



## A Proposed Framework to Determine the Reliability and Spare Parts Replacement for Medical Devices

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### ABSTRACT

The lack of malfunction of medical equipment has the potential to significantly impact the medical industry and pose a threat to the well-being of billions of individuals globally. Subsequently, maintenance services are executed to ascertain that the equipment is functioning following the standards set by the manufacturer and upheld at the desired level of quality. Downtime resulting from equipment breakdowns can significantly impact the operational efficiency of equipment, leading to decreased output, heightened operating expenses, and disruptions in customer services. The main objective of this conceptual framework is to explore on the spare parts replacement and their impact on the maintenance function of the health system. The proposed approach uses the Failure Mode and Effects Analysis (FMEA) method to identify potential failures effectively. It will describe how obtained scores are used to set up guidelines for appropriate spare parts replacement for improved maintenance strategies. To forecast the demand for spare parts for medical devices, this paper proposes a semi-supervised learning algorithm to solve the problem. Through the use of data-driven insights and predictive analytics, machine learning algorithms can enhance decision-making processes about the timing and selection of spare parts replacement.

## 1. Introduction

According to WHO Global Model Regulatory for Medical Devices, Section 2 of Act 737, "medical device" means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material, or other similar [1]. Developing and implementing a well-defined spare parts replacement for medical devices is crucial to ensure healthcare equipment's availability, functionality, and reliability. It supports the smooth operation of healthcare facilities and helps maintain patient safety and quality of care.

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In the context of the Malaysian government, in 2021, there was no clear policy on the use and replacement period for medical equipment in public hospitals. According to the 2019 Auditor General Report Series 2, which revealed that 24,098 pieces of medical equipment categorized as Beyond Economic Repair (BER) or more than 20 years old were still being used in 144 hospitals without proper maintenance [2].

Over the course of the device's lifespan, total maintenance costs typically are higher than the device's cost of acquisition. Most developing nations recognize a similar situation, particularly Malaysia, whereby the Ministry of Health's asset values for medical equipment came to RM7.775 billion in the Auditor's General Report from 2016 to 2020. There are many old medical equipment in Malaysian public hospitals, and as these devices get older, so does the price of maintenance. Among the active medical device population, 40.7 percent has been in use for fewer than ten years, 39.7 percent for eleven to twenty years, 16.7 percent for twenty to thirty years, and 2.9 percent for more than thirty years yet remain in use. High maintenance costs highlight that medical equipment is often engaged in patient incidents that lead to grave injuries and deaths. Medical device reliability is paramount in the healthcare industry as it directly affects patient safety and outcomes [2]. A reliable medical device consistently performs its intended functions without failure or error when used according to its specifications. Some factors contributing to medical device reliability are design and manufacturing, quality assurance, regulatory compliance, testing and validation, post-market surveillance, maintenance and servicing, user training and competency, feedback and improvement, device tracking and traceability, and collaboration and industry standards [3].

The probability that medical equipment will carry out its intended function for a given amount of time, or the device's capacity to work without malfunction and predict future effectiveness, is known as medical device reliability analysis. It is reported that up to 80% of medical equipment presently used in public health organizations is worn out or obsolete, making it challenging to guarantee reliability and efficiency and the safety of medical equipment [4]. According to the World Health Organization (WHO), an absence of a maintenance schedule, a lack of expertise, and an inclination to prioritize corrective maintenance over preventative maintenance account for between 50 and 80 percent of equipment's continued equipment malfunction. Regular maintenance and inspections of medical equipment can help identify potential safety hazards, prevent equipment malfunctions, and ensure that the equipment provides accurate readings. It involves preventive maintenance, including cleaning and lubricating equipment, checking for wear and tear, and ensuring safety protocols are followed.

Maintenance is a key area within the Industry 4.0 concept. Indeed, equipment maintenance can significantly impact the uptime and efficiency of entire devices. The hospital's biomedical and clinical engineering departments are generally responsible for inspecting and managing medical equipment maintenance, ensuring that equipment breakdown and accidents made during diagnosis and treatment are avoided. As one of the proposed solutions, this paper aims to evaluate the criticality of medical devices and develop a framework for assessing the replacement of spare parts for medical equipment in the event of an unexpected and rapid breakdown.

