

DEVELOPMENT DESIGN STUDY OF HEART
RATE, SPO₂, AND TEMPERATURE
MEASUREMENT ON INFANT USING NON-
INVASIVE INFAWRAP DEVICE

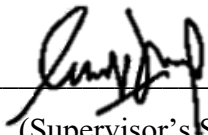
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MASTER OF SCIENCE

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We hereby declare that We have checked this thesis and in our opinion, this thesis is adequate in terms of scope and quality for the award of the degree of Master of Science



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I hereby declare that the work in this thesis is based on my original work except for quotations and citations which have been duly acknowledged. I also declare that it has not been previously or concurrently submitted for any other degree at Universiti Malaysia Pahang or any other institutions.

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ABSTRAK

Rawatan bukan invasif ialah pilihan rawatan konservatif yang harus dipertimbangkan untuk merawat pesakit dan kanak-kanak tanpa menyebabkan kesakitan dan memberikan hasil yang lebih baik daripada teknik invasif. Oleh itu, parameter fisiologi bayi telah dibangunkan menggunakan teknik bukan invasif yang dipanggil peranti *InfaWrap*. Pembangunan *InfaWrap* sebelum ini memerlukan penambahbaikan dalam pelbagai aspek seperti saiz, berat, kebolegunaan dan kefungsiannya. Oleh itu, reka bentuk kaedah kuantitatif berdasarkan metodologi berulang telah digunakan untuk menilai kebolegunaan peranti *InfaWrap* oleh pengguna akhir. Dalam kajian ini, soal selidik kebolegunaan telah dibangunkan dan digunakan dengan kumpulan fokus yang melibatkan profesional kesihatan dan ibu bapa. Tambahan pula, analisis reka bentuk, ujian impak/jatuh, dan ujian ketepatan pengukuran telah dijalankan untuk menilai integriti struktur dan kebolehpercayaan peranti *InfaWrap*. Selain itu, peranti *InfaWrap* digunakan untuk menilai ketepatan kadar denyutan jantung, SpO₂, dan suhu badan khusus pesakit sebenar. Disebabkan oleh keperluan pengguna yang berbeza-beza, kami membuat semakan reka bentuk dan menambah fungsi IoT. Peranti *InfaWrap* pada masa ini lebih kecil dan ringan untuk bayi. Sementara itu, keputusan ujian kejatuhan bagi kedua-dua ujian kejatuhan rata dan ujian kejatuhan tepi dengan ketinggian 1-meter menunjukkan peranti tersebut masih berfungsi untuk kedua-dua spesimen. Di sisi negatif, beberapa bahan seperti lubang skru, selongsong dan skrin LCD telah patah terutama untuk spesimen tiruan. Selongsong *InfaWrap* tiruan menunjukkan keretakan dan calar yang boleh dilihat akibat daya hentaman jatuh yang dihasilkan semasa ujian simulasi berbilang. Dalam analisis reka bentuk, peranti *InfaWrap* boleh diterima dengan tegasan maksimum 4.138 MPa apabila daya 12 N dikenakan. Mengikuti keputusan ujian ketepatan, penerima boleh dipercayai dan tepat apabila mengukur tanda-tanda penting pada seseorang individu. Penemuan kadar denyutan jantung, ketepatan oksigen, dan bacaan suhu yang diperoleh dengan peranti *InfaWrap* menunjukkan bahawa *InfaWrap* adalah tepat untuk ketiga-tiga parameter dalam kedua-dua kaki. Kami membuat kesimpulan bahawa profesional perubatan dan ibu bapa percaya bahawa *InfaWrap* membantu mereka mengawasi bayi baru lahir mereka dengan lebih berkesan. SpO₂ dan suhu pesakit adalah gambaran paling tepat bagi keadaan normal dan sihat mengikut kadar denyutan jantung pesakit dan nilai SpO₂ yang disahkan. Nilai parameter untuk kadar denyutan jantung dan ketepatan SpO₂ menggunakan *InfaWrap* khusus untuk pesakit sebenar masih dalam julat nilai untuk nilai normal. Hasilnya, keputusan menunjukkan bahawa *InfaWrap* memberikan bacaan yang tepat untuk digunakan di hospital atau di rumah.

