SpO_2 Monitoring
Performance Digest

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Fighting Disease with Electronics
NIHON KOHDEN

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1. Introduction

The pulse oximeter is a non-invasive device to percutaneously measure oxygen saturation in the blood with a finger probe. The principle of pulse oximetry was developed by Takuo Aoyagi, a researcher at Nihon Kohden Corporation, and first presented at the Japanese Society for Medical and Biological Engineering (formerly The Japan Society of Medical Electronics & Biological Engineering) in 1974.[1]

Before pulse oximeters were developed, the common method of measuring oxygen saturation in arterial blood was spectroscopic analysis. However, this method is time consuming and not suitable for continuous measurement so it was difficult to detect sudden changes in patient's condition. The pulse oximeter provides non-invasive, continuous and real-time measurement. In the 1980s, pulse oximetry attracted much attention as an effective way to prevent medical accidents during surgery. Its advantages in respiratory and safety management became widely recognized and use of the pulse oximeter has spreaded rapidly in intensive care units (ICU), neonatal intensive care units (NICU), emergency rooms (ER) and other areas. Now, pulse oximetry is a standard measurement technique in patient monitoring.

The development and widespread use of pulse oximeters has created a demand for more advanced technology in clinical practices. This demand has accelerated the development and improvement of the technology by pulse oximeter manufacturers.

However, even the best technology can have unexpected negative consequences if it is used inappropriately. Since the pulse oximeter is easy to use and provides important vital information, there is the danger that it might be used inappropriately or in a way that is beyond its performance capabilities. This can be prevented by using the device properly and understanding its measurement principle and performance limitations.

This document describes Nihon Kohden's pulse oximeter technology and performance as well as its measurement principle and related international standards in order to promote appropriate use and better understanding of the pulse oximeter.

2. APPLICATION AND MEASUREMENT PRINCIPLE OF PULSE OXIMETRY

2.1. SpO_2 Applications

The pulse oximeter is commonly used for patient care including management of anesthesia and respiration in ICU patients. With the development of smaller devices and transmitters, it has become a standard for both inpatients and outpatients. With the trend toward downsizing and price reductions, it is also widely used in homecare.

As a device for continuously monitoring SpO_2, the pulse oximeter has the important functions of detecting hypoxia and alerting the medical staff with an alarm, especially during monitoring of severely ill patients. For neonatal patients in the NICU, SpO_2 monitoring plays an important role in preventing hyperoxia which could cause retinopathy in the premature infant.

The pulse oximeter is used for different types of patients in different areas, so several types of pulse oximeters and probes have been developed for different applications.

Table 1. Pulse oximeter applications

Operating Room Recovery Unit	• Oxygenation evaluation during and after anesthesia induction
ICU	• Respiratory management during ventilator use • Criteria for ventilator weaning • Respiratory management for patients taking sedatives or painkillers
NICU	• Detection of hypoxemia • Oxygen-level management to prevent retinopathy of prematurity (ROP)
Ward	• Vital sign monitoring with SpO_2 and pulse rate • Respiratory management for patients taking sedatives or painkillers • Spot check of oxygen level during medical rounds
Emergency Patient Transport	• Oxygenation management
Endoscopy	• Detection of hypoxemia by bronchoscopy or endoscopy
Homecare	• Oxygen therapy • Respiratory management • Screening of sleep apnea syndrome (SAS)

2.2. Principle of Measurement

Oxygen Saturation and Hemoglobin

The pulse oximeter measures oxygen saturation in arterial blood with a non-invasive probe. Oxygen saturation measured by spectroscopic analysis of sampled blood is called SaO_2 and requires a blood draw to obtain a sample for analysis. Oxygen saturation measured by a pulse oximeter is called SpO_2. The "p" stands for pulse because the principle of SpO_2 makes use of the change in blood with each pulse wave.

Hemoglobin in the blood has a property that only allows red light to easily pass through. Hemoglobin which has oxygen bound to it is called oxygenated hemoglobin or oxyhemoglobin. Hemoglobin which does not have oxygen bound to it is called deoxyhemoglobin. Oxygen saturation in the blood is the ratio of oxygenated hemoglobin to deoxyhemoglobin.

Arterial blood has a high concentration of oxygenated hemoglobin and appears bright red. Venous blood appears darker as it has discharged oxygen into the body. This difference in color is because oxyhemoglobin and reduced hemoglobin have optical absorption properties. Therefore, from the color of the blood, we can measure the amount of oxygen which is bound to the hemoglobin. In other words, we can measure the oxygen saturation.

Pulse Oximeter and Light Wavelengths

The pulse oximeter shines light through a fingertip or alternate relatively thin tissue and measures the intensity of light which is transmitted through to the other side. The waveform which is obtained from the change in the intensity of transmitted light over time is called the photoplethysmographic wave, or the pulse wave.

In Nihon Kohden's SpO_2 measurement, the optical absorbance of the arterial blood can be extracted and used to determine oxygen saturation by using the pulse waves which are obtained from shining two light wavelengths (660 nm red light and 940 mm infrared light). The amplitudes of the pulse waves indicate the change in blood volume with each pulse. The differing amplitudes of the pulse waves for each wavelength of transmitted light indicate the change in optical absorption. The optical light wavelength and its optical absorption by the blood are related as shown in Figure 1. Even if the volume of blood doesn't change, the amount of light absorbed by the blood is different at different wavelengths. The amplitudes of the pulse waves at the two light wavelengths are different because the optical absorbance changes according to the degree of oxygen saturation. The pulse oximeter obtains the ratio, ϕ, of the pulse wave amplitudes at the red and infrared light wavelengths and oxygen saturation is calculated from ϕ (Figure 2).

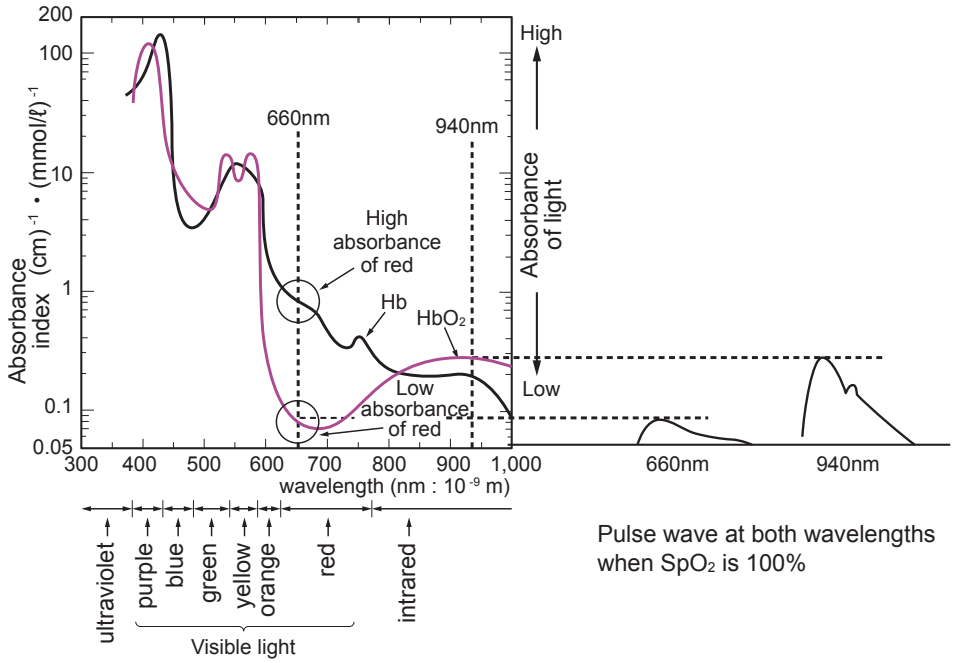


Figure 1. Optical absorption of oxyhemoglobin (HbO_2, pink line) and reduced hemoglobin (Hb)[2]

