

2-Channel EMG-Biofeedback

SineBravo

Medical Device



Operators Manual

CE 0123



Please read this manual before using the device!

Content

Please read the Operators Manual carefully
before using the device and pay attention
to all references !



In the following you'll find all information directly necessary for performing the treatment
with grey background.

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Delivery & Accessories

Included in the delivery:

REF: 010E-087: 1 unit **SineBravo**, 2 dual pin lead wires to connect the electrodes, 1 single pin reference lead wire, 8 self-adhesive electrodes (40 x 40 mm), 1 stand, 4 batteries type AA and 1 operators manual

Accessories:

REF

011E-006: 1 unit self adhesive electrodes 40x40 (4 pieces)

011E-007: 1 unit self adhesive electrodes 40x80 (4 pieces)

011E-008: 1 vaginal probe “IncoProbe V”

011E-009: 1 rectal probe “IncoProbe R”

011E-017: 1 vaginal probe “Probe V plus”

011E-018: 1 rectal probe “Probe R plus”

Spare parts:

REF

012E-120: 1 lead wire to connect the electrodes

012F-037: 1 tube electrode jelly for probes

012F-086: 1 carrying case

012F-083: 1 reference lead wire

012F-805: 4 batteries type AA

012E-097: 1 operators manual **SineBravo**

SineBravo shall only be used with original accessories.

The expected service life of **SineBravo** is 5 years. The batteries life is approximately 12 hours or more. The storage time of the batteries is approximately 2 years. The service life (expiry date) of electrodes, probes and electrode jelly is printed on each package.

Medical Device Reporting:

If there is a serious deterioration in the state of your health when using the medical device, report this to your distributor or to the manufacturer and to the competent authorities of your country.

Technical Data

1. Dual Channel
2. EMG Range: 0.2 to 2000 μ V RMS (continuous)
3. Sensitivity: 0.1 μ V RMS
4. Selectable Bandpass filter - 3db Bandwidth,
 - a. Wide: 18 Hz +/- 4 Hz bis 370 Hz +/- 10 % - Reading below 235 microvolts
10 Hz +/- 3 Hz bis 370 Hz +/- 10 % - Reading above 235 microvolts
 - b. Narrow: 100 Hz +/- 5 Hz bis 370 Hz +/- 10 %
5. Notch filter: 50 Hz - 33 dbs
6. Common Mode Rejection Ratio: 130 dbs Minimum @ 50 Hz
7. Batteries: 4 x AA
8. Work / Rest periods: 2-99 seconds
9. Number of Trials: 2-99
10. Dimensions: L 141,6 mm / W 74 mm / H 40,4 mm
11. Weight of the device: 270 g (incl. batteries)
12. Firmware version 3.1B or later

Max. environmental conditions for transportation: -25 to +70 degree centigrade, 0-93% atmospheric humidity. Recommended environmental conditions for storage: -25 to +40 degree centigrade, 0-93% atmospheric humidity. The device shall not to be stored in direct sunlight. Allow up to one hour for the device to return to normal operating temperature if stored in conditions below +5°C or above +40°C.

Environmental conditions for use: +5 to +40 degree centigrade, 0-93% atmospheric humidity, air pressure 700-1060 hPa. During use the surface temperature of the device can be 41°C or higher, but never exceeds 48°C.

The **SineBravo** is protected against debris larger than 12.5 mm in diameter from entering the cabinet and is not water resistant and rated IP20.

Radio Link:

RF Frequency Range: 2.4000 GHz to 2.4835 GHz

RF Default Output Power: \leq 1,0 mW

RF Maximum Output Power: \leq 2,52 mW

Antenna Gain: 0 dBi

This device is quality controlled and fulfills all legal requirements for medical products. Therefore this device carries the CE-sign „CE 0123“. The serial number is on the rear of the unit.



Manufacturer: MTR+ Vertriebs GmbH,
Kamenzer Damm 78, 12249 Berlin - Germany
www.mtrplus.com

Explanation of Symbols

	Attention Warning		Manufacturer
	Type BF applied parts		Date of manufacture
	Serial-Number of the product		CE-mark: conforms to essential requirements of the MDD 93/42/EEC
	Keep dry		Not suited for persons with cardiac pacemaker
	Batch code		Read the instructions 
	Medical Device		Unique Device Identifier

Introduction – What is SineBravo ?

The **SineBravo** is a modern device for EMG biofeedback. The term biofeedback refers to a method to perceive biological processes with the help of a technical device. This instrument measures physical activity - even if there are no visible or no voluntary muscle contractions - and converts them to optical and/or sound signals. **SineBravo** is a combined two-channel device that can be flexibly used for EMG biofeedback training. Doctors and patients are the intended operators for this unit.

The clip on the back of the unit allows the user to fasten the device to the clothes, the unit is intended to be supported by hand during normal use. The belt clip is for temporary relief only. During treatment it's not necessary to hold **SineBravo**, since it can stand upright on a flat surface in its stand. This allows the patient to train without help while observing the success of the individual efforts. The muscle activity is indicated by a yellow-green bargraph on each side of the screen and by numerical values in the bottom-line of the display.

At the end of each session, the screen automatically displays the average values of muscle activity in this session. The **SineBravo** can be used with or without connection to a personal computer. The stored treatment data can be transmitted to the PC at a later date using software available separately.

Indications

The device for EMG biofeedback training, **SineBravo**, can be used according to the instructions of the attending physician or of a physiotherapist to assist in muscle training for the following indications.

Elimination of light to mid strength faecal incontinence
Elimination of light to mid strength urinary incontinence

- Urge-incontinence
- Stress-incontinence
- Mixed-incontinence

Stroke Rehabilitation

Relaxation Training

Contraindication



During the application of the **SineBravo** it is necessary to take precautions.

SineBravo may not be used in the following cases:

- while operating machinery with dangerous potential.
- if patients cannot use the device properly, due to mental or physical limitations.
- while driving a vehicle.

SineBravo is an electronic device, therefore users with cardiac pacemakers may be at risk of interference. Although EMG is not expected to interfere with pacemakers, MTR + does not permit the use of the **SineBravo** for people with pacemakers.

