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# Business Analysis of FlexPacer: The Viability and Profitability of Rechargeable Pacemakers

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# The Viability and Profitability of Rechargeable Pacemakers

**by**

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## Executive Summary

Heart disease being as prominent as it is in the United States enables medical technology manufacturers to create lucrative businesses and products for cardiothoracic and cardiovascular physicians and patients. As a proposed rechargeable pacemaker (PM) that uses piezoelectric energy harvesting technology, FlexPacer has the chance to eliminate the need for battery replacement surgeries. This paper aims to outline the current issues in PM products and technology, identify the potential risks and benefits of FlexPacer, and discuss FlexPacer's potential for profitability.

## Introduction

With heart failure affecting 5.8 million Americans and 200,000 pacemakers (PM) being inserted annually, the effectiveness and profitability of these products has become increasingly important. [1, 2] Tens of thousands of lives are saved with the help of pacemaker technology, but not without a cost. Hospitals usually purchase an average PM for between $4,000 and $6,250. [14] The average cost of implanting a PM is $14,290. [21] Unfortunately, because a PM's battery life only lasts 5 – 7 years on average, many patients must endure and finance this procedure more than once. [12]

Not only does undergoing this procedure more than once have financial consequences, but it also increases the probability of surgical complications and other risks (such as surgical site infection) for the patients. Bai's article for Stanford University further discusses the issue of PM battery longevity and how implanting new PMs can expose patients to serious complications. [4] Bai explains that a PM with shorter battery life means having to perform more replacement surgeries, "...which come with a 1 – 5 percent infection rate." [4] Furthermore, up to 80 % of PMs are implanted in elderly patients averaging 75 years old. [3] Research shows that putting elderly patients under general anesthesia can also have dire consequences and add additional risks to this procedure. [3, 27]

FlexPacer, a proposed rechargeable pacemaker, aims to solve the issue of short battery life in PMs. By doing so, FlexPacer would provide a more cost effective and safe PM option for hundreds of thousands of Americans. Research has proven the feasibility of rechargeable PMs, so why hasn't this technology been put to work? [14] I will analyze the attitude towards rechargeable PMs, the benefits, costs, and risks of using this technology, and the barriers to entry and process of approval for this product. I will use the analysis of these factors to present a business case for FlexPacer that will help determine whether FlexPacer is a beneficial and profitable product.

## Statement of the Problem

The American Heart Association originally projected that 100 million Americans would be diagnosed with cardiovascular disease by 2030. [5] However, by 2015 the United States had already surpassed this benchmark. Now the AHA has revised their original estimation and cautions that 45 % of the U.S. population and more than 131 million patients will be impacted by cardiovascular disease by 2035. [5] *Figure 1,* from the American Heart Association (AHA) and

American Stroke Association (ASA), shows how the population of Americans with various heart diseases (such as any cardiovascular disease [CVD], hypertension, coronary heart disease [CHD], congestive heart failure [CHF], stroke, and atrial fibrillation [AFib]) will steadily increase through 2035. [5]

