Statement on unnecessity of periodic calibration for manufactured Fingertip Pulse Oximeter from ChoiceMMed

Because of its structure design and working principles on both software and hardware, Fingertip Pulse Oximeter is free from periodic calibration. The oxygen saturation is calculated through the specific value of red light and infrared light absorbed, so factors not related to it won't influence the accuracy of oxygen saturation monitoring.

Proportionality coefficient of red light and infrared light in the oximeter is related to the congruent relationship of SpO_2 value, which is built in the software of the oximeter and won't change as time goes by, so no calibration is needed. As long as the MCU functions well, no problem would appear.

Factors influencing the proportionality coefficient of red light and infrared light in the oximeter mainly are from three aspects, and respectively they are: 1. the structure design 2. hardware signal processing 3. Software.

Firstly, from the perspective of structure design, the whole structure design of the oximeter is supposed to guarantee the stability of SpO_2 monitoring chain, which means within service life of the manufactured oximeter (ChoiceMMed oximeter's life expectancy is 5 years), the stability of the chain (namely, luminous flux, the optic path of red light and infrared light travelling from the emitter to the detector) from the perspective of structure during SpO_2 monitoring is guaranteed. This is determined by the mechanical life of oximeter. In the process of designing, it is

guaranteed that the structure of the oximeter is stable and has no relative change as it operates within service life.

The oximeter calculates the oxygen saturation through the measurement of red light and infrared light. In the aspect of structure design, it is necessary to guarantee that the optic path of red light and infrared light always keeps the same, which is of great importance in SpO_2 theoretical modeling. That the optic path of the two beams keeps the same means they travel the same distance and penetrate the same organs; the intensity of the two beams increases or decreases simultaneously, or it would lead to inaccuracy of SpO_2 monitoring. Therefore, in the aspect of structure design the sensor holder and sensor itself in the oximeter should guarantee that whatever angle it is opened or closed at, the optic path of red light and infrared light keeps the same.

What controls the angle at which the Fingertip Pulse Oximeter opens and closes is the spring on the clip part. Based on the assumption that the oximeter opens 10 times per day, the total times it opens within the 5-year service life is 22,000 (10*365*5*1.2=21900). The total designed opening and closing times of the spring in ChoiceMMed Fingertip Pulse Oximeter are more than 30,000, which is sufficient to guarantee the 5-year service life. As for other mechanical parts or ABS parts, the service life is far more than this number.

The second crucial factor affecting the oximeter accuracy is the hardware processing part. What matters most in hardware design is the red light/infrared

light emitter and detector. The service life of other electronic components are normally more than hundreds of thousand hours (10 years), which is long enough compared to that of Fingertip Pulse Oximeter. Therefore, the mere crucial index that affects the accuracy is the emitter and detector. As for the detector, if it influences the accuracy, what is indicated is that relative change happens in it. However, the fact is that the service life of the detector itself is above hundreds of thousand hours, which is stable on performance during the service life of Fingertip Pulse Oximeter. So, there is no necessity for considering the detector, and what needs consideration is the emitter. Two indexes affect the stability of the emitter.

The first one is wavelength. The LED emitter factories are required to control the wavelength in the range of 660±3nm and according to different wavelength the infrared light (ChoiceMMed normally chooses 905 or 940) is controlled at the range of ±10nm.

In LED model selection, usually ChoiceMMed requires that the service life is above 20,000 hours. The typical operation mode of Fingertip Pulse Oximeter is spot-check. Based on the assumption that the continuous using hour is 8 per day, the stability of the emitter wavelength can meet the requirement during its service life, which is about 6 years (20000/8/365=6.8).

The controlling of emitter wavelength is the most crucial factor during the production instruction process of Fingertip Pulse Oximeter; if the wavelength drifting happens, especially the red light wavelength, great influence would be

caused on SpO_2 measurement. In other words, if emitters of different wavelength are used in the same oximeter, human body' s absorption of the two wavelengths would be different, which will thus lead to different values on oxygen saturation detection.

Wavelength drifting is mainly of two types: one is thermal drift which means changes will happen on wavelength as temperature varies while using; the other is time drift which means changes happen on wavelength as using time varies. Thermal drift is temporary while time drift is chronic (half-year drift would be different from one-year drift).

Thermal drift changes in every measurement, and can be controlled by impulse type emitting. Impulse type emitting means the emitting time is extremely short (normally at the level of millisecond), such as emitting within 20 or 10 milliseconds. And for the rest time, LED is not working. Thus, the temperature raise will be controlled within the range of the LED performance requirement (typically it is no more than 40C°).

As for time drift, it can be avoided through the entire software design of the Fingertip Pulse Oximeter.

The intensity change of red light and infrared light is another factor affecting the LED emitter performance. The intensity of LED emitter would gradually decrease as time goes by, which is similar with the daily used lamb bulb. ChoiceMMed Fingertip Pulse Oximeter controls the electric current to adjust the intensity of LED emitter

through software. In the case when the LED emitting intensity decreases, the software automatically adjusts the electric current to increase the LED intensity and thus it can meet the oximeter monitoring requirement and become applicable to different human bodies.

In the above, explanation on guarantee from the perspectives of structure and hardware are made. The third perspective is from software. After the settlement of the Fingertip Pulse Oximeter design, relating parameters would be stored in MCU and software, which would not change as time goes by and thus calibration is not needed in this part.

In conclusion, periodic calibration is not necessary for ChoiceMMed Fingertip Pulse Oximeter after manufacture.