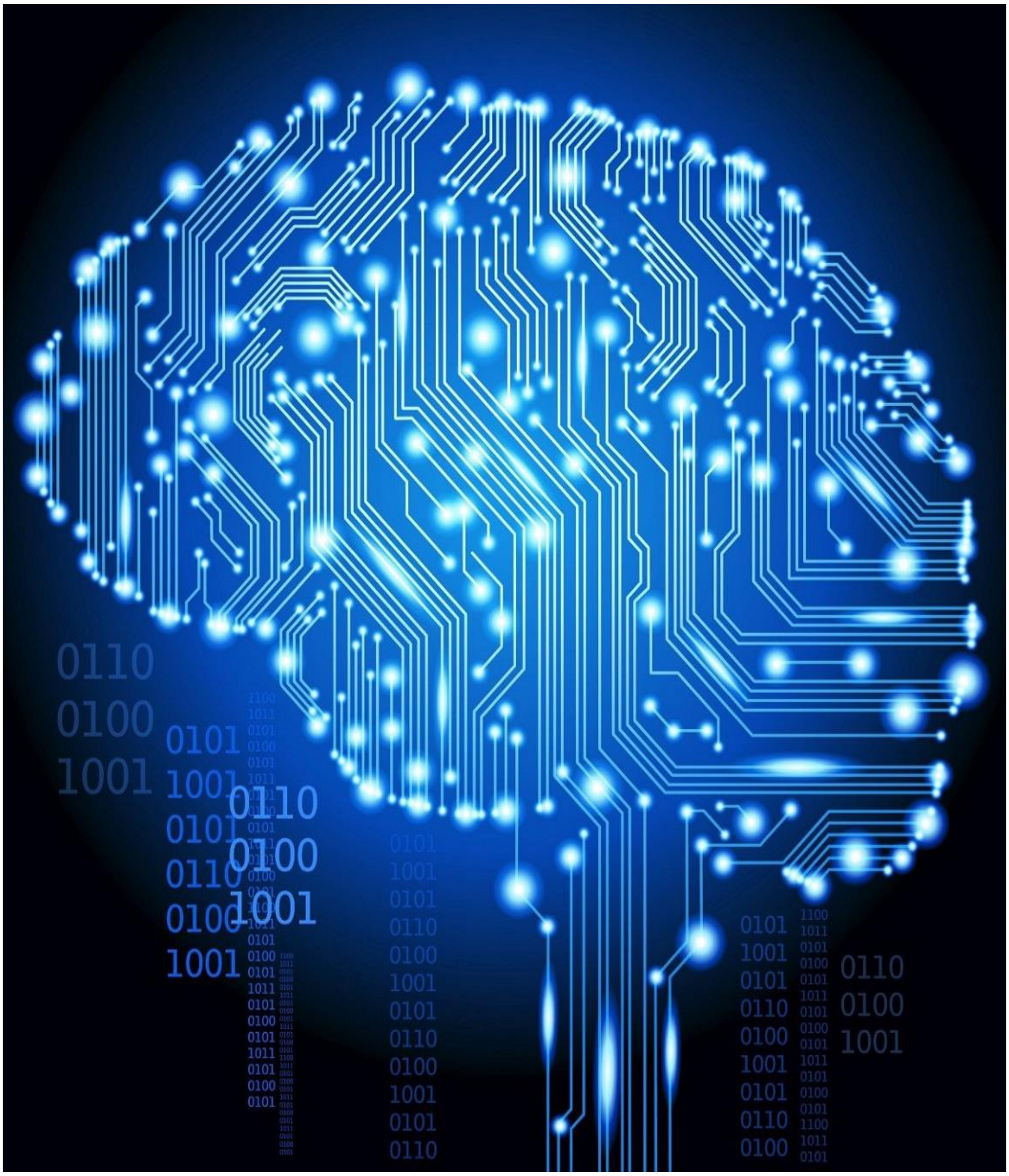

Technology Report

Standardization and Application of Brain-computer Interface (BCI)

Executive summary

In recent years, brain-computer interface (BCI), an emerging technology that facilitates communication between brain and computer, has garnered significant attention. BCI has impacted a variety of industries, such as healthcare, neuroscience research, education, and human machine interactions.

To foster international collaboration and highlight recent innovations in BCI technology, the ISO/IEC JTC 1/SC 43 organized **Brain-computer interface symposium: bridging innovation and application** in partnership with the IEC Academy and Standards Australia. Held in Sydney, Australia, on September 4th, 2024, the symposium served as a platform for experts to discuss technological advancements, product applications, ethical considerations, legal frameworks, and standardization. This report encapsulates the key discussions and outcomes from the symposium.

Acknowledgments

This report is an output of the **Brain-computer interface symposium: bridging innovation and application**, hosted by the the ISO/IEC JTC 1/SC 43 in collaboration with the IEC Academy and Standards Australia on September 4th.

The invited speakers of the forum included: Teahwa Han, Jiahui Pan, Lin Yao, Kiwon Lee, Lorraine Finlay, Jiangbo Pu, Maria Cristina Gaeta, Young-Im Cho, Thomas Do, Avinash K Singh, Chin-Teng Lin, Zheng Zhang, Sam John, Luciana Lorenzon.

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Web seminar presentations and recordings are available at: https://www.iec.ch/academy/ webinars

Table of contents

List of abbreviations

Technical and scientific terms

ADHD	Adult Attention-Deficit/Hyperactivity Disorder
ASD	Autism Spectrum Disorder
BCI	Brain-computer Interface
CBT	Cognitive-Behavioral Therapy
CNV	Contingent Negative Variation
DOC	Disorders of Consciousness
ECoG	Electrocorticography
EEG	Electroencephalography
ERD	Event-Related Desynchronization
ERP	Event-related potential
fMRI	Functional Magnetic Resonance Imaging
fNIRS	Functional Near-Infrared Spectroscopy
ICT	Information and Communication Technology
LFP	Local Field Potential
MEG	Magnetoencephalography
MDD	Major Depressive Disorder
MCS	Minimally Conscious State
MI	Motor Imagery
PTSD	Post-Traumatic Stress Disorder
rTMS	Repetitive Transcranial Magnetic Stimulation
SMR	Sensorimotor Rhythm
SSSEP	Steady-State Somatosensory Evoked Potential
SSVEP	Steady-State Visual Evoked Potential
sEEG	Stereoelectroencephalography
tACS	Transcranial Alternating Current Stimulation
tFUS	Transcranial Focused Ultrasound Stimulation
UWS	Unresponsive Wakefulness Syndrome
XR	Extended Reality

Organizational terminology

AAL	Active Assisted Living
AhG	Ad Hoc Group
AG	Advisory Group
BFE	Biofeedback Federation of Europe
CAG	Chair’ s Advisory Group
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
JTC 1	ISO and IEC Joint Technical Committee
CINB	Italian Centre of Neurofeedback and Biofeedback

LCG	Liaisons and Communications Advisory Group
ReCEPL	Research Centre in European Private Law
SC	Subcommittee
WG	Working Group

Section 1 Introduction

Brain-computer interface (BCI) has emerged as a groundbreaking technology in various areas, including healthcare, industrial controls, learning, education and training, smart home and entertainment (see Figure 1).

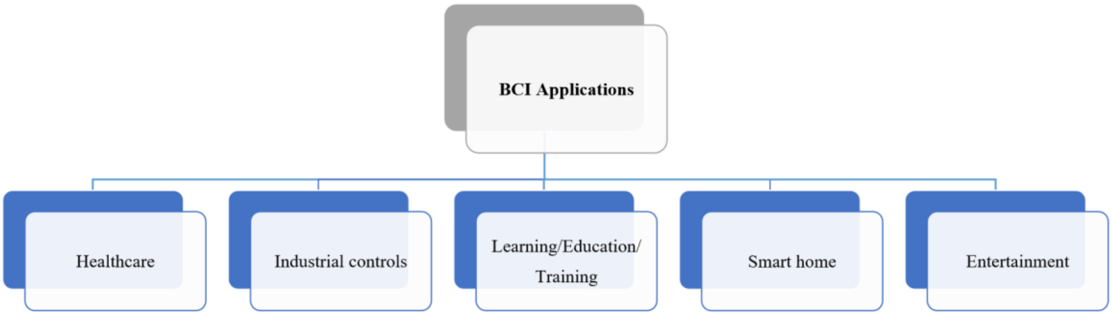


Figure 1 BCI applications

A BCI is a direct communication pathway between the brain and an external device, bypassing conventional pathways of peripheral nerves and muscles. In 1973, Jacques J. Vidal of UCLA coined the term Brain-Computer Interface in his paper "Toward Direct Brain-Computer Communication" (see Figure 2)[1]. Figure 3 illustrates the history of BCI. BCIs enable users to control devices or interact with software through brain activity alone, without the need for physical movement (see Figure 4). In general, BCI provides the following benefits:

- Empowering people: Enhancing quality of life for individuals with disabilities.
- Advancing healthcare: Improving diagnosis, treatment, and rehabilitation processes.
- Pushing technological boundaries: Paving the way for innovative interfaces and interaction paradigms.

The BCI market is experiencing significant growth. According to Modor Intelligence, the Global Brain-computer Interface Market size is estimated at USD 2 billion in 2024, with expectations of reaching USD 3.25 billion by 2029, growing at a CAGR (compound annual growth rate) of 10.29% during the forecast period from 2024 to 2029 (see Figure 5). Notably, the Asia-Pacific region, especially in countries like China and Japan, is expected to see substantial growth in the BCI market (see Figure 6).

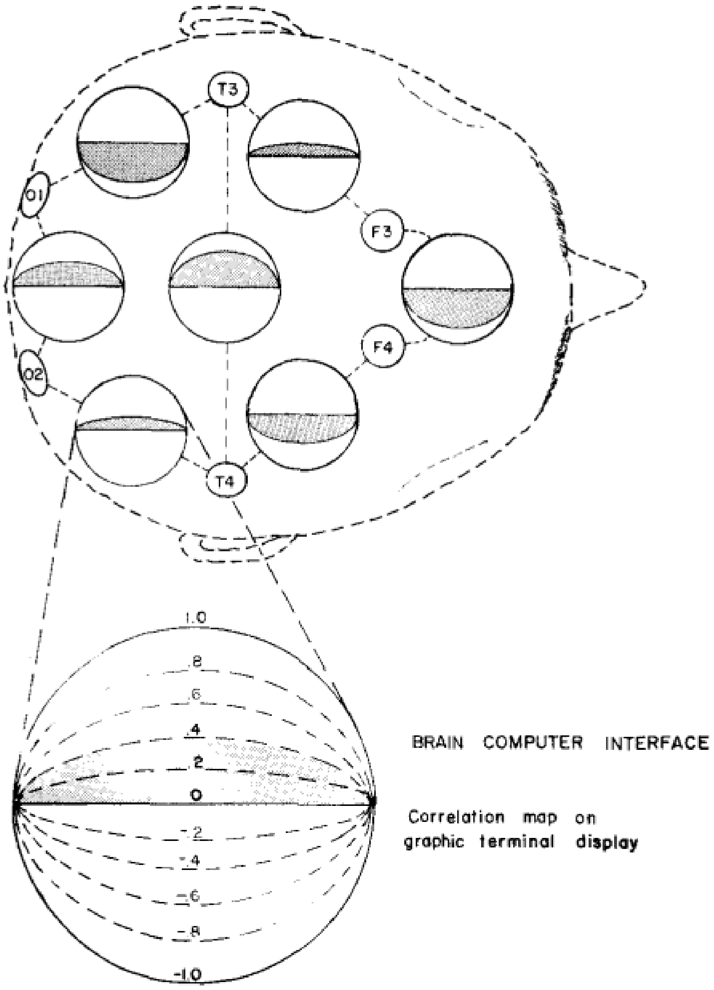


Figure 2 The term 'Brain-Computer Interface' was first proposed by Jacques Vidal in 1973[1].

- Emerged in 1960s, BCI concept evolved over decades
- 1973: Dr. Jacques J. Vidal coined the term "BCI"
- 1980s-1990s: Signal processing and neural recording techniques advanced
- Early 2000s: Practical applications in assistive technology emerged
- 2020s: Growing interest in consumer-grade BCIs for various applications

Figure 3 History of BCI

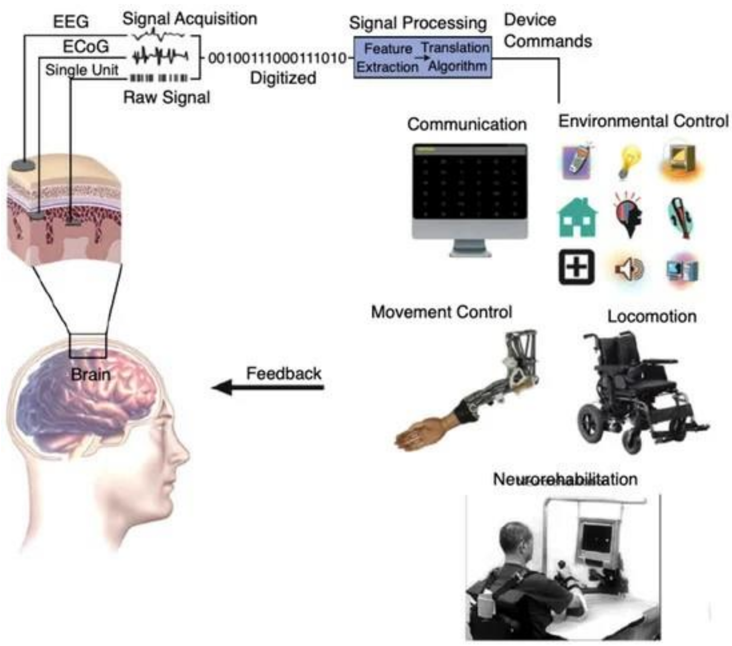


Figure 4 Components of a typical BCI system

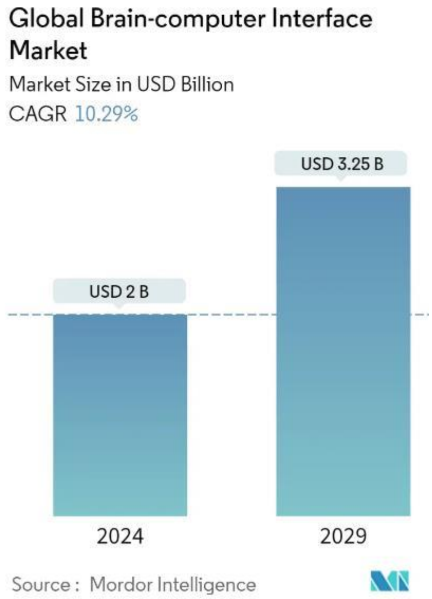


Figure 5 Global BCI market

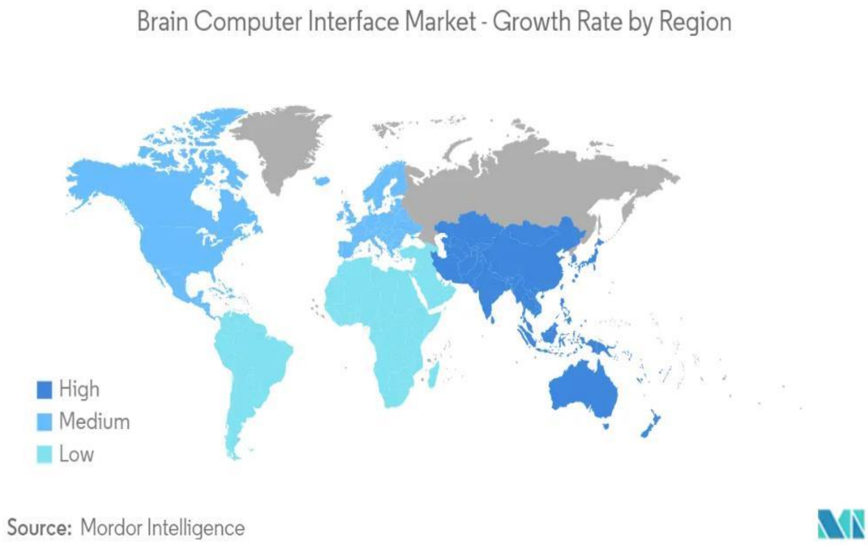


Figure 6 BCI market - growth rate by region

Section 2 Standardization work within ISO/IEC JTC 1/SC 43

BCI shows promise but requires standardized procedures. Standardizing BCI improves effectiveness, enhances patient safety, and reduces costs of medical treatments. Establishing standardization in BCI processing is crucial to ensure reliable and valid results across different settings. Efforts include developing automated methods for artifact removal and standardized BCI data interpretation.

ISO/IEC JTC 1/SC 43 is the first international standards committee in the field of BCI. The subcommittee is created as a systems integration entity where it will work with other ISO, IEC and JTC 1 committees. As stated in the scope, SC 43 will:

- Serve as the focus and proponent for JTC 1's standardization program on Brain-computer Interfaces, including the development of foundational standards.
- Provide guidance on Brain-computer Interfaces to JTC 1, IEC, ISO, and other entities developing applications of BCI.

SC (Subcommittee) 43 has set up 3 WGs (Working Groups), 2 AGs (Advisory Groups), 2 AhGs (Ad Hoc Groups) covering the following aspects:

- WG 1 on Foundational standards: Is currently responsible for the development of ISO/IEC 8663 Information Technology - Brain-computer Interfaces - Vocabulary, ISO/IEC 27572 Information Technology - Brain-computer Interfaces - Reference Architecture and PWI (Preliminary Work Item) JTC1-SC43-4 Information Technology - Brain-computer Interfaces - Hardware interfaces and protocols. Terms of Reference include: Development of Information Technology - Brain-computer Interfaces - Vocabulary; development of foundational standards for Brain-computer Interfaces, such as a reference architecture; where appropriate, alignment with the standing document by JTC 1/AG 8 (JTC 1 N16431) meta reference architecture.
- WG 2 on Applications: Is currently responsible for ISO/IEC TR (Technical Report) 27599 Information Technology - Brain-computer Interfaces - Use Cases. Besides this, WG 2 is dedicated to collecting more use cases, analyzing standardization requirements and developing cross-domain application standards.
- WG 5 on BCI data: Is currently responsible for the development of ISO/IEC TS (Technical Specification) 27571 Information Technology - Brain-computer Interfaces - BCI data format for Non-Invasive brain information collection and PWI JTC1-SC43-3 Information Technology - Brain-computer Interfaces - Invasive BCI Multi-modal Neural Data Format. Terms of Reference include: Development of a BCI Data framework; development of BCI Data processing regarding collection, representation, visualization, transmission and storage in BCI Data framework; development in the following areas: BCI Metadata; brain information

acquisition and data fusion specification; standardization of neural data representation; characterization, standardization of multiple-modal information.

- AG 3, Chair' s Advisory Group (CAG): Its terms of reference is tracking the development of technologies in this field, finding the standardization requirements in this field, and developing business plans and roadmaps.
- AG 4, Liaisons and Communications Advisory Group (LCG): AG 4 has objectives to provide support for the liaisons and communications with other SDOs and strengthen the communications between SC 43 and its liaisons and other SDOs.
- AhG 6 on Ethics and Trustworthiness: It focuses on tracking the issues and concerns, and identifying potential work items related to ethics, robustness, reliability, security, safety, privacy, etc. in the field. Besides, AhG 6 is dedicated to facilitating the development of the work for PWI TR JTC1-SC43-1 Information Technology - Ethical Guidelines of Brain-computer Interfaces, and PWI JTC1-SC43-2 Information Technology - Brain-computer Interfaces - Safety and Security General Requirements.
- AhG 7 on Application of Non-Invasive BCI for Disorders of Consciousness: It focuses on tracking the issues and concerns, and identifying potential works related to the BCI application for disorders of consciousness. Besides, AhG 7 is dedicated to facilitating the development of a PWI on application of Non-Invasive BCI for disorders of consciousness and conducting the gap analysis of relative standards.

SC 43 launched a series of seminars focused on BCI to explore their applications, investigate new technologies, discuss future development directions, and foster collaboration in the establishment of standards for BCI. The remainder of this report will outline the details of the international BCI Symposium.

Section 3 Brain-computer Interface Symposium

3.1 Overview

This section presents a comprehensive overview of BCIs, focusing on various aspects including design considerations, medical applications, commercialization cases, ethical and legal implications, and standardization efforts. By exploring these aspects, we seek to contribute to the ongoing development and improvement of BCI technology.

3.2 User-Centric Design

Teahwa Han, a professor at Health-IT Center, Yonsi University Severance Hospital and the Vice Chair and Working Group 5 convenor of IEC SyC (Systems Committees) AAL (active assisted living), gave a presentation titled "Design considerations on the BCI: User-centric perspective".

User-centric BCIs are designed with a primary focus on the needs, preferences, and experiences of the end user. Unlike traditional BCIs that may prioritize technical specifications or clinical outcomes, user-centric BCIs emphasize usability, accessibility, and personalization to enhance the overall user experience. User-centric design considers the user's perspective at every stage of the design process, from wireframing and prototyping to usability testing. Relevant definitions are illustrated in Figure 7, Figure 8 and Figure 9. Particularly, usability is a critical aspect of BCI, as it directly impacts the effectiveness and acceptance of these technologies by users. A comparison of key attributes, history of usability, and testing methods for usability like PCA analysis, can be found in Figure 10, Figure 11, and Figure 12, respectively.

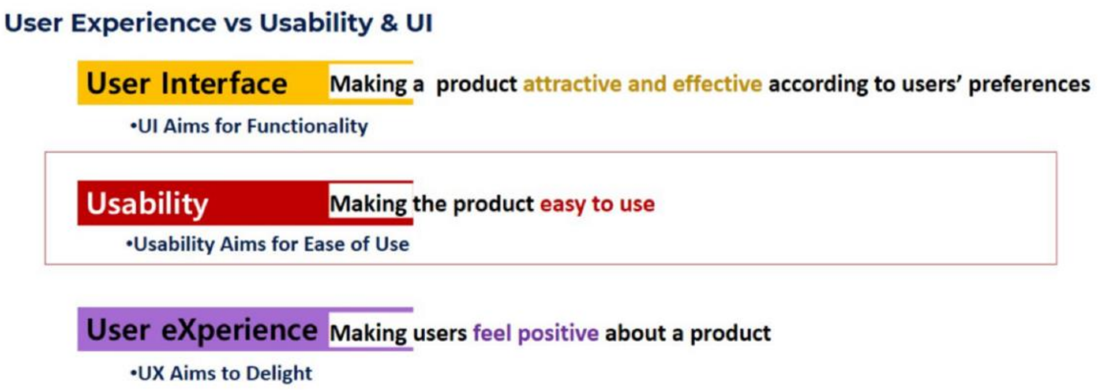


Figure 7 UI, usability and user experience

"*Usability* refers to the ease with which **a user can interact with a product, system, or service to achieve a specific goal."** (**Nielsen, 1993**)

Usability = Learnability, Efficiency, Memorability, Error rate, Satisfaction

"*Usability* encompasses several key attributes that focus on **the ease and effectiveness of user interaction with** a product or system."(**Jordan, 1998**)

two Key attributes: guessability, learnability (interaction focus)
Guessability: How easily users can guess how to interact with the product.
Learnability: How easily users can learn to use the product.

