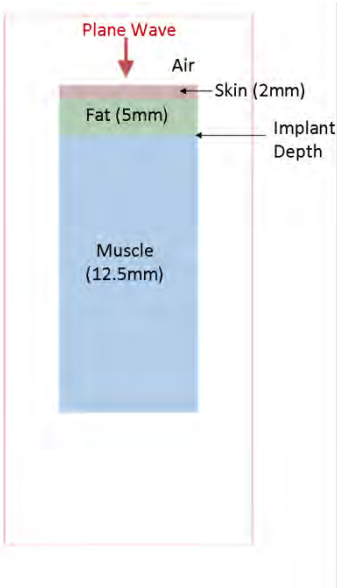


Figure D-1: Torso simulator irradiated with the MMW AIT-1 simulation system.

Using the above information we developed a worst-case torso simulator for testing implanted devices. The simulator features exposure of the device's electronics in air and placement of the device's sensing and stimulation leads in saline to provide signal paths required for proper operation of the devices (Figure D-2 and D-3). Commercially available MMW absorbing material is placed between the device and saline to minimize reflection from the surface of the saline. This provides worst-case (maximum) E-fields to the device. The alternative of placing the implanted device less than 5 mm below the saline surface was evaluated as impractical due to steep fall-off of the E-field in the first few millimeters of saline depth. Also the use of saline of less than 5 mm was evaluated as impractical due to variations in saline depth from mechanical tolerances of the device-support structure and due to saline evaporation during testing.

Table D-1. E-field at the implantable device's surface in human tissues versus submersion in 5 mm saline.

Frequency (GHz)	Ratio of E-field
30	11.48
27	6.9
24	5.19
13	1.30
6	0.86

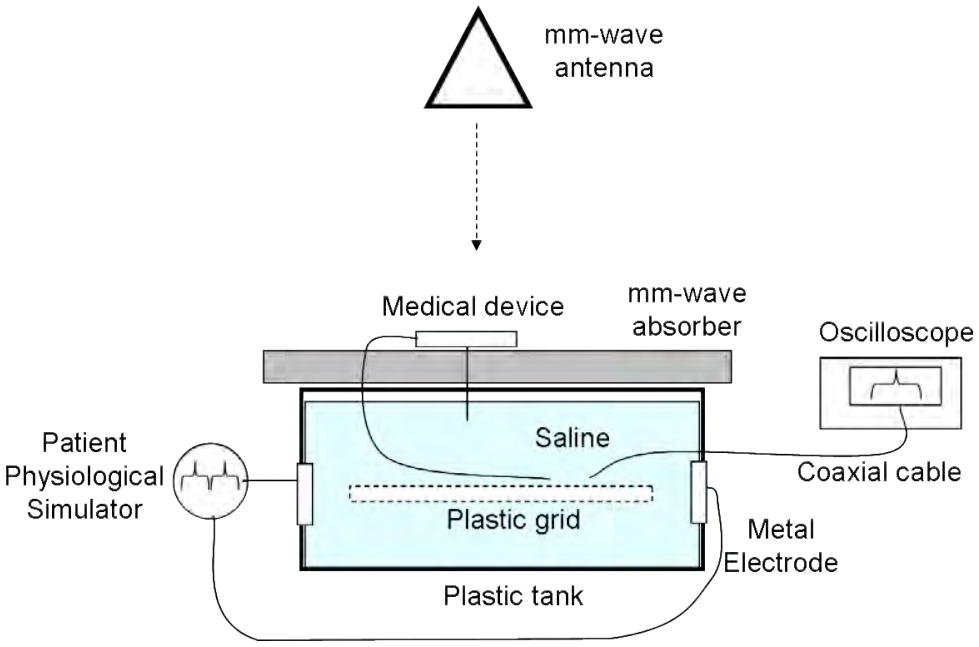


Figure D-2: Horizontal torso simulator irradiated with the MMW AIT-1 simulation system.

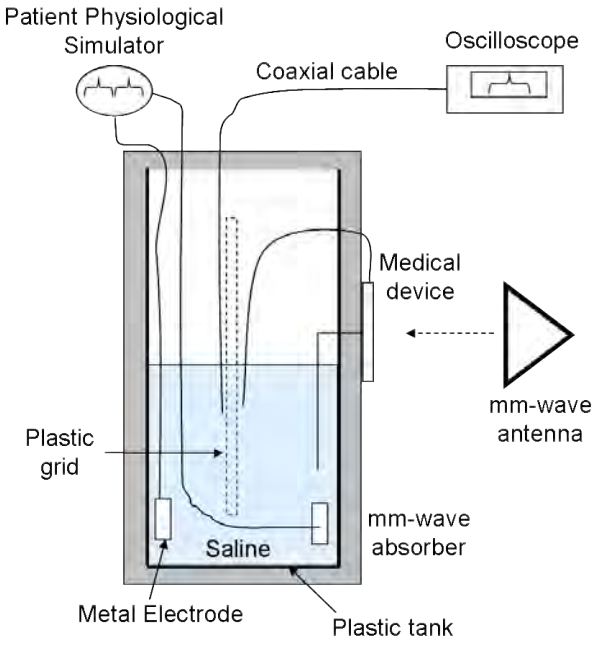


Figure D-3: Vertical torso simulator irradiated with the MMW AIT-1 system.

16. Appendix E: MMW AIT Simulator

16.1 Overview of MMW AIT Simulation System

The millimeter wave simulator shown in Figure E-1 consists of a Hewlett Packard signal generator 8673B that produces a fundamental signal from 13.25 – 15 GHz. This signal is connected to a Spacek Labs frequency multiplier which outputs a signal twice the frequency of the fundamental, 26.5 – 30GHz. The output of the frequency multiplier then feeds through a Hughes (45721H) mechanical waveguide attenuator to manually adjust the output power when prompted by the simulator control program. Amplitude modulation and control are accomplished using a Millitech voltage controlled attenuator (VCA) which is driven by an arbitrary function generator (Hewlett Packard 33120A providing a pulsed output of the MMW RF to the antenna. Between the VCA and the frequency multiplier is a Millitech isolator to protect the frequency multiplier from reflected power produced by the VCA. The RF then passes through a Hughes (45321H-2110) dual port waveguide directional coupler to provide ports to measure the forward and reflected power. The output of the directional coupler is connected through a series of curved and straight waveguide sections to a Quinstar (MN:QWH-APRS00) standard gain horn to transmit the output signal onto a test surface above a torso simulator where the device under test (DUT) is placed. The distance from the horn antenna should be no less than 0.70 meter distance above the device being tested to stay in the far field. Height adjustments could be made by adjusting the height of the torso simulator tank and by raising or lowering the simulator hardware. The distance should be verified before testing each device because transmit power is calculated based on distance. The output signal is from 26.5 – 30 GHz, simulating the frequencies of an AIT-1 unit.

16.2 E.2 Test Frequencies Used

Waveguide that operate in the frequency range 24 – 30GHz are either: WR-42 (18 – 26.5GHz), WR-34 (22 – 33GHz), or WR-28 (26.5 – 40GHz). Waveguide sizes WR-42 and WR-28 are most common and readily available from manufacturers and from test equipment sources. Waveguide components with WR-34 specifications are not usually in stock nor are commonly used in general purpose equipment such as power sensors or attenuators. And since the low frequency cutoff for WR-28 is 21.08GHz, and components were readily available, it was chosen as the standard waveguide size for the simulator.

In addition, when the simulator was being developed, only power sensors with WR-28 (26.5 – 40GHz) waveguide input were available to the CDRH lab at the time. And since they are not calibrated below 26.5GHz, device testing with the simulator during this initial version was done in the frequency range: 26.5 – 30GHz in order to maintain calibrated power levels.

The millimeter wave simulator is connected according to Figure E-1. The equipment is listed in Table E-1 along with the item numbers corresponding to Figure E-1.

16.3 Monitoring PMED Performance

When a device is being exposed to the simulated MMW signal, pulses from implantable devices and body worn devices such as insulin pumps are recorded with a Measurement Computing A/D module for a time before, during, and after RF exposure. The pulses are used as an indication of the device's normal function by observing consistency of parameters such as: pulse rate, amplitude, width, shape, and loss of pulses. An open ended waveguide (OEWG) probe beside the device under test is curved upward to pick up the E-field exposure during radiation of the device. A typical field distribution is shown in Figure E-2. The OEWG was connected to the Spacek Labs low noise amplifier (LNA) which was connected to a Millitech waveguide envelope detector. The output of the waveguide envelope detector was terminated into 50Ω, amplified, and coupled to a digital oscilloscope and a channel of the Measurement Computing A/D module. This provided a detected pulse from the RF to trigger the A/D module to start recording the device activity, and as an indication of the presence of pulsed MMW signal. If any device responded to the MMW simulator's exposure, it would be used to correlate device activity with MMW exposure.

Table E-1. List of equipment and modules required to simulate millimeter wave emissions.

Item Number	Item	Function	Settings
1	Hp8673B Synthesized signal generator	Fundamental signal source	Freq: one half the desired test frequency
2	Florida RF labs Conformable RF cable SMS-BJ141-20.0-SMS, 741	Connect output of signal generator to input of frequency multiplier	
3	Spacek Labs Frequency multiplier module Model: A276-2X-23, SN: 0D15	Output a frequency 2 times the input signal	Powered by: 12VDC
4	Hughes 45721H-2200, SN: 094	Waveguide attenuator	Typically 10 – 15db
5	Millitech isolator FBI-28-SSESO	Protect frequency multiplier from reflected power	n/a
6	Voltage controlled attenuator (0-30dB) Millitech VCA-28-SIFSO	Voltage controlled amplitude (VCA) modulation of RF output	Powered by ±12VDC to pins, SMA input connected to Arbitrary function generator
7	Hughes 45321H-2110 directional coupler, SN: 022	Coupling ports to measure forward and reflected power	Power sensors attached to ports: forward power port nearest output
8	Millitech Load/ termination WTR-28-S0000	Attached to reflected port of Hughes 45321H-2110 directional coupler	n/a
9	Agilent R8486A 26.5 – 40GHz Power sensors	Measure forward and reflected power	Ch A Forward power Ch B Received Power OEWG
10	Agilent E4419B dual power meter	Digital display of forward and reflected power	Dual channel, dBm settings

11	Hp33120A Arbitrary function generator	Provide pulsed or amplitude modulation to VCA	Freq: 123.762kHz, Square wave Amplitude: 2Vrms, offset: 1V,Duty cycle: 30% Freq: 322Hz Square wave Duty cycle: 80%
12	Standard gain horn antenna: Quinstar MN:QWH-APRS00	To radiate RF energy field to device under test.	Attached to extended waveguide section from output of coupler
13	Open ended waveguide (OEWG) L shaped probe	Calibrated field pickup probe for measuring received power in test area	Input – no flange, Output – UG-599/U flange, L shaped
14	Low Noise Amplifier (LNA) Spacek Labs Model: SL266-20-3W SN: 0D16	Amplifies signals from OEWG probe for measurement with power sensor	Powered by +12VDC, 100mA
15	Waveguide Coupler, PRD A414	Couples power received to side port (-10dB) for power sensor and through port to detector	Connected to output of LNA
16	Millitech DET-28-SPFWO Waveguide detector	Converts MMW RF to DC as a function of amplitude	Connected to output of LNA
17	EG&G Instruments 5113 Pre-amp	Amplifies envelope detector output for display on oscilloscope and recording with A/D module	Connected to output of envelope detector through 50 ohm feedthru termination. Output to scope and A/D module
18	Measurement Computing A/D converter Model 1608FS	Records pulses from device under test and pulses from detected RF	Triggers on the detected RF pulse from the OEWG probe
19	LeCroy LT-264 digital oscilloscope	Monitors pulses from device under test and detected pulses from RF picked up by OEWG probe	
20	Data Acquisition Computer:	Records the output of the DUT and monitoring system	
21	Control computer: IBM ThinkPad T-41	Runs MatLab code to control instruments for running tests.	Connected to instruments using NI USB-GPIB-HS adapter by GPIB cables
22	USB to GPIB converter	Connect the control computer to the test instruments via GPIB	

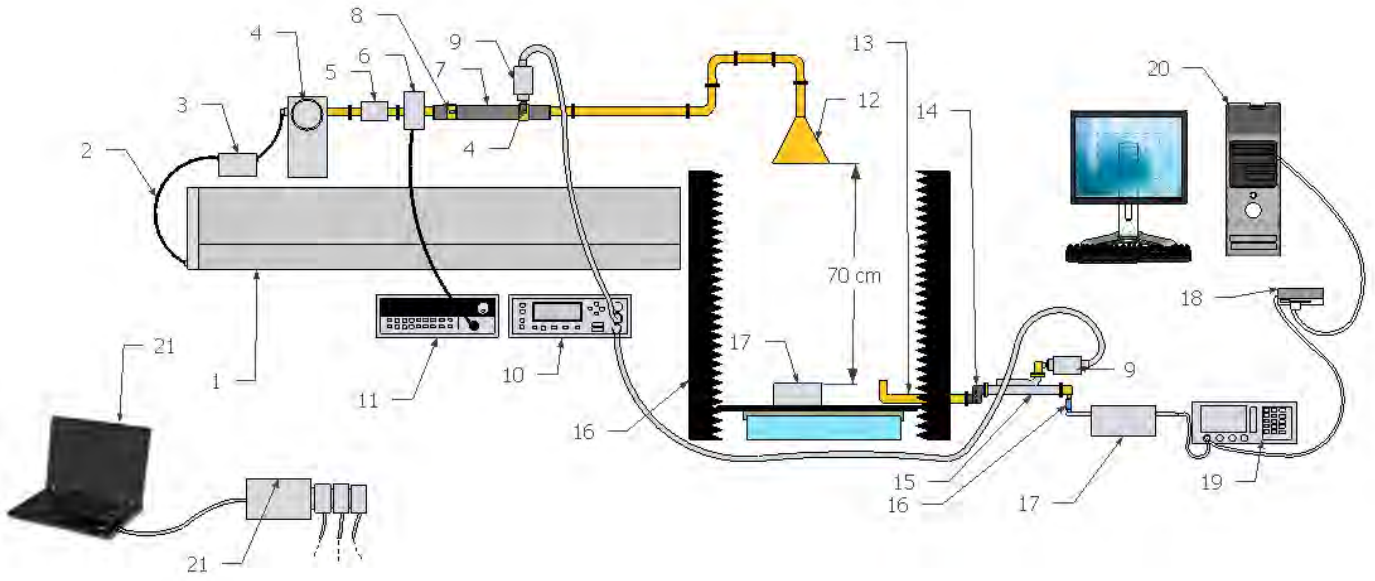


Figure E-1: Millimeter Wave Simulator.

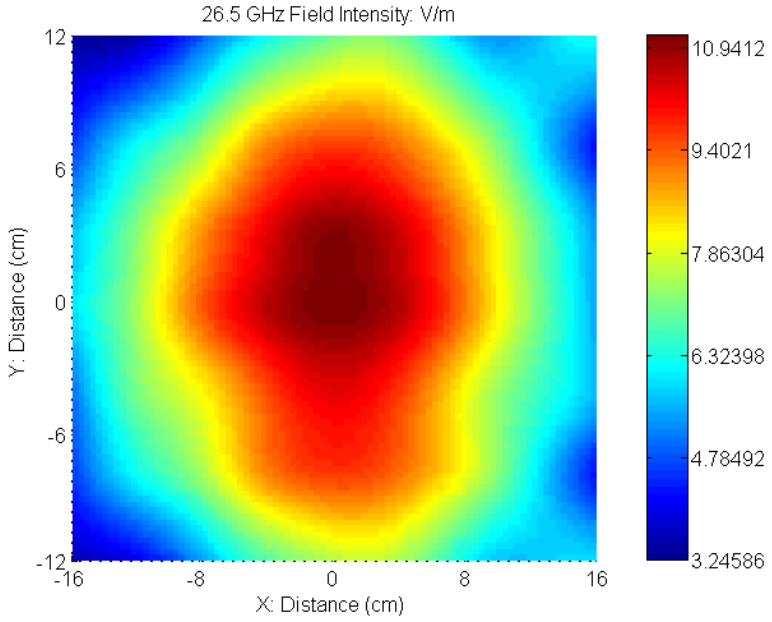


Figure E-2: Beam Pattern for Millimeter Wave Simulator.

16.4 Calculation of MMW RF levels and Calibration

The objective of the simulator was to expose devices with constant field strength over the frequency range 26.5 – 30GHz in 5 frequency steps with modulation resembling the actual AIT-1 unit. The basis of calculations of the power to generate a known field level is from the formulas:

(E.1) Power transmitted (Watts) $P_t = \frac{4\pi \bullet P_d \bullet R^2}{G_t}$

Where R is distance between the device and the transmit antenna in meters and G_t is the numerical antenna gain of the transmitting horn antenna.

