

Machine learning and failure mode and effects analysis for sustainable medical equipment spare parts management

Fabian Halley Pata Alban Dattu¹, Syed Tarmizi Syed Shazali², Shirley Johnathan Tanjong²,
Abdul Rani Achmed Abdullah², Nurlaila Rosli³

¹Department of Mechanical Engineering, Faculty of Engineering and Technology, i-CATS University College, Kuching, Malaysia

²Department of Mechanical and Manufacturing Engineering, Faculty of Engineering, University Malaysia Sarawak,
Kota Samarahan, Malaysia

³Faculty of Computing and Software Engineering, i-CATS University College, Kuching, Malaysia

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ABSTRACT

Spare parts for essential medical equipment are vital to ensure uninterrupted healthcare provision, especially in areas where resources are limited. This paper presents an integrative approach that integrates failure mode and effects analysis (FMEA) with supervised machine learning (ML) models in order to allow better predictive maintenance and optimize management of spare parts. In order to increase the accuracy of the forecast, FMEA was first used to compute risk priority numbers (RPNs) of the components, quantifying the risk of each component, and then using it as an important input feature to the ML algorithms. Data from six hospitals and ten critical medical devices, such as ventilators, defibrillators, dialysis machines, and computed tomography (CT) scanners, were analyzed to identify high-risk failure modes and prioritize maintenance tasks. Three different supervised learning models (random forest (RF), artificial neural network (ANN), and support vector machine (SVM)) was built and tested based on four metrics: accuracy, precision, recall, and F1-score. The precision of RF and ANN was 1.00 and SVM showed an excellent recall value of 0.94, indicating promising results for practical applications. The solution proposed consists of a hierarchical decision system, connecting risk assessment carried out by experts with data-driven forecasts, to create proactive and sustainable management of spare parts. This approach helps healthcare entities lessen the risk of equipment breakdowns, adhere to international healthcare standards, and increase system reliability and efficiency.

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Corresponding Author:

Fabian Halley Pata Alban Dattu

Department of Mechanical Engineering, Faculty of Engineering and Technology, i-CATS University College
Stampin Timur Street, Kuching, Sarawak 93350, Malaysia

Email: fabian.halley@icats.edu.my

1. INTRODUCTION

Industrial health care operations have to be able to run without interruption, and access to critical medical device spare parts is essential for this. Medical equipment such as ventilators, infusion pumps, and defibrillators requires spare parts, and in some instances, the parts are not available or delivered on a time-consuming basis, leading to a significant deterioration of patient care and operational failure [1]. In many healthcare environments, the requirement for service is high, and equipment operates at a high intensity, so organizations need to focus on the need for constant access to critical parts of medical equipment [2]. Spare parts planning and maintenance strategies were previously based on scheduled-based and react-based approach but failed to take into account the operational conditions and risk variables [3].

These limitations result in ineffectiveness, as well as higher costs and unexpected machine downtime. The healthcare industry relies on predictive as well as data-driven techniques with machine learning (ML) methods to improve maintenance procedures and spare part supply chains [4]. Supervised ML has the potential to give manufacturers an efficient modelling capability by learning from data sets, which include predefined information about maintenance records, usage hours, environmental conditions, and failures [5]. The models produce forecasts for potential failures, which enable proactive spare part inventory management to reduce healthcare facility downtime and enhance delivery.

Failure mode and effects analysis (FMEA) works hand-in-hand with these processes and is the systematic approach to identify and evaluate medical device failure modes and determine their criticality. FMEA carries out component criticality assessment, which provides useful information for features of ML models, including priority failure areas and common failure points [6]. FMEA and ML is a combination that allows enhancement of failure prediction and also provides risk-dependent targeted spares part provisioning strategies [7]. The objective of this study is to assess the effect of supervised ML techniques to improve the availability of critical medical devices by combining the FMEA analysis to increase the prediction and prioritization of failures. The specific objectives are to i) apply FMEA to identify high-risk components and prioritize potential failure modes and ii) develop supervised ML models to predict spare part needs.

