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A Case Study On Decision Making of Medical Devices Electrical Safety Priority Index In Jordan

Mohammed Rawashdeh, Institute of Biomedical Technology (Jordan); Ahmed Alkouz, Institute of Biomedical Technology (Jordan), Alaa Alhaddadien, King Hussein Medical City (Jordan); Dena Al Dalabeh, King Hussein Medical City (Jordan)

Abstract
Each department having the medical devices must designate one or more persons to be responsible for medical device safety control. To achieve this and to provide suitable medical services for population, medical safety Programs are considered critical part to hospitals as a means of addressing the issues of risk control and quality assurance.Electrical safety in hospitals today clearly requires that appropriate attention be paid to the electrical environment of the patients. In this research a Medical Devices Electrical Safety Priority Index (MDESPI) was developedinvolving different classification criteria in order to provide a numeric code indicating the device priority in terms of the electrical safety, as well as the frequency in what the tests most be applied.

Introduction

Over the past decades, progress in the field of healthcare services became evident,resulting from the vast progress in the field of medical devices and their application inmedical centers or in hospitals [1].

Medical devices have been a part of medicine since antiquity but their formal regulation (e.g., for safety, efficacy, adulteration, and misbranding) is much more recent. In that respect, while medical device safety is currently evidenced through globally harmonized device/material biocompatibility testing using in vitro andin vivo systems, device performance is preferentially evaluated through human clinical trials, both prospective and retrospective [2].

To maintain these achievements and to provide suitable medical services for population, medical safety Programs are considered critical part to hospitals as a means of addressing the issues of risk control and quality assurance.Electrical safety in hospitals today clearly requiresthat appropriate attention be paid to the electrical environment of the patients [3].

Literature review

There is a growing body of literature highlighting the issues related to medical devices safety. Posadas et al, developed 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 appliedThus, to run a process plant highly skilled experienced maintenance personnel are required.For efficient functioning, it is essential that various systems of the plant remain in upstate as far as possible. However, during operation they are liable to fail in a random fashion [3].

Ezawa presented the statistical results of a series of 404 safety tests of medical devices, reports the electrical safety problems encountered, and suggests electrical design considerations for safety[4].

Zhang et al discussed the Severity rating scale in modifying the traditional heuristic evaluation method of assessing software usability so that it can be applied tomedical devices and used to evaluate the patient safety of those devicesthrough the identification and assessment of usability problems [5].

In this research a Medical Devices Electrical Safety Priority Index (MDESPI) was developed involving different classification criteria in order to provide a numeric code indicating the device priority in terms of the electrical safety, as well as the frequency in what the tests most be applied.

Methodology

A three classifications concerning different aspects of medical devices 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 relev-

ance factor (ρ) to each of them, depending on its impact in the electrical risk [3].

C1. Classification by Static Risk

This classification considers two aspects of the medical device: its function, which defines the application, and environment in which the device operates, and itsphysical risk which defines the worst-case scenario in the event of device malfunction [6].

In this classification the device has a numerical code assigned representing the relevance of each aspect considering the degree of interaction with the patient as illustrated in tables 1 and 2.

Table 1 Relevance factor assigned to the device function

Type	Device function	ρ
Therapeutic	Life Support	30
	Surgical and Intensive Care	26
	Therapeutic	21
Diagnostic	Surgical and Intensive Diagnostic Care Monitoring	17
	Additional Monitoring and Diagnostic	13
Analytical	Analytical Laboratory	11
	Laboratory Accessories	9
	Analytical	7

Table 2Relevance factor assigned to the device physical risk

Device physical risk	ρ
Patient or Operator Death	27
Inappropriate Therapy or Misdiagnosis	21
Patient or Operator Injury	17
Patient Discomfort	10
No significant Risk	4

The static risk (SR) is calculated by the addition of the values assigned to the device function (EF) and the physical risk (PR): SR = EF + PR. The maximum SR value obtained by adding he greater value that EF can obtain, in this case is lifesupport = 30, and the greater physical risk, which is death of the patient oroperator = 27 therefore SR = 30+27=57. This factor was used to standardize the SR function into the interval [0, 1]. Thus, the function for SR was modified as in equation (1).

$$SR = \frac{EF + PR}{57} \quad (1)$$

C2. Classification by Insulation

This classification analyzes the electrical risk according to the type of the electrical insulation that the device has and considers three classes: Class 1, the device has a protective earth. Class 2, the device has either double insulation or reinforced insulation. Class 3, the device does not operate voltages greater to 25 VAC or 60 VDC [7].

