Circuit model of medical equipment for electrical safety purposes

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Abstract

In order to assess the risk of electric shock during a surgical procedure, it's important to know the insulation paths and the values of the insulation impedances of Medical Electrical (ME) equipment and then to draw "leakage circuits" and monitor the intensity of "leakage currents".

The aim of this work is to propose a circuit based model of a ME equipment to simulate the leakage currents measured during electrical safety tests. The set-up of these measures are described in the standard EN 60601-1, which also describes the insulations composing a ME equipment and where they are placed. While the standard EN 62353 describes the insulation resistances should be measured. This information is the references for the model development which is subsequently implemented with the circuit simulation software National Instruments Multisim. The application of the circuit model allows the simulation of an earth leakage current, touch current and patient leakage current similar to real equipment, both in normal and in single fault conditions. The values of the electrical parameters of the model from a measurement report of a commercial defibrillator are assigned. The results of circuit model leakage currents are compared with the measurement data. The output of this comparison may be considered quite satisfactory. In this paper the extension of the model to other ME equipment is also discussed in view of the assessment of the risk of electrical shock during a surgical procedure.
Keywords: microshock risk, medical equipment, circuit model of the defibrillator, floating type applied part, risk analysis, electrical safety.

1   Introduction

Healthcare facilities are critical infrastructures where safety of patients and medical operator must be ensured. The mutual relationship between the ME equipment, the patient, the health personnel and the related environment needs to be carefully considered because of the health status of the patient. In some medical procedures, low current is sufficient to cause respiratory paralysis ($\approx$ 10 mA) or potentially fatal ventricular fibrillation ($\approx$ 20 mA). The low resistance pathway via skin penetration and the decreased patient defences because of anesthesia, increase the risk of electric shock under faulty condition, as reported by Amicucci *et al.* [1].

For the purpose of risk analysis in a surgical room information is required about the power system installed into the medical structure, as well as technical data of ME equipment. But the leakage currents from every ME equipment used during the surgical procedure, the values of their insulation impedances and the insulation paths through which currents flow, are often not available.

The standard ISO/DIS 13824 [2] considers the use of engineering models to estimate the risk of a system where data are lacking. Corbellini [3] suggested the use of software for the simulation and modelling. Spalding *et al.* [4] shows an electrical model of a ME equipment supplied from an IT-M distribution system to explain how detect and measure the microshock risk by computer simulations and hardware equipment.

In this paper a novel approach is presented to evaluate the leakage currents from real ME equipment tested in accordance with standards CEI EN 60601-1 2nd ed. [5] and CEI EN 62353 [6]. In particular the layout and the electrical parameters values of the circuit model are presented.

2   Circuit model

The two last editions of standard CEI EN 60601-1 [5, 7] have constituted the key publications of reference for modelling the circuit shown in Fig. 1. The older edition of such standard specifies the construction details, as the type of insulation and where this should be placed. While the newer edition specifies the limit values of leakage currents and specifies the measurement set-up to evaluate whether they are exceeded from the equipment under test. Moreover standard CEI EN 62353 [6] is also important to understand how many insulations should be calculated for the leakage current estimation. It requires that insulation resistance shall be measured at voltage of 500 V dc between:

    a)   the mains part and protective earth for class I equipment;
    b)   the mains part and (non-earthed) accessible conductive parts for class I and class II equipment;
    c)   the mains part and the applied parts;
    d)   floating type applied part and protective earth for class I equipment;
    e)   floating type applied part and (non-earthed) accessible conductive parts for class I and class II equipment.

