

METHODS

## Characterization and maintenance of hospital equipment: a case study on the institute of molecular medicine João Lobo Antunes

## A. Serafim<sup>1</sup>, S. Santos<sup>2</sup> and N. Domingues<sup>1\*</sup>

<sup>1</sup>Polytechnic Institute of Lisbon/Lisbon Higher Institute of Engineering, Lisbon, Portugal <sup>2</sup>Instituto de Medicina Molecular João Lobo Antunes (iMM), Edifício Egas Moniz, Lisbon, Portugal

\***Correspondence:** N. Domingues, nndomingues@gmail.com

Received: 10 February 2023; Accepted: 17 February 2023; Published: 24 February 2023

**Objective:** The objective of this study was to conduct a study on the characterization and maintenance of equipment in a hospital environment and apply it in the case study conducted as part of an internship at the *Instituto de Medicina Molecular* João Lobo Antunes (iMM), with a duration of 11 months. This work contributed to the identification of improvements to be applied in the *Safety and Compliance Department*, in the maintenance, calibration, and monitoring of medical-hospital equipment (MHE), to improve their reliability and efficiency, the reduction of costs and downtime, and the probability risk to the patient, engineer, or user associated with the equipment.

**Materials and methods:** This is an MHE study of the iMM, also monitoring the maintenance and calibration of different equipment by technicians and engineers responsible internally and externally.

**Discussion and Practical Results:** A maintenance *software* for the iMM was chosen to help the institute to have all the equipment information in a more organized way. Monitoring of some iMM equipment was conducted.

**Conclusion:** It was found that the safety of patients, engineers, or users who manage MHE is an extremely principal factor. For this factor not to be harmed, constant monitoring, maintenance, and calibration of the equipment are necessary, ensuring the safety of the user and their proper functioning.

Keywords: medical-hospital equipment (MHE), Maintenance, Calibration, Monitoring, Safety

## 1. Introduction

## 1.1. Framework

In Portugal, the use of work equipment continues to be a factor that leads to accidents. However, companies and organizations act in a preventive way, to improve the conditions of effectiveness and reliability of equipment. This is essential for a significant reduction in the number of accidents at work, which can result from insufficient safety conditions of the equipment (1, 2).

Medical equipment (ME) regardless of the function for which they were produced are of significant importance in research and medicine, because without them, it would not be possible to obtain results for the treatment of diseases, nor would it be possible for the acquisition of medical images for later diagnosis (3, 4).

In hospitals and research environments, there is a constant need for a good characterization of ME, their maintenance, calibration, and their application. In addition, the equipment is extraordinarily complex, which requires it to be constantly monitored, maintained, and/or calibrated (3, 4).

This final master's work aims to study, characterize, monitor, and evaluate the institute's medical-hospital equipment (MHE) and contribute to an analysis and identification of good practices in the Safety and Compliance Department. As a secondary objective, benchmarking of maintenance software was conducted and subsequent selection and evaluation for adoption, according to the



needs and requirements defined by iMM: assistance in the maintenance and/or calibration of the MHE, were conducted to improve their reliability and efficiency, reducing costs and downtime.

### 1.2. Literature review

#### 1.2.1. Previous studies

According to Bahreini et al. (5), MHE is necessary for health systems. The authors highlight that MHE is introduced and used for the diagnosis and treatment of patients. They also mention that MHE must always be in a safe condition, to avoid injury to patients or the user of the equipment. Furthermore, the authors mentioned that, according to the World Health Organization (WHO), approximately 412 dollars were spent on MHE maintenance in 2010. As a result, the authors also stated that maintenance management systems are particularly important to improve safety, cost efficiency, and reliability of ME. Bahreini et al. (5) also highlighted the example that planned and adequate maintenance can prolong the lifespan of MHE (5).

According to Arab-Zozani et al. (6), the maintenance of MHE is especially important to provide the most appropriate treatment for patients and reduce dispatch costs, mortality, and risk during patient treatment and patient complaints. The authors also considered the maintenance to be an integral part of the life cycle (LC) of an MHE. They stated that the cost of maintenance is much higher than the cost of acquiring the MHE itself. Arab-Zozani et al. (6) also mentioned that MHE maintenance consists of all actions that help hospitals to promote or protect the performance of their MHE to work efficiently and regularly, and to provide an adequate level of service. Therefore, these authors intended to show that maintenance management is a fundamental procedure of hospital management (6).

According to Jamshidi et al. (7), the maintenance of MHE is as important as its development and design. The authors pointed out that there are much less costs with the purchase of the MHE than with the maintenance over the lifetime of a single component of the equipment (7).

Regarding the maintenance of specific equipment mentioned throughout this work, such as the 7500 Fast Real-Time PCR System, the 7300/7500/7500 Fast Real-Time PCR System Installation and Maintenance Guide (8) shows that the maintenance of this equipment results from the following way (8):

- 7500 Fast Real-Time PCR System disk is checked.
- Afterward, the file or backup copy of document files, of the plates used in the equipment, is always conducted.
- Turn off the equipment in question and connect it to the computer.
- The equipment components are cleaned. It is important to note that organic solvents should never be used to clean them.

- The desired calibrations are conducted.
- Finally, clean the computer's hard drive.

The AKTA: 2008 Protein Purifier feature has a more specific maintenance. According to the AKTA Pure data file (9, 10), the equipment is extremely sensitive; therefore, it needs special care in its maintenance. This must be constantly monitored, and the same person should always conduct the monitoring. Maintenance starts with cleaning the equipment and all its components. Then, with the equipment turned off, it is connected to the computer to verify its data and conduct tests to see if there is a problem with it. Furthermore, it is always checked that it is at 20% ethanol, so that there is no possibility of excess samples remaining in the circuits after the experiments are conducted, which could damage the equipment in the long term. It is important to note that AKTA Pure data file is a document of an AKTA Pure Protein Purifier, which is the latest version of AKTA: Protein Purifier 2008. However, its care is the same (9, 10).

Another piece of equipment mentioned in the work is the High-Speed Centrifuge AVANTI<sup>TM</sup> J-25. According to AvantiJ-25 High Performance Centrifuge Instruction Manual (11), equipment maintenance proceeds as follows (11, 12):

- Check the interior of the High-Speed Centrifuge regularly. Dust and glass particles are cleaned from the tubes used in the centrifuge.
- Conduct deep cleaning of the equipment.
- Regularly inspect the air filter on the rear panel, to check whether there are obstructions.
- Keep the centrifuge ventilation openings unobstructed and clean.
- Use a clean cloth to clean the condensation in the rotor area, to avoid the formation of ice in the chamber.
- If ice forms in the chamber, defrost the system and clean the chamber of moisture before use. To defrost the system, adjust the temperature to 30°C for 20 min.

In accordance with the SIGMA 6-16K Maintenance Protocol, the SIGMA 6-16K Centrifuge also has an awfully specific maintenance procedure. This protocol mentions that the maintenance performed is divided into three essential phases (13):

- Cleaning the outside and inside of the centrifuge, as cleaning is particularly important for the correct functioning of the equipment. This involves extracting all the dirt that can cause errors in the centrifuge and jeopardize its reliable performance.
- Verification of SIGMA 6-16K constituents/components. When starting maintenance, the professional responsible for it checks all the components of the equipment. In this step, you can see whether it is necessary to replace any mechanical or electronic component.
- Finally, performance tests were conducted.

According to the Microbiological User Manual Safety Telstar Bio II Advance Cabinets Plus (14), maintenance of the Telstar BIO II Advanced Camera Plus, mentioned in the course of the work, is normally conducted once a year. In this one, you start by cleaning the equipment, followed by the verification of its constituents. In addition, this equipment performs several tests, such as (14):

- Integrity test of exhaust filters.
- Integrity test of downflow filters.
- Descent air velocity test.
- Inlet air velocity test.
- Light test.
- Smoke test.
- Noise-level test.