Please don't use a probe:

- during the menstrual period.
- during pregnancy.
- if an inflammation of the vagina, anus or urinary tract is present.
- in the presence of symptoms of a bladder infection.

Warnings



- **SineBravo** is a type BF equipment
- Do not immerse **SineBravo** into water or any other liquids.
- Do not use **SineBravo** in presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.
- If using rechargeable batteries be sure to use a CE approved battery charger. Never connect the **SineBravo** directly to the mains, to a battery charger or to any other net-powered equipment.
- The operator may not touch the battery contacts & patient simultaneously.
- To avoid the effects of electromagnetic interference never use the **SineBravo** in the EMG-mode, with less than 4 metres distance to a cellular telephone or near any other powerful radio interference producing equipment that causes electrical signals etc. In the EMG Mode, the **SineBravo** may be susceptible to strong interfering radio type emissions that may lead to temporarily increased EMG microvolt readings. If suspected interference is causing a problem with EMG readings, change position of the device and move away from any electrical emitting equipment. The reading will immediately return to the correct value when the interference ceases.
- The power supply of some laptop computers or devices which do not have an earth connection may cause significant interference affecting the DuoBravo. As a precautionary measure please make sure that the power cord of the laptop or the devices are as far away as possible from the lead wires of the patient. If interference persists, remove the power cable from your computer and use it with its battery. Winding the lead wires around a limb (arm or leg) may also help this interference.
- If in the case of treatment with the incontinence probes, pain or irritation appear in the area of the pelvis, or bleeding in-between menstruation, interrupt the therapy and consult your doctor.
- If you have swallowed any part of the device or any of its accessories, please contact a doctor immediately.
- Remove batteries and battery cover, drain water from device and allow (SineBravo) to dry normally for 48 hours if accidentally submerged in water.

Please, keep this device stored out of the reach of children. Do not leave the lead wires in reach of children, since strangulation is possible due to the length of the lead wires.

Advice on Application of Electrodes



Make sure that **SineBravo** is turned off (no indication visible on the LCD display).

Now connect the single poled ends of the lead wires with the electrodes.

The output plugs of the electrode lead wires will be plugged into the channels A or B of the **SineBravo**. The reference lead wire will be connected to its jack as well.

Furthermore make sure, that all plugs fit completely into the electrode sockets as well as the device sockets.

If you are using a probe, lubricate it with water or a gel suitable for electrotherapy.

Now place the electrodes or the probe according to the instructions of your doctor or physiotherapist. The self-adhesive skin electrodes are provided with a sticky gel and can be re-used after removal from the skin. Replace these electrodes when the adhesive force is weak.

Electrodes which are damaged due to careless handling may not be used.

Electrodes with damaged lead wire insulation (e.g. visible copper wire) may not be used.

Electrodes with damaged, missing or stained aluminium coating or carbon layer, also with insufficient adhesive gel may not be used.

Electrodes may not be altered or tampered with (e.g. by scissors or other tools).

Do not pull the electrodes by force on the electrode lead wire. To remove the electrodes from the skin, please lift the electrode at the rim towards the middle.

Do not use electrodes with ointments or creams (especially which enhance the blood flow or act as local anaesthesia).

Apply the electrodes on clean and healthy skin only.

In the case of strong bodily hair growth, the hair should be shaved or shortened with scissors.

Neither stretch the skin nor the electrodes when applying the electrodes.

For standard treatment we recommend the use of our self-adhesive electrodes with a minimum area of 40x40 mm. This size is suited for the reference electrode as well. For best results please make sure that the reference electrode is placed on a bone near the treatment area, not on muscles.

For treatment of the muscles of the pelvic floor we recommend the use of our vaginal- (IncoProbe V) or rectal-probes (IncoProbe R).

If using a probe, please clean it carefully before and after use with a mild detergent (without alcohol) and ensure the probe is rinsed thoroughly to remove all cleaning residues. Ensure the connectors are not submerged in water as they may corrode. Ensure the probe is completely dry before storage.

After all electrodes have been removed, wash the skin with mild soap and rinse thoroughly.

Then dry your skin.

All electrodes or probes are for single person use only.

Skin electrodes as well as probes can contain amounts of nickel. Allergy sufferers should check this before using. Should skin irritation occur whilst using the **SineBravo**, please interrupt the application and inform your doctor, so that an allergic reaction can be excluded.

Maintenance

SineBravo has been designed to be maintenance free. Nevertheless, please adhere to the following advices:

If needed, please clean **SineBravo** with a mild detergent, water and a damp cloth. Do not expose **SineBravo** to extreme humidity and do not submerge under water. You may clean the lead wires with a damp cloth. You may also from time to time treat the lead wires with talcum powder in order to prevent cracks and to improve the lead wires life. A clean cloth, moistened with an alcohol free disinfection liquid can be used to clean the device. Please follow all instructions of the manufacturer of the liquid.

The **SineBravo** does not require calibration. **SineBravo** is not repairable and contains no user serveable parts. No modification to the **SineBravo** is allowed.

After termination of the therapy, **SineBravo** can be re-used by other patients. Please clean the device with a mild disinfectant cleaner before it is used by other patients.

Warranty

MTR+ Vertriebs GmbH provides a 24 month warranty, commencing from the date of our delivery (invoice date), that in case of failure, the **SineBravo** will be serviced or replaced free of charge. All returns must first be authorised by MTR+ Vertriebs GmbH in advance.

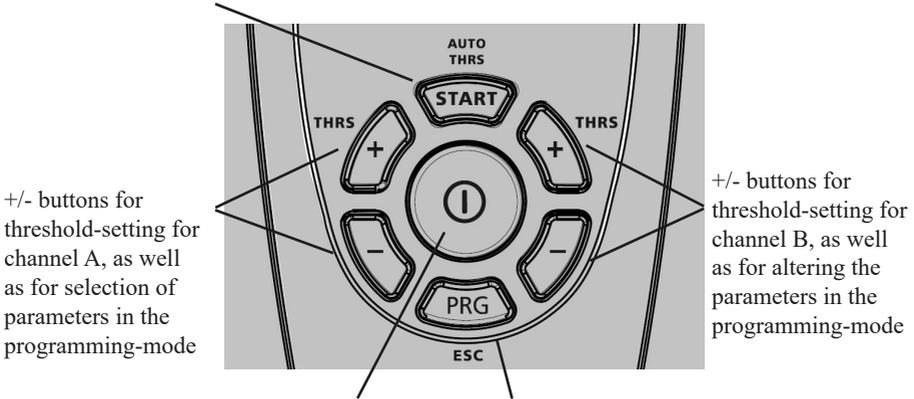
Excluded from this warranty are failures of the **SineBravo** which result from excessive use, careless or improper handling as well as damage by force.

