PRIORITISATION ASSESSMENT AND ROBUST PREDICTIVE MODEL FOR A COMPREHENSIVE MEDICAL EQUIPMENT MAINTENANCE USING MACHINE LEARNING TECHNIQUES

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PRIORITISATION ASSESSMENT AND ROBUST PREDICTIVE MODEL FOR A COMPREHENSIVE MEDICAL EQUIPMENT MAINTENANCE USING MACHINE LEARNING TECHNIQUES

ABSTRACT

Medical equipment reliability is critical to the quality of healthcare services. Nevertheless, maintaining the reliability of medical equipment in terms of availability, durability, safety, and economical is a challenging mission. A comprehensive and cost-effective medical equipment maintenance management covering preventive maintenance, corrective maintenance, and replacement plan is needed to achieve the three goals. The study aims to develop a comprehensive strategic maintenance management for sustaining the medical equipment reliability in a cost-effective way. Data such as maintenance history and inventory information on 13,350 units of medical equipment located in health clinics in fourteen states throughout Malaysia were used as samples. The datasets are established according to nineteen features and criteria for this study. The development of predictive models for objectives 1 and 2 of this study involves the application of seven supervised machine learning algorithms. The effectiveness of these models is assessed through eleven performance evaluation parameters. Classifiers that produce the best models are selected for the optimisation process. The optimal models are produced by adjusting the selected classifiers' hyperparameters to reduce the misclassification rate during the prediction process. The achievement of objective 1 demonstrates that the SVM, DT, and NN classifiers have developed optimised predictive models for first failure, failure to year ratio, and failure rectification action, respectively. Meanwhile, the development of predictive models to achieve research objective 2 involves two techniques for assessment of maintenance priorities, namely k-means and classification. The results of these prioritisation assessment techniques are then applied in the development of predictive models. A comparison of the effectiveness demonstrates that the combination of k-means and the NN classifier has developed optimised predictive models for all maintenance management activities at an accuracy rate of over 99.5%. The development of a comprehensive strategic maintenance management includes the elements of maintenance prioritisation and failure analysis to achieve objective 3. It involves the rationalisation of priorities for preventive maintenance, corrective maintenance, and replacement plan predictive models. Moreover, this rationalisation is combined with a first failure analysis prediction, which involves the adjustment of the frequency of planned preventive maintenance and maintenance costs. Integration between rationalisation and a combination of elements shows a reduction in preventive and corrective maintenance costs through the implementation of cost analysis. The results of the analysis found that a 61.4% cost-saving was obtained from the current maintenance costs. This cost-saving can cover 10% of the total estimated cost of procurement of obsolete equipment. This percentage is equivalent to 1,982, which is 40% of the total obsolete equipment proposed for replacement. The establishment of a comprehensive maintenance management through a combination of failure analysis and maintenance prioritisation predictive models can be a mechanism for the implementation of predictive maintenance. Furthermore, it also serves as a tool for clinical engineers in implementing more effective and efficient medical equipment maintenance management.

Keywords: Medical device, biomedical instrumentation, intelligent system, failure analysis, maintenance prioritisation.

PENILAIAN KEUTAMAAN DAN MODEL RAMALAN YANG TEGUH BAGI PENYELENGGARAAN PERALATAN PERUBATAN YANG KOMPREHENSIF MENGGUNAKAN TEKNIK-TEKNIK PEMBELAJARAN MESIN

ABSTRAK

Kebergantungan peralatan perubatan adalah kritikal kepada kualiti penyampaian perkhidmatan kesihatan. Walaibagaimanapun, pengurusan ke arah kebolehpercayaan peralaran perubatan dari sudut ketersediaan, ketahanan, keselataman, dan penjimatan adalah suatu misi yang mencabar. Pengurusan penyelenggaraan peralatan perubatan yang komprehensif dan keberkesanaan perbelanjaan merangkumi penyelenggaraan pencegahan, pembaikan, perancangan penggantian adalah perlu dalam mencapai ketiga-tiga tahap tersebut. Matlamat utama kajian ini adalah membangunkan satu pengurusan penyelenggaraan strategik yang komprehensif bagi mengekalkan kebolehpercayaan peralatan perubatan dengan perbelanjaan yang effektif. Pengunaan sampel melibatkan data-data sejarah penyelenggaraan dan maklumat inventori merangkumi 13,350 unit-unit peralatan perubatan bertempat di klinik-klinik kesihatan di 14 buat negeri di Malalysia. Pembangunan dataset adalah berdasarkan 19 ciri-ciri dan kriteria-kriteria dalam kajian ini. Pembangunan model-model ramalan bagi objektif kajian 1 dan 2 melibatkan pengaplikasiaan tujuh algoritma pembelajaran mesin tersedia. Keberkesanaan model-model ini diukur menerusi sebelas parameter-parameter penilaian prestasi. Pengkelas yang menghasilkan model ramalan terbaik dipilih bagi proses pengoptimaan. Penghasilan model-model yang optima dicapai dengan melaras hiperparameter pengkelas terpilih bagi mengurangkan kadar ralat semasa proses ramalan. Pencapaian objektif kajian 1 menunjukkan pengkelas-pengkelas SVM, DT, NN telah menghasilkan model-model ramalan optima masing-masing bagi kegagalan pertama, kadar kegagalan tahunan, dan tindakan pembetulan kegagalan. Sementara itu, pembangunan model-model ramalan bagi mencapai objektif kajian 2 melibatkan dua teknik untuk penilaian keutamaan

penyelenggaraan, iaitu k-means dan pengelasan. Keputusan keluaran daripada teknik-teknik ini kemudiannya digunakan dalam membangunkan model-model ramalan. Hasil perbandingan keberkesanan mendapati gabungan k-means dan pengkelas NN telah membangunkan model-model ramalan yabg optima bagi ketiga-tiga aktiviti pengurusan penyelenggaraan pada kadar ketepatan melebihi 99.5%. Pembangunan pengurusan penyelenggaraan strategik dan menyeluruh meliputi elemen-elemen keutamaan penyelenggaraan dan analisa kegagalan bagi mencapai objektif kajian 3. Ia melibatkan rationalisasi keutamaan daripada model-model ramalan penyelenggaraan pencegahan, penyelenggaraan pembaikan, dan perancangan penggantian. Tambahan lagi, rasionalisasi ini digabungkan dengan ramalan analisa kegagalan pertama, dimana melibatkan pelarasan kekerapan penyelenggaraan pencegahan berkala dan kos-kos penyelenggaraan. Integrasi antara rasionalisasi dan gabungan elemen-elemen menunjukkan penurunan kos-kos penyelenggaraan pencegahan dan pembaikan yang dibuktikan melalui analisa kos. Keputusan-keputusan analisa mendapati penjimatan kos sebanyak 61.4% diperolehi daripada kos-kos penyelenggaraan sedia ada. Penjimatan ini boleh membiayai sebanyak 10% daripada anggaran kos-kos pembelian baru peralatan yang telah usang. Peratusan ini bersamaan 1,982 unit, iaitu sebanyak 40% daripada jumlah peralatan yang usang dan dicadangkan untuk penggantian. Pencapaian sebuah pengurusan penyelenggaraan strategik yang komprehensif melalui kombinasi model-model ramalan analisa kegagalan dan keutamaan penyelenggaraan menjadi mekanisma pelaksanaan penyelenggaraan ramalan. Tambahan lagi, ia juga menjadi sebagai perkakasan kepada jurutera-jurutera klinikal dalam melaksanakan pengurusan penyelenggaraan peralatan perubatan yang lebih berkesan dan efisien.

Kata kunci: Peranti perubatan, peralatan bioperubatan, sistem pintar, analisa kegagalan, keutamaan penyelenggaraan.

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AHP	:	Analytic Hierarchical Process
AI	:	Artificial Intelligence
ANN	:	Artificial Neural Network
ASHE	:	American Society for Healthcare Engineering
AUC	:	Area Under Curve
BER	:	Beyond Economical Repair
BT	:	Bagged Trees
CAGR	:	Compound Annual Growth Rate
CAMMS	:	Computerised Asset Maintenance Management System
CBM	:	Condition-Based Maintenance
CMMS	:	Computerised Maintenance Management System
COVID-19	:	Coronavirus Disease 2019
DA	:	Discriminant Analysis
DT	:	Decision Tree
EU	:	European Union
FDA	:	Food and Drug Association
FMEA	:	Failure Modes and Effect Analysis
FN	:	False Negative
FP	:	False Positive
FPR	:	False Positive Rate

GHTF	:	Global Harmonization Task Force
HTA	:	Health Technology Assessment
ICU	:	Intensive Care Unit
IEC	:	International Electrotechnical Commission
IMDRF	:	International Medical Device Regulators Forum
ISO	:	International Organization for Standardization
KNN	:	K-nearest Neighbour
MCC	:	Matthews Correlation Coefficient
MCDM	:	Multi Criteria Decision Making
MILP	:	Mixed-Integer Linear Programming
ML	:	Machine Learning
MOH	:	Ministry of Health
MTTR	:	Mean Time To Repair
NB	:	Naïve Bayes
NN	:	Neural Network
PAL	:	Paraconsistent Annotated Logic
PAM	:	Physical Asset Management
PPM	:	Planned Preventive Maintenance
QA	:	Quality Assurance
QFD	:	Quality Function Deployment
RCM	:	Reliability-Centred Maintenance

RF	:	Random Forest
ROC	:	Receiver Operating Characteristic
SEM	:	Structured Equation Modelling
SVM	:	Support Vector Machine
TBM	:	Time-Based Maintenance
TN	:	True Negative
TOPSIS	:	Technique for Order Performance by Similarity to Ideal Solution
TP	:	True Positive
TPR	:	True Positive Rate
UMDNS	:	Universal Medical Device Nomenclature System
UN	:	United Nation
US	:	United States
WHO	:	World Health Organisation

CHAPTER 1: INTRODUCTION

1.1 Introduction

High quality healthcare services are essential for preventing diseases and enhancing the overall quality of life. Healthcare professionals provide a wide range of services at healthcare facilities, including diagnostics, therapeutics, rehabilitative means, and consultative services (Englander *et al.*, 2019; Leone *et al.*, 2018; Yang & Yang, 2020). Apart from such services, healthcare facilities also conduct research to improve services and provide health education to the community (Huynh *et al.*, 2020; World Health Organization, 2020b). As a result of increased public awareness and globalisation, the healthcare industry has experienced significant growth, and has emerged as one of the most critical segments of a country (Dixit *et al.*, 2019; Javed *et al.*, 2019).

The growth of numerous diseases have had a devastating impact on the economy and social consequences toward society. For instance, the world's population had been afflicted by Coronavirus Disease 2019 (COVID-19) over the past 2 years. The virus has had a significant impact on the world economic and financial markets, in addition to becoming a worldwide pandemic and public safety disaster (Pak *et al.*, 2020). The disease's mitigation measures have resulted in significant revenue reductions for many countries, an increase in unemployment, and disruptions in the industrial, transportation, and service sectors. Apart from that, the recent COVID-19 crisis has been associated with substantial psychosocial implications to the general community (Saladino *et al.*, 2020). Many studies have revealed that those who are most exposed to such impacts, particularly youngsters, students, and health personnel, are much more prone to acquire post-traumatic stress disorder (PTSD), depression, anxiety, and other signs of distress. According to this viewpoint, telepsychology and technical equipment play critical roles in mitigating the harmful consequences of the epidemic. Furthermore, it impacts the education sector (Joaquin *et al.*, 2020). Many countries have chosen to implement quarantine measures and momentarily restrict their educational institutions in order to contain the spread of COVID-19. As a result, over a billion pupils have been impacted worldwide.

The emergence of the COVID-19 outbreak offered significant challenges in facility management, particularly when medical equipment was used. It was critical to rely on medical equipment to counter and manage the issues during the COVID-19 outbreak (Koç & Türkoğlu, 2021). According to Anderson *et al.* (2020), apart from research concerning the COVID-19 spread control, epidemic effect detection, and the promotion of various relevant studies, one of the four priorities for tackling the global pandemic was the availability of medical equipment. The need for patient care medical equipment used in intensive care units such as monitoring systems, pulse oximeters, infusion pumps, and ventilators, helped in monitoring and treating infected patients during the pandemic (Garzotto *et al.*, 2020). As such conditions causes the human respiratory system to fail, mechanical ventilators were in great demand, and continue to be. This technology not only functions independently, but it also needs embedded systems to centralise oxygen and water, both of which are readily available at health facilities. It is reported that approximately 2% of COVID-19 patients worldwide require this equipment's assistance (Solomon *et al.*, 2020). In addition, the use of this equipment also requires the expertise of medical professionals for preparing, managing it, and the necessary skills in handling the equipment to ensure the patient's recovery (Canelli *et al.*, 2020). The problem will worsen when the medical equipment in the healthcare institution is scarce and insufficient to cope with sudden outbreaks (Belhouideg, 2020). Italy had been severely impacted due the lack of medical supplies. The government had acquired over 3000 ventilators and more than 29 million other equipment on an emergency basis to prevent the surge of the pandemic (Armocida *et al.*, 2020). Therefore, it is crucial for the healthcare providers to ensure that the medical equipment is reliable not only during screening, but also for aiding the treatment processes. The medical equipment reliability needs to be assessed during routine maintenance exercises and continuous assessment plans should be in place.

A healthcare delivery which is both effective and affordable for the citizens is one of the most challenging tasks faced by any government around the world (Brar, 2017). After 60 years of independence, the average lifespan of Malaysians has grown by approximately 20 years. Figure 1.1 illustrates the population statistics of Malaysians aged 65 and above over the last 10 years.

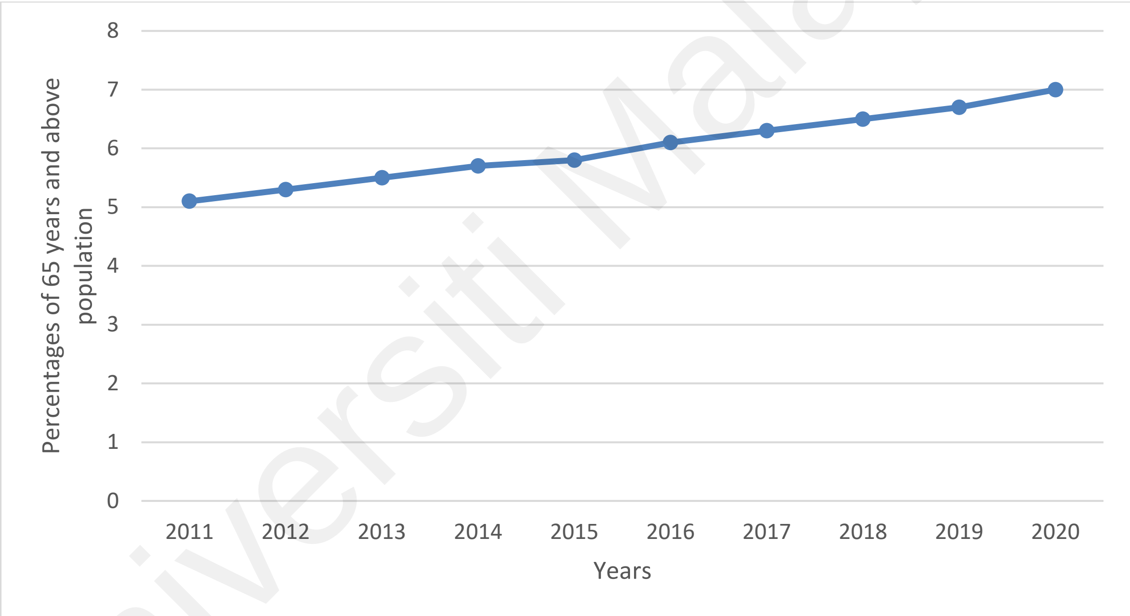


Figure 1.1: Malaysia's population over 65 years and above from 2011 to 2020 (Ministry of Health Malaysia, 2014, 2017a, 2019a, 2021).

These statistics show that the average percentage of the population increased each year by 0.21%. By 2020, it had reached 7%, equivalent to 2.3 million Malaysians. Moreover, the Department of Statistics Malaysia (2017) projected that the population of this group will rise to 14.5 in 2040, which is equal to 41.5 million people. The WHO forecasted that the world’s population over 60 years will climb to 22%, which was double compared to that in 2015 (World Health Organization, 2022b).

Despite the fact that humans live longer lives today, this has not led to a better life quality for the majority of them (United Nations *et al.*, 2019). This scenario has increased the demand for healthcare services in Malaysia. Furthermore, to meet this demand, conventional hospital atmospheres have been transformed into innovative healthcare standards. Based on the forecasts by Frost & Sullivan, the total healthcare investment in Malaysia was anticipated to grow close to 54%, from MYR52 billion at the end of 2017, to MYR80 billion by the end of 2020 (Zainul, 2018). Aside from that, the Government of Malaysia needs to commit more subsidies toward the development of medical tourism, as an increasing number of tourists are projected to obtain medical care in the nation. The need for healthcare is increasing, and is expected to continue relentlessly, creating the potential for enhancements and modernisation in diagnosis and medications. Inflation pressure and budgetary restrictions on the other hand, continue to place an enormous financial burden on the healthcare service delivery. As the population becomes older, the burden of non-transmissible and infectious diseases, new technologies, and patient needs will cause the healthcare costs to continue to climb (Lum, 2018).

The expansion of healthcare services necessitates the need for continual review in terms of acceptability, efficacy, and the adoption of technologies, which can be accomplished through health technology assessments (HTA) (Oliveira *et al.*, 2019; Rosina *et al.*, 2014). HTA is an essential technique for increasing healthcare quality by integrating evidence with responsible decision-making for acknowledging the critical results of health technologies (Whitty, 2018). The tool likewise incorporates engineering considerations as well as economic, ecological, human factors, and ethics into its design (Polisena *et al.*, 2018). HTA has been defined as a link between research in clinical and health policy decision-making. It is the process of evaluating evidence concerning the safety, feasibility, and effectiveness of innovative technology, as well as other possible advantages, such as those linked to equity or patient preferences, or the cost-efficiency of technological advances, before implementing a new system. In most cases, the objective of an evaluation is a suggestion on the policy, its availability, or financing. The tool mechanisms might include processes concerning the initial identification and assessment of technological advancements, referred to as prospect monitoring, and functions related to the recent monitoring and evaluation of technologies after they have been approved for use and implemented in clinical settings. There are five kinds of variations which might influence HTA methods, which are product lifespan, clinical assessments, user challenges, price and economic assessments, and property rights.

Strong strategic planning, training and education, adequate resources, effective supply management, workforce, procedures, and organizational support among providers, may indeed help to enhance healthcare quality (Mosadeghrad, 2014). The healthcare industry strongly relies on support services, such as facility management, to deliver effective and efficient services to the public (Che-Ani Adi & Ali, 2019). Apart from asset management, property, human capital, and finance are part of the FM multidisciplinary in the healthcare industry (Amankwah, 2019; Kamaruzzaman Syahrul *et al.*, 2018). Furthermore, the FM's main aim is not only to cut the costs, but also to improve customer happiness (Shohet & Lavy, 2017; Yousefli *et al.*, 2017). FM provides a structured and systematic approach for planning, executing, sustaining, improving, and replacing asset expenses effectively and safely, while preserving the intended level of service over the asset's useful life. FM was initially implemented in Malaysia to fulfil the needs for public services, particularly in the healthcare sector. Additionally, it supports the privatisation of general maintenance services, as outlined in the 6th Malaysian Plan from 1990 to 1995 (Kamaruzzaman Syahrul *et al.*, 2018).

1.2 Medical Equipment in Healthcare Facilities

Medical equipment is one of the key assets managed by the facility management team. Medical equipment is a vital part that significantly enhances the effectiveness of healthcare services (Badnjević *et al.*, 2015). The development of advanced equipment has resulted in a considerable improvement in the community's wellness (Chaudhary & Kaul, 2015; Eliash *et al.*, 2020). The efficiency of medical equipment is critical for the procedures involved in healthcare processes, ranging from diagnostic to treatments, rehabilitation, detection, prevention, and observation (Khalil *et al.*, 2018). Advanced equipment significantly aids healthcare practitioners in the early stages of symptom recognition, thereby preventing health depreciation (Yong *et al.*, 2021). Today's technology enables healthcare services, of which medical equipment plays a role across each process (Pallikarakis & Bliznakov, 2016). This diverse and evolving technological equipment necessitates a much more exceptional standard of research and development of the manufacturing processes, and has developed into the world's most advanced industry (Iadanza *et al.*, 2019).

Medical equipment is a sub-section of medical devices that includes a variety of equipment. The use of this tangible asset is for detecting, reinstating, correcting, or carrying out alterations for the prevention, diagnosis, or treatment of certain health conditions (Eze *et al.*, 2019; Robert Davis, 2016). As a result of improving diagnostic and treatment measures, medical equipment has unquestionably contributed toward an improvement in the overall quality of life (Bahreini *et al.*, 2019; Oshabaheebwa *et al.*, 2020). Therefore, for ensuring that such medical equipment is effective, safe, and efficient before it is applied in a medical setting, medical equipment manufacturers must adhere to strict requirements on its design and operation (Hale *et al.*, 2019). The World Health Organization (WHO) has advised that specific policies in the sector needs to be governed by the governmental authorities who are empowered to manage the deployment of medical equipment (Badnjević *et al.*, 2018; World Health Organization, 2003, 2016). In 2012, the Malaysian government formed the Medical Device Authority, which is an authorised local organisation that regulates medical devices. This regulatory organisation was established in compliance with the Medical Device Authority Act 2012 to regulate and control various activities associated with medical equipment during the pre-market, on-market placement, and post-market stages of their respective lifecycles (Medical Device Authority, 2012a, 2012b). Furthermore, other official entities, namely the Department of Occupational Safety and Health for pressurised pieces of machinery, and the Atomic Energy Licensing Board for radiation-generated equipment, are responsible for issuing the respective certificates of compliance (Atomic Energy Licensing Board, 2006; Department of Occupational Safety and Health, 2006). The compliance mission is to guarantee that the equipment is used safely and legally in a controlled setting.

The reliability of medical equipment is dependent on its durability, availability, and safety, all of which are important factors for its effectiveness. Thus, in attaining such objectives, maintenance management is essential. Maintenance management is a part of FM which is essential for securing the medical equipment and ensuring that it operates at the specified quality and standard provided by the manufacturer (Chong *et al.*, 2019; Salim *et al.*, 2019). It is necessary to do routine maintenance activities such as calibration on specialised equipment, which requires accurate and precise measurements throughout the examination process to be undertaken on the patient (Ramana *et al.*, 2020). According to the definitions, preventive and corrective maintenances are the primary components for medical equipment maintenances (Corciovă *et al.*, 2020). These maintenance practices consist of a simple input and output system. Information about malfunctioning components, materials, consumables, functional logs, and documentation, are required as inputs. On the other hand, the output includes reliable equipment as a result of good maintenance management practices.

Services in healthcare without proper maintenance of medical equipment are practically impossible to be achieved (Wang, 2012). Thus, the devices must be sustained by carrying out the appropriate calibration, maintenance, restoration, training, and decommissioning, all of which are typically handled by clinical engineers (World Health Organization, 2011a). Clinical engineers in a healthcare facility are in charge of regulating and implementing an effective management programme for the dependability and safety of such medical equipment (Kim *et al.*, 2020). Due to rapid technological advancements, medical equipments have become increasingly sophisticated, and as a result, the costs of procurement and maintenance have increased (Wang, 2012).

Referring to Kohani and Pecht (2018), increasing medical equipment functionality depends on the internal electronic system. This reliance is sensitive to electronic discharge, leading to uncertain circumstances, and placing users and patients in danger. As a result, maintenance management is necessary to guarantee that medical equipment utilisation meets manufacturer specifications, and ensures the safety of patients and users (Salim *et al.*, 2019). Appropriate maintenance execution may help avoid catastrophic problems or disruptions that could negatively impact healthcare operations, and lead to serious injuries to the patients.

Kutor *et al.* (2017) stated that inappropriate handling and storing, initial failure, misuse, inadequate maintenance, environmental factors, unpredictable malfunction, improper recovery approaches, and fatigue breakdown, are the most common causes of equipment breakdown. It highlighted that poor maintenance and a scarcity of highly experienced personnel are accountable for around 50 to 80% of equipment failures. Moreover, there were additional of four most significant reasons for those failures included avoidable occurrence, a lack of technical expertise, a lack of data, and an absence of predictive maintenance. Therefore, it is possible to make continuous improvements by recognising the elements that influence medical equipment maintenance and management. Based on the 29 existing studies as reviewed by Bahreini *et al.* (2018), various factors influence medical equipment. This study concluded that the management, resources, archives, services, inspections, education, and quality control, are among the aspects which affect medical equipment.

The WHO has classified the financial resources required for medical equipment maintenance into two categories: 1) capital expenditures and 2) continuous operational expenses (World Health Organization, 2011b). Additional data from Corciovă *et al.* (2020) revealed that maintenance expenses accounted for between 15 and 60% of the total operating costs of the healthcare system in 2011. According to Bahreini *et al.* (2019), unprofessional maintenance execution negatively impacts the healthcare institution´s overall performance, safety, and costs. As indicated by Wu and Liu (2010), good maintenance management managed to cut operating expenses by more than 1 million dollars while simultaneously increasing the availability of assets.

Several studies have been carried out in order to determine the global market value of medical equipment maintenance services. These investigations included the sorts of preventive, corrective, and operational services for a range of critical equipment. They were conducted with the participation of leading manufacturers and service providers. According to the study performed by MarketsandMarkets (2018), the global market for medical equipment maintenance was valued at USD29 billion in 2018. By 2023, the value is predicted to reach an estimated USD48 billion. The expected annual growth rate for the investment period, or Compound Annual Growth Rate (CAGR), is expected to be 10.4% during this period. FutureWise (2020) projected that this value exceeded USD62 billion with a CAGR of more than 10% from 2020 to 2027. The estimate additionally suggests that the CAGR will increase by 9.4% from 2020 to 2030 (Prescient & Strategic

Intelligence, 2020). The primary drivers of these rising rates included increased motivation for preventative maintenance, increased demand for equipment, the introduction of advanced financing mechanisms, the acquisition of reconditioned equipment, and the enforcement of tight regulatory standards.

In Malaysian healthcare facilities, similar trends can be observed. In 2018, the government invested around MYR27 million in public healthcare institutions through new procurements and equipment upgrades (Ministry of Health Malaysia, 2018b). The government introduced a new rental program for 6 major units of medical equipment over a 5-year tenure commencing in 2019, which included a MYR19.7 million maintenance scheme. In 2019, one of Malaysia's most prominent private healthcare providers spent MYR136 million on medical equipment, which was a 32% increase over the previous year (KPJ Healthcare Berhad, 2019). In light of these initiatives, it is clear that the significant expenditure for medical equipment purchase and maintenance is required in order for providing effective healthcare services to the community. The service chain for medical equipment in the healthcare sector is shown in Figure 1.2.

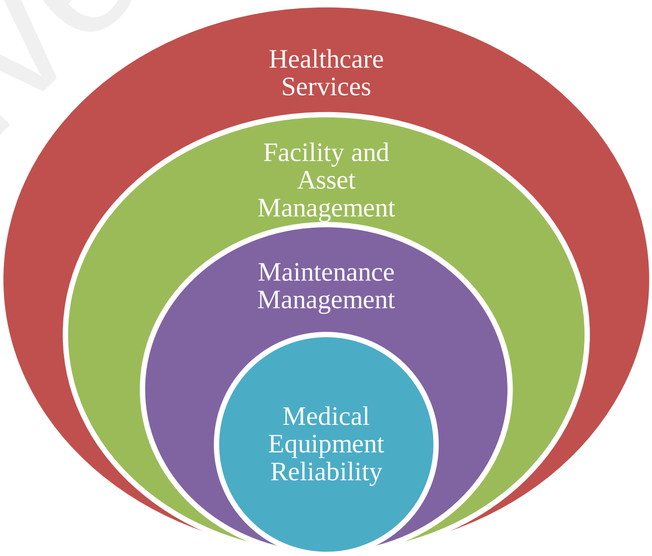


Figure 1.2: Service-chain of medical equipment in the healthcare field.

The high quality of maintenance management effectiveness and efficiency involves the use of a supportive tools during the implementation process. Thus, the computerised maintenance management system (CMMS) is one of the asset management technologies utilised in healthcare institutions (Gentles, 2020; Lopes *et al.*, 2016). The CMMS is an essential tool for managing inventories and work orders when dealing with massive data (Cohen *et al.*, 2020; Iadanza *et al.*, 2020). Nonetheless, administering medical equipment maintenance and analysing the data stored in a CMMS is a complex undertaking. Clinical engineers are accountable for leading the supervision of medical equipment while interacting with other stakeholders from the medical, nursing, and administrative disciplines (Clark *et al.*, 2019). According to Lencina *et al.* (2019), a healthcare institution with a clinical engineering team operated much more efficiently with lower expenses, increased availability of medical equipment, and overcame complex difficulties. Clinical engineers utilise CMMS to gather, save, and analyse data pertaining to medical equipment maintenance in order for improving medical equipment management inclusively (Subhan, 2013). In order to measure the improvement, a medical equipment dependability indicator is required. Clinical engineers can use the indicator to aid them in making the best decision and prioritising their daily operations associated with medical equipment maintenance (Oshiyama *et al.*, 2014; Spahic *et al.*, 2020). Hence, a methodological tool such as a structured and systematic evaluation of medical equipment can assist the clinical engineer in performing his or her daily duties.

1.3 Problem Statement

Administering the operation of medical equipment entails a wide range of tasks and responsibilities. With regards to equipment maintenance management, proper planning and implementation is required, including qualified staff, specific materials, promising approaches, and appropriate scheduling. The full cooperation of all stakeholders, including manufacturers, authorised service providers, the supervision team, healthcare institution administrators, and regulatory agencies, is essential for effective management. Lack of preparedness in carrying out medical equipment maintenance activities can harm the functionality and operation of the equipment, which can in return harm the users and patients.

The facility manager's roles and responsibilities as a middle person in the healthcare facility's support services management is critical, particularly for ensuring that the medical equipment performs well (Birken *et al.*, 2018). These professionals establish a link between strategies and day-to-day activities. Among the critical responsibilities are data collection, analysis, and interpretation in order to produce coherent and comprehensive relevant information. This information must be disseminated to the maintenance personnel and the healthcare institution's administrator. Communication between diverse professional parties inside a healthcare institution is extremely difficult, particularly when transmitting information (Foronda *et al.*, 2016; O'Daniel & Rosenstein, 2008). Without a system to analyse precise and systematic data, it is difficult for all involved parties to comprehend their responsibilities and roles to be able to make the right decision.

Since the medical equipment is such a high-tech instrument, it necessitates a well-planned maintenance programme to guarantee that it is in good working order. A medical equipment replacement program for aged units and obsolete spare parts must be introduced. However, equipment replacement results in significant capital expenditure for the healthcare institution. The absence or inefficiency of a replacement plan will impact the availability of equipment, and as a result, will cause disruptions in the delivery of healthcare services to patients. Therefore, it is essential to develop an accurate assessment method for anticipating the performance of existing medical equipment so that a replacement plan, including a provisional budget, can be developed and implemented at an early stage.

The Malaysian Government, represented by the Ministry of Health (MOH), is deeply concerned about ensuring that the available range of medical equipment are always reliable, safe, available and durable. According to the internal audit report published by the Ministry of Health over 4 consecutive years, it was discovered that a lack of medical equipment adversely affected the delivery of healthcare and medical services. Additionally, both services were disrupted as a result of the deficiencies in the performance of repairs on malfunctioning equipment, and the failure to complete them in accordance with the established schedule (Ministry of Health Malaysia, 2017b, 2018a, 2019b, 2020). As previously stated, these issues were also addressed in the Auditor General's Federal Report between the years 2018 and 2019 (National Audit Department Malaysia, 2018, 2019). Following the report's publication, 4 local mainstream media companies released the matter on 29th September 2021 (BERNAMA, 2021; BH Online, 2021; Teh Athira Yusof, 2021; The Star, 2021). In general, all of the reports concluded that the shortcomings in the analysis of the available data which is recorded in an asset management system can assist parties involved in making the best decisions possible in terms of the effectiveness of preventative and corrective maintenances, and replacement plans.

The following three key research problems were listed after conducting a review of past studies focusing on medical equipment dependability assessments:

RP1: Insufficient research focused on comprehensive maintenance management of medical equipment, which includes preventive maintenances, corrective maintenances, and a fitting replacement strategy.

RP2: Inconsistencies in mathematical techniques necessitates manual involvement in determining the weighting factors of the criteria in the reliability assessment.

RP3: Limited previous predictive models, which are applicable to the myriad of medical equipment.

Therefore, designing and developing a standardised and systematic comprehensive assessment technique which includes failure analysis, preventative maintenance, corrective maintenance, and a replacement plan is necessary. The application of Artificial intelligence (AI) with its sub-disciplines Machine Learning and Deep Learning have been gaining increased attention in healthcare, with the opportunity to change lifestyles and achieve better clinical care in a variety of healthcare fields (Davenport & Kalakota, 2019; Serag *et al.*, 2019). Therefore, AI could be used to speed up and improve the accuracy of prediction processes, which cover failure analysis and maintenance prioritisation. Predictive models are useful for implementing predictive maintenances. For that reason, the application of machine learning in medical equipment assessments can generate better accuracy for assessing and predicting the equipment failure and prioritisations in maintenance management.

1.4 Research Questions

Based on the research problems indicated in the previous section, the research questions in this study are as follows:

RQ1: What are the standard features and criteria of medical equipment assessments required for failure analysis, preventive maintenances, corrective maintenances, and replacement plans?

RQ2: What is the technique used for the development of medical equipment predictive models for failure analysis and maintenance prioritisation?

RQ3: What are the main elements for establishing the medical equipment failure analysis?

RQ4: What is the assessment technique used to develop a much better performance for maintenance prioritisation predictive models?

RQ5: How are the predictive model techniques used for a myriad of medical equipments for comprehensive maintenance management?

RQ6: How is it possible to assure that the developed system for assessing and predicting the medical equipment performs well?

RQ7: How is it possible to achieve cost-effective maintenance management based on failure analysis and maintenance prioritisation models?

1.5 Research Objectives

The primary goal of this study is to develop the prioritisation assessment model for medical equipment using machine learning techniques. The following are the objectives to attain the primary aim:

RO1: To predict medical equipment failure from an unlabelled dataset using machine learning algorithms.

RO2: To estimate the maintenance priorities from an unlabelled medical equipment dataset.

RO3: To propose a cost-effective maintenance management framework for medical equipment.

Table 1.1 tabulates the mapping of research problems and research questions against the research objectives at the end of this chapter.

1.6 Research Scopes and Limitations

The preparation of this research work involved several specific scopes and limitations. Firstly, the samples used in the development of the assessment and prediction techniques were medical equipment at the health clinic level. The health clinic is a healthcare institution, where physicians and medical practitioners carry out primary care activities to help the community for maintaining good health. Primary healthcare settings such as health clinics are essential in controlling and preventing epidemic and pandemic diseases (Basu *et al.*, 2019; Rawaf *et al.*, 2020; Wei *et al.*, 2020). The effectiveness of health services at the primary care level with the support of reliable medical equipment can mitigate the admission of patients to a secondary care level, which is categorised as a hospital. Therefore, improving the quality of services at the primary care level helps in improving the health of a country. Meaning that, the application of medical equipment at the health clinic level is just as crucial, as the same equipment is used in hospitals and other healthcare institutions. Thus, the proposed assessment and prediction techniques can be applied to medical devices used in other health institutions.

The medical equipment database, which consists of information such as inventory and maintenance history, was taken from the computerised asset maintenance management system at the health clinic level. The data was for the period of 2015 to 2020. The period was taken after all inventory information and maintenance records were collected and harmonised into a centralised computerised system. The data taken was categorised as raw, unlabelled data.

The medical equipment used consisted of 19 types of medical equipment. These equipment described the main functions of the equipment used in the delivery of health services to patients in health clinics. Furthermore, these types of equipment are also widely used in hospitals and other healthcare institutions. The devices involved were active and passive devices, and did not involve implantable medical devices.

The study involved the development of prioritisation assessments and prediction of medical equipment using machine learning algorithms. The model was a stand-alone application, which was not integrated with a real-time CMMS.

1.7 Research Contributions

At the conclusion of this research, numerous vital findings can aid in the management of medical equipment used in healthcare facilities. First, it will be a standardised and systematic process which will assist in improving medical equipment maintenance practises at healthcare institutions. The institution will be able to optimise operation expenditures with the allocated provisional budget, by applying effective maintenance management practices.

Secondly, the systematic method in assessing and predicting the reliability of medical equipment may assist clinical engineers in educating healthcare institution administrators on the equipment's current condition. The standardised technique can increase the common understanding of the medical equipment’s current state among the healthcare professionals. The technique is capable to generate a quick and precise assessment and prediction result.

Thirdly, by identifying the replacement equipment required by the institution in the early stages, the management can allocate an appropriate budget to ensure the availability of equipment up to the norm, and provide better healthcare services to the patients. Moreover, it can assist all related parties in making the right and quick decision.

1.8 Thesis Organisations

The division of the thesis consists of 5 chapters. Chapter 1 introduces the overview of the healthcare and medical fields, the importance of health technology assessments, the criticality of healthcare facility management, and the medical equipment’s background. In this chapter, the research problems, research questions, and research objectives are listed. Furthermore, this chapter also points out the scopes, limitations, and contributions of the research work.

Chapter 2 briefs on the overviews of the medical equipment by defining and differing between medical technologies, medical devices, and medical equipment. Furthermore, this chapter also explains the international and national relevant regulations and standards with regards to the medical equipment, and the requirements of the medical equipment maintenance management. Related previous studies on medical equipment assessments are explained and summarised in terms of features, criteria, techniques, and gaps identified.

Chapter 3 briefs the development of medical equipment assessment and predictive models, including the characteristics of the dataset, the proposed features and criteria, the application of machine learning techniques, and the performance evaluation parameters. Moreover, this chapter explains the proposed maintenance management framework and cost analysis for verification.

Chapter 4 presents the results of the medical equipment's failure analysis and maintenance prioritisation prediction, by applying the techniques of machine learning algorithms. This chapter also exhibits the accomplishment of a proposed maintenance management framework in terms of cost-effectiveness. In addition, all the results obtained from the study and the research's contributions are then discussed.

Last but not least, Chapter 5 explains, concludes, and summarises the findings, outcomes of the research, and recommendations for future works.

Table 1.1: Mapping between research problems, research questions, and research objectives.

Research Problems	Research Questions		Research Objectives
RP1: Insufficient research focused on comprehensive maintenance management of medical equipment, which includes preventive maintenances, corrective maintenances, and a replacement strategy. **RP2:** Inconsistencies in mathematical techniques necessitates manual involvement for determining the weighting factors of the criteria in the reliability assessment. **RP3:** Limited previous predictive models, which are applicable to the myriad of medical equipment.	**RQ1:** What are the standard features and criteria of medical equipment assessment required for failure analysis, preventive maintenances, corrective maintenances, replacement plans? **RQ2:** What is the technique used for the development of medical equipment predictive models for failure analysis and maintenance prioritisation? **RQ3:** What are the main elements for establishing the medical equipment's failure analysis? **RQ4:** What is the assessment technique used to develop better performance for the maintenance prioritisation predictive models?	**RQ5:** How are the predictive model techniques used for a myriad of medical equipment for comprehensive maintenance management? **RQ6:** How to assure that the developed system for assessing and predicting the medical equipment performs well? **RQ7:** How to achieve the cost-effective maintenance management based on failure analysis and maintenance prioritisation models?	**RO1:** To predict medical equipment failure from an unlabelled dataset using machine learning algorithms. **RO2:** To estimate the maintenance priorities from an unlabelled medical equipment dataset. **RO3:** To propose a cost-effective maintenance management framework for medical equipment.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter presents the important elements associated with medical equipment, and its good practice for maintenance management. The chapter consists of 7 sections, which concentrate on the medical equipment overview and background, regulatory compliance, medical equipment maintenance, reliability assessment, gap identification and summary. Firstly, the overview of the medical equipment describes the general definition, purposes, functionality, compliance with statutory regulations, and fulfilment of the relevant standards.

The second sub-section, namely the medical equipment management in healthcare facilities, briefs on the phases in the medical device's lifespan, it's application on the human body's autonomy and physiology, and the general operational functionality of medical equipment. The next sub-section explains the establishment of international and Malaysian regulatory compliances. Furthermore, the professional agencies and organisations, which produced the relevant standards, are elaborated in this section. The fourth sub-section explains the medical equipment's maintenance management, covering corrective maintenances, preventive maintenances, and replacement plans. Then, the fifth sub-section deliberates on the importance of medical equipment reliability assessments and derives previous related studies. Last but not least, the sixth sub-section identifies the gap in light of the analysis of previous studies.

2.2 Medical Equipment in Healthcare Facilities

One of the most significant tools for delivering healthcare services is the medical equipment. It is essential to understand the definitions and terminologies commonly used to differentiate them from other types of equipment. Due to the advancement in technology, different types of medical equipment are marketed worldwide. While ensuring that medical equipments are optimally functional during its life cycle, a precise nomenclature is required during its procurement, utilisation, legal compliance, and maintenance. As a medical equipment is categorised as equipment used only for humans and other living creatures, complying with legislations and standards is essential to ensure that safety requirements are always met.

Medical equipment can be classified in many ways. The most frequently used definitions are those found in the United States (US), Food and Drug Administration (FDA), and the medical device directive of the European Union (EU). It can be described briefly as any instrument, software, material, or other comparable or related objects intended to diagnose, prevent, monitor, treat, or relieve disease. As one of the medical device's subsets is the medical equipment itself (Eze *et al.*, 2019), hence, the terms are frequently used interchangeably in this thesis.

Medical devices comprise approximately one million five hundred thousand distinct devices which can be classified into more than ten thousand broad categories. These devices come in many diverse types from multifaceted capital-intensive devices with substantial financial worth, to common devices. These devices require calibration, maintenance, repair, user trainings, and decommissioning, of which the clinical engineers are responsible to execute such tasks. The equipment carries the explicit functions of diagnosing and treating disease and rehabilitation. It may be used together with any accessories, consumables, or other parts of medical equipment. Medical equipment does not include implanted, single-use, or disposable medical instruments (World Health Organization, 2022c).

Figure 2.1 illustrates 7 major phases in the life span of medical equipment, which includes; 1) conception and development, 2) manufacture, 3) packaging and labelling, 4) advertising, 5) sale, 6) use and 7) disposal. The first phase of the medical equipment lifecycle involves accurate concept triangulation, adequacy of the design, and its construction. It also includes the verification, validation, and clinical trials, of which scientific experts will scrutinize. This ensures that the medical equipment design and performance does not impose any unnecessary risks.

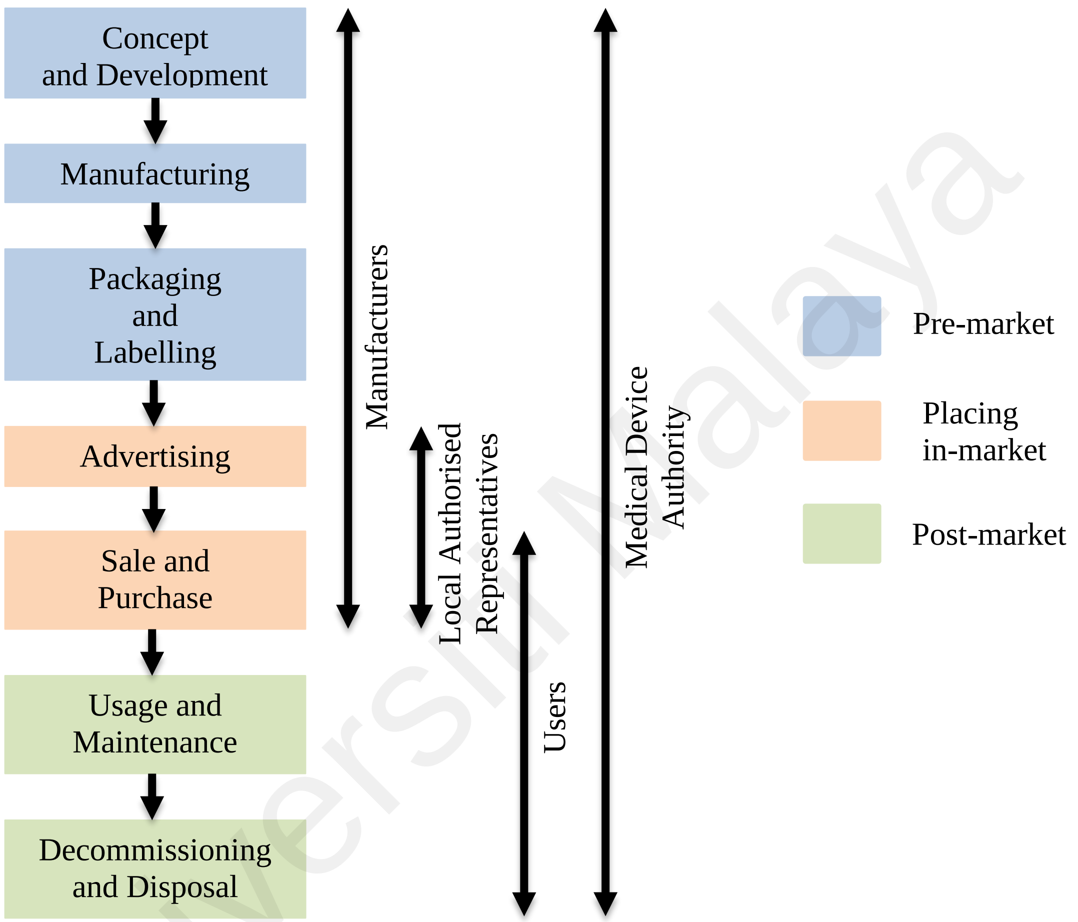


Figure 2.1: Phases in medical device lifespan.

Phases 2 and 3 involve good manufacturing practices and adequate packaging and labelling of medical equipment, respectively. These phases are meant to ensure that non-conforming devices can be filtered during the production line before it is marketed to the public. The 4th and 5th phases of the lifecycle are related and dependent on each other. It is important to ensure that the medical device's marketing and sale adheres to the regulations of the responsible authorities. If the vendor does not comply with these regulations, there is a higher risk of exposing ineffective devices to the public with potential hazards. The 6th phase is where inventory management is required, of which necessary procedures which occur throughout the medical device's life cycle is monitored. For monitoring purposes, a specific system of laws, codes, and definitions used by healthcare organizations must be established to ensure their optimum performance during operation according to the underlying scientific principles (Iadanza *et al.*, 2021). The last phase of the medical equipment cycle is the disposal of certain types of devices that should follow strict safety rules. This is because such specific devices could be contaminated after being used, such as a syringe or any hazardous toxic chemicals.

The functionality of the medical equipment consists of 2 main factors, namely passive and active. Passive medical equipment are equipment which does not use any sources of energy, however, energy is directly generated from the human body or through gravity (Food Drug Administration, 2021). Usually, the design of this type of equipment is not extraordinarily complex, however, it is used to assist the medical personnel in diagnosing or treating patients. One of the most common passive devices is the ambu bag, which is normally used with other life support equipment. The ambu bag is also generally referred to as a manual resuscitator. It is a portable tool that provides positive pressure respiration to individuals who are unable to breathe, or not breathing well enough. Contrary to passive equipment, the active medical equipment does not require self-generated energy sources, however, it requires an external energy source such as electrical energy. Various types of active medical equipment are produced to facilitate healthcare delivery services.

The reliance on electronic technology has motivated the medical industry to advance and pioneer the technical revolution in terms of its functionality, and the performance of the medical devices (Kohani & Pecht, 2018). Fundamentally, the principal function of such medical equipment is to measure or determine the presence of any physical quantities which can in some manner aid medical practitioners in making better diagnoses and treatments. The human body generates a broad range of biological signals. Professionals have learnt how to understand this sensory information in order to provide consultation to a particular patient. It is important that the connection and communication between the electronic medical equipment and the patient is well established to measure or observe the signals (Rajathi *et al.*, 2014). Biomedical signals are information that may be used to build a link between humans and the equipment.

The electronic medical equipment consists of 4 fundamental functional components: measurand, transducer, signal conditioner, and display system, which read, interpret, and tell the medical practitioner about the state of the patient as shown in Figure 2.2 (Khandpur, 2005; Webb, 2018).

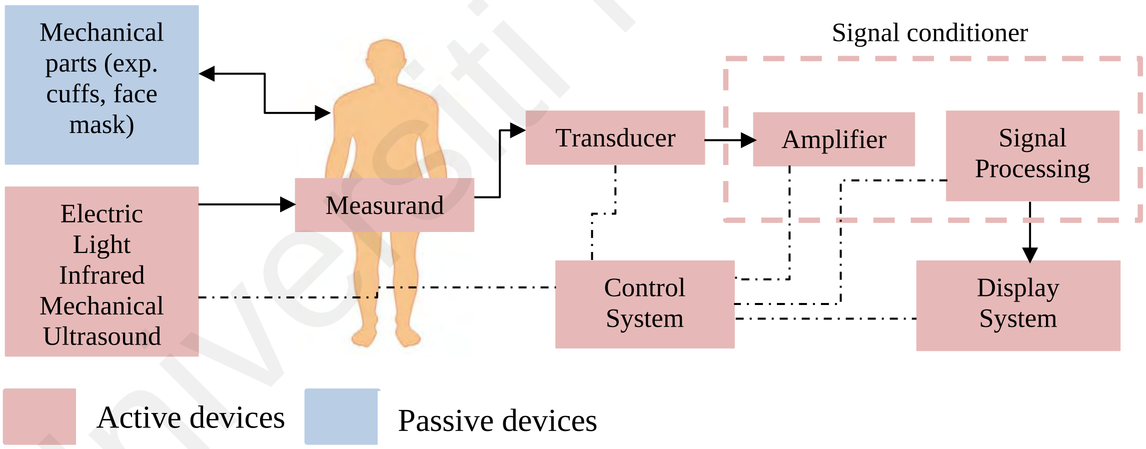


Figure 2.2: General block diagram of medical equipment.

The measurand is the physical state that produces a variety of signals that the instrumentation system monitors as an input. The measurand could be blood pressure in a heart chamber, or on the surface of the body. A device that converts one form of energy to another is known as a transducer or sensor. Because of the well-known benefits of electric and electronic methods of measurement, it is common practice to utilise a transducer to transform any non-electrical phenomena related to the measurand into electrical values. The principal function of the transducer is to provide a useable output in response to the measurand, which might be identified as a specific physical amount, quality, or situation.

The signal conditioner turns the output of the transducer into electrical signals that will be captured by the display or recording devices. Amplification, filtering, analogue-to-digital and digital-to-analogue conversion, and signal transmission circuitry are parts of the signal conditioner’s circuit. The measured parameters are represented visually as displacement either on a scale, on a recorder's chart, on a cathode ray tube's screen, or in numerical form. It can also be a type of aural communication. Microprocessors, microcontrollers, and computer-based intelligent medical devices are used to optimise operations in terms of dependability, efficiency, self-maintenance, and user-friendliness.

2.3 Regulatory Compliance

In ensuring all medical equipment are safe without unacceptable risks, they must perform and function with high compliance in-line with regulations set by regulating bodies. Furthermore, due to the evolving field of biomedical engineering, the diversity and innovativeness of medical devices significantly contributes toward improvements in the quality and efficiency of healthcare services (Badnjević *et al.*, 2018). Although manufacturers are accountable to produce comprehensible equipment, device malfunction during treatment still can exist, and thus exposes patients to potential risks. Adequate guidelines for medical equipment have been initiated to secure the safety of users and patients (Madihally, 2019). Prior to the commercialisation of a medical equipment, it must pass compliance testing and a device clearance stage. Compliance with regulatory authorities is crucial for medical device manufacturers and designers. Regulatory bodies have categorised regulatory requirements based on the degree of the hazard toward the patient, recognising the cost implications for every medical equipment.

2.3.1 International Regulatory Compliance

The World Health Organization (WHO) which was established in 1948, is a United Nations (UN) coordinating body that focuses on worldwide health (World Health Organization, 2022a). This prominent international body is responsible for critical health care issues and partnership participations, preparing agendas and knowledge transfer, setting standards, supervising the implementation of such standards, providing technical assistance for constructing appropriate infrastructure, and monitoring health trends. One of the critical health topics is medical device utilisation.

In 1993, the Global Harmonisation Task Force (GHTF) was formed by the government and industry representatives from Australia, Canada, Japan, the EU, and the United States of America (US), to address the issues of standardised medical device regulations. Ever since, the GHTF has been spearheading initiatives for encouraging the convergence in standards and regulatory practices related to the safety, performance, and the quality of medical devices. A new forum was established in 2011 from the strong foundation of GHTF, called the International Medical Device Regulators Forum (IMDRF) to address new emerging difficulties, while protecting and enhancing public health and safety (International Medical Device Regulators Forum, 2022; World Health Organization, 2017).

Maintaining safety by laying forth the standards that medical devices and accompanying treatments must achieve before they can be commercially utilised is the most important task for regulators. In the US, one of the most popular medical device regulators is the FDA, which is responsible for regulating any matters concerning drugs and medical devices which need to comply with the legislative Federal Food, Drug, and Cosmetic Act (Kramer *et al.*, 2014; U.S. Food and Drug Administration, 2018). The ultimate objective is to ensure the safety and effectiveness of the medical devices in the market. Other medical device restrictions include the EU, which is currently governed under Regulation (EU) 2017/745 (Lissel *et al.*, 2016). In Japan, a regulatory agency called the Pharmaceutical and Medical Devices Agency regulates and monitors medical device manufacturing and distribution activities in the country (Pharmaceuticals and Medical Devices Agency, 2022). The regulation has been gazetted following Japan's Pharmaceutical Affairs Law, which is continuously amended by Japan's Minister of Health, Labour and Welfare. All GHTF and IMDRF regulations have quality system requirements for manufacturers who are obliged to enable periodic inspection by the government and/or accredited third-party agencies as summarised in Table 2.1.

Table 2.1: Tools and general requirements of the five members of the GHTF.

Member	**Pre-market**	**Placing on-market**		**Post-market**
	Clearance identification	**Establishment control**	**Promotion control**	**After-sale requirements**
US	Letter of approval (PMA) and Clearance for marketing (510k)	Registration of establishment	Advertisement prohibition before receiving marketing approval	1) Problem reporting 2) Implant registration 3) Distribution records 4) Recall procedure 5) Complaint handling
EU	Conformitè Europëenne (CE Mark)	Registration of responsible person		
Canada	Device licence	Licence of establishment		
Japan	Approval and notification (Shounin and Todokede)	Manufacturer licence, import licence, and sales notification		
Australia	Australian register of therapeutic goods (ARTG No.)	Enterprise identification (ENTID)		

Several groups, including professional organisations, have worked together to set standards for enhancing the overall quality of medical equipment. The International Electrotechnical Commission (IEC) and the International Organization for

Standardization (ISO), are the 2 largest international organisations which have contributed to the development of many medical equipment standards (Badnjević *et al.*, 2018; International Electrotechnical Commission, 2022; Madihally, 2019). There are more than 50 countries which support the IEC. The Technical Committee of the IEC is in charge of developing medical electrical equipment standards. The IEC has introduced a series of safety standards and regulations that are specific to electromedical equipment. It is possible to utilise these standards to ensure that electrical and electronic equipment communicate with one another, regardless of where it is developed, manufactured, assembled, or used. The ISO is a global organization for standards supported by more than 140 nations across any related activities to ease international trade, and for the development of intellectual, scientific, technical, and economic cooperation (International Organisation for Standardisation, 2022). The ISO is responsible for ensuring the safety, quality, and performance of medical devices through the standardisation of regulatory processes. Complying with the most developed standards is purely voluntary (World Health Organization, 2003). However, as soon as the government or an international trade agreement mandates a standard, it usually becomes legally binding as a result of the government's laws, or contracts between international organisations. The establishment of standards has various advantages, including:

1) Providing the necessary reference for the medical equipment's criteria, involving processes, devices, and services;
2) Improving the safety, reliability, and performance of the developed equipment;
3) Enhancing the compatibility between products, which in turn gives more choice to consumers during the procurement process; and
4) Improving the compatibility in terms of consumables and spare parts.

Table 2.2 tabulates several general standards for medical devices developed by the IEC and ISO.

Table 2.2: Medical devices general standards by IEC and ISO.

