



Manual



Statik-Relax[®]-basic
Statik-Relax[®]-science
V 2.xx / February 2014

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Manufacturer:



THUMEDI GmbH & Co. KG
Straße der Freundschaft 68B
09419 Thum-Jahnsbach
Germany

Scope of delivery

1-Channel-SEMG-measurement device Statik-Relax®
PC-Software (Microsoft® Windows® 2000, XP, Vista®, 7, 10 – 32 or 64 Bit)
Manual Statik-Relax®-basic/-science
Quick Reference Statik-Relax®
2 Batteries type AAA
20 Electrodes (Covidien H92SG or H93SG)



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Critical Safety instructions

Appropriated expandable materials:

ECG-electrodes (Ag/AgCl, Hydrogel, Foam) by Covidien “31.1925.21 – H92SG” (48*34mm) or “31.1935.21 – H93SG” (35*26mm).



It is only allowed to open the enclosure of the Statik-Relax[®] at the battery compartment.



Don't bring the device in contact with liquids and protect it against humidity. If there are any liquids or solid bodies inside the device, switch the device immediately off and let it check by the manufacturer!

Only use type AAA batteries or accumulators (see “Usable accumulators”)!
Never connect a power supply to the battery contacts, because in this case is danger of life for the electrical connected person!

It is not allowed to use the Statik-Relax[®] at the same time with electrical therapy devices (e.g. HF-Chirurgical devices, muscle stimulation devices, short-wave therapy devices, defibrillators)! It is not allowed to use the Statik-Relax[®] for supervising of vital functions!

Users of the Statik-Relax[®] must be at least 14years old and must have normal cognitive abilities.

It is only allowed to apply surface electrodes for conducting the electrical signals on healthy skin. Normally the included surface electrodes (foam or patch Ag/AgCl- electrodes) irritate the skin marginal. Users with a sensitive skin or with stronger sweating can feel a slight itching or the skin gets a slight redness. These symptoms should be gone after a few hours after removal of the electrodes and skin cleaning. Take medical advice, if there are stronger symptoms (strong redness of the skin, extreme itching)! If necessary, experiment with different electrodes for longer application durations.

The Statik-Relax[®] is for externally use only!

A nonobservance of these safety instructions can lead to a endangering of the health of the subject and examiner.

Supplementary safety instructions for the use of the Statik-Relax

Protect the device against dust, humidity, strong staining and condensing moistness!

Condensing moistness can occur, when the device was carried or stored in a cold environment and is brought to a room with warmer air. There is also condensate inside the device, if condensate on the surface occurs. By no means use the device, because a connected user can be endangered through electric current! Let the device rest at least one hour in a warm and good-vented environment. A dry surface does not mean a dry inside of the device!

Regard that an incorrect application (primarily wrong muscle, not along the muscle fibre, too high connection resistance) leads to incorrect measurements and corresponding with that to misinterpretations.

Observe during the interpretation of biofeedback data, that you analyse actual received data (green communication check).

Regard the correct assignment of stored data and subject in the database if you use the science version. An incorrect assignment leads normally to not to the subject adapted strain analyses.

The Statik-Relax[®]-science is only dedicated for the determination of muscular stress and strain of an individual under real working or laboratory conditions in terms of occupational scientific analyses. As a result you can evaluate the individual working intensity and you can create individually adapted arrangements regarding working place, working tools and flow of work. Regard that not the health condition of the subject is evaluated or therapie decisions are made, but the activity and the working environment is judged and these are adapted to the subject.

Please report each accident, damage and any thread which could be provoked by the Statik-Relax[®] to the THUMEDI GmbH & Co. KG immediately!

Supplementary safety instructions for the change of batterie or accumulator

Do not use metal objects to remove the battery or accumulator, because this can cause a short-circuit which can lead to the destruction of the accumulators and the device.

Observe the polarity of the batteries and accumulators
(destruction possible! No case of warranty!)

The signal lamp flashes yellow and a signal sounds twice, if the remaining working time of the batteries or accumulators is less than 5 to 30 minutes. The device switches off automatically, if the batterie or accumulator is empty.

Remove the empty batterie or accumulator from the device!

Supplementary safety instructions for storage and disposal



Remove batteries or accumulators before you store or dispose the device. Exhausted batteries or accumulators are hazardous waste!

Don't dispose the device in domestic waste. It is regulated that electrical and electronical devices has to be recycled. The THUMEDI GmbH & Co. KG does this for its products. If you want to recycle a Statik-Relax[®], send an information email to entsorgung@thumedi.de and send the device and its accessory to:

THUMEDI GmbH & Co. KG
- Altgeräteentsorgung -
Straße der Freundschaft 68b
09419 Thum-Jahnsbach
Germany

If you have any questions relating to these safety instructions ask the THUMEDI GmbH & Co. KG by letter or email.



In order to not endanger the user or the examiner you are not allowed to use the Statik-Relax[®], if you haven't understood all safety instructions. A nonobservance of these safety instructions can lead to a endangering of the health of the subject and examiner.

Type plate



Signs and Symbols



manufacturer



observe manual and safety instructions



medical device type BF (body-float)



serial number of the device

Hints of the locations of use

The product is designed for the use at the following locations:

- Residential buildings / living space like houses, accommodation, rooms and so on
- Sales area like stores, warehouses...
- Office rooms like administration, banks...
- Social areas like cinemas, restaurants...
- Small business rooms like workshops, laboratories, service centres...

There are some problems possible with not sufficient noise immunity in more disturbed environments like typical industry areas. This can lead to malfunctions and measurement disturbances in rare cases.

Environmental conditions

For the use of the Statik-Relax[®]:



Protect the device against strong solar irradiation, strong electromagnetic fields and electrostatic discharges, against dust, humidity and strong staining!



Environmental temperature 0 to +40°C



relative humidity >30 .. <75%, not condensing!

Cleaning

- Only clean with a dry or wettish (not wet) cloth!
- Don't use solvents or abrasives!

Power supply

Before you can use the Statik-Relax, You need to put in batteries or accumulators in the battery compartment of the device.



! Observe polarity !

We recommend you to use NiCd (Nickel-Cadmium) or even better NiMH- (Nickel-metal-hydride) – 1.2V Micro-Accumulators (type AAA). Accumulators don't tolerate deep discharge! (see section "Protection of the device") You can also use 1.5V alkaline or lithium batteries, but this is not efficient, if you use the device often. Don't use carbon-zinc batteries.

The operation time of the Statik-Relax[®] depends strongly on an active Bluetooth[®]-connection.

Operation time: see attachment no. 1

Observe the contacts when putting in the batteries or accumulators. If these are oxidised, remove the oxide film, because this increases the contact resistance and this can lead to a complete loss of function of the Statik-Relax[®].

Charge of the accumulators

Please consider the manual of the used charging device.

Functionality and field of application

It is not allowed to use the Statik-Relax[®] for supervising of vital functions! It is not allowed to use the Statik-Relax[®] at the same time with electrical therapy devices (e.g. HF-Chirurgical devices, muscle stimulation devices, short-wave therapy devices)! The device is not protected against discharges of defibrillators. The Statik-Relax[®]-science is only dedicated for the determination of muscular stress and strain of an individual under real working or laboratory conditions in terms of occupational scientific analyses. As a result you can evaluate the individual working intensity and you can create individually adapted arrangements regarding working place, working tools and flow of work. Regard that not the health condition of the subject is evaluated or therapie decisions are made, but the activity and the working environment is judged and these are adapted to the subject.

The Statik-Relax[®] is a one-channel surface electromyographic biofeedback device and is used for the prevention of muscular hardenings and painful effects in the forearm generated through fast repetitive movements (RSI-Syndrome). Both effects are caused or alleviated by certain muscular strains. Long lasting steady (static) muscular tensions leads usually to hardenings. Relaxing respectively alternating (dynamic) strains counteract these hardenings. In the area of the RSI-Syndrome the fast repetitive movements of the fingers like typing or mouse use are the hurtful strains. Slow movements respectively resting counteract the effects of the RSI-Syndrome.

