

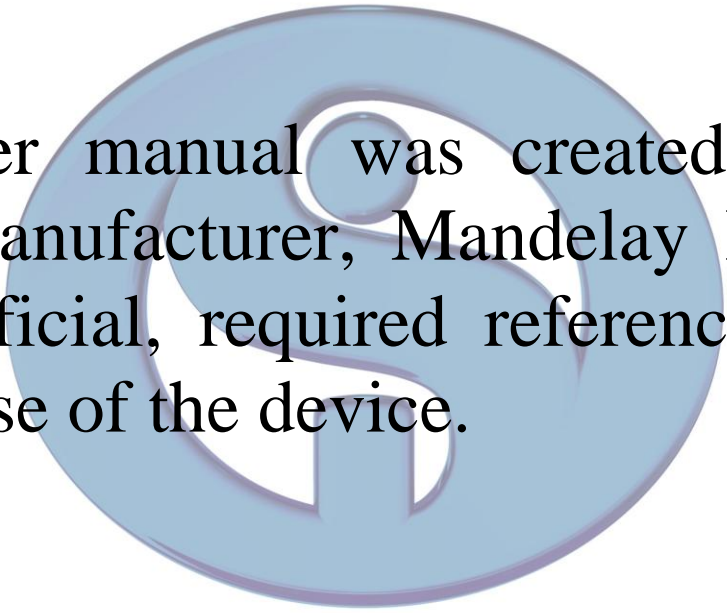
BUDAPEST HOME OFFICE (BHO)

Budapest, Hungary

# SCIO

# User Manual

This user manual was created by the SCIO manufacturer, Mandelay Kft. and is an official, required reference to the proper use of the device.



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Special thanks go to Dr. John Kelsey, PhD, ND, who helped create the first version of this manual on which this current version is based.

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Important Note: It should be noted that the official version of this SCIO User Manual 200003 is always the latest revision (as shown by the letter following the title "SCIO User Manual 200003-*letter*") and always the English language version.

The translated versions of the SCIO User Manual are completed as best as possible by qualified translators. However, Mandelay Kft. can only endorse the statements in the English language version of the SCIO User Manual. For the definitive statement always refer to the English language version.

# BUDAPEST HOME OFFICE (BHO)

## Budapest, Hungary

### Table of Contents

<b>WELCOME LETTER .....</b>	<b>5</b>
<b>PART 1 - WHAT IS THE SCIO?.....</b>	<b>7</b>
<b>PART 2 - SCOPE.....</b>	<b>7</b>
<b>PART 3 - INDICATIONS FOR USE.....</b>	<b>8</b>
<b>PART 4 - DISCLAIMER .....</b>	<b>9</b>
<b>PART 5 - CLIENT SAFETY .....</b>	<b>9</b>
PART 5.1 - OPERATION INSTRUCTIONS .....	9
PART 5.2 - WARNINGS .....	9
PART 5.3 – CAUTIONS.....	10
PART 5.4 – UNDESIRABLE SIDE EFFECTS.....	10
PART 5.5 - HARNESS RULES AND CONNECTIONS .....	11
PART 5.6 - HARNESS CHECK LIST .....	11
PART 5.7 - CLEANING THE HARNESS .....	11
<b>PART 6 - ELECTRICAL SAFETY .....</b>	<b>12</b>
PART 6.1 - ELECTRICAL SAFETY ELEMENTS .....	12
PART 6.2 - CONNECTING THE SYSTEM .....	12
PART 6.3 - CLEANING THE DEVICE.....	13
PART 6.4 – X-RAY EXPOSURE.....	13
<b>PART 7 - COPYRIGHT .....</b>	<b>13</b>
<b>PART 8 - ACCURACY.....</b>	<b>13</b>
<b>PART 9 - A BRIEF HISTORY OF BIOFEEDBACK.....</b>	<b>13</b>
<b>PART 10 - SYMBOLS .....</b>	<b>18</b>
<b>PART 11 - COMPUTER SPECIFICATIONS FOR THE ‘CLASP32’ - SCIO.....</b>	<b>20</b>
PART 11.1 - CACHE AND RAM (RANDOM ACCESS MEMORY) .....	20
PART 11.2 - COMPUTER SPECIFICATIONS.....	21
<b>PART 12 - COMPUTER PREPARATIONS FOR THE ‘CLASP32’ – SCIO .....</b>	<b>22</b>
<b>PART 13 - INSTALLATION &amp; ACTIVATION PROCEDURE – SCIO.....</b>	<b>23</b>
PART 13.1 – ONLINE ACTIVATION .....	23
PART 13.2 - INSTALLATION.....	24
<b>PART 14 - NECESSARY PROGRAMS FOR THE ‘CLASP32’ .....</b>	<b>26</b>
<b>PART 15 - USB-TO-USB CABLE INSTALLATION INSTRUCTIONS.....</b>	<b>27</b>
<b>PART 16 - CONFIGURING THE PORT .....</b>	<b>28</b>
<b>PART 17 - IMPORTANT PROCEDURE TO COMPLETE INSTALLATION .....</b>	<b>29</b>
<b>PART 18 - GETTING STARTED.....</b>	<b>29</b>
PART 18.1 - PERSPECTIVES ON STARTING WITH THE PROGRAM .....	29
PART 18.2 - BASIC PRINCIPLES FOR NAVIGATION.....	30
PART 18.3 - CORE ELEMENTS TO PRACTICE.....	30

# BUDAPEST HOME OFFICE (BHO)

## Budapest, Hungary

PART 18.4 - BASIC PRINCIPLES FOR CLIENTS .....	30
PART 18.5 - TIMEFRAMES .....	32
<b>PART 19 - PRACTICALITIES.....</b>	<b>33</b>
PART 19.1 - ACCESSING THE FUNCTIONS.....	33
PART 19.2 - FROZEN SCREENS .....	33
PART 19.3 - RESTORING A CLIENT .....	34
PART 19.4 - BIOFEEDBACK AND DEMONSTRATION VERSIONS .....	34
<b>PART 20 - CHECKING THE SCIO INTERFACE .....</b>	<b>35</b>
<b>PART 21 - QUICK START .....</b>	<b>36</b>
PART 21.1 - PROGRAM OPENING: CLIENT DATA ENTRY .....	36
PART 21.2 - CALIBRATION .....	37
<b>PART 22 - SAVING PATIENT DATA.....</b>	<b>37</b>
<b>PART 23 - RESTORING CLIENT DATA.....</b>	<b>38</b>
<b>PART 24 – REPAIRING OR REFURBISHING YOUR DEVICE.....</b>	<b>39</b>
<b>PART 25 - GLOSSARY .....</b>	<b>39</b>
<b>APPENDIX A - ACCESSORIES POLICY .....</b>	<b>43</b>
<b>APPENDIX B – GOOD MANUFACTURING PRACTICE (GMP) INFORMATION .....</b>	<b>49</b>
<b>APPENDIX C – WARRANTY CONTRACT .....</b>	<b>52</b>
<b>APPENDIX D – SOFTWARE LICENSE AGREEMENT .....</b>	<b>54</b>
<b>APPENDIX E – REVISION HISTORY .....</b>	<b>56</b>

# BUDAPEST HOME OFFICE (BHO)

B u d a p e s t , H u n g a r y

## Welcome Letter

Dear Friends of the SCIO,

We would like to take this opportunity to welcome you to the newest wave in Universal Electrophysiological Biofeedback Systems. We hope that you are enthusiastic about joining the worldwide family of SCIO Users.

It is required to read through these pages before first connecting, turning on, or using your SCIO and to always keep this User Manual as a reference for future uses of your SCIO. This will assist you in using your SCIO.

Please read this User Manual thoroughly. Should you have any questions, please contact the representative from whom you purchased the device.

At the end of the manual you can find the Revision History which tells you what has been changed since the previous version. Please reference this to help you understand what has been changed. Please note the following:

1. Effective 20 February 2009, the Clasp32 Software will NOT be included in your shipment from the Manufacturer, Mandelay Kft. in Budapest, Hungary. Instead, you should get the Clasp32 Software **by downloading and activating the latest version of the software from our website, [www.qxsubspace.com](http://www.qxsubspace.com)**. Your Broker can help you through this process if it is your first time.
2. Our experience shows that the USB cable that connects the laptop to the SCIO should NOT be more than 2meters long.
3. All users of the device must be registered on our official website [www.qxsubspace.com](http://www.qxsubspace.com). This ensures that you get the latest information, news and updates regarding your device.

Furthermore, this revision of the SCIO User Manual includes the terms of the Warranty Contract. Please take a moment to familiarize yourself with your warranty, which is automatically initiated based on the shipment date of your device.

In our never-ending search for excellence, we work closely with many of our users in the improvement and expansion of the program. If, after you are familiar with the program, you find that the program does not perform a particular function you would like to use, please feel free to drop us a line with a thorough but concise explanation of what you would us to consider adding to the program. All suggestions will be brought before the Board of Directors for consideration.

Our software, The Clasp32, is by far the largest and best software package in the field of Energetic Medicine today. However, it is not exempt from a few minor programming

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

errors. Throughout the years we have found that most problems come from a faulty computer, a faulty installation of the Operating System, and in most cases from inappropriate computer maintenance. If you have any problems, please contact your Representative.

We urge you to try to get the best possible training regarding the use and applications of our system. The better you know our system the more benefit your clients are going to have. Please see our website [www.qxsubspace.com](http://www.qxsubspace.com) as well as our conference website [www.qxconference.com](http://www.qxconference.com) for more information. Our system is the most sophisticated tool in the market but it can only perform as good as the therapist who handles it.

Welcome to the cutting edge in Universal Electrophysiological Biofeedback!!

Yours faithfully,  
The Mandelay Kft.'s Team





# BUDAPEST HOME OFFICE (BHO)

B u d a p e s t , H u n g a r y

## Part 1 - What is the SCIO?

The SCIO (Scientific Consciousness Interface Operations System) is a universal electrophysiological biofeedback system. It coordinates a complex electro-modal, biofeedback program with computer software in order to gather bioenergetic information of a client's subconscious. The information is gathered from the body through electrodes in head and limb straps providing an accurate and precise picture of the client's general status. This information is selected and listed by the SCIO in order of the highest reaction and the stressors are analyzed in the course of a stress management session.

## Part 2 - Scope

This User Manual is created by the manufacturer, Mandelay Kft. It supplies the basic information and operation of the SCIO software and device interface. This manual does NOT provide medical interpretation or medical advice in any way.

This is a basic User Manual instructing the user on how to get started with the device and basic important information.

Any statement within the manual is not intended to indicate a medical claim or diagnosis or therapy facility for a specific condition. The use of any facility described should not be considered as approaching or substituting in any way for medical advice, diagnosis or therapy. Clients and users of the SCIO should exercise due diligence in ensuring that they are informed and consult with a licensed healthcare practitioner.

Any statement within the manual is not intended to indicate a diagnostic claim. Only a licensed diagnostician can diagnose with any information available under the diagnostician's expertise. The device is for medical biofeedback therapy only. The device is intended for stress detection and stress reduction biofeedback therapy.

In all locations, independent of any specific wording or terminology, the SCIO system is designed with the sole purpose of:

- Assisting in facilitating the assessment and evaluation of stress that may be relevant to the client's wellbeing;
- Assisting in facilitating awareness within the organism of stress to help in the mobilization of the client's stress reduction resources.

Stress is a medical disease and concern. The World Health Organization's International Classification of Diseases #9 (ICD#9) lists 308.0 as Acute Reaction to Stress and 308.3 Stress, Acute Situational Disturbance, and the ICD#10 lists F43 Reaction to severe stress,  
Page 7 of 63 SCIO User Manual 200003-K

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

and adjustment disorders and F43.0 Acute stress reaction, F43.1 as Post-traumatic stress disorder, F43.2 as Adjustment disorders, F43.8 as Other reactions to severe stress and F43.9 as Reaction to severe stress, unspecified. The opinion of the word “acute” is to be made by the therapist or the patient and is not the responsibility of the manufacturer of the SCIO, nor this manual, nor the SCIO itself.

