**Methodology to be used to verify effectiveness of the pulse oximeter**

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| --- | --- | --- | --- |
| Nature of verification method | Verification method | Description | Validation method |
| Design functional requirement | Testing of measurement sensitivity of input to the signal processing unit | This method consists in measuring the electrical current/voltage that results from the direct output from the photodiode. | Demonstration and analysis |
| Testing of measurement sensitivity of output to the signal processing unit | This method consists in measuring the electrical current/voltage that results from the direct output from the signal processing unit. | Demonstration and analysis |
|  | Testing of electrical input to the CPU subsystem | This method consists in measuring the electrical current/voltage that results from the direct input value to the CPU as received from the signal processing unit | Test and demonstration |
| Testing of the device accuracy by comparison to the reference calibration | This method consists in observing the output value from the CPU on the LCD screen interface with the output observed from the reference device. | Inspection |
| Design operational requirement | Testing of the measurement of the device in comparison with a more accurate pulse oximeter | This method consists in using another oximeter with better calibration to check for accuracy of the readings | Inspection |
| Comparing measurement from different parts of the body | This method consists in measuring the SpO2 level on different fingers of the same person with little time frame of interval between each measurement. | Inspection and analysis |
| Repeating measurement on the same part of the body | This method consists in measuring the SpO2 level on the same finger of the same person with little time frame of interval between each measurement. | Inspection and analysis |
| Perform tests on healthy female/male adult and compare with measurement from healthy female/male child (10- to 14-year-old) | This method consists in measuring the SpO2 level on the same finger of the same amount of female and male person with little time frame of interval between each measurement. | Inspection and analysis |
| Testing for accuracy in case the user has polished nails | This method consists in measuring the SpO2 level on the same finger of the same person with different colours of nail polishing with little time frame of interval between each measurement. | Inspection and analysis |

**References**

[1] AIP Conference Proceedings 1883, 020024, “Development of theoretical oxygen saturation calibration curve based on optical density ratio and optical simulation approach”, [Online], September 2017. Available: <https://doi.org/10.1063/1.5002042>

[2] “8888 Oxygen Oximeter Pulse Oximeter”, [Online]. Available: <https://za.rs-online.com/web/p/gas-detectors/2020776/?cm_mmc=ZA-PLA-DS3A-_-google-_-PLA_ZA_EN_Test_%26_Measurement_Whoop-_-(ZA:Whoop!)+Gas+Detectors+(2)-_-2020776&matchtype=&aud-827186183926:pla-302917891561&gclid=CjwKCAjw-ZCKBhBkEiwAM4qfF4JplGJPDW_gU0KmLNs2mEePgdSlXZpKMPlgGPwrYK8kxygZ2G4-6xoCar8QAvD_BwE&gclsrc=aw.ds>

Note:

Oximeter emit;

Red light with wavelength of about 650 nm

Infrared light with wavelength of about 950 nm

Find pulse oximeter calibration table

AC: pulsatile measurement

DC: non-pulsatile measurement

PI: Perfusion index

PI = AC/DC x 100%