A Novel Approach for Healthcare Equipments Lifespan Assessment

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***Abstract* — Medical equipments contribute to the quality of healthcare services on several levels. They play a key role in the diagnosis, the treatment, and the rehabilitation of the medical impairment and diseases. However, as any operating machine, medical equipments have a definite lifespan that expires after a period of time. Theoretically, studies specified ten years as the lifespan of medical equipments. In fact, the status of the medical equipments defines its age. This status should be addressed according to a list of criteria that evaluate the efficiency and the performance of these equipments. The purpose of this study is to develop a well-designed plan for evaluating medical equipments. According to this evaluation, the equipments that should be replaced can be ranked in the descending order of urgency, taking into account many criteria and sub-criteria.**

Keywords – efficiency; healthcare; lifespan; medical equipments; performance.

I. LITERATURE REVIEW

Assessment of medical equipment is increasingly becoming the concern of healthcare institutions [1]. For several years, great effort has been devoted to the study of reliability and maintenance of medical technology and the investigation of their malfunctions. In the early 1990s, the world raised the attention to the device-related activities and many regional offices were opened all over Europe, the Middle East, and Asia Pacific [2]. Moreover, the International Medical Device Regulators Forum (IMDRF) discussed the future directions in medical device regulatory harmonization [3]. Furthermore, the International Organization for Standards (ISO) defined ISO 13485 as a standard for assessing and maintaining the efficacy of medical equipments. It deals with the specifications of medical technology to meet healthcare requirements for healthier outcomes [4]. In addition, the US Food and Drug Administration (FDA) generated a Device Evaluation Intern Program (DEIP) to monitor the efficiency, safety, and degree of risk to public health of the medical equipments [5].

Many researchers paid considerable attention to the criticality of medical devices and the significance of the stringent environment surrounding them, so they dedicated their research to the classification of medical equipments and analyzed their preventive maintenance data using Failure Mode and Effects Analysis (FMEA) [6]. Similar studies measured maintenance effectiveness with failure codes as an evidence-based maintenance, where they compared different maintenance strategies adopted for seven types of medical equipments [7], [8]. Other studies focused on the importance of managing the regular maintenance process in hospitals, and proposed programs to increase the efficiency of the utilization of the medical equipments through a Medical Equipment Management Program (MEMP) [9], [10]. Kirisits and Redekop highlighted the economical evaluation as a critical key point that stands behind the decision making for an equipment-upgrading program [11]. Khalaf proposed a maintenance model for minimizing the risk and optimizing the cost-effectiveness of medical equipments [12]. Another study dealt with the problem from another perspective, where it shed the light on the relationship between the reliability of critical medical equipment (CME) and the effectiveness of CME maintenance management in relation to patient outcomes [13]. The clinical investigation of medical devices in Europe focuses on outlining the risks that may threaten both the patient and the staff [14].

All the above studies discussed the importance of preventive maintenance and its effect on the lifespan of medical devices. However, the most interesting approach in this issue has been proposed by a new Canadian systematic study for preventive maintenance prioritization of medical equipments. This study classifies the medical equipments into five levels of prioritization for preventive maintenance. However, this study is limited to the metering of the risks on the medical equipments using the quality function deployment (QFD) as a new concept in preventive maintenance classification [15]. Nevertheless, among all the calls regarding the evaluation of medical equipment, a study done by Sharareh Taghipour in 2011 assigned six main criteria in which some of them are branched into sub-criteria [14]. Taghipour focused on the recalls and hazard alerts that may occur for medical equipments. Moreover, concerning the risks, a great deal of attention was given to the failure frequency, the possible redetect of the risk, and the failure consequences, where we investigated the safety and environment effect of the device.

On the other hand, Taghipour raised the attention to the operational and the non-operational consequences of a failure, to inspect the cost of repair. This inspection covers

the 'manpower' and the 'spare parts' costs to fix a defect. Besides, the Canadian study boosted the attention to the out of service periods and the number of waiting patients due to those failures, defined as the downtime of the device.

Here, a new evaluation technique, similar to the Canadian one, which will be highlighted later in the paper, is proposed but with less required data. In our model, we tried to make the investigation simple and direct so we focused on the function and the age of the medical equipment, as well as we focused on the mission criticality, the risks, and the maintenance requirements. Actually, collecting data for each criterion is very hard and requires a long questionnaire, so we designed a checklist questionnaire to gather the required data about each equipment. As a case study, we applied this model on a Lebanese public hospital and we came back with a list of equipments that should be replaced after a period of time as defined by the hospital.

In this paper, we propose the methodology of the study in Section II. Then, we show the way to derive the weights and the intensities of the tested criteria in Section III. After that, we present the missions to accomplish the assessment plan through Section IV. In Section V, we analyze the obtained results and make decisions accordingly. This is followed by a "Case Study" in Section VI to test the validity of the presented technique. After that, we move to the professionals' evaluation in Section VII, where we re-assess the medical equipments from the professionals' perspective. In Section VIII, we go through the budgetary quotation for the procurement process for purchasing the nominated medical equipments. Finally, we end up with a conclusion and our further expectations through Section IX.

II. PROPOSED METHODOLGY

Medical devices play a significant role in providing healthcare, as they affect the patient and the care providers directly. Besides, the design of the medical equipments gives a share in the safety of the environment [16]. The excessive use of the medical equipments is directly proportional to its performance with time, which will shorten its expected lifespan. The clinical evaluation of medical technology should be based on a comprehensive analysis that covers relevant criteria and parameters to appraise the efficiency of the equipment.

This paper proposes a model to evaluate the medical equipments according to measurable criteria and quantitative parameters that identify the time after which this equipment should be replaced. To start, we are going to identify some main criteria in which some of them are branched into sub-criteria. To make our work measurable, we assigned each criterion and sub-criterion to a specific weight that defines its criticality.

Many methods can be used to appraise and weigh clinical data. In our study, we take into account five main criteria in which some of them are divided into sub-criteria. The main criteria are: function, mission criticality, age, risks, and the maintenance requirements of the medical equipment. Among those main criteria, mission criticality is evaluated by two sub-criteria, the utilization of the equipment and the availability of alternative devices. Besides, the risks on the equipment are evaluated through three sub-criteria related to risks: the failure frequency, the detectability of failure, and the failure consequences. Each criterion has a certain weight that specifies its weight in the study. Moreover, each criterion is limited to a certain range of choices, where every choice is assigned to certain intensity. For a clear top view, we summarized the main criteria with their sub-criteria in Table I below.

Table I. OVERVIEW OF THE MEDICAL EQUIPMENT ASSESSMENT CRITERIA.

