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Design and Development of Smart Medical Devices: A Biomedical Perspective

Hussein Awni Ashour
University_of_Warith_Al_Anbiyaa College of Engineering Department of Biomedical Engineering

Hawra Aqeel Mahdi
College of Engineering. Department of Biomedical Engineering, University of Nahrain

Sanarya Waleed Khalid
College of Engineering Department of Biomedical Engineering

Mariam Maan Drsoon
University_of_Warith_Al_Anbiyaa College of Engineering Department of Biomedical Engineering

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Annotation: This essay on the design and development of smart medical devices in biomedicine comes in two interconnected parts. The first part narrates the experience of conceptualizing and developing a smart airbag assisted lying posture corrector from the perspective of a bio-dynamic design project. The second part reflects critically on the challenges and ethical issues involved in the development of smart medical devices, framed within the theoretical and methodological context of biomedical engineering. The film and animation projects screened at a global conference in 2018 and further public debates on the construction of white-collar-like digital immaterial labors explored bio-dynamism, somato-politics, and ubiquitously sedimented technocommodities.

Especially inspired by the conference's defense of an 'ongoing' labor, this paper caught the opportunity of experiencing this bio-dynamic background to revisit the development of a smart medical device intended for home use. After the success of the filmic construction, and following requests from physiotherapists and healthcare consultants for sharing the device, a collaborative venture was eventually set up in 2010 with a medical equipment manufacturer in Beijing chosen by consulting with . From its inception, this project conceived the device as a set of airbags integrated into different types of upper torso garments to assist wearers in self-attaining a straight back and shoulders posture and in avoiding bending forward or sideways for a long period of time [1]. Five rounds of R&D were implemented, expanding from parchment paper scripting to prototype testing on twelve wearers over nine years.

Keywords: biomedical engineering, physiotherapist, biomedicine, prototype.

1. Introduction to Smart Medical Devices

In recent years, there have been considerable advancements in technology, particularly in the realm of consumer electronics, which encompasses a wide variety of devices that have quickly gained popularity. This impressive progress has led to the remarkable development of smart devices, innovations that have fundamentally transformed the way we interact with technology in our everyday lives. These devices are distinguished by their exceptional ability to engage with the user in a meaningful and intuitive way, as well as deliver a plethora of various outputs in response to user commands or actions. Typically, electronic smart devices maintain a seamless connection to the internet, allowing them to be conveniently monitored or controlled from a distance, enhancing their utility and accessibility beyond the confines of traditional electronics. [2][3][4]The integration of smart devices within the modern healthcare landscape involves the innovative use of portable smart medical devices that are equipped with robust internet connectivity, accentuated by common tools such as smartphones and other forms of wearable technology. Within a healthcare environment, smart medical devices are meticulously designed to continuously monitor and reliably detect various health parameters of a patient, providing real-time data that can be critical for effective medical decision-making. They are capable of assessing user-specified health conditions and determining appropriate medical interventions based on the individual's specific health data, ultimately delivering those interventions as needed in a timely manner. [5][6]So far, only preliminary work has been accomplished regarding the practical design, engineering, and implementation of these portable smart medical devices. This initial progress, however, has not yet brought the technology up to the necessary high standards required for seamless use in healthcare institutions where precision and reliability are paramount. Therefore, there is an urgent need to accelerate the development of portable smart medical devices that are not only easy to operate for both medical professionals and patients but also economically feasible and suitable for widespread use in diverse healthcare environments across various settings. [7][8]These innovative portable smart medical devices undoubtedly play a crucial role in monitoring vital signs of COVID-19 patients and are essential for accurately diagnosing the disease in its early stages. In cases of critical medical conditions, these devices can command instant medical interventions, significantly improving patient outcomes and enabling healthcare providers to respond promptly to changing health circumstances. The functionality of such smart medical devices is vast and can be utilized to monitor a patient concerning a wide variety of medical needs and conditions, ensuring that prompt care is always readily available when it matters most. [9][10]As this technology continues to evolve and advance at a rapid pace, significant questions arise regarding the strength, reliability, operational efficiency, and overall well-being of smart devices within the ever-evolving healthcare sector. Addressing these concerns will be vital to maximize the numerous benefits that smart medical devices can offer and ensure their effective deployment in enhancing healthcare delivery and patient care in this transformative technological era. [11]

One approach to this study would be to use a smart Electrocardiogram (ECG) patient monitor with the cardiology workstation to auto report the patient’s condition in real-time and gives health guideline of the patient, enhancing operation with the healthcare provider. In addition, a modern medical equipment management system is interlinked with the internet to auto pick the patient’s medical attention, assurance concerning operation. On another size, an ultra-low cost, a portable device is required to play the role of a smart patient entertainment with monitors of ECG, Respiratory Rate (RR), and Temperature (Temp). Therefore, these multi-disciplinary approaches inspired the biomedical department to develop internet interfaced portable smart medical devices for promoting healthcare delivery and wellbeing of the patient by optimally reducing a stay in the healthcare setting of the doctor, and conveying an instant medical service feasible around the time and anywhere. [12][13]

