A Monte Carlo Simulation Based-Approach for Medical Equipment Risks Forecasting

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***Abstract*—As any technology, medical equipments provide benefits to patients, but they also present significant risks that can affect and compromise patient safety. In healthcare organizations, clinical engineering departments play a vital role in maintaining the safety and reliability of medical equipments. In order to mitigate failures of such equipments and control risks, a proper Medical Equipment Management Program (MEMP) should be established. The purpose of this paper is to forecast risks by using Failure Mode and Effect Analysis (FMEA) method and apply it on Monte Carlo simulation which adds risks analysis to Excel® by @RISK tool. The data of some medical devices is extracted from a hospital's maintenance management system and are identified according to their likelihood, severity, and difficulty of detection. However, the results of this mathematical simulation are integrated in a probability distribution function that enables us to identify medical equipments risks that affect patients, staff, and the work environment and reduce them by providing contingency plans, policies, strategies, and other risk management tactics.**

Keywords-medical equipment; risk management; FMEA; Monte Carlo simulation.

I. INTRODUCTION

As medical technology becomes more complicated, a MEMP must be deployed in healthcare facilities to ensure that medical devices operate according to safety, accuracy, reliability, and performance criteria. Maintenance is one of the most important processes to improve safety, decrease the risk of equipment failure, and minimize the unplanned downtime [1]. However, the money spent on maintenance and failure of equipment is rapidly increasing because of the development of many types of complex medical equipments, the stringent environment they are operating under, and the lack of proper management.

The management program includes a risk management process, which comprises the identification, assessment, and prioritization of risks (defined in ISO 31000 as the effect of uncertainty on objectives) followed by coordinated and economical application of resources to minimize, monitor, and control the probability and/or impact of unfortunate events [2]. The causes of the risks are identified and relevant changes in the system are made accordingly in order to reduce the probability of the error occurring in the future thus reducing harm to patients and providing a safer patient care experience.

Most healthcare organizations follow the manufacturer's recommendations concerning the maintenance program [3]. Campbell and Jardine [4] defined the maintenance excellence as the balance of performance, risk, resource inputs and cost to reach to an optimal solution. In the last decade, maintenance techniques have been notably improving, but most of the healthcare organizations do not profit from the maintenance excellence that Campbell and Jardine established. Moreover, some devices that are similar in their function and design have manufacturer-recommended intervals that vary by one or two factors thus leading to potential financial and time losses. In addition, excessive maintenance can have the same impact as an insufficient level of maintenance; moderation should be the rule.

The status of research on maintenance of medical devices is presented in different models. A model proposed by Fennigkoh and Smith [5] classified equipments according to three parameters: function, physical risks, and maintenance requirements. It was known later as risk-based inclusion criteria that allowed clinical engineering professionals to apply maintenance on limited parts of medical devices.

Ridgway, in the beginning, noted that Preventive Maintenance (PM) is an important factor in terms of reliability, but later on, he indicated that PM does not prevent failure for all equipment and it is not the ideal solution. However, Ridgway provided methods for equipment management such as Reliability Centered Maintenance (RCM). This technique is a corporate-level maintenance strategy that is implemented in any healthcare organization to optimize the maintenance program. Endrenyi [6] indicated that RCM selects the critical component in the equipment and initiates a maintenance management process to correct the failure. Further on, he recognized that RCM is good for indicating the budget and for comparing policies, but it cannot help in achieving real optimization.

According to Hall [7], the two keys of RCM are having a good maintenance history of the medical equipment and the age of the equipment. Furthermore, he indicated that RCM is applicable for younger equipments. However, to balance

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between preventive and corrective maintenance, Condition Based Maintenance (CBM) is presented to observe and forecast real-time status of machines [7]. CBM is performed when some indicators show that the equipment will fail.

Taghipour et al. [8] presented a multi-criteria decision-making model to prioritize medical devices according to their criticality. Furthermore, in terms of prioritization, Jamshidi et al. [9] developed a fuzzy healthcare failure modes and effect analysis (HFMEA). HFMEA is a systematic method that identifies and prevents equipment problems before they occur by ensuring a safe and clinically desirable outcome [10].

