A COMPREHENSIVE MEDICAL EQUIPMENT MANAGEMENT SOFTWARE SYSTEM FOR INCREASED PATIENT SAFETY

by

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ACADEMIC ETHICS AND INTEGRITY STATEMENT

I, Neslişah Akyüz, hereby certify that I am aware of the Academic Ethics and Integrity Policy issued by the Council of Higher Education (YÖK) and I fully acknowledge all the consequences due to its violation by plagiarism or any other way.

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ABSTRACT

A COMPREHENSIVE MEDICAL EQUIPMENT MANAGEMENT SOFTWARE SYSTEM FOR INCREASED PATIENT SAFETY

A medical equipment system was developed to include the inventory of medical equipment, the failure management process, the maintenance and repair periods, the management and the scheduling for calibration and preventive maintenance. The software system keeps all necessary information, analyzes and converts this information into meaningful results and graphical charts. It can report the failure types, the leading causes for the failures, and the cost analysis for each failure. The user determines the frequency for the preventive maintenance according to this information. Scheduling makes it easier to control and stick by the layout of the hospital process. This web-based software project was written by Entity Framework code first system in ASP.NET MVC 5 area on SQL server 2016 database, which was created on the Microsoft Azure Cloud System server. The upgrades and maintenance of the system could be done while the system is operational. The screens are limited by access authorization of each type of user.

Keywords: Medical Equipment Management System, Preventive Maintenance, Analyze.

ÖZET

HASTA GÜVENLİĞİNİ ARTTIRMAK İÇİN KAPSAMLI BİR YAZILIM SİSTEMİ

Geliştirilen tıbbi ekipman sistemi, bir envanter, arıza yönetim süreci, bakım ve onarım süreleri, yönetim ve kalibrasyon, bakım ve önleyici bakım için bir program içerir. Sistem gerekli tüm bilgileri saklar, analiz eder ve bu bilgileri anlamlı grafik tablolara dönüştürür. Hata türlerini, arızaların ana sebebini ve her bir arıza için maliyet analizini raporlayabilir. Kullanıcı, bu bilgiye göre koruyucu bakımın sıklığını belirler. Bu web projesi, Microsoft Azure Cloud Sistemi sunucusunda oluşturulan SQL Server 2016 veri tabanındaki ASP.NET MVC 5 alanındaki Entity Framework Code First sistemi ile yazılmıştır. Sistemin geliştirmeleri, güncellenmeleri ve bakımı sistem kullanım halindeyken yapılabilir. Kullanıcılar kisiye özel şifreye sahiptir.

Anahtar Sözcükler: Tıbbi Ekipman Yönetim Sistemi, Önleyici Bakım, Analiz.

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LIST OF ABBREVIATIONS

ECRI	Emergency Care Research Institute
MEDQ	Medical Equipment Management System
FDA	Food and Drug Administration
SQL	Standardized Query Language
AHA	The American Hospital Association
ISO	International Standards Organization
MVC5	Model View Controller 5
AEM	Alternative Equipment Maintenance
PM	Preventive Maintenance
ICU	Intensive Care Unit
NICU	Neonatal Intensive Care Unit
OR	Operating Room
ER	Emergency
CE	Clinical Engineering
UMDNS	Universal Medical Device Nomenclature System
WHO	World Health Organization
ASHE	American Society for Healthcare Engineering
MAUDE	The Manufacturer and User Facility Device Experience
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
JCI	The Joint Commission International

1. INTRODUCTION

The clinical engineer (CE) is defined as a professional who supports and advances patient care by applying engineering and management skills to healthcare technology [2]. Aruna et al. categorized the problems in the CE department as minor and major ones [3]. The inventory, maintenance, and calibration issues were defined as major problems; while documentation and labelling were indicated as minor problems.

Medical devices are the essential component of modern health care, and medical equipment investment has the largest share in the hospital budget. The disruption of these devices, causing them to be idle, causes significant deficits in the hospital budget. The life span of devices if they are not maintained regularly is shorter. Sometimes the repair costs approach the acquisition cost of the medical equipment. Medical device management and maintenance issues are not considered enough in hospitals. The growth in the ability to manage or maintain medical equipment is far behind the rate of equipment deployment.

It is a big challenge for a healthcare institution to use medical resources adequately and maintain equality, access, and quality at the same time. There exist limited resources available for medical care. The healthcare services need to be used more effectively by preventing unnecessary or inadequate procedures and developing and defining the best approaches [4].

The Joint Commission International (JCI) accreditation standard stipulates healthcare organizations to plan and maintain a program for monitoring, testing and maintaining medical devices, and recording their results to generate three-monthly performance reports [5].

The main goal of JCI is to increase patient safety, and patient safety-related topics of the Joint Commission are published yearly as National Patient Safety Goals

[6].

Below mentioned standards had been used during the design of the software system.

1. Medical Device Software of the British Standards Institution helps to understand the working principle of the medical devices and design the software structure of the MEDQ study [7].
2. World Health Organizations guidelines are used to the requested information on the registration page and creating the ID number of the medical equipment [1].
3. The Joint Commission International (JCI) accreditation standard demands from the hospital, which is a member of the JCI reports evaluating the situation of the medical equipment. The reports are created according to the JCI regulations. It is also recommended that healthcare facilities collect data for medical device management and use them for device improvement and replacement in the long term [8].
4. The failure codes and sub-codes are supplied from ISO 19218-1 Medical Devices-Hierarchical Coding Structure for Adverse Events [9].
5. ECRI created the Universal Medical Device Nomenclature System (UMDNS) to identify the medical equipment in the hospitals. This system is also used in our study [10].
6. FDA published Medical Device Reporting (MDR) regulation (21 CFR Part 803) to record adverse events. The requested information in the adverse event form is taken from this regulation [11].
7. John Hopkins Alarm guidelines are used to deciding the prioritization of the medical equipment and designing the form to change clinical alarm limits [12].

In addition to traditional operation management and the use of hospital management devices, patient safety, operational performance in cost-effective analysis, risk

assessment and control are important issues [13]. Our newly developed system could also deal with the potential risks of the clinical engineering department.

The proposed MEDQ software system, as a first step, creates an inventory and gives a unique identification number (ID) for each medical equipment, and lists the inventory following filtering with several options. It is also able to define different user types and access limitations. Recording failures, adverse events and false nuisance alarms, costs of each repair, and repeated failures are also included in the system. It makes it easier to follow up the calibration and maintenance, to schedule and to control the calibration process on a device basis. The CE department could add preventive maintenance, according to the Emergency Care Research Institute (ECRI). The system allows the user to define causes of the alarms and to specify them, prioritize clinical alarms in the intensive care unit (ICU), the neonatal intensive care unit (NICU), the operating room (OR), and the emergency (ER) departments. The system has a special equipment replacement process and advises replacement depending on the cumulative repair costs. Also, performing an annual survey to evaluate the performance of the CE department is available in the MEDQ system.

Currently, available medical equipment management systems instead focus on three common areas such as hazards, failures and inventory [14]. However, the MEDQ software system collects a broader range of information relevant to patient safety as follows:

Inventory: medical equipment in the inventory could be listed by considering their risk value. Inventory is a detailed list of all assets of an organization. For the inventory to be useful, it must be continuously updated to reflect the current state of each asset; continuity in the inventory is essential. Changes should be followed up and recorded. The inventory should be up-to-date.

Failures: the system calculates the repeated failures, uptimes, and cumulative repair costs.

Inventory of Clinical Alarms: the inventory has a high priority for medical devices in the critical care departments. This module involves the alarm limits for default settings and settings adjusted for patients. As a result of this module, the false or nuisance alarms are eliminated.

Calibration: the system prepares a schedule to follow up the preventive maintenance and the calibration of each medical device, and it helps with completing the procedure.

Equipment Replacement: the system calculates the value for compatibility in the five years-plan. The MEDQ system recommends that a device needs to be replaced when the yearly failure costs are higher than the 20% of the acquisition cost. The system recommendation for replacement is shown in the inventory under Replacement column and as a YES or NO type advice with green and red colours, respectively. The replacement cost in the inventory is the acquisition cost of a new device, under the same Universal Medical Device Nomenclature System (UMDNS) developed by ECRI [10].

Benchmarking Indicators: indicators such as cost, number of failures, idle time, authorized company response time, calibration completion time, the efficiency of the CE department is accepted as measurable benchmark parameters. These parameters are evaluated at regular intervals, and changes in the status of medical equipment and related personnel are updated. The benchmarking indicators are used to measure two main fields in performance and function [15]. They measure and display the performance with the information provided internally by measuring what was done and how. Indicators are necessary for quality enhancement and controlling process. Different indicators are essential, depending on the preferenced of the facility. The indicators may be able to measure internal operations, quality improvement, and external benchmarking [16].

2. LITERATURE REVIEW

In the literature, there exist numerous software system studies for managing medical equipment and collecting information about the functioning of the hospital. The starting point in all these systems is the generation of an inventory. The inventories are often organized according to the risks of the devices. The maintenance and calibration services are followed up. However, none of these systems in the literature had an adverse event recording feature and clinical alarms. MEDQ software system focuses on adverse events and clinical alarms to support patient safety in addition to standard features such as inventory creation, calibration, and maintenance monitoring.

As one of the first studies, Yardimci and Ulgen developed a medical equipment management software in 2007 [17].The system is based on Joint Commission on Accreditation of Healthcare Organizations Medical (JCAHO) recommendations and E 6.10 standards. An EM number is calculated for each medical equipment to classify and add them to the preventive maintenance, performance, measurement, and testing program. EM number is the sum up of function, risk, and maintenance. A schedule for preventive maintenance and calibration designed monthly.

In another study, the Medical Equipment Management System (MEMS) was developed by Chien et al. in 2010 to collect and manage hospital data [13]. MEMS connects to HIS (Hospital Information System) and retrieves the information about medical equipment from HIS. The network and software architecture of the system is robust and detailed. The users have different levels of authorization and roles, such as clinical staff, administrator, and biomedical engineer. MEMS is generous for results and graphics. It can analyze the failures of medical equipment. They have ten different modules for necessary information, procurement, acceptance, discard, maintenance, installation verification, warranty inspection, prevent maintenance, and contract management.

Later, Freye et al. developed a software system for managing medical equipment called MAGUSS in 2013 [18]. MAGUSS is suitable for use in small and medium-sized medical facilities. The serial numbers of medical equipment are used as their ID number. There were three different user types with limited access levels: the administrator, the user, and the supervisor. MAGUSS has twelve screens, including the alarm setting. In the alarm setting screen, the user must enter the reminder date, frequency, task, and priority level. The alarm entries were listed on the home page chronologically. The system allowed the user to add spare parts and accessories, and it was able to list them. As a result, the system created an inventory to follow up the medical equipment and their maintenance procedures. The MAGUSS system also recorded clinical alarms..

Kanamala and Teelckdharry implemented a quality management system (QMS) in 2015 [19]. It had been used in a biomedical engineering department at Niagara Health for three years. During those three years, they collected enormous data about medical equipment and operation process. QMS was defined as a strategic management system for leading to the continuous improvement of the process by the Canadian Medical and Biological Engineering Society (CMBES). There are five main aims of QMS, which are strategic management, continuous improvement, staff engagement, quantitative methods, and customer satisfaction. The authors mentioned that there were still some recommendations from CMBES for further improvements, which they have not implemented yet. These improvements included all the diagnostic equipment, developing five years plan, modifying the unbudgeted requests, and setting up a committee that plans for technology assessments.

Saleh et al. developed a software system in 2017, which was called the Medical Equipment Management Program (MEMP) [20]. It is mainly used to gather and analyze the data and to follow up the maintenance. This system had eight screens, which consists of users, departments, vendors, equipment, maintenance, maintenance schedule, repair, calibration, and summary. As their claim, this system was suitable for small scale hospitals. The medical equipment identification system recommended by WHO was used in MEMPS and in the MEDQ system too. The MEMP system had tailor-made solutions, calculation of up and down times and an ability to determine the

service costs. It was low cost. On the other hand, MEMP collected limited information about medical equipment. The summary screen gave information about the status of the medical equipment, but it was not able to serve detailed reports and graphics.

Aruna et al. conducted a different kind of project in 2017 [3]. The collections of data and information gathered since 2010 were compiled and analyzed. Medical equipment as inventory was managed on Microsoft Excel in the selected hospital. It was shown that there was 900 medical equipment in total. Since the inventory was recorded manually, missing out updates, calibrations or maintenances was highly possible. Enterprise Asset Management (EAM) was recommended to the hospital. Enterprise Asset Management system uses inventory as a tool to manage calibration, maintenance, workshops, training, replacement, and ordering spare parts and accessories. The system recorded a significant decrease in the percentage of errors between 2015 and 2017. That project was focused on a specific hospital to detect and solve the issues. It proved that inventory management was effective to manage the budget, the staff, and the medical equipment, and it reduced the errors in medical equipment management.

The AssetPlus software system of GE Healthcare has actively used since 2013 as an asset management solution [21]. This software is used in all departments in the hospital such as biomedical department, technicians, finance and IT departments to ensure that the hospital works in synchronization. Although this software is suitable for hospital management, it is insufficient to follow medical equipment failures, calibrations, and clinical alarms. Another disadvantage of the AssetPlus system is its high price.

3. METHODOLOGY AND MODULES

3.1 Methodology

3.1.1 The Software

The MEDQ web project was implemented by Entity Framework code first system in ASP.NET Model View Controller 5 (MVC5) area on Standardized Query Language (SQL) server 2016 database created on Microsoft Azure Cloud System server. The website could be accessed at; http://portalmedq.com/. Users must enter a user name and password provided by the super administrator.

ASP.NET MVC is a framework developed by Microsoft to add the MVC pattern to ASP.NET. MVC is one of the most critical architectural patterns, especially in web application development. MVC was chosen, because it is easy to control, test and, create the system, using a layer by layer structure. The model layer is where the application data is stored and is usually in the database. The model separates the data layer from the application, so there is no need to specify where the data layer is in other segments. The model layer could be created by using Entity Framework or other tools like Nhibernate. The view layer is the interface in which the components of the chosen bootstrap template was used. It is possible to use the latest version technologies such as HTML5 and CSS3 in the view layer. The controller layer performs tasks, such as processing the request and bridging the Model and View layers.

As a result of its web-based algorithm, the user is not required to carry a specific device to enter the MEDQ system, and all the information is stored on the cloud. The MEDQ web project is also easy to upgrade. When compared with desktop systems, web projects have the main advantage of accessing the system even via a mobile phone.

3.1.2 UMDNS Codes

The management section is for evaluating all data about facilities. It is restricted, and reachable only by the super administrator could reach this section. It is created for the management and control of the hospitals, administrators, and information regarding the UMDNS list [10].

The lifetime of medical equipment, the frequency of calibrations, and the risk number of medical equipment are assigned to the UMDNS list, as shown in Figure 3.1. The American Hospital Association published a reference about the life expectancy of medical equipment. Also, the risk numbers of medical equipment were assigned by using the management monograph published by ASHE [22]. The manufacturer also supplied the frequency of calibration information.

3.1.3 Type of Users

The MEDQ system assumes two types of users. The CE department members and managers are considered as the first type of users. These users have a broad authorization in the system; being able to add new devices, follow up the calibrations and update the failure forms. They are the primary users of the system, and they have full control over it. The second type of users is departmental nurses. The nurses can follow the status of their medical equipment and request modifications in the clinical alarm settings, but they can only reach the system in the read-only form.

3.1.4 ID Number of Medical Equipment

All medical equipment was registered to the system and placed in the inventory according to the WHO criteria (Shown in Appendix A Fig. A.1 and Fig. A.2.). The system also asks for uploading the user and service manuals during registration.

At the end of the registration, a unique ID is assigned to each medical device. In the literature, similar techniques are used in creating a unique ID system for medical equipment. N. Saleh used the alphabetical symbol to define a device such as ICU 005 V for the ICU ventilator [20]. In the MEDQ system, the ID has three different fields for identification such as ANE-10-145-001, where the first alphabetic field represents the location of the device and ANE is for the Anesthesia Department. The middle area contains the UMDNS codes created by ECRI, and the last area is a counter.

Two devices with the same UMDNS number at the same location may count, but they would not have the same ID. Registered medical devices can be reorganized for the risk number for each device, technology index, failure costs, and counts [23].

3.1.5 Medical Equipment Replacement Process

The system automatically reports medical equipment failures. If the repair costs over a year are over 20% of the acquisition cost, the system may recommend a replacement.

The software calculates an improved merit number, recognizing that some of the factors are more important and must be included in an equation rather than being measured alone, an account could be used. The system also calculates a replacement coefficient for compatibility in five years plan for each device, as, shown in Eq.3.1

$$\begin{aligned}\text{Replacement Coefficient} = \text{Age/Life Expectancy} \\ \times 1.00 + \text{ Number of repair work orders} \times 0.5 + \\ \text{Total Repair Cost/Acquisition cost} \times 2.00 + \text{ Evaluation in Technology} \times 0.5\end{aligned} \tag{3.1}$$

The system automatically calculates the age of the device. The system assigns the life expectancy, the number of repair work orders, total repair cost and acquisition cost. The evaluation of the advancement in technology is the only subjective parameters is the system and defined by the clinical engineering department during the registration and can be updated in time.

This calculation is evaluated by modifying the previously published merit number system [24]. The replacement coefficient number aims to give an idea to managers about the current performance of the device. With this calculation, changes in the device technologies are a subjective evaluation and scored by the CE department, between zero and five. The database supplies other parameters. The hospital compares the calculated values and determines the usability of the devices for plans â the lower the number, the higher the compliance with the 5-year plan of the institution.