The warranty loses its lawful meaning if the producer MTR+ Vertriebs GmbH has not given its consent in writing prior to repairworks or servicing being carried out. Without this written consent the manufacturer will not return the device.

The manufacturer reserves the right of technical changes, which may serve to increase treatment success, the functionality of the device or its accessories.

Operating Elements

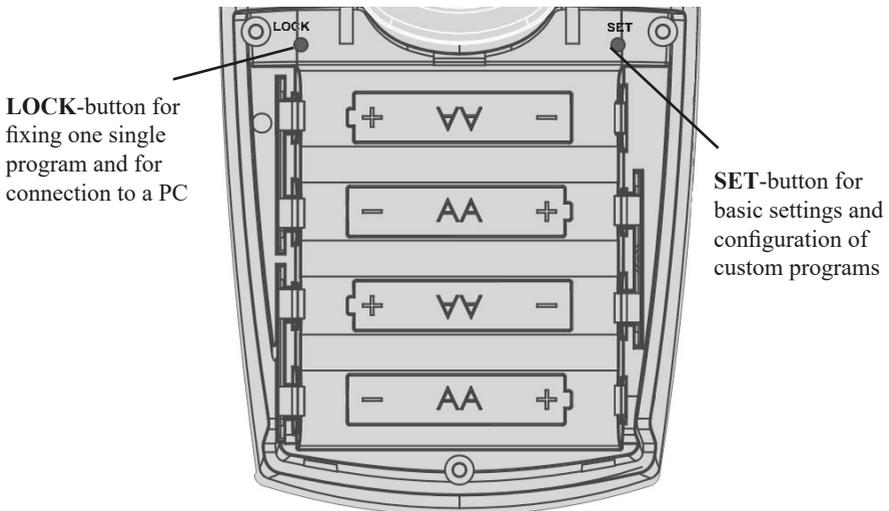
The **START**-button allows the choice of automatic (press) or manual (hold the button pressed for 3 seconds) threshold-setting. The program will start after the **START**-button is released.



Central On-/Off-button

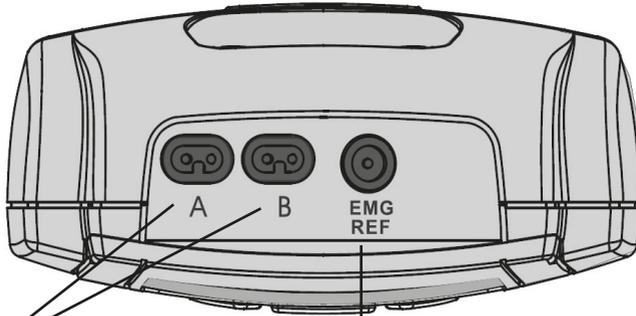
PRG-button for choice of program and for storing the individual parameters. Hold PRG for one second to select next phase.

Battery Compartment



Scheme for placement of 4 batteries type AA

Connections



Jacks to connect the electrode-lead wires of channel A and/or B, each suited for surface-electrodes or probes.

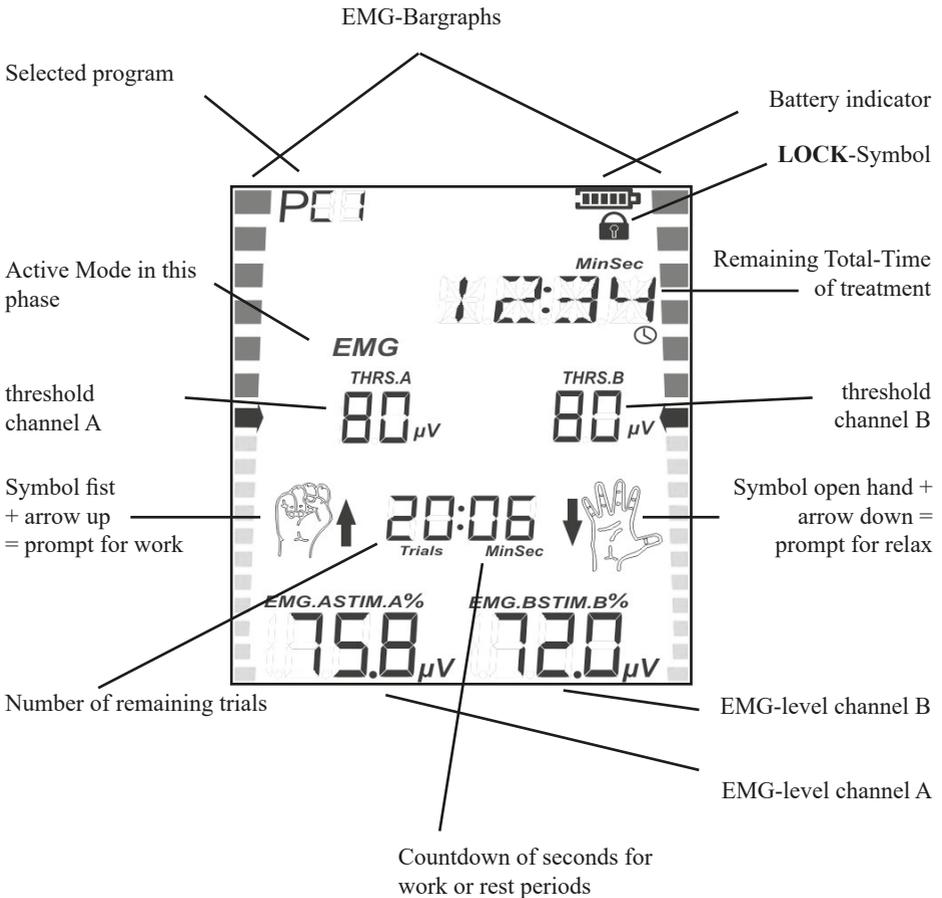
Jack for the single pin EMG-reference lead wire (skin-electrode)

Attention: Even if the device is used with a probe, please always connect the single pin reference lead wire.

