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INVITED PAPER

Malfunctions of Medical Devices Due to Electrostatic Occurrences

Big Data Analysis of 10 Years of the FDA's Reports

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ABSTRACT An electrostatic discharge (ESD) event can cause a medical device to fail and pose a threat to patients'safety. This paper presents the data mining analysis of ESD failures in medical devices, over the last ten years, using the U.S. FDA's manufacturer and user facility device experience database. The most frequent failure modes and activities resulting in ESD events were identified and correlated with key environmental factors. Recommendations are then presented to medical device manufacturers and hospitals.

INDEX TERMS MAUDE database, FDA, electrostatic discharge, medical devices, humidification.

I. INTRODUCTION

The medical industry has been moving toward greater dependence on electronics to add functionality and improve the performance of medical devices. However, electronics, especially microelectronic components, are susceptible to electrostatic discharge (ESD), rendering the medical devices unreliable and, in some cases, unsafe.

ESD occurs when objects at different electrical potentials come in close enough proximity to electrically break down the medium between them. For instance, when a person walks across a carpeted floor, static charges can accumulate and transfer to an item, with a current flow that is sufficient to burn internal circuitry or cause dielectric breakdown. In such cases the damage is unrecoverable. The discharge of the accumulated static charges can also generate electromagnetic fields that induce voltages beyond the noise margin of logic devices, leading to data corruption [1]. In these cases, the medical device may be temporarily corrupted (i.e., recoverable), but the malfunction can nevertheless jeopardize the patient's safety.

Numerous malfunctions of medical devices due to ESD have been reported in the literature [2]–[4]. We data-mined the U.S. Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database over the 10-year period of January 2006 to December 2016, to determine the extent of ESD malfunctions of medical devices and to identify the number and types of malfunctions and their impact on patient health. However, the general consensus by both regulatory bodies and standards organizations is that ESD malfunctions are underreported and not well understood [2]–[5].

This paper discusses the data-mining, classification and analysis of ESD malfunction information obtained from the MAUDE database. We present data analytics of ESD malfunctions in the database for different types of devices, failure types (recoverable vs non-recoverable), failure modes, and the user activities and environmental conditions that resulted in the ESD events. We conclude with recommendations for medical device manufacturers and healthcare facilities to mitigate the risk of ESD malfunctions.

II. ESD MALFUNCTION REPORT ANALYSIS

The FDA's website stores the reports of adverse medical device events in their MAUDE database [6]. Each adverse event report has an event description and is labeled with a variety of information such as ''product problem''. However, because malfunction reports are often submitted by technicians and hospital staff who may not be familiar with ESD terminology and ESD failure characteristics, an algorithm was developed to data-mine terms that describe ESD events (see Figure 1). The process thus requires domain knowledge and looping to identify the keywords used to describe ESD events and then use them to find new events and in turn obtain additional keywords.

The data-mining algorithm extracted some 2,500 reports from the MAUDE database, of which 1342 were related to ESD. In addition, there were 11 other reports on ESD malfunctions, which were not explicitly associated with ESD