ABSTRACT

Non-invasive treatments are a conservative treatment option that should be considered to treat patients and infants without causing pain and provide them with better outcomes than their invasive counterparts. In light of the advantages of the former, in this study, the physiological parameters of the infants were measured using a non-invasive device called the *InfaWrap*. The previous development of *InfaWrap* needs improvement in a variety of aspects such as size, weight, usability, and functionality depending on user requirement. Thus, a quantitative method design based on an iterative methodology was used to evaluate the usability of the *InfaWrap* device by end-users. In this study, the usability questionnaire was developed and applied with focus groups involving health professionals and parents. Furthermore, the design analysis, impact/fall testing, and measurement accuracy testing were carried out to determine the structural soundness and reliability of the *InfaWrap* device. Besides that, the *InfaWrap* device was used to assess the accuracy of heart rate, SpO₂, and actual patient-specific body temperature. Owing to varying user requirements, we made design revisions and added IoT functionality. The *InfaWrap* device is currently smaller and lighter for infants. Meanwhile, the drop test results for both the flat drop test and the edge drop test with a height of 1 meter indicated that the device still functions for both specimens. On the negative side, several materials such as screw hole, casing and LCD screen was broken particularly for dummy specimens. The dummy *InfaWrap* casing shows visible cracks and scratches due to the falling impact force produced during multiple simulated tests. In the design analysis, the *InfaWrap* device can be accepted a maximum stress of 4.138 MPa when a force of 12 N is applied. According to the results of the accuracy test, the sensors are reliable and accurate when measuring the vital signs of an individual. The heart rate, SpO₂, and temperature readings acquired with *InfaWrap* indicated that *InfaWrap* was accurate for all three parameters in both legs. The medical professionals and parents who participated in this study believed that *InfaWrap* helps them keep an eye on their infants more effectively. Patient SpO₂ and temperature are the most accurate representations of normal and healthy state according to the validated patient heart rate and SpO₂ values. The parameter values for heart rate and SpO₂ precision using a real patient-specific *InfaWrap* are still within the normal range. Consequently, the results, based on hospital data reference, demonstrated that *InfaWrap* gives accurate readings to be used in hospital or home.

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REFERENCES

- [ANALYSIS] MALAYSIA Market Overview and Importations of Medical Devices. (n.d.). Retrieved March 4, 2022, from <https://www.qualtechs.com/en-gb/article/237>
- Agrawal, S. (2008). *Normal Vital Signs in Children : Heart Rate , Respirations , Temperature , and Blood Pressure*. 3–4. www.ComplexChild.com
- Alharbi, M., Kong, I., & Patel, V. I. (2020). Simulation of uniaxial stress–strain response of 3D-printed polylactic acid by nonlinear finite element analysis. *Applied Adhesion Science*, 8(1), 1–10. <https://doi.org/10.1186/s40563-020-00128-1>
- Anderson, E. S., Petersen, S. A., & Wailoo, M. P. (1990). Factors influencing the body temperature of 3-4 month old infants at home during the day. *Archives of Disease in Childhood*, 65(12), 1308–1310. <https://doi.org/10.1136/adc.65.12.1308>
- Andrade, V., Andrade, F., Riofrio, P., Nedel, F. B., Martin, M., & Romero-Sandoval, N. (2020). Pulse oximetry curves in healthy children living at moderate altitude: A cross-sectional study from the Ecuadorian Andes. *BMC Pediatrics*, 20(1), 1–7. <https://doi.org/10.1186/s12887-020-02334-z>
- Azrul, M., Mohd, H., Asyrul, M., Rashid, A., Hazreen, N., & Hasni, M. (2019). *Development of Smart Infant-Wrap (InfaWrap) Device for Neonates*. July, 1–2.
- Bahorski, J., Repasky, T., Ranner, D., Fields, A., Jackson, M., Moultry, L., Pierce, K., & Sandell, M. (2012). Temperature Measurement in Pediatrics: A Comparison of the Rectal Method Versus the Temporal Artery Method. *Journal of Pediatric Nursing*, 27(3), 243–247. <https://doi.org/10.1016/j.pedn.2010.12.015>
- Balasubramanian, S., Suresh, N., Ravichandran, C., & Dinesh Chand, G. H. (2006). Reference values for oxygen saturation by pulse oximetry in healthy children at sea level in Chennai. *Annals of Tropical Paediatrics*, 26(2), 95–99. <https://doi.org/10.1179/146532806X107421>
- Bancalari, A., Araneda, H., Echeverría, P., Alvear, M., & Romero, L. (2016). Arterial oxygen saturation and heart rate after birth in newborns with and without maternal bonding. *Pediatrics International*, 58(10), 993–997. <https://doi.org/10.1111/ped.12991>