A limited number of studies have been conducted in the literature that involve FMEA and supervised ML for strategic spare parts management of critical medical equipment. The combined methodology is useful to build healthcare systems that are stable in limited resource environments where equipment failure poses a risk to patient safety [8]. This study focuses on the following research questions:

- i) RQ1: can integrating FMEA-derived risk scores with supervised ML models improve spare parts prediction accuracy?
- ii) RQ2: which supervised model best balances precision and recall for critical component forecasting?
- iii) RQ3: how can this predictive framework support sustainable maintenance planning?

This study differs from the previous studies on the use of ML and FMEA separately by proposing an ML-FMEA framework where the risk-prioritized features are intrinsically integrated into predictive models using real data from multiple hospitals. This integration not only delivers predictive accuracy but also provides operationally interpretable insights, combining the power of expert judgement with data-driven forecasting.

2. LITERATURE REVIEW

Availability of critical medical equipment spare parts is essential to ensure continuous healthcare services and patient safety. Availability of components can be a source of delay and cause major disruption in operations, which can compromise critical care delivery [9]. The healthcare industry has traditionally been dominated by traditional maintenance methods, which are typically based on reactive or scheduled maintenance. However, these methods are not adaptive to real equipment conditions or to new types of risk patterns that might arise, resulting in inefficiencies, high costs, and unforeseen machine downtimes [10].

In recent years, to overcome these challenges, healthcare organizations have turned to predictive and data-driven maintenance strategies. ML techniques have been widely adopted in the industrial and manufacturing domain for predicting equipment failures based on the historical operational data, particularly, supervised learning models have been used [11]. Recent research has shown how effective AI-driven predictive maintenance frameworks can be in the area of infrastructure and facilities management, with the potential to boost asset reliability, minimize downtime, and facilitate data-driven maintenance decisions [12]. Leveraging models like random forests (RF), support vector machines (SVM), and neural networks, supervised ML has started to be used in healthcare to not only assist in the diagnostic process but also in the operation of healthcare facilities, such as monitoring equipment health and managing resources [13]. These models can be used for proactive maintenance scheduling and inventory planning, based on the prediction of the potential failure of components from the historic maintenance records, the sensors, and the environmental conditions [14].

However, predictive models in healthcare environments are mainly applied to clinical data, and predictive infrastructure maintenance, in particular for spare parts management, is an emerging research field [15]. While ML can enable powerful predictive analytics, effective spare parts forecasting also needs structured risk prioritization to make sure high-criticality parts are properly monitored [16]. AI-based decision support systems developed under the Industry 4.0 paradigm have been widely applied to maintenance planning, operation optimization, and asset lifecycle management to provide structured intelligence to support complex engineering decisions [17].

FMEA is a systematic way to identify possible failure modes in complex systems and to also be able to identify risk by using risk priority number (RPN) methodology [18]. The RPN is a quantitative evaluation

of the criticality of the component in terms of severity, occurrence, and detection and provides a structured framework for prioritization in maintenance and spare parts provisioning [19]. In the health-care setting, FMEA has traditionally been used to improve evaluations of equipment safety and maintenance planning [20].

Recent research indicates that combining the output from FMEA with ML models can also enhance the performance of predictive maintenance by prioritizing the learning of the algorithm to the most important failure areas [21]. This integration has been tried in manufacturing and aerospace, but it is not fully utilized in the area of spare parts management in healthcare [22]. Additionally, deep learning models for predictive maintenance have been shown to greatly enhance the performance of asset management in non-industrial areas like finance, where advanced AI models can be applied to diverse asset-intensive sectors [23]. Furthermore, the adoption of sustainable management practices with technical efficiency, cost-effectiveness, and long-term operational resilience is increasingly recognized as part and parcel of modern healthcare systems [24]. This study fills the gap in existing research and presents a novel approach of using RPN scores obtained from the FMEA with supervised ML algorithms to predict the need for replacement of critical medical devices' spares. The proposed framework is a blend of data-driven techniques and risk-based prioritization, with the objective of enhancing the availability of spare parts, maximizing equipment uptime, and ensuring sustainable healthcare operations.

