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Date: 17 octobre 2000

A - To: Dr. Éric Goyer
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**Message**

Cher docteur Goyer,

Tel que convenu, je vous fais parvenir l'information sur les effets potentiels des interférences électromagnétiques sur les pacemakers et défibrillateurs implantables de la compagnie Medtronic.

Je suis toujours à la recherche d'information sur les champs magnétiques vs les valves cardiaques mécaniques.

Veuillez communiquer de nouveau avec moi si vous avez d'autres questions.

De - From: Bernard Soucy, B.Ing.,M.Sc.A

Nombre de pages incluant celle-ci:
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# High Power Voltage and Pacemakers

There are two kinds of electromagnetic interference to which your patient may be exposed. The first, conducted interference, may be defined as that occurring when the skin comes in contact with the apparatus producing the interference, i.e., electric shock. The body becomes a path for current flow and the pacemaker detects the voltage developed across the pacemaker electrodes as a result of the current.

The second form of interference is radiated and may be defined as the effect on a pacemaker system caused by electromagnetic fields. The operation of the pacemaker may be affected, even though there is no dir, contact with the apparatus. This may occur in the presence of high voltage lines, transformers, etc.

If the interfering signal is larger than the pacemaker's threshold of susceptibility, then the modulation of the signal (variation in the signal strength with time) determines the effect on the pacemaker. There are three types of possible responses which can occur.

Continuous signals such as 60 Hertz sine wave interference, e.g., commercial power line, will cause the pacemaker to revert to asynchronous operation. Asynchronous pacing may result in a pacing pulse being delivered during the T-wave of an intrinsic depolarization sequence. Such operation, known as competition, may cause arrhythmias in those patients that are susceptible.

Regular, transient or pulsed signals that occur in a frequency rate of 1 to 8 Hertz can continuously inhibit the pacemaker. Signal frequencies greater than 8 Hertz generally cause the pacemaker to revert. Single transient signals may result in inhibition of a single pacing pulse but would not cause continuous inhibition.

Radiated interference may be in the form of electric fields, magnetic fields, or both. Static magnet fields greater than approximately 10 gauss at the pacemaker site will cause asynchronous operation. Pulsed or amplitude modulated magnetic fields may produce inhibition or reversion depending on their frequency if the pulse amplitude or modulation peak exceeds roughly, a 1 gauss threshold.

Both inhibition and reversion are temporary. They will last until either the strength of the interference is reduced or the patient moves away from the interfering source. The strength of electromagnetic fields diminishes rapidly as the distance from the source increases.

Bipolar pacemakers are up to ten times less sensitive to interference than unipolar devices. This difference in sensitivity is a result of the larger distance between electrodes for unipolar as compared to bipolar electrodes.

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It is difficult to predict precisely what the response of the pacemaker will be in your patient's work environment due to the complexity of the actual electromagnetic interference signals and the effects of those signals on the device in vivo. The most likely response would be reversion in the presence of large continuous signals. This would be the case when standing near the high voltage lines and substations. As a result, the pacemaker may compete with the patient's own rhythm, so the medical implications are primarily centered on susceptibility to arrhythmias. In addition, there may be single beats that are inhibited during transient interference signals such as occur with power switching.

Pacemaker parameter changes may limit the effects of interference. For example, by decreasing the programmed sensitivity to the least sensitive setting that still maintains proper sensing of intrinsic ventricular depolarizations, the chances of interaction are decreased.

With regard to specific distances to maintain from high voltage power lines, we recommend a patient maintain a two to three foot distance from the pacemaker to high voltage lines for every 10,000 volts. Other machinery will present no problem if it is in good working order, properly grounded, and adequately maintained. Installing cables should not present electrical interference difficulties. Work in a bucket truck presents a bit of concern as a patient may not be able to readily move away from an interference source if he experiences symptoms. Working on ladders and elevated walkways may be contraindicated if the work being performed has a high probability for causing inhibition.

Perhaps the best way to determine if there will be any interaction between the patient's work environment and the pacemaker is to have the patient monitored while he performs his normal tasks. This may be accomplished by using either a Holter monitor or a telemetry transmitter wrapped in aluminum foil with very short leads to avoid interference. The leads should be shielded, wrapped in a braided fashion, and also covered with aluminum foil. Since the effects on the pacemaker are uncertain, I would strongly suggest that the patient be accompanied at all times when he enters into a new work environment in the event that he becomes symptomatic.

