Light Technology in Medical Devices

Alicia Corona, Claire Mitchell, Norma Munoz

Project Description

- Design and develop a medical device capable of monitoring blood flow and oxygen circulation emphasizing the cardiovascular system in a patients body
- Features data transmission capabilities; enables real-time communication via external unit
- Incorporates a set of red LED lightsand inf-redsensors, and a rechargable battery, utilizing photobiomodulation technologies
- Work with EE and CS Capstone department; improving our collaboration skills

Project Description: Who & Why

- Client: Jesslynn Armstrong; President of Light Matter Solutions, LLC
- Importance of Project:
    - Transformative tool in modern medical technology: Photo-biomodulation (PBM) Therapy
        - Light-emitting diodes wavelengths to simulate biological processes at the cellular level; enhancing mitochondrial function, promotes tissue repair, and modulates inflammation
    - Usage in Medical Industry: MedTech
        - Medical institutions, rehabilitation centers, military organizations, sports teams can integrate PBM into their therapeutic protocols
    - Opens possibilities for patient care
        - Offers non-invasive solution for monitoring/ improving the Cardiovascular system

Background & Benchmarking

LOVTRAVEL LED Light Therapy Pad

Garmin HRM-Dual

Innovo Finger Pulse Oximeter

Products

Product 1 Reference [26], Product 2 Reference [27], Product 3 Reference [28]

Requirements

Customer

- Cleanable
- Without need of on/off switch
- Automatic shut down
- Non-invasive
- Reuseable
- Cost effective

Engineering

- Power (20-50 W)
- Battery Life Expectancy (120 min)
- Sanitation Time (5 min)
- Treatment Duration (20 min)
- Portability

QFD

- Relationship between customer needs & technical requirements
- Battery life is our most important technical requirement
- Ratings of products against customer needs

System QFD

Project:	**Tensegrity Medical Light Therapy**
Date:	**9/17/2024**

		Battery Power	Battery Life	Sanitation Time	Treatment Duration	Portability
1	Battery Power					
2	Battery Life	9				
3	Sanitation Time					
4	Treatment Duration	3	9			
5	Portability	3	9		3	

Legend

A	LOVTRAVEL LED Light Therapy Pad
B	Garmin HRM-Dual Heart Rate Monitor
C	Innovo iP900BP-B Finger Pulse Oximeter

			Technical Requirements					**Customer Opinion Survey**				
	Customer Needs	**Customer Weights**	Battery power	Battery Life	Sanitation Time	Treatment Duration	Portability	1 Poor	2	3 Acceptable	4	5 Excellent
1	Cleanable	4			9				A	B		C
2	Rechargeable/battery life	3	9	9		3				C	A	
3	Without need of on/off switch	4					9	AC				B
4	Time Duration	3			3	9				AC		B
5	Automatic shut down	1	3	9				BC		AC		
6	Non-invasive	4				1						ABC
7	Reusable	3	3	9								ABC
8	Cost effective	3							A		BC	
	Technical Requirements Units		W	min	min	min	mts					
	Technical Requirements Target		20-50	120	5	20	-					
	Absolute Technical Importance		39	63	45	40	36					
	Relative Technical Importance (%)		17.49	28.25	20.18	17.94	16.14					

Literature Reviews: Alicia Corona 1

[1] Journal 1: Advance Flexible Skin-Like Pressure and Strain Sensors for Human Health Monitoring

i. Discusses the invention of a sensor that is flexible enough to wrap around the human body instead of using bulky sensors.

[2] Book 1: Lasers and Optical Fibers in Medicine (Chapter 8)

i. Used to help calculate power density. Discusses lasers and optical fibers used in the medical field.

[3] Journal 2: A Review of Current Advancements for Wound Healing: Biomaterial Applications and Medical Devices

i. Discusses common materials used in medical devices for wound healing.

[4] Book 2: Biomedical Devices: Materials, Design, and Manufacturing

i. Provides insight on materials used in biomedical devices and different techniques for designing and manufacturing.

Literature Reviews: Alicia Corona 2

[5] Journal 3: Proposed Mechanisms of Photobiomodulation or Low-Level Light Therapy

i. Provides an explanation of the science that goes into photobiomodulation and discusses near-infrared light.

[6] Online Source 1: LED Light Therapy Wavelengths: Everything You Need To Know

i. Gives an overview of the common wavelengths used in light therapy and how far into the tissue the wavelength reaches.

