Ensuring Accuracy: A Report on Calibration Challenges in Medical Devices with Case Studies

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Introduction

The increasing sophistication of medical technology and the growing emphasis on patient safety have heightened the relevance of medical metrology, a discipline characterized by inherent technical complexities. These challenges include: the need to navigate numerous national and international standards, each with specific requirements and parameters; the essential task of establishing and maintaining traceability to primary standards for ensuring measurement accuracy and uncertainty quantification; and the complex nature and variability of modern medical devices, demanding suitable and advanced calibration techniques. Recognizing the critical importance of accurate and reliable equipment in Intensive Care Units (ICUs), where even small errors can have severe consequences, this work centers on this vital area. Specifically, we present case study of four key calibrators, devices designed for the precise verification and calibration of critical ICU equipment, thus playing a crucial role in ensuring patient well-being.

1 Three prime Challenges, from metrologist point of view

1.1 Identification of source

When developing calibration standards or systems, utilizing medical devices as quantity sources for analyzers offers a seemingly straightforward approach. Examples include infusion pumps serving as sources for infusion pump analyzers and defibrillators providing energy for defibrillator analyzers. However, from a metrological perspective, this approach presents challenges. The metrologist is tasked with designing a system that ensures measurement interoperability through appropriate instrumentation, instrument interfacing, and synchronized data collection. The inherent 'closed-source' design of many medical devices, often implemented to minimize human intervention and potential faults, significantly complicates this task. This design limitation restricts direct quantity access, making it more difficult to develop integrated, automated systems with the robust synchronized data collection that is essential for achieving reliable measurement interoperability.

Medical Device Analyzer/Simulator	Parameter(s)	Source Device
Defibrillator Analyzer	Energy, Pulse Duration, Waveform	Defibrillator/Energy Source
Infusion Pump Analyzer	Flow Rate, Volume Accuracy	Infusion Device/Pressurized Tank
Neonatal Incubator Analyzer	Temperature, Humidity, Sound, Airflow	Neonatal Incubator / Wind Tunnel, Temperature or humidity enclosures
Electrical Safety Analyzer	Leakage Current, Ground Resistance, Insulation Resistance	Voltage and current source Device, Decade resistance box
Transcutaneous Pacer Analyzer	Pulse Rate, Amplitude, Pulse Width	Transcutaneous Pacer, Pacing Signal generator, Function generator, Defibrillator
Patient Monitor Simulator	Blood Pressure, Oxygen Saturation, Heart Rate	Patient Monitor
ECG Simulator	ECG Waveform, Heart Rate	ECG Machine
Electrosurgical Unit (ESU) Analyzer	Power Output, Leakage Current, High-Frequency Leakage	Electrosurgical Unit/Reference Loads

Table 1: Parameter Sources for Medical Device Analyzer Calibration

Feature	Medical Device	Standard Source
Standard Development	Relatively quick and simpler	Time-consuming and complex
Skill Requirements	Primarily "plug-and-play"	Systems integration and data acquisition
System Architecture	Closed source/hardware	Open source/hardware
Uncertainty Contribution	Higher	Lower
Quantity Access	Restricted (closed source)	Facilitated (open source)

Table 2: Comparison of Medical Devices and Standard Sources from a Metrological Perspective

It is crucial to recognize that employing a medical device as a quantity source inherently involves the use of a closed-source system, which typically contributes to a source with higher uncertainty.

