ANALYSIS AND PROCESSING OF BRAINWAVES FOR INTELLECTUAL DISABILITY PERSONS

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Preface

This book delves into the ethical implications of integrating Cyber-Physical Systems (CPS) in neural engineering. It examines various aspects, such as real-time applications of CPS in neural engineering, integration of CPS technologies for enhanced neural interfaces, ethical considerations regarding data privacy and security, and the impact of CPS on neurorehabilitation and brain-computer interfaces.

The collaborative efforts of researchers and teachers contribute their expertise and research findings to the book. Our primary focus is to explore the real-time applications of CPS in neural engineering, considering its potential benefits and challenges, while addressing ethical concerns and incorporating insights from research and teaching experiences.

To ensure accessibility to a wide range of readers, we have made a deliberate effort to avoid excessive technical jargon and complexity in the content. Biased perspectives and preferential treatment of specific technological solutions have been consciously avoided, aiming for a balanced and objective exploration of CPS applications in neural engineering. Ethical concerns and dilemmas are presented without oversimplification, acknowledging their nuanced nature and promoting thoughtful discussions and critical thinking among readers. Our goal is to provide a comprehensive and approachable resource that fosters understanding and responsible exploration of the topic.

We sincerely appreciate the readers' choice to engage with this book. We hope it serves as an informative and insightful resource, imparting valuable knowledge and deepening their understanding of real-time applications of CPS in neural engineering.

Acknowledgement

The authors express their sincere gratitude and appreciation to the Management and Administrative Officials of Universiti Tun Hussein Onn Malaysia (UTHM), Malaysia, Kongu Engineering College (KEC), India, and the National Institute for Empowerment of Persons with Multiple Disabilities (Divyangjan) in Chennai, India. Their unwavering support and assistance were invaluable in successfully conducting this research. The authors would like to extend their heartfelt thanks for providing the necessary resources, facilities, and guidance throughout the project. Their contributions played a vital role in the accomplishment of the research objectives. The authors are deeply grateful for the opportunity to collaborate with these esteemed institutions, whose commitment to academic excellence and research advancement has been instrumental in shaping the outcomes of this study.

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Dr. Ashok Vajravelu Senior Lecturer at Universiti Tun Hussein Malaysia (UTHM), holds a Bachelor of Electronics and Communication Engineering from Kongu Engineering College, Tamilnadu, India (2002). He also has a Master's degree in Process Control and Instrumentation Engineering from Annamalai University, Tamilnadu, India (2005), and a Ph.D. in Medical Electronics from Anna University, Chennai, Tamilnadu, India. His academic journey includes serving as a Lecturer at Velalar College of Engineering and Technology, Tamilnadu, India (2005-2009), Assistant Professor (2010-2012), Professor, and Head of the Department at Nandha College of Technology, Tamilnadu, India (2012-2015). Then he also worked as an Associate Professor at Kongu Engineering College, Tamilnadu, India (2015).

His expertise lies in several areas, notably Biomedical Engineering, Discrete Electronics Design, and Development, Embedded Systems, and Signal Preprocessing. He has also gained valuable industry experience, having worked as a Design Engineer at United Industries, India, and as a junior development Engineer at Megawin Switchgear, India. Throughout his career, he has inspired and mentored numerous students and medical practitioners. His passion for the applications of cyber-physical systems in neural engineering has been instrumental in fostering their interest and providing valuable insights. His teachings and guidance have helped students and professionals better understand the field. He has also contributed to consultancy projects like Android Application Development for IoT-based RO Plant Controlling and Database Management. These projects demonstrate his practical approach to utilizing technology in solving real-world problems. With his extensive academic background, industry experience, and research interests, he brings a wealth of knowledge and expertise to the field of neural engineering. His dedication to teaching, research, and practical applications has made him a respected figure among students and medical practitioners alike, inspiring them to explore the potential of cyber-physical systems in improving healthcare and biomedical technologies.

Dr. Muhammad Mahadi Bin Abdul Jamil started his further education with a higher national diploma in medical electronic engineering at the British Malaysian Institute. He then moved on to the University of Bradford where he gained a Bachelor's Degree with Honours in Medical Engineering in year 2003. Later completed his higher education in 2007. This is when Dr. Mahadi gained his Ph.D. degree in Medical Engineering from the same university. Dr. Mahadi's career began in 2008. He shared his extensive knowledge by lecturing at UTHM, Batu Pahat, Johor. He has gained a vast range of specializations since then. From then on he has also joined and participated in a variety of professional societies, currently being the Board of Engineers Malaysia and the International Association of Engineers. One of his many accomplishments consists of the various publications he has produced during the 14 years of his career. Not to forget the many research grants and contracts he has acquired over the years. Alongside this, he has kept himself busy by supervising numerous students on their Bachelor Degree, Master and Ph.D. projects. His research interest and focus are in the field of biomedical engineering systems and applications technology.

Mr. Mohd Helmy Bin Abd Wahab is a Senior lecturer and a former Head of the Multimedia Engineering Lab and Intelligent System Lab at the Department of Computer Engineering, Faculty of Electrical and Electronic Engineering, Universiti Tun Hussein Onn Malaysia (UTHM) in 2014 and 2009. He is currently a Principle Research Fellow at the Advanced Telecommunication Research Center, Faculty of Electrical and Electronic Engineering, UTHM (2021 – 2025) and Visiting Research Fellow for the Center of Excellence on Advanced in Computing, Universiti Malaysia Perlis (UNIMaP) (2021 – 2022). In addition, he was a visiting research fellow at the Center of Excellence on Geopolymer and Green Technology under cluster Green ICT, Unimap from 2018 – 2020. He received a Bachelor of Information Technology with Honours from Universiti Utara Malaysia and a Master of Science (Intelligent System) from the same university in 2002 and 2004 respectively. He has completed several research grants; won several medals in research and innovation showcases and awarded several publication and teaching awards. At the latest, he received 2nd runner-up for Grand Prize Award category Innovation Video Challenge for the project "Online Learning System with Authentication and identification mechanism using Neuro-fuzzy Algorithm" and the same project also received 1st Grand Prize Award for FB Post and contest as well as GOLD medals respectively at Asia International Innovation Exhibition 2020 (AIINEX2020) organized by Connection Asia and UNIKL. He also received an international award GOLD medal for the project "Portable Dwi-Switch Home Control Appliance for Elderly and Disabled People" at the 2020 Bangkok International Intellectual Property, Invention, Innovation, and Technology Exposition (IPITEx 2020) in conjunction with Thailand Inventors' Day 2020 on 2 - 6 February 2020. He has authored and co-authored 2 academic books in database and WAP application, published several both local and international book chapters as well and published more than 100 technical papers in conferences and peer-reviewed journals. He also served as Editor-in-chief in Advances in Computing and Intelligent System Journal and guest editor for a Special Issue in Wireless and Mobile Networks in the International Journal of Advanced Computer Science and Applications and as Deputy Editor-in-chief for Int. Journal of Software Engineering and Computing and scholarly contributed as the committee for conferences, editorial team, and manuscript reviewers. His research interests are in data mining, artificial intelligence and computer vision, mobile and wireless computing, and web-based applications. He is currently a senior member of IEEE, IEEE Computer Society, IAEng, and Senior member of IACSIT.

Dr. Asmarashid Bin Ponniran is a distinguished electrical engineer who earned his bachelor's degree in electrical engineering from Universiti Tun Hussein Onn Malaysia (UTHM) in 2002, followed by a master's degree in engineering (Electrical Power) from Universiti Teknologi Malaysia (UTM) in 2005. His pursuit of advanced knowledge led him to achieve a Ph.D. in Electrical Engineering from Nagaoka University of Technology (NUT), Japan in 2016. He is currently working as an associate professor and researcher at Universiti Tun Hussein Onn Malaysia. His research interests in power electronics encompass a wide range of areas, such as power converter circuit structure optimization, switching strategies for modular multilevel power converters, achieving high power density in power converters, developing high voltage gain power converters, and exploring high-frequency power converters. These research interests are focused on their practical applications in renewable energy (RE), electric vehicle (EV) technology, smart grid power systems (SGPS), and data center power systems (DCPS).

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CHAPTER 1

INTRODUCTION TO NEURAL ENGINEERING

Dr. Ashok Vajravelu
Bio Medical Engineering and Measurement System (BioMEMS)

1.1 INTRODUCTION

Neural engineering is a discipline that centres around the intersection of neuroscience and engineering. Initially, it was primarily concerned with the interface between the brain and machines; however, its scope has since expanded to encompass a broader range of topics. Neural engineering now encompasses experimental, computational, and theoretical aspects of various areas such as neural interfaces, neuro electronics, neuromechanical systems, neuro informatics, neuroimaging, neural prostheses, biological neural circuits, neural control, regenerative tissue, and neural signals. One of the key objectives in neural engineering is the development of selective interfaces for the peripheral nervous system.

Neurophysiology, the physiology branch in which neural system operation. Neural engineering is a biomedical engineered discipline that applies engineering techniques in the understanding, repair, replacement, enhancement, or otherwise exploitation of neural system features and functions. In most cases, neural engineering is necessary for the establishment of an interface between electrical and biological neural tissues. This paper explores the beginnings of neural engineering, the explosive development and gadget development in approaches and devices dating from the late 1950s. There are many and various obstacles to electronic interfacing devices with live neural tissue and, as a result, number of Halt have taken place and start. There will be discussion of representative examples. Without a thorough understanding of the neurophysiology concerned, none would have been conceivable.

Neural system engineering encompasses brain-related work and includes areas like restoring lost sensory and motor abilities through replacement or restoration techniques. 'Neural engineering is an emerging cross-disciplinary field of research that brings together neurosciences and technological methods in analysis. The development of interconnection between mind and computer was enthusiastic not only because of its largely unexplored potential to treat people with neurologically diseased disease, like diseasing, stroke or epillemia. The field of neural system engineering, as defined by the Editorial Board of the Journal of Neural Engineering, pertains to endeavours aimed at the replacement or restoration of lost sensory and motor capabilities.

1.1.1 Ethical Impacts

Ethical consequences may vary based on the impairment type for people with disabilities. We look at two groups: (1) persons who can make their own choices entirely; and (2) people who are not totally capable of making their own selections.

For ethical reasons relating to autonomy, this divergence is particularly important. Cyber Physical Systems (CPS) might perhaps do handicap jobs and work smartly without commands. Does this influence the autonomy of the disabled person or the perception of independence? Consider this example: an intelligent environment may detect patterns which could indicate that someone is considering suicide or could even share suicide ideas with the CPS. Should the CPS be prepared to take action to avoid this by telling others, and when? Should the user agree to these measures? Is that different for persons who can take their own decisions or cannot (completely) make them? Is it ethically linked to CPS?

Ethical issue of paternalism or the ability for CPS to override human choices is also part of CPS's autonomy. CPS systems that monitor physiologic conditions such as stress contribute to better recovery from a heart attack or stroke for vulnerable persons. Details from surveillance may divulge harmful conduct information. What is the system supposed to do? Do you signal harmful activities to medical staff, warn the person, prevent or should it be established in order to avoid these decisions together? Should people live without risk, even if they are at risk and treated by medical staff? What can be done with a CPS system for prevention or rehabilitation?

Regardless of this decision, the acceptance of technology, especially among elderly individuals, still poses a hurdle for CPS in the home care industry. Do people prefer robots or intelligent technology for their care, or do they prioritize human attention? How much technology are people generally willing to incorporate into their lives? This is partly a matter of confidence, as effective treatment can only be provided on the basis of trust. Do disabled individuals trust CPS to assist them in their daily lives, and how can this trust be improved? Additionally, the role of CPS in helping doctors monitor the progress of their clients should not jeopardize the confidence in the patient-physician relationship.

The owner-conscious personal monitoring equipment should ensure that the CPS (Caregiver-Patient System) certifies the identity of the disabled individual. This becomes especially crucial in households where multiple residents, including visitors, coexist. The system should only allow the designated resident to perceive and measure its functions. Consent should be obtained for any other actions, and the data necessary for providing effective care to the person with a disability should be handled with confidentiality. Furthermore, the privacy of other individuals should not be compromised.

The CPS always interacts with the disabled person. In addition, several elements of the CPS also interact. How should both worlds be arranged to make the technology secure and reliable for users? This is both a technological aspect and an ethical one, involving the interaction between humans and machines.

1.2 GENERAL STUDY

1.2.1 Human Evaluation

The growth of the brain is the most important triumph of human development. At birth, the biological brain contains billions of nerve cells. A nerve cell connects with too many nerve cells to be counted, meaning there are literally trillions of nerve connections in the brain. Nature's most amazing and daunting creation, an organ that can hope to understand itself.

Neural Systems Engineering is trying to understand these neural connections and adapt them to the artificial environment. The field of neural engineering comprises neuroscience, neuroscience experiment, clinical neurology, electrotechnics and the signage of neural tissue life, cybernetic, computer, neural tissue engineering, material science and nanotechnological components. There are many differences between biological brain and electronically designed computers. Both have a complex structure. A biological brain is a slow running system that is flexible, susceptible to errors. Inflexible, accurate, decisive and speedy computers. But recently, scientists have tried to put the advantages of biological brain in the computer system. Why are they trying to do that? This brain has very high concomitance and malfunctioning, both of which are characteristics which we want to supply in constructed systems. Our understanding of how the brain reaches such an advanced structure can make it easier for the brain to transfer to the machine. On the other hand, since there is no emotional transition in a system in which the computer is located, interactivity will be decreased. In this case it can have a depressing effect on people. If we communicate with a computer just a little bit more like communicating with someone else, life for so many people would be lot easier.

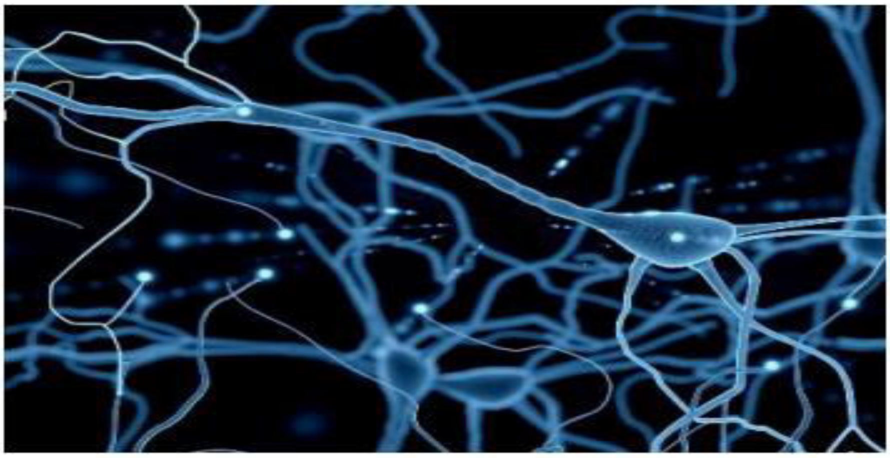

Figure: 1.1 Neurons Transmitting Messages.

There are many machines that allow us to observe how neural activity corresponds to sensory stimuli. However, each nerve has its own coding mechanisms. How do they encode high-level knowledge, modularity, transient behavior, attention, and, most importantly, consciousness? One of the major challenges in computer research is comprehending the architecture of the brain and mind. It is a transdisciplinary, long-term project conducted at multiple abstract levels.

1.2.2 Human Physiology - 11 Systems

Our bodies consist of 11 fundamental organ systems that collectively perform vital functions. Despite their interdependence, these systems can occasionally become out of sync. In such instances, the other systems will strive to restore balance if one is not functioning correctly. All systems work together to establish a state of homeostasis or equilibrium in the body.

Among the 11 organ systems are the integumentary system (skin), skeletal system (skeleton), lymphatic system (lymphatic), respiratory system, digestive system, nervous system, and endocrine system.

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1. **Integumentary System - (**Skin, Hair, Nails)
2. **Skeletal System -** (Bones, Joints)
3. **Muscular system -** (Cardiac, Smooth, and Skeletal Muscles)
4. **Lymphatic System** - (Red Bone Marrow, Thymus, Lymphatic Vessels, Thoracic Duct, Spleen, Lymph Nodes)
5. **Respiratory System –** (Nasal Cavity, Pharynx, Larynx, Trachea, Bronchus, Lung)
6. **Digestive system -** (Oral Cavity, Esophagus, Liver, Stomach, Small Intestine, Large Intestine, Rectum, Anus)
7. **Nervous System** – (Brain, Spinal Cord, Nerves)
8. **Endocrine System** – (Pineal Gland, Pituitary Gland, Thyroid Gland, Thymus, Adrenal Gland, Pancreas, Ovary, Testis)
9. **Cardiovascular (Circulatory) System** – (Heart, Blood Vessels)
10. **Urinary system -** (Kidney, Ureter, Urinary Bladder, Urethra)
11. **Reproductive Systems**

1.2.3 Nervous System – Peripheral Nervous system, Central Nervous system

Similar to majority of cells in the human body, these cells comprise different components, such as surface membranes (carrying ion and biochemical receptors), nuclei (containing DNA and chromosomes specific to each cell), mitochondria, ribosomes, endoplasmic reticula, Golgi complexes, and so on. The populations of nerve cells (neurons) within the human nervous system are considered functional units.

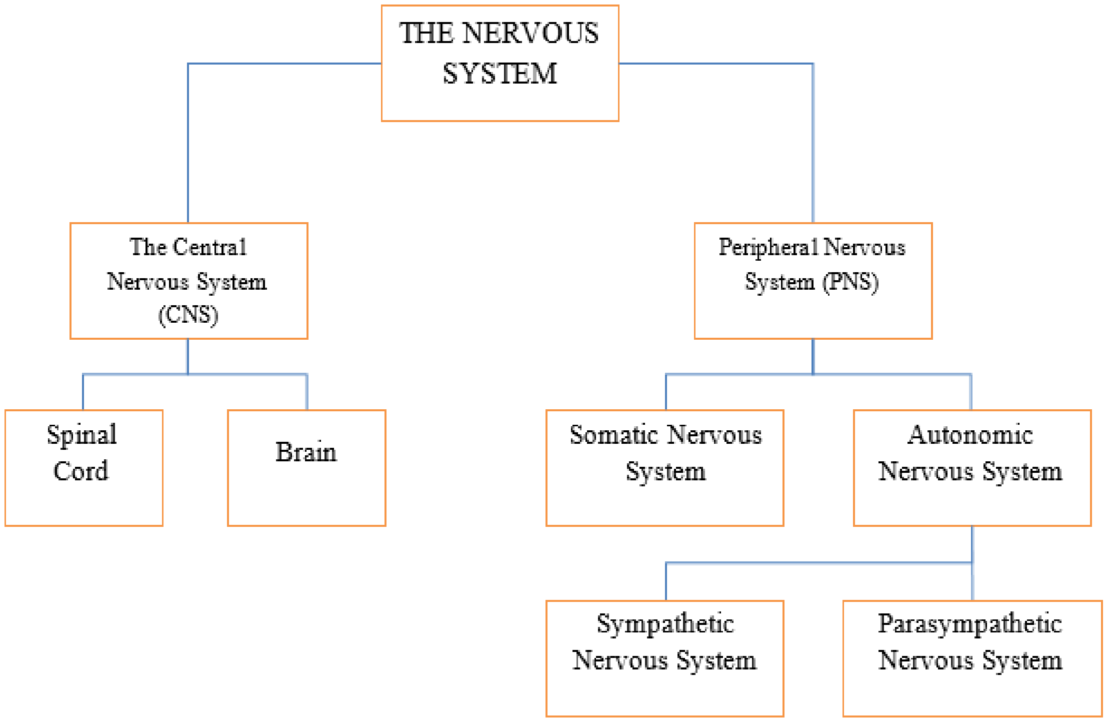

Figure: 1.2 Nervous System Classification: Peripheral & Central Nervous System

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1.2.4 Central Nervous System - About Brain and its functions, Lobes, Neurons, Neuron functions

Taking into consideration the broad functions of the human brain, four different systems can be identified: (1) a combined system involving cognitive function and awareness, (2) a limbic system controlling emotions and feelings, (3) a motor system responsible for voluntary and involuntary postural movement and control, and (4) an emotional and feeling-controlled vegetative system. It should be noted that these zones are somatotopically organized, starting from the complete context of dermal and visceral receptors, projecting to the thalamus, and ultimately reaching the cortex in the peripheral sensory area.

1.3 THE NEURON

The neuron is the fundamental biological control element. Neurons, also referred to as nervous cells, receive sensory information from the external world, transmit motor commands to our muscles, and convert and transmit electrical impulses at each intermediate step within the brain and the nervous system. Additionally, their interactions shape our individuality. With that said, our roughly 100 billion neurons closely interact with other types of cells [2].

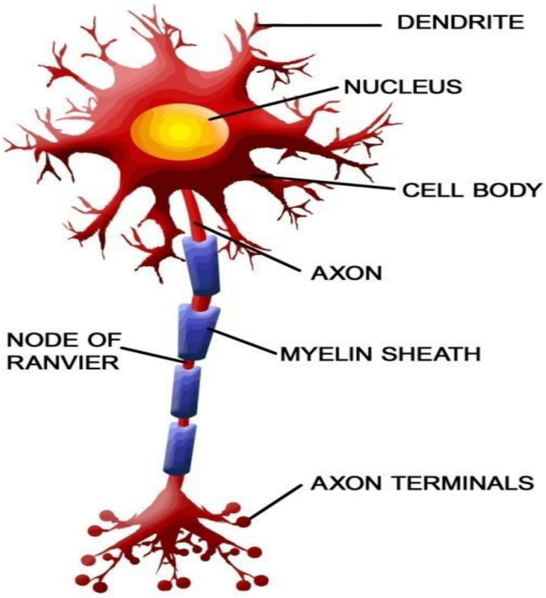

Figure:1.3 Neuron Anatomy Illustration

The axon serves as the output structure of the neuron, producing an electrical message called an action potential that travels along the entire length of the axon when the neuron intends to communicate with another neuron. The soma, located at the nucleus, houses the neuron's DNA and facilitates the transmission of proteins throughout the axon.

1.3.1 Neuron Communication

When a neuron receives multiple inputs from other neurons, these inputs accumulate until they reach a certain threshold. Once the threshold is exceeded, the neuron is triggered to transmit an impulse, known as an action potential, along its axon. This action potential is generated by the movement of electrolyzed atoms (ions) across the membrane of the axon. Resting neurons have a negative charge relative to the surrounding fluids, typically around -70 mV. When a nerve cell receives enough impulses to initiate firing, the cell undergoes depolarization, where the membrane potential rapidly increases and then decreases within approximately 1/1000th of a second. This depolarization propagates to the next segment of the axon, leading to a cascade of depolarization along the entire length of the axon.

After each firing, there is a brief hyperpolarization state where the threshold is temporarily reduced, making it less likely for the neuron to be immediately triggered again. In most cases, the action potential is generated by the movement of potassium (K+) and sodium (Na+) ions. Ion channels and pumps facilitate the movement of these ions in and out of the axon in response to voltage changes.

1.4 The Process Can Be Summarized as Follows:

Na+ channels open, leading to an influx of Na+ ions into the cell, causing depolarization. Once the cell reaches a sufficient charge, K+ channels open, allowing K+ ions to exit the cell. Subsequently, Na+ channels close, while K+ channels remain open, resulting in the cell maintaining a positive charge. This process may involve membrane fluctuations. The K+ channels close when the membrane potential is restored. At this point, Na+ ions are back inside the cell, and K+ ions are prepared for the next cycle. The action potential follows an "all-or-nothing" principle, as it consistently has the same magnitude. However, the strength of a stimulus is often transmitted through the frequency of neuronal firing. For example, a moderate boost may lead to less frequent firing, whereas a strong signal may result in more frequent firing.

1.4.1 Comparing biological neurons with artificial neurons from an (engineering perspective).

Although scientists observed artificial neurons and neural networks inspired by the biological processes in the brain as far back as the 1950s, there are several key differences between these artificial counterparts and their biological counterparts. Just as modern vehicles do not resemble the skeletal structures of flying birds or galloping horses, artificial neurons have distinct characteristics compared to their biological counterparts. However, within their specific domain, these engineered systems can be even more powerful and useful for humans than their animal "ancestors" could ever be.

It is important to be cautious when anthropomorphizing deep neural networks for AI research, as artificial and biological neurons differ not only in their physical materials but also in significant ways.

The theory behind perceptrons, which are precursors to artificial neurons, involves replicating specific components of neurons, such as dendrites, cell bodies, and axons, using mathematical models based on our limited understanding of their internal processes. In this model, dendrites receive signals, and axons transmit signals once, several signals have been received. This signal can then be used as input for other neurons, creating a repetitive process. Some messages are deemed essential, and certain neurons are more likely to fire. Connections between neurons can strengthen or weaken, new connections can form, and existing connections can disappear. By summing the weighted inputs and applying a specific threshold, the majority can be replicated by

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generating a feature that includes a list of weighted input signals and corresponding outputs.

It is important to note that this simplified model does not simulate the generation or elimination of neuron-like connections (dendrites or axons) or consider signal timing.

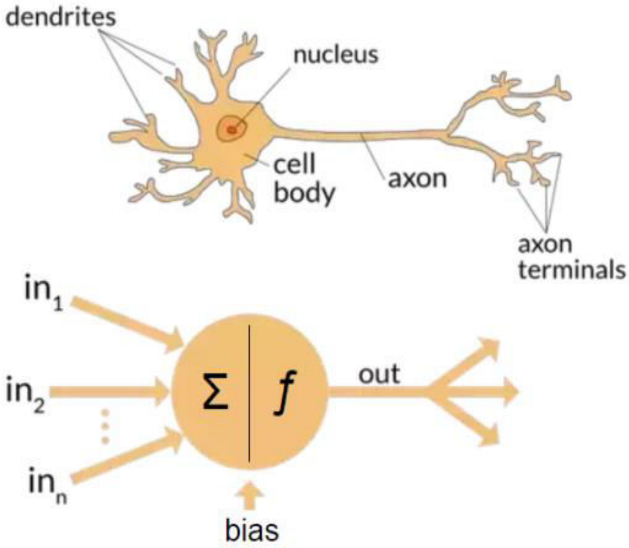

Figure: 1.4 (a) Biological and an artificial neuron

1.4.2 Different Artificial Neural Network Structures with Applications and Examples

Generally, there are two types of ANN

a. Feed Forward ANN

The information flow in this network is unidirectional, where each information unit receives input and passes it to another unit. There are no feedback loops present in this system. The primary purpose of this network is pattern recognition, as the inputs and outputs are predetermined and remain fixed.