To minimize risk and optimize the cost-effectiveness of medical equipment, a maintenance model is suggested by Khalaf et al. [11]. They evaluated both elements and the results showed poor performance concerning cost and risk management. Therefore, Khalaf et al. [12] developed a new model in order to be used in Palestinian hospitals, which is a mathematical model that uses a mixed integer based approach for maintenance operations schedules for medical equipments. They also proposed a greedy algorithm for an initial solution for the model. In addition, some data extracted from maintenance history of infusion pumps and ventilators were used in a global model that measures the probability of equipment being available and they were analyzed using Matlab. However, this model was validated by developing a model that measures the survival of equipment as function of maintenance and age of equipment using survival analysis approach.

The studies reported above proposed models that share a common theme; different risks are calculated using a single measure that is defined and applied to lead safety, performance inspections, and preventive maintenance activities. These models are simple to use and effective in reducing general risks; yet they lack the ability to identify specific risks. They are far from achieving optimal risk minimization. Also, research into comprehensive frameworks for prioritizing critical medical devices or outsourcing of medical device maintenance is still in its infancy. Researchers should apply new risk-based maintenance models including different new uncertainties to replace the traditional empirical models. Existing advances in risk management for other disciplines should be investigated and taken advantage of.

In our model, a Complete Risk and Decision Analysis Toolkit from Palisade: "The Decision Tools Suite" is used. It is an integrated set of programs for risk analysis and decision-making under uncertainty that runs under the popular Microsoft Excel®. The main tool that was used is @RISK, which adds risk analysis to Excel® using Monte Carlo simulation. The Monte Carlo simulation is a technique used to understand the impact of risk and uncertainty in financial, project management, cost, and other models to identify risks related to medical equipments [13]. FMEA method was also used to prevent failure of equipments. Data related to maintenance and failures of equipments was obtained from a Lebanese hospital to apply it in our proposed model in order to verify and validate its functionality, applicability, and performance.

The proposed methodology is presented in Section II. The implementation process is presented in Section III. This latter, includes collecting data, and integrating FMEA method using Monte Carlo simulation. This is followed by results and discussion summarized in Section IV. Finally, a conclusion and our further expectations are presented in Section V.

II. METHODOLOGY

Medical devices are used in healthcare organizations to support patient care in terms of health and safety. Currently, modern medical devices are complex and operate under severe conditions because of the rapid development and evolution of equipments due to substantial advances in technology. Most of the existing strategies in hospitals have difficulties and challenges in identifying risks and applying optimal risk reduction activities because they lack proper management processes. Therefore, a well-operated management process could be expected to enhance the functioning of medical devices across different healthcare organizations.

The proposed model is meant to identify and assess risks of medical equipments according to q mathematical approach using different parameters. It starts with collecting data concerning medical devices from the healthcare institution in question; a Lebanese hospital in our case. The needed numbers such as the likelihood, detectability, and impact of medical equipment failure are then extracted and analyzed.

There are several methods to calculate the risk value, yet the FMEA method is used as the preferred choice in the current model. FMEA is selected among other methods because it contributes to improved designs for products and processes, to cost savings, and to the development of control plans, testing requirements, optimum maintenance plans, reliability growth analysis and related activities [14]. Furthermore, it is a well-established and widely used method in many other disciplines and has been proven to be effective and efficient by numerous researchers. The FMEA procedure starts with determining the ways in which the input can go wrong, and then determining effects for each failure mode. After that, it identifies potential causes for each mode and list current controls for each cause. Consequently, a risk priority number can be determined and contingency plans and actions should be developed accordingly.

After applying the FMEA method, it will be integrated in Monte Carlo simulation tool that includes @Risk toolkit. @Risk adds risk analysis to Excel® using Monte Carlo simulation. Then the simulation will be performed and the results will be assessed to draw a conclusion.

