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Calibration of Medical Devices: Method and Impact on Operation Quality

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ABSTRACT

Medical devices play a pivotal role in modern healthcare, aiding in accurate diagnosis, monitoring, and treatment of patients. The reliability and accuracy of these devices are indispensable for ensuring patient safety and well-being. This project highlights the critical importance of calibrating medical devices to maintain their accuracy, precision, and performance, ultimately safeguarding the lives of patients. Calibration of medical devices is a systematic process that verifies and adjusts their measurements to a known standard. This process ensures that medical devices consistently provide accurate data and results. In the absence of proper calibration, there is a significant risk of incorrect readings, misdiagnoses, and inappropriate treatment plans, all of which can lead to patient harm. Regular calibration is essential not only for maintaining patient safety but also for meeting regulatory requirements and quality assurance standards. It helps identify and rectify deviations or drifts in device performance, preventing potential hazards in healthcare settings. Compliance with calibration protocols ensures that medical institutions and professionals can deliver reliable and effective care. Moreover, calibrated medical devices enhance the efficiency and cost-effectiveness of healthcare systems by minimizing the need for repeated tests and procedures due to inaccurate results. Patients can have confidence in the reliability of the devices used in their care, fostering trust in healthcare providers and institutions.

Keywords: *Medical device; Calibration; Patient safety; Artificial Pacemaker; Ventilator; Defibrillators; Insulin pump; X-ray Machine.*

Introduction

Medical devices are an important part of health care, yet they are an extraordinarily heterogeneous class of products. The term medical device includes such technologically simple items as ice bags and tongue depressors on one end of the continuum and very sophisticated items such as cardiac pacemakers and proton therapy devices on the other end. Broadly based on the function of medical device they may be classified as preventive care device, assistive care

device, diagnostic device and therapeutic device. Perhaps these are the unique challenges like safety concerns and diversity of products coupled with the sheer number of different devices in market that makes the development of an effective and efficient regulatory scheme a unique challenge for domestic as well as international regulatory bodies. Regulators and governments count on standards to help develop better regulation [1]. There are many types of medical

devices, depending on their intended use, design, and classification. According to the World Health Organization (WHO), a medical device can be any instrument, apparatus, implement, machine, appliance, implant, and reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose [1]. The WHO estimates that there are an estimated 2 million different kinds of medical devices on the world market, categorized into more than 7000 generic devices groups. Some examples of medical devices are: Implantable devices, such as pacemakers, vascular grafts, clips, filters, and end osseous implants [2]. Life-saving and life-sustaining devices, such as ventilators, oxygenators, defibrillators, blood filters, and circulators [2]. Priority medical devices for the COVID-19 response, such as oxygen therapy, pulse oximeters, patient monitors, thermometers, infusion and suction pumps, X-ray, ultrasound and CT scanners as well as personal protective equipment [3]. The growing sophistication of medical equipment has significantly improved the individual and society's health [4]. The advancement has improved survivability in the face of disease or injury and greatly enhanced patients' life quality through an improved diagnosis and therapeutic results. Managing assets and facilities is one of the significant features in ensuring the continuity of primary and support business activities in healthcare services [5]. The delivery of healthcare services to the communities are significantly affected without effective management implementation [6]. Medical equipment is a crucial asset that substantially contributes to the effectiveness and healthcare services quality enhancement [7]. As the medical equipment aids various services in the healthcare sector, the management representative, such as clinical engineers, must monitor and upkeep the assets by performing several maintenances works throughout the equipment life cycle [8]. Medical devices are an important part of health care, yet they are an extraordinarily heterogeneous class of products. The term medical device includes such technologically simple items as ice bags and tongue depressors on one end of the continuum and very sophisticated items such as cardiac pacemakers and proton therapy devices on the other end. Broadly based on the function of medical device they may be classified as preventive care device, assistive care device, diagnostic device and therapeutic device. Perhaps these are the unique challenges like safety concerns and diversity of products coupled with the sheer number of different

devices in market that makes the development of an effective and efficient regulatory scheme a unique challenge for domestic as well as international regulatory bodies. Regulators and governments count on standards to help develop better regulation [9]. Medical devices are used for the diagnosis and treatment of disease, as well as the rehabilitation of patients during post-treatments. It can be used independently or in conjunction with any accessory, consumable, or other pieces of medical device. The reliability, maintainability, availability, and safety of medical devices are the ultimate goal in maintenance strategy, where medical devices should not fail frequently and must be repaired promptly when the failures are detected. Numerous investigations have associated medical device failures with severe patient injuries and deaths. The world health organization (WHO) estimates that 50% to 80% of equipment is non-functional due to the lack of maintenance culture, competency, and a tendency to focus on corrective maintenance rather than preventative maintenance. Ineffective medical device maintenance causes crucial equipment downtime, diminished device performance, monetary waste, and depletion of resources. Older technological devices require more attention due to a lack of service or user manuals and manufacturer guidance [10]. Medical devices range from basic tongue depressors to complex radiation systems with over 10,000 different types, and 1.5 million unique medical devices are recorded globally. Medical device expenditure climbed from USD 145 billion in 1998 to USD 220 billion in 2006, which indicates an annual growth rate of more than 10% [11]. Medical devices maintenance market projection demonstrates that the medical devices maintenance market is expected to grow at a compound annual growth rate (CAGR) of 10.4% to USD 74.2 billion by 2026, which will increase drastically from USD 45.2 billion in the year 2021 [12]. The medical devices industry has grown rapidly and incessantly over the past century. The sophistication and complexity of the designed instrumentation is nowadays rising and, with it has also increased the need to develop some better, more effective and efficient maintenance processes, as part of the safety and performance requirements [13]. For the health industry, be it hospitals or manufacturers of medical devices, nothing counts more than the safety of a patient [14]. Therefore, all quality conscious hospitals consider the periodic testing and calibration of devices, a permanent feature in their quality control regimen that they strictly adhere to. It is a significant mark to their dedication and commitment to quality

