



HOH (Health Optimizing Homeostasis) User Manual Clasp Portal



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Special thanks to Dr John Kelsey, PhD, ND, who helped in the preparation of the first version of the Manual, which served as a basis of this version.

Prepared by:

Mandelay Kft. as MANUFACTURER

Szigetszentmiklós 2310, 12001/33 Gyártelep Hrsz, Hungary

Name and Address of authorized representatives can be found at: https://www.scio-eductor.com/contacts/brokers

Manufacturer ensures the availability of the User Manual throughout the period of time that the product is marketed.

All device owners must notify Manufacturer about any personal contact changes (name, address, mail) in order for Manufacturer to be able to inform owners about any User Manual upgrades (info@scio-eductor.com).

The current version of the free User Manual is available for all owners (as a non-editable, read-only pdf file), available at: www.scio-eductor.com

A pdf reader is required for reading of the User Manual (e.g.: Adobe Acrobat Reader).

Official web page of the Manufacturer: <u>www.scio-eductor.com</u>



Welcome Letter

Dear device User,

Welcome to the world of the latest universal electro-physiological biofeedback system.

Before turning on or starting to use the device for the first time, it is necessary to read through the following pages and use this User Manual later as a reference book. This manual will be a great help for you in using the device. We hope that you are enthusiastic about joining the worldwide family of Biofeedback Users.

Our website, https://www.scio-eductor.com, where you can also download this manual and fulfil requirements of personal data protection, according to REGULATION (EU) 2017/745 on the protection of individuals with regards to the processing of personal data and on the free movement of such data.

Please, read this Manual carefully. If you have any questions, do not hesitate to call one of our representative, from whom you have bought the device. You can find the list of representatives on our web page at: https://www.scio-eductor.com/contacts/brokers

At the end of the Manual, previous versions from the first edition are listed. Please refer to updates in this document at Part 30. Please take into consideration the following facts:

- 1. The manufacturer, Mandelay Magyarország Kft. (Budapest, Hungary) dispatch in the package the Software, together with other components of the device. The latest version of the software can be downloaded and activated from our web page: www.scio-eductor.com. Our representative of the Budapest Home Office (BHO) will help in completion of the required procedures at the first time. Please pay attention to always use the latest version of the software.
- 2. Every user must register on our official web page: www.scio-eductor.com This will allow validation of the individual warranty of your device and accessing the newest pieces of information, news and updates for your device.
- 3. User Manual does not include the terms of policies (for example: The Warranty policy). Please take a moment to familiarize yourself with all policies, which are automatically initiated based on the shipment date of your device. https://www.scio-eductor.com/download/policies-and-procedures
- 4. Manufacturer continually cooperates with the Clients in ensuring the excellence of the device and our processes, to ensure continuous development and expansion of the features of the device. After getting acquainted with the program and finding out that any function of it fails to satisfy your expectations or comfort needs, please, do not hesitate to write a detailed, but concise explanation on ideas and suggestions regarding further development of the software (and if possible, please illustrate explanation with pictures). Every suggestion will be taken into consideration, studied by our developers' team for consideration. Your opinions are outmost welcome on this e-mail address: info@scio-eductor.com.
- 5. Our software is a product of several years of program development in the field of integrative medicine. It is, however, not free from minor programming failures. According to our many years of experience, the cause of most problems is the inappropriate installation of the computer or the operating system (Windows), and in most cases, the lack of computer maintenance. If you experience any troubles, please call a Representative. https://www.scio-eductor.com/contacts/brokers
- 6. Our Representative will provide information on reflecting to the aim of use and will provide training in the proper use of the device.



The more you know on our program, the more effective support you'll be able to give to your Clients. For more information, please visit our web page – www.scio-eductor.com – or our conference page: conference.scio-eductor.com. Our system is one of the most complex devices in the market, and its performance requires the intervention of a qualified biofeedback technician or professional. Please call our Representative with training requests: https://www.scio-eductor.com/contacts/brokers

Welcome to the Universal Electro-physiological Biofeedback Team.

Best regards,

the BHO Team of Mandelay Kft.



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Part 1.1 – What is HOH?

HOH (Health Optimizing Homeostasis) is a universal electro-physiological biofeedback system. It harmonizes the complex electro-modal biofeedback program with a computer software in order to collect bioengineering information with the support of the EDR. Pieces of information are collected by head straps (on the forehead) and straps put on the extremities (wrist, ankle), which provide an image on the general state of the stress the Client is burdened with. These pieces of information are ranked by the device with the help of the program and lists them starting from the strongest reactions.

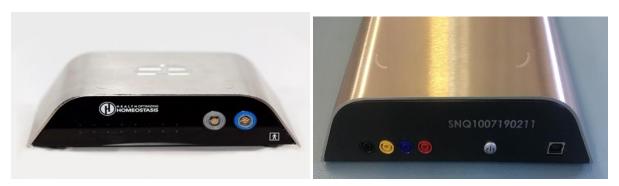
For stress harmonization, the system is providing audio - visual signals for the client with the help of the screen, speakers and the harnesses. The music is created by a special method meaning that special frequencies are coded into the music and the videos. This system is a complex biofeedback system used for the harmonization of several levels of stress.

Its components are:

- Device for Transmitting and receiving of information;
- Electrodes / harnesses;
- USB Cable to connect the device to a computer/ LAPTOP;

A motherboard which contains power and control modules.

On the front panel, a led is placed to indicate functions and jacks for connecting the electrodes to the Client (LIMB - for feet and hands, HEAD - forehead) and on the rear panel are ON / OFF switch and jacks for connecting the device to the computer (USB) and to other functions.



The device is controlled by computer via a software installed on it.

Part 1.2 – Identification

The device is fitted with a unique ID and a hologram label. Its accessories are fitted with serial numbers, helping to ensure safety and protection of the user and the Clients.

Please do not take over the device if the ID, the serial number or the hologram label is missing or damaged, and notify the seller forthwith, because the warranty of your device will be terminated in the aforementioned cases immediately.



Part 1.3 – End-user owner responsibility

We as Mandela Kft need to take records on the proper registration and operation of each and every device according to the Medical device directive (COUNCIL DIRECTIVE 93/42/EEC) & Medical device regulation (REGULATION (EU) 2017/745).

The aim of this is to be able to trace where the active devices are and who should be notified to the changes, rules, possible bans on machine revocations.

This responsibility lies with the end-user.

Mandelay Kft applies the Transfer of Ownership administration fee for those clients who bought used devices (Mandelay QUEST9, SCIO, EDUCTOR) and was previously registered at www.scio-eductor.com.

This fee relates to those clients who already registered and have activated accounts with Mandelay kft company and would like to resell their units to new owners. The new owner of the device needs to pay the administration fee amount to Mandelay Kft's bank account.

It will not affect new device registrations/or any other USED devices that were not registered on our system before

You can find more information at the following link: https://scio-eductor.com/news/89-important-note-regarding-transfer-of-ownership-devices

Always check on the official Mandelay website for the latest updates and news.



Part 2 – Overview

This User Manual was prepared by Mandelay Magyarország Kft., the manufacturer of the device. The Manual provides basic information on the device and the software that belongs to the users and offers support to its operation.

This Manual is NOT going to provide medical evaluation or opinion in any way.

This is a basic User Manual, in which the user finds instructions on how to start the device and other basic and important information about its use.

The information of this Manual is not to be construed as a medical opinion, diagnosis or therapeutic harmonization of any concrete state of health. None of the harmonization methods delineated here are deemed as medical opinion, diagnosis or therapy, or methods that would replace them. Clients and users should act with due care in order to seek information and consultations with officially accepted and authorized physicians.

On the basis of the available pieces of information, only authorized personnel can offer valid diagnoses relying on his/her expertise in diagnostics.

The device can be used for biofeedback only.

The device is indicated for the demonstration and mitigation of stress. Please take into account, that the regulation can be very different by countries in this regard, therefore please always refer to the current applicable legislation in your country.

The purpose of the system in any areas, regardless of the special language or terminology, is to serve – exclusively – the following objectives:

Helping and facilitating

- the survey and evaluation of the personal stress that might be important for the health of Clients;
- the mobilization of the stress recognition capability of the human body and of the internal resources of Clients

Stress is a medical state of health that gives cause for concerns. BNO #10 lists the matter in the following way: F43 – Reacting to severe stress and adjustment disorders; and F43.0 – Acute stress reaction; F43.1 – Post-traumatic stress disorder (PTSD); – F43.2 – Adjustment disorders; F43.8 – Other reactions to severe stress; and F43.9 – Reaction to severe stress, unspecified. The interpretation of the word "acute" is the liability of the therapist or the Clients, and not of the manufacturer of the device or the Manual.

The device is designed to be used in typical domestic or clinical environments and is approved in accordance with the harmonized standards of Medical Device Regulation.

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Part 3 – How to Use Your HOH?

The use of the device is indicated as a universal electro-physiological biofeedback system (see details in Part 1.1 hereto).

The device can be continuously used on different Clients (it is considered as a non-disposable device).

Part 3.1 – Indications for use

- a) the detection and reduction of stress,
- b) the muscular re-education of injury, muscle weakness, dystonia, muscletension, and/or muscle spasm,
- c) the reduction of pain,
- d) the healing of trauma and/or wounds

Part 3.2 - Clients

The clientele should be men and women between age 18 and 65 or pets that are older than 6 months (see exception among prohibitions in Part 5 – Safety of the Client).

The physical or mental limitation is determined in Part 5

Human Weight: > 20 kg

Nationality: not relevant

Health: see limitation in Part 5 – Safety of the Client

Frequency of use: non limited; proposed: up to 2 times / day

If the client is a user: see expectation in Part 3.4 – The User

Part 3.3 – Environment of Use

To ensure proper operation of the device, please assure that at the point of use, the requirements below are met.

Protecting the Client and the user is absolutely necessary and a requirement of legislation. Injuries can be caused from two sources, but can be avoided by using computer battery without being plugged into the socket, or using a medical protective against voltage:

- A short circuit when current is directed towards the earth by the customer;
- Surge and lightning.

They may not happen when the computer only uses battery as power source. However, a battery is drained quickly (an hour or two). Therefore, it is practical to work while connected to the mains, which means that a protector must be used. A protector is known as "medical transformer". Protecting the Client and the user can be provided using the following specific components:

- Short circuit: RCD (Residual Current Device) or ELB (Earth/Ground Leakage Protector), available;
- **Lightning / mains power supply**: a protective plate, available at specialty stores.



