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Time-efficient EMI Risk Evaluation Method in a Hospital Environment

Mumpy Das
University of Twente
Enschede, The Netherlands
mumpy.das@utwente.nl

Robert Vogt-Ardatjew
University of Twente
Enschede, The Netherlands

Bärbel van den Berg
MST Hospital
Enschede, The Netherlands

Frank Leferink
University of Twente, Enschede
Thales Nederland, Hengelo

***Abstract*— Hospitals are one of the most critical and sensitive environments where possible EMI issue may have life-threatening effects. Although the electronic equipment placed within satisfies various EMC standards, a risk of EMI still exists. Due to the high complexity and dynamics of this system, the electromagnetic environment substantially differs from the one of an EMC laboratory. A full risk-based EMC analysis can significantly help mitigate this problem but requires plenty of effort, time, and careful management. In this paper, we present a simplified but robust, time efficient method of evaluating the electromagnetic risks, as an intermediate step before implementing a full risk-analysis campaign. Such an analysis allows to get the first impression about the environment and its influence on the medical device within.**

Keywords*— *Electromagnetic compatibility, medical devices, electromagnetic interference, discone antenna

I. Introduction

Hospitals are one of the most critical and sensitive environments where possible electromagnetic interference (EMI) issue may have life threatening effects [1]. Because of that, before admittance to a medical environment, medical devices have to undergo specific tests to ensure electromagnetic compatibility (EMC) [2]. The medical electronic devices placed within often satisfy EMC standards like IEC 60601-1-2 [3], where they follows rule-based EMC approach. The concept of the rule-based approach lies in creating a simple and fixed measurement platform delivering repeatable and consistent results throughout different laboratories. The measurements are often conducted in an anechoic chamber (AC) mimicking free-space conditions. The equipment under test (EUT) is illuminated by a single source with fixed parameters such as field strength, frequency, and modulation. Those parameters are however quite simplified, e.g. by using a single frequency component, and generalized, e.g. by using a single type of modulation. Although a certain EMC margin exists between the emission and immunity levels, these setups often do not sufficiently represent the intended environment of the tested EUT.

The actual electromagnetic environment of a hospital is very different than that of a laboratory where the tests are done following different standards. In a hospital, the number of sources affecting a victim medical device are not predictable and are often not strategically located. Apart from the surroundings being far from free-space conditions, different devices operate and emit in different directions at different times, so considering one source and a single direction of illumination is not an ideal representation of a hospital environment. This mismatch is often the reason for a risk of EMI still existing in hospitals.

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Because of EMI concerns, previously, patients, doctors, hospital workers, etc., were not allowed to use their mobile phones in the hospital [4]. This is even still the case in some hospitals. As shown in Fig.1, they are required to keep the mobile phone 1.5 m away from the medical devices, so that interference between the wireless sources and the medical devices does not occur. It shows that it is still not feasible to obtain EMC purely by adopting the rule-based EMC strategy,or at least not in its current state. That is the reason why there is a need of better and much more effective solution known as risk-based EMC approach [5] is required. A full risk-based EMC analysis can significantly help mitigate this problem but requires plenty of effort, time, and careful planning. In [6] it has been mentioned how important is the electromagnetic (EM) environmental analysis of the hospital. Even, in the Guide on the EMC directive [7] the importance of the EM environmental analysis to understand the risk of EMI is mentioned. The risk-based EMC approach requires four vital steps to consider as mentioned in [8].

The steps include a detailed analysis of the environment of the hospital, where the list of the possible victims along with the estimated severity of potential EMI, and the sources with the estimated probability of causing EMI, is made. Then, based on these parameters, the risk assessment of every source-victim pair is included [6]. As it is a long-term goal, it needs the completion of many actions that take a lot of time. That is why, as an initial phase before introducing a complete risk-analysis campaign, we introduce a simplified but effective and time-efficient method of assessing EM risks in this paper. Such an analysis makes it possible to get the first impression of the environment and its impact on the medical devices inside it. The measurement is performed by incorporating various parameters and behaviors to estimate the practical worst-case scenario.

