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A Cost-Effective Pulse Oximeter Designed in Response to the COVID-19 Pandemic

HARDWARE METAPAPER

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ABSTRACT

This paper introduces the design of a small and cost-effective optical pulse oximeter, including a finger clip, sensor readout electronics, and associated firmware. The device is based on widely-available commercial optical sensors that are designed for the wearables market and measure the reflection of different wavelengths of light. This design was produced in response to a request from the Royal United Hospital in Bath UK, in light of the severe shortage of clinical pulse oximeters during the 2020 COVID-19 pandemic. Products based on this design have not been submitted for medical device approval; the design documents here should be considered purely for research, educational and development purposes.

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KEYWORDS:
pulse oximetry; optical measurement; medical devices

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METADATA OVERVIEW

- Main design files: *https://gitlab.com/openoximeter/*, in particular the Electronics, MAX3010x Breakout Board, Firmware, and Finger Clip repositories.
- Target group: medical device developers, biomedical engineers
- Skills required: Arduino – intermediate, electronics – intermediate, 3D printing – easy;
- Replication: This was developed by a team working remotely and has been replicated by different members of the team, and has also been replicated by reviewers of the manuscript and colleagues at other institutions.
- See section "Build Details" for more detail.

HARDWARE OVERVIEW

INTRODUCTION

The worldwide COVID-19 pandemic produced an unprecedented strain on the resources of many healthcare systems. Within England that strain was felt most acutely within the Accident and Emergency (A&E) wards that continue to deal with rapid triage and admissions of many patients. A key component of triage has been the monitoring of a patient's Saturated Percentage of Oxygen (SpO_2), particularly with reference to respiratory conditions. The SpO_2 metric has been heavily used in both the triage and the prognostication of patients with suspected COVID-19. As the numbers of cases increased dramatically around the world the pressure on healthcare providers at both the national and international level became almost unmanageable. The need for point of care monitoring of SpO_2 for large numbers of patients led directly to both a supply shortage and a cost increase of commercial sensors.

A request was therefore made by the Royal United Hospital (RUH) in Bath, England, to the Faculty of Engineering and Design at the University of Bath to design and manufacture *indicative* SpO_2 sensors that might be used to triage patients upon arrival at the hospital. Thus, this paper describes the design and implementation of such a device, which can be produced using a 3D-printer without the need for specialist electronics assembly tools and at a reasonable cost.

The NHS has recently produced guidance about the usage of pulse oximetry to detect early deterioration of patients with COVID-19 [1]. This includes the usage of pulse oximeters at home, potentially requiring larger numbers of devices to be available.

IMPLEMENTATION AND DESIGN

Pulse Oximetry

The pulse oximeter is a device for non-invasive, continuous measurement of oxygen saturation within arterial blood. A pulse oximeter uses two separate technologies in order to achieve this: photoplethymography where reproduction of the pulsatile component takes place, and spectroscopy where absorption of light of specific wavelengths by tissues takes place. Pulse oximeters use light-emitting diodes (LEDs) to emit two different wavelengths of light, usually 660nm (red) and 940nm (infrared) in order to compare the absorption specta of oxyhaemoglobin (HbO_2) and deoxyhaemoglobin (H Hb). ***Figure 1*** shows the absorbtion spectra, in the range red to infrared, of both H Hb and HbO_2 [2, 3]. It can be seen that at 600nm deoxygenated haemoglobin (H Hb) absorbs more light than oxygenated haemoglobin (HbO_2), while at 940nm the inverse is true. Pulse oximeters may operate in either a *transmission* or *reflection* mode, whereby the absorption characteristics are measured by either the amount of light transmitted through the tissue or the amount of light reflected back by the tissue.

The oximeter alternately switches between emitting and measuring light at the two different wavelengths at a rate of about 400 Hz. Absorption of red and infrared light in the tissue of the finger is not confined to arterial blood but will also occur within the nail, muscle, fat, and venous blood. However, the absorption from these "off target" tissues is relatively constant (DC), whereas absorption within the arterial blood is pulsatile (AC) in response to changes in blood pressure during the cardiac cycle. Thus, the role of the oximeter processing system is to eliminate the DC component and to measure the ratio of light absorption between the pulsatile (AC) red and infrared components. The inset in ***Figure 2*** illustrates graphically the AC and DC signals.