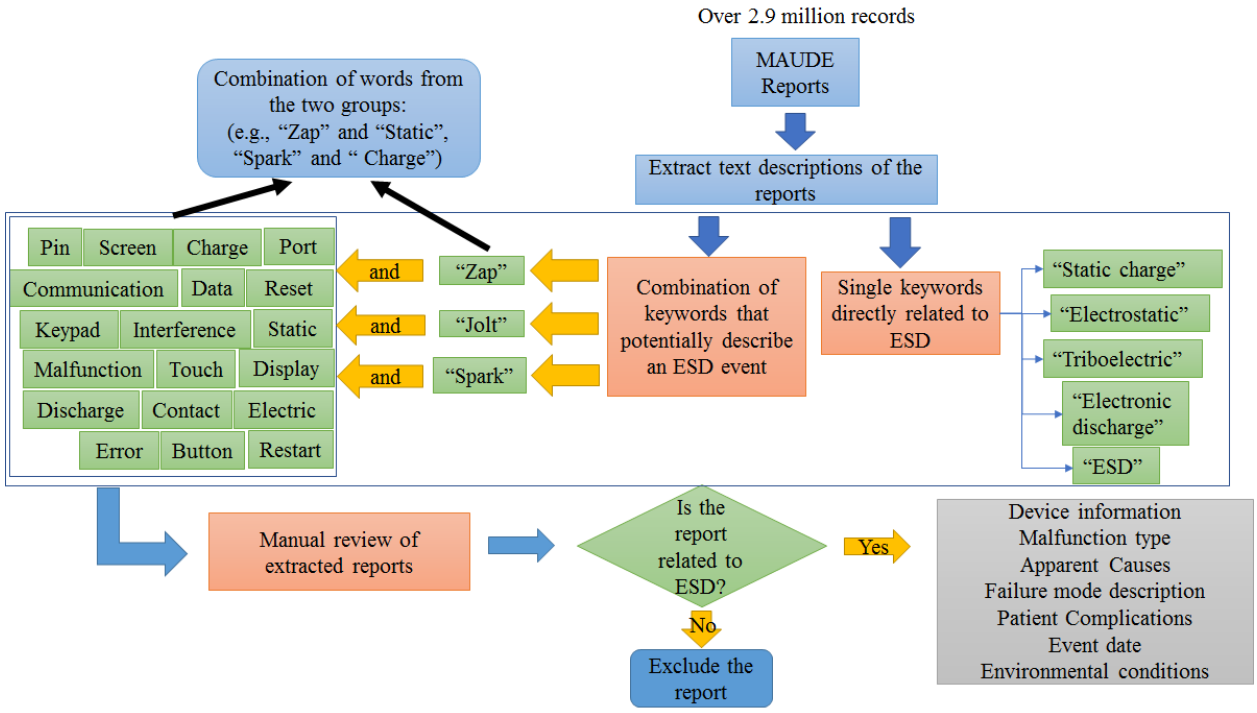

FIGURE 1. Procedure for analyzing ESD reports in the MAUDE database.

in the MAUDE database, but provided to us by the FDA in conjunction with the manufacturer. For each ESD related report, information pertaining to the device type, malfunction type, failure mode description, patient complications, event date, environmental conditions and apparent causes of ESD events, was extracted (see Table 1).

Analyzing the patient complications for these adverse events revealed 5 reports of patient deaths and 46 injuries where ESD may have occurred and caused device malfunction. Although some reports did not mention that device malfunction was the exact root cause of the adverse event, we noted ESD to be at least a contributing factor. ESD malfunction of class III devices, which are the most safety-critical medical devices according to FDA's classification [7], was identified in all of the death reports and 20 of the injuries. In 15 injury reports, ESD malfunction of class I devices, which require the least regulatory control, were noted, while in 11 injuries, class II devices, which require greater regulatory control than class I, but less than class III devices, had ESD malfunctions.

In addition to injuries and deaths, patients with neuro-stimulators (72 reports) and cochlear implants (18 reports) required re-implantation procedures resulting in new surgery and the associated anesthesia and recovery. Other examples of adverse ESD events included an explosion involving a tissue processor, skin burns involving a nebulizer, and pain or static sensation involving neuro-stimulators, cell counters, dentistry machines, clinical chemistry analyzers, and a robotic surgery console.

ESD malfunctions were also found to result in non-recoverable failures of premature battery depletion and unresponsive (frozen) keypads and displays, caused by short circuits in the integrated circuit (IC). ESD also resulted in recoverable malfunctions of memory, changes in the device settings (e.g., date and time of dose injection), artifacts in the data, interrupted or wrong dose delivery, intermittent or delayed communication issues, and inaccurate sensor reading. Some recoverable malfunctions were found to be due to an IC latch-up that caused an unexpected reset and data corruption in the controller board. The possibility of recoverable malfunctions due to IC latch-up during an ESD event has been reported [8], [9]. Some recoverable malfunctions had detrimental consequences, for instance, corruption of the memory in the controller of heart assist devices resulted in two deaths.

The most frequently reported medical device affected by ESD was a clinical chemistry analyzer, manufactured by Abbott Laboratories [10]. The malfunction reports noted that incorrect values and error messages were displayed on the screen when the ESD events occurred. The manufacturer identified that the root cause was static charge buildup on the surface of a highly insulating reaction vessel made of polypropylene resin.

Infusion pumps were identified to have the second highest number of ESD malfunctions, 173, with 164 of those due to the failure of the display shield of a bedside infusion pump, manufactured by Baxter Healthcare, which resulted in an interruption of the insulin delivery. In the remaining

TABLE 1. ESD malfunction reports from the MAUDE database between January 2006 and December 2016.