1.2 Critical Parameters in Medical Device Evaluation

Although medical devices are characterized by a multitude of parameters, metrology institutes typically focus on the uncertainty analysis of individual parameters during the calibration of analyzers and calibrators. In clinical practice, however, medical practitioners emphasize "critical" parameters, which are deemed essential for diagnostic and therapeutic decisions. As shown in table 1 each device has multiple parameters.
In a study, with objective of flow rate measurement with associated uncertainty was carried out with infusion devices (syringe pump and linear peristaltic infusion pump) using the gravimetric-based method (primary method for the calibration of infusion devices). In this case study two different infusion devices (Syringe Pump and Infusion Pump) are calibrated using the gravimetric method (GM). The measurement uncertainty of two infusion devices are compared and it is observed that the syringe pump offers relatively lower uncertainty in the proposed range with respect to linear peristaltic infusion pump.
Infusion devices (Syringe Pump and Infusion Pump) were evaluated at three flow rates (10 mL/hr, 20 mL/hr, and 50 mL/hr) using the Gravimetric Method (GM). Measured flow rates and their associated expanded uncertainties (U, k=2) were determined. Analysis revealed that the Infusion Pump may not be suitable for low flow rates (10 mL/hr) as the uncertainty values were comparable to the maximum permissible error of the infusion pumps. This limited the ability to confidently assess conformity.
However, incorporating occlusion pressure into the evaluation could potentially favor the Infusion Pump over the Syringe Pump. This case study exemplifies how multiple parameters (e.g., flow rate, occlusion pressure) significantly influence the selection and performance assessment of medical devices.

1.3 Sampling of data

Parameters crucial for anomaly identification include data interval and sampling frequency. The sampling strategy directly influences the accuracy of data. While excessively short intervals place a burden on instrumentation, overly long intervals can lead to misleading results. Therefore, determining the optimal sampling interval is critical.
While developing primary standards, the comparison method is often used to establish values. Systems with a fixed inbuilt sampling rate can present challenges while comparing results. This discrepancy in sampling can lead to difficulties in accurately correlating measurements.
Consider the following examples:

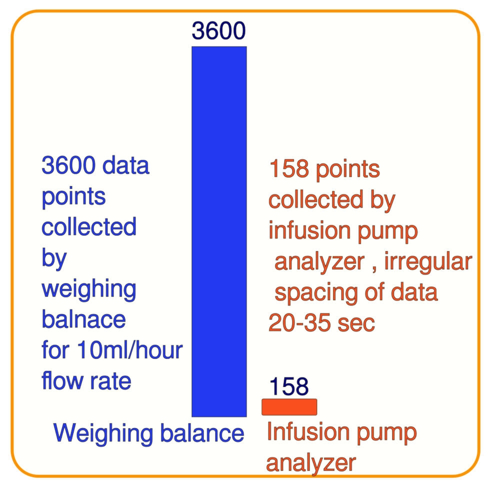

Figure 1: **Issue 1**: Two devices operate at Different time frame, **Issue 2**: We have no control over Frequency of data recorded By infusion pump analyser, **Issue 3**: So How do we compare and incorporate Error? Number of data points and comparison issue with closed system

1. **Defibrillator analyzers** utilize a time interval or sampling frequency as an inbuilt parameter.
2. **Infusion pump analyzers** have a fixed inbuilt sampling rate, while the data interval is often inconsistent with parallelly recorded measurements, hindering accurate comparison.
3. **Neonatal incubator analyzers** employ multiple probes with varying sampling intervals.

Sampling rates in medical devices depend on clinical purpose. Continuous blood pressure requires high-frequency data; temperature checks, less frequent. Standards and calibration protocols must ensure these rates meet intended use.

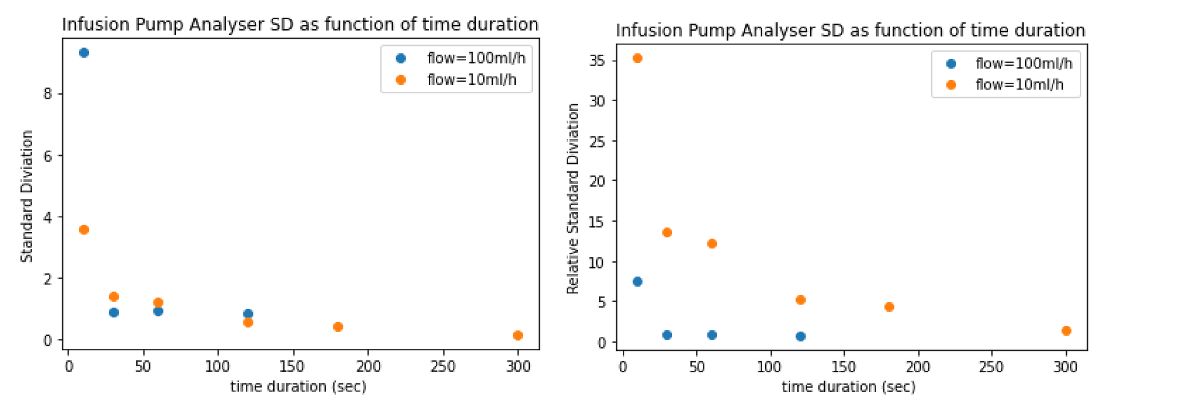

Figure 2: Effect of Capture Time duration/ Interval.