Table 1 provides a summary of some relevant studies in the past few years regarding the use of ML and FMEA techniques for predictive maintenance and parts management. Although the use of ML for fault detection and manufacturing applications has been shown to be useful in previous research [11], [24] few studies have systematically considered using FMEA risk metrics together with supervised ML models for healthcare spare parts prediction. Previous studies look at either an overall predictive maintenance model without risk prioritization [25] or FMEA improvement without the ML components [6]. To fill this gap, this study presents a hybrid ML-FMEA method based on real data provided by the six hospitals, involving critical medical devices and comparing the results of various supervised learning models to improve the prediction of spare parts needs.

Table 1. Summary of related works on ML and FMEA for predictive maintenance and spare parts management

Reference	Application	ML techniques	Integration with FMEA	Key findings	Identified gaps
Mahale <i>et al.</i> [24], 2025	Automotive predictive maintenance	RF and SVM	Not applied	ML models achieved high accuracy in detecting faults based on operational data.	Lacks integration of risk analysis for spare part prioritization; focused on automotive.
Lambán <i>et al.</i> [25], 2022	Industry 4.0 and 5.0 maintenance	Hybrid AI models	Not applied	Proposed predictive frameworks for various industries.	Frameworks are conceptual; do not reflect actual CMMS data or outcomes of the spares.
Soltanali and Ramezani [6], 2023	Safety-critical systems	FMEA enhancement	Yes (Smart FMEA)	Proposed smart FMEA for risk prioritization in Industry 4.0.	No integration with ML algorithms to support predictive spare parts planning.
Kausik <i>et al.</i> [11], 2025	Manufacturing quality assurance	SVM and ANN	Not applied	Comparative study of ML performance metrics for quality prediction.	No prioritization of risks, and medical equipment context.
This study	Critical medical devices	RF, ANN, and SVM + FMEA	Yes (hybrid framework)	Achieved 1.00 accuracy and improved recall using FMEA features for spare parts prediction.	Bridges AI modelling to risk-based maintenance in healthcare based on actual CMMS data.

3. METHOD

Figure 1 illustrates a research methodology employed to construct a predictive model for the management of spare parts in medical equipment, emphasizing sustainability, and efficiency. This study outlines the approach to developing a predictive spare parts management system for medical devices using ML. The research begins with the establishment of main objectives and a literature search to find out the current practices and limitations. Records on maintenance and failure of six important medical equipment such as ventilators, defibrillators, dialysis machines, and infusion pumps were obtained from six hospitals. The collected data enable FMEA execution by identifying main failure modes with critical components. The maintenance data collected ranged from extensive amounts of preventive maintenance schedules, corrective work orders, fault descriptions, device specifications, component failure history, and FMEA-derived risk scores. The data for this analysis came from the computerized maintenance management system (CMMS) platforms in 6 hospitals for the 2018-2023 period.

