The Visible Assets, Inc. RuBee™ IV Visibility Network: Electromagnetic Interference, Electromagnetic Compatibility and Safety Issues
DOC V 3.15C

1 Summary

1.1 Overview

The Visible Assets Inc. (VAI) RuBee system (including RuBee devices, tags, readers, loop antennas, and active shelves) is a low frequency inductive (LF), ultra-low power, two-way, smart radio tag system. The RuBee IV protocol was designed to work reliably over a long range, wide area (50'-100') in harsh environments (i.e., near metals and liquids), with an extended battery life (10-15 years), and a safety standard consistent for use in any healthcare application. The system design goal was to create a two-way radio tag that could be safely used in hospital patient-based settings, hospital operating rooms, airports and other public facilities with no risk to hearing aid wearers, pacemaker, or IDC patients and with no Electromagnetic Interference (EMI) or Electromagnetic Compatibility (EMC) issues.

The RuBee protocol uses a full duplex 131 KHz data carrier with phase and amplitude modulated data communications. Due to the long wavelength, very little, if any, energy is dissipated at these low frequencies in the form of an electric field (**E**), and most radiated energy (99.99%) is in the form of a magnetic field (**H**). The radio tags, typically, require a minimum signal of 0.1 mgauss to a maximum of about 3 mgauss for reliable communication. The strongest field in direct contact with a typical RuBee antenna is 800 mgauss and within one meter drops to about 2 mgauss. To help provide some context for these values, the earth's magnetic field is 300-600 mgauss.

1.2 Conclusions

Based on material provided below and an independent laboratory certification under 47CFR15.209 (see **Appendix A**), we conclude that the VAI RuBee protocol:

1. Meets FDA, FCC and AHA recommendations for safe use in hospitals, as suggested by 47CFR15.209.

2. Has no serious known Electromagnetic Interferences (EMI) or Electromagnetic Compatibility (EMC) issues or safety issues in hospitals, airports, public buildings, homes, or other likely operating environments.

3. Has no known effect on biologics, biochemicals or living systems.

4. Is below all government and peer-reviewed published specifications for both electric and magnetic fields for safe use near pacemakers, IDCs, and all known medical equipment.

The VAI system radiates far less electric and magnetic power than most appliances found in any home, including vacuum cleaners, drills, hair dryers, power lines, electric blankets, electric stoves, televisions, most fluorescent lighting systems and computers. RuBee tags emit thousands (1,000's) of times less power and RuBee routers emit tens (10's) times less power than airport security systems or anti-theft security systems found in retail stores. In general, one of the major advantages of the RuBee system is that it is ultra-low power and safe in any known setting, yet can work over long ranges as well as around steel and liquids.

2 Summary of the Government Regulations and Safety Recommendations

Many organizations have established safety standards for electromagnetic radiation including the FCC, FDA, OSHA, IEEE, ANSI, IEC, ACGIH, and AHA. Most importantly is the FCC since they regulate use of radio transmitters and issue licenses to operate any radio transmitter in the U.S. The FCC allows for many exemptions at specific frequencies, providing the power that is transmitted is below certain limits. This unlicensed use of the airwaves regulation is known as a “Part 15” exemption.

Unfortunately, no universal electromagnetic field safety standard exists. Government recommendations, and even the units and measurement methods used to specify field strength, vary widely from one organization and one country to another. We provide a brief summary of each regulation and/or known recommendation below with a comparison to the VAI field strength under each regulation or recommendation.

1. **47CFR15.209** - VAI RuBee tags and readers as used on hospital smart shelves have been independently certified (see ***Appendix A***) under the FCC Part 15.209, also known as "Part 15" certification, and have a signal strength of 183 uV/m at 30 meters. This means the FCC has, effectively, said we do not need a license to transmit.

2. **47CFR18.101-18.311** - 47CFR Part 18 is the safety act that defines and limits power for all radio transmitters used in industrial, scientific and medical (ISM) equipment. The VAI system falls into the category of below 1.7 MHz and meets this regulation by virtue of meeting Part 15 certification in "1." (noted above). Specifically, we do not interfere or overlap with any of the prohibited frequency bands listed in 18.303, used for search and rescue or safety frequencies.