Figure 8 "Usability" definitions in papers

ISO 9241-11:2018

" The extent to which a system, product, or service can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use."

Key Attributes:
***Effectiveness:** The accuracy and completeness with which users achieve their goals.*
***Efficiency**: The resources used in relation to the accuracy and completeness with which users achieve goals.*
***Satisfaction**: The extent to which users find the product acceptable and pleasant to use.*

ISO/IEC 25010:2023 **(* ISO/IEC 25010:2023 is published. It may can be different now.)**

"Degree to which a product or system can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use."

Key Attributes: ***Appropriateness Recognizability, Learnability, Operability, User error Protection, User interface aesthetics, Accessibility***

Figure 9 "Usability" definitions in standards

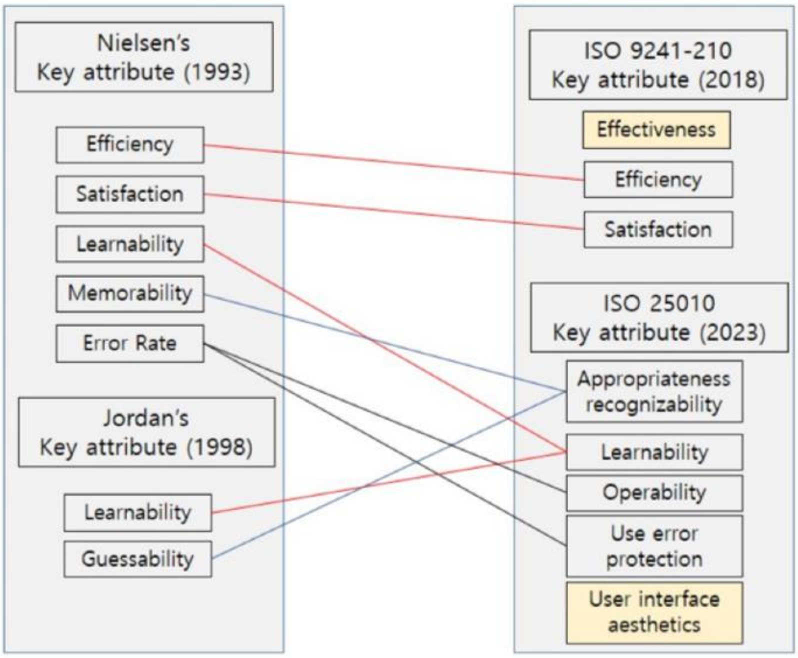


Figure 10 Comparison of key attributes for usability

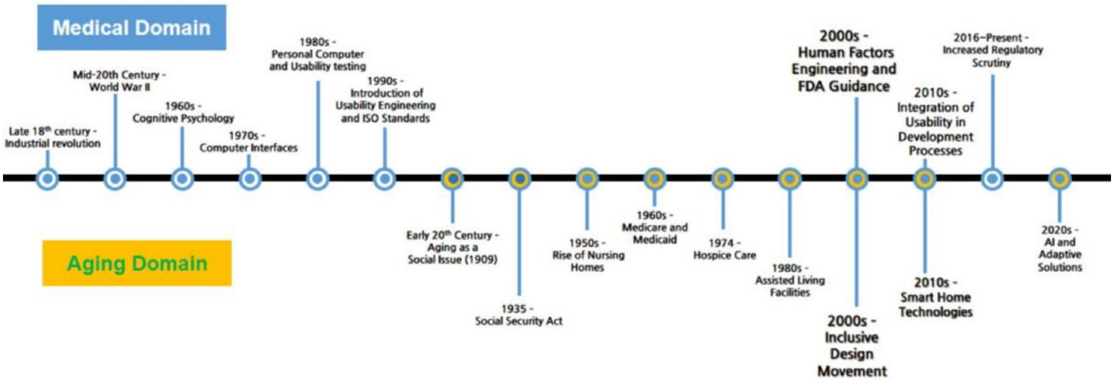


Figure 11 History of usability

Methods	Description	Development Stage (TRL based)
Advisory Panel Reviews	Involves gathering insights and feedback from a panel of experts, stakeholders, or end-users to refine product requirements and features.	TRL 3~5
Brainstorm Use Scenario	A method to collaboratively generate and explore potential use cases and scenarios for the device to identify usability challenges.	TRL 2~3
Cognitive Walkthrough	Experts walk through the tasks users would perform, analyzing potential usability issues from the user's perspective.	TRL 3~5
Contextual Inquiry	Observing users in their natural environment to understand how the device will be used in real-world settings.	TRL 4~6
Day-in-the-life analysis	A detailed observation of users throughout their day to understand context, workflows, and how the device fits into their routine.	TRL 4-6
Expert Reviews	Usability experts evaluate the device interface and functions to identify usability problems based on best practices and standards.	TRL 4~5
FMEA and FTA (Failure Modes and Effects Analysis & Fault Tree Analysis)	Techniques to identify potential failure modes and their causes/effects to enhance usability and safety.	TRL 5~7
Focus Group Interview	A moderated group discussion with target users to gather diverse insights about their needs, preferences, and experiences.	TRL 3~5
Function Analysis	Analyzing the functions and features of the device to ensure they meet user needs and usability standards.	TRL 3~5
Heuristic Analysis	Usability experts use a set of predefined heuristics to evaluate the device interface for potential usability issues.	TRL 4~5
Observation	Direct observation of users interacting with the device to identify usability issues without interference.	TRL 5~7
One-on-one interviews	In-depth interviews with individual users to gather detailed feedback and insights on their experiences and needs.	TRL 3~5
Participatory design	Involving users in the design process to co-create solutions that better meet their needs and expectations.	TRL 2~4
PCA Analysis	A statistical technique used to reduce the dimensionality of usability data and identify key usability factors.	TRL 4~6
Simulation	Creating realistic simulations of the device's operational environment to test usability and identify potential issues.	TRL 6~7
Standard Reviews	Reviewing the device against relevant standards and guidelines to ensure compliance and usability.	TRL 5~7
Surveys	Gathering quantitative data on user experiences, satisfaction, and preferences through structured questionnaires.	TRL 3~5
Task Analysis	Analyzing tasks that users will perform with the device to identify usability requirements and potential bottlenecks.	TRL 3~5
Time-and-motion studies	Observing and measuring the time and movements required to complete tasks with the device to optimize efficiency and ergonomics.	TRL 6~8
Usability Test	Direct testing with representative users to evaluate the effectiveness, efficiency, and satisfaction of the device.	TRL 5~9
Workload Assessment	Evaluating the physical and cognitive workload associated with using the device to ensure it is manageable for users.	TRL 6~8

Figure 12 Usability testing methods

In 2023, the global population aged 80 and over is estimated at 160 million, making up about 2% of the total population. By 2100, this group is expected to grow significantly, comprising 38.9% of the elderly population. With the rapidly growing elderly population, there has been significant interest in research related to the use of BCIs[2–5]. However, there are several unique BCI usability challenges when designing for elderly users. These challenges encompass cognitive barriers, physical impairments, motivational issues, and perception barriers, which are detailed in the following paragraphs (see Figure 13). They stem from a combination of age-related factors including cognitive decline, brain shrinkage, increased disease risk, and physical decline. These factors must be carefully considered to develop effective and accessible technology.

- Cognitive barriers: Elderly individuals may struggle with BCI products due to cognitive impairments such as memory loss, attention deficits, reduced working memory, and diminished spatial awareness (see Figure 14). A potential solution is to design user-friendly interfaces specifically for the elderly users.

- Physical impairments: BCI systems should integrate requirements addressing physical disabilities during the design phase to avoid usability issues and enhance comfort for elderly users (see Figure 15). A potential solution is to ensure designs accommodate physical limitations and improve user comfort.

- Motivational issues: Advanced technology can cause anxiety or resistance in elderly users due to unfamiliar concepts, complexity, and fear of failure (see Figure 16). A potential solution is to develop BCI tools that are comfortable, easy to use, and robust to support users effectively.

- Perception barriers: sensory signal discrepancies can make it difficult for BCIs to interpret brain signals and provide feedback accurately for elderly users (see Figure 17). A potential solution is to simplify interactions and design with accessibility in mind to address perceptual barriers.

By overcoming these hurdles, developers can create more effective user-centric BCIs that significantly enhance the lives of elderly individuals. Figure 18 demonstrates BCI use cases for stroke rehabilitation.

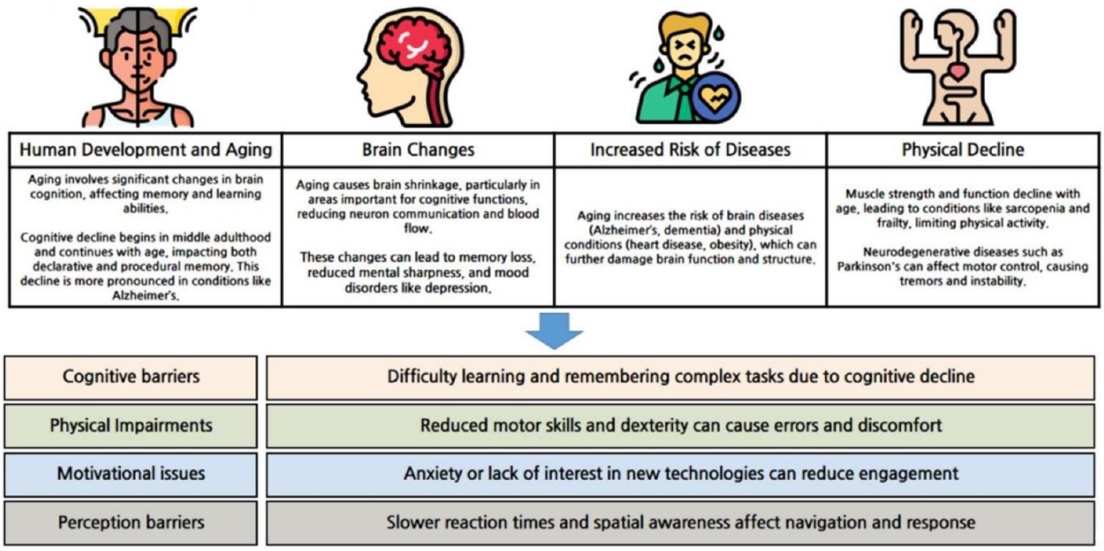


Figure 13 Ageing-related changes and barriers

Challenges	Design Consideration	Description
Memory Impairment	Use Memory Aids and Reminders	Incorporate visual or auditory reminders and prompts to assist users in remembering steps or actions.
	Simplified Task Sequences	Design tasks that require fewer steps to minimize memory load.
Attention Deficits	Use Clear Visual Hierarchy	Prioritize important information with larger fonts or distinct colors to guide attention.
	Limit On-Screen Distractions	Minimize the amount of information presented at one time to avoid overwhelming users.
Reduced Working Memory	Provide Step-by-Step Instructions	Offer clear, concise instructions broken down into small, manageable steps.
	Consistent Layout and Navigation	Keep a consistent interface layout to help users quickly learn and remember how to navigate.
Decreased Spatial Cognition	Use Simplified Navigation Options	Ensure interface navigation is intuitive and spatially clear, reducing the need for complex spatial reasoning.

Figure 14 Cognitive barriers

Challenges	Design Consideration	Description
Reduced Hand-Eye Coordination	Alternative Input Methods	Offer alternative input methods like voice control, eye-tracking, or large, easy-to-press buttons.
Limited Joint Flexibility	Ergonomic Device Design	Design devices that are lightweight, with adjustable and flexible controls to accommodate limited dexterity.
Decreased Balance and Movement	Stability-Enhanced Interfaces	Use stable and secure interface designs that require minimal movement or balance.
Slow Speed Performance	Adjustable Interaction Speed	Allow users to adjust the speed and sensitivity of the interface to match their physical abilities.
Fatigue from Extended Use	Short Interaction Cycles	Design tasks that can be completed in shorter durations to prevent fatigue.
	Include Rest and Break Prompts	Provide regular prompts for breaks to reduce physical strain during extended use.

Figure 15 Physical impairments

Challenges	Design Consideration	Description
Negative Attitudes Toward Technology	User-Friendly Onboarding	Provide a welcoming and easy-to-follow introduction to the technology to reduce initial resistance.
Low Trust in Technology	Build Trust Through Transparent Feedback	Offer clear feedback on the device's actions and results to build trust in the technology's reliability.
Anxiety and Fear of Failure	Positive Reinforcement Mechanisms	Use positive reinforcement, such as rewarding successful interactions to build user confidence.
Varied Computer Literacy	Tailored Instruction Levels	Provide different levels of instruction complexity based on the user's familiarity with technology.
Perceived Lack of Benefit	Highlight Benefits in User Terms	Clearly communicate how the BCI can benefit users in terms they find meaningful and relevant.

Figure 16 Motivational issues

Challenges	Design Consideration	Description
Reduced Visual Acuity	High-Contrast, Large Font Interfaces	Design interfaces with high-contrast colors and large, easily readable fonts.
Slower Visual Processing Speed	Simplified and Slower Visual Transitions	Use slower, smoother transitions between screens to accommodate slower visual processing speeds.
Color Vision Deficiency	Avoid Color-Coding Critical Information	Ensure that important information is not solely reliant on color-coding for accessibility.
Decreased Peripheral Vision	Center Important Information	Place critical controls and information in the central visual field to accommodate reduced peripheral vision.
Difficulty with Motion Perception	Minimize Moving Elements	Reduce or avoid moving elements in the interface to prevent confusion and difficulty in perception.

Figure 17 Perception barriers

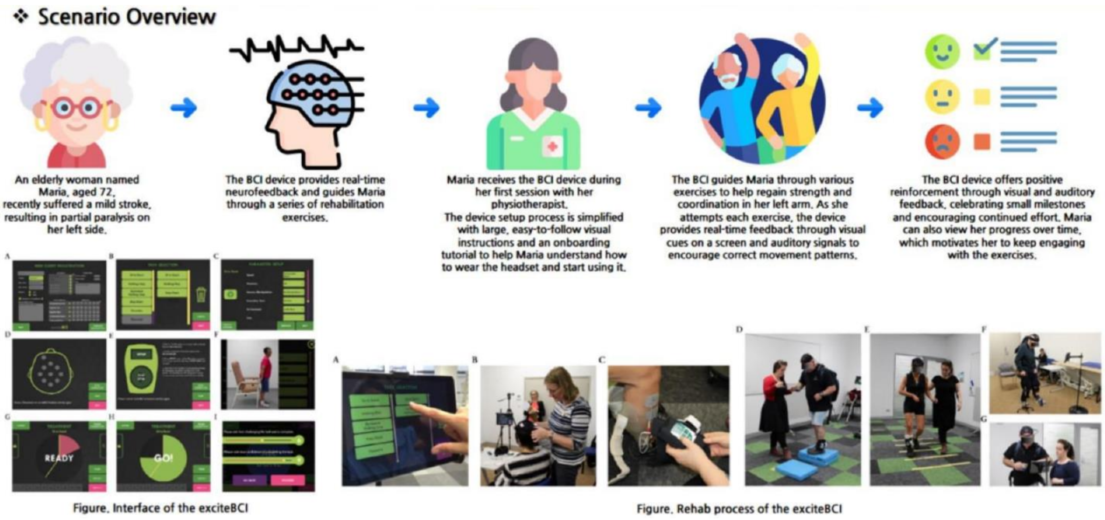


Figure 18 BCI use cases for stroke rehabilitation

Various standards guide usability, including ISO/IEC guidelines for software quality, user interface accessibility, and medical device safety (see Figure 19). These standards ensure products meet high usability and accessibility requirements. Besides, regulations like the ADA (Americans with Disabilities Act), the EU (European) Accessibility Act, and WHO (World Health Organization) guidelines promote usability and accessibility (see Figure 20). These regulations ensure that products are designed with all users in mind, providing equal access and functionality.

IS No.	Organization and TC/SC	Title
IEC 62368-1:2023	IEC TC 108	Audio/video, information and communication technology equipment - Part 1: Safety requirements
European Standard EN 301 549	ESTI	Accessibility requirements for ICT products and services
ISO 21801-1:2020	ISO/TC 173	Cognitive Accessibility – Part 1: General Guideline
IEC 60601-1-6:2010/AMD2:2020	IEC TC 62 / SC 62A	Medical electrical equipment - Part 1-6 General requirements for basic safety and essential performance Collateral standard: Usability
ISO 14971:2019	ISO TC 210	Medical devices - Application of risk management to medical devices
ISO 9241-11:2018	ISO TC 159 / SC 4	Ergonomics of human-system interaction Part 11: Usability: Definitions and concepts
ISO/IEC 29138-1:2018	JTC 1 – SC 35	Information technology — User interface accessibility Part 1: User accessibility needs
ISO 13485:2016	ISO TC 210	Medical Devices - Quality Management Systems Requirements for regulatory Purposes
ISO/IEC 25000:2014 (with series)	JTC 1 – SC 7	Systems and software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Guide to SQuaRE
ANSI/AAMI HE75:2009 (R)2013	AAMI	Human Factors Engineering - Design of medical devices
ISO/IEC 40500:2012	JTC 1	Information technology – W3C Web Content Accessibility Guidelines (WCAG) 2.0.
ISO/IEC 24786:2009	JTC 1 – SC 35	Information technology – User interfaces – Accessible user interface for accessibility settings.
ISO 20282-1:2006	ISO TC 159 / SC 1	Ease of operation of everyday products – Part 1: Context of use and user characteristics.

Figure 19 Related standards activities

Nation	Title	Summary
UN	2008 - United Nations Convention on the Rights of Persons with Disabilities (UNCRPD)	- This international human rights treaty promotes and protects the full and equal enjoyment of all human rights by persons with disabilities.
UN	1992 - United Nations Principles for Older Persons	- Although not a binding regulation, these principles encourage governments to incorporate the needs of older persons into national policies, emphasizing independence, participation, care, self-fulfillment, and dignity.
UN	1976 - International Covenant on Civil and Political Rights (ICCPR)	- While not specific to disabilities, the ICCPR underscores the inherent dignity and equal rights of all individuals, indirectly supporting the rights of persons with disabilities through broader human rights protections.
UN	1976 - International Covenant on Economic, Social and Cultural Rights (ICESCR)	- This covenant commits states to ensure economic, social, and cultural rights for all individuals, including the right to health, education, and an adequate standard of living.
WHO	2011 - World Report on Disability	- This report provides comprehensive data on the global disability landscape and recommends policies and practices to enhance accessibility and usability in health services, rehabilitation, and supportive environments
USA	1998 - Section 508 of the Rehabilitation Act	- This section requires federal agencies to make their electronic and information technology accessible to people with disabilities, aligning with the WCAG standards for digital contents.
USA	1990 - Americans with Disabilities Act (ADA)	- The ADA is a comprehensive civil rights law that prohibits discrimination against individuals with disabilities in all areas of public life.
EU	2019 - European Accessibility Act	- This EU directive aims to improve the accessibility of products and services for people with disabilities, including ICT, transport, and the built environment.
EU	2016 - EU Web Accessibility Directive	- This directive mandates that public sector websites and mobile applications be accessible to people with disabilities, following the Web Content Accessibility Guidelines (WCAG) to ensure digital inclusivity (National Disability Authority).

Figure 20 Considerable current regulations

To effectively develop user-centric BCI for older adults, it is essential to establish specific usability criteria that address cognitive, physical, motivational and perception challenges (see Figure 21). By focusing on adaptive interfaces, ergonomic designs, personalized experiences, and robust privacy measures, it can enhance the usability and adoption of BCIs, ultimately improving the quality of life and independence for older users. Figure 22 illustrates key considerations for elderly BCI users.

Figure 21 Users' perception for BCI

Design BCI PSS to address cognitive, physical, motivational, and perceptual challenges for elderly users.

•**Targets:** Both AAL and BCI focus on the elderly and disabled populations.

•**Market Insight:** Continuous monitoring of the medical device market is crucial.

•**Key Focus:** Introducing user-centric design considerations for the elderly-specified BCI PSS

•**Usability Evaluation:** Currently essential in the medical device field, with the expectation that BCI will soon be included.

•**Next Steps:** Needs to collaborate on preparing the User-centeric consideration focused on BCI P/S/S

Figure 22 Key considerations for elderly BCI users

3.3 Application

3.3.1 Clinical Application

3.3.1.1 DOC

Professor Jiahui Pan, the Vice Dean of the School of Artficial Intelligence at South China Normal University, presented progress and challenges in BCI for patients with Disorders of Consciousness (DOC).

Disorder of consciousness is a state of prolonged altered consciousness, with cognitive motor dissociation (CMD) being a subset of this condition. Conventional clinical assessments may fail to detect residual cognitive function in DOC patients. BCIs could be utilized to detect covert awareness through neuroimaging techniques like electroencephalography (EEG) or functional magnetic resonance imaging (fMRI), providing valuable information about the patient's consciousness. BCIs have the potential to improve assessment methods, facilitate communication, and open up new possibilities for therapeutic avenues.

The potential application of BCIs for DOC patients in diagnosis and prognosis has recently been demonstrated in several studies. Severe brain injury and low level of cognitive functions of patients bring challenges to BCI-based awareness detection. The challenges mentioned above can be addressed by utilizing hybrid BCIs and optimizing paradigm designs. Hybrid BCIs such as combining P300 and SSVEP (Steady-State Visual Evoked Potential), EEG with eye-tracking, and integrating visual and auditory stimuli, have been successfully employed in tasks like photo recognition, number recognition, emotion recognition and Yes/No communication (see Figure 23). Automatic sleep staging and spindle detection offer valuable insights into neurological disorders, enhancing the diagnosis of sleep disorders and improving monitoring and treatment. These tools are also utilized in consciousness assessment and prognosis in DOC patients. Distinct sleep architectures are observed in healthy individuals, minimally conscious state (MCS) patients who exhibit a reproducible but inconsistent awareness and unresponsive wakefulness syndrome (UWS) patients who are characterized by arousal without awareness.

These means can enhance the effectiveness of BCI-based awareness detection, auxiliary diagnosis, prognosis and rehabilitation.

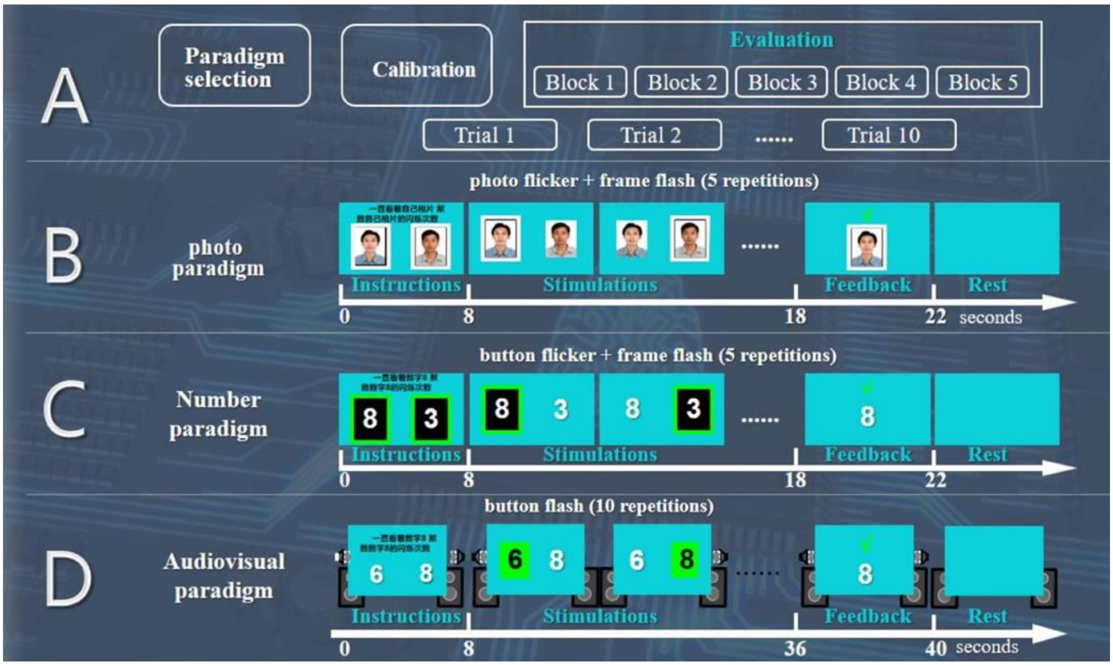


Figure 23 BCI paradigm (Audiovisual paradigm) for DOC

3.3.1.2 Neuromodulation

Professor Lin Yao, the founder of the Italian Centre of Neurofeedback and Biofeedback, introduced current trends and practices in BCI-based neuromodulation.