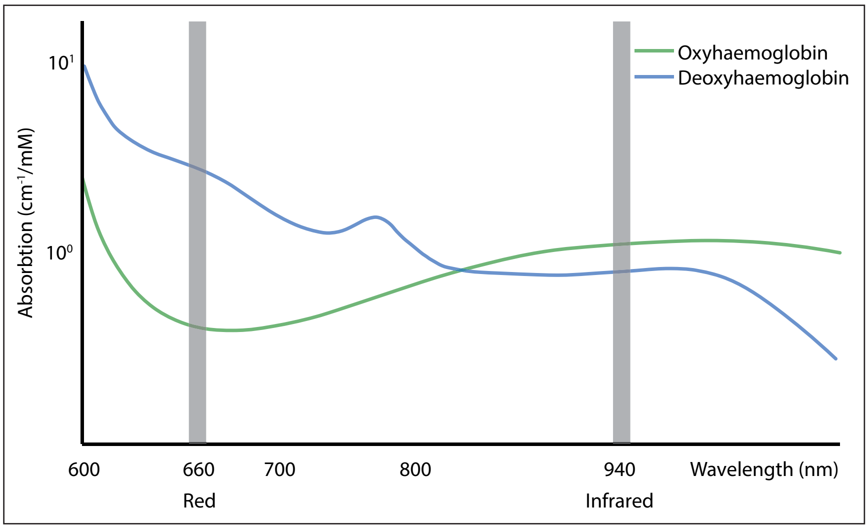

Figure 1 The absorption spectra for oxyhaemoglobin and deoxyhaemoglobin over thee range 600 nm to 1000 nm. Note that the y axis is logarithmic.

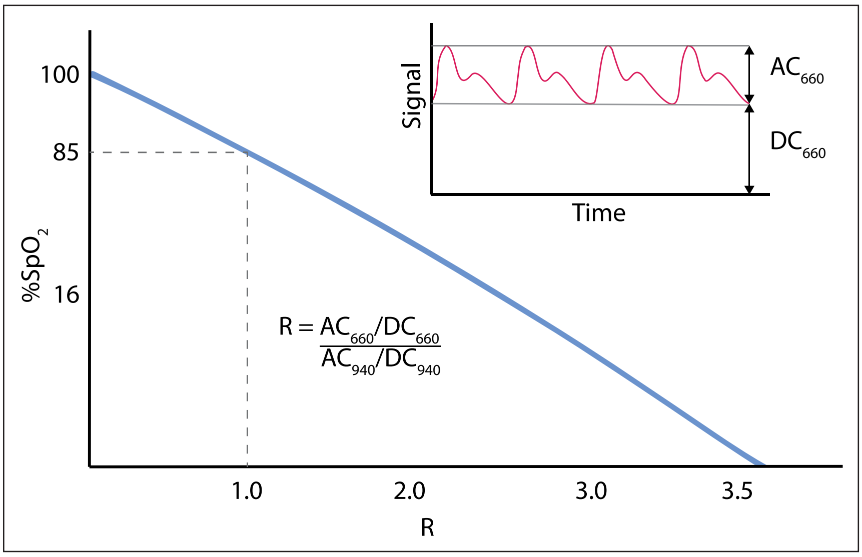

Figure 2 Typical calibration curve relating the R ratio the SpO_2, note that for R = 1 SpO_2 = 85%. Inset: example received signal for a 660 nm wavelength demonstrating the pulsatile AC component and the DC component caused by absorption in other tissues such as the nail and bone.

Mathematically this ratio, *R* is defined as:

$$R = \frac{AC_{660} \,/\, DC_{660}}{AC_{940} \,/\, DC_{940}} \quad (1)$$

An empirical calibration curve (based on data measured using simultaneous blood gas analysis) is then used to convert the *R* ratio to an SpO_2 value. ***Figure 2*** shows a typical calibration curve, note that for R = 1 SpO_2 = 85% [2, 3]. The final reading is usually a time average of commonly 10 to 20 seconds. Simultaneously, a peak detection algorithm can measure the time between each successive peak in either of the AC components in order to measure the heart rate. Errors in the reading are common, and can stem from movement artefacts, ambient light, occlusion of the pulsatile component by clamping force, nail polish, and any number of physiological conditions such as hypertension or vasoconstriction. Despite the numerous sources of error, pulse oximetry remains an invaluable, and generally reliable, measure of saturated oxygen content.