3.1.6 Planning The Preventive Maintenance

Much medical equipment requires periodic attention to ensure that they continue to operate correctly and safely. Some devices are highly critical compared to others. It is accepted that there is a lack of consensus on how to determine which devices should be included in the critical device category, and which ones could be omitted from this periodic attention. This regular attention is called Preventive Maintenance(PM). PM includes cleaning, lubrication, adjusting, and minor component replacement to extend the useful life of the equipment. The primary objective of the PM is to avert predictable and preventable device failure. The Standard EC.2.10.3, published by JCAHO, states that performance and safety testing should be conducted at least annually [25].

Typical PM intervals are six months and 12 months. By considering the device

failure rate, this interval could be altered. Those that fail more frequently must have shortened (PM) interval. Devices that should be included in a monitored maintenance program are those that meet the following two criteria:

1. Critical medical devices in the sense that they have a significant potential to cause injury if they do not function properly, and
2. Devices that are maintenance sensitive in the sense that they have a significant potential to function improperly if they are not provided with an adequate level of PM.

To establish an effective and efficient PM system; once the equipment has been registered in the inventory, the PM program should be created. It may be necessary to develop a reminder system to notify the CE personnel on a timely basis.

The system automatically creates performance and Calibration/Preventive Maintenance schedule. PM intervals are initially generated according to Equipment Management number. In general, intervals are six to twelve months. However, they can be altered for each device by considering their frequency of failures. Total calibration time, the number of devices calibrated, and from the Details link, estimated calibration duration, and total duration for the entire group of equipment could be accessed. Performance and safety testing forms are uploaded together with the unique procedures to the system database, separately for each medical device. The (CE) department could download the forms; filled in and reuploaded to the system for reporting.

3.2 Modules

3.2.1 Homepage

The home page contains general information about the healthcare facility, such as the title of the hospital, the device number, total failure and maintenance records.

Final five failures and maintenances are also displayed separately in detail, as in Figure 3.2. The software system has both Turkish and English language options.

3.2.2 Reports

Reports are classified under four categories such as device, malfunction, maintenance and location. Also, the system lists devices that are idle under device report section. It could calculate how long these devices were inactive, and this calculation allows to identify the active time of the corresponding device during its lifetime and to estimate its uptime duration.

3.2.3 Medical Devices

The device module could be used to add new devices, access the inventory, and make updates on the device records. The requested information during the registration of new medical equipment is based on WHO criteria. The inventory gives an idea about the devices with potential risk, the prices, their failure counts and costs, and most importantly, their calculated replacement time. Appendix B shows the screenshot of all registered medical equipment in the MEDQ system.

3.2.4 Failures

Failure causes are defined according to ISO 19218-1 Medical Devices-Hierarchical Coding Structure for Adverse Events [9]. Devices are under the responsibility of the department staff. Whenever maintenance or a failure record is created, the system alerts the responsible person with an email, to keep up with the process. The system has 20 principal failure codes and a total of 83 sub-codes to precisely define the failures supplied from mentioned ISO standard. With this approach, identifying the exact cause of each failure is possible. Table 3.1 shows a sample of mechanical failure causes

a screen. All of the failure codes could be shown in Appendix C.

Table 3.1
Sub-failure causes of a mechanical failure.

Major Cause of Failure	Sub Failure Causes
Mechanical	Calibrations
	Detachment of device or device component
	Dislodged or dislocated
	Leak
	Mechanical Jam
	Retraction Problem
	Unintended Movement

The failure inventory is available in the failure module and involves the failure records with details (Figure 3.3). The failure codes and their explanations provided by the user could be obtained within the failure module. The failure period is essential since the idle time is calculated from this period.

The MEDQ system sends an email to inform the responsible nurse/staff when a failure record is created. This email contains information about medical equipment. An example of the email can be shown in Figure 3.4.

3.2.5 Maintenance

The manufacturer for each device defines periodic services and their intervals. In some instances, the equipment may require additional maintenance. This module covers these issues. There is also a schedule to follow up with future maintenance.

3.2.6 Clinical Alarms

Clinical alarms are generally the nuisance alarms for nurses in the ICU, NICU or OR. Therefore each clinical alarm should be controlled separately. False or nuisance alarms eventually reduce the sensitivity of the nurses to even alarms. Clinical alarms, after a while, push the nurses to disable, silence or ignore the given warnings. So, annoying alarms are counterproductive, resulting in desensitization [26].For high-risk equipment in the inventory; alarms of high importance must be prioritized, and their limits set accordingly. IEC 60601-1-8 includes the general requirements for clinical alarm systems, and it focuses on the standards to be applied to all medical devices with alarms. Also, the characteristics of visual and audible alarms signals are defined. Thus it can be used to prioritize all clinical alarms [27].

In the American Journal of Emergency Medicine, 99.4% of the clinical alarms were mentioned to be false, with approximately 1% of all clinical alarms resulting in a change of patient management [28]. Out of 2200 adverse cases reported in the ECRI alarm records, 12% were related to clinical alarms. Out of these, 64% were due to patient monitor, infusion pump and intensive care ventilators [29].

The alarm management aims to avoid the injury of patients caused by improper alarm limits. To re-adjust the alarm limits, the user should fill a written request form to explain the reason for such a demand and the responsible nurse is alerted by an email for a confirmation [12].

The software tracks the alarms and the devices, why the alarm sounded, and how long it sounded, to prioritize and differentiate actionable alarm signals, daily. It is possible to eliminate as much as 30% of alarms by performing a fault tree analysis. There is a unique form for each device in the system to keep the details of the clinical alarms. It involves the risk value, location, sound and differentiation steps. This form could be found in Appendix D.

As a result, safety checks and revisions are performed on alarm settings if nec-

essary. The main classification of clinical alarms is shown in Table 3.2 [30]. After this classification, the clinical alarms could be categorized as false alarms, true alarms, nuisance alarms, or not actionable alarms. From the literature, the false or not actionable alarms have the highest ratio of 88-90% among total clinical alarms [31].

Table 3.2
Classification of the clinical alarms.

Patient Safety Alarms (Patient Death, injury)
Functional Alarms (Device Failures)
Informative Alarms (Process)

D.M. Korniewicz, T. Clark, and Y. David developed a National Online Survey to define the main issue related to alarms in healthcare facilities. According to the survey, "frequent false alarms reducing attention to patient care" and "inadequate staffing to respond to the alarms" had the have the highest-ranking level [32].

3.2.7 Equipment Performance Measurement

The performance measurement process is scheduled according to the preventive maintenance, calibration frequencies, and UMDNS codes prepared by ECRI. Medical equipment with the same UMDNS code has identical calibration due times, and the dates of calibration are automatically assigned. The system contains forms and procedures for preventive maintenance, calibration, and electrical safety.

The CE department should follow the procedures to apply proper maintenance or calibration. Then, the report form is filled out. The result of the process may be failing or pass. If the device cannot pass the process, a failure record form is filled out, and the repairment procedure begins. On the other hand, if the device passes, the active use of the device continues. This complete calibration procedure is shown in Figure 3.5.

3.2.8 Device Location

The number and type of device locations depend on the size of the hospital. The responsible nurse or staff must be defined, and then the user could add new locations to the system. The system asks for the communication information of the responsible nurse or staff when the staff wants to send an email about an update on device conditions such as failure or alarm limit change request.

3.2.9 Adverse Events

Reporting device-related adverse events and product problems about medical equipment is an obligation in the USA. Hence the FDA announced the Medical Device Reporting (MDR) regulation (21 CFR Part 803). It includes some mandatory requirements for manufacturers, importers, and device user facilities.

The Manufacturer and User Facility Device Experience (MAUDE) online database is a compulsory reporting system by the Food and Drug Administration (FDA) in the USA. The MAUDE is an international database, which serves to clinicians all around the world. It includes reports of adverse events caused by equipment failure, death or severe injury. If a device is defective or is at risk, the FDA may issue or withdraw warnings. MAUDE is updated quarterly [33].

Revealing the consequences of adverse events is essential to improve the quality of medical care. Accurate assessment of the impact of adverse events increases the functionality of doctors, healthcare workers and the hospital [34]. The user facility should report the device-related death, severe device-related injury, and annual summary of death serious injury to both the manufacturer and authorities.

Another alternative system for reporting the adverse events, and its form contains the ID, location, and cause of an adverse event is the MedWatch [35]. In the MedQ system, the adverse event reporting form is evaluated by the MedWatch system.

Records of adverse events are typically followed up by the CE department. In the system, the CE department could reach the previous adverse event reports easily. These records help to guide the biomedical and clinical engineers to manage an adverse event situation. The source of the adverse must be mentioned to define the exact cause. The cause of the event could be patient, the user or medical equipment(Fig.3.6).

3.2.10 Evaluation Form

The CE department is evaluated annually by rating the effectiveness of the biomedical engineering program to develop their skills further. The test includes questions about the necessary documentation and standards, inventory of the devices, requirements for the calibration, and maintenance and storage of the data. Each section has its overall effectiveness rating over a total of 100 points. The form aims to compare the ratings of previous years and to determine the progress level of the CE department [36].

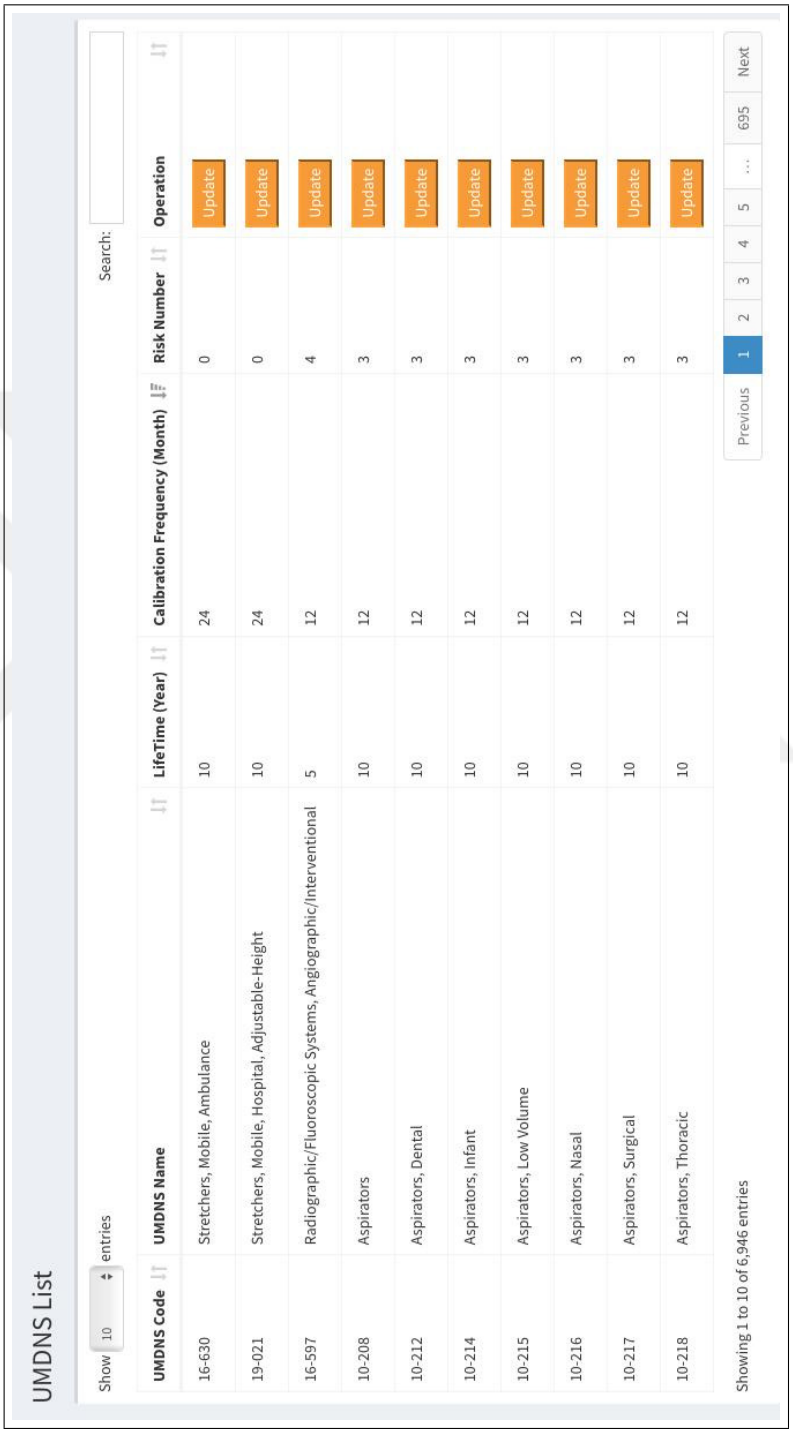


Figure 3.1 The screenshot of the UMDNS list in the system.

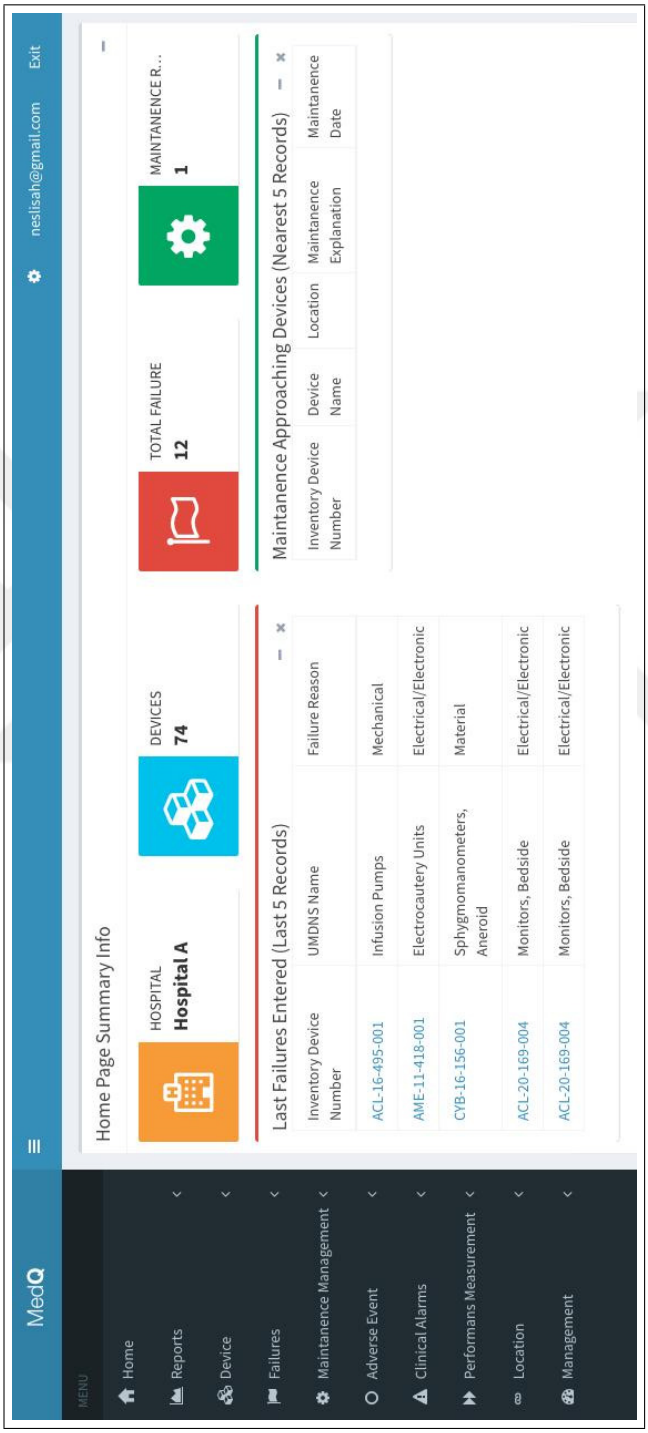


Figure 3.2 The homepage screenshot.

Figure 3.3 The failure inventory screenshot.

Figure 3.4 An example of the system email.

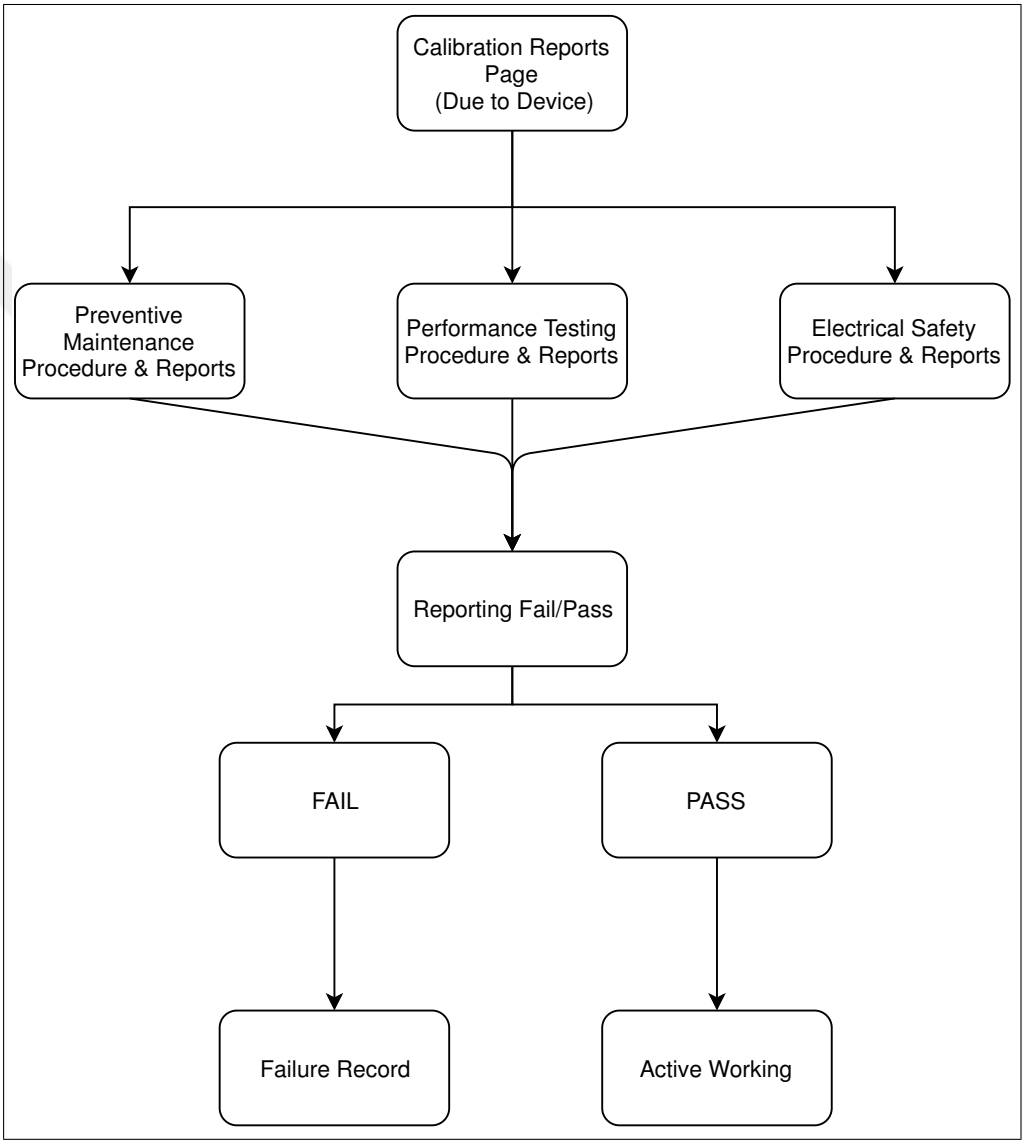


Figure 3.5 The flow chart for calibration/P.M. process.