Neuromodulation is a rapidly-growing area of research that includes a diverse range of both implantable and non-invasive technology-based methods for treating neurological and neuropsychiatric disorders. It refers to interfacing and intervening with the nervous system using chemical, electrical, electromagnetic, or optogenetic methodologies to achieve long-term inhibition, activation, modification, or regulation of neural activity[6]. Therapies such as magnetic stimulation, electrical stimulation, ultrasound stimulation, and sound stimulation have all demonstrated encouraging outcomes for a variety of neurological and neuropsychiatric disorders. Different modalities for non-invasive brain stimulation are illustrated in Figure 24 and Figure 25. Neuromodulation like tACS (transcranial alternating current stimulation) stimulation, rTMS (repetitive transcranial magnetic stimulation), tFUS (transcranial focused ultrasound stimulation), auditory stimulation, tactile modulation, have been shown to shown to enhance working memory, alleviate depression, manage Parkinson's disease, aid in stroke recovery, and improve prosthesis control. After discussing current trends in BCI-based neuromodulation, he provided examples of digital neuromodulation for ADHD/ASD children and sensory modulation for BCI-deficiency problem to highlight practices for brain modulation.

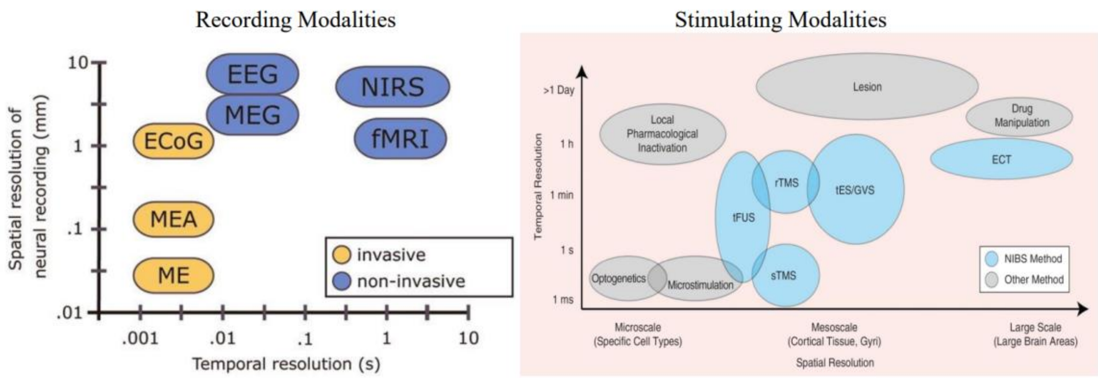


Figure 24 Different modalities for non-invasive brain stimulation

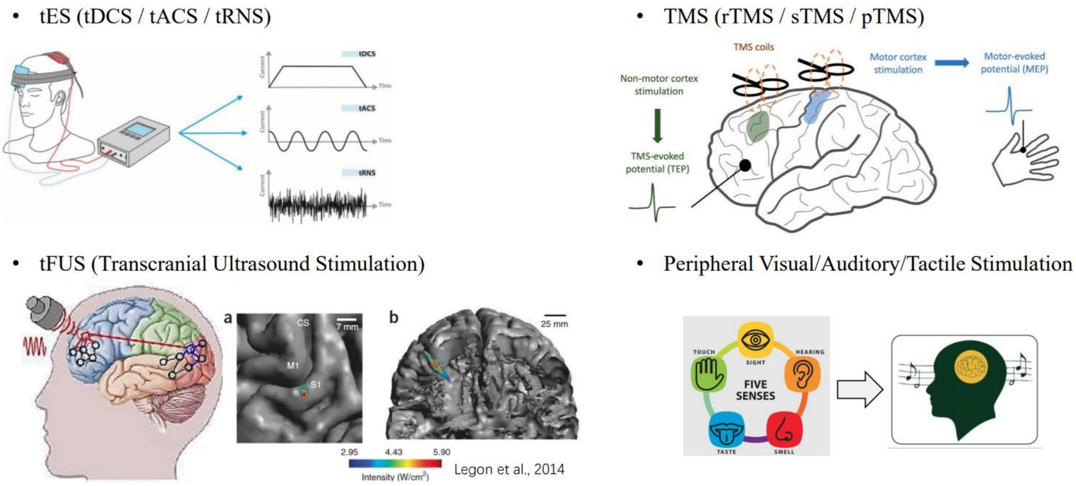


Figure 25 Widely used non-invasive techniques for neuromodulation

Attention-deficit/hyperactivity disorder (ADHD) is one of the most prevalent psychiatric disorders in children, characterized by symptoms such as impulsivity, hyperactivity, and inattention. Autism spectrum disorder (ASD), commonly known as autism or autistic disorder, is a widespread neurodevelopmental condition that typically occurs in early childhood. Key features of ASD include challenges with speech communication, difficulties in social interactions, repetitive behaviors, restricted interests, and often intellectual impairments. The prevalence of ADHD and

ASD among children in China and the United States are illustrated in Figure 26. Both ADHD and ASD are associated with various adverse health outcomes for those affected and impose significant financial burdens on families and societies. Conventional therapies, including medication and cognitive-behavioral therapy (CBT), are frequently challenged by problems such as poor compliance, side effect, subjectivity and high cost. The emerging technology of BCI-based digital modulation offers a promising supplement to these existing treatment methods. Core symptoms of ADHD and ASD and closed-loop modulation are presented in Figure 27. EEG and eye-tracking technologies have been employed to quantify symptoms in areas such as emotion evaluation, sustained attention evaluation and social joint attention evaluation. In terms of closed-loop modulation, a hybrid multi-task digital game has proven effective in helping children with ADHD enhance their sustained attention. Besides, a system that integrates BCI with ChatGPT is designed to assist children with ASD in improving social engagement and language communication.

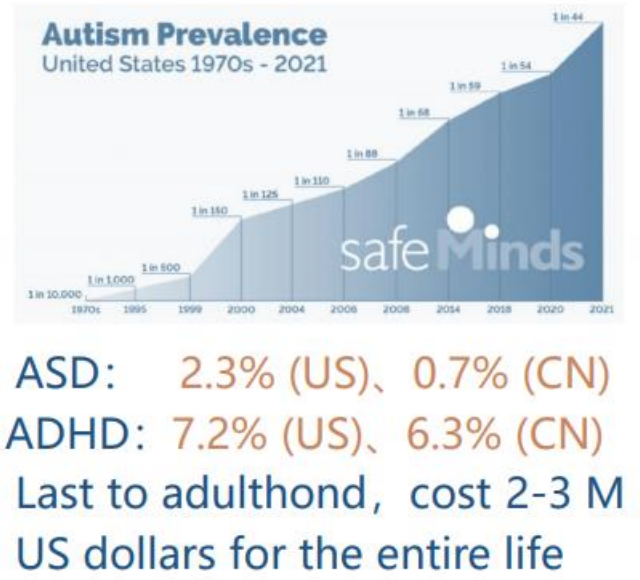


Figure 26 ASD and ADHD prevalence

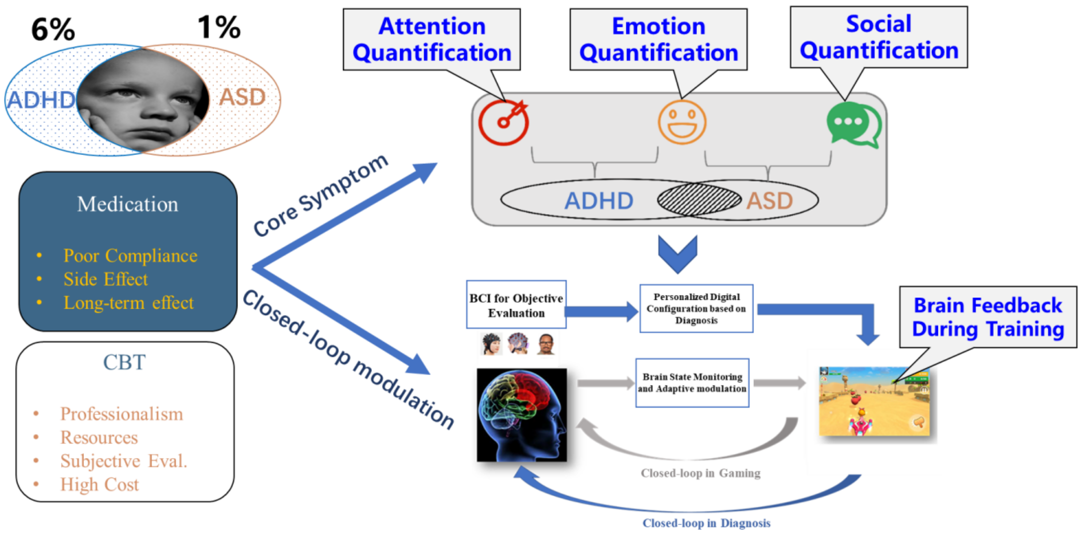


Figure 27 Core symptoms of ADHD and ASD and closed-loop modulation

Motor imagery based BCI is the key paradigm for stroke rehabilitation. There is BCI-deficiency problem in stroke population during BCI motor control - experiments evidence illustrates that there exists about 30% of people, whose BCI performance is less than 70% accuracy[7]. Neurofeedback-based training is challenging for BCI-control. Performance can be enhanced by optimizing the decoding algorithm and the paradigm design. When it comes to decoding algorithms, deep learning approaches have shown superior performance in MI-based BCI decoding compared to traditional machine learning methods like CSP and FBCSP. For stoke patients, transfer learning has been shown to improve decoding accuracy. Regarding paradigm design, incorporating tactile stimulation has been found to boost BCI performance. Brain signal modalities with respect to tactile BCI construction include steady-state somatosensory evoked potential (SSSEP), tactile P300 and tactile ERD (event-related desynchronization) (see Figure 28). Tactile sensation tasks can induce ERD on the contralateral hemisphere. The imagined tactile task and the real tactile stimulation task exhibit similar cortical patterns for discriminating left and right-hand tasks. Furthermore, the somatosensory cortex is mainly activated during the real/imagined tactile tasks. Tactile-assisted MI training has been shown to enhance performance, enabling faster calibration. Tactile-assisted BCI is beneficial for BCI-deficient users in closed-loop modulation (see Figure 29). Specifically, the experimental paradigm by integrating motor attempt with tactile stimulation has been shown to enhance BCI accuracy in stroke patients. Physiological analyses revealed that tactile stimulation during motor attempts led to significantly greater cortical activation in the sensorimotor area, and corresponding brain patterns are more discriminative. This improvement in physiological characteristics led to a notable increase in BCI decoding accuracy. Collectively, these findings suggest that somatosensory input is essential for motor execution, and that suitable tactile stimulation enhances BCI classification accuracy in stroke patients. The innovative SMR-BCI paradigm holds significant potential for enhancing the practical application of BCI-based stroke rehabilitation (see Figure 29, Figure 30)[8].

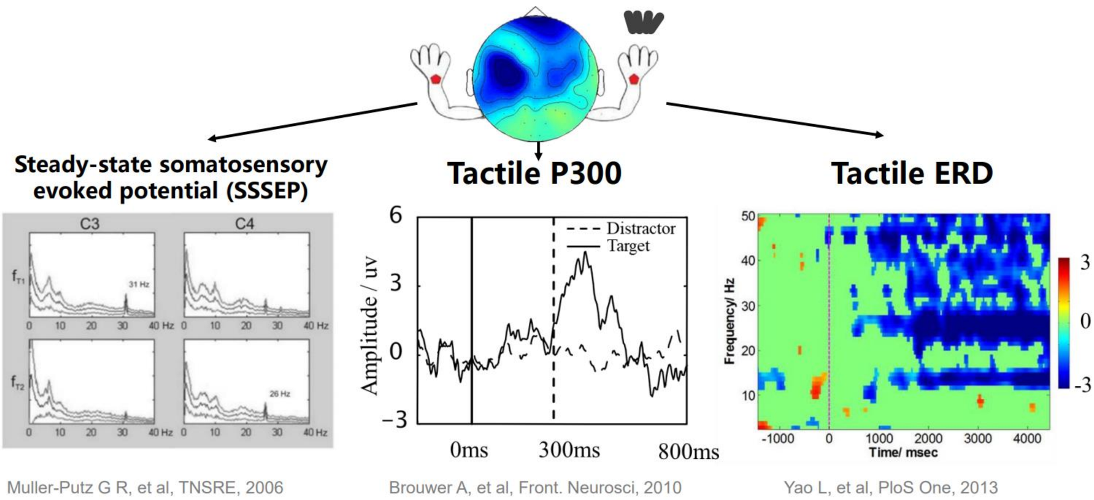


Figure 28 Brain signal modality with respect to tactile BCI construction

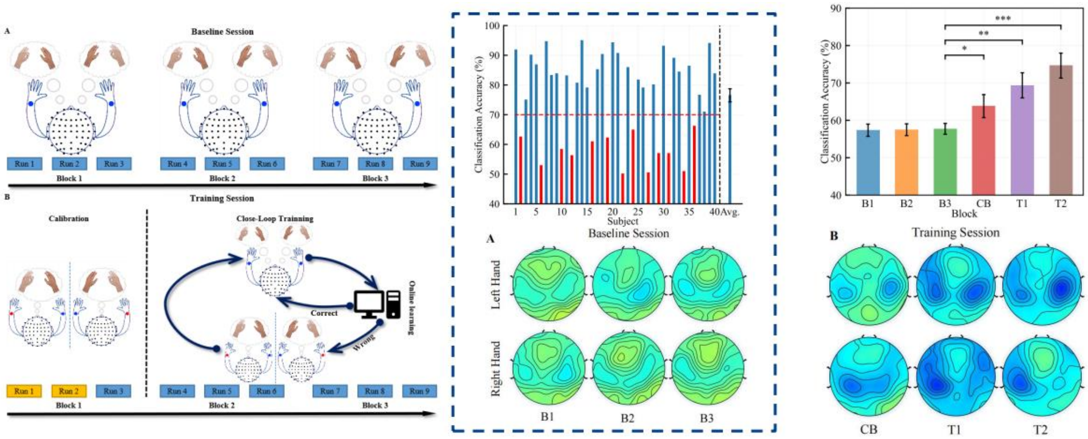


Figure 29 Closed-loop tactile modulation for BCI-deficient users

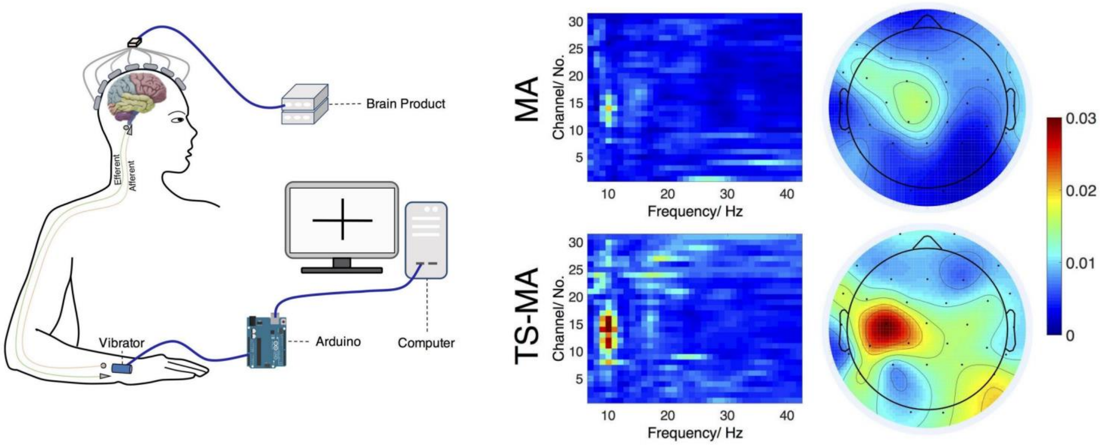


Figure 30 Tactile-assisted MI Decoding in BCI-driven Stroke Rehabilitation

In the future, efforts will concentrate on adaptive modulation, moving from open-loop to closed-loop modulation. Additionally, there will be a focus on BCI-based hybrid digital evaluations and interventions that combine different modalities such as EEG, eye-tracking, and behavioral data.

By integrating genetic, metabolomic, behavioral, neuroimaging and EEG data, precision medicine aims to develop a more comprehensive understanding of health conditions, leading to improved diagnosis, treatment selection, and patient outcomes. Achieving precision psychiatry requires large and diverse datasets, along with the integration of different data types.

3.4 Industry

Dr. Kiwon Lee, CEO of Ybrain, delivered a presentation titled “Industry-driven BCI Development in South Korea : Regulatory Status and Commercialization Cases”.

Emotional conditions like depression (see Figure 31), along with cognitive impairments like dementia and the effects of aging (see Figure 32), can lead to slower brain activities and challenges in processing information. Furthermore, individuals with physical disabilities, such as patients with spinal cord injuries, are unable to send brain signals to their muscles, resulting in an inability to move despite having a healthy brain (see Figure 33). In the field of BCI, there are two kinds of approaches to deal with these challenges. The first approach involves changing brain status through stimulation, which can be utilized in medical devices (electroceuticals) for treatment or brain enhancement. The second approach focuses on decoding brain signals to provide new mobility devices individuals with disabilities, as well as using these signals in XR (extended reality) and Metaverse applications.

Figure 31 Brain activity - emotion / depression

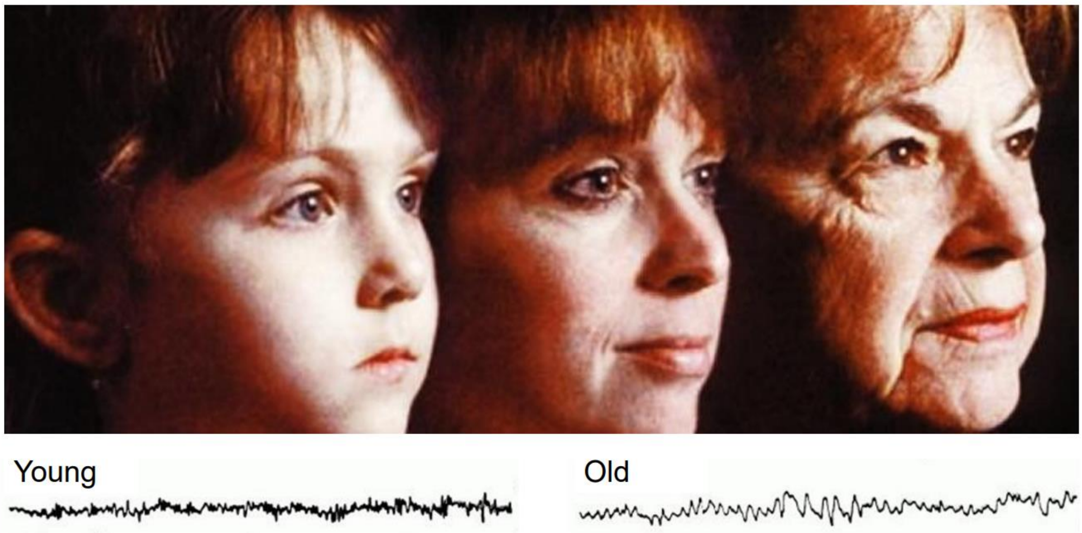


Figure 32 Brain activity - cognition, aging / dementia

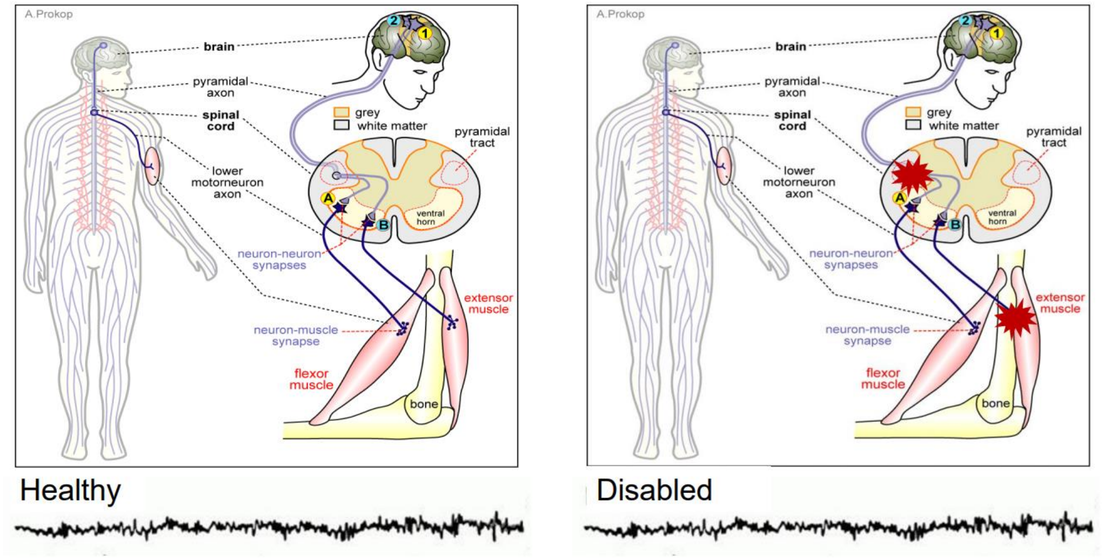


Figure 33 Brain activity - movement / disability

The regulatory status of BCI devices is illustrated in Figure 34. In Korea, non-invasive BCI devices used for monitoring are categorized as Class 2 medical devices, while those intended for stimulation fall under Class 3, indicating that the Korean government views stimulation as relatively riskier than monitoring. In contrast, the US FDA classifies all non-invasive BCI devices as Class 2, regardless of their application in monitoring or stimulation. Overall, manufacturers of brain stimulation devices face increasing challenges when trying to enter markets. To target medical applications effectively, they must meet specific requirements such as biocompatibility.

