Motion performance - Pulse oximeter comparison study

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Introduction

Pulse oximetry is next to electrocardiography (ECG) and blood pressure one of the most relevant diagnostic method in the clinical environment. It gives very fast a good overview on the patient's pulmonary constitution with the parameters oxygen concentration (SpO2), heart rate and perfusion.

The technique [1] of the pulse oximeter is about 30 years old. Hemoglobin consists of functional derivatives namely oxyhemoglobin (HbO2) and deoxyhemoglobin (HHb). Besides these, there are dysfunctional hemoglobin derivatives which are not used for the oxygen transport, namely methemoglobin (MetHb) and carboxyhemoglobin (COHb). While here the focus lies on the functional derivatives, there is a trend to include the dysfunctional derivatives into the pulse oximeter readings [2].

Although the pulse oximetry, as a standard diagnostic procedure, is still facing difficulties during difficult conditions as they occur during motion or low perfusion. In such a case the output can be corrupted and give false readings and false alarms. A motion tolerant pulse oximeter is mandatory for different applications as patient transport or neonates movements.

This paper presents the validation of different available well established pulse oximeter products.

Method

In a study from Gerhing et al. [3] a motion table was introduced to test pulse oximeters during desaturation. The drawback of such a study is the enormous effort to repeat these studies because the subjects have to be desaturated and it is not possible the repeat the measurement under same condition to prove the results due to the dependence of the subject properties. For this reason the pulse oximeter motion test was split into two parts. The first one is based on a pulse oximeter simulator Index II by Fluke Biomedical [4] which was also used in a study by Stabile et al. [5]. This simulator offers up to 24 predefined patterns with different conditions of oxygen concentration, heart rate, perfusion and most important motion. The second part is based on a motion table which is able to produce repeatable motion patterns.

To evaluate the performance and to compare the results in an objective way the tests were performed with pulse oximeter simulator Index II and following devices were compared: BCI OEM, Bluepoint MEDICAL SMARTsat, Medlab Pearl 10, Nellcor N-395, Nellcor N-595, Nellcor PM10N, Nonin OEM III and Dolphin 2100.

In the second part a test with a human subject and a motion table was performed. Different motion patterns were programmed and simulated while two different pulse oximeters were attached (Bluepoint MEDICAL SMARTsat and Nellcor N-595).

Validation with the pulse oximetry simulator Index II

The pulse oximetry simulator Index II by Fluke Biomedical is capable to simulate various SpO2 levels, heart rates, and transmission levels. Furthermore 16 motion patterns are offered which are combined with different oxygenation levels and heart rates to simulate eg. shiver during hypoxia. The Index II simulates the first 16 pattern in an endless continues loop. However the last eight patterns are alternating motion phases with normal phases. In figure 1 the principle setup is shown.

Fig. 1: Setup of exemplary pulse oximeters

Every pulse oximeter was tested with every motion pattern. For the first 16 patterns the readings were taken after 60 s and for the last eight patterns at the end of the motion phase. The readings from the devices under test where compared with the simulator settings. The results are split for heart rate and saturation. A test is passed when the deviation to the setting is less or equal to 4 digits SpO2 or heart rate respectively. A fail is defined by a deviation of more than 6 digits.

Validation with the motion table

A two-axis motion table was designed and programmed with various repeating motion patterns. Every motion pattern lasts for 60 s. In between the motion table is not moving for 60 s to return to a steady state. See figure 2 for a typical test run.

On the non-moving hand a pulse oximeter will be placed which acts as reference. A test is passed when the deviation to the setting is less or equal to 4 digits SpO2 or heart rate respectively.

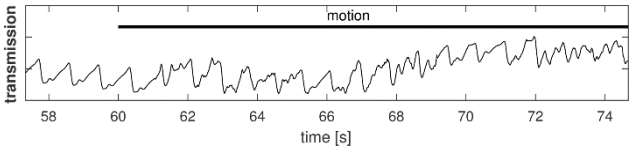

Fig. 2: Typical example of transmission signal during motion

Results

Validation with the Index II

Table 1 states the results of the different pulse oximeter saturation readings. The only pulse oximeter that passes all motion patterns within the accepted deviation was the bluepoint SMARTsat and medlab PEARL 10

Validation with the motion table

Figure 3 shows the results of the tests with the motion table and that the device from bluepoint SMARTsat follows the reference and pass the defined acceptance criteria, while the Nellcor N-595 has a saturation deviation of 7 digits and fails the criteria.

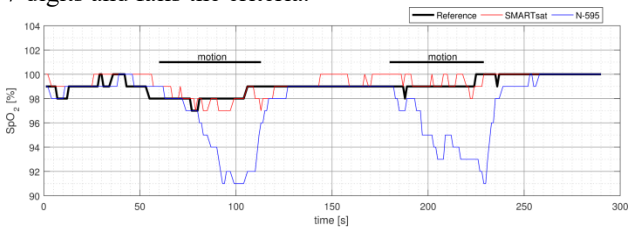

Fig. 3: Two-axis motion table results

Discussion

To test pulse oximeters repetitive and objective is a challenging task which was solved by using the patient simulator Index II. Although it is a technical signal the Index II simulates, it reflects typical motion patterns of real subjects in a proper way. In addition to the simulator the motion table seems to be an ideal method to produce repetitive motion patterns with real subjects.