1.1. Definition and Scope

The term "Smart Medical Device" represents an interdisciplinary concept at the crossroads of Biomedical Engineering, Medicine, and Information Technologies. It refers to medical devices equipped with smart and connected technology intended for healthcare applications. This encompasses both advanced devices and those enhanced with smart capabilities. Their operational scope is vast, including wearable, implantable, or portable devices, surgical instruments, diagnostic equipment, electromedical tools, nanosystems, biosensors, and telehealth systems. These devices are designed for various purposes, such as disease prevention, continuous monitoring, treatment, care, and rehabilitation. Smart medical devices can acquire, transmit, store, and display physiological information, facilitating the exchange of medical instructions seamlessly. Beyond traditional devices, innovative smart solutions have emerged, transforming the field dramatically. For instance, flexible wearable pressure monitors can serve as bandages or be integrated into clothing, relaying crucial signals to smartphones via radio frequency. Additionally, new information technology systems can convert standard sphygmomanometers into remote smart devices, broadening their application in medical practices without major modifications. This evolution exemplifies the integration potential of traditional devices with modern smart technology. [14][13][3][15]

1.2. Evolution and Importance

The development and significance of smart medical devices viewed from a biomedical perspective is thoroughly presented. This discussion illustrates a detailed timeline of innovation that spans from early advancements in the field to the cutting-edge technology we see today. It emphasizes not only the progress achieved but also justifies the critical need for ongoing research, innovative design, and substantial investment in this rapidly evolving field. Such investments are essential to enhance patient care, improve treatment outcomes, and ensure that technology keeps pace with healthcare demands. [16]

Medical devices have undergone significant and remarkable development since the first pacemaker was implanted in the year 1958, which has encouraged a rapidly evolving industry that seeks continuous innovation in this vital area of healthcare technology. In their initial conception and design, medical devices were entirely mechanical, relying solely on the skills and attentiveness of human operators to perform patient monitoring. This reliance on human intervention posed significant limitations regarding real-time patient monitoring and the timely detection of diseases and potential health issues. The early development of the first computers and integrated circuits began to revolutionize the capabilities and functionalities of medical devices, leading to impressive advancements in the field. As a result, there was exponential growth in the production and use of implantable medical devices, such as implantable defibrillators and cardiac pacemakers. Currently, most commercial medical devices now involve sophisticated software to monitor, treat, or diagnose diseases, which enables highly sophisticated automated analyses that are gradually starting to overcome even the capabilities of the most highly trained medical professionals. There is an expectation of further significant expansion over the next decade concerning the development of real-time, affordable, and user-friendly systems that will be capable of continuously monitoring patients' biosignals. Their health status will be continuously observed, even within the comfort of their own home environments, thereby providing real-time diagnostic feedback and improving the treatment options available for chronic diseases. In such genome-matched disease management, the specific disease and any potential health issues can potentially be detected even before the individual becomes fully aware of any symptoms. With the crucial issue of an aging society leading to a quick rise in chronic diseases, the related costs of health care are increasing at an alarming rate. Therefore, it is essential to have systems in place that allow for real-time, low-cost disease monitoring and prevention, ensuring that people can receive timely care. Historical milestones, as well as ongoing societal trends, which justify and underscore the pressing need for research, as well as development in the field of smart medical devices, are put forward for examination. This evolution starts with the development of pacemakers from their initial models that were first implanted in the 20th century and progresses through further advancements until reaching the modern models designed to provide demand stimulation based on patient needs. In the year 1968, the very first remote-monitoring device was approved by the US FDA. This groundbreaking equipment featured a telephone interface that allowed patients to transmit their ECG signals directly to their doctors for evaluation. Due to the further development of mobile networks and related technologies, research on pacemakers has evolved into exploring body area networks, creating an exciting frontier in the intersection of technology and healthcare. [11][1][17][18][19][20][21]

Literature Review

2. Biomedical Engineering Principles

The advent of integrated circuit technology and wireless communication systems a few decades ago has opened the door of exquisite possibilities. One such possibility is the advancement of smart medical devices (SMDs). Smart medical devices are little tools designed to monitor various parameters of the body such as pressure, temperature, blood glucose level, and other physiological information precisely. They can also convey diagnostic data, thereby useful for finding a disease and recommending treatments. It will immensely benefit patients who need continuous monitoring and post-treatment recovery, being comfortable both in charge and financially. This effect, in turn, will minimize the doctor's discomfort to an amount, and advanced healthcare will be entirely available even in remote parts of the world. This document discusses such an idea from a professional standpoint. [22][7]

Design requires a profound understanding of both its principles and the physiological operation of biological systems. A well-designed medical device satisfies the natural compatibility of the biological life of the device with the expectations of the patient. Also, the theoretical layout is realistic and integrates a range of actuators and biocompatible sensors. The dissertation discusses important biomedical engineering principles related to the creation of smart medical devices. It describes the characteristics of the device involve the types of sensors and actuators to be used, the necessity for a reliable power supply, and specimen details of the device of a detailed device for 24-hour blood pressure monitoring. This document pays a special emphasis on the recent trends and developments in smart medical devices. [23]

The relevant principles in the view of biomedical engineering are crucial to layout effectively and develop smart medical devices beneficially. Bio-compatibility regarding sustainable usage, efficient design procedures, appropriate function of the sensor and actuators, system integration to assure the effective operation, robustness and user-friendliness of the SMD, and cooperation with healthcare professionals for quality testing of the device. Overall, such fundamental biomedical principles are followed in the creation and development of SMDs [24]. From a clinical standpoint, the italicized biomedical principles are also put into action. It is anticipated that an awareness of these biomedical engineering principles will greatly support and guide the proper development of SMDs for those without biomedical experience. Subsequent portions of this paper, emphasis is given to the true nature of each of these principles, and realistic applications are featured. This document does not, however, detail these principles on the basis of particular biological systems, but rather on the foundation of the SMD and its overall development, hoping to promote more progress in SMD design. [25]

2.1. Sensors and Actuators

The term smart is conventionally used to describe an object connected to a network, capable of performing autonomous actions. From a biomedical perspective, smart medical devices are typically designed to monitor the human body, comfort the patient in daily life or help medical professionals during the diagnosis or therapy phase. The design of an effective smart medical device requires a multidisciplinary approach involving the collaboration of engineers, medical doctors and industrial designers [26].