As per the Advanced Camera maintenance process plus (14), the equipment is cleaned and disinfected again so that contamination does not occur in the cabin. This is done to improve the user's safety and the equipment's performance (14).

According to the Fume Hoods Manual (15), chemical's regular preventive maintenance (PM) Hood BECOME RB reduces the possibility of danger to the user and guarantees good reliability in the equipment. This can be done monthly, quarterly, annually, or bi-annually. Chemical maintenance Hood BECOME RB starts with general cleaning of the equipment. Then, the filters are checked, that is, it is verified whether they are in condition to remain in the equipment. One of the last steps is the observation and recording of the air velocity at the entrance and other tests, such as those mentioned for the Telstar BIO II Advanced Camera Plus. Finally, the equipment is cleaned and disinfected again (15).

According to the CO<sub>2</sub> Service Manual Incubator MCO-18AIC, the SANYO CO<sub>2</sub> Incubator also presents steps to follow in your maintenance process, such as (16):

- The sterilization of the chamber and its accessories.
- Removing all accessories from the incubator.
- Filling the humidifier plate with water at 37 C.

The maintenance of this incubator ends again with the necessary cleaning and disinfection procedures for it and all its accessories. Then, they are placed back inside the equipment (16).

According to the Operating Panasonic Instructions (17), the maintenance of Panasonic  $CO_2$  Incubators starts with a thorough cleaning of all equipment. Remove all internal accessories with proper care and clean the chamber and all internal accessories. It is important to note that when there is excessive dirt, it is necessary to contact the equipment representative. After cleaning all the equipment and if there is no problem with it, install all the internal accessories (17).

It is important to mention that all the maintenance procedures covered will depend on the problems that each piece of equipment may present. If there is any error, failure, or damage with the MHE, it is resolved within the maintenance process. In addition, it is also important to mention that all the maintenance described above can only be conducted by a technician, engineer, or electromedical professional, or in a similar area, who has the correct training to be able to conduct MHE maintenance (18).

With this review of previous works, it is possible to verify the diversity of existing maintenance procedures. This highlights the importance of knowing the characteristics of the equipment, to conduct the best maintenance process. This is because all equipment has distinct characteristics, and they need different maintenance processes. However, it should be noted that in all cases, the cleaning stage of all equipment and its components is always mentioned, which is a key stage in the maintenance process.

The present work also addresses the equipment maintenance procedures referred to by the authors, or documents, highlighted above. In addition, it addresses maintenance procedures in more detail, due to errors or problems presented by the equipment during the procedure, or that already existed before it happened.

#### 1.2.2. Checking work equipment

Work equipment is all appliances, installations, machines, or tools used in the work environment. The verification of work equipment consists of a rigorous test, conducted by certified personnel. This verification has as its main objective confidence in using the equipment in safe conditions (1, 2).

Professionals who conduct this type of verification need to comply with laws, which establish minimum health and safety conditions for the use of work equipment by their users. The verification must be conducted, also considering the characteristics of the equipment, the conditions for its use, and the manufacturer's rules. The certifying company is responsible for providing the guarantee that the work equipment has the necessary checks before its use. In addition, it is also the certifying company that conducts the verifications, using certified personnel from the company itself or subcontracting to a certified external entity (1, 2, 19).

## 1.2.3. Medical devices, medical equipment, and medical-hospital equipment

A medical device (MD) consists of any equipment, material, instrument, software, or other devices, which is intended to be used on patients or any individual in need. These can be used individually or together, depending on the device type. In addition, there are numerous medical purposes for which MD can be used, such as for researching, diagnosing, monitoring, preventing, predicting, alleviating, or treating a disease, disability, or injury. They can also be used to provide information, based on in vitro tests, with samples from the patient under study (20, 21).

There is a distinction between MD and ME. An ME is any piece of equipment that needs constant maintenance, calibration, and adjustment so that it is working correctly and providing the most reliable results possible (20–22).

In addition, ME users also need training and education so that they are used correctly. It should be noted that an ME is any device that is used for the treatment of diseases, research, diagnostic purposes, and rehabilitation after an operation or injury, excluding from this group single-use, implantable, or disposable MD. It should be noted that the project in question is focused on the ME of the iMM, more specifically on MHE (20–22).

The MHE is all equipment used in the health area that has as its purpose a laboratory, medical, and physiotherapeutic objective, among others. In addition, MHE is used for patient monitoring, therapy, rehabilitation, or diagnostic purposes. These types of equipment can also be classified according to their complexity, that is, there are MHEs of low complexity, medium complexity, and high complexity (23, 24).

#### 1.2.4. European conformity standard – CE

In Portugal, ME is subject to a set of rules and processes, which presents the objective of guaranteeing the safety and quality of the equipment in question, as can be seen in **Figure 1** (2). It is important to mention that the metrological guarantee of the ME, which is one of the main quality requests, is not considered, since this requirement oversees the ME holders (2, 25).

The European Conformity standard (CE) shows the equipment's compliance with European Union legislation. This standard is present in all equipment as soon as it is placed on the market, except for those that are made to measure and those that are intended for research (2, 25).

# **1.2.5.** Life cycle of medical-hospital equipment and its management

Technology plays an especially important role in healthcare. With its advancement, there is a need to conduct the constant replacement of elements used in the health sector, such as MHE, or its components, replacing them with new and more effective elements, to create ways to prevent and treat patients (24, 26).

The LC consists of the fact that all equipment is "born," "grows," "reaches a level of maturity," and, finally, "stops." There is a constant need to research measures that aim to increase the durability of the LC of the MHE, such as, for example, with planned maintenance, calibrations, and monitoring, among other procedures. The MHE LC has five phases, namely, innovation, initial diffusion, incorporation, large-scale use, and abandonment (24).

#### 1.2.6. Maintenance of medical-hospital equipment

Maintenance consists of the preservation, conservation, or repair of certain systems or equipment, which must always present optimal operating conditions. Its structure consists of several actions that help in the satisfactory performance of production, such as the use of MHE (5, 18). The correct functioning of ME has a direct impact and is of significant importance to patient safety and health, as well as an essential role in determining efficiency and performance in health institutions, such as hospitals, and clinics, among others. What determines the seriousness of hospitals and other health institutions is the efficiency and quality of their MHE, that is, there is a constant need for maintenance, monitoring, and calibration so that the MHE works correctly (27, 28).

Maintaining an MHE is an important, complex, and critical process. This is not just for the repair of equipment after some damage to it. The main objective of maintaining an MHE is to ensure that the equipment performs its function for as long as possible and at its maximum capacity, always putting the safety of the patient or user in question first. It should be noted that there is more than one type of maintenance, that is, MHE maintenance is divided into two large groups, planned and unplanned maintenance. Planned maintenance is divided into corrective maintenance (MC) and PM. PM is divided into systematic and conditional/predictive. In contrast, unplanned maintenance consists only of MC. In addition to these main types, there is also calibration, which is of immense importance (7, 29, 30).

#### 1.2.7. Prevention measures in MHE maintenance

Preventive measures in conducting maintenance, calibration, or MHE monitoring are extremely important, as they have the objective of reducing the risk of infection for the patient or the user of the equipment, whether a health professional, an engineer, or a technician.

To reduce the risk of infection, it is necessary to develop preventive measures, considering identified and unidentified sources of infection. In addition, it is important to consider those that may contain infections, such as body fluids, blood, and secretions, among others, even without knowing the patient's condition. Thus, preventive measures are the use of personal protective equipment (PPE), correct hand hygiene, and disinfection (2, 22, 31).