3. **47CFR2 and 95** - Rules allocating new frequencies for wireless medical telemetry, under docket 99-255 dated June 12, 2000. By virtue of Part 15 certification, VAI RuBee systems do not have any power in any of the allocated medical telemetry frequencies.

4. **OET Bulletin 56** - This document summarizes safety issues related to RF exposure and its use in the workplace, and is an FCC summary reference document for OSHA federal regulations, as well as for EPA regulations (OET Bulletin 56, Questions and Answers about Biological Effects and Potential Hazards of Radio Frequency Electromagnetic Fields, R.F. Cleveland and J.L. Ulcek, Aug. 1999, 4th ed.). These safety regulations actually exclude frequencies under 300 KHz, presumably because they have no known risk and, therefore, do not provide any suggested maximum power levels for 131 KHz.

5. **ANSI C63** - VAI systems meet the recently issued ANSI C63 standard for hearing aids. We have minimal unintentional power in the range used by t-Coil systems or by inductive loops used in t-Coil communication systems. We have not obtained an independent test, but have carried out internal tests and have used selected t-Coil systems to confirm that we do meet ANSI C63. A t-Coil-equipped hearing aid placed in t-Coil mode must be within 8-10 inches of a long-range directional RuBee antenna for audible t-Coil detection, and one to three inches for all other antennas. This noise is similar to noise heard in a t-Coil mode hearing aid when within 10 inches of a CRT or within 10 inches of a fluorescent light ballast. Hearing aids in normal mode (that is, not in t-Coil mode), have no audible effects or other effects near a RuBee antenna.

6. **FDA and AHA** - As a result of Part 15 certification, VAI systems also meet the 3 V/m @ 1 meter safety standard suggested by the FDA for safe use of RF equipment in hospitals (see Medical Devices and EMI: The FDA Perspective, Don Witters, Jan. 13, 2000). The American Hospital Association has also endorsed this as a safe level. Under our Part 15 certification, the VAI power level at 1 meter is 0.50 V/m, or about 6 times lower than the suggested maximum.

7. **ACGIH** - The VAI system is, typically, below the international standard of 100,000 nT (or 1,000 mgauss) for magnetic fields for safe exposure to wearers of pacemakers and IDC's set by the American Conference of Industrial Hygienists (ACGIH). The VAI average field strength in areas where tags are read is 1-3 mgauss, or 250 to 1000 times less than the standard. The maximum field strength at 8 inches from the antenna is 100-200 mgauss, 5-10 times below the standard. The VAI systems are below published levels that may cause interference (see Hitchcock and Paterson 1994, Harris et. al. 2000, McIvor et. al. 1998, Silny 1998, Boivin et. al. 2003, Frank 2000, Hayes 2000).

8. **ACGIH -** The VAI systems are below the international standard of 5,000 V/m for electric fields for safe exposure to wearers of pacemakers and IDC's set by the American Conference of Industrial Hygienists (ACGIH). The VAI average electric field strength in areas where tags are read is from 100mV/m to 1 V/m, about 5000 times less than the recommendation.

9. **IEC 60118-4** - VAI large area loop antennas are about 50% below the international IEC 60118-4 standard for optimal field strength used in Audio Loop Systems (ALS), which are placed in auditoriums for hearing aid t-Coil wearers. The normal center field strength in the center of the loop is 400mA/m or about 6.2 mgauss. We, typically, have 200 mA/m (about 1-3 mgauss) in the center of any large area loop antennas.

10. **IEC 60601-1-2** - The International Standard for medical electrical equipment – general requirements for safety and electromagnetic compatibility (EMC), requirements and tests. IEC 60601 has no requirements for intentional radiators with frequencies below 150Khz. The RF EMC requirements it does have refer to standards maintained by country of use with some limits.

11. **IEEE STD C95.1 1999** - The IEEE standard for safety levels to electromagnetic fields (STD C95.1 1999) sets a maximum level for magnetic fields in the workplace for 131 KHz of 163 A/m (2,047 mgauss). VAI has a maximum field strength at the antenna of about 3.4 times less on direct contact of the antenna and 1,000 less than this level and typical field strength (1-3 mgauss) or -30db (1,000) times less than this level in most typical locations.