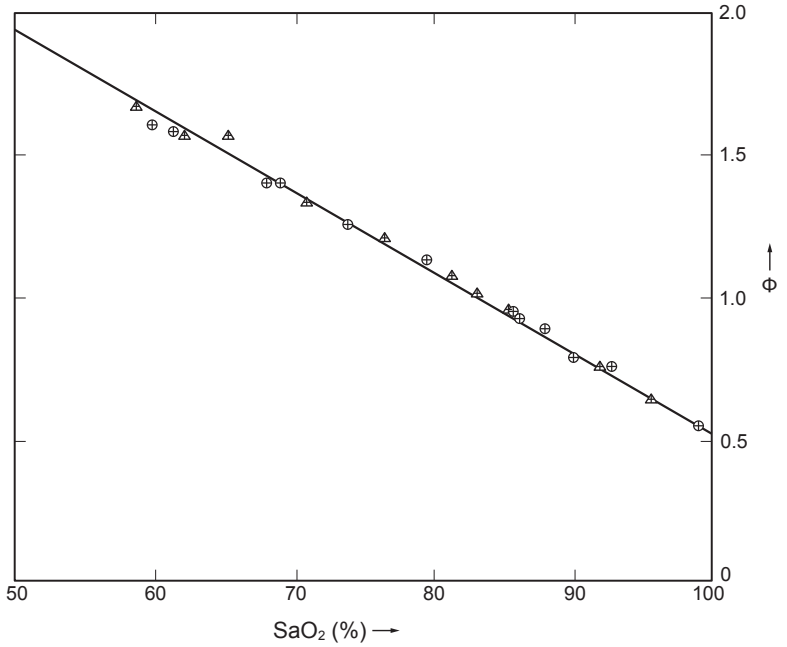


Figure 2. Ratio (ϕ) of the pulse wave amplitudes at 660 and 940 nm as SpO_2 changes[3]

3. INTERNATIONAL PULSE OXIMETER STANDARD

ISO 9199, the international standard for pulse oximeter equipment, was issued in 1992. It defined basic requirements for medical devices; safety, environmental conditions protection against different hazards and labeling. Thereafter, it was revised and published as ISO 80601-2-61:2011 "Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment". In addition to the basic requirements, this edition further defines specific and essential features of pulse oximetry, including measurement accuracy and temperature at the sensor/skin interface. The development process of this requirement is included in the appendix.

These requirements will be explained in this section so you can understand the necessary conditions for the use of a pulse oximeter.

3.1. SpO_2 Accuracy

Measurement Criteria

ISO 80601-2-61:2011 specifies that accuracy of SpO_2 measured by a pulse oximeter should be evaluated by comparing the SpO_2 reading of the pulse oximeter equipment to values of SaO_2 determined by a CO-oximeter. The CO-oximeter is considered the gold standard.

Definition of Accuracy and Acceptable Range

ISO 80601-2-61:2011 specifies that SpO_2 accuracy should be stated in terms of the root-mean-square (RMS) difference between the SaO_2 (reference) value in operation manuals. It also defines the acceptable range of SpO_2 accuracy to be an RMS difference of less than or equal to 4% SpO_2 over the range of 70% to 100%. This RMS difference means that about two-thirds of the SpO_2 values measured can be expected to fall within the range of RMS. In other words, about one-third of SpO_2 values could be out of range. After active discussions at international standards meetings, this range, at the current level of technology, was defined as the minimum acceptable range in consideration of various factors that cause errors such as color of skin, sex, age, and pathosis.

Accuracy Validation Method

Accuracy Validation of Controlled Desaturation Study on Adult Volunteers

It is important to eliminate error causing factors to properly compare SpO_2 and SaO_2. For example, SpO_2 and SaO_2 could be different due to different body parts used for drawing a blood sample and probe application. Also, the values may vary depending on the timing of the blood analysis, and the difference between the values might be recognized as an error. To precisely perform an accuracy validation, it is necessary to eliminate these error causing factors. One of the most effective ways to validate the accuracy is a controlled desaturation test on adult volunteers since it can be performed under well controlled conditions. The desaturation test on adult volunteers has some advantages: 1) equally distributed data can be obtained without deflection in specific SaO_2 range because SaO_2 values are under control, 2) easy to perform on various subjects of different races, sexes, ages, etc., 3) statistically reliable data can be obtained.

ISO 80601-2-61:2011 also accepts validation by comparing the readings of pulse oximeter equipment under test to "secondary standard" pulse oximeter equipment that has previously been directly validated against a CO-oximeter.

Accuracy Validation Applicable to Various Clinical Situations

Not every feature of pulse oximeter equipment is theoretically clarified. Therefore, the impact of various error factors on accuracy need to be demonstratively validated in consideration of each application purpose. This is mentioned in the ISO 80601-2-61:2011 SpO_2 standard, but the validation method is not specified by any international standard. Traditionally, clinical validations have been conducted in a manner that is consistent with the primary purpose of medical treatments. You may refer to these methods as useful references.

Performance Validation under Conditions of Motion and Low Perfusion

For performance validation under conditions of motion artifacts or weak signals due to low perfusion, there is no internationally defined method. These validations are conducted in consideration of each clinical condition.

3.2. Skin Temperature at the Pulse Oximeter Probe

The maximum limit for skin temperature at the probe is defined to not exceed 41°C for skin temperature of 35°C in use with normal conditions or a single fault-condition. The pulse oximeter probe generates a small amount of heat due to the light-emitting diode (LED). When the pulse oximeter probe is applied to the patient's skin where heat loss is prevented due to poor circulation, the temperature of the skin in contact with the probe might increase and this could increase the risk of low temperature burn. In the revision of ISO 80601-2-61 :2011, thorough discussion and reviews of literature on this matter led to the industry standard conclusion that it is appropriate and safe to retain the 41°C limit for infants under the age of 1 year and apply the adult limit (42°C for 8 hours, 43°C for 4 hours) for all older patients.

3.3. Probes and Connected Monitors

ISO 80601-2-61:2011 requires manufacturers to conduct tests to ensure that all pulse oximeter probe requirements are met by each pulse oximeter monitor with which the probe is intended to be used. All pulse oximeter monitors with which compatibility is claimed should be listed in the accompanying documents including the operation manual. Also, ISO 80601-2-61:2011 is applicable not only to new probes, but to reprocessed ones. Therefore, manufacturers are responsible to validate their processes to ensure that any new or reprocessed probe complies with the requirements in regard to safety and basic performance.

3.4. Notification and Alarm of Measurement Condition

Data Update Period

It is required that at least a low priority alarm should be generated when SpO_2 or pulse rate (PR) data update period exceeds 30 seconds. When the data update period is less than 30 seconds, it should be disclosed in the instructions for use.