Please use the device with a computer that only works with battery, without being directly connected to an AC power source.

The device can be used at home (Home Use), by professional (Professional Use) and feasible for Indoor use.

The device has to be put in the middle of a stable support/table to avoid falling to the floor. In case of an accident, the device safety is not compromised, however, has to be sent back for investigation Part 23.1 – Service.

Requirements vis-a-vis premises: The area of the room must be at least 12 m² that serves the meeting between the qualified biofeedback technician or professional and the Clients, fitted with proper heating and lighting that can be easily approached from public places; fitted with waiting room and toilets and hot-water wash-hand basin for the Clients.

It is important that Clients should be able to spend easily at least 45 minutes in a comfortable environment (armchairs, bed).

Relaxing and soothing music and light are allowed, if these do not disturb the Clients (ambient luminance: 100 - 500 lux; ambient temperature: 20-24 °C).

It is advisable to ensure the availability of fresh water for the Clients before and after sessions.

(see exception among prohibitions in Part 5 – Safety of the Client and Part 27 – Technical data).



Part 3.4 – The User

In its design and way of use, the device has no differences whether it is operated by ordinary people or professionals, because the risk analysis of the outcome provided by ordinary people or professionals do not justify differentiation regarding design.

Visually impaired individuals (who are unable to see the information and suggestions displayed by the screen or mentally disabled operators (who are unable to follow the appearing information and suggestions) are not able to use the device independently.

Ordinary people cannot operate the device in accordance with its purpose, without basic training, meaning that

- the operation will be longer,
- the device stops working if used improperly,
- or initiates another kind of relaxation,

These occurrences do not bear any risk that could be detrimental to health, if the user keeps the instructions of Parts 3 and 5 hereto.

Users of the device

- education is not limited if the below requirements are met;
- mentally competent (client too, if client is a user),
- must take part in a basic training in the operation of the device and the software offered by the seller, which will teach them how to map the stress and how to achieve harmonization (about 6 hours);
- must have read and understood the actual User Manual;
- the users must show a basic level of fluency in one of the languages in which the software is available (English, French, German, Spanish);
- must make contact with the seller in case of any problem, misunderstanding, open question, ... to avoid all unexpected effects concerning usage or change;
- understands hygiene (cleaning).
- Warnings: Manufacturer has to be informed about all changes concerning of the user's or device's identifications, availabilities (name, address, mail, device, ...).

Part 4 – Disclaimer

The device should be used as an electro-physiological biofeedback system developed to relief of stress.



Part 5 – Safety of the Client

This information is at outmost importance and must always be kept available. These important pieces of information are viable in operating the device safely.

Regarding the basic requirements against medical engineering and therapeutic devices, the items listed under the paragraph must be worded and stated clearly in view of the safe operation of the device. Therefore, on the basis of a risk analysis, the following Warnings are to be considered during the use of the device. If you have any question, please turn to the Customer service of Manufacturer on the following e-mail address: info@scio-eductor.com

If you experience any problem, please call one of our local Representative: https://www.scio-eductor.com/contacts/brokers

Using the wrongly selected harmonization will not have a detrimental effect on the customer.

If the device or the program stops for any reason, even during training, feel free to restart the device and/or program and continue the Client's harmonization.

Damage to the Client cannot happen if the program stops.

It may take less time to finish the training after the restart ,as the harmonization has already started before that.

If the wrong harmonization has been selected, then either the program can be interrupted, switched off or continued, and then the planned area can be harmonized at the end of the unplanned training. Damage to the Client cannot happen due to the unplanned harmonization.

Harmonization strengthens the trained area but has a neutral effect on a properly harmonized area, without any negative effect.

Part 5.1 – 1 Instructions for Use

- Please, read over all instructions of this User Manual before use.
- System is intended only for use by qualified personnel.
- The device of Universal Electrophysiological Biofeedback System is not intended for use as the sole method of harmonization of diseases and cannot substitute for approved medical opinions.
- ▲ EEG (electro-encephalopathy) biofeedback, brain wave stress relieving and ECG (electro-cardiogram), EMG (electromyography) and GSR (galvanic skin reaction) data are indicative only and prepared in view to stress relieving; they cannot be used for obtaining medical opinion, intervention, therefore these are strictly prohibited.
- Do not move the any connection of harnesses, nor the device at any time during the session.
- Please, save the data obtained for later reference.
- Please, follow all Warnings and Precautions appearing on the product or below, in this document.

Part 5.2 – ! Warnings

The Warnings must be worded and stated clearly in view of the safe operation of the device – this is a basic requirement against medical engineering and therapeutic devices. On the basis of a risk analysis, the following Warnings are to be considered during the use of the device. If you have any question, please turn to the Customer service of Manufacturer on the following e-mail address: info@scio-eductor.com



- Do not use the device, if you have suspicions regarding its proper functioning.
- Do not use the device on Clients
 - o suffering from epilepsy or who have epilepsy in their medical histories.
 - who are crippled, handicapped, or unable to move freely, based on a licensed healthcare practitioners' statement,
 - with a serious head trauma,
 - o who are pregnant, breastfeeding or planning pregnancy,
 - o with serious mental health illness such as dementia or schizophrenia, psychiatric hospitalization in past two years,
 - who has prior cardiac surgeries such as cardiac bypass, heart transplant surgery,
 - o who DO NOT know the purpose and ability of use of the device,
 - o with pacemakers,
 - o with electric hyperactivity,
 - o under the influence of narcotic drugs or alcohol,
 - o with infection or wound or any other external trauma in the areas to which the electrode bands of the device are to be attached,
 - o with moist thin or punctured skin where the electrode bands of the device are to be attached,
 - o with participation in a clinical study or other type of research in the past 30 days.
- ⚠ DO NOT use the harnesses on irritated, inflamed, red or injured skin.
- ⚠ DO NOT use the device on individuals lacking full legal capacity or on incapacitated study subjects.
- Use caution with psychotic clients or clients with histories of electro-shock.

Ignoring warnings may lead to the immediate loss of warranty and Manufacturer shall not be liable for the consequences for breaching activities.

Part 5.3 – Precautions

- ⚠ DO NOT let the metallic parts of the harnesses touch the surface of the skin directly.
- ⚠ Be careful with psychotic Clients or with Clients, who have psychotic traces in their medical history.
- ⚠ Do not use the device during the running, installation or updating of other computer programs.
- Do not use the device with tools and accessories marketed by other sellers than Manufacturer.
- ⚠ There must be at least 2m distance between the Client and the device.
- The USB cable must be minimum 1.8m long and must not be longer than 2.0m, otherwise it can cause problems during its future use.
- DO NOT put anything on the USB cable.
- △ Do not use the device with damaged USB or electrode cables.
- △ DO NOT put the device on an unstable cart, stand or table.
- △ Do not use the device in the vicinity of explosive or flammable substances. Flammable anesthetic substances or gases resulting from oxidation, such as nitrous oxide [N2O] and oxygen should be avoided!
- A Before use of the device it must be ensured that flammable solvents and solutions used for cleaning and disinfection has evaporated completely. Special attention must be paid for ignition of endogenous gas!



ATTENTION: The device can only be supplied from a laptop through USB cable. Use of other elements can damage the device! Connect the device only with the USB port of your computer! Use



the device from a computer with rechargeable battery, while the computer is not plugged into the wall socket or use a charger that satisfies the requirements of medical standards.

- ★ Keep the device away from children.
- Users must verify the device, ensuring that it is sufficiently clean before each use.
- Clean the harnesses after each use (especially, if the risk of infection is suspected).
- ⚠ Substances, cleaning solvents or other chemicals must be stored in separate areas to avoid their self-ignition.
- ⚠ Do not use the device, along with devices that provide oxygen to Clients with respiratory disorders.
- A Before disposal, cleaning, or examination of the presence of failures, shut down the device and pull out the USB cable from it.
- ⚠ Do not attempt to clean the device by means of dry heat or wet.
- ♠ DO NOT use the device near liquids.
- Do not immerse the device in liquid and do not allow it to become wet, so that the liquid to drain.
- △ Do not expose to temperatures, humidity higher than indicated in Part27 Technical data
- △ Do not attempt to open, disassemble or service the unit.
- △ Do not crush, puncture, short external contacts, and do not remove them from fire or water.
- Examine the presence of faults in power cables and components. In case of any defect, do not use the device until its replacement.
- To reduce the risk of fire or electric shock, use only accessories recommended and do not expose the device, to rain or moisture.
- ⚠ Do not disassemble; device contains no parts that can be repaired by the user. For troubleshooting, call the service personnel.
- ⚠ Use only accessories and spare parts supplied by Manufacturer; use of other accessories can reduce the operational safety of the device.
- 1 It is not permitted to modify these devices.
- ⚠ Electromagnetic Interference (EMI) can affect the proper performance of the Universal Electrophysiological Biofeedback System device. It can return to normal operation by eliminating the source of interference.
- For optimum performance, it is recommended that all electronic devices such as cell phones, radios or other devices of this kind, to be at a distance of at least 1.5 meters. This reduces the potential for external interference. However, it is possible to keep the computer in a radius of 1.5 meters, if the Wi-Fi option is disabled.

Ignoring precautions may lead to the immediate loss of warranty and Manufacturer shall not be liable for the consequences for breaching activities.

Part 5.4 – Undesirable Side-Effects

Manufacturer performs risk analyses continually in order to decrease potential undesirable side-effects that may rise during the use of the device. Post-market surveillance and marketing experiences show that some Clients have suffered from undesirable reactions.

• Minor dizziness after harmonization. Please, note that this may result due to the state of health of the Client, e.g. From high blood-pressure or can be triggered after harmonization by standing up from an extended loose, leaned-back position of the body.



If this feeling is uncommon from any point of view and gives grounds for concerns, the Client must visit his/her General Practitioner or Family Doctor.

• In the transcutaneous biofeedback interaction with the central nervous system, the device may trigger a vegetative nervous system cascade that may lead to a vasovagal crisis. The Client may become overly perspiring, he/she may have nausea or dizziness. If this would occur, lay a cool and wet cloth on the eyes of the Client with a gentle and light pressure and tell him/her to relax, take deep breaths and wait app. 5 to 10 minutes, until the vasovagal crisis faints away. In extreme cases, fainting may occur.

If this feeling is uncommon from any point of view and gives grounds for concerns, the Client must visit his/her General Practitioner or Family Doctor.

• Some Clients may show extraordinary sensitivity to certain plastics, rubber derivatives or metals. Generally, they are the people, who do not wear many jewelries and do not use too much cosmetics and odoriferous substances. Some Clients may develop light redness on his/her skin at the touching points of the harnesses.