## 1.3. Study case

This work presents the characterization and maintenance of equipment in a hospital environment and its application in the case study conducted. In the beginning, engineers, technicians, or electromedical professionals were monitored. These began by explaining the MHE with which to work, its purpose, its characteristics, and its way of use. In addition, they mentioned that there are numerous rules associated with MHE maintenance and calibration, and it is mandatory to follow them. That is, if the necessary maintenance or calibration procedures are not conducted, following all the rules, errors, failures, or damage to the equipment may occur and may even cause problems for

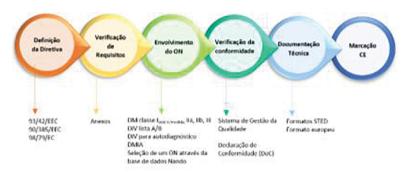


FIGURE 1 | Ordem das atividades/processos para a fixação da marcação CE. Adaptado de (2).

the electromedical professional who is conducting the work without complying with the rules.

After sharing this information, the electromedical technician or professional, responsible for the maintenance of the MHE, conducted a general assessment of it, to verify whether it presented any problem, error, or damage to its components. While this was happening, the professional explained what he was doing, always highlighting the MHE components and their functionalities. He also explained how the equipment would work if any of its components failed.

The referred professional proceeded to start the maintenance or calibration, which was planned to be performed on the equipment. It is important to mention that all maintenance or calibrations performed were planned at specific times, considering the state of the MHE, its operation, and its characteristics.

Then, the full monitoring of the maintenance or calibration of the MHE was conducted. Where, in some cases, errors or failures were observed that visually and manually did not appear to exist, which demonstrated the importance of conducting planned maintenance and calibrations in the MHE. After conducting the procedure, the electromedical professional conducted the final tests to verify that the equipment is working properly for use. This is in order not to harm the safety and health of the future user. In addition, the professional also cleaned the MHE and its constituents and mentioned how important it is to completely clean the equipment and its components.

In this follow-up, it was also noticed that although some MHEs do not present problems after the maintenance or calibrations are conducted, it is essential to have these procedures planned at the proper time, to improve the reliability and efficiency of the MHE and guarantee the safety of the user.

After the monitoring of electromedical professionals, in the maintenance or calibrations conducted at various MHEs, calibrations were monitored, but monthly. That is more specific calibrations for equipment that needs this type of monitoring once a month, due to the frequency of its use and the problems that it can cause if there is a problem. Typically, this type of calibration occurs in MHE working with chemical reagents. These can create excess contamination in the equipment, which can create harmful effects on the user and can also lead to errors in the investigations conducted by the MHE.

The monitored monthly calibrations were performed by Maria Cabral, a member of the *Instituto de Medicina Molecular* João Lobo Antunes (iMM), more specifically from the Safety and Compliance Department.

In these, procedures like those discussed above were conducted, such as following the MHE calibration rules and evaluating it, to verify if it showed any damage. Then, help was provided in the calibration performed, always under the supervision of the iMM professional who was responsible for the calibration. Data were collected throughout the process. When the process was finished, the final tests were conducted to verify that the MHE was working correctly. Finally, the MHE and all its components were cleaned.

After monitoring these calibrations, research and selection of a maintenance software suitable for the work environment and the iMM equipment was conducted, to help with the organization. Comparisons were made between various software, until reaching the most suitable one, in terms of quality, price, and needs.

Then, at the request of the Safety and Compliance Department, temperature monitoring was conducted on some equipment, such as refrigerators and freezers for specific uses. A portable probe was first placed inside the equipment, already stabilized. The data provided by the equipment and by the probe were collected at 10-min intervals for 1 h. Then, the measured values were corrected, considering the correction values provided by the iMM.

It is important to emphasize the importance of monitoring, as it has several advantages such as providing knowledge of the status of the MHE, increasing user safety when working with the equipment, and providing the possibility of marking or planning future maintenance (29).

With the completion of this work, there was also the possibility of making a visit to the Metrology Laboratory, EIA of METROCAL. In this, the work conducted in their laboratories was monitored, having verified that each laboratory has different functions and purposes.

This visit also made it possible to learn more about the science of metrology. This is present in a large part of our day-to-day and encompasses everything related to measurement, whether practical or theoretical, regardless of the field of application or measurement uncertainty (30).

#### 1.3.1. Scope

The project entitled "Characterization and Maintenance of Hospital Equipment: the *Instituto de Medicina Molecular* João Lobo Antunes (iMM) as a case study," was developed as an 11-month internship at the Safety and Compliance Department from the iMM and within the scope of the master's in biomedical engineering (MEB) of the *Instituto Superior de Engenharia de Lisboa* (ISEL). The internship started in October 2021 and ended in September 2022.

## 1.4. Instituto de Medicina Molecular João Lobo Antunes

Instituto de Medicina Molecular João Lobo Antunes was found in 2002. It promotes basic, clinical, innovative biomedical research in the translational and life sciences, providing a vibrant and dynamic scientific environment. In addition, it supports the post-graduate scientific training of young graduates, doctors, and other healthcare professionals. The institute also supports scientific dissemination and the provision of international services in the areas of specialized diagnosis and quality control. The aim of iMM is to pave the way for an increasingly innovative science, to improve life through excellent biomedical research (32, 33).

The Finance and Operations Office comprises five departments, called Accounting, Project Management, Legal and Human Resources, Purchases and Procurement, and Safety and Compliance. Its main purpose is to maintain an agile structure, to be able to provide the best possible help to researchers and the entire scientific community, which can be seen as the internal client of iMM. However, it is important to mention that the work described here focuses on the Safety and Compliance Department (34, 35).

The iMM Safety and Compliance Department's mission is to ensure that all requirements for equipment, materials, and infrastructure for carrying out high-quality investigations are guaranteed and fulfilled, in order to guarantee a healthy and safe environment in the work environment, reducing occupational illnesses, which can arise from contact with an MHE, or minimizing the risk of injury. It conducts work in areas such as training, prevention, compliance with legal obligations in safety, and the assessment of potential risks in relation to health and safety at work (35).

## 2. Materials and methods

The iMM contains numerous MHEs, such as polymerase equipment chain reaction (PCR), thermocyclers, protein

purifiers, fume hoods, centrifuges, freezers, and refrigerators with specific purposes, among others, mentioned in topic one, used for research. The main objective of the internship at iMM is to characterize some equipment and help the Safety and Compliance Department to characterize the MHE and perform some calibration, maintenance, and monitoring of the equipment in question.

## 2.1. 7500 real-time PCR system

The 7500 Real-Time PCR System of applied Biosystems<sup>TM</sup> aims to provide high-performance, real-time, multi-color PCR. This PCR is fluorescence-based to provide quantitative detection of target nucleic acid sequences using real-time analysis, qualitative target detection, and post-PCR (endpoint) analysis, and provides qualitative analysis of the PCR product (obtained by melting curve analysis that occurs post-PCR) (36, 37).

This equipment offers maximum performance in minimum time. It consists of a real-time multicolor PCR, fully optimized for fast cycling, and delivers high-quality results in just 30 min. This equipment features a specially designed fast block consisting of a power supply, a light source (lamp), and a 96-well optical reaction plate, which guarantees thermal uniformity at maximum speeds (38, 39).

The high software resolution melting (HRM) is available on your system and provides accurate results in a standard 96-well format. This software enables more sophisticated fusion analysis with an easy-to-follow workflow and minimal subjective data analysis steps. This equipment needs PM and/or a calibration from year-to-year, to be sure that the electronics of the equipment are working correctly and that its components do not need replacement (39, 40).

After checking the equipment, if it is working correctly and does not require maintenance, it is calibrated (39, 40).

A test was conducted on the equipment, where it was observed that the electronics of the equipment were working correctly. Then, the lamp was cleaned. Regarding the block, it is known that it quickly reaches the desired temperature, so rubber was placed to seal it.

A test was conducted through the Gemini MTSS program, where it was verified that the voltages are all normal. Then, in another test, it was verified that the alignment of the equipment's camera was correct, and it was noticed that it was within the intended range. Then, the filter wheel was calibrated, which consists of the part of the equipment that passes the light from the lamp. The Gemini software also provides information on internal calibrations, that is, the parameterization of the 7500 Fast Real-Time PCR.

