Bill as Introduced

HB 1138 – AS INTRODUCED

2000 SESSION

00-2042
01/09

HOUSE BILL ***1138***

AN ACT requiring warnings for certain antitheft devices.

SPONSORS: Rep. Ruffner, Rock 25; Rep. Pilliod, Belk 3; Rep. Martel, Hills 45; Rep. Batula, Hills 18; Rep. Millham, Belk 4; Sen. D'Allesandro, Dist 20; Sen. Squires, Dist 12

COMMITTEE: Commerce

ANALYSIS

This bill requires merchants to place appropriate signage within 5 feet of an antitheft device to warn persons with pacemakers.

Explanation: Matter added to current law appears in ***bold italics.***
Matter removed from current law appears [~~in brackets and struckthrough.~~]
Matter which is either (a) all new or (b) repealed and reenacted appears in regular type.

00-2042
01/09

STATE OF NEW HAMPSHIRE

In the Year of Our Lord Two Thousand

AN ACT requiring warnings for certain antitheft devices.

Be it Enacted by the Senate and House of Representatives in General Court convened:

1 Chapter Heading Changed. Amend the chapter heading of RSA 358-M to read as follows:

MERCHANT'S [~~CHECK ACCEPTANCE~~] POLICIES

2 New Subdivision Heading; Provision of Credit Card Number or Expiration Date Not Required. Amend RSA 358-M by inserting the following subdivision heading preceding RSA 358-M:1:

Provision of Credit Card Number or Expiration Date Not Required

3 New Subdivision; Warning Signs Required for Antitheft Devices. Amend RSA 358-M by inserting after section 1 the following new subdivision:

Warning Signs Required for Antitheft Devices

358-M:2 Warning Signs Required for Antitheft Devices. Persons using acoustomagnetic EAS systems otherwise known as shoplifting gates shall place an appropriate sign warning persons with pacemakers not to linger near such devices. The signs shall be at least 8" by 10" and shall be placed within 5 feet of such device. Any person who violates the provisions of this section shall be guilty of a violation.

4 Effective Date. This act shall take effect January 1, 2001.

Speakers

SIGN UP SHEET

To Register Opinion If Not Speaking

Bill # HB 1138 Date 2-15-00

Committee Commerce

**** Please Print All Information ****

Name	Address	Phone	Representing	(check one) Pro	Con

Study of effect of EAS EMF exposure

Total Patients	Patients affected	Clinical effect	Exposure Duration and Distance from device
150	3	Ventricular Tachycardia	6" for 2 minutes
150	4	Pacemaker inhibition	6" for 2 minutes

Hearing Minutes

HOUSE COMMITTEE ON COMMERCE

PUBLIC HEARING ON HB 1138

BILL TITLE: requiring warnings for certain antitheft devices

DATE: February 14, 2000

LOB ROOM: 302 **Time Public Hearing Called to Order:** 10:10 AM

Time Adjourned: 11:40 AM

(please circle if present)

Committee Members: Reps. Hunt, Francoeur, Herman, Tsiros, Belanger, McGough, Kenney, Langley, Pappas, Avery, Dalianis, DiFruscia, Marshall, M. Clark, Crosby, Russell, T. Reardon, Vachon, Taylor, Curran, Garrish and Keye.

Bill Sponsors: Reps. Ruffner, Pilliod, Martel, Batula and Millham and Sens. D'Allesandro and Squires

TESTIMONY

* Use asterisk if written testimony and/or amendments are submitted.

***Rep. Ruffner** – prime sponsor. Provided written testimony and background.

Sen. Squire – Began as co-sponsor of this bill. Previously I also implanted pacemakers as a surgeon. I also followed up with Dr. Hawthorne and read a very detailed study and concluded that the danger is not very real and that the downside of creating unnecessary fear in the general public outweighs the need for this to be public policy.

Rep. Batula – co-sponsor. Supports bill for mitigation of the possible risk that exists but understands there are two sides of the story and scientific data is conflicting.

Rep. Pilliod – co-sponsor. Supports this bill so patients can be warned of potential harm.

Q: Rep. Hunt – If there are so many devices that could possibly effect a pacemaker, then why are we singling out this device?

A; Well, if there is a possibility of abuse effects then people should be warned. I have wavered in my support for this bill.

Christopher Gallagher, representing Sensormatic, manufacturer of EAS – Introduced panel of three doctors to refute testimony ??? presented from sponsors and Dr. McIvor.

Dr. Warren Hawthorne, MA General Hospital, cardiologist – While the data presented may be technically accurate, representative of test results provided in a laboratory, this data is also

clinically irrelevant. It is possible to take a pacemaker device and place it on top of an EAS's coil and produce intermittent aberrations, it is almost impossible and even more unlikely that this would ever occur in reality. Passage of this bill would most likely introduce undue terror in patients. I urge you not to support this bill.

Q: Rep. Langley – Do you keep educational material like these brochures available?

A: Yes, we have thorough patient education processes including these brochures and consultations directly with patients.

Dr. Douglas Zipes, University of Indiana – opposes bill. Here to provide information on study refuting Dr. McIvor's findings. Dr. Zipes conducted a study of over 150 patients testing pacemakers implanted with a 10-15 second exposure to DAS electromagnetic fields and not a single patient experienced so much as the slightest problem. We want patients to lead normal lives. This type of fear-inducing legislation would not help with this effort to keep patients' lives normal.

Study of Effects of EAS/EMF Exposure

TOTAL PATIENTS	PATIENTS EFFECTED	CLINICAL EFFECTS	EXPOSURE DURATION & DISTANCE FROM DEVICE
150	3	VENTRICULAR TACHYCARDIA	6 INCHES FOR 2 MINUTES
150	4	PACEMAKER INHIBITION	6 INCHES FOR 2 MINUTES

Q: Rep. McGough – Your testimony included an examination of Dr. McIvors data, what would cause him to study dand present it in this erroneous fashion?

A: I can't get into his head but can only say there are rumors as to his motivation but they are not appropriate for this committee hearing.

Dr. Gerald Addonizio, Cornell University – Here today to express opposition to this legislation because of the excessive fear it will generate in the average pacemaker patient. Patients will vbe more likely to stay home and not enjoy normal lives and therefore will likely increase mortality/morbidity in this population.

Nancy Kyle, Retail Merchants' Association – Written testimony.

Respectfully Submitted:

Tim S. McGough, Clerk Pro Tem

HOUSE COMMITTEE ON COMMERCE

PUBLIC HEARING ON HB 1138

BILL TITLE: requiring warnings for certain antitheft devices

DATE: 2-14-00

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Time Adjourned: 11:40?

(please circle if present)

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Bill Sponsors: Reps. Ruffner, Pilliod, Martel, Batula and Millham and Sens. D'Allesandro and Squires

TESTIMONY

* Use asterisk if written testimony and/or amendments are submitted.

* Rep. Walt Ruffner - prime sponsor provided written testimony and background

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Rep. Batula - Co-Sponsor - supports bill for mitigation of the possible risk that exists but understands there are two sides of the story and scientific data is conflicting

Rep Pilliod - Cosponsor - supports this bill So patients can be warned of potential harm

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Rep Pillsd (cont.) -

Rep Hunt Q: If there are so many devices that could possibly effect a pacemaker, then why are we singling out this device?

Rep Pillsd A: Well, if there is a possibility of these effects then people should be warned. I have wavered in my support for this bill.

Chris Gallagher: representing Sensormatic, mfr of EAS
Introduces panel of 3 doctors to rebute testimony (here-say) presented from sponsor and Dr McIvor.

Dr. Warren Hawthorne - Massachusetts General Hospital, Cardiologist
While the data presented may be technically accurate representations of test results produced in a laboratory, these data are also clinically irrelevant. It is possible to take a pacemaker device and place it on top of an EAS's coil and produce intermittent aberrations, it is almost impossible and even more unlikely that this would ever occur in reality. Passage of this bill would most likely induce undue terror in patients. I urge you not to support this bill.