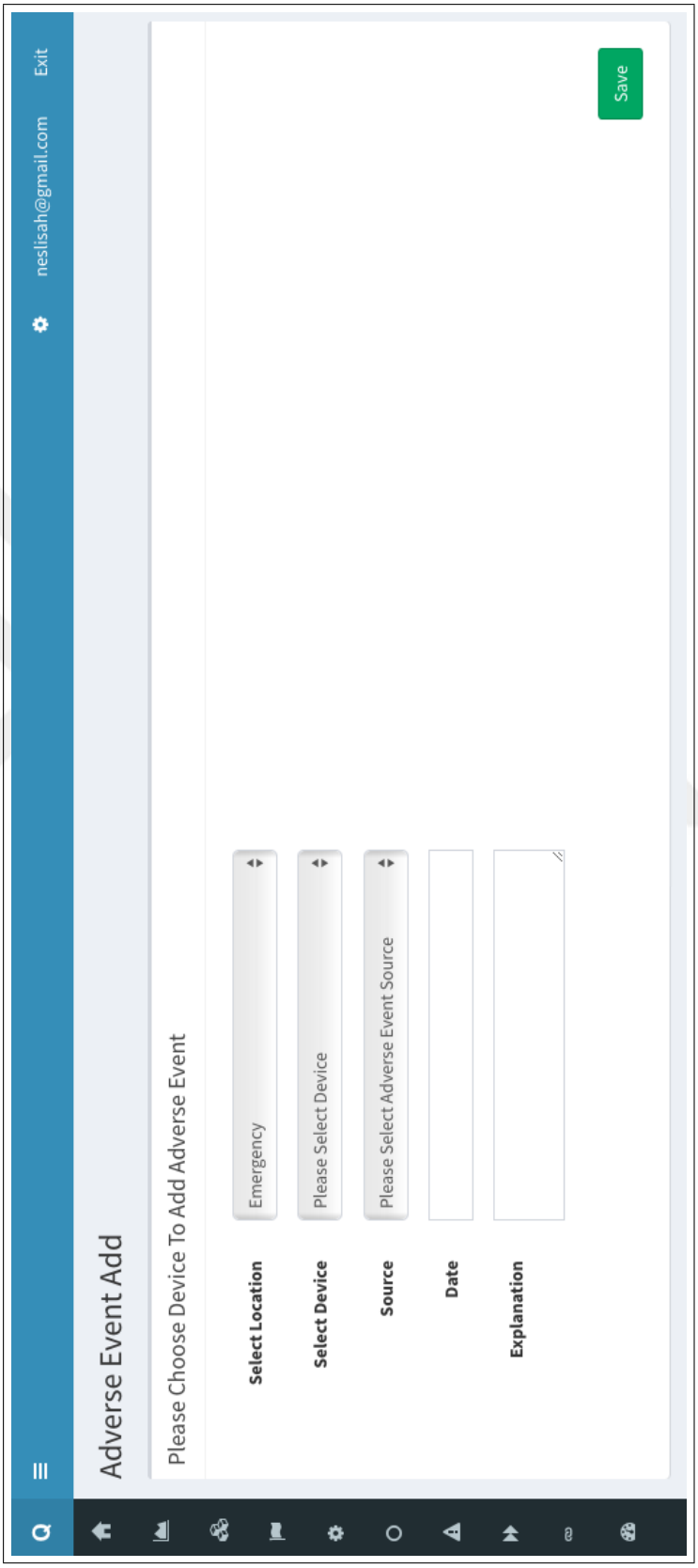


Figure 3.6 The adverse event form.

4. RESULTS

The system was partially tested in selected departments of a small sized hospital for two months. In total, 74 pieces of medical equipment were registered. The details belong to the medical equipment that could be shown in Appendix B. The range of use provided some specific results about patient safety. Synthetic data was used to test the modules added later, such as clinical alarms, adverse events and idle times.

One of the aims of the MEDQ was to detect and prevent nuisance false alarms. Thirty-two medical devices were marked as high-risk and also added to the alarm inventory to follow up their alarms(Figure 4.1). Increased audible, visual alarms reduced the sensitivity and reflex of nurses. As a novelty, determining the correct alarm limits and changing them with the approval of relevant nurses were some of the solutions offered by the system.

Secondly, a detailed follow-up list for each device was created in the medical equipment performance report. This approach helped to manage and complete the calibration process for all devices. A sample calibration report is given in Figure 4.2.

When calibration tests were not completed in 6 devices out of 13 patient monitors, since they were connected to the patients, the system kept this information to accomplish their calibrations later. By making sure that devices were maintained and calibrated correctly, and the clinical alarms were checked, the distress of the patients caused by the medical equipment was minimized, and MEDQ software system overall helped with increasing patient safety. During a calibration session of the medical equipment, some of the devices could be in use, connected to the patient or unavailable for calibration for several reasons. The CE members confirm each device in the list after completing the calibration properly. For remote devices, the status becomes a red cross to emphasize that they did not complete or start the calibration tests, as shown in Figure 4.3.

In the Reports module, data were compiled according to various parameters and presented graphically for the user, as shown in Figure 4.4. As a result of these reports, causes of breakdowns for a specific location or medical device could be easily determined, and necessary measurements could be taken immediately considering patient safety.

The idle time of medical equipment was calculated to define the uptime. This calculation was also referred to in determining the repair time of each failure record (Figure 4.5). The reports for idle time compiled the information in the failure records and converted them to easy-to-read statements. Device faults were resolved within approximately 48 hours. In the case of expecting spare parts from the seller/manufacturer, this period may be extended to a few days.

The system also recorded expenditures on faults. These records are presented in detail in the fault price report (Figure 4.6). Out of 12 failures recorded, 4 had repair costs.

When the detailed malfunction table of the devices was examined, 33% of the failures were caused by electricity or electronics (Figure 4.7). Mechanical failures followed this at a rate of 20%. In this case, it could be stated that either caused malfunctions by the device or the institution infrastructure. The institution could make long-term warranty agreements to reduce the costs of breakdowns. User training is also recommended in the multiplicity of user-related faults.

The system collected the failure data and arranged them based on their locations (Figure 4.8). The purpose of this report is to identify the departments that give the most device malfunction within the hospital. Thereby, the system provided a solution to the source of the problem to decrease the failure rate.

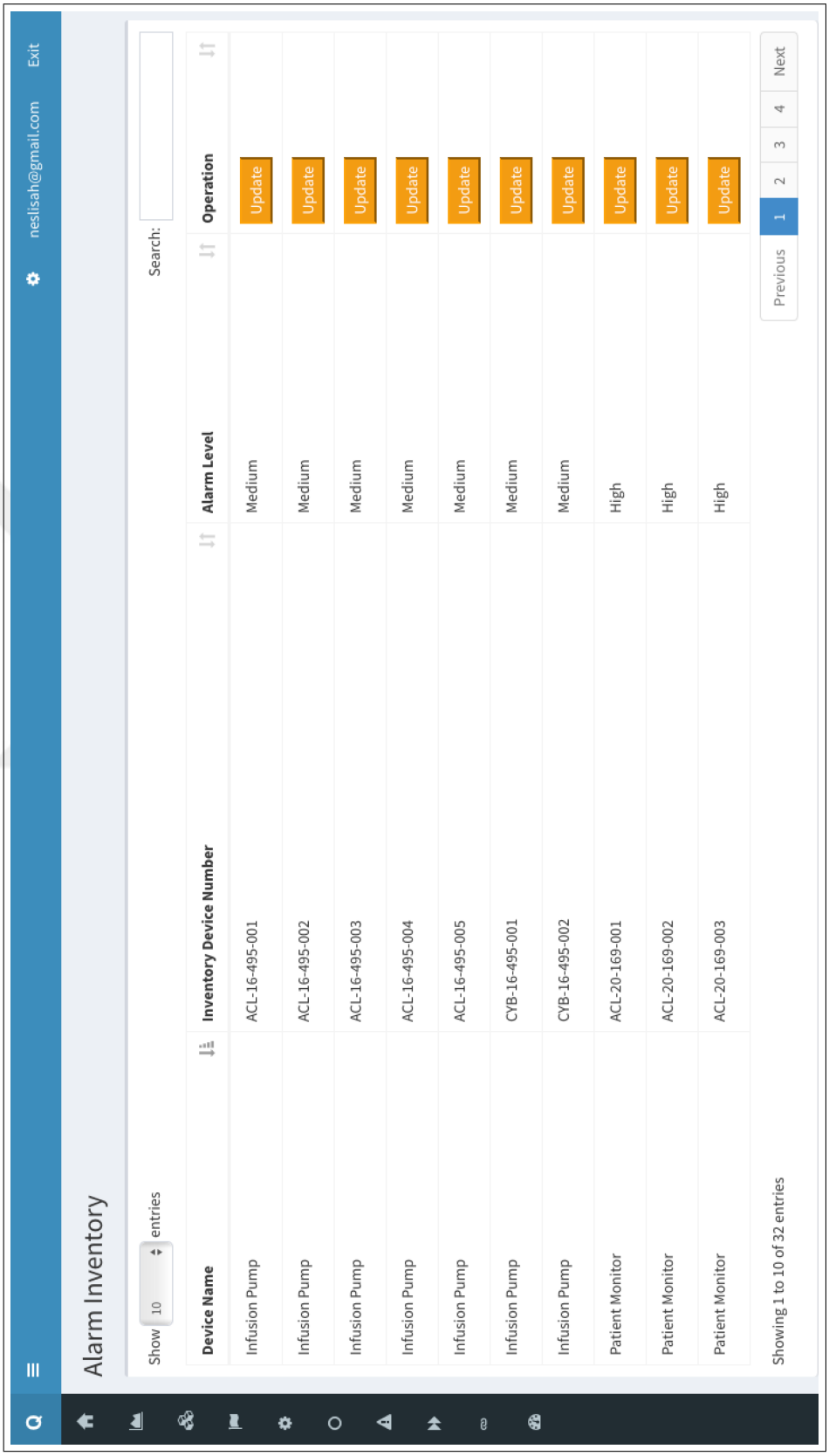


Figure 4.1 The clinical alarm inventory screen.

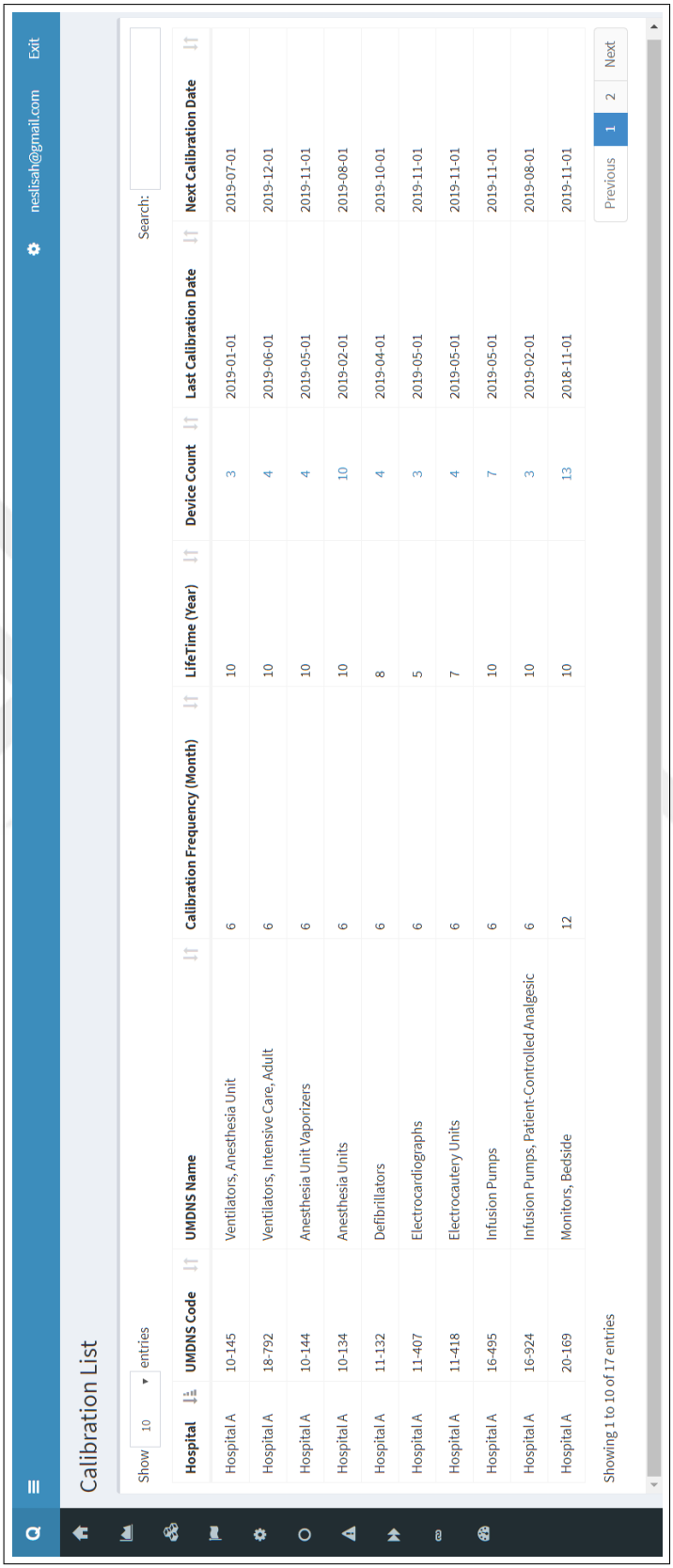


Figure 4.2 Calibration report screenshot.

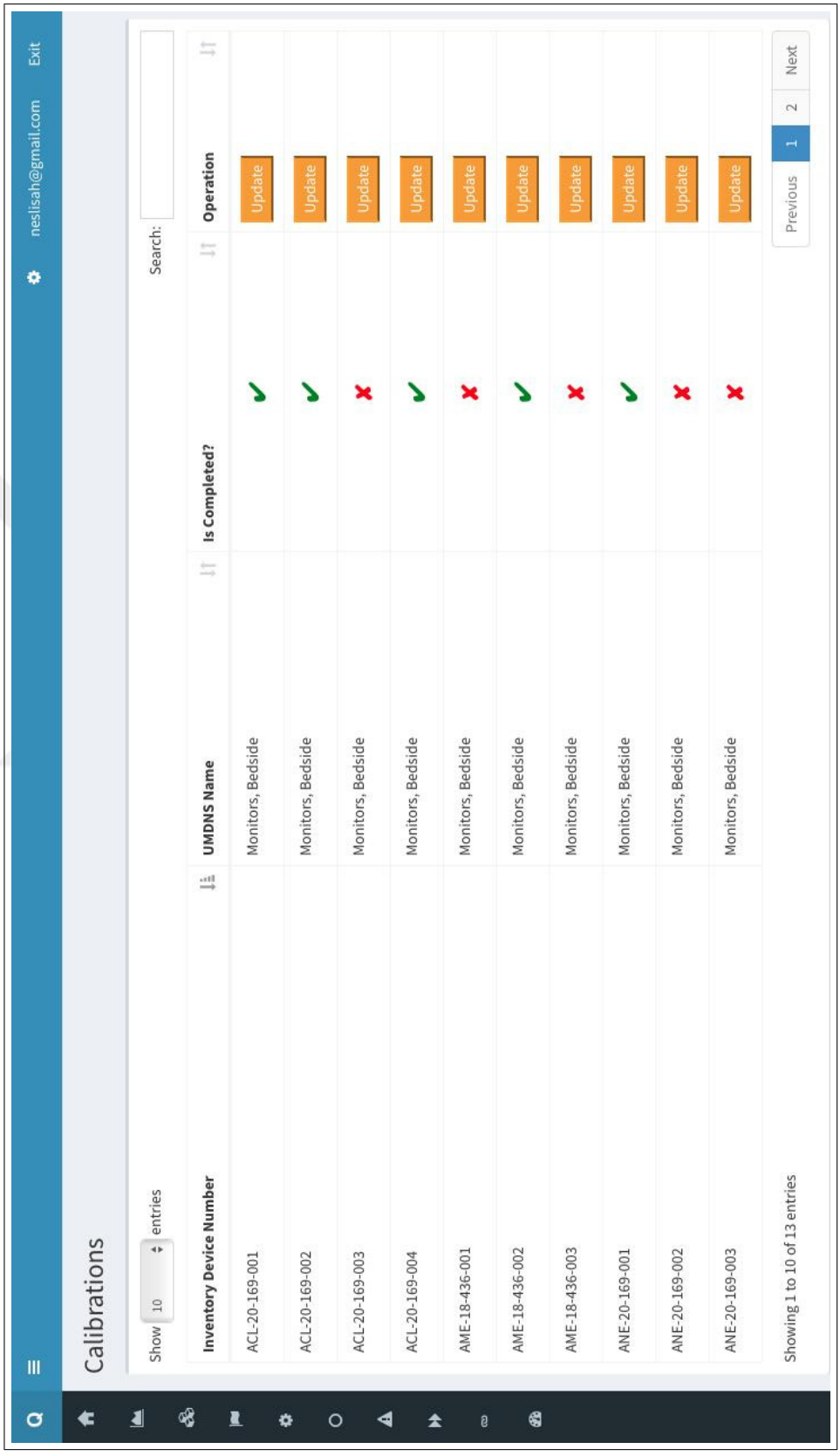


Figure 4.3 Calibration status change screen.

