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BCI devices and their capacity to express human will having legal value: A model of risk-based classification

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Abstract

One of the ultimate frontiers in biotechnology is Brain-computer-interface. BCI devices are currently developed for therapeutic purposes (e.g., as assistive tools) but also recreational ones. A BCI system detects brain activity, allowing a decoding of patterns of neural signals, then 'translatable' in commands a computer can understand and even carry out in the external reality. That's why BCI is now becoming more used (or experimented), considering the advantages that could derive from it. Nevertheless, it also raises some questions from a legal perspective. This Paper focuses on BCI-based devices used for assistive and augmented communication of users, and wonders what legal regime should be accorded to the personal will expressed through those tools. Once the risks have been identified, the parameters and requirements a BCI device must meet, for the human will expressed through it having legal value, are outlined. The Paper proposes, in conclusion, a self-assessment strategy to operationalize BCI technologies applicable to the context of legal relations, implementing methods of risk evaluation and management. A risk-based classification model is also suggested.

Keywords: BCI, Brain-Computer Interface; Regulatory perspectives; Vulnerable people; Human enhancement; Legal capacity; Legal relations; Contracting; Risks; Classification; Impact.

1. Introduction.*

For generations, humans have imagined communicating and interacting with machines through thought and creating devices that can analyze a person's thoughts.

In fact, the cyberpunk movement, especially in the figure of W. Gibson, brought forward the idea of 'jacking in', understood as the possibility of hooking the human or animal mind into software capable of reproducing brain impulses. Outside of the myth, for the last 30 years or so, science has been progressing more and more in the field of 'bioengineering', understood as a medical field that uses methodologies and technologies specific to engineering to solve problems in medicine, biology and the life sciences in general. This medical-scientific field is the result of a mixture of tools of various kinds, relating to chemistry and molecular biology, applied mathematics, mechanics, electronics, computer science, etc., as well as combinations of these disciplines.

This contribution focuses on the use of electromyographic bio-signals derived from neural activity. These signals are used today to construct and 'educate' brain-machine interfaces (BCIs). One of the major fields of application of BCI technology today concerns tetraplegic patients, who, by means of robotic arms, are able to command their thoughts to grasp objects and, conversely, receive sensory stimuli in the brain.

It is generally possible to distinguish three types of BCI:

Invasive BCI, where a connection takes place at the neural level. The invasive

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BCIs used today are used to repair damaged vision and provide new functionality to paralysed people. But they are subject to the accumulation of scar tissue that causes weakening and loss of signal as the body reacts to a foreign object in the brain.

Partially invasive BCIs are implanted inside the skull, but are placed outside the brain. The signals produced have better resolution than non-invasive BCIs and have a lower risk of forming scar tissue in the brain than the former.

Non-invasive BCIs allow muscle implants to be powered in order to restore movement as close as possible to natural motion. These implants are based on connections totally outside the cranial box and, although they are easy to wear, have the lowest signal resolution of the three types of BCIs, as they scatter and blur the electromagnetic waves created by neurons. The subject must undergo rehabilitation to bring the body to 'fuse' with the BCI but they are suitable for temporary and limited needs, as well as being low cost.

The paragraph II deals with the relationship between Transhumanism and BCI and the application of Italian and European legislation in this field.

Paragraph III deals with the possibility of expressing a contractually valid consent through the bci taking into account the characteristics and vulnerabilities of the bci, in a perspective of the application of the concept of error and violence as vices of the will.

The paragraph IV deals with the legal aspects of BCI used for assisted or augmented communication of will to create legal relations and proposes a risk-based classification model and approach to the use of their applications.

2. Transhumanism and BCI experimentation: legal context and new challenges.

The development of the BCI has increased the closeness between man and technology. Transhumanism is a cultural movement that supports the use of scientific and technological discoveries to increase physical and cognitive abilities and improve the human condition[1]. Such technologies can be a support for vulnerable people, such as people with disabilities[2]. The use of such technologies raises some legal issues.