System Architecture

The system is designed to measure both heart rate and saturated oxygen content using dual-wavelength photoplethysmography. The optical sensors are from the MAXIM range of integrated circuits (MAX30100, 30101, or 30102) [4, 5, 6] and include all the required drive and sense electronics. Data is transferred from the optical sensor to an Arduino Nano, which computes a time averaged heart rate and SpO_2 for display on an OLED screen based on the SSD 1306 OLED driver.

An architectural plan of the system is shown in ***Figure 3***.

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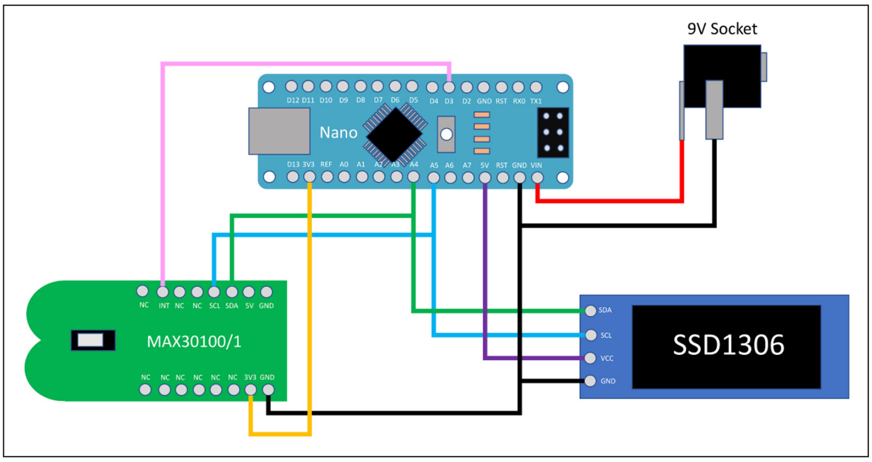

Figure 3 Electronics architecture.

Design Methodology

Given the unique circumstances of the COVID-19 pandemic, and the lockdown restrictions placed on the design team, it is useful to describe the design environment and design process. The team members were all working at separate locations (at home) with varying levels of capability to undertake manufacture and testing of the devices. Some of the team had access to 3D printers, some to solder stations for electronics assembly and some had access to software design tools for printed circuit board design, software development and 3D CAD modelling.

One of the main challenges was to coordinate the efforts of the team members and to enable both independent manufacture and test of the devices. At the time of writing it should be noted that the team members have yet to all meet in person, and therefore it is remarkable that a batch of completed monitors have already been delivered to the RUH.

Initial development was performed using breakout boards and breadboards. The MAX3010x breakout boards were available in limited quantities, and were sufficient to build approximately 20 devices without the need for custom PCBs. Once the team expanded to include 3D printing and device design expertise a fully custom PCB and finger clip were designed.

The team made extensive use of open source or freely available design tools wherever possible. Eagle was used for PCB design, Inventor, FreeCAD and OpenSCAD were used for CAD design, with the final designs being implemented in FreeCAD and OpenSCAD using scripts to enable easy customisation of the design modules.

The decision to use the Arduino platform was based on the concept of simplicity. The Arduino nano has a small footprint, contains on board power management, and hardware I2C interfaces required for communication with display and sensor. While it would have been eminently possible to develop boards using the ATMega328P microprocessor used on the Arduino boards, the cost and time constraints made this an unattractive option for this project.

The team worked using online repositories to share information and manage the design data, first using Microsoft Teams and then migrating to the gitlab online repository system. Microsoft teams was used for conference calls, design discussions and engagement with clinical experts or engineering specialists where required. Three distinct sites were set up with the capability to 3D print devices and assemble electronics to enable validation of the manufacture process and independent assembly and testing.

Finally, trial devices were delivered to a contact in the RUH for testing and results shared back electronically to the team for further analysis and development.

It is also important to stress the urgency that was placed on the project. The RUH were predicting that their intrinsic capacity for monitoring SpO_2 would be overwhelmed within 14–21 days of the project starting.