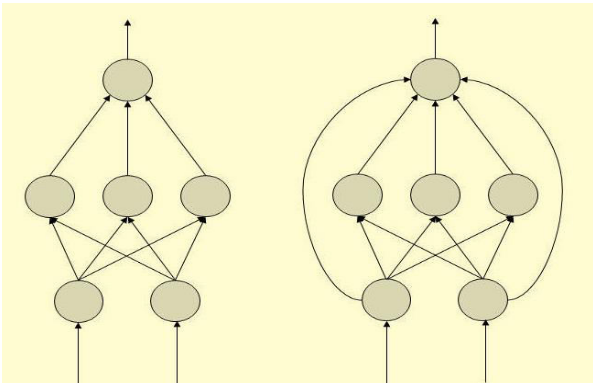

Figure: 1.4 (b) Feed Forward ANN Artificial Network Types

b. Feed Back ANN

In this specific Artificial Neural Network, feedback loops are allowed, allowing the incorporation of feedback information into the network's processing. It can also be used for adjusting memory content.

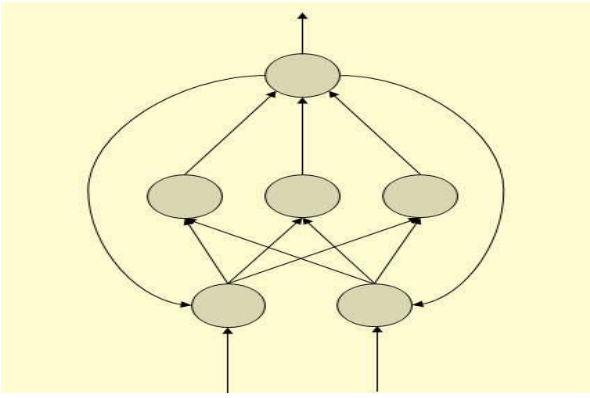

Figure: 1.4 (c) Artificial Networks Types – Feedback ANN

c. How Does Artificial Neural Networks Works?
You will study it everything in depth in these topology diagrams.

In this scenario, every arrow represents a connection between two neurons. The information flow path has been defined, and each connection is assigned a weight, indicated by an integer number. The transmission of signals between the two neurons is regulated.

If the network output is satisfactory, there is no need to change the weights. However, if the performance is average, the system will likely adjust its weights in order to improve the results.

1.4.2.1 Machine Learning in ANNs
As there are too many learning machines, let us see each:

a. Supervised Learning
In general, an instructor is involved in this learning. ANN must be known to that teacher.

For example:
Only examples are given by the teacher. The professor knows the answers already.

b. Unsupervised Learning
If no data set is available this learning strategy is thus necessary.

c. Reinforcement Learning
Observation forms the basis of this machine training technique. However, if the networks produce negative outcomes, they need to modify their weights. This allows them to make different and necessary decisions in future instances.

1.4.2.2 Back Propagation Algorithm
It is commonly referred to as an algorithm for training and learning, as these networks are highly effective in recognizing patterns and mapping tasks.

1.4.2.3 Bayesian Networks (BN)
We utilize graphical structures to represent this network primarily for expressing probabilities. This network consists of a random set of variables and is commonly referred to as a Bayesian network or a belief network.

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In these graphical representations, each node represents a random variable and specific statements.

The only allowed arcs in a Bayesian network are those that indicate direct dependencies between variables. Consequently, subsequent arcs do not need to return to the originating node.

As a result, Bayesian networks can be recognized as directed acyclic graphs (DAGs). We use Bayesian networks to effectively handle multivariate variables.

Thus, BN variables composed of two dimensions −

- Range of prepositions
- Probability assigned to each of the prepositions.

1.5 Artificial Neural Networks Applications

A neural artificial network utilized for different tasks. This task also works with people but is not easy for a machine.

a. Aerospace:

In autopilot airplanes, Artificial Neural Networks (ANNs) are commonly employed. They are used to detect airplane defects.

b. Military:

ANNs are utilized in the military in various ways, such as target tracking, artillery orientation, and steering.

c. Electronics:

Artificial Neural Networks are extensively used in the field of electronics. They are employed for tasks like code prediction, IC chip layout, and the study of chip failure.

d. Medical:

The medical field incorporates numerous machines that utilize Artificial Neural Networks in different ways. For example, they are used for examining cancer cells, EEG (electroencephalogram), and ECG (electrocardiogram).

e. Speech:

ANNs are employed for speech recognition and classification purposes.

f. Telecommunications:

Artificial Neural Networks have diverse applications in telecommunications. They are used for automated information services, including image and data compression.

g. Transportation:

Artificial Neural Networks are commonly used in transportation for various purposes, such as diagnosing truck brakes and programming vehicles.

h. Software:

Pattern recognition also utilizes Artificial Neural Networks. For instance, face identification, optical character identification, and other similar tasks.

i. Time Series Prediction:

Artificial Neural Networks are used for time series prediction. They are also employed to provide predictions related to inventory management and natural disasters.

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CHAPTER 2

ROLE AND SCOPE OF ENGINEERS IN THE FIELD OF DISABILITY

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Bio Medical Engineering and Measurement System (BioMEMS)

2.1 INTRODUCTION

India's health sector is experiencing rapid growth. In recent years, there has been a simultaneous increase in the incidence and sensitivity of neurological and neuromuscular disorders. According to studies conducted by India's National Commission on Population and the United Nations Statistics Division on Demographic and Social Statistics, the senior population is projected to steadily rise from 9.3% in 2016 to approximately 20% by 2050. This demographic shift is expected to exacerbate health issues among the elderly, leading to a higher prevalence of degenerative brain diseases such as Alzheimer's and Parkinson's. Additionally, disorders like epilepsy, stiffness, and paralysis resulting from neurotrauma, including stroke and spinal cord/head traumas, can significantly impact individuals. Experts suggest that various factors such as ethnicity, economic conditions, lifestyle, gender, and age contribute to the spread of neurological and neuromuscular ailments across the Indian subcontinent (Durand, 2007).

However, despite this growing demand, there is a significant shortage of sanitary facilities and healthcare staff. To address this disparity, a crucial strategy is to establish health-focused learning and research opportunities. This approach would involve creating international neurological facilities and research laboratories, as well as educating the next generation of health workers, engineers, and scientists. Collaboratively, they can strive to enhance the quality of life for individuals affected by diverse neurological disorders.

2.1.1 Scope of Neural Engineering

- Brain-machine (computer) interface
- Neural interfacing
- Neuro-technology
- Neuro-electronics
- Neuro-modulation
- Neural prostheses
- Neural control
- Neuro-rehabilitation
- Neuro-diagnostics
- Neuro-therapeutics
- Neuromechanical systems
- Neuro-robotics

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- Neuro-informatics
- Neuro-imaging
- Neural circuits: artificial and biological
- Neuro-morphic engineering
- Neural tissue regeneration
- Neural signal processing
- Theoretical and computational neuroscience
- Systems neuroscience
- Translational neuroscience

2.2 DISABILITIES AND ITS TYPES

Any physical or mental impairments that make it challenging for individuals to perform specific tasks (activity limitations) and interact with their environment can result in participation restrictions for people with disabilities.

According to the Americans with Disabilities Act (ADA), a disabled person is defined as someone with a physical or mental impairment that substantially limits one or more major life activities.

Under the Disability Rights Act (RPwD Act), "individuals with disabilities" are described as individuals with long-term physical, mental, intellectual, or sensory impairments that hinder their full and equal participation in society, particularly when interacting with barriers.

The RPwD Act contains handicap types:

1. Physical Disability

a. Locomotor Disability

i. Leprosy Cured Person

ii. Cerebral Palsy

iii. Dwarfism

iv. Muscular Dystrophy

v. Acid Attack Victims

b. Visual Impairment

i. Blindness

ii. Low Vision

c. Hearing Impairment

i. Deaf

ii. Hard of Hearing

d. Speech and Language Disability

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2. **Intellectual Disability**
a. Specific Learning Disabilities
b. Autism Spectrum Disorder
3. Mental Behaviour (Mental Illness)
4. Disability caused due to-
a. Chronic Neurological Conditions such as-
i. Multiple Sclerosis
ii. Parkinson's Disease
b. Blood Disorder-
i. Haemophilia
ii. Thalassemia
iii. Sickle Cell Disease
5. **Multiple Disabilities**

In all countries and legislation, the definition and types of disability may differ.

Additional medical conditions requiring the support of technical equipment include:

- Epilepsy
- Alzheimer's disease and other dementias
- Migraine and other headache disorders
- Brain tumors
- Neurological disorders as a result of malnutrition

2.3 SUPPORTING AIDS

Illustrations of assistive technology include:

Examples of assistive technology include:

- Mobility aids such as bicycles, wheelchairs, walkers, canes, crutches, prosthetic devices, and orthotic equipment.
- Hearing aids to improve hearing or amplify sound.
- Cognitive assistive tools that support individuals with memory, attention, and reasoning difficulties, including computer and other electronically assisted devices.
- Portable computers and assistive devices for individuals with visual impairments or physical disabilities, such as speech recognition programs, screen readers, and screen enhancement applications.
- Tools like automatic page turners, book holders, and adapted pencil grips to facilitate participation in educational activities for students with disabilities.
- Closed captioning to enable individuals with hearing impairments to enjoy movies, TV programs, and digital media.

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- Physical modifications to the environment, such as ramps, grab bars, and wider doorways, to enhance accessibility in buildings, businesses, and workplaces.
- Lightweight and high-performance mobility devices that allow individuals with disabilities to participate in sports and physical activities.
- Adaptive switches and utensils that enable individuals with limited motor abilities to eat, play games, and perform other tasks.
- Specialized handles, grips, reach-extending devices, and lights on phones and doorbells are just a few examples of products and tools that assist with tasks like cooking, dressing, and grooming.
- Accessible buildings and public spaces, including features like ATMs, elevators, and other facilities.
- Customizing homes to meet the specific needs of individuals with disabilities, such as modifying kitchen requirements based on the type of impairment and the person's abilities.

UNADDRESSED NEEDS:

Detecting and indicating biological needs such as toileting, hunger, and physical discomfort, among others.

2.4 NEED OF ENGINEERING ASSISTIVE EQUIPMENT TO MANAGE DISABILITY

Neural engineering is a rapidly expanding discipline that involves the development of brain implants connected to external technology. Its primary goal is to restore and enhance human function by establishing direct communication between the nervous system and artificial technologies. Currently, extensive research is being conducted to understand the encoding and processing of information within sensory and motor systems. This knowledge serves as a foundation for engineering devices such as brain-computer interfaces (BCIs) and neuro prosthetics, enabling them to effectively intervene and interact with the neural pathways.

Peripheral nerve regeneration, spinal cord tissue regeneration, and retinal tissue regeneration are among the numerous applications of neuro engineering devices. To design these gadgets, neural engineers require a comprehensive understanding of the functioning and dysfunctions of the nervous system. The generation of extracellular field potentials and synaptic transmission in brain tissue is influenced by various signals, including chemical, electrical, magnetic, and optical stimuli.

Signal processing techniques and computer simulations can be utilized to study the characteristics of brain activity. Neuronal coding, is a signal processing method that involves converting voltage variations across neuronal membranes into equivalent codes. One aspect of this research involves un rave-ling how the brain encodes basic instructions through various mechanisms such as central pattern generators, movement vectors, the cerebellar internal model, and somatic mappings. This investigation delves into understanding how the brain processes and represents simple directions.

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2.4.1 Correcting Anomalies in Central Nervous System

Neuroscientists and engineers have collaborated to develop medical treatments for conditions resulting from brain damage or dysfunction, aiming to enhance our understanding of the peripheral and central nervous systems.

Many biomedical technologies have advanced tremendously in recent years, including those that facilitate the transfer of pharmacological drugs, electrical signals, or other types of energy stimuli to the nervous system, aiming to modulate and regulate nervous system activity by either increasing or decreasing it. With the advancements in technology, these signals can now be delivered and analysed in closed loops within the brain, offering greater sensitivity, biocompatibility, and survivability. This progress opens opportunities for the development of new therapies and clinical applications that can be tailored to assist individuals with various forms of neurological injuries.

Recently, neuromodulation has garnered significant interest as a treatment approach for a variety of disorders due to its targeted effect on specific regions of the brain, as opposed to systemic approaches that can have negative consequences on the entire body. Microelectrode arrays, which serve as neuromodulator stimulators, offer the capability to both stimulate and record brain activity, leading to improved outcomes. Additionally, there is a growing emergence of drug and stimulus delivery devices that are responsive and adjustable.

2.4.2 Neural interfaces and neuro prosthetic devices

Engineered devices that selectively record electrical activity from interconnected circuits can be employed to gather information on nervous system activity. These devices, known as neural interfaces, have the potential to enhance or replace neuronal function.

Furthermore, they possess the capability to stimulate specific areas of the body, thereby restoring the function or perception of the corresponding tissue. Materials that possess mechanical properties matching those of brain tissue are utilized in microelectrode arrays. The key lies in controlling the body's response to external substances. Light-sensitive optical neural interfaces employ optogenetic stimulation and optical recording techniques to activate brain cells.

By implanting fibre optics in the brain, scientists can stimulate and record the brain's photon activity without the need for electrodes.

When discussing neuro prosthetics, we refer to devices designed to stimulate and record the activity of the nervous system, aiming to compensate for lost functionality within the system.

To execute the desired actions instructed by the transmitted signals, electrodes can be incorporated into these devices. Artificial sensors are employed in sensory prostheses to replace any lost neuronal input. Engineers working on these devices face the challenge of developing a safe and long-term artificial interaction with neural tissue.

One of the most successful examples of sensory prostheses is the cochlear implant, which has restored hearing for individuals with hearing impairments. Visual prostheses are also being developed to assist the visually impaired in regaining vision.

Motor prostheses leverage functional electrical stimulation (FES) of the biological neuromuscular system to replace brain or spinal cord control systems. FES aims to assist patients in regaining motor functions such as standing, walking, and grasping with their hands. Smart prostheses can facilitate muscle and nerve transplantation from an amputee's residual limb. These devices can decode signals and utilizing the information to operate the prosthetic limb.

2.4.3 Brain computer interface

Neurofeedback is a technique that involves direct communication with the patient's nervous system to monitor and treat neurological diseases. Deep Brain Stimulation (DBS) is the commonly used method for treating movement disorders, as it utilizes high-frequency stimulation of neural tissue to alleviate symptoms such as tremors in Parkinson's disease.

An incredibly valuable application of neuro engineering is the enhancement of human neural systems, also known as human enhancement, achieved through engineering techniques. Patients who have undergone DBS for neurological disorders have reported improved memory recall following the procedure. DBS has the capacity to influence emotions and personalities, as well as enhance motivation and alleviate inhibitions in patients. Latest DBS implantable devices.

As a result of the development of Boston Scientific's Vercise directed DBS devices for treating Parkinson's disease (PD), a neurodegenerative condition characterized by muscle rigidity, delayed movement, and tremors, performing everyday activities can become increasingly challenging. DBS therapy involves the use of an implanted pulse generator (IPG) to deliver precise electrical stimulation to specific brain regions.

While therapies can alleviate Parkinson's symptoms, they do not halt or slow down the progression of the disease. Therefore, it is crucial to have options for adjusting treatments as the disease advances. Patients with Parkinson's disease require a therapy that can adapt to their changing needs.

Boston Scientific focused on cochlear implants, which restore hearing and help users recognize different sounds, voices, and music. This approach allowed doctors to make prompt adjustments to a patient's treatment as their symptoms evolved or progressed. Inspired by this concept, Boston Scientific developed Vercise PC and Vercise Gevia DBS devices, which enable users to finely adjust the intensity, shape, location, and direction of electrical stimulation.

Vercise directional DBS devices utilize individually regulated electrodes on each lead, providing adaptable brain stimulation tailored to changes in brain impedance. This offers neurologists enhanced control over the shape and size of the stimulation field. As the technology of the system continues to advance, various mechanical, electrical, and software aspects will undergo changes:

Current can be transmitted in any direction around the lead by using Cartesia directional leads. Boston Scientific's STIMVIEW software allows neurologists and doctors to visualize the formation of the stimulation field on a screen, making it easy to align the shape of the stimulation field with the brain's target region.

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Engineering continuously enhances the capabilities of these devices, which includes miniaturizing electronics and mechanical packaging, improving power supply, and adding software functionalities. This is all part of an ongoing process of progress. Computer simulations and in vitro tests ensure that updates are effective and yield positive outcomes.

These devices are designed to interact seamlessly with the body's tissues. With a lifespan of 15 years, they are long-term biocompatible. As neural prostheses, the developers aspire to make the systems smarter, more autonomous, and more aesthetically natural-looking.

Researchers in Grenoble, France, have developed an implantable wireless device that enables tetraplegic patients to walk and use an exoskeleton with both arms through a brain-computer interface (BCI). Tetraplegia occurs when a spinal cord lesion impairs the neurological system's ability to control all four limbs. The CEA lab in Grenoble's university hospital, Clinatec, has created a device to control a four-legged exoskeleton that captures and decodes brain impulses. The exoskeleton is powered by an implant that monitors real-time brain activity and utilizes the data for control.

The device was tested on a tetraplegic patient who was able to walk and utilize both arms using the neuro prosthetic. It successfully recorded, transmitted, and decoded brain signals.

A significant innovation from Clinatec's clinical investigation under the BCI Project is the device's ability to continuously capture high-resolution brain electrical activity and wirelessly transfer it in real-time to a computer for decoding, enabling control of the movement of all four limbs of an exoskeleton. The medical implanted device, called WIMAGINE, tracked electrical activity in the sensorimotor cortex.

An array of semi-invasive cranial implantation electrodes contacted the dura mater to acquire electrocorticograms (ECoG) (a membrane that surrounds the brain and part of the spinal cord).

Microelectronics engineers at CEA-Leti also developed electronic boards for the acquisition and digitalization of electrocorticograms (ECGs), along with a remote power supply and wireless data transfer system utilizing a secure radio link to an external base station.

2.4.4 Optimising the use of Exoskeleton

Sensorimotor cortex impulses are emitted when a person imagines movement and are captured by WIMAGINE, an implanted device. A tetraplegic individual can control their exoskeleton simply by thinking about it. This technology represents a significant advancement in empowering individuals with severe mobility limitations.

Real-time decoding of electrocorticograms identifies the patient's imagined purposeful movements and utilizes those decoded impulses to drive the corresponding limbs of the exoskeleton. Decoding electrocorticograms requires the development of highly powerful artificial intelligence (AI) and machine learning (ML) algorithms, as well as software to enable real-time control of the exoskeleton's movements.

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2.5 LIMITATIONS OF EXISTING TECHNOLOGIES AND NEED FOR IMPROVEMENT

2.5.1 Principles of Assistive Technology Assessment

In addition to comprehending the physical principles that guide their designs, rehabilitation engineers must adhere to some key principles that govern the application of technology for people with impairments. To be effective, assistive technology must carefully consider the requirements, preferences, talents, limits, and even the environment of the person seeking it. There are at least five widespread myths about assistive technology:

Myth 1: Assistive technology is a panacea for all ills. Even though assistive gadgets might make life a little simpler, they cannot eliminate all the challenges that come with a disability.

Myth 2: People with the same disability require the same assistive technology. Assistive technology must be tailored to the specific needs, interests, and preferences of individuals with similar disabilities (Wessels et al., 2003).

Erroneous belief number three: Assistive technology is inherently difficult and expensive. Sometimes, low-tech devices are the best option due to their simplicity, ease of use and maintenance, and low cost.

Just because someone uses assistive technology does not mean that their prescription is correct or appropriate. Experiments show that the use of technology by people with impairments is imperfect and will evolve over time. Users of assistive technology and the rehabilitation specialists who provide support will need to periodically reevaluate their needs as their health, living environment, preferences, and circumstances change.

Belief 5: Assistive technology will always be employed. U.S. Census Bureau data shows that roughly a third of assistive gadgets acquired but not critical for survival are left unused or abandoned after only three months.

Additionally, there are certain principles that have been demonstrated to be helpful in matching appropriate assistive technology with the user or consumer. By following these recommendations, it is more likely that the final assistive technology will be well received and fully utilized.

- ❖ **Principle one:** Identifying and incorporating the user's specific aims, objectives, and tasks as early as feasible in the intervention process is a key component. Checklists and pre-made forms should be used to avoid missing important details like needs and objectives.
- ❖ **Principle two:** Involving a diverse group of rehabilitation providers will increase the odds of a positive outcome. Many people should be included in the process of matching assistive technology to a person's needs, according to what it will be used for and in what context.
- ❖ **Principle three:** There must be a thorough evaluation of the user's preferences, cognitive and physical abilities, or limits, living environment, technology tolerance, and probable future changes. Rehabilitation engineers need to transform nontechnical

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professionals' usage of highly descriptive terminology and qualitative language into quantitative qualities.

- **Principle four:** Careful and thorough evaluation of available technologies for solving user demands is required to avoid overlooking potentially important solutions. Electronic databases can provide an initial overview of potentially effective prescription, modification, and delivery devices.
- **Principle five:** When selecting an assistive technology equipment, keep in mind the preferences and choices of the person who will use it. Failure to consider the requirements and preferences of the users is the biggest reason assistive technology is rejected or underutilized.
- **Principle six:** The device for assistive technology needs to be adapted to its intended use and placed in the appropriate environment. Seemingly harmless circumstances at the usage location can often determine the success or failure of assistive technology implementation.
- **Principle seven:** Anyone who will accompany or care for the user should understand the device's intended purpose, benefits, and limitations.
- Adjustments in communication and behaviour may be necessary for both the user and the people around them to fully utilize an augmentation communication device.

Ongoing monitoring, reassessment, and adjustment based on changing patterns and expectations of users are necessary. Adapting an assistive technology to a changing person or circumstance may require changes in the technology itself.

2.6 ROLE AND SCOPE OF ENGINEERS IN THE FIELD OF DISABILITY

There are numerous methods to classify the main activities in this discipline. Recognizing its depth and breadth can be as simple as classifying the various forms of assistive technology developed by rehabilitation engineering (Table 5.2). Orthopaedist's, prosthetists, and orthotists, as well as computer professionals, all contribute to the development of these technological gadgets. Digital signal processing chips, memory chips, and complex software developed by electrical and computer experts are all critical components in many assistive devices.

A team of engineers, physicians, informed end users or consumers, and caregivers must work together to design, develop, and apply assistive technology devices correctly.

Table 2.1: Categories of Assistive Devices

Prosthetics and Orthotics
Artificial hand, wrist, and arms
Artificial foot and legs
Hand splints and upper limb braces
Functional electrical stimulation orthoses
Assistive Devices for Persons with Severe Visual Impairments
Devices to aid reading and writing (e.g., closed circuit TV magnifiers, electronic Braille, reading machines, talking calculators, auditory and tactile vision substitution systems)
Devices to aid independent mobility (e.g., Laser cane, Binaural Ultrasonic Eyeglasses,

Handheld Ultrasonic Torch, electronic enunciators, robotic guide dogs)
Assistive Devices for Persons with Severe Auditory Impairments
Digital hearing aids
Telephone aids (e.g., TDD and TTY)
Lipreading aids
Speech to text converters
Assistive Devices for Tactile Impairments
Cushions
Customized seating
Sensory substitution
Pressure relief pumps and alarms
Alternative and Augmentative Communication Devices
Interface and keyboard emulation
Specialized switches, sensors, and transducers
Computer-based communication devices
Linguistic tools and software
Manipulation and Mobility Aids
Grabbers, feeders, mounting systems, and page turners
Environmental controllers
Robotic aids
Manual and special-purpose wheelchairs
Powered wheelchairs, scooters, and recliners
Adaptive driving aids
Modified personal licensed vehicles
Recreational Assistive Devices
Arm-powered cycles
Sports and racing wheelchairs
Modified sit-down mono-ski

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CHAPTER 3

APPROACHES TOWARDS RESEARCH IN SOCIAL SCIENCE

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3.1 Resources and Materials for Research (Examples with a few Disorders)

One of the preeminent striking instances of neural engineering, specifically brain-machine interfaces, is the bio arm. The DEKA Arm, for example, is currently in clinical trials at the VA. With many US officials coming home from Iraq and Afghanistan having had their arms amputated, the VA aimed to supply a prosthetic limb far more advanced than the basic hook used since World War II. DARPA (The Defence Advanced Research Projects Agency) enlisted Segway inventor Dean Kamen to develop an arm that would allow amputees to grasp a raisin or grape and differentiate between them without looking at it. The hand could be no larger than an average human hand and weigh no more than nine pounds. The DEKA Arm was created by a team of over 300 researchers, including engineers, neuroscientists, and psychologists, from DARPA and Kamen's DEKA Research and Development Corporation.

To achieve this, understanding how neurons work is even more fundamental. Biomedical engineers specializing in neural engineering can seek approaches to either stimulate or disrupt this neurocircuitry. Implantable devices are comparable to the pacemakers used in the heart setting (see Cardiopulmonary Systems Engineering), which can be used to control nervous system disorders like Parkinson's disease, paralysis, and epilepsy. California-based Neuro-Pace, Inc., is currently in clinical trials with their responsive neurostimulation (RNS®) system, which monitors and blocks abnormal electrical activity in the brain during seizures.

If we consider nerves as wires, these wires—or neurocircuits—can either be stimulated or impeded. In the future, high-frequency electrical induction could be used on peripheral nerves in the arms and legs to specifically induce sensations such as pain without interfering with other communication. The ability to provide incredibly localized and reversible sedation would be one use of this advancement. Another example can be drawn from "bladder control."

Most bladder control issues are typically the result of the inability to control the neurons that signal to an individual when they need to void.

High-frequency electrical stimulation through an external device can be used to assist with functions that the body which cannot handle, especially important for those who are incapacitated.

Visual Prostheses: A phony retina has become a reality, as various research groups are enthusiastically developing devices to replace damaged retinas. For example, a consortium of researchers in Australia is working on bionic vision, which aims to restore sight to people with degenerative vision conditions such as retinitis pigmentosa or age-related macular degeneration. In both conditions, there is a problem in the part of the eye that processes light, but the neural hardware and visual processing capacity of the brain remain intact. Using a camera attached to a combination of glasses, signals are

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transmitted to a microprocessor implanted inside the retina. From there, small electrical currents are sent to surviving neurons in the brain. Current technology limits the number of implanted electrodes to approximately 100, so the information captured by the camera is processed and reduced to form simple images. However, these images can make a world of difference to someone who was previously unable to see. The Australian development underwent trials on people until 2013 and may take some more time unless it reaches the market. Second Sight in California is currently in clinical trials on a similar retinal prosthesis system that provides 60 terminals. Additionally, a German consortium has taken a different approach that provides more terminals, but they are not encapsulated and therefore not long-lasting. The German system is also being tested in individuals.

The few yet extraordinary research studies in neural engineering seem like science fiction, but they are truly scientific reality. We have seen a robot controlled through sophisticated neurons in a dish, a monkey wired to electrodes controlling the movements of a robot, and a remote-controlled rat responsive to the press of a button.