The absence of specified data acquisition intervals in the applicable standards presented a significant obstacle. Moreover, during calibration of flow rate analyzers, we observed that system uncertainty was inversely proportional to the data interval, with a substantial rise in uncertainty below 30 seconds, and a continued increase at shorter intervals, as demonstrated in the figure 2.
These metrological challenges extend beyond flow rate analyzers, manifesting during the calibration of diverse devices, including defibrillator analyzers and neonatal incubators, underscoring the need for robust calibration protocols.

2 Calibration systems

2.1 Defibrilator analyzer

Assesses the accuracy of delivered energy and timing of defibrillation pulses, crucial for restoring normal heart rhythm.

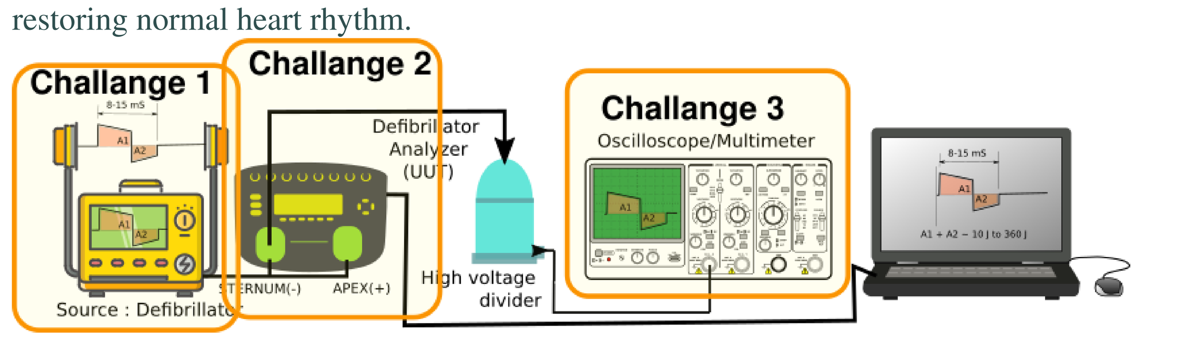

Figure 3: Schematic representation of the calibration system of Defibrillator analyser at NPL India.
Issue 1 : Using Defibrilator as source. Results in complex waveform, and operates at higher uncertainty. Complex waveform is burden during analysis.
Issue 2 : The system measures energy, time, and resistance. Uncertainty in any of these impacts current measurement uncertainty. **Energy (Joules)**: A primary function of a defibrillator analyzer is to measure the energy delivered by a defibrillator. This is very important to ensure the defibrillator is providing the correct amount of energy. **Voltage (Volts)**: Defibrillators deliver high-voltage electrical pulses. Therefore, analyzers must measure voltage accurately. **Current (Amperes)**: Along with voltage, the current delivered is a critical parameter, as it is Current(charge) and not the energy that defibrillates . **Time (Seconds)**: The duration of the defibrillation pulse is also crucial. Analyzers measure pulse width, which is a measure of time. **Resistance (Ohms)**: Defibrillator analyzers often simulate patient impedance, This allows testing of defibrillator performance under various load conditions. **Frequency (Hertz)**: When testing ECG simulations within a defibrillator analyzer, the frequency of the simulated heart rhythm is measured.
Issue 3: rate of signal capturing in defibrillator analyzer is different from oscilloscope. Defibrillator analyzer only works with individual company proprietary software, and most of defibrillator do not have provision to interface with computer.

2.2 Infusion pump analyzer

Measures flow rate and volume accuracy, ensuring precise delivery of fluids, medications, and nutrients.