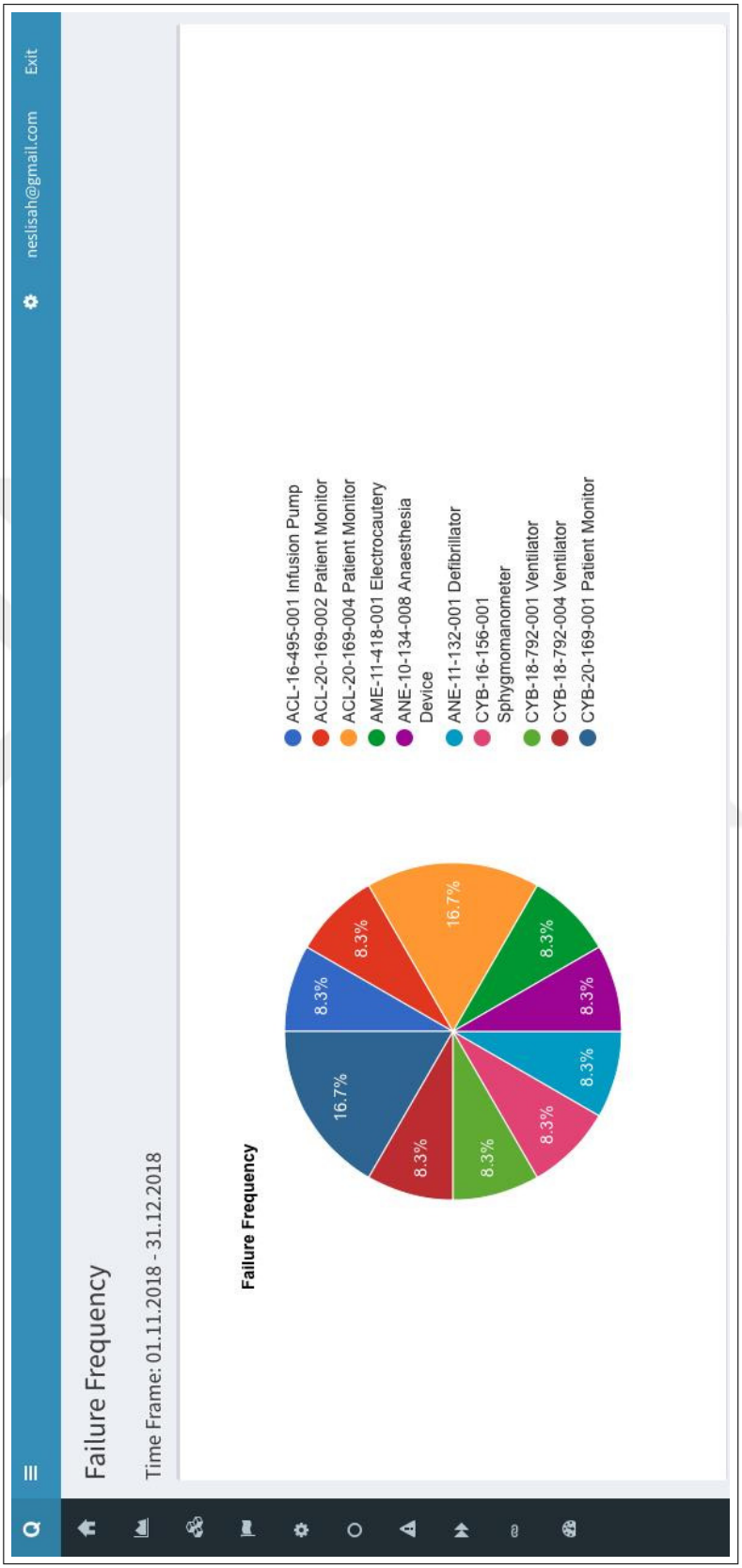


Figure 4.4 The percentage of failures for medical equipment.

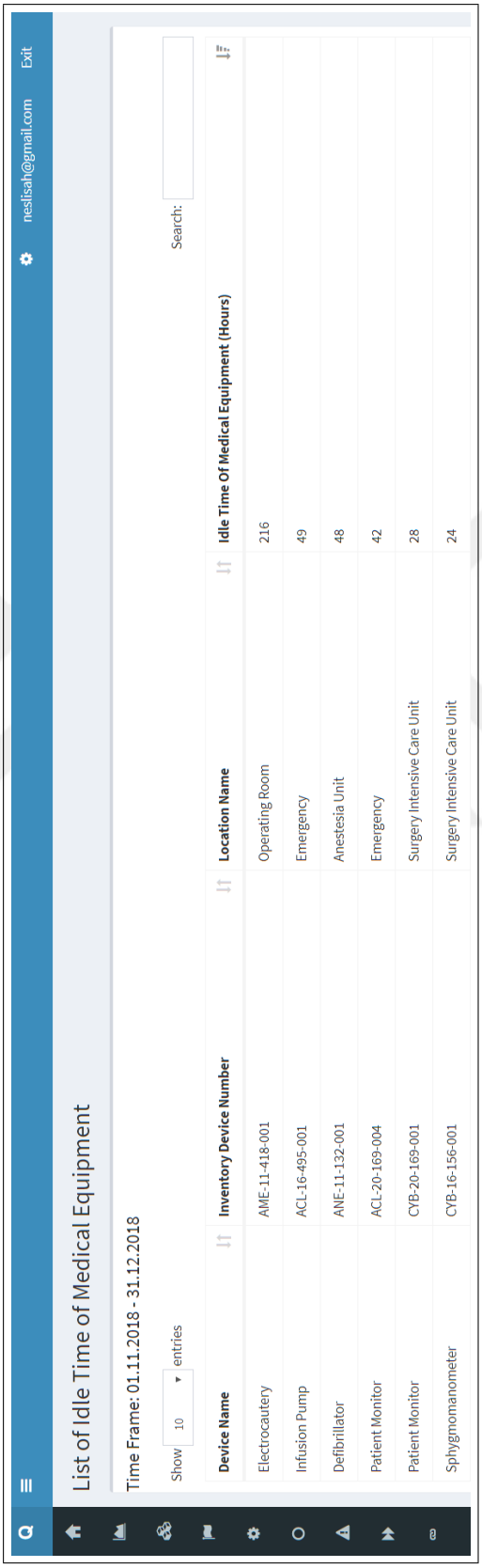


Figure 4.5 The idle time of medical equipment.

Figure 4.6 The device failure cost report.

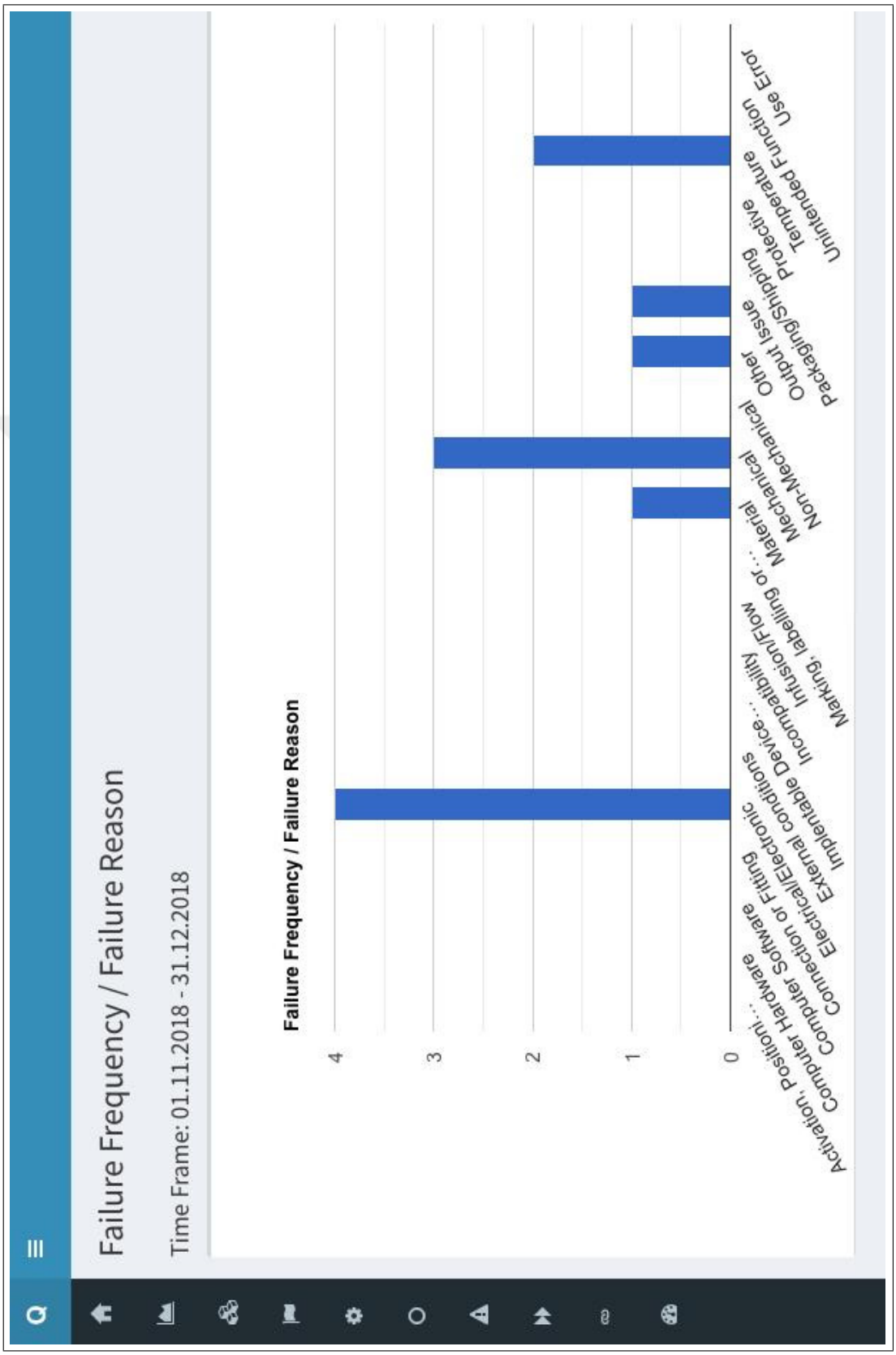


Figure 4.7 The failure number/failure cause chart.

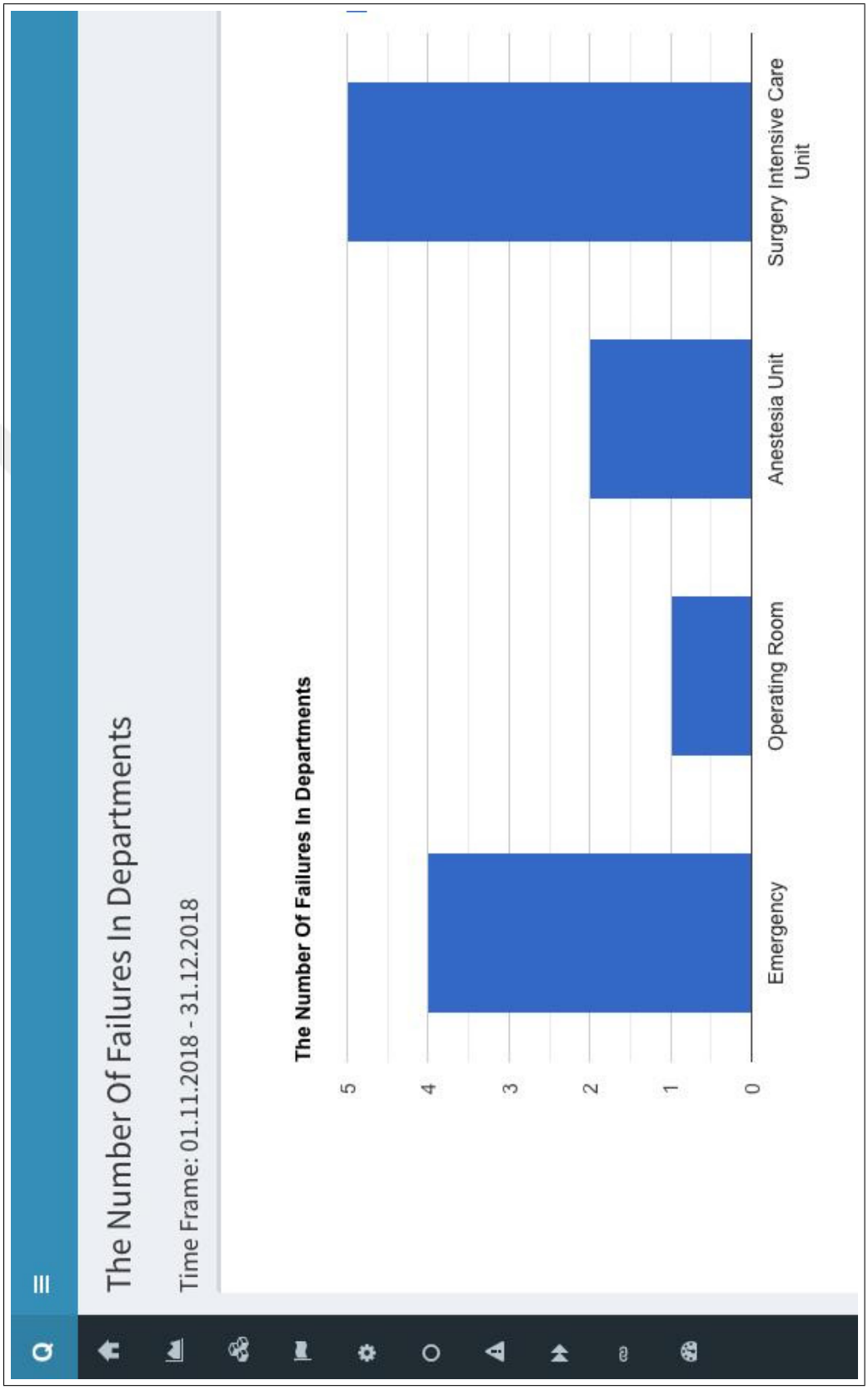


Figure 4.8 The number of failures in each location.

5. DISCUSSION AND CONCLUSION

The MEDQ system provides software to control and management of medical equipment. This system collects all available data from medical equipment for hospital management. For this system to work effectively and correctly, users in all departments must be well trained. The results of the system help to identify the main problems associated with the practical and safe use of medical equipment. One of the most critical inferences of the system is that it can direct the user to solve these problems. For example, user training can be organized in departments with high failures due to user error. The problems caused by the infrastructural deficiencies of the institution can be solved by making various investments. Depending on the results presented, higher quality consumables can also be selected. Accurate evaluation of the reports provided by the system leads the organization to more precise solutions.

The data about adverse events and clinical alarms are using to increase patient safety. The adverse event directly affects the patients in all departments in the hospital and cause unintended harm, injury or death. On the other hand, departments like ICU is suffering primarily from nuisance/false clinical alarms. The nuisance/false clinical alarms cause distractibility in the nurse and reduce performance on time. Properly detection of the problems of adverse events and nuisance/false clinical alarms is the first step to defeat them.

The program offers a convenient solution to meet critical requirements for managing medical equipment that is cost-effective compared to pre-packaged software packages. The system is flexible, and the functionality of the program can be customized to provide other customized solutions. Software systems are always open to further development and can be changed at user request. A work order is among the planned events. A job order allows the user to assign a system-defined job to other users defined in the system. A specified user can assign work in the program to biomedical engineers to share work and avoid any conflict with the work. Creating a work order page will

be developed as a future feature.

One of the limitations of this software was that it does not register consumables and spare parts. The life-consumption environment at the facility was not under control. The system can also be extended to include sections for spare parts and consumables. Besides, the latest technologies can be adapted to the system to make the interface more user-friendly and easier to use. For example, the barcode reader can be added to the system for this purpose. In the local market, each device has a barcode label and will facilitate the control of MEDQ system and medical equipment.

6. List of publications produced from the thesis

1. Accepted-A Comprehensive Medical Equipment Management Software System For Increased Patient Safety, N. Akar, A. Y. Ülgen, E. Öztürk Işık,*Medical Measurement and Applications*, Istanbul, 2019.