The methodology may be summarized in the following flowchart:

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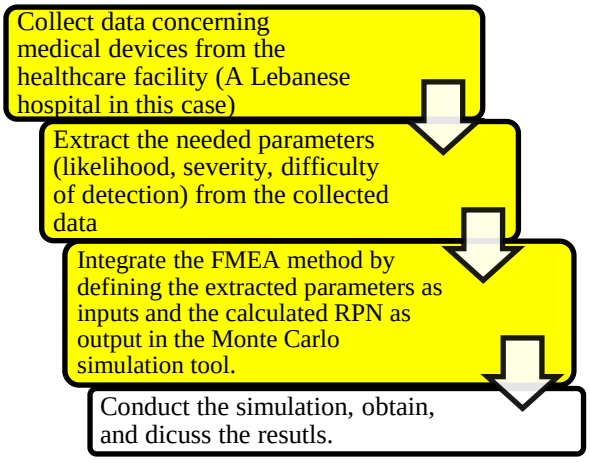

Figure 1. The proposed methodology

Fig. 1 summarizes the required steps to accomplish our evaluation. Such assessment requires some parameters and equations. The derivations of all those relations are explained in the subsequent sections.

III. IMPLEMENTATION PROCESS

A. Collecting and Extracting Data

First, to apply the FMEA method, specific data concerning medical devices is collected.

Likelihood of the medical device in this case is the probability of failure of the machine. Fig. 2 shows the number of repeated failures per year with respect to medical devices. These numbers are then converted to a scale of 1-10 as shown in Table I using the following equation:

Number of repeated failures*(10/ Highest number of repeated failures)

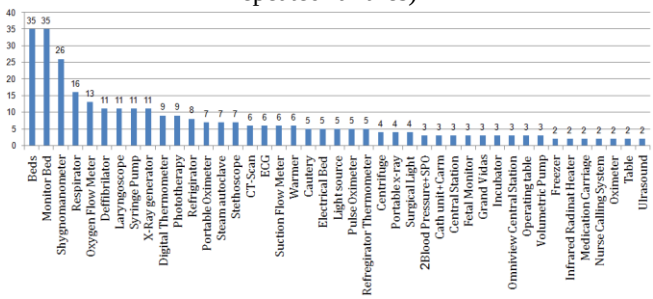

Figure 2. Number of repeated failure.

The scores of likelihood of medical devices failures are assigned according to the following criteria [15]:

{1, 2}: Improbable, manifestations of the hazard are very unlikely

{3, 4}: Remote, manifestations of the hazard are possible but not likely

{5, 6}: Occasional, some manifestations of the hazard are likely to occur

{7, 8}: Probable, hazard will be experienced

{9, 10}: Frequent, hazard likely to occur

Severity of medical device is defined as the extent to which the defect of equipment can affect patients. The scores of severity are assigned according to the following criteria [15]:

{1, 2}: Negligible, no significant risk of injury

{3, 4}: Minor, potential for minor injury

{5, 6}: Moderate, potential for minor injury

{7, 8}: Critical, potential for severe injury

{9, 10}: Catastrophic, likely to result in death

Detection is the ability of the current control scheme to detect and then prevent a hazard from occurring. The scores of detection are assigned according to the following criteria [11]:

{1, 2}: Almost certain (detection probability is between 81-100%), potential hazard will almost certainly be detected

{3, 4}: High (detection probability is between 51-80%), high chance that potential hazard will be detected

{5, 6}: Moderate (detection probability is between 26-50%), moderate chance that potential hazard will be detected

{7, 8}: Low (detection probability is between 10-25%), low chance that potential hazard will be detected

{9, 10}: Remote (detection probability <10%), very remote chance that potential hazard will be detected

TABLE I. EXTRACTED PARAMETERS.

Equipment	Likelihood	Severity	Difficulty of Detection
Beds	10.00	6	1
Sphygmomanometer	7.43	5	1
Defibrillator	3.14	10	4
Ultrasound	0.57	3	3

All values of likelihood, severity, and difficulty of detection of equipment were provided by the hospital. Table I shows the scores of likelihood, severity, and difficulty of detection for twenty-six medical devices on a scale of 1-10.

B. Integrating FMEA Method in Monte Carlo Simulation Tool

The parameters extracted from the collected data will be employed in a systematic technique called FMEA.

FMEA is one of the first highly structured, systematic techniques for failure analysis. It was developed by reliability engineers in the late 1940's to study problems that might arise from malfunctions of military systems [16]. It is a step-by-step systematic approach for identifying all possible failures in a design, a manufacturing or assembly process.

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Failures are prioritized according to how severe their consequences are, how likely they may occur and how difficult is it to detect them. The main purpose of the FMEA is to take preliminary actions to reduce failures, starting with the highest priority ones [17].

