STUDY OF THE EFFECTS OF ADAMS ELECTRONICS HAND HELD METAL DETECTORS WITH HEART PACE MAKERS AND DEFIBRILLATORS.

Summary of work:

Tests and studies into the interaction of the Electromagnetic Fields generated by Security Hand Held Metal Detectors and implanted medical devices (Pacemakers and Defibrillators)

Introduction:

In accordance with Adams Electronics Inc. policy statements for Quality Assurance in addition to any Legal imperatives, studies are undertaken to evaluate potential risks and ensure product safety. The effects of Electromagnetic Radiation on the environment is the subject of significant research. Whilst some standards and legal requirements are in place; knowledge of the totality of the potential effects from this type of radiation is incomplete: Therefore, the work carried out by Adams Electronics Inc. in this area is of two types:-

> **Testing**: Direct evaluation of the equipment in controlled conditions to ensure that any existing legal requirements are fully met; Additional tests to increase confidence in product safety in general or specific terms.
>
> **Studies**: Evaluation of available literature and standards to provide a theoretical basis for confidence in product safety.

The following document refers to Security Hand Held Metal Detectors typical of the entire range of detectors exclusively manufactured by Adams Electronics Inc. For technical reasons associated with the technology and basis of operation, the following information, results and conclusions can apply to Adams Electronics product range only and are not applicable to other manufactures of Hand Held Metal Detectors or similar devices.

Security Hand Held Metal Detectors are primarily used in the screening of people on an individual basis for the presence of metal objects that may form a potential threat. For example: a concealed weapon. The detector is activated and held about one to two inches from the body area to be screened. Usually the detector is swept across the body in a pattern designed to cover all areas that may be used to conceal metal objects (See attached search pattern). Metallic objects may be concealed in the subjects clothing or in certain cases within the body cavity itself. The output of the detector interacts with the metal, thus causing an effect in the Electromagnetic field which is displayed as an audio visual alarm. The fields generated by the detector effectively deliver energy into the metal target itself. As pacemakers and defibrillators contain metallic components, including electrical circuitry: It is obviously crucial that the energy around the pacemaker will not affect its operation in any way, shape or form.

Basis of Operation:

Not all metal detectors operate on the same principal. Various methods are used to achieve the detection of a metallic object. Examples are as follows: Pulse induction, Balance Bridge, Beat Frequency Oscillation (BFO) etc: However, the technology in the Detectors manufactured by Adams Electronics Inc. produces a Continuous Wave (CW) signal. This proprietary detection method utilizes extremely low signal levels. This signal can be visualized as a single frequency sine wave in the area of 20kHz. There are, essentially, no harmonic frequencies present. This fact minimizes the energy of the radiated field from the equipment. The power generated in an object by electromagnetic radiation is proportional to the frequency and the square of the Electric Field Voltage. The frequency is only just above that necessary to produce a radiated wave. Also the original voltage source is very low, at 5 Volts Peak to Peak. This means that most of the energy effects will be in the induction field close to the detector. This field falls off inversely with the square of the distance.

Equipment Testing:

Given the basis of operation outlined above, a measurement of the magnetic flux density at the surface of the detector head is very important. The attached report carried out by an independent test laboratory gives the RMS flux density across the frequency spectrum. The peak value of 79.3 dBpT (decibel pico-Tesla) is centered at the operational frequency (~21.5 kHz). The first harmonic frequency flux density measured at 45 kHz, is 23dB down at 56.1 dBpT. No discernable harmonics are found above 150kHz. This would obviously be typical for a continuous wave device. The full range of scanning was carried out to 30MHz. These tests show that no high energy radiated fields exist and the induction field strength is very low at the surface of the detector. With the fall off of the induction field with distance, the field experienced by an implanted device will be much lower. What this means is Pacemakers and other medical implanted devices are at no risk of interference.

"CE" Mark:
Adams Electronics Inc and its parent company Adams Electronics (International) Limited manufacture Security Hand Held Metal Detectors for use in countries world wide including those of the European Union. It is a requirement in these countries that all such equipment receives the *CE mark* to confirm compliance with the ***European Directive on Electromagnetic Compatibility* (EMC(89/336/EEC).** Again, Adams Electronics detectors have undergone rigorous, separate, independent laboratory tests to obtain this *CE mark* and once more have confirmed compliance with the following standards:

Radiated Emissions EN50081-1: 1992

Immunity to Electromagnetic Fields: EN50082-1: 1992

The tests carried out to confirm Immunity to electromagnetic fields is similar to that required for **BS EN 60601-2-31** (Specification for external cardiac pacemakers with internal power supplies) clause 36 (Electromagnetic Compatibility). Unfortunately this standard for the safety of pacemakers does not directly address the acceptable levels for continuous or pulsed induction fields. In fact, it addresses only the threat from electrostatic discharge. As can be seen from the preceding tests no discharges of this nature arise from the detector signal.

However, as the pacemakers are used in the European Union they should also be subject to the same *CE* marking requirements. In this case, as the detectors comply with the *directive* and carry the *CE mark*, it follows that they should not interfere with a correctly constructed and fully functioning pacemaker.

Clinical Testing:
In addition to this, Adams Electronics felt it mandatory to carry out further testing and investigations at a leading U.K. heart hospital. A Consultant Cardiologist at the Royal Brompton Hospital in London England carried out extensive tests using Adams Electronics detectors on patients using pacemakers and defibrillators from a wide range of different manufacturers. In all cases the equipment detected the pacemaking device, but did not, in any way affect the function either in terms of electrocardiographic disturbance or in programming. These results together with the conclusion of the attached report gave further confidence and assurance in the operational safety of these detectors. As the consultant cardiologist concludes in his own words: ***"It is therefore believed that they are safe to use with pacemaker patients in any circumstances".***

Conclusions:
In the absence of definitive standards, the above testing and investigation go as far as is practicable, to ensure the safety of using Adams Electronics detectors for medical applications and with pacemaker users. The energy levels found in using these detectors is virtually unmeasurable in comparison to other types of popular electronic equipment in general public use today (e.g. Mobile communications and portable data systems).

For users with pacemakers in good functional condition there are several, far greater risks, from the general electromagnetic environment. Without further clinical or device testing it is very reasonable to conclude that this particular type of detector is extremely safe for use on all individuals with pacemakers and medically implanted devices.