APPENDIX A. WHO Inventory Criteria

A.1 WHO Inventory Main Criteria

Table 1. Inventory data

Item	Brief description/ purpose	Type of inventory
Minimum data included in inventory records		
identification Equipment number	Unique identifier for each piece of equipment	Medical equipment
Type of equipment/ item	Identifies what the item is, using standard and uniform nomenclature, such as the Universal Medical Device Nomenclature System (UMDNS) or Global Medical Device Nomenclature (GMDN)	All
Brief description of equipment/ item	Describes the item, including its function/ purpose	All
Manufacturer	Identifies the company that makes the item, including the name, address and contact details of the manufacturer	All
Model/ part	Unique identifier of the product line (assigned by the manufacturer)	All
Serial number	Unique identifier of the item (assigned by the manufacturer)	All
Physical location within health-care facility	Includes room number or department; allows medical equipment to be located when preventive maintenance is due; may include storeroom information for consumables and spare parts	All
Condition/ operating status	Identifies equipment as "in service" or "out of service"; includes reason for being out of service, such as calibration due, preventive maintenance due, under repair, awaiting spare parts or damaged beyond repair	Medical equipment, testing equipment
Power requirements	Clarifies the required power to run the equipment, such as 110V, 220V, 380V or three-phase; may be useful for identifying equipment that requires transformers or other special attention	Medical equipment, testing equipment
Operation and service requirements	Identifies any special requirements needed in operation or service of equipment	Medical equipment
Date inventory performed/ updated	Date the equipment was entered into the inventory and the last date the information was updated	All
Maintenance service provider	Lists details of provider including name, contact details and contract details when medical equipment is maintained by an outside service organization (including when under warranty by manufacturer) or peripheral workshop; information on maintenance performed	Medical equipment, testing equipment
Purchase supplier	Used as a point of contact regarding purchase, reorders, warranty replacements, etc.	All

Figure A.1 WHO [1] Inventory Criteria.

A.2 WHO Inventory Criteria - Expanded

Additional useful information		
Lot number	May be assigned for consumables or reagents manufactured in the same batch; can assist in identifying defects; useful for stock-control systems for consumables	Consumables
Current software and firmware version numbers	Used for equipment run with computer software or electronics (firmware); can be used to identify software- or firmware-related problems	Medical equipment, testing equipment
Department ownership details	Identifies point of contact for notification in service delays, and to schedule preventive maintenance	Medical equipment
Purchase cost	Serves as an input to capital inventory values and for budgeting purposes	All
Purchase date	In the case of capital assets, used to calculate depreciation values or replacement/ obsolescence determination. In the case of consumables or spare parts, may be used to determine usage rates, reorder requirements and expiration dates	All
Warranty expiration date	Useful in tracking warranty validity and expiration	All
Installation date and acceptance testing information and results	Serves as a foundation for the service history record and is used as a reference when troubleshooting	Medical equipment, testing equipment
Safety/ risk assessment/ classification	Includes the risk assessment performed (or other rationale, if needed) that determined inclusion of equipment in the inventory; may also be used to determine equipment testing and repair priority	Medical equipment
Preventive maintenance schedule and procedures	Outlines frequency of preventive maintenance intervals and procedures for maintenance	Medical equipment, testing equipment
Calibration dates performed and results, dates due and procedures	Serves as a reference when troubleshooting equipment and ensures equipment is within calibration dates	Medical equipment, testing equipment
Stock and reorder quantities	When used in stock-control systems, serves as a trigger point for reorder when stock numbers reach an identified level	Spare parts, consumables
Associated devices/ systems/ accessories/ consumables/ spare parts	Identifies important supportive equipment, including any apparatus or accessories required to run a piece of equipment; part numbers for accessories, spare parts and consumables are helpful	Medical equipment, testing equipment
Year of manufacture	Used to calculate the age of the equipment; used with expected equipment lifetime as an input to determine when an item needs to be replaced, retired or discarded	Medical equipment, testing equipment
Expected equipment lifetime	Lists the expected amount of time (typically in years) that a piece of equipment may be safely and effectively in service; may be used as an input to determine when an item needs to be replaced, retired or discarded	All
Operating and service history	May include user or maintenance logbooks (for operation or service), work order or service reports, preventive maintenance reports and other information regarding the operation and service of the equipment; can be used when troubleshooting failures, evaluating purchases of new, similar equipment, and determining when an item needs to be replaced, retired or discarded	Medical equipment, testing equipment
History of recalls and reported hazards	Used to identify and follow up on any potential hazards associated with machine use	Medical equipment, testing equipment
Any other desired information	An inventory is useful to a health-care facility only if it contains important information needed by the facility; therefore, any data fields can be added as deemed necessary	All

Figure A.2 WHO [1] Inventory Criteria-Expanded.

APPENDIX B. The Inventory

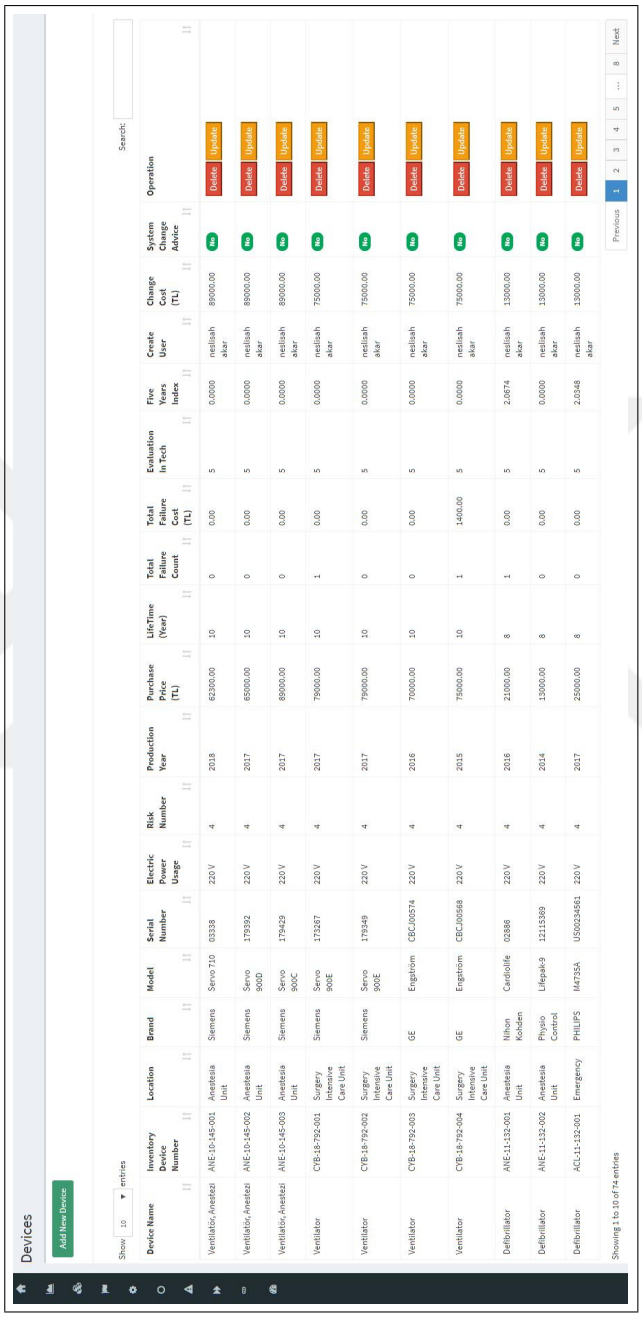


Figure B.1 The Inventory Page 1.

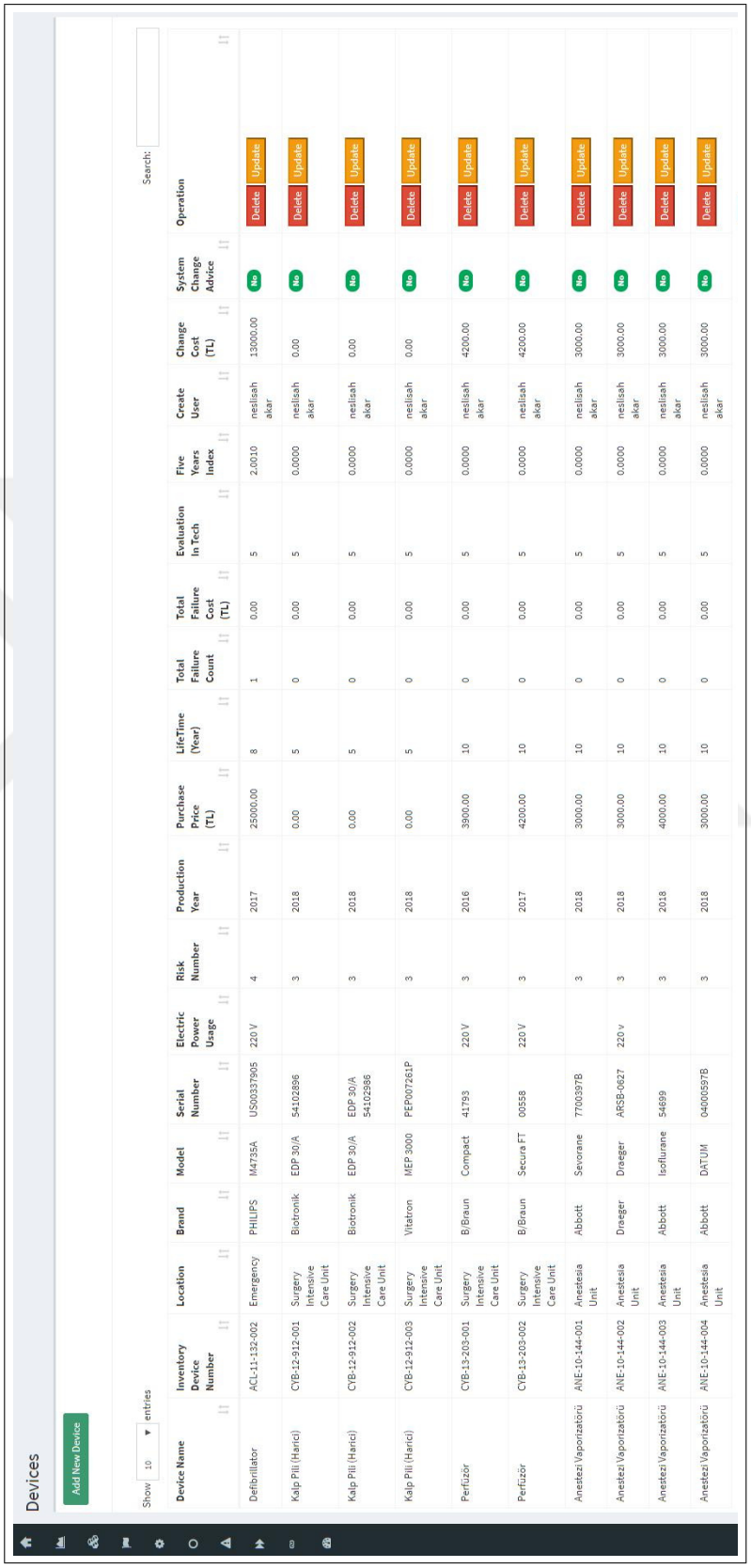


Figure B.2 The Inventory Page 2.

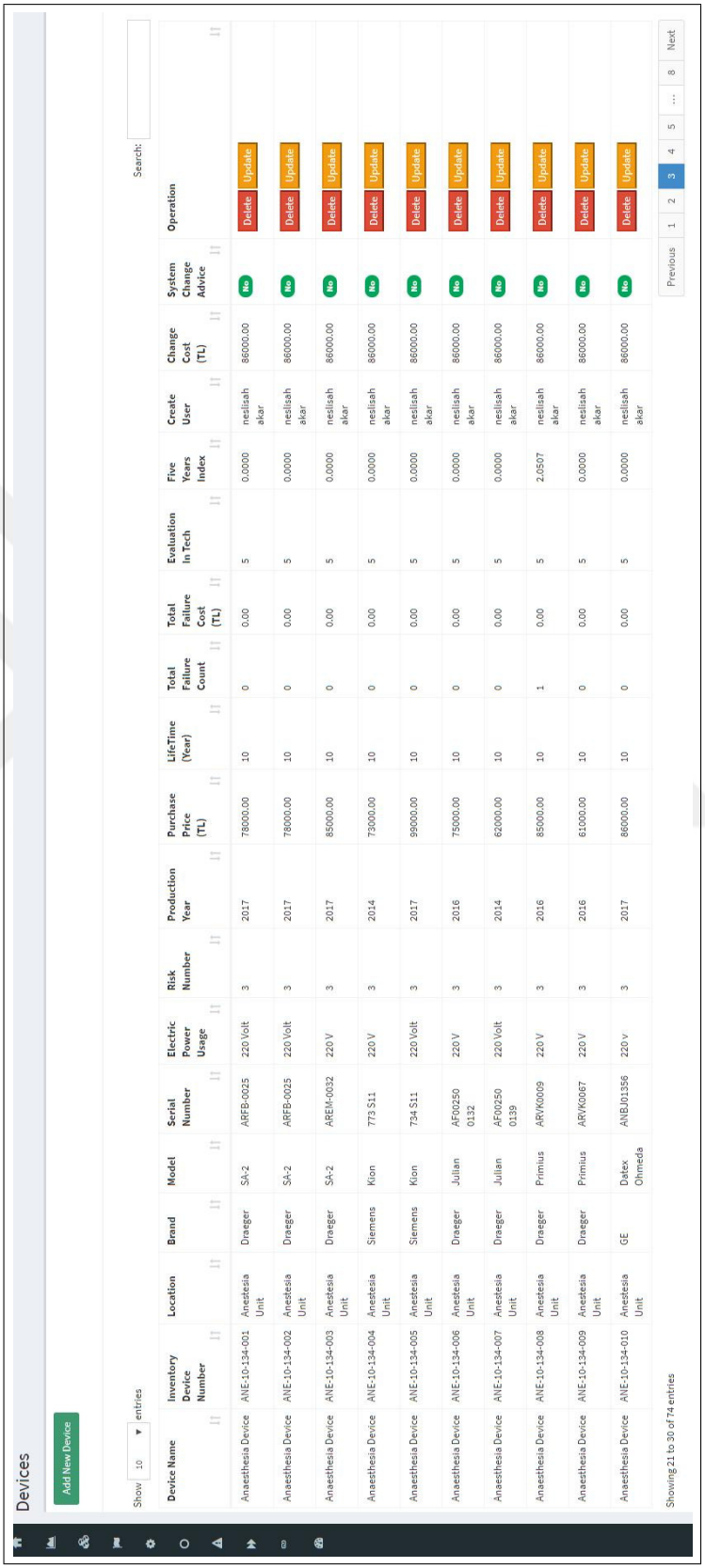


Figure B.3 The Inventory Page 3.

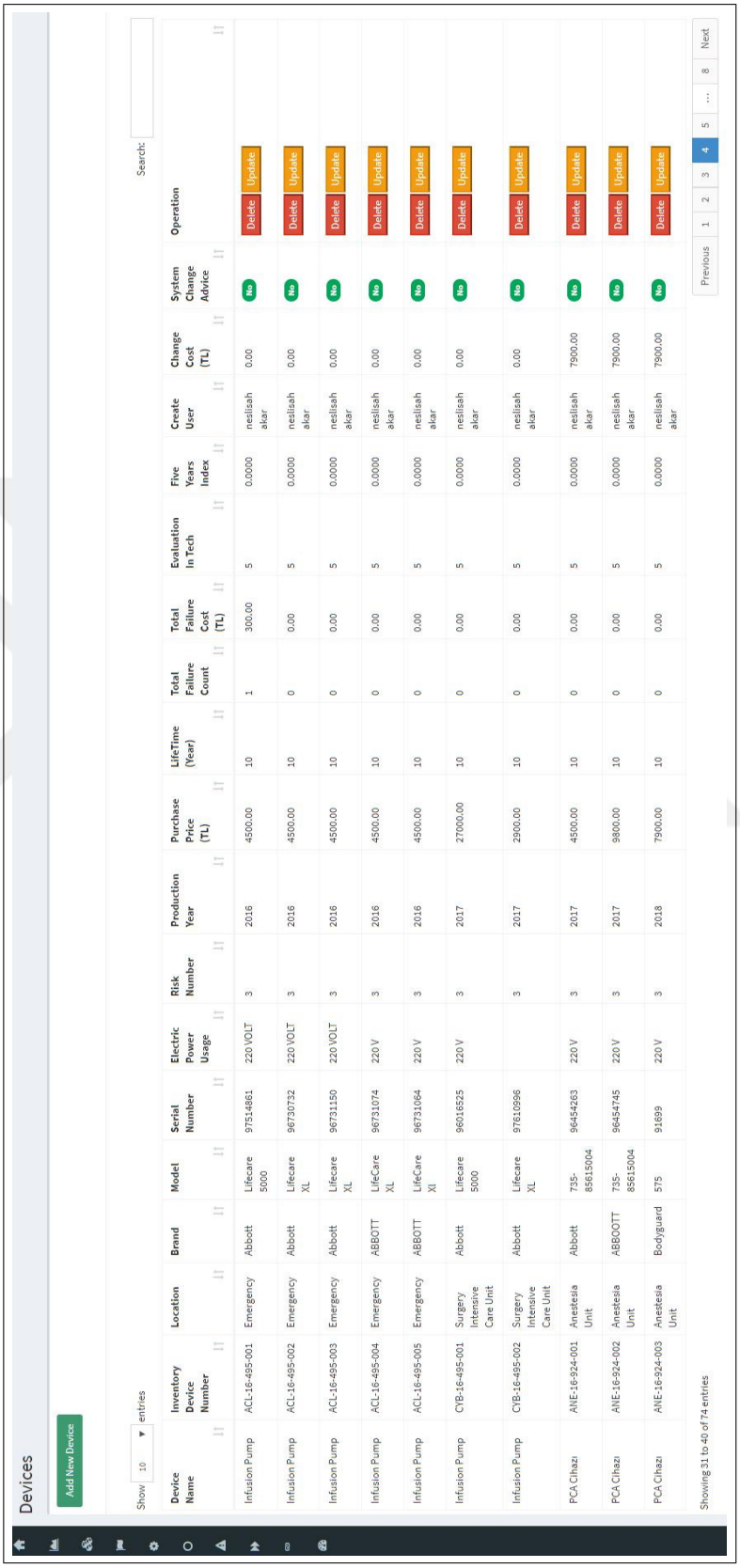


Figure B.4 The Inventory Page 4.

