Anexa 35 Echipament de terapie combinată (2 canale de electroterapie cu o gamă extinsă de curenți, ultrasunete) cu ecran digital cu posibilitatea tratării a 2 pacienți în același timp cu terapii diferite,

#### PhisyoGo.Lite COMBO, Astar

Echipament de terapie combinată (2 canale de electroterapie cu o gamă extinsă de curenți, ultrasunete) cu
ecran digital cu posibilitatea tratării a 2 pacienți în același timp cu terapii diferite

#### Specificatii tehnice ofertate Specificația solicitata PhisyoGo.Lite COMBO, Echipament de terapie combinată (2 canale de electroterapie cu o gamă extinsă de curenti, ultrasunete) Echipament de terapie combinată (2 canale de cu ecran digital cu posibilitatea tratării a 2 pacienți în electroterapie cu o gamă extinsă de curenți, același timp cu terapii diferite - Brosura, pag 1 ultrasunete) cu ecran digital cu posibilitatea Protocoale pentru diferite domenii medicale (recuperare, tratării a 2 pacienți în același timp cu terapii ortopedie, medicină sportivă, stomatologie, ginecologie, diferite. dermatologie, ORL, pediatrie, medicină generală) Da -pag Protocoale pentru diferite domenii medicale 8,97->105, manual de utilizare (recuperare, ortopedie, medicină sportivă, Protocoale de tratament predefinite de producator: 304 stomatologie, ginecologie, dermatologie, ORL, Protocoale de tratament predefinite de utilizator: >100 pediatrie, medicină generală) Da brosura pag. 2; Protocoale de tratament predefinite de utilizator Forme de undă de frecvență joasă și medie Diadinamic -Forme de undă de frecvență joasă și medie brosura pag. 2; Diadinamic, Traebert 2-5 - brosura pag. 2; Traebert 2-5, Neofaradic - brosura pag. 2; Neofaradic galvanic (Iontoforeza) - brosura pag. 2; galvanic (Iontoforeza), impulsuri rectangulare- brosura pag. 2; impulsuri rectangulare, TENS-simetric/asimetric - brosura pag. 1; TENS-simetric/asimetric, alternat și 2 poli interferenta, 4 poli interferenta, impulsuri alternat și 2 poli interferenta, 4 poli interferenta, triunghiulare - brosura pag. 1, 2; impulsuri triunghiulare, impulsuri exponențiale cu creștere, impulsuri combinate, impulsuri exponențiale cu creștere, impulsuri secvențe programabile de curenți diadinamici și alți curenți combinate, selectați - brosura pag. 2; secvențe programabile de curenți diadinamici și Sonde de emisie ergonomice multi-frecvență (1 și 3 MHz) alți curenți selectați. de 5 & 1 cm2 Da - brosura pag. 3,6,7 (**GU-1+GU5**); Sonde de emisie ergonomice multi-frecvență (1 și Dispozitivul poate fi folsit cu sonda ultrasunet SnG 17.3 3 MHz) de 5 & 1 cm2 Da cm2 – accesoriu optional. Frecvența de emisie ultrasunete Până la 3MHz Frecvența de emisie ultrasunete Până la 3MHz - brosura Mod de emisie Continuu sau pulsat pag. 3; Sonde rezistente la apă Da Mod de emisie Continuu sau pulsat - brosura pag. 2; Bază de date a pacientului Da Sonde rezistente la apă Da brosura pag. 6, 7; Afisor digital Da Bază de date a pacientului Da - brosura pag. 1; Panou de comandă Ecran tip touch-screen Afișor digital Da brosura pag. 1; Număr de canale independente 4 Panou de comandă Ecran tip touch-screen - brosura pag. 1; Alimentare 230V 50Hz Număr de canale independente 3- brosura pag. 1; Alimentare 100-240V 50/60Hz- brosura pag. 3;

# PhysioGo.Lite COMBO

## multifunctional unit





#### **ERGONOMICS**

- 5" color touchscreen
- three independent treatment channels
- · intensity in patient circuit can be adjusted for both channels simultaneously or separately
- · electrodes test
- possibility of two SnG heads operating simultaneously, their total area of head front in dualsection equals 34,6 cm<sup>2</sup>
- · manual mode
- · treatment programs selected by name or medical field
- preset treatment programs database
- preset treatment sequences database (electrotherapy)
- · user programs database
- user sequences database (electrotherapy)
- list of favorite programs
- names of user programs and sequences can be edited
- · built-in encyclopedia with treatment methodology
- availability of LIPUS therapy
- · statistics of performed treatments
- buzzer volume adjustment
- · optional battery



#### **ELECTROTHERAPY**

- CC (constant current) mode or CV (constant voltage) mode operation
- complete galvanic insulation between the channels in each mode

#### **CURRENTS AND METHODS**

- isoplanar interferential currents
- dynamic interferential currents
- one-channel AMF interferential current
- TENS symmetric
- TENS asymmetric
- TENS with alternately changing polarization
- TENS Burst
- TENS for spastic paralysis



- Kotz' current (Russian stimulation)
- tonolysis
- Hufschmidt stimulation
- diadynamic currents (MF, DF, CP, CP-ISO, LP, RS, MM)
- rectangular pulse currents
- triangular pulse currents
- Ultra Reiz current (Träbert's current) (2 5)
- Leduc's current (1 9)
- neofaradic pulse currents
- unipolar sine surge
- bipolar sine surge
- galvanic current
- microcurrents
- medium frequency MF currents
- IG pulses
- EMS currents
- H-waves
- exponential pulses



#### **ULTRASOUND THERAPY**

- · water resistant heads
- continuous/ pulse emission mode
- lack of US head contact detection (effective treatment time measured)
- US head temperature control
- · US head sensitivity adjustment

#### **ULTRASOUND HEADS**

GU-1 type  $1 \text{ cm}^2$ ; 1/3 MHz GU-5 type  $5 \text{ cm}^2$ ; 1/3 MHz  $17,3 \text{ cm}^2$ ; 1/3 MHz  $17,3 \text{ cm}^2$ ; 1/3 MHz

#### **COMBINED THERAPY**

• CC (constant current) mode or CV (constant voltage) mode operation

#### **CURRENTS IN COMBINED THERAPY**

- TENS pulse currents
- AMF current
- Kotz' current
- Medium frequency currents
- EMS

#### TREATMENT PROGRAMS

•	preset treatment programs, including:	304
	pre-defined treatment programs for electrotherapy	71
	pre-defined treatment programs for ultrasound therapy	156
	pre-defined treatment programs for combined therapy	77
•	user-defined programs – electrotherapy	50

- user-defined programs ultrasound therapy
   50 (for each applicator)
- user-defined programs combined therapy 50
- · favorite programs



#### **TREATMENT SEQUENCES**

preset treatment sequences for electrotherapy
 user-defined sequences
 10



#### **TECHNICAL SPECIFICATION**

Electrotherapy parameters

max. current intensity in patient circuit (CC mode)

unipolar sine surge
 galvanic, IG
 diadynamic
 bipolar sine surge, Hufschmidt stimulation
 interferential TENS (Actal stimulation pulse surrents AE)

 interferential, TENS, Kotz's stimulation, pulse currents, MF, tonolysis, EMS, H-waves, exponential pulses

- microcurrents  $1000 \ \mu A$  • max. voltage amplitude in the patient circuit (CV mode)  $140 \ V$ 

• treatment timer 1 – 60 minutes

Ultrasound parameters

frequency of operation
 total area of the head front GU-1; GU-5; SnG
 1 MHz and 3 MHz
 1 cm<sup>2</sup>; 5 cm<sup>2</sup>; 17,3 cm<sup>2</sup>

• max. ultrasound intensity 2/3 W/cm<sup>2</sup>

• frequency in pulse mode 10 – 150 Hz with a variable step

for GU-1, GU-5, SnG

1 kHz LIPUS

140 mA

• regulated duty factor in pulse mode

• treatment timer 30 s – 30 minutes

General parameters

• device dimensions 25,0 x 27,0 x 16,5 cm

weight max. 3 kg
 battery type (optional) Li-lon
 battery capacity (optional) 2100 mAh

mains supply
 100 – 240 VAC, 50/60 Hz,

24 VDC, 2,5 A



#### **STANDARD ACCESSORIES**

STANDARD ACCESSORIES	
mains cable with filter	1
switch mode power supply	1
• patients' cables	2
• electrodes 6x6 cm	4
• electrodes 7,5x9 cm	2
• viscose covers 8x8 cm	8
• viscose covers10x10 cm	4
• velcro belt 40x9 cm	2
• velcro belt 100x9 cm	2
• USG gel	1
touchscreen stylus pen	1
touchscreen cleaning cloth	1
masking covers with cutout	2
• spare fuses	1
• instructions for use	1



• electrical safety test report

#### **OPTIONAL ACCESSORIES**

- self-adhesive electrodes 5x5 cm, 5x10 cm
- point electrodes with adapter 6 mm, 10 mm, 15 mm, 20 mm

1

- sand bags 21x14 cm, 21x28 cm
- GU-1 head; 1/3 MHz; 1 cm<sup>2</sup> with holder
- GU-5 head; 1/3 MHz; 5 cm<sup>2</sup> with holder
- SnG head; 1/3 MHz; 17,3 cm<sup>2</sup> with holder
- bag for the unit and accessories
- Versa/Versa X/Versa XUVC trolley
- battery





# hands-free ultrasound head/LIPUS





#### **ULTRASOUND THERAPY**

- LIPUS mode
- possibility of one US head operating in single-transducer mode, as in classical ultrasound therapy
- possibility of one US head operating in dual-transducer mode resulting from the use of the switching sequence of the ultrasonic transducers and the modulation of the ultrasonic wave
- possibility of two US heads operating in quadruple-transducer mode (dual-section)
- water resistance (IPX7)
- · continuous/ pulse mode
- · lack of contact detection
- US head temperature control
- · US head sensitivity adjustment
- hook-and-loop belts make US head strapping to the patient's body easy



#### **TECHNICAL SPECIFICATION**

Ultrasound therapy parameters

acoustic working frequency
 1 MHz, 3 MHz,

1/3 MHz (switching frequency every 8 seconds)

and LIPUS (1 MHz)

effective radiation area of one head
 total area of head front
 total area of 2 head front
 34,6 cm²

#### General parameters

dimensions without connection cable
 weight
 6,8 x 2,8 x 13,0 cm
 max. 0,5 kg



# GU-5, 5 cm<sup>2</sup>, 1/3 MHz

# ultrasound head/LIPUS





#### **ULTRASOUND THERAPY**

- LIPUS mode
- water resistance (IPX7)
- continuous/ pulse mode
- · lack of contact detection
- US head temperature control
- · US head sensitivity adjustment



#### **TECHNICAL SPECIFICATION**

Ultrasound therapy parameters

acoustic working frequency

• total area of the head front

· effective radiating area

General parameters

• dimensions without connection cable

weight

1 MHz, 3 MHz,

1/3 MHz (switching frequency every 8 seconds)

and LIPUS (1 MHz)

5 cm<sup>2</sup> 3,4 cm<sup>2</sup>

5,5 x 3,7 x 18,4 cm

max. 0,5 kg



# GU-1, 1 cm<sup>2</sup>, 1/3 MHz

# ultrasound head/LIPUS





#### **ULTRASOUND THERAPY**

- LIPUS mode
- water resistance (IPX7)
- continuous/ pulse mode
- · lack of contact detection
- US head temperature control
- · US head sensitivity adjustment



#### **TECHNICAL SPECIFICATION**

Ultrasound therapy parameters

acoustic working frequency

• total area of the head front

· effective radiating area

General parameters

• dimensions without connection cable

weight

1 MHz, 3 MHz,

1/3 MHz (switching frequency every 8 seconds)

and LIPUS (1 MHz)

1 cm<sup>2</sup> 0,7 cm<sup>2</sup>

5,5 x 3,7 x 18,4 cm

max. 0,5 kg





# PhysioGo.Lite Combo Instructions for use



#### **Contents**

1.	BASIC	INFORMATION	6
	1.1 MA	NUFACTURER	F
		K MANAGEMENT PROCESS	
_			_
2.	INTEN	DED USE	7
	2.1 INTE	ENDED USERS	8
	2.2 Use	ER TRAINING	9
3.	WARR	ANTY AND MANUFACTURER'S RESPONSIBILITY	10
4.		ATIONAL SAFETY	
	4.1 MA	NINS SUPPLY AND OPERATION MODE	11
		DRAGE, OPERATION AND TRANSPORT CONDITIONS	
		ARNINGS AND SAFETY NOTES	
		PLOSION PROOF ENVIRONMENT.	
		CTROMAGNETIC ENVIRONMENT	_
	4.6 OPE	ERATION OF TOUCH-SENSITIVE DISPLAYS	16
	4.7 App	PLIED PARTS	16
	4.8 Ess	ENTIAL PERFORMANCE	16
	4.8.1	Test of essential performance and basic safety	17
	4.9 Disi	POSAL	18
5.	UNIT [	DESCRIPTION	19
		NERAL CHARACTERISTICS	
		ONT PANEL	
	5.2.1	Operation status and battery level indicators	
		ME PLATE	
	5.4.1	UDI code	
		RRENT AND VOLTAGE STABILIZATION — CC AND CV MODE	
		DTECTION	
	5.6.1	Detection of a high resistance in the patient circuit	
	5.6.2	Electrodes condition control	
	5.6.3	Current accuracy control in CC mode	26
	5.6.4	Overcurrent in CV mode	26
	5.6.5	Information on the features of generated signal	
	5.6.6	Signaling the lack of contact of the ultrasound heads	
	5.6.7	Temperature control of ultrasound heads	
		TRASOUND HEADS	
	5.7.1	Main features of SnG head	29
6.	DEVIC	E INSTALLATION AND START-UP	30
	6.1 Uni	IT INSTALLATION	
	6.1.1	Connection of patient's cables and application of electrodes	
	6.1.2	Assembling of the holders	
	6.1.3	Connection of ultrasound heads	
	6.1.4	Connection in combined therapy	
	6.1.5	First operation	
	6.2 SET	UP MODE	
	6.2.2	Language	
	6.2.3	Global settings	
	6.2.4	Functional settings	
	6.2.5	Control functions	
	6.2.6	Information	
		ANSPORT POSITION — TROLLEY FOR THE UNIT	
7.	UNIT (	OPERATION	an
•			
	7.1 PAT 7.1.1	TIENT PREPARATION AND TREATMENT PERFORMANCE	
	7.1.1 7.1.2	General information  Electrotherapy	
	7.1.2 7.1.3	Ultrasound therapy	
	,		+ + + + + + + + + + + + + + + + +