The surface electromyography (SEMG) allows determining in which way the state of the measured muscle changes. It is possible to recognise if the muscle is tensed respectively relaxed or if it gets tired or recovers. The Statik-Relax[®] also classifies the SEMG-signal in the domains "statically" and "fast dynamical", "slow dynamical" and "relaxing". By means of this measurement method the device assigns the actual strain to the described "hurtful" (statical, fast dynamical) or "beneficial" (slow dynamical, relaxing) strains. Corresponding to the configuration it calculates the risk of the developing of muscular hardenings or the RSI syndrome. This risk is used as a biofeedback parameter and the device warns the user against the described "hurtful" strains. That's why the Statik-Relax[®] is especially dedicated to people, who works mainly at the computer. The device can observe the muscular behaviour of the user the whole working day. It warns the user before painful hardenings or effects of the RSI-Syndrome occur. It also can assist the user with ergonomic changes of the working place. The display of the actual muscular activation allows a direct feedback of the results of the changes at the working place and working behaviour. Additionally the science device is capable to store the values of the risk internally. These can be transferred to the computer and stored in a database after the measurement. You can find more information about the mode of operation and the scientific background on the homepage of the THUMEDI GmbH & Co. KG (section "Downloads").

Attention: The measure of the risk is always zero after a device start. The Statik-Relax[®] assumes that there was no previous strains for the muscle at begin of the measurement. This means that the measurement has to be started at begin of the observed working task. If you interrupted the measurement for just a short period, e.g. for changing the accumulator, you can continue this measurement, if you start these by the computer, PDA or SR-Display.

Controls of the Statik-Relax®



Signal lamp

Button

Measuring with the Statik-Relax[®]

The button functions

The button allows you to use all the functions of the Statik-Relax[®]. The device responds with a short acknowledge sound to each press of the button. There are different possibilities depending on the situation and duration of the button press:

Long button press (longer than 3 seconds)	switches the device on or off (three tone melody with rising or falling tone sequence)
Short button press	
<i>During start mode (direct after start, before calibration)</i>	starts the calibration (calibration start melody sounds)
<i>During measurement mode (after successful calibration)</i>	switches through the sound volume steps off – low – loud → a short button acknowledge sound and after that a long sound with the chosen sound volume level (at volume “off” no long sound)

The sound and light signals

The Statik-Relax[®] uses different tone and light signals according to the situation:

Sound signals		
During start mode (direct after start, before calibration)	Used configuration	
	Measurement of the hardening risk	Melody low-low-high
	Measurement of the RSI risk	Melody high-high-low
	Invalid configuration	Melody high-high-high
	Calibration	
	Calibration start / finish	Sequence short-short-long
	Discarded calibration	3 x 3 short tones

Standard signals	Button acknowledge	short tone
	Biofeedback warning	short tone (every 20s)
	Biofeedback alarm	two short tones (every 20s)
	Change of sound volume	a short button acknowledge sound and after that a long sound with the chosen sound volume level (at volume "off" no long sound)
	Overmodulation of EMG signal or loose electrodes	3 short tones
	Auto power down (accu / battery at device start empty)	3 x 3 short tones, followed by a three tone melody with falling tone sequence
	remaining working time of the batteries or accumulators is less than 5 to 30 minutes	3 x 3 short tones (combined with yellow light signal)
	Recognised errors of the internal memory	3 x 3 short tones
	Response of communication check through PC	two short tones
	Data storage full (only science version)	3 x 2 short tones
Light signals (every 10 seconds)		
Colour	Full capacity of Accu / Battery	green
	remaining working time of the batteries or accumulators is less than 5 to 30 minutes	yellow
Occurrence	Configuration for measuring the hardening risk	one flash (every 10s)
	Configuration for measuring the RSI risk	two flashes (every 10s)

Preparing the PC for the first connection with the Statik-Relax®

You need to install a serial Bluetooth®-connection between the PC and the device before the first use of the Statik-Relax®. You find the description about this in the documentation of the Bluetooth®-hardware of your PC. Press the button longer than three seconds to switch the Statik-Relax® on. A melody with a rinsing tone sequence sounds.

The Bluetooth®-key for the Statik-Relax® is: 0815

Initial launch

You need to configure the Statik-Relax[®] for your application before you can use the device. In order to do that you need to start the PC-program. This leads through the configuration of the device. If you have done this once, this configuration is loaded at every start and the Statik-Relax[®] can be used without a PC connection.

Start of the measurement

You can use the Statik-Relax[®] with or without a PC connection.

Attention: The measure of the risk is always zero after a device start. The Statik-Relax[®] assumes that there was no previous strains for the muscle at begin of the measurement. This means that the measurement has to be started at begin of the observed working task.

If you start the measurement by the computer you have the possibility to continue the previous measurement. The Statik-Relax[®] stores the last calculated risk continuously. If you switch off the device for just a short period (< 30 minutes, e.g. for accumulator changing), it is possible with this function to start the new measurement with the risk level like before switching off the device. Regard, that the device can't recognise how long it was switched off. You have to observe by yourself that not too much time elapsed between switching off and on the device.

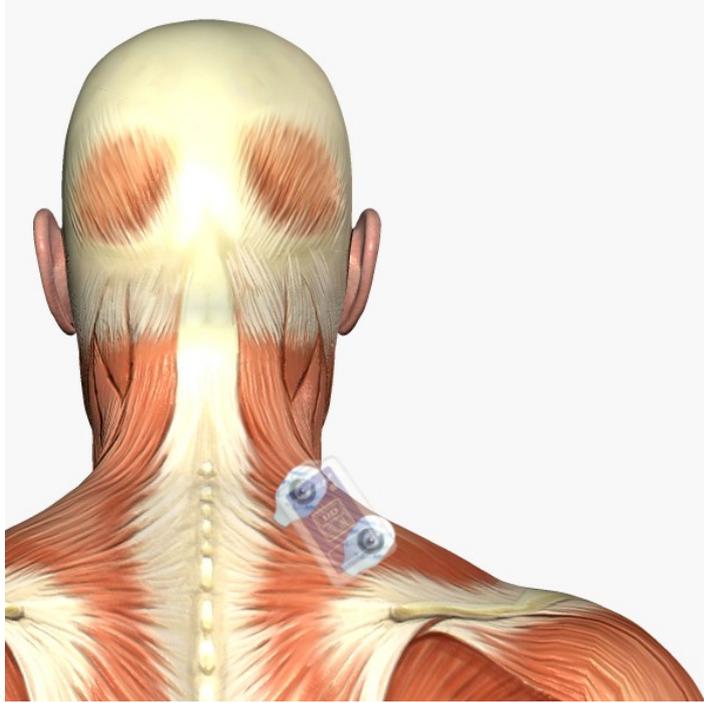
During the device start the Statik-Relax[®] checks the internal memory. If this is defective and the automatic repair fails, the device will switch off automatically. Contact the manufacturer for repairing the device.

It also checks the voltage of the battery / accumulator. If the energy storage is already discharged (less than one third energy content left) the Statik-Relax[®] will also switch off automatically.

Start without a PC connection

Clean the skin on your shoulder (hardenings) or on your forearm (RSI) with a clammy towel (rub effectual at least 10 seconds) or use abrasive skin preparation paste (e.g. „Every – Abrasive skin cleaning paste“ by Covidien Ref.-Nr. 3550000160). If necessary remove adhesive leftover from previous measurements. Snap the electrodes into the snap-fasteners at the bottom side of the device (The THUMEDI GmbH & Co. KG recommends the ECG-electrodes by Covidien 31.1935.21 – H 93 SG Arbo or by Golmed G 30 SG). Remove the protection film and apply the Statik-Relax[®] as shown on the pictures on the dedicated muscle.



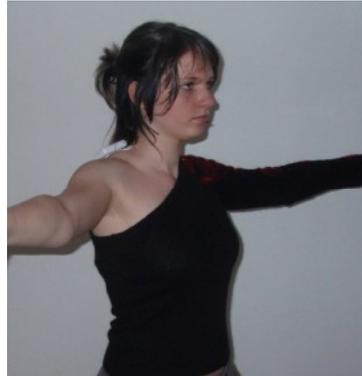


Press the button longer than three seconds until the device starts. A melody with a rising tone sequence sounds. The Statik-Relax[®] is now in the starting mode and indicates the preset configuration with a tone sequence:

low – low – high à measurement of hardening risk
high – high - low à measurement of RSI risk

Now you need to calibrate the Statik-Relax[®]. There is a special calibration posture for each application.