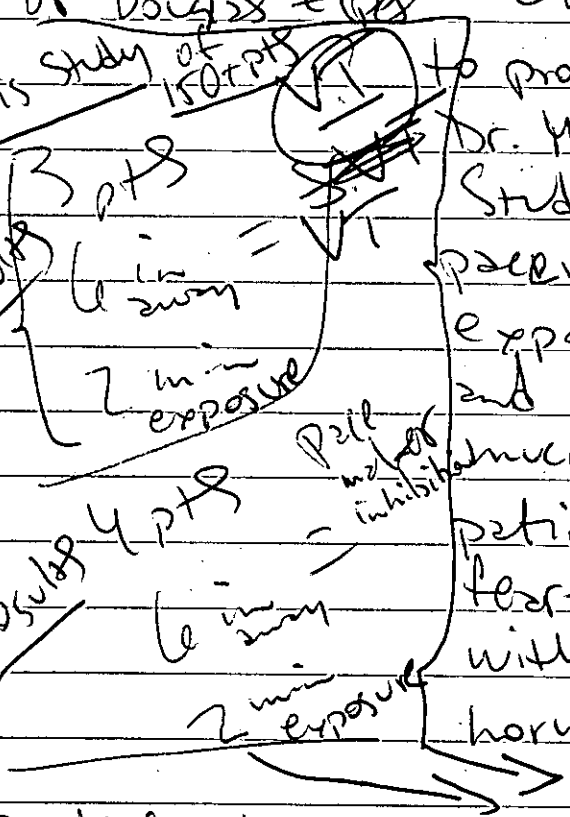
Q: Rep Langley - Do you keep educational material like these brochures available?

(2)

Dr Hawthorne A: Yes, we have thorough patient education processes including these brochures and consultations directly with patients.

(See chart - back of blue sheet)

Dr Douglas Zipes - Univ. of Indiana - opposes bill, here to provide information on study refuting Dr. McIvor's findings. He conducted a study of over 150 patients testing pacemaker implantees with a 10-15 second exposure to EMS electromagnetic fields and not a single patient experienced so much as the slightest problem. We want patients to lead normal lives. This type of fear-inducing legislation would not help with this effort to keep patients lives normal.



Rep Mcbeath Q: Your testimony included examination of Dr McIvors data, what would cause him to study and present it in this erroneous fashion?

Dr. Zipes: A: I can't get into his head but can only say there are reasons as to his motivation but they are not appropriate for this committee hearing.

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Dr. Gerard Addonizio - Cornell University

Here today to express opposition to this legislation because of the excessive fear it will generate in the average pacemaker patient. Patients will be more likely to stay home and not enjoy normal ~~lives~~ lives and therefore will likely increase mortality/morbidity in this population

*Nancy Kyle - Retail Merchants Association - written testimony

Testimony

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Testimony of Nancy C. Kyle
Executive Vice President, Retail Merchants Association of NH
to the House Commerce Committee
Tuesday, February 15, 2000

In Opposition of HB 1138

Requiring warnings for certain anti theft devices

Good morning. My name is Nancy Kyle and I am the Executive Vice President of the Retail Merchants Association of New Hampshire (RMANH). RMANH is a state-wide non-profit association that promotes the success of the New Hampshire retail community. We have nearly eight hundred member locations in the state, ranging in size from small, single person businesses, to large corporations.

The Retail Merchants Association of New Hampshire opposes HB 1138, which would require merchants to place appropriate signage within 5 feet of an antitheft device to warn persons with pacemakers.

Primarily we believe that this should be argued among the medical experts, and between a doctor and his or her patient. However, in researching this issue, we feel that anti-theft systems do not pose a public health hazard. The FDA concluded the same after extensive study and public hearings.

Walking through an anti theft system appears to pose no greater health threat to people with pace makers than using a cellular phone, power tools, cordless telephone, etc. None of these items require warnings for people with pace makers, nor should a retailer be required to post such a notice. According to the Weinberg Group, a Washington DC based scientific advisory firm, passing through an anti-theft system at a local mall is more than 1,000 times safer for a cardiac implant patient than driving to that mall.

Retail theft is a huge problem for retailers in this state. Nationwide, there are 1.2 million shoplifting incidents everyday, at a loss rate of $18,000 dollars stolen per minute. If all thefts including robbery, bank robbery, auto theft and theft other than retail theft were combined, they would not total the $26 billion dollar a year of external retail theft. These anti-theft systems are important devices for retailers, and are their tools to prevent shoplifting.

Just last week, the House of Representatives in this state passed HB1264, making it a misdemeanor for a person to use a device so that these anti-theft systems don't work. By passing that bill, the NH House of Representatives recognized how important these devices are for retailers. Posting warning signs on them would create the misimpression that there is a serious health hazard at the local store, which just is not true.

When these warning signs were posted in France, consumer groups, in an organized effort, requested retailers to take their anti-theft systems out of stores. These systems are crucial to running a retail business and significantly decrease shoplifting incidents. If they were removed from retailers stores, shoplifting incidents, which are already at record highs, would escalate to unbearable levels, which may force retailers to close.

In New Hampshire, these anti-theft systems are in place in hundreds of retailer locations. Stores such as Ames Department Stores, Auto Palace, Auto Zone, BJ's Wholesale Club, Bell Atlantic Nynex, Borders Book and Music, Brooks Pharmacy, Cherry and Webb, Coconuts, CVS Pharmacy, Disney Store, Home Depot, K Mart, Marshalls, Record Giant, Record Town, Rite Aid, TJ Maxx, Waldenbooks, Woodworkers Warehouse, Target Department Stores, and Wal-mart, to just name a few, all utilze these systems.

Each day, thousands of people in this state walk through these devices with no impact on their health. For this reason, the Retail Merchants Association of NH urges members of this committee to reject HB1138.

Pacemaker, defibrillator malfunct

REUTERS

Magnetic fields from antitheft gates at store exits can make implanted pacemakers and defibrillators malfunction, sometimes with fatal results, doctors said in a report appearing today.

The first of two reports in today's New England Journal of Medicine detailed how a 72-year-old man, who had a defibrillator to shock his heart automatically whenever it beat improperly, suffered four unnecessary shocks as he stood near an antishoplifting gate.

The electromagnetic field apparently acted as a signal to the defibrillator that the heart was beating improperly.

A nurse pulled him away from the gate and probably saved his life, said a group led by Dr. Peter A. Santucci of the Rush-Presbyterian-St. Luke's Medical Center in Chicago.

In another case, two doctors, trying to explain why a 30-year-old woman with a pacemaker felt nauseous, breathless, and dizzy when she passed through surveillance gates at stores, discovered that the antitheft devices had made her pacemaker send out improper signals.

Not all types of antitheft surveillance systems create the type of magnetic interference that can dis-

ions tied to store antitheft shields

rupt pacemakers, said the authors of the second report, Dr. Michael McIvor of the Heart Institute of St. Petersburg, Fla., and Dr. S. Sridhar of Affiliated Cardiologists in Phoenix.

However, they suggested that patients with pacemakes should "minimize their contact" with such systems "by passing quickly through the gates." Even then, symptoms can occur, they warned.

Newer systems "can be unobtrusive, located behind walls or beneath flooring," McIvor and Sridhar said. They urged clear marking of areas where the strong magnetic fields are present. In addition, "merchandise should not be displayed next to electronic surveillance equipment," Santucci's team said.

"With the increasing use of both implantable defibrillators and antitheft surveillance devices, potentially serious interactions may be more common in the future unless preventive measures are undertaken," they said.

About 400,000 electronic antitheft surveillance devices are present in stores, libraries, and other locations worldwide. Other sources of electromagnetic interference, such as slot machines and remote control devices for toys, are also known to disrupt devices designed to sense and correct erratic heart rhythms.

