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The accuracy of SpO_2 with dark skin

- Marketing Center -
Beijing Choice Electronic Tech. Co., Ltd.

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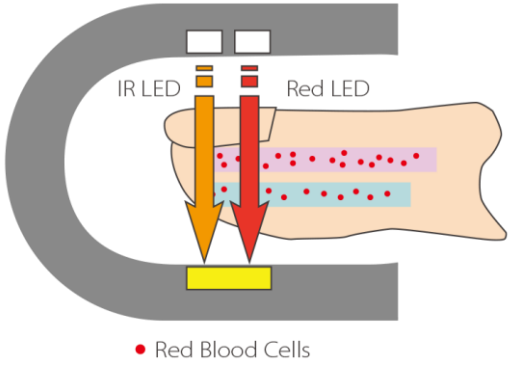
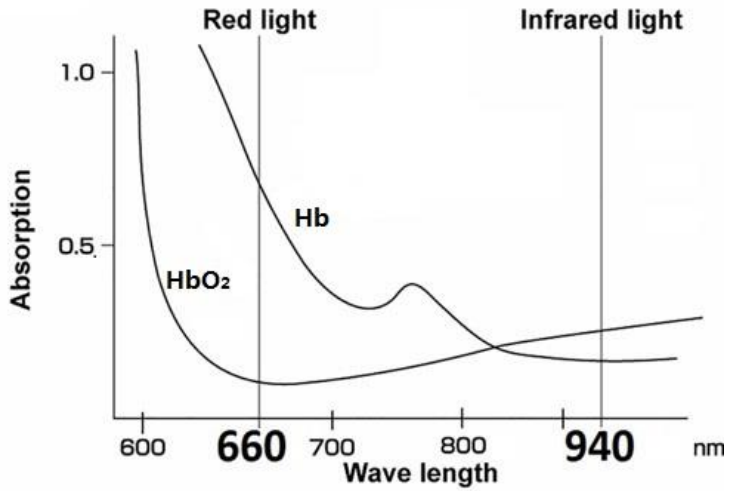
The working principle of oximeter

SpO_2 (blood oxygen saturation) measurement is determined by fixing the fingertip pulse oximeter on the patient nail bed, using two different wavelengths of light (usually a wavelength of **660 nm red**, **905/940 nm infrared**) as a light source. **Hemoglobin concentration and oxygen saturation were calculated by measuring the light conduction intensity of tissue bed.**



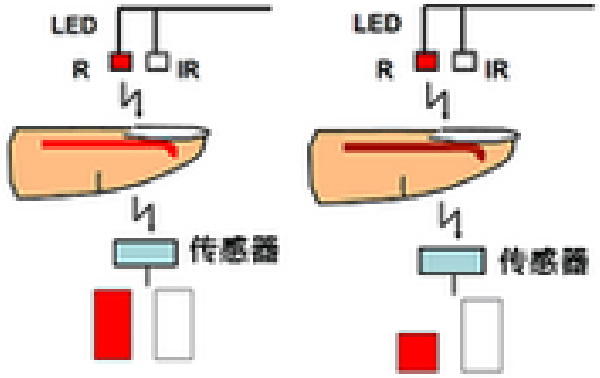
SpO_2 = HbO2/(HbO2+Hb)*100%

The graph on the right is called the absorbance curve, which shows what kind of light can be absorbed in a large amount of hemoglobin (HbO2) that binds to oxygen and hemoglobin (Hb) that releases oxygen. The color is represented by the wavelength on the horizontal axis. The two curves in the figure indicate which wavelengths HbO2 and Hb can absorb in large quantities, and which wavelengths are difficult to absorb. It means that the farther below the line, the less likely it is to absorb its wavelength (good passability).