Electronics

The electronics consisted of three main components, an Arduino Nano microprocessor, a MAX3010x pulse oximeter breakout board, and an SSD1306 based display. The electronic components were connected as shown in *Figure 3*. An external power source was provided by

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a PP3 9V battery chosen due to high power density and low cost. A simple PCB interposer was implemented to connect the three main components and to reduce the assembly time to a few minutes.

Various options for powering the device were considered including integrating a small battery, such as a coin cell, AA, AAA or pp3 9V battery, or using an external power source. One of the disadvantages of a fully integrated battery was that in a clinical setting there would be the need for frequent replacement of the battery. This would therefore require a procedure of repeated disassembly, cleaning, and reassembly prior to redeployment with a patient. The decision was taken therefore to use an external power source. The external power source could be either a battery or DC supply from an external power supply. This also had the potential advantage of being able to be powered perpetually using a small mains powered charger in a hospital setting, or using an off the shelf, readily available battery holder. Both options were designed to plug into the pulse oximeter hardware using a standard 9V plug, making it an easy and rapid battery replacement (with no need for removal of battery cover perhaps requiring specialist tools such as a screwdriver) or switching between a AC mains supplied charger and external battery pack of the patient was required to be moved.

Initially the design was implemented using a commercially available MAX3010x pulse oximeter breakout board, however, unfortunately, a global shortage of MAX3010x breakout boards meant that it was necessary to design an alternative that could be manufactured if required. This board, shown in ***Figure 4***, was designed to utilise the same header and pin layout as the commercial breakout boards. Multiple suppliers were contacted and found to have large stock levels of the base parts. This design, combined with the teams readily available board assembly facilities, was therefore deemed reasonable mitigation in event of commercial board shortage.

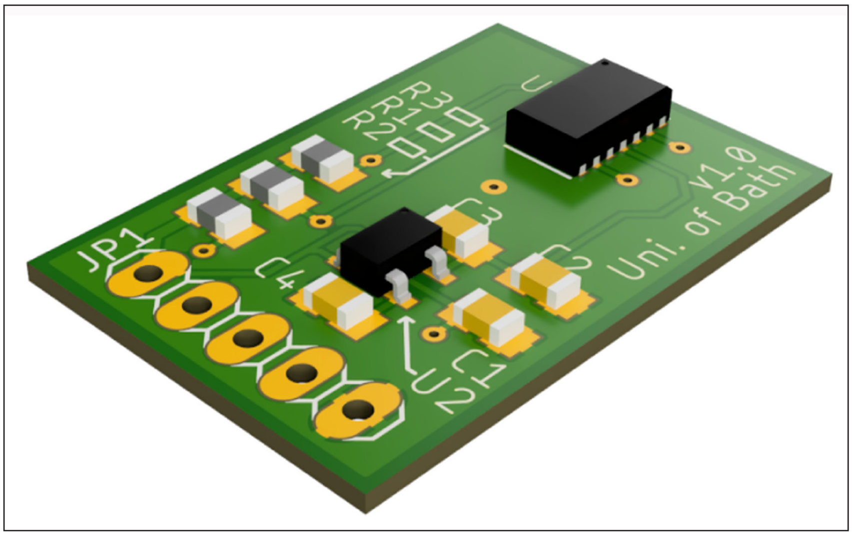

Figure 4 MAX3010x breakout board, developed as a drop-in replacement in case of commercial breakout board supply shortage.

The PCB design of the interposer, the MAX3010x breakout board, and the assembly sequence are given in the electronics repository contained in the following link:

https://gitlab.com/openoximeter/Electronics

Firmware

The firmware runs directly on the Arduino Nano and consists of four main components: Top-level main file, MAX3010x library, SSD1306 library, and a beat detection and processing library.

The flow diagram for the top-level main file is shown in ***Figure 5***. This file handles the overall operation of the pulse oximeter, utilising separate hardware libraries and operation specific classes and functions where appropriate. This modular approach ensured that the design team were able to easily reuse elements of the firmware if any hardware elements changed due to supply issues. This code built upon the work by the tinyPulsePPG project [7] and the Arduino-MAX30100 project [8] combining and enhancing best practices and techniques found in each.

