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Standard Practice for Security Checkpoint Metal Detector Screening of Persons with Medical Devices[1]

This standard is issued under the fixed designation F2401; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 The following practice is intended to address the needs and concerns of persons with implanted, active, medical devices or active ambulatory medical devices, as well as passive implanted medical devices, while maintaining the integrity of the security checkpoint.

1.2 Active and passive implanted medical devices are being used at an increasing rate as a means to prolong and improve quality of life. Although these medical devices are typically designed to operate in the electromagnetic environment experienced in daily life, there is a potential for the disruption of active medical device function when exposed to certain electromagnetic fields emitted by commonly encountered electrically powered products, including handheld and walk-through metal detectors used in security checkpoint screening. In addition, some active or passive implanted devices may trigger the unintended alarm of the metal detector.

1.3 The values stated in SI units are to be regarded as the standard. The values shown in parentheses are for information only.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ISO Standards:*[2]

ISO 14117 Active implantable medical devices – Electromagnetic compatibility – EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices

ISO 14708-1 Implants for surgery – Active implantable medical devices – Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

ISO 14708-2 Implants for surgery – Active implantable medical devices – Part 2: Cardiac pacemakers

ISO 14708-3 Implants for surgery – Active implantable medical devices – Part 3: Implantable neurostimulators

ISO 14708-4 Implants for surgery – Active implantable medical devices – Part 4: Implantable infusion pumps

ISO 14708-5 Implants for surgery – Active implantable medical devices – Part 5: Circulatory support devices

ISO 14708-6 Implants for surgery – Active implantable medical devices – Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)

ISO 14708-7 Implants for surgery – Active implantable medical devices – Part 7: Particular requirements for cochlear implant systems

3. Terminology

3.1 *Definitions:*

3.1.1 *active medical devices, n*—electrically powered medical devices, usually employing electronic circuitry, for human physiological monitoring or to deliver medical treatment or therapy such as drugs or electrical stimulation. These devices can be implanted, patient worn, or both.

3.1.2 *ambulatory medical devices, n*—any medical device (active or nonactive) that can be body mounted, worn, implanted, or otherwise mobile with the patient and thus subject to screening at the security checkpoint.

3.1.3 *archway, n*—physical structure of a walk-through metal detector.

3.1.4 *electromagnetic field, n*—when referenced in this practice, it describes the energy field created by the metal detector as a means to produce a response to materials with electrical conductivity or magnetic susceptibility, or both. The electromagnetic fields used in metal detectors for security screening applications are typically low frequency and vary with time and locations.

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[2] Available from International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, http://www.iso.org.

3.1.5 *handheld metal detector, n*—portable metal detector product used by a security screener to provide localized searches of a person.

3.1.6 *passive (nonactive) medical devices, n*—nonelectrically powered medical devices. These types of medical devices may have sufficient metallic content to cause a response from a metal detector. These devices can be implanted, patient worn, or both.

3.1.7 *security checkpoint, n*—access point equipped with personnel and screening devices used as a means to control the flow of weapons or contraband material, or both.

3.1.8 *security screener, n*—trained person performing the necessary functions at a security checkpoint.

3.1.9 *walk-through metal detector, n*—a stationary metal detector that is typically permanently fixed in a particular location but may be temporarily fixed, is typically constructed in an archway form, and that provides a search of the entire body as a person passes through the portal of the detector.

4. Summary of Practice

4.1 This practice provides the means to identify, evaluate, and screen persons with ambulatory medical devices and report incidences involving medical device users.

4.2 These means shall include security checkpoint layout, signage, screening procedures, screener training, and information for the medical community (physicians, nurses, device manufacturers, patients, and so forth) about checkpoint security procedures to encourage the standardization of information and media provided to persons with medical devices.

5. Significance and Use

5.1 This practice is intended to be used as a guide for the design, configuration, and operation of security checkpoints to minimize exposure of ambulatory medical devices to the electromagnetic fields emitted by metal detector security systems. Guidance is presented for signage and information to help identify persons with ambulatory medical devices and process them through the security checkpoint.