The Display

After selecting a program with the **PRG**-button **SineBravo** shows information about those parameters in its "Home Screen" that are used in the first phase of the program (number of trials, threshold, etc.). Start the treatment by pressing or holding **START**, the display changes to work-screen and shows necessary information for treatment in the active phase.

Work-Screen



The Info-Line

The info line in the upper part of the screen shows always the remaining time of the entire program during treatment.

Outside a treatment session, it provides more additional information:

- While setting the clock or when choosing the language, it shows values to be set in plain text.

The info line displays all custom settings for configuring the device. In the following you find all expressions and abbreviations that are used in the programming-loop in alphabetical order:

CH.B. ON / CH.B. OFF: Channel B is switched on or off

FB.ABOVE / FB.BELOW: Feedback above or below the threshold

FB. CONT: Continuous acoustic feedback

FB. OFF: No acoustic feedback

INHIB.OF: Inhibition switched off

INHIB.ON: Inhibition of feedback on channel B

NARROW: Narrow bandpass filter

PC SWC: Connection to PC by secured wireless connection

PC OFF: Connection to PC is switched off

REST: Duration of rest-sequences in seconds

THRESH: Threshold-adjustment during treatment automatically (AUTO) or manually (MAN)

TRIALS: Number of repetitions

VOLUME: Sound volume of beeps and spoken instructions

WIDE: Wide bandpass filter

WORK: Duration of work-sequences in seconds

Basic Settings

In all programs, even in the preset programs, individual settings can be made as follows. After you have put in four batteries type AA (s.p. 38) and you have turned on the device with the **ON/OFF**-button, you enter the configuration mode by pressing the **SET** button in the battery compartment for three seconds. Now you can adjust the settings of the selected program.

The parameter that can be changed is shown in the info line and can be altered by pressing the + button of channel B. Pressing the + button of channel A will confirm the choice and the next variable parameter is displayed. This system - changing settings with B / storage and stepping forward with A - remains the same during the entire process.

Please note that the following settings you make here, are automatically stored for all other programs as well. Of course you can change any setting at any time in the same way again.

The following functions can be influenced:

- Sound-volume
- Automatic threshold-adjustment on or off
- Wide- or narrow-filter for channel A
- Channel B switched on or off
- Filter for channel B if it is in use
- PC - Select off or SWC (wireless)

In the customizable programs PC1 - PC4 of course you have the ability to set additional parameters in the same way as described on page 47.

Setup Real Time Clock

Before first use of **SineBravo** the “Real Time Clock” that is integrated should be set. It’s necessary for future therapy-control. **SineBravo** has a small assistance battery that will support the clock with energy for several years. For this reason, there is no need to set again, even if the 4 main batteries have been substituted or removed. But we recommend to check and readjust periodically.

For setting time and date, please select any program and press the **SET**-button for at least 3 seconds. You’ll reach the configuration-mode. Now press **SET** once again for 10 seconds. On screen HOUR is indicated and you can set the hour with the +button of channel B (00-23).

By pressing the +button of channel A you confirm this choice and step forward to the setting of MINUTE. This is indicated on the screen as well, giving the opportunity to select the minutes via +button of channel B in the same way as before.

This way you are able to set one after the other:

- HOUR
- MINUTE
- DAY
- MONTH and
- YEAR

If all settings are finished, please press the **ESC**-button on the frontside of the device. All values will be automatically stored and the clock starts working.

Setup Language

SineBravo is able to show 6 different languages. If you are in the setting-mode of the RTC (see above), please press the **SET**-button for 10 seconds once again. Now you can select German-, English-, French-, Spanish-, Italian- or Polish-language with the B-buttons. Finally you store your choice with the **ESC**-button.

Preparation of Therapy

1. Open the battery compartment at the back by pushing down the lid and insert 4 batteries type AA by hand according to the instructions on page 38. Then shut the battery-compartment.
2. Please make sure, that **SineBravo** is switched off (no indication in LCD-display). Connect the single pin ends of the electrodes plugs to the surface-electrodes or to a probe.
3. Insert one electrode-lead wire into the jack named A in the head of the device. If you want to use both channels, insert the second lead wire into jack B.
4. Additionally, put the black round EMG-reference plug into the bigger round jack, named “EMG-REF” and connect the other ends to a skin-electrode.
5. Furthermore, make sure that all plugs fit completely into the electrode sockets as well as the device sockets.
6. If you are using a probe, lubricate it with water or a gel suitable for electrotherapy. Don’t use oil, ointment or cream, since all these have an insulating effect.
7. Now place all electrodes according to the instructions of your therapist on clean unwounded skin only. If you are using a probe, place the single reference-electrode onto the hip bone and then insert the probe.
8. Now switch on **SineBravo** by pressing the central **ON/OFF**-button once. You can see the version of the device for 3 seconds before the last used program appears, showing its parameters.
9. If the device is not locked to a single program, you can select your kind of treatment by repeatedly pressing the **PRG**-button. There are two preset and three custom EMG programs available.
10. After selecting a program, you always see the “Home Screen” first, with all information regarding the parameters, that can be used in this program. If you want to use the automatic threshold-setting, no adjustments have to be done and the treatment starts by pressing the **START**-button shortly. Follow the work/rest prompts, so the device can automatically select the threshold setting for you.
If you prefer manual threshold setting, please hold the **START**-button pressed for three seconds. Then you can set the threshold by use of the +/- buttons.
11. EMG is susceptible for interference. For best results do not use lead wires longer than 1.5 m and keep the lead wires as close to your body as possible.

Therapy with SineBravo

SineBravo is a versatile device for biofeedback-treatment.

The device has two pre-set EMG-programs (P01 + P02), that can be used without further adjustment. But if you like to create your own treatment with custom parameters, you can select one of the three custom programs (PC1 - PC3). Here you can configure your own programs to meet your therapy requirements.