- Bangladesh University of Engineering and Technology. Department of Computer Science and Engineering, Bangladesh University of Engineering and Technology. ACM Chapter, IEEE Communications Society. Bangladesh Chapter, & Institute of Electrical and Electronics Engineers. (2015). (NSysS) : 5-7 January, 2015, Dhaka, Bangladesh. *IEEE*.
- Becker, F., & Parsons, K. S. (2007). Hospital facilities and the role of evidence-based design. *Journal of Facilities Management*, 5(4), 263–274. <https://doi.org/10.1108/1472596071082259>
- Bhushan, B., & Caspers, M. (2017). An overview of additive manufacturing (3D printing) for microfabrication. *Microsystem Technologies*, 23(4), 1117–1124. <https://doi.org/10.1007/s00542-017-3342-8>
- Blackstone, M. S. (2005). (12) *United States Patent U . S . Patent*. 1(12), 0–7.
- Böhm, A., Kiss, R. G., Bogyi, P., & Duray, G. Z. (2016). Temporary severe bradycardia due to pacemaker programming. *Netherlands Heart Journal*, 24(7–8), 488. <https://doi.org/10.1007/s12471-016-0855-1>
- Borsci, S., Macredie, R. D., Martin, J. L., & Young, T. (2014). How many testers are needed to assure the usability of medical devices? *Expert Review of Medical Devices*, 11(5), 513–525. <https://doi.org/10.1586/17434440.2014.940312>
- Chen, H., Xue, M., Mei, Z., Oetomo, S. B., & Chen, W. (2016). A review of wearable sensor systems for monitoring body movements of neonates. *Sensors (Switzerland)*, 16(12), 1–17. <https://doi.org/10.3390/s16122134>
- Chen, S. C., Wang, H. L., Huang, L. T., & Wang, Y. C. (2007). Drop test system with orientation repeatability for 3C products. *IECON Proceedings (Industrial Electronics Conference)*, 00, 2910–2915. <https://doi.org/10.1109/IECON.2007.4459972>
- Chen, W., Oetomo, S. B., Feijs, L., Bouwstra, S., Ayoola, I., & Dols, S. (2010). Design of an integrated sensor platform for vital sign monitoring of newborn infants at Neonatal Intensive Care Units. *Journal of Healthcare Engineering*, 1(4), 535–554. <https://doi.org/10.1260/2040-2295.1.4.535>
- Children neglected because parents are too busy | The Star*. (n.d.). Retrieved November 1, 2021, from <https://www.thestar.com.my/opinion/letters/2014/07/28/children-neglected-because-parents-are-too-busy>