Neural engineering combines a diverse range of disciplines, including neuroscience, mathematics, engineering, biophysics, computer science, and psychology. This interdisciplinary work is providing valuable insights into our understanding of dementia, Parkinson's disease, brain damage, strokes, and other neurological deficits.

For a long time, there has been renewed interest in the potential applications of neural engineering, as evidenced by notable initiatives such as the United States' BRAIN Initiative, which has generated a lot of excitement for the advancement of modern developments in the field. The diversity of potential uses of neural engineering is indeed remarkable.

For example, neural implants have the potential to alleviate memory impairments caused by Alzheimer's disease, restore lost or damaged vision, and even enable prosthetic limbs to be controlled by thought.

Currently, deep brain stimulation, which involves implanting an electrode that delivers messages to specific targets in the brain, is used to treat Parkinson's disease and severe cases of obsessive-compulsive disorder and depression.

Another emerging trend that seems promising in neural engineering is the stimulation of the autonomic nervous system to treat various chronic diseases, ranging from epilepsy to conditions indirectly caused by an impaired nervous system, such as hypertension and diabetes. For instance, in type 1 diabetes, pancreatic transplantation would be the preferred option, but due to a lack of donors and immune compatibility issues, this treatment is least favourable. Neural engineering, on the other hand, is making tremendous efforts to overcome this issue by utilizing chip-based technology to control the insulin release system.

In summary, neural engineering has been showing promising results for the development and advancement of society, helping people achieve the unimaginable. However, with abundant research, careful oversight is needed to ensure its utilization towards a more promising future without risking potential dangers.

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3.2 Peer research group In India and Abroad – (Those who are doing research in the relevant areas). (Address and works they are doing currently) - Private and Government Institutes…

Disability research in India is primarily conducted by national institutes such as NIEPVD, AYJNISHD, NIEPID, and NIEPMD, as well as institutes under the Ministry of Social Justice and Empowerment, including AIIMS, NIMHANS, PGIEMR, and JIPMER. Additionally, IITs are involved in research to a certain extent.

Several nonprofit organizations, such as Sense International, SCARF, The Banyan, Action for Autism, and HelpAge India, are also actively engaged in research in this field.

Please feel free to explore information on a global scale.

3.3 How to Approach the Resources, Materials and People (Research Institutes as well as the Disabled Persons)? Disabled Persons - To be reworded as Persons with Disabilities

Organizations under the control of the Indian government, as well as non-governmental organizations (NGOs), are generally receptive to working on research projects with other institutions, both locally and internationally. An effective method of approaching them is to bring up an academic research topic that focuses on their goals and requirements.

If you are trying to reach people with disabilities in rural or semi-rural areas for the purpose of conducting research, it is highly recommended that you utilize a structured group that includes Anganwadi workers, Asha volunteers, teachers working on the Sarva Siksha Abhiyan program, community groups, or a prominent NGO in that field.

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CHAPTER 4

ETHICAL CONSIDERATIONS AND PROCEDURES FOR ETHICAL CLEARANCE

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4.1 Ethics

When discussing the ethical issues surrounding neural engineering enhancement, we enter the broader debate on whether modern medical technology can be utilized to enhance human traits. The arguments described below also play a significant role in relation to other forms of augmentation, such as aesthetic surgery, growth hormone treatment, or the use of psychopharmacology to enhance intellect or mood states.

Furthermore, a second set of arguments focuses on aspects specific to brain engineering, which are unique to this field of study. Before delving into the ethical implications of brain engineering-based enhancement, it is important to note that this paper adopts a cautiously optimistic stance towards enhancement in general, without providing an in-depth justification. We do not perceive medical augmentation as a heinous transgression of human nature, nor do we agree with the claim that improvement is a problematic objective for medicine or society. Consequently, we do not consider enhancement to be inherently bad. However, upon closer examination, it becomes evident that the widespread application of neural engineering for performance enhancement may give rise to several problematic issues. Several ethical concerns need to be addressed before brain engineering can be responsibly developed and utilized.

4.2 Consideration of Ethics in Research

Proportionality: The benefits and risks of a medical intervention should be balanced. Moreover, therapy is often considered more valuable and inherently more useful than augmentation (Daniels, 2000). Since the body being enhanced is already healthy, enhancement therapies are rarely deemed necessary. Consequently, it can be assumed that patients are more willing to accept the risks associated with therapeutic interventions than with enhancement interventions.

- Predicting the risks of cutting-edge neural engineering techniques is challenging.

If neural implants are involved, the risks primarily relate to surgical procedures for implantation, as well as the maintenance or updates of the implant. Risks may also be associated with the possibility of the human body rejecting a specific implant. If expertise gained from therapeutic neural engineering can also aid future interventions aimed at improving quality of life, it is possible to achieve an ideal balance between benefits and risks over time in this field as well. Several new technologies might be used both as a medical tool and an enhancer simultaneously, without additional risks beyond those associated with the development of promising new therapeutic therapies. The deliberate and extensive development of deep brain stimulation with a defined therapeutic purpose and careful risk-benefit evaluation serves as notable examples of such dual uses.

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In the future, DBS surgery may be considered a routine procedure with well-defined risks and benefits. Exploring DBS's potential for enhancement in such cases would be straightforward, at least in terms of risk proportionality. However, there are numerous neural engineering applications that will require significant advancements in current technology, going beyond simple dual usage. The development of such devices would initially focus on their use as enhancers, as no medical condition necessitates rapid information assimilation or sensory integration from multiple individuals.

The specific type of surgery, the type of chip/prosthesis, and the knowledge gained about neuro implants through therapeutic applications serve as technological components that developers can utilize. However, there is currently insufficient research on how the human brain responds to rapid information intake or sensory fusion. Understanding these issues would require extensive experimentation. The notion that institutional review boards would readily approve surgical research techniques involving healthy volunteers is unfounded, especially when the objective is to create a device primarily for enhancement rather than medical purposes (Foster, 2006).

Assessing the favourable risk-to-benefit ratio in brain engineering methods designed solely for enhancement purposes is significantly more challenging than in those originally intended for therapeutic applications, both in the short and long term. Since neuro-implants are still in the early stages of research, it is difficult to predict how the various risk factors will play out in the future.

4.2.1 The transparent society

Privacy can be defined as the ability of an individual or group to control the disclosure of their personal information. It entails the capacity to keep private information confidential and only share it with chosen individuals. According to Brin (1998), privacy is at risk due to the advancements in surveillance, communication, and information technology. He argues that there are two possible outcomes of this development. One option is to restrict surveillance powers to "the authorities," which may create an illusion of privacy but would ultimately be deceptive. Alternatively, society could strive for equal access to surveillance tools, sacrificing the sense of privacy but enabling transparency and accountability. Brin advocates for a society where the public has the same monitoring capabilities as those in power.

Brin makes a valid point regarding the risks of monopolizing surveillance. However, his research overlooks the potential impact of the development and widespread use of brain engineering technologies, which could significantly increase the risks to privacy and further blur the line between humans and machines. For instance, the extensive application of brain-computer interfaces (BCIs) could establish permanent connections between people's brains and computers for various purposes. The brain could directly interface with databases to retrieve information, and neurological engineering could facilitate deeper connections between individuals. Technologies like the cyber think communication system could enable continuous contact with geographically distant individuals through direct brain-to-brain links. Furthermore, these technologies could make it easier to track and record the exact location, actions, and thoughts of those connected to the internet or integrated into such systems.

If the widespread use of neural engineering technologies indeed leads to significant privacy limitations, it raises the question of what privacy restrictions can still be justified in the light of the benefits provided by these technologies. In other words, what compromises between privacy and enhancement can be considered reasonable? Additionally, research is needed to explore how surveillance monopolies can be avoided.

4.3 Bylaws and Strategy of the Ethical Committee with Respect to the Nation

Research ethics committees examine research proposals involving human participants to ensure compliance with internationally and locally accepted ethical guidelines.

They monitor studies once they have commenced and, when applicable, participate in follow-up actions and surveillance after the research is completed.

These committees possess the authority to select researchers, reject studies, or terminate research altogether. Furthermore, they may propose legislation or express views on ongoing ethical challenges in the field of scientific investigation.

Research involving human participants must undergo review by an ethics committee in accordance with international and national ethical guidelines and laws. Reviews may be required based on the regulations of the country providing support for the study, even if the host country's own laws do not mandate them for international collaborative research. Review is also necessary if researchers intend to publish the results of their investigation since most medical journals refuse to publish research that has not been approved by an ethics committee. The primary responsibility of a research ethics committee is to safeguard potential research subjects, while also assessing the risks and benefits of the research for the broader community. Ultimately, their aim is to promote adherence to high ethical standards within health research institutions.

4.4 Ethical Committee and Members

4.4.1 Structure and functions of research ethics committees

Most of our research ethics committees are regional or national in scope, although some are situated within research institutes and referred to as "institutional review boards" (IRBs). Having research ethics committees within research institutes offers the advantage of closer monitoring of ongoing studies since they are familiar with the local settings. However, these committees may face constraints when it comes to rejecting or requesting significant alterations to studies due to the institution's financial interest in receiving external research funding.

On the other hand, regional and national committees can provide better consistency and credibility in the eyes of the scientific community and the general public, despite their distance from the study site.

In countries with large number of committees, it is crucial to establish systems that promote consistency and reduce duplication of effort.

Research ethics committees assess and evaluate the risks and benefits of research, as well as the processes and materials (such as written documents and other instruments) used to obtain informed consent from participants. They also review the recruitment process, incentives offered to participants, risks to confidentiality (and associated risks of bias), and the adequacy of confidentiality measures.

The committee represents the interests of the local population in international research, ensuring equitable benefits for participants and the communities they represent.

Studies involving medical interventions, such as HIV prevention trials, require ethics boards to ensure that participants receive appropriate medical care and treatment. The use of placebo controls can exacerbate this issue (see Declaration of Helsinki, Section 322). Committees should consider the provision of medical attention to study participants who experience harm as a result of their participation or due to pre-existing conditions. Sponsors should implement an informed consent process before the research begins to ensure that potential participants are aware of their responsibility to provide care in certain situations.

4.5 Why Ethical Committee – What For

Research ethics committees examine research proposals involving human participants to ensure compliance with internationally and locally accepted ethical guidelines. They monitor studies once they have commenced and, where applicable, participate in follow-up actions and surveillance after the research is completed. These committees possess the authority to select researchers, reject studies, or terminate research entirely. Furthermore, they may propose legislation or express views on ongoing ethical challenges in the field of scientific investigation. Research involving human participants must undergo review by an ethics committee in accordance with international and national ethical guidelines and laws. Even if not required under the rules of the host country, international cooperative research may still need assessment under the laws of the supporting country.

Review is also necessary if researchers intend to publish the results of their investigation, as most medical journals refuse to publish research that has not been approved by an ethics committee.

The primary responsibility of a research ethics committee is to protect potential research subjects, while also assessing the risks and benefits of the research to the broader community. Ultimately, their goal is to promote adherence to high ethical standards within health research institutions.

4.6 Documents Required for Getting Approval from Ethical Committee.

What are the key points for evaluating informed-consent procedures?

- Determining the necessary details that potential participants should be provided with.
- Ensuring that the information document and accompanying aids contain all the essential information.
- Assessing the comprehensibility of the materials, considering the target audience.
- Evaluating the procedures and methods used to communicate the information.
- Examining any limitations that might impact the consent process.
- Assessing the specific cultural and social characteristics and their influence on the validity of consent.

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4.7 Sample Formats

A DOCUMENT FROM ETHICAL COMMITTEE CHAIR

Date

To

Submitted Person

Respected Sir,

Subject: Approval of Institutional Ethical Committee – Research Project – Reg.,

Name of Ethical Committee Host Institution - Institutional Ethics Committee reviewed and discussed your application to conduct the project titled, **"Title."**

The following protocol was submitted and reviewed.

Protocol No: Version No.: Date:

TITLE	**Title of the Project**
A.	REFERENCE ARTICLES FOR REVIEW
B.	PROPOSED METHODOLOGY
C.	SUPPORTING LETTERS/ MEMORANDUM OF UNDERSTANDING (MoU) / MEMORANDUM OF AGREEMENT (MoA) WITH COLLABORATORS
D.	ROLES AND RESPONSIBILITIES OF HOST INSTITUTION MEMBERS, COLLABORATORS AND SUPPORTERS
E.	PROPOSED ARTICLE PUBLICATIONS IN REPUTED NATIONAL AND INTERNATIONAL JOURNALS AND CONFERENCES
F.	PATIENT CASE HISTORY AND CONSENT FORM
G.	PROPOSED BUDGET OF THE PROJECT

A.	**REFERENCE ARTICLES FOR REVIEW**	
Sl. No.	**DOCUMENT**	**Volume No., Issue No., Year of Publication & Page No.**
01.		
02.		

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C.	**SUPPORTING LETTERS/ MEMORANDUM OF UNDERSTANDING (MoU) / MEMORANDUM OF AGREEMENT (MoA) WITH COLLABORATORS**	
Sl. No	Name of the Institution/Company	Letters/ MoU/MoA Signed Date
01.		
02.		
03.		

D.	**ROLES AND RESPONSIBILITIES OF KONGU ENGINEERING COLLEGE, COLLABORATORS, AND SUPPORTER**	
HOST INSTITUTION AND MEMBERS		
Sl. No.	Name of the person with designation	Roles and Responsibilities
COLLABORATORS/MoU/MoA		
Sl. No.	Name of the person with designation	Roles and Responsibilities

E.	**PROPOSED ARTICLE PUBLICATIONS IN REPUTED NATIONAL AND INTERNATIONAL JOURNALS AND CONFERENCES**
Sl. No.	Papers to be prepared and published
01.	Autism
02.	Psychological & Neurological aspects of Normal and ASD Children
03.	Clinical Observations
04.	Procedure for Acquiring Data
05.	Survey Paper (Science Based)
06.	Survey Paper (Engineering Based)
07.	Preprocessing, Classification and Percentage in the Determination of Autism
08.	Hardware Design
09.	Practical Issues in Hardware Design
10.	Simulated Results

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11.	Budget Involved in Project from Scratch to Completion of the Project as Product
12.	Research Methodology of this Project (Overall)

F.	**PATIENT CASE HISTORY AND CONSENT FORM**
Annexure 1	

G.	**PROPOSED BUDGET OF THE PROJECT**	
Overall Consolidated Budget		
Sl. No.	**Items**	**Budget in Rupees**
A	**Recurring**	
	Manpower	
	Consumables	
	Travel	
	Training Programme	
	Contingency	
	Overheads	
	Total (**A**)	
B	**Non-Recurring**	
	Permanent Equipment	
	Fabrication Costs	
	Total (**B**)	
Grand Total (A+B)		

The following members of ethics committee were present at the meeting held between (time) to (time) on (date) at (Name of the Ethical Committee) - Institutional Ethics Committee, having its office at (Address).

Sl.No.	**Name of the Member and Specialization**	**Role in Ethics Committee**	**Opinion** (Approved/Disapprove)	**Signature and Date**
1				
2				
3				

We **approved and recommended /disapproved and not recommended** for the revision of the protocol (**Protocol No.: Version No.: Date:**) to be conducted in its presented form. The validity period of this approval is (Number of Years) year/s from the date of this letter.

CHAIRMAN

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[HOST INSTITUTION – SUPPORTERS/MoU/MoA - RESEARCH PROJECT]

"Title of the Project"

PATIENT CASE HISTORY AND CONSENT FORM

Research ID Number : ____

Data Set : - / - / - / -

Date of Assessment : ____

Site of Study : ____

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PART I – INFORMED CONSENT FORM (ENGLISH)

"Title"

About Principle Investigator and the roles and responsibilities of supporters, MoU,MoA.

Project Description – Activities and Commitment:

Medication Details -

Benefits of the study:

Risks presented in the study:

Confidentiality and Privacy:

Voluntary Participation:

Questions:

If you have any questions regarding the research study, please contact us at via phone at **(contact numbers)** or email us at **(email address)**

Please keep the prior portion of the consent form for your records.

If you agree to participate in the research study, please sign below.

Tear or cut here

Signature(s) for Consent:

I agree to participate in the research project entitled, "**Title**" I understand that I can change my mind about participating in this project, at any time, by notifying the researcher.

Your Name (capital letters) :

____

Parent/ Caregiver of :

____

Your Signature : ____

Date : ________________

Place : _________________

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PART II – SOCIO DEMOGRAPHIC VARIABLES

2.1: Basic Details of the subject:

Subject Name:	**Age:**	**DOB:**
Sex: Female / Male	**Order of Sibling:** First/ Middle / Last / Single Child	
Family Type: Nuclear / Joint / Broken	**Nationality:** Indian / Other	
Father's Name:	**Father's Age:**	
Mother's Name:	**Mother's Age:**	
Contact Number 1:	**Contact Number 2:**	

Example:

2.2: Kuppuswamy Rating Scale (2018 Update):

A. Occupation of the head of the household

Occupation of the Head	**Score**
Legislators, Senior Officials & Managers	10
Professionals	9
Technicians and Associate Professionals	8
Clerks	7
Skilled Workers and Shop & Market Sales Workers	6
Skilled Agricultural & Fishery Workers	5
Craft & Related Trade Workers	4
Plant & Machine Operators and Assemblers	3
Elementary Occupation	2
Unemployed	1

B. Education of the head of the family

Education of the Head	**Score**
Professions and honours	7
Graduate	6
Intermediate and/or Diploma	5
High School Certificate	4
Middle School Certificate	3
Primary School Certificate	2
Illiterate	1

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C. Total monthly income of the family

Total Income of the House	Score
>126,360	12
63,182 – 126,356	10
47,266 – 63,178	6
31,591 – 47,262	4
18,953 – 31, 589	3
6327 – 18949	2
< 6323	1

- **Kuppuswamy Rating Scale Interpretation**

Total Score	Socioeconomic Class
26 – 29	Upper (I)
16 – 25	Upper Middle (II)
11- 15	Lower Middle (III)
5 -10	Upper Lower (IV)
< 5	Lower (V)

PART III – MEDICAL PARAMETERS AND HISTORY

Date of Administration: ____

Name of the Administrator: ____

3.1: Health Parameters:

Height:	**Weight:**	**Blood Type:**	**Handedness:**
Diagnosis:		**Body Temperature:**	
Head Circumference:		**Immunization:**	

3.2: Milestone History:

Is the subject having a history of delay in milestones? Yes/ No

(If yes, answer the following questions. If no, proceed to subsection 3.3)

S. No	Milestone	Age of Completion	Normal (N) / Delayed (D)/ Regression (R)
1.	Head Control		
2.	Turning Over		
3.	Sitting up Straight		

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4.	Standing		
5.	Walking Independently		
6.	Eye Contact		
7.	Responding to one's name		
8.	Smiling at others		
9.	Chewing hard food		
10.	Cooing / babbling		
11.	First words		
12.	Full Sentences		
13.	Bowel Control		
14.	Bladder Control		
15.	Reaching out for Objects		
16.	Following Instructions		

3.3: Neurological History:

Does the subject been diagnosed with any Neurological Condition prior to this interview?

Yes/ No

(If yes, please answer the questions below; If no, please proceed to subsection3.4)

Kindly tick marks all that is relevant:

Neurological Disorder	Age of Onset	Neurological Disorder	Age of Onset
☐ Hydrocephaly		☐ Movement Disorder	
☐ Microcephaly		☐ Cerebral Palsy	
☐ Seizures / Epilepsy		☐Spina Bifida	
☐ Mitochondrial Disease		☐Traumatic Brain Injury	
☐Auto – Immune Disorders		☐Tumours	
☐ Other (Please Specify)			

Kindly write down a brief description of illness in the space provided below:

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3.4: Other Medical History:

Does the subject have any known history of any medical illnesses? Yes/ No

(If yes, please answer the questions below; If no, please proceed to subsection3.5)

Kindly add a Tick Mark to all that is relevant:

Medical Illness	**Age of Onset**	**Medical Illness**	**Age of Onset**
☐ Eating Disorder		☐ Cardiac Disorders	
☐ Allergies		☐ Diabetes	
☐ Respiratory Disorders		☐ Sleeping Disorders	
☐ Hormone Related Disorders		☐ ENT Complications	
☐ GI Disorders		☐ HIV/ AIDS	
☐ Other (Please Specify)			

Kindly write down a brief description of illness in the space provided below:

3.5: Drug Allergies:

Does the subject have a known history of drug allergies? Yes/ No

(*If yes; kindly describe in the space provided below; If No, please proceed to Part IV)*

Part IV –AUTISM CHECKLIST

4.1: Childhood Autism Rating Scale:

A. What is the total score of the client on the CARS II? ________________________

B. Interpretation of the Score ____

4.2: Indian Scale for Assessment of Autism:

A. What is the total score of the client on the ISSA? ___________________________

B. Interpretation of the Score ____

4.3: Child behaviour Checklist:

A. What is the total score of the client on the CBCL? _______________________

B. Interpretation of the Score ____

4.4: Sensory Processing Checklist:

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Kindly place a tick mark in all that is relevant and write down the CARS score for the following

1.	Tactile Sensitivity		5.	Auditory Filtering	
2.	Taste and Smell Sensitivity		6.	Low Energy or Weak	
3.	Movement Sensitivity		7.	Visual / Auditory Sensitivity	
4.	Under responsive/ Seeks Sensations				

Describe the sensory processing difficulties in the space provided below:

4.8 Obtaining the Approval from Ethical Committee

4.8.1 Applying for ethical approval: Basic principles

These forms and local instructions can help you understand what information should be included in your application and what issues should be addressed if you are looking for ethical authorization to conduct research with human subjects or personal data at the institution.

The committee's request for information will be based on your area of study and the type of research you want to do.

Ethics committees, on the other hand, typically expect you to have addressed the following issues in your application:

Recognizing and honoring individuality

Ethics committees will look for evidence that you aim to respect the autonomy of those who participate in your research whenever possible. It is common for this to include the following:

- Providing research subjects with enough information to enable them to decide whether to participate in the research
- Assuring participants that they would not be forced to participate or penalized for not doing so.
- Assuring participants that they can opt out of the study at any moment without explanation or consequence.
- Protecting and protecting the personal data submitted by participants by using appropriate and strict methods for confidentiality and anonymization.

✓ ***Maximizing benefit***

Ethics committees want to see evidence that your study is worthwhile and will have positive outcomes that outweigh the dangers it poses (see below). Beneficiaries will differ from project to project, but may include society, science, scholarship, health, and/or the participant themselves. Research advantages should be conveyed in a reasonable and non-overstated manner.

You owe it to study participants and the scholarly and ethical committees to make the most out of your work, so you should make every effort to do so. Typically, this would include:

- To ensure quality and integrity while also increasing the likelihood of producing useful results, research should be designed, reviewed, and conducted in this manner.
- Assuring that research findings are widely and appropriately communicated.
- Assuring that the research's objectives are clear and that the methodology being used is appropriate for addressing them.

✓ ***Minimizing harm***

Committees examining the ethical implications of your study will expect you to have considered the potential harm that could be caused to research subjects or others as a result of your work. You will be asked to assess all potential harms, acknowledging that some, such as distress, embarrassment, or fear, may be difficult to anticipate. In general, efforts should be made to avoid harm, and you will be expected to demonstrate how you will achieve this when it is recognized. Ethics committees seek evidence that you have made significant efforts to mitigate risks and address harm if it occurs despite preventive measures.

The principle of proportionality should guide the assessment of harm, where the risk and severity of harm should be balanced against the potential benefits of the research. Both the ethics committee and the researcher must carefully weigh the risks and benefits before granting approval to the research.

Promoting fairness and justice is another key aspect considered by research ethics committees. They expect researchers to demonstrate that they have made efforts to distribute the benefits, risks, and burdens of the research equitably whenever possible. It is important to ensure that the research does not unfairly discriminate against specific individuals or groups, considering the nature of the research.

Maintaining one's moral character is also a responsibility of researchers to conduct their research in an ethical and transparent manner.

Research ethics committees expect researchers to be honest and truthful throughout the ethical approval process and disclose any actual or potential conflicts of interest. Any plans to withhold information from research participants must be explained and justified in the request for ethical approval.

4.9 Summary

Ethical approval applicants must consider the fundamental principles mentioned above and ensure that they address any relevant issues in their application. Failure to address these issues may result in delays in obtaining ethical approval.

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It is crucial for researchers to thoroughly address both the risks and potential benefits associated with their research in their applications. Research ethics committees specifically assess whether the benefits of the research outweigh the risks of harm and evaluate the application based on this criterion. Therefore, it is essential to address both aspects in a manner that is directly applicable to the research being conducted.

4.10 Progress Update to the Ethical Committee in appropriate duration.

Research protocols undergo evaluation to assess their value, integrity, and the use of appropriate and rigorous methodology. Additionally, adherence to the principle of non-maleficence is essential. When conducting this type of research, it is important to adhere to established scientific principles. Proper utilization of resources and enrollment of participants should be ensured, even if these aspects are not the primary focus of the discussion. Furthermore, it is crucial to maintain academic integrity in terms of citations and authorship when utilizing research tools and instruments. Interactions with participants typically receive significant attention, starting from the initial contact and offering of the study, through enrollment, and all subsequent steps leading to the study's completion, including any necessary follow-up.

4.9.1 Common mistakes

A primary care ethics body, known as the ethical committee of the Health Minister's Northern Regional Administration, was established in Portugal in 2009.

This regional health authority serves approximately 3.5 million people and collaborates with around 9,000 other institutions in the area, including 2,776 physicians and 2,829 nurses. With extensive expertise, they have reviewed over 1,200 processes by the end of last year, with 95% of them being research projects in primary care settings. Additionally, they have contributed to ethical education for healthcare providers by offering numerous courses focused on research ethics. During this time, there has been a growing interest among physicians and researchers in ethical issues, partly due to changes in Portuguese legislation governing ethical committees and the use and protection of personal data. Ethics, being a shared commitment, is not limited to any specific individual.

However, being a member of an ethical committee encourages broad thinking and individual decision-making. Through their monthly meetings, the committee has continuously improved their knowledge and practices. Each project serves as a topic for debate, providing an opportunity to enhance ethical awareness in an increasingly globalized and knowledgeable society, albeit one that may have limited time for reflection. Ultimately, over 80% of projects were accepted without any ethical constraints.

Despite this, many of the initiatives that were nominated for awards revealed ethical limitations, illustrating the gap between research methodologies and ethical details:

1. Absence of free, prior, and informed consent: Informed consent is often debated, with some researchers considering it unnecessary and others recognizing its significance in providing participants with relevant information for voluntary and knowledgeable agreement. Merely obtaining a signature on a document undermines the importance of comprehensive explanations and understanding.

