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MODELING MEDICAL ELECTRICAL EQUIPMENT FOR ESTIMATION OF LEAKAGE CURRENTS DURING A SURGICAL PROCEDURE

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ABSTRACT
During a surgical procedure leakage currents can flow through the heart of the patient. The values of such currents can be estimated by an electrical circuit model. More specifically, three medical electrical equipment in an operating theatre, in contact with the patient and fed by an isolated power supply, are considered and are simulated. Two of them are always involved in a surgical procedure: an operating table and a patient monitor, the third one is a defibrillator which can be put into operation during emergencies.
The comparison between the leakage currents simulated by the circuit and the ones measured are presented. The agreement is quite satisfactory. An estimation of the model sensitivity due to the uncertainty in the knowledge of the model parameters has been performed too, by using the Monte Carlo method.
The proposed model is applied to study critical scenarios in which leakage currents flowing into the patient's chest in normal, single and double fault conditions could be dangerous and could introduce a risk of microshock not tolerable.

KEY WORDS
Operating theatre, electrical safety, microshock risk, electrical circuit model, patient monitor, defibrillator, operating table.

1. Introduction

A safe use of the Medical Electrical Equipment (MEE), to preserve patients and medical staff from possible electrical injuries, can be accomplished by selecting proper circuit mitigating interventions [1, 2]. The simulation of a surgical procedure by a safety oriented electrical circuit model can be a useful tool to investigate potentially dangerous leakage currents flowing through the patient's heart [3, 4].
There are some statistical data on injuries occurred to patients caused by microshock [5, 6, 7]. Such phenomenon is an electric shock by a very weak current concentrated in the heart area, causing cardiovascular collapse and ventricular fibrillation. Limit values in international standards are based on a series of studies (see for instance [8]). However, since similar threshold limits are chosen on a probabilistic base to be effective for a large fraction of population, some authors consider as possibly dangerous also lesser values [9]. In fact, currents less than 50 μA could be dangerous for patients with some heart disease during cardiac surgical procedures. In a study performed on 40 patients affected by several cardiac pathologies [10], an alternate current was given through a pacing catheter placed near right ventricular apex. New limit values were recorded as potentially dangerous for patient. These are 20 μA, 32 μA and 49 μA.
The insulation of an electrical equipment, which has been put into operation at AC voltage, should be modeled through lumped elements by using resistances and capacitances. In fact, insulation capacitances should be considered too when one settles a model for determining reasonable values of the leakage currents. Actually, insulation capacitances are often not available neither in the datasheets of the MEE. For such reason the best way to built a circuit model for simulation purposes is composed by three steps [3]:

- To measure resistances by using DC voltage;
- To measure leakage currents by using AC voltage;
- To obtain capacitances by reversing formulas and by using the measured resistances and leakage currents.

In literature there exist already examples of electrical models of power distribution systems in an operating theatre for the simulation of possible electrical faults (see for instance [11]), but usually these models do not consider insulation capacitances of MEE.
In a previous paper [3] a circuit model of a typical MEE by using information on electrical insulations from IEC 60601-1 [12] was presented. From that circuit, a model of a real defibrillator was originated. In such a paper, it has been used the standard IEC 62353 [13] to accomplish

measurements, the procedures to measure leakage currents according to have been followed.
In the present paper an electrical circuit model of three MEE connected to the patient during a surgical procedure and supplied by AC voltage is proposed. The identification of the parameters of the model and the estimation of leakage currents are discussed in the section 2.

2. Circuit model of MEE during a surgical procedure

2.1 Medical Electrical Equipment considered

Two of the three MEE chosen to evaluate the situation of leakage currents in operating theatres are always involved in surgical procedures: the operating table and the patient monitor. The third equipment is a defibrillator which can be put into operation during emergencies, for example when a ventricular fibrillation occurs.
Equipment leakage currents (ELCs) and applied part leakage currents (APLCs) are monitored by direct test method, one of the three methods contained in the standard IEC 62353 [13]. The circuits are simulated with Multisim, a software by National Instruments.

