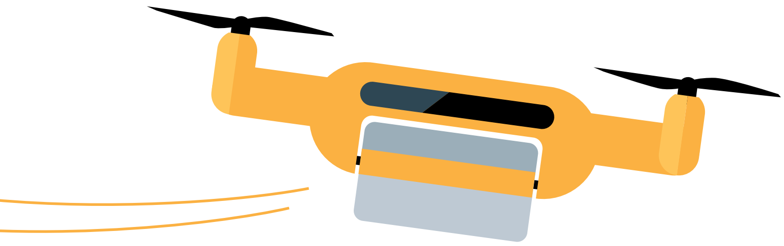

Stimulation through bioelectronics

Abridged version of the TA-SWISS study «Wenn Menschen ihren Körper mit Technik vernetzen. Grundlagen und Perspektiven nicht-medizinischer Bioelektronik»

TA-SWISS, the Foundation for Technology Assessment and a centre for excellence of the Swiss Academies of Arts and Sciences, deals with the opportunities and risks of new technologies.

This abridged version is based on a scientific study carried out on behalf of TA-SWISS by an interdisciplinary project team under the leadership of Dr. Anne Eckhardt (risicare GmbH, Zollikerberg). The abridged version presents the most important results and conclusions of the study in condensed form and is aimed at a broad audience.

Wenn Menschen ihren Körper mit Technik vernetzen. Grundlagen und Perspektiven nicht-medizinischer Bioelektronik

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Bioelectronics in a nutshell

Thanks to miniaturisation and flexible, but strong new materials, it is now possible to develop tiny sensors and measuring devices that can be worn on, or even implanted in, the body. Bioelectronic systems have been in use in the medical sector for many years in the form of cardiac pacemakers or implants for the hearing impaired. But a variety of non-medical devices and appliances are now also being brought onto the market that permit direct interaction between technology and the human organism. In the future, it could be possible for people to control computers, lighting systems, vehicles, drones, etc., intuitively via hand movements, muscle contractions or even thought processes. Bioelectronic systems could then be used to activate the brain and thus produce a calming or stimulating effect. It is non-medical applications of bioelectronics that are the focus of this report.

Opportunities …

Bioelectronic systems, including those of a non-medical nature, can have a positive effect on our health. They collect a quantity of physiological data that can motivate users to become more active and pay more attention to their diet, and they can also draw attention to potential health risks at an early stage.

Bioelectronics can be used to simplify the operation of various technical installations, and thus enables us to more efficiently manage everyday tasks.

Bioelectronics also enables us to immerse ourselves in virtual realities with all our senses. It not only intensifies gaming experiences, but can also be used as a teaching aid in that trainees can be guided through realistic exercises.

It is conceivable, too, that bioelectronic activation of the brain could give rise to calming or pick-up effects similar to those produced by tranquillisers or pharmaceutical stimulants.

… risks

Bioelectronic influences on the brain place in question our conventional understanding of what constitutes a human being. If stimulation of the brain can change our perceptions, desires or intentions, this touches on our notion that there is an innermost and permanent core of human personality.

Youths under pressure to perform could feel tempted to enhance their learning progress through bioelectronic stimulation of their brain. But the brain of an adolescent is not yet fully formed, and it is unclear whether modulation of nerve functions could have a detrimental influence on its development.

Physiological data collected by bioelectronic systems are sensitive. They not only disclose a great deal about users' state of health, but can also reveal their personal inclinations. Identified brain activity patterns could even permit conclusions to be drawn regarding personal intentions and attitudes, and this would be equivalent to a violation of the intellectual private sphere.

... and a few recommendations

Based on the findings from the medical sector, it is important to determine the impacts non-medical bioelectronics could have on developing organisms of adolescents, and especially on their brain. Unanswered questions could form the basis for comprehensive studies.

The question needs to be examined as to which regulations and guidelines relating to addictive substances could also be applicable to stimulation of the brain by bioelectronic systems, and whether – and to what extent – supplementary provisions would be required.

Another question to be clarified is whether a regulatory model needs to be developed for non-medical bioelectronics that meets the special requirements of this product category and promotes the innovative capacity of small and medium-sized companies.

The report, "When people network their body with technology: principles and perspectives of non-medical bioelectronics", was authored by a project group under the leadership of Anne Eckhardt (risicare GmbH, Zollikerberg). The interdisciplinary study is based on a comprehensive analysis of the scientific literature, plus interviews with specialists and practitioners. Two interviews with youths provided an insight into the viewpoint of the particular age group that will have to engage with bioelectronic innovations in the future.

Use of electricity on human beings

In ancient Egypt already, people were astonished by the ability of stingrays and electric eels to capture their prey with the aid of electric shocks. After centuries of research, scientists have discovered ways to use electricity as a means of communication between technical components and organs of living beings.

In the second half of the eighteenth century, scientists and the general public were enthralled by electricity. Following the invention of the first capacitor – the Leyden Jar – in 1746, members of the upper classes amused themselves by giving themselves electric shocks and marvelling at artificially created flashes of lightning. Before long it was discovered that electricity could be used not only as a source of amusement, but also as a means of saving lives. In 1794, the Royal Humane Society in England reported a case in which a three-year-old girl, Sophia Greenhill, had fallen from a window and been declared dead by a surgeon from a nearby hospital and a pharmacist, but was subsequently revived through the use of electric shocks. This is the earliest written evidence of the use of an improvised defibrillator (though of course it was not called this at that time).

Luigi Galvani was the first scientist to realise – on the basis of experiments conducted initially on frogs and later on warm-blooded animals – that it was not only electricity applied to the exterior of the body that caused limbs to twitch. In his work published in 1791 on the effects of animal electricity on the movement of muscles, the physician, biologist and natural scientist from Bologna was able to clearly demonstrate from his experiments that animals possess their own internal electricity. Galvani speculated on diseases that could be attributable to imbalances of energy flow, and on the possibility of using electricity for therapeutic purposes.

From measurement to therapy ...

In the 1930s, medical and electro-technology specialists began to develop appliances such as defibrillators and pacemakers that bring a vital heart muscle that has become arrhythmic back into a rhythmic state. The first pacemaker was fully implanted into a patient's body in 1958. The function of a pacemaker is controlled by signals emitted by the heart; thus the body and the device communicate with one another so that the stimulation frequency is adjusted according to immediate need.