Mr. Chairman & Esteemed members of the Commerce Committee:

My name is Walt Ruffner and I represent District 25 in Rockingham County. This district comprises North Hampton and Stratham..

Before presenting my documentation, I would like to decipher a couple of acronyms. EAS = Electronic Article Surveillance sometimes called anti-theft warning systems and ICD = Implantable Cardioverter Defibrillator, usually called pacemakers.

It is my understanding that expert witnesses have been gathered to convince this committee that there is no real potential danger in exposure to the specific EAS, I am going to speak about and they are partially right. There is no real danger when a person just passes through the area of an EAS, but I feel it is my job to try and convince you that there is a very existent danger if the wearer of a pacemaker lingers in that area.

At the top of your copies of my presentation is the newspaper article from the Boston Globe that was given to me by a concerned constituent. It awakened me to the actuality of a peril to users of pacemakers that I had been totally unaware of along with the necessity of being part of an attempt to remediate it.

In the interest of expediency, I will not read the entire article, but would like to call your attention to the first two paragraphs, which explain the existing danger to pacemaker wearers..

This is followed by a few documented incidents that have occurred as a result of this peril. Luckily, there have been no deaths, as yet, but the question" will it happen?" could validly be replaced with "when will it happen?" Needless to say, much trauma has been experienced by those that have experienced these episodes.

Accompanying my testimony are responses to my inquiries from the following three eminent sources that indicate the important validity and importance of this proposed legislation. *With your permission,for the record, I would like to refer to them as my volunter expert witnesses.*

1. Dr. Michael McIvor, Medical Director of The Heart Institute of St. Petersburg.

2. Dr. Peter A. Santucci, Director of Cardiology/Electrophysiology at the Rush - Presbyterian - St. Lukes Medical Center, Chicago, Il.

3. Dr. James M. Schmitz, cardiologist of Portsmouth, NH.

Although all three letters are of significant value, I will refer only excerpts from the Dr. McIvor letter as the others are a repetitive assessment of the same existent risks, along with appropriate measures of remediation.

I have numbered certain passages of this letter that I believe will explain in an informational pattern, some of the more relevant facts surrounding this study.

Numbers one through ***four*** on pages one and two indicate the four basic interactions that take place when a pacemaker is exposed to an EAS.

Number five, on page 2, indicates that of the existing three types of EAS, the type that causes the greatest hazard is called the acoustomagnetic system. This is the latest and most used, of the four systems and is widespread through an abundance of retail stores..

At this time, because I believe it will awaken you to the importance of this problem as it did me, my testimony will proceed citing relevant excerpts from this letter. I have underlined and numbered these excerpts for your consideration.

Number 6, page 2 Here, a few of the documented cases are listed.

Number 7, page 3 In this paragraph, Dr. McIvor indicates that it would not be wise to panic and indicates that the only time danger is evident is when the pacemaker wearer lingers in the immediate area of an EAS.

Number 8, page 3 "While it is important not to panic the pacemaker population, it is important to educate the population that there is the potential for interaction." Even with acoustomagnetic systems, interactions could be totally avoided by appropriate ***signage*** advising pacemaker patients not to linger within several feet of these systems wherever this type of EAS system is deployed.

I have underlined these same recommendations for signage in the other two letters. Reading all three of them, in their totality, has deepened my appreciation for the seriousness of this problem, as I think it will, yours.

My research through our own NH resources and NCSL have indicated that there has been no previous legislation regarding this problem.

Adding one last comment, I was approached with the statement that such a move would frighten people. Cumberland Farms and 7-11 convenient stores have similar signs posted by their micro-wave ovens. I have asked clerks at these stores if anyone had been frightened by the signs. The answer was "not to my knowledge".

It beguiles me to think an industry producing such a useful and efficient asset to businesses would feel threatened by the mere presence of an inoffensive sign educating pacemaker wearers to avoiding lingering around such an instrument.

Thank you for listening to me.

THE HEART INSTITUTE
OF ST. PETERSBURG

January 13, 1999

John P. Hoche, M.D., PA, FACC
Jeffrey R. Witt, M.D., PA, FACC
Michael E. Melvin, M.D., PA, FACC
Andrew D. Rosenthal, M.D., PA, FACC
John W. Walsh, M.D., PA, FACC
James R. Post, M.D., PA, FACC
James L. Mason, M.D., FACC

Electrophysiology
Robert C. Sheppard, M.D., PA, FACC

Administrator
Thomas J. Borschel

Walter D. Ruffner
10 Benjamin Rd.
Stratham, NH 03885

Dear Mr. Ruffner:

This letter is in response to your recent query. We at The Heart Institute of St. Petersburg have been interested in the interaction between implanted medical devices and shoplifting gates (Electronic Article Surveillance systems, or EAS systems) for quite some time. In 1995 we first reported an interaction between one such EAS system and a patient of ours who had an implantable cardioverter defibrillator (ICD). An ICD is a device that monitors the heartbeat, and if the patient has a cardiac arrest, the ICD shocks the patient back to life. In our patient, the ICD interpreted the magnetic field generated by the EAS system as a cardiac arrest and shocked the patient inappropriately. Since then, other reports have emerged of ICDs being triggered inappropriately by EAS systems. In formal studies of this issue, it appears that for an ICD to have such an interaction, the patient must be standing within or near an EAS gate for some time. ICDs are designed so that an abnormal rhythm which lasts only for a few heartbeats does not trigger a shock, so ICD patients likely will need to be exposed to an EAS field for a minute or two for any interaction to occur. Not all patients with an ICD will interact with shoplifting gates; our best information to date suggests that one patient in fifty who has an ICD and stands next to an EAS system will have such a shock. For the unfortunate few, such interactions were described by one author as life threatening, but for most ICD patients a shock will be uncomfortable but not lethal.

We also became interested in the interactions between EAS systems and pacemakers, since pacemakers *can* be interfered with on a beat by beat basis, i.e., they do not require several minutes of exposure for an interaction. In our study, published in the October issue of PACE, we found that 96% of pacemakers interact with EAS systems. Four types of interactions were detected:

#1 First, the pacemaker could become confused, which would trigger it to revert to a simpler mode of pacing (called asynchronous pacing).

#2 The second interaction would be seen with a 2 chamber pacemaker in which the pacemaker would falsely detect a rapid heart rate. In such circumstances the

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pacemaker would speed up to track this phantom heart rate (termed atrial oversensing or "EAS induced tachycardia").

#3 The third type of interaction would occur when the pacemaker falsely interpreted the magnetic fields of an EAS system as normal heartbeats and would turn itself off, causing prolonged pauses which could produce dizziness or fainting spells (ventricular oversensing or pacemaker inhibition).

#4 The fourth type of interaction is when the magnetic field of the EAS system is so strong that it can actually cause a current to flow in the pacemaker wire itself, directly causing extra pacemaker beats (EAS induced pacing).

During our study, which carries the acronym SPICED TEAS, we tested the three types of EAS systems commonly deployed in the United States. These three systems differ markedly in the level of magnetic field generated. The oldest type of system is called a swept radio frequency system and generates such a low level of magnetic field that current pacemakers will totally ignore these systems. The second type of system is called a magnetic audiofrequency system and only produces transient and clinically inconsequential interactions. It is the third type of system, the acoustomagnetic system, that produces interactions in 96% of

#5 pacemakers. With this type of system, 16% of patients interact just walking through the system. Closer and more prolonged contact increases the frequency of interactions to 96%.

#6 Questions have arisen as to whether such interactions occur in the "real world" situation. In November we reported a pacemaker patient who experienced palpitations, nausea, breathlessness and dizziness whenever she passed through an acoustomagnetic EAS system. In the same issue of the New England Journal a patient with an ICD who was standing near, but not within, an acoustomagnetic EAS system suffered 4 inappropriate shocks to his heart. His backup pacemaker was then inhibited by the magnetic fields of the acoustomagnetic system, such that after the shocks he had no heartbeat at all for several seconds.

