

Ensuring The Validity of Ventilator Measurement in Indonesia Through Interlaboratory Comparison



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01 Introduction

As a country, Indonesia needs to ensure the validity of medical device measurements, including ventilators, in order to protect itself from any potential risks. According to ISO/IEC 17025:2017 clause 7.7, interlaboratory comparison can be used to ensure the validity of measurement results. Therefore, in 2023, SNSU BSN (National Measurement Standards – National Standardization Agency of Indonesia) with BPAFK Surabaya (Center for the Security of Health Equipment and Facilities, Surabaya – Ministry of Health) conducted an interlaboratory comparison for ventilator measurements on one of its parameters, tidal volume. In addition, the aim of the comparison is to evaluate laboratory capability in volume tidal measurement of ventilators. The artifact for this comparison was a ventilator owned by BPAFK Surabaya. The standards of the participants were ventilator testers or ventilator analyzers.

02 Methodology

This comparison involved 24 calibration laboratories in Indonesia, using reference values from SNSU BSN. The measurement points were 400 mL, 500 mL, and 600 mL. The deviations of the measurement result from reference values were reported with its uncertainties

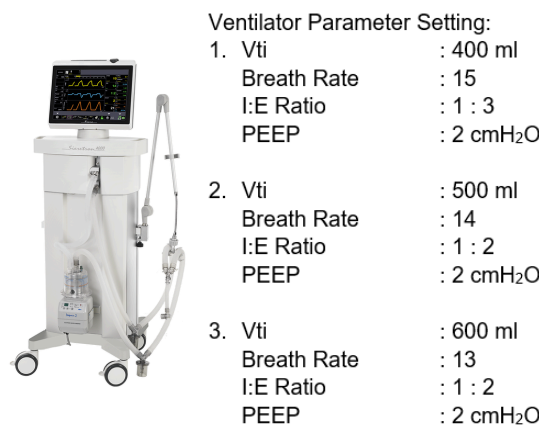


Fig 1. Artifact of the comparison

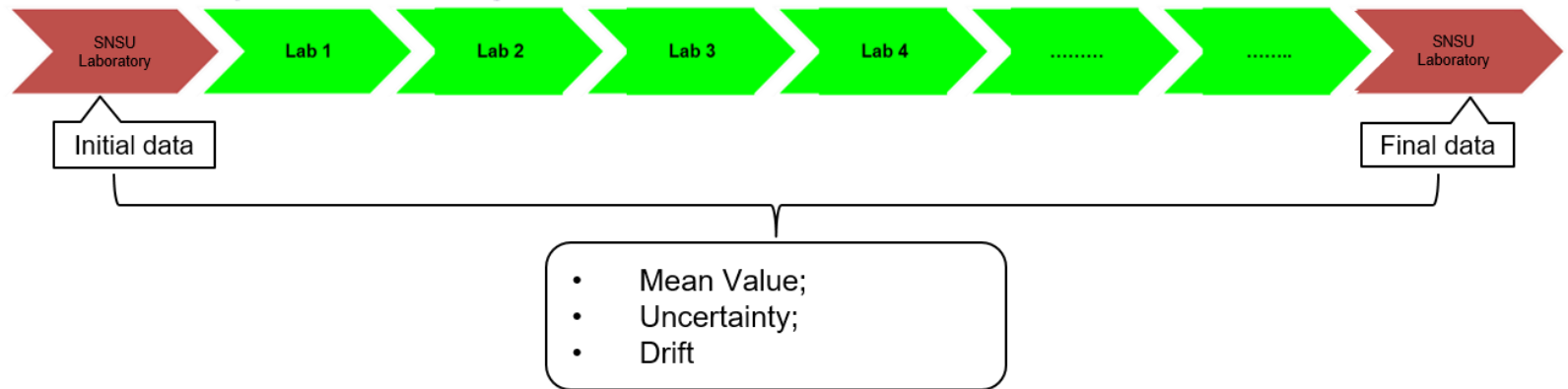


Fig 2. Cycle of the comparison

03 Results

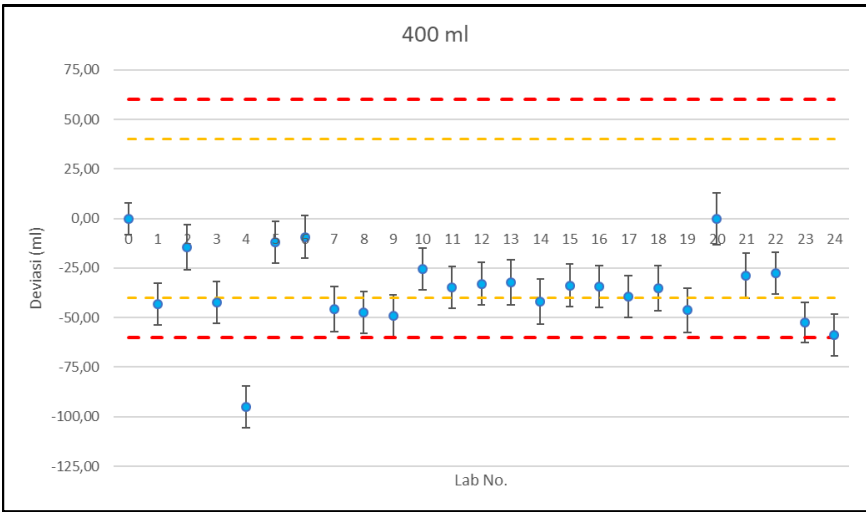


Fig 3. Result of the comparison at 400 mL Measurement point

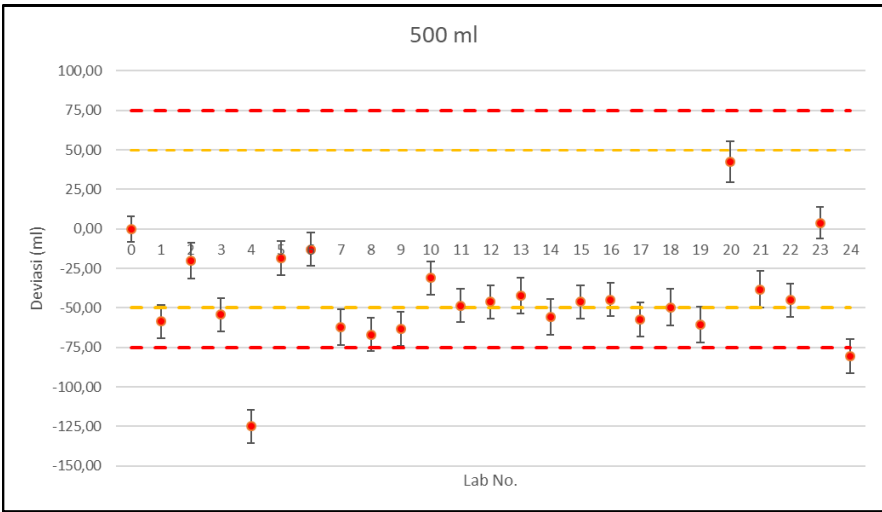


Fig 4. Result of the comparison at 500 mL Measurement point

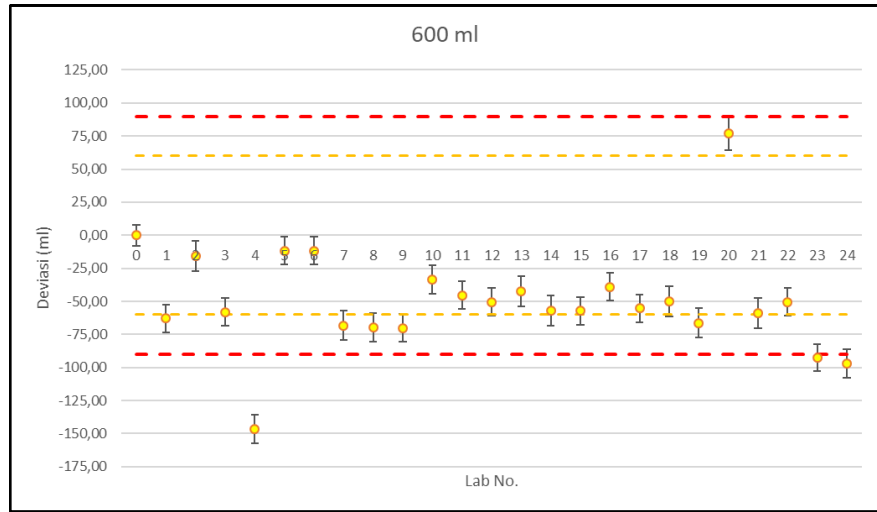


Fig 5. Result of the comparison at 600 mL Measurement point

04 Conclusion

Referring to the regulation of the Indonesian Minister of Health No. HK.02.02/V/5771/2018, the tolerance value for the tidal volume parameter is $\pm 15\%$. In this comparison, $\pm 10\%$ was defined as the initial limit (warning limit), and $\pm 15\%$ as the acceptance limit for the ventilator calibration results. Based on the comparison, almost all laboratories obtained values within the acceptance limit.

References

- [1] ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories
- [2] JCGM 100:2008 Evaluation of measurement data - Guide to the Expression of Uncertainty in Measurement
- [3] ISO/IEC 17043 Conformity assessment – General requirements for proficiency testing