EME Electric Supervision embedded on gas panel with microshock dangerousness degree

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***Abstract*—Medical teams have the support of Electromedical Equipment (EME) during surgery procedures. The benefits are countless and a great part of them play vital roles to patients. To assure the patient safety, Clinical engineering teams manage the EME and execution procedures of corrective and preventive maintenance. However, the monitoring of EME during their use in patients needs to be improved, especially when considering microshock events. These shocks can be undetectable to the medical team, because the value of the electric current is under the human perception threshold of 1.0 mA, for most part of the population. In this paper we propose an innovative solution to electrical supervision of EME. The proposed solution was implemented in a device responsible for such supervision and embedded in a real gas and outlet panel in a hospital. Different experiments was conducted in a real hospital scenario and the analysis of results demonstrates that the only microshock risk alert is insufficient for supervision. However, it constitutes an important step to attempt a complete supervision solution. Hence this work contributes significantly to advance the state of the art in microshock detection and electric supervision. As a consequence, the paper propose a microshock dangerousness scale based on the RMS value of differential current is proposed.**

Keywords—Electric Supervision; Microshock dangerousness; Healthcare; Embedded system;

I. INTRODUCTION

The ElectroMedical Equipment (EME) is an electronic device that helps the medical team during a medical procedure. Many of these equipment perform vital functions and the patient's life depends on them, especially those admitted in Surgical Centers and Intensive Care Units (ICU). The use of these equipments in hospitals and other institutions that provide services in the health field is increasingly greater.

The use of EME throughout the years has brought benefits in the aid of diagnosis and therapies, as well as in surgical interventions. However, these benefits also produce risks of electric shock. Besides those evident to the medical team, known as macroshocks, there are shocks undetectable to the medical team, because the value of the electric current is under the human perception threshold of 1.0 mA, for most part of the population [1]. Patients under the effect of this microshock do not react in a visible way, because in most cases they are under anesthesia. However, studies from the 1930's decade show that small currents such as 67 μA, when passing through a cardiac muscle may produce a cardio-respiratory arrest [2]. Hospital engineers and managers have proposed many efforts to minimize the impact of microshock and EME electrical failures [3], especially since 1971. The results from these efforts are: the adoption of equipment manufacturing and installation norms, as IEC 60601 [4] revised in 2005, and IEC 60364 [5].

The problem is that even with the advances in safety norms and manufacturing, and management processes, the EME continue to fault producing health hazards. This occurs evidently during their use, when connected to the patient [6].

The scientists and researchers have proposed automated solutions to detect the microshock risk, in order to solve the perception problem described early. One of these proposed solutions is called Protegemed, which was addressed in 2009 [7] and extended in 2013 [6]. This system detects the risk of microshocks by monitoring the differential current of EME connected to the patient during a surgical procedure. The system was used in a surgical center and during the data collection, we generated large amounts of alerts microshock risk. However, Protegemed is unable to produce a scale with degrees of health hazard to patients and this constitutes a limitation of the Protegemed system. This scale was produced in this work. With this scale it is possible to prioritize the actions of engineers to meet the most severe cases.

This paper presents a new solution to EME electric supervision extending Protegemed system. Assuming that a

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microshock occurs and Protegemed triggers an risk alert event, means of quantifying health hazards to the patient are required. The proposed solution is based on the simultaneous capture of waveforms from different EME connected to the patient. From this information, a scale with degrees of microshock dangerousness is proposed. The solution is designed to operate embedded in the gas and outlet panel, without altering surgical operation routine led by the medical staff.

The remainder of the paper is organized as follows: Sect. 2 presents related works with their strengths and weaknesses; Sect. 3 presents the model for supervision of multiple EME; Sect. 4 shows the validation with a brief description of implementation and software support; Sect. 5 discusses the results and proposes a scale of microshock dangerousness. Finally, Sect. 6 concludes the paper and describes future works.

II. Related Works

Electric shock is extensively studied and cited in literature. Several papers can be found, but the main one is by Dalziel et al. [8], which is intensively mentioned and it is the basis for electric safety of equipment and installations. However, this work is focused on microshock associated to small currents that circulate a patient in circumstances that cannot be related to electric shock (macroshock). Microshock is usually the result of equipment leakage currents, which may also be originated by voltage difference among grounded conductors and may flow towards the heart [9]. Ferris et al. [2] proved that a small current of 67 µA going through the cardiac muscle might cause heart fibrillation.