(E.2) Power density (Watts/meter^2) $P_d = \frac{E^2}{120\pi}$

Where E-field level $E = \frac{V}{m}$ volts/meter

The E-field test level was derived from a report of measured emissions at one frequency by EMC International services [letter dated June 26, 2005]. This letter stated that the measured radiated emissions were 4.83 x 10^{-2} volts/meter at a distance of 2.5 meters from the AIT-1 unit. Without any more detail at the time, we estimated that the worst-case E-field level at a few cm's from the inside acrylic shield of the MMW AIT-1 unit could be as much as 12.1 V/m or 0.39 W/m^2. (Note that after performing independent measurements CDRH determined that the field strength levels that PMEDs would be exposed to are much lower and thus the 12.1 V/m is a high worst-case exposure). This level was used during the simulator testing where each device under test was placed above a layer of MMW absorbing material (absorber), in air, to expose devices to the worst-case level of MMW E-fields. At lower radiofrequencies, implanted medical devices are tested under a 5 mm depth of saline. For the present study we exposed devices in air instead of under saline. This was done because implantable devices such as pacemakers are placed in patients under the skin and fat layers, but above muscle. At frequencies emitted by the MMW AIT-1, the absorption of the E field by a few millimeters of saline is very large. Saline is much more absorbing than the fat and muscle tissues that lie above an implanted device like a pacemaker. Therefore, use of saline as a simulant for body tissues overlying an implanted medical device is inappropriate at the MMW frequencies and could lead to erroneous finding of a lack of interference by the MMW AIT-1. To more closely model the absorption of skin and fat that lie over a medical implant we developed an open air exposure system. This offered a consistent, worst-case E-field exposure level that could be used across all devices and alleviated the need to create a new experimental testing model with simulated skin and fat layers representative of various patients. In addition some devices we tested are worn outside the body (insulin pumps, etc.) and would receive direct RF exposure without the

attenuation of skin, fat, or muscle. Our open air model works well for this application. A detailed explanation about the torso simulator can be found in Appendix D.

To accurately set the transmit power, the output of the directional coupler was measured at each frequency step to create a calibrated lookup table for measuring power transmitted at the antenna vs. power at the forward coupling port at each frequency. The antenna gain G_t was calculated for each frequency using standard methods published in literature.

(E.3) $$G = \frac{4\pi A}{\lambda^2} e_A$$

Where:

- G is the gain of the horn antenna transmitting the MMW RF,
- A is the physical area of the aperture,
- λ is the wavelength,
- e_A is the effective aperture or aperture efficiency,

The desired E-field level and distance R were entered by the operator, then the simulator control software calculated power density (P_d) from equation (E.2) at distance R for each frequency step, then calculated the transmit power (P_t) from equation (E.1) required at the antenna to produce that power density and field level using the gain of the horn antenna (G_t) from equation (E.3) since antenna gain is a function of wavelength (frequency). Losses in coupling to the antenna, the nonlinear characteristics of the frequency multiplier, and the transmit power varied with frequency, requiring the operator to manually adjust the power through the coupler at each frequency change using the mechanical waveguide attenuator listed in Table E-1 and shown in Figure E-1. The control software displayed the required transmit power.

16.5 Modulation of Exposure E-fields

The principal radio frequency interaction in implanted cardiac devices is from EMI coupled onto pacing leads or the header. The most interference occurs due to RF modulation that is demodulated inside the device.

If the modulation frequencies are similar to the pulsating cardiac signal sensed by a cardiac device, then the potential for misinterpretation by the device is likely. RF modulation frequencies that simulate physiological signal characteristics were included in the test protocol to represent this worst-case scenario by using a rate and pulse width that lies within the band pass of an implantable pulse generator. To simulate the modulation that occurs from the AIT-1 screening unit the RF is pulsed ON for 5.59μS and OFF for 2.49μS, representing a 123.762 kHz rate with a 70% duty cycle. As the Masts rotate through the arc of a scan, full vertical scans are repeated at a 322 Hz rate. This modulation frequency was also included in the protocol. All devices were exposed to 123.762 kHz and 322 Hz pulse modulation that simulated the AIT-1.

Other modulation frequencies that were used consisted of normal heart rhythm 1Hz (60 beats per minute), 3Hz (180 beats per minute) representing a potential arrhythmic heart beat that needed shock therapy, and transmit frequencies of the programmers for each implantable device: 1.1KHz, 76.8KHz, 100KHz and 178KHz. Additional 200Hz modulation frequency was used for neurostimulator testing as recommended by ANSI 14708-3:2008 [5]. Modulation of the RF was achieved using waveforms from the arbitrary function generator driving the voltage controlled attenuator (VCA) in Figure E-1. The duty cycle was adjustable to produce RF ON times similar to that of the actual MMW AIT-1.

16.6 Test Sequence

During testing, the software selected each frequency from a look up table, performed the calculations discussed in Calculations of MMW RF levels and Calibration section (E.4) above and prompted the operator to adjust the mechanical waveguide attenuator for the desired transmit power while monitoring the power with the power meter. The software then applied modulation, sequencing through up to six modulation frequencies, to perform exposure tests on the devices before stepping to the next frequency in the table. At each new test frequency in the lookup table, new power calculations were performed, and the operator was prompted again to adjust the power to the level calculated in the software. Table E-2 contains a list of the test frequencies along with typical levels of power meter settings for the E-field level used during these tests.

Table E-2. Test frequency table with typical forward power levels for desired field level, power density, and distance.

Hp8673B Frequency	Output Frequency	Ch A on power meter	Field level	Power density	Distance
13.25 GHz	26.5 GHz	0.65 dBm	12.057 V/m	0.387 W/m^2	0.70 meters
13.5 GHz	27.0 GHz	0.51 dBm	12.057 V/m	0.387 W/m^2	0.70 meters
14.0 GHz	28.0 GHz	0.67 dBm	12.057 V/m	0.387 W/m^2	0.70 meters
14.5 GHz	29.0 GHz	0.21 dBm	12.057 V/m	0.387 W/m^2	0.70 meters
15.0 GHz	30.0 GHz	-0.41 dBm	12.057 V/m	0.387 W/m^2	0.70 meters

During exposure to the MMW signal, pulses from each device were monitored and recorded with a digital oscilloscope and an A/D converter to capture any anomalies that could be the result of MMW exposure. Tests were repeated with a 90º rotation of the device relative to the antenna to expose the device and its leads to both vertical and horizontal polarization as it is standard procedure in most EMC testing.

17. Appendix F: MMW AIT-1 Test Location

PMEDS were tested at locations in and around the MMW AIT-1 near the unit radiating antennas and other out of band sources of electromagnetic energy. The primary consideration in choosing these locations was the places around the system where people would be located. The table below describes the locations used to perform PMED testing and emissions measurements as shown in Figure F-1. Position 6 is the same location as position 2 with the exception that the AIT-1 emitters are in a special stationary mode where the antenna masts are emitting MMW energy from a fixed mid-point position instead of being in motion as occurs during the security scanning process. This was done to investigate a potential worst-case exposure situation.

Location	Description
Position 1	At the center of the scanner
Position 2	10 cm away from AIT-1 unit mast
Position 3	1 meter away from the north side of unit
Position 4	1 meter away from the southeast corner of the unit (in between touch screen and UPS)
Position 5	1 meter away from the southwest corner of the unit (from the stepper motor module)
Position 6	10 cm away from unit mast but with unit in stationary mode

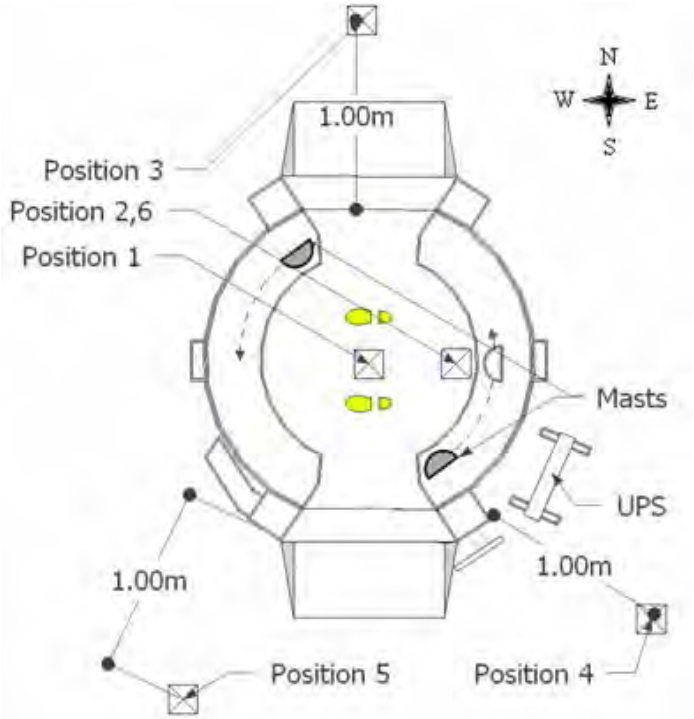


Figure F-1: The test positions in and around the AIT-1 unit.

Based on the human anthropomorphic data found in ISO/TR 7250-2 : Basic human body measurements for technological design [11] for shoulder and waist heights, implantable

devices were tested at two different heights above the floor (1m and 1.4m), and insulin pumps were tested at three different heights above the floor: 0.25m, 1m and 1.4m, as shown in Figure F-2. The additional height for insulin pump devices was recommended by a PMED manufacturer as a typical placement area for insulin pumps.

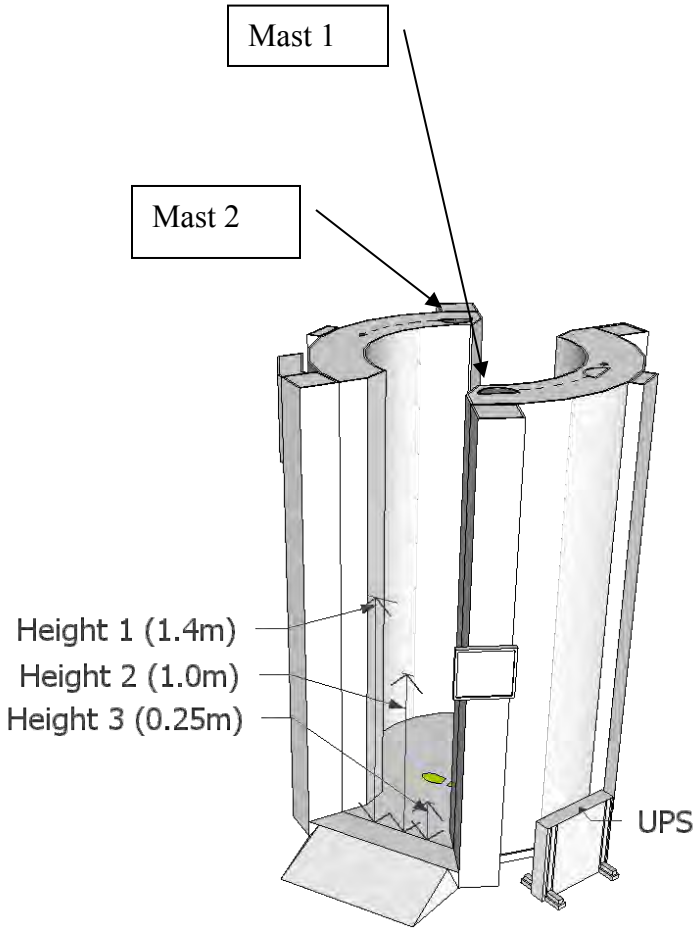


Figure F-2: The three heights tested for each position.

18. Appendix G: Procedures for Medical Devices with AIT-1

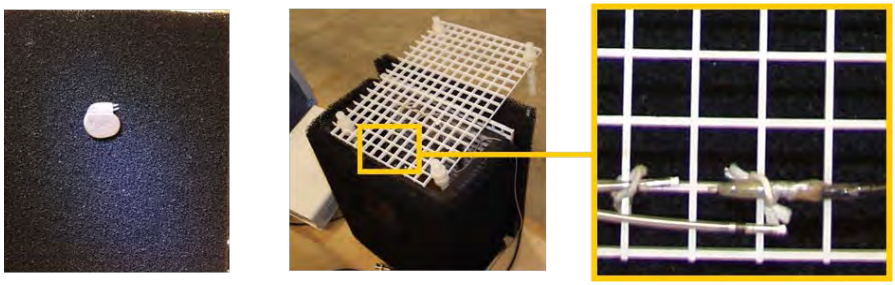
18.1 G.1 Procedure for Testing Implantable Cardiac Pacemakers for Exposure In/Near MMW AIT-1

Prepare AIT-1

1. Power and log ON to AIT-1.
2. Calibrate the AIT-1 system.

Setup Monitoring System

3. Mount the device under test (DUT) on the torso simulator and connect the monitoring or pacing leads as shown in the Figure below.



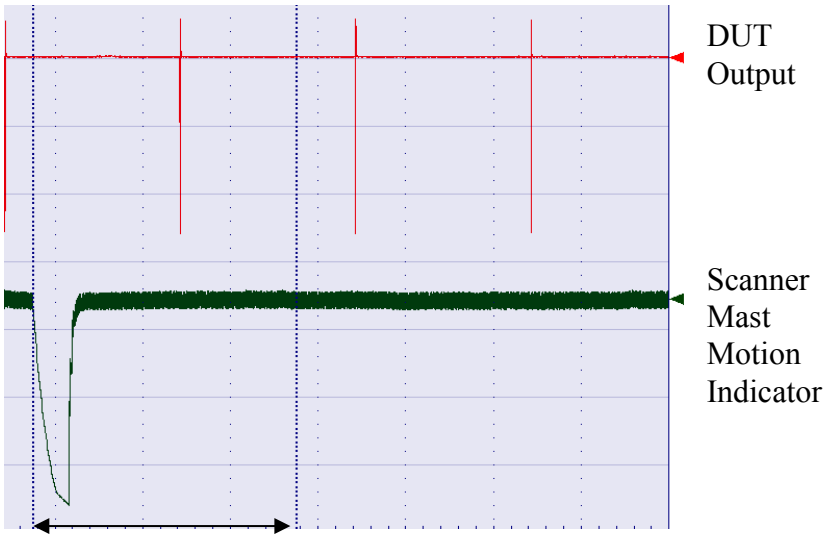
4. Connect DUT monitoring cable leading out of the torso simulator to a digital oscilloscope.
5. Connect DUT monitoring cable (with a BNC-T) to A/D converter and linked with the control PC.
6. Place the photo detection system in place and connect the output to the A/D converter for measurement trigger.
7. Set up the measurement acquisition software to trigger on the pulse from the photo detection system when the mast begins to swing at the start of a scan.

Conduct DUT Measurements

8. Check torso simulator and cables on the oscilloscope to verify minimum noise from the exposure.
9. Program DUT according to device setting in appendix H.
10. Start external cardiac signal generator and connect to torso simulator using a shielded cable and prepared lead. Determine the minimum a voltage level need to be applied to inhibit pacing. Double the minimum voltage level to find the voltage level need to be applied for injected simulated heart signal test. Once determined, turn the cardiac injected signal off.
11. To verify DUT operation, place DUT/torso simulator at a distance of at least 2 meters from the AIT-1 unit, run a baseline test recording pulses from the device.
12. Set up the torso simulator inside the AIT-1 unit facing east at position 1 and a height of 1.4 meter from the floor (see appendix F). DUT monitoring and cardiac signal injection cables are fed in and out of the AIT-1 unit through a hallow fiber

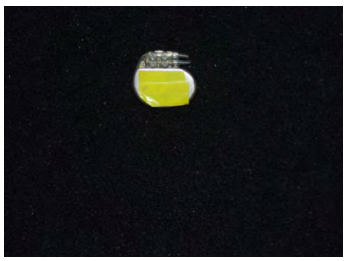
glass tubing oriented parallel to the floor (perpendicular to the radiated electric field and wrapped with a millimeter wave absorber).

13. Record the DUT's orientation, operating mode and settings.
14. Set trigger of data acquisition on oscilloscope and software to the output of the photo detector system setup by the mast of AIT-1 unit.
15. Prepare security system for a scan.
16. Start scan and capture DUT's output signal during exposure. Figure below is an example of DUT's output.

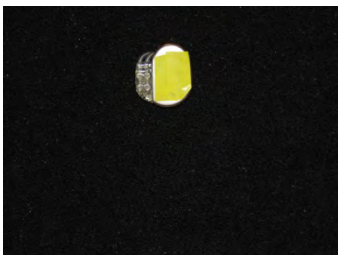


Duration of one scan (1.5 sec)

17. Repeat steps 15 and 16 five (5) times, recording any effects or spurious data over 30 seconds period.
18. Repeat steps 13-17 with cardiac injected signal on.
19. Rotate the DUT by 90 degrees to a new orientation as shown in the Figure below and repeat steps 13 - 18.



a) DUT Orientation: Horizontal



b) DUT Orientation: Vertical

20. Change operating mode to a new setting and repeat steps 13 – 19.
21. Change location of the torso simulator to a height of 1 meter from the floor as shown on Figure F-2 of appendix F and repeat steps 13 – 20.
22. Change location of the torso simulator to a new position on the location table shown in appendix F and repeat steps 13 – 21.

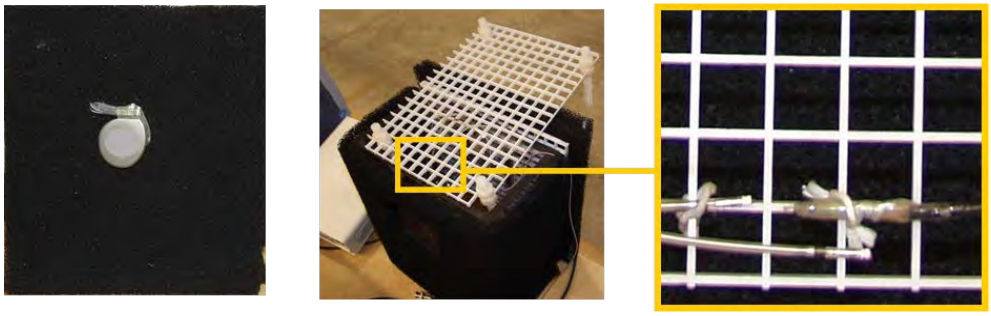
18.2 G.2 Procedure for Testing ICDs for Exposure In/Near Security Screening System

Prepare Security Screening Unit

1. Power and log ON to AIT-1 unit.
2. Calibrate the security system.

Setup Monitoring System

3. Mount the device under test (DUT) on the torso simulator and connect the monitoring or pacing leads as shown in the Figure below.