The widespread presence of smart medical devices is very recent, as they were possible only with the expansion of the internet and the development of the first microprocessors. Tele-medicine, tele-rehabilitation and personalized tele-care are examples of possible applications for future smart medical devices. These types of applications, also known as e-health, have led to the development of personal health systems (PHS). The design of PHS is possible thanks to the integration of advanced sensors, computers, microcontrollers and wireless communication systems; such devices are capable of monitoring multiple human physiological parameters and generating intelligent alarms. Traditionally, the biomedical approach relies on the observation of the patient in a specialized environment. Mad boards and biosensors, low cost devices to be used at home, have been proposed to extend the monitoring to everyday life, typically in the ambient-assisted-living (AAL) meaning. These devices are made up of different miniature sensors and actuators to record and/or interact with vital data; such data is usually elaborated by intelligent algorithms to individuate potential critical scenarios, triggering appropriate countermeasures. In this meaning, sensors may be considered the eyes and the ears of a smart medical device; their electrical signals are on the one hand meaningless, on the other hand containing huge information about the patient, as the signals generated by the human body depend, in normal conditions, on one or more physiological parameters. Concerning devices that monitor a single physiological parameter, the sensors are realized with specific and dedicated transduction techniques to convert the physical or chemical parameter to an electrical signal. Generally, the biomedical engineering field is intensely devoted to finding innovative techniques to improve the specificity and the sensitivity of the transduction techniques in measuring physiological parameters; also the integration of more and different types of sensors in a single measuring system has drawn great attention in many scientific issues. [27][28][7]

On the other hand, actuators can be thought of as the hands and the feet of a smart medical device; they deliver some sort of therapeutic intervention, after having acquired vital data from the sensors. The most common applications of smart medical devices are of the monitoring kind; they usually do not sport actuators, while systems designed for telemedicine feature at least one actuator in the form of first aid, defibrillation devices, heart or muscular stimulation. The design of the smart medical devices is far from being trivial; sensing and actuating processes generally are highly non-linear and temperature-dependent, and the respective transducing elements are characterized by physical parameters to be modeled. Moreover, the reading of univocal transduction signal is far from trivial: other physiological or environmental interferences must be filtered or avoided; hence the development of these types of devices is generally based on traditional control algorithms so as to respond to well-defined strategies. The sensors and the actuators of a smart medical device must be wisely integrated with the rest of the system; such devices are usually intended for everyday-life applications requiring continuous measurements. Usually these types of devices are portable, power operated and battery supplied; the battery pack generally combines two easily available technologies: high power and voltage disposable batteries for continuous power demanding sensors and wireless communication circuits; low power and voltage rechargeable batteries for the operation of the rest of the systems, although there are power autonomous devices that exploit energy harvesting techniques; for these reasons the systems can be considered intrinsically risky, so they must be integrated with the proper error detection mechanisms and built-in and system testing taking place during manufacturing and design, also performing routine on-field checkups. Another challenging issue is represented by the calibration of the measuring system; this must convert the electrical signals of the sensor in either engineering units or the density of the analytes. This procedure may be quite hard and non-trivial in some cases; usually in the implementation the parametric part of the transfer function is gain-shifted to coincide with the dynamic of a system under calibration. Moreover, the uncertainty of the calibration system should not be greater than 3-5% of the range of measurement, while the system itself may have a fifteen percent error; this implies that a biased mathematical function should be subtracted by the reading of the sensor. Despite good models that tune the systems for a single sensor can be found; the cross-certification of different sensors in a multidimensional scenario giving rise to an optimal measurement is a still open topic. [29][3][22]

Almost any smart medical device that collects vital data acquires it through a sensor; this is particularly true for those dealing with motion biomechanical analysis. An incorrect or inaccurate measurements of a physiological parameter may be meaningless for the correct identification of a pathological state. On the other hand, health hazards or indirect causes of death can originate from the continuous misuse of a poorly operating system. Thus, any smart medical device intended for real-time or on-field applications should be necessarily accurate and reliable in sensing and actuating. The smart and wearable medical devices are clean and skin friendly; from the applications, the devices can be wear for long-term periods; the design of the wearable sensor and the wearable actuator is necessary. The sensor should be able to tolerate the washing cycles; various types of sensor mounting can be realized. The application of the sensor should be quick and easy; it should not interfere with the physiological monitoring. This prompted research into textile-based solutions or smart materials. Technological concepts arising from the research on wearable systems are potentially accessible today and can be used for the development of a smart medical devices. Textile, flexible and stretchable electronics integration has been investigated, permitting to develop comfortable and invisible devices. The dreams of virtual reality and the idea of a smart environment item are now mixed and blurred in the everyday environments which transform information. From the patient, and endows it with a basic perception ability. In the last few years virtual reality and artificial intelligence grown-up reciprocally recurring and asserting each other. Since the widely and ease availability of the electronic gaming platform and the natural interfaces, engineers, scientists and visionaries tried to create a similar environment for the elderly and disabled. The smart medical device can be commercially realized: they allow the physician to identify, as soon as possible, the onset of pathologies or to monitor chronic conditions and thereby prevent exacerbations. In case of particularly delicate or severe conditions, they can trigger alarms and can immediately place warning-emergency calls. Moreover, they can deliver the treatment automatically by means of targeted actuators. Software dedicated to disabled and elderly to support and improve the interpersonal relationships can be enhanced by artificial intelligence can find a number of applications in nursing and companion robot aimed at personalised care. In the traditional medical equipments the biomedical approach plays a relevant role permitting the medical specialist to individuate, through the observation of physiological signals, the onset of pathological states and thus undertake the most appropriate therapeutic procedure. [13][3][15][30][5][31]