This software also controls the temperature (offset), Heated Cover Calibration in the Gemini software, which is one of the exchanges that perform the most, if necessary.

Various probes and plates are used for calibration. The plate and probe are suspended, and the equipment block rises and meets them. A thermometer is used to read three important pieces of information, the heated cover, the precision, which will give information about the nine probes in the block, and the uniformity of the probes in the block, that is, the probe is made up of several pins and they have that there is a temperature uniformity.

With the calibration performed, a temperature of  $85^{\circ}$ C (heated cover) was obtained. Then, the precision at  $75^{\circ}$ C was analyzed, and for  $45^{\circ}$ C, it was analyzed for high and low temperatures. If the block does not heat up at the rate expected from a 7500 Fast Real-Time PCR, it means that it is not behaving as it is supposed to, so it must be replaced. Repeated cycles (25 cycles) are conducted so that in the last 10 s, the temperature of the equipment is stable. A final heated cover of  $103^{\circ}$ C was observed.

Next, the cleaning of contamination of the block was carried out with a "swab" and ethanol. Contamination can be observed through the blue dots that appear on the computer image, through the software.

Moving on to the equipment's controller software, known as SDS, the user software is used to perform spectral calibrations. This has the function of detecting which filters are correct for each specific probe. The spectral calibrations consist of four, namely, ROI, Background, Optical, and Dye. In addition to these, a performance check called RNasep is also conducted. This verification consists of running the PCR, to evaluate if the equipment can distinguish two different populations of DNA.

Background calibration, the reading of the 12 wells of the plate in the block, was obtained. It was observed that well 9A still contained some level of contamination after cleaning the block. When this is done, the well is cleaned again and the background spectral calibration is "run" again, using the SDS software. After this cleaning, a new reading of the 12 wells was obtained and it was concluded that there was no longer any contamination, that is, the calibration was successfully completed.

Regarding the ROI, Optical, and Dye calibrations, the equipment responded well to all and passed maintenance.

### 2.2. AKTA – 2008 protein purifier

AKTA is a chromatography system from Amersham Pharmacy Biotech, which is flexible, high-efficiency, and intuitive, with the aim of performing protein purification for studies, investigations, among others (10, 41).

As it is a faster system for protein purification, it has the advantage of time management. The AKTA Purification System is intended for the purification of Tricorn proteins using HiTrap and HiScreen columns. AKTA can be used at flow rates up to 150 mL/min for fast protein liquid chromatography of tens of grams of protein. This high flow rate is necessary when working with high-flow resins in large columns. Columns can even be packed at flow rates up to 300 mL/min (10, 41).

This equipment has particular care after its use, that is, after running the samples that were previously purified, it is passed through the water circuit and the circuit is always left at 20% ethanol. If this procedure is not conducted after all the purifications are performed, as the room temperature is favorable, excess samples may remain in the circuits, which damages the equipment in the long term (9, 10).

The equipment consists of six pumps, each of which has two pistons, one on each side, and at its tip are the undercarriages. The pump is used to inject proteins when volumes are high; however, when volumes are low, injection is usually done by hand. It also has a pressure sensor, which has a high sensitivity. Another component of the equipment is the Fluor restrictor (FR) which consists of a spring that performs pressure and removes the air from inside the pumps of the equipment. This constituent must be cleaned frequently with ultrasound because the liquid being compressed tends to be gas (9, 10).

The AKTA is overly sensitive equipment, because of this it needs specific care and specific handling. Handling should be limited, that is, as few people as work with the equipment, one or two, at most, to take care of the equipment, so that there is a minimum probability of human errors occurring with it. AKTA is only cleaned by your responsible engineer. It is also known that when using biological material, particular care must always be taken with a chromatography system (9, 41).

Initially, the AKTA in question did not work correctly, as it made a "noise" that was not normal. Initially, it appeared to be a mechanical problem, but then it was thought that it was a problem with the board, as it was not reading the pump position sensor. The defective sample pump plate was repaired. Then, the pump was assessed with a syringe, to purge the pump, to make it ready for use with the equipment.

After the test was performed on the pump with the fixed plate, it was found that it was the damaged plate that was not reading the position sensor correctly. This is because, when it was fixed, the equipment was evaluated again, and it was noticed that the "noise" that had previously occurred no longer occurred. With this, it was realized that it consisted of a communication problem from the board to the sensor, which is extremely sensitive.

However, when the pump was removed for repair, it was found that there was also a leak coming from a damaged pump tube, which resulted in incorrect connections. Despite the pump plate arrangement, the sensor was still not getting the intended reading.

Then, a self-calibration was tried on the new board for the pump, using different software. This consisted of service software to access the modules individually and try to understand what the problem really was. Initially, it was thought that the problem could come from the pressure sensor that was not working as intended. Then, the flow in the software was increased to verify if the problem in the pump remained. Then, it was observed that there was still a leak of water from one of the holes in the pump. It was noticed that the problem came from the wheels, which are on top of the pistons of the damaged pump.

It was concluded that the best, in terms of quality and price, would be to change the pump and replace the tube that was worn out. After replacing the damaged pump, the equipment was checked again to see if it was working properly.

# 2.3. High-speed centrifuge AVANTI J-25 and SIGMA 6-16K

Beckman centrifuge Avanti J-25 aims to deliver faster deceleration and acceleration rates without compromising large volume and microplate capabilities. The centrifuge addressed provides exceptionally large G forces, from 25,000 rpm to 75,000 rpm. This allows bioprocessing with 4 liters per "run," or up to 4 liters per hour. In addition, this centrifuge enables high-force microplate applications and up to ten microplates in a single "run" (11, 42).

Your system features a dynamic rotor inertia check to ensure user safety and proper rotor rating. It is important to note that the equipment motor breaks out at a temperature of approximately  $40^{\circ}$ C (11, 12).

With the constant use of this equipment, it ends up presenting problems, over time, in the coil that performs the cooling when it is at high speed. That is, when being at high speeds, if the coil has problems and does not perform the supposed cooling, the equipment ends up overheating at certain speeds, which can cause serious problems (11, 43, 44).

Typically, users of this equipment want it to reach maximum speeds (25,000 rpm) at an exceptionally low temperature. However, the opposite is normal because the equipment is not "cooled" enough. That is, for a higher speed, the temperature also tends to increase. The care that must be taken before using the centrifuge is to place its rotor in a chest, or in a refrigerator so that it cools down. This will help to stabilize the temperature so that it is as low as possible when the equipment is in use (12, 44, 45).

To start the maintenance of the centrifuge, it was first cleaned. It is known that this centrifuge has a problem with the temperature sensor. In this way, the inside was cleaned with a "vacuum cleaner," which is located next to the sensor. Afterward, the dome and temperature sensor were cleaned. Cleaning was conducted with isopropyl alcohol. The temperature sensor was then tightened with a screwdriver and vacuumed in the dome and coils. The coils around the dome are of significant importance, because to have good thermal contact, the coil must have good contact with the dome.

Then, the rotor suitable for the equipment was placed and it was put to work to monitor the speeds and temperature. After the centrifuge has finished working, when opening the lid, more ice accumulates on the top, where the coils are around the rotor.

Four tests were conducted on the equipment. The first showed that the equipment could have a temperature problem, due to ice created in the dome around the coils, but not at the bottom. The second test was conducted at a speed of 22,000 rpm and the objective was to reach a set point at 4°C. Then, the speed was increased to 23,000 rpm, to try to get the temperature to also settle at 4°C, for a slightly higher speed. As soon as the equipment reached 3°C and the refrigeration system was turned off and from the moment it reached 5°C, the refrigeration system was turned on again. In the third test, a speed of 24,000 rpm was changed and the same procedure was performed. Finally, in the fourth test, the same procedure was used as in the previous tests, for a speed of 23,500 rpm (= 65.503 × G).