and continuous improvement. Testing and calibration of devices ensures accuracy, effectiveness in diagnosis and treatment and long life of devices, which ultimately enables one to achieve the highest degree of quality control and patient safety. Medical errors are a recognized cause of harm in the health care system, but clinical measurement errors are seldom, if ever, identified as causes of adverse events [15]. In recent years, a growing number of patients have suffered from adverse events due to medical devices malfunction [16]. In addition to knowledge and experience of medical doctors, correct diagnosis and appropriate patient treatment largely depend on accuracy and functionality of medical devices. In a large number of serious medical situations, devices proper functionality of medical devices is crucial for patients. Therefore, it is necessary to carry out as strict and independent testing of functionalities of medical devices as possible and to obtain the most accurate and reliable diagnosis and patient treatment [17]. The objective of this paper is to examine the impact of calibration on medical devices performance and patient's safety by investigating the performance of selected sample of medical devices against international standard reference or manufacturer recommendations. This paper considers several common medical equipment's used in hospital as the research object, their maintenance procedure, calibration methods and results before and after calibration of the equipment.

Importance of Calibration

According to the International Organization for Standardization calibration is the set of operations that establish, under specified conditions, the relationship between values indicated by a measuring instrument, a measuring system or values represented by a material measure, and the corresponding known values of a measured [18]. Accuracy and reliability of all measurements would be doubtful if the instruments used were not calibrated. Calibration ensures that a measuring instrument displays an accurate and reliable value of the quantity being measured. Calibration is the process of reporting measurement results by comparing the reference measurement device, which is ascertained to its accuracy, with another measurement device whose accuracy cannot be ascertained. Calibration is not an adjustment operation maintenance or the repair of a device [19]. The importance of calibration has been increasing in devices used in healthcare. Since the World Health Organization (WHO) considers medical calibration measurements as part of quality health care, it publishes guidelines for standard practice and seeks to ensure that health care providers focus on the issue [20]. The calibration of inspection, measuring, and test equipment is crucial in the medical device industry. Properly calibrated equipment ensures accurate and reliable measurement data, which directly impacts the quality of manufactured devices. Each manufacturer is obligated to ensure that their inspection, measuring, and test equipment, including mechanical, automated, or electronic equipment, is suitable for its intended purposes and is capable of producing valid results (Figure 1).

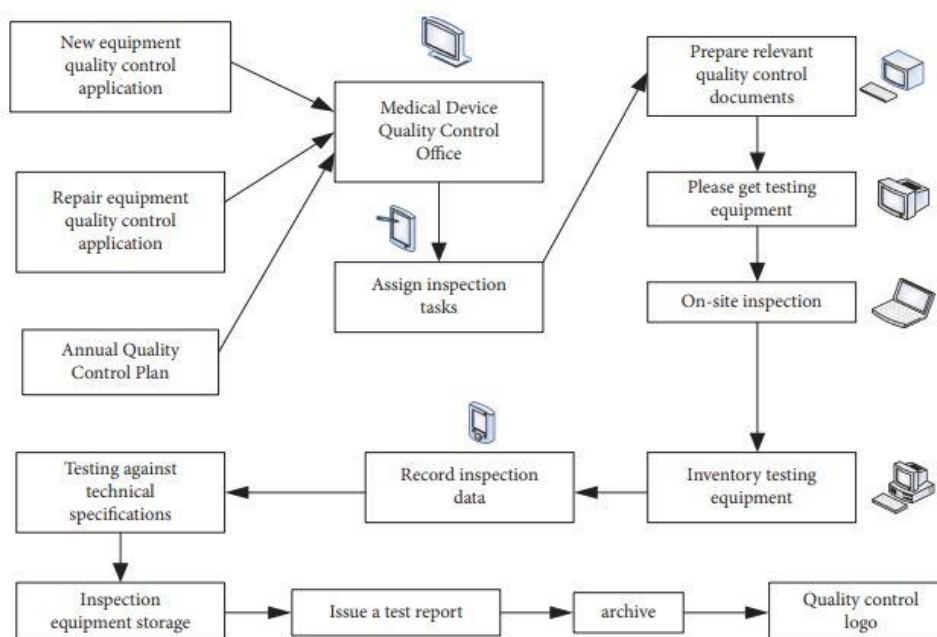


Figure 1: Quality control system of medical devices.

Challenges in maintenance and quality control of medical devices

While the regulations are designed to maintain the highest standards, the medical device industry faces several challenges when it comes to the calibration of inspection, measuring, and test equipment. These challenges can vary depending on the size of the organization, the complexity of the equipment, and the scope of their manufacturing operations. Some of the key challenges include:

Compliance with Specific Directions and Limits:

Calibration procedures, as outlined in Section 820.72(b) of the QSR, require manufacturers to adhere to specific directions and limits for accuracy and precision. This poses a significant challenge, particularly for companies with diverse equipment types and applications. Calibration requirements can vary greatly based on the nature of the medical devices being manufactured, necessitating extensive and detailed calibration procedures tailored to each piece of equipment [21].