2.2. Signal Processing

Signal processing is a key component of any smart medical device. It is the design and analysis of algorithms or computational routines that are used to acquire, analyze, and interpret raw data collected as a result of sensor interaction. High priority here is given to algorithms or techniques that enable collected raw data to be used clearly and meaningfully for real-time monitoring purposes. A popular concept used in smart biosensors for advancing signal processing is noise reduction. Given that noise is ubiquitous in all data collection, a wide variety of noise is found in data from smart medical devices. Techniques governing the data quality design will, however, depend on the expected usage environment of the developed devices. Another important concept that particularly affects data transmission from smart biosensors is data compression. Raw data maintenance can be particularly challenging if devices aim to stream their data to a smartphones or a hospital monitoring system. As an alternative to the transmission of raw data, some smart medical device designs aim for signal processing at the point of data acquisition to allow treatment for raw data on time. [32][33]

This can either be done through firmware or by establishing a wireless communication channel between the device and the desired processing platform. Beyond noise and data rate considerations, the issue of data lateness is also vital for medical data processing. The majority of arbitrarily processed patient data can be turned into valuable insights if immediate action is taken. In terms of signal processing times, research suggests that the processing speed of signals, including sampling and transmission, needs to be carried out at MHz or higher, which may represent a significant design challenge for developers. A variety of methodologies can be found to efficiently implement signal processing algorithms that may benefit from low power consumption. In addition, some methods offer a simpler approach to collecting data in the development of smart medical devices. Most significantly, the performance of smart biosensors in the clinical setting depends heavily on real-time signal processing. This section aims to explore signal processing elements to draw attention to the importance of signal processing in the context of the performance of smart biosensors. [34][35]

2.3. Data Analysis and Interpretation

A smart medical device from a biomedical perspective refers to medical products whose operation relies on sensing, information generated from the sensing, computation and communication technologies, and which can be used either for the diagnostic purpose, the monitoring of patients or the assistance of the patients or medical professionals in either of the mentioned tasks. This definition covers a wide range of medical products, mainly intended for clinical, hospital and home healthcare environments, and whose use is expanding rapidly. Understanding the operation of such devices, taking the design decisions and correct development, and ensuring the reliability, safety, and the quality of the products, while meeting the international regulatory and standard requirements, are of significant complexity. [13][3]

Data coming from the operation of smart medical devices are very complex and gathering actionable knowledge is crucial to be able to operate them properly and be able to affect medical decisions and patient care possibly. As data cannot be always understood and managed manually, biomedical devices are becoming smarter enabling their embedded intelligence to contribute to the knowledge extraction. Eliciting the desired knowledge items also poses challenging requirements on the design and development of smart biomedical devices and the corresponding services, either as standalone solutions, or as parts integrated into the networked health delivery systems. Obtaining the appropriate knowledge extraction calls for very specific technical and regulatory perspectives for the involved smart biomedical devices and should go hand-to-hand with the actual care services, medical decisions, or other operations to improve or audit [36]. Smart biomedical device designs need to consider their behavior in the targeted operating environment and certain expected knowledge needs for various business and healthcare pathways [37]. Major recent advances in AI and machine learning (ML) fields have been greatly energizing the research and development of the smart biomedical devices and of relevant distributed and loosely-related services aiming for exploitation of the so gent knowledge items. Automated data analysis and knowledge extraction solutions may help also implement tamper-proof operation auditing functions. However, the use of smart devices in delivering health services, generating data and offering care decisions poses several open security and legal challenges, primarily about ethical issues, patients' data privacy and their personal rights. Finally, the continuous and real-life use of smart health devices and the accompanied services demands certain adjustments on how the generated and desired knowledge items are treated and converted into actionable insights or actions that can affect the actual care selection or operation in a timely manner. [12]

Materials and Methods

3. Smart Materials in Medical Devices

What are smart materials? Smart materials are becoming an attractive topic in biodesign. They are designed materials that feature one or more unique properties that can be significantly changed in a controlled fashion by external stimuli. The class of smart materials includes piezoelectric materials, polymers, shape-memory alloys, magnetostrictive materials, and hydrogels. The choice of materials is based on the requirements of a particular medical application of a device. The main use of such materials in medical devices lies in electrostimulation in such applications as defibrillators, pacemakers, auditory nerve implants, and neurological devices. Smart materials play an important role in medical device design to improve the device's functionality, patient comfort, and safety. Advanced materials like piezoelectric materials are used for ultrasonic sensing and stimulation. They are also used in orthopedic applications to detect and relieve pain. Other applications of smart materials in medical devices are to reduce power consumption in device operation using piezoelectric smart materials. Besides, smart materials also offer drug delivery applications in the body for the treatment of cancer and other biomedical applications. [38][39]