It was concluded, after maintenance, that the equipment has a temperature problem, due to the factors discussed above, that is, it is difficult to keep the equipment at low temperatures (3°C) as intended. This problem was noted and there will be subsequent maintenance to improve its reliability and end the temperature problem associated with the AVANTI J-25.

Regarding the SIGMA 6-16K centrifuge, it has the purpose of creating amazingly fast acceleration and deceleration rates. It has a better cooling system than the AVANTI J-25 centrifuge. The SIGMA 6-16K centrifuge reaches higher speeds at a low temperature (4°C). In addition, it presents more advantages in relation to the previously discussed equipment system. This equipment can reach speeds up to 47,000 rpm (13).

The SIGMA 6-16K is made up of various electronic and mechanical components. It also features angled and tilting rotors. Its lid presents a relatively easy opening, due to its pneumatic support. The equipment has a maximum capacity of  $4 \times 800$  ml microtubes with different adapters. It also features a maintenance-free induction drive motor and microcontroller, which controls the speed or gravitational field and time (13, 46).

The first step was to clean the inside and outside of the equipment. Afterward, the centrifuge components were checked and inspected. The last step consisted of conducting tests to see if everything was working correctly with the equipment. This did not present any problems, but PM was conducted. When the equipment stopped in the first test performed, the dome lid was opened and the temperature in one of the rotor wells, which was stabilized at  $5.6^{\circ}$ C, was checked for 20 min. The supposed temperature would have reached  $4^{\circ}$ C, but as the procedure lasted only 20 min, it was considered a very short test, which would be difficult to stabilize at  $4^{\circ}$ C. It was noticed that the equipment does not show temperature problems. A second test, also lasting 20 min, was performed and the rotor temperature was measured again. In this one, the rotor stabilized at  $5^{\circ}$ C, which shows that the temperature dropped a little, compared to the first test, which is a positive factor.

Finally, the equipment defrosting process was conducted, to make sure that there was not too much ice left in the centrifuge, which could lead to further corrosion.

It was concluded that the centrifuge does not present any problem; however, it is always important that there is a beneficial use of it.

## 2.4. Telstar BIO II advanced plus biological safety camera

Telstar BIO II Advanced plus was developed to collaborate with agents harmful to health, in other words, pathogens, levels 1, 2, and 3. In addition, it was designed with exacting standards of reliability, safety, ease of use, energy efficiency, and ergonomics. This chamber is considered one of the safest in the biological product market. This belongs to the new generation of second-class biological safety chambers (47, 48).

Telstar BIO II Advanced Plus Features Light Emitting Diode (LED) and CE fans make the product one of the best energy-efficient and low-noise cameras available on the market. It also features a reinforced mechanism for opening the window, to facilitate the user's work (47, 48).

In a biological safety chamber, the most important feature, together with good contamination prevention, is its containment capacity. This camera was designed with these features. Its laminar flow needs to remain constant, so it is constantly monitored by a speed sensor, due to the clogging compensation technology of its filter. The camera also features independent alarm systems, which emit acoustic and visual alerts. It also has a work surface that is divided into sections that facilitate cleaning and even later autoclave sterilization. Furthermore, it provides comfortable working for its user, as it encourages a safe working position and the display is slightly turned toward the user, to increase accessibility and visibility (47, 48).

This equipment has a great advantage, which is the fact that it has reduced maintenance, which avoids unnecessary costs. That is, it contains a self-compensating technology, which has filter loading to keep the speed of the laminar flow constant inside, optimizing its lifetime and thus minimizing equipment maintenance (47, 48).

Maintenance was first performed on the Telstar BIO II Advanced Plus, with the help of the company Stech Comply. It started with general cleaning of all the equipment and the verification of its components, to understand whether there was any associated problem.

Then, a test was conducted on the velocity (m/s) of the air entering the chamber, up to 120 cm. First, a test was conducted up to 60 cm, then another up to 90 cm, and finally, 120 cm. Then, another speed test was conducted, but with

descending air inlet. The state of the two filters that constitute was also verified.

Afterward, a luminosity test was conducted at four points on the camera bench. This test is performed with the biological safety chamber turned on, due to its standard. A few more procedures were conducted, such as cleaning all the equipment.

It was verified that the camera was working correctly and that there was no failure in the equipment or its components.

### 2.5. Chemical hood BECOME RB

The chemicals Hoods, known as Fume cupboards, by iMM, belong to the Burdinola company. These are designed to be used in investigations and work, which involve the release of a wide variety of unconcentrated chemicals, but which do not present copious amounts of heat. There are several types of chemicals Hoods from Burdinola, but the one found at iMM, and in this study, is Chemical Hood BECOME RB (49, 50).

This type of fume hood is used for handling radionuclides that emit ionizing particles, more specifically beta particles (49). These devices are recommended for procedures with low levels of radiotoxicity. Its interior is made of polyester and fiberglass and has round corners to facilitate any decontamination that may occur. This fume hood also features a frontal protection, called a movable window, with a thickness of 10 mm in polycarbonate, which overlaps the work area, to guarantee safety for the user (49, 50).

The described hoods feature a set of three filters that combine absolute filters with an impregnated carbon filter. These filters aim to ensure user safety, constantly filtering the air inside the equipment (49, 50).

First, the velocity in m/s of the incoming air was evaluated. The first test was performed up to 100 cm, then a second test was performed up to 130 cm, followed by a third test up to 160 cm, and finally, the fourth test up to 190 cm.

Then, a test of the speed of the air at the exit of the equipment was conducted. In addition, a leak test was conducted on the filters, that is, a leak test, which consists of injecting an aerosol before placing the filters.

A smoke test was also conducted, which consists of releasing smoke inside the equipment, with the aim of verifying the direction in which the air is circulating, that is, to see how the air behaves and if it is the correct. This is because the air must be extracted by the equipment, through its upper area, and cannot go out of it, around the equipment where the user who works with the equipment is. Finally, all the equipment was cleaned.

The equipment passed all the maintenance tests conducted, which proved to be working correctly.

## 2.6. SANYO CO<sub>2</sub> incubator

The SANYO  $CO_2$  Incubator was developed with the aim of working with research cultures. It features unprecedented temperature and humidity control technology and provides flexible and robust stability control for research crops. It also has a direct cooling system that eliminates the constant use of water in the incubator and provides heat through the door, side, and bottom of the equipment (36, 37).

It uses an infrared  $CO_2$  sensor that is unaffected by changes in temperature or humidity and maintains constant conditions through microprocessor control and automatically calibrates using ambient air temperature as a reference. In addition, it has a safe Cell UV system for contamination control (36, 37).

The purpose of this incubator is to maintain an ideal environment for cell growth by providing carbon dioxide control in a humidified, constant-temperature atmosphere (36, 37).

High filter efficiency private air (HEPA) is used as a biosafety method. In addition, the incubator is made up of other complex components, including fans and ducts to draw air through the filter and redistribute it into the equipment chamber. However, despite the air being filtered, there is always the possibility of contamination of the equipment. This equipment requires constant cleaning, disinfection, scheduling of regular maintenance, and investment in new filters, to maintain a contamination-free environment for reliable cell growth (36, 37).

The SANYO  $CO_2$  Incubator also has a UV lamp that consists of a transparent tube and is usually isolated from the cell culture chamber by a specific lid, which aims to eliminate harmful organisms (36, 37).

The CO<sub>2</sub> concentration in the incubator chamber was measured, to see if it was within the acceptance criteria. Then, the status of the equipment was checked, where it was verified that it was at an adequate CO<sub>2</sub> and N<sub>2</sub> supply pressure, the operation of the display LEDs, the status of the cable and the voltage of the power supply, and the condition and tightness of the CO<sub>2</sub> and N<sub>2</sub> connections. In addition, the rubbers, the door switch, and the fan operation were checked. Afterward, the verification of the existence of leaks was conducted, using a leak detector. The equipment has a CO<sub>2</sub> sensor, as mentioned, which is located inside a box called CO<sub>2</sub> box. This box shows the need to be at 45°C and if it is below 30°C, the equipment will sound an alarm. It was verified that it was at the desired temperature.