	7.1.4	Combined therapy	
	7.1.5	Method of ultrasound therapy treatment performance	
		EN CONFIGURATION	
		ERAL CONFIGURATION	
	7.3.1	Treatment channel configuration	
	7.3.2 7.3.3	Channel selection tabs	
	7.3.3 7.3.4	Current selection screens  Configuration of detachable parts for ultrasound therapy	
	7.3.4 7.3.5	Limitations	
		LAY DESCRIPTION	
	7.4.1	Electrotherapy	
	7.4.2	Ultrasound therapy	
	7.4.3	Combined therapy	
	7.5 TREA	TMENT TIMER	51
	7.6 OPER	RATION WITH PRESET TREATMENT PROGRAMS AND SEQUENCES	51
	7.7 Favo	DRITE PROGRAMS	53
	7.8 MAN	IUAL MODE OPERATION	54
	7.9 User	R PROGRAMS	54
		JSER SEQUENCES	
		/t curve	
	7.12	AFE SHUTDOWN PROCEDURE	59
8.	DEFINI	TIONS AND PARAMETERS	60
	8.1 ELEC	TROTHERAPY	60
	8.1.1	Terminology	
	8.1.2	Output signal modulations	
	8.1.3	TENS pulse current	
	8.1.4	Interferential currents	62
	8.1.5	Kotz' current (Russian stimulation)	
	8.1.6	Medium frequency currents	
	8.1.7	SP-TENS pulse current	
	8.1.8	Diadynamic currents	
	8.1.9	Galvanic current	
	8.1.10 8.1.11	Ultra Reiz current (Träbert's current) Unipolar and bipolar sine surge	
	8.1.12	Leduc's current	
	8.1.13	Rectangular pulse currents	
	8.1.14	Triangular pulse currents	
	8.1.15	Neofaradic pulse currents	
	8.1.16	Microcurrents	79
	8.1.17	IG pulses	80
	8.1.18	EMS	
	8.1.19	H-waves	
	8.1.20	Exponential pulses	
	8.1.21	Hufschmidt stimulation	
	8.1.22	Tonolysis	
	8.2 ULTF 8.2.1	ASOUND THERAPYStandard ultrasound heads (GU-5, GU-1)	
	8.2.2	SnG head – single-transducer mode	
	8.2.3	SnG head – dual-transducer mode	
	8.2.4	SnG head – quadruple-transducer mode	
	8.2.5	Characteristics of pulse parameters	
	8.3 Com	BINED THERAPY	
	8.4 INTE	NDED CLINICAL BENEFITS OF THE THERAPIES	97
Э.	INDICA	TIONS AND CONTRAINDICATIONS	100
	INDI	CATIONS	100
	9.1.1	Electrotherapy	
	9.1.2	Ultrasound therapy	
	9.1.3	Combined therapy	
	9.2 Con	TRAINDICATIONS FOR ELECTROTHERAPY	
	9.3 Con	TRAINDICATIONS FOR ULTRASOUND THERAPY	106
	9.3.1	Absolute	
	932	Therapy limitations	106

9.4	CONTRAINDICATIONS FOR COMBINED THERAPY	106
10.	MAINTENANCE, CLEANING, DISINFECTION	107
10.	CLEANING OF THE UNIT, SWITCH MODE POWER SUPPLY AND MAINS FILTER CASING	107
10.2	2 Cleaning of Touchscreen	107
10.3		
10.4		
10.		
10.		
10.		_
10.	SEE TEST NOCES ONE	
10.9		
10.		
11.	SPECIFICATION AND PARTS OF THE UNIT	
11.:		
11.		
11.		_
11.4	4 Optional parts of the unit	117
12.	APPENDIX A. SYMBOL DESCRIPTION, I(T) CURVE DIAGRAM	118
12.	1 CONTROLLER, PARTS OF THE UNIT, PACKAGING	118
12.	2 SWITCHED-MODE POWER SUPPLY — CASING	121
Table (	of figures	
	4-1. The method of correct connection of the SMPS, mains filter and controller	11
_	5-1. General view	
_	25-2. Unit rear panel view	
	5-3. Arrangement of front panel components	
	5-4 .The battery installation method	
-	5-5. Name plate of PhysioGo.Lite Combo device	
_	5-6. Label with parameters	
_	·	
_	5-7. UDI code – example	
_	5-8. Rough diagram of the output circuit of the unit working in CV mode (one channel)	
	5-9. Presentation of information about the high resistance in the patient circuit	
	5-10. Signalization of worn electrodes	
_	5-11. SnG ultrasound head	
_	5-12. Way of inserting the hook-and-loop belt through the head eyelets	
	6-1. Electrotherapy sockets label	
_	6-2. Connection of electrodes	
Figure	6-3. Method of mounting the standard ultrasound head holder	31
Figure	6-4. Method of mounting the SnG head holder	32
Figure	6-5. Ultrasound heads sockets	33
Figure	6-6. Connections in combined therapy	33
	7-1. Field description	
	7-2. Screenshot sample view for dual circuit electrotherapy A+B	
_	27-3. Screenshot sample view for single circuit electrotherapy A and B	
_	7-4. Screenshot sample view for electrotherapy sequences	
	27-5. Screenshot sample view for standard ultrasound head GU-1 and SnG	
	27-6. Screenshot sample view for combined therapy	
_	27-5. Screenshot sample view for combined therapy	
	: 7-7. Manual time setting	
rigure	10-1. The unit error signaling and information visible after closing of the error message	110

#### 1. Basic information

# Read this Instructions for use carefully before starting the unit operation! Follow the recommendations presented in this Instructions for use!

Multifunctional unit PhysioGo.Lite Combo should be installed and started off by the seller.

The recipient has the right to insist on the product operation training. The unit may only be operated by qualified personnel or under supervision of such personnel!

WARNING: The device is intended for adult patients only. It is not intended for use in a home healthcare environment.

Description of symbols used in this manual:



Read appropriate passage of this Instructions for use, warnings or important information. Failure to observe warnings can lead to injuries.



Important notices and information.



Following texts marked with this symbol facilitates device operation.

#### NOTE:

The outlook of screens shown in this manual may slightly differ from their actual outlook during device operation. These differences may concern size and type of fonts and size of symbols. There are no differences in the content of shown information.

#### NOTE:

This manual contains instructions for use and technical description. This instructions for use is provided in the paper form. It is possible to receive a copy of the instructions in the form of a file. To do this, please submit the form available at <a href="https://astar.eu/instructions/">https://astar.eu/instructions/</a>.

WARNING: No modification of this equipment is allowed!

#### 1.1 Manufacturer

ASTAR Sp. z o.o.
p
43-382 Bielsko-" h
www.astar.eu

#### 1.2 Risk management process

The manufacturer conducts continuous risk management process referring to the device construction, its intended use, method of operation and maintenance. Residual risks are presented in this User Manual in form of information about precautions, contraindications and warnings.

#### 2. Intended use

Multifunctional unit PhysioGo.Lite Combo is an active, non-invasive therapeutic device, intended for carrying our treatment procedures using:

- bipolar (bidirectional) and unipolar (unidirectional) low frequency currents,
- bipolar (bidirectional) and unipolar (unidirectional) medium frequency currents,
- standard ultrasound therapy, low-intensity pulsed ultrasound (LIPUS) therapy and phonophoresis,
- combination method of current and ultrasounds.

Treatments are performed by direct contact method with non-injured skin. Parts of the body intended for treatments with PhysioGo.Lite Combo are back, upper limbs (shoulder, arm, forearm, hand), lower limbs (hip, thigh, shank, foot), neck and face for interaction with body tissues such as muscle, skeletal, nervous system and/or skin.

Its specific medical purposes are:

- treatment or alleviation of disease,
- treatment or alleviation of an injury or disability.

The unit is equipped with three fully independent treatment channels. The list of available therapies in particular channels is shown in the Table 2-1.

Table 2-1

Channel Therapy		
1	Single circuit electrotherapy – A	
1	Dual circuit electrotherapy – A+B	
	Single circuit electrotherapy – B	
2	Combined therapy – ultrasound therapy and electrotherapy	
3	Ultrasound therapy	

Detailed information about available configurations is presented further in this manual.

The unit possesses the base of preset treatment procedures along with therapeutic encyclopedia, which significantly increases comfort of operation.

There is also a possibility to create own user-defined:

- programs for all therapies,
- sequences for electrotherapy.

The unit may perform treatments by:

- TENS, BURST and formed in packages to spastic paralysis SP-TENS currents,
- interferential currents dynamic and isoplanar,
- one-channel sine wave current (AMF),
- Kotz' Russian stimulation,
- diadynamic according to Bernard MF, DF, CP, CP-ISO, LP, RS, MM currents (in continuous and interrupted mode),
- ionophoresis and galvanization of constant current (in the continuous and interrupted mode),
- Träbert (Ultra Reiz), Leduc' and neofaradic (in continuous and interrupted mode),
- medium frequency current,
- unipolar and bipolar sine surge currents,
- triangular or rectangular pulses (in continuous and interrupted mode),
- microcurrents,

- IG pulses,
- EMS currents,
- H-waves,
- exponential pulses,
- tonolysis and Hufschmidt stimulation to spastic paralysis,
- qualitative and quantitative electrodiagnostic of the nervous-muscle system.

As regards to ultrasounds, the unit may be operated with:

- GU-5 standard ultrasound head, which generates an ultrasound wave with a frequency of 1 MHz or 3 MHz, with a total area of the head front of 5 cm<sup>2</sup>, for classic ultrasound therapy and LIPUS therapy, as well as combined therapy,
- GU-1 standard ultrasound head, which generates an ultrasound wave with a frequency of 1 MHz or 3 MHz, with a total area of the head front of 1 cm<sup>2</sup>, for classic ultrasound therapy and LIPUS therapy, as well as combined therapy,
- SnG hands-free ultrasound head, which generates an ultrasound wave with a frequency of 1 MHz or 3 MHz, with a total area of the head front of 17.3 cm<sup>2</sup>, for stationary ultrasound therapy and LIPUS therapy.

Standard heads are operated by the operator during treatment. The hands-free head simulates the movements of the therapist due to the switching sequence of the ultrasonic transducers and the modulation of the ultrasonic wave. Details – see chapter 5.7.1.

#### The unit enables the simultaneous connection of two ultrasound heads.

Further information on supported types of ultrasound heads are given in sections 5.7 and 8.

The unit can be used to treat diseases in the following areas:

- orthopedics,
- sports medicine,
- aesthetic medicine,
- rheumatology,
- neurology,
- urology,
- dermatology,
- angiology.

#### Detailed information about indications and contraindications are presented in chapter 9.

Due to the optional battery supply, the unit is perfectly suited for use:

- in sports medicine in case of training camps, etc.,
- wherever there are problems with power supply quality.

#### 2.1 Intended users

#### The patient should not be the operator.

Users (operators) of PhysioGo.Lite Combo can be:

- specialists in the field of the electrotherapy, ultrasound therapy, combined method of electrotherapy and ultrasound therapy
- physiotherapists specializing in the therapy of the musculoskeletal system,
- sports medicine specialists,
- aesthetic medicine specialists,
- trained personnel performing treatments under the supervision of the above-mentioned specialists.

The user should have:

 knowledge about the indications and contraindications for the use of electrotherapy and ultrasound therapy,

- knowledge of the terminology and technical terms used in the manual (e.g. knowledge of units of physical quantities),
- practical skills in performing therapeutic treatments using devices for electrotherapy and ultrasound therapy, resulting from education, experience and training.

Physical and cognitive requirements of the operator:

- eyesight enabling to recognize elements of screen and keyboard,
- hearing enabling to hear the patient's voice,
- reading comprehension that allows to read the instructions of use and information on the screen of the device,
- two functional upper limbs that allow to perform treatments and other activities related to the operation of the device (e.g. cleaning of accessories and detachable parts),
- age in the range of admissible value of professional activity (depending on the regulations of the country where the device is used).

