Pulse Oximeter testing for the Acute Medical Unit's Virtual Ward at the Royal Berkshire NHS Foundation Trust

Rapid Communication

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Tests on Pulse Oximeters
by Marcus Durand PhD and Ali Mohamed

In response to a concern raised within the South East Clinical Engineering Network by a colleague at another Trust, we decided to have a closer look at the "finger clip" mini pulse oximeters that were supplied by NHSEI to the Royal Berkshire Hospital. We were sent photographic evidence of one particular model that showed a significantly higher SPO_2 compared to a hospital grade device.

We obtained a sample of three of each of the four models of devices available to the Royal Berkshire Hospital's AMU Virtual Ward team and tested them using four different experiments:

1. Three of each model on a Fluke SPOT Light SpO_2 simulator set to the Welch Allyn Nelcor algorithm.
2. Three of each model on a Fluke SPOT Light SpO_2 simulator set to the Nihon Kohden algorithm.
3. Three of each model on a Fluke SPOT Light SpO_2 simulator set to the Philips algorithm.
4. One of each model on a healthy human subject re-breathing into a sealed bag until their SpO_2 measured on a pulse oximeter within a standard hospital ward vital signs machine fell below 90%.

The Guangdong Biolight Meditech Model M70, has a stated accuracy of +/- 2% between SpO_2 readings of 70% -100%

- In experiment 1, this device was within the stated accuracy.
- In experiment 2, this device was within the stated accuracy at SpO2 readings of 98%, 95% and 90%, but at SpO2 readings of 85% it was reading 82% across all three samples (3% difference).
- In experiment 3, it was within the stated accuracy.
- In experiment 4, this device showed a difference beyond its stated accuracy. At an SpO_2 of 94% measured by the standard device, this device showed an SpO_2 of 97% (3% difference). At an SpO_2 of 89% measured by the standard device, this device showed an SpO_2 of 98% (9% difference).

The OxyWatch ChoiceMMed Model MD300C11, has a stated accuracy of +/- 2% between SpO2 70% - 100%

- This device was within the stated accuracy across all experiments.

The Medlinket Model AM801, has a stated accuracy of +/- 2% between SpO2 70% - 100%

- In experiment 2, this device was within the stated accuracy at 98%, 95% and 90%, but at 85% was reading 82% across all three samples (3% difference).
- In the rest of the experiments, this device was within the stated accuracy.

The Shenzhen Creative Industry Model PC60B1, with a stated accuracy of 2%

- In experiment 4, this device was within the stated accuracy at readings over 90%, but at 89% the device displayed 92% (3% difference).
- In the rest of the experiments, this device was within the stated accuracy.

It should be noted the biggest limitation of experiment 4 is that the SpO_2 level was relatively fleeting compared to that of an unwell patient, which gives the devices less time to settle into an accurate reading.

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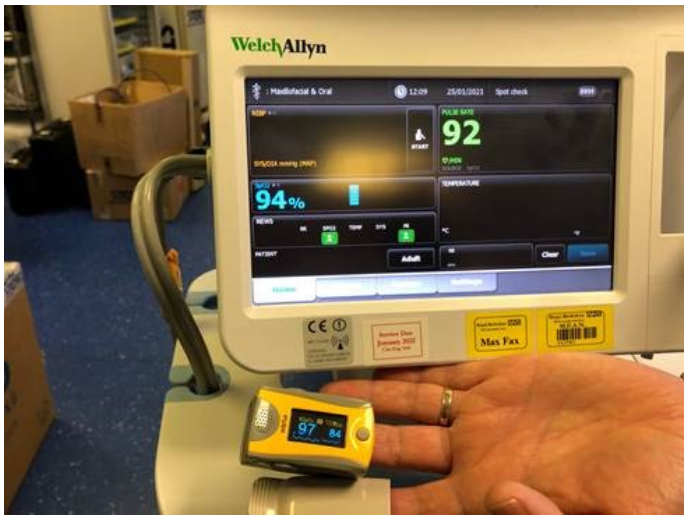
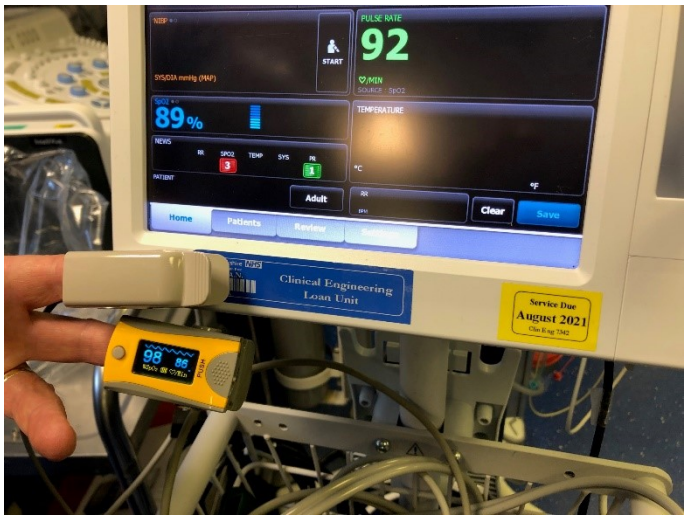
The photographs below document the results from experiment 4 that fall outside the stated accuracy of the Guangdong Biolight Meditech Model M70 and the Shenzhen Creative Industry Model PC60B1.