Remedial Action and Impact on Device Quality:

In cases where calibration limits are not met, the regulation demands provisions for remedial action to reestablish the limits. The challenge lies in promptly identifying calibration deviations and initiating the appropriate corrective actions. Additionally, manufacturers must assess whether the deviation had any adverse effects on the quality of the medical device produced using the equipment during the non-conforming period.

Traceability to National or International Standards:

To ensure the accuracy and reliability of calibration, the regulation mandates that calibration standards used must be traceable to national or international standards. However, in certain situations, achieving traceability may be impractical or unavailable. This challenge arises when specific calibration standards are not readily accessible, or when medical devices require unique and specialized calibration processes.

Independent Reproducible Standards and In-house Standards:

In the absence of applicable standards, manufacturers are required to establish independent reproducible standards or in-house standards. Developing and maintaining such standards necessitates substantial

resources and expertise. Creating independent standards that align with the precision and accuracy required for medical devices can be resource-intensive and time-consuming.

Documentation and Record-Keeping:

The regulation emphasizes the importance of proper documentation of calibration activities, including equipment identification, calibration dates, personnel responsible for calibration, and the next calibration date. Maintaining accurate and up-to-date records is crucial but can be a labor-intensive process for manufacturers, particularly for those with a large number of equipment items requiring regular calibration.

Ensuring Routine Calibration and Maintenance:

Manufacturers must establish and maintain procedures for routine calibration, inspection, and maintenance of equipment. This involves managing a complex schedule to ensure timely calibrations without disrupting the production process. The challenge lies in effectively coordinating and scheduling calibration activities to minimize equipment downtime while complying with the regulatory requirements.

Training and Competency of Personnel:

The successful implementation of calibration processes relies on the competency of personnel responsible for conducting calibrations. Manufacturers must invest in adequate training and qualification programs to ensure that personnel possess the necessary skills and knowledge to perform calibrations accurately.

Compliance with the regulations regarding the calibration of inspection, measuring, and test equipment is fundamental to the medical device industry's success. Adherence to Subpart G, Section 820.72, of the Quality System Regulation is essential for maintaining product quality, safety, and efficacy. Despite the challenges faced by the industry in meeting these requirements, it is through rigorous calibration practices and diligent record-keeping that manufacturers can continue to deliver high-quality medical devices that save and enhance lives.

Calibration procedure and maintenance or quality control outcome of some common medical devices

Artificial Cardiac Pacemaker

An artificial cardiac pacemaker (artificial pacemaker, and sometimes just pacemaker, although the term is

also used to refer to the body's natural cardiac pacemaker) is a medical device, nowadays always implanted, that generates electrical pulses delivered by electrodes to one or more of the chambers of the heart, the upper atria or lower ventricles. Each pulse causes the targeted chamber(s) to contract and pump blood, thus regulating the function of the electrical conduction system of the heart [22].

The primary purpose of a pacemaker is to maintain an adequate heart rate, either because the heart's natural pacemaker is not fast enough, or because there is a block in the heart's electrical conduction system. Modern pacemakers are externally programmable and allow a cardiologist, particularly a cardiac electrophysiologist, to select the optimal pacing modes for individual patients. Most pacemakers are on demand, in which the stimulation of the heart is based on the dynamic demand of the circulatory system. Others send out a fixed rate of impulses (Figure 2).

A specific type of pacemaker called an implantable cardioverter-defibrillator combines pacemaker and defibrillator functions in a single implantable device [23] Others, called biventricular pacemakers, have multiple electrodes stimulating different positions within the ventricles (the lower heart chambers) to improve their synchronization.



Figure 2: Artificial Pacemaker.

Methods for calibration of an artificial pacemaker

ECG (Electrocardiogram) Guided Calibration:

This is the most common method for pacemaker calibration. An ECG is performed to assess the

patient's heart rate, rhythm, and any underlying abnormalities.

The pacemaker is then programmed to pace the heart when needed, typically by sensing the patient's intrinsic heart rate (atrial or ventricular) and delivering electrical impulses when necessary to maintain an appropriate heart rate and rhythm.

Telemetry-Based Calibration:

Many modern pacemakers are equipped with remote monitoring capabilities, allowing healthcare providers to adjust pacemaker settings remotely.

Telemetry-based calibration enables healthcare professionals to monitor the patient's heart rhythm and adjust the pacemaker settings as needed without the need for in-person visits.

Rate-Response Calibration:

Some pacemakers are equipped with rate-responsive sensors that can adjust the pacing rate based on the patient's physical activity and metabolic needs.

Calibration of rate-responsive pacemakers may involve setting parameters related to sensor sensitivity, response rate, and upper and lower rate limits.

Threshold Testing:

Threshold testing is performed to determine the minimum amount of electrical energy required to capture the heart and initiate a heartbeat.

This involves gradually reducing the pacing energy until the pacemaker no longer captures the heart. The energy is then set slightly above this threshold to ensure reliable pacing.

Mode Switching Calibration:

Some dual-chamber pacemakers have the ability to switch between pacing modes (e.g., DDD, VVI) based on the patient's natural rhythm.

Calibration for mode switching involves setting parameters that determine when the pacemaker should switch from one mode to another, such as detecting atrial or ventricular events.

