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ESD Events To Wearable Medical Devices In Healthcare Environments—Part 1: Current Measurements

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***Abstract*—Wearable medical devices are widely used for monitoring and treatment of patients. Electrostatic discharge can render these devices unreliable and cause a temporary or permanent disturbance in their operation. In a healthcare environment, severe electrostatic discharge (ESD) can occur while a patient, lying down or sitting on a hospital bed with a wearable device, discharges the device via a grounded bedframe. To protect the devices from ESD damage, the worst-case discharge conditions in the usage environment need to be identified. Previous studies by authors revealed that such events could be more severe than the conventional human metal model (HMM). However, the impact of various body postures and device location on the body and the severity of the discharge current compared with HMM have not been investigated for healthcare environments. This study is an attempt to address the gap in the literature by investigating severe discharges in such environments and characterizing their current waveforms for three postures (standing on the floor, sitting, and lying down on a hospital bed), two device locations (hand and waist), and four body voltages (2, 4, 6, and 8 kV). This study highlights that the IEC 61000-4-2 standard may not be sufficient for testing wearable medical devices.**

***Index Terms*—Discharge current, electrostatic discharge, medical device, peak current, peak current derivative, wearable device.**

I. Introduction

WEARABLE medical devices, such as wearable biosensors, ECG, blood oxygen, and blood pressure monitors, are designed to remain attached to patients while performing daily activities, and the device and the body can be assumed to be at equipotential [1], [2], [3]. Once the static charges, which accumulate on the subject's body during various routine activities, discharge to the ground (e.g., while touching the metallic bedframe of a hospital bed), a significant amount of charge (exceeding 2 μC) can be released. This discharge current may enter the internal circuitry of the wearable device and cause transient disturbances and/or destroy the integrated circuit if the device is not sufficiently protected against the electrostatic discharge (ESD) events. Malfunctions of wearable medical devices due to ESD have resulted in numerous device recalls, patient injuries, and deaths [4], which can be blamed on insufficient ESD test methods, test levels, or their incorrect application.

To ensure the immunity of medical devices against ESD events, the U.S. Food and Drug Administration recommends manufacturers to conduct ESD testing according to the IEC 61000-4-2 standard test method [5]. The discharge waveform in realistic usage configurations need to be compared with the discharge of an ESD gun to determine whether the testing configuration of IEC 61000-4-2 standard is sufficient for ESD immunity of wearable medical devices.

The ESD current waveform depends on the impedance of the discharge path, which is determined by the impedance of the human body, the current-carrying structures (e.g., discharge wires), and the time-varying spark impedance between the device and the grounded object [6]. The IEC 61000-4-2 standard describes the most severe discharge configuration with the human metal model (HMM) in which a discharge via a handheld metal rod to a vertical ground wall is initiated by a charged subject in a standing posture. In fact, the circuit design specifications of the ESD gun (i.e., the capacitance and resistance of the discharge path) is supposed to reflect the impedance of the human body in such a discharge configuration.

While the HMM discharge scenario can be well-suited for a tabletop device, it is not compatible for devices attached to a human body, whose impedance relative to ground varies at different body postures (sitting and lying down) and locations on the body (waist, hand, etc.), especially for healthcare settings in which metal frame beds are common. A relevant example of such discharge scenarios occurs in a healthcare environment where multiple wearable monitoring devices could be attached

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to patients during transportation or operation. In these situations, the patients are more likely to be sitting or lying down on a hospital bed with grounded metal frames. This inconsistency between HMM's test conditions and the real use case could lead to insufficient ESD protection for wearable devices in these safety-critical environments.

The majority of the literature on ESD from a human body only focus on the HMM configuration as the most severe test method to evaluate ESD susceptibility of a device [7], [8], [9]. Few studies have been conducted in recent years to address the inconsistency between the HMM and the realistic discharges affecting wearable devices.

Ishida et al. [10], [11] studied the impact of various discharge locations on the body, including head, arm, or waist, on the discharge current waveform for 1 kV air discharge. A semispherical metal piece was used in lieu of a wearable device. The peak discharge current was found to be the largest for waist-mounted devices, which was about 1.5 times larger than HMM.