With BCIs, an artificial communication system is created that, using special sensors, allows the reception of data from the brain and their transfer to a computer. So, the question arises whether technological tools can be considered suitable for effective communication directly from the brain. And consequently, whether the will expressed through technology can be considered attributable to the subject. This problem is even more important when the person to whom the technology is applied is physically disabled[3].

This entails the need to identify "neurorights", which protect human rights

[1] AP Karanasiou, 'On being trans-human: commercial Bcis and the quest for autonomy, The Cambridge Handbook of the Law of Algorithms' (CUP 2020).

[2] Ministero della salute – Commissione per lo studio delle problematiche concernenti la diagnosi, la cura e l'assistenza dei pazienti affetti da sclerosi laterale amotrofica, 'Rapporto di Lavoro' (13/12/2004, https://www.salute.gov.it/imgs/C_17_pubblicazioni_450_allegato.pdf, 3).

[3] S Amato, 'Biodiritto 4.0. Intelligenza artificiale e nuove tecnologie' (Torino 2020, 120). P Perlingieri, 'Note sul "potenziamento cognitivo', Comparazione e diritto civile (1 2021, 209 ff).

within the mental and neurocognitive sphere of the individual. In this regard, it is noted that, also in the context of cognitive technologies, some articles of the Italian Constitution are applied.

Art. 13, in fact, recognizes freedom as an inviolable right, even when it is denied by physical impediments. The second paragraph of the article states that no form of restriction of personal freedom is permitted, except by a reasoned act of the judicial authority (Art. 111, c. 1, 2) and only in the cases and ways provided for by law (Art. 25, c. 3). This principle also extends to freedom of expression.

In addition, Article 32, co. 2 establishes respect for the human person as a limit to compulsory medical treatment, and Article 21 recognizes freedom of expression by all available means.

The right to physical and mental integrity is also protected at the European level. Article 3 of the Charter of Fundamental Rights states that "every person has the right to his or her physical and mental integrity", and Article 8 of the European Convention on Human Rights, according to which "every person has the right to respect for his or her private and family life, home and correspondence".

The contamination between the human body and technology could mean that the acts of will of a subject are vitiated by a highly technological element that is even grafted into the physicality of the human being, that is why it is essential that the right to continue to operate, observing reality and finding solutions through new imputation criteria.

If the BCI is used as a tool to test the will of the subject used as evidence during a study, a neuroscientific test implies a physical and psychological intrusion, so that in this case, too, personal freedom is taken into account and balanced with the constitutional principles that stipulate that every individual has the right of defense and the proof of the right to a fair trial governed by law.

In this field, it is important that the legal research combines skills and technical knowledge with ethical principles and at the same time as the reference regulatory framework to protect the fundamental rights of the persons involved.

Therefore, a proactive approach in research is appropriate, which also consists in examining, from the design, the legal aspects, the acquisition of informed consent, the cost/benefit ratio for the people involved, which also take into account the protection of their rights.

3. BCI and the new (possible) frontiers of contractual capacity.

BCIs, in view of the characteristics outlined in the introductory paragraph, are able to play a role as true game changers in the contractual landscape and, more specifically, in the context of subjects who might not be able to express a valid consent for contractual purposes.

In fact, through these aids they could:

- obtain information on the contractual relationship in which one is interested;

- express consent or even a counter-proposal.

To exemplify the matter, consider a person in a state of paralysis, such as that of Amyotrophic Lateral Sclerosis, a neurodegenerative disease affecting the motor neurons of the spinal cord, brain stem and motor cortex[4]. Again, suppose a person suffers a particularly violent stroke that renders him or her almost paralysed and unable to communicate[5].

In such cases, it would be impossible to communicate any consent for the purpose of assuming obligations.

However, with the use of BCIs to assist affected individuals, it would be possible to enable them to regain the communicative capabilities necessary to express a valid consent for contractual purposes, perhaps by operating a brain link between a tablet/pc and a brainwave conversion system or other equally efficient BCIs, in the same way that the use of BCIs for non-therapeutic purposes is being experimented with[6], or even to perform 'biometric' authentication via EEG[7]. Similarly, with devices such as cochlear implants or systems to compensate for vision loss, it becomes possible to be aware of the characteristics of the contract[8].

