Design of Pulse Oximeter Simulator Calibration Equipment

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Abstract -Saturation of peripheral oxygen (SpO_2) is one of the most important parameters of vital signs. Pulse oximeter which based on near-infrared spectroscopy is commonly used as a non-invasive method to measure SpO_2[1] ,Currently, medical device manufacturers as well as metrology measurement agencies in China usually use pulse oximeter simulator as the commonly accepted functional calibration equipment for pulse oximeters. So far, there is no experimental protocol or devices can be used to test the accuracy and reliability of a pulse oximeter simulator, therefore, a set of new metrology apparatus with the name of pulse oximeter simulator calibration equipment have been designed in order to make a traceable system for the calibration or verification of pulse oximeter simulators. The principles and some research methods of this pulse oximeter simulator calibration equipment will be discussed in this paper. Besides that, many experiments have been applied in order to guarantee the accuracy as well as traceability of this set of equipment

I. INTRODUCTION

Principle of Pulse Oximeter

SpO_2 is determined by the relative proportions of oxygenated hemoglobin (HbO_2) and reduced hemoglobin (Hb) in arterial blood.

$$SpO_2 = HbO_2/ (HbO_2+ Hb)*100\% \qquad (1)$$

Pulse oximeter is based on two physical principles: (a) the presence of a pulsatile signal generated by arterial blood, which is relatively independent of non-pulsatile arterialblood, venous and capillary blood, and other tissues, as shown in Fig.1; (b) the fact that HbO2 and Hb have different absorption spectra of red and infrared light, as shown in Fig.2 .

LED Sensor, which seems like a finger clip, is an important component of pulse oximeter. One side is LEDs that emitting red (around 660nm) and infrared light (around 940nm) alternately, while the other side is a photodiode for receiving attenuated light and then translate into electrical signal, see Fig. 3. As shown in Fig. 1 and 3[2].

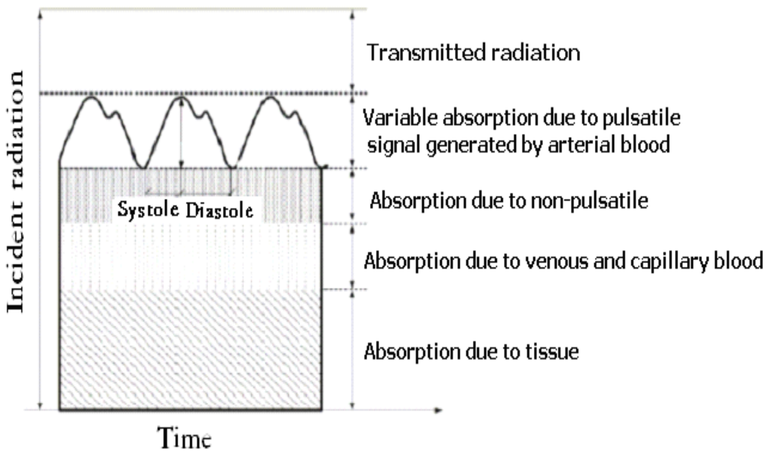

Fig. 1. Physical Principle of Pulse Oximeter - (a)

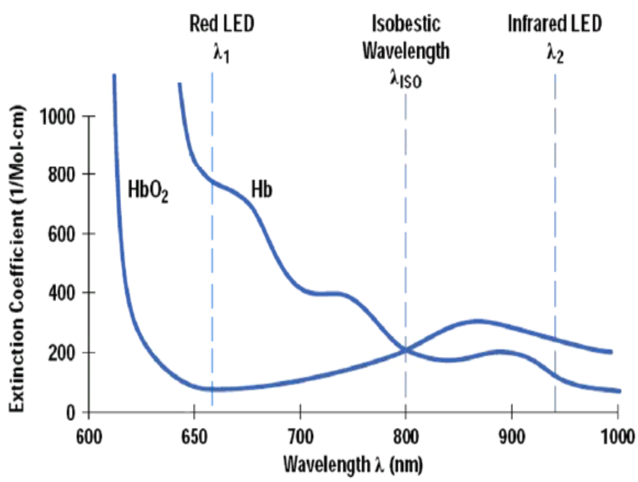

Fig. 2. Physical Principle of Pulse Oximeter - (b)

