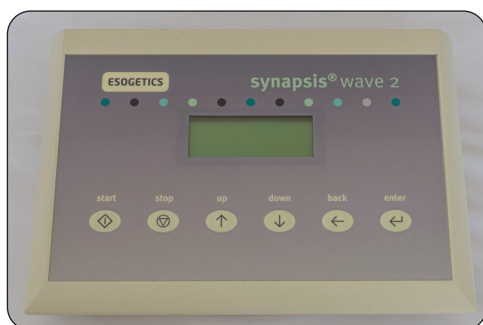


synapsis® wave 2



INSTRUCTION MANUAL



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1. General Description, Purpose and Effect

1.1 General Description

The electro-therapy system Synapsis Wave 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 Medical Purpose

The purpose of the generic Synapsis family of products is to support the treatment of depression, mental exhaustion/ stress and insomnia through electro-therapy stimulation. The application is through cuffs at the wrists and/or sticky electrodes or the use of a point applicator at zones and acupuncture points of the skin (stratum corneum).

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, Schriftenreihe Esogetische Medizin: „Die Induktionstherapie“;

Robert Füß: Die Induktionstherapie, Esogetics GmbH, Bruchsal.

1.3 User Groups, Prospective patients, Environment

The intended users are instructed trained therapists or professionals (therapist, physician, naturopath), as well as patients who have been instructed by a therapist.

The Synapsis Wave 2 instrument is used in the clinical setting.

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

2. First Use - Proper Handling



illustr. 1 – Instrument, manual and packaging

The electro-therapy system Synapsis Wave 2 consists of a standing unit, powered by an external power supply, a connector cable and a manual. The Synapsis Wave 2 device and its accessories are packaged in case (illustr. 1).



adapter from the back

When using the device, an approved power adapter is attached at the back of the instrument and connected to the electric outlet. Please insert the round plug of the power adapter into the back of the device and connect the adapter to the outlet.

illustr. 2 – Synapsis Wave 2 device and power



illustr. 3 – Instrument/ socket

The Synapsis Wave 2 instrument also has a socket for the hookup of the connector cable (illustr. 3).

The connector cable of the Synapsis Wave 2 instrument possesses an interface for the attachment of appropriate merchandise like certified sticky electrodes and certified wrist cuffs.



illustr. 4 – Instrument, connector cable and 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. 3).



illustr. 5 – Instrument, connector cable and sticky electrodes

Connect the respective corresponding ends with the certified wrist cuffs (illustr. 4) or the certified sticky electrodes (illustr. 5). The instrument is now ready for use.

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. 6).

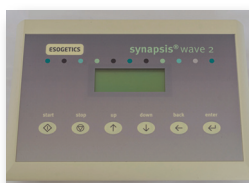
Alternatively you can use the single use electrodes at the wrist (illustr. 7).







illustr. 6 and 7 – Connector cable and cuffs/sticky electrodes at the wrist




After adequate training/ instruction the sticky electrodes (single use electrodes) may also be positioned at select zones and acupuncture points on the skin (stratum corneum), taking the listed indications into account (see 1.2. Medical Purpose)

To switch the instrument on you move the power switch at the back of device to ON. The instrument is now ready.



With the  button you enter the selection menu. The  and the  buttons allow you to choose the desired program. To confirm your selection you push the  button once more.

illustr. 8 – Synopsis Wave 2 device with buttons from above

The display is now showing the selected program, its duration and its readiness. To start the program please push the  button. The displays shows that the program is running for the set time and frequency. To terminate the program prematurely you may push the  button. To return you can select the  button. If there is no active application running, please switch the instrument off in the back.


The round plug may stay in the socket in between applications.

If you are not using the instrument for an extended period, we recommend unplugging it.

Further programs can be stored in the instrument. A SD card for the storage of additional programs is sent to you. To store the program the following steps need to be followed:



illustr. 9 und 10 – Synapsis Wave 2 device from the back


Turn the power switch in the back of the instrument to o (OFF). Place the chip card into the back of the device (illustr. 10). The contacts are pointing downward. Turn the power switch in the back of the instrument to I (ON) and push the button .

The device is storing 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. 11)

illustr. 11 – Synapsis Wave 2 device and SD card

 **Caution:** The interface is only approved for use with the SD card and the explicit purpose of installing new programs. The patient needs to be disconnected from the device before doing so. Connections with other devices require their certification according to IEC 60601-1.



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 Wave 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 Wave 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 Wave 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 Wave 2. You can clean the casing and accessories with a damp cloth and regular, mild household cleansers and disinfectants.

 **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 Monitoring Proper Function




illustr. 12 – Device/ socket/ indicator bulb

In order to monitor its proper function the instrument has an indicator bulb (illustr. 12/B) at the back of the instrument beside the port for the round plug. To test the proper function, please insert the round plug into the port at the back (illustr. 12/A). Attach the cuffs to the connector cable and start an application, as described in chapter 2.2



Touch the silver plated surfaces of the cuffs to each other (illustr. 13/A)

illustr. 13 – Cuffs

In case of proper function the orange indicator bulb (illustr. 12/B) will be flashing. Terminate the program by pushing the  button.

6.2 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 Wave 2
Power supply:	12 V
Nominal current:	70 mA
Type of construction:	Table unit
Protection rating:	IP 40
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:	1200 g
Measurements:	300 x 227 x 54 mm
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 Wave 2, instruction manual, 2 connector cables for wrist cuffs

Spare Parts and Accessories:

Spare connector cable.



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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Download of the instruction manuals under:

www.esogetics.com/downloads

Esogetics is a manufacturer of wellness equipment as well as a registered medical device manufacturer and. We adhere to a certified and monitored quality management system.

Appendix

10. Symbols:



Confirm selection



Back



Scroll down (program selection)



Scroll up (program selection)



Start 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.



Note the polarity of the electrical adapter



Serial Number

Serial Number

The Serial no. of your Synapsis device is configured as follows:

XX **JJJJ** - **xxxxxx** Continuous serial no.

└─ Production year

└─ Device Type

(**SP 2** = „point 2“; **SW 2** = „wave 2“; „**SH 2** = home 2“)

Example:

SW 2 2017 03937 = synapsis wave 2 from 2017 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 synopsis wave 2, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The synopsis wave 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the synopsis wave 2 should assure that it is used in such an environment.

Not mentioned test sections are not applicable for synopsis wave 2.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The synopsis wave 2 uses RF energy only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The synopsis wave 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.

Guidance and manufacturer's declaration - electromagnetic immunity

The synopsis wave 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the synopsis wave 2 should assure that it is used in such an environment (wave 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	$V_1 = 6$ Vrms 150 kHz – 80 MHz $V_1 =$	6 Vrms	
Radiated RF IEC 61000-4-3	$E_1 = 10$ V/m for wave 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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