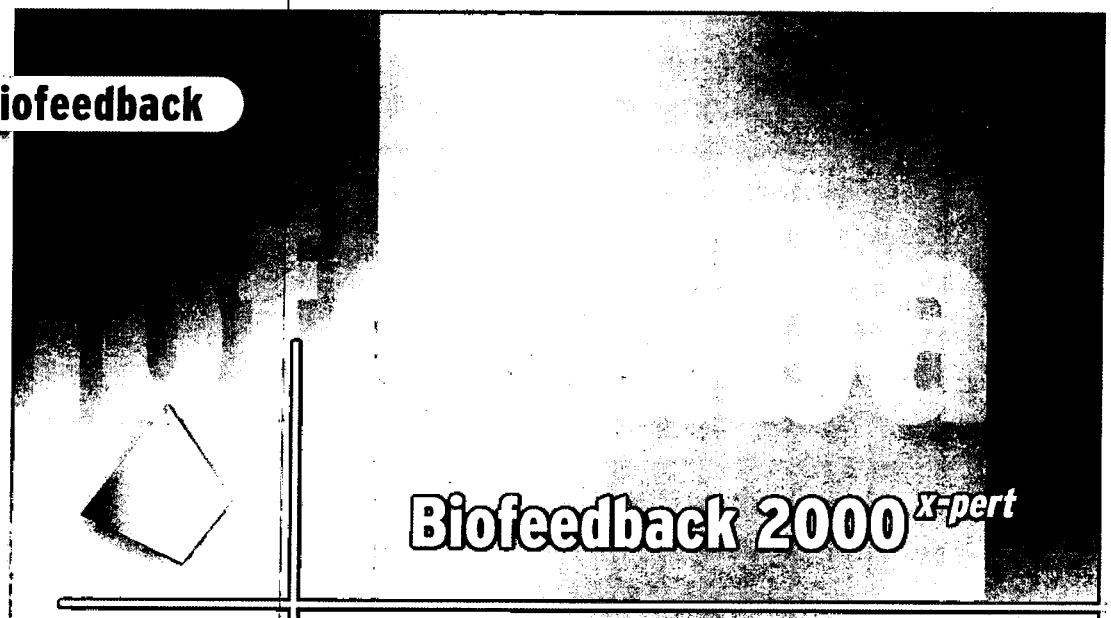
Biofeedback



Hardware manual

Version 3.0

CE 0408

SCHUHFRIED

Qualität durch Kompetenz

CONTENTS

Release (date / name): 2.6.2008 / Kösl

1 GENERAL

The modular and portable Biofeedback 2000 x-pert system provides feedback of physiological parameters. Sensors record the signals non-invasively from the skin surface. In the various radio modules these sensor signals are filtered, amplified, digitalized and transmitted via a cordless Bluetooth connection to a computer. The digitalized data is then processed by the Biofeedback 2000 x-pert software and displayed diagrammatically on the screen. Thus clients receive immediate feedback from their biodata or biosignature while undergoing treatment or training.

The sensor cables are kept very short, so that restrictions on the patient during recording are kept to a minimum. The sensor plugs are colour-coded and are grooved in a way that makes it impossible for them to be connected to the wrong sockets.

The new modular radio system is compatible with the existing Physiorecorder S/E system.

The exchange of data between the radio modules and the computer is effected via a cordless Bluetooth connection. The data transfer is protected against unauthorized intervention by means of pairing and the use of a password. Up to seven radio modules (depending on the number of transmission channels) can communicate with a computer simultaneously.

The modules will run for between 5 and 9 hours on the integrated lithium polymer battery, depending on the intensity of use and the condition of the battery (batteries deteriorate with age). When the radio modules are not in use they are plugged into the charger and recharge automatically. The charger thus functions simultaneously as a module storage device. To ensure that, for safety reasons, the modules cannot be used while they are charging, they are automatically deactivated when in the charger.

IMPORTANT! The system is not a diagnostic device and must not be used as such.

1.1 Description of the modules

The following separate modules are available for the Biofeedback 2000 x-pert system:

MULTI module

EMG module

RESP module

EEG module

Any combination of up to 7 radio modules (with up to 32 channels) can be used together with one computer. If radio modules of the same type are used at the same time, the Biofeedback 2000 x-pert software will ask you to assign them different device numbers on start-up. All radio modules are supplied with the device number 1 as default.

The radio modules record the following signals:

Module	Input	Brief description
EMG	EMG1	Electromyography, recorded from surface electrodes
	EMG2	as for EMG1
EEG	EEG1	Electroencephalogram, recorded from surface electrodes
	EEG2	as for EEG1
MULTI	EDA	Electrodermal activity – skin conductance
	TEMP	Skin temperature
	PULS	Changes in blood flow just below the skin surface
	MOT	Motility (increase of rate of movement)
RESP	RESP1	Abdominal respiration – change in abdominal circumference
	RESP2	Thoracic respiration – change in chest circumference

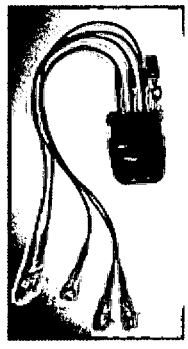
2 DESCRIPTION OF THE RADIO MODULES

2.1 EMG module

Recorded parameter:

EMG ..... Electromyography

Channel	Colour
EMG1	Dark green
EMG2	Light green
REF	Black



Recommended electrodes:

We recommend the use of the following electrodes, which can be purchased separately:

- Self-adhesive Ag/AgCl disposable electrode with snap connector
  Manufacturer: 3M Health Care
  Type: Monitoring electrode 2223
- Self-adhesive disposable tab electrodes
  Manufacturer: Skintact
  Type: RT34
- Vaginal electrode NEEN HealthCare
- Anal electrode: NEEN HealthCare

Important: use only CE marked electrodes.

Attaching the electrodes:

The electrodes are attached as described in the following instructions or in the software Help.

Recording from muscle strands:

Attach a disposable electrode to the belly of the muscle as a reference. At equal distances from the reference electrode, attach one of the two other electrodes to each end of the muscle; this records the biggest difference in potential. Then attach the black tab clip (reference electrode connection) of the EMG electrode cable to the electrode on the muscle belly, and the green tab clips to the electrodes on the muscle ends (dark green for channel 1 and light green for channel 2). Connect the electrode cables to the EMG module in accordance with the colour coding. To record from a second muscle, attach a disposable electrode to each end of the muscle and connect these to the second EMG channel as described above. There is no need for a second reference electrode.

To compare readings of the strength of two different muscles, attach the recording electrodes of one channel to the bellies of the muscles that are to be compared – as described above – and attach the reference electrode to a neutral site with little muscle activity, such as the cervical vertebra. This reduces any artefacts of movement.

In technical terms channels 1 and 2 and the electrode cables are identical; they are therefore interchangeable.

Vaginal and anal electrodes:

Connect the white plug of the vaginal or anal electrode to the EMG electrode cable. Then plug the EMG electrode cable into channel 1 of the EMG module (dark green socket). It can alternatively be connected to channel 2. Attach a disposable electrode to the surface of the abdomen and connect it to the tab clip of the black reference electrode cable, which is plugged into the black socket of the EMG module.

IMPORTANT!

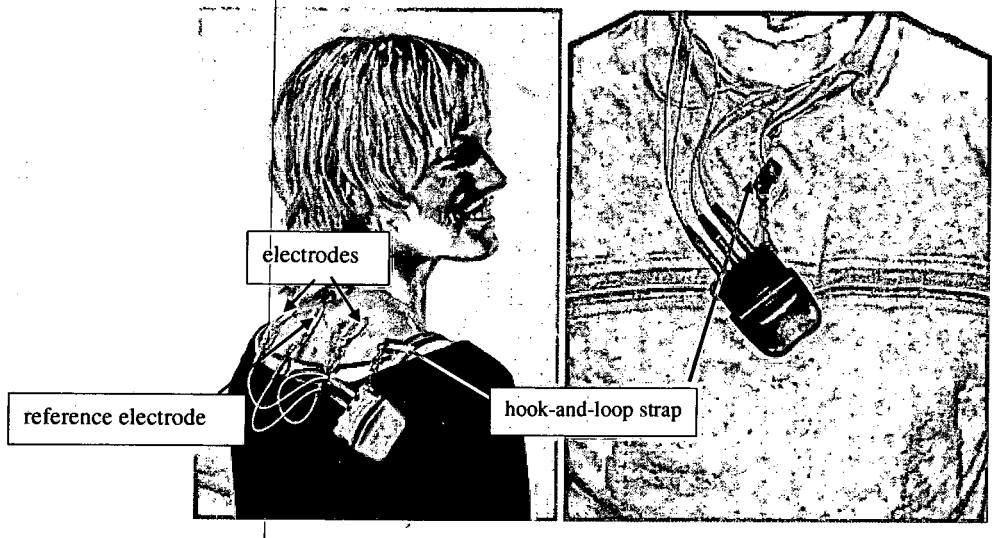
Never connect the vaginal and anal electrodes to the yellow EDA port of the MULTI module.
Use only an electrode gel intended for this purpose.

The strength of the recorded signal is significantly influenced by the positioning of the electrodes – that is, by the distance between the electrodes and by their exact location. For readings to be consistent and comparable with each other, the positioning of the electrodes therefore needs to be standardized. A universal standard has, however, not yet been defined.

→ **It therefore follows that a comparison between two readings does not necessarily yield accurate results; such comparisons should be treated with caution!**

To prevent inaccurate readings caused by poorly attached electrodes, the area of skin from which recordings are to be taken must be cleaned with ethyl alcohol (70%). This ensures a good electrical and mechanical contact with the skin.

The EMG module is attached to the clothing close to the site from which readings are to be taken, using the clip that forms part of the module.



Attaching the electrodes: taking comparative readings with the EMG

Technical details:

When EMG signals are recorded from the skin surface, the action potentials of all the muscles under the electrode are measured in the form of a gross potential. The potentials are amplified, rectified and

meaned by integration with a time constant of *250 ms*. The reported parameter therefore corresponds to the rectified mean of the reading. The formula used for this calculation is:

$$EMG = \frac{1}{T} \int_{t_0}^{t_0+T} | x(t) | \, dt$$

where x(t) is the recorded muscle signal and T the integration constant (*250 ms*). Because the mean is calculated on a moving basis, a meaned reading is obtained each time a reading is taken.

Seven different measurement ranges are available. Depending on the choice of treatment, these can be pre-set or self-selected. The resolution of the measurement depends entirely on the measuring range selected. This makes it possible both to measure large signals resulting from muscle tension and to obtain a relaxation reading from very small signals. By adjusting the frequency range it is also possible to measure slow and fast muscle fibres separately.

The following table shows the ranges (upper limit of each range) with their associated resolutions in *µV*:

Range [µV]	*1000*	*500*	*250*	*125*	*60*	*30*	*15*
Resolution [µV]	*0.767*	*0.384*	*0.192*	*0.096*	*0.048*	*0.024*	*0.012*

In addition there is a choice of four different frequency bands. The sampling rate is set automatically in accordance with the sampling theorem and is dependent on the frequency range.

Muscle type	Lower cut-off frequency [*Hz*]	Upper cut-off frequency [*Hz*]	Sampling rate [sample/sec.]
Slow twitch muscle fibres	*25*	*80*	*500*
Fast twitch muscle fibres	*100*	*200*	*500*
Slow and fast twitch fibres	*25*	*100*	*500*
Wide range	*25*	*500*	*1.000*

Default settings:

Frequency range: 100 - 200 Hz; ECG interference is outside this frequency range

Measurement range: 60 µV; optimum sensitivity for all standard EMG measurements.

These settings are suggestions only; the user can change them at any time and define new defaults.

Digital line filters, filtering at *50 Hz* or 60 Hz, are used to reduce line disturbance. The correct line filter for your location will be set when the software is first installed. In the event of a change of country, the line frequency can be changed in the software settings.

2.2 MULTI module

With the MULTI module the following four parameters can be measured simultaneously:

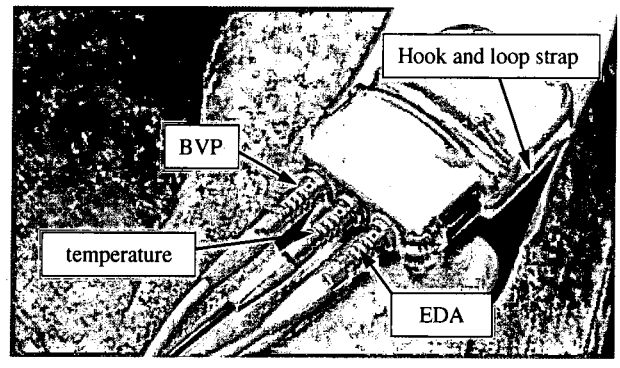
- skin conductance (EDA),
- temperature (TEMP),
- blood volume pulse (BVP) by means of external sensors
- 3D acceleration (MOT) by means of an internal sensor

The sockets of channels that are not required should ideally be left empty (i.e. with no sensors plugged in). The MULTI module is attached to the wrist or head using a hook-and-loop strap system.

The three external channels are colour coded as shown in the following table and illustration:

Channel	Colour
EDA	Yellow
TEMP	Red
BVP (Pulse)	Purple

Sensor connections of the MULTI module



Examples of application for peripheral recording and monitoring of a vasoconstriction

2.2.1 EDA

Electrodermal Activity

Recorded (calculated) parameters:

SCL..... Skin Conductance Level – tonic level of skin conductance

SCR..... Skin Conductance Reflex – brief (phasic) variation in electrodermal activity, usually in response to a stimulus

The electrical conductivity of the skin varies with the activity of the sweat glands - the amount of sweat in the sweat channels affects the skin conductance.

Recommended disposable electrodes:

Manufacturer: 3M Health Care

Type: Monitoring electrode 2223

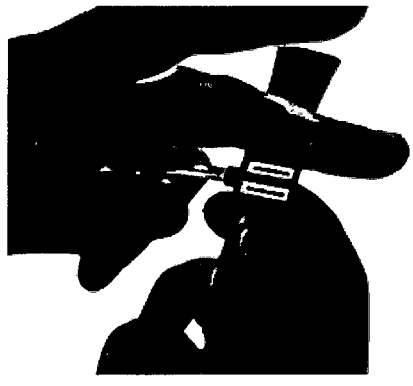
The electrode cables are connected to the yellow socket.

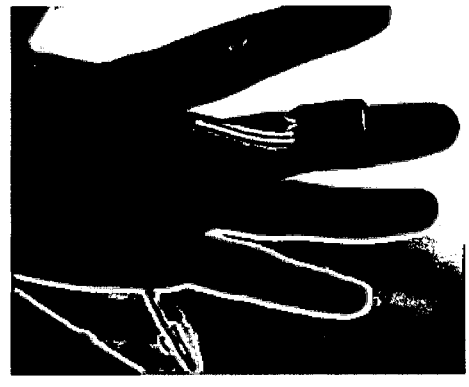
Attaching the electrodes:

Electrodermal readings should preferably be taken from the palm of the non-dominant hand (because the outer layer of the epidermis is thinner here) or from the middle joint of a finger. Details of the use of the different recording sites are given below:

- *Single-finger recording with EDA1 sensor:*

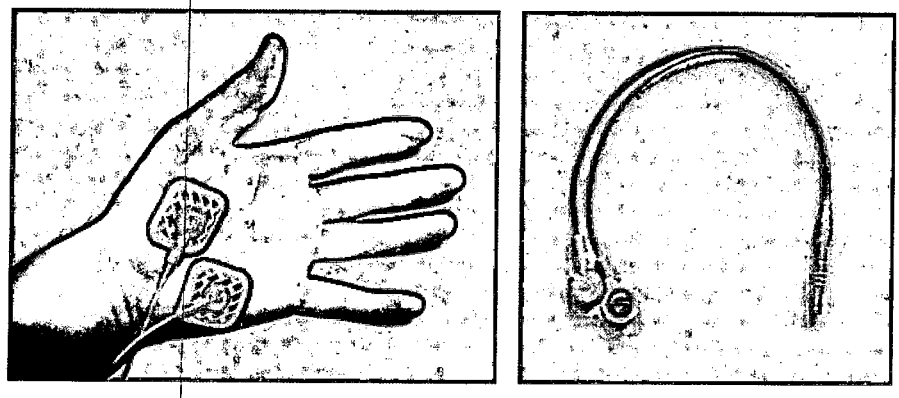
  The skin conductance is recorded from any part of the finger using gold electrodes that are already attached to a finger strap. This EDA sensor can simply be plugged into the yellow EDA socket. It is not necessary to use any electrode gel, but both the sensor surface and the skin surface should be cleaned with alcohol before the sensor is attached. This ensures better contact between the skin and the electrode.





- *Recording with disposable electrodes and EDA2 electrode cable:*

Two disposable electrodes are attached to the palm of the hand as in the illustration below. The clips of the yellow EDA2 electrode cable are snapped open and connected to the yellow EDA socket of the MULTI module:



Before the electrodes are attached the client should wash the hand in warm water. If the skin is greasy the site should also be cleaned with ethyl alcohol (70%).

→ **Important!** Washing the hand with soap causes the skin to swell and reduces skin conductance.

→ **Important!** The jacks must not be touched while readings are being taken. Contact – for example, by a wristwatch – could short out the signal, causing 0 µS to be displayed.

Technical details:

The skin conductance is measured by recording the electrical potential. A square wave signal with a frequency of *20 Hz* and an amplitude of *±1.42 V* is applied to the skin. The electrical current flowing over the skin is recorded by the MULTI module, and from this the skin conductance level (SCL) is calculated. The skin conductance reflex (SCR) is obtained by calculating the difference between the current value and the mean of previous signal values.

Polarization of the skin is avoided by using an alternating measurement signal.

Measuring range for SCL: *0* to *50µS*

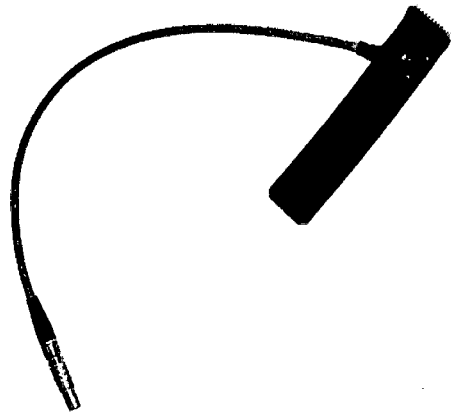
Resolution: *0.001µS (=1nS).*

Standard values for the SCL parameter:

Maximum range: *0 - 50µS*

Modal values: *1 - 10µS*

2.2.2 TEMP



Recorded parameter:

TEMP ..... Skin **temp**erature

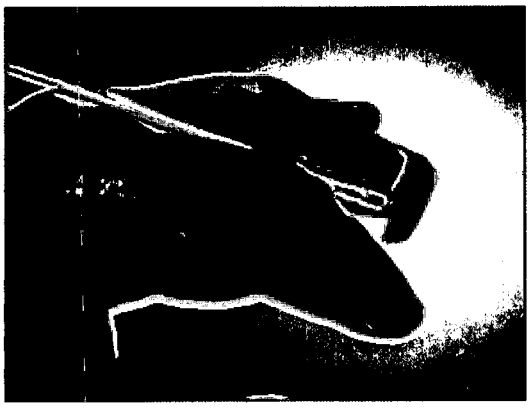
Recommended sensor:

The temperature sensor (available separately) is used. It is colour-coded in red.

This illustration shows the side of the sensor that is applied to the skin.

Attaching the sensor:

Place the sensor on the required part of the body and attach by using a hook-and-loop finger strap or adhesive tape (e.g. Leukoplast), or by placing a headband over it. By default the temperature sensor is provided with a hook-and-loop strap by means of which it can be attached to a finger. This hook-and-loop strap can be easily changed if necessary for hygiene reasons or in the event of damage.



The temperature sensor should preferably be attached to the top part of a free finger by means of a hook-and-loop strap, as shown in the illustration. If the temperature is recorded from a different part of the body, remove the hook-and-loop strap and attach the sensor to the skin either with adhesive tape or by holding it in place with a headband. Take care to position the sensor the right way up, with the sensing surface against the body, as shown in the illustrations.

Connect the sensor to the red socket of the MULTI module.

Technical details:

The temperature data is processed in the sensor and transmitted to the MULTI module in digital form. Within a range of *0 – 40°C* the temperature is measured at a resolution of *0.01°C* and with an accuracy of *0.5°C*.

2.2.3 PULS

Recorded parameters:

BVP..... **B**lood **v**olume **p**ulse - measurement of the mean flow of blood near the surface of the skin by means of photoplethysmography relative to the maximum recordable range (see below).

PVA..... **B**lood **v**olume **a**mplitude - measurement of the peak-to-peak value of the BVP relative to the maximum recordable range (see below).

PULS..... **Puls**e rate - the number of heartbeats per minute (bpm - beats per minute) is calculated from the BVP.

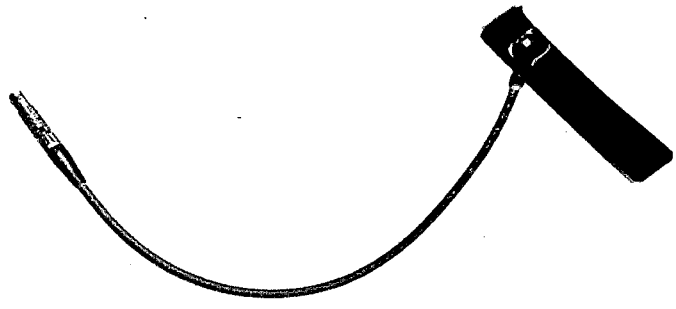
Red blood corpuscles absorb infra-red light. If tissue to which there is a good blood supply is exposed to infra-red light, minute fluctuations in the intensity of the reflected or transmitted light can be detected. These fluctuations, caused by the flow of red blood corpuscles, are filtered out and processed.

Sensor:

Reflex pulse sensor.....for recording from the finger tip (hook-and-loop strap) or from the surface of the skin (e.g. at the temples)

The PULS sensor is colour-coded in purple.

After attachment to the body the sensor is connected to the purple socket of the MULTI module.

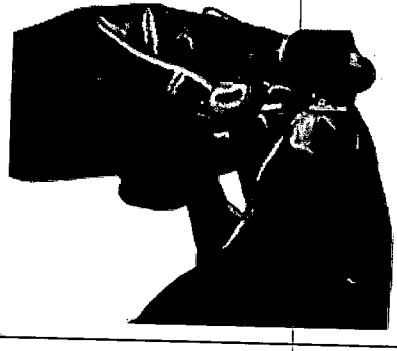


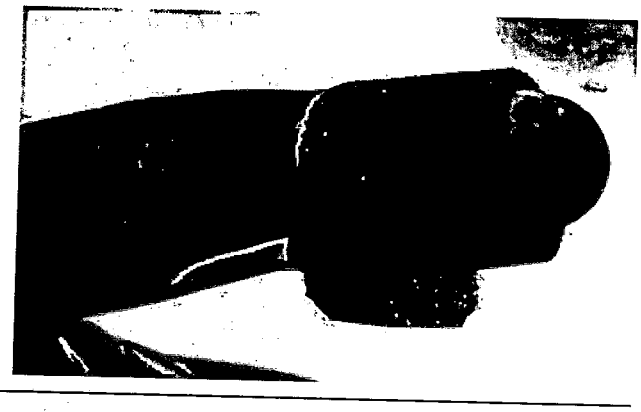
Attaching the sensor:

Finger pulse sensor / Reflex pulse sensor:

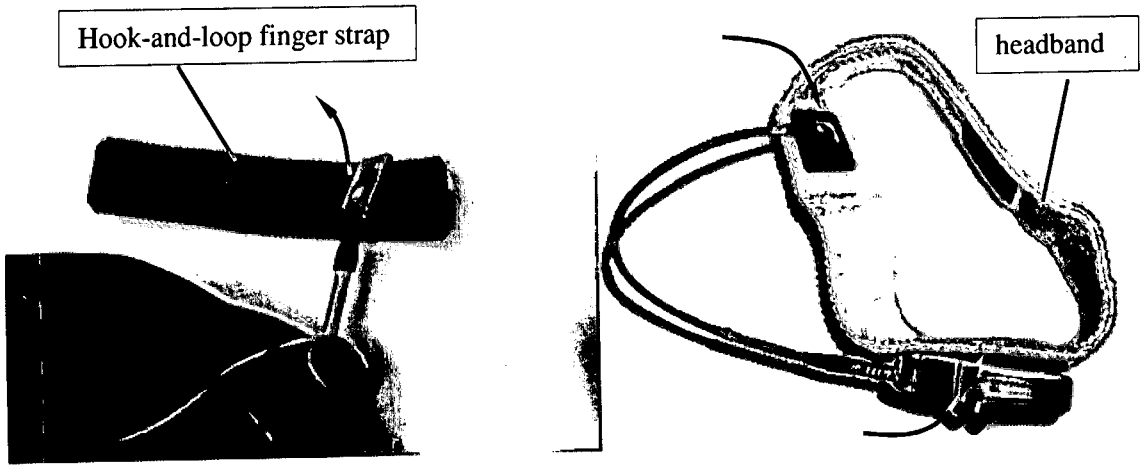
The finger pulse sensor is designed as a reflex sensor and it can be attached as required either to the finger or to any other part of the body, such as the temples.

When *used on the finger*, the sensor is attached by means of the hook-and-loop strap (supplied), as shown in the following pictures.





When *used as a reflex pulse sensor*, the sensor should preferably be attached to the temples or forehead, using either the hood-and-loop surfaces on the sensor and a headband or adhesive tape (such as Leukoplast) and ensuring that the sensing surface is next to the skin. When used in this way the sensor is removed from the hook-and-loop finger strap and attached to the headband, as shown in the picture below. The module is also attached to the headband. The headband must then be positioned in such a way that a strong pulse signal is displayed on the BVP graph in the Biofeedback 2000 x-pert software. When the correct position has been found, re-calibrate the device (see the Biofeedback 2000x-pert manual).



Fluctuations in intensity caused by movement fall within the same frequency as the working data and thus interfere with accurate recording and display. Care should therefore be taken to ensure that the client remains as still as possible.

Technical details:

The sensor consists of an infra-red light source and an infra-red receiver. The infra-red light source operates at constant intensity. The pulsating change in blood flow causes fluctuations in the brightness of the reflected or transmitted light. These fluctuations are filtered out, amplified, and displayed as the BVP parameter (relative change in blood flow). To compensate for interference, the BVP parameter is smoothed by a moving calculation of the mean.

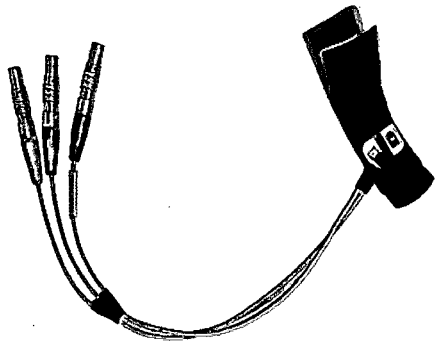
Before measurement starts, the pulse sensor is attached to the client. When recording is activated (START in the Biofeedback 2000 x-pert software), the reading is calibrated - that is, it is amplified to the point at which the BVP signal occupies approximately one-quarter of the display. **The client must not move during this calibration phase.** If movement takes place the artefacts of movement are recorded as part of the signal being measured and calibration is interrupted. If this happens, the calibration process must be repeated.

The PULS parameter is calculated by measuring the period of the BVP curve (R-R interval); it corresponds to the heart rate. The PVA value is the difference between the maximum and minimum BVP values during one heart cycle.

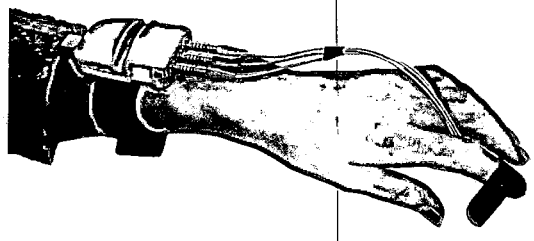
The BVP and PVA are relative values, expressed in terms of the maximum values that can be displayed. The range of the BVP and PVA values is *0 - 100 %* at a resolution of *0.25 %*. The range of the PULS parameter is *30 - 200 bpm (beats per minute)* at a resolution of *0.004 bpm*.

2.2.4 Multi-sensor

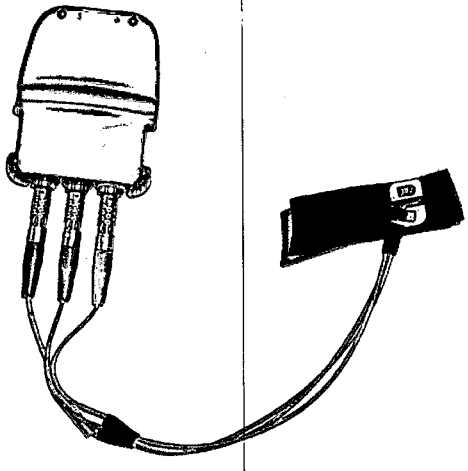
The multi-sensor makes it possible to record the vegetative parameters of EDA, TEMP and BVP from the same fingertip. The functionalities and properties of the individual parameters are the same as for the individual channels described above.



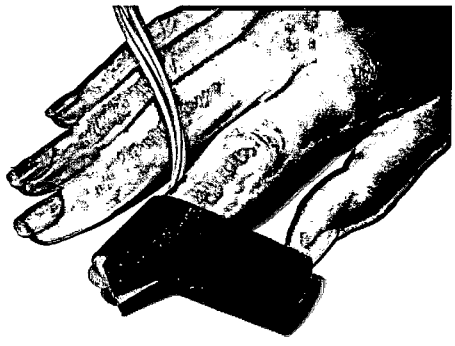
Attaching the sensor:



If the hook-and-loop strap is fastened in the shape of a ring, with the adhesive surfaces placed exactly over one another, the sensor does not press evenly against the finger and artefacts of movement interfere with the quality of the recording. Plug the sensor jacks into the correspondingly coloured sockets of the MULTI module.



The sensor should be attached to a fingertip of the non-dominant hand. In order to minimize **artefacts of movement**, users have found it helpful to wrap the hook-and-loop strap **diagonally** across the finger *(see picture below)*, forming a finger-shaped cone.



2.2.5 MOT

Recorded parameter:

MOT ..... **Mo**tor movement (motility)

Used to record the client's movement.

Attaching the sensor:

The sensor is located inside the module and is thus attached by fixing the module in place. For accurate measurement the module should be attached using the hook-and-loop strap.

Technical details:

Motility is calculated by measuring acceleration on all three axes of movement. The basis of evaluation is the difference between the sum signal of the three axes and the smoothed mean of previous readings. Smoothing is optimized so that the recorded change in acceleration amounts to at least *2 Hz*; this is the optimal way of measuring the shaking of tremor patients. The measuring range of the MOT sensor is $0 - 20\ m/s^2$ at a resolution of $0.01\ m/s^2$.

Important!

When attaching the sensors, all the sensor cables should be positioned so that they run between the index and middle fingers to the module on the forearm, as shown in the illustration. This minimizes artefacts of movement. In the case of the pulse sensor, the best position on the finger must be found by trial and error; this is because of anatomical differences between clients.

2.3 RESP module

Recorded parameters:

RESP-1 ..... Abdominal **resp**iration - abdominal respiration curve

RESPA-1 ..... Abdominal **resp**iration **a**mplitude - the depth of abdominal respiration, the amplitude of the abdominal respiration curve

RESPF-1..... **Resp**iration **f**requency - the number of breaths per minute, calculated from the abdominal respiration curve (RESP-1)

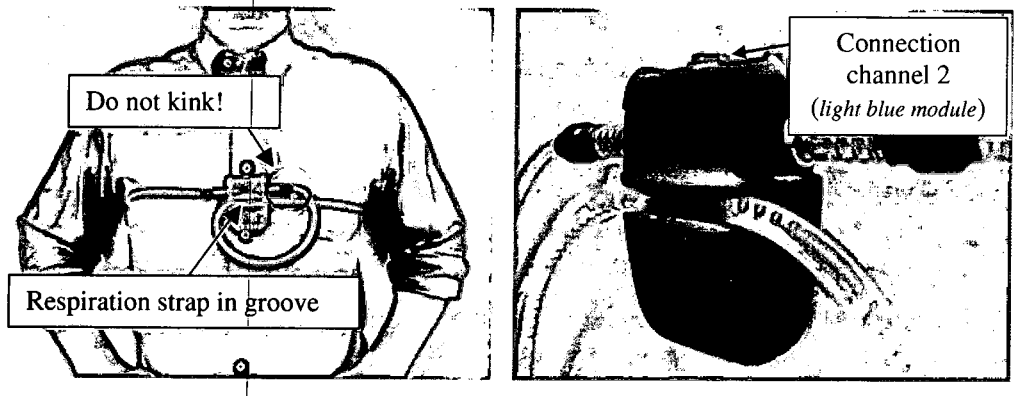
RESP-2 ..... Thoracic **resp**iration - thoracic respiration curve

RESPA-2 ..... Thoracic **resp**iration **a**mplitude - the depth of thoracic respiration, the amplitude of the thoracic respiration curve

RESPF-2..... **Resp**iration **f**requency - the number of breaths per minute, calculated from the thoracic respiration curve (RESP-2)

Recommended sensor:

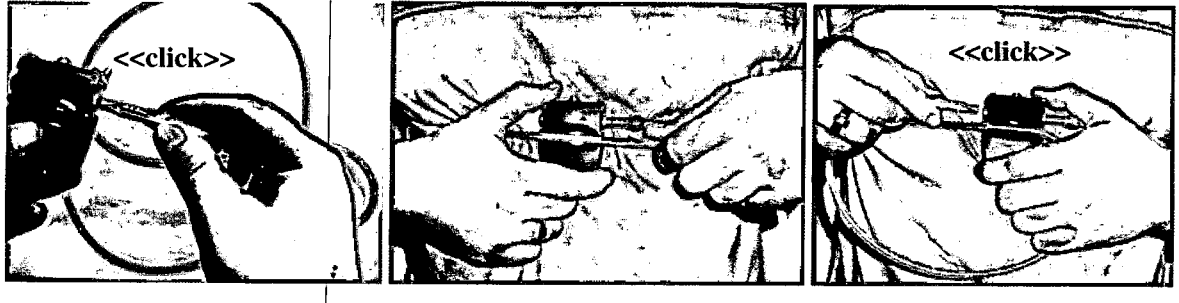
Measurement is carried out using the respiration strap, which is available separately. The sensors are colour-coded in blue.



Attaching the sensor:

Insert one end of the respiration strap into a dark blue socket of the RESP module until it locks into place. Place the respiration strap around the body (chest or abdomen) and press it into the groove on the module. The module should now be held in place on the body. Form a loop with the unattached end of the respiration strap and insert its connector into the second blue socket on the module.

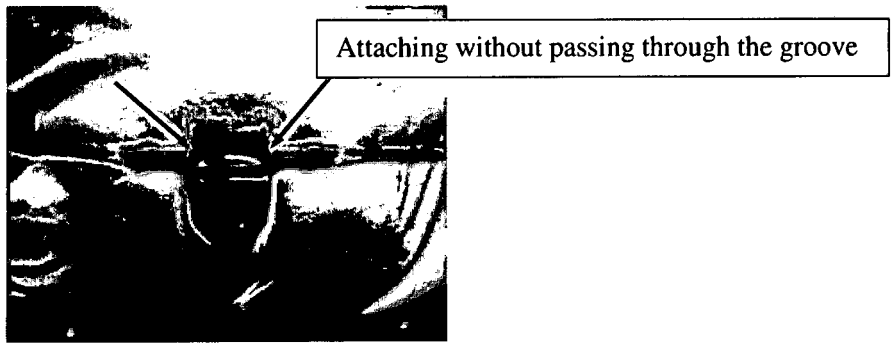
Ensure that the strap is not sharply bent or kinked, as this will make readings impossible.



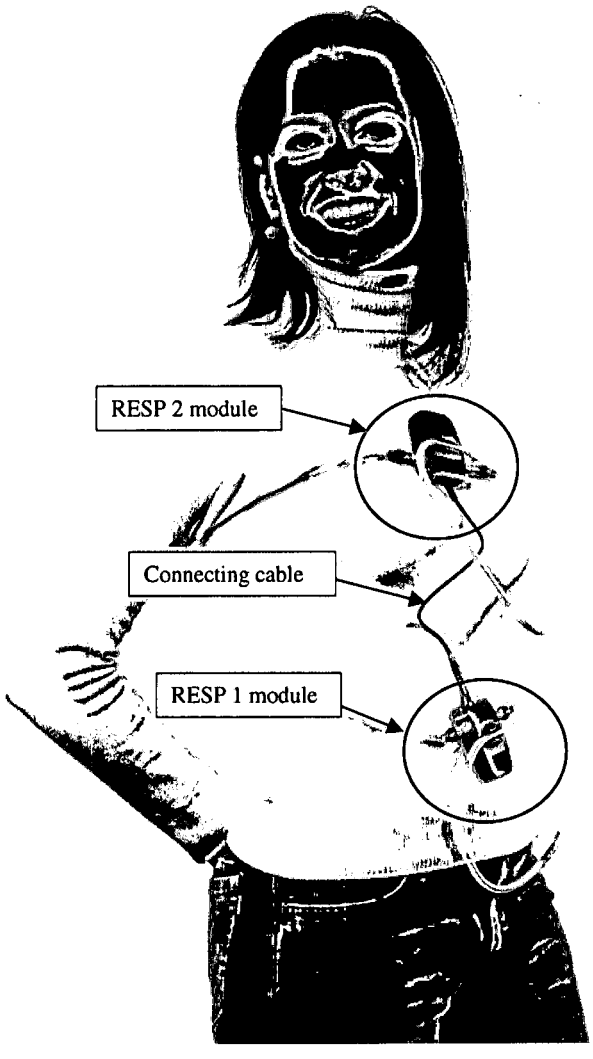
Attaching the respiration strap

If the client's body circumference is so large that the respiration strap cannot be looped back on itself without kinking, the strap should be attached without passing through the groove in the module. In this

case the module is attached to the body simply by plugging each end of the respiration strap into the module, as shown in the picture below.



As each client has a different body circumference, the state of the strap is inevitably undefined - that is, because of the varying mechanical tension its longitudinal extension is different each time it is used. To compensate for this the RESP module is calibrated in the middle range at the start of every session. This calibration can also be carried out while recording is taking place by using the "calibrate device" function. This can accommodate a change in circumference of ± 10 cm. If the second measurement channel is used, the RESP and RESP2 modules must be linked by a connecting cable inserted into the light blue socket on the end of each module. The second respiration strap is attached in the same way as the first (see illustration).



Technical details:

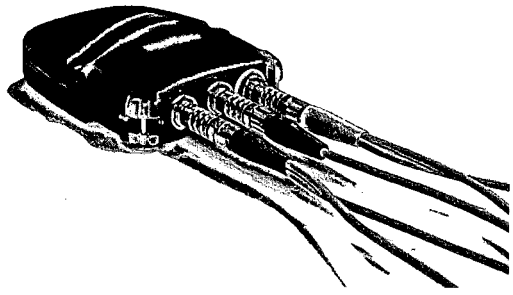
The change in circumference is measured using an ultrasound signal. If the belt needs to be adjusted during a session it is essential to re-calibrate the device in order to maintain the accuracy of readings.

The RESP signal indicates the distance moved by the respiration strap at each time point and corresponds to the respiration curve with an accuracy of 1 mm, a resolution of of 0.2 mm and a range of ± 10 cm. RESPA gives the difference between the maximum and minimum of this respiration curve. RESPF calculates the respiration rate from the the respiration curve with a range of 60 ventilations/min and a resolution of 0.02 ventilations/min. The length of the respiration strap is 1.4 m.

2.4 EEG module

Recorded parameter:

EEG ..... Electroencephalography



Channel	Colour
EEG1	Grey
EEG2	White
REF	Black

Recommended electrodes:

We recommend the use of the following electrodes, which can be purchased separately:

- Self-adhesive Ag/AgCl disposable electrodes with snap connector
  Manufacturer: 3M Health Care
  Type: Monitoring electrode 2223

- Gold cup electrodes used with electrode paste
  Manufacturer: SCHUHFRIED GmbH

- Electrode paste
  Manufacturer: Grass
  Type: EC-2

Important: use only CE marked electrodes.

The electrodes are connected to the EEG module by means of the colour-coded EEG electrode cables. Depending on the recording site, gold cup electrodes may be used instead of self-adhesive electrodes. The electrodes should be attached in accordance with the following instructions or the instructions for the particular treatment type. The grey and white electrode cables are connected to the monitoring electrodes and the black cable to the reference electrode.

General:

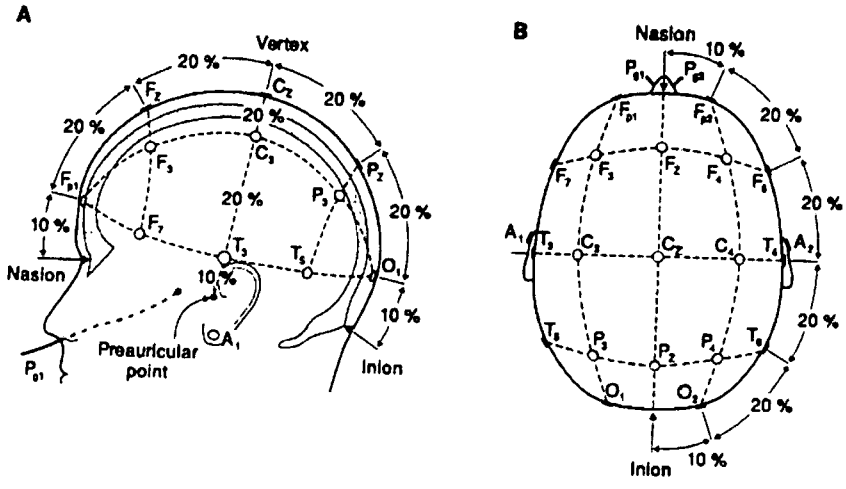
For EEG recordings the recording site is determined by means of the 10-20 system. A detailed description can be found in the software help on recording positions.

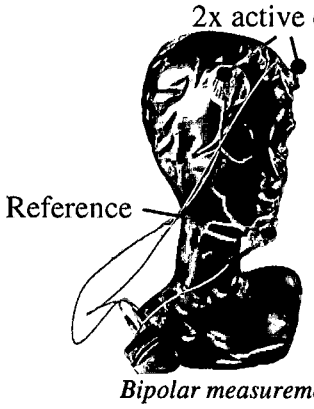
In the international standardized 10-20 system 21 electrode positions are defined. The positions are determined as follows:

(i) Measure the distance between the reference points from the nasion (root of the nose, at eye level) via the vertex to the inion (spur at the back of the head);

(ii) Now measure the distance between the two preauricular points, also via the vertex.

iii) The electrodes are then positioned at 10% and 20% of these distances (see illustration). It is this which gives the system its name.

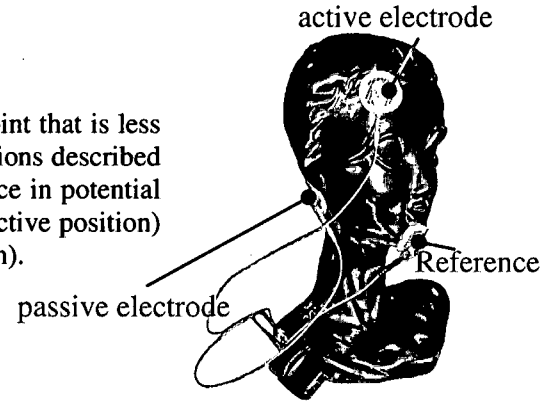




Bipolar measurement

If *both electrodes of a channel* are positioned at electrically active points on the head, the recording is described as ***bipolar***; it reflects the *difference in potential* between two electrically active positions. In order to reduce common-mode interference and to create a defined reference potential, readings are compared with those from a reference electrode. In this procedure the *reference electrode* is frequently placed on the head (e.g. at Cz). Other suitable reference points are the ear lobe, the mastoid bone behind the ear, the lower edge of the nose and the chin.

If, however, *one of the two electrodes* is positioned at a point that is less electrically active (e.g. one of the reference electrode positions described above), this results in a ***monopolar*** recording; the difference in potential is measured between a target electrode (in an electrically active position) and a reference electrode (in an electrically inactive position).

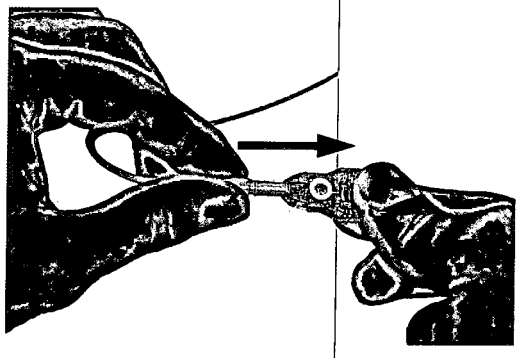


Monopolar measurement

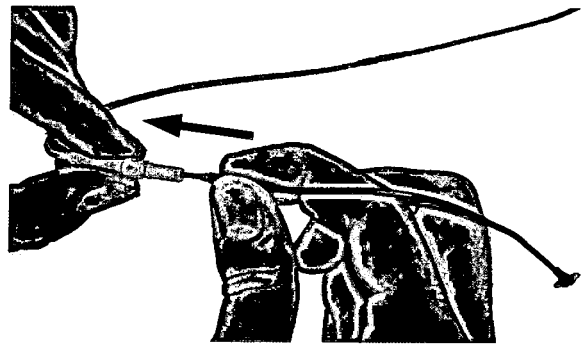
Attaching the electrodes

If readings are taken in the ***frontal*** area, disposable electrodes can be used. The reference electrode (black) is then normally attached to the nose, mastoid bone or chin using a multi-clip and a disposable electrode. For **monopolar recording** the active electrodes are attached to the frontal and mastoid bones; for **bipolar recording** both active electrodes are attached to the frontal bone. If a second recording channel is used the electrodes are normally placed in the same positions on the other side of the head.

If readings are taken from an ***area of the head that is covered with hair***, **gold cup electrodes** (supplied) are used instead of the multi-clips. In this case remove the multi-clip from the electrode cable as shown in the pictures (this may initially be difficult; a certain degree of force is required) and insert the gold cup electrode cable.

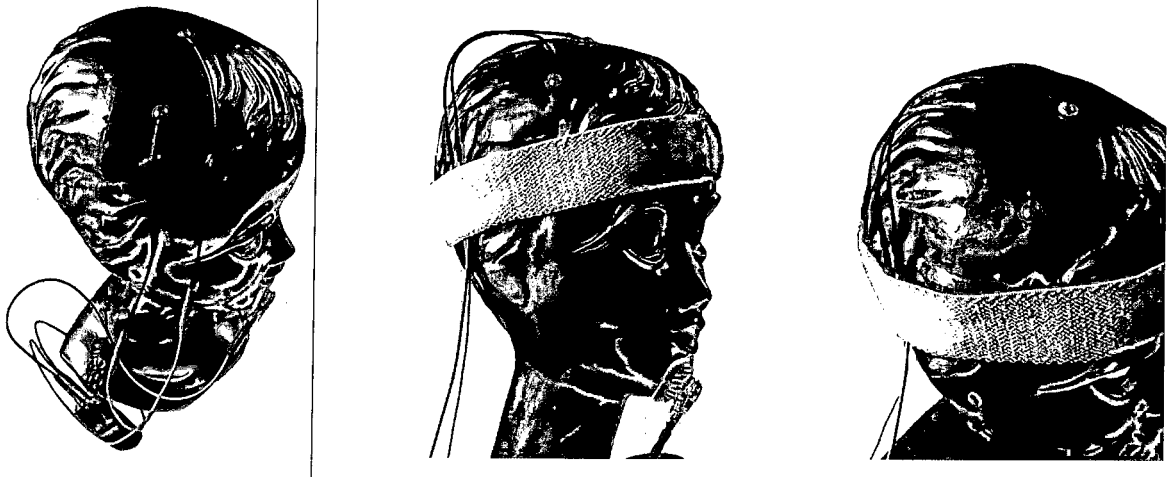


Remove multi-clip



Insert gold-cup electrode cable

Before attaching the electrode to the head, rub some **electrode paste** into the skin of the head. The gold cup should also be filled with electrode paste and pressed onto the treated area of the head.



To prevent the electrodes becoming detached from the head, position a headband over the electrode cables, as shown in the illustrations. Since the electrode paste is self-adhesive (paste contains collodium), the electrode contact resistance remains roughly constant; combined with the very high input resistance of the amplifier (~GOhm) this provides a high-quality EEG recording.

Technical details:

The EEG potential is amplified by a difference amplifier with very high input resistance (> 2 GOhm) and digitalized using a 24-bit processor with a sampling rate of 200 Hz. To prevent aliasing, the amplified signal is band-limited before digitalization with an eighth-order filter at a cut-off frequency of 40 Hz. In order to minimize common-mode interference, the reference channel is provided only with a driven right leg circuit. This DRL circuit generates a "floating mass" that increases the common-mode rejection ratio (CMMR) and provides the necessary reference potential for the EEG recording. These raw signals are transmitted via a Bluetooth radio link to the computer, where the software uses the data to calculate the necessary training parameters. The raw signal is divided into the usual EEG frequency bands by means of a **fast Fourier transformation**[1]. The FFT provides a spectral analysis of the real and imaginary parts of the recorded and digitalized EEG potential. The formula

$$|U_{EEG}(f)| = \sqrt{(re(f)^2 + im(f)^2)}$$

gives the amplitude of the EEG signal.

Display options:

- **FFT display**: shows the change in the amplitude spectrum over time in µV
- **Bar and multi-lines chart of the frequency bands:** Gross potential of a frequency band in µV (Summing of all frequency components within a band, e.g. the α band)
- **Lines EEG1 and EEG2:** Raw signal – amplitude change as a function of time

.Six **sensitivity settings** can be set via the default settings:

Upper limit of measurement range	Resolution
± *100 µV*	*3 nV (0.003 µV)*
± *200 µV*	*6 nV*
± *400 µV*	*12 nV*
± *800 µV*	*16 nV*
± *1600 µV*	*32 nV*
± *3200 µV*	*48 nV*

Frequency bands calculated:

Delta:	*0.4 ... 4 Hz*
Theta:	*4 ... 8 Hz*
Alpha:	*8 ... 12 Hz*
SMR:	*12 ... 15 Hz*
Beta:	*15 ... 20 Hz*
High Beta:	*20 ... 30 Hz*
Gamma:	*30 ... 45 Hz*

[1] Number of data points N=200, buffer width 256 = moving time window 1.28s → FFT bar width = 0.78 Hz

3 SETUP

3.1 System requirements

COMPUTER

- PC or laptop with Pentium or compatible CPU (e.g. Celeron, Athlon), min. 1.5 GHz
- at least 512 MB RAM
- graphics card (suitable for playing videos)
- 16-bit MIDI-capable sound card with speakers or headphones
- CD or DVD drive
- hard disk (with at least 1 GB free space)
- mouse, keyboard
- 1 USB port for the radio pyramid (if radio modules are used)
- serial ports for **physiorecorder**, marker cable or control of an external device (if used)
- operating system: Windows 2000, Windows XP or Windows Vista 32

Please ensure that no programs are installed on the computer that could interfere with the presentation of training (e.g. through high CPU usage or unwanted on-screen messages).

MONITOR

- CRT or TFT colour monitor with at least 15" visible screen diagonal.

PRINTER (OPTIONAL)

- Laser or inkjet printer, black and white or colour

SAFETY DEVICES

If Biofeedback is used within the healthcare service, the use of the following devices may be required:

- Medical grade isolating transformer in accordance with EN 60601.
- Galvanic medical network insulation in accordance with EN 60601 (if the computer is connected to a data network).

Please ask your in-house health and safety officer.

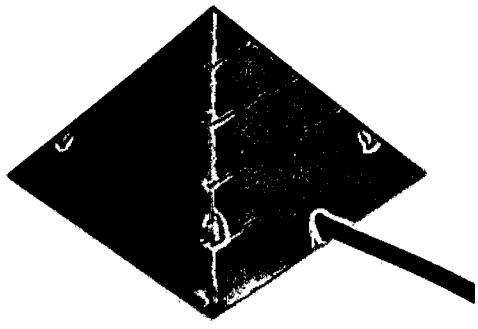
Products of SCHUHFRIED GmbH are developed and produced to meet the requirements of European Directive 93/42/EEC. The CE mark confirms that our products comply with technical safety regulations, electro-magnetic compatibility guidelines (EN60601), bio-compatibility guidelines (EN30993) product-specific requirements and quality management standards. Please consult us before purchasing new devices; we shall be pleased to help you select the most appropriate items for your purposes.

3.2 Installation

The following installation instructions explain how to set up the system. The system installs largely **automatically** if the **instructions are followed during installation.**

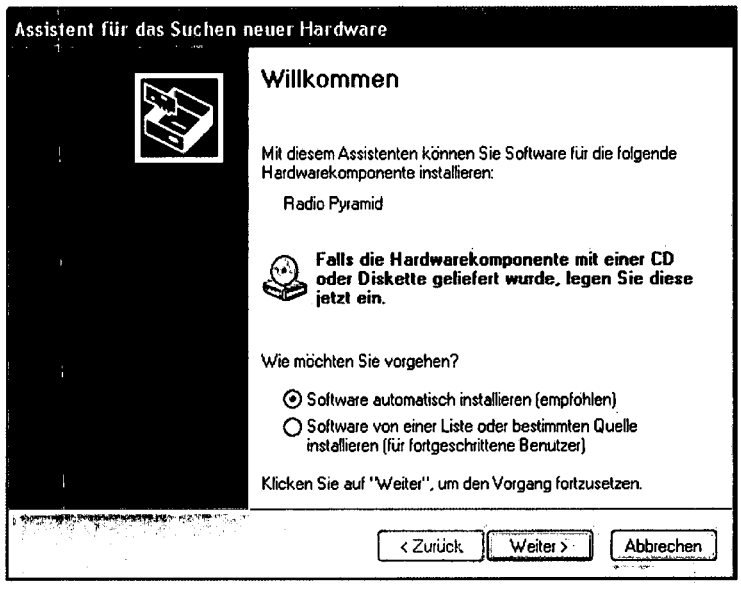
Start the computer and log on as an **Administrator** or as a user with administrator rights. Insert the Biofeedback 2000 x-pert CD in a CD-ROM drive - setup starts automatically. If installation does not start automatically, you should launch the setup.exe file that is contained on the CD.

When installation is finished, insert the **yellow radio pyramid into a free USB port.**

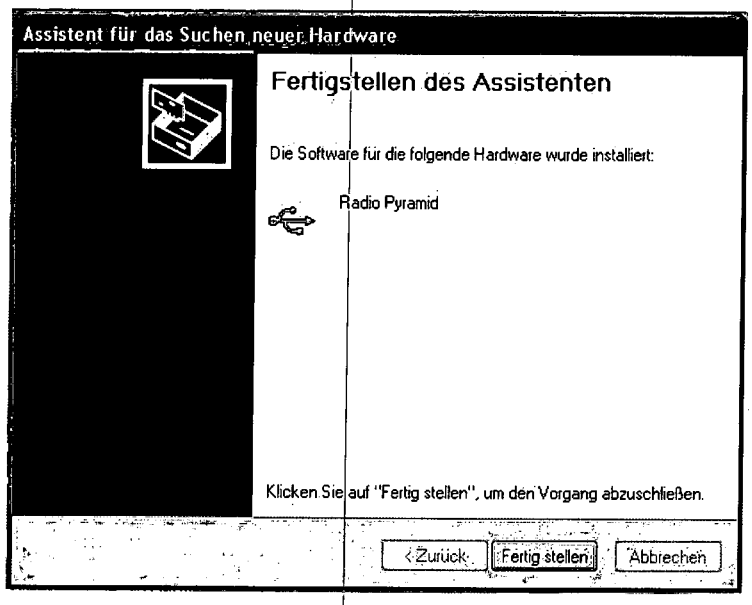


The driver for the radio pyramid will be automatically installed by the operating system. Follow the instructions displayed by the operating system –

in **WIN XP**:



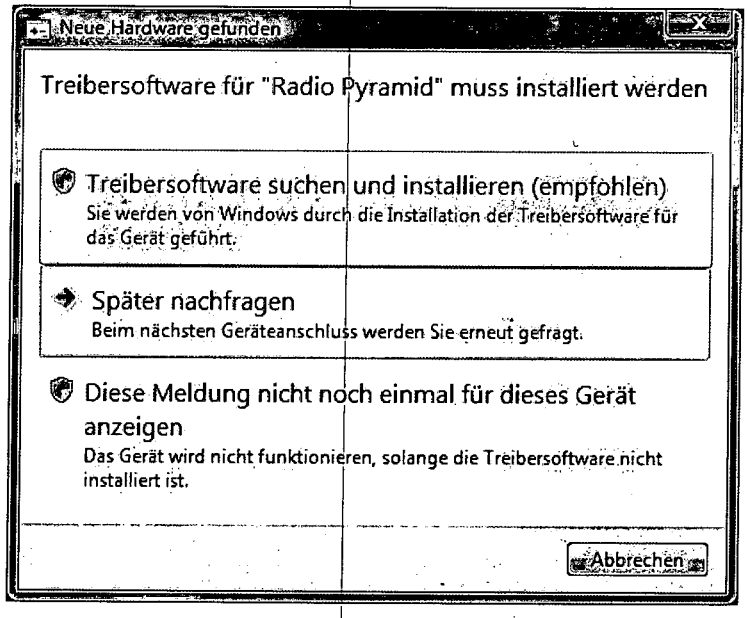
Select *"Install software automatically"* and click *"Next"*.



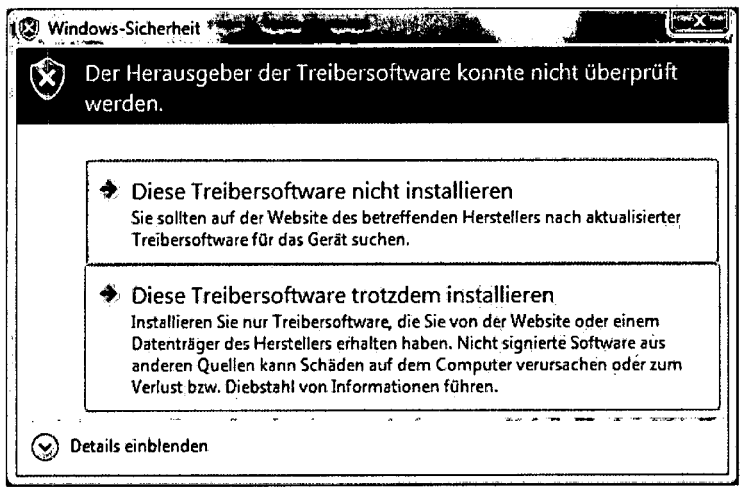
Click on *"Finish"*.

Installation is now completed and the system is ready for use.

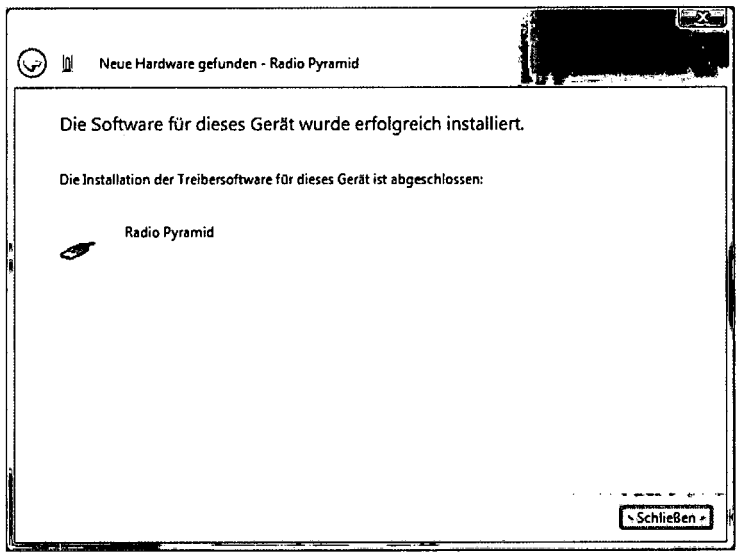
in **VISTA**:



Select *"Find and install driver software"*.



Select *"Install this driver software anyway"*



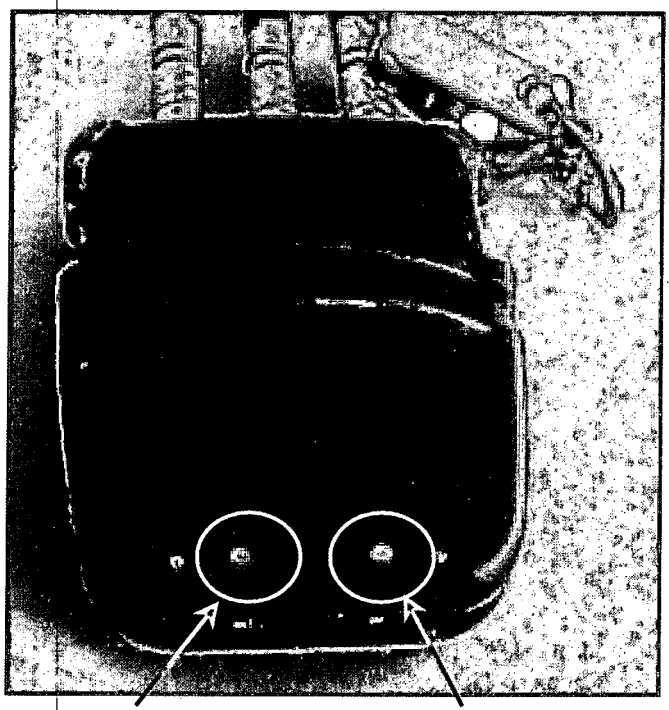
The driver has been successfully installed on your system. The radio pyramid is now ready for use. Finish the installation by clicking *"Close"*.

Activate your radio modules (by removing them from the charger) and start the Biofeedback 2000 x-pert software. The system will now search for all radio modules within range of the radio pyramid and automatically connect them to the Biofeedback program. Change the settings to *"only search for known devices"* (see software manual). In this mode the system searches only for radio modules that have already been initialized (rather than searching the whole Bluetooth environment); Biofeedback will therefore start faster next time the program is launched. The system is now ready for use.

3.3 LED functions

Each module is provided with two light-emitting diodes (LEDs). These indicate the module's operating status:

- The green LED indicates the battery status. It begins to flash when the battery power has dropped to the point where it is sufficient for approximately 45 minutes of further use.
- The blue LED indicates the status of the Bluetooth connection. If the light is illuminated, communication with the computer is fully functioning.
  Communication is interrupted if you move out of range (between 3-7 metres, depending on the type of environment). Flashing of the blue LED indicates that the radio connection has been lost and recording interrupted. When you move back into the reception range, the blue LED lights up again, the connection with the module is restored and data transfer continues in real time. While the connection is interrupted a straight line is displayed and a warning marker is inserted.



3.4 Deactivation, storage and transport of the radio modules

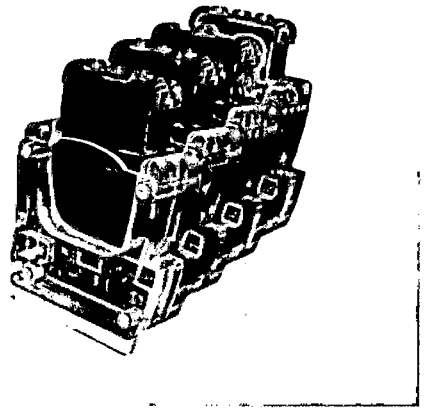
Place the charger with the radio modules on your desk and connect the charger only with the power cord supplied with it. Between sessions, and when the module is not required, modules should be placed in the charger, where they will be deactivated and recharged. This ensures that they are ready charged for their next use. For transport the modules should also be kept in the charger, as shown in the illustration below. The radio modules are held securely in place for transport by the foam in the lid of the case.

3.5 Charging the radio modules

When the radio modules are activated the battery state is checked. If the battery level is low (approx. 45 minutes operating time remaining), the green LED begins to flash. If the battery power falls below this level while the module is in use, the software displays an additional warning. At the latest when the green light flashes the module should be recharged.

Plug the power cord into a mains socket and the round jack into the socket of the transparent charger – a green LED on the power cord and on the front of the charger should illuminate. To charge a radio module push it into a vacant slot; this deactivates the module. The charger now identifies the battery's capacity and initializes charging. While the battery is being charged, the blue LED on the right-hand side of the charger flashes. When the battery is fully charged, the blue LED is steadily illuminated. A complete charging cycle takes between three and four hours.

The radio modules can be kept permanently in the charger. If the charger's power cord is disconnected from the mains (e.g. if sockets are switched off at night), the radio modules retain their battery charge.



Important! When in the charger the radio modules are deactivated and therefore cannot be used.

4 ADDITIONAL INFORMATION

4.1 Warnings

This symbol means:
Warning, read the instructions.

This symbol indicates that for electrical safety purposes the device is classed as type BF. This means that it has applied parts that are not earthed.

SN: JJJJ TBX1-xxxx

Serial number of the radio module. The first four digits JJJJ indicate the year of manufacture. The module identifier U, M, R or G takes the place of X, and xxxx is a unique product number.

This symbol indicates that the device contains an HF transmitter.

Additional warnings:

The system is not a diagnostic device and must not be used as such.

The device may only be opened by authorized persons.

Assembly, upgrades, re-setting, alterations or repairs may only be carried out by appropriately trained staff.

The device is not intended for setup or use in damp environments or places where there is a risk of explosion.

Do not expose the device or its accessories to any source of heat or to a heat sink (e.g. fan heater, radiator, air-conditioning, direct sunshine etc.).

The device should not be stored, set up or used in a dusty or dirty environment.

The device should only be used in the environmental conditions described (see Section 4.99).

Unless a medical isolating transformer and a mains separator are used with the computer, the computer and monitor must not be placed in the immediate vicinity of the patient and must meet the requirements of EN 60950 (distance from the computer at least 1.5 m).

HF transmitters such as mobile phones should not be used within 1 metre of the device.

The simultaneous connection of the patient to a high-frequency surgery device can cause burns under the sensors.

The Biofeedback system must not be used at the same time as a defibrillator.

The sensors are very sensitive electronic components. They must not be scratched or exposed to mechanical pressure.

Advice should be sought from an appropriately qualified doctor before treating a client with an implanted electronic device (e.g. a heart pacemaker).

Skin conductance readings (EDA) should not be taken from the thorax (chest and back).

The sensors should not be attached to damaged skin.

The EEG electrode paste must not come into contact with the eyes or mucous membranes; it should be applied only to the skin of the head.

The EEG electrode paste must not be applied to a vaginal or anal electrode.

The clips contain nickel and should not come into direct contact with the skin of anyone who has a nickel allergy.

In the event of an electrostatic discharge the Bluetooth connection may be interrupted. When the session is re-started the module will initialize itself automatically. This poses no risk to the patient.

No earthed parts should be within reach of the patient.

Accidental contact with conductive parts that do not form part of the attached component and with other conductive parts including those connected to the earth should be avoided.

MEDICAL ELECTRICAL DEVICES must conform to particular EMC requirements and must be installed and used in accordance with the EMC guidelines in Section 4.2.

The use of a radio connection means that other radio devices may cause interference even when used in accordance with the instructions.

4.2 Electromagnetic compatibility regulations

4.2.1 Electromagnetic emissions

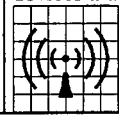
The radio modules are intended for use in environments as described below. The client or user of the radio modules should ensure that they are used in an environment of a suitable type.

Interference emission levels	Conformance	Electromagnetic environment guidelines
HF emissions in accordance with CISPR 11	Group 1	The radio module uses HF power only for its internal functioning. Its HF emissions are therefore very small and are unlikely to affect nearby electronic devices.
HF emissions in accordance with CISPR 11	Class B	The radio module is intended for use in institutions of all types including living areas and other buildings that are directly connected to a public electricity supply that also serves buildings used for residential purposes.
Harmonic current emissions in accordance with IEC 61000-3-2	Class A	

4.2.2 Electromagnetic immunity

The radio modules are intended for use in environments as described below. The client or user of the radio modules should ensure that they are used in an environment of a suitable type.

Immunity test	IEC 6061 test level	Conformance level	Electromagnetic environment guidelines
Power frequency magnetic field (50 Hz/60 Hz) in accordance with IEC 610000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should correspond to the typical levels found in business and hospital environments.

Immunity tests	IEC 6061 test level	Conformance level	Electromagnetic environment guidelines
			Portable and mobile radio devices should not be used any closer to the biofeedback module (including cables) than the recommended safety distance appropriate to the transmitter frequency, as calculated by the following formula. Recommended safety distance:
Conducted HF disturbances in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 → $V1$ in V	$d = \left(\frac{3,5}{V1}\right) * \sqrt{P}$
Radiated HF disturbances in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 → $E1$ in V/m	$d = \left(\frac{3,5}{E1}\right) * \sqrt{P}$ for 80 MHz to 800 MHz
			$d = \left(\frac{7}{E1}\right) * \sqrt{P}$ for 800 MHz to 2.5 GHz
			where P is the maximum nominal output of the transmitter in watts (W) as stated by the manufacturer and d is the recommended safety distance in metres (m). The field strength of stationary radio transmitters as determined by on-site testing[a] should at all frequencies be less than the conformance level[b]. Interference may occur in the vicinity of devices that bear this symbol. 

Note 1 At 80 MHz and 800 MHz the higher frequency range applies.

Note 2 These guidelines may not be applicable in all cases. The propagation of electromagnetic fields is affected by the absorption and reflection of buildings, objects and people.

[a] It is not theoretically possible to determine precisely in advance the field strength of stationary transmitters such as the base stations of radio telephones and mobile terrestrial radio services, amateur radio stations, AM and FM radio transmitters and television transmitters. It is advisable to carry out on-site testing to establish the electromagnetic environment arising from stationary HF transmitters. If the field strength at the location of the radio module is found to exceed the above conformance level, the performance of the radio module at that location should be monitored. If unusual aspects of performance are observed, it may be necessary to take additional measures, such as changing the orientation or the location of the radio module.

[b] Above the frequency range of 150 kHz to 80 MHz the field strength should be less than [V1] V/m.

4.2.3 Recommended safety distances

The radio modules are intended for use in an electromagnetic environment in which HF disturbances are monitored. The client or user of the radio module can help to avoid electromagnetic interference by observing the minimum distances between portable or mobile HF telecommunication devices (transmitters) and the radio modules – depending on the output of the communication device – as given below.

Recommended safety distances between portable and mobile HF telecommunication devices and the radio modules			
Nominal output of the transmitter W	**Safety distance depending on transmitter frequency m**		
	150 kHz to 80 MHz $d = \left(\frac{3,5}{V1}\right) * \sqrt{P}$	**80 MHz to 800 MHz** $d = \left(\frac{3,5}{E1}\right) * \sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left(\frac{7}{E1}\right) * \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
If the maximum nominal output of the transmitter is not shown in the above table, the distance can be calculated by using the formula in the relevant column, where P is the maximum nominal output of the transmitter in watts as stated by the manufacturer of the transmitter.			
Note 1	At 80 MHz and 800 MHz the higher frequency range applies.		
Note 2	These guidelines may not be applicable in all cases. The propagation of electromagnetic fields is affected by the absorption and reflection of buildings, objects and people.		

4.3 Cleaning and maintenance

Cleaning:

All sensors, with the exception of the vaginal and anal electrodes, should only be cleaned with a soft cloth moistened with alcohol. **During cleaning the sensors must be unplugged from the radio module.** The sensors and their fixings (hook-and-loop straps, headband) should be cleaned as necessary or disposed or as residual waste.

The EEG gold cup electrodes should be cleaned with a mild detergent. The conductive paste will be more easily removed if they are cleaned immediately after use (the paste hardens and dries quickly).

The vaginal and anal electrodes should be cleaned as described in their instructions.

Only mild cleaning agents applied with a cleaning cloth should be used to clean the radio modules. To avoid fluids penetrating the casing of the modules, never apply cleaning agents direct to the module.

Maintenance (see also Section 4.7):

Maintenance, repairs and alterations must be carried out in accordance with the Medical Devices Act.

Alterations and repairs carried out by unauthorized companies invalidate the manufacturer's warranty.

All faulty parts must be replaced with original spares.

Wiring diagrams, parts lists and descriptions can be made available upon request to suitably trained maintenance technicians.

The radio modules contain a Li-polymer battery that has a life of approximately 3 years, depending on frequency of use. The battery can only be changed by the manufacturer, who will recalibrate the radio module at the same time.

4.4 Accessories

IMPORTANT!

All accessories must bear the CE mark and/or be supplied through SCHUHFRIED GmbH.

4.4.1 Basic accessories

Manual
Mains cord: AC Adapter TR30RAM050 from Cincon Electronics Co. Ltd.
Charger: TBSn – xxxx
Radio pyramid: TBPn-xxxx

4.4.2 Approved accessories

Input	Description	Manufacturer
EDA, TEMP, PULS	Multi-sensor	SCHUHFRIED GmbH
PULS	Pulse sensor (reflex sensor)	SCHUHFRIED GmbH
	Ear pulse sensor	Nonin Medical Inc.
TEMP	Temperature sensor	SCHUHFRIED GmbH
EDA	EDA1...EDA sensor with gold electrode surfaces EDA2...EDA electrode cable for disposable electrodes	SCHUHFRIED GmbH
RESP	Respiration strap	SCHUHFRIED GmbH
EMG	EMG electrode cable with multi-clip	SCHUHFRIED GmbH
	Reference electrode cable	SCHUHFRIED GmbH
	VAG/REK electrode cable	SCHUHFRIED GmbH
	Anal electrode	NEEN HealthCare
	Vaginal electrode	NEEN HealthCare
	Pack of 60 disposable electrodes 2223	3M Health Care
EEG	EEG electrode cable with multi-clip	SCHUHFRIED GmbH
	Pack of 60 disposable electrodes 2223	3M Health Care
	Gold cup electrode cable	SCHUHFRIED GmbH

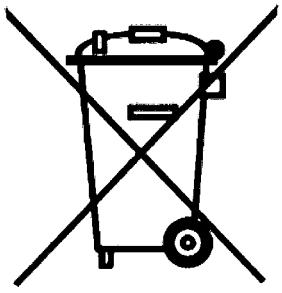
Consumables		
	Hook-and-loop straps	SCHUHFRIED GmbH
	Headband	SCHUHFRIED GmbH
	EEG electrode paste self-adhesive EC-2	Grass

4.5 Liability

The manufacturer or supplier can only be held responsible for matters affecting safety or performance of the device if

- assembly, upgrades, re-setting, alterations or repairs are carried out by persons authorized by him.
- the electrical installation at the place of use conforms to IEC or ÖVE EN 7 regulations.
- accessories manufactured by the supplier or authorized by him are used.
- the device is used in accordance with the manual, and
- the use of the radio modules conforms with the requirements of the Medical Devices Act.

4.6 Disposal



This symbol indicates that this device must be disposed of via a specific collection for electrical devices or returned to the manufacturer for disposal.

4.7 Servicing of the device

The system should be checked in accordance with ÖVE/ÖNORM E8751-1 (DIN VDE 0751-1) or generally recognized technological standards. The recommended service interval is two years (three years in the case of low-level usage).

During servicing the casing and identification plate must be checked to ensure that they are undamaged.

Accessories should be checked for defects.

The following should be measured:

- Alternative device leakage current at the charger
- Patient auxiliary currents of the EMG, EEG and EDA inputs.

The modules are calibrated and the accuracy of their readings tested when the battery is exchanged (i.e. every 2 – 3 years). No calibration is necessary during the intervening period.

4.8 CE conformity declaration

See the attached copy of the conformity declaration.

4.9 Technical data

Power supply via Li-polymer battery: ..... 3.7 V nominal, 550 mAh,
(short-circuit proof, protection against derating and overload) .....

Mode of operation: ..... continuous
Accuracy ..... better than ± 10%
External dimensions (w x h x d): 67x51x24mm
Weight 44g

Permitted environmental conditions:

Storage and transport temperature: ..... 0 to 50 °C
Operating temperature: ..... 10 to 36 °C
Relative atmospheric humidity: ..... 30 – 75 %

Bluetooth specification of the radio modules:

Transmission and reception frequency band ..... 2.402 to 2.480 GHz
Sensitivity of the receiver ..... -84 to -74 dBm
Bluetooth transmission power ..... Class 2
Transmitter output ..... -2 to 3 dBm

Bluetooth specification of the radio pyramid:

Transmission and reception frequency band ..... 2.000 to 2.4835 GHz
Signal modulation ..... FSK
Bluetooth transmission power ..... Class 1
Transmitter output ..... 0 dBm

PROTECTION RATING BF

CLASS IIA MEDICAL DEVICE

Available inputs for the radio modules EMG, MULTI and RESP:

Module	Input	Recorded parameters:	Time constants	Measuring range			Resolution	
			ms	From:	To:	Unit		
EMG	EMG1	EMG-1	250	0 ... 1000	15 ... 1000	µV µV	0.012 ... 0.07	µV µV
	EMG2	EMG-2	250	0	1000	µV	0.012-0.07	µV
EEG	EEG1	EEG-1	---	-100 ... -3200	+100 ... +3200	µV µV	0.012-0.07	µV
	EEG2	EEG-2	---	-100 ... -3200	+100 ... +3200	µV µV	0.012-0.07	µV
MULTI	EDA	SCL	500	0	50	µS	1	nS
		SCR	500	0	50	µS	1	nS
	TEMP	TEMP	---	10	40	°C	0.01	°C
	PULS	PULS	---	30	200	bpm	0.004	bpm
		BVP	xx	0	100	%	0.025	%
		PVA	xx	0	100	%	0.025	%
	MOT	MOT	50	0	20	m/s^2	0.05	m/s^2
RESP	RESP1	RESP-1	---	0	20	cm	0.2	mm
		RESPA-1	---	0	20	cm	0.2	mm
		RESPF	---	0	30	min^{-1}	0.02	min^{-1}
	RESP2	RESP-2	---	0	20	cm	0.2	mm
		RESPA-2	---	0	20	cm	0.2	mm
		RESPF	---	0	30	min^{-1}	0.02	min^{-1}

The "Resolution" column gives the resolution of the device.

SCHUHFRIED

Qualität durch Kompetenz

CE - Konformitätserklärung
CE – Declaration of Conformity

Produktspezifikation / *Product details*	
Produktbezeichnung *product name*	Biofeedback – System "Biofeedback 2000$^{x\text{-}pert}$" inkl. Software "Biofeedback 2000$^{x\text{-}pert}$" Vers. CB1023 *Biofeedback system "Biofeedback 2000$^{x\text{-}pert}$"* *Incl. Software "Biofeedback 2000$^{x\text{-}pert}$" Vers. CB1023*
Type *type*	TBM1 (EMG), TBR1 (RESP), TBU1 (MULTI), TBG1 (EEG)
Kompatibilität mit *Compatibility*	EDV-Anlage mit Trenntrafo gemäß EN 60601 oder EN 60601 taugliche EDV Anlage *EDP-system with isolation transf. Acc. To EN 60601* *or EDP-system which is capable to EN 60601*
Klassifizierung nach RL93/42/EWG, Anhang IX *Classification according to RL93/42/EEC, annex IX*	IIa nach Regel 10 *IIa per rule 10*
Klassifizierung nach RL99/5/EG, Anhang IV *Classification according to RL99/5/EC, annex IV*	Geräteklasse I *Device class I*

Konformitätsbewertung / *Assessment details*	
Benannte Stelle *Notified body*	*TÜV Östereich (0408)* *TÜV Austria (0408)*
Verfahren nach RL93/42/EWG *Procedure according to RL93/42/EEC*	Anhang II (vollständiges QM-System) *Annex II (complete QM-system)*
Verfahren nach RL99/5/EG *Procedure according to RL99/5/EC*	Anhang IV *Annex IV*

Angewandte Normen / *Used standards*	
Harmonisierte Normen *Harmonized standards*	ÖVE EN 60601-1 (A1+A2 eingearbeitet / *A1+A2 included*) +A12+A13/ 1996-03 EN 60601-1-2:2001+A1:2006 EN 60601-1-2: 2007 EN 60601-2-26: 2003 EN 60601-2-40: 1998 EN 14971: 2007 EN 60825-1+A11+A2: 2002 EN 300328-2 V1.7.1 EN 301489-17 V1.2.1 EN 50371: 2003

Wir erklären hiermit in alleiniger Verantwortung, daß die oben beschriebenen Produkte den Anforderungen der Richtlinien 93/42/EWG und 99/5/EG entsprechen.
Die Produkte werden mit dem CE-Kennzeichen und der Kennummer 0408 versehen.
We declare under sole responsibility that the products described above are in compliance with directive 93/42/EEC and 99/5/EC.
The Products are CE-marked with the number 0408.

Unterschrift / *Signature*

Mödling, 11.12.2008

Datum der Ausstellung / *Date of issue*

Geschäftsführer / *General Manager*

TBFB039F.doc

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TÜV Österreich, vom österreichischen Bundesministerium für wirtschaftliche Angelegenheiten akkreditierte Prüf-, Überwachungs- und Zertifizierungsstelle
TÜV Austria testing, inspection and certification body accredited by the Austrian Ministry for Economic Affairs

TÜV ÖSTERREICH

Zertifikat - Certificate

Nr.: TÜV-A-MT-1/07/E032R2

Konformitätsbescheinigung des Qualitätsmanagementsystems
Quality management system approval certificate

Unternehmen: *Company:*	SCHUHFRIED GmbH 2340 Mödling, Hyrtlstrasse 45, Austria
Geltungsbereich: *Scope:*	Forschung, Entwicklung, Fertigung, Verlag und Vertrieb von computergestützter psychologischer Diagnostik und kognitiver Rehabilitation Entwicklung, Produktion und Vertrieb von medizinischen elektrischen Geräten, im speziellen Biofeedback- und Reizstromgeräte *Research, development, production, editing and sales of computer assisted psychological diagnostics and cognitive rehabilitation* *Development, production and sales of electrical medical devices, in particular biofeedback- and stimulant current devices*
Normen: *Standards:*	EN ISO 13485:2003 Qualitätsmanagementsystem Medizinprodukte *Quality management system Medical devices*
Bericht(e): *Report(s):*	06MT0672LUS

Hiermit bescheinigt der TÜV Österreich, daß das oben angeführte Unternehmen für den angeführten Geltungsbereich ein Qualitätsmanagement eingeführt hat und anwendet. Durch ein Audit wurde der Nachweis erbracht, daß die Forderungen der Nachweis-Normen erfüllt sind.
TUV Austria certifies that the above mentioned manufacturer has introduced and uses a quality management system for the led scope. By an audit the proof was furnished that the demands of the standards are fulfilled.

07.01.2007	Dipl.-Ing. Dr. Robert Messner	06.01.2012
Datum der Ausstellung *Date of issue*	Zertifizierungsbeauftragter *Certification representative*	Ende der Gültigkeit *End of validity*

Erstausstellung/ *First issue:* 16.02.2004

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TÜV Austria testing, inspection and certification body accredited by the Austrian Ministry for Economic Affairs

TÜV ÖSTERREICH

Zertifikat - Certificate

Nr.: TÜV-A-MT-1/07/Q030R1

EG-Konformitätsbescheinigung des vollständigen Qualitätssicherungssystems (Anhang II der Richtlinie 93/42/EWG über Medizinprodukte)
Full quality assurance system approval certificate (Annex II of the directive 93/42/EEC on medical devices)

Produkt: *Product:*	detailliert im Anhang aufgeführt *for details see annex*
Produktkategorie: *Product category:*	Stimulatoren (13-762) *stimulators*
	Biofeedback-Systeme (10-396) *Biofeedback systems*
Antragsteller: *Applicant:*	SCHUHFRIED GmbH 2340 Mödling, Hyrtlstrasse 45, Austria
Hersteller: *Manufacturer:*	SCHUHFRIED GmbH 2340 Mödling, Hyrtlstrasse 45, Austria
Bericht(e): *Report(s):*	06MT0672LUS

Hiermit bescheinigt der TÜV Österreich als benannte Stelle (ID-Nr. 0408), dass das vollständige Qualitätssicherungssystem des/der oben angeführten Produktes/Produktkategorie überprüft wurde und den Anforderungen nach Anhang II (Abschnitt 3) der Richtlinie 93/42/EWG über Medizinprodukte entspricht.
TUV Austria as notified body (ID-Nr. 0408) certifies that the full quality assurance system of the above mentioned product/product category has been examined and meets the relevant requirements of annex II (section 3) of the directive 93/42/EEC on medical devices.

CE 0408

Technischer Überwachungs-Verein TÜV ÖSTERREICH Österreich

07.01.2007	Dipl.-Ing. Dr. Robert Messner	06.01.2012
Datum der Ausstellung *Date of issue*	Zertifizierungsbeauftragter *Certification representative*	Ende der Gültigkeit *End of validity*

Erstausstellung/ *First issue:* 07.01.2002