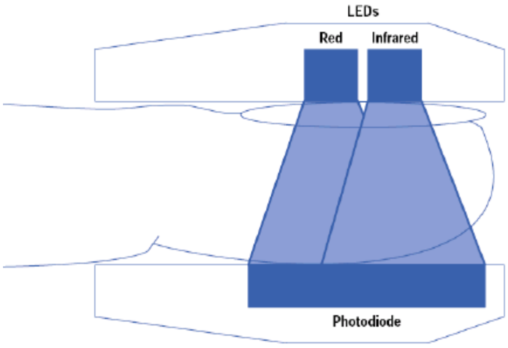

Fig. 3. LED Sensor of Pulse Oximeter

After passing through finger, the variable absorption by arterial blood is considered as the "AC signal", while the constant absorption by venous, capillary blood, and other tissues is considered as the "DC signal". Therefore, based on Lamber-Beer Law, the main algorithm, normally named as "R-SpO_2 curve" are simply summarized:

1) Calculating the absorption ratio (R value) between red and infrared light, different manufacturers usually adopt red and infrared light with various wavelength :

$$R = \frac{(AC/DC)_{RED}}{(AC/DC)_{IR}} \qquad (2)$$

2) Actually, the corresponding relation between R value and SpO_2 is on the bases of a great amount of clinical test data and statistic analyses, the constant A,B,C are all empirical values from each manufacturer.

$$SpO_2 = C - B*R - A*R^2 \qquad (3)$$

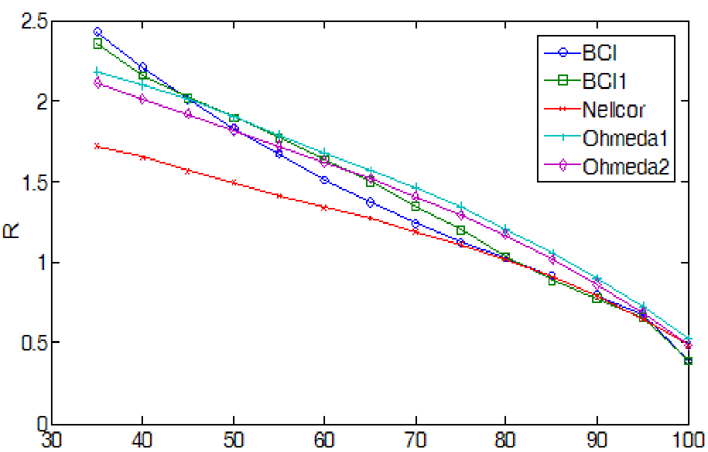

Fig. 4. some typical R-Sp02 curves

Currently, according to some statistics, about 100 R-SpO_2 curves or more are commercially used, as shown in Fig.4. However, these curves possess one characteristic in common, that is R value is in approximately inverse proportion with SpO_2.

The Principle of Pulse Oximeter Simulator

Pulse oximeter simulator is used to simulate the light attenuation during passing through human fingers by blood absorption. The test probe, which seems like an artificial finger, is a typical optical unit. One side with photodiode is used for detecting the red and infrared light signals, while the other side is equipped with LEDs[3]. After detecting the light from light sensors of pulse oximeter, the micro-processor system controls the LEDs emitting corresponding light intensity with certain frequency according to the default Sp02 and pulse rate values, as shown in Fig. 5.

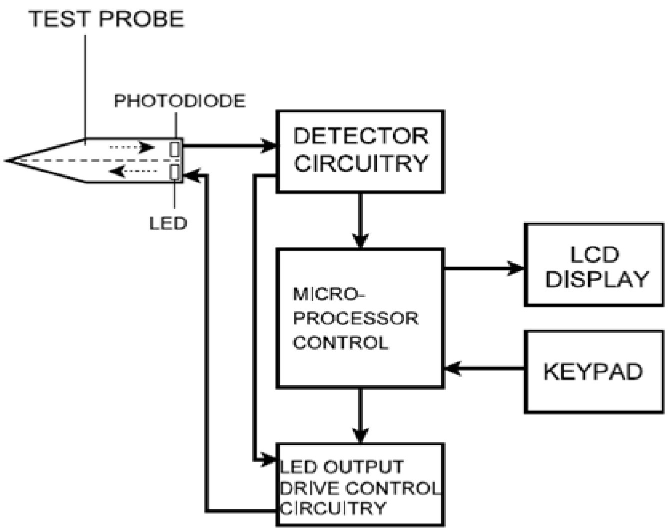

Fig. 5. Principle of Pulse Oximeter Simulator

II. DESIGNING PULSE OXIMETER SIMULATOR CALIBRATION EQUIPMENT

This set of pulse oximeter simulator calibration equipment consists about three main parts, there are standard sensors, a hardware unit and a computer which is equipped with specialized software. After connecting with pulse oximeter simulator, the whole equipment can be used to measure the accuracy and reliability of SpO_2 and plus rate values which are stimulated by pulse oximeter simulator, as shown in Fig. 6.