This is not a new scenario for national judges, since a tutelary judge has decided that an ALS sufferer, respecting precise conditions, can avoid being subject to support administration and use BCIs to express his or her wishes[9]. Yet, it is not clear whether this can actually lead to the expression of an effective consent[10].

This is for two reasons.

Firstly, the 'information acquisition' phase is relevant where the subject is forced to use implants that allow for a recovery of hearing and/or visual capabilities. Since these implants do not all guarantee first-class quality of sensory information (think of cochlear implants, which in any case do not cover

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[4] Ministero della Salute - Commissione per lo studio delle problematiche concernenti la diagnosi, la cura e l'assistenza dei pazienti affetti da sclerosi laterale amiotrofica, 'Rapporto di Lavoro', p. 3, 13/12/2004, https://www.salute.gov.it/imgs/C_17_pubblicazioni_450_allegato.pdf.

[5] M. Poloni, E. Vitelli, S. Fumagalli, A. Valente, Ictus: cause, tipi e sintomi dell'ictus cerebrale, https://www.marionegri.it/magazine/ictus-cerebrale.

[6] P. Nuyujukian, J. Albites Sanabria, J. Saab, C. Pandarinath, B. Jarosiewicz, CH. Blabe, et al. (2018) 'Cortical control of a tablet computer by people with paralysis'. PLoS ONE 13(11): e0204566. https://doi.org/10.1371/journal.pone.0204566. A. Al-Hamadani, M. Al-Faiz, "Inverse Kinematic Based Brain Computer Interface to Control Humanoid Robotic Arm", International Journal of Mechanical & Mechatronics Engineering IJMME-IJENS Vol:20, No:01, 2020, Available at SSRN: https://ssrn.com/abstract=3566851. M. Blankertz, C. Tangermann, Vidaurre, Siamac Fazli, C. Sannelli, S. Haufe, C. Maeder , L. Ramsey, I. Sturm, G. Curio, K.R. Müller, 'The Berlin brain–computer interface: non-medical uses of BCI technology', Frontiers in neuroscience, 2010, doi: 10.3389/fnins.2010.00198.

[7] A. Mosslah, R.H. Mahdi, Shokhan M. Al-Barzinji, 'Brain Computer Interface for Biometric Authentication by Recording Signa', The International Journal of Multimedia & Its Applications (IJMA) Vol.11, No.03, 2019, available at SSRN: https://ssrn.com/abstract=3438143 or http://dx.doi.org/10.2139/ssrn.3438143.

[8] See https://www.amplifon.com/it/news/tipologie-impianto-cocleare; Nitish Kumar, 'BRAIN COMPUTER INTERFACE - A SEMINAR REPORT', 2008, p. 3, https://www.academia.edu/35433827/BRAIN_COMPUTER_INTERFACE_A_SEMINAR_REPORT. https://support.apple.com/en-gb/HT201466

[9] F. G. Pizzetti (2011), 'Libertà di autodeterminazione e protezione del malato nel «Brain-Computer interfacing»: un nuovo ruolo per l'amministratore di sostegno?', Rivista Critica del Diritto Privato, Jovene Editore, disponibile su https://www.academia.edu/12219908/Libert%C3%A0_di_autodeterminazione_e_protezione_del_malato_nel_Brain_Computer_interfacing_un_nuovo_ruolo_per_lamministratore_di_sostegno.

[10] R. Sacco e G. De Nova, Il contratto, t. I, IIIed., in R. Sacco (dir.), Trattato di diritto civile, (Torino, 2004) 134 ss.

the entire spectrum of sound frequencies), it may well be the case that the potential contracting party is misled by exploiting the limitations of the BCI and does not understand all the contractual conditions. In that case, there would be a misled consent and the aggrieved contracting party would be able to request the annulment of the contract under Art. 1427 of the Civil Code.

The same problem arises with BCIs designed to express consent, i.e. tablets or even an electronically controlled arm, since the user may not be able to fully coordinate the movements and functions of the BCI, perhaps having not yet completed the rehabilitation process in order to use it properly.