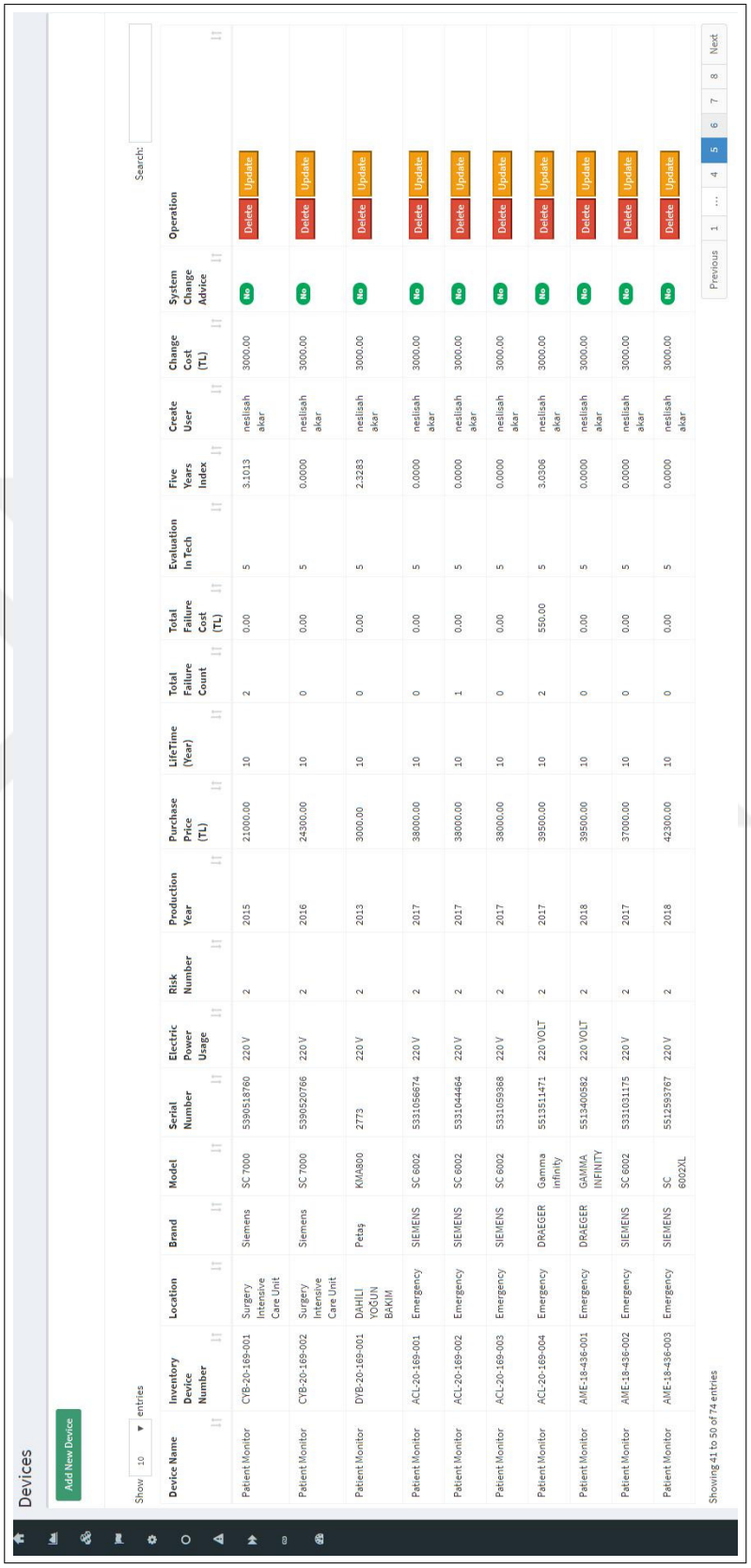


Figure B.5 The Inventory Page 5.

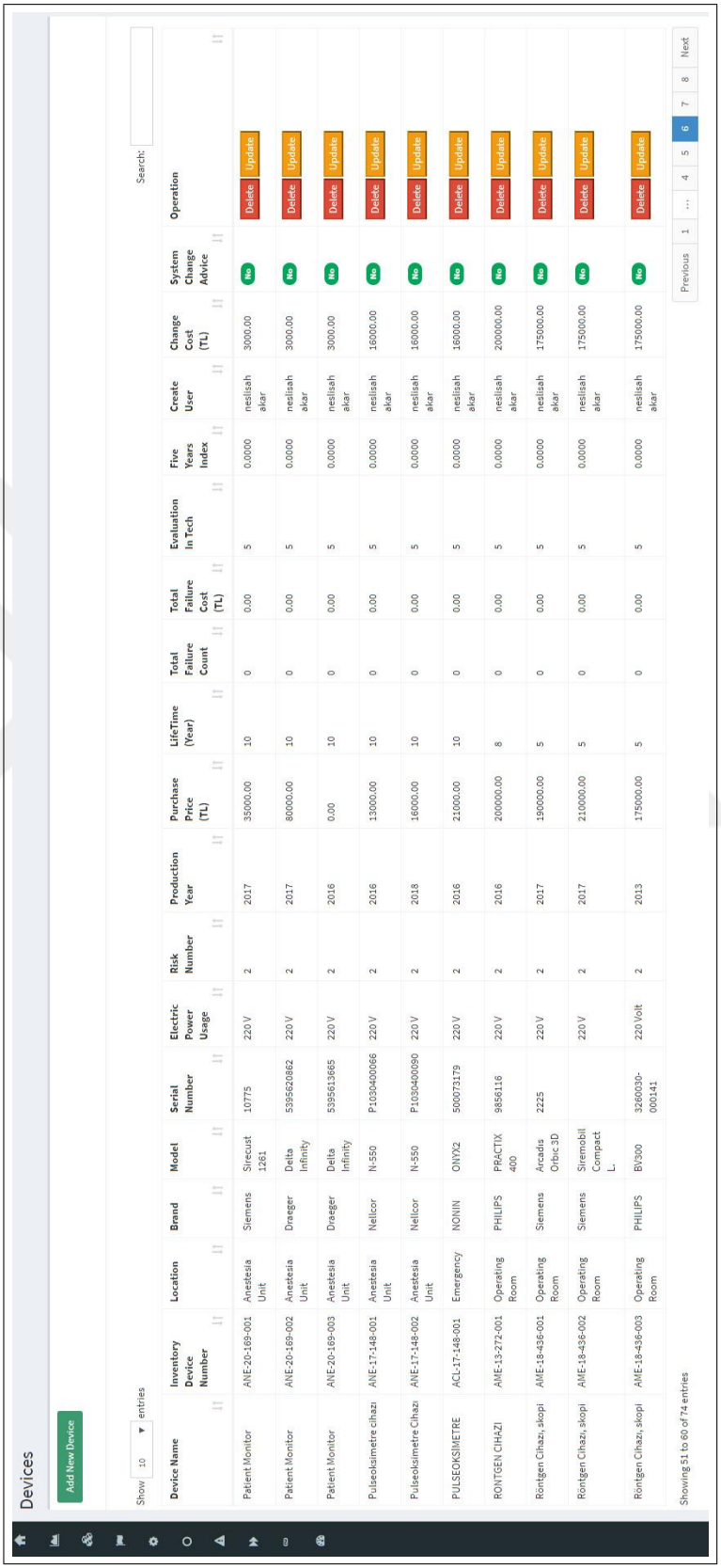


Figure B.6 The Inventory Page 6.

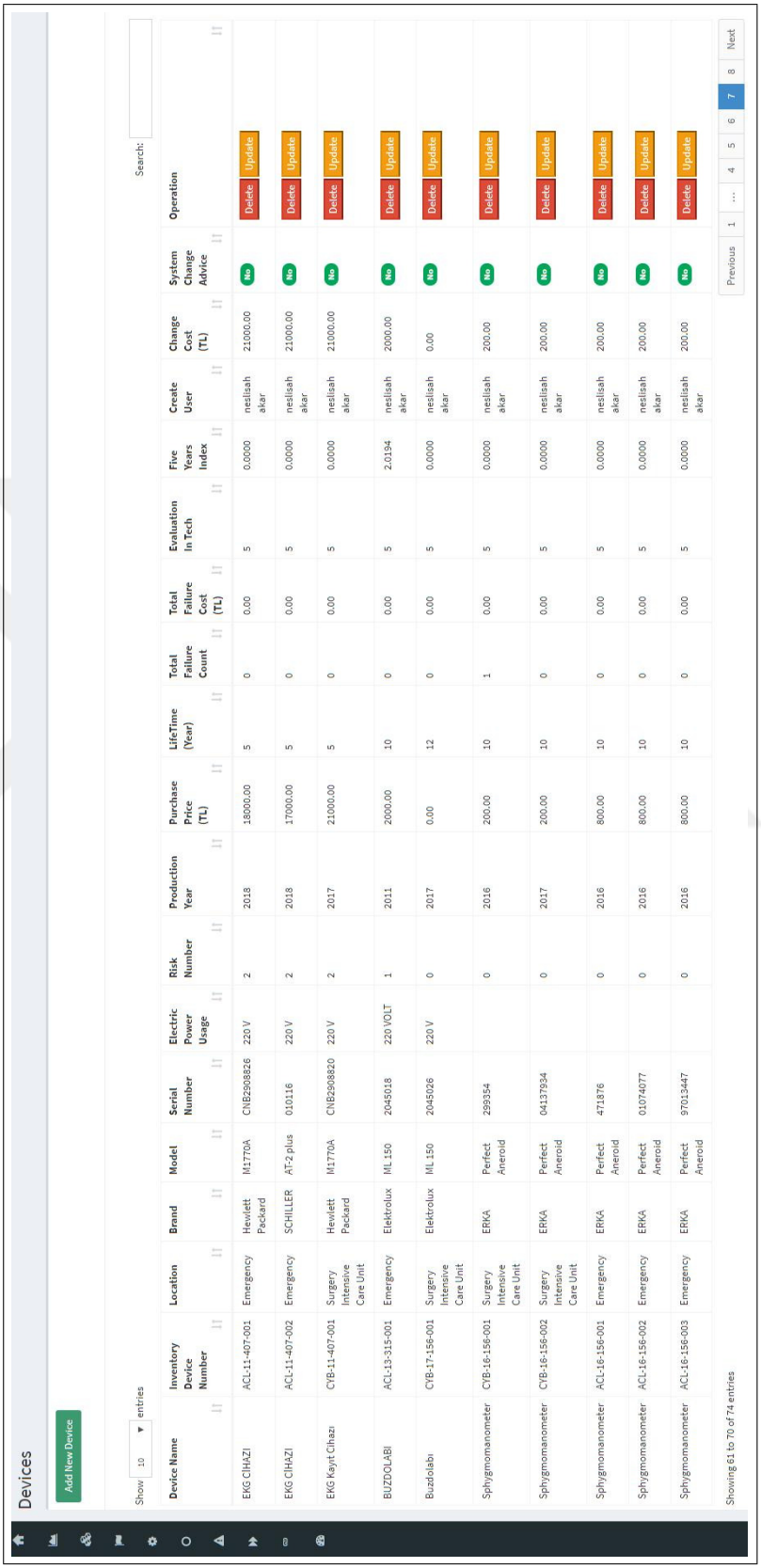


Figure B.7 The Inventory Page 7.

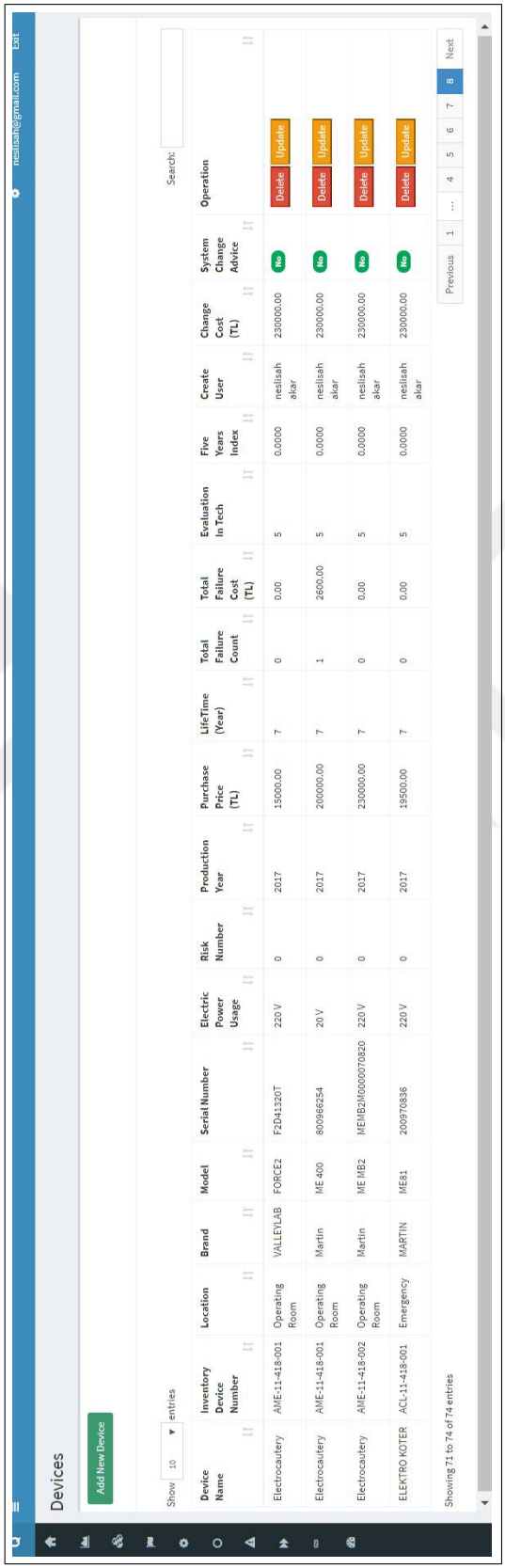
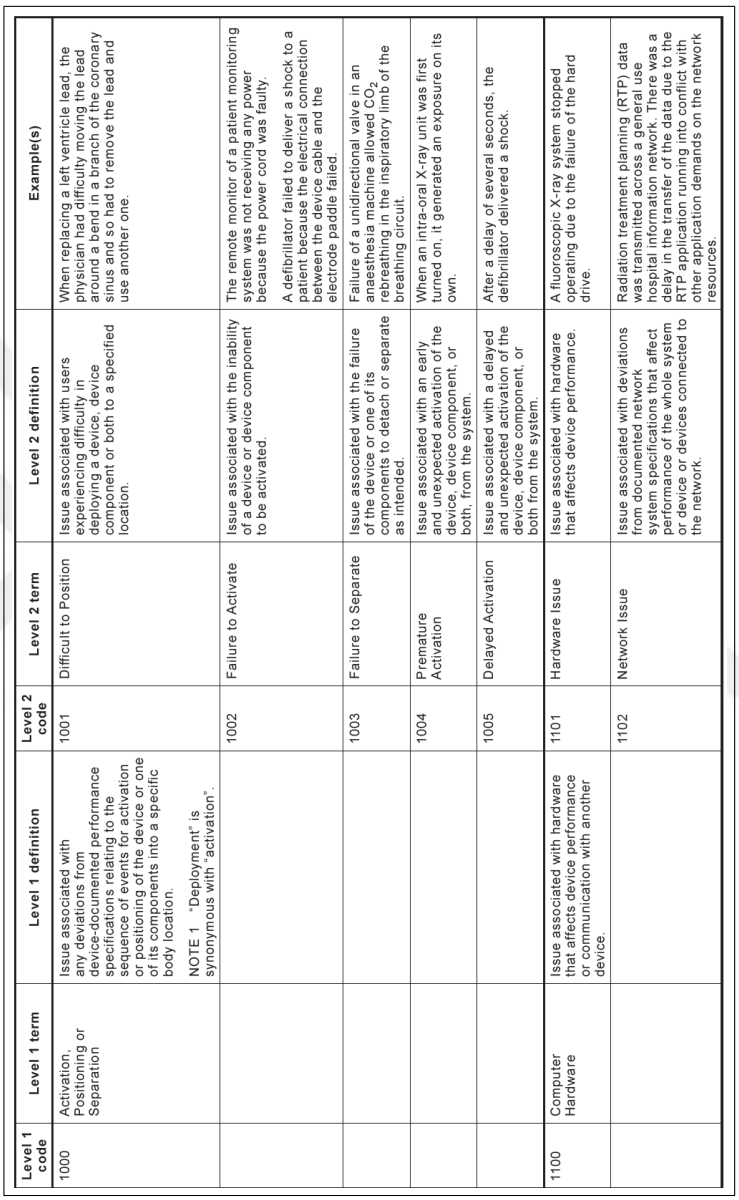


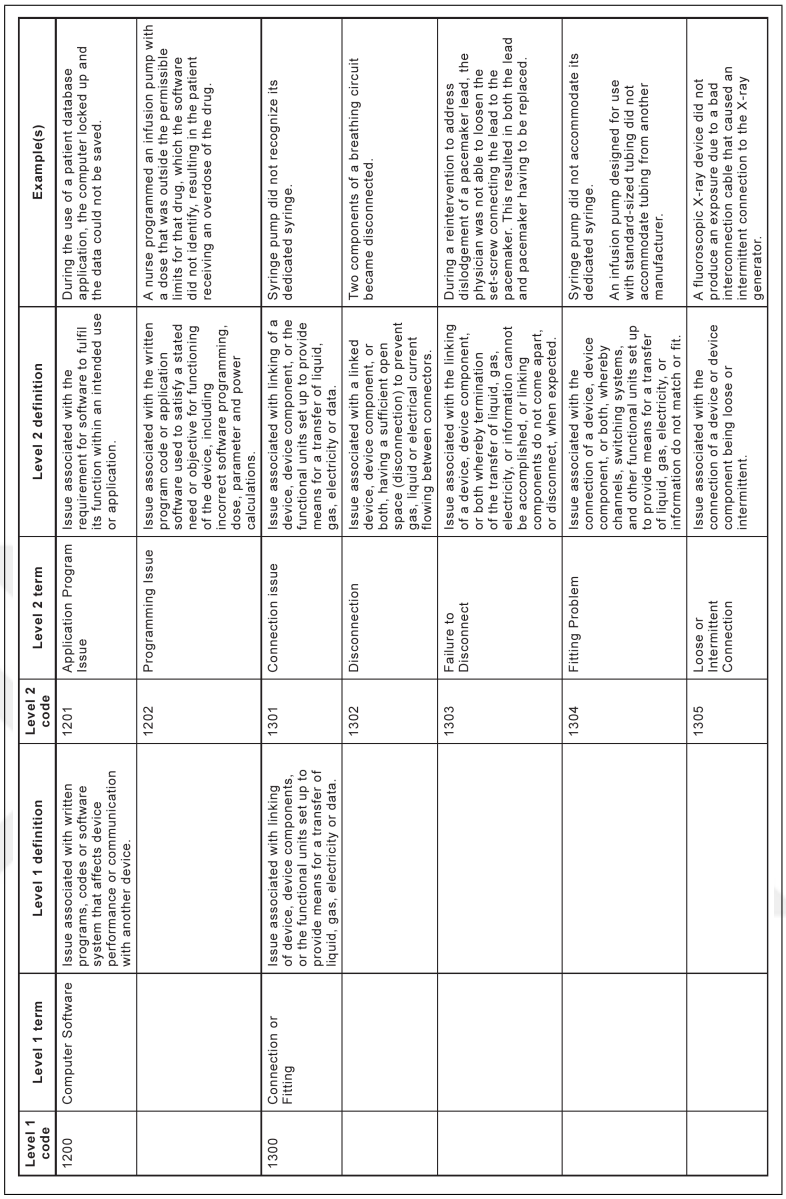
Figure B.8 The Inventory Page 8.