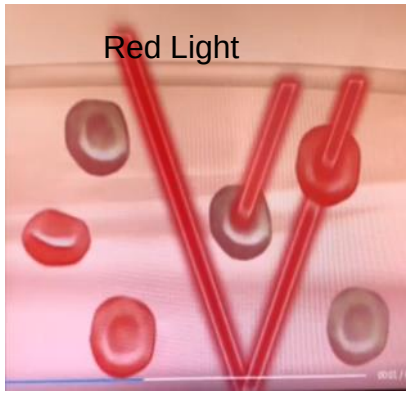


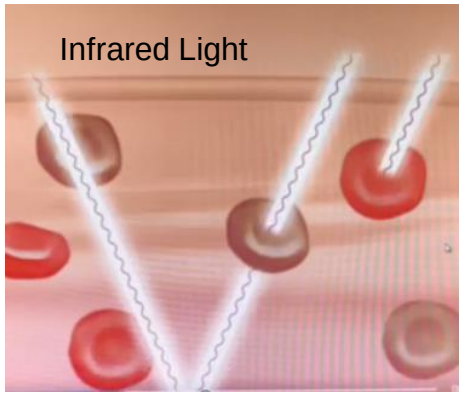
The working principle of oximeter

The hemoglobin bound to oxygen is red, because the red color is not absorbed and passes through. That is, the absorbance of red is low. On the other hand, the hemoglobin after the release of oxygen becomes dark. This is due to the large amount of light absorption. After the red (R) is irradiated to the blood, if hemoglobin is more combined with oxygen, a corresponding large amount of light passes through the finger, so the amount of light received by the sensor increases. Regardless of whether hemoglobin is combined with oxygen or not, infrared light (IR) will pass through the blood without much change. If HbO_2 increases and Hb decreases, the red light (R) received by the sensor will increase, while the infrared light (IR) will not change much. On the contrary, the red light is reduced, and the infrared light still does not change much. and the infrared light still does not change much. In other words, if you know the ratio of R/IR received by the sensor, you can clarify the ratio of HbO_2 to Hb, that is, oxygen saturation.



Hemoglobin reflectivity under different light sources





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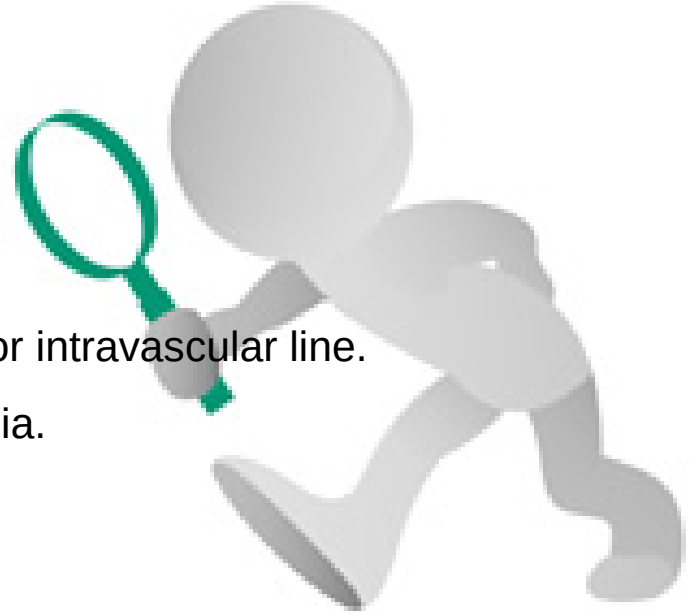
Factors affecting the performance of oximeter

Inaccurate measurements may be caused by:

- Significant levels of dysfunctional hemoglobin (such as carbonyl - hemoglobin or methemoglobin).
- Intravascular dyes such as indocyanine green or methylene blue.
- High ambient light. Shield the sensor area if necessary.
- Excessive patient movement.
- High-frequency electrosurgical interference and defibrillators.
- Venous pulsations.
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
- The patient is in cardiac arrest or is in shock.
- Fingernail polish or false fingernails.
- Weak pulse quality (low perfusion).
- Low hemoglobin.



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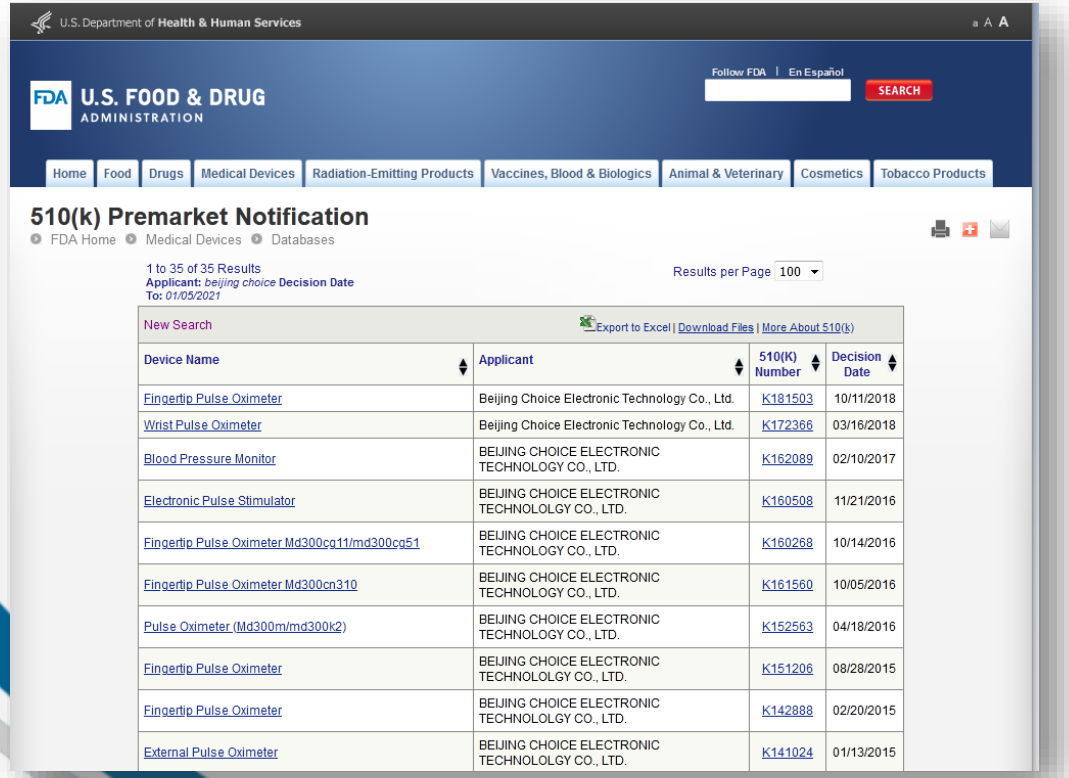
ChoiceMMed oximeter meets the requirements of FDA-510(K) clinical test