Code	Description of Standards
ISO 9000: 2015	Quality management systems - Fundamentals and vocabulary
ISO 20417: 2021	Medical devices - Information to be supplied by the manufacturer
ISO 16142-1: 2016	Medical devices - Recognized essential principles of safety and performance of medical devices - Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards
ISO 16142-2: 2017	Medical devices - Recognized essential principles of safety and performance of medical devices - Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards
ISO 15223-1: 2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
ISO 15223-2: 2010	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 2: Symbol development, selection and validation
ISO/TR 20416: 2020	Medical Devices - Post-Market Surveillance for Manufacturers
ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
ISO 14971:2019	Medical devices - Application of risk management to medical devices
IEC 60364-7-710:2021	Low-voltage electrical installations - Part 7-710: Requirements for special installations or locations - Medical locations
IEC TR 60788: 2004	Medical electrical equipment - Glossary of defined terms
IEC TR 60513: 1994	Fundamental aspects of safety standards for medical electrical equipment
IEC 62366-1:2015/ AMD 1: 2020	Medical devices — Part 1: Application of usability engineering to medical devices — Amendment 1
IEC 62304:2006/ AMD1:2015	Amendment 1 - Medical device software - Software life cycle processes

Table 2.2: Continued.

Code	Description of Standards
IEC 80001-1: 2021	Application of risk management for IT-networks incorporating medical devices - Part 1: Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software
IEC 60601-1: 2022	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 61010-1:2010+AMD1: 2016	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
IEC 62353: 2014	Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment

2.3.2 Malaysian Regulatory Compliance

Malaysia is one of the 11 countries in Southeast Asia with a geographical size of 330,534 square kilometres and a population of 32.7 million as of 2021 (Department of Information, 2022; Department of Statistics, 2022). To date, Malaysia has 135 public hospitals and 210 private hospitals, among other healthcare facilities as shown in Table 2.3.

Table 2.3: Public and private healthcare facilities in Malaysia (Ministry of Health Malaysia, 2019a).

<table>
<tr><th colspan="2">PUBLIC</th><th colspan="2">PRIVATE</th></tr>
<tr><th>Facility type</th><th>No.</th><th>Facility type</th><th>No.</th></tr>
<tr><td>Hospital</td><td>135</td><td>Hospital</td><td>210</td></tr>
<tr><td>Special hospital, institution and centre</td><td>9</td><td rowspan="2">Others (homes, centres)</td><td rowspan="2">646</td></tr>
<tr><td>Non-MoH* hospitals (army, universities)</td><td>10</td></tr>
<tr><td>Clinics (health, community, mobile)</td><td>2,885</td><td>Medical clinics</td><td>7,718</td></tr>
<tr><td>Dental (clinics, mobile)</td><td>2,294</td><td rowspan="3">Dental clinics</td><td rowspan="3">2,311</td></tr>
<tr><td>1Malaysia (clinics, mobile)</td><td>354</td></tr>
<tr><td>1Malaysia dental (clinics, mobile)</td><td>30</td></tr>
</table>

In Malaysia, a regulatory body called the Medical Device Authority was established in 2012, and was mandated to enforce and monitor the activities in manufacturing, marketing, and utilisation of medical devices. This regulatory body directly reports to the Ministry of Health Malaysia. The establishment of this agency is in line with the legislation that has been enforced through the Medical Device Authority Act 2012, or simply known as the Act 738 (Medical Device Authority, 2012b).

The main task of the Medical Device Authority is to enforce the Medical Device Act 2012 legislation (Medical Device Authority, 2012a). The Act, also known as Act 737, comprises three main activities, namely pre-market, placement in the market, and the post-market activities, as shown in Figure 2.1. The pre-market stage involves activities by the manufacturer, consisting of the registration of companies and equipment, compliance with the safety and performance instructions, and labelling, packaging, and marking, as prescribed by the relevant authorities. In the in-market placement phase, advertising processes and permits for exportation must comply with the guidelines that have been established to avoid confusion. In the post-market phase, the act also enforces regulations related to the use, operation and maintenance, which involves competent parties ensuring that it is completely safe and operates optimally.

The development of medical equipment standards is also aggressively pursued by Malaysian authorities for ensuring that the user's and patient's safety is constantly prioritised. The Department of Standards Malaysia, in collaboration with a commercial institution known as SIRIM, is in charge of developing these standards (Department of Standards Malaysia, 2022; SIRIM Berhad, 2022). The establishment and role of the Department of Standards Malaysia are in line with the legislation, referring to the Standards of Malaysia Act 1996 (Act 549) (Department of Standards Malaysia, 2012).

Table 2.4 shows the general standards for medical devices developed by the Department of Standards Malaysia.

Table 2.4: Medical devices general standards by Department of Standards Malaysia.

Standard Code	**Description**	**Normative reference from International Standards**				
		IEC				**ISO**
		(A)	**(B)**	**(C)**	**(D)**	**(E)**
MS 2739:2021	Code of practice - Requirements for installation, testing and commissioning and acceptance of medical device	✓	✓	✓	✓	
MS 2650:2015	Guidance on disposal of medical devices					
MS 2366:2010	Guidance on The Application of MS IEC 60364-7-710 For Group 2: Medical Locations					
MS 2261:2009	Medical devices - Guidance on the selection of standards in support of recognised essential principles of safety and performance of medical devices					
MS 2219:2009	General Testing Procedures for Medical Electrical Equipment		✓	✓	✓	
MS 2058:2018	Code of practice for good engineering maintenance management of active medical devices (Second revision)	✓	✓	✓	✓	✓

Note: (A): IEC 60364-7-710; (B): IEC 60601-1; (C): IEC 61010-1; (D): IEC 62353; (E): ISO 14971.

Although Malaysia has developed several standards or codes of practice, Malaysia has been adopting international standards to assist the parties involved with the implementation of maintenance management. These standards have been assisting national regulatory bodies to develop and update regulations at the national level, and helps in ensuring the implementation and harmonisation of medical equipment maintenances.

For the implementation of medical equipment maintenance management in Malaysia, the Department of Standards Malaysia and SIRIM have published a standard entitled MS2058: 2018, which is a code of practice for good engineering maintenance management of active medical devices (Department of Standards Malaysia, 2018a). This standard is intended to be used as a reference for implementing active medical equipment maintenance in any healthcare institution, and for equipment used only on humans. It covers the life cycle of such equipment from the purchasing process, to its disposal. The maintenance activities involved are preventive maintenances, corrective maintenances, and replacement programs. In addition, these standards also apply manpower, training, warranty management, quality assurance, technical audits, and information management.

2.4 Medical Equipment Maintenance Management

The management of the medical equipment maintenance activity is implemented by a supporting unit called the clinical engineering department. For executing the medical equipment management, the clinical engineering department constantly employs ideas and approaches to improve the technological procedures of a facility (Barrera-Saavedra & González-Vargas, 2019). This requires an effective maintenance strategy that conforms with the country's legislation and current standards, considers the demands of users and technological employees, and provides information and reporting access.

This department consists of engineers who are responsible for ensuring that the medical equipment is operating at the optimum level to support the primary business of delivering the necessary healthcare service. In the American continent, the engineer is called a clinical engineer, while in European regions, they are known as biomedical engineers (Saide Jorge Calil, 2020). Professional clinical engineers are essential toward sustaining a safe and cost-effective healthcare system through good healthcare management. This is because, and it has been discovered, that the healthcare system's performance has deteriorated owing to the lack of qualified clinical engineers (Hossain *et al.*, 2015). A Clinical engineer's supporting and advancing care role comprises a variety of actions that help hospital administration and healthcare professionals, to be able to easily incorporate healthcare technology into clinical practices (Hegarty *et al.*, 2014).

Obtaining an adequate list of the assets possessed by the organisation is an important preliminary approach for managing the business's assets (Gentles, 2020; Muftinisa *et al.*, 2017). In healthcare institutions, one of the crucial technological tools for managing the medical equipment inventory is a CMMS. The device inventory management and work order handling are available in CMMS (Cohen *et al.*, 2020). Any clinical engineering department operation requires a precise and detailed medical equipment database.

The major role of a CMMS as an archive for all activities and information subsequently furnishes the clinical engineers with information necessary for strategising the maintenance execution (Lopes *et al.*, 2016). The specific functions of the CMMS are as tabulated in Table 2.5.

Advanced medical organisations deal with massive volumes of data related to assets and staff that must be managed and synergized. The CMMS is an electronic information platform that was created to aid clinical engineers in the maintenance, repair, and calibration of medical devices (Fuaddi & Sabarguna, 2019; Medenou *et al.*, 2019). Iadanza *et al.* (2020) stated that these tools may be highly beneficial for the management efforts in terms of performance and risk evaluations, as well as company management and development.

Table 2.5: Specific functions of CMMS.

Function	Criteria	Description
Asset Management	Maintenance historical records	Records of number of failure event etc.
	Asset general information	Name of manufacturer, model, serial number, purchased date, asset status etc.
Work order management	Time caption	Date and time of user failure report, duration of repair time
	Maintenance task to a technician	List of technician names, speciality, corrective maintenance work notification
Maintenance management	Planning	Preventive maintenance
	Scheduling	Equipment frequency of inspection
	Control	Equipment performance indicator
Inventory control	Replacement part	List of spare parts, available quantity, price, and name of suppliers
	Consumable part	List of consumable parts, available quantity, price, and name of suppliers
Reporting management	Process large data	Analysis of maintenance historical records
	Generate performance indicators	Equipment performance, uptime, downtime

Therefore, healthcare technology asset management is one aspect of a comprehensive management system, which requires continuous development by medical institutions. Healthcare technology asset management is a challenging task. According to Van Hoof *et al.* (2018), the implementation of asset management reinforces general ethical principles in healthcare services covering the 10 aspects as tabulated in Table 2.6.

Medical equipment are one of the most important physical assets in an organization that provide healthcare and medical services. Organisations have demonstrated a commitment to both the theoretical and practical aspects of physical asset management (PAM). PAM has become a critical component of asset-intensive enterprises, and has turned out to be a pivotal component in Industry 4.0 efforts (Maletič *et al.*, 2020; Maletič *et al.*, 2017). Asset management is a cost-effective technique for running, maintaining, and disposing assets which are utilised by many businesses. PAM is seen purely based on cost alone, but as a genuine investment. Table 2.7 shows the important elements in effective implementation of asset management.

Table 2.6: General ethics in healthcare technology (Van Hoof *et al.*, 2018).

Principle	Description
Autonomy	Provide accurate information to parties involved in health care.
Reliability	Ensure that the treatment given complies with the prescribed procedures.
Equitable resources	Ensure the patients can benefit from the facilities and financial resources.
Safety and security	Ensure the resources used during treatment are safe and comply with all requirements by the authorities.
No harm	Ensure the treatment process does not harm the patient.
Trust and responsibilities	Be responsible for all the consequences that might occur during the treatment process.
Well-being	Ensure the patients are satisfied with the services provided.
Integrity	Uphold the trust to ensure patients receive appropriate treatment.
Dignity	Provide treatment options appropriate to the patient's condition.
Privacy	Safeguard records of patient information.

Table 2.7: Important elements in Asset Management (Al Marzooqi *et al.*, 2019).

Element	Description
Staff competencies	Highly skilled workers
Systematic practices	Preventive maintenance, corrective maintenance, predictive maintenance.
Resources	Human resources, technological reporting and communication system, financial resources
Partnership	Collaboration with industrial players such as manufacturers and service providers
Training	Continuous development of knowledge among team members
Workplace environment	Appropriate workstation, good relation from top to bottom organisational team

Healthcare practitioners expect requirements for these assets to work under a rigorous environment. The healthcare services providers need to verify that their medical equipment is safe, accurate, dependable, and able to operate according to the industry standards. In ensuring that the equipment meets the necessary criteria, these assets must undergo proper maintenance. Typically, many resources are allocated for equipment maintenance actions throughout the device's lifespan, rather than during its procurement (Dhillon, 2011). Medical equipment, in contrast to other forms of healthcare technologies such as disposal items, implant devices, and medications, requires planned and unplanned maintenance programmes throughout its lifecycle.

Fundamentally, maintenance actions are concerned with repairing equipment after it has broken down. They are intended to restore the malfunctioned device to original state failing, and to repair its deterioration as a result of prolonged use (Kumar & Kumar, 2018). The objectives of maintenance management are summarised in Figure 2.3. It is necessary to enhance the equipment and system availability, and to ensure that the resources are utilised as efficiently as possible (Deighton, 2016). This is because unexpected breakdowns of designed items could be fatal, and have repercussions for both humans and the environment. A proper maintenance strategy should not only enhance the economics of operations, but also prevent the threats and implications it may bring to the public (Mohammed Ben-Daya *et al.*, 2016). According to the study made by Bahreini *et al.* (2019), there are seven crucial elements, which lead to an effective maintenance management of medical equipment, as presented in Figure 2.4.

Maintenance management is commonly divided into 2 categories, which are reactive maintenance (unscheduled), and proactive maintenance (scheduled) (Deighton, 2016). Unscheduled maintenance, such as breakdown and corrective maintenance, is referred to as reactive maintenance, and occurs due to unforeseen device failure. Proactive maintenance relates to the actions taken before a problem demands them, and is routinely conducted to prevent any breakdown. It is used to identify and fix situations which might result in equipment degradation, which could incur high repair expenses.

Maintenance cost minimisation	• Reduce repair cost • Spare part inventory
Equipment idle time minimisation	• Repair time
Equipment lifetime maximisation	• Usage optimisation • Wear and tear minimum rate
Resources optimisation	• Accurate records
Gain full advantages	• Optimum equipment performance
Consistent supply	• Zero breakdown
Better utilisation of resources	• Technical personnel • Machinery

Figure 2.3: Maintenance management objectives.

Designing & Execution	• Maintenance strategic • New acquisition and replacement planning
Resources	• Staffs (technical and administration) • Assets (parts, tools, etc.) & finance
Documentation / Information System	• Reporting & database • Work order
Service	• Maintenance performance • Service contract
Inspection	• Stock and parts • Functional and physical checks
Education	• Continuous training • Competency certification
Quality control	• Quality assurance • Regulatory and standard compliance

Figure 2.4: Crucial aspects in medical equipment maintenance management.

2.4.1 Corrective Maintenance

Corrective maintenance is the process of discovering and resolving faults without following a predefined routine (Dhillon & Liu, 2006). This maintenance strategy reinstates equipment to its initial operating condition by replacing components or parts (Lo, 2004; Pintelon *et al.*, 2008; Wang *et al.*, 2010). Repair and replacement (Endrenyi *et al.*, 2001), breakdown maintenance, failure-based maintenance, fire-fighting maintenance, and run-to-failure (Chandima Ratnayake, 2010), are also referred to as corrective maintenance. The corrective maintenance goal is to resolve the equipment's malfunction after the detection is established (Antosz & Stadnicka, 2014; Chandima Ratnayake, 2010; Pintelon *et al.*, 2008; Slack *et al.*, 2005). Maintenances are necessary because random, unstable equipment failures and breakdowns are complex and difficult to forecast. This maintenance strategy is particularly helpful when the breakdown of an apparatus or device does not result in unwarranted hazards, or violates the worker safety regulations (Antosz & Stadnicka, 2014).

Corrective maintenance seems to be an advantageous method for assets with low failure rates, and inexpensive breakdown costs (Pintelon *et al.*, 2008). However, corrective maintenance can be much more expensive over time, as compared to preventive maintenance. This is because when corrective maintenance is required, it indicates that an unfortunate incident has occurred, and that generates unwanted delays due to the wait for replacement parts, random troubleshooting situations, and unanticipated disruptions in service operations (Lo, 2004). As a result, despite corrective maintenance, it is often a costly option when administered alone.

2.4.2 Preventive Maintenance

Preventive maintenance refers to the routine operations carried out regularly and planned in order to keep the equipment in good operating order during inspections and the service period (Dhillon & Liu, 2006; Wang *et al.*, 2010). Maintenances are commonly performed to prevent or reduce failures and depreciation rates (Shahanaghi & Yazdian, 2009). Planned maintenance is another term which represents maintenance management (Antosz & Stadnicka, 2014; Endrenyi *et al.*, 2001; Wang, 2019). The facts prove that the main benefits obtained through preventive maintenance is the high-performance reliability of the equipment (Pongrac *et al.*, 2019).

According to Lo (2004), integrated PM techniques may provide an effective maintenance plan for reducing equipment breakdown, and avoiding the possible dangers of using the medical equipment. Wang *et al.* (2006) speculated that the preventive maintenance of medical equipment may reduce dependability and "existing failure". Ridgway (2009) investigated how much this maintenance measure improves machine performance in terms of the downtime and safety. The investigation discovered that PM has an influence on the function of specific types of equipment, and has a favourable impact on the equipment's uptime. The study also claimed that a well-adopted PM approach would result in enhanced safety, reduced downtime, and lower repair costs.

The execution of PM can be accomplished through Time-Based Maintenance (TBM) and Condition-Based Maintenance (CBM). TBM involves inspecting the system at predetermined intervals, and deciding if a maintenance operation is needed (Buchholz *et al.*, 2018). As most maintenance systems can only be partially observed or tested, this strategy is usually based on limited knowledge about the system's state. CBM has grown in popularity in recent decades, with the goal of performing preventive measures on a timely basis (Shi *et al.*, 2020). CBM focuses on the present state of the system or subsystems, which has a considerable influence on the healthcare facility's maintenance costs, by giving real-time defect reporting utilisation projections (Prajapati *et al.*, 2012).

2.4.3 Replacement Initiative

It is critical to have a strategy to replace medical equipment in healthcare facilities within its lifecycle. This effort has the potential to improve the consistency of medical equipment availability, while also reducing disruptions in the delivery of healthcare services. In the planning process, replacements are a critical component. The history of successes and failures for similar technology over their utilisation periods, which have been fed into the CMMS are often utilised in the replacement planning. At the same time, the replacement initiative is also needed due to the emergence of new technologies which could provide benefits, such as cheaper costs, improved healthcare delivery techniques such as network integration of medical devices, or improved overall health benefits (Clark, 2020).

In the study conducted by Ouda *et al.* (2010), a mathematical model was proven to be a robust quantitative technique, since it allowed more thorough investigations, for accurate judgement on the required replacement. This study concluded that the medical equipment should meet three crucial criteria; technical, financial, and safety, before considering it in the replacement plan. The findings indicated an improvement from the previous study on the replacement plan model developed by Robson *et al.* (2005), where only two main features were considered, which were likelihood and consequences. Likelihood consists of 3 sub-criteria, which are the equipment's condition, its utilisation, and its compliance. Consequence takes into consideration the aspects of business, safety, and finances.

2.5 Reliability Assessment of Medical Equipment

One of the most important concerns for providing high-quality treatment, cost-efficient health services, and conserving finite resources is proper maintenance management of the medical equipment (Arab-Zozani *et al.*, 2021). To evaluate a medical equipment, the level of reliability needs to be identified. This requires specific maintenance data consisting of three main elements; the input, the analytical process, and the output. According to Corciova *et al.* (2017), the data used as an input to the evaluation process consists of two types, namely perceived, and quantitative. The perceived risk assessment style is qualitative, informal, intuitive, and mostly unrecorded. This is a reactive process that requires quick reacting strategies by clinical engineers to reduce the occurrences of risk or situations in the hospital. Clear, formal, precise measurements are recorded for analysing quantitative risk assessments, which are peer-reviewed during the routine maintenance.

Several approaches, such as AI and classical mathematical models, are used to analyse quantitative input data (Gupta *et al.*, 2017; Spahic *et al.*, 2020). The produced output is used as an indication to the relevant authority for performing the necessary maintenance of the medical equipment. With the implementation of assessments on the medical equipment, the responsible parties for overseeing the maintenance management can make initial preparations in the process of work scheduling and resource management, in terms of its financial and technical personnel. Early preparation on the maintenance management can maintain the reliability of medical equipment in the healthcare institution.

Medical equipment maintenance activities are essential throughout the asset's life cycle and useful lifespan. Maintenance techniques depend on the current state of the medical equipment, where periodical inspection activities are necessary to establish the relevant data. The data also needs to be documented into an integrated asset system and updated from time to time. This data collection can then be used as an input in the assessment process of the medical equipment. The assessment procedure is seen as one of the techniques and ways which can be applied in the implementation of medical equipment maintenance management. With the availability of more effective assessment techniques, it is possible to assist in identifying the current state of a medical equipment, and in return, assist clinical engineers in performing appropriate maintenance activities depending on available resources. Early preparation is much more effective with the availability of predictive maintenance techniques that can provide a comprehensive maintenance strategy. Preparation of the required resources can be managed during the earlier stages of the medical equipment's life cycle. Therefore, the reliability of medical equipment in terms of safety, availability, and durability can be maintained, further assisting medical practitioners in delivering improved health services to the public.

Evaluating an effective medical device requires an effective technique for ensuring that it produces much more accurate and precise outputs. From previous studies which have been carried out, it has been proven that strategic maintenance management of a medical equipment is vital toward sustaining its functionality and safety, subsequently providing better healthcare services to the patient. The healthcare institution must execute systematic asset management to ensure that the medical equipment functions as an asset to the organization, and establishes the required cost optimisation. To make things happen, there is a need to understand and monitor the life cycle of the medical equipment by a qualified person. All information about the medical equipment in terms of its specification, maintenance history, the procurement, need to be kept in a proper record list for future reference. This can be achieved by applying the Computerised Maintenance Management System (CMMS), and the data must be continuously maintained from time to time.

Therefore, an effective and comprehensive medical equipment assessment is crucial for improving the device's life cycle management. Available data in terms of the equipment's details, it's purchase information, operational performance, and maintenance activities, can be leveraged to provide significant indicators for strategising management planning.

2.5.1 Structural Equation Modelling (SEM)

According to Taghipour *et al.* (2011), the identification and prioritisation of critical medical equipment can ensure that functional failures can be mitigated. The hospitals need to regulate the maintenance management program to cater for an ever-growing quantity and complexity of medical equipment, so that the equipment can function at the desired performance levels. Taghipour *et al.* (2011) believed that prioritising the critical medical equipment can reduce maintenance costs and expenditure within the provisional budget. The development of a system by applying the Multi-Criteria Decision Making (MCDM) method, known as the Analytical Hierarchy Process (AHP). By establishing the AHP, the construction of a SEM was done to assist decision makers on the maintenance of the medical equipment. A study was conducted in 2011 in Canada involving 11,365 non-imaging and 2,241 imaging medical equipment.

By identifying the critical criteria of related medical equipment, Taghipour *et al.* (2011) adopted 6 main criteria and 10 sub-criteria, which were extracted from literature works, as tabulated in Table 2.8. The determination of the weightage value for each criterion and sub-criteria is done by referring to the opinion of experts who are knowledgeable in the maintenance and operation of such medical equipment. Taghipour *et al.* (2011) has also set grades and intensities for every criterion from the available literature. The assessment of the related medical equipment was done by referring to all available criteria and sub-criteria, and deciding on the grades and intensities accordingly. The medical equipment's final score and rankings were established by computing all criteria and sub-criteria intensities and weightages. The final score value was then transformed into a percentage at the end of the process, and cross-checked based on the proposed criticality class, as tabulated in Table 2.9.

Table 2.8: Table Main criteria, sub-criteria, and weights (Taghipour *et al.*, 2011).

Main criteria (weight)	**Sub-criteria (weight)**	**Sub-criteria (weight)**	**Sub-criteria (weight)**
Function (0.45)	Utilisation (0.7)	-	-
	Availability (0.3)	-	-
Mission criticality (0.1)	-	-	-
Age (0.06)	-	-	-
Risk (0.16)	Failure frequency (0.3)	-	-
	Detectability (0.24)	-	-
	Failure consequences (0.46)	Operational (0.16)	Downtime (1.00)
		Non-operational (0.08)	Repair cost (1.00)
		Safety and environment (0.76)	-
Recalls and hazards alerts (0.16)	-	-	-
Maintenance requirement (0.07)	-	-	-

*Note: () – The value of weights for each criterion determined by experts in the medical equipment maintenance field.

Table 2.9: Proposed criticality class for maintenance prioritisation by Taghipour *et al.* (2011).

Criticality class	**Transformed score**	**Maintenance arrangement**
Low	TSV < 21%	Corrective maintenance
Medium	21% < TSV < 41%	Time-based maintenance
High	41% < TSV	Predictive or time-based maintenance

The study showed that the proposed equipment evaluation technique may help clinical engineers in planning the maintenance strategy. The indication may help to trigger the maintenance personnel in identifying the problems and finding a better solution. Nonetheless, the result of prioritisations may not always be accepted by certain parties, and therefore, an adjustment of the weightage and intensity of every grade should be reassigned.

Referring to the preliminary study conducted by Hamdi *et al.* (2012) discovered that the use of the system for a medical equipment does not take into account the impact element of the equipment’s downtime in the priority process. As a result, a priority model was developed for each maintenance request by calculating a priority index. Hamdi *et al.* (2012) developed a modelling equation for the medical equipment evaluation technique. The study was conducted in 2012, with 50 units of medical equipment, and 28 work orders.

An analysis of the available medical equipment data was done by taking into account the 3 main factors consisting of corrective maintenances, preventive maintenances, and quality control. The inputs from the 3 factors are shown in Table 2.10. The identification of these criteria values were assisted by an assessment rubric, and each criterion was represented by a weightage value. The identification of the prioritisation required for the equipment was produced through mathematical calculations using a numerical form called the priority index. This priority index was calculated for each equipment involved in this study. By producing a priority index, the determination of the priority for each equipment involved in corrective maintenance activities, and the determination of the frequency of preventive maintenance can be achieved. Therefore, the study concluded that the developed system which produced a quantitative output can effectively prioritise the required maintenance based on maintenance requests and the determination of preventive maintenance scheduling much more effectively, to increase the reliability and availability of medical equipments in health institutions in Jordan.

Oshiyama *et al.* (2012) found that there were challenges in the extraction of important information from large datasets of medical equipment to aid maintenance management.

Decisions in maintenance management were based on simple perception without using any more effective techniques or methods. Thus, Oshiyama *et al.* (2012) have developed a system consisting of a combination of 2 techniques for categorising the class of the medical equipment. The first technique is known as the ABC analysis, and the second is the Paraconsistent Annotated Logic (PAL) technique. The study was conducted at the University of Campinas, Sao Paulo, Brazil in 2012, with a total of 2,134 units which consisted of various types of medical equipment.

Table 2.10: Input features of work-order prioritisation by Hamdi *et al.* (2012).

Factor	**Criteria**	**Description**
Corrective Maintenance	Function	Intention of equipment
	Location	Location of equipment use
	Hospital load	Number of beds
	Request time	Duration between user report time to initial repair time.
	Alternative availability	Number of backup equipment
	Distance to the nearest alternative	Distance in kilometres to the nearest available backup unit
Preventive Maintenance	Repair time	Duration required by maintenance personnel to complete rectification work.
	Failure rate	Measurement of equipment failure frequency.
Quality Control	Failure probability	Possibility of equipment to fail.
	Number of failures	Number of equipment failure events.
	Downtime	Duration of equipment fail to operate
	Service life before failure	The period of equipment effectiveness before it fails to function for the first time.

There were 2 main types of data taken from the CMMS, namely the information of the equipment and the corrective maintenance data. The equipment information consisted of its identification number, location, manufacturer, model, and purchased cost. The corrective maintenance data consisted of the number of maintenance events, the total number of repair times, and repair costs. For the ABC analysis, these 3 corrective maintenance data were used to calculate the primary maintenance indicators, which were then identified as the frequency, time and cost of the corrective maintenance. At the end of this ABC analysis, each instrument involved would be represented by the cumulative sum value. This cumulative sum is presented in the form of a percentage, and the result of the calculation involved the frequency, time, and cost of the corrective maintenance. Oshiyama *et al.* (2012) proposed that, if the cumulative sum value was below 71%, then the equipment was classified as a C. The equipment was classified as a class B if the cumulative sum value was between 70% to 90%, and a class A when the value exceeded 90%.

According to the Oshiyama *et al.* (2012), the classification of such equipment may cause inconsistencies. Therefore, the output of the ABC analysis was included in the second level of the analysis, namely PAL, as a supporting tool to determine the consistency of the equipment's classification. From the results obtained using the PAL technique, 85.5% of the results produced by the ABC analysis were consistent. This meant that 14.5% of the ABC analysis output was found to be inconsistent or partially complete. An indefinite situation was detected between class C dan B. To overcome this problem, further studies need to be done to obtain additional information to improve the consistency. However, Oshiyama *et al.* (2012) recommended that the class C equipment should be given priority in terms of replacement activities, where it was found that the maintenance performance on equipment in that class was the most wanting.

Faisal and Sharawi (2015) stated that there were weaknesses in making assessments to assist the relevant parties in deciding on the replacement of medical equipment in Egypt. Decisions on the implementation of medical equipment replacement were not based on accurate information, and did not use scientific techniques. The information used did not take into account matters relating to cost, the age of the equipment, and the current conditions of equipment. Therefore, Faisal and Sharawi (2015) developed an AHP medical equipment evaluation technique to identify the ranking and prioritisations needed for the replacement of the medical equipment. The study was conducted at the University of Cairo Egypt in 2015, where a total of 30 units consisting of 5 types of medical equipment were studied in the intensive care unit (ICU). The analysis of this medical equipment data took into account 7 main criteria and 8 sub-criteria. These criteria are shown in Table 2.11.

Table 2.11: Replacement prioritisation criteria and sub-criteria adapted from Faisal and Sharawi (2015).

Main criteria	**Sub-criteria**
Maintenance cost	-
Function	-
Clinical acceptability	-
Support availability	Vendor support
	Alternative support
Age	Device
	Technology
Operational	Utilisation
	Backup
Performance	Failure rate
	Efficiency coefficient

The determination of these criteria was assisted by an assessment rubric, and each criterion was represented by a weightage and score values. The determination of the equipment's priority for replacement purposes was labelled as the priority replacement index. The calculation of the priority replacement index was done manually for each equipment involved in this study. The limit for the priority replacement index was from 0.00 to 1.00. The results of this study found that the highest priority replacement value was 1.00, and the lowest value was 0.09.

The value of the priority category specified by Faisal and Sharawi (2015) was compared to each medical equipment represented by this priority replacement index. If the priority replacement index of medical equipment is less than 0.5, the equipment is then considered as a low priority replacement. However, if the priority replacement index is constant and surpasses 0.5, the equipment is then classified as having a high replacement priority. The replacement, on the other hand, must take into account the hospital's current budget. According to Faisal and Sharawi (2015), the approach created can assist the hospital's engineering management department in making decisions on the medical equipment's replacement by systematically considering relevant parameters.

Saleh *et al.* (2015) noticed the necessity for improvement of the management and control, as the dimensions of maintenance tasks increased due to a growing variety of medical equipment. It becomes a challenging task due to the limited numbers of people and resources involved in a medical equipment maintenance management program. Saleh *et al.* (2015) believe that it can be resolved by prioritising the equipment maintenance by focusing on critical criteria based on the outlined customer requirements.

To establish this aim, Saleh *et al.* (2015) developed a new preventive maintenance prioritisation system, by applying the Quality Function Deployment (QFD) method. It consists of 3 domain framework models; requirements, functions, and concepts. The requirement domain comprises of two elements, which are customer desires, and technical characteristics. Moreover, the functional domain consists of top technical requirements and critical criteria, as well as equations and inspection values for the concept domain which are done by engineers. The medical equipment score is then determined by applying 11 parameters, guided by the critical matrix. The parameters are shown in Table 2.12.

Table 2.12: Critical parameters and proposed scores of preventive maintenance prioritisation adapted from Saleh *et al.* (2015).

Parameter	**Proposed scores (Range)**
Function	1-5
Physical risk	1-5
Maintenance requirement	1-5
Utilisation level	1-3
Area criticality	1-5
Device criticality	1-3
Failure rate	1-3
Useful life ratio	1-3
Device complexity	1-3
Missed maintenance	1-3
Downtime	1-3

To generate the final score of medical equipment, the calculation involved specific criteria weightages, of which the values were then proposed by the experts in the field. To test the practicability of this technique, the data from across 70 types of medical equipment, which consisted of 200 unit in the year of 2012, were used. The final score in the form of a percentage was referred to for the preventive priority index groups. The equipment was prioritised based on 5 priority levels: very high, high, medium, low, and minimal.

The study found out that there was a high correlation present between the medical equipment's risk assessment and it's preventive maintenance management. Furthermore, the prioritisation of the critical medical equipment was able to be solved by applying the QFD method. The risk-based criteria of the medical equipment was a major influence on the preventive maintenance prioritisation. However, the accuracy of the results depended on the existence of the medical equipment's detailed history, so that it would then assist in the decision making. The study also proposed that the customer requirements can be improved by applying a specific model to clarify the customer satisfaction attitudes, and the QFD model can also be implemented in future acquisitions and procurements.

Each medical device produced has a lifespan as typically specified by the manufacturer. Aridi *et al.* (2016) found that excessive use of a medical equipment can reduce the equipment's performance and shorten its lifespan. Therefore, Aridi *et al.* (2016) developed a ranking assessment system based on the medical equipment for replacement purposes. This evaluation study was conducted at the Lebanese International University Beirut, Lebanon in 2016. The case study was performed at the Lebanese and public university hospitals, where 324 units consisting of 35 types of medical equipment were used in dialysis and critical care units. The equipment data was collected based on input from across 24 medical professionals and engineering staff.

The development technique used traditional mathematical models involving several inputs. These inputs consisted of 5 main criteria and 5 sub-criteria, as shown in Figure 2.5. The values for each medical equipment criteria and sub-criteria were calculated using a SEM to produce a transformed score value. The values for each main criteria and sub-criteria were calculated by referring to the values of the weightages and intensities. These values were guided by available literature review conducted by Aridi *et al.* (2016).

The calculation of the transformed score value for each equipment involved was in the form of a percentage. For equipment that had a transformed score value exceeding 65%, it was categorised as highly critical, where the replacement of the equipment needed to be done immediately. The equipment was categorised as medium criticality for a transformed score value between 51% to 65%. Equipment under this category must be replaced within 6 months to a year. The equipment should be changed after 3 years when the transformed score value was below 51%. The results were validated by comparing with the findings of a response survey by medical professionals. The result of the validation for the description of the replacement classification based on criticality level is shown in Table 2.13.

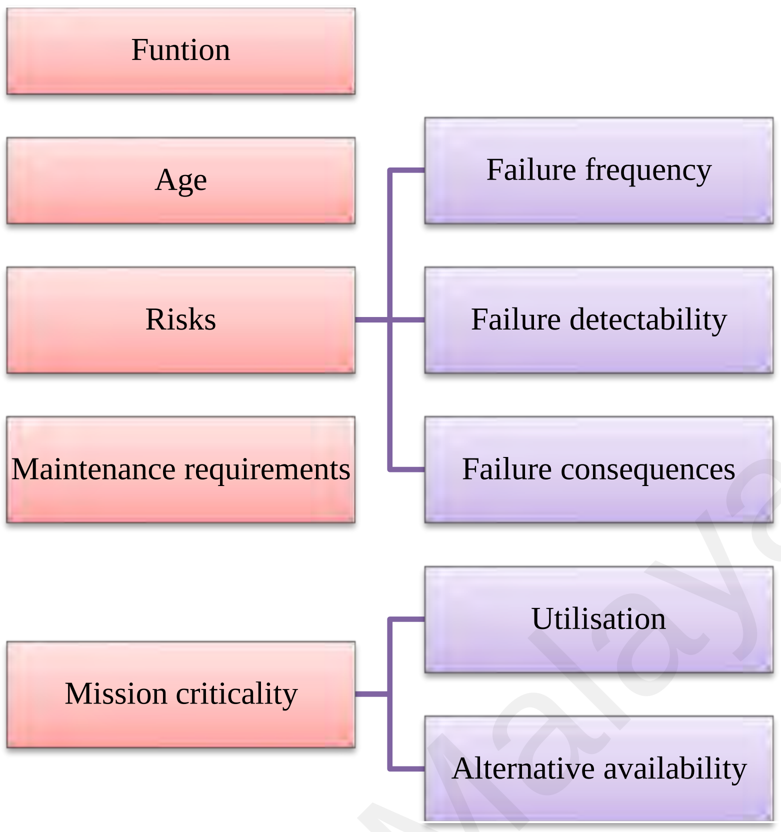


Figure 2.5: Five main criteria dan sub-criteria of equipment lifespan assessment (Aridi *et al.*, 2016).

Table 2.13: Table Replacement program based on criticality level adapted from Aridi *et al.* (2016).

Criticality level	**Description**
High	Replacement of equipment should be executed immediately.
Medium	Replacement of equipment can be postponed for a short time period.
Low	Replacement of equipment can be postponed for a longer time period. Equipment is safe to be used on the patient.

The application of this technique may assist healthcare institutions in planning the medical equipment replacement program, by focusing on critical levels, subject to the available provisional budget, and the cost of new procurement.

According to Ben Houria *et al.* (2016), high maintenance costs were due to wrong decisions in selecting the correct maintenance strategy. Furthermore, there was no technique for switching the medical equipment maintenance strategy from one to another in current practice. Therefore, by prioritising the medical equipment and selecting the best maintenance strategy, this effectively establishes maintenance cost optimisation. To test the practicality of the framework, the study used 2,000 units of medical equipment in a hospital in Tunisia.

Ben Houria *et al.* (2016) developed the framework by applying a combination of 3 methods; AHP, Technique for Order Performance by Similarity to Ideal Solution (TOPSIS), and Mixed-Integer Linear Programming (MILP). Table 2.14 shows the purpose of these three techniques in the study. To measure the criticality and identify the rankings of the medical equipment, 7 main criteria and 6 sub-criteria were proposed based on judgments by experts and from literature reviews, as tabulated in Table 2.15.

Table 2.14: The purposes of applying AHP, TOPSIS and MILP adapted from Ben Houria *et al.* (2016).

Stages	Purposes
AHP	To decide equipment criticality & establish ranking according to an increasing order.
TOPSIS	To rank and classify different maintenance strategies (CM, TBM, CBM).
MILP	To select optimal strategy for each medical equipment while keeping the total maintenance costs within a predetermined budget.

Table 2.15: Criteria and sub-criteria of quantitative techniques for medical equipment maintenance management (Ben Houria *et al.*, 2016).

Criteria	Sub-criteria
Maintenance complexity level	-
Function	-
Age	-
Recalls and user errors	-
Equipment classes	-
Risk	Detectability
	Frequency
	Downtime
	Safety
Mission importance level	Utilisation rate
	Alternative availability

The calculation for determining the criticality score of the medical equipment was based on weightages for every criteria and sub-criteria opined by the maintenance service personnel at the Tunisian hospital. To develop the maintenance strategies for the medical equipment, the calculation was made by multiplying the normalised performance matrices with the criteria weightages achieved from the previous stage. The normalized performance matrix was calculated based on the weightages from the maintenance service team. The final stage was selecting the appropriate maintenance strategy for every medical equipment used in this study. The MILP technique defined the thresholds by separating the medical equipment into the specified maintenance strategies. The estimation of the provisional budget was taken into consideration in the calculation. The optimal medical equipment maintenance strategies were done by considering the availability of the budget tabulated in Table 2.16.

Table 2.16: Optimal medical equipment maintenance strategies proposed by Ben Houria *et al.* (2016).

Criticality	Maintenance Strategies
High ($4.66 \leq T2$)	Time-based maintenance (TBM)
Medium ($3.04 \leq T < 4.66$)	Condition-based maintenance (CBM)
Low ($T1 < 3.04$)	Corrective Maintenance (CM)

The study expressed that the selection of maintenance strategies were based on the medical equipment's criticality as an effective and proven way through computational studies. Furthermore, maximising the equipment availability and increasing its reliability can be done through the MILP model, which looks for the best number available for the equipment, which is maintained in the CBM and TBM. Moreover, by applying this technique, it shows which equipment is maintained in the CBM and TBM if a sufficient budget is allocated toward the maintenance activities.

Ismail *et al.* (2018) stated that the technology of the medical equipment does not guarantee the safety of patients. With the lack of effective maintenance implementation, even high-tech medical equipment can jeopardise the delivery of health services for the patients. Hence, emphasising a proper medical equipment maintenance program is able to improve the performance and control the risks which may occur. The implementation of an effective maintenance program can be achieved with a risk forecasting system for the medical equipment. Ismail *et al.* (2018) conducted the study in 2018 at the Lebanese International University Beirut, Lebanon. A total of 43 units consisting of various types of medical equipment were housed in Lebanese hospitals.

This medical equipment's maintenance and dysfunctional data considered the three main elements of severity, likelihood, and failure detection. The value for each element ranged from 0 and 10. The determination of the value of each of these elements resulted from the monitoring of the medical equipment by parties who specialised in the maintenance and operation of the involved equipment. The higher the value of a given element, the higher the probability of the risk. This technique is also known as the Failure Modes and Effects Analysis (FMEA). Once the values of these elements have been determined, the calculation of the risk priority number is then performed. The value of the risk priority number for each equipment is placed in the range of 1-1000. Once each tool has this risk priority number allocated to them, these values are then integrated into the risk simulation tool using the Microsoft Excel application's Monte Carlo simulation technique. At the end of the simulation process, the decision is integrated in the probability distribution function. The probability distribution function is a statistical method and it depends on several factors, such as the mean distribution and standard deviation. The results of this simulation will display the percentage of the probability distribution with reference to the risk priority number.

The risk priority number for each equipment will be compared with the risk severity matrix. Equipments with a risk priority number value of less than 30 are categorised as low risk. For a risk priority number in the range of 30 to 300, the equipment is categorised as a medium risk. When the risk priority number exceeds 300, it is categorised as a high risk. Therefore, by applying a mathematical approach for classifying an equipment's risk, much more effective maintenance and planning of the development of medical equipments in a health institution can be performed.

Hernández-López *et al.* (2019) observed that the frequency of the scheduled maintenance was permanently altered by the organization due to the local environment. The reason for doing that was because the maintenance activities seemed to disturb the delivery of healthcare services, especially involving critical equipment. Due to the improper adjustment made, Hernández-López *et al.* (2019) proposed an indexing model that can be used to schedule preventive maintenances annually. To test the practicality of the indexing model, the study applied eight types of medical equipment, which consisted of 16 units located in the National Institute of Respiratory Diseases in Mexico.

This indexing model could assist users in prioritising the number of preventive maintenances required in a year, extending the lifespan of the equipment, and reducing the costs of the required operations. This model was developed using a mathematical model by considering 7 proposed features, which are 1) types of equipment, 2) equipment function, 3) maintenance requirements, 4) calibration, 5) equipment age, 6) equipment location, and 7) equipment hazards. These features were based on the proposal from the WHO, and literature reviews done by Hernández-López *et al.* (2019). It also comprised of 49 qualitative domains, which were expressed with specific quantitative values. The inspection description of the medical equipment was based on these variables, for both qualitative and quantitative domains. For generating these accurate results, the inspection requires personnel who possesses lots of experience and knowledge about the medical equipment. Then, the equipment description is calculated by applying a mathematical formula, which consists of the specified weightage value to generate the numerical value of 0 to 1. Finally, this value is mapped with the proposed interval for the maintenance priority table, to identify the priority and equipment maintenance intervals. Table 2.17 shows the intervals for the maintenance priority.

Table 2.17: Interval for Maintenance Priority (Hernández-López *et al.*, 2019).

Output value	Priority	Interpretation
0 - 0.39	Low	One maintenance intervention annually
0.4 - 0.69	Medium	Two maintenance intervention annually
0.7 - 1	High	At least three maintenance intervention annually

The study shows that the age and location of the equipment significantly influences the results of the priority for the same description of the equipment. Therefore, the proposed index model permits the priority and the number of preventive maintenance interventions required annually for one unit of a medical equipment. Furthermore, the model output can be a supplementary criterion for other medical institutions to prioritise the annual preventive maintenance plans.

According to Hutagalung and Hasibuan (2019), the decline in reliability, availability, and the increase in maintenance costs of a medical equipment in a health institution is due to the increase in the number of equipment used in health institutions. In addition, the diversity and complexity of modern equipment also contributes to these problems. These factors become a challenge for the management for prioritising maintenance activities. Thus, the development of a system to determine the priority levels of the medical equipment by using the AHP technique. The study was conducted at Mercu Buana University, Jakarta, Indonesia in 2019, where a total of 29 units consisting of various types of medical equipment in the Out-Patient Department of Eye Hospital was conducted.

Several criteria and sub-criteria for the medical equipment were proposed as an input to the developed system. These criteria and sub-criteria were based on national guidelines and previous studies conducted. The criteria and sub-criteria used are shown in Figure 2.6. The evaluation process refers to the valuation matrix, in which the values of these criteria were based on the input from the views of experts skilled in the maintenance and operation of such medical equipment in the department using a questionnaire. The calculation to obtain the total score of the medical equipment was done using a traditional mathematical approach. The determination of the total score involved the calculation of three elements for a medical device, namely the weight criteria, the weight sub-criteria, and its intensity. The values of the weightage and intensity were based on literature reviews and feedback from experts.

The determination of the priority of the manufacturing equipment is based on the generated total score, also known as the risk assessment value. The higher the total score value, the higher the priority which should be given to the medical equipment. Therefore, the management in health institutions can formulate a plan for maintenance activities based on the generated total score.

Jarikji *et al.* (2019) stated that it is challenging to determine the factors that could impact the efficiency of maintaining the medical equipment throughout the equipment's life cycle. Typically, estimations of a medical lifetime are based on the technical aspects without considering environmental factors, where these 2 factors could significantly affect the decision-makers in the case the medical equipment fails. This study introduced a new SEM approach for assessing the medical equipment by referring to these 2 main criteria; technical factors and environmental factors.

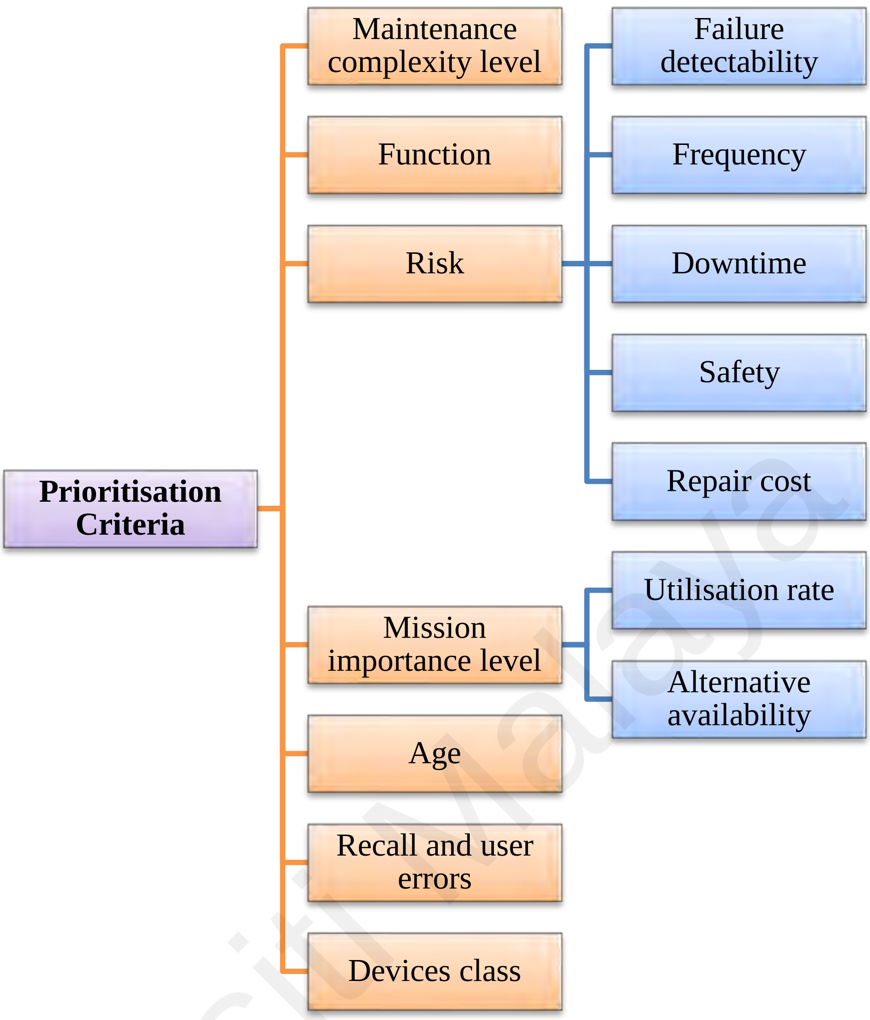


Figure 2.6: Criteria and sub-criteria of prioritisation proposed by Hutagalung and Hasibuan (2019).

There are 5 criteria under the technical factors which were adopted from literature. These criteria are; 1) Function, 2) Age, 3) Mission Criticality, 4) Risks and 5) Maintenance Requirements. The environmental factors consist of; 1) Political, 2) Geographical, 3) Governmental and 4) Economics. To test the reliability of the technique, 3 units of medical equipment used in the Lebanese hospital were used as samples, which were the defibrillator, the ICU monitor, and the pulse oximeter. The weightage criterion for the technical and environmental factors were collected via a survey, whereas the intensity was calculated through specific equations used in the study. The results of the total score also known as the transformed score value for each equipment represented the criticality and required maintenance actions. Table 2.18 tabulates medical equipment's criticality and maintenance actions according to total score. In conclusion, the outcomes of this study expressed that the model could assist the clinical engineers in making the appropriate decisions on maintenance activities for the medical equipments by considering the economic aspects.

Table 2.18: Medical equipment criticality and maintenance action (Jarikji *et al.*, 2019).

Criticality	Total Score (TS)	Maintenance Action
High	70% < TS < 100%	To be changed urgently
Medium	30% < TS < 70%	To be changed after a year and a half
Low	0% < TS < 30%	To be changed after three years

Technological advances involving medical equipment development have established a standard compliance to a higher level. The higher standard compliance improves the quality and safety of the healthcare service delivery to the community. Abirami and Sudheesh (2020) stated that the improvements in technology and higher compliance to these standards may cause the implementation of medical equipment maintenances which become complicated. Therefore, Abirami and Sudheesh (2020) suggested that medical equipment parts that frequently fail should be prioritised during the implementation of preventive maintenances. Abirami and Sudheesh (2020) developed an AHP assessment technique for the medical equipment components for priority purposes during maintenance implementation activities. Among the equipments involved in this study were ventilators, syringe pumps, and haemodialysis units. The equipment datasets included a 7-year damage record from Narayana Health, India.

The analysis of the parts prioritisation for the 3 types of medical devices involved 5 criteria. The criteria were; 1) Age, 2) Utilisation, 3) Materials, 4) Environmental condition, and 5) User relatedness. To determine the priority of these parts during preventive maintenance, a set of questionnaires was distributed to 15 individuals consisting of biomedical and service engineers. The survey involved 5 parameters represented by the reference scale, and the respondents needed to submit scores based on their experience and knowledge related to the equipment. The obtained scores were then used for the calculation of the weights and final scores for each of the proposed parameters. Abirami and Sudheesh (2020) also calculated the consistency ratios to achieve the reliability of the priority component sequences for the three medical devices.

Based on the analysis conducted, Abirami and Sudheesh (2020) summarised that the utilisation of the medical equipment parts was a major factor that caused equipment failure. This was followed by the age, materials, environmental conditions, and user-relatedness, respectively. It was found that the feedback from the engineers were consistent for determining the priority factors of the medical equipment components. In summary, the parts which are frequently used during treatment should be given priority in the preparation of preventive maintenance checklists. The other four factors also need to be listed to achieve a much more comprehensive inspection result. However, Abirami and Sudheesh (2020) suggested that the involvement of other relevant parties in determining the score should be implemented, and thus the determination of the priority factors of the medical equipment parts is much more accurate.

The summary of 12 relevant studies that applied the SEM technique is tabulated in Table 2.19.

Table 2.19: Summary of 12 studies using SEM.

Reference	**Criteria of Assessment**	**Maintenance Strategy**
Taghipour *et al.* (2011)	**Six main criteria:** 1) function, 2) mission criticality, 3) age, 4) risk, 5) recalls and hazard alerts, and 6) maintenance requirements	Preventive and corrective maintenance

Table 2.19: Continued.

Reference	Criteria of Assessment	Maintenance Strategy
Taghipour *et al.* (2011)	**Ten sub-criteria:** 1) utilisation, 2) alternative unit availability, 3) failure frequency, 4) failure detectability, 5) failure consequence, 6) operational consequence, 7) downtime, 8) non-operation consequence, 9) repair cost, and 10) safety and environment consequences	Preventive and corrective maintenance
Hamdi *et al.* (2012)	**Six factors for corrective maintenance:** 1) function, 2) location, 3) hospital load, 4) time since request made, 5) alternative availability, and 6) distance to the nearest alternative **Two factors for preventive maintenance:** 1) repairs (in hour) per year and 2) failures (in hour) per year **Four factors for quality control:** 1) failure probability, 2) no. of failure ratio per year relative to a total number of medical equipment, 3) mean down per year, and 4) mean service life before the first failure	Preventive and corrective maintenance
Oshiyama *et al.* (2012)	**Three main variables:** 1) corrective event number, 2) time, and 3) cost	Replacement plan
Faisal and Sharawi (2015)	**Seven main criteria:** 1) support availability, 2) performance, 3) maintenance cost, 4) age, 5) function, 6) operational impact, and 7) clinical acceptability **Eight sub-criteria:** 1) vendor support, 2) alternative service support, 3) failure rate, 4) efficiency coefficient, 5) device age, 6) technology age, 7) utilisation, and 8) availability of backup equipment	Replacement plan

Table 2.19: Continued.

Reference	Criteria of Assessment	Maintenance Strategy
Saleh *et al.* (2015)	**Eleven main parameters:** 1) function, 2) physical risk, 3) maintenance requirements, 4) utilisation level, 5) area criticality, 6) device criticality, 7) failure rate, 8) useful life ratio, 9) device complexity, 10) missed maintenance, and 11) downtime ratio	Preventive maintenance
Aridi *et al.* (2016)	**Five main criteria:** 1) function, 2) mission criticality, 3) age, 4) risks, and 5) maintenance requirements **Five sub-criteria:** 1) utilisation, 2) alternative unit availability, 3) failure frequency, 4) failure consequences, and 5) failure detectability	Replacement plan
Ben Houria *et al.* (2016)	**Seven main criteria:** 1) maintenance complexity degree, 2) function, 3) risk, 4) age, 5) mission importance degree, 6) recalls and user errors, and 7) equipment class **Six sub-criteria:** 1) detectability, 2) frequency, 3) downtime, 4) safety, 5) utilisation rate, and 6) alternative unit availability One criterion (TOPSIS): 1) cost of repair	Preventive and corrective maintenance
Ismail *et al.* (2018)	**Three main criteria:** 1) failure probability, 2) severity from failure, and 3) failure detection.	Preventive and corrective maintenance
Hernández-López *et al.* (2019)	**Seven main factors:** 1) type, 2) function, 3) maintenance requirement, 4) calibration, 5) age, 6) hazards, and 7) location	Preventive maintenance
Hutagalung and Hasibuan (2019)	**Seven main criteria:** 1) maintenance complexity level, 2) function, 3) risk, 4) mission importance level, 5) age, 6) recalls and user errors, and 7) class of medical equipment	Preventive and corrective maintenance

Table 2.19: Continued.

Reference	Criteria of Assessment	Maintenance Strategy
Hutagalung and Hasibuan (2019)	**Seven sub-criteria:** 1) failure detectability, 2) failure frequency, 3) downtime, 4) safety, 5) repair cost, 6) utilisation, and 7) alternative availability	Preventive and corrective maintenance
Jarikji *et al.* (2019)	**Two main dimensions:** 1) technical, and 2) environmental. **Five criteria (technical):** 1) function, 2) age, 3) mission criticality, 4) risk, and 5) maintenance requirements **Four (4) criteria (environmental):** 1) political, 2) geographical, 3) governmental, and 4) economical	Replacement plan
Abirami and Sudheesh (2020)	**Five main criteria:** 1) Age, 2) Utilisation, 3) Materials, 4) Environmental condition, and 5) User related	Preventive maintenance

2.5.2 Fuzzy Logic

Referring to the study conducted by Tawfik *et al.* (2013), most hospitals in developing countries suffer from a lack of funds and scale, qualified technical personnel. This deficiency leads to improper and irregular maintenance activities on the medical equipment. Thus, the development of a risk assessment of the medical equipment by applying fuzzy logic techniques to overcome the problem. The study was conducted at the University of Cairo, Egypt in 2013. A total of 136 units consisting of five types of medical equipment located across 4 hospitals in Egypt were used as the study sample. Data analysis of this medical equipment took into account 4 main features and 3 sub-features. The features are as shown in Figure 2.7. These criteria referenced available literature reviews. The values for each criterion and sub-criteria were determined by experts knowledgeable on the functions and operation of the equipment involved based on the set weightage range.