Fig. 1. Keep mobile phone 1 and half meter away from the medical devices

II. Measurement Premises

According to the rule-based EMC approach, the immunity of the victim is measured by placing it in a known field defined by one of the corresponding standards [3]. However, as discussed earlier, the hospital environment is not same as the free-space environment or an anechoic chamber, where the medical devices are tested before introducing in a hospital. In the complex hospital environment, many sources, many victims, many different interactions and various behaviors are present. This overwhelming chaos creates a dynamic environment that cannot be described deterministically, and surely does not resemble clean laboratory conditions. Using macro-parameters that statistically describe the distributions or estimations of its characteristics could be considered instead. Within the scope of the risk-based EMC, the initial step is to describe the EM environment and all the interactions with the victim device [6]. Based on this, the probability of causing EMI can be established. Relating this probability to the severity of malfunction, the EMI risk can be calculated, and managed. It is however still difficult to separate and describe all the influential parameters and investigate their effects on the victim independently. Although useful to a great extent, the risk-based EMC approach is a time-consuming process that requires plenty of effort and careful management. On the other hand, every medical device placed in the given environment will be exposed to these same factors acting simultaneously once placed within it. Therefore, in this work we focus on performing a measurement that incorporates all of the known parameters for the estimation of the risk of EMI. Since all of the influential parameters are mixed together, the results do not yield the information how to deal with the possible EMI. They do however provide the insight regarding the possibility of EMI in the given space in general. This approach then allows hospitals to minimize the EMI cases by being able to predict their potential occurrences.

The premise of this measurement is based on exposing a model of a medical device to the presumably unknown fields present in a hospital in various spatial and temporal configurations, and observing its reaction. As opposed to - classical E-field measurements [9], here an antenna mimics an actual medical device. Although the concept is similar in execution, the rationale of this approach emphasizes the power effectively coupled to a critical component of the modelled medical device, and not just a description of the field. In our case we used a discone antenna. Further considerations include the following aspects:

1. The antenna is broadband so we have access to the information about all frequency components from that band. Medical devices however would usually have a narrower susceptibility bandwidth.
2. The discone antenna is omnidirectional so it collects energy from around it with consistent and known gain. The gain of the medical devices is generally unknown. It can however be estimated using the unintentional radiator principle [10] depending on their physical size. Therefore, the antenna measurement results can be corrected for that gain to represent a range of various medical devices.
3. The total power received by the antenna can be measured in a hospital and compared to the power received when placed in the standard test field, e.g. 3 V/m, against which the medical device is tested for immunity. It is then possible to compare these levels and state whether the medical device would survive these conditions and with what margin, rather than just see whether it malfunctioned or not.

III. Measurement Setup Considerations

The measurement setup in this work is shown in Fig.2 and consists of the aforementioned discone antenna connected to a portable spectrum analyzer. The Signal Hound USB-SA44B has been used here as it is small in size and easy to carry during measurement. Similar spectrum analyzers are very cost-effective compared to proper EMI receivers and allow to effortlessly perform measurements on-site.

The measurement procedure is crafted to address the chaotic behavior of the EM environment. The exposure to the various spatial and temporal configurations is optimized to provide usable results within a reasonable timeframe. To satisfy these two requirements, the measurement is fundamentally a combination of the pre-scan worst-case detection [11] with the volume sampling of the walk-around technique [12]. The detailed explanation is linked to the three dimensions and is presented in the following subsections to show how the proposed measurement gives the optimal results.

Fig. 2. Measurement Set-up with the discone antenna

A. Frequency

The presented measurement focuses on the radiated EMI, and in this experiment covers the frequencies starting from 300 MHz to 3 GHz. Although the lower frequency range analysis is definitely desirable [13], it requires using a larger antenna that becomes troublesome to use while performing measurements on-site. On the other hand, due to the presence of multiple reflectors such as walls, coated windows, metallic objects, doors, cabinets, etc., a hospital can act as a reverberant environment [6]. Considering the size of a typical hospital room, this behavior becomes apparent from a couple of hundred megahertz. Below that frequency, a classical stationary measurement is recommended as no strong resonances are expected, and is not considered here. This work focuses on the range where the hospital environment becomes reverberant, as such behavior yields a strong variability in the local field magnitude. It is common that the E-field magnitude is locally increased by up to 6 dB in regular rooms [14], and even 20 dB in rooms exhibiting very strong resonant behaviors [15]. Furthermore, many intentional radiators that are a common cause of EMI issues, used for communication, such as GSM (see Fig.1) or Wi-Fi are present around the gigahertz frequency range, making it especially attractive for EMC considerations. In the end, the frequency range is dictated by the antenna and spectrum analyzer available. In this work we performed frequency sweeps in the range between 300 MHz and 3 GHz.

Because we have to make multiple full-spectrum sweeps in many points in space according to the walk-around technique, we cannot use the standard CISPR settings [16] due to impractical time constraints. To combat that, we used a much higher 5 MHz resolution bandwidth (RBW) along with a peak detector. Although not comparable with the standard EMI tests, such a combination allows to perform a full sweep in only 1.2 s. This makes the volume sampling realistic as well as allows to find the worst-case measurements based on the pre-scan premise. In such a simple measurement made in such a sensitive environment, it is better to overestimate the EMI risk than miss it.