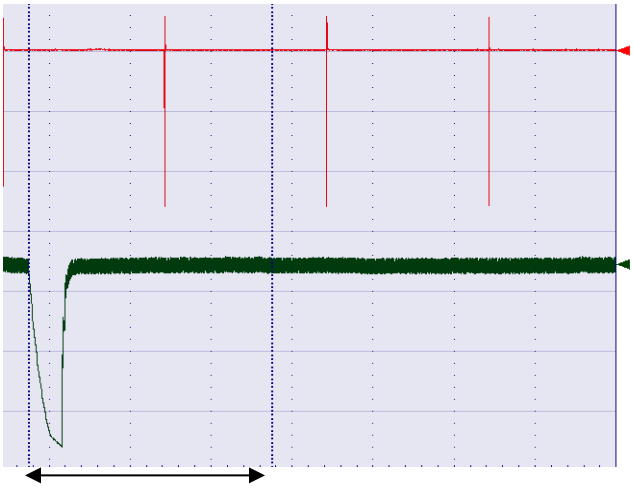


4. Connect DUT monitoring cable leading out of the torso simulator to a digital oscilloscope.
5. Connect DUT monitoring cable (with a BNC-T) to A/D converter and linked with the control PC.
6. Place the photo detection system in place and connect the output to the A/D converter for measurement trigger.
7. Set up the measurement acquisition software to trigger on the pulse from the photo detection system when the mast begins to swing at the start of a scan.

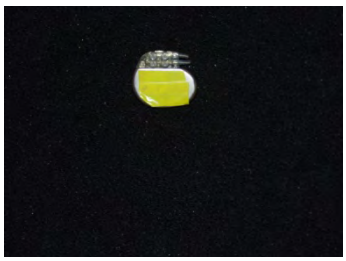
Conduct DUT Measurements

8. Check torso simulator and cables on the oscilloscope to verify minimum noise from the exposure.
9. Program DUT according to device setting in appendix H.
10. Start external cardiac signal generator and connect to torso simulator using a shielded cable and prepared lead. Determine the minimum a voltage level need to be applied to inhibit pacing. Double the minimum voltage level to find the voltage level need to be applied for injected simulated heart signal test. Once determined, turn the cardiac injected signal off.
11. To verify DUT operation, place DUT/torso simulator at a distance of at least 2 meters from the AIT-1 unit, run a baseline test recording pulses from the device.
12. Set up the torso simulator inside the AIT-1 unit facing east at position 1 and a height of 1.4 meter from the floor (see appendix F). DUT monitoring and cardiac signal injection cables are fed in and out of the AIT-1 unit through a hallow fiber glass tubing oriented parallel to the floor (perpendicular to the radiated electric field and wrapped with a millimeter wave absorber).
13. Record the DUT's orientation, operating mode and settings.

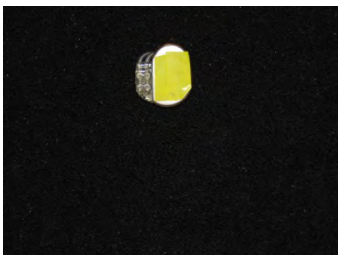
14. Set trigger of data acquisition on oscilloscope and software to the output of the photo detector system setup by the mast of AIT-1 unit.
15. Prepare security system for a scan.
16. Start scan and capture DUT output signal during exposure. Figure below is an example of DUT's output.



17. Repeat steps 15 and 16 five (5) times, recording any effects or spurious data over 30 seconds period.
18. Repeat steps 13-17 with cardiac injected signal on.
19. Rotate the DUT by 90 degrees to a new orientation as shown in the Figure below and repeat steps 13 - 18.



a) DUT Orientation: Horizontal



b) DUT Orientation: Vertical

20. Change operating mode to a new setting and repeat steps 13 – 19.
21. Change location of the torso simulator to a height of 1 meter from the floor as shown on Figure F-2 of appendix F and repeat steps 13 – 20.
22. Change location of the torso simulator to a new position on the location table shown in appendix F and repeat steps 13 – 21.

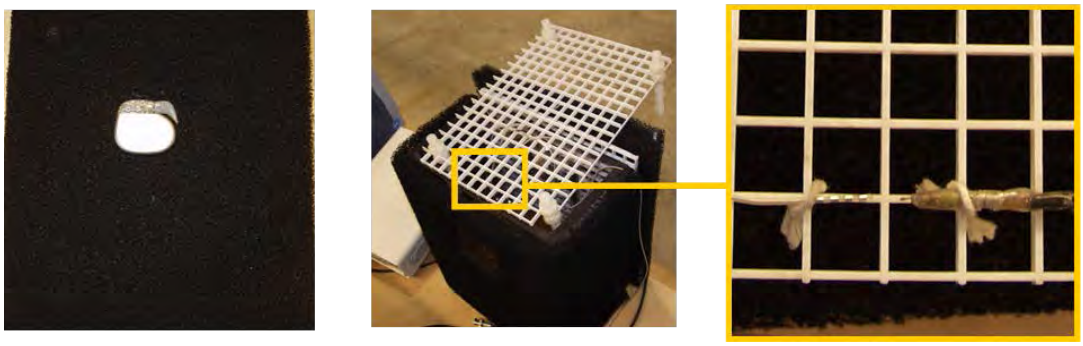
18.3 G.3 Procedure for Testing Neurostimulators for Exposure In/Near screening unit

Prepare Security Screening Unit

1. Power and log ON to AIT-1 unit.
2. Calibrate the security system.

Setup Monitoring System

3. Mount the device under test (DUT) on the torso simulator and connect the monitoring or pacing leads as shown in the Figure below.

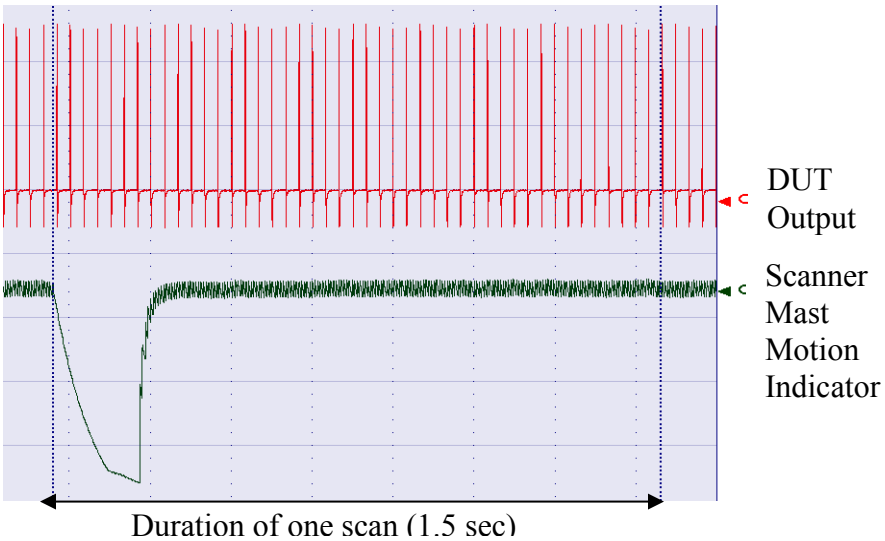


4. Connect device monitoring cables leading out of the torso simulator to a preamplifier input.
5. Connect a digital oscilloscope to the output of the preamp to monitor output signals from the device under test.
6. Connect the preamplifier output (with a BNC-T) to A/D converter and linked with the control PC.
7. Place the photo detection system in place and connect the output to the A/D converter for measurement trigger.
8. Set up the measurement acquisition software to trigger on the pulse from the photo detection system when the mast begins to swing at the start of a scan.

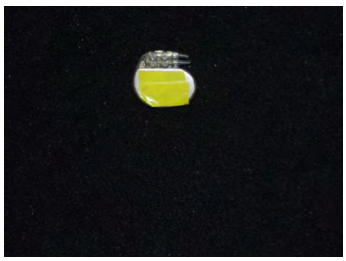
Conduct DUT Measurements

9. Check torso simulator and cables on the oscilloscope to verify minimum noise from the exposure.
10. Program DUT according to device setting in appendix H.
11. To verify DUT operation, place DUT/torso simulator at a distance of at least 2 meters from the AIT-1 unit, run a baseline test in all modes of operation to be tested.
12. Set up the torso simulator inside the AIT-1 unit facing east at position 1 and a height of 1.4 meter from the floor (see appendix F). DUT monitoring cable is fed in and out of the AIT-1 unit through a hallow fiber glass tubing oriented parallel to the floor (perpendicular to the radiated electric field and wrapped with a millimeter wave absorber).
13. Record the DUT's orientation, operating mode and settings.
14. Set trigger of data acquisition on oscilloscope and software to the output of the photo detector system setup by the mast of AIT-1 unit.

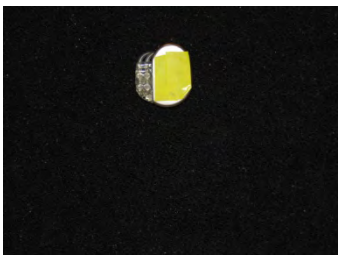
15. Prepare security system for a scan.
16. Start scan and capture DUT output signal during exposure. Figure below is an example of DUT's output.



17. Repeat steps 15 and 16 five (5) times, recording any effects or spurious data over 30 seconds period.
18. Rotate the DUT by 90 degrees to a new orientation as shown in the Figure below and repeat steps 13 - 17.



a) DUT Orientation: Horizontal



b) DUT Orientation: Vertical

19. Change operating mode to a new setting and repeat steps 13 – 18.
20. Change location of the torso simulator to a height of 1 meter from the floor as shown on Figure F-2 of appendix F and repeat steps 13 – 19.
21. Change location of the torso simulator to a new position on the location table shown in appendix F and repeat steps 13 – 20.

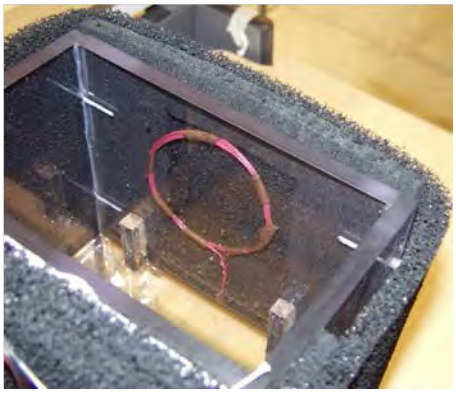
18.4 G.4 Procedure for Testing Medical Insulin Pumps for Exposure In/Near Screening Unit

Prepare Scanner

1. Power and log ON to AIT-1 unit.
2. Calibrate the security system.

Setup Monitoring System

3. Mount the device to be tested (DUT) on the torso simulator and place the 5 turn, 10 cm diameter, pickup loop behind the millimeter wave absorber as shown in the Figure below.

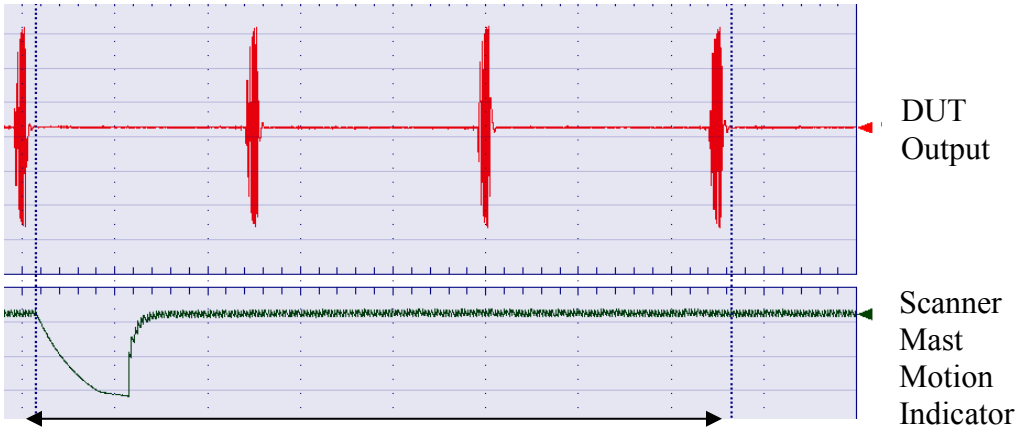


4. Connect device monitoring cable leading out of the human body simulator torso simulator to a preamplifier input.
5. Connect a digital oscilloscope to the output of the preamp to monitor output signals from the device under test.
6. Connect the preamplifier output (with a BNC-T) to A/D converter and linked with the control PC.
7. Place the photo detection system in place and connect the output to the A/D converter for measurement trigger.
8. Set up the measurement acquisition software to trigger on the pulse from the photo detection system when the mast begins to swing at the start of a scan.

Conduct Measurements

9. Check torso simulator and cables on the oscilloscope to verify minimum noise from the exposure.
10. With the DUT on the torso simulator at a distance of at least 2 meters away from the AIT-1 unit, run a baseline test recording signals from the device as if it were being tested. This is to verify that the device is functioning normally before being placed in the AIT-1 unit.
11. Set up the torso simulator inside the AIT-1 unit facing east at position 1 and a height of 1.4 meter from the floor as shown on the location map in appendix F. Monitoring are fed into the AIT-1 unit through a hallow fiber glass tubing oriented parallel to the floor (perpendicular to the radiated electric field and wrapped with a millimeter wave absorber.)

12. Record the DUT's orientation, operating mode and settings.
13. Set trigger of data acquisition on oscilloscope and software to the output of the photo detector system setup by the mast of AIT-1 unit.
14. Prepare security system for a scan.
15. Start scan and capture DUT's output signal during exposure. Figure below is an example of DUT's output.



16. Repeat steps 14 and 15 five (5) times, making note of any effects or spurious data.
17. Rotate the DUT clockwise by 90 degrees and repeat steps 14 - 16.
18. Change operating mode to a new setting and repeat steps 14 – 17.
19. Change location of the torso simulator to a height of 1 meter from the floor as shown on Figure F-2 of appendix F and repeat steps 14 – 18.
20. Change location of the torso simulator to a height of 0.25 meter from the floor as shown on Figure F-2 of appendix F and repeat steps 14 – 19.
21. Change location of the torso simulator to a new position on the location table shown in appendix F and repeat steps 14 – 21.

19. Appendix H: PMED Device Under Test Settings

PMED sample device under test (DUT) included implantable cardiac pacemakers cardioverter defibrillators, implantable neurostimulators, and insulin pumps and blood glucose monitors. Each PMED had a number of settings and functions that can be used to treat patients. With some PMEDs there are many settings and thousands of possible combinations. For this project key functions and settings were used for the devices based upon experience with the devices, history of EMI issues, and suggestions by the device manufacturer. The following information provides more details about these DUT sample PMEDs and the settings on these devices used during EMC testing.

The implantable cardiac devices (pacemaker and ICD) were tested both with and without injected simulated cardiac signal. Table H-1 describes the major device modes and functions typical for these device types. The devices were tested in the VVI and AAI modes if available in the device. DDD settings were used if the programmer was not available and the device could not be switched to the desired test mode. Some of the modes tested utilize the cardiac rate response, where the device senses the heart rate and makes adjustments to the device output rate. For rate response mode the device tries to replicate the normal heart behavior and changes the pacing rate in response to patient needs for their physical activity. For the most of the devices tested, this setting was disabled because it introduces significant a waiting time period after DUT setup until the DUT settles to back normal condition. Because this project concentrates on testing that assumes the human subject in a stationary location, the rate response was determined to not add significant information for our testing and thus was not used during the tests.

The nominal device sensitivity settings were used for most of the testing to provide a common basis for settings across the different manufactures. The maximum sensitivity settings were used at the location where the worst case scenario is assumed, which is the position 2. For ICDs, the DUT was set so that actual device output for cardiac shock was off or set for minimum energy to prevent equipment damages or personal injuries.

Table H-1: Test modes used for Implantable cardiac devices.

AAI	Atrial pacing, Atrial sensing and inhibition upon Atrial sensing
VVI	Ventricular pacing, Ventricular sensing and inhibition upon Ventricular sensing
DDD	Atrial and Ventricular pacing, Atrial and Ventricular sensing and inhibition of each chamber when sensed from the same chamber
AAIR	Atrial pacing, Atrial sensing and inhibition upon Atrial sensing with Rate response
VVIR	Ventricular pacing, Ventricular sensing and inhibition upon Ventricular sensing with Rate response
DDDR	Atrial and Ventricular pacing, Atrial and Ventricular sensing and inhibition of each chamber when sensed from the same chamber with Rate response

Implantable neurostimulator devices were tested with settings that are most comparable across the different devices and manufactures. These devices were tested for their output on and off period. Some of the devices have electrical periodic and magnetically induced modes for stimulation. Electrical periodic mode is simply on mode and magnetically

induced mode is the mode activated when the device is exposed to certain magnetic field strength.

Insulin pump devices were tested with bolus delivery, alarm, and idle mode. Alarm and idle modes were tested for any unintended delivery or mode switch. Glucose monitors were tested for their data collection and data transmission capability.

The general settings involved with the each device category are shown in Table H-2. Only the part of the settings presented in the Table H-2 is applicable to the particular mode tested. For example, for ICD tested with AAI mode, all the settings for right and left ventricular are disregarded. The refractory setting for implantable pacemaker and ICDs is the time period where the device becomes unresponsive to the cardiac signals and does not sense.

