



NapTrackr – A Wireless, Rechargeable Interface Integrated

Pulse Oximetry System



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INTRODUCTION

Sleep Apnea, more specifically Obstructive Sleep Apnea (OSA), is a condition characterized by blockage of the airway by soft tissue, resulting in frequent episodes of interrupted breathing throughout the sleep cycle. Residual effects of untreated OSA are often detrimental to patient health, with the most common being excessive daytime sleepiness, psychological and cognitive decline, heart tissue damage, hypoxia, and death¹.

The most common treatment for OSA is Continuous Positive Airway Pressure (CPAP) therapy. During CPAP use, the upper respiratory tract is ventilated with a constant pressure flow to allow continuous airway expansion necessary for unobstructed breathing. Currently there are approximately 8 million adult CPAP users in the US—with anticipated growth of 8-9% users annually². Of these consumers, 13 long and short-term CPAP users were interviewed exclusively for the purpose of this project. With knowledge gained through these interviews, market research, and published and personal experiences with OSA, surveys were generated and dispersed to determine the primary problems associated with CPAP usage. From this, a universal concern among interviewees was determined—a lack of accurate, continuous validation of proper oxygenation with minimal discomfort.

With consumer needs and concerns in mind, SleepSound Therapeutics has created a cost-effective, durable device which accurately tracks apneatic events using biological measurements during sleep. Predicate devices are expensive, inaccurate and uncomfortable solutions. Our novel device is a potential solution capable of validating the efficacy of oxygen supplementation and/or CPAP therapy. We have developed an affordable, comfortable device which accurately measures oxygen saturation throughout the sleep cycle and presents this data in an easy-to-interpret format.

CUSTOMER STATEMENT

In the OSA market, there is a need for accurate validation of a patient's blood oxygenation levels when using a CPAP mask. Here we approach this problem, with the help of our consumers.

FUNCTIONAL SPECIFICATIONS

SPECIFICATION	PASS PARAMETERS	TEST NO.
SENSOR ACCURACY	>95% Accuracy	WI. 1.1
FAIL-SAFE ALERT SYSTEM	Alert at inadequate data relay	WI. 2.1
LOW BATTERY ALERT SYSTEM	Alert at 20% Remaining Charge	WI 3.1
REAL-TIME DATA RELAY	<10 second signal delay	WI 4.1
COMFORTABILITY	Likert-Scale Rating	WI 5.1

Table 1: Functional Specifications for the NapTrackr device.

FINAL PRODUCT

ITEM NO.	PART NUMBER	DESCRIPTION	MATERIAL	QTY.
1	63571	Elbow Connector	PLA	1
2	63572	Mask Body	PC	1
3	63573	Electrical Housing	PC	1
4	63574	Microcontroller	Adafruit Composite	1
5	63575	Connection Component	PC	1
6	63576	Interface	Silicone Elastomer	1
7	63577	Pulse Oximeter Sensor	PCB	1

Figure 1: Rendered image of (a) exploded view of device and (b) Rendered image of device in use.

TRACEABILITY MATRIX

Test Case ID	Test Case Description
TC #001	Verify if sensor detects SpO2 from the fingertip.
TC #002	Verify if sensor detects SpO2 from the intended sensor location (nose).
TC #003	Verify if sensor has accuracy above 95%, in comparison to clinical-grade sensor.
TC #004	Verify if sensor alert system engages only at faulty data (signal) relay.
TC #005	Verify if battery charge detection is accurate.
TC #006	Verify if low-battery alert system engages only at low battery.
TC #007	Verify if data is relayed and stored in real-time.
TC #008	Verify if the device is considered comfortable over an extended time period (30 days).

Functional Requirement ID	Functional Requirement/Use Case	Priority	Test Case Document
WI 1.1	Sensor SpO2 Detection – Fingertip	Medium	TC #001
WI 1.1	Sensor SpO2 Detection – Nose	High	TC #002
WI 1.1	Sensor Accuracy – Nose	High	TC #003
WI 2.1	Fail-Safe Alert System Function	High	TC #004
WI 3.1	Battery Tracking Accuracy	High	TC #005
WI 3.1	Low-Battery Alert System Function	High	TC #006
WI 4.1	Verify if data is relayed and stored in real-time.	Medium	TC #007
WI 5.1	Verify material comfortability	Medium	TC #008

Table 2, 3: Traceability matrix for NapTrackr, used to ensure functional and customer requirements are appropriately tested.