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## Magnetic Fields

Static magnetic fields cause Medtronic pacemakers to revert to fixed rate. The minimum magnetic field necessary to revert a Medtronic pacemaker is 10 to 20 gauss. A static magnet field will not cause Medtronic pacemakers to turn off or inhibit.

The magnet field strength associated with large industrial crane magnets drops off very rapidly with distance from the magnet. A gauss meter could be used to survey the area in the immediate vicinity of the crane and magnet. The results of this survey can be used to establish a safety perimeter around the area associated with the crane magnet.

Power frequencies [60 Hz] can also affect Medtronic pacemakers. Medtronic pacemakers classify all electrical signals based on frequency into two categories, physiologic and non-physiologic. If the rate of the detected signal is 300 bpm [5 Hz] or less, it is considered physiologic. The pacemaker is designed to inhibit in response to a signal in this rate range. Rates above 300 bpm are considered non-physiologic. The non-physiologic rates cause the pacemaker to revert [turn on all the time].

The reversion rate during the exposure of the pacemaker to a non-physiologic signal source may be either the activity rate or the programmed lower rate. The duty cycle characteristic of the interfering signal determines which reversion rate will occur.

The duty cycle of an electrical signal is the percentage of time that the signal is on or active in relation to the signals repetitive interval. For example, the repetitive interval for a [60 Hz] power line is approximately [16 ms]. The signal from a power line is characterized by a sine wave that is active the entire [16 ms] of that interval. Thus, a signal from a power line or power transformer would have 100 percent [long] duty cycle. A signal from another source might also have a similar [16 ms] interval, but the electrical signals may only be active for [1.6 ms]. This results in a gap of 14.4 ms from the end of one signal to the beginning of another. No electrical activity is present during this gap. Since the signal is active for only 1/10 of the interval, this signal is said to have a 10 percent [short] duty cycle.

Interference from a power frequency source [50/60 Hz sine wave], with a long duty cycle causes the pacemaker to revert to the activity rate. However, interference of the same frequency [60 Hz] but from a source that has a short duty cycle will cause the pacemaker to revert to the programmed lower rate.

In either case, the pacemaker is designed to revert to an asynchronous rate in the presence of strong continuous interference at rates greater than 300 bpm [5 Hz].

A Holter monitor may be prescribed to aid in the evaluation of the pacemaker when the patient is actually in his work environment. It has been our experience, however, that in most cases the Holter is obscured before the pacemaker is affected. The Holter can be useful in evaluating the level of interference in the patient's work environment.

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# Electrical Power and ICDs

The Medtronic implantable cardioverter defibrillator (ICD) device has a highly selective filter designed to avoid sensing of electromagnetic interference (EMI). Some types of EMI can exceed the capability of this filter to reject it and cause the ICD to erroneously detect the EMI as a rapid heart rate and deliver an electrical therapy.

EMI from high voltage/current power sources, such as power plants, substations, and high voltage lines can be in the form of conducted current, radiated electric fields, or magnetic fields.

If poorly grounded equipment is touched, the body becomes a path for current flow and the ICD detects the voltage developed across its electrodes as a result of the current in the body. This would result in the ICD delivering an inappropriate therapy, since the ICD can sense voltages as low as 0.3 mV. Leakage currents not perceived by humans could trigger a therapy from the ICD.

The second form of interference is radiated electric field interference. High frequency electric fields less than 140 volts/meter intensity measured at the skin over the ICD leads will not interfere with correct ICD sensing of cardiac events. Low frequency electric fields (under 1 kHz) will not interfere with sensing if the intensity in the vicinity of the patient is under 6000 V/m. Electric fields in excess of these levels could cause erroneous detection and inappropriate therapy as described above.

The third form of interference is radiated magnetic field. A constant (DC) magnetic field measured at the skin to be 10 Gauss or greater could suspend the arrhythmia detection of the ICD. Thus, if the patient develops a life threatening arrhythmia while in this very strong constant magnetic field, the ICD may not deliver appropriate therapy. This detection capability will be restored, unaltered, as soon as the patient moves out of the field.

Alternating magnetic fields produced by high current, AC power equipment can induce a voltage on the leads of the ICD, and this could be inappropriately sensed as a fast heartbeat by the ICD. An AC magnetic field of 1.0 gauss measured at the skin of the person with an implanted ICD could induce up to 0.5 millivolts on an underlying ICD lead system.