In a more comprehensive study, Zhou et al. [12] investigated the air discharge waveform from a metal piece (in lieu of a wearable device) mounted on arm, waist, head, and hand, for a standing subject for a brush-by discharge configuration. The peak current via a waist-worn metal piece was found to be 2–4 times larger than the HMM scenario. A circuit model was also developed for the impedance of the discharge path from the human body according to the location of the body-attached device. Motivated by Zhou et al. [12], Oganezova et al. [6] developed a three-dimensional simulation model of human body to predict the ESD current waveform from a standing subject discharging a handheld metal piece to a grounded plane, using a method of moment frequency-domain solution. The largest capacitance and, thus, the lower impedance were associated with body postures that resulted in a large portion of the subject's body positioned near a ground plane. In a more recent study, Luo et al. [13] developed an artificial dummy to replicate the HMM discharge scenario and compared the impedances between the discharge point (the dummy's hand) and the ground to human volunteers.

In all the aforementioned studies, the posture of the human subject was standing on the floor. However, the discharge event in a realistic scenario could occur while the patient's posture is other than standing (e.g., sitting and lying down on the bed) due to the changes in the body impedance.

Kohani et al. [4], [14], [15], [16] have previously conducted a series of surveys and studies in a hospital and controlled laboratory environments to identify the most critical configurations that could lead to ESD events in a healthcare. Three body postures associated with the most severe discharges were sitting and lying down on a hospital bed and standing on the floor [14]. Kohani et al. [15] developed a realistic discharge setup for a wearable device to measure the current waveform and the transient magnetic field during discharges from a charged subject wearing a small metal piece (used in lieu of a wearable medical device) on hand or waist at five voltage levels (2–10 kV). This study confirmed that the peak and maximum current derivative of the measured ESD events was larger than the discharge obtained from the calibration setup of an ESD gun. The goal of the present study is to further investigate the impact of different body postures (including sitting, lying down on a bed, and standing on the floor) on the current waveform and compare the severity of the discharges with that of the ESD gun (3.75 A/kV).

This study is presented in two parts of measurement and simulation to avoid excessive article length. In part I of this article, the discharge configurations and the current waveform measurement setup are discussed. Moreover, the effect of body posture and device location on the waveform parameters, including peak current, peak current derivative, and charge transfer, during the ESD events form a body-worn metal piece (in lieu of a wearable medical device). In part II of this work, an equivalent circuit is developed to predict the discharge waveform and analyze the effect of posture and body locations in terms of circuit elements.

The rest of this article is organized as follows. Section II specifies the discharge configurations and the current measurement setup. Section III discusses the discharge current measurement results and the trends of the waveform parameters. Finally, Section IV concludes this article.

II. Discharge Configurations

Kohani et al. [14] previously performed studies to obtain the most critical patient activities that could results in severe ESD events in a healthcare environment. The largest body voltages were observed in three activities: patient transfer using a sliding board, sitting and lying down on the hospital bed, and rising from it. In these activities, the largest peak body voltages (exceeding 20 kV) were observed while the subject was lying down or sitting on a hospital bed, or standing on the floor near the bed [14]. These three postures are investigated in the present study to evaluate the most severe current waveforms during ESD of wearable medical devices. Based on the previous observations and studies, two body positions were selected for the location of the wearable device: hand (wrist) and waist.

Fig. 1 shows the discharge configuration for the charged subject lying down on a hospital bed while a metal piece is mounted on the subject's hand. The wearable device is emulated by a small thin metal piece (5 cm $\times$ 5 cm $\times$ 3 mm) made of copper. The same setup was used for sitting and standing posture as well as metal piece worn on the subject's waist. It is assumed that the ESD occurs when the metal piece mounted on the charged body inadvertently touches the metallic frame of the hospital bed. To replicate the worst-case discharge and the large capacitance of hospital bed to ground, the metallic frame is assumed to be grounded. During field visits at a few healthcare facilities, authors have seen these types of beds.