12. **29CFR 1910.97. OSHA regulation relies on IEEE STD C95.1.** For normal environmental conditions and for incident electromagnetic energy of frequencies from 10 MHz to 100 GHz, the radiation protection guide is 10 mW/cm^2 (milliwatt per square centimeter) as averaged over any possible 0.1-hour period. This means the following: Power density: 10 mW/cm^2 for periods of 0.1-hour or more. Energy density: 1 mW.-hr./cm^2 (milliwatt hour per square centimeter) during any 0.1-hour period. It does not comment or provide for field strength below 10 Mhz. We assume reduced risk because of the published Specific Absorption Rate (SAR) used by OSHA (see below details.)

3 Other EMI, EMC and Safety Considerations

1. Frequencies below 500 KHz have been approved in many medical devices by the FDA for implantation into humans, including use in programming pacemakers, IDC and RF-ID tags, again, emphasizing the general acceptance of devices operating at the below 500 KHz range in a healthcare setting.

2. VAI systems (from a previous company) have been in use in retail stores for over 15 years and 100's of millions of consumers have been exposed to these systems. In that 15 year period, not a single untoward event has ever been reported.

3. Electronic Article Surveillance (EAS) used in most retail stores to prevent theft have fields as high as 13,400 mgauss at the antennas exposed in the store, with electric fields of 23.8 V/m (Boivin, et al. 2003; Frank et al., 2000; Hayes et al., 2000, and Harris et al. 2000). Over the last ten years, approximately 60 cases have been reported of pacemaker wearers skipping a beat when too close to the vertical. The FDA sent an information letter in September of 1998 saying that risk was low and even the reported events caused little risk to patients, but suggested that cardiologists tell patients with implanted devices to not "hug" or stand too close to the vertical pillars. The VAI systems have field strengths under Part 15; many thousand times lower than any EAS system.

4. Metal detectors at airports have been reported to produce signals of 3,000 to over 4,000 mgauss (Boivin, et al., 2003; Frank et al., 2000; Hayes et al., 2000, and Harris et al., 2000) and the same FDA letter issued in September 1998 recommended caution for pacemaker wearers. Again, the VAI systems are many hundreds of times lower power than any of the walk-through metal detectors, including hand-held detectors. The standards for these detectors are (since 9/11) regulated by the Justice Department (NIJ Standard-0601.02) and the FAA, and power ranges appear to no longer be limited to Part 15 standards.

5. Electric drills, hairdryers, electric blankets, televisions using a CRT, and computer terminals using a CRT are all known to act as electromagnetic radiators. VAI systems produce magnetic and electric fields many times less than most common household appliances.

6. CRT's (computers and televisions) may be affected by AC magnetic fields in the 1,000 mgauss range. We find that the image on a CRT may be distorted if a long-range directional antenna is placed within about 6 inches of direct contact to any CRT. It is not affected by area loop antennas or the active shelves. If an EKG machine were placed on top of an antenna, it might affect the quality of the display.

In short, the signals produced by the VAI system are many hundreds of times lower than the signal produced by walk-through security systems now used at all airports, and EAS systems used in retail stores. The VAI system produces about the same field strength as a 24-inch TV screen or computer screen, and much less than an electric blanket. Similar systems to VAI's have been in use in retail and other public settings for over two decades without a single reported untoward event.

4 Comparison VAI Field Strength with Other Common Radiators

We have compiled a list of the field strengths given by many common items and compared them to field strengths found in VAI systems. We have converted all readings to North American standard for **H** of mgauss or milligauss.

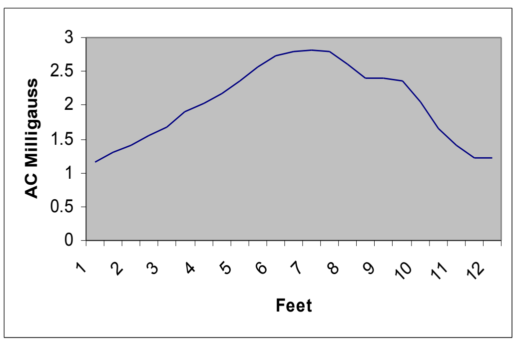
Item	**Field (milligauss)**	**Distance**	**REF**
Electric Blanket	30-90	Surface	1
Microwave Oven	10-100	Surface	1
IBM Personal Computer	5-10	Top of Monitor	1
IBM Personal Computer	0-1	15" from Monitor	1
Electric Drill	500-2000	At Handle	1
Hair Dryer	200-2000	At Handle	1
HF Transceiver	10-100	Top Cabinet	1
HF Transceiver	1-5	15" from Cabinet	1
1-kW RF Amplifier	80-1000	Front Top Cabinet	1
1-kW RF Amplifier	1-25	15" from Front	1
Walk-Through Metal Detector	2,000-3,741	In Detector	3

