Calibration method research and uncertainty evaluation of End-tidal carbon dioxide concentration of Multifunction Patient Monitoring Instruments

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Abstract. The monitoring of end-tidal carbon dioxide concentration has the characteristics of non-invasive and quick response, which has become one of the important ways of clinical vital signs monitoring. This monitoring equipment is widely used in emergency operating room, critical care and other important departments. The calibration of end-tidal carbon dioxide concentration can effectively test the accuracy and safety of equipment, and the research of calibration method and the evaluation of uncertainty are of great significance.

1. Introduction
The multifunction patient monitoring instruments can simultaneously carry out real-time and continuous monitoring of multiple physiological parameters such as ECG, respiration, blood pressure, oxygen saturation, body temperature, cardiac output, end-tidal carbon dioxide concentration. It has the function of automatic alarm and recording. End-tidal carbon dioxide partial pressure (PetCO2) refers to the concentration of carbon dioxide in the exhaled air at the End of breath, which has a certain correlation with the end-tidal carbon dioxide partial pressure. The monitoring of end-tidal carbon dioxide concentration can reflect the respiratory and pulmonary circulation function and metabolic status directly, easily and quickly, and is an important detection index for anesthesia patients and patients with respiratory metabolic system diseases. The American Association of Anesthesiologists (ASA), the American Association of Respiratory Therapy (AARC) and the American Heart Association (AHA) have adopted carbon dioxide monitoring as a routine guideline and rule [1]. With the progress of clinical research on PETCO2, the monitoring of end-tidal carbon dioxide concentration has been applied more and more widely. In addition to confirming the position of intubation, monitoring the effect of cardiopulmonary resuscitation, and monitoring of anesthesia, many new applications have been expanded in patients with COPD, pulmonary embolism and shock, etc. Monitoring end-tidal carbon dioxide concentration has important clinical significance in assisting disease diagnosis, monitoring disease progression, predicting disease prognosis and other aspects [2]. The calibration of end-tidal carbon dioxide concentration can effectively test the accuracy of measurement parameters, ensure the safety and reliability of monitoring data, and provide a method basis for the traceability of the value of this parameter.
2. Principle of Measurement
End-tidal carbon dioxide concentration of Multifunction Patient Monitoring Instruments is mainly monitored by infrared ray method. The principle is that carbon dioxide has a characteristic absorption peak at the wavelength of 4.26μm when irradiated in the infrared spectrum, as shown in figure 1. The concentration of CO2 is related to how much energy is absorbed. When the infrared ray penetrates the CO2 sample, some of its energy is absorbed by the CO2. During the respiration process, the measured CO2 concentration is mapped with the corresponding time to obtain the CO2 curve, as shown in figure 2.

![Figure 1. The absorption characteristics of Infrared spectrum to CO2.](image1)

![Figure 2. Normal CO2 waveform.](image2)

The end-tidal carbon dioxide waveform is divided into four parts: ascending branch, alveolar platform, descending branch and baseline. Exhalation starts from P point of the ascending branch and passes through Q to R point. QR represents the alveolar platform (also known as peak phase). R point is the peak of the alveolar platform, which represents the CO2 concentration at the end of expiratory (also known as the end of moisture). The beginning of the drop branch means that the inhalation begins, with fresh air intake, carbon dioxide concentration gradually back to the baseline. So P.Q.R is the exhalation phase and R.S.P is the inhalation phase. The area between the curve and the baseline can be likened to CO2 emissions.

3. Calibration method
At present, China has issued the national metrology verification regulation JJJG 1163-2019 for the multifunction patient monitoring instruments[3], which provides the equipment and calibration method for the calibration of end-tidal carbon dioxide concentration for the multi-parameter monitor. Connect the devices according to figure 3. The regulation requires the calibration of the ambient temperature (10~40)°C; Relative humidity: 10%~95%. The monitor was calibrated using a respiratory rhythm.
generator (measuring range (3 to 60) times/min, with a maximum allowable error of ±1 times/min) and the carbon dioxide standard gas with a concentration of 5% volume percentage (equilibrium gas is nitrogen, with a maximum allowable error of ±2% (relative value)). The respiratory rhythm generator is set at 20 times/min. After the monitor entered the normal working state, the measurement results of three breathing times were read continuously.

4. Assessment of uncertainty in measurement of end-tidal carbon dioxide concentration

The measurement uncertainty of end-tidal carbon dioxide concentration was evaluated and expressed according to JJF 1059.1-2012 Evaluation and Expression of Uncertainty in Measurement [4] and GUM method was used to evaluate.

4.1. Measurement Model

\[
\Delta D = \bar{D} - D_0
\]

In the formula:
- \(\Delta D\) — Indication error of end-tidal carbon dioxide concentration, kPa(mmHg);
- \(\bar{D}\) — Mean of three measurements of end-tidal carbon dioxide concentration, kPa(mmHg);
- \(D_0\) — Standard value of end-tidal carbon dioxide concentration, kPa(mmHg).