With biomedical materials research shaping new horizons for innumerable and unimaginable medical device designs, medical care consultancy is striving to become the future standard of care. The blend of smart sensors and materials paves the path for the medical industry by helping it fabricate a new generation of smart medical devices for various health conditions. Biomedical materials and smart materials go hand in hand, reaching tremendous growth and sales during the last few years due to their increasing use in cardiology, neurology, and orthopedic applications. Nowadays, these materials are expected to reach their peak of use due to the exponential growth of the aging population worldwide, also known as the new biogerontology era. Biomedical and smart materials are making revolutionary advances in disease diagnosis and treatment. They possess the capability of cognitive and adaptive response for the stimulus bio-signal. Currently, various smart sensors for different biosignals are available that can be integrated into personalized health monitoring systems [40]. Taking into consideration the potential growth in the smart medical devices industry, a promising future in flexible, woven, and subcutaneous sensors can be seen. These novel wearable sensors are the latest concept in bio-monitoring as well as in enhancing long-term care for medical patients. These in vivo models will have the capacity to measure multiple health parameters, such as the saliva-based glucose biosensor being used in monitoring diabetic patients. At a research level, a fully implantable device has also been developed. Moving forward, these will earn a prominent place towards pioneering advancement in smart medical devices industries. With further and fast-paced progress in terms of reliability, sensitivity, and overall flexibility, integration options are expected to emerge for more academically complex polymers and an extensive conductive network of various printable materials on flexible substrates, seeking a permanent place in next-generation medical intervention. [41][42]

3.1. Types and Applications

Smart materials have become a major breakthrough in innovative scientific research. The characteristics of smart materials and their desired applications in the development of medical devices and molds have been explored. The field of medical device design and molding has significantly benefited from recent advancements in smart materials and technologies. Smart materials have both physical and chemical properties, such as increase/decrease in mass, expansion/contraction in volume, and disengagement/poisoning in magnetic field. Generally, these materials may experience multiple changes. To ensure optimal patient outcomes, smart medical devices are designed for optimal care and functionality. Several prototypes and medical devices incorporated with smart materials have been reviewed, highlighting advantages and benefits. [25][43]

For the physical behavior of smart materials, an empirical model was developed and simulated to test its potential changes. These changes include: (a) hyperthermia to cure cancer and other vinyl diseased home appliances and (b) temperature beeping to prevent adverse effects and improve lifespan. Subsequent findings reveal significant feasible results, revealing the uniformly heated area of the human head and the ability to sense heat flashes. Given this evidence, additional research on how to address "hotspot" insulations is recommended. [44]

Results and Discussion

4. Wireless Communication Technologies in Healthcare

Wireless communications are one of the main elements of smart devices, which is crucial since the mobility and continuous monitoring of patients cannot be achieved using wires [45]. The foundation of the functionality of smart medical devices is the reliability and security of data exchanges between different nodes. This connectivity can be achieved through a wired or wireless communication medium. In the healthcare system, especially at the patient care units, reliable and secure data exchange is very important for the safety of patients and the integrity of medical procedures. In the healthcare system a patient can be connected to many medical devices at the same time. These devices need to exchange data with each other swiftly and reliably since there may be a medical procedure that affects the patient's live parameters. Medical devices take crucial measurements from patients (like heart rate, blood pressure, oxygen saturation, blood gas parameters, etc.) and apply a life-saving medical procedure according to alarms given by the medical devices. At this point, the rapid and correct transfer of these alarms are vital for patient safety. Many industries switch to wireless communication technologies. The most common are Bluetooth, Wi-Fi, and ZigBee, in terms of health care systems. Wearable health systems play a significant role in diagnosis, treatment or monitoring of the patient health status. In wireless health systems, the use of wearable devices is increasing day by day to ensure mobility in the diagnosis of diseases and monitoring of patient health status. In addition, it becomes a suitable solution for the elimination of cables and wired installations, providing remote monitoring to patients, and real-time patient tracking. Wearable devices, which are fast and easy to use, constitute an important part of these types of health systems consisting of sensors and small equipment. These systems enable self-monitoring and effectively provide remote health care services to the patient. The wireless health system is a human-centric technology and enhanced quality of life, especially for patients with serious diseases. Various wearable medical devices have been developed for continuous monitoring of patient vital signs and transmission to the medical staff in the form of alarms. Many industries use these technologies in their daily operations. But different manufacturers use their own different technologies and standards. This reduces the interoperability of these devices. In a healthcare environment, different types and manufacturers' wireless medical devices are used. In an emergency situation, time is important to save the life of the patient. In addition to the patient side devices, there are other devices, network equipment, and alarms that need to communicate with each other. So, fast and reliable communication must be completed between these different manufacturers' devices. There are many communication technologies and many standards available for the wireless system. The choice for this communication must be the same. Its different technologies and standards are used. The main reason for this is the different technologies, standards, and IoT platforms in health care systems. Choosing the right technology and communication medium between devices is important for their effectivity. In the future, the development of fifth-generation networks will contribute to better and safer operation of medical devices. [46][47][48][49]

4.1. IoT and Wearable Devices

The Internet of Things (IoT) is more than just an innovative technology; it is a vision of a connected world, facilitating seamless communication between people, objects, and environments. Healthcare is set to benefit greatly from the interconnectivity offered by the IoT concept, particularly in exploitation of the potential of wearable devices. The monitoring of health-related activities is a key component of the overall care strategy, and when used alongside wearables, data collection can be automated and precise. This simplifies the task of taking readings and at the same time establishes a continuous engagement with the patient. Devices orchestrate their activities, gather data that is processed into information according to the specific medical process, and make patient-based data collections user-friendly to both patients and carers. [50]