The development of the fuzzy logic model was done using the MATLAB application. The output for the input data analysis was a risk score representing each instrument involved. Based on this risk score, the equipment was classified into 4 levels of risk, namely very low, low, medium, and high risk. The limits for each risk classification were not specified in the study. The evaluation of the medical equipment was classified according to this technique and done by a third party with extensive experience in the handling of the equipment involved for the finalisation. If healthcare institutions have a limited maintenance budget, it was a recommendation that they should take fast action on any equipment categorised as medium or high risk. However, this study has a disadvantage, in the sense that it relies on medical equipment experts to provide judgments for each of the equipment's criterion.

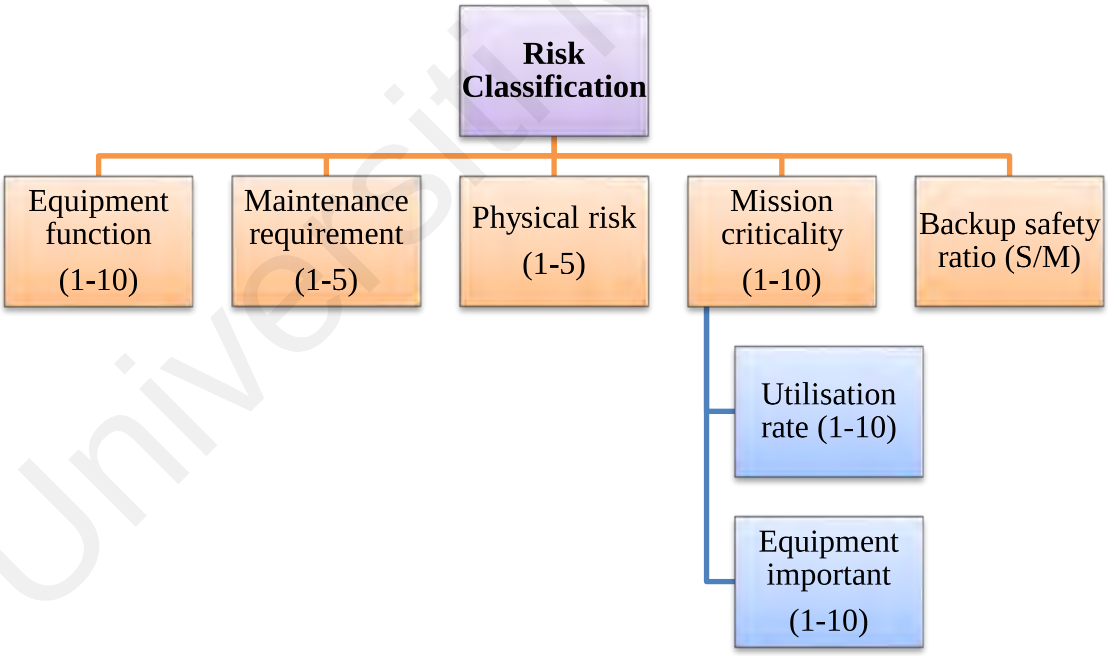


Figure 2.7: Criteria and weightage values of medical equipment risk classification proposed by Tawfik *et al.* (2013).

According to Jamshidi *et al.* (2015), the deterioration of the medical equipment's performance due to ineffective maintenance executions may affect the safety of the medical staff and patients. Moreover, the preliminary study discovered that there were additional important criteria which could be improved from previous literature works. This improvement allowed managers to classify and prioritise the medical equipment maintenance tasks according to criticality scores, and hence increase the availability of the equipment in healthcare institutions. The study was conducted in Canada, in 2015, using 5 types of medical equipment. The equipment was an infant incubator, defibrillator, infusion pump, surgical light, and automatic radiographic processor.

The development of the prioritisation frameworks comprised of 3 main steps. The first step was the application of a fuzzy failure modes and effects analysis (FFMEA). It considered some risk assessment factors, which consisted of 3 main criteria and 9 sub-criteria, as shown in Figure 2.8. The criteria are fuzzified using the proposed membership functions, and defuzzified to obtain the equipment's index. The fuzzy ratings, which existed between 0 to 10 were defined in accordance with the experience of the Jamshidi *et al.* (2015), in addition to the opinions of the maintenance staff.

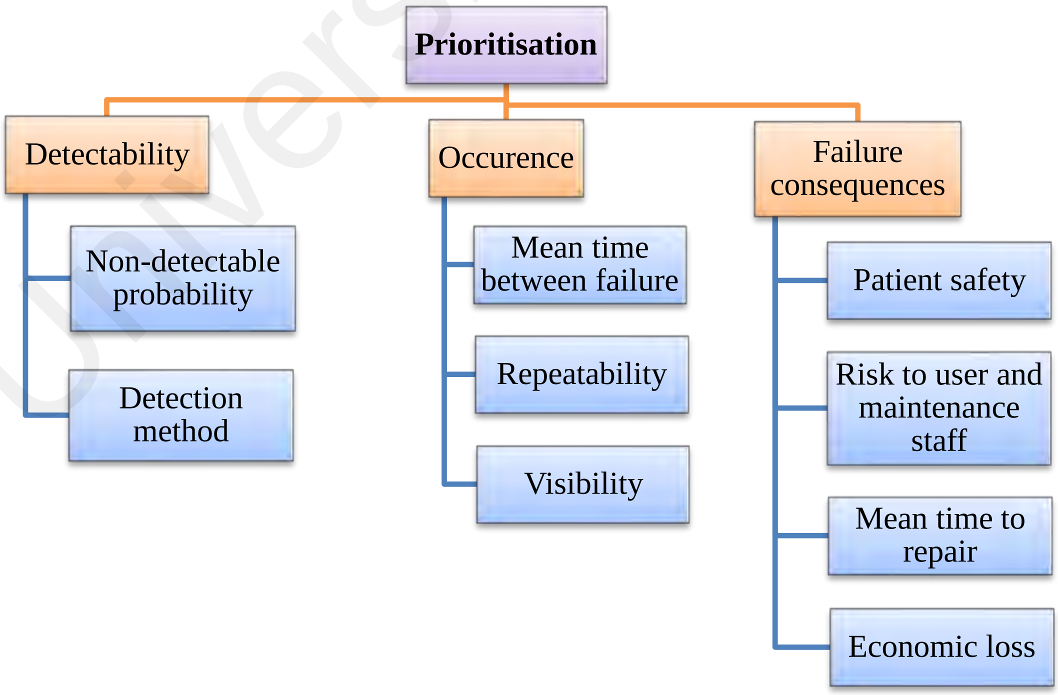


Figure 2.8: Criteria and sub-criteria of fuzzy risk-based maintenance framework (Jamshidi *et al.*, 2015).

The second step involved 7 miscellaneous criteria to acknowledge the prioritisation of the medical equipment in all areas of hazards and risks. Those criteria were the age, usage-related hazards, utilisation, number of available identical equipment, recalls and hazard alerts, functions, and maintenance requirements. The total intensity of the equipment was obtained by measuring all the intensities and weights of each dimension. The weighing of each dimension was based on the experience and knowledge of the experts. The final step comprised the identification of the optimal maintenance strategy for every equipment based on the scores generated from Step 1 and Step 2, through the maintenance planning diagram as shown in Figure 2.9. It can be concluded that the equipment risk-based prioritisation was practical for prioritising maintenance activities, and allocating resources to the maintenance activities in healthcare institutions. Furthermore, numerous multidisciplinary experts helped in listing the significance of the criterion as well as the evaluation of the alternatives.

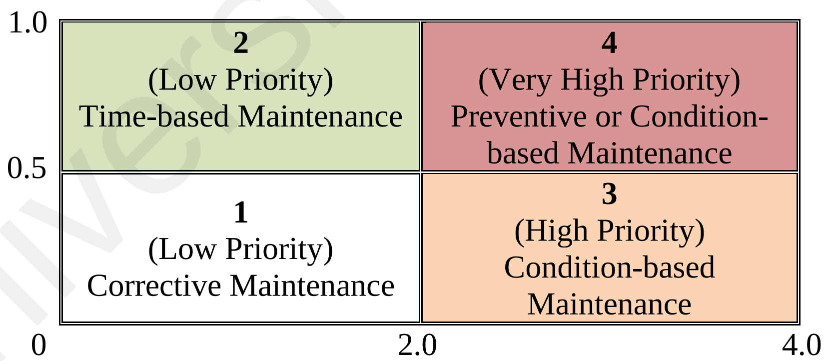


Figure 2.9: Maintenance planning diagram proposed by Jamshidi *et al.* (2015).

Saleh and Balestra (2015) observed that there may be an increase in the medical equipment's risk level, waste of resources, and ineffective deployment of labour, if the implementation of preventive maintenance is done in random and ad hoc sequences. Hence, by designing and maintaining an effective preventive maintenance system, safety, efficiency of medical equipment, and equipment longevity, this can be enhanced. The study used 50 types of medical equipment consisting of 140 units in 2 Italian hospitals.

The framework consisted of two cascaded models which were QFD and fuzzy logic. The purpose of applying QFD was to select the most crucial criteria for the process of prioritisation, whereas the fuzzy logic was employed to categorise the equipment's priority through selected criteria consideration. The medical equipment required preventive maintenances as an input to the QFD, and it was selected based on the customer's desires and technical requirements. The output of the QFD is the list of criteria sorted by importance. However, only the top six criteria were used in the next step, i.e., the input of fuzzy logic. The 6 criteria were the functions, physical risks, failure rates, maintenance requirements, useful life ratios, and the device criticality. Each criterion was proposed with specific scores between 1 to 5. These 6 major criteria were evaluated using 41 IF-THEN rules in the fuzzy logic system to generate the fuzzy scores for the preventive maintenance classification of the medical equipment. Saleh and Balestra (2015) proposed five preventive maintenance classifications: very high, high, medium, low, and almost none. Table 2.20 shows the classification of the medical equipment preventive maintenances.

Table 2.20: Preventive Maintenance Classification of Medical Equipment (Saleh & Balestra, 2015).

Priority	PM Classification
Very High	High risk criteria, Maintained within two weeks
High	PM within one month
Medium	PM within two months
Low	PM within three months
Almost None	New equipment & stable equipment

From the study, there was a strong correlation presence between the priority decisions of the preventive maintenance and risk-based criteria. Furthermore, the technique had proven its validity in the actual environment, and could adequately separate equipment based on the preventive maintenance necessity. In addition to the medical equipment's criticality and age, the risk-based criteria contributed a huge effect toward the preventive maintenance's prioritisation decisions. Lastly, to provide better guidance to decision makers, existing past data from the medical equipment is very important, and must be kept in proper record from time to time.

The maintenance of a medical device is very important and assessments based on the appropriate parameters helps in the process of prioritisation. Azadi Parand *et al.* (2021) specified that among the important elements in assessments are expert opinions, risk factors, and equipment types. By considering these elements, the medical equipment can be prioritised during the maintenance activity. Thus, Azadi Parand *et al.* (2021) developed a risk assessment system for medical devices using fuzzy logic techniques. The medical equipment used in the development of the risk assessment system is a defibrillator, infusion pump, surgical light, and surgical suction.

The risk assessment analysis for the four types of medical equipment included three main criteria, namely severity, detection, and probability. These criteria were adopted from a study conducted by Jamshidi *et al.* (2015). Referring to the 3 criteria, the list of 8 sub-criteria as tabulated in Table 2.21.

The medical equipment risk assessment step began by circulation of a set of surveys, which assessed the specified criteria across 4 types of equipment. The respondents comprised of five individuals, who were highly skilled in the operation and maintenance of the medical equipment. The respondents were required to provide scores, which contained one to five ratings based on the structured evaluation sheet. The results obtained from the respondents were used for the calculation of the risk priority number.

Subsequently, the fuzzy logic technique was applied to determine the overall ratings based on the ordered weighted average operator. This operator entailed the fuzzy rating and levelling proposed by Jamshidi *et al.* (2015). Based on the evaluation of the overall risk priority number for each equipment, it can be concluded that the maintenance management can determine the priority of the medical equipment during the implementation of the maintenance.

Table 2.21: Main criteria and sub-criteria proposed by Azadi Parand *et al.* (2021).

Main criteria	Sub criteria
Detectability	Difficulty levels in detecting equipment failure
	The application of specific technique in detecting the equipment failure
Probability	Mean time between failures
	Possibility of equipment to fail again
	The visibility of cause of equipment failure
Severity	Potential equipment failure affects the safety of patient
	Potential equipment failure affects the safety of user and maintenance team
	Mean time to repair

The summary of the 4 related studies using the fuzzy logic technique is presented in Table 2.22.

Table 2.22: Summary of four studies using fuzzy logic.

Reference	Criteria of Assessment	Maintenance Strategy
Tawfik *et al.* (2013)	**Four main criteria:** 1) function, 2) maintenance requirements, 3) physical risks, and 4) mission criticality **Three sub-criteria:** 1) utilisation rate, 2) equipment importance, and 3) backup safety ratio	Preventive and corrective maintenance
Jamshidi *et al.* (2015)	**First step, three main failure criteria:** 1) detectability, 2) occurrence, and 3) consequences	Preventive and corrective maintenance

Table 2.22: Continued.

Reference	Criteria of Assessment	Maintenance Strategy
Jamshidi *et al.* (2015)	**Nine failure sub-criteria:** 1) non-detection probability, 2) detection method, 3) mean time between failures (MTBF), 4) repeatability, 5) visibility, 6) patient safety, 7) potential risk to operator and maintenance personnel, 8) mean time to repair (MTTR), and (9) economical loss **Second step, seven main criteria:** 1) age, 2) hazard, 3) utilisation, 4) number of available identical equipment, 5) recalls and hazard alerts, 6) function, and 7) maintenance requirement	Preventive and corrective maintenance
Saleh and Balestra (2015)	**Eleven main criteria:** 1) function, 2) physical risk, 3) maintenance requirements, 4) utilisation level, 5) area criticality, 6) device criticality, 7) failure rate, 8) useful life ratio, 9) device complexity, 10) missed maintenance, and 11) downtime ratio	Preventive maintenance
Azadi Parand *et al.* (2021)	**Three main aspects:** 1) Detectability, 2) Probability, and 3) Severity **Eight sub-criteria:** 1) detection probability, 2) failure identification method, 3) mean time between failures, 4) repeatability, 5) visibility, 6) patient safety, 7) operator and maintenance staff safety, and 8) mean time to repair.	Preventive maintenance

2.5.3 Predictive Model using Supervised Learning

In 1959, Arthur Samuel created the phrase "Machine Learning," in the context of using a computer to solve a checkers game (Joshi, 2020). The phrase denotes a computer software that can learn to perform actions that aren't expressly designed by the program's inventor. Instead, it has the capability to disclose behaviours which the developer is completely unaware of. The 3 elements that influenced the way habits are learnt are as follows:

1) The data that the software reads.
2) A measurement that quantifies the errors or gaps between the current and ideal behaviours; and
3) A feedback mechanism that guides the programme to provide a much better behaviour in the following instances by using the quantified error.

The machine learning theory approaches are critical in the development of artificially intelligent systems.

In developing the Machine Learning model, it is important to know that this AI technique consists of 3 main elements, which are the available datasets, models, and trainings (Paluszek & Thomas, 2019). Data is at the heart of all the learning processes. The proposed model is trained using data sets. Individuals may collect and alter these sets, or other software programmes may gather them on their own. As the systems starts to work, the control systems may gather data from the sensors and utilise that data to discover relevant parameters, or teach the system. In learning systems, models are frequently utilised. A mathematical framework for learning is provided by a model. The model is created by humans, and is based in its observations. To map an input to an output in a meaningful manner, a system must be trained. Machine learning systems, like people, require training to accomplish tasks. Giving the system input and its associated output, as well as updating the structure (models or data) in the learning machine, allows mapping to be learnt.

Machine learning and AI have received much interest in recent years, primarily due to the vast amounts of data and computing power available, as well as the development of better learning algorithms (Badillo *et al.*, 2020). According to Ngiam and Khor, machine learning analysis of big data provides significant benefits for the absorption and assessment of enormous volumes of complicated health-care data (Ngiam & Khor, 2019).

Furthermore, machine learning algorithms have the capacity to analyse a variety of data sources, such as laboratory discoveries, demographic statistics, imaging data, and physicians' free-text notes), and combine them into disease risks, diagnosis, prognosis, and recommended treatments predictions.

The machine learning algorithms are broadly classified into 3 types, which are Supervised learning algorithms, Unsupervised learning algorithms, and Reinforcement learning algorithms (Joshi, 2020). When historical data containing a set of outputs for a set of inputs is used in conjunction with the available learning data, supervised learning is used. This data would then be recognised as a training dataset, with the inputs and outputs accessible for the model to be trained. Then, in a supervised way, an appropriate machine learning model may be trained. The tagged data is not available in the unsupervised learning paradigm. In such instances, unsupervised learning techniques may be used to identify a specified number of measurement clusters automatically. To find the cluster to which, they are closest and categorise them into one of them is done with a new set of measurements. As reinforcement learning uses inputs from the environment, it does not use a collection of labelled samples for training. Instead, the system interacts with the environment to constantly produce the desired behaviour and receives feedback from it.

Classifications and regressions are the two forms of supervised machine learnings (Watt *et al.*, 2020). The main distinction between the 2 is that, rather than anticipating a continuous-valued output, the classification predicts discrete values or categories. According to Wang and Dong (2021), the construction of supervised machine learning architecture involves several stages, as shown in Figure 2.10. Among the algorithms that are often used in supervised machine learning are the K-nearest Neighbor (KNN), Support Vector Machine (SVM), Decision Tree (DT), Logistic Regression, Random Forest (RF), Naïve Bayes (NB), and Neural Network (NN). For unsupervised machine learning, clustering is a popular technique, namely partitioning clustering, and hierarchical clustering (Jayatilake & Ganegoda, 2021).

The development of a machine learning model is incomplete without going through the performance appraisal process. Through the performance evaluation process, the model developer can find the effectiveness of the prediction after the training process is carried out. Among the parameters commonly used to measure the level of performance of supervised machine learning are accuracy, recalls, the precision, and f-scores (Joshi, 2020). These parameters are assisted by the construction of a confusion matrix. Based on the results produced through the evaluation process, it helps users to carry out fine-tuning to produce much more accurate model performances.

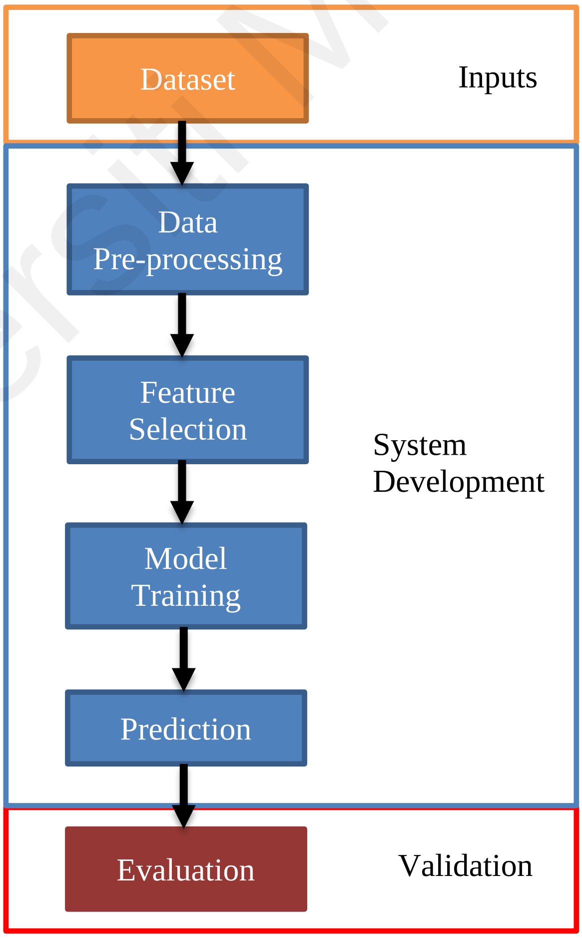


Figure 2.10: Architecture of supervised machine learning system (Wang & Dong, 2021).

The use of machine learning helps the industry in making better decisions. Among the advantages of applying machine learning compared to traditional mathematical techniques is the production of faster, efficient, accurate, and cost-effective computations (Jayatilake & Ganegoda, 2021). Therefore, the use of machine learning is a tool for analysing huge datasets that can help users in making more accurate predictions.

The evolvement of machine learning application in healthcare industry seems to have a significant impact on the better quality of service outcomes. It turns to be an instrument in assisting the stakeholders in the decision making procedures (Jayatilake & Ganegoda, 2021). Generating accurate and quick decisions using the effective techniques are capable to solve the clinical concerns based on past data with relevant features. It can replace routine and redundant practices so that the clinical practitioners are able to focus on process that need more attention. Furthermore, machine learning applications can provide accurate predictions based on the results of diagnostic examinations from medical equipment (Santosh *et al.*, 2022). The generated prediction makes the diagnostic process easy and the subsequent steps can be performed promptly.

The machine learning is also used in analysing and evaluating the performance and condition of medical equipment (Shamayleh *et al.*, 2020; Spahic *et al.*, 2020). The assessment prediction proved that several benefits are gained such as reducing the risk of malfunctioning equipment exposed to users and patients, helping to identify potential breakdowns, and prioritising maintenance activities at an earlier stage. The machine learning application on medical devices has also received attention in the development of standards and regulatory framework to ensure that performance and safety aspects are always emphasised (Rob Turpin *et al.*, 2020).

Traditional maintenance procedures have evolved from Corrective Maintenance, into Preventive Maintenance, and subsequently, Predictive Maintenance, as evidenced by the advancement of current tools such as AI and machine learning (Ran *et al.*, 2019). The enormous sophistication, precision, and adaptability of modern industrial systems make predictive maintenance a potential technique for reducing machine downtime, thereby improving the overall system dependability, and lowering operating costs (Aboul-Yazeed *et al.*, 2017).

Predictive maintenance's primary aim is to prepare maintenance at a time when it is most cost-effective, and before the equipment performance and functionality begins to deteriorate (Wang *et al.*, 2017). It is necessary to have access to data derived from continuous and periodic monitoring that can provide insights into the running state of the equipment, to construct a model of predictive maintenance (Andritoi *et al.*, 2019). The internal operational condition of most types of important corporate equipment is recorded in the form of archives, or system notifications. This information is then analysed using structured modelling approaches to predict the chance of failure of an asset in its operational environment. This is an important scientific research subject that must be addressed (Mahfoud *et al.*, 2016).

Maintenance management packages such as Reliability-Centered Maintenance (RCM) employs the predictive maintenance procedures as part of its overall maintenance management strategy (Endrenyi *et al.*, 2001). RCM analysis is a structured and systematic assessment technique that may be used to plan and elevate the maintenance programme (Mohammed Ben-Daya *et al.*, 2016). The primary focus of RCM is on the system's function, rather than on restoring the equipment to its optimal condition. RCM comprises of 4 key features, as shown in Figure 2.11.

Badnjevic *et al.* (2019) claimed that unregulated and inadequately monitored medical equipment bring about a high threat of patient diagnosis and treatment services. Furthermore, the growing complexity of the system's technology, and incidents involving defibrillator failures are unfortunately common. To this statement, Badnjevic *et al.* (2019) developed an automated system for a medical device supervision mechanism procedure to overcome these challenges, and eventually optimise the cost of maintenance and effective equipment management. The proposed automated system was able to predict the defibrillator equipment's performance and possibility of performance failures by applying the machine learning algorithms. Seven sets of features were used, which are 1) performance test results, 2) safety test results, 3) manufacturer, 4) age, 5) type, 6) preventive and corrective maintenance information, and 7) inspection decisions.

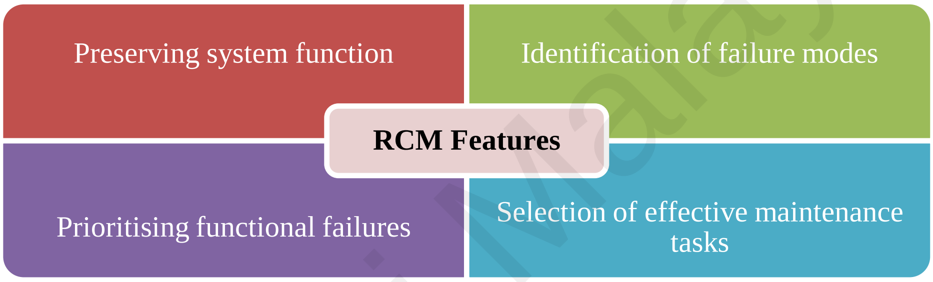


Figure 2.11: Key features of RCM.

The developed system was tested using 5 different algorithms, which are 1) Decision Tree, 2) Random Forest, 3) K-nearest Neighbor, 4) Support Vector Machine and 5) Naïve Bayes. A further three algorithms were used as feature selectors, which are 1) Info Gain, 2) Decision Tree and 3) Wrapper. The study utilised 7 group of features as input, which are; 1) performance results, 2) safety inspection results, 3) age, 4) manufacturer, 5) type, 6) information of preventive/corrective maintenance and 7) inspection decisions.

During the system development, 1,221 units of various model of defibrillators were considered. A total of 974 units were used in development process, while 274 unit were used to validate the performance of the system. The database for the equipment was taken from the year 2015 to 2017 across public and private healthcare institutions in Bosnia Herzegovina. The inspection was carried out by an ISO 17020 accredited laboratory. The results showed that the Random Forest algorithms produced the highest accuracy and proven its function in its classification and prediction. Badnjevic *et al.* (2019) concluded that the accuracy of the system depended on the precision of the testing equipment's measurement and also the dataset applied in the system for training purposes. Furthermore, the same algorithms can be developed to recognise the medical equipment's risks and instruct relevant preventive tasks to the equipment as a recommendation.

Kovacevic *et al.* (2019) also employed a similar approach for machine learning as used by Badnjevic et al. to predict the performance and potential failure on the infant incubator equipment in Bosnia Herzegovina. In order to develop the system, 140 infant incubator units were used, where 112 units were used for the development process, whereas 28 units were used to validate the performance of the system. The results showed that the Decision Tree algorithm produced the highest accuracy and proven function in its classification and prediction. The outcome of study revealed that the improvement should be made in terms of equalizing training datasets with more samples of the failure status. A combination of this system with a real-time updated database will be an effective technique for post-market surveillances by the Bosnian National Notified Body as a future work.

Malfunctioning medical equipment functionality leads to safety risks and errors in measurements during the treatment process. Therefore, Hrvat *et al.* (2020) developed a system for predicting the performance of medical equipment to ensure the safety and efficiency of treatment to patients is always at an optimal level. The development of this prediction system was conducted using applying artificial neural networks (ANN) techniques, which encompassed a dataset of 1,738 infusion equipment and perfusion pumps. The annual equipment inspection records were taken from the year of 2015 to

2019 at a healthcare facility in Bosnia Herzegovina. The inspection records were based on the legal metrology framework for medical devices.

The performance prediction analysis for these 2 types of medical equipment consisted of 3 main inspection criteria, namely the visual inspection, measurement of the performance parameters, and the inspection results. The description for each of the inspection criteria is described in Table 2.23. The system development involved two main processes, namely the system training and validation. The dataset was divided into two, of which 80% of the total number of equipment was used for training purposes, whereas 20% for validation. The system performance measurement was evaluated by calculating the accuracy values. As a result of the study, Hrvat *et al.* (2020) successfully developed a performance prediction system for infusion and perfusion pumps by achieving an overall accuracy of 98.41%.

Table 2.23: Descriptions of inspection criteria by Hrvat *et al.* (2020).

Criteria	**Description**
Visual inspection	Physical cleanliness
	Casing reliability
	Labelling and marking
	Accessories functionality
Measurement of equipment performance	Readings of flow volumes in millilitres
Result of inspection	Pass or Fail. If any of the parameters in visual inspection and performance measurement is fail, the overall inspection result is failed.

Hrvat *et al.* (2020) concluded that the results obtained were similar to the findings of the previous studies conducted by Badnjevic *et al.* (2019) and Kovacevic *et al.* (2019). However, the additional of parameters such as the maintenance history may enhance the effectiveness of the medical equipment's performance predictive system. Hence, the machine learning application is significantly helpful in the planning and implementation of predictive maintenances.

Machine learning techniques are also applied for determining the risk classification of medical equipments established by the national authority. However, according to Ceross and Bergmann (2021), consumers faced difficulty in categorising the risk classification of medical devices, according to the national authority body regulations as exhibited in the online system. This was because the guidelines from the national regulator are difficult to read, and the terms used are dense. To resolve this matter, Ceross and Bergmann (2021) developed a system by using the machine learning classifier to attain a much more effective medical equipment risk classification result. This system was used as an evaluation tool for the identification of the risk classifications by the Australian Medical Device Regulator, namely the Therapeutic Goods Authority (TGA).

The medical equipment risk classification in Australia under the Therapeutic Goods (Medical Devices) Regulations 2002 is divided into 4 categories. These classes are determined based on the probability of risk to the public's health. Class 1 refers to the no or low risk, Class 2a refers to low or moderate risks, Class 2b refers to moderate or high risks, while Class 3 refers to high risks. The risk classification identification analysis was conducted by extracting the legal text through the Australian government's online page (Federal Regsiter of Legislation Australian Government, 2021). These texts were then converted into plain text. The online registration data involved 60,806 medical devices from 2004 to 2020, and were taken for system development training. Ceross and Bergmann (2021) set four types of rules for the system development, namely, non-invasive, invasive, active devices, and special rules. Special rules involved additional processes such as measurements and sterilisations. The development of this medical equipment risk classification system used the Support Vector Machine as a classifier. To ensure that the system could produce accurate results, three performance evaluations were used, namely precision, recalls, and f1.

As a result of the study, the study demonstrated that the use of machine learning for developing a system may increase the level of readability for identifying the risk classification of the medical devices. However, the risk classification determination system can be improved by creating a data-driven approach for the consumers.

Referring to Liao, Boregowda, *et al.* (2021) stated that the medical equipment can suffer various types of failures, and thus, repairing them is vital. However, studies on medical equipment failure rectification processes are scarce. In addition, there was an inadequacy of the techniques use involving data science and machine learning in assisting to improve the quality of medical equipment maintenance management. Therefore, the identification of failure types using machine learning algorithms can assist the maintenance team in setting the repair work strategy. For the purpose of the system's practicability, 2 types of infusion pumps were used. A limited 5 years of equipment dataset was obtained from one of the largest healthcare providers in the US.

The development of the repair predictive system and maintenance requirements were divided into 2 main phases. In the first phase, Liao, Boregowda, *et al.* (2021) used a regression technique, i.e., the multilayer perceptron model (MLP). The inputs for this model were the failure time and the repair time, whereas the outputs were the predictions for the next failure time, the next repair time, and the next repair time's z-score. The 2nd phase involved the development classification model, of which 3 main classifiers were applied, namely the Naïve Bayes, Support Vector Machine, and the K-nearest Neighbor. The three outputs for the 1st phase were used as inputs for the 2nd phase. The analysis for the 2nd phase was meant to predict the type of failures that will occur for the infusion pumps. To determine the predictions of these failures, there was a set of medical equipment 3 failure types, namely random failures, physical damages, and no problems found. Liao, Boregowda, *et al.* (2021) also developed a maintenance recommendation system using the Gaussian Mixture Model (GMM). The output parameters of the 2nd phase were used as inputs for this system. The output was divided into 3 groups, namely, Group A, Group B, and Group C. The segregation of these 3 outputs referred to the duration of the mean time between failure. Table 2.24 displays the descriptions for each group. The low mean time between the failures means that the infusion pumps are able to operate well.

Table 2.24: Descriptions of each proposed maintenance activity groups adapted from Liao, Boregowda, *et al.* (2021).

Group	**Description**
Group A	Less mean time between failure for physical damage and random failure. Regular maintenance is required to enhance the lifespan of equipment.
Group B	Less value for physical damage, but high for random failure in terms of mean time between failure. Therefore, the focus of maintenance activity must be allocated on physical damage.
Group C	Less value for random failure, but high for physical damage in terms of mean time between failure. Therefore, the focus of maintenance activity must be allocated on random failure.

As a result of the conducted analysis, Liao, Boregowda, *et al.* (2021) proved that the machine learning techniques are capable of making accurate predictions using limited datasets. The results also showed that K-nearest Neighbor produced the most accurate predictions compared to the other classifiers. These predictions can help technical personnel in managing the available resources. The consideration of other parameters in the development of predictive systems using machine learning techniques for future work.

In the same year, Liao, Cade, *et al.* (2021) developed a medical equipment failure rectification predictive system using machine learning techniques. Based on the observation, the factors associated with medical equipment failures were due to design errors, unclear utilisation methods, poor production conditions, and a lack of reliability. The Support Vector Machine was used as a classifier because the reliability of this algorithm had been proven from previous studies. Diagnostics and therapeutic equipments such as infusion pumps, pulse detectors, and oximeters, were used to test the effectiveness of the developed system. Records of the maintenance and repair of such equipment were taken from 2004 to 2018 from one of the largest healthcare providers in the US.

The input for the development of a predictive system is failure time. Failure time refers to the period starting from the current breakdown, until the next breakdown occurs. This input is typically in the form of cumulative seconds. The analysis of the cumulative seconds is meant to generate a predicted time, where the equipment will fail over the next 3 failure events in the future. These predictions are based only on the detection of random failures.

Performance evaluation of the system in forecasting the timing of the next failure events showed that the Support Vector Machine produced an accurate predictive model. Liao, Cade, *et al.* (2021) concluded that by establishing the predicted timing of the next failure, this can give immediate notification to the corrective maintenance team for managing the resources and provisional costs. The quick notification may increase the quality of the repair works for all three medical devices, in return increasing the availability rate of such equipment. As a recommendation, other classifiers may be used to produce better predictive quality.

The summary of 6 relevant supervised machine learning studies for medical equipment predictive systems is tabulated in Table 2.25.

Table 2.25: Summary of six studies using supervised machine learning.

Reference	Criteria of Assessment	Maintenance Strategy
Badnjevic *et al.* (2019)	**Seven groups of features:** 1) performance result, 2) safety result, 3) age, 4) manufacturer, 5) type, 6) information about preventive/ corrective maintenance, and 7) inspection decision	Preventive and corrective maintenance
Kovacevic *et al.* (2019)	**Seven groups of features:** 1) performance result, 2) safety result, 3) age, 4) manufacturer, 5) type, 6) information about preventive/ corrective maintenance, and 7) inspection decision	Preventive and corrective maintenance
Hrvat *et al.* (2020)	**Three main criteria:** 1) visual inspection, 2) performance measurements, and 3) inspection result	Preventive and corrective maintenance
Ceross and Bergmann (2021)	**One aspect:** 1) equipment types.	None
Liao, Boregowda, *et al.* (2021)	**Two main criteria:** 1) failure time, and 2) repair time	Corrective maintenance
Liao, Cade, *et al.* (2021)	**One criterion:** failure time	Corrective maintenance

2.6 Identification of Gaps

The thematic analysis of the previous studies led to the identification of maintenance management. Five studies aimed at improving the preventive maintenance, and two studies focused on enhancing the strategies for corrective maintenance activities. A total of 4 studies focused on implementing a better replacement plan, and ten studies produced an indication for establishing the best maintenance strategy implementation. Furthermore, a specific method were applied for assessing the medical equipment in order to yield the desired outputs, eventually establishing the study's outcomes. There were 12 studies which employed SEM, 3 studies which used fuzzy logic, and 1 study which used the combination of fuzzy logic and QFD. Six research studies used supervised machine learning algorithms to process the databases of several medical equipment types, which comprised of specifics, characteristics, and maintenance records. The summary of the 22 studies on the related topics of medical equipment assessment techniques are tabulated in Table 2.26.

Table 2.26: Assessment technique and maintenance management.

Reference	**Assessment Technique**	**Maintenance Management**		
		PM	**CM**	**RP**
Taghipour *et al.* (2011)	SEM (AHP/FMEA)	✓	✓	
Hamdi *et al.* (2012)	SEM (AHP)	✓	✓	
Oshiyama *et al.* (2012)	SEM (ABC analysis and Paraconsistent Annotated Logic)			✓
Faisal and Sharawi (2015)	SEM (AHP)			✓
Saleh *et al.* (2015)	SEM (Quality Function Deployment/AHP)	✓		
Aridi *et al.* (2016)	SEM (AHP)			✓
Ben Houria *et al.* (2016)	SEM (AHP, TOPSIS and MILP)	✓	✓	
Ismail *et al.* (2018)	SEM (FMEA)	✓	✓	
Hernández-López *et al.* (2019)	SEM (AHP)	✓		
Hutagalung and Hasibuan (2019)	SEM (AHP)	✓	✓	
Jarikji *et al.* (2019)	SEM (AHP)			✓
Abirami and Sudheesh (2020)	SEM (AHP)	✓		
Tawfik *et al.* (2013)	Fuzzy Logic	✓	✓	
Jamshidi *et al.* (2015)	Fuzzy Logic (FMEA)	✓	✓	
Saleh and Balestra (2015)	Fuzzy Logic (QFD and Fuzzy Logic)	✓		
Azadi Parand *et al.* (2021)	Fuzzy Logic (AHP)	✓		
Badnjevic *et al.* (2019)	Machine Learning (Supervised learning)	✓	✓	
Kovacevic *et al.* (2019)	Machine Learning (Supervised learning)	✓	✓	
Hrvat *et al.* (2020)	Machine Learning (Supervised learning)	✓	✓	
Ceross and Bergmann (2021)	Machine Learning (Supervised learning)			

Table 2.26: Continued.

Reference	Assessment Technique	Maintenance Management		
		PM	PM	PM
Liao, Boregowda, *et al.* (2021)	Machine Learning (Supervised learning)		✓	
Liao, Cade, *et al.* (2021)	Machine Learning (Supervised learning)		✓	

Note: PM, Preventive Maintenance; CM, Corrective Maintenance; RP, Replacement Plan; AHP, Analytical Hierarchy Process.

Observations on 22 previous studies found that the use of AI techniques, namely machine learning, is much more effective than other techniques. This is because, the construction of the system architecture is much easier to understand for developing a predictive system for the medical equipment. The evaluation of the model's performance is also easy to implement, and the desired output is much more accurate and consistent. Therefore, the use of supervised machine learning with several classification algorithms to develop a predictive system for determining the performance of the medical equipment is the best.

Following a review of past studies, it was discovered that there were several significant gaps as follows:

1) As a starting point, none of the studies contributed to, or emphasised on a comprehensive strategic maintenance management, which includes preventive maintenance, corrective maintenance, and a replacement plan, among other things. Corrective maintenance, preventative maintenance, or replacement plans were the only topics covered in the reported research works, which resulted in only preliminary assessments being presented to healthcare facility providers. The identification of standard features and criteria are crucial in

assessing the comprehensive strategic maintenance management of medical equipments.

2) Secondly, early research assessment methodologies included a manual intervention which needed clinical engineers to establish the criteria weightages. The values may differ based on their level of knowledge, and the methodologies may provide inconsistent outputs. The machine learning techniques are required to provide a consistent medical equipment assessment output and alleviate the manual intervention by the users.

CHAPTER 3: METHODOLOGY

3.1 Introduction

This chapter describes the techniques and processes for developing a comprehensive strategic maintenance management and reliability assessment for medical equipment. This section is divided into seven sub-sections, where the first sub-section provides an overview of the medical equipment maintenance management system concepts. In this sub-section, the input and output parameters of the machine learning model will be defined. The 2nd sub-section describes the data preparation and labelling processes attained from the medical equipment inventory and maintenance history records. This explanation covers the categories and characteristics of the selected medical equipment. The third sub-chapter describes the data pre-processing stage, where data selection and normalization are performed prior to the classification process.

The fourth sub-section describes the development of the failure analysis predictive models. This sub-section deliberates thoroughly on the prediction of the medical equipment's first failure, the failure to year ratio, and the failure rectification actions which are then determined. In the 5th sub-section, the assessment and prioritising predictions of the medical equipment's maintenance management will be discussed. The development of the models are divided into 2, namely clustering and data mining classifications. The sixth sub-section explains the process of designing a comprehensive strategic maintenance management framework to enhance the maintenance prioritisation predictive models. The cost analysis section discusses the impact of the developed predictive model on the comprehensive strategic maintenance management practices toward achieving the optimal expenditure. Last but not least, this chapter is then summarised in Section 3.7.

3.1.1 Research Overview

The development of comprehensive strategic maintenance management efforts for medical equipment includes three main activities during the maintenance phase, namely i) preventive maintenance, ii) corrective maintenance, and iii) replacement plans. Fundamentally, the comprehensive strategic maintenance management is developed using predictive models from machine learning, that involves three main phases of input identification, processing and analysis, and predictive outcomes.

Figure 3.1 shows the overview of the proposed methodology. The utilisation of the medical equipment data as a sample includes two main types of information, namely inventory information and maintenance history. The procurement of new equipment needs to undergo maintenance to upkeep it's reliability. Medical equipment data, including the procurement and maintenance history, were recorded into a database system called CMMS. This integrated system is important to assist clinical engineers in planning and implementing the effective maintenance of the medical equipment. Two main predictive models were developed, namely failure analysis and maintenance prioritisation models. The analyses attained from these developed models will then provide a comprehensive strategic maintenance management system for three main maintenance activities, which are preventive maintenance, corrective maintenance, and replacement plans.

The analysis attained from this model will provide valuable information toward assisting clinical engineers to provide effective operational execution. This effectiveness includes availability, durability, and the safety of the medical equipment. In addition, the proposed methodology can optimise maintenance expenses throughout the maintenance phase, which comprises the maintenance and replacement activities of the medical equipment.

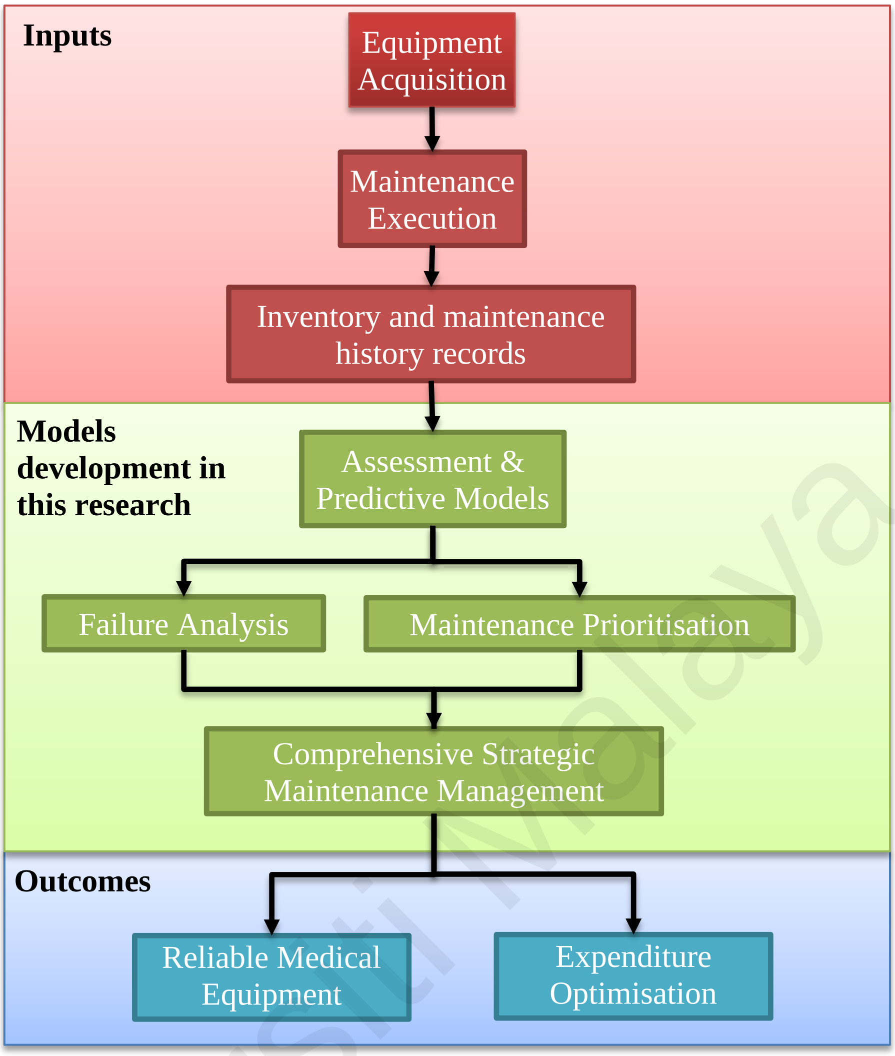


Figure 3.1: Fundamental of research's input, processing and analysis, and output stages.

3.1.2 Development of Comprehensive Strategic Maintenance Management

Creating a systematic strategic maintenance management plan for medical equipment requires multiple crucial steps. This is to ensure that the real data can generate accurate output and aid clinical engineers through efficient maintenance management. Figure 3.2 depicts the entire process of comprehensive strategic maintenance management for the medical equipment utilised in this study.

The development of this system began with the extraction and compilation of the inventory and maintenance history information across several categories of medical equipment from the CMMS. The extracted information was in the form of unprocessed

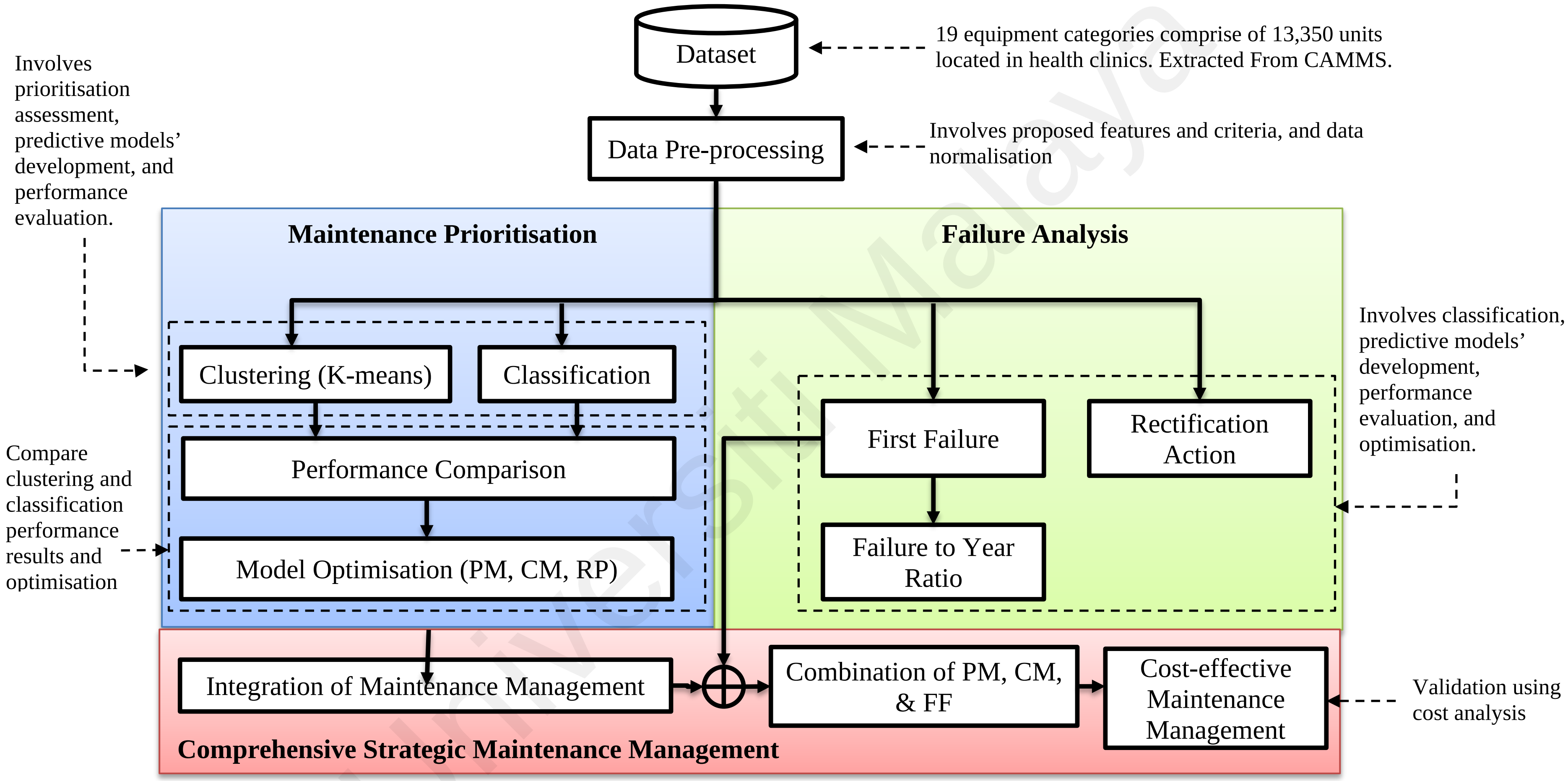


Figure 3.2: Overall process of a comprehensive strategic maintenance management.

data. This data must be pre-processed for further analysis. The analytical process for evaluation and forecasting involved organisations based on a particular set of characteristics and criteria. Therefore, the data was organised according to the specified characteristics and criteria for each medical equipment sample. The dataset was utilised as an input in the development of the assessment and predictive models for failure analysis and maintenance prioritisation. Although the dataset was organised according to a particular set of characteristics and criteria, the numbers were still highly variable. The dataset was subjected to a data normalisation procedure in order to standardise the values.

The development of a comprehensive strategic maintenance management plan for the medical equipment is divided into 2 main functions, namely maintenance prioritisation and failure analysis. The block for maintenance prioritisation is the process of assessment and the development of predictive models to determine the priority of the medical equipment for preventive maintenance, corrective maintenance, and the replacement plan. It is divided into 2 techniques, namely clustering and classification. Both of these techniques were used to develop the assessment systems and predictive models for the maintenance activities. Several performance evaluation parameters were applied for testing the effectiveness of both these techniques. The selection of an accurate and precise predictive model was based on the performance results. The selected models were then optimised to produce a much more accurate and precise output. A framework was proposed to integrate the results of these three maintenance activities so that an initial formation of a comprehensive strategic maintenance management plan could be established. The failure analysis block is the process of assessing and developing the predictive models for determining three outcomes, namely the first failure, the failure to year ratio, and the failure rectification predictive models. The output of the first failure predictive model feeds into the design and development of the failure to year ratio.

As a result of these two main blocks, a cost analysis process was carried out by taking the outputs from the maintenance prioritisation predictive models and the first failure predictive models. Therefore, the combination of these 2 blocks resulted in a comprehensive strategic maintenance management for the medical equipment. The outcomes of a comprehensive strategic maintenance management may enhance the reliability of a medical equipment which is utilised in a healthcare institution or facility, and also optimise the cost of operation and maintenance activities.

3.2 Data Selection and Labelling

In this study, the datasets of the medical equipment inventories and maintenance histories were acquired from the CMMS. This information was recorded by clinical engineers who monitored and managed the medical equipment's maintenance activities in the CMMS. Specifically, this CMMS system is known as the Computerised Asset Maintenance Management System (CAMMS). This integrated system contains information on the medical equipment which are utilised in the public health clinics across 9 states throughout Malaysia. The number of clinics and equipment in the 9 states involved are shown in Figure 3.3.

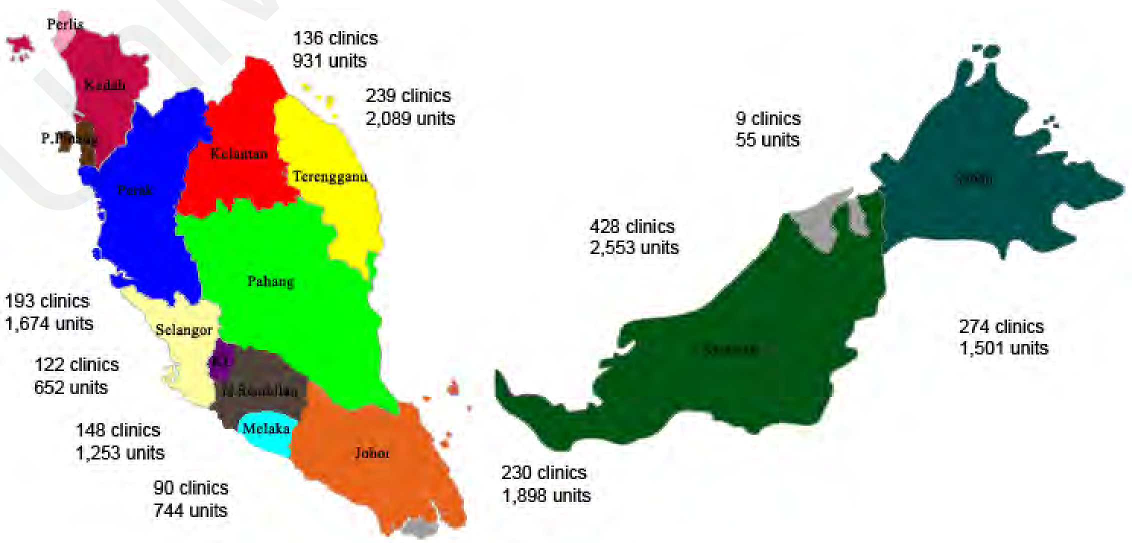


Figure 3.3: Numbers of clinics and medical equipment in nine states in Malaysia.

The raw data was extracted and compiled from the CAMMS and involved nineteen categories of medical equipment. These categories referred to the functionality and purpose of specific treatments concerning the UMDNS list. From these categories, a total of 13,350 units of medical equipment comprising of various brands and models were used. Although these nineteen categories contained various brands and models from various manufacturers, their operations were similar in terms of delivering healthcare services for the public health clinics. The selection of 19 categories were made to ensure that the developed model was robust and inclusive of all types of medical equipment available at the public health clinics.

The datasets of these 19 medical equipment categories were extracted from the year 2015 to 2020. As for the analysis and predictive model development, a cut-off date was set on October 31, 2020. The selection of the medical equipment in this study covered a wide range of healthcare services provided by public health clinics in Malaysia. The study aims to ensure that the assessment system and predictive models developed can be applied to other healthcare institutions and facilities such as hospitals, medical research centres, and training institutions. Table 3.1 tabulates the general descriptions of the 19 categories of medical equipment.

The term active and passive refers to the medical equipment itself, which requires external power supply to operate. Some of equipment are battery-operated, such as automated external defibrillators, rigid laryngoscopes, and pulse oximeters. The pulmonary resuscitator however does not require electricity to operate when applied to the patient. Functionality denotes the purpose of the equipment in the healthcare service application, and the maintenance scope refers to maintenance activities required for each medical equipment. These 2 items are elaborated further in sub-section 3.3.1.

Table 3.1: General descriptions of nineteen categories of medical equipment.

UMDNS Code	Medical Equipment Category	Quantity	Active/ Passive	Functionality	Maintenance Scope	PM Frequency per annum	Location
15551	Analysers, Laboratory, Clinical Chemistry, Automated	137	Active	Analytic	PM	Twice	Laboratory
15109	Bilirubinometers, Laboratory	777	Active	Analytic	PM	Twice	Laboratory
17116	Defibrillators, External, Automated	861	Active	Life support	PM	Twice	Emergency
11132	Defibrillators, External, Manual	204	Active	Life support	PM	Twice	Emergency
16548	Densitometers	46	Active	Miscellaneous	PM and calibration	Once	Diagnostic imaging
12113	Incubators, Infant	31	Active	Life support	PM	Twice	Women and child
13215	Infusion Pumps, General-Purpose	16	Active	Therapeutic	PM	Once	Emergency, women and child
15076	Laryngoscopes, Rigid	1,473	Active	Miscellaneous	RI	Once	Outpatient, women and child
12636	Monitoring Systems, Physiologic	1,251	Active	Life support	PM	Once	Outpatient, women and child
15045	Nebulizers, Nonheated	2,297	Active	Therapeutic	PM	Once	Outpatient, women and child
17148	Oximeters, Pulse	1,319	Active	Diagnostic	PM	Once	Outpatient, women and child
15731	Phototherapy Units, Ultraviolet	28	Active	Therapeutic	PM	Once	Women and child
11757	Radiographic/Fluoroscopic Systems, General-Purpose	151	Active	Diagnostic	PM and statutory certification	Twice	Diagnostic imaging

Table 3.1: Continued.

UMDNS Code	Medical Equipment Category	Quantity	Active/ Passive	Functionality	Maintenance Scope	PM Frequency per annum	Location
13367	Resuscitators, Pulmonary, Manual	832	Passive	Life support	PM	Once	Emergency
15175	Scales, Clinical, Pharmacy	690	Active	Miscellaneous	PM	Once	Pharmacy
15976	Scanning Systems, Ultrasonic, General-Purpose	647	Active	Diagnostic	PM	Twice	Women and child
16563	Sensitometers, Radiographic	44	Active	Miscellaneous	PM and calibration	Once	Diagnostic imaging
13746	Sterilising Units, Steam	2,416	Active	Miscellaneous	PM and statutory certification	Twice	Various
14141	Treadmills	130	Active	Therapeutic	PM	Once	Rehabilitation

*Abbreviation: PM – Preventive Maintenance, PPM – Planned Preventive Maintenance.

