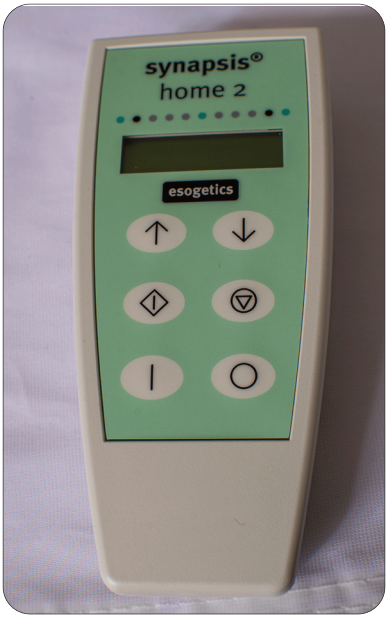
synapsis ® home 2



Instruction Manual

ESOGETICS
healing power of colors

Table of Contents

1. General Description, Purpose and Effect

1.1 General Description

The electro-therapy system Synapsis Home 2 produces low frequency pulsations of very low voltage amplitude and specific frequency scanning. They are administered at the wrists or at selected cutaneous zones stratum corneum) and acupuncture points.

As very low voltages are used, only an infinitesimal energy transfer takes place. The effect results from the resonance of the applied rhythmic signals with the sensitive sensory mechanisms of the skin surface and their regulatory interaction with functionally important cerebral areas. The administered specific frequency patterns encompass the range from 1 Hz to 100 Hz and are thus corresponding to the frequency sequences of the human brain.

1.2 Purpose/Operating environment

The purpose of the generic product family Synapsis is the supportive application for mood swings, mental exhaustion/stress symptoms and sleep disorders by means of electrotherapy stimulation. Mental fatigue/stress and sleep disorders by means of electrotherapy stimulation achieved by applying the device via cuffs to the wrists and/or via adhesive electrodes or a point applicator selectively to zones and acupuncture points of the skin (stratum corneum).

The Synapsis Home 2 instrument is used in the clinical setting or at home.

The Synapsis Home 2 instruments can be used by all users starting at the age of 9, independent of size, weight or gender.

The International Mandel Institute, Esogetics GmbH and partners of the Esogetics GmbH are offering trainings and courses for the electro-therapy (induction therapy).

Literature about the electro-therapy stimulation (induction therapy):

Peter Mandel: The Induction Therapy of Esogetic Medicine

1.3 User Groups, Prospective users, Environment

The intended users are people who have been instructed by an experienced user.

2. First Use - Proper Handling

The electro-therapy system Synapsis Home 2 consists of a convenient battery-powered regulatory unit, a connector cable and the manual. The instrument and its parts are kept in a plastic case (illustr. 1).

illustr. 1 – Instrument, connector cable, manual and case

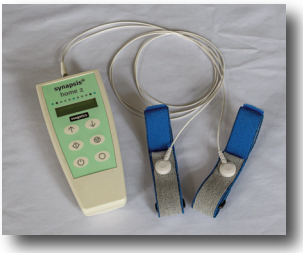
The Synapsis Home 2 instrument has a socket for the hookup of the connector cable (illustr. 2).

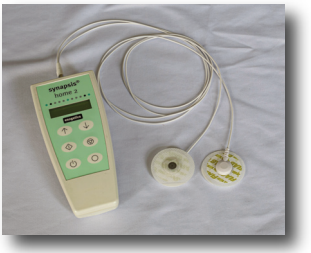
illustr. 2 – Instrument/ socket

The connector cable of the Synapsis Home 2 instrument possesses an interface for the attachment of certified sticky electrodes (one time use electrodes) and certified wrist cuffs.

To get the instrument ready insert the round plug of the connection cable into the socket on the top of the instrument, aligning the two red dots (illustr. 2).

Connect the respective corresponding ends with the certified wrist cuffs (illustr. 3) or the certified sticky electrodes (illustr. 4). The instrument is now ready for use



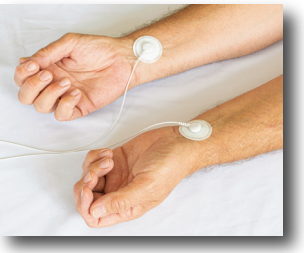


illustr. 3 and 4 – Instrument, connector cable and cuffs/sticky electrodes

2.2 This is how you start a treatment

To start a treatment, attach one wrist cuff to the left wrist and the other to the right one (illustr. 5).