If this raises concerns, the Client must think over whether to return to the next session before he/she visits his/her GP of family doctor.

In case of any inconvenience caused by the use of the device, please have the client visit his/her family doctor and inform us accordingly (Part 5.10 – Discomforts and Complaints, Part 5 – Safety of the Client).

Part 5.5 – Rules Regarding Harnesses and Connections

Only use harnesses and other accessories marketed together with the device. Other harnesses (electrodes) and/or accessories that are not part of the original registered kit shall be used by the users under their own responsibility, but Manufacturer will not be liable for the outcomes of the use. Please refer the photographs of the originally registered harnesses in Part 26. Harness parts are exposed to tear and wear, therefore in case of ageing, please purchase new ones with the help of our Representative: https://www.scioeductor.com/contacts/brokers

The limb harnesses are designed to be comfortable, flexible, and easy to use, while maintaining a high-quality level. The straps are painted four colors that you have become very familiar with, red, blue, yellow and black, colors that indicate which extremity to connect the strap to.

Connect harnesses in the following way:

Red strap to the right wrist Yellow strap to the left wrist





Black strap to the left ankle Blue strap to the right ankle



Head harness onto the forehead (the streaks must face the forehead; it is important to have the cable on the right side).



For achieving best results, or if the harnesses have to touch the skin directly; **the use of electro conductive spray or cream is recommended.** The effectiveness of harmonization can be decreased or hindered, if any other material is inserted between the harness and the skin (e.g. a tissue).

Part 5.6 – Harness Check List

In favor of your Client, please, always check whether the above warnings are taken seriously.

- Before starting the program, put the harnesses on the skin of the Client in accordance with the color code.
- Explain the functions of the harnesses to the Client, their locations and the time they must be worn.
- Check whether the Client had any unpleasant experiences in the past, which evokes unpleasant feelings or makes him/her fearful in connection of wearing of electrodes (e.g. a previous electroconvulsive therapy)



Part 5.7 – Cleaning of Harnesses

In order to evade skin irritation, clean each time before and after use, the part of harnesses that touch the skin of the Client with cleaning solution (3 - 5% peroxide or 10% alcohol solution). Do not use aggressive cleaning agents, because these may damage the rubberized fabric, whereby the harness may lose its conductivity. Sometimes clean the harnesses with warm soapy water.

Part 5.8 – Biocompatibility

The surface of the skin of the Client (on his/her head/forehead, wrists and ankles) is touches by plastic, rubber derivatives and metal. The composition of these materials is accepted by the skin of the Clients with average sensitivities (they do not contain live or dead animal tissues). The metal part is covered, in order to eliminate the risk of bruises, sore or blisters when working with Clients with electrical hyper reactivity.

If redness appears on the skin at any point where the electrodes touch the skin and this raises concerns, the Client must think over whether to return to the next session before he/she visits his/her GP of family doctor.

Part 5.9 – Maintenance

If the devise is used in accordance with the requirement of intended use, it needs no maintenance.

Upon request, we check the operation of the device and the software on our annual conferences. You may read more about these conferences on our web page: conference.scio-eductor.com

Part 5.10 – Discomforts and Complaints

For the sake of your safety and the safety of others, we ask you to report all discomforts, sensitivities, injuries or accidents in connection with the device to the seller of the device or to our Budapest Home Office:

https://www.scio-eductor.com/contacts/brokers or info@scio-eductor.com

With your help, we'll be able to further develop the device and its services.

Part 5.11 - Troubleshooting

1, Led lights are not on at all:

Indicates no connection with the device. Make sure that the device is switched on.

Change the USB cable, as it could be damaged, and turn on and off the box approximately 10-15 times to remove the oxidation from the switch.

2, Only one Led light is on:

the software did not recognize the device.

- "This serial number does not exist in our database"
- Missing registration. Log into your SCIO-EDUCTOR.COM account. Click on "Order System" and select "My devices". If you do not see your Serial Number in the list, please add it by clicking on the 'Assign a Device to My Account' button. Enter all relevant information and then send the request. One of our Administrators will review your request and contact you soon.



- Incorrect Serial Number of your device. It is stored on a label on the device and inside the device in a chip. When those two serial numbers do not match, you will receive this message at the activation process. If this message appears, please contact us at info@scio-eductor.com.
- 3, The Software does not recognize the device.
 - Unplug the USB cable from the device and plug it back in
 - Unplug the USB cable from the computer and plug it back in
 - Plug the USB cable in a different USB port of your computer
 - Check whether your driver is installed successfully (See 'How can I install the USB driver of the device?')
 - Verify if the communication (COM) port is set to COM1 (See 'Configuring the System's communication port (COM port)') and reset the type of the device set in the Interface Type program (See 'Choosing your Interface Type').

4, Main Warnings:

First be sure the computer, device and the USB cable are in place.

- Access violation problem message: memory overloaded, need to restart the laptop.
- Read of address problem message: missing item picture or video.
- No MCI device: missing video.
- Commain Exe Read of address: installation problem, reinstall.
- Please connect your device and reactivate the software.
- USB connection lost: check the cable and restart the software.

In case the above list do not help, collect all relevant information and then contact Manufacturer at info@scio-eductor.com. One of our Administrators will review your request and contact you soon. In case our Administrator cannot help, you need to send your device for a checkup. The Administrator will guide you through the process of shipping the device.



Part 6 – Electric Safety

Evidences show that operating characteristics of the device are safe and are in line with the provisions of all internationally accepted and harmonized standards (EMC, safety). Please find below examples of basic information on electric safety, and ensuring of safe operation that is in line with the intended use of the device will become even more easy.

Part 6.1 – Basic Concepts of Electric Safety

The ampere draw may cause deadly electric shock, not voltage. In our homes – 115V (USA) or 230V (Europe) alternation current is the used voltage together with 1A amperage.

An electric shock caused by 3A is generally fatal, but even a much weaker 0.2A may cause injuries if the current moves through the heart. If your country does not fit in the above list, please ask questions about the local circumstances from your electricity supplier.

It is evidenced by tests thoroughly that the DEVICE uses absolutely safe micro-current, milliamp, furthermore, its hardware is fitted with protection against overvoltage and over amperage (overcurrent). The DEVICE is electrically supplied through USB cable from a computer, whereby the risk of injuries is minimal as evidenced by tests – the device fully satisfies all safety requirements.

Please, use the device from the chargeable battery of the computer, when the computer is working in battery mode, or use a medically safe source fitted with safe overvoltage-protected circuit with protecting switch and charger.

It is a basic requirement of law against electric safety that we must protect our Clients from injuries. Injuries may result from two kinds of sources that can be phased out by using the device with battery supply or by using a circuit-breaker that protects from overcurrent:

- (1) In case of short circuit, when the current flows into the ground directly through the body of the Client. (Think of e.g. a knife put into the toaster.)
- (2) Overvoltage in the network by a thunderbolt.

It cannot occur, if the device is operated from the battery of a computer. But batteries can run low within a relatively short time (1 to 2 hours). Therefore, it is more practical to operate the device from the city network. This, however, requires the use of protective devices. These are called "Medical Transformers".

The protection can be ensured with the use of special components:

- Short circuit: an RCD (Residual Current Device/Sensor) or an ELB (Earth Leakage Breaker) can be purchased normally for 30 mA.
- Lightning/Network surge protection: this is an overvoltage protector available in computer shops.

Part 6.2 - Connection of the System

Power supply

- Connect the USB cable from the computer to the device.
- Connect your computer to the network through the electric safety devices.



• From the network socket to the RCD/ELB, from there, to the overvoltage protector and lastly, to the computer.

Part 6.3 – Cleaning of the Device

The device should be cleaned time to time with a cleaning agent similar to those used for the cleaning of electrodes (Part 5.7). It is not necessary to clean the product after each Client.

The device does not require sterilization or special cleaning techniques.

Part 6.4 - Protection Against X-Rays

The device was designed to resist at least 50 X-ray radiations (equaling to about 0.5 sievert), which is 1 million times higher than the X-ray radiation of our checkpoints/safety gates (i.e. The device can be taken through X-ray gates 1 million times). Devices exposed to radiation doses higher than this must be taken to safety reviews. The buyers may experience a limited connection between the device and the software; the LEDs can be somewhat gloomier than before, which also calls the owners' attention to the need to check the device. Please, indicate the problem to the seller or to the Budapest Home Office:

(https://www.scio-eductor.com/contacts/brokers or info@scio-eductor.com)

Part 6.5 – Detachment from the Supply Network

The tool of detachment can be the connector of the device or the detachable plug.

The positioning of the device must allow the easy operation of the tool of detachment.

In this case, disconnection of the device is to be implemented by pulling out the USB connector from the socket of the computer.

Part 6.6 – Disabling Procedure

The operation of the device can be terminated safely by detaching it from the power supply, e.g. by pulling out the USB cable from its socket.



Part 7 – Copyright

All rights reserved, independently of the source of purchase. No part of the device shall be copied, and the data stored shall not be forwarded in any form, neither partially nor in whole without the prior written approval of Mandelay Kft, aka the facturerfacturer.

Part 8. - Data

No data can be deemed as a substitute or replacement of prescriptions of any medical expertise. Following of medical instructions given by a doctor, is a must. The device can be used by a trained biofeedback technician or professional.

Part 9. - The Short History of Biofeedback

Modern medicine has been measuring the electrical activity of human body successfully since a long time. With the help of ECG, EEG or EMG, the electric activities of the heart, the cortex or the skeletal muscle are no secrets anymore. Diagnostics operating under the principle of biofeedback rest on similar foundation, but in this case, the work is not done by a single machine only: successful diagnostics and harmonizations required human intervention, too.

During biofeedback relaxation, sensors attached to our body are able to measure the key functions of our biological organism. The aim of biofeedback is to help us more fully understand how our body functions. This information is very useful, because by this, we'll be able to keep control over certain bodily functions the belong to us. By learning the proper technology, we can learn, how the human body reacts to certain stress factors and stimuli and how are we able to fend off deliberately.

Recognition of the Importance of Biofeedback

The biofeedback method could break through, because the connection between electricity and biology that is, live organisms was recognized. The recognition showed out that every material possesses a unique electric frequency or vibration. Among scientists, the name of Dr Reinhard Voll glares out, who confirmed the assumption that certain characteristics of materials change, if they are connected to electric power of different strength. This method can be effective also in supporting and strengthening the tissues of the human body.