Table H-2: General settings used for DUTs

Device Category	Nominal Setting	Maximum Sensitivity Setting
Implantable Pacemaker	Atrial Amplitude: 3.5 V Atrial Pulse Width: 400 uSec Atrial Sensitivity: 0.3 - 0.75 mV Atrial Refractory: 250 ms Ventricular Amplitude: 2.5 - 5 V Ventricular Pulse Width: 400 - 1000 uSec Ventricular Sensitivity: 0.9 - 2.8 mV Ventricular Refractory: 230 - 325 ms	Atrial Amplitude: 3.5 V Atrial Pulse Width: 400 uSec Atrial Sensitivity: 0.15 mV Atrial Refractory: 250 ms Ventricular Amplitude: 2.5 - 3.5 V Ventricular Pulse Width: 400 uSec Ventricular Sensitivity: 0.25 - 0.5 mV Ventricular Refractory: 125 - 250 ms
Implantable Cardioverter Defibrillator (ICD)	Atrial Amplitude: 2.5 - 3.5 V Atrial Pulse Width: 400 - 500 uSec Atrial Sensitivity: 0.25 - 0.3 mV (or Auto) Atrial Refractory: 280 ms Right Ventricular Amplitude: 2.5 - 5.0 V Right Ventricular Pulse Width: 400 - 500 uSec Left Ventricular Amplitude: 2.5 - 4 V Left Ventricular Pulse Width: 400 - 500 uSec Ventricular Sensitivity: 0.3 - 0.6 mV (or Auto) Ventricular Refractory: 250 ms Shock: Monitor only or Minimum Energy	Atrial Amplitude: 2.5 - 3.5 V Atrial Pulse Width: 400 - 500 uSec Atrial Sensitivity: 0.15 - 0.2 mV Atrial Refractory: 190 - 280 ms Right Ventricular Amplitude: 2.5 - 5.0 V Right Ventricular Pulse Width: 400 - 500 uSec Left Ventricular Amplitude: 2.5 V Left Ventricular Pulse Width: 500 uSec Ventricular Sensitivity: 0.15 - 0.2 mV Ventricular Refractory: 125 - 250 ms Shock: Monitor only or Minimum Energy
Implantable Neurostimulator	Amplitude: 5.0 V (or 1 mA) Pulse Width: 450 - 510 uSec Pulse Rate: 20 - 31 Hz On Time: >30 sec Off Time: >30 sec	N/A
Insulin Pump and Glucose Monitor	Bolus Delivery: >30 sec	N/A

20. Appendix I: PMED Test Findings

The general PMED setting and explanation about the test modes are in Appendix H.

Table I-1: Test data of sample Implantable Pacemakers.

Device	Location	Height	Test Mode	Lead Config	Observed Reaction
A1	P1	1m	AAI VVI	Bipolar Unipolar	None
		1.4m	AAI VVI	Bipolar Unipolar	None
	P2	1m	AAI VVI	Bipolar Unipolar	None
		1.4m	AAI VVI AAI (Max Sensitivity) VVI (Max Sensitivity)	Bipolar Unipolar	None
	P3	1m	AAI VVI	Bipolar Unipolar	None
		1.4m	AAI VVI	Bipolar Unipolar	None
	P4	1m	AAI VVI	Bipolar Unipolar	None
		1.4m	AAI VVI	Bipolar Unipolar	None
	P5	1m	AAI VVI	Bipolar Unipolar	None
		1.4m	AAI VVI	Bipolar Unipolar	None
	P6	1m	AAI VVI	Bipolar Unipolar	None
		1.4m	AAI VVI	Bipolar Unipolar	None
A2	P1	1m	VVI	Bipolar Unipolar	None
		1.4m	VVI	Bipolar Unipolar	None
	P2	1m	VVI	Bipolar Unipolar	None
		1.4m	VVI VVI (Max Sensitivity)*	Bipolar Unipolar	None
A3	P1	1m	VVI	Bipolar Unipolar	None
		1.4m	VVI	Bipolar Unipolar	None
	P2	1m	VVI	Bipolar Unipolar	None
		1.4m	VVI VVI (Max Sensitivity)*	Bipolar Unipolar	None

Device	Location	Height	Test Mode	Lead Config	Observed Reaction
	P3	1m	VVI	Bipolar Unipolar	None
		1.4m	VVI	Bipolar Unipolar	None
	P4	1m	VVI	Bipolar Unipolar	None
		1.4m	VVI	Bipolar Unipolar	None
	P5	1m	VVI	Bipolar Unipolar	None
		1.4m	VVI	Bipolar Unipolar	None
	P6	1m	VVI	Bipolar Unipolar	None
		1.4m	VVI	Bipolar Unipolar	None
A4	P1	1m	DDDR	Bipolar	None
		1.4m	DDDR	Bipolar	None
	P2	1m	DDDR** AAIR VVIR	Bipolar Unipolar	None
		1.4m	DDDR** AAIR VVIR	Bipolar Unipolar	None
A5	P1	1m	DDDR	Bipolar	None
		1.4m	DDDR	Bipolar	None
	P2	1m	DDDR	Bipolar	None
		1.4m	DDDR	Bipolar	None
	P3	1m	DDDR	Bipolar	None
		1.4m	DDDR	Bipolar	None
	P4	1m	DDDR	Bipolar	None
		1.4m	DDDR	Bipolar	None
	P5	1m	DDDR	Bipolar	None
		1.4m	DDDR	Bipolar	None
	P6	1m	DDDR	Bipolar	None
		1.4m	DDDR	Bipolar	None

*These Modes were only tested with Unipolar Setting
**These Modes were only tested with Bipolar Setting

Table I-2: Test data of sample Implantable Cardioverter Defibrillator.

Device	Location	Height	Test Mode	Lead Config	Observed Reaction
B1	P1	1m	AAI VVI	Bipolar	None
		1.4m	AAI VVI	Bipolar	None
	P2	1m	AAI VVI	Bipolar	None
		1.4m	AAI VVI AAI (Max Sensitivity) VVI (Max Sensitivity)	Bipolar	None
	P3	1m	AAI VVI	Bipolar	None
		1.4m	AAI VVI	Bipolar	None
	P4	1m	AAI VVI	Bipolar	None
		1.4m	AAI VVI	Bipolar	None
	P5	1m	AAI VVI	Bipolar	None
		1.4m	AAI VVI	Bipolar	None
	P6	1m	AAI VVI	Bipolar	None
		1.4m	AAI VVI	Bipolar	None
B2	P1	1m	VVI	Bipolar	None
		1.4m	VVI	Bipolar	None
	P2	1m	VVI	Bipolar	None
		1.4m	VVI VVI (Max Sensitivity)	Bipolar	None
B3	P1	1m	AAI VVI	Bipolar	None
		1.4m	AAI VVI	Bipolar	None
	P2	1m	AAI VVI	Bipolar	None
		1.4m	AAI VVI AAI (Max Sensitivity) VVI (Max Sensitivity)	Bipolar	None
	P3	1m	AAI VVI	Bipolar	None
		1.4m	AAI VVI	Bipolar	None

Device	Location	Height	Test Mode	Lead Config	Observed Reaction
	P4	1m	AAI VVI	Bipolar	None
		1.4m	AAI VVI	Bipolar	None
	P5	1m	AAI VVI	Bipolar	None
		1.4m	AAI VVI	Bipolar	None
	P6	1m	AAI VVI	Bipolar	None
		1.4m	AAI VVI	Bipolar	None
B4	P1	1m	DDDR	Bipolar	None
		1.4m	DDDR	Bipolar	None
	P2	1m	DDDR	Bipolar	None
		1.4m	DDDR	Bipolar	None
	P3	1m	DDDR	Bipolar	None
		1.4m	DDDR	Bipolar	None
	P4	1m	DDDR	Bipolar	None
		1.4m	DDDR	Bipolar	None
	P5	1m	DDDR	Bipolar	None
		1.4m	DDDR	Bipolar	None
	P6	1m	DDDR	Bipolar	None
		1.4m	DDDR	Bipolar	None
B5	P1	1m	DDD	Bipolar	None
		1.4m	DDD	Bipolar	None
	P2	1m	DDD	Bipolar	None
		1.4m	DDD	Bipolar	None
B6	P1	1m	VVIR	Bipolar	None
		1.4m	VVIR	Bipolar	None
	P2	1m	VVIR	Bipolar	None
		1.4m	VVIR	Bipolar	None

Table I-3: Test data of sample Implantable Neurostimulator.

Device	Location	Height	Test Mode	Lead Config	Observed Reaction
C1	P1	1m	Electrical Periodic Magnetically Induced Off	N/A	None
		1.4m	Electrical Periodic Magnetically Induced Off	N/A	None
	P2	1m	Electrical Periodic Magnetically Induced Off	N/A	None
		1.4m	Electrical Periodic Magnetically Induced Off	N/A	None
	P3	1m	Electrical Periodic Magnetically Induced Off	N/A	None
		1.4m	Electrical Periodic Magnetically Induced Off	N/A	None
	P4	1m	Electrical Periodic Magnetically Induced Off	N/A	None
		1.4m	Electrical Periodic Magnetically Induced Off	N/A	None
	P5	1m	Electrical Periodic Magnetically Induced Off	N/A	None
		1.4m	Electrical Periodic Magnetically Induced Off	N/A	None
	P6	1m	Electrical Periodic Magnetically Induced Off	N/A	None
		1.4m	Electrical Periodic Magnetically Induced Off	N/A	None
C2	P1	1m	Electrical Periodic Magnetically Induced Off	N/A	None
		1.4m	Electrical Periodic Magnetically Induced Off	N/A	None
	P2	1m	Electrical Periodic Magnetically Induced Off	N/A	None

Device	Location	Height	Test Mode	Lead Config	Observed Reaction
		1.4m	Electrical Periodic Magnetically Induced Off	N/A	None
C3	P1	1m	Cycling On Cycling Off	N/A	None
		1.4m	Cycling On Cycling Off	N/A	None
	P2	1m	Cycling On Cycling Off	N/A	None
		1.4m	Cycling On Cycling Off	N/A	None
C4	P1	1m	Continuous On Continuous Off	N/A	None
		1.4m	Continuous On Continuous Off	N/A	None
	P2	1m	Continuous On Continuous Off	N/A	None
		1.4m	Continuous On Continuous Off	N/A	None
	P3	1m	Continuous On Continuous Off	N/A	None
		1.4m	Continuous On Continuous Off	N/A	None
	P4	1m	Continuous On Continuous Off	N/A	None
		1.4m	Continuous On Continuous Off	N/A	None
	P5	1m	Continuous On Continuous Off	N/A	None
		1.4m	Continuous On Continuous Off	N/A	None
	P6	1m	Continuous On Continuous Off	N/A	None
		1.4m	Continuous On Continuous Off	N/A	None
C5	P1	1m	Cycling On Cycling Off	N/A	None
		1.4m	Cycling On Cycling Off	N/A	None
	P2	1m	Cycling On Cycling Off	N/A	None
		1.4m	Cycling On Cycling Off	N/A	None
C6	P1	1m	Cycling On Cycling Off	N/A	None
		1.4m	Cycling On Cycling Off	N/A	None

Device	Location	Height	Test Mode	Lead Config	Observed Reaction
	P2	1m	Cycling On Cycling Off	N/A	None
		1.4m	Cycling On Cycling Off	N/A	None
	P3	1m	Cycling On Cycling Off	N/A	None
		1.4m	Cycling On Cycling Off	N/A	None
	P4	1m	Cycling On Cycling Off	N/A	None
		1.4m	Cycling On Cycling Off	N/A	None
	P5	1m	Cycling On Cycling Off	N/A	None
		1.4m	Cycling On Cycling Off	N/A	None
	P6	1m	Cycling On Cycling Off	N/A	None
		1.4m	Cycling On Cycling Off	N/A	None

Table I-4: Test data of sample Insulin Pump and Glucose Monitor.

Device	Location	Height	Test Mode	Lead Config	Observed Reaction
D1	P1	0.25m	Bolus delivery alarm idle	N/A	None
		1m	Bolus delivery alarm idle	N/A	None
		1.4m	Bolus delivery alarm idle	N/A	None
	P2	0.25m	Bolus delivery alarm idle	N/A	None
		1m	Bolus delivery alarm idle	N/A	None
		1.4m	Bolus delivery alarm idle	N/A	None
D3	P1	0.25m	Data Transmission	N/A	None
		1m	Data Transmission	N/A	None
		1.4m	Data Transmission	N/A	None
	P2	0.25m	Data Transmission	N/A	None
		1m	Data Transmission	N/A	None
		1.4m	Data Transmission	N/A	None
D7	P1	0.25m	Data Collection	N/A	Defective Device
		1m	Data Collection	N/A	Defective Device
		1.4m	Data Collection	N/A	Defective Device
	P2	0.25m	Data Collection	N/A	Defective Device
		1m	Data Collection	N/A	Defective Device
		1.4m	Data Collection	N/A	Defective Device
D8	P1	0.25m	Data Collection	N/A	Defective Device
		1m	Data Collection	N/A	Defective Device
		1.4m	Data Collection	N/A	Defective Device
	P2	0.25m	Data Collection	N/A	Defective Device
		1m	Data Collection	N/A	Defective Device
		1.4m	Data Collection	N/A	Defective Device
D9	P1	1m	Data Collection	N/A	None
	P2	1m	Data Collection	N/A	None
D11	P1	0.25m	Bolus delivery alarm idle	N/A	None
		1m	Bolus delivery alarm idle	N/A	None

Device	Location	Height	Test Mode	Lead Config	Observed Reaction
		1.4m	Bolus delivery alarm idle	N/A	None
	P2	0.25m	Bolus delivery alarm idle	N/A	None
		1m	Bolus delivery alarm idle	N/A	None
		1.4m	Bolus delivery alarm idle	N/A	None
D12	P1	0.25m	Bolus delivery alarm idle	N/A	None
		1m	Bolus delivery alarm idle	N/A	None
		1.4m	Bolus delivery alarm idle	N/A	None
	P2	0.25m	Bolus delivery alarm idle	N/A	None
		1m	Bolus delivery alarm idle	N/A	None
		1.4m	Bolus delivery alarm idle	N/A	None
	P3	0.25m	Bolus delivery alarm idle	N/A	None
		1m	Bolus delivery alarm idle	N/A	None
		1.4m	Bolus delivery alarm idle	N/A	None
	P4	0.25m	Bolus delivery alarm idle	N/A	None
		1m	Bolus delivery alarm idle	N/A	None
		1.4m	Bolus delivery alarm idle	N/A	None

Device	Location	Height	Test Mode	Lead Config	Observed Reaction
	P5	0.25m	Bolus delivery alarm idle	N/A	None
		1m	Bolus delivery alarm idle	N/A	None
		1.4m	Bolus delivery alarm idle	N/A	None
	P6	0.25m	Bolus delivery alarm idle	N/A	None
		1m	Bolus delivery alarm idle	N/A	None
		1.4m	Bolus delivery alarm idle	N/A	None

21. References

1. IEEE Std C95.1-2005: IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz. Institute of Electrical and Electronics Engineers 19 April 2006.

2. ICNIRP: Guidelines for Limiting Exposure to Time-Varying Electric, Magnetic, and Electromagnetic Fields (up to 300 GHz). Health Physics 1998; 74 (4): 494-522.

3. IEC 60601-1-2: 2007: Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests. International Electrotechnical Commission March 2007.

4. ANSI/AAMI PC69:2007: Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators. Association for the Advancement of Medical Instrumentation 2007.

5. ANSI/AAMI/ISO 14708-3 2008: American National Standard for Implants for Surgery – Active implantable Medical Devices – Part 3: Implantable Neurostimulators. Association for the Advancement of Medical Instrumentation 2008.

6. BS EN ISO 14971:2009: Medical devices — Application of risk management to medical devices. BSI British Standards 2009.

7. Hayes D, Wang P, Reynolds D, et al. Interference with cardiac pacemakers by cellular telephones. New England Journal of Medicine 1997; 21:1473-1479.

8. Kanda M and Orr D. Near-Field Gain of a Horn and an Open-Ended Waveguide: Comparison between Theory and Experiment. IEEE Transactions on Antennas and Propagation 1987; 35 (1): 33-40.

9. Laurent A, Mistretta F, Bottigioli D, et al. Echographic measurement of skin thickness in adults by high frequency ultrasound to assess the appropriate microneedle length for intradermal delivery of vaccines. Vaccine 2007; 25: 6423-6430.

10. Communications with Brian Lewis, M.D., Cardiologist, PDLB, Division of Cardiovascular Devices, Office of Device Evaluation, Center for Radiological Devices and Health, U S Food and Drug Administration.

11. BS EN ISO 7350-2: Basic human body measurements for technological design. BSI British Standards 2010.

CKC Laboratories, Inc. Radio Frequency Electromagnetic Exposure Statement Of Compliance (January 2009)

RADIO FREQUENCY ELECTROMAGNETIC EXPOSURE STATEMENT OF COMPLIANCE

FOR THE

FCC ID: TUZ-S-100

SECURITY PORTAL, PROVISION
MODEL NUMBER, SC-100
PART NUMBER, 750-26625

DATE OF ISSUE: JANUARY 27, 2009

PREPARED FOR:

Safe View, Inc.
910 East Franklin Road
Meridian, ID 83642

W.O. No.: 85484

PREPARED BY:

CKC Laboratories, Inc.
5046 Sierra Pines Drive
Mariposa, CA 95338

Report No.: FC06-056A-RS

Purpose:

To demonstrate compliance with United States, Canada and International Radio Frequency (RF) Exposure requirements for Mobile Equipment (devices used >20cm from the body), where Maximum Permissible Exposure (MPE) Calculations apply.