In the late 1960s, with the aid of a cochlea implant it was possible to largely compensate loss of hearing in certain cases. The implant stimulates the auditory nerve electrically and thus triggers personal auditory perceptions; in intensive training sessions, people with these implants learn how to allocate the new signals to established hearing patterns.

Towards the end of the 1980s, the treatment of the brain with electric stimuli was introduced, initially for patients suffering from uncontrolled tremors. Today, deep brain stimulation is approved for the treatment of various problems, including movement disorders such as tremors or Parkinson's, certain forms of epilepsy, chronic pain, depression, etc. Here, electrodes are implanted in the brain and are controlled via a pacemaker inserted beneath the skin near the clavicle.

… and from therapy to optimisation

In the past few decades, the US armed forces have been carrying out pioneering research into ways in which the brain can be influenced through electromagnetic radiation emitted from a source located outside the skull – for example, in headphones or a helmet. Through the use of transcranial magnetic stimulation, the US army hopes to enhance the learning and response capacity of its soldiers, as well as to ward off fatigue electromagnetically. This procedure is also used in the healthcare sector to treat patients suffering from depression and as therapy for stroke patients.

With the progress of digitalisation, there is growing interest in the simple and intuitive use of electronic devices. How would it be if computers and drones could be controlled by feelings, or if mere thought were to suffice for dimming lighting or changing a music programme? Such notions could become reality thanks to bioelectronics – the term applied by the scientific community to refer to the application of microelectronic systems both on and inside the body, which facilitate direct exchange or communication between organisms and electro-technical appliances.

Unidirectional, bidirectional, self-contained

Electronic components can interact in different ways with the living beings fitted with them. Unidirectional systems act in only one direction, either from the organism to the device or vice versa. Most of these are used for recording measured biological variables or influencing specific bodily functions.

By contrast, bidirectional systems enable a reciprocal exchange between the organism and technology; an example here is the use of exoskeletons that support people during manual labour.

In addition to the direction of the signals, the way in which the overall system is controlled plays a role. In the case of open-loop systems, control is carried out independently of the targeted effect or feedback; the targets are specified in advance and the system ensures that they are met. As a rule, it is the user who controls this type of system.

On the other hand, closed-loop systems adapt themselves autonomously to the organism, i.e. with no external control. Implanted insulin pumps, which constantly monitor the blood sugar levels of diabetics and adjust the release of insulin as necessary, are an example of this type of system. But to date these are only used in the healthcare sector; as yet, no non-medical variants of closed-loop systems are available on the market.

The focus of the TA-SWISS study summarised here is on non-medical bioelectronics, which is currently primarily used to enhance people's well-being and performance, and to simplify the operation of technical appliances. Entertainment – for example, spending time in a virtual environment – is still a secondary aspect. At present, it is wearables such as fitness wrist bands, smart watches and virtual reality headsets that are predominant.

Impulses transmitted via the nerves

For many people, wearables are already an integral part of their daily life. The range of non-medical bioelectronic products and their uses is constantly increasing: these include fitness trackers, which measure athletic performance but can also evaluate recovery and sleep periods; smart watches, which analyse a broad variety of physiological influencing factors; and special work clothing fitted with sensors that measure physical strain and provide support during particularly strenuous activities.

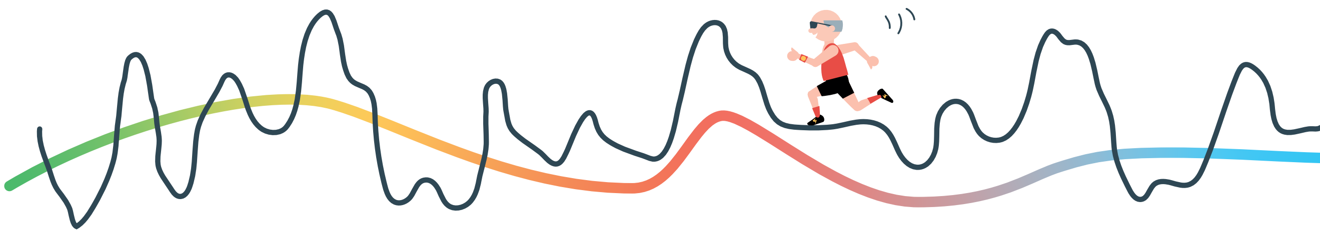
From an app for controlling external services by mere thought processes, through to a series of games designed to release children from anxiety, and apps for managing stress and improving attentiveness, the list of products from outlets such as NeuroSky – one of many companies that pride themselves on identifying mental states in real time – is a lengthy one. These apps all have one thing in common, namely that they have to be used in combination with a headband that measures electrical activity in the brain and matches the effect of the app with the detected brain waves.

Self-monitoring devices

While the neuro-headsets referred to above might appear somewhat futuristic, smart watches and fitness trackers in the form of wrist bands, rings or pendants have long since become part of everyday life. These devices not only count steps, they also measure the pulse as well as a broad range of other parameters such as blood pressure and body fat percentage. Evaluation software often provides tips for more effective training or encouragement to keep going. Smart watches and fitness trackers are the most basic type of bioelectronic systems and are classified "Type 1" of seven defined in the study: their signals are only transmitted in one direction, from the wearer to the measuring and analysis device. It is up to the users to decide whether or not they want to share their data.

There is already a wide range of attractive products on the market that are designed for different user groups and generally speaking are simple to use. Progress is also being made with respect to the utilised materials. For example, research teams are focusing on the development of special inks for tattoos, which could pave the way for bioelectronic tattooing at some point in the future.

Sensors are becoming increasingly accurate, and the risk to wearers of a Type 1 device is negligible. However, challenges remain with respect to the handling of personal data.



Patch to boost performance

Type 2 bioelectronic systems go a step further than smart watches, etc., in that they influence body parameters. The "Feelzing Energy Patch" is one such product in this category: it is placed behind the ear and is designed to stimulate the vagus nerve, which is involved in the regulation of the majority of organs. The stimulation of this nerve brings the user of the patch into a state of "calm alertness". According to the product advertising, the patch increases concentration capacity and facilitates better sleep.