[7] Online Source 2: LED Light Therapy: How It Works, Colors, Benefits & Risks

i. Provides an explanation of how light therapy works, the colors/wavelengths used, what are the benefits and who should not use it for medical reasons.

[8] Standard 1: IEC 60601-2-57:2023

i. Provides safety and performance of using non-laser light sources for equipment that are used for therapeutic purposes.

Literature Reviews: Claire Mitchell 1

[9] Book 1: All You Really Need to Know to Interpret Arterial Blood Gases (Chapter 5)

i. Describes how to calculate oxygen content in the blood as well as describes the contents of the blood

[10] Article 1: What are Blood Oxygen Levels

i. Outlines how much oxygen should be in the blood as well as talks about what to do when you have high/low blood oxygen levels

[11] Article 2: Physiology, Oxygen Transport

i. Talks about how oxygen moves through the blood and how it may differ based on someone with a blood deficiency such as anemia

[12] Paper 1: A Controlled Trial to Determine the Efficacy of Red and Near-Infrared Light Treatment in Patient Satisfaction, Reduction of Fine Lines, Wrinkles, Skin Roughness, and Intradermal Collagen Density Increase

i. Paper based on a trial regarding how well red-light therapy worked on the skin

Literature Reviews: Claire Mitchell 2

[13] Paper 2: Battery Design Guide for Portable Electronics

i. Talks about how you should design a battery with certain components in mind: voltage requirement, capacity, runtime, etc.

[14] Paper 3: Development of a LED light therapy device with power density control using a Fuzzy logic controller

i. Describes a test done on how the skin reacts to different colors and different wavelengths of LEDs

[15] Book 2: Battery Operated Devices and Systems: From Portable Electronics to Industrial Products (Chapter 3.3: Medical Applications)

i. Outlines how with medical devices, you need more requirements as well as more safety when designing a battery

[16] Standard: ISO 80601-2-61:2017
Medical electrical equipment

Literature Reviews: Norma Munoz 1

[17] Article 1: Anti-inflammatory effects of PBM

i. *Frontiers in Neuroscience* examine PBM effects, by adjusting how proteins are produced and controlled in the body; potentially providing therapeutic benefits in neuroinflammation

[18] Article 2: PBM and Neurological Damage

i. *Neuroscience Bulletin* investigates how PBM might help repair brain damage from COVID-19 by improving how the brain uses and balances oxygen levels; supporting better brain function and recovery

[19] Article 3: PBM for Cognitive Improvement

i. *Journal of Translational Medicine* focuses on how PBM can improve brain function by boosting the production of Adenosine triphosphate (ATP; source of energy) encouraging growth of brain cells by using infrared lights

[22] Paper 1: Effects of Transcranial LED Therapy (TCLT)

i. *Salgado et al.* Explores the effects of Light Therapy on cerebral blood flow. Where PBM enhances blood flow in elderly patients, potentially combating neurodegenerative conditions

Literature Reviews: Norma Munoz 2

[21] Book 2: low-level laser therapy effects on Vascular and endothelial function

i. *Calderhead, R. G., & Vasilyeva, E.* discuss how PBM works on cardiovascular deseases and cellular mechanisms; they go into depth on dosage, wavelengths, and power density

[23] Paper 2: Role of PBM in Cardiovascular Health: Systematic Review and Meta-Analysis

i. Details how PBM impacts cardiovascular parameters, such as blood circulation. Providing information on clinical studies that confirm PBM's ability to enhance microcirculation in patients with cardiovascular conditions

[24] Paper 3: Efficacy of PBM therapy in Older Adults: A systematic review

i. Details whether there is any available evidence on the efficacy of PBM therapy in older adults, by holding literature searches.

[20] Book 1: LibreText: Chemistry

i. Describes Beer Lambert law—attenuation of light to the properties of the material through which the light is traveling-- and how it relates to photobiomodulation research

[25] Standard: "ISO/IEC 17025 testing and calibration laboratories," ISO, 2017. https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html

Mathematical Modeling

Alicia Corona 1

$$P_{flux} = \frac{P_{light}}{A}$$

$$P_{flux} = flux\ of\ radiant\ energy\ (watts/cm^2)$$

$$P_{light} = total\ power\ of\ light\ source\ (watts)$$

$$A = area\ illuminated\ by\ light\ (cm^2)$$

$$A = \pi r^2$$

Flux/Power Density (Irradiance)

Measures how much power is distributed over a certain area.