B. *Space*

The goal of this work is to estimate a potential EMI possibility in a medical device placed somewhere in the environment. Since the actual target position of the device in the environment is unknown, we have to assume that it could be positioned anywhere. Inversely, the position of the environment around the device is also unknown due to the movement of the, often hidden, sources. Therefore, any spatial relations are assumed to be undefined. By getting closer to a source, the power received is expected to be the highest. Since their location is unknown, we have to check many spatial positions within that environment, where the equipment could possibly be located.

Furthermore, as mentioned in the previous subsection, the hospital environment is reverberant so there are hot and cold spots due to the standing waves. The E-field strength behavior is not deterministic and does not even steadily decrease with the increased distance from a source [8]. Hot spots might occur in any point in space, including the middle of a seemingly empty room, far away from any objects. It is therefore necessary to perform the volume sampling in the whole space. The polarization of the field is unknown too so the antenna movement has to be adapted accordingly.

For the sake of calculating the probability of occurrence of the potentially harmful fields for the EMI risk estimation, a statistical analysis is performed. In order to maximize the correctness of this analysis, sample independence is desired. Although it is impossible to obtain entirely independent data due to the strong correlation coming from e.g. deterministic components from the line-of-sight illumination, it can be maximized to obtain a reasonable optimum. Firstly, based on the reverberation chamber techniques, two samples are generally considered to be independent if they are measured at least half wavelength of the lowest measured frequency away. Secondly, an orthogonal polarization removes any sample correlation. Thirdly, it is desired to avoid repeatedly performing a measurement in the same spatial positions. Considering the above, an optimal antenna track, velocity, and motion can be defined. In this case, a 0.75 m distance should be covered in a 1.2 s sweep. However, since the polarization is changed within that motion, the optimal velocity is around 0.3 m/s.

C. *Time*

In the today's world, the nature of the radiated fields is generally strongly time-variant. This is caused by the digital modulation schemes used in the telecommunication systems, or switching electronics. To properly capture the highest emissions, EMC standards like CISPR 11 used quasi peak detector. This makes the total measurement very time-consuming. In laboratory conditions this is not really a problem apart from the financial issues. However, it does become burdensome in case of performing measurements on site. And definitely impossible in case of the walk-around technique which is based on performing multiple of such sweeps. It is acknowledged that within a single fast sweep, information about the highest coupled field might be lost. A counterargument to that issue lies in the fact that many sweeps are performed. This effectively summarizes the time spent at each frequency point but in different time intervals, hence increases the chances of recording a true peak. Following this idea, performing more sweeps within the volume minimizes this error. Although not applicable in this paper, the usage of modern high frequency time-domain receivers entirely eliminates this problem.

IV. Results and Discussion

A test measurement has been performed in an empty office room for demonstration purposes according to the premises discussed in Section II and Section III. The dimensions of the measured room are 15 m x 15 m. Using the walk-around technique, 87 frequency sweeps were recorded while moving the antenna within the reachable volume, with the focus on the locations where the medical devices could potentially be positioned. The whole measurement took less than two minutes. The received power results are shown in Fig. 3. Such a way of storing the data is preferred over using the trace max hold function as it allows for statistical processing discussed later.

Furthermore, an additional measurement was conducted in an anechoic chamber to relate the power received in the environment to the power received by the same discone antenna in a calibrated 3 V/m standard test field. This means that the power received that is below this reference level should not cause EMI if the medical device was successfully tested against 3 V/m. As seen in Fig. 3, the maximum power received is significantly below this reference level for all of the performed sweeps. That is because only one or two cell phones and one laptop was present within the room during this particular measurement. The EM fields created within can be mild in the office room, but there is a different environment in the hospital. More patients could use wireless devices in one room, and not only that, there could be more than five medical devices operating at a time. The metal bed, cupboard, desk, etc. can be more reflective and high field strength can be produced [8].

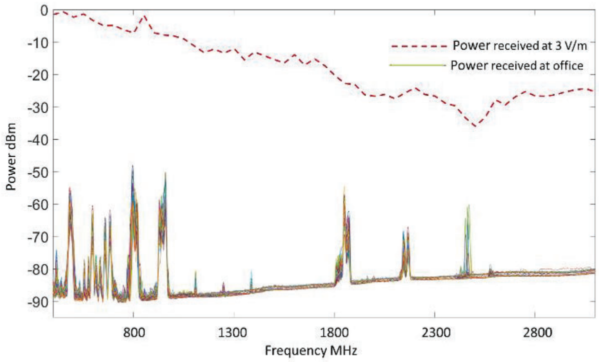

Fig.3. Multiple sweeps of the power received during the measurement in an empty office room compared to the power received in a 3 V/m field with corrected gain.