During the experiment, the charged subject discharged the metal piece, mounted on their hand or waist, into a small metal rod (about 10 cm long and 10 mm in diameter). The rounded tip of the rod facilitated the generation of a spark during the discharge event. The metal rod was attached to a short wire (about 30 cm long), which was connected to the aluminum foil layers under the bed that represented a grounded bedframe of a hospital bed. There was a large ground plane (1 m $\times$ 1.5 m) under the bed connected to the Al foil with a 1 m long wire. This long wire is used to ensure proper grounding of the aluminum foil via the mains ground plane under the floor. The ground plane

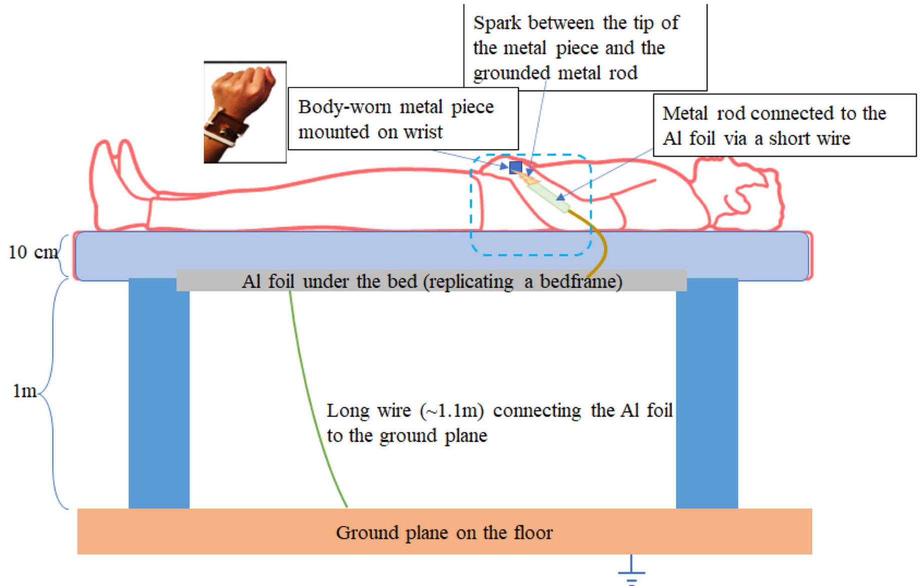

Fig. 1. ESD setup for a charged subject lying down on the hospital bed, wearing a body-mounted metal piece. Detailed view of the metal piece is shown in Fig. 2.

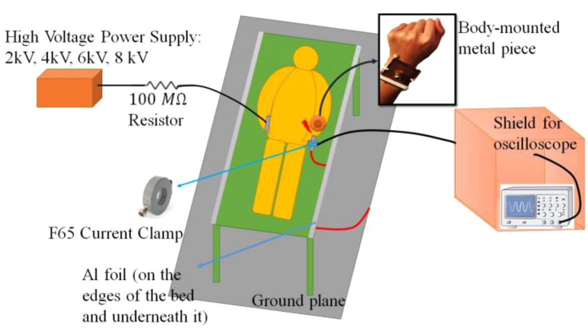

Fig. 2. ESD current measurement setup while the subject is lying down on the hospital bed. A short wire is attached to the Al foil, and a longer wire connects between the Al foil and the ground plane.

under the bed emulates the flooring system, which is often made from reinforced concrete.

Fig. 2 shows the experimental setup to measure the discharge current. The subject is initially charged by a high-voltage power supply to voltages of 2, 4, 6, and 8 kV to be consistent with the contact-mode test levels specified in the IEC 61000-4-2 standard. This allows comparing the discharge waveform from the wearable device with the ESD gun results (in contact mode).