Sensitivity Adjustments:

Pacemakers are calibrated to sense the heart's intrinsic electrical activity. Sensitivity adjustments ensure that the device accurately detects these signals.

Sensitivity settings may need to be adjusted if there are issues with oversensing (detecting signals that are not intrinsic heartbeats) or under sensing (not detecting genuine heartbeats).

Rate Limits and Hysteresis:

Setting upper and lower rate limits ensures that the pacemaker paces within a predefined heart rate range.

Hysteresis settings allow the pacemaker to maintain a higher heart rate for a period after an episode of slow heart rate, reducing unnecessary pacing.

Testing Under Different Conditions:

Calibration may involve testing the pacemaker under various conditions, such as during exercise or sleep, to

ensure it responds appropriately to changes in heart rate and activity.

It's important to note that pacemaker calibration should always be performed by qualified healthcare professionals, such as cardiologists or electrophysiologists, who are experienced in managing cardiac devices. Regular follow-up appointments are essential to monitor the device's performance and make any necessary adjustments to optimize its function for the patient's specific needs.

From the data obtained from Asia Hospital, Patna between January to July 2023, out of 35 artificial pacemakers it can be observed that a significant pass rate is obtained after successful calibration and maintenance (Figure 3).

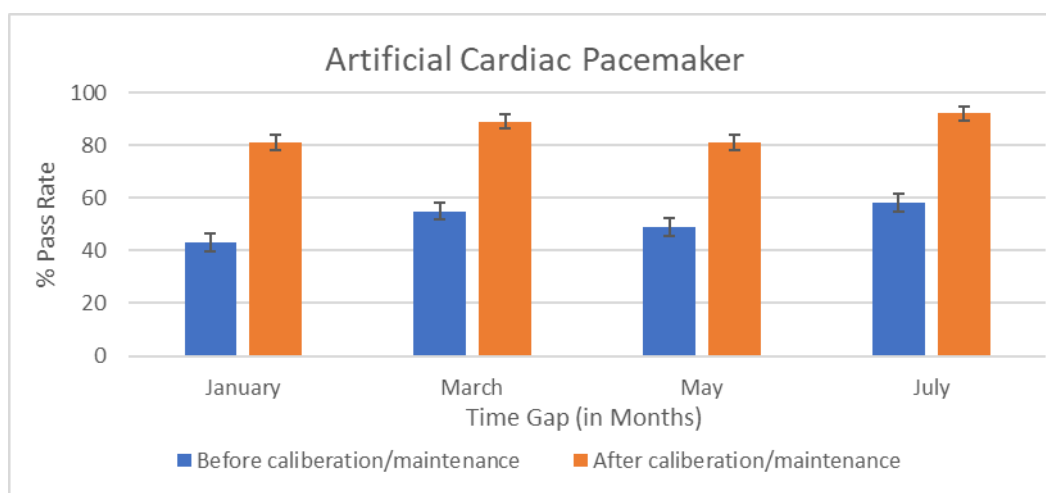


Figure 3: Graph of pass percentage before and after calibration of artificial pacemaker.

Insulin Pump

Insulin pumps are small, computerized devices. They are about the size of a small cell phone. Insulin pumps deliver doses of insulin on a pre-programmed schedule. Insulin is the hormone that regulates your blood sugar. People who have diabetes don't make enough insulin naturally. Instead, they have to use insulin injections to manage their blood sugar. Pumps offer a steady stream of insulin so that you can have fewer needle sticks. They're also a good option for children or anyone who has trouble remembering their insulin injections. Because insulin pumps stay attached to the body, some people find an insulin pump more convenient than insulin pen injections [24].

Insulin pumps can also be a good option for young people with Type 1 diabetes. A pump can deliver a steady supply of insulin, even for children and others

who might have trouble sticking to a schedule for insulin injections.

Methods for calibration of an insulin pump

Calibrating an insulin pump is a crucial step in ensuring its accurate delivery of insulin to manage blood glucose levels in individuals with diabetes. Here are some common methods and considerations for calibrating insulin pumps:

Blood Glucose Monitoring:

The primary method for calibrating an insulin pump is through blood glucose monitoring. Individuals with diabetes typically use a blood glucose meter to measure their current blood sugar levels.

This measured blood glucose value is used to inform the insulin pump about the appropriate insulin dosage required to maintain target blood glucose levels.

Entering Blood Glucose Values:

Most insulin pumps have a screen or interface where users can manually enter their current blood glucose levels. This value serves as the basis for the pump's calculations. Users should follow their healthcare provider's recommendations for how often to enter blood glucose values, which can vary depending on the individual's treatment plan.

Continuous Glucose Monitoring (CGM) Integration:

Some insulin pumps are compatible with CGM systems that provide continuous real-time glucose readings. CGM-integrated insulin pumps can automatically adjust basal insulin rates and provide alerts or suggestions for bolus insulin doses based on real-time glucose data.

Insulin-to-Carbohydrate Ratio (ICR) and Correction Factors:

Calibration may also involve setting and periodically adjusting the ICR and correction factors. These parameters help the insulin pump determine the bolus insulin dose needed to cover meals and correct high blood sugar levels. Healthcare providers work with individuals to determine these ratios based on their unique insulin sensitivity and carbohydrate intake.