5.2 This practice is intended to help in the training of checkpoint screeners to address the concerns of persons with ambulatory medical devices and to respond to their needs.

5.3 This practice is intended to aid the medical community in advising medical device users who may be affected to identify themselves at security checkpoints so their concerns may be addressed.

5.4 This practice is intended to aid medical device manufacturers to provide consistent information for medical device users, patients, and checkpoint screeners.

6. Procedure

6.1 *Checkpoint Layout*—The security checkpoint shall be arranged and configured to minimize medical device exposure to the metal detector emissions. This shall be facilitated by free traffic flow through the checkpoint, which in turn minimizes the duration of time a person remains inside the archway. To accomplish this checkpoint layout, the following points should be considered.

6.1.1 Provide an area for divestiture of metallic objects before screening.

6.1.2 Provide identifiable queuing area for the human traffic flow through the security checkpoint. The traffic start point should be at least 30 cm before the archway entrance.

6.1.3 Provide a path of free flow to ensure that no distractions or obstructions prevent a person from freely passing through the archway unhindered. A distance of at least 1 m beyond the archway exit where stopping for hand inspection of parcels or retrieving items from the baggage screening X-ray system is recommended.

6.1.4 Provide no-standing zones of 40 cm on each side of the walk-through metal detector archway for security personnel.

6.1.5 Provide a secondary screening area for manual scanning with a handheld metal detector or hand searching, or both, as provided by the security policy.

6.1.6 Provide a means for bypass of the walk-through detector directly to the secondary screening area, if allowed by security policy.

6.2 *Signage*—Typically security checkpoint metal detectors are visible and identifiable. Signage is suggested to alert persons with concerns about their medical devices and direct them to security staff for assistance. An example is “Metal detector in use. Persons with medical devices needing assistance should notify security personnel.”

6.3 *Reporting*—Incidents of medical device disruption from exposure to the security equipment that result in injury to the device user or complaint should immediately be reported to the security personnel, preferably to the checkpoint supervisor. Information about the incident should be recorded with as much of the following information as appropriate and available under the circumstances.

6.3.1 Date, time, and location of incident (for example, facility name or address and security checkpoint location).

6.3.2 *Security Equipment and Personnel Involved*—Type of equipment (for example, handheld metal detector or walk-through metal detector), manufacturer, model, model number, serial number, and settings.

6.3.3 *Patient Information*—Name, address, telephone number, e-mail, patient age, sex, height, weight, and if available, patient’s physician name and contact information.

6.3.4 *Medical Device Information*—As much detail about the active medical device as possible, including the medical device type (for example, type, make, model, and serial number), device location on or implanted in body, and medical device settings (if known). A photocopy of the patient’s medical device implant identification card (if available) may provide some portion of this information.

6.3.5 *Summary of Incident*—A description of what happened, including communication with the patient before, during, and after the incident. For walk-through metal detectors, how long the patient was in the archway, and for handheld metal detectors, how long the detector was held over or near the medical device location and at what distance. A

figure of the patient and screening equipment showing the patient location and direction is useful.

6.3.6 *Patient Complaint*—Summary description of what the patient experienced and when, and what the consequences of the incident were for the patient and medical device.

6.3.7 Any communications with the patient's physician after the event.

6.3.8 All incidents involving medical devices that result in patient injury or complaint should be reported to the FDA's voluntary reporting program, MedWatch.[3]

6.4 *Screening Procedures:*

6.4.1 *Identify*—The use of signage and trained operators helps to identify persons with medical devices who are concerned about potential medical device disruption and those who are concerned that their devices may cause the metal detectors to alarm. Notification by the medical device user to the checkpoint screener should be done before the medical device user enters the archway or is scanned by a handheld metal detector. The screener should be prepared to handle information discreetly when privacy is a concern.

