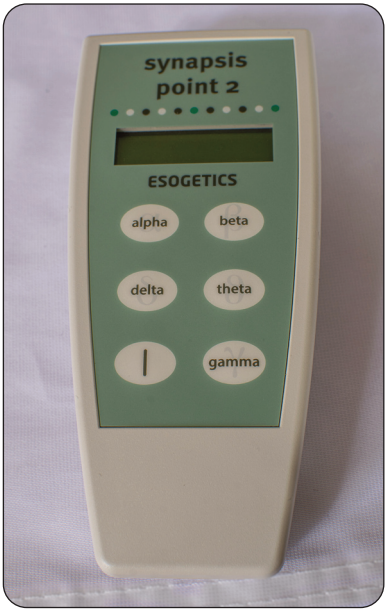
synapsis ® point 2



Instruction manual

ESOGETICS
healing power of colors

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1. General Description, Purpose and Effect

1.1 General Description

The electro-therapy system Synapsis Point 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

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 Point 2 instrument is used in the clinical setting.

The Synapsis Point 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

The electro-therapy system Synapsis Point 2 consists of a convenient battery-powered regulatory unit, a point applicator and a handheld electrode, as well as the manual. The instrument and its accessories are kept in a plastic case (illustr. 1).

illustr. 1 – Instrument, point applicator, manual and case

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

illustr. 2 – Instrument/ socket

The connector cable of the Synapsis Point 2 instrument possesses an interface for the attachment of the point applicator accessory.

To get the instrument ready, please insert the round plug of the point applicator into the socket on the top of the instrument, aligning the two red dots (illustr. 2 and 3). The instrument is now ready for use.

illustr. 3 – Instrument and point applicator

2.2 This is how you start a treatment

By pushing the ⏻ button the device is switched on. While the patient is holding the cylindrical electrode in his hand, the practitioner is positioning the point applicator on a selected zone or acupuncture point (illustr. 5) of the skin (stratum corneum). Then the program button Beta, Delta, Alpha, Theta or Gamma is pushed to start the chosen program (illustr. 4).

illustr. 4 – Synapsis Point 2 device with buttons from above

The running application is visualized through a blinking indicator light. A repeated pushing of the program button Beta, Delta, Alpha, Theta or Gamma will terminate the program immediately at any

time. After the completion of the program sequence the instrument switches off automatically. The round plug can remain in the socket in between applications. If you are not using the device for an extended period, you might want to remove the round plug.

illustr. 5 – Example of use

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 Point 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 Point 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 Point 2 System and a high-frequency surgical instrument is inadmissible.

4. Cleaning and Maintenance

No special maintenance is required for the Synapsis Point 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.

5. Inspection, Maintenance and Repairs

5.1 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.

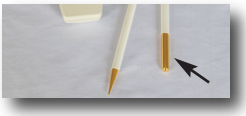
Caution: Disconnect the patient from the device prior to battery replacement. If you are not using your equipment for an extended time, please remove the battery. Any battery leakage might otherwise destroy your unit.

5.2 Monitoring Proper Function

In order to monitor its proper function the instrument has an indicator bulb on top of the instrument beside the port for the round plug (illustr. 6).

illustr. 6 – Device/ socket/ indicator bulb

To test the proper function, please insert the round plug into the port on top (illustr. 6). Attach the point applicator and start an application, as described in chapter 2.2



illustr. 7 – Point applicator and hand electrode

Touch the point applicator (illustr. 7) to the hand electrode (illustr. 7). In case of proper function the orange indicator bulb (illustr. 6) will be flashing. Terminate the program by pushing the program button once more.

5.3 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.

6. 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.

7. Technical Data of the Control Unit

Type designation:	Synapsis Point 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:	30 second timer with auto-off 30 sec. after the last keystroke
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 Point 2, instruction manual, point applicator and a hand electrode.

Spare Parts and Accessories:
Point applicator and hand electrode.

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/Symbols:

Device on

Beta

Delta

Alpha

Theta

Gamma

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.

SN Serial Number

Serial Number

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

XX JJJJ - xxxxx — Continuous serial no.
- JJJJ: Production year
- XX: Device Type
  (**SP 2** = „point 2“; **SW 2** = „wave 2“; „**SH 2** = home 2“)

Example:

SP 2 2017 03937 = synapsis point 2 from 2017 with the no. 3937.

Appendix 1

EMV Tables

Leitlinien und Herstellererklärung
Elektromagnetische Aussendungen

Warnung: Die Verwendung dieses Geräts neben oder in Verbindung mit anderen Geräten sollte vermieden werden, da dies zu Fehlfunktionen führen kann. Wenn eine solche Verwendung notwendig ist, sollten diese Ausrüstung und die andere Ausrüstung beobachtet werden, um zu überprüfen, dass sie normal funktionieren.
Warnung: Die Verwendung von Zubehör, Wandlern und Kabeln, die nicht vom Hersteller dieses Geräts angegeben oder zur Verfügung gestellt werden, kann zu erhöhten elektromagnetischen Emissionen oder einer verringerten elektromagnetischen Immunität des Gerätes führen und dessen unsachgemäßen Betrieb bedingen.
Warnung: Tragbare HF-Kommunikationsgeräte (einschließlich Peripheriegeräten wie Antennenkabeln und externen Antennen) sollten nicht näher als 30 cm (12 Zoll) an irgendeinem Teil des synapsis point 2 verwendet werden.
Das synapsis point 2 ist für den Betrieb in einer wie unten angegebenen Umgebung bestimmt. Der Kunde oder der Anwender des synapsis point 2 sollte sicherstellen, dass es in einer derartigen Umgebung betrieben wird. Nicht erwähnte Prüfabschnitte sind für das synapsis point 2 nicht anwendbar.