According to FDA's guidance information,

we need to submit the clinical test report for the oximeter which needs a 510K number.



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510(k) Premarket Notification

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1 to 35 of 35 Results
Applicant: *beijing choice* **Decision Date To:** *01/05/2021*

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Device Name	Applicant	510(K) Number	Decision Date
Fingertip Pulse Oximeter	Beijing Choice Electronic Technology Co., Ltd.	K181503	10/11/2018
Wrist Pulse Oximeter	Beijing Choice Electronic Technology Co., Ltd.	K172366	03/16/2018
Blood Pressure Monitor	BEIJING CHOICE ELECTRONIC TECHNOLOGY CO., LTD.	K162089	02/10/2017
Electronic Pulse Stimulator	BEIJING CHOICE ELECTRONIC TECHNOLOLGY CO., LTD.	K160508	11/21/2016
Fingertip Pulse Oximeter Md300cg11/md300cg51	BEIJING CHOICE ELECTRONIC TECHNOLOGY CO., LTD.	K160268	10/14/2016
Fingertip Pulse Oximeter Md300cn310	BEIJING CHOICE ELECTRONIC TECHNOLOGY CO., LTD.	K161560	10/05/2016
Pulse Oximeter (Md300m/md300k2)	BEIJING CHOICE ELECTRONIC TECHNOLOGY CO., LTD.	K152563	04/18/2016
Fingertip Pulse Oximeter	BEIJING CHOICE ELECTRONIC TECHNOLOLGY CO., LTD.	K151206	08/28/2015
Fingertip Pulse Oximeter	BEIJING CHOICE ELECTRONIC TECHNOLOLGY CO., LTD.	K142888	02/20/2015
External Pulse Oximeter	BEIJING CHOICE ELECTRONIC TECHNOLOLGY CO., LTD.	K141024	01/13/2015

4.1.1 *In vivo* testing for SpO_2 accuracy under laboratory conditions

We recommend you follow Clause 201.12.1.101.2 and Annex EE.2 of ISO 80601-2-61:2011 *Procedure for invasive laboratory testing on healthy volunteers*, or equivalent method to validate the SpO_2 accuracy specifications of your pulse oximeter system by comparing each value from your system and a simultaneous value from co-oximetry of an arterial blood sample. We recommend you submit a detailed clinical report for this testing. Your report should describe the device configuration tested and include the following:

- test apparatus used, including means for arterial catheterization and blood sampling, means for recording SpO_2 values, and means for delivering medical grade oxygen-nitrogen mixtures of varying fractional inspired oxygen (FiO_2) levels;
- inclusion and exclusion criteria;
- number of subjects;
- number of samples taken per subject;
- specific conditions of testing, including laboratory conditions, subject motion, low pulse amplitude;
- type and frequency of motion for testing under motion conditions, if applicable;
- criteria and methods for determining stability of reference arterial blood oxygen saturation (SaO_2) at the pulse oximeter sensor site;
- desaturation profile, including target saturation plateaus and ranges; and
- formula used for determination of root mean square difference (A_{rms}). (See Clause 201.12.1.101.2.2 of ISO 80601-2-61:2011 for recommended formula.)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?start_search=1&Center=&Panel=&ProductCode=&KNumber=&Applicant=beijing%20choice&DeviceName=&Type=&ThirdPartyReviewed=&ClinicalTrials=&Decision=&DecisionDateFrom=&DecisionDateTo=01%2F05%2F2021&IVDProducts=&Redact510K=&CombinationProducts=&ZNumber=&PAGENUM=100

