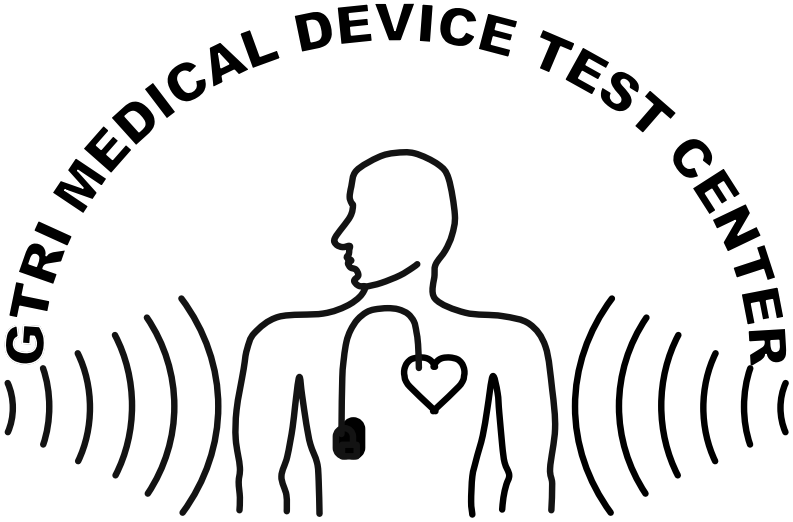
E3 TEST PROTOCOL
FOR
MEDICAL DEVICES
TO
SECURITY AND LOGISTICAL SYSTEMS

Ver 9.0

February 2018



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With the increasing use of electromagnetic (EM) field-producing equipment in industry, it is desirable to determine whether such fields, sometimes intense, can produce detrimental EM environmental effects (E3) in Medical Devices. These Medical Devices may be either implantable or externally worn by the patient. They include cardiac pulse generators (pacemakers, implantable cardioverter defibrillators (ICD's), and cardiac resynchronization therapy (CRT) devices), cardiac monitors, ventricular assist devices, circulatory support systems, neurostimulators, drug infusion pumps, glucose monitors, programmable valves, hearing and sight prosthesis systems, and other sensors and technologies used for various medical therapies. The potential for compromise of these devices' performance by E3 has been recognized for some time and specific EM interference (EMI) tests are regularly performed on such devices before they are used with patients.

Security and Logistical Systems (SLS's) are sources of EM fields that may have the potential to produce EMI in Medical Devices. SLS's include Electronic Article Surveillance (EAS) Systems, EAS Tag Deactivators, Radio Frequency Identification (RFID) Systems, and Metal Detectors. The first three types of SLS's emit EM fields to detect, deactivate/reactivate, and/or interrogate uniquely identifiable Tags attached to objects such as merchandise, materials, and personnel for the purpose of security, theft prevention, tracking, and inventory control. They are usually installed in retail stores, libraries, government buildings, warehouses, offices, and medical facilities. The last type of SLS emits EM fields to detect the presence of metal objects such as in airport and building security systems.

The growing use of SLS's in public areas is such that a large segment of the general public is regularly exposed to their detection, interrogation and deactivation EM fields. With the proliferation of patient-worn Medical Devices, there is a corresponding rise in the likelihood that such a patient will be exposed to the EM fields produced by the SLS's. Potential disruption of the functioning of the Medical Device by the SLS fields is of serious concern to the wearer of the device, the manufacturer of the device, and the manufacturer of the SLS. Therefore, potential interactions between Medical Devices and these systems must be determined so that appropriate steps can be taken to minimize undesired E3.

SLS's utilize a wide range of frequencies, modulation types, power levels and technologies and are available from various manufacturers. The Georgia Tech Research Institute's (GTRI's) **Medical Device Test Center** (formerly the GTRI **EAS/Medical Device E3**

Test Center) was established in 1995 to permit the measurement of the responses of Medical Devices to the EM fields emanating from current representative EAS Systems and Tag Deactivators. Since that time other current representative SLS's have been added to the **Test Center**. All of the SLS's installed in the **Test Center** were selected to be representative of the SLS's currently in use and to which the public may be exposed. These SLS's were furnished and installed by their respective manufacturers. Periodically, they replace their systems with newer models so the SLS's in the **Test Center** represent the most up-to-date systems in terms of these manufacturers' installed bases.

Currently there are twenty-six (26) SLS's in the **Test Center** including eleven (11) EAS Systems, six (6) EAS Tag Deactivators, four (4) RFID Systems, and five (5) Metal Detectors. Since the initial eight (8) EAS Systems were first installed in the **Test Center**, the EAS System manufacturers have replaced five (5) of their systems with newer models, two (2) systems have been removed, and three (3) manufacturers have added five (5) systems to make up the eleven (11) EAS Systems that are currently in the **Test Center**. In addition, Tag Deactivator manufacturers have added six (6) Tag Deactivators, RFID Systems manufacturers have added four (4) RFID Systems, and Metal Detector manufacturers have added five (5) Metal Detectors as representative EM sources in the **Test Center**.

1.0 SECURITY AND LOGISTICAL SYSTEMS DESCRIPTIONS

1.1 EAS Systems Descriptions

EAS Systems consist of EM field emitters and receivers to detect, identify, and track articles of merchandise, material, or equipment assets to which a uniquely identifiable EAS "Tag" has been attached. The EAS System emits an EM field with specific field characteristics which illuminates the merchandise and the affixed Tag. When an object with an activated Tag is in the EM field produced by an EAS System, the Tag "responds" by re-radiating an EM field that is received by the EAS System. The EAS System detects and processes the signal from the re-radiated field and generates an alarm indicating that an active Tag is present. EAS Systems are widely used to track and monitor merchandise, for inventory control and theft prevention, and, in some cases, to track living specimens. EAS systems are being used in a widening circle of installations such as department stores, grocery stores, pharmacies, clothing stores, sporting goods stores, hardware stores, medical facilities, commercial buildings, etc. There are over one million (1,000,000) EAS systems currently in use. EAS Systems are typically located near the exit of the retail stores, buildings, and libraries.

EAS Systems vary over a wide range of installations. In general, two types are most frequently found: **aisle** and **exit** installations.

Aisle systems are typically located toward the exit of the checkout lane of a supermarket or department store, for example. The customer will be relatively stationary near the EAS System during transactions. It is most likely that the customer will be facing the checkout clerk, and the front of the customer's body will be parallel to the face of the EAS pedestal. When the

customer exits the checkout lane, the plane of the body front will be nominally perpendicular to the face of the EAS pedestal.

In a small retail store, **exit** systems are typically located near a narrow doorway. Since customers may be simultaneously entering and exiting the store, they will tend to move through the system near the center of the right and left halves of the exit. In a large retail store, **exit** systems are typically located near a wide doorway. While some of the wider systems may be installed in an exit-only doorway, many are installed in wide bi-directional doorways.

Eleven (11) EAS Systems representative of current aisle and exit class equipment provide EM exposure fields for the E3 tests of Medical Devices in the **Test Center**. The general characteristics* of these systems are

- **EAS System A2:** System A2 has an operating frequency less than 150 kHz. The transmission is pulsed RF and has a duty cycle less than 20%. The transmission is emitted through an antenna pair comprised of loop coils housed in pedestals with height = 145 cm and width = 41 cm.

- **EAS System B1:** System B1 is a photocell-activated, magnetic system with a fundamental operating frequency greater than 100 Hz and less than 5 kHz. When the system's light beam is broken, the system emits a magnetic field pulse that is less than 10 milliseconds in length generated by coils housed in two detection panels spaced 90 cm from each other. The magnetic field energy measured at the center of the corridor is less than 0.3 mT.

- **EAS System C1:** System C1 is a magnetic system with a fundamental operating frequency greater than 5 kHz and less than 50 kHz. The transmission is a CW signal generated by coils housed in two detection panels spaced 90 cm from each other. The magnetic field energy measured at the center of the corridor is less than 0.3 mT.

- **EAS System D1:** System D1 has an operating frequency greater than 100 Hz and less than 1 kHz. There are a separate electronic chassis and two antenna panels, each containing both transmit and receive coils. The CW transmit signal is generated by a crystal controlled circuit; this signal is filtered to remove harmonics and amplified to a useable level. Receive coils located in both panels detect the signal re-radiated from a tag. Signal processing circuits trigger an alarm when appropriate.