#### 2.2 User training

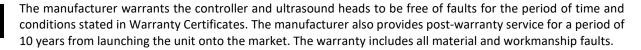
The PhysioGo.Lite Combo user has to be properly trained in the device safe and effective use, before starting the operation. Training in the rules of operation can be carried out by representatives of the manufacturer or seller, based on this user manual.

Recommended training positions:

- information about the intended use of the device,
- occupational safety information,
- information on the construction and method of the output signals generation,
- information on available settings and operation modes,
- instructions for use,
- indications and contraindications for the therapy,
- information on recommended maintenance, cleaning and disinfection,
- handling in the event of a technical malfunction.

Due to requirements of local law and regulations in different countries, additional training activities may be required. The user should inform the seller about such requirements in order to receive complete information.

## 3. Warranty and manufacturer's responsibility



The manufacturer undertakes to observe the warranty agreement, if the following conditions are met:

- all repairs, changes, extensions and calibrations of equipment are performed by manufacturer or authorized service personnel,
- firmware updates are performed by the manufacturer, an authorized service personnel or distributor,
- the mains supply system in the treatment room meets requirements of standards in force,
- the unit is operated by qualified personnel, in compliance with instructions presented in this manual,
- the unit is operated in compliance with its intended use.

The warranty does not include consumables, such as electrodes, viscose covers, connection cables, mains cables, patient's cables, holders and fuses, as well as faults or damage caused by:

- improper placement, installation or configuration of the device,
- misuse or failure to observe the instructions presented in this user manual,
- inaccurate or inadequate maintenance carried out by the operator,
- improper environmental conditions specified for the product,
- unauthorized opening of the outer casing,
- adjustment and/or unauthorized tuning,
- use of non-original parts of the unit.

The warranty does not cover any damage due to a failure to adhere to the recommendations stated in chapters 4.3 and 10 hereof.

The manufacturer is not liable in case of transmission of infection by parts of the unit.

#### The expected "life time" of the device is 10 years.

After elapse of 10 years from date of introduction of device, accessories and detachable parts in the market the manufacturer is not liable for device, accessories and detachable parts faults or its consequences. After elapse of the expected life time of the device the user bears the complete responsibility for the occurrence of medical incidents.

The manufacturer bears no responsibility for results of faulty installation, wrong diagnosis, wrong use of the device and parts of the unit, failure to observe Instructions for use and performance of repairs by unauthorized persons.

Inside the device there are no user serviceable components, except for fuses and battery. No parts can be serviced or maintained when the device is in use with a patient.

The firmware that is part of the device is not intended to be installed, configured or updated by the user. See section 6.2.6.1 for details.

On demand, the manufacturer makes available technical diagrams, parts lists, descriptions, instructions for calibration or other helpful information to appropriately qualified user's technical staff to repair these parts of unit, which are described by the producer as a reparable.

## 4. Operational safety

#### 4.1 Mains supply and operation mode

The unit is designed for supply from AC mains with rating 100-240 V and frequency 50/60 Hz. It is a medical device under safety class II, type BF. The unit may be used only in rooms, where the electric system is executed in compliance with standards in force. The unit is intended for continuous operation. It is not necessary to switch it off from the mains between particular treatment procedures.

An external switched-mode power supply (SMPS) HPU63B-108 by Sinpro (constant output voltage 24V, rated current is 2.62A) treated as part of the device is the source of supply for the device. The type of switched-mode power supply approved for use with the device are placed on the identification label on the bottom of the device.

The SMPS may be connected to the mains only by a special, detachable mains power supply cord integrated with the PLMF2A anti-interference filter. This filter is used to reduce electromagnetic disturbance that is generated during ultrasound therapy treatments.

The power supply cord is equipped with a mains plug that isolates the device from the supply mains on all poles simultaneously.

The socket in the device where the plug of the switched-mode power supply is connected is marked with symbol and safety sign ISO 7010 - M002.

Connecting to the mains and the proper operation of the switched-mode power supply is signaled by the green LED indicator located on its housing.

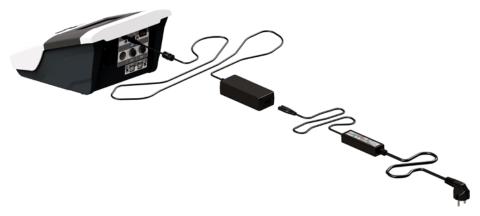


Figure 4-1. The method of correct connection of the SMPS, mains filter and controller

Recommendations related to isolation the device from the supply mains:

- do not position the PhysioGo.Lite Combo so that it is difficult to operate the disconnection of the device from the supply mains,
- to isolate the device from the supply mains, hold the mains socket-outlet with one hand, grasp the mains plug with second hand and disconnect it from the mains socket-outlet.

Disconnection from the mains takes place after:

- switching the mains switch to the "0" position,
- removing the SMPS output cord plug from the socket on the unit,
- removing the mains cable plug from the mains power socket.

There is an option to equip the device with a battery which allows for operation without, or in conditions of reduced quality of power supply.

#### 4.2 Storage, operation and transport conditions

The PhysioGo.Lite Combo unit must be stored in closed rooms, where the atmosphere is free from vapors and caustic substances and:

- the temperature is maintained between + 5°C and +45°C,
- relative humidity does not exceed 75%,
- atmospheric pressure value is between 700 and 1060 hPa (70-106 kPa).

The unit is intended for operation under the following conditions:

- ambient temperature between +15°C and +30°C,
- relative humidity between 30% to 75%,
- atmospheric pressure between 700 to 1060 hPa (70-106 kPa).

If further transport of the device is required, use the delivery packaging. Transport shall be performed with covered transport means.

Recommended transport conditions:

- ambient temperature between -10°C to +45°C,
- humidity between 20 and 95%,
- atmospheric pressure between 700 and 1060 hPa (70-106 kPa).

The above conditions refer also to the battery module.

#### 4.3 WARNINGS and safety notes

The PhysioGo.Lite Combo unit has been designed and manufactured in such a way that its use does not cause a hazard to the health and safety of patients, operators and third parties, as well as the unit provides therapeutic benefits to patients if it is operated in appropriate conditions and in accordance with its intended purpose.

#### General:

- PhysioGo.Lite Combo unit may be operated by qualified personnel in compliance with instructions (see 2.1).
- In order to ensure conformity with the requirements relating to electromagnetic disturbance, the device should be connected to grounded mains supply (mains socket with grounding pin). This solution is a functional earthing.
- The SMPS may be connected to the mains only by a special, detachable mains power supply cord integrated with the PLMF2A anti-interference filter.
- No modification of this equipment is allowed!
- The treatment station (bed, couch, chair) shall be located away from other electric devices and water supply / sewerage installation / central heating system, so that it is impossible for the patient to touch any of them during treatment procedure.
- Do not position PhysioGo.Lite Combo so that it is difficult to operate the disconnection of the device from the supply mains.
- Do not remove warning signs and labels put by the manufacturer on the unit casing, accessories and detachable parts.
- The unit and ultrasound heads shall be protected against high temperatures and atmospheric conditions (e.g. direct sunlight).
- Detachable parts and accessories of the unit should be regularly inspected. Damaged cables, electrodes and/or heads shall be replaced immediately. Pay special attention to the casing cracks, threadbare insulation and partially torn interconnecting cables.
- Prevent any fluid from penetrating inside the unit, SMPS or mains filter. In case of any fluid getting inside
  the unit, SMPS or mains filter, switch the unit immediately off, isolate from the mains and contact service
  to inspect the unit.
- . By any means do not cover the vents. Do not insert any objects into the ventilation sockets.
- The unit may be only used with accessories, detachable parts, spare parts and disposable items which
  have been determined to be safe and appropriate inspection bodies have not issued contraindications
  against their use.

- Ultrasound heads are sensitive to mechanical damages that is why they should be used with caution.
   Throwing, banging against hard surfaces and similar actions that may lead to damage of the head shall be avoided. Careless use of the head may make its properties worse.
- Ultrasound heads are particularly sensitive to very low and very high temperatures. Special attention should be paid, so not connect the device to the mains supply when it is too much cooled (e.g. winter period, right after delivering by the forwarder).
- Ultrasound heads may only be connected to the sockets when the mains supply is switched off. Each head
  contains memory with calibration data that are checked by microprocessor during self-test phase.
  Plugging head to switched on unit will make the head be undetected, so its use will not be possible.
  Sometimes it may also damage the ultrasound head.
- The ultrasound head has dedicated transport packaging. The front of the head is protected by rubber cover, which secures it against mechanical damage during delivery. The cover must be removed before use. It is not recommended to use it between treatments due to the possibility of damaging head parts.
- After switching the unit off, wait for 10 seconds before you switch it on again.
- Each serious incident concerned with the device should be reported to the manufacturer and competent
  authority of the country, where the user or patient resides. Serious incident means any incident that
  directly or indirectly led, might have led or might lead to any of the following:
  - the death of a patient, user or other person,
  - the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
  - a serious public health threat.

#### Therapeutic – general:

- The device is intended for adult patients (patient has to be conscious). Minor patients only on the doctor's explicit recommendation, after considering contraindications.
- It is impermissible for the patient to carry out the treatment on their own.
- It is prohibited to leave the patients unattended during treatments.
- It is necessary to continuously update knowledge and follow literary activities in the scope of therapy.
- Patients with implanted electronic devices (e.g. cardiac pacemakers, cardioverter defibrillator, spinal cord stimulator) or other metal implants should be consulted with a physician prior to treatment.
- Before treatment it is necessary to interview the patient, including the occurrence of relative and absolute contraindications to conduct therapy.
- It is necessary to keep records of the treatment, including the parameters of the therapy, the area of treatment, treatment technique, dose and symptoms after therapy.
- Do not perform treatments on patients under the influence of alcohol.
- Do not perform treatments on patients under the influence of intoxicants.
- It is necessary to ensure the adequate interval between treatments for the patient, in order to avoid an increase of the risk of complications.
- Take special care with patients with disturbed superficial sensation.
- Immediately disconnect the patient in the case of appearing warning on error messages on the display.
- Sitting or reclining position should be applied to the patients with respiratory disorders or breathing difficulties.
- The patient should be in a position causing loosening of the part of the body subjected to therapy.
- The patient should immediately report an increase of pain or other unpleasant sensations.

#### Therapeutic – electrotherapy:

- Treatment parameters and electrodes placement should be as indicated by the physician.
- Connect the electrodes to the patient at a time when the device does not generate the current to avoid the risk of electric shock.
- Electrodes should not be placed alongside the carotid artery (carotid sinus), in the area of reproductive organs, in the lower abdomen and over the internal organs.
- It is necessary to take precautions in case of the occurrence of surface metal implants in the spot of application.
- Do not use electrotherapy at the area of application of surgical staples in the skin, or on tissues protected with dressings or materials containing metal ions (silver, zinc).
- If it is possible, the treatment polarity should be adjusted so that the negative pole ought to be "further" from the heart than the positive one.

- It is not recommended to place electrodes in chest area, as it may increase the risk of ventricular fibrillation.
- Do not place electrodes on the neck and transcranially for epileptic patients, because stimulation may cause seizures.
- Unless specifically indicated by a doctor, avoid placing electrodes that form the circuit on the chest and upper back or crossing over the heart.
- Unless specifically indicated by a doctor, avoid applying electrical stimulation directly on the eyes or mouth.
- In case of treatment performed near the head, the patient should be in lying position.
- Simultaneous performance of electrotherapy treatments and therapies with the use of high frequency equipment (diathermy and electro surgery) may result in burns where electrodes are applied.
- It is necessary to use operational and sanitized electrodes. Inadequate choice of electrodes may cause skin irritations or burns.
- It is recommended to differentiate the electrodes size according to performed treatment in order to do not exceed the current density:
  - 0.2 mA/cm² for currents with constant component (unipolar) galvanic, diadynamic, pulse currents, unipolar sine surge, tonolysis,
  - 2 mA/cm<sup>2</sup> for bipolar currents TENS, Kotz', interferential.

Improper selection of electrodes can cause skin irritation and burns.

- Carrying out treatments, where for the applied electrodes it is necessary to set the current/voltage so
  that the current density does not exceed 2 mA/cm², may require particular attention of the
  physiotherapist.
- Irritation and skin burns may occur during performing electrical stimulation. If such syndromes occur you are obliged to interrupt the treatment and immediately consult with a doctor.
- It is not recommended to apply unidirectional currents in CV mode due to the possibility of skin burns. It is necessary to apply CC mode.
- Unless specifically indicated by a doctor, it is not recommended to treat pregnant women with electrotherapy.
- Special caution must be kept during electrotherapy treatments in older people.