In 1908, Edmund Jacobson developed the progressive muscle relaxation technique (1958).

The research in the conditioning of muscle relaxation occurred 50 years ago, the findings are valid even now. For example, most biofeedback therapies use the technique of regular relaxation. The system of Jacobson has changed deeply together with the time passing, but his ideas and research methods are used many contemporary clinicians.

It is important to mention the name of McGuigan, who was the first who used a certain kind of medical engineering and therapeutic instrument in order to get feedback about the physiological reactions. McGuigan (Jacobson and McGuigan, 1978) used a prototype of the modern biofeedback instruments. In this procedure, an observer using oscilloscope determines the tension of the muscle stretching the lower arm. Later, Wolpe (1973) modified the technique of Jacobson and popularized his version as a part of the systematic emotional release technique.



In 1958, Kamiya (1969) started to study the changes of consciousness showed by human subjects parallel to changes in the alpha rhythm of EEG. He elaborated a task, where a bell rang regularly, and the subject was asked to indicate if he/she perceived the release of EEG alpha waves directly before the bell rang. Many were able to learn how to fulfil this task, which later led to the skill they begun to possess and with it they were able to regulate the alpha-waves of their brain without the noise of the bell. Although the first statements of the alpha-wave examiners were excessive, Kamiya and his colleagues continued their research, which later led to the development of more effective clinical methods. Due to the unpredictability of results, the clinical usefulness of the training in the creation of EEG alpha rhythms is still problematic (Miller, 1974).

The biofeedback as therapeutic technique was used in several areas even in the 1970ies, e.g. For psychologic disturbances, gastrointestinal problems, caused by vasoconstriction disease or for headache origination from muscle tension.

The feedback technique is able to treat headache caused by muscle contraction. Client were taught by EMG trainings how to decrease the tension in their frontal (forehead) muscle. These procedures were used for the diminution of blood vessel contraction, and at the same time, another technique was used for the increase of muscle contractions.

Ancoli and Kamiya (1978) examined several problematic areas in connection with EEG biofeedback. For example, one of the unsolved questions was whether the recorded increase of EEG alpha was the result of the decreased visual and oculomotor reaction, or not. Ancoli and Kamiya revised altogether 45 different EEG biofeedback studies between 1968 and 1976 and came to the opinion that most of them had methodological deficiencies. In their opinion, many negative results came about because of the shortness of study results and due to the inadequacy of the conditions of the experiments. They suggested to the scholars for the future to implement at least 4 examinations on one subject, which meant a quantitative development, and to implement experimental examinations on the basis of continuous feedback, for at least 10 minutes.

One of the interesting areas of their examinations was the empirical validation of the operant conditioning of the visceral or involuntary muscles. Since 1938, when Skinner could not prove the operant conditioning of the vasoconstrictor reaction, researchers showed interest in these areas of the discipline.

Neal Miller and his colleagues (the late Leo DiCara) had been taking part mainly in the research studying the instrumental autonomous conditioning of animals for years. In 1968, DiCara and Miller observed that lab rats were able to learn how to evade shock by decreasing their own heart rate. Miller tried to reproduce these results in the next year in vain. But in the same period, other researchers showed out that visceral conditioning can be pointed out in humans through the use of feedback techniques (Miller and Dworkin, 1974).

Independently of the fact that the original findings of Miller proved to be artificially provoked in the midst of the changing complex interactions, these remained undefined further on. Unquestionably, his early publications on the visceral conditioning of animals inspired other to a great extent towards initiating similar researches involving humans, whereby these scholars were able to develop more refined biofeedback techniques.

The less known H. D. Kimmel (1960) spent years in the research of the instrumental conditioning of the human vegetative nervous system. The results of the previous experiments on galvanic skin reactions (GSR) induced Kimmel and his students to continue experiments and these found that the GSR of subjects can be regulated through pleasant fragrances. Kimmel (1974) summarized the researches finished until 1967. A part of these were 16 GSR studies, five heart rate and three vasomotor reaction studies. All findings of these studies supported the idea that ANS can be influenced through operant conditioning.



Katkin and Murray (1968) challenged these findings and argued that these results came out because of the musculoskeletal agents only and produced positive results even after. For example, Lang and Melamed (1969) were able to treat a 9-months old child, who suffered of ruminative vomiting. Beyond these, Frezza and Hollandia (1971) pointed out that human salination cannot be controlled instrumentally.

Afterwards, the biofeedback procedure was used for clinical problems. In 1973, 2 innovative therapeutic procedures were developed, which are widely used today with certain technical upgrades. Elmer and Alyce Green (1977) elaborated a clinical protocol to create thermal feedback. They inferred the extent of of vasodilatation (aneurism) from the temperature of the peripheral skin and combined feedback on the temperature of the skin with the "Autogenic Training" of Schultz and Luthe (1969). Sargent, Green and Walters (1972) applied temperature biofeedback to the treatment of migraine. Clients were thought to increase the temperature in the fingers (vasodilatation), while they decreased the temperature on their foreheads (vasoconstriction). Almost 75% of the subjects were able to decrease the length and intensity of their migraine attacks. Later studies were able to reinforce these results.

While Sargent, Green and Walters developed their therapy to the treatment of migraine, Thomas Budzynski (1973) and his colleagues at Colorado University elaborated a feedback technique for the treatment of headache by muscle contraction (tension). Client were taught by EMG trainings how to decrease the tension in their frontal (forehead) muscle. The results showed that on average, the voltage dropped from 10 to 3.5 micro-Volt in the muscles, and the intensity of headache decreased gradually during the 16-weeks training period. Two control groups with members suffering from headache took part in the experiment: one of these groups got a "fake" feedback or pseudo-feedback, and the other got no feedback at all. No members of these control groups improved to an extent that members of the EMG therapy group could actually achieve. Since then, mixed results have come about on the effectiveness of EMG biofeedback as compared to the effectiveness of the simple relaxation methods.

The clinical studies reviewed until this time, feedback was used to decrease the contraction of muscles and blood vessels ("physiological vigilance"); at the same time, the method used for the increase of muscle contraction (a kind of EMG biofeedback training) had been existed since almost 25 years. The early studies of John Basmajian (1979), published first time in

1963, indicated already that Clients were able to intensify the operation of a one motor unit with the use of an EMG biofeedback. Even earlier, Marinacci and Horande (1960) showed that EMG feedback can be used to improve the neuromuscular function for several abnormalities. Basmajian and his colleagues designed specially structured biofeedback devices used in rehabilitation, e.g. a miniature EMG feedback device. They used such instruments against different types of diseases, including spastic diseases. There are no significant differences between EMG units used for rehabilitation or treating psycho-physiological diseases. The aim of biofeedback units used in rehabilitation to transfer information on the unique motor units or on the operation of a certain muscle. ost EMG units used for intensifying relaxation, however, summarizes bioelectronic information about a group of muscles. The resulting feedback in this latter case is somewhat less concrete.

Before 1970, relatively few studies occurred about biofeedback techniques. Since then however, several hundred studies were organized, and the amount of data was simply marvelous. Therefore, BSA working parties were created in order to map up the existing literature and to summarize the current state or biofeedback used in several fields: psycho-physiologic disturbances (Fotopoulos and Sunderland, 1978), gastrointestinal problems (Whitehead, 1978), vasoconstriction diseases (Taub and Stroebel, 1978), muscle tension, headache (Budzynski, 1978) and others.



From the point of biofeedback, another important insight was shown up by Winfried Otto Schumann, who realized that a vibration of extremely low frequency is perceivable and measurable all over the Earth. The frequency of this vibration equals to the frequency of certain waves of the human brain that appears at the borderline of sleep and waking.

These so-called Schumann Waves form a magnetic field of force and this can be controlled in order to oversee our state of health. The essence of this technology is the strengthening of harmonic waves that show health and to terminate discordant waves that cause different problems in the body.

In 1989, Nelson suggested and proved that biofeedback should not be necessarily called as only conscious or only oral procedure. By biofeedback, the human body, with the use of transcutaneous interactions produced by electricity or the CNS (central nerve system) TVEP (Trans-Dermal Voltammetry Triggered Electric Potential) stimulation. The aim of the biofeedback device was to realize biofeedback transcutaneous interaction with the Client's CNS.

Summary: in certain conditions, individuals may learn to control different vital processes as a result of biofeedback harmonization.

Neuro-Anatomic and Physiological Bases of Biofeedback:

Neurophysiologists and clinical physicians know that the brain behaves itself as a kind of whole unit of the central nervous system and that the operation of its components influence the performance on most components of the other side. It is clear though that certain areas cooperate with each other – through their physiologic connections – more closely than other areas. The different regions have their own roles, and while they can be replaced to some extent with other regions, these functions operate more effectively, if their role is taken by areas directly dedicated to this task. Generally speaking, the tasks of the brain can be assigned into three large groups:

- 1. Reception of stimuli (this is the sensory system)
- 2. The association of stimuli and analysis if the incoming stimuli
- 3. Producing motoric responses to stimuli or vegetative responses to internal and external stimuli.



Part 10 - Symbols (EC/765/2008; EN ISO 15223-1)

Description of markings that may appear on the label and box of the device:

European Conformity Compliance marking, with which the manufacturer indicates the device satisfies the requirements worded in the applicable EU harmonization legislation that also provide for the use of this mark. Caution Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. The symbol variant ISO 7000, symbol 0434B ("Caution") may be used. Manufacturer Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. This symbol shall be accompanied by the name and address of the manufacturer (i.e. the person placing the medical device on the market), adjacent to the symbol. Consult instructions for use Indicates the need for the user to consult the instructions for use Serial Number Indicates the menufacturer's derail number so that a specific medical device can be identified. This symbol shall be accompanied by the manufacturer's serial number. The serial number shall be adjacent to the symbol. PART APPUED, "BF" TYPE: It means the classification of the allowed screened current and the safe earthing of the current. "BF" TYPE OF THE PART APPLIED: It means the classification of the allowed screened current and that the safe earthing of the current is ensured. Symbol of the crossed bin with wheels – a common sing of electric and electronic equipment. Fragile, handle with care Indicates a medical device that can be broken or damaged if not handled carefully. Protect from heat and radioactive sources Indicates a medical device that needs protection from heat and radioactive sources. Keep dry Indicates a medical device that needs to be protected from moisture. Temperature limit		
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	<u>ili</u>	Keep dry
Temperature limit		Indicates a medical device that needs to be protected from moisture.
	. **	Temperature limit



	Indicates the temperature limits to which the medical device can be safely exposed.
	The upper and lowest limits of temperature shall be indicated adjacent to be upper and lower horizontal lines.
IP21	First digit: protection against solid objects and dust; 2: touch (objects with a diameter of >12.5 mm); Second digit: protection against moisture and water; 1: dripping water
	Humidity limitation
	Indicates the range of humidity to which the medical device can be safely exposed. The humidity limitation shall be indicated adjacent to the upper and lower horizontal lines.