The planned preventive maintenance (PPM) per annum indicates the number of maintenance activities required for a year, which is to be recommended by the manufacturers. Subsequently, the location describes the units, where the equipment is mostly used in the health clinic facilities.

All 19 categories of equipment used in this study are critical toward ensuring that the treatment and health care services are at an optimal level. Several devices, however, were also used for treatment services, particularly for COVID-19. Table 3.2 summarises the medical equipment used for COVID-19 treatment by clinical area.

Table 3.2: The medical equipment used for COVID-19 treatment by clinical area adapted from World Health Organization (2020a).

Equipment	**Triage**	**Severe patients**	**Critical patients**	**1st level**	**2nd level**	**3rd level**
Infusion Pumps, General-Purpose		✓	✓		✓	✓
Laryngoscopes, Rigid		✓	✓		✓	✓
Monitoring Systems, Physiologic		✓	✓		✓	✓
Oximeters, Pulse	✓	✓	✓	✓	✓	✓
Radiographic/Fluoroscopic Systems, General-Purpose		✓	✓		✓	✓
Resuscitators, Pulmonary, Manual		✓	✓		✓	✓
Scanning Systems, Ultrasonic, General-Purpose		✓	✓		✓	✓

3.3 Data Pre-processing

This sub-section elaborates on 2 main activities, which are the proposed features and criteria, and the normalisation of the dataset. These activities are essential for the assessment and predictive model development.

3.3.1 Proposed Features and Criteria of Medical Equipment

The identification of the medical equipment's features for preparing the final datasets was carried out by reviewing past studies, and referring to the Malaysian Standard, namely the Code of Practice for Good Engineering Maintenance Management of Active Medical Devices (MS 2058:2018). This identification was done by employing a thematic analysis which produced eight main categories of significant features for assessing the performance and reliability of the medical equipment. These eight categories are: 1) inventory information, 2) function, 3) maintenance requirement, 4) performance, 5) risk and safety, 6) availability and readiness, 7) location, and 8) cost. These characteristics are relevant as input parameters for the AI/ML architecture. Using the AI/ML approaches to measure these factors would greatly improve the monitoring of the medical equipment performance and utilisation status via a predictive maintenance model. This predictive model can aid in preventing future failures, degradation, and obsolescence. Past research has employed a variety of terms, however, some of them can be grouped as one group of features.

The correlation with the input parameters set by MS 2058:2018 (Department of Standards Malaysia, 2018a) was conducted to ensure that the 8 categories can contribute toward the effectiveness of the medical equipment, and comply with the national standard. The Standards of Malaysia Act 1996 (Act 549) governs this body's core role, which is to foster and promote global competitiveness via dependable standardisation and accreditation services (Department of Standards Malaysia, 2012).

A total of 10 parameters were recommended in the Annex P of the MS 2058:2018 for evaluating the medical equipment for replacement plans. These parameters may also be utilised as an input to assess the medical equipment’s condition for maintenance prioritisation, based on the observations and comparisons performed with the included studies, as indicated in Table 3.3. Initially, the asset age was directly comparable to the first category, based on the analysis in this study, namely the equipment’s characteristics, according to the observation of the variables presented in the MS 2058:2018.

Furthermore, most studies heavily relied on the equipment's age to determine which maintenance and replacement plan should be prioritised. Obsolescence is the second factor, which is comparable to the inventory information category. This component is very similar to service support, in that if there is no service support available on the market, the restoration job entails the delivery of replacement parts or any maintenance services for the linked equipment. As a result, the asset's age and obsolescence are comparable to the equipment's attributes.

Table 3.3: Comparison between factors proposed in MS 2058:2018 and included studies.

Replacement Factor	**Included Studies Factor**
Asset condition	Failure detectability
Asset status	Performance
Asset usage	Mission criticality; operational impact; utilisation
Frequency of breakdowns	No. of corrective maintenance, frequency of failures, rate of failures
Asset age	Device age
Obsolescence	Support availability; technology age; vendor support
Safety alert	Risk; failure consequences; recalls and hazard alerts
Maintenance cost	Cost of corrective maintenance
Availability of backup equipment	Alternative availability
User recommendation	Clinical acceptability

The results of the comparisons between all the factors proposed in the MS 2058:2018 with 2 of the 8 categories, namely function and the maintenance requirement, found no similarity. The subsequent criteria included the performance area, including efficiency, failure, downtime, uptime, and the number of corrective maintenance activities conducted. In comparison to MS 2058:2018, the performance category appeared to be equal to the frequency of breakdowns, where the failure rate of the medical equipment may be used to judge its performance. Furthermore, this category appeared to be linked to criteria such as the asset's status and quality.

The investigation then moved on to the following area, which was risk and safety. This category is essential for eliminating any possible risks to the patient and physicians. Based on this comparison, the MS 2058:2018 safety alert factor was shown to be connected to the risk and safety categories. The link was established because of the risk and safety category, which included recalls and hazard warnings which can be declared, or issued by the local authority body (Medical Device Authority, 2012a), the manufacturer, or a locally authorised agent. The availability and readiness were part of a category that included the aspect of the equipment's service criticality correlation. The availability of a backup equipment and user recommendations were found to be the most comparable criteria in the MS 2058:2018. These considerations highlighted the need to guarantee equipment availability for sustaining healthcare services at a clinically acceptable level.

One of the 10 elements mentioned in MS 2058:2018 was the asset usage, which reflected the extent to which the medical equipment is used. There was a direct resemblance with the category of usage when compared to the categories in this study. The maintenance cost factor provided in MS 2058:2018 and the cost category in this study have a very strong similarity. The association between the 8 categories summarised based on the review in this study and the 10 criteria provided in MS 2058:2018 are tabulated in Table 3.4.

Previous research has shown how important it is to examine medical equipment while preparing for essential action in healthcare facilities. The first step in making a medical equipment performance evaluation is to choose the right input parameters (Bahreini *et al.*, 2018). However, no one method can be used to account for all of the input variables. The input parameters used must be appropriate, and related to the desired outcome. The conclusion of the medical equipment evaluation is linked to maintenance methods, according to Mahfoud *et al.* (2017). One of the criteria for determining the optimal input parameters is the availability of an existing dataset containing medical equipment information and maintenance history. The differences in input parameters can be used to provide comparable results. Table 3.5 shows the recommended nineteen features and their criteria in this study, organised into 8 groups based on the thematic analysis.

Table 3.4: Correlation between study categories and factors in MS2058:2018.

Study Category	**MS 2058:2018**
Inventory Information	Asset age, Obsolescence
Function	None
Maintenance Requirement	None
Performance	Frequency of breakdown, Uptime, Asset status, Asset condition
Risk and Safety	Safety alert
Availability and Readiness	Availability of backup equipment, User recommendation
Utilisation	Asset usage
Cost	Maintenance cost

From Table 3.5, the category of medical equipment comprised 8 elements. These elements were produced based on the thematic analysis from previous studies. From these categories, 19 features were proposed for failure analysis and maintenance prioritisation studies. This combination of novel features were never used in previous studies. Each feature is represented by a certain criterion, which is in the form of numerical values. Some of the criteria are within specific ranges. However, there are 8 features, of which, the criteria vary.

The medical equipment data regarding 19 proposed features and criteria were extracted from CAMMS. Some of the required data cannot be directly assessed, as the data in the CAMMS was raw. Therefore, a specific calculation needed to be made with the raw data from the CAMMS.

Table 3.5: Proposed medical equipment features and criteria.

Category	Feature	Criteria (Range)
Inventory Information	Equipment Category	Numerical (vary)
	Equipment Age	Numerical (vary)
	Support Service	Obsolescence (1); Available (0)
Function	Function	Life support (5); Therapeutic (4); Diagnostic (3); Analytic (2); Miscellaneous (1)
Maintenance Requirement	Preventive Maintenance Status	Not in schedule (2); Open (1); Completed (0)
	No. of Missed Planned Preventive Maintenance	Number of undone planned preventive maintenance (vary)
	Maintenance Complexity	Extensive maintenance (3); Average maintenance (2); Visual inspection and basic check (1)
	Maintenance Scope	PPM (Twice annually) and Statutory Certification (5); PPM (Twice annually) (4); PPM (Once annually) and Calibration (3); PPM (Once annually) (2); Routine Inspection (1)
	Repair Time	Mean Time to Repair (day)
	Response Time	Mean time of technical personnel to respond on the failure equipment (day)
	Problem Category	Problem detection codes (8-1)
	Failure Rectification	Repair (1); Replacement (2)
Performance	Downtime	Mean time of equipment malfunction (year)
	Asset Condition	Beyond economical repair (BER) (2); Proposed for disposal (1); Active (0)
Risk and safety	No. of Failures	Number of failures on the equipment (vary)
	Asset Status	Malfunctioning (1); Functioning (0)
Availability and Readiness	Backup or Alternative Unit	Yes (0); No (1)
Utilisation	Operations	Utilisation rate (6-1)
Cost	Repair Cost	The accumulative cost of repair work (vary)

3.3.1.1 Equipment Category

The equipment category refers to the groups of medical equipment. The equipment category plays a crucial feature in the assessment process (Gonnelli *et al.*, 2018; Iadanza *et al.*, 2019). In this study, there were 19 categories of medical equipment. The categories of equipment were converted into numerical form as tabulated in Table 3.6.

Table 3.6: Codes of medical equipment categories.

Category	Code
Analysers, Laboratory, Clinical Chemistry, Automated	1
Bilirubinometers, Laboratory	2
Defibrillators, External, Automated	3
Defibrillators, External, Manual	4
Densitometers	5
Incubators, Infant	6
Infusion Pumps, General-Purpose	7
Laryngoscopes, Rigid	8
Monitoring Systems, Physiologic	9
Nebulizers, Nonheated	10
Oximeters, Pulse	11
Phototherapy Units, Ultraviolet	12
Radiographic/Fluoroscopic Systems, General-Purpose	13
Resuscitators, Pulmonary, Manual	14
Scales, Clinical, Pharmacy	15
Scanning Systems, Ultrasonic, General-Purpose	16
Sensitometers, Radiographic	17
Sterilising Units, Steam	18
Treadmills	19

3.3.1.2 Equipment Age

The lifespan of the equipment is determined by its age. According to Khalaf *et al.* (2010), one of the elements that indicates the effectiveness of the equipment's functionality is the age of the equipment. The age of the medical equipment has a direct relationship with its performance (Badnjevic *et al.*, 2019; Kovacevic *et al.*, 2019). As a result, the performance of the medical equipment depreciates as it becomes older. The following formula was used to calculate the age of medical equipment:

$$Equipment\ Age = Cut - off\ Date - \ Purchased\ date \tag{3.1}$$

The cut-off date for this study was October 31, 2020. The equipment’s procurement date was the acceptance date after the testing and commissioning had been completed satisfactorily. The age of the medical equipment utilised in this investigation ranged from 0 to 30 years, as a result of this pre-processing.

3.3.1.3 Support Service

The medical equipment is manufactured using cutting-edge technology. Regular maintenance and replacement of consumable components are required and must be undertaken and carried out by approved parties for the equipment to work at its best. The medical equipment’s maintenance activity will be jeopardised due to the obsolescence of spare parts and the unavailability of service providers (Faisal & Sharawi, 2015). The equipment manufacturer's estimated life cycle was used to establish the obsolescence status in this investigation. This feature indicates if the medical equipment is no longer relevant to provide broader services, has failed to function as intended, or a new equipment is needed to replace the modality (Ancellin, 1999; Ouda *et al.*, 2010). It also established the equipment's usable life span, with the American Society for Healthcare Engineering's (ASHE) life expectancy baseline being used in this study (American Society for Healthcare Engineering (ASHE), 1996). The medical equipment’s support service is determined using the following formula:

$$Obsolescence = Equipment\ age > Life\ Expentency\ (year) \tag{3.2}$$

3.3.1.4 Function

The term function refers to the medical equipment's primary purpose or service objectives. Given the functional component, 5 criteria are involved: life support, therapeutics, diagnostics, analytical, and miscellaneous. If the failure of the unit causes damage or death, the device is classified as life support. The units that treat or provide a solution for any ailment or condition that the patient is suffering from are referred to as therapeutic equipment. Diagnostic equipment refers to medical equipment that is used to detect any ailment or diseases. Analytical equipment refers to any unit needed to support the laboratory's operation of analysing patients' samples, whereas miscellaneous equipment refers to any unit used to assist the primary healthcare and medical activities. As a result, this feature is very important when it comes to figuring out how much risk patients could face if a medical equipment does not work properly (Corciova *et al.*, 2017; Hernández-López *et al.*, 2019).

3.3.1.5 Preventive Maintenance Status

Information on preventative maintenance is crucial in establishing the quality of the medical equipment (Badnjevic *et al.*, 2019; Kovacevic *et al.*, 2019). In this study, this component is made up of 3 criteria: 'completed', 'open', and 'not in schedule'. The term 'completed' refers to the PPM tasks that were successfully done and consistent with the manufacturer's service manual instructions. The completion of the preventive maintenance is one of the factors in the maintenance checklist, according to Al-Bashir *et al.* (2012). 'Open' maintenance work refers to any yearly PPM of medical equipment scheduled for the current year, but not completed. This indication is critical for alerting clinical engineers to begin PPM tasks.

The term 'not in schedule' refers to the clinical engineer's failure to prepare the PPM schedule for the equipment due to their oversight. This could lead to an incomplete PPM for the year, which could affect the performance of the equipment.

3.3.1.6 Number of Missed Planned Preventive Maintenance

The condition 'not in schedule' as indicated in sub-section 3.3.1.5 may result in incomplete PPMs for the current year, or for the 1st frequency of PPMs for the equipment that requires PPM twice annually. If suitable procedures are not done, PPMs for the prior year may be possibly skipped. The more PPMs that are missed, the greater the risk of a medical device's failure. According to the WHO, almost 80% of faulty medical equipment situations could have been avoided with a regular maintenance schedule (Kutor *et al.*, 2017). The following formula was used to calculate the number of missed PPM using the CAMMS data:

$$Missed\ PPM\ = Completion\ of\ PPM > Due\ Date\ of\ PPM \tag{3.3}$$

$$Total\ No.of\ Missed\ PPM\ = \sum_{n=1}^{n} Missed\ PPM\ for\ each\ schedule \tag{3.4}$$

From this pre-processing, the number of missed PPM of the medical equipment used for this study ranged from 0 to 7 times.

3.3.1.7 Maintenance Complexity

The degree of difficulty in completing maintenance operations is referred to as maintenance complexity (Ben Houria *et al.*, 2016; Hutagalung & Hasibuan, 2019). Extensive maintenances, moderate maintenances, and basic inspections are the three criteria that make up this characteristic. Extensive maintenance refers to a complicated system, in which the medical equipment is outfitted with mechanical systems such as pneumatic, hydraulic, motorised, and others. According to Fennigkoh and Smith (1989), the complex system's equipment requires the most extensive maintenance. As a result, well-trained, qualified, and highly competent people are required to do this task, guaranteeing that the whole system operates in accordance with the manufacturer's specifications and legal requirements. Furthermore, it necessitates the use of particular instruments, because performing maintenance operations takes time. Moderate maintenance necessitates several checks and tests, including performance and safety tests.

Visual inspection, operational tests, battery replacement, and cleaning, are all part of the basic inspection.

3.3.1.8 Maintenance Scope

Maintenance work conducted by a competent individual in accordance with the manufacturer’s standards, national approved bodies, and the healthcare facility administrator, is referred to as a maintenance scope. Several manufacturers of equipment specify a yearly maintenance period. Certain equipment, such as a radiography equipment, that exposes the surrounding region to radiation, requires statutory certification (Anis *et al.*, 2020). This equipment must be examined, and the dose of radioactive exposure must be kept below the defined limits (Atomic Energy Licensing Board, 2006; Department of Standards Malaysia, 2018b). To obtain an exact result, specific measurement medical equipment must be calibrated. Routine inspections, on the other hand, refers to standard maintenance tasks such as physical inspections, regular operational testing, and other related qualitative tests.

3.3.1.9 Response Time

The request for Repair or Response Time refers to the period of time between the user's failure report, and the arrival of technical professionals to carry out the problem detection procedure. The longer the response time, the longer the medical equipment is unavailable for use, because the cause of failure is unknown, and the patient healthcare services are eventually disrupted (Hamdi *et al.*, 2012). The following formula was used to calculate the mean reaction time for each piece of medical equipment:

$$NF = Total\ No.of\ breakdown\ events \tag{3.5}$$

$$Response\ Time = \frac{1}{NF}\sum_{n=1}^{n}(RespD - RepD) \tag{3.6}$$

Where, NF is the number of failures, RespD is the response date, and RepD is the reported date.

3.3.1.10 Repair Time

Repair time, also known as Mean Time to Repair (MTTR), is the time it takes for technical personnel to complete repairs, restorations, or rectification works. The longer it takes for technical personnel to repair the equipment, the longer the healthcare services will be disrupted. As a result, repair and response times are critical components of the medical equipment's maintenance management, and has to be kept under control (Al-Bashir *et al.,* 2012; Bahreini *et al.,* 2018). The calculation of the repair time is determined by the following formula:

$$Repair\ Time = \frac{1}{NF}\sum_{n=1}^{n}(CompD - RespD) \quad (3.7)$$

Where, NF is the number of failures, CompD is the completion date, and RespD is response date.

3.3.1.11 Problem Category

Problem category refers to the symptoms or early prediction of malfunctioning medical equipment from the time the users launch the failure report. For a better course of action, the problems reported by the users were classified into 8 categories.

Table 3.7 tabulates and describes the 8 categories of problems reported. This problem category gives an insight for technical personnel to prepare the necessary tools and parts required for further inspections, and for troubleshooting assignments during corrective maintenances (Liao, Boregowda*, et al.*, 2021; Liao, Cade, *et al.*, 2021). Better preparation and insights make the process of troubleshooting and rectification quicker. Therefore, the clinical engineers might reduce the duration of the equipment's failure in terms of repair time and downtime.

Table 3.7: Eight categories of equipment problems.

Problem Category	Description	Symptoms or Source of Failures
1	Power	Power supply, battery
2	Active component and electronic part	Sensors, probes, gauges, photometers, pads, motors
3	Interface	Operating systems, firmware, software, communication
4	Calibration	Quality control, quality assurance
5	Mechanical part	Doors, enclosures
6	Sub-system	Pneumatic, hydraulic, heater
7	User	Request for inspection, further training, mishandling
8	Passive component	Gaskets, filters, tubing

3.3.1.12 Failure Rectification

Failure rectification refers to the activities or course of actions required for restoring the original condition while complying with the manufacturer's specifications (Liao, Boregowda, *et al.*, 2021; Liao, Cade, *et al.*, 2021). In this study, there are 2 types of general restoring works, which are the repairs and replacements. Repairs denotes servicing, calibration, modification, adjustment, testing, cleaning, lubrication, reconditioning, resetting, repositioning, or proposed retraining. This type of work does not require any replacement of equipment parts, consumables, or components. Whereas, replacements represent the changing of parts, consumables, or components to make the equipment function once again. The replacement term does not imply replacing the entire medical equipment.

3.3.1.13 Downtime

Downtime represents the time when the medical equipment is out of operation, and therefore unable to function according to the manufacturer's specifications, for the duration of its useful life. Downtime is inversely proportional to uptime, where downtime refers to the period of failure and malfunctioning medical equipment. The average downtime per year is the unit of equipment downtime. The longer the equipment is out of commission, the less safe it is to use, and the longer the patient's medical care is disrupted. The amount of downtime also reveals the overall functioning of the medical equipment. According to Hutagalung and Hasibuan (2019) and Jamshidi *et al.* (2015), one of the vital factors in preventive maintenance is the downtime of the equipment. The calculation of downtime refers to the following formula:

$$Downtime = \frac{1}{(Service\ year * Day\ in\ a\ year)} \sum_{n=1}^{n} (Downtime) \qquad (3.8)$$

3.3.1.14 Asset Condition

The medical equipment is typically in 3 states; active, proposed for disposal, and beyond economic repair (BER) (Department of Standards Malaysia, 2018a). If the equipment can perform at its best according to the manufacturer's requirements, it is deemed active. Some equipment is still deemed as functional, however it will be considered for disposal because it is no longer needed or used. The suggestion is to set aside a limited amount of operational space or decrease any maintenance expenditures. When the equipment malfunctions, the unit might be designated as BER. The repair cost exceeds certain percentages of the equipment's worth, or any other causes stipulated by the healthcare facility’s management.

3.3.1.15 Number of Failures

The number of failures refers to the number of occasions during the equipment's useful life when it is unable to function. Failures can be identified by looking at the failure reports generated by the users. Clinical engineers can estimate future breakdowns by looking at the history of failures. It was caused by a lack of maintenance, and this symptom can be utilised to choose a replacement approach (Aboul-Yazeed *et al.*, 2017). Equipment that regularly fails in operation must be given special attention. Excessive failures mean that the equipment should be checked often and carefully to avoid more system damage.

3.3.1.16 Asset Status

To improve the equipment’s performance, it is critical to prevent medical equipment failure. There are only 2 types of asset statuses; functional and dysfunctional. A functioning medical equipment is defined as medical equipment which can operate according to the manufacturer’s specifications without getting a failure report from the user. Nonetheless, when medical equipment is unable to perform properly, it is classified as malfunctioning. Simultaneously, when the unit fails to deliver medical services to the patients, the user files a breakdown report. Although the equipment may function normally in some situations, failures in any of the system's components might jeopardise the equipment's efficiency, and overall operations (Toporkov, 2007). From the extracted dataset, 1,028 units malfunctioned out of 13,350 available medical equipment.

3.3.1.17 Backup or Alternative Unit

Any substitute equipment used temporarily to offer medical services if the main equipment fails is referred to as the backup, or alternative unit (Ouda *et al.*, 2010; Tawfik *et al.*, 2013). Because of the importance and significant aspects involved in delivering crucial medical services, there are various alternate or backup units which can be employed temporarily to avoid service disruptions. The backup units guarantee that users may continue their tasks while repairs to the breakdown equipment can be completed promptly. From the dataset, there are only 20 backup units covering 7 categories of the medical equipment.

3.3.1.18 Operations

Operations refer to the utilisation rate, which indicates the equipment usage for providing medical services in healthcare facilities (Aridi *et al.*, 2016; Hutagalung & Hasibuan, 2019). The indication of the utilisation rate is according to the average operating hours of the medical equipment based on the healthcare facility's working hours per day. In this study, the feature is divided into 6 criteria, which indicate the equipment's average operating hours per day as tabulated in Table 3.8. The segregation is made through continuous monitoring by maintenance personnel, and based on the degree of utilisation by the users. These criteria were then registered in the asset management record system.

Table 3.8: Utilisation criteria.

Utilisation Category	Operating Hour
1	< 2 hours
2	2 hours ≤ x < 3.5 hours
3	3.5 hours ≤ x < 5 hours
4	5 hours ≤ x < 6.5 hours
5	6.5 hours ≤ x < 8 hours
6	≥ 8 hours

3.3.1.19 Repair Cost

The repair cost is a financial term that refers to the overall cost of repairing malfunctioning medical equipment throughout its service life (Ben Houria *et al.*, 2016; Hutagalung & Hasibuan, 2019; Ouda *et al.*, 2010). The cost of repair includes the cost of materials, labour, and other related costs. The increasing cost of repairs associated with medical equipment exhibits the bad performance of the unit. Effective and efficient preventive management prevents medical equipment from certain failures, which also reflects the mitigation of related repair costs. The calculation of accumulated repair costs associated with each medical equipment refers to the following equation:

$$Repair\ cost = \sum_{n=1}^{n} (Repair\ cost\ per\ breakdown) \tag{3.9}$$

3.3.2 Data Normalisation

Nineteen features comprising different scales of criteria, as mentioned in the previous section, were used. Since the features and the criteria were diverse from one another, the values were notably dynamic and varied, especially when it came to the 8 medical equipment features. Among the features were the equipment's category, age, number of missed PPMs, repair time, response time, downtime, number of failures, and repair costs. According to Borkin *et al.* (2019), the range of raw data values tends to have varied scales. In this instance, the objective functions in some machine learning algorithms will not perform well without data normalisation. As a result, the scaling through a standard normalisation approach was established (Watt *et al.*, 2020).

Data normalisation is a pre-processing approach, whereby the data is scaled or altered to ensure that each characteristic contributes equally toward the machine learning (Singh & Singh, 2020). By switching to the provided input measurement, the approach normalises the distribution of each feature and criterion dimension in a dataset. It consists of a 2-step method, that begins with mean-centring, and ends with rescaling of each feature by inversing the standard deviation. The approach improves the performance of the used algorithm in terms of the learning speed. Similarity measurements are trustworthy across many sectors, and the data quality is very much improved (Abdar *et al.*, 2019; Dudoit & Fridlyand, 2002). Moreover, it avoids the average expression level across features from being impacted by a single feature's expression level.

The standard normalisation, known as the z-score, was used in this study. This method converted data by scaling the characteristics with a mean of 0, and a uniform standard deviation of one (Sree & Bindu, 2018). According to Khond (2020), the z-score approach is often employed when the input data varies greatly on scales, and to efficiently deal with the outliers. The following equations were used in the calculation process:

$$z - score = \frac{\chi - \mu}{\sigma} \quad (3.10)$$

$$\mu = \frac{1}{n}\sum_{n=1}^{n}(X_n) \quad (3.11)$$

$$\sigma = \sqrt{\frac{1}{n-1}\sum_{i=1}^{n}(\chi - \mu)^2} \quad (3.12)$$

Where, x is the criteria, μ is the mean, σ is the standard deviation, and n is the total number of medical equipment.

3.4 Failure Analysis Predictive Models

One of the objectives of this work is to build a failure analysis predictive model. The prediction model is meant to cover three forms of failure analysis, including the first failure of the medical equipment, the failure to year ratio, and the failure rectification works. The development of the failure analysis predictive models employed a supervised machine learning algorithm. The failure analysis predictive models were developed using MATLAB R2021a, supported by Statistics and the Machine Learning Toolbox, and the Classification Learner App.

3.4.1 Supervised Machine Learning Techniques

The primary objective of the supervised machine learning was to predict the classification and regression outcomes (Badillo *et al.*, 2020). In this study, the classification technique was used to generate the output classes. During the training and validation stages, the labelled dataset was measured using the AI classification approach known as supervised machine learning. The supervised machine learning technique was utilised in a variety of applications, including data mining, predictive analytics, and image processing, all of which require direction throughout the learning process (Joshi, 2020; Mahesh, 2020).

Several well-known classifiers, such as the Decision Tree (DT), K-nearest Neighbor (KNN), Naive Bayes (NB), Support Vector Machine (SVM), Bagged Trees (BT), and ANN, can be found in previous research works (Bichitrananda Behera & Kumaravelan, 2020). As a result, these 6 classifiers were chosen for predictive model creation in this investigation, as they had previously been shown to provide high accuracies in comparable studies (Badnjevic *et al.*, 2019; Hrvat *et al.*, 2020; Kovacevic *et al.*, 2019; Liao, Boregowda, *et al.*, 2021; Liao, Cade, *et al.*, 2021). Additionally, a classifier known as the Discriminant Analysis (DA) was utilised because of its excellent performance on large and multiclass datasets (Shiferaw *et al.*, 2019). Another rationale for using the seven different types of classifiers was their capacity to measure the numerical data points in the dataset.

DT is a tree-based algorithm which is widely used in machine learning, image processing, and pattern recognition. It is a classifier which is simple to use, fast to construct, and straightforward to interpret (Charbuty & Abdulazeez, 2021). The classifier can handle multi-dimensional data with mixed numerical and categorical data types, distinguish outliers, and minimise overfitting (Danjuma, 2015). The first route in the prediction process using this classifier starts at the root, separates the replies to the branches using the if-then logic, and arrives at the predictive results of the leaf node. In this study, the Gain Index was applied for constructing the tree. This index assessed the inequality in the medical equipment data (Patel & Prajapati, 2018). The Gain Index can be illustrated as:

$$\text{Gini Index} = \sum_{i=0}^{n} Pi^2 \tag{3.13}$$

Where, i is the number of classes, and Pi is the probabilities of each of these classes.

DA is one of the first widely used supervised machine learning classification algorithms, developed by R. Fisher in 1936 (Xanthopoulos *et al.*, 2013). This classifier's objective is to locate the projection hyperplane by minimising the interclass differences, while increasing the distance between the projected classes. The classifier identifies a lower domain measurement by comparing it to the initial dimensions of the separable data, which was established during the model's training. The mean value and variance calculations are referred to as "separability". It is utilised when there are at least 2 classes (Siraj-Ud-Doulah & Alam, 2020). Additionally, it is quicker, simpler to comprehend, and capable of processing enormous amounts of data. On the other hand, the classifier's data processing capabilities are restricted to numerical predictors, and not categorical predictors.

The Bayes formula, which posits that predictors are provisionally independent and unconnected with other predictors in a dataset, is used to classify data using the NB (Mahesh, 2020). The classifier assesses parameters like the mean and variance throughout the classification process by referring to the estimated probability of a characteristic supplied in the training data (Danjuma, 2015). It also seeks to improve the posterior probability of the classification identification. NB is simple to understand, works with multiclass datasets, and can be used to calculate both numerical and categorical sample parameters. For a high-dimensional dataset, however, the prediction is middling and sluggish. The following is a mathematical formulation of Bayes' Theorem:

$$P(A|B) = \frac{P(B|A).P(A)}{P(B)} \tag{3.14}$$

Where, A,B are the events, P(A|B) is the probability of A given B is true, P(B|A) is the probability of B given A is true, and P(A) and P(B) are the independent probabilities of A and B.

SVM is one of the most accurate binary classification algorithms (Liu *et al.*, 2017), and it can be used for both binary and multiclass classifications. The hyperplane, which divides the data points of one class from those of other classes, is used to produce the classification (Belavagi & Muniyal, 2016). With the maximum width of the margin, the best-constructed hyperplane can conduct data point separations. The distance between the data points closest to the separating hyperplane are used to estimate the thickness of the margin. This is referred to as a support vector. This classifier can be used on numerical samples and/or categorical parameters. Nonetheless, it is time-consuming and difficult to comprehend during the forecast for the multiclass case. A hyperplane is defined as:

$$W.X + b = 0 \tag{3.15}$$

Where, W is the vector weight, X is the data, and b is bias.

In this study, the KNN classifier was also applied. KNN is a popular data mining approach which provides straightforward and accurate answers to a variety of real-world classification issues (Abu Alfeilat *et al.*, 2019). This strategy is the ideal solution for the user who has minimal experience with data dissemination. The predicted output is based on the majority voting method, and the classification is done by measuring and comparing feature data points with the training set (Wieland & Pittore, 2014). In terms of interpretability, the forecast speed is sluggish and difficult. It does not apply to mixed predictors, though. Using the Euclidean distance, the degree of similarity is determined between all the data, and the new data points.

$$d = \sqrt{(X_2 - X_1)^2 + (Y_2 - Y_1)^2} \tag{3.16}$$

Where, d is the distance, and X and Y are the datasets.

One of the classifier instruments used in the study is the BT. It's an ensemble learning system that's also known as the Random Forest (RF) (Bichitrananda Behera & Kumaravelan, 2020). This classifier combines DT classifiers, which separate random vector values with the same range, and are created for all trees in the forest to identify each tree's feature (Breiman, 2001). In terms of interpretability, the prediction speed is moderate and demanding. It cannot be used in the dataset for either numerical, or categorical predictors.

An ANN is a sophisticated artificial system based on mathematical models of the human brain and nervous system's function, structure, and information processing abilities (Huang *et al.*, 2022). An ANN is a self-learning system that learns to anticipate outputs by conducting repeated iterations, similar to the human brain. After the weighting function, all types of ANN nodes are then used as the input for the following node, similar to neurons in the human brain. They are divided into 3 levels; input layers, hidden layers, and output layers (Çınar *et al.*, 2020). The weights are changed using a systematic technique during the learning process. To improve the output accuracy, the ANN frequently employs the backpropagation learning algorithm, which entails performing an iteration, calculating the error with the output and actual values, propagating backwards, and updating the weights and biases with the error, to ensure that the output accuracy is high after several such forward and backward propagations.

The dataset was partitioned into subgroups for training and validation processes, to avoid overfittings caused by each classification model. Cross-validation is the term for the division's procedure. The k value was fixed at 10 folds in this study to increase the classification's accuracy (Liu *et al.*, 2017; Mishra *et al.*, 2021; Yadav & Shukla, 2016).

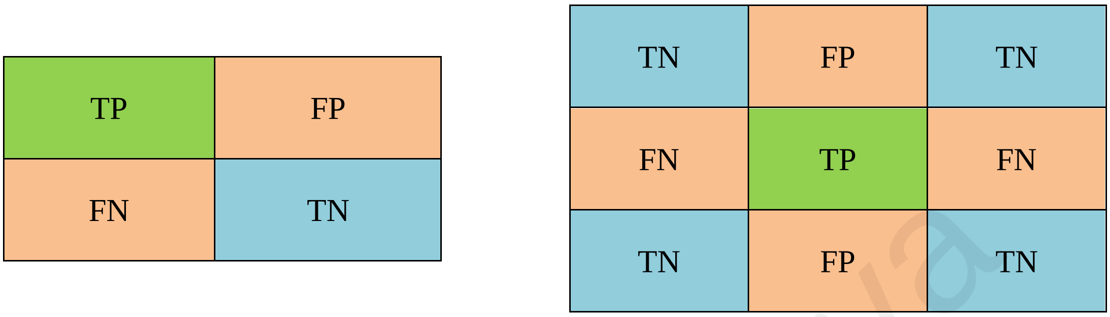
3.4.2 Performance Evaluation

The prioritised predictive model for failure analysis, preventive maintenance, corrective maintenance, and the replacement plan must be validated to ensure that the output is reliable and consistent. For evaluating the accuracy of a prediction model and guiding the development of categorisation model, it is necessary to use the proper assessment methods (Tharwat, 2021). The 4 primary categories used to evaluate categorisation modelling are the true positive (TP), false positive (FP), true negative (TN), and false negative (FN). Table 3.9 describes each measuring parameter pertinent to the topic of inquiry.

Table 3.9: Definition of measuring parameters.

Parameter	Description
TP	The number of equipment that was initially identified as positive is now appropriately classed as positive
FP	The number of equipment that was initially identified as negative is now incorrectly classed as positive
TN	The number of equipment that was initially identified as negative is now appropriately classed as negative
FN	The number of equipment that was initially identified as positive is now incorrectly classed as negative

A contingency table, sometimes referred to as a confusion matrix, directs the 4 parameters (Sujatha & Rajagopalan, 2017). As indicated in Figure 3.4, the descriptive examples of binary and multiclass confusion matrices were utilised to guide the calculation of additional performance matrices. A sum of 11 performance assessment matrices were used in this study to assess the classifier's efficiency; accuracy, recalls, precision, specificity, f-measure, Matthews Correlation Coefficient (MCC), Kappa, Receiver Operating Characteristic (ROC), misclassification rate, prediction speed, and training duration.



(a) (b)

Figure 3.4: (a) Binary class, (b) Multiclass.

The term accuracy refers to the degree to which the measurement results are close to the true value (Azhagiri & Rajesh, 2018). Accuracy is determined by dividing the number of correct predictions by the entire sample size. The accuracy of a perfect prediction model is equal to 1. The accuracy parameter is defined by the following equation:

$$Accuracy = \frac{TP + TN}{TP + FP + TN + FN} \tag{3.17}$$

The precision metric represents the fraction of pairings that are precisely allocated to the same cluster (Azhagiri & Rajesh, 2018). This is often referred to as a positive prediction value. A score of 1 indicates that the prediction model is perfectly precise. The following formula may be used to perform the calculation:

$$Precision = \frac{TP}{TP + FP} \tag{3.18}$$

Recalls can be referred to as sensitivity, which relates to the ability to discern genuine pairs (Azhagiri & Rajesh, 2018). A score of 1 indicates that the prediction model is perfectly sensitive. This parameter may be calculated using the equation below:

$$Recall = \frac{TP}{TP + FN} \tag{3.19}$$

Specificity is sometimes referred to as the true negative rate, and is the inverse of the recall, which relates to the division of negative pairs (Tharwat, 2021). A score near to one indicates that the prediction model is more specific. The specificity value is defined using the following equation:

$$Specificity = \frac{TN}{TN + FP} \tag{3.20}$$

F-measure, sometimes referred to as the f-score, is a product of the harmonic mean of the accuracy and recall (Azhagiri & Rajesh, 2018). The maximum value is equal to 1, while the minimum value is equal to 0. The following formula is used to determine the value of the f-measure:

$$F - Measure = 2 * \frac{Precision * Recall}{Precision + Recall} \tag{3.21}$$

MCC is another performance metric. According to earlier research works, this metric is a much more robust and dependable statistical fraction that quantifies the classifier's performance as a definitive number (Chicco & Jurman, 2020; Chicco *et al.*, 2021). It provides a high score value only if the prediction model performs well across all the confusion matrix categories. MCC may be calculated using the following equation:

$$MCC = \frac{(TP * TN) - (FP * FN)}{\sqrt{(TP + FP) * (TP + FN) * (TN + FP) * (TN + FN)}} \quad (3.22)$$

Kappa is used in the classifier system to determine the similarity of the units within a group (Kou & Wu, 2014). The value ranges from -1 to 1. If the computed number is close to one, then there is a high degree of agreement. When the Kappa value approaches -1, there is strong disagreement, whereas 0 indicates a chance-level agreement (Tallón-Ballesteros & Riquelme, 2014). The following equation describes how the Kappa score is calculated in principle:

$$Kappa = \frac{P(A) - P(E)}{1 - P(E)} \quad (3.23)$$

Where, *P(A)* is the classifier accuracy, and *P(E)* is the likelihood that the classifier agreement is due to change.

The ROC curve analysis is a widely used statistical technique for describing the accuracy of the models (Bowers & Zhou, 2019; Obuchowski & Bullen, 2018). The ROC plot displays the false-positive rates (FPR) and the true-positive rates (TPR) on the X and Y axis, respectively, and it illustrates the trade-offs between the 2 rates. The area under the curve (AUC) in the ROC analysis is between 0.5 and 1.0, and it is used to specify the model's accuracy (Mallick *et al.*, 2021). TPR and FPR are calculated using the following equations:

$$TPR = \frac{TP}{TP + FN} \quad (3.24)$$

$$FPR = \frac{FP}{FP + TN} \tag{3.25}$$

The misclassification rate is calculated as the proportion of samples incorrectly classified, which are then divided by the total number of samples (Dwivedi, 2018). The misclassification rate was determined in this study by dividing the number of equipment which was incorrectly predicted by the total number of equipment participating in each failure analysis and maintenance operation. Two additional performance metrices were included in this study; the prediction speed and training time. The predicting speed parameter denotes the time necessary to test the classifier, whereas the training time parameter denotes the time required to train the classification model (Kou & Wu, 2014).

3.4.3 First Failure Predictive Model

Identifying the first failure event of any medical equipment enables clinical engineers to successfully plan the required maintenance management. The goal of the first failure predictive model development is to forecast the initial failure event of a medical device, from the date of the purchase. The official date of the equipment acquisition is the date that the medical equipment successfully completes the testing and commissioning process as specified by the manufacturer's representative, and is fully accepted by the consumer.

To develop the first failure predictive model, a total of 13,350 units consisting of nineteen equipment categories are shown in Table 3.1 tabulated in sub-section 3.2. The dataset for these medical devices includes the 9 proposed features. The development of the first failure predictive model for the medical equipment involves the identification of the class of the equipment involved. In this study, 3 categories represent the first failure prediction. Table 3.10 tabulates these features, classification, and the number of the equipment for the first failure predictive model development.

Table 3.10: Features, classification, number of medical equipment for first failure predictive model.

Equipment Feature	Output	
	Classification	**No. of Equipment**
Equipment age	Class 1: No failure	7,202
Function	Class 2: ≤ 6 years	2,832
Preventive maintenance status	Class 3: ≥ 6 years	3,316
Number of failures		
Maintenance scope		
Maintenance complexity		
Downtime		
Operations		

This classification was subdivided using arbitrary algorithms based on the equipment dataset patterns. Class 1 indicates that no medical equipment had failed during its service life since the date of its acquisition. Class 2 represents the first equipment breakdown that occured within the first 6 years of service life. Whereas, Class 3 represents the first failure of the medical equipment after 6 years of service. Utilising these 7 classifiers, the predictive model was created and trained. Eleven performance evaluation measures were used to validate each of the created models. The optimal model option was determined by the performance measures with the highest rank. To ensure the optimal performance of the first failure predictive models for the medical equipment, the best-selected model was then optimised via the hyperparameter optimisation.

3.4.4 Failure to Year Ratio Predictive Model

The combination of the first failure and failure to year ratio predictive models provides clinical engineers with a clearer signal for maintaining medical equipment.

For the development of the failure to year ratio predictive model, 6,148 units from 19 equipment categories were employed as samples. As stated in Table 3.10, the selection of the amount of equipment is dependent on the malfunction status of the equipment. This medical equipment dataset has four proposed features. For the creation of the predictive model, the failure to year ratio classes are identified as shown in Table 3.11. The table lists the equipment's attributes, classification, and quantity of failure to year ratio prediction model development. This classification was divided using arbitrary techniques according to the pattern in the dataset across 6,148 units of equipment. Referring to Table 3.11, the output of the first failure of a medical equipment's predictive model was used as one of the entries for the development of this predictive model. Class 1 refers to the frequency of the equipment's failures exceeding 1 year. For example, the medical equipment failures can occur once every 2 years. Class 2 failures typically occur once a year. Whereas, Class 3 refers to the frequency of equipment failure being more than once a year. The predictive model was developed and trained using 7 classifiers. All the developed models were validated using 11 measures of performance assessment. The optimal model option was determined by the performance measures with the highest rank. The selected model was then optimised using hyperparameter optimisation to ensure that the failure to year ratio predictive model performs at the highest level.

Table 3.11: Features, classification, number of medical equipment for failure to year ratio predictive model.

Equipment Feature	**Output**	
	Classification	**No. of Equipment**
First Failure Classes	Class 1: <1	5,124
Equipment Category	Class 2: =1	246
Equipment Age	Class 3: >1	778
Maintenance Scope		

3.4.5 Failure Rectification Action Predictive Model

Determining the type of rectification work is an important aspect for clinical engineers in making initial preparations for the implementation of corrective maintenances. The objective of the predictive model development is to predict the type of rectification work based on the equipment's damage in the past.

To create the failed rectification action predictive model, 14,449 work orders for corrective maintenances were utilised. The justification for picking this amount of work orders was to cover all 19 equipment categories, involving 5,895 units. In addition, the decision was based on the number of equipment failures, which ranged from one to 7 for each piece of equipment. According to the observations conducted across the work orders, the number of work orders that exceeded seven indicated a pattern of failure.

The datasets consisted of work orders concerning the problem categories as shown in Table 3.7. The dataset for these medical devices included 12 proposed features. The objective of the predictive model development was to forecast the failure rectification action classes, which were comprised of two features. Table 3.12 tabulates these features, classifications, and the number of the equipment for failure rectification action's predictive model development.

This classification was subdivided using arbitrary algorithms based on the equipment dataset pattern's Class 1, which refers to repair works without involving any replacement parts, consumables, or components. Class 2 denotes the replacement works, which comprises of changing the part, consumables, or components. The predictive model was developed and trained using 7 classifiers. All the developed models were validated using 11 measures of the performance assessment. The best model selection was based on the highest rank of performance measures. To certify that the first failure's predictive model for the medical equipment performed at the optimum level, the best-selected model was then optimised using the hyperparameter optimisation.

Table 3.12: Features, classification, number of medical equipment for failure rectification action predictive model.

Equipment Feature	Output	
	Classification	**No. of Equipment**
Equipment Category	Class 1: Repair	7,014
Function		
Equipment Age		
Response Time (each work order)		
Repair Time (each work order)		
Downtime (each work order)		
Maintenance Scope	Class 2: Part replacement	7,435
Maintenance Complexity		
Operations		
Backup or Alternative Unit		
Problem Category		
Number of Failures (by a sequence of work order)		

3.5 Maintenance Prioritisation

The development of a maintenance prioritisation system involved 3 main activities, namely preventive maintenances, corrective maintenances, and replacement plans. The prioritisation assessment involved 2 techniques, namely clustering and classification of the maintenance prioritisation. The results of these 2 techniques were fed to the machine learning predictive model. The performance of the maintenance-priority models were based on these 2 techniques, and was then compared. The selection of the best techniques and models were made to ensure that the highest accuracy of the prediction of the maintenance priorities can be achieved.

3.5.1 Clustering Assessment

The prioritising evaluation used a numerical criterion for the medical equipment characteristics as an input. During this stage, the numerical inputs were analysed and partitioned using an unsupervised machine learning approach. This method was used to cluster medical equipment based on the criterion value of its attributes. The clustering algorithm generated 3 output parameters; high, medium, and low. As a result, each unit of the medical equipment was classified into 3 categories for each maintenance management activity; preventative maintenances, corrective maintenances, and replacement plans respectively.

Prioritising medical equipment using machine learning increases assimilation and measurement significantly, particularly for large and complicated datasets. The advantage of this strategy is that it is adaptable and scalable, which is a shortcoming of the standard statistical methods (Ngiam & Khor, 2019). Another advantage is the ability to investigate and solve problems involving a variety of different sorts of data without requiring specialised computer programming. The k-means approach was used to split the datasets into 3 groups in this study.

K-means is a well-known non-hierarchical clustering technique that divides a large dataset into smaller pieces. It has been demonstrated to be able to increase the efficiency of the statistical analysis in the areas of prioritisation, classification, and criticality assessments (Choi & Kwak, 2018; Koksal *et al.*, 2017). Additionally, the performance is quick and simple to execute (Chen *et al.*, 2018). Wu *et al.* (2020) revealed that the k-means is the best clustering strategy for the multi-criteria decision analysis, after comparing 6 unsupervised machine learning algorithms across diverse datasets.

The k-means algorithm requires an initial class identification number (Dudoit & Fridlyand, 2002). It is an iterative process that begins by randomly selecting the centroid of the clusters. Then, it assigns each item to the closest centroid, resulting in the formation of a new cluster. The calculation of the new cluster centroid involves the practice of defining the entity in terms of its nearest centroid, and is repeated until a convergence occurs. The convergence is complete when the lowest distance summations of all the alternatives to cluster centroids are reached (Chen *et al.*, 2018). As a result of this method, the features of the medical equipment within a cluster are relatively similar, but the characteristics of the medical equipment within other clusters are significantly divergent.

There were two critical criteria which were considered before the partitioning procedures; the distance metric and replication. The resemblance between the two items we used to establish the distance metric measurement (Gu *et al.*, 2017). The distance of a squared Euclidean was proposed in this work, using the following mathematical equation:

$$distance(x, c) = (x - c)(x - c)' \tag{3.26}$$

Where, x is the equipment criteria value, and c is the centroid.

Another consideration is the replication, which involves repeatedly executing alternative starting centroids depending on a predetermined number, before choosing the shortest sum of distances between the centroids and objects (Abdar *et al.*, 2019). Thus, these 2 parameters were considered for each maintenance management activity before analysing the 3 priority clusters.

An internal measure was utilised to evaluate the outcomes of the prioritisation assessment. The approach for evaluating clustering results (Rendón *et al.*, 2011) is a key difficulty in the clustering analysis, as there is no ground truth or gold standard to compare. As a result, an internal measure was used to evaluate the clustering conclusions, which are only based on evidence in the data (Liu *et al.*, 2010; Wani & Riyaz, 2016). It calculates the qualities of the generated clusters in terms of its spherical nature, separation, and compact attributes, without requiring any further input. By assessing the quality of the data provided through the clustering analysis, the priority levels of each medical equipment for preventive maintenance, corrective maintenance, and replacement plans can be evaluated.

As for preventive maintenance, 9 features of the medical equipment dataset were required, as listed in Table 3.13, to divide the equipment into 3 categories; high, medium, and low priority. There were 13,350 pieces of equipment used in total.

As for the corrective maintenance prioritisation, another set of 9 features of the medical equipment datasets were utilised as tabulated in Table 3.13. The clustering of the corrective maintenance technique, however, only took into account the faulty equipment. This is because, corrective maintenance only occurred when the faulty equipment required a repair. As a result, only 1,028 equipment units were chosen.

As for the replacement strategy, 11 medical equipment features were required as tabulated in Table 3.13. Although more features were considered in the replacement strategy clustering, the same units of equipment were utilised as preventive maintenance prioritisation clustering. Table 3.13 shows a summary of the medical equipment features for each of the 3 maintenance management approaches.

Once the features and medical equipment data have been clustered based on 3 different prioritisation (high, medium and low), the predictive models for the preventive maintenance, corrective maintenance, and replacement plans were developed using the supervised classification technique. The developed models were compared and validated using 11 performance measurements, which will be elaborated in the next sub-section.

3.5.2 Classification of Maintenance Prioritisation

The priority classification of the medical equipment for preventive maintenance, corrective maintenance, and the replacement plan is also divided into 3, namely high, medium, and low. This classification was divided using arbitrary techniques based on the patterns in the medical equipment dataset. The applied dataset for the prioritisations classification assessment and the development of the predictive models is the same as that used for the clustering techniques.

Table 3.13: Features of medical equipment prioritisation model development.

Preventive Maintenance	**Corrective Maintenance**	**Replacement Plan**
Age	Function	Age
Function	Response Time	Obsolescence
Preventive Maintenance Status	Maintenance Complexity	Function
Missed Planned Preventive Maintenance	Repair Time	Maintenance Scope
Maintenance Scope	Number of Failures	Downtime
Maintenance Complexity	Backup & Alternative Unit	Number of Failures
Downtime	Operations	Asset Status
Operations	Repair Cost	Backup & Alternative Unit
Number of Failures	Problem Category	Operations
	Asset Status	Repair Cost
		Asset Condition

There are minor differences for the equipment classification compared to the clustering techniques. To classify the equipment for preventive maintenance, 8 features were used as predictors, while the feature number of failures were used as a response. The dataset used consisted of 13,350 units. For the equipment classification in the corrective maintenance purpose, 8 features were used as predictors, while the repair time was used as a response. In contrast to the replacement plan, nine features were used as predictors, while two features were combined in response to the predictive model. Table 3.14 tabulates these features, classifications, and the number of the equipment for the maintenance prioritisation predictive model's development.

Table 3.14: Features, classification, number of medical equipment for maintenance prioritisation predictive models.

Maintenance Management	Feature	Output	
		Classification	No. of Equipment
Preventive Maintenance	Equipment age Function PM Status Missed PPM Maintenance Scope Maintenance Complexity Downtime Operations	**Number of Failures** Class 1: None; Class 2: 1 ≤ x ≤ 2; Class 3: ≥ 3	 7,202 3,497 2,651
Corrective Maintenance	Function Response Time Maintenance Complexity Number of Failures Backup & Alternative Operations Repair Cost Problem Category	**Repair Time** Class 1: Never fail; Class 2: < 10 days; Class 3: > 10 days	 278 359 391
Replacement Plan	Equipment Age Function Maintenance Scope Downtime Asset Status Backup & Alternative Operations Repair Cost Asset Condition	**Support Service & Number of Failures** Class 1: Available and none failure; Class 2: Available and ≥ 1 failure; Class 3: Obsolescence	 5,611 2,760 4,981

For the preventive maintenance prioritisation classification, Class 1 refers to the occurrence of no failures, or has occurred for the preventive maintenance classification. Equipment which fail between 1 and 2 times are classified as Class 2, while equipment which fails more than twice is classified as a Class 3.

Class 1 for corrective maintenance priority classification refers to equipment that has never failed, or has zero repair time. Class 2 refers to an average repair time of fewer than 10 days. A total of 391 units of equipment were categorised as Class 3 due to the average repair time exceeding 10 days.

The classification of the medical equipment for the replacement plan was also divided into 3, where the support services were still available, and the equipment which had never failed during its service life was categorised under Class 1. A total of 2,760 units of equipment were categorised as Class 2. This meant that the equipment had failed at least once, but the support services were still available. No more support services were provided by the authorised service parties for the 4,981 units, as they were categorised under Class 3.

The predictive model was developed and trained using 7 classifiers. All the developed models were validated using 11 measures of the performance assessment. The best model selection was based on the highest rank of the performance measures. To certify that the first failure predictive model for the medical equipment performed at the intended optimum level, the best-selected model was then optimised using a hyperparameter optimisation.

3.6 Comprehensive Strategic Maintenance Management Framework

A comprehensive strategic maintenance management which was developed covered the 3 main maintenance activities, namely preventive maintenance, corrective maintenance, and the replacement plan. The development of the predictive models can provide accurate predictions, which give early indications to the clinical engineers to be able to administer the necessary medical equipment reliability assessments in the healthcare facilities.

The development of the prediction priority models for the 3 activities through clustering and classification of the maintenance prioritisation were compared by monitoring the performance evaluation values. This aimed to identify the best assessment methods for producing the predictive models which gave the most accurate output.

Once the selection was made, the models which ranked highest in most performance measurements were optimised through the hyperparameter optimisation method. Through this procedure, the models will be able to make much more accurate future forecasts based on the available new data. The process of optimisation was continued by applying the proposed comprehensive strategic maintenance management framework, as illustrated in Figure 3.5.

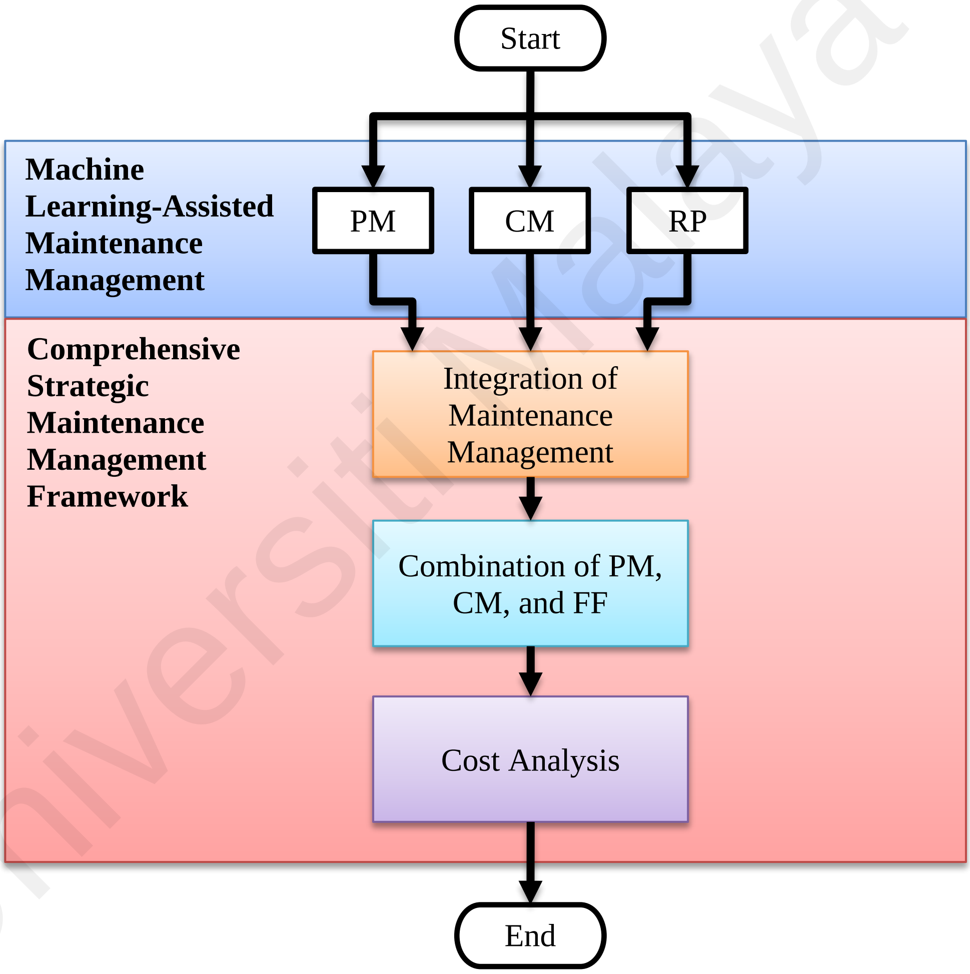


Figure 3.5: The comprehensive strategic maintenance management framework.

As shown in Figure 3.5, the development of a comprehensive strategic maintenance management is comprised of three stages. The processes involved in the 1st stage is the integration of the maintenance management, and is presented in Figure 3.6.