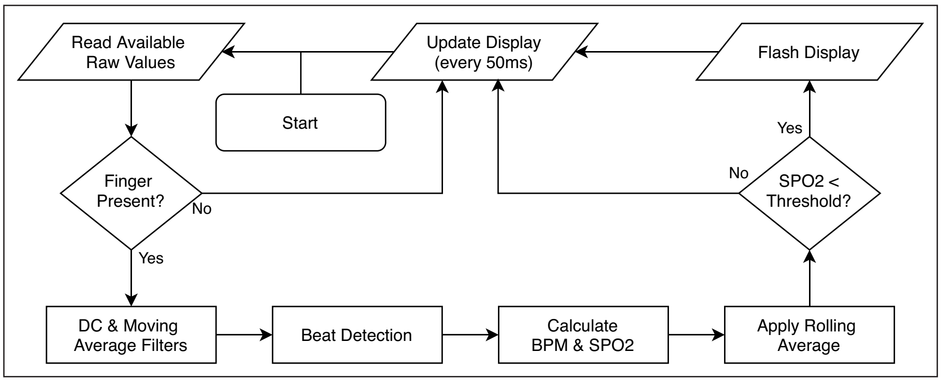

Figure 5 Flow diagram for the top-level Arduino loop. It should be noted that the display update time of 50 ms delay is non-blocking, meaning that the code could continue without freezing on this element.

Most existing oximeter projects utilised hardware specific libraries for their sensors. This was not suitable for this application as supply chains were unreliable, making part sourcing challenging. It was therefore decided that a generic MAX3010x library should be developed, supporting any of the MAX3010x family of oximeter sensors. Development of a system for dynamic detection of the sensors model was not a practical use of time or on-board memory, so a single define statement was utilised at the top of the library header file to ensure that correct memory mapping was achieved with minimal redundant compiled code. Future iterations of this work could explore dynamic chip detection, allowing removal of this define statement and making this generic library fully plug-and-play.

The official Adafruit SSD1306 library [9] was found to be both too large and too slow for this application, causing a violation of the oximeter sensor's relatively high minimum read frequency requirements. As a result the light-weight and reduced SSD1306 library used in the tinyPulsePPG project was adapted to provide the desired functionality. This new library proved significantly faster and smaller than the Adafruit library, resulting in a significantly more stable SpO_2 reading.

An advanced beat detection class was developed, combining the light-weight moving average and DC filters of the tinyPulsePPG project with the reliable and parametrised beat detector state machine logic of the Arduino-MAX30100 project. This hybrid code was found to produce a more accurate and stable measure of both the heart-rate and SPO2 values, while the parametrisation allowed rapid calibration and tuning of the detection logic against commercial devices.

The firmware was designed to boot into an operational mode (shown in ***Figure 6***) without any input from the user, ensuring that it was fast and practical to use in a hospital environment. If the patients SPO2 levels were detected to have dropped below 95%, the firmware flashes the screen at 2 Hz to draw the attention of medical staff. The patient would then be fitted with a commercial and medically approved pulse oximeter to confirm their SPO2 levels. The firmware developed for this project is available from:

https://gitlab.com/openoximeter/arduinocode

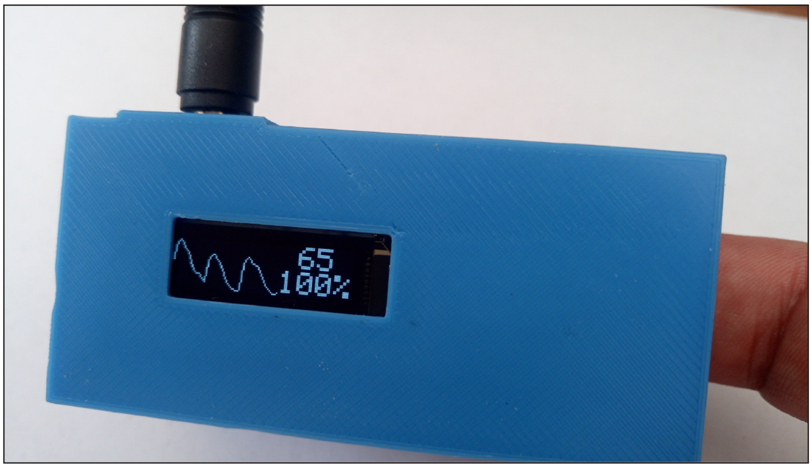

Figure 6 Example of the finger clip display when operational.