#### Therapeutic – ultrasound therapy:

- The treatment parameters and the part of the body undergoing therapy should be as indicated by the physician.
- If two heads are connected, the head which is not used should be placed in the holder. If any of the head is not used for a longer period of time, it is recommended to disconnect this head.
- Do not perform ultrasound treatments on the cervical spine above the 3<sup>rd</sup> vertebra as the ultrasound energy could affect the medulla oblongata.
- Avoid applying ultrasound energy to internal organs of the abdominal cavity, thorax (i.e. heart area) and gonads.
- Avoid application of ultrasounds in continuous mode directly over joints with cement or plastic endoprostheses. Ultrasounds in LIPUS mode can be used with caution.
- Avoid application of ultrasounds in continuous mode (causing a thermal effect) in case of dermatological
  diseases that are sensitive to heat, such as eczema, psoriasis. Ultrasound in the pulse mode can be used
  to treat open wounds with precautions (head disinfection, sterile gel, correct treatment method). The
  skin condition should be monitored and in case of its deterioration, the treatment should be stopped.
- Avoid application of ultrasounds in continuous mode (causing a thermal effect) over damaged nerves, because they can cause unpleasant sensations (e.g. needles and pins) and do not accelerate their regeneration.
- The choice of the ultrasound head should take into account the recommended technique of performing a specific treatment. For details see chapter 7.1.5.
- When performing treatments with standard heads, a dynamic or semi-stationary technique should be applied. The stationary technique is only allowed for LIPUS therapy.
- Only a stationary (static) technique should be applied when performing treatments with hands-free SnG heads.
- GU standard heads are not identical to GS heads used in previous ultrasound therapy devices such as Etius, PhysioGo, Sonaris.
- GU heads and GS heads cannot be used interchangeably.

- SnG head is not supported by Etius, PhysioGo and Sonaris devices.
- Avoid placing the hands-free head on superficial osteophymas, in order not to cause periosteal pain by a
  thermal dose. It is also necessary to carefully attach the head with the original hook-and-loop belts
  provided by the manufacturer, to limit its movement.
- Use a coupling gel for ultrasound devices. The gel should be a medical equipment, marked with the conformity mark (the CE mark in EU). Avoid using a gel with undocumented origin.
- Where it is necessary to use other coupling medium (e.g. liquid paraffin), test the quality of contact detection first (see 5.6.6).
- It is recommended to use distilled water when performing treatments in water, preferably after its
  degasification. To degas water, boil it for 30 minutes, then close a container tightly and put it in the
  refrigerator to cool. Heat water to the comfort temperature for the patient before use. The presence of
  air bubbles during therapy may cause deterioration of operation parameters, especially at the stationary
  positioning of the head.
- The surface of the front head of the ultrasound transducer can degrade and its parameters can deteriorate if you use tap water with the addition of minerals, disinfectants or other chemical agents. In the extreme case, the transducer may damage.
- The therapist should keep his or her hand outside of water during treatment.
- If you use a plastic container, the dose should be corrected, because the plastic absorbs reflected ultrasound energy. If you use a metal container, the reflected energy returns to the treated body part and there is no need to correct the dose.

#### <u>Therapeutic – combined therapy of current and ultrasounds:</u>

• See warnings and information for electrotherapy and ultrasound therapy.

#### Therapeutic – combined therapy of current / ultrasounds and vacuum therapy:

- The unit may be operated in connection with vacuum therapy unit.
- It is recommended to cooperate with the Avaco units manufactured by Astar due to the complete compatibility.
- For information on how to make combination between devices and how to use them safely, please refer to the manual for the vacuum therapy device.

#### Battery use (optional):

- Rechargeable battery UR18650A 5S1P is designed for use only with PhysioGo.Lite range of devices.
- If you suspect that a battery-powered unit is not working properly, remove the battery.
- In case of mechanical damage to the battery module, there is a risk of fire, explosion or burns, due to used lithium-ion cells.
- Do not throw the battery or hit it. Do not heat it or incinerate.
- Do not short-circuit the contacts or disassemble the casing.
- Do not immerse in liquids.
- Operation, storage and transport conditions are presented in chapter 4.2.

#### 4.4 Explosion proof environment

PhysioGo.Lite Combo is not adopted to operation in rooms, where combustible gases or their vapors occur. It is recommended to avoid anesthetics or oxygen derivate gases, such as nitrous oxide ( $N_2O$ ) and oxygen. Some materials (e.g. cotton, wool) may after saturation with oxygen become combustible at high temperatures generated with normal operation of equipment. It is recommended that solutions of adhesive and combustible solvents be vaporized before equipment is operated. It is also recommended to pay attention to the danger of ignition of endogenous gases. The unit must be separated from the mains before approaching the disinfection room, where it is installed.

#### 4.5 Electromagnetic environment

The SMPS may be connected to the mains only by a special, detachable mains power supply cord integrated with the PLMF2A anti-interference filter. This filter is used to reduce electromagnetic disturbance that is produced during ultrasound therapy treatments.

- Due to the intended use the device can be used in hospitals, clinics, health centers, GP practices, rehabilitation offices and other health care facilities, under the supervision of qualified personnel.
- Simultaneous operation of unit with devices generating strong electromagnetic field, such as short wave and
  microwave diathermies, high frequency surgical equipment, MRI systems, may disturb unit operation. For
  this reason, it is recommended to maintain appropriate distance between these devices or to switch off the
  generator of strong fields during therapy with the PhysioGo.Lite Combo unit. Manufacturer doesn't claim
  compatibility of the PhysioGo.Lite Combo unit with high frequency surgical equipment.
- If the device is subjected to electromagnetic interference with an intensity that exceeds the compliance levels declared in section 11.2, the display may be affected, generation may be interrupted or the device may restart.
- WARNING: Use of the PhysioGo.Lite Combo adjacent to or stacked with other equipment should be avoided
  because it could result in improper operation. If such use is necessary, the PhysioGo.Lite Combo and the
  other equipment should be observed to verify that they are operating normally.
- It is recommended to use original accessories, detachable parts, spare parts and equipment of Astar.
- WARNING: Use of accessories, detachable parts, 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 PhysioGo.Lite Combo, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The PhysioGo.Lite Combo meets requirements of electromagnetic interference emission and immunity standards and shall not pose a threat to correct operation of the other devices. Compliance levels for emissions and immunity are given in the chapter 11.2.

#### 4.6 Operation of touch-sensitive displays

Table 4-1. Recommendations for the operation of touch screens

Type of display	Method of operation of the display		
5" with a resistive touch panel	Recommended:  • Pen designed for resistive screens – preferably with a narrow plastic tip Admissible:		
	<ul> <li>Operator's finger – much lower comfort of operation compared to the pen</li> </ul>		

#### 4.7 Applied parts

The PhysioGo.Lite Combo unit has an applied part of BF type. It includes:

- electrotherapy sockets along with plugs and patient's cables,
- ultrasound therapy sockets along with plugs, cables and ultrasound heads.

The elements of the applied part are connected together. Physical contact of the electrodes and ultrasound head with patient's body during normal use is essential for the device to perform its function.

The specification of the leads, along with the location of the output sockets is described in detail in the chapters 5.1 and 5.7. The appropriate symbol of the BF type applied part is placed on the sockets label.

#### 4.8 Essential performance

Essential performance, in relation to the areas of physical therapy available in the PhysioGo.Lite Combo device, is presented in Table 4-2.

Table 4-2 Functioning characteristics of the PhysioGo Lite Combo unit

Physical therapy	Essential performance characteristics			
Electrotherapy	<ul> <li>The generation of current and voltage signals with frequencies, shapes and amplitudes corresponding to the waveforms recognized and used in this therapy. Unidirectional (unipolar) and / or bidirectional (bipolar) currents are available.</li> <li>The device meets the requirements of IEC 60601-2-10 standard, which specifies:</li> <li>maximum amplitudes of the output currents depending on the frequency of the waveform,</li> <li>permissible pulse energy,</li> <li>duty factor, pulse frequencies and amplitude tolerances.</li> </ul>			
Ultrasound therapy	The generation of an ultrasonic wave with a frequency in the range of 500kHz-5MHz in:  continuous mode or  pulse mode — with adjustable duty factor and frequency of packets, with the use of ultrasonic transducers.  The device meets the requirements of IEC 60601-2-5 standard, which specifies:  the maximum effective intensity,  the accuracy of output power, effective radiating area and effective intensity (power density),  the acceptable level of unwanted ultrasound radiation,  the temperature limits of ultrasonic transducers.			
Combined therapy	As for electrotherapy and ultrasound therapy.			

#### 4.8.1 Test of essential performance and basic safety



Calibrating or servicing the device shall be carried out by the manufacturer or an authorized service personnel in accordance with separate guidelines. If the warnings given in this manual are followed, there is no risk for persons performing the above mentioned activities.

The user of unit must perform technical inspection of the unit at year's intervals. The inspection must be performed by a unit authorized by the manufacturer. The inspection is performed at the user's expense.

Table 4-3. Essential performance and basic safety testing recommendations

Test item	Method of checking	Acceptance criteria	Required measuring equipment
Safety test:      patient leakage current measurement,      touch current measurement,      insulation resistance if necessary	The manufacturer allows the methods compliant with the requirements of the standards:  IEC 60601-1  IEC 62353	The measurement results are within the limits specified by the applied standard	Safety tester meeting the:  IEC 60601-1  IEC 62353 requirements
Control of correctness of the performed self-test	Visual inspection	No errors	No requirements
Evaluation of keyboard function and operation	Manual and visual inspection	The keys respond properly to pressure	No requirements
Evaluation of touchscreen function and operation	Manual and visual inspection	The touch panel responds correctly to pressing	No requirements
Inspection of the controller condition for casing defects and	Visual inspection	No deformation or cracks of the casing	- No requirements
damage of sockets	visual irispection	Undamaged sockets	-
Inspection of the patient cables and connectors	Visual inspection	No loosened sockets  No tear and bending of cable insulation	No requirements
and connectors		Undamaged connector	

Test item	Method of checking	Acceptance criteria	Required measuring equipment
Inspection of the heads condition for casing defects and damage of interconnecting cables and connectors	Visual inspection	No deformation or cracks of the casing  No tear and bending of cables insulation  Undamaged connectors	No requirements
Inspection of the SMPS condition for casing defects and damage of interconnecting cables and connectors	Visual inspection	No deformation or cracks of the casing  No tear and bending of cable insulation  Undamaged connector	No requirements
Inspection of the mains filter condition for casing defects and damage of interconnecting cables and connectors	Visual inspection	No deformation or cracks of the casing  No tear and bending of cable insulation  Undamaged connector	No requirements
Test of the power emitted by ultrasound heads	The manufacturer allows the methods compliant with the requirements of the IEC 60601-2-5 standard	The accuracy of the power indication is within a tolerance of ± 20%	Radiation force balance or ultrasonic power meter
Verification the accuracy of current and voltage amplitudes	The manufacturer recommends to apply methods compliant with the requirements of the IEC 60601-2-10 standard	Accuracy of time / frequency parameters and the amplitude is within ±20% tolerance	Oscilloscope, digital multimeter, 500 $\Omega$ reference resistor
Open circuit detection	Visual inspection	Triggering of a bad contact message in both channels	No requirements
Detection of lack of contact of the ultrasound head	Visual inspection	Signaling by LED indicator / indicators on the head Bars presenting the ultrasound head contact quality are not highlighted. Message on the screen	No requirements

The inspection must also include control over the quality of applied accessories, detachable parts and treatment materials. No action is required to maintain basic safety and essential performance with respect to electromagnetic interference during device "life time".

Positive result of the technical inspection confirms that basic safety and essential performance is maintained.

#### 4.9 Disposal

In case, when the disposal of the unit will become necessary (e.g. after elapse of its service life), please contact the manufacturer or manufacturer representative, which must react in an appropriate way i.e. collecting the unit from the user. The user may also contact companies specialized in removal and/or disposal of electrical devices or computer equipment. Under no circumstances should you place the unit along with other wastes. The name plate includes an appropriate symbol (see **Appendix A**).

The unit is marked with an appropriate symbol complying with the directive on waste electrical and electronic equipment (WEEE) – see table with description of the symbols used to label the product presented in **Appendix A.** 

## 5. Unit description

#### 5.1 General characteristics

Multifunctional unit PhysioGo.Lite Combo is a highly specialized medical device based on modern microprocessor platform.

The unit has a plastic console casing. It is equipped with a color touch LCD display with a diagonal of 12,7 cm (5"). On the rear side of the casing are located:

- power switch,
- fuse socket,
- mains socket,
- sockets for connection of patient's cables and ultrasound heads.

General view of the unit is presented in Figure 5-1, view of the rear panel in Figure 5-2.



Figure 5-1. General view



Figure 5-2. Unit rear panel view

# 5.2 Front panel

Arrangement of front panel components is shown in Figure 5-3.



Figure 5-3. Arrangement of front panel components

Table 5-1 Description of front panel components

Symbol	Description	Function		
1.	Liquid crystal display	The unit is equipped with a touch-sensitive display. The screen clearly displays all information related to the device operation.		
2.	Operation status and battery level indicators	See 5.2.1.		
3.	Turn ON/OFF key (STANDBY)	This key is marked with the symbol .  In order to activate the unit in the case of battery operation, please hold on for at least 5 seconds. Extension of the holding time prevents unintentional activation during transport.		
4.	Edit keys	These keys are marked with symbols .  Pressing any of them results in change of value of edited parameter or setting in setup mode.  Keep holding the key down to change a parameter quicker.		
5.	START/STOP key	This key is marked with the symbol  It is used with the sequence of starting emission. Its pressing, after setting of treatment procedure parameters starts emission.  Pressing of this key once again stops the treatment procedure. The emission of signal is stopped.		