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2. Invitation to participate: Patients receiving care in a clinic may feel obliged to participate if invited by their healthcare provider.
3. Extra precautions, such as involving a neutral team member, should be taken to ensure voluntary participation. This is particularly crucial in primary care where the doctor-patient relationship is close.
4. Compilation of data: Clinical records often contain health-related information that may be relevant for research purposes.
5. However, reusing this data requires obtaining informed consent from patients or their representatives. The ethical committee may grant exceptions but strict measures must be taken to protect and anonymize the data.
6. Variables being researched: Patient identity variables, such as name, birth date, or health system number, should be avoided in research data collection forms. Including such identifiers poses risks to data anonymity and confidentiality. These variables are typically unnecessary for research and should only be included if properly justified.
7. Use of copyrighted surveys: Many questionnaires are protected by copyright and require permission from the original authors for use. Even if a questionnaire is in the public domain, intellectual property rights should be respected, and permission should be obtained from the authors before usage.
8. Lack of clear statistical analysis strategy: In quantitative research, a clear statistical analysis strategy is essential. Exploratory approaches may be suitable for developing new theories, but hypothesis testing requires pre-specification of statistical models and testing methods. This step is crucial in preventing biased practices like "p-hacking."
9. Lack of participant feedback: Researchers have an obligation to inform participants if they discover any health or social issues during the study that require action. Adverse event definitions and protocols for reporting and handling should be established whenever possible.
10. Conflict of interest disclosure: Conflict of interest extends beyond financial ties and includes academic commitments, personal relationships, political or religious beliefs, and institutional affiliations. Researchers should individually assess which characteristics may create conflicts of interest in specific situations. Transparency and honesty in disclosing conflicts of interest are ethical obligations.

4.10 Weaknesses of ethical review

The current trend in ethical assessment suggests that obtaining ethical approval may become less time and cost efficient, as well as sustainable. Weaknesses can be identified at different stages of the ethical review process.

Ethics encompasses various schools of thought, ranging from Aristotelian virtue ethics to Kantian deontology, deterministic theories to the situational view, and the Buberian relational perspective, among others. As ethics is not a precise science, different viewpoints can lead to different conclusions and decisions.

Clinical research carries inherent risks, including privacy violations, inadequate informed consent, and the protection of personal data. Patients often have limited control over the procedures outlined in a research project, making them vulnerable. However, they can also play a crucial role in mitigating biases that may affect the interpretation of results. Therefore, it is essential to have robust measures in place to protect informed consent, enabling participants to make responsible decisions based on appropriate information, particularly when researchers are involved in their healthcare.

In the present day, many researchers submit their study ideas to research ethics boards using standardized forms.

While this approach resolves the issue of inconsistent paperwork required by different committees or members, it often prolongs the overall process, forcing researchers to modify their study protocols to fit a predefined, rigid format. Instead of streamlining the process, this may generate more paperwork.

Obtaining informed consent is key to validating participants' involvement. However, the requirement for consent itself may introduce bias into the study. In primary care, socio-epidemiological studies are common, and surveys frequently employ methodological tactics. Requiring written authorization may increase administrative burden and potentially lead to participant dropouts, thereby reducing response rates and biasing the results.

The information required for ethical approval is of utmost importance and serves as a central component of the ethical review process. This information can be formulated as a series of questions, which need to be adequately addressed and considered.

- Is it possible to modify the research protocol to mitigate risks while still addressing the research question?
- Can the research protocol incorporate measures to minimize the likelihood of harm from the remaining hazards?
- Do the risks or hazards involved in the research outweigh the value of the potential new knowledge that could be obtained?

Inexperience in particular scientific domains or methodological approaches is another shortcoming frequently observed in ethics panels. In order to draw sound conclusions, members of research ethics committees should be well-versed in ethical principles, as well as different study designs and research topics. However, individual members of research ethics committees often do not have sufficient expertise in all these fields. For this reason, increasing the representation of people of color on research ethics review boards is a good initial step. Recently, Portugal's health ministers updated the regulations governing health and research ethics committees, increasing the maximum number of members from nine to eleven and requiring the inclusion of people from various fields such as medicine, justice, philosophy and ethics, theology, nursing, and pharmacy as necessary.

Additionally, there are concerns regarding response time. To some extent, this is due to the bureaucratic challenges inherent in the internal workings of ethics committees, which are not always widely understood and often unnecessary. However, the most significant reason is more critical. Projects that raise concerns and require additional reflection and time to develop opinions based on individual knowledge, sensitivities, experiences, and values should be given the necessary time to mature. This time can be extended through self-education and consultation with other experts, if needed.

Humanity will tend to normalize its perspective of itself, leading to predetermined technical judgments of the ready-to-wear variety.

This occurs more frequently over time as habits are formed. However, decisions need to be made on an individual basis in each instance. Each project requires unique consideration, and this takes time to accomplish during the implementation stage.

An ethics committee is no different from any other type of organization in that it struggles to admit its own shortcomings. This blindness results in a lack of self-criticism and the assumption that the decision is so wonderful that everyone should embrace it without reservation.

As a workaround, ethical committees should foster a deliberative climate that encourages the open exchange of ideas and consensus-building, rather than relying solely on imposed voting to make decisions.

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CHAPTER 5

QUANTITATIVE ANALYSIS ON PATIENT DATA

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Bio Medical Engineering and Measurement System (BioMEMS)

- Problem Identification (Qualitative Analysis) – To Doctors, To Subjects, Online Statistics, From Public, From Care Takers - Patient History Study Sheet Preparation.
- Data Collection - Quantitative Aspects (Example number of days the issues persist, situations, From Doctors Reports)
- Preliminary Observations and Analysis.
- Collection and Analysis of Reports (Similarities and differences).
- Framing the research methodology.
- Ethical formulation and Issues in Data collections.

5.1 Problem Identification (Qualitative Analysis)

Nurses are progressively taking a patient's history, which is one of the most crucial parts of patient assessment (Crumbie, 2006). This technique allows patients to express their perspective and provides valuable information to the healthcare practitioner. The responsibilities of nurses continue to grow, as does their ability to perform assessments. While history taking is typically performed by a nurse practitioner or a professional nurse, it can also be applied to various nursing assessments. It is common for the patient's history to be used in combination with other methods of gathering information, such as the single assessment procedure and nurse assessment.

5.1.1 Creating an Optimal Environment for History-Taking

The preparation of the environment is the initial and crucial step in every history-taking procedure, as well as in most patient encounters. Nurses may interact with patients in various settings, including emergency rooms, general wards, department areas, primary care centres, health centre clinics, or even the patient's own home or workplace. It is essential to ensure that both the patient and the nurse have a comfortable, uninterrupted, and safe environment to facilitate the process.

Maintaining a non-judgmental and professional approach while respecting the patient's perspectives and values is fundamental during the evaluation process.

Demonstrating respect requires providing a private and quiet environment free from disturbances. In cases where complete privacy is not feasible, the nurse should take all necessary measures to safeguard patient information and maintain confidentiality (Crouch and Meurier, 2005).

Allocating sufficient time to complete the history is crucial, as inadequate time may result in insufficient information and subsequently impact patient care.

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5.2 Preliminary Observations and Analysis

- **The History-Taking Process**

When conducting patient interviews, it is important to follow certain general guidelines. Here are a few key points:

- **Introductions:** Begin by setting the context, introducing yourself, stating your objectives, and obtaining the patient's consent. Once this is established, it is ideal to start by verifying the patient's identification and asking how they prefer to be addressed (Hurley, 2005). Additionally, gather basic demographic information such as the patient's name, age, and occupation.
- **Order and Organization:** The process outlined in Box 2 serves as a general guide for history taking. Both medical and nursing texts emphasize the importance of a rational and systematic approach (Douglas et al., 2005; Crumbie, 2006). While many resources suggest a specific order for gathering information (Douglas et al., 2005; Shah, 2005), it is not mandatory to strictly adhere to this order.

BOX 1

History-taking sequence

- The presenting complaint.
- Past medical history.
- Mental health.
- Medication history.
- Family history.
- Social history.
- Sexual history.
- Occupational history.
- Systemic enquiry.
- Further information from a third party.
- Summary

5.2.1 Gathering the Patient's History

If the structure proposed by Douglas et al. (2005) is followed, the history should commence with an inquiry about the patient's presenting complaint.

Open-ended questions like "What is the problem?" or "Tell me about the problem?" can be used to gather information regarding the complaint. The patient should provide a wide range of useful information, although not necessarily in the order you prefer. To obtain more detailed information, it is advisable to begin with the most critical aspects. It is important to focus on symptoms rather than making a diagnosis in order to avoid missing any relevant information.

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Textbooks often provide a list of cardinal symptoms for each body system, which are the most essential symptoms to inquire about to ensure a comprehensive history. Box 4 presents examples of cardinal symptoms for each body system.

5.2.2 Previous Medical History

Before inquiring about the patient's past medical history, it is crucial to obtain a comprehensive history of the patient's current complaint. This initial step can offer valuable background information, including details about the patient's family history of conditions such as diabetes, hypertension, or cancer. When gathering the patient's past medical history, it is important to include the following details:

- **Diagnosis.**
- **Dates.**
- **Sequence.**
- **Management.**

5.3 Data Collection - Quantitative Aspects

✓ Psychological Well-Being

According to the NHS Confederation (2007), approximately one in four individuals may experience mental health challenges at some point in their lives. Interestingly, nurses are found to be more susceptible to mental health concerns compared to the general population. Considering this, nursing skills, including the approaches previously discussed, can assist nurses in inquiring about the patient's current coping strategies. These may include concerns related to health issues such as suspected cancer, upcoming surgeries, or pending test results, as well as more severe mental health conditions like bipolar disorder or schizophrenia.

✓ Previous Med History

This aspect is crucial and should consider not only the current medications the patient is taking but also any previous medications they have been prescribed.

It is important to inquire specifically about over-the-counter drugs, including homeopathic and herbal remedies, as these are readily available without a prescription from drugstores or supermarkets.

Obtaining background information about the patient's family is also important. Certain conditions may have a genetic component, and knowledge of the family history can help guide treatment. Utilizing a combination of open-ended and closed-ended questions can be effective in gathering information about any significant family history related to the patient's condition.

✓ Historical Background of Society

The ability of a patient to cope with health changes is influenced by their social well-being. A baseline of daily function should be established during the history-taking phase. It is the nurse's responsibility to know the patient's present functional level and any temporary or permanent change in function due to prior or current disease.

✓ **Sexual Orientation History**

Bringing up the topic of a person's sexual history can be challenging, and it may not always be necessary to delve into extensive details (Douglas et al., 2005). However, in situations where it is appropriate, addressing related questions objectively and acknowledging the sensitivity of the matter can be helpful. A considerate approach could begin with a statement such as: "I hope you don't mind, but I need to ask some questions concerning..." This approach shows respect for the individual's privacy while allowing for open and honest communication when required.

✓ **Employment History**

Including a person's past and current employment history is an essential part of the process. For individuals unable to work due to illness, factors beyond the job itself can significantly impact their social well-being. Working in a heavy industrial setting, for instance, can lead to respiratory and musculoskeletal issues. Therefore, it is important to gather information about the person's occupation history, as it can provide valuable insights into potential occupational-related health challenges.

✓ **A Thorough Examination of the Situation.**

The concluding step in history-taking involves conducting a systematic exploration. This entails inquiring about other body systems that have not been directly related to the presented complaint. The purpose is to ensure that no crucial information has been overlooked.

Symptoms related to cardiovascular, pulmonary, gastrointestinal, genitourinary, musculoskeletal, and dermatological issues are comprehensively investigated to ascertain the underlying cause of the condition.

5.4 Collection and Analysis of Reports (Similarities and Differences):

In the discipline of biomedical engineering, particularly in the area of brain engineering, the gathering and interpretation of reports is of utmost importance. Both tasks entail obtaining and analysing data in order to make inferences and come to conclusions. When it comes to the gathering and processing of reports in the context of biomedical engineering, notably focused on neural engineering features, there are definite parallels and variations.

5.4.1 Similarities:

5.4.1.1 Data Gathering:

Gathering pertinent data is a step in both collection and analysis. This might involve gathering research articles, clinical trial data, case studies, experimental results, patient records, and any other pertinent material in the context of biomedical engineering. The goal is to assemble a comprehensive dataset that serves as the basis for additional investigation.

5.4.1.2 Literature Review:

It is essential to do a literature study before collection and analysis. This entails looking for and analysing previously published studies, articles, and publications pertinent to the field of interest, such as brain engineering. The literature review assists in identifying knowledge gaps, comprehending the state of the subject, and ensuring that the data gathered is current and in line with previous studies.

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5.4.1.3 Data Management:

Both the gathering phase and the analysis phase require effective data management. This entails structuring, classifying, and archiving the data that has been gathered. Data management procedures guarantee that the information is readily available, thoroughly recorded, and capable of being quickly accessed and evaluated as required. Utilizing databases, spreadsheets, and specialist software tools are common techniques.

5.4.1.4 Statistical Analysis:

Both the gathering of data and its processing share a similar thread: statistical analysis. Following the collection of the data, statistical techniques are used to derive useful insights and reach conclusions. It is usual practice to find patterns, correlations, trends, and other pertinent information within the dataset using descriptive statistics, inferential statistics, regression analysis, and machine learning methods.

5.4.2 Differences:

5.4.2.1 Focus of the Collection:

In biomedical engineering, information collecting primarily pertaining to neural interfaces, brain-computer interfaces, neuroprosthetics, and other parts of neural engineering is the emphasis of the collection phase. Studies, experiments, and developments in the field of neural engineering—such as novel electrode designs, signal processing approaches, or strategies for brain stimulation—are highlighted during the collecting process.

5.4.2.2 Data Sources:

Data collection in biomedical engineering entails gathering information from a variety of sources.

These resources may consist of academic journals, scholarly gatherings, therapeutic trials, experimental research, and even partnerships with medical specialists or neuroscientists. The collecting phase's generated dataset, as well as any extra data processing and refinement that may be required, are the main emphasis of the analysis phase.

5.4.2.3 Analysis Techniques:

The methods used during the analysis phase may vary, even though statistical analysis is a common component of both collecting and analysis. Biomedical engineering reports analysis frequently calls for specific methods like signal processing, image analysis, computer modelling, or bioinformatics. Using these methods, one may analyse neural signals, decode brain activity, evaluate the effectiveness of neural implants, or create prediction models from the data that has been gathered.

5.4.2.4 Interpretation and Conclusion:

The interpretation of the data and the generation of relevant conclusions are the analysis's ultimate goals. When it comes to biomedical engineering, this entails analysing how advances in neural engineering will affect healthcare, finding possible uses in diagnosis or treatment, evaluating the efficacy and safety of neural devices, and providing guidance for future research and development initiatives. The findings of the study may guide future research, clinical trials, or the development of brain engineering technologies.

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5.5 Framing the research methodology:

It is a crucial stage in carrying out research in the area of biomedical engineering, particularly in the field of neural engineering. The choice of relevant methodologies, data-gathering strategies, and analytic techniques are all guided by the research methodology, which acts as a road map for the whole research process.

The following factors need to be considered while structuring the research technique in the context of biomedical engineering, with an emphasis on neural engineering aspects:

5.5.1 Research Questions and Objectives:

The basis for framing the research approach is a clear definition of the study questions and objectives. These inquiries and goals must be SMART (specific, measurable, attainable, relevant, and time-limited). They direct the whole study process and aid in keeping the investigation's attention on the most important areas of brain engineering. The research issues could concern, for instance, the creation of a novel brain interface technology or the assessment of a neuro prosthetic device's effectiveness.

5.5.2 Literature Review:

A thorough literature assessment is essential for defining the study technique. Reviewing current research, writings, and developments in the area of brain engineering is required for this.

The literature review assists in identifying knowledge gaps, gaining an understanding of the state of the art, and guiding the choice of the best research approaches. Additionally, it assists in expanding on prior studies and minimizing duplication of effort.

5.5.3 Research Design:

The overarching strategy and approach for carrying out the research are described in the research design. It involves choices about the research's design (experimental, observational, or computational), its size (single-centre vs. multi-centre), the participants to be used (patients, healthy volunteers, or animals), and the project's overall timeline. The research design for neural engineering should consider the objectives and limitations of the neural engineering elements under study.

5.5.4 Data Collection Methods:

For the collection of accurate and trustworthy data, choosing the right data-collecting techniques is essential. Data collecting approaches used in neural engineering research may comprise a variety of methodologies, including clinical assessments, neuroimaging (such as Electroencephalography (EEG) and functional Magnetic Resonance Imaging (fMRI)), electrophysiological recordings, and computer simulations. The selection of data-collecting techniques should be in line with the goals of the study and the characteristics of the neural engineering components being examined.

5.5.5 Data Analysis:

A key component of defining the research technique is the data analysis process. This involves selecting the proper computer modelling strategies, statistical analysis tools, or signal processing techniques to be used.

Data analysis in the subject of neural engineering may entail deriving characteristics from neural signals, examining the performance of brain-computer interfaces, assessing

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the effectiveness of neurostimulation methods, or creating prediction models for clinical outcomes.

5.5.6 Ethical Considerations:

Research in biomedical engineering, including brain engineering components, must give the highest care to ethical issues. Particularly when involving human subjects or animal models, researchers must make sure that their study complies with ethical standards and laws. Informed permission must be obtained, participant privacy must be maintained, and possible dangers resulting from the study techniques must be kept to a minimum.

5.5.7 Validation and Evaluation:

The methods for validation and assessment should also be included in the research methodological framework. Planning for the validation of the study results and assessing the effectiveness, safety, and performance of the under-investigation neural engineering features are included in this. Validate the suggested procedures or technologies, which may entail doing tests, clinical trials, or simulations.

5.6 Ethical formulation and addressing ethical issues in data collection:

In the domain of neural engineering, it is crucial in biomedical engineering. It is essential to preserve the rights, privacy, and welfare of human participants and animal models since neural engineering research frequently entails the collecting of sensitive data from them. An overview of the ethical concerns and formulation in biomedical engineering data collecting, with an emphasis on neural engineering elements, is provided below:

5.6.1 Informed Consent:

A basic ethical need for data collecting is to get informed permission. Participants must be informed in a clear and thorough manner about the research's goal, methods, possible risks and benefits, and their rights. By obtaining informed consent, participants can decide whether to engage in the study of their own will and with full knowledge.

5.6.2 Privacy and Confidentiality:

Data on participants must be always kept private and confidential. Researchers must put suitable safeguards in place, such as anonymization or encryption methods, to protect the confidentiality of data obtained. Any identifying information must be kept safely and should only be accessible by authorized persons. Building confidence and preserving anonymity are important for encouraging study involvement.

5.6.3 Data Security:

The ethical duty of researchers is to protect the confidentiality of the data that they have obtained. This entails safeguarding data against loss, theft, and illegal access. To ensure data integrity and minimize risks related to data breaches, secure data storage systems, encryption techniques, and regular backups are crucial steps.

5.6.4 Risk Mitigation:

Researchers must evaluate and reduce any possible dangers related to data collecting. This involves assessing any dangers to participant’s physical health, mental health, or social interactions. Adequate precautions should be taken to reduce these hazards, including adequate participant selection, monitoring for unfavourable outcomes, and offering support systems or access to counselling services as needed.

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5.6.5 Inclusion and Diversity:

Ensuring inclusion and diversity in participant selection is necessary for ethical data collection. A broad group of subjects should be sought by researchers, who should consider aspects including age, gender, ethnicity, and socioeconomic status. This encourages fair representation, prevents biased outcomes, and guarantees that study findings may be used broadly.

5.6.6 Animal Welfare:

When using animal models, researchers are required to abide by moral standards and laws governing animal care. This entails reducing suffering, using suitable anaesthetics and analgesics, and adhering to recognized guidelines for animal experiments. When feasible, researchers should take other approaches into account and make sure that any potential damage to the animals included in the study is outweighed by the potential benefits of the study.

5.6.7 Institutional Review Board (IRB) Approval:

Before starting to gather data, researchers should get the go-ahead from a similar ethical committee or an institutional review board. The IRB makes sure that the study conforms with applicable laws, ethical standards, and guidelines, as well as participant rights and well-being. An impartial assessment of the study project's ethical issues is made possible by IRB approval.

5.6.8 Conflict of Interest:

Any possible conflicts of interest that could develop while collecting data should be disclosed by researchers. This includes any financial or interpersonal connections that could have an impact on the conduct or results of the research. The integrity and objectivity of the study are guaranteed by transparency in the disclosure of conflicts of interest.

5.6.9 Responsible Data Sharing:

Data sharing must be done ethically and in a transparent manner, according to researchers. This entails trying to disclose anonymized or de-identified data while maintaining participant privacy. Sharing data responsibly foster teamwork, repeatability, and the expansion of scientific knowledge.

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CHAPTER 6

DESIGN OF BRAIN COMPUTER INTERFACE SYSTEM

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6.1 What is a Brain-Computer Interface (BCI)? Applications, Significance (for individuals with disabilities)

Recent discoveries in brain function and the exploration of innovative applications, extensive research is being conducted on brain-computer interfaces (BCIs). The aim of this review is to provide an overview of the different stages involved in the BCI design life cycle. This includes measuring brain activity, classifying data, providing feedback to the user, and studying the effects of feedback on brain activity. The article delves into the critical steps of the BCI cycle, identifies existing challenges, and discusses potential future implications. Furthermore, it explores how new insights into neurocognition, particularly regarding the brain's representation of received information, intended actions, and emotions, can contribute to the advancement of BCIs. This is an opportune time to explore the benefits that real-time, online BCIs can offer to cognitive neuroscientists and how they can complement the existing toolkit.

Although brain-computer interface (BCI) systems are still in their early stages of real-world application, this research proposes the integration of a mobile and wireless electroencephalogram (EEG) device and a signal processing platform based on a cell phone to create an online wearable BCI. The feasibility and implications of SSVEP-based (steady-state visual evoked potential) BCI are demonstrated by implementing and testing the SSVEP-based device. Online signal processing algorithms in the time and frequency domains were used to detect SSVEPs, as implemented and tested in this study. Regarding techniques for behaviour change, researchers have developed various layouts for behaviour change technologies (BCTs). Figure 1 illustrates the signal acquisition and signal processing modules, which are crucial components of the BCT system. During the signal acquisition process, brain signals can be captured using scalp electrodes (internal/external), on the cortical surface, or even within the brain itself.

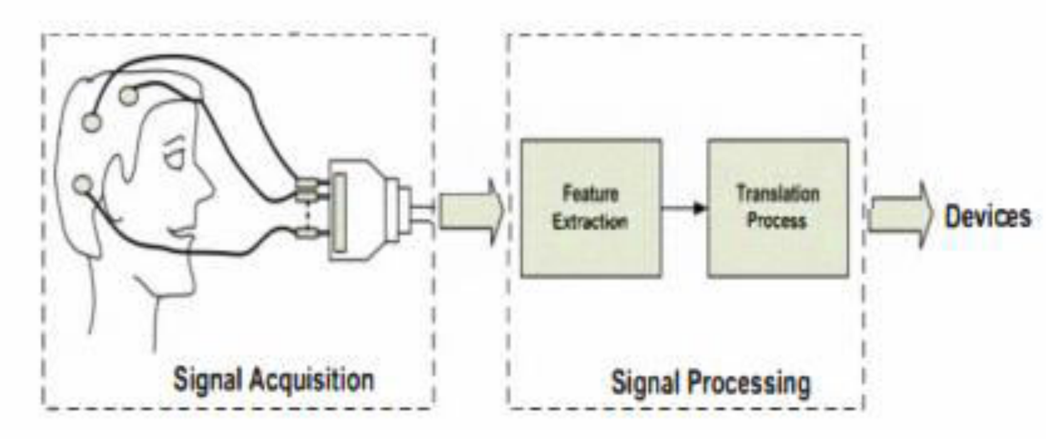

Figure: 6.1 Basic design and operation of any BCI system

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Typical input signals for behaviour change technologies (BCTs) encompass various brain activity patterns, including slow cortical potentials (SCP) [2], P300 potentials [5], motion-onset visual evoked potentials [7], steady-state visual evoked potentials (SSVEP) [8], auditory evoked potentials [9], and sensor motor rhythms (SMR). Signal processing techniques extract specific features such as evoked potential amplitudes, sensory motor cortex rhythms, and cortical firing rates from the collected data. These features are then transformed into commands that can operate and control devices.

BCI systems can utilize either wired or wireless data transfer methods. Current BCI systems often rely on cables to connect their components, which can be cumbersome and limit the user's freedom of movement. For practical everyday use in work or home environments, wireless data transmission in BCI systems is more convenient. The integration of wireless chips in common devices such as laptops, cell phones, and handheld devices [10] offers portability and reliability.

BCTs are typically used in either asynchronous (self-paced) or synchronous (timed) modes of operation. In asynchronous BCT, the system's output is influenced by the user's intentions when the system is activated. Self-paced BCI systems can have a 2-state or 3-state design, with the 2-state system referred to as LF-ASD (Low Frequency-Asynchronous Switch Design) [11]. The 3-state self-paced BCI system provides additional benefits, allowing users to control multiple devices and offering greater device control compared to the 2-state system.

6.2 BCI types (Invasive, Non-Invasive)

BCI systems exhibit various characteristics, including being invasive (ECoG, spikes) or non-invasive (EEG, NIRS, fMRI, MEG) (Leuthardt, 2004; Owen, 2008; Velliste, 2008; Wolpaw, 2003; Pfurtscheller, 2010a, 2010b). They can be portable (EEG) or stationary (fMRI, ECoG, spikes) (Sellers, 2010). These systems offer high throughput, extended training times, and sensor options that can range from cheap (EEG, NIRS) to expensive. A comprehensive review by Allison (2007) covers these features extensively. Over the years, the significance of some features has evolved, and new technologies have emerged, leading to new applications and cost reductions in BCI systems. Notable system upgrades were implemented in the late 1990s.

The primary goal of BCI research is to develop interfaces that enable paralyzed individuals to control computers, robotic arms, or neuro prostheses. BCI systems use electroencephalogram (EEG) or electrocorticogram (ECoG) data recorded from scalp or subdural electrodes as input.

EEG-based BCIs are user-friendly but suffer from low spatial resolution, making it challenging to accurately predict user intentions. Users often require extensive training to master their utilization. These systems also have limited information transfer rates [3], [4]. Enhancing the quality of input signals to BCI systems can improve the accuracy of anticipated user intentions (classification accuracy). Compared to EEG signals, ECoG signals offer superior spatial resolution and a higher signal-to-noise ratio [5]. These advantages position ECoG as a promising input signal source for BCIs, yielding encouraging results.

The effectiveness of a BCI application heavily relies on employing algorithms that achieve improved classification accuracy while utilizing fewer channels and more task-relevant features. Other researchers have conducted detailed analyses on the Data Set I signal, which are thoroughly described in section 2. Section 4 presents a comparison of the study's classification accuracy and speed with that of other research studies.