The relevance factor assigned to these Classes is shown in table 3. The greater relevance was assigned to Class 1because it has less insulation than the others.

Table 3 Relevance factor assigned to the Insulation level classification

Class	Relevance %
Class 1	70
Class 2	40
Class 3	20

C3. Classification by Physical Risk through exposure

This classification concerns with the risk to which the user is Exposed to the medical device based on three categories: Class I, a reasonable probability exists that use of/orexposure 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 health consequences is remote. Class III, use of/or exposure to the device is unlikely to cause adverse health consequences [8].

The relevance factor assigned to these classes is shown in table 4. Class I has thegreater importance because the device can cause the death of the user.

Table 4 Relevance factor assigned to the Physical Risk through exposure

Class	Relevance %
Class I	45
Class II	30
Class III	15

For integrating the information, table 5 shows the three classifications described above, a relevance factor (ω) was assigned to each of them, taking into account the importance of the aspect they analyzed.

This assignation was made considering that the ESPIME were going to evaluate theelectrical risk. In this sense, classification C3 got the highest value (ω=0.50) because it analyzed the Physical Risk through exposure. Then, classifications C2 (Classification by Insulation) and C1(Classification by Static Risk) got arelevance of ω= .35 and ω= .20 respectively.

Table 5 Relevance ω for each classification

Classification (Ci)	Aspect analyzed	ω
C1. Classification by Static Risk	Device function and physical risk	0.50
C2. Classification by Insulation	Electrical isolation	0.35
C3. Classification by Physical Risk through exposure	Patient risk through exposure	0.20

Equation (2) integrates these three classifications with their relevance factor as shown below:

$$MDESPI = \omega i \sum_{i=1}^{3} Ci \quad (2)$$

Where:
Ci is the classification to be evaluated (i = 1, …, 3).
ωi is the relevance factor of each classification

Substituting each factor in expression (2):

MDESPI = 0.50*C1 + 0.35*C2 + 0.20 *C3 (3)

$$MDESPI = 0.50 * \frac{EF+PR}{57} + 0.35*C2j + 0.20*C3k \quad (4)$$

Where j, k, correspond to the relevance of the different conditions or criteria (the domain) of each Classification. Observe that j = {1, 2, 3}; k== {I, II, III}.

MDESPI 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 device can have in order to apply their electrical safety test.

As stated earlier, the objective of this research is to provide a strategy for assign the priority to realize the electrical safety tests to the medical device, depending on their electrical risk when it is used. Once the MDESPI is obtained, three intervals associated with a priority level: high, medium and low were established as shown in table 6.

Table 6 priority and frequency to realize the electrical safety tests of medical devices

Priority Level	Range	Frequency
High Priority	[0.7,1]	2 months
Medium Priority	[0.4,0.7)	6 months
Low Priority	[0,0.40)	1 year

This priority interval assigns the first 0.30 points for high priority and the second 0.30 points for medium priority, taking 60% of full interval [0, 1], guarantying that the balance of majority of the device were incorporated in these two priorities and the feasibility of applying this strategy because of budget limitation.

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

Results and Conclusion

For illustrating the use of the MDESPI, the index was calculated for a 50 medical devices, each device was evaluated in each classification (one by one) and takes the value corresponding to the domain. For instance, the index was calculated for Patient Ventilator, For the first classification (C1) the value for EF= 30, because it is a life support device as shown in table 1.The value for PR=27, because the worst-case scenario for Patient Ventilator means a wrong diagnostic as shown in table 2.Applying expression (1) obtaining SR= 1 for the static risk.

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For C2, the device was placed at For C2, the device was placed at Class 1 with a value of 0.8.For C3, the device was placed at Class II with a value of 0.35.

For calculating the MDESPI, we substitute the values in the expression (3):

MDESPI (Patient Ventilator) = 0.50*1 + 0.35*0.8 + 0.20 *0.35

=0.5+0.28+0.07

=0.85

The result obtained for the index was 0.85, meaning that the Patient Ventilator has a high priority to apply their electrical tests with a frequency of two months (six times a year).

According to the priorities, it could be noticed that twenty seven devices have high priority, meaning that it is necessary to schedule the application of their electrical safety tests six times a year. The next seven teen devices have medium priority and their tests most be applied twice a year, and for the last devices just once ayear.

Electrical safety is a vital component of all hospital'scomprehensive safety program that requires the coordinated effort of the entire health-care delivery system. Eachhospital, through theclinical engineering department,should develop procedures to handle electrical hazards[1 origin].
The results obtained were recommended defining which set of medical devices would be the first for developing and applying electrical safety tests by the biomedical engineering department of KHMC .

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