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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.

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[1] This practice is under the jurisdiction of ASTM Committee F12 on Security Systems and Equipment and is the direct responsibility of Subcommittee F12.60 on Controlled Access Security, Search, and Screening Equipment.

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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.

3.1.3 *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.

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*—~~permanently placed~~a stationary metal detector ~~product typically in an archway form~~ 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~~ 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~~ MedWatch.~~(3 1).~~

6.4 *Screening Procedures:*

6.4.1 *Identify*—The use of signage and trained operators ~~allows the identification of~~ helps to identify persons with medical devices ~~whom~~who are concerned about potential medical device disruption and those who are concerned that their devices may cause the metal detectors to alarm. ~~Identification~~Notification by the medical device user ~~or notification~~ 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.

[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.

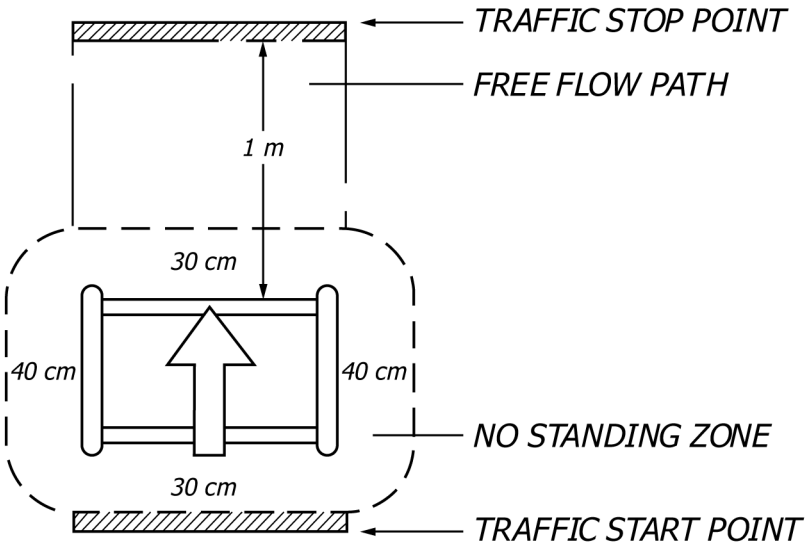

FIG. 1 Walk-Through Metal Detector Traffic Flow and Exclusion Zone for Medical Active Device Patients