Then, the temperature of the incubator was measured using a thermometer. This was at 37°C. Finally, cleaning procedures were conducted.

Regarding the measurement of the chamber's  $CO_2$  concentration, it presented a concentration of 4.9 in the equipment and of 4.7 in the  $CO_2$  meter, which is an acceptable value, that is, a stable value, since the acceptance criterion goes up to 5.0. This demonstrates

that the equipment is stable. The equipment had no problems or errors.

## 2.7. Panasonic CO<sub>2</sub> incubators

 $CO_2$  Incubators were developed with the goal of being able to create an ideal cell culture and to work with high-value samples, including reagents that are difficult to grow and sensitive to contamination. These have applications such as stem cell research, and the culture of hypersensitive and transgenic cells, among others (51, 52).

These are extremely easy to use, clean, and avoid contamination to create an ideal cell culture. This is optimized for high-value samples, including reagents that are difficult to grow and sensitive to contamination. These types of equipment consist of integrated tray supports that are part of the chambers, providing more space for trays, and allowing the incubator to accommodate more culture vessels. These also include UV lamps and a liquid crystal display (LCD) which improves the operation, allowing full control over different protocols (51, 52).

In addition, they have optimal humidity control, maximum security control, precise temperature control by direct heating and air conditioning system, precise  $CO_2$  control through a single beam with  $CO_2$  infrared system with the dual detector, and finally, a fast, effective, and safe (51, 52) H<sub>2</sub> O<sub>2</sub> decontamination control.

These incubators, like the SANYO incubator, need regular maintenance, as they are extremely sensitive equipment, because they work with cell growth and there is a need to maintain a contamination-free environment for reliable growth (51, 52).

The maintenance process for the two Panasonic incubators was quite simple. It started by cleaning the incubators. All internal accessories were removed, and the chambers of each incubator were cleaned.

Next, the  $CO_2$  concentration in the incubator chambers was measured to see if they were within the acceptance criteria. Next, it was verified whether they maintained an adequate  $CO_2$  and  $N_2$  supply pressure, the operation of the LEDs on the displays, the status and tightness of the  $CO_2$ and  $N_2$  connections, and the condition of the cables were also verified supply voltages. In addition, the operation of the fans, the rubbers, the switches of the doors of each, and the rest of the components of the equipment was verified. The state and functioning of the lamps and the temperature of the  $CO_2$  box were also verified.

Regarding the measurements of the CO2 concentration in the incubators' chambers, they showed concentrations of 4.8 and 4.9 in the equipment and of 4.7 and 4.8 in the CO2 meter, which are acceptable values. This demonstrates that the equipment is stable, as the acceptance criterion goes up to 5.0. It was also observed that there are no leaks in the equipment. It was concluded after the maintenance that the incubators did not present errors. Finally, both incubators were cleaned.

### 2.8. Critique analysis

Regarding the 7500 Fast Real-Time PCR System, the maintenance performed on the iMM showed some differences compared to what is referred to in the 7300/7500/7500 Fast Real-Time PCR System Installation and Maintenance Guide (8), mentioned in topic one. However, the differences are minimal. The maintenance performed on the iMM started with a self-test of the equipment, to observe if the equipment had any problems, such as contamination. In the 7300/7500/7500 Fast Real-Time PCR System Installation and Maintenance Guide (8), the first step is to check the equipment's disk and then make a backup copy of the equipment's files. It should be noted that these first procedures were the only ones that presented differences in the two cases.

Then, in both cases, the equipment was connected to the computer, conducting some tests. After this step, the equipment components were cleaned. Then, the desired calibrations were performed. However, after this step, only the 7300/7500/7500 Fast Real-Time PCR System Installation and Maintenance Guide (8) mentioned cleaning the computer's hard disk. The maintenance performed on the iMM was concluded with the completion of the calibrations.

Regarding the AKTA, Protein Purifier of 2008 was noticed both in the maintenance in the iMM and through what is mentioned in the AKTA Pure data file (9, 10), that the equipment has great sensitivity, and it is advisable that it is always the same user to perform its monitoring. In addition, both mention the fact that it is essential that the equipment is always at 20% ethanol, so that there is no possibility of excess samples remaining in the circuits, after the experiments are conducted, which could cause damage to the equipment in the long term. In the maintenance performed on the iMM, the equipment had a problem in one of the pumps, so the maintenance process was focused on that problem, to find a solution (solution presented in subchapter 2.2.4). The AKTA Pure data file (9, 10) shows a regular maintenance process, without the occurrence of equipment problems.

As for the High-Speed Centrifuge AVANTI J-25, both in the maintenance performed on the iMM and on the Avanti<sup>TM</sup>J-25 High-Performance Centrifuge Instruction Manual (11), the initial maintenance procedure consists of cleaning the equipment. However, in the maintenance performed on the iMM, particular care was taken, such as cleaning the interior of the equipment with a "vacuum cleaner" and, mainly, the temperature sensor, as the equipment had a problem with this component. However, in both cases, procedures are mentioned to avoid ice formation in the equipment chamber/dome. In addition, steps are described for defrosting the system and adjusting the temperature in both cases.

About the SIGMA 6-16K Centrifuge, the maintenance performed on the iMM was conducted in the same way as mentioned in the SIGMA 6-16K Maintenance Protocol. That is, in both cases, the equipment was first cleaned, internally and externally. All components of the centrifuge were checked to see whether it would be necessary to replace any. Finally, several performance tests were conducted, to see if the equipment was working correctly.

Regarding Telstar BIO II Advanced Camera Plus, the maintenance performed on the iMM was conducted in an equivalent way as mentioned in the User Manual Microbiological Safety Telstar Bio II Advance Cabinets plus (14). Both start by showing the cleaning of all the equipment and the verification of its constituents. Afterward, all the intended tests, and tests were conducted, both mentioned in subtopic 1.2.1 of Topic 1, and in subtopic 2.4, of this chapter. Finally, both mentioned cleaning and disinfecting the centrifuge, to ensure user safety and the correct functioning of the equipment.

As for Chemical Hood BECOME RB, the maintenance on the iMM and the maintenance procedure mentioned in the Fume Hoods Manual (15) had different initial steps. The Fume Hoods Manual (15) mentioned cleaning the equipment and checking the filters, to see if they are still in good condition. While in the iMM maintenance, no initial cleaning and component checking processes were mentioned, instead assessments and trials were conducted straight away. Finally, both mentioned cleaning all equipment.

Regarding the SANYO  $CO_2$  Incubator, the maintenance procedure referred to in the Service Manual CO2 Incubator MCO-18AIC is very reduced and focused on the main points of maintenance, such as sterilizing the chamber and its accessories, removing all these accessories, and filling the equipment humidifier plate with water at 37 C. Meanwhile, the maintenance performed on the iMM, on a SANYO  $CO_2$ Incubator, presents many more steps such as measuring the  $CO_2$  concentration in the incubator chamber, to see if it was within the acceptance criteria, the status and tightness of the  $CO_2$  and  $N_2$  connections, checking the operation of the display LEDs, the lamp life level, temperature measurement, among others, mentioned in subtopic 2.6. However, both end with the equipment cleaning procedure.

Finally, the Panasonic  $CO_2$  Incubators both in iMM maintenance and in the maintenance, a process referred to in Operating Instructions Panasonic (17), started by cleaning the equipment and then removing all the internal accessories from each one. The chamber of each incubator and all accessories were cleaned. However, after this step, the maintenance mentioned in Operating Instructions Panasonic (17) refers to just one more step that consists of installing all the internal accessories if there is no problem with the equipment. Meanwhile, maintenance on the iMM has more maintenance steps, such as checking the  $CO_2$  and N <sub>2</sub> supply

pressure, measuring the  $CO_2$  concentration of the incubator chambers, operating the LEDs on the displays, and checking for the existence of leaks in incubator tubes, among others, mentioned in subtopic 2.7.