- Chirakanphaisarn, N., Thongkanluang, T., & Chiwpreechar, Y. (2018). Heart rate measurement and electrical pulse signal analysis for subjects span of 20–80 years. *Journal of Electrical Systems and Information Technology*, 5(1), 112–120. <https://doi.org/10.1016/j.jesit.2015.12.002>
- Cited, R., Examiner, P., & Lefkowitz, E. (2005). (12) *United States Patent*. 2(12).
- Clause, D., Detry, B., Rodenstein, D., & Liistro, G. (2008). Stability of oxyhemoglobin affinity in patients with obstructive sleep apnea-hypopnea syndrome without daytime hypoxemia. *Journal of Applied Physiology*, 105(6), 1809–1812. <https://doi.org/10.1152/jappphysiol.90860.2008>
- Dawson, J. A., Kamlin, C. O. F., Wong, C., Te Pas, A. B., Vento, M., Cole, T. J., Donath, S. M., Hooper, S. B., Davis, P. G., & Morley, C. J. (2010). Changes in heart rate in the first minutes after birth. *Archives of Disease in Childhood: Fetal and Neonatal Edition*, 95(3). <https://doi.org/10.1136/adc.2009.169102>
- Drugă, C., Șerban, I., Braun, B., & Tulică, A. (2021). Analysis of the Influence of the Layer Height on the Strength of 3D Printed Structures. *11th International Conference on Information Science and Information Literacy*, 177–181. <https://doi.org/10.2478/9788395815065-019>
- Ewer, A. K., Middleton, L. J., Furnston, A. T., Bhoyar, A., Daniels, J. P., Thangaratinam, S., Deeks, J. J., & Khan, K. S. (2011). Pulse oximetry screening for congenital heart defects in newborn infants (PulseOx): A test accuracy study. *The Lancet*, 378(9793), 785–794. [https://doi.org/10.1016/S0140-6736\(11\)60753-8](https://doi.org/10.1016/S0140-6736(11)60753-8)
- Examiner, P., & Winakur, E. F. (2000). *United States Patent* (19). 19.
- Fezari, M., & Dahoud, A. Al. (2018). Integrated Development Environment “ IDE ” For Arduino. *ResearchGate*, October, 1–12. <https://www.researchgate.net/publication/328615543%0AIntegrated>
- Foundation, B. H. (2014). *Your-Heart-Rate-Is23*.
- Gambi, E., Agostinelli, A., Belli, A., Burattini, L., Cippitelli, E., Fioretti, S., Pierleoni, P., Ricciuti, M., Sbröllini, A., & Spinsante, S. (2017). Heart rate detection using microsoft kinect: Validation and comparison to wearable devices. *Sensors (Switzerland)*, 17(8). <https://doi.org/10.3390/s17081776>

- Gonçalves, R. A. S., Feitosa, S., De Castro Selestrin, C., Valenti, V. E., De Sousa, F. H., F Siqueira, A. A., Petenusso, M., & De Abreu, L. C. (2014). Evaluation of physiological parameters before and after respiratory physiotherapy in newborns with acute viral bronchiolitis. *International Archives of Medicine*, 7(1), 3–7. <https://doi.org/10.1186/1755-7682-7-3>
- Goyal, S., Papadopoulos, J. M., & Sullivan, P. A. (1998a). The dynamics of clattering I: Equation of motion and examples. *Journal of Dynamic Systems, Measurement and Control, Transactions of the ASME*, 120(1), 83–93. <https://doi.org/10.1115/1.2801325>
- Goyal, S., Papadopoulos, J. M., & Sullivan, P. A. (1998b). The dynamics of clattering II: Global results and shock protection. *Journal of Dynamic Systems, Measurement and Control, Transactions of the ASME*, 120(1), 94–102. <https://doi.org/10.1115/1.2801327>
- Goyal, Suresh, & Buratynski, E. K. (2000). Methods for Realistic Drop-Testing. *The International Journal of Microcircuits and Electronic Packaging*, 23(1), 1063–1674.
- Goyal, Suresh, & Eugene, J. (2002). (12) *United States Patent*. 1(12).
- Granelli, A. D. W., Meberg, A., Ojala, T., Steensberg, J., Oskarsson, G., & Mellander, M. (2014). Nordic pulse oximetry screening - Implementation status and proposal for uniform guidelines. *Acta Paediatrica, International Journal of Paediatrics*, 103(11), 1136–1142. <https://doi.org/10.1111/apa.12758>
- Granelli, A. D. W., Wennergren, M., Sandberg, K., Mellander, M., Bejлум, C., Inganäs, L., Eriksson, M., Segerdahl, N., Ågren, A., Ekman-Joelsson, B. M., Sunnegårdh, J., Verdicchio, M., & Östman-Smith, I. (2009). Impact of pulse oximetry screening on the detection of duct dependent congenital heart disease: A Swedish prospective screening study in 39 821 newborns. *BMJ (Online)*, 338(7687), 145–148. <https://doi.org/10.1136/bmj.a3037>
- Haghsefat, K., & Tingting, L. (2020). FDM 3D Printing Technology and Its Fundamental Properties. *ICIRES - International Conference on Innovation and Research in Engineering Sciences, June*.
- Hanafi, M., Rahim, A., Azrul, M., Mohd, H., & Ba-, M. Z. (n.d.). *Infant-Wrap (InfaWrap) device as Pediatric Technology Tool : The heart rate and SpO² monitoring for Neonates*. 1–8.