Alternatively you can use the single use electrodes at the wrist (illustr. 6).



illustr. 5 and 6 – Connector cable and cuffs/sticky electrodes at the wrist

After adequate training/ instruction the sticky electrodes (single use electrodes) may be positioned at select zones on the skin (stratum corneum) as well, taking the listed indications into account (see 1.2. Purpose/Operating environment)

To switch the instrument on you use the ⏽ button. That leads you to the selection menu with the ⏵ button. With the ↑ button and the ↓ button you choose the desired program, which you would like to use for the treatment. The chosen program is marked on the display with an arrow pointing towards the right

illustr. 7 – Synapsis Home 2 device with its buttons from above

After the selection of the program the application is activated by pushing the ⏵ button. Now the application has turned active. The display shows you the selected program, the treatment time remaining and the frequency that is put to use at the moment. The treatment can be terminated ahead of time by pressing the ⏹ button. If the treatment runs its full course the end of the treatment will be indicated by a triple audio signal. You can also turn off the instrument by pressing the ⏻ button.

The instrument will automatically shut down, if no treatment is active and no buttons have been pressed for the past 30 seconds. This will conserve your battery life.

The round plug may stay in the socket in between treatments. If you should not be using the device for a longer period, then you may unplug it.

Additional programs can be installed in the instrument. In order to do so, please perform the following steps:

illustr. 8 and 9 – Device and SD card

Insert the SD card into the slot on the left side of the instrument. The contacts are pointing up (illustr. 8)

Switch the instrument on with the ⏻ button. Afterwards press the ⏎ button. The instrument will install the additional programs. Remove the SD card from the instrument. A slight pressure will activate the spring-loaded mechanism to eject the card from the device (illustr. 10)

illustr. 10 – Device and SD card from the side

Caution: The interface is only approved for use with the SD card and the explicit purpose of installing new programs. The user needs to be disconnected from the device before doing so.

3. Contraindications, Precautions and Adverse Effects

3.1 Contraindications

- Pregnancy
- Severe myocardial disease or severe cardiac arrhythmia
- Cardiac pacemaker, especially with treatments in the upper part of the body
- Treatment near the carotid sinus (on the side of the neck)
- Treatments on damaged skin, or open wounds, or other invasive treatment.

3.2 Side-effects

In adherence to the above listed contraindications and the designated use of the instrument there are no known side-effects. In case there are any undesirable side-effects or events, they should immediately be reported to the manufacturer Esogetics GmbH in Bruchsal.

3.3 Precautions

In case of any of the following symptoms or indications it is mandatory to consult your physician or non-medical practitioner prior to treatment with the Synapsis Home 2:

- highly inflammatory illnesses accompanied by fever,
- advanced, malignant tumors,
- thromboses,
- psychoses,
- epilepsy,
- spastic paralysis,
- inflammatory skin conditions,
- metallic implants in the area of the treatment,
- active implants.

The Synapsis Home 2 device may never be used in the vicinity of a therapeutic shortwave or microwave device (minimum distance requirement 1 m = 3 ft.) The simultaneous treatment with the Synapsis Home 2 System and a high-frequency surgical instrument is inadmissible.

4. Number of Treatments and Intervals between Treatments

You can use the treatment programs daily. The duration of a program is a maximum of 45 minutes. Please note that only one program may be used per day.

5. Cleaning and Maintenance

No special maintenance is required for Synapsis Home 2. You can clean the casing and accessories with a damp cloth and regular, mild household cleansers and disinfectants.

To clean the wristbands, use detergents (non ionic surface active agents) and disinfecting solutions (components with quaternary ammonium of 0,1 – 0,2%) must be used. For the use of these products follow the relative instructions. After cleaning rinse the wristbands under running water.

The life of the bracelets is a direct result of the applications, the conditions of maintenance and storage. As soon as any signs of material deterioration appear the wristbands must be eliminated. **In any case, it is recommended that the wristbands be replaced every 6 months.**

Attention: Never clean the device with organic solvents or abrasive cleansers. These substances may damage the casing or the keypad.

To clean the cuffs please follow the instructions of the manufacturer.