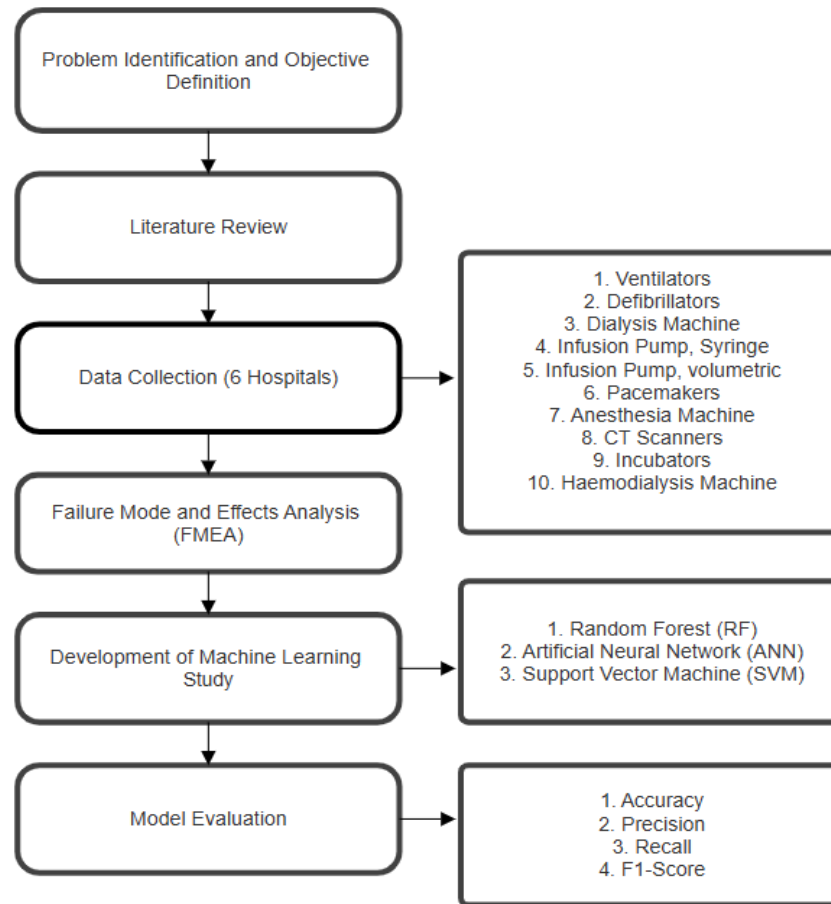


Figure 1. Research framework for predictive spare parts management in medical devices using ML

The detail of the data (timestamps, device ages, maintenance histories, and description of faults) and the richness of the data also play an important role in the performance of the model. Ventilators, defibrillators, dialysis machines, CT scanners and infusion pumps were chosen because they are important to patient care. With high-quality and consistent data, supervised learning models can identify complex relationships between component degradation and the need for replacement, further enhancing failure prediction capabilities. The FMEA-based ML workflow used in the study is shown in Figure 2. The workflow starts with the data from the CMMS, which is followed by the severity, occurrence, and detection assessment, RPN calculation, feature encoding, ML, model development, and finally the prediction of spare parts.



Figure 2. FMEA-based ML workflow

The severity (s), occurrence (o), and detection (D) scores presented by the experts during the FMEA were encoded numerically and normalized before the training of the model. A composite risk feature $RPN = S \times O \times D$ was calculated and used as the RPN. Each individual sub-factor and the resulting overall RPN were assessed as inputs into the ML models so as to capture granular and holistic risk information.

The FMEA is used to create an ML study utilizing three models, such as RF, artificial neural network (ANN), and SVM. First, these models are designed to forecast possible fault to optimize

operational efficiency. These models are then evaluated in terms of their accuracy, precision, recall, and F1-score to assess their performance. This approach would facilitate a structured maintenance process and promote the sustainable management of healthcare equipment, minimizing downtime and optimizing the use of spare parts.

The data for this study was gathered from the six hospitals during the five-year period (2018-2023) for ten crucial medical devices. A total of 1,016 maintenance records were extracted, which included attributes like device name, failure description, FMEA scores (SOD), RPN, preventive maintenance histories, device age, and device type. The output label was the spare part replacement status, which was "replacement required" or "no replacement required". The data was partitioned into 80% training data and 20% testing data for creating and testing ML models.

RF, ANN, and SVM algorithms were used for the model development. The RF model was set up with 100 estimators (trees), maximum depth of the trees was set to 10, and the impurity measure was set to Gini. The ANN was a three-layer network with 64, 32, and 16 neurons, respectively, with a rectified linear unit (ReLU) activation function and trained using the Adam optimizer with a learning rate of 0.001 for 100 training epochs. The SVM was trained with a radial basis function (RBF) kernel, which was used to capture nonlinear relationships in the data. These configurations were chosen to be a balance of model complexity, training time and prediction capability.

The dataset was randomly partitioned into 80% training data and 20% testing data before training the models. The data was scaled and encoded as necessary to accommodate ML algorithms. Supervised learning models were trained with input parameters including the type of device, work order trade, work order status, fault description, and FMEA risk scores, and the output label was whether or not spare parts replacement was needed. Grid search was used to fine-tune hyperparameters and maximize performance. The performance of the models was evaluated on the unseen test data and results were computed using confusion matrices of the predicted and actual lab values; using the accuracy, precision, recall, and F1-score.