Main Criteria	**Sub-criteria**
Function	---
Mission criticality	Utilization
	Availability of alternative devices
Age	---
Risks	Failure frequency
	Detectability
	Frequency consequences
Maintenance Requirements	---

After defining the grades and intensities for all criteria, the model will be ready for use to assess the devices. To compute the final score, we need to calculate the total score that is the summation of the product of intensities and weights for each criterion. After that, we should calculate the Normalized Score Value (NSV) that indicates the relative importance of each device in comparison with other devices, from which we generated the Transformed Score Value (TSV). The transformed score value is the value that allows us to rank the medical device according to its importance. In order to better understanding the whole process, we illustrated the main steps in Figure 1 below.

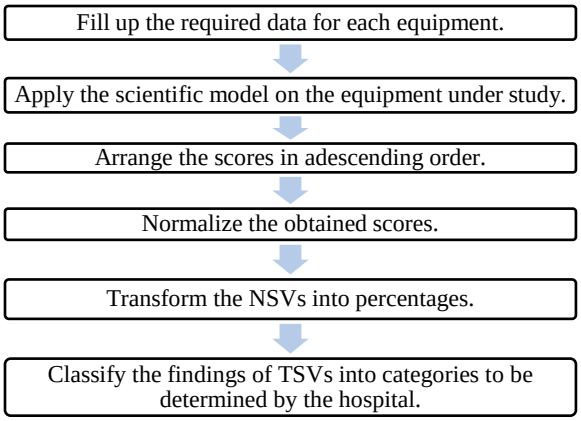

Figure 1. Flow chart of the scientific evaluation.

The above flow chart summarizes the required steps to accomplish the scientific evaluation. Going through such assessment requires a lot of parameters and equations. The

derivation of all the scientific relations is explained in the following section.

Before going through the steps of the study in details, we are going to define some key terms in order not to mix up between them.

- Missions: the steps taken by our study to apply the quantitative part of the model. We assigned five consecutive missions; each mission deals with a main criterion at a time.
- Criteria: the standards and norms of evaluation. We considered five main criteria to assess the medical equipments: function, mission criticality, age, risk, and maintenance requirements.
- Parameters: the measurable factors used in our study, such as the weights and the intensities.

III. PARAMETERS

For reliable measurements on medical devices, some grades known as intensities and weights for each criterion and sub-criterion should be introduced. The grades may encounter several classes for one criterion. For example, the maintenance requirements of a device may be high, medium, or low. The definition of each class differs from one hospital to another depending on the decision makers at each hospital. Consequently, the term 'low' for maintenance requirements differs from hospital to another.

If the criterion of a device contributes with its maximum capacity to the upper-level of this criterion, then its intensity should record a value of 1.

According to Sharareh, the intensities and the weights are obtained from a pairwise comparison matrix of qualitative grades, which is built using expert opinion [16], [17].

The weight of each grade is obtained in (1):

$$v_i = \frac{(\prod_{j=1}^{5} a_{ij})^{\frac{1}{5}}}{\sum_{i=1}^{5}(\prod_{j=1}^{5} a_{ij})^{\frac{1}{5}}} \quad (1)$$

where i = 1 to 5 and j = 1 to 5.

The intensity of each grade is obtained in (2):

$$Intensity = \frac{v_i}{\max(v_i)} \quad (2)$$

where i = 1 to 5.

TABLE II. PAIRWISE COMPARISON MATRIX FOR THE GRADE OF THE CRITERION 'FUNCTION'.

	Life saving	Therapeutic	Diagnostic	Analytic	Misc.
Life saving	1.00	5.00	6.00	8.00	9.00
Therapeutic	0.20	1.00	1.60	1.40	1.80
Diagnostic	0.17	0.63	1.00	1.25	1.50
Analytic	0.13	0.71	0.80	1.00	1.29
Misc.	0.11	0.56	0.67	0.78	1.00

Table II shows the pairwise comparison matrix for the grades of the first criterion, 'Function', as assigned by expert opinion. Using the above table and formulas, we can calculate the intensities and the weight for the criterion 'Function'. We listed the results in Table III, using (3) and (4):

$$a = (\prod_{j=1}^{5} a_{ij}) \quad (3)$$

$$b = (\prod_{j=1}^{5} a_{ij})^{\frac{1}{5}} \quad (4)$$

Table III. CALCULATING THE INTENSITIES OF THE CRITERION 'FUNCTION'.

	a	b	v_i	Intensity
Life saving	2160.00	4.64	0.62	1.00
Therapeutic	0.81	0.96	0.13	0.21
Diagnostic	0.20	0.72	0.10	0.16
Analytic	0.09	0.62	0.08	0.13
Miscellaneous	0.03	0.50	0.07	0.11
$\sum_{i=1}^{5} b = 7.45$				

In our model, we discarded the sixth criterion, which is "Recalls and Hazards" from the study, as it is not available in the hospital where the study was done. Hence, we distributed 0.16, the weight of recalls and hazards, equally on the other criteria by adding 0.032 on each of the five criteria ($0.16 \div 5 = 0.032$). For example, the weight of the criterion "Function" was 0.45. After adding 0.032 it becomes 0.482.

IV. MISSIONS

Assessment of medical equipments requires five consecutive missions, where each one deals with a criterion. In the first mission, we classify the function of the equipment. In the second mission, we specify the mission criticality of the equipment through its rate of utilization and availability of alternative devices. In the third mission, we identify the age of the equipment. In the fourth mission, we investigate the risks on the equipment by looking into its failure frequency, detectability of the failure, and the failure consequences. Finally, in the fifth mission, which is the last one, we study the maintenance requirements of the equipment. The core of each mission is gathering data. Before going through any of the missions, we made up an identity card for each equipment by filling up its name, its serial number, its brand, and its manufacturer. This information will not affect our study, but the aim is rather to identify each equipment to make sure that there is no overlapping in case the equipment is shared among the units and departments.

The intensities are obtained from a pair-wise comparison of grades; experts construct these grades as elaborated by the work of Taghipour.

First Mission: In the first mission, we classified the function of each medical equipment into five categories: lifesaving, therapeutic, diagnostic, analytic, and miscellaneous according to the classification developed by Fennigkoh, Smith, and Dhillion [18]. The weight of the

TABLE IV. THE INTENSITIES OF THE FUNCTION OF THE EQUIPMENT.

Function (0.482)				
Life saving	Therapy	Diagnostic	Analytic	Miscellaneous
1.00	0.21	0.16	0.13	0.11

function and the intensity of each category are shown in Table IV.

Second Mission: This mission accomplishes the second criterion; mission criticality of weight (0.132) is divided into two sub-criteria: the utilization and the availability of alternative devices, as shown in Figure 2.

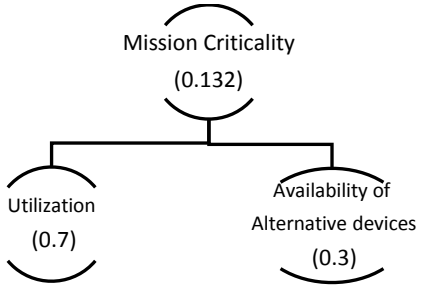

Figure 2. Hierarchy for mission criticality.