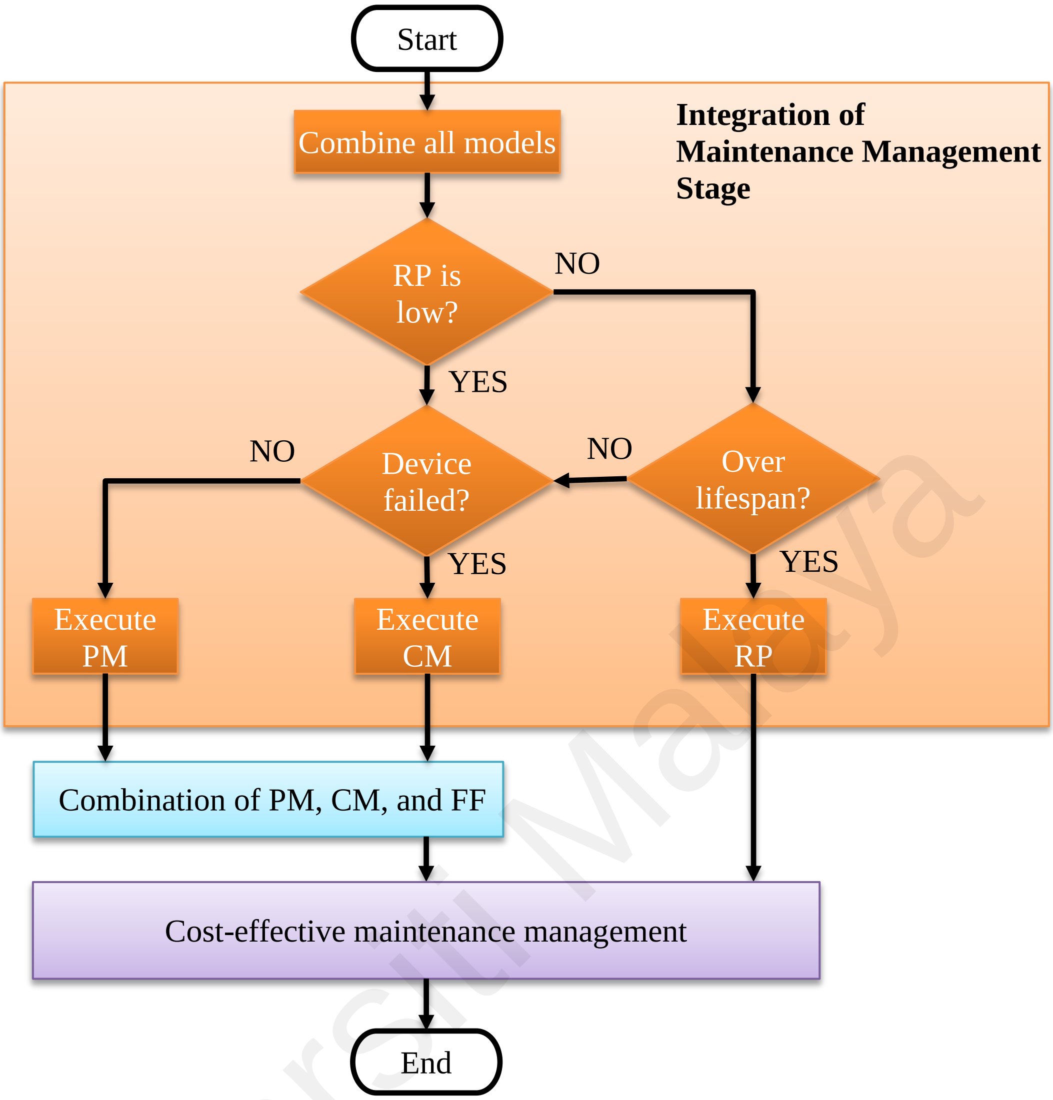


Figure 3.6: Integration of maintenance management stage.

As shown in Figure 3.6, the process of building a comprehensive strategic maintenance management system begins with the compilation of all 13,350 medical equipment priority forecast results for the 3 maintenance tasks. This combination returned a list of 13,350 pieces of equipment, that contained all the 3 priority types. In the first part of the replacement plan, the high and medium categories of the equipment were divided. The longevity of this segregated equipment was then considered. For equipment that had outlived its intended lifespan, a replacement is strongly advised. In addition, clinical engineers might prioritise the replacement of the prescribed equipment.

The clinical engineers need to continue routine preventive maintenance on the equipment which is categorised as low, and under the replacement plan activities, but is still performing well. If a defective equipment is discovered, the corrective maintenance takes precedence. Based on the classes assigned during the forecast process, the numbers of equipment classified as either preventative or corrective maintenance can be prioritised. By referencing this proposed framework, clinical engineers can select the most appropriate maintenance assignment and correspondingly prioritise the repair efforts.

3.6.1 Cost Analysis

The responsibility of the clinical engineers are not to only ensure that the medical equipment in the healthcare facilities functions optimally, but also to optimise the expenditure for the maintenance activities. A cost analysis was conducted to determine that the suggested comprehensive strategic maintenance management can benefit the healthcare organisations.

As mentioned in sub-section 3.6, the predictive results generated from the optimised models of the 3 maintenance activities were integrated to form a comprehensive maintenance management structure. This management structure was then incorporated with the predictive results produced by the first failure predictive model, to ultimately establish a comprehensive strategic maintenance management.

The cost analysis was conducted by identifying the annual maintenance cost of the 13,350 units of the medical equipment. The annual maintenance cost per medical equipment was then computed by referring to the annual maintenance cost rate, and procured cost of the equipment (Altayyar, 2017; Aunión-Villa *et al.*, 2020). The annual maintenance cost per equipment was calculated using the following equation:

$$Annual\ Maintenance\ Cost = Maintenance\ Rate * Purchased\ Cost \quad (3.27)$$

Referring to raw data in the CAMMS, the annual maintenance rate for every 19 categories of the medical equipment is tabulated in Table 3.15.

Table 3.15: Annual maintenance rates.

Equipment Category	**Rate**
Analysers, Laboratory, Clinical Chemistry, Automated	6.60
Bilirubinometers, Laboratory	4.95
Defibrillators, External, Automated	6.05
Defibrillators, External, Manual	6.05
Densitometers	7.15
Incubators, Infant	7.15
Infusion Pumps, General-Purpose	6.60
Laryngoscopes, Rigid	4.95
Monitoring Systems, Physiologic	6.05
Nebulizers, Nonheated	6.60
Oximeters, Pulse	6.05
Phototherapy Units, Ultraviolet	6.60
Radiographic/Fluoroscopic Systems, General-Purpose	11.55
Resuscitators, Pulmonary, Manual	6.60
Scales, Clinical, Pharmacy	4.95
Scanning Systems, Ultrasonic, General-Purpose	6.60
Sensitometers, Radiographic	4.95
Sterilising Units, Steam	4.95
Treadmills	7.70

The annual maintenance cost for each unit of medical equipment based on the rate tabulated in Table 3.15 covers 2 maintenance activities, which are preventive maintenance and corrective maintenance. For preventive maintenance, there are 8 categories, comprising of 5,224 units, where the frequency of the PPM was set to twice per annum. The PPM frequency was set to once per annum for the 11 categories, which encompassed 8,126 units. Referring to the study performed by Stenström *et al.* (2016), the results showed that the annual preventive maintenance cost per equipment was estimated at 10% to 30% of the total annual maintenance cost. In this study, the annual preventive maintenance cost for the equipment, which required one frequency per annum, was set to 20%, and the annual corrective maintenance cost was set at 80%. As for the equipment that required twice the frequency per annum of the PPM, the annual preventive maintenance was set to 30%, and the remainder was allocated to the annual corrective maintenance cost. Table 3.16 summarises the annual preventive and corrective maintenance ratios for further cost analysis.

Table 3.16: Annual preventive and corrective maintenance ratio.

Number of Categories	**Unit of Equipment**	**Annual PPM Frequency**	**Maintenance Ratio**	
			Preventive Maintenance	**Corrective Maintenance**
Eight	5,224	Twice	30	70
Eleven	8,126	Once	20	80

The appropriate maintenance activity and priority for each unit of equipment were determined through the formation of the integration maintenance management stage. After all the 13,350 units were assigned to the dedicated maintenance activities and priorities, the annual preventive maintenance and corrective maintenance costs were then determined by referring to the output classes of the first failure predictive model.

Table 3.17 tabulates the proposed adjustment of the PPM frequency and corrective maintenance budget allocation. From Table 3.17, the flow of determining the annual preventive maintenance and corrective maintenance for each medical equipment is as illustrated in Figure 3.7.

The annual preventive maintenance and corrective maintenance expenses for each piece of equipment were then computed using the adjustment in Table 3.17 with the flow in Figure 3.7. The saving amount was then determined by comparing the new yearly maintenance cost for each piece of equipment to that of the current annual maintenance cost. This combination of the maintenance prioritisation and first failure predictive models will establish a complete strategic maintenance management for the medical equipment. The construction of a framework will contribute to the effectiveness of the maintenance actions, and the optimisation of the maintenance expenses.

Table 3.17: Proposed adjustment of planned preventive maintenance frequency and annual corrective maintenance allocated budget.

First Failure Category	Description	Adjustment of PPM Frequency	Adjustment of CM Budgetary
Class 1	None of failure	Twice to once per annum	Remove budget for CM
Class 2	≤ 6 years	Remains as current practice	Remains budget as current practice
Class 3	≥ 6 years	Twice to once per annum	Remains budget as current practice

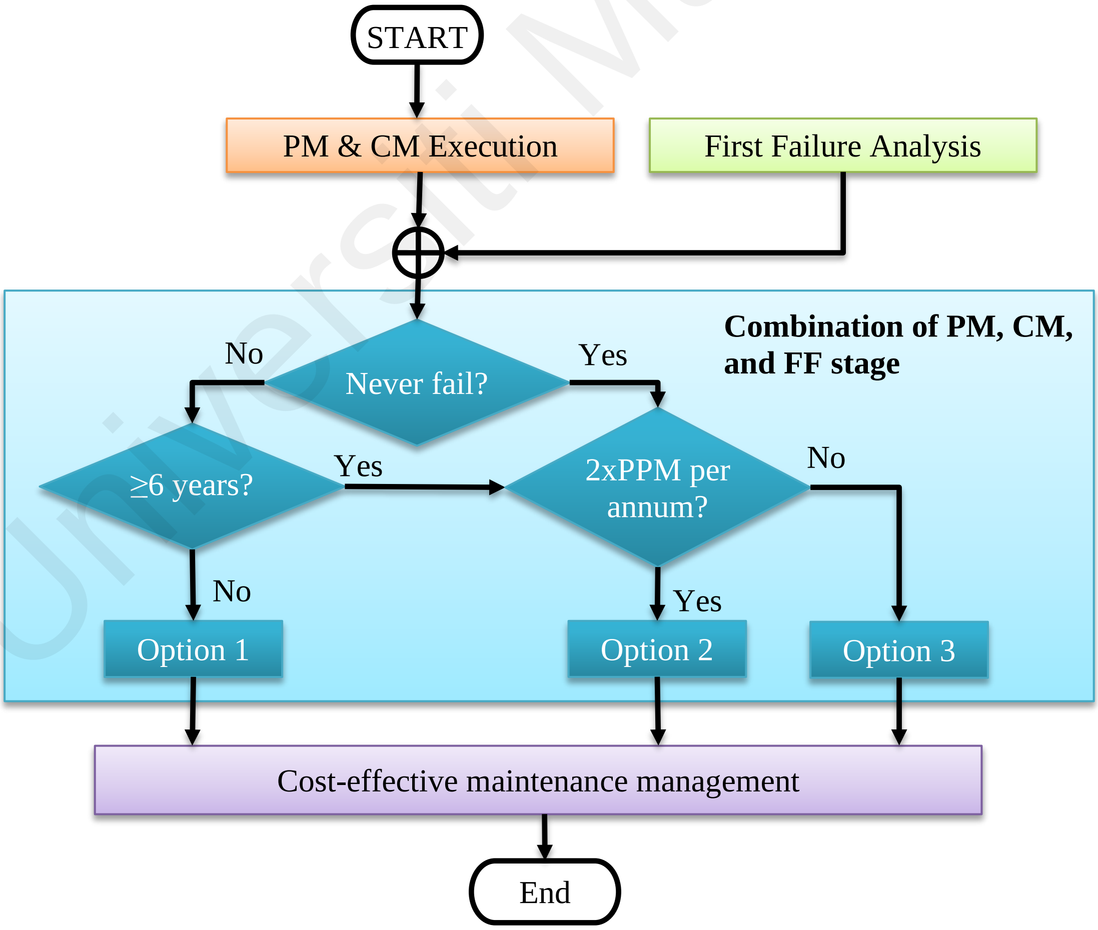


Figure 3.7: Flow of identifying the new maintenance costs for each medical equipment.

3.7 Summary

The development of the failure analysis and maintenance prioritisation predictive models began with the extraction of the raw data for the 13,352 units of medical equipment utilised in the public health clinics. This medical equipment data contained information concerning the aforementioned nineteen features. The data was then transformed into the appropriate format using the normalisation technique.

Table 3.18 summarises the medical equipment's features and criteria used in the development of the failure analysis and maintenance prioritisation predictive models.

Two techniques were used for the development of the maintenance activities prioritisation, namely k-means, and the classification of the maintenance prioritisation. The technique aims to categorise the medical equipment into 3 classes, i.e., high, medium, and low, reflecting the 3 main activities of the maintenance stage. Then, the predictive models of the maintenance activity's prioritisation were trained using the 7 supervised machine learning classifiers, and validated using the 11 performance parameters. The production of the predictive models from these 2 techniques were compared to select the best technique and model. The selected models were then tuned using the optimisation hyperparameters. The outputs generated from the optimised maintenance prioritisation models were combined in the integration maintenance management stage, which was an initial process to form a comprehensive strategic maintenance management plan.

The evolution of the failure analysis incorporated 3 primary models; first failure, failure to year ratio, and the failure rectification action. The classification of each model's equipment was determined arbitrarily. The training and validation of the models were based on 7 classifiers, and 11 performance metrices. The hyperparameter optimisation was performed to assure the model's optimal performance. The construction of a comprehensive maintenance management for the medical equipment comprised of the results from the integration of the maintenance management, and the first failure predictive model. To determine the efficiency of the comprehensive strategic maintenance management, the yearly maintenance cost savings were determined using the cost analysis method.

Table 3.18: Summary of medical equipment features and criteria used in predictive models.

Category	Feature	Criteria	Range	Failure Analysis			Maintenance Prioritisation		
				FF	FYR	FRA	PM	CM	RP
Inventory information	Equipment Category	Numerical	Vary		✓	✓			
	Equipment age	Numerical	Vary	✓	✓	✓	✓		✓
	Support service	Obsolescence; Available	1 & 0						✓
Function	Function	Life support; Therapeutic; Diagnostic; Analytic; Miscellaneous	1 - 5	✓		✓	✓	✓	✓
Maintenance requirement	Preventive maintenance status	Not in schedule; Open; Completed	0 - 2	✓			✓		
	No. of missed planned preventive maintenance	Number of undone planned preventive maintenance	Vary				✓		
	Maintenance complexity	Extensive maintenance; Average maintenance; Visual inspection and basic check	3 - 1	✓		✓	✓	✓	
	Maintenance scope	PPM (Twice annually) and Statutory Certification; PPM (Twice annually); PPM (Once annually) and Calibration; PPM (Once annually); Routine Inspection	5 - 1	✓	✓	✓	✓		✓
	Repair time	Mean Time to Repair (day)	Vary			✓		✓	
	Response time	Mean time of technical personnel to respond on the failure equipment (day)	Vary			✓		✓	
	Problem category	Problem detection codes	8 - 1			✓		✓	
	Failure rectification	Replacement; Repair	2 -1			✓			

Table 3.18: Continued.

Category	Feature	Criteria	Range	Failure Analysis			Maintenance Prioritisation		
				FF	FYR	FRA	PM	CM	RP
Performance	Downtime	Mean time of equipment malfunction (year)	Vary	✓		✓	✓		✓
	Asset condition	Beyond economical repair (BER); Proposed for disposal; Active	2 - 0						✓
Risk and Safety	No. of Failures	Number of failures on the equipment	Vary	✓		✓	✓	✓	✓
	Asset status	Malfunctioning; Functioning	1 - 0					✓	✓
Availability and readiness	Backup or alternative unit	No; Yes	1 - 0			✓		✓	✓
Utilisation	Operations	Utilisation rate	6-1	✓		✓	✓	✓	✓
Cost	Repair cost	The accumulative cost of repair work	Vary					✓	✓

*Note: FF – First Failure; FYR – Failure to year ratio; FRA – Failure Rectification Action; PM – Preventive Maintenance; CM – Corrective Maintenance; RP – Replacement Plan.

CHAPTER 4: RESULTS AND DISCUSSION

4.1 Introduction

This chapter discusses the outcomes of the failure analysis and maintenance prioritisation conducted during the development of the predictive models. There are 5 sub-sections, and this chapter begins with an organisation and explanation of each sub-section. The second sub-section presents the results of the experiment, which are divided into three failure analysis predictive models. The 3 predictive models are the first failure, failure to year ratio, and failure rectification action.

The third sub-section describes the results of the prioritisation of the medical equipment maintenance management plan. Clustering and data mining classifications are the 2 approaches used in the prioritisation process. For the clustering technique, the outputs of the k-means and predictive model trainings are also presented. Moreover, the outcomes from the classification are also demonstrated in this sub-section. The outcomes of the experiments involving output comparisons, model selections, model fine-tuning, and the proposed comprehensive framework for the machine learning-assisted maintenance management are then provided.

The fourth sub-section demonstrates the outcomes of the cost analysis and the development of a comprehensive strategic maintenance management plan for the medical equipment. The research contributions are presented at the end of the chapter.

4.2 Failure Analysis of Medical Equipment

The first objective of the study is to develop a predictive model for the medical equipment's failure analysis. The failure analysis comprises of 3 main analysis, which are the first failure prediction, the failure to year ratio prediction, and the prediction of failure corrective measures. This sub-section elaborates and discusses the findings obtained from these 3 analysis.

4.2.1 First Failure Predictive Model

The ability to forecast the first breakdown or failure of the medical equipment is of considerable assistance to clinical engineers in their day-to-day management duties. The classification of the medical equipment data comprises of maintenance and inventory information, and was undertaken with the first failure prediction model. Table 4.1 tabulates the number of medical equipment which had been categorised according to the classes which had been set in Table 3.10, and discussed in Chapter 3.

Table 4.1: Number of medical equipment categories according to first failure analysis classes.

Category	Class 1	Class 2	Class 3	Total
Analysers, Laboratory, Clinical Chemistry, Automated	55	73	9	137
Bilirubinometers, Laboratory	312	195	270	777
Defibrillators, External, Automated	627	157	77	861
Defibrillators, External, Manual	56	47	101	204
Densitometers	24	4	18	46
Incubators, Infant	17	3	11	31
Infusion Pumps, General-Purpose	10	2	4	16
Laryngoscopes, Rigid	1,279	64	130	1,473
Monitoring Systems, Physiologic	451	673	127	1,251
Nebulizers, Nonheated	1,273	443	581	2,297
Oximeters, Pulse	1,009	194	116	1,319
Phototherapy Units, Ultraviolet	16	2	10	28
Radiographic/Fluoroscopic Systems, General-Purpose	34	58	59	151
Resuscitators, Pulmonary, Manual	793	9	30	832
Scales, Clinical, Pharmacy	654	34	2	690
Scanning Systems, Ultrasonic, General-Purpose	158	184	305	647
Sensitometers, Radiographic	26	4	14	44
Sterilising Units, Steam	322	662	1432	2,416
Treadmills	86	24	20	130
Total	**7,202**	**2,832**	**3,316**	**13,350**

Table 4.1 tabulates that Class 1 had the greatest number across the 3 medical devices, which were the rigid laryngoscopes, the nonheated nebulisers, and the pulse oximeters. In contrast, the physiologic monitoring systems, the steam, the sterilising units, and the nonheated nebulisers accounted for the highest number of Class 2 devices. The steam sterilising units, the nonheated nebulisers, and the general-purpose ultrasonic scanning systems accounted for the majority of the Class 3 equipment

Based on these findings, it was established that the nonheated nebulisers have the highest number (i.e. have the most units) among all the medical equipment classifications. 55% of the total number of units in this study however, belonged to Class 1. In contrast, the rigid laryngoscope equipment and the pulse oximeters accounted for 87% and 76% of the total units, respectively. During the duration of its service, none of the medical equipment malfunctioned. 87% of the steam sterilising units failed, where 27% failed within the first 6 years of operation. In addition, after 6 years of service, this equipment may malfunction for the first time.

Seven supervised machine learning classifiers were used to train the first failure predictive models for the 19 medical equipment categories. The performance of these predictive models were then evaluated using several assessment parameters to select the best model.

As shown in Figure 4.1, the results of the training and performance measurements are displayed through confusion matrices The trainings were conducted for each of the 7 first failure predictive models (based on the algorithms as shown in Figure 4.1) based on the configuration of the predefined parameters provided by the MATLAB application. The purpose of this configuration was to obtain the highest possible performance out of each classifier. Table 4.2 shows the parameters which have been set up for each of the 7 classifiers.

		Predicted Class		
		1	2	3
True Class	1	7202	0	0
	2	0	2572	260
	3	0	208	3108

(a) Decision Tree

		Predicted Class		
		1	2	3
True Class	1	6619	0	583
	2	1357	1218	257
	3	687	101	2528

(b) Discriminant Analysis

		Predicted Class		
		1	2	3
True Class	1	7202	0	0
	2	0	2419	413
	3	0	320	2996

(c) Naïve Bayes

		Predicted Class		
		1	2	3
True Class	1	7202	0	0
	2	2	2600	230
	3	0	185	3131

(d) Support Vector Machine

		Predicted Class		
		1	2	3
True Class	1	7123	22	57
	2	45	2388	399
	3	77	349	2890

(e) K-nearest Neighbor

		Predicted Class		
		1	2	3
True Class	1	7202	0	0
	2	0	2604	228
	3	0	246	3070

(f) Random Forest

		Predicted Class		
		1	2	3
True Class	1	7202	0	0
	2	0	2596	236
	3	0	199	3117

(g) Neural Network

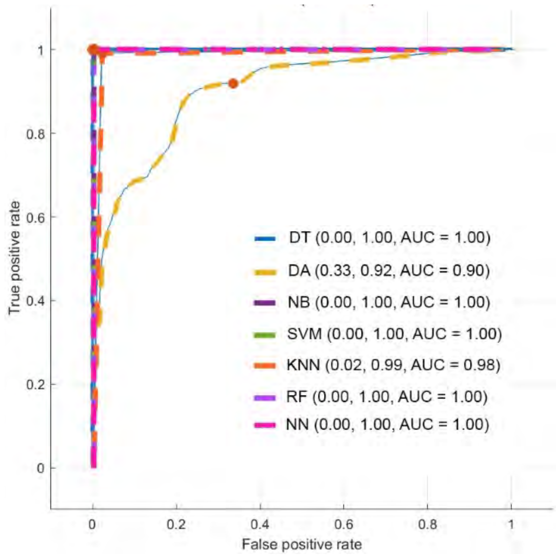
Figure 4.1: Confusion matrices of first failure predictive models (a-g).

The performance of the first failure predictive models are also shown by the ROC graphs. The AUC can be calculated using the ROC curves, and the TPR and FPR parameters. The ROC and AUC values for the 7 classifiers displayed curves were based on the first 3 failure classes. Figure 4.2 depicts these ROC curves, the TPR and FPR values, and the AUC for the first failure prediction models.

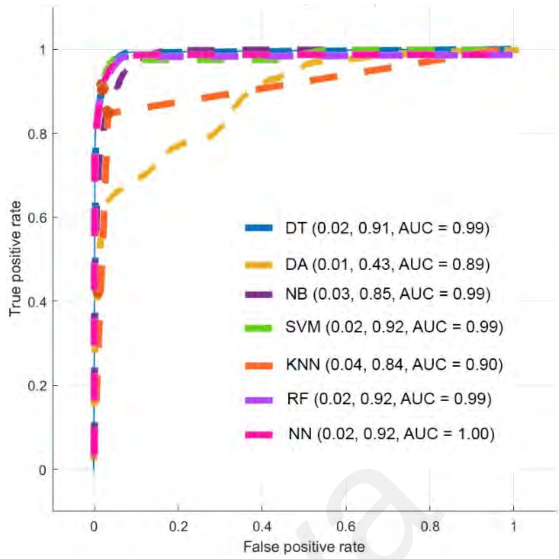
Table 4.2: Classifiers' parameters of first failure predictive models.

Classifier	**Parameter**	
Decision Tree	Split criterion	Gini's diversity index
	Maximum number of splits	100
	Preset	Fine tree
Discriminant Analysis	Preset	Linear
	Covariance structure	Full
Naïve Bayes	Preset	Gaussian
Support Vector Machine	Kernel function	Quadratic
	Kernel scale	Automatic
	Box constraint level	1
	Multiclass method	One-vs-one
	Standardise data	True
K-nearest Neighbor	Preset	Fine
	Number of neighbours	1
	Distance metric	Euclidean
	Distance weight	Equal
	Standardise data	True
Random Forest	Ensemble method	Bag
	Learner type	Decision tree
	Maximum number of splits	13,349
	Number of learners	30
	Number of predictors to sample	Select all
Neural Network	Number of fully connected layers	3
	First layer size	10
	Second layer size	10
	Third layer size	10
	Activation	ReLU
	Iteration limit	1000
	Standardised Data	True

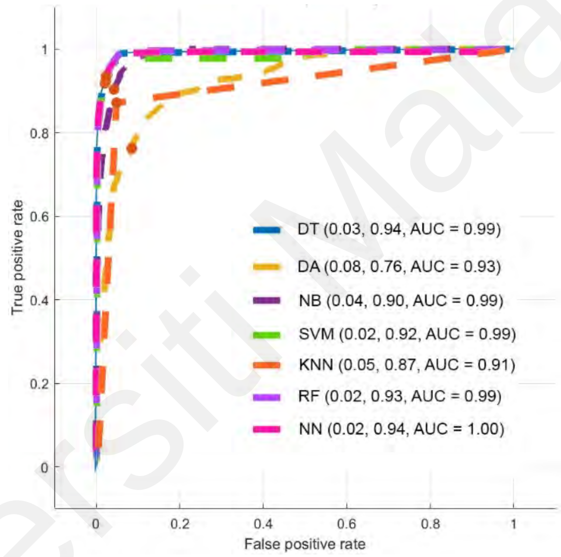
As shown in the graphs, the 2 classifiers which are the DA and KNN, achieved the lowest values compared to the other 5 classifiers. DT, NB, SVM, RF, and NN achieved much better performances with higher TPR and FPR parameters, as well as for AUC values for each class which were greater than 0.99. This was due to the fact that these 4 algorithms were able to generate accurate forecasts for all 3 groups, particularly Class 1. Due to the imbalanced dataset, the DA and KNN were unable to accurately generate a better prediction for all classes.



a) Class 1



b) Class 2



c) Class 3

Figure 4.2: ROC curves for first failure predictive model (a-c).

Overall, the model's performance was monitored based on the results of the 11 evaluation parameters, namely: 1) accuracy, 2) precision, 3) recall, 4) specificity, 5) f-measure, 6) MCC, 7) kappa, 8) ROC, 9) misclassification rate, 10) prediction speed, and 11) training time. The numbers displayed on the confusion matrices, as illustrated in Figure 4.1, were used to perform calculations on the 8 performance metrices. Table 4.3 presents the results of the first failure predictive models. The findings demonstrated that the 5 classifiers DT, NB, SVM, RF, and NN achieved among the highest results. The achievement of the high percentage values for the 7 metrics exceeded 90%. In addition, these 5 models were able to achieve an error rate of less than 733 out of 13,350 samples during the prediction procedure. Moreover, despite the use of unbalanced datasets, these models performed admirably in the prediction process for all 3 classes.

Table 4.3: Performance evaluation for first failure.

Cla	**Acc (%)**	**Pre (%)**	**Rec (%)**	**Spec (%)**	**FM (%)**	**MCC (%)**	**Kap (%)**	**Mis (%)**	**Speed (obs/sec)**	**Train (sec)**
DT	96.5	94.9	94.8	98.5	94.9	93.4	94.2	468	~320k	5.17
DA	77.6	81.3	70.4	85.8	75.4	62.1	60.5	2985	~120k	2.05
NB	94.5	92.1	91.9	97.6	92.0	89.6	90.9	733	~60k	2.80
SVM	**96.9**	**95.5**	**95.4**	**98.6**	**95.5**	**94.1**	**94.8**	**417**	**~41k**	**770**
KNN	92.9	90.4	90.1	96.6	90.3	87.0	88.2	949	~31k	192
RF	96.4	94.8	94.8	98.5	94.8	93.3	94.1	474	~15k	255
NN	96.7	95.3	95.2	98.6	95.3	93.8	94.6	435	~160k	863

*Note: 1) Abbreviation: Cla – Classifier, Acc – Accuracy, Pre – Precision, Rec – Recall, Spec – Specificity, FM – F-Measure, MCC – Matthews Correlation Coefficient, Kap – Kappa, Mis. – Misclassification, Speed – Prediction Speed, Train – Training Time, DT – Decision Tree, DA – Discriminant Analysis, NB – Naïve Bayes, SVM – Support Vector Machine, KNN – K-nearest Neighbor, RF – Random Forest, NN – Neural Network, obs/sec – observations per second, sec – second. 2) The bold classifier is the best compared to the others.

In comparison to the other 6 classifiers, it can be concluded that the SVM was the best classifier. This was demonstrated by the fact that the average percentage of the 7 performance criteria, including accuracy, precision, recall, specificity, f-measure, MCC, and kappa, reached 96%, the highest among all the classifiers. In addition, this classifier had the lowest error rate of 417. Furthermore, with a sample size of 13,350, this classifier can predict the likelihood of the first failure of the medical equipment at a good rate, taking less than 1 second. This prediction model (i.e. SVM), on the other hand, took significantly longer to develop than the other 5 classifiers.

To ensure that the first failure predictive model reached an optimal level, an optimisation process involving the hyperparameter tuning was carried out. This stage was only conducted for the best classifier model (i.e. the SVM classifier) identified during the performance comparison. The optimisation method employed a Bayesian optimisation and 30 iterations. The minimum classification error was obtained by measuring all of the SVM classifier's parameters. The lowest value of the minimum classification error provided by this classifier can be used to establish an optimised first failure predictive model. Figure 4.3 shows the best point hyperparameter, and the least amount of classification errors after the optimisation process. From the graph, both achievements were reached at the 2nd iteration of the optimisation process. The estimated and observed minimum classification errors were quite close from that of the 4th to 8th iterations. Whereas, starting from the 9th iteration onward, the difference between both readings were significant and consistent to that of the 13th iteration.

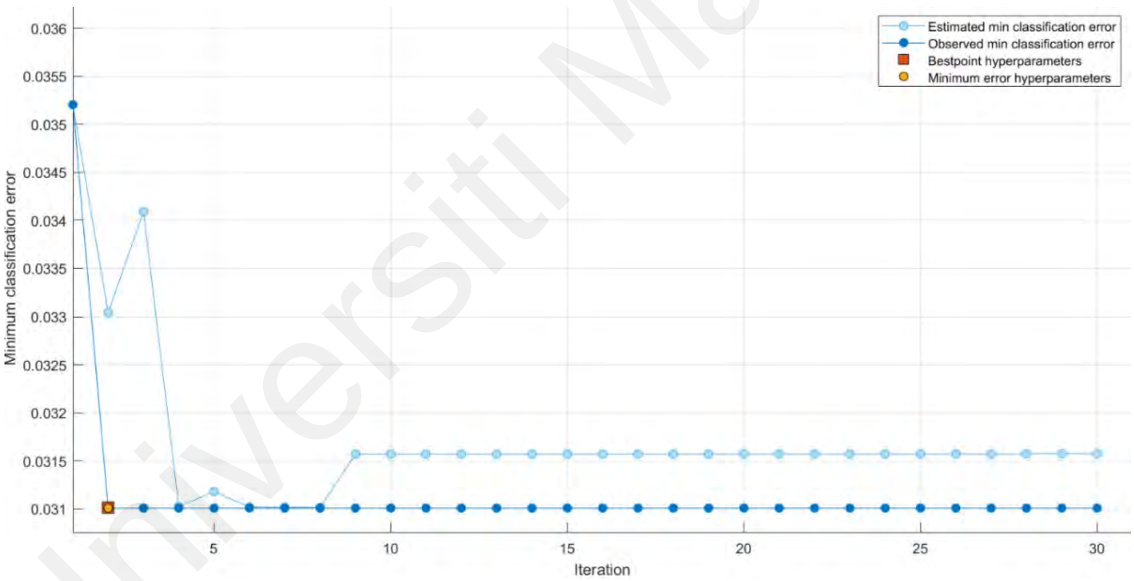


Figure 4.3: Minimum classification error plot for optimised first failure predictive model.

Several parameter adjustments were discovered as a result of the optimisation procedure. The hyperparameter's tuning of the SVM classifier following the optimisation procedure is shown in Table 4.4. Figure 4.4 and Table 4.5 show the overall findings of the performance evaluation of the optimised first failure predictive model. Several performance indicators have improved as a result of these findings. Referring to Figure

4.4 (c) as compared with (d), the TPR value grew by 2%, according to the ROC curve of Class 3. Furthermore, the improved prediction model lowered the rate of misclassification from 417 to 414 observations.

Table 4.4: Optimised hyperparameter for first failure predictive model.

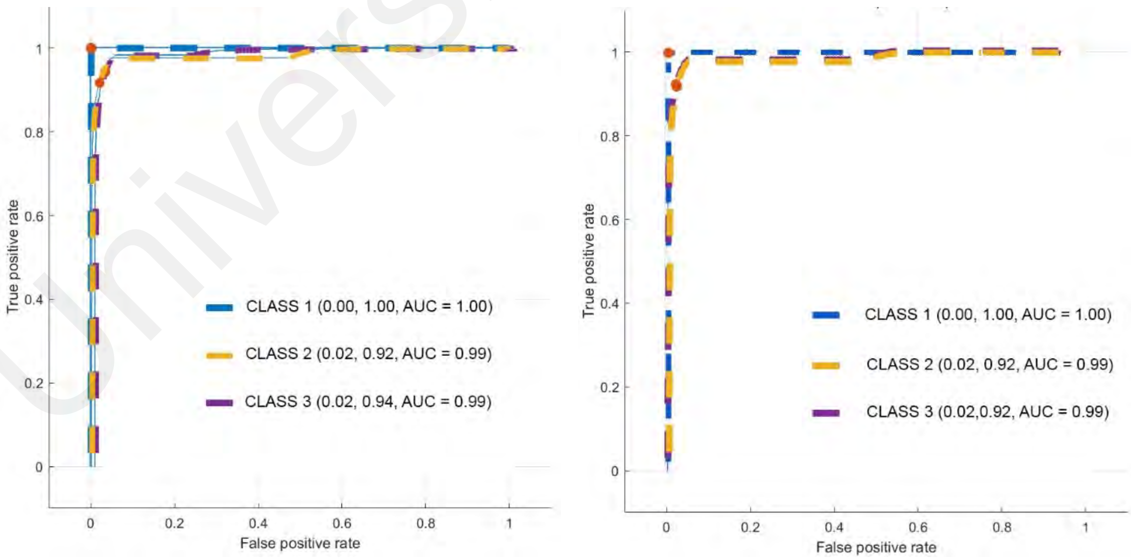
Classifier	SVM
Kernel function	Quadratic
Kernel scale	1
Box constraint level	4.8554
Multiclass method	One-vs-one
Standardise data	True
Observed min classification error	0.031009

		Predicted Class		
		1	2	3
True Class	1	7202	0	0
	2	2	2601	229
	3	0	183	3133

(a) Optimised

		Predicted Class		
		1	2	3
True Class	1	7202	0	0
	2	2	2600	230
	3	0	185	3131

(b) Non-optimised



(c) Optimised (d) Non-optimised

Figure 4.4: Comparison of confusion matrices and ROC curves between optimised and non-optimised first failure predictive model (a-d).

The increase in forecast time, which was up to 80.5%, demonstrated the model's improved performance. As a result, the SVM classifier had effectively constructed an optimal predictive model compared to the other classifiers, which improved the level of prediction in terms of the reducing the prediction error and increase in the speed.

Table 4.5: Comparison of performance between optimised and non-optimised first failure predictive model.

Evaluation Parameter	Performance of Models	
	Optimised	**Before**
Accuracy (%)	96.9	96.9
Precision (%)	95.5	95.5
Recall (%)	95.4	95.4
Specificity (%)	98.6	98.6
F-Measure (%)	95.5	95.5
MCC (%)	94.1	94.1
Kappa (%)	94.8	94.8
Misclassification (obs)	414	417
Prediction Time (obs/sec)	74,000	41,000
Training Time (sec)	467	770

Anticipating the first failure event is a critical indicator in the maintenance management of medical equipment used in healthcare facilities. Medical equipment failures can have an impact on the quality, and how fast the healthcare services can be provided to the community. Referring to Table 4.1, 87% of all steam sterilising units experienced their initial failure less than, or greater than 6 years into their operational life. Despite being classified as miscellaneous equipment, its failure inhibited the sterilisation of the devices which required it. As a result, such devices cannot be used to treat patients with safe and timely medical care means.

4.2.2 Failure to Year Ratio Predictive Model

The effectiveness of maintenance management in a healthcare institution can be improved by indicating the failure to year ratio frequency, following the first failure detection of a medical device. The failure to year ratio classes are determined using a classification approach that takes into consideration critical information such as the maintenance history and equipment's inventory. Results from the first failure classification of the medical equipment are also included in the development of the failure to year ratio predictive models. Table 4.6 tabulates the number of medical equipment categories according to the classes which have been set in Table 3.11 as elaborated in Chapter 3. The classification of this equipment revealed that three medical devices, i.e., the steam sterilising units, nonheated nebulisers, and the physiologic monitoring systems, were among the highest in Classes 1 and 2.

Table 4.6: Number of medical equipment categories by classes of failure to year ratio analysis.

Category	**Class 1**	**Class 2**	**Class 3**	**Total**
Analysers, Laboratory, Clinical Chemistry, Automated	57	4	21	82
Bilirubinometers, Laboratory	338	25	102	465
Defibrillators, External, Automated	231	2	1	234
Defibrillators, External, Manual	143	3	2	148
Densitometers	22	0	0	22
Incubators, Infant	14	0	0	14
Infusion Pumps, General-Purpose	6	0	0	6
Laryngoscopes, Rigid	194	0	0	194
Monitoring Systems, Physiologic	713	33	54	800
Nebulizers, Nonheated	995	16	13	1,024
Oximeters, Pulse	308	1	1	310
Phototherapy Units, Ultraviolet	12	0	0	12
Radiographic/Fluoroscopic Systems, General-Purpose	66	6	45	117
Resuscitators, Pulmonary, Manual	39	0	0	39
Scales, Clinical, Pharmacy	36	0	0	36
Scanning Systems, Ultrasonic, General-Purpose	422	15	52	489
Sensitometers, Radiographic	18	0	0	18
Sterilising Units, Steam	1,466	141	487	2,094
Treadmills	44	0	0	44
Total	**5,124**	**246**	**778**	**6,148**

In Class 3, the steam sterilising units, nonheated nebulizers, and the general-purpose ultrasonic scanning devices had the highest number of units. Table 4.6 tabulates the number of medical equipment categories according to the established classes.

The classification of this equipment revealed that the three medical devices, (steam sterilising units, nonheated nebulisers, and physiologic monitoring systems) are among the highest in Class 1 and 2. The highest medical equipment in Class 3 were the steam sterilising units, nonheated nebulizers, and the general-purpose ultrasonic scanning devices.

These findings show that, despite the fact that the steam sterilising machines experienced the highest rate of initial failures, their annual failure rate was as high as 70%. This suggested that just 30% of the failures occured once or more than once, per year. This also applied to the nonheated nebulizer equipment and physiologic monitoring systems. For the nonheated nebulisers and the physiologic monitoring systems, 97% and 89%, respectively, had a failure of more than one per year. This situation also applied to vast majority of other equipment categories. This proves that equipment categories, which are prone to breakdowns, do not necessarily occur frequently. Failures may occur multiple times in a year, once a year, or once over several years. Table 4.6 demonstrates that the number of equipment classified under Class 2 and 3 is quite low, compared to Class 1.

Similar to the development of the first failure predictive models, the failure to year ratio predictive models for the 19 categories of medical devices were trained using 7 supervised machine learning classifiers. For selecting the best predictive models, several parameters were used for evaluating the performance of the trained models. The results generated from the training and performance measurement processes were presented using the confusion matrices as shown in Figure 4.5.

Before advancing to the predictive model training operations, the default parameters of the 7 classifiers in the Classification Learner App toolbox were configured. The goal of this configuration was to identify the classifiers which are capable of developing the best performance predictive model. Table 4.7 shows the parameters configured for the 7 classifiers.

(a) Decision Tree

		Predicted Class 1	2	3
True Class	1	5044	0	80
	2	224	0	22
	3	666	0	112

(b) Discriminant Analysis

		Predicted Class 1	2	3
True Class	1	5124	0	0
	2	246	0	0
	3	778	0	0

(c) Naïve Bayes

		Predicted Class 1	2	3
True Class	1	5106	0	18
	2	246	0	0
	3	778	0	0

(d) Support Vector Machine

		Predicted Class 1	2	3
True Class	1	5124	0	0
	2	246	0	0
	3	778	0	0

(e) K-nearest Neighbor

		Predicted Class 1	2	3
True Class	1	5059	0	65
	2	227	0	19
	3	692	0	86

(f) Random Forest

		Predicted Class 1	2	3
True Class	1	5020	3	101
	2	222	0	24
	3	662	1	115

(g) Neural Network

		Predicted Class 1	2	3
True Class	1	5041	0	83
	2	224	0	22
	3	666	0	112

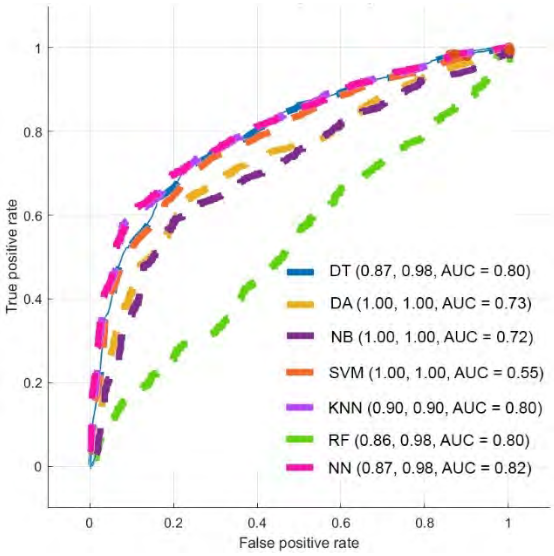
Figure 4.5: Confusion matrices of failure to year ratio predictive models (a-g).

The performance of the predictive models were evaluated from the standpoint of all 3 classes using the ROC curves and the AUC values of the 7 classifiers. Figure 4.6 presents the ROC curves, TPR, FPR, and the AUC for all the predictive models. It shows that the highest AUC for the failure to year ratio classes were achieved from NN classifiers. This was followed by the DT, KNN, and RF classifiers. The development of the predictive models trained with these 4 classifiers produced an AUC value which was greater than 0.69 in all classes.

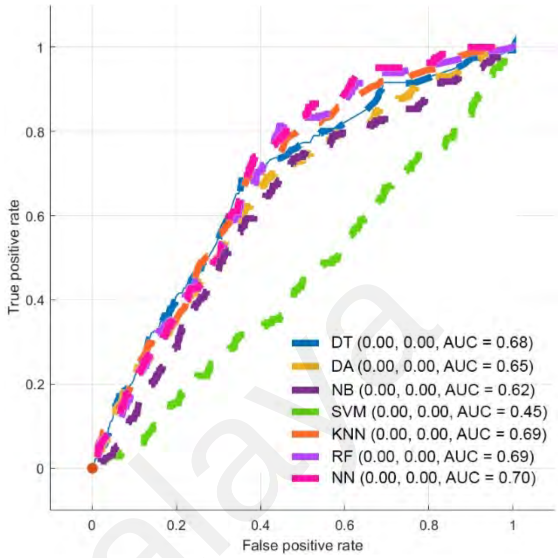
Table 4.7: Classifiers' parameters of failure to year to ratio predictive models.

Classifier	Parameter	
Decision Tree	Split criterion	Gini's diversity index
	Maximum number of splits	100
	Preset	Fine tree
Discriminant Analysis	Preset	Linear
	Covariance structure	Full
Naïve Bayes	Preset	Kernel
	Kernel type	Gaussian
Support Vector Machine	Kernel function	Linear
	Kernel scale	Automatic
	Box constraint level	1
	Multiclass method	One-vs-one
	Standardise data	True
K-nearest Neighbor	Preset	Coarse
	Number of neighbours	100
	Distance metric	Euclidean
	Distance weight	Equal
	Standardise data	True
Random Forest	Ensemble method	Bag
	Learner type	Decision tree
	Maximum number of splits	6,147
	Number of learners	30
	Number of predictors to sample	Select all
Neural Network	Number of fully connected layers	1
	First layer size	100
	Activation	ReLU
	Iteration limit	1000
	Standardised Data	True

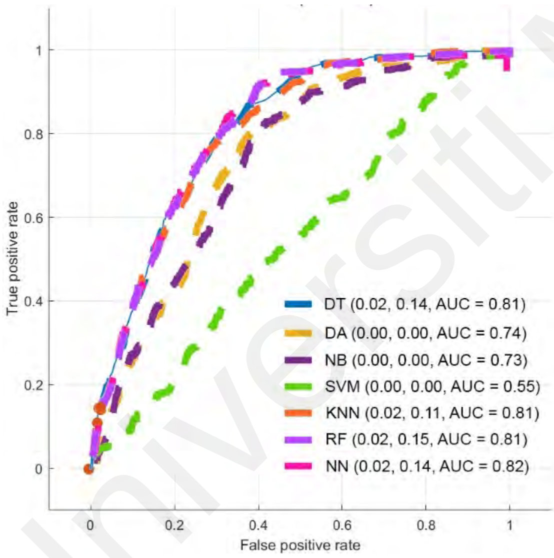
Referring to the ROC curves for Class 2, the values of the TPR and FPR were 0. This was because the predictive models developed from all 7 classifiers failed to make an accurate prediction. Subsequently, it affected the values of the AUC, which range between 0.45 to 0.70. This was categorised as low values.



a) Class 1



b) Class 2



c) Class 3

Figure 4.6: ROC curves for failure to year ratio predictive model (a-c).

Overall, the performance of the failure to year ratio predictive models can also be evaluated based on 10 parameters only. The construction of confusion matrices as shown in Figure 4.5 formed the basis for the calculation of the parameters, such as the accuracy, precision, recalls, specificity, f-measure, MCC, kappa and misclassification. The performance of these predictive models are shown in Table 4.8. The results showed that the 4 classifiers achieved a higher performance compared to the other classifiers, as displayed in the ROC curves. Misclassification values below 995, on the other hand, showed that the DT and NN classifiers worked better.

Table 4.8: Performance evaluation for failure to year ratio.

Cla	**Acc (%)**	**Pre (%)**	**Rec (%)**	**Spec (%)**	**FM (%)**	**MCC (%)**	**Kap (%)**	**Mis (%)**	**Speed (obs/sec)**	**Tra (sec)**
DT	**83.9**	**45.8**	**37.6**	**70.4**	**41.3**	**15.4**	**15.6**	**992**	**~200k**	**1204**
DA	83.3	27.8	33.3	66.7	30.3	0.0	0.0	1024	~140k	1204
NB	83.1	27.8	33.2	66.6	30.2	1.5	0.5	1042	~1.3k	25
SVM	83.3	27.8	33.3	66.7	30.3	0.0	0.0	1024	~39k	25
KNN	83.7	45.1	36.6	69.6	40.4	13.2	12.3	1003	~14k	39
RF	83.5	44.3	37.6	70.4	40.7	14.4	15.4	1013	~9.9k	56
NN	83.8	45.5	37.6	70.4	41.2	15.2	15.5	995	~84k	360

*Note: 1) Abbreviation: Cla – Classifier, Acc – Accuracy, Pre – Precision, Rec – Recall, Spec – Specificity, FM – F-Measure, MCC – Matthews Correlation Coefficient, Kap – Kappa, Mis. – Misclassification, Speed – Prediction Speed, Train – Training Time, DT – Decision Tree, DA – Discriminant Analysis, NB – Naïve Bayes, SVM – Support Vector Machine, KNN – K-nearest Neighbor, RF – Random Forest, NN – Neural Network, obs/sec – observations per second, sec – second. 2) The bold classifier is the best compared to the others.

In comparison to the other 6 classifiers, the overall findings showed that the DT was the best classifier. The percentage values for the 7 performance criteria demonstrated this. In addition, this classifier had the lowest error rate of 992. This classifier can also analyse the failure to year ratio forecast at a maximum rate of 200,000 observations per second, which takes less than 1 second when using a sample size of 13,350.

The optimisation process can be used to determine the values of the hyperparameters for the DT classifiers. The aim is to improve the model's ability to predict the equipment's failure to year ratio. The model was optimised using a Bayesian optimisation configuration at a rate of 30 iterations. This iteration rate was sufficient for achieving the optimal level of the model, as can be seen in Figure 4.7. All parameters of the DT classifier were applied in the training and evaluation processes to obtain the values of the hyperparameters. To achieve the lowest possible error value, the minimum value of the classification error was monitored. During the optimisation process, the best point hyperparameters and minimum classification error values were identified at the 27th iteration, as denoted in yellow in Figure 4.7. Table 4.9 shows the values of the DT hyperparameters which were obtained during the optimisation process. The configuration of these classifier's hyperparameters values led to an optimised failure to year ratio for the medical equipment.

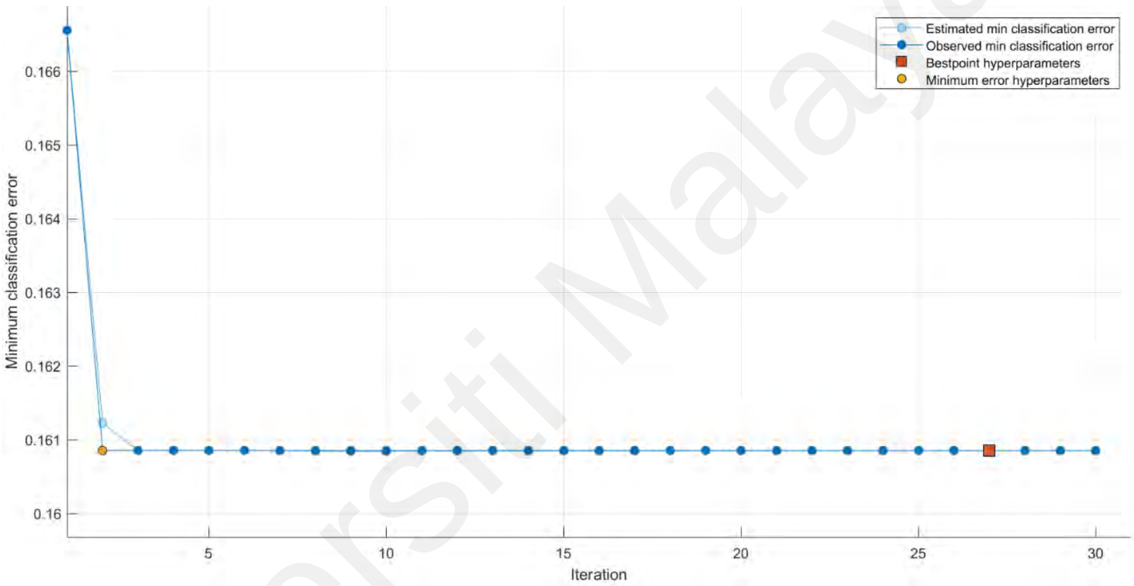


Figure 4.7: Minimum classification error plot for optimised failure to year ratio predictive model.

Table 4.9: Optimised hyperparameter for failure to year ratio predictive model.

Classifier	Decision Tree
Split criterion	Gini's diversity index
Maximum number of splits	636
Observed min classification error	0.16086

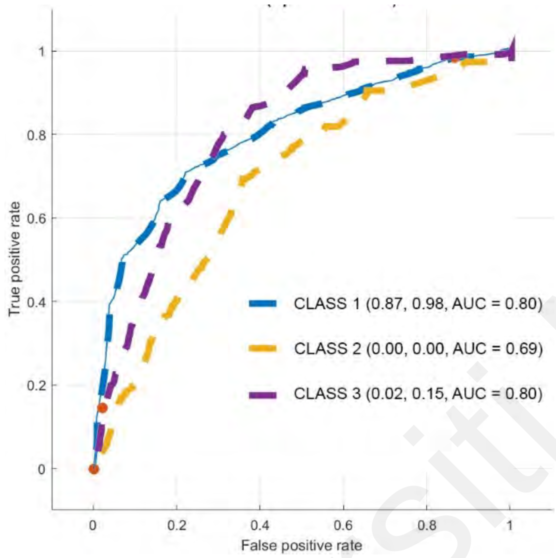
The performance evaluation values for the optimised failure to year ratio predictive model trained with the configuration of the DT hyperparameters were validated in Figure 4.8 and Table 4.10. An improvement in the model's performance of approximately 0.3% can be seen based on the 7 evaluation parameters, i.e., precision, recall specificity, f-measure, MCC, kappa, and misclassification. The reduction in the misclassification rate produced by the optimised predictive model slightly dropped from 992 to 989 observations.

True Class \ Predicted Class	1	2	3
1	5045	0	79
2	224	0	22
3	664	0	114

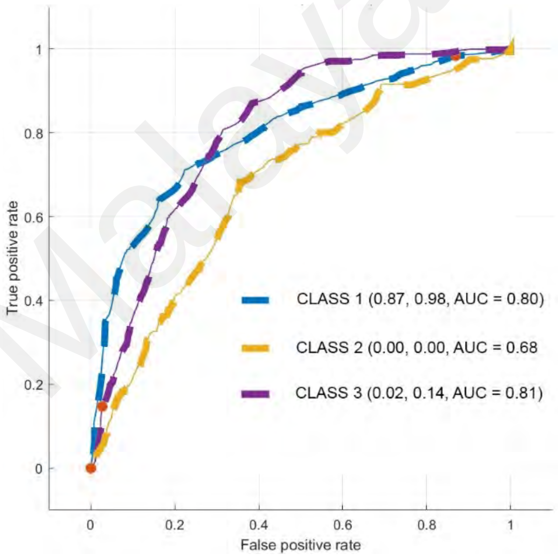
(a) Optimised

True Class \ Predicted Class	1	2	3
1	5044	0	80
2	224	0	22
3	666	0	112

(b) Non-optimised



(c) Optimised



(d) Non-optimised

Figure 4.8: Comparison of confusion matrices and ROC curves between optimised and non-optimised failure to year ratio predictive model (a-d).

In addition, there was a decrement in prediction time, where the percentage of the prediction time decreased from 200,000 to 46,000 observations per second. This was due to an increase in the value of the maximum number of splits from 100 to 636. However, this optimised predictive model was still considered high-speed, where it could analyse the prediction of the failure to year ratio in less than 1 second, by taking into account the same number of samples used in this study.

Table 4.10: Comparison of performance between optimised and non-optimised failure to year ratio predictive model.

Evaluation Parameter	Performance of Models	
	Optimised	Before
Accuracy (%)	83.9	83.9
Precision (%)	46.0	45.8
Recall (%)	37.7	37.6
Specificity (%)	70.5	70.4
F-Measure (%)	41.4	41.3
MCC (%)	15.6	15.4
Kappa (%)	15.9	15.6
Misclassification (obs)	989	992
Prediction Time (obs/sec)	46,000	200,000
Training Time (sec)	6.34	1204

Looking at the performance evaluation parameters such as precision, recall, f-measure, MCC, and kappa, the forecast percentage value was significantly low, which was below 50%. This was because this optimised predictive model is unable to predict accurately, especially for Class 2. The dataset for the 6,148 units of medical equipment used as samples in this study seemed to be significantly imbalanced. A total of 83.3% of the total samples were found in Class 1, while only 4.8% were in Class 2. This significant difference affected the forecast model's ability to analyse the failure to year ratio forecast accurately, especially for Class 2. With a balanced dataset between these classes, the DT classifier with a configuration of hyperparameters as in Table 4.9, can produce a much better-predicted output.