To strength external validity, leave one hospital out validation strategy was implemented. A total of five hospital data were used for training and the rest was used as an unseen test set in each iteration. It was performed in the same manner for all six hospitals, which enabled to generalize the model for the various healthcare environment. To prevent overfitting and to make sure that the performance of the models was properly evaluated, a 10-fold cross-validation method was used for all supervised learning models. To check the accuracy of the proposed method, the data set was divided randomly into 10-folds; 9-folds were used for training and 1-fold for validation in each iteration. Performance metrics (accuracy, precision, recall, and F1-score) were calculated for each fold and the result is reported as a $\pm$ mean standard deviation of all folds.

The study combined structured FMEA results with sophisticated ML architectures to create a predictive maintenance framework that is able to predict spares with a high level of accuracy. This systematic approach builds on traditional risk assessment, but also uses powerful data-driven risk assessment tools to improve the accuracy of the forecast, in keeping with the intent to create a sustainable and pro-active medical device management system. A paired t-test was used on the cross-validation results to determine if the differences in performance between the models was statistically significant. The null hypothesis was that there was no model that performed significantly better than the others. A significance level of $p < 0.05$ was adopted. The findings substantiated the conclusions of the comparative evaluation and showed that the proposed hybrid and ensemble models yielded statistically significant results as compared to the base models.

4. RESULTS AND DISCUSSION

Table 2 is a systemization of various critical failure modes that have been identified as a result of FMEA studies, such as ventilators, as well as infusion pumps, CT scanners and pacemakers. Failure categories were shown in a separate row in Table 1: mechanical component failure, power failure, sensor malfunction, and software error. It also contains the devices involved with these failures, their RPNs and ML characteristics for prediction analysis. These values in the RPN represent the severity and the danger of failure modes, and can thus inform the maintenance teams which failure modes have to be dealt with first. The mechanical component failure has the highest RPN of 216 and manufacturers are advised to pay more attention to the forecasting of spare parts and preventions to this most critical fault.

Although FMEA is a structured method for risk prioritization, it is subjective and static because severity, occurrence, and detection scores can be different in different institutions and vary with time and rely on expert judgement. This means that traditional FMEA alone may not be sufficient to reflect the changing failure patterns in complex healthcare settings. When processing past maintenance records, the ML features, such as asset description, WOTrade, and work status, are included, affecting the learning capability of the model. These properties allow the system to identify patterns such as extended periods of mechanical failure and sensor readings; patterns that it correlates with specific devices and repair trades. The predictive system optimizes maintenance planning by predicting part needs, minimizing system downtime.

Table 2. Failure modes and ML features for spare part prediction in critical medical devices

FMEA failure mode	Device(s)	RPN	ML features	Relevance to spare part prediction
Mechanical component failure	Ventilator	216	AssetDescription, WOTrade, WorkStatus	The most common mode of failure: the model detects repetitive asset-trade patterns associated with component substitutions.
Power failure	Incubator, Pacemaker, Infusion Pump	144-168	AssetDescription, WorkStatus	Model identifies assets and tasks where power disruptions impair device functionality, resulting in the necessity for spare parts.
Sensor malfunction	CT Scanner, Pacemaker	168, 147	AssetDescription, WOTrade	The model identifies devices and transactions related to recurring sensor-based problems requiring replacements.
Software error	Pacemaker	147	Problem descriptions, WorkStatus	Available problem descriptions indicate jobs initiated by programming or control malfunctions.

The ML identification of asset failure modes that significantly impact spare part needs is shown in the last column of the table. This document acts as a bridge between traditional risk assessment and maintenance preparation based on data. Model evaluation was done based on the models' predictive performance as presented in Table 3. Standard metrics derived from the model predictions on the testing dataset were used to evaluate the models, as described as follows.