During the operation, the frequency of electrical equipment is equal to 50 Hz in Europe and insulation should be modelled with an ohmic-capacitive parallel impedance. In fact when frequency is not null, capacitance ("insulation capacitance" in the paper) reduces impedance and increases current that flow over the equipment through the earth or the patient.
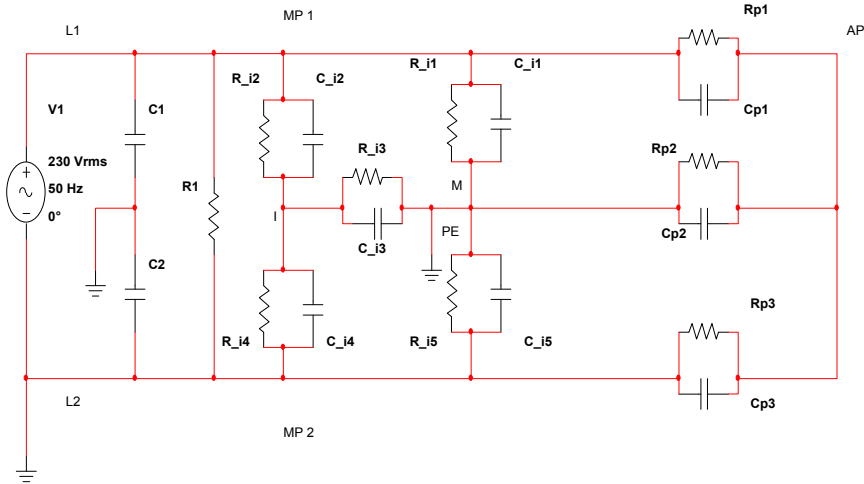

Figure 1:   Electrical circuit model of the generic ME equipment with floating (F) type applied part.

Fig. 1 shows the phase-neutral with floating (F) type applied part circuit model of a generic ME equipment. It follows the explanation of the circuit parameters:

- *MP:* mains part or alive part;
- *I:* enclosure;
- *M:* ground;
- *AP*: applied part;
- *L1:* supply phase L1 (one of the two alive parts);
- *L2*: supply phase L2 (the other of the two alive parts);
- *V1*: root mean square value of the supply voltage of the ME equipment. The value is equal to 230 V and the frequency is equal to 50 Hz;
- *C1, C2*: electromagnetic interference (EMI) filter capacitances;
- *R1*: ME equipment resistive load which absorbs electrical power;
- *Ri1, Ci1 and Ri5, Ci5:* basic insulation between alive parts and conductive accessible parts that are protectively earthed (named "ground" in the paper);
- *Ri2, Ci2 and Ri4, Ci4*: double insulation or reinforced insulation between alive parts and conductive accessible parts non-protectively earthed (named "enclosure" in the paper), for example moving parts for

which PE connection is not recommended due to its poor reliability (in general for class II equipment);

- *Ri3, Ci3*: insulation between ground and enclosure. It is indicated in [5] that this insulation would be in addition to the insulations interposed to alive parts;
- *Rp1, Cp1 and Rp2, Cp2 and Rp3, Cp3*: insulations between applied part and one of the two supply phases, applied part and conductive accessible part, applied part and the other of the two supply phases respectively.

The circuit model described in Fig. 1 allows us to simulate leakage currents similar to that of a real equipment. It has been successful applied in the case of a commercial defibrillator. In Fig. 2 the electrical diagram of commercial defibrillator for electric safety measurements in an Italian hospital is presented. The diagram is drawn on the software platform National Instruments Multisim, which is particularly suitable to perform simulations.

The commercial defibrillator under test is a class I ME equipment, with a basic insulation between alive parts and ground. Touch current values measured during tests shows that all conductive accessible parts are protectively earthed. The defibrillator is composed by three cardiac floating (CF)-type applied parts and two body floating (BF)-type applied parts. The CF-type applied parts are ElectroCardioGraphic (ECG) electrodes ("electrodes" in the paper) and the BF-type applied parts are paddle electrodes ("paddles" in the paper) from which the electrical discharge is delivered. Fig. 2 shows the Measuring Device (MD) that is modelled as reported in [7] where the resistance of 1 kΩ represents the human body. So this circuit models a specific defibrillator put into operation on a laboratory bench to test earth leakage current, touch current and patient leakage current. These currents are measured in:

- normal condition (NC);
- when a supply conductor or the protective earth conductor are open (single fault conditions SFC);

both with normal supply polarity and reversed supply polarity. Defibrillator has not been placed in an operating room, where other electrical equipment as insulation transformers, supply lines, etc. would be modelled in addiction.

In Fig. 2 switches J1 and J3 are shown. They are drawn to simulate the inversion of supply polarity. Switch J2 is drawn to simulate disconnection of one supply phase while switch J4 simulates the disconnection of PE. The insulation between applied parts and alive parts can be double, or composed by basic insulation + secondary circuit protectively earthed, basic insulation + metallic shield or by impedances. The insulation between applied parts and conductive accessible parts can be solid considering creepage distances, or air considering air clearance.