In order to quantify the risk value, a Risk Priority Number (RPN) is used as a measure when assessing risk to help identify critical failure modes. The RPN values range from 1 (absolute best) to 1000 (absolute worst). It is the product of three ratings on a scale of 10 (likelihood of occurrence, severity of impact, and difficulty of detection):

$$RPN = Likelihood\ x\ Severity\ x\ Difficulty of Detection$$

Table II illustrates the extracted parameters and the calculated RPN for each equipment:

TABLE II. CALCULATED RPN.

Equipment	Likelihood	Severity	Difficulty of Detection	RPN
Beds	10.00	6	1	60.00
Sphygmomanometer	7.43	5	1	37.15
Defibrillator	3.14	10	4	125.60
Ultrasound	0.57	3	3	5.13

After calculating the risk priority numbers, the model is now ready to be integrated in the @Risk simulation tool. The first step is to insert Table II in an Excel® sheet and define inputs (likelihood, severity and difficulty of detection) as normal distributions. Usually, high standard deviation is selected in situations where resources are limited or gathering real data would be too expensive or impractical. In this situation, the data is extracted from a real hospital management system, hence a very small standard deviation is selected (0.1); as depicted in Fig. 3:

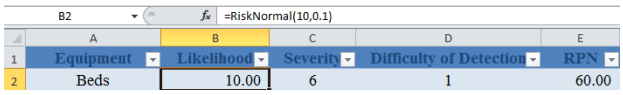

Figure 3. Definition of inputs as normal distributions.

RPN is the output in our model; Fig. 4 illustrates how RPN is defined as an output in the Monte-Carlo simulation tool "RiskOutput("RPN")":

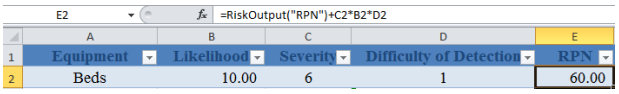

Figure 4. Adding @Risk output.

C. Simulation and Results

@RISK monitors a set of convergence statistics on each output distribution during a simulation. During monitoring, @RISK calculates these statistics for each output at selected intervals (such as: every 1000 iterations) throughout the simulation.

As more iterations run, the amount of change in the statistics becomes less and less until they reach the Convergence Tolerance [18].

Convergence tolerance specifies the tolerance allowed for the statistics being tested. For example, the current applied settings specify that the estimated mean of each output is simulated within 3% of its actual value [18].

In our model in Fig. 5, we will be performing 5000 iterations in one simulation:

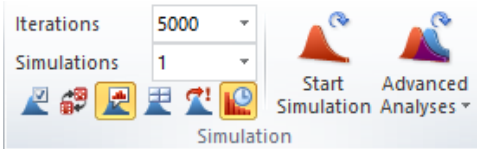

Figure 5. Changing the number of iterations and starting simulation.

At the end of the simulation, the results are integrated in a probability distribution function. A probability distribution is a statistical function that describes all the possible values and likelihoods that a random variable can take within a given range [19]. This range will be between the minimum and maximum statistically possible values, but where the possible value is likely to be plotted on the probability distribution depends on a number of factors, including the distributions mean and standard deviation.

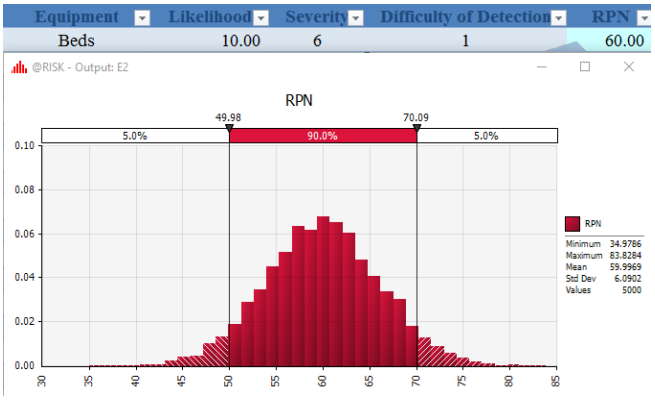

Figure 6. Results after simulation.