Fingertip Pulse Oximeter: Guangdong Biolight Meditech
Model M70,
Stated accuracy : +/- 2% between SpO_2 70% - 100%





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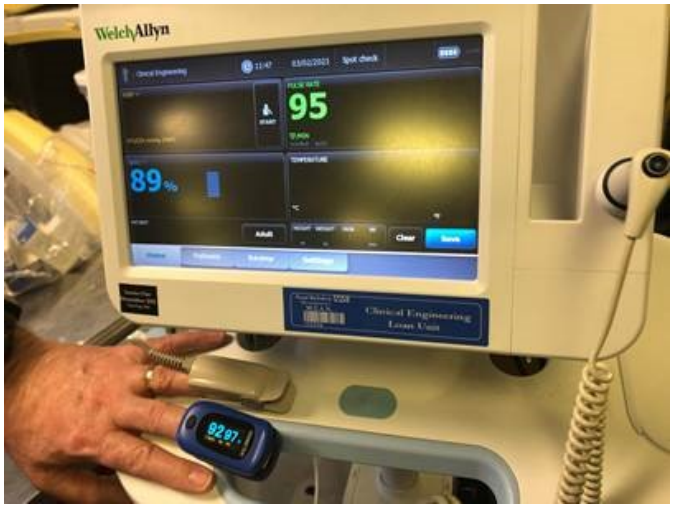
Shenzhen Creative Industry
Model PC60B1
Stated Accuracy: ≤ 2%



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Clinical Relevance of these findings
by Dr Joseph Nunan and Dr Andy Walden

In April 2020 we (the above authors) developed a triage pathway for COVID-19 called TICC-19 (which stands for Triage into the Community for COVID-19)[1]. An important part of this triage pathway is that it allows patients to be sent home with a pulse oximeter and then managed remotely. Thus was created one of the UK's first 'COVID virtual wards'[2].

Patients in the virtual ward are in their own homes and called daily. The patients report on 1) their symptomatology and 2) their oxygen saturations and heart rate whilst resting and then after walking 30 metres.

Whilst some patients have lower oxygen saturations normally, for most patients, if the oxygen saturations >= 95% at rest with a <=5% drop after walking 30 metres, the patient can have their COVID managed at home rather than in hospital[3]. Between SpO2 of 93-94% it is up to the senior clinician to make a judgement about whether or not to bring the patient in. At oxygen saturations of 92% or below, the patient is brought into hospital.

In the above experiments, two of the pulse oximeters showed inaccuracies which concern us. The Guangdong Biolight Meditech Model M70 shows oxygen saturations of 98% when the oxygen saturations are actually 89%. A patient with oxygen saturations of 98% would generally be advised to remain at home, and would be contacted later to ensure the levels have improved. However a patient with oxygen saturations of 89% would have a category 2 ambulance sent out (arriving in about 18 minutes to bring the patient into hospital for oxygen therapy). Thus patients using the Guangdong Biolight Meditech Model M70 would be falsely reassured by their oxygen saturations and could come to harm. This is especially the case in patients with COVID-19 as some patients can develop 'silent hypoxia' – ie low oxygen saturations without the sensation of shortness of breath – whilst others exhibit shortness of breath but have normal oxygen saturations.

The Shenzhen Creative Industry Model PC60B1 also concerns us. Patients with COPD and chronic hypoxia have lower oxygen saturations at baseline (88-92%). Within the TICC-19 pathway, these patients can be safely discharged if their oxygen saturations are over 90%[4]. However if they are 90% or below, the patient needs to be recalled to hospital for oxygen therapy. Thus this device reading oxygen saturations of 92% when they are actually 89% would cause the patient to be kept at home instead of coming by category 2 ambulance into hospital.

Conclusion:
The AMU Virtual Ward aims to offer patients the expertise of the hospital in the comfort and safety of their own homes. Our model of virtual ward has helped to form much of the basis for the excellent work NICE has done to roll out COVID virtual wards nationally[5]. Safety must be paramount to the managing of patients at home and thus collaboration with local clinical engineering and medical physics departments is imperative to ensure the safety of medical devices. Although there are many obvious limitations to the above experiments carried out by the clinical engineering team at the Royal Berkshire Hospital, pending further experiments we have decided not to use the following two makes of pulse oximeter: Fingertip Pulse Oximeter: Guangdong Biolight Meditech and Shenzhen Creative Industry Model PC60B1.

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Footnotes:

1) Please visit www.ticc19.com for more details
2) Please visit https://www.bmj.com/content/369/bmj.m2119
3) For the TICC-19 triage pathway please visit: https://ticc19.com/wp-content/uploads/2020/11/Triage-document-website.pdf. For modified pathways for patients with other conditions (frailty, pregnancy, renal failure) please visit: https://ticc19.com/resources/
4) Please visit: https://ticc19.com/wp-content/uploads/2020/11/Triage-document-website.pdf.
5) https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2021/01/C1041-letter-supporting-hospital-discharge-covid-virtual-wards-13-jan-21.pdf and the paper of the first 300 patients to be managed in the virtual ward can be read here: https://acutemedjournal.co.uk/wp-content/uploads/2020/11/p183-191-1.pdf