Values of impedance and capacitance have been calculated by means of formulas (1), (2), (3) and (4). Resistance values are assigned by measurement tests listed in [6] and written as a), b), c), d) and e) at the beginning of this section. The EMI filter capacitance is assigned equal to 1 nF which is a reasonable value and its variations don't influence the results of the model.
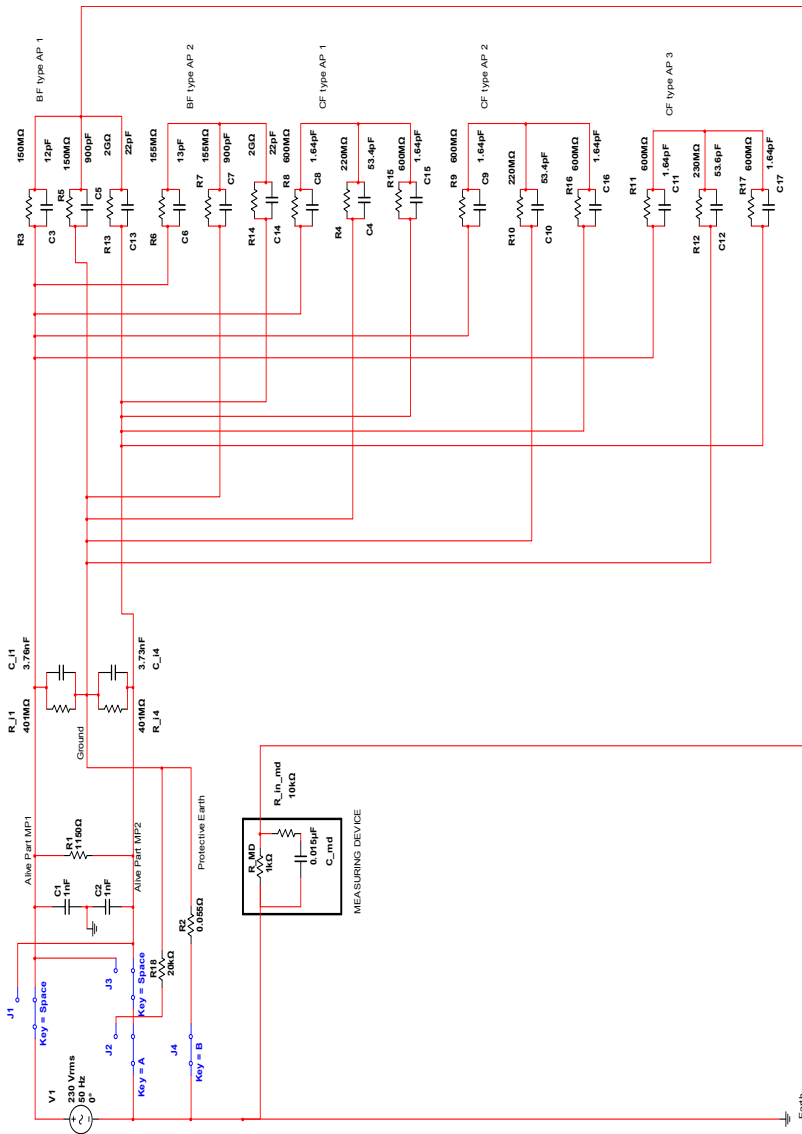
Figure 2: Electrical safety based circuit model of a commercial defibrillator.

$$Z = \left(\frac{1}{R} + j\omega C\right)^{-1} = \frac{R}{1+j\omega CR} \Rightarrow \frac{R}{1+j\omega CR} \cdot \frac{1-j\omega CR}{1-j\omega CR} =$$

$$\frac{R}{1+(\omega CR)^2} - j\frac{\omega CR^2}{1+(\omega CR)^2} \tag{1}$$

$$|Z| \sqrt{\left(\frac{R}{1+(\omega CR)^2}\right)^2 + \left(-\frac{\omega CR^2}{1+(\omega CR)^2}\right)^2} \tag{2}$$

$$|Z| = \frac{V_{rms}}{I_{rms}} \tag{3}$$

$$C_{1,2} = \pm\sqrt{\frac{-\left(2|Z|^2\omega^2R^2 - \omega^2R^4\right) \pm \sqrt{\left(2|Z|^2\omega^2R^2 - \omega^2R^4\right)^2 - 4\left(\omega^4R^4|Z|^2\right)\left(|Z|^2 - R^2\right)}}{2\omega^4R^4|Z|^2}} \tag{4}$$

The parameters of the circuit model are shown in Table 1.