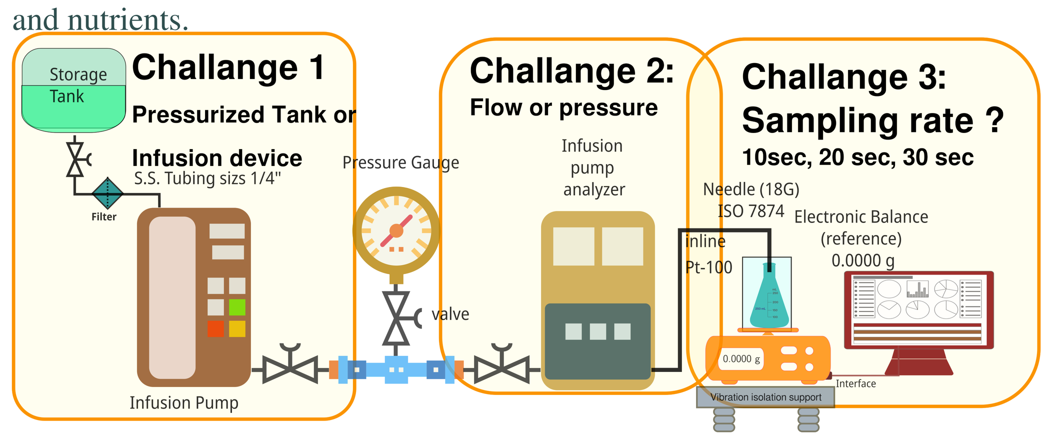

Figure 4: Schematic representation of the calibration system of Infusion device Analyzer at NPL India.
Issue 1: We need sources that reads flow and pressure it delivers. However Current infusion devices only measure flow, not pressure (just low/high alarm).
Issue 2: We had discussed this case study in 1.2
All parameters: pressure, flow Crucial parameter: flow
Issue 3: This we have discussed in 1.3

2.3 Transcutaneous Pacer Analyzer

Measures pulse rate, amplitude, and pulse width, ensuring accurate delivery of pacing therapy.
Issue 1: Plenty of options for source as shown in table 1, with varied reliability as discussed earlier. It is done using comparison method, where reading from analyzer is being compared to the same readout at the oscilloscope. Most of defibrillator has this included.
Issue 2: Parameters: pulse current, pulse rate, pulse width. The output of the pacing signal is measured at 50 ohm load resistance. This load resistance can vary in real scenario and hence may require output measurement at different test loads.

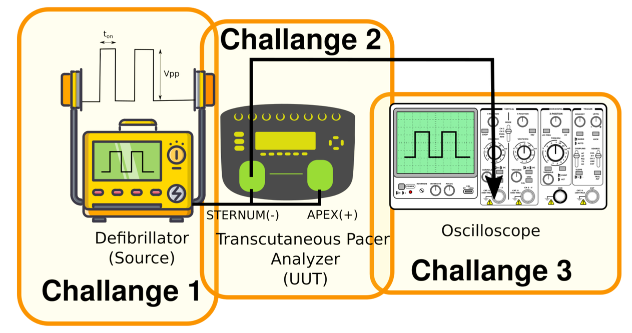

Figure 5: Schematic representation of the calibration system of Transcutaneous Pacer Analyzer at NPL India.

While pacing signal is generate by pacer in this case.
Issue 3: It is fairly simpler system, with rectangular pulse shape, thus sampling is not very critical. But overall interfacing of the equipment is challange while we consider medical devices as source.

2.4 Neonatal incubator analyzer

Assesses temperature and humidity control, crucial for providing a stable environment for vulnerable newborns.