6.4.2 *Assess*—Methods to assess concerns of persons with medical devices may include a brief interview with the person to identify the type of medical device, any medical device user safety concerns, or advice received by the device user from their healthcare provider. Additional information may be obtained from medical device information cards often supplied by medical device manufacturers. The checkpoint operator should check this card to verify patient's name, type and location of medical device, and any recommended restrictions to metal detector exposure. Checkpoint operators should respect the requests of the patient while following security screening procedures.

6.4.3 *Address Concerns*—Methods of addressing patient concerns may vary depending on the type of security requirement and the availability of alternate screening methods. Proper training of security personnel will allow appropriate assessment and implementation of a prescribed security screening method. The patient may have concerns that include the medical device may cause the security equipment to alarm or the patient has been advised to minimize or avoid exposure to handheld or walk-through metal detectors.

6.5 *Alternative Screening Procedures*—Alternative procedures are often useful in addressing the needs and concerns of patients. The following alternative procedures should be considered when establishing security policy.

6.5.1 Limited searches with handheld metal detectors that minimize medical device exposure by using hand searches in the area of the medical implant.

6.5.2 Hand search for a patient who has been advised to avoid metal detector searches entirely.

6.5.3 It must be recognized that for some security applications hand searches may not be considered adequate and may result in a denial of access to certain areas.

6.6 *Minimize Exposure*—The most basic method of addressing concerns is to minimize exposure. Examples of methods to minimize exposure are:

6.6.1 Checkpoint layout designed for free flow through a walk-through detector without obstructions that would cause a person to stop within the archway.

6.6.2 Checkpoint supervision that encourages persons to walk through the center of the archway of a walk-through metal detector at a reasonable pace without pausing.

6.6.3 Checkpoint prescreening procedures that encourage the divesting of metallic objects as a means to minimize the need for multiple security checkpoint screening operations.

6.6.4 Allowing the patient to describe the location of a medical device and to allow the area to be quickly scanned or perhaps avoided during the use of a handheld metal detector device. Likely, many medical devices will be detected by a

[3] Burlington, D.,"Important Information on Anti-Theft and Metal Detector Systems and Pacemakers, ICDs, and Spinal Cord Stimulators," *Food and Drug Administration Notification and Reference List*, Available: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062288.htm. http://www.fda.gov/cdrh/safety/easnote.html, Sept. 1998.

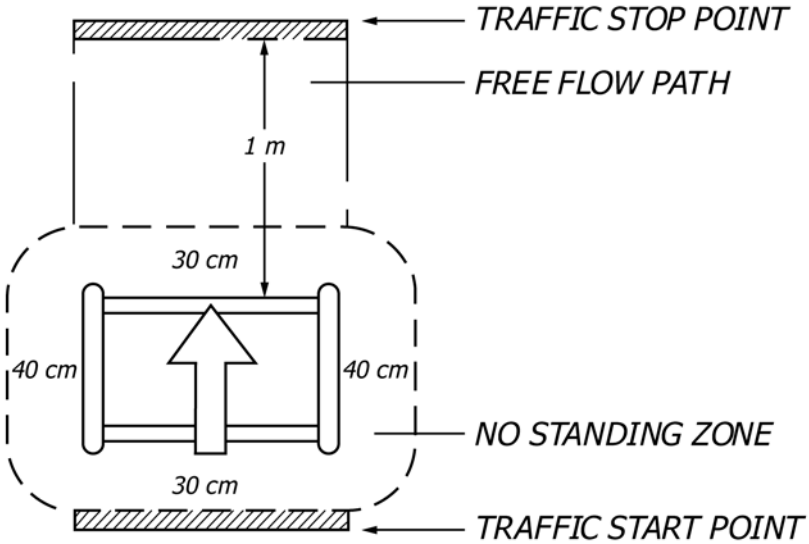

FIG. 1 Walk-Through Metal Detector Traffic Flow and Exclusion Zone for Medical Active Device Patients

handheld metal detector. Knowledge of the location of the medical device can allow a checkpoint screener to expedite a search in that body area.

6.6.5 Keeping a handheld metal detector at least 2.5 cm from a patient's body when passing over a known area containing a medical device.