Hanafi, M., Rahim, A., Azrul, M., Mohd, H., & Zairi, M. (n.d.). *Improving the Infant-Wrap (InfaWrap) Device for neonates using MyI-Wrap Mobile Application*. 1–11.

Health checks for babies | Pregnancy Birth and Baby. (n.d.). Retrieved November 1, 2021, from <https://www.pregnancybirthbaby.org.au/health-checks-for-babies>

Henson, R. K. (2001). Understanding internal consistency reliability estimates: A conceptual primer on coefficient alpha. *Measurement and Evaluation in Counseling and Development*, 34(3), 177–189.
<https://doi.org/10.1080/07481756.2002.12069034>

Hewitt, T. L. (1990). *Blood Pressure and Heart Rate Monitoring Method and Apparatus*. 19, 1–5.
<https://linkinghub.elsevier.com/retrieve/pii/0375650585900112>

Hulin, C., Cudeck, R., Netemeyer, R., Dillon, W. R., McDonald, R., & Bearden, W. (2001). Cronbach's alpha on two-item scales. *Journal of Consumer Psychology*, 10(1–2), 55–69.
<http://www.sciencedirect.com/science/article/pii/S105774080170246X>

Hutchon, D. J. R. (2016). The normal range of heart rate at birth in a healthy term neonate: A critical review of the evidence. *Current Pediatric Research*, 20(1–2), 7–10.

Incarbone, L., Evain, S., Ben Hassen, W., Auzanneau, F., Dupret, A., Bonhomme, Y., Morel, F., Gabet, R., Solange, L., & Zanchetta, A. (2015). OMTDR based integrated cable health monitoring system SmartCo: An embedded reflectometry system to ensure harness auto-test. *Proceedings of the 2015 10th IEEE Conference on Industrial Electronics and Applications, ICIEA 2015, June*, 1761–1765.
<https://doi.org/10.1109/ICIEA.2015.7334396>

IoT in Healthcare Industry | IoT Applications in Healthcare - Wipro. (n.d.). Retrieved November 1, 2021, from <https://www.wipro.com/business-process/what-can-iot-do-for-healthcare-/>

Islam, M. M., Rahaman, A., & Islam, M. R. (2020). Development of Smart Healthcare Monitoring System in IoT Environment. *SN Computer Science*, 1(3).
<https://doi.org/10.1007/s42979-020-00195-y>

ISO/ASTM International. (2015). ISO/ASTM 52900: Additive manufacturing - General principles and Terminology. *International Standard*, 5(978-84-9042-335-6), 1–26.

<https://www.iso.org/obp/ui/#iso:std:69669:en%0Ahttps://www.iso.org/standard/69669.html%0Ahttps://www.astm.org/Standards/ISOASTM52900.htm>