4.2. Analysis of Standard Uncertainty Component

The main source of uncertainty of end-tidal carbon dioxide concentration: (1) Uncertainty component introduced by measuring repeatability \(u_1\); (2) Uncertainty component introduced by carbon dioxide standard gas \(u_2\); (3) Uncertainty component introduced by error value of respiratory rhythm generator \(u_3\).

4.2.1. Uncertainty component introduced by measuring repeatability \(u_1\): Class A method assessment.

The standard gas with a concentration of 5.0% volume percentage CO2 was used, and the respiration rate was set at 20 times per minute. After the monitor entered the normal working state, 10 independent repeated experiments were carried out, and the standard deviation of a single experiment was calculated according to Bessel formula. The specific data were shown in Table 1.

| Numbers | 1  | 2  | 3  | 4  | 5  | 6  | 7  | 8  | 9  | 10 |
|---------|----|----|----|----|----|----|----|----|----|----|
| Results (mmHg) | 37 | 38 | 37 | 39 | 38 | 37 | 38 | 37 | 37 | 38 |

The best estimate to be measured:

\[
\bar{D} = 37.6 \text{mmHg}
\]
Standard deviation of a single measurement:

\[ s = \sqrt{\frac{1}{n-1} \sum_{i=1}^{n} (D_i - \bar{D})^2} = 0.70 \text{mmHg} \]

During routine testing, the arithmetic mean of the three measurements is taken as the measurement result, so the standard uncertainty of the best estimate caused by the measurement repeatability, \( u_1 \):

\[ u_1 = \frac{s}{\sqrt{3}} = 0.41 \text{mmHg} \]

The relative standard uncertainty, \( u_{rel1} \):

\[ u_{rel1} = \frac{0.41 \text{mmHg}}{37.6 \text{mmHg}} = 1.1\% \]

4.2.2. Uncertainty component introduced by carbon dioxide standard gas \( u_2 \), Class B method assessment.

The maximum allowable error for carbon dioxide standard gas is ±2% (relative value), in uniform distribution, \( k = \sqrt{3} \). The relative standard uncertainty component introduced by carbon dioxide standard gas \( u_{rel2} \):

\[ u_{rel2} = \frac{2\%}{\sqrt{3}} = 1.2\% \]

4.2.3. Uncertainty component introduced by error value of respiratory rhythm generator \( u_3 \), Class B method assessment.

The maximum allowable error of the respiratory rate of the respiratory rhythm generator is ±1 times/min, in uniform distribution, \( k = \sqrt{3} \). The uncertainty component introduced by error value of respiratory rhythm generator \( u_3 \):

\[ u_3 = \frac{1 \text{times/min}}{\sqrt{3}} = 0.58 \text{times/min} \]

During calibration, respiratory rate was set at 20 times per minute, so relative standard uncertainty, \( u_{rel3} \):

\[ u_{rel3} = \frac{0.58 \text{times/min}}{20 \text{times/min}} \times 100\% = 2.9\% \]

4.2.4. List of components of standard uncertainty.

List of components of standard uncertainty is shown in table 2.

| components of standard uncertainty, \( u_i \) | Source of uncertainty | method of evaluation | \( u(X_i) \) | \( u_{rel} \) |
|---------------------------------------------|------------------------|----------------------|----------------|----------------|
| \( u_{rel1} \) | repeatability of measurement | A | 1.1% | |
| \( u_{rel2} \) | carbon dioxide standard gas | B | 1.2% | 3.4% |
| \( u_{rel3} \) | respiratory rhythm generator | B | 2.9% | |

Table 2. Source of uncertainty.
4.2.5. Relative composite standard uncertainty.

\[ u_{relc} = \sqrt{u_{rel1}^2 + u_{rel2}^2 + u_{rel3}^2} = 3.4\% \]

4.2.6. Related expanded uncertainty.

\[ U_{rel} = ku_{relc} = 7\%(k=2) \]

5. Conclusion

The monitoring of end-tidal carbon dioxide concentration by multifunction patient monitoring instruments is becoming more and more widely used in clinical application. The main monitoring principle of end-expiratory carbon dioxide is infrared method, there is no relevant simulator method for detection at present, and only CO₂ standard gas can be used for calibration [5]. Equipment calibration can ensure the accuracy and reliability of equipment value, and better guide clinical application. However, in clinical use, the accuracy of the measurement is affected by many factors, including the temperature at which the patient breathes, the amount of water vapor during breathing, the measurement of atmospheric pressure and other gases (mainly N₂O and O₂ in the air) [6]. At present, the influence of these mixed gases is not considered in the measurement and calibration process. With the progress of science and technology, the measurement and calibration methods need to be further optimized. The precision of measurement and calibration method will further improve the quality of equipment and provide more safe and effective monitoring data for patients.

References

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