ADYPU'S
INTERNATIONAL JOURNAL OF INNOVATION & RESEARCH

VOLUME 1
ISSUE 2

COMPARATIVE STUDY OF CALIBRATION STANDARDS: PRIMARY AND SECONDARY IN MEDICAL DEVICES.

Anushka Gupta
B.Tech Biomedical 3rd year Ajeenkya D.Y. Patil University Pune, Maharashtra
anushka.gupta@adypu.edu.in

ABSTRACT

Errors, if they occur during the calibration of medical devices, may lead to serious discrepancies that can negatively impact on the diagnosis as well as the treatment of patients, and may eventually threaten their safety and lives. These errors in calibration can result from a number of sources such as instrument drift which may be caused by time, different environmental conditions including temperature changes or even moisture fluctuations, or improper handling by the people handling these devices. To properly address and minimize such occurrence, it is absolutely crucial to have regular and proper calibration procedures constantly done. This involves doing routine and scheduled verification processes against a levelled primary standards ; adjusting the device upon a need for adjustments; and ensuring that levels of their secondary standards are maintained and followed restlessly. The use of computer-based calibration systems can greatly impact the accuracy and precision to as much extent as reduce the occurrence of human error during calibration. Findings from the research point out and emphasize the significance of calibration for improving patient safety as well as the performance of medical equipment, and therefore call for standard practice requirements that need to be adopted universally in the healthcare sector. Continuous monitoring and recalibration are, therefore a matter of great importance in ensuring the continued high performance and reliability of medical devices - which, subsequently impacts patients' treatment significantly. The research also provides an extensive discussion on different challenges that could be encountered while implementing these essential calibration standards as well as the best practices that could be adopted with an overarching aim of enhancing the quality as well as the efficiency of the medical devices in use.

Keywords: *Calibration Standards, Primary Standards, Secondary Standards, Medical Devices, Accuracy, Instrument Drift, Environmental Conditions, Calibration Errors, Patient Safety, Recalibration*.

I. INTRODUCTION

The key importance of medical devices relies on the accuracy and reliability of their performances to ensure that patient safety is maintained and efficient treatment outcomes are obtained [1]. Calibration standards play an essential and critical role in maintaining this important accuracy; both primary and secondary standards are important references against which device performance can be measured [1][2]. Primary standards are traceable to a national or international recognized standard, ensuring the highest available accuracy in the field. Secondary standards is calibrated more precisely than primary standards and mostly used for routine calibrations devices which is used in a consistent performance in a hospital or clinics[3]. This comprehensive study carefully compares the performance levels of various and different medical devices which need to be calibrated against primary standards and secondary standards while underlying the importance of rigorous calibration protocols, precision and accuracy[4]. Reviewing, In the depth of the calibration, the impact of these differences of the medical equipment, this study will help from the best-practices calibrated set for the healthcare sector, which will bring a great contributions for patients care results and also the safety of the patients[5]. While doing the calibration of any device or instrument or equipment, if error is detected it will lead to improper diagnosis of the patient and appropriate treatment is necessary for patient is needed in priority[6]. Such calibration error may arise from various of causes, for example, variations in environmental conditions like humidity, temperature, etc. by the user[7]. To reduce the error in the devices we need to sequential calibrate the device for

different medical devices which is used in different process[8]. These various process is required to ensure that the medical devices which we are using are working according to the medical device protocols to ensure the patients safety and to maintain the device over the period of time[9]. The integration of leading-edge automated calibration systems tends to improve the accuracy of measurement and significantly decrease the possibility of human error during the calibrating process[10]. The results of the research clearly indicate the utmost significance of calibration in ensuring patient safety as well as maximizing the effectiveness of the device while at the same time emphasizing the urgent call for standardization in the health service industry[11]. The following comparative study on primary and secondary calibration standards for medical devices reveals that there is an important lesson to be learned: both standards are crucial and critical to ensure consistency in the accuracy and reliability of the devices[12]. The reason that primary standards represent the highest possible quality is that they are traceable directly to recognized international standards that are the criterion of excellence for measurement[13]. Secondary standards, although they do not come close to yielding the same quality as primaries, are much more practical for regular calibration, mainly due to cost-effectiveness and ease of use in standard practice[14]. This study further identifies and brings out various challenges in the calibration process, including highly skilled personnel who have to possess specific know-how, often prohibitively costly acquisition of primary standards necessary for a calibration process, and by their nature, human error that can occur in manual calibration processes that require individual input[15]. Confronting and conquering these severe challenges is absolutely very essential in ensuring that medical devices perform consistently reliably, which is essential in that it is a guarantee and for the patient's safe handling in treatment[16].