2.2 Circuit layout

In Figure 1 a circuit model of a patient monitor is shown. The patient monitor is a class I MEE, that can be supplied with 230 V AC. It is composed by four cardiac floating-type (CF) applied parts, which are the ElectroCardioGraphic (ECG) electrodes, and two body floating-type (BF) applied parts, which are a pulse oximeter and a sphygmomanometer to monitor the blood oxygen saturation SpO_2 and the blood pressure respectively .
Figure 1 represents an ELC measurement. The direct method permits to measure the leakage current on the chassis of the electrical equipment by simulation of the fault condition in which the Protective Earth conductor (PE) is disconnected.
It is to note that in Fig.1 a simplified model by grouping the applied parts performing the same function has been reported. In the case of this circuit only three functions are different, namely the ECG monitoring, the oxygen saturation monitoring and the blood pressure monitoring. Briefly, it is possible to recognize:

- the mains voltage V1 is 230 V at 50 Hz;
- the PE, simulated by resistance R13, disconnected;
- two live conductors L1 and L2 (or mains parts MP1 and MP2);
- the ground, i.e. the conductive accessible part protectively earthed;
- the load simulated by resistance R1;
- the ElectroMagneticInterference (EMI) filters C1 and C2;

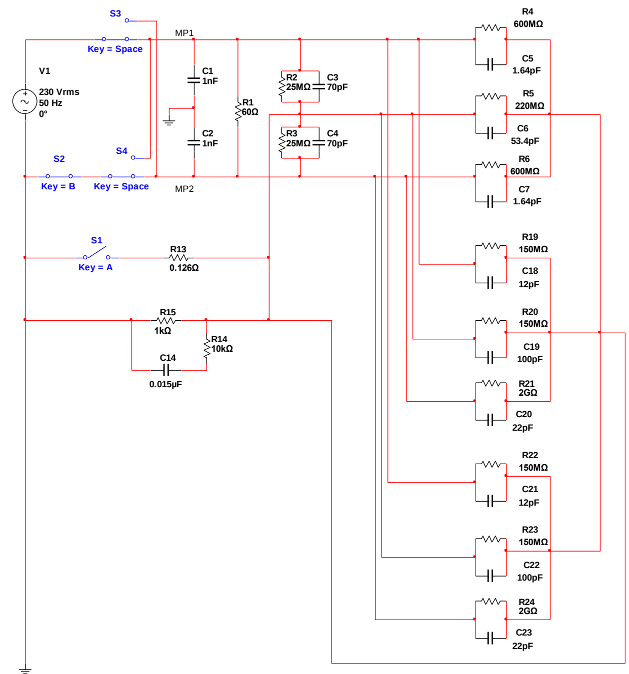

Figure 1. Electrical circuit model of a patient monitor for the simulation of equipment leakage current

- the resistances and capacitances R2, C3 and R3, C4 modeling the basic insulation impedance from mains parts and the ground;
- the resistances and capacitances R4, C5 and R5, C6 and R6, C7 modeling insulation impedance between ECG electrode and MP1, the ground and MP2 respectively;
- R19, C18 and R20, C19 and R21, C20 modeling insulation impedance between pulse oximeter and MP1, the ground and MP2 respectively;
- R22, C21 and R23, C22 and R24,C23 modeling insulation impedance between sphygmomanometer and MP1, the ground and MP2 respectively;
- the Measuring Device (MD) simulating the human body impedance composed by R15, fixed at 1 kΩ according to IEC 60601-1 [12], R14, fixed at 10 kΩ, and C14, fixed at 15 nF;
- switches representing different measuring conditions as inversion of supply polarity, disconnection of a mains part and the disconnection of PE.

2.3 Identification of the electrical parameters of the patient monitor

The electrical impedances of the circuit are evaluated on the basis of the data obtained in the MEE datasheets, in literature and in a campaign of measures accomplished by the Clinical Engineering Unit (CEU) of the hospital Campus Bio-Medico in Rome.
More specifically, the load resistance value (R1) is assigned on the basis of data reported in datasheets while the EMI filters capacitance values (C1 and C2) are assigned equal to those suggested in [8]. The PE resistance

Table 1
Comparison between the measured electrical parameters of a patient monitor and those assigned to its circuit model