To reduce the current flowing from the power supply to the subject's body during charging, a 100 MΩ current-limiting resistor was added to the wire. The wire from the power supply was held by the subject's right hand and the metal piece was mounted on their left hand or waist. The time required for the body to reach the voltage level set by the power supply is extremely short, given the low capacitance of the body. According to IEC 61000-4-2, the body capacitance in standing posture is about 150 pF. This value could change at various postures and increases while the subject positions next to a large ground plane. Using the IEC standard's assumption, the time constant of charging the body capacitance via the current-limiting resistor is $\tau = RC \approx 100\,\text{M}\Omega\ \times 150\,\text{pF} = 0.015\,\text{s}$). To initiate the discharge, the subject touched the metal rod, which was connected to the short ground wire to release the accumulated charge via a spark. The discharge path was from the metal piece to the metal rod and the Al foil and from there to the ground plane on the floor. To capture the discharge current, an F65 current clamp (1 GHz bandwidth) was used around the metal rod that was connected to the short wire. Since the sensitivity of the current clamp reduces at frequencies below 1 MHz, a deconvolution method was employed to correct for the frequency response in this frequency range [17]. The oscilloscope was placed inside a metal shield to protect it against electromagnetic field coupling due to the ESD events.

At the onset of discharge, a spark occurs between the hemispherical tip of the metal piece and the rod. The length of the spark is a critical parameter that determines the rising edge of the waveform. Since the measurement of the spark length in the setup was not practical, ESD tests were performed at a slow speed of approach (about 2 cm/s) to ensure that the spark length is close to the value predicted by Paschen's law. Moreover, pencil marks were added to the surface of the hemispherical tip of the metal piece to increase electron emission, and thereby minimize the statistical time lag [18]. This increased electron emission is facilitated by free electrons of graphite [18]. Due to the variabilities in air discharge events, each test was performed four times (based on experience from previous studies) and the worst-case waveform was selected for analysis.

Temperature and relative humidity were measured at 25 °C and 25% RH, respectively. The IEC 61000-4-2 mentions the RH range for ESD test method to be between 30% and 60%. However, this study was performed at a slightly lower RH level since healthcare facilities tend to lower RH level to prevent bacteria growth. A new ventilation standard for healthcare facilities has also lowered the minimum limit of RH from 30% to 20% for energy saving purposes [19].

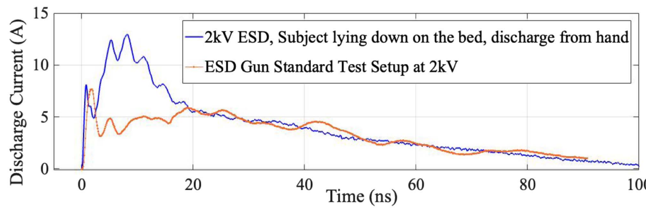

Fig. 3. Comparison between the discharge waveform from a subject lying down on a grounded bed (while wearing a metal piece on hand) with the standard ESD calibration setup at 2 kV.

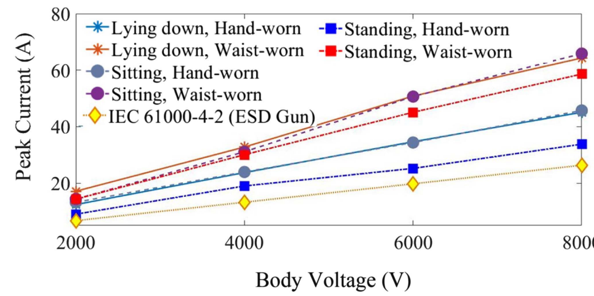

Fig. 4. Comparison of the measured peak ESD current for six test configurations and ESD gun calibration setup (IEC 61000-4-2 Standard) as a function of body voltage.

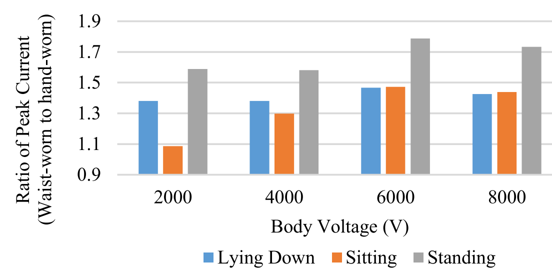

Fig. 5. Comparison between the ratio of the peak current from waist- to hand-worn discharges at each voltage.

