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Signal Processing For Medical Device Development

Dr. Nidhi Mishra[1], Venu Anand Das Vaishnav[2], Soumi De[3]
[1]Assistant Professor, Department of CS & IT, Kalinga University, Raipur, India.
ku.nidhimishra@kalingauniversity.ac.in, 0009-0001-9755-7950
[2]Assistant Professor, Department of Pharmacy, Kalinga University, Raipur, India.
ku.venuananddas@kalingauniversity.ac.in, 0009-0005-3775-6156
[3]Assistant Professor, New Delhi Institute of Management, New Delhi, India., E-mail: soumi.de@ndimdelhi.org, https://orcid.org/0009-0007-3615-2291

Abstract

Software development for a medical device has to take into account what motivates the product's value by examining the market (i.e., the end user) while factoring in the feasibility, regulatory, and safety nuances involved with its use. In contrast to most consumer-software firms, which can beta test new applications with a large, diverse group of end users. In the initial phase of the software development life cycle, officially the idea or concept phase, clinical professionals will examine the customer (the doctor) and the marketplace. Next, in collaboration with clinical partners, cardiac professionals will create proposals for possible new product concepts or reasons for redesigns that would be advantageous to the physician customers and, ultimately, the patients being treated. From there, proposals are commented upon by software engineers based on feasibility, time, cost, and other related requirements that could pose development issues. The design & development phase is where most of the design work takes place and gets documented, and where most of the costs of developing a new product are incurred. The next step is to draft the software requirements specification (SRS) and user requirements specification (URS) after the terms of product development have been agreed upon. The SRS describes the specific features and anticipated performance of the program, while the URS identifies the physician's needs, which is somewhat self-evident.

Keywords: *EEG, frequency, diagnose epilepsy, biomedical*

1. INTRODUCTION

Risk management activities start at the design & development stage and go on throughout the life cycle of the device. For instance, if a software component fails to work, a possible mitigation mechanism could be that the deficiency will have no impact on patient safety. But mitigation mechanisms are not always so simple [1]. The issue may need to be assessed by the Change Control Board (CCB) and go through the FMEA process, depending on the degree of risk management. The development team members who are in charge of overseeing the development process make up the Change Control Board. They will meet on a regular basis to review any changes to the software that have been proposed, issues, defects, etc. Organizations tend to forget the Change Control Board's role, and projects often fail as a result of insufficient CCB intervention [9]. Early communications regarding changes and making sure all stakeholders who need to know are informed about the project needs and objectives, however, are essential to the development process [2]. Advanced signal processing capabilities can fulfill the universal healthcare need for better, more efficient data analysis tools. Digital signal processing means extracting and analysing data and physiological information from the body in order to make clinical diagnosis or treatments better informed. For the case of cardiology, software for signal processing can provide cardiologists with improved cardiac signal information that could potentially enhance physicians' workflow and decision-making as well as procedural outcome [3]. Utilizing this kind of cutting-edge technology takes a properly executed software development process, requirements, and some group of engineers skilled at harmonizing complicated, abstract mathematics and algorithms. Inserting sophisticated software into an implantable cardiac device depends on an information technology professional, a digital signal processing (DSP) engineer.

2. NEED OF THE STUDY

Software is increasingly becoming a key product differentiator in the medical device market. Launching an innovative product is no easy accomplishment, but ensuring your new device remains relevant and

competitive could be the biggest challenge in the marketplace [10]. New or upgraded software is essential to this effort, but developing, updating, and enhancing software capabilities comes with its own set of complications and obstacles to overcome [13].
Then, as the development engineers code to implement the software features, the software test engineers create verification test design (VTD) cases to prove that the product runs in compliance with the intended requirements[4]. VTD is among the most important components of the design and development process and is always listed as number one on the FDA inspection findings. Evolved over time during the software development process, the VTD's are objective progress reports that evaluate whether the software is fulfilling its intended end use and end user requirements. In the event software weakness or failure are encountered, the engineering teams will be required to collaborate in designing mitigation measures [5].

3. MATERIALS AND METHODS

Competitive algorithms rely on the DSP engineer's capability to analyze amounts of signal frequencies and amplitudes to create the best algorithms that consider the end user's requirements, the hospital or healthcare organization's objectives, and the feasibility constraints set by software engineers, clinical trial outcomes, and regulations. After the signal processing engineer has completed designing the optimum software algorithms, the engineer would need to prove their algorithm clinically, then work with the software engineers to put the algorithms in the user interface [6]. During the development life cycle, the utmost importance is maintaining the sophisticated software intuitive to the end user. Software usability is probably the greatest issue in the medical device world, so user requirements defined up front are absolutely necessary throughout the life cycle of the development process [11].