Electrical parameter	Real monitor	Simulated monitor
Load	60 Ω	60 Ω
PE	0,126 Ω	0,126 Ω
Basic insulation resistance	(*)	25 MΩ
Basic insulation capacitance	(*)	70 pF with respect to L1 and L2
BF-type electrode insulation resistance with respect to ground	(*)	150 MΩ
BF-type electrode insulation capacitance with respect to ground	(*)	100 pF
BF-type electrode insulation resistance with respect to live parts	(*)	150 MΩ with respect to L1 2 GΩ with respect to L2
BF-type electrode insulation capacitance with respect to live parts	(*)	12 pF with respect to L1 22 pF with respect to L2
ECG electrode insulation resistance with respect to ground	(*)	220 MΩ
ECG electrode insulation capacitance with respect to ground	(*)	53,4 pF
ECG electrode insulation resistance with respect to live parts	(*)	600 MΩ with respect to L1 and L2
ECG electrode insulation capacitance with respect to live parts	(*)	1,64 pF with respect to L1 and L2

(*) data not measured by CEU

(R13) of every MEE is assigned equal to the measured value.
The basic insulation resistances (R2 and R3) of the patient monitor, which were not measured by CEU, are assigned equal to the minimum value required by the ANSI/NETA standards and fixed at 25 MΩ [14]. As anticipated in section 1, the value of the basic insulation capacitances have been identified by using the insulation resistances and the measured leakage currents in the Ohm's circuit equations and then by reversing formulas.
Differences between simulated and measured currents have to be analyzed taking into account the accuracy range of the MD, which in the case of measures on the patient monitor, is 5 % of read value.
Table 1 shows the comparison between real patient monitor electrical parameters and those assigned to the model.

2.4 Estimation of the leakage currents of the patient monitor

As cited in section 2.1, the MEEs chosen for simulation are tested in accordance with the direct method described in IEC 62353 [13]. In Figure 1 it is shown the set-up measurement of ELC on a patient monitor, while APLC test is not shown for shortness. Here, a voltage of 230 V AC is established between applied parts and earth to prove floating properties of applied parts.

The Table 2 shows the comparison between ELC and APLC values obtained through measurements carried on the patient monitor and the values obtained by simulation of its circuit model.

2.5 Identification of the electrical parameters and estimation of the leakage currents of the defibrillator and of the operating table

The evaluation of the electrical parameters of the circuit models of defibrillator and operating table is performed with the same method adopted for the patient monitor.
In particular, the operating table is a class I equipment with body type (B) applied part, i.e the table top where the patient lies during the surgical procedure. The defibrillator is a class I equipment with three CF-type applied parts which perform the ECG monitoring and two BF-type applied parts which are the defibrillator electrodes.
The values of the electrical parameters of the two circuit models and the leakage currents, are not reported for shortness. Those of the defibrillator can be found in [3].
Moreover, an evaluation of the model output, due to the uncertainty in the estimation of model parameters, has been performed by the Monte Carlo method. The results take evidence that a variation of ±10% of parameter values influences the leakage current values approximately of ±10%.

Table 2
Comparison between leakage currents measured during safety tests on a patient monitor and those assigned to its circuit model

Leakage current	Measured value [µA]	Simulated value [µA]
ELC with normal supply polarity	15	15
ELC with inverted supply polarity	15	14
APLC from sphygmomanometer with normal supply polarity and normal applied polarity	< 25(*)	8,97
APLC from sphygmomanometer with inverted supply polarity and normal applied polarity	< 25(*)	8,65
APLC from pulse oximetry with normal supply polarity and normal applied polarity	< 25(*)	8,97
APLC from pulse oximetry with inverted supply polarity and normal applied polarity	< 25(*)	8,65
APLC from ECG electrode with normal supply polarity and normal applied polarity	< 25(*)	16,9
APLC from ECG electrode with inverted supply polarity and normal applied polarity	< 25(*)	16,9

(*) the minus sign is shown in the screen of the tester and printed on the report

2.6 Circuit model of a typical surgical layout

The present study focuses on the evaluation of the leakage currents that could flow through the patient's trunk when more than one MEE is operating during a surgical procedure. The international standard IEC 60364-7-710 [15] recommends the installation of measures to avoid electric shocks in an operating theatre. They are the medical IT system (IT-M), which supplies MEE, and the equipotential bonding. In particular the standard fixes equal to 500 µA the maximum admissible value of the earth leakage current of an unloaded isolation transformer used in the medical IT system.
Moreover this standard fixes to 200 mΩ the maximum admissible value of the conductor and connection resistances between the earth terminal of the mains plug and the equipotential bonding bus bar. The IEC 62353 admits equal to 300 mΩ the maximum value of resistance between the earth terminal of the mains plug and the protectively earthed accessible conductive parts of the MEE. In the circuit model obtained the PE conductors complies with such admissible values, as can be seen in Figure 2.