- **Measurement of hardening risk:**
Stand up and let both shoulders **hang relaxed** and stretch out your arms horizontal, slightly forward. Hold your head straight ahead.



- **Measurement of RSI risk:**
Put your arm relaxed on a table and close your hand. Pull the closed hand backwards **slightly**.



Now start the calibration with a short button press and adopt the calibration posture immediately. The device starts the calibration procedure (lasts 10 seconds) and frames these with two-tone sequences – short, short, long. Hold the calibration posture the whole time between the signals! The device checks the validity of the calibration results. If the quality is not sufficient, because of bad positioning of the Statik-Relax[®] or bad skin contact, the device signals the measurement abort with repeated high tones. You can rerun the calibration with a short button press. The Statik-Relax[®] can't proof, if you adopted the calibration posture in the described way. A bad performed calibrations leads to false measurements. If you think you haven't done a correct calibration, switch off the device and restart the measurement. If the device recognised the calibration as sufficient, it switches automatically to the measurement mode.

Start with a PC connection

With the start of the Basic-PC-Program a small tutorial begins, which supports you with the application and calibration of the Statik-Relax[®] as described in “Start without a PC connection”.

You can start the tutorial with a click on the button “Prepare / start measurement” if the program is already running.

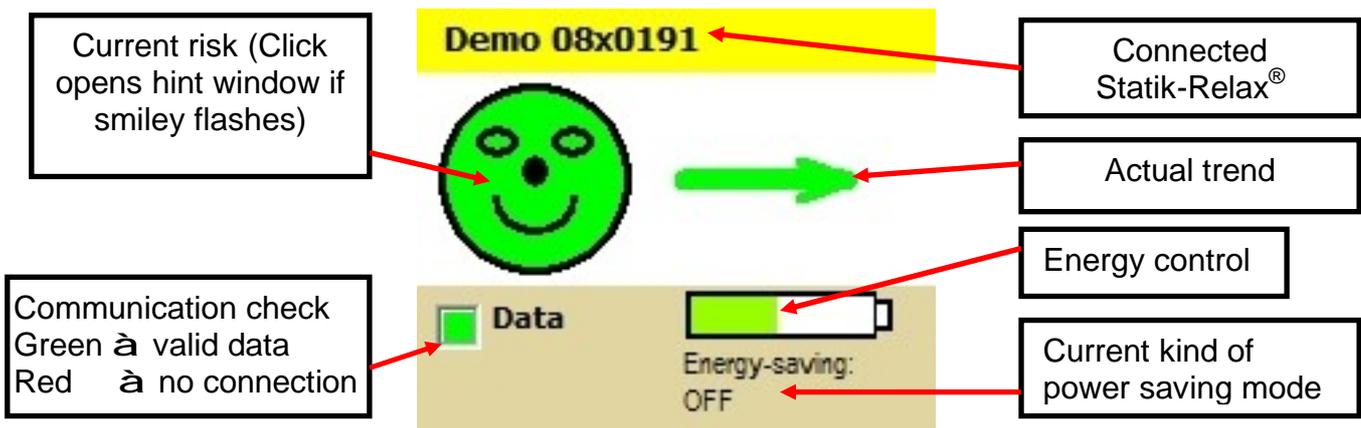
If you start a measurement of a Statik-Relax[®]-science device with activated data storage, you can't reconfigure this with the Basic-software for safety reasons. So you can't change the configuration of the measurement task or switch off the data storage by accident. You will get the help for applying and calibration as supplied before.

Specials at the start of the Statik-Relax[®]-science

The Statik-Relax[®]-science is capable to store the calculated values of the hardening / RSI risk internally. This data storage function is controlled by the configuration via the Statik-Relax[®]-science computer software. If a device is configured with active data storage, every start of the device – whether with or without computer program – will start the data storage. If you start the measurement via the computer program (both basic and science), the start time will be transferred to the device and the measurement can be assigned to this point of time. No time will be assigned, if the measurement is started without the computer software. You can set a starting time after you transferred the stored data to the PC. The Statik-Relax[®]-science can store up to 40 measurements with a cumulative measurement time of up to 141 hours. A 10 minute mean value is stored every 10 minutes. If at a start of a new measurement the preceding stored measurement is shorter than 30 minutes, the preceding measurement will be overwritten.

Biofeedback during the measurement

The Statik-Relax[®] shows the user the calculated measures of the hardening or RSI risk in different ways. Exceeds the risk the limit of 25% a short warning tone sounds as acoustic biofeedback. Exceeds the risk the limit of 50% an alarm with two short tone sounds. There are more biofeedback possibilities, if the Statik-Relax[®] is connected to a PC. The biofeedback window shows the risk in Smiley form.



The Smiley changes his colour and appearance with the actual risk. He is smiling and has a green colour at 0% risk. With rising risk the colour changes to yellow (25% risk) and towards red (50% risk). Moreover the mood of the Smiley sinks. Additionally the actual trend of the risk is shown. It shows, how the actual strain affects the risk. A red upwards pointing arrow indicates the increase, a green downwards pointing arrow indicates the decrease of the risk. A yellow horizontal arrow shows a strain situation neutral to the actual risk.

Attention: A hurtful strain like static activation of the shoulder muscles in case of hardenings or fast dynamic movements in case of RSI doesn't affect the trend immediately. These have to be long lasting to increase the risk. They are only hurtful and can be recognised in the trend, if they appear for a certain time.

The PC-program monitors the progress of the risk in the background. It warns the user in intervals of 10 to 30 minutes according to the risk, if the risk increases continuously. These warnings are shown through a blinking Smiley and a sound. A click on the Smiley opens a window with some hints to lower the strain situation. You can also switch off these warnings for 30 minutes (e.g. if you don't want do get disturbed at focussed work).

The Statik-Relax[®] has an increased energy demand, if a Bluetooth[®] connection is established. This leads to a significant shortening of the operation time. The computer program, PDA and SR-Display provides an "energy save" and "automatic energy save" functionality. If you activate the "energy save", the computer program, PDA and SR-Display requires every 10 minutes a risk value from the Statik-Relax[®],

visualises it via the smiley and adds the Value to the diagram. In the meantime the Bluetooth® connection is inactivated. During this time no trend or muscular activation can be shown! The “automatic energy saving” mode starts in normale Operation state and change to the “energy saving” mode after 10 minutes by itself, if the current risk is below 25% and returns automatically to normal mode if current risk rises above 25%.

Additionally you can observe the chronological progress of the risk and of the actual muscular activation at the control window.

End of the measurement

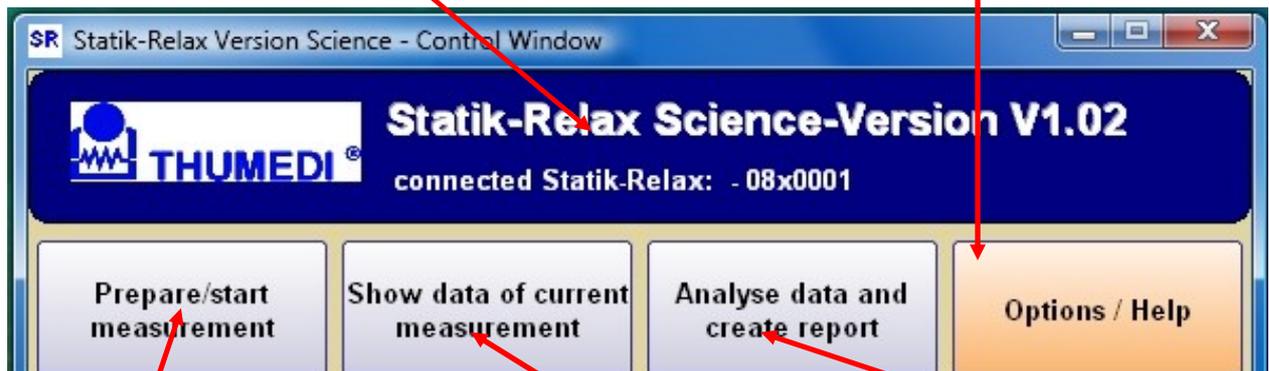
Press the button longer than three seconds to switch the Statik-Relax® off. A melody with a falling tone sequence sounds. Close the PC-program if necessary.