The usage of the device and its back-up devices identify the load of work on that device. Moreover, using the equipment excessively will increase the failure on the equipment [19]. In the first sub-criterion, utilization of a device is the total hours the device is used on average in a hospital (the unit can be defined as hours per day or days per week or weeks per year). In our proposed model, we considered the 'average hours a device is used per week' for the utilization criterion divided into three classes as shown in Table V.

TABLE V. THE WEIGHT AND INTENSITIES OF THE USAGE OF MEDICAL EQUIPMENT.

Usage hour/week (0.70)		
24≤	12≤x<24	<12
1.00	0.34	0.15

On the other hand, the availability of alternatives affects the mission criticality as it represents the number of similar or backup devices for one equipment. However, as the number of similar devices at hand becomes fewer because of lack of backup of the medical equipment, the risks on that equipment will increase. Furthermore, having several similar devices with low demand may also harm the device by affecting its performance from one side, and by costing the hospital regular preventive maintenance from the other side. The weight and the intensities of the availability of alternatives are shown in Table VI.

TABLE VI. THE WEIGHT AND THE INTENSITIES OF THE ALTERNATIVES.

Alternatives (0.30)		
≤1	1< x≤4	>4
1.00	0.34	0.20

Third Mission: The third mission deals with the third criterion, which is the age of the equipment. The age of the medical device is based on the actual age of a device and its predictable lifespan. In general, 10 years is the average lifespan for a medical device. The equipments are divided into five categories according to the actual age of the equipment divided by the lifespan as shown in Table VII. As the ratio approaches 1, the equipment is considered as old; otherwise, it is considered to be new as the ratio approaches zero. The age ratio is expressed in equation (5):

$$Age\ Ratio = \frac{Actual\ Age}{LifeSpan} \quad (5)$$

TABLE VII. THE WIGHT AND THE INTENSITIES OF THE AGE OF THE MEDICAL EQUIPMENT.

Age (0.092)				
>1	0.75< x≤1	0.5<x≤0.75	0.25<x≤0.5	0≤x≤0.25
1.00	0.67	0.43	0.17	0.12

Fourth Mission: The fourth mission addresses the fourth criterion, which is the risk of a device (of weight 0.192). In a patient-centric environment, managing risk is the top priority that occupies a worthy space under the umbrella of healthcare [20]. The risk of a device is the summation of all risks threatening patients. These risks can be estimated from the actual failures, which have occurred in that device, and are shown in the figure below.

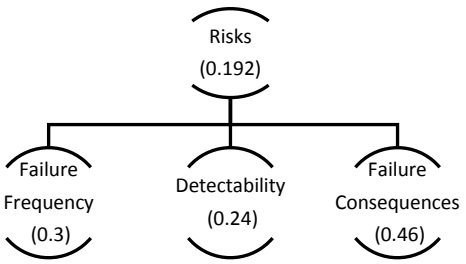

Figure 3. Hierarchy for risks on the medical equipment

Figure 3 illustrates the three sub-criteria of risks. The consequences associated with the risks of a device are assigned by the failure frequency, the detectability, and the failure consequences. These should be extracted or estimated from historical data and device maintenance archives [21].

The frequency of failure indicates how often the failure occurs. In order to capture this dimension, we considered four levels for the frequency of failure as outlined in Table VIII. If the failure is frequent, it means that the failure is likely to occur (several occurrences in 1 year). On the other hand, if the failure is occasional, it means that it probably will occur (several occurrences in 1 to 2 years). Then, if it is uncommon, this means that there is a possibility of occurrence (one occurrence in 2 to 5 years). Finally, if it is remote, it means that it is unlikely to occur (one occurrence in 5 to 10 years).

TABLE VIII. THE WEIGHT AND INTENSITIES OF THE FREQUENCY OF FAILURE.

Frequency of Failure (0.3)			
Frequent	Occasional	Uncommon	Remote
1.00	0.33	0.20	0.15

Failure detectability is the ability to detect a failure when it occurs. This is the most important criterion to assess harm [20]. We can detect the failure at many different levels. In our model, we used four levels of detectability. The failure maybe detected by error, that is when the equipment stops working, or by inspection during the regular preventive maintenance rounds, it might be visible by naked eye or it can be detected by self-announcement, as summarized below in Table IX.

TABLE IX. THE WEIGHT AND INTENSITIES OF THE DETECTABILITY.

Detectability (0.24)			
Error	Inspection	Visible	Self-announcement
1.00	0.33	0.20	0.13

The failure consequences, of weight (0.46) deals with the safety and the environment where we discuss the effect of the failure on the patient and the staff [22]. The failure of the medical equipment may harm the patient at different levels. It may cause death in extreme cases, injury in which it may disable the patient, inappropriate therapy, misdiagnosis, which makes the situation worse or failure, which may cause a delay in the treatment. Finally, in some other situations, it may cause nothing. The intensities of those failures are summarized in Table X.

TABLE X.THE WEIGHT AND INTENSITIES OF THE FAILURE CONSEQUENCES.

Failure Consequences (0.46)				
Death	Injury	Inapp. Therapy or misdiagnosis	Delay in treatment or diagnosis	Non
1.00	0.34	0.21	0.14	0.09

The risk value can then be estimated as a function of frequency, consequence, and detectability for each failure mode. As a result, the risk of the device is the total risk of all its failure modes.

Fifth Mission: The last criterion, which is the fifth one where we studied the maintenance requirement for every medical equipment, is covered in the fifth mission. The availability of the medical equipments should be based on maintenance history and the maintenance requirements [23]. According to Fennigkoh and Smith [24], equipment that is predominantly mechanical, pneumatic, or fluidic often requires the most expensive maintenance. A device is considered to have an average maintenance requirement if it requires only performance verification and safety testing.

Equipment that receives only visual inspection, a basic performance check, and safety testing is classified as having minimal maintenance requirements. We defined each of these classes as high, medium, and low with their corresponding intensities as shown in Table XI.

TABLE XI. THE WEIGHT AND INTENSITIES OF THE MAINTENANCE REQUIREMENTS.

Maintenance Requirements (0.102)		
High	Medium	Low
1.00	0.50	0.17

Identifying the main and the sub-criteria of each equipment allows us to determine their relative importance according to their goal or their upper level criterion using Saaty's eigenvector technique – a mathematical technique that assigns a total score value for each medical device under study. This technique is used in multi-criteria decision-making missions [25]. This total score is generated from the weights and the intensities of those medical devices from the matrix of criteria and sub-criteria observed [26], [27]. Figure 4 shows a schematic diagram of the main and sub criteria of the evaluation test.