- **EAS System E1:** System E1 has an operating frequency greater than 500 Hz and less than 5 kHz. There are a separate electronic chassis and two antenna panels, each containing both transmit and receive coils. The CW transmit signal is generated by a crystal controlled circuit; this signal is filtered to remove harmonics and amplified to a useable level. Receive coils located in both panels detect the signal re-radiated from a tag. Signal processing circuits trigger an alarm when appropriate.

* These characteristics were provided by the EAS System manufacturers or derived from non-proprietary manufacturer's literature which resulted in varying levels of detail.

- **EAS System H:** System H has operating frequencies greater than 1 kHz and less than 10 kHz. Two interrogation fields are amplitude modulated at less than 100 Hz. Multiple receiving coils detect the signature produced by the product tag. Signal processing circuitry separates the signal produced by the tag from the external electromagnetic environment.

- **EAS System I:** System I is a magnetic system with a fundamental operating frequency greater than 100 Hz and less than 5 kHz. The system emits a continuous wave from each of two panels, which are separated by 90 cm. The maximum magnetic field amplitude as measured at the center of the system corridor is less than 0.25 mT.

- **EAS System J:** System J has an operating frequency less than 150 kHz. The transmission is pulsed RF and has a duty cycle less than 20%. The transmission is emitted through an antenna pair comprised of loop coils housed in pedestals with height = 159 cm and width = 68 cm.

- **EAS System K:** System K has an operating frequency less than 150 kHz. The transmission is pulsed RF and has a duty cycle less than 20%. The transmission is emitted through an antenna pair comprised of loop coils housed in pedestals with height = 155 cm and width = 50.9 cm.

- **EAS System L:** System L has an operating frequency less than 150 kHz. The transmission is pulsed RF and has a duty cycle less than 20%. The transmission is emitted through an antenna pair comprised of loop coils housed in pedestals with height = 165 cm and width = 41.9 cm.

- **EAS System M:** System M is a pulse-listen EAS detection system consisting of three main components including the two antennas, the Primary Electronics, and the power supply. The antennas are constructed with two "cancelling" loop designs consisting of a 2-Loop, a 3-Loop, and a single-Loop which is a "shorted turn" contributing to far-field EM cancellation. The Primary Electronics detects targets in the field of the primary antenna in which it is mounted. The pulse-listen EAS system monitors one or more detection zones in the 7.2 MHz to 9.9 MHz band, and triggers an alarm when a non-deactivated target is detected.

These exposure EAS Systems are arranged in the **Test Center** as shown in Figure 1. Automated (computer controlled) linear positioners which pass through the EAS Systems are used to accurately position and move the Medical Device (Test Specimen) in or on a Torso Simulator through each EAS System and, hence, its EM field.

1.2 Tag Deactivators Descriptions

Tag Deactivators also consist of EM fields emitters and receivers to detect and deactivate and/or reactivate EAS Tags which have been attached to articles of merchandise, material, or equipment assets which are placed in the Tag Deactivator's transmitted EM fields. Tag

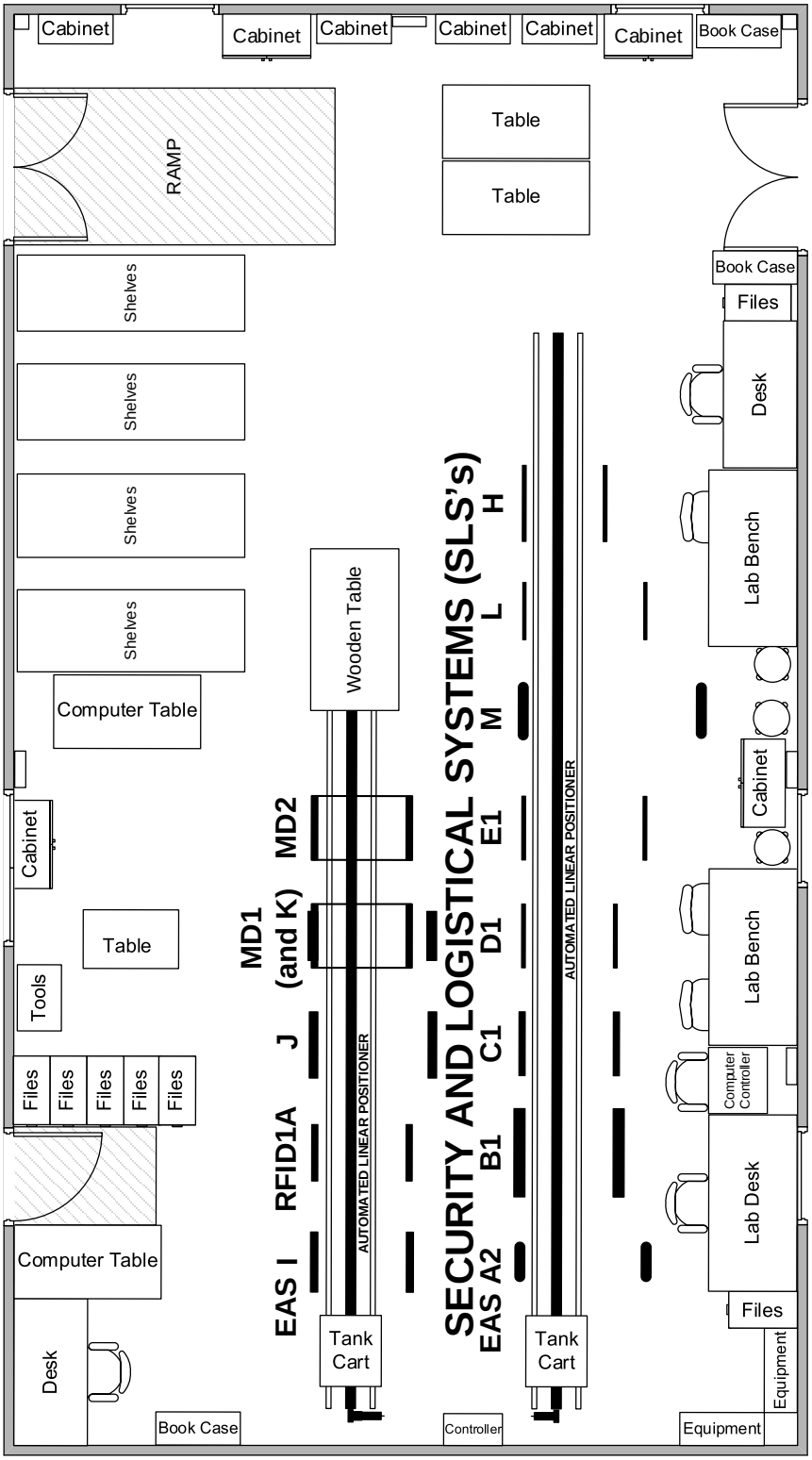


Figure 1. GTRI Medical Device Test Center Layout

Deactivators are widely used in almost all retail establishments that utilize EAS Systems. Tag Deactivators are typically located near the cashier or librarian at the checkout of retail stores and libraries.

EAS Tag Deactivators also vary over a wide range of installations. Tag Deactivators may be of the **proximity** or **photocell-activated** type.

A **proximity** Tag Deactivator only deactivates EAS Tags. This type of Deactivator continuously emits an EM "detection field" similar to that emitted by an EAS System, but lower in field strength, which illuminates the merchandise and the affixed Tag. When an object with an activated Tag is in proximity to the Deactivator and, hence, in its detection field, the Tag "responds" as it would when it is in the EM field of an EAS System. The Tag Deactivator detects the presence of the active Tag and emits an EM field "burst" which deactivates the Tag. If the product is not tagged, the Deactivator continues to emit only its detection field and the burst is not transmitted. Typically, the Deactivator's detection field is turned off for a short period of time during and immediately following the generation of an EM field burst.

A **photocell-activated** Tag Deactivator either deactivates (desensitizes) or reactivates (sensitizes) EAS Tags depending on the Deactivator and its settings. This type of Deactivator does not emit a detection EM field to detect the presence of an active Tag. The operator places the tagged product on the Deactivator so that it breaks the light beam to the unit's photocell. When the light beam to the Deactivator's photocell is broken, the Deactivator emits an EM burst to alter the state of the EAS Tag from "activated" to "deactivated," or vice-versa.

Six (6) EAS Tag Deactivators representative of current proximity and photocell-activated equipment provide EM exposure fields for the E3 Tests in the **Test Center**. The general characteristics** of these Tag Deactivators are

- **Tag Deactivator 1**: This horizontally mounted Deactivator senses the presence of Tags by emitting an interrogation field with an operating frequency less than 150 kHz. The transmission is pulsed RF and has a duty cycle less than 20%. If a Tag is detected, a transient deactivation field (burst) is generated. The burst is characterized by changing frequency while decreasing in amplitude in less than 0.3 second.