Regular Review and Adjustments:

Calibrating an insulin pump is an ongoing process. It's essential to regularly review blood glucose data, pump settings, and insulin delivery patterns. Adjustments may be needed to fine-tune the insulin pump settings

and maintain stable blood glucose levels. These adjustments are typically made under the guidance of a healthcare provider.

Educating Users:

Proper education and training are crucial for individuals using insulin pumps. They need to understand how to calibrate the pump, interpret blood glucose data, and make informed decisions about insulin dosing.

Healthcare providers and diabetes educators play a significant role in providing this education.

Manufacturer Guidelines:

It's important to follow the specific guidelines provided by the insulin pump manufacturer for calibration and operation. These guidelines may vary depending on the brand and model of the pump.

Individuals with diabetes should work closely with their healthcare providers and diabetes care teams to establish and maintain appropriate insulin pump settings and calibration methods that align with their unique treatment goals and needs.

From the data obtained from Asia Hospital, Patna between January to July 2023, out of 53 insulin pumps it can be observed that a significant pass rate is obtained after successful calibration and maintenance (Figure 4).

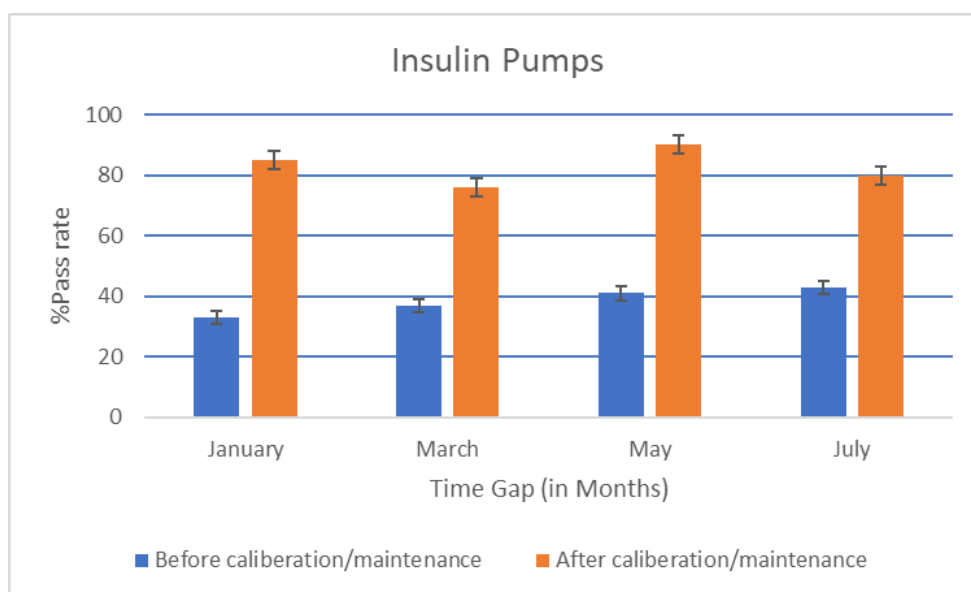


Figure 4: Graph of pass percentage before and after calibration of insulin pumps.

Defibrillators

Defibrillators are devices that apply an electric charge or current to the heart to restore a normal heartbeat. If the heart rhythm stops due to cardiac arrest, also known as sudden cardiac arrest (SCA), a defibrillator may help it start beating again. A sudden cardiac arrest is fatal unless treated right away with CPR (cardiopulmonary resuscitation) and a defibrillator [25].

Defibrillators can lower the risk of sudden death among people who have a known arrhythmia or a high risk of a life-threatening arrhythmia from causes such as genetic diseases, heart failure, or a prior cardiac arrest.

Methods for calibration of defibrillators

Calibration of defibrillators is crucial to ensure that these life-saving devices are operating correctly and delivering the appropriate electrical shocks when needed. Here are the steps and considerations for calibrating defibrillators:

Check Power Source and Battery:

Ensure that the defibrillator has a fully charged or properly functioning battery. Defibrillators are often used in emergency situations, so having a reliable power source is critical.

Inspect Electrode Pads and Leads:

Examine the electrode pads and leads for any damage or wear. Ensure that they are properly connected to the defibrillator and that the adhesive on the pads is still effective. Replace any damaged or expired components.

Verify Proper Functionality

Turn on the defibrillator and perform a self-check or system test, if available. This test will assess the internal components, including the electronics and display.

Verify that the device's alarms, indicators, and audio signals are functioning correctly.

Check Electrode Pad Expiration Date:

Electrode pads typically have an expiration date. Ensure that the pads are within their expiration date to guarantee their effectiveness during defibrillation.

Check Electrode Pad Conductivity:

Some defibrillators have a feature that checks the conductivity of the electrode pads when they are

connected to the device. Ensure that the defibrillator confirms the pad's connectivity.

Calibrate Energy Levels:

Many defibrillators allow for calibration of energy levels, ensuring that the device is delivering the appropriate amount of electrical energy during a shock. Follow the manufacturer's instructions to calibrate the energy settings, typically using a specialized calibration tool or process.

Test Defibrillation Shock:

In a controlled and simulated environment, perform a defibrillation test using a mannequin or a test load to verify that the device delivers the correct energy levels and monitors the patient's rhythm accurately.

Review and Document Results:

Keep detailed records of the calibration process, including any adjustments made, test results, and the date of calibration. This documentation is essential for regulatory compliance and quality assurance.

Regular Maintenance and Recalibration: Schedule regular maintenance and recalibration according to the manufacturer's recommendations and regulatory requirements. Calibration should be performed by trained technicians or authorized service providers.