- Jim Moon, Devin Mc Combie, Marshal Dhillon, M. B. (2017). Body-Worn Pulse Oximeter. In *United States Patent* (Vol. 2, Issue 12).
<https://patentimages.storage.googleapis.com/92/1e/93/4d38e05e76b128/US9596999.pdf>
- Jr, J. F. H., Black, W. C., Babin, B. J., Anderson, R. E., Black, W. C., & Anderson, R. E. (2018). *Multivariate Data Analysis*. <https://doi.org/10.1002/9781119409137.ch4>
- Katre, S., Dakhole, P., & Patil, M. (2020). IoT based healthcare monitoring systems: A review. *Journal of Advanced Research in Dynamical and Control Systems*, 12(6 Special Issue), 51–57. <https://doi.org/10.5373/JARDCS/V12SP6/SP20201006>
- Keogh, S., Flynn, J., Marsh, N., Higgins, N., Davies, K., & Rickard, C. M. (2015). Nursing and midwifery practice for maintenance of vascular access device patency. A cross-sectional survey. *International Journal of Nursing Studies*, 52(11), 1678–1685. <https://doi.org/10.1016/j.ijnurstu.2015.07.001>
- Kheir, A. E. M., & Hamza, M. E. M. (2016). Pattern of Oxygen Saturation, Heart Rate and Respiratory Rate in Healthy Term Neonates in Khartoum State. *Journal of Basic and Applied Research International*, 19(2), 105–110.
- Kim, G., & Bae, J. (2017). A novel approach to forecast promising technology through patent analysis. *Technological Forecasting and Social Change*, 117, 228–237. <https://doi.org/10.1016/j.techfore.2016.11.023>
- Kimmo, J., Data, R. U. S. A., Examiner, P., & Winakur, E. F. (2000). *United States Patent* (19). 19.
- Kitsommart, R., & Phatthanasiriwetin, S. (2005). Accuracy and Precision of Digital Temperature Measurement. *Siriraj Medical Journal*, 57(5), 128–131.
- Krishnan, D. S. R., Gupta, S. C., & Choudhury, T. (2018). An IoT based Patient Health Monitoring System. *Proceedings on 2018 International Conference on Advances in Computing and Communication Engineering, ICACCE 2018*, 1(I), 1–7. <https://doi.org/10.1109/ICACCE.2018.8441708>
- Kusuoka, H., Yamane, T., & Chairperson, D. (2016). *Discussions on Evaluation of*

Medical Devices in Pediatric Use Subcommittee on Evaluation of Medical Devices in Pediatric Use Subcommittee on Evaluation of Medical Devices in Pediatric Use. 17, 1–8.

- Lasensky, P. J., Fehrenbach, M. E., & Rohmann, R. E. (2009). (12) United States Patent Date of Patent : *System and Method for Programming a Weighing Scale Using a Key Signal To Enter a Programming Mode*, 1(12), 14.
- Lealin, S. (2015). Stress Analysis, Frame Analysis and Calculation of Metal Structures in Inventor Software. *Applied Mechanics and Materials*, 809–810(February), 871–877. <https://doi.org/10.4028/www.scientific.net/amm.809-810.871>
- Lindekugel, E., Medina, Lily, A., & Raley, D. (2003). (43) *INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT). 1.*
- Lou, D., Chen, X., Zhao, Z., Xuan, Y., Xu, Z., Jin, H., Guo, X., & Fang, Z. (2013). A Wireless Health Monitoring System based on Android Operating System. *IERI Procedia*, 4, 208–215. <https://doi.org/10.1016/j.ieri.2013.11.030>
- Lu, Y. C., Wang, C. C., Lee, C. M., Hwang, K. S., Hua, Y. M., Yuh, Y. S., Chiu, Y. L., Hsu, W. F., Chou, Y. L., Huang, S. W., Lee, Y. J., & Fan, H. C. (2014). Reevaluating reference ranges of oxygen saturation for healthy full-term neonates using pulse oximetry. *Pediatrics and Neonatology*, 55(6), 459–465. <https://doi.org/10.1016/j.pedneo.2014.02.004>
- Malaysia Medical Device Target Market | Andaman Medical.* (n.d.). Retrieved March 4, 2022, from <https://andamanmed.com/target-markets/malaysia/>
- Memon, S. F., Memon, M., & Bhatti, S. (2020). Wearable technology for infant health monitoring: A survey. *IET Circuits, Devices and Systems*, 14(2), 115–129. <https://doi.org/10.1049/iet-cds.2018.5447>
- Merrick, E., & Hayes, T. (1976). Continuous noninvasive measurement of arterial blood oxygen levels. *Hewlett-Packard*, 28(2), 1–10. <http://www.rsp-italy.it/Electronics/Magazines/HP Journal/1976-10.pdf>
- Miyasaka, K., Shelley, K., Takahashi, S., Kubota, H., Ito, K., Yoshiya, I., Yamanishi, A., Cooper, J. B., Steward, D. J., Nishida, H., Kiani, J., Ogino, H., Sata, Y., Kopotic, R. J., Jenkin, K., Hannenberg, A., & Gawande, A. (2021). Tribute to Dr. Takuo Aoyagi, inventor of pulse oximetry. In *Journal of Anesthesia* (Vol. 35, Issue