## 3. Discussion and practical results

## 3.1. Fracttal software

The activities described below were conducted in the context of helping iMM. Initially, the Safety and Compliance department needed new maintenance software, to have a better organization of data from all iMM equipment. Therefore, an evaluation of the data of the software proposals that had been presented was conducted. In addition, a survey was conducted to see if there were more software that showed interest.

The software presented by the different companies was the software ManWinWin Business, with the possibility of choosing between two licenses; the ManWinWin Professional software; the software Infraspeak – Hypothesis 1 and Hypothesis 2, and the software Archiconsult. After the research, the software was also found Fracttal. Then, a meeting was scheduled with a representative of the Fracttal company, to understand if this software would be a reliable hypothesis. Software differences were evaluated and each one was evaluated, to understand which software is most suitable for the department.

After an evaluation of the cost, benefits, and disadvantages of each software, it was realized that the Fracttal software was the best choice. This is because it is the best in terms of price and advantages, compared to other software.

The Fracttal software is very complete. Its objective is to help companies with numerous types of equipment, to be practical for those who use it, and to help end the work of Excel and paper. It proposes to give companies, such as iMM, the possibility of having a specific program to place all the information and data of the equipment. This software is presented in the form of an application, and it was made to be used on a mobile phone. However, the platform can also be used on a computer, but for this, there is an online version in the Google browser, which is more practical (53, 54).

The application features a 24-h technical assistance zone in case there is a problem detected. In addition, Fracttal has an academy that shows the completion of certain tasks, within the application, and offers various online activities such as classes, help sessions with experts on the platform, and webinars, among other activities (54, 55).

The application is divided into Fracttal X, aimed at static equipment, and into Fracttal on board, used for moving equipment. The platform allows the segmentation of all equipment data (53, 55).

This platform is not just a maintenance management software, it manages to control several phases and helps to remember each step that must be conducted in a maintenance and/or equipment calibration process (53, 55).

#### 3.2. iMM equipment monitoring

The temperature ( $^{\circ}$ C) of iMM equipment was monitored every 10 min, for 1 h for each equipment. To monitor the temperature of the MHE they need, a portable probe is placed inside the equipment.

It should be noted that the temperature check is conducted on the equipment being monitored and on the portable probe, to understand if there is a large temperature difference between the equipment display and the portable probe display. This is an aid to make the necessary corrections at the end, that is, to check and correct the errors obtained from the measured temperature.

The portable probe was first placed inside the equipment and then waited a few minutes for it to reach stability inside the equipment. While waiting, the equipment and probe data were filled in a document called "Test Report," provided by the Safety and Compliance department.

As the temperature of the probe reached a stable temperature, the temperature value in °C on the display of the equipment and the temperature value on the display of the portable probe began to be observed every 10 min. Then, the acquired values were pointed out and the measured values were corrected, considering a correction value provided for each equipment.

Finally, the calculations of the corrected value of the portable probe and the error in the display were conducted, and the final data were filled in the "Test Report."

## 4. Conclusion

Security is a fundamental aspect of any organization and company, namely in the medical and hospital area. The safety of patients connected to/dependent on MHE and of the technical personnel who manage them is an extremely key factor. For it not to be harmed, there is a need for constant studies, characterizations, monitoring, planned maintenance, and calibration of the equipment in question. This is to ensure their safety and proper functioning, both for treating patients, as well as for hospitals, as well as for investigations, among others.

The experience of integration in the work context that the internship provided allowed us to confirm how much PM is extremely important. MP prevents MHE errors, operational damage, and unnecessary risks to engineers, patients, or equipment users from occurring. This is an asset for all companies that work with MHE, as it is a type of maintenance performed at pre-established time intervals, that is, it is planned maintenance, to reduce unnecessary costs for companies. The iMM features this type of maintenance on all MHEs, to improve their reliability and efficiency. Additionally, it was noticed the difference that can occur in the operation of MHE with constant maintenance, monitoring, and/or calibration planned and in time. Without these, it would not be possible to detect errors that are not easily found visually and manually, but that can create problems for the equipment eventually. Furthermore, it can cause unnecessary costs for companies such as iMM or even risks to MHE users, among others.

The internship lasted 11 months, offering the possibility that all the equipment that was studied needed calibrations (monthly and/or after the maintenance performed), making a link between theory and practice, which is fundamental for understanding the maintenance steps, the intervention process to be conducted and the work organization that it implies. As with other companies, if the MHE is not properly calibrated, there is a high probability of compromising their functioning, because despite the PM conducted, there is equipment in which calibration is an essential process for their correct functioning. It is concluded that the planned calibration of the MHE is an essential procedure to guarantee the quality of their functioning in the long term.

Additionally, it is concluded, based on the comments described for each equipment in topic 2, that some equipment had errors previously observed, but that was corrected during the maintenance and/or calibrations performed. This can be observed with the 7500 Fast Real-Time PCR equipment, where during the spectral calibrations performed, some level of contamination was verified in two wells of the plate. Other equipment presented more complex problems and was difficult to detect during the maintenance conducted, such as the AKTA: Protein Purifier from 2008. However, with many of the equipment, no problems were detected during the maintenance and/or calibrations performed, such as the example in the maintenance of the Telstar BIO II Advanced Biological Safety Chamber Plus. Despite this, it is always important to conduct routine maintenance, as these are what increase the reliability of the equipment, even if it does not appear to have any errors.

With the monitoring conducted on certain MHEs of the iMM, it was noticed how important a correct monitoring is. This is because, if an error occurs in a probe, other types of equipment are involved, or the MHE in question is not prepared for the monitoring process, it can lead to the provision of incorrect data. This is highlighted in the first monitoring conducted, in the fridge and freezer, both Liebherr brand, where an error occurred in the probe that was being used, which showed that it was damaged. It was replaced and the data provided by the new probe, for the same MHE, are different from those provided previously by the damaged probe.

It was also possible to observe the organization of the iMM, more specifically the Safety and Compliance Department, belonging to the Finance and Operations Office. This department presents the planned maintenance, calibration, and monitoring, among others, as very well organized. However, the department needed help finding the most suitable maintenance software to help with this organization. After a lot of searching, meetings, and comparison with other software, the Fracttal software was chosen to help organize the department in question, regarding the management of MHE.

This work allowed the characterization and maintenance of the MHE of the iMM. With the characterization of all the equipment studied and its maintenance, it was realized how extremely important a good characterization of the MHE, and its maintenance, calibration, or monitoring process is. This is because, without a good characterization of an MHE, it would not be possible to conduct correct maintenance, calibration, or monitoring.