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pulse-oximeters-premarket-notification-submissions-510ks-guidance-industry-and-food-and-drug

ChoiceMMed oximeter meets many other certifications & standards

Safety: IEC 60601-1

Specific standard of Pulse Oximeter: ISO 80601-2-61

Software: IEC 62304

Risk management: ISO 14971

EMC: IEC 60601-1-2

Biocompatibility: ISO10993-1， ISO10993-5, ISO10993-10

Usability: IEC 60601-1-6

Data transfer: RED、FCC

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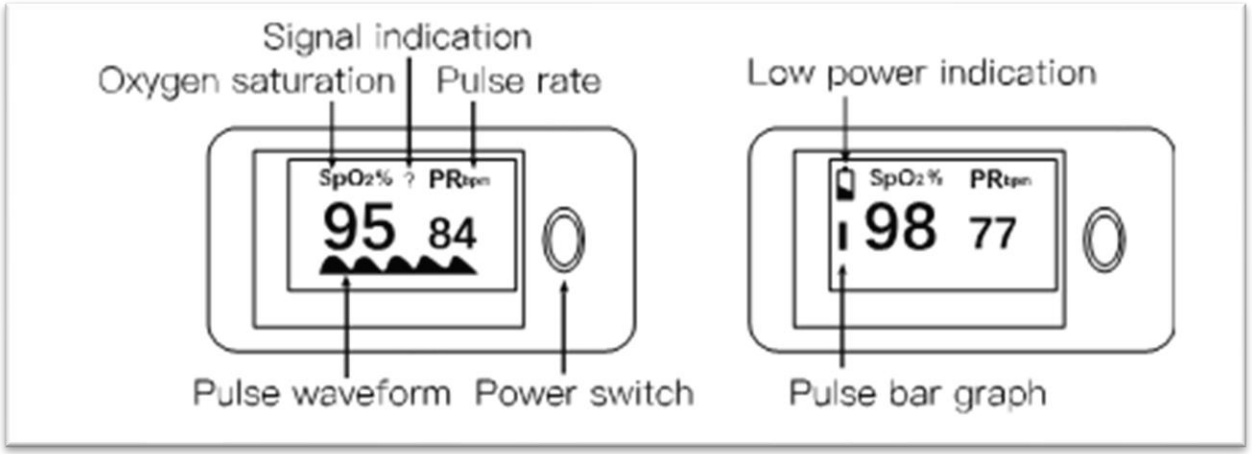
The unique functional design of ChoiceMMed oximeter ensures accurate readings



UNSTABLE OR WEAK SIGNAL PROMPT FUNCTION

When the signal is unstable or weak, the screen will flash ? , to inform the user that the measured value at this time may be inaccurate and needs to be measured again. When the signal is worse and the SpO_2 value cannot be calculated, there will be no figures displayed.

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The clinical accuracy test of SpO_2 of ChoiceMMed oximeter with dark skin

Arms (Accuracy Root Mean Square) is a statistical computation comparing two different data points. FDA outline the typical Arms between measured values (SpO2) and reference values (SaO2) under normal conditions ranging **from 70% to 100% SpO_2 is ≤ 3%.**

According to ISO 80601-2-61:2011 Annex EE (informative) Guideline for evaluating and documenting SpO2 ACCURACY in human subjects: Each system was evaluated during steady state / non-motion conditions with various levels of induced hypoxia (let the subjects inhale mix gas) resulting in stable oxygen saturation levels between 100% and 70% SaO2. Arterial blood samples were drawn during simultaneous data collection from the test oximeters. The blood sample was immediately analyzed on Reference CO-Oximetry providing the functional SaO2 for the basis of the oximeter SpO2 accuracy comparison.

We calculated the data for the subjects with dark skin.

We can see that the accuracy (Arms) is in the reasonable range.

Result:
The Arms of ChoiceMMed's oximeter with dark skin in the SpO_2 range from 70% to 100% is ≤ 3%, ChoiceMMed oximeter fully meets the requirements of FDA regulations and can be accurately measured for people with dark skin

Black subjects	Valid data set
90	1949

	60-70	70.1-80	80.1-90	90.1-94	94.1-100
Average difference	0.38	-0.15	0.11	0.59	0.21
Arms	2.07	2.57	2.6	2.54	2.03
Standard Deviation	2.11	2.57	2.6	2.55	2.03

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THANK YOU
FOR YOUR ATTENTION

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