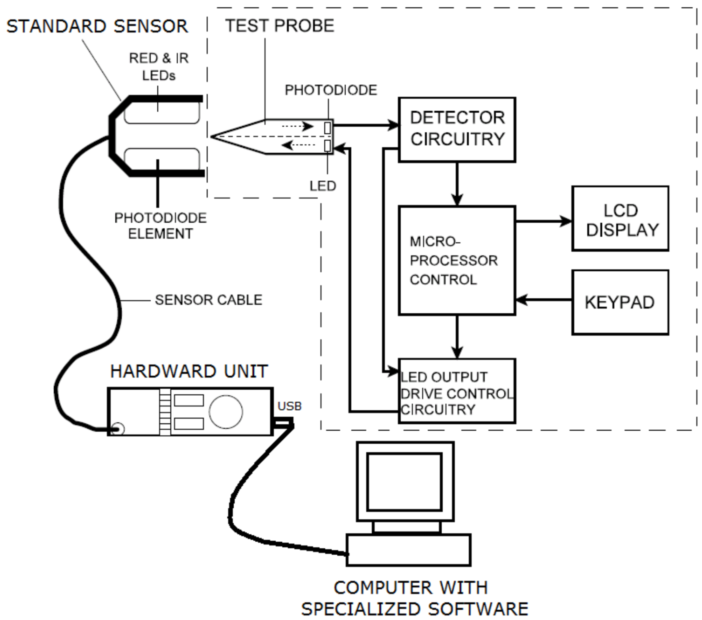

Fig. 6. Design of Pulse Oximeter Simulator Calibration Equipment

A. Standard Sensors

As different R-SpO_2 curves get different wavelengthes of red and infrared light, therefore, 4 standard sensors are prepared for Nellcor, Omeda, BCI and Masimo cureves, which are widely used ones. Moreover, Standard sensors can be renewed according to the further requirement. In order to accommodate dissimilar sizes of test probes of pulse oximeter simulators, standard sensors are designed with two important characteristics: thickness adjustable and light proof[4].

B. Hardware Unit

In this part, the SCM plays a leading role in system controlling. For example, generating signals with certain frequency in order to make the standard sensor emitting red and infrared light alternatively, and after receiving the attenuated light from light activated diode, the operational amplifier as well as the photoelectric converter will transfer the light into voltage signals which are then input into Data Acquisition Card for further processing. Besides that, negative feedback circuit is applied in order to make the standard sensors emitting stable light sources. The hardware unit makes the stability of standard sensor (light sources emitting and attenuated light detecting) better than 0.5%.

C. Computer with Specialized Software

This specialized software has got two general functions, one is data processing, and the other is automated experimentation flow. For data processing, the software program not only abstracts and separates light signals that received by standard sensors, but also calculates the R value, which is corresponding to Sp02 value, from the attenuated light signals. Finally, the calculated results (both Sp02 and pulse rate values) will be compared with the default values from the pulse oximeter simulator and displayed on the user interface, meanwhile, all of the test data can be saved and printed in the form of test report.

The purpose of designing the pulse oximeter simulator calibration equipment is to form a complete traceability system for the test of SpO_2 as well as pulse rate value. In order to guarantee the accuracy together with traceability of this set of equipment, a lot of experimentations have been carried out. For the test of SpO_2 value, which is verified by standard illuminant and neutral density filters, it can be traced to National Measurement Standard of Primary Photometric. While the pulse rate value, which can be verified by standard signal generator, could be traced to National Measurement Standard of Primary Frequency in China. Since this set of equipment has been designed and completed, it realizes an integrated chain for the metrology of the pulse oximeter and its correlative instruments, as shown in Fig. 7.

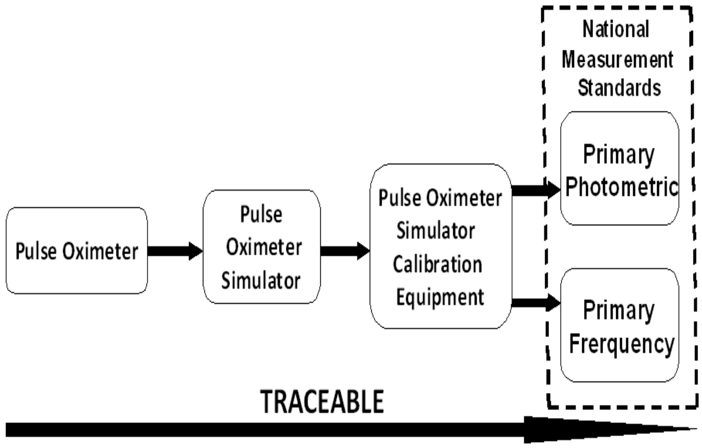

Fig. 7. Integrated Chain of Traceability

III. EXPERIMENTAL DATA ANALYSIS

As different R-SpO_2 curves have distinct sensors, take the sensor of Necllor curve for example, it provides the 660nm red light and the 890nm infrared light. As the simulator imitates the intensity attenuation informationof red and infrared light, consequently, if the standard sensor provides stable and normative optical trigger according to the corresponding curve, the pulse oximeter simulator can be calibrated. In other words, stability is the key indicator for the standard equipment. In this section, several experiments are used to detect the accuracy and stability of this equipment.

