

What Do The Experts Say About The Safety of EAS Systems For Pacemaker And Defibrillator Wearers?

"[N]o significant harm to patients has resulted," and it is important to "avoid generating unnecessary anxiety in patients with implanted devices." The European Society of Cardiology, May 1999.

"There is no reason for implant patients to be worried about potential interactions between their pacemakers (or other similar devices) and anti-theft devices." Asia-Pacific Working Group on Cardiac Pacing and Electrophysiology, September 1999.

"Interactions with EAS systems and metal detectors are unlikely to cause clinically significant symptoms in most patients." U.S. Food and Drug Administration 9/28/98 Letter to Cardiologists, Cardiovascular Surgeons, Emergency Physicians and others.

What Are EAS Manufacturers Doing To Assure Compatibility With New Medical Implants?

Manufacturers of electronic anti-theft systems and of medical implants are strongly committed to working together to maintain, and enhance, the electro-magnetic compatibility between their respective products. Their ongoing joint efforts include:

The establishment and active use for over seven years of a joint test facility at the Georgia Tech Research Institute in Atlanta, Georgia, where over 300 medical implants under development have already been tested for compatibility with a wide variety of anti-theft systems.

Permanent installations of anti-theft systems at the R&D facilities of all major medical implant development companies.

Participation in the CENELEC committee responsible for establishing appropriate EU standards for pacemakers, including protection or immunity of medical implants from EMFs.

The ongoing work of a committee, chaired by the FDA, of the Association for the Advancement of Medical Instrumentation (AAMI), to develop U.S. standards for medical implants focusing on the immunity of those implants from EMFs. This AAMI committee includes manufacturers of medical implants and of electronic anti-theft systems.

Manufacturers of electronic anti-theft systems and manufacturers of medical implants have long recognized the importance of these efforts to maximize electromagnetic compatibility, and have maintained an active dialogue on this subject for years.

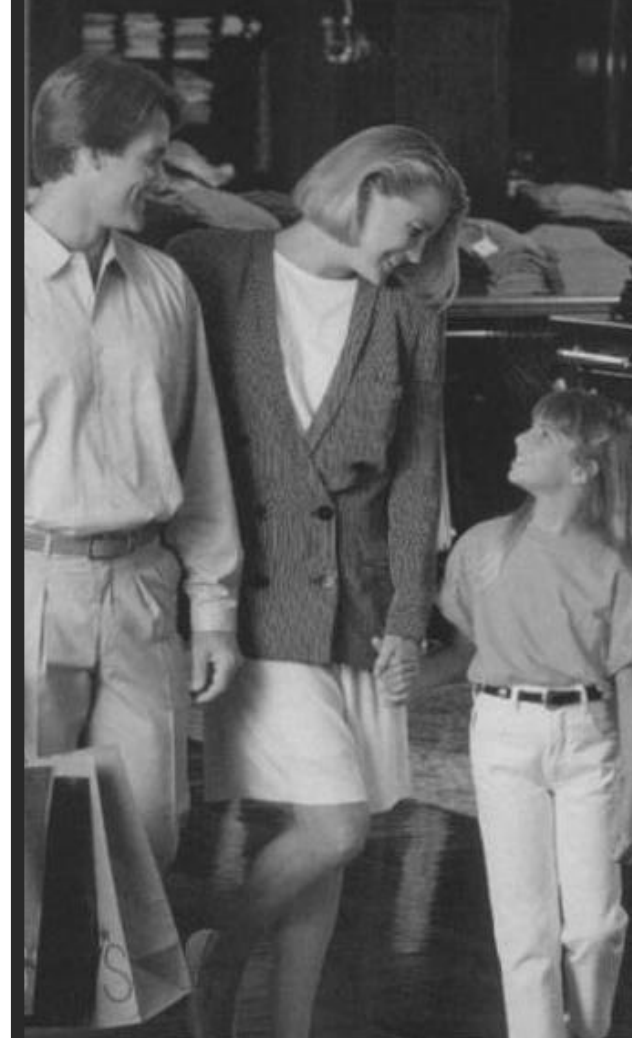
Regulatory groups, physician groups and the manufacturers of medical implants and anti-theft systems have all worked closely together to educate patients, to enhance future device compatibility and to develop joint industry standards. These efforts have already proven successful and will continue in the future, with the goal of maintaining an already excellent safety record.



