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Electrical Safety Priority Index for Medical Equipment

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Abstract — **Due to the wide variety of equipment existing in clinical areas, there is an important question: which and how often electrical safety tests most be applied to the medical equipment. There are important differences about the electrical safety, such as the electrical insulation or the hazard considering the connection between patient and electrical instrumentation. The objective of this work was to develop an Electrical Safety Priority Index for Medical Equipment (ESPIME) involving different classifications related with electrical safety, in order to provide a numeric code indicating the priority and frequency for applying the electrical safety tests to medical equipment. The index were applied to the medical equipment in critical care locations and the result, were used to defined which set of medical equipment would be the first for developing and applying electrical safety tests in a private hospital in Mexico City.**

I. Introduction

In today's health care environment, medical safety programs are critical to hospitals as a means of addressing the issues of risk control and quality assurance. Furthermore, these programs, which involve the collection of data concerning various hazards and incidents and their correction, belong to the domain of the clinical engineering department. Electrical safety in hospitals today clearly requires that appropriate attention be paid to the electrical environment of the patients. To achieve this goal, it is necessary to implement a periodic maintenance check of all line-operated equipment and to establish a good record-keeping scheme to keep track of tests conducted and the relative status of the equipment tested [1].

Due to the wide variety of equipment existing in clinical areas, there is an important question: which and how often electrical safety tests most be applied to the medical equipment. There are important differences in terms of its electrical insulation and the hazard considering the connection between patient and electrical instrumentation. There are several classifications for medical equipment related with electrical safety, however their just attend a particular electrical aspect, such as the physical risk [2], or the safety arrangements [3], or the connection to the patient [3]. Although all these classifications have some relation, it is important to note that each of them have a particular scope and reports different information about the equipment.

For these reasons, it is necessary to have a methodology for decision making about which is the priority and what would be the frequency to apply the electrical safety tests to a particular type of medical equipment, by integrating the information from the classifications mentioned.

The objective of this work was to develop an *Electrical Safety Priority Index for Medical Equipment* (ESPIME) involving the different classification scopes, in order to provide a numeric code indicating the equipment priority in terms of the electrical safety, as well as the frequency in what the tests most be applied. The index were calculated for the medical equipment placed in critical care locations and this result were used to defined which set of medical equipment would be the first for developing and applying electrical safety tests in a private hospital in Mexico City [4].

II. Methodology

Five classifications that consider different aspects related with the medical equipment electrical risk were analyzed. Each of them are described by the particular aspect analyzed, the different criteria or conditions considered and it is proposed a relevance factor (ρ) to each of them, depending on its impact in the electrical risk.

C_1. Classification by Static Risk

This classification considers two aspects of the equipment: its *function*, which defines the application, and environment in which the equipment operates, and its *physical risk* which defines the worst-case scenario in the event of equipment malfunction [2]. In this classification the equipment has a numerical code assigned representing the relevance of each aspect considering the degree of interaction with the patient (see Tables 1 and 2).

TABLE 1
Relevance Factor Assigned to the Equipment Function

Type	Equipment function	ρ
Therapeutic	Life Support	25
	Surgical and Intensive Care	23
	Physical Therapy and Treatment	20
Diagnostic	Surgical and Intensive Care Monitoring	18
	Addicional Monitoring and Diagnostic	15
Analytical	Analytical Laboratory	13
	Laboratory Accessories	10
	Computer y Related	8
Misc.	Patient Related and Other	5

TABLE 2
Relevance Factor Assigned to the Equipment Physical Risk

Equipment physical risk	ρ
Patient or Operator Death	25
Patient or Operator Injury	20
Inappropriate Therapy or Misdiagnosis	15
Patient Discomfort	10
No significant Risk	5

The static risk (SR) is calculated by the addition of the values assigned to the equipment function (EF) and the physical risk (PR): SR = EF + PR. The maximum value that

RE can have, is obtained adding the greater value that EF can obtain, in this case is *life support* = 50 (see Table 1) and the greater physical risk, which is *death of the patient or operator* = 50 (see Table 2), therefore SR = 25 + 25 = 50. This factor was used to standardize the SR function into the interval [0, 1]. Thus, the function for SR was modified as in expression (1).

$$SR = \frac{EF + PR}{50} \quad (1)$$

C_2. Classification by the Degree and Quality of Safety Arrangements

This classification evaluates the equipment risk as a function of the electrical safety arrangements under three conditions: *Type H*, has a safety rating which is comparable with that of domestic equipment. *Type B*, has a high safety rating; it would normally be used with an external connection to the patient. *Type C*, has the highest electrical safety rating; it may be used with an internal connection to the patient [3]. In Table 3 is shown the relevance factor assigned to each of these types. Observe that the greater relevance factor was assigned to Type C because in this case the patient is more exposed.