Detection of Fault in Pulse Oximeter Probe or Probe Cable Extender

When any fault occurs in the probe or probe cable extender such as disconnection or short-circuit, it should create a notification. If the pulse oximeter equipment has an alarm function, it should generate an alarm. If it does not have any alarm function it should provide indication of abnormal operation.

SpO_2 Calculation in the Presence of Inadequate Input Signal

The pulse oximeter is required to provide an indicator of signal inadequacy to the operator if the displayed SpO_2 or PR values may be incorrect due to low quality input signal caused by artifacts. The pulse waveform displayed together with the signal strength may help the user judge whether the signal is adequate for measurement.

4. CLINICAL CONSIDERATIONS

SpO_2 is a parameter that provides important information for respiratory management and the pulse oximeter has the great advantage of being easy to use. However, various factors can cause measurement errors such as the patient's hemodynamics, the condition of the skin at the probe, probe attachment, and measurement algorithm. This section describes instructions and directions for clinically proper and safe use of the pulse oximeter.

4.1. Difference between Different Models and Manufacturers

Not every feature of the pulse oximeter has been validated or defined, so proper caution is necessary when using a pulse oximeter.

- The measurement accuracy and safety of pulse oximeter is validated by a combination of a specific probe and measurement circuit. Therefore, if you use a different probe, it is necessary to validate the performance of the combination. Some manufacturers specify a specific probe to work with their pulse oximeter equipment.
- Each manufacturer has different specifications, including wavelength errors, correction constant and signal processing methods. Even if the performance based on these specifications is within acceptable range, it is still recommended to refer to the technical information provided by each manufacturer for proper use of the equipment.

Figure 3 compares SpO_2 readings provided probes from Nihon Kohden (blue line) and another manufacturer (purple line) which is not validated for use with the monitor (BSS-9800, Nihon Kohden), to which these probes are connected.[4] Compared to the reference value provided by the Nihon Kohden probe, probe which is not validated shows incorrect values at all the measurement points throughout the measurement for one and a half hours. As you can see in this example, any probe not validated for use with the SpO_2 equipment should be avoided. And, care must be taken as some manufacturers may indicate that their probes are made to "work with" or have a "compatible connector". This does not mean the probe has been tested by Nihon Kohden, nor does it mean the probe will perform as expected.

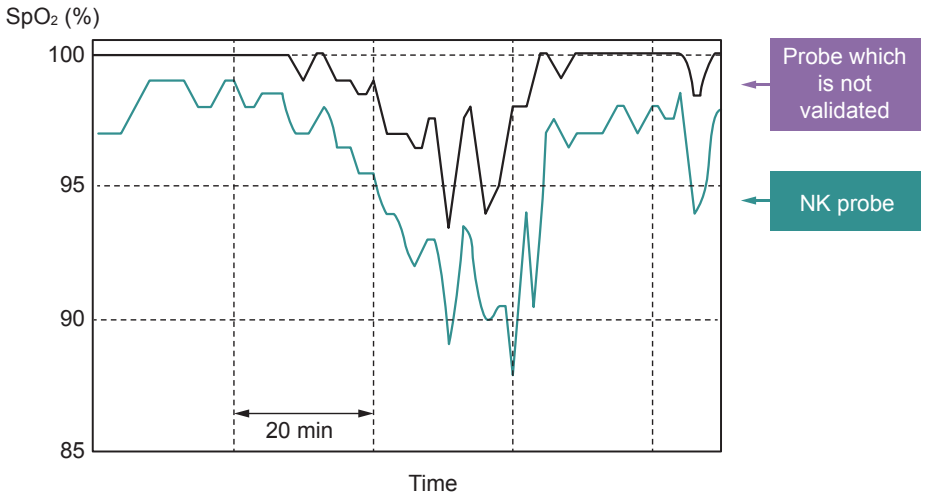


Figure 3. SpO_2 trend with probes from Nihon Kohden and another company, connected to a BSS-9800 bedside monitor

4.2. Probe Placement

The light-emitting part and light-receiving part should be placed so they are facing each other. When using a clip finger probe, ensure that the probe covers the finger properly. Otherwise, some of the light will not pass through the tissue to reach the light-receiving part and this will lead to incorrect measurement results.

The more distant the light-emitting and light-receiving parts, the weaker the transmitted light intensity becomes. Also, a thinner body part tends to have less blood volume and a weaker pulse signal. The most suitable thickness of the probe site is about 10 mm.

4.3. Interference from Light and Movement

The pulse oximeter can be affected and interfered with by many factors such as ambient light and motion artifact.

In order to reduce such interference, it is advisable to avoid any strong ambient light, use lighter and smaller probes, and keep the cable from moving by taping it to the finger.

Although there have been numerous technical advancement to improve the performance of the pulse oximeter, such as filters to reject motion artifacts, it is still necessary to pay attention to light and motion interference to ensure accurate measurement.

4.4. Peripheral Circulatory Failure

In patients with decreased blood flow due to peripheral circulatory failure, the pulse at the probe site (e.g. fingertip) may be too weak to be measured. In these cases, alternate measurement sites must be used and whenever the probe is attached, it must be attached in a way that does not block or restrict the blood flow.

4.5. Skin Injuries Caused by Probes

The site where the probe is applied gets pressure regardless of what type of probe is used. Clip type probes can give high pressure on the finger depending on the structure of the probe or size and shape of the finger. Skin injuries such as erythema and marking or impressions can be caused by high local pressure from the hard component parts of the probe, including light-emitting diode (LED) and photodetector (PD). On the other hand, self-adhesive type disposable probes can block the blood flow if the probe is attached too tightly or supplemental tape is applied. We recommend not to use elastic wrap to hold the sensor in place because pressure from the tape can increase over time.

The light-emitting part of the probe can increase the skin temperature by about 2°C. Because the temperature increase is slight, low temperature burns are not common (Refer to 6.5 for more information about temperature increase at the probe site). But the skin at the attachment site should be checked at specified intervals.

The body naturally eliminates heat by increasing blood flow in the skin. If the probe applies excessive pressure, it could block the blood flow so that metabolic heat can't be released and the local skin temperature at the probe site may increase.[5] Skin burns from the probe seem to be caused by a combination of pressure from the probe and heat from the light-emitting part. There are also reports that the LED temperature can rise when using the pulse oximeter with probes from other manufacturers. Therefore, to prevent skin injury it is recommended to avoid using probes which have not been validated in regard to the synergistic combination of burn and high local pressure from the probe.

It is recommended that the probe not be continuously applied at the same site for a long period of time and that the probe should not be attached too tightly. The measurement site should be changed every 8 hours for disposable probes and every 4 hours for reusable probes.

4.6. Effects of Abnormal Hemoglobin

In addition to oxyhemoglobin and deoxyhemoglobin, there are abnormal forms of hemoglobin, carboxyhemoglobin (COHb) and methemoglobin (MetHb). COHb attaches firmly to carbon monoxide instead of oxygen so it has no capability of delivering oxygen. MetHb contains Fe3+ instead of Fe2+ and cannot carry oxygen effectively.