Cappa et al. developed a device to monitor the leakage current of biomedical equipment. The goal was to monitor the leakage current in the grounding conductor of equipment in intensive care units. Furthermore, an analysis of situations potentially harmful to health with on and off equipment is proposed [10]. The work was not applied in surgical procedures nor performs the analysis of waveforms, although the developed device presents an interface to collect the values of phase and leakage currents. The scale of situations potentially harmful to health considers the provisions of the norm IEC60601-1 [4], meaning that harmful values would be those surpassing 500 µA in equipment.

Protegemed is a system designed to detect the risk of microshock based on the supervision of equipment differential current [7]. It is meant to be used in surgical procedures. Integrated with monitoring software it produces alerts for possible microshock risks. Its patent was acknowledged in 2004 and it is able to capture the waveforms of power and differential currents from an outlet for future analysis [11].

Hu et al. proposed a device to assess the leakage current of medical equipment. The developed device is meant to be used by the body of clinical engineering of hospitals during the process of equipment quality and safety tests [12]. Thus, it seeks to reduce the cases in which equipment may produce leakage currents when used in patients. Because it is not applicable during surgical procedures, it leaves the clinical engineering team without monitoring electric failures during the use in patients.

Protegemed2 [6] was the result of the first extension of Protegemed system. It performs an initial processing of power and differential waveforms; it also allows automatically identifying the source equipment of the differential current by radiofrequency (RFID).

This work seeks to extend the developments in [6], allowing the capture of EME leakage currents connected to a patient, and adding a method to quantify microshock dangerousness, which is a feature not found in any other related work. Such function is performed by analyzing current waveforms (WF) produced by EME, besides more data related to microshock.

III. Electric Supervision of multiple EME

Different factors contribute in determining health hazards caused by an electric shock. They are the following: (a) the amount of current ; (b) the path taken by the current; (c) the duration of the shock; (d) the frequency of the current [13]. Correctly determining these factors is not always a simple or trivial task, especially when the object to be protected is represented by individuals in a surgical procedure, particularly the patient. The intervention aimed at monitoring these values (current, frequency, course, and time) directly in patients may interfere in the ongoing procedure, bringing more complications than benefits.

The monitoring of currents used by EME with the Protegemed2 provides some of such information. For example, in the case of producing an alert of risk the microshock it is possible to determine the leakage current of the equipment, as well as the frequency spectrum of the waveform. However, to determine the path taken by the leakage current, for example if it went from one equipment to another, the simultaneous monitoring of several EME is required. The prototype developed in [6] allows monitoring up to four EME, which is insufficient for major surgeries where is of greater health hazard to the patient.

Hence, a new solution was developed where every supervision device was designed to work in integration with other similar, increasing the number of EME simultaneously supervised. Furthermore, new information are produced and the support computing system was expanded, allowing information from supervision to be used in the attempt to determine the dangerousness of a microshock risk event.

Figure 1 illustrates a surgery room with monitored EME currents, and integrated support system providing information to the clinical engineering team.

With the new solution embedded in the gas and power outlet panels it is possible to increase the number of protected power outlets and, therefore, the number of EME under supervision. Moreover, a possible interference of the leakage current of a device in another one may be detected.

The operation of the new solution occurs with the supervision of EME currents. When there is a leakage current event above the set threshold a microshock risk event is produced [6], containing EME identification and values that represent the leakage current waveform. At this time, a control signal (leakage occurrence) is sent alerting other Protegemed installed in the room. Upon receiving the signal of leakage occurrence “follow-up” events are produced with supervision data of active EME. Leakage and follow-up events are stored and processed by the support system, producing more accurate alerts to the clinical engineering team.