Compliance with Regulations:

Ensure that the calibration process complies with applicable regulations and standards, such as those set forth by health authorities or regulatory agencies in your region.

Training:

Ensure that healthcare professionals and emergency responders who use the defibrillator are trained to operate it correctly and understand the importance of regular maintenance and calibration.

Calibration of defibrillators is critical for patient safety, as it ensures the device's effectiveness during life-threatening situations. Regular checks and maintenance help maintain the device's reliability and readiness for use in emergencies. Always refer to the specific guidelines provided by the defibrillator manufacturer and follow local regulations and standards.

From the data obtained from Asia Hospital, Patna between January to July 2023, out of 41 defibrillators it can be observed that a significant pass rate is obtained after successful calibration and maintenance (Figure 5).

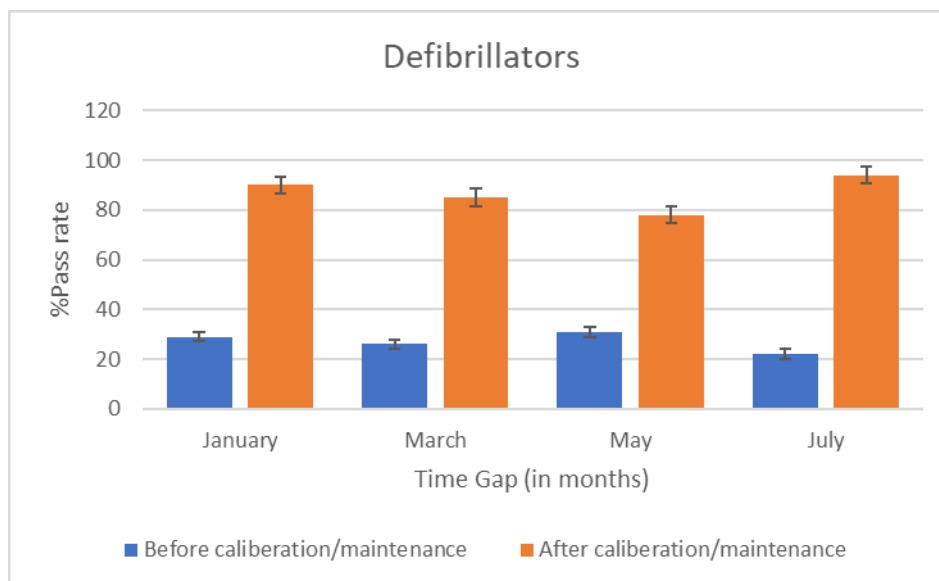


Figure 5: Graph of pass percentage before and after calibration of defibrillators.

Ventilator

A ventilator is a machine that helps you breathe. Just like crutches support your weight, the ventilator partially or completely supports your lung functions. Intubation and mechanical ventilation often happen together, but they're not the same. When a provider intubates, they put a tube down your throat into your airway (trachea). Then, a provider will connect the tube in your throat to a ventilator. Sometimes a face mask connects you to the ventilator and you don't have to be intubated.

Modern mechanical ventilators use positive pressure to push air into your lungs. Positive pressure ventilation can be invasive or non-invasive [26].

Invasive mechanical ventilation: This means you have a tube in your airway connected to a ventilator. This tube can go through your mouth (intubation) or neck (tracheostomy).

Non-invasive ventilation: This uses a face mask connected to a ventilator. Straps hold the mask to your head to hold it tight. The ventilator pushes air into your lungs. Forms of non-invasive ventilation include devices you might use at home, like CPAP or Bi Level positive airway pressure.

Methods for calibration of ventilators

Calibration of ventilators is essential to ensure that these medical devices deliver accurate and reliable respiratory support to patients. Proper calibration helps maintain patient safety and ensures the ventilator functions as intended. The calibration process may vary depending on the type and model of the ventilator, but here are some general steps and

considerations:

Preparation

Ensure that the ventilator is clean and free from any debris or contaminants.

Confirm that the ventilator is connected to a stable power source or has a fully charged battery.

Manufacturer's Guidelines

Refer to the manufacturer's user manual and guidelines for calibration procedures specific to your ventilator model.

Follow the manufacturer's recommended maintenance schedule, which typically includes calibration.

Perform a Self-Test:

Many modern ventilators have a built-in self-test or diagnostic mode that checks various components and sensors for proper functioning.

Initiate the self-test according to the manufacturer's instructions and note any errors or issues detected during the test.

Inspect and Calibrate Sensors:

Ventilators have various sensors (e.g., pressure sensors, flow sensors, oxygen sensors) that need calibration to ensure accurate readings.

Follow the manufacturer's guidelines to access and calibrate these sensors using calibration gases or reference standards, if applicable.

Check Ventilator Display and Alarms:

Verify that the ventilator's display is functioning correctly and that all alarms are operational. Test alarm

limits and ensure that they trigger appropriately when set conditions are met.

Verify Gas Delivery Accuracy

If your ventilator delivers specific gases (e.g., oxygen, air, medical air), confirm that it accurately delivers the intended gas concentrations and flow rates.

Use calibrated flow meters and gas analysers to measure and verify gas delivery accuracy.

Calibrate Pressure and Flow:

Check and calibrate pressure sensors and flow sensors to ensure they provide accurate measurements. Use calibrated reference standards or tools provided by the manufacturer for this purpose.