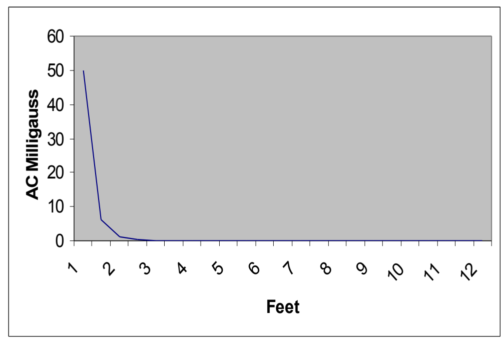
Hand-held	50-76	Next To Detector	3
Hand-held	120	Next To Detector	2
Electronic Article Systems (EAS)	5,000-13,384	Next To Antenna	4
VAI RuBee System			
Visible Active Shelf	250-40	Surface	2
Visible Shelf	2-3	12" from Front	2
HiGain Directional Antenna	700	Surface	2
HiGain Directional Antenna	5-10	12"	2
HiGain Directional Antenna	2-3	24"	2
LoGain Directional	15-30	Surface	2
LoGain Directional	2-3	12"	2
Floor Loop 24' Side	10-20	On Top of Loop	2
Floor Loop 24' Side	2-3	1 meter over Surface	2

Source 1	Chapter 9 of the 1997 ARRL Handbook for Radio Amateurs, Copyright © 1996, (ARRL RF Safety Committee)
Source 2	Visible Assets Internal Measurements
Source 3	Characterization of the magnetic fields around walk-through and hand-held metal detectors. Boivin, W., Coletta, J., Kerr, L., Health Phys. 2003 May; 84(5):582-93.

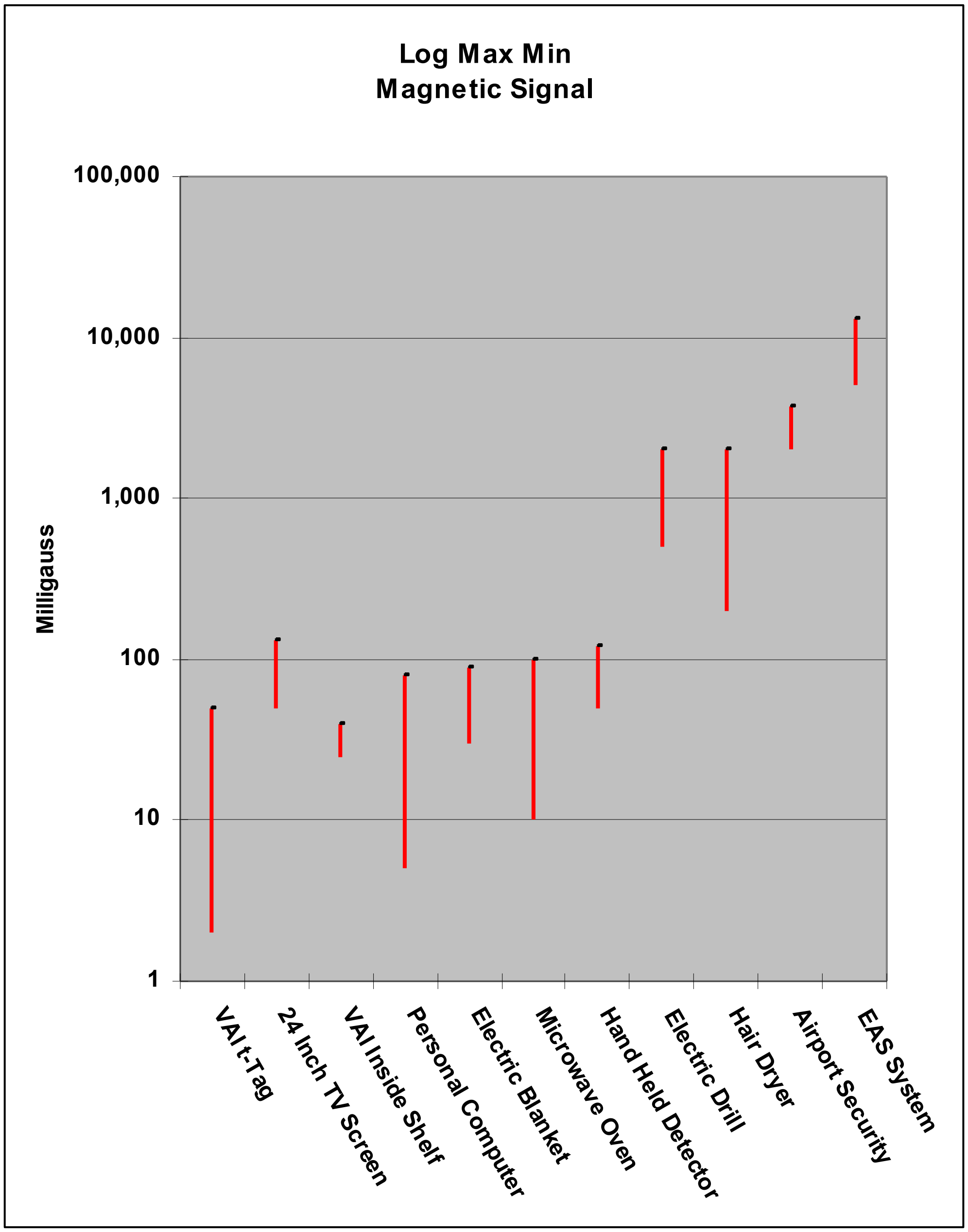
Source 4	Electromagnetic field strength levels surrounding electronic article surveillance (EAS) systems. Harris, C., Boivin, W., Boyd, S., Coletta, J., Kerr, L., Kempa, K., Aronow, S.; Health Phys. 2000 Jan; 78(1):21-7.