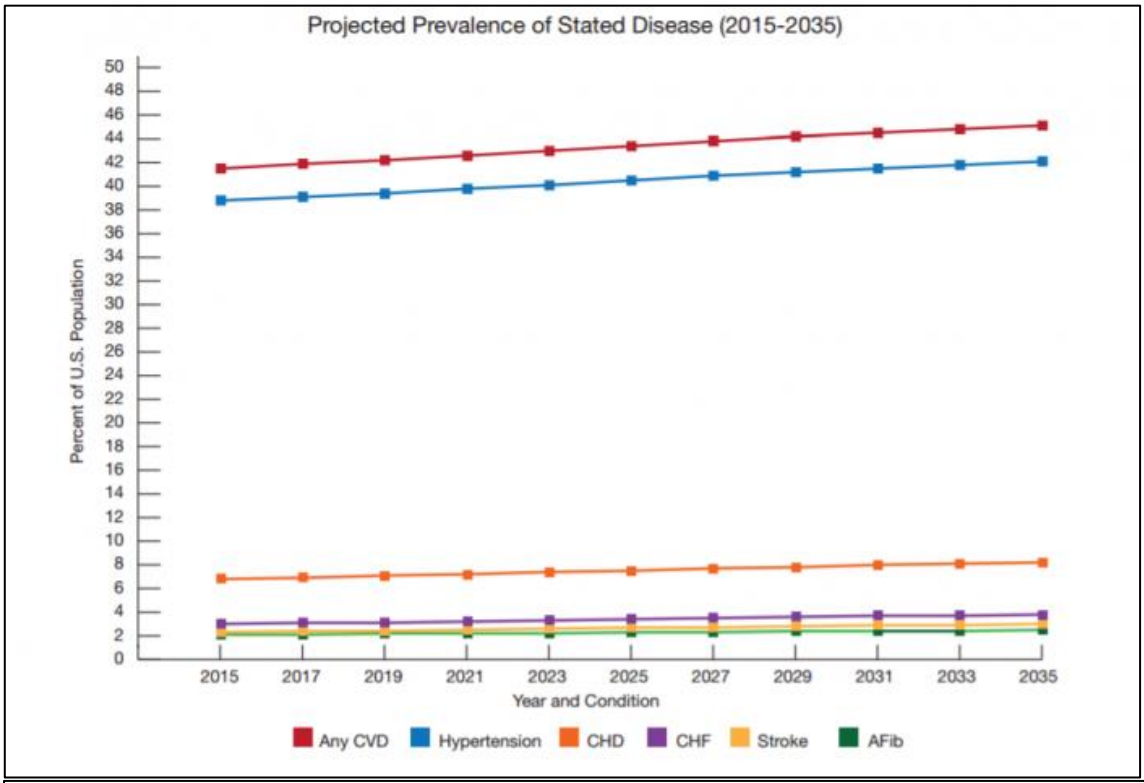


*Figure 1*. Cardiovascular Disease: A Costly Burden for America - Projections through 2035. Shows the increase of U.S. population with heart disease, specifically AFib. [5]

With the number of Americans affected by cardiovascular disease consistently increasing, the market for life saving products, such as pacemakers, becomes exponentially more important, specifically for those patients with AFib. One of the biggest shortcomings of pacemaker (PM) technology is the fact that the lifespan of PM batteries is often not long enough, resulting in patients having to undergo multiple surgeries to replace these batteries. There has been significant technological advancement in PM design, generator size, and battery longevity. PMs are now able to last, on average 5 – 7 years. [12] This is a substantial improvement from the original 1960s PM, but PM battery life innovation has seemed to stall here. Despite feasibility for rechargeable PM being proven, few steps have been taken to turn this kind of product into reality. There are various reasons why this is the case. Some physicians are not willing to accept a new, experimental product into their practice at the risk of losing their reputation and credibility. Some manufacturers are reluctant to support R&D for rechargeable PMs because it would eventually lead to a decrease in the number of PMs implanted per year. However, we have to consider and determine whether PM manufacturers and physicians have a social responsibility to innovate and do their part in advancing this technology for their patients or not. Along with the determining responsibility of physicians and manufacturers to strive to provide the best possible option for their market, eliminating the need to implant new PMs once the previous

PM's battery has died would solve other issues such as surgical complications of implanting the new PM, surgical complications and risks of putting the elderly (average age demographic for PM patients) under anesthesia, unaffordability, and the environmental impact of excess medical device waste.

Replacing pacemakers exposes patients to surgical complications, such as life-threatening infections. These infections could potentially cause cardiac sepsis, which is frequently fatal among patients with pre-existing heart conditions. A study found that there are surgical complications in 3 – 4 % of cases. [3] Looking at the age demographic of average PM patients, we see that over 80 % of PM patients are considered "elderly". [3] When performing surgical procedures on the elderly, one must consider the additional risks that come with putting older patients with pre-existing heart conditions under general anesthesia. Strom, Rasmussen, and Seiber discuss the different complications that can occur when putting elderly patients under anesthesia. [28] This research shows that it is better to put elderly patients under anesthesia as little as possible, which current PM technology does not allow for. To be able minimize the amount of time elderly patients spend under anesthesia the PM industry must work towards a rechargeable pacemaker, which FlexPacer proposes.