APPENDIX C. ISO 19218-1Medical devices-Hierarchical Coding Structure Part 1: Event Type Codes



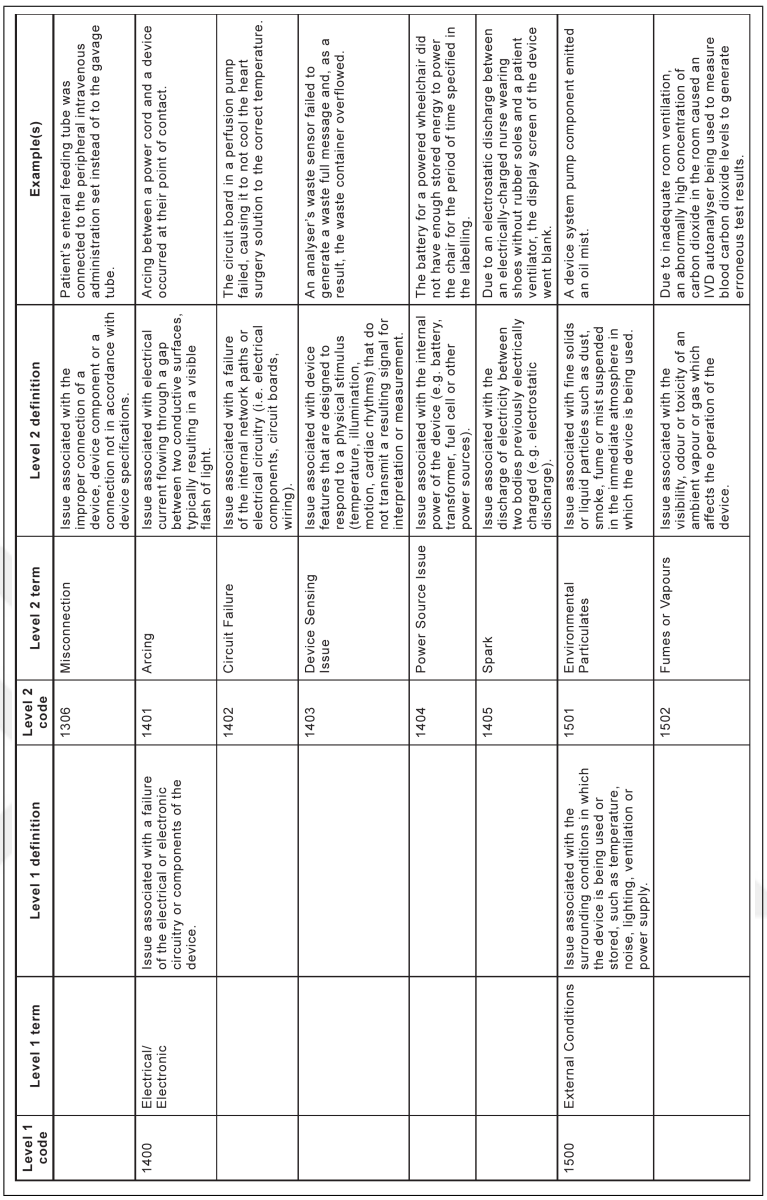
Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition	Example(s)
1000	Activation, Positioning or Separation	Issue associated with any deviations from device-documented performance specifications relating to the sequence of events for activation or positioning of the device or one of its components into a specific body location. NOTE 1 "Deployment" is synonymous with "activation".	1001	Difficult to Position	Issue associated with users experiencing difficulty in deploying a device, device component or both to a specified location.	When replacing a left ventricle lead, the physician had difficulty moving the lead around a bend in a branch of the coronary sinus and so had to remove the lead and use another one.
			1002	Failure to Activate	Issue associated with the inability of a device or device component to be activated.	The remote monitor of a patient monitoring system was not receiving any power because the power cord was faulty. A defibrillator failed to deliver a shock to a patient because the electrical connection between the device cable and the electrode paddle failed.
			1003	Failure to Separate	Issue associated with the failure of the device or one of its components to detach or separate as intended.	Failure of a unidirectional valve in an anaesthesia machine allowed CO_2 rebreathing in the inspiratory limb of the breathing circuit.
			1004	Premature Activation	Issue associated with an early and unexpected activation of the device, device component, or both, from the system.	When an intra-oral X-ray unit was first turned on, it generated an exposure on its own.
			1005	Delayed Activation	Issue associated with a delayed and unexpected activation of the device, device component, or both from the system.	After a delay of several seconds, the defibrillator delivered a shock.
1100	Computer Hardware	Issue associated with hardware that affects device performance or communication with another device.	1101	Hardware Issue	Issue associated with hardware that affects device performance.	A fluoroscopic X-ray system stopped operating due to the failure of the hard drive.
			1102	Network Issue	Issue associated with deviations from documented network system specifications that affect performance of the whole system or device or devices connected to the network.	Radiation treatment planning (RTP) data was transmitted across a general use hospital information network. There was a delay in the transfer of the data due to the RTP application running into conflict with other application demands on the network resources.

Figure C.1 ISO 19218-1Medical devices-Hierarchical Coding Structure Part 1: Event Type Codes.



Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition	Example(s)
1200	Computer Software	Issue associated with written programs, codes or software system that affects device performance or communication with another device.	1201	Application Program Issue	Issue associated with the requirement for software to fulfil its function within an intended use or application.	During the use of a patient database application, the computer locked up and the data could not be saved.
			1202	Programming Issue	Issue associated with the written program code or application software used to satisfy a stated need or objective for functioning of the device, including incorrect software programming, dose, parameter and power calculations.	A nurse programmed an infusion pump with a dose that was outside the permissible limits for that drug, which the software did not identify, resulting in the patient receiving an overdose of the drug.
1300	Connection or Fitting	Issue associated with linking of device, device components, or the functional units set up to provide means for a transfer of liquid, gas, electricity or data.	1301	Connection issue	Issue associated with linking of a device, device component, or the functional units set up to provide means for a transfer of liquid, gas, electricity or data.	Syringe pump did not recognize its dedicated syringe.
			1302	Disconnection	Issue associated with a linked device, device component, or both, having a sufficient open space (disconnection) to prevent gas, liquid or electrical current flowing between connectors.	Two components of a breathing circuit became disconnected.
			1303	Failure to Disconnect	Issue associated with the linking of a device, device component, or both whereby termination of the transfer of liquid, gas, electricity, or information cannot be accomplished, or linking components do not come apart, or disconnect, when expected.	During a reintervention to address dislodgement of a pacemaker lead, the physician was not able to loosen the set-screw connecting the lead to the pacemaker. This resulted in both the lead and pacemaker having to be replaced.
			1304	Fitting Problem	Issue associated with the connection of a device, device component, or both, whereby channels, switching systems, and other functional units set up to provide means for a transfer of liquid, gas, electricity, or information do not match or fit.	Syringe pump did not accommodate its dedicated syringe. An infusion pump designed for use with standard-sized tubing did not accommodate tubing from another manufacturer.
			1305	Loose or Intermittent Connection	Issue associated with the connection of a device or device component being loose or intermittent.	A fluoroscopic X-ray device did not produce an exposure due to a bad interconnection cable that caused an intermittent connection to the X-ray generator.

Figure C.2 ISO 19218-1Medical devices-Hierarchical Coding StructurePart 1: Event Type Codes-Cont.



Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition	Example(s)
			1306	Misconnection	Issue associated with the improper connection of a device, device component or a connection not in accordance with device specifications.	Patient's enteral feeding tube was connected to the peripheral intravenous administration set instead of to the gavage tube.
1400	Electrical/ Electronic	Issue associated with a failure of the electrical or electronic circuitry or components of the device.	1401	Arcing	Issue associated with electrical current flowing through a gap between two conductive surfaces, typically resulting in a visible flash of light.	Arcing between a power cord and a device occurred at their point of contact.
			1402	Circuit Failure	Issue associated with a failure of the internal network paths or electrical circuitry (i.e. electrical components, circuit boards, wiring).	The circuit board in a perfusion pump failed, causing it to not cool the heart surgery solution to the correct temperature.
			1403	Device Sensing Issue	Issue associated with device features that are designed to respond to a physical stimulus (temperature, illumination, motion, cardiac rhythms) that do not transmit a resulting signal for interpretation or measurement.	An analyser's waste sensor failed to generate a waste full message and, as a result, the waste container overflowed.
			1404	Power Source Issue	Issue associated with the internal power of the device (e.g. battery, transformer, fuel cell or other power sources).	The battery for a powered wheelchair did not have enough stored energy to power the chair for the period of time specified in the labelling.
			1405	Spark	Issue associated with the discharge of electricity between two bodies previously electrically charged (e.g. electrostatic discharge).	Due to an electrostatic discharge between an electrically-charged nurse wearing shoes without rubber soles and a patient ventilator, the display screen of the device went blank.
1500	External Conditions	Issue associated with the surrounding conditions in which the device is being used or stored, such as temperature, noise, lighting, ventilation or power supply.	1501	Environmental Particulates	Issue associated with fine solids or liquid particles such as dust, smoke, fume or mist suspended in the immediate atmosphere in which the device is being used.	A device system pump component emitted an oil mist.
			1502	Fumes or Vapours	Issue associated with the visibility, odour or toxicity of an ambient vapour or gas which affects the operation of the device.	Due to inadequate room ventilation, an abnormally high concentration of carbon dioxide in the room caused an IVD autoanalyser being used to measure blood carbon dioxide levels to generate erroneous test results.

Figure C.3 ISO 19218-1Medical devices-Hierarchical Coding Structure Part 1: Event Type Codes-Cont.

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition	Example(s)
			1503	Inadequate Storage	Issue associated with inadequate or inappropriate storage of the device.	As a result of the user storing the test strips in a plastic bag instead of the original container, the glucose monitor reported erroneous readings that resulted in unnecessary treatment.
			1504	Loss of Power	Issue associated with the failure of primary power provided by the facility, e.g. electrical, gas, fluid pressure.	A patient was being transported by helicopter. The intra-aortic balloon pump was plugged into a power inverter that failed, which resulted in loss of power to the balloon pump.
1600	Implantable Device Failure	The migration, malfunction or failure of an implanted device (active or non-active).	1601	Migration of Device or Device Component	Issue associated with an undesired movement of a device, device component, or both, related to its movement away from or dislodging from a source.	After a stenting procedure was completed, it was determined that the stent migrated and no longer completely covered the lesion.
			1602	Osseodisintegration Issue	Issue association with interconnection between bone and an implanted device.	Due to loosening of the connection between the hip implant and the femur, the patient required revision to address persistent pain.
1700	Incompatibility	Issue associated with the device not being compatible with another device component, patient or substance (medication, body fluid, etc.) that it contains or transports.	1701	Component or Accessory Incompatibility	Issue associated with the incompatibility of any device, device component, or both, while being operated in the same use environment thereby leading to a dysfunction between the device and its components.	When the bulb in a phototherapy lamp burned out, the neonatal intensive care unit nurse replaced it with a bulb that did not meet the manufacturer's specifications. The lamp overheated and burned the baby's skin.
			1702	Device-Device Incompatibility	Issue associated with the incompatibility of two or more devices while being operated in the same use environment thereby leading to a dysfunction of more than one device.	Users of a newly distributed enhanced algorithm found the algorithm was incompatible with the electrocardiograph's operating software, resulting in operational errors.
			1703	Patient-Device Incompatibility	Issue associated with the interaction between the patient's physiology or anatomy and the device that affects patient or device (e.g. biocompatibility or immunological issues).	During a procedure to replace a right ventricular lead, the placement was not successful due to the size of the patient's vein.
1800	Infusion/Flow	Issue associated with the device failing to deliver liquids or gases as intended (e.g. delivering drugs at incorrect rate, issues with drawing fluid from a system, etc.).	1801	Deflation Issue	Issue associated with the inability of a device, device component, or both, to release its contents.	After the balloon of a percutaneous transluminal angioplasty (PTA) balloon dilatation catheter was inflated, it could not be deflated without surgical intervention.

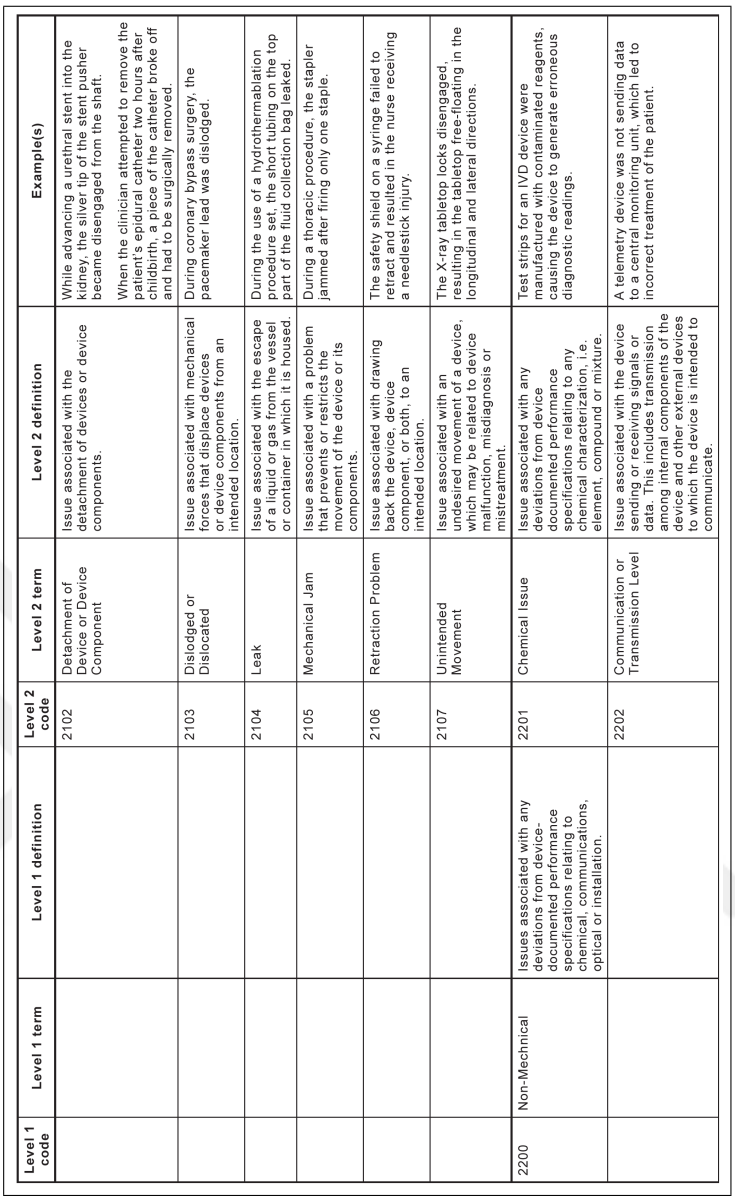
Figure C.4 ISO 19218-1Medical devices-Hierarchical Coding Structure Part 1: Event Type Codes-Cont.

