OB1203

REGULATORY CERTIFICATIONS

FEB. 2021
RUDI HECHFELLNER
DIR. SENSING
IIBU
RENESAS ELECTRONICS CORPORATION

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EXECUTIVE SUMMARY
## OB1203 REGULATORY CERTIFICATIONS

An independent test laboratory has concluded that **OB1203** can **meet and exceed requirements for** regulatory authorities such as:

FDA, CE, ISO, CCC, ICMR

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TEST CERTIFICATE

- Physio Monitor (an independent certification lab) has certified that OB1203 is capable of measuring accurately even on the most difficult human subjects
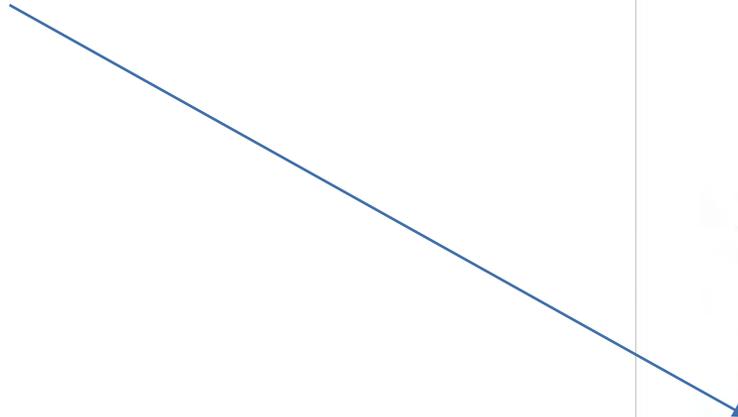
Performance test report - Renesas OB1203

PHYSIO MONITOR

Performance Test of Renesas OB1203

Using OB1203SD-RL-EVK

Digitally signed by Mike Bernstein
Date: 2021.02.18 13:27:31 -08'00'

Mike Bernstein, CTO Physio Monitor

Objective

The objective of this test is to qualify the OB1203 for use in pulse oximeters across the range of human characteristics including skin color and tissue blood perfusion.

Abstract

A method was developed to test performance on dark skin and low perfusion using a simulator. The OB1203 Biosensor was tested. We conclude that the OB1203-RL-EVK hardware and demo algorithm are capable of measuring accurate saturations on the most difficult subjects normally encountered in clinical testing, those with dark skin and low perfusion. The perfusion level we were able to achieve was 0.3% which would be sufficient for accurate monitoring for dark skinned and very purely perfused human subjects.

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TEST RESULTS

- Typical dark skin perfusion is 0.5%

- OB1203 exceeds requirements

- OB1203 can even meet requirements on humans with skin twice as dark as typical worst case

Table 1: Test results equivalent to dark skin test subjects

Perfusion	Sat error	Observations	Comments
2%	+1%	Stable	
1%	+1%	Stable	
0.5%	+1%	Stable	
0.4%	+1%	Stable	
0.3%	+2%	Stable	Min. usable perfusion exceeding threshold of 0.5%
0.2%	+4	Wander +/- 1%	Not recommended

The test was repeated by simulating a subject with skin twice as dark and setting the AECG100 tester IR to 220mV and red 625mV.

Table 2: Test results equivalent to "twice as dark" as typical worst case

Perfusion	Sat error	Observations	Comments
2%	+1%	Stable	
1%	+1%	Stable	
0.5%	+2%	Stable	Even for subject with much darker skin than the typical worst case the reading is correct
0.4%	+4%	Wander +/- 1%	Not recommended

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TEST REPORT

Please request the complete test report by contacting:

Rudi Hechfellner

Technical Director Sensing

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