Outlook

In future the test will be expanded with more pulse oximeters. It is planned to use the motion table during hypoxia to compare the results with technical signal of the Index II and prove the systems under real conditions.

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Tab. 1: Index 2 validation: saturation readings of devices

		Index 2					Saturation															
							bluepoint SMARTsat		Nellcor N-395		Nellcor N-595		Nellcor PM10N		Nonin OEM III		BCI		medlab PEARL 10		Dolphin 2100	
	#	Motion Preset	Perf. [%]	Motion Freq [Hz]	SpO2 Index2 [%]	Pulse Index2 [bpm]	meas. [%]	abs error SpO2 [digit]	meas. [%]	abs error SpO2 [digit]	meas. [%]	abs error SpO2 [digit]	meas. [%]	abs error SpO2 [digit]	meas. [%]	abs error SpO2 [digit]	meas. [%]	abs error SpO2 [digit]	meas. [%]	abs error SpO2 [digit]	meas. [%]	abs error SpO2 [digit]
Level 0 Presets	1	Normal	5.00	-	98	55	97	-1	98	0	98	0	98	0	99	1	97	-1	98	0	97	-1
	2	Weak	0.65	-	90	95	90	0	91	1	90	0	90	0	91	1	89	-1	91	1	88	-2
	3	Bradycardia	5.00	-	88	45	88	0	88	0	88	0	88	0	90	2	87	-1	89	1	87	-1
	4	Hypoxic	2.00	-	70	95	70	0	71	1	71	1	71	1	72	2	68	-2	71	1	68	-2
	5	Neonate	1.00	-	90	180	90	0	90	0	90	0	90	0	91	1	89	-1	91	1	88	-2
	6	Tachycardia	1.20	-	85	130	85	0	86	1	86	1	86	1	87	2	84	-1	86	1	84	-1
	7	Geriatric	2.40	-	92	95	92	0	92	0	92	0	92	0	93	1	91	-1	92	0	90	-2
	8	Obese	3.00	-	93	90	93	0	94	1	93	0	93	0	93	0	92	-1	93	0	91	-2
Level 1 Presets	9	Normal/Tap	5.00	2.5	98	55	98	0	83	-15	80	-18	0	-98	78	-20	76	-22	98	0	97	-1
	10	Normal/Shiver	5.00	6.0	98	55	98	0	80	-18	79	-19	79	-19	0	-98	0	-98	98	0	97	-1
	11	Weak/Tap	0.65	4.3	90	95	90	0	63	-27	0	-90	62	-28	78	-12	57	-33	90	0	88	-2
	12	Weak/Shiver	0.65	6.0	90	95	90	0	62	-28	62	-28	62	-28	0	-90	0	-90	88	-2	88	-2
	13	Brachy/Shiver	5.00	6.0	88	45	87	-1	70	-18	68	-20	70	-18	0	-88	0	-88	89	1	87	-1
	14	Hypoxic/Tap	2.00	4.3	70	95	70	0	55	-15	54	-16	53	-17	0	-70	47	-23	71	1	68	-2
	15	Hypoxic/Shiver	2.00	6.0	70	95	70	0	51	-19	51	-19	52	-18	0	-70	0	-70	71	1	68	-2
	16	Neonate/Shiver	1.00	6.0	90	180	90	0	73	-17	73	-17	73	-17	0	-90	0	-90	88	-2	88	-2
Level 2 Presets	17	BradyTap#2	5.00	3.9	88	45	88	0	93	5	92	4	95	7	95	7	99	11	89	1	98	10
	18	HypoxTap#2	2.00	4.3	70	95	69	-1	71	1	86	16	100	30	80	10	97	27	72	2	73	3
	19	WeakTap#2	0.90	1.0	80	95	81	1	82	2	98	18	100	20	82	2	97	17	82	2	96	16
	20	NormalTap#2	5.00	2.5	93	55	92	-1	96	3	96	3	95	2	0	-93	0	-93	94	1	92	-1
	21	Asystole	2.00	1.1	0	0	0	0	0	0	0	0	0	0	99	99	90	90	0	0	0	0
	22	LowFreq1	1.00	0.5	80	75	79	-1	82	2	80	0	81	1	84	4	90	10	82	2	94	14
	23	LowFreq2	1.00	0.5	70	75	70	0	72	2	67	-3	74	4	71	1	0	-70	72	2	98	28
	24	SlowTap	1.00	2.0	80	75	80	0	78	-2	96	16	83	3	83	3	99	19	82	2	98	18
							|abs. error| >		|abs. error| >	4		|abs. error| <=	4						