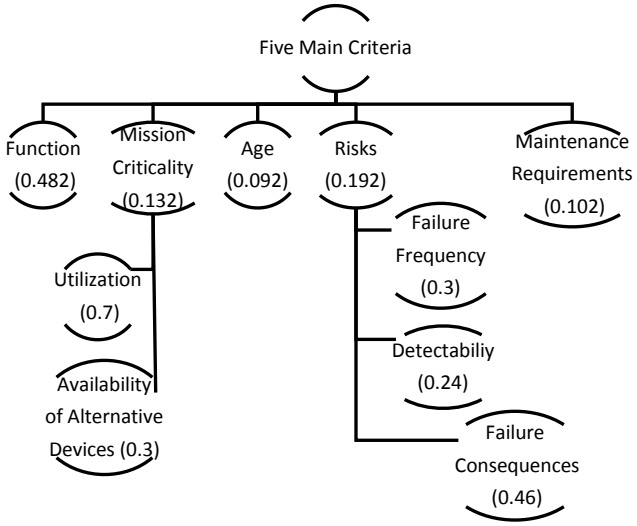

Figure 4. Hierarchy for the five main criteria.

After filling the questionnaire for each equipment, we can compute the scores using the assigned weights and intensities. The total score of each equipment is the

$$Total\ Score = w_{function} \times i_{function} + w_{age} \times i_{age} + w_{mission\ criticality} \times [w_{usage} \times i_{usage} + w_{back-up} \times i_{back-up}] + w_{risks} \times [w_{failure\ consequences} \times i_{failure\ consequences} + w_{detectability} \times i_{detectability} + w_{frequency} \times i_{frequency}] + w_{maintenance\ requirements} \times i_{maintenance\ requirements}$$

summation of the weight × intensity for the five criteria, which is illustrated in (6) below:

$$Total\ Score = \sum_{j=1}^{5} w_j s_{ij} \quad (6)$$

where "w" is the weight of each criterion "j" = 1, 2 … 5 and "i" is the intensity of each class.

At this stage, the total score for the equipments is listed in descending order from the highest score to the lowest score. This rank helps in calculating the normalized score value that indicates the relative criticality of a device compared to other devices. Therefore, the Normalized Score Value of each equipment is expressed in equation (7):

$$NSV = \frac{Total\ score\ of\ each\ device}{Maximum\ total\ score} \quad (7)$$

The aim of this study is to prioritize the medical devices according to their criticality. To do so, we have to calculate the transformed score value from the above procedure, which can be used for prioritizing or ranking of devices. The TSV depends on the NSV of each device involved in the model, and on the minimum and the maximum scores that could be achieved. The TSV plays an important role in assessing the medical equipments according to a percentage. In our proposed model, devices can have a total score between (0.1257592, 1.0) where score 1.0 is for a device, which gets the highest intensity when assessed against every single criterion, and 0.1257592 is obtained when the device gets the lowest intensity from all criteria. The calculation is shown below using (6):

$$\begin{aligned} MinimumTotalScoreValue &= (0.482 \times 0.11) \\ &+ 0.132[(0.7 \times 0.15) + (0.3 \times 0.2)] \\ &+ (0.092 \times 0.12) \\ &+ 0.192[(0.3 \times 0.15) + (0.24 \times 0.13) \\ &+ (0.46 \times 0.09) + (0.102 \times 0.17) \\ &= 0.1257592 \end{aligned}$$

Similarly, we can calculate the maximum value using equation (6):

$$\begin{aligned} MaximumTotalScoreValue &= (0.482 \times 1) \\ &+ 0.132[(0.7 \times 1) + (0.3 \times 1)] \\ &+ (0.092 \times 1) \\ &+ 0.192[(0.3 \times 1) + (0.24 \times 1) + (0.46 \\ &\times 1) + (0.102 \times 1) = 1 \end{aligned}$$

As it was expected to be, the maximum score value recorded a total score 1. This is because the intensity of each criterion and sub-criterion is the highest.

However, the total scores of devices can be used as absolute measurements for classification. The ranking of the medical devices can be done according to the normalized score value, however, for a better reading we can express the results in percentage, and so the normalized score value can then be mapped to (0, 100%) Transformed Score Value using the following equation:

$$TSV = \frac{Score\ value - Minimum}{Maximum - Minimum} \times 100 \quad (8)$$

The whole process of doing these calculations is summarized in Table XII.

TABLE XII. THE TRANSFORMED SCORE VALUE.

Equip.	Total Score	NSV	TSV
↓	Descending order	$\frac{(Total\ score\ of\ each\ device)}{max.\ Total\ score}$	$\frac{Score\ value - minimum}{maximum - minimum} \times 100$
			$\frac{Score\ value - 0.1257592}{1.00 - 0.1257592} \times 100$
			$\frac{Score\ value - 0.1257592}{0.87311} \times 100$

As an example, let us apply our model on the monitors of ICU. Starting with the first mission, the monitor is classified as diagnostic equipment (intensity = 0.16), then the score of the function can be calculated as follows: $w_{function} \times i_{function}$= 0.482 × 0.16=0.07712

In the second mission, we found that the usage of the monitor is more than 24 hours per week (intensity = 1). Besides, our investigation showed that there are more than four back-up monitors in the ICU (intensity = 0.2) and hence the score of the mission criticality can be calculated as follows:

$$w_{mission\ criticality} \times [w_{usage} \times i_{usage} + w_{back-up} \times i_{back-up}]$$
$$= 0.132 \times [0.7 \times 1 + 0.3 \times 0.2] = 0.10032$$

In the third mission, we checked for the age of the monitor and the result is obtained below:

$w_{age} \times i_{age}$= 0.092 × 0.67=0.06164

In the fourth mission, we examined the risks on the monitor of the ICU through the three sub-criteria of risks; frequency of failure, detectability, and failure consequences. The failure on the monitor is frequent so its intensity is high (intensity = 1), this failure is detected by error (intensity = 1), and the consequences of that failure results an inappropriate therapy or misdiagnosis (intensity = 0.21). Hence, the risks on the ICU monitor scores:

$w_{risk} \times [w_{failure\ frequency} \times i_{failure\ frequency} + w_{detectability} \times i_{detectability} + w_{failure\ consequences} \times i_{failure\ consequences}]$=$0.192 \times [0.3 \times 1 + 0.24 \times 1 + 0.46 \times 0.21] = 0.1222272$

Finally, coming to the fifth mission, the maintenance requirements on the monitor of the ICU is low (intensity = 0.17). The score of the maintenance requirements is:

$w_{maintenance\ req.} \times i_{maintenance\ req.} = 0.102 \times 0.17 = 0.01734$

Using equation (6), we can substitute the intensities and weights for the monitor of ICU, as follows:

TSV= $0.07712 + 0.10032 + 0.06164 + 0.1222272 + 0.01734 = 0.3786472$

As illustrated in Table XII, in order to determine the normalized score value of the monitor in the ICU, we should compute all the total scores of the devices under study to find the maximum total score.

Similarly, we computed the total score for all the equipments under study in which we obtained a list of total scores. Among those scores, the defibrillator scored the highest value (Total score = 0.470601297). Using the total score of the defibrillator as the maximum score, we got the normalized scores for all other equipments. Since the defibrillator has the maximum total score, its NSV is 1.