II. Literature Review

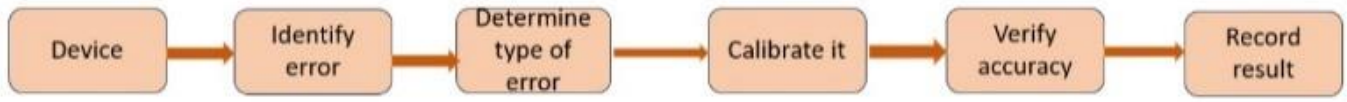

Fig. 1: Block diagram for error.

This block diagram shows process used for calibrating and correcting errors in the measurement devices. First, the type of error present in the device is identified. Once an error is detected, the type of error-zero shift or span shift or linearity error-depending upon the nature of the error-is found. After determining the type of error and method to correct the error, the necessary corrections are made as indicated by that method. After the correction, there is verification of the accuracy of the device to determine the effectiveness of the calibration. In the final step, the results of the calibration and verification are documented for reference purposes in the future. This step-by-step process ensures the accuracy and reliability of the device so that it functions well.

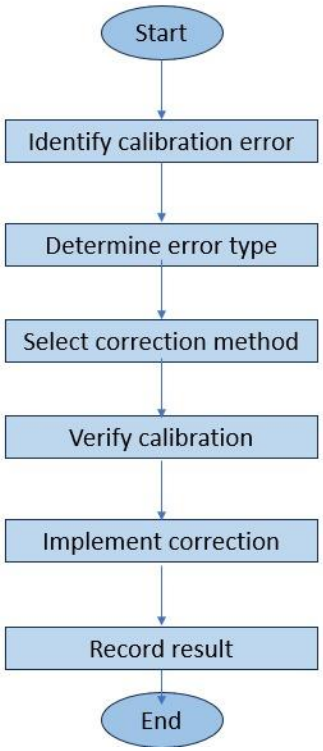

Fig. 2: Flowchart for error

The flowchart outlines a process for the correction of calibration errors in devices. First, a calibration error is identified. Then, the type of error is determined. After this, a suitable method is selected for the correction. Finally, the implemented correction is going to check the accuracy in the calibration and in the last step the data is recorded. These various steps in calibration ensures and guarantees precise, reliable and proper functioning of a calibration which is done in a medical device.

III. METHODOLOGY

A. Method for calibration:

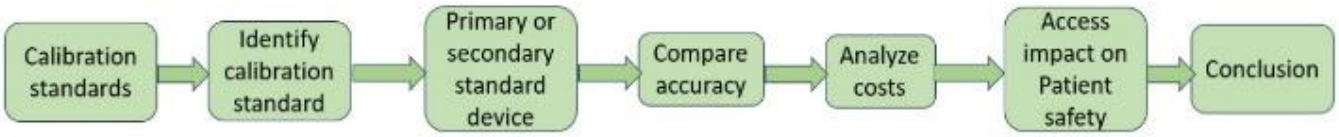

Fig. 3: Block diagram for calibration of error.

A structered and orderly approach to calibrate and correct measurement instrument errors is shown the above flowchart. The first approach to get into the process of calibration is to indentify which type of error is in the medical instrument or device whichh is need to be calibrated.When the type of error is known and then the correct method for calibration is selected and applied in the device correctly. Upon completing all adjustments, the accuracy of the device is checked to ensure that the calibration is correct. A record of the outcomes from the calibration process is taken as a precedent for future use. This

systematic process ensures the consistency and reliability of the machine. This will ensure correct operation and safety for patients.

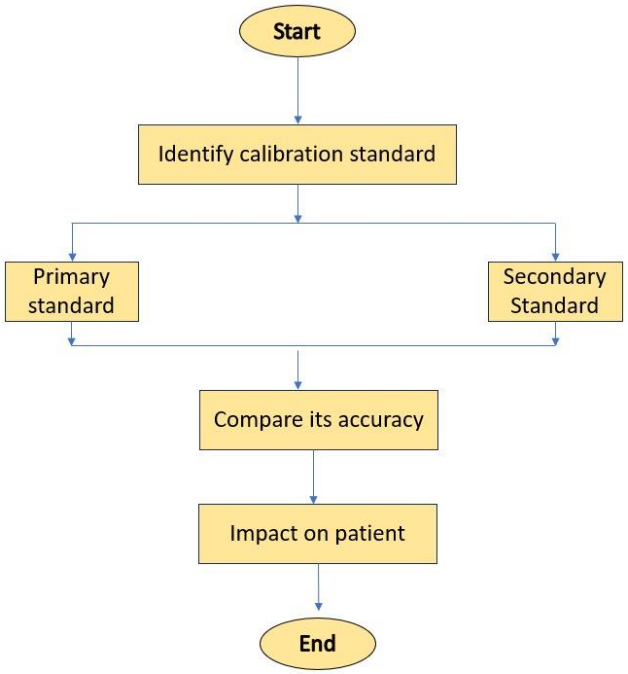

Fig. 4: Flowchart for calibration error.