	Classification	Class 1	Class 2	Class 3	Class 4
Korea FDA	Gerneral Criteria	No Risk	Low Risk	Mid Risk	High Risk
	For BCI		Non-Invasive BCI Monitoring	Non-Invasive BCI Stimulation	Invasive BCI Monitoring/ Stimulation
US FDA	Classification	Class 1		Class 2	Class 3
	General Criteria	Low Risk		Mid Risk	High Risk
	For BCI	-		Non-Invasive BCI Monitoring/ Stimulation	Invasive BCI Monitoring/ Stimulation

- A neurostimulation product that claims to improve memory, due to the risks to a user's safety from electrical stimulation.
- A product that claims to enhance a user's athletic performance by providing suggestions based on the results of relative lactic acid testing, when the product uses venipuncture to obtain the blood samples needed for testing. Such a product is not low risk because it is invasive (e.g., obtains blood samples by piercing the skin) and also because the product involves an intervention that may pose a risk to the safety of the user and other persons if specific regulatory controls are not applied (e.g., venipuncture may pose a risk of infection transmission).

Following such request, the Commission adopted the Commission Implementing Regulation (EU) 2022/2347 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards reclassification of groups of certain active products without an intended medical purpose. The brain stimulators are reclassified in class III.

Figure 34 Regulatory status

The electroceuticals industry is experiencing a shift from invasive to non-invasive stimulation techniques for at-home treatment, with an increasing number of novel indications including cancer, essential tremor, migraine, and ADHD. However, the influx of medical devices into the market faces significant challenges due to the complexities of healthcare systems involving multiple stakeholders: the receiver, provider, and financier (see Figure 35). These systems can be classified into three types - national health service, national health insurance and free market, based on the relationships among these stakeholders (see Figure 36). The healthcare system in Korea is illustrated in Figure 37, Figure 38 and Figure 39. In contrast to consumer products, healthcare products involve more stakeholders, with the roles of government and the medical community being particularly significant (see Figure 40). Therefore, Dr. Kiwon Lee emphasized the importance of government-driven innovation and collaboration with the medical society.

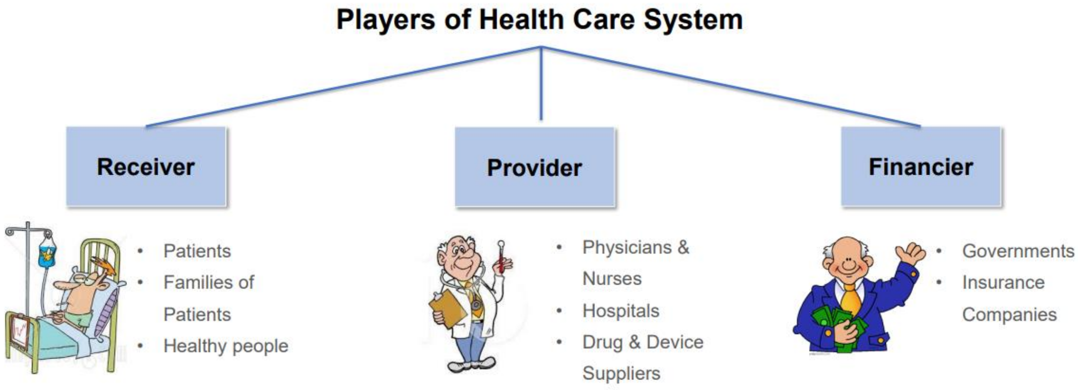


Figure 35 Players of health care system

Figure 36 Types of healthcare system

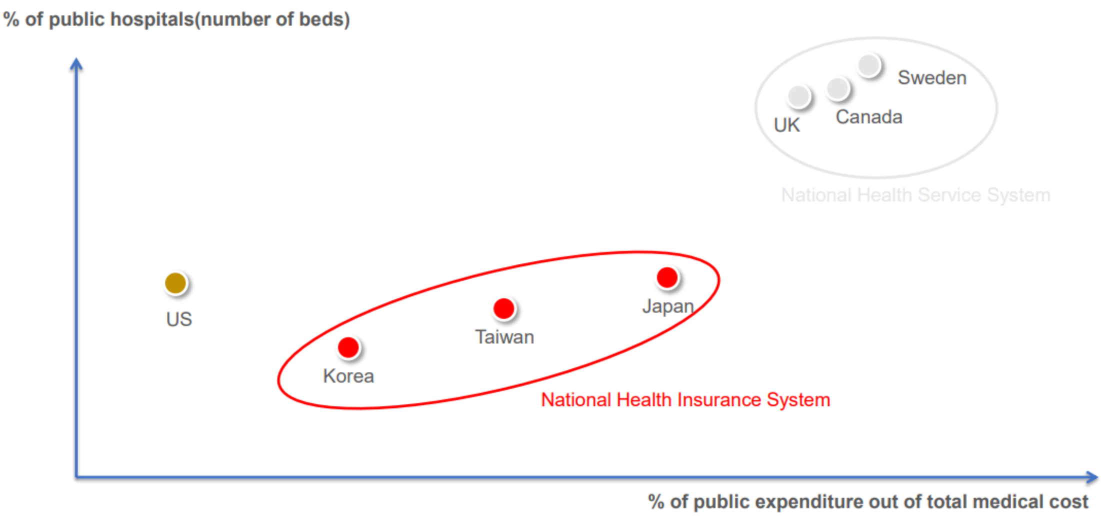


Figure 37 Healthcare system

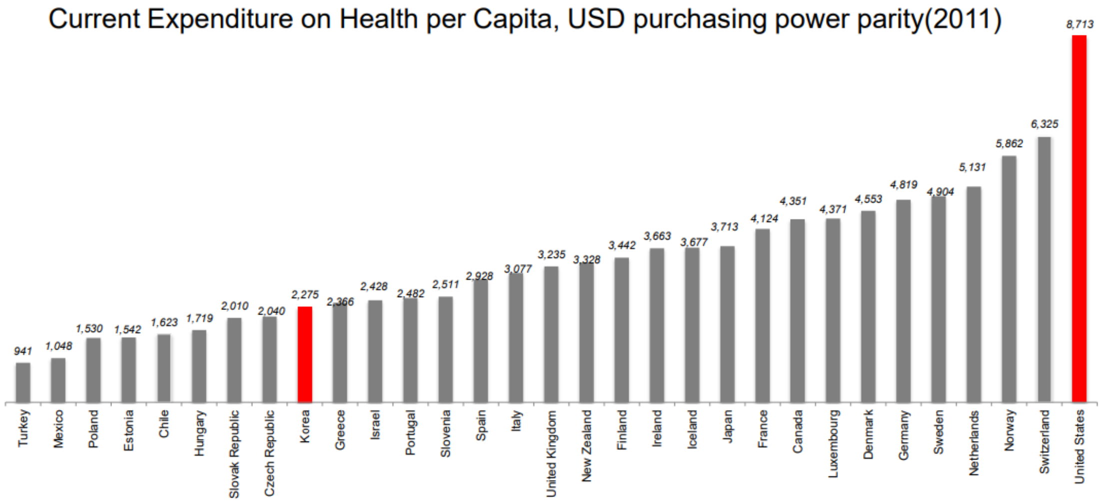


Figure 38 Current expenditure on health

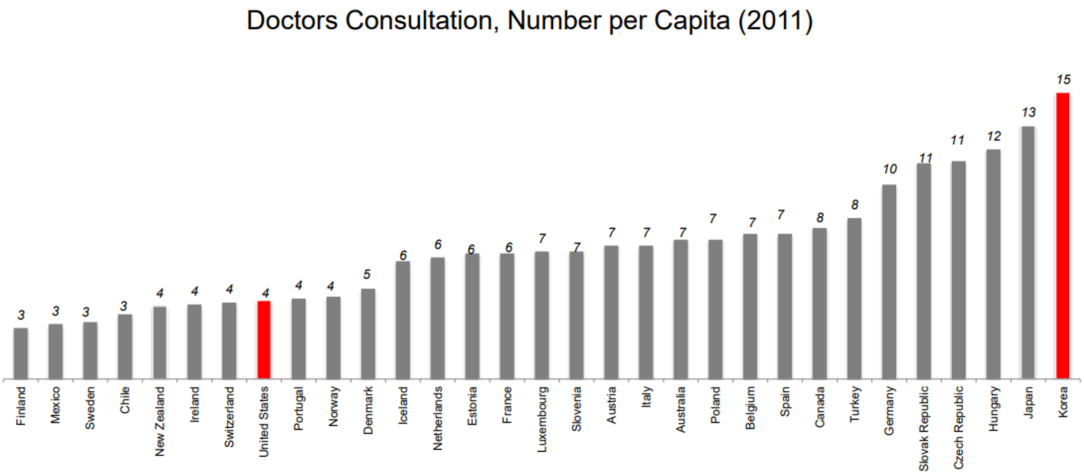


Figure 39 Doctors Consultation

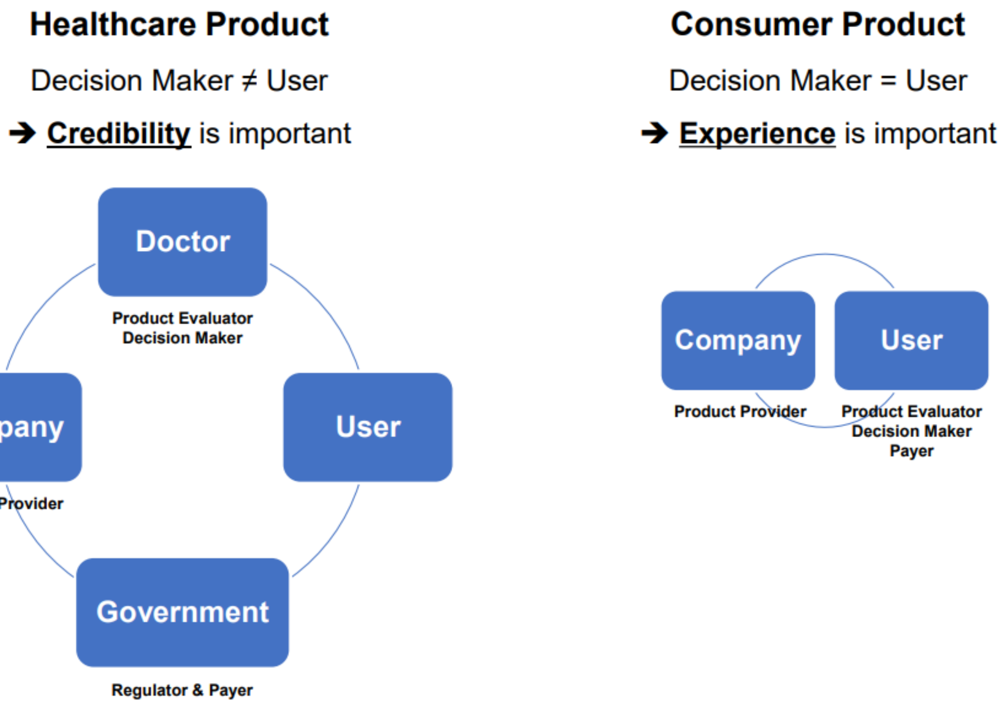


Figure 40 Healthcare vs. consumer product

Subsequently, Dr. Kiwon Lee presented non-invasive BCI for medical applications, using Ybrain as a case study. Ybrain is a manufacturer that has developed non-invasive BCI stimulators for treating depression, and many clinical trials have demonstrated the efficacy and safety of these BCI devices (see Figure 41 and Figure 42). The company has collaborated with both the medical society and the government, receiving recognition from them (see Figure 43, Figure 44 and Figure 45). These non-invasive BCI devices have proven successful in treating major depressive disorder (MDD) and are currently the only non-pharmaceutical treatment option available in the South Korean market. The company is also commercializing BCI-based diagnosis support and monitoring systems to improve the platform's integrity (see Figure 46). The usage of Ybrain's BCI platforms by psychiatry clinics is depicted in Figure 47. Furthermore, the company aims to expand its applications in collaboration with major players in other industry sectors (see Figure 48). He then presented commercialization cases from these sectors covering fields such as driver management, military applications, and cosmetics (see Figure 49 - Figure 54). Notably, there have been no commercial cases in the field of invasive BCIs. However, a transition from non-invasive mobility BCIs to invasive mobility BCIs is currently underway to provide new solutions for disabled patients. What's more, to facilitate development and commercialization, standardization is crucial. Benefits and opportunities for standardization are highlighted in Figure 55.

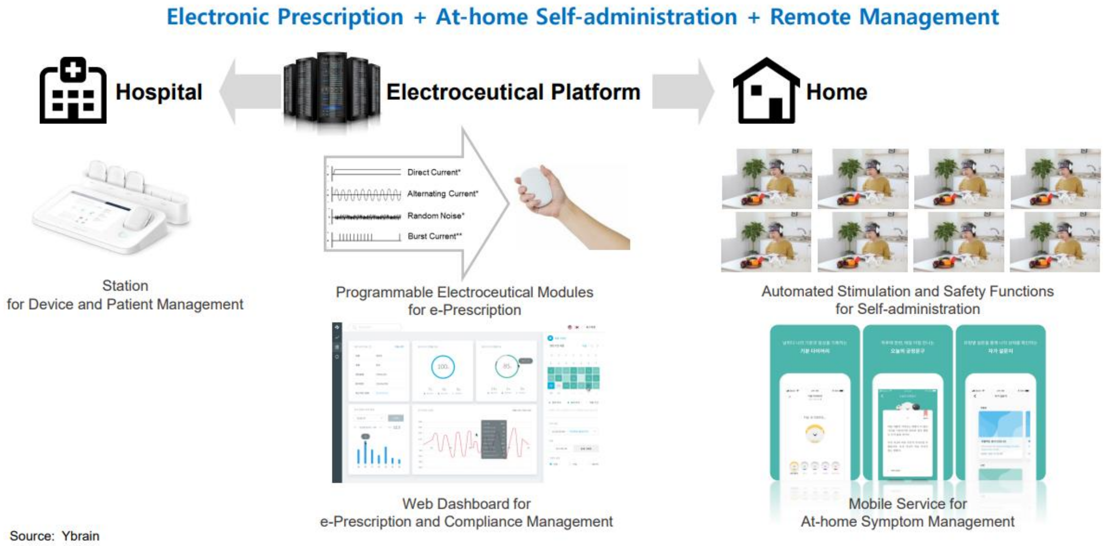
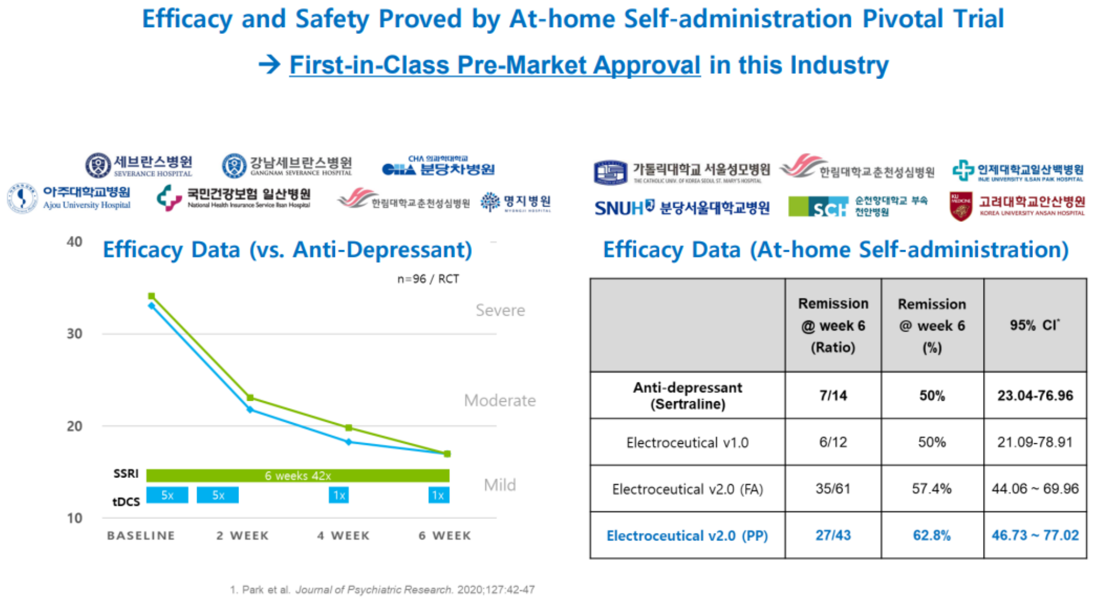


Figure 41 Non-invasive BCI (stimulation) - clinic-to-home electroceutical platform



	Remission @ week 6 (Ratio)	Remission @ week 6 (%)	95% CI*
Anti-depressant (Sertraline)	7/14	50%	23.04-76.96
Electroceutical v1.0	6/12	50%	21.09-78.91
Electroceutical v2.0 (FA)	35/61	57.4%	44.06 ~ 69.96
Electroceutical v2.0 (PP)	27/43	62.8%	46.73 ~ 77.02

Figure 42 Non-invasive BCI (stimulation) - pivotal clinical trial (major depressive disorder)