Recently, the Food & Drug Administration (FDA) has become interested in this area and has asked cardiologists to report their own experience with pacemaker patients interacting with EAS systems, in order to collect a national experience and gain an appreciation for the magnitude of this problem.

Our results have been confirmed by the Medical Device Bureau of Canada (the Canadian equivalent of the US FDA) in that 95% of pacemakers interacted with the acoustomagnetic EAS system. It was recommended by the Canadian investigators that patients who are pacemaker dependent not linger within 33 cm. of an acoustomagnetic system.

There is no question that interactions occur between acoustomagnetic EAS systems and pacemaker patients in both formal testing and in the real world setting. Even medical consultants for the manufacturer of the acoustomagnetic system say the increased incidence of interactions with that EAS system was "predictable from knowledge of pacemaker circuit design..." The question is what to do with these findings.

#7 First, I think it is important not to create a panic among pacemaker patients. Most pacemaker patients do not use their pacemaker on a consistent basis. A pacemaker patient may use his pacemaker for a minute or two this week, five minutes next week, and half an hour the week thereafter. If a patient is not using his or her pacemaker, there may be no symptoms even if an interaction between the pacemaker occurs with an acoustomagnetic EAS gate. It is only the 20% of pacemaker patients who are pacemaker dependent who are most at risk. Even in a pacemaker dependent patient, if the patient walks quickly through an acoustomagnetic system, clinically significant events should occur only in a minority of instances. Even if a pacemaker stops for a second, the patient would be still be pacing 1 beat per second, or 60 beats per minute, which should be enough to prevent any symptoms. The problem occurs when a patient lingers within the magnetic field of an EAS system. This occurs because current EAS systems are being made more powerful, and are being placed underneath flooring, behind walls, in ceilings, etc. A pacemaker dependent patient who lingers, for example, at the edge of a mall store may not be aware that he or she is within the magnetic field of an EAS system.

#8 Therefore, while I think it is important not to panic the pacemaker population, it is important to educate this population that there is the potential for interaction. Further, I think the entire EAS industry should not be painted with the same brush. Acoustomagnetic systems do present the potential for a symptomatic interaction for some patients but other EAS systems pose little such potential. Even with acoustomagnetic systems, interactions could be totally avoided by appropriate signage advising pacemaker patients not to linger within several feet of these systems wherever this type of EAS system is deployed. Such an approach has been adopted in some parts of Europe. This approach is consistent with the "don't lean, don't linger" advice that the manufacturer of acoustomagnetic EAS systems has advocated.

HP's do this now

It is also my hope that some sort of cross industry standard can be established so that engineers working in the pacemaker industry will know that their devices need to be able to protect themselves within given ranges of environmental interference, such as is produced by the EAS systems. On the other hand, with such a common standard, the engineer in the EAS industry would know that if his system operates within certain frequencies, and generates magnetic fields of certain magnitudes, implanted medical devices such as pacemakers will not be affected. Again referring to the European example, there is a European norm, known as EN 5006/A1 which designates which frequencies for which

pacemakers must provide protection against interference. Swept radio frequency EAS systems operate below this level so are ignored by pacemakers. Magnetic audiofrequency systems are within the protected range so pacemakers can easily handle this sort of interference. Unfortunately, acoustomagnetic systems fall above the range of specified protection, so produce unpredictable results in pacemakers.

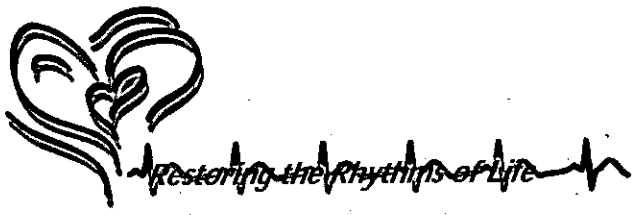
#8 It is my feeling that no products need to be removed from the market. However, since the acoustomagnetic systems are the number one seller in the United States with 90,000 such systems deployed in stores across the country, advisory signage for patients, education for physicians who can then appropriately advise their patients, and the establishment of cross industry standards is a prudent approach that will prevent the occurrence of clinically relevant symptoms.

I hope this information is helpful to you as you consider this issue. Please let me know if I can be of further assistance. I would be happy to provide reprints of our work in this field, or other assistance you may require as you deliberate whether this is a significant problem for your constituents.

Sincerely,

Michael E. McIvor, MD
Medical Director, Research Section
Heart Institute of St. Petersburg

MEM/kdm



Common Questions About Electrical Interference and Your Medtronic Pacemaker

Medtronic

Q *What is EMI?*

A Things that use electricity and magnets have electromagnetic fields around them. These fields are usually weak and will not affect your pacemaker. However, **strong** electromagnetic fields have the potential to alter the function of your pacemaker. This is called EMI (electromagnetic interference). A strong magnetic field can "blind" the pacemaker to your heart rhythm and keep the pacemaker from treating you, or cause your pacemaker to send pacing beats when your heart does not need it. If you move away from the source of EMI, your Medtronic pacemaker will return to normal.

There are several safeguards built into your Medtronic pacemaker including electronic filters that differentiate between natural heartbeat signals and EMI signals, and the metal housing surrounding the pacemaker's battery and circuitry.

It is important to know which EMI sources do and do not affect your pacemaker.

Q *Are household appliances safe?*

A Properly maintained electrical household items are unlikely to interfere with your pacemaker. Safe appliances include:

- Microwave ovens
- Televisions, radios, video games, C-D players, stereos (see precaution for large speakers)
- Electric blankets and heating pads
- Tabletop appliances such as toasters, blenders, electric can openers, food processors
- Handheld items such as home (and salon) hair dryers, shavers
- Large appliances including washers, dryers, electric stoves
- Vacuum cleaners, electric brooms
- Outdoor equipment such as electric hedge clippers, leaf blowers, lawn mowers, snow blowers. (If gas powered, see precautions under automobile engine).

Remember, all household equipment should be kept in good repair. Proper maintenance greatly reduces the chance of electrical interference.

Q *May I use a cellular phone?*

A Cellular phones are unlikely to interfere with your pacemaker if proper precautions are followed:

- A distance of at least 6 inches should be maintained between a cellular phone and your pacemaker.
- When using a cellular phone, you should hold it to the ear opposite the side of the body in which the pacemaker is implanted.
- When set to receive calls, a cellular phone should not be carried in a pocket on the same side as the pacemaker.

For portable and mobile phones (phones transmitting above 3 watts), maintain a distance of at least 12 inches between the base of the antenna and the pacemaker and follow the above precautions as well.

Q *Can I use power tools safely?*

A Generally, yes. However, it is very important to remember the following guidelines:

- Keep all equipment in good condition to avoid electrical shock.
- It is best not to operate power tools alone.
- Be certain that the tool is properly grounded. If you use power machinery frequently, a ground fault interrupt system would be a wise investment. This inexpensive device is a good safety measure because it prevents a sustained electrical shock.
- Avoid using any power tool locked in the "on" position.
- Avoid using a chain saw because your hands and body come into close contact with the electric spark generating components, and the chain saw may cause bodily harm if you lose control of the saw.

Q *Can I work on an automobile engine safely?*

A Caution is necessary when near the coil, distributor, or spark plug cables of a running engine. Any adjustments to the distributor should be made when the engine is not running.

Q *Should I be concerned about EMI in my workplace?*

A Office and most shop equipment is unlikely to interfere with your pacemaker if it meets current electrical safety standards. This includes such items as:

- Computers, electric typewriters
- Copying machines, FAX machines
- Small wood- and metalworking shop tools

If you work in a heavy industrial environment, it is best to ask the advice of your physician about the possible risk of EMI. Some probable sources of EMI include:

- Electric arc welding equipment
- Dielectric heaters, used in industry to bend plastic
- Electric steel furnaces
- Large generators and power plants
- Large magnets, such as those used in some stereo speakers
- Antennas used to operate CB or ham radios and other radio transmitters

- Large TV or radio transmitting towers and power lines carrying over 100,000 volts (maintain a distance of 25 feet between you and towers or lines)

Q Are screening devices a concern?