Electromagnetic fields (EMF) have been measured at power plants, substations, steel mills, and other industrial environments. In general, measured fields one foot away from large generators, large and small motors, transformers, and switchgear were well below the 1 gauss that could affect the ICD at power frequencies of 50 or 60 Hz. Only substation transformers had a large enough field; but at three feet away the field was considerably diminished so that it was not a concern.

Power transmission components that required more the arm's length away for safety are bus bars carrying extremely high currents and high voltage power transmission lines. It is recommended to stay at least six feet away from these types of bus bars and 25 feet from power lines over 100,000 Volts.

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## ElectroMagnetic Interference (EMI) & ICDs

The Medtronic implantable cardioverter defibrillator (ICD) device has a highly selective filter designed to avoid sensing of electromagnetic interference (EMI). Some types of EMI can exceed the capacity of this filter to reject it and cause the ICD to erroneously detect the EMI as a rapid heart rate and deliver an electrical therapy.

There are three kinds of EMI which could affect the operation of an ICD. The first, conducted interference, may be defined as that occurring when the skin comes in contact with the apparatus producing the interference. The body becomes a path for current flow and the ICD detects the voltage developed across its electrodes as a result of the current. An example of this would be a very small electrical current flow which occurs by contacting poorly grounded electrical equipment.

The second form of interference is radiated electric field interference. High frequency electric fields less than 140 volts/meter intensity measured at the skin over the ICD leads should not interfere with correct ICD sensing of cardiac events. An example of this would be the electrostatic field produced by a 50 kW induction heater used for metal forging, annealing or brazing. At a distance of 1.2 meters from the heater, the field may be 3 V/m but this field intensity would increase to 106 V/m at a distance of 0.3 meters. Low frequency electrostatic fields (under 1 kHz) will not interfere with sensing if the intensity in the vicinity of the patient is under 6000 V/m. Electric fields in excess of these levels could cause erroneous detection and inappropriate therapy as described above.

Another radiated electric field source is the electrical ignition systems used in propane-powered fork lifts. Pulsed voltages over 15 kV are near the spark plugs and the cables. The fields may be sufficiently intense (> 140 V/m) to be sensed by a ICD if the patient is very close to the ignition system high voltage components, that is, within arm's length. However, the heavy metal structure of most forklifts prevent any appreciable EMI from reaching the operator.

Machine operators of high frequency dielectric heaters are commonly exposed to intense electric fields. Dielectric heaters are used by industry to heat, melt, or cure materials such as plastic, rubber, or glue. A 1988 Swedish survey reported that 79% of tarpaulin machines and 35% of the automatic machines had field intensities greater than 194 V/m measured at the chest level of the operators.

The third form of interference is radiated magnetic field. A constant (DC) magnetic field measured at the skin to be 10 gauss or greater could suspend the arrhythmia detection of the ICD. Thus, if the patient develops a life threatening arrhythmia while in this very strong constant magnetic field, the ICD will not deliver appropriate therapy. This detection capability will be restored, unaltered, as soon as the patient moves out of the field. Magnetic field intensity decreases rapidly with separation from the source.

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Alternating magnetic fields are produced by high current, AC powered equipment. An AC magnetic field of 1.0 gauss measured at the skin could induce up to 0.5 millivolts on an underlying ICD lead system. This could be inappropriately sensed as a fast heartbeat by the ICD since they are frequently programmed to sense signals as low as 0.3 mV of amplitude.

The electrode and cables of an arc welding machine operating at 300 amps could produce a magnetic field of up to 60 gauss. However, at an arm's length distance from the source, this field intensity would be about 1.0 gauss.

A 50 kW induction heater could produce an AC magnetic field strength of 0.9 gauss at a distance of 0.6 meters and field of 3.0 gauss at half that distance.

Steel induction furnaces use low frequency electric current for smelting, hardening and heat treatment. Operators are exposed to AC magnetic field strengths of 1 to 80 gauss.

AC motors of varying horsepower up to 250 hp are common in factories. Low horsepower motors commonly produce magnetic field levels similar to those from the larger motors. The very large motors appear to have a massive steel structure that provides better containment of magnetic fields. The magnetic field strength at the patient position is not likely to interfere with ICD sensing.