- 5). Springer Singapore. <https://doi.org/10.1007/s00540-021-02967-z>
- Modi, D., Vyas, J., & Shah, P. (2014). *Android based patient monitoring system 1*. *I(9)*, 790–793.
- Morley, C. J., Hewson, P. H., Thornton, A. J., & Cole, T. J. (1992). Axillary and rectal temperature measurements in infants. *Archives of Disease in Childhood*, *67*(1), 122–125. <https://doi.org/10.1136/adc.67.1.122>
- Nakib Ul Hasan, M., & Negulescu, I. I. (2020). *Wearable technology for baby monitoring: a review*. *6*(4), 112–120. <https://doi.org/10.15406/jteft.2020.06.00239>
- Necessities, H., Or, M., Science, V., & Therapy, R. (2020). *Cooperative Patent Classification Human Necessities Medical or Veterinary Science ; Hygiene*. 1–10.
- Ngo, T. D., Kashani, A., Imbalzano, G., Nguyen, K. T. Q., & Hui, D. (2018). Additive manufacturing (3D printing): A review of materials, methods, applications and challenges. *Composites Part B: Engineering*, *143*, 172–196. <https://doi.org/10.1016/j.compositesb.2018.02.012>
- Palmer, B. R., Stough, C., Harmer, R., & Gignac, G. (2009). *Assessing Emotional Intelligence* (Issue April 2009). <https://doi.org/10.1007/978-0-387-88370-0>
- Parreira, P., Sousa, L. B., Marques, I. A., Santos-Costa, P., Cortez, S., Carneiro, F., Cruz, A., & Salgueiro-Oliveira, A. (2020). Usability assessment of an innovative device in infusion therapy: A mix-method approach study. *International Journal of Environmental Research and Public Health*, *17*(22), 1–13. <https://doi.org/10.3390/ijerph17228335>
- Patil, M., Madankar, A., & Khandait, P. D. (2019). Heart Rate Monitoring System. *2019 5th International Conference on Advanced Computing and Communication Systems, ICACCS 2019, May 2018*, 574–576. <https://doi.org/10.1109/ICACCS.2019.8728501>
- Paul Levin, Santa Cruz, C. (1998). *Adjustable pulse oximetry sensor for pediatric use*. *19*, 1–6. <https://patents.google.com/patent/US5991648A/en?q=pediatric&q=pulse+oximeter&oq=pediatric+pulse+oximeter>

- Data Bridge Market Research*. (n.d.). Retrieved January 14, 2022, from <https://www.databridgemarketresearch.com/reports/global-pediatric-medical-devices-market>
- Perez, A., Van Der Meer, F., & Singer, D. (2019). Target body temperature in very low birth weight infants: Clinical consensus in place of scientific evidence. *Frontiers in Pediatrics*, 7(JUN), 1–7. <https://doi.org/10.3389/fped.2019.00227>
- Pole, Y. (2002). Evolution of the pulse oximeter. *International Congress Series*, 1242(C), 137–144. [https://doi.org/10.1016/S0531-5131\(02\)00803-8](https://doi.org/10.1016/S0531-5131(02)00803-8)
- Pratap, R., Javaid, M., Haleem, A., & Suman, R. (2020). *Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID- 19 . The COVID-19 resource centre is hosted on Elsevier Connect , the company ' s public news and information . January.*
- Product, R., Environ-, D., Containers, M. T., Cases, L. S., Cases, L. S., & Materials, S. H. (2008). *Standard Test Method for Drop Test of Loaded Containers by Free Fall I. 98(Reapproved 2004)*, 1–8.
- S, D. A., Arisgraha, F., & Apsari, R. (2016). Bradycardia and Tachycardia Detection System With Artificial Neural Network Method. *Indonesian Journal of Tropical and Infectious Disease*, 3(2), 86. <https://doi.org/10.20473/ijtid.v3i2.206>
- Sainsbury, C. P. Q., Gray, O. P., Cleary, J., Davies, M. M., & Rowlandson, P. H. (1986). Care by parents of their children in hospital. *Archives of Disease in Childhood*, 61(6), 612–615. <https://doi.org/10.1136/adc.61.6.612>
- Severinghaus, J. W. (2007). Takuo aoyagi: Discovery of pulse oximetry. *Anesthesia and Analgesia*, 105(SUPPL. 6), S1. <https://doi.org/10.1213/01.ane.0000269514.31660.09>
- Shan, H., Su, J., Badiu, F., Zhu, J., & Xu, L. (2006). Modeling and simulation of multiple impacts of falling rigid bodies. *Mathematical and Computer Modelling*, 43(5–6), 592–611. <https://doi.org/10.1016/j.mcm.2005.06.009>
- Smit, M., Dawson, J. A., Ganzeboom, A., Hooper, S. B., Van Roosmalen, J., & Te Pas, A. B. (2014). Pulse oximetry in newborns with delayed cord clamping and immediate skin-to-skin contact. *Archives of Disease in Childhood: Fetal and Neonatal Edition*, 99(4), 309–315. <https://doi.org/10.1136/archdischild-2013->

- Song, Y., Li, Y., Song, W., Yee, K., Lee, K. Y., & Tagarielli, V. L. (2017). Measurements of the mechanical response of unidirectional 3D-printed PLA. *Materials and Design*, *123*(February 2017), 154–164. <https://doi.org/10.1016/j.matdes.2017.03.051>
- States, U., & Accountability, G. (2011). *Report to Congressional Committees PEDIATRIC MEDICAL DEVICES Provisions Support Development , but Better Data Needed for Required Reporting. December.*
- Structures, M. B. (1983). Evaluation of Pulse Oximetry. *Anesthesiology*, *59*(4), 349–351.
- Tempelman, E., Dwaikat, M. M. S., & Spítás, C. (2012). Experimental and Analytical Study of Free-Fall Drop Impact Testing of Portable Products. *Experimental Mechanics*, *52*(9), 1385–1395. <https://doi.org/10.1007/s11340-011-9584-y>
- Tofail, S. A. M., Koumoulos, E. P., Bandyopadhyay, A., Bose, S., O’Donoghue, L., & Charitidis, C. (2018). Additive manufacturing: scientific and technological challenges, market uptake and opportunities. *Materials Today*, *21*(1), 22–37. <https://doi.org/10.1016/j.mattod.2017.07.001>
- Us, C. A., Lamego, M., Us, C. A., Merritt, S., Forest, L., Us, C. A., Dalvi, C., Forest, L., Ni, O., Lesmana, F., Niguel, L., Us, C. A., Olsen, G., & Llp, B. (2020). (12) *United States Patent. 1.*
- Valsalan, P., Baomar, T. A. B., & Baabood, A. H. O. (2020). IoT based health monitoring system. *Journal of Critical Reviews*, *7*(4), 739–743. <https://doi.org/10.31838/jcr.07.04.137>
- Wang, H., Chen, S., Huang, L., & Wang, Y. C. (n.d.). 8 th International LS-DYNA Users Conference Simulation and Verification of the Drop Test of 3C Products. *Mechanical Engineering*, 7–18.
- Wilkinson, C. R., & De Angeli, A. (2014). Applying user centred and participatory design approaches to commercial product development. *Design Studies*, *35*(6), 614–631. <https://doi.org/10.1016/j.destud.2014.06.001>
- Wilson, I., Devon, R., & Hospital, E. (2009). Pulse Oximetry – Part 1 Anaesthesia

Tutorial of the Week 123. *Atotw*, *June*, 1–7.

Zhu, Z., Liu, T., Li, G., Li, T., & Inoue, Y. (2015). Wearable sensor systems for infants. *Sensors (Switzerland)*, *15*(2), 3721–3749. <https://doi.org/10.3390/s150203721>