It is true that here one would not have an error resulting from the conduct of others, but it is difficult to admit the validity of such a consent.

To this must be added the computer vulnerability of the BCIs themselves, which are now hyper-connected and can also be used via smartphone apps, leading to the creation of sensitive 'spots' through which computer intrusions can be conducted[11].

These attacks can first and foremost harm the privacy of the user and even evolve into veritable 'brain spyware', aimed at granting the counterparty an undue informational advantage over the BCI user, as it could abstractly be assumed that the counterparty understands the objections that he is about to make to the contract proposal, thus being able to prepare answers 'in advance'.

Again, the BCIs themselves could be manipulated as tablets and electronic arms, making them perform movements not ordered by the user but favourable to the manipulator. Certainly, in such a hypothesis, there would be cases of consent extorted with malice or violence and this would lead to the annulment of the contract that may have been 'concluded'.

It follows that, as long as secure standards for the protection of BCIs from external intrusion are not established and in the absence of a discipline to ascertain whether or not there is a validly given consent, BCIs may be useful for communicating with the outside world but certainly not for expressing a position for contractual purposes.

4. Brain-computer interfaces (BCI) to create legal relations. The frontiers of contracting abound with doubts.

4.1. BCI-inducted restoration of legal capacity.

Brain-Computer-Interfaces can successfully allow people suffering from severe medical conditions, such as complete paralysis or locked-in-syndrome,

[11] Q. Li, D. Ding, M. Conti, 'Brain-Computer Interface Applications: Security and Privacy Challenges' (2015) 10.1109/CNS.2015.7346884; A. Krausová, "Legal aspects of brain-computer interfaces" (2014) Masaryk University Journal of Law and Technology 8. 199-208. T. Bonaci, R. Calo, H. Chizeck, "App Stores for the Brain: Privacy & Security in Brain-Computer Interfaces", May 23, 2014. IEEE International Symposium on Ethics in Science, Technology and Engineering, pp. 1-7, 2014, IEEE Technology & Society Magazine, Vol. 34, No. 2, pp. 32-39, 2015, University of Washington School of Law Research Paper No. 2788104, Available at SSRN: https://ssrn.com/abstract=2788104. B.J. Maiseli, L.V. Massawe, M. Mbise, K. Mkocha, N. Ally, M. Ismail, J. Michael, S. Kimambo, "Brain Computer Interface: Future, Challenges, and Potential Threats". BSPC-D-22-00311, Available at SSRN: https://ssrn.com/abstract=4073630 or http://dx.doi.org/10.2139/ssrn.4073630

to autonomously communicate and physically interact with the environment around them. Without any doubt, this is a medical-engineering achievement that marks a life-changing milestone for so many people who have ended up paralyzed due to accidents or illness.

Indeed, BCI systems have been proven able to help patients to perform handwriting or to typewrite, despite the inability to move, simply by decoding the patient's imagined handwriting or spelling from recorded signals of neuronal activity[12] . It results in better living conditions and the restoration of relational possibilities for them, including of relevant legal nature. Through these systems, it becomes indeed possible to establish a communication with subjects otherwise unable to express themselves; to determine whether they are conscious and able to voluntarily respond and make relevant decisions (e.g., informed consent in health care or making end-of-life decisions).

Such particular use of BCI devices raises some legal questions; namely, whether, under what conditions and to what extent, the individual's will, expressed through brain-computer interface communication methods, might or might not have legal value. The answer to this question is far from irrelevant and challenges the current notion of legal capacity: as mentioned in the previous paragraph, the subject who possesses intact mental competence, hitherto considered legally incapacitated just because physically unable to express their will, would regain (and be legally granted) the full right to self-determination in all relevant matters affecting them[13].