It is important to note that insulation resistances between applied parts and alive parts are not measured during tests. Their values in the model are assigned on the basis of the leakage currents measured taking into account the accuracy range of the MD: 1% of read value ± 1μA.

3 Results

The circuit model results of leakage current are compared with the measurement data obtained from tests carried using a commercial defibrillator.

It is important to note how the data returned by the model are in line with what was expected. In fact, the earth leakage current, the touch current and the patient leakage currents which flow through the circuit in single fault conditions are greater than those found in normal condition. While the measurement data show that there is no difference in the values of touch current and the patient leakage currents when a supply conductor is open compared to the normal condition. The range accuracy of the MD justifies the difference between the experimental data and simulated ones.

As it can be noticed, the simulated patient leakage currents from the paddles when a supply conductor is open are not twice the same currents in normal condition as it happen for the simulated patient leakage currents from the

electrodes. Moreover, the values of these currents are slightly different when the polarity is reversed. The asymmetry values of the insulation impedances of the paddles with respect to the two alive parts, justifies this difference shown in the Table 2.

Table 1:   Comparison between electrical parameter values measured on a commercial defibrillator and simulated ones.

Electrical parameter	Real defibrillator	Simulated defibrillator
Load resistance	1150 Ω	1150 Ω
PE	0.055 Ω	0.055 Ω
Basic insulation resistance	OVER (> 400 MΩ maximum of the MD measurement range)	401 MΩ
Basic insulation capacitance	unknown	3.76 nF with respect to the phase L1 3.73 nF with respect to the phase L2
LL pad insulation resistance with respect to the ground	150 MΩ	150 MΩ
LL pad insulation capacitance with respect to the ground	unknown	900 pF
LL pad insulation resistance with respect to the alive parts	unknown	150 MΩ with respect to L1 2 GΩ with respect to L2
LL pad insulation capacitance with respect to the alive parts	unknown	12 pF with respect to L1 22 pF with respect to L2
V pad insulation resistance with respect to the ground	155 MΩ	155 MΩ
V pad insulation capacitance with respect to the ground	unknown	900 pF
V pad insulation resistance with respect to the alive parts	unknown	155MΩ with respect to L1 2 GΩ with respect to L2
V pad insulation capacitance with respect to the alive parts	unknown	13 pF with respect to L1 22 pF with respect to L2
RA electrode insulation resistance with respect to the ground	220 MΩ	220 MΩ
RA electrode insulation capacitance with respect to the ground	unknown	53.4 pF
RA electrode insulation resistance with respect to the alive parts	unknown	600 MΩ with respect to the alive parts
RA electrode insulation capacitance with respect to the alive parts	unknown	1.64 pF

Table 1:   Continued.

Electrical parameter	Real defibrillator	Simulated defibrillator
RL electrode insulation resistance with respect to the ground	220 MΩ	220 MΩ
RL electrode insulation capacitance with respect to the ground	unknown	53.4 pF
RL electrode insulation resistance with respect to the alive parts	unknown	600 MΩ with respect to the alive parts
RL electrode insulation capacitance with respect to the alive parts	unknown	1.64 pF
LA electrode insulation resistance with respect to the ground	230 MΩ	230 MΩ
LA electrode insulation capacitance with respect to the ground	unknown	53.6pF
LA electrode insulation resistance with respect to the alive parts	unknown	600 MΩ with respect to the alive parts
LA electrode insulation capacitance with respect to the alive parts	unknown	1.64 pF

4   Conclusions

In this work we have shown the circuit model of a real ME equipment suitable for assessment of microshock risk.

The model contains all insulation resistances that are considered in standards CEI EN 60601-1 and CEI EN 62353. Values of model parameters may be obtained from electrical safety tests on the considered ME equipment and by simple application of Ohm's law, which allow to calculate resistances and capacitances that constitute insulation impedances.

