



Pilot Comparison and Capacity Building for Medical Ventilator Testers

NIM China led an APMP regional metrology effort to ensure accurate clinical ventilator performance and thus protect patient safety

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The Challenge

Medical ventilators serve as indispensable life-support devices for critically ill patients. Their importance across the Asia-Pacific region was greatly highlighted during the COVID-19 pandemic. Accurate ventilator performance is essential for ensuring reliable clinical treatment and patient safety, and for directly supporting sustainable industrial development goals related to the provision of necessary equipment to the health industry.

Ventilator testers serve as a critical safeguard, ensuring that ventilators operate accurately and reliably in clinical care. However, many developing economies in the Asia Pacific Metrology Programme (APMP) region lacked harmonized calibration standards, reliable measurement traceability, and standardized verification procedures for ventilator testers. Without consistent measurement assurance, the safety and functional performance of clinical ventilators could not be credibly verified across national borders. Poorly calibrated ventilator testers would result in inaccurate static flow, static pressure, and tidal volume delivered by ventilators, bringing direct risks to critically ill patients and compromising treatment outcomes. This measurement gap also hindered the fair distribution and cross-border deployment of qualified medical devices and weakened regional public health emergency response capacity. Driven by this urgent public health demand, the National Institute of Metrology (NIM) of China led a dedicated APMP regional metrology project from 2020 to 2023 to bridge the measurement gap and strengthen regional healthcare security.

The Solution

To advance the goals of good health and well-being, targeted metrology actions were rolled out to enhance medical measurement capacity across the APMP region. In order to support DENs to develop and improve their measurement system for the ventilator tester, a one-on-one mentoring mechanism was established between 6 NMIs, which were CMS/ITRI and NPLI, NMIA, and SNSU-BSN, NIM, and NIS. The first APMP regional pilot interlaboratory comparison of ventilator testers was launched, focusing on three parameters essential to ventilator performance, and hence for patient treatment: 1) static flow, 2) static pressure, and 3) tidal volume. Harmonized technical protocols, unified measurement conditions, test specifications, and evaluation criteria were developed, ensuring all participating laboratories conducted assessments following the same rigorous requirements.

The regionally unified calibration guideline,¹ currently available as *Draft:2023.10.01*, have been developed for prospective issuance and implementation. These standardized procedures establish a robust, consistent framework for metrologically traceable measurements across the region, enabling participating economies to deliver credible local calibration services for their own ventilator testers. By underpinning the reliable, accurate calibration of ventilator testers, the initiative keeps clinical ventilators operating within safe, optimal performance ranges. This ensures stable, precise life-support ventilation for patients, minimizes clinical risks associated with inaccurate medical device output, and safeguards patient well-being.

A Quantifiable Impact

From 2020 to 2022, eight NMIs introduced their measurement capacity or research plan on the metrology of ventilators and ventilator testers, including CMS-ITRI, NIM, NIMT, NIS, NMIA, NPL, NPLI, and SNSU-BSN. A workgroup for drafting the protocol for the international comparison was formed. Six regional laboratories participated in the pilot interlaboratory comparison, covering static flow (50, 100, and 150 L/min), static pressure (5, 10, 20, and 50 cm H₂O), and tidal volumes (200, 400, 600, and 800 mL). These parameter sets represent clinical working points that denote typical combined operating configurations of flow, pressure, and tidal volume for conventional adult mechanical ventilation regimens. This pilot interlaboratory comparison exercise demonstrated high measurement consistency among participants; all six laboratories (100 % of participants) performed satisfactorily, with deviations across all key parameters within clinically acceptable limits.

The project has delivered sustainable regional benefits: participating economies have acquired an independent, standardized capability to calibrate ventilator testers locally. Reliable, metrologically traceable calibration enables routine verification of in-service ventilators, maintaining their performance at safe, optimal levels for clinical use. The uniform calibration guidelines formulated under this project are now routinely adopted by all participating regional economies. Additionally, these guidelines have served as core technical references for drafting subsequent regional documentary standards and relevant international metrology specifications for medical ventilation equipment.

In public health practice, consistent ventilator accuracy ensures effective life-support treatment for critically ill patients, reduces preventable clinical risks, and protects patient life safety. At the regional level, harmonized measurement standards facilitate cross-border mutual recognition of medical device quality, advance equitable access to reliable life-support equipment across the Asia-Pacific region, and deliver tangible progress toward implementing good health and well-being goals.

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¹ Calibration Guidelines for Ventilator Testers (Draft:2023.10.01, NIM, China) Medical Metrology Focus Group, Asia Pacific Metrology Programme