The failure to year ratio analysis can provide additional information for the first failure prediction model's output. The frequency of failure can be forecasted based on the first indication of the failure of the medical equipment, which was detected from the date of the equipment’s procurement. With a detailed understanding of the failure frequency for a specific category of medical equipment, the clinical engineer may be able to plan follow-up actions.

4.2.3 Failure Rectification Action

The third step in analysing the failure of a medical equipment is to identify the corrective measures (*i.e.* failure rectification actions). Based on the 12 features and criteria of the medical equipment, this failure rectification action analysis informs the clinical engineer of the repair works that must be performed. Predictions regarding repair works are divided into 2 classes, namely repairs and replacements. The information based on these features includes maintenance the history, inventory, and faults discovered during the initial inspections. A dataset that includes this information can be used to develop a failure rectification action prediction model.

Table 4.11 tabulates the number of medical equipment categories according to the failure rectification action classes, as specified in Table 3.12 in chapter 3. Referring to Table 4.11, the distribution of medical equipment units in the dataset seems to be relatively balanced in the development of the prediction model. For Class 1, the pharmacy clinical scales equipment, the general-purpose ultrasonic scanning systems, and the automated clinical chemistry laboratory analysers were seen as equipment that mostly required service works rather than a part replacement. The physiologic monitoring systems, manual external defibrillators, infant incubators, and general-purpose infusion pumps were the top three highest percentages which required part replacements, rather than servicing. In addition, the general-purpose radiographic/fluoroscopic systems equipment also largely required the replacement of parts during the restoration work procedure. As for the steam sterilising equipment, although the number of units that required repair work were the highest compared to the other 18 equipment categories, it was seen to be quite balanced with units that required part replacement.

Table 4.11: Number of medical equipment categories by classes of failure rectification action.

Category	Class 1	Class 2	Total
Analysers, Laboratory, Clinical Chemistry, Automated	194	59	253
Bilirubinometers, Laboratory	637	739	1,376
Defibrillators, External, Automated	139	148	287
Defibrillators, External, Manual	90	162	252
Densitometers	24	5	29
Incubators, Infant	7	12	19
Infusion Pumps, General-Purpose	3	5	8
Laryngoscopes, Rigid	126	96	222
Monitoring Systems, Physiologic	195	1,656	1,851
Nebulizers, Nonheated	708	914	1,622
Oximeters, Pulse	161	239	400
Phototherapy Units, Ultraviolet	4	12	16
Radiographic/Fluoroscopic Systems, General-Purpose	273	163	436
Resuscitators, Pulmonary, Manual	21	22	43
Scales, Clinical, Pharmacy	39	3	42
Scanning Systems, Ultrasonic, General-Purpose	965	265	1,230
Sensitometers, Radiographic	15	7	22
Sterilising Units, Steam	3,375	2,905	6,280
Treadmills	38	23	61
Total	**7,014**	**7,435**	**14,449**

Several supervised machine learning classifiers were used in the training and development processes of the predictive models for the 19 categories of the medical devices. It had been evaluated with several performance evaluation parameters for the selection of a model which can make accurate predictions. The results were generated by referring to the confusion matrices as shown in Figure 4.9.

The results, which were demonstrated in confusion matrices for each classifier as shown in Figure 4.9, refers to the configuration of the predefined parameters during the training and model development processes. Table 4.12 presents the parameters for the 7 classifiers.

		Predicted Class	
		1	2
True Class	1	5240	1774
	2	1726	5709

(a) Decision Tree

		Predicted Class	
		1	2
True Class	1	4910	2104
	2	3029	4406

(b) Discriminant Analysis

		Predicted Class	
		1	2
True Class	1	4653	2361
	2	2196	5239

(c) Naïve Bayes

		Predicted Class	
		1	2
True Class	1	5178	1836
	2	1680	5755

(d) Support Vector Machine

		Predicted Class	
		1	2
True Class	1	4896	2118
	2	2062	5373

(e) K-nearest Neighbor

		Predicted Class	
		1	2
True Class	1	5346	1668
	2	1768	5667

(f) Random Forest

		Predicted Class	
		1	2
True Class	1	5187	1827
	2	1558	5877

(g) Neural Network

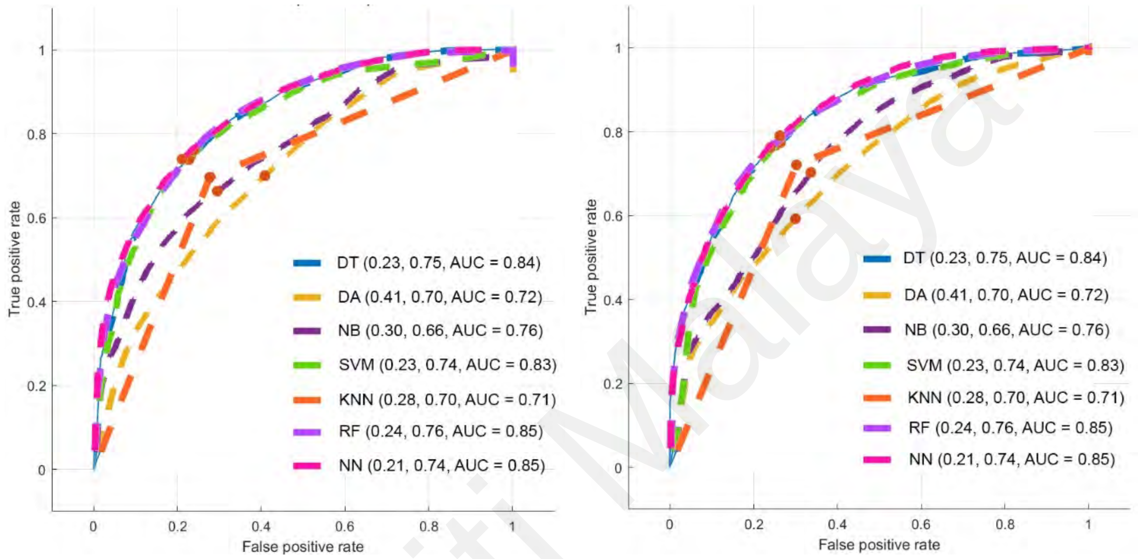
Figure 4.9: Confusion matrices of failure rectification action predictive models (a-g).

The analysis performance for these 2 classes can be observed in Figure 4.10. The results proved that the DT, SVM, RF, and NN classifiers achieved higher values for the AUC parameters compared to the other classifiers. These 4 classifiers achieved AUC values which were above 0.83 for both classes of the failure rectification action.

Table 4.12: Classifiers' parameters of failure rectification action predictive models.

Classifier	Parameter	
Decision Tree	Split criterion	Gini's diversity index
	Maximum number of splits	100
	Preset	Fine tree
Discriminant Analysis	Preset	Linear
	Covariance structure	Full
Naïve Bayes	Preset	Kernel
	Kernel type	Gaussian
Support Vector Machine	Kernel function	Gaussian
	Kernel scale	0.87
	Box constraint level	1
	Multiclass method	One-vs-one
	Standardise data	True
K-nearest Neighbor	Preset	Fine
	Number of neighbours	1
	Distance metric	Euclidean
	Distance weight	Equal
	Standardise data	True
Random Forest	Ensemble method	Bag
	Learner type	Decision tree
	Maximum number of splits	14,448
	Number of learners	30
	Number of predictors to sample	Select all
Neural Network	Number of fully connected layers	3
	First layer size	10
	Second layer size	10
	Third layer size	10
	Activation	ReLU
	Iteration limit	1000
	Standardised Data	True

Performance evaluations for all classifiers were also determined based on the values mapped in the confusion matrices as shown in Figure 4.9. Table 4.13 also validated the 4 classifiers which achieved among the highest performances compared to the other classifiers, similar to those shown in the results of the ROC curves. Based on the overall results, it was concluded that NN was the best classifier compared to the other 6 classifiers. This was evidenced by the percentage values for the 8 performance parameters, namely accuracy, precision, recall, specificity, f-measure, MCC, and kappa, beyond other classifiers. This classifier also achieved the lowest error rate from the 3,385 observations. Furthermore, this classifier can analyse the prediction for failure rectification actions at a higher rate of 140,000 observations per second, which is also the highest rate compared to the other classifiers.



a) Class 1 vs. rest   b) Class 2 vs. rest

Figure 4.10: ROC curve for failure rectification action predictive model (a-b).

Table 4.13: Performance evaluation for failure rectification action.

Cla	**Acc (%)**	**Pre (%)**	**Rec (%)**	**Spec (%)**	**FM (%)**	**MCC (%)**	**Kap (%)**	**Mis (%)**	**Speed (obs/sec)**	**Tra (sec)**
DT	75.8	75.8	75.7	75.7	75.8	51.5	51.5	3500	~39k	11
DA	64.5	64.8	64.6	64.6	64.7	29.4	29.2	5133	~82k	4
NB	68.5	68.4	68.4	68.4	68.4	36.8	36.8	4557	~100	556
SVM	75.7	75.7	75.6	75.6	75.6	51.3	51.3	3516	~6.3k	120
KNN	71.1	71.0	71.0	71.0	71.0	42.1	42.1	4180	~5k	1204
RF	76.2	76.2	76.2	76.2	76.2	52.4	52.4	3436	~11k	616
NN	**76.6**	**76.6**	**76.5**	**76.5**	**76.5**	**53.1**	**53.1**	**3385**	**~140k**	**612**

*Note: 1) Abbreviation: Cla – Classifier, Acc – Accuracy, Pre – Precision, Rec – Recall, Spec – Specificity, FM – F-Measure, MCC – Matthews Correlation Coefficient, Kap – Kappa, Mis. – Misclassification, Speed – Prediction Speed, Train – Training Time, DT – Decision Tree, DA – Discriminant Analysis, NB – Naïve Bayes, SVM – Support Vector Machine, KNN – K-nearest Neighbor, RF – Random Forest, NN – Neural Network, obs/sec – observations per second, sec – second. 2) The bold classifier is the best compared to the others.

The capability of the model in forecasting the failure rectification action had been demonstrated by carrying out an optimisation process. The optimised model was achieved by specifying hyperparameters for the NN classifiers with a Bayesian optimisation configuration at a rate of 30 iterations. The determination of the hyperparameters was done by running all the parameter combinations of the NN classifiers. The practicality of the hyperparameters on the NN classifier were seen at the minimum value of the classification error during the optimisation process. The best point hyperparameters and minimum classification error values are shown in Figure 4.11. From the graph, as shown in Figure 4.11, the decrease in the minimum classification error for the estimated and observed occurrences took place at the 16th iteration, and continued consistently until the 30th iteration. Therefore, the best point hyperparameters and the least amount of classification error were reached at the 16th iteration during the optimisation process.

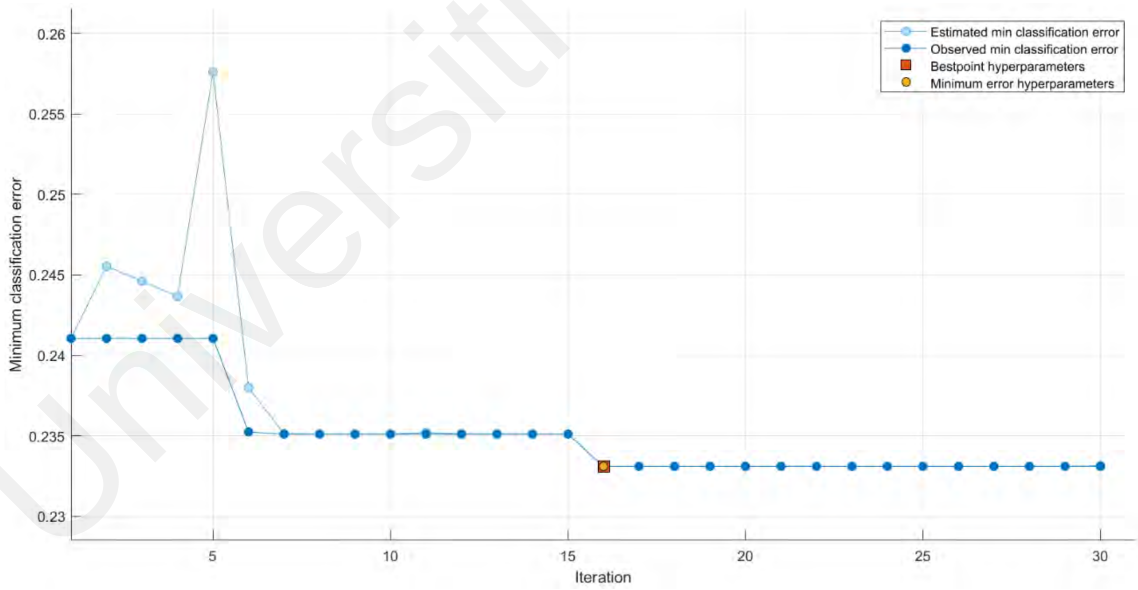


Figure 4.11: Minimum classification error plot for optimised failure rectification action predictive model.

As a result of the optimisation process, the hyperparameter values for the NN classifier had been achieved as shown in Table 4.14. With the configuration of the hyperparameter values, the NN classifier can produce an optimised failure rectification action predictive model, which analyses the future datasets of the medical equipment.

Table 4.14: Optimised hyperparameters for failure rectification action predictive model.

Classifier	Neural Network
Number of fully connected layers	3
First layer size	10
Second layer size	10
Third layer size	10
Activation	ReLU
Iteration limit	1000
Standardise data	No
Observed min classification error	0.2331

The performance evaluation results generated by this optimised predictive model are shown in Figure 4.12 and Table 4.15. An improvement in the performance between 0.1% to 0.3% can be seen across the 7 evaluation parameters. A reduction of the error rate in the forecasting process was also achieved, with a decrease of 19 observations, equivalent to 0.6% from the previous configuration. The ROC curves also showed an increase of 6.8% in the TPR values for the Class 2 based on the comparison presented in Figure 4.12 (c) and (d). In addition, there was a 21.4% reduction in the prediction speed. However, the rate for this optimised predictive model was still high, where the prediction process can be achieved in less than 1 second, even though the capacity of the dataset samples exceeded seven times the value which was used in this study.

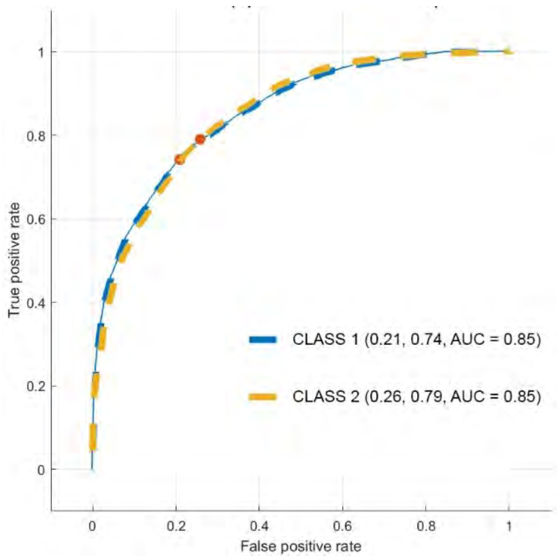
Referring to the study conducted by Mallick *et al.* (2021), a predictive model is considered good when the AUC value exceeds 0.70. Referring to the ROC curves displayed in Figure 4.12, it is shown that the AUC value obtained based on this study was 0.85 for both classes. Hence, the optimised predictive model which was made with this NN classifier is practicable and can make a good prediction.

		Predicted Class 1	Predicted Class 2
True Class	1	5204	1810
	2	1556	5879

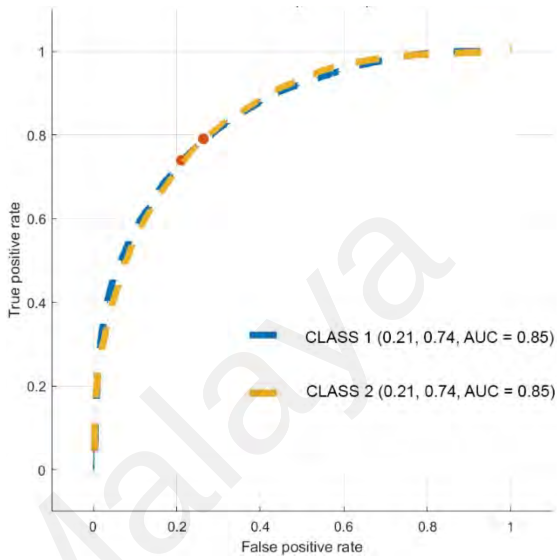
(a) Optimised

		Predicted Class 1	Predicted Class 2
True Class	1	5187	1827
	2	1558	5877

(b) Non-optimised



(c) Optimised



(d) Non-optimised

Figure 4.12: Comparison of confusion matrices and ROC curves between optimised and non-optimised failure rectification action predictive model (a-d).

Table 4.15: Comparison of performance between optimised and non-optimised failure rectification action predictive model.

Evaluation Parameter	**Performance of Models**	
	Optimised	**Before**
Accuracy (%)	76.7	76.6
Precision (%)	76.7	76.6
Recall (%)	76.6	76.5
Specificity (%)	76.6	76.5
F-Measure (%)	76.7	76.5
MCC (%)	53.4	53.1
Kappa (%)	53.3	53.1
Misclassification (obs)	3,366	3,385
Prediction Time (obs/sec)	110,000	140,000
Training Time (sec)	109	612

4.2.4 Summary

Failure analysis of the medical equipment involved three main areas, namely the prediction of the first failure, prediction of the failure to year ratio, and the prediction of the failure rectification action. The development of these predictive models involved the training of the 7 supervised machine learning classifiers. To verify the performance of the predictive models which were developed, 11 performance assessment metrices were used.

In the first failure analysis for the medical equipment, the SVM classifier achieved the best performance in comparison to the other classifiers. This was evidenced by a decrease in the misclassification rate, and an increase in the prediction speed, based on the configuration of the SVM classifier's hyperparameters. The results of the analysis also demonstrated that the monitoring of the first failure was also crucial, since the medical equipment were heavily utilised for delivering healthcare services to the community. If the equipment was not maintained accordingly, the improper functionality may affect the quality and cause delays in the healthcare and medical services to the patients.

The development of a failure to year ratio predictive model requires inputs from the outputs of the medical equipment’s initial failure. As a result of the study conducted, it was found that the optimised failure to year ratio predictive model was developed with the configuration of the DT classifier's hyperparameters. The use of this DT classifier revealed an improvement based on the 8 evaluation parameters. According to the ROC curves, the AUC values also increased marginally. However, this optimised predictive model was not seen to be able to predict accurately for Class 2 equipment. This was due to the imbalance and limited numbers of such equipment in each class. The model's optimised performance for making predictions can be made better by having a balanced dataset and more samples in each class.

The NN classifier generated an optimised failure rectification action predictive model compared to the other classifiers. This can be seen by the percentage rise across the 9 performance evaluation parameters. The increase in the TPR value for the Class 2 also indicated an enhancement of the optimised predictive performance of this model.

Forecasting and determination of the rectification work was critical to ensure that the restoration process was conducted efficiently. Based on this analysis, it can provide a sign of the need for the availability of spare parts and components according to the equipment requirements. In addition, the expertise of specialists in performing repairs can be determined by referring to the number of equipment for each particular class.

Therefore, with the availability of an accurate initial failure, failure to year ratio, and failure rectification action predictive model, clinical engineers can construct an effective maintenance management system for the medical equipment in the healthcare facility.

4.3 Machine Learning-Assisted Maintenance Management

This sub-section elaborates on the development of a maintenance prioritisation predictive model for medical equipment. Throughout the maintenance phase of the equipment's life cycle, the predictive models included 3 main activities, namely preventive maintenance, corrective maintenance, and replacement plans. Machine learning techniques have been employed during the model training process. This study utilised 2 major techniques. First, the maintenance priority was assessed using unsupervised machine learning techniques, namely k-means clustering. The second technique used data mining classification. The results generated from the prioritisation assessment of these 2 techniques were then used to construct predictive models for the maintenance prioritisation. The development of these predictive models utilised seven classifiers during the training process of the supervised machine learning. The performance of the predictive models from both techniques were compared, and the selection of the best classifiers were made based on the values of the evaluation parameters. The process of optimisation was done on the selected classifiers to improve their accuracy rates.

4.3.1 Clustering K-means

The results of all three predictive models which were development are explained under this sub-section. It involved the assessment of the maintenance prioritisation using a clustering technique, namely k-means.

4.3.1.1 Preventive Maintenance

The replication value was set to 100 for the assessment of the preventive maintenance prioritisation for the medical equipment. This value was reasonable to ensure that the total sum of distances for each observation and centroids reached the minimum value. Table 4.16 displays the values of the replicates, iterations, and sum of distances between the observations and centroids. It shows that the achievement of the best total sum of distances was on the 5th replicate with an iteration of 23. Table 4.17 displays the values of the centroids according to the 9 medical equipment features. The determination of the centroid point values were critical in ensuring that the number of the medical equipment were partitioned into appropriate clusters based on the defined features and criteria. Therefore, these values can be used for the evaluation and forecasting of the preventive maintenance prioritisation for the new datasets.

Table 4.16: The values of replicate, iteration, and the total sum of distances between observations and centroids for preventive maintenance.

Replicate settings	100
Replicate and Iteration	5 and 23
A best total sum of distances (all clusters)	77,633.1
The best total sum of distances (within a cluster)	23121.6660213319 (Cluster 1)
	18204.1502323626 (Cluster 2)
	36307.3050366849 (Cluster 3)

Table 4.17: Centroids and features for preventive maintenance clusters.

		Cluster 3	Cluster 2	Cluster 1
Features	Age	0.6769	-0.6735	-0.0521
	Function	-0.7769	0.8502	0.0236
	PM Status	-0.0709	0.7361	-0.3059
	Missed PPM	0.7885	-0.3867	-0.2468
	Number of Failures	1.3182	-0.0497	-0.6917
	Maintenance Scope	1.3070	0.1354	-0.7722
	Maintenance Complexity	0.5918	-0.1847	-0.2345
	Downtime	0.8906	-0.2232	-0.3786
	Operations	-0.1765	-0.8841	0.5094

As a result of achieving the total value of the sum of distances, 13,350 units of medical equipment were partitioned into 3 prioritisation clusters, namely high, medium, and low. Figure 4.13 shows the numbers and percentages of the medical equipment partitioned according to the prioritisation clusters. Based on the figures, it was found that a large number of medical equipment were at a low priority. The breakdown of the number of medical equipment categories by clusters are shown in Table 4.18.

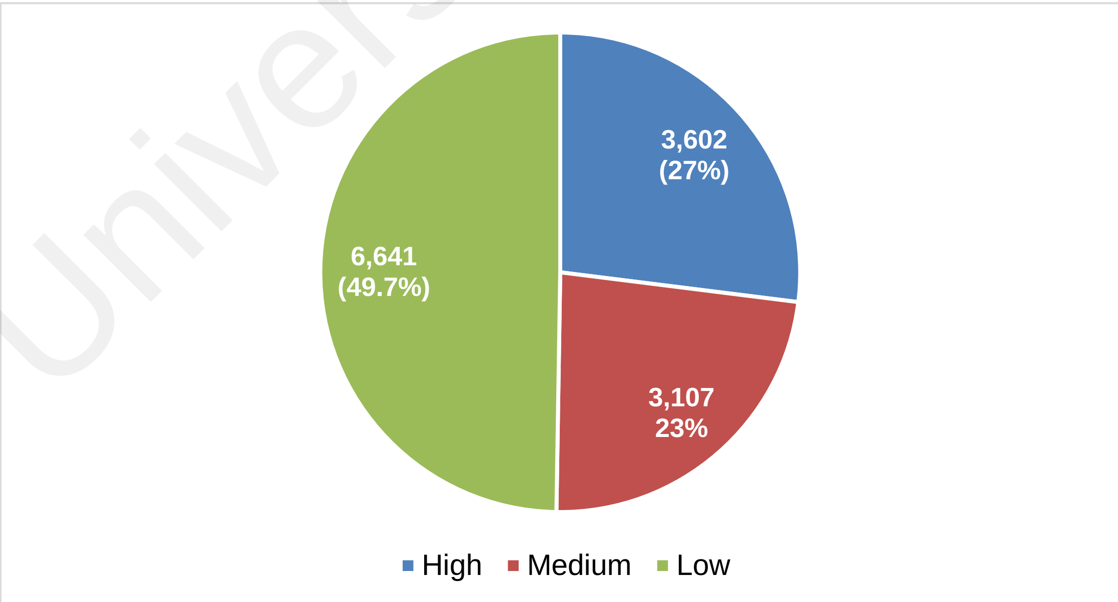


Figure 4.13: Numbers and percentages of medical equipment partitions according to preventive maintenance prioritisation clusters.

Table 4.18: Number of medical equipment categories according to preventive maintenance prioritisation clusters.

Category	High	Medium	Low	Total
Analysers, Laboratory, Clinical Chemistry, Automated	67	55	15	137
Bilirubinometers, Laboratory	279	217	281	777
Defibrillators, External, Automated	41	745	75	861
Defibrillators, External, Manual	70	125	9	204
Densitometers	3	1	42	46
Incubators, Infant	10	21	0	31
Infusion Pumps, General-Purpose	1	8	7	16
Laryngoscopes, Rigid	1	39	1,433	1,473
Monitoring Systems, Physiologic	15	1,236	0	1,251
Nebulizers, Nonheated	4	158	2,135	2,297
Oximeters, Pulse	1	79	1,239	1,319
Phototherapy Units, Ultraviolet	0	2	26	28
Radiographic/Fluoroscopic Systems, General-Purpose	126	25	0	151
Resuscitators, Pulmonary, Manual	0	70	762	832
Scales, Clinical, Pharmacy	0	169	521	690
Scanning Systems, Ultrasonic, General-Purpose	571	34	42	647
Sensitometers, Radiographic	13	4	27	44
Sterilising Units, Steam	2,396	20	0	2,416
Treadmills	4	99	27	130
Total	**3,602**	**3,107**	**6,641**	**13,350**

As shown in Table 4.18, 4 categories of medical equipment achieved the highest percentage in the High Cluster, namely the steam sterilising units, the general-purpose ultrasonic scanning systems, the general-purpose radiographic/fluoroscopic systems, and the automated clinical chemistry laboratory analysers. This position was determined by the proportional value of the total equipment categories. The similarities between these 4 pieces of equipment can be seen based on the type of maintenance complexity. These categories of equipment required an extensive maintenance procedure during the implementation of the preventive maintenance. The physiologic monitoring systems, automated external defibrillators, and treadmills, are the three equipment types which reached the highest rank in the medium cluster. In terms of the complexity of maintenance, these 3 types of equipment had commonalities, requiring an average maintenance procedure. The 6 equipment categories with the largest percentages for the Low Cluster were rigid laryngoscope, pulse oximeters, nonheated nebulisers, ultraviolet phototherapy units, manual pulmonary resuscitators, and densitometers. The implementation of the maintenance for these 6 types of equipment were identical to that of High Cluster and Medium Cluster, requiring only basic or visual examination.

The characteristics of the medical equipment for each preventive maintenance cluster can be seen by performing internal measures. Table 4.19 tabulates the results of the internal measures for the preventive maintenance of these clusters. The results obtained through internal measures found that the characteristics of the medical equipment reflected the partitioning of the preventive maintenance priority clusters. The difference in the division between the High, Medium, and Low Clusters can be seen across the 7 features such as age, preventive maintenance status, missed planned preventive maintenances, maintenance scope, maintenance complexity, downtime, and the number of failures. Based on the centroid values shown in Table 4.17, 13,350 units were partitioned according to these preventive maintenance clusters.

It was also shown that the segregation into specific clusters did not give priority to the medical devices based on their functions and operations. The 9 features of the medical devices contributed significantly to the assessment of the preventive maintenance prioritisation. The priority for preventive maintenance was based on the pattern analysis of the 9 features of the equipment datasets referring to the centroid values which were achieved.

Table 4.19: Internal measures of clustering for preventive maintenance.

Feature	Range		
	High	**Medium**	**Low**
Age	0-30 years;	0-28 years;	0-30 years;
	70% is ≥ 10 years	69% is 2≤age≤15 years	74% is ≤ 10 years
PM Status	Incomplete and not in schedule	Incomplete and not in schedule	Completed.
Missed PPM	0-7 times;	0-4 times;	0-5 times;
	22% is none;	70% is none;	57% is none;
	78% is 1≤x≤7 times	30% is 1≤x≤4 times	31% is once;
			12% is ≥ once
Maintenance Scope	5 (2 x PPM and statutory certification)	2-4 (2 x PPM, calibration, and 1 x PPM)	1-2 (1 x PPM frequency and routine inspection)
Maintenance Complexity	3 (Extensive maintenance)	2 (Average maintenance)	1 (Visual and basic inspection)
Downtime	0-548 days;	0-242 days;	0-252 days;
	13% is none;	62% is none;	73% is none;
	12% is < 1 day;	13% is < 1 day;	9% is < 1 day;
	76% is ≥ 1 day	25% is ≥ 1 day	18% is ≥ 1 day
Number of Failures	0-41 times;	0-14 times;	0-11 times;
	13% is none;	62% is none;	73% is none;
	87% is 1≤x≤11 times;	38% is 1≤x≤14 times;	27% is 1≤x≤11 times;
	9.3% is ≥ 10 times;	0.4% is ≥ 10 times	0% is ≥ 10 times
	2.5% is ≥ 15 times		
Function	1-2 (77%);	1-2 (16%);	1-2 (35%);
	3 (19%);	3 (4%);	3 (19%);
	4-5 (4%)	4-5 (79%)	4-5 (46%)
Operations	1-2 (78%);	1-2 (85%);	1-2 (13%);
	3-4 (0.2%);	3-4 (11%);	3-4 (65%);
	5-6 (22%)	5-6 (4%)	5-6 (23%)

The achievement of preventive maintenance prioritisation clusters were used to label datasets in order to construct prediction models for the preventive maintenance prioritisation. In addition to developing failure analysis prediction models, 7 classifiers were used to train and construct preventive maintenance prioritisations for the prediction models. As a result, a performance evaluation was performed to determine the best classifier. Figure 4.14 presents the performance evaluation results through confusion matrices for the 7 employed classifiers.

		Predicted Class		
		1	2	3
True Class	1	6582	9	50
	2	37	3015	55
	3	50	65	3487

(a) Decision Tree

		Predicted Class		
		1	2	3
True Class	1	6546	33	62
	2	218	2757	132
	3	215	92	3295

(b) Discriminant Analysis

		Predicted Class		
		1	2	3
True Class	1	6285	218	138
	2	110	2910	87
	3	11	19	3572

(c) Naïve Bayes

		Predicted Class		
		1	2	3
True Class	1	6627	4	10
	2	26	3074	7
	3	4	12	3586

(d) Support Vector Machine

		Predicted Class		
		1	2	3
True Class	1	6610	10	21
	2	10	3083	14
	3	31	39	3532

(e) K-nearest Neighbor

		Predicted Class		
		1	2	3
True Class	1	6610	2	29
	2	7	3067	33
	3	25	52	3525

(f) Random Forest

		Predicted Class		
		1	2	3
True Class	1	6636	2	3
	2	1	3104	2
	3	2	3	3597

(g) Neural Network

Figure 4.14: Confusion matrices of clustering prediction for preventive maintenance (a-g).

The depicted performance evaluation results were based on the configurations of the preset parameters for each classifier used. This configuration aimed to get the best performance which can be produced for each classifier. Table 4.20 shows the parameters which have been configured for the 7 classifiers for developing the predictive models.

Table 4.20: Classifiers' parameters of clustering prediction for preventive maintenance.

Classifier	Parameter	
Decision Tree	Split criterion	Gini's diversity index
	Maximum number of splits	100
	Preset	Fine tree
Discriminant Analysis	Preset	Linear
	Covariance structure	Full
Naïve Bayes	Preset	Gaussian
Support Vector Machine	Kernel function	Linear
	Kernel scale	Automatic
	Box constraint level	1
	Multiclass method	One-vs-one
	Standardise data	True
K-nearest Neighbor	Preset	Fine
	Number of neighbours	1
	Distance metric	Euclidean
	Distance weight	Equal
	Standardise data	True
Random Forest	Ensemble method	Bag
	Learner type	Decision tree
	Maximum number of splits	13,349
	Number of learners	30
	Number of predictors to sample	Select all
Neural Network	Number of fully connected layers	2
	First layer size	10
	Second layer size	10
	Activation	ReLU
	Iteration limit	1000
	Standardised Data	Yes

The performance of the developed models were evaluated through the ROC curves. Figure 4.15 displays the ROC curves, which comprises of the TPR, FPR, and the AUC values for each classifier and cluster.

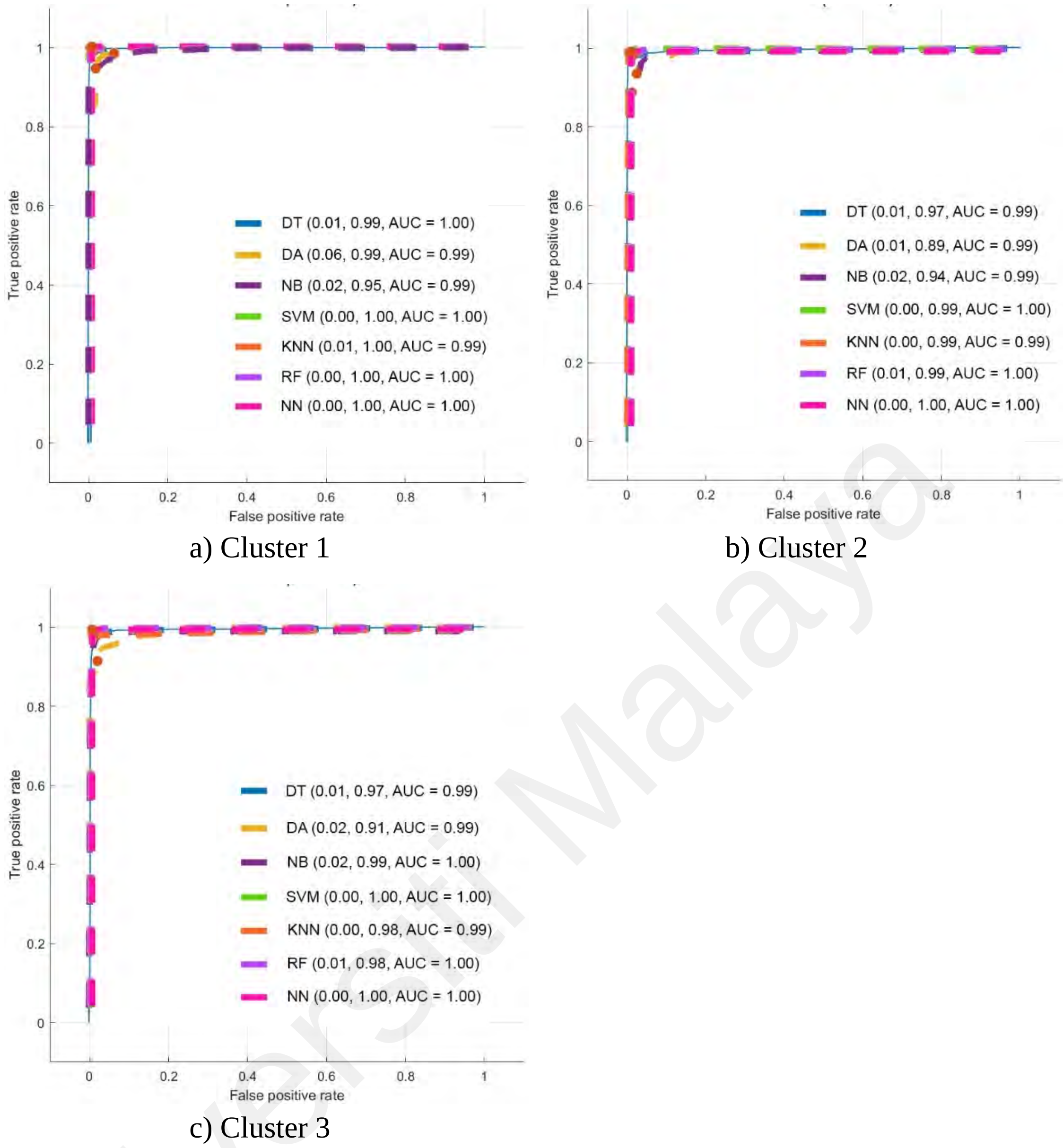


Figure 4.15: ROC curves of clustering prediction for preventive maintenance (a-c).

It demonstrated that 3 classifiers, namely the SVM, RF, and NN, achieved the highest AUC values for each cluster, compared to the other classifiers. The performance of the predictive models were also seen through ten performance evaluation parameters. Table 4.21 exhibits the performance of each classifier in the development of a preventive maintenance prioritisation predictive model. The results obtained found that the 4 classifiers achieved among the highest performances, namely the SVM, KNN, RF, and NN. This was evidenced by the achievement of the highest percentage values exceeding 98.1% for the 8 evaluation parameters. Furthermore, these 5 models managed to achieve a minimal error rate after the evaluation was completed, which was below the value of 148 out of a total of 13,350 samples. These models achieved a good performance in the prediction process for all 3 classes, even though the datasets used were imbalanced.

Table 4.21: Performance evaluation of clustering prediction for preventive maintenance.

Cla	Acc (%)	Pre (%)	Rec (%)	Spec (%)	FM (%)	MCC (%)	Kap (%)	Mis (%)	Speed (obs/sec)	Tra (sec)
DT	98.0	97.8	97.7	99.0	97.7	96.7	96.8	266	~44k	1206
DA	94.4	94.6	92.9	96.8	93.8	90.8	90.9	752	~37k	10
NB	95.6	94.9	95.8	97.9	95.4	93.0	93.1	583	~52k	6
SVM	99.5	99.5	99.4	99.7	99.5	99.2	99.2	63	~43k	34
KNN	99.1	98.9	98.9	99.5	98.9	98.5	98.5	125	~17k	74
RF	98.9	98.7	98.7	99.5	98.7	98.1	98.2	148	~11k	133
NN	**99.9**	**99.9**	**99.9**	**99.9**	**99.9**	**99.8**	**99.8**	**13**	**~83k**	**177**

*Note: 1) Abbreviation: Cla – Classifier, Acc – Accuracy, Pre – Precision, Rec – Recall, Spec – Specificity, FM – F-Measure, MCC – Matthews Correlation Coefficient, Kap – Kappa, Mis. – Misclassification, Speed – Prediction Speed, Train – Training Time, DT – Decision Tree, DA – Discriminant Analysis, NB – Naïve Bayes, SVM – Support Vector Machine, KNN – K-nearest Neighbor, RF – Random Forest, NN – Neural Network, obs/sec – observations per second, sec – second. 2) The bold classifier is the best compared to the others.

Based on the overall results obtained, it can be concluded that NN was the best classifier compared to the other 6 classifiers. This was evidenced by the average of the seven performance parameters, (accuracy, precision, recall, specificity, f-measure, MCC, and kappa), which reached 99.9%. This was the highest compared to the other classifiers. This classifier also achieved the lowest error rate of the 13 observations. In addition, this classifier could analyse the forecast of the preventive maintenance clusters at an excellent rate, which was the highest compared to the other classifiers. However, the development of this predictive model was slightly higher than the other 5 classifiers. This was not a significant issue because the development of the model was done at an early stage, and it was only developed once.

4.3.1.2 Corrective Maintenance

Initially, the replicate value was set to 100 to ensure that the total sum of distances for each observation and centroids reached the lowest value. This value can result in a good assessment of the prioritisation of the clusters for corrective maintenances. Table 4.22 displays the values of the replicates, iterations, and sum of distances between the observations and centroids for the prioritisation assessment. The results demonstrated that the achievement of the best total sum of distances was a replication of 37 readings with iterations of 5. Table 4.23 also tabulated the values of the centroids according to the 9 medical equipment features. The determination of the values of the centroids is important and can be used in the assessment and forecasting of the corrective maintenance prioritisations in the future. As shown in Figure 4.16, the 1,028 units of medical equipment were partitioned into three dedicated clusters, namely High, Medium, and Low. Based on the results, it was found that the majority of the units were in the Medium Cluster. Meanwhile, the number of medical equipment allocated under the low cluster was very minimal, which was only 2 units out of the total number of samples. Table 4.24 shows in detail the quantities of medical equipment categories for the corrective maintenance clusters.

Table 4.22: The values of replicate, iteration, and total sum of distances between observations and centroids for corrective maintenance.

Replicate settings	100
Replicate and Iteration	37 and 5
A best total sum of distances (all clusters)	6,675.08
The best total sum of distances (within a cluster)	7.04118303127080 (Cluster 1)
	2810.99661667486 (Cluster 2)
	3857.04573908948 (Cluster 3)

Table 4.23: Centroids and features for corrective maintenance clusters.

		Cluster 3	Cluster 2	Cluster 1
Features	Function	-0.5031	0.5699	-1.0250
	Response Time	0.0553	-0.1505	0.2711
	Maintenance Complexity	0.9849	-0.5057	0.9066
	Repair Time	0.0045	-0.1834	0.3307
	Number of Failures	1.8385	-0.2423	0.4270
	Backup and Alternative Unit	-22.6385	0.0441	0.0441
	Operations	0.4382	0.3190	-0.5776
	Repair Cost	0.6473	-0.1690	0.3012
	Problem Class	-0.1101	-0.0772	0.1399

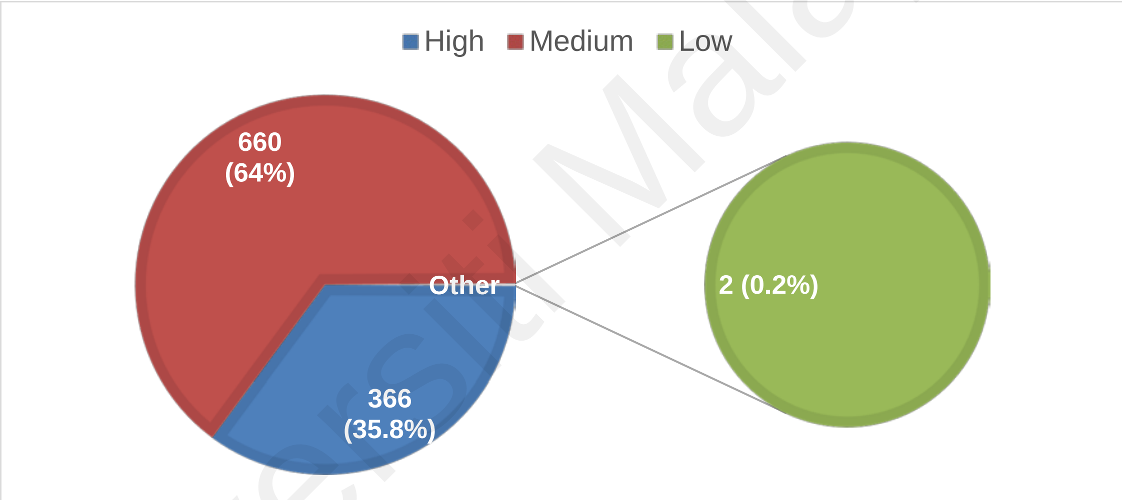


Figure 4.16: Numbers and percentages of medical equipment partitions according to corrective maintenance prioritisation clusters.

Table 4.24 reveals that the categories of medical equipment which achieved the top 3 in terms of percentages in the High Cluster reached 99.9 were automated clinical chemistry laboratory analysers, steam sterilising units, and general-purpose radiographic/fluoroscopic systems. The determination of this position was based on the percentage value of the total equipment categories. The similarities between these 3 pieces of equipment can be seen based on the type of maintenance complexities, where they required extensive maintenance procedures during the implementation of the maintenance.

Table 4.24: Number of medical equipment categories according to corrective maintenance prioritisation clusters.

Category	High	Medium	Low	Total
Analysers, Laboratory, Clinical Chemistry, Automated	4	0	0	4
Bilirubinometers, Laboratory	10	49	0	59
Defibrillators, External, Automated	1	61	0	62
Defibrillators, External, Manual	0	47	0	47
Densitometers	0	8	0	8
Incubators, Infant	1	7	0	8
Infusion Pumps, General-Purpose	0	1	0	1
Laryngoscopes, Rigid	1	24	0	25
Monitoring Systems, Physiologic	0	31	0	31
Nebulizers, Nonheated	0	158	0	158
Oximeters, Pulse	0	77	0	77
Phototherapy Units, Ultraviolet	0	5	0	5
Radiographic/Fluoroscopic Systems, General-Purpose	14	22	1	37
Resuscitators, Pulmonary, Manual	0	38	0	38
Scales, Clinical, Pharmacy	0	3	0	3
Scanning Systems, Ultrasonic, General-Purpose	13	108	0	121
Sensitometers, Radiographic	2	5	0	7
Sterilising Units, Steam	320	0	1	321
Treadmills	0	16	0	16
Total	**366**	**660**	**2**	**1,028**

For the Medium Cluster, three equipment categories were ranked in the top 3, namely the automated external defibrillators, densitometers, and the general-purpose infusion pumps. For the Low Cluster, only two categories of equipment were involved, namely the steam sterilising units, and the general-purpose radiographic/fluoroscopic systems. Both of these equipment categories required extensive maintenances, twice PPM frequency per-annum, and were obliged to meet valid statutory certifications issued by the national regulatory bodies to be able to operate.

The implementation of the internal measurements indicated the need for unique properties associated with the medical equipment for each corrective maintenance cluster.

Table 4.25 tabulates the results of the internal measures for the corrective maintenance clusters. The partitioning of these clusters were highly influenced by the characteristics of the equipment samples. The differences between the High, Medium, and Low Clusters can be seen across 6 features, such as response time, maintenance complexity, repair time, number of failures, backup and alternative units, and repair costs. Based on the values of the centroids shown in Table 4.23, the medical equipment totalling 1,028 units was segregated appropriately according to the predetermined corrective maintenance clusters.

It also demonstrated that the segmentation of the equipment into specific clusters did not prioritise equipment based on the features such as function, operation, and the problem's class. These 9 features of the medical devices contributed significantly to the assessment of the corrective maintenance prioritisations. The priority for corrective maintenance was based on the pattern analysis of the 9 features in the equipment dataset, and referred to the centroids achieved. The dataset was labelled for the development of the predictive models based on the prioritisation of these clusters. The performance evaluation results of the models for the 7 classifiers are presented in Figure 4.17.

The performance evaluation results displayed are based on the configuration of the predefined parameters. This configuration is crucial for producing accurate predictive models. Therefore, Table 4.26 shows the parameters which have been configured for the 7 classifiers in the development of the corrective maintenance prioritisation predictive model.

The ROC curves and the AUC values show that the performance obtained from the classifiers which were applied. Figure 4.18 demonstrates the findings, where 2 classifiers, namely SVM, and NN achieved the highest AUC values for every cluster compared to the other 5 classifiers. Table 4.27 exhibited 3 classifiers which achieved among the highest performances, namely the SVM, KNN, and NN. This was indicated by the high percentage values achieved for the 7 parameters, which exceeded 98.4%. In addition, all 3 models were able to have more than 15 out of a total of 1,028 samples. In addition, despite the imbalanced nature of the datasets employed, these models performed well for the prediction processes for all 3 classes. This can be demonstrated by the precise predictions for the Low Cluster, which consisted of only 2 devices.

Table 4.25: Internal measures of clustering for corrective maintenance.

Feature	**Range**		
	High	**Medium**	**Low**
Asset Status	Malfunctioning	Malfunctioning	Malfunctioning
Response Time	0-147 days;	0-68 days;	≤6 days
	20% is none;	31% is none;	
	51% is <1 day;	54% is <1 day;	
	29% is >1 day	15% is >1 day	
Maintenance Complexity	94% is extensive maintenance	Basic and average maintenance	Extensive maintenance
Repair Time	0-478 days;	0-253 days;	0-29 days;
	20% is none;	31% is none;	
	71% is >1 day;	52% is >1 day;	
	53% is >10 days;	30% is >10 days;	
	15% is >100 days	3% is >100 days	
Number of Failures	0-26 times;	0-9 times;	0-8 times
	20% is none;	31% is none;	
	80% is ≥1 time;	69% is ≥1 time	
	7.1% is >9 times		
Backup and Alternative Unit	No	No	Yes
Repair Cost	<MYR86,000	<MYR11,000	<MYR8,000
	48% is none;	80% is none;	
	52% is yes	20% is yes	
Function	1-2 (92%);	1-2 (14%);	1-2 (50%);
	3 (7%);	3 (31%);	3 (50%);
	4-5 (1%)	4-5 (55%)	4-5 (0%)
Operations	1-2 (91%);	1-2 (29%);	1-2 (50%);
	3-4 (0%);	3-4 (37%);	3-4 (0%);
	5-6 (9%)	5-6 (34%)	5-6 (50%)
Problem Class	2 (38%);	2 (40%);	1 (50%);
	5 (28%)	1 (19%)	5 (50%)

(a) Decision Tree

True Class \ Predicted Class	1	2	3
1	351	15	0
2	16	644	0
3	1	1	0

(b) Discriminant Analysis

True Class \ Predicted Class	1	2	3
1	331	17	18
2	0	660	0
3	2	0	0

(c) Naïve Bayes

True Class \ Predicted Class	1	2	3
1	288	69	9
2	194	466	0
3	0	0	2

(d) Support Vector Machine

True Class \ Predicted Class	1	2	3
1	361	5	0
2	3	657	0
3	0	0	2

(e) K-nearest Neighbor

True Class \ Predicted Class	1	2	3
1	357	9	0
2	6	654	0
3	0	0	2

(f) Random Forest

True Class \ Predicted Class	1	2	3
1	358	8	0
2	11	649	0
3	2	0	0

(g) Neural Network

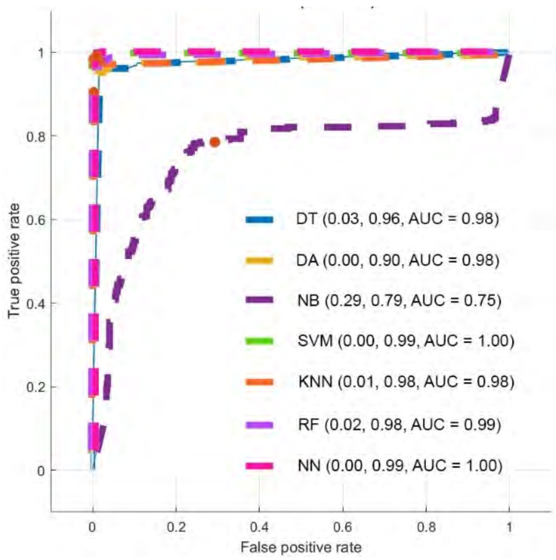
True Class \ Predicted Class	1	2	3
1	362	4	0
2	2	658	0
3	0	0	2

Figure 4.17: Confusion matrices of clustering prediction for corrective maintenance (a-g).

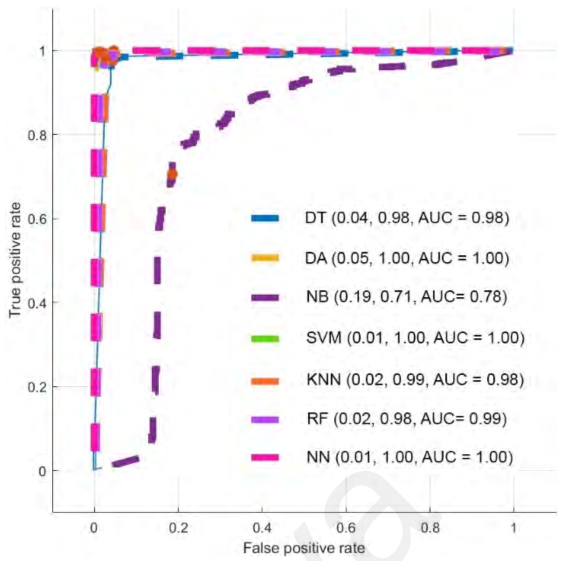
Considering the overall performance, it can be concluded that NN was the best classifier compared to the other 6 classifiers. This was demonstrated by the average of the 7 performance parameters, namely the accuracy, precision, recall, specificity, f-measure, MCC, and kappa, which reached 99.4%, which was the highest compared to the others. Additionally, this classifier had the lowest error rate of 6. In addition, this classifier had the best rate for analysing the forecast of the corrective maintenance clusters at a very good rate, which was the highest compared to the 2 classifiers that produced the highest outcomes. The development duration of this predictive model was also considered low, as it could perform model training within 10 seconds.

Table 4.26: Classifiers' parameters of clustering prediction for corrective maintenance.

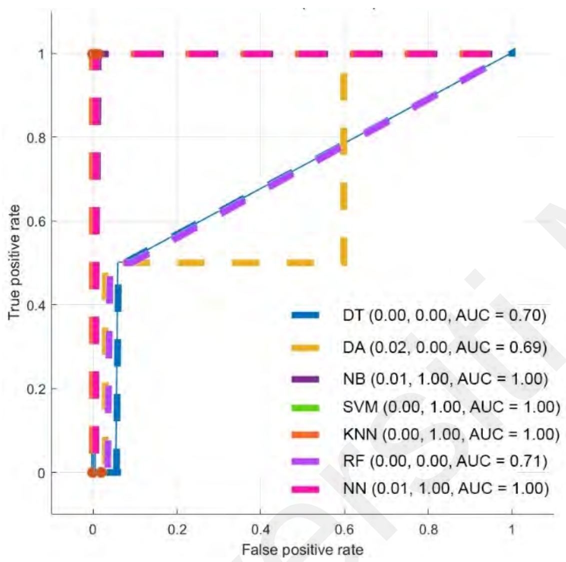
Classifier	Parameter	
Decision Tree	Split criterion	Gini's diversity index
	Maximum number of splits	100
	Preset	Fine tree
Discriminant Analysis	Preset	Linear
	Covariance structure	Diagonal
Naïve Bayes	Preset	Kernel
	Kernel type	Gaussian
Support Vector Machine	Kernel function	Cubic
	Kernel scale	Automatic
	Box constraint level	1
	Multiclass method	One-vs-one
	Standardise data	True
K-nearest Neighbor	Preset	Fine
	Number of neighbours	1
	Distance metric	Euclidean
	Distance weight	Equal
	Standardise data	True
Random Forest	Ensemble method	Bag
	Learner type	Decision tree
	Maximum number of splits	1,027
	Number of learners	30
	Number of predictors to sample	Select all
Neural Network	Number of fully connected layers	1
	First layer size	100
	Activation	ReLU
	Iteration limit	1000
	Standardised Data	Yes



a) Class 1



b) Class 2



c) Class 3

Figure 4.18: ROC curves of clustering prediction for corrective maintenance (a-c).

A predictive model's performance can be enhanced by the existence of datasets with more evenly distributed numbers, and a greater number of units in the Low Cluster. With more categories and much more balanced numbers in the Low Cluster, it can help improve the predictive performance of this model. In addition, by analysing the low clusters, it is hoped that this will provide the model with additional data to help it generate more accurate predictions.

Table 4.27: Performance evaluation of clustering prediction for corrective maintenance.

Cla	Acc (%)	Pre (%)	Rec (%)	Spec (%)	FM (%)	MCC (%)	Kap (%)	Mis (%)	Speed (obs/sec)	Tra (sec)
DT	96.8	64.3	64.5	97.7	64.4	62.1	93.0	33	~9.7k	1204
DA	96.4	65.6	63.5	97.8	64.5	62.7	92.2	37	~36k	1.4
NB	73.5	55.0	83.1	83.7	66.2	46.5	47.0	272	~690	26
SVM	99.2	99.5	99.4	99.4	99.4	98.9	98.3	8	~4.2k	7
KNN	98.5	99.0	98.9	98.9	98.9	97.9	96.8	15	~3.1k	4.4
RF	98.0	65.1	65.4	98.6	65.2	63.9	95.6	21	~1.5k	9.7
NN	**99.4**	**99.6**	**99.5**	**99.5**	**99.6**	**99.2**	**98.7**	**6**	**~9.8k**	**10**

*Note: 1) Abbreviation: Cla – Classifier, Acc – Accuracy, Pre – Precision, Rec – Recall, Spec – Specificity, FM – F-Measure, MCC – Matthews Correlation Coefficient, Kap – Kappa, Mis. – Misclassification, Speed – Prediction Speed, Train – Training Time, DT – Decision Tree, DA – Discriminant Analysis, NB – Naïve Bayes, SVM – Support Vector Machine, KNN – K-nearest Neighbor, RF – Random Forest, NN – Neural Network, obs/sec – observations per second, sec – second. 2) The bold classifier is the best compared to the others.

4.3.1.3 Replacement Plan

In addition to the preventive and corrective maintenances, the evaluations for the replacement plan prioritisation for the medical equipment was achieved with the replication values of 100. Table 4.28 displays the values of these replications, iterations, and sum of distances between the observations and the centroids. The results obtained showed that the achievement of the best total sum of the distances was on the 5th replicate with iterations of 11. Table 4.29 displays the values of the centroids according to 11 medical equipment features.