Figure 43 Collaboration with medical society and government

Figure 44 Nation-wide campaign for depression education and treatment

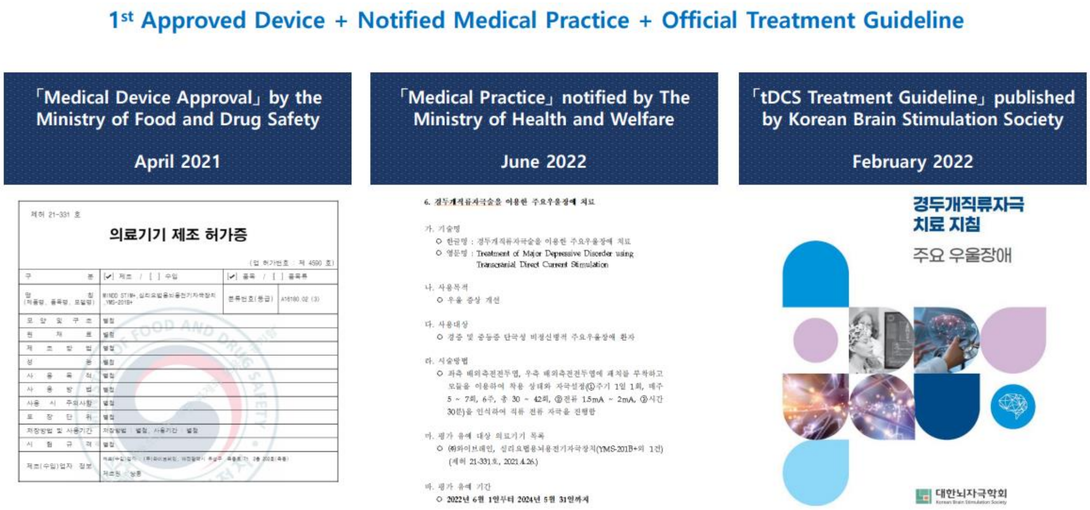


Figure 45 Recognition by medical society and government

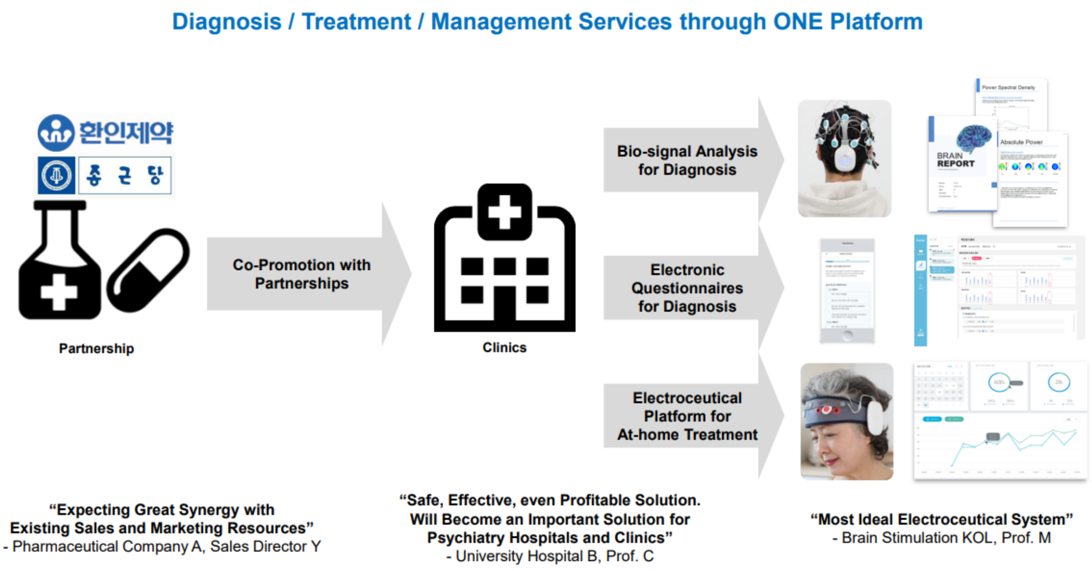


Figure 46 Non-invasive BCI (monitoring/stimulation) - psychiatry clinics

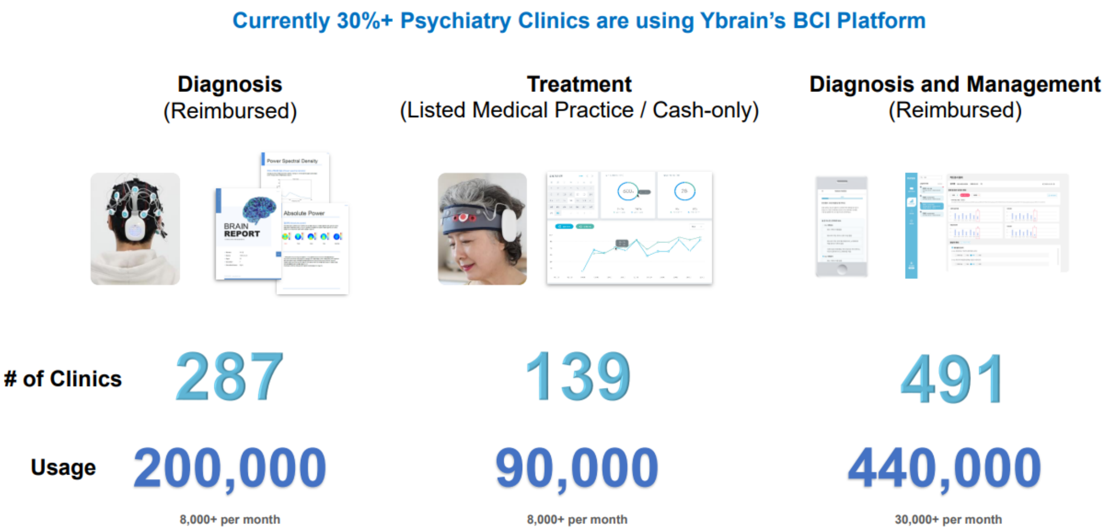


Figure 47 Usage of Ybrain's BCI platforms

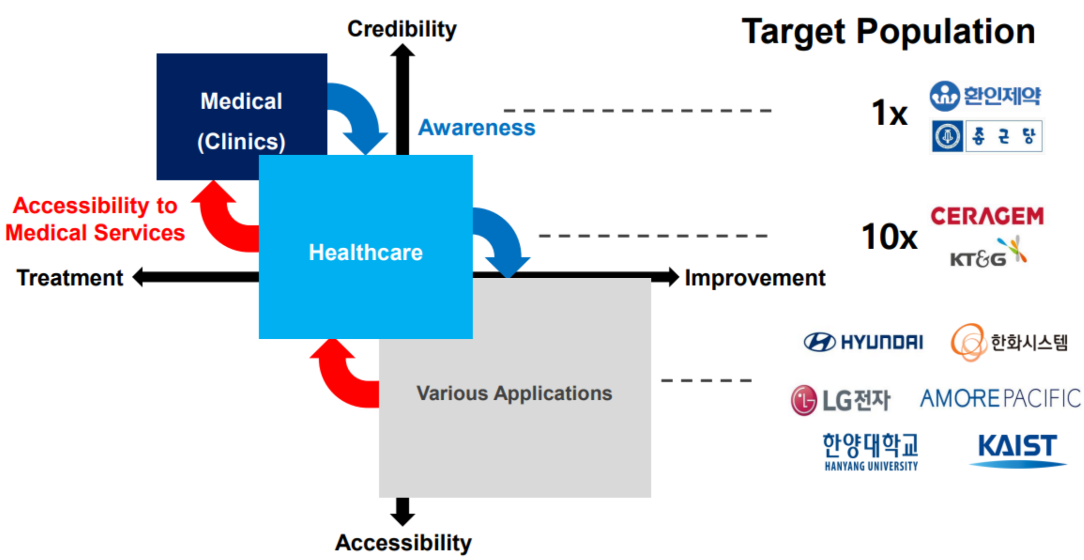


Figure 48 Expansion strategy

Figure 49 Non-invasive BCI (monitoring) - mobility BCI for disabled

Figure 50 Non-invasive BCI (monitoring) - driver monitoring BCI for safety

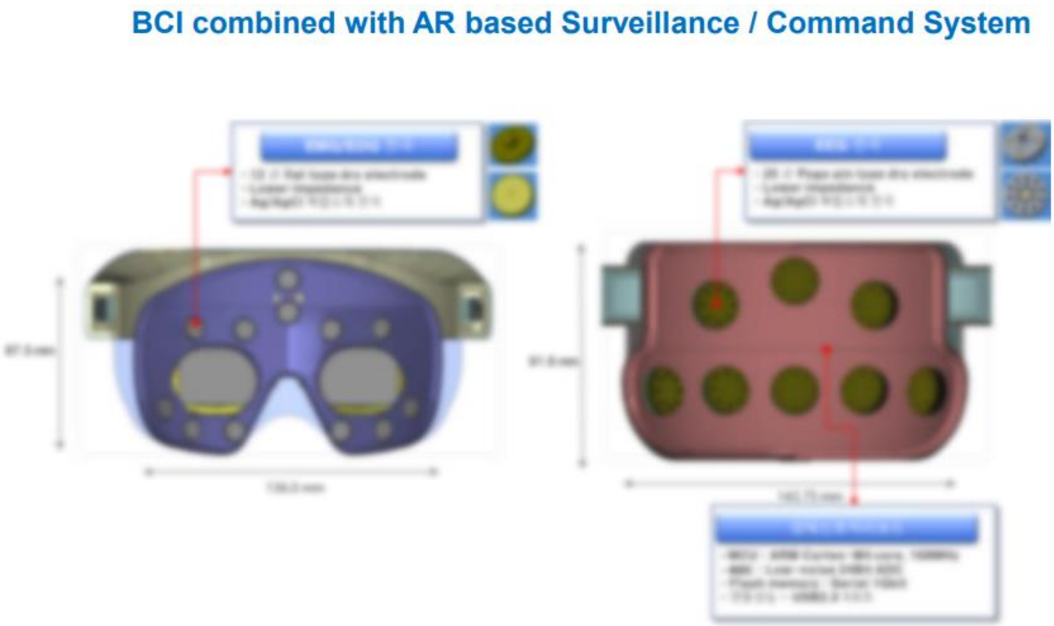


Figure 51 Non-invasive BCI (monitoring) - military BCI for command system

Figure 52 Non-invasive BCI (monitoring) - wearable BCI for epilepsy patients

BCI combined with personalization programs for perfumes and cosmetics

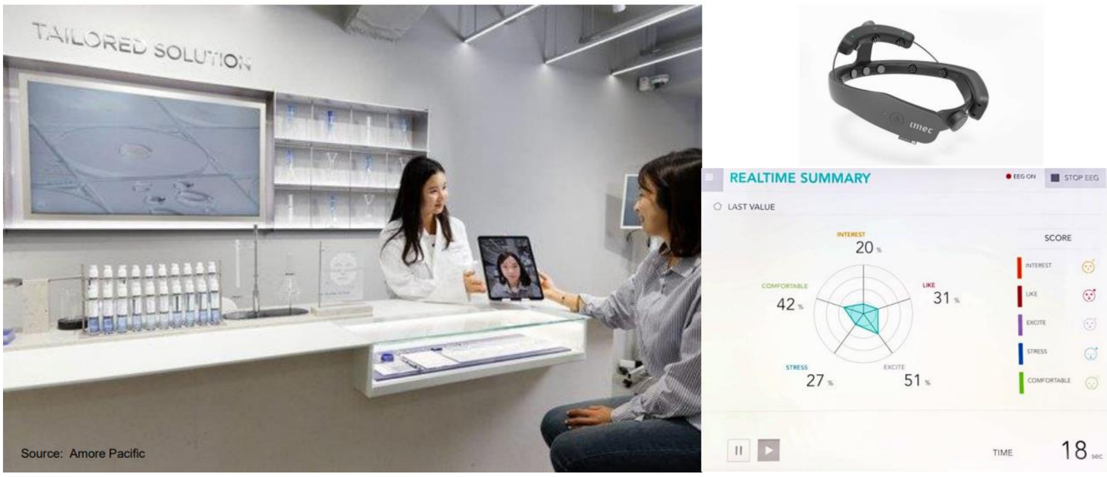


Figure 53 Non-invasive BCI (monitoring) - BCI for personalized cosmetics

BCI combined with sound therapy for mental health and sleep

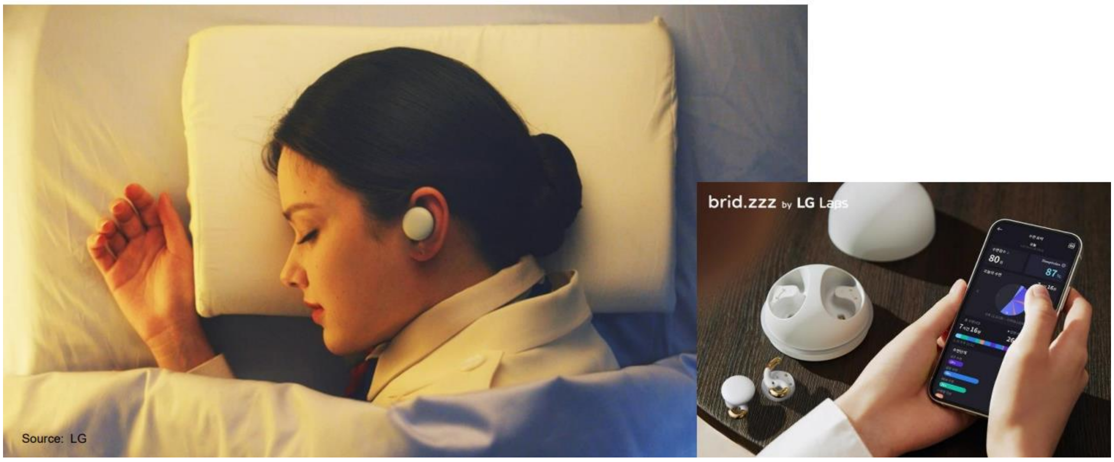


Figure 54 Non-invasive BCI (monitoring) - earbud BCI for mental health and sleep

Benefits

1. Users can easily achieve medical/non-medical objectives with maximized comfort and safety.
2. Users can easily use multiple devices/services with comfort and safety.
3. The compatibility and interoperability can result in fast development, commercialization, and fair competition in between device manufacturers and service providers.

Opportunities

1. Standardization of device **specification**
2. Standardization of device **connection APIs**
3. Standardization of **data acquisition protocol** between devices, software, or servers.
4. Standardization of **data formats** for devices, software, or server-based services
5. Standardization of **data/signal processing methods** for specific medical/non-medical applications

Figure 55 Standardization benefits and opportunities

3.5 Ethics and laws

BCI represents a rapidly evolving frontier in neuroscience research, with the potential to revolutionize numerous domains, such as medicine, communication, entertainment, education, industry, military applications, and crime and criminal justice applications. However, these promising developments also give rise to a range of ethical, social, and legal challenges that require careful examination and discussion.

Lorraine Finlay, the Human Rights Commissioner at the Australian Human Rights Commission, gave a presentation entitled "Protecting Cognition: Neurotechnology and Human Rights". The application of BCI technology needs to follow strict ethical principles to ensure the protection of patients' rights and interests.

First, she presented the project on the human rights implications of new technologies completed by the Australian Human Rights Commission (see Figure 56). The project helps to take advantage of new technologies, while safeguarding human rights. As these technologies reshape our world, they bring both significant opportunities and threats to human rights. People want fair and safe technology, highlighting the intrinsic link between technology and human rights in both digital and physical worlds. It is essential to use technology responsibly and ethically, which requires stronger laws and policies to protect human rights effectively.

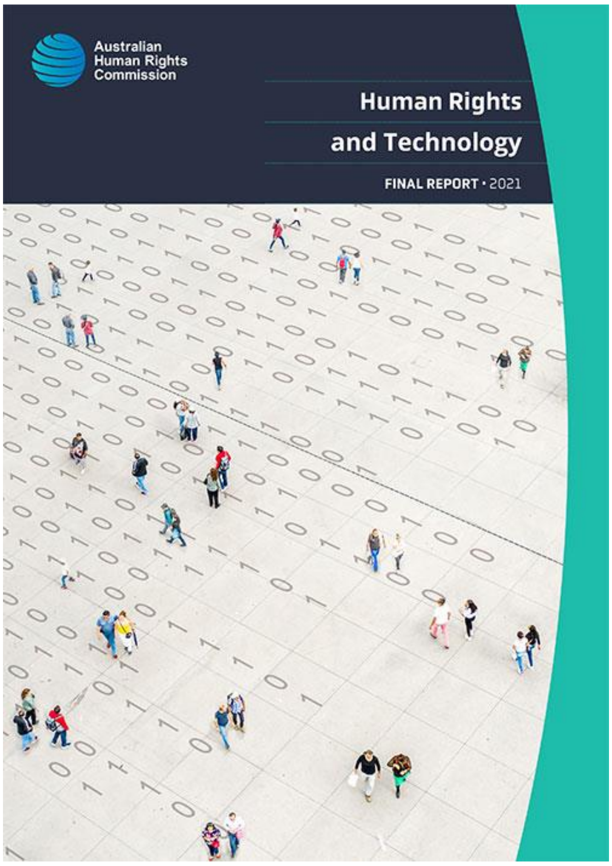


Figure 56 Human Rights and Technology Project

Then, she presented the project on "Protecting Cognition: Background Paper on Human Rights and Neurotechnology" (see Figure 57). The project seeks to identify the human rights risks associated with neurotechnologies, particularly focusing on the rights to privacy、freedom of thought, conscience and religion or belief、right to equality and non-discrimination. The right to privacy is protected under article 17 of the International Covenant on Civil and Political Rights (ICCPR). Because neurotechnologies can collect sensitive neural information, there is a significant risk to privacy. Additionally, article 18 of the ICCPR protects the right to freedom of thought - yet thought processes may be manipulated by neurotechnology. The right to non-discrimination is protected under articles 2 and 25 of the Universal Declaration of Human Rights. Without proper safeguards, the technology could develop biases which unduly impact specific groups. Besides, people with disability may face particular challenges of human rights due to neurotechnologies, as outlined in the Convention on the Rights of People with Disability—specifically regarding insufficient protections when their implants are decommissioned or rendered redundant. Young people and children may be particularly vulnerable to any side effects of long-term use of neurotechnologies, given that their minds are still developing. Therefore, it is essential to prioritize the best interests of children during the application of neurotechnology, in accordance with article 3 of the Convention on the Rights of the Child. The project also explores immersive technologies, military applications and the use of neurotechnologies in the criminal justice system.

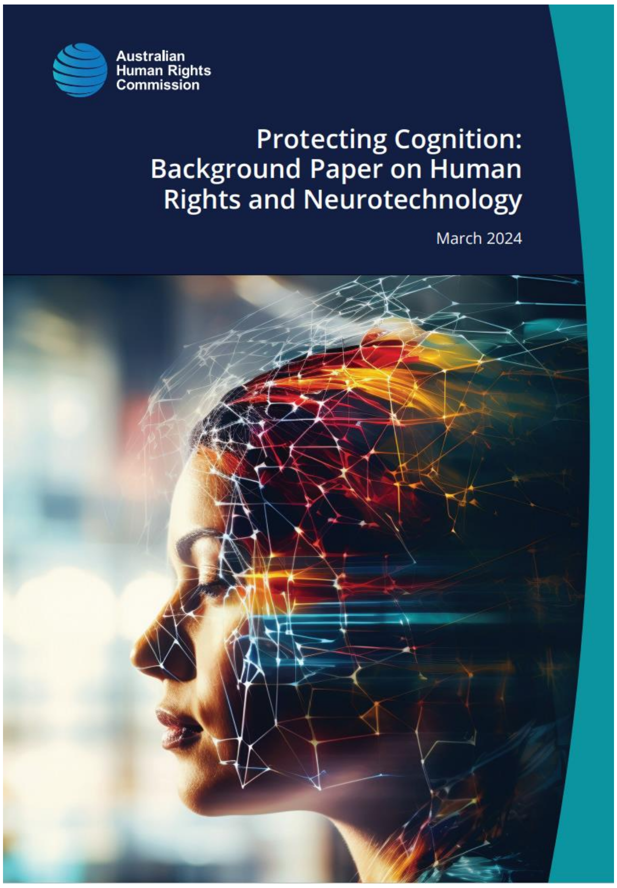


Figure 57 Protecting Cognition: Background Paper on Human Rights and Neurotechnology

Dr. Jiangbo Pu, an Associate Professor at Chinese Academy of Medical Sciences and Peking Union Medical College, delivered a presentation that explores the ethical implications of neurotechnology as detailed in UNESCO's International Bioethics Committee report. Highlighting the potential of neurotechnology in treating mental and neurological disorders (see Figure 58), it also addresses ethical concerns related to brain access and manipulation (see Figure 59). Key areas covered include neuroimaging, neurodevices, brain-computer interfaces, and AI in neuroscience (see Figure 60), emphasizing principles such as mental integrity, human dignity, personal identity and psychological continuity (see Figure 61-Figure 65).

What is Neurotechnology? Definition & Types

Neurotechnology is the field of devices and procedures used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of the neural systems of animals or human beings.

- Technical and computational tools that **measure and analyze** chemical and electrical signals in the nervous system, be it the brain or nerves in the limbs.
  - May be used to identify the properties of nervous system activity, understand how the brain works, diagnose pathological conditions, or control external devices (neuro-prosthesis, BCIs)
- Technical tools that **interact with** the nervous system **to change** its activity, for example to restore sensory input, such as cochlear implants to restore hearing or deep brain stimulation to stop tremor and treat other pathological conditions.
  - Either record signals from the brain and 'translate' them into technical control commands, or to manipulate brain activity by applying electrical or optical stimuli.