On the bottom side of the device, the following label is seen:



Nr. next to CE mark: DNV Product Assurance AS identification

On the back side:

SN: the serial number on the back plate of the device is written in the following format: SNQ ddmmyy, where:

SNQ = serial number

dd/nn = the day of production

mm/hh = the month of production

yy/éé = the last two figures of the year of manufacturing; e.g.: 20 = 2020

xxxx = four sequential serial numbers of manufacturing; so, the device with ser. no. 1234 was produced just before the device with ser. no. 1235 in the manufacturing process.

Only with the purpose to be mentioned in the User Manual, because these are recommendations only, not requirements:

For sake of optimal operation and performance, it is advisable to keep away all kinds of electronic devices, like mobile phones, radio, electrostatic air cleaner and similar devices, at least at a 1.5m distance from this device. This way the appearance of external electric voltage in the form of interference decreases. The use of the operating computer within this distance is though possible within 1.5m, but it is advisable to disconnect the computer from the wireless network.



Part 11 – Computer Specifications

On this part, information is provided about the size of memory, speed and other system requirements of the computer from which the device is operated and that ensure the best compatibility with the device.

- It is advised to dedicate a separate computer exclusively for the program. On the basis of experiences, if it is not possible, it is strongly recommended not to store or install any other software on this computer. We suggest installing only the recommended programs and to follow the instructions entitled "Preparation of the computer".
- Processor (CPU), accepted: Intel® Core™ i3, i5, i7.
- Processor (CPU) not supported: AMD or Celeron processors
- Memory (RAM): 8 GB or more
- Video card: Intel HD 3000 or better, minimum 256 MB video RAM
- Storage (Hard Drive, Disk): 30 GB empty space available, maximum one storage
- Storage (Hard Drive, Disk) not supported: RAID, SCSI,
- Resolution: 1920 x1080 display resolution, Full HD or better; size: 15.6 cols
- Supported operating system for the software; please, use Windows® 10/11 with the latest upgrade
- Inappropriate operating system: Windows XP, Vista, or Windows 7-8
- Protection against viruses: ESET Smart Security, ESET NOD32 Antivirus, Kaspersky
- Activation requires internet connection
- USB ports:
- HOH: USB 2.0 interface
- Apple products are not supported!

NOTE: Due to the continuous development of the IT sector, the data above may change without prior notice.



Part 12 – Preparation of the Computer for the 'Clasp64' Device

We suggest following of the steps below, before installation of the software.

- 1. Clean the "Start-up" Menu: Go to menu item Start Program of the Start-up menu and delete all programs and applications found there. This can be done by clicking on the right mouse button then by selecting the Delete item.
- 2. It is advisable to keep only shortcuts on the Desktop, each having a small arrow in its lower left corner. All other documents should be stored in the Documents folder. If possible, store on Desktop only shortcuts of the most frequently used applications.
- 3. Screen adjustment: If Windows 7, Windows 8 or Windows 10 is used, go to Desktop/right mouse button, then Click on the Personalization option (in Windows 7, immediately the Settings option appears), then click on the Display Settings element. Set Screen Resolution to 1920x1080 pixels, or to the possible highest, which the screen is able to display. Adjustment of power use: Set the screensaver to "None" value, then click on the Power Supply button and set the value to zero (0).
- 4. Empty the Recycle Bin and restart the computer.

Disclaimer: This document is for reference only. Manufacturer shall not be liable for data losses or for any other kind of losses generated by the following of these instruction or that might have been generated by following these instructions. In case of urgency, ask the support of the administrator or an IT professional.



Part 13 – Installation and Activation Procedure

Before starting of the program, please read the paragraphs below carefully. The latest version of the program is always available at web page www.scio-eductor.com. These instructions are expressly connected to the latest version. Beyond these, many videos are available on YouTube channels in installation and activation.

Carefully unpack the package and check its contents. The packaging has been specifically designed to ensure optimum protection of the device and its accessories during transport; however, if a certain part is damaged or missing, do not use the device; contact your representative. Keep the original package for the eventual return of the device, if unforeseen events occur that require repair or service it.

Inside the box you will find the following:

HOH device	1 piece
Limb harnesses	1 set
Forehead harness	1 piece
USB-to-USB Cable (connection with laptop/computer)	1 piece
Pendrive (User Manual, software,)	1 piece
Folder (welcome letter, warranty card, Check list, Declaration of EU conformity)	1 piece
Bag of laptop	1 piece

Cleaning the device and its accessories before the first usage is not necessary, as the original packaging protect them, and sterilization is not needed.

The device connects to your computer via a USB-to-USB cable.

The device is portable; It can be located and conveniently positioned near the treating area [for example, may be placed on a table].

Before moving the device, make sure that the following conditions are met:

- The device is off;
- All accessories and cables are disconnected;
- If the device is placed on a table or other support, make sure that they are fixed and not subject to shocks, vibration or other uncontrolled movement (see Part 5).

Part 13.1 – Activation On-Line

With the aim to provide a whole service to our customers, we have created a 7/24 on-line activation service. Please, follow the below instructions and in case you experience any problem, contact the seller for further advices.

1. Please, register on the following web page: www.scio-eductor.com – By clicking the Sign up! button.



2. Start Clasp Portal program, send the activation ID to <u>license@scio-eductor.com</u>, after you receive the license key. You need to copy to license key section and click on activate license.

If you have any question or concern, please, write to support@scio-eductor.com e-mail address.

Part 13.2 – Installation

1. Turn on your computer, then check, whether you are present on the 'Windows Desktop' and no other programs are active.

If you use Windows 7, it is necessary to deactivate UAC (User Account Control). Please follow these steps:

a. Go to the Control Panel and click twice on the User Account in Classical View or Vista view, then to User Account and Family Safety, where chose User Accounts element. In both cases, you'll find an option for Turn Off or In the User Account Control. Click on it. In the opening window, you'll find a box with the text: 'User Account Control (UAC) to help protect your Computer', where you should delete the check mark.

NOTE: The User Account Control must be in off state they will ensure the stability of the program, even during the installation of the Clasp Portal software.

- b. Re-start your computer, then wait until the system becomes ready for running.
- 2. The software can be installed from two locations: a: With the help of Mandelay_downloader, b: With Pendrive.

A: Start Mandelay_downloader and sign in with username from scio-eductor.com, then click on the picture of the program you want to install.

B: Insert the Pendrive containing the Clasp Portal software into the USB port of your computer and find the installer of the Clasp Portal software, then start the setup.exe.

- 3. Select the 'I Accept the agreement' option, then follow the instructions of the Installation Wizard.
- 4. In the second window of the Installation Wizard, click on the 'Next' button.
- 5. The next window will show the name of the software as it will appear in the Start menu. Click "Install".
- 6. Then the Interface Type Selector windows will appear. Chose the appropriate device from the photographs, then enter its serial number in the field below. Click on **OK**.
- 7. The next and at the same time, the last installer is a general driver installer. To start installation, click on the **Next** button and in the next pop-up window, click on the **Install** button, then the **Finish** button.
- 8. To finish the whole installation procedure, click on the **Finish** button.



Part 14 – Programs Required by the Computer

This part delineates the programs to be installed on the operating system. You can upload these before and after installing the software. Certain components are contained by the installation.

1. Programs needed

- Microsoft Word. This is necessary for the display of the many written information. There will be programs that will lead you over the program.
- Web browser. This is needed for the on-line activation process.
- Adobe Reader DC or newer version. This application is required for the reading of documents included in the software. The free version can be downloaded from: www.adobe.com

2. It is not indispensable, but useful:

• Microsoft Office, besides 'Word' (word processor), also contains 'Access' (data base manager), 'Excel' (spreadsheet) and 'PowerPoint' (presentation maker).



Part 15 – Instructions for the installation of USB and USB cables

Note that the device does not require an external power source, because it is supplied directly from the computer.

Do not forget that the proper USB connecting cable is minimum 1.8m long and maximum 2m long. An USB cable that is longer than this can decrease the stability of the communication between the operator laptop and the device, that may cause chokepoints and disruption of the operation.

If you have installed the 'Clasp 64' program from the USB, please take the steps below to install the new device:

- 1. Plug in the USB in the machine
- 2. Connect the USB cable. (This is the point where the connection of the interface box is necessary.)
- 3. The 'Hardware installation wizard' offers you the device to be installed in the appearing dialog window.
- 4. A dialog will popup asking whether you want to logon the internet. Select the las option: 'No, not this time'. The 'Next >' button becomes active. Click on it.
- 5. The 'Found New Hardware Wizard' dialog opens. Select 'Install the software automatically (Recommended)'. Click on the 'Next >' button.
- 6. Another dialog pops up, which indicates that the program is not a 'Microsoft' product. Click on the 'Continue Anyway' button.
- 7. After the installation procedure finishes, click on the 'Finish' button.
- 8. The dialog 'Hardware installation wizard' appears again. Please, repeat the procedure.
- 9. On the 'Windows task bar', the 'Your new hardware is installed and ready to use' message appears.

Continue with the next step: 'Adjustment of the Port'

If you have installed the 'Clasp Portal' program downloadable from the internet, please, take the steps below to install the new device:

- 1. Connect the USB cable. (This is the point where the connection of the device is necessary.)
- 2. The 'Hardware installation wizard' offers you the device to be installed in the appearing dialog window.
- 3. A dialog will popup asking whether you want to logon the internet. Select the las option: 'No, not this time'. The 'Next >' button becomes active. Click on it.
- 4. The 'Found New Hardware Wizard'

dialog opens. Select 'Install from a list or specific location (Advanced)', then click on the 'Next >' button.

5. Select the 'browse' option and find the folder, where you have installed the

'Clasp Portal' software. Select the USB Drive folder. Click on OK, then click on 'Next >'.

- 6. Another dialog pops up, which indicates that the program is not
- a 'Microsoft' product. Click on the 'Continue Anyway' button.
- 7. After the installation procedure finishes, click on the 'Finish' button.



- 8. The dialog 'Hardware installation wizard' appears again. Please, repeat the procedure.
- 9. On the 'Windows task bar', the 'Your new hardware is installed and ready to use' message appears.