A Airport screening devices are unlikely to affect your pacemaker, but they may detect the metal housing of your device and set off the security alarm. To obtain clearance, show your pacemaker identification card, request scanning with a hand-held screening device, or request a hand search.

There are a variety of anti-theft systems used in stores and libraries. Walk normally through the theft detectors and do not linger in adjacent areas.

Q Are medical procedures safe?

A Always be certain to tell any medical personnel about your pacemaker. With proper precautionary measures, most medical procedures are unlikely to interfere with your pacemaker. These include:

- Diagnostic X-rays, including routine chest X-rays, dental X-rays, and mammography. Mammograms require a tight enclosure of the breast by X-ray equipment and adjustments that lessen pressure on the pacemaker implant site are sometimes used to make the patient more comfortable.
- Dental procedures, including the use of dental drills and ultrasonic probes used to clean teeth.
- Therapeutic ultrasound and electrolysis, provided this equipment is not used directly over the implant site. Your technician should call Medtronic if there are questions.

Radiation therapy, Electrosurgery, Diathermy, External Defibrillation and Lithotripsy are procedures that produce high levels of EMI. A consultation with your physician will help to weigh the risks and benefits of such procedures.

Pacemakers can be reprogrammed before the procedure to lessen the chance of interfering with or damaging the pacemaker's function.

Warning: Magnetic Resonance Imaging (MRI) is not recommended for pacemaker patients.

Q How can I learn more about my pacemaker?

A Your physician or cardiology nurse is best suited to answer questions about your pacemaker.

Medtronic publishes a patient newsletter periodically. This newsletter contains educational articles of interest to pacemaker wearers. If you wish to receive a free subscription to this newsletter, please contact Medtronic at this address:

Medtronic, Inc.
Patient Services T154
7000 Central Avenue NE
Minneapolis, MN 55432-3576
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James J. Putzke
Biography

James J. Putzke recently retired from Guidant Corporation's Cardiac Rhythm Management division (CPI) after nearly eleven years of service. Prior to his retirement, Mr. Putzke served as an engineering director of Guidant Corporation. He has 27 years of experience with the implantable medical device industry. He is currently providing consulting services to Sensormatic Electronics Corporation on matters related to the compatibility of implantable medical devices with electronic article surveillance systems.

Mr. Putzke is a graduate of the University of Minnesota with a BS degree in Electrical Engineering. His experience in the implantable medical device industry dates back to 1973, when he joined Medtronic Corporation as a senior electrical designer. He was the electrical designer for Medtronic's first pacemaker using a lithium power source and also designed the first hand-held programmer used to program implantable pulse generators via a radio frequency signal. He subsequently held various management positions at Medtronic before being promoted to Director of the Pulse Generator Engineering group in 1982. In this position, he was responsible for the group doing development for Medtronic's entire line of implantable products.

In 1989, Mr. Putzke joined Cardiac Pacemakers Incorporated (CPI) as Director of Pacemaker Engineering. CPI was part of Eli Lilly Corporation's Medical and Diagnostic Division. In 1994, CPI was split-off, along with 4 other previously held Lilly companies, into a new entity, which became Guidant Corporation. Mr. Putzke continued to serve as an engineering director in the research and development organization with Guidant Corporation until his retirement in January of 2000.

Mr. Putzke holds one US patent, has represented Guidant on various national and international standards committees, and has authored or co-authored technical articles for several trade journals. In September of 1998, Mr. Putzke was selected to represent the Health Industry Manufacturer's Association (HIMA) and presented to FDA's TEPRSSC committee regarding the potential for interactions between implantable devices and electronic article surveillance systems.

Douglas P. Zipes, M.D.

Douglas P. Zipes, M.D. is a Distinguished Professor of Medicine, Pharmacology and Toxicology at Indiana University, as well as Director of both the university's Cardiology Division and the Krannert Institute. Dr. Zipes has served as President of the North American Society of Pacing and Electrophysiology (NASPE), the preeminent physician professional group dealing with pacemaker and implantable cardioverter defibrillator (ICD) issues. He currently serves on the Board of Directors/Trustees of NASPE and the American Board of Internal Medicine, and he is editor-in-chief of the *Journal of Cardiovascular Electrophysiolgy*, *Cardiology in Review*, and *Contemporary Treatments of Cardiovascular Disease*. Dr. Zipes is the recipient of both the American college of Cardiology and NASPE Distinguished Scientist Award, and the Distinguished Achievement Award and the Herrick Award from the American Heart Association. He is widely recognized as one of the world's leading experts on matters involving ICDs.

GERARD ADDONIZIO, M.D.

Gerard Addonizio, M.D., is Unit Chief of an inpatient psychiatric unit for older adults at the New York Presbyterian Hospital-Westchester Division, an institution he has been affiliated with since 1982. He is also an Associate Professor of Clinical Psychiatry at the Weill Medical College of Cornell University. Dr. Addonizio is a recognized authority in the psychiatric treatment of older adults. He is a frequent lecturer and trains Cornell Medical Students and Residents in Geriatric Psychiatry. He has authored a book and has many manuscripts published in leading psychiatric journals, many of which deal with older adults. Dr. Addonizio has lectured to groups of older adults in the community as well as to groups of psychiatric professionals, and has conducted radio programs which deal with the problems of aging.

John Warren Harthorne, M.D.

John Warren Harthorne, M.D. is Director of the Pacemaker Laboratory at Massachusetts General Hospital, an institution he has been affiliated with since 1962. He is also an Associate Professor of Medicine at the Harvard Medical School. Dr. Harthorne has been engaged in the practice of medicine since 1957 and is one of the nation's recognized leaders in matters involving cardiac pacing and related technology. He is a frequent lecturer and has authored over 100 manuscripts and books on pacemakers. Dr. Harthorne has been Chairman of the Pacemaker Committee of the American College of Cardiology. He has previously served as President of the North American Society of Pacing and Electrophysiology (NASPE), the preeminent physician professional group dealing with pacemaker issues -- a worldwide organization he helped found.

Olin S. Giles
Biography

Olin S.Giles recently retired as an executive officer of Sensormatic Electronics Corp after nearly fifteen years of service, and he is currently retained as a consultant to the company. Prior to his retirement Mr. Giles served as the CEO of the SensorID product Division of the company.

Mr. Giles is a graduate of North Carolina State University with a BS degree in Electrical Engineering and an MS degree in Physics. He joined the General Electric Company in 1962, where he held a variety of assignments leading to his appointment as Manager - Engineering for GE's communication equipment business, where he was responsible for the development of mobile communications and cellular telephone equipment.

In 1985, he joined Sensormatic Electronics Corp. as Vice President of Engineering. Later he served as Vice President of Operations. This led eventually to Mr. Giles being named to the position of Senior Vice President and Chief Technical Officer for the company in 1995. In this position, he was responsible for directing all of the company's research and development activities.

Mr. Giles holds several US patents and has published a number of technical articles for trade journals. Currently, he serves as the Chairman of the International Electronic Article Surveillance Manufacturers Association's Technical Committee, which coordinates industry-wide standards development.

O.S. Giles

MASSACHUSETTS GENERAL HOSPITAL

HARVARD MEDICAL SCHOOL

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J. Warren Harthorne, M.D.
Associate Professor of Medicine
Harvard Medical School

Note to the Commerce Committee:

From: J. Warren Harthorne, M.D.

Dear Colleagues, 2-14-00

There is a distinct possibility of my not being able to attend the very important meeting of the Commerce Committee on Tuesday, 2-15 due to an unexpected personal attack of diverticulitis which is not responding, as anticipated, to oral antibiotics at this time.