Figure 58 Definiton and types of neurotechnology

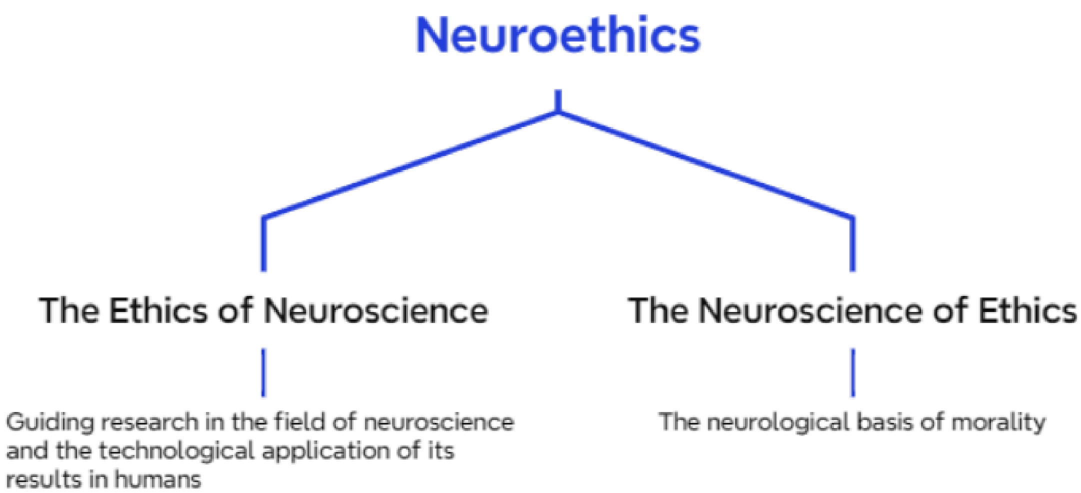


Figure 59 Neuroethics

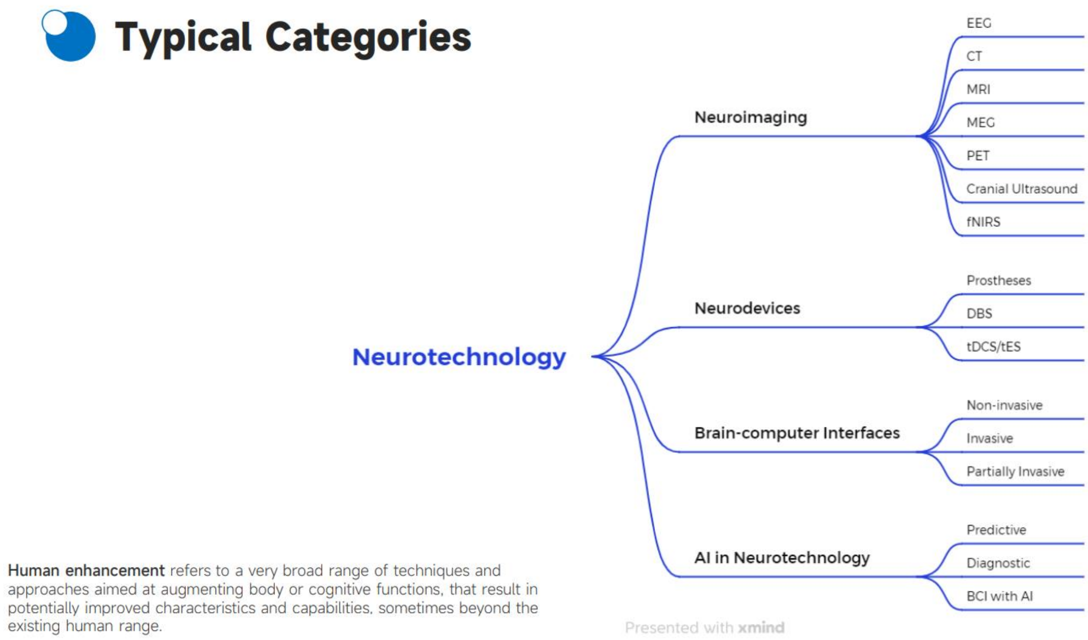


Figure 60 Typical categories

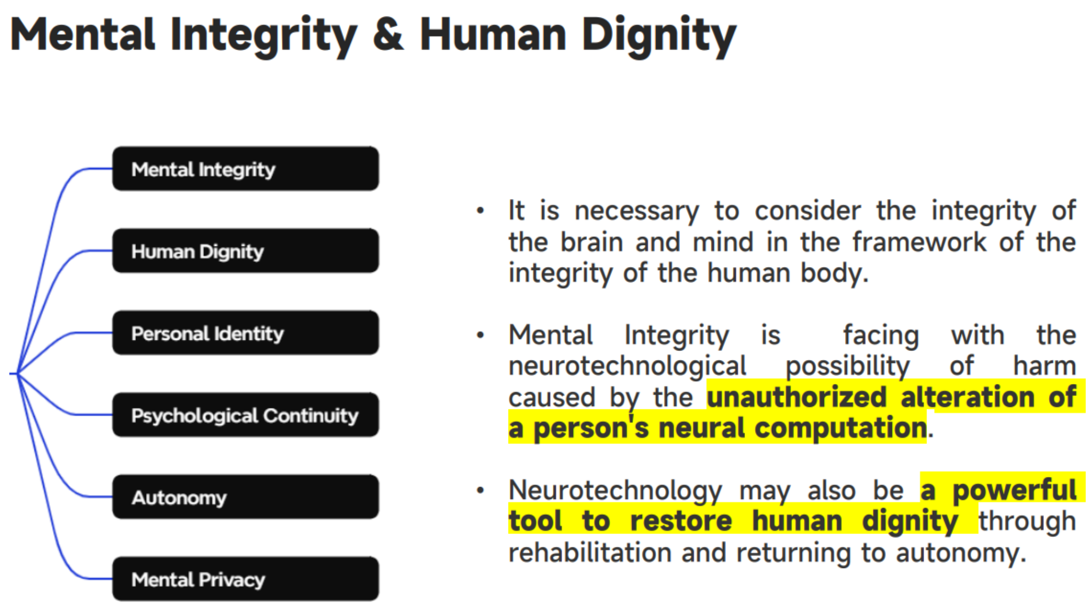


Figure 61 Mental integrity and human dignity

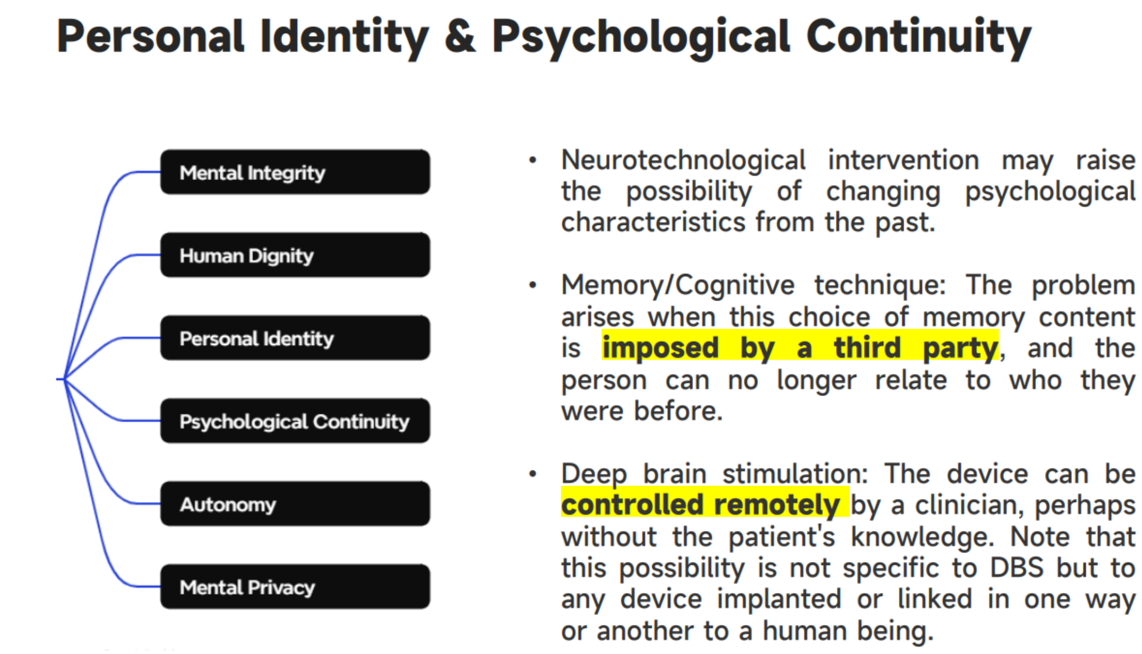


Figure 62 Personal identity and psychological continuity

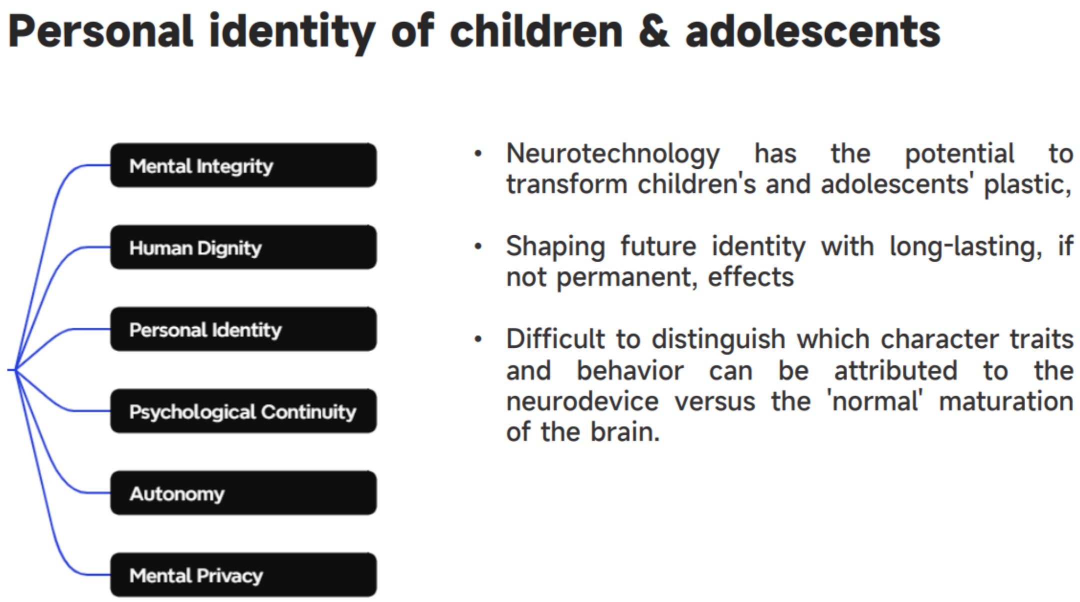


Figure 63 Personal identity of children and adolescents

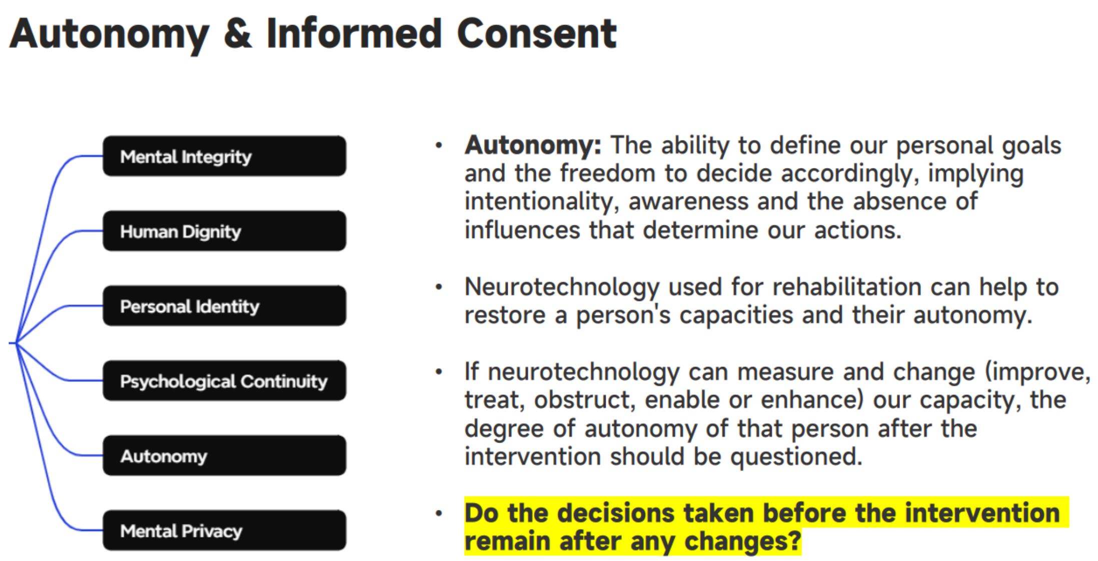


Figure 64 Autonomy and informed consent

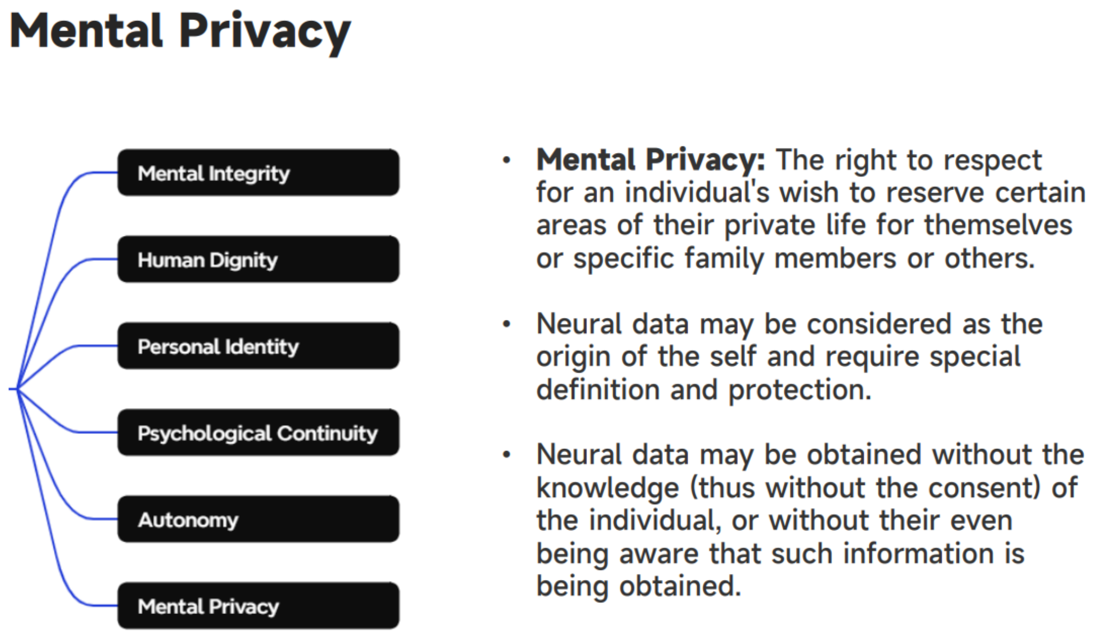


Figure 65 Mental privacy

In addition to individual rights, neurotechnology raises challenges related to accessibility and social justice. Since there is a higher incidence of neurological and mental disorders in populations living in poverty. There may be increasing demand for the medical applications of neurotechnology among these populations. However, access to these advanced neurotechnologies is uneven, with a higher concentration in affluent regions and limited availability in low-income areas. This disparity could exaggerate existing inequalities, as those who have access to neurotechnology might gain cognitive or physical advantages over those who do not, particularly in regions with inadequate healthcare infrastructure. It is essential to ensure that these neurotechnologies are distributed equally and used responsibly to prevent exacerbating social inequalities. Embracing the principles of responsible innovation is crucial, including ensuring public accountability, inclusiveness, representativeness, enforceability and active participation during the process of both design and application. To achieve equitable access to neurotechnologies, effective governance of data-sharing practices is also necessary. Moreover, risks associated with neuro-cognitive enhancement are addressed in Figure 66.

- **Neuro-cognitive enhancement:** Interventions designed to improve mental and emotional performance considered as 'normal', which can be identified as enhancing human capabilities, 'beyond' therapy.
- **Including:**
  - Psychotropic drugs affecting mental processes
  - Neuroimaging technologies to assess or alter brain function via neurofeedback
  - Neurostimulation technologies to transiently alter brain function
  - Brain implants
  - Brain-computer interface
  - ……
- **Off-label use** in medical fields for enhancement purposes or for well-being
- **"Drug Abuse" Risk** of a sort of medicalization and pathologization (searching for drugs and technologies to improve performances), of not considering the social/environmental causes and of disease-mongering to market pharmaceuticals.

Figure 66 Neuro-cognitive enhancement

The presentation examines clinical ethics and research ethics (Figure 67 and Figure 68) in the context of neurotechnology, highlighting the importance of informed consent. The rise of neurotechnology, which has the potential to intervene in brain activities, raises significant challenges regarding consent to the use of brain data. Brain data (neural data) include data relating to brain structure and neural activity. While human beings typically have the capacity to consciously filter the flow of information and decide which portions they wish to share and not share, neuroimaging technology may compromise this mental privacy, allowing for the extraction of brain data without a person's awareness. Moreover, decoding of the brain may produce neural data that involve not only conscious thoughts but in fact all brain activity, and this could be subject to commodification. Brain data is a much sought-after commodity which carries the risk of possible de-identification, hacking, unauthorized re-use of information, and digital surveillance. The predictive value of some neural data (for instance, brain imaging) calls for further precautions. Brain data obtained through neurotechnology should be used with proper informed consent. This consent is predicated on the ability of individuals to make free and competent decisions, but in the context of neurotechnology, the technology itself may interfere with such capacity. Additionally, information and understanding prior to consent is often unknowingly incomplete since consenting individuals ignore or have difficulties grasping which and how much data they are giving up, how these data are being used and what might be learned by third parties about these data. These concerns raise important questions about whether the traditional informed consent instruments and guidelines are adequate for the uses of neurotechnology and if there is a need to provide additional safeguards to protect confidential information or what are known as 'informational privacy' and 'brain privacy' given their exceptionally sensitive nature.

Dr. Jiangbo Pu concluded with recommendations for responsible innovation (see Figure 69) and public engagement (see Figure 70), emphasizing the necessity for aspects like privacy through standardized design, equality, proper informed consent, and scrutiny of uses of neurotechnology to ensure that human rights are protected alongside the development of neurotechnology (see Figure 71 and Figure 72).

Neurotechnology & Clinical Ethics

- **Clinical ethics:** Making ethical decisions within a healthcare setting which incorporates many of the ethical principles and rules fundamental to bioethics, such as:
  - Respect for the autonomy of persons
  - Beneficence and non-maleficence
  - Confidentiality
  - Informed consent
  - Decision-making capacity
  - Risk-benefit analysis
  - The best interest standard
  - The right to refuse treatment, withdrawing treatment
  - Procedural and distributive justice.
- Esp. For Neurotechnology: Protecting personal privacy and the confidentiality of data, meticulous informed consent processes, and seeking to benefit others from the data obtained during the process of neuro-technological developments.

Figure 67 Clinical ethics

Neurotechnology & Research Ethics

- Research in neurotechnology must comply with accepted ethical standards for research
  - Declaration of Helsinki
  - 2016 International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences (CIOMS)
  - …
- All proposals to conduct research that involve human participants must first be submitted for a review of their scientific merit and ethical acceptability by an independent ethical review committee, which must give its approval in order for the research to proceed.
- As the neurotechnological developments progress, ethical review of the process should also proceed hand-in-hand with the scientific development.

Figure 68 Research ethics

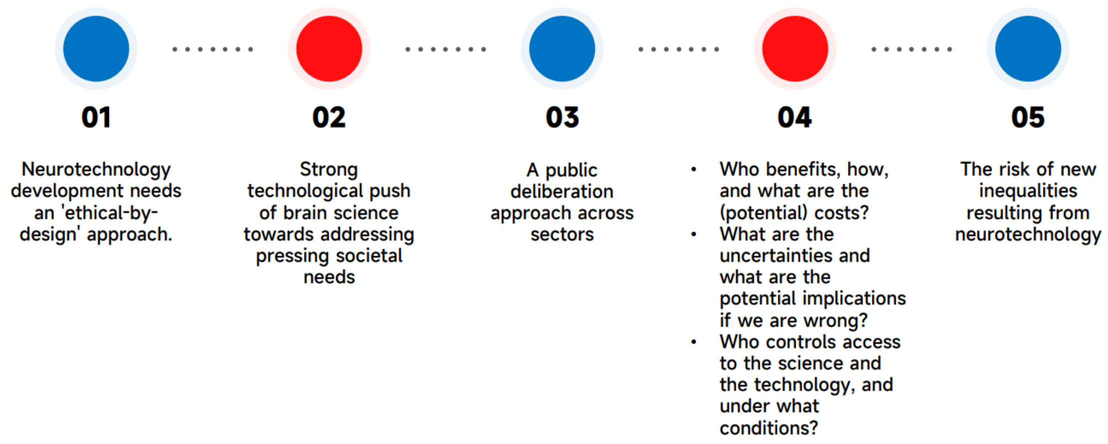


Figure 69 Responsible innovation

- Responsible innovation in neurotechnology must be a collaboration between science and society.
  - Educating the public on the possible cognitive and emotional effects of neurotechnology is a pre-requisite to public engagement.
  - Helps to eliminate unrealistic expectations that can erode public trust.

- Key players from the private sector as well as start-ups are at the forefront of neurotechnology innovation.
  - Vigilance and post-marketing surveillance
  - Reinforcement of the responsibility
  - Reinforcement of verification processes and obligation
  - Identification of devices: obligation of traceability
  - Information: Manufacturers will be required to provide a clear and understandable summary of the safety and clinical performance of devices
  - Clinical evaluation, post-marketing follow-up, clinical research: stricter rules.

Figure 70 Engaging with the public and industry

- Harmonized standards for neurotechnology innovation to ensure a positive impact on health and society.

- Standardisation of neurotechnology system specification and interoperability helps
  - Communication and collaboration across major brain research initiatives and the sectors
  - Standardizing personal brain data collection, curation, and sharing are essential for driving new discovery and obtaining broader value from the data

- Privacy by Standardized design should also be a backbone of any neurotechnology device, given the highly sensitive nature of brain data.

Figure 71 Standardization

- All humans have a right to protection of their brain activities regardless of race, gender, socio-economic status and cognitive abilities.

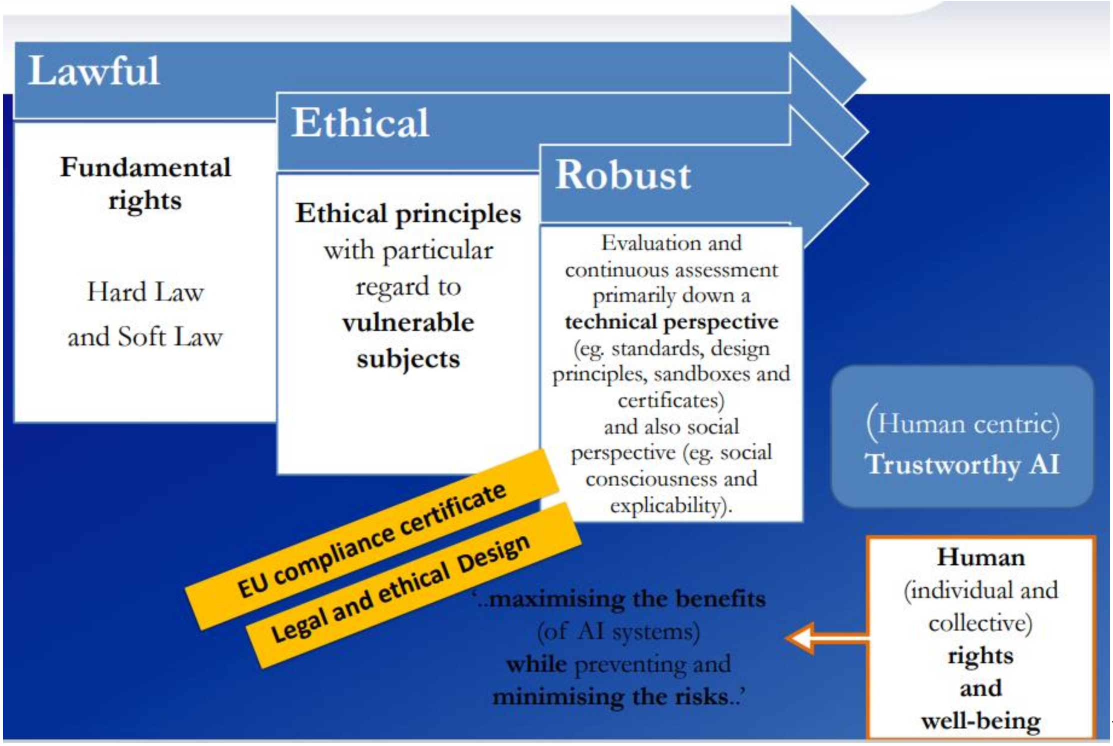
- Brain data obtained from, with, or via neurotechnology must never be used for surveillance or profiling without proper informed consent, and never for potential discrimination based on cognitive or other mental features.

- Uses of neurotechnology by state and non-state actors should be scrutinized for possible violations of human rights.

- Promoting dissemination of information, education and dialogue on neurotechnology is of paramount importance to ensure responsible and ethical use.

Figure 72 Recommendations

Maria Cristina Gaeta, a Lecturer (RTD-A) in Private Law at the Suor Orsola Benincasa University of Naples, presented on the topic of "BCI devices and their legal compliance: standardization challenges". The Research Centre in European Private Law (ReCEPL), developing research itineraries on the relationship between law and new technologies, has conducted research in the field of BCI. The main objective of this research is to protect human beings and their rights in the digital environment, since this environment places them in a position of vulnerability (technological vulnerability). To achieve this, it is necessary to verify and measure the risks that can arise from these new technologies, and guarantee the ethical and legal compliance by design of the BCI application under an anthropocentric point of view, underling the legal importance of standardization. The research employs multiple methods, including: critical analysis of the legal state of the art (hard law and soft law, judicial decisions, literature, research studies and standards); Human-Machine-Interaction and User Experience approach (HMI&UX); Empirical Legal Studies (ELS); and technical and technological regulation based on measurement. Additionally, impact measurement of AI, which is also applicable to lots of BCI technologies, in Italy (see Figure 73 and Figure 74) and Europe (see Figure
75



)

was discussed.

Three objectives of the assessment concerning trustworthy AI are outlined in Figure 76. Following that, a critical analysis of the main legal issues, including safety, privacy, and cybersecurity issues related to BCI devices and their legal compliance is discussed (see Figure 77, Figure 78 and Figure 79). Further details can be found in related papers (see Figure 80).

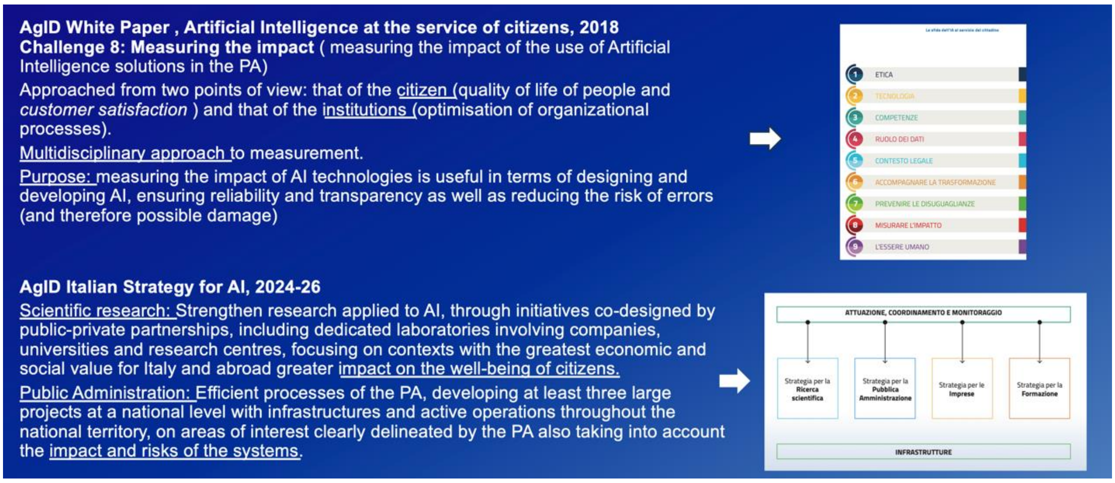


Figure 73 Italian Strategy for AI

The Council of Ministers of 23 April 2024 approved the **Italian bill** for the introduction of provisions and government powers **on artificial intelligence, in line with the AI Act**

The Italian AI bill regulates the principles relating to the experimentation, development, adoption and application of AI systems, promoting their correct, transparent and responsible use, in an anthropocentric dimension, as well as ensuring supervision of economic risks and social rights and, specifically, **on the impact of AI on fundamental rights** (art. 1).

It also introduces rules of principle and sector provisions for:

- promote the use of new technologies to improve citizens' living conditions and social cohesion
- provide risk management solutions based on an anthropocentric vision.

The DDL intervenes in five areas:

- national strategy,
- national authorities,
- promotional actions,
- copyright protection,
- criminal penalties.

Figure 74 Italian AI bill

AI Act (Regulation 2024/1689/EU)
Risk - based **measurement of the impact of AI** ***approach***

Art. 9 - Risk management system for high-risk AI systems

The risk management system is understood as a continuous iterative process planned and executed throughout the entire life cycle of a high-risk AI system, requiring constant and systematic review and updating. It includes the following stages:
(a) identification and analysis of known and reasonably foreseeable risks that the high-risk AI system may pose to health, safety and fundamental rights
b) estimation and evaluation of the risks that may emerge from the use of the high-risk AI system in accordance with its purpose and under conditions of reasonably foreseeable misuse;
c) assessment of any other risks deriving from the analysis of the data collected by the post-market monitoring system;
d) adoption of appropriate and targeted risk management measures aimed at addressing the risks identified pursuant to letter a).

Art. 27 - Impact assessment on fundamental rights for the expressly indicated high-risk AI systems

For expressly indicated high-risk systems, they carry out an assessment that includes the following elements:
deployer 's processes in which the high-risk AI system will be used in line with its intended purpose;
(b) a description of the time period within which each high-risk AI system is intended to be used and how frequently;
c) the categories of natural persons and groups likely to be affected by its use in the specific context;
d) the specific risks of harm that may affect the categories of natural persons or groups of persons identified pursuant to letter c);
(e) a description of the implementation of the human surveillance measures, according to the instructions for use;
f) the measures to be taken if such risks materialise, including provisions relating to internal governance and complaints mechanisms.