The "Feelzing Energy Patch" functions unidirectionally, i.e. stimulates users regardless of their current state. The users decide when they want to apply the patch and also have the option of setting the decisive parameters. One of the strengths of devices of this type is that they are easy to control and convenient to use. They have the potential to substitute active pharmacological substances such as stimulants and tranquillisers, the use of which can often result in undesirable side-effects. One of the weaknesses of Type 2 systems, however, is the current lack of evidence of their efficacy.

Adjusting lighting with the eyelids

Type 3 bioelectronic systems are designed for intuitively controlling external appliances. The signals are transmitted unidirectionally from the organism to a computer, vehicle, drone, or even room lighting: instead of using a keyboard or other control unit, tensioning a muscle or blinking is all that is required in order to tilt a window, for example, or defeat the monster in a video game. In this category, jackets have already been developed for controlling drones through body movements, as though the user were a bird in flight. The development of lenses that recognise when the wearer becomes tired based on the movement of the eyelids, and thus intensify the lighting in the room, is also conceivable.

Intuitive process control is simpler to learn than the operation of conventional control devices. Thus the main attraction of devices in this category is that they can be operated easily and intuitively. In addition, they are able to autonomously detect whether, for example, a change of background music is required, or the room lighting needs to be intensified, thus eliminating the need for the user to make the corresponding changes manually. However, systems of this type are not entirely free of risk: for example, liability issues arise if an intuitively controlled drone should crash, and for users neither physiological nor mental longer-term dependencies can be ruled out. Furthermore, there is the risk that users could become too closely tied to the providers of such systems and thus be reliant on their support. And here too, guaranteeing data security remains a challenge.

On-demand support

Exoskeletons were originally designed to enable paraplegics to walk again, but are also used by armed forces: supports fitted with joints and motors help soldiers carry heavy loads and march over long distances. In the meantime, exoskeletons are being used in the work environment. For example, workers at a large German automotive factory wear an upper body exoskeleton weighing around two kilograms in order to relieve the burden on their shoulders and arms when they assemble vehicle bodies on a production line for hours at a time.

Exoskeletons are classified as Type 4 bioelectronic systems. They function bidirectionally and are open-looped, i.e. their function is adjusted on the basis of predefined parameters. The main strength of these systems is that they can be controlled by their users. Furthermore, the stimulating and supporting effect adjusts itself to the physical condition of the wearer and the predominant circumstances. However, the repercussions on the wearer's image could prove to be somewhat problematic: how authentic is someone whose peak performance is attributable to bioelectronic support? And there are also questions regarding liability if an accident should occur under the influence of this type of system.

Activation of the vagus nerve

The apps available from NeuroSky (see above), which are used together with a headset, belong to the bioelectronic systems defined as Type 5 in the study. These closed-loop systems have a calming or activating effect on the organism depending on the measured brain waves. Many of their uses are based on the stimulation of the vagus nerve.

The head is especially suitable for the use of bioelectronic applications: this technology can interact with the brain via headbands, caps or headsets, and can also procure data regarding the user's hearing and eyesight thanks to smart headphones and glasses. Stimulating headsets such as those available from NeuroSky, Emotiv and other suppliers function bidirectionally and are closed-loop systems. The effect of these devices – calming or stimulating – is based on the measured brain waves.

Because their function is based on physiological signals received from the user's organism, Type 5 systems could be conveniently used. Users can enhance their attentiveness as required and thus improve their performance or increase their capacity for relaxation and recovery. However, there are uncertainties concerning the degree of acceptance of these systems.

Compared with Type 4 systems, the devices in this category are designed to function on a differentiated basis that is precisely adapted to the organism. This means that their users have to be prepared to accept the loss of autonomous control. There is also the risk that systems of this type could be hacked and the user could thus be manipulated or harmed.

Extended reality

Type 6 bioelectronic systems extend sensory perception. Research is focusing on smart glasses or contact lenses that display additional information about objects that enter the user's field of vision. With the aid of gloves, suits and helmets equipped with sensors, it is possible for users to immerse themselves entirely into an artificially created environment. They can imagine they are on a beach, hear the waves, smell the sea water and see the seagulls, for example, or are in a sports car on a winding road, can feel the motor's vibrations and experience the centrifugal force. The strength of these systems is that they respond to the user's movements. They are primarily used in gaming, but could also be useful for facilitating a virtual tour of a holiday resort, for example, or for visualising a planned residential zone. They are mainly designed as wearables, but there are also examples of implants.

A broad variety of control methods are available with varying degrees of autonomy for the user. Thanks to the fact that the sensors incorporate the user's movements, these devices provide a convincing and complete experience of virtual realities. Their weaknesses are that little is known to date about their efficacy and security, and that with the use of implants, which enable new sensory impressions, certain health risks already exist as a result of the required surgical procedure. Repercussions on the user's psyche and self-perception are also conceivable.

Full control

Type 7 bioelectronic systems can also be used for monitoring purposes. One of the potential applications under consideration concerns care of the elderly, for example locating people suffering from dementia who have wandered off and gone missing. The use of neuro-headsets in order to control the attentiveness of pupils in the classroom, or bioelectronic gloves that not only protect workers' hands, but also measure their performance on the production line, is also conceivable.

Here the autonomy of the wearers of such devices is influenced, especially if they are not using the device voluntarily, or because they are only able to influence it to a limited extent or not at all. The benefits of these systems are entirely on the side of the monitoring entities, who in theory have the ability to efficiently control a large number of people. If the device is in the form of an implanted chip, it cannot be lost or discarded.

Blending biology and technology
A cyborg is an organism that is enhanced or controlled by a technological device. Neil Harbisson, a musician and avant-garde artist, was the first person to persuade a government – the British – to officially recognise him as a cyborg. He was born with a form of colour-blindness and could only see the world in grey shades. To compensate this deficit he wears a device on his head that enables him to perceive colours as sounds. Detected colours are recorded by a special sensor attached next to his eye. A chip then converts the colour frequencies into audible ones and enables him to interpret them. Harbisson also has an antenna attached to his skull that receives electromagnetic radiation and can convert it into audible vibrations. In 2012, he extended the bandwidth of his perception into frequencies in the infrared and ultraviolet ranges, as a result of which he now "sees" more than people do with their eyes.