Device type	Number of ESD malfunctions	Number of deaths/ injuries	Number of non-recoverable/ recoverable malfunctions	Apparent causes and/or failure modes of ESD events
Clinical chemistry analyzer	769	0/12	5/764	Buildup of static charge on the sample holder or the plastic diffuser (due to low RH); user touched the metallic barcode; ESD resulted in inaccurate readings or error messages on the screen.
Infusion pump	173	0/6	167/6	Lightning or touching keypad or screen while battery replacement; ESD caused date and time changes in the log files, unexpected restart, or wrong dose delivery.
Heart assist devices (wearable defibrillators, ventricular assist devices)	122	4/4	89/33	The surgeon touched the device with surgical tools; the patient was wearing a silk suit; riding in a car; sitting on a sofa; plugging in a laptop; or replacing batteries; ESD resulted temporary pump motor controller restart).
Neuro-stimulator	33	1/3	17/16	Patient touched the programmer, while wearing a static dissipation belt on waist that caused shocking sensation, loss of therapy, unexpected rest; ESD resulted in wrong values for remaining battery life.
Imaging system (portable X-ray, MRI, CT)	19	0/0	2/17	While the mobile system was being moved down a ramp; touched a metal frame or entered an elevator; ESD caused unintended sporadic movement of wheels, and artifacts displayed on the screen.
Cochlear implant	18	0/4	18/0	During surgery, the surgeon touched the hex screw of the device; while patient was sliding down a plastic slide.
Pulse generator	18	0/0	0/18	When the surgeon touched the hex screw of the device, ESD resulted in wrong values and error messages for remaining battery life.
Ventilator	17	0/2	8/9	A charged user touched the operation panel with hand or stethoscope during intra-hospital patient transport; while changing the bed sheet and connecting an ungrounded cable to a port; ESD caused intermittent communication, unexpected shutdown, and inaccurate values.
Pain relief stimulator	13	0/0	0/13	Static charge from lightning caused shocking sensation.
Anesthesia unit	10	0/0	0/10	When a charged user touched a metallic arm of the device, ESD caused intermittent communication, unexpected shutdown, or inaccurate values.
Heart/lung machine	8	0/0	0/8	Static charge created due to friction of the roller pump with PVC tubes caused noise in the ECG data (probably due to low RH).
Blood glucose monitor	9	0/2	0/9	Time and date was changed due to ESD.
Battery charger	6	0/0	0/6	ESD caused communication error and displayed a "replace battery" message.
Intracranial pressure monitor	4	0/4	0/4	Inaccurate reading after ESD events.
Eye surgery device	4	0/3	0/4	ESD caused shock to users.
Surgery instrument	3	0/0	0/3	Triboelectric charging of the sensor with disposable plastics caused intermittently delayed response.
Cardiopulmonary bypass monitor	2	2/0	0/2	Static charge buildup from the hand-piece caused ESD shocks to users.
Dermatology laser	2	0/0	0/1	ESD caused inaccurate reading, which was reproduced by exceeding ESD test criteria
Slit lamp	2	0/2	2/0	ESD caused inaccurate reading, which was reproduced by exceeding ESD test criteria.
Powered patient bed	1	0/0	0/1	ESD caused temporary lockup of motor controller board
Cell counter	2	0/0	0/2	ESD caused unexpected shut down and shock to user while plugging cables into a USB connector.
Pulse oximeter	1	0/0	0/2	ESD testing on the USB port and chassis caused temporarily frozen screen.
Powered wheelchair	1	0/0	1/0	Triboelectric charging of the joystick caused ESD malfunction.