Table 1 Field strength of various devices compared to VAI RuBee System.





On the left, is the 131 KHz field strength at one meter height over an area loop antenna with a diameter of 10 feet. The graph shows that the field varies between 1 and 2.7 mgauss. On the right, is the field strength for a directional loop antenna (2 feet x 1.5 feet) used in the active asset shelves. Distance is from the center of the loop. The measured maximum in direct contact with the loop is about 50 mgauss and drops rapidly at three feet to below 1 mgauss.



Graph adapted from **Table 1** plots - max/min of many devices on log scale. On the left is the VAI RuBee system.

5 Pacemaker and ICD Safety Issues

The FDA issued an "informational" letter in September 1998 that suggested physicians warn pacemaker and ICD implant patients to be cautious near Electronic Article Systems' (EAS) antennas, as well as near airport metal detectors. This letter was based on what the FDA categorized as "very few" and minor reported incidents over the course of the last ten years.

In general, the manufacturers and other professional organizations recommend caution, but none believe or suggest that individuals are in any serious danger from these systems (see AHA guidance below) and many independent studies have shown that extremely high fields in the range of 20,000 mgauss or more are required to have any effect on implantable devices (see Hitchcock and Paterson, 1994; Harris et al., 2000; McIvor et al., 1998; Silny, 1998; Bovin et al., 2003; Frank, 2000; Hayes, 2000). The VAI RuBee system has many thousands of times less power than any airport security or EAS system and is 10,000 times below the levels suggested in the literature that might put an individual at risk.

Many of the implantable devices are programed using below 500 KHz Part 15 frequencies (e.g., Medtronic 147 KHz). However, the communications protocol used to program a unit is a proprietary protocol with an encrypted password and login at the start and an additional security word several bytes long linked to each block transmission, making it impossible to accidentally login and program the unit. Medtronic has assured the company that it is impossible to maliciously or accidentally re-program any implantable unit.

American Heart Association Pacemaker Recommendation

If you have an artificial pacemaker, be aware of your surroundings and the devices that may interfere with pulse generators:

Home appliances

CB radios, electric drills, electric blankets, electric shavers, ham radios, heating pads, metal detectors, microwave ovens, TV transmitters and remote control TV changers, in general, have **not** been shown to damage pacemaker pulse generators, change pacing rates or totally inhibit pacemaker output.

