Studying the Probability of EMI through Timevariance Behavior of Environment on Medical Devices

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Abstract— Various studies have been conducted to monitor the electromagnetic (EM) environment of the hospital, where an emitter is mounted near medical devices. They placed their antenna in a specific area to test the maximum amplitude of power obtained by the antenna as well as explore the environment without identifying the time-variance behavior. The main goal of this paper is to observe the time-variance behavior of the emitters over the course of a 24-hour period when a receiving antenna is installed in a room and the effect they have on the EM environment. It will provide the probability of EMI from the perspective of the emitters, which will help to use it further for the risk-based EMC approach. In this paper, the discussion about the different types of time-variance behavior is done with examples, statistically explained the results.

Keywords— Electromagnetic environment, Electromagnetic compatibility, Medical device, Electromagnetic interference, Discone antenna

I. INTRODUCTION

Effect of electromagnetic interference (EMI) on the standard operation of medical devices has been studied extensively since past several years. The cause of such EMI can be categorized into intentional emitters and unintentional emitters. Where intentional emitters (mobile phone, radio, metal detector, walkie-talkie, etc. [1]) are generally communication or treatment devices that are designed to generate electromagnetic radiation, unintentional emitters (MRI, LED lights, leakage of microwave ovens etc. [2]), on the other hand, generates radiation as a byproduct of their intended operation. In order to achieve electromagnetic compatibility (EMC), by efficiently eliminating EMI, medical devices are inspected as per FDA Reviewer Guidance document or the European IEC 60601-1-2 standards [3]. This is called rule based approach. However, according to Maude's data base, such approach is not sufficient to ensure EMC because of following shortcomings: a) it does not consider assembly, maintenance, repair or aging of medical devices [4], b) frequent introduction or addition of new technologies (like considerably changes the electromagnetic (EM) environment making rule based approach obsolete as rule-based tried to ensure EMC in the presumed created environment and c) statistical analysis or probability of occurrence of EMI due to time-variant behavior of emitters are not well documented in rule based approach.

In order to overcome aforementioned challenges a better and robust risk-based EMC approach has been introduced wherein analyze the probability of the occurrence of EMI and the severity



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of the EMI issues. In our previous work [5], we studied the effect of three macro-parameters; frequency, space and power; on EM environment. We utilized walk around technique [6] wherein non-radiating receiving discone antenna was carried in a confined space having various emitters of frequency ranging from 300 MHz to 3 GHz. That experiment was carried for short period of time (less than 2 mins). It allowed us to optimize measurement procedure by collecting enough data from a spatial distribution. However, due to switching electronics and digital modulation schemes radiated fields from the emitters are strongly time-variant. Time-variance can be defined as fluctuation in power received with respect to time which can impact EMC. Our previous work provided the time-variance which was combined with spatial effects, and vastly undersampled, reducing the probability of getting higher power peaks with respect to longer time frame and did not provide an accurate picture of optimized statistical model. Hence, there is a need to study the effect of time in order to create a better worstcase estimations from the measurements.

Through this work, we studied the effect of time which later can be used in complement with our previous work. In this paper, we initially discussed different types of time-variance behavior, with several examples, of emitters. Furthermore, we discussed how we studied the mid- term time-variant behavior in a semi-reverberant environment. We observed fluctuation in power amplitude for a period of 24 hours in a set frequency range (300 MHz to 3.6 GHz). Establishing the fact that studying the time-variance is required to completely understand EM environment. This work laid a strong foundation for our upcoming future works.

II. TIME-VARIANCE EFFECT ON MEDICAL DEVICE

The risk-based EMC approach begins with an analysis of the hospital environment, followed by the steps outlined in [1]. The probability of the EMI and the severity of the malfunction on the medical devices helps to create the risk analysis. The timevariance behavior of emitters are one of the important factors because it allows us to estimate the probability of EMI.

The time-variance behavior of these emitters can be divided into three categories: short-term, mid-term and long-term time-variance.