Continue with the next step: 'Adjustment of the Port'



Part 16 – Adjustment of the Port

Follow the steps below that will help with setting the port:

- 1. On the desktop of 'Windows 7' or 'Windows 8', click on My Machine with the right mouse button.
- 2. Select: Properties.
- 3. Select Hardware.
- 4. Select Device Manager.
- 5. Select 'Ports'.
- 6. Right-button click on the port on which the cable has been installed, e.g. 'USB Serial

Port (COM XX)'.

- 7. Select Properties.
- 8. Select Port Settings.
- 9. Select 'Special'.
- 10. Set 'COM Port Number' to 'COM 1'.
- 11. Click on 'OK' in every window until you arrive back to the Desktop.
- 12. Go to Device Manager to check whether the changes have appeared or not, e.g. 'USB Serial Port (COM 1)'.
- 13. Plug the cable always in the same USB socket, which you have set just now.
- 14. Sometimes in may look like that the port COM 1 is in use, while in reality it is not even connected. In this case, select the port, then click on 'OK'. This message will be displayed: This COM name is used by another device (e.g. Another port or modem). (If you use same names to different things, it may lead to the unavailability of your devices and to changes in the settings.) Disregard the message and click on the 'Yes' option.
 - Sometimes the computer needs restart to take effect the changes in your port settings.
 - You have the opportunity to set the device for the use of all available USB sockets, and in this case, you DO NOT have to remember, which is the port that receives the device according to your previous settings.



Part 17 – Start

The device and the software form a very complex system and time is needed to fully understand it as a whole. Please find few suggestions bellow to start, broken down to the following sections:

- Perspectives of Starting with the Program
- Navigation
- Practicing the key elements
- Basic principles of Clients
- Navigation

Part 17.1 – Perspectives of Starting with the Program

It is suggested to remember that the benefits offered by the device are attributable to the developments of science and technology. It is important to use the computer comfortably and to navigate the software. To use the device successfully, we suggest you take the following steps:

- If you are lacking experience with computers, we recommend you go to a locally organized course to learn how to use Windows. The use of computers is not hard to learn, but what you do not know can appear sometimes as something frightening. The time you spend with learning how to use Windows is extremely useful, because it will accelerate the use of the program.
- Learn how to navigate in the program.
- Practice, practice, practice!
- Take advantage of the opportunity that you are able to learn on-line from your home and have the opportunity to use many independent sources.
- Take part on lectures and conferences, of which you can gather information on this web page: conference.scio-eductor.com
- There is no learning that would be able to replace practicing in reality.
- Our Representatives have the right to use our Training Manual and to add to this their own experience
 to support your learning process, however, this User Manual is the highest-level manual of the
 manufacturer, which will always be offered to users as our official source of information.

Part 17.2 – Navigation

Some suggestions have been provided to help in the understanding of the basic principles of navigation:

- During taking the first steps, navigation is in focus
- Do not spend hours with the device a mind can be totally filled with too many information, independently of how obsessed with the ideas now.
- You are able to learn to use the software without connecting anyone to the harnesses.

Part 17.3 – Practising the key elements

It is suggested to take some time to practice the key elements of the program. As soon as you collect enough experience to navigate comfortably, you may continue with the device.



- Opening the program
- Add or choose client
- Choose the part of the program what you want to use (TAP, AID, Basic Training)
- Choose the program what you want to work
- Set the time
- Click start

Part 17.4 – Basic Principles in Connection with Clients

Here are some suggested principles that you need to keep in mind when meeting Clients.

- 1. Please, always fill the client information.
- 2. More is not necessarily better: spend about 50 minutes together with the Client. But be resilient and use your intuitive skills and the interactions with your Client to decide at last, what is the best to your Client.
- 3. Suggested working time:

Step Function Timing

Demography and instructions on expectations
 7 minutes

2. Support for stress relieving rehabilitation 20 minutes

3. Different multimedia biofeedback instructions 5-10 minutes

4. Talking with the Client on changes in his lifestyle and asking questions; provision of the necessary support 5-10 minutes

Agree in the objective(s) of the next visit WHOLE TIME 47 minutes

Part 17.5 - Follow-up

We suggest applying these intervals on a case by case basis. You must decide what is the best for you and the Client.

You can practice the use of the software with fictive Clients until you get accustomed with the harmonization of a real individual.

To show and to mitigate the stress in the Clients, we suggest one weekly 50-minutes harmonization. During harmonization procedures, you can focus on the basic opportunities, as seen in the above "Basic principles of Clients" list.

You may allow visits in cases of acute stress Clients for 2 or 3 times a week, but the maximum time you spend with harmonization should be 50 minutes in similar cases, too.

In working with chronic stress Clients, we suggest a 6-week harmonization therapy in line with the acupuncture instruction: once a week, then control. The time for harmonization should be max. 50 minutes further on.



Talk to each Client about changes in lifestyle, and you can agree with them, for example in these complementary opportunities.

- training programs,
- methods of stress relieving,
- yoga,
- weight losing,
- reducing smoking,
- muscle rehabilitation,
- selection of a diet,

What to choose and what to avoid; say no to medicines, eradication of addiction; and about healing the body in natural ways.



Part 18 – Useful Hints

The following hints will be useful in solving some problems in connection with the use of the device.

Part 18.1 – Accessing of functions

There are many methods for starting and stopping the device:

- Buttons: if you click on a button, one operation starts
- Text Box: these are to enter pieces of information by typing or by clicking twice onto certain elements
 on different screens. Information may be changed in any text box similarly to the way when you work
 with a word processor, e.g. by using backspace or delete keys etc.
- Buttons have double functions in many cases in the dropdown list of the Toolbar of the program. If the cursor is drawn on it, the list will most probably appear. By clicking on the element, a pre-defined activity will be started, e.g. relaxation or routing to another screen.

Part 18.2 - Frozen Screens

If the computer is used for a long period, or if the power of the computer is too weak, it may lead to the freeze of the screen or the computer. In this case it may be perceived that the window cannot be closed.

1. With the help of the "-"sign in the upper right corner, try to minimize the window.

This may disclose an information panel in the background. Close this panel.

- 2. If, during the operation of the device, clicking is made with the mouse cursor on more point of the window, this may confuse the system and that might lead to its freezing. By pushing the Ctrl-Alt-Del combination, the Task Manager can be activated. After clicking on the Applications tab, select the Clasp Portal option and click on the termination of the program. During reloading, the program will ask whether to restore the last Client. If 'yes' is answered, the system will restore all previously entered data of the Client. Give the password as usual, check if the proper Client appears under Demography, and continue, where session was finished last time.
- 3. If this procedure fails, use the Task Manager to turn the computer off.
- 4. As a last resort, keep the ON button of the computer pushed down at least for 10 seconds, while it turns off.

Part 18.3 – Restoration of Clients

Use this procedure only if the program breaks down and you were able to turn the computer off with the Task Manager only. If data of the last Client has to be restored, the device must be restarted. If that program was not closed properly, during restart, the system will ask, whether data of the last Client is to be restored – select 'yes'. In the usual way, please, enter the password in the 'Password' window, check if the proper Client appears under Demography, and continue, where session was finished last time.



19. Part – Check of the Device

The device contains a micro-processor, which is the heart of the device. The power supply of the LEDs is received from the computer through a USB cable. The LEDs have a long life and normally they do not become defective. If a LED fails to shine, check the connection first. If the light is not operating, the setting of the computer might be the problem. Check the proper setting of the COM port (as delineated in Part 16). If there is a problem with the LEDs, send the device to a servicing center that possesses the required authorization, where it will be examined, and the problem will be repaired. If you want to know more about this issue, please visit the following page: https://www.scio-eductor.com/download/policies-and-procedures.

Turning on: Every LED gleam, a short sound alarm is heard indicating that the device is ON.

Upon starting the software, at 25% the 'HOH found' message pops up.

All LEDs are on during the test.

Blue LED (current): is on, when the device is connected to the computer with a USB cable, and the device is ON (rear unit).

Red Channel 18 LEDs indicate the operation of the communication channels. The number of lighting LEDs depend on the running program.

DaVinci LEDs known from the older devices (5 LEDs, first row on the left side) glow in white in this order: right wrist, right ankle, head, left ankle, left wrist and indicate the activity of the harnesses.

The software has no alarm system because the client cannot be in danger.



20. Part - Quick Start

This is a basic guide to the first setup steps. It is advisable for the users to follow these steps. Do not forget that the skills of a qualified therapist, communication with Clients, the needs of the Clients, their actual state and the results achieved in harmonization will define the steps. These steps below only provide aid to the initial actions.

Part 20.1 – Opening the Program: Entering the Data of the Client

Step Action Note/ Options

- 1. The CLASP Portal Icon: Click twice The program boots: upload it looks for the DEVICE. Upon finding it, the program displays the option for checking the contacts. Close it to continue.
- 2. Client Fill the client information
- 3. Demographics
 - 3.1. New Client
 - 3.2. Old Client

Part 20.2 – Calibration

Step Action

- Main Screen> Basic Training
- 2. Click on the chosen program
- 3. Set the time
- 4. Click on start
- 5. Main Screen> AID
- 6. Click on the chosen program
- 7. Click start
- 8. Main Screen> TAP
- 9. Type in your affirmation
- 10. Type in for who
- 11. Click on Do above affirmation



Part 20.3 - ECG, EEG

ECG and EEG measurements are initiated by the software, with a user-selectable option from the menu where the user selects whether to initiate ECG or EEG measurement. By starting the measurement, the software sends a command to the device, which switches the given circuit to an active state and transmits the measurement result to the software until it is stopped by the user. The software displays the obtained raw digital data / results to the user on a graph.

During an EEG or ECG measurement, the client is disconnected from other circuits both in the device and in the software to ensure that no other circuits or functions interfere during the measurement.

The inputs of the EEG circuit 4 electrodes are in the headband on the client's forehead.

For ECG measurement, the device uses a dedicated ECG chip. The client-side connection of the ECG circuit is 3 electrodes, 1-1 on the client's wrists and 1 on the right ankle.

Part 20.3. 1 - ECG

- Opening the program
- · Choose the Basic Training
- Click on ECG
- Pre ECG
- ECG tested

Wait 1 minute until the system calibrates and shows the ECG

To Close click on the X at the top right corner of the panel

Part 20.3.2 - EEG

- Opening the program
- · Choose the Basic Trainng
- Click on EEG
- Pre EEG
- EEG tested

Wait 1 minute until the system calibrates and shows the ECG

To Close click on the X at the top right corner of the panel

Part 20.4 - GSR

- Opening the program
- Choose the Basic Training
- Click on GSR
- Pre GSR



· GSR tested

Wait 1 minute until the system calibrates and shows the GSR

To Close click on the X at the top right corner of the panel

BODY RESISTANCE AND HEAT EFFECTS OF ELECTRIC CURRENT

Body resistance (measured in ohms/cm2) is concentrated primarily in the skin and varies directly with the skin's condition.