Several of these devices have a remote potential to cause interference by occasionally inhibiting a single beat. However, most people can continue to use these devices without significant worry about damage or interference with their pacemakers.

6 Occupational Safety & Health Administration 29CFR 1910.97

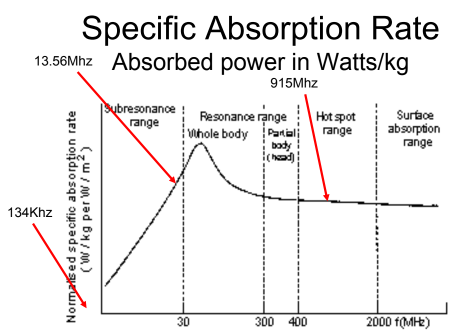
The Occupational Safety & Health Administration (OSHA) works under 29CFR 1910.97 and places upper limits on any RF radiator in the workplace. Much of 1910.97 relies on IEEE and ANSI C95 regulation. 29CFR1910.97 is currently a voluntary regulation and not enforcable in "General Industries".

For normal environmental conditions and for incidental electromagnetic energy of frequencies from 10 MHz to 100 GHz, the radiation protection guide is 10 mW/cm^2 (milliwatt per square centimeter), as averaged over any possible 0.1-hour period. This means the following:

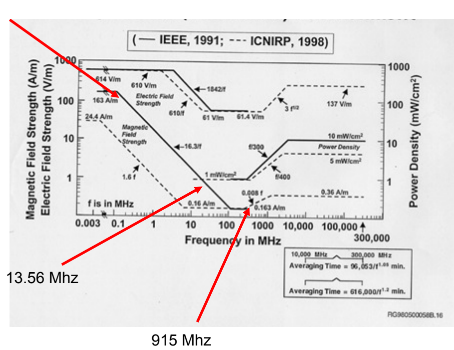
- Power density: 10 mW/cm^2 for periods of 0.1-hour or more.

- Energy density: 1 mWhr./cm^2 (milliwatt hour per square centimeter) during any 0.1-hour period.

The regulations do not include restrictions near 131 Khz, presumably because the Specfic Absorption Rate (SAR) curves (see below) show little absorption at these frequencies. The Maximum Permissible Exposure (MPE) also show high safety values for 131Khz (300 times higher for 13.56Mhz, and 1,000 times higher for 915 Mhz). This means that power may be nearly 1,000 times greater at these low frequncies under 1910.97 and C95 before OSHA considers what might be a health risk.



SAR vs. Frequency



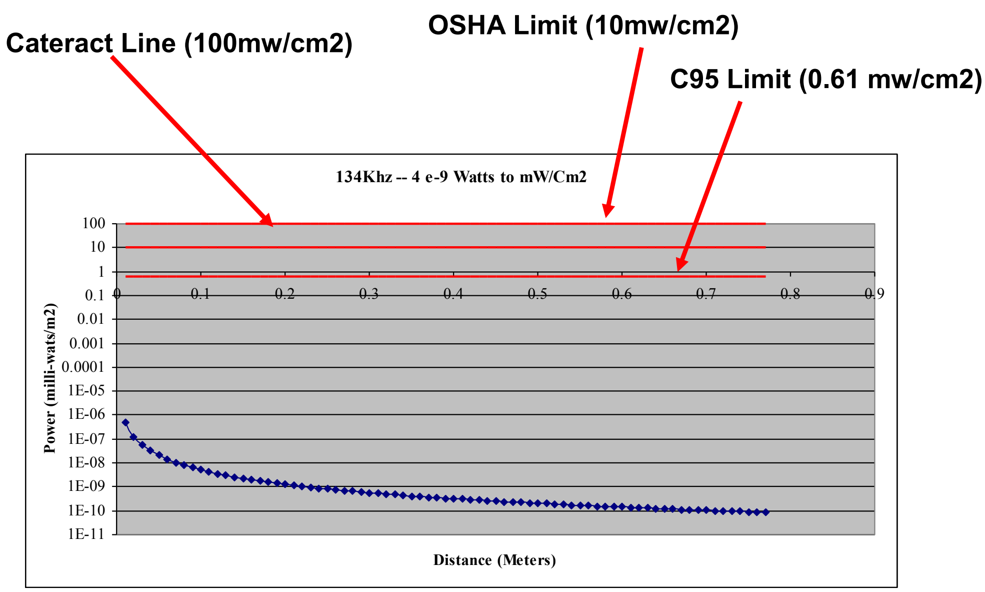
Two figures on left taken from OSHA presented Power Point; **Non-Ionizing Radiation: Standards and Regulations; Bob Curtis, OSHA Salt Lake Technical Center; October 2002.**

Note: Red arrows added by VAI.