The cost of implanting pacemakers is nowhere near what the average person would refer to as "affordable". On average, this procedure and the PM itself cost ~$14,290. [16, 23] Additionally, patients will have to incur this cost multiple times depending on their age, the lifespan of their individual PMs battery, etc. FlexPacer would be able to reduce these costs for both patients and hospitals by removing the need for battery replacement surgeries. Hospitals usually purchase individual PMs at an average price of $4,000 - $6,250, based on the proposed Bill of Materials (BOM), producing each FlexPacer unit would only cost ~4,000 rupees (which converts to roughly 53.73 USD), creating an incredible profit margin for manufacturers. [17] Understanding the severity of the world's climate crisis and being environmentally conscious is being more important every day, so we must consider the environmental impact of the PM industry. U.S. hospitals produce nearly 6 million tons of medical waste each year, which includes the waste from removing old PMs. [22] When PMs are replaced, not only is the battery discarded, but the entire PM is replaced, even though the rest of the PM is still functional. This means there are actual tons of working PM parts being put into landfills each year. By decreasing the number of procedures performed, the number of PMs inserted, and the number of PMs discarded, FlexPacer becomes the more cost effective and environmentally conscious option. The previous paragraphs explain the shortcomings of current pacemaker technology, such as price, excess waste, safety concerns, etc. Now I will discuss how FlexPacer and rechargeable PMs can be used to solve these issues.

# Discussion of Solution

## *Benefits*

FlexPacer, a proposed rechargeable pacemaker (PM) would eliminate the need for patients to undergo multiple implantation procedures due to dead PM batteries. Eliminating the need to replace PM batteries, FlexPacer reduces the risk of surgical site infection and other complications of this procedure, which typically occur in 3 – 4 % of cases (specifically those

complications found in elderly surgical patients). [3, 28] By being able to reduce the number of PM implantation procedures and the number of times elderly patients are put under general anesthesia, FlexPacer directly reduces the number of PM implantation-related complications that occur per year. Considering that FlexPacer is able to reduce these numbers, it is clear that a rechargeable PM is much more cost effective than what is currently being used. Hospitals typically have to pay anywhere between $4,000-$6,250 for an average PM. [17] The Bill of Materials (BOM) [*Figure 4*] shows that it would most likely cost ~4,000 rupees (or $53.73) to produce each FlexPacer unit [14]. FlexPacer is able to be produced at a very low cost, meaning manufacturers have the opportunity to dramatically increase their profit margin. FlexPacer also enables hospitals to decrease costs. Furthermore, FlexPacer is able to reduce the number of PMs implanted and discarded. All of these factors ensure that FlexPacer is the most cost-effective option for hospitals/manufacturers and the most financially responsible PM for patients.

Research by the American Heart Association (AHA) and the American Stroke Association (ASA) shows that the already huge population of Americans affected by cardiovascular issues will continue to grow through 2035. [Figure 1] [5] By getting ahead of the curve and investing in rechargeable PMs, companies will be able to take advantage of this growing market and show their dedication to corporate social responsibility and corporate social innovation. Economist Milton Friedman believed that a corporation's sole purpose and goal should be to make as much money for their shareholders as possible. [8] However, a study by Cone Communications stated that 70 % of Americans believe that corporations have an additional responsibility to take action and, "...improve social and environmental issues…" [7]. This being said, pacemaker manufacturers have an opportunity to show their commitment to corporate social responsibility and innovation by risking a decrease in production to innovate and create a more cost effective, environmentally friendly, and safe pacemaker option for their future patients.

As previously mentioned, U.S. hospitals produce nearly 6 million tons of medical waste each year, including the waste from removed PMs. [22] Waste from medical device manufacturing can include solvents, wastewater, and unused medical devices. [13] Corporate social responsibility also plays a role in environmentally friendly manufacturing. In Europe, the medical technology industry, "...recognizes its duty to act responsibly and work in a sustainable way." [10] FlexPacer and the idea of rechargeable PM technology gives U.S. manufacturers the opportunity to take advantage of an untapped market and produce in a more eco-friendly and efficient way at the same time. Innovating and utilizing the groundbreaking technology to create a rechargeable PM gives manufacturers the chance to market FlexPacer at a higher price to make up for the difference in profits from the inevitable production of less PMs.