The two-wavelength pulse oximeter cannot distinguish normal and abnormal hemoglobin, so if the abnormal hemoglobin level increases, it can cause considerable error in the measurement. Normal COHb level is about 1%, and in smokers up to about 5%. COHb level within this range rarely has impact on SpO_2. However, extra attention is needed when hemoglobin is increased due to carbon monoxide poisoning or methemoglobinemia.

4.7. Nail Polish

A probe site that is very soiled or covered with nail polish could block light transmission and interfere with the measurement. Figure 4 shows how the effects of nail polish on the accuracy of SpO_2 measurement. If the probe site gets dirty with blood or the patient wears nail polish, clean the probe site or remove nail polish before measurement. For the case where nail polish cannot be removed, it has been reported that reorienting the probe in the lateral direction on the fingertip could diminish the effect of nail polish on the accuracy of SpO_2 measurement.[6, 7]

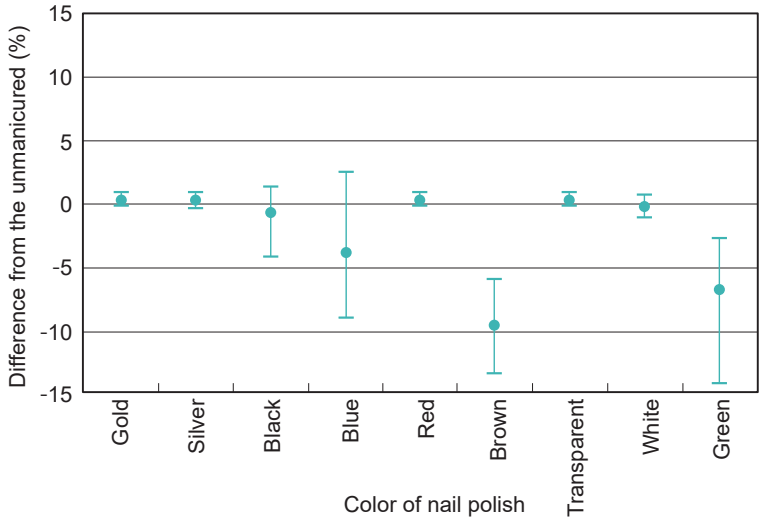


Figure 4. Effect of nail polish[8]

5. NIHON KOHDEN SpO_2 TECHNOLOGY

Over the course of many years of improving SpO_2 measurement technology — whose full scope has not yet been uncovered — Nihon Kohden has given primary consideration to optimizing the SpO_2 measurement system in regard to the different uses and applications in various clinical practices.

Quality SpO_2 signals can be obtained using various combinations of probes, sensor performances, signal detection circuits, and signal processing algorithms. Proper attachment and handling of the probe are also important. It is necessary to consider all possible elements related to SpO_2 measurement in order to provide optimum performance.

Nihon Kohden has a wide range of SpO_2 sensor technologies including BluPro series reusable probes and disposable probes in different sizes and shapes with connection cables that focus on continuous monitoring of SpO_2.

Nihon Kohden also offers a wide variety of SpO_2 monitoring devices for different applications. All devices have different power consumptions and shapes and it is necessary to consider all these differences in the process of developing and improving SpO_2 technology.

Nihon Kohden has also developed an original measurement circuit and algorithm (*NPi* algorithm) that works with every Nihon Kohden device.

Any component other than the arterial pulse which is superimposed on the input signal can become artifact in SpO_2 measurement. Artifacts such as light interference by surgical light and sunlight, improper attachment of probe, and body movement can be mistaken as pulse waves or can interfere with pulse wave detection. This causes incorrect SpO_2 measurement. Nihon Kohden SpO_2 technology has been designed to extract the pulse wave derived information and calculate the ratio of pulse wave amplitude, φ, as accurately as possible.

5.1 Introduction of *NPi* Algorithm

The basic processing of Nihon Kohden pulse oximeters includes filtering of the A/D converted input signal, calculation of the ratio of pulse wave amplitude φ, weighted moving average, and calculation of the SpO_2 value.

The characteristic features of the *NPi* algorithm include a filtering function which removes artifacts from the pulse waves. The artifact removal is performed using narrow-band filtering based on the fundamental frequency that is extracted by frequency analysis (Figure 5). This narrow-band filtering is especially effective when there are relatively large artifacts, especially in the ICU and NICU, such as restless patients with peripheral circulation insufficiency neonatal patients presenting with respiratory variation.

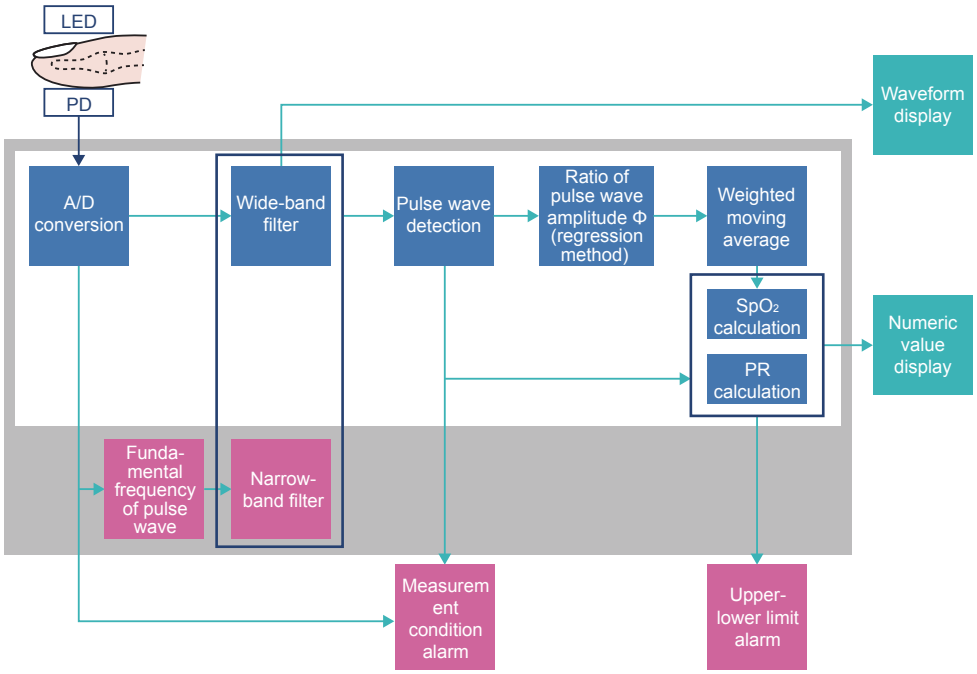


Figure 5. Construction of NPi algorithm

Pulse waves contain a fundamental frequency of the pulse rate and constant multiples of the frequency (Figure 6a). When performing frequency analysis in the presence of large artifacts superimposed on pulse waves, it is difficult to identify the pulse wave frequency because the pulse signal gets lost in the artifact (Figure 6b). In such cases, Nihon Kohden's original coordinate-transform method is used to enhance the discrimination between pulse wave and artifact (Figure 7). By performing frequency analysis on the pulse signals obtained by the coordinate-transform method, the fundamental frequency of the pulse wave can be identified (Figure 6c).