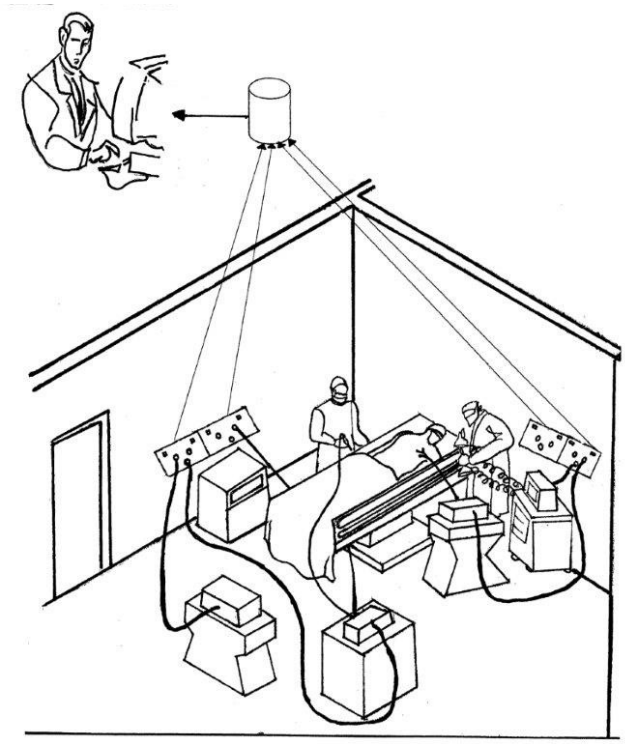


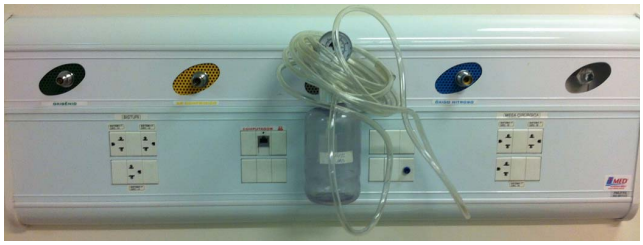
Fig. 1. Surgery room with gas panel and its connections.

Besides follow-up information, other information may be extracted from the new solution embedded in the gas and outlet panel. As an example, it is now possible to determine the time and duration of a leakage event, as well as analyzing the similarity among waveforms from different EME connected to a patient. This information may be used as base for creating a rising scale of health hazard produced from a microshock.

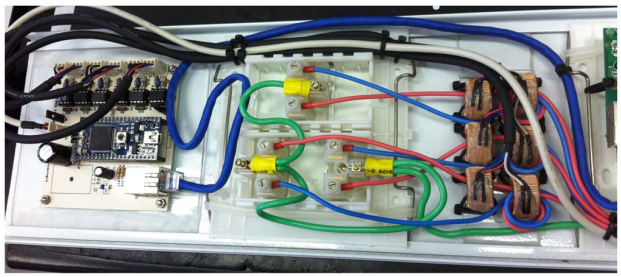
IV. Implementation and Validation

The solution presented in Figure 1 has been tested and validated in a surgical center of a large hospital with 617 beds and 18 surgical rooms in south of Brazil. Figure 2 illustrates the front and the back of one gas and outlet panel.

Figure 2a shows a gas and outlet panel from room 1 of SVPH (São Vicente de Paulo Hospital) surgical center. Figure 2b shows an internal part with the microcontroller kit (left), outlet connections (center), and toroids to measure power and leakage currents from three power outlets. For more information about the technique used to measure the power and leakage currents, as well as the use of toroids, see [6, 7].



(a)



(b)

Fig. 2. Protegemed installed how it looks to users (a). and internally (b)

A. Implementing Protegemed with MBED

The new solution for electric supervision embedded on a gas and outlet panel was implemented based on mbed NXP LPC1768 kit, equipped with 32-bit ARM Cortex-M3 (LPC1768) µc [14]. The prototype implemented in [6] was based on an ARM AT91SAM7X-EK development kit, equipped with 32-bit ARM (AT91SAM7X256) µc [15]. We chose the ARM technology due to its wide acceptance, good documentation, and large-scale use.

Changing the development platform from AT91SAM7X-EK to mbed NXP LPC1768 was given due to better computing capabilities of mbed in relation to the Atmel kit. Moreover, the development tools provided for the mbed kit and their best integration with Ethernet interface also contributed to the change. Table 1 illustrates some differences regarding the developed prototype with the Atmel kit in relation to the mbed one.

The NXP kit has a bigger clock than the Atmel kit, allowing less time consumed in tasks like the calculation of the Root Mean-Square (RMS), and the pre-analysis of waveform data, such as the calculus of the Fourier Fast Transform (FFT). Such fact may be proved by the reduction of these values on a scale greater than the increase of the clock. This can be explained by the change in µc architecture from ARM7TDMI to Cortex-M3, which is superior in terms of performance [16].

TABLE I. AT91SAM7X256 VERSUS MBED NXP LPC1768

Applied in Protegemed		
	AT91SAM7X256	NXP LPC1768
Clock (MHz)	48	96
Flash Memory (Kb)	256	512
SRAM Memory (Kb)	64	32
Number of supervised outlets	4	3
Time of calculation of RMS value per outlet	3 ms	711 µs
Time of calculation of FFT value per outlet	50 ms	11.5 ms

Another determining factor for changing the development platform was the higher capacity of Flash memory where the application is stored. This allowed new features, such as sending and reception of follow-ups to be applied. The fact that the amount of RAM memory for application is lower in the NXP kit in relation to the Atmel kit did not influence the application since the amount of manipulated data in the operation perfectly fits to the amount of memory available.

Each monitoring device implemented enables the supervision of up to three outlets with the NXP kit, one less compared to the Atmel kit. This is because in the project of the NXP kit two I/O pins for analogical/digital (A/D) converters were shared with the serial communication interface. Hence, it was not possible to use all eight A/D available, but only six, resulting in three supervised outlets, one A/D is used for the power current and the other one for the leakage current in each outlet. This reduction in the number of outlets does not hinder large-scale application because integration with other monitoring equipment is possible through follow-up messages.

B. Support Software

The support software processes the informations from the devices embedded in the panel and are stored in the database (Figure 1). It manipulates EME electrical supervision information considering information regarding the power current and the leakage current. It was developed in Java language and it is working along with the Department of Biomedical Engineering of São Vicente de Paulo Hospital.

With the values from the power current it accounts the real usage time of an EME, making the process of preventive maintenance easier. Moreover, the software calculates the runtime of the surgical procedure, from the first EME turned on in the room until the last one is turned off. With the values from the leakage current, microshock risk alerts are produced informing the clinical engineering team that unusual current events are taking place in the EME.

The main function of the support software is to produce alerts to the clinical engineering team. The results of occurred leakages are informed by room and are reported to the user in near real time, approximately 1s after the occurrence. Upon being informed of the occurrence of a microshock risk event the operator may visualize the waveform (WF) of the leakage current that produced the event, as well as the WF of all EME connected to the patient. Furthermore, information such as the runtime of the leakage current, RMS value, and mean value are provided. To validate the quality of WF obtained, an oscilloscope was used with reference. The same calibration has been performed using the RMS values and FFT.

When receiving an event from a given EME the operator has access to the last waveforms stored, as well as the WF registered as standard when releasing it to clinical engineering team use.

Information are periodically updated every second and the software presents a resource for offline data analysis, that is after the occurrence of events. These analyses allow the user to carry out a detailed study of the electrical situation of supervised EME.

V. RESULTS AND DISCUSSION

The system presented in Figure 1 and Figure 2 was installed in operation room 1, in May 2012, producing approximately 4.8 million events until the beginning of the month of June 2013. Two electric supervision systems were installed, embedded in the gas and outlet panel with a total of six monitored outlets (or six EME monitored). From these events, 114,369 are leakage current events, meaning they represent microshock risk. The remaining are events related to the power current of equipment (turns on and off), and leakage follow-ups.

Leakage events present an average of 0.9 mA RMS. The distribution of these events gathered by RMS leakage current (If) is (author's choice):

- If ≤ 0.018 mA 2,679
- 0.018 mA < If ≤ 0.05 mA 1,732
- 0.05 mA < If ≤ 0.5 mA 25,621
- 0.5 mA < If ≤ 1.0 mA 47,443
- 1.0 mA < If ≤ 1.5 mA 16,610
- 1.5 mA < If ≤ 2.0 mA 8,657
- 2.0 mA < If ≤ 2.5 mA 10,670
- 2.5 mA < If ≤ 3.0 mA 947
- If > 3.0 mA 0nly 10 events

It is noticed that 26,25% of microshock risk events occurs with low current values of up to 0.5 mA. Thus, grades were introduced to the limit of 0.5 mA, according to Table II. When these values are applied to microshocks they become potentially harmful to health since values above 67 µA may cause ventricular fibrillation [2] when applied to the cardiac muscle. However, as the values are not measured directly in patients but by EME leakage current, maybe not all microshock risk events detected have the potential to cause health hazards[7]. On the other hand, it is possible that microshock risk events detected may be harmful to health, especially the ones with higher leakage current.

Producing microshock risk alerts alone is insufficient for the electrical supervision of EME in surgeries. The research to minimize false positives leads to the need to gather information

to the alerts and produce a scale of patient health dangerousness. In this context, a false positive is perceived as a microshock risk event that is not harmful to health. Moreover, the creation of a scale may aid the clinical engineering team by separating the events with greater impact from the ones considered close to acceptable.

Several tables describing the physiological effects of different current intensities applied in people are found in literature. They consider the effects of macroshocks where human body resistance is higher, between 15 KΩ and 1.0 MΩ. This resistance is mostly from dry and clean skin. In case the skin gets wet or presents wounds, the resistance drops to 1% of these values [9]. In microshock studies, the protection offered by dry and clean skin cannot be considered because patients have the internal part of their bodies exposed.

Literature indicates that currents from 10 μA may represent a microshock [17]. These values are measured along with the body of the patient, however such procedure is not always possible. Thus, a rating of microshock dangerousness from the leakage current of EME is required. Table II is produced from macroshock values [8,13] and adapted to the lower resistance of exposed human body.