4.2. BCI-mediated intention to create legal relations.

The personal will of an individual, for it to be accorded legal value, must be manifested - i.e., externalized - to reveal the purpose pursued or the arrangement of interests intended to be realized and regulated. A typical example is that of the manifestation of consensus for the conclusion of a contract. Normally, the intention of a subject to create some juridic consequences (e.g. the acceptance of an offer) must be expressed by way of declaration of intent (and meet all legal requirements) to have legal effects (and for the contract to be binding). This declaration can be expressed, manifesting the intention, e.g., through language - whether written or spoken - (as is normally the case), or implied by a behavior, that is a conduct that unambiguously makes tacitly manifest a specific intention (e.g., mouse click on a 'purchase' button).

Whereas this manifestation of will traditionally occurs through bodily and muscle movements, activated by neural activity, in the case of BCI-mediated declarations, that occurs by means of artificial systems, devices, or mechanical

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[12] J. Xue, "Handwriting with brain computer interface" in J. Phys. (2021) Conf. Ser. 1865 042026; K. T. Huang, Z. B. Moses, J. H. Chi, "Advances in implanted brain–computer interfaces allow for independent communication in a locked-in patient, in Neurosurgery 80 (2017) 5, 30-31; P. Chaudharya, R. Agrawalb, "Emerging threats to security and privacy in brain computer interface", in IJASSR, Special Issue based on proceedings of 4th International Conference on Cyber Security, (2018).

[13] R. Folgieri, "Brain computer interface and transcranial magnetic stimulation in legal practice and regulations", in A. D'Aloia, M. C. Errigo (eds.), "Neuroscience and Law. Complicated crossings and new perspectives" (Springer, 2020), 273; F. G. Pizzetti, "Brain-computer interfaces and the protection of the fundamental rights of the vulnerable persons", in A. D'Aloia, M. C. Errigo (2020), 291

prostheses on the impulse of executable commands resulting from a translation of those very same neural signals.

On a strictly phenomenological level, these BCI-mediated actions are, of course, suitable to express a legally binding will, as long as it is not equivocal; what raises some questions, however, is the artificial translation of patient's mental decisions into control signals and the level of accuracy of the analysis and decoding of their bioelectrical brain activity.

4.3. A legal standpoint: the need for accuracy. Critical issues and key requirements.

In BCI operation, of any kind, 4 stages can be outlined[14]:

1) brain signal acquisition;
2) feature extraction;
3) feature translation;
4) device output;

Each of these steps involves a margin of error. Initially, a recording interface (e.g., electrodes) tracks neural signals reflecting the subject's intent embedded in the on-going brain activity (EEG, etc.); therefore, this information is automatically processed twice: first, an algorithm analyzes the data to map and classify electrophysiological features and filter those having strongest correlations with the user's intent that will be used to control the BCI (thus eliminating 'noise' and irrelevant activity); then, a second algorithm translates the extracted signal features into executable device commands. These commands eventually activate a device that will produce a certain output: letter writing, movement of a cursor[15], operation of a prosthetic arm, etc. Errors could occur at each of these stages; the neural information collected could be not sufficiently accurate or complete (e.g., because of the obsolescence of an implanted interface that has been in place for some time) and thus result in a crucially flawed automatic processing as a consequence; the algorithms may not be properly trained or be biased; the device could end up responding to neural activity accidentally (and not willfully) produced or misinterpreted.

Not only that, on an ethical level, a high level of accuracy is particularly important in situations where the system could directly impact human lives, potentially causing harm; accuracy, but also traceability and transparency at every stage of BCI model construction (especially when AI is involved) are also very relevant on a legal level. If, indeed, a certain level of reliability about the consistency between the subject's will and its BCI-mediated manifestation cannot be demonstrated, it is very difficult for a will or consent that are so manifested to be considered legally valid (and the paralyzed person, therefore, legally capable). In a not-so-different case, for example, the Italian

[14] S. S. Borikar, S. R. Kochre, Y. D. Zade, "Brain computer interface", in NCETMS (2014), 1-4
[15] P. Nuyujukian et al., "Cortical control of a tablet computer by people with paralysis", PLoS ONE 13(2018)11

Guardianship Judge of Sassari declared able to legally self-determinate a patient suffering from Amyotrophic Lateral Sclerosis (ALS) who was using an eye-controlled device to communicate, basing their decision on a technical assessment of 'consistency' between the tool-mediated manifestation of will and what the patient wanted to express. As Pizzetti (2020) states[16], according to this ruling, a biotechnological communication device, as the BCI-based ones, may be considered legally reproducing a person's will only where, after a proper evaluation, it can be considered technically 'suitable' to realize an effective and reliable directly-from-the-brain communication, which can be considered surely 'attributable' to the subject.