Observe the manufacturer's recommendations in regard to the life expectancy of the wrist cuffs.

6. Inspection, Maintenance and Repairs

6.1 State of the Battery Charge

If battery power is too low, a "Low-Battery" message will appear on the display. To change the battery, open the battery case at the back of the instrument and remove the battery

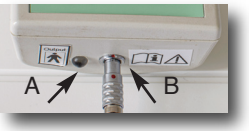
Attention : Batteries are hazardous waste and must be disposed of according to regulations. Specialty retailers usually supply battery disposal boxes.) Observing the correct polarity, attach the battery clip to the new battery and close the battery case.

Caution: Disconnect the user from the device prior to battery replacement.

If you are not using your equipment for an extended time, please remove the battery. Any battery leakage might otherwise destroy your unit.

6.2 Monitoring Proper Function

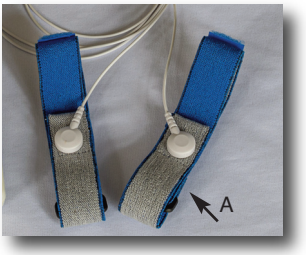
In order to monitor its proper function the instrument has an indicator bulb (illustr. 11/A) on top of the instrument beside the port for the round plug (illustr. 11/B).



illustr. 11 – Device/ socket/ indicator bulb

To test the proper function, please insert the round plug into the port on top. Attach the cuffs to the connecting cable and start an application, as described in chapter 2.2.

Touch the silver plated surfaces of the cuffs to each other (illustr. 12/A)



illustr. 12 – Cuffs

In case of proper function the orange indicator bulb (illustr. 10/A) will be flashing. Terminate the program by pushing the button ⏻.

6.3 Maintenance

There is no special maintenance required for the instrument. In case of uncertainties or complaints about the functionality, please contact the manufacturer directly: Esogetics GmbH in Bruchsal, Germany.

Only the manufacturer or persons appointed by the manufacturer are authorized to repair or make changes to the instrument.

We assume no liability for inappropriate changes and handling that does not conform to the described purpose of use.

7. Warranty

The warranty period for the instrument is one year from the date of purchase. Please contact the manufacturer directly, if your instrument does not work properly although you have handled it correctly. Your faulty unit will be immediately repaired or substituted.

8. Technical Data of the Control Unit

Type designation:	Synapsis Home 2
Power supply:	9 V E-Block / 6LR61 / 6LF22
Nominal current:	17 mA
Type of construction:	Hand-held unit
Protection rating:	III
Humidity protection rating:	IP 65
Duration of treatment:	45 minutes maximum
Auto-Off:	At the end of the treatment
Output voltage (unloaded 1 kOhm)	5V pp; 1,6 V rms
Output voltage (loaded 1 kOhm)	5V pp; 0,5 V rms
Output current (loaded 1 kOhm):	0,5 mA
Output frequency:	1 Hz – 100 Hz
Output current (loaded 1 kOhm)	0,5 mA
Weight:	155 g (including battery)
Measurements:	141 x 63 x 34mm
Service conditions:	+5°C to 35°C
Storage:	-20°C to 70°C
Air pressure:	800 hPa to 1030 hPa
Air humidity:	30% to 93%

Contents of the package:
Control unit Synapsis Home 2, instruction manual, connector cables for wrist cuffs

Spare Parts and Accessories:
Spare connector cable, adapter for 2 connector cables

9. Applied Standards and Guidelines
Electrical Safety: “Elektrische Sicherheit” DIN EN 60601-1:2013
Electromagnetic Compatibility: “Elektromagnetische Verträglichkeit” DIN EN 60601-1-2:2016

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Mail: Info-de@esogetics.com

Appendix
10. Symbols:


Device on


Device off


Scroll down (program selection)


Scroll up (program selection)


Select the highlighted program


Terminate the running program immediately


The conformity of the device with the relevant EU directives is validated through the CE sign.


Refers to the necessity for the user to consult the manual.


Device type BF according to IEC/EN 60601-1


Refers to the necessity for the therapist to consult the manual in regard to important security related statements, like warnings or cautionary alerts, which could not be attached to the product directly for a variety of reasons.


Indicates the manufacturer of the product.