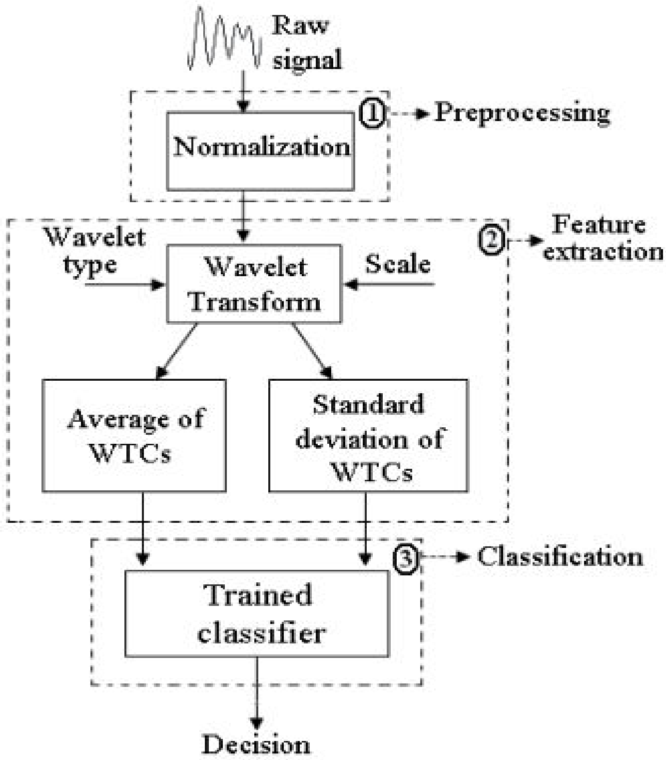

Figure 6.2 Block diagram of the proposed method

6.2.1 Wavelet Analysis

The continuous wavelet transform (CWT) mathematically represents the convolution of the signal x(t) with the wavelet function Ψ_ (τ, s) (t). It can be expressed as:

$$\boldsymbol{CWT_x^{\Psi}(\tau, s) = \frac{1}{\sqrt{|s|}} \int x(t)\Psi^{*}\left(\frac{t-\tau}{5}\right) dt} \qquad \textbf{(1)}$$

Where Ψ_ (τ, s) (t) represents the dilated and shifted version of the wavelet function Ψ(t) and is defined as follows:

$$\boldsymbol{\Psi_{\tau,s}\phi' = \frac{1}{\sqrt{s}}\Psi\left(\frac{t-\tau}{s}\right)} \qquad \textbf{(2)}$$

Here, t, τ, and s represent the time parameter, the shift parameter, and the scale parameter, respectively [18]. The wavelet function Ψ_τ, s(t) has a zero mean, as given in equation (3).

$$\boldsymbol{\int_{-\infty}^{+\infty} \Psi_{\tau,s}(t)\, dt = 0} \qquad \textbf{(3)}$$

The choice of a specific wavelet function is crucial in wavelet analysis. Among the various wavelet functions available, the Morlet wavelet function has been selected for its superior frequency localization compared to others.

However, it is also important to consider the similarity between the wavelet function and the signals under examination in order to obtain meaningful information. The Morlet wavelet exhibits a close resemblance to the input signals in terms of shape, unlike other types of wavelets.

6.3 Implementation of Non-Invasive BCI

These ideas sparked a research project aimed at creating a functional prototype of an assistive communication platform by integrating multiple technologies, such as a Brain-Computer Interface (BCI) and a robotic platform. The goal of the project was to demonstrate the practical application of BCI technology in the daily lives of individuals with mobility impairments. As part of the ASPICE project (Assistive System for Patients' Increase of Communication, Ambient Control, and Mobility in the Absence of Muscular Effort), an assistive system is being developed to enhance or restore mobility and facilitate communication for individuals with motor disabilities.

The key components of the system include:

1. User-friendly computer interfaces, such as the mouse, joystick, eye tracker, voice recognition, and EEG-based BCI systems, which capture brain signals non-invasively. Multiple access methods are incorporated to accommodate a wide range of users while adapting to varying degrees of patient disability. Additionally, the system can track changes in a patient's ability to interact based on residual muscular activity at different stages of the disease progression.
2. Intelligent motion device controllers capable of executing complex trajectories with minimal commands.
3. Communication and demotics systems that facilitate information exchange between users and their controlled devices.

The development of this system aims to address the specific needs of individuals with neuromuscular conditions by integrating existing technologies into a unified platform. The utilization of readily available hardware components allows for easy replication of the system in other homes.

The system was initially validated using healthy volunteers and later tested on individuals with severe motor deficits caused by neurodegenerative diseases. These individuals participated in a rehabilitation program where they learned to operate a prototype system equipped with various access methods.

6.4 Subjects and Clinical Experimental Procedures

This research included individuals with and without Duchenne muscular dystrophy (DMD) or spinal muscular atrophy type II (SMA II). These neuromuscular conditions result in progressive and severe global motor impairments, significantly reducing patients' independence and necessitating round-the-clock care from nursing staff. The study was approved by the ethics committee, and participants were informed about the general features and objectives of the study. Informed consent forms were signed by all participants (and their relatives, if necessary). Extensive discussions with patients and their loved ones were conducted to assess individual needs and customize the system accordingly. Table 1 provides personal characteristics of the patients involved in the study.

Most patients had been unable to walk since adolescence and relied on electric wheelchairs, operated using a joystick adapted to accommodate their limited finger or wrist movements. Muscular strength in both proximal and distal arm muscles was generally poor among all patients, and mechanical neck support was required to maintain proper posture. However, eye movement control remained intact in all patients. It is important to note that none of the patients had previously used technologically advanced aids. The clinical experiment took place in a hospital setting, specifically in a three-room facility resembling a typical household, dedicated to Occupational Therapy. Patients were enrolled in a neurorehabilitation program at the hospital. Medical specialists conducted interviews and physical examinations as part of the clinical procedure. The degree of motor impairment, reliance on caregivers for daily activities, familiarity with various input devices (such as sip/puff, switches, speech recognition, and joysticks), and the ability to communicate with unfamiliar individuals were evaluated using standardized scales (e.g., Barthel Index).

Pre- and post-training assessments were conducted, and patients were asked a set of questions to gauge their satisfaction with the system's performance on a scale from 0 (not satisfied) to 5 (very satisfied). This feedback helped determine the system's effectiveness in meeting their needs.

Patients and their caretakers engaged in weekly training sessions with the system for 3 to 4 weeks, with the assistance of an engineer and a therapist throughout the project, apart from the BCI instruction.

6.5 Design

❖ System Prototype Input and Output Devices

Figure 7.3 depicts the system architecture, including the data capture and transmission devices. The actuators of the system were installed in a three-room hospital suite designed to simulate a typical home environment. The goal was to create an installation that could be easily replicated in most homes. The suite was equipped with a laptop computer running the main software (refer to Section 3). This software's core functionality could be utilized by individuals with varying levels of motor capacity. For instance, input devices such as joysticks, trackballs, keyboard and mouse, and buttons on the touchpad were available, allowing users with residual motor skills to access the system. These input devices were customized to accommodate everyone is remaining motor abilities. Additionally, users were able to utilize any assistive devices they were already familiar with, which could be interfaced to provide low-level input to the more advanced assistive system. This approach ensured adaptability to the changing functional abilities of patients as they aged, mitigating the impact of degenerative disorders on their ability to operate the system.

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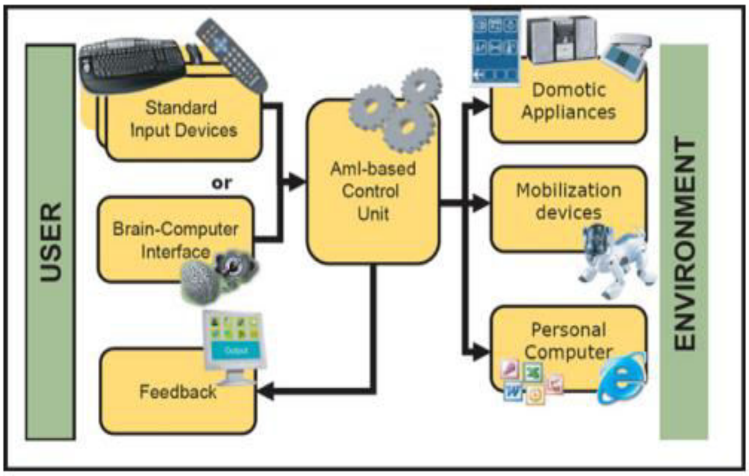

Figure: 6.3 For a comprehensive understanding of the ASPICE project's architecture, an overview can be accessed at this link.

The image illustrates how the system establishes a connection between the user and the external world. It achieves modularity by utilizing a core unit that receives input from various possible input devices and sends commands to one or multiple actuators. Feedback is provided to the user to keep them informed about the system's progress.

The patients were advised to undergo BCI training as a contingency plan in case they became unable to use any of the a forementioned devices due to the progression of their degenerative condition.

For system output devices, we considered basic demotics devices such as neon lights, bulbs, TVs, stereos, motorized beds, sound alarms, front door openers, telephones, and wireless cameras. These devices were selected while taking into consideration the specific requirements and preferences of the patients, including the ability to monitor different rooms in the house. Additionally, a robotic platform (a Sony AIBO) was included in the system, allowing patients to navigate around the house with the assistance of the robot.

The AIBO was programmed to perform basic tasks with minimal commands from the system control unit. As mentioned earlier, the system was designed to accommodate a wide range of patient illnesses and limitations, resulting in the development of one-step, semi-autonomous, and autonomous modes for robot control. The system control unit featured a Graphical User Interface for each navigation mode.

6.6 Availability of Open-Source Hardware and Software in the Market

BCI2000 - BCI20002 is a versatile software platform for BCI research that serves various purposes, including data collection, stimulus provision, and brain activity monitoring. The development of BCI2000 has been led by the Wadsworth Centre of the New York State Department of Health in Albany, New York, USA, in collaboration with the Institute of Medical Psychology and Behavioural Neurobiology at the University of Tubingen, Germany.

Open ViBE is a freely available open-source software platform designed for the design, testing, and utilization of brain-computer interfaces (BCI). It offers a user-friendly

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graphical user interface that allows even non-programmers to utilize the platform effectively. Open ViBE enables the easy coupling of different components to create fully functional BCIs.

TOBI - The TOBI Common Implementation Platform (CIP)14 integrates various components of BCI systems through cross-platform interfaces. It utilizes a standardized interface to ensure uniform data transmission over the network. The TOBI CIP facilitates distributed BCI research and fosters collaboration between different BCI platforms and systems, allowing for interoperability and resource sharing among researchers.

BCILAB20 is a MATLAB toolbox specifically designed for advanced BCI research. It provides a range of well-established algorithms, including Common Spatial Patterns and shrinking LDA, as well as newer advancements. BCILAB20 supports both graphical and scripting user interfaces, enabling rapid prototyping, real-time testing, offline performance evaluation, and comparative analysis of BCI methods.

BCI++23 is an open-source graphics engine built on top of BCI++ framework, offering tools for creating brain-computer interfaces and other forms of human-computer interaction.

xBCI27 (also known as xBCI27a) is a generic platform for developing online brain-computer interfaces, providing a user-friendly system development tool that saves time and simplifies the development process. It is primarily developed by I P Susila and S Kanoh.

BF++28 (Body Language Framework in C++) aims to provide tools for implementing, modelling, and analysing BCI and HCI systems. The project focuses on developing original methodologies and terminologies independent of existing protocols, such as P300, SSVEP, or SMR BCIs. BF++ adopts an abstract model as the foundation for its methods and tools.

Pyff29 (Pythonic feedback framework) is a platform and framework designed for neuroscientific studies, specifically for the rapid development of experimental paradigms in BCI feedback and stimulation applications. Pyff aims to simplify and accelerate the software development process to keep up with the increasingly ambitious and complex stimulation and feedback paradigms used in experiments.

6.7 Hardware Selection

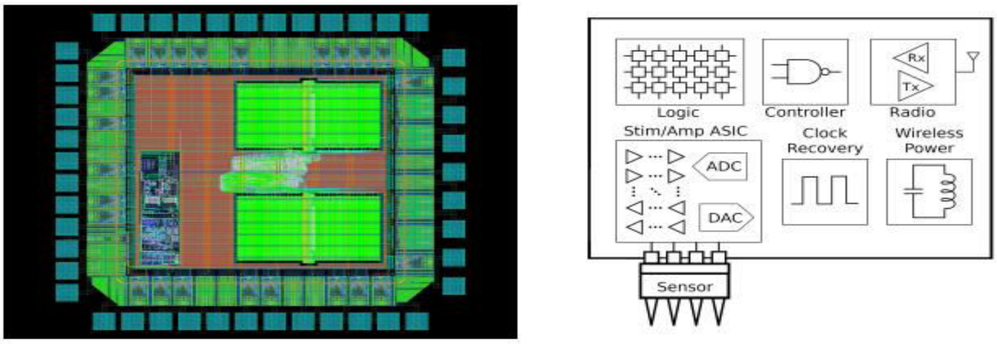

Figure 6.1: The circuit diagram on the left represents our initial 28nm HALO tape out.

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Figure 6.2 illustrates an implanted BCI model on the right. BCIs are implanted in the brain using sensors that penetrate a few milli-meters deep. These devices can be housed in either a titanium or a hermetically-sealed silica capsule.

Beyond the preparatory equipment, there are several crucial building blocks to consider:

Sensors: BCIs utilize sensors that range from single cathodes for individual neurons to an array of microelectrodes capable of recording and stimulating 5-10 neurons independently and several hundred neurons collectively [22, 23, 58]. Over time, sensors will be able to collect data from an increasing number of biological neurons. Currently, widely used Utah clusters offer up to 256 microelectrode channels [16, 22]. Future approaches, such as Neuralink's "strings" and DARPA NESD projects, aim for thousands to millions of channels, although they are not yet functionally viable.

Sensor data requires amplification and digitization using Analog-to-digital converters (ADCs) as part of the Analog front-end. Different BCIs employ ADCs with varying sampling rates and resolutions, although 8-16 bits per sample at 20-50 KHz are common ranges [20, 74, 88, 89].

BCIs utilize RF connections within the frequency range of low MHz to GHz, with 2.4 GHz being the most prevalent [119].

The FCC and FDA impose specific absorption rate limits of 1.6 W/kg over 1g of tissue and 1 W/kg over 10g of tissue, respectively, due to the heating effect of RF radiation on brain tissue [13, 94, 110, 125]. Therefore, the focus is on achieving power budgets of 15mW while minimizing radio transmission power.

Powering BCIs typically involves non-rechargeable or rechargeable batteries, or inductive power transfer. Caution should be exercised regarding the authority of these power sources. Non-rechargeable batteries have a service life of 12-15 years due to the surgical procedure required for replacement [3, 26]. Both battery-powered and inductively powered BCIs require transcutaneous wireless charging [43, 45, 67, 119] and should minimize the transfer of heat to avoid excessive warming.

The Hardware Architecture for Low-power BCIs (HALO) should be compatible with any variation of 1-4 and must full fill two objectives to be widely applicable: none of the BCI components should exceed 15mW, and the RF transmission bandwidth should be limited to minimize power absorption in brain tissue.

6.8 Software Selection

List of Supported BCI Tasks

Our system supports a wide range of BCI tasks, some of which involve closed-loop operations for treating neurological conditions, while others focus on reducing radio transmission through modulation of neuronal activity:

a) **Seizure Prediction:** Implantable BCIs used in epilepsy treatment can predict seizure onset based on neuronal firing patterns. If a seizure is anticipated, specific brain regions are electrically stimulated to disrupt feedback loops in neural circuits responsible for seizures, thereby reducing seizure severity. Seizure prediction is an active area of research, and our HALO algorithm combines multiple integral

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approaches [99]. Similar closed-loop BCI algorithms are applied in treating major depressive disorder, psychosis, and obsessive-compulsive disorder [66, 117].

b) **Motor Intention:** For individuals with essential tremors, Parkinson's disease, and other movement disorders, therapeutic stimulation of the motor cortex can alleviate symptoms. Implantable BCIs can continuously stimulate the brain, but this can lead to energy wastage when the affected limb is not in use and may cause clinical side effects. An alternative approach is to stimulate brain tissue only when neuronal firing indicates intention to use the affected limb. In paralyzed individuals, neuronal signals can be decoded to control prostheses. Advanced algorithms leverage the drop in neuronal firing in the 14-25Hz band in the motor cortex region as an indication of movement intention, which can be detected using FFT analysis [49, 108].

c) **Compression:** Compression techniques reduce radio transmission and are beneficial for high-bandwidth brain communication. While lossy compression could be considered, the brain's electrophysiological data is not well understood enough to identify which parts can be safely discarded. Therefore, lossless compression methods are more commonly used in the neuroscience community. HALO supports various lossless compression schemes, including LZ4, LZMA, and a custom discrete wavelet transform (DWT) compression algorithm. Compression ratios and power consumption may vary depending on the brain region and patient activity [91].

d) **Spike Detection:** Spike detection is the initial step in spike sorting pipelines that extract activity of specific neurons from recorded signals. While spike sorting is typically performed externally, our BCI includes spike detection to transmit only the parts of the signal containing detected spikes, effectively compressing the transmitted data. Spike detection significantly reduces signal transmission bandwidth due to the rarity of spikes, resulting in lower device power consumption and reduced radio-induced power deposition in brain tissue. Non-linear energy operators (NEOs) or DWT are commonly used for spike detection [44].

e) **Encryption:** Although current state-of-the-art devices do not currently support encryption, we anticipate its necessity in future BCIs to ensure patient data security during data exfiltration from the device. Encryption standards such as AES with a minimum key length of 128 bits, as mandated by HIPAA, NIST, and NSA, are expected to be utilized [5, 11, 109].

Furthermore, our system promotes integration and shared control. During the proof-of-concept demonstration, multiple workstations were connected based on this concept, with each hosting a distinct module of the BCI system. Notably, all modules were from different BCI labs and were interconnected through the TiA-TiD interfaces.

The unused TiB and TiD interfaces, which were not defined prior to the proof-of-concept, were not utilized since the BCI bindings were not segregated.

6.9 User Interface

✓ Hardware-Software Co-Design

When it comes to compression, LZ4 and LZMA are excellent options. For spike detection, NEO and DWT have shown good performance. As a result, HALO can be configured into one of eight separate pathways in re al-time by a doctor or technician.

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Instead of using eight typical monolithic ASICs, HALO employs PEs (Processing Elements) that implement independent processing kernels to support various tasks, as illustrated in Figure: 7.4. Each PE has its own unique computing requirements and operates at different frequencies with specific components. While providing cached access to global RAM for PEs may have some advantages, further assessment is needed.

In contrast to a power-hungry packet-switched network, decomposing BCI tasks into PEs allows for an ultra-low-power on-chip circuit-switched network for asynchronous communication. Some PEs, such as LZ and FFT, consume more power/area as the number of sensors increases due to their computational intensity.

To address this issue, a separate interleaver is implemented to buffer and rearrange data, enabling multiple processor elements to work on a single channel simultaneously. HALO incorporates a low-power micro-controller that assembles PEs into pipelines to execute BCI tasks using programmable circuit switches in the network, and it can run algorithms for which dedicated PEs are not yet available.

The PE-centric approach of HALO eliminates the need for a global clock or phase-locked loops. Its modular and extendable nature allows for easy integration of additional PEs to support new neuroscientific algorithms as our understanding of brain functionality advances.

6.10Significance of Electrode Selection

The complexity of dividing BCI algorithms into PEs varies depending on the level of segregation between algorithmic phases. It is important to note that the decomposition of PEs should not compromise computational capabilities, such as algorithmic accuracy or compression ratio.

Some BCI tasks possess distinct computational kernels that can be effectively divided through PE decomposition. For instance, seizure prediction involves a combination of Fourier transform, cross-correlation, Butterworth Bandpass Filtering, and support vector machine kernels, all of which can operate in parallel without data dependencies. By utilizing separate PEs for each kernel, power can be conserved, particularly considering that XCOR's calculation (e.g., divisions, square roots) scales quadratically with channel count. For low-latency and linearly scalable filtering, BBF is the preferred choice. By employing distinct PEs for XCOR and BBF, the filtering logic in BBF can be timed at a significantly slower pace than the cross-correlation logic.

Numerous BCI tasks involve the adaptation of well-known computational kernels in slightly modified forms. To leverage this, we have drawn inspiration from the functional unit sharing in CPU microarchitecture and developed configurable PEs that can be shared among BCI tasks.

For example, movement intent can be decomposed into FFT, and subsequent logic can be employed to determine if the FFT output falls within the appropriate spectral range. To identify when a PE's output lies within a specific numerical range, we have created a threshold PE (THR), as depicted in Figure 2. This allows the FFT to be shared between movement intent and seizure prediction tasks. In order to detect decreases in signal power and determine movement intent, the FFT PE utilizes 14-25-point FFTs, while seizure prediction utilizes 1024-point FFTs. Despite the added complexity of

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configurable PEs (refer to VI), we believe it is worthwhile as it facilitates reuse and provides a more flexible platform.

6.11Available closed source Hardware and software in Market

Brain activity can be recorded and valuable signals can be extracted using a variety of techniques and operating mechanisms.

✓ **Communication and Control**

BCI Systems Using Slow Cortical Potentials (SCP)

❖ **The TTD System**

Slow cortical potentials (SCPs) are EEG-based signals used in brain-computer interface (BCI) devices, but they require user training to manipulate the polarity of these potentials.

Almost twenty years ago, a groundbreaking study was conducted involving two patients with locked-in syndrome (LIS) and amyotrophic lateral sclerosis (ALS) using SCP on EEG-BCI (Birbaumer et al., 1999).

The patients were trained to generate voluntary SCPs lasting 2–4 seconds, and during specific response periods, they were instructed to produce either higher negativity or positivity exceeding a certain threshold amplitude. Subsequently, a training technique called Thought Translation Device (TTD) was developed (Birbaumer et al., 2000). The TTD teaches LIS individuals how to self-regulate their SCPs, enabling them to select letters, words, or pictograms from computerized language assistance software. This study demonstrated the significance of the TTD system in daily life and highlighted the considerable improvement in self-regulation and accurate response observed after extensive training for LIS participants.

❖ **Web Browsers**

Karim et al. were the first to use the "Descartes" approach to employing the TTD system for handling a Web Browser (2006). One ALS patient used the embedded system for testing. After several training sessions, Descartes supplied feedback on SCP amplitude time-locked way. To pick a command, the participant had to generate positive SCP alteration (over a threshold of 7 V) and move the cursor downward, whereas to discard a command, the participant had to generate negative SCP and move the cursor upward.

❖ **BCIs Using Sensorimotor Rhythm (SMR)**

The SMR generated when a given movement is performed or simply envisioned can be modulated by people with NMDs (MI).

✓ **Graz BCI System**

One of the prominent studies in the field of sensorimotor rhythm-based brain-computer interfaces (SMR-BCI) is the "Graz-BCI" experiment, which was conducted on a severely paralyzed participant with cerebral palsy (CP) who had completely lost the ability to communicate (Neuper et al., 2003). After 80 trials, the participant was able to select letters and compose words by utilizing self-regulation of their SMR.

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This study demonstrated the effective decoding of SMR changes related to motor imagery, achieving a classification accuracy of 70% in letter selection using the "Graz-BCI."

In addition, Wolpaw and McFarland (2004) developed an EEG-BCI system based on SMR guidelines. In their study, the target location was block-randomized into eight squares, while the cursor was displayed on the screen.

The movement of the cursor was determined by a weighted combination of the amplitudes in the mu (8–12 Hz) or beta (18–26 Hz) frequency range over the right and left sensorimotor cortices.

✓ **Game Applications**

An important study aimed to address the issue of long training periods required for individuals with motor impairment to learn how to operate an EEG-BCI system.

The study proposed a game-based approach that could achieve successful BCI operation in less than 30 minutes (Kauhanen et al., 2007). Specifically, six tetraplegic participants were instructed to move a circle, displayed at the center of the screen, to the left or right by performing specific upper limb movements (e.g., closing the fist) and imagining them during the task. This game-based approach aimed to expedite the training process and enhance the usability of the EEG-BCI system.

✓ **Virtual Conditions**

Another study investigated how a tetraplegic subject, sitting in a wheelchair, could control his movements in a virtual environment (VE) using a self-paced (asynchronous) BCI system (Leeb et al., 2007).

The use of the VE framework with interactive symbols ensured that the experiment was novel and engaging, providing sufficient stimuli like a real-world street environment. After four sessions, the subject achieved 100% accuracy in performing the tasks. This study was the first to incorporate symbols and a VE, introducing new approaches for interaction and control of applications for individuals with motor impairment in a virtual environment using motor imagery (MI) techniques.

✓ **Control of Outer Gadgets**

There are also numerous studies that have emphasized the importance of EEG-BCI for controlling external devices. In the study by Cincotti et al. (2008b), it was demonstrated that individuals with severe neuromuscular disorders (NMDs) can acquire and maintain control over discernible patterns of brain signals, and use this control to operate devices. The subjects were instructed to execute or imagine movements of their hands or feet upon the presentation of specific cues.

❖ **BCIs Using P300**

An EEG methodology commonly employed for operating a BCI system is the well-known P300 component, which is a late positive component elicited in response to a task-relevant external stimulus. The P300 component has been specifically utilized for device control, such as wheelchairs, operating real and virtual environments, and enabling users to interact with paint interfaces or browse the Internet.

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✓ **Speller Frameworks**

Speller frameworks are the primary BCI applications that utilization the P300 methodology. One original work (Sellers and Donchin, 2006) examined whether P300-BCI could be utilized as an elective EEG-based BCI methodology for correspondence in ALS populace. They assessed the adequacy of a BCI framework by distinguishing P300 evoked by one of four arbitrarily introduced improvements (i.e., YES, NO, PASS, END) and by testing this to both physically fit and ALS members.

✓ **Internet Browsers**

Another methodology alludes to BCI frameworks for Internet access. More as of late another arrangement of web access, the "genuine web access," was proposed by Mugler et al. (2010) where web surfing could be effectively executed through a P300BCI program.

✓ **Paint Application**

Another application of a P300-BCI system is aimed at assisting users in painting (Münßinger et al., 2010). Specifically, the "Brain Painting" system involved a 6x8 grid of cells that contained symbols representing color, objects, grid size, object size, transparency, zoom, and cursor movement.

✓ **Control of Outer Gadgets**

Another application of P300-based systems is the control of external devices. A recent study by Piccione et al. (2006) developed a BCI system that was tested with two groups of participants. They were tasked with selecting a specific path for a virtual object to reach a target point using the P300 response. The study revealed differences in P300 amplitudes between individuals with motor disabilities and physically fit individuals. Interestingly, both groups achieved successful trials quickly without any training session, and no improvement was observed after training. However, the most severely impaired participants performed worse compared to others, indicating that the P300 response is affected by severe impairments.