Making plastics organic

The electrical properties of the cells and tissues of living beings, as well as the chemical composition of sweat and tears, contain a large quantity of data. Thanks to new materials optimally adapted to the organism, it is possible to obtain a great deal of information about a person's physiological state from the skin and various bodily fluids.

Every bioelectronic product essentially comprises three components: a measuring device that converts an input variable into a predefined output variable (i.e. a measuring transformer), electrical connections and electronic switches. Each of these components can be conceived and manufactured from a broad variety of materials, depending on the corresponding production process. Thus one type of device primarily measures ion flows into and out of the cell, and the electrical status of tissues, while a second type measures gases such as oxygen or carbon dioxide, and a third type analyses the content of minerals, lactic acid and uric acid in sweat.

The various measuring transformers in turn are able to process (bio)chemical, acoustic, optical and electromagnetic signals, as well as thermal and mechanical signals such as acceleration, pressure and current.

Life needs pliability

Combining the different components of a bioelectronic system is a particularly challenging task. If these devices are to be worn comfortably on the body or be implanted inside it, fixed wiring is not suitable. The requirements in terms of design of the system and choice of material are also demanding: whereas biological communication is based on ions, electrons are predominant in the field of information technology. Switching circuits and electronic devices have to be protected from moisture in order to prevent them from disintegrating, but the bodies of living beings consist of a high proportion of water and secrete moisture.

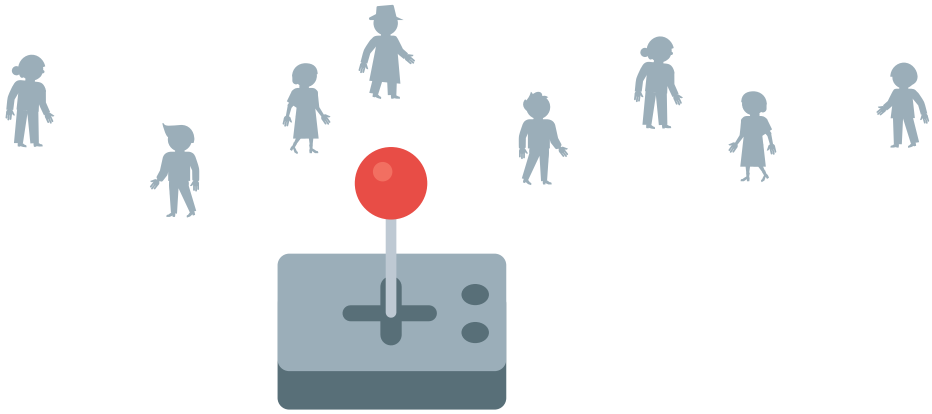
Today, numerous fields of research are investigating ways in which the incompatibility between bioelectronic systems and their targeted tissues can be overcome. And researchers are coming up with solutions: the first to some extent pliable display devices are now available, and bioelectronic systems miniaturised to the tiniest dimensions are being embedded in flexible or soft material layers that are also washable and watertight.

The development of hydrogels (water-insoluble plastics that are able to bind moisture) is a promising solution. These substances are readily compatible with living organisms and can be used as contact lenses or pliable implants. They can also be used as sleeves of bioelectronic components or in the form of hydrogel-electronic systems. Initial prototypes have been developed and the results of tests appear to be highly promising.

Thin, soft and flexible bioelectronic devices that transmit signals wirelessly enable a high degree of comfort for the user, and this can be expected to facilitate wider acceptance of the many gadgets.

Remote controlled insects

In April 2015, a research group from Texas A&M University published a scientific article that was also cited in daily and weekly newspapers. They had succeeded in fitting a cockroach with electrodes, a printed circuit board and a battery in order to control it with electrical impulses. To accomplish this, they stimulated nerve nodes that coordinate the insect's movement. The researchers were able to control its legs and move it in any desired direction. The higher the frequency of the electrical impulses, the more precisely the insect can be steered round corners. Apart from pursuing their research interest, the team also examined potential social benefits of their work. Here, for example, remote controlled cockroaches could be used for finding earthquake victims, because the insects can enter tiny gaps in rubble. Today, kits for assembling "bioelectronic cockroaches" are available on the Internet, and detailed tutorials for their "construction" can be viewed on YouTube. In the meantime, researchers have also succeeded in remote-controlling rats with the aid of bioelectronic implants. The aim here is to also use the rats for rescue purposes, and in addition they can help with the defusing of land mines. But many people have voiced their criticism over the use of live animals. They doubt whether the bioelectronic control of animal behaviour is reconcilable with the dignity of living beings as laid down in the Swiss Federal Constitution and elsewhere. But this kind of manipulation of animals could perhaps be justified through a legitimate interest, for example if it can save human lives. In any case, remote control of rats for mere entertainment purposes would be prohibited under Swiss legislation governing the protection of animals. But because the legal provisions do not apply to insects, influencing them with bioelectronic systems is not unlawful here.



Bioelectronic consumer products: the bright promise

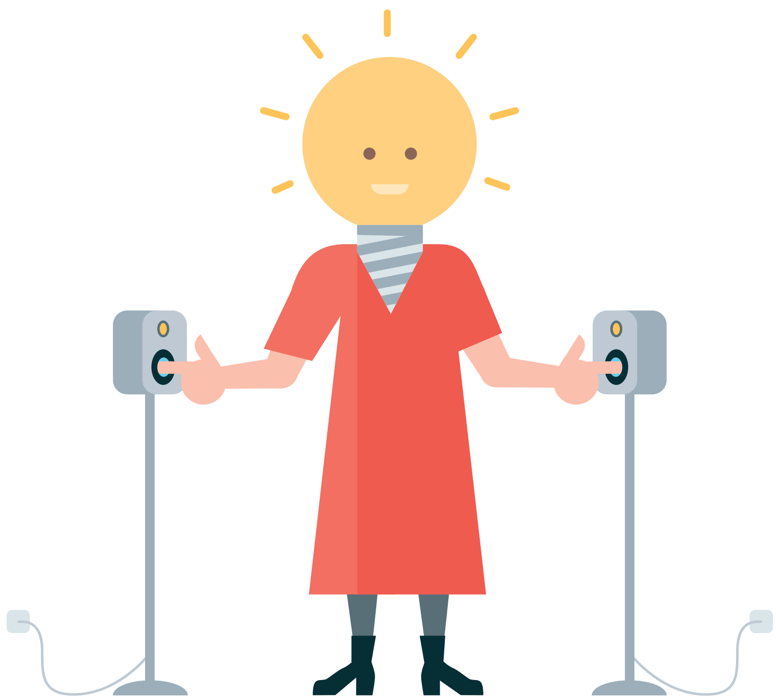
Medical products may only be brought onto the market after they have been rigorously tested and their effectiveness and safety have been firmly established. Although bioelectronic systems used in sport or for entertainment purposes make use of findings from life sciences and medical research, they do not have to be subjected to in-depth tests.