- **Tag Deactivator 2**: This Deactivator is an accessory for an EAS Detection System and is used at an operator workstation. It is comprised in part of a multi-turn coil and its purpose is to alter the state of the detection markers (i.e., Tags) from the "on" state (sensitized) to the "off" state (desensitized), or vice-versa. When the device's photocell is covered by an item, the unit produces a magnetic field for a period less than 25 ms. This field is either a dc or a decaying ac field depending on the unit's setting. The operating frequency is 400 Hz and the peak field strength experienced at the operator's location is approximately 0.4 mT.

- **Tag Deactivator 3**: This vertically mounted Deactivator senses the presence of Tags by emitting an interrogation field with an operating frequency less than 150 kHz. The

** These characteristics were provided by the Tag Deactivator manufacturers or derived from non-proprietary manufacturer's literature which resulted in varying levels of detail.

transmission is pulsed RF and has a duty cycle less than 20%. If a Tag is detected, a transient deactivation field (burst) is generated. The burst is characterized by 60 Hz frequency, decreasing in amplitude to zero in less than 0.4 second.

- **Tag Deactivator 4**: This horizontally mounted Deactivator senses the presence of Tags by emitting an interrogation field less than 150 kHz. The transmission is pulsed RF and has a duty cycle less than 20%. If a Tag is detected, a transient deactivation field (burst) is generated. Two bursts are generated, one on axis the other orthogonal, with each fixed frequency burst decaying to zero amplitude in less than 0.3 second.

- **Tag Deactivator 5**: This hand held Deactivator senses the presence of Tags by emitting an interrogation field with an operating frequency less than 150 kHz. The transmission is pulsed RF and has a duty cycle less than 20%. If a Tag is detected, a transient deactivation field (burst) is generated. The burst is characterized by fixed frequency while decreasing in amplitude in less than 0.3 second.

- **Tag Deactivator 6**: This Deactivator is an accessory for an EAS Detection System and is used at an operator workstation. It is comprised in part of a multi-turn coil and its purpose is to alter the state of the detection markers (i.e., Tags) from the "on" state (sensitized) to the "off" state (desensitized), or vice-versa. When the device's photocell is covered by an item, the unit produces a magnetic field for a period less than 120 ms. This field is either a dc or a decaying ac field depending on the unit's setting. The spectral content of the unit's field falls between 0 and 400 Hz and the peak field strength experienced at the operator's location is approximately 1.0 mT.

The Medical Device (Test Specimen) is placed in or on a Torso Simulator on the "Wooden Table" or "Tank Cart" in the **Test Center** as shown in Figure 1. The exposure Tag Deactivators are placed one at a time on the "Wooden Table" or "Tank Cart" (see Figure 1) which is manually moved along the linear positioner's tracks away from, or toward, the Medical Device varying the intensity of the Tag Deactivators' EM fields at the position of the Medical Device. Thus, the Medical Device is exposed to the EM fields of each Tag Deactivator independently.

1.3 RFID Systems Descriptions

RFID Systems, like EAS Systems, consist of EM fields emitters and receivers to detect, identify, and track articles of merchandise, material, or equipment assets to which a uniquely identifiable RFID "Tag" has been attached. The RFID System emits an EM field with specific field characteristics which illuminates the asset and the affixed Tag. The Tag may be either passive or active. When an object with a passive RFID Tag is in the EM field produced by an RFID System, the Tag "responds" by re-radiating an EM field that is encoded with specific information about the asset to which the Tag is attached. The EM field radiated from the RFID Tag is received by the RFID System. The RFID System detects and processes the signal from the re-radiated field and interprets the encoded information about the asset. If the Tag is an active RFID Tag, it radiates its unique EM field encoded with its identification information using a self-contained power source. When an object with an active RFID Tag is within the

appropriate range of an RFID System, the RFID System detects and processes the signal from the Tag's radiated field and interprets the encoded information about the asset. RFID Systems are being used in a widening circle of installations such as distribution centers, medical facilities, libraries, office and commercial buildings, etc.

Four (4) representative RFID Systems are installed in the **Test Center** to provide EM exposure fields for the E3 tests of Medical Devices. The general characteristics*** of these systems are

- **RFID System RFID1A:** The RFID1A Detection System operates per the specifications set forth in the ISO 18000-3 standard for RFID communication. The system operates with a carrier frequency in the 13.56 MHz ISM band. The RF transmitter provides 10.0W output power to the antenna system which radiates the power to interrogate RFID tags.

- **RFID System RFID2:** The RFID2 System operates at 125 kHz with amplitude shift keying (ASK) modulation and supports EM4001/EM4002 compatible transponders. The dimensions of the radiating antenna are 240 x 240 x 35mm and it is designed for personnel identification access control, parking systems, and hands free applications with an expected read distance of 90 - 110cm.

- **RFID System RFID3:** The RFID3 System operates at 125 kHz with amplitude shift keying (ASK) modulation and supports EM4001/EM4002 compatible transponders. The dimensions of the radiating antenna are 420 x 320 x 45mm and it is designed for personnel identification access control, parking systems, and hands free applications with an expected read distance of 80 - 120cm.

- **RFID System RFID4:** The RFID4 System operates at 134.2 kHz with half duplex (HDX)/frequency shift keying (FSK) modulation per the specifications set forth in the ISO 11785 standard for RFID communication and has a typical read range up to 200cm. The dimensions of the radiating antenna are 200 x 200 x 25mm and it is designed for access control, vehicle identification, container tracking, as well as asset and waste management applications.

The walk-through RFID System RFID1A is located in the **Test Center** as shown in Figure 1. An automated (computer controlled) linear positioner which passes through the RFID System is used to accurately position and move the Medical Device in or on a Torso Simulator through the RFID System and, hence, its EM field.

For the other RFID Systems (which are not walk-through systems), the tests are performed in the same manner as for the EAS Tag Deactivators described above. For these tests, the RFID Systems RFID2, RFID3, and RFID4 are placed one at a time away from, or toward, the

*** These characteristics were provided by the RFID System manufacturers or derived from non-proprietary manufacturer's literature which resulted in varying levels of detail.

Medical Device varying the intensity of the RFID System's EM fields at the position of the Medical Device. Thus, the Medical Device is exposed to the EM fields of each RFID System independently.

1.4 Metal Detector Systems Descriptions

Metal Detector Systems also consist of EM field emitters and receivers to detect the presence of metal objects. The Metal Detector System emits an EM field with specific field characteristics which illuminates an object or a person. If the object contains metal or the person has any metal objects on them, the presence of the metal perturbs the Metal Detector Systems' EM field in such a manner that can be detected by the Metal Detector System. The detection of the presence of metal causes the Metal Detector System to sound an alarm.

Metal Detector technologies are currently utilized such that their technologies are an ever increasing part of the public's lives with a range of uses that spans from recreational to work to safety. Metal Detectors are widely used in airports, office buildings, schools, government agencies, and prisons to help ensure that no one is bringing a weapon onto the premises. Metal Detectors are also used by the public to locate buried or lost metal objects. Metal Detectors may be either walk-through systems or handheld wands.

Five (5) representative Metal Detectors are used to provide EM exposure fields for the E3 tests of Medical Devices in the **Test Center**. The general characteristics**** of these systems are

- **Metal Detector MD1:** Metal Detector MD1 is an archway (walk-through) type metal detector intended for security applications. The metal detector's pulse induction technology employs multiple emitters in each side panel to produce fields of varying orientations. The pulse width is approximately 150 microseconds and the pulse repetition rate is approximately 960 pulses per second. Field strength at the center of the archway is approximately 5 A/m p-p.

- **Metal Detector MD2:** Metal Detector MD2 is an archway (walk-through) type metal detector intended for security applications. The metal detector's pulse induction technology employs a single emitter in one side panel. The pulse width is approximately 150 microseconds and the pulse repetition rate is approximately 480 pulses per second. Field strength at the center of the archway is approximately 5 A/m p-p.

- **Metal Detector MD3:** Metal Detector MD3 is a handheld Metal Detector intended for security applications requiring that the probe (wand) be passed within 5 cm of the body. The unmodulated continuous wave magnetic field operates at a frequency near 100 kHz. The RMS field strength at 2.5 cm from the center of the probe is approximately 0.5 A/m.