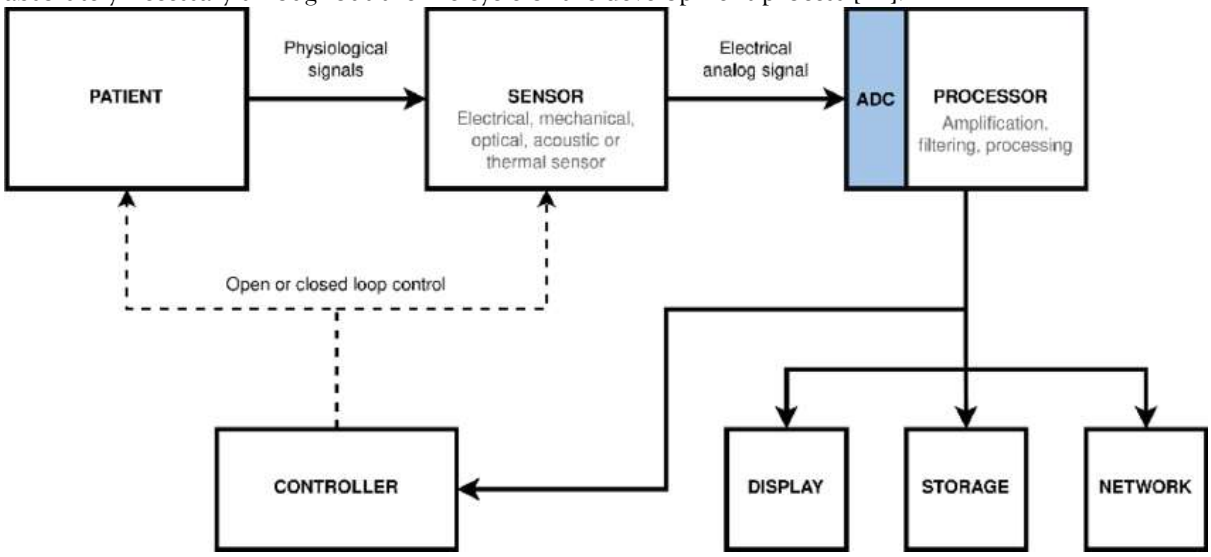


Figure 1: Sample design (source: web)

In my own experience, the only justification for adding an advanced signal processing software is to make the end user more efficient, accurate, and intelligent in what they can accomplish with clinical data. As a clinical decision-support tool, the benefit of this kind of software lies in both the quality of the information that it delivers and the smooth provision of that information to the end-users who require it. Once the development life cycle is finished and the product is ready to be manufactured and distributed, the work of the software engineer is still an important part of the equation. Once the product is released, your business can monitor the end user's experience to gather useful data and confirm product satisfaction. Either via direct observation (heart rates, for example) or by external excitation (ultrasound), a variety of natural occurrences, including those that occur in human bodies, can be detected and transformed into continuous electrical signals. Digital signal processing (DSP) may analyse and inspect the digitized and sampled signal to provide visuals and data that can assist doctors in making the correct diagnosis [7]. DSP can be used on general-purpose processors, embedded processors with DSP extensions, dedicated ASICs, FPGAs, GPUs, and DSP chips. In terms of performance, power, manufacturing cost, development effort, and flexibility, each has advantages and disadvantages. For a portable, mass-market medical device, for example, a dedicated ASIC can provide the best performance, power, and production

cost. However, it would offer the least amount of flexibility but would require incredibly expensive development resources. Although a GPU can provide great flexibility and high performance, in certain applications its cost and power consumption may be unreasonably high. However, GPU is the best option for a high-end ultrasound machine where algorithms are still being developed.

4. RESULT

In A&W, our designers have used algorithm for all platform listed. We can conduct extensive research and supply you with ideal implementation choice. DSP algorithms are written in development environment such as MATLAB, providing an extensive range of design, visualization and analysis tools [7].