Bioelectronic devices for use in healthcare are the precursors for non-medical bioelectronics. The fact that transcranial (i.e. passing through the skull) magnetic stimulation is able to counteract depression has been established through scientific studies, as has its positive effect on certain developmental disorders of the nervous system of adolescents. This research thus provided certain reference points for the effective application of bioelectronics for non-medical purposes. Transcranial magnetic stimulation should therefore be able to prompt the brain to perform certain tasks more quickly and precisely.

High requirement of precision for consumer products

Companies that contact their customers directly and advertise bioelectronic consumer products cite apparently scientific evidence as sales arguments. But very few of these companies have in fact carried out studies on their products. Most of them simply rely on existing laboratory findings which are barely applicable to the everyday use of such products.

Numerous companies claim that, thanks to neuro-feedback, their products enhance attentiveness and concentration, relieve stress and foster recovery. Some also promise improvements of cognitive and athletic performance, as well as enhanced learning ability and memory capacity. However, the design of consumer products does not permit measurements of brain activity that are even remotely as precise and reliable as measurements carried out by medical devices. Furthermore, only very few compa-



nies have scientifically studied the efficacy of their products, and instead have merely interpreted the available data in a greatly simplified form. Thus the evidence is lacking that activity patterns in the brain can be identified from the detected brain waves – in other words, the prerequisite for fulfilling the promises made in their advertising. A survey of more than 300 people who had purchased a transcranial magnetic stimulation device revealed that 40 percent of the respondents do not use these products regularly, mainly because of their lack of effect.

Feedback from customers who purchased a neuro-headset from Amazon paint a clear picture: in addition to the lack of instructions for use (or the availability of manuals in English only), complaints include painful pressure on the skin, frequently interrupted connection between the headset and the evaluation app on their mobile phone, and the app's huge appetite for data.

Malleable brain

Although the effects of neuro-headsets do not match the claims cited in the advertising, it would be wrong to conclude that their effects are harmless. The most common negative effect is a discomfort in the part of the head where stimulation is initiated. It is already well established that spending lengthy periods (i.e. more than an hour) in a virtual environment can cause various physiological disorders. Cyberkinetosis is a condition that leads to symptoms such as nausea, dizziness and sometimes vomiting, headaches, problems with visual acuity, recognition of objects and the ability to see colours. These symptoms are usually temporary. The interaction of perception and movement (sensorimotor function) can also be temporarily affected. Pregnant women, migraine sufferers and people suffering from anxiety are especially at risk of developing cyberkinetosis.

Adolescents could fall into the temptation to use bioelectronic products such as patches purported to stimulate attentiveness (cf. Box on page 15) in order to be more successful at school. Yet it is precisely the effects of the use of brain stimulation devices by adolescents that have barely been studied. At this age, the nervous system is still developing and the brain is correspondingly malleable. The cranial bone of adolescents is also thinner than that of adults, and this means the stimulation could penetrate more deeply into the brain.

Children and youths between the ages of nine and 14 are a major target group for games involving extended or virtual reality. Recent studies indicate that young children have difficulty in maintaining their balance and controlling their comportment if they enter into a virtual world full of visual stimuli. Experts are also debating how interactive new technologies can influence the process of identity formation of young children and their autonomy and capacity to act.

Self-knowledge data

No negative impacts on health are to be anticipated from the use of widely disseminated gadgets worn as armbands or medallions in order to monitor physical activity. On the contrary: they foster a health-conscious lifestyle by encouraging users to carry out more sports activities.

There are however certain risks associated with the handling of the collected data. If they are shared on the platforms of the providers, the possibility exists that they could be analysed and misused by third parties. With regard to neurological data there are even greater concerns: neurological characteristics can be used, for example, for obtaining indications of personality traits such as sexual orientation or a person's current emotional state. Furthermore, the risk that a user's behaviour could be manipulated via neuro-stimulation cannot be ruled out.

Invasive bioelectronics and surgical risks

At present, the majority of bioelectronic systems are worn next to the body, but in future the use of bioelectronic implants could increase. The risks that can arise in connection with the handling of personal data and the side-effects of electronic stimulation would be supplemented by those associated with surgical intervention. When a foreign object is implanted, there is always a risk of infection, scarring or undesirable adjustment effects in the nervous system. In addition, the body's defence reaction could influence the functionality of the implant.

Nerds as present-day pop stars

Whether in the form of data glasses, fitness armbands, smart watches or even bioelectronic tattooing, numerous wearables are available today that meet a broad variety of needs and are popular among the respective target groups. But how bioelectronically extended perception affects users' self-image over the long term is not yet clear.

Until only a few years ago, someone who constantly checked their mobile phone or ceaselessly played with another gadget was quickly labelled a nerd. In the meantime, constant consultation of fitness trackers and sport apps has become socially acceptable. In 2020, around 10 percent of the Swiss population possessed a fitness armband, smart watch or similar device. Wearables are a growing trend: in the same year, the sale of these devices rose by 7 percent. Then there are mobile phones, which thanks to apps can be used to collect physiological data. More than 90 percent of adults in Switzerland possess a smartphone.

Bringing out the best in ourselves

In today's performance-oriented society everyone is expected to bring out the best in themselves. Thus the constant monitoring of performance and condition is resulting in two social trends: healthy lifestyle and self-optimisation.