Use of pre-set programs

1. Connect the electrodes to the device (s.p. 39)
2. Place electrodes or probe according to the instructions of your therapist
3. Switch on **SineBravo** with the central **ON/OFF**-button
4. Select the desired program with the **PRG**-button
5. Press **START** and the threshold will be set automatically by doing two short work/rest-periods. If that's not required, you can switch off this function by holding the **START**-button for three seconds (s.p. 48) In this case you can set threshold manually with the +/-button of the respective channel before starting the program.

The device indicates a pre-set rhythm of work and rest, that the patient shall execute as precisely as possible.

During work-period the symbol of the fist with arrow up is displayed on the screen. The feedback regarding the success of your own muscular activities is given by the increasing numbers in the lowest line and by the yellow/green bargraph on each side of the display. Reaching the green area shows that the threshold - regardless whether it has been detected automatically or has been set manually - is met and the trial was successful. Additionally this success is indicated by beeps. Please take care to keep your efforts active, until the time, that is indicated beside the fist, has counted down to zero and the symbol of the open hand with arrow down appears. Then relax the muscle as much as possible.



If you have chosen automatic threshold adjustment during treatment, threshold will be reduced if you are not successful and it would be easier to succeed in the next trial. If this next trial is successful again, the threshold will increase.

The whole process of work and rest shall be repeated until the number of remaining trials 00 (s.p. 39). Please note that the display doesn't change before the rest-phase is completed.



If relaxation is the target for the treatment, the positive signal will be given during the work period (that is indicated by the fist), if muscle tension is below the threshold.

Programs

Program	Nr.	No. of Trials	Work Time	Rest Time
EMG Urology	P01	40	8 sec.	8 sec.
EMG Neurology	P02	30	8 sec.	12 sec.
Custom EMG	PC1	2-99	2-99 sec.	2-99 sec.
Custom EMG	PC2	2-99	2-99 sec.	2-99 sec.
Custom EMG	PC3	2-99	2-99 sec.	2-99 sec.

Options for Configuration of SineBravo

Additionally to the use of pre-set programs as described in the previous chapter, **SineBravo** offers a great variety of possibilities to adapt the therapy-parameters according to individual needs.

This concerns the pre-set programs that can vary in regard of the basic adjustments as well as the 3 customizable programs, in which the experienced therapist or user is able to create completely new programs.

Configuration of Custom Programs

Creating a new program is not difficult, because the programming always follows the same easy scheme. The device leads in a loop to each parameter that can be chosen - indicated by flashing bars.

1. Switch on **SineBravo** with the **ON/OFF**-button
2. Select PC1, PC2 or PC3 with the **PRG**-button.
3. Hold the **SET**-button in the battery-compartment pressed for 3-5 seconds. Then **SineBravo** changes to programming mode and the bars beside the first parameter that can be set will flash.
4. In the following the right “+/-”buttons (channel B) are responsible for changing the flashing parameter, while the left “+” button (channel A) is used to store the choice and step forward to the next parameter. With the left “-”button it is possible to go one step back.

With the described scheme “right side changing / left side storing and step forward” all necessary settings can be adjusted. If the first parameter is shown a second time, the configuration is complete. Now the program can be stored by pressing ESC. This configuration will stay memorized until a new program is configured in it’s place or the device is reset to it’s default state.

Parameters of Custom Programs

PC 1-3 are single-phase EMG-programs. With A+ the following parameters can be chosen and then altered by B+, if necessary.

- **Volume** - (indicated in display: VOLUME) - sets the volume of sounds for feedback in steps 1-10
- **Duration of work-period (WORK)** - sets the time one single muscle contraction is held for
- **Duration of rest-period (REST)** - sets the time of relaxation after contraction
- **Number of trials (TRIALS)** - sets the number of active exercises that shall be done
- **Threshold (THRESH)** - defines whether automatic threshold-adjustment during therapy is switched on (AUTO) or off (MAN).
- **EMG Sound Feedback** – a) Off (FB.OFF). On (FB.ON), Above Threshold (FB.ABOVE) – normally used when training muscle force, Below Threshold (FB.ABOVE) – normally used for relaxation training.
- **Wide or narrow filter (WIDE / NARROW)** for channel A - this choice is necessary to avoid wrong measurement, caused by heart beat (60-120 Hz). Narrow filter should be used for the torso, wide filter should be used for legs and arms.
- **Channel B (CH.B. ON / CH.B. OFF)** switched on or off
- **Wide or narrow filter** for channel B
- **Feedback inhibition (INHIB.OF / INHIB.ON)** - will be selected, if the user shall get positive feedback only, if (s)he will be above threshold of channel A and below threshold of channel B. This method is used to avoid wrong EMG-results, caused by contraction of wrong muscles, which might be near the muscles that shall be measured.
- and **PC-Interface (PC SWC / PC OFF)** - here you can decide whether all treatment data will directly be transferred during treatment to a PC with optional therapist-software by secured wireless connection or not. During home-therapy PC OFF should always be selected to save battery-power.

The work- and rest-periods can be adjusted between 1 and 99 seconds by steps of 1 second.

Lock-Button

Lock is used if the therapist wants to lock a program in place for their patient preventing other programs from being selected. To lock a program select the desired program and press the **LOCK**-button with a thin pin. For this you can use the electrode connector. You'll hear a short beep and the symbol of a padlock appears on screen.

If you want to use any other program later, or if you need to unlock all programs, **LOCK** must be pressed in Home Screen once again and

- DAYS in use will appear and an arrow at the top of the screen will flash indicating the device is ready to transmit data to the PC.
- NO.STATS (= no statistics) will appear.

Hold the **PRG** button pressed for 3 seconds, the display changes to Home Screen and all programs will be available. Press **PRG** for less than one second to return to the Home Screen with the unit still locked.

Threshold

The threshold is a target value that shall be achieved by personal effort. It is measured in microvolts and displayed for both channels in the middle line of the screen. The arrows in the middle of the bargraph on the left and right side of the display represent the thresholds. Since all biofeedback-programs refer to a threshold, it is necessary to set this threshold at the beginning of each program.