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition	Example(s)
			1802	Improper Flow or Infusion	Issue associated with the unsubstantiated regulation and delivery of therapy, e.g. air, gas, drugs or fluids into a device or a patient under positive pressure that is being generated by a pump.	An infusion pump delivered a larger volume of drug than programmed to deliver. The total parenteral nutrition solution was improperly mixed and, when the bag was connected for infusion, the pump was unable to deliver the solution because it clogged the tubing.
			1803	Inflation Issue	Issue associated with the inability of a device, device component, or both, to expand or enlarge with the intended inflation agent (e.g. saline or air).	During a blood pressure reading, the limb cuff continued to inflate to a level beyond normal practice.
			1804	No Flow	Issue arising from the device failing to deliver the specified liquid or gas.	A ventilator alarmed due to a valve stuck in a closed condition blocking flow of oxygen to the patient.
			1805	Excessive Flow or Overinfusion	Issue associated with an overdose of delivery therapy, such as drugs or fluids being delivered into a device or a patient under positive pressure.	The infusion pump operator inadvertently entered an inappropriately high value for the volume of drug to be infused.
			1806	Insufficient Flow or Underinfusion	Issue associated with an underdose of therapy, e.g. epidural, intrathecal, intravenous, subcutaneous, such as drugs or fluids being delivered into a device or a patient under positive pressure.	During a phacofragmentation procedure, the viscous gas fluid injection system indicated that there was a reduced flow from the system.
1900	Marking, Labelling or Instructions for Use	Issue associated with the accuracy and appropriateness of any written, printed, graphic or audio/visual matter that is supplied with a medical device or its package. NOTE 2 Includes markings that appear directly on the device.	1901	Instruction for Use Issue	Issue associated with any matter that accompanies a medical device including instructions related to identification, technical description and use of the medical device provided by the device manufacturer.	During a procedure to implant a pacing lead, the physician was confused by a figure of the helix gap that appeared in the lead's instructions for use and contacted the manufacturer for clarification.
			1902	Markings Issue	Issue associated with the written, printed or graphic material that is affixed to a medical device or any of its packaging or accompanying materials.	The radiopaque marker bands on the balloon catheter, required for repair of an arterial lesion, were unable to be visualized under fluoroscopy. Re-positioning the balloon and changing imaging techniques were unsuccessful in allowing visualization of the radiopaque marker bands.

Figure C.5 ISO 19218-1Medical devices-Hierarchical Coding StructurePart 1: Event Type Codes-Cont.

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition	Example(s)
2000	Material	Issue associated with any deviations from device-documented performance specifications relating to the limited durability of all material used to construct the device.	2001	Burst	Issue associated with the pressure inside a vessel or container rising to such a degree that the container or vessel ruptures.	In the process of using a radio frequency sealer to seal the passageways between the large and small compartments of a cord blood freezing bag, the bag burst.
			2002	Crack	Issue associated with an undesired separation or a visible opening along the length or width in the materials that are used in device construction.	During the adjustment of a monitor the supporting arm cracked, causing the monitor to fall out of position.
			2003	Degrade	Issue associated with a deleterious change in the chemical structure, physical properties or appearance in the materials that are used in device construction.	The insulation on the atrial and ventricular leads on a patient's implanted cardiovascular pacemaker had degraded to the point that the leads had to be replaced. A reusable artery clamp showed signs of pitting and corrosion after several uses.
			2004	Material Discoloured	Issue associated with an undesired streak, pattern or a noticeable change in colour.	An implanted intraocular lens showed a brownish discolouration.
			2005	Material Fragmentation	Issue associated with small pieces of the device breaking off unexpectedly.	During a surgical procedure, the tip of the stainless steel surgical scissors broke off and fell into the surgical site.
			2006	Material Perforation	Issue associated with an undesired material damage characterized by closely spaced punched or drilled holes.	During preparation for an angioplasty procedure, the guide wire came out the side of the balloon catheter.
			2007	Material Separation	Issue associated with an undesired disassociation or breaking apart of device materials.	A patient's incision reopened because the surgical mesh used in the closure procedure became delaminated.
2100	Mechnical	Issue associated with any deviations from device-documented performance specifications relating to mechanical defects, including moving parts or subassemblies, etc.	2101	Calibration	Issue associated with the operation of the device, related to its accuracy, and associated with the calibration of the device.	The electronic gas delivery system would not calibrate during the preparation of the device for use in a cardiopulmonary bypass procedure and an error message was observed.

Figure C.6 ISO 19218-1Medical devices-Hierarchical Coding StructurePart 1: Event Type Codes-Cont.



Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition	Example(s)
			2102	Detachment of Device or Device Component	Issue associated with the detachment of devices or device components.	While advancing a urethral stent into the kidney, the silver tip of the stent pusher became disengaged from the shaft. When the clinician attempted to remove the patient's epidural catheter two hours after childbirth, a piece of the catheter broke off and had to be surgically removed.
			2103	Dislodged or Dislocated	Issue associated with mechanical forces that displace devices or device components from an intended location.	During coronary bypass surgery, the pacemaker lead was dislodged.
			2104	Leak	Issue associated with the escape of a liquid or gas from the vessel or container in which it is housed.	During the use of a hydrothermabiation procedure set, the short tubing on the top part of the fluid collection bag leaked.
			2105	Mechanical Jam	Issue associated with a problem that prevents or restricts the movement of the device or its components.	During a thoracic procedure, the stapler jammed after firing only one staple.
			2106	Retraction Problem	Issue associated with drawing back the device, device component, or both, to an intended location.	The safety shield on a syringe failed to retract and resulted in the nurse receiving a needlestick injury.
			2107	Unintended Movement	Issue associated with an undesired movement of a device, which may be related to device malfunction, misdiagnosis or mistreatment.	The X-ray tabletop locks disengaged, resulting in the tabletop free-floating in the longitudinal and lateral directions.
2200	Non-Mechnical	Issues associated with any deviations from device-documented performance specifications relating to chemical, communications, optical or installation.	2201	Chemical Issue	Issue associated with any deviations from device documented performance specifications relating to any chemical characterization, i.e. element, compound or mixture.	Test strips for an IVD device were manufactured with contaminated reagents, causing the device to generate erroneous diagnostic readings.
			2202	Communication or Transmission Level	Issue associated with the device sending or receiving signals or data. This includes transmission among internal components of the device and other external devices to which the device is intended to communicate.	A telemetry device was not sending data to a central monitoring unit, which led to incorrect treatment of the patient.

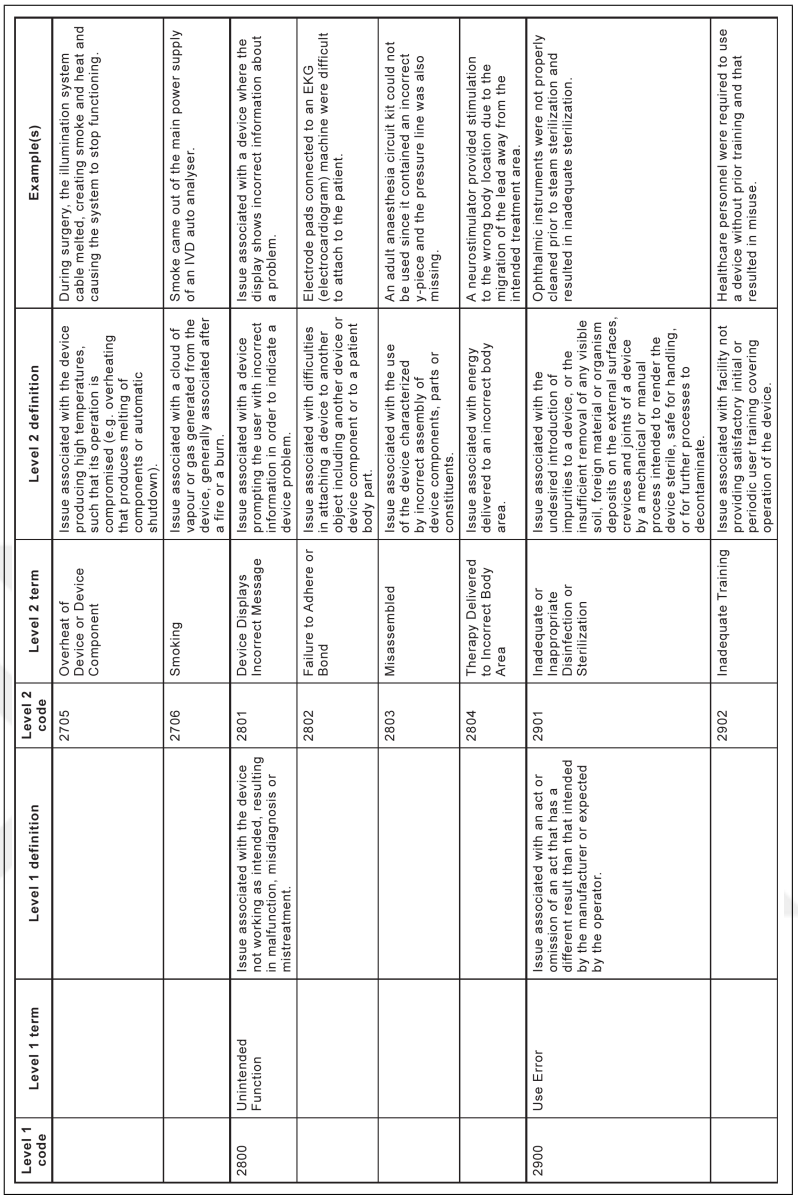
Figure C.7 ISO 19218-1Medical devices-Hierarchical Coding Structure Part 1: Event Type Codes-Cont.

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition	Example(s)
			2203	Installation-Related	Issue associated with unsatisfactory installation, configuration or setup of a specific device or technology.	A mammography machine was set up without beam filtration and resulted in extreme radiation overexposure to the patient.
			2204	Optical Issue	Issue associated with problems transmitting visible light affecting the quality of the image transmitted or otherwise affecting the intended application of the visible light path.	During a vein harvesting procedure the endoscopic device transmitted an inadequate amount of light making the displayed image very dark.
			2205	Telemetry Discrepancy	Issue associated with variability of the transmission of signals, which can be characterized as telemetry channel coding, a method of processing data sent from a source to a destination so that distinct messages are created which are easily distinguishable from one another.	The algorithm incorporated into a telemetry receiving unit was intended to correct signal errors without needing to interrogate the sending unit. Due to an error in the software logic, the receiving unit accepted incorrect data but did not apply the algorithm to correct the errors before it stored the data.
2300	Other	An event type not otherwise included in this table resulting in a device-related event.	2301	Other	An event type not otherwise included in this table resulting in a device related event.	
2400	Output Issue	Issue associated with any deviation from a device's intended performance relating to the end result (e.g. data or test results).	2401	Energy Output to Patient Tissue Incorrect	Issue associated with the amount of energy directed to patient tissue.	During surgery a patient was burned due to an electrosurgical unit that delivered excessive energy.
			2402	Incorrect or Inadequate Result	Issue associated with end results provided by the device that does not conform to its performance specifications.	A prothrombin meter used by a patient at home returned test results that were inaccurately low, causing the patient to self-medicate inappropriately.
			2403	No Device Output	Issue associated with no measurement outcome, value, or data obtained from the device.	A prothrombin home test meter did not report an INR (international normalized ratio) value. Despite a patient's repeated attempts to use and recalibrate a glucose meter, the screen continually displayed an error message.
2500	Packaging/ Shipping	Issue associated with packaging or shipping.	2501	Damage Prior to Use	Issue associated with packaging or shipping damage prior to the use of the device.	An intraocular lens was damaged while being removed from its packaging.
			2502	Delivered as Unsterile Product	Issue associated with the device delivered unsterile due to loss of packaging integrity.	Due to a compromised seal that allowed ingress of microorganisms, the sterile device could not be used during surgery.

Figure C.8 ISO 19218-1Medical devices-Hierarchical Coding Structure Part 1: Event Type Codes-Cont.

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition	Example(s)
			2503	Packaging	Issue associated with the materials used for protective shipping or shipping instructions.	The device was damaged due to packaging materials that were too weak to withstand rough handling during transportation.
			2504	Item Contaminated during Shipping	Issue associated with the presence of any unexpected foreign substance found on the surface or in the package materials, which may affect performance for its intended use.	During shipment to the hospital, a solvent soaked into the device packaging.
			2505	Difficult to Open or Remove Packaging Material	Issue associated with difficulty for end-users to operate the device, specifically as it relates to the opening or removal of the outer wrapping.	The aseptic presentation of a sterile device was compromised when a nurse had difficulty opening its packaging due to excessive seal strength. When the nurse pulled hard enough to overcome the seal, the packaging opened suddenly and the device fell to the floor.
2600	Protective	Issue associated with any deviations from device-documented performance specifications relating to the implemented and inherited design features specific to devices used for reducing risks to patient or care-giver or maintaining risks within specified levels.	2601	Device Alarm System Issue	Issue associated with the failure of an alarm system.	A ventilator did not alarm when an obstruction in the patient airway caused reduced airflow to the patient.
			2602	Fail-Safe Issue	Issue associated with a device feature that prevents the unsafe use of the device.	Prior to a biopsy procedure, the reusable core biopsy driver was found to be firing while the safety was on.
2700	Temperature	Issue associated with the device producing unintended temperatures.	2701	Burned Device or Component	Issues associated with a discolouration or destruction as a result of thermal decomposition of the device or its components.	Burn marks were observed on the inside face of the glucose monitor display.
			2702	Fire	Issues associated with the combustion of device components, resulting in any of the following: light, flame, smoke.	A break in a cable caused an electrical spark during a surgical procedure that resulted in the patient wrapping catching on fire.
			2703	Flare or Flash	Issue associated with device-related burn with an unsteady flame.	When a breast pump was plugged into an electrical outlet, a flash of flame was seen and the plug was irreparably damaged.
			2704	Insufficient Cooling	Issue associated with the device or device parts being insufficiently cool in either device active (working) or non-active (non-working) state.	A magnetic resonance imaging device failure was caused by the radio frequency (RF) coils reaching high temperatures due to the failure of the cooling system.

Figure C.9 ISO 19218-1Medical devices-Hierarchical Coding StructurePart 1: Event Type Codes-Cont.



Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition	Example(s)
			2705	Overheat of Device or Device Component	Issue associated with the device producing high temperatures, such that its operation is compromised (e.g. overheating that produces melting of components or automatic shutdown).	During surgery, the illumination system cable melted, creating smoke and heat and causing the system to stop functioning.
			2706	Smoking	Issue associated with a cloud of vapour or gas generated from the device, generally associated after a fire or a burn.	Smoke came out of the main power supply of an IVD auto analyser.
2800	Unintended Function	Issue associated with the device not working as intended, resulting in malfunction, misdiagnosis or mistreatment.	2801	Device Displays Incorrect Message	Issue associated with a device prompting the user with incorrect information in order to indicate a device problem.	Issue associated with a device where the display shows incorrect information about a problem.
			2802	Failure to Adhere or Bond	Issue associated with difficulties in attaching a device to another object including another device or device component or to a patient body part.	Electrode pads connected to an EKG (electrocardiogram) machine were difficult to attach to the patient.
			2803	Misassembled	Issue associated with the use of the device characterized by incorrect assembly of device components, parts or constituents.	An adult anaesthesia circuit kit could not be used since it contained an incorrect y-piece and the pressure line was also missing.
			2804	Therapy Delivered to Incorrect Body Area	Issue associated with energy delivered to an incorrect body area.	A neurostimulator provided stimulation to the wrong body location due to the migration of the lead away from the intended treatment area.
2900	Use Error	Issue associated with an act or omission of an act that has a different result than that intended by the manufacturer or expected by the operator.	2901	Inadequate or Inappropriate Disinfection or Sterilization	Issue associated with the undesired introduction of impurities to a device, or the insufficient removal of any visible soil, foreign material or organism deposits on the external surfaces, crevices and joints of a device by a mechanical or manual process intended to render the device sterile, safe for handling, or for further processes to decontaminate.	Ophthalmic instruments were not properly cleaned prior to steam sterilization and resulted in inadequate sterilization.
			2902	Inadequate Training	Issue associated with facility not providing satisfactory initial or periodic user training covering operation of the device.	Healthcare personnel were required to use a device without prior training and that resulted in misuse.

Figure C.10 ISO 19218-1Medical devices-Hierarchical Coding StructurePart 1: Event Type Codes-Cont.

Level 1 code	Level 1 term	Level 1 definition	Level 2 code	Level 2 term	Level 2 definition	Example(s)
			2903	Maintenance Issue	Issue associated with the servicing of a device.	Failure to perform required disinfections of the water system of a dialysis machine resulted in a pyrogenic outbreak.
			2904	Refurbishing Issue	Issue associated with the refurbishing of a device.	A third party refurbished an endoscope but did not replace a critical component, causing the device to fail.
			2905	Use of Device Issue	Issue associated with the user's failure to process, service, or operate the device according to the manufacturer's recommendations or recognized best practices.	Personnel used a device in a way that was in conflict with information delivered through training and in the manufacturer's labelling, including the instructions for use.
			2906	Device Inoperable	Issue associated with the device being in a non-functional or inoperable state.	When the defibrillator was turned on, it showed the selftest screen and then locked up.

Figure C.11 ISO 19218-1Medical devices-Hierarchical Coding Structure Part 1: Event Type Codes - Cont.

APPENDIX D. List of Clinical Alarms and Evaluation of Priorities

LIST OF CLINICAL ALARMS AND EVALUATION OF PRIORITIES
(Each unit will fill separately for its own devices.)

Patient Safety Risk Value
1. High Risk Value
2. Middle Risk Value
3. Low Risk Value

Audible Sound Level
1. Proper
2. Improper!

Patient Location
1. Close to the Nurse Desk
2. Close to nurse
3. Continuous Nurse Surveillance

Differentiation
1. Defined in Noise
2. Undefined in Noise!

ALARM	Patient Care Location	Not Patient Care Location	Risk Value	Audible Sound Level	Patient Location	Differentiation

Figure D.1 The list of clinical alarms and evaluation of priorities.

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