



Review of Smartphone-Connected Pacemakers

Paige Willms, PharmD Candidate 2025¹

¹*University of Findlay College of Pharmacy*

Abstract

Smartphones have quickly become an important accessory in everyday life. With the growing rise of smartphone applications, it seems that a person can do anything with their phone. The use of a smartphone has even reached the medical field. Companies are now focusing on ways to help patients become more connected to their healthcare. There are many different health aspects that can be monitored via a smart device, and heart health is now one of them. The Azure™ pacemaker is a pacemaker that is able to sync to an application on a smart device allowing patients to connect to their medical information anytime, anywhere.



Since the 1950s, many medical advances have been made to the pacemaker. A traditional pacemaker is a small device that is implanted in the chest to help control the heartbeat.¹ There are three main types of pacemakers: the single chamber, dual chamber, and the biventricular pacemaker. The single chamber pacemaker is used to carry electrical impulses to the right ventricle of the heart.¹ The dual chamber pacemaker is used to regulate the timing of contractions between the two chambers of the heart by sending electrical impulses to the right ventricle and the right atrium of the heart.¹ The biventricular pacemaker is used in patients suffering from heart failure and heartbeat abnormalities.¹ This type of pacemaker uses electrical impulses to stimulate the right and left ventricles of the heart resulting in a more controlled heartbeat.¹

Pacemakers have two general parts, the pulse generator, and the leads. The pulse generator is a small metal container that contains the battery as well as the electrical circuitry that controls the rate of the electrical impulses that are sent to the heart.¹ The leads, or electrodes, are flexible wires that are placed in the chambers of the heart.¹ The electrical signal is carried along these wires and helps control the pace of the heart.

Pacemakers are used to help control the heart in order to keep it beating regularly. Pacemakers can help to correct problems with the SA node, the natural pacemaker. The

SA node sends electrical signals to the heart to keep it beating at regular intervals.² When the SA node is not functioning properly it can cause bradycardia (abnormally slow heartbeat), or tachycardia (abnormally fast heartbeat).²

Another condition that would require the need for a pacemaker to be implanted, would be atrial fibrillation. Atrial fibrillation causes the heart to beat irregularly and often times too quickly.² This condition is also associated with heart palpitations.²

Pacemakers are also used to treat certain types of heart blocks. Depending on the severity of the heart block, a pacemaker can be used. Heart blocks occur when regions of the heart are blocked, causing electrical signal sent by the SA node to travel incorrectly through the heart.² This inhibits the SA node from communicating with the heart correctly, which can cause the heart to beat irregularly.² When the signal being sent from the SA node is unable to be received, the AV node is able to keep the heart beating.² Since this isn't the AV nodes' primary responsibility, it is not able to keep the heart beating as well as the SA node can. This results in the heart beating much slower than normal.² The implantation of a pacemaker is able to stabilize this signal and keep the heart beating properly.

The different types of pacemakers are used to treat different types of heartbeat abnormalities.



Like most chronic illnesses, the use of a pacemaker must be monitored. It is extremely important that the device is monitored so that malfunctions can be recorded and corrected.¹ It is also important for the battery life of the device to be monitored so that patients know when it will need to be changed. Pacemaker batteries usually last 5 to 15 years.¹ Surgery will be needed in order to replace the battery, so it is beneficial to have a general idea how much life is left in the battery.

Monitoring heart rate is also helpful for physicians. Knowing when and how frequently a patient is having an irregular heartbeat can be important for monitoring the disease state.³ This helps to track progression and improvement, as well as show if any changes need to be made to the current therapy.³ Pacemakers may be adjusted to change the strength and the length of the impulses being sent to the heart muscle to control how fast the heart will beat.³ The process of checking a pacemaker's settings is called interrogation.³ The special programming tool is placed over the patient's chest and the information from the pacemaker is sent directly to the doctor.³ The information can be transmitted from the doctor's office or from the patient's home.³ Transmitters that a patient can use at home are connected to a phone line or internet and help to decrease the frequency of visits to their doctor's office.³

Many issues with the transmitters can arise. For example, if a patient is supposed to send this information at a specific time, it is possible that they could forget. Additionally, if a patient is away from home, they may not have access to their transmission machine. This can lead to lack of adherence to and monitoring.

With the advance in technology over the last few decades, it seems like no one can go anywhere without their smartphone. With this in mind, Medtronic, a medical technology company based in Ireland, created the world's first smartphone-connected pacemaker.⁴ Azure™ is available in both a single chamber and a dual chamber model.⁴ The Azure™ pacemaker features BlueSync technology which enables automatic and secure wireless remote monitoring via the Medtronic CareLink Network.⁴ The Azure™ pacemaker uses the BlueSync technology to connect to the MyCareLink Heart (MCLH) app and allows patients to monitor their pacemaker at any moment.⁴

The Azure™ pacemaker was approved by the by U.S. Food and Drug Administration on November 20, 2017.⁴ Since this initial release, Medtronic has created three other types of pacemakers featuring the BlueSync technology.

The Azure™ pacemaker not only features the BlueSync technology but is also more efficient than previous models. The Azure™ pacemaker has improved longevity



up to 15.8 years which shows a 24 percent improvement from previous models.⁷ This update reduces the amount of device replacements required. This helps to reduce the amount of risk associated with routine surgeries for device maintenance because less maintenance will be required. Patients using the Azure™ pacemaker also have the ability to have MRI scans.⁷

Although this technology isn't new, it has been gaining traction over the past few years. The Cleveland Clinic ranked the "smartphone-connected devices" number three on its annual Top 10 Medical Innovations for 2021.⁵ Also stating that the "breakthrough technology of these devices allows for patients to gain great insight into the health data from the pacemakers and to transmit the health information to their physicians."⁵

In a study published in May 2020 by Medtronic the MCLH mobile app was compared to traditional bedside monitoring devices.⁷ The study found that on average patients using the MCLH completed 30 percent more of their scheduled remote monitoring transmissions to their health care provider than patients using the traditional bedside monitors.⁷ Not only is the app useful for regular maintenance transmission, but the implanted device has the ability to transmit alerts in emergency situations.⁵

The convenience and accuracy of the remote monitoring can be very useful, but like everything it has its drawbacks. Because

this remote monitoring relies on the internet and the use of a smartphone application, it is at risk for a cyber-attack. Medtronic ensures users that their information is secure but does not provide how the information is secured.⁴ The pacemaker is not directly connected to the internet so that it is not able to be controlled by another device.⁹ The pacemaker is only able to transmit data.⁹ This data is encrypted within the pacemaker before being sent to the application.⁹ The encryption is created using NIST government standard encryption.⁹ Fortunately, so far there has not been any hacking or cyber attacks reported with the use of these devices, but that does not mean there will not be one in the future.⁸ Cyber safety is a factor that should be considered before choosing to use these devices.

Another drawback to smartphone connected pacemakers is that they are not able to be used in all patients. Pacemakers in general may be contraindicated for a patient for a variety of reasons. The Azure™ specifically, cannot be used in patients that are contraindicated due to the use of another bradycardia device.¹⁰ This device also cannot be used in patients who cannot tolerate pacing rates above the programmed Lower Rate, or in patients with persistent supraventricular tachycardias.¹⁰

There is also the potential for adverse events associated with the implantation of the device. The patient could develop an air embolism, bleeding, cardiac dissection or



ARCH

Annual Review of Changes in Healthcare



perforation, endocarditis, and many more complications.¹⁰ These risks for an adverse event can be associated with all pacemakers.¹⁰

In conclusion the ability to closely monitor a pacemaker is exceedingly important. Providing patients and caregivers a better way of monitoring a patient's pacemaker may help to create better health outcomes for the patient. It will be interesting to see how pacemaker technology will be further advanced in the future.



References

1. Pacemaker [Internet]. Mayo Clinic. Mayo Foundation for Medical Education and Research; 2021 [cited 2022Jan17]. Available from: <https://www.mayoclinic.org/tests-procedures/pacemaker/about/pac-20384689>
2. NHS choices. NHS; [cited 2022Apr10]. Available from: <https://www.nhs.uk/conditions/pacemaker-implantation/why-its-done/>
3. Cardiac device monitoring [Internet]. Cardiac Device Monitoring | Michigan Medicine. [cited 2022Jan17]. Available from: <https://www.uofmhealth.org/health-library/aa108095>
4. Medtronic plc. Medtronic announces FDA approval and U.S. launch of Next Generation Pacemakers [Internet]. GlobeNewswire News Room. Medtronic plc; 2017 [cited 2022Jan17]. Available from: <https://www.globenewswire.com/news-release/2017/11/20/1197522/0/en/Medtronic-Announces-FDA-Approval-and-U-S-Launch-of-Next-Generation-Pacemakers.html>
5. Smartphone-connected heart devices among top innovations for 2021 [Internet]. Medtronic News. [cited 2022Jan17]. Available from: <https://news.medtronic.com/connected-heart-devices-named-top-innovation>
6. Kelly S. Medtronic Links Patients' pacemakers with their smartphones [Internet]. MedTech Dive. 2019 [cited 2022Jan17]. Available from: <https://www.medtechdive.com/news/medtronic-links-patients-pacemakers-with-their-smartphones/546175/>
7. iData Research. Medtronic's newest form of communication with the heart [Internet]. iData Research. 2020 [cited 2022Jan17]. Available from: <https://idataresearch.com/medtronics-newest-form-of-communication-with-the-heart/>
8. Kapoor A, Vora A, Yadav R. Cardiac devices and cyber attacks: How far are they real? how to overcome? [Internet]. Indian Heart Journal. Elsevier; 2020 [cited 2022Apr10]. Available from: <https://www.sciencedirect.com/science/article/pii/S0019483220300237?via%3Dihub>
9. Medtronic. Azure pacing system [Internet]. Home. [cited 2022Apr10]. Available from: <https://europe.medtronic.com/xd-en/healthcare-professionals/products/cardiac-rhythm/pacemakers/azure.html>
10. Instructions printing instructions - manuals.medtronic.com [Internet]. [cited 2022Apr10]. Available from: https://manuals.medtronic.com/content/dam/emanuals/neuro/M006348C002A_view.pdf