Setting of threshold before start of treatment

By default, the threshold is determined automatically when **START** is pressed. Pressing the **START** button causes the appearance of the open hand in the display, while the time-indicator for this rest-period runs to 0. At 0, the display switches to the symbol of the fist and the time for this 5-second period of work runs to zero again. **In this short work period, you should try to contract the muscle with the maximum possible effort.** Subsequently a rest period follows and a further work-period. During these two initial work/rest trials for threshold-detection the word TEST is indicated in the infoline. The threshold is calculated automatically after the second phase of work, and is set at 80% of the average value of the period with higher performance. Please note that the first second of each work-phase is not relevant for the average value.

Now the treatment begins with the threshold set and the total time counts down in the infoline.

Alternatively, the automatic setting can be skipped. This is achieved by holding the **START** button pressed for about 3 seconds. In this case, the threshold of the last treatment appears and could be altered manually by pressing the +/- buttons before starting the program.

Automatic adjustment of threshold during treatment

Once the threshold is set, it will stay the same for the entire duration of the treatment until you make a new setting - except if you have selected "automatic threshold adjustment." In this case, the threshold would be adjusted during the treatment according to your performance. The new threshold will be set to 80% of the average work that have been done in the last trial before.

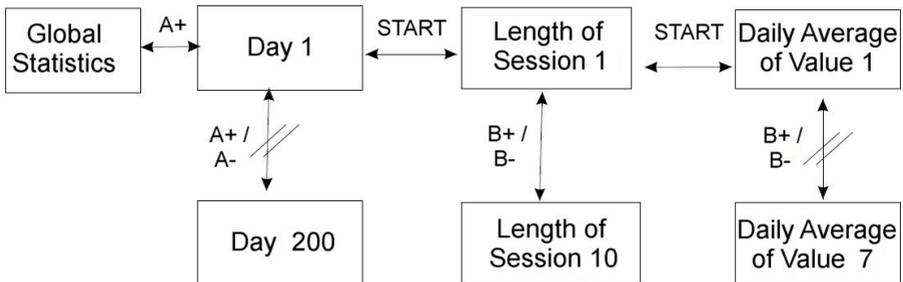
Therapy-Control

SineBravo displays statistics after each program has been completed. All values of this completed session, which are described on page 51 will be indicated on the screen automatically. With A+ you can scroll through the statistics. **SineBravo** saves these statistics to its memory for download to the optional software.

Up to 200 days of treatment data is stored in the **SineBravo** memory. When 201 days of data are reached, consecutive days will overwrite the earliest days. For this reason the statistics will always show the actual data of the last 200 treatment days. To access the statistics, press the LOCK button in the battery compartment once if the device was locked in a program - or twice if it was not. The **SineBravo** displays the number of treatment days saved, the total usage time and the most used program.

Press the A+ button to access the individual treatment days (1 to 200) with the respective number of sessions displayed. Press the START button to check the session data for the selected day. The duration of the session and start time will be displayed. Press B+ to view the start time for up to 10 consecutive sessions for that day. Press the START button again to view the accumulated daily data. Press B+ to scroll through the average daily data for EMG, ETS and STIM. Up to 7 values can be viewed as described on page 51.

Pressing A+ will select the next day



Therapy-Control

The additional software is required to transfer the stored data to a PC. An electronic patient record, which allows the graphical presentation of the treatment progress, can easily be created. This optional software is very helpful for therapists for statistical and/or scientific reports. To transfer the data please insert the USB dongle, which is supplied with the software, into the computer.

Please note that data transfer is not possible while checking the daily statistics on the unit.

The transfer of stored data can be done as follows:

- Start the optional software on your PC.
- Create or select the patient.
- Switch on the **SineBravo**.
- Press the LOCK-button once, if the device was locked – or twice if it was unlocked.
- The arrows in the display of the unit will flash one after the other indicating the statistics can be transferred to the computer. The statistics will be transferred to the computer when the screen displays the number of days and time used. “NO-STATS” will be displayed if the memory is empty.
- The data transfer starts automatically and your PC shows a message that it is receiving the statistics.
- The transfer may take several minutes depending on the amount of data stored in the **SineBravo** memory.
- When the statistics have been uploaded, the software will confirm that the transfer is complete.

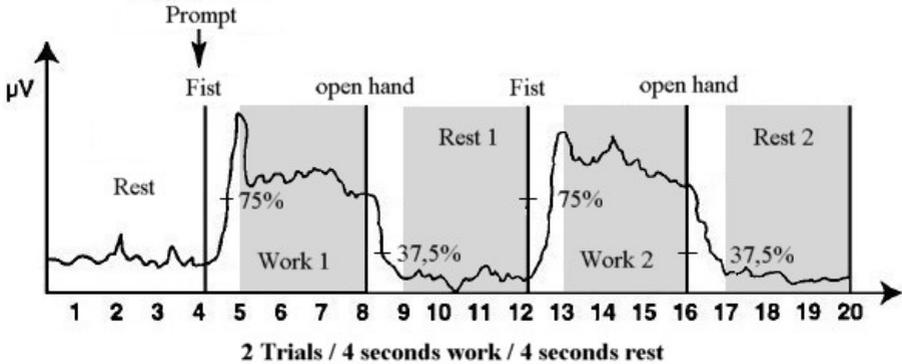
The values in the therapeutic memory are retained after they are read, so it is possible to check therapy at any time, without losing information.

If the memory needs to be deleted, it can be done with the following button-combination. Press the LOCK button in the battery compartment until DAYS (of treatment) is displayed and then successively SET, B +, B- and SET once again. You will hear a sound to confirm the statistics are being deleted. This action will also reset all custom settings in the freely customizable programs back to the original state.

The deletion of the memory is required:

- before the device is used by a new patient

Statistics



After termination of a treatment session **SineBravo** shows statistics on its screen as follows. The info-line indicates what value is shown.

WORK.AVG - Work Average: The average value in microvolts of all the work-segments excluding the first second of each segment.

REST.AVG - Rest Average: The average value of the rest-segments excluding the first second.

ONSET - Average Onset: The average time taken after each respective “**work**” prompt to reach 75% of the average value of the previous work period. If the onset of trial(s) is longer than 2 seconds, it will be rejected. The display will indicate the average of only those trials, where onset lasts 2 seconds or less. The number of valid onsets is displayed above the onset value. If the number of valid onsets is lower than the number of trials, it means some onsets were rejected.