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Finger Clip

The finger clip was constructed using conventional 3D printing in such a way that the electronics described in the Electronics section above could be easily integrated. Each of the individual finger clip elements (apart from the metal spring and screws) were designed for rapid printing, with an allowance for the variety of finger sizes across different patients.

The 3D printed parts were designed to be printed using standard PLA or ABS plastic, with standard settings on a commercially available 3D printer. The clip was tested with a number of different printers including an Ultimaker 2+ and the RepRap-based [10] Prusa i3 Mk3S.

The clip was split into three main components to be 3D printed: Top Finger Clip – to apply pressure to the finger, Base Plate – to hold the clip and have a window for the sensor, and a box for the electronics. The printed components use approximately 25 g of PLA filament and take fewer than 4 hours to print. ***Figure 7*** illustrates each component and the overall assembly.

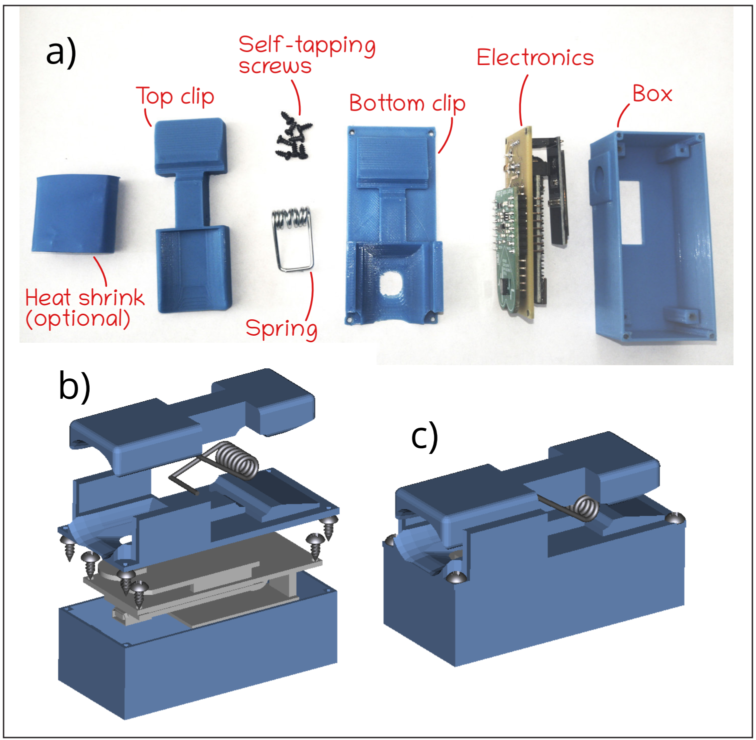

Figure 7 a) Finger clip components prior to Assembly. **b)** An exploded render of the assembly. **c)** A render of the assembled finger clip.

During the design process, various options for the implementation were reviewed including using an external box for all the electronics and power apart from the sensor itself. While this has some advantages, as it decreases the weight on the finger, it adds complexity to the electronic assembly by requiring customised cabling and robust connectors. However, as the finger clip and electronic assembly is sufficiently light (~55 g) this was not deemed necessary.

The finger clip was designed with a curved surface for the finger and the curvature designed to accommodate a number of different finger sizes. The top part of the clip was designed such that a piece of soft 3/4" tubing (such as heat shrink tubing) can be used to provide cushioned support for smaller fingers. The test piece was designed for an adult finger size, however one of the advantages of the modular design is that this single piece of the design could easily be replaced to a different size such as children or small adults.

The base plate was designed with a holder for the spring clip, the base of the plate curves smoothly down to a window for for the sensor. The filleted window has approximately 2.5 mm clearance from the sensor on all sides, and the top of the sensor sits approximately 0.5 mm above the base of the clip. This allows the pad of the finger to protrude slightly through the window maintaining a firm, but comfortably supported, contact with the sensor. An indent on the underside of the base was designed to fit the electronic surface mount components so that the base and oximeter PCB maintain a flush fitting. This indent is not cantilevered and prints well in PLA if the layer height is 0.2 mm or below, though may require support if printed in ABS.