The model simulates "leakage currents" from ME equipment in normal condition and in single fault conditions.

It has been validated by the application to a commercial defibrillator and results of simulated leakage currents are to be considered in quite satisfactory agreement taking into account the accuracy range of the MD used for tests.

The method presented to construct the circuit model of a ME equipment can be extended to draw the safety based model of any other ME equipment by assigning the values of insulation impedances from the results of laboratory tests, required by the regulations. In fact, even if ME equipment are physically much different, they must comply with the requirements of the standards. So, the model of each of the equipment is composed by insulations which are to be measured as is written in [6] and its leakage currents must comply with limit values as is reported in [7]. This does not exclude that in constructing the circuit model of a ME equipment is necessary to take into account its own

particularities, for example the class of the electrical equipment or the number and the type of applied parts.

The modelling of ME equipment used in a surgical procedure is important to assess the risk of microshock in the operating room.

Table 2:   Comparison between leakage current values measured during the electrical safety tests on a commercial defibrillator and simulated values from its electrical circuit model.

Device's component Operating condition	Measured value [μA]	Simulated value [μA]
PE Earth leakage current in normal condition	274	274
PE Earth leakage current when a supply conductor is open	522	518
PE Earth leakage current in normal condition and supply polarity reversed	273	273
PE Earth leakage current when a supply conductor is open and supply polarity reversed	525	518
Enclosure Touch current in normal condition	0	0.015
Enclosure Touch current when a supply conductor is open	0	0.03
Enclosure Touch current when PE is open	270	274
Enclosure Touch current in normal condition and supply polarity reversed	0	0.015
Enclosure Touch current when a supply conductor is open and supply polarity reversed	0	0.03
Enclosure Touch current when PE is open and supply polarity reversed	273	273
Electrode RA Patient leakage current in normal condition	0	0.4
Electrode RA Patient leakage current when a supply conductor is open	0	0.8
Electrode RA Patient leakage current when PE is open	2	2.23
Electrode RA Patient leakage current in normal condition and supply polarity reversed	0	0.4
Electrode RA Patient leakage current when a supply conductor is open and supply polarity reversed	0	0.8
Electrode RA Patient leakage current when PE is open and supply polarity reversed	2	2.22
Electrode RL Patient leakage current in normal condition	0	0.4
Electrode RL Patient leakage current when a supply conductor is open	0	0.8

Table 2:   Continued.

Device's component Operating condition	Measured value [μA]	Simulated value [μA]
Electrode RL Patient leakage current when PE is open	2	2.23
Electrode RL Patient leakage current in normal condition and supply polarity reversed	0	0.4
Electrode RL Patient leakage current when a supply conductor is open and supply polarity reversed	0	0.8
Electrode RL Patient leakage current when PE is open and supply polarity reversed	2	2.22
Electrode LA Patient leakage current in normal condition	0	0.4
Electrode LA Patient leakage current when a supply conductor is open	0	0.8
Electrode LA Patient leakage current when PE is open	2	2.23
Electrode LA Patient leakage current in normal condition and supply polarity reversed	0	0.4
Electrode LA Patient leakage current when a supply conductor is open and supply polarity reversed	0	0.8
Electrode LA Patient leakage current when PE is open and supply polarity reversed	2	2.22
Paddle LL Patient leakage current in normal condition	2	1.76
Paddle LL Patient leakage current when a supply conductor is open	2	2.96
Paddle LL Patient leakage current when PE is open	30	30.1
Paddle LL Patient leakage current in normal condition and supply polarity reversed	2	1.59
Paddle LL Patient leakage current when a supply conductor is open and supply polarity reversed	2	2.96
Paddle LL Patient leakage current when PE is open and supply polarity reversed	31	30.6
Paddle V Patient leakage current in normal condition	2	1.76
Paddle V Patient leakage current when a supply conductor is open	2	2.99
Paddle V Patient leakage current when PE is open	30	30.1
Paddle V Patient leakage current in normal condition and supply polarity reversed	2	1.59
Paddle V Patient leakage current when a supply conductor is open and supply polarity reversed	2	2.99

Acknowledgement

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