Equipment operational details:

Device and Antenna Operating Configuration:

Measurements based from EMC Test Report: CKC Laboratories, Inc, test report number: FC06-056A. The device is operating at maximum output power with continuous transmission.

The manufacturer declares the "SC-100" is equivalent to the model number listed in the original report, "Scout 100."

Evaluation Procedure:

This equipment is evaluated in accordance with the guidelines set forth in OET Bulletin 65 & ANSI/IEEE C95.1 for the US, Health Canada Safety Code 6 & RSS 102 for Canada and International Comission on Non-Ionizing Radiation Protection (ICNIRP) Guidelines.

Statement of Compliance:

The device identified herein passes the specified limits of FCC OET Bulletin 65, ANSI/IEEE C95.1, RSS-102 and ICNIRP Guidelines at a distance of 5cm (approximately 2 inches) at the maximum output power under normal operating conditions. CKC Laboratories, Inc. notes that the closest distance to the transmitting antenna is greater than 5 cm. Therefore by design of the equipment, human subjects are assured to maintain sufficient separation distance from Radio Frequency Exposure.

This device demonstrates compliance under the operating conditions specified in this document. Under normal operating conditions, the antenna is designed to be installed in accordance with the manufacturer's instructions in such a manor to maintain the minimum separation distance. The L-3 communicatios Provision, SC-100 is compliant with the RF exposure requirements of the United States Federal Communications Commission and international requrirements as indicated above.

Evaluating Engineer:

Senior EMC / Wireless Testing Engineer
Manager, Telecommunications Certification Body (TCB: US0103)

CKC Laboratories, Inc. Addendum to L-3 Communications Safeview Inc. Test Report ETS07-041A (Excerpt)

CKC LABORATORIES, I

Testing the F

ACCREDITED
Certicate Numbers
803.01, 805.02, 803.05, 803.06
EMC

ADDENDUM TO L-3 COMMUNICATIONS SAFEVIEW, INC.
TEST REPORT ETS07-041A

ETSI EN 300 440-2 V1.1.2 (2004-07)

Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Short Range Devices; Radio Equipment to be used in the 1 GHz to 40 GHz Frequency Range for the

SAFESCOUT OR PROVISION

DATE OF ISSUE: DECEMBER 7, 2007

PREPARED FOR:

L-3 Communications SafeView, Inc.
469 El Camino Real, Ste. 110
Santa Clara, CA 95050

P.O. No.: 4490 E
W.O. No.: 85822

PREPARED BY:

CKC Laboratories, Inc.
5046 Sierra Pines Drive
Mariposa, CA 95338

Date of test: November 8-27, 2006

Report No.: ETS06-041A1

TABLE OF CONTENTS

ADMINISTRATIVE INFORMATION

DATE OF TEST:	November 8-27, 2006
DATE OF RECEIPT:	November 8, 2006
MANUFACTURER:	L-3 Communications Safeview, Inc. 469 El Camino Real, Ste. 110 Santa Clara, CA 95050
REPRESENTATIVE:	
TEST LOCATION:	CKC Laboratories, Inc. 1120 Fulton Place Fremont, CA 94539
TEST METHOD:	EN 300 440-2 V1.1.2 (2004-07) EN 300 440-1 V1.3.1 (2001-09)
PURPOSE OF TEST:	**Original Report:** To demonstrate the compliance of the SafeScout 100, S-100 with the requirements for EN 300 440-2 devices. **Addendum A1:** Revises the name of the product to "Safescout or Provision". No additional testing performed.

SUMMARY OF RESULTS

As received, the Safescout or Provision was tested in accordance with the following standards and specifications:

European Union

- EN 300 440-2 V1.1.2 (2004-07)

Note: 89/336/EEC Article 7.1 stipulates that a national standard transposed from the harmonized standard published in the OJ is to be used to show compliance. However, for convenience and to reduce confusion, the date of the CENELEC harmonized standard is used in the report. Should questions arise, the national standard transposed from the harmonized (BS EN) is the official standard used.

CONDITIONS FOR COMPLIANCE

Modifications to the EUT were necessary to comply.
1) Added ferrite 2 wraps to SCU serial line.
2) Taped AC line cable down, added two ferrites on AC line to motor controller.
3) Add ferrite to each DB37 cable at ISU.
4) Changed to custom made shielded encoder cable.
5) 6 dB attenuator on both masts at FVIV.
6) Ethernet cable inside control tower, routed into the corner along the vertical edge on the side away from the power supply AC input wires.

Note: Receiver testing is not applicable because the receiver and transmitter transmit and receive simultaneously.

APPROVALS

QUALITY ASSURANCE:

rector of Engineering Services

lity Assurance Administrative Manager

1C Engineer/Lab Manager

TEST PERSONNEL:

IC Engineer

EQUIPMENT UNDER TEST (EUT) DESCRIPTION

The customer declares that the EUT tested by CKC Laboratories was representative of a production unit. The scanner uses millimeter wave technology to scan a person, generate a hologram, and detect objects that might be carried by the person. The scanner operates between 24.25 GHz and 30 GHz.

Since the time of testing the manufacturer has chosen to use the following model name in its place: **Safescout or Provision.** Any differences between the names does not affect their EMC characteristics and therefore meets the level of testing equivalent to the tested model name shown on the data sheets

EQUIPMENT UNDER TEST

Safescout or Provision

Manuf:	L-3 Communications Safeview, Inc.
Model:	S-100
Serial:	A100062300146

PERIPHERAL DEVICES

The EUT was tested with the following peripheral device(s):

Computer/Monitor

Manuf:	MPC
Model:	CLIENTPRO 474
Serial:	4007670-0001

Keyboard

Manuf:	MPC
Model:	SK-1688
Serial:	C0602086090

Computer Power Supply

Manuf:	Lite-on Technology Corp.
Model:	PA-1221-03
Serial:	5Y00045302

Mouse

Manuf:	Microsoft
Model:	Basic Optical Mouse 1.0A
Serial:	NA

LIST OF MEASUREMENTS

ETSI EN 300 440-2		
CLAUSE/ SUBCLAUSE	PARAMETER TO BE MEASURED	√ if tested
4.1	**Transmitter Requirements**	
4.1.1	Effective Isotropically Radiated Power	√
4.1.2	Permitted Range of Operating Frequencies	√
4.1.3	Spurious Emissions	√
4.1.4	Duty Cycle	√
4.2	**Receiver Requirements**	
4.2.1	Adjacent Channel Selectivity	
4.2.2	Adjacent Band Selectivity	
4.2.3	Blocking or Desensitization	
4.2.4	Spurious Radiations	

MEASUREMENT UNCERTAINTIES

Note: Each table has individual measurement uncertainties listed. Reported uncertainties represent expanded uncertainties expressed at approximately the 95% confidence level using a coverage factor of k=2. Statements of compliance are based on the nominal values only. The uncertainty represents a compilation of the worst case data obtained from all CKC Laboratory Test sites.

Ambient Temperature: 25°C

Relative Humidity: 49%

4.1 TECHNICAL REQUIREMENTS

EFFECTIVE ISOTROPICALLY RADIATED POWER

EN 300 440-2

Subclause 4.1.1

Rated Output Power (maximum): **0. 1 mW**

Duty cycle of the equipment during the test x = 1.0

Non-spread spectrum transmitters with a –6dB bandwidth upto 20MHz

Transmitter was measured in CW mode, sweeping stopped.

Test conditions		Transmitter Power (mW)		
		Lowest Frequency	Middle Frequency	Highest Frequency
T_{nom}(25)°C	V_{nom}(230)V	.0065	.0060	.0051
T_{min}(0)°C	V_{min}(207)V	.0060	.0058	.0054
	V_{max}(253)V	.0058	.0052	.0052
T_{max}(55)°C	V_{min}(207)V	.0115	.0024	.0042
	V_{max}(253)V	.0096	.0022	.0042
Measurement uncertainty		3.703 dB		

Tested By:

LIMIT SUBCLAUSE 7.1.3

Power Class (note 1)	Power Level (conducted or radiated)
8	10 mW
9	25 mW
10	100 mW
11	500 mW (see note 2)
12	1 W
13	2 W
14	4 W
14a	4 W (see note 2)
Note 1: Class designation is based on CEPT/ERC Recommendation 70-03(1). Note 2; For RFID applications, see Annex C of the present document.	

A separate page shall be filled in for each antenna assembly submitted for type testing.

REFERENCE NUMBER(S) OF TEST EQUIPMENT USED (for reference see Table A): 1, 2, 3, 4, 5, 36, 37, 38.

Ambient Temperature: 26°C

Relative Humidity: 50%

PERMITTED RANGE OF OPERATING FREQUENCIES Subclause 4.1.2

EN 300 440-2

Test conditions		Frequency (MHz) At which –30 dBm rbw = 30 kHz occurred	
		Lowest	Highest
T_{nom}(25)°C	V_{nom}(230)V	*	*
T_{min}(0)°C	V_{min}(207)V	*	*
	V_{max}(253)V	*	*
T_{max}(55)°C	V_{min}(207)V	*	*
	V_{max}(253)V	*	*
Measured frequencies (lowest and highest)		f_L = f_H =.....	
Measurement uncertainty		5.774×10^{-10}	

Tested By: .

***The signal was below the –30 dBm level at all frequencies.**

Where FL Lowest frequency at the appropriate spurious emission level

FH Highest frequency at the appropriate spurious emission level

LIMIT SUBCLAUSE 7.2.4

The width of the power envelope is $f_H - f_L$ for a given operating frequency. In equipment that allows adjustment or selection of different operating frequencies, the power envelope takes up different positions in the allowed band. The frequency range is determined y the lowest value of f_L and the highest value of f_H resulting from the adjustment of the equipment to the lowest and highest operating frequencies.

For all equipment the frequency range shall lie within the frequency band allocated for use. For non-harmonised frequency bands the available frequency range may differ between national administrations.

REFERENCE NUMBER(S) OF TEST EQUIPMENT USED (for reference see Table A): 1, 2, 3, 4, 5.

Ambient Temperature: 26°C

Relative Humidity: 50%

SPURIOUS EMISSION Subclause 4.1.3

RADIATED SPURIOUS EMISSION

Rated Output Power (maximum): **0. 1 mW**

Transmitter: Signals above 1 GHz in the first table below were measured with the EUT in CW mode on lowest, middle, or highest frequency.

Modulated <1 GHz/ Unmodulated >1 GHz

Lowest Frequency (CW Mode)			Middle Frequency (CW Mode)			Highest Frequency (CW Mode)		
f (MHz)	Band-width* (kHz)	Level (nW)	f (MHz)	Band-width* (kHz)	Level (nW)	f (MHz)	Band-width* (kHz)	Level (nW)
12349.2	1000	23	9343.9	1000	14	11619.5	1000	15
12345.6	1000	13	9343.7	1000	14	12425.7	1000	14
3087.8	1000	12	11544.8	1000	14	11199	1000	14
6175.2	1000	10	11619.3	1000	10	11796.9	1000	11
9262.9	1000	9	11675.5	1000	9			
1096.5	1000	3	11889.7	1000	9			
Measurement uncertainty			3.373 dB					

Tested By.

Transmitter: Signals below 1 GHz, in the table below, were measured with the EUT operating in the sweeping mode.

766.6	120	2.3	778.8	120	2.0			
765.77	120	1.5	500	120	3.2	778.5	120	1.8
766.74	120	1.3	766.18	120	1.3	763.9	120	1.3
764.2	120	1.3	763.7	120	1.1	764.9	120	1.0
765.0	120	0.9	204.5	120	0.9	765.7	120	0.9
Measurement uncertainty (dBμA/m)			.673 dB					

Tested By

LIMITS EN 300 440-1 SUBCLAUSE 7.3.7

State	47 to 74 MHz 87,5 to 118 MHz 174 to 230 MHz 470 to 862 MHz	Other frequencies ≤ 1000 MHz	Frequencies > 1000 MHz
Operating	4 nW	250 nW	1 μW
Standby	2 nW	2 nW	20 nW

REFERENCE NUMBER(S) OF TEST EQUIPMENT USED (for reference see Table A): 2, 3, 4, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23 , 24, 25, 26, 27, 28, 30, 31, 32, 33, 34, 35.

Ambient Temperature: 26°C

Relative Humidity: 50%

RADIATED SPURIOUS EMISSION

Subclause 4.1.3

Rated Output Power (maximum): **0. 1 mW**

Transmitter: Standby

Standby

Lowest Frequency			Middle Frequency			Highest Frequency		
f (MHz)	Band-width* (kHz)	Level (nW)	f (MHz)	Band-width* (kHz)	Level (nW)	f (MHz)	Band-width* (kHz)	Level (nW)
934.3	120	1.9	289.2	120	0.8			
311.5	120	1.8	625	120	0.8			
778.6	120	1.4	622.8	120	0.7			
778.7	120	1.3	299.1	120	0.7			
467.2	120	1.2	9338.4	1000	15.4			
250	120	1.1	9337.8	1000	10.6			
304.8	120	1.1	9337.0	1000	6.3			
750	120	1.1	1400.9	1000	4.0			
500	120	1.1	5915.7	1000	3.1			
398.4	120	0.8	3113	1000	2.2			
Measurement uncertainty			3.373 dB					

Tested By:

LIMITS

EN 300 440-1 SUBCLAUSE 7.3.7

State	47 to 74 MHz 87,5 to 118 MHz 174 to 230 MHz 470 to 862 MHz	Other frequencies ≤ 1000 MHz	Frequencies > 1000 MHz
Operating	4 nW	250 nW	1 µW
Standby	2 nW	2 nW	20 nW

REFERENCE NUMBER(S) OF TEST EQUIPMENT USED (for reference see Table A): 1, 6, 7, 8, 9, 10, 11, 12, 13, 15, 17, 25, 28, 29.

Ambient Temperature: 25°C

Relative Humidity: 49%

DUTY CYCLE
EN 300 440-2

Subclause 4.1.4

Measured/Declared Duty Cycle: Measured pulse cuty cycle=64%
Declared duty cycle=8.4%

Duty Cycle Class: 3

Tested By: Art Rice

For software controlled or pre-programmed devices, the applicant shall declare the duty cycle class or classes for the equipment under test, see table.

For manually operated or event dependant devices, with or without software controlled functions, the applicant shall declare whether the device once triggered, follows a pre-programmed cycle, or whether the transmission is constant until the trigger is released or manually reset. The applicant shall also give a description of the application for the device and include a typical usage pattern. The typical usage pattern as declared by the applicant shall be used to determine the duty cycle and hence the duty class, see table.

Where an acknowledgement is required, the additional transmitter on-time shall be included and declared by the manufacturer.

LIMITS

EN 300 440-1 SUBCLAUSE 7.4.3

Duty Cycle Class	Duty Cycle Ratio
1	< 0.1%
2	< 1.0%
3	< 10%
4	Up to 100%

REFERENCE NUMBER(S) OF TEST EQUIPMENT USED (for reference see test equipment listing): 2, 39, 40

TABLE A

LIST OF TEST EQUIPMENT AND ANCILLARIES USED FOR TESTS

No.	Asset #	Equipment	Serial #	Cal Date	Cal Due
1	02668	E4446A Spectrum Analyzer	US44300408	01/13/2005	01/13/2007
2	02694	Active Horn 18-26GHz	1087835	10/25/2005	10/25/2007
3	02695	Active Horn 26-40GHz	1097854	10/25/2005	10/25/2007
4	P02715	Cable, HF	NA	08/09/2005	08/09/2007
5	P05315	Cable, HF	NA	07/12/2005	07/12/2007
6	02662	S.A., Display HP-85662A	2542A12169	11/28/2005	11/28/2007
7	02663	S.A., RF Section HP-8568B	2601A02492	11/28/2005	11/28/2007
8	00683	QP Adapter	2521A00909	07/12/2006	07/12/2008
9	00852	Antenna	2630	01/24/2005	01/24/2007
10	P05299	Cable	NA	06/21/2005	06/21/2007
11	P05300	Cable	NA	06/21/2005	06/21/2007
12	P05296	Cable	NA	06/21/2005	06/21/2007
13	00501	HP8447F opt H64 preamp	2944A03850	03/05/2005	03/05/2007
14	01406	S.A. HP 8564E	3623A00539	10/27/2006	10/27/2007
15	02810	Preamp, Agilent 83051A	00323	02/27/2006	02/27/2008
16	00785	Preamp, HP83017A	3123A00283	05/09/2005	05/09/2007
17	02061	Antenna, Horn	1064	03/08/2005	03/08/2007
18	P05200	Cable, HF 36"	NA	02/08/2005	02/08/2007
19	P05201	Cable, HF 48"	NA	02/08/2005	02/08/2007
20	P05318	Cable, HF	NA	02/20/2006	02/20/2008
21	P05317	HF-Cable-72" Pasternack	NA	07/12/2005	07/12/2007
22	02693	Active Horn 12-18GHz	1088714	09/22/2005	09/22/2007
23	P00928	12.4-18GHz WaveGuide	NA	12/19/2005	12/19/2007
24	P02718	Cable, HF	NA	08/09/2005	08/09/2007
25	P04241	Cable, 6'	NA	06/07/2006	06/07/2008
26	P05239	Cable HF	NA	03/08/2005	03/08/2007
27	02410	HP8564E SA	3623A00539	10/27/2006	10/27/2008
28	P05138	Cable HF	NA	02/20/2006	02/20/2008
29	01956	HF Cable	NA	03/09/2005	03/09/2007
30	P05314	Cable, HF	NA	07/12/2005	07/12/2007
31	P00929	18-26.5GHz WaveGuide	NA	12/20/2005	12/20/2007
32	P00930	26.5-40GHz WaveGuide	NA	12/20/2005	12/20/2007
33	1045025	S.A. Agilent 8564EC	3946A00232	01/19/2005	01/19/2007
34	02347	40-60GHz mixer M19HWA	U91211-1	09/26/2006	09/26/2008
35	02347	40-60GHz Horn M19RH	NA	09/28/2006	09/28/2008
36	02721	Thermotron SM-8C Mini-Max	10911-S	11/17/2005	11/17/2007
37	00864	Pacific 345AMXT-UPC32	0246	12/02/2004	12/02/2006
38	02131	Tektronix DMM914	141024	09/12/2005	09/12/2007
39	00697	HP 54615B	US35420829	08/31/2005	08/3120/07
40	P05406	Agilent 8474C detector	2905A00025	11/01/2005	11/01/2007