The electronics box was designed with internal pillars to locate the electronics assembly at the correct height for the sensor to fit into the base plate window and for the display to fit correctly in the display window. A side hole was placed to allow the external power source to be plugged in using a barrel type 2.5 mm connector.

One key aspect of the system is ease of cleaning, although for large scale production the compatibility of the printed components with standard hospital cleaning procedures would need to be considered.

Prior Art

There have been several Open Source projects that have developed pulse oximeters based on a similar architecture and with related goals to the work presented in this manuscript. They are all based on the Arduino micro-processor but differ in the optical sensor used and in the overall functionality. The GliaX/mechloud Oximeter [11, 12] uses a simple photodiode circuit with two different light sources to perform the measurement, and an Adafruit SSD1306 display to communicate the resulting measurements in text form. The xcoder123 Oximeter [13, 14] uses a MAX30100 integrated sensor but does not include a visual display (data is communicated via serial). Neither of these projects have seen any updates in the past 4 years.

More recently an Open Source Pulse Oximeter for COVID-19 was reported [15]. This is based on the MAX30102 integrated sensor and uses an OLED screen for displaying data. This design also included a finger-clip and was focussed on the COVID-19 pandemic. When compared to the prior art, the work presented in this manuscript has a number of specific advantages.

- The pulsatile waveform is displayed on the screen in real time, which provides a good visual indicator of the measurement reliability.
- The alarm feature alerts clinicians to a dangerous drop in the SpO_2 level.
- The software libraries developed support the entire range of integrated MAX devices, enabling deployment even with hardware shortages.

Testing and Feedback

Assembled devices were tested by both members of the design team and by clinicians at the RUH. Fundamentally, calibration and validation of pulse oximeters over a wide range of SpO_2 values remains a challenging task. The best reference values are typically obtained via an arterial blood gas analysis, but these are spot samples and simultaneous comparison to measurements taken from a peripheral pulse oximeter is not trivial. Ideally an oximeter would be calibrated across a wide range of SpO_2 values, but this is also problematic. It is possible to use environmental chambers to lower the SpO_2 in a healthy person, but values much below 80% begin to lead to mental impairment and those below 75% to loss of consciousness [2]. Thus it becomes both technically and ethically problematic to obtain reference measurements at lower levels of saturation.

In this project a simple set of comparative tests were performed against a number of commercial pulse oximeters, mainly within the clinical environment. The design described in this paper performed strongly in terms of heart rate estimation but consistently under-estimated the SpO_2 when reference values were below 98%. These correspond to the ranges that are hard to obtain in a healthy person without an environmental chamber. Formal calibration is beyond the scope of this work, but this work has highlighted the need for a phantom or other model that can be used for the development and calibration of pulse oximeters.

General feedback from the clinicians was positive, the devices were tolerated well by patients and proved to be both reliable and easy to clean. The main request for improvement was that the oximeters be remotely linked, so that low SpO_2 alarms could be observed centrally. This could be readily integrated in future designs.

Future work

As presented here, the system represents a working pulse oximeter, capable of displaying and recording SpO_2 and Heart Rate. It is not certified for clinical use, and we expect that the tolerances on critical components, particularly the optical sensor, will be looser than those on components supplied under contract to medical device manufacturers. However, as an indicative point of care device for rapid triage it is fit for purpose. Future work is therefore to develop robust calibration methods to characterise the sensor (in particular the wavelengths of the LEDs) and realistic but easy to use "phantom" fingers that enable repeatable testing of devices. Networking devices via Bluetooth to mobile phone applications is also of interest as basic statistical analysis could be performed including the capability of uploading information on-line for further clinical analysis.

CONCLUSION

This paper introduces the design of an open source and low cost pulse oximeter that can be easily assembled with minimal tooling. It uses widely available components to provide indicative measurements of SpO_2 and Heart Rate that have been used for triage purposes during the COVID-19 crisis. The design is not certified for use as a medical device, but is instead a robust and flexible platform for the future development of sensors based on the MAX3010x suite of optical sensors. The software libraries developed have been optimised for size and speed, and have been adapted so that any of the MAX3010x sensors can be used with no code changes.