Pulse wave components are selectively passed through a narrow-band filter of the fundamental frequency so that SpO_2 values can be calculated using pulse wave components without artifacts. This Nihon Kohden original technology, which is based on a well-established signal processing technology, has been patented.[9]

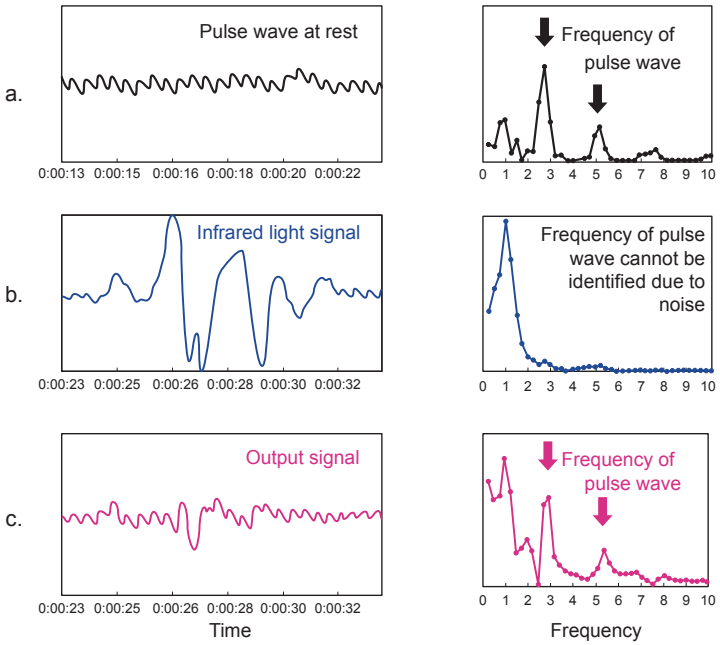


Figure 6. Frequency component of pulse wave

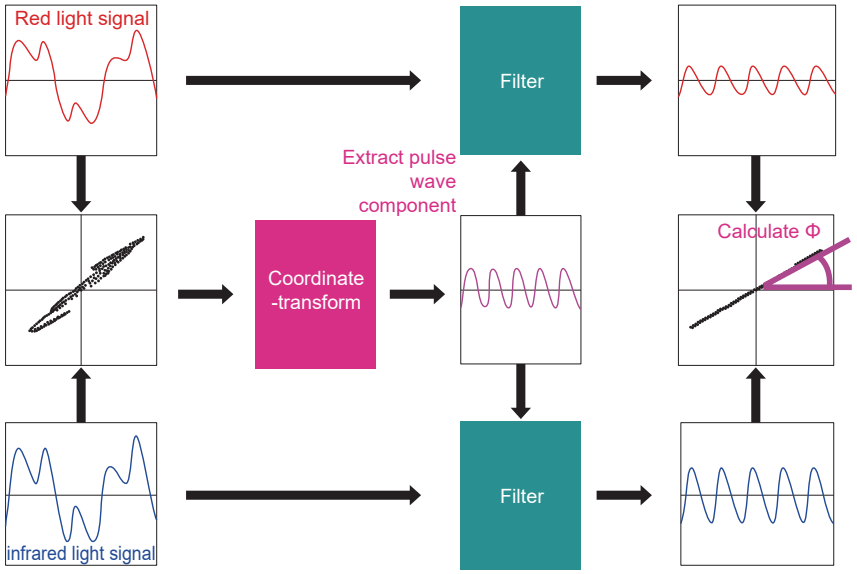


Figure 7. Identification of fundamental frequency and filtering using coordinate-transform method

The ratio of pulse wave amplitude, φ, is calculated using the filtered pulse waves. The pulse oximeter calculates the SpO_2 value based on φ which can be obtained from two LEDs of red and infrared light. Correct calculation of φ leads to accurate SpO_2 measurement. In Nihon Kohden's SpO_2 measurement, data obtained at every sampling interval are plotted. The x-axis is the pulse signal of the red light and the y-axis is the pulse signal of the infrared light (Figure 8). φ is derived based on the slope of the regression line obtained by the least squares method.[10]

By using the entire waveform instead of using only the maximal and minimal amplitude, accurate calculation of φ can be achieved even in conditions such as peripheral circulation insufficiency with lower amplitude pulse waves.

Furthermore, a weighted moving average is applied according to the degree of variation in the φ obtained every beat to limit the influence of SpO_2 variation due to artifact.

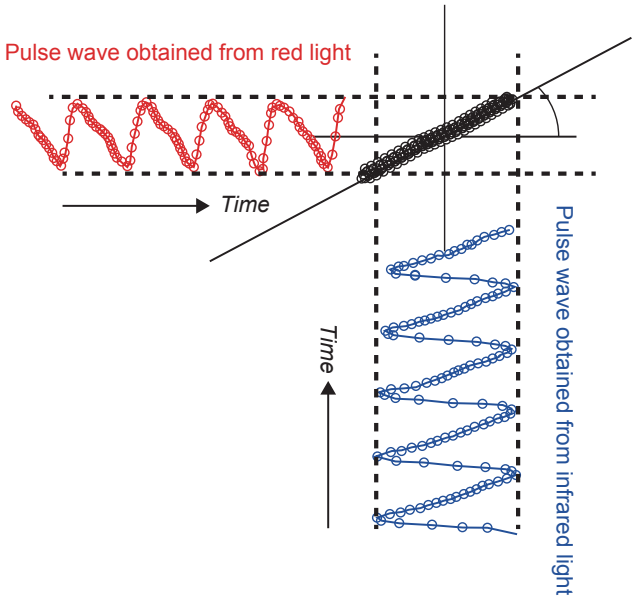


Figure 8. Calculation of φ using regression method

6. NIHON KOHDEN SpO_2 MEASUREMENT PERFORMANCE

This chapter describes the basic performance of Nihon Kohden's SpO_2 measurement including measurement accuracy, measurement range of input signals, responsiveness, temperature increase at probe site, as well as how the basic performance was verified. In addition, measurement performance under noisy conditions due to artifact is shown with waveform examples.

6.1. SpO_2 Measurement Accuracy

The SpO_2 measurement accuracy has been evaluated in comparison with CO-oximeter readings (SaO_2) in adult volunteers and pediatric patients with cyanotic heart disease.

Measurement Accuracy: SpO_2 Validation on Adult Volunteer Subjects

The result of accuracy validation using a Nihon Kohden OLV-3100 pulse oximeter and four types of probes is presented here. Hypoxia was induced to different levels of arterial oxyhemoglobin saturation between 70% and 100% by controlling the inspired oxygen concentration. The SpO_2 readings of the pulse oximeters were recorded simultaneously with arterial blood sampling. Two CO-oximeters (OSM3®, Radiometer Inc.) were used to determine the reference SaO_2 values by analysis of arterial blood samples from the radial artery. Statistical analysis was performed to compare the SpO_2 readings and the reference SaO_2. Exclusion criteria for the statistical analysis were predefined. Data was excluded if:

- There was considerable change in SpO_2 value (4% or more during a 10-second period).
- Co-oximeter values disagreed by 2% or more.