Störaussendungen	Übereinstimmung	Elektromagnetische Umgebung – Leitfaden
HF-Aussendungen CISPR 11	Gruppe/Group 1	Das synapsis point 2 verwendet HF-Energie ausschließlich zu seiner internen Funktion. Daher ist seine HF-Aussendung sehr gering, und es ist unwahrscheinlich, dass benachbarte elektronische Geräte gestört werden. Das synapsis point 2 ist für den Gebrauch in allen Einrichtungen einschließlich denen im Wohnbereich und solchen, geeignet, die unmittelbar an ein öffentliches Versorgungsnetz angeschlossen sind, das auch Gebäude versorgt, die zu Wohnzwecken benutzt werden.
HF-Aussendungen CISPR 11	Klasse/Class B	

Leitlinien und Herstellererklärung
Elektromagnetische Aussendungen

Das synapsis point 2 ist für den Betrieb in einer wie unten angegebenen Umgebung bestimmt. Der Kunde oder der Anwender des synapsis point 2 sollte sicherstellen, dass es in einer derartigen Umgebung betrieben wird (häusliche Pflegeumgebung - außer im Freien, Fahrzeugen und an öffentlichen Orten).
Nicht erwähnte Prüfabschnitte sind für das synapsis point 2 nicht anwendbar.

Störfestigkeits-prüfungen	**IEC 60601 Prüfpegel**	**Übereinstim-mungspegel**	**Elektromagnetische Umgebung – Leitlinien**
Entladung statischer Elektrizität (ESD) IEC 61000-4-2	± 8 kV Kontaktentladung ± 15 kV Luftentladung	± 8 kV ± 15 kV	Fußböden sollten aus Holz oder Beton bestehen oder mit Keramikfliesen versehen sein. Wenn der Fußboden mit synthetischem Material versehen ist, muss die relative Luftfeuchte mindestens 30 % betragen.
Magnetfelder bei der Versorgungs-frequenz (50/60) Hz IEC 61000-4-8	30 A/m	30 A/m	Magnetfelder bei der Netzfrequenz sollten den typischen Wert, wie sie in der Geschäfts- und Krankenhaus-umgebung vorzu-finden sind, entsprechen.
Geleitete HF-Störgrößen IEC 61000-4-6	V1 = 6 Vrms 150 kHz – 80 MHz V1 =	6 Vrms	
Gestrahlte HF-Störgrößen IEC 61000-4-3	E1 = 10 V/m für häusliche Gesundheits-umgebung 80 MHz – 2,7 GHz	10 V/m	Die Feldstärke stationärer Funk-sender sollte bei allen Frequenzen gem. Einer Unter-suchung vor Ort geringer als der Übereinstimmungs-pegel sein. In der Umgebung von Geräten, die das folgende Bild-zeichen tragen, sind Störungen möglich

Leitlinien und Herstellererklärung - Hochfrequente drahtlose Kommunikationseinrichtungen				
Prüf-frequenz (MHz)	**Funkdienst / Service**	**Leistung (W)**	**Entfernung (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 Band 7 (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

Programmname	Beschreibung der Anwendungsbereiche	t/min
Entspannungsprogramme		
Ruhe 1	Programm zur tiefen, inneren Entspannung	30
Ruhe 2	Bei allen aktuellen Stressbelastungen	30
Schlaf 1	Unterstützt bei Ein- und Durchschlafstörungen	30
Schlaf 2	Reguliert besonders die Schlafrhythmik	45
Traum	Anregung der Traumaktivität	45
Konfliktlösungsprogramme		
Konflikt	Lösen und ordnen von individuellen Konflikten	40
Kinder 1	Bei Belastungen zwischen dem 6. und 9. Lebensjahr	35
Kinder 2	Bei Belastungen zwischen dem 9. und 12. Lebensjahr	35
Gamma lang	Lösung von Blockaden mit der Kraft der Meditatiosschwingung	42
Gamma kurz	Lösung von Blockaden über spezifische Reflexzonen	10
Stressprogramme		
StressBasis	Zur Lösung psychischer Verkrampfungen	30
StressImmun	Zur Unterstützung bei stressbedingten Belastungen des Immunsystems	35
StressHormon	Zur Unterstützung bei stressbedingten Belastungen des hormonellen Symptomen	40
StressKrampf	Basisprogramm zur Unterstützung bei stressbedingten cerebralen Verkrampfungen	42
Depression/Psyche		
Psyche 1	Zur Unterstützung bei Müdigkeit, Erschöpfung, Abgeschlagenheit	30
Psyche 2	Zur Unterstützung bei Nervosität und Stimmungsschwankungen	30
Psyche 3	Zur Unterstützung bei hormonellen Stimmungsschwankungen	38
Cerebral/Mentale Programme		
Cerebral	Aktivierung der Gehirntätigkeit, Steigerung der Wachheit	35
Lernen	Unterstützt bei Lernschwäche und Konzentrationsstörung	35
Erinnerung	Steigerung der intellektuellen Fähigkeit, Anregung der Kreativität	35
Weitere Programme:		
Erwachen	Zur Unterstützung bei Erschöpfung, Rekonvaleszenz, unüberwindliche Müdigkeit, Altersbeschwerden	35
Degeneration	Aufbauprogramm tiefer Erschöpfung und Lösung von Blockaden	45
Power-Nap	Regenerationsprogramm zum Abbau des täglichen Stress	15
Sucht	Zur Unterstützung bei stressbedingten Suchtbelastungen	45

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