ESD gun tests were performed according to the calibration setup of the IEC 61000-4-2 standard, where an ESD gun directly injects a pulse into a current target. These ESD tests were performed in four voltage levels of 2, 4, 6, and 8 kV. The severity parameters of each waveform, including peak current ($I_{\max}$), peak current derivative ($(\frac{dI}{dt})_{\max}$), and charge delivered to ground (Q_{ESD}), were extracted for comparison with the six discharge configurations of the wearable device.

III. Measurement Results and Discussions

This section provides the results of the current measurement for six discharge scenarios of the body-mounted metal piece and comparison with the ESD gun. The effects of body posture and device location on the waveform parameters are discussed.

Peak current is a severity indicator for ESD waveforms related to hard failures (permanent damage to components). Fig. 3 shows the trend of the peak current of the test configurations and the ESD gun discharge according to body voltage. In all the test configurations, the peak current for all the test conditions increases with voltage. The peak current of the ESD gun discharge is linearly increasing with voltage since there is no spark during contact mode. However, the peak currents from human discharges, which involve sparks between the tip of the metal piece and the metal rod, show deviations from a linear relationship. These variations could be attributed to the presence of the spark and the differences in the spark lengths in various test configurations. Despite the slow speed of approach during measurements, spark length may vary from Paschen's length and, consequently, lead to variations in the peak current results.

The peak current from the 24 human discharge conditions, consisting of six configurations at four voltages, results in a larger peak current than the ESD gun. The average peak current for these conditions is two times larger than the ESD gun results. This is a result of the lower impedance of the discharge path during this specific human discharge compared with the impedance of the ESD gun. An example measurement waveform is shown in Fig. 3, where the air discharge from subject's hand at 2 kV, while lying down on the bed, is compared with the contact discharge of an ESD gun calibration setup at the same voltage. The most striking difference between the two figures is that the peak current from human discharge is almost 50% larger than the ESD gun discharge. Also, the discharge waveform for human displays an initial peak, which is smaller and occurs a few nanoseconds sooner than the peak current.

The overall comparison between different discharge waveforms of body postures and the ESD gun is shown in Fig. 4. The smallest peak currents from the human discharge scenarios belong to the standing posture while the metal piece is worn on the hand. This discharge scenario is the closest to the wrist-worn brush-by scenario investigated by Ishida et al. [10] or Zhou et al. [12]. The main difference is that, in our experiments, the discharging structure is the short wire and the bed frame, while in the literature, the subject usually discharges to a large vertical ground plane, which is not likely to be the case in a hospital bed.

The largest peak currents among human discharges belong to the waist-worn configurations. The average peak currents from waist-worn configurations are 2.4 times larger than the ESD gun, while this ratio for hand-worn configurations is 1.6. The ratio of the peak current from waist-worn to a hand-worn metal piece in three postures and all the voltage levels are computed and displayed in Fig. 5. The ratio ranges from 1.1 to 1.8 for all postures. Considering the four body voltage levels, the largest ratio of the peak current belongs to the standing posture (1.7 times on average). The ratios for the other two postures are lower than the standing posture (1.4 for lying down and 1.3 for sitting postures).

The larger peak currents from waist-worn configurations are a result of the lower impedance of the discharge path in these discharge scenarios, as suggested the authors in [10] and [12]. Part II of this study investigates this deeper by impedance measurement and its modeling.

The maximal current derivative is a critical waveform parameter that affects the susceptibility of an equipment to soft failures (i.e., device upsets) during an ESD event [12], [20]. Fig. 6 shows the comparison between the peak current derivative of the test

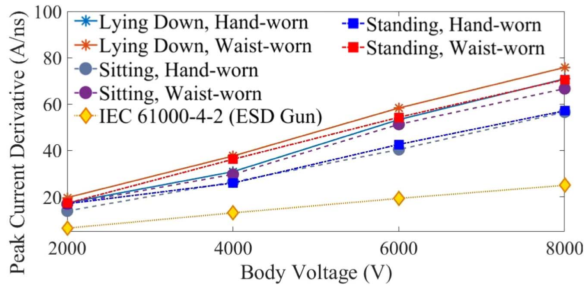

Fig. 6. Comparison of the measured peak ESD current derivative for six test configurations and the ESD gun calibration setup (IEC 61000-4-2 Standard) as a function of body voltage.