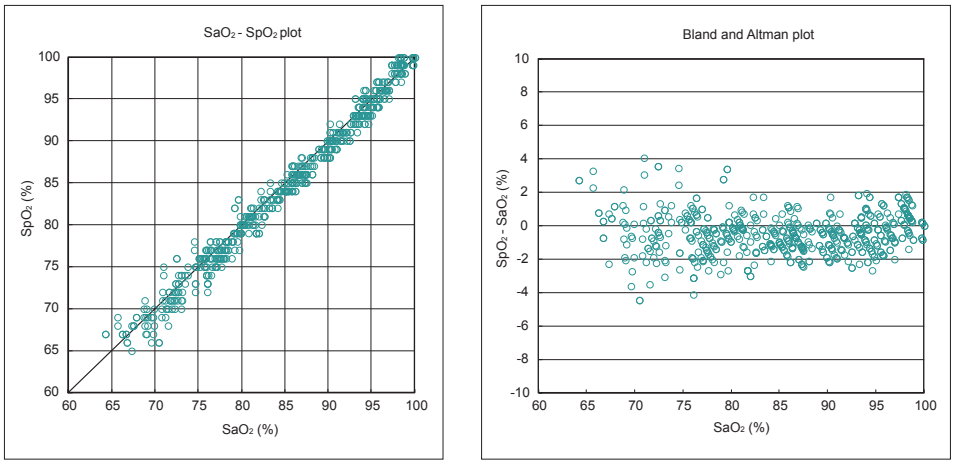
Table 2 shows the result of the accuracy analysis of the validated probes, along with the measurement accuracy standard of Nihon Kohden pulse oximeters and the ISO 80601-2-61:2011 requirement.

All pulse oximeters are designed and manufactured to meet Nihon Kohden's SpO_2 accuracy standard which is stricter than the ISO 80601-2-61:2011 requirements of 4%. The results in Table 2 show that all validated probes have met the accuracy requirements.

Table 2. SpO_2 accuracy of hypoxia test on adult volunteers (RMS)

		SaO_2 Range	
		70–80%	80–100%
Finger probe	TL-201T	1.62%	1.07%
Multi-site Y probe	TL-260T	1.83%	1.56%
Multi-site Y probe with clip adapter for ear lobe	TL-260T	2.14%	1.62%
Finger probe	TL-631T	2.79%	1.45%
Disposable SpO_2 probe	TL-271T	2.05%	1.39%
Disposable SpO_2 probe	TL-051S	1.93%	1.59%
Disposable SpO_2 probe	TL-535U	2.01%	1.37%
Nihon Kohden pulse oximeter SpO_2 accuracy		3% or less	2% or less
ISO80601-2-61 SpO_2 accuracy		4% or less	4% or less

Figure 9 shows the data plot obtained from the validation of TL-201T. The left figure shows good correlation between SpO_2 and SaO_2. The right figure shows the difference between SpO_2 and SaO_2. SaO_2 values in the range of 70–80% tend to vary more widely than the range of 80–100%. A previous study has reported that SaO_2 values are more likely to be variable at low SaO_2.[11] In consideration of this characteristic, the accuracy of Nihon Kohden pulse oximeter was evaluated in two different SaO_2 ranges.



Pulse oximeter: OLV-3100, Probe: TL-201T
CO-oximeter: OSM3® (Radiometer)

Figure 9. TL-201T SpO_2 and SaO_2 data comparison

For more details on the validation study, refer to *SpO_2 Monitoring Pulse Oximeter Accuracy Study* (extracts from a test report from the Hypoxia Research Laboratory, University of California, San Francisco) (No. 0604-905574A).

Measurement Accuracy: SpO_2 Validation in Neonate Patients with Cyanotic Heart Disease

Pulse oximeter probes come in a variety of types for patients of different ages and different probe sites. The overall performance of all pulse oximeters and probes should be evaluated in consideration of each application and usage.

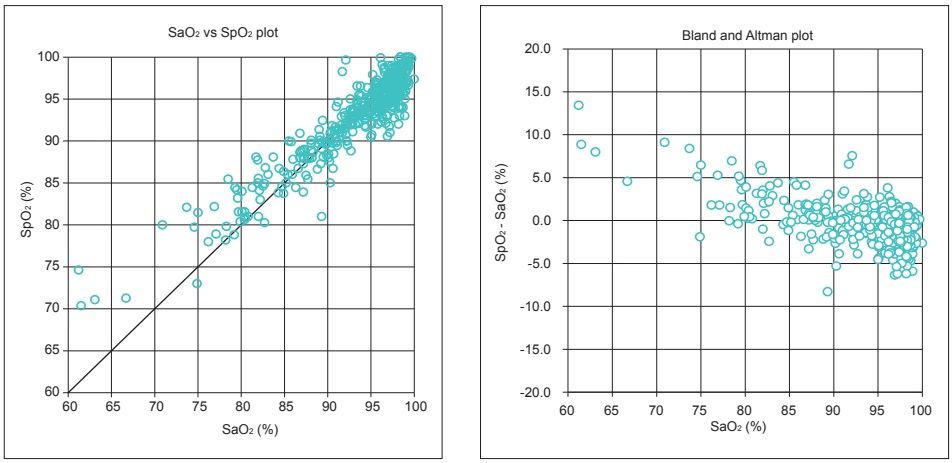
However, the same kind of studies that are carried out in adult volunteers as well as induced hypoxia studies cannot be conducted in children.

Clinical functionality of a Nihon Kohden TL-535U has been demonstrated in comparison with the SaO_2 of a CO-oximeter on a population of hospitalized neonate patients. The data presented here was obtained from 19 neonatal patients below the age of 1 month.

The results are presented in Table 3 and Figure 10. The results show that the TL-535U probe met the standard of the SpO_2 accuracy criteria.

Table 3. SpO_2 accuracy in neonatal patients at the NICU

CO-oximeter SaO_2 range	70–100%
Number of subjects	19 (6 subjects weighing ≤1000 g, 13 subjects weighing ≥1000 g and ≤2000 g)
Number of data	422
SpO_2-SaO_2 average	-0.25%
SpO_2-SaO_2 standard deviation	2.43%
SpO_2-SaO_2 RMS	2.25%



Pulse oximeter: Nihon Kohden OLV-3100, Probe: Nihon Kohden TL-535U
CO-oximeter: OSM3® (Radiometer)

Figure 10. Comparison of SpO_2 and SaO_2 data for TL-535U probe

6.2. Magnitude of Input Signal and Waveform

The transmitted light intensity becomes weaker when the probe is attached to a thick body part because more LED light is absorbed by the tissue. Also, pulsations in the artery become weak when the peripheral circulation at the probe applied part is poor. This leads to smaller pulse components of the transmitted light signals from the probe.

Figure 11 shows data of the thickness of the finger and the strength of the input signal from the probe. The vertical axis shows the percentage of pulsatile signal in the entire transmitted infrared radiation (IR) signal, This value is called the Pulse-amplitude Index (PI) and can be displayed on the monitor. The area within the blue lines is the measurable range of Nihon Kohden pulse oximeters. When the finger thickness is about 10 mm, PI of 0.02% is the limit of the pulse wave detection. On a monitoring screen, the pulse wave amplitude increases in accordance with higher ratio of the pulse component. An amplitude of about 10 mm in the ×1 sensitivity setting means a PI of 1%.

In figure 11, the measurement condition becomes more challenging as the distance from the lower left corner decreases. In challenging measurement conditions, the input signal becomes smaller and the artifact becomes relatively higher so the input signals tend to be susceptible to artifacts. For optimum measurement, avoid attaching the probe to a body part that is too thick and observe the monitoring screen to make sure that proper pulse wave amplitude is obtained.