TABLE 1. *(Continued.)* **ESD malfunction reports from the MAUDE database between January 2006 and December 2016.**

Weight scale	1	0/0	0/1	ESD caused unexpected reset after the patient (wearing a wool sweater) touched a metal bar.
Dentistry machine	1	0/0	1/0	Static charges accumulated on the doctor's hand possibly caused ESD shocks to users.
Patient lift	1	0/0	1/0	ESD malfunction occurred when the nurse pressed a button of the device.
Laparoscope camera	1	0/0	0/1	Buildup of static charge on the keypad due to poor grounding of the camera head caused ESD malfunction.
Wound therapy pump	1	0/0	1/0	ESD malfunction occurred when a nurse (wearing a nylon gown) touched a button of the device.
Coagulation analyzer	1	0/0	1/0	Static charge buildup due to low RH caused ESD malfunction.
Tissue processor	1	0/0	1/0	ESD malfunction occurred when a charged user touched the device's lid when RH was too low.
Nebulizer	1	0/0	1/0	ESD malfunction occurred while plugging the device into an adapter.
Aspiration pump	1	0/0	1/0	-

9 reports, ESD affected wearable infusion pumps, manufactured by Medtronic and Baxter Healthcare, and caused apparent recoverable failures such as blank displays, unresponsive buttons, interrupted delivery, time and date changes, and non-recoverable failures such as damage to the integrated circuit. Over the same 10-year period, FDA issued 4 recalls for infusion pumps due to their ESD malfunctions [11]–[14]. In one case, the reason for the recall was that the LCD did not meet the immunity standard to withstand ESD events [12]. The remaining 3 recalls were issued due to static charge buildup caused by improper grounding systems [11], faulty ESD protection circuitry [13] or non-conforming gaskets used in the pump [14]. The resulting ESD events caused pump failure, interrupted the therapy, or generated alarms during patient use. These recalls affected over 31000 infusion pumps distributed globally.

The third highest number of ESD malfunction reports was associated with heart assis devices, including ventricular assist devices and wearable defibrillators, manufactured by Medtronic, Boston Scientific, Thoratec, and Syncardia. The ESD events occurred when the user touched the exposed ports of the controller during battery replacement. Of the 122 malfunction reports, 33 noted ESD resulted in IC latch-up that caused unexpected resets and data corruption in the motor controller of a ventricular assist device manufactured by HeartWare. The remaining 89 reports noted that ESD caused internal short circuits in the IC and resulted in non-recoverable damage to ESD protection diodes in the external programmer of implantable cardioverter defibrillators.

FDA's recall database shows 3 recalls for heart assist devices over a 10-year period that affected over 41000 devices globally, one of which was due to the susceptibility of the battery pack to ESD malfunctions that could prevent the battery from recharging [15]. The reason for the other two recalls was the alleged potential damage to electronics due to ESD [16], [17].

III. SOURCE ANALYSIS OF ESD ADVERSE EVENTS

An evaluation of the sources of ESD includes both users and the device itself (Figure 2). For example, reports noted that human body charging occurred during routine activities of sitting on a sofa or bed, laying down or rolling out of bed, that involved friction between people and insulating materials. Other reports noted that charge buildup occurred while wearing insulating clothes, for instance, while a hospital staff was wearing a nylon gown or while the patient was wearing silk or wool clothing. Human body charging was also reported during interaction with mobile equipment such as movable stretcher beds, or while driving in a car. In addition friction between the wheels of mobile X-ray machines and the floor resulted in charge buildup and subsequently caused ESD malfunctions. And charge buildup occurred in heart-lung machines due to friction between PVC tubes and pump rollers that resulted in faulty sensor readings. This phenomenon has also been reported as a significant cause of signal noise in heart-lung machines [18].

Four common discharge scenarios were identified: discharge via hand, tools, cables and the device itself. Some malfunction reports noted that ESD occurred when the user's hand touched a metallic part of the device, for instance during battery replacement or maintenance. Examples of the metal parts mentioned in the reports are the metal barcode, handpiece, joystick, metal arm, operation panel, hex screw, button, sample holder, screen, or the lid.

Discharge via tools occurred when the user touched the metallic parts of the device while holding a metallic object, such as a surgical tool or a stethoscope. Some reports note that when the user was plugging cables into a connector of the device, an ESD event occurred due to accumulated static charge on the cable. In particular, some ESD malfunction reports involved mobile X-ray machines that discharged to a grounded metal object, after the wheels of the machine, which was being moved on a carpet by a nurse, touched a metal frame or entered an elevator.