A. The accuracy of standard sensor's wavelength

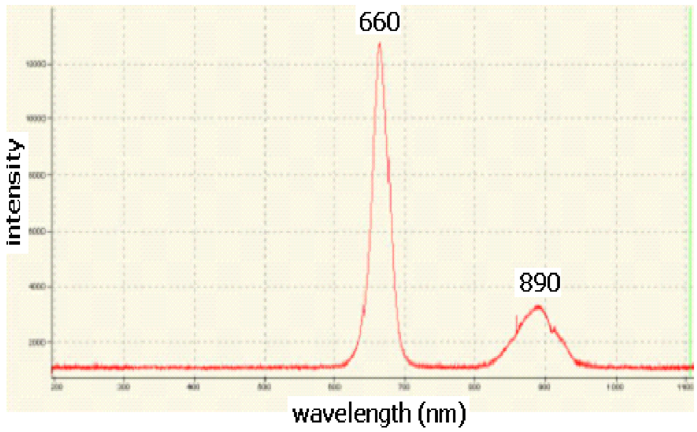

Fig. 8. wavelength test

As shown in Fig.8, the part of experiment should be tested about every month, if the wavelength is not accurate, the standard sensor must be adjusted.

B. The detection of standard sensor

In this part, signal generator is used to test the accuracy and stability of pulse rate, standard light source and neutral density filters are together with the use of checking light stability and accuracy of the sensor.

TABLE I

ACCURACY OF PULSE RATE

Nominal Value (BPM)	30	50	100	150	200	300	400	Tollere-nce ±1
Measure Value (BPM)	30	50	100	151	200	300	400	Mean Error
Error (BPM)	0	0	0	1	0	0	0	±1

TABLE II

ACCURACY OF SpO_2

Nominal Value (%)	30	50	60	70	80	90	100	Tollere-nce ±1
Measure Value (%)	30	50	60.3	70	80	90	100	Max Error
Error (%)	0	0	0.5	1	0	0	0	±0.67

TABLE III

STABILITY OF SENSOR

0.1% Neutral Density **Filter**	Time (s)	10	30	50	70	90	110	Max Fluctu-ation
	Fluctuation (%)	0.1	0.2	0.2	0.1	0.3	0.2	0.3
1% Neutral Density **Filter**	Time (s)	10	30	50	70	90	110	Max Fluctu-ation
	Fluctuation (%)	0.3	0.3	0.2	0.4	0.1	0.2	0.4
5% Neutral Density **Filter**	Time (s)	10	30	50	70	90	110	Max Fluctu-ation
	Fluctuation (%)	0.1	0.3	0.2	0.2	0.2	0.3	0.3
10% Neutral Density **Filter**	Time (s)	10	30	50	70	90	110	Max Fluctu-ation
	Fluctuation (%)	0.2	0.1	0.1	0.2	0.2	0.2	0.2

IV. CONCLUSION

Designing a set of pulse oximeter simulator calibration equipment is a challenge for metrology engineers. According to all the analysis and results above, pulse oximeter simulator calibration equipment can be used to calibrate the value of SpO_2 as well as pulse rate of pulse oximeter simulator. The stability of light source is better than 0.5%, and on the basis of theoretical analysis and lots of experimentation, the whole equipment gets the measurement range of SpO_2 — (30-100%, with the precision of 1%), and has a mean difference (bias) of < 1%, while the measurement range of pulse rate is (0-400BPM, with the precision of 0.1BPM), and has a mean difference (bias) of < 1BPM. This set of pulse oximeter simulator calibration equipment can be traced to Primary Photometric and Primary Frerquency of National Measurement Standards in China, and it has also been figured as an intending National Measurement Standard for Pulse Oximeter Simulators.

REFERENCES

[1] Jubran A: Pulse Oximeter. In: Tobin MJ (ed). Principles and Practice of Intensive Care Monitoring. New York: McGraw Hill, Inc.; 1998. pp.261 - 287.

[2] Hornberger Ch, A prototype device for standardized calibration of pulse oximeters II. J ClinMonit 2002; 17: pp.203-209.

[3] Natasha Stabile, Karen J. Reynolds. Technological Review of Pulse Oximeter Simulators. Journal of Clinical Engineering, Fall 2002; pp. 287-297

[4] Marco Fernandez, Evaluation of A New pulse Oximeter Sensor. American Journal of Critical Care. 2007;16: pp.146-152.