TESTING RESULTS

WI 1.1 – Sensor Accuracy Testing

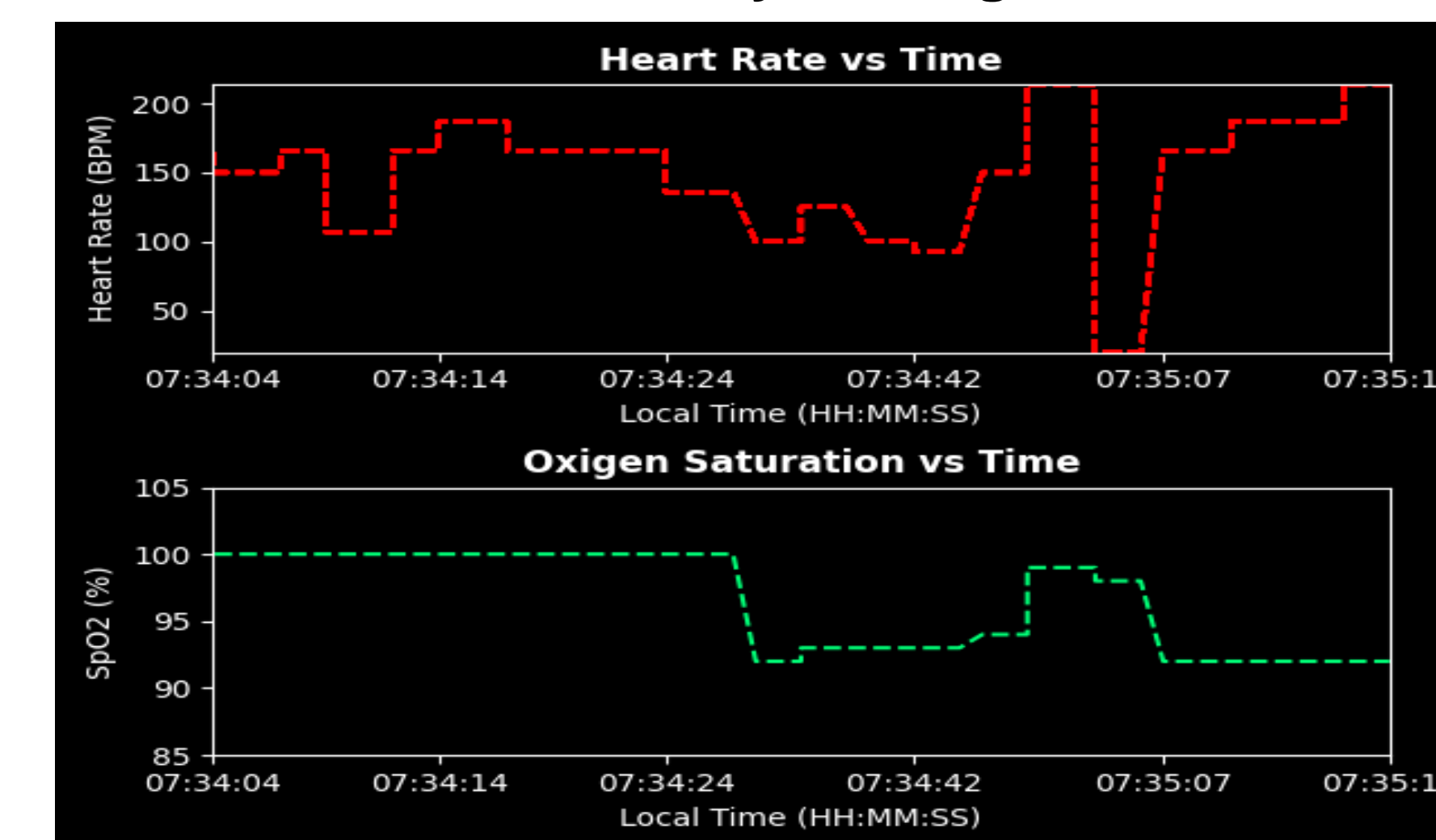


Figure 2: a graphic representation of sensor accuracy

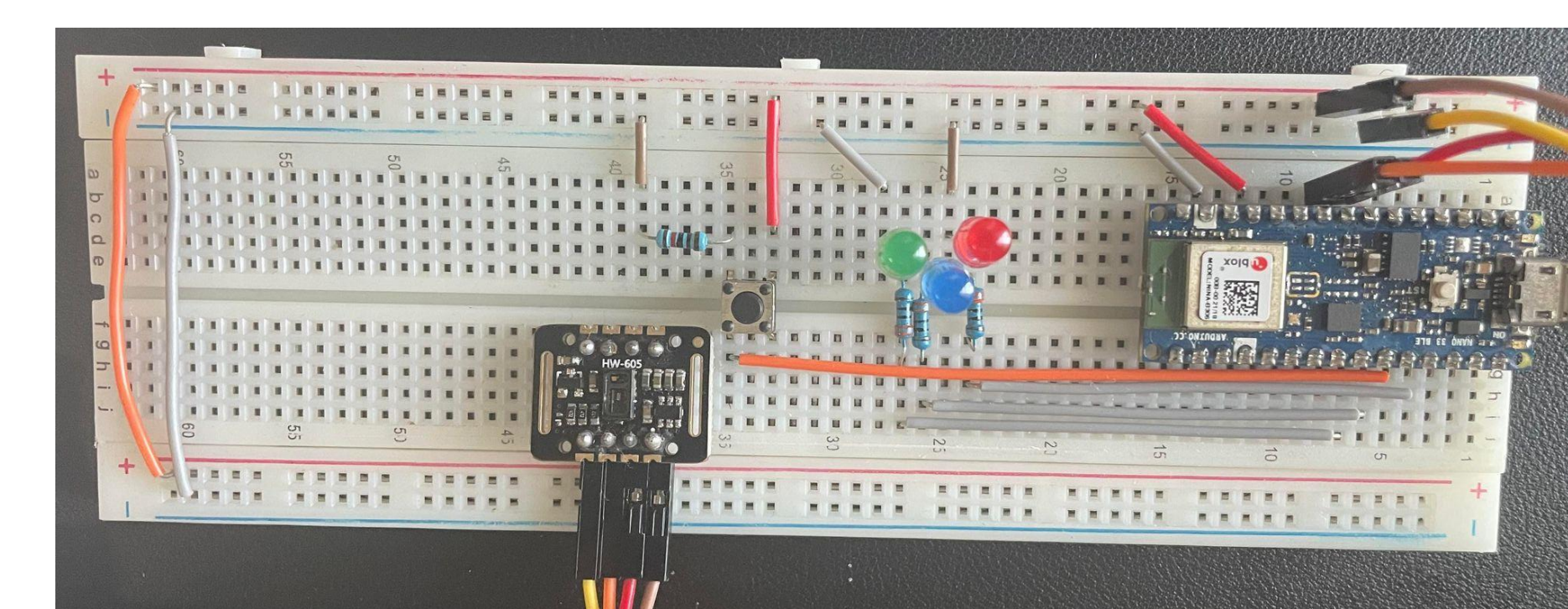


Figure 3: First prototype.

TESTS IN PROGRESS

- WI 2.1 – Fail-Safe Alert Testing
- WI 3.1 – Low Battery Alert Testing
- WI 4.1 – Signal Relay Testing
- WI 5.1 – Material Comfortability Testing

PERSONNEL AND REPORTING

Labor	Total Time (hrs) – SD I	Total Time (hrs) – SD II	Cost per hour	Total Cost
Senior Project Manager - Dr. Laura Gaviria	20	--	\$180	\$3,600
Senior Project Manager - Dr. Don Petersen	20	50	\$180	\$9,000
Senior Engineer - Dr. Mario Flores	4	--	\$150	\$600
Senior Engineer - Dr. Caleb Roth	1	--	\$150	\$150
Senior Engineer – Dr. Pratap Khanwilkar	0.5	--	\$150	\$75
Engineer 1 - Ashley Larweck	229	170	\$120	\$47,880
Engineer 2 - Jose Calderon	189	--	\$120	\$22,680
Engineer 3 - Natnael Abraha	188	--	\$120	\$22,560
Engineer 4 - John Ojediran	188	--	\$120	\$22,560

Table X: Calculated personnel time and Reporting Costs over the design process.

MANUFACTURING COSTS

Total Prototype Cost: \$163.95

CLAIMS

- This product will be able to perform and function as a CPAP mask with the addition of accurate and precise SpO2 analysis, substantial pressure dosage and user-friendly reports.