NSV (defibrillator) = $\frac{0.49337955}{0.49337955} = 1$

NSV (ICU Monitor) $= \frac{Total\ Score(ICU\ monitor)}{Max.Total\ Score} = \frac{0.3786472}{0.49337955} = 0.76745621$

TSV (defibrillator) = $\frac{NSV(Monitor\ ICU) - 0.1257592}{0.8742408} = \frac{0.76745621 - 0.1257592}{0.8742408} = \frac{0.64169701}{0.8742408} = 0.734004876$

Following the same procedure, we obtained a long list of medical equipments with their transformed score values (TSV).

The obtained list of medical equipments can be classified into many categories according to the prioritizing plan of the hospital, which is related to the budget assigned by the decision makers. In our study, the criticality of a device is classified into three categories in which a transformed score value should belong. The first category is for those which should be replaced urgently. The second one for those which should be replaced after a year and a half (their replacement can be limited to a deadline defined by the hospital according to their budget). The third one is for those which are still functioning normally and can work for several years to come. Using the transformed score value, we can sort the medical equipments according to their urgency using Table XIII.

TABLE XIII. THE CRITICALITY OF A DEVICE FROM THE TRANSFORMED SCORE VALUE.

Criticality class	Transformed Score Value	Maintenance Strategy
High	70% <TSV≤ 100%	To be changed urgently
Medium	30% < TSV ≤ 70%	To be changed after a year and a half
Low	0% ≤ TSV ≤ 30%	To be changed after three years

Before knowing the final scores of the medical devices under study, we cannot assign the suitable thresholds for the evaluation classes. Many factors contribute to the classification of the evaluation classes. One of these factors is the result obtained in the TSV list, the load of work in the hospital, and the rate of in-patient. On the other hand, thresholds should be adjusted after applying the model of inventory of a hospital [28] and studying the obtained transformed score values. The classes in the table below are suggested by Taghipour[16].

Generally speaking, we can classify equally the equipments of a hospital in the order of their urgent need for replacement. If the equipment's score is between 70% and 100%, it means that the equipment should be replaced immediately. If its score ranges between 30% and 70%, then the equipment should be replaced after a while. Finally, if its score is less than 30%, this means that the replacement of the equipments does not need to happen in the near future. This was an example on how to classify the results in a hospital. Keep in mind that we can consider other intervals to sort the tested devices according to the hospital's financial contribution.

The decision makers at the hospital, where the study was applied, set the interval of criticality to be between 65% and 100%. Therefore, referring to our example, the monitor in the ICU scores 73.4%, this belongs to the first class of criticality and should be replaced immediately.

VI. CASE STUDY

In this section, we are going to apply the assessment model on the medical equipments found in some units of a Lebanese hospital in order to evaluate them for an updating program.

The professional work hours needed to apply such a model varies from hospital to another. It depends on the number of units running in the hospital, which implies the variety of sections and fields we are dealing with, and the rate of in-patients in the hospital, which implies the load of work on the professionals and so their availability to cooperate with the ongoing study.

In this case, the study was launched in a public university hospital that includes 430 beds (in-patient treatment), 14 operation rooms, 15 units, and over than 1200 medical items. Besides, the medical staff was busy all around the clock and so scheduling appointments was barely possible. Over and above, because hospitals operate 24 /7 all over the year,

emergencies might take place at any time forcing us to reschedule for another appointment with the concerned doctor. On the other hand, the team was built up of four full-timers who dedicated four months working six days a week, six hours a day. This ended up with dedicating about 860 working hours.

All the above factors contribute to the achievement of the evaluation model in a specific duration. Consequently, we cannot define a common timeline for the application of this assessment mission, but we can set definite milestones for the process of whole project.

The whole process is depicted in Figure 5, where firstly, it is very important to start the study by getting introduced to the environment that we are going to work in, to know the units, the technicians, and most importantly, the medical equipments – the core of our study. Based on this step, we can build up our team, and assign the missions for the team members.

Once this stage is attained, the team should be ready to launch the investigation officially, by assigning an opening session that should be held with the presence of the chief of the Biomedical Engineering Department, the biomedical engineers, all the people in charge in all units, the technicians, and every person who work in contact with the medical equipments. The purpose of this session is to introduce the medical staff to the aim of our study and the importance of their cooperation and contribution in every single information they might offer. After the opening session, we need to check on the equipments by launching excessive rounds on floors.

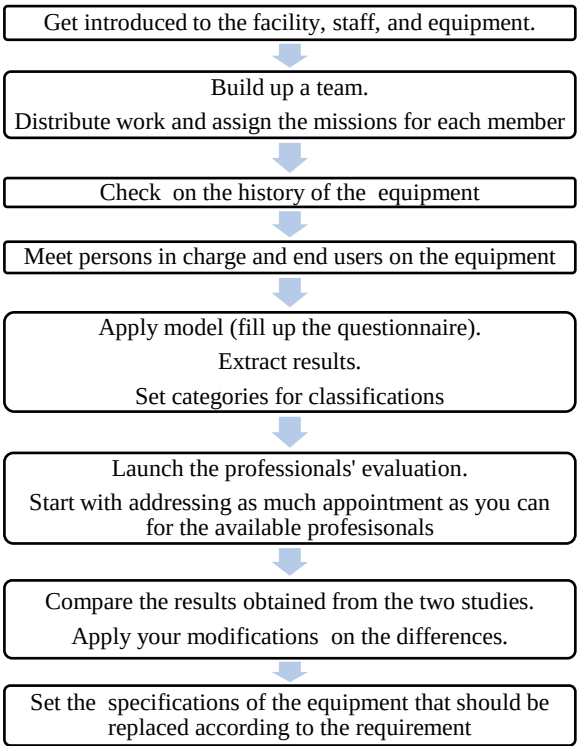

Figure 5. Flow chart showing the steps of the whole study.

This step lead to start filling up the data for the scientific evaluation by questioning the end users on floors. After gathering the required information, we can apply the scientific model theoretically to end up with a list of TSVs. With the help of the Biomedical Engineering Department, the suitable categories for the replacement plan can be classified. According to the list of results, scheduling appointments for the professionals' evaluation can be started.

At this stage, it is extremely important to respect the nature of work of the professionals that we are dealing with, as their job might require a lot of emergencies. Considering that they are on-call workers, rescheduling several times might occur.

At this level, two results emerge: the match between these two findings indicates the precision of the work, one being the user of the equipments and the other being the calculated total score value (TSV) based on the model. However, it is normal to highlight some differences in the ranking of the two results. We can align those expected differences by applying some modifications with the help of the chief of Biomedical Engineering Department, so that to end up with one unified list of equipments nominated for replacement according the classification defined before.