The 13,350 units were partitioned into three clusters as shown in Figure 4.19. Based on these results, it was found that the majority of the medical equipment were under the low priority, followed by the high and medium priorities. Table 4.30 shows in detail the number of medical equipment categories according to prioritisation clusters.

Table 4.28: The values of replicate, iteration, and total sum of distances between observations and centroids for replacement plan.

Replicate settings	100
Replicate and Iteration	5 and 11
A best total sum of distances (all clusters)	93,267.1
The best total sum of distances (within a cluster)	27135.1592264207 (Cluster 1)
	12366.7349006340 (Cluster 2)
	53765.1776920695 (Cluster 3)

Table 4.29: Centroids and features for replacement plan clusters.

		Cluster 3	Cluster 2	Cluster 1
Features	Age	-0.6787	0.9958	1.0093
	Support Service	-0.7632	0.9442	1.1763
	Function	0.1715	-0.0789	-0.2957
	Maintenance Scope	-0.3087	0.5434	0.4378
	Downtime	-0.2432	0.8049	0.2559
	Number of Failures	-0.3235	0.1905	0.5482
	Asset Status	-0.2884	3.4620	-0.2888
	Backup and Alternative Unit	0.0290	-0.0116	-0.0504
	Operations	-0.0387	0.1116	0.0447
	Repair Cost	-0.1426	0.0588	0.2476
	Asset Condition	-0.2963	3.4094	-0.2618

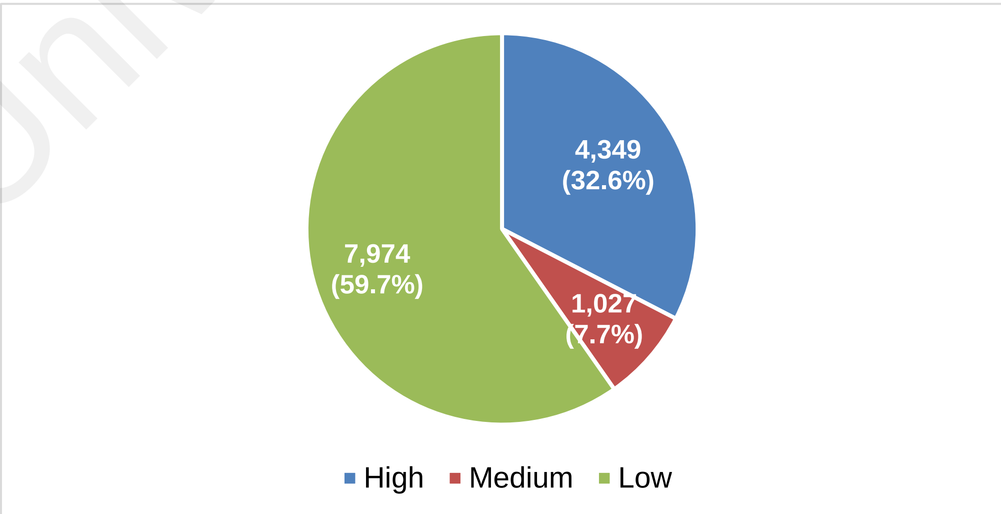


Figure 4.19: Numbers and percentages of medical equipment partitions according to replacement plan prioritisation clusters.

According to Table 4.30, the three medical equipment categories with the highest percentage among the High Cluster were the steam sterilising units, infant incubators, and the ultraviolet phototherapy units. This determination was based on the percentage value of the total equipment categories. There were 3 categories of equipment which were ranked in the top 3 in the Medium Cluster, namely the general-purpose radiographic/fluoroscopic systems, the manual external defibrillators, and the infant incubators. The Low Cluster revealed the equipment such as the pharmacy, clinical scales, physiologic monitoring systems, and the automated clinical chemistry laboratory analysers reached among the highest percentages. These results indicated that the priority of the replacement plan can occur in any category of the equipment without focusing on the equipment's purposes. It depends on the overall features and characteristics of the unit. Table 4.31 tabulates the results of the internal measures for the replacement plan clusters.

The segregation of the replacement plan prioritisation clusters were influenced by the overall characteristics of the equipment. The differences between the clusters can be seen across 6 features such as age, support service, maintenance scope, number of failures, repair costs, and asset conditions. Based on the value of the centroids obtained, the medical devices of the 13,350 units were distributed accordingly to dedicated clusters. It also demonstrated that the segregation into the dedicated clusters did not prioritise equipment based on the specific features, such as it's functions and operations. All the features of the medical devices contributed significantly to the evaluation of the replacement plan prioritisation. It can be concluded that the priority to the replacement plan prioritisation is based on the analysis of the pattern of the 11 features in the equipment dataset, referring to the values of the centroids achieved. Based on the cluster's establishment, the dataset has been labelled to develop the replacement plan prioritisation predictive models. The performance evaluation results of the predictive models for the 7 classifiers are shown in Figure 4.20.

Table 4.30: Number of medical equipment categories according to replacement prioritisation clusters.

Category	High	Medium	Low	Total
Analysers, Laboratory, Clinical Chemistry, Automated	21	4	112	137
Bilirubinometers, Laboratory	313	59	405	777
Defibrillators, External, Automated	101	62	698	861
Defibrillators, External, Manual	113	47	44	204
Densitometers	25	8	13	46
Incubators, Infant	18	7	6	31
Infusion Pumps, General-Purpose	6	2	8	16
Laryngoscopes, Rigid	396	25	1,052	1,473
Monitoring Systems, Physiologic	169	31	1,051	1,251
Nebulizers, Nonheated	687	158	1,452	2,297
Oximeters, Pulse	244	77	998	1,319
Phototherapy Units, Ultraviolet	16	5	7	28
Radiographic/Fluoroscopic Systems, General-Purpose	52	36	63	151
Resuscitators, Pulmonary, Manual	201	38	593	832
Scales, Clinical, Pharmacy	17	3	670	690
Scanning Systems, Ultrasonic, General-Purpose	312	121	214	647
Sensitometers, Radiographic	17	7	20	44
Sterilising Units, Steam	1,615	321	480	2,416
Treadmills	26	16	88	130
Total	**4,349**	**1,027**	**7,974**	**13,350**

The performance evaluation results shown in Figure 4.20 are based on the configuration of the existing parameters for producing an accurate predictive model. Thus, Table 4.32 shows the parameters which have been configured for the 7 classifiers in the development of the replacement plan prioritisation prediction models.

Table 4.31: Internal measures of clustering for replacement plan.

Feature	Range		
	High	**Medium**	**Low**
Age	2-30 years;	3-30 years;	0-10 years;
	12% is ≤ 10 years;	18% is ≤10 years;	81% is ≤5 years;
	88% is 10≤age≤30 years;	82% is ≥10 years;	19% is 5≤age≤10 years
	13 units are 30 years	7 units are 30 years	
Support Service	Obsolescence	Available (17%)	Available
		Obsolescence (83%)	
Maintenance Scope	3-5 (1xPPM frequency, calibration, 2xPPM, and statutory certification	2-4 (1xPPM frequency, calibration, and 2xPPM)	1-2 (1xPPM frequency and routine inspection)
Number of Failures	0-41 times;	0-26 times;	0-11 times;
	31% is none;	27% is none;	70% is none;
	65% is 1≤x≤11 times;	72% is 1≤x≤11 times	30 % is ≥1 time
	4.1% is >11 times		
Repair Cost	<MYR212,000;	<MYR86,000	<MYR22,000
	51% is none;	68% is none;	83% is none;
	49% is MYR1<x< MYR212k;	32% is MYR1<x< MYR86k	17% is MYR1<x< MYR22k
	8 units are >RM86k		
Asset Condition	Active and proposed for disposal	BER	Active
Function	1-2 (55%);	1-2 (41%);	1-2 (35%);
	3 (14%);	3 (23%);	3 (15%);
	4-5 (31%)	4-5 (36%)	4-5 (50%)
Downtime	0-418 days;	0-548 days;	0-244 days;
	31% is none;	27% is none;	70% is none;
	58% is >1 day;	65% is >1 day;	19% is >1 day;
	34% is > 10 days;	42% is > 10 days;	5% is > 10 days;
	5% is >100 days	12% is >100 days	0.5% is >100 days
Asset Status	100% is functioning	100% is malfunctioning	100% is functioning
Backup and Alternative Unit	No	No	No
Operations	1-2 (54%)	1-2 (51%)	1-2 (43%)
	3-4 (22%)	3-4 (24%)	3-4 (43%)
	5-6 (24%)	5-6 (25%)	5-6 (14%)

The performance of these prediction models were trained using the 7 classifiers which can be seen in Figure 4.21. It displays the ROC curves for the performance of the replacement plan prioritisation prediction models, of which 6 classifiers achieved high AUC values for each cluster compared to the NB classifier.

True Class \ Predicted Class	1	2	3
1	7925	1	48
2	0	1027	0
3	33	0	4316

(a) Decision Tree

True Class \ Predicted Class	1	2	3
1	7943	0	31
2	0	1027	0
3	249	0	4100

(b) Discriminant Analysis

True Class \ Predicted Class	1	2	3
1	7936	0	38
2	2	1021	4
3	203	5	4141

(c) Naïve Bayes

True Class \ Predicted Class	1	2	3
1	7961	0	13
2	0	1026	1
3	10	0	4339

(d) Support Vector Machine

True Class \ Predicted Class	1	2	3
1	7954	0	20
2	0	1026	1
3	25	0	4324

(e) K-nearest Neighbor

True Class \ Predicted Class	1	2	3
1	7954	1	19
2	0	1027	0
3	34	0	4315

(f) Random Forest

True Class \ Predicted Class	1	2	3
1	7968	1	5
2	2	1023	2
3	5	1	4343

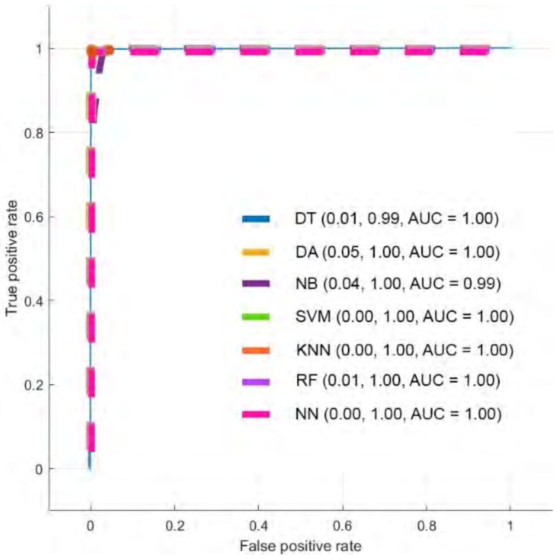
(g) Neural Network

Figure 4.20: Confusion matrices of clustering prediction for replacement plan (a-g).

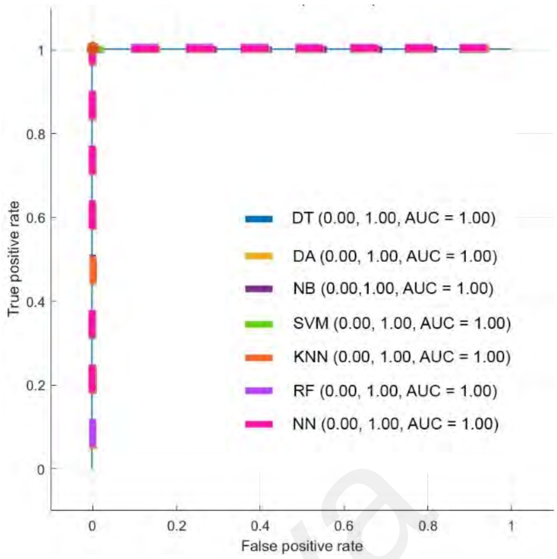
Table 4.33 displays the performance of each classifier in the development of the models. The results showed that 5 classifiers achieved the highest performances, namely the DT, SVM, KNN, RF, and NN. This was verified by the achievement of the highest percentage values for the 7 parameters, which exceeded 98.8%. Furthermore, these 5 models managed to achieve a low error rate after the evaluation was done, which was below the value of 82 out of a total of 13,350 samples used. Moreover, these models achieved a good performance in the prediction process for all 3 classes even if the datasets used were unbalanced.

Table 4.32: Classifiers' parameters of clustering prediction for replacement plan.

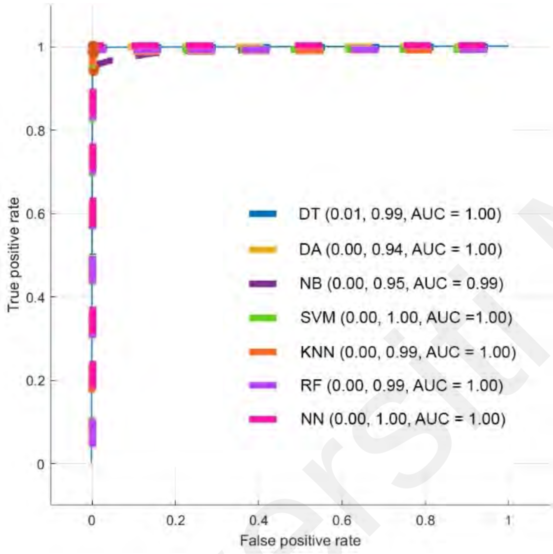
Classifier	**Parameter**	
Decision Tree	Split criterion	Gini's diversity index
	Maximum number of splits	100
	Preset	Fine tree
Discriminant Analysis	Preset	Linear
	Covariance structure	Diagonal
Naïve Bayes	Preset	Kernel
	Kernel type	Gaussian
Support Vector Machine	Kernel function	Cubic
	Kernel scale	Automatic
	Box constraint level	1
	Multiclass method	One-vs-one
	Standardise data	True
K-nearest Neighbor	Preset	Fine
	Number of neighbours	1
	Distance metric	Euclidean
	Distance weight	Equal
	Standardise data	True
Random Forest	Ensemble method	Bag
	Learner type	Decision tree
	Maximum number of splits	13,349
	Number of learners	30
	Number of predictors to sample	Select all
Neural Network	Number of fully connected layers	1
	First layer size	10
	Activation	ReLU
	Iteration limit	1000
	Standardised Data	Yes



a) Class 1



b) Class 2



c) Class 3

Figure 4.21: ROC curves of clustering prediction for replacement plan (a-c).

Based on the overall performance evaluation results, it can be concluded that NN was the best classifier compared to the other 6 classifiers. This was evidenced by the average of 7 performance parameters, namely accuracy, precision, recall, specificity, f-measure, MCC, and kappa, which attained 99.8%, which was the highest compared to other classifiers. This classifier also achieved the lowest error rate of 16. In addition, this classifier could execute predictions at an excellent rate, which was the highest compared to the other 4 classifiers. This forecasting model was also expected to have a short development time, because it could train models for a sample capacity of 13,350 units of equipment.

Table 4.33: Performance evaluation of clustering prediction for replacement plan.

Cla	Acc (%)	Pre (%)	Rec (%)	Spec (%)	FM (%)	MCC (%)	Kap (%)	Mis (%)	Speed (obs/sec)	Tra (sec)
DT	99.4	99.5	99.5	99.6	99.5	99.1	98.8	82	~67k	1204
DA	97.9	98.7	98.0	98.3	98.3	97.0	96.0	280	~260k	1.4
NB	98.1	98.7	98.1	98.6	98.4	97.1	96.4	252	~200	308
SVM	99.8	99.9	99.8	99.9	99.8	99.7	99.7	24	~42k	37
KNN	99.7	99.7	99.7	99.8	99.7	99.5	99.4	46	~5.4k	63
RF	99.6	99.7	99.7	99.7	99.7	99.4	99.2	54	~17k	126
NN	**99.9**	**99.9**	**99.8**	**99.9**	**99.8**	**99.8**	**99.8**	**16**	**~98k**	**153**

*Note: 1) Abbreviation: Cla – Classifier, Acc – Accuracy, Pre – Precision, Rec – Recall, Spec – Specificity, FM – F-Measure, MCC – Matthews Correlation Coefficient, Kap – Kappa, Mis. – Misclassification, Speed – Prediction Speed, Train – Training Time, DT – Decision Tree, DA – Discriminant Analysis, NB – Naïve Bayes, SVM – Support Vector Machine, KNN – K-nearest Neighbor, RF – Random Forest, NN – Neural Network, obs/sec – observations per second, sec – second. 2) The bold classifier is the best compared to the others.

4.3.2 Medical Equipment Maintenance Classification

This sub-section elaborates on the results obtained from the development of the preventive maintenance, corrective maintenance, and predictive maintenance replacement plans. It involves maintenance prioritisation assessment using classification techniques.

4.3.2.1 Preventive Maintenance

The development of a predictive model for the preventive maintenance begins with the segregation of the medical equipment by using the classification techniques. This distribution was according to the 3 classes, namely high, medium, and low. Table 4.34 tabulates the distribution of the number of medical equipment categories according to the prioritisation classes.

Table 4.34: Number of medical equipment categories according to preventive maintenance prioritisation classes.

Category	High	Medium	Low	Total
Analysers, Laboratory, Clinical Chemistry, Automated	49	33	55	137
Bilirubinometers, Laboratory	271	194	312	777
Defibrillators, External, Automated	27	207	627	861
Defibrillators, External, Manual	38	110	56	204
Densitometers	1	21	24	46
Incubators, Infant	1	13	17	31
Infusion Pumps, General-Purpose	0	6	10	16
Laryngoscopes, Rigid	9	185	1,279	1,473
Monitoring Systems, Physiologic	339	461	451	1,251
Nebulizers, Nonheated	231	793	1,273	2,297
Oximeters, Pulse	28	282	1,009	1,319
Phototherapy Units, Ultraviolet	1	11	16	28
Radiographic/Fluoroscopic Systems, General-Purpose	85	32	34	151
Resuscitators, Pulmonary, Manual	0	39	793	832
Scales, Clinical, Pharmacy	3	33	654	690
Scanning Systems, Ultrasonic, General-Purpose	243	246	158	647
Sensitometers, Radiographic	1	17	26	44
Sterilising Units, Steam	1,319	775	322	2,416
Treadmills	5	39	86	130
Total	**2,651**	**3,497**	**7,202**	**13,350**

Table 4.34 shows that 3 categories of medical equipment achieved the highest percentages in the High Class, namely the general-purpose radiographic/fluoroscopic systems, the steam sterilising units, and the general-purpose ultrasonic scanning systems. The determination of this position was based on the percentage value of the total equipment category. The similarities between these 3 types of equipment could be seen based on the criteria of the maintenance complexity. This equipment required an extensive maintenance procedure during the implementation of the preventive maintenance.

Three categories of the equipment were denoted to be in the highest ranks in the Medium Class, namely the manual external defibrillators, the densitometers, and the infant incubators. These 3 categories also had similarities which involved average and basic maintenance procedures. For the lower classes, there were 6 categories of equipment which achieved the highest percentage, namely the manual pulmonary resuscitators, the pharmacy clinical scales, and the rigid laryngoscopes. The similarities between these 3 categories of equipment required basic or visual inspections.

The dataset containing 13,350 units of medical equipment were then labelled according to the prioritisation classes. This aimed to develop predictive models for the preventive maintenance activities. These models were trained using seven classifiers, and the performance results of each model were displayed through confusion matrices as shown in Figure 4.22. The performance of each model was based on the configuration of the predefined parameters for each classifier used for training purposes. Table 4.35 shows the parameters which have been configured for the 7 classifiers in the development of the preventive maintenance prioritisation predictive models.

The performance of the preventive maintenance prioritisation predictive models can be seen in Figure 4.23. It was found that 4 classifiers, namely the DT, NB, RF, and NN achieved the highest AUC values among the classes compared to the other 3 classifiers. The results obtained through the evaluation parameters as shown in Table 4.36 also demonstrated that the 4 classifiers achieved among the highest performances. This was demonstrated by achieving the highest percentage values for the 7 parameters, which was more than 71.9%. Furthermore, all of the 4 models managed to achieve a low error rate, which was below the value of 1,765 out of a total of 13,350 samples. In addition, these models achieved good performances during the prediction process for all 3 classes, although the datasets used were significantly imbalanced.

True Class \ Predicted Class	1	2	3
1	7200	2	0
2	13	2647	837
3	0	754	1897

(a) Decision Tree

True Class \ Predicted Class	1	2	3
1	6601	243	358
2	2069	474	954
3	710	321	1620

(b) Discriminant Analysis

True Class \ Predicted Class	1	2	3
1	7202	0	0
2	13	2463	1021
3	0	937	1714

(c) Naïve Bayes

True Class \ Predicted Class	1	2	3
1	7202	0	0
2	826	1893	778
3	70	781	1800

(d) Support Vector Machine

True Class \ Predicted Class	1	2	3
1	6913	207	82
2	491	2084	922
3	102	997	1552

(e) K-nearest Neighbor

True Class \ Predicted Class	1	2	3
1	7202	0	0
2	13	2635	849
3	0	903	1748

(f) Random Forest

True Class \ Predicted Class	1	2	3
1	7199	3	0
2	191	2574	732
3	1	813	1837

(g) Neural Network

Figure 4.22: Confusion matrices of preventive maintenance prediction classes (a-g).

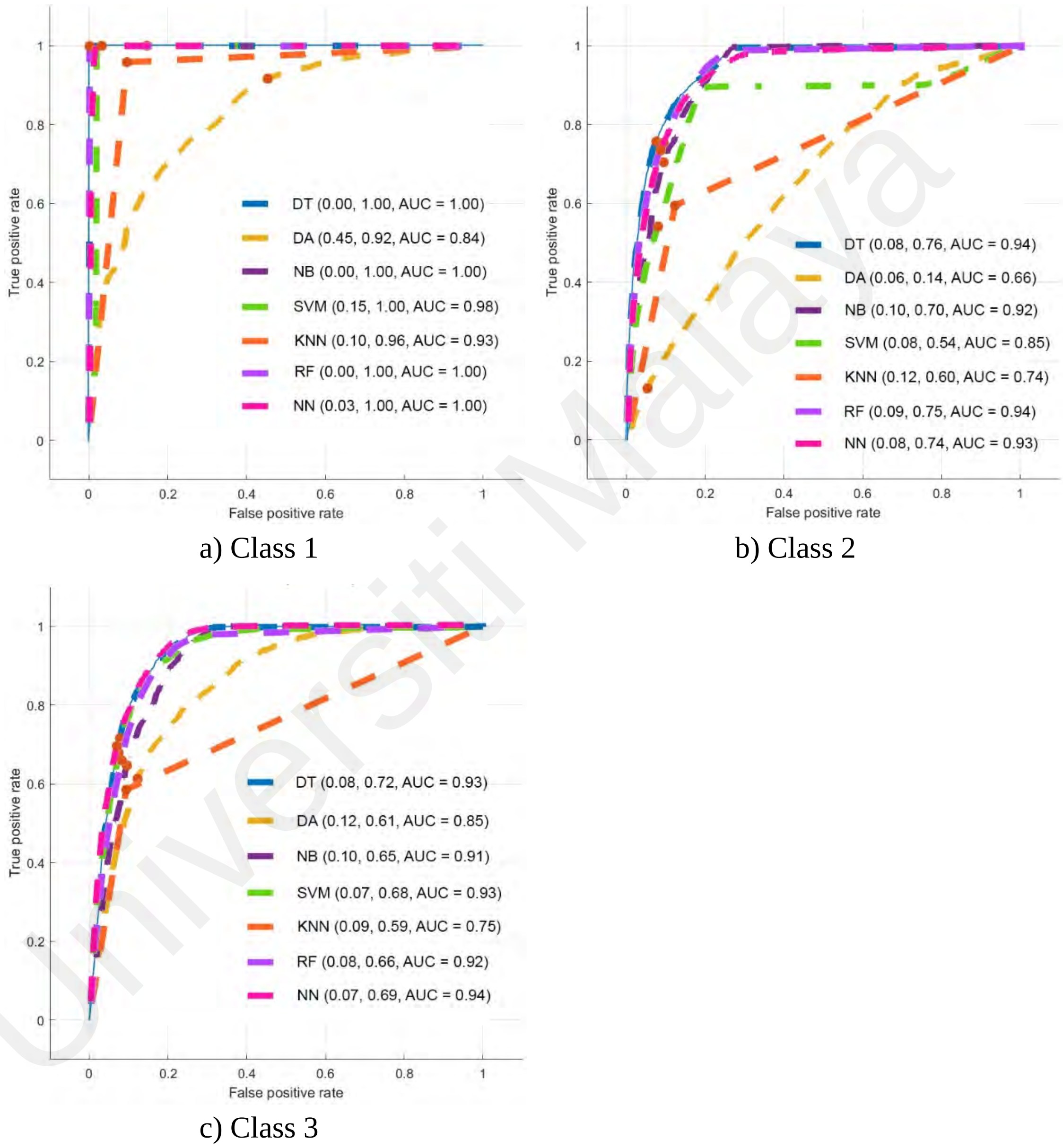
Comparing the DT classifier to the other 6 classifiers, it can be concluded that the DT classifier was superior. This was evidenced by the average of 7 performance measures, namely accuracy, precision, recall, specificity, f-measure, MCC, and kappa, which reached 83.8%, which was the highest compared to the other classifiers. This classifier also achieved the lowest error rate of 1,606. In addition, this classifier could forecast the preventive maintenance clusters at an excellent rate, which was among the highest compared to the other classifiers.

Table 4.35: Classifiers' parameters of preventive maintenance prediction classes.

Classifier	**Parameter**	
Decision Tree	Split criterion	Gini's diversity index
	Maximum number of splits	100
	Preset	Fine tree
Discriminant Analysis	Preset	Linear
	Covariance structure	Full
Naïve Bayes	Preset	Gaussian
Support Vector Machine	Kernel function	Quadratic
	Kernel scale	Automatic
	Box constraint level	1
	Multiclass method	One-vs-one
	Standardise data	True
K-nearest Neighbor	Preset	Fine
	Number of neighbours	1
	Distance metric	Euclidean
	Distance weight	Equal
	Standardise data	True
Random Forest	Ensemble method	Bag
	Learner type	Decision tree
	Maximum number of splits	13,349
	Number of learners	30
	Number of predictors to sample	Select all
Neural Network	Number of fully connected layers	1
	First layer size	25
	Activation	ReLU
	Iteration limit	1000
	Standardised Data	Yes

4.3.2.2 Corrective Maintenance

For dataset labelling, a total of 1,028 units of medical equipment were categorised according to the 3 prioritisation classes. Table 4.37 shows the distribution of the number of medical equipment categories according to the corrective maintenance prioritisation classes. Referring to Table 4.37, it was found that the 3 categories of medical equipment achieved the highest percentages in the High Class, namely the automated, the clinical chemistry laboratory analysers, the general-purpose radiographic/fluoroscopic systems, and the general-purpose infusion pumps. The determination of this arrangement was based on the percentage value of the total equipment category.



c) Class 3

Figure 4.23: ROC curves of preventive maintenance prediction classes (a-c).

Table 4.36: Performance evaluation of preventive maintenance prediction classes.

Cla	Acc (%)	Pre (%)	Rec (%)	Spec (%)	FM (%)	MCC (%)	Kap (%)	Mis (%)	Speed (obs/sec)	Tra (sec)
DT	**88.0**	**82.3**	**82.4**	**94.8**	**82.4**	**77.1**	**80.0**	**1606**	**~45k**	**1207**
DA	65.1	57.1	55.4	78.9	56.3	36.9	37.4	4655	~38k	10
NB	85.2	78.3	78.4	93.6	78.3	71.9	75.4	1971	~58k	7
SVM	81.6	76.5	74.0	90.1	75.2	66.4	68.4	2455	~18k	4285
KNN	79.0	72.1	71.4	89.6	71.7	61.6	64.7	2801	~24k	436
RF	86.8	80.5	80.4	94.2	80.5	74.7	78.0	1765	~8.3k	524
NN	87.0	81.6	81.0	93.9	81.3	75.4	78.2	1740	~84k	832

*Note: 1) Abbreviation: Cla – Classifier, Acc – Accuracy, Pre – Precision, Rec – Recall, Spec – Specificity, FM – F-Measure, MCC – Matthews Correlation Coefficient, Kap – Kappa, Mis. – Misclassification, Speed – Prediction Speed, Train – Training Time, DT – Decision Tree, DA – Discriminant Analysis, NB – Naïve Bayes, SVM – Support Vector Machine, KNN – K-nearest Neighbor, RF – Random Forest, NN – Neural Network, obs/sec – observations per second, sec – second. 2) The bold classifier is the best compared to the others.

Meanwhile, 3 categories of equipment were in the highest positions in the Medium Class, namely the radiographic sensitometers, the general-purpose infusion pumps, and the nonheated nebulizers. For the Low Class, there were three categories of equipment that achieved the highest percentage, namely the manual pulmonary resuscitators, the pharmacy clinical scales, and the ultraviolet phototherapy units. Unlike other classes, the similarities between these 3 categories of equipment can be seen in terms of the maintenance complexity, where it requires only basic or visual inspections.

The dataset containing 1,028 units of non-functioning medical equipment was then labelled according to prioritisation classes to develop predictive models. Figure 4.24 displays the performance results for each model, while Table 4.38 shows the parameters which have been configured for the 7 classifiers in the development of the predictive modes.

Table 4.37: Number of medical equipment categories according to corrective maintenance prioritisation classes.

Category	High	Medium	Low	Total
Analysers, Laboratory, Clinical Chemistry, Automated	3	1	0	4
Bilirubinometers, Laboratory	25	23	11	59
Defibrillators, External, Automated	16	20	26	62
Defibrillators, External, Manual	23	13	11	47
Densitometers	0	4	4	8
Incubators, Infant	1	2	4	7
Infusion Pumps, General-Purpose	1	1	0	2
Laryngoscopes, Rigid	5	9	11	25
Monitoring Systems, Physiologic	12	14	5	31
Nebulizers, Nonheated	43	79	36	158
Oximeters, Pulse	24	23	30	77
Phototherapy Units, Ultraviolet	2	0	3	5
Radiographic/Fluoroscopic Systems, General-Purpose	22	14	1	37
Resuscitators, Pulmonary, Manual	2	6	30	38
Scales, Clinical, Pharmacy	0	1	2	3
Scanning Systems, Ultrasonic, General-Purpose	48	49	24	121
Sensitometers, Radiographic	1	4	2	7
Sterilising Units, Steam	159	89	73	321
Treadmills	4	7	5	16
Total	**391**	**359**	**278**	**1,028**

Figure 4.25 reveals that four classifiers, namely the DT, SVM, RF, and NN, achieved among the highest AUC values for each prioritisation class compared to the other 3 classifiers.

		Predicted Class		
		1	2	3
True Class	1	278	0	0
	2	0	298	61
	3	0	165	226

(a) Decision Tree

		Predicted Class		
		1	2	3
True Class	1	266	12	0
	2	34	222	103
	3	23	153	215

(b) Discriminant Analysis

		Predicted Class		
		1	2	3
True Class	1	278	0	0
	2	0	357	2
	3	0	363	28

(c) Naïve Bayes

		Predicted Class		
		1	2	3
True Class	1	278	0	0
	2	0	301	58
	3	4	178	209

(d) Support Vector Machine

		Predicted Class		
		1	2	3
True Class	1	269	8	1
	2	7	223	129
	3	1	143	247

(e) K-nearest Neighbor

		Predicted Class		
		1	2	3
True Class	1	278	0	0
	2	0	249	110
	3	0	131	260

(f) Random Forest

		Predicted Class		
		1	2	3
True Class	1	278	0	0
	2	0	257	102
	3	0	152	239

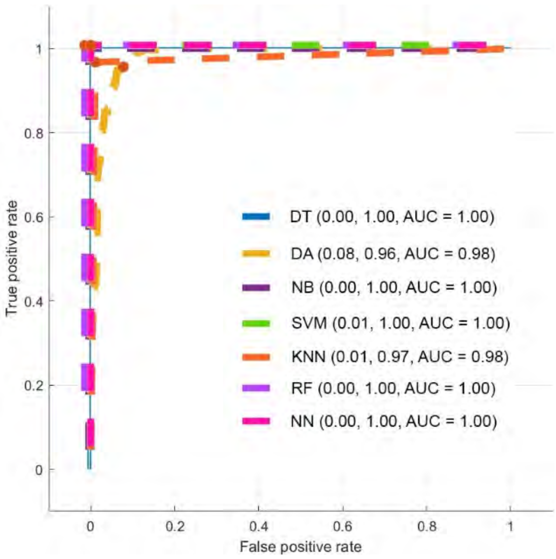
(g) Neural Network

Figure 4.24: Confusion matrices of corrective maintenance prediction classes (a-g).

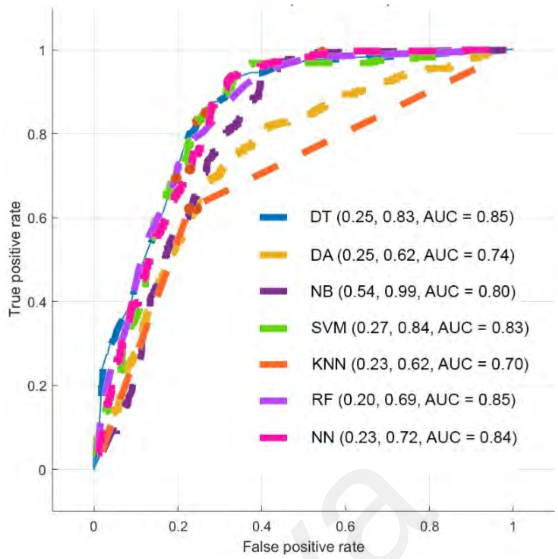
Table 4.38: Classifiers' parameters of corrective maintenance prediction classes.

Classifier	Parameter	
Decision Tree	Split criterion	Gini's diversity index
	Maximum number of splits	20
	Preset	Medium
Discriminant Analysis	Preset	Linear
	Covariance structure	Full
Naïve Bayes	Preset	Gaussian
Support Vector Machine	Kernel function	Quadratic
	Kernel scale	Automatic
	Box constraint level	1
	Multiclass method	One-vs-one
	Standardise data	True
K-nearest Neighbor	Preset	Fine
	Number of neighbours	1
	Distance metric	Euclidean
	Distance weight	Equal
	Standardise data	True
Random Forest	Ensemble method	Bag
	Learner type	Decision tree
	Maximum number of splits	1,027
	Number of learners	30
	Number of predictors to sample	Select all
Neural Network	Number of fully connected layers	1
	First layer size	10
	Activation	ReLU
	Iteration limit	1000
	Standardised Data	Yes

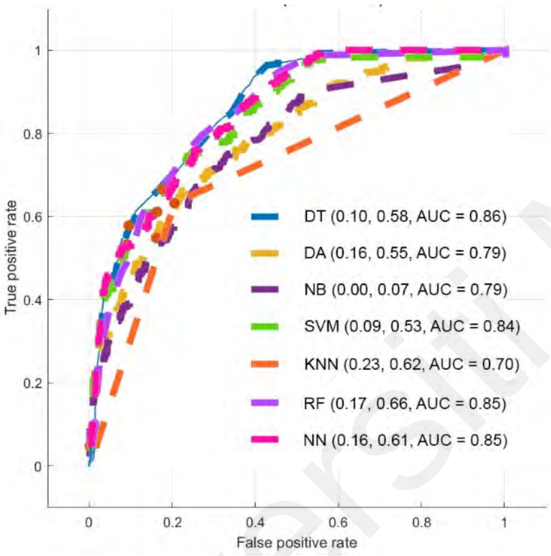
The effectiveness of the predictive models were also measured through 10 performance evaluation parameters. Table 4.39 displays the performance of each classifier in the development of the predictive models. The results obtained through the evaluation parameters also found that the 4 classifiers achieved among the highest performances, as shown in the ROC graph. This was verified by the achievement of the percentage values among the highest for the 7 parameters. Furthermore, all the 4 models managed to achieve a low error rate, which was below the value of the 254 out of a total of 1,028 samples.



a) Class 1



b) Class 2



c) Class 3

Figure 4.25: ROC curves of corrective maintenance prediction classes (a-c).

Referring to the overall results, it can be concluded that the DT classifier was the best compared to the other 6 classifiers. This was demonstrated by the average across the 7 performance parameters, which reached 77.8%. This was the highest compared to the other classifiers. This classifier also achieved the lowest error rate of 226. In addition, this classifier could predict the dedicated classes at a good rate, where it was among the fastest compared to the other classifiers.

Table 4.39: Performance evaluation of corrective maintenance prediction classes.

Cla	Acc (%)	Pre (%)	Rec (%)	Spec (%)	FM (%)	MCC (%)	Kap (%)	Mis (%)	Speed (obs/sec)	Tra (sec)
DT	**78.0**	**81.0**	**80.3**	**88.6**	**80.7**	**69.4**	**66.9**	**226**	**~45k**	**1207**
DA	68.4	69.1	70.8	83.9	70.0	53.9	52.5	325	~38k	10
NB	64.5	81.0	68.9	81.8	74.4	55.6	47.1	365	~58k	7
SVM	76.7	79.9	79.1	87.9	79.5	67.6	64.9	240	~18k	4285
KNN	71.9	74.1	74.0	85.3	74.1	59.4	57.4	289	~24k	436
RF	76.6	78.6	78.6	87.7	78.6	66.3	64.5	241	~8.3k	524
NN	75.3	77.6	77.6	87.1	77.6	64.7	62.7	254	~84k	832

*Note: Cla – Classifier, Acc – Accuracy, Pre – Precision, Rec – Recall, Spec – Specificity, FM – F-Measure, MCC – Matthews Correlation Coefficient, Kap – Kappa, Mis. – Misclassification, Speed – Prediction Speed, Train – Training Time, DT – Decision Tree, DA – Discriminant Analysis, NB – Naïve Bayes, SVM – Support Vector Machine, KNN – K-nearest Neighbor, RF – Random Forest, NN – Neural Network, obs/sec – observations per second /second, sec – second.

4.3.2.3 Replacement Plan

The dataset labelling based on the replacement plan prioritisation classes was performed on the datasets containing 13,350 units of medical equipment. Table 4.40 details the distribution of the number of medical equipment categories involved. The distribution of the equipment found that 3 categories of medical equipment achieved the highest percentages in the High Class, namely the infant incubators, the manual external defibrillators, and the steam sterilising units. The determination of this highest ranking was based on the percentage value of the total equipment category.

In the meantime, the automated clinical chemistry laboratory analysers, the physiologic monitoring systems, and the general-purpose radiographic/fluoroscopic systems were the top 3 equipment types in the Medium Class. 3 categories of equipment obtained the highest percentages for the lowest classes; the pharmacy clinical scales, the manual pulmonary resuscitators, and the rigid laryngoscopes. It may be inferred that the replacement plan's priority can occur in any category of equipment, depending on the equipment's features and characteristics.

Table 4.40: Number of medical equipment categories according to replacement plan prioritisation classes.

Category	High	Medium	Low	Total
Analysers, Laboratory, Clinical Chemistry, Automated	9	73	55	137
Bilirubinometers, Laboratory	346	171	260	777
Defibrillators, External, Automated	152	151	558	861
Defibrillators, External, Manual	154	28	22	204
Densitometers	32	5	9	46
Incubators, Infant	25	3	3	31
Infusion Pumps, General-Purpose	9	2	5	16
Laryngoscopes, Rigid	412	105	956	1,473
Monitoring Systems, Physiologic	197	626	428	1,251
Nebulizers, Nonheated	787	582	928	2,297
Oximeters, Pulse	339	141	839	1,319
Phototherapy Units, Ultraviolet	20	3	5	28
Radiographic/Fluoroscopic Systems, General-Purpose	61	59	31	151
Resuscitators, Pulmonary, Manual	218	12	602	832
Scales, Clinical, Pharmacy	19	35	636	690
Scanning Systems, Ultrasonic, General-Purpose	357	207	83	647
Sensitometers, Radiographic	22	7	15	44
Sterilising Units, Steam	1778	528	110	2,416
Treadmills	42	22	66	130
Total	**4,979**	**2,760**	**5,611**	**13,350**

For the goal of creating prediction models, the dataset containing 13,350 articles of the medical equipment was subsequently classified according to the prioritisation classifications. Table 4.41 provides the parameters which have been configured for the 7 classifiers in the construction of the predictive prioritisation model replacement plan. Figure 4.26 illustrates the performance results for each model.

Figure 4.27 depicts the predictive prioritisation replacement plan's performance in terms of the ROC and AUC values. According to the graphs, 3 classifiers, DT, RF, and NN, had the highest AUC values for each prioritising class when compared to the other 4 classifiers.

Table 4.41: Classifiers' parameters of replacement plan prediction classes.

Classifier	Parameter	
Decision Tree	Split criterion	Gini's diversity index
	Maximum number of splits	100
	Preset	Fine tree
Discriminant Analysis	Preset	Linear
	Covariance structure	Full
Naïve Bayes	Preset	Gaussian
Support Vector Machine	Kernel function	Quadratic
	Kernel scale	Automatic
	Box constraint level	1
	Multiclass method	One-vs-one
	Standardise data	True
K-nearest Neighbor	Preset	Fine
	Number of neighbours	1
	Distance metric	Euclidean
	Distance weight	Equal
	Standardise data	True
Random Forest	Ensemble method	Bag
	Learner type	Decision tree
	Maximum number of splits	13,349
	Number of learners	30
	Number of predictors to sample	Select all
Neural Network	Number of fully connected layers	1
	First layer size	25
	Activation	ReLU
	Iteration limit	1000
	Standardised Data	Yes

The performance evaluation results obtained are shown in Table 4.42. It demonstrated that the same 3 classifiers achieved among the highest performances as shown on the ROC graph. The evidence of this achievement can be observed in the percentage values, which were among the highest for the 7 parameters. Furthermore, all 3 models managed to achieve a low error rate, which was below the value of 151 out of a total of 13,350 samples.

Table 4.42: Performance evaluation of replacement plan prediction classes.

Cla	Acc (%)	Pre (%)	Rec (%)	Spec (%)	FM (%)	MCC (%)	Kap (%)	Mis (%)	Speed (obs/sec)	Tra (sec)
DT	**99.8**	**99.8**	**99.7**	**99.9**	**99.7**	**99.6**	**99.6**	**30**	**~300k**	**1203**
DA	81.3	80.8	73.2	89.6	76.8	67.0	69.6	2500	~190k	1205
NB	85.7	88.2	86.0	92.1	87.1	79.8	77.5	1913	~51k	1209
SVM	94.6	95.0	92.9	97.1	93.9	91.2	91.5	721	~82k	1884
KNN	97.6	97.4	96.8	98.8	97.1	96.0	96.3	314	~13k	327
RF	99.8	99.8	99.7	99.9	99.8	99.7	99.7	29	~17k	391
NN	98.9	98.9	98.4	99.4	98.7	98.1	98.2	151	~150k	644

*Note: 1) Abbreviation: Cla – Classifier, Acc – Accuracy, Pre – Precision, Rec – Recall, Spec – Specificity, FM – F-Measure, MCC – Matthews Correlation Coefficient, Kap – Kappa, Mis. – Misclassification, Speed – Prediction Speed, Train – Training Time, DT – Decision Tree, DA – Discriminant Analysis, NB – Naïve Bayes, SVM – Support Vector Machine, KNN – K-nearest Neighbor, RF – Random Forest, NN – Neural Network, obs/sec – observations per second, sec – second. 2) The bold classifier is the best compared to the others.

In comparison to the other classifiers, it can be concluded that the RF classifier was the best. This was demonstrated by the fact that the average of 7 performance criteria, namely accuracy, precision, recall, specificity, f-measure, MCC, and kappa, reached 99.7%, which was the highest among all the classifiers. The lowest error rate of 29 is likewise to be achieved by this classifier. Furthermore, this classifier is capable of quickly analysing the forecast of the corrective maintenance classes and performing the forecast process using the same dataset capacity.

		Predicted Class		
		1	2	3
True Class	1	5611	0	0
	2	11	2743	6
	3	8	5	4966

(a) Decision Tree

		Predicted Class		
		1	2	3
True Class	1	5315	288	8
	2	1856	854	50
	3	256	42	4681

(b) Discriminant Analysis

		Predicted Class		
		1	2	3
True Class	1	5611	0	0
	2	10	2536	214
	3	1454	235	3290

(c) Naïve Bayes

		Predicted Class		
		1	2	3
True Class	1	5527	6	78
	2	299	2333	128
	3	123	87	4769

(d) Support Vector Machine

		Predicted Class		
		1	2	3
True Class	1	5580	21	10
	2	103	2559	98
	3	7	75	4897

(e) K-nearest Neighbor

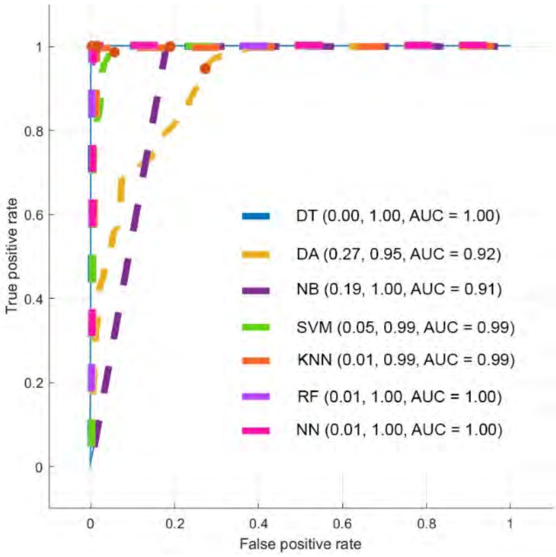
		Predicted Class		
		1	2	3
True Class	1	5607	0	4
	2	12	2744	4
	3	6	3	4970

(f) Random Forest

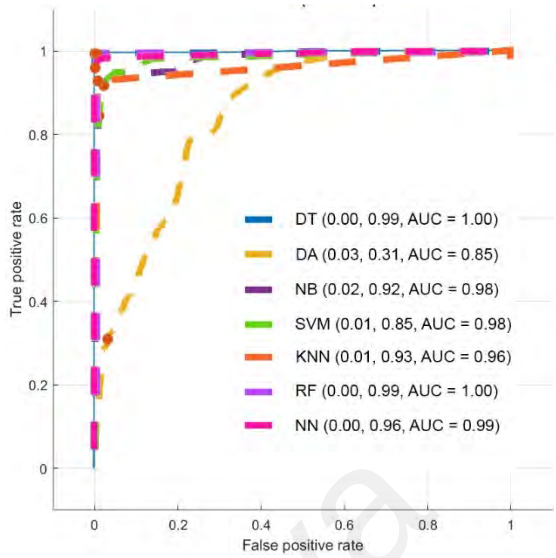
		Predicted Class		
		1	2	3
True Class	1	5597	10	4
	2	92	2648	20
	3	7	18	4954

(g) Neural Network

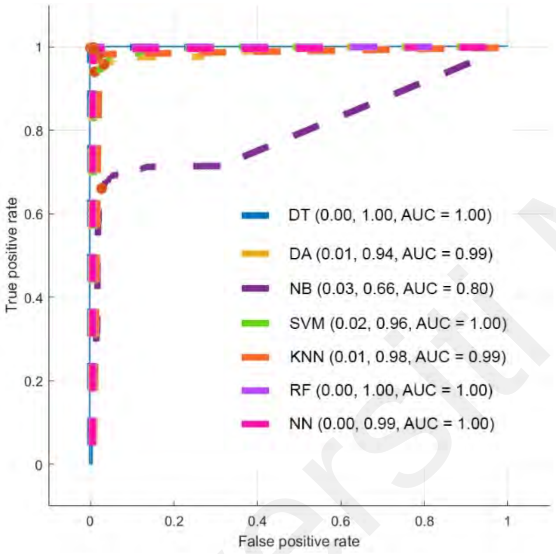
Figure 4.26: Confusion matrices of replacement plan prediction classes (a-g).



a) Class 1



b) Class 2



c) Class 3

Figure 4.27: ROC curves of replacement plan prediction classes (a-c).

4.3.3 Optimisation of Maintenance Prioritisation Predictive Models

A comparison of the predictive model's performance was made between the assessment findings obtained using the k-means and classification techniques. The goal was to find a classifier that could create the most effective maintenance prioritisation prediction models with the least amount of misclassification. NN was the most successful classifier for developing the 3 main maintenance operations, according to the data obtained through sub-sections 4.3.1. According to sub-section 4.3.2, the construction of the prediction models utilising the classification technique for the preventive maintenance, the corrective maintenance, and the replacement plan was DT and RF, respectively. The performance results obtained from the use of the 3 classifiers according to the maintenance activities involved are tabulated in Table 4.43.

Table 4.43: Comparison of predictive models performance between k-means and classification.

PEP	PM		CM		RP	
	NN(K)	**DT(C)**	**NN(K)**	**DT(C)**	**NN(K)**	**RF(C)**
Acc (%)	**99.9**	88.0	**99.4**	78.0	**99.9**	99.8
Pre (%)	**99.9**	82.3	**99.6**	81	**99.9**	99.8
Rec (%)	**99.9**	82.4	**99.5**	80.3	**99.8**	99.7
Spec (%)	**100**	94.8	**99.5**	88.6	**99.9**	99.9
FM (%)	**99.9**	82.4	**99.6**	80.7	**99.8**	99.8
MCC (%)	**99.8**	77.1	**99.2**	69.4	**99.8**	99.7
Kap (%)	**99.8**	80	**98.7**	66.9	**99.8**	99.7
Miss (%)	**13**	1606	**6**	226	**16**	29
Speed (obs/sec)	**~83k**	~45k	**~9.8k**	~45k	**~98k**	~17k
Train (sec)	**177**	1207	**10**	1207	**153**	391

*Note: PEP – Performance evaluation parameters, Acc – Accuracy, Pre – Precision, Rec – Recall, Spec – Specificity, FM – F-Measure, MCC – Matthews Correlation Coefficient, Kap – Kappa, Mis. – Misclassification, Speed – Prediction Speed, Train – Training Time, PM – Preventive Maintenance, CM – Corrective Maintenance, RP – Replacement Plan, DT – Decision Tree, RF – Random Forest, NN – Neural Network, K – k-means, DMC – Classification, obs/sec – observations/second, sec – second.

According to the collected data, the NN classifier had the best performance percentage of the three primary tasks for the medical equipment maintenance. Furthermore, when compared to the other 2 classifiers, this classifier had the lowest misclassification rate. Additionally, across all 3 activities, the predictive models constructed using the NN classifier showed benefits in terms of prediction speed and training time. As a result, in terms of training and establishing predictive models, NN was the best classifier. The performance of the prediction models for the 3 main tasks of the medical equipment maintenance was also considerably aided by the evaluation of the maintenance prioritisation using the clustering approach, namely the k-means.

4.3.3.1 Optimised Preventive Maintenance Prioritisation Predictive Model

To enhance the performance of the preventive maintenance prioritisation prediction model, an optimisation procedure involving modifications to the hyperparameters of the NN classifier were executed. The optimisation technique used the Bayesian optimisation and 30 iterations. By evaluating all of the NN classifier's parameters, the classification error could be kept to a minimum. The lowest value of the minimal classification error obtained by this classifier could be used to evaluate the performance of the optimised preventive maintenance priority prediction model. Figure 4.28 depicts, the following the optimisation procedure, the optimal hyperparameter point, and the minimum classification error value. As depicted in the graph, the decline in the minimum classification error for the estimated and observed values occurred gradually starting from the eleventh to the 30th iteration. However, the optimal point hyperparameters and classification error values were achieved during the optimisation's 29th iteration.

Several parameter adjustments are discovered as a result of the optimisation procedure of the NN classifier. After the optimisation procedure, the hyperparameter values for the NN classifier are shown in Table 4.44. The hyperparameters for the NN classifier have resulted in an optimal prediction model for the medical equipment preventative maintenance prioritisation.

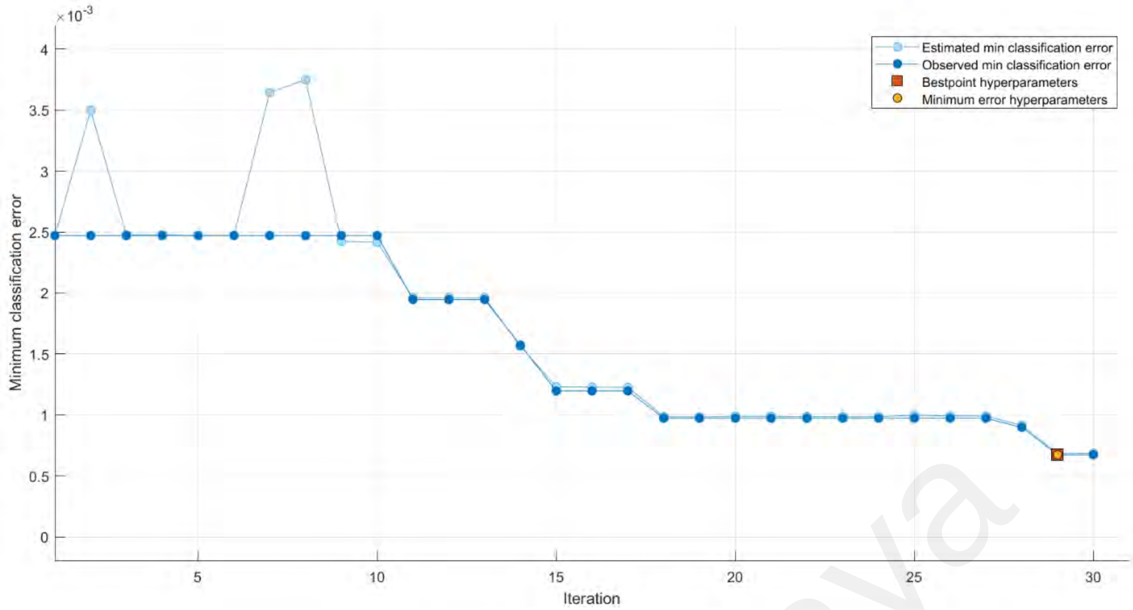


Figure 4.28: Minimum classification error plot for optimised preventive maintenance predictive model.

Figure 4.29 and Table 4.45 illustrate the performance assessment results provided by the optimised predictive model constructed using the hyperparameters configuration for the NN classifier.

Table 4.44: Optimised hyperparameters for preventive maintenance predictive model.

Classifier	Neural Network
Number of fully connected layers	2
First layer size	18
Second layer size	3
Activation	None
Standardise data	Yes
Observed min classification error	0.00067374

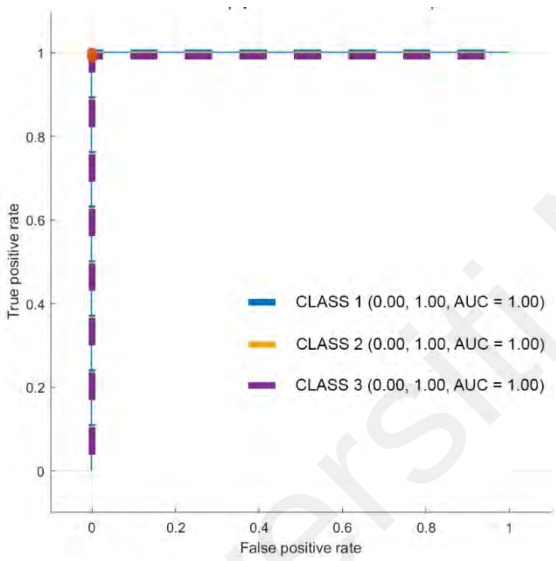
The performance improvement may be noticed in the assessment criteria like the MCC and kappa, which have both increased by 0.1%. A reduction in the error rates was also accomplished, with a drop of 4%, or 0.44%, compared to the earlier model. On the ROC curves, the AUC values were unchanged from the original model. The prediction time parameter, on the other hand, was reduced by 37%. The prediction time rate for this enhanced predictive model, however, remains high, with the prediction process taking less than 1 second on a dataset sample capacity, which is more than 3 times that of the sample utilised in this study. Overall, the enhanced preventive maintenance prioritising prediction model trained with the NN classifier improved its performance.