In addition, the use of bioelectronic devices is being fostered through the democratisation of science. The existence of movements such as Citizen Science is encouraging a broader acceptance of science and technology, and more and more people are becoming accustomed to the management of data. New communities are being formed, whose members support one another with the collection and interpretation of data. Platforms supporting the exchange of data are also being provided by suppliers of wearables in order to pursue their own commercial interests: thanks to user data, these companies are able to optimise their products and market them more effectively. The process of digital transformation that is increasingly penetrating daily life is additionally supporting the advance of bioelectronics.

Furthermore, findings from brain research and their dissemination in popular science magazines or science-fiction literature are giving rise to an altered perception of the brain as a malleable and optimisable resource. Consequently, products that claim to enhance cerebral performance are growing increasingly popular.

Where does self-perception end and technology take over?

The use of bioelectronic devices can have consequences in terms of perception, including self-perception. For example, someone who could succeed in perceiving ultraviolet or infrared radiation (in other words, see colours beyond the "normal" spectrum) thanks to the use of a bioelectronic implant would live in their own world. Immersion in virtual worlds that are populated by perfect-looking celebrities and influencers whose physical flaws have been airbrushed out and who present themselves in luxurious surroundings, could influence a person's self-perception and the nature of their own identity. This is an issue that is currently being debated in the context of children and youths in particular.

Today, the majority of wearables are in the form of small devices that are worn next to the body and collect physiological data. This also gives rise to issues concerning data protection and control of the device: if the user is able to control the device and manage the data, this increases the level of its acceptance. Inherent problems arise if bioelectronic devices interact with the brain, which at least in our culture is regarded as the seat of our personality and thus of our intelligence, discernment, personal identity and autonomy.

Bioelectronic "crutches"

The notion according to which human beings as "creatures of deficiency" can overcome limitations through implanted technical aids, is presented in numerous novels and films and has reached a wide public via mass media and the Internet. Various companies are fervently endeavouring to viably realise this concept. Ideas range from additional sensory organs through to an "outsourced" memory: prostheses, implants or systems controlled via an app become an integral part of the human perception apparatus so that corresponding information is no longer exclusively stored in the brain, and instead is partially entrusted to a technical aid or a platform on the Internet. Thus, not only do the technological and biological systems begin to merge, but the question also arises concerning the importance that will be attached to our brain in terms of self-image and interpersonal exchange.

While some experts regard the use of bioelectronic "prostheses" as a means of enhancing personal autonomy and an opportunity for remedying "shortcomings", others fear they could restrict individual self-determination. People could come under pressure to enhance their performance through the use of bioelectronic aids, and the risk also exists that they could unintentionally or unknowingly consent to the interpretation of their neurological data. In addition, the argument is being put forward that mental laziness could be fostered if data would no longer have to be called up via the memory, and instead were to be outsourced to a bioelectronic system. The use of bioelectronic devices is therefore double-edged and can be regarded as both an opportunity and a risk for the autonomy of the individual.

From an ethical point of view, it is important that bioelectronic aids are distributed equitably. If the use of performance-enhancing gadgets is reserved for only a small portion of the population, this would contradict the principle of equitable access. People should also not be discriminated against if they voluntarily choose not to use bioelectronic aids in order to remedy physiological deficits – or cannot afford to purchase such a device.

Fictitious "FocusUself" application – a thought experiment

FocusUself is a fictitious attentiveness stimulator that can be purchased in pharmacies or electronics outlets. Since its use is only licensed for people over 25, proof of age is required in order to purchase it and a corresponding declaration must be signed. FocusUself consists of a reusable patch that is affixed to the head, plus an evaluation and control element that functions via a smartphone app. The recorded data are stored and analysed on an Internet platform. The factory default setting is for automatic control and analysis, but users have the option of switching this off. The stimulator is used in order to maintain or enhance performance capacity. It is often also used in order to improve the quality of experience during outdoor activities, when travelling or during gaming. Various side-effects such as dizziness, heightened irritability, altered perception capacity, feelings of anxiety, etc., during its use have been documented and are cited in the product description. In some areas, for example scientific and other creative professions, there is strong social pressure to use FocusUself. And some parents use the patch in an effort to improve their children's learning capabilities at home. On the other hand, youths buy the patch on the grey market in order to enhance their performance at school and while gaming.
This fictitious example shows how difficult it is to restrict the use of such gadgets. Not even the specification and verification of an age limit can guarantee that a given device will only be used by the defined group of people. From an ethical point of view, importance has to be attached to the question whether the frequent use of FocusUself has an influence on individual wishes and preferences, and thus on social relations. Should this be the case and these changes were to persist after the patch has been removed, then FocusUself would lead to a qualitatively new form of impairment of personal autonomy; and individual continuity, which is understood to be the core of personality, could also be at risk.

From an idealistic vision to viability calculation

The development of bioelectronic systems is being expedited by medical research, but many companies that are active in the medical sector are also bringing non-medical bioelectronic devices and applications onto the market. Other bioelectronic innovations are being contributed by technology visionaries.

In Switzerland, several funds invest in promising pharmaceutical and medical innovations, and they contribute amounts of up to 10 million Swiss francs to aspiring companies. Bioelectronics thus enjoys a positive status here. Swiss universities and colleges of technology are well positioned in the fields of life sciences and information technology, including the development of games. In addition, various national research programmes and projects include bioelectronics in their activities, though here the main focus is on medical applications.

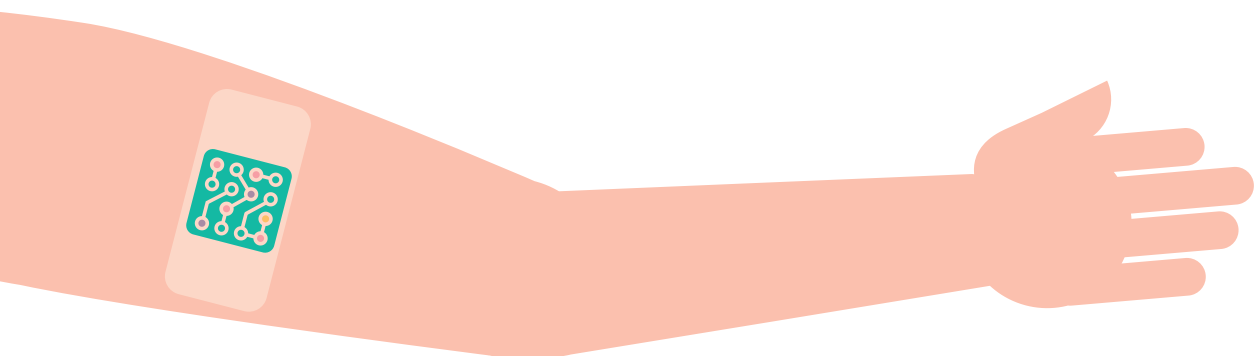
Utopians with an eye on profit

Whereas research programmes in the public sector focus on medical applications, in the private sector the situation is very different. Up until 2019, Elon Musk – who above all is known for his visionary activities in the fields of terrestrial and cosmic mobility – contributed 158 million US dollars to a company called Neuralink, whose activities include the development of bioelectronic implants for the brain. Initially the focus is on medical objectives, but later its aim is to use its neuro-prostheses for enhancing the capacity of the brain.