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EAS SYSTEMS AND MEDICAL IMPLANTS



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What Are Electronic Article Surveillance (EAS) Systems? EAS systems are electronic anti-theft devices that are used to deter shoplifting and to protect merchandise and equipment in stores, libraries, hospitals and other establishments. EAS systems include tags or labels which are placed on or in the goods to be protected, and sensing devices, such as a pair of pedestals, that are placed at the exit or in the aisle. The systems also include accessories such as tag deactivators used at the checkout area. The tag is either removed, deactivated or passed around the sensing devices by the checkout operator at the time of purchase. An alarm sounds when an active tag passes between the pedestal sensing devices.

Do EAS Systems Have Safety Standards And Certification Procedures? Do EAS Systems Comply? Yes, EAS systems are governed by and comply with numerous safety standards from around the world. These include the ANSI/IEEE C95.1-1991 American National Standards Institute and Institute of Electrical & Electronics Engineers standard governing safety in the presence of electromagnetic fields (EMFs). In addition, EAS systems comply with the EMF limits recently set by ICNIRP (International Commission for Non-Ionizing Radiation Protection), which is sponsored by the United Nations World Health organization. The ICNIRP limits have been incorporated into European Recommendation 1999/519/EC, and are included in European EAS safety product standards.

What Are Pacemakers And Defibrillators? Pacemakers and defibrillators are electronic devices implanted in the body to assist the heart in maintaining rhythm by providing an artificial stimulus signal if and when it is required. A pacemaker provides a weak electrical signal to trigger a heart beat when the wearer's natural signal is irregular or stops. A defibrillator provides a strong electrical signal when a heart starts to fibrillate (a weak, rapid, unsynchronized heart beat) to restore rhythm.

Do Pacemakers And Defibrillators Have Safety Standards And Certification Procedures? Do They Comply? Pacemakers and defibrillators must comply with global safety standards and guidelines such as those issued by CENELEC (European Committee for Electrotechnical Standardization) and the US FDA (Food and Drug Administration) prior to marketing. These guidelines provide comprehensive requirements regarding the performance of the device, including safeguards for interference from EMFs. These guidelines must be met in order to ensure proper operation in everyday environments, including environments in which EMFs are present. EMFs that may interact with medical implants are generated by a wide variety of everyday items, including cellular telephones, power tools, automobile engines, stereo speakers, lawnmowers, and anti-theft systems.

Are EAS Systems Compatible With Pacemakers And Defibrillators? Implant manufacturers are aware of the various types of EAS systems and other sources of EMFs, and design their implantable products to be compatible. All implant models have built-in safeguards against interference from EMFs, though the particulars of such safeguards vary between models and manufacturers. Thus, while device interactions are possible, these were anticipated and present no clinically significant risks to patients.

Do Doctors And Pacemaker And Defibrillator Manufacturers Endorse Walking Through EAS Systems? Yes. A worldwide consensus has emerged among the regulatory agencies, treating physicians and medical implant manufacturers that have examined this issue: cardiac implant patients have nothing to fear in passing through electronic anti-theft systems. Patients should simply observe the common sense advice, already widely disseminated by treating physicians and in patient literature, to walk through EAS systems at a normal rate, and avoid lingering near, or leaning on, EAS systems. This practical patient advice, which anti-theft system manufacturers have likewise endorsed for years, is captured by the slogan, "don't linger/don't lean."

If It Is Suggested To Walk Through An EAS System At A Normal Rate, How Can I Identify The Location Of An EAS System ? EAS systems are usually located at the exit or in a checkout lane of a retail store. They are also used at the exits in libraries, hospitals and other commercial establishments. In many instances, an EAS system can be identified as a pair of pedestals that you walk through. Some EAS systems may be installed inconspicuously at the exits, in places such as the wall, floors, or overhead. It is therefore recommended that pacemaker and defibrillator patients pass through such entrances and exits without lingering.

Can A Pacemaker Or Defibrillator Cause An EAS System To False Alarm? The pacemaker or defibrillator is highly unlikely to alarm an EAS system because EAS systems are carefully designed to alarm only by detecting the presence of a unique sensor called a tag.

Some people confuse EAS systems with airport security systems. Airport security systems are designed to detect metals and are very likely to alarm due to the metal case of the implant.

What Has Been the Experience Of The EAS Industry With Respect To Pacemakers And Defibrillators? EAS systems have been in widespread use for over 30 years with approximately one million systems installed around the world. Since there are over two million pacemaker and defibrillator users around the world, it is estimated that they pass safely through EAS systems hundreds of millions of times each year.