Shapley additive explanations (SHAP) have been used to enhance interpretability at both the global and local level. SHAP values provide a sense of the individual's contribution of each feature to the prediction and allow to clearly understand why a particular spare part replacement decision was made. This interpretability layer enables biomedical engineers and maintenance managers to bridge the gap between the model output and clinically and operationally meaningful factors to boost confidence, audibility, and the practical adoption of the proposed framework. The RF model's SHAP summary plot is shown in Figure 3. Figure 3 shows the contribution of AssetDescription, Problem_Description, AssetNumber, WorkStatus, and WOTrade to the prediction output. The value of each feature is represented by the absolute SHAP value; larger values mean that the feature has a greater impact on the model; positive (negative) values mean that the feature increases (decreases) the probability of predicting the need for the spare part replacement.

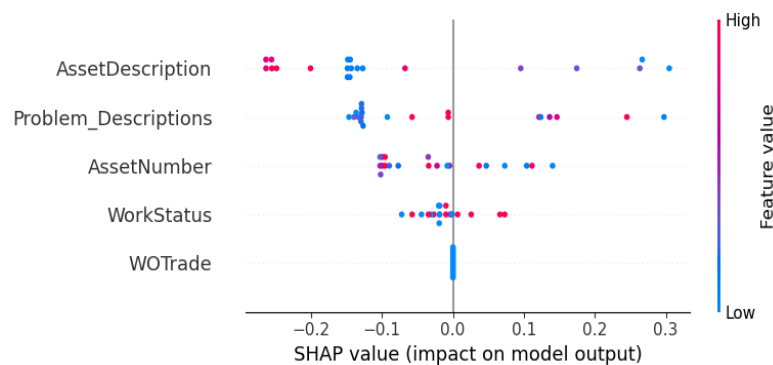


Figure 3. SHAP summary plot for the RF model

The evaluation metrics accuracy, precision, recall, and F1-score were calculated based on the predictions made by each ML model on the testing dataset, which comprised 20% of the total maintenance records. For each record, the model predicted if a spare part replacement was necessary and compared these labels to the actual outcomes. Based on this comparison, the number of true positives (TP), true negatives (TN), false positives (FP), and false negatives (FN) were obtained and used to calculate the performance measures. Accuracy is the overall correctness of the model, precision is the percentage of predicted replacements that are correct, and recall is the percentage of needed replacements that are correctly predicted. As the F1-score is the harmonic mean of precision and recall, it indicates that there is a balance between the number of replacements correctly identified and the number of false alarms. These metrics do not only measure the correctness of the overall model, but also a detailed assessment of how well each model can be used for predictive maintenance and planning of spare parts.

Table 3 presents three predictions of essential medical equipment spare parts that have come from an ANN and RF along with SVM. The determination of the predictive accuracy and dependability of the models is done using accuracy, precision, F1-score and recall. In the final analysis, both ANN and RF were able to achieve 1.00 test accuracy due to correctly identifying 100% of test samples. Strong performance of the SVM model was demonstrated, which leads to achieving 0.93 accuracy that is better than the other metrics. These ML models were shown to detect certain machine parts likely to fail. For example, the RF model identified the mechanical drive assembly of the ventilator as a common failure point; this was identified by high RPN score in the FMEA. With the computed tomography (CT) scanners, frequent forecasting's were associated with X-ray tube sensor failure. Likewise, for infusion pumps, there were early signs of power supply board failure. The results were corroborated with maintenance history records and showed that the predicted parts did have more interventions and replacements during the previous years of operation.

Table 3. Mean $\pm$ SD performance of ML models using 10-fold cross-validation

Model	Accuracy	Precision	F1-score	Recall
ANN	1.00	0.88	0.90	0.87
RF	1.00	0.88	0.90	0.93
SVM	0.93	0.83	0.88	0.94

A sensitivity analysis was done to explore the effect of changes in the weights of the FMRA sub-factors on the model performance and maintenance decisions. In particular, the weighting of S, O, and D was varied in the risk scoring expression keeping the same ML pipeline. The results show that recall is increased for high criticality components by increasing the weighting placed on severity (missed failure), but too much weighting on occurrence may lead to more false positives and less precision. In summary, balanced weighting of S, O, and D offers the best overall performance in terms of accuracy, F1-score, and recall, enabling consistent risk-based spare parts planning.