Figure 75 EU AI Act

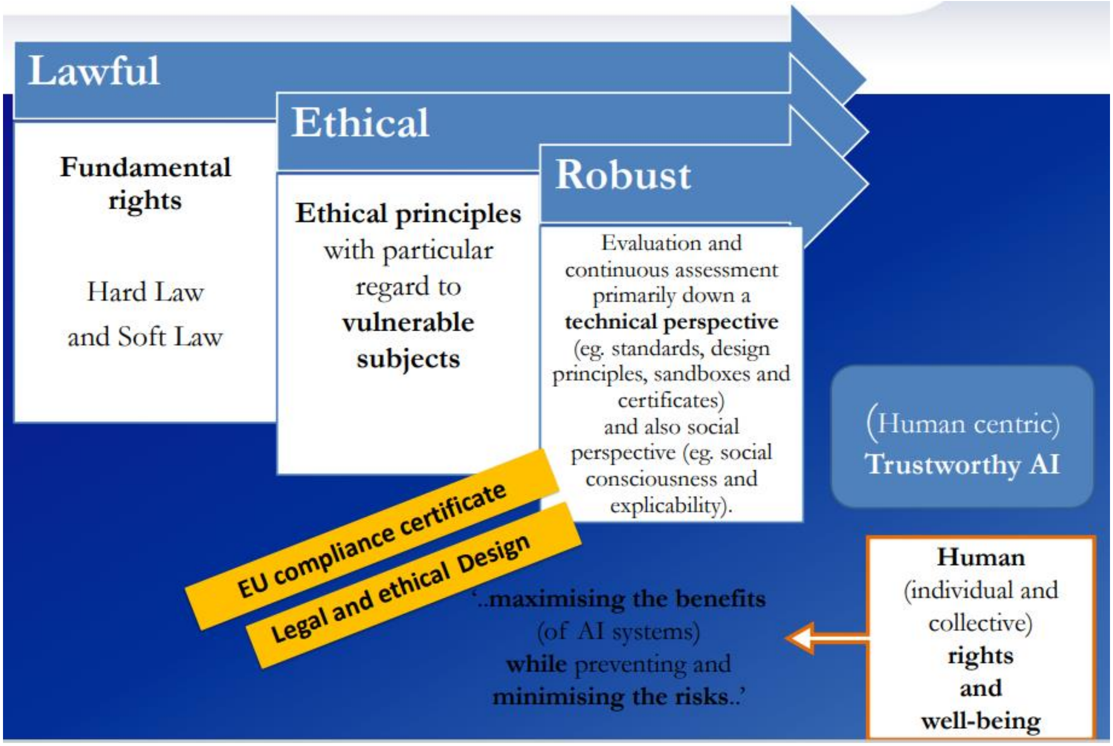


Figure 76 Three objectives of the AI assessment

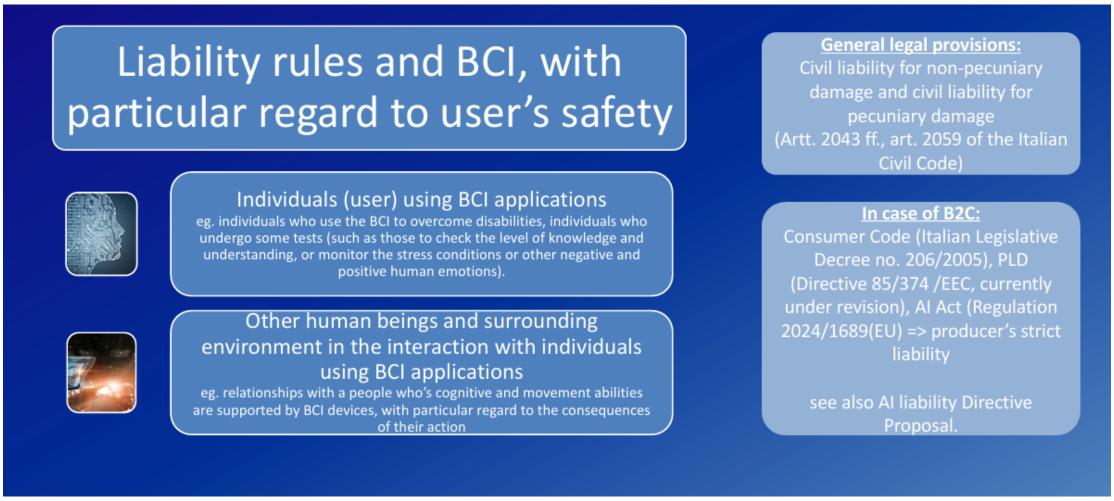


Figure 77 Safety issues related to BCI

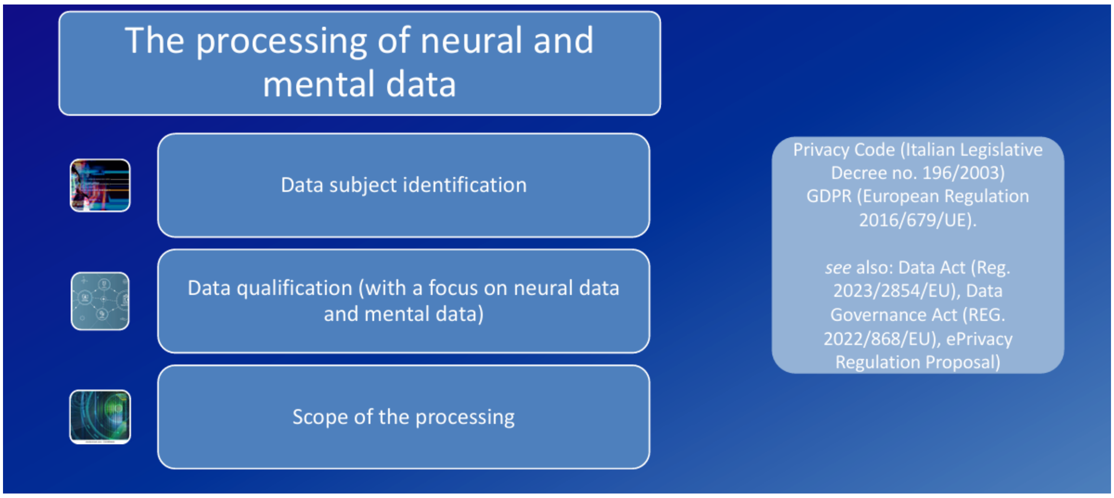


Figure 78 Privacy issues related to BCI

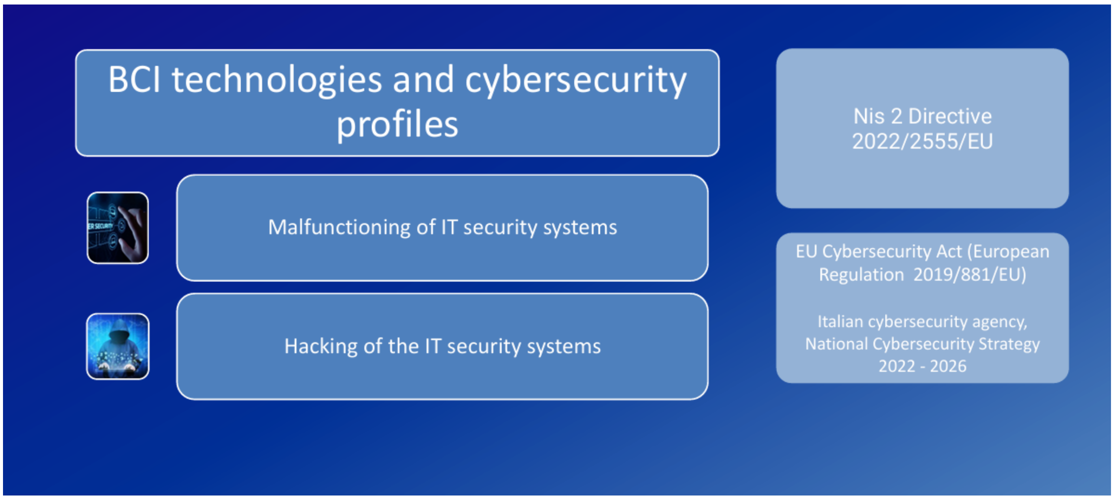


Figure 79 Cybersecurity issues related to BCI

Figure 80 Papers discussing the critical analysis of the main legal issues related to BCI

devices and their legal compliance

Standardization in the area of BCI for Information and Communication Technology (ICT), is essential to enable lawful ethical and robust communication and interaction between brain and computers. Nevertheless, the standardization of BCI technology worldwide is still in its infancy currently, lacking unified and reliable systems. Standardization is important to protect consumers and support companies in the expanding BCI market, as it can improve safety, privacy, cybersecurity, interoperability, and accessibility. Compliance to BCI safety standard, BCI privacy standard, and BCI cybersecurity standard constitutes the structure of the tool prototype which is being developed at the Research Centre in European Private Law to measure the impact of BCI devices on human rights (see Figure 81).

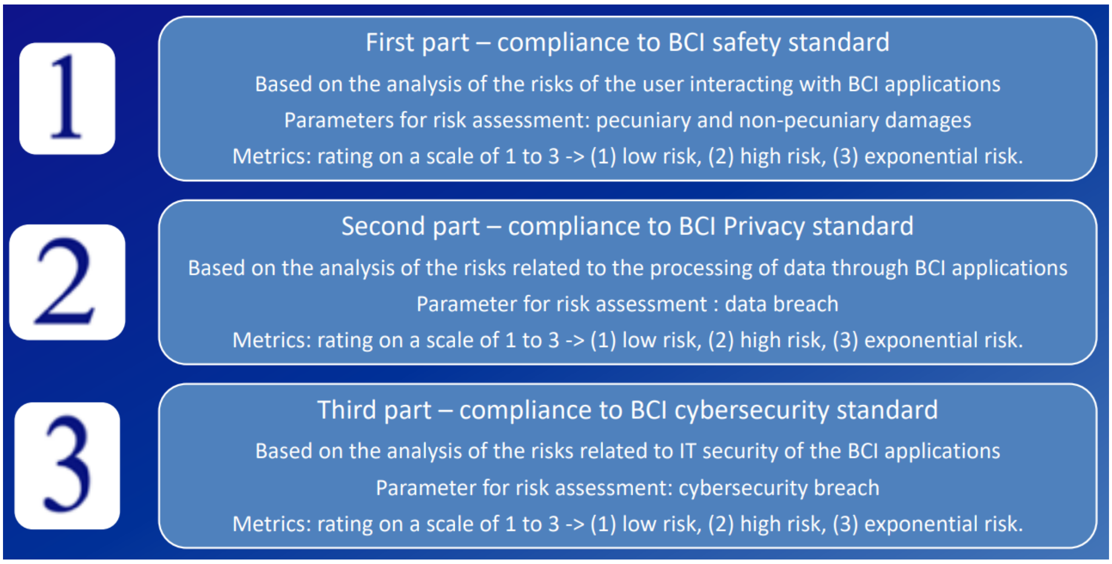


Figure 81 Structure of the tool prototype to measure the impact of BCI devices on human rights

In conclusion, the current legal framework does not provide for specific regulation of BCI (in particular in relation to security, privacy and cybersecurity). A preventive legal analysis of BCI devices and related risks is necessary in order to avoid situations of ‘technological vulnerability’. An innovative but necessary approach to a proper techno-regulation is needed to guarantee the ethical and legal compliance of BCI applications. Hybridization of knowledge is essential for effective measurement and regulation in this context (see Figure 82).

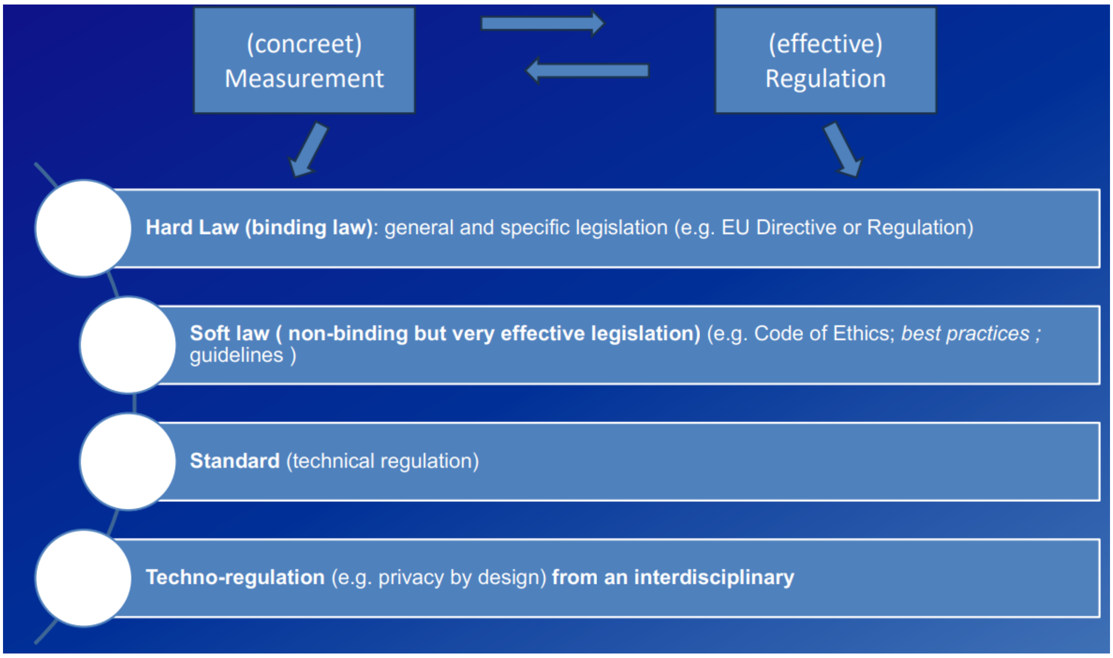


Figure 82 Measurement and regulation in the perspective of the hybridization of knowledge

3.6 Standardization projects of BCI data

BCI data comprises neural signals collected from the brain, serving as the foundation for brain-computer interface systems. This data holds immense significance as it enables the translation of brain activity into actionable commands, facilitating communication between the brain and external devices.

BCI is classified into two categories based on how neural signals are recorded: non-invasive BCI and invasive BCI (see Figure 83). Invasive BCI data formats are designed to capture and interpret neural signals obtained directly from the brain using implanted electrode arrays that are positioned close to target neurons in the cortex or deep brain structures, using techniques such as electrocorticography (ECoG) (see Figure 84). Typically, these electrode arrays are surgically implanted within the cranial cavity, specifically targeting regions of the brain's cortex where neural activity associated with motor control, sensory perception, or other cognitive functions is localized. In contrast, non-invasive BCIs collect neural signals from the surface of the scalp or other external points on the body without the need for surgical intervention or direct penetration into the brain tissue, using techniques such as magnetoencephalography (MEG), fMRI, functional near-infrared spectroscopy (fNIRS) and EEG (see Figure 85Figure 85). Figure 86 provides a summary of important milestones and representative developments in this area.

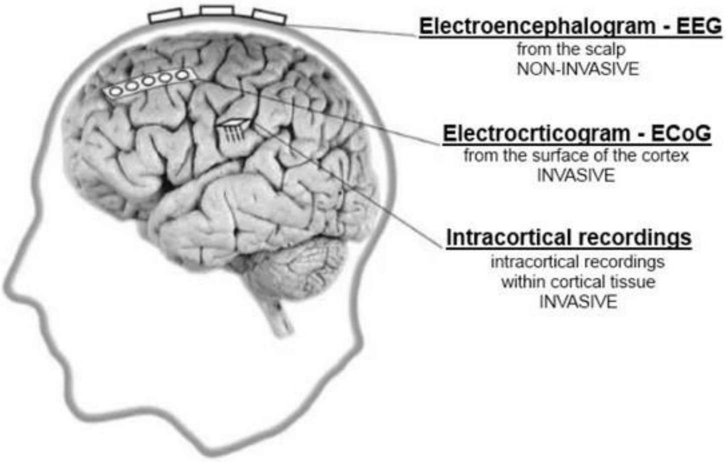


Figure 83 Different methods for electrical activity of brain recordings.

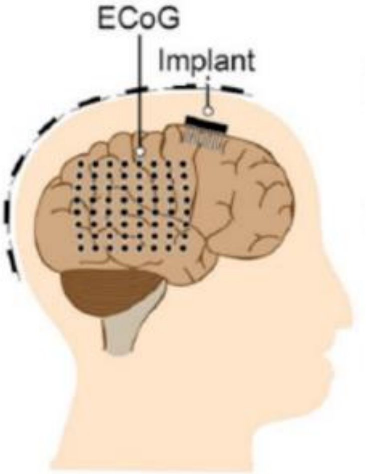


Figure 84 Examples of invasive BCI data formats: ECoG involves placing electrode arrays directly on the surface of the brain's cortex, beneath the skull.

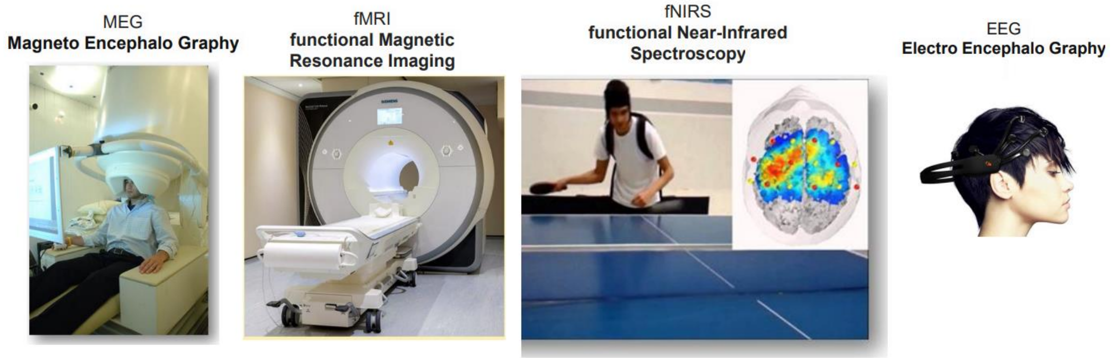


Figure 85 Non-invasive BCI

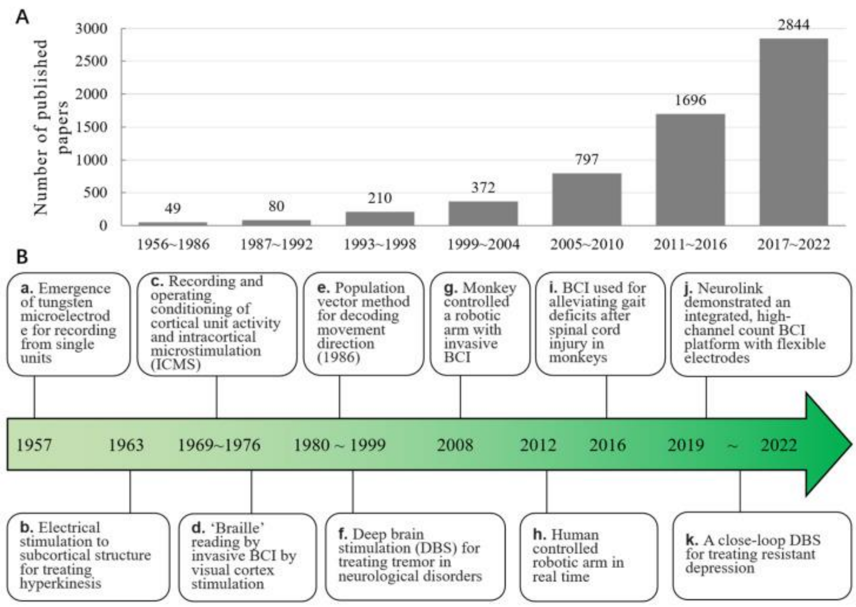


Figure 86 The historical timeline for major breakthroughs and representative developments in invasive BCI.

Professor Young-Im Cho, a member of the Faculty of Computer Engineering and convenor of ISO/IEC JTC 1/SC 43 WG 5, presented current standardization projects of BCI data developed under JTC 1/WG 5. Terms of reference and relationships of WG 5 with other WGs in ISO/IEC JTC 1/SC 43 are illustrated in Figure 87.

BCIs hold immense potential across various fields, from neurorehabilitation to human-computer interaction. However, the lack of standardized data formats for non-invasive BCI technologies poses significant challenges to data sharing, integration, and analysis. A standardized data format that harmonizes metadata and data structures across multiple non-invasive is essential for ensuring that data from different modalities like EEG, MEG, fNIRS, and fMRI are easily comparable and interpretable (see Figure 88 and Figure 89). In the block diagram, standardized non-invasive data formats serve as the backbone that facilitates seamless communication and interoperability between the different blocks of the BCI system. These formats ensure that data collected from various non-invasive BCI devices, such as EEG, MEG, or fNIRS, adhere to consistent structures and conventions, enabling easy exchange and integration. The lack of standardized formats results in the following problems:

- Fragmentation: Without standardized formats, data collected from different BCI devices often adhere to proprietary or ad-hoc formats, leading to fragmentation within the BCI ecosystem.
- Data Silos: In the absence of standardized formats, researchers and institutions tend to maintain proprietary data formats, resulting in isolated data silos.
- Technical Barriers: Converting and interoperating between diverse data formats is technically challenging and resource-intensive.
- Reproducibility Concerns: The lack of standardized data formats undermines research reproducibility and the validity of scientific findings.

Standardizing BCI data formats for non-invasive methods involves establishing uniform specifications for organizing, storing, and exchanging data collected from non-invasive BCI technologies such as EEG, MEG, fNIRS, and fMRI. This standardization ensures consistency and compatibility across different BCI systems, enabling seamless integration and analysis of data from various sources (see Figure 90). ISO/IEC TS 27571 ED1, *Information technology — Brain-computer interfaces — BCI data format for non-invasive brain information collection*, provides the definition of basic data elements, technology-specific information and metadata, design of an extensible and modular data structure, specification of metadata and annotation information, and the development of a standardized data format and naming convention for BCI data files (see Figure 91 and Figure 92). ISO/IEC TS 27571 ED1 outlines a unified data format for Brain-Computer Interface datasets, utilizing a standardized naming convention that integrates details such as modality, subject ID, session, and task into a cohesive and accessible file structure, streamlining the organization and analysis of BCI data across different neuroimaging techniques (see Figure 93). Benefits of BCI data format are demonstrated in Figure 94.