*Figure 2.* Perceived User Value (PUV) [14]

| | Total Score | Safety | Infection Rate | Comfort | Feasibility | Surgical Risk |
|---|---|---|---|---|---|---|
| | | 5 = significantly safer | 5 = significantly lower | 5 = no need to change daily routine | 5 = established base technology in healthcare | 5 = lessens chance for human error |
| | | 3 = current | 3 = current | 3 = some critical daily change | 3 = established base technology in other field | 3 = current process/approach |
| | | 1 = significantly more unsafe | 1 = significantly higher | 1 = severe restriction | 1 = theory plausible, but not proven | 1 = more complex than current surgery |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | 0 = hospital bound/bedridden | | |
| FlexPacer | 23 | 5 | 5 | 5 | 5 | 3 |
| Traditional | 19 | 3 | 3 | 5 | 5 | 3 |
| Multipliers | | X2 | X2 | | | X2 |
| FlexPacer (w/ multiplier) | 36 | 10 | 10 | 5 | 5 | 6 |
| Traditional (w/ multiplier) | 28 | 6 | 6 | 5 | 5 | 6 |

*Figure 2* shows that when considering variables such as cost effectiveness, safety, infection rate, comfort, feasibility, and surgical risk, FlexPacer or a PM with a rechargeable battery is perceived to be more valuable than a traditional PM. Specifically, FlexPacer is able to significantly reduce infection rates and is viewed as significantly safer than a traditional PM. This is because the use of a rechargeable battery eliminates the need for implanting new PMs after a patient's first PM is implanted, which then removes the complications that would usually stem from replacing the old PMs.

*Figure 3.* Minimum Viable Product (MVP)

| FlexPacer/Rechargeable PM | Traditional PM |
|---|---|
| • Rechargeable battery<br>• Battery uses piezoelectric energy harvesting technology to produce electricity from the vibration that is produced by the beats of the heart, itself (meaning the battery is constantly charging)<br>• One-time implantation<br>• Decreased production cost | • Must be replaced every 5-7 years<br>• Multiple implantation procedures required<br>• Requires more PMs to be produced<br>• Entire PM discarded when battery dies |

## *Costs*

*Figure 4.* Bill of Materials (BOM) [14]

| **Vendor** | **Link** (available in references) | **Item Name** | **Quantity** | **Price** (in rupees) (Item & Shipping) | **Usage/Rationale** |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| Amazon | Item #1 | Arduino start-up kit | 1 | 2,300 | |
| Amazon | Item #2 | Piezoelectric sensor* | 5 | 750 | |
| | | Microprocessor | 1 | ≈ 2,000 | |
| Digi-Key | Item #3 | DAC (Digital Analog Converter) | 1 | 300 | Converts the digital inputs of the pulse sensor to analog for filtering |
| ElectronicsComp | Item #4 | Pulse Sensor | 1 | 205 | |
| | | Stepper motor* | 1 | | External power for heart |
| | | Sponge* | 4 | | Model of the heart |

*Available from InnAccel

Based on *Figure 4*, we can see that the production cost of FlexPacer would be extremely low, roughly 4,000 rupees ($53.73) per unit. However, because FlexPacer uses groundbreaking piezoelectric energy harvesting technology to recharge the PM, it will be able to be marketed at a higher price, creating a robust profit margin. Because FlexPacer also eliminates the need to have multiple PMs implanted over one's lifetime, the manufacturer will be able to increase the sale price even more. Many patients would rather pay more now and never have to have their PM replaced, than have to purchase a new PM every 5 – 7 years, when their traditional PM battery dies. [12]

## *Time-Scale*

Overtime manufacturers of FlexPacer will be able to gradually decrease their cost of production, this is because of economies of scale. [15] As the manufacturer continues manufacturing FlexPacer and as the number of FlexPacer units being produced increases, production will become more efficient and lead to lower production costs, thus increasing FlexPacer's profit margin.