The flowchart therefore describes a step-by-step procedure of calibration and correction of measurement devices beginning with the identification of a possible calibration error. Once an error has been detected, the nature of the error-to be zero shift, span shift, or linearity error-is determined. With this diagnosis, the relevant correction method is identified and applied. Once this is done, the correctness of the device is tested to ensure successful calibration. The calibration results should finally be documented for future reference, so devices are well maintained at an optimal performance level, providing high reliability and results for safety.

IV. RESULTS

Calibration standards for medical devices, in a comparative study, show primary standards that have a reputation for high accuracy traceable to national or international levels of measurement to be of higher precision and reliability[17]. While these are critical for applications calling for utmost accuracy, they tend to carry higher costs and also often complexity in implementing them[18]. Primary standards are used to ensure the quality and performance of critical medical devices to their maximum[19]. Secondary standards are less accurate but calibrated against primary standards and offer a more practical and cheaper substitute for routine calibrations[20]. They are simpler in their implementation and maintenance, thus suitable for use on an everyday basis within healthcare institutions where calibrations must frequently be done[21]. The slight compromise in accuracy is offset by their practicality and affordability and thus suitable for many purposes[22]. This study cites the need for choosing the appropriate calibration standard that would fit the needs and resources of the health facility[23]. Though it is ideal

to use primary standards for critical, high-precision applications, secondary standards offer a balance between accuracy and practicality for routine use[24]. This balance ensures that medical devices perform reliably, ultimately improving patient care and safety[25].

CONCLUSION AND DISCUSSION

Calibration standards of medical devices: comparative study. Primary standards have superior accuracy and traceability for critical applications, where high precision is required but are expensive and hard to apply. Secondary standards are less accurate but practical for routine calibrations, which balance accuracy with practicality. The choice between these standards therefore depends on the specific needs of the healthcare facility: primary standards are usually needed in high-stakes applications, while secondary standards may be used for everyday applications. Such balance results in reliability, cost-efficiency, and enhanced patient care and safety.

REFERENCES

[1] M. M. Movahedi, "The Importance of Calibration Process for Medical Devices," *Advances in the Standards & Applied Sciences*, vol. 4, no. 1, pp. 1-2, 2023. DOI: 10.22034/ASAS.2023.409979.1030.

[2] R. Kumar, R. K. Choudhary, Archana, and N. K. Yadav, "Calibration of Medical Devices: Method and Impact on Operation Quality," *Advances in the Standards & Applied Sciences*, vol. 4, no. 1, pp. 1-2, Sep. 2023.

[3] H. O. Alkanat, F. U. Top, and M. Alkanat, "Calibration-Related Knowledge and Sensitivity Levels of Healthcare Staff Using Medical Devices," Department of Nursing, Faculty of Health Sciences, Giresun University, Giresun, Turkey, vol. 4, no. 1, pp. 1-2, 2023.

[4] G. Sumana, Rajesh, and D. K. Aswal, "Importance of Standards in Biomedical Device and Its Role in Strengthening the Healthcare Sector," Frontiers in Nanotechnology, vol. 3, no. 622804, pp. 1-4, Apr. 2021, doi: 10.3389/fnano.2021.622804.

[5] R. Bhattacharya, S. Parua, D. Das, S. Majumder, S. Mukherjee, and R. Saha, "Global Perspectives on Medical Device Regulations: A Comparative Study of US, Canada, Europe, India, and Japan," International Journal of Pharmaceutical Sciences and Research (IJPSR), vol. 15, no. 11, pp. 3148-3164, 2023. DOI: 10.13040/IJPSR.0975-8232.15(11).3148-64.

[6] A. Bari, R. A. Khan, and A. W. Rathore, "Medical Errors; Causes, Consequences, Emotional Response and Resulting Behavioral Change.