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CHAPTER 7

REAL TIME APPLICATIONS OF CYBER PHYSICAL SYSTEMS FOR NEURAL ENGINEERING

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7.1 Introduction to Cyber Physical System (CPS)

The term "cyber-physical systems" (CPS) refers to a new generation of systems that combine computational and physical capabilities, enabling interactions with humans in various ways. Computation, communication, and control play vital roles in driving future technological advancements, as they enhance our ability to interact with and enhance the capabilities of the physical world. The field presents numerous research opportunities and challenges, including the development of advanced aircraft and space vehicles, gas-electric hybrid cars, fully autonomous city driving, and brain-controlled prosthetics.

Researchers and engineers in the domains of systems and control have been at the forefront of developing powerful methods and tools in these areas, such as time and frequency domain techniques, state space analysis, system identification, filtering, optimization, and predictive modelling. In the field of computer science, significant progress has been made in new programming languages, real-time computing techniques, visualization methods, compiler designs, embedded system architectures, software development, and innovative approaches to ensuring computer system reliability, cyber security, and fault tolerance. Computer science researchers have also contributed to the development of modelling formalisms and verification tools.

To advance CPS science and supporting technologies, researchers in the field of cyber-physical systems integrate knowledge and engineering principles from various engineering disciplines, such as computing and networking, as well as from other fields, including biomedical, chemical, and electrical engineering. This interdisciplinary approach enables the fusion of expertise and promotes the development of new solutions in CPS.

➢ Research Imperatives in CPS

The study of CPS is still in its early stages within the scientific community. Due to professional and institutional barriers, the science and engineering disciplines in academia have developed in narrow and specialized research and education domains. Various subfields exist, such as sensor technology, wireless communications, control theory, mathematics, and software engineering, each focusing on specific aspects of CPS. Modelling formalisms and tools are utilized for system design and analysis, with each formalism emphasizing certain characteristics while disregarding others. For instance, physical processes are often modelled using differential equations, while discrete behaviour and control flow are modelled using Petri nets and automata.

This division of expertise within the workforce leads to decreased productivity, safety, and efficiency. Although this approach of modelling and formalisms may be adequate for supporting a component-based "divide and conquer" approach to CPS development, it poses a significant challenge when it comes to verifying the overall correctness and safety of system-level designs and the complex interactions between components, both in terms of physical and behavioural aspects.

In order of these challenges, it is necessary to address several research requirements for CPS. These requirements include developing integrated modelling formalisms that capture the cyber-physical nature of systems, creating comprehensive verification techniques for ensuring correctness and safety at the system level, designing robust and resilient control mechanisms, addressing issues related to real-time constraints and resource optimization, and exploring interdisciplinary collaborations to bridge the gaps between different domains of expertise.

By addressing these research requirements, the field of CPS can advance towards more holistic and integrated approaches, enabling the development of highly efficient, reliable, and safe cyber-physical systems.

- **Abstraction and Architectures**

For efficient CPS design and implementation, novel abstraction methodologies and architectures that facilitate seamless integration of control, communication, and computing are necessary. In communication networks, standardized interfaces across multiple layers have been established, enabling targeted advancements within each layer.

Once these interfaces are in place, modular systems can be easily assembled, fostering innovation, widespread technology adoption, and the growth of the Internet.

Currently, there is a lack of systematic, efficient, robust, and modular CPS design and development based on contemporary scientific and engineering principles. It is crucial to establish standardized abstractions and architectures that promote integration, interoperability, and similar breakthroughs in the field of cyber-physical systems [2].

- **General Architecture**

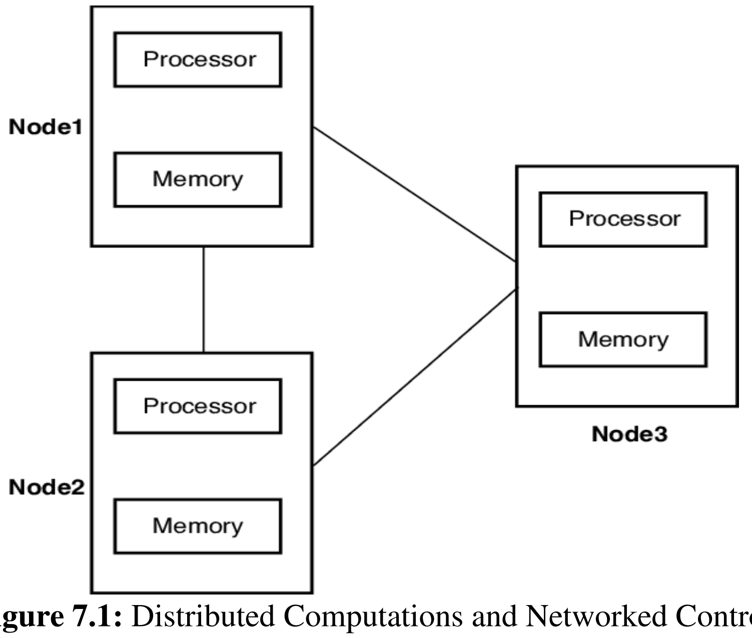

Figure 7.1: Distributed Computations and Networked Control

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The design and deployment of networked control systems present numerous challenges pertaining to time and event-driven computing, software engineering, variable time delays, failures, reconfiguration, and distributed decision support systems. Key issues for CPS researchers include developing protocols that ensure real-time quality-of-service guarantees over wireless networks, striking a balance between control law design and the complexity of real-time implementation, and bridging the gap between continuous and discrete-time systems.

Furthermore, there is a need for frameworks, algorithms, methodologies, and tools that can address the demanding requirements of reliability and security in diverse cooperating components operating within a complex, interconnected physical environment, encompassing various spatial and temporal scales.

- **Verification and Validation**

There is a critical need to develop new hardware and software components, middleware, and operating systems that surpass the current capabilities.

These advancements should prioritize reliability, reconfigurability, and, when applicable, certification, spanning from individual components to fully integrated systems. The existing cyber infrastructures often lack the necessary trustworthiness for such complex systems. For instance, the development of new safety-critical technologies in aviation alone is expected to consume more than half of the resources allocated for certification. Similar efforts are required in sectors such as healthcare, automotive, and energy systems. While overdesigning has been a common approach to ensure safety, it is becoming impractical for increasingly intricate designs and systems that require interoperability. Simply testing until resources are depleted is not a viable strategy, and there is a need for science- and evidence-based methods to reason about system reliability. To integrate software and system verification and validation into the control design process, new models, algorithms, methodologies, and tools must be developed.

- **Biomedical and Healthcare Systems**

CPS research is uncovering numerous opportunities and challenges in the field of medicine and biomedical engineering. These include intelligent operating rooms and hospitals, image-guided surgery and treatment, fluid flow control for drug and biological tests, and the development of physical and neural prostheses. Healthcare increasingly relies on clinical devices and systems that are networked and need to adapt to the needs of patients with unique conditions. Therefore, there is a need for dynamically reconfigurable and deployable medical devices and systems that can interact with patients and caregivers in complex environments.

For example, devices such as infusion pumps for anaesthesia, ventilators and oxygen delivery systems for respiratory support, and various sensors for patient monitoring are used in operating rooms.

Often, these devices need to be integrated into a new system architecture to match specific patient or procedural requirements. The challenge lies in developing systems and control approaches that are authentic, safe, secure, and reliable for designing and operating these systems.

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Research challenges in medical technology and healthcare were addressed in a series of studies summarized in a report by the U.S. National Information Technology Research and Development (NITRD) [4].

The report recommends research in new system science and engineering with the following objectives:

- ✓ Interoperable and open clinical frameworks;
- ✓ Distributed observing, dispersed control, and continuous remote organizations for clinic escalated care offices;
- ✓ Certification techniques for clinical gadget programming and frameworks and arranged patient checking and help;

7.2 Application of Cyber Physical System in Neural Engineering

The research on CPS in healthcare is still in its early stages. In CPS, the integration of dynamic user data such as intelligent feedback systems, electronic health records, and passive user data such as biosensors and smart devices in healthcare settings can support efficient decision-making through data acquisition. This combination of data acquisition and dynamic environment has yet to be thoroughly explored in healthcare applications, making it a topic of high research interest. Opportunities for utilizing CPS in healthcare include the integration of interoperable and adaptive devices, as well as new concepts for managing and operating medical physical systems using computation and control, miniaturized implantable smart devices, body area networks, programmable materials, and novel manufacturing approaches.

Although several CPS models have been proposed in the literature, the number of CPS frameworks specifically designed for healthcare applications [22, 55] is limited.

Hu et al. [56] proposed a service-oriented architecture (SOA)-based medical CPS concept; however, it lacks a comprehensive engineering framework. Wang et al. [1] presented a secure CPS architecture for healthcare that utilizes a wireless sensor network (WSN)-cloud integrated system.

Banerjee et al. [42] proposed modelling and analysis of medical CPS, but it does not address the security and privacy issues. Figure 1 depicts a conceptual CPS for healthcare based on the literature, which will facilitate further discussions in the subsequent sections of this paper.

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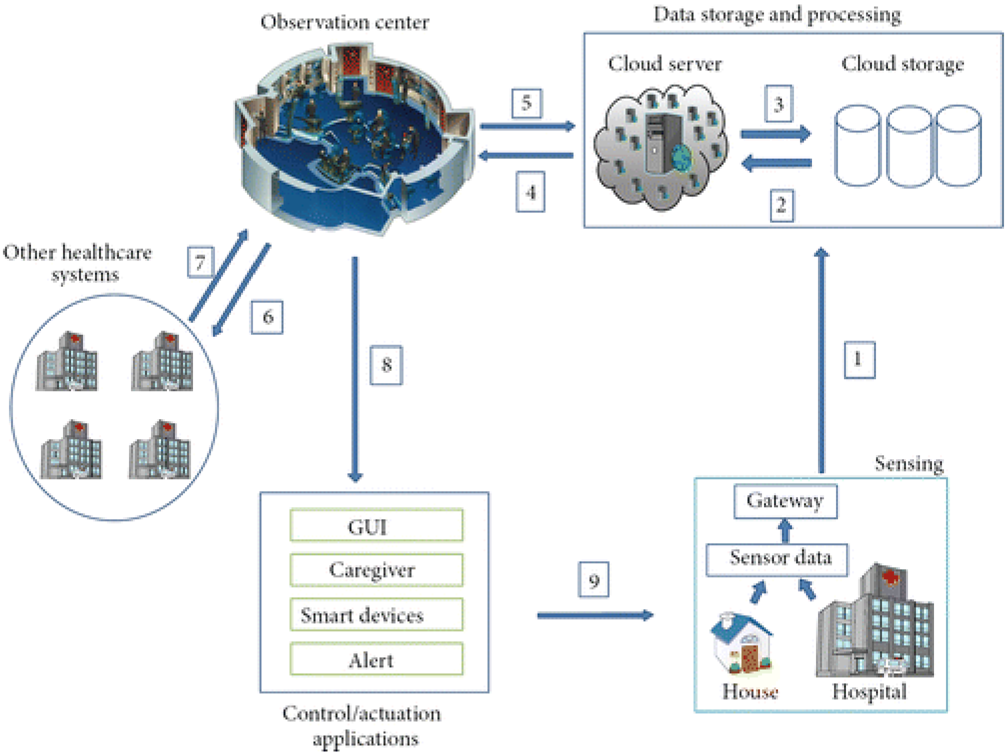

Figure: 7.2 CPS for medical care considered from writing [1, 22, 55]

The process flow for the CPS in healthcare is as follows:

1. Information gathered from patients using various sensors is transmitted to distributed storage via a gateway.
2. The sensor data is processed and analyzed in real-time, with queries being handled by a cloud server.
3. Historical sensor data is processed and utilized when responding to queries.
4. Calculations are performed, and if necessary, alerts are generated and sent to a visualization center.
5. Clinicians at the visualization center can access patient data from the cloud.
6. When needed, clinicians can interact with other healthcare systems for consultation.
7. Responses are received from other healthcare systems.
8. Clinicians and experts provide decisions and recommendations to the activation component.
9. Necessary actions and interventions are carried out on the patients.

This process allows for continuous monitoring, analysis, and decision-making in healthcare using CPS, enabling timely interventions and optimal patient care.

7.2.1 Taxonomy of CPS in Healthcare

It is beneficial to have a comprehensive scientific classification that describes and defines the approaches of CPS in healthcare. Based on a literature review, we present in

Figure 8.2 a scientific classification for CPS in healthcare, consisting of the following elements:

(1) Application,

(2) Architecture,

(3) Sensing,

(4) Data Management,

(5) Computation,

(6) Communication,

(7) Security, And

(8) Control/Activation.

In this section, we discuss the subcategories within each of these elements in detail.

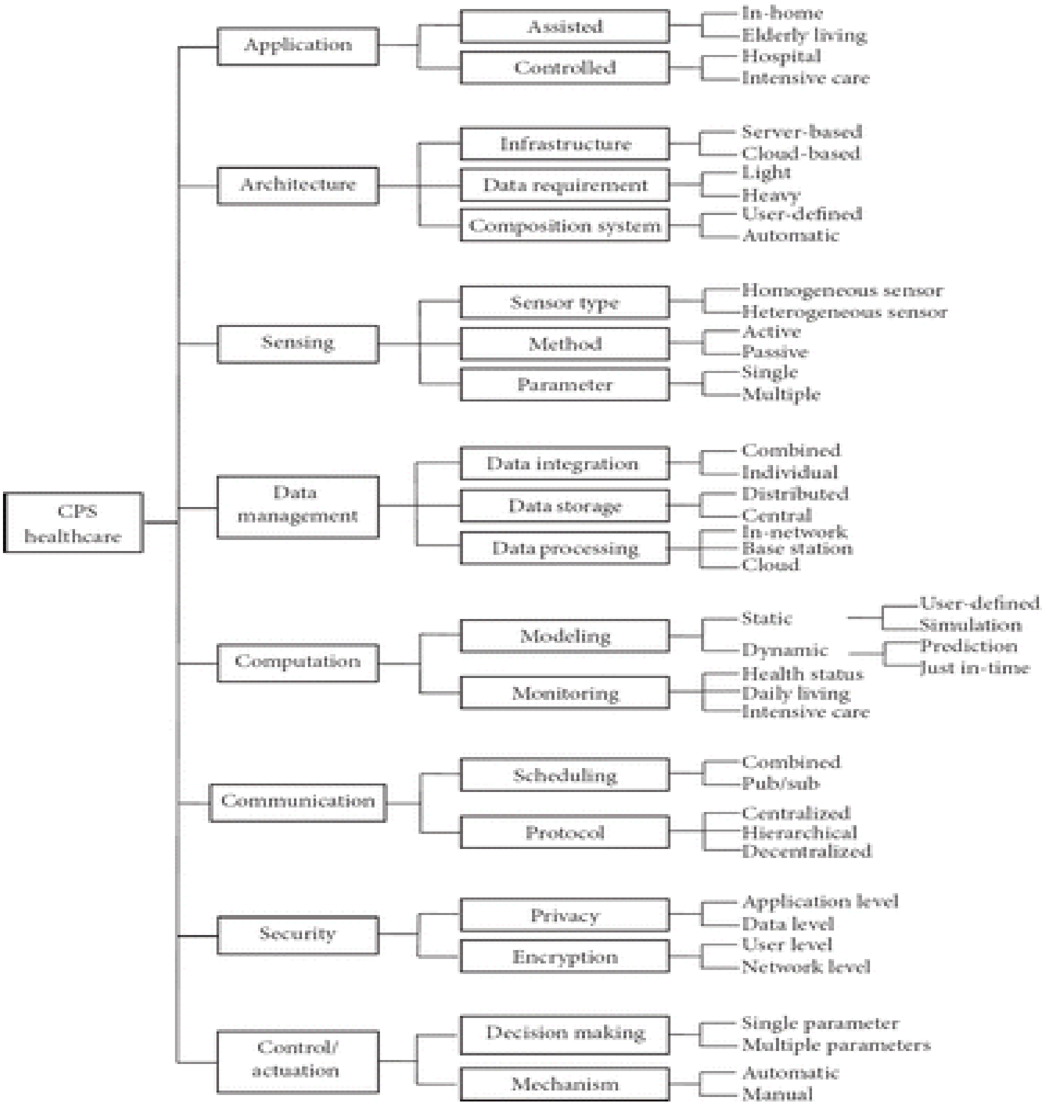

Figure: 7.3 A taxonomy of CPS in healthcare

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- **Application**

CPS in healthcare encompasses a wide range of applications, including hospitals, assisted living facilities, and elderly care. The complexity of the system architecture varies depending on the specific application. Architecture elements may require customized integration based on the relevant area. For instance, in a controlled environment like a hospital emergency unit, the architecture may include tightly regulated components. On the other hand, in an assisted living home, the architecture may involve a larger number of automated components. CPS applications in healthcare can be broadly categorized into two areas: assisted and controlled environments.

- **Assisted**

The assisted application involves monitoring health without restricting an individual's everyday activities. It enables the provision of medical advice to individual patients by continuously collecting physiological data through biosensors. By considering the unique medical needs of individual, it becomes possible to support and care for an increasing number of elderly individuals in both assisted living facilities and their own homes. Progressive and gradual loss of motor, sensory, and/or cognitive abilities often hinders seniors from living independently, eventually leading to hospitalization. This results in significant emotional and financial burdens. Computational technologies present interesting opportunities for in-home health and independence, such as ANGELAH [50].

- **Controlled**

The application in a controlled environment encompasses hospitals and intensive care units, where immediate medical assistance is readily available. In such a controlled setting, the level of monitoring and surveillance is high and comprehensive. In hospitals, data from various sources, including bedside monitors, biosensors, and clinicians' observations, is integrated to guide interventions. Closed-loop systems with human oversight can improve clinical workflows and enhance patient safety. Emerging technologies aimed at enabling remote patient care will provide healthcare professionals with insights into how daily activities impact healthcare and empower them to make more informed decisions regarding interventions. The integration of these currently separate aspects of healthcare would transform the healthcare system into a large, complex, and mission-critical cyber-physical system with numerous benefits and challenges [22].

- **Design**

The design of CPS in medical care is vital for the quality and execution of the framework. To work with the CPS for medical care applications, the design should be created dependent on the application space, client information necessity, and framework incorporation. Engineering in CPS can be described by three components:

(a) Framework,

(b) Information prerequisite,

(c) Synthesis.

(a) Framework

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The CPS architecture for healthcare can be designed from the perspective of infrastructure, such as server-based or cloud-based systems. Server-based infrastructure is suitable for smaller-scale designs and requires individual maintenance, while recent works utilize cloud-based systems for their scalability, cost-effectiveness, and accessibility. However, due to the complexity and resource constraints, both the digital and physical components of CPS can be vulnerable to various challenges. Therefore, special efforts are necessary when designing CPS for healthcare applications.

✓ **Information Requirement**

Managing CPS design for healthcare involves handling various types of data, including input data, historical data, and output data. In healthcare, the data size can vary depending on the type of biosensors used. There can be simple data such as temperature, while large image data such as magnetic resonance imaging (MRI) also needs to be processed. Yilmaz et al. [57] stated that the data acquisition and transmission may vary depending on the applications. Examples of low data rate applications include temperature and heart rate, while high-density surface Electromyogram (EMG) is an example of a high data rate application. Additionally, it may be necessary to access historical data from storage. Therefore, the data requirements of the architecture can be classified into two types: light and heavy.

- **Structure**

The design of CPS in healthcare often involves concurrent execution of computation and communication processes. The system architecture should be able to identify the system configuration based on the application. The applications can be developed dynamically or manually according to the system setup or user requirements. For example, Avrunin et al. [23] proposed a smart checklist to assist and guide human participants with their tasks; however, the system architecture can be considered as user-defined. Interaction with devices and software applications is also supported by the system. The dynamic component would involve the computation and communication processes to be performed without human intervention.

- **Detecting**

The physical component of CPS in healthcare is carried out through sensing. Biomedical sensors are responsible for collecting important physiological data, which is then processed and transmitted to the system for further use [58]. Sensing is a critical aspect of healthcare applications as the sensed characteristics are used as input parameters for the system. Sensing procedures can often be uncomfortable or painful for patients. For example, detecting blood glucose levels in diabetic patients typically involves pricking the finger and collecting a blood sample. To address this, non-invasive methods for blood glucose monitoring using radio-based sensors have been employed [57].

The elements from a sensing perspective include **(a)** sensor type, **(b)** method, and **(c)** parameter.

(a) Sensor Type

In healthcare applications, the number and types of sensors can vary widely. Sensors can be both homogeneous, meaning they are of the same type, or heterogeneous, meaning they are different types. There can be a single sensor for monitoring a group of

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individuals or multiple sensors for monitoring the health status of an individual. The complexity of the system largely depends on the type of sensing process involved. CPS involves many sensors with diverse sensor data. In some cases, sensors may report abnormal or unusual readings, which could compromise the integrity of the monitored data and the accuracy of important predictions. To enhance the system's performance and facilitate user decision-making, it is important to analyse the sensed data efficiently using multidimensional information [59].

(b) Method

Modern biosensors have the capability to efficiently collect vital patient information [37]. These sensors can gather patient data either in a hospital setting or at home, and the collected information is transmitted to a sink or controller. The sink can utilize the data locally or transmit it to other entities such as a cloud service provider through a gateway [60]. The sensors can be part of a remote sensor network. In terms of sensing, data can be acquired either actively or passively.

For example, electrocardiogram (ECG) data can be actively sensed, while heart rate can be obtained passively from the ECG data. Therefore, selecting the appropriate sensing method is crucial for optimizing efficiency in CPS for healthcare [32].

(c) Boundary

To enhance the computation and communication system, the specification of parameters is crucial. A simple single-parameter system may be sufficient for individual health applications; however, a comprehensive health monitoring system may require multiple parameters. Wearable and wireless sensors seamlessly monitor vital information such as heart rate [38], oxygen levels, blood flow, respiratory rate, muscle activities, movement patterns, body posture, and oxygen uptake [2–4, 39, 40], and feed these into a multiparameter system. The wide range of sensor parameters in terms of dimensions, designs, and processes can pose a challenging task for monitoring health status.

7.3 Interfacing of BCI with CPS

✓ ***Model cross breed BCI framework***

The proposed hybrid BCI system for biomedical CPS applications consists of a combination of mental task-based BCI, SSVEP-based BCI, and eye closure detection using a two-channel wireless EEG and embedded systems. The block diagram in Figure 8.3 illustrates the three main modules of the model, which utilize embedded system controllers as functional blocks.

The first module is a wireless EEG system, which includes both analog and digital components. The analog section consists of amplifiers and filter circuits. The digital component is handled by a combined microcontroller and 2.4 GHz RF transmitter (Nordic Semiconductor), which processes the data and transmits it wirelessly.

The same wireless microcontroller on the receiver side captures and sends the data to the second module, which uses the main microcontroller MCF5213 Coldfire® (Freescale™) for signal processing, feature extraction, and classification.

The third module, the LED trigger box, incorporates the Atmega128 microcontroller (Atmel®) to control three LEDs for the SSVEP-based BCI system.

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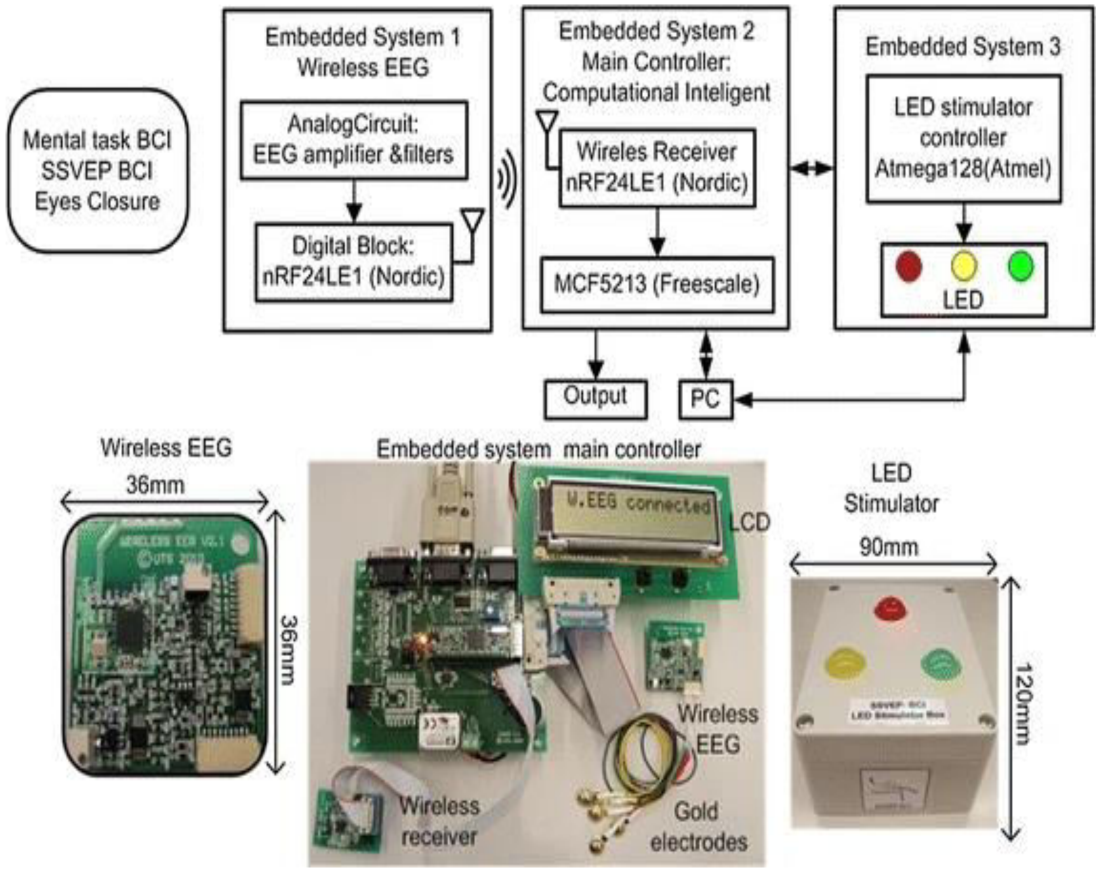

Figure: 7.4 Hybrid BCI system, EEG based CPS module

7.4 Wireless EEG, main Controller, and Stimulator Box

The EEG amplifier in the proposed system requires a high common mode rejection ratio (CMRR) of over 80 dB to effectively reject interfering noise. Additionally, the amplifier should be able to detect EEG signals within the range of 5-300 µVolts [46].

As shown in Figure 8.4, the proposed wireless EEG system is divided into analog and digital sections. The EEG is based on a two-channel bipolar EEG configuration. Each channel consists of non-inverting inputs (CH1+ and CH2+), inverting inputs (CH1- and CH2-), and a reference input electrode. The amplifier design utilizes a DC-coupled amplifier with two stages. The first stage employs a precision current mode instrumentation amplifier (In-Amp) AD8553, which includes a voltage-to-current amplifier, a current-to-voltage converter, and a high-precision auto-zero amplifier. To handle the DC offset from the electrodes that could saturate the amplifier, the gain of the In-Amp is set to a low value of 10.