Check Inspiratory and Expiratory Valve Functionality

Verify that the inspiratory and expiratory valves open and close properly, and that there are no leaks or obstructions.

Perform a leak test to ensure the system maintains the desired pressure during inspiration and expiration.

Document Calibration Results:

Maintain a detailed record of the calibration process, including the date, calibration values, any adjustments

made, and the technician's or operator's name.

This documentation is essential for regulatory compliance and quality assurance.

Regular Maintenance and Recalibration:

Schedule regular maintenance and recalibration intervals as recommended by the manufacturer. Adhere to local regulations and standards governing medical device calibration and maintenance.

Training:

Ensure that healthcare professionals responsible for operating and maintaining the ventilator are properly trained in calibration procedures and understand the importance of accurate calibration for patient safety. Proper calibration and maintenance of ventilators are critical for patient care, especially in critical care settings. Following manufacturer guidelines and maintaining a rigorous calibration schedule helps ensure that the ventilator performs reliably and accurately.

From the data obtained from Asia Hospital, Patna between January to July 2023, out of 23 ventilators it can be observed that a significant pass rate is obtained after successful calibration and maintenance (Figure 6).

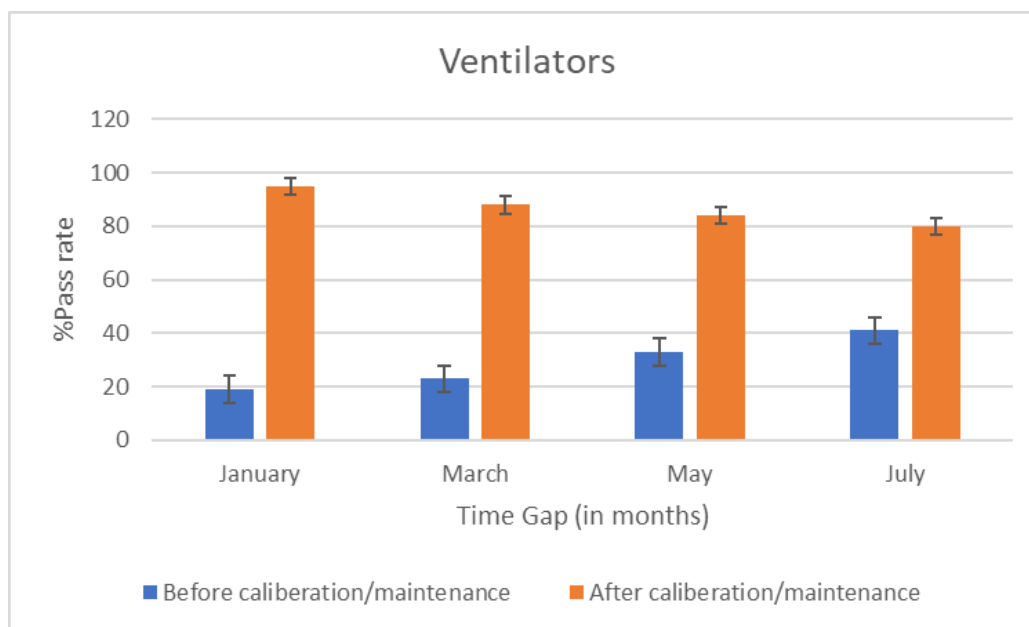


Figure 6: Graph of pass percentage before and after calibration of ventilators.

X- ray Machine

X-rays are a form of electromagnetic radiation, similar to visible light. Unlike light, however, x-rays have higher energy and can pass through most objects, including the body. Medical x-rays are used to

generate images of tissues and structures inside the body. If x-rays traveling through the body also pass through an x- ray detector on the other side of the patient, an image will be formed that represents the "shadows" formed by the objects inside of the body [27].

Methods for calibration of X-ray machine

Calibration of X-ray machines is a crucial process to ensure accurate and safe medical imaging while minimizing radiation exposure to patients and healthcare professionals. Calibration procedures for X-ray machines typically involve several steps and considerations:

Regulatory Compliance:

Ensure that all calibration procedures adhere to local, national, and international regulations and standards, such as those set by the Food and Drug Administration (FDA) in the United States, the International Electrotechnical Commission (IEC), and the National Council on Radiation Protection and Measurements (NCRP).

Manufacturer's Guidelines:

Refer to the manufacturer's user manual and guidelines for calibration procedures specific to your X-ray machine model. Manufacturers often provide detailed instructions and recommended calibration schedules.

Safety Precautions:

Ensure that the X-ray machine is turned off, and all safety interlocks are engaged before starting calibration. Safety must be a top priority throughout the calibration process.

Beam Quality and Output:

Calibrate the X-ray tube's beam quality and output using a calibrated dosimeter or ionization chamber. Measure the radiation output to ensure it meets the required specifications.

Beam Collimation:

Verify that the beam collimation system is functioning correctly, ensuring that the X-ray beam is properly aligned and focused.

Exposure Time and Dose:

Check and calibrate the exposure time settings to ensure that the X-ray machine delivers the correct dose of radiation for various imaging procedures.

Filtration and Half-Value Layer (HVL):

Measure and verify the filtration in the X-ray beam, which is necessary to control the energy spectrum of X-rays. Ensure that the X-ray machine meets the required HVL specifications for the intended use.

Automatic Exposure Control (AEC):

If the X-ray machine is equipped with AEC, calibrate it to ensure that it responds accurately to changes in patient anatomy and tissue density.