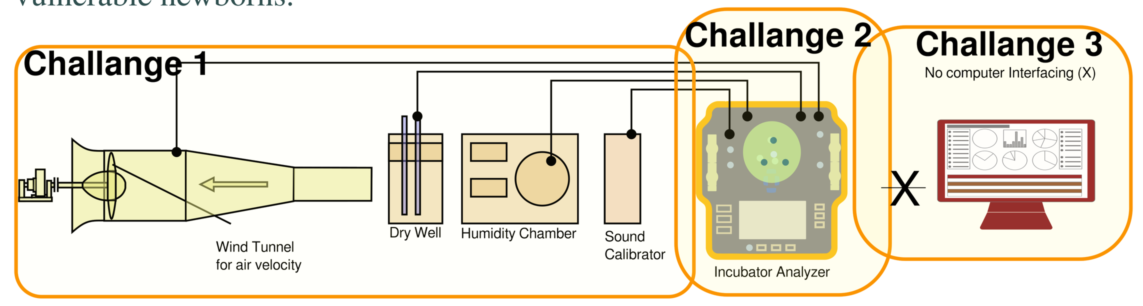

Figure 6: Calibration Setup of neonator inclubator analyzer at NPL India.

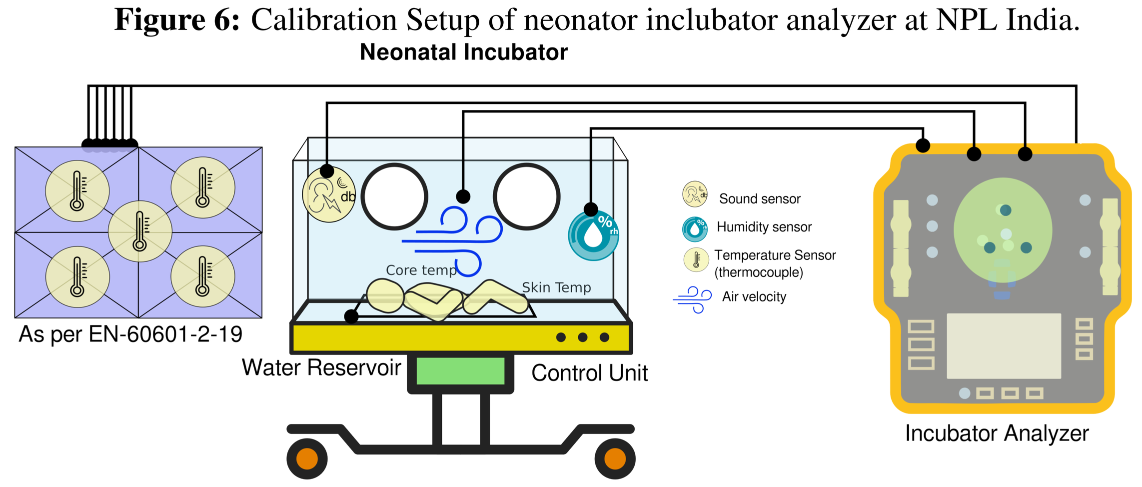

Figure 7: Medical Device as source for parameters/ Testing Setup of neonator inclubator analyzer at NPL India.
Issue 1: We have used individual sources(wind tunnel, dry well, humidity chamber) for each parameter instead of incubator as source. Incubator as source would result in much higher uncertainty, and a study comparing results from two approches is ongoing.
Issue 2: Temperature is the most critical parameter. Incubators with superior temperature stability should be prioritized.
Issue 3: Interfacing the equipments is serious challange in case of developing automated system with neonatal incubator as source.
Probes are typically calibrated individually, not simultaneously.

Conclusions

1. **Parameter Source Difficulty:** Identifying reliable parameter sources for medical devices is a significant hurdle, often necessitating the use of simulators.
2. **Multi-Parameter Complexity:** The combination of numerous parameters in medical devices exceeds the capabilities of single technical groups.
3. **Intercomparison Challenges:** Due to multi-parameter dependencies, intercomparisons of medical device analyzers are complex, requiring multiple intercomparisons across different technical committees.
4. **Policy-Level Attention:** The intricate nature of medical device metrology demands urgent policy-level intervention to standardize and streamline calibration and intercomparison processes.
5. **Sampling Rate Research:** Determining optimal sampling rates for medical device standards is a critical area for further research across multiple metrology institutes.
6. **Automated System Limitations:** Closed-source equipment poses challenges for interfacing and designing automated calibration systems.
7. **Real-World Calibration Gaps:** Current calibration methods, performed in controlled environments, fail to account for interacting instrument influences in real-world medical settings, requiring improved protocols.

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