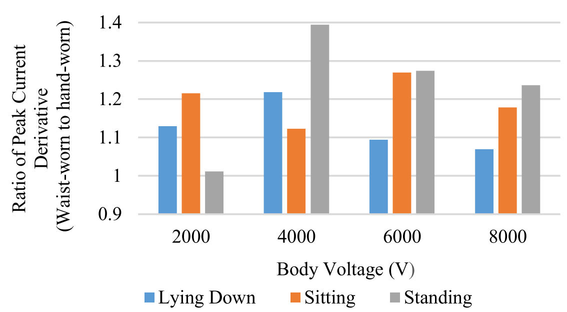

Fig. 7. Comparison between the ratio of the peak current derivative from waist- to hand-worn discharges at each voltage.

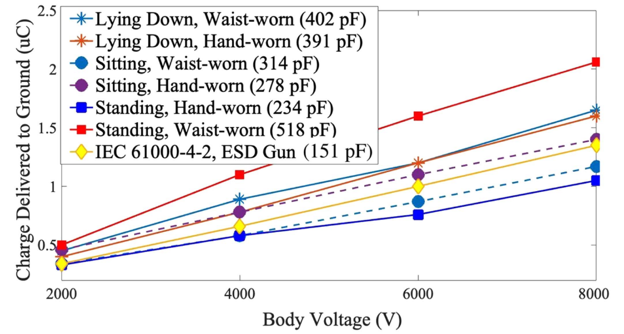

Fig. 8. Comparison of the measured charge delivered to the ground for six test configurations and ESD gun calibration setup (IEC 61000-4-2 Standard) as a function of body voltage. The equivalent capacitance of each condition is shown in parenthesis.

configurations and the ESD gun calibration setup. The maximal current derivative for the ESD gun varies linearly over the four voltage levels, while for the discharges from a body-worn metal piece, the results deviate from a linear relationship. The variations in the spark lengths for the test configurations can be blamed for the fluctuations in the results for human discharges.

In all voltage levels, the maximal current derivative from the metal piece exceeds that of the ESD gun waveform. The largest $(\frac{dI}{dt})_{\max}$ occurs when the subject is lying down the bed and the metal piece is worn on his waist. On average, the peak current derivative of the test configurations is 2.6 times larger than the ESD gun results.

Figs. 6 and 7 show that for all the voltage levels, $(\frac{dI}{dt})_{\max}$ for the discharges from a waist-worn metal piece are larger than hand-worn discharges, similar to the peak current results. The ratio of the $(\frac{dI}{dt})_{\max}$ for waist-worn to hand-worn discharges (Fig. 6) changes from 2 to 8 kV, probably due to the variation of the spark length. The ratio for all postures varies from 1.1 to 1.4. The results of Zhou et al. [12] also shows that the peak current derivatives for the waist-worn brush-by scenarios have relatively larger values than HMM scenarios.

The fluctuations between the ratios are more pronounced than the peak current results, which could imply that the variation of spark length has a higher impact on $(\frac{dI}{dt})_{\max}$ than $I_{\max}$. An analytical estimation of the current waveform using circuit elements to describe the current path is treated in part II of this study.

The amount of charge transferred to the ground during an ESD event is an indicator of the risk of permanent damage to components (i.e., hard failure) [21]. The area under the current–time curve was calculated for each test condition and the results were compared with that of the ESD gun. The amount of charge transfer is influenced by the capacitance of the body relative to the ground (in case of the wearable discharges) or the internal capacitance of the ESD gun (around 150 pF [22]).