- Is functional with the inclusion of a CPAP machine.
- Accessible for patients that are diagnosed and suffer from Data User obstructive sleep apnea.

CONCLUSIONS

- NapTrackr meets the functional needs of our consumer requirements
- Device testing has commenced.
- Our future plans aims to further develop our algorithm to detect apneatic events.

TEAM MEMBERS & MENTORS



Natnael Abraha Ashley Larweck Iyanuoluwa Ojediran Jose Calderon

Mentors:
 Mario Flores Ph.D – Faculty Mentor
 Caleb Roth Ph.D – Research Advisor
 Raul Espinoza – Business Advisor
 Pratap Khanwilkar Ph.D – Prod. Dev.

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REFERENCES

1. S. S. Mostafa, J. P. Carvalho, F. Morgado-Dias and A. Ravelo-Garcia, "Optimization of sleep apnea detection using SpO2 and ANN," 2017 XXVI International Conference on Information, Communication and Automation Technologies (ICAT), 2017, pp. 1-6, doi: 10.1109/ICAT.2017.8171609.
 2. Fabio Mendonca, Sheikh Shanawaz Mostafa, Fernando Morgado-Dias, Juan L. Navarro-Mesa, Gabriel Juliá-Serdá, Antonio G. Ravelo-García, "A portable wireless device based on oximetry for sleep apnea detection", Computing, vol. 100, pp. 1203, 2018.