Mathematical Software

WolframAlpha

[8] Standard: IEC 60601-2-57:2023
[2] Lasers and Optical Fibers in Medicine (chapter 8)

Mathematical Modeling

Alicia Corona 2

EXAMPLE III: A beam of power P is incident on an area A for time t.

The irradiance (or power density) is P/A.

The total energy delivered to the area is $E = Pt$.

The fluence is $F = E/A = Pt/A$.

Flux/Power Density (Irradiance)
Measures how much power is distributed over a certain area.

Mathematical Software
WolframAlpha

[8] Standard: IEC 60601-2-57:2023
[2] Lasers and Optical Fibers in Medicine (chapter 8)

Mathematical Modeling

Alicia Corona 3

$$P_{light} = 3\ W$$

$$r = 6.35\ cm$$

$$A = \pi r^2$$

$$A = \pi * (6.35\ cm)^2$$

$$P_{flux} = \frac{P_{light}}{A}$$

$$P_{flux} = \frac{3\ W}{\pi*(6.35\ cm)^2}$$

$$P_{flux} = 0.024\ \frac{W}{cm^2}$$

Flux/Power Density (Irradiance)
Measures how much power is distributed over a certain area.

Mathematical Software
WolframAlpha

[8] Standard: IEC 60601-2-57:2023
[2] Lasers and Optical Fibers in Medicine (chapter 8)

Mathematical Modeling

Claire 1

What equation did you use?

$$C_aO_2 = [Hb \times 1.34 \times S_aO_2] + [P_aO_2 \times 0.003]$$

$C_aO_2 =$ Oxygen per 100mL of blood $\left(\frac{mL\ O_2}{100mL\ blood}\right)$

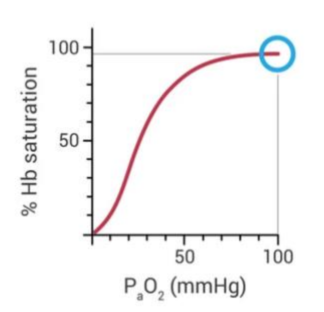
$Hb =$ Hemoglobin $\left(\frac{gm\ Hb}{100mL\ blood}\right)$

$1.34 =$ Content of oxygen that will bind for each gram of Hb $\left(\frac{mL\ O_2}{gm\ Hb}\right)$

$S_aO_2 =$ Oxygen Saturation (%)

$P_aO_2 =$ Partial Pressure of Oxygen $(mmHg)$

$0.003 =$ Constant $\left(\frac{mL\ O_2}{mmHg\ 100mL\ blood}\right)$



Oxygen Content Equation
This equation can help determine how much oxygen is in the blood

Oxyhemoglobin Dissociation Curve

[16] Standard: ISO 80601-2-61

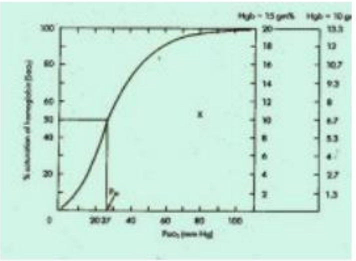
Mathematical Modeling

Claire 2

Example problem from textbook [1]

Clinical Problem 5-3. Using Figure 5-2 to determine SaO_2, calculate O_2 content of a patient with hemoglobin 12 gms/dl, PaO_2 50 mm Hg, pH 7.40.

Figure 5-2.



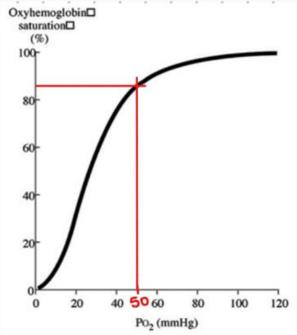
Oxygen Content Equation

This equation can help determine how much oxygen is in the blood

Oxyhemoglobin Dissociation Curve

Mathematical Modeling

Claire 3



Given:

$PaO_2 = 50$ mm Hg

Hb = 12 gm/dL

Solution:

$$CaO_2 = [Hb \times 1.34 \times SaO_2] + [PaO_2 \times 0.003]$$

$$= \left[\left(12 \frac{g}{100mL}\right)\left(1.34 \frac{mL\,O_2}{g}\right)\left(0.85\right)\right] + \left[\left(50\,mm\,Hg\right)\left(0.003 \frac{mL}{mmHg\ 100mL}\right)\right]$$

$$= 14.13\,\% \left(\frac{mL\ O_2}{100mL\ blood}\right)$$

Normal:

Hb: 12-16 g/dL

SaO2: >92%

PaO2: >80mmHg

CaO2: 16-20%

Oxygen Content Equation

This equation can help determine how much oxygen is in the blood

Oxyhemoglobin Dissociation Curve

Mathematical Modeling

Norma Munoz 1

$$A = \log_{10}\left(\frac{I_o}{I}\right) \text{ or } \epsilon * c * d$$

$$\epsilon = \frac{A}{c * d}$$

$$A = Absorbance$$
$$I_o = initial\ intensity$$
$$I = final\ intensity$$
$$\epsilon = molar\ absorption$$
$$c = concentration\ \left(\frac{mol}{L}\right)$$
$$d = l = length\ of\ path$$

The Beer-Lambert Law for Light Absorption

Describes how light reduces as it passes through a material such as tissue; estimates the penetration depth of light into tissue

Mathematical Software

help perform the necessary calculations
Excel: plotting data
MATLAB: advanced modeling and simulation

Spectrophotometer

Measures the intensity of light

[20] The Beer-Lambert Law - ChemistryLibreTexts

Mathematical Modeling

Norma Munoz 2

Example 2: Guanosine

Guanosine has a maximum absorbance of 275 nm. $\epsilon_{275} = 8400 M^{-1} cm^{-1}$ and the path length is 1 cm. Using a spectrophotometer, you find the that $A_{275} = 0.70$. What is the concentration of guanosine?

Solution

To solve this problem, you must use Beer's Law.

$$A = \epsilon l c$$

$$0.70 = (8400\ M^{-1}\ cm^{-1})(1\ cm)(c)$$

Next, divide both side by [(8400 M^{-1} cm^{-1})(1 cm)]

$$c = 8.33 \times 10^{-5}\ mol/L$$

Example 3

There is a substance in a solution (4 g/liter). The length of cuvette is 2 cm and only 50% of the certain light beam is transmitted. What is the extinction coefficient?

Solution

Using Beer-Lambert Law, we can compute the absorption coefficient. Thus,

$$-\log\left(\frac{I_t}{I_o}\right) = -\log(\frac{0.5}{1.0}) = A = 8\epsilon$$

Then we obtain that

$$\epsilon = 0.0376$$

Example 4

In Example 3 above, what is the molar absorption coefficient if the molecular weight is 100?

Solution

It can simply obtained by multiplying the absorption coefficient by the molecular weight. Thus,

$$\epsilon = 0.0376 \times 100 = 3.76\ L \cdot mol^{-1} \cdot cm^{-1}$$

The Beer-Lambert Law for Light Absorption

Describes how light reduces as it passes through a material such as tissue; estimates the penetration depth of light into tissue

Mathematical Software

help perform the necessary calculations
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[20] The Beer-Lambert Law - ChemistryLibreTexts

Mathematical Modeling

Norma Munoz 3

$$A = log_{10}\left(\frac{1000}{820}\right) = log_{10}(1.22) = 0.086 \approx 0.10$$

$$\epsilon_{820} = \frac{0.10}{0.02*5} = 1\,L * mol^{-1} * cm^{-1}$$

The Beer-Lambert Law for Light Absorption

Describes how light reduces as it passes through a material such as tissue; estimates the penetration depth of light into tissue

Mathematical Software

help perform the necessary calculations
Excel: plotting data
MATLAB: advanced modeling and simulation

Spectrophotometer

Measures the intensity of light

[25] Standard: ISO 17025

Currently on	Ahead	Behind	Done

Schedule

Task (collectively)		Week						
		1	2	3	4	5	6	7
1	Time Cards							
2	Staff Meetings							
3	Presentation 1							
4	Homeworks							
5	Presentation Feedback							
6	Pear Evaluations							

Budget: Pricing Strategy

Up to $5000; additional funding subject to the disbursement within each capstone group involved

- Analogue Test Estimation
  - Light intensity ($400-$1500)
  - Sensor/Signal Testing ($600-$3,000)
  - Power Consumption ($550-$2150)
  - Signal Integrity ($500-$7500)
  - Battery Performance ($150-$650)
- Total cost Estimation
  - Low end : ~ $2200
  - High end: ~$15,000

Project budget	$5K
Anticipated Expenses (estimated)	$3K
Actual Expenses (to date)	$0
Resulting Balance (to date)	$5K

Thank You, Questions?