**** These characteristics were provided by the Metal Detector manufacturers or derived from non-proprietary manufacturer's literature which resulted in varying levels of detail.

- **Metal Detector MD4:** Metal Detector MD4 is a handheld Metal Detector intended for security applications requiring that the probe (wand) be passed within 5 cm of the body. The unmodulated continuous wave magnetic field operates at a frequency near 100 kHz. The RMS field strength at 2.5 cm from the center of the probe is approximately 0.5 A/m.

- **Metal Detector MD5:** Metal Detector MD5 is a handheld Metal Detector intended for security applications requiring that the probe be passed within 5 cm of the body. The unmodulated continuous wave magnetic field operates at a frequency near 100 kHz. The RMS field strength at 2.5 cm from the center of the probe is approximately 1 A/m.

The walk-through Metal Detectors are arranged in the **Test Center** as shown in Figure 1. An automated (computer controlled) linear positioner which passes through the Metal Detectors is used to accurately position and move the Medical Device in or on a Torso Simulator through each walk-through Metal Detector and, hence, its EM field.

For the handheld Metal Detectors, the tests are performed in the same manner as for the EAS Tag Deactivators described above. For these tests, the handheld Metal Detectors are placed one at a time away from, or toward, the Medical Device varying the intensity of the Metal Detectors' EM fields at the position of the Medical Device. Thus, the Medical Device is exposed to the EM fields of each handheld Metal Detector independently.

2.0 MEDICAL DEVICE MOUNTING AND MONITORING

In order to measure the responses of a Medical Device Test Specimen during exposure to the EM fields of the representative SLS's (i.e., EAS Systems, Tag Deactivators, RFID Systems, and Metal Detectors) in the **Test Center**, the Medical Device is mounted in a standard, representative configuration. For Medical Devices with output pulses/signals, its output is monitored as the device is positioned in, and moved through, each EAS System, the walk-through RFID System, and each walk-through Metal Detector and moved away from each Tag Deactivator, RFID Reader antenna, and handheld Metal Detector. For Medical Devices with no output signals, the monitoring of the device as it is exposed to the EM fields of each SLS is mutually agreed upon prior to the start of the tests.

For Implantable Medical Devices with lead(s)/catheters(s), they are arranged as shown in Figure 2 by fastening them to an electromagnetically transparent support with rubber bands. Any excess length of lead(s) is wound around the case of the Implantable Medical Device. This loop arrangement is chosen to emulate a typical implant configuration of a Medical Device with leads and/or a "worst-case" magnetic field pick-up configuration; however, other lead configurations and/or loop areas can be mutually agreed upon prior to the start of the tests. For devices without metallic leads, the device is mounted at the position designated by the center of the Test Specimen arc in Figure 2. Other test positions can be mutually agreed upon prior to the start of the tests. The mounted, Implantable Test Specimen is then immersed in a 0.03 Molar saline

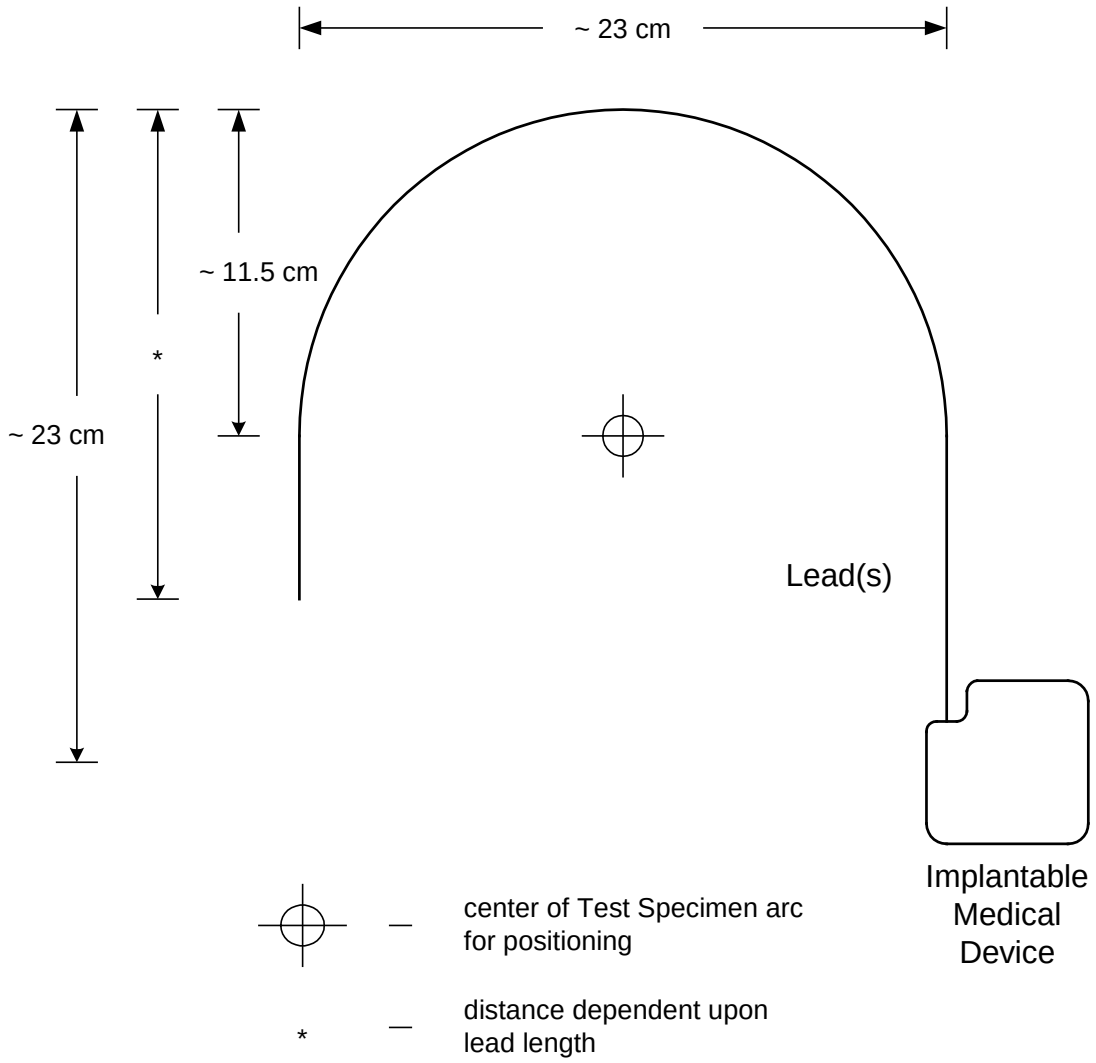


Figure 2. Test Specimen Mounting Configuration

solution at room temperature in an electromagnetically transparent tank (Torso Simulator). The 0.03 Molar concentration simulates the electrical characteristics of body tissue and fluid. For the EAS Systems and walk-through RFID System and Metal Detector E3 tests, the tank is supported on the "Tank Cart" in Figure 1 which is also electromagnetically transparent and, for the Tag Deactivator, RFID Reader, and handheld Metal Detector E3 tests; the tank is supported on the "Wooden Table" or "Tank Cart" in Figure 1.

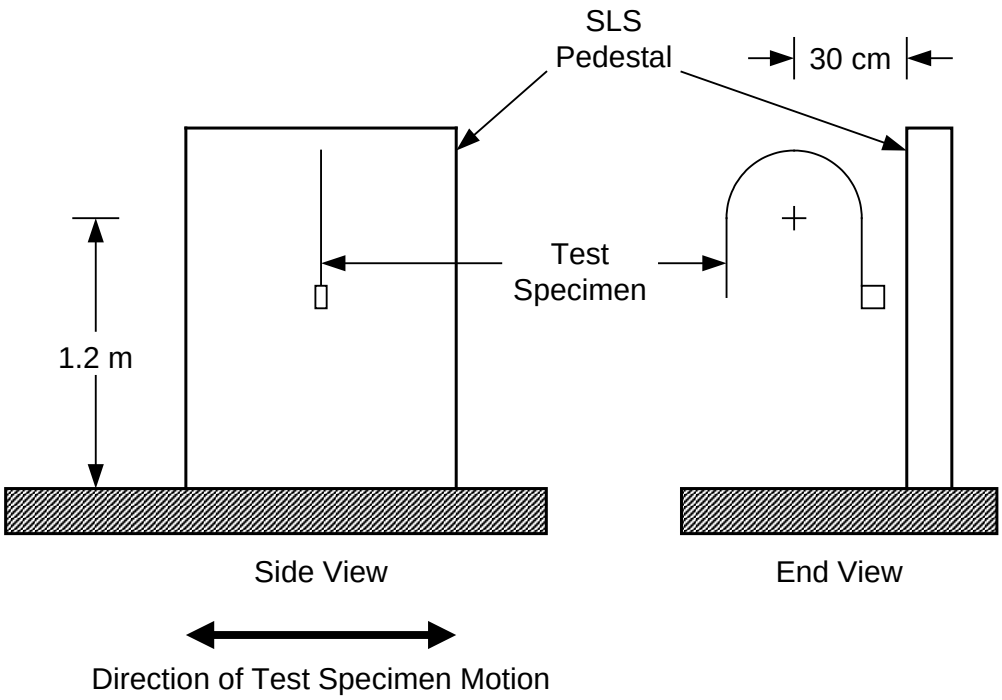
For externally worn Medical Devices, the Test Specimen is mounted on the exterior of the Torso Simulator containing the 0.03 Molar saline solution. The exact mounting location is chosen to simulate where the Medical Device is worn on the patient's body and is mutually agreed upon prior to the start of the tests. The Test Specimen is then exposed to the SLS EM field source as described above for Implantable Medical Devices.