I wanted to offer my own plea regarding the substance of Bill 1138 which proposes to require the positioning of warning signs at the entrance to stores that are equipped with electronic article surveillance (EAS) devices. This subject has been discussed on numerous occasions both at the Food and Drug Administration as well as at several national and international meetings. The dominant response to EAS systems of a cardiac arrhythmia device, such as a pacemaker, depends largely upon the type of pacemaker device and its programmed settings. An extensive study by the Georgia Tech Institute of Research and others indicate that close proximity (measure in inches) to the transmitter in certain specific orientations may initiate isolated extra paced beats or skipped beats that are of no consequence to such patients. Some devices will revert to the designed "back-up" mode, a safety setting especially intended by the device engineers to avert sustained inhibition of stimulation in the presence of electromagnetic interference of many different forms. This backup mode is "asynchronous"; that is, it causes competition with native heart rhythms and is transitory, lasting only such time as exposure to the source on interference is sustained. That this type of transitory competitive pacing is innocuous is demonstrated by the telephone monitoring services which record the heart rhythm of literally thousands of such patients on a daily basis during intentional magnet application over the pacemaker device which induces identical transitory competition.

On a more compassionate note, such signs can only lead to further anxiety and apprehension among this often elderly and easily alarmed population of patients, many of whom make daily visits to malls, particularly during winter months for prescribed exercise. A recent estimate of the population of New Hampshire (Encycl.Britanica 1999 Yearbook) is of 1.7 million people. The leading manufacturer of cardiac arrhythmia devices (Medtronic) estimates that there are 5000 New Hampshire residents with these devices. Perhaps equally important are the hundreds of thousands of tourists who visit New Hampshire for summer and winter activities, many of whom have these cardiac support devices. One can imagine the consternation of the individuals at shops, malls, department stores etc when signs warning them of possible physical harm are at every entry way. There are but a handful of case reports in the medical literature of patients who have experienced symptoms from close and sustained proximity to such systems and no deaths or serious consequences. Such signage is not being supported by the various Cardiology societies in this country or in Europe or by the U. S. Food and Drug Administration . Such signs cannot be complete enough to define the many details of proximity, body orientation, or duration of contact to the transmitter source that may induce symptoms and would tend

to open a Pandora's box of imaginary, anxiety induced, but unrelated symptoms that cause needless consternation to the patient and their physicians. The ability to demonstrate in a research laboratory setting that temporary alterations in pacemaker function can be induced through unnatural exposure to EAS systems should not be construed as indicating that such alterations occur with any regularity or are of clinical significance. The posting of warning signs of the proposed type will do more psychologic harm than clinical good as far as patient welfare is concerned.

Respectfully Submitted,

J. Warren Harthorne, M.D.
Director, Pacemaker Service
MGH

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THE NEW YORK HOSPITAL-CORNELL MEDICAL CENTER
WESTCHESTER DIVISION

DEPARTMENT OF PSYCHIATRY
WESTCHESTER DIVISION

December 19, 1997

Dear Mr. Taber:

I have reviewed various materials regarding the effects of electromagnetic interference (EMI) on cardiac implant function. While I am not an expert in cardiology, the cardiac risks appear practically negligible for someone with such an implant walking through an electronic article surveillance device at a normal pace. On the other hand, I do have serious concerns about the potentially harmful psychological effects that unwarranted concern about this issue would have on people who use cardiac implants. It is well documented that the implantation of a pacemaker can have profound emotional effects (1-5). People who require these devices often feel a loss of autonomy and control (1). Many develop overwhelming fear that the device will malfunction and that they will suddenly die (2). It has been observed that "this situation imposes a strain that many psyches do not find tolerable" (1). A significant percentage of these patients go on to develop anxiety and depressive disorders in the aftermath of the pacemaker implantation (2,5) In my opinion, unwarranted concern about EMI could provoke excessive fear in these individuals which will cause further difficulty

in adapting to these life-saving devices and create a greater sense of impending danger. This type of a negative effect can only further increase anxiety and depression in these individuals and frustrate their attempt to lead a normal life (6).

Most people who require pacemakers are elderly. This group is particularly vulnerable to being unduly influenced by claims of environmental threats (7,8). It is not uncommon for an elderly person to literally become a shut-in because of some real or perceived threat to their health. Throughout their lives, the elderly have endured many losses including family, friends, bodily functions and community participation. For many of them, shopping becomes a mainstay of social contact, a way for them to move among people and to feel the movement of everyday life, while they simultaneously obtain their food, medication and other necessities. Many older individuals come to know store employees and look forward to their brief, friendly social exchanges. Inhibiting this process by creating the misimpression that they are walking through a mine field could have serious consequences that promote social isolation. Furthermore, we know that both the incidence and prevalence of dementia increases with age (9), thereby making it more difficult for such cognitively impaired elderly to adequately assess the absence of risk of walking through an electronic article surveillance device. Numerous studies have clearly documented the robust

association between social isolation and death from all causes, and in particular, cardiovascular disease (10-19). These unintended consequences of raising undue fear could therefore result in substantial adverse consequences.

In my opinion, the patient with a cardiac implant would be far better served by being educated by the physician and nurses who treat them on a regular basis. In this way patients would be supportively informed of any precautions, and any unnecessary fears could be immediately addressed by their doctor before these fears get out of control and take on a life of their own. Our goal should be to enhance our patients' mastery over their lives and not to have them become paralyzed, terrified hostages of a perceived hostile onvironment.

Sincerely,

Gerard C. Addonizio, M.D.
Associate Professor of Clincial Psychiatry

GCA:ah

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PULSAR/PULSAR MAX ← PACEMAKER SYSTEM GUIDE (PHYS. MAN.)

Home and Occupational Environments

Patients should be advised of the following potential sources of EMI:

- Avoid electromagnetic fields near extremely high-voltage transmission lines, because they might generate enough EMI to interfere with pacemaker operation if approached too closely.
- Exercise caution when in the vicinity of such communication equipment as microwave transmitters, linear-powered amplifiers, or some high-powered amateur transmitting systems, because they might generate enough EMI to interfere with pacemaker operation if approached too closely. In general, well-shielded and maintained systems assembled in a proper fashion do not disturb pacemaker operation.
- Certain types of antitheft devices such as those used at entrances/exits of department stores, libraries, and other public establishments can cause inhibition of pacing or temporary reversion to asynchronous pacing while the patient is in the immediate area of the detector. Patients should be instructed to walk at a normal pace and avoid lingering when passing through the entrances/exits of these establishments.
- Commercial electrical equipment such as arc welders, induction furnaces, and resistance welders might generate enough EMI to interfere with pacemaker operation if approached too closely.
- In general, normal operation of such electrical equipment as household appliances, electrical shop tools, and amateur RF transmitters should not affect a pacemaker. If interference occurs, however, normal pacemaker function should resume as soon as the patient moves away or turns off the source of EMI. There are reports of pacemaker disturbances caused by electric hand-tools or electric razors used directly over the skin over the pacemaker.

Cellular Phones

- Recent studies[1] have indicated there may be a potential interaction between cellular phones and pacemaker operation. Potential effects may be due to either the radio frequency signal or the magnet within the phone and could include inhibition or asynchronous pacing when the phone is in close proximity (within 6 inches [15 cm]) to the pacemaker. Based on testing to date, effects resulting from an interaction between cellular phones and implanted pacemakers have been temporary. Simply moving the phone away from the implanted device will return it to its previous state of operation. Because of the great variety of cellular phones and the wide variance in patient physiology, an absolute recommendation to cover all patients cannot be made.

1. Barbaro V. et al. GSM cellular phone interference with implantable pacemakers: in vitro and in vivo observations [slides]. Instituto Superiore di Sanita, Rome, Italy.