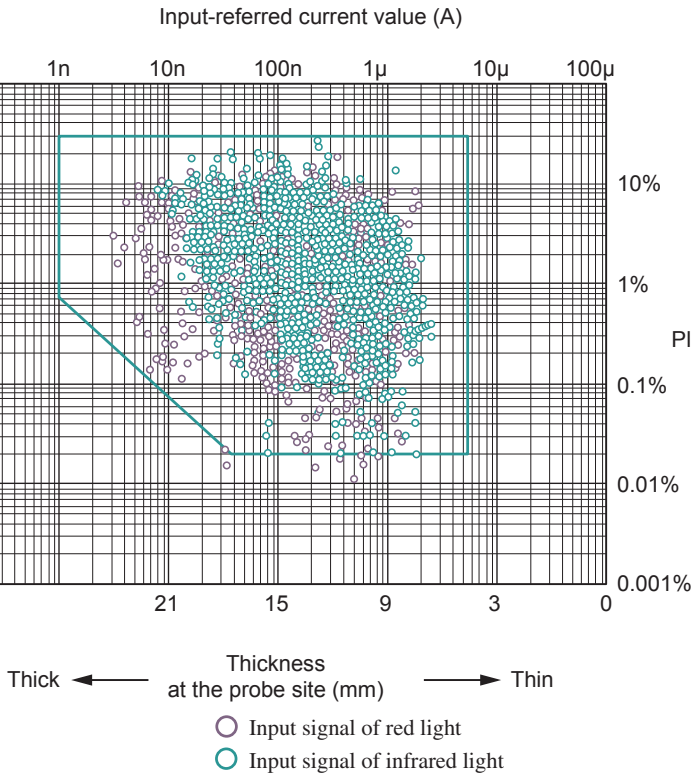


Figure 11. Thickness of probe site and strength of input signal from probe

6.3. Sensitivity Setting

PI of 0.02% used to be the limit of pulse wave detection. However, the NPi algorithm can detect even weak pulses buried in noise. The limit of pulse wave detection can be extended by setting the SpO_2 measurement sensitivity mode.

Normally, select NORMAL mode. The NORMAL setting enhances the performance of the pulse oximeter in identifying improper probe attachment and in distinguishing physiological pulses from non-physiological pulses.

Consider using the MAX setting when it is difficult to detect the pulse such as when monitoring the following patients.

- Patients with low perfusion
- Patients undergoing intra-aortic balloon pumping (IABP) where non-physiological pulses or signals exist

The limit of pulse wave detection is extended up to about 0.01% when MAX is selected. Therefore, even non-physiological pulses (e.g. pulse wave of patients undergoing IABP), which is normally not measured, is detected so that SpO_2 can be displayed. The MAX setting prioritizes detection of weak pulses over identifying probe disconnection and non-physiological pulses.

It is important to set the appropriate sensitivity setting according to the performance characteristics of each sensitivity mode (see Table 4).

Table 4. Performance of each sensitivity mode in different algorithms

Algorithm \ Sensitivity Mode	NORMAL	MAX
Detection of improper probe attachment	Good	Fair
Measurement in the presence of distorted R, IR waveform	Good	Good
Measurement in the presence of respiratory waveform superposition	Good	Good
Detection of pulse wave with low amplitude	Fair	Good

6.4. Responsiveness

The responsiveness of Nihon Kohden pulse oximeters can be set by the user (response setting). The response setting is the setting for SpO_2 averaging time, and the responsiveness relies on this setting. As specified in ISO 80601-2-61:2011, the responsiveness of the Nihon Kohden pulse oximeter is presented as a graph as shown in Figure 12. Signals in which the SpO_2 values changed by 0.6% every second were input in a simulated hypoxia to obtain the response time of different responsiveness settings (Figure 12). The signals were input at the rate of 140 per minute which is equivalent to a typical neonatal heart rate.

The response setting can be set in three stages: fast, normal and slow, and the averaging time can be selected from 4, 8 and 16 seconds. The longer the averaging time, the more stable SpO_2 values become. But, longer averaging time leads to lower responsiveness and decreased fidelity to changes in SpO_2. As an example, Figure 13 shows the graph which is in ISO 80601-2-61 :2011.

The default setting of the response setting is “normal”. “Slow” is appropriate to suppress the number of alarms triggered by the decrease in SpO_2 values. If it is necessary to accurately record the frequency and severity of apnea, select “fast”. For neurology applications and products from Nihon Kohden, it is required to use “extra fast” and averaging should be performed every 3 beats.

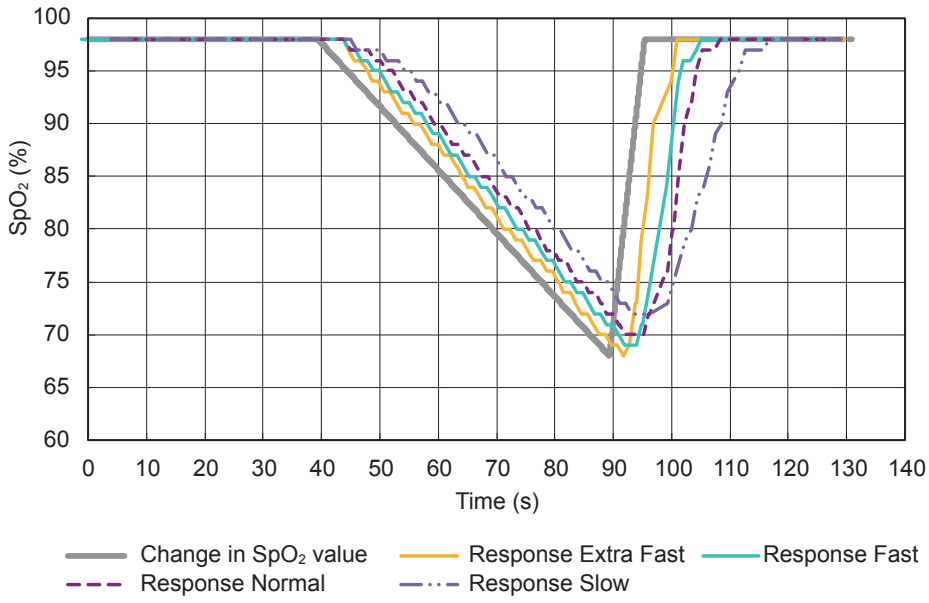


Figure 12. Responsiveness of different settings (PR 140/min)

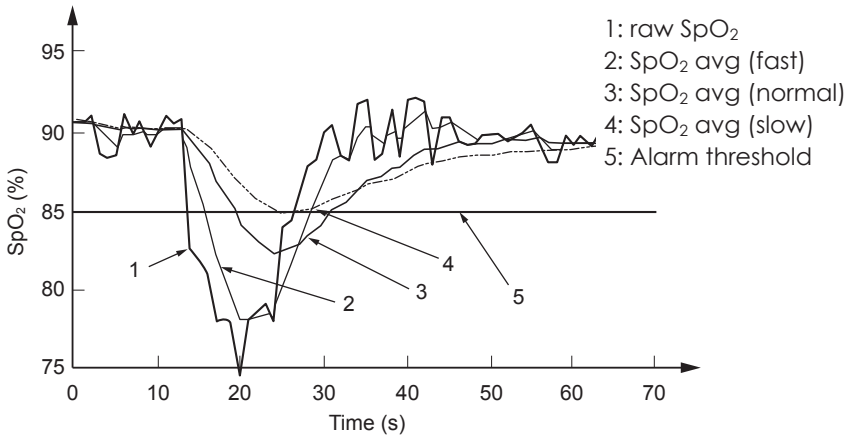


Figure 13. Effect of each response setting at low oxygen saturation[12]

