WHITE PAPER

MEDICAL DEVICE DEVELOPMENT ON MOBILE PLATFORMS – INSIGHTS INTO BEST PRACTICES ON HARDWARE CONSIDERATIONS AND SOFTWARE DEVELOPMENT

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1. Introduction.

Mobile devices are immensely popular and pervasive. As 5G software ushers in more bandwidth, it will also bring in a better quality of video streaming, thus boosting bandwidth-intensive medical applications. The development of medical applications using mobile platforms has disrupted the healthcare industry delivering a host of benefits and leading to greater adoption of these technologies.

Medical applications on mobile platforms go beyond fitness or wellness as medical device manufacturers venture into remote patient monitoring or address critical functions such as programming Cardiac Implantable Electronic Devices (CIED).

This document presents a view on the considerations for creating medical devices on mobile platforms or integrating medical devices with mobile platforms. We also look at aspects to be considered while developing software for medical devices on mobile platforms.

The document addresses architectural and design considerations and provides best practices to be adopted. These views are derived from the author's experience developing Class 3 Medical device software on mobile platforms.

In addition, this document -

- Does not focus on any specific mobile operating system that can be used as part of medical software development.
- Does not focus on the regulatory details that need to be provided when using Off-The-Shelf (OTS) software. The reader can refer to regulatory guidance such as document [1] listed in the Reference section

2. Target Audience

The document targets medical product designers and medical application developers who intend to use mobile platforms. It explores hardware design impact and best practices for developing mobile platforms-based software for medical devices that need regulatory approval. It also presents potential architectural and design solutions derived from the author's experience, which can be utilized.

3. Usage of mobile platforms in medical devices – A market perspective

The adoption of mobile platforms to develop healthcare applications has disrupted the healthcare industry in recent years. As a result, mobile applications were mostly in the realm of fitness and activity tracking but have now entered areas such as diagnosis, monitoring and even treatment of chronic diseases.

Integrating the mobile application with medical devices significantly disrupts the delivery of treatment. Some examples include continuous glucose monitoring wearable sensors integrated with a mobile application, cardiac implants programmed using applications running on mobile platforms and cardiac monitoring implants managed by mobile apps. [10],[9].

Amid the COVID-19 crisis, the global market for Mobile Medical Apps was estimated at USD 6.6 Billion in the year 2022 and is projected to reach a USD 16.6 Billion by 2026, growing at a CAGR of 25.5% over the analysis period. Medical Monitoring, one of the segments analyzed in the report, is projected to grow at a 25.3% CAGR to reach USD 5 Billion by the end of the analysis period. [11]

4. Why choose mobile platforms for medical device software development?

There are several reasons why medical device manufacturers adopt mobile platforms as part of medical device development, including -

- Mobile devices are owned by the majority of healthcare providers, caregivers and patients
- Mobile devices ensure intuitive user experiences such as touch, swipe, pinch to zoom and tap to medical apps
- Mobile devices offer excellent network connectivity options such as Cellular mobile networks, Wireless LAN networks, Bluetooth networks and NFC communication
- Mobile app deployment strategy is well understood and can be easily adapted to incorporate app security practices, software downloads and app rollouts.

5. Design choices when creating medical devices using mobile platforms

Developing medical device apps on mobile platforms presents a new set of challenges that medical device manufacturers must address. Some of the challenges and ways to overcome them are discussed below.

5.1 Hardware design impacts

Medical devices are typically designed using custom hardware that delivers all the functionality expected from the device. However, when medical devices are created by integrating them with mobile platforms, the design of the hardware system will change.

So, the hardware functions unique to the medical device must be identified to create specialized hardware components to deliver those functions. In addition, commercial-off-the-shelf mobile platform features such as network connectivity and display must be harnessed. As a result, all medical device features can be realized by integrating the commercial off-the-shelf mobile platform with specialized hardware components.

For example, a Cardiac Implantable Electronic Device (CIED) Programmer uses a commercial-off-the-shelf mobile platform to display ECG waveforms. The programmer connects to a specialized ECG hardware system and programs the CIED through the same mobile platform by utilizing its network connectivity feature.