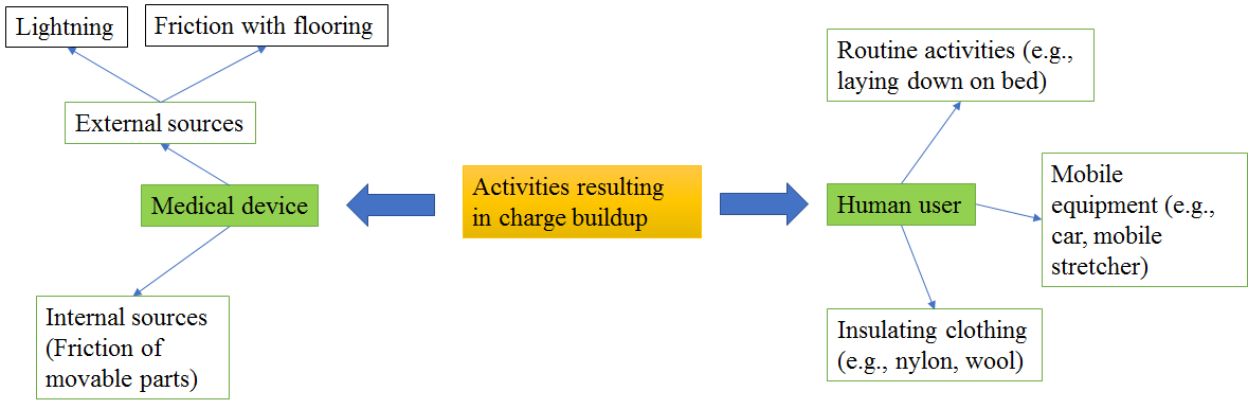

FIGURE 2. Reported activities that resulted in ESD malfunctions.

When the ESD malfunctions were correlated with the occurrence date (i.e., month), it was found that nearly half of the ESD events occurred during the coldest months of December, January, and February, whereas only 7.7% occurred during hottest months of June, July, and August (see Figure 3). These results could be attributed to lower RH levels in cold months due to indoor heating. Some malfunction reports explicitly noted that low RH at the event location was a contributing factor for charge accumulation and the subsequent ESD events. More statistical analysis should be conducted in this area.

IV. ENVIRONMENTAL INFLUENCE ON ESD EVENTS

The risk of ESD events is dependent on the moisture in the air. Moisture contributes free charge carriers and lowers surface resistivity of materials, resulting in reduced charge buildup and faster dissipation of the accumulated charge to the ground. In electronic assembly areas, the recommended minimum level for RH is 30% [19]. The instruction for use (IFU) of many medical devices provide specifications for the minimum operating RH level (most commonly 30% RH), to minimize charge buildup and consequent ESD malfunctions of the device. However, humidity guidelines for medical facilities are more concerned with infection transmission, rather than ESD malfunction of electronics [20].

Some ESD malfunction reports explicitly noted that the RH at the event location was lower than 30%, i.e., the minimum RH recommended in the IFU of the device. These devices include clinical chemistry analyzers (764 reports), heart-lung machines (8 reports), a heart assist device, a ventilator, a coagulation analyzer, a tissue processor and an aspiration pump. The majority of these devices are stationary medical devices that were used in a hospital room where RH was most likely controlled above a minimum limit to provide comfort for the staff. A possible reason for the low RH could be that the ventilation system was not active at the time of the event, or the RH level was set to a value lower than 30%.

In 2010, the Addendum D to ASHRAE 170 standard [21], titled ''ventilation of healthcare facilities'' lowered the original minimum 30% RH level in critical care areas to 20%, primarily to minimize humidification costs. For example, we estimated that a hospital in Nevada would save over $10,000 per year by implementing this standard. However, the minimum RH level of 20% is not compatible with the RH requirements of most microelectronic devices [22], since higher voltage ESD events are directly related to lower RH values. Unfortunately, this standard has been adopted by several key federal regulatory organizations such as the Centers for Medicare and Medicare Services (CMS), which issued a waiver in April 2013 that permits hospitals to keep RH level of critical care areas above 20% [23]. The ASHRAE 170 standard has still not updated its minimum RH level for critical care areas. A newer categorical waiver by CMS [24] instructed hospitals to ensure compliance of the new minimum RH limit with the instruction for use of the medical equipment in the facility, before electing to use the previous waiver [23].

V. CONCLUSIONS AND RECOMMENDATIONS

Despite the long history of ESD considerations in the electronics industry, our analysis shows that manufacturers of medical devices do not implement adequate ESD prevention. Furthermore, the number of malfunction reports, recalled devices and patient complications indicate that ESD immunity standards for medical devices may not be adequate, including those specified in IEC 61000-4-2.

Medical device manufacturers need to implement ESD mitigation programs to prevent device malfunctions. The failure mode, effect and criticality analysis (FMECA) [25], [26] is one method to classify all possible failure modes based on their associated risks. In an FMECA procedure, a criticality index is assigned to each failure mode caused by ESD, such as frozen display or date and time reset, and a criticality index is calculated based on the severity of the effect of each failure mode and their probability of occurrence. The severity should depend on patient complications, noting that both recoverable (e.g., data corruption) and non-recoverable malfunctions (e.g., device shut down) can result in patient injury or death.

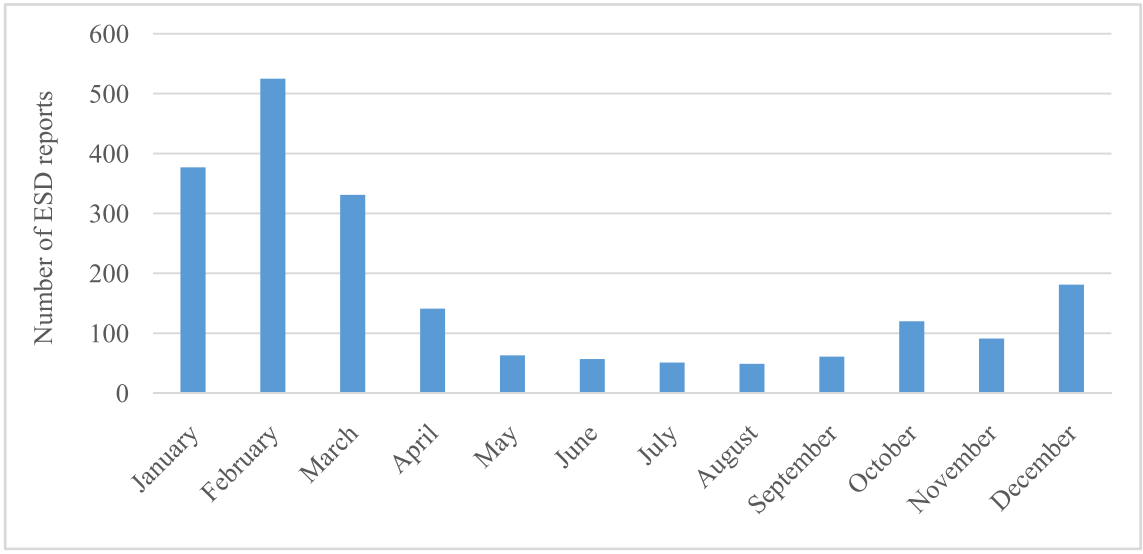

FIGURE 3. ESD malfunctions per month (2006-2016) for 1353 reports.

The occurrence rate for each failure mode can be found using field return data. However, although the MAUDE database contains records of medical device malfunctions, it tends to under-report malfunctions.

This analysis also shows that seemingly uncritical device malfunctions (date and time reset, intermittent drop in communications, artifacts in sensor readings) caused by ESD events have resulted in patient complications. While these malfunctions did not cause permanent damage to the device electronics, there are cases of resulting patient injury and death.

Our analysis further shows the relationship between low RH and occurrence of ESD malfunctions. In particular, the number of ESD malfunctions during cold (dry) months were almost 6 times higher than that of summer (more humid) months. In fact, manufacturers themselves noted that ESD malfunctions more often occurred when the RH was lower than the level specified in the device instructions (typically 30%) and blamed healthcare facilities. As a result, hospitals must maintain at least 30% RH level, and that the minimum RH limit (20%) provided by Addendum D to ASHRAE 170-2010 must be changed back to the 30% in its previous version [21].

Finally, it was observed that manufacturers could often reproduce the reported device malfunction in their facility by conducting ESD tests exceeding the maximum voltage limit specified in the standards. Thus, manufacturers of medical devices must simulate maximum critical charging and discharging scenarios, including those associated with daily activities, touching a keypad or screen, rolling out of bed, and plugging connectors into the device, where the friction between the user's skin and an insulating object causes charge buildup. Discharging scenarios must include touching exposed device ports, memory locations, and batteries.

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