QUALITY CONTROL

This design is not a certified medical device, and should not be used for monitoring of patients in a clinical setting.

Characterising the wavelength of the LEDs and their relative intensity is important; we plan to create hardware and software to facilitate this in the future.

It is important that the clip is sufficiently tight to stay attached to the patient's finger for the duration of monitoring, but not so tight as to affect the circulation. This can be approximately tested by attaching it to a finger for 30 minutes and noting any discomfort or unusual readings. The design is based on clothes pegs purchased from a supermarket in the UK, but has parametric hole locations to allow adjustment of the clip tension by changing the angle through which the spring is stretched.

APPLICATION

This sensor is intended to monitor the saturated oxygen content in a patient's bloodstream, and their heart rate. The design is not suitable for clinical applications and should be considered an educational design, shared to provide a functional project that can be further developed by the community.

BUILD DETAILS

AVAILABILITY OF MATERIALS AND METHODS

We have selected components for ease of availability – the MAX3010x optical sensor is stocked by most major electronics suppliers, and other electronic parts are widely available. 3D printing is used for all mechanical parts, except screws and the spring, which is taken from a clothes peg.

EASE OF BUILD

Mechanical assembly should take less than one hour for someone familiar with basic assembly tasks. Assembling the breakout board requires surface mount soldering. Alternatively, a motherboard was developed to support the interfacing of existing MAX3010x breakout boards with an Arduino nano and display. This motherboard requires only through-hole soldering and uses the Arduino board to reduce the number of components required during assembly. ***Figure 8*** depicts this motherboard with the sensor breakout board fitted. Whichever hardware option is selected, firmware can be uploaded using the Arduino IDE.

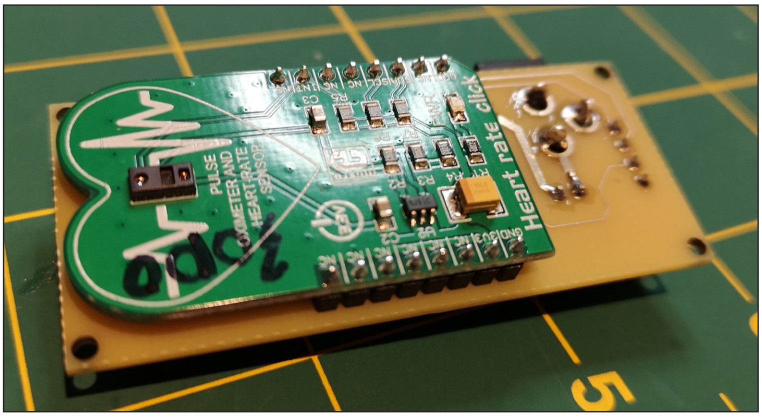

Figure 8 A motherboard was developed to allow connection of existing MAX3010x breakout boards with an Arduino Nano and display. This board utilises through-hole assembly to make the build process possible with minimal equipment requirements. The Arduino and display fit to the rear side of the system.

OPERATING SOFTWARE

The monitor is self-contained, and displays the readings on a small screen. Firmware resides in the “Arduino Code” repository.

DEPENDENCIES

There are no dependencies.

HARDWARE DOCUMENTATION AND FILES LOCATION

Archive for hardware documentation, and editable design files

Name OpenOximeter Organisation on GitLab

Electronics *https://gitlab.com/openoximeter/Electronics*

Sensor breakout board *https://gitlab.com/openoximeter/max3010x-breakout-board*

Finger clip and enclosure *https://gitlab.com/openoximeter/springfingerclip*

Motherboard assembly instructions *https://openoximeter.gitlab.io/Electronics/*

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SOFTWARE CODE REPOSITORY

Name OpenOximeter Organisation on GitLab

Arduino code *https://gitlab.com/openoximeter/arduinocode*

License GNU GPL v3

Publisher University of Bath

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DATA AVAILABILITY STATEMENT

Data, code, and hardware designs referenced in this manuscript are available from our repositories.

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COMPETING INTERESTS

The authors have no competing interests to declare.

AUTHOR CONTRIBUTIONS

All authors contributed to discussions and writing of the manuscript.

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