6.6.6 Using hand searches in the area of the medical device if allowed by the policy.

6.6.7 Maintaining a "No Standing Zone" in and around a walk-through metal detector. This includes an area 30 cm before the entrance and beyond the exit of a walk-through metal detector and 40 cm around the sides of the walk-through metal detector (see Fig. 1). The electromagnetic field emission from walk-through metal detectors decrease rapidly with distance. Beyond these zones, concern for medical devices is minimal.

7. Keywords

7.1 active medical devices; electromagnetic fields; handheld metal detector; medical devices; security checkpoint; security screener; walk-through metal detector

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 This practice addresses the environment in the vicinity of security checkpoints that use metal detectors. These metal detectors have the potential of disrupting the function of active, ambulatory medical devices. Although instances that require additional precautions are rare, awareness to these possibilities is important. A procedure for addressing medical devices benefits the safety and well-being of the patients and the effectiveness of the security checkpoint. A uniform established procedure also assists physicians and medical device manufacturers in providing advice to their patients and allows checkpoint operators to establish procedures consistent with this advice. By following these procedures, the patient is accorded a minimal amount of intrusion while maintaining the integrity of the security checkpoint.

X1.2 The use of ambulatory medical devices to care for patients is increasing. These ambulatory medical devices generally fall into two categories: active devices that are electrically powered (for example, cardiac pacemakers, implanted nerve stimulators, and hearing aid devices) and passive devices (for example, joint replacements such as hip implants, bone screws and plates, and heart valves). There are also active and passive patient-worn devices (for example, prosthetic arm or leg). Some active medical devices may have both an implanted component and removable or wearable component (for example, drug infusion devices) or be worn on the body for several days to monitor the patient's physiological condition (for example, Holter monitor for cardiac monitoring).

X1.3 Medical device manufacturers strive to build their equipment in a manner so that they are compatible with the electromagnetic fields in the environment in which the devices are used. However, there are often physical and technical constraints that limit the level of medical device immunity to electromagnetic emissions from metal detectors. In addition, with new advanced techniques in medical devices and continuous changes in our daily environment, assurance of complete immunity from disruption may not always be possible. It is therefore important to address the potential effects of the emissions from metal detection equipment on active implanted or patient-worn medical devices, or both. In addition, for proper function of the security checkpoint, the accurate resolution false alarm indications by the security metal detectors that may be caused by the presence of ambulatory medical devices must also be addressed.

X1.4 *Medical Device Specific Information*—The following information may be used to assist in addressing specific checkpoint screening requirements when no other information is available. It is important to address all concerns of a patient and follow any specific information provided by the medical device manufacturer or the physician.

X1.4.1 *Metallic Implants (Joints, Plates, and Pins)*—Metal detectors do not affect these devices, and these devices generally do not cause walk-through-type metal detectors to alarm. However, certain combinations of shape, size, material, and settings of the metal detector may result in unwanted security system alarms. Most medical implants of this type will be detected by a handheld metal detector. Security screening protocol may require a physical search of the body area to insure that a weapon is not disguised as an implant. In some cases, it may be helpful to refer to the patient identification card that may be provided to the patient to clarify further the nature of the alarm.

X1.4.2 *Cardiac Pacemakers*—These devices contain cardiac-sensitive monitoring circuitry that may be affected by electromagnetic fields in the environment, which may mimic signals that are similar to signals produced by the body. Recommended practice for screening with a walk-through metal detector is for the patient to walk through the center of the archway at a normal pace. The patient should not remain within 30 cm of the entrance or 40 cm of the sides of the detector for longer than a few seconds. When scanning with a handheld metal detector, the operator should limit to a few seconds (less than 5 s) the time spent over the upper chest area (where the pacemaker generator is usually located) and make a minimum number of passes to locate the device and determine that a weapon is not disguised. The pacemaker generator is typically about 5 cm (2 in.) in diameter and located in the upper

chest area on the left or right side, and in some cases, there may be more than one implanted cardiac device. The pacemaker generator case will not cause a walk-through metal detector to alarm unless the detector is set at a very high sensitivity level. A handheld metal detector will in most cases detect a pacemaker generator case.