## *Risks*

While the feasibility of a rechargeable pacemaker (PM) has been proven, of course there are risks associated with this new technology. [26] According to Dr. Richard Fogoros, there are two main reasons that rechargeable PMs have failed in the past. First, even though they're rechargeable, the NiCad batteries that were originally used to create a rechargeable PM had a very short service life, so they still required replacement after a few years, defeating the point of the recharging ability. [26] Second, the technology required that the patients themselves recharge

their PMs by following a rigorous schedule. [26] This resulted in PM companies risking being held liable for the PM failure, whether or not the failure was the fault of the company or the patient, and furthermore, risking bankruptcy. [26]

This obviously made the idea of rechargeable PM batteries very unattractive to PM companies. Especially considering that a rechargeable PM battery would mean producing less PMs, which decreases profits for companies like Medtronic (producer of half the world's PMs). [16]

Calkin discusses how rejecting rechargeable PMs is not only about protecting the financial interests of these companies. [16] He discusses how in the medical market 10 years is a very long time. When pacemakers are removed, it isn't only the battery that is replaced, it is the entire pacemaker. Because a patient will only need to replace their PM every 5 – 7 years, it is to be expected that there has been technological advancement, since their first PM was implanted. Their new device could be smaller, more efficient, etc. so for many patients, Calkins believes it is in their best interest to replace their PM, not only because the battery must be replaced, but also because if they do not, they could miss out on valuable technological advancements. [16] Furthermore, Calkins and Nesbitt (a cardiac electrophysiologist whose opinion on rechargeable PMs is included later) both agree that they would rather perform the procedure to replace the battery, than depend on a new, unpredictable rechargeable battery because the timeline for replacing said battery is gradual and very predictable. Because of these reasons, Calkins is very pessimistic about the future of rechargeable PM batteries. [16]

### *Barriers to Entry*

There are many factors to consider when researching how new technologies will be accepted by medical professionals and patients. In my interview with Dr. Nesbitt, who is a cardiac electrophysiologist (meaning he specializes in heart rhythm problems, such as bradycardia), he discussed his hesitation with accepting and using new technology in his practice. As someone who has been practicing medicine for a number of years and has been able to build a practice of his own, Nesbitt explained how important his reputation and the relationship he has with his patients is to the success of his practice. The issue with this new technology is that for him to be willing to incorporate it into his practice, it must be extremely regulated and have a virtually non-existent complication rate. He would much rather continue using the technology he is using now than risk both his reputation and his patients' wellbeing.

Dr. Nesbitt mentioned how when he first began practicing medicine, he took part in a study for rechargeable pacemakers. Unfortunately, the study was unsuccessful and resulted in him having to take out all the PMs that he inserted. From here I wanted to analyze how the attitude toward using new technology can differ between those medical professionals with their own practices, who have been practicing medicine for many years versus the attitude of those physicians working at a teaching hospital or who have less experience and less of a reputation under their belt.

A survey by Medscape found the following:

> "Medscape surveyed 1423 healthcare providers, including 847 physicians, and 1103 patients to assess their attitudes toward emerging technologies in medicine. The survey found that

> physicians' attitudes toward technology correlated with their age. The greatest proportion of physicians who felt that technology was exciting and use it as often as possible were younger than 35 years; in contrast, the greatest proportion of physicians who felt that technology was 'a bit beyond me' were older than 55 years." [24]

Which reinforces that there is a divide in attitudes towards these new technologies. It is understandable for a physician to be cautious and protective of their reputation and their relationship with their patients. However, it is also imperative that these new technologies be utilized to continue to encourage technological advancement and ensure that patients are given the best possible option, especially when something as important as your heart is being affected. This is where teaching hospitals and medical schools play a vital role. They hold the most potential for being able to utilize and experiment with new technologies because they don't have to risk a groomed reputation, they are still learning.

Another barrier to entry for this kind of product is the passing the process of approval. The process of approval for medical devices by the Food and Drug Administration (FDA) is a long and rigorous one and will be discussed in detail under the *Process for Approval* section.