5.2 Wireless connectivity to other systems

Medical devices may use proprietary radio technologies, But when medical devices are created on mobile platforms, hardware must adapt to use popular wireless network technologies such as Bluetooth. Secure network connections then become a challenge.

5.3 Secure network connectivity

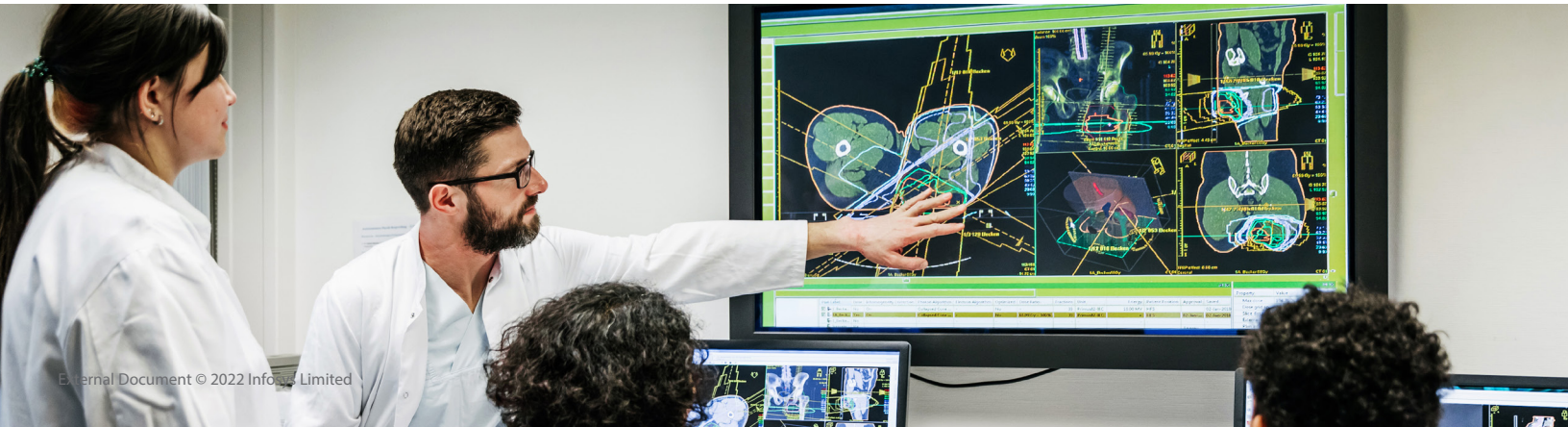
Medical devices using proprietary wireless communication based on inductive telemetry have a secure mode of communication. However, with newer wireless technologies like Bluetooth emerging, medical device software will need to be designed for secure communication.

5.3.1 Application software to be designed for secure network communication

- Trusted remote connection – Design the medical device communication to connect only to a known gateway. Provide the details of the communication link to the gateway over an out-of-band close-range wireless communication link like NFC.
- Data transfer security – Adopt a secure data transfer strategy, such that data encryption is done both at the network and the application layers. Adopt an out-of-band communication link, such as NFC or inductive telemetry, to transfer the encryption keys. Use encryption keys of a minimum of seven octets recommended by wireless standard bodies, e.g., Bluetooth SIG in the Bluetooth Core Specification.[3]
- Data Integrity checks – Ensure data is always encapsulated into packets with a cyclic redundancy check (CRC). The receiver should then evaluate the CRC for validity.
- Malicious attacks on the medical device - The medical device could be subject to malicious attacks. One way to mitigate an attack is for the medical device to discard the data when it finds the received data is invalid on opening a connection. Then, terminate the connection based on repeated occurrences of invalid data received.
- Software Patch Upgrades- Cyber vulnerabilities may risk the safe operation of networked medical devices using OTS mobile platforms. Put in place a well-defined mechanism to apply software patches from the OTS software vendor on time. [2]

5.4 Network co-existence issues

- As medical devices adopt popular wireless technologies like Bluetooth, tests need to be done to verify if wireless connectivity drops because of interference with other network technologies in the operating environment.
- For example, Wi-Fi networks operating in the 2.4GHz radio frequency could cause Bluetooth connection interference, resulting in Bluetooth connections dropping. Network configurations may need to be altered to ensure Wi-Fi routers use the 5GHz band and have Wi-Fi devices connect to this band.