#### 5.2.1 Operation status and battery level indicators

Symbols and description of unit operation status signaled by LED indicators are summarized in the table below.

Table 5-2. Non-battery unit

Symbol	Color	Indicator status	Mains switch	Explanation	
(h)	Green	No light	OFF ("0")	The unit is turned off. Turning ON:  Turn the mains switch on Press the STANDBY key	
Operation status indicator		Blinks	ON ("1")	Unit is in standby mode. Turning ON:  Press the STANDBY key	
		Steady light	ON ("1")	The unit is ready for operation.	
Battery level indicator	Orange	No light		No battery.	

Table 5-3. Unit equipped with battery

Comple ed	Color	Indicator status		Nationa assistati	Fundametica
Symbol		Readiness	Battery	Mains switch	Explanation
<u></u>	Green Orange	No light	No light	OFF ("0")	The unit is turned off. Turning ON:  Turn the mains switch on Press the STANDBY key
		Blinks slowly	No light	ON ("1") Mains cable connected	Unit is in standby mode. Battery is fully charged. Turning ON:  Press the STANDBY key
		Blinks slowly	Blinks slowly	ON ("1") Mains cable connected	Unit is in standby mode. Battery is being charged. Turning ON:  Press the STANDBY key
		Steady light	Blinks slowly	ON ("1") Mains cable connected	The unit is turned on. Battery is being charged.
		Steady light	No light	ON ("1") Mains cable connected	The unit is turned on. Battery is fully charged.
		No light	Steady light	ON ("1") Mains cable disconnected	Unit is running on battery supply.

Table 5-4. Additional information about battery indicator

Symbol	Color	Battery indicator status	Explanation		
4		Blinks fast for 4 seconds	Battery module has been disconnected.		
		3 pulses	Battery low.		
	Orange	5 pulses	Battery error. Turn the unit off using STANDBY key and switch the power switch off. Restart it after 10 seconds. If the problem repeats, contact your authorized service.		

#### 5.3 Battery installation

PhysioGo.Lite Combo can be optionally fitted with a battery. Users can install the battery by themselves.

WARNING: Before performing the below actions, turn the device power off and disconnect the SMPS from the mains.

The battery assembly method is illustrated in the following figures.

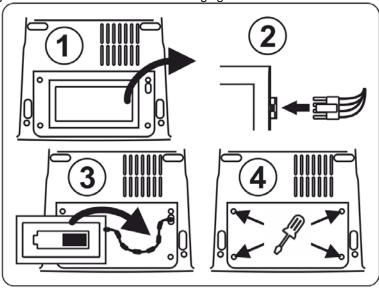


Figure 5-4 .The battery installation method

Table 5-5. The battery installation method

Action no.:	Description	
	Turn the device over.	
1.	Unscrew four battery cover screws.	
	Remove the stabilizing cartridge. Keep it for further use.	
2.	Connect battery cable to the battery socket.	
3.	Place the battery in the enclosure.	
	Reinstall battery cover by means of 4 screws.	
4.	Turn the device over to its normal position. Connect power supply to the mains. Switch on the unit and check If it starts correctly.	

The above information is summarized on labels placed on the battery cover.

#### 5.4 Name plate

The name plate is located on the bottom of unit casing. Among others there are following data on the name plate (see **Appendix A**):

- device name and version,
- UDI-DI code,
- serial number and manufacture date UDI-PI code,
- nominal voltage and frequency of operation,
- type of applied fuses,
- IP protection class,
- manufacturer's data.



Figure 5-5. Name plate of PhysioGo.Lite Combo device

The label with ultrasonic wave parameters is located on the bottom of unit casing (see **Appendix A**):

- acoustic working frequencies (f<sub>awf</sub>),
- waveforms,
- values of pulses durations (pd), pulses repetition periods (prp), duty factors (DF).

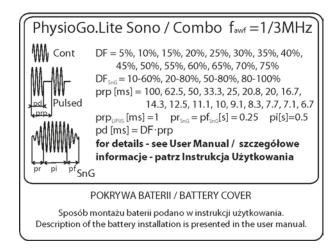


Figure 5-6. Label with parameters

#### 5.4.1 UDI code

Regulation (EU) 2017/745 of The European Parliament and of The Council defines "Unique Device Identifier" ('UDI') as a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market (def.15). The code development process is supported by entities designated by Commission (EU) Implementing Decision. The manufacturer has chosen to cooperate with the GS1 organization.



Figure 5-7. UDI code – example

ID	Symbol	Description	UDI code part
(01)	GTIN	Unique GTIN code assigned by GS1 organization	UDI-DI

ID	Symbol	Description	UDI code part
(11)	PROD DATE	Production date format: RRMMDD A record limited to the year and month is acceptable in the format: RRMM00	UDI-PI
(21)	SERIAL	Serial number	_

## 5.5 Current and voltage stabilization – CC and CV mode

In the range of electrotherapy, the unit may be operated in one of two modes:

- CC mode (constant current) when output current is stabilized,
- CV mode (constant voltage) when output voltage is stabilized.

In CC mode the current in patient's circuit is independent (within certain limits) from the resultant of resistance of skin, tissues, electrodes (with moist pads) and cables. Effective operation of the unit for very high resistance is possible due to its structure. At the maximum current value of 140 mA, stabilization within a full range of current intensity regulation is provided for resistance values from 500 to 750  $\Omega$ . For higher values of resistance, the maximum obtainable current intensity is lower. It means that increasing on the keyboard current intensity over the limiting value does not result in further increase of current in the output circuit. This will be signaled by the blinking electrodes symbol and at the end of the treatment the information about poor contact of electrodes will be shown on the display (see section 5.6.2). In the case, when resistance is too high (e.g. used electrodes, electrode viscose pads are not moistened enough), the information about high resistance in the patient circuit will be shown on the display (see 5.6.1).

In CV mode, the voltage generated by the unit, which value is set up on the keyboard, is spread out (according to Kirchhoff voltage law) between the unit's output resistance and resistance of a load. Rough diagram of operation system in CV mode for one channel is presented in Figure 5-8.

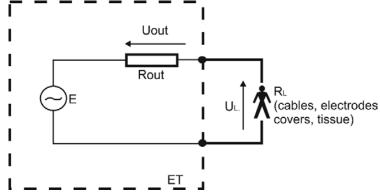


Figure 5-8. Rough diagram of the output circuit of the unit working in CV mode (one channel)

Symbols used in figure:

- E the value of output voltage set on the keyboard
- Uout drop of the voltage on unit's output resistance
- Rout unit's output resistance
- U<sub>L</sub> − load voltage
- R<sub>L</sub> − load resistance

The value of voltage in the patient's circuit depends on the quotient of unit's output resistance by the resultant of resistance of skin, tissues, electrodes (with moist pads) and cables. During the unit operation, on the display there are shown the internal settings and voltage value in patient's circuit.



It is recommended to use CV mode while performing non-stationary treatment procedures, e.g. combination therapy of current and ultrasounds or using the point electrodes. A momentary loss of contact between the electrode and patient's body does not result in interruption of treatment procedure, contrary to CC mode.

The calibration settings for CC mode are being defined with the load which has a resistance of 500  $\Omega$ . The calibration settings for CV mode are being entered in the idle operation mode of the unit.



#### 5.6 Protection

#### 5.6.1 Detection of a high resistance in the patient circuit

In the case, when at the start or during an electrotherapy / combined therapy treatment procedure, the device detects a state of high resistance in the patient circuit, which may be caused by:

- incorrect connection of electrodes,
- a poor contact between electrodes and tissue (e.g. viscose pads are not moistened enough),
- worn electrodes,
- damaged interconnection cables,

the information about a probable cause of the problem will be shown on the display.



The detection system of a high resistance in the patient circuit is active during the treatment procedure. The detection system works when current value is more than 2,5 mA or voltage is set above 15 V. Detailed description of cables and electrodes condition control is given in chapter 10.5 and 10.6.

Depending on the conditions of a high resistance detected in the patient circuit, the device displays the messages that are shown in Figure 5-9.

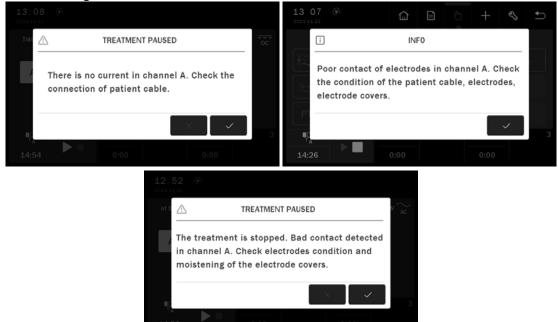


Figure 5-9. Presentation of information about the high resistance in the patient circuit

#### 5.6.2 Electrodes condition control

This function is intended to inform about deteriorating condition of electrodes, so as to give the operator time to stock up on new accessories.

The condition of the electrodes is signaled by the color of the electrotherapy indicator on the treatment screen (Figure 5-10):

- white electrodes in good condition,
- flashing yellow worn electrodes.

If wear of the electrodes is detected, the device will display an appropriate message at the end of the treatment – see Figure 5-9 ("Poor contact of electrodes").



Figure 5-10. Signalization of worn electrodes

#### 5.6.3 Current accuracy control in CC mode

While performing the electrotherapy treatment in stabilized output current mode (CC), the unit controls the accuracy of current intensity. In the case when the difference between the setting and output value is higher than 20%, the treatment will be interrupted and the message will appear on the display.

#### 5.6.4 Overcurrent in CV mode

While performing the electrotherapy treatment in stabilized output voltage mode (CV), the unit controls whether the maximum current value is not beyond the limits. If the voltage setting for current value is higher than the allowed limit (specified for the stabilized output current in CC mode), the treatment will be interrupted and the message will appear on the display.

#### 5.6.5 Information on the features of generated signal

This function is intended to inform about:

- · classification of currents due to their polarity,
- warning threshold of the current value that requires an operator's special attention in the generation phase (e.g. training programs, modulations, pulse current).

Detailed information and symbols are provided – see Table 5-6.

Table 5-6. Currents classification

No.	Signal	Shape of the current	Classification		Threshold for warning
		symmetric			10 mA
1.	TENS pulse currents	asymmetric	bipolar	AC	10 mA
		alternating		$\sim$	10 mA
2.	Isoplanar interferential current	sinusoidal	bipolar	AC	10 mA
3.	Interferential current with vector scanning	sinusoidal	bipolar	AC	10 mA
4.	Single channel interferential current	sinusoidal	bipolar	AC	10 mA
5.	Kotz' current	sinusoidal	bipolar	AC	10 mA
6.	Medium frequency currents	sinusoidal	bipolar	AC	10 mA
7.	SP-TENS pulse currents	symmetric	bipolar	$\sim$	10 mA
	SP-TENS pulse currents	asymmetric	ырогаг	AC	10 mA
8.	Diadynamic currents	semi-sinusoidal	unipolar	DC	5 mA
9.	Galvanic current	constant	unipolar	DC	5 mA
10.	Ultra Reiz	asymmetric	unipolar	DC	5 mA
	6:	semi-sinusoidal	unipolar	DC	5 mA
11.	Sine surge	sinusoidal	bipolar	2	10 mA
12.	Leduc's current	asymmetric	unipolar		5 mA
13.	Rectangular pulse current	asymmetric	unipolar		5 mA
		asymmetric	unipolar		5 mA
14.	Triangular pulse current	symmetric	bipolar	~ AC	10 mA
15.	Neofaradic current	asymmetric	unipolar	DC	5 mA
	Microcurrents	rectangular positive		DC	5 mA
16.		rectangular negative	unipolar	DC	5 mA
		alternating	bipolar	~	10 mA
17.	IC nulsas	unipolar	unipolar	DC	5 mA
17.	IG pulses	bipolar	bipolar	2	10 mA
18.	EMS current	symmetric	bipolar	$\sim$ ac	10 mA
19.	H-waves	symmetric	bipolar	$\sim$ AC	10 mA
20	Funancial nulses	asymmetric	unipolar		5 mA
20.	Exponential pulses	symmetric	bipolar	$\sim$ ac	10 mA
21.	Hufschmidt stimulation	rectangular	unipolar		5 mA
	Tonolysis	A triangular			5 mA
		A rectangular			5 mA
22.		B semi-sinusoidal	- unipolar oc		5 mA
۷۷.		B semi-rectangular			5 mA
		B sinusoidal			5 mA
		B triangular			5 mA

#### 5.6.6 Signaling the lack of contact of the ultrasound heads

The unit has a system controlling the quality of contact between a head and the patient's body during the treatment process, which aids the operator in a proper treatment performance. In case the quality of contact worsens (e.g. not enough gel, bones too close), the output power of the head is reduced to the minimum level ensuring the continuity of the generator operation.

The way the device reacts (the time after which the message is displayed and the way the treatment timer works) depends on the type of applied head and the settings saved by the user – see chapter 6.2.4.5.

The quality of contact during the treatment is presented on the display in the form of bars of different heights – see chapter 7.3.

The standard heads have an LED indicator that signals the contact quality. This indicator status should be interpreted as follows:

- if it does not light up during the treatment it means that the head is in good contact with the patient's body,
- if it blinks or glows continuously during the treatment it means poor contact of the head with the patient's body.