This is followed by a passive RC high-pass filter circuit to remove the DC offset. The second stage amplifier also utilizes an operational amplifier OPA333 to form a non-inverting amplifier circuit with an adjustable gain of up to 1000 using a potentiometer.

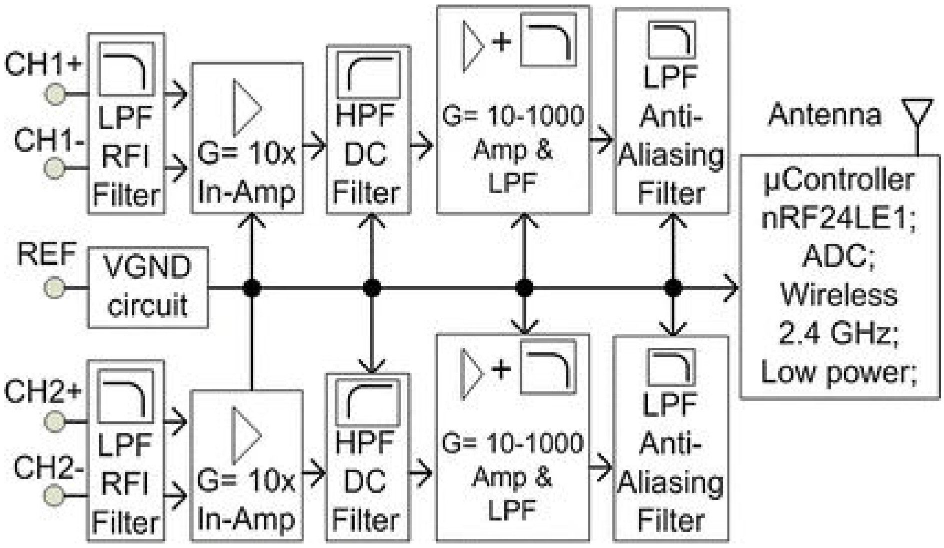

Figure: 7.5 Wireless EEG module

A differential low-pass filter circuit is included in the amplifier design to reduce radio frequency interference (RFI). The second stage of the amplifier incorporates an additional channel with a low-pass filter configuration to further attenuate high-frequency noise. An anti-aliasing filter is introduced at the end of the analog block before it is connected to the microcontroller. The bandwidth of these filters is set to 1.5 kHz. The total noise measurement is 3.5 µVolts referring to the input.

The analog-to-digital converter (ADC) used in the system has a 12-bit resolution and is configured in differential mode to enhance common mode rejection. For additional noise reduction, four ADC samples are taken and then averaged for each reading. This technique is particularly effective in eliminating internally generated noise by the microcontroller.

7.5 Experimental Data Collection

- **Prototype Testing**

During the initial testing, an EEG test equipment (MinSim300 - Netech) was used to inject a sinusoidal signal with adjustable frequency and amplitude. The results demonstrate that the remote EEG system has the potential to detect the simulated signal with a minimum 10 V test signal at various frequencies.

As shown in Table 1, the remote EEG system utilizes a compact square-shaped printed circuit board (PCB) with a surface area of 36 mm2. It consists of two EEG channels, each with two electrodes and one reference electrode, resulting in two bipolar montages and five terminals in total. The CMRR measurement was conducted by connecting the input of the remote EEG to a signal generator and the resulting output to an oscilloscope. The signal generator's amplitude was maximized using full normal mode voltage. The CMRR was found to have a value of 95 dB at 50 Hz, which is considered typical, but it can be increased to a maximum of 104 dB. During continuous operation, the remote EEG consumed 5 mA when in power-saving mode and while running computer applications.

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The noise was measured at 3.5 μV. With such low current consumption, the remote EEG can run on a coin cell battery for up to 45 hours before requiring replacement.

The daily Fast Fourier Transform (FFT) routine on the MCF5213 microcontroller has a processing time of 520 s and demonstrated a similar result to the FFT Mat-lab function shown in Figure: 8.6, with a 3 percent discrepancy.

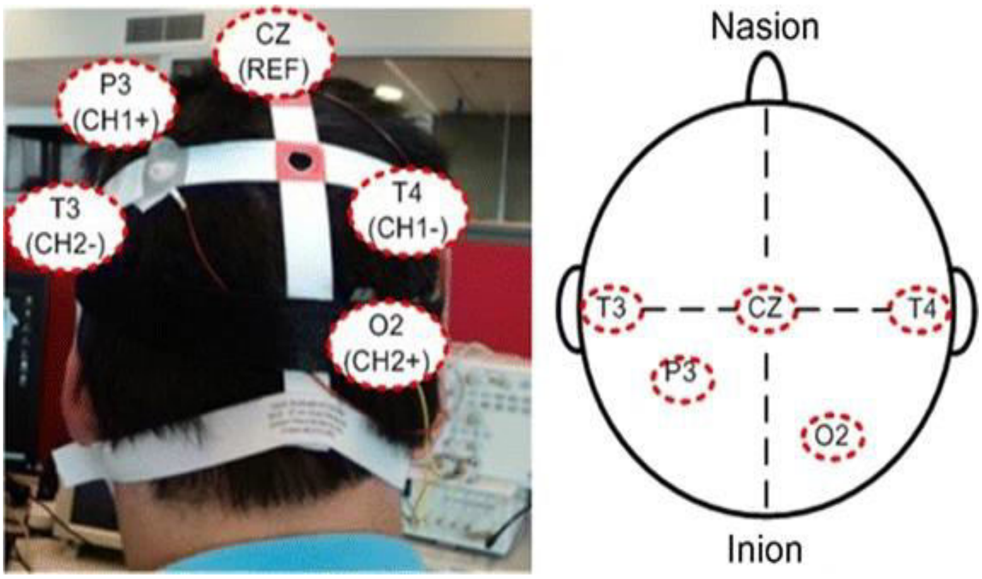

Figure: 7.6 Two channels bipolar EEG electrodes placement

The important assignments utilized are as per the following:

- **Mental Math:** Participants envisioned intellectually taking care of a non-inconsequential augmentation issue.
- **Mental Figure Pivot:** Participants were approached to envision a 3D shape being continued ahead.
- **Mental Letter Creating:** Participants made a straightforward word to them.
- Participants mentally counted on a slate by imagining a number appearing and disappearing.
- **SSVEP 6 Hz:** Participants were approached to focus on a LED that persistently flashes at 6 Hz.
- **SSVEP 13 Hz:** Participants were approached to think a LED that consistently glimmers at 13 Hz.
- **SSVEP 16 Hz:** Participants were approached to think a LED that consistently glimmers at 16 Hz.
- **Eyes Shut:** This task is used to find out how many alpha waves are generated during brain stimulation. Members were asked to relax by doing an activity that required them to keep their eyes closed.
- **Baseline:** Participants were instructed to be carefree and open-minded, with no preconceived notions.

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7.6 Real Time Applications and Implementation of CPS using Open-Source Tools

General-purpose software development has made significant progress in recent years, thanks to the adoption of powerful programming languages, agile frameworks, software tool pipelines, standardization, and open-source development. However, the same level of progress has not been fully realized in the field of cyber-physical systems (CPS). Instead, many CPS languages and tools remain proprietary, often limited to specific application domains, and lack precise language definitions and APIs. This makes interoperability with other tools and languages challenging and prone to errors.

There is still a ton of work to be finished in regards to the incorporation of the displaying and model-based improvement devices into a full item advancement cycle (like the one in Figure 8.6), with research continuous in regions like necessity confirmation, testing and circulated assemblage.

A few industry concepts exhibit laxity in terms of text and outlines, lacking unambiguous grammar and semantic meaning. This is evident in standards such as IEC 61131-3 for programmable logic controllers and OMG SysML for systems. Consequently, different vendors interpret these standards differently, employ their own serialization formats, and implement vendor-specific extensions. The collaborative efforts and interoperability of Functional Mock-up Interface (FMI) and VHDL-AMS, which enable model portability and reuse among tools, are disrupted by this situation.

To address these challenges, this study focuses on open approaches and open-source implementations that leverage advances in current language technology and software development methodologies. In the modelling community, similar approaches have led to the emergence of open formal modelling languages and standards, such as Distributed Co-Simulation Protocol (DCP) and System Structure and Parameterization (SSP). Modelica and FMI are examples of widely used standards in this context.

While the industry has seen successful adoption of open-source and collaborative tool development, the development approaches and tools for CPS based on these languages have not yet reached the same level of maturity as some general-purpose software development tools. This lack of maturity hampers tool interoperability, portability among tools, and leads to vendor lock-in and increased development costs. However, there are also a few industrial standards that have more precisely defined semantics, such as Modelica. In the following, we provide an overview of the current state-of-the-art and ongoing work on CPS languages and tools that utilize open formal language definitions. We highlight key elements that are essential in languages for modelling and developing cyber-physical systems, based on our experience and research in this field. The discussed aspects include CPS languages, grammatical correctness, semantic rigor, integration with general-purpose programming languages, and tool interoperability:

- CPS dialects
- Textual versus graphical programming,
- Formal semantics—language and recreations,
- 3D perception,
- Debugging, testing, necessity check,

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- Traceability,
- Control applications.

✓ **CPS Languages and Tools**

A Cyber-Physical System (CPS) integrates physical components with computer programming, often depicted as control systems connected to physical systems. Model-based approaches to CPS development involve simulating both the physical and software aspects using models, allowing for the complete system to be emulated prior to deployment.

This enables virtual prototyping, facilitating extensive testing, verification, and optimization through simulations. Simulation is commonly used in conjunction with physical systems, such as in hardware-in-the-loop simulation, or to fully replicate a physical entity, as in the case of digital twins. Control software can be represented using CPS languages, and so can the components themselves. The Functional Mock-up Interface (FMI) enables the integration of models written in different languages. To facilitate the exchange and co-simulation of precompiled models, FMI and System Structure and Parameterization (SSP) are open standards that define a model description format using C language for behaviour and XML for the interface (discussed further in Section 2.4).

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CHAPTER 8

CODING IN PYTHON FOR NEURAL ANALYSIS

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Most introductory texts on Neural Networks often use brain analogies when describing them. However, it is simpler and clearer to describe Neural Networks as mathematical functions that map a given input to a desired output, without delving into brain analogies.

8.1 Data Set Preparation

Neural Networks consist of the following components

- An **input layer**, x
- An arbitrary amount of **hidden layers**
- An **output layer**, $\hat{y}$
- A set of **weights** and **biases** between each layer, *W, and b*
- A choice of **activation function** for each hidden layer, σ. use of Sigmoid activation function.

The graph below illustrates the structure of a two-layer Neural Network. It is worth noting that the input layer is typically not counted when specifying the number of layers in a Neural Network.

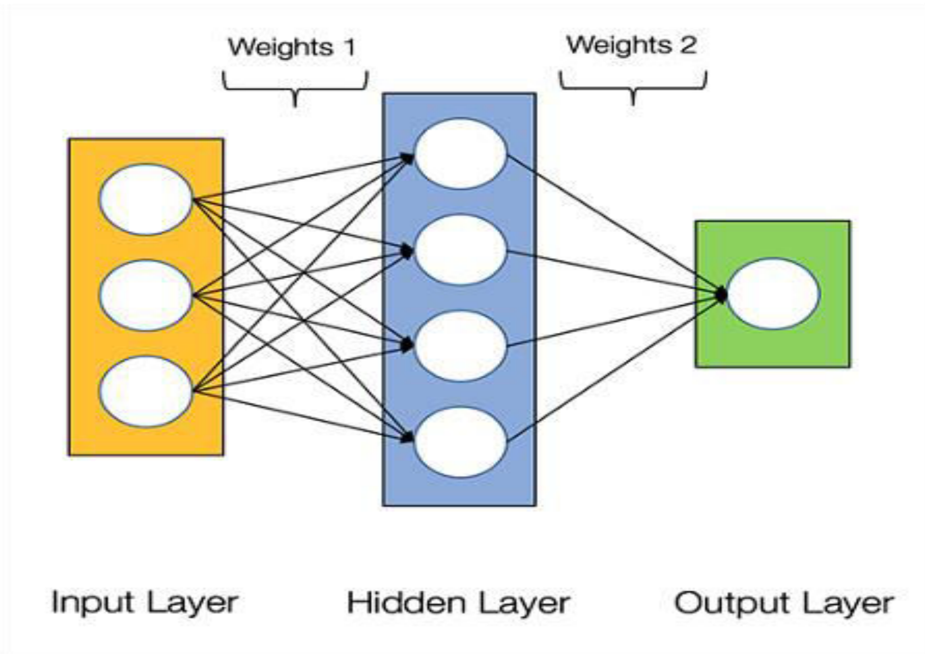

Figure: 8.1 Architecture of a 2-layer Neural Network

8.2 Algorithms for EEG Signal and for Brain Image Implementation

Creating a Neural Network class in Python

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```
Class Neural Network:
Def __init__ (self, x, y):
Self.input     = x
Self.weights1   = np.random.rand (self.input.shape [1], 4)
Self.weights2   = np.random.rand (4, 1)
Self.y         = y
self.output     = np.zeros (y.shape)
```

- **Training the Neural Network**

The output $\hat{y}$ of a simple 2-layer Neural Network is:

$$\hat{y} = \sigma(W_2\sigma(W_1x + b_1) + b_2)$$

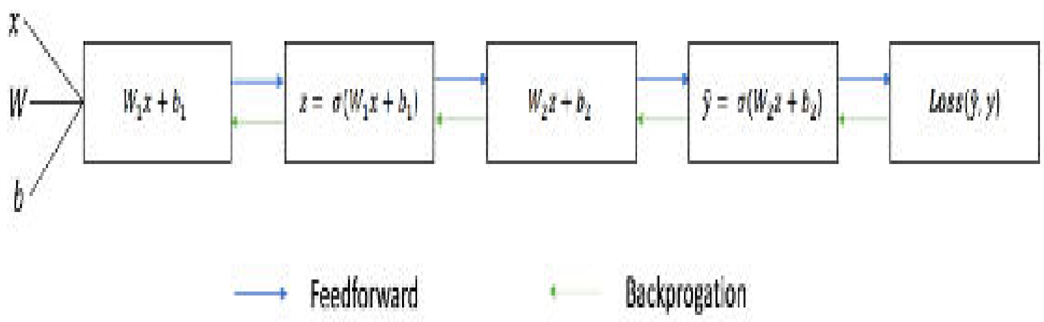
Clearly, the loads W and predispositions B are key determinants of the yield in the example above.

Normally, the strength of the expectancies is determined by the appropriate qualities for the loads and inclinations. Preparing the Neural Network is the process of fine-tuning the loads and predispositions gleaned from the data.

Every cycle of the preparation interaction comprises of the accompanying advances:

- Calculating the anticipated yield ŷ, known as feedforward
- Updating the loads and predispositions, known as backpropagation

The Successive Chart underneath Shows the Interaction.



8.2.1 Feedforward

It turns out that feedforward is basic algebra, and for a two-layer neural architecture that is necessary, the Neural Network's output becomes:

$$\hat{y} = \sigma(W_2\sigma(W_1x + b_1) + b_2)$$

Consider adding a feedforward operation to our python source code to accomplish this. The predispositions should be zero if effortlessness is the goal.

class NeuralNetwork:

```
def __init__(self, x, y):
self.input      = x
self.weights1   = np.random.rand(self.input.shape[1],4)
self.weights2   = np.random.rand(4,1)
self.y          = y
self.output     = np.zeros(self.y.shape)
def feedforward(self):
self.layer1 = sigmoid(np.dot(self.input, self.weights1))
self.output = sigmoid(np.dot(self.layer1, self.weights2))
```

Despite this, do we really require a method for evaluating the "decency" of our forecasts? Using the Loss Function, we can achieve just that.

8.3 Loss Function

There are numerous accessible misfortune capacities, and the idea of our concern should direct our decision of misfortune work. In this instructional exercise, we will utilize a straightforward amount of-squares blunder as our misfortune work.

$$Sum - of - Squares\ Error = \sum_{i=1}^{n} (y - \hat{y})^2$$

That is, the amount of-squares mistake is just the amount of the contrast between each anticipated worth and the genuine worth.

The most important factor is the square root, which allows us to calculate the exact dollar value of the difference. In preparing, our goal is to find the best combination of loads and inclinations that minimizes the unfortunate labor.

8.4 Backpropagation

Since we have calculated our expectation's mistake (misfortune), we need to figure out how to generate the blunder again and to refresh our loads and predispositions.

To realize the fitting add up to change the loads and predispositions by, we need to know the subsidiary of the misfortune work concerning the loads and inclinations.

Review from analytics that the subordinate of a capacity is essentially the incline of the capacity.

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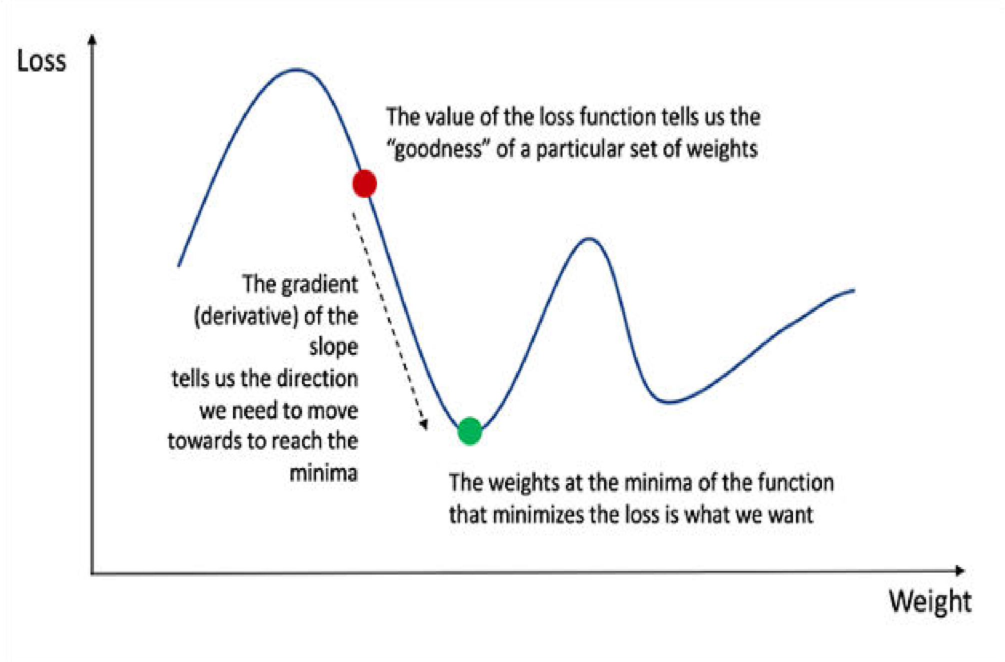

Figure: 8.2 Gradient descent algorithm

If we have the derivative, we can update the weights and biases by incrementing/decrementing them according to it (refer to the graph above). This process is known as gradient descent.

However, we cannot directly calculate the derivative of the loss function with respect to the weights and biases because the expression of the loss function does not explicitly involve the weights and biases. Therefore, we need the chain rule to help us compute it.

$$Loss(y,\hat{y}) = \sum_{i=1}^{n}(y - \hat{y})^2$$

$$\frac{\partial\, Loss(y,\hat{y})}{\partial W} = \frac{\partial Loss(y,\hat{y})}{\partial \hat{y}} * \frac{\partial \hat{y}}{\partial z} * \frac{\partial z}{\partial W} \quad \text{where } z = Wx + b$$

$$= 2(y - \hat{y}) * \text{derivative of sigmoid function} * x$$

$$= 2(y - \hat{y}) * z(1\text{-}z) * x$$

The chain rule allows us to calculate the derivative of the loss function with respect to the weights. Please note that for simplicity, we have only shown the partial derivative assuming a 1-layer Neural Network.

By finding the derivative (slope) of the loss function with respect to the weights, we can adjust the weights accordingly.

class NeuralNetwork:

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```
def __init__(self, x, y):
self.input      = x
self.weights1   = np.random.rand(self.input.shape[1],4)
self.weights2   = np.random.rand(4,1)
self.y          = y
self.output     = np.zeros(self.y.shape)
def feedforward(self):
self.layer1 = sigmoid(np.dot(self.input, self.weights1))
self.output = sigmoid(np.dot(self.layer1, self.weights2))
def backprop(self):
# application of the chain rule to find derivative of the loss function with respect to weights2 and weights1
d_weights2 = np.dot(self.layer1.T, (2*(self.y - self.output) * sigmoid_derivative(self.output)))
d_weights1 = np.dot(self.input.T, (np.dot(2*(self.y - self.output) * sigmoid_derivative(self.output), self.weights2.T) * sigmoid_derivative(self.layer1)))
# update the weights with the derivative (slope) of the loss function
self.weights1 += d_weights1
self.weights2 += d_weights2
```

Our feedforward and backpropagation Python code is complete. Now, let us test our neural network on a real-world problem.

In order to accurately represent this function, we need to determine the optimal set of weights for our neural network. It is important to note that visually inspecting the weights alone is not a simple task.

One approach we can take is to train the neural network for 1500 iterations and evaluate the results. As shown in the graph below, the loss steadily decreases towards zero. This aligns with our understanding of the gradient descent algorithm and its ability to minimize the loss function.

Overall, our neural network appears to be performing well on the given problem.

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Deep Learning technologies like TensorFlow and Keras make it easy to design deep networks without fully understanding how a neural network works, but it is beneficial for aspiring data scientists to understand neural networks better.

8.5 Concluding Results with Respect to the Different Disorders.

- ✓ The study of cadaveric brains may lead to new insights into brain structure, but this research is limited because the brain is no longer alive.
- ✓ Lesion studies provide useful information on the consequences of lesions in various brain areas.
- ✓ Animals can have their brain activity recorded using electrophysiology to directly observe their thinking process.
- ✓ Electroencephalography (EEG) and other methods that measure brain electrical activity are used to analyze brainwave patterns and activity.
- ✓ Brain blood flow is monitored using functional magnetic resonance imaging (fMRI), which reveals information about neuron activity and the functions of distinct brain locations.
- ✓ Transcranial magnetic stimulation (TMS) allows for temporary deactivation of a small brain region. It is a safe method that enables researchers to determine the impact of such deactivation on behavior.

Add one more example (At least 1)

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CHAPTER 9

TESTING AND VALIDATION

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Activities such as medical product verification and validation typically occur after the design phase. Once the design phase is complete, the product will have well-defined design inputs, detailed design features, and production procedures. The design output, which is the final product, then undergoes verification and validation processes to ensure that it meets both engineering criteria and user requirements.

Design verification focuses on confirming that the product has been manufactured correctly, adhering to the specified engineering specifications. It ensures that the product has been produced according to the intended design and meets the predefined criteria.

On the other hand, design validation aims to verify that the correct product has been developed, one that fulfills the needs and expectations of the customer. It involves assessing the product's performance in its intended environment and confirming that it satisfies the intended purpose and user requirements. Both design verification and validation play crucial roles in ensuring the quality, safety, and effectiveness of medical products before they are released to the market.

9.1 What are the Goals of Verification and Validation?

To achieve DV&V, engineers employ techniques such as physical testing, inspections, revisiting specifications, and material analysis. All design inputs are listed, and methods for verifying and validating them are identified. The project team develops a precise process with quantifiable acceptance criteria for each test or analysis. Evaluation data and results are documented in formal reports. Regulatory agencies and auditors expect a comprehensive and well-documented DV&V plan, along with test methodologies and outcomes. These documents serve as evidence to regulatory authorities that the product is safe and effective. Often, DV&V reports are provided to regulatory agencies in written or summarized formats.

When it comes to medical electrical equipment, a regulator will look at things like: • Has the product safety been proved to be in conformity with international standards like IEC 60601-1, CDSCO, India's major medical regulatory authority, is the Central Drugs Standard Control Organization. The FDA in the United States oversees medical device regulation (FDA). Manufacturing, repackaging, re-labelling and/or importing medical device enterprises are all subject to regulation by FDA's Centre for Device and Radiological Health (CDRH). The UK medical devices market is regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA).

- Have all applicable biological safety tests been completed for a product that will meet a patient?
- Has the product's performance been proven, even in the worst-case scenario?

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9.1.1 What are the Design Verification Activities?

Design verification ensures that the design outputs of the product meet the specified engineering requirements. Various testing procedures are employed depending on the specific features of the device being evaluated. These may include physical testing such as benchtop mechanical or electrical tests, benchtop biological tissue tests, preclinical evaluations, and more.

9.1.2 What Activities are Involved in Design Validation?

To guarantee that the product design matches specified user needs, it is necessary to perform design validation. Preclinical research, clinical trials, and usability studies can all be used to validate user demands. Users' interactions with the device or its overall functionality are often evaluated in these tests. Clinical trials can only commence after all other tests have been performed and submitted to the appropriate regulatory body.

9.1.3 What Happens at the End of DV&V?

A medical product is ready for regulatory submission or marketing after successful verification and validation, depending on the product's regulatory classification.

The manufacturing transfer phase is usually the next step, which ensures that high-quality items can be created in sufficient quantities.

9.2 Validation of Results with Medical Practitioners.

9.2.1 Developing and Validating Classifiers

There are various processes involved in creating a classifier that uses SVMs or another classification technique: Steps in the analysis process include picking a technique for analyzing data, deciding on a collection of characteristics or traits to be used in classifying subjects, developing a classifier, and then testing it to see if there are any errors. Prejudice and inaccuracy could sneak into the work at every stage.

9.2.2 Choice and Number of Attributes

For a classifier to be effective, it must have an adequate quantity and diversity of attributes. Overfitting occurs when a classifier solely learns from the data without considering the underlying patterns (e.g., individuals with illnesses), resulting in a poor fit. Although a high-order polynomial may provide a satisfactory fit when fitting data, it may fail to capture underlying trends and lack predictive value for future data if the polynomial's order is excessively large compared to the number of data points.

To achieve a classifier with reliable predictive value, it is recommended to have more than 10 "events" for each attribute [12]. Ideally, the training set should consist of an equal number of healthy and unhealthy subjects, resulting in a training set with over 20 times the number of attributes. In biomedical engineering studies, where participant numbers are often limited and the parameters defining biomedical signals are virtually limitless, caution should be exercised to avoid overfitting.

The selection of attributes is also crucial [13–15]. For the attributes to serve as diagnostic indicators, they must be directly linked to the condition under consideration. Physicians often examine physiological data, such as an ECG, searching for specific traits that indicate medically significant occurrences, such as the polarity of certain ECG waves.

On the other hand, the biomedical engineering community frequently employs abstract features of a signal, such as entropy or wavelet coefficients, to train classifiers.