TABLE 3
RELEVANCE FACTOR FOR THE DEGREE AND QUALITY CLASSIFICATION

Class C_{2j} $j=\{C, B, H\}$	Relevance %	ρ
Type C	60	1.0
Type B	30	0.5
Type H	10	0.16

C_3. Classification by Insulation

This classification analyzes the electrical risk according to the type of the electrical insulation that the equipment has and considers three classes: *Class 1*, the equipment has a protective earth. *Class 2*, the equipment has either double insulation or reinforced insulation. *Class 3*, the equipment does not operate voltages greater to 25 VAC or 60 VDC [5]. In Table 4 is shown the relevance factor assigned to these classes. The greater relevance was assigned to Class 1 because it has less insulation than the others.

TABLE 4
RELEVANCE FACTOR FOR INSULATION LEVEL CLASSIFICATION

Class C_{3k} $k=\{1,2,3\}$	Relevance %	ρ
Class 1	50	1.0
Class 2	40	0.8
Class 3	10	0.2

C_4. Classification by Physical Risk

This classification refers recall policies for cancellation of medical equipment according to the risk to which the user is exposed based on three categories: *Class I*, a reasonable probability exists that use of/or exposure to the device will cause serious injury or death. *Class II*, use of/or exposure to the device may cause temporary or medically reversible health consequences, or the probability of serious adverse heath consequences is remote. *Class III*, use of/or exposure to the device is unlikely to cause adverse health consequences [1], [6]. In Table 5 is shown the relevance factor assigned to these classes. Observe that Class I has the greater importance because the equipment can cause the death of the user.

TABLE 5
RELEVANCE FACTOR FOR PHYSICAL RISK CLASSIFICATION

Class $C4_I$ $I=\{I,II,III\}$	Relevance %	ρ
Class I	55	1.0
Class II	40	0.72
Class III	5	0.09

C_5. Classification by the Equipment Contact with the Patient

This classification defines three types of patients with whom the equipment can have contact: *General* (G): Includes all those patients who are unlikely to come into more than casual contact with electrical instrumentation. *Susceptible* (S): Includes all those patients who are intentionally connected to electrical instrumentation, through a low impedance external connection. *Critical* (C): Includes all those patients with a direct electrically conductive path to the left of right ventricle of the heart [3]. In Table 6 is shown the relevance factor assigned to each type of patient. In this case, the critical patients are those that are more exposed, therefore they have assigned the greater relevance factor.

TABLE 6
RELEVANCE FACTOR FOR THE EQUIPMENT CONTAC CLASSIFICATION

Class C_{5m} $m=\{G,S,C\}$	Relevance %	ρ
Class C	60	1.0
Class S	30	0.5
Class G	10	0.16

ESPIME: Electrical Safety Priority Index for Medical Equipment

For integrating the information of the five classifications described above, a relevance factor (ω) was assigned to each of them, taking into account the importance of the aspect they analyzed (see Table 7). This assignation was made considering that the ESPIME were going to evaluate the electrical risk. In this sense, classification C_3 got the highest value (ω=0.30) because it analyzed the electrical insulation of the equipment. Then, classifications C_2 and C_5 got a relevance of ω=0.25, because they analyzed the patient contact with the equipment. For classifications C_1 and C_4, ω=0.10 because they analyzed the physical risk of the equipment. Although these two last classifications do not specifically mention the electrical risk, it is known that this risk could be translated into a physical risk.

TABLE 7
RELEVANCE ω FOR EACH CLASSIFICATION

Classification (C_i)	Aspect analyzed	ω
C_1. Static risk	Equipment function and physical risk	0.10
C_2. Degree and Quality	Safety arrangements	0.25
C_3. IEC	Electrical isolation	0.30
C_4. FDA	Physical risk	0.10
C_5. Hill	Type of patient	0.25

The function that integrates these five classifications with their relevance factor is shown in expression (2):

$$IPSEEM = \omega_i \sum_{i=1}^{5} C_i \quad (2)$$

Where:

C_i is the classification to be evaluated (i = 1, …, 5).