## **2. Literature Review**

One definition of reliability is dependability, and the International Electrotechnical Commission (IEC) describes dependability as "availability effectiveness and its contributing variables: reliability performance, maintainability performance, and maintenance support performance." Various studies were held and implemented concerning the failure of medical equipment, and spare parts replacement programs are presented in this section. For instance, Individuals experiencing cardiac

arrest unexpectedly can get life-saving electrical shocks from Physio-Control's LIFEPAK 15 heart monitor and defibrillator, which also helps to restore their heart's regular rhythm. In January 2017, the American manufacturer of portable defibrillators was compelled to recall 139 apparatus units. This occurred after it was found that the device might not be able to provide the charged shock necessary to bring a patient out of cardiac arrest due to electrical malfunctions. According to the Food and Drug Administration, there might be death, brain damage, or irreversible organ damage if the shock is not administered promptly. Indeed, the insufficient upkeep and deterioration of medical equipment give rise to danger levels that are deemed intolerable. The primary concerns for healthcare organizations at present are the risks associated with the use and maintenance of medical devices.

[5] The research by Emmerling *et al.* evaluates the current condition and operational effectiveness of medical equipment at hospitals located in Honduras, Rwanda, and Cambodia. The study's primary objective was to identify the obstacles and challenges associated with repairing and maintaining such equipment. The newly given equipment lost 4% of equipment effectiveness during the shipping process, while the other donated equipment saw the highest loss of 5% of equipment effectiveness during the installation phase or shortly afterward. During the use process, both donated and acquired equipment had an extra loss of 15% in terms of equipment. The aggregate of donated equipment had a notably higher rate of equipment being out-of-service compared to the equipment purchased directly by the hospital. The research posits that implementing training programs for local technicians and adopting equipment lease arrangements may provide a more sustainable and efficacious approach than conventional equipment donation or outright purchase practices.

[6] A.B. Khalf offers a mathematical framework for evaluating the impact of maintenance on the likelihood that medical equipment will survive depending on maintenance history and age. The model underwent testing using empirical data obtained from infusion pumps and ventilators. The findings indicate that using preventative maintenance measures may significantly enhance the longevity of the equipment. Preventative maintenance (PM) and corrective maintenance (CM) impact the likelihood of equipment availability.

[7] Anthony *et al.* develop a mathematical maintenance cost model for the maintained system. The model aims to present a predictive-maintenance structure for a deteriorating system, including optimal inspection and replacement decisions. The results show that optimizing the maintenance policy by finding the preventive replacement (PR) threshold and inter-inspection time function that minimizes the long-run expected maintenance cost rate can lead to cost savings. The deterioration model used in the study is based on Gamma stochastic processes and follows minimal hypotheses on the actual deterioration process.

[8] Patricia *et al.* proposed a methodology for replacing advanced medical equipment (MEs) using economic assessment and business process analysis in their study. The technique has three key components: cost-effectiveness analysis, intermediate effectiveness analysis, and process workflow analysis. Additionally, the research paper examines a specific instance involving the replacement of sterilization equipment inside a hospital setting. The findings indicate that replacing equipment can enhance the process and reduce costs. The authors conclude that the use of this technique has the potential to enhance the effectiveness and excellence of healthcare services while also enabling cost-effective decision-making within management.

[9] Selin *et al.* propose a predictive maintenance architecture using big data technologies for healthcare services. The researcher aims to improve the quality and efficiency of healthcare services by integrating information technologies, social networking technologies, digitization and control of biomedical devices, and big data technologies. The methods allow data analysis results to predict the device's health status and real-time maintenance schedules through device notifications and live

charts. Real-time notifications and live charts may also ease biomedical device tracking virtually, managing the devices' conditions by looking at their current situations and early behaviors.