A linear relationship between the total charge transfer and the body voltage is expected for all the test configurations, varying according to the body capacitance (as shown in Fig. 8). While the charge transfer for the ESD gun varies linearly with voltage, there are deviations in the results of the test configurations from linear behavior, which could be due to slight changes in the posture of the subject during the ESD tests. As shown in Fig. 8, all configurations, except hand-worn discharges in standing and sitting postures, exceed the charge transfer to the ground compared with that of the ESD gun to the current target. The average charge transfer for the hand-worn sitting and standing configurations is 12% and 19% lower than the results of the ESD gun. For the remaining four discharge scenarios, the average charge transfer was 35% larger than the ESD gun. The results of Fig. 8. also shows that the charge transfer at each posture varies with the location of the metal piece on the body. Given the fact that the charge transfer behaves similar to the trend of body capacitance, the variations in the results for waist-worn from hand-worn configurations imply that there might be differences in the body capacitance relative to the ground between these two device locations. The largest deviation is observed for the standing posture (84% difference on average), and the lowest deviation belongs to lying down posture (5% difference on average). The larger body capacitance of waist worn compared with the hand-worn configuration at each posture could be due to the proximity of the metal piece to the Al foil on the edges of the bed (as illustrated in Fig. 2) while performing the ESD tests. A potential approach to investigate this problem is to measure the body impedance at each test condition and compare the body capacitance results (which is performed in part II of this study).

IV. Conclusion

This study is aimed at addressing the gap in the ESD literature on the impact of human body posture on the severity of ESD current waveform with emphasis on healthcare settings, which often contain a metal frame bed. This study analyzed the discharge current waveforms associated with six discharge scenarios of a body-worn metal piece (in lieu of a wearable medical device) to highlight the effect of body postures (standing on the floor, sitting, and lying down on the hospital bed) and two device locations (hand and waist) on the waveforms. The results are compared with the IEC 61000-4-2 standard setup waveforms.

This analysis indicated that the average values of three waveform parameters $(\frac{dI}{dt})_{\max}$, $I_{\max}$, and Q_{ESD} (four out of six configurations), at four voltage levels (2–8 kV), exceed the upper limit of the discharge current from an ESD gun (i.e., calibration setup). The larger values of these severity indicators for discharges from body-worn metal pieces compared with the ESD gun reveal that the ESD test setup according to the IEC 61000-4-2 standard configuration may not be sufficient to ensure the ESD immunity of wearable medical devices in a hospital bed setting.

It is suggested to develop new standard test setups for ESD immunity of wearable medical devices [3], [23], [24], based on the test configurations of the present study. The new standard test method needs to consider the differences between the human body impedance in realistic severe discharges in a hospital setting compared with the simplistic *RC* circuitry of an ESD gun. For instance, the capacitance of the ESD gun (150 pF) was found to be far less than the body capacitance in various postures (up to 518 pF), which leads to less charge transfer in ESD gun scenario. Also, the higher peak current of the body discharge scenarios indicates a lower impedance in realistic scenarios than the ESD gun. Therefore, an appropriate standard test method for wearable medical devices needs to consider the proper impedance (using equivalent circuitry of the human body impedance) for various postures. This idea will be further investigated in part II of the article.

In all three postures, the average values of $(\frac{dI}{dt})_{\max}$ and $I_{\max}$ for waist-worn discharges exceeded that of the hand-worn discharges. These results imply that the impedance of the discharge path for the waist-worn configuration was lower than that of the hand-worn configuration. The ratio of these two waveform parameters for the waist-worn to hand-worn configuration was the largest for standing people, compared with sitting and lying down postures. This trend could also be related to the variation of the impedance for the three postures, which needs to be investigated by performing impedance measurements. As expected, the variation of charge transfer for all test conditions follows a relatively linear trend with body voltage.

In part II of this study, the body to ground impedance for each discharge configuration is measured and a current prediction model based on lumped physical elements of the setup is presented. The prediction model and impedance measurements in part II can be used to interpret the trends of the waveform parameters as seen in the measurement results presented in part I.

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