ω_i is the relevance factor of each classification

Substituting each factor in expression (2):

$$IPSEEM = 0.10(C_1) + 0.25(C_2) + 0.30(C_3) + 0.10(C_4) + 25(C_5) \quad (3)$$

$$IPSEEM = 0.10\left(\frac{FE + RF}{50}\right) + 0.25(C2_j) + 0.30(C3_k) + 0.10(C4_l) + 0.25(C5_m) \quad (4)$$

Where j, k, l y m correspond to the relevance of the different conditions or criteria (the domain) of each classification (see Table 8). Observe that j = {H, C, B}; k = {1, 2, 3}; l = {I, II, III} and m = {G, S, C}. Note that IPSEEM is limited into the range [0, 1], this is because all relevance factors were standardized. The zero value means the lowest priority and the one value means the highest priority that equipment can have in order to apply their electrical safety test.

TABLE 8
RELEVANCE OF THE DOMAIN OF EACH CLASSIFICATION

Classification	Domain	ρ
$C2_j$	H	0.16
	B	0.5
	C	1.0
$C3_k$	1	0.55
	2	0.65
	3	1.0
$C4_l$	III	0.09
	II	0.72
	I	1.0
$C5_m$	G	1.0
	S	0.5
	C	0.16

As we mentioned, the objective of this evaluation is to provide a strategy for assign the priority to realize the electrical safety tests to the medical equipment, depending on their electrical risk when it is used. Once the ESPIME were obtained, we establish three intervals associated with a priority level: *high, medium* and *low* (see Table 9). This priority interval assigns the first 0.40 points for *high* priority and the second 0.40 points for *medium* priority, taking 80% of full interval [0, 1], guarantying that the majority of the equipment were incorporated in these two priorities, in order to assurance the application of the electrical safety tests twice a year, in the case of *medium* priority. The interval for *low* priority incorporates the 0.20 points reminded and the less amount of equipment.

TABLE 9
PRIORITY AND FREQUENCY TO REALIZE THE ELECTRICAL SAFETY TESTS TO MEDICAL EQUIPMENT

Priority Level	Range	Frequency
High Priority	[1, 0.60]	3 Months
Medium Priority	(0.6, 0.20]	6 Months
Low Priority	< 0.20	12 Months

It was also assigned the period (frequency) in what the electrical safety tests most be applied to the equipment. For high priority, it is proposed three months; for medium priority is proposed six months and for low priority, at least once a year. Observe that for high values of the ESPIME, higher is the priority and so on the frequency for realizing the tests to the medical equipment.

III. RESULTS

For illustrating the use of the ESPIME, the index was calculated for a vital signal monitor (MVS) as follows:

- The monitor was evaluated in each classification (one by one) and takes the value corresponding to the domain (see Table 10).
- For the first classification (C_1) the value for EF=18, because the monitor is a *diagnostic* device (see Table 1) and the value for PR=15, because the worst-case scenario for monitor means a wrong diagnostic (see Table 2). Further we applied expression (1) obtaining SR= 0.66 for the *static risk*.
- For C_2, the equipment was placed at *Type B* with a value of 0.5.
- For C_3, the monitor was placed at *Class 2* with a value of 0.8.
- For C_4, the equipment was placed at *Class II* with a value of 0.72
- For C_5, the monitor was placed at *Type S* with a value of 0.5.

TABLE 10
VALUES ASSIGNED TO A MVS IN EACH CLASSIFICATION

Classification	Domain	Result
C_1	EF = 18, PR = 15	0.66
C_2	j =B	0.50
C_3	k = 2	0.66
C_4	l = II	0.72
C_5	m = S	0.5

For calculating the ESPIME, we substitute the values on Table 10 in the expression (3):

$$IPSEEM_{MSV} = 0.10(0.66) + 0.25(0.5) + 0.30(0.8) + 0.10(0.72) + 0.25(0.5)$$

$$IPSEEM_{MSV} = 0.066 + 0.125 + 0.24 + 0.072 + 0.125 = 0.628$$

The result obtained for the index was 0.628, meaning that the monitor has a high priority to apply their electrical tests with a frequency of three months (four times a year).