Therefore, the received power in a hospital is expected to be significantly higher, potentially exceeding the 3 V/m reference level. We conducted another measurement in the ICU room of the hospital as shown in Fig.4, the received power did not exceed the 3V/m reference level as the room was very empty, no medical device was working.

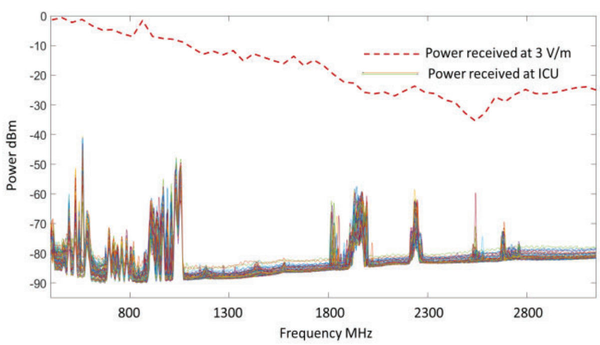

Fig.4. Multiple sweeps of the power received during the measurement in an empty ICU room compared to the power received in a 3 V/m field with corrected gain.

Although the measurements are performed using an antenna, the results can be used to estimate the power coupled to a medical device of any size using the unintentional radiator model [10]. The estimated gain of a medical device is defined as,

$$\langle D \rangle = 1/2 \cdot (0.577 + ln(Ns) + 1/(2Ns)) \quad (1)$$

Here, D is the gain, Ns describes the number of necessary sampling points for representing the radiation pattern in three dimensions. It is further defined as,

$$Ns = 4 \cdot (ka)^2 + 8 \cdot ka \quad (2)$$

where the term ka describes the electrical size of the device and is defined as the product of the wave number $k = 2\pi/\lambda$ and the radius a of the minimum sphere enclosing the radiator. For example, if we analyze the potential power received by medical device enclosed in a sphere of radius a=0.3 m for 1.5 GHz, then its maximum gain would be around 3.3 dBi. The used discone antenna has again of 2 dBi, therefore the power received by that medical device would be 1.3 dB higher than the results measured using the discone antenna.

Using this approach, it is possible to estimate the maximum gain of a medical device and correct the received power results using the used antenna accordingly. Since the hospital is considered to be a reverberant environment, the field is assumed to be isotropic, therefore the actual orientation of the device is not important. Only the maximum gain is used as the worst-case scenario.

Although the datasets are rather limited and the sample independence is questionable, a statistical processing may yield additional information. For each frequency, a histogram can be plotted from the 87 sweeps. By using power density function (PDF) fitting tools, a probability of exceeding a critical value can be estimated and used in the risk analysis. For example, Fig. 5 shows the histogram of the power received at 959 MHz with a fitted Gaussian PDF. Although the various parameters described in Section III surely cause this distribution to be very complex and perhaps even impossible to define, a Gaussian distribution is usually the best first assumption. Fig. 6 shows the cumulative distribution function (CDF) of the same fitted distribution where we can estimate the cumulative probability of exceeding a critical level, e.g. the 3 V/m reference level from Fig. 3. With the help of this analysis we can provide the probability of getting high power which can cause EMI in the hospital environment. Estimating the probability of the occurrence of the EMI and the severity of that EMI are required for the risk-based EMC approach.

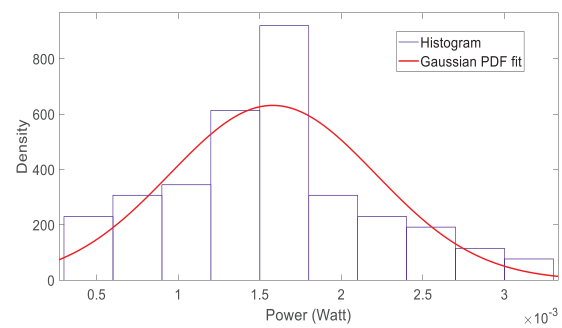

Fig. 5. Histogram and the fitted Gaussian PDF of the power received at 959 MHz for the different sweeps

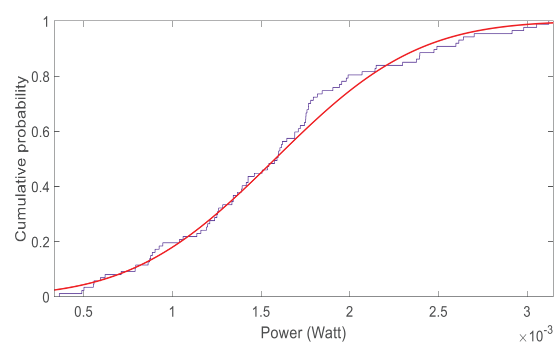

Fig. 6. The cumulative distribution function (CDF) of the same gaussian fitted distribution

V. Conclusion

We used our walk-around technique in an empty office room. Example data measured in an empty office is shown and the steps necessary to estimate the EMI risk of a medical device in a hospital are presented.