### *Process for Approval*

The first step of getting most medical devices approved is to put the device under laboratory and animal testing to ensure the device is safe. Next, the device's data from its laboratory study is reviewed by the FDA. The FDA then classifies the medical device based on its potential risk. Class I devices are very low risk, such as oxygen masks and surgical tools and Class III devices support or sustain life, such as PMs. Because Class III devices are inherently riskier, they must undergo premarket approval (PMA), which is, "...the most stringent approval process for medical devices in the U.S." [25]. In addition to this intense process, it costs a manufacturer, on average, $94 million to put a Class III medical device through PMA and into the market, whereas it only costs $31 million for Class I devices.

Not only does manufacturing a Class III medical device require incredible financial support, but it also requires an abundance of patience. In 2009, it took PMA an average of 427 days to decide on the approval of medical devices. [11] Within 6 years, they were able to reduce this number by 35 %. [11] However, the approval process can still take anywhere from 3 – 7 years. [21]

These factors result in manufacturers preferring to not submit their device for approval by PMA if they can help it. But one advantage to going through with the grueling process that is PMA is that it is much more difficult for consumers to sue the device manufacturers, decreasing their liability. [11] Because of the cost and the time that manufacturing a new medical device requires, the process for approval is one of FlexPacer's largest barriers to entry.

# Conclusion

In conclusion, after a careful analysis of the benefits, costs, risks, environmentally impact, etc., we have been able to determine that FlexPacer is a beneficial and profitable product. FlexPacer enables pacemakers to solve issues such as, surgical complications from implanting new PMs, risks of putting elderly patients under anesthesia, and excessive waste. FlexPacer is able to

directly decrease complication rates by removing the need for additional PM implantation procedures, saving both hospitals and patients money. FlexPacer and the idea of rechargeable PMs introduces an important issue in the medical field and in medical device production. FlexPacer is one example of the divide between the medical field and corporate social responsibility, some medical technology manufacturers are reluctant to innovate and create better products because of the risk of rendering their old products obsolete, and some physicians are unwilling to use new technologies because they worry about damaging their reputation or relationship with their patients. As corporate social responsibility becomes more important to customers and patients, manufacturers and physicians will have to take these risks to show that their focus is not on their bottom line, but on what is best for their customers/patients.

Rechargeable PMs are the most cost effective and environmentally conscious option in the realm of PMs. FlexPacer has a relatively low production cost per unit, and because of FlexPacer's innovative technology, it will be able to be marketed at a higher sell price (which is pleasing to manufacturers) but cost less in the long run because customers will not have to undergo multiple implantation procedures (which is attractive to both hospitals and patients). Further, because of economies of scale, overtime manufacturers of FlexPacer will be able to gradually decrease their cost of production. Lastly, because rechargeable PMs will decrease the number or PMs inserted annually, rechargeable PMs will also decrease the amount of waste that is produced from removing and discarding PMs with old batteries. In summary, the reasons previously listed make it abundantly clear that FlexPacer is a profitable product and investing in FlexPacer's technology is not only environmentally and socially beneficial, but also beneficial for manufacturers who are ahead of the curve and invest in rechargeable PMs early.

### *Future Plans*

Technically, the next step for FlexPacer is to create a physical prototype. Meaning the team must analyze different insertion methods and construct a prototype based on the most cost effective and functional method. In a business sense, the next step for FlexPacer is to begin branding and marketing this evidence to various manufacturing companies in hopes of finding a manufacturer that can provide the abundant financial support that is necessary to approve new medical devices and begin the premarket approval process. Rechargeable PMs are the future of PM technology but for it to be successful it is imperative that the complication rate be as low as possible and the technology be marketed properly. There are opposing views on the future of PMs, so it is essential that the technology be marketed in a way that is going to be accepted by every teaching hospital. Once the technology is able to prove itself at the teaching hospital stage, the hope is for it to weave its way into private practices through younger and more adventurous physicians.