When working with hands-free heads, the lack of contact is signaled:

- by lighting of the LED indicator in the single-transducer mode as for standard heads,
- only by the bars of different heights (see 7.3) in multi-transducer mode.

#### 5.6.7 Temperature control of ultrasound heads

The ultrasound heads are equipped with temperature sensors. By using them the controller periodically controls the temperature of the heads' fronts. This mechanism prevents the temperature from rising above the limit specified in IEC 60601-2-5. The moment when the temperature is measured is signaled by the LED indicator of the head turning off.

#### 5.7 Ultrasound heads

The unit can operate with following types of ultrasound heads:

Head type	Characteristics and intended use			
GU-5	<ul> <li>standard head</li> <li>basic type of head for carrying out the ultrasound therapy, phonophoresis, LIPUS and combined therapy</li> <li>total area of the head front – 5 cm²</li> <li>effective radiating area – 3.4 cm²</li> <li>integrated temperature sensor</li> </ul>			
GU-1	<ul> <li>standard head</li> <li>head intended to small body parts</li> <li>total area of the head front – 1 cm²</li> <li>effective radiating area – 0.7 cm²</li> <li>integrated temperature sensor</li> </ul>			
SnG	<ul> <li>hands-free head</li> <li>head for carrying out the ultrasound therapy, phonophoresis and LIPUS</li> <li>2 ultrasonic transducers in one head – it can operate in single-transducer and dual-transducer mode</li> <li>possibility to operate in single-section (A/B) or dual-section (A+B) mode</li> <li>total area of the head front in single-section mode – 17.3 cm², in dual-section mode – 34.6 cm²</li> <li>effective radiating area – 3 cm²</li> <li>integrated temperature sensor</li> </ul>			

The following data are located on the ultrasound head name plate (see **Appendix A**):

- acoustic working frequency,
- beam type,
- beam non-uniformity ratio,
- nominal power,
- effective radiating area,
- manufacturer's data
- serial number, reference number, production date, version,
- degree of protection provided by the enclosure,
- symbols, e.g. applied part type,
- conformity mark.

### 5.7.1 Main features of SnG head

The hands-free SnG head has two ultrasonic transducers placed in one housing. The general view is shown in Figure 5-11. The head is intended basically for stationary therapy, and thanks to eyelet, it can be attached to the patient's body with hook-and-loop belts. The attachment method is shown in Figure 5-12.

SnG heads have LED indicators to show which front is currently active.



Figure 5-11. SnG ultrasound head

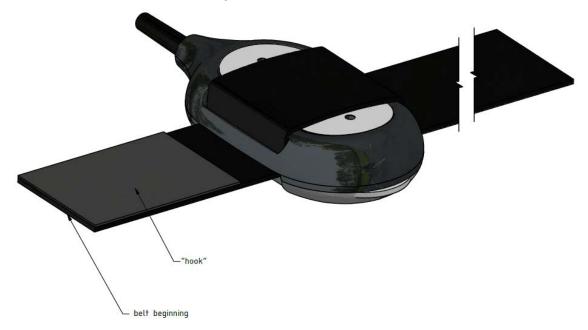


Figure 5-12. Way of inserting the hook-and-loop belt through the head eyelets

It is possible to combine two SnG heads into dual-section work, which allows for the treatment of larger areas simultaneously.

# 6. Device installation and start-up

### 6.1 Unit installation

The first installation should be performed by a qualified manufacturer's or distributor's representative!

After removing the unit from the carton, check if the complete unit has been delivered. In case of any inconsistencies contact the distributor or manufacturer.

After removing the unit from transportation packaging, depending on conditions during transport, wait approximately two hours before proceeding to next installation steps. This is aimed at adaptation of the unit to conditions in operation room.

The unit shall be placed on a table, trolley or in a cabinet near mains socket with power input 100-240V and frequency 50/60 Hz. The device can only be connected to socket with a grounding pin. It is recommended to place the unit at such a height that it would enable convenient operation from the front panel.

The light shall enable easy readout of display indicators, however the unit shall not be exposed to direct sunlight.

### 6.1.1 Connection of patient's cables and application of electrodes

Electrotherapy cables should be connected to electrotherapy socket according to Figure 6-1. Electrotherapy sockets are marked with symbols: **PA** and **B**.



Figure 6-1. Electrotherapy sockets label

Patient cables are terminated with banana type 4 mm or 2 mm plugs – two are red and the other two are black. Channels are marked with appropriate symbols. Electrodes should be connected to those plugs.



Figure 6-2. Connection of electrodes

After switching the unit on, red plugs are connected to positive pole, and black plugs are connected to negative pole. Electrode connection polarity matters in case of treatments with galvanic currents as well as unipolar currents of low and medium frequency.

As a standard accessory, the unit is equipped with elastomer-carbon electrodes. Parameters of such electrodes facilitate performing treatment procedures within a full range of available values of output signals amplitudes. It is recommended to operate with the unipolar currents using metal – tin or aluminum electrodes, as they wear out much slower than the electrodes made from other materials.

As optional accessories you can purchase self-adhesive electrodes in different dimensions. This type of electrodes is suitable for use with bipolar currents, especially TENS currents. **They shall not be used for therapy with unipolar currents!** Selection of the electrodes type to a particular treatment should be based on doctor's or physiotherapist's knowledge and experience.

### 6.1.2 Assembling of the holders

According to possessed parts, to the unit casing you can mount holders for ultrasound heads.

In order to mount the holder:

Step	Description
1.	Loosen the clasps and remove the holder masking cover – black parts of the casing located on the left and right side of the screen.
2.	Adjust the holders and screw bolts in according to Figure 6-3 and Figure 6-4.
3.	Reattach the masking cover. Pay attention to the orientation of the SnG head in the holder.

Method of mounting the holders is presented in the following figures.

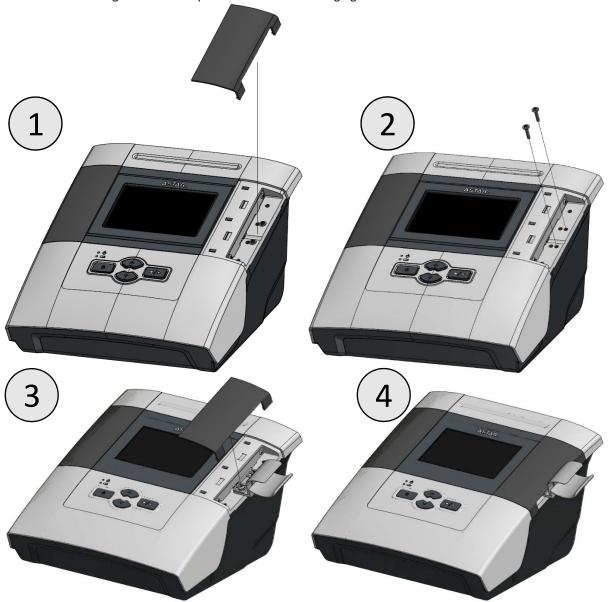


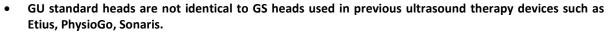
Figure 6-3. Method of mounting the standard ultrasound head holder



Figure 6-4. Method of mounting the SnG head holder

### 6.1.3 Connection of ultrasound heads

Ultrasound heads should be connected to sockets according to Figure 6-5. All connectors are protected against pulling out. When plugging a connector in, twist the thread to secure it.



- GU heads and GS heads cannot be used interchangeably.
- SnG head is not supported by Etius, PhysioGo and Sonaris devices.

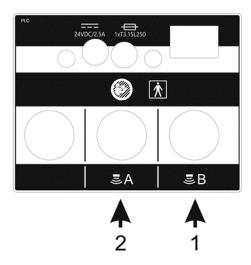


Figure 6-5. Ultrasound heads sockets

### 6.1.4 Connection in combined therapy

To perform the combined therapy procedure, use a standard ultrasound head and patient cable — B channel leads. When the power is switched on, the front of the selected head is connected to the negative pole. The red plug of channel B is connected to the positive pole.

The black plug of channel B is inactive in combined therapy and no electrode should be connected to it.

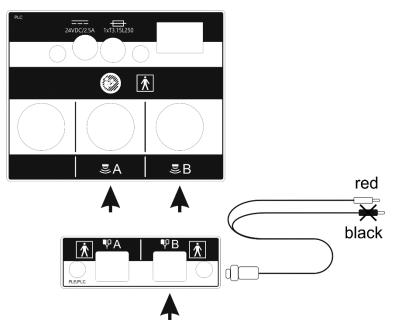


Figure 6-6. Connections in combined therapy

## 6.1.5 First operation

Connect the SMPS to the mains using the cable with integrated mains filter. Then connect output cord of the SMPS to the device socket marked with symbol , located on the back of the unit. Switch the power switch on. Then press the STANDBY key to start the operation. After switching the mains supply on proper work of all blocks are tested.

In the case of battery operation, please hold on for at least 5 seconds the STANDBY key . Extension of the holding time prevents unintentional activation during transport.



If after switching on mains supply the display is illegible, check whether mains fuse or mains cable operate correctly. Care shall be given to apply fuses with rating given on the name plate. If fuse and cables are working properly, contact the authorized service.

If after performed self-test on the screen there is an indication of a problem with device or connected accessory and/or detachable parts, turn the unit off and contact the authorized service.

The device is properly installed and is ready to perform safely and as intended by the manufacturer if:

- it is connected to a mains socket (with grounding pin) with a voltage in the range 100-240 V and a frequency of 50/60 Hz by a specified SMPS with mains filter,
- · accessories and detachable parts appropriate for the user's intended therapy are connected,
- after switching on the unit, the display is legible,
- self-test result is positive.

Do not touch the screen during the system start-up.

### 6.2 Setup mode

#### 6.2.1 Basic information

Keyboard components designed for the unit operation are called "keys".

The area on the screen, where after its pressing a specific unit reaction is followed, is called "button".

The area on the screen that has the possibility to select or deselect any item, is called "selection field".

To enter <i>Setup</i> mode, press	<i>E</i>
To leave <i>Setup</i> mode, press	<b>✓</b>
To leave <i>Setup</i> mode without changes, press	×
To go back one level, press	



Setup mode is available only if the treatment is not performed. Some setting options depend on the connected accessories and detachable parts. In the absence of some accessories and/or detachable parts, the options will not be available.

### 6.2.2 Language

Information on the display may be presented in different language versions (depending on the software version). The user is free to select language options.

To set the language version, press the **Language** button in the list of setup options, then press the desired version. The version is changed after the operation is confirmed.

### 6.2.3 Global settings

### 6.2.3.1 Date and time

In this section there is a possibility to adjust date and time. To change these settings, press the button *Edit*. Using arrows, set the required value. Confirm settings using *Set* button or leave the edition mode by pressing *Cancel*.

### 6.2.3.2 Sounds

The user may configure settings of acoustic signals, which occur during unit operation. Description of available configuration options:

- Keys sound
- Sound during treatment
- End of treatment sound
- Warning sounds
- Initial sound
- End of treatment sound see table below

Setting	Device reaction
0	No signal
1-10	Number of signals
∞ (infinity symbol)	Signal active until disabled by the operator

Sound tone – type of emitted signal.

In order to set the appropriate option, select or clear the selection field by its pressing. For the "End of treatment sound" and "Sound tone" parameters, click on the value to change it.

#### 6.2.3.3 Volume

The user may adjust sound volume level. To perform this action:

- press the volume bar at desired place, or
- use buttons () on the screen.

### 6.2.3.4 Display

The user may adjust display brightness level. To perform this action:

- press the value bar at desired place, or
- use buttons on the screen.

### 6.2.4 Functional settings

### 6.2.4.1 Channel operation mode selection

This function allows the user to set preferred style of unit operation.

Option	Explanation
Manual mode – automatically	After therapy selection, the unit is set in manual mode of the operation.
Program mode – automatically	After therapy selection, the unit is set in program mode of the operation.
Mode selection pop-up	After therapy selection, the unit displays a window with a list of operation mode selection options.

In order to set the appropriate option, select or clear the selection field by its pressing.

### 6.2.4.2 Program groups / medical fields

This function allows the user to set filters of available program mode options according to the preferred program groups or medical fields. In order to set the appropriate option, select or clear the selection field by its pressing.

For program groups, the following options are available:

- Preset programs
- Preset sequences only for electrotherapy
- User programs
- User sequences only for electrotherapy
- I/t curve only for electrotherapy, channel A

For medical fields, instead of the preset treatment programs and sequences the following options classified by medical nomenclature are available:

- Orthopedics
- Sports medicine
- Aesthetic medicine
- Rheumatology
- Neurology
- Urology
- Dermatology
- Angiology

The classification of preset treatment programs and sequences into the above-mentioned categories do not limit their applications in other fields, according to the knowledge and experience of doctors and physiotherapists.

### 6.2.4.3 The battery save mode

When the mode is activated, the device switches automatically into the standby mode after two hours of inactivity, which prolongs the battery life.

### 6.2.4.4 US head sensitivity

### For advanced users only!

It is possible to modify sensitivity of ultrasound heads in terms of no contact detection. According to treatment specifics, the sensitivity can be improved or reduced beyond default settings.

To change it you need to:

Step	Description
1.	Enter the setup mode. Select the <i>Functional settings</i> tab, then select the <i>US head sensitivity</i> .
2.	Select the ultrasound head type.
3.	Set a new sensitivity value.