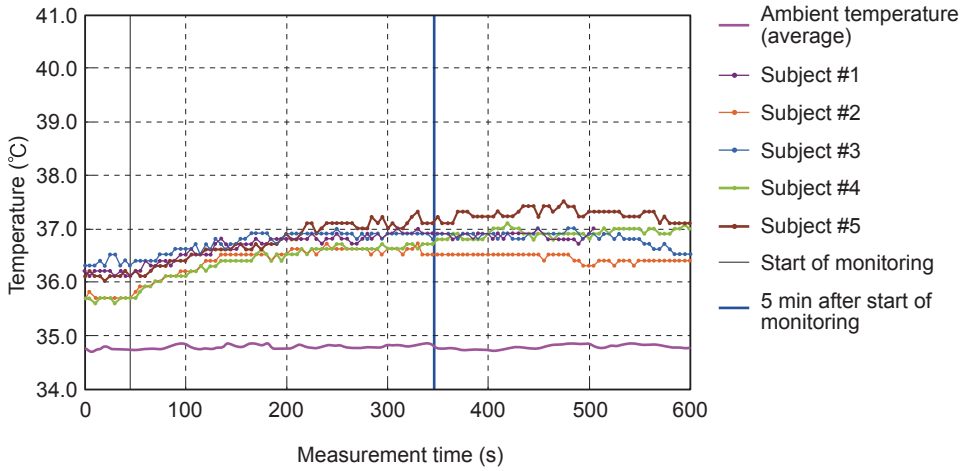
6.5. Temperature Increase at the Probe Site

The probe generates heat due to the LED light. But a cooling effect of blood flow limits the increase in surface temperature of the pulse oximeter probe-tissue interface to around 2°C. Temperature changes at the probe attachment site were evaluated in 5 adult volunteers at an ambient temperature of 35°C (Fig 14). The temperature at the probe attachment site was 36.8±0.22°C five minutes after starting SpO_2 monitoring, and after that the temperature remained around 37°C. This meets the ISO 80601-2-61:2011 temperature requirement of 41°C or less.

However, it should be noted that if the blood flow at the probe attachment site decreases due to poor peripheral circulation or disruption of blood flow, the blood flow cooling effect does not work sufficiently so further temperature increase could be expected.

Therefore, the following should be noted when using the probe:

- Change the measurement site every 4 hours for reusable probes and every 8 hours for disposable probes and reusable finger-tip type probes (TL-631T/T3).
- Do not wrap the probe tape too tightly to avoid poor circulation.
- Take extreme care to change the measurement site more frequently in patients with fever or poor peripheral circulation, and neonates or low birth weight infants with delicate skin.



Subjects	Five adult male volunteers
Pulse oximeter	Nihon Kohden OLV-3100
Probe	TL-260T (placed on fourth finger)
Temperature	35.3–36.6°C (36.0±0.3°C) (first finger)
Environment	35°C ambient temperature, 80% humidity

Figure 14. Temperature increase at attachment site of TL-260T SpO_2 probe

7. MESSAGES AND ALARMS

7.1. Messages and Alarms Related to SpO_2 Monitoring

Messages are displayed on the monitor screen in different situations. Some messages are output as alarms. When SpO_2 values cannot be calculated for any reason, the measured value remains unchanged for 30 seconds and is then displayed as "---". SpO_2 cannot be calculated when the measurement has interference from artifact or when the pulse wave is too small to detect. SpO_2 measurement can be affected by both external factors and physiological factors.

Table 5. SpO_2 monitoring related messages

Message	Status	SpO_2/PR Display
CANNOT DETECT PULSE	Pulse wave cannot be detected from signals. This message appears in conditions such as no physiological pulse wave, probe is too tight or too loose, or too much noise due to body movement.	---
CHECK PROBE or CHECK PROBE SITE	Appropriate signal cannot be obtained. Probe may be detached or not attached properly. This message also appears when measurement cannot be performed for 30 seconds.	---
DETECTING PULSE	Searching for the patient pulse. This message is displayed until pulses are detected after the probe is attached to the patient. If this status continues for 30 seconds, a "CHECK PROBE" message appears.	---
LIGHT INTERFERENCE	Intense light such as surgical light or a phototherapy device is interfering with measurement. Invisible light can also affect the measurement. In most cases, measurement becomes possible by covering the attachment site with a blanket to block any light interference, but care must be taken to ensure proper circulation and probe should continue to be moved at proper intervals.	---
LOW QUALITY SIGNAL	Pulse wave is unstable and signal quality is low. Measurement continues as long as there is an appropriate input signal. But when the quality of the signal is too low to obtain SpO_2 value, the measured value remains unchanged for 30 seconds and is displayed as "---".	SpO_2 value/ ---
WEAK PULSE	Pulse-amplitude Index (PI) is very small. This message appears when peripheral circulation is poor or when the probe is too tight or too loose.	SpO_2 value

7.2. SQI

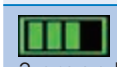
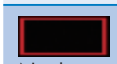
The signal quality index (SQI) bar graph shows the quality of the pulse waveform signal which is used to calculate SpO_2 (Table 6). When the signal quality is low, update of the measured SpO_2 value can become intermittently unavailable.

When the messages frequently occur or the signal quality remains low, SpO_2 monitoring is not being properly performed and critical patient conditions such as low oxygen saturation may not be correctly detected.

Take action to address the possible causes of the displayed messages. Also, appropriate use of the probe is essential for proper SpO_2 monitoring. Make sure to choose the right probe for the measurement site and check that the probe and all cables are properly connected.

The SQI bar graph shows the signal quality of the pulse waveform in 5 levels as shown in Table 6.

Table 6. SQI bar graph

SQI Bar Graph	Quality of Pulse Waveform	Action
 4 green bars	The signal quality is high.	-
 3 green bars	There may be some artifacts.	-
 2 yellow bars	The signal quality is reduced due to large artifact. If this state continues for a long time, check the patient and probe attachment.	If this status continues, check the condition of the patient and probe and reattach the probe if necessary.
 1 red bar	The signal quality is very low. Check the patient and probe attachment.	If the problem persists, SaO_2 measurement using a blood sample is recommended.
 No bars	The signal cannot be measured properly.	Follow the other messages that appear on the screen.

8. CONCLUSION

Since the invention of pulse oximetry by Nihon Kohden researcher Dr. Takuo Aoyagi, the pulse oximeter is one of the most widely used medical devices. Continued industry advances have improved SpO_2 measurement accuracy, but clinicians need to be aware of proper placement and care relative to the patient status. Nihon Kohden is committed to continued development and improvement of SpO_2 technology to meet the needs of healthcare professionals and contribute to the advancement of medical technology.

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