X1.4.3 *Implanted Cardiac Defibrillators/Cardioverters*—These devices contain sophisticated physiologic sensing circuitry for sensing cardiac activity, and in many cases, include pacemaker functions as well. The defibrillator electrical cardiac "shock" therapy is appropriately delivered within 10 to 20 s of the onset of a dangerously fast heart rhythm. Delivery of unneeded therapy is a serious matter and must be avoided. Although it is unlikely that a handheld or walk-through metal detector would cause unwanted therapy, the scanning procedures described for pacemakers should be followed. A defibrillator is typically larger than a pacemaker and smaller than the size of a cigarette package and is typically located in the upper chest on the left or right side, although some earlier models are larger and located in the lower abdomen. Because of their larger size, some defibrillators may cause a walk-through metal detector to alarm and will be easily detectable by a handheld metal detector.

X1.4.4 *Cardiac Assist Devices*—These devices involve new technology and may include multiple implanted and external components and complex electronic circuitry. Examples include left ventricular assist devices that are implanted near the heart to help pump blood. Security screeners should follow procedures supplied by the medical device manufacturer.

X1.4.5 *Neural Stimulators and Functional Electrical Stimulators (FES)*—There are several types of implantable neural and functional electrical stimulators used to control pain (for example, spinal cord stimulators), control tremors (deep brain stimulators), or stimulate muscles or organs such as the bladder (functional electrical stimulators). The stimulator generator is approximately the size of a pacemaker and is typically implanted in the abdomen or upper torso/chest area. It is attached to metallic wires that may be routed to many areas in the body (brain, spinal cord, arms, and legs). Although it is unlikely, the fields from a metal detector could interact with the stimulator and could cause pain or muscle contractions, or both. However, some simple precautions can minimize the chance for adverse device reactions. A recommended practice for screening is for the patient to turn off the stimulator if possible (this may not be possible for certain types of therapy), then walk through the center of the metal detector at a normal pace. The patient should not lean or brush against the metal detector archway or remain any longer than necessary or closer than 30 cm to the archway. When scanning with a handheld metal detector, the operator should limit the time spent over the stimulator area to a few seconds, making a minimum number of passes to locate the device and keeping as far away from the stimulator as practical to determine that a weapon is not disguised. It is possible that the battery and electronic module of the stimulator can cause a metal detector to alarm, especially if the metal detector is set to high sensitivity. Be aware that the manufacturer's labeling for the stimulator device may recommend the person request an alternative search.

X1.4.6 *Drug Delivery Systems*—Drug delivery systems may be either fully implantable or partly implantable with an externally worn device. Implantable systems are typically implanted in the abdomen and externally worn systems are generally worn near the belt line; there are also combination implant and external-type devices. These devices may contain metal or batteries, or both that may cause a metal detector to alarm. Security screeners should follow procedures supplied by the medical device manufacturer or recommendations of the physician as conveyed by the patient.

X1.4.7 *Cochlear Implants*—These implanted devices are used to assist hearing impaired patients and may output to the patient a perceptible tone or hum when in the proximity of a metal detector. The patient may wish to switch the system off before being scanned by a metal detector. However, it is unlikely that the battery and electronic module of the cochlear implant would cause a metal detector to alarm. The screener should keep the handheld metal detector at least 2.5 cm (1 in.) from the patient's body when passing near known body areas containing a medical device implant or its associated control box.

X1.4.8 *Hearing Aids*—These devices are used to assist hearing impaired patients and may output a perceptible tone or hum when in the proximity of a metal detector. These may be worn by the patient in or behind the ear or as a small box around the neck or in a pocket. The patient may wish to switch the system off before being scanned by a metal detector. It is unlikely that the self-contained hearing aid would cause a metal detector to alarm; however, it is likely that the battery and electronic module of the small box-type aids would cause a metal detector to alarm.

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