Main features of sensitivity settings are listed below.

Sensitivity settings	Advantages	Disadvantages
Default	Default manufacture	er settings
High	<ul> <li>forced use of precise treatment technique, i.e. for training purposes</li> <li>protection of the ultrasound head against too fast usage</li> </ul>	<ul> <li>improved sensitivity on load's changes</li> <li>treatment timer stops more frequently</li> </ul>
Low	<ul> <li>reduced sensitivity on load's changes</li> <li>facilitated treatment performing on small parts of the body</li> <li>facilitated treatment performing on areas including bones, e.g. hands</li> <li>facilitated phonophoresis treatment performing</li> <li>treatment timer does not stop frequently</li> </ul>	<ul> <li>rapid usage of ultrasound head – possible overheat</li> <li>reduced comfort of patient's sensations – possible increase of heat feeling in the tissue</li> </ul>

#### 6.2.4.5 US head contact signaling

This function allows you to set the time after which in case of US head weak contact the treatment will be interrupted.

Option	Explanation
Default	The treatment will be interrupted after ten seconds when the US head will lose the acceptable level of contact quality with the patient's body.
Delayed	The treatment will be interrupted after 20 minutes when the US head will lose the acceptable level of contact quality with the patient's body.
Correction of treatment time	Option selected – treatment timer is not stopped after detecting lack of contact.
Correction of treatment time	Option unchecked – treatment timer is stopped after detecting lack of contact.

In order to set the appropriate option, select or clear the selection field by its pressing.

#### 6.2.5 Control functions

#### 6.2.5.1 Miscellaneous

In this section there is a possibility to manage some basic service functions:

- **Delete user programs** button allows you to remove user-defined programs.
- **Calibrate the touch panel** button starts the display calibration procedure. Follow the messages on the screen. First, touch three points, then validate the operation by touching five points on the screen.

You can also calibrate the display by pressing the key combination simultaneously when starting the device. The progress bar will change to green and the calibration screen will be displayed when started.

- **Test the touch panel** button allows you to check the touch screen operation on the touched spots an indicator occurs:
  - red at the pressed spot,
  - yellow at the pressure detection spots,
  - white at the spot where the pen or finger is removed (it should coincide with the red one). Press the START/STOP key to exit the test mode.

### 6.2.5.2 Date of inspection

There is possibility to enter into the device the date of the next inspection – it will automatically remind you about the need to perform an annual technical inspection.

#### 6.2.5.3 Electrodes test

This function allows the user to quickly check the usage status of electrodes applied in electrotherapy treatments. It can also be successfully used to assess the continuity of patient's cables.

In order to exercise the option, follow the instructions shown on the display. Detailed description of the function is described in the chapters 10.5 and 10.6.

#### 6.2.5.4 US head calibration

In order to exercise the option, follow the instructions shown on the display. This function allows you to adjust the head settings associated with the contact quality detection with the patient's body during treatment. It is recommended to carry it out in case of problems during normal operation.

In order to properly perform the procedure clean and dry out the ultrasound head.

Step	Description
1.	Prepare a plastic container with a capacity of 1 liter of water.
2.	Switch on the unit.
3.	Press the field
4.	Select the tab <b>Control functions</b>



Step	Description
5.	Select the tab <i>US head calibration</i>
6.	Select the head and press the field.
7.	Measure the head without load – "in the air". Press the ■/ ▶ button.
8.	Put the ultrasound head into the container filled with water. Press the <b>button</b> .
9.	If necessary, adjust the US head sensitivity settings by selecting a different field from the default.
10.	Press <i>Save the calibration</i> to save the settings or <i>Return</i> to cancel and return to the procedure beginning.

### 6.2.6 Information

#### 6.2.6.1 Info

Provides information about the serial number, version of the unit, software, interface and software build date.

#### 6.2.6.2 Manufacturer

Provides information about the manufacturer together with the contact details.

#### 6.2.6.3 Distributor

Provides information about the distributor in a given country together with the contact details. The "Change contact data" button can be use only by authorized unit, after entering the access code. The full data consists of:

- the company name
- the company address
- the company website
- the company phone number
- the company e-mail

If data is not entered, the "----" characters will be shown.

### 6.2.6.4 Technical support

Provides information about technical staff (the manufacturer's or distributor's) in a given country together with the contact details. The "Change contact data" button can be use only by authorized unit, after entering the access code. The full data consists of:

- the company name
- the company address
- the company website
- the company phone number
- the company e-mail

If data is not entered, the "----" characters will be shown.

The "Show logs" button supports service diagnostics, by displaying information about all saved device errors.

### 6.2.6.5 Unit statistics

Provides information about the number of treatment procedures performed. Statistics can be deleted. If you want to delete statistics, press *Delete programs counters* button.

#### **6.2.6.6** Accessories statistics

There appears the information on connected accessories and detachable parts.

# 6.3 Transport position – trolley for the unit

Step	Description
1.	Click the UNIT ON / OFF (STANDBY) button on the front panel .
	A message will appear on the display:
2.	Are you sure to switch off the unit?
3.	Press   to shut down the system correctly.
4.	Disconnect from the controller the power cord and parts of the unit.
5.	Remove the device and parts of the unit from the trolley.
6.	Then unlock all wheel brakes of the trolley.
7.	Transport the trolley. Move the device and parts of the unit separately.
8.	After arranging the trolley in the destination place, lock the brakes.
9.	Place the device on the upper shelf. Reconnect the switched-mode power supply and the parts of the unit.

# 7. Unit operation

The unit may operate in one of two modes:

- program mode,
- manual mode.

Notes – unit operation:

- In the program mode you can use preset procedures of treatment programs and sequences, as well as userdefined programs and sequences.
- In the program mode you cannot edit the preset programs and sequences parameters. However, programs can be easily "copied" to the manual mode. In order to do it, press the button .
- There is a possibility to repeat the completed treatment. In order to do it, press

### 7.1 Patient preparation and treatment performance

#### 7.1.1 General information

To perform safe and effective treatment procedure you are obliged to:

- make sure if there are no contraindications to perform the treatment,
- the patient should be placed in a comfortable position while providing relaxation of tissues in the treatment area, the patient should be in lying position in case of treatment performed near the head,
- sitting or reclining position should be applied to patients with respiratory disorders or breathing difficulties,
- inform the patient about the possible feelings occurring during treatment procedure.

The treatment effectiveness depends on the choice of parameters to the current patient's condition. The patient's condition changes over time. Its observation and assessment should take place before, during and after therapy. Such an action is necessary for changing the parameters in order to adapt them to the actual condition of the patient.

It is recommended to keep the records of treatment, including the parameters of the therapy, the area of treatment, treatment technique and symptoms after therapy. If the treatment does not generate the intended effects, change of treatment parameters should be taken into consideration. It is necessary to continuously update knowledge and follow literary activities in the scope of therapy.

When performing therapy, it is recommended to follow the guidelines given in the following sections.

### 7.1.2 Electrotherapy

- Before electrotherapy it is necessary to check the correct operation of the device and check the technical condition of cables and electrodes using a tester or the built-in device function see 10.5 / 10.6.
- Use only disinfected and in good condition electrodes.
- Improper selection of electrodes can cause skin irritation and burns.
- In case of direct current and unidirectional pulse currents of long pulse duration it is necessary to use tin electrodes.
- It is necessary to use properly moistened pads for electrodes, they may be made of viscose or fine mesh gauze to "keep" water properly. For unidirectional currents it is necessary to use properly moistened pads and of adequate thickness, however water should not drip from them.
- The water should be warm so as not to cause vasoconstriction in the area of performed treatment, you should use casual tap water.
- For low and medium frequency bipolar currents a gel coupling the electrodes with the patient's body can be applied (e.g. aloe Vera) if there are no viscose or gauze pads.
- Properly attach the electrodes with viscose pads to the patient's body, e.g. by Velcro belts, elastic bandage or sand bags.



- In the place of the arrangement of the electrodes it is necessary to estimate the continuity of the skin and exteroceptive sensation.
- In order to decrease the resistance of skin you can clean it with alcohol or water with soap, after wiping leave the skin moist. Small skin damages should be secured with medical or cosmetic petroleum jelly.
- During the first therapy it is necessary to use rather lower doses of current than the recommended ones.
   Intensity (sensory threshold level or motor threshold) depending on the goal of therapy, it is necessary to increase in accordance with the patient's sensations and maintaining comfort during treatment.
- In case of reporting burning it is necessary to stop the treatment and examine the skin.
- The electrodes should be used in accordance with the indications of the manufacturer and should be replaced periodically, depending on the degree of wear. Loss of electrical properties by the electrodes causes the risk of burning the patient.
- Due to the need to ensure the accuracy of the output parameters of the device, it is not possible to set amplitudes lower than:
  - o 0.3 mA unipolar currents in CC mode,
  - 0.5 mA bipolar currents in CC mode,
  - 1.5 V or 2 V currents in CV mode.

These values are so small that they do not pose a threat to the patient and do not cause unpleasant sensations.

### 7.1.3 Ultrasound therapy

- Before the treatment it is necessary to check the efficiency of functioning of the equipment and to control the cables and ultrasound head.
- It is necessary to explain to the patient the method of treatment and sensations during the treatment (always painless). This can be done with the help of the encyclopedia containing figures, description of the treatment methodology and parameters.
- It is necessary to clean the skin (or soap or alcohol 70%) in the place of application. If skin is very hairy in the place of treatment, it is necessary to shave it gently, cover the remaining parts of the body in order to avoid undercooling.
- The position of the therapist should facilitate free access to the equipment in such a way that the
  ultrasound head should remain for the whole time of treatment in contact with the skin of the patient.
  Proper pressure is necessary in order to ensure firm contact between the skin and the head which enables
  optimal transmission of ultrasound energy.
- It is necessary to use the coupling medium conducting the ultrasounds, preferably gel.
- Coupling medium should be applied on the surface of skin, make continuous movements in the form of
  overlapping or longitudinal circles, the head shall not be removed from skin, in case of pain or burning it
  is necessary to stop therapy and change parameters.
- It is necessary to locate the tissue affected by the disease (incl. determination of its type, depth), the surrounding tissues and its repair phase, to:
  - choose frequency of ultrasounds (up to 6 cm frequency 1 MHz, up to 1 cm frequency 3 MHz),
  - distinguish if it is an acute condition (only mechanical effect of ultrasounds recommended), or chronic condition (mainly thermal effect),
  - choose a method of application (direct, indirect),
  - determine proper starting position: without pain, relaxing position, with treated tissues positioned as close to the surface of skin as possible.
- Ultrasounds in water bath are used if part of the body subjected to therapy is of irregular shape or there
  is a spot sensitivity enabling direct contact with ultrasound head. Most often it is used in therapy of
  palms, forearms, feet and ankles. Part of the body subjected to therapy should be immersed in degassed
  water with temperature pleasant for the patient. Waterproof head must be placed at the distance of 1-2
  cm and move parallel to the treated surface. Intensity must be increased by 30-50%, to obtain a dose like
  in direct therapy.
- Output power must be switched on if the head is in direct contact with the skin and at the same time it
  is in motion. Such a procedure allows to avoid damages to the converter and prevent skin injuries, which
  may occur if a sufficient amount of energy is taken back to the head. Control system which monitors the
  contact of the head reduces the output power, if the head's contact is inadequate.

### 7.1.4 Combined therapy

- Combined therapy consists in simultaneous effect of ultrasounds and pulsed current of low or medium frequency on the tissues.
- Influence of ultrasounds increases permeability of the skin for the current, owing to which it is allowed
  to use smaller doses of amperage. Combination of activity of ultrasounds and currents produces bigger
  therapeutic effects than in case of their separate application.
- In combined therapy it is possible to precisely localize the place of application with a very small dose of current as the ultrasounds increase the sensitivity of nerve fibers.
- Ultrasounds prevent or clearly decrease the effect of habituation which is negative from the therapeutic
  point of view, therefore the electric stimulus is more efficient and may be applied in long term without
  adverse effects.
- Combined therapy is of huge importance both in diagnostics (searching for trigger points, hyperacusis zones and Head's zones) and in treatment.
- In combined therapy ultrasounds are combined with bidirectional pulsed currents (TENS, HVS, average frequency) in order to limit the occurrence of electrochemical reactions and ensure proper depth of penetration.
- Choice of frequency of ultrasounds depends on the localization of trigger point. Frequency 1 MHz is used
  for treatment of myofascial trigger points and localized in connective tissue, whereas frequency 3 MHz in
  treatment of surface points in skin.
- The power density of ultrasounds used in combination therapy amounts to 0.5 to 1.5 W/cm².
  - The power density of 0.5W/cm² is employed in the area of face and neck, it is recommended in case of active trigger points and significant painful conditions.
  - The power density of 0.5 to 1.0 W/cm² is employed in the paraspinal area, it is recommended in case of active trigger points and painful conditions of medium intensity and in slim patients.
  - The power density of 1.0 to 1.5 W/cm² is recommended in painful conditions of low intensity, on limbs, in the area of hips and buttocks in stout patients.
- Most often impulse emission of ultrasounds is applied, with duty factor of 20-75%.
- Current parameters in diagnostics of trigger points:
  - traditional, symmetric TENS frequency 100Hz, pulse time 0.1ms, intensity above sensory threshold,
  - dipole interference, AMF frequency 100Hz, intensity above sensory threshold.