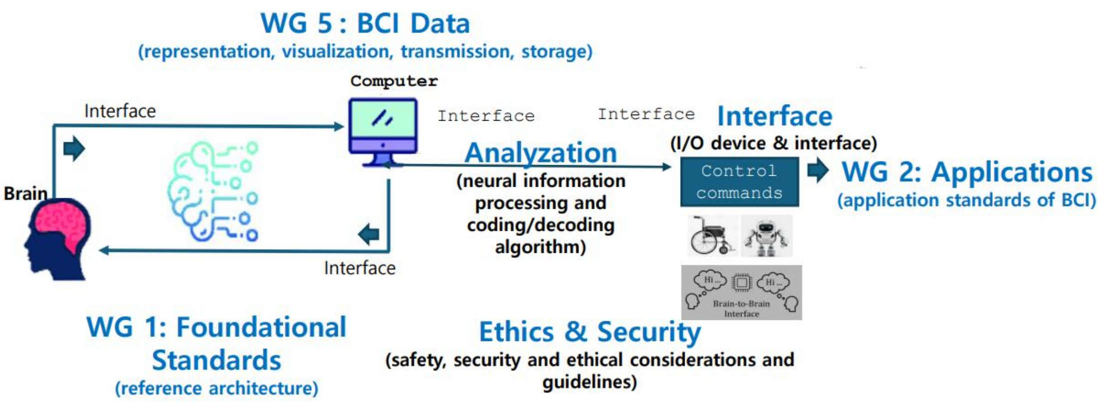


Figure 87 Relationship of WG 5 with WGs

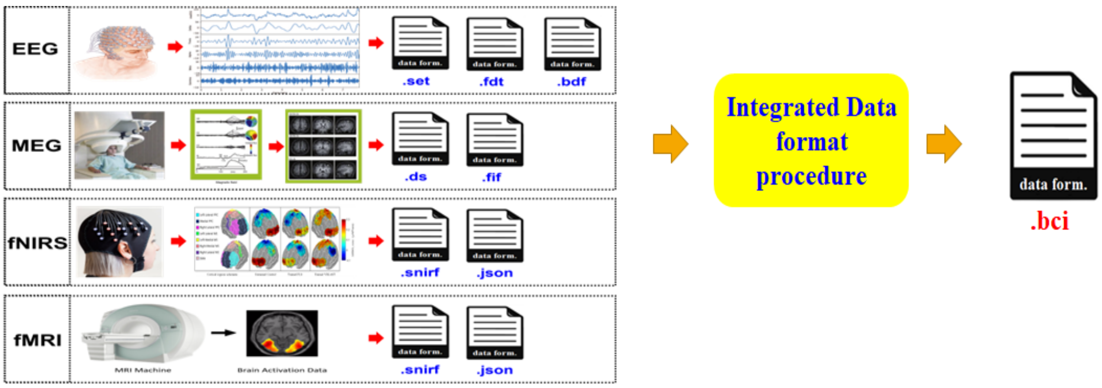


Figure 88 Non-invasive BCI data unified data formatting procedure

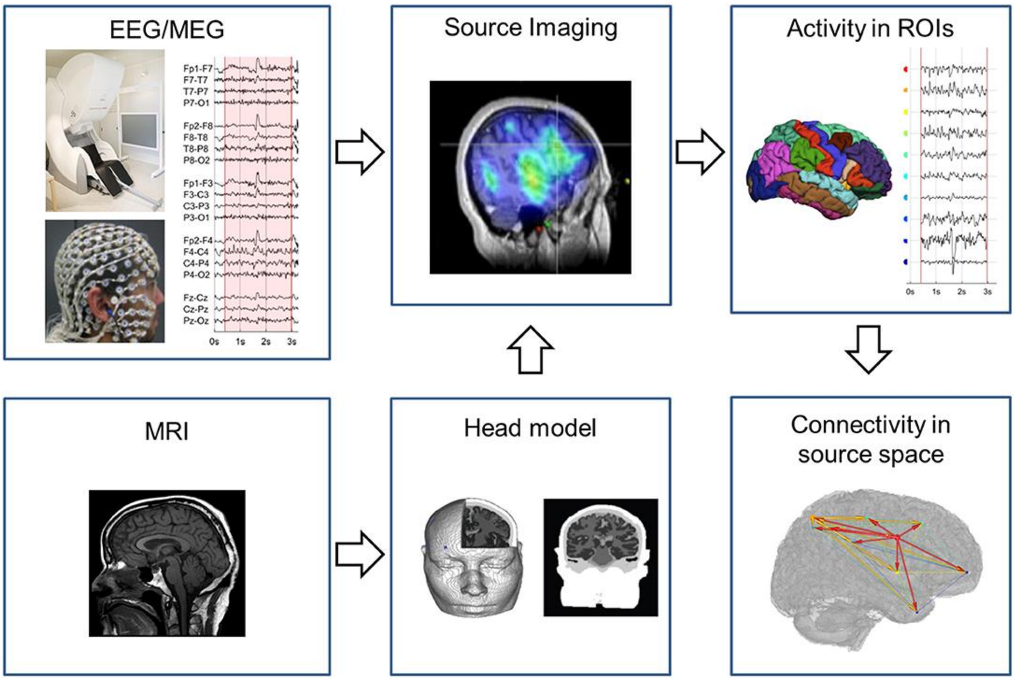


Figure 89 Data structures across multiple non-invasive BCI technologies. Source space connectivity patterns from EEG/MEG are extracted using a head model constructed based on MRI.

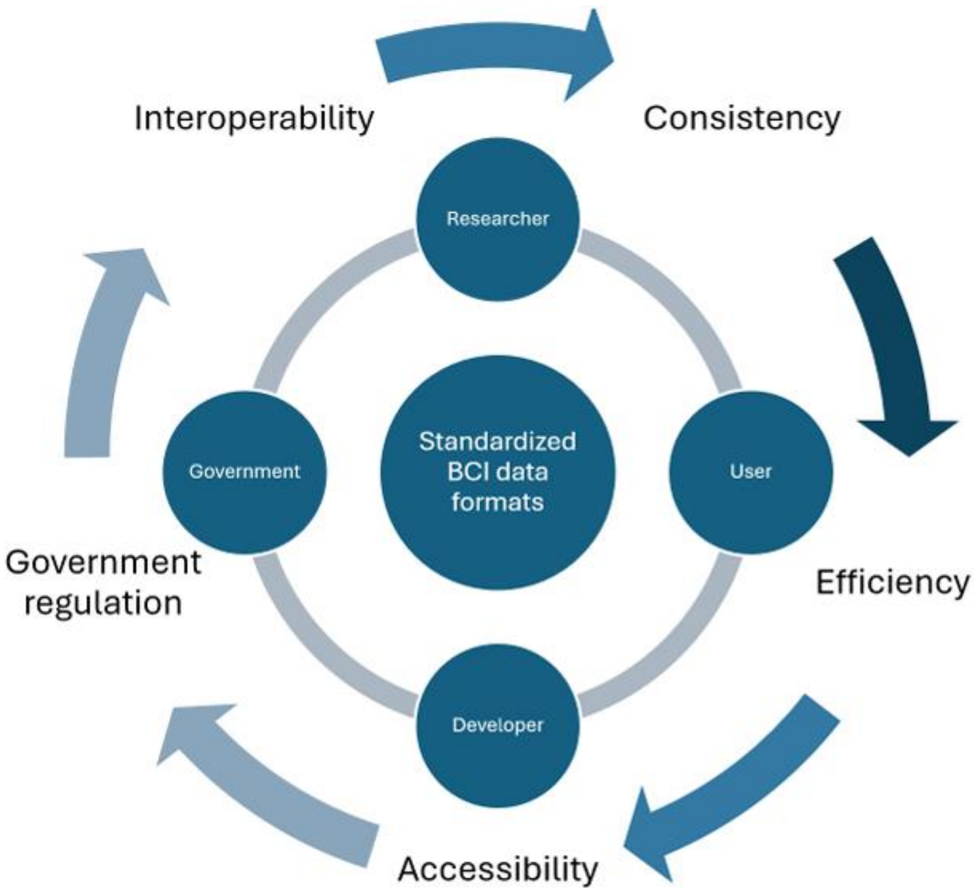


Figure 90 The standardization ensures consistency and compatibility across different BCI

systems, enabling seamless integration and analysis of data from various sources.

ISO/IEC TS 27571 ED1

- *Information Technology - Brain-computer Interfaces - BCI data format for Non-Invasive brain information collection*

SCOPE
(AS DEFINED IN ISO/IEC DIRECTIVES, PART 2, 14):

This document specifies the basic BCI data format including brain-computer interface the definition of basic data elements, technology-specific information and metadata, design of an extensible and modular data structure, specification of metadata and annotation information, and the development of a standardized data format and naming convention for BCI data. This document is applicable to non-invasive BCI technologies, such as EEG, MEG, fNIRS, and fMRI, and provides a comprehensive approach to BCI metadata formats in the product development environment. It takes into consideration various applications, ranging from neurological rehabilitation to human-computer interaction.

Project editor:

Mr. Doniyorjon Mukhtorov (KR)

Current stage					
ACD			2023-12		
Proposed target date for submission of a					
CD	2024-12-31	DTS	2025-07-31	TS	2026-07-31

Figure 91 ISO/IEC TS 27571 ED1, *Information technology — Brain-computer interfaces — BCI data format for non-invasive brain information collection*

Meetings		
Date	Meeting	Summary
2024-01-22	1st e-meeting	Presentation of the history of TS 27571 ED1 by the WG 5 convenor Current stage is ACD
2024-02-26	2nd e-meeting	Presentation of the history of TS 27571 ED1 by the WG 5 convenor Current stage is ACD
2024-03-25	3rd e-meeting	Discussion and resolution of JP NB's comments based on PDoc for CC_JTC1-SC43/53/NP
2024-04-16	4th e-meeting	Discussion of major comments except USA NB's comments due to toe limited time. Tianjin plenary
2024-04-30	5th e-meeting	Meeting with a TFT
2024-06-24	6th e-meeting	Discussion of major comments from excepts and organize a 2nd TFT
2024-09-03	7th e-meeting	Discussion at Sydney plenary

Figure 92 Meetings for ISO/IEC TS 27571 ED1

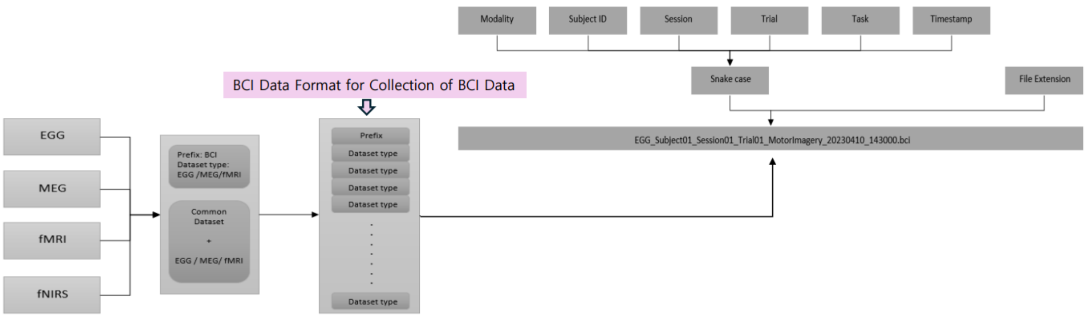


Figure 93 A unified data format for BCI datasets

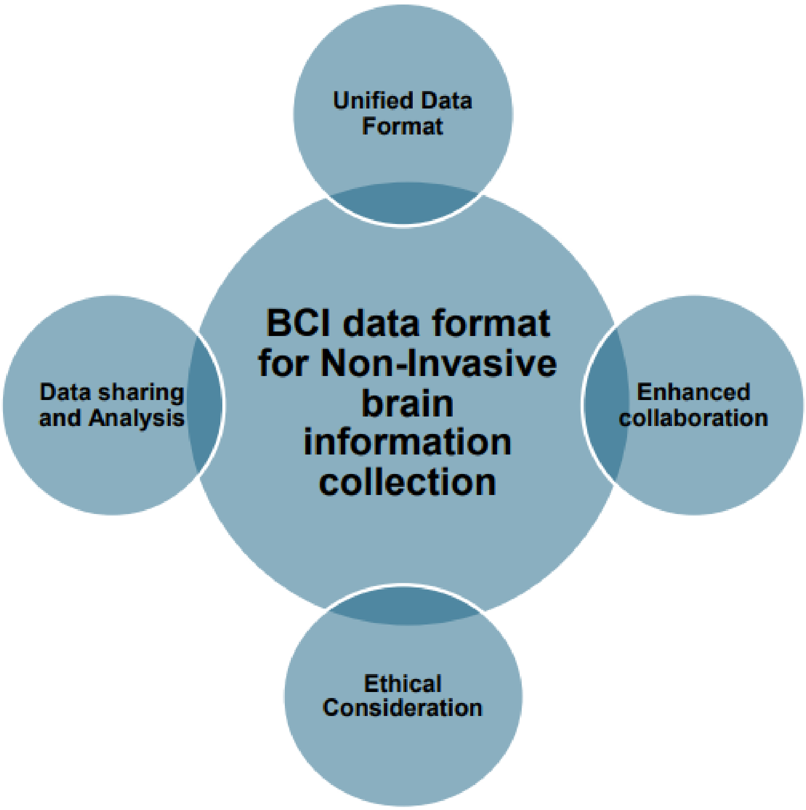


Figure 94 Benefits of BCI data format

Additionally, Professor Young-Im Cho gave a brief overview of PWI SC 43-3, *Information Technology - Brain-computer Interfaces - Invasive BCI Multi-modal Neural Data format* (see Figure 95). Related standardization groups are illustrated in Figure 96. The integration of multi-modal data is crucial in the development and enhancement of BCI. By combining information from various sources, researchers can gain a more comprehensive understanding of brain activities. This holistic approach allows for improved signal interpretation, leading to more accurate and responsive BCIs. Multi-modal data enhances the robustness of BCI systems by providing complementary insights that can mitigate the limitations inherent in single-modality approaches, leading to more accurate and effective BCI. PWI SC 43-3 describes a standardized data format for invasive BCI, which includes the following types of data (see Figure 97 and Figure 98):

- Neural Data: The data format encompasses neural activities including sEEG, ECoG, LFP (local field potential), and Spike. The raw signals of sEEG (Stereoelectroencephalography), ECoG, and LFP can be represented as time series of unit data collected by one or more channels.
- Behavior Data: Behavior information plays a crucial role in understanding the relationship between neural activity and motor or cognitive tasks. It typically includes detailed records of the subject’s actions, responses, and cognitive states during experiments.
- Stimulation Data: Stimulation information details the parameters and protocols of external stimuli administered to the subject, including modality, intensity, duration, and timing.

- Feedback Data: Feedback information refers to the multi-sensory responses that guide and improve subject performance based on their neural activity. Feedback can be classified into continuous feedback, delivered at regular intervals, and discrete feedback.
- General Data: General data refers to information in the experiment that is not tightly coupled with time. It is indispensable for a comprehensive description of the experiment.

Meetings		
Date	Meeting	Summary
2024-04-16	1st e-meeting	Registered as a PWI at Tianjin Plenary
2024-09-03	2nd e-meeting	Discussion in detail at Sydney plenary

Figure 95 Meetings for PWI SC 43-3

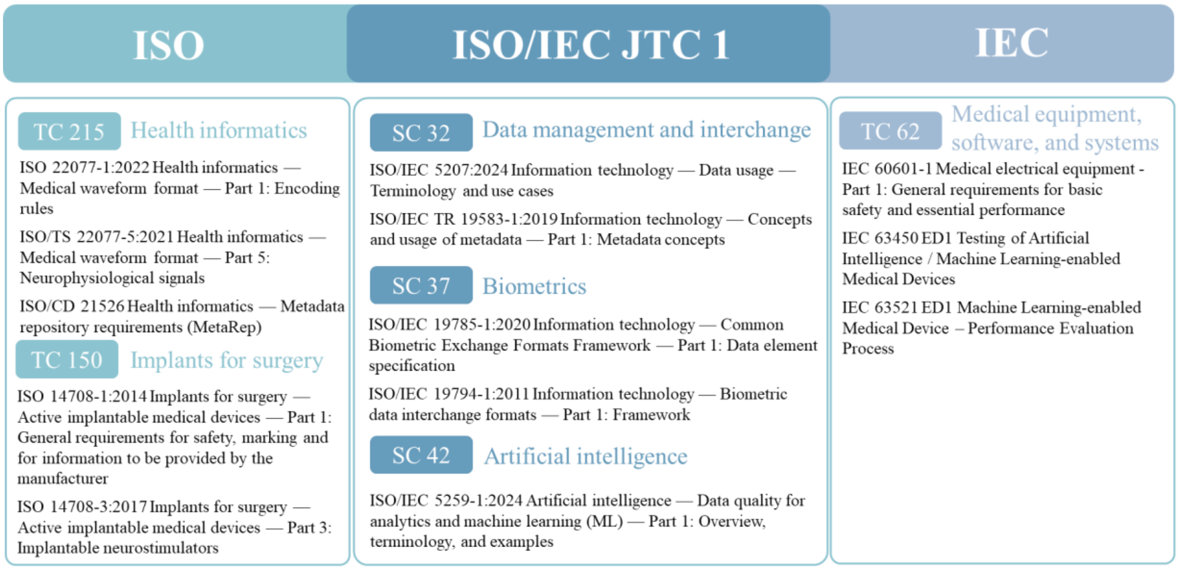


Figure 96 Related standardization groups

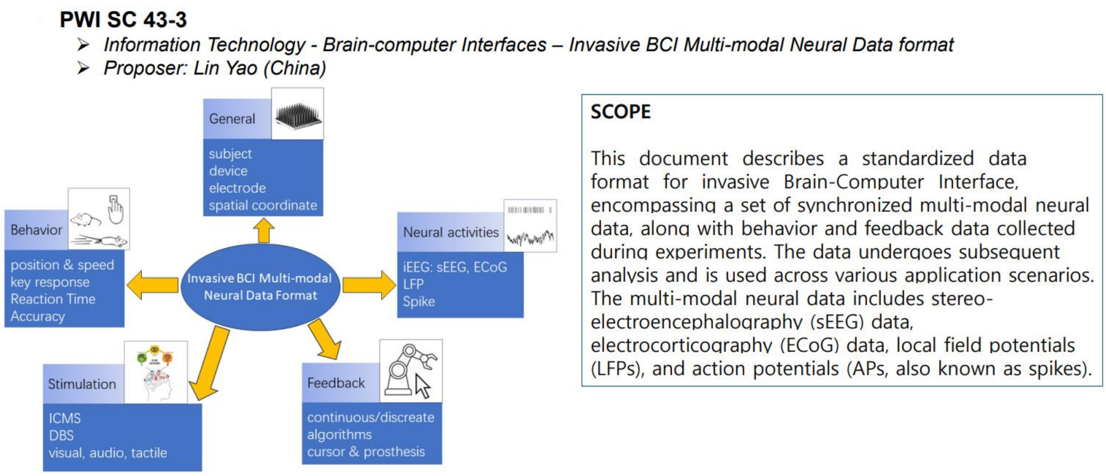
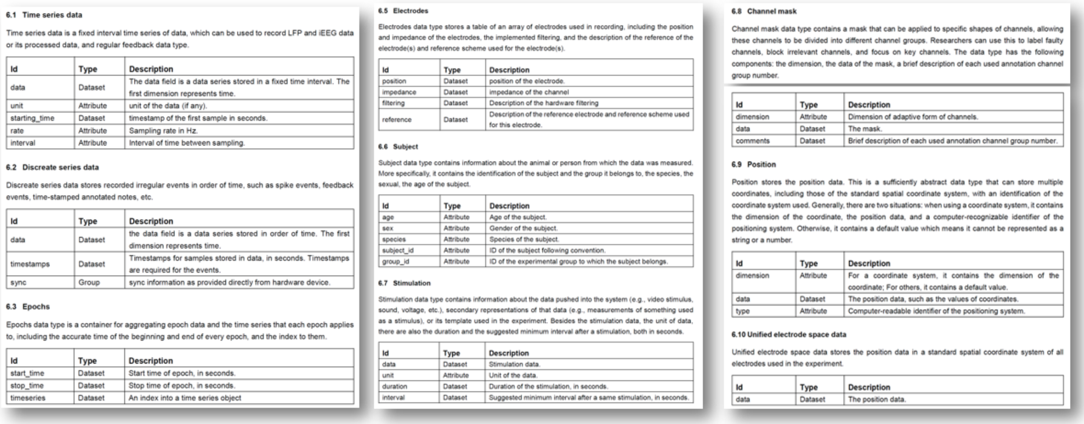


Figure 97 Invasive BCI multi-modal neural data format



6.1 Time series data

Time series data is a fixed interval time series of data, which can be used to record LFP and iEEG data or its processed data, and regular feedback data type.

Id	Type	Description
data	Dataset	The data field is a data series stored in a fixed time interval. The first dimension represents time.
unit	Attribute	unit of the data (if any).
starting_time	Dataset	timestamp of the first sample in seconds.
rate	Attribute	Sampling rate in Hz.
interval	Attribute	Interval of time between sampling.

6.2 Discreate series data

Discreate series data stores recorded irregular events in order of time, such as spike events, feedback events, time-stamped annotated notes, etc.

Id	Type	Description
data	Dataset	the data field is a data series stored in order of time. The first dimension represents time.
timestamps	Dataset	Timestamps for samples stored in data, in seconds. Timestamps are required for the events.
sync	Group	sync information as provided directly from hardware device.

6.3 Epochs

Epochs data type is a container for aggregating epoch data and the time series that each epoch applies to, including the accurate time of the beginning and end of every epoch, and the index to them.

Id	Type	Description
start_time	Dataset	Start time of epoch, in seconds.
stop_time	Dataset	Stop time of epoch, in seconds.
timeseries	Dataset	An index into a time series object

6.5 Electrodes

Electrodes data type stores a table of an array of electrodes used in recording, including the position and impedance of the electrodes, the implemented filtering, and the description of the reference of the electrode(s) and reference scheme used for the electrode(s).

Id	Type	Description
position	Dataset	position of the electrode.
impedance	Dataset	impedance of the channel
filtering	Dataset	Description of the hardware filtering
reference	Dataset	Description of the reference electrode and reference scheme used for this electrode.

6.6 Subject

Subject data type contains information about the animal or person from which the data was measured. More specifically, it contains the identification of the subject and the group it belongs to, the species, the sexual, the age of the subject.

Id	Type	Description
age	Attribute	Age of the subject.
sex	Attribute	Gender of the subject.
species	Attribute	Species of the subject.
subject_id	Attribute	ID of the subject following convention.
group_id	Attribute	ID of the experimental group to which the subject belongs.

6.7 Stimulation

Stimulation data type contains information about the data pushed into the system (e.g., video stimulus, sound, voltage, etc.), secondary representations of that data (e.g., measurements of something used as a stimulus), or its template used in the experiment. Besides the stimulation data, the unit of data, there are also the duration and the suggested minimum interval after a stimulation, both in seconds.

Id	Type	Description
data	Dataset	Stimulation data.
unit	Attribute	Unit of the data.
duration	Dataset	Duration of the stimulation, in seconds.
interval	Dataset	Suggested minimum interval after a same stimulation, in seconds.

6.8 Channel mask

Channel mask data type contains a mask that can be applied to specific shapes of channels, allowing these channels to be divided into different channel groups. Researchers can use this to label faulty channels, block irrelevant channels, and focus on key channels. The data type has the following components: the dimension, the data of the mask, a brief description of each used annotation channel group number.

Id	Type	Description
dimension	Attribute	Dimension of adaptive form of channels.
data	Dataset	The mask.
comments	Dataset	Brief description of each used annotation channel group number.

6.9 Position

Position stores the position data. This is a sufficiently abstract data type that can store multiple coordinates, including those of the standard spatial coordinate system, with an identification of the coordinate system used. Generally, there are two situations: when using a coordinate system, it contains the dimension of the coordinate, the position data, and a computer-recognizable identifier of the positioning system. Otherwise, it contains a default value which means it cannot be represented as a string or a number.

Id	Type	Description
dimension	Attribute	For a coordinate system, it contains the dimension of the coordinate; For others, it contains a default value.
data	Dataset	The position data, such as the values of coordinates.
type	Attribute	Computer-readable identifier of the positioning system.

6.10 Unified electrode space data

Unified electrode space data stores the position data in a standard spatial coordinate system of all electrodes used in the experiment.

Id	Type	Description
data	Dataset	The position data.

Figure 98 Data type definition

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