A. Short-term time-variance

Short-term time-variance is mainly the detector level, equipment response time, dynamics of the envelope within a

standard measurable dwell time, summation of sources, etc. For example, the GSM has a duty cycle of 1:8 [7]. It is not a continuous signal but a pulsed modulation which is a very high intensity short duration pulse. It is important to check if the identified sources use similar modulation schemes as the tested ones or not, and identify them as a risk if the modulation scheme is completely different from the tested ones. For instance, if it has been tested at 2.4 GHz using a 1 kHz 80 % AM modulation and then the source is employing a frequency hopping modulation with a 256 Quadrature Amplitude Modulation (QAM) this can be a risk.

Our previous measurement was fine to measure this pulse modulation but as we are not aware when will this emission is going to occur we need a longer measurement. The essential threat above 800 MHz comes from digital radio telephones using non-constant envelope modulation. We used 5 MHz RBW to quickly capture any changing envelops. We used peak detector here instead of the quasi peak even though it is a time-function because quasi peak assigns a weight to each component based on its repeat rate: the higher the repetition rate, the greater the weight [8]. But here the repetition is almost impossible due to the change in the environmental factors.

Another example of short-time variance behavior is the interference between Bluetooth and Wi-fi Because of same frequency spectrum. When a Bluetooth communication happens on a frequency that overlaps with a simultaneous Wi-Fi transmission, there is a chance of interference, depending on the intensity of each signal [9]. It can occur anytime in the day and also changes the probability of occurrence, if it is of low probable then the risk automatically reduces.

B. Mid-term time-variance

Mid-term time-variance is the randomness created within a stationary process (movement of people, emitters, etc.) and nonstationary due to different behavior of the hospital at different times. If a medical device is kept inside the room it will be exposed to these emitters for longer period of time. TV, mobile phones, laptops, Wi-Fi routers, light emitting diode (LED) lamps [10], Bluetooth transmitters, radio transmitters, etc. could be present inside the room for more than 24 hours.

Interference can be caused by a TV in standby mode. When devices are on standby, the interference can be much worse than when they are turned ON. Another similar example is a mobile phone, which emits a peak amount of power not only during the ringing phase [11,12] but also during standby mode [13]. So practically there will be a TV or mobile phones near the medical devices in the patients room, and if it is not in an OFF mode but in standby mode, there is a risk of EMI in the room.

During visiting hours, it is impossible to prevent people from bringing their phones into the hospital room. What happens if a large number of people with portable gadgets, such as a mobile phone, laptop, iPad, or other tablet, wait outside the emergency room, this may cause interference with the emergency room's current operating medical devices.

This also depends on the availability of number of wireless devices in the hospital as it changes with time. The number of patients, their families, staff, nurses, physicians, and other employees can be higher in the morning or during operating hours than at night. As a result of the increased use of many wireless devices, there are now more emissions. But the addition of power or increment of power occurs when the received signals are in phase and contributes to constructive addition.

This measurement will help us to predict the maximum power possibly received in a day, which can cause interference. The probability can also be noticed and can be used further in the source-victim matrix.

C. Long-term time-variance

Long-term time-variance behavior includes the timeframe more than a month or a year. Electronic aging of the medical devices, corrosion in the medical devices, changes of the infrastructure, introduction of new technologies, updating of the IEC standard in every 5 years etc., leads to the long-term time-variance behavior effect on the medical devices. The medical devices goes through ageing like corrosion. Old parts of the medical devices might emits and create interference with other new medical devices as shown in [14]. This emphasizes the importance of dealing with older medical devices that was not equipped with EMI immunity in mind.

Bio electrochemical sensors are essential in most medical devices used for monitoring vital parameters of the human body. Operation amplifier used in this showed a gradual reduction of immunity level with increasing aging time [15]. As a result, if the parts of medical devices lose their immunity with time or as they age, the medical devices will do the same.