To meet this requirement, more accurate systems can be developed implementing adaptive algorithms, which are also capable of detecting patterns related to response errors and conflicts in decision making, thus acting as an automatic decision controller in real time, improving BCI performance. In any case, it is important, when occasionally inaccurate algorithmic processing cannot be avoided, to ensure that at least the system is able to indicate the probability of these errors.

It should be acknowledged, actually, that many of the published trial results report rather encouraging average error rates; even significantly better where auto-correct mechanisms are provided[17]; however, it has to be considered that these experimentations took place in a controlled environment and applying systems trained on the specifics of each individual selected tester: it is entirely unpredictable what might happen in a normal setting, under presence of more disturbing factors, and in case of broad unsupervised use.

Lastly, BCI systems are exposed to possible misuse and cyberattacks, which can easily result in intentional or unintentional alteration of their functioning[18].

The assessment of this risks' impact on fundamental human rights, is finally essential. In fact, even the use of an assistive or augmentative communication device capable of expressing a perfectly reliable individual's will must in fact be evaluated – for it to be granted a legal value - by balancing all the benefits (e.g, the right to communicate and self-determine) and risks (for the fundamental rights involved). This will be addressed in the following section.

4.4. A risk-based classification model and approach.

Based on the critical issues and key requirements as set out in the previous sections, this section proposes a self-assessment strategy to operationalize BCI technologies applied or potentially applicable to the context of legal relations

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[16] F. G. Pizzetti, "Brain-computer interfaces and the protection of the fundamental rights of the vulnerable persons", in A. D'Aloia, M. C. Errigo (2020), 291

[17] J. Xue, "Handwriting with brain computer interface" in J. Phys. (2021) Conf. Ser. 1865 042026; K. T. Huang, Z. B. Moses, J. H. Chi, "Advances in implanted brain–computer interfaces allow for independent communication in a locked-in patient, in Neurosurgery 80 (2017) 5, 30-31; P. Nuyujukian et al., "Cortical control of a tablet computer by people with paralysis", PLoS ONE 13(2018)11

[18] I. Olaronke et al., "Prospects and problems of brain computer interface in healthcare", CJAST, 29(2018)6, 1-17; Chaudharya, R. Agrawalb, "Emerging threats to security and privacy in brain computer interface", in IJASSR, Special Issue based on proceedings of 4th International Conference on Cyber Security, (2018).

and juridic self-determination, implementing methods of technology risk evaluation and management.

The proposal - standing at this stage as a work-in-progress developing approach - consists, in particular, in a risk-based BCIs classification model, which provides - for each item given (i.e., a critical issue) - the attribution of a progressive score (1;2;3.) according to increasing level of associated potential risk, where risk means the misalignment between the user's negotiating will and its BCI-mediated manifestation. The highest misalignment item-associated risk will be assigned a value of 3; the lowest will be assigned a value of 1 (TABLE I).

TABLE I.

ITEM	- **Risk[a] Level score +**		
	1 (low risk)	***2***	***3(high risk)***
Technique used and accuracy of brain signal acquisition	*<Accurate>*[b]	*<Acceptable>*	*<Inaccurate>*
Feature extraction method/s	*< >*	*< >*	*< >*
Machine-learning algorithm accuracy and traceability	*<Sufficient>*	*<Acceptable>*	*<Insufficient>*
Adaptive model and auto-correct method/s implementation and responsiveness	*<Adequate>*	*<Acceptable>*	*<Inadequate>*
Scalability and resistance to disturbing /interfering factors in uncontrolled setting	*<High>*	*<Medium>*	*<Low>*
Propensity to misuse	*<Low>*	*<Medium>*	*<High>*
Resilience to attack and security	*<High>*	*<Medium>*	*<Low>*

a. The risk is represented by the misalignment between the user's will and its BCI-mediated manifestation.

b. The words in brackets <...> represent the to-be-defined technical-legal parameter of reference by which to make the classification.