Things to avoid

Most of the things you handle or work around on a daily basis are not going to affect the AICD system. **However, your AICD system is sensitive to strong electrical or magnetic fields.** Keep the following potential sources of strong electrical or magnetic fields at least 12 inches (30 cm) away from your AICD pulse generator:

- Stereo speakers that are in large stereo systems, transistor radios, "boom boxes," etc.
- Strong magnets
- Magnetic wands used by airport security, and magnetic wands used in "Bingo" or other games, etc.
- Industrial equipment such as power generators and arc welders
- Battery-powered cordless power tools such as screwdrivers, drills, etc.

You should also avoid leaning over any electric engine that is running. Alternators of automobiles frequently contain magnets. Also avoid standing near anti-theft devices in doorways of department stores and public libraries. You may walk through them at a normal pace. Your pulse generator may be sensitive to these devices.

Check with your physician about using radio frequency, remote-controlled transmitters used for toy cars and airplanes. These devices may affect some AICD pulse generators.

Your AICD system may make sounds if you are too close to a magnet. The device may beep (about once per second) or make a continuous tone. Move away from the object or location immediately and call your doctor.

Cellular Phones

In certain cases, a cellular phone could affect how your AICD system senses arrhythmias. **Some phones that are closer than 6 inches (15 cm) to the pulse generator may affect its operation.** This effect is temporary. Moving the phone away from the pulse



generator location will return the AICD system to proper f
To reduce the chance of any affect, follow these precautio

- Maintain a distance of at least 6 inches (15 cm) bet
the cellular phone and your AICD pulse generator.
phone transmits more than 3 watts, increase the dist
12 inches (30 cm).
- Hold the cellular phone on the opposite side of you
from your AICD pulse generator.
- Don't carry a cellular phone in a breast pocket or o
if that places the phone within 6 inches (15 cm) of
AICD pulse generator.

These precautions apply only to cellular phones, not t
hold cordless phones, because household phones transmit
signal with less energy.

If you have questions about any situation or piece
ment, contact your doctor. You may also call CPI/Guic
1-800-227-3422.

HB 1138
ANTI-THEFT SYSTEMS AND IMPLANTED MEDICAL DEVICES

FACT SHEET

Anti-Theft Systems Do Not Pose a Public Health Hazard

- The U.S. Food and Drug Administration (FDA) undertook extensive study of the possible interaction between anti-theft systems and implanted medical devices, including public hearings, and found that anti-theft systems "do not pose a major public health problem at all."

- No states have enacted laws requiring warning signs.

- The American Heart Association, the European Society of Cardiology, their Asia-Pacific equivalent, their South American equivalent and the United Kingdom Medical Devices Agency have all advocated positions identical to the FDA.

- It is estimated that people with implanted medical devices pass through these systems approximately 200 million times annually (2 billion in the last decade), and there is not one death or serious injury to a cardiac implant patient attributed to these systems.

- Nationwide, over the past 10 years, the FDA has averaged fewer than 5 reports per year of possible interactions between anti-theft systems and cardiac implants. A U.S. Department of Veterans Affairs' review of 43,000 pacemaker patients who receive veterans' benefits found a "total absence of any complaints."

- According to the Weinberg Group, a Washington, D.C.-based scientific advisory firm, cardiac implant patients face more than a 1000 times greater risk simply driving to a mall, than from passing through an anti-theft system at the mall.

HB 1138
ANTI-THEFT SYSTEMS AND IMPLANTED MEDICAL DEVICES

FACT SHEET

HB 1138 Could Create a Health Risk to Cardiac Implant Patients, and Negatively Impact Patients' Quality of Life

- It is well documented that people who require cardiac implant devices often feel a loss of autonomy and control due to fear that the device will malfunction and that they will suddenly die. Mandating the posting of warning signs is likely to significantly increase their anxiety and risk of depression.

- Because of the profound emotional effects associated with implant devices, an ongoing, supportive physician-patient relationship is critical to patients living normal lives. HB 1138 would interfere with that relationship by creating unwarranted concern.

- Physicians who specialize in cardiac implant devices, as well as manufacturers and health education organizations, already educate patients about everyday exposures to electromagnetic fields, including cell phones, car engines, power tools, lawn mowers, anti-theft systems and many other devices. None of these devices have, or should have, warning signage.

- Many people who require pacemakers are elderly. This group is particularly vulnerable to being unduly influenced by unwarranted claims of environmental threats.

HB 1138
ANTI-THEFT SYSTEMS AND IMPLANTED MEDICAL DEVICES

FACT SHEET

HB 1138 Poses a Threat to New Hampshire Retailers

- Warning signs, such as those proposed in HB 1138, would create the misimpression that there's a serious potential hazard at the local store (i.e. - that patrons are passing through a danger zone just to go in and out of a store).

- Such signs could scare some people away from shopping or restrict their shopping. This could include many people without cardiac implants, who will unnecessarily wonder whether they too are at risk from the fields generated by anti-theft systems.

- Manufactures and retailers are taking the responsible step of marking anti-theft systems as "Anti-theft Systems" to remove any ambiguity as to where they are.

- It is estimated that retail theft costs every person in the United States hundreds of dollars annually in higher product costs.

- Anti-theft systems are very effective at catching shoplifters and discouraging crime.

FORBES MAGAZINE JANUARY 25, 1999
STRATEGIES.TRENDS. MANAGEMENT.
Companies

It's pretty hard to live down a health scare, especially when you have to contend with a nasty competitor and a pack of gullible journalists.

The zapping of Sensormatic

By Michael Fumento

WHAT'S WRONG WITH this picture? Sensormatic Electronics Corp. dominates the market for antitheft systems in retail stores. Rebounding from a slump that began a few years ago, the Boca Raton, Fla.-based company should report 40 cents a share in earnings in the current fiscal year and 70 cents in the next. But the stock languishes at $8.63, well below book value.

What's poisoning this stock? Quack science, propagated by short-selling sharks, sloppy journalists and Sensormatic's shrewd archrival, Checkpoint Systems, Inc. Scary newspaper stories have warned that electronic antitheft systems may interfere with pacemakers and defibrillators in 1.1 million Americans. It ain't so.

Checkpoint itself funded one study condemning the Sensormatic system; then it placed press releases and full-page ads touting its own systems as "free from pacemaker interference." Checkpoint, based in Thorofare, N.J., is less than half the size of Sensormatic, so the counterpunching would be fair game if the pacemaker threat were real. But it isn't. The U.S. Food & Drug Administration reviewed the matter last fall and deemed the threat insignificant. The American Heart Association has weighed in similarly.

Says Sensormatic President Robert Vanourek: "Look, Coke battles Pepsi, Ford battles GM. But there's a sense of playing by the rules. When you engage in company assassination by innuendo, you've gone beyond the pale." Checkpoint says it's only trying to avoid getting hurt by the scare—which it has helped perpetuate.

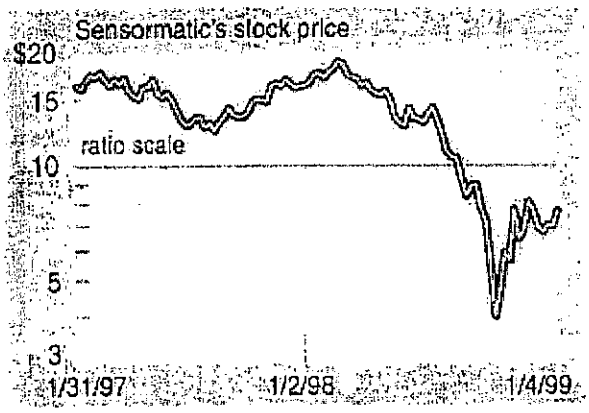
Sensormatic's image problems began in May 1995 with a report by Dan Dorfman, then an on-air rumormonger for CNBC. His key source: a public relations guy who had worked for Sensormatic, lost the account and quickly took on Checkpoint as a client. Within days Sensormatic's stock had lost one-fifth of its value as short-sellers pounced.