# Appendix

## *References*


1. Guha A, Xiang X, Haddad D, Buck B, Gao X, Dunleavy M, Liu E, Patel D, Fedorov VV, and Daoud EG, "Eleven-year Trends of Inpatient Pacemaker Implantation in Patients Diagnosed with Sick Sinus Syndrome," Journal of Cardiovascular Electrophysiology, vol. 28, iss. 8, pp. 933-943, Jun 2017.
2. Bhatia N, and El-Chami M, "Leadless Pacemakers: A Contemporary Review," Journal of Geriatric Cardiology, vol. 14, iss. 4, pp. 249-253, Apr 2018.
3. "Are Elderly at Increased Risk Following Pacemaker Implantation?" *Medscape*, 23 Feb. 2012, www.medscape.com/viewarticle/758640_4#:~:text=Surveys%20have%20shown%20that%20up,%25%E2%80%934%25%20of%20cases.
4. Bai, James. "Pacemaker Battery Longevity", *Stanford University*, 30 Nov. 2017, http://large.stanford.edu/courses/2017/ph240/bai1/.
5. "Cardiovascular Disease: A Costly Burden for America - Projections Through 2035." *American Heart Association, American Stroke Association*, 2017, http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_491543.pdf
6. Cingolani, Eugenio, et al. "Next-Generation Pacemakers: from Small Devices to Biological Pacemakers." *Nature Reviews. Cardiology*, .U.S. National Library of Medicine, Mar. 2018, www.ncbi.nlm.nih.gov/pmc/articles/PMC6261336/.
7. Cone Communications CSR Study, conecomm.com/research-blog/2017-csr-study, https://static1.squarespace.com/static/56b4a7472b8dde3df5b7013f/t/5947dbcf4f14bc4eadcd025d/1497881572759/CSRInfographic+FINAL2.jpg
8. "Corporate Social Responsibility in Health Care: No Such Thing." *PNHP*, 10 June 2016,pnhp.org/2016/06/10/corporate-social-responsibility-in-health-care-no-such-thing/.
9. "Corporate Social Responsibility in Healthcare." *Health Works Collective*, 17 June 2020, www.healthworkscollective.com/corporate-social-responsibility-healthcare-sectors/.
10. "The Environmental Impact of Medtech." *MedTech Europe*, 9 Oct. 2018, www.medtecheurope.org/news-and-events/default/the-environmental-impact-of-medtech/.
11. "FDA Approval - Process of Approving Drugs & Medical Devices." *Drugwatch.com*, www.drugwatch.com/fda/approval-process/.
12. "Frequently Asked Questions About Pacemakers and Implantable Cardioverter Defibrillators (ICDs)." *Johns Hopkins Medicine*, www.hopkinsmedicine.org/health/treatment-tests-and-therapies/frequently-asked-questions-about-pacemakers-and-implantable-cardioverter-defibrillators-icds.
13. General Kinematics. "Waste Disposal for Medical Device Manufacturers." *General Kinematics*, General Kinematics, 31 May 2018, www.generalkinematics.com/blog/waste-disposal-for-medical-device-manufacturers/#:~:text=Typically%2C%20unused%20medical%20device%20waste%20is%20incinerated%20or,sent%20to%20landfills%20if%20they%20cannot%20be%20recycled.
14. S. Gururaj, A. Applequist, S. Bhattarai, A. M. Appaji and P. Kadambi, "Self-Powered Cardiac Pacemaker: The Viability of a Piezoelectric Energy Harvester," *2020 International Conference on COMmunication Systems & NETworkS (COMSNETS)*, Bengaluru, India, 2020, pp. 70-75.
15. Kenton, Will. "Economies of Scale." *Investopedia*, Investopedia, 4 Mar. 2021, www.investopedia.com/terms/e/economiesofscale.asp.
16. LaFrance, Adrienne. "Who Killed the Rechargeable Pacemaker?" *The Atlantic*, Atlantic Media Company, 5 Feb. 2014, www.theatlantic.com/health/archive/2014/02/who-killed-the-rechargeable-pacemaker/283365/.
17. Lee, Jaimy. "CRT-P Pacemaker Prices Drop 12% as Hospitals Step up Bargaining Pressure." *ModernHealthcare*, 12 May 2014, www.modernhealthcare.com/article/20140512/NEWS/305129923/crt-p-pacemaker-prices-drop-12-as-hospitals-step-up-bargaining-pressure#:~:text=CRT%2DP%20pacemakers%2C%20which%20are,was%20flat%20year%20over%20year.
18. Meier, B. Hip implants U. S. rejected sold overseas. *New York Times*, February 12, 2012: A1.