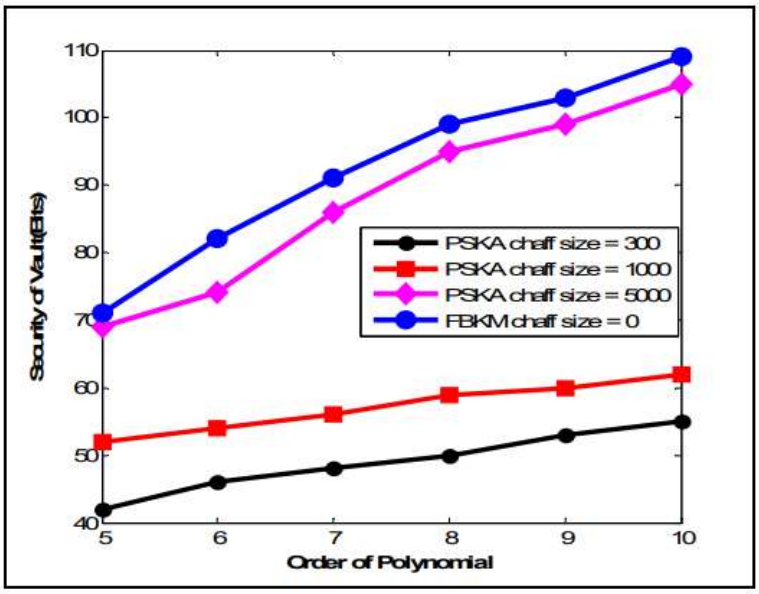
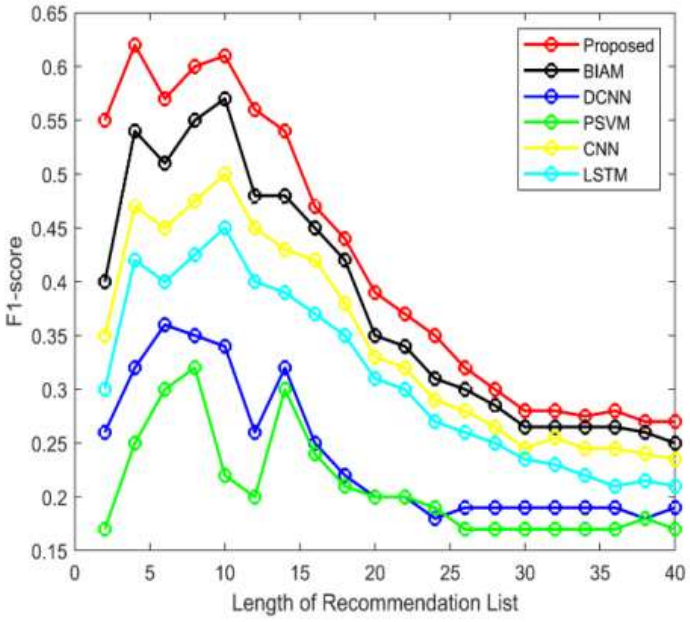
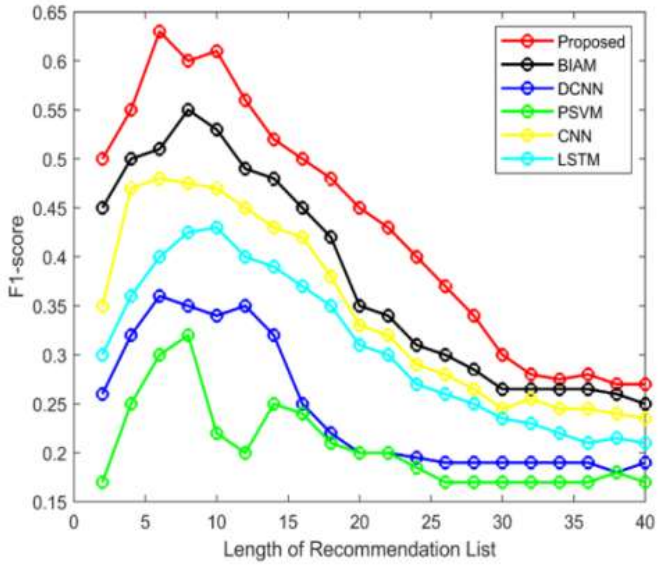


Figure 2: Fuzzy vault Strength

The developer can utilize this environment in order to apply various DSP methodologies and test in short time periods in order to get the result in the required signal or picture. However, using such an environment while collecting real-time data and throughout the implementation process is problematic.