Finally, the specifications of the ordered equipments according to the requirements of the professionals can be addressed. This declares the end of the study, but they went further, by contacting medical companies for the best of their offers. Besides, they gathered the received offers and handled them to the biomedical engineering department and they took it from there. The whole process is illustrated in Figure 5.

In this study, in order to do the scientific evaluation, the researchers have chosen the Dialysis and the Critical Care Units as a sample study. These units normally have the Intensive Care Unit (ICU), which is dedicated to treat patients, who are seriously ill. Besides, we have the Coronary Care Unit (CCU), where patients with a pacemaker, intra-aortic balloon pump, or with cardiac telemetry are treated. Moreover, there is the Cardiac Surgical Unit (CSU), where patients having open-heart, lung, or vascular surgery are recovered. In addition, the Neonatal Intensive Care Unit (NICU) is the unit that monitors the neonates, who are facing newborn problems. Finally, the Pediatric Intensive Care Unit (PICU) is the intensive care specialized for pediatrics.

In these units, the team dealt only with the medical equipments that are in direct contact with the patient and that might affect the patients' safety. The equipments that are related to the ward medical equipments, housekeeping equipments, mortuary equipments, general furniture and accessories, are considered as not urgent at all so they are kept away from the study with "to be replaced after a determined period of time" as a general status. The team gathered the required data for 324 equipments distributed over 35 different items by questioning 24 of the end users,

most of them are physicians, nurses, and technicians, and five biomedical engineers who are responsible for the regular maintenance of those equipments. After the feedback of the above professionals, the results listed in Table XIV were compiled. As one can notice from the obtained results, the same item may record different grades when used in different units. For example, the ECG in the ICU records a grade of 57.35 whereas the ECG in the NICU recorded a grade of 42.88. These two different grades for the same item reflect the different mode of use and different urgency of that equipment at its unit.

TABLE XIV. SCORES AND GRADES FOR EACH ITEM.

Nb.	Name	Normalized Score	Transformed Score (%)
1	Defibrillator	1	100
2	Blood Gas system	0.84776143	82.563644
3	Pulse Oximeters	0.83167396	80.721096
4	Infusion pump (CCU)	0.80675075	77.866563
5	Monitor (ICU)	0.76745621	73.400487
6	Oximeters	0.76154527	72.689039
7	Syringe pump (ICU)	0.75121329	71.505686
8	Dialysis	0.74112659	70.350424
9	Monitor (CCU)	0.69471468	65.034724
10	**Monitor (Endoscopy)**	**0.68912238**	**64.394221**
11	**Syringe pump (PICU)**	**0.68817904**	**64.286177**
12	Refrigerator Pharmacy)	0.68541098	63.969142
13	Monitor (Dialysis)	0.68198543	63.576804
14	Incubator(PICU)	0.67304633	62.552981
15	Refrigerator (NICU)	0.66928522	62.122209
16	Refrigerator (PICU)	0.66928522	62.122209
17	Incubator (mobile)	0.66080627	61.151088
18	Syringe pump (floors)	0.65123852	60.055265
19	Incubator (Therapeutic)	0.64902559	59.801811
20	ECG (ICU)	0.62764624	57.353167
21	Fetal Monitor	0.62328606	56.853783
22	x-ray (ICU)	0.60806278	55.110213
23	Ultrasound Unit	0.59212049	53.284293
24	Reanimation & warming table	0.58451048	52.412695
25	ECG (CCU)	0.57761153	51.622536
26 *	**ECG (Dialysis)**	**0.56972919**	**50.719747**
27	**Infusion Pump (NICU)**	**0.56173091**	**49.80368**
28	**Infusion Pump (floors)**	**0.54855002**	**48.294032**
29	Lactina Electric pulse	0.52413795	45.498041
30	CPR	0.52413795	45.498041
31	ECG (NICU)	0.50133159	42.885958
32	Fetal Doppler	0.48090312	40.546222
33	Incubator (Delivery Unit)	0.43585151	35.386322
34	Otoscope	0.39837394	31.093899
35	Bair Hugger	0.24364574	13.372397

At this time, the team is able to make an educated decision. According to the hospital's budget, and with the help of head of Biomedical Department, three consecutive categories were set, each bounded within an interval of grades that matches the updating strategic plan of the hospital. In this case study, the three categories were assigned based on a strategic updating plan set by the hospital. The decision makers at that hospital were planning to spend a certain budget after the results of the study, and another amount after a year and a half and finally another amount after three years. Consequently, the coming three missions, as seen in Table XV, were set; the equipments with grades between 65% and 100% should be replaced directly. Those with grades between 50% and 65% can be replaced after a year and a half, and finally, those with grades below than 50% can be replaced after three years from the first updating plan.

Table XV. THE CRITICALITY OF A DEVICE FROM THE TRANSFORMED SCORE VALUE - CASE STUDY

Criticality class	Transformed Score Value	Maintenance Strategy
High	65% <TSV≤ 100%	To be changed urgently
Medium	50% < TSV ≤ 65%	To be changed after a year and a half
Low	0% ≤ TSV ≤ 50%	To be changed after three years

Based on the above three ranges of grades, one can summarize the three groups of medical equipments as shown in Table XVI.

TABLE XVI. RESULTS FOR THE UPDATING PLAN.

To be changed urgently	To be changed after a year and a half	To be changed after three years
High 70% <TSV≤ 100%	**Medium** 50% < TSV ≤ 70%	**Low** 0% ≤ TSV ≤ 50%
Defibrillator	Monitor (Endoscopy) *	Infusion Pump (NICU) *
Blood Gas System	Syringe pump (PICU)	Infusion Pump (floors) *
Pulse Oximeter	Refrigerator (Pharmacy)	Lactina Electric pulse
Infusion pump	Monitor (Dialysis)	CPR
Monitor (ICU)	Incubator(PICU)	ECG (NICU)
Oximeters	Refrigerator (NICU)	Fetal Doppler
Syringe pump (ICU)	Refrigerator (PICU)	Incubator (Delivery Unit)
Dialysis	Incubator (mobile)	Otoscope
Monitor (CCU)	Syringe pump (floors)	Bair Hugger
	Incubator (Therapeutic)	
	ECG (ICU)	
	Fetal Monitor	
	x-ray (ICU)	
	Ultrasound Unit	
	Reanimation & warming table	
	ECG (CCU)	
	ECG (Dialysis)**	

From the above table, the hospital can conduct a plan of three phases for upgrading its medical equipments. Each phase would be set along a period of time, according to the procurement process and the installation program that should be launched for each equipment based on its requirements.

VII. PROFESSIONALS' EVALUATION

To make sure that the obtained results are correct and the devices that are changed meet the hospital's requirements, a survey was designed that questions the physicians, the technicians, and the nurses, where the questions were about the equipments that should be replaced directly. Interestingly, a list that matched the above one, which was achieved by the scientific study, was obtained.