The results of the 10-fold cross-validation were used to perform paired t-tests on the F1-score distributions of the different models to statistically evaluate the significance of the differences in their performances. The results show that the RF model was statistically significant ($p < 0.05$) than SVM, suggesting that both models have similar predictive capabilities. Precision levels are converging between ANN and RF, but their F1-scores reveal little differences and show different trends in the relationship between the sensitivity and the precision-recall balance. The performance of ANN was 0.87 recall, and RF was 0.93 recall; RF increased its ability to capture the true need for spare parts. Though it had a slightly lower value for precision of 0.83, the SVM model had a better part need identification, which gave it a supreme recall value of 0.94. Both ANN and RF models offer the best predictive accuracy, with SVM being the best option between complexity and generalizability and interpretability. As per the performance criteria, the RF model is the best one for the spare parts prediction. It achieves a perfect precision (1.00), stability on precision (0.88), F1-score (0.90), and recall (0.933), which indicate high accuracy and reliability in identifying true needs for spare parts. It performs well on all measures and is interpretable and robust, making it the best model for practical use.

The results obtained from these ML models, which provide predictive insights, are very relevant for the operation of hospitals. By proactively identifying high-risk components, biomedical engineering departments can strategically keep crucial spare parts on hand, minimizing equipment downtime and emergency procurement expenses. The proposed framework would demonstrate tangible improvements towards sustainability and operational efficiencies, including potential reductions of 18-22% in emergency spare parts procurement and 12-15 hours of equipment downtime per device and year. These reported reductions are not theoretical estimates but are based on the analysis of retrospective data from CMMS and simulation of model-based preventive intervention. These improvements aim at optimizing resources and services, maximizing cost-effectiveness, and maintaining continuity of health-care provisioning. Predictive risk prioritizes scheduled maintenance actions, thereby improving resource and technician efficiencies.

Furthermore, service contracts with third parties can be adjusted, and health care facilities can be transitioned towards a more proactive and sustainable asset management strategy, enhancing the reliability of patient care delivery. These predictive models could potentially be incorporated into hospitals' existing CMMS system, providing real-time monitoring dashboards that highlight at-risk devices and components. The prediction reports can be used by the maintenance manager to create maintenance schedules based on risk, or used by the procurement team to optimize inventory needs to the parts forecasted by the prediction reports. In addition, clinical engineering staff can be educated on how to interpret the results of the models and will be notified when a component is approaching important failure parameters. This allows the hospital

to transition from the “old” method of maintenance organization to the new “data-driven” maintenance decision-making method and align the hospital with international best practice in predictive maintenance management. This data-informed direction also fits with the overall digital health direction to effective deployment of digital technologists to support health system and service delivery [26].

5. CONCLUSION

The findings show that by adding FMEA-based risk scores to ML models, precise and clinically relevant predictions can be made, especially for high-priority elements. The evaluated models, namely RF and ANN models, have been shown to perform better in the prediction with risk-prioritized feature sets. This allows healthcare institutions to move away from reactive or scheduled maintenance strategies and towards predictive, cost-effective, and sustainable spare parts management. This also aligns with the healthcare goals of increasing equipment availability, patient safety, and resource efficiency that exist around the world, particularly in low- and middle-income areas where many healthcare facilities lack equipment.

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AUTHOR CONTRIBUTIONS STATEMENT

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Name of Author	C	M	So	Va	Fo	I	R	D	O	E	Vi	Su	P	Fu
Fabian Halley Pata Alban Dattu	✓	✓		✓	✓	✓		✓	✓	✓			✓	
Syed Tarmizi Syed Shazali		✓		✓		✓	✓	✓	✓	✓		✓		✓
Shirley Johnathan Tanjong		✓		✓	✓					✓	✓	✓	✓	
Abdul Rani Achmed Abdullah	✓					✓	✓	✓		✓			✓	✓
Nurlaila Rosli		✓	✓	✓	✓					✓	✓			

C : **C**onceptualization

M : **M**ethodology

So : **S**oftware

Va : **V**alidation

Fo : **F**ormal analysis

I : **I**nvestigation

R : **R**esources

D : **D**ata Curation

O : Writing - **O**riginal Draft

E : Writing - Review & **E**ditng

Vi : **V**isualization

Su : **S**upervision

P : **P**roject administration

Fu : **F**unding acquisition

CONFLICT OF INTEREST STATEMENT

Authors state no conflict of interest.