Sources

[1] X. Liu, Y. Wei, and Y. Qiu, “Advanced Flexible Skin-Like Pressure and Strain Sensors for Human Health Monitoring,” *Micromachines*, vol. 12, no. 6, p. 695, Jun. 2021, doi: https://doi.org/10.3390/mi12060695.
[2] A. Katzir, *Lasers and Optical Fibers in Medicine*. Elsevier, 2012. (Chapter 8)
[3] X. Deng, M. Gould, and M. A. Ali, “A review of current advancements for wound healing: Biomaterial applications and medical devices,” *Journal of Biomedical Materials Research Part B: Applied Biomaterials*, May 2022, doi: https://doi.org/10.1002/jbm.b.35086.
[4] Raymond and W. Chen, *Biomedical Devices*. Springer, 2019.
[5] L. F. de Freitas and M. R. Hamblin, “Proposed Mechanisms of Photobiomodulation or Low-Level Light Therapy,” *IEEE Journal of Selected Topics in Quantum Electronics*, vol. 22, no. 3, pp. 348–364, May 2016, doi: https://doi.org/10.1109/jstqe.2016.2561201.
[6] “LED Light Therapy Wavelengths: Everything You Need to Know,” *Celluma*, Jun. 13, 2023. https://www.celluma.com/blogs/blog/what-is-the-most-effective-color-for-led-light-therapy?srsltid=AfmBOopSDy07TqY-QallnrGtiMSxJWA7KmxDdreBu-hQ_OZQJtSv5R24 (accessed Sep. 17, 2024).
[7] Cleveland Clinic, “LED Light Therapy: How It Works, Colors, Benefits & Risks,” *Cleveland Clinic*, Feb. 12, 2021. https://my.clevelandclinic.org/health/treatments/22146-led-light-therapy
[8]“Standard | IECEE,” *Iecee.org*, 2023. https://www.iecee.org/certification/iec-standards/iec-60601-2-572023 (accessed Sep. 18, 2024).
[9] L. Martin, All you really need to know to interpret arterial blood gases. Philadelphia: Lippincott Williams & Wilkins, 1999.
{10] https://www.facebook.com/Health, “When Should You Be Concerned About Your Blood Oxygen Level?,” Health, 2024. https://www.health.com/blood-oxygen-level-8425396#:~:text=Blood%20oxygen%20levels%2C%20or%20oxygen%20saturation%2C%20typically (accessed Sep. 18, 2024).
[11]C. E. Rhodes, D. Denault, and M. Varacallo, “Physiology, Oxygen Transport,” PubMed, 2024. https://www.ncbi.nlm.nih.gov/books/NBK538336/#:~:text=%5B9%5D%20Thus%2C%20when%20the
[12] A. Wunsch and K. Matuschka, “A controlled trial to determine the efficacy of red and near-infrared light treatment in patient satisfaction, reduction of fine lines, wrinkles, skin roughness, and intradermal collagen density increase,” Photomedicine and Laser Surgery, vol. 32, no. 2, pp. 93–100, Feb. 2014, doi: https://doi.org/10.1089/pho.2013.3616.
[13] M. Manna, “Battery Design Guide for Portable Electronics Battery Design Guide for Portable Electronics An Approach in Simple Terms.” Accessed: Sep. 18, 2024. [Online]. Available: https://www.ultralifecorporation.com/PrivateDocuments/BR_Battery-Design-Guide-for-Portable-Electronics.pdf
[14] D. T. Phan et al., “Development of a LED light therapy device with power density control using a Fuzzy logic controller,” Medical Engineering & Physics, vol. 86, pp. 71–77, Dec. 2020, doi: https://doi.org/10.1016/j.medengphy.2020.09.008.
[15] D. T. Phan et al., “Development of a LED light therapy device with power density control using a Fuzzy logic controller,” Medical Engineering & Physics, vol. 86, pp. 71–77, Dec. 2020, doi: https://doi.org/10.1016/j.medengphy.2020.09.008.