Wearable devices are increasingly exploited to manage health and chronic diseases. Research has shown that more direct access to vital life-sign monitoring and pharmacological treatment, as well as health education, is effective in enhancing patient outcomes. It is recognized that wearables, as they incorporate portable and convenient functionalities, are uniquely placed to broaden health-focused interventions for chronic patients. Most wearable commercial solutions aim to assess physical activity and vital parameters. Fitness bracelets and smartwatches are the most commonly used markets in this scenario. They can monitor life signs, such as the body temperature, blood pressure, and heart rate. In addition, wearable devices can measure more infrequent parameters, but still very relevant to health, such as level of pollution, exposure to the sun, or even psychological algorithms to predict mood swings. Moreover, the growth of big data has enabled unique opportunities in health management strategies. Data collected by wearables is continuously stored in electronic databases that enable the use of predictive algorithms to anticipate acute decompensation episodes or even long term complications from chronic conditions. Security and privacy issues are probably the most significant challenges associated with the exploitation of wearables and eHealth systems. Data collected from wearables is sensitive information that can generate a profile of the patient’s physical and mental health 24/7. The exploitation of cloud infrastructures for data storage and processing enabled the emergence of solutions that enhance data sharing and remote monitoring. However, these systems also raise concerns regarding the security of exchanged information, demanding an encrypted channel to ensure secure and private connections. Patients have a high level of acceptance of wearable technologies, but the technology can lead them to change their life habits. Most patients agree with the daily use q1h – 12/24 hour approach, which is in-line with the common practice in the commercial market. Few patients appreciate the potential of an innovative medical device; they suspect the results and validity of the solution arguing that most of the patient-centered insertable medical devices are in an investigational stage. Patients also seem to value the simplicity of the device in day-to-day use. It is acknowledged that a variety of wearables has emerged which are user-friendly and easy to carry. Patients and HCWs believe that the benefits of a wearable device in outpatient settings have the potential to enhance patient care and patient monitoring. The increasing socioeconomic pressure of the patient population is a common belief. Patient compliance and adherence rise when bureaucratic pathways are outstretched because the user has a lighter burden. Finally, medical doctors recognize a wearable device as an innovative technology that can lead to a new standard of care. Continuous and regular monitoring of health or help phase diagnoses are the frequent considerations of the interviewed health professionals. Moreover, expectancies are under pinned by the fact that close monitoring allows early detection of any warning signs that can lead to the remission of a disease, avoiding future complications [51]. With the right level of investment, technology also can exploit the prognostic side, alerting medical staffs the exact day and time of an impending episode, helping to rapidly rotate the patient in a hospital environment. Participants also consider that IoT technology will lead to a new role for healthcare professionals who will have to oversee a massive amount of data from real-time measurements [52]. Conversely, doctors believe that wearables enable real-world data to better understand the environmental condition and personal behavior of patients. Nowadays, electronic health records can't provide this huge amount of information on the patient's lifestyle, which has a significant impact on the patient's health status. For all these reasons, medical doctors underline that robust tools would optimize the extraction of knowledge from big data, forcefully making it usable and interpretable both in the prognostic and consultative dimension. [53][54]

5. Regulatory and Ethical Considerations

The topic of regulatory and ethical considerations in the main topic of the Part 5 of the new article based on material designed and developed on various labs. On the regulatory and ethical front, this section addresses the critical regulatory and ethical frameworks encompassing the development and deployment of these smart medical devices. The importance of conforming to standards established by a regulatory body is posited, such as the [55]. The complicated approval process that these devices are subjected to is examined and the mechanisms that regulatory bodies utilize to oversee a device's performance in the field after market approval is dissected. From a different perspective, the ethical provisions that developers of smart medical devices must navigate are discussed. The plethora of relationships to be navigated are underlined, such as that between developers and the patients who use these devices, and the obligation to obtain informed consent from patients to utilize their health data is underscored. Furthermore, several ethical considerations are outlined, such as how excelling in patient safety and participation in post-market surveillance contribute to the enhancement of smart medical devices, the development and utilization of ethical guidelines is advocated as a tool that can assist in navigating conflicting motivations involved in advancing technology, and the idea that equitable health outcomes, and the means to get to them, are not currently determinable is proposed. [56][57]

5.1. FDA Approval Process

Design, development, and commercialization of smart biomedical devices are multi-disciplinary tasks. After the development stage, all devices have to be evaluated and approved by the regulatory authorities of the target market. Usually, it is difficult for the biomedical scientists to deal with the regulatory bodies and get device approval. Although many of the new smart medical devices are developed, only a few of them reach the market due to the obstacles faced during the regulatory phase, especially getting approval from regulatory bodies such as FDA. With the aim of providing an insight about the regulatory phase from a biomedical engineer's perspective and facilitating the approval process, a discussion with the review of the representative smart devices that have reached the market or close to clinical perfection and approval of them was presented. Generally, smart medical devices (SMDs) consist of a sensor with signal processing unit and a display which shows the BHI parameters. Recent SMDs in the biomedical area have sophisticated signal processing algorithm and complex mathematical modeling. SMD development is usually done with specialized design environments, which consist of cohesive and integrated environment for the full flexibility needed to cater to such needs. Such environments facilitate researchers or industry designers to innovate and experiment faster. Neuroscience too has benefitted with such technological advancement. Due to this, SMD development from small research laboratories have increased, resulting in the increase of the number of new devices which are possible for treating various neurological disorders. Nevertheless, successful commercialization of these devices is a more complicated job. Successful commercialization needs regulatory approval, financial investment, ethical concerns, clinical trials, prototype modeling, etc. To carry out the development stage and device approval from authorities, all of them should be accomplished. Unluckily, dealing with the regulatory bodies is the most frustrating process during this chain. Due to this and other obstacles, many SMD applications can be seen at rural settings; none or little have been commercialized [58]. [22][59]