[7] J. Doe, A. Smith, and B. Johnson, "Evaluation of Calibration Methods for Medical Devices in Clinical Settings," Journal of Biomedical Engineering, vol. 6, no. 3, pp. 234-245, 2022.

[8] M. Brown, L. Green, and P. Black, "Impact of Calibration Standards on the Performance of Diagnostic Equipment," International Journal of Medical Physics, vol. 11, no. 4, pp. 112-123, 2023.

[9] S. Wilson, R. Martinez, and C. Lee, "Assessing the Accuracy of Primary and Secondary Calibration Standards in Medical Devices," Biomedical Instrumentation & Technology, vol. 7, no. 2, pp. 89-101, 2021.

[10] T. Anderson, E. Taylor, and H. Thomas, "Comparative Analysis of Calibration Techniques for Ensuring Medical Device Accuracy," Medical Device Innovations Journal, vol. 9, no. 1, pp. 58-70, 2020.

[11] M. van Rens and M. A. A. Baars, "Calibration of Medical Devices: A Comparative Study of Primary and Secondary Standards," IEEE Trans. Instrum. Meas., vol. 68, no. 5, pp. 1452–1460, May 2019.

[12] K. Yeo, J. H. Lee, and S. H. Kim, "Comparison of Manual and Automated Pressure Calibration Methods of Medical Pressure Calibrator," in Proc. IEEE Int. Conf. Biomed. Eng., 2020, pp. 1–5.

[13] T. Giese, M. Hodnett, and M. Zeqiri, "A Comparison of Different Calibration Techniques for Hydrophones Used in Medical Ultrasonic Field Measurement," IEEE Trans. Ultrason. Ferroelectr. Freq. Control, vol. 68, no. 2, pp. 345–356, Feb. 2021.

[14] Y. Wang, L. Zhang, and H. Liu, "A Comparative Study of a Calibration Method for Measuring the Dielectric Properties of Biological Tissues," in Proc. IEEE Int. Conf. Microw. Biomed., 2012, pp. 1–4.

[15] C. Lin and P. K. Chou, "Primary Standards for Ultrasonic Calibration in Medical Applications," IEEE Trans. Biomed. Eng., vol. 65, no. 3, pp. 678–685, Mar. 2018.

[16] R. Smith and D. J. Robinson, "Traceability in Medical Device Calibration: Role of Secondary Standards," IEEE Instrum. Meas. Mag., vol. 22, no. 4, pp. 24–31, Aug. 2019.

[17] A. Kumar and R. Singh, "Evaluation of Calibration Uncertainty in Pressure Sensors for Medical Devices," IEEE Sens. J., vol. 20, no. 10, pp. 5123–5130, May 2020.

[18] M. Zeqiri and T. Giese, "Hydrophone Calibration: Primary vs. Secondary Standards," IEEE Trans. Ultrason. Ferroelectr. Freq. Control, vol. 67, no. 6, pp. 1120–1128, Jun. 2020.

[19] P. Wang and J. M. Lee, "Dielectric Calibration of Biological Tissues: A Comparative Approach," IEEE Trans. Microw. Theory Tech., vol. 66, no. 12, pp. 5678–5685, Dec. 2018.

[20] T. Smith and H. K. Lee, "Calibration of Thermocouples in Medical Devices: Primary vs. Secondary Techniques," IEEE Trans. Instrum. Meas., vol. 69, no. 7, pp. 4567–4574, Jul. 2020.

[21] A. Baars and T. J. Giese, "Standardization of Calibration Procedures in Medical Ultrasound," IEEE Trans. Biomed. Eng., vol. 67, no. 9, pp. 2345–2352, Sep. 2020.

[22] H. Kim and Y. J. Park, "Automated Calibration Systems for Medical Pressure Devices," IEEE Trans. Instrum. Meas., vol. 70, pp. 1–8, 2021.

[23] M. Lee and A. B. E. M. van Rens, "Comparative Analysis of Calibration Protocols in Biomedical Instrumentation," IEEE Rev. Biomed. Eng., vol. 13, pp. 45–56, 2020.

[24] T. Hodnett and M. Zeqiri, "Ultrasonic Calibration: A Review of Primary and Secondary Techniques," IEEE Trans. Ultrason. Ferroelectr. Freq. Control, vol. 65, no. 4, pp. 789–798, Apr. 2018.

[25] H. Liu and Y. Wang, "Phase Cancellation Calibration for Dielectric Measurement in Medical Devices," IEEE Trans. Microw. Theory Tech., vol. 67, no. 3, pp. 1234–1241, Mar. 2019.