TABLE II. CURRENT VALUES (MA) FOR MACROSHOCKS AND MICROSHOCKS

Macroshock		***Microshock measured by the leakage current of EME***	
Grade	***Meaning***	***Grade***	***Scale***
0.4	No sensation on the hand	0.004	**N**ormal
1.1	Threshold of sensation	0.011	
1.8	Shock, not painful & muscle control not lost	0.018	**N**ormal **R**ange
5.0	Maximum harmless current	0.05	
9.0	Painful Shock, but muscle control not lost	0.09	**R**equires **A**ttention and may require *I*ntervention
16.0	Painful Shock (Let Go Threshold)	0.16	
23.0	Painful & Severe Shock, muscles contract, breathing difficulty	0.23	
50.0	Onset of pain	0.5	**R**equires **I**mmediate **I**ntervention
100[a]	Possible ventricular fibrillation	1.0	
275[a]	Ventricular fibrillation, often fatal; depending on heart cycle	2.75	

a Values for a long shock (3.0 s), for short shocks (0.03s) multiply by 10 the current.

The Table II presents four microshock dangerousness tracks from the leakage current of EME: Normal (N), Normal Range (NR), Requires Attention or Intervention (RAI), and Requires Immediate Intervention (RII). This is the authors' proposal to sort the dangerousness of a microshock only the RMS value of the leakage current.The team of clinical engineering that monitors surgical procedures with the support software should perform the intervention suggested in the scales.

Another parameter that directly influences health hazard caused by electric shock is the runtime of shock. It is verified that the average duration of leakages computed is compatible with long shocks. In long shocks, meaning 3.0 s or more, lower currents values may be harmful. However, a significant number of leakages are related to short shocks from 0.03s. The runtime of leakages was computed by second-precision, and 31,138 last less than 1.0 s; 22,736 last 1.0 s; 11,389 last 2.0 s; and 5,855 last 3.0 s. A clear reduction in the number of microshock risk events is noticed as runtime increases. A scale for microshock dangerousness that considers the runtime of shock must be created.

Determining microshock dangerousness should not only concern the leakage current and time of exposure to shock. Matters regarding current frequency and taken by the current must be also considered. The structure proposed and implemented in this article includes information about the frequency spectrum of waveform of a leakage current. These values may be used to create a scale for microshock hazard risk concerning the current by its frequency.

The path taken by the current is a variable harder to analyze when using the differential current of EME to detect the risk of microshock. Studies may be performed with the goal to find similarities among waveforms of leakage currents from different EME connected to a patient. A similar technique is cited in [10] stating that if there is a leakage current above the threshold set in norm IEC60601-1 in EME connected to the patient, but it is turned off, this current is from another EME and it possibly goes through the patient. Depending on the level of similarity among waveforms of different equipment it may be concluded that microshock is occurring (or not) and then create a rising scale of microshock hazard from waveform similarity.

The scale proposed in Table II must be refined when combined with the one to be created for time of exposure to shock, current frequency, and path taken by current producing a scale for microshock dangerousness. The connection of these different hazard scales may be performed with the Complex Event Processing (CEP) technique. CEP provides an effective solution to process event near real time for today's dynamic business environment [18]. With the addition of a CEP to the support system, alerts may be produced according to the scale for microshock dangerousness directed to the clinical engineering team, thus providing enhanced quality in electrical supervision of EME in surgeries.

VI. CONCLUSIONS AND FUTURE WORK

This paper described a solution to electrical supervision of EME with the device responsible for supervision embedded in the gas and outlet panel. It described the hardware used in application, as well as it presented results from microshock risk events collected over one year of use. From the analysis of results, it is verified that the microshock risk alert alone is insufficient for quality supervision. Therefore, factors that influence the hazard caused by electric shock were presented, and a scale for microshock dangerousness was proposed based in the RMS value of differential effective current of EEM in use in operation room.

Aiming to improve the accuracy of the results, the hardware monitoring is being enhanced to decrease the electromagnetic susceptibility. The results for values over 0.5 mA may seem alarming. However, the researchers believe that some surgeries may occur the use of more than one EME connected to the outlet being monitored through the use of extensions. Even though some of these data may be skewed, the proposed method is proving a good solution for electric

supervision and determination of dangerousness of a microshock.

The future work will include scales for microshock health hazards concerning time of exposure to shock and current frequency. Moreover, a scale considering waveforms similarity of EME connected to the same patient whenever one of them presents current leakage, will also be created. The goal is a scale for microshock dangerousness with take account the amount of current, the path taken by the current, the duration of shock and the frequency of the current. This is a rising scale, will be implemented with a Complex Event Processing, enhance the system support features, improving the electrical safety in surgical procedures.

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