Mark Zuckerberg's Meta is another international heavyweight. His company is not only working on a human-to-computer interface, but is also developing a "metaverse" – a new extended reality that combines elements of the real world with fictitious content and is intended one day to play a major role in our daily lives. The metaverse is being developed in Meta's Reality Lab. To date, Zuckerberg has invested around 10 billion US dollars in the development of his artificial cosmos.

Switzerland at the point of transition from medical to non-medical bioelectronics

Switzerland is home to MindMaze, a start-up that is working on neuro-rehabilitation systems that can be used in clinics and for the continuation of recovery at home. It was established in 2012 and benefited from start-up support from the Gebert Ruf Foundation. Via video recordings, sensors that record movement patterns and measurements of brain waves, its system collects data that are entered into a training software which works intensively with virtual realities. Recently, MindMaze has been carrying out research on pain management and intends to market products directly to consumers. In 2015 already, MindMaze presented its software for computer games, and in the following year it achieved the status of a "unicorn", i.e. a start-up valued at more than a billion US dollars.



Aleva Neurotherapeutics can also be regarded as a domestic company because its main investors are domiciled in Switzerland. To date they have invested 52 million US dollars in this company, which is focusing in particular on deep brain stimulation for patients suffering from Parkinson's and tremors. Idun Technologies (a spin-off from the Federal Institute of Technology, Zurich) is developing headphones for monitoring the brain via the ear canal and recording eye and jaw muscle activities. It is focusing on recording and interpreting the data, and can, for example, support the monitoring of epilepsy patients. It is receiving support from Sony (including financial contributions). Other companies with bioelectronic products in their portfolio and which are active in Switzerland or even have their head office here, include Dynavisual, Neurosoft Bioelectronics and Onward Medical. These companies focus on medical applications.

The textiles industry is also opening up opportunities for bioelectronics. Here, companies could integrate a variety of attractive functions into sportswear, protective clothing and other special textile products. However, the necessary cooperation between the IT and textiles sectors has not yet become sufficiently established. In Switzerland, the development of non-medical products is also being hampered due to the fact that existing regulations and structures are primarily oriented towards medical bioelectronics.

Shared responsibility between humans and technology?

In the view of Italian Renaissance philosopher Giovanni Pico della Mirandola, it is freedom of will that is the distinguishing characteristic of humankind. But is this characteristic still intact if our brain is stimulated electromagnetically? Bioelectronic influences on the brain could change our understanding of what constitutes a human being, with implications for our actions and their legal consequences.

We can only be found guilty of an offence or causing damage if we can be held culpable. The prerequisite for this is that we have to be able to exercise our free will and judgement. But what is the situation regarding these capabilities if bioelectronic brain stimulation influences our sensory impressions and aspirations? If people can increase their performance capacity through neuro-stimulation, the possibility cannot be ruled out that they could pursue other aspirations and express a will that differs from the "unaltered normality". From this perspective, bioelectronics leads into controversial legal territory in that it touches on the question of what truly constitutes a human being.

When technology causes interference

Article 16 of the Swiss Civil Code cites a variety of conditions that interfere with the ability "to act in a reasonable manner": mental disability, intoxication, psychological disorders, childhood. Bioelectronic influences could give rise to effects similar to those conditions cited in the Civil Code, and thus reduce a person's ability to exercise free will and be held culpable.

Questions concerning liability do not only arise in the context of use of a bioelectronic device, however. Compensation claims could also be asserted against the manufacturer of such a gadget. If, for example, a person fitted with an exoskeleton unintentionally makes a sweeping arm movement and breaks a valuable vase or even injures someone, who is liable? Questions of liability also arise if a bioelectronic device has an adverse effect on the user. In accordance with product liability legislation, the manufacturer is always liable for harm caused by a faulty product. But in view of the complexity of bioelectronic systems, it is difficult to prove that the harm was caused by a fault in the system rather than its improper use.

From both an ethical and a legal perspective, those bioelectronic systems are especially problematic that function autonomously, i.e. independently of any decisions or actions on the part of the user. Where free will is replaced by technological automation, it is also necessary to clarify the question of liability if the product does not function correctly.

Protection of data and privacy

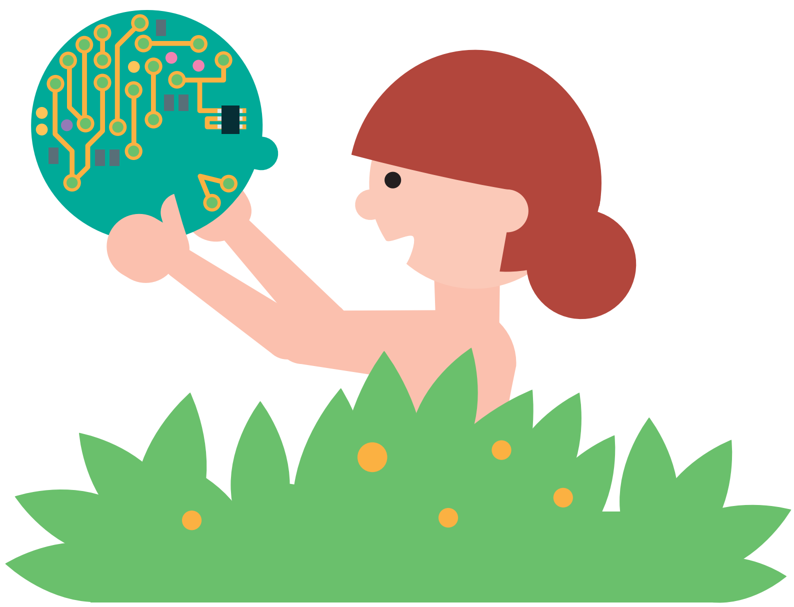
If a bioelectronic system identifies and acts on energy flows in the brain, this touches on the user's innermost being. It is therefore essential to protect the identified and recorded neurological data. Specialists refer to this risk as "brain hacking". If unauthorised persons were to gain access to a bioelectronic implant, it is conceivable that they could obtain all sorts of sensitive information, including about the user's most personal predispositions, and could also control or even manipulate their actions.