Afterward, the ESPIME function was calculated for the equipment that most be available in critical care locations (operating rooms, intensive care unit, emergency room), according to the reference information about "basic equipment" published by the Instituto Mexicano del Seguro Social-IMSS [7] and the Mexican Health Council [8], as well as the Mexican Official Norm NOM 197 [9]. The equipments shown in Table 11 were evaluated in each classification and then we obtain their ESPIME. Observe that in the case of C_1 there were incorporated both values, the equipment function (EF) and the physical risk (PR), necessary to obtain the static risk (SR), which is the final value used for calculating the ESPIME.

According to the priorities (see Table 9), we can observe in Table 11 that the first six equipments have *high* priority, meaning that it is necessary to schedule the application of their electrical safety tests four times a year. The next nine equipments have *medium* priority and their tests most be applied twice a year, and for the last equipments just once a year.

TABLE 11
IPSEEM FOR THE MEDICAL EQUIPMENT IN CRITICAL AREAS

Equipment	C_1			C_2	C_3	C_4	C_5	ESPIME
	FE	*RF*	RE					
Electrosurgery Eq.	*23*	*20*	0.86	1.0	0.8	1.0	1.0	0.926
Defibrillator	*20*	*25*	0.9	0.5	0.8	1.0	0.5	0.680
Cardiotocograph	*15*	*10*	0.5	0.5	1.0	0.72	0.5	0.672
Electric Bed	*5*	*15*	0.4	0.5	1.0	0.72	0.5	0.662
Patient Monitor	*18*	*15*	0.66	0.5	0.8	0.72	0.5	0.628
Electrocardiograph	*18*	*15*	0.66	0.5	0.8	0.72	0.5	0.628
Patient Ventilator	*25*	*25*	1.0	0.16	1.0	1.0	0.16	0.580
Heart Lung Machine	*23*	*25*	0.96	0.16	1.0	1.0	0.16	0.576
Incubator	*20*	*25*	0.9	0.16	1.0	1.0	0.16	0.570
Microscope	*23*	*5*	0.56	0.16	1.0	0.09	0.16	0.445
Colposcope	*23*	*5*	0.56	0.16	1.0	0.09	0.16	0.445
Endoscope	*23*	*5*	0.56	0.16	1.0	0.09	0.16	0.445
Suction Pump	*20*	*5*	0.5	0.16	1.0	0.09	0.16	0.439
Body Weight	*15*	*5*	0.4	0.16	1.0	0.09	0.16	0.429
Negatoscope	*5*	*5*	0.2	0.16	1.0	0.09	0.16	0.409
Headlamp	*0*	*5*	0.1	0.16	1.0	0.09	0.16	0.399
Anesthesia machine*	*23*	*15*	0.76	0.16	0.2	0.72	0.16	0.288
Infusion Pump	*20*	*15*	0.7	0.16	0.2	0.09	0.16	0.219
Sphygmomanometer	*15*	*15*	0.6	0.16	0.2	0.09	0.16	0.209
Surgical Lamp*	*23*	*5*	0.56	0.16	0.2	0.09	0.16	0.205
Humidifier	*20*	*5*	0.5	0.16	0.2	0.09	0.16	0.199
Nebulizer	*20*	*5*	0.5	0.16	0.2	0.09	0.16	0.199
Digital Termometer	*15*	*5*	0.4	0.16	0.2	0.09	0.16	0.189
Diagnostic Instr	*15*	*5*	0.4	0.16	0.2	0.09	0.16	0.189

* These equipment are connected to an insulation transformer.

Due to the prevalence of electrical devices, electrical safety is a vital component of all hospital's comprehensive safety program that requires the coordinated effort of the entire health-care delivery system. Each hospital, through the clinical engineering department, should develop procedures to handle electrical hazards. In this sense, the results obtained in Table 11 were used by the biomedical engineering department of a secondary-care private hospital in Mexico City, to define which set of medical equipment would be the first for developing and applying their electrical safety tests [4].

IV. CONCLUSION

To have a method to help in decision making related with medical technology management, results a very useful tool in activities such as maintenance and safety of the equipment, because there are wide types of equipment with complex technologies which require different maintenance procedures. In this way, the ESPIME provides information to the technical personal from the hospital clinical engineering department for programming services as preventive maintenance relates with electrical safety that most do in all available equipment in the clinical unit.

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