Another thing which can cause the long-term time- variance is the outdated standards. After buying a new medical devices before implementation it goes through certain tests to ensure EMC. But, with the passing of time, could medical devices avoid adhering to the latest requirements that were recently published? For example, IEC 60601-1-2 titled "General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility" is for the EMC of medical equipment, is updated more than every five year. As shown in [16], the immunity test level changed every time. If an old medical device following the 1st edition of the standard may not work according to the recent edition. Old medical device might emit radiation which can cause EMI with other nearby new medical device.

Not only these every minute there is new invention going on and new technologies are introduced in the medical field. [17] shows the expected growth of global connected and IoT device installed base till 2025. Cellular technologies can also be used by installing 5G [18] in hospitals and other healthcare environments. In the 2020–2030 decade, it is projected to be widely used. 5G is a radio-only technology, while 6G [19] is an advanced networking network that covers many frequency ranges (in the low GHz bands, mm-waves and THz bands). The internet of things (IoT) and the internet of medical things (IoMT) are two new networking paradigms that will definitely be seen in the upcoming hospital.

Owing to the increased use of wireless devices in hospitals, EMI problems would become more prevalent. If we can see, the picture will be different in 2025, as 6G, IoMT, autonomous robotics, hospital automation, and other examples will demonstrate how complex the hospital world will be in the future. In recent years, the time-variance behavior of these wireless systems has also been unprecedented. During this process, a risk-based EMC approach is critical to act based on the probability of EMI occurrence and the severity of the risk. In the next section we discussed about the short measurement set-up to statistically estimate the probability of occurrence of interference. We focused mostly on the mid-term time-variance because we can statistically predict what will happen in future with the help of our previous work and the mid-term time-variance measurement done in this paper.

III. MEASUREMENT SET-UP

In our previous work measurement was of less time consuming and not perfect because of limited number of measurement by using 5MHz resolution bandwidth and a peak detector. As discussed above, this can lead to the loss of information about the highest coupled field. However, in our previous work, we did several frequency sweeps to minimize such losses. In order to get an estimation about the risk analysis long-term timevariance behavioral study of emitters are required. Because of its time consuming nature, in-compatibility with walk around technique, which we used in our previous work; long-term time-variance behavior was practically not possible. Therefore, we relied on mid-term time-variance behavior measurement. As mentioned in previous section, mid-term time-variance behavior measurement can be used to observe parameters such as the operation mode of emitters, the time of day, and people's local movement, etc. Furthermore, with the statistical approach, results obtained in this measurement can be extrapolated in order to understand long-term time-variance behavior of the emitters. Hence, mid-term time-variance behavior of emitter was studied in order to fill the gap between our previous work and the realistic EM environment.

The measurement setup, shown in Fig.2, in this work consisted of the similar discone antenna, as used in our previous work, which was connected to a portable Signal Hound USB-SA44B spectrum analyzer. Similar to our previous work, discone antenna was subjected to chaotic EM environment and frequency range was also set between 300 MHz to 3.6 GHz. Similar space, as in our previous work, was also utilized in this work to understand the EM environment. The discone antenna has a gain of 2 dBi and, with our measurements, coupled power on any medical device of any size can be estimated using unintentional radiated model.



Fig.2. Measurement set-up

IV. RESULTS AND DISCUSSIONS

Measurements were performed in an empty office with 2 cell phones and 2 laptops (15m x 15m) but the building was not empty, there other devices were working so the antenna was

placed at a specific location. Power received by the antenna was measured every second for 24 hours in order to analyze change in the power with respect to time. Measurement was initiated at 3pm [t(0)]. Power received initially by the antenna is shown in Fig.4. However, in an actual hospital environment larger number of emitters can be present that can impact the magnitude of the power.

After 1 hour [t(1)] in the experiment(\sim 4pm), some changes, appearance of a new peak at frequency 2432 MHz and reduction in received power at 2146 MHz (from ~ -67.5 dBm to 72.5 dBm) (Fig.3), was observed in received power signal. Appearance of a new peak can be attributed to introduction of a Wi-fi signal in a measurement room. Furthermore, as shown in Fig.5, considerable fluctuation in the power received at this particular frequency (2432 MHz) by a discone antenna was observed during 24 hours of experiment. Fig.4 shows that power received at 2432 MHz frequency has reached maximum value \sim -45 dBm which was almost twice the value we obtained during the initial hours of the experiment. These values could have been enhanced further if the Wi-fi usage increased inside the room and can be a potential risk of EMI. This established the fact that the received power is time dependent and should be studied in order to correctly study the EM environment.