The Test Specimen is exposed to the EAS System and walk-through RFID System and Metal Detector SLS EM sources with the plane of the device and its lead(s) in two orientations relative to the plane of each SLS's transmit pedestal: parallel and perpendicular. These two orientations are defined in Figure 3. The Test Specimen is exposed to each Tag Deactivator source with the plane of the device and its lead(s) vertical and oriented as shown in Figure 4. For Tag Deactivators 1 and 4 the plane of the Test Specimen loop is perpendicular to the top horizontal face of the Tag Deactivator; for Tag Deactivators 2 and 6, the plane of the Test Specimen loop is perpendicular to the top surface of the Tag Deactivator and is parallel to the horizontal edge of the deactivation surface; and for Tag Deactivators 3 and 5, the plane of the Test Specimen loop is parallel to the vertical face of the Tag Deactivator. The Test Specimen is exposed to each RFID Reader antenna with the plane of the device and its lead(s) vertical and oriented as shown in Figure 5. The Test Specimen is exposed to each handheld Metal Detector source with the plane of the device and its lead(s) vertical and oriented as shown in Figure 6. For each RFID Reader antenna and handheld Metal Detector, the plane of the Test Specimen loop is parallel to the loop in the RFID Reader antenna or handheld wand with the center of the antenna or wand loop aligned with the center of the Test Specimen loop. If the loop in the antenna or handheld wand is rectangular, its largest dimension is placed horizontal.

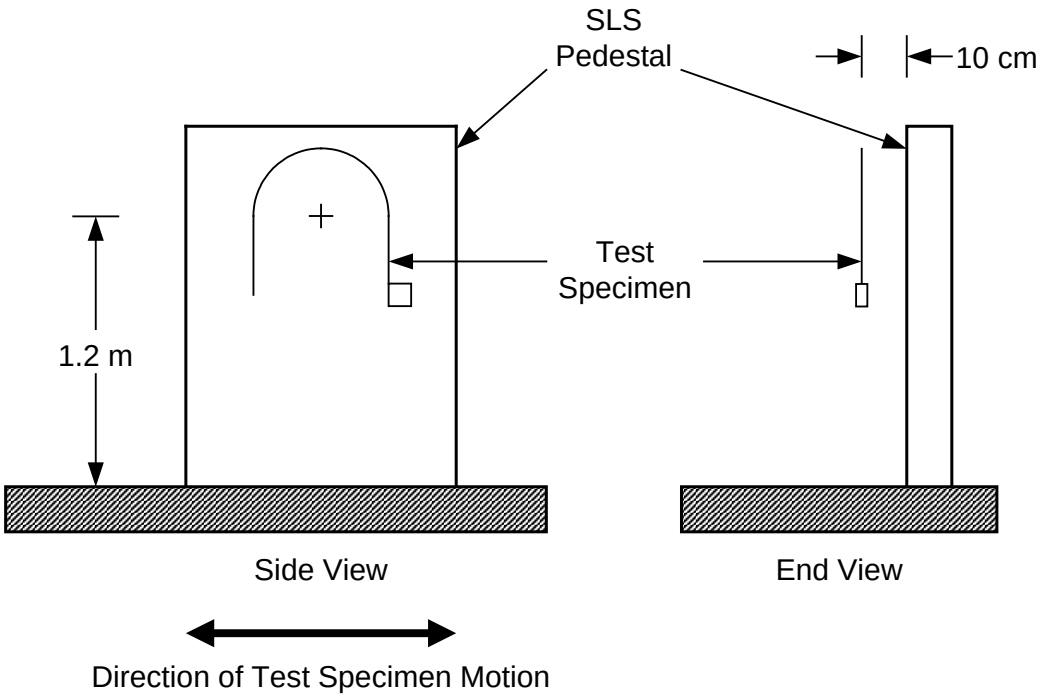
All of these orientations relative to the SLS's are chosen to represent typical scenarios which patients with Medical Devices would encounter while walking through a walk-through SLS, waiting in a check-out line near an SLS, or being scanned with a handheld SLS.

The E3 tests monitoring instrumentation setup for Implantable Medical Devices which produce output pulses/signals is shown in Figure 7. The Test Specimen's output pulses are "picked up" by using extra leads submerged in the saline solution near the output terminals of the Test Specimen. For bipolar operation, an extra bipolar lead is positioned in the saline solution near the bipolar tip of the Test Specimen's lead(s). For unipolar operation, one terminal of a bipolar lead is positioned near the unipolar tip of the Test Specimen's lead(s) and a second unipolar lead (dotted in Figure 7) is positioned near the Test Specimen's case. A twisted pair of wires is connected between these two sensing electrodes and the input of a differential amplifier, which has a built-in low-pass filter. The upper cut-off frequency of this filter is set to provide an adequate Test Specimen signal to the oscilloscope while discriminating against other signals, e.g., the SLS's radiated fields. The output of this differential amplifier is routed to two digital oscilloscopes, to two counters, and to an audible device monitor. The oscilloscopes provide real-time indications of the presence of the Test Specimen's output pulses, the periods between pulses, the pulse amplitudes, and the pulse widths. The counters measure the pulse periods, which yield the pulse rates and the audible device monitor provides an instantaneous indication of any changes in the responses.

When evaluating the effects of EM environments on a Medical Device, it is essential to operate the Test Specimen in each of its normal operating modes. Also, if the Test Specimen has sensing inputs, it is appropriate to determine how the EM field is affecting these inputs. Therefore, it may be necessary to inject external simulated biological signals via the saline solution into the sensing inputs of the Test Specimen.