Since the aim of this evaluation is to check the validity of the scientific approach used, it was assumed that there would be some error within a short interval $\pm \varepsilon$. Consequently, the team expected to make some fine-tuning on the results obtained, especially for the equipments with grades close to the boundaries chosen. Hence, according to the evaluation of the professionals and of the persons on charge, one can add or remove an epsilon ($\pm \varepsilon$) to the grade of the equipments whose score is close to the boundaries of the intervals chosen, where epsilon is the discrepancy between the end user recommendation and the findings of our model. For example, the endoscopy monitor recorded 64.39%, so it should belong to the second category in the updating program. As we can notice here, even though 64.39% is very close to 65 but we cannot move it to the first category in the program. However, if the professionals, who work on the endoscopy monitor, recommended an urgent replacement for this monitor for specific reasons to be discussed, we can move it to the first category and add it to the equipments to be replaced directly. This will not be considered an error since the endoscopy monitor is on the boundary so it may belong to both categories.

On the other hand, this step played an important role on checking the accuracy of the results obtained. It also served on checking if the professionals recommend any additional new equipment that was not available at the hospital, and consequently not included in the study done.

Moreover, questioning the end user helped in setting out the desired specifications and requirements of the equipments to be replaced. To do so, two forms were designed: the first one is a general form to check if the units being questioned needed any equipment to be replaced, or if they recommended any new medical technology that they saw might raise the level of the medical care at their unit. The second form is a specific one to highlight the requirements and specifications of the desired equipments.

1) The General Form:

The aim of this form is to specify the list of equipments needed in each unit as suggested by the end users. In this form, the name of the requesting person and his/her position is identified, to make sure that his/her job description empowers him/her to suggest the medical technology used in the unit. The requester should provide his/her extension number so that the team can refer to him/her any time a clarification or further information is needed.

The main part of this form contains a table of three columns, the first column to list the name of the new equipment, the second column to specify if the named equipment is replacing an old one already found in the unit, and the third one to specify some details concerning the old equipment that is being replaced. The general form is shown in Appendix A (CED-F-03).

2) The Specific Form:

This form includes detailed information about each equipment named in the first form. In this form, care is taken about some other information related to the replacing decision, such as the clinical application of the named device, the accessories that should be provided with that device. Attention is also paid to underline some suggested

brands and models for that device with some external notes if required. Identifying a specific brand for each equipment serves in the purchasing process while making the decision among many several offers and budgetary quotations.

If the equipment under discussion is replacing an old one, then the third part of the form titled: "Old Equipment Identification" will be filled.

Finally, in the last part of this form that has many sections, some specifications concerning the new equipments are highlighted. The end user is asked to clarify the status of the old equipments that should be replaced; whether it is of old technology, obsolete, out of order, or affects patients' safety.

The other section of this part is designed to make sure that the nominated equipment satisfies the suitable conditions to meet the international standards for medical equipments. One of these conditions is that the equipment should comply with the actual clinical standards. Moreover, the requester should mention whether his/her recommendation is cost effective or not. Besides, some other specifications will increase the acceptance of the proposal, such as whether the equipment of the new brand results in a better patient care.

Following the above section, the frequency of use of the named equipment as well as we asked for the requirements of replacing it was probed. In this manner, a check is made whether this replacement requires new installation or whether it requires training of the staff.

On the other hand, the professionals have to justify the choice of the new suggested equipment. At this stage, it is preferable to list two to three other accredited hospitals using the proposed technology; this will empower the suggestion in hand. Finally, the value of each request according to the emergency status should be specified:

i. High – so that the equipment should be replaced immediately without any delay
ii. Medium – means the replacement is critical but can be delayed for a short period of time
iii. Low – means that the equipment has no harm on patient and the replacement can be postponed for a longer period of time.

The "Specific Form" is shown in Appendix B (CED-F-04).

3) Experimental Versus Theoretical Evaluation:

The "Professionals' Evaluation" served in checking the accuracy of the results obtained from the scientific study. Although this step made a slight change in the three categories obtained, it did not induce a fundamental change in the list of equipments chosen. As discussed in the example above, the endoscopy machine recorded a score close to the lower boundary of the first category, and hence can be kept in the second category, or can be move to the first one based to the evaluation of the main users of this machine.

After consulting with the chief of the endoscopy unit, and in the presence of the physician and technician working there, the above-mentioned two forms were filled. The results showed that the endoscopy monitor is seriously facing some technical problems and some unexpected failures form time to time, and hence needed to be replaced immediately.

Based on that evaluation, the grade of the endoscopy machine requires an ε upward, so that the grade becomes $64.39 + \varepsilon$, and hence can be included in the first category, raising the status of the endoscopy to an urgent call. The same thing is applied on the other equipments with grades close to the upper and lower boundaries.

At the end of this evaluation, some modifications were deemed necessary. Actually, these modifications were expected, as they were related to the medical equipments with grades close to the upper and lower boundaries of the three categories.

The endoscopy monitor and the syringe pump recorded 64.39 and 64.28, respectively, so they should belong to the second category. However, according to the evaluation of the end users and the technicians working on them, it was found that they constitute risks and should be replaced directly. Considering their grades, an ε can be added to each one and move them to the most critical category. Similarly, the professionals recommended a very soon replacement for the infusion pumps for the floors and the Neonates Intensive care Unit. Consequently, the infusion pump was moved to the second category with those medical equipments to be replaced after a year and a half.

On the other hand, the person in charge of the dialysis unit found that the ECG at their unit is functioning normally and there is no load on it, so the replacement of this equipment can be postponed for a longer period of time. However, the ECG recorded 50.71, which places it in the second category, but the recommendation of the second evaluation moves it to the third category of replacement.

It is worth noting that the questionnaire was filled by thirteen professionals in charge of the seven units under study, as shown in table XVII.

Most of those professionals' suggestions were the same as those obtained theoretically by the study. However, there was a slight mismatch between the results obtained by the

Table XVII: NUMBER OF PROFESSIONALS WHO ANSWERED THE QUESTIONNAIRE.

Unit	Number of professionals
Delivery Unit	2
Dialysis Unit	3
ICU	2
CCU	2
CSU	2
NICU	1
PICU	1

model and the recommendation of the persons in charge and this refers back to the reason that the user tends to recommend new technologies when it comes to his/her choice, whereas the quantitative results show reasonable real values. To better assess the correlation between the scientific and the professional's evaluation, let's denote by R the non-zero ratio of the scientific results to the professional one.

$$R = \frac{X+1}{Y+1} \quad (9)$$

where X is the number of equipments that should be replaced as obtained from the scientific model, and Y is the number of equipments that should be replaced as recommended by the professionals' evaluation. Getting R=1 means that there is a match between the equipments obtained by the scientific evaluation and those nominated by the professionals.