		Predicted Class 1	Predicted Class 2	Predicted Class 3
True Class	1	6638	1	2
	2	0	3105	2
	3	1	3	3598

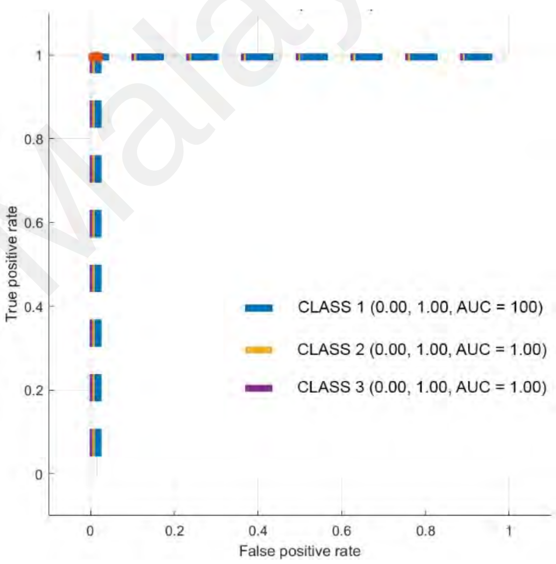
(a) Optimised

		Predicted Class 1	Predicted Class 2	Predicted Class 3
True Class	1	6636	2	3
	2	1	3104	2
	3	2	3	3597

(b) Non-optimised



(c) Optimised



(d) Non-optimised

Figure 4.29: Comparison of confusion matrices and ROC curves between optimised and non-optimised preventive maintenance predictive model (a-d).

Table 4.45: Comparison of performance between optimised and non-optimised preventive maintenance predictive model.

Evaluation Parameter	Performance of Models	
	Optimised	**Before**
Accuracy (%)	99.9	99.9
Precision (%)	99.9	99.9
Recall (%)	99.9	99.9
Specificity (%)	100.0	99.9
F-Measure (%)	99.9	99.9
MCC (%)	99.9	99.8
Kappa (%)	99.9	99.8
Misclassification (obs)	9	13
Prediction Time (obs/sec)	52,000	83,000
Training Time (sec)	132.9	177

4.3.3.2 Optimised Corrective Maintenance Prioritisation Predictive Model

To increase the model's prediction capabilities, an optimisation procedure was used to determine the values of the hyperparameters for the NN classifiers. This model's optimisation was done using a Bayesian optimisation setup with 30 iterations. This iteration rate is sufficient for generating an optimal predictive model. To reach the level of the hyperparameters, all of the parameters of this NN classifier were utilised in the training and assessment procedure. The minimal value of the classification error was monitored to accomplish the lowest value of the minimum classification error which this classifier can create. The values were relatively close between the observed and estimated classification errors, and consistently started from the 5th iteration onwards. The values started to slightly decline between the 13th and 16th iterations. As illustrated in Figure 4.30, the best point hyperparameters and minimal classification error values were identified at the 16th iteration throughout the optimisation phase.

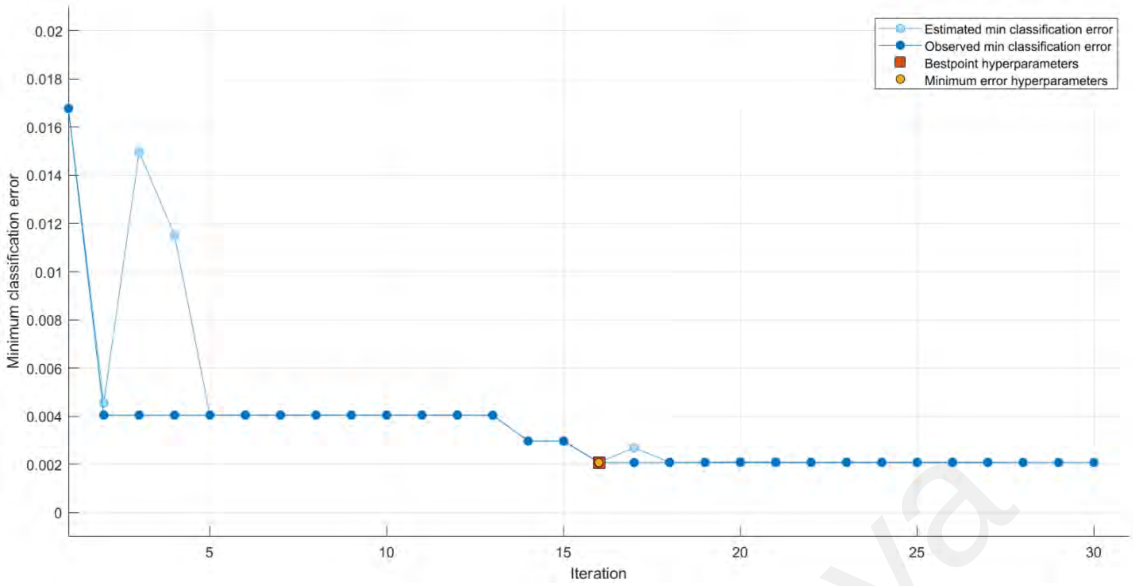


Figure 4.30: Minimum classification error plot for optimised corrective maintenance predictive model.

As a result of the optimisation process, the parameters of the NN classifier were adjusted. The hyperparameter parameters of the NN classifier resulted in an optimum corrective maintenance, which prioritised the prediction model for the medical equipment and is shown in Table 4.46.

Table 4.46: Optimised hyperparameter for corrective maintenance predictive model.

Classifier	Neural Network
Number of fully connected layers	1
First layer size	3
Activation	ReLU
Standardise data	Yes
Observed min classification error	0.0020761

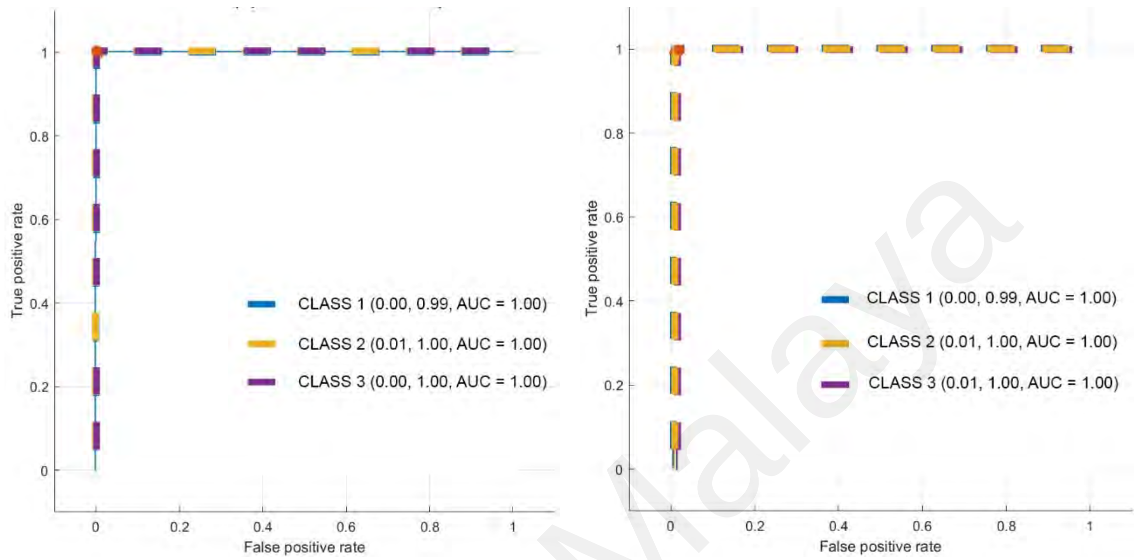
Figure 4.31 and Table 4.47 illustrate the performance assessment results derived by the optimised predictive model constructed with the NN hyperparameter's classifier setup. The evaluation measures such as accuracy, precision, recall, specificity, f-measure, MCC, and kappa, have all improved by 0.5%.

		Predicted Class 1	Predicted Class 2	Predicted Class 3
True Class	1	363	2	0
	2	2	659	0
	3	0	0	2

(a) Optimised

		Predicted Class 1	Predicted Class 2	Predicted Class 3
True Class	1	362	4	0
	2	2	658	0
	3	0	0	2

(b) Non-optimised



(c) Optimised (d) Non-optimised

Figure 4.31: Comparison of confusion matrices and ROC curves between optimised and non-optimised corrective maintenance predictive model (a-d).

Table 4.47: Comparison of performance between optimised and non-optimised corrective maintenance predictive model.

Evaluation Parameter	Performance of Models	
	Optimised	**Before**
Accuracy (%)	99.6	99.4
Precision (%)	99.7	99.6
Recall (%)	99.7	99.5
Specificity (%)	99.7	99.5
F-Measure (%)	99.7	99.6
MCC (%)	99.4	99.2
Kappa (%)	99.2	98.7
Misclassification (obs)	4	6
Prediction Time (obs/sec)	31,000	9,800
Training Time (sec)	341	10

There has also been a decrease in the misclassification rate, which was down by 2 from the previous model. On the graph of the ROC curves, the AUC values were found to be unaltered from the original prediction model. However, the improvement can be seen in the slightly decreased value of the FPR in Class 3, as illustrated in Figure 4.31. The forecast time parameter drastically increased and turned into a high speed for the predictive model. In contrast, the training time dropped from 10 to 341 seconds. Overall, the performance of the optimised corrective maintenance prioritising the prediction model developed using the NN classifier was improved.

4.3.3.3 Optimised Replacement Plan Prioritisation Predictive Model

With a Bayesian optimisation configuration and 30 iterations, the accuracy of the replacement plan priority predictive model constructed by the NN classifier was acquired. As illustrated in Figure 4.32, the best point hyperparameters and minimal classification error values were determined throughout the optimisation process. Starting at the point of the 5th iteration, the error of the estimated and observed minimum classification were observed to be relatively close and consistent until the 30th iteration. However, best point hyperparameters and minimal classification error values were attained on the 16th iteration of the optimisation procedure, as shown in the graph below.

The NN classifier's parameters changed as a result of the optimisation procedure. Table 4.48 shows the hyperparameter parameters for the NN classifier which were used to make a model for predicting the best replacement plan priority for the medical equipment.

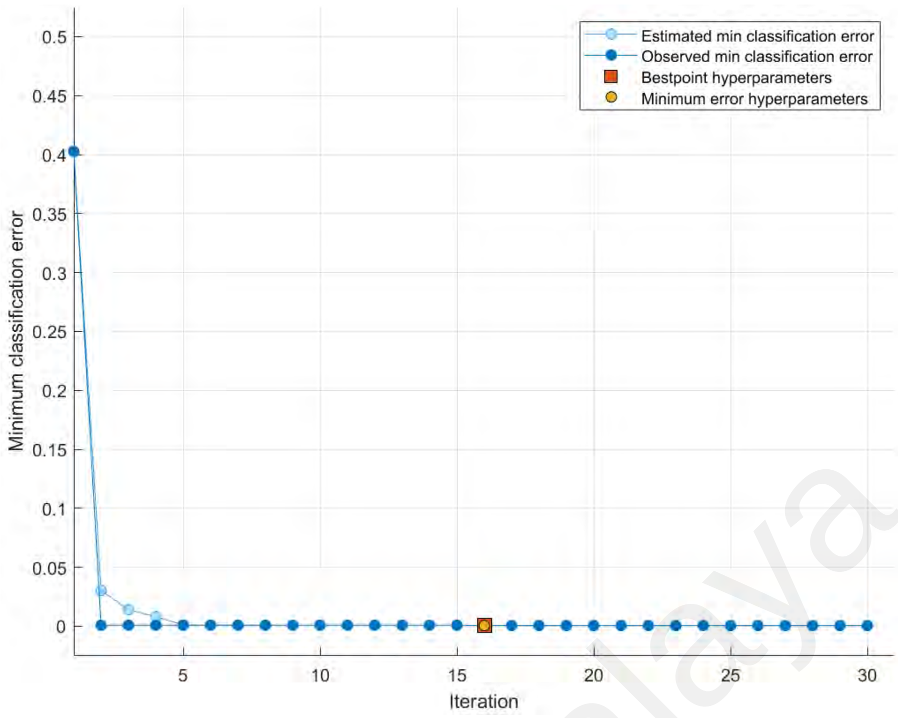


Figure 4.32: Minimum classification error plot for optimised replacement plan predictive model.

Table 4.48: Optimised hyperparameter for replacement plan predictive model.

Classifier	Neural Network
Number of fully connected layers	2
First layer size	297
Second layer size	70
Activation	Sigmoid
Standardise data	Yes
Observed min classification error	0.00059913

Figure 4.33 and Table 4.49 demonstrate the performance assessment results of the optimised predictive model constructed using the NN hyperparameters classifier settings. An increase of up to 0.5% had been achieved in the values of the assessment metrics such as recalls, f-measures, and the MCC. Furthermore, the rate of misclassification was reduced, with 11 out of 16 observations previously attained, revealing a reduction. On the ROC curves, the AUC values were found to be unaltered from the original prediction model. Furthermore, a 12.2% improvement in the prediction time was realised. Overall,

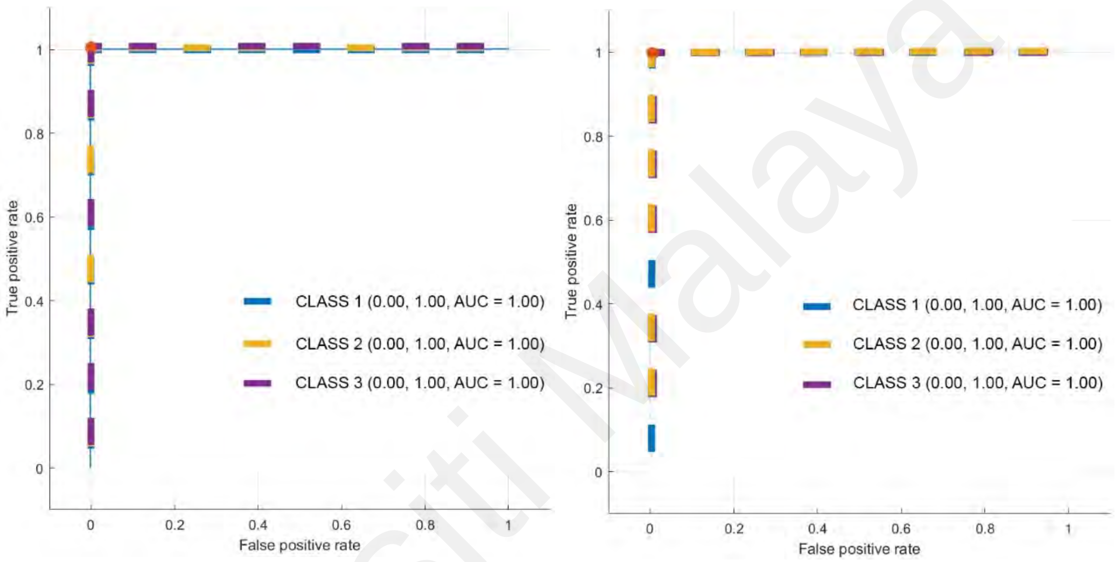
the performance increase of the NN classifier-trained optimum replacement plan prioritisation predictive model can be inferred to.

True Class \ Predicted Class	1	2	3
1	7967	2	5
2	0	1027	0
3	4	0	4345

(a) Optimised

True Class \ Predicted Class	1	2	3
1	7968	1	5
2	2	1023	2
3	5	1	4343

(b) Non-optimised



(c) Optimised (d) Non-optimised

Figure 4.33: Comparison of confusion matrices and ROC curves between optimised and non-optimised replacement plan predictive model (a-d).

Table 4.49: Comparison of performance between optimised and non-optimised replacement plan predictive model.

Evaluation Parameter	**Performance of Models**	
	Optimised	**Before**
Accuracy (%)	99.9	99.9
Precision (%)	99.9	99.9
Recall (%)	99.9	99.8
Specificity (%)	99.9	99.9
F-Measure (%)	99.9	99.8
MCC (%)	99.9	99.8
Kappa (%)	99.8	99.8
Misclassification (obs)	11	16
Prediction Time (obs/sec)	110,000	98,000
Training Time (sec)	227.9	153

4.3.4 Summary

The development of an accurate predictive model for preventive maintenance, corrective maintenance, and the replacement plan has been successfully implemented. The combination of medical equipment features, unsupervised machine learning, and supervised classifier results in the effectiveness of the maintenance prioritisation evaluation and forecasting processes for the 3 main maintenance activities were elaborated on.

The establishment of 3 maintenance prioritisation prediction models was successfully done using the k-means clustering and a NN classifier. Combining these two strategies resulted in models which can evaluate and predict medical equipment based on its priority level. The implementation of the performance evaluation with internal metrices and 11 evaluation parameters proved this achievement.

A realistic prioritisation evaluation system may be developed using a clustering algorithm for the given properties of several types of medical equipment. Furthermore, the clustering analysis used to determine the strategic maintenance management priority level relied only on the medical equipment database, which required an extensive expertise and knowledge. In the operation of the medical equipment and the execution of the maintenance management, more expertise and knowledge is required. Furthermore, this involvement introduced an inaccuracy and bias into the analytical process (Hum *et al.*, 2021). The priority level was determined by examining the patterns and trends in the medical equipment over the previous 5 years. As a result, the findings of the study added to the technical, clinical, and managerial aspects of the medical equipment. Furthermore, the priority level outputs can be promptly created, as well as driving a consistent analysis.

The research found that the unsupervised machine learning techniques are capable of measuring the datasets from medical equipment without focusing on the function or kind of equipment in particular. All of the proposed criteria contributed significantly to the evaluation of the medical equipment for the prioritisation of preventive maintenances, corrective maintenances, and the replacement programmes. the prioritisation is determined by assessing the pattern of these features in the dataset, and determining the closest Euclidean distance with the activity's centroids. Therefore, the classification of the clusters for preventive maintenance, corrective maintenance, and the replacement plan is not based on the nature or functioning of the medical equipment alone.

The implementation of the maintenance is necessary, and it must include various types of equipment, regardless of whether they are high-cost, low-cost, critical or non-critical equipment (Corciovă *et al.*, 2020). As a result of combining the approach and characteristics in this study, non-critical and low-cost equipment can be highly prioritised for preventive maintenance if it is old, in need of maintenance, and unable to function as intended. Furthermore, if there is an accessible backup unit, it can be assigned as a low priority for corrective maintenances, provided that it is adequately maintained according to the manufacturer's suggestions and statutory requirements, and has a simple maintenance method, or performs effectively. Non-critical and low-cost devices, related to equipment types and utilisation rates, are much more likely to be prioritised for replacement if they are obsolete, no longer accessible on the market, or have a high failure rate.

Observing each feature and medical equipment criterion when analysing and creating the priority levels helps to better comprehend the equipment's present state, and the recommendations for further steps. The following scenarios may arise, necessitating further action:

1) The low frequency of failures or downtime might suggest that the equipment is underutilised. To maximise the use of the equipment, it may be necessary to relocate it to other buildings or departments.
2) A significant number of failures or downtime, despite the fact that the system is still new, might indicate mishandling or human mistakes (Zhang *et al.*, 2003). As a result, suitable user training must be organised in order to improve the utilisation method.
3) The high number of missed PPMs may indicate that certain equipment are being heavily utilised. As a result, routine maintenance operations cannot be carried out (Gupta *et al.*, 2017). Thus, a user must be notified in advance of a preventative maintenance programme to provide better healthcare services.

Greater prediction rates for each maintenance activity was determined to be dependent on the classification algorithms, and a combination of the proposed features from various types of hospital-intended medical equipment. Furthermore, strategic maintenance management via a predictive prioritising system may operate automatically without the need for operator involvement. For rapid decision-making support, the predictive system may quickly create outputs by measuring the old medical equipment datasets alongside the new datasets. This approach can be proven to be a reliable categorisation method which can be used for a wide range of medical devices, and is not limited to a single type of device. The system could act as an adequate basis for healthcare services, including a vast array of equipment, including both critical and non-critical devices. Consequently, this predictive prioritisation system may be utilised in any healthcare facility, including hospitals, clinics, and tertiary healthcare institutes which utilise a variety of medical equipment. In addition, the system may provide a comprehensive forecast related to the strategic maintenance management, enabling the prioritisation of the most effective decision-making approaches.

The addition of a new set of medical equipment databases will help with prioritisations and predictive model outcomes. This enhancement will allow the system to deliver higher accuracies and precisions, while lowering the rate of forecast misclassification. As a consequence, the system will produce better priority evaluations and prediction outcomes in the future, if the methodologies are routinely applied across a larger number of medical devices. Furthermore, the results of this investigation showed that the established method may be duplicated across a variety of medical equipment utilised in hospitals.

4.4 Comprehensive Strategic Maintenance Management

This sub-section presents the development of a comprehensive strategic maintenance management for the medical equipment. It covers 3 main activities throughout the maintenance phase of the medical equipment's lifecycle, namely preventive maintenance, corrective maintenance, and the replacement plan. The goal of developing a comprehensive strategic maintenance management system is to improve the efficiency of selecting maintenance activities which will improve the reliability and cost-effectiveness of the medical equipment's utilisation. Using an enhanced failure analysis and maintenance prioritisation predictive model, the projected output is then incorporated.

4.4.1 Integration of Maintenance Management

First, a total of 13,350 pieces of medical equipment were collated and assigned priority forecasts for each of the 3 basic maintenance duties. Then, using the proposed framework illustrated in Figure 3.6, the list of this medical equipment was then integrated. Based on the suggested integration system, Figure 4.34 depicts the allocation of the number of medical equipment types to the maintenance operations.

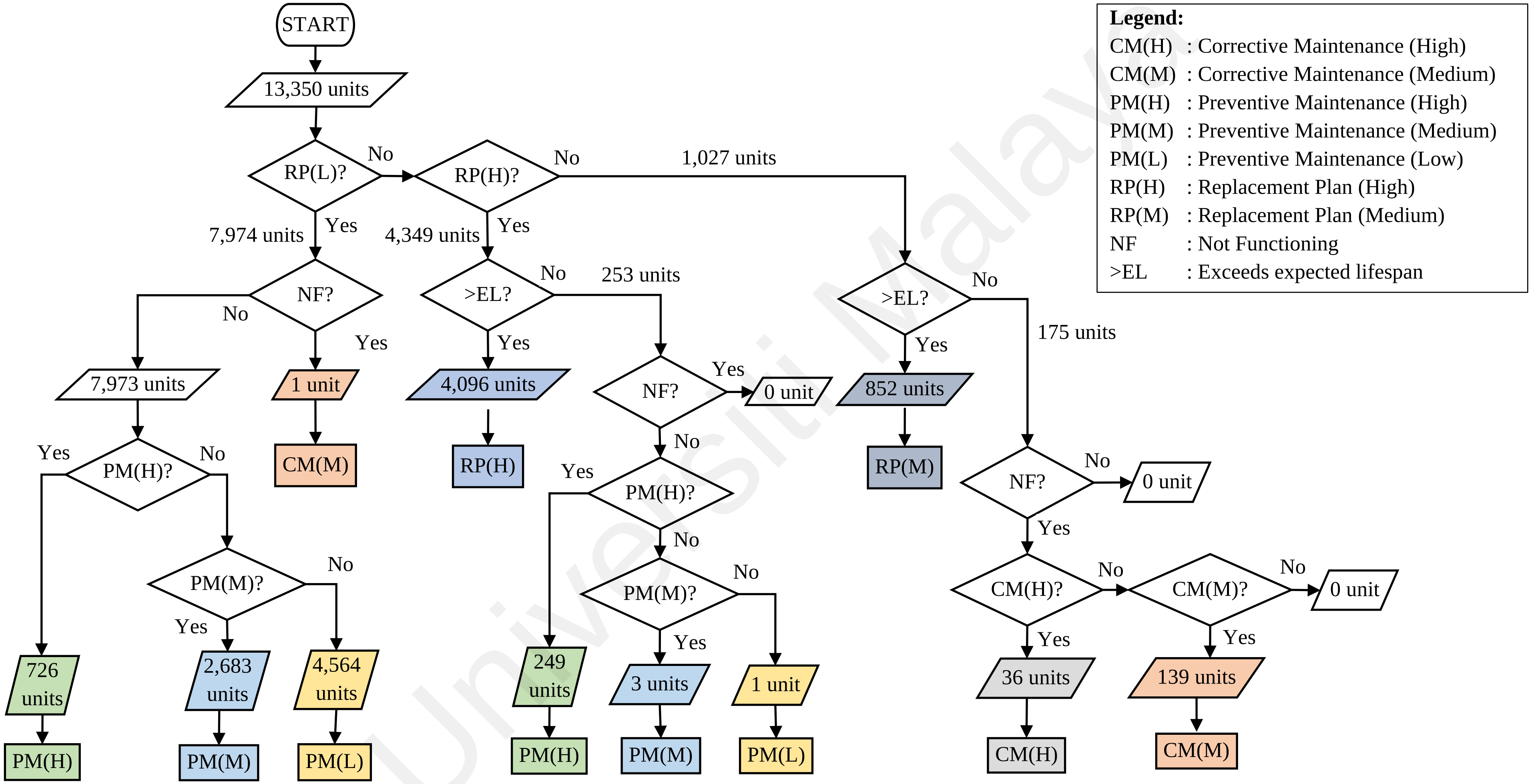


Figure 4.34: Distribution of medical equipment according to the proposed framework.

Figure 4.34 indicates that up to 62% of all units require a continuous and preventive maintenance. The corrective maintenance and replacement percentage distributions were 1.3% and 37%, respectively. According to the preceding study, each of the following maintenance activities had been labelled with a priority level. The following conclusions may be drawn from the findings given in Figure 4.34:

1) Preventive maintenance must be continued for a total of 8,226 units of equipment. These units have been prioritised based on the characteristics, such as low priority for a replacement plan, still functioning well, and still available in terms of support services. Maintenance schedules can be organised according to the selected priority levels.
2) Corrective maintenance was proposed for a total of 176 units. These equipment exhibited features associated with one of the combinations of not performing according to its intention, and the support service was still available in the market segment.
3) It is strongly advised that the 4,948 pieces of equipment should be replaced. This was because this equipment exhibited the characteristics of 1 of the high or medium replacement plan priorities. Furthermore, the support service was unavailable on the market. This also implied that if the equipment malfunctioned and was declared obsolete, a replacement should be prioritised. It is to guarantee that the availability to maintain the equipment's functionality for the delivery of healthcare services needs to be constantly sustained.

According to Figure 4.34, a total of 8,402 medical equipment units required preventive and corrective maintenance. This number of medical devices were then multiplied by the results of the first failure analysis, as discussed in sub-section 4.2.1, to determine the degree of cost-effectiveness associated with the maintenance activities. The goal was to reduce the cost of the preventive and corrective maintenance procedures. Figure 4.35 depicts the allocation of the number of medical devices based on the results of the first failure analysis, as shown in Figure 3.27 explained in Chapter 3.

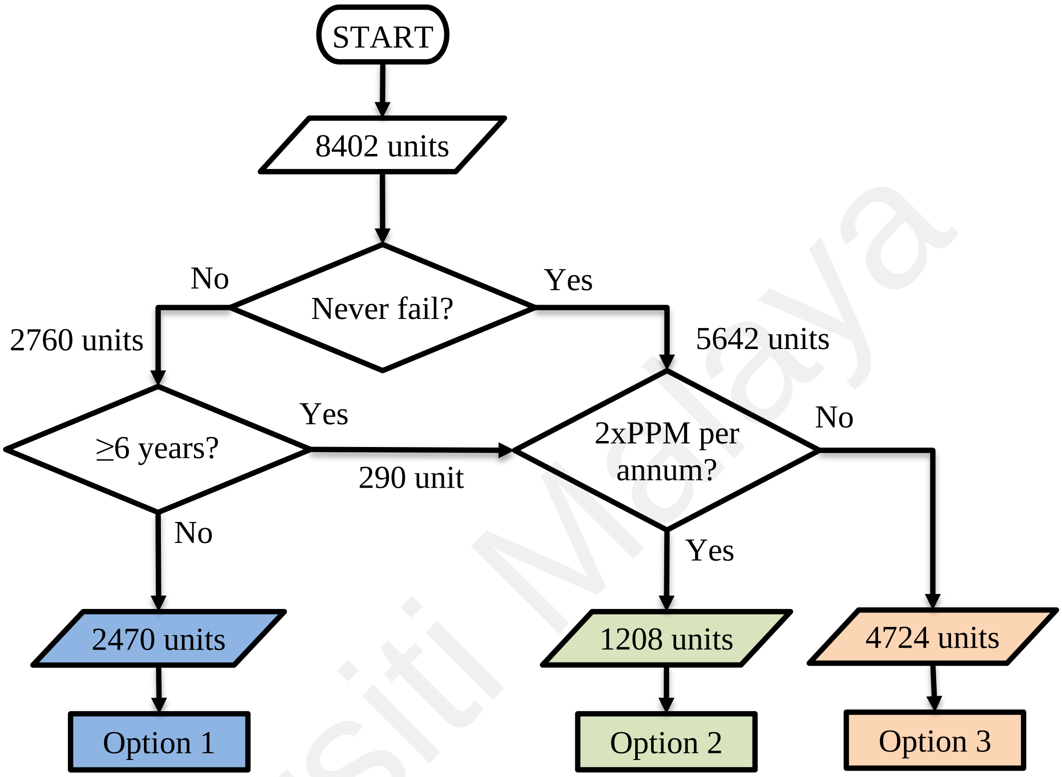


Figure 4.35: Combination of preventive maintenance, corrective maintenance, and first failure analysis.

The expenditure allocation for preventive maintenances and corrective maintenances refers to the options shown in Figure 3.7. Based on the results obtained, a total of 2,470 units of equipment were found to have suffered the initial failure less than 6 years of service life. An assignment to Option 1 for this equipment was proposed, where the frequency of the PPM and budget allocation for the corrective maintenance needed to be maintained. A total of 1,208 units of equipment were found to have the initial failure after 6 years from the purchase date. This amount of equipment was proposed for Option 2, where the frequency of the current PPM and budgetary maintenance was adjusted. Meanwhile, 4,724 units of equipment were proposed for Option 3. This option required adjustments to the current corrective maintenance cost. Details of the number of equipment categories according to maintenance activities and options for the budget allocation are shown in Table 4.50. Referring to Table 4.50, the equipment which requires a high priority replacement plan was the equipment that required the most attention compared to the other equipment, accounting for 31% of the total 13,350 units. Steam equipment sterilising units accounted for 36% of the total. Option 3 needed low priority preventative maintenances for 28% of the 13,350 units. Rigid laryngoscopes and nonheated nebulizers had the largest percentage of such maintenance actions, at 26% and 25%, respectively. Option 3 had the smallest amount of equipment for the high-priority corrective maintenances of any of the other options.

4.4.2 Cost Analysis

A cost analysis was conducted to assess the cost savings which may be gained as a result of the comprehensive strategic maintenance management framework. Table 4.51 tabulates the cost savings which may be possible by considering the distribution of the medical equipment according to the maintenance activities, prioritisation levels, and option settings. According to the comparison list, the cost of preventative maintenance was reduced by 49.8%, or MYR2,091,779.44. The cost of corrective maintenance decreased by 66.1%, or MYR6,828,825.33. The overall cost savings generated as a consequence of the cost savings for these 2 maintenance tasks was 61.4%, or MYR8,920,604.77. According to Table 4.51, the replacement plan called for a total of 4,948 units of equipment. Table 4.52 shows the expected purchasing costs for each category by numbers.

Table 4.50: Details of the number of medical equipment categories according to maintenance activities and options for budget allocation.

Equipment Category	PM(H)			PM(M)			PM(L)			CM(H)			CM(M)			RP(H)	RP(M)
	Op1	Op2	Op3	Op1	Op2	Op3	Op1	Op2	Op3	Op1	Op2	Op3	Op1	Op2	Op3		
Analysers, Laboratory, Clinical Chemistry, Automated	52	4	0	13	42	0	4	11	0	2	0	0	0	0	0	7	2
Bilirubinometers, Laboratory	36	8	0	56	139	0	64	126	0	0	0	0	1	1	0	289	57
Defibrillators, External, Automated	5	2	0	128	537	0	7	20	0	0	0	0	4	6	0	100	52
Defibrillators, External, Manual	9	0	0	14	22	0	1	0	0	0	0	0	2	2	0	111	43
Densitometers	0	0	0	0	0	1	3	0	9	0	0	0	0	0	1	25	7
Incubators, Infant	0	0	0	3	3	0	0	0	0	0	0	0	0	0	0	18	7
Infusion Pumps, General-Purpose	0	0	0	2	0	6	0	0	0	0	0	0	0	0	0	6	2
Laryngoscopes, Rigid	0	0	0	0	0	39	58	0	955	1	0	0	4	0	4	396	16
Monitoring Systems, Physiologic	2	0	0	613	0	437	0	0	0	0	0	0	5	0	0	168	26
Nebulizers, Nonheated	1	0	0	13	0	138	387	0	914	0	0	0	36	0	21	686	101
Oximeters, Pulse	0	0	0	1	0	75	134	0	789	0	0	0	6	0	2	243	69
Phototherapy Units, Ultraviolet	0	0	0	0	0	2	2	0	3	0	0	0	0	0	1	16	4

Table 4.50: Continued.

Equipment Category	PM(H)			PM(M)			PM(L)			CM(H)			CM(M)			RP (H)	RP (M)
	Op1	Op2	Op3	Op1	Op2	Op3	Op1	Op2	Op3	Op1	Op2	Op3	Op1	Op2	Op3		
Radiographic/ Fluoroscopic Systems, General-Purpose	47	13	0	4	21	0	0	0	0	4	0	0	1	0	0	29	32
Resuscitators, Pulmonary, Manual	0	0	0	0	0	70	7	0	516	0	0	0	2	0	19	201	17
Scales, Clinical, Pharmacy	0	0	0	7	0	162	27	0	474	0	0	0	0	0	1	17	2
Scanning Systems, Ultrasonic, General-Purpose	138	56	0	3	30	0	14	23	0	6	0	0	14	6	0	262	95
Sensitometers, Radiographic	1	0	4	0	0	3	2	0	10	0	0	1	0	0	1	17	5
Sterilising Units, Steam	482	114	0	8	12	0	0	0	0	12	10	0	0	0	0	1,479	299
Treadmills	1	0	0	18	0	64	3	0	2	0	0	0	0	0	0	26	16
Total	**774**	**197**	**4**	**883**	**806**	**997**	**713**	**180**	**3,672**	**25**	**10**	**1**	**75**	**15**	**50**	**4,096**	**852**

*Note: PM(H) – Preventive Maintenance (High), PM(M) – Preventive Maintenance (Medium), PM(L) – Preventive Maintenance (Low), CM(H) – Corrective Maintenance (High), CM(M) - Corrective Maintenance (Medium), RP(H) – Replacement Plan (High), RP(M) – Replacement Plan (Medium), Op1 – Option 1, Op2 – Option 2, Op3 – Option 3.

Table 4.51: Maintenance costs comparison for the current and proposed framework.

Class	Current Practice				Option	Comprehensive Strategic Maintenance Management			
	Unit	PM (MYR)	CM (MYR)	Total		Unit	PM (MYR)	CM (MYR)	Total
1	7,202	1,286,959.06	3,279,306.31	4,566,265.37	**1**	2,470	1,331,297.60	3,245,986.82	4,577,284.43
2	2,832	1,434,256.62	3,507,819.61	4,942,076.23	**2**	1,208	643,296.04	232,127.22	875,423.25
3	3,316	1,482,140.48	3,542,170.04	5,024,310.52	**3**	4,724	136,983.08	22,356.59	159,339.67
Total	**13,350**	**4,203,356.16**	**10,329,295.96**	**14,532,652.12**	**Total**	**8,402**	**2,111,576.72**	**3,500,470.63**	**5,612,047.35**

Table 4.52: Estimated purchasing costs of medical equipment categories.

Equipment Category	Unit	RP(H) (MYR)	RP(M) (MYR)	Total (MYR)
Analysers, Laboratory, Clinical Chemistry, Automated	9	1,422,470.00	406,420.00	1,828,890.00
Bilirubinometers, Laboratory	346	2,959,360.00	583,680.00	3,543,040.00
Defibrillators, External, Automated	152	2,176,000.00	1,131,520.00	3,307,520.00
Defibrillators, External, Manual	154	3,195,801.00	1,238,013.00	4,433,814.00
Densitometers	32	98,250.00	27,510.00	125,760.00
Incubators, Infant	25	476,640.00	185,360.00	662,000.00
Infusion Pumps, General-Purpose	8	36,180.00	12,060.00	48,240.00
Laryngoscopes, Rigid	412	708,840.00	28,640.00	737,480.00
Monitoring Systems, Physiologic	194	2,335,200.00	361,400.00	2,696,600.00
Nebulizers, Nonheated	787	1,245,776.00	183,416.00	1,429,192.00
Oximeters, Pulse	312	1,358,370.00	385,710.00	1,744,080.00
Phototherapy Units, Ultraviolet	20	64,960.00	16,240.00	81,200.00
Radiographic/Fluoroscopic Systems, General-Purpose	61	6,670,000.00	7,360,000.00	14,030,000.00
Resuscitators, Pulmonary, Manual	218	209,040.00	17,680.00	226,720.00
Scales, Clinical, Pharmacy	19	58,259.00	6,854.00	65,113.00
Scanning Systems, Ultrasonic, General-Purpose	357	23,580,000.00	8,550,000.00	32,130,000.00
Sensitometers, Radiographic	22	51,000.00	15,000.00	66,000.00
Sterilising Units, Steam	1,778	17,486,217.00	3,535,077.00	21,021,294.00
Treadmills	42	177,840.00	109,440.00	287,280.00
Total	**4,948**	**64,310,203.00**	**24,154,020.00**	**88,464,223.00**

Based on the cost-saving achieved through the adjustment of the preventive and corrective maintenances, it can be used to replace some of the equipment listed in Table 4.53. A total of 1,947 units of equipment can be replaced with an emphasis on the high priority replacement plan as a result of the cost-saving achieved. The balance after this purchase was MYR53,619.77. Based on this value, the purchase of the same equipment can be achieved for the medium priority replacement plan. There was a total of 35 units of equipment under this maintenance activity, and the balance after the purchase was MYR445.77. The total purchase price for these 1,982 units was MYR8,920.159.00, which was equivalent to 99.9% of the cost-saving amounts achieved.

Table 4.53: Proposed categories and quantities of equipment for replacement.

Equipment Category	**RP(H)**		**RP(M)**	
	Unit	**RP(H) Cost (MYR)**	**Unit**	**Cost (MYR)**
Analysers, Laboratory, Clinical Chemistry, Automated	7	1,422,470.00	-	-
Bilirubinometers, Laboratory	289	2,959,360.00	-	-
Densitometers	25	98,250.00	-	-
Incubators, Infant	18	476,640.00	-	-
Infusion Pumps, General-Purpose	6	36,180.00	-	-
Laryngoscopes, Rigid	396	708,840.00	16	28,640.00
Nebulizers, Nonheated	686	1,245,776.00	-	-
Oximeters, Pulse	243	1,358,370.00	-	-
Phototherapy Units, Ultraviolet	16	64,960.00	-	-
Resuscitators, Pulmonary, Manual	201	209,040.00	17	17,680.00
Scales, Clinical, Pharmacy	17	58,259.00	2	6,854.00
Sensitometers, Radiographic	17	51,000.00	-	-
Treadmills	26	177,840.00	-	-
Total	**1,947**	**8,866,985.00**	**35**	**53,174.00**

As a result of the 1,982 unit allocation spent on the equipment purchases, the remaining number of equipment units proposed for the high priority slot was 2,149 units, involving 6 categories. The medium priority was 817 units from 16 different categories. Under the high and medium priorities, the total estimated allocation to cover the equipment replacement expenses was MYR55,443,218.00 and MYR24,100,846.00, respectively. Taking the balance of MYR445.77 into account, a total of MYR79,543,618.23 must be allocated for the replacement of the remaining units.

4.4.3 Summary

With a combination of the first failure analysis, and a proposed comprehensive strategic maintenance management framework, the capabilities of the machine learning-assisted maintenance management were enhanced. These combinations integrated the 3 main maintenance activities throughout the lifecycle of the medical equipment. The enhancement was performed by optimising the best classifiers for each failure analysis and maintenance prioritisation predictive models. Table 4.54 tabulates the summary of optimised predictive models' performance for the failure analysis and maintenance prioritisation.

Table 4.54: Summary of optimised predictive models' performance.

Description	**PM**	**CM**	**RP**	**FF**	**FYR**	**FRA**
Classifier	NN	NN	NN	SVM	DT	NN
Accuracy (%)	99.9	99.6	99.9	96.9	83.9	76.7
Precision (%)	99.9	99.7	99.9	95.5	46.0	76.7
Recall (%)	99.9	99.7	99.9	95.4	37.7	76.6
Specificity (%)	100.0	99.7	100.0	98.6	70.5	76.6
F-Measure (%)	99.9	99.7	99.9	95.5	41.4	76.7
MCC (%)	99.9	99.4	99.9	94.1	15.6	53.4
Kappa (%)	99.9	99.2	99.8	94.8	15.9	53.3
Misclassification	9	4	11	414	989	3366
Prediction Time (obs/sec)	52K	31K	110K	74k	46k	110k
Training Time (sec)	132.9	34	227.9	466.95	6.34	108.86

Note: PM – Preventive Maintenance, CM – Corrective Maintenance, RP – Replacement Plan, FF – First Failure, FYR – Failure to Year Ratio, FRA – Failure Rectification Action.

The proposed options for adjusting the frequency of the PPM and maintenance costs improved the system's efficacy. The options available were determined by the condition and attributes of the medical equipment. According to the cost analysis, a comprehensive strategic maintenance management resulted in significant savings from a preventive and corrective maintenance point of view. These savings were deemed necessary to finance the replacement of the medical equipment, particularly that which had become obsolete.

The development of a comprehensive strategic maintenance management seemed to be a cost-effective maintenance approach for the medical equipment. The sign of savings gave an indication to the clinical engineers in terms of administering expenses in terms of procuring materials, tools, and acquiring external experts for maintaining the medical equipment. It can also optimise the reliability and availability of the medical equipment through the evidenced selection of the maintenance activities based on the condition and characteristics. It also assisted the clinical engineers in terms of preparing structured reports, so that the document could be presented to non-technical stakeholders for allocating the required resources.

4.5 Research Contribution

The use of predictive models to provide analysis and assessments of failures and maintenance priorities are viewed as an essential way of implementing medical equipment maintenance management theories. Combining these 2 analysis improves the outcomes of the predictive models, resulting in a comprehensive strategic maintenance management for the medical equipment. The development of this framework is perceived as a cost-effective way to improve the effectiveness and efficiency of the medical equipment's maintenance management.

The clinical engineers might use the strategic maintenance management priority levels to better understand the probable equipment states and features. Understanding the features of the medical equipment allows for more detailed reporting on the device's performance. According to O'Daniel and Rosenstein (2008), deficiencies in conveying crucial information relate to poor interaction. In addition, according to Foronda *et al.* (2016), inefficient information interchange leads to inefficiencies in the healthcare service's quality. The technical report, which includes preventive maintenance, corrective maintenance, and replacement programmes, is extremely important for healthcare management in terms of guiding, planning, and scheduling the clinical workforce to maintain the facility's healthcare service quality. The proposed prediction model can be used to gain a better understanding of the prioritisation management. The results are consistent with the findings of Curtis *et al.* (2011), who found it difficult to encourage other professions in the healthcare industry to prioritise medical equipment maintenance. However, Curtis *et al.* (2011) discovered that by speaking systematically, these issues could be avoided. As a result, a quantitative study of the prioritisation analysis could aid in better planning.

The system may be used to assist in the management of medical equipment maintenance tasks. Clinical engineers can prioritise maintenance expenses, such as purchasing consumables replacement parts, the internal appointment of highly skilled personnel, labour costs, materials, and tools to complete maintenance according to the priority level during the preventive and corrective maintenance activities, to better manage financial matters appropriately. The expenditure on replacement plans can also be arranged by prioritising high-priority medical equipment to ensure constant medical equipment availability and minimise interruptions in the healthcare services. As a result, the WHO-recommended startup and running costs may be tailored to keep the medical equipment at the healthcare institution in good working order (World Health Organization, 2011b).

Clinical engineers can also manage daily routines by planning preventive and corrective work schedules based on priority levels. The clinical engineers might be prompted to conduct a comprehensive inspection based on the indications provided by the prioritisation systems in terms of assessing the real state of the medical equipment and the causes of the failures. Based on the current state, proper maintenance may be carried out. According to Kutor *et al.* (2017), equipment failure might be caused by a lack of maintenance or wear-out. Hence, clinical engineers may devise a better maintenance strategy to guarantee that the medical equipment is dependable and safe for clinicians to utilise.

Strategic maintenance management using a predictive prioritisation system may operate automatically without the need for manual interaction from the user. For immediate decision-making support, the predictive system may quickly generate outputs by measuring the present medical equipment datasets alongside the new datasets. Furthermore, this methodology was proven to be a reliable categorisation method which can be used for a wide range of medical equipment, and is not limited to a single kind. The system might provide an adequate foundation in healthcare services including a wide range of equipment, both essential and non-critical devices. As a result, this predictive prioritisation system may be used in any healthcare facility, including hospitals, clinics, and tertiary healthcare institutes that use a variety of medical equipment. Furthermore, the system may give a thorough forecast of the strategic maintenance management, allowing for the best decision-making approaches to be prioritised.

Clinical engineers can use machine learning classifications to predict maintenance operations, which can help them manage maintenance activities, especially for a new set of medical equipment database. The prediction process may be started by using the outputs of the prioritisation system from the current database, which labels each piece of equipment with a priority level. By assessing the existing labelled data, the machine learning technology can forecast the new set of equipment outputs. In future forecasting procedures, the new prediction output may be combined with the old labelled data to better anticipate outcomes. Clinical engineers can develop a forecast for the anticipated maintenance charges, and seek a budget at an early stage based on the outcome of this projection, particularly when it comes to replacement units.

Furthermore, clinical engineers might strategise the optimum maintenance procedures in light of the preventive maintenance, corrective maintenance, and replacement programme prediction outcomes. It would be useful to prepare early schedules for future tasks to effectively implement such maintenances. Insufficient usage of medical equipment, according to Belhouideg (2020), is one of the reasons which contributed to the high pandemic fatality rates. Regular maintenance combined with appropriate scheduling can improve the dependability and availability of the medical equipment in the healthcare institutions. The system uses a unique approach for assessing equipment conditions which can help with scheduling, operational stability, functional dependability, resource usage, and spare part management (Dhillon & Liu, 2006; Endrenyi *et al.*, 2001).

Sharma and Sharma (2020) stated that the COVID-19 infection cases and mortality rates increased daily. The pandemic affected the economy and exacerbated health problems, posing a critical challenge to the entire world (Areepong & Sunthornwat, 2020; Farman *et al.*, 2021). Within a short amount of time, the virus spreads via the strategies nasal canal and into the human lungs (Zuber *et al.*, 2020). As a result, important medical equipment such as ventilators were essential (Canelli *et al.*, 2020; Epstein & Dexter, 2020). To deliver the greatest healthcare services during this vital period, the medical equipment's availability and dependability needed to be at a high level. The urgency necessitated quick actions to guarantee that the medical equipment met manufacturer requirements, and could withstand any hurdles (Garzotto *et al.*, 2020). Thus, the full prioritisation prediction system needed to be able to give timely support and indications during the decision-making period, in order to be able to prioritise the execution of preventive, corrective, and replacement maintenance programmes.

The use of predictive maintenances might be aided by achieving a comprehensive strategic maintenance management. Predictive maintenance, according to Endrenyi *et al.* (2001), can help with outage scheduling, operational stability, equipment dependability, resource utilisation, and effective spare parts management. The study also articulated that predictive maintenance is a proactive intervention that employs certain strategies to avoid the probability of equipment breakdown. In addition, the Reliability-Centred Maintenance component of the maintenance programme was incorporated into the predictive maintenance exercise. Pintelon *et al.* (2008) backed this up as well, and stated that predictive maintenance is much more advanced than conventional maintenance approaches, since it is based on specialised inspection methods, statuses, and risk-based techniques. This maintenance technique made condition monitoring equipment much more accessible and cost-effective. As a result, the study's complete strategic maintenance management may be utilised as a tool in predictive maintenance executions to improve the medical equipment’s dependability, availability, and safety.

The proposed system may be used to help clinical engineers manage the whole maintenance programme, including budgeting, laying out the proper maintenance schedule, managing better technical people and supplies, creating relevant reporting documents, and organising the replacement plan. It may also help policymakers prepare a new method and update current rules for better-organised maintenances and procurement, by providing an early warning based on the predictive models. As a result, clinical engineers may oversee medical equipment maintenances to guarantee that the desired levels of dependability, availability, and safety are met. Medical equipment must be consistent in terms of dependability, availability, and safety, especially during pandemic outbreaks such as the COVID-19.

Various forms of medical equipment utilised in different sorts of healthcare institutions, such as hospitals, medical research centres, and tertiary healthcare facilities, might benefit from a comprehensive planned maintenance management programme. Additional features, on the other hand, may be necessary for the application's compatibility. Proper planning in the maintenance of the medical equipment not only improves the equipment's dependability and saves money, but also maximises the availability and utilisation of the equipment. The expansion of the availability allows the medical equipment to reach its full potential (Chaudhary & Kaul, 2014). The availability of a full-potential medical equipment result in a high-quality healthcare services will help to improve worker satisfaction rates and patient confidence levels (Kim *et al.*, 2017; Mousazadeh *et al.*, 2019; Torkzad, 2019).

CHAPTER 5: CONCLUSION AND FUTURE WORKS

5.1 Conclusions

The primary aim of this research is to propose a comprehensive strategic maintenance management for the medical equipment under discussion. To achieve the primary aim, there are 3 objectives outlined as presented in Section 1.5. The accomplishments of these objectives are summarised as follows.

The 1st objective **(RO1)** of this research was to predict medical equipment failure from an unlabelled dataset using machine learning algorithms. The failure analysis covers 3 elements, which are the first failure, failure to year ratio, and the failure rectification action. The first step of preparing all 3 failure analysis prediction models were classified and labelled according to the medical equipment's datasets using the data mining technique. Then, the predictive models were trained using 7 supervised machine learning platforms. The selection of the best classifier was done by observing the performance generated using the 11 performance evaluation parameters. The performance of selected classifiers was boosted by executing the hyperparameter's optimisation. The optimised predictive models of the first failure, failure to year ratio, and failure rectification action were the SVM, DT, and NN, respectively. The optimised SVM classifier produced highest accuracy among others with above 94% measured with 7 performance metrics. Moreover, the optimised DT classifier for failure to year ratio predictive model generated the error only 989 observations, which was the lowest misclassification rate compared to other 6 classifiers. Meanwhile, the highest accuracy of NN classifier generated 3,366 misclassification rate and achieved fast prediction speed of 110,000 observations per-second. In can be concluded that, these 3 classifiers produced a better performance for the failure analysis predictive models for the medical equipment. However, with a greater balanced number of medical equipment datasets, this can enhance the accuracy of the predictive models, especially for the failure to year ratio.

The 2nd objective (**RO2**) of this research was to estimate the maintenance priorities from an unlabelled medical equipment dataset. The maintenance prioritisation comprised of the main activities, which were the preventive maintenances, corrective maintenances and the replacement plan. The initial preparation of these development models comprised of 2 techniques, which were the k-means and classification techniques. The purpose of applying these 2 techniques was to segregate the medical equipment into 3 categories, which were the high, medium, and low values for each maintenance activity. This segregation of each category was analysed using 9, 10, and 11 proposed novelty features for the preventive maintenance, corrective maintenance, and replacement plans, respectively. Seven classifiers were used to train and develop the predictive models using the labelled datasets, and the outputs generated were evaluated with performance assessment parameters. The comparison of the predictive model's performance using k-means and classifications were made, and the most accurate classifiers were selected. The performance of all 3 predictive models were increased by implementing the hyperparameter's optimisation. The optimised predictive maintenance produced matching outputs. The results showed that the k-means successfully segregated the medical equipments into the appropriate categories, and NN was the best classifier compared to the others across all 3 maintenance activities. The optimised NN algorithm produced highest accuracy and precision at above 99.8% with more than 31,000 observations per-second for prediction speed. Furthermore, the performance evaluation parameters showed that the models produced accurate predictions for the unbalanced medical equipment datasets.

The 3rd objective (**RO3**) of this research was to propose a cost-effective maintenance management framework for the medical equipment. The proposed framework, namely comprehensive strategic maintenance management integrated the preventive maintenance, corrective maintenance, and replacement plan developed in RO2. The integration determined the most appropriate maintenance activity for each unit of the medical equipment. Then, the total number of equipment, which required preventive maintenance and corrective maintenance was compiled, and the segregation was made by considering the first failure classes. The segregation was based on 3 elements, which were set across the equipment which never had a failure, one with a failure which was detected within six years of its service life, and labelled the last one with a failure after six years of utilisation. These 3 categories led to the 3 options, in terms of the annual PPM frequencies and the maintenance costs. Option 1 recommended keeping the current practice, in terms of the frequency of the PPM and maintenance costs. Option 2 offered adjustments of 2 times to once annually, in the PPM, and eliminated the corrective maintenance cost. Whereas, Option 3 proposed the removal of corrective maintenance cost for well-performed medical equipment. The cost analysis showed that the implementation of a novelt,y comprehensive strategic maintenance management reduced the costs by 61.4% (MYR8,920,604.77) of the preventive maintenance and corrective maintenance significantly. There were 40.1% (1,982 units) out of 4,948 equipment, which were proposed in the replacement plan, which can be replaced using the savings generated from the other 2 maintenance activities.

5.2 Novelty

From the literature review and research conducted, this study introduces 2 novelties. The first novelty refers to the combination of medical equipment features and criteria. It covers 19 specific features, which generally contains the information of inventory and maintenance history. The selection of features was based on 8 categories of medical equipment assessment, which introduced by referring to the thematic analysis and correlation with Malaysia Standard MS 2058. These 19 features were never tested and experimented before in related previous studies. Moreover, the features are appropriate to assessment and predict the comprehensive maintenance management prioritisation for myriad medical equipment. From this combination of features, it was proven that the development of failure analysis and maintenance prioritisation predictive models using a specific dataset achieved highest accuracy and precision observed from performance metrics. Therefore, it can be used as a tool in applying predictive maintenance for medical equipment management throughout the maintenance phase of asset life cycle.

The second study novelty refers to the development of comprehensive strategic maintenance management for medical equipment. It combines two elements of integration of maintenance management, and combination of failure analysis and maintenance prioritisation predictive models. From the literature study, this proposed framework was never applied in relevant previous study. Besides, it may workable for myriad medical equipment and covers failure analysis and maintenance prioritisation. From the cost analysis, it demonstrated that the application of comprehensive strategic maintenance management reduced significant savings compared to current settings. The savings can be used to capitalize into the new replacement unit. The application of comprehensive strategic maintenance management framework may assist the clinical engineer in planning procedures in terms of finance, workforce, and material. Thus, the high quality of healthcare services can be achieved by sustaining the availability of medical equipment.

5.3 Future Works

There are a few recommendations for future works which can be implemented concerning this comprehensive strategic maintenance management. The recommendations for future works are stated as follows:

1. Assessing the reliability of the medical equipment and prioritising the appropriate maintenance activity is vital for administering the operations in a healthcare institution. However, there are other types of machinery and equipment involved such as medical gas systems, heating, ventilation, and air-conditioning systems, cold water systems, and other mechanical systems which are equipped in healthcare buildings. Moreover, there are electrical systems like the main switchboards, generator sets for supplying the essential supply, and uninterruptable power supply. Furthermore, the healthcare facility becomes intelligent through electronic equipment systems such as queue management systems, nursing call systems, and communication systems. These systems act as essential organs to a healthcare institution, for supporting the primary services to the community. Therefore, this comprehensive strategic maintenance management should be carried out to assess and predict the reliability of these systems. By applying this comprehensive strategic maintenance management to the entire systems of a healthcare facility, it will be a total, complete, and full-ranging maintenance management system to assist the clinical engineer in terms of upkeeping the entire healthcare assets.
2. From this study, this maintenance management framework will be successfully applied to a myriad of medical equipment utilised in the health clinic environment. Hence, this concept should be further studied in hospitals and other healthcare institution setups, for identifying its effectiveness in other environments, Furthermore, there could be additional features and criteria

needed to support the system for generating better accuracy in terms of the prediction models. To enhance the comprehensive maintenance management, the consideration of deep learning technique would be beneficial based on the characteristics of available dataset. By studying other types of healthcare facilities, this comprehensive strategic maintenance management can be a highly robust intelligent systems for assessing the reliability of medical equipment and prioritising the appropriate maintenance activities.

3. This comprehensive strategic maintenance management provides valuable information for the clinical engineering team in terms of managing the operation of the medical equipment. The production of predictive outputs is fast and an immediate course of action, which can be made instantly. As a result, this all-encompassing strategic maintenance management framework should be integrated with a real-time database for the healthcare asset management systems. This framework is proven to be realistic and practical, by regularly providing instant and quick responses for clinical engineers to make quick and correct decisions. A user-friendly application would benefit from the asset management system's interactive dashboard. The system's information can be accessed and viewed at any time, and from any location.

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