The PC-program

The Statik-Relax[®]-PC-program increases the functionality of the device. The functions are ordered in four tasks. You can start each task by clicking on the buttons at the top area. If you are already executing a task, a click on a button restarts the task or aborts the processed task and starts the chosen. The executed task is red highlighted. The F1-key shows this manual.

A double click starts the communication test. The connected device answers with two short tones. You can find the connected device easily in that way, if you are using several devices.

This task leads you to the Options Window. There you can change the program language, open the manual, get in contact with the THUMEDI or activate additional software modules. You can get additional information about your device by clicking the button "Statik-Relax-Info".

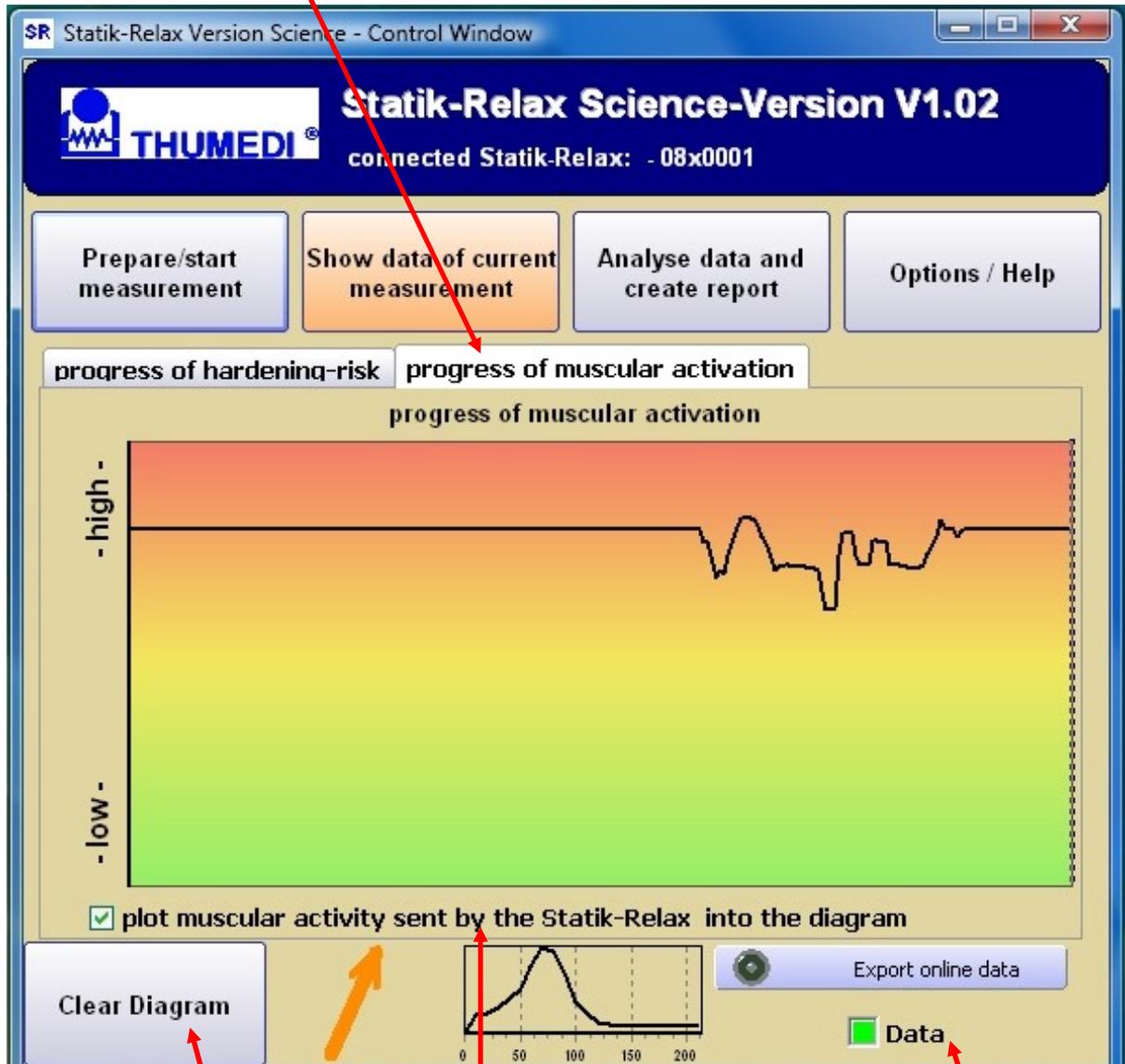


This task supports you with the start of a measurement as described in "Start with a PC connection" – from the application to the calibration of the device

This task allows you to show the chronological progress of the hardening / RSI risk. You can also observe the actual muscular activation. This also opens the Biofeedback-Window.

This task allows you to create a report including the measured data shown in the diagrams and also to save and print this report.

Selection of the shown diagram



Deletes the content of the shown diagram

Checked
à measures of the actual muscular activation are plotted into the diagram

Communication check
Green à valid data
Red à no connection

Important hints:

The measure of the risk is always zero after a device start. The Statik-Relax[®] assumes that there was no previous strains for the muscle at begin of the measurement. This means that the measurement has to be started at begin of the observed working task.

If you start the measurement by the computer you have the possibility to continue the previous measurement. The Statik-Relax[®] stores the last calculated risk continuously. If you switch off the device for just a short period (< 30 minutes, e.g. for accumulator changing), it is possible with this function to start the new measurement with the risk level like before switching off the device. Regard, that the device can't recognise how long it was switched off. You have to observe by yourself that not too much time elapsed between switching off and on the device.

The trend arrow in the biofeedback window is updated every second. The measures of the hardening or RSI risk are sent every 10 seconds. The measures of the actual muscular activation is plotted four times a second.

If the Statik-Relax[®] is connected to the PC and it is in measurement mode, the chronological progress of the risk is plotted constantly in the corresponding diagram, even if this is not visible. The measures of the actual muscular activation are only plotted in the diagram, if this diagram is shown and the plotting is activated. This is to save energy. As less the Statik-Relax[®] sends data as less energy is necessary and the operation time increases. If you have activated the energy save function one risk value is requested from the Statik-Relax[®] and visualised via the smiley and diagram every 10 minutes. The trend and the chronological progress of the actual muscular activation can't be shown. If the "automatic energy saving" mode is activated, the device will change to "energy saving" mode after 10 minutes by itself. The dependence for these action is that the risk value is lower than 25% and no activation is done over a time of 10 minutes in the program (no change of settings and/ or no change of the diagram).

If the risk value is above 25% the "energy saving" mode will be turned off. Now the trend arrow and the risk values are shown again and will be updated continuously. If the user changes its muscular activity and the risk will go below 25% the program will change to "energy saving" mode by itself again. This should be a good compromise between detecting dangers and optimal operation time.

The Window[®] system software reacts sensitive in combination with Bluetooth[®]-devices. Fast activation / deactivation or fast connection and disconnection of Bluetooth[®] devices can lead to heavy interferences with the system software. This can also lead to disturbances in the Statik-Relax[®]-PC-program. Activate Your Bluetooth[®] hardware before you start the PC-program and don't deactivate it until the PC-program is closed. Also avoid often and fast connection tries with the Statik-Relax[®]. Close the PC-program and deactivate the Bluetooth[®] hardware, if there are problems during the connection to the Statik-Relax[®]. Activate the Bluetooth[®] device again and start the PC-program. It could be necessary to delete and recreate the virtual Com-port in rare cases.

The THUMEDI supplies different software modules for the Statik-Relax[®], like the science-module, which you can purchase. These software modules can be activated

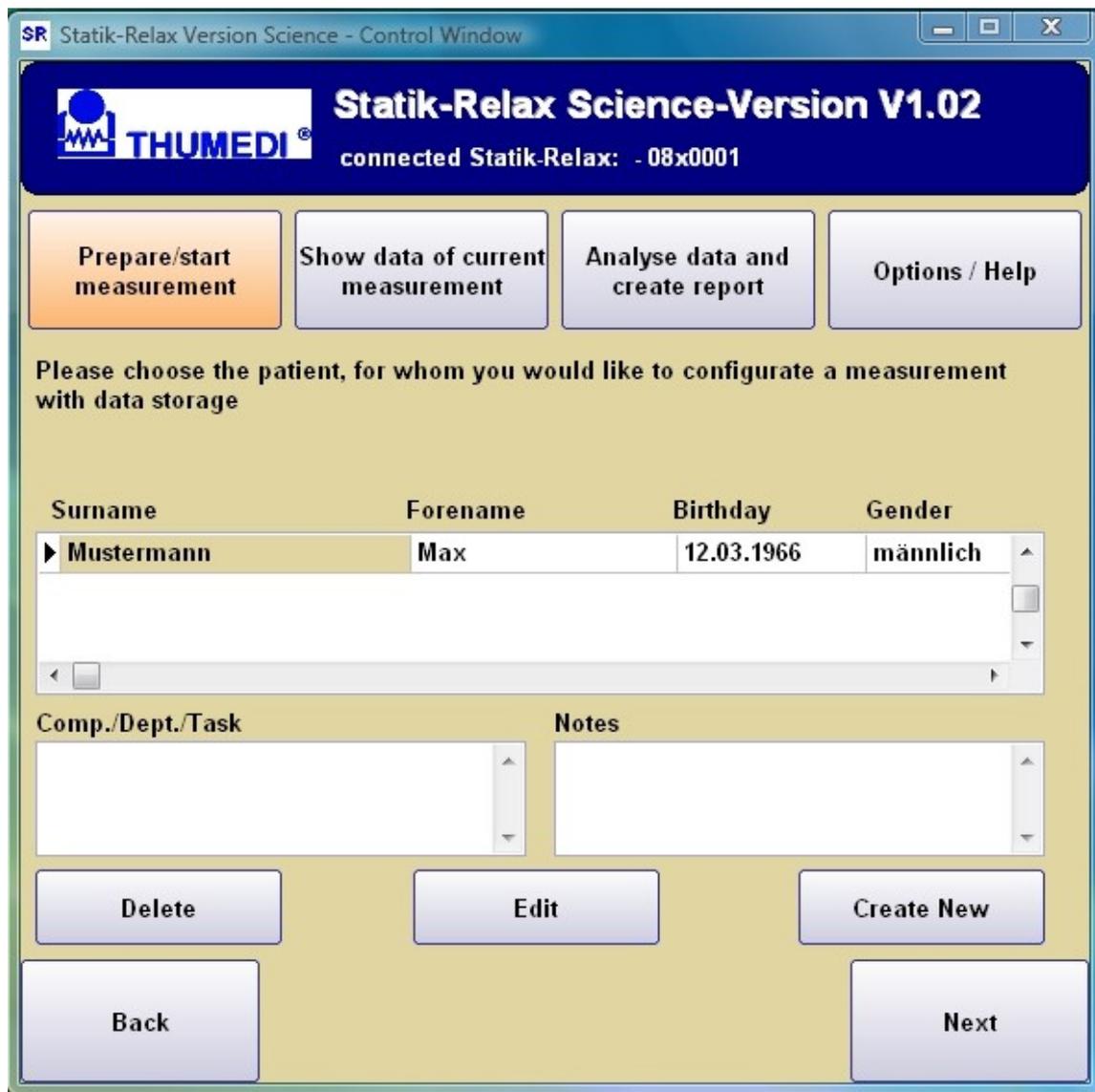
subsequently. You can find the possibility to perform this activation on the options window. The Statik-Relax provides you an "Activation-Request-Code". You can purchase an Activation-Code with this and the serial number of the device.

Only Statik-Relax®-science

The Statik-Relax®-science software guides you through the different tasks like the basic version. But there are a lot more functions included. The main differences are the subject database, the ability of the internal data store of the risk values in the Statik-Relax® and the enhanced report creation. Of course you can also configurate and use the Statik-Relax®-basic.

Configuration of the device

The difference to the basic version is that you can configurate a measurement with the internal data storing. Thereby the measurement is assigned to a special subject in the database. So it is assured that the stored transferred data from the device to the computer can be assigned to the correct subject in the database (Provided that the measurements belong to the accordant subject.).



After a successful configuration you can start the measurement or you can finish the configuration without starting the measurement.

Reading out the stored data

You can transfer the stored data from the Statik-Relax® to the computer by clicking the button >>Analyse data and create report<<. The program shows you to which subject the measurement belongs. If the data belongs to another subject contrary to the configuration, you can assign the data manually.

During the next step you can choose which measurement shall be transferred to the database, you can assign a start time manually if needed and create remarks for each measurement.

Prepare/start measurement Show data of current measurement **Analyse data and create report** Options / Help

Now choose the measurements, which you want to store into the database. If there are measurements without a saved starting time, you can supplement these now

1. Measurement 06.05.2008 20:19:00

24.02.2008 ▾

__ : __

Back Next

Creation of diagrams and reports

You have the possibility to create two different types of reports. You can create a report with the chronological progress of the risk and the actual muscular activation, similar to the basic version.

Prepare/start measurement Show data of current measurement **Analyse data and create report** Options / Help

You can now analyse the data stored in the database or fill the report with the biofeedback diagrams of the PC-Program.

Report with the biofeedback diagrams of the PC-Program

report with the measurement data from the data base

Back Next

You can also create different diagrams with the measurements stored in the database. These diagrams can be arranged to a report.

Prepare/start measurement Show data of current measurement Analyse data and create report Options / Help

Choose the measurements, which you want to show in the diagram.

Mustermann Max 23.03.1966 männlich

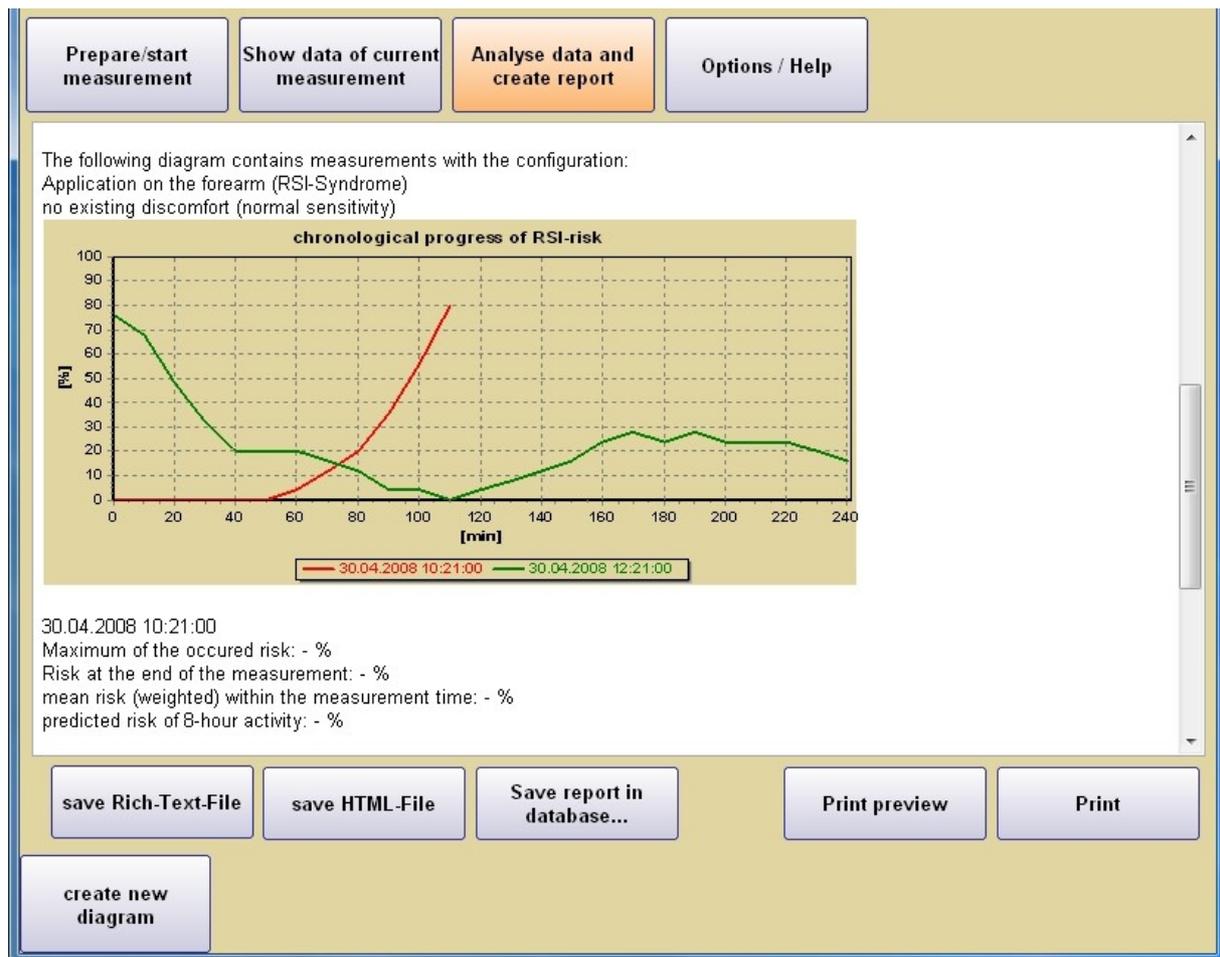
- Meas. from 22.03.2008 09:50:00 RSI mit Beschwer.
- Meas. from 04.04.2008 09:10:00 Versp. ohne Beschwer.
- Meas. from 29.04.2008 09:53:00 RSI ohne Beschwer.
- Meas. from xx.xx.xxxx xx:xx RSI ohne Beschwer.
- Meas. from 29.04.2008 14:39:00 RSI ohne Beschwer.
- Meas. from 30.04.2008 07:24:00 RSI ohne Beschwer.
- Meas. from 30.04.2008 10:21:00 RSI ohne Beschwer.
- Meas. from 30.04.2008 12:21:00 RSI ohne Beschwer.
- Meas. from 06.05.2008 12:31:00 Versp. mit Beschwer.

Edit notes

Delete measurement

Back Next

Regard that only measurements with the same configuration can be displayed in one diagram simultaneously. You can create a report in this way, which you can print and export to different data formats (e.g. *.rtf, *.html). Both types of reports can be stored into the database and are assigned to the corresponding subjects. (You can only store reports with online data diagrams, if the measurement data are from a Statik-Relax[®] with an active „Science“ software module.)



Generation of a COPY of the Database of Statik-Relax

A copy of the Database of the Statik-Relax contains all the data of the patients and examinations, the measurement data and the reports up to the actual date.

You can use these Copy(s) in case of emergency if the original data base was destroyed (e.g. by a hard disk defect) or loosen (e.g. the computer was stolen).

You should make these copies of the database regularly!

You should save the copy of the Statik-Relax database outside of these computer (e.g. USB-MassStorage, external Storage) at a save place (since the database contains unsecured data of your patients).

Klick consecutively on the buttons << Options/Help >> and << copy database >> to make a copy.

Recovery of a Statik-Relax database by using a safety copy

You need administration rights to do the following Steps!

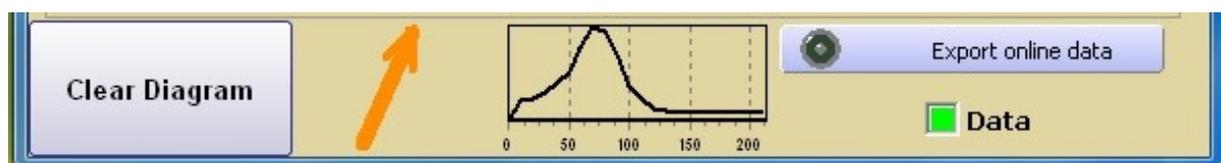
The Statik-Relax program has to be closed!

1. Search the program directory of the Statik-Relax program
(e.g. C:\Programme\Thumedi\Statik-Relax\
or C:\Programme (x86)\Thumedi\Statik-Relax\)
2. Open the subdirectory „DB“ (... \Statik-Relax\DB\)
3. Rename the file „Statik_Relax_V_1_0.mdb“ to
„Statik_Relax_V_1_0.mdb.err“
4. Copy the desired safety-copy of the Statik-Relax database to this directory
(... \Statik-Relax\DB\).
5. Rename the safety-copy to „Statik_Relax_V_1_0.mdb“.
6. Check the name of the file: It has to be exactly correct! Otherwise the Statik-Relax-Medic and the Statik-Relax-Science programs will not work. The Statik-Relax version “Basic” do not use the database.

Additional Indicators

During the displaying of the actual muscular activation the frequency spectrum of the EMG signal is shown on the bottom of the window. This is actualised four times per second.

The arrow on the left is an indicator for the actual strain situation. Unlike to the trend arrow on the biofeedback window this strain situation is judged independent to the actual risk situation. According to the height and static portion of the muscular activation the arrow shows with it's colour and direction the potential of hurtful effects caused by the actual strain situation. Red and an upwards pointing arrow shows a hurtful, yellow and a horizontal arrow shows an acceptable and green and a downwards pointing arrow a beneficial or neutral strain.



You can real time export the received values (Electrical Activity [μV], Electrical Activity relative to the calibration, Median Frequency [Hz]) to an ASCII-file with the help of the button >>Export online data<<. The chart “progress of muscular activation” must be shown continuously for this real time export!

!!!!

Starting with version numer 2.40 of the pc program, the real time export of the above named values to an ASCII-file is also possible using the “basic” version of the pc program if a Statik-Relax[®] device is connected which contains the module “science”.

!!!!

Software installation

If you have already installed a version of the „Statik-Relax[®]-PC-program“, you need to uninstall these. (Start → Settings → System control → Software).

Put the program-DVD (or CD) in the DVD (CD) drive of your PC and install the program. You can start the installation by executing the file “Statik-Relax-Setup.exe” (placed in the root directory of the DVD (CD)) as the PC administrator (If the PC is configured suitable, the installation procedure starts automatically).

To ensure that no subject and measurement data is lost accidentally during the deinstallation of the computer program the database is not deleted. If you don't need the data anymore delete the database manually!

Updates, update service and support

The THUMEDI GmbH & Co. KG supports you with suitable firmware- and PC-program updates free of charge during the whole product lifecycle. This includes identified software bugs, small enhancements of the functionality and adaptation to changed hardware or system software. These updates are made available sporadic. You can download these updates from our internet server.

Open the webaddress www.thumedi.de and choose the THUMEDI GmbH & Co. KG. Then click on downloads. You can find the relating files and also information of identified errors at the Statik-Relax[®] section.

In case of eventual technical questions and for support you can send us an email to support@thumedi.de

Please consider: As exact the error description or question is, as faster we can help you. You can write your mail in English or German. Please include in your description the name of the device (Statik-Relax[®]-basic, Statik-Relax[®]-science), the serial number and the firmware version of the device, the software version of the used PC-program and the version of the operating system (incl. service pack number) of the used PC! We cannot handle your enquiry otherwise!

Please visit our internet homepage for detailed support information. In order to that, open the webaddress www.thumedi.de and choose the THUMEDI GmbH & Co. KG. Then click on support.

System requirements

The program is optimised and tested for the system software Windows[®] 2000/ XP/ Vista[®] / 7/ 10. We can't guarantee the function in combination with other system software.

A Bluetooth[®] device connected to the PC is necessary to use the Statik-Relax[®]-PC-program. This is not included in delivery. You can use a usual in trade Bluetooth[®] device as they are sold as a dongle or already installed in a laptop.

Minimal PC performance features:

800 MHz / 1024 MB RAM

Microsoft[®] Windows[®] 2000 (SP4), Microsoft[®] Windows[®] XP (SP2)

1000 MHz / 2048 MB RAM

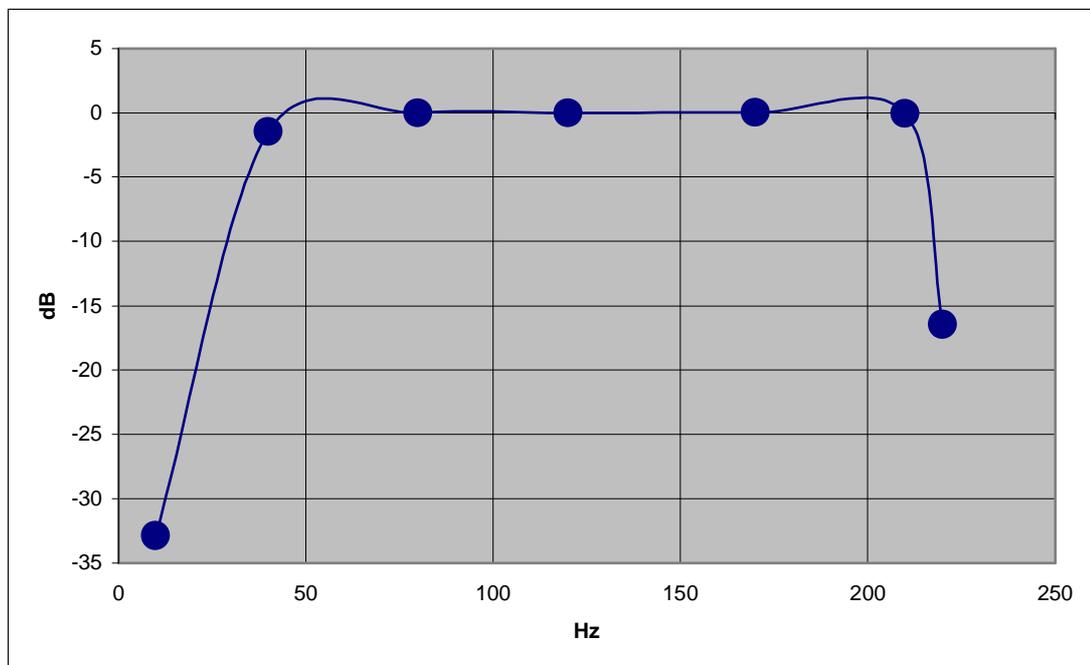
Microsoft[®] Windows[®] Vista[®], Microsoft[®] Windows[®] 7 (32 / 64 Bit),

Microsoft[®] Windows[®] 10 (32 / 64 Bit)

Technical data

Statik-Relax® - one-channel surface electromyographic biofeedback device

- count of SEMG-Channels: 1
- measured parameters:
 - amplitude / Electrical Activity (EA)
as effective value (Root-Mean-Square, RMS)
 - risk of a muscular hardening respectively of a RSI-Syndrome
- maximal amplitude / resolution:
abbr. 1.1 mV Peak-Peak / abbr. 1.2 μV P-P
- frequency range (-3dB) / resolution:
abbr. 40..210 Hz / 10 Hz



- error of measurement
electrical activity: typ. $< \pm 3\% \pm 10\mu\text{V}$, max. $\pm 6\% \pm 20\mu\text{V}$
median frequency: typ. $< 1\text{Hz}$, max. 2Hz
- frequency constant filters:
at 50, 100, 150, 200Hz average,
filter width: centre frequency $\pm 5\text{Hz}$,
type: digital
- power supply: 1..1,5V / 0.2 W
with 1 NiCd/NiMH-Accumulator or 1.5V alkaline or lithium battery (type AAA)
- data storage: max. 40 measurements
cumulative measurement time appr. 141,5 hours

- Class IIa, type BF, IP20 – Protect the device against humidity!
- It is not allowed to use the Statik-Relax[®] at the same time with electrical therapy devices (e.g. HF-Chirurgical devices, muscle stimulation devices, short-wave therapy devices, defibrillators)!
It is not allowed to use the Statik-Relax[®] for supervising of vital functions!
- Statik-Relax[®] is not protected against discharges of defibrillators.

Statik-Relax[®]-Display

(no longer available)

- Operating voltage: 5 V/DC +/- 5%
- Current consumption: operation: 300mA
standby: 3mA
- Power consumption: operation: 1,5 W
standby: 0,015W
- Dimension W x H x L: 11,2cm x 6,9cm x 9,8cm
- Weight: 215g
- Display: resolution 240 x 360 Pixel with touchscreen
- USB-connection: USB-port 1.0, 2.0, 3.0
- Bluetooth[®] 2.0 + EDR, Class 1 (R&TTE)

Functional overview Statik-Relax programs

PC

Basic

- Assistant with detailed help to the program steps
- Configuration of the Statik-Relax[®] without data storage
(If a measurement **with** data storage is configured the Basic-program can **not** reconfigure the Statik-Relax[®] (Safety-function)).
- Starting and continuing a measurement with application and calibration assistance
- Display of the smiley and the trend arrow
- Display of chronological progress of risk and muscular activation
- Hints for the improvement of the strain situation with warning according to the current risk situation
- Display of the charge condition of the battery/accu
- Power-saving function
- Creation of reports from on-line diagrams, printable and exportable
- Activation of additional software-modules of the Statik-Relax[®]
- Selection of the language versions in the program
- Writing real time online measurement data into a file on PC (ASCII, 4 datasets per second) if a Statik-Relax[®] device is used which contains the module "science" and the chart "progress of muscular activation" is shown continuously:
 - time
 - electrical activity (EA)
 - electrical activity relative to the calibrated value (EA rel)
 - median frequency (MF)

Science

additional to Basic:

- Database for the storage of patient data and measurement results
- Configuration of the Statik-Relax[®] with data storage
- Display of spectrums of frequencies
- Readout of the stored data in the Statik-Relax[®]
- Creation of reports with the data of the database
- Creation of reports with comparison of measurements
- Reports storable in database

System Requirements

- Operating system:
Microsoft Windows[®] 2000(SP4), Windows[®] XP(SP3), Windows Vista[®] (SP1), Windows 7 (32- and 64-Bit), Windows 10 (32- and 64-Bit)
- screen resolution at least 800x600 pixel
- Bluetooth[®]-interface supporting the „Serial Port Profile“ (SPP)

Android-Device, Win-Mobile-Smartphone, Win-PDA

- Assistant with detailed help to the program steps
- Configuration of the Statik-Relax[®] without data storage (If a measurement **with** data storage is configurated the Basic-program can **not** reconfigure the Statik-Relax[®] (Safety-function)).
- Starting and continuing a measurement with application and calibration assistance
- Display of the smiley and the trend arrow
- Display of chronological progress of risk and muscular activation
- Display of the charge condition of the battery/accu
- Power-saving function
- Selection of the language versions in the program
- Readout of the stored data in the Statik-Relax[®] and display on PDA/Smartphone (no storage on the PDA/Smartphone/Table)
- Restrictions:
 - no creation of reports
 - no software-modul activation
 - no Hints for the improvement of the strain situation
 - no support

System Requirements Android-Phone

- Android 4.03 and above
- Bluetooth[®]-interface supporting the „Serial Port Profile“ (SPP)
- Screen resolution: 480*240 and above
- Installation of Apps from other sources than PlayStore must be allowed

System Requirements Windows-Mobile

(no future releases, development suspended)

- Operating system:
Microsoft Windows Mobile[®] 2003, Windows Mobile[®] 2003SE, Windows Mobile[®] 5.0, Windows Mobile[®] 6 (newer other Windows operating systems are possible but not tested)
- Microsoft[®] .Net Compact Framework 3.5
- screen resolution: 240x320 pixel or 480x640 pixel
- Bluetooth[®]-interface supporting the „Serial Port Profile“ (SPP)

EMC-guidelines

Warnings:

- Medical electrical equipment needs special precautions regarding EMC. The following EMC guidelines must be observed during installing and put into service of the device.
- Portable and mobile RF communications equipment can affect medical electrical equipment.

Guidance and manufacturer's declaration - electromagnetic emissions		
The Statik-Relax is intended for use in the electromagnetic environment specified bellow. The costumer or the user of the Statik-Relax should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Statik-Relax uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interface in nearby electronic equipment.
RF-emissions CISPR 11	Class B	The Statik-Relax is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	not applicable	

Guidance and manufacturer's declaration - electromagnetic emissions			
The Statik-Relax is intended for use in the electromagnetic environment specified bellow. The costumer or the user of the Statik-Relax should assure that it is used in such an environment.			
Immunity test	IEC 60601-1 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6kV contact +/- 8 kV air	+/- 6kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/ output lines	-	not applicable
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	-	not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% for 5s <5% for 0,5 cycles 40% for 5 cycles 70% for 25 cycles	-	not applicable
Power frequency (50/60Hz) magnetic fields IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of the typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic emissions			
The Statik-Relax is intended for use in the electromagnetic environment specified bellow. The costumer or the user of the Statik-Relax should assure that it is used in such an environment.			
Immunity test	IEC 60601-1 test level	Compliance level	Electromagnetic environment - guidance
conducted RF IEC 61000-4-6	3 V _{eff} 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Statik-Relax, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation distance: $d = 1,17 * \text{SQRT}(P/W)$
Radiated IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/ m	$d = 1,17 * \text{SQRT}(P/W)$ for 80 MHz to 800 MHz $d = 2,33 * \text{SQRT}(P/W)$ for 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the symbol "nonionising radiation".

NOTE: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.

NOTE : This guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strength from fixed transmitters, such as base stations for radio (Cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.

To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Statik-Relax is used exceeds the applicable RF compliance level above, additional measures may be necessary, such as reorientation or relocating the Statik-Relax.

Recommended separation distances between portable and mobile RF communications equipment and the Statik-Relax

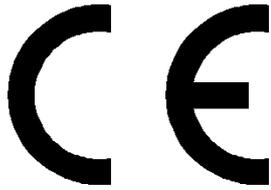
The Statik-Relax is intended for use in an electromagnetic environment in which the radiated RF disturbances are controlled. The costumer or the user of the Statik-Relax can help prevent electromagnetic interference by maintaining a minimal distance between portable and mobile RF communications equipment (transmitters) and the Statik-Relax as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter P in W	Separation distance according to frequency of transmitter in m		
	80 MHz to 800 MHz	800 MHz to 2,5 GHz	150 KHz to 80 MHz
	$d=1,17 * \text{SQRT}(P/W)$	$d=2,33 * \text{SQRT}(P/W)$	$d=1,17 * \text{SQRT}(P/W)$
0,01	0,12	0,23	0,12
0,1	0,37	0,74	0,37
1	1,17	2,33	1,17
10	3,70	7,37	3,70
100	11,70	23,30	11,70

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.

NOTE : This guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



EC-Declaration of conformity

The manufacturer

THUMEDI GmbH & Co. KG
Europäisches Institut für betriebliche und individuelle Gesundheitsförderung
Straße der Freundschaft 68b, 09419 Thum-Jahnsbach, Germany

declares under sole responsibility that the products

„Statik-Relax[®] - basic”
„Statik-Relax[®] - science”

based on the conformity assessment according to appendix VII, Council Directive 93/42/EEC are compliant with the essential requirements of Annex I of the Directive on medical products.

The above-mentioned Products are active medical devices of class I in accordance with Annex IX, Rule 12 of the Directive. They do not have measuring function in the meaning of Directive 93/42/EEC, as they are not intended to use for medical diagnosis and therapy, but for scientific research and industrial engineering.

The products are not sterile.

This declaration is valid for all market introduced above-named products starting from February 4, 2014 up to the release of a newer version of this document.

Thum-Jahnsbach, February 4, 2014

THUMEDI GmbH & Co. KG
Dipl.-Ing. Robert Seibt, Head of R&D

Warranty conditions

This product has been manufactured to the highest quality standards and is warranted to the original purchaser or gift recipient only. This warranty is not transferable. The product is guaranteed to be free from defects in workmanship and parts for a period of 24 months from the date of purchase. Defects that occur within this warranty period, under normal use and care will be repaired or replaced at our discretion, solely at our option with no charge for parts or labour.

THUMEDI reserves the right to replace the Product or relevant part with the same or equivalent Product or part, rather than repair it. Where a replacement is provided the Product or part replaced becomes the property of THUMEDI. THUMEDI may replace parts with refurbished parts. Replacement of the Product or a part does not extend or restart the Warranty period. The benefits conferred by this warranty are in addition to all rights and remedies in respect of the product that the consumer has under the state and territory laws. The Warranty is transferable to a new owner, in the event of sale of the Product, provided the new owner has the receipt of purchase and the Product is still within the guaranteed period.

Please keep your purchase docket or receipt as proof of purchase and as proof of the date on which the purchase was made. The purchase docket or receipt must be presented with the warranty when making a claim under this warranty. If in the event the receipt of purchase is not presented, then this warranty is invalid.

In the event that this product is Dead On Arrival (DOA), the owner has 14 days in which to return the Product to the retailer or place of purchase for a new replacement. If the owner does not return the product within 14 days then the Product will be treated under normal warranty conditions. Under normal warranty conditions the product must be returned to the THUMEDI GmbH & Co. KG. Please ensure that the product is properly packaged so as to ensure that no damage occurs to the product during transit. Also make sure you have included an explanation of the problem. Should the goods be found in working order the owner may be charged a fee.

In the event that no identical Product is available for service repair, THUMEDI has the right to replace the Product with a device of equal capacity, or offer the customer the choice of a Product upgrade, which may incur an extra cost. This warranty is limited to defects in workmanship or parts. All defective products or parts will be repaired or replaced. This warranty does not extend to accessories. This warranty does not cover manuals and packaging. This warranty does not cover batteries, electrodes or any other consumable item. This warranty does not cover any defect caused by an accident, misuse, abuse, improper installation or operation, lack of reasonable care, unauthorised modification, loss of parts, tampering or attempted repair by a person not authorised by the distributor. The warranty will not apply if the factory-applied serial number has been altered or removed from the Product. The warranty will not apply if damage, malfunction or failure resulting from alterations, accident, misuse, abuse, fire, liquid spillage, mis-adjustment of customer controls, use on an incorrect voltage, power surges and dips, thunderstorm activity, acts of God, voltage supply problems, tampering or unauthorised repairs by any persons, use of defective or incompatible accessories, exposure to abnormally corrosive

conditions or entry by any insect, vermin or foreign object in the Product. THUMEDI will not be liable for any loss, damage or alterations to third party hardware, software or data. This warranty does not cover normal wear and tear of the Product or parts. THUMEDI excludes all other warranties, conditions, terms, representations and undertakings, whether express or implied.

Attachment no. 1 - Operation time

Maximum operation time

The following example describes the maximal operation time by using a fully charged NiMH-accumulator with a **real amount of electricity of 850 mAh**. These values are effective from Statik-Relax[®] firmware version 2.1.

Statik-Relax[®] without connection to PC, Tablet/PDA or SR-Display: 9h:30min

Statik-Relax[®] with connection to PC, Tablet/PDA or SR-Display:

<u>Graph</u>	<u>Energy saving mode</u>	<u>Maximum operation time</u>
activation	OFF	7h:00min 8h:00min ^{*1}
risk	OFF	8h:15min
risk	AUTOMATIC	8h:20min bis 8h:40min
risk	ON	8h:50min

^{*1} Depends on distance to the receiver and the number of surrounding devices using Bluetooth and/or WLAN.

Usable accumulators / batteries

1. accumulators

SANYO XX (powered by eneloop) AAA (HR03) 900 mAh

GP ReCyko+ ALWAYS READY, AAA, NiMH, 850mAh

SANYO eneloop, AAA, NiMH, 800 mAh

2. batteries

Lithium-batteries:

Energizer Ultimate Lithium AAA

Alkali-Mangan- batteries:

Energizer Ultimate Alkali AAA