The resistance of dry well-keratinized intact skin is 20-30 k Ω /cm2.

The resistance of moist thin skin is about 0,5 k Ω /cm2.

The resistance of punctured skin may be as low as 0,2-0,3 k Ω /cm2.

If skin resistance is low, few, if any, burns occur, although cardiac arrest may occur if the current reaches the heart. If skin resistance is high, much energy may be dissipated at the surface as current passes through the skin, and large surface burns can result in the entry and exit points.

Internal tissues are burned depending on their resistance; nerves, blood vessels, and muscles conduct electricity more readily than denser tissues (e.g., fat, tendon, bone) and are preferentially damaged.

Wet conditions are common during low-voltage electrocutions. Under dry conditions, human skin is very resistant. Wet skin dramatically drops the body's resistance.

Dry Conditions: Current = Volts/Ohms = 120/100,000 = 1mA = a barely perceptible level of current. Wet conditions: Current = Volts/Ohms = 120/1,000 = 120mA = sufficient current to cause ventricular fibrillation

If the extensor muscles are excited by the shock, the person may be thrown away from the circuit. Often, this can result in a fall from elevation that kills a victim even when electrocution does not. When muscular contraction caused by stimulation does not allow the victim to free himself from the circuit, even relatively low voltages can be extremely dangerous, because the degree of injury increases with the length of time the body is exposed to the circuit.

	Probable Effects on Human Body
1 mA	Perception level. Slight tingling sensation. Still dangerous under certain conditions.
5 mA	Slight shock felt; not painful but disturbing. Average individual can let go. However, strong involuntary reactions to shocks in this range may lead to injuries.
6 - 16 mA	Painful shock, begin to lose muscular control. Commonly referred to as the freezing current or "let-go" range.
17 – 99 mA	Extreme pain, respiratory arrest, severe muscular contractions. Individual cannot let go. Death is possible.
100 – 2000 mA	Ventricular fibrillation (uneven, uncoordinated pumping of the heart.) Muscular contraction and nerve damage begin to occur. Death is likely.



Intended use: 4-1 Volt / 10 Ohms = 0,4-0,1 mA or smaller depending of

the body weight

Worst case: 4 Volt / 1 Ohms = 4 mA

Part 21. – Saving of Client Information

It is reasonable to make a backup save of all-important pieces of information before updating the software.

Part 22. – Restoring of Client Information

After the installation of the software, the process of this is just the opposite. It must be done before running the program.



Part 23. – Device Handling

Part 23.1 - Service

Repairs of the device must be performed only by qualified personnel who have been authorized by Manufacturer; otherwise, Manufacurer is not responsible for safety, reliability and performance of the device.

If any error is detected in connection with the electrodes of the device and/or during the electrode test and if the system indicates that the electrodes are not working, the electrodes must be replaced or repaired. Otherwise, efficient operation of the device will not be achieved. Non-functioning electrodes do not pose any danger to the human body because in this case the electrodes do not transmit any useful or useless information. However, it is important to replace the electrodes immediately or have them serviced by a professional. Any other solution to the problem may endanger the operation of the device.

Part 23.2 - Loss of warranty

The warranty is 3 years.

Any warranty or claims to Manufacturer are void if the user or an unauthorized person tries to repair the device.

If it is believed that the device is not operating in line with the intended use, please, indicate this immediately to the seller and/or to the Budapest Home Office:

https://www.scio-eductor.com/contacts/brokers or info@scio-eductor.com

Part 23.3 - Description of defect

To enable Manufacturer to conduct repairs in a short time, send the device to Manufacturer, accompanied by a detailed description of the defect. Description should include the following:

- Serial number of device,
- Accurate description of the defect,
- Date of delivery,
- Copy of invoice (for possible warranty),
- Warranty of the device,

Part 23.4 - Handling of device before shipping

To protect Manufacturer's personnel, before sending the device for repair or for trade in, cleaning and disinfecting is required. Manufacturer has the right to refuse repairs of devices, if they are dirty or contaminated, for safety reasons.

Part 23.5 - Shipping

To send device back, use the original packaging; if this is not possible, pack the device and its removable parts in polyurethane foam sheets and then into a carton box.



Part 23.6 - New component

If during renovation, a new component is built into the device (different from the original component), Manufacturer will indicate this fact with re-labelling.

Part 23.7 - Packaging

The devices and its accessories are marketed in accordance with the packaging instructions.

If the packaging of the manufacturer becomes damaged or removed from use, it is reasonable to use the bag that is a part of the kit, where every accessory has its own place, without suffering damages. If the buyer wishes to use his/her unique bag, we suggest using a bag with reinforced side walls.

Part 23.8 – Storage

The device must be stored at a safe place, where no damage is to occur, far from dust, moisture, rain, sunshine and radiation. Please pay attention to the soundness of the cables. Do not put anything on the device or its accessories.

If the device was out of use for a longer time, before continued use, it is advised to dust it off and to clean the harnesses (Part 5.7), and to check the conductivity of the harnesses (checking of harnesses enabled within the software). After a certain period of time, the harnesses face ageing. Steps can be made to replace harnesses through the Seller:

https://www.scio-eductor.com/contacts/brokers

Part 23.9 - Destruction

The device must be recycled as an electronic device, meaning that it has to be handed over to an official company that has the authorization to dispose electronic devices, or sent back to the Seller or directly to our Budapest Headquarter:

https://www.scio-eductor.com/contacts/brokers or https://www.scio-eductor.com/contact/#anchor

The device should not be put into the general household waste.

The proper handling of the product as waste helps to save valuable resources and may prevent possible negative effects it exercises on the health of people and the environment caused by non-compliant waste management.



Part 24 – Glossary

Allersode: Food energy template, inhaler etc., 30 degree C sensitivity effectiveness

Body Capacitance: A rate of up-filling until the potential, as an indicator of the characteristic energy storing capacity of the body

Calibration: The process by which the interface creates the connection with the Client, where the optimal reaction of the Client (the time of exposition) is based with different (app. 20) elements

Client (Patient): Words "Client" and "Patient" are interchangeable, since both expressions refer to the very same person, who is connected to the device. If the therapist possesses authorization, he/she may refer to the Patient as a "Client." If the therapist does not possess authorization, he or she may refer to the individual connected to the device as "Client".

Coherence: A percentage of measurement – how near is the signal received to the original input signal. It generally increases together with the harmonic reaction of the Client; from 75%, a positive reaction may be spoke of.

EPR: Electro-Physiological Reactivity

FE: See, Flower Essences

Floating: Upon entering a screen, the elements of that screen are re-arranged. The basic fact is that some interactions are not quantic and not repeated.

Fourier Number: A mathematical ration of the result of the 7-part harmonic analysis.

Hyperreactivity: The body of the Client reacts too quickly.

Hypo reactivity: The energetics of the Client's body produces weak reactions.

Impedance: AC resistance; a quotient of the complex voltage in an electric AC network and the values of complex current.

Imponderable: Energetic pattern of a non-physical material. Such as emotions, geomagnetic effects and essentially everything, which is not solid.

Interface Value (Calibration): Indication of the accuracy of the interface, which helps the testability of most Clients. At 98%, 1 from 50 can be tested, at 95%, 1 from 20, at 90%, 1 from 10. At 85%, the study procedure is a nominal objective; 49 are testable from 50.

Isode: Energetic pattern of a toxic material.

Major Resonant Frequency: The major frequency of the energetic organism of Clients.

Muscle Disturbance: A high number indicated disturbance, but it is not necessarily important in tissues. Especially, where the sarcode resonance is heard, probably a secondary external source is also at present.

Muscle Tension: Higher numbers mean higher tension or a tension.



Nosode: Energetic pattern from tissues or pathogens in issue.

Client: Words "Client" and "Patient" are interchangeable, since both expressions refer to the very same person, who is connected to the device. If the therapist possesses authorization, he/she may refer to the Patient as a "Client." If the therapist does not possess authorization, he or she may refer to the individual connected to the device as "Client".

Phase Angle: Delay between the stimulating current and the voltage produced by a current alternation on 50 KHZ in the conductor media; phase shift is measured in degrees. The whole cycle of the current represents 360 degree, therefore a phase shift of 6 degrees represent a 6/360 shift or 1.67%.

Phase Contrast: A method for visualizing blood disturbances by a special microscope.

Proton Pressure: The level of pressure exercised by the proton content of the electricity of the Client's body. The normal value varies between 65m² and 70m². Under 65, is deemed to be acidic and above 70, alcalice. No correlation exists between the electric measurement of the body and the urine, saliva or other body fluids.

Purple Color Band: Elements for which the reaction of the Client exceeds the twice of the basic reaction.

Reactance: In the examination of AC current electric circles, reactance means the imaginary part of impedance created by the circuit. Tangibly, reactance in the circuit brings about a time-lag between voltage and the current.

Reactance Speed Index: A number indicating, how many times did you have to decrease in order to get an optimal reaction about the electricity of the Client

Reactivity: Characteristics of the score resulting in the energetic reaction of the Client after one item between exposition 1/80 and 1/110 per seconds.

Reactivity Dysfunction: See above – hypo/hyperreactivity.

Rectified: A signal referring to the improvement of an energetic disturbance according to the measurement of the device. It cannot tell, how long shall the replacement exist.

Red Value Color Band: Elements for which the reaction of the Client exceeds the thrice of the basic reaction.

Resistance: A component of impedance referring to energy loss in the material.

Resonance: Reaction of the Client after 1 second of exposition, indicating the importance of one element.

Sarcode Resonance: Indicates, how much resonance exists in a healthy energetic sample. High values indicate hyperfunction or too much energy, which is probably normal, but stressful because of external sources. A value below 50 refers to underactivity or too little energy, i.e. to a presumably unhealthy or disturbed tissue.

Selye Stress Scale: Valuation with t stress scale showing, where the body-electricity of the Client is in danger, where was it able to adapt itself or where has it depleted.

SOC: Healing of oppression or occlusion calculated in accordance with the demographic panel.

Test Matrix Item: These are the stress energetic samples, which are prepared electronically for the energetic characteristics before a homeopathic measurement.