## References

- iep. Verification of Work Equipment in Organizations. Available online at: https://www.iep.pt/verificacao-de-equipamentos-de-trabalhodl502005/
- Fernandes R. Procedures for Maintenance and Verification of Medical Equipment. [Curriculum Internship Report submitted to satisfy the requirements of the Master's degree in Computer Engineering and Medical Instrumentation]. Porto: Instituto Superior de Engenharia do Porto (2017).
- Braz R. The Importance of Reliability of Medical Equipment [Internet]. (2021). Available online at: https://blog.arkmeds.com/2021/11/26/ equipamentos-medicos/
- Wei Y, Yu H, Geng J, Wu B, Guo Z, He L, et al. Hospital efficiency and utilization of high-technology medical equipment: a panel data analysis. *Health Policy Technol.* (2018) 7:65–72.
- Bahreini R, Doshmangir L, Imani A. Factors affecting medical equipment maintenance management: a systematic review. *J Clin Diagn Res.* (2018) 12:IC 01–7.
- Arab-Zozani M, Imani A, Doshmangir L, Dalal K, Bahreini R. Assessment of medical equipment maintenance management: proposed checklist using Iranian experience. *Biomed Eng Online*. (2021) 20:49.
- Jamshidi A, Rahimi S, Ait-Kadi D, Ruiz A, Ruiz Bartolome A. Medical Devices Inspection and Maintenance; A Literature Review. (2016). Available online at: https://www.researchgate.net/publication/ 287176949
- 8. Pcr System. 7300/7500/7500 Fast Real-Time PCR System Installation and Maintenance Guide. (2006).
- Cytiva. ÄKTA Pure Protein Purification System. Available online at: https://www.cytivalifesciences.com/en/de/shop/chromatography/ chromatography-systems/akta-pure-p-05844
- MedicalExpo. ÄKTA Pure Liquid Chromatography System. Available online at: https://www.medicalexpo.com/en/prod/ge-healthcare-lifesciences/product-80554-532685.html
- 11. Avanti TJ. 25 High Performance Centrifuge Instruction Manual. (1995).
- 12. Avanti J. Avanti J 25I PT Maintenance Protocol.
- 13. Sigma. Protocol Sigma 6-16k Maintenance.
- 14. Telstar. User Manual Microbiological Safety Cabinets Telstar Bio II Advance Plus. (2018).
- 15. Smoke. Smoke Hoods Manual. (2022).
- 16. Incubator. Service Manual CO2 Incubator MCO-18AIC.
- 17. Operating. Instructions Panasonic. (2014).
- Gerônimo M, Leite B, Oliveira R. Maintenance management in hospital equipment: a case study. *Exactly* (2017) 15.

- 19. Ministry OE. Decree-Law no. 50/2005 of the 25th of February.
- Infarmed. Frequently Asked Questions: What are medical devices? (2016). Available online at: https://www.infarmed.pt/web/infarmed/perguntasfrequentes-area-transversal/dm
- Mwanza Bupe G, Mbohwa C. An assessment of the effectiveness of equipment maintenance practices in public hospitals. *Proc Manuf.* (2015) 4:307–14.
- Marmolejo-Correa D, Juarez-Valdivia RG, Rodriguez-Navarro A. Optimization of preventive maintenance program for imaging equipment in hospitals. In: *Computer Aided Chemical Engineering*. (2016). p. 1833–8. Available online at: https://www.sciencedirect.com/ science/article/abs/pii/B9780444634283503106?via%3Dihub
- Godoi C, Pazeto A, Rezende M, Oliveira R, Milagre S. Methodology for Classification of Medical-Hospital Equipment in Hospital de Clinicas de Uberlândia.
- 24. Suassuna A. Training in Medical-Hospital Equipment: From Course to Assessment [Course Completion Work]. Lagoa Nova: Federal University of Rio Grande do Norte (2017).
- SGS. Consumer and Retail Goods CE Marking. Available online at: https://www.sgs.pt/pt-pt/consumer-goods-retail/electrical-andelectronics-total-solution-services/audio-video-and-householdappliances/certification/ce-marking
- 26. Bajur T. Know the Life Cycle of Hospital Equipment. Blog.arkmeds (2016).
- Blog.arkmeds. Maintenance of Hospital Equipment. Available online at: https://blog.arkmeds.com/manutencao-de-equipamentos-hospitalares/
- Faria C. Maintenance Management of Hospital Facilities and Equipment. Ph.D. Dissertation. Porto: Faculty of Engineering of the University of Porto (1999).
- Martins R. The Importance of Monitoring. Computerworld. (2011). Available online at: https://www.computerworld.com.pt/2011/11/09/aimportancia-da-monitorizacao/
- Portuguese Institute of Quality. *International Vocabulary of Metrology*. (2012). Available online at: www.ipq.pt
- Portuguese Security Association (APSEI). Safety at Work. Available online at: https://www.apsei.org.pt/areas-de-atuacao/seguranca-notrabalho/equipamentos-de-protecao-individual/
- João Lobo Antunes Institute of Molecular Medicine. Chasing Questions: Since 2002. João Lobo Antunes Institute of Molecular Medicine (2002).
- Mota M. Director's Message. João Lobo Antunes Institute of Molecular Medicine.
- 34. Carvalho F. *Finance and Operations Office*. João Lobo Antunes Institute of Molecular Medicine.
- Santos S, Cabral M, Lemos F, Costa C, Gomes E, Alibhai B, et al. Safety & Compliance. João Lobo Antunes Institute of Molecular Medicine.
- Marshall Scientific. Marshall Scientific. Sanyo MCO-18AIC(UV) CO2 Incubator. Available online at: https://www.marshallscientific.com/ Sanyo-MCO-18AIC-UV-CO2-Incubator-p/sa-mco18.htm

- 37. Hartmann I, Wagener J. CO2 Incubators Best Practices for Selection, Set-up, and Care. Eppendorf. Available online at: https://www.eppendorf.com/product-media/doc/en/151861/ Eppendorf\_CO2-Incubators\_White-Paper\_029\_CO2-Incubators\_ Best-Practices-Selection\_Set-up-Care.pdf
- ThermoFisher Scientific. ROI & Background Calibration Kit, 96well. Available online at: https://www.thermofisher.com/order/catalog/ product/4432626?SID=srch-hj-4432626
- ThermoFisher Scientific. 7500 Fast Real-Time PCR System, Laptop. Available online at: https://www.thermofisher.com/order/catalog/ product/4351106?SID=srch-srp-4351106
- 40. ThermoFisher Scientific . *Real-Time vs. Digital PCR vs. Traditional PCR.* Available online at: https://www.thermofisher.com/en/en/home/lifescience/pcr/real-time-pcr/real-time-pcr-learning-center/real-timepcr-basics/real -time-vs-digital-vs-traditional-pcr.html#2
- 41. Cytiva. Protein Purification Methods. Available online at: https://www.cytivalifesciences.com/en/us/solutions/protein-research/ knowledge-center/protein-purification-methods?extcmp=g-se-paid& gclid=CjwKCAiA78aNBhAlEiwA7B76pxMylZ1SwJRzaep8FbfONAB-DZ8BDBR81gLaeupOkZpupUj8XbFO-RoCPC4QA
- 42. Forward J. (2019).
- 43. Avanti J. Qualification Tests Avanti J-25i SN JJ99K15.
- 44. Avanti \*. Instruction Manual TM TM Avanti \* J-25 High-Performance Centrifuge.
- Avanti \*. Intervention report nr 4364\_2021 Avanti J-25i SN JJ99K15 Maintenance.
- 46. Sigma. Operating Manual. Available online at: www.sigmazentrifugen.de
- Telstar. Class II Microbiological Safety Cabinet Bio II Advanced Plus. Available online at: https://www.telstar.com/lab-hospitals-equipment/ biological-safety-cabinets/bio-ii-advance-plus/
- 48. Telstar. Bio II Advanced Plus Class II Biological Safety Cabinet. Telstar
- 49. Burdinola. Smoke Cupboards. (2022). Available online at: https://www. burdinola.com/en/fume-cupboards/
- American Laboratory Trading (ALT). Centrifuges. Available online at: https://americanlaboratorytrading.com/product-category/centrifuges\_ 72?SubCat=213
- PHC. CO2 Incubators: MCO-170AIC-PE IncuSafe CO2 Incubator. (2020). Available online at: https://www.phchd.com/eu/biomedical/ incubation/CO2incubators/mco-170aic
- Richmond Scientific. Panasonic KM-CC17R2E 165L CO2 Incubator. (2022). Available online at: https://www.richmondscientific.com/ product/panasonic-km-cc17r2e-165l-co2-incubator
- 53. Fracttal. *Fracttal Software. Advice software.* (2021). Available online at: https://www.softwareadvice.com/cmms/fracttal-profile/
- 54. Fracttal. *Maintenance Management*. (2022). Available online at: https://www.fracttal.com/en/blog/tag/maintenance-management
- 55. Fracttal. *The Smart Maintenance Platform*. (2022). Available online at: https://www.fracttal.com/en/