## Part 3 - Indications for Use

The SCIO is indicated for use as a Universal Electrophysiological Biofeedback System. The Universal Electrophysiological Biofeedback System is made up of the following Eight Universal Items which are functions of the SCIO:

1. Stress Reduction and Lifestyle Stressors Questionnaire;
2. Simple EEG [electroencephalography measuring volts] biofeedback brain wave stress reduction;
3. Three-pole ECG [electrocardiography measuring amps] simple heart awareness and biofeedback stress reduction;
4. EMG [electromyography measuring volts and amps] biofeedback for simple reeducation of muscles;
5. GSR [galvanic skin response measuring resistance] biofeedback and TVEP [transcutaneous voltammetric evoked potential] biofeedback (electrophysiological reactivity);

Since GSR biofeedback requires a microcurrent voltammetric stimulation to measure GSR, then the microcurrent has the following secondary functions as performed through the biofeedback loop:

6. Microcurrent Transcutaneous electro nerval stimulation (MENS) for pain reduction in the cybernetic biofeedback loop;
7. Trauma or wound healing and electro-osmosis in the biofeedback loop;
8. Global Voltammetric Charge Stability (Hydration, Oxidation, Proton balance) in the biofeedback loop;

All of these functions combine to form a Universal Electrophysiological Biofeedback System for the following treatments:

- a. the detection of stress and reduction of stress,
- b. the treatment of injury, muscle weakness, dystonia, muscle tension and/or muscle spasm through muscular re-education,
- c. the reduction of pain (MENS [microcurrent transcutaneous electro nerval stimulation]),
- d. the healing of trauma and/or wounds,
- e. measurement and rectification of the following terms: charge stability which is EEG Volume, (a measurement of EEG Voltage and Amperage over a course of time); skin resistance (hydration impedance of the transcutaneous resistance of the skin); and redox potential (electrophysiological changes during respiration). Collectively these



# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

are measurements of VARHOPE (voltage, amperage, resistance, hydration, oxidation, proton and electron pressure).

The SCIO is for biofeedback use only. All claims are for biofeedback only.

## Part 4 - Disclaimer

The SCIO is to be used as a universal electrophysiological biofeedback system. It is designed for stress detection and stress reduction.

The device does not diagnose any issue other than stress. Stress can come from many sources; this system uses many multimedia therapies to reduce stress. This device also measures client's electrophysiological reactivity which is another way to represent stress. Only a licensed healthcare practitioner can diagnose a client.

The system is calibrated to measure the very fine and subtle electrical reactions to a group of biological and medical stressors. The sensitivity is set so fine so as to pick up the earliest sign of distress and issues related to distress. Therefore, the results might be below the client recognition. The readings should be evaluated by trained biofeedback technicians. Always consult with a licensed healthcare practitioner. Always use additional tests or referrals. No claims other than stress detection and stress reduction may be made.

## Part 5 - Client Safety

The information here is very important and this information should always be readily available. Following these important instructions is vital to ensuring safe use of the device. If you have any questions please contact your Representative.

### ***Part 5.1 - Operation Instructions***

1. **Read all of these instructions in this User Manual.**
2. **Save them for later reference.**
3. **Follow all Warnings and Cautions marked on the product and included below.**
4. **Unplug the device from the USB cable before cleaning it.**
5. **DO NOT use this device near water.**
6. **DO NOT place this device on an unstable cart, stand, or table.**
7. **DO NOT allow anything to rest on the USB cord.**

### ***Part 5.2 - Warnings***

In following with the Essential Requirements of a medical device, Warnings must be clearly worded and stated to ensure the safe use of the device. Therefore, the following Warnings

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

have been established based on our Risk Analysis and must be implemented in your use of the device. If you have any questions, please contact the Quality Manager of the Manufacturer, Mandelay Kft., directly.

1. **Do not use on patients with epilepsy or a history of epilepsy.**
2. **Do not use this device with a pacemaker.**
3. **Do not use on patients with electrical hyper reactivity.**
4. **Do not use over irritated, inflamed, red or broken skin.**
5. **Do not use on pregnant women.**
6. **Do not use on children under 3 years of age.**
7. **Do not use on patients who are under the influence of drugs or alcohol.**

### ***Part 5.3 – Cautions***

In following with the Essential Requirements of a medical device, Cautions must be clearly worded and stated to ensure the safe use of the device. Therefore, the following Cautions have been established based on our Risk Analysis and must be implemented in your use of the device. If you have any questions, please contact the Quality Manager of the Manufacturer, Mandelay Kft., directly.

1. **Do not allow the metal part of the limb harnesses to directly touch the skin.**
2. **Use caution with psychotic clients or clients with histories of electro-shock.**
3. **Use this device with a computer on battery mode free from wall current or with a medically safe surge protector.**
4. **Clean the harness after every use (especially when there is a suspicion of infection).**

### ***Part 5.4 – Undesirable Side Effects***

Mandelay Kft. has performed a Risk Analysis to mitigate any possible undesirable side effects that may arise from the use of the SCIO. However, post-market surveillance shows that some patients have experienced these undesirable side effects:

- A slight feeling of light-headedness after a session. Please note that this may be due to the patient's own health such as high blood pressure or the sudden standing up after being in a relaxed, reclined position during the session. If this feeling feels in any way abnormal or of a concern, then the patient should see their primary healthcare practitioner.
- Through biofeedback transcutaneous interaction with the CNS the SCIO may induce an autonomic nervous system cascade that can lead to a vasovagal crisis. The patient might sweat excessively, report nausea and dizziness. If this occurs, place a cool wet rag over the eyes gently with light pressure, tell the patient to relax breathe

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

deeply, and wait about 5 to 10 minutes for the vasovagal storm to pass. In extreme cases there might be syncope.

- Some patients are highly sensitive to certain plastics, rubbers, or metals. These are usually people who do not wear a lot of jewellery and who do not use a lot of lotions or perfumes. Some patients have noted a slight redness of skin where the harnesses were connected to the patient. If this of concern, then the patient should consider returning for another session until they see their primary healthcare practitioner.

### ***Part 5.5 - Harness rules and connections***

The use of harnesses and/or accessories that are not part of the original registered device are at the user's own risk. Please see Appendix A "Accessories Policy" for a photograph of the original registered device including harnesses.

The connections are as follows:

- Black lead to left ankle
- Blue lead to right ankle
- Red lead to right wrist
- Yellow lead to left wrist

Head harness to forehead (or other body part when doing specific therapies) (with the strips in contact with the client forehead: it is not important which side the cable is- left or right).

It is best if the contact is with the skin: use of an electroconductive spray or lotion is recommended.

### ***Part 5.6 - Harness Check List***

Please check each time in the interests of your client the above warnings and cautions.

1. Explain to the client the straps, their position, and how long they will be present.
2. Check if the client has had a previous experience which makes them fearful or uncomfortable with straps (e.g. electroshock therapy).

### ***Part 5.7 - Cleaning the Harness***

Wipe clean the harness with a sterilising solution (3 to 5% peroxide dilute, 10% alcohol solution or equivalent) between each use. Avoid the use of strong cleaners that may damage the rubberized material. Periodically clean the harness with warm soapy water.

## Part 6 - Electrical Safety

The device has been proven to be safe and effective to all internationally recognized harmonized standards. Here is some basic information on electrical safety to ensure that you are fully aware of how to safely and properly use the SCIO.

### ***Part 6.1 - Electrical Safety Elements***

It is current (amps) that can kill and not volts. House supply is 115 volts (USA) and 230 volts (Europe) AC (alternating current) but with 1 amp. 3 amps will usually kill a much smaller dose of even .2 amps directed through the heart can do damage.

The SCIO works at medically absolutely proven safe micro-current milliamps and has safety devices in the SCIO box to stop over-current and volts. The SCIO is powered by the USB connection to the computer and thus the possibility of harm from mains power supply is minimal: further measures are indicated below to conform with safety requirements.

***Please use the SCIO with a computer on battery mode or with a medically safe circuit breaker surge protector.***

It is fundamental and part of electrical safety legislation to protect the client from harm. This can come from two sources: that are impossible with proper use of battery or circuit surge breaker:

- (1) A short circuit, where electricity passes directly to earth/ground via the client. (e.g. a knife in the toaster)
- (2) A mains surge or lightning strike.

This cannot occur when the computer is operating on batteries. However batteries don't last for long in the computer (1-2 hours). Therefore, it is practical to work on mains power. This dictates that safety equipment is used. This is what is referred to as a "Medical Transformer". Essentially the protection can be afforded using specific components:

*Short Circuit:* a RCD (Residual current Device/Detector) or ELB (Earth Leakage Breaker), normally available at 30 ma.

*Lightning/Mains Surge:* a surge protector board, available from computer shops.

### ***Part 6.2 - Connecting the System***

*Power supply*

- 1 Plug the USB from the computer to the SCIO.
- 2 Connect the computer to mains power via the electrical safety devices.



# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

- 3 From the Mains Socket, to the RCD/ ELB, to the Surge Protected Plug Board, to the Computer.

### ***Part 6.3 - Cleaning the device***

The device may be cleaned periodically as needed with a similar compound used to clean the harnesses. It is not necessary to clean the device after every client. To clean the device use either peroxide or alcohol. The recommended concentration is 10% alcohol or 3 to 5% peroxide solution for the harnesses and it is recommended to use the same concentration to wipe down the outside of the device.

### ***Part 6.4 – X-ray Exposure***

The device is designed to withstand some X-ray exposure. We estimate about 50 (fifty) normal X-ray checks. We believe that after 50 (fifty) X-ray exposures the device should be refurbished. Customers would notice limited recognition between device and software; lights will be dimmer than before which would suggest that it might be time for refurbishment. For options of refurbishment, please contact an Authorized Service Center under the Service Center Policy, which can be found on [www.qxsubspace.com](http://www.qxsubspace.com).

## **Part 7 - Copyright**

The right of Mandelay Kft. as the author of this manual has been asserted by the company in accordance with Copyright, Designs and Patents Act, 1988, and all associated international protection.

All rights are reserved independent of the sourcing route. No parts may be reproduced, stored in a retrieval system or transmitted in any form by any means without the prior written permission of the author.

## **Part 8 - Accuracy**

Every effort has been made to ensure the accuracy of the information provided. No information is intended to be used or should be used as a substitute for information from a licensed healthcare practitioner.

## **Part 9 - A Brief History of Biofeedback**

Edmund Jacobson in 1908 developed the progressive muscle relaxation technique (1958). Although most of his research on the conditioning of muscle relaxation was conducted 50 years ago, it remains relevant. For example, most therapeutic applications of biofeedback



# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

include the use of a systematic relaxation technique. Although Jacobson's system has been modified over time, his ideas and research methods have much to offer clinicians and researchers. Based on an interview reported by McGuigan, he may have been the first researcher to use medical instrumentation to provide feedback about physiological responses (Jacobson and McGuigan 1978). His procedure, employing a prototype of modern biofeedback instrumentation, involved an individual observing an oscilloscope to determine the level of tension in his forearm extensor muscle. Later, Wolpe (1973) modified Jacobson's technique and popularized it as part of the systematic desensitization procedure.

In 1958, Kamiya (1969) began to study the changes in Consciousness that accompanied variations in EEG alpha rhythm of human subjects. He developed a discrimination conditioning task in which a bell was rung periodically and the subject was requested to indicate if he had been generating EEG alpha just prior to the auditory stimulus. Many subjects were able to learn this task and this led to further research of alpha rhythm control. Kamiya and his associates later discovered that subjects could suppress alpha when given auditory feedback concerning its presence or absence. Although the initial claims of alpha wave trainers were found to be exaggerated, research by Kamiya and others continues and may eventually lead to the development of more effective clinical methods. Due to the unpredictability of the results so far, the clinical utility of EEG alpha rhythm training remains problematic (Miller, 1974).

Ancoli and Kamiya (1978) reviewed several areas of controversy surrounding EEG biofeedback. For example, one unresolved issue is whether or not the reported increases in EEG alpha are due to reductions in visual and oculomotor responding. Ancoli and Kamiya reviewed 45 different EEG biofeedback studies from 1968 to 1976 and concluded that a majority of the studies suffered from methodological weaknesses. They believed that many negative results occurred because training times were too short and experimental conditions were not optimum. They suggest that, in the future, researchers should employ at least 4 training sessions, use continuous feedback with quantitative progress scores and use experimental trials which have a duration of at least 10 minutes.

One of the intriguing areas of investigation concerns the search for empirical validation of visceral or smooth-muscle operant conditioning. Since 1938, when Skinner could not demonstrate operant conditioning of the vasoconstrictory responses, researchers have been interested in this area of learning.

Neal Miller and his colleagues most notably, (the late Leo DiCara) have been involved in research on instrumental autonomic conditioning in animals for a number of years. In 1968, DiCara and Miller observed that curarized rats could learn to avoid a shock by lowering their heart rate. Miller's attempts to replicate this finding in subsequent years, however, met with frustration. Nevertheless, during this time other investigators showed that visceral conditioning, through the use of feedback techniques, could be demonstrated in man (Miller and Dworkin, 1974).

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

Whether or not Miller's original findings were artifactual or due to complex interactions of variables are still undetermined. There is no doubt, however, that the publication of his early research on visceral conditioning in animals did much to stimulate others to investigate similar issues in man, and more sophisticated biofeedback techniques were developed.

Although less well known, H D Kimmel (1960) spent years investigating instrumental conditioning of the autonomic nervous system (ANS) in man. Stimulated by results of earlier experiments in conditioning of the galvanic skin response (GSR), Kimmel and his students found that subjects' GSR's could be conditioned using pleasant odors. Kimmel (1974) summarized the research up to 1967, including 16 studies of GSR, five of heart rate and three of the vasomotor response. Results of all these studies supported the contention that the ANS could be modified through operant conditioning.