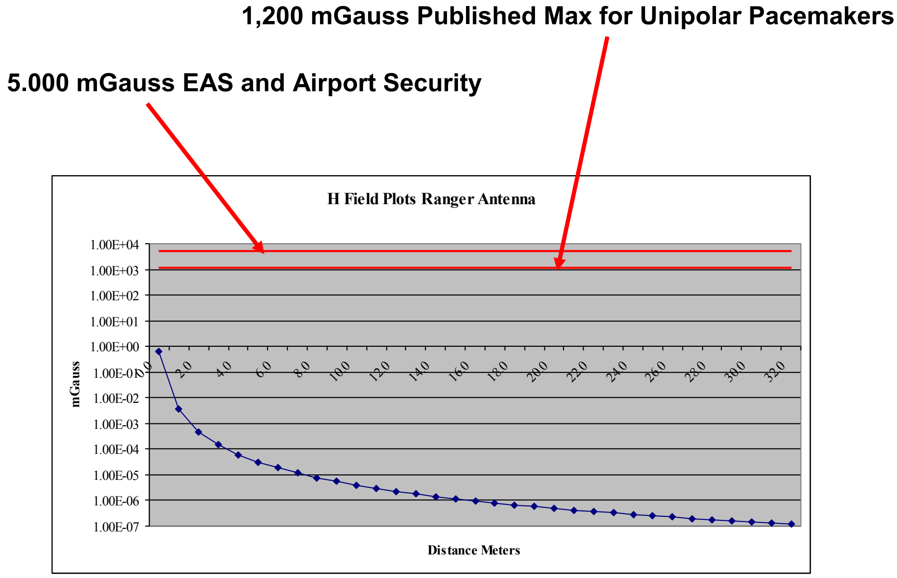
7 Rubee Power Measurements and Summary

A standard ranger antenna using Blaster 10 was used to measure both E and H fields as a function of distance. The E graphs shown below include red lines representing the danger levels for cataract formation, as well as the OSHA limits discussed in Section 6 above and the ANSI C95 for 131 Khz. The Y axis is a log scale. It is clear that the maximum RuBee power levels produced by a standard configuration are many orders of magnitude below these limits. The measured maximum E field is actually about 40 nano-watts.

The lower graph shows the H field as a function of distance from the same ranger antenna. The red lines show the level in mgauss for EAS portals found at many retail stores (5,000 mgauss), as well as the level that has been reported in literature that may affect unipolar pacemakers (1,200 mgauss). The typical bipolar pacemaker (most common today) is 20,000 mgauss and is not shown on the graph. These values are shown in the table on the following page. Again, the maximum RuBee field is significantly below any of the known safety limits. In most cases, exposure is at least a meter or more away from the antenna.



E Field RuBee P1902.1



H Field RuBee P1902.1

Table 2.- Electromagnetic Interference Levels Capable of Pacemaker Interference in Work Environments

Sensitivity	Atrial*		Ventricular*	
setting, mV	Unipolar	Bipolar	Unipolar	Bipolar
0.5	4,509	17,984	1,720	14,240
0.75	5,744	20,000	NA	NA
1.0	7,679	20,000	4,705	18,100
1.5	10,143	20,000	NA	NA
2.0	11,790	20,000	7,454	19,630
3.0	15,034	20,000	10,003	20,000

NA, not available.

*Values in milligauss units.

From Hayes D.L. & Strathmore N.F., Electromagnetic Interference with Implantable Devices. In "Clinical Cardiac Pacing and Defibrillation." Second Edition. Edited by K.A. Ellenbogen, G.N. Kay, B.L. Wilkoff. Philadelphia, W.B. Saunders Company, 2000, pp. 939-952.

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