Image Receptor Calibration:

Calibrate the image receptor or detector to ensure it accurately captures and records X-ray images. Verify that the image receptor's exposure response is consistent and linear.

Image Quality:

Assess and calibrate the image quality parameters, such as contrast, resolution, and noise, to meet the diagnostic requirements of specific imaging procedures.

Dose Monitoring and Display:

If your X-ray machine displays patient dose information, ensure that the dose values shown on the control panel are accurate and correspond to the actual radiation exposure.

Radiation Safety:

Ensure that the X-ray machine is equipped with appropriate radiation shielding and protective measures for operators and patients.

Confirm that all safety features, such as lead aprons and protective barriers, are in place and functioning correctly.

Documentation:

Maintain detailed records of all calibration procedures, including the date, calibration values, any adjustments made, and the technician's or physicist's name. Documentation is essential for regulatory compliance and quality assurance.

Regular Calibration and Quality Assurance:

Establish a routine schedule for calibration and quality assurance checks. Regularly review and update the calibration process to account for changes in equipment performance or regulations.

Training:

Ensure that qualified and trained personnel, such as medical physicists or radiologic technologists, perform X-ray machine calibration. Continuous education and

training are crucial to maintain proficiency in calibration procedures.

X-ray machine calibration is a critical aspect of ensuring the safety and accuracy of medical imaging.

Healthcare facilities should have a comprehensive quality control program that includes calibration,

routine maintenance, and ongoing quality assurance to provide safe and high-quality radiological services.

From the data obtained from Asia Hospital, Patna between January to July 2023, out of 7 X-ray machine it can be observed that a significant pass rate is obtained after successful calibration and maintenance (Figure 7).

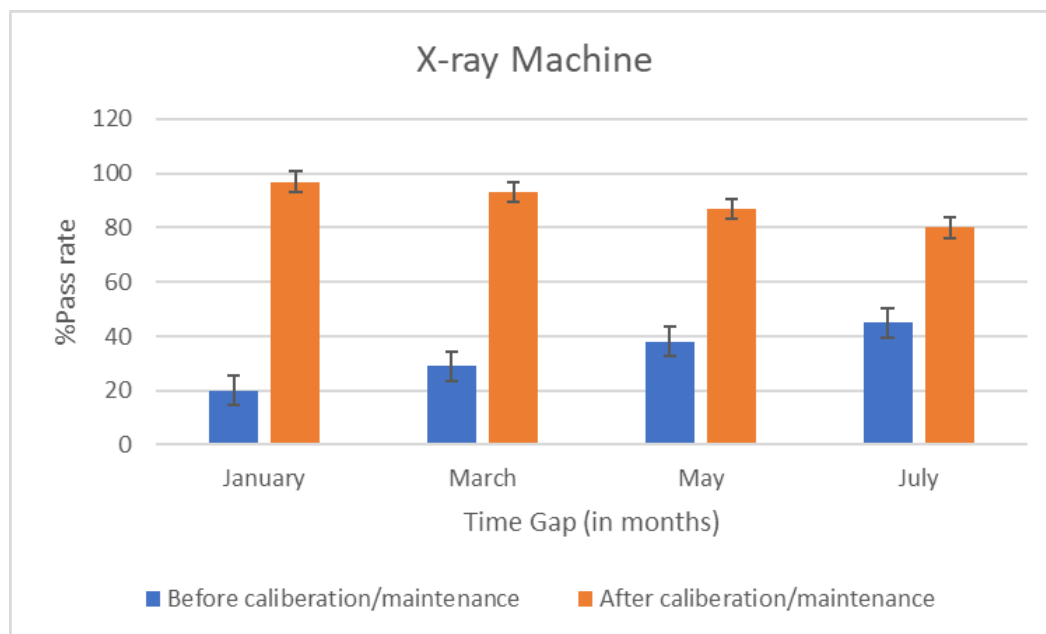


Figure 7: Graph of pass percentage before and after calibration of X-ray machines.

Conclusion

In conclusion, the calibration of medical devices is of paramount importance for ensuring the safety of patients in healthcare settings. The proper functioning and accuracy of these devices directly impact the quality of patient care, diagnosis, and treatment outcomes. Calibrated medical devices provide healthcare professionals with reliable data and measurements, enabling them to make informed decisions and provide the best possible care to patients. Failure to calibrate medical devices can lead to incorrect readings, misdiagnoses, improper dosages, and potentially life-threatening errors. The consequences of such errors can be devastating for patients, their families, and healthcare providers. Regular calibration not only enhances patient safety but also ensures compliance with regulatory standards and quality assurance protocols. It helps in detecting and rectifying any deviations or drifts in device performance, preventing potential risks and liabilities in the healthcare industry. Furthermore, calibration contributes to the overall efficiency and cost-effectiveness of healthcare systems by reducing the need for repeated tests and treatments due to inaccurate

results. It promotes trust between patients and healthcare providers, as patients can have confidence in the reliability of the medical devices used in their care.

In essence, the calibration of medical devices is an indispensable component of modern healthcare, safeguarding patient well-being, maintaining the integrity of medical data, and upholding the highest standards of patient safety and care. Therefore, healthcare organizations, professionals, and regulatory bodies must prioritize and invest in the regular calibration of medical devices to ensure the continued advancement of medical practice and the protection of patients' lives.

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Conflict of Interest

None declared.

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