These findings were criticized by Katkin and Murray (1968) who argued that such results may be due to skeletal mediators and have still obtained positive results. For example, Lang and Melamed (1969) were able to condition aversively a 9-month-old child who suffered from ruminative vomiting. In addition, Frezza and Holland (1971) demonstrated that human salivation can be instrumentally conditioned.

Subsequently biofeedback procedures were applied to clinical problems. In 1973, two innovative therapy procedures were developed which are widely used today, with certain technical refinements. Elmer and Alyce Green (1977) developed a clinical protocol for thermal feedback training. They used peripheral skin temperature as a measure of vasodilatation and combined skin temperature feedback with Schultz and Luthe's (1969) "Autogenic Training". Sargent, Green and Walters (1972) applied temperature biofeedback training to treat migraine. Clients were taught to increase the warmth in their fingers (vasodilatation) while decreasing the temperature of their foreheads (vasoconstriction). They found that almost 75 percent of the subjects were able to decrease both the duration and intensity of migraine attacks. Later studies have confirmed these results.

While the Green's were developing their therapy technique for migraine, Thomas Budzynski (1973) and his associates at the University of Colorado developed a feedback technique to treat muscle contraction (tension) headaches. They used EMG training to teach clients to reduce the tension in their frontalis (forehead) muscles. Their results showed that average muscle tension levels dropped from 10 to 3.5 (microvolts) and headaches intensity was reduced over the 16-week training period. Two control groups of headache clients were employed in the experimental design; one group received "false" or pseudofeedback and the other group received no feedback at all. Neither of these groups improved as much as the EMG therapy group. Since then, the results have been somewhat mixed regarding the effectiveness of EMG biofeedback compared with simple relaxation methods.

The clinical research which has been reviewed thus far has involved procedures where feedback is used to reduce muscle and blood vessel contraction ("physiological arousal");

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

however, a technique to increase muscle contraction (a form of EMG biofeedback training) has existed for almost 25 years. John Basmajian's (1979) early research, first published in 1963, indicated that clients can increase the functioning of single motor units through the use of EMG biofeedback. Even earlier, Marinacci and Horande (1960) demonstrated that EMG feedback could be applied to improve neuromuscular functioning in several disorders. Basmajian and his colleagues have designed specially constructed biofeedback instruments for use in rehabilitation, e.g., a miniature EMG feedback device. They have applied such instrumentation to various disorders including paralytic foot-drop. There is significant difference between the EMG units used in rehabilitation and those adapted for use with psychophysiological disorders. The biofeedback units employed in rehabilitation are designed to transmit information about single motor units or the functioning of a specific muscle. Most of the EMG units used to enhance relaxation, however, summate the bioelectrical information of a particular muscle group. The resulting feedback is somewhat less specific.

Prior to 1970, relatively few studies were conducted using biofeedback techniques. Since then, however, hundreds of investigations have been done and the accumulation of data has been impressive. For this reason, BSA task forces were developed to survey the current literature and summarize the current status of biofeedback as a therapeutic technique in a number of areas including: psychophysiological disorders (Fotopoulos and Sunderland, 1978), gastrointestinal issue (Whitehead, 1978), vasoconstrictive disorders (Taub and Stroebe, 1978), muscle tension headache (Budzynski, 1978) and others.

In 1989 Nelson proposed and proved that biofeedback need not be just a conscious or verbal process. By biofeedback transcutaneous interaction with the body electric or CNS (central nervous system) the system can autofocus TVEP (transcutaneous voltammetric evoked potential) stimulation. The SCIO was designed to do biofeedback transcutaneous interaction to the client's CNS.

In summary, individuals in certain circumstances can learn to control various physiologic processes as a result of biofeedback training.

### Neuroanatomical and Physiological Basis of Biofeedback

Neurophysiologists and clinical neurologists are aware of the fact that the brain acts as a CNS whole unit and that the functioning of each and every part of it affects the performance of most of the other parts. Clearly, however, certain areas are more closely allied than others by anatomical or physiological links. Also, there is a localization of function such that the different regions of the brain are specialized for certain activities and although their role can be substituted to a certain extent, they operate most effectively only when carrying out their particular function. Broadly speaking, the tasks of the brain can be divided into three great categories:

1. The reception of stimuli (this is the sensory system)
2. The association of stimuli and the analysis of perception of incoming stimuli

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

3. The motor response to those stimuli, or the autonomic response to internal and external stimuli.

This is the end of a very brief history of Biofeedback. If you are interested in researching this topic further there is numerous information available.









# BUDAPEST HOME OFFICE (BHO)

B u d a p e s t , H u n g a r y


## Part 10 - Symbols

As you look at the biofeedback box itself, you will see the following symbols. Here is an explanation of the meaning of the symbols.

On the bottom:

	<b>Symbol for “MANUFACTURER”</b>
[yyyy] 	<b>Symbol for “DATE OF MANUFACTURE” with year of manufacture.</b>
#####-[x]	<b>Control number for the label followed by the revision number.</b>
	<b>Symbol for “CAUTION”:</b> means that it is imperative that users read this SCIO User Manual before using the device for the first time and as a reference for all future uses.
	A CE Mark is issued by a Notified Body, as identified by the four-digit number next to the CE Mark. The four-digit Notified Body number can be found on the CE Certificate.

On the back:

	<b>TYPE BF APPLIED PART:</b> It stands for the classification of a permissible filtered current as well as assurance of grounding for safety regarding this current.
---	--

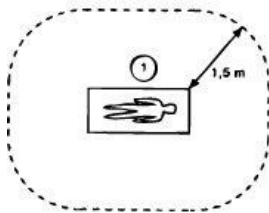
The Serial Number found on the back of the device is in the following format SXxxxxxxxxxx.



# BUDAPEST HOME OFFICE (BHO)

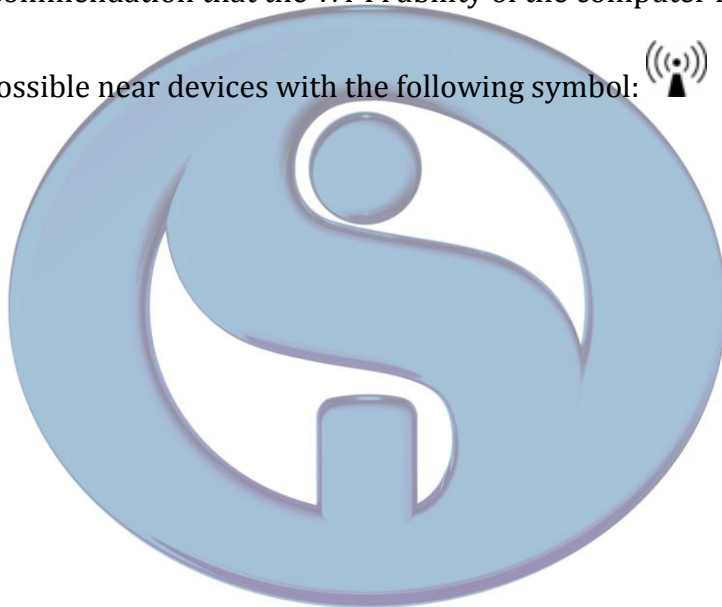
## B u d a p e s t , H u n g a r y

Only to be included in this User Manual as these are only a recommendations and not requirements:



For the best optimum performance, it is recommended to keep any other electronic equipment such as cell phones, radios, electro-static air cleaner and other such devices, a minimum of 1.5 meters out of the device's radius. This will reduce the potential for outside interference. However, it is possible to keep the operating computer within this 1.5 meter radius, with the recommendation that the Wi-Fi ability of the computer is turned off.

Disturbances are possible near devices with the following symbol: 



## Part 11 - Computer Specifications for the 'Clasp32' - SCIO

This page will inform you about computer memory size, speed, and other requirements that are best compatible with the SCIO.

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### **Part 11.1 - Cache and RAM (Random Access Memory)**

The difference between the different CPUs (Central Processor Unit) is the speed, and the cache (The memory built into the processor itself). An AMD\* CPU normally will perform faster than an Intel\*\* CPU at the same speed. The Celeron\*\*\* CPU normally has less cache.

The 'Clasp32' (Software required by the 'SCIO'), will first look for the space it needs to perform in the cache memory, this is extremely fast. If it does not find enough space it will go to memory built into the memory on the motherboard, slower but still fast (This is the RAM). If it still does not find the space there it has to go to the hard drive (Slow) and execute the instructions. This however will only happen with the 'Clasp32' at very low RAM (e.g. 512 Mb). Thus the program may run but slowly. However, this is NOT recommended at all.

The 'Clasp32' is a large application program running in real time. The Operating System 'Windows' does not run in real time. The 'Clasp32' sends a signal to the box (Rx light flashes once), then box starts to generate the appropriate frequencies (Tx light flashes once) and then the 8 red lights. The 'SCIO' includes its own processor to be able to do this, thus the CPU of the computer is free.

The computer needs a high resource capacity, because the 'Clasp32' Database (the core of the program), uses the 'SQ Lite Database engine'. Due to the phenomenal amount of information generated, the database engine has been stretched to its maximum capabilities. Other aspect is the image generated animations, these require a lot of

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\* **Advanced Micro Devices:** Global supplier of integrated circuits for the personal and networked computer and communications markets headquartered in California, USA.

\*\* **Intel:** American electronic corporation headquartered in California, USA. It is the World's major producer of a variety of electronics and computer components (including semi conductors, microprocessors, chipsets, and more.

\*\*\* **Celeron:** New computer processor from the Intel Corp. Slower than the Pentium chip, it was designed for the home computer market in the lower price range.

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

resources. The specifications focus on the RAM but 'Cache' must be taken into consideration.

### **Part 11.2 - Computer Specifications**

- It is advisable to dedicate a laptop to the program. However, if this is not possible then it is highly recommended that no other programs of medical nature be installed as conflicts have been reported in the past. It is advisable to only install the recommended software and to follow the 'Computer preparation' instructions.
- If possible, avoid the cloned types as many problems have been reported due to their architecture, their timer chips and in some cases the cheap components.
- It is recommended to have an Intel Core CPU (Core 2 duo) with a speed over 2 GHz. Try to avoid Celeron, because of the less 'cache' factor.
- The program itself requires about 5 GB of hard drive space for installation. Always maintain at least 10 GB free in the hard drive so that regular maintenance can be carried out.
- 2 GB of RAM is recommended.
- The 'SCIO' has a USB port. You may be connected directly using a USB cable. To install the USB Cable, please see the page "USB – to – USB Cable Installation Instructions."
- Monitor TFT/XGA\*\*\*\*: Pixel size must be set at 1280x1024 or higher for optimum viewing of the 'Clasp32'.
- Video and Sound cards are required with a minimum 128 MB memory available.
- The Operating Systems needed is 'Windows XP', 'Windows 7' or 'Windows Vista', the 'Professional' version is recommended.

**NOTE: Due to changes in computer technology, the information above may change without notice.**

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\*\*\*\* **TFT/XGA:** Thin Film Technology / Extended Graphics Array, which allows displaying up to 65000 colors

## Part 12 - Computer Preparations for the 'Clasp32' – SCIO

It is recommended to follow these procedures before the Clasp32 has been installed.

1. Clearing your "Startup" Menu: Go to Start / Programs / Startup and delete any program loaded there. This is done clicking over the name of the program with the right button of the mouse to display the sub-menu. Choose 'Delete'.
2. On the 'Desktop' it is advisable to only keep 'Shortcuts', these are the icons with a little arrow in the bottom left corner. Any other document should always be kept in 'My Documents'. The desktop should only contain the shortcuts to the most often used programs. In fact, I recommend to only having the 'Recycling Bin' in the 'Desktop' and the 'Shortcuts' in the 'Taskbar' (The bar at the bottom of the screen). To do that it is necessary to drag the icon from the 'Desktop' and drop in the 'Taskbar'. For the 'Taskbar' to allow icons it must be unlocked: click with the right button of the mouse and in the contextual menu have the check mark next to 'Unlock'.
3. Setting up your Display: For Windows Vista or Windows 7, go to the Desktop / right click / click on Personalize (for Windows 7 the next option is Screen Resolution) / click on Display Settings. Set the 'Screen Resolution' at 1280 x 800 pixels or **bigger** if you have a 15 inch screen. Power configuration: In the 'Screen Saver' set to 'None', click on 'Power' and set all the values to 'Never'.
4. Empty the 'Recycle Bin' and restart the computer.

**Disclaimer:** This document for guidance only. Mandelay Kft. is not responsible in any way for any damages, file lost or otherwise, caused or derived from or as a result direct or indirect of this information.

Once the 'Clasp32' has been installed and activated as well as the recommended programs installed it is advisable to execute this routine so that the computer stays tuned up to better run the 'Clasp32'.

## Part 13 - Installation & Activation Procedure – SCIO

Please read thoroughly before loading the 'Clasp32' program into your computer. The most current version of the 'Clasp32' is always available on [www.qxsubspace.com](http://www.qxsubspace.com). These instructions specifically relate to the most current version of the program. Furthermore, there are numerous Video Tutorials available on [www.qxsubspace.com](http://www.qxsubspace.com) for easy reference on the Installation and Activation Procedures.

### **Part 13.1 – Online Activation**

In order to provide a more professional service to our customers we are now able to offer 24 hour internet activation. Please follow the instructions below and if you have any difficulties please contact your broker for assistance.

These instructions are for users to activate their own software online. If you do not have internet access please contact your broker.

You will be able to pay with PayPal, either with your own PayPal account or your credit card.

1. Register on [www.qxsubspace.com](http://www.qxsubspace.com) – Sign up!
2. Run the SCIO Software by clicking on the 'Eductor' or 'Clasp32' icon on the desktop.
3. Click 'Close' on the 'SCIO Is Working' screen when the program reaches 25%.
4. On the following screen, please click on „Continue”.
5. Then click on „Password”.
6. If this is your first activation on the laptop/desktop, right after the installation, please enter your name and country in the „Password” screen and then click on „I agree to all terms and save”.
7. Read the installation instructions than click on „Close” in the „Biofeedback device installation instruction” screen.
8. On the „Password” screen click on „Activation”.
9. Please choose between the „A,B or C” options and select the type of purchase. Enter the purchase date and click on „Close”.
10. Click on „Continue”.
11. The 'Internet' button is always active, whether you have Internet access or not. If you have Internet access on the computer, please select 'Internet'.
12. In the 'Activation window' please enter your [www.qxsubspace.com](http://www.qxsubspace.com) Username and Password and click on „Send to the Server”. You will be automatically redirected to Paypal.



# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t ,   H u n g a r y

13. There are two options of paying the activation fee:

1. Through a Paypal account
2. Through a credit or debit card (if you do not have a Paypal account). To do so, please fill in the form and click on „Review order and Continue”.

14. Click on „Pay Now”.

15. In the next screen click on „Return to QX ltd”. This can be either a link or a button, depending on the Paypal site.

16. As soon as the payment is complete, the following message appears: „Your computer is activated, Congratulations...”. Click on „OK” to proceed.

17. Click „OK” on the following message to close the program.

18. The Software is now ready to use.

The current activation fee you can find on our website [www.qxsubspace.com](http://www.qxsubspace.com).

If you have any questions or problems regarding this please write to, Ibolya Molnar-Bodzsar, Broker Relations Manager at [ibolya@qxsubspace.com](mailto:ibolya@qxsubspace.com).

### **Part 13.2 - Installation**

1. Switch your computer on and make sure that you are at your Windows desktop and that no other programs are running.

In case if you have **WINDOWS VISTA or Windows 7** on your computer you need to turn off the UAC (User Account Control). Please do the following steps:

- a. Go into the Control Panel and double click on the User Accounts (Classical view) or open the User Accounts and Family Safety and the User Account (Vista view). There you will find a link called „Turn User Account Control on or off”, open it. In the next screen you will find a checkbox called „User Account Control (UAC) to help protect your Computer”, uncheck it. **NOTE:** The UAC must be turned off for the stabil running, and the installation of the Clasp 32 software.
- b. Reboot your computer, and wait until the boot sequence is finished.

2. If you have the software on DVD, place the DVD in the appropriate drive. Wait a minute (quite literally). The DVD should auto load. Should that not occur because either the setting ‘auto run’ of the drive is not activated or the drive does not properly register the DVD, double click on the desktop icon ‘My Computer’, right click on the DVD drive, choose ‘Explore’ and double click on the torch icon ‘Start’. If you have downloaded the software it will install on the drive that you selected.

3. Click on ‘Clasp32’ and then follow the Installation Wizard’s instructions.

4. On the second screen of the Installation Wizard the software automatically selects all of the additional programs to be installed (Clasp32 Database, BodyViewer, Disease Lexicon and Ant-Smoking). Click ‘Next’.

5. On the following screen you can select where to install the software (we **STRONGLY** recommend the default folder). Click ‘Next’.

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t, H u n g a r y

6. On the following screen Click 'Next' to confirm and proceed with the installation.
7. Click 'Finish' when the installation is complete.
8. Click on 'Close' until you get back to the Windows desktop.
9. Remove DVD from drive.
10. Restart the computer.



### Part 14 - Necessary Programs for the 'Clasp32'

This page details programs you need to have on your operating system. This can be done either before or after installing the Clasp32.

1. Necessary:
  - a. **DivX Player and DivX Codec:** Please visit the website [www.divx.com](http://www.divx.com) and download DivX 7. Please see the page "Installation and Activation Procedure." These are necessary to visualize some of the videos in the 'Clasp32' and in particular those included in the 'Biofeedback' section.
  - b. **Microsoft Word.** This program is necessary to visualize the great amount of written information available in the 'Clasp32.' There are some documents that will guide you through the "Clasp32."
  - c. **Internet Explorer 4 or later Web browser.** This program is necessary to go through the Online Activation process.
  - d. **Adobe Reader 7.0 or later.**  
Free version can be downloaded from [www.adobe.com](http://www.adobe.com). This software is the global standard for electronic document sharing. It is the only PDF file viewer that can open and interact with all PDF documents. Use Adobe Reader to view, search, digitally sign, verify, print, and collaborate on Adobe PDF files.
  - e. **Notepad.** With this program users can write small notes and open small documents.
2. Not vital but helpful:
  - a. **Microsoft Office Suite.** Besides 'Word' (Text editor), it contains 'Access' (Databases), 'Excel' (Spread sheets), 'PowerPoint' (Presentations).
  - b. **Norton Utilities.** This program is very useful to maintain the computer 'tuned up'. We have noticed that the great compatibility of this program with the 'Clasp32'.
  - c. **Norton Antivirus.** This program is necessary to keep the computer free of viruses. It is important to remember that this program or any other anti virus program must be installed after the Clasp32. It is always necessary to use an anti-virus and a 'utilities' program from the same manufacturer as conflicts may arise. Again, we recommend Norton Anti-Virus and Norton Utilities.

### Part 15 - USB-to-USB Cable Installation Instructions

Note that the SCIO does not need an external power source as power is drawn directly from the computer.

Note that the MAXIMUM recommended length of a USB cable is 2 meters (6 feet 7 inches). A USB cable longer than this will most likely reduce the communication between the operating laptop and the SCIO.

If you have installed the Clasp 32 from DVD please follow the following steps in order to set up this new SCIO:

1. Leave the DVD in the drive.
2. Plug in the USB-to-USB cable (It is necessary that the SCIO is connected at this point).
3. The 'Hardware installation wizard' will advice you of the new hardware and its dialogue box will pop up.
4. The dialogue box will ask you if you want to connect to the Internet. Select the last option 'No, not this time'. The button 'Next >' will activate. Click on it.
5. The 'Found New Hardware Wizard' dialogue box will appear. Select the 'Install the software automatically (Recommended)' option. Click 'Next >'.
6. A second dialogue box will pop up to let you know that the software being installed is not a 'Microsoft' production. Click on 'Continue Anyway'.
7. Once the installation is complete click on the 'Finish' button.
8. The 'Hardware installation wizard' will pop up again and its dialogue window will appear again. Please repeat procedure.
9. In the 'Windows task bar' the message 'Your new hardware is installed and ready to use' will appear.

Continue onto the next step, "**Configuring the Port.**"

If you have installed the Clasp 32 from the internet downloaded version, please follow the following steps in order to set up this new SCIO:

1. Plug in the USB-to-USB cable (It is necessary that the SCIO is connected at this point).
2. The 'Hardware installation wizard' will advice you of the new hardware and its dialogue box will pop up.
3. The dialogue box will ask you if you want to connect to the Internet. Select the last option 'No, not this time'. The button 'Next >' will activate. Click on it.



# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

4. The 'Found New Hardware Wizard' dialogue box will appear. Select the 'Install from a list or specific location' (Advanced) option. Click 'Next >'.
5. Select 'browse' and search for the folder where you downloaded the Clasp 32 install DVD. Select the USB driver folder. Click OK. Click 'Next >'.
6. A second dialogue box will pop up to let you know that the software being installed is not a 'Microsoft' production. Click on 'Continue Anyway'.
7. Once the installation is complete click on the 'Finish' button.
8. The 'Hardware installation wizard' will pop up again and its dialogue window will appear again. Please repeat procedure.
9. In the 'Windows task bar' the message 'Your new hardware is installed and ready to use' will appear.

**Continue onto the next step, "Configuring the Port."**

## Part 16 - Configuring the Port

Before setting up the COM Port, please make sure the driver of the device is properly installed. The following steps will guide you to set the communication port to COM1:

1. On the 'Windows XP' or Windows Vista desktop right click on 'My Computer'. If you cannot find this icon on the desktop, open the 'Start menu' and look for the 'Computer' icon there and right click on it.
2. Select 'Properties'.
3. Select 'Hardware'.
4. Select 'Device Manager'.
5. Select 'Ports'.
6. Right click on the port that corresponds to the one where the drivers for the cable has been installed, i.e. 'USB Serial Port (COM XX)'.
7. Select 'Properties'.
8. Select 'Port settings'.
9. Select 'Advanced...'
10. In 'COM Port Number' select 'COM 1'.
11. Click 'OK' in all Windows to return to desktop.
12. Go the 'Device Manager' to check changes have taken place i.e. 'USB Serial Port (COM 1)'.
13. Always connect the 'USB to Serial' cable to the same USB port you have just configured.
14. It is possible to sometimes see that the 'COM 1 (in use)' when in reality nothing is attached to it. Select the Port anyway and click 'OK'. The message 'This COM name is being used by another device (such as another port or modem). Using duplicate names can lead to inaccessible devices and changed settings. Do you want to continue?' Simply ignore the message and click on 'Yes'.



# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t, H u n g a r y

- Sometime it might be necessary to reboot the computer to save changes in the ports configuration.
- You may install the drivers of the SCIO in all the available USB ports of the computer, this way you do not need to remember which port you have configured to be used with the SCIO.

## Part 17 - Important Procedure to Complete Installation

To finish the installation of the SCIO you must specify what type of interface box you are using. From the Windows task bar follow:

1. Start / Programs / Clasp32 NEW / Interface type
2. Type your device serial number in the box at the bottom of the screen and click 'Load Number'.
3. Select the appropriate interface device and click 'OK'.
  - You only need to do this one time.
  - If you select the wrong type or change your interface box simply repeat this procedure. This is necessary because each interface box uses a different 'Baud' rate.

## Part 18 - Getting Started

The SCIO is a highly intricate and complex system and time should be taken to learn and understand the system. Here are some suggestions to help you get started, broken down in the following sections:

- Perspectives on Starting with the Program
- Basic Principles for Navigation
- Core Elements to Practice
- Basic Principles for Clients
- Timeframes

### ***Part 18.1 - Perspectives on Starting with the Program***

We recommend that you keep in mind that the benefits of the SCIO are due to the advances in science and technology. It is important to be comfortable with how to use a computer and navigate through the software. We highly recommend the following steps to success with your SCIO:

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

1. If you have no computer experience we suggest you do a short local course in Windows. Computers are not difficult but the unfamiliar is often a little daunting! Taking time to learn Windows is time very well spent and will accelerate your use of the program.
2. Learn to navigate the program.
3. Practice, practice, practice.
4. Take advantage of the home study and on-line distance learning facilities available from many independent sources.
5. If possible get some live training.
6. There is no learning substitute for real practice.
7. Representatives are authorized to create their own training manuals and multimedia to assist in the learning process, but this User Manual is the top level manual from the Manufacturer and must always be referenced as the official reference for all users.

### ***Part 18.2 - Basic Principles for Navigation***

Here are a few suggestions towards understanding some basic principles of navigation:

- Focus on Navigation
- Don't spend hours in one sitting: you will become saturated, fascinating as it will be!
- You can learn the software without having anyone in harness.

### ***Part 18.3 - Core Elements to Practice***

We suggest that you take some time to practice these core elements of the SCIO. Once you feel comfortable with these then you will be ready to go further with the SCIO.

- Opening the program
- Password Screen
- Demographics: lifestyle
- Calibration
- Testing: getting a focus: Themes
- First layer general stress balancing
- Second layer stress balancing
- Third layer stress balancing – specific areas of focus

### ***Part 18.4 - Basic Principles for Clients***

When meeting with Clients, here are some **suggested** principles to keep in mind.

1. Always do Demographics. Energetic type therapies will work much better with lifestyle support. Play with the numbers and recalculate the SOC to show the Client

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

the changes needed to get the SOC down to between 100 and 50. Guide your Client to set goals.

2. You can do Fast Track Calibration.
3. More is not better – keep the sessions with your Clients to approximately 50 minutes. But be flexible and use your own intuition and client interaction to finally decide what is best for your client.
4. Here is a suggested session guideline:

<b>Step</b>	<b>Function</b>	<b>Timing</b>
1	Demographics and briefing session on what to expect	7 minutes
2	Calibration	2 minutes
3	Test and assay	6 minutes
4	Stress Reduction muscular Re-education Support	20 minutes
5	Miscellaneous multi-media biofeedback therapy	5-10 minutes
6	Discuss and debrief the Client lifestyle changes and support needed	5-10 minutes
Agree on targets for the next visit(s)		<b>TOTAL TIME 50 minutes</b>

# BUDAPEST HOME OFFICE (BHO)

B u d a p e s t , H u n g a r y

## ***Part 18.5 - Timeframes***

These timeframes are suggested and you should decide on an individual basis what is best for you and your Client.

You can do Software Practice with a fictitious client as long as you wish within your comfortable timeframe of learning and practicing.

With Clients for basic stress detection and stress reduction we suggest weekly meetings of 50 minutes per session. During these sessions you can focus on basic therapies such as those listed above under "Basic Principles for Clients."

With Clients for acute stress, you can meet 2-3 times per week but still keep the sessions at a maximum of 50 minutes per session.

With Clients for chronic stress, we suggest the guidelines of Acupuncturists who see Clients weekly for 6 weeks and then review. Still keep the sessions at maximum of 50 minutes per session.

With all patients discuss lifestyle changes, such as supplement assistance, exercise programs, stress reduction therapy, network and social support themes, guided imagery, yoga, weight loss, smoke reduction, muscular reeducation, diet choices what to use what to avoid, say no to drugs, addiction release, and how to best grow and heal the body naturally.



## Part 19 - Practicalities

The following practicalities will be helpful in using the device and also in some troubleshooting solutions.

### ***Part 19.1 - Accessing the Functions***

There are several methods of initiating and terminating operations within the device:

- *Buttons*: clicking on these will initiate an action
- *Edit box*: information can be added into these by typing or in some screens by double clicking on an item. Edit boxes can have information altered in them in the same way as any text or word processing i.e. using backspace/delete keys etc.
- In many cases button functions are duplicated in *drop down lists* from the top program toolbar. Moving the mouse to the drop down list will generally open it up. Clicking on an item in the list will initiate the described action i.e. therapy or routing to another screen.
- In some screens single or double clicking on an item will initiate a therapy.
- In many cases the label for an item e.g. test may contain an underscore e.g. T. In these cases typing the letter T (or Alt. T) is an option to initiating the action.
- To further assist when a mouse is moved near a button or a picture on the screen a small hint will often appear for 3 seconds.

### ***Part 19.2 - Frozen Screens***

During periods of extended use or with a reduced specification system lock up or screen freezing may occur. It may seem unable to exit a screen.

1. Try minimizing the screen using the “-” at the top right. This may reveal an information panel below. Close this. This appears to happen mainly with Windows XP.
2. If you have minimized a panel it will show as “Consciousness” on the bottom toolbar. Click to restore the view and close the minimized panel.
3. There may be a SCIO operation in progress: this will disable Windows. A red Windows Interrupted and/or SCIO is Working panel will generally show. Wait until this disappears. At times this stays: if you are sure that the operation has finished then double click in the top right corner to remove the panel or use the close button on the interrupt.
4. You have played with the mouse when there is a SCIO operation (Windows Interrupt). This can confuse the system leading to a lock up. Ctrl-Alt-Del is your only option- this will display Task manager. Select “Consciousness” in the Applications tab and “End Program”. During reloading you will be asked if you want to restore the last client: saying yes will restore all the client information. Enter password

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

details as normal, ensure that the correct client displays in Demographics and proceed from where you left off.

5. If this fails use the task manager to close down the computer.
6. The final port of call is to use the power button to close down the computer (crashing). Hold the power button for 10+ seconds until it shuts down.

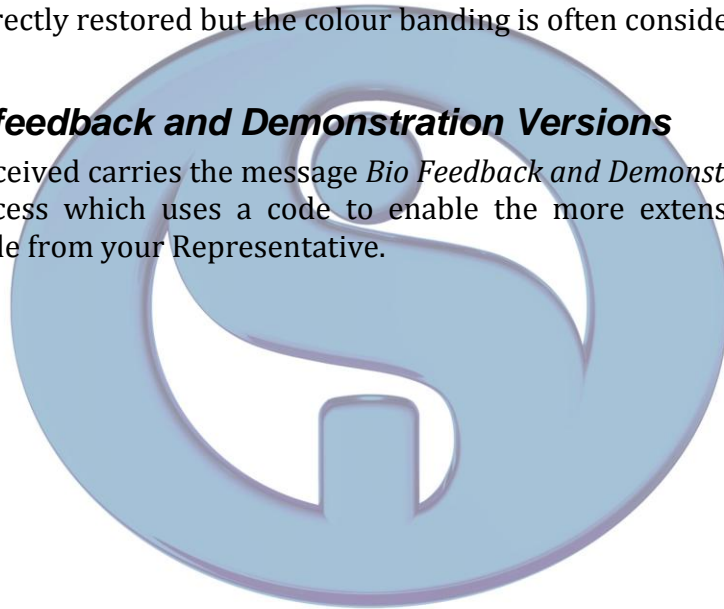
### **Part 19.3 - Restoring a Client**

This part is only applicable if the program crashes and is closed by using the closing function of Task Manager. If you then need to restore a client you will be given this opportunity on restarting SCIO. As it opens you will be asked if you want to restore the last client: answer yes. Enter password details as normal, ensure that the correct client displays in Demographics and proceed from where you left off.

There are also prompts after calibration just to access the last client data on the info panel. The scores are correctly restored but the colour banding is often considerably altered.

### **Part 19.4 - Biofeedback and Demonstration Versions**

The program as received carries the message *Bio Feedback and Demonstration Version* only. An activation process which uses a code to enable the more extensive facilities to be accessed is available from your Representative.



## Part 20 - Checking the SCIO Interface

The SCIO interface contains the digital interface device, a microprocessor and connects together the necessary cabling. The power for the LED's (lights) originates from the USB connection, which draws on computer power. LED's have a very long life and generally do not fail. If a LED does not illuminate as below check connections first. If the lights are not functioning, there may be a problem with the computer settings (and not with the device). Check that the UAC is turned off (as explained in Part 13.2 above) and check that the COM port settings are correct (as explained in Part 16 above). If there is a LED issue then the device may be sent to an authorized Service Center listed under Policies & Procedure in the Service Center Policy.

**Power on:** All LED's will flash briefly and there will be an audible beep when the SCIO is powered on.

**Program Opening:** a SCIO found message will display.

**Calibration:** all illuminate, with Rx and Tx having intermittent operation.

**Test:** all except Tx illumines.

**Therapy:** The daVinci and channel LED's will illuminate continuously with the Rx and Tx illuminating at intervals.

**Green LED (power):** will display when  
The SCIO is connected to the computer by the USB cable  
The SCIO is switched on (rear of unit)

### **LED Integrity**

All LED's will flash briefly when the SCIO is powered on.

### **Rx and Tx LED's**

Rx (receiving) indicated that signals are being sent to the client.

Tx (transmitting) indicates that client transmissions are being monitored: signals are being received from the client.

The Rx and Tx LED's will flash briefly:

- 1 On power up
- 2 When the SCIO has been found by the program on opening.

### **Red Channel 1-8 LED's**

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

These indicate the communication channels that are in operation. The number of LED's that illuminate will depend on the specific program aspect in operation.

*The DaVinci LED's*

These are indicative of harness activities.

## Part 21 - Quick Start

This is the basic guide to get your started. It is suggested to follow these steps with every Client. Remember that your training as a certified biofeedback technician, your dialogue with the Client, the Client's reason(s) for the session(s), and the Client's progress should determine your course of action during the session. The following steps are just to get started.

### Part 21.1 - Program Opening: Client Data Entry

Step	Action	Notes/ Options
1	<b>CLASP 32 Icon:</b> Dbl Clk	Program loads: stops at 25% to look for DEVICE: if found displays connection check facility. Close to continue.
2	<b>Continue</b>	Either large or small button
3	<b>Password</b> >OK>0210>OK	
4	<b>Demographics</b>	
4.1	<b>New Client</b>	
	Enter Name, Sex, SOC table info	
	<b>Patient Data</b> (Load New or Previous Patient)	
	New Patient>OK>Enter DoB>Save Current Patient>Close	
4.2	<b>Old Patient (second visit):</b>	
	Patient Data (Load New or Previous Patient)	
	Select Client in List>Previous Patient	



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B u d a p e s t , H u n g a r y

5	<b>Demographics</b>  Has client SOC Changed?  <ul style="list-style-type: none"><li>○ NO&gt;Close</li><li>○ YES&gt;Change values&gt; Patient Data (Load New or Previous Patient)&gt;Modify&gt;Save&gt;Close</li></ul>	
---	---	--

## Part 21.2 - Calibration

### Step Action

1 Main Screen>Calibration

2 FAST Track Calibration

After the test there are options according to needs and expertise.

### Calibration Messages

#### **Difficulty/Extreme Difficulty in Calibration- dangerous to proceed**

This may appear during calibration or early in Test. It indicates that the signals dialogue with the client is not clear or clean. History indicates the most likely reason is a high level of activity/stress within the client. The message is thus probably a real indicator of the client stress condition. The following actions can be considered:

1. Dialogue with client to elicit potential origins of apparent current high stress.
2. Consider general stress reduction approach e.g. Biofeedback>Biofeedback>Reduce Stress in nerves.

## Part 22 - Saving Patient Data

It is prudent to have back ups of any important information as a matter of course and as security before updating the software.

To back up your clients first you need to install the „Backup Restore program 2010 Paradox and SQLite” software. Please follow the procedure as outlined below:

- If you have the Clasp32 installer on a DVD put it in to the DVD drive; the auto runner will start the installation.
- If you downloaded the Clasp32 installer please open „My Computer” and go to „C” drive.

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

- On the „C” drive you will find the „Clasp32 Install DVD” folder; open it and run the „Start.exe”.
- The installation begins with a „Clasp32 Install” window with 4 buttons on it. (Backup Data, Clasp32, Video Codec, Restore Data).
- Please click on the „Backup Data” button.
- The „Backup Restore program 2010 Paradox and SQLite” Installation wizard comes up with a Welcome screen where you need to click the „Next” button.
- On the next window you can select where to have the shortcut. Click on „Next” to start the installation.
- As soon as the installation is finished 2 windows come up. The 1st window is the „Installation Successful” window, where you need to click on „Finish”; the 2nd window is the Backup Restore software’s 1st screen, explained in the next step.
- The installation is now successfully finished.

After installing the Backup Restore software, you can run it with the „Backup Restore for Clasp32 Sqlite” icon from the Desktop. To back up your clients you need to go through the following steps:

- Run the Backup Restore software.
- The 1st window is a question: „Do you want to run the BackupRestore software in Paradox mode?” You have 2 options „Yes” and „No”. Choose „No”.
- The 2nd window is the Backup Restore software. You will see 4 buttons (Make a Backup, Restore, Set Folder, Close). With the „Set Folder” you can select where your Clasp32 software’s „Data” folder is („C:\Clasp32\Data” is the default setting). You need to use this button only if you installed the Clasp32 software to a different place.
- Click on the „Make a backup” button.
- At this point the backup process begins; a small window appears, with the following message: „Backup is Done”. This marks the end of the process; you need to click on „OK”.
- Click on „Close”. You have now successfully backed up your clients.

## Part 23 - Restoring Client Data

To restore the client files saved with the Backup/Restore Program, please follow the procedure as outlined below:

- Run the installed Backup Restore software, the “Client Backup Tool” from the [www.qxsubspace.com](http://www.qxsubspace.com) under DOWNLOADS/SOFTWARE. Double click on the 'Backup Restore for Clasp32 SQLite' icon on your desktop to start the program.
- The 1st window is a question: „Do you want to run the BackupRestore software in Paradox mode?” You have 2 options: „Yes” and „No”. This depends from the Clasp32

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

software version. If your software version is 2009 or older, please choose „Yes”, if you have 3-3-2010 or a newer version please choose „No”.

- The 2nd window will display the Database type you have. Click “OK” to proceed.
- Click on the „Restore” button to restore your client files.
- The next window is a question: „Do you want to delete your original patients?” Please click “Yes” or “No” depending on whether you have entered new patients before restoring the Patient Files.
- At this point the restore process begins; a small window appears, with the following message: „Restore is Done”. This marks the end of the process; please click on „OK”.
- Click on „Close”. You have now successfully restored your clients.

## Part 24 – Repairing or Refurbishing Your Device

For various reasons, your device may need to be sent in for repair. If you find that your device is not functioning as it normally way, then you can send it in for repair or refurbishment to an Authorized Service Center. For more information on Service Centers, please see the Service Center policy under DOWNLOADS - Policies & Procedures on the website [www.qxsubspace.com](http://www.qxsubspace.com).

## Part 25 - Glossary

<i>Allersode</i>	Energetic pattern of food, inhalant etc. at the sensitizing potency of 30C.
<i>Body Capacitance</i>	The ratio of charge to potential, being an indicator of the body's energy storing characteristics
<i>Calibration</i>	The initial process of establishing interface with the client, where the clients optimum reactivity response (time of exposure) is established to a variety of items (approximately 20)
<i>Client</i>	The terms “Patient” and “Client” can be interchangeable as they refer to the person who is connected to the device. If the Therapist has a license then the therapist can refer to the person connected to the device as a “Patient.” If the therapist does not have a license, then the therapist can refer to the person connected to the device as a “Client.”

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

<i>Coherence</i>	A measurement of the percentage of how close the return signal is to the original input signal. Generally increases if there is a harmonic reaction of the client, with numbers above 75 indicating a positive reaction
<i>EPR</i>	Electro Physiological Reactivity
<i>Floating</i>	Each time a screen is entered a retest of the item occurs. The basis is that some interactions are quantic and do not repeat
<i>Fourier Number</i>	A dimensionless number that characterizes heat conduction.
<i>Hyperreactivity</i>	Clients body energetic is reacting too quickly or an hyper-immune mediated response
<i>Hyporeactivity</i>	Clients body energetic is weakly reacting
<i>Impedance</i>	The ability of a medium to conduct current, being the ratio of an induced voltage to injected current in a conductive media and having the two components of resistance and reactance
<i>Imponderable</i>	A non physical substance's energetic pattern. They include emotions, geopathics. Essentially anything that is not substantial.
<i>Interface Value (Calibration)</i>	Indicative of an accuracy of interface facilitating the testing of the majority of clients. At 98% 1 in 50 could be tested, at 95% 1 in 20, at 90% 1 in 100. At 85%, nominal target in the test process, 49 out of 50 can be tested
<i>Isode</i>	Energetic pattern of toxic material
<i>Major Resonant Frequency</i>	The predominant frequency of the clients energetic body
<i>Muscle Disturbance</i>	A high number indicates a disturbance but not necessarily intrinsic in the tissue. Especially if the sarcode resonance is sound then there is likely to be a secondary external source
<i>Muscle Tension</i>	The higher number indicating a higher tension or tightness.
<i>Nosode</i>	Energetic pattern of issue tissue or pathogens
<i>Patient</i>	The terms "Patient" and "Client" can be interchangeable as they refer to the person who is connected to the device. If



# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

the Therapist has a license then the therapist can refer to the person connected to the device as a "Patient." If the therapist does not have a license, then the therapist can refer to the person connected to the device as a "Client."

### *Phase Angle*

Time delay between a stimulating current and the voltage generated by an alternating current of 50 KHZ in the conductive media, expressed in degrees of phase shift. One complete cycle of current represents 360 degrees, so a phase shift of 6 degrees represents a shift of 6/360ths of a cycle or 1.67%

### *Phase Contrast*

A method of viewing blood for disturbances under a specialized microscope system

### *Proton Pressure*

An indication of the pressure exerted by the proton content of the clients body electric. Normal target is 65 to 70. Below 65 is considered acidic and above 70 alkaline. There is no correlation between this body electric measurement and urine, saliva, other body fluids

### *Purple Color Band*

Items that the client has a reactivity to of more than two standard deviations from the mean reactivity

### *Reactance*

The component of impedance related to the storage of energy in a conductive media

### *Reactance Speed Index*

The number of times that the device has had to adjust the testing speed downwards in order to get an optimum reaction from the clients body electric

### *Reactivity*

The client energetic response resulting in a score relating to the significance that a client may place on an item after an exposure of between 1/80<sup>th</sup> and 1/110<sup>th</sup> of a second

### *Reactivity Dysfunction*

See hypo/hyperreactivity above

### *Rectified*

An indication that an energetic disturbance has been repaired according to the way the device measures. It does not indicate how long this rectification will hold

### *Red Value Color Band*

Reflect items that the client has a high reactivity to of three or more standard deviations from the mean reactivity

### *Resistance*

The component of impedance related to the dissipation of energy in a conductive media

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

<i>Resonance</i>	The client reactivity to an item after 1 second exposure. Indicative of ongoing significance of an item
<i>Sarcode Resonance</i>	Indicates how much resonance there is to a healthy energetic pattern. High values indicate over functioning, too much energy, probably healthy but stressed from outside source. Below 50 indicates under functioning, too little energy, with a possibility of unhealthy or disturbed tissue
<i>Selye Stress Scale</i>	A stress scale rating that indicates where the client body electric is in terms of alarm, adaptation and exhaustion
<i>SOC</i>	Suppression and obstruction to cure, as calculated in the demographics panel
<i>Test Matrix Item</i>	These are energetic patterns of stressors, prepared as a homeopathic prior to measurement of their energetic characteristics in an electrical way
<i>Therapist</i>	The terms "User" and "Therapist" can be interchangeable as they refer to the person who operates the device. Someone using the device for themselves, for personal use on themselves or their family, would call themselves a "User." If they see someone outside of their family on a regular basis they would call themselves is a "Therapist."
<i>Trivector</i>	The description given to the three dimensional electrical holograph that is used in the device to characterize the body electric comprising resistance (conductance), static (capacitance, amperage), magnetic (inductance, voltage).
<i>User</i>	The terms "User" and "Therapist" can be interchangeable as they refer to the person who operates the device. Someone using the device for themselves, for personal use on themselves or their family, would call themselves a "User." If they see someone outside of their family on a regular basis they would call themselves is a "Therapist."
<i>Yellow Color Band</i>	Items that the client has a reactivity of more than one standard deviation from the mean reactivity
<i>Xrroid</i>	The name coined by the developer, for the reactivity testing employed at biological speeds

# BUDAPEST HOME OFFICE (BHO)

B u d a p e s t , H u n g a r y

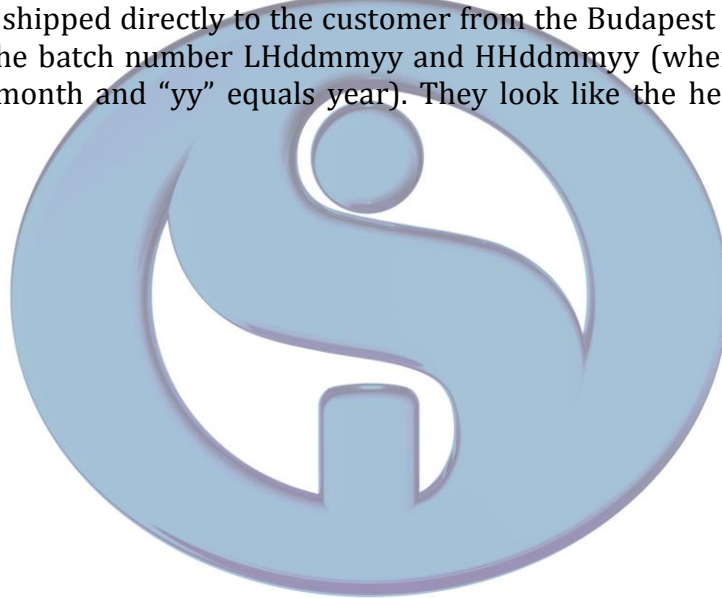
## Appendix A - Accessories Policy

### ACCESSORIES POLICY

All of the company Policies and Procedures are found on our official website [www.qxsubspace.com](http://www.qxsubspace.com). However, as mentioned in this User's Manual under Client Safety: Harness Rules and Connections, this Accessories Policy is included here.

The Budapest Home Office can only support the safety and effectiveness of the limb harness (LH) and head harness (HH) that is part of the registered device as made by us.

The **only** accessories that are registered as part of the original device is the head and limb harnesses that are shipped directly to the customer from the Budapest Home Office. These are marked with the batch number LHddmmyy and HHddmmyy (where "dd" equals date and "mm" equals month and "yy" equals year). They look like the head and limb straps below:



# BUDAPEST HOME OFFICE (BHO)

B u d a p e s t , H u n g a r y



The use of any other accessory including head or limb harness is at the risk of the user. Please be aware that only the above pictured head and limb harnesses are tested for safety and effectiveness and are registered with the SCIO.

We are currently working on updates to the limb and head harnesses for improved comfort and use, but this is a timely process as all steps of the manufacture and use have to be in compliance with the current registrations.

Please note that the Budapest Home Office cannot take any responsibilities for use of any other harnesses and/or accessories made by a Third Party. Using such harnesses and/or accessories are at the user's own risk.

Please always note that the Third Party is responsible for getting their harnesses and/or accessories safety tested by a proper testing body.

The user has the right to ask the Third Party for a safety certificate of the harnesses and/or accessories. Please note that as of 1 November 2008, this policy comes into effect. However,



# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

Third Parties are given six (6) months to get the safety certificate. Therefore, from 1 May 2009 the user should be asking for a safety certificate of harnesses and/or accessories.



# BUDAPEST HOME OFFICE (BHO)

B u d a p e s t , H u n g a r y

## NEW LIMB HARNESS

The Budapest Home Office is proud to present the new and more improved limb harnesses for your device, designed to be more comfortable and flexible to use, while maintaining a high quality level. This harness is unique in the market today, not only because it offers you simpler ways of working with a patient, but because it is using the highest quality in materials and further maintenance.

In our 20 years of experience in the field of energetic medicine and biofeedback, volcanic rubber has proved to be the safest and the most conductive material for the harness therefore we have kept the same material in manufacturing the new harnesses.



With the covering of the metal part that at the previous model was in direct contact with the skin, we have created an even safer harness, eliminating the risk of bruises, sore or blisters when working with patients with electrical hyper reactivity.

The new design of the harness will make it more comfortable for you to deal with the patient during the biofeedback session. The cables that connect the plug to the straps are now made from a different, flexible, more resistant and soft material. Also, you will notice that the bananas are painted the four colors that you have become very familiar with, red, blue, yellow and black, colors that indicate which extremity to connect the strap to. In the past, that was indicated by the small colored buckle located on the straps. In order to prevent tangling of the harness and provide easy handling, the cables have been tied together at an appropriate length, so you can connect your patient with no effort. The length can be adjusted according to your needs.

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

The connection of the straps to the cables is now made through banana plugs. This way, if during the session your patient needs to be disconnected from the harness for any reason, you can do so with a simple click.



You can either remove the strap or unplug it, as seen in the pictures below.



When your patient returns and is ready to go back on the device, you simply re-connect the patient in the correct way, following the colored hints.

Another exciting advantage of this design is the fact that it increases the duration of the harness' life cycle. If, for whatever reason, your harness is damaged, you no longer need to exchange the whole harness and purchase a new one. The new design allows you to order only the damaged part and replace it, the cost of maintenance being significantly reduced.

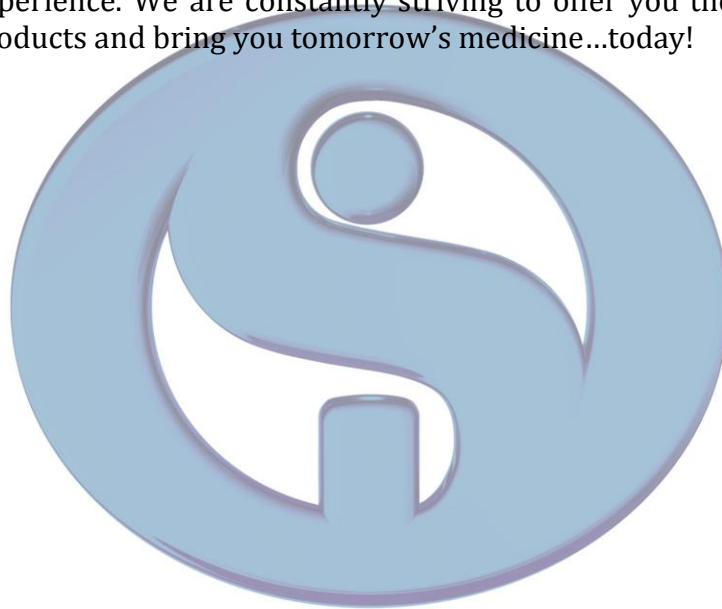
# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

We used the same serial plug for the new harness, so it is compatible with the SCIO device.



We hope that with the new model of the limb harness, we have improved the quality of your work with the SCIO Universal Electrophysiological Biofeedback System, so that you and your patients will be able to enjoy these advantages and have a more pleasant biofeedback experience. We are constantly striving to offer you the highest quality in services and products and bring you tomorrow's medicine...today!



## Appendix B – Good Manufacturing Practice (GMP) Information

The following general information is required in following with Good Manufacturing Practice (GMP).

### Information on Disposal for Users of SCIO

The SCIO device you are using is an electronic product that should not be mixed with general household waste.

For proper therapy, recovery and recycling please take this device to designated collection points where they may be accepted or return it to Mandelay Kft. (ÁTI-Sziget Ipari Park 11. Ép., H-2310 Szigetszentmiklós).

Disposing of this product correctly will help to save valuable resources and prevent any potential negative effects on human health and the environment which could otherwise arise from inappropriate waste handling.

**For users in the European Union:** If you wish to discard this electronic equipment, please contact Mandelay Kft. (ÁTI-Sziget Ipari Park 11. Ép., H-2310 Szigetszentmiklós) for further information.

### Function of Banana Jacks on the Back Side of the Device

For electrodes which is not a product of Mandelay Kft.: 3M 2223 – Monitoring Electrode, 1<sup>st</sup> class,

F9042M4, connector cables for clip electrodes 4 mm plug 8 different colours, supplied pack of 6 pieces.

### Specifications

#### Power

Power Uptake max. 100 mA

#### DC Power

Input	5 V DC (USB Port)
Generated Signals	Any Way You Want Ponalt/Negalt (See below)
Output Ports	12 (Freely Exchangeable Channels)
Time of Change of Signal	max. 300 ms
Time of Change of Channel	max. 100 ms



# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

Output voltage	0 – 4 V DC
Resolution of output voltage	up to $\pm 1.5\%$ of the final amplitude
Accuracy of Output voltage	up to $\pm 1.5\%$ final amplitude
Output Resistance	min. 1 k $\Omega$ , max. 5k $\Omega$
Output Frequency	0 – 100 kHz
Resolution of Frequency	0,1 Hz
Accuracy of Frequency	up to $\pm 1.5\%$ of the measured value
Applied Fuse	MF-R030 (Bourns; Self-Recepting Fuse)

### Physical Specifications

Length	200 mm
Width	175 mm
Height	75 mm

### Environmental Specifications

Operating Temperature	10 ° – 35 ° Celsius
Storage Temperature	-15 ° – 70 ° Celsius
Humidity	less than 80%

To reduce the chance of electrostatic discharge, the best suggested surfaces are floors of wood, concrete or ceramic tiles. If the floor is tiled with synthetic material the relative air humidity should be 30% at least. If carpeted floors, a metallic surface should be touched first to discharge any electrostatic build up before touching the SCIO. Fires in fireplaces should not be in use in the same treatment room as the SCIO.

### Manufacturer's Data

Mandelay Kft.  
ÁTI-Sziget Ipari Park 11.ép  
H-2310 Szigetszentmiklós  
Telephone numbers:  
In Europe +36-21-252-3503  
In The USA +1 (989) 681-1063  
In South Africa +27-21-813-6020

### List of Accessories

- 1 Software (which can be downloaded from our website: [www.qxsubspace.com](http://www.qxsubspace.com))
- 1 USB Cable
- 1 Head Strap
- 1 Limb Strap

### Manufacturer of Case

OKW  
Friedrich-List-Straße 3  
D-74722 Buchen

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

Germany

Applied Material: high-impact polystyrene (UL 94 HB).

Manufacturer of Harnesses, Sub-Contracted to:

Pentavox Kft.

Dugonics utca 11.

1043 Budapest

Hungary

Materials used in harnesses: vulcanized elastomer 60%; carbon plaque 30%; curing system 7%; and oil plasticiser 3%.



### Appendix C – Warranty Contract

#### WARRANTY CONTRACT

**Please refer to the Warranty Contract and contact your Broker/Networker/Trainer if you have any questions regarding the Warranty Contract.**

##### 1. Products Cover

The device ("The System") and the limb and head harness ("The straps") designed and manufactured by Mandelay Kft. ("The Manufacturer"). Based on industry standards of the materials used and the fact that the device does not have movable parts, the life of the device has been established to be up to 10 years and perhaps longer than 10 years. There is no expiration date on the life of the device as some are known to be using their device since 1997 with no problems. The harnesses are considered to be movable parts and therefore have a recommended lifetime of up to 3 years from the first use and are easily replaced. The device has a shelf-life of up to ten (10) years from the date of manufacture, and should be refurbished within that time frame.

##### 2. Warranty Cover

"The Manufacturer" warrants to the final user ("The User"), that "The System", will be free from defects in materials and workmanship under normal use and service as directed, during the warranty period described in paragraphs 3 and 4.

##### 3. Warranty Initiation

The warranty will begin on the day "The User" takes possession of "The System". Dated proof of purchase must exist in "The Manufacturer" records for "The System" returned for warranty service consideration.

##### 4. Length of Cover

The warranty of "The System", excluding consumable items, is two (2) years and the warranty of "the straps" is for six (6) months. The warranty of "the System" automatically expires if an unauthorized person opens "The System" or alters "the Straps." Only "The Manufacturer" or an authorized Service Center, as authorized by "The Manufacturer" may repair "the System."

##### 5. Proof of Purchase

Proof of Purchase is automatic from the date the device is shipped out to "The User."

##### 6. Manufacturer's Actions

If "The System" covered under this warranty becomes defective in material or workmanship during the applicable warranty period, "The Manufacturer" will, at its option, either repair or replace the defective product without charge for parts and labor, or provide a replacement in exchange for "The System" defective. "The Manufacturer" reserves the right to provide, at no extra cost, a more current upgrade model for replacement, if available.

##### 7. Not Warranted

- I. Systems that have been opened by anyone other than an Authorized Service Center, or subjected to misuse, accident and physical damage, improper installation, abnormal operation or handling, neglect, inundation or fire.
- II. Systems that have been damaged due to repair, alteration or modification by any other than an authorized representative of "The Manufacturer".
- III. Defects caused by components, parts or accessories not compatible with the warranted System.
- IV. Systems, whose warranty/quality, product serial number, electronic serial numbers, stickers or plates have been removed, altered, rendered illegible or tampered with.
- V. Accessory items and Consumables.
- VI. The shipping costs to and from an authorized Service Center or "The Manufacturer" is not covered.

Any other warranties, including but not limited to the implied warranties of merchantability and fitness for a particular purpose, shall be limited in duration to the duration of this warranty.

# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

"The Manufacturer" assumes total liability for damages for any cause related to, or arising out of, the use or inability to use "The System", whether in contract, negligence, strict tort or based on any other legal aspect, shall not exceed the original price paid for "The System".

In no case shall "The Manufacturer" be liable for any indirect special, incidental, or consequential damages based upon breach of warranty, breach of contract, negligence, strict tort or any other legal theory, such damages include, but are not limited to, loss of profits, loss of savings nor revenues, inability to use "The System" or any associated equipment, cost of capital, cost of any substitute equipment, facilities or services, claims by Third Parties other than "The User", and injury to property.

### 8. Warranty Service

If "The System" requires warranty service, "The User" must first contact an Authorized Service Center through "the User's" online account with [www.qxsubspace.com](http://www.qxsubspace.com) to order the service. "The System" must be returned at the cost of "The User" along with a description of "The System" malfunction or difficulty and the address where "The System" must be returned. Warranty status must be substantiated as explained in paragraph 5.

"The Manufacturer" assumes no risk for damage or loss in shipment. If in "The Manufacturer's" sole opinion, "The System" failure is not covered under this warranty, "The User" will be notified and an authorization will be requested for any further repair activity. "The System" repaired under warranty will be returned to "The User" at the cost of "The Manufacturer". If "The System" is repaired and it is not under warranty it will be returned to "The User" at the cost of "The User".

Judgment on all situations and/or occurrences that may arise and are not listed in paragraph 7 will be left to the discretion of "The Manufacturer". All decisions made by "The Manufacturer" are final and absolute.

### 9. Agreement

Unless modified in writing, signed by both "The Manufacturer" and "The User", this warranty is understood to be the complete and exclusive agreement between the parties, superseding all prior agreements, oral or written, and all other communications between the parties in relation to the subject matter of this warranty. Neither Agent nor Employee of "The Manufacturer" may make modifications to this warranty and, if so, such representations should not be relied upon.

# BUDAPEST HOME OFFICE (BHO)

B u d a p e s t , H u n g a r y

## Appendix D – Software License Agreement

### Mandelay Kft. Software License Agreement

This is a legal agreement between you, the user, and Mandelay Kft. This agreement covers all Software that is distributed with the 'SCIO', for which there is a separate agreement between you and Mandelay Kft. By inserting the DVD with the software in your computer or laptop, installing or downloading the Software, or using the Software that has been preloaded or is embedded in your computer, you agree to be bound by the terms of this agreement. If you do not agree with these terms, promptly return all Software items (disks, manuals, and packing), and delete any preloaded or embedded Software.

You may use one copy of the Software in only three computers at a time. If you have multiple licenses for the Software, you may use as many copies at any time as you have licenses. 'Use' means loading the Software in temporary memory or permanent storage on the computer. Installation on a network server solely for distribution to other computers is not 'use' if (but only if) you have licenses for each computer to which the Software is distributed. You must ensure that the number of persons using the Software installed on a network server does not exceed the number of licenses that you have. If the number of users of Software installed on a network server will exceed the number of licenses, you must purchase additional licenses until the number of licenses equal the number of users before allowing additional users to use the Software. If you are a commercial customer of Mandelay Kft., you hereby grant Mandelay Kft., or an agent selected by Mandelay Kft., the right to perform an audit use of the Software during normal business hours, you agree to cooperate with Mandelay Kft.. In such audit, you agree to provide Mandelay Kft. with all records reasonably related to your use of the Software. The audit will be limited to verification of your compliance with the terms of this agreement.

The Software is protected by copyright laws and international treaties. You may make one copy of the Software solely for backup or archival purposes or transfer it to a single hard disk, provided you keep the original solely for backup or archival purposes. You may not rent or lease the Software or copy the written materials accompanying the Software, but you may transfer the Software and all accompanying materials on a permanent basis if you retain no copies and the recipient agrees to the terms hereof. Any transfer must include the most recent update and all previous versions. You may not reverse engineer, decompile or disassemble the Software.

#### Limited Warranty

This warranty is limited to you and it is not transferable.

Mandelay Kft. does NOT warrant that the functions of the Software will meet your requirements or that operation of the Software will be uninterrupted or error free. You assume responsibility for selecting the Software to achieve your intended results and for the use and results obtained from the Software.

MANDELAY KFT. DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, FOR THE SOFTWARE AND ALL ACCOMPANYING WRITTEN MATERIALS. This limited warranty gives you specific legal rights; you might have others, which vary from jurisdiction to jurisdiction.

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#### U.S. Government restricted rights

The Software and documentation are 'commercial items' as that term is defined at 48 C.F.R. 2.101, consisting of 'commercial computer software' and 'commercial computer software documentation' as such terms are used in 48 C.F.R.



# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

12.212. Consistent with 48 C.F.R. 12.212 and 48 C.F.R. 227.7202-4, all U.S. Government end users acquire the software and documentation with only those rights set forth herein. Contractor/manufacturer is Mandelay Kft., ÁTI-Sziget Ipari Park 11. Ép., H-2310 Szigetszentmiklós.

### General

This contract is effective until terminated. It will terminate upon the conditions set forth above, or if you fail to comply with any of its terms. Upon termination, you agree that the Software and accompanying materials, and all copies thereof, will be destroyed. This agreement is governed by Hungarian law. Each provision of this agreement is severable. If a provision is found unenforceable, this finding does not affect the enforceability of the remaining provisions, terms, or conditions of this agreement. This agreement is binding on successors and assigns. Mandelay Kft. agrees and you agree to waive, to the maximum extent permitted by law, any right to a jury trial with respect to the Software or this agreement. Because this waiver may not be effective in some jurisdictions, this waiver may not apply to you. You acknowledge that you have read this agreement, that you understand it, that you agree to be bound by its terms, and that this is the complete and exclusive statement of the agreement between you and Mandelay Kft. regarding the Software.



### Appendix E – Revision History

The following is a list of the major changes in the User Manual 200003. This table is updated with the most recent change at the top.

Revision	Effectivity Date	Description of Change	Originator
K	21 February 2011	<p>1. To change the name of the manufacturer from Maitrya Kft. to Mandelay Kft.</p> <p>2. To change the address of the manufacturer to the current address of Mandelay Kft.</p> <p>3. Modified Indication for Use b) Under Part 3.Indications for Use to state: the treatment of injury, muscle weakness, dystonia,muscle tension and/or muscle spasm through muscular re-education, measuring volts, measuring amps, measuring volts and amps, measuring resistance, and electro-osmosis, Hydration, Oxidation, Proton balance</p> <p>4. Deleted Symbol CE mark from the front of the device and ISO 9001 and ISO 13485 from the back of the device under Part 10.Symbols</p> <p>5. Updated Part 13.1 – Online action to reflect the new process of the online activation, and last paragraph, to change Sue Rado as Broker Relations Manager to Ibolya Molnar-Bodzsar.</p> <p>5. Updated last bullet of Part 11.2 Computer Specifications to include „Windows 7”</p> <p>6. Updated Part 14, section 1.a to change „this” to „these”; small changes to the Adobe Reader; added „e. Notepad. With this program users can write small notes and open small documents”; and deleted Adobe Acrobat.</p> <p>7. Part 16 – Configuring the Port is updated.</p> <p>8. Updated Part 22. Saving Patient Data to reflect the new process of saving client files</p> <p>9. Updated Part 23. Restoring Client Data to reflect the new process of restoring client files</p> <p>10. At Part 24. Added DOWNLOADS word before Policies and Procedures</p>	Edit Barota

# BUDAPEST HOME OFFICE (BHO)

## Budapest, Hungary

		<p>11. Deleted "FE See Flower Essences" from Part 25. Glossary</p> <p>12. Capitalized "Essentially" under Part 25. Glossary (Imponderables)</p> <p>13. Updated Appendix A to reference the new electrodes, added word "the bananas", and new pictures about the new harness</p> <p>14. Updated Appendix B to change the following:</p> <p>a. Density of Output to "Resolution of output voltage up to <math>\pm 1.5\%</math> of the final amplitude"</p> <p>b. Accuracy of output to "Resolution of output voltage up to <math>\pm 1.5\%</math> of the final amplitude"</p> <p>c. Output resistance to "min. 1 k<math>\Omega</math>, max. 5k<math>\Omega</math>"</p> <p>d. Density of Frequency to "Resolution of Frequency"</p> <p>e. Accuracy of Frequency to "up to <math>\pm 1.5\%</math> of the measured value"</p> <p>f. Humidity to "less than 80%"</p>	
J	26 July 2010	<p>1. Important Note on page 2 regarding how the revision of the manual is shown as well as that the English language version is the definitive version of this manual.</p> <p>2. Under Part 2 – Scope, revisions were made to include the statement that only a diagnostician may offer a diagnosis, and clear statements that this manual and the SCIO do not diagnose.</p> <p>3. Under Part 2 – Scope, the ICD codes and explanations were added.</p> <p>4. Under Part 3 – Indications for Use, the following revisions were made; c) the reduction of pain (reduction was added), and e) the rectification of charge stability (rectification was added).</p> <p>5. Throughout the manual, the database used for the software programming has been changed from Borland Database to SQLite Database.</p> <p>6. Part 12 section 3 has been revised to explain more how to change the resolution of your computer monitor.</p> <p>7. Part 13.2 Installation has been majorly revised to explain the current installation process of downloading and activating from the website <a href="http://www.qxsubspace.com">www.qxsubspace.com</a>.</p>	Richard Lloyd


# BUDAPEST HOME OFFICE (BHO)

## B u d a p e s t , H u n g a r y

		<p>8. With this online downloading and activation process, Part 13.3 Installing the BodyViewer has been removed as this is now part of the process explained in Part 13.2.</p> <p>9. In Part 14, Adobe Reader has been added as a necessary computer program for reading some documents and files.</p> <p>10. Throughout the document, any references to Navigation Manuals have been removed. This is due to the fact that on screen hints and instructions meet the Essential Requirements to instruct users how to use the software.</p> <p>11. Throughout the manual the word "interface box" has been changed to SCIO where appropriate.</p> <p>12. Under Definitions the "Fourier Number" and "Muscle Tension" definitions have been revised. The definitions for "Combination Therapy," "DR Combination Therapy" and "Flower Essence" have been removed.</p> <p>13. The following clauses under Clause 4 of the Warranty Contract have been added, "The warranty of "the System" automatically expires if an unauthorized person opens "The System" or alters "the Straps." Only "The Manufacturer" or an authorized Service Center, as authorized by "The Manufacturer" may repair "the System."</p> <p>14. The following has been added to Clause 7 VI: "The shipping costs to and from an authorized Service Center or "The Manufacturer" is not covered."</p> <p>15. Under the Software License Agreement, under the section Limited Warranty, the terms of the software warranty have been removed, as they fall under the warranty of the entire system.</p>	
I	9 March 2010	<p>16. In Welcome Letter (on page 5) to remind customers of the change to the software being available online from May 2009 by changing the text to say "by downloading and activating the latest version of the software from our website, <a href="http://www.qxsubspace.com">www.qxsubspace.com</a>. Your Broker can help you through this process if it is your first time."</p> <p>17. In the Scope (Part 2) to reference the Navigation Manual 200022 [DRAFT].</p> <p>18. In the Indications for Use (Part 3) to use the same</p>	Richard Lloyd

# BUDAPEST HOME OFFICE (BHO)

## Budapest, Hungary

		<p>wording for the Indications for Use as in Clinical Evaluation CT-103-05.</p> <p>19. In Symbols on the Device (Part 10) to make the years, numbers and revision letters generic so that this part does not have to be changed if there is a change in the label (for example in Manufacture Date)</p> <p>20. In Good Manufacturing Practice (GMP) Information in Appendix B adding the Manufacturer of the Harness as well as the materials used in the harnesses.</p> <p>21. Clarification of biofeedback transcutaneous interaction with the CNS in Part 5.4 and 9.</p> <p>22. In Appendix B the word "Celsius" written next to the Environmental Specifications.</p> <p>23. In Appendix B to include the following per Table 202 of EN 60601-1-2; "To reduce the chance of electrostatic discharge, the best suggested surfaces are floors of wood, concrete or ceramic tiles. If the floor is tiled with synthetic material the relative air humidity should be 30 % at least. If carpeted floors, a metallic surface should be touched first to discharge any electrostatic build up before touching the SCIO. Fires in fireplaces should not be in use in the treatment room."</p> <p>24. In Section 10 "Symbols", the wording "on the Device" will be removed as there is one symbol (the radius of 1,5m that is only included in this manual as it is only a recommendation and not a requirement. The recommendation will be added as a result of Table 204 of EN 60601-1-2 to state: For the best optimum performance, it is recommended to keep any other electronic equipment such as cell phones, radios, electro-static air cleaner and other such devices, a minimum of 1.5 meters out of the device's radius. This will reduce the potential for outside interference. However, it is possible to keep the operating computer within this 1.5 meter radius, with the recommendation that the Wi-Fi ability of the computer is turned off." Furthermore, the following has been added, "Disturbances are possible near devices with the following symbol: </p> <p>25. The following Definitions have been added in the Glossary "Client," "Patient," "Therapist," and "User." For the full definition please see the Glossary terms.</p> <p>26. In part 6.4 correction that it is 50 (fifty) exposures</p>	
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# BUDAPEST HOME OFFICE (BHO)

## Budapest, Hungary

		<p>to X-ray. One sentence was written with 50 and the other with 5, but the correct amount is 50. Additionally, the following clause was added to the end: ...under the Service Center Policy which can be found on <a href="http://www.qxsubspace.com">www.qxsubspace.com</a>.</p> <p>27. Part 24 Repair or Refurbishment to Your Device has been added to include the following: For various reasons, your device may need to be sent in for repair. This is due to the normal wear and tear of internal parts. If you find that your device is not functioning as it normally way, then you can send it in for repair or refurbishment to an Authorized Service Center. For more information on Service Centers, please see the Service Center policy under Policies &amp; Procedures on the website <a href="http://www.qxsubspace.com">www.qxsubspace.com</a>.</p> <p>28. The Glossary is now Part 25 (changed from Part 24).</p> <p>29. We suggest that a Navigation Manual which is endorsed by Maitreya Kft. should be used. Regarding any unendorsed Navigation Manual please be cautious of any suggestions of off-label use.</p> <p>30. Section 5.2 the Caution regarding patients with a "history of epilepsy" was removed and this added to the Warnings stating "Do not use on patients with epilepsy or a history of epilepsy."</p> <p>31. The following clarification was added to Section 10 regarding the CE Mark: "The four-digit Notified Body number can be found on the CE Certificate."</p> <p>32. In Part 11.1 the low RAM was changed to 512 MB, and later in the document the term MB was corrected (from the incorrect version MV).</p> <p>33. In Part 20, the following was revised: "If the lights are not functioning, there may be a problem with the computer settings (and not with the device). Check that the UAC is turned off (as explained in Part 13.2 above) and check that the COM port settings are correct (as explained in Part 16 above). If there is a LED issue then the device may be sent to an authorized Service Center listed under Policies &amp; Procedure in the Service Center Policy."</p> <p>34. In Appendix C – Warranty Contract, under section 1 the following has been added, "Based on industry standards of the materials used and the fact that the device does not have movable parts, the life of the device has been established to be up to 10 years and</p>	
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# BUDAPEST HOME OFFICE (BHO)

## Budapest, Hungary

		<p>perhaps longer than 10 years. There is no expiration date on the life of the device as some are known to be using their device since 1997 with no problems. The harnesses are considered to be movable parts and therefore have a recommended lifetime of up to 3 years from the first use and are easily replaced. The device has a shelf-life of up to ten (10) years from the date of manufacture, and should be refurbished within that time frame.”</p> <p>35. Under Appendix C – Warranty Contract Section 8, the following changes have been made: “an Authorized Service Center through “the User’s” online account with <a href="http://www.qxsubspace.com">www.qxsubspace.com</a> to order the service.”</p> <p>36. Under Part 13 the following sentence has been added, “Furthermore, there are numerous Video Tutorials available on <a href="http://www.qxsubspace.com">www.qxsubspace.com</a> for easy reference on the Installation and Activation Procedures.”</p>	
H	16 July 2009	<ol style="list-style-type: none"> <li>1. Inclusion of “Do not use on pregnant women” and “Do not use on children under 3 years of age”, under Part 5.2. Warnings</li> <li>2. Modifying Section 13.1 Online Activation, point 2 to “Open program and go to password screen, enter name and country. Click on 'I agree all terms' button. Click 'Close' button to hide the Biofeedback device installation instructions. Click 'Activation'. Select 'Internet'.”</li> <li>3. Modifying Section 13.1 Online Activation point 3 to “In Activation Window enter your qxsubspace.com username and password and click on Send to the server”</li> <li>4. Adding in Section 13.2 Installation, point 2: “If you have the software on DVD, place the “MASTER DVD 1” in the appropriate drive”.</li> <li>5. Adding in Section 13.2 Installation, point 2: “If you have downloaded the software it will install on the drive that you selected”.</li> <li>6. Adding in Section 13.2 Installation, point 3: “Install program”.</li> <li>7. Updating Section 15 USB to USB Cable Installation Instructions, to installation from DVD and installation from internet downloadable version.</li> <li>8. Adding point 2 to Section 17 Important Procedure to</li> </ol>	Andrea Taflan

# BUDAPEST HOME OFFICE (BHO)

## Budapest, Hungary

		<p>Complete Activation: "Type your device serial number in the box at the bottom of the screen and click 'Load Number'".</p> <p>9. Inclusion of Section 6.4 X-ray Exposure</p>	
F	9 June 2009	<p>1. Inclusion of section 5.4 Undesirable Side Effects.</p> <p>2. Inclusion of Caution Use this device with a computer on battery mode free from wall current or with a medically safe surge protector.</p> <p>3. Reference to use battery mode or with medically safe surge protector in section 6.1.</p> <p>4. Inclusion of "It is current (amps) that can kill and not volts. House supply is 115 volts (USA) and 230 volts (Europe) AC (alternating current) but with 1 amp. 3 amps will usually kill a much smaller dose of even .2 amps directed through the heart can do damage" in Section 6.1.</p> <p>5. Serial number explanation under Part 10.</p> <p>6. Adding Part 13.1 Online Activation</p>	Richard Lloyd
E	28 May 2009	<p>1. Update Part 14 subsection 1 subsection A. the first sentence to say "<b>DivX Player and DivX Codec:</b> Please visit the website <a href="http://www.divx.com">www.divx.com</a> and download DivX 7".</p> <p>2. Add Part 14.1 section C "<b>Internet Explorer 4 or later Web browser.</b> This program is necessary to go through the Online Activation process."</p> <p>3. Update Part 14 subsection 2 subsection B. to show the website only as <a href="http://www.adobe.com">www.adobe.com</a>.</p> <p>4. Part 18.1. section 7 change of the word "Operator" to "User" in referencing this manual.</p> <p>5. In Appendix C part 5 proof of purchase was updated to state that it's from the date of purchase.</p>	Richard Lloyd
D	15 May 2009	<p>1. The Installation Manual 200002 is obsolete. The information contained in the Installation Manual is now included in this User Manual.</p> <p>2. The Operator Manual 200003 has been changed to the User Manual. The information contained in the Operator Manual is now included in this User Manual.</p>	Richard Lloyd
C	20 March 2009	<p>1. Effective 20 February 2009, the Clasp32 Software</p>	Richard Lloyd

# BUDAPEST HOME OFFICE (BHO)

## Budapest, Hungary

	(Note that this date was the revision date to the Installation Manual but this information should be included in this revision history)	<p>will NOT be included in your shipment from the Manufacturer, Maitreya Kft. in Budapest, Hungary. Instead, you should get the Clasp32 Software <u>from your Broker</u> from whom you purchased the SCIO.</p> <p>2. Our experience shows that the USB cable that connects the laptop to the SCIO should NOT be more than 2meters long. If you ever chose to use another USB cable we recommend that you use a cable that is no longer than 2meters.</p>	
B	7 April 2009 (Note that this date was the revision date to the Operator Manual but this information should be included in this revision history)	To include Appendix B: information as required by Good Manufacturing Practice (GMP)	Richard Lloyd
A	1 May 2008	Initial Release	Richard Lloyd