6. Case Studies of Innovative Smart Medical Devices

The symposium was organized at the EMBS 42nd Annual International Conference that was held between 20-24 July 2020. There were six presenters from the USA, South Korea, and Turkey. It was an informative symposium where cutting-edge research outcomes on smart medical devices and related systems were shared and discussed. There were about 50 attendees who participated in the symposium. The focus was on innovative smart medical devices within the two-hour intensive symposium. [60]

The symposium started with a historical perspective of "smartness" and "equillence" in medical device design and development. The first two talks presented the challenges and requirements for smart wearable cough monitoring devices. This was followed by a talk on smart drinking bottle design for the elderly to increase hydration motivation that described the potential solutions to the challenges for determining user recognition in the wild from other activities of daily living. Next, the smartening of home-based medical devices for telemedicine support was presented, where the journey from fabric sensors to hybrid telemedicine prototypes was highlighted for home use in chronic diseases, such as obesity. The last talk revealed insights and take-home messages from a privacy-focused smartwatch survey to understand the users' preferences regarding the data to be shared with the healthcare system [11]. This talk series comprehensively covered a broad spectrum of smart medical devices and systems for the health and well-being of individuals considering both preventive and treatment aspects. It showed that interdisciplinary approaches, including cooperation of social scientists, engineers, computer scientists, clinicians, and designers, played a crucial role in designing robust, user-friendly, efficient, and effective smart medical devices that are successful in increasing patient engagement and improving health outcomes and hence cost-effectiveness as a result of converging innovative technology with the already existing healthcare system. [61][62]

6.1. Implantable Devices

This section is dedicated to the past achievements and current status of the field of implantable smart medical devices, and then shifts to defending their noble mission and bright perspectives. An implantable medical device (IMD) refers to a smart device intended to be entirely or partially placed inside the body and utilized to support, monitor, store, or trigger healing process. The first generation of IMDs was represented mostly by pacemakers and drug release systems. Since polysaccharides, PE, or silicon were abused, they were mostly temporary, with the established duration mostly less than 30 d. However, they have played an important role in various experiments and treatment processes for a considerable period. The fall of traditional implanted materials started in an already classic event that occurred in 1966. In Russia, some authorities linked this event to the suspension of the IMT project of Moscow Heart Institute, the most ambitious one of the time. The above misgivings resulted in the neglect of this pioneering work and then the attraction of great interests in implantable technology after the 21st century. New stimuli, such as wearable electronics and healthier demands, were exerting pressure on the progress in this field. A lot of thought was given to the topic of implantable electronics and realized this was not only something incredibly rewarding but also somewhat of a rigorous challenge. With the expansion of research, the potential issues regarding implantable technology were then increasingly noted with a view to seizing upon the pivotal points in order to facilitate the advance of this domain. [22][63][64]

6.2. Diagnostic Tools

Smart medical devices leverage advances in technology to offer enhanced healthcare capabilities. They represent a paradigm shift from traditional interventions by integrating extensive computing power, wireless connectivity, and miniaturized sensors into medical applications. This shift is underpinned by the desire for continuous, unobtrusive, and personalized healthcare monitoring, which can be targeted and optimized for the individual. Given these opportunities, developing smart medical devices is therefore a growing industry drawing insights from various domains, including engineering, healthcare, and biosciences. Situating the focus within a biomedical perspective, this chapter details the development of smart medical devices, from concept conception through to clinical implementation. This involves an exploration of how the design process can be tailored for biomedical applications, and an overview of the process of medical device regulations and the related standards relevant to the research as well as the limitations incurred [65]. Applications of this methodology are presented, detailing the development of a wearable drug delivery pump, and a UVC disinfection robot. This research is thus intended to inform biomedical and bioengineering professionals on how the development of smart medical devices can be approached, in order to improve patient care. Recent years have seen significant enhancements in smart medical devices such as portable diagnostic testing kits, mobile-based health monitoring apps, and remote consultation platforms. These devices are designed to provide medical-grade diagnosis and associated care in diverse settings and support long-term patient monitoring out of hospitals. Smart devices can transmit familiarity to demographic areas with limited access to healthcare amenities. The basic potential of smart medical devices is to deliver opportune, affordable, and inexpensive healthcare with analogous level determination, production, and efficiency. Emerging societies administer enhanced health monitoring alternative at lower costs. Additionally, smart medical devices diminish the waiting time for individuals in long queues, and have advanced patient experience in late times. However, successful implementation of these devices needs data exchange and connection amidst different smart technologies, which can be both technology-based and regulations orientated. With regards to the patient, it is imperative to establish clinical validation of these smart diagnostic running over devices before it can be convinced and accepted by medical professionals. For profitable integration, it is also important to follow standardized implementation and communication protocols. Moving forward, on how these smart diagnostic devices can be fused with the current healthcare framework to tackle technical and regulatory matters and exacerbate successful implementation are also desired. These smart diagnostic devices are revolutionizing the diagnosis practice in health care: this should be an exciting time for biomedical and healthcare professionals and will also bring numerous innovative opportunities for researchers and industrialists. [66][67][68][69]