Some experts are therefore calling for a specific core of human personality to be protected under constitutional law, while in view of the developments in the field of neuro-technology, others are advocating for the protection of not only the right to mental self-determination, but also of the right to the mental private sphere, mental integrity and mental continuity.

New interpretation of "personality"

In the medium term, the merging of humans and technology could result in the need to adapt the legal interpretation of "personality" to the changed circumstances. Here, for example, the colour-blind artist Neil Harbisson succeeded not only in having bioelectronics recognised as an integral part of his body, but also in having the device depicted on his passport photo. With regard to bodies equipped with and enhanced by technological devices it could become necessary to introduce a new normative category called "Engineered person" – a move that would deviate from the existing legal opposites of objects (i.e. property) and people.

> In order to perform their various functions, bioelectronic devices rely on a broad range of personal data that they collect autonomously. In view of this, the legislation governing bioelectronics will have to attach sufficient importance to the protection of sensitive data. Because similar issues arise in the context of other wearables and have already been dealt with in depth in the TA-SWISS study, "Quantified Self" (2018), the topic of data protection has not been closely re-examined in the present study.



Exploiting potentials without obscuring the risks

Until now it has mainly been specialists who have concerned themselves with bioelectronics. But the time has come for initiating a broad-based discussion on this topic: the use of bioelectronic systems is now beginning to spread into our daily lives.

The future development of non-medical bioelectronics will affect the fundamental values of our society, as well as the world of science, the economy, the healthcare system and the environment. The recommendations derived from the study target the corresponding fields of action.

Neither rapturous enthusiasm nor rejection

The field of non-medical bioelectronics is currently welcomed with rapturous enthusiasm or else rejected. Distorted views – regardless in which direction – prevent a professional evaluation of the potentials and risks that non-medical bioelectronics opens up for science and the economy, and ultimately for users. Readily accessible and comprehensible means of communication such as videos and podcasts, alongside lectures and discussion events, could encourage objective debate among the general population.

Learning the lesson from addictive substances

Bioelectronic influence on the brain can give rise to similar effects to those resulting from the use of addictive substances or psychoactive medicaments. A comparative study should be carried out in order to ascertain which regulations and recommendations concerning the use of psychoactive substances could be applied to the use of bioelectronics.

Special protection for adolescents

The improper use of bioelectronic devices could potentially result in health problems. The consequences of improper electronic stimulation of the brain are particularly difficult to assess. Youths are especially at risk because their developing brain is still malleable and could become permanently influenced by electronic impulses. Based on findings from the medical sector, a study should set out to identify the potential long-term effects on the organism – in particular the brain – of adolescents and, if necessary, form the basis for further investigations.

Rendering the abstract tangible

The efforts of scientists from a broad variety of disciplines, together with players from the business world, are flowing into the development of non-medical bioelectronics. This is providing illustrative material for the widely observed interweaving of science and technology – a topic that is often abstractly discussed in scientific circles, but is seldom brought to the attention of the general public. Specific applications such as smart patches could serve as a springboard for broad-based discussion about the development of the convergence of science and technology, and thus reach a public that has barely taken note of this phenomenon to date, but which is likely to be affected in some way by its consequences.

Open-minded regulatory approach for innovations

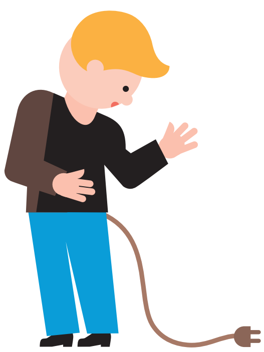
The existing regulations governing the approval of bioelectronic systems are oriented on medical applications. There are increasing calls for the same criteria to apply to both non-medical and medical bioelectronics for safety reasons. But this would hamper the innovative activities of small and medium-sized companies. It is therefore necessary to ascertain whether it would be expedient to develop a new regulatory model for bioelectronic products that are not explicitly designed for either medical or non-medical use. This concerns not only legal requirements, but also technical as well as private-sector and industry-wide standards. In addition, the question should be examined whether special ethical guidelines need to be formulated for research and development in the field of neuro-electronic products.

Strengthening of specialist networks

In view of the significant potentials of both medical and non-medical bioelectronics, there is a need to foster discussion on this highly important field of research and development. An initiative should be launched to bring together researchers from a broad variety of scientific disciplines, as well as practitioners and industry representatives, in order to strengthen the network of bioelectronics specialists. A seven to ten-year initiative could be specifically oriented on projects that enter into uncharted scientific and entrepreneurial territory, and could target the promotion of both medical and non-medical bioelectronics.

Engineering of animals

To date, the application of bioelectronic systems on animals has largely been limited to research. Clarification now needs to be made as to whether the increasing engineering of animals will make regulatory amendments necessary.



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New technology often leads to decisive improvements in the quality of our lives. At the same time, however, it involves new types of risks whose consequences are not always predictable. The Foundation for Technology Assessment TA-SWISS examines the potential advantages and risks of new technological developments in the fields of life sciences and medicine, information society as well as mobility, energy and climate. The studies carried out by the Foundation are aimed at the decision-making bodies in politics and the economy, as well as at the general public. In addition, TA-SWISS promotes the exchange of information and opinions between specialists in science, economics and politics and the public at large through participatory processes. Studies conducted and commissioned by the Foundation are aimed at providing objective, independent, and broad-based information on the advantages and risks of new technologies. To this purpose the studies are conducted in collaboration with groups comprised of experts in the relevant fields. The professional expertise of the supervisory groups covers a broad range of aspects of the issue under study.

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