Sources

[16] standard
[17] Shamloo S, Defensor E, Ciari P, Ogawa G, Vidano L, Lin JS, Fortkort JA, Shamloo M and Barron AE and (2023) The anti-inflammatory effects of photobiomodulation are mediated by cytokines: Evidence from a mouse model of inflammation. Front. Neurosci. 17:1150156. doi: 10.3389/fnins.2023.1150156
[18] "Neuroscience Bulletin," SpringerLink. https://link.springer.com/journal/12264 (accessed September 17, 2024).
[19] W.-T. Pan, P.-M. Liu, D. Ma, and J. Yang, "Advances in photobiomodulation for cognitive improvement by near-infrared derived multiple strategies," vol. 21, no. 1, Feb. 2023, doi: https://doi.org/10.1186/s12967-023-03988-w.
[20] J. Clark, "The Beer-Lambert Law," Chemistry LibreTexts. https://chem.libretexts.org/Bookshelves/Physical_and_Theoretical_Chemistry_Textbook_Maps/Supplemental_Modules_(Physical_and_Theoretical_Chemistry)/Spectroscopy/Electronic_Spectroscopy/Electronic_Spectroscopy_Basics/The_Beer-Lambert_Law
[21] Calderhead, R. G., & Vasilyeva, E. (2021). Meta-analysis of low-level laser therapy's effects on vascular and endothelial function.
[22] Salgado et al, SpringerLink. https://link.springer.com/ (accessed September 17, 2024)
[23] Godaert, L.; Dramé, M. Efficacy of Photobiomodulation Therapy in Older Adults: A Systematic Review. Biomedicines 2024, 12, 1409. https://doi.org/10.3390/biomedicines12071409
[24] Godaert, L.; Drame, M. The Role of Photobiomodulation in Cardiovascular Health: A Systematic Review and Meta-Analysis. Biomedicines 2023, (accessed September 17, 2024)
[25] International Organization for Standardization, "ISO/IEC 17025 testing and calibration laboratories," ISO, 2017 https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html
[26] LOVTRAVEL, Accessed: Sep. 17, 2024. [Online]. Available: https://www.amazon.com/LOVTRAVEL-Infrared-Therapy-Devices-Wearable/dp/B08T81VXJS/ref=sr_1_1?adgrpid=1345803848118334&dib=eyJ2IjoiMSJ9.dF2j6B-pYbURefxouxt2S_S4XQTvi2eULlUvYa42_3n3lFRFFj3SJsudQylx3uPzdc8QKYThW7MzXZEl6Aj3lNqGBd0o5wNocqQi_yUQUcFUh_lv2ZfGvrZHq_dSuwEopecQ7EsslYkodNdafltynalSV4bgL7Zvlu8XHUEOSSloF30Z3MTpgnhJLJBOwFZpMfv87nTr0_ZVjHNS0dyLgPjT3xQy2YvHwOZAS7CoLd4qoDnOOA1UnyM1BvRT8byHOEsL9-jWC3b1KypAXTwZ9z9Jt1ZfvyrmoOf0v0wPk3Y.80SBe12lnRD28XK3rIaCe1SciyWygyDA9lnzQVK-9dw&dib_tag=se&hvadid=841129959300568&hvbmt=be&hvdev=c&hvlocphy=81950&hvnetw=o&hvqmt=e&hvtargid=kwd-84113734337091%3Aloc-190&hydadcr=26412_11678926&keywords=lovtravel+led+light+therapy&msclkid=0cb8ceac90061f96aa4aa84410ed93f0&qid=1726513398&sr=8-1
[27] Rogue, "Garmin HRM-Dual Heart Rate Monitor" Accessed: Sep. 17, 2024. [Online]. Available: https://www.roguefitness.com/garmin-hrm-dual-heart-rate-monitor?msclkid=287babf232761cb18fc0cd1a47e384b6&utm_source=bing&utm_medium=cpc&utm_campaign=Dynamic%20Search&utm_term=roguefitness&utm_content=All%20pages
[28] Innovo , "2024 Innovo iP900BP-B Bluetooth Fingertip Pulse Oximeter, Blood Oxygen Monitor with Free App, Plethysmograph, andPerfusion Index (Snowy White)" Accessed: Sep. 17, 2024. [Online]. Available: https://www.amazon.com/Innovo-Fingertip-Oximeter-Plethysmograph-Perfusion/dp/B077ZJ1ZKZ