Figure 6 shows the ratio R for the seven units under study in the three assigned classes. As it is clearly shown in the graph below, there is a good match between the equipments ordered upon the scientific evaluation and those ordered by the professionals' evaluation and this is the case in the three critical units, ICU, CCU, and CSU. On the other hand, the criticality of some medical equipments was increased, as recommended by the professionals, such as the endoscopy monitors and the syringe pump for the PICU, which were classified in middle class by the model, yet were recommended by the professionals for an urgent replacement, so their criticality was boosted to the first class. Similarly, the infusion pump was classified theoretically, as third class in criticality, however, the professionals recommended an earlier replacement.

On the contrary, the ECG was moved from the second to the third class, as the professionals showed an acceptable satisfaction of its work as compared to other devices.

Referring to Table XIII, one can notice the four medical equipments that required a $+\varepsilon$ to their obtained grades, marked in bold face. Besides, the ECG that required a $-\varepsilon$ to its grade is also bolded.

At the end of the evaluation, the four equipments that required displacement from their category to an upper one were designated with a single asterisk (*), and those requiring moving to a lower category with double asterisks (**), as shown in Table XVI. The professionals' evaluation did not fundamentally change the results obtained from the scientific evaluation done before; yet, it introduced some little modifications – or fine tuning – to the equipments at the boundaries of the categories chosen. We cannot consider this change an error since it was expected to occur. Consequently, the professionals' evaluation served as an experimental tool to test the validity of the theoretical evaluation.

VIII. BUDGETARY QOUTATIONS

After updating the results, a list of equipments that should be replaced directly was compiled. At this phase,

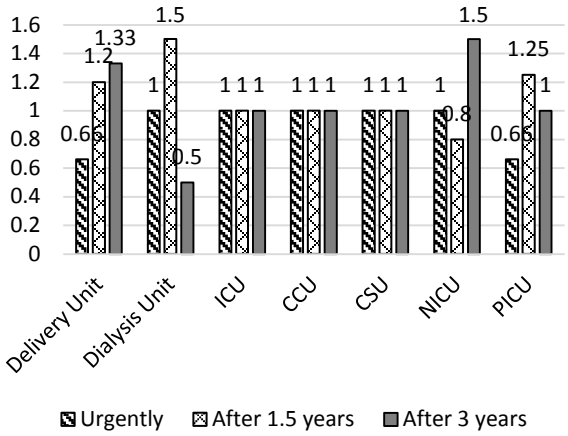

Figure 6. Ratio of the scientific evaluation to the professionals' evaluation

several companies were contacted asking for a budgetary quotation for each ordered equipment.

In the request, the specifications of the equipments needed to be replaced were identified. The description of that equipment and the unit to which it belongs were mentioned, as well as the minimal requirements and the quantity needed. Actually, mentioning the number of the ordered item was very effective from a budget aspect. Offers streamed positively with higher quantities of each item.

Besides, the ordered equipment should comply with the international standards for medical equipments, such as FDA approval or CE certificate. In addition, the electrical specifications were matched with the British standards, as recommended by the hospital. Finally, a budgetary price for the equipment and all the spare parts that may function with it were sought, as depicted in Appendix C.

After collecting the budgetary quotations received from several companies, the team listed them according to the best specifications and offers provided. Several offers from different companies were received for each piece of medical equipment, and that required some excessive meetings for the decision-taking committee at the hospital to come up with a verdict. At this level, the list was raised to that committee to decide on the equipments that best suit their demand.

Whenever the decision is made, the biomedical engineering department can launch the procurement process for purchasing the chosen medical equipments.

IX. CONCLUSION

Medical equipment is a critical interface between the patient and the diagnosis, the treatment, or the rehabilitation process. It provides an opportunity for a better medical service. Consequently, medical devices are expected to operate in the required way providing the ultimate results of accuracy, safety, and reliability for an efficient and healthy contribution. As such, this study provides a new model for

assessing the life of medical equipment based on its actual usage, and not only speculated based on its suppositional lifespan. This method would result in a more accurate scheme that would most probably extend the life and usage of the equipments thus resulting in substantial savings to the healthcare institution from one side, and would serve as an assessment tool based on a multi criteria decision-making approach from the other side.

Using such a model of evaluation, the wheel of change in the assessment of medical equipments can be turned to overreach several sectors in the world of machinery. Moreover, adapting an automated management system to monitor the evaluation of the medical equipments will be revolutionary move towards safety and efficiency. Furthermore, the proposal assessment approach would be further enhanced by using information technology, where the lifespan of the equipments may be monitored in real time. This can be addressed by integrating the equipments with information technology software and hardware through the usage of the internet. When done, precise and up-dated reports may be generated anytime and anywhere, to assess the present status of the equipments' lifespan.

X. APPENDICES

Appendix A:

Here is the general form for listing the medical equipment that should be replaced.

	Evaluation of Medical Technology Platform And Updates at RHUH	CED-F- 03	
	Medical Equipment Suggestion Form	Edition 1	Page 1/1

This form is to be filled upon suggesting equipments. Kindly, fill in the details and attach any additional documents if needed.

Requester Identification	
Department/ unit:	Name:
Extension Number:	Position:
Date:	

New Equipments	Replacing an Old Equipment(Yes/No)	Old Equipments

Signature: _____

Appendix B:

Here is the specific form for interpreting the reason of replacement and the specifications of the new recommended medical equipments.

	Evaluation of Medical Technology Platform And Updates at RHUH	CED-F- 04	
	Medical Equipment Suggestion Form	Edition 1	Page 1/1

This form is to be filled upon suggesting equipments. Kindly, fill in the details and attach any additional documents if needed.

End User Identification	
Department/ unit:	Name:
Extension Number:	Position:
Date:	

New Equipment Identification	
Equipment name:	Quantity Requested:
Clinical Application:	Sample brands and models suggested:
Accessories:	Notes:

Old Equipment Identification (if replacing)	
Brand:	Quantity Available:
Date of Purchase:	

Suggestion Justification
☐ The used equip. is of old technology/ obsolete ☐ The used equip. is out of order ☐ The used equip. affects the patient's safety
☐ The suggested equip. is cost effective ☐ The suggested equip. complies with actual clinical standards ☐ The suggested equip. is of better quality ☐ The suggested equip. is better for patient care ☐ Other reason:
Frequency of use:
Requirements: ☐ Training ☐ New Installation
Name of other hospitals using this new equipment: _____
Who can work on this equipment? _____

State of request: ☐ urgent ☐ normal ☐ can be postponed

Appendix C:

Here is the request as emailed to the companies for a budgetary quotation.

	Evaluation of Medical Technology Platform And Updates at RHUH	CED-F-05	
	Request for Budgetary Quotation and Specifications	Edition 1	Page 1/1

Item Identification	
Item Number	
Needed Item	
Description	
Department/Unit to be used in	
Minimal Requirement	
Quantity Needed	
Electrical Standards	B.S.
International Standards	FDA/CE or others to be specified
Special Requirements	Optional accessories shall be quoted separately

Remark: The supplier is kindly recommended to provide us with a budgetary price quotation, in addition to the technical specifications and details in hard soft copy (when possible).

Clinical Engineering Department

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