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Fig. 6 illustrates one example of the results obtained; the risk priority number of hospital Beds (60) is centered between 49.98 and 70.09 for 90% of the probability distribution. The x-axis represents the possible risk priority numbers and the y-axis represents the probability of occurrence for each probable RPN incrementing by 0.02 on a scale of 0.1.

IV. RESULTS AND DISCUSSION

The result of the Monte Carlo Simulation via @RISK is a probability distribution. Figs. 6 and 7 show the probability density for the chosen examples: beds and defibrillator.

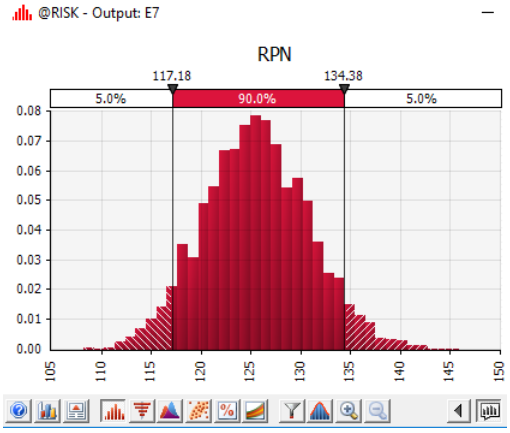

Figure 7. Probability distribution for defibrillator.

TABLE III. SUMMARY OF THE RESULTS.

	Beds	Defibrillator
Minimum	34.97	108.23
Maximum	83.82	145.19
Mean	59.99	125.6

The results presented in Fig. 6, Fig. 7, and Table III are interpretable as follows:

1. The mean figure for RPN will be 60 for beds and125.6 for defibrillator. That means, the simulated result will be equal to the original calculated RPN.
2. The minimum figure for RPN will be 36.57 for beds and 108.23 for defibrillator. This means that the minimum probability will be lower than the calculated RPN by 23.43 for beds and by 17.37 for defibrillator. But these figure are the bottom lines and will only be achieved if all negative circumstances would occur. Hence, with a probability of 5 %, the figure for RPN will fall low to 36.57 and 108.23. In other words, with a probability of 95 % the RPN will not fall below these numbers.
3. The maximum value for RPN will be 85.69 for beds and 145.19 for defibrillator. That is, the maximum probability will be higher than the calculated RPN by 25.69 for beds and by 19.59 for defibrillator. But these figures are the upper limits and will only be achieved if all positive circumstances would occur. Hence, with a probability of 95 %, the figure for RPN will not exceed 85.69 and 145.19. In other words, with a probability of 5% the RPN will exceed these numbers.

An additional evaluation is possible to show where an individual risk has a main influence of the final risk priority number. Figs. 8 and 9 show the results of those evaluations as regression coefficients. This indicates that the difficulty of detection has a huge influence of the RPN of beds and the likelihood has the higher influence on the RPN of the defibrillator. Therefore, these risk factors have to be monitored very carefully within an effective healthcare management system.

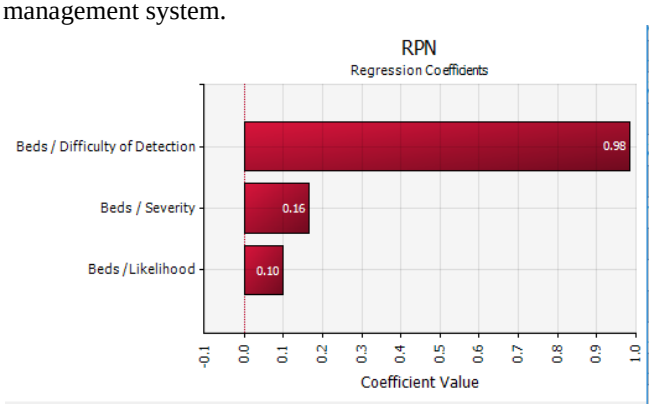

Figure 8. Regression coefficients for beds.

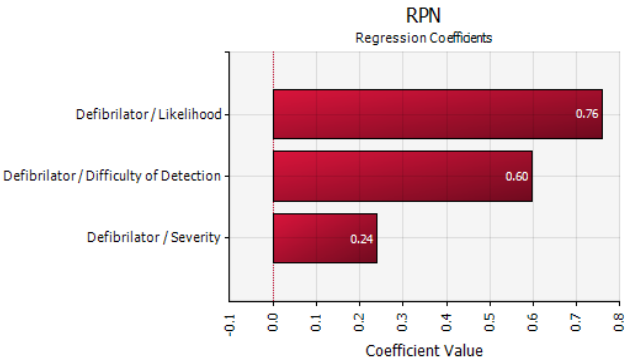

Figure 9. Regression coefficients for defibrillator.

Finally, a risk severity matrix is employed to raise awareness and increase visibility of risks so that proper decisions on certain risks can be made. The risk matrix is shown in Fig. 10. Once the risks have been placed in the cells of the matrix that corresponds to the appropriate likelihood, severity and difficulty of detection, it becomes visibly clear as to which risks must be managed at what priority. This is a well-known and widely used tool in the world of risk management.

Each of the risks will fall under one of the categories, for which different colors have been used. Here are some details on each of the categories:

High: The risks that fall in the cells colored in red are the risks that are most critical and that must be addressed on a high priority basis. Example: 'D' Defibrillator.

Medium: If a risk falls in one of the yellow zone, it is best to take some reasonable steps and develop risk management strategies in time, even though there is no hurry to have such risks dealt with early. Example: 'B' Sphygmomanometer and 'C' Beds.

Low: The risks that fall in the green cells can be minimally monitored and managed as they usually do not pose any significant problem. However, if some reasonable steps can help in fighting these risks, such steps should be taken to improve overall performance Example: 'A' Ultrasound Machine.

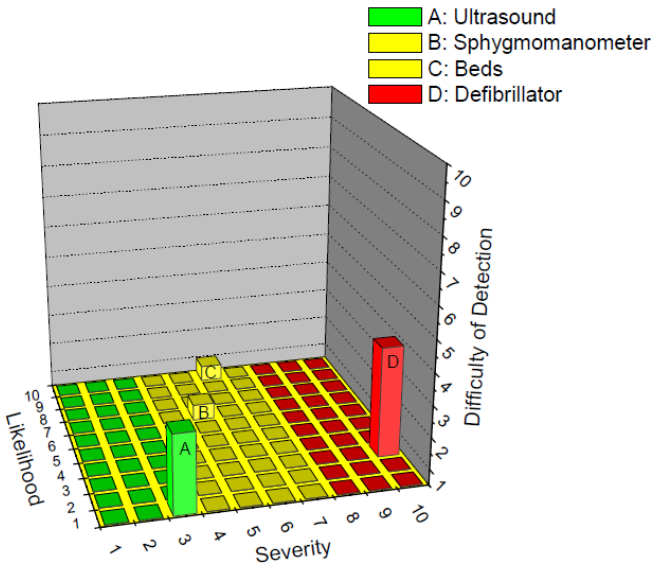

Figure 10. Risk severity matrix.

After analyzing the results, some recommendations could be deduced to reduce risks such as having alternative or redundant devices in the healthcare facility, pay special attention to the to the life span of the equipment and its working hours when purchasing used devices, and to have a well operated maintenance program.

V. CONCLUSION AND FUTURE WORK

The rapid evolution of medical equipments had a huge impact on the improvement and progress of medical services. Accordingly, medical devices are expected to operate under stringent safety, accuracy, and reliability criteria to ensure a protected and efficient environment for patients, staff, and the surrounding work setting. As such, this research work provided a new methodology for identifying and assessing risks based on a mathematical approach and not only empirical ones. This method results in a more precise scheme that would most likely reduce the risks resulting from medical equipments and further provide proper management practices in healthcare organizations. Moreover, this model can be integrated in healthcare facilities to identify and forecast risks according to risk distribution of Monte Carlo simulation and risk severity matrix that classifies and prioritizes medical devices risks.

This proposed assessment maybe further enhanced to achieve risk response development, and risk response control of medical equipment by developing a complete tool that can be used in the medical equipment industry across the world. Thus, manufacturers, organizations, and clinical engineering departments can use this tool in planning for maintenance and for the development of medical equipment. Also, it can be deployed as monitoring system in service at healthcare facilities where it can provide real time data on the risks of operating medical equipment. Another venue for future work in this area would involve further research in the field of optimal outsourcing of medical devices.

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