5.5 Upgrade strategy

When using mobile platforms, medical devices can utilize software upgrade mechanisms available for mobile applications in the Google "Play Store" or the Apple "App Store," for example. These bring in the benefits of remote software upgrades but will need a more secure strategy to upgrade, as discussed below.

- Remote software upgrades- The software upgrades can happen through the platform app stores. Typically, a two-phase strategy would be adopted. The first phase would be to deploy the medical application from a device manufacturer hosted app server. The next phase would be to deploy the application from the standard mobile platform app stores.
- Software partitioned for secure deployment- We recommend partitioning the software into libraries representing the device manufacturer's core IP or offering generic functionality. The core IP software can be deployed through the device manufacturer hosted app server, thus ensuring the download happens after authentication. The generic libraries can be downloaded through the platform app stores.

5.6 User experience impact

Medical devices typically tend to be developed using custom display panels with wider displays. Application design and the display will be impacted when they are being designed on mobile platforms. We suggest these best practices -

- Display - The display screen sizes of commercially available phones or tablets will need to be considered. If existing medical device applications are to be migrated to mobile platforms, there may be a need to redesign existing screen layouts and screen navigation patterns.
- Other application Interference - The mobile application design will need to ensure that it will not be interrupted by other messaging or call applications, when in the foreground. These can be achieved by using the interfaces provided by the mobile platform.

6. Ease of incorporating newer technologies such as Artificial Intelligence – AI

The use of AI algorithms for image analysis in medical imaging solutions is increasing. AI algorithms are useful in applications such as medical imaging and diagnosis, hospital workflow management, and drug discovery with technologies such as Machine Learning (ML) and Natural Language Processing [8]

- Mobile platforms have specialized AI chips that power ML algorithms supported by AI APIs. Many ML frameworks, such as TensorFlow Lite and CoreML, are optimized on mobile platform hardware. Medical application developers can use these to create medical apps that incorporate AI. [4][5]

7. Software test automation strategy

The length of the validation phase is highly significant during the development of medical device software and could account for as much as 40% of the software development lifecycle. These best practices can be adopted to reduce the time spent -

- Tap into the mobile platform provided test automation tools like Robotium [7] or off-the-shelf commercially available mobile test automation tools from vendors such as digital.ai [6].
- Automation tools can help monitor the system's CPU usage and memory while executing the tests and can throw light into any memory issues that the software may be causing.

8. Summary

Here is a recap of the best practices discussed in the document -

- When medical devices are created by integrating them with mobile platforms, the design of the hardware system will change. So, identify the hardware functions unique to the medical device and create specialized hardware components to deliver those functions. Then, use the commercial-off-the-shelf mobile platform features such as network connectivity and display.
- Mobile platforms have specialized AI chips that power ML algorithms. Therefore, capitalize on the platform provided AI API that is hardware accelerated for optimal performance.
- As medical devices adopt popular wireless technologies like Bluetooth, medical device software will need to be designed for secure communication. Adopt a secure data transfer strategy such that data encryption is done both at the network and application layers. Adopt an out-of-band communication link, such as NFC or inductive telemetry, to transfer the encryption keys.
- For remote software upgrade strategy, adopt a two-phase approach. In the first phase, deploy the medical application from the device manufacturer hosted app server. In the next phase, deploy the application from the standard mobile platform app stores
- Design the mobile application so it will not be interrupted by other messaging or call applications, when in the foreground.
- Use the mobile platform provided test automation tools or off-the-shelf commercially available mobile test automation tools.

The adoption of mobile platforms to create medical devices can transform medical products and drive innovation. The powerful features of wireless connectivity that comes with mobile platforms can streamline workflows where these medical products are deployed. In addition, careful hardware partitioning into core device features and non-core features, such as display and network connectivity, can deliver cost optimization to the product. Successful creation of medical devices on mobile platforms can be achieved through careful design of hardware and software using the best practices followed by industry leaders, as discussed in the paper.

About the Author

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