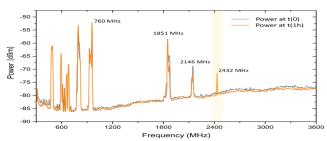


Fig.3. Received power by the discone antenna changes over time. New peak arose at 4pm at the frequency 2432 MHz.

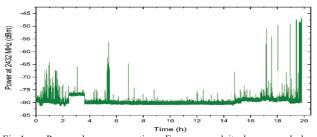


Fig.4. Power changes over time. Every second it changes and showed maximum of \sim -48 dBm at 20 hours.

In order to obtain additional information statistical processing can be done. A histogram, for each frequency, can be graphed from $\sim 80,000$ sweeps and probability of crossing critical value can be evaluated using power density function (PDF). This can be used in risk analysis. Herein, we statistically analyzed power distribution at 2432 MHz frequency as shown in Fig.5. Gaussian distribution was used to fit the histograms, even though several parameters such as space, frequency might impact the distribution, as it is considered the best first assumption. Furthermore, cumulative distribution function (CDF) of the same fitted power distribution at 2432 MHz

frequency can help us to evaluate the cumulative probability of exceeding any set critical value (Inset of Fig.5). This can help us in analyzing probability of obtaining high power by any emitter at any time that can cause EMI in the hospital environment. Therefore, time dependence probability of EMI occurrence is required for enhancing the impact of risk-based EMC approach.

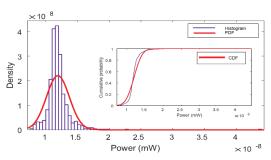


Fig.5. Histogram and the fitted Gaussian PDF of the power received at 2432 MHz for the different sweeps and also the cumulative distribution function (CDF) of the same gaussian fitted distribution

V. CONCLUSION

In our previous works, we studied the probability and severity of EMI through extensive investigation of probable source and victim and collecting enough data from spatial distribution that allowed us to analyze the risk. Previously, we studied the effect of common parameters such as frequency, space, and power on the electromagnetic environment. In this paper our main focus was to understand the time-variance behavior of emitters. So. initially, we discussed different types of time-variance behavior; like short-term, mid-term, and long-term timevariance; of the emitters. Further, we discussed how and why studying mid-term time-variance behavior of emitters can allow us to understand and picture the EM environment. Measurement was then setup using discone antenna, similar to our previous work, placed at a constant place for longer period of time (\sim 24 hrs.) and the power fluctuation in received signal was measured in frequency range of 300 MHz to 3600 MHz. every second for whole day. We not only observed considerable change in the power fluctuation at predicted frequencies but also observed appearance of new high power peaks at new frequencies (such as 2432 MHz). Enhancement in the power signal at new frequencies with time was also observed which not only indicated that emitters, operating at that frequency, could be a potential risk for EMI but also proved that studying time-variance behavior of emitter is required to predict the EM environment. Using statistical tools, we showed possibility of predicting the possibility of occurrence of EMI by introduction of new emitters with time. Such information can be lost while studying only short-term time-variance behavior of emitters. Overall, this work brings us closer to predicting the actual EM environment. In this work, the measurement was done in the office room with hardly 2 laptops and 2 mobile phones working. This led to lower value of power received that did not surpass the critical values, as mentioned in our previous paper. This decreases the probability of occurrence of EMI. Therefore, it will be interesting to see the results in the actual hospital environment wherein multiple emitters are present and the effect of time can play a significant role in enhancing the probability of occurrence of EMI. In our future work we will be utilizing similar set-up in different places of the hospital for 24 hours in order to analyze the true EM environment in medical facilities.

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