The crossed out trashcan symbol on your product signifies that this product is an electrical and electronic device that is subject to special waste disposal regulations. To enforce recycling, and WEEE waste management (Waste Electrical and Electronic Equipment) and to save the environment and protect health, the European regulations proposes two options for the selective collection of devices taken out of service:

- The dealer takes the old item back, when you buy a new one.
- Old items can be recycled at specific collection sites.

Defines the temperature limits that the product can safely be subjected to.

Defines the range of humidity in which the product functions securely.

Defines the air pressure, which the product safely tolerates.

Serial Number
Serial Number
XX JJJJ - xxxxx — Continuous serial no.
└ Production year
└ Device type
(**SP W** = „point 2“; **SW W** = „wave 2“; **SH W** = „home 2“)

Example:
SH W 2023 03937 = synapsis home 2 from 2023 with the no. 3937.

Appendix 1

EMV Tables

Guidance and manufacturer's declaration - electromagnetic emissions

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
Warning: Use of accessories, transducers and cables 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.
Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the synapsis home 2, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
The synapsis home 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the synapsis home 2 should assure that it is used in such an environment.
Not mentioned test sections are not applicable for synapsis home 2.

Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The synapsis home 2 uses RF energy only for ist internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The synapsis home 2 is suitable in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	

Guidance and manufacturer's declaration - electromagnetic immunity			
The synapsis home 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the synapsis home 2 should assure that it is used in such an environment(home healthcare environment – excluding outdoors, vehicles and public places).			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV ± 15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
magnetic field Power frequency (50/60) Hz magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	V1 = 6 Vrms 150 kHz – 80 MHz V1 =	6 Vrms	
Radiated RF IEC 61000-4-3	E1 = 10 V/m for home healthcare environment 80 MHz – 2,7 GHz	10 V/m	Field strengths 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

Guidance and manufacturer's declaration - high frequency wireless communication devices				
Test frequency (MHz	**Service**	**Maximum power (W)**	**Distance (m)**	**Test level (V/m)**
385	TETRA 400 (380... 390MHz)	1,8	0,3	27
450	GMRS 460, FRS 460 (430...470MHz)	5	0,3	28
710, 745, 780	LTE Band 13/ 17 (704...787MHz)	0,2	0,3	9
810, 870, 930	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 (800...960MHz)	2	0,3	28
1720, 1845, 1970	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1/ 3/ 4/ 25, UMTS (1.7...1.99GHz)	2	0,3	28
2450	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band7 (2.4...2.57GHz)	2	0,3	28
5240, 5500, 5785	WLAN 802.11 a/ n (5.1...5.8GHz)	0,2	0,3	9

Name of the program	Description of the fields of application	t/min
Relaxation Programs		
Rest 1	Program for deep, inner relaxation	30
Rest 2	For any present time stress	30
Sleep 1	Supportive in problems of falling or staying asleep	30
Sleep 2	Regulates particularly the sleep rhythm	45
Dream	Stimulating dream activity	45
Conflict Resolution Programs		
Conflict Resolution Programs	Resolution and organization of individual conflicts	40
Children 1	Stress between ages 6 and 9	35
Children 2	Stress between ages 9 and 12	35
Gamma long	Resolution of blockages through the use of the meditative vibration	42
Gamma short	Resolution of blockages through specific reflex zones	10
Stress Programs		
Stress Basic	Resolution of psychological tension	30
Stress Immune	To support the immune system in the case of stress-related strains	35
Stress Hormone	For support with stress-related strains of hormonal symptoms	40
Stress Spasm	Basic program for support in cases of migraine and headaches	42
Depression/Psyche		
Psyche 1	For support with Fatigue, weariness, listlessness	30
Psyche 2	For support with nervousness and mood swings	30
Psyche 3	For support with hormonal mood swings	38
Cerebral/Mental Programs		
Cerebral	Stimulation of brain activity, increasing wakefulness	35
Learning	Supports in case of learning disabilities and concentration problems	35
Memory	Increase of intellectual ability and stimulation of creativity	35
Additional Programs		
Waking	For support with exhaustion, reconvalescence, chronic fatigue, complaints of the elderly	35
Degeneration	Basic therapy in all degenerative diseases	45
Power-Nap	Regeneration program for the elimination of daily stress	15
Addiction	For support in the case of stress-related addictions	45

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