Cut to two years later: Checkpoint gives a $100,000 grant to Michael McIvor, a cardiologist at the Heart Institute of St. Petersburg, Fla., to study the pacemaker problem. Both Checkpoint and Sensormatic sell similar systems that emit magnetic radio waves to detect tags that haven't been removed or desensitized at a checkout counter. Checkpoint's systems simply operate at a higher frequency.

The findings were golden for Checkpoint: McIvor said the Sensormatic system interacted with 48 of 50 pacemakers; Checkpoint systems caused no interactions. The results ran 18 months later in the October 1998 medical journal *PACE*, just as the November issue of the *New England Journal of Medicine* ran a short article about one case and a letter, coauthored by McIvor, about a second.

Left for dead?

Sensormatic'santitheft systems aren't risky. But the stock is another story.



The press ran wild. "Shoplifting gates can be hazardous," the Associated Press blared. CNN, *USA Today*, the *Chicago Tribune*, the *New York Daily News* and the *Washington Post* picked up the story. Reuters declared the systems can "make implanted pacemakers and defibrillators go haywire, with sometimes fatal results"—and later issued a correction saying there was no evidence of deaths.

The fine print was far less frightful, but few noticed. Fifty people is a terribly small sample. An "interaction" usually is nothing more than a skipped heartbeat. Only three of the people who walked briskly through the antitheft gates had an interaction; the other interactees were told to stand between the gates or lean on a transmitter—for up to five minutes.

Featured prominently in the coverage was McIvor, who wasn't the most objective investigator. He sought out Checkpoint, among other antitheft system makers, to fund his study after a patient had trouble with the sensors. He put out his own press release, pushed the FDA to investigate and laid out the risks at a retailers' seminar.

Sensormatic fought back. It forked over $25,000 to get access to McIvor's results and still hasn't received the data. As the company fired off press releases and letters to the editor defending itself, it only focused more attention on the whole mess—and journalists are loath to retract their scare stories.

The frustrating thing for Sensormatic is that most experts firmly agree no real risk exists. A review of 43,000 pacemaker patients who get U.S. veterans' benefits found a "total absence of any complaints." A study of 150,000 patient histories in London found much the same. The FDA has logged about 20 reports. Worst reaction: "chest pain."

Yet with 1.1 million patients, and 60,000 stores using antitheft systems, if the risk is real, "Something should *happen*. There ought to be people lying on the floor at Home Depot," says J. Warren Harthorne, director of the pacemaker lab at Massachusetts General Hospital in Boston.

Serious problems "are extremely unlikely to happen," adds Douglas P. Zipes, vice president-elect of the American College of Cardiology and a professor at Indiana University. He has just submitted a new study for publication: One hundred seventy patients with implanted defibrillators walked through Sensormatic systems, and "zero interactions" were found. "This whole thing is just a tempest in a teapot," he says.

And just who funded Zipes? Sensormatic, fighting fire with fire.

Voting Sheets

HOUSE COMMITTEE ON COMMERCE

EXECUTIVE SESSION on HB 1138

BILL TITLE: **requiring warnings for certain antitheft devices.**

DATE: February 16, 2000

LOB ROOM: 302

Amendments:

Sponsor: Rep. OLS Document #:

Sponsor: Rep. OLS Document #:

Sponsor: Rep. OLS Document #:

Motions: OTP, OTP/A, (ITL), Re-Refer, Interim Study (Please circle one.)

Moved by Rep. McGough

Seconded by Rep. Francoeur

Vote: 14-0 (Please attach record of roll call vote.)

Motions: OTP, OTP/A, ITL, Re-Refer, Interim Study (Please circle one.)

Moved by Rep.

Seconded by Rep.

Vote: (Please attach record of roll call vote.)

CONSENT CALENDAR VOTE: Yes 14-0

(Vote to place on Consent Calendar must be unanimous.)

Statement of Intent: Refer to Committee Report

Respectfully submitted,

Rep. Stephen G. Avery, Clerk

Steph G. Avery

HOUSE COMMITTEE ON COMMERCE

EXECUTIVE SESSION on HB 1138

BILL TITLE: **requiring warnings for certain antitheft devices.**

DATE: 2/16/00

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Motions: OTP, OTP/A, (ITL), Re-Refer, Interim Study (Please circle one.) 14-0

Moved by Rep. McGough

Seconded by Rep. Francoeur

Vote: (Please attach record of roll call vote.)

Motions: OTP, OTP/A, ITL, Re-Refer, Interim Study (Please circle one.)

Moved by Rep.

Seconded by Rep.

Vote: (Please attach record of roll call vote.)

CONSENT CALENDAR VOTE: {Type VOTE} - 14-0

(Vote to place on Consent Calendar must be unanimous.)

Statement of Intent: Refer to Committee Report

Respectfully submitted,

Rep. Stephen G. Avery, Clerk

OFFICE OF THE HOUSE CLERK 2000 SESSION

COMMERCE

Bill #: 1138 **Title:** Warnings for certain antitheft devises

PH Date: ___/___/___ **Exec Session Date:** 2/16/00

Motion: ITL **Amendment #:**

MEMBER	YEAS	NAYS
Hunt, John B, Chairman		
Francoeur, Sheila T, V Chairman	✓	
Herman, Keith R	✓	
Tsiros, William B		
Belanger, Ronald J	✓	
McGough, Tim S	✓	
Avery, Stephen G, Clerk	✓	
Kenney, Joseph D	✓	
Langley, Jane S	✓	
Pappas, Marc P	✓	
Dalianis, Griffin T	✓	
DiFruscia, Anthony R		
Marshall, Gene B	✓	
Clark, Martha Fuller		
Crosby, Toni M		
Russell, Ronald G	✓	
Reardon, Tara G	✓	
Vachon, Dennis P		
Taylor, Kathleen N	✓	
Curran, James C		
Garrish, Linda L		
Keye, Harvey	✓	
	14	0
TOTAL VOTE:		

Printed: 12/30/1999

Committee Report

COMMITTEE REPORT

COMMITTEE: **Commerce**

BILL NUMBER: **HB 1138**

TITLE: requiring warnings for certain antitheft devices

DATE: Feb. 16, 2000 CONSENT CALENDAR YES ☒ NO ☐

☐ OUGHT TO PASS

☐ OUGHT TO PASS WITH AMENDMENT

☒ INEXPEDIENT TO LEGISLATE

☐ RE-REFER

☐ REFER TO COMMITTEE FOR INTERIM STUDY
(Available only in second year of biennium.)

STATEMENT OF INTENT
(Include Committee Vote)

The medical evidence offered at the public hearing by acknowledged medical experts overwhelmingly demonstrated that electronic anti-theft systems pose no public health threat hazards to persons with pacemaker implants or to others. Further, it was convincingly established that disclosures by the manufacturers and provided by physicians to patients at the time of implant and continuously thereafter, are far more effective than the signage required by this bill. The committee unanimously felt that such signage would interfere with the doctor-patient relationship and unreasonably and unnecessarily alarm persons wearing pacemakers.

Vote 14-0.

Rep. Tim S. McGough
FOR THE COMMITTEE

Original: House Clerk
cc: Committee Bill file

USE ANOTHER REPORT FOR MINORITY REPORT

CONSENT CALENDAR

Commerce

HB 1138, requiring warnings for certain antitheft devices INEXPEDIENT TO LEGISLATE

Rep. Tim S. McGough for Commerce: The medical evidence offered at the public hearing by acknowledged medical experts overwhelmingly demonstrated that electronic anti-theft systems pose no public health threat hazards to persons with pacemaker implants or to others. Further, it was convincingly established that disclosures by the manufacturers and provided by physicians to patients at the time of implant and continuously thereafter, are far more effective than the signage required by this bill. The committee unanimously felt that such signage would interfere with the doctor-patient relationship and unreasonably and unnecessarily alarm persons wearing pacemakers. Vote 14-0.