A. Perpendicular Orientation



B. Parallel Orientation

Figure 3. Test Specimen Orientations Relative to Walk-Through SLS

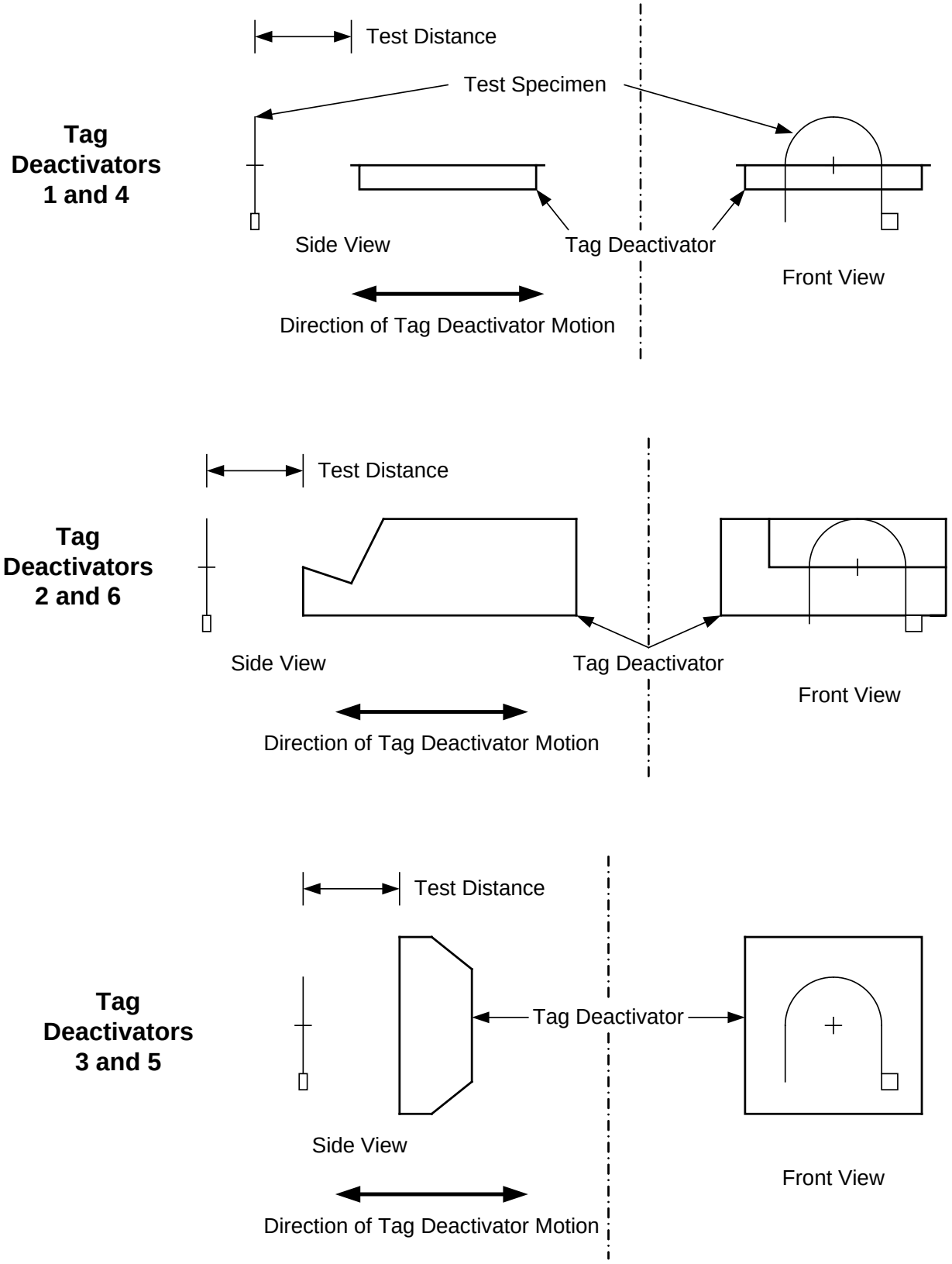


Figure 4. Test Specimen Orientation Relative to Tag Deactivators

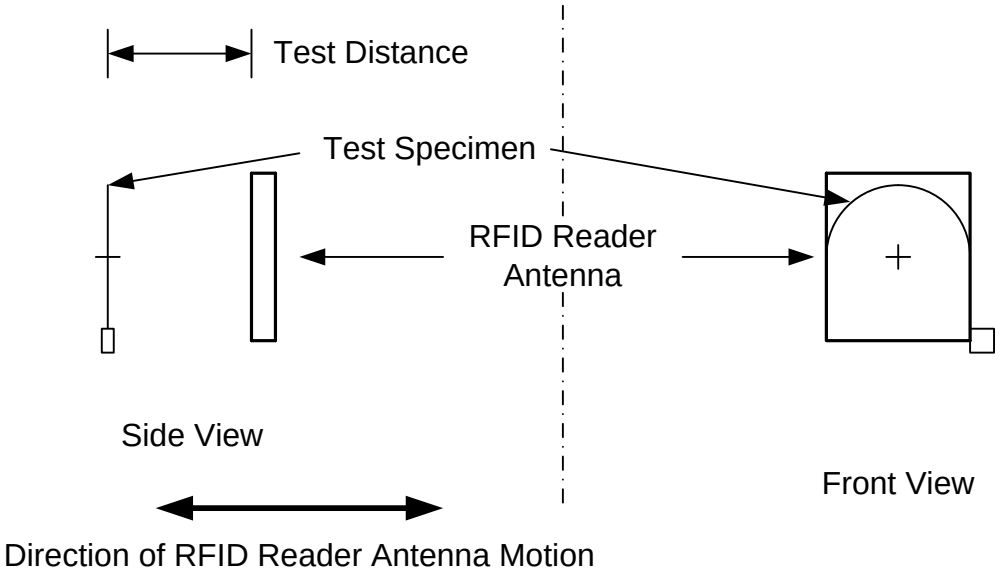


Figure 5. Test Specimen Orientation Relative to RFID Readers

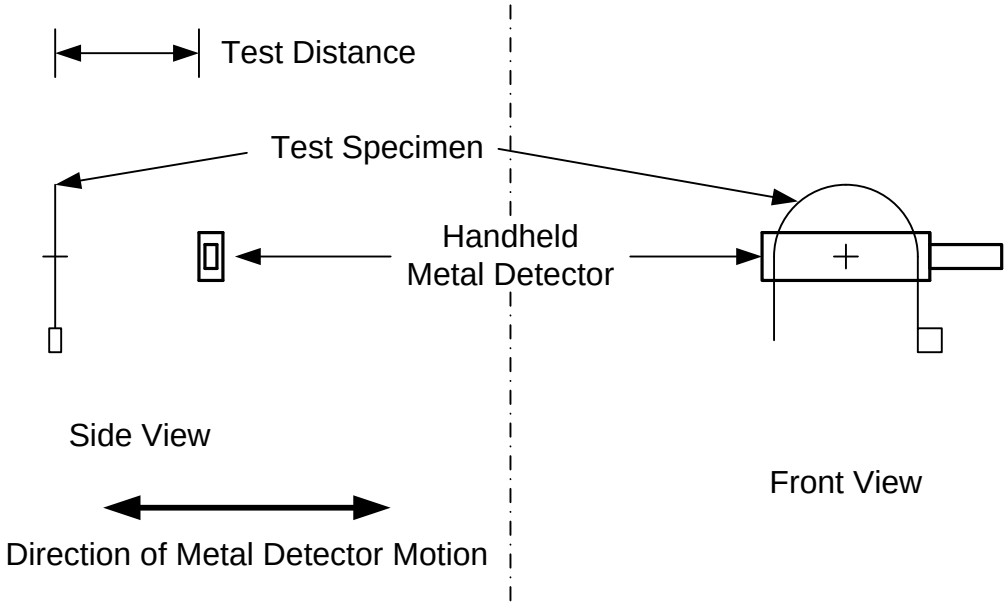
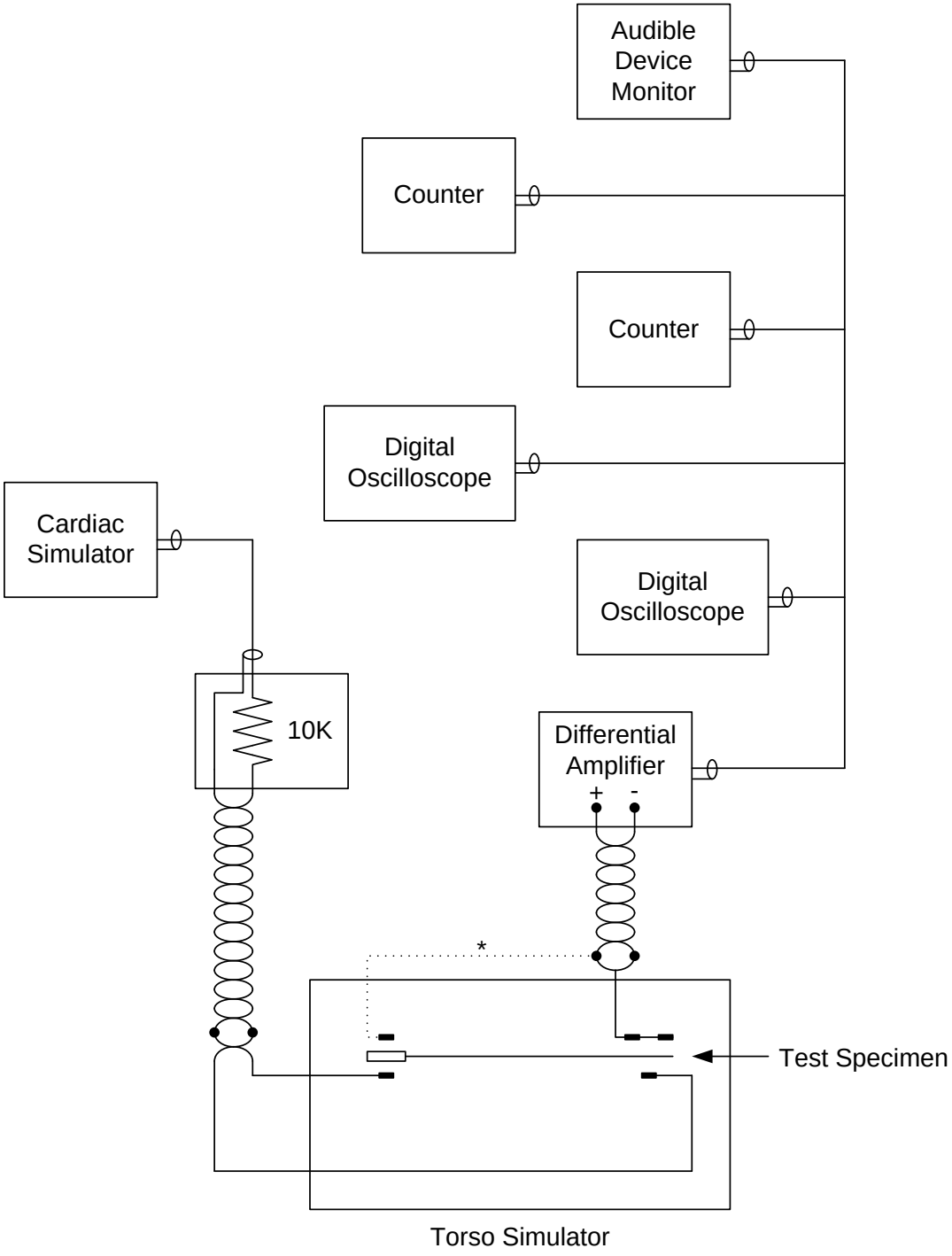