In this figure, the circuit model of a surgical layout composed by Medical IT system, the three circuit models of MEE and the human body electrical resistance is shown. Mains parts, i.e. the parts at a voltage of 230 V are coloured by red, the grounds and every link to the grounds are coloured by yellow, the earth and every PE conductor are coloured by green, BF-type applied parts are coloured by blue, CF-type applied parts are coloured by light green, B-type applied part is coloured by purple.
For the simulation, according to [16], the patient's human body resistance has divided into five bipolar elements representing left arm, R25, trunk, R51, left leg, R50, right arm, R1 and right leg, R26. The sum of three resistances belonging to one side of the human body is equal to the conventional value of 1 kΩ. It is the same for the other side of the human body. Indeed a percentage of 47,2% of the total body resistance is assigned to one arm, which is mainly composed of bones, a 1,3% is assigned to trunk, assumed to be a cylinder full of saline water highly conductive with a discrete amount of bones, and a percentage of 51,5% is assigned to each leg, which is larger than the arm but with similar organic content.

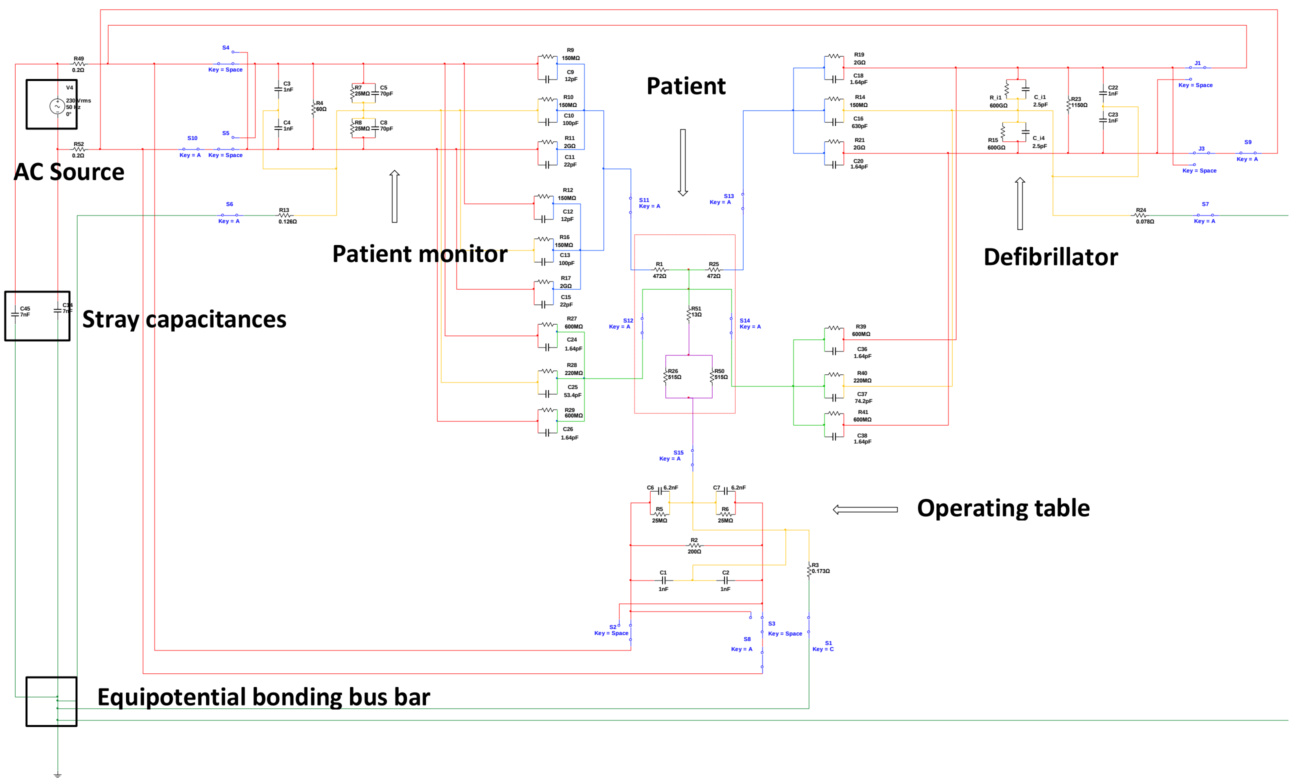

Figure 2. Electrical circuit model of three MEE in contact with the patient in an operating theatre

The circuit model of Figure 2 contains some switches schematizing different scenarios that could occur during a surgical procedure. In particular it is possible to simulate conditions as disconnection of PE conductor, the disconnection of a mains part, the inversion of the supply polarity and the connection of a MEE with the patient.