RELEASE - Average Release: The average time taken, after the “**rest**” prompt to reach 37.5% of the average EMG from the previous work period. If any release of the trials is longer than 2 seconds then it will be rejected. The display will indicate the average of only those trials where release lasts 2 seconds or less. The number of valid releases is displayed above the release value. If the number of valid releases is lower than number of trials, it means some releases were rejected. If all the releases are above 2 seconds, ABOVE2 will appear on the screen.

W/R PEAK - Work/Rest Peak: It is the peak value during the whole cycle of all the trials.

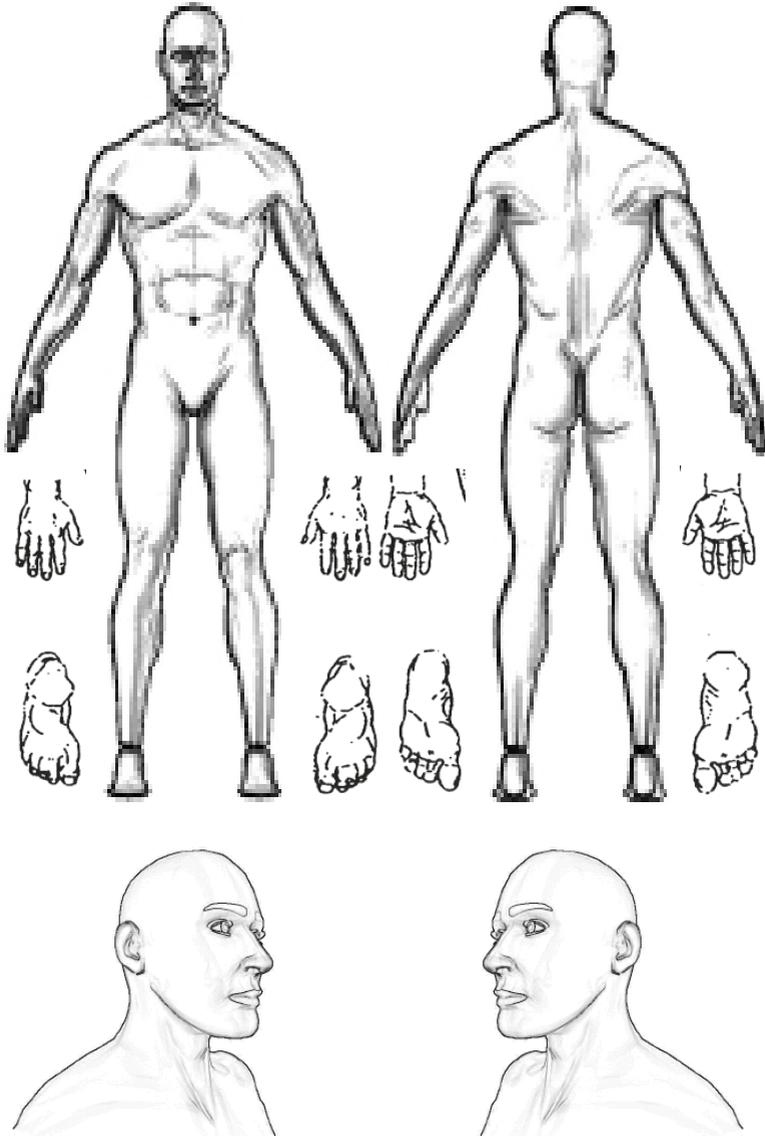
WORK DEV - Average deviation (per second) of work: It is the average deviation of the quarter-second samples from the average value in the second in which they occur (excluding the first second of each work-segment). If deviation is more than 20% it is considered problematic.

REST DEV - Average deviation (per second) of rest. The average deviation of the quarter-second samples from the average value in the second in which they occur (excluding the first second of each rest-segment). If deviation is more than 20% it is considered problematic.

Trouble Shooting Guide

Fault	Possible Cause	Solution
Device does not power on.	Flat battery or no batteries installed in device.	Check / Replace batteries.
	Battery installed in wrong orientation.	Remove batteries and install according to diagrams in battery compartment.
	Battery connector damaged or flattened.	Remove batteries, check metal parts in battery compartment for damage.
	Device is damaged.	Return to manufacturer for repair.
Device powers off during use.	Batteries almost flat.	Check battery icon during use and replace batteries if low.
	Device is damaged.	Return to manufacturer for repair.
EMG Reading is unstable	Reference electrode not used	Place reference electrode
	Device is being used with a notebook computer.	Disconnect power from notebook computer if being used.
	Device is in use near a device emitting strong radio or magnetic interference.	Move at least four meters away from offending device.
	Patient cannot relax muscles.	A relaxed muscle will read below 4 μ V.
	Output peaks in conjunction with heart beat while electrodes attached to main sections of body.	Device is reading the heart beat. Change device to Narrow band to filter out heart beat.
Treatment is painful or uncomfortable when using skin electrodes.	Patients skin has cuts or abrasions.	Discontinue use until skin is fully healed.
Treatment is painful or uncomfortable when using a probe.	Patient reaction to probe materials.	Discontinue use and consult a doctor if discomfort continues.
Skin becomes red after treatment.	Device is being used for periods which are too long for the patient.	Use device for a shorter treatment duration.