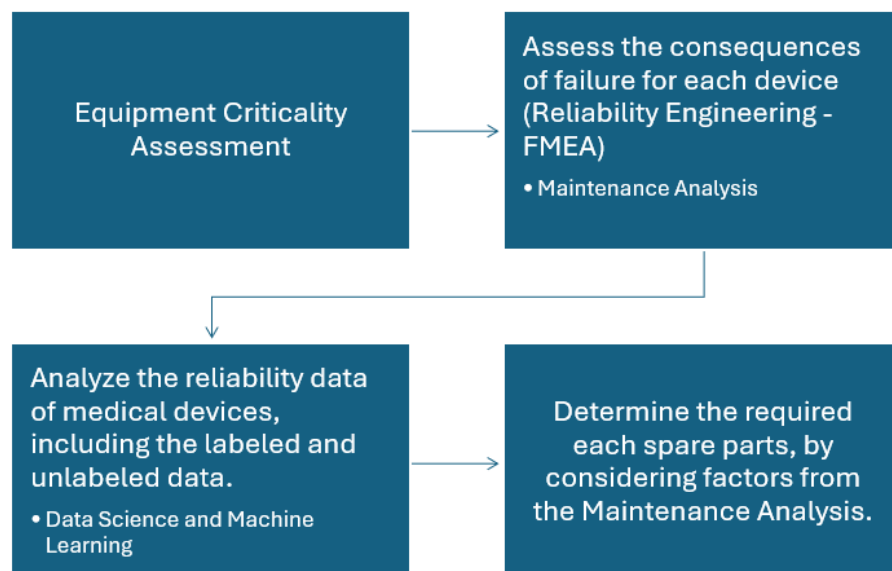
[10] In this study, Salim *et al.* provide a conceptual framework that utilizes Reliability Centred Maintenance (RCM) to effectively identify the underlying causes of failures and reduce their frequency. The RCM (Reliability Centred Maintenance) process encompasses many vital stages, including data preparation, analysis, task selection, and job comparison and review. The efficacy of the maintenance program may be evaluated by conducting a comparative analysis of the frequency of equipment failures before and after its implementation. Reliability Centred Maintenance (RCM) can decrease superfluous maintenance chores and mitigate breakdown occurrences if performed with efficacy [11].

This study addresses identified gaps based on the literature review as follows:

- i. None of the studies combined failure of assessment and spare parts replacement for medical equipment.
- ii. None of the studies consider the impact of different maintenance strategies on risk failure prediction.
- iii. There is limited work on spare parts demand forecasting in the maintenance and repair field, particularly to replace the new equipment

### 3. Proposed Work

This proposed framework uses reliability data analysis to determine the spare parts replacement methods for medical equipment. The cause of the breakdown is first identified for the solution to identify the high risk of equipment failure. The FMEA process is then to be implemented. The spare parts replacement is to recommend a new process, wherein this context is the new maintenance program in computerized maintenance management system (CMMS) for medical devices, by comparing it with the current practice of maintenance services.



**Fig. 1.** The proposed process flow-chart to determine spare parts replacement for medical devices.

From the FMEA data, different equipment with the same failure is identified. The RVP score from the FMEA is used as the selection for the critical risk. Reliability data from the maintenance work are used to comply with the machine learning method to identify spare parts inventory management.

### 3.1 Reliability Factors

Using reliability analysis in medical equipment may enhance the equipment's operational availability and efficiency. The process of identification of possible issues inside equipment is facilitated, and recommendations for enhancements may be generated as well. By identifying potential causes of failure in medical equipment, reliability analysis lowers the possibility of malfunctions that could endanger patients' well-being by reducing the possibility of unfavorable events or patient injuries and ensuring that medical equipment functions as designed. Additionally, it aids in enhancing the caliber of patient treatment and mitigating expenses linked to upkeep and repairs.

Reliability analysis may also help identify possible dangers linked to the use of medical equipment and guide how to mitigate such risks. Furthermore, this assessment can monitor and assess the long-term functionality of medical equipment, enabling the identification of patterns and tendencies in its performance. Hence, reliability analysis can potentially enhance the equipment's operational efficiency and guarantee its optimum performance [12].

**Table 1**  
Factors of Reliability of Medical Devices

No	Reliability Factors	Description
1.	Materials and components	High-quality, durable, and medically approved materials are essential for long-lasting and dependable devices.
2.	Testing and quality control	Identifying and addressing potential defects and weaknesses in the devices.
3.	Maintenance and services	Regular maintenance and servicing of medical devices.
4.	Electrical safety and grounding	Preventing electrical hazards and ensuring reliable device operation.
5.	Environmental considerations	Temperature, humidity, and exposure to liquids or chemicals.

The lack of maintenance in ensuring dependability, availability, and safety has a detrimental effect on the quality of healthcare services. This issue also has a notable influence on operational expenditures. In this study, five (5) reliability factors will be taken into consideration in FMEA. The factors are (i) materials and components, (ii) testing and quality control, (iii) maintenance and services, (iv) electrical safety and grounding, and (v) environmental considerations.

### 3.2 Failure Mode and Effects Analysis (FMEA) Steps

Failure Mode and Effects Analysis, also known as FMEA, is a systematic way of assessing and ranking probable modes of failure in a system, good, or procedure together with their possible impact on their overall performance and efficiency. Numerous sectors, like production, aviation, healthcare, and more, employ FMEA extensively. The main objective of FMEA is to strategically detect and mitigate risks and increase comprehensive performance and reliability. To make the process of maintenance of medical equipment more efficient, it is necessary to consider the use of a maintenance program for the equipment that takes into account its characteristics and the defects that appear in the medical equipment [14].

**Table 2**  
Failure Mode and Effects Analysis (FMEA) Steps

Process	Description
Analysis of product	10 devices were used in this study.
Identified potential failures	The failures of each of the devices are identified.
Evaluate the frequency and severity.	Determine the RPN and the severity of the failure.
Evaluation of the problems	Identify the cause of the problem from the maintenance report.
Identification of the correction action	Calculate the FR and MTTR for the reliability analysis.

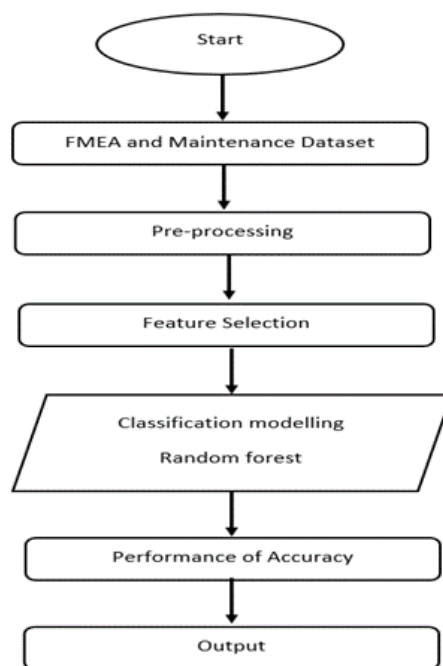
In this framework, the FMEA is a tool for assessing the risk, failure, faults, or errors of medical devices. There are three main factors for scoring namely, Detection, Severity, and Occurrence, and results in the risk priority number (RPN) that can score each device by that. The effect or repercussions of a failure mode on the system, procedure, or consumer are represented by its severity. A scale of 1 to 10 is usually used to grade it, with 1 denoting a minimal influence and 10 denoting serious consequences. There is more potential danger the higher the severity level. The failure mode's probability or rate of occurring is evaluated by occurrence. Additionally, a scale of 1 to 10 is used to grade it, with 1 denoting a low possibility and 10 denoting an elevated possibility. An increased occurrence rating indicates a greater likelihood of the failure mode occurring. The possibility of identifying the failure mode before it affects the end consumer or causes danger is assessed by detectability. It is scored on a scale ranging from 1 to 10, corresponding to severity and occurrence, where 1 denotes high detectability (easy to detect) and 10 denotes low detectability (difficult to detect). Devices with lower critical risk scores are assigned a lower priority in a maintenance management program. However, risks with higher scores will be investigated in detail to find the reasons for finding an appropriate spare part replacement.

This study describes ten (10) devices with their failures; the devices are ventilators, defibrillators, dialysis machines, infusion pumps, pacemakers, anesthesia machines, MRI machines, CT Scanners, incubators, and surgical lasers. Then, they will assess based on three main factors of FMEA: occurrence, detection, and severity. The main research question of this study is as follows:

1. What are the main failures of medical devices related to their applications?
2. Which sub-factors are the most influential in the three main criteria of FMEA?
3. How could spare parts replacement be prioritized using the FMEA?

### 3.3 Spare Parts Replacement

Medical equipment is usually composed of a variety of parts, which are categorized into parts that significantly impact the equipment and parts that have less impact on the equipment. A component is critical if its failure effects are massive to the equipment. The medical equipment replacement decision is typically based on three (3) criteria: (i) technical, (ii) financial, and (iii) safety [15].



**Fig. 2.** Proposed work of Spare parts replacement [16]

The use of machine learning has substantial potential in the optimization of spare component replacement strategies for medical equipment. Through the use of data-driven insights and predictive analytics, machine learning algorithms can enhance decision-making processes about the timing and selection of spare parts replacement. This proposed framework uses a semi-supervised learning algorithm to solve the problem of replacement of medical device spare parts [17]. The forecasting model developed includes critical variables such as the number of breakdowns that cause parts to change, the number of periodic maintenances, the mean time between failures, and demand quantity in previous years [18]-[19].

Spare parts replacement strategies for medical devices are crucial for maintaining reliability and performance. They must employ appropriate strategies, including intervals for maintenance activities. The selection and availability of spare parts for each piece of equipment are important for the reliability of the devices [20]. However, little research has been presented in the literature to address the proper strategies and methods for selecting spare parts replacement for medical devices. Machine learning can significantly improve the selection of spare parts for medical devices. It can predict which parts will fail first, allowing for timely replacements and minimizing costs associated with procurement and replacement [21]. Data-driven approaches can analyze maintenance data, predicting part repair states as "Efficient," "Repaired," or "Replaced." Semi-supervised learning techniques can improve the accuracy of demand prediction by combining maintenance and spare part information [22].

#### 4. Discussion

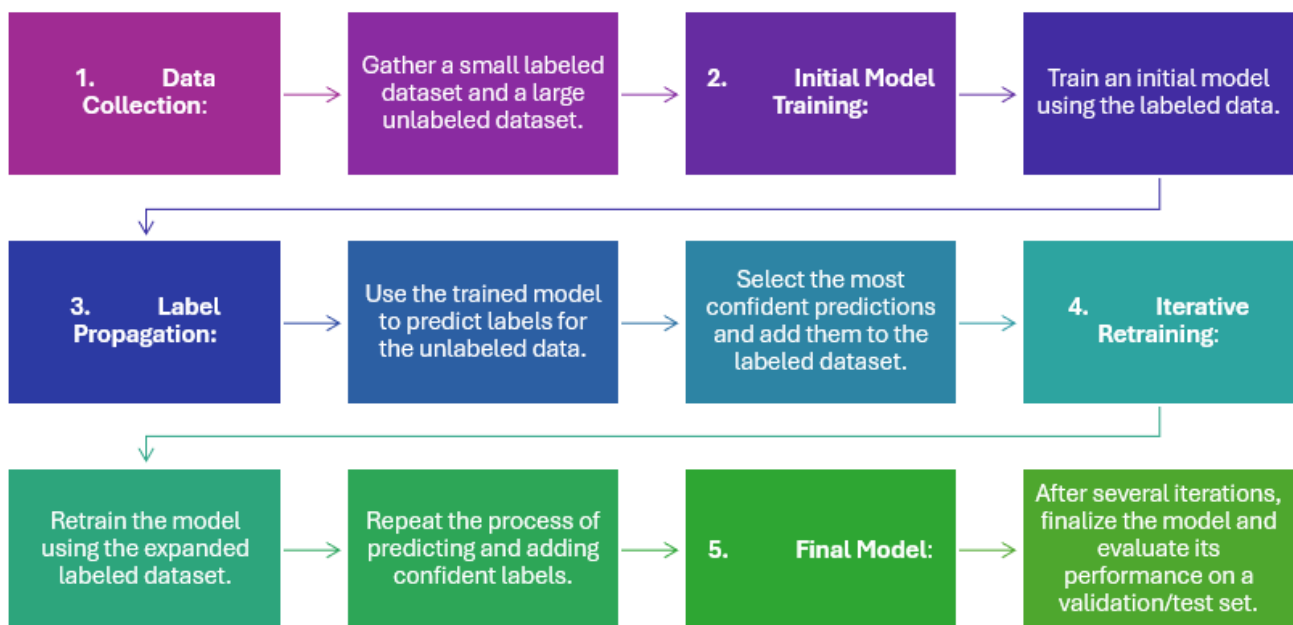
This proposed framework will help the biomedical engineer determine the priority of the spare part replacement and assist the hospital's technical department in identifying the root cause of the medical equipment failure. The main contributions of this research compared to previous studies are as follows:

1. Understanding the factors contributing to failures and planning replacements accordingly.

2. Machine learning to determine the optimal time to replace a part based on factors. This prevents premature replacements and extends the lifespan of parts.
3. Allows for proactive replacement before a breakdown occurs, minimizing downtime and reducing the chances of catastrophic failure.

This is the first study to investigate risk factors (occurrence, severity, and detection). Then, the risk factor is used to estimate the spare parts replacement for the high RVP. It will describe how obtained scores are used to set guidelines for appropriate spare parts replacement for improved maintenance strategies.

In this study, a spare parts replacement model will be developed to solve the reliability problem of medical devices in hospitals. The frameworks will be tested only once based on the FMEA analysis of the devices. It is important to state that this framework could be customized for maintenance agencies to organize their PM programs for different healthcare organizations. Moreover, the proposed framework for a spare parts replacement model for the reliability of medical equipment can be used as an assessment tool that could impact equipment management decision-making within the clinical engineering department. Figure 3 shows the process workflow that will involve a machine-learning approach.



**Fig. 3.** Process workflow for machine-learning approaches

## 5. Limitations

Medical devices and equipment may be used frequently for some time or may be idle for a long time. This leads to the aging of equipment no longer becoming regular, the maintenance time of spare parts is not fixed, and the number cannot be too small to meet the maintenance needs. The prediction of medical devices' spare parts has become particularly important.

The study focused on predicting spare parts consumption based on a limited set of factors, such as the name of the spare parts, the urgency of maintenance, and the annual usage of maintenance. Other factors influencing the consumption of spare parts that were not considered in this study could affect the accuracy of the predictions.

## 6. Conclusion

Rapid technological advances have led to the development of a broad range of medical equipment that offers better healthcare services to diagnose, treat, and mitigate an illness or a disease. Preventive maintenance is considered one of the most critical stages throughout the medical equipment life cycle that should be adequately managed. Machine learning methods have been developed for demand forecasting due to the variability and uncertain nature of the concept. This approach will support the precision and suitability of the clinical engineer's decision-making process in case of equipment failure. Future work will focus on collecting data from more CMMS to meet the proposed approach's aim and objectives.

The results obtained from the research are expected to benefit the biomedical maintenance management personnel and the academicians involved in the maintenance and management of the medical equipment industry. The benefits provided through the research are:

- i. The research eases the maintenance management team's selection and planning of planning strategies for a particular piece of equipment.
- ii. The research helps the maintenance team determine the replacement of spare parts.
- iii. Identification of cost-related variables for maintenance strategies, which can help management allocate a sufficient budget for maintenance activities.
- iv. The study is able to contribute its research findings to the body of knowledge in biomedical and academic industries, demonstrating the importance of maintenance strategies and maintenance performance.

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