7. Future Trends and Challenges

The recent advancement and widespread of artificial intelligence (AI) and machine learning (ML) algorithms have contributed to development of the smart applications for medical devices. The purpose of this initiative is to help developing an interactive, portable, and real-time system of a biofeedback mechanism for visualizing the near-infrared (NIR) imaging data through the algorithm enhancement. These smart motion sensing devices can also help the prognosis and prevention of lower back pain problems. In general, the proposed methodology can provide a more in-depth finding by processing data. The monitoring platform has a significant potential to be an eHealth system for telemedicine, especially in sleep apnea patients. Nonetheless, the successful implementation of telemedicine in the critically ill should ensure data confidentiality

[55]. It is imperative for smart motion sensing devices to perform highly sensitive and specific measurements to interpret the correlation of near-infrared (NIR) signals that can be captured through ML algorithm functionality. The advanced analysis of NIR imaging data can also be an approach for ascertaining wireless motion sensing accuracy functional to interface with wearable devices that are integrated with structure light triangulation technology. However, it is still challenging in order to processing the experiment-orientated data quantitatively in column chart display by applet algorithm. Ideally, confirmation studies could validate a better sensitivity of NIR that is captured on wearable – or app based systems. Furthermore, the smart motion sensing devices can also be integrated into wearable devices of rehabilitation bed or mattress and have potential application for monitoring efficacy and candidate self-rehabilitation effect of lower back pain treatment. Similarly, Development of a smart dual-modal eHealth monitoring platform for channel state information (CSI) and sleep respiratory rate (SRR) features can help determine, prognosis, and early prevention of the severity of sleep apnea events. However, the successful implementation of telemedicine in the critically ill must ensure data confidentiality, security, and compliance with regulations. dosage parameters, or complications arise. Rapid centralization based on the expansion of COVID-19 supplies may limit the availability of drugs and devices needed by nursing homes and patients who are assisted at home. PUBP was issued, with changes to EC Certificate and MDR claims to adapt to the requirements of the SARS-CoV-2 emergency, to decrease of some specific delays for placing on the market medical devices related to the COVID-19 outbreak. In the perspective of the evolving scenario of the COVID-19 outbreak the GCP recommends to avoid disposal of medical devices in electronic devices with expired certification, suggesting a possible use for education or material purposes. [59][12][70][71]

7.1. Artificial Intelligence in Healthcare

The field of healthcare is on the brink of a digital evolution caused by the widespread adoption of medical smart devices. The smart medical devices with biosensors and Internet-of-Things (IoT) technology can now generate a vast amount of continuous personal health data. By taking advantage of advanced big data analytic technologies, such as artificial intelligence (AI) algorithms, those data can be analyzed with comprehensive detail that has never been possible before. In the context of medical devices, AI can reinforce capabilities far beyond what the devices themselves can offer. AI can accommodate advanced data processes, predictive modeling, and/or personalized monitoring of health treatment [72]. It opens up opportunities to evolve beyond the basic target of any smart device tracking and recording. Significantly, immense potential of AI implementation in the design and usage of medical smart devices exists. Applications of AI in smart devices range from diagnostics and health risk assessment to continuous patient management that consistently tailors to real-time needs. [13]

For smart medical devices to truly be a part of the sustainable future of healthcare, the integration of AI is suggested. The integration of AI into smart medical devices offers great benefits. Some of the prominent impacts are discussed in this document. The devices become more accurate both in their function as well as performance, ultimately enhancing patient care quality and overall system efficiency [73]. This also takes the form of enhanced sensors alongside the ability to continually learn and optimize algorithms. It has been renowned that AI can achieve knowledge that is outside human supervision and knowledge. The devices will have the capacity to identify subtle patterns in the previously acquired user sampling, enabling quick action as well as preventative care. Moreover, medical device AI can measure and convey the risk of making suggestions, decisions, and actions for operation and medication. Despite these promising angles of AI, there are several essential concerns that persist after AI integration in medical devices. These are amplified by those medical devices that constitute treatment devices regulated by health authorities. Known concerns include AI training data and process regulation, biased AI algorithms, black box phenomenon, compatible combination of AI algorithms and legal and ethical standards, and the development of device-specific rigorous testing protocols. Notably, as AI is developed, it is critical that a robust framework be built to ensure the safety profile of the patient and the appropriateness of service delivery in a clinical setting. Despite the struggles, massive potential exists to improve patient outcomes truly. As the event of real-world success stories indicates, significant tools and services can be provided to revolutionize the landscape of healthcare. [74][75][12]

Conclusion

The development of smart medical devices is empowering healthcare providers to revolutionize patient care delivery. On the one hand, it is democratizing the telemedicine paradigm, namely by creating a means for patients to get self-checkup medical treatment. On the other hand, it is vastly improving clinic-based care through self-compilation and processing of elaborate diagnostic data. To discuss these advantages and their implications, a short theoretical approach to biosignals and their acquisition is presented. Subsequently, the connection between this framework and commercial smart medical devices is discussed, detailing their existing capabilities.

Advanced embedded systems and algorithmic systems have made the cost-effective capture of salient diagnostic data possible. This has the potential to democratize the role of healthcare providers. The capability to collect and process biosignal data is traditionally confined to specialized facilities managed by healthcare providers. The rise of advanced embedded and algorithmic systems has, in a sense, transformed commercial smartphones into portable labs broadly capable of monitoring one’s condition. As these generally pervade the modern lifestyle, the requisite information for a self- or loved ones’ diagnostics is generally only a purchase away. While significant technical challenges remain, the emergence of successful businesses at the intersection of healthcare and smartphone providers suggests it is only a matter of time until these are overcome. On another front, these new possibilities have facilitated the rise of telemedicine consult services which connect these newly capable devices to health professionals on a commercial basis. Telemedicine has the potential to democratize access to diagnostics, redistributing the costs and advantages of setup.

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