3 Results and discussions

3.1 Simulations of leakage currents in fault conditions

The international standard IEC 60601-1 [12], on safety of MEE, recommends the measurements of leakage currents in normal condition and in fault conditions. In particular single fault conditions are considered while double fault conditions are ignored because of very small probability of occurrence. Several simulations on the circuit model illustrated in Figure 2 have been performed. These are:

a) Operation of three MEE without faults;
b) Single fault condition to each MEE in turn, i.e. the disconnection of a mains part;
c) Double fault condition to each MEE in turn, i.e. the disconnection of PE and the disconnection of a mains part;
d) Disconnection of PE conductor of each MEE in turn;
e) Normal polarity of all equipment, inverse polarity of all equipment, and inverse polarity of each apparatus in turn.
f) Unbalanced installation of medical IT system schematized as an asymmetric impedance of cables originated from secondary winding of medical isolation transformer eliminating a stray capacitance between a mains part and the earth.

Values of potentially dangerous leakage currents flowing through the resistance of the trunk, R51, are shown in Table 3.

Table 3
Leakage currents simulated in different fault conditions

Fault condition	Balanced IT-M electrical system	Unbalanced IT-M electrical system
Disconnection of a mains part and disconnection of PE of the operating table	58,8 μA	89,0 μA
Disconnection of a mains part and disconnection of PE of the defibrillator	29,7 μA	39,4 μA
Disconnection of a mains part and disconnection of PE of the patient monitor	16,3 μA	21,4 μA
Disconnection of PE of the operating table	1,41 μA	33,6 μA

It is clear that the double fault condition (case c) is characterized by the most dangerous currents. In particular the operating table, composed by a B-type applied part, is associated with the more severe condition because of a leakage current roughly equal to 60 μA when a double fault occurred at the same equipment. It is possible that the patient could touch the chassis of the table with a foot or an hand or indirectly by means of an operator. Moreover, this is the reason for which it is suggested to operating the table by battery and disconnecting it from the mains supply. For what concern the defibrillator, in case of double fault condition (case c), currents through the trunk are roughly equal to 30 μA. Potentially dangerous currents flow through the trunk when a fault occurs to the patient monitor in conjunction with another equipment, for example the disconnection of the PE conductor of the monitor and the disconnection of a mains part of another equipment. This condition is not summarized in the Table 3 because can be considered very rare and then negligible. Values very close with respect to those reported in Table 3 are simulated when supply polarity of all MEE is reversed and when the supply polarity of each apparatus in turn is reversed (case e).
Moreover, when the installation of IT-M is unbalanced (case f), it is noted that the leakage currents increase.
In such case also the single fault condition as the disconnection of PE of the operating table (case d), could lead to a potentially dangerous currents of 33 μA through the trunk, when polarity of at least one apparatus is reversed. A double fault condition at the operating table could lead the circulation of a current roughly equal to 90 μA. However double fault conditions are not considered by standards since they are scarcely probable to occur.

4 Conclusion

This study focus on circuit modeling of some MEE in contact with the patient in an operating theatre for evaluation of leakage currents during a surgical procedure.
The identification of circuit parameters of each equipment model has been obtained by data collected in literature, datasheets and measures. Results of comparison between currents simulated by circuits and those obtained during measurements, show a good agreement considering the simulated values limited into the accuracy range of the MD used.
Moreover, an analysis of the uncertainty in the leakage current simulation by Monte Carlo method has allowed to verify that for a variation of ±10% of parameter values, the leakage current values range approximately between ± 10%.
Then, several simulations of leakage currents flowing through the patient's trunk in the situation of more equipment in contact are presented. The results show that double fault conditions appear to be the most hazardous. In particular, when these faults occur to the operating table, the values of the leakage currents could be too high. It is to note, however, that standards consider double fault condition as a negligible condition. Moreover, it has been verified that an unbalanced installation of IT-M system may lead to currents which can be potentially dangerous, even in a single fault condition.
In conclusion, this study is an important step to assess the microshock risk and to simulate leakage currents during a real surgical procedure in which several MEE are involved.

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