Figure 6. Test Specimen Orientation Relative to Handheld Metal Detectors



* Dotted catheter and one lead of bipolar catheter used for monitoring of unipolar Test Specimens.

Figure 7. Monitoring Instrumentation Setup for Cardiac Pulse Generator Test Specimens

For example, if the Test Specimen has a pacemaker function, it is necessary to have a means of determining if, and when, the pacemaker function is operating in its fixed-rate (reverted) noise mode. For both pacemaker and ICD E3 tests, an external simulated electro-cardiac signal is injected into the saline solution to simulate the various electrical activities of the heart. Specifically, for pacemaker E3 tests, this Cardiac Simulator Signal is a 5-ms wide pulse with a pulse rate of approximately 1.5 pps (i.e., ≈90 ppm). Its amplitude is adjusted without theSLS activated so that it is approximately twice the level necessary to completely inhibit the pacemaker operating in its non-reverted (demand) mode. The application or removal of the Cardiac Simulator Signal thus permits the E3 measurements to be performed with the pacemaker operating in its two common modes: with and without a "heart beat" present. Also, its application permits the determination of whether or not the pacemaker has switched to its fixed rate (reverted) mode in the presence of an SLS EM field. If the pacemaker is operating in its non-reverted mode, the application of the Cardiac Simulator Signal results in complete inhibition; however, if it is in its reverted mode, no change in output is noted

For ICD E3 tests, the pulse rate of the external Cardiac Simulator Signal is adjusted to a higher rate, e.g., ≥4 pps (≥240 ppm) when a simulated fibrillation signal is required. The application of this “fibrillation signal” by simply increasing the Cardiac Simulator’s pulse rate simulates a heart going from its normal rate into fibrillation.

For E3 tests of other types of Medical Devices, the Test Specimen mounting and monitoring are adapted to meet the requirements and operation of the device and are mutually agreed upon with the device manufacturer prior to the start of the E3 tests. Also, for other types of Medical Devices, any required external simulated biological signals are selected and mutually agreed upon with the manufacturer prior to the tests.

3.0 TEST PROCEDURE

3.1 General Approach

The E3 measurements are performed in the **Medical Device Test Center** by exposing the Medical Device to the EM fields produced by one SLS at a time and monitoring/recording the responses of the Test Specimen. This test procedure simulates the types of exposure that a Test Specimen would encounter during exposure to typical SLS installations.

3.1.1 EAS Systems, Walk-through RFID Systems, and Walk-through Metal Detectors

The level of exposure to each walk-through SLS is varied by moving the Test Specimen through the SLS parallel to the plane of the transmit pedestal as illustrated in Figure 3. For Implantable Medical Devices with lead(s)/catheters(s), the location is recorded as the horizontal distance in the plane of motion from the center of the SLS pedestal to the center of the Test Specimen/lead(s) loop. Since the EM fields of the SLS can not be assumed to be electromagnetically symmetrical, the Test Specimen is exposed to both sides of the system in the

direction of motion. The height of the center of the lead(s) loop is 1.2 m which is representative of the height of a device implanted in a short adult.

For each SLS except EAS B1, the System continuously emits the EM field that it would emit under normal operation. For EAS System B1, its normal operation is simulated by manually breaking its light beam 10 times in approximately 10-15 seconds resulting in 10 EM pulses approximately 1.0-1.5 sec apart. EAS System B1 can also be operated in a mode such that the system emits a magnetic field pulse approximately once a sec. This mode of operation is utilized for the EAS System B1 tests unless the test sponsor prefers something different.

Based on the scenarios of typical walk-through SLS installations (see Section 1.0), three types of E3 tests are performed:

1. **Dynamic Test -** This test models the scenario of the patient walking slowly through an SLS. The response of the Test Specimen is measured as it is moved through each SLS while mounted in the perpendicular orientation, i.e., the plane of the lead(s) loop is perpendicular to the face of the SLS pedestal as shown in Figure 3A. In this orientation and with the configuration shown in Figure 2, the center of the loop is 30 cm from the transmitting pedestal, which represents the distance when the customer's body just clears the face of the pedestal.

2. **Static Test 1 -** This test represents the situation where a patient is waiting near or within the exit or checkout lane and is facing the lane exit. The response of the Test Specimen is measured while it is nearly stationary (or stationary) at discrete distances from the center of the SLS pedestal. As in the Dynamic Test, the Test Specimen is mounted in the perpendicular orientation and the center of the lead(s) loop is 30 cm from the transmitter pedestal.

3. **Static Test 2 -** This test models the scenario where a patient is waiting within the exit or checkout lane and facing the transmit pedestal or the clerk. As in Static Test 1, the response of the Test Specimen is measured while it is nearly stationary (or stationary) at discrete distances from the center of the SLS pedestal; however, it is mounted in the parallel orientation, i.e., the plane of the lead(s) loop is parallel to the face of the SLS pedestal as shown in Figure 3B. In this orientation, the plane of the loop is 10 cm from the transmitting pedestal which represents the distance when the customer's body is almost against the transmit pedestal while facing the pedestal or the checkout counter.

For other types of Test Specimens, the Test Specimen's location, orientation, and height relative to the SLS pedestal are mutually agreed upon with its manufacturer prior to the start of the tests.

3.1.2 Tag Deactivators

The level of exposure to each Tag Deactivator is varied by moving the Tag Deactivator horizontally away from, or toward, the Test Specimen as shown in Figure 4. For Implantable Medical Devices with lead(s)/catheters(s), the plane of the Test Specimen/lead(s) loop is vertical and perpendicular to the path of motion of the Tag Deactivator. For Tag Deactivators 1 and 4, the center of the lead(s) loop is at the same height as the horizontal top surface of the Tag Deactivator and the test distance (i.e., the "Distance from Device") is measured horizontally from the vertical plane of the lead(s) loop to the edge of the top surface. For Tag Deactivators 2 and 6, the center of the lead(s) loop is at the same height as the horizontal edge of the Deactivator's deactivation surface and the test distance is measured horizontally from the vertical plane of the lead(s) loop to this horizontal edge of the deactivation surface. For Tag Deactivators 3 and 5, the center of the lead(s) loop is the same height as the center of the vertical surface of the Tag Deactivators and the test distance is measured horizontally from the plane of the lead(s) loop to the vertical surface of the Tag Deactivator.

For other types of Test Specimens, the Test Specimen's location, orientation, and height relative to the Tag Deactivator are mutually agreed upon with its manufacturer prior to the start of the tests.

The rate of deactivation (i.e., the rate of the EM bursts) for a proximity Tag Deactivator depends on the cashier, the product throughput, and the percentage of the product that is tagged. Some studies have shown that the maximum scan rate is 38 products per minute, which would result in approximately 1.5 sec between deactivation bursts if 100% of the products were tagged. For this reason, the period between deactivation bursts for these tests is selected to be approximately 1.5 sec. This deactivation rate is much greater than what should be typical since the maximum percentage of products that are tagged is typically 10%. For purposes of uniformity, the deactivation/ activation rate for the photocell-activated type Deactivator is selected to be the same as the proximity type Deactivator (i.e., approximately 1.5 sec between deactivation bursts).