The model is addressed to developers and users of contracting BCIs, so that it can be of guidance in the design of these systems or in the adoption of appropriate-to-the-case mitigation measures or documentation practices. The model is also believed to be a useful tool for policy-makers to consider where they intend to intervene with an ad hoc regulatory framework guided by a balanced and proportionate horizontal approach that is limited to the minimum requirements necessary to address BCI-related risks, without unreasonably hindering or making excessively costly their technological development.

The research will proceed by defining for each level of risk related to a given item, a precise technical-legal parameter of reference by which to make the classification. A search and analysis of the principal scientific publications and studies related to the design and testing of BCI applications that are eligible for the proposed model will be conducted.

A different, but interconnected classification model might instead consider the level of impact of BCI applications on human rights and from an ethical and social sustainability perspective.

TABLE II.

Impact area	- **Ethical/Human rights impact score +**		
	1(low impact)	***2***	***3(high imp.)***
Application /domain	*<therapy>* [d]	*<recreational>*	*<human enhancement>*
User Safety	*<high>*	*<medium>*	*<low>*
Interface invasiveness	*Non-invasive*	*Semi-invasive*	*Invasive*
Potential harm (fundamental rights impact)	*<low risk>*	*<acceptable risk>*	*<high risk>*
Propensity to misuse	*<low>*	*<medium>*	*<high>*

c. The score represents the level of impact of a given BCI tool (from low to high) on the human rights involved as defined in each relative impact area.

d. The words in brackets <…> represent the to-be-defined technical-legal parameter of reference by which to make the classification.

The model proposed here (TABLE II) involves, in particular, an increasing scoring scheme (from 1 to 3) in proportion to the level of impact (from minor to major) on the human rights involved[19] and certain ethically critical areas[20]. The purpose of the model is to facilitate a risk-benefit analysis in the context of the human rights framework that can orient possible judicial decisions and policy choices aimed at balancing them fairly.

Indeed, the benefit/risk ratio is the ultimate prerequisite for BCI-communicative applications to be compatible with the legal system and for the individual's will expressed through their use to be considered of legal value. In fact, in general, the assessment and possible acceptability the risk represented is determined in relation to the possible benefits[21].

The research will proceed with the definition of all relevant "impact areas," meaning the fundamental rights and principles exposed to be either fulfilled or threatened by the use of BCIs.

To this end, for example, the right to self-determination and communication, as well as the right to mental and physical health and well-being or privacy and

[19] A. D'Aloia, M. C. Errigo (eds.), "Neuroscience and Law. Complicated crossings and new perspectives" (Springer, 2020)
[20] I. Olaronke et al., "Prospects and problems of brain computer interface in healthcare", CJAST, 29(2018)6, 1-17; A. Coin, M. Mulder, V. Dubljevic, "Ethical aspects of BCI technology: what is the state of the art?", Philosophies, 5 (2020)31
[21] M. C. Errigo, "Neuroenhancement and law", in A. D'Aloia, M. C. Errigo (2020),189

data protection, will be considered, now as justification, now as a limitation on the use of tools. Newly created rights and principles proposed by some scholars in response to the emerging issues of neurotechnologies will also be considered[22].

For each level of impact related to a given area, a precise technical-legal parameter of reference will be then defined to guide the classification. Example of such a parameter is, e.g., the definition, reconstructed on the basis of the prevalent scientific literature, of the difference between therapy (that could be defined, for example, according to some[23] as the use of BCI for treatment of individuals affected by diseases, disabilities or other impairments to restore their natural health status) and enhancement (which could be defined, on the contrary, as the use of BCI beyond what it is necessary to maintain or restore their natural health status).

[22]M. Ienca, R. Andorno, "Towards new human rights in the age of neuroscience and neurotechnology", Life Sciences, society and Policy, [2017]

[23] M. C. Errigo, "Neuroenhancement and law", in A. D'Aloia, M. C. Errigo (2020),189