CKC Laboratories, Inc. Addendum to L-3 Communications Safeview Inc. Test Report Ets07-009a for the Safescout Or Provision: ETSI EN 301 489-3 V1.4.1 (2002-08) Testing (Excerpt)

ADDENDUM TO L-3 COMMUNICATIONS SAFEVIEW, INC.
TEST REPORT ETS07-009A

FOR THE

SAFESCOUT OR PROVISION

ETSI EN 301 489-3 V1.4.1 (2002-08)

TESTING

DATE OF ISSUE: DECEMBER 7, 2007

PREPARED FOR:

L-3 Communications Safeview, Inc.
469 El Camino Real, Suite 110
Santa Clara, CA 95050

PREPARED BY:

CKC Laboratories, Inc.
5046 Sierra Pines Drive
Mariposa, CA 95338

P.O. No.: 4490 E/5224
W.O. No.: 85822/86967

Date of test: November 7, 2006 – September 20, 2007

Report No: ETS07-009B

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ADMINISTRATIVE INFORMATION

DATE OF TEST:	November 7, 2006 - September 20, 2007
DATE OF RECEIPT:	November 7, 2006
MANUFACTURER:	L-3 Communications Safeview, Inc. 469 El Camino Real, Suite 110 Santa Clara, CA 95050
REPRESENTATIVE:	[redacted]
TEST LOCATION:	CKC Laboratories, Inc. 1120 Fulton Place Fremont, CA 94539 and L-3 Communications Safeview, Inc. 469 El Camino Real, Suite 110 Santa Clara, CA 95050
TEST METHOD:	ETSI EN 301 489-3 V1.4.1 (2002-08) ETSI EN 301 489-1 V1.5.1 (2004-11)
PURPOSE OF TEST:	**Original Report:** To test the SafeScout 100, S-100 with the requirements for ETSI EN 301 489-3 V1.4.1. **Addendum A** adds new Radiated Emissions, EFTB and Conducted Immunity results using an alternate unshielded ethernet cable for the SCU/LCU link and adds new Surge results for testing which was performed using a new MOV configuration. The previous data is still valid for earlier versions of the ethernet cable and MOV. The new alternate data is provided on Pages 27-34. **Addendum B** revises the name of the product to "Safescout or Provision". No additional testing performed.

SUMMARY OF RESULTS

The L-3 Communications Safeview, Inc. Safescout or Provision was tested to the following standard and specifications:

European Union

- ETSI EN 301 489-3 V1.4.1 (2002-08)

CONDITIONS DURING TESTING

For Radiated Emissions and I/O Conducted Emissions testing:

1) Added ferrite 2 wraps to SCU serial line.
2) Taped AC line cable down, added two ferrites on AC line to motor controller.
3) Added ferrite to each DB37 cable at ISU.
4) Changed to custom made shielded encoder cable.

For I/O Conducted Emissions testing the following additional conditions were required:

1) 6 dB attenuator on both masts at FVIV.
2) Ethernet cable inside control tower, routed into the corner along the vertical edge on the side away from the power supply AC input wires.

Radiated Immunity above 1 GHz was not tested in standby mode.
ESD HCP in standby mode was not tested.
Voltage Dips testing was not performed at 30% and 60% in standby mode.

TEMPERATURE AND HUMIDITY DURING TESTING

The temperature during testing was within +15°C and + 35°C.
The relative humidity was between 20% and 75%.

APPROVALS

Steve Behm, Director of Engineering Services

QUALITY ASSURANCE:

Quality Assurance Administrative Manager

TEST PERSONNEL:

Test Technologist

EMC Engineer

Test Technologist

EMC Engineer/Lab Manager

EQUIPMENT UNDER TEST (EUT) DESCRIPTION

The customer declares the EUT tested by CKC Laboratories was representative of a production unit.

The following model was tested by CKC Laboratories: **S-100**

Since the time of testing the manufacturer has chosen to use the following model name in its place. Any differences between the names does not affect their EMC characteristics and therefore meets the level of testing equivalent to the tested model name shown on the data sheets: **SC-100**

Addendum B changed the name to **Safescout or Provision.** Any differences between the names does not affect their EMC characteristics and therefore meets the level of testing equivalent to the tested model name shown on the data sheets.

EQUIPMENT UNDER TEST

Safescout or Provision
Manuf: L-3 Communications Safeview, Inc.
Model: SC-100
Serial: A100062300146

Safescout or Provision
Manuf: L-3 Communications Safeview, Inc.
Model: T-Cop
Serial: NA

PERIPHERAL DEVICES

The EUT was tested with the following peripheral device(s):

Computer/Monitor
Manuf: MPC
Model: CLIENTPRO 474
Serial: 4007670-0001

Computer Power Supply
Manuf: Lite-on Technology Corp.
Model: PA-1221-03
Serial: 5Y00045302

Keyboard
Manuf: MPC
Model: SK-1688
Serial: C0602086090

Mouse
Manuf: Microsoft
Model: Basic Optical Mouse 1.0A
Serial: NA

EUT OPERATING FREQUENCY

The EUT was operating at 24.25 GHz - 30 GHz.

EQUIPMENT TYPE AND CLASSIFICATION

The EUT is designated as Type I, Class 3 and Base Station Equipment.

Equipment Type*	Technical nature of the primary function
I	Transfer of messages (digital or analogue signals)
II	Transfer of audio (speech or music)
III	Others

*ETSI EN 301 489-3 Subclause 4.1, Table 1.

Class of SRD Equipment**	Result of too low performance
1	Physical risk to a person
2	Inconvenience to persons, which can not simply be overcome by other means
3	Inconvenience to persons, which can simply be overcome by other means (e.g. manual)

**ETSI EN 301 489-3 Subclause 6.1, Table 3. Performance Criteria for each Class is listed in Subclause 6.3, Table 4 of ETSI EN 301 489-3.

Equipment Classification***	
The radio and/or associated ancillary equipment under test shall be classified into one of the following three classes:	Base Station Equipment
	Mobile Equipment
	Portable Equipment

***ETSI EN 301 489-3 Subclause 5.5.

ETSI EN 301 489-3 CLAUSE 7 APPLICABILITY OVERVIEW

Phenomenon	Application	Equipment Test Requirement			Reference
		Radio and ancillary equipment for fixed use (base station equipment)	**Radio and ancillary equipment for vehicular use (mobile equipment)**	**Radio and ancillary equipment for portable use (portable equipment)**	**Subclause in ETSI EN 301 489**
Radiated Emission	Enclosure of ancillary equipment	**Applicable for stand alone testing**	Applicable for stand alone testing	Applicable for stand alone testing	EN 301 489-1 8.2
Conducted Emission	DC Power input/output port	**Applicable**	Applicable	Not Applicable	EN 301 489-3 8.3
Conducted Emission	AC mains input/output port	**Applicable**	Not Applicable	Not Applicable	EN 301 489-3 8.4
Harmonic Current Emissions	AC mains input port	**Applicable**	Not Applicable	Not Applicable	EN 301 489-1 8.5
Voltage Fluctuations and Flicker	AC mains input port	**Applicable**	Not Applicable	Not Applicable	EN 301 489-1 8.6
Conducted Emission	Telecommunication Port	**Applicable**	Not Applicable	Not Applicable	EN 301 489-1 8.7
RF electromagnetic field	Enclosure	**Applicable**	Applicable	Applicable	EN 301 489-3 9.2
Electrostatic Discharge	Enclosure	**Applicable**	Applicable	Applicable	EN 301 489-1 9.3
Fast transients common mode	Signal, Telecommunication and control ports, DC and AC power ports	**Applicable**	Not Applicable	Not Applicable	EN 301 489-1 9.4
RF common mode	Signal, Telecommunication and control ports, DC and AC power ports	**Applicable**	Applicable	Not Applicable	EN 301 489-3 9.5
Transients and surges	DC power input ports	**Not Applicable**	Applicable	Not Applicable	EN 301 489-1 9.6
Voltage dips and interruptions	AC mains power input ports	**Applicable**	Not Applicable	Not Applicable	EN 301 489-3 9.7
Surges, line to line and line to ground	AC mains power input ports, telecommunication ports	**Applicable**	Not Applicable	Not Applicable	EN 301 489-1 9.8

Ambient Temperature: 25°C Relative Humidity: 49%

REPORT OF MEASUREMENTS

The following tables report the worst case emissions levels recorded during the tests performed on the EUT. All readings taken were peak readings unless otherwise stated.

Table 1: Six Highest Radiated Emission Levels

FREQUENCY MHz	METER READING dBµV	CORRECTION FACTORS Ant dB	Amp dB	Cable dB	Dist dB	CORRECTED READING dBµV/m	SPEC LIMIT dBµV/m	MARGIN dB	NOTES
204.458	50.0	9.0	-25.6	1.4	-10.0	24.8	30.0	-5.2	VQ
766.138	48.4	21.6	-27.0	2.5	-10.0	35.5	37.0	-1.5	VQ
766.218	45.3	21.6	-27.0	2.5	-10.0	32.4	37.0	-4.6	VQ
766.320	46.8	21.6	-27.0	2.5	-10.0	33.9	37.0	-3.1	VQ
778.791	44.7	21.5	-27.0	2.5	-10.0	31.7	37.0	-5.3	VQ
971.155	42.8	23.6	-26.7	3.0	-10.0	32.7	37.0	-4.3	HQ

Test Method: ETSI EN 301 489-1 V1.3.1 (2001-09)
Spec Limit: EN55022 Class B
Test Distance: 3 Meters
Tested By:

NOTES: H = Horizontal Polarization
V = Vertical Polarization
Q = Quasi Peak Reading

COMMENTS: The SafeScout S-100 Security Portal is operating and running on an auto-cycle pause time of 6 seconds. The SafeScout S-100 is connected to a support PC by an ethernet connection. The support PC triggers the SCU to begin a security scan. The software is setup to repeatedly run scan while the system is under test. Radiated Emissions 30-1000 MHz.

1) Added ferrite 2 wraps to SCU serial line.
2) Taped AC line cable down, added two ferrites on AC line to motor controller.
3) Add ferrite to each DB37 cable at ISU.
4) Changed to custom made shielded encoder cable.

(ETSI EN 301 489-1 Subclause 8.2.3, Table 4)

Frequency Range	Quasi-peak
30 - 230 MHz	30 dBuV/m
>230 - 1000 MHz	37 dBuV/m

REFERENCE NUMBER OF TEST EQUIPMENT USED (see Table A).

Ambient Temperature: 25°C Relative Humidity: 49%

Table 2: Six Highest Conducted Emission Levels

FREQUENCY MHz	METER READING dBµV	CORRECTION FACTORS Cable dB	Att dB	HPF dB	Lisn dB	CORRECTED READING dBµV	SPEC LIMIT dBµV	MARGIN dB	NOTES
0.157272	38.2	0.0	9.8	3.4	0.4	51.8	55.6	-3.8	W
0.177634	38.9	0.0	9.8	1.7	0.4	50.8	54.6	-3.8	B
0.325255	35.2	0.0	9.8	0.2	0.4	45.6	49.6	-4.0	B
0.357000	35.2	0.1	9.7	0.1	0.3	45.4	48.8	-3.4	WA
0.358000	34.2	0.1	9.7	0.1	0.4	44.5	48.8	-4.3	BA
0.430699	33.3	0.1	9.7	0.0	0.3	43.4	47.2	-3.8	W

Test Method: ETSI EN 301 489-1 V1.3.1 (2001-09)
Spec Limit: EN55022 Class B
Tested By:

NOTES: A = Average Reading
B = Black Lead
W = White Lead

COMMENTS: The SafeScout S-100 Security Portal is operating and running on an auto-cycle pause time of 6 seconds. The SafeScout S-100 is connected to a support PC by an ethernet connection. The support PC triggers the SCU to begin a security scan. The software is setup to repeatedly run scan while the system is under test. Note: Different motor installed. Conducted Emissions 0.15 - 30MHz.

AC Mains Limits **(ETSI EN 301 489-1 Subclause 8.4.3 Table 8)**

Frequency Range	Quasi-peak	Average
.150-.500 MHz	66-56 dBuV	56-46 dBuV
>.500-5 MHz	56 dBuV	46 dBuV
>5-30 MHz	60 dBuV	50 dBuV
Note: The limit decreases linearly with the logarithm of frequency in the range .150 MHz to .500 MHz.		

REFERENCE NUMBER OF TEST EQUIPMENT USED (see Table A).

Ambient Temperature: 25°C Relative Humidity: 49%

Table 3: Six Highest I/O Conducted Emission Levels

FREQUENCY MHz	METER READING dBµV	CORRECTION FACTORS Lisn dB	Cable dB	dB	dB	CORRECTED READING dBµV	SPEC LIMIT dBµV	MARGIN dB	NOTES
0.540195	35.0	4.1	-26.3	0.2		13.0	20.0	-7.0	E
0.541468	35.0	4.1	-26.3	0.2		13.0	20.0	-7.0	E
0.599197	35.9	3.6	-26.3	0.2		13.4	20.0	-6.6	E
2.447780	41.5	-1.6	-26.3	0.3		13.9	20.0	-6.1	EA
2.579880	41.3	-1.8	-26.4	0.2		13.3	20.0	-6.7	EA
2.712485	41.3	-1.9	-26.4	0.2		13.2	20.0	-6.8	E

Test Method: ETSI EN 301 489-1 V1.3.1 (2001-09)
Spec Limit: ETSI EN 301 489-3 V1.3.1
Tested By:

NOTES: Q = Quasi Peak Reading
A = Average Reading
B = Black Lead
W = White Lead

COMMENTS: The SafeScout S-100 Security Portal is operating and running on an auto-cycle pause time of 6 seconds. The SafeScout S-100 is connected to a support PC by an ethernet connection. The support PC triggers the SCU to begin a security scan. The software is setup to repeatedly run scan while the system is under test. Telecom Conducted Emissions 0.15 - 30MHz. Current method on shielded Gigabit Ethernet RJ45 cable.

3) Added ferrite 2 wraps to SCU serial line.
4) Taped AC line cable down, added two ferrites on AC line to motor controller.
5) Add ferrite to each DB37 cable at ISU.
6) Changed to custom made shielded encoder cable.
7) 6 dB attenuator on both masts at FVIV.
8) Ethernet cable inside control tower, routed into the corner along the vertical edge on the side away from the power supply AC input wires.

Limits for conducted emissions from telecommunication ports.
(ETSI EN 301 489-1 Subclause 8.7.3 Table 10)

Frequency Range MHz	Voltage Limits dB (μV)		Current Limits dB (μA)	
	Quasi-peak	Average	Quasi-peak	Average
>0.150-0.5 MHz	84 to 74	74 to 64	40 to 30	30 to 20
>0.5-30 MHz	74	64	30	20

Note 1: The limits decrease linearly with the logarithm of the frequency in the range 0.15MHz to 0.5MHz.

Note 2: The current and voltage disturbances limits are derived for use with an impedance stabilization network (ISN) which presents a common mode (asymmetric mode) impedance of 150 Ω to the telecommunication port under test (conversion factor is 20 $\log_{10}$ 150/1 = 44dB).

Note 3: The emission requirement only applies to telecommunication ports as specified in EN55022[7]. The provisional relaxation of 10 dB will be reviewed no later than 3 years after the date of withdrawal based on the results and interference cases seen in this period. Wherever possible it is recommended to comply with the limits without the provisional relaxation.

REFERENCE NUMBER OF TEST EQUIPMENT USED (see Table A).

Ambient Temperature: 23°C Relative Humidity: 55%

ETSI EN 301 489-1

Table 4: EN61000-3-2
Tested By:

Harmonic Emissions	Pass / Fail
√	Pass

Note: See Table A for test equipment used.

Table 5: EN61000-3-3
Tested By:

Voltage Fluctuations and Flicker Emissions	Pass / Fail
√	Pass

Note: See Table A for test equipment used.

REFERENCE NUMBER OF TEST EQUIPMENT USED (see Table A).

Ambient Temperature: 23°C Relative Humidity: 55%

ETSI EN 301 489-3

Table 6: Radiated Immunity (EN61000-4-3)
Tested By:

Frequency Range MHz	Modulation	Test Distance	Front V/H	Back V/H	Left Side V/H	Right Side V/H	Performance Criterion
80-1000	80% 1kHz AM	3M	Pass	Pass	Pass	Pass	CT/CR / A
1400-2000	80% 1kHz AM	NP	NP	NP	NP	NP	NP

V = Vertical H = Horizontal NP = CKC Laboratories not contracted to perform this test.

- CT=Continuous [phenomena applied to] Transmitters
- CR=Continuous [phenomena applied to] Receivers

Notes: 3V/m with EUT transmitting. The field strength at the required 40 cm height was 3.2V/m.

Table 7: Radiated Immunity (EN61000-4-3)
Tested By:

Frequency Range MHz	Modulation	Test Distance	Front V/H	Back V/H	Left Side V/H	Right Side V/H	Performance Criterion
80-1000	80% 1kHz AM	1.5M	Pass	Pass	Pass	Pass	CT/CR / A
1400-2000	80% 1kHz AM	2M	Pass	Pass	Pass	Pass	CT/CR / A

V = Vertical H = Horizontal

- CT=Continuous [phenomena applied to] Transmitters
- CR=Continuous [phenomena applied to] Receivers

Notes: 3V/m with EUT in standby mode (in-situ testing).

Radiated Immunity Performance Criteria **(ETSI EN 301 489-3 Subclause 6.4 and 6.6)**

Class 3 SRD Equipment		
Criteria	During Test	After test
A and B	May be loss of function (one or more) No unintentional responses *For transceivers-CR:* Under no circumstances shall the transmitter operate unintentionally during the test.	Operate as intended, for equipment type II the communication link may be lost, but shall be recoverable by user No degradation of performance Lost functions shall be self-recoverable

Transmit Mode Testing

Equipment	Asset #	Manufacturer	Model #	Serial #	Cal Date	Cal Due
Antenna (F-C3)	00852	Schaffner	2630	CBL6111C	12/30/06	12/30/08
Amplifier	00640	AR	50W1000A	14508	5/25/05	5/25/07
Spectrum Analyzer	02663	HP	8568B	2601A02492	11/28/05	11/28/07
SA Display	02662	HP		2542A12169	11/28/05	11/28/07
Signal Generator	00687	Marconi	2022D	119229/016	9/20/05	9/20/07
Function Generator	02237	BK Precision	4011	9902 0294	9/2/05	9/2/07
Field Probe	00996A	AR	FP2000	13793	7/8/05	7/8/07
Field Monitor	0951A	AR	FM2000	18327	3/16/05	3/16/07

Standby Mode Testing

Equipment	Asset #	Manufacturer	Model #	Serial #	Cal Date	Cal Due
Antenna (BLG)	02511	EMCO	3143	9602-1239	3/7/05	3/7/07
Antenna (HRN)	02061	ARA	DRG-118/A	1064	3/8/05	3/8/07
Amplifier LF	00640	AR	50W1000A	14508	5/25/05	5/25/07
Amplifier HF	02691	OPHIR	5162	1020	8/21/06	8/21/08
Signal Generator LF	00687	Marconi	2022D	119229/016	9/20/05	9/20/07
Signal Generator HF	02547	HP	8673C	2447A00198	8/22/06	8/22/08
Field Probe LF	00996A	AR	FP2000	13793	7/8/05	7/8/07
Field Probe HF	00870	AR	FP2080	24792	6/21/06	6/21/08
Field Monitor	01208	AR	FM2000	18328	3/16/05	3/16/07

Ambient Temperature: 23°C Relative Humidity: 55%

ETSI EN 301 489-1

Table 8: ESD - Indirect Discharge (EN61000-4-2)
Tested By

Location on EUT	Indirect Discharge Contact ± 4 kV		Performance Criteria / Met
	VCP	HCP	
Front	Pass	Pass	TT/TR / A
Back	Pass	Pass	TT/TR / A
Left Side	Pass	Pass	TT/TR / A
Right Side	Pass	Pass	TT/TR / A

VCP = Vertical coupling plane HCP = Horizontal coupling plane

- TT=Transient [phenomena applied to] Transmitters
- TR=Transient [phenomena applied to] Receivers

Notes: EUT was tested in transmit mode.

Table 9: ESD - Direct Discharge (EN61000-4-2)
Tested By

Location on EUT	Direct Discharge		Performance Criteria / Met
	Contact ± 4 kV	Air ± 8 kV	
Front	Pass	Pass	TT/TR / A
Back	Pass	Pass	TT/TR / A
Left Side	Pass	Pass	TT/TR / A
Right Side	Pass	Pass	TT/TR / A
Top	Pass	Pass	TT/TR / A

- TT=Transient [phenomena applied to] Transmitters
- TR=Transient [phenomena applied to] Receivers

Notes: EUT was tested in transmit mode.

Table 10: ESD - Indirect Discharge (EN61000-4-2)
Tested By:

Location on EUT	Indirect Discharge Contact ± 4 kV		Performance Criteria / Met
	VCP	HCP	
Front	Pass	NP	TT/TR / A
Back	Pass	NP	TT/TR / A
Left Side	Pass	NP	TT/TR / A
Right Side	Pass	NP	TT/TR / A

VCP = Vertical coupling plane HCP = Horizontal coupling plane NP = CKC Laboratories not contracted to perform this test.

- TT=Transient [phenomena applied to] Transmitters
- TR=Transient [phenomena applied to] Receivers

Notes: EUT was tested in standby mode (in-situ testing).

Table 11: ESD - Direct Discharge (EN61000-4-2)
Tested By:

Location on EUT	Direct Discharge		Performance Criteria / Met
	Contact ± 4 kV	Air ± 8 kV	
Front	Pass	Pass	TT/TR / A
Back	Pass	Pass	TT/TR / A
Left Side	Pass	Pass	TT/TR / A
Right Side	Pass	Pass	TT/TR / A
Top	Pass	Pass	TT/TR / A

- TT=Transient [phenomena applied to] Transmitters
- TR=Transient [phenomena applied to] Receivers

Notes: EUT was tested in standby mode (in-situ testing).

ESD Performance Criteria **(ETSI EN 301 489-3 Subclause 6.5 and 6.7)**

Class 3 SRD Equipment		
Criteria	During Test	After test
A and B	May be loss of function (one or more) No unintentional responses *For transceivers-CR or TR only:* Under no circumstances shall the transmitter operate unintentionally during the test.	Operate as intended, for equipment type II the communication link may be lost, but shall be recoverable by user No degradation of performance Lost functions shall be self-recoverable

Equipment	Asset #	Manufacturer	Model #	Serial #	Cal Date	Cal Due
ESD Simulator	2167	Schaffner	NSG 435	AA3125	12-18-06	12-18-08

Ambient Temperature: 23°C Relative Humidity: 55%

ETSI EN 301 489-1

Table 12: Electrical Fast Transient Burst (EFTB) Power Cable (EN61000-4-4)
Tested By:

EFTB insertion point	+ 1 kV	- 1 kV	Performance Criteria / Met
Line to Ground	Pass	Pass	TT/TR / A
Neutral to Ground	Pass	Pass	TT/TR / A
Protective Earth (PE) to Ground	Pass	Pass	TT/TR / A
Line/Neutral/PE to Ground	Pass	Pass	TT/TR / A

- TT=Transient [phenomena applied to] Transmitters
- TR=Transient [phenomena applied to] Receivers

Notes: EUT was tested in transmit mode (at the lab) and standby mode (in-situ testing).
Notes: 2.5kHz Pulse Repetition Frequency

Table 13: Electrical Fast Transient Burst (EFTB) Signal, I/O, DC Ports (EN61000-4-4)
Tested By:

Cable tested	+ 0.5 kV pass / fail	- 0.5 kV pass / fail	Performance Criterion
Signal Lines			TT/TR / A
Ethernet	Pass	Pass	
Ethernet (Green)	Pass	Pass	
Ethernet (Red)	Pass	Pass	
Ethernet (Front)	NA	NA	
Control Lines	NA	NA	NA
DC power input	NA	NA	NA

- TT=Transient [phenomena applied to] Transmitters
- TR=Transient [phenomena applied to] Receivers

NA=Not Applicable because the Front Ethernet cable is not longer than 3 meters, and the EUT has no control or DC power lines.
Notes: EUT was tested in transmit mode (at the lab) and standby mode (in-situ testing).

Fast Transient common mode Criteria **(ETSI EN 301 489-3 Subclause 6.5 and 6.7)**

Class 3 SRD Equipment		
Criteria	During Test	After test
A and B	May be loss of function (one or more) No unintentional responses *For transceivers-CR or TR only:* Under no circumstances shall the transmitter operate unintentionally during the test.	Operate as intended, for equipment type II the communication link may be lost, but shall be recoverable by user No degradation of performance Lost functions shall be self-recoverable

Equipment	Asset #	Manufacturer	Model #	Serial #	Cal Date	Cal Due
EFT Generator	Amplifier Research	UCS 500-M	0844	29101	2-16-06	2-16-08
Capacitive Coupling Clamp	Amplifier Research	None	00868A	24945	7-18-05	7-18-07

ETSI EN 301 489-1

Table 14: Transients and Surges in the Vehicle Environment - 12 VDC Supply (ISO 7637-1)

Test Pulse	Pass/fail	Performance Criterion
1	NA	NA
2	NA	NA
3a	NA	NA
3b	NA	NA
4	NA	NA
7	NA	NA

NA = Not Applicable because this test is only required for units that will be used in a vehicular environment.

Table 15: Transients and Surges in the Vehicle Environment - 24 V DC Supply (ISO 7637-2)

Test Pulse	Pass/fail	Performance Criterion
1a	NA	NA
1b	NA	NA
2	NA	NA
3a	NA	NA
3b	NA	NA
4	NA	NA

NA = Not Applicable because this test is only required for units that will be used in a vehicular environment.

Ambient Temperature: 23°C Relative Humidity: 55%

ETSI EN 301 489-3

Table 16: Conducted Immunity (EN61000-4-6)
Tested By:

Cable Tested:	Amplitude	Frequency Range	Pass/fail	Performance Criteria / Met
AC Power	3 Vrms	.150-80MHz	Pass	CT/CR / A
Signal Lines				
Ethernet	3 Vrms	.150-80MHz	Pass	CT/CR / A
Ethernet (Green)	3 Vrms	.150-80MHz	Pass	CT/CR / A
Ethernet (Red)	3 Vrms	.150-80MHz	Pass	CT/CR / A
Ethernet (Front)			NA	NA

- CT=Continuous [phenomena applied to] Transmitters
- CR= Continuous [phenomena applied to] Receivers

NA=Not Applicable because the Front Ethernet cable is not longer than 3 meters.
Notes: EUT was tested in transmit mode (at the lab) and standby mode (in-situ testing).

RF common mode Performance Criteria **(ETSI EN 301 489-3 Subclause 6.4 and 6.6)**

Class 3 SRD Equipment		
Criteria	During Test	After test
A and B	May be loss of function (one or more) No unintentional responses *For transceivers-CR:* Under no circumstances shall the transmitter operate unintentionally during the test.	Operate as intended, for equipment type II the communication link may be lost, but shall be recoverable by user No degradation of performance Lost functions shall be self-recoverable

Transmit Mode Testing

Equipment	Asset #	Manufacturer	Model #	Serial #	Cal Date	Cal Due
Coupling Decoupling Network	00696	FCC	FCC-801-M3-25	56	4/5/06	4/5/08
Injection Probe	00699	FCC	F-120-3	24	8/18/05	8/18/07
Amplifier	01211	AR	150A100A	18240	6/6/05	6/6/07
Directional Coupler	00866	Werlatone	C2630	5155	4/20/05	4/20/07
Spectrum Analyzer	02663	HP	8568B	2601A02492	11/28/05	11/28/07
SA Display	02662	HP		2542A12169	11/28/05	11/28/07
Signal Generator	00687	Marconi	2022D	119229/016	9/20/05	9/20/07
Function Generator	02237	BK Precision	4011	9902 0294	9/2/05	9/2/07

Standby Mode Testing

Equipment	Asset #	Manufacturer	Model #	Serial #	Cal Date	Cal Due
Coupling Decoupling Network	00710	Fischer	P/N: FCC-801-M3-16	221	4/5/06	4/5/08
Injection Probe	00699	Fischer	F-120-3	24	8/18/05	8/18/07
Monitor Probe	00731	Fischer	F-35	296	5/4/05	5/4/07
Amplifier	01211	AR	150A100A	18240	6/6/05	6/6/07
Directional Coupler	00866	Werlatone	02650	5155	4/20/05	4/20/07
Spectrum Analyzer	00313	HP	8568A	2049A01408	8/22/06	8/22/08
SA Display	02509	HP	85662A	2112A02174	8/22/06	8/22/08
Signal Generator	00687	Marconi	2022D	119229/016	9/20/05	9/20/07

Ambient Temperature: 23°C Relative Humidity: 55%

ETSI EN 301 489-3

Table 17: Voltage Dips & Interrupts (EN61000-4-11)
Tested By:

Interrupts (% of nominal)	Time	Notes	Pass/fail	Performance Criteria
30% of nominal	10ms	3 interrupts	Pass	CT/CR / A
60% of nominal	100ms	3 interrupts	Pass	CT/CR / A
>95% of nominal	5 secs	1 drop out	Pass	TT/TR / B

- TT=Transient [phenomena applied to] Transmitters
- TR= Transient [phenomena applied to] Receivers

Notes: EUT was tested in transmit mode.

Table 18: Voltage Dips & Interrupts (EN61000-4-11)
Tested By:

Interrupts (% of nominal)	Time	Notes	Pass/fail	Performance Criteria
30% of nominal	10ms	3 interrupts	NP	NP
60% of nominal	100ms	3 interrupts	NP	NP
>95% of nominal	5 secs	1 drop out	Pass	TT/TR / B

- TT=Transient [phenomena applied to] Transmitters
- TR= Transient [phenomena applied to] Receivers

NP = CKC Laboratories, Inc. was not contracted to perform this test.
Notes: EUT was tested in standby mode (in-situ testing). Testing was done by manually cycling power at the breaker for 5 seconds and system was able to be brought back to normal operation after.

Voltage Dips and Interruptions Performance Criteria **(ETSI EN 301 489-3 Subclause 6.5 and 6.7)**

Class 3 Equipment		
Criteria	During Test	After test
A and B	May be loss of function (one or more) No unintentional responses *For Transmitters TT* - tests shall be repeated in standby mode. *For transceivers TR ONLY:* Under no circumstances shall the transmitter operate unintentionally during the test.	Operate as intended, for equipment type II the communication link may be lost, but shall be recoverable by user No degradation of performance Lost functions shall be self-recoverable

Equipment	Asset #	Manufacturer	Model #	Serial #	Cal Date	Cal Due
Programmable Power Source	00864	Pacific	345AMXT-UPC32	0246	12-4-06	12-4-08

Ambient Temperature: 23°C Relative Humidity: 55%

ETSI EN 301 489-1

Table 19: Surge -AC Mains (EN61000-4-5)
Tested By:

Voltage level	Insertion points:	0 degrees input +voltage-	90 degrees input +voltage-	180 degrees input +voltage-	270 degrees input +voltage-	Performance Criteria
1 kV	Line 1 – line 2	Pass	Pass	Pass	Pass	TT/TR / A
2 kV	Line 1 – ground	Pass	Pass	Pass	Pass	TT/TR / A
2 kV	Line 2 – ground	Pass	Pass	Pass	Pass	TT/TR / A

- TT=Transient [phenomena applied to] Transmitters
- TR= Transient [phenomena applied to] Receivers

Notes: EUT was tested in transmit mode (at the lab) and standby mode (in-situ testing).

Table 20: Surge –Telecommunication Port (EN61000-4-5)
Tested By:

Voltage level kV	Cable	pass / fail +	pass / fail -	Performance Criterion
0.5	Telecommunication Port (connected directly to a telecom network) Ethernet	NA	NA	NA

NA = Not Applicable because the ethernet cable is not used as a network connection since it connects to a locally located host PC.
Notes: Transmit Mode.

Table 21: Surge –Telecommunication Port (EN61000-4-5)
Tested By:

Voltage level kV	Cable	pass / fail +	pass / fail -	Performance Criterion
0.5	Telecommunication Port (connected directly to a telecom network) Ethernet	Pass	Pass	TT/TR / A

Notes: EUT was tested in standby mode (in-situ testing).

Surges common and differential mode Criteria **(ETSI EN 301 489-3 Subclause 6.5 and 6.7)**

Class 3 SRD Equipment		
Criteria	During Test	After test
A and B	May be loss of function (one or more) No unintentional responses *For Transmitters TT* - tests shall be repeated in standby mode. *For transceivers CR or TR ONLY:* Under no circumstances shall the transmitter operate unintentionally during the test.	Operate as intended, for equipment type II the communication link may be lost, but shall be recoverable by user No degradation of performance Lost functions shall be self-recoverable

Equipment	Asset #	Manufacturer	Model #	Serial #	Cal Date	Cal Due
Surge Generator	Amplifier Research	UCS 500-M	0844	29101	2-16-06	2-16-08

Table 22: Radiated Emission Levels – 8/23/07 Testing

FREQUENCY MHz	METER READING dBµV	CORRECTION FACTORS Ant dB	Amp dB	Cable dB	Dist dB	CORRECTED READING dBµV/m	SPEC LIMIT dBµV/m	MARGIN dB	NOTES
44.991	58.0	11.5	-26.9	0.7	-10.0	33.3	40.0	-6.7	V-1
533.324	55.3	19.0	-27.8	2.3	-10.0	38.8	47.0	-8.2	V-1
62.942	62.3	6.4	-26.8	0.9	-10.0	32.8	40.0	-7.2	V-2
53.098	60.4	8.1	-26.9	0.7	-10.0	32.3	40.0	7-7	V-2

Test Method: ETSI EN 301 489-1 V1.3.1 (2001-09)
Spec Limit: EN55022 Class A
Test Distance: 3 Meters
Tested By:

NOTES: V = Vertical Polarization
1=SC-100
2=T-Cop

COMMENTS: **Model SC-100** - Unshielded CAT 6 Ethernet cable is routed outside the chamber to a remote workstation LCU. Changed the configuration to transfer large files between the SCU and the LCU at 1000BaseT. Radiated emissions 30-1000 MHz.
Model T-Cop: Equipment is on top of wooden table 80 cm above ground. I/O cables are routed up from the Touch Panel to a PVC support pipe, then back down to the SCU. AC adapter is on the table. Current production cables for video and USB, no ferrites. Power supply cable for touch panel is from manufacturer, contains a ferrite. Radiated emissions 30-1000 MHz.

(ETSI EN 301 489-1 Subclause 8.2.3, Table 5)

Frequency Range	Quasi-peak
30 - 230 MHz	40 dBuV/m
>230 - 1000 MHz	47 dBuV/m

REFERENCE NUMBER OF TEST EQUIPMENT USED (see Table A).

Table 23:Conducted Emission Levels – 8/23/07 Testing									
	METER	CORRECTION FACTORS				CORRECTED	SPEC		
FREQUENCY MHz	READING dBµV	Cable dB	Att dB	HPF dB	Lisn dB	READING dBµV/m	LIMIT dBµV/m	MARGIN dB	NOTES
9.427	41.9	0.1	9.7	0.1	0.1	51.9	60.0	-8.1	W
9.391	41.7	0.1	9.7	0.1	0.1	51.7	60.0	-8.3	B
9.427	41.5	0.1	9.7	0.1	0.1	51.5	60.0	-8.5	B
28.499	40.9	0.2	9.8	0.2	0.3	51.4	60.0	-8.6	W
28.109	40.8	0.2	9.8	0.2	0.3	51.3	60.0	-8.7	W
28.301	40.8	0.2	9.8	0.2	0.3	51.3	60.0	-8.7	W

Test Method: ETSI EN 301 489-1 V1.3.1 (2001-09)
Spec Limit: EN55022 Class A
Tested By:

NOTES: W = White
B = Black

COMMENTS: **Model T-Cop**: Equipment is on top of wooden table 80 cm above ground. I/O cables are routed up from the Touch Panel to a PVC support pipe, then back down to the SCU. AC adapter is on the table. Current production cables for video and USB, no ferrites. Power supply cable for touch panel is from manufacturer, contains a ferrite. Conducted emissions 15-30 MHz.

AC Mains Limits **(ETSI EN 301 489-1 Subclause 8.4.3 Table 8)**

Frequency Range	Quasi-peak	Average
.150-.500 MHz	66-56 dBuV	56-46 dBuV
>.500-5 MHz	56 dBuV	46 dBuV
>5-30 MHz	60 dBuV	50 dBuV
Note: The limit decreases linearly with the logarithm of frequency in the range .150 MHz to .500 MHz.		

REFERENCE NUMBER OF TEST EQUIPMENT USED (see Table A).

ETSI EN 301 489-1

Table 23: Electrical Fast Transient Burst (EFTB) Power Cable (EN61000-4-4) – 9/20/07
Tested By:

EFTB insertion point	+ 2 kV	- 2 kV	Performance Criteria / Met
Line to Ground	Pass	Pass	TT/TR / A
Neutral to Ground	Pass	Pass	TT/TR / A
Protective Earth (PE) to Ground	Pass	Pass	TT/TR / A
Line/Neutral/PE to Ground	Pass	Pass	TT/TR / A

- TT=Transient [phenomena applied to] Transmitters
- TR=Transient [phenomena applied to] Receivers

Notes: 2.5kHz Pulse Repetition Frequency. EUT was tested in-situ.

Table 24: Electrical Fast Transient Burst (EFTB) Signal, I/O, DC Ports (EN61000-4-4) – 9/20/07
Tested By:

Cable tested	+ 1 kV pass / fail	- kV pass / fail	Performance Criterion
Signal Lines: Ethernet Cable LCUSCU	Pass	Pass	TT/TR / A
Control Lines	NA	NA	NA
DC power input	NA	NA	NA

- TT=Transient [phenomena applied to] Transmitters
- TR=Transient [phenomena applied to] Receivers

NA=Not Applicable because the EUT has no control or DC power lines.
Notes: EUT was tested in-situ.

Fast Transient common mode Criteria **(ETSI EN 301 489-3 Subclause 6.5 and 6.7)**

Class 3 SRD Equipment		
Criteria	During Test	After test
A and B	May be loss of function (one or more) No unintentional responses *For transceivers-CR or TR only:* Under no circumstances shall the transmitter operate unintentionally during the test.	Operate as intended, for equipment type II the communication link may be lost, but shall be recoverable by user No degradation of performance Lost functions shall be self-recoverable

Equipment	**Asset #**	**Manufacturer**	**Model #**	**Serial #**	**Cal Date**	**Cal Due**
EFT Generator	Amplifier Research	UCS 500-M	0844	29101	2-16-06	2-16-08
Capacitive Coupling Clamp	Amplifier Research	None	00868A	24945	7-9-07	7-9-09

ETSI EN 301 489-3

Table 25: Conducted Immunity (EN61000-4-6) – 9/20/07
Tested By: [illegible]

Cable Tested:	Amplitude	Frequency Range	Pass/fail	Performance Criteria / Met
Signal Lines:				
Ethernet Cat6, unshielded LCU/SCU	3 Vrms	.150-80MHz	Pass	CT/CR / A
Ethernet (Green)	3 Vrms	.150-80MHz	Pass	CT/CR / A
Ethernet (Red)	3 Vrms	.150-80MHz	Pass	CT/CR / A
Ethernet (Front)	3 Vrms	.150-80MHz	Pass	CT/CR / A

- CT=Continuous [phenomena applied to] Transmitters
- CR= Continuous [phenomena applied to] Receivers

Notes: EUT was tested in-situ.

RF common mode Performance Criteria **(ETSI EN 301 489-3 Subclause 6.4 and 6.6)**

Class 3 SRD Equipment		
Criteria	During Test	After test
A and B	May be loss of function (one or more) No unintentional responses *For transceivers-CR:* Under no circumstances shall the transmitter operate unintentionally during the test.	Operate as intended, for equipment type II the communication link may be lost, but shall be recoverable by user No degradation of performance Lost functions shall be self-recoverable

Equipment	Asset #	Manufacturer	Model #	Serial #	Cal Date	Cal Due
Coupling Decoupling Network	00710	Fischer	P/N: FCC-801-M3-16	221	4/5/06	4/5/08
Injection Probe	00699	Fischer	F-120-3	24	7/17/2007	7/17/09
Monitoring Probe	00731	Fischer	F-35	296	4/10/07	4/10/09
Amplifier	01367	Amplifier Research	150A100A	18241	6/1/07	6/1/09
Directional Coupler	00866	Werlatone	02650	5155	7/12/07	7/12/09
Spectrum Analyzer	01377	HP	8568B	2601A02378	6/30/06	6/30/08
SA Display	01377A	HP	85662A	2542A10641	6/30/06	6/30/08
Signal Generator	01363	Marconi	2022D	119194/005	1/22/07	1/22/09

ETSI EN 301 489-1

Table 26: Surge -AC Mains (EN61000-4-5) – 9/20/07
Tested By:

Voltage level	Insertion points:	0 degrees input +voltage-	90 degrees input +voltage-	180 degrees input +voltage-	270 degrees input +voltage-	Performance Criteria
0.5 kV	Line 1 – line 2	Pass	Pass	Pass	Pass	TT/TR / A
1 kV	Line 1 – line 2	Pass	Pass	Pass	Pass	TT/TR / A
0.5 kV	Line 1 – ground	Pass	Pass	Pass	Pass	TT/TR / A
1 kV	Line 1 – ground	Pass	Pass	Pass	Pass	TT/TR / A
2 kV	Line 1 – ground	Pass	Pass	Pass	Pass	TT/TR / A
0.5 kV	Line 2 – ground	Pass	Pass	Pass	Pass	TT/TR / A
1 kV	Line 2 – ground	Pass	Pass	Pass	Pass	TT/TR / A
2 kV	Line 2 – ground	Pass	Pass	Pass	Pass	TT/TR / A

- TT=Transient [phenomena applied to] Transmitters
- TR= Transient [phenomena applied to] Receivers

Notes: EUT was tested in-situ.

Surges common and differential mode Criteria **(ETSI EN 301 489-3 Subclause 6.5 and 6.7)**

Class 3 SRD Equipment		
Criteria	During Test	After test
A and B	May be loss of function (one or more) No unintentional responses *For Transmitters TT* - tests shall be repeated in standby mode. *For transceivers CR or TR ONLY:* Under no circumstances shall the transmitter operate unintentionally during the test.	Operate as intended, for equipment type II the communication link may be lost, but shall be recoverable by user No degradation of performance Lost functions shall be self-recoverable

Equipment	Asset #	Manufacturer	Model #	Serial #	Cal Date	Cal Due
Surge Generator	Amplifier Research	UCS 500-M	0844	29101	2-16-06	2-16-08

TABLE A: TEST EQUIPMENT LIST - EMISSIONS

The following list of test equipment was used during emissions testing. For equipment used during immunity testing, refer to the individual immunity tables.

Radiated Emissions

Function	S/N	Calibration Date	Cal Due Date	Asset #
S.A., Display HP-85662A	2542A12169	11/28/2005	11/28/2007	02662
S.A., RF Section HP-8568B	2601A02492	11/28/2005	11/28/2007	02663
QP Adapter	2521A00909	07/12/2006	07/12/2008	00683
Antenna	2630	01/24/2005	01/24/2007	00852
Cable	None	06/21/2005	06/21/2007	P05299
Cable	None	06/21/2005	06/21/2007	P05300
Cable	None	06/21/2005	06/21/2007	P05296
HP8447F opt H64 preamp	2944A03850	03/05/2005	03/05/2007	00501

Conducted Emissions

Function	S/N	Calibration Date	Cal Due Date	Asset #
Attenuator	none	10/20/2005	10/20/2007	02223
LISN	9408-1006	05/23/2005	05/23/2007	00493
TTE High Pass Filter	H4120	04/20/2005	04/20/2007	05258
20' RG214		04/12/2006	04/12/2008	P00888
Cable, Preamp to Analyzer	CNT-195	01/03/2005	01/03/2007	01187
SA Display	2112A02174	08/22/2006	09/22/2008	02509
SA RF	22049A01408	08/22/2006	08/22/2008	00313

I/O Conducted Emissions

Function	S/N	Calibration Date	Cal Due Date	Asset #
S.A., Display HP-85662A	2542A12169	11/28/2005	11/28/2007	02662
S.A., RF Section HP-8568B	2601A02492	11/28/2005	11/28/2007	02663
Attenuator	none	10/20/2005	10/20/2007	02223
LISN	9408-1006	05/23/2005	05/23/2007	00493
TTE High Pass Filter	H4120	04/20/2005	04/20/2007	05258
QP Adapter	2521A00909	07/12/2006	07/12/2008	00683
Cable		06/13/2006	06/13/2008	AN 00880

Flicker and Harmonics Emissions

Function	S/N	Calibration Date	Cal Due Date	Asset #
Programmable Power Source	0246	12/02/2004	12/02/2006	00864
Universal Power Analyzer	AB2955	11/22/2004	11/22/2006	00840

Radiated Emissions 8/23/07

Function	S/N	Calibration Date	Cal Due Date	Asset #
Antenna	2630	12/30/2006	12/30/2008	00852
Pre-amp	2944A03850	01/02/2007	01/02/2009	00501
E4446A Spectrum Analyzer	US44300408	03/05/2007	03/05/2009	02668
Cable	None	04/02/2007	04/02/2009	P05299
Cable	None	04/02/2007	04/02/2009	P05296
Cable	None	04/05/2007	04/05/2009	P05300

Conducted Emissions 8/23/07

Function	S/N	Calibration Date	Cal Due Date	Asset #
LISN, Emco 3816/2	9408-1006	04/02/2007	04/02/2009	00493
QP Adaptor	2521A00904	08/22/2006	08/22/2008	02495
S.A., Display HP-85662A	2112A02174	08/22/2006	08/22/2008	02509
S.A., RF Section HP-8568A	2049A01408	08/22/2006	08/22/2008	00313
TTE High Pass Filter	H4120	01/17/2007	01/17/2009	05258
10 dB Pad		10/20/2005	10/20/2007	02223
15' RG214		03/01/2006	03/01/2008	P00875

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EMC International Services: Radiated Emissions Testing and Power Density Calculations

June 26, 2005

Safeview, Inc.
Suite 110
469 El Camino Real
Santa Clara, CA 95050

Subject: Radiated Emissions Testing and Power Density Calculation

Dear Mr. ,

This letter provides details on a power density calculation that is based on a field strength measurement taken on the Guardian 100 system in our 10 meter semi-anechoic chamber on April 25, 2005.

The unit under test was configured to transmit a continuous wave signal (sweeping stopped) at 26.378 GHz. A field strength of 93.67 dBμV/m was measured from a distance of 2.5 m from the unit.

Converting this field strength into μV/m we have:

Peak Field Strength (μV/meter) = $10^{\text{field strength in dB}\mu\text{V}/20}$ = 4.83×10^{4} μV/meter = 4.83×10^{-2} volts/meter

The theoretical equivalent isotropic radiated power (EIRP) of the unit under test is given by the formula:

EIRP (Watts) = $((\text{field strength})^2 \times 4 \times \text{Pi} \times R^2)/120 \times \text{Pi}$ where R is the distance between the unit under test and the measurement antenna.

At 2.5 meters from the antennas the EIRP is:

EIRP (Watts) = $((4.83 \times 10^{-2})^2 \times 4 \times 3.1416 \times 2.5^2)/377 = 4.86 \times 10^{-4}$ Watts

Converting this to dBm we have:

EIRP (dBm) = 10 Log (4.86×10^{-4} Watts) = -3.14 dBm

This represents the theoretical transmit power of the unit under test in terms of a point (isotropic) source.

When the unit under test operates as intended (with the sweeping not stopped), the transmitter sweeps from 24.25 to 30 GHz on one antenna. After this sweep is done, the next antenna in the array is swept. This process repeats until all antennas in the array have been swept. Due to the sweeping and also the spatial variance of transmitting from different antennas, a duty cycle figure can be calculated to determine how often transmission occurs at any one given frequency and at any one point in space. The following calculations show the duty cycle correction:

Duty Cycle calculation:

1. Duty Cycle (frequency ramp)

   Frequency bandwidth = 24.25-30 GHz = 5750 MHz

   Sweep rate = 1.1MHz/ns

   Therefore, active ramp time per element (nsec) = 5.43 microseconds

   The system then pauses for 2.65 microseconds between sweeps.

   Total spatial sample time per element = 5.43 + 2.65 = 8.08 microseconds

   Duty cycle (ramp time) = 10 Log (5.43/8.08) = -1.7 dB

2. Duty cycle (data sampling)

   The full mast of elements system takes 3.1 msec for a complete cycle:

   Spatial sample time per element x 2 sweeps/element x 192 elements/mast
   = 7.8 microseconds x 2 x 192 = 3.1 msec.

   Each mast samples 362 times around the periphery of the portal system

   Total data sampling time = 3.1 msec x 362 = 1.12 seconds

   Total system scan time = 1.5 seconds, to complete a scan, including movement of doors, motor latency, etc…

   Duty cycle (data sampling time) = 10 Log (1.12/1.5) = -1.3 dB

3. Duty Cycle (total system sweep time)

   Total system scan time = 1.5 seconds, to complete a scan, including movement of doors, motor latency, etc…

   The sweep interval (time between one scan and the next scan (system max throughput) = 10 seconds

   Duty cycle (data sampling time) = 10 Log (1.5/10) = -8.2 dB

4. Duty Cycle (assuming a person is scanned once every 30 minutes)

   Total system scan time = 10 seconds, to complete a scan, including movement of doors, motor latency, etc…

   The sweep interval (time between one scan and the next scan (system max throughput) = 30 minutes

   Duty cycle (data sampling time) = 10 Log (10/1800 sec) = -22.5 dB

With the above duty cycles it is possible to correct the theoretical EIRP to account for the transmitter time and space variances.

EIRP + sum(combined duty cycles)

EIRP (dBm) = -3.1 – 1.7 – 1.3 – 8.2 – 22.5 = -36.8 dBm = 0.208 μW

Now that we have determined the corrected EIRP, the power density is given by the formula:

Power density = $(\text{Field strength})^2/120 \times \text{Pi}$

We can represent field strength in terms of theoretical EIRP by:

$(\text{Field Strength})^2 = \text{EIRP} \times 120 \times \text{Pi}/4 \times \text{Pi} \times R^2$

Using the above field strength calculation in the above power density equation results in:

Power density = $\text{EIRP}/ 4 \times \text{Pi} \times R^2$

The smallest distance a person can physically be from an antenna is 2 cm. This is due to the positioning and presence of the radome. A typical distance a user would be is 40 cm but we choose to use to the 2 cm distance to show the worst case.

Power density = $0.208\ \mu W/ (4 \times 3.14 \times (2cm)^2) =$ **$0.004\ \mu W/cm^2 = 4 \times 10^{-6}\ mW/cm^2$**

Based on the measurement data we made and the above calculations we concur that the unit under test does not exceed a power density of 1 mW/cm^2.

Please feel free to contact us if you have any further comments or questions.

Sincerely,

Staff Engineer

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