For the classifier to be valuable, these attributes must capture a substantial amount of medically relevant information and preferably be independent, avoiding confounding variables. The initial step in the broader clinical validation process is to demonstrate that a set of abstract coefficients can be utilized to construct diagnostic applications, often necessitating extensive clinical trials.

9.2.3 Validation of Predictive Model

Validating a classifier involves testing it on a separate group of individuals, known as the test set, who were not part of the training process. When dealing with large datasets, the dataset can be divided into a training set and a test set using the hold-out method. For smaller datasets, leave-one-out cross-validation is a powerful approach where one sample is removed from the training set at a time, and the classifier is recalculated using the remaining training set while using the holdout sample as a test. This process is repeated for each member of the training group. There are other computationally less expensive validation approaches available, and some machine learning techniques incorporate the training and validation of classifiers into a single step [16, 17]. However, it is important to note that the classifier cannot be validated using the same data that were used to train it, as this would introduce circularity into the process.

The concept of "independence" is crucial for the model's external validity. Even if ECG records are from different days, they may not be sufficiently independent for an ECG analysis project if they come from different patients. If a test is intended to be used in different medical centers by different doctors, it may be necessary to establish a medical diagnostic procedure with multiple cohorts of participants, such as patients of the same physician.

The quality of biomedical engineering literature on these topics varies greatly. Many articles at the lower end of the quality scale do not disclose any validation studies but only demonstrate that the classifier performs well on the training set, which does not provide any insight into its predictive value when presented with new data. In many other research papers, validation procedures are not described in sufficient detail for readers to assess the validity of the work. Article reviewers should ensure that the validation process employed in the study has appropriate scientific validity before making judgments on its findings.

9.2.4 Illustrations of Pitfalls In Using Classifiers

The following three examples demonstrate the problems associated with the application of support vector machines (SVM). One utilizes a classifier trained on a random number generator, in contrast, the other studies employ ultrasound pictures from patients with Hashimoto's inflammation, an autoimmune thyroid disorder, as well as healthy controls [18].

9.3 Random dataset

Case study participants were split evenly between "healthy" and "sick" groups to create a synthetic training set. Each person was given a unique set of ten qualities, all generated at random. The traits have no predictive value because they were selected independently of the class to which they belong. When applied to a validation set with the same number of "healthy" and "ill" patients, the classifier's accuracy would be 50% only by chance.

To use a linear SVM to train a classifier, we built a fictional dataset (MATLAB Statistics Toolbox, MathWorks, Natick MA). Figure 1 shows the results of training sets of various sizes on the same training set that was used to build the classifier. Because of the cyclical nature of this (clearly incorrect) training/validation, the classifier in Figure 1 looked to approach 100 percent accuracy for small training sets (4–6 people per characteristic, including patients and controls). There is therefore no predictive value to the classifier. Use a large training/validation set, such as 200 "patients," to observe how well the classifier works.

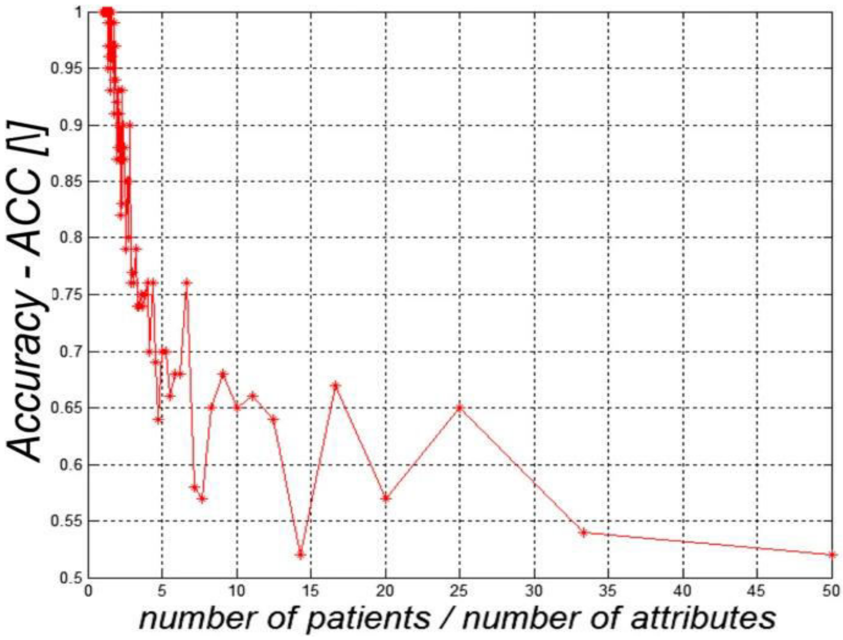

Figure: 9.1 To achieve a reliable accuracy, enough patients and attributes are required.

Consider Figure 10.1, for example. Using a random number generator to generate ten attributes for each subject, the classifiers' apparent accuracy (ACC) is measured in synthetic training sets with an equal number of "healthy" and "sick" participants on each side. The horizontal axis represents the ratio of "ill" individuals to the total number of attributes (10 in each case). As the training set size decreases, the accuracy increases due to the use of an insufficient training set and post-hoc reasoning. The classifier's accuracy should be 50% since there were an equal number of "sick" and "healthy" individuals in the dataset.

9.4 Clinical Ultrasound Images – Hashimoto's Disease

In a previous study [19], the accuracy of a classifier in detecting Hashimoto's thyroiditis using ultrasound images was investigated in relation to feature selection. Dr. W. Zielenik and his team [18] collected photographs of patients, and each subject's medical condition was verified by a physician using ultrasound images and other clinical data. In this example, we consider 250 photographs from Hashimoto's patients and an equal number of healthy individuals, with each image representing a different person.

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Ten characteristics were used to analyze each image, including the average image power spectrum, three parameters from the image's square-tree decomposition, image smoothness, minimum brightness value, and the location of the GLCM matrix gravity's center (for more details, refer to [18]).

Custom software (MATLAB, The MathWorks, Natick MA) was employed to evaluate the photos. A classifier was trained on SVM with a linear kernel using MATLAB's Statistics Toolbox.

a. Size of Training Set.

Using photos from Hashimoto's patients and a similar number of healthy controls, we look at the impact of using training sets of varying sizes on performance. There were 100 photos in each validation set, 50 from healthy people and 50 from people who had been held out as a test group (and not used in the training set).

Figure 9.2 shows the sensitivity (SEN) and specificity (SPC) of the classifier in relation to the number of Hashimoto's patients in the training set.

SPC indicates the proportion of successfully identified true negatives while SEN measures the number of correctly identified true positives by the classifier. True positive, true negative, false negative, and false positive are all abbreviations for the same thing: SPC. The classifier's accuracy is expressed as the percentage of correctly categorized cases, which includes both true positive and true negative detection rates. Figure: 9.2 illustrates that the classifier's performance changes greatly for training sets with fewer than about 60 samples (see text for more information) (plus an equal number of healthy controls). It is possible that for medical applications, the classifier's performance could approach 75-85 percent sensitivity and specificity for bigger training sets.

Although the validation was statistically correct (pictures from distinct persons were included in both the validation and training sets), the classifier performed badly when trained with fewer than roughly 100 photographs. In order to train and understand a meaningful classifier, a large training and evaluation set is required.

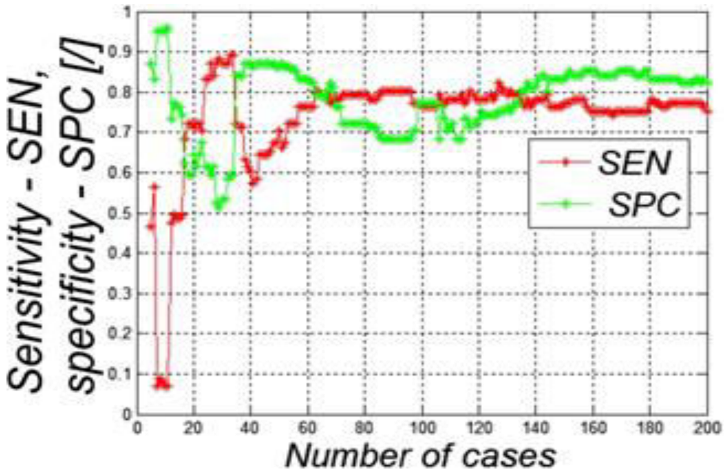

Figure 9.2 A classifier's sensitivity (SEN) and specificity (SPC) were evaluated on a validation group comprising 50 asymptomatic individuals and 50 symptomatic individuals.

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The sensitivity (SEN) and specificity (SPC) of a classifier were evaluated on a validation group comprising 50 healthy individuals and 50 individuals experiencing symptoms. The training group consisted of an equal number of healthy individuals and patients with Hashimoto's disease.

The test group comprised individuals who were not part of the training group. Each image had ten distinct attributes.

b. **Effect of Different Operators and Equipment.**

Next, we evaluate the classifier's performance on images captured by two operators using two separate ultrasound machines in two different medical facilities. Medical units 1 and 2 are utilized by both operators 1 and 2. There were 50 healthy people and 50 sick patients in the classifier's training set, and it was applied to validation sets of the same size that were collected by either the first or second operator (Table 1). Operator 1 (the person who had collected the data) used the classifier more efficiently than Operator 2.

Table 9.1 has some information. In this case, the SVM was trained with 100 photographs (50 of healthy patients and 50 of ill patients) taken by Operator 1 and validated with two sets of identical-sized images taken by either Operator 1 or 2. When using data from device 1 (which provided the data), classifier performance is generally better when using Operator 1.

However, there are peaks and valleys in classifier performance. Two different pieces of equipment were used by the two operators to gather the data.

Table 9.1 The SVM was trained with 100 photographs

Operator\device	1	2
1	SEN = 75%	SEN = 68%
	SPC = 82%	SPC = 61%
2	SEN = 68%	SEN = 58%
	SPC = 59%	SPC = 70%

c. Assessment of Attribute Relevance

We should have a look at how the attributes we choose effect the classifier's performance on the previously specified photos next. All the attribute combinations were included in the input set of 10 attributes, resulting in a total of 1023 SVM classifiers. Table 9.2 shows combinations of variables that were used to train the classifier and test it on a control sample of 100 people who were either ill or well (half healthy, half ill). As seen in Table 9.2, the classification is sensitive, precise, and accurate (ACC). MATLAB’s Statistics Toolbox offers four unique kernel functions for the quadratic kernel foundation. Table 9.2 displays the findings. Table 9.2: Classifier training outcomes using SVM (quadratic kernel) with 400 ultrasound images (half from healthy people, half from patients with Hashimoto's sickness) and a validation set of 100 persons, half of whom had the ailment

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Table 9.2: Classifier training outcomes using SVM

Attribute number from 1 to 10 (1 - occurs, 0 – does not occur)										**SEN**	**SPC**	**ACC**
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**			
1	0	1	0	1	0	0	0	0	0	0.831	0.792	0.811
1	1	1	0	1	1	0	1	0	0	0.792	0.831	0.811
1	1	1	0	1	0	1	1	0	0	0.772	0.851	0.811
1	1	1	0	1	0	0	0	0	0	0.831	0.782	0.806
0	1	0	1	1	0	0	0	0	0	0.772	0.841	0.806
1	1	0	1	1	0	0	0	0	0	0.782	0.831	0.806
1	1	1	1	1	1	1	1	1	1	0.732	0.811	0.772

Table 9.2 demonstrates that the classifier achieved better performance with a smaller number of attributes, particularly when only 3-4 attributes were included. Overfitting may have adversely affected the classifier's performance due to the inclusion of additional attributes. To mitigate overfitting, it is advisable to keep the training sets as small as possible, reducing the number of attributes and improving classification speed. This simplifies medical interpretation by focusing on the most crucial aspects. It is important to acknowledge the post-hoc nature of retrospective attribute selection and prioritize the choice of characteristics in subsequent studies. These examples highlight the challenges of constructing reliable classifiers from limited training sets and the potential for misleading results. The issue of independence between training and validation sets is non-binary and should be carefully considered to avoid overconfidence in the classifier. Additionally, classifiers trained on small datasets (Figure 10.2) are more likely to underperform in real-world scenarios.

For better or for worse, substantially larger data sets are required for the development of usable classifiers.

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CHAPTER 10

SOURCING OF HARDWARE COMPONENTS, SPECIFICATIONS, AND IMPLEMENTATION

Mr. P. P. Janarthanan
Signal Preprocessing

1.1 APPLICATIONS OF BRAIN COMPUTER INTERFACE

- Medical applications
- Neuro ergonomics and smart environment
- Educational and self-regulation
- Games and entertainment
- Security and authentication

10.1.1 ELECTROENCEPHALOGRAM

The human brain is the most important part of the human nervous system, which also includes the spinal cord. It has over 100 billion nerves. The human brain serves as the central processing unit for the whole nervous system. A neuron is a type of cell that utilizes electrical and chemical impulses to process and send information. Continuous electrical activity in the brain is necessary for normal brain function. This activity is recorded by an electroencephalogram. Brain waves refer to the patterns of neuronal electrical activity that have been recorded. The brain waves of everyone are distinct. Table 11.1 lists the five different kinds of brain waves based on frequency.

Table 10.1 Frequency of different brain waves

WAVES	FREQUENCY
Delta	0.1 – 4 Hz
Theta	4 – 8 Hz
Alpha	8 – 12 Hz
Beta	12 – 40 Hz
Gamma	40 – 100 Hz

Each brain wave serves a specific function in helping us cope with various situations, whether it is facilitating information processing and learning or promoting relaxation following a stressful day.

Table 10.2 Brain waves with its associated mental state

WAVES	ASSOCIATED MENTAL STATE
Delta	Deep, dreamless sleep
Theta	Light sleep or extreme relaxation.
Alpha	Deep relaxation, lovely daydream or during light meditation
Beta	An alert, logical, and critical state of mind when awake and in the normal waking condition
Gamma	Idea generation, language and memory processing, and many forms of education

Table 11.2 illustrates that each brain wave is associated with a specific mental state. Typically, individuals without cognitive impairments can articulate their preferences, whereas those with mental disabilities may struggle to do so. However, their brains still possess the ability to express emotions in some capacity. The objective of this project is to analyse the brain waves of individuals with cognitive challenges to ascertain their preferences.

10.2 EEG RECORDING EXISTING SYSTEM

To capture the electrical activity of the brain, electroencephalography (EEG) is utilized, which is a form of electrophysiological monitoring. Typically, electrodes are placed on the scalp, making it a non-invasive procedure, although invasive electrodes may be used in certain cases. EEG records voltage fluctuations in the neurons of the brain caused by ionic currents.

10.2.1 System

The 10-20 system is a widely recognized method for specifying and positioning scalp electrodes in EEG experiments or tests. Its purpose is to ensure consistency and reproducibility across studies, enabling researchers to compare results longitudinally and between individuals.

This system is based on the correlation between electrode placement and the corresponding area of the cerebral cortex. The numbers "10" and "20" indicate that the distances between adjacent electrodes are either 10% or 20% of the total front-back or right-left dimensions of the skull.

10.2.2 Single Channel EEG

Electrodes are positioned on the scalp using the 10-20 electrode placement technique. Typically, multi-channel EEG is utilized for research purposes. However, both single-channel and multi-channel EEG data can be utilized in constructing BCIs. Multi-channel EEG is preferred in most EEG applications due to the limited information provided by single-channel EEG. Figure 11.1 showcases the results of a recording of brain waves from a single frontal lobe electrode.

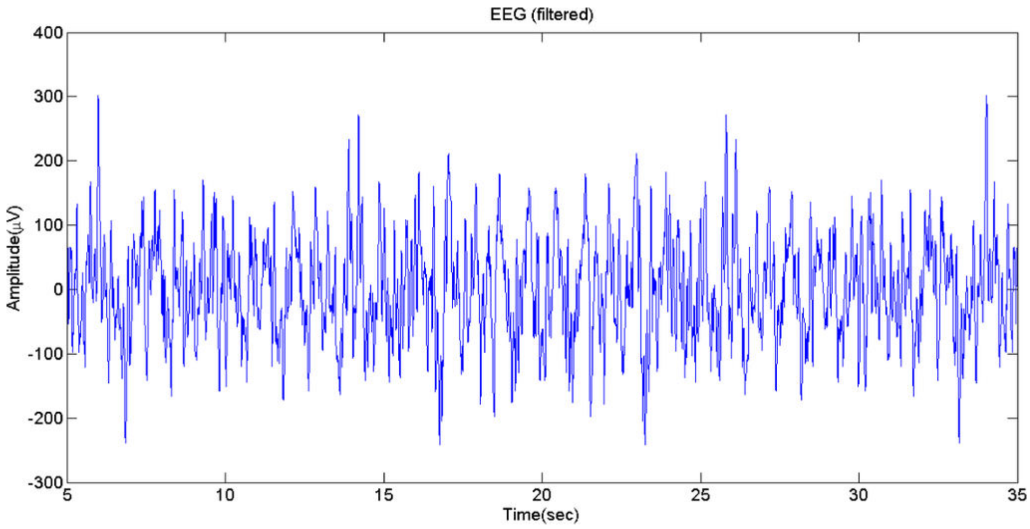

Figure:10.1 The Fp1 position is commonly used for recording a typical single-channel EEG.

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10.3 INTELLECTUAL DISABILITY

Intellectual disability (ID), previously referred to as mental retardation, is characterized by below-average IQ or mental aptitude, along with deficits in essential daily life skills. Individuals with intellectual disabilities can acquire new skills, albeit at a slower pace. The severity of intellectual disability can vary, ranging from mild to profound.

10.3.1 Causes of Intellectual Disability

Intellectual disability is most often caused by:

- **Genetic Disorders:** Down syndrome and fragile X syndrome are two examples of this.
- Alcohol and drug use, hunger, certain diseases, and preeclampsia are all dangers to a developing fetal brain. All these things might happen at any time during your pregnancy.
- If a baby is delivered too early or without enough oxygen during delivery, it is more likely to suffer from intellectual handicap.
- Children with meningitis, whooping cough, or measles may have intellectual problems. There are numerous factors that can contribute to it, including serious head traumas, drowning, excessive starvation, infections in the brain, toxic compounds like lead, and severe neglect or abuse.
- Nothing of the sort: For two-thirds of all children with intellectual disabilities, there is no recognized reason.

10.3.2 Diagnosis of Intellectual Disability

Diagnosing intellectual disability involves evaluating two crucial components, namely:

- ✓ **Intellectual Functioning:** This refers to the ability to learn, understand, solve problems, and comprehend the world, as measured by an IQ test.
- ✓ **Adaptive Functioning:** This pertains to an individual's capacity to independently navigate daily life and meet the demands of their environment.

An IQ test is commonly employed to assess intellectual functioning, with the average score being 100. Scores ranging between 70 and 75 are indicative of intellectual disability. Professionals assess adaptive behaviour by comparing a child's abilities to those of their peers, considering specific skills necessary for functioning effectively:

- Daily living skills include things like getting dressed, using the toilet, and eating one is self.
- Communication abilities, such as the ability to comprehend what is being said and to respond appropriately.
- The ability to interact socially with others, including peers, family members, and adults.

The pace at which you acquire new information or skills is slightly slower than average. With appropriate support, adults with intellectual disabilities can generally live independently. Individuals with low scores face significant disadvantages. However, both diagnostic methods are time-consuming and require ongoing monitoring.

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10.3.3 Signs of Intellectual Disability

Children with intellectual disabilities may exhibit a wide range of symptoms, which can appear as early as infancy or as late as the child's first year of school. The severity of the disability plays a significant role in determining the specific symptoms. Here are some common symptoms associated with intellectual disabilities:

a) Slow crawling or walking as a means of mobility.

b) Difficulty with verbal expression, such as speaking slowly or struggling to communicate.

c) Challenges in activities like potty training, dressing oneself, and feeding.

d) Poor memory or difficulty recalling information.

e) Lack of understanding the connection between actions and consequences.

f) Behavioral issues, including violent outbursts.

g) Problems with reasoning and problem-solving abilities.

Children with severe or profound intellectual disabilities may also experience additional health issues. These can include seizures, mood disorders (such as depression or autism), motor skill deficits, vision problems, and hearing impairments.

10.4 HARDWARE SETUP

The system's hardware comprises a 12V transformer, a power supply unit, a controller unit, a motor driver circuit, and a rotating chamber.

10.4.1 The Controller Setup

Figure 11.2 depicts the hardware set-up, which consists of a separate unit. They do have the ability to

- Power supply unit
- Motor driver unit
- Controller unit

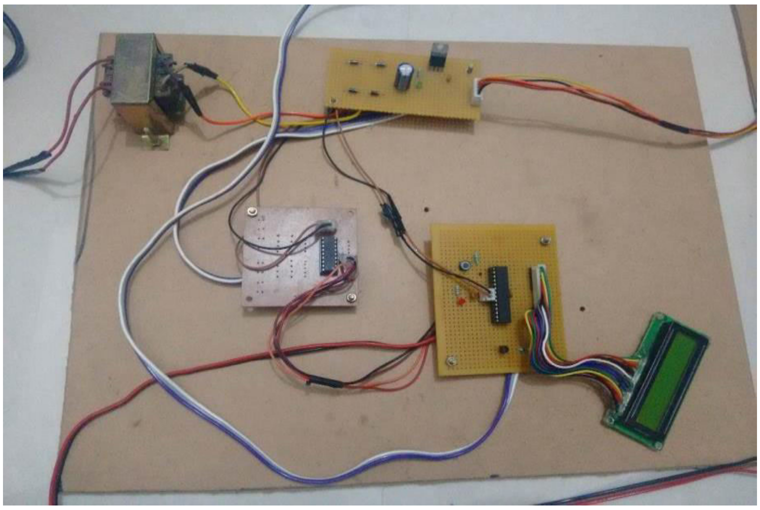

Figure: 10.2 The controller setup

A step-down transformer and a bridge rectifier are employed in the power supply unit to convert AC to DC. The bridge rectifier consists of four diodes. A 1000F capacitor is utilized for filtering, and a 7805 Regulator is used to convert the 12 V DC to 5 V DC, which is supplied to both the microcontroller and the stepper motor. The motor driver circuit, ULN2803, acts as the driving force for the driver module and enables the operation of the stepper motor.

The controller unit consists of an Atmega8 microprocessor for overall management, a reset button to reset the rotating chamber to its initial position, a BC547 transistor to prevent sensor triggering, and a 16 * 2 LCD to display the results. A USB to TTL converter cable is required for serial communication, connecting MATLAB to the controller for output.

10.4.2 Rotating Chamber with IR Sensor

Figure 11.3 depicts the spinning chamber. A stepper motor and an infrared sensor drive the rotating chamber.

Figure 10.3 The rotating chamber with IR sensor

The fruits displayed in the spinning chamber are identical to those shown to the subjects. The chamber is divided into four sections by walls, and all the fruits are present in these sections. The chamber is powered by a stepper motor with a 12 V supply. An IR sensor is positioned in the correct area to guide the subjects back to their starting point. The chamber rotates based on the instructions from the controller to align the fruit in front of the subject. The fruit remains in front of the patient for four seconds before the chamber returns to its initial position. To detect the starting location, an IR sensor is used, and the back of the first slot is painted black. The IR sensor is typically seen as a dark Gray or black colour, which facilitates the identification of its initial position.

10.4.3 Entire Hardware Setup

Figure 11.4 depicts the full system, including the input fruits, hardware unit, and operating system.

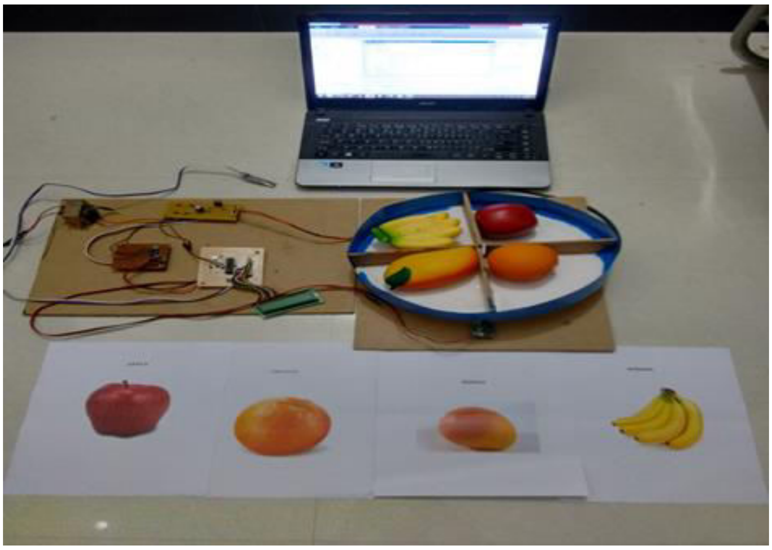

Figure 10.4 Entire hardware setup

At intervals of 10 seconds, one of the four input fruits (Apple, Orange, Mango, and Banana) is presented. When the brainwaves reach the predetermined threshold value, MATLAB displays the name of the corresponding fruit. Data is transferred to the ATMEGA 8 controller through serial communication.

The name of the fruit is displayed on the LCD screen. The spinning chamber contains the same four fruits in the same order as the input, with each fruit placed in a slot. Once the controller detects the specific fruit, the chamber rotates using a stepper motor driven by a ULN2803 driver circuit. The rotation positions the subject's preferred fruit in front of them, making it easier for them to access and pick the fruit.

If multiple favorite fruits are selected, the first one is displayed on the LCD screen, and the chamber is rotated to keep that fruit in front of the subject for four seconds. Then, the second fruit is displayed on the LCD screen and spun in front of the participant for another four seconds before returning to its starting location. After a two-second pause, the chamber returns to its original position. This process enables the test subjects to easily select their preferred fruits.

An IR sensor is utilized to detect the starting location, and the back of the first slot is painted black to assist in identifying the initial point. The black color enhances the visibility of the IR sensor, aiding in the precise determination of the starting position. Like fruits, other inputs are displayed in a similar manner to help users identify their personal favorites. The objective of this study is to identify popular movies and TV shows among individuals with intellectual disabilities. By surrounding them with their favorite things, it is possible to enhance their brain's ability to a level comparable to that of neurotypical individuals, enabling them to live independently.

10.5TREATMENT

It is important to note that intellectual disability is classified as a disability rather than a sickness by most classifications. Currently, there is no "cure" for a diagnosed intellectual impairment. However, with the appropriate support and education, most individuals with intellectual disabilities can learn and accomplish various tasks.

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ABOUT THE BOOK

This book will act as a real-time technical and specialized analysis tool for the Electroencephalogram (EEG). This book deals with neural engineering, the role, and scope of engineers in the field of disability, the impact of work in social science, ethical issues, considerations, and procedures for the clearance, quantitative analysis of the patient data with conflict of data, brain-computer interfacing design how the data processing and communication using cyber-physical system, testing and validation of data with and real-time project. This book will convince the readers would become heroes from zero in the field of EEG signal analysis.

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