DATA AVAILABILITY

Data availability is not applicable to this paper as no new data were created or analyzed in this study.

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BIOGRAPHIES OF AUTHORS



Ts. Fabian Halley Pata Alban Dattu     is currently pursuing his Ph.D. in Mechanical Engineering at Universiti Malaysia Sarawak, focusing on strategic and sustainable spare parts management for medical devices through machine learning approaches. His research integrates predictive maintenance, semi-supervised learning, and sustainability frameworks to improve equipment reliability and optimize resource allocation in healthcare settings. At i-CATS UC, he has led programmer development aligned with MBOT, MQF, and ETAC standards, while also coordinating mechanical workshop upgrades, industrial collaborations, and STEM outreach initiatives. His academic interests include predictive maintenance, sustainable engineering, artificial intelligence in healthcare, and curriculum innovation. He can be contacted at: fabian.halley@icats.edu.my.



Assoc. Prof. Ir. Dr. Syed Tarmizi Syed Shazali    received a Ph.D. in Mechanical and Manufacturing Engineering from the University of Loughborough, United Kingdom. He has over 25 years of experience as an academician at the Universiti Malaysia Sarawak. He holds the associate professor position researching manufacturing management, manufacturing servitisation, engineering materials, and vibrations. Published various journal papers on engineering education and human behavior modeling. He is a member of the Board of Engineers Malaysia and the Institution of Mechanical Engineers, United Kingdom, earning the distinguished title of professional engineer (Ir.). He can be contacted at email: starmizi@unimas.my.



Ir. Ts. Dr. Shirley Johnathan Tanjong    is a senior lecturer and postgraduate research coordinator at the Department of Mechanical and Manufacturing Engineering, Faculty of Engineering, Universiti Malaysia Sarawak. She holds professional recognition as both an engineer and professional technologist. Her academic and research expertise lies in mechanical and manufacturing engineering, with contributions to postgraduate supervision, curriculum development, and collaborative research projects. She actively promotes research excellence within the faculty and has published in various engineering domains. She can be contacted at email: jtshirley@unimas.my.



Dr. Abdul Rani Achmed Abdullah    earned his B.Sc. in Electrical Engineering from Purdue University and M.Sc. in Engineering Business Management from Warwick University. He completed his doctoral degree from Universiti Teknologi Malaysia. He is the founder and chief executive of CWorks, Inc. and serves as an adjunct professor at Universiti Malaysia Sarawak. He has led several project implementations, including computerized maintenance management systems for 72 government hospitals and the national construction material price index. Previously, he served as a council member of the Master Builder Association Malaysia and the Malaysia Asset and Project Management Association. He has also served on ISO/TC 267 for the development of facility management standards. He can be contacted at email: rani@cworks.com.my.



Ts. Nurlaila Rosli    is a senior lecturer at the Faculty of Computing and Software Engineering, i-CATS University College, Kuching. She holds a master of science in Information Technology from Universiti Teknologi MARA (2013) and a Bachelor of Science in Information Technology (software engineering) from Universiti Malaysia Terengganu (2010). She is a professional technologist registered with the Malaysia Board of Technologists (MBOT). Her teaching and research focus on artificial intelligence, cybersecurity, and software development. She has actively contributed to various academic and industry collaborations, including technology sharing sessions such as “Tech Me radio SharingRED FM: artificial intelligence, internet of things, and cybersecurity” (2024). She also served as chairperson for the MBOT diploma ICT evaluation panel at Kolej Vokasional Betong in 2024. She can be contacted at email: nurlaila@icats.edu.my.