Semi-stable technique, treatment time from several seconds to 2 minutes per one point.

- In combined therapy an active electrode is the ultrasound head, placed above the pain location. Possibilities of placing a passive electrode:
  - outside the area where the treatment is carried out,
  - above the nerve supplying the pain area,
  - above the spot of referenced pain,
  - within a given dermatome, where pain area is located.
- In local therapy the parameters of ultrasounds and current are adapted to the actual condition of tissues.
- Additionally, pay attention to the technique of electrotherapy treatment performance.

### 7.1.5 Method of ultrasound therapy treatment performance

Method	Features
Dynamic	The head is moved in a continuous way, by exercising pressure, parallel to the skin, by applying steady, rhythmical motion patterns at average speed of 4cm/sec. Too fast motions cause too low accumulation of ultrasound energy, too slow motions cause overheating of tissues in case of using higher intensities of ultrasounds.
	Choice of the method of moving the head depends on the shape of treated surface. In case of treating surfaces with irregular shape, motion pattern may appear as overlapping circles. This method requires from the therapist to make circular motions of small diameter, the size of ultrasound head should be such that the subsequent circular sliding motion overlaps the half of the previous motion.

Method	Features
	In case of treating larger, flat surfaces it is necessary to carry out longitudinal movements. This method requires from the therapist carrying out sliding movement with the adequate rhythm and carrying out side movements of length equal to half of the ultrasound head's diameter. As far as possible it is recommended to slightly press the head to the skin surface as this increases the penetration of ultrasounds deep into the tissues.
Sem-stationary	Even during treatment of relatively small areas, such as trigger points, elements of scars or tendons it is necessary to make even very small but continuous movements with the head.
Stationary (static)	The head remains motionless during the treatment.
	SnG heads are attached permanently to the patient's body with hook-and-loop belts.
	In multi-transducer application, protection against tissue overheating is achieved by a sequence of switching of ultrasonic transducers and ultrasonic wave modulation.
	In single-transducer application, protection against tissue overheating is achieved by the ultrasonic wave modulation.
LIPUS	The head remains motionless during the treatment.

Examples of app  Method	Head	Example
Dynamic, semi- stationary	- GU-5	
LIPUS		
Dynamic, semi- stationary	GU-1	
LIPUS		
Combined therapy	GU-5 / GU-1	

# 7.2 Screen configuration

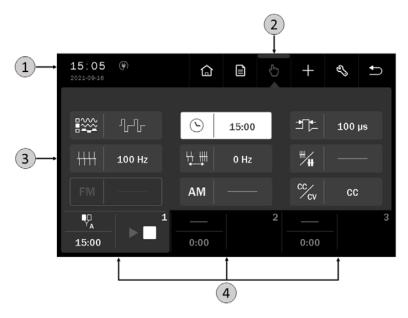


Figure 7-1. Field description

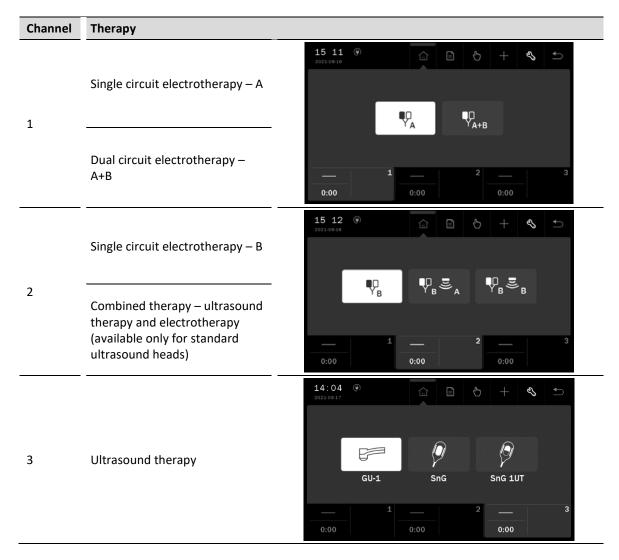
Symbol	Field	Description		
		Date and time		
1	Status tab		Battery – quality level battery charging symbols	
		<del>(#)</del>	Mains cable connected	
			Therapy selection menu	
			Program mode	
2	Main menu	$\bigcirc$	Manual mode	
2	Main menu	+	User-defined treatment programs edition mode	
		ñ	Information mode	
		8	Setup mode	
3	Edition field	This field shows:      available therapies, accessory and detachable parts     treatment parameters in manual mode (see chapter 8)     list of preset treatment programs and sequences     list of user-defined treatment programs and sequences     settings		
4	Channel selection tabs	Details are descr	ibed in chapter 7.3.2	



Note: If the edition / main menu field is grayed out, it means that it is inactive.

# 7.3 General configuration

### 7.3.1 Treatment channel configuration



### 7.3.2 Channel selection tabs

The screen displays two channel selection tabs. They present:

- selected therapy symbol,
- treatment time,
- information related to the particular channel operating status.

The color of the tab is identical to the background color of the edition field. In the background, other operating tabs are black.

The table below explains the meaning of the symbols presented in tabs:

Symbol	Description	
■ A	Channel 1	Selected single circuit electrotherapy – socket A
A+B	Channel 1	Selected dual circuit electrotherapy – socket A and B
■ B	Channel 2	Selected single circuit electrotherapy – socket B
<b>P</b> B € A	Channel 2	Selected combined therapy – electrotherapy socket B, head connected to socket A

Symbol	Description		
₽D <sub>B</sub> ≡ B	Channel 2	Selected combined therapy – electrotherapy socket B, head connected to socket B	
<u>.</u>	Channel 3	Selected ultrasound therapy	
	Ongoing treatment (white symbol)		
	Treatment interrupted (white symbol)		
<u>.</u>	Error (yellow symbol)		

### 7.3.3 Current selection screens

Navigation between the three current selection screens is carried out using arrows:

- the first screen to the second screen,
   second screen to the third screen,
   the first screen,

• 1	third screen	– to the second screen.					
Screen	Currents	rrents					
	TENS	transcutaneous electrical nerve stimulation					
	IF	interferential currents	15:09 (h) (a) (b) (b) (c) (c) (c) (c) (c) (c) (c) (c) (c) (c				
	RS	Kotz' current (Russian stimulation)	TENS 1-1 4p +++++++++++++++++++++++++++++++++++				
1	MF	medium frequency currents					
	SPS	SP-TENS	DIA DC UR SURGE				
	DIA	diadynamic currents					
	DC	galvanic current	5:00   D 1				
	UR	Ultra Reiz (Träbert's current)	5.00				
	SURGE	sine surge					
	LEDUC	Leduc current	15:10 ®				
	REC	rectangular pulses	LEDUC REC TRIAN NEOFA MICRO				
2	TRIAN	triangular pulses					
	NEOFA	neofaradic	<b>&gt;</b>				
MICRO	microcurrents	5:00 1 2 3					
	IG	IG pulses	15 11 ® 🚡 🕒 + 🗞 🕏				
	EMS	electrical muscle stimulation					
3	H-WAVE	H-waves					
	EXP	exponential pulses	IG EMS H-WAVE EXP HFS				
J	HFS	Hufschmidt stimulation (A+B only)	<				
	TONO	tonolysis (A+B only)	5:00 1 <u>—</u> 2 <u>—</u> 3				

## 7.3.4 Configuration of detachable parts for ultrasound therapy

# Connected ultrasound head

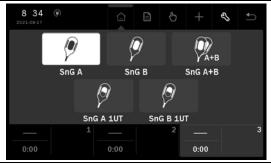
- standard ultrasound head (GU-1)
- standard ultrasound head (GU-5)



- standard ultrasound head (GU-1)
- SnG head



- SnG head
- SnG head



## 7.3.5 Limitations

The list of limitations in the unit operation:

Condition	Limitations
Treatment channel 1	In channel 2 it is possible to set only ultrasound therapy till the end of
Set electrotherapy mode A+B	performed treatment in channel 1 and escaping from edition mode
Treatment channel 2 Selected electrotherapy B or combined therapy	In channel 1 there is a possibility of setting only electrotherapy A
Treatment channel 2 Connected SnG head	Treatment channel 2 – combined therapy not available
Treatment channel 2 Selected combined therapy	Treatment channel 3 – ultrasound therapy not available
Treatment channel 3 Selected ultrasound therapy	Treatment channel 2 – combined therapy not available
I/t curve	I/t curve available only in channel 1 for electrotherapy A

# 7.4 Display description

Display		Description
	Α	Electrotherapy circuit – socket A
	В	Electrotherapy circuit – socket B
Output signals of circuits and amplitude settings		Effective intensity, also called output power density [W/cm²]
identifiers	Р	Output power [W]
	Amplitude settings of:	
	<ul> <li>current and ve</li> </ul>	oltage for electrotherapy circuits
	<ul> <li>power density</li> </ul>	y for ultrasound head
Information field	7.2 V	/ mode – the voltage value and the estimated intensity current flow, where: one column – current < 10 mA, two columns – current in the range of 10÷20 mA, three columns – current in the range of 20÷30 mA, four columns – current in the range of 30÷40 mA, five columns – current > 40 mA.
	ar Qu Th	uality of the ultrasound head contact. The more bars e highlighted, the better the contact is.  uality of the ultrasound head contact in LIPUS mode. he more bars are highlighted, the better the contact is.
Time indication	·	eatment elapsing time.  herapy sequences, indication of the sequence step.  otly executing step is blinking.

# 7.4.1 Electrotherapy

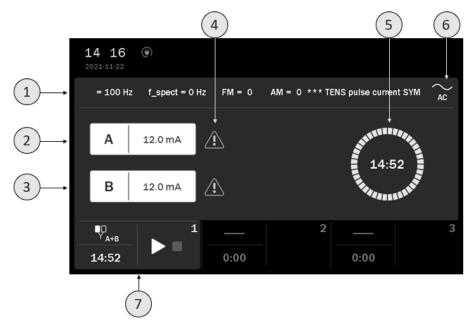


Figure 7-2. Screenshot sample view for dual circuit electrotherapy A+B

Symbol	Description			
1	Manual mode current name and shortened information on treatment parameters			
	Program mode	program name		
2	A circuit identificat	A circuit identification and amplitude value		
3	B circuit identification and amplitude value			
4	Indication of a current flow with an amplitude above a certain threshold (see 5.6.3)			
5	Presentation of the treatment elapsing time			
6	Current identification (AC/DC) (see 5.6.5)			
7	Tab field – channel 1			





Figure 7-3. Screenshot sample view for single circuit electrotherapy A and B

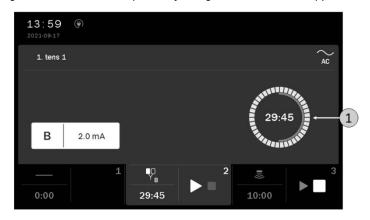


Figure 7-4. Screenshot sample view for electrotherapy sequences

Symbol	Description
1	Indication of the treatment elapsing time and sequence step

# 7.4.2 Ultrasound therapy

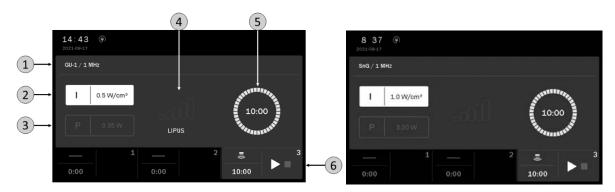


Figure 7-5. Screenshot sample view for standard ultrasound head GU-1 and SnG  $\,$ 

Symbol	Description		
1	Manual mode	head identifier / frequency	
1	Program mode	program name	
2	Effective intensity (output power density) [W/cm²]		
3	Output power [W]		
4	Information field (quality of the ultrasound head contact)		
5	Treatment timer		
6	Tab field – channel 3		

## 7.4.3 Combined therapy

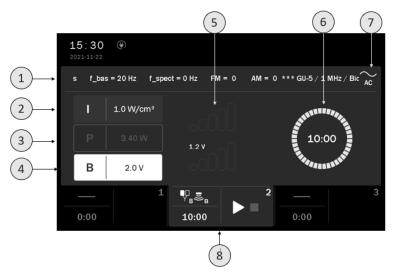


Figure 7-6. Screenshot sample view for combined therapy

Symbol	Description		
1	Manual mode	head identifier / frequency / current identifier and shortened information on treatment parameters	
	Program mode	program name	
2	Effective intensity (output power density) [W/cm²]		
3	Output power [W]		

Symbol	Description
4	B circuit identification and amplitude value
5	Information field (quality of the ultrasound head contact)
6	Treatment timer
7	Current identification (AC/DC) (see 5.6.5)
8	Tab field – channel 2

### 7.5 Treatment timer

The treatment time is adjustable from 1 - 60 minutes with a step of 1 minute. It is also possible to adjust manually by "holding" the field with time by means of a pen / finger – in increments of 1 s (Figure 7-7)



Figure 7-7. Manual time setting

### 7.6 Operation with preset treatment programs and sequences

The simplest method of unit's operation is to use its preset programs or treatment sequences. The unit includes a database containing several dozens of most frequently met disorders together with suggested treatment types and parameters. In