19. "The Need for Corporate Accountability in Healthcare Organizations." *George WashingtonUniversity*, 18 Dec. 2019,healthcaremba.gwu.edu/blog/need-corporate-accountability-healthcare-organizations/.
20. Nemo, Leslie. "New Wireless Pacemaker Could Prevent Common Complications." *Scientific American*, Scientific American, 1 Sept. 2017, www.scientificamerican.com/article/new-wireless-pacemaker-could-prevent-common-complications/.
21. Norman, Gail A. Van. "Drugs, Devices, and the FDA: Part 2: An Overview of Approval Processes: FDA Approval of Medical Devices." *JACC: Basic to Translational Science*, Elsevier, 27 June 2016, www.sciencedirect.com/science/article/pii/S2452302X16300183.
22. Overstreet, Sarah. "INFOGRAPHIC: 10 Things to Know About Medical Waste Compliance." *Sharps Compliance Blog*, 19 Jan. 2021, blog.sharpsinc.com/10-things-to-know-about-medical-waste-compliance#info.
23. "Pacemaker and Implantable Cardioverter-Defibrillator (ICD) Implant Procedures in California Hospitals." *Berkeley Center for Health Technology*, https://bcht.berkeley.edu/sites/default/files/Vol.2.8.Pacemakers.pdf
24. *Physician and Patient Attitudes Toward Technology in Medicine*, www.medscape.com/features/slideshow/public/technology-in-medicine.
25. "Premarket Approval (PMA) Process - Medical Device Safety." *Drugwatch.com*, www.drugwatch.com/fda/premarket-approval/.
26. Richard N. Fogoros, MD. "Why You Get A Whole New Pacemaker When Your Battery Is Low." *VerywellHealth*, www.verywellhealth.com/pacemaker-low-battery-replacement-1746230.
27. Stewart, Conor. "Pacemakers Market Volume Worldwide in Units 2023 Forecast." *Statista*, 22 Oct. 2020, www.statista.com/statistics/800794/pacemakers-market-volume-in-units-worldwide/.
28. Strøm, C, et al. "Should General Anaesthesia Be Avoided in the Elderly?" *Anaesthesia*, U.S. National Library of Medicine, Jan. 2014, www.ncbi.nlm.nih.gov/pmc/articles/PMC5207212/.
29. "Working Strategically toward a More Sustainable Medtech Industry." *Elos Medtech*, 4 July 2018, elosmedtech.com/working-strategically-toward-a-more-sustainable-medtech-industry/.

## *Bill of Materials (BOM) Item Links*

Item #1
https://www.amazon.in/gp/product/B00BT0NDB8/ref=ox_sc_act_title_2?smid=AE0J5NJKQBP5F&psc=1

Item #2
https://www.amazon.in/Easy-Electronics-Piezoelectric-Sensor-Transducer/dp/B073WD9Z18/ref=sr_1_1?keywords=Piezoelectric&qid=1571214541&sr=8-1

Item #3
https://www.digikey.in/product-detail/en/texas-instruments/DAC0808LCN%2FNOPB/DAC0808LCN%2FNOPB-ND/4653?cur=INR&lang=en&utm_adgroup=Data+Acquisition&mkwid=sBUCuEVJm&pcrid=381185762156&pkw=&pmt=&pdv=c&productid=4653&&gclid=Cj0KCQjw_5rtBRDxARIsAJfxvYDNu2AtLqhGRQZ4pNhm8c4hmyICQV6jxP22PACtLyfTUiqMG-Ep22QaAmdkEALw_wcB

Item #4
https://www.electronicscomp.com/pulse-sensor-india?gclid=Cj0KCQjw_5rtBRDxARIsAJfxvYDA2oIkQq8ql0UKBwkVi2KGteMqPQUx2uih2WIUr7Lr0osJwdQy5bEaApXKEALw_wcB