3.1.3 RFID Readers

The level of exposure to each RFID Reader is varied by moving its antenna horizontally away from, or toward, the Test Specimen as shown in Figure 5. For Implantable Medical Devices with lead(s)/catheters(s), the plane of the Test Specimen/lead(s) loop is vertical and perpendicular to the path of motion of the antenna. For each RFID reader, the antenna is positioned vertically, the center of the lead(s) loop is the same height as the center of the vertical surface of the antenna, and the test distance is measured horizontally from the plane of the lead(s) loop to the vertical surface of the antenna.

For other types of Test Specimens, the Test Specimen's location, orientation, and height relative to the RFID Reader are mutually agreed upon with its manufacturer prior to the start of the tests.

3.1.4 Handheld Metal Detectors

The level of exposure to each handheld Metal Detector is varied by moving the handheld Metal Detector horizontally away from, or toward, the Test Specimen as shown in Figure 6. For Implantable Medical Devices with lead(s)/catheters(s), the plane of the Test Specimen/lead(s) loop is vertical and perpendicular to the path of motion of the handheld Metal Detector. For each handheld Metal Detector, the Metal Detector is held horizontal, the center of the lead(s) loop is the same height as the center of the vertical surface of the Metal Detector, and the test distance is measured horizontally from the plane of the lead(s) loop to the vertical surface of the Metal Detector.

For other types of Test Specimens, the Test Specimen's location, orientation, and height relative to the handheld Metal Detector are mutually agreed upon with its manufacturer prior to the start of the tests.

3.2 Measurement Process

First, the Test Specimen is mounted on the dielectric support in the appropriate configuration as described in Section 2.0. Next, the Test Specimen is positioned in the saline solution (if appropriate) and in the correct orientation for the type of E3 test to be performed (and, as appropriate, for the type of Test Specimen). It is then programmed to a selected operational (program) mode using the programmer and instructions supplied by the manufacturer. Finally, the Test Specimen is interrogated with the programmer to ensure that its programmed parameters are set correctly and, if an ICD, to note the number of previous discharges.

Prior to energizing the SLS, if the Test Specimen is a Cardiac Pulse Generator, the external Cardiac Simulator Signal's amplitude is adjusted to approximately twice the level that reliably inhibits the Cardiac Pulse Generator. The Cardiac Pulse Generator's "pacemaker stimulation pulse" is monitored with an oscilloscope and counter to confirm that its pulse period (pulse rate) is as desired. If the Test Specimen is also an ICD, the simulated fibrillation signal from the Cardiac Simulator is used to intentionally cause the ICD to deliver a therapy pulse to confirm proper operation.

3.2.1 EAS Systems and Walk-through RFID System/Metal Detectors

For each Test Specimen, the three types of tests described in Section 3.1.1 are performed during exposure to each of the walk-through SLS (eleven EAS Systems, one walk-through RFID System, and two walk-through Metal Detectors) with only one System activated at a time. The number and order in which the three types of tests are performed is determined at the time of the test or based upon the manufacturer's request. For Implantable Medical Devices with lead(s)/catheter(s), the specific process for each type of test is as follows:

1. **Dynamic Test** – The Test Specimen/lead(s) loop is placed in the perpendicular orientation with the plane of the loop positioned 115 cm from the center of the

pedestal of the first SLS. This SLS is then activated and the Test Specimen is moved through the system at 30 cm/sec between +100 cm and –100 cm to a final position of 115 cm on the other side of the SLS. Its response is continuously monitored and the locations of changes in its response and the types of changes are recorded. This test is repeated for each walk-through SLS.

2. **Static Test 1** – The Test Specimen/lead(s) loop is placed in the perpendicular orientation with the plane of the loop positioned 100 cm from the center of the pedestal of first SLS System. This SLS is then activated and the Test Specimen is moved either at a very slow velocity (e.g., 1 cm/sec) or in discrete steps through the SLS to a final position of 100 cm on the other side of the system or until the Test Specimen and saline container are outside the physical extents of the SLS **and** the response of the Test Specimen at the last three consecutive test positions has been the same as when the SLS is not active. The slow velocity test approach is the default; however, the discrete steps test approach is used if the Test Specimen's manufacturer so requests.

   If a slow velocity is used, the velocity used (e.g., 1 cm/sec) is a function of the Test Specimen's response time and is selected based on the advice of the Test Specimen's manufacturer. The Test Specimen is slowly moved and its response is monitored until a change in response is observed. It is then moved back to a location prior to the detection of the change in response and its response, distance moved, and velocity are recorded. The test proceeds in discrete steps from that location until the final test position for that SLS is reached or until no change in response is observed at three consecutive test positions. If no change in response is observed at three consecutive test positions, the slow velocity process is resumed until another change in response is observed. This entire process is repeated until the final test position for that SLS is reached.

   If discrete steps are used, the Test Specimen is moved in 10-cm increments and at each position its responses are observed and recorded. The "dwell time" at each position (e.g., 10 sec) and the speed between positions are functions of the device's response time and are selected based on the advice of the Test Specimen's manufacturer. In addition, as the Test Specimen is moved between positions, its response is continuously monitored. When a change in response is noted, the E3 tests are continued in 10-cm increments if the location of the response change is not required to be determined any closer than within 10 cm. However, if the location of the response change must be known closer than the 10-cm increments, the device is repositioned to a location prior to the detection of the change. Then the device is moved in 2-cm increments in the original direction of motion while measuring the response at each position. This 2-cm step measurement process is continued until there is no change observed in the Test Specimen's response at three consecutive test positions. Then the 10-cm step measurement process is resumed until another change in response is observed. This entire process is repeated until the final test position for that SLS is reached.

   This test is repeated for each SLS.

3. **Static Test 2 -** The lead(s) loop is placed in the parallel orientation and the measurement process of Static Test 1 is performed for each SLS.

For other types of Medical Devices, the walk-through SLS measurement process is adapted to accommodate the configuration and operation of the device and is mutually agreed upon with the manufacturer prior to the tests.

Following the SLS E3 tests on a Test Specimen, it is again interrogated with the manufacturer's programmer to ensure that the SLS exposure field has not changed its programmed parameters and, if an ICD, to confirm the total number of discharges that occurred during the tests.

3.2.2 Tag Deactivators, RFID Readers, and Handheld Metal Detectors

For each Test Specimen, the tests described in Section 3.1.2 are performed during exposure to each of the Tag Deactivators, RFID Readers, and handheld Metal Detector with only one SLS activated at a time. For Implantable Medical Devices with lead(s)/catheter(s), the Test Specimen/lead(s) loop is placed in a vertical plane as described in Section 2.0 with the plane of the loop positioned 5 cm from the Tag Deactivator or RFID Reader or 3 cm from the handheld Metal Detector. The SLS is activated and the Test Specimen is moved in discrete steps away from the SLS to a final position of 100 cm from the SLS or until the response of the Test Specimen at the last two consecutive test positions has been the same as when the SLS is not active. For Tag Deactivators and RFID Readers, the Test Specimen is moved in discrete increments with specific test positions of 5, 10, 15, 20, 30, 40, 60, 80, and 100 cm. For handheld Metal Detectors, the Test Specimen is moved in discrete increments with specific test positions of 3, 5, 10, 15, 20, 30, 40, 60, 80, and 100 cm.

For other types of Test Specimens, the Test Specimen’s location, orientation, and height relative to the SLS are mutually agreed upon with its manufacturer prior to the start of the tests.

The Test Specimen’s responses are observed and recorded at each test position. The “dwell time” at each position (e.g., 10 sec) is a function of the device’s response time and is selected based on the advice of the Test Specimen’s manufacturer. For Tag Deactivators, at each test position the Test Specimen’s response to the Tag Deactivator’s detection EM field (if present) is monitored and recorded. Then the Tag Deactivator is operated such that a deactivation (activation) EM burst is emitted approximately 10 times in 15 sec resulting in 10 EM bursts approximately 1.5 sec apart while its response is monitored and recorded. For RFID Readers and handheld Metal Detectors, at each test position the Test Specimen’s response to the SLS’s EM field is monitored and recorded.

This test is repeated for each SLS. Following these E3 tests on a Test Specimen, it is again interrogated with the manufacturer's programmer to ensure that the SLS exposure field has not changed its programmed parameters and, if an ICD, to confirm the total number of discharges that occurred during the tests.