In the hospital, the environment will be different than the empty office and higher measured values are expected, but the presented measurement procedure can still be applied.

Here, the discone antenna mimics the medical devices. The gain of the medical devices can be estimated with the help of the unintentional radiator principle, which depends mainly on the physical size of the medical device. Therefore, the risk analysis can be made for any device intended to be placed in the hospital only by performing a single measurement. This vastly simplifies the procedure. Although the results are not perfectly accurate, the method presented here can be applied by hospitals without significant cost and time investments.

To provide a proper guideline to reduce the risk of EMI, in future we are going to use the same set-up in a really dense hospital environment to get the actual data. We can follow the steps above to predict the severity and probability of occurrence of risk in the hospital environment.

References:

[1] https://www.ebme.co.uk/articles/clinical-engineering/electromagnetic-compatibility-emc

[2] J. L. Silberberg, "Achieving medical device EMC: the role of regulations, standards, guidelines and publications," *2001 IEEE EMC International Symposium. Symposium Record. International Symposium on Electromagnetic Compatibility (Cat. No.01CH37161)*, Montreal, Que., Canada, 2001, pp.

[3] "IEC 60601:2014(E) Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances – Requirements and tests," International Electrotechnical Commission, Geneva, Switzerland, International Standard, February 2014.

[4] L. Yang, M. Frize and P. Eng, "Exploring current risks of mobile telephony in hospital and clinical environments," *Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (IEEE Cat. No.03CH37439)*, Cancun, 2003, pp. 3609-3612 Vol.4,

[5] F. Leferink, J. van der Ven, H. Bergsma and B. van Leersum, "Risk based EMC for complex systems," 2017 XXXIInd General Assembly and Scientific Symposium of the International Union of Radio Science (URSI GASS), Montreal, QC, 2017.

[6] M. Das, S. Jeunink, R. Vogt-Ardatjew, B. van den Berg and F. Leferink, "Introduction of Wireless Services and Devices in a Hospital Environment Following a Risk-based EMC Approach," 2020 International Symposium on Electromagnetic Compatibility - EMC EUROPE, Rome, Italy, 2020, pp. 1-6,

[7] "March 2018 Guide for the EMCD (Directive 2014 / 30 / EU)," no. March, pp. 1–67, 2018.

[8] M. Das, R. Vogt-Ardatjew, B. van den Berg and F. Leferink, "Risk-based EMC Approach in Hospital Environment," 2020 IEEE International Symposium on Electromagnetic Compatibility & Signal/Power Integrity (EMCSI), Reno, NV, USA, 2020, pp. 676-680

[9] C. Kurnaz and T. Aygun, "Characterization of Indoor and Outdoor Electric Field Strength Levels at Hospitals," *2018 26th Telecommunications Forum (TELFOR)*, Belgrade, 2018, pp. 1-4,

[10] B. Menssen, D. Hamann and H. Garbe, "Extension of the emission measurements for alternative test methods above 1 GHz for unintentional electromagnetic radiators," *2015 IEEE International Symposium on Electromagnetic Compatibility (EMC)*, Dresden, 2015, pp. 444-449

[11] https://connectivity-staging.s3.us-east-2.amazonaws.com/s3fs-public/2019-03/Pre-Scan-White-Paper-v1_0.pdf

[12] G. B. Tait and M. B. Slocum, "Random-Walk Technique for Measuring the Electromagnetic Environment in Electrically Large Reflective Spaces," in IEEE Transactions on Instrumentation and Measurement, vol. 60, no. 3, pp. 1003-1009, March 2011

[13] https://radiocrafts.com/antenna-size-matters/

[14] International Electrotechnical Commission, "International Standard Basic EMC Publication," no. 183493, p. 84, 2002

[15] F. B. J. Leferink, D. J. G. Boerle, and F. A. G. Sogtoen, "In-situ EMI Measurements Using a Vibrating Intrinsic Reverberation Chamber," Internatioanl Sympoisium EMC Eur., 2000.

[16] CISPR 11, Industrial, scientific and medical (ISM) radio-frequency equipment – Electromagnetic disturbance characteristics – Limits and methods of measurement.