Therapist: The expressions "User" and "Therapist" are interchangeable notions, since both refers to the person, who operates the device. Those, who use the device to their own benefit or their family members,



call themselves as "Users". Those, who beyond their personal benefit use the device regularly on others outside the family, are "Therapists".

Trivector: 3D electric holograms are prepared during the use of the device in order to characterize the electrical resistance (conductivity), static (capacitive, amperage) and magnetism (inductance, voltage) of the body.

User: The expressions "User" and "Therapist" are interchangeable notions, since both refers to the person, who operates the device. Those, who use the device to their own benefit or their family members, refer to themselves as "Users". Those, who, beyond their personal benefit, use the device regularly on others outside the family, are "Therapists".

Yellow Color Band: Items, where the reactivity of the Clients is higher than the average.

Xrroid: This name was created by the developer and refers to the fact that the reactivity test is able to work with biologic speed.



25. Part – Definitions

Please avoid using the following words with care in connection with the use of the device:

DO NOT evaluate, **DO NOT** advise, **DO NOT** heal, **DO NOT** perceive, **DO NOT** make a diagnose, **DO NOT** cure, **DO NOT** identify, **DO NOT** make promises, **DO NOT** prescribe, **DO NOT** offer, **DO NOT** repair, **DO NOT** examine, **DO NOT** make tests, **DO NOT** treat and **DO NOT** use the word illness.

There are references to medical treatment behind these words; after the explanation of the word, you can read the suggested expressions.

Therapy (do not use):

To remedy, attend, improve, regenerate, rehabilitate, mitigate, restore, handle or to help otherwise the individual's recuperation from any kind of medical or psychological state.

The healing or treating of any kind of state or illness is unlawful it is practiced by someone, who do not possess authorization.

Re-education and relaxing (use these instead of "therapy"):

Re-train or re-education with new objectives; re-build or re-start.

Relaxation: in order to alleviate tension, rigidity or hard, please, relax; relaxation of muscles; to relieve or alleviate nervousness of the consequences of tension and anxiety; to become less hot-tempered.

To make a diagnosis (do not use!):

Analysis, assessment, examination, calculation, projection, testing, making experiments with, measure, finding out, investigation, judging, ranking or counting any kind of medical or physiologic state. Diagnosing of any kind of medical or psychologic stated by someone who does not have the proper authorization is illegal.

Relaxation (use this instead of making diagnosis):

in order to alleviate tension, rigidity or hard, please, relax; relaxation of muscles; to release or alleviate nervousness of the consequences of tension and anxiety.

Biofeedback is a practice that allows to the individual to learn, how to relax and how to change certain physiological activities with the aim to improve health.

Disease (do not use!):

An organ, part of body or system that works abnormally or improperly caused by genetic or developmental defects, infection, toxin, eating disorder or malnutrition or adverse environmental conditions; disease; being physically unwell; malaise. Diseases can be treated only by medical professionals possessing proper authorization.

Stress (use this instead of disease):



Biological reaction to physical, emotional, mental, psychological or spiritual stimuli that endangers normal functioning.

Patient/ sick (do not use!)

The expression "patient" covers those clients, who are under the treatment of authorized medical professionals.

Client (use this instead of patient):

client; an individual, who uses professional services of other persons. Qualified biofeedback technicians and professionals use this expression: "client".

Prescribe, order (do not use!)

Giving advice, use therapies, enforce, to suggest, manipulate, popularize, offer, demand, to propose or treat the client in any other way.

Educate (use this instead of prescribing or order)

Training with formal instruction and oversight; give information.

Coach (use this instead of prescribing or order):

An individual, who educates or trains.

We educate and coach the clients to increase their awareness as certified biofeedback technicians.

To test (do not use!):

A certain procedure or method for studying and evaluation; study or evaluation.

Therapies (do not use!)

Treatment of a disease or the patient with some curative, rehabilitative or healing procedure; healing power or quality.

Electro Dermal Response (EDR): (Use this instead of "therapies")

A method, by which sensors check the electric resistance of the skin. Biofeedback devices measure the voltage, current and resistance of the skin. Attested biofeedback technicians and professionals are trained in the use of biofeedback devices to measure the stress reactions of electro-dermal responses and to teach to their clients, how to relax and how to teach again to our muscles to be able to learn stress and pain.

Training programs (use this instead of "therapies"):

In order to use words properly, we call biofeedback programs as training programs. As attested biofeedback technicians and professionals, we teach people, how to relax, how to teach again or muscles to decrease stress and pain.



Healer (do not use!)

An individual specialized in the provision if a certain therapy, in which area he/she may give treatments.

Attested biofeedback technician or professional (use this instead of healer):

An individual, who is trained in the use of the biofeedback device, which measures the biologic activity of his/her clients in order to teach the clients how to relax and re-train our muscles in view to the alleviation of stress and pain.

Therapy (do not use!)

Treatment of a disease or the patient with some curative, rehabilitative or healing procedure; healing power or quality.

Relaxation training (use this instead of "therapies"):

in order to alleviate tension, rigidity or hard, please, relax; relaxation of muscles; to release or alleviate nervousness of the consequences of tension and anxiety; to become less hot-tempered.

Change words therapy, treatment or to treat to "teach" or "training program". Biofeedback is a process that helps clients to measure and change biological activities by smoothening muscles and re-training them in helping the alleviation of stress and pain.

Treatment, to treat (do not use!)

Attending a disease or patient in view to alleviation or healing; medical or operative care or treatment.

Educate or teach (use these instead of "treatment"):

Make changes on the basis of education or exhortation; to teach in a way that is the best for the client; to prepare ourselves or to exercise

Biofeedback training programs use electric impulses in order to decrease electro-dermal stress reactions.

Treatment is an attempt to heal with different tools.

In most jurisdictions, it is prohibited to professionals not possessing authorization to treat any kind of medical or psychological state, disease or abnormality.



Part 26 – REGULATION ON ACCESSORIES

All regulations and procedures applied by Manufacturer can be found on the official web page: www.scio-eductor.com.

But as mentioned previously, under titles 'Safety of the Client' and 'Rules Regarding Harnesses and Connections' the rules pertaining to Accessories can be found here.

The Budapest Home Office of Manufacturer can guarantee the safety and effectiveness of hand, foot and head harnesses only that are part of the registered device package manufactured by Manufacturer.

The only accessories that are registered together with the original device are head, hand and foot harnesses supplied by Manufacturer to the Client directly from the Budapest Home Office. These are fitted with sequential serial numbers and indication of Q HH ddmmyy and Q LH ddmmyy (where "dd" means the day, "mm" means the month and "yy" means the year).

Here is, how they look:





The use of any other type of hand, foot or head harnesses is the liability of the user. We call your attention that the electrodes (harnesses) seen on the pictures went through safety tests that is registered to the device.

Please consider that Manufacturer shall not be responsible for the use of electrodes manufactured by any third party. The use of such electrodes or accessories belong under the scope of the user's responsibility and influences results accordingly.



27. Part – Technical Specifications

Mobility: portable device

Electrical capacity max. 0.6A DC

Input 5V DC (USB Port)

Generated signal form arbitrarily programmable (see below)

Focused ports 12 (freely replaceable channel)

Changing speed of the signal form max. 300 ms

Changing speed of the signal form max. 100 ms

Output voltage 0 – 4 Vpp DC

Breakdown of output voltage 1%

Accuracy of output voltage 5%

Output resistance min. 1 kOhm

Outgoing frequency 0 – 75 kHz

Frequency breakdown 0.01 Hz

Frequency accuracy 0.1%

Fuse applied SD260-06 (self-healing fuse)

Physical data

Length 220mm

Width 185mm

Height 60 mm

Weight: 1.340 kg

Environmental regulations

Operating temperature +10 ° - +35 ° Celsius

Storing temperature $5\sqrt[4]{70}$ (5 ° -70 ° Celsius)

Humidity 10 (10 - 90%)

Decreasing of the possibility of electric discharges; suggested best surface is the wooden floor. If the floor is finished with a synthetic material, the relative humidity should be at least 30%. If the surface is wall-to-wall carpeting, then the touch of a metallic surface is required at first in order to become free from electrical discharge, before we touch the device. No use of naked flame of any kind is advisable in the space of the device.



Manufacturer's information: Mandelay Kft., Gyártelep HRSZ 120001/33, H-2310 Szigetszentmiklós, Hungary

List of accessories

- 1 software (downloadable from our web site: <u>www.scio-eductor.com</u>)
- 1 USB cable
- 1 head electrode (harness)
- 1 hand-foot electrode (harness)

The materials of components and accessories used in the frame of manufacturing do not endanger living beings and their environment during and after their useful life. They do not contain prohibited (toxic) materials that would be harmful to human and biologic lives.

Manufacturer of the external box: Mandelay Kft.

Used material: Stainless steel

Manufacturer of electrodes: Mandelay Kft.

Material used for the production of electrodes:

60 % vulcanised elastomer, IIR (butile) natural rubber,

30 % coal-board (EC soot),

3 % Paraffin oil

Other materials: ZnO, stearic acid, sulphur, tetra-methyl-thiuram-disulphide

The components of the electrodes and the materials for the box are standard materials commonly available in the marketplace and do not have toxicity issues and do not have carcinogenic issue.

The device and electrodes do not contain any kind of prohibited materials, in higher concentration, above the permitted quantity (RoHS3).

Part 28 – Expected lifetime

The expected lifetime for the device is 5 years and for harnesses, as wear parts, are 2 years.

In case of device the extra check is not necessary (19. Part – Check of the Device). If the local regulations require regular inspections/maintenance activity, please, indicate this on info@scio-eductor.com.

Check your Harnesses regularly for use after six months. Verification is provided by the CLASP Portal software every time you use it.



Part 29 - Policies

Pieces of information not detailed in this User Manual are found on the web site of Manufacturer: https://www.scio-eductor.com/download

Part 30 - Change

Part	Description of change	Date
	first edition (based on user manual Clasp 64 2020.05.25.)	2020.05.25.
10	Notified body name changed: DNV Product Assurance AS	2021.05.18.
1 page	add CE 2460	21.07.2021.
2 page	address according to MDD certificate	
1.3	Add.: End-user owner responsibility	
10	modification of the symbols definitions and label	
11	Storage deleted: M.2 Solid State Drive or Flash are not appropriate Supported op. sys. change: Windows 11; Add inappr.op. sys.: Windows 8	
23.1	Add service	16.05.2022.
23.2	Add The warranty is 3 years.	