(a)



(b)

Figure 3: F1 comparison curve

A&W have developed a lightweight environment called ADE (algorithm development environment), which includes many of the fundamental tools needed for data analysis and visualization[8]. It can be supplied as an executable that easily interfaces with portable medical data collection hardware and can be quickly installed on a clinician's laptop[12][14]. Large medical corporations and research labs are constantly discovering new developments in medical signal processing. Some of these innovations are improvements to the current modalities that provide faster data rates and higher resolutions [15].

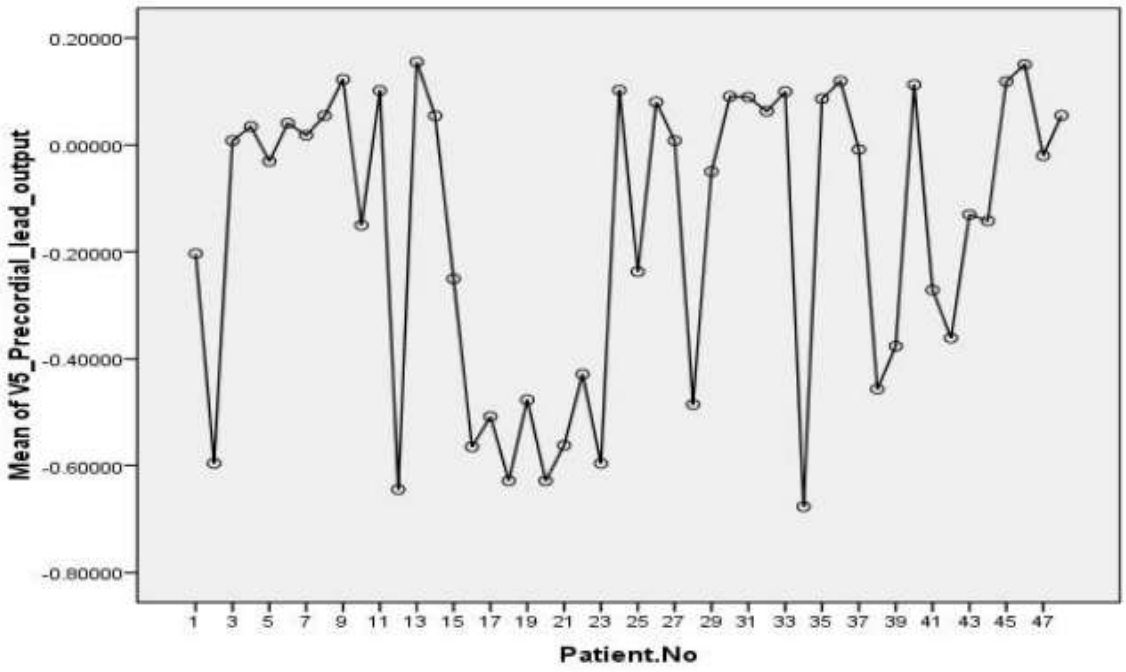


Figure 4: Mean plot for 48 patients

Others focus on new measurement techniques and modalities. Machine learning using medical data and photographs is one of the breakthroughs that is revolutionizing the game. In addition to producing better data or photos, algorithms have made it possible for computers to understand medical data and images. We are establishing a cooperation network at A&W with partners that are capable of bringing these innovations to you.

5. CONCLUSION

Finally, biological diagnosis and therapy may be augmented with robust signal processing methods. To enhance patient outcomes and customized care, scientists and practitioners may apply advanced methods like adaptive filtering, wavelet transform, independent component analysis (ICA), machine learning, and others to mine information from physiological signals and medical images. In spite of technical adversity, interpretability issues, and data privacy issues, policymakers need to promote their proper integration into healthcare systems. Through research and development funding, the development of standards and guidelines, education and training, and cooperation and data exchange promotion, policymakers can maximize the potential of strong signal processing methods to enhance patient outcomes and healthcare delivery. To develop and deploy trustworthy signal-processing techniques in medical applications, there needs to be creativity and cross-disciplinary collaboration. Through the solution of technical problems, ensuring algorithm verification and transparency, and promoting rightful data management, researchers and policy-makers can employ these measures to revolutionize medicine and improve patients' lives. In conclusion, robust signal processing techniques can facilitate improved treatment and biological diagnosis and their ethical incorporation into medical systems can revolutionize medicine. Robust signal processing techniques are capable of revolutionizing healthcare delivery and enhancing patient outcomes with collaboration from researchers, physicians, legislators, and business partners.

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