Anatomy



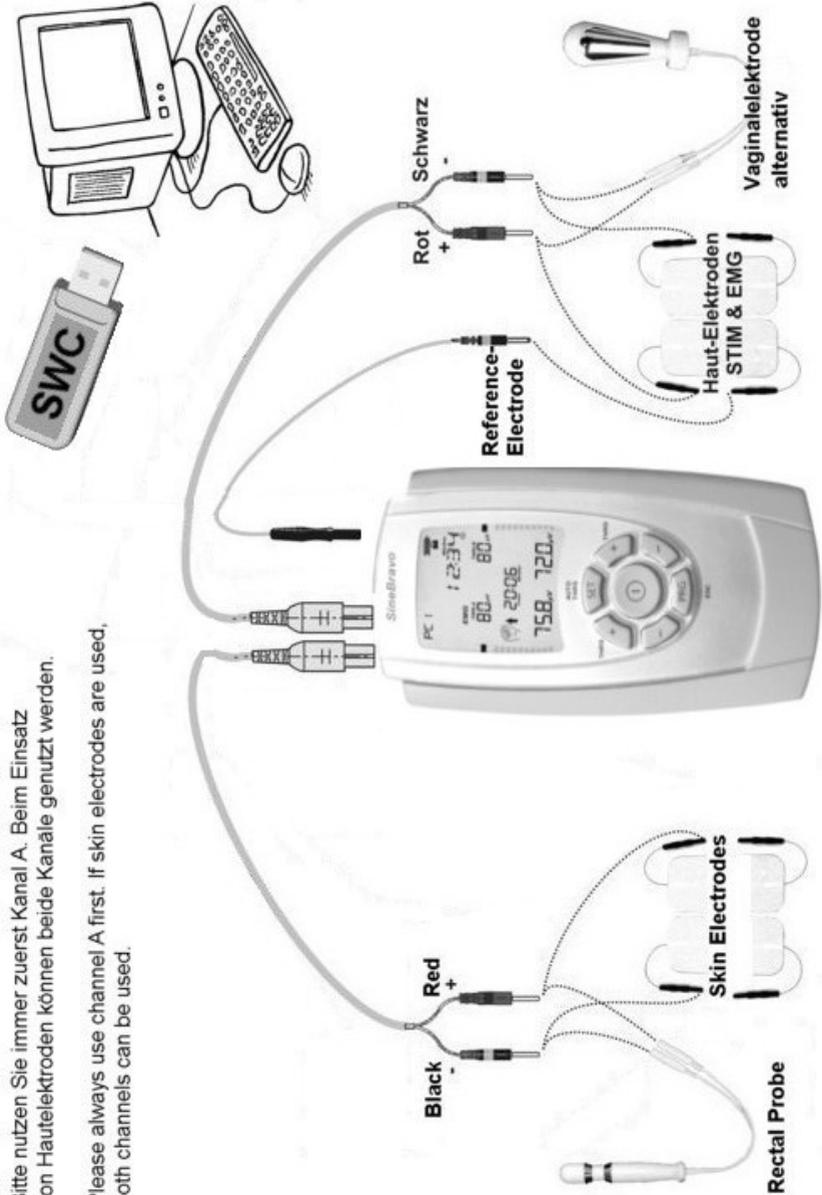
Mark the points of electrode placement if necessary.

Configuration

Configuration

Bitte nutzen Sie immer zuerst Kanal A. Beim Einsatz von Hautelektroden können beide Kanäle genutzt werden.

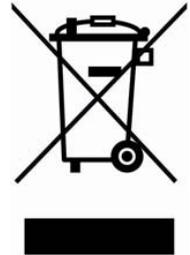
Please always use channel A first. If skin electrodes are used, both channels can be used.



Waste Disposal

In accordance with European regulations [1], used electrical and electronic equipment may not be discarded in household or unsorted municipal waste. Use separate collection facilities. Contact your local government or council for information regarding the collection systems available. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the ground water and get into the food chain damaging the health and well being of people and animals.

[1] European Community directive 2012/19/EU on waste electrical and electronic equipment.



Recycling of Batteries

The batteries should be replaced when they are drained or stop functioning. The batteries supplied with the **SineBravo** are recyclable. Remove the batteries from the unit and follow your local recycling guidelines.

Literature

A list of literature regarding the topics of this manual can be found on our website „www.mtrplus.com“.

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Electromagnetic Compatibility

If the device is used according to the instructions given in this manual, it corresponds to the safety requirements for medical electrical systems IEC 60601-1. **SineBravo** was checked and is in accordance with the limits set for medical products in the standard IEC 60601-1-2:2020. These limits serve to the safety of the user regarding electromagnetic disturbances. The **SineBravo** is a Class B device and is suitable for home healthcare environments as well as typical clinical environments.

Guidance and manufacturer's declaration - electromagnetic emissions		
The SineBravo unit is intended for use in the electromagnetic environment specified below. The customer or the user of the SineBravo should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The SineBravo uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The SineBravo is suitable for use in all establishments, including domestic and medical establishments 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	

Please adhere to these warnings when using the device:

Don't use **SineBravo** near active HF surgical equipment or RF shielded rooms used for magnetic resonance imaging, where the intensity of EM disturbances is high.

Use of this equipment adjacent to, or placement on top of other equipment should be avoided in case the EMG reading of the **SineBravo** is effected. If this is necessary, Both the **SineBravo** and the other equipment should be monitored to verify that they are both operating normally.

Use of accessories and lead wires other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used not closer than 4 meters to any part of the **SineBravo**, including lead wires specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Electromagnetic Compatibility

Guidance and manufacturer's declaration - electromagnetic Immunity			
The SineBravo is intended for use in the electromagnetic environment specified below. The customer or the user of the SineBravo should assure that it is used in such an environment			
Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: ±2 kV input/output lines: ±1 kV	Not Applicable	SineBravo is powered by batteries
Surge IEC 61000-4-5	line(s) to line(s): ±1 kV. line(s) to earth: ±2 kV. 100 kHz repetition frequency	Not Applicable	SineBravo is powered by batteries
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phases 0% U _T for 0.5 cycle And at single phase 0° 0% U _T for 1 cycle 70% U _T for 25/30 cycles 0% U _T for 250 cycles 0% U _T for 300 cycles	Not Applicable	SineBravo is powered by batteries
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC61000-4-6	150 KHz to 80 MHz: 3 Vrms 6 Vrms (in ISM and amateur radio bands) 80 % AM at 1 kHz	150 KHz to 80 MHz: 3 Vrms 6 Vrms (in ISM and amateur radio bands) 80 % AM at 1 kHz	Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	
NOTE 1: U _T is the a.c. mains voltage prior to application of the test level. NOTE 2: At 80 MHz the higher frequency range applies. NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Electromagnetic Compatibility

Guidance and manufacturer's declaration - electromagnetic Immunity

The **SineBravo** is intended for use in the electromagnetic environment specified below. The customer or the user of the **SineBravo** should ensure that it is used in such an environment

Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
	450	380 – 390	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
	745						
	780						
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28
	870						
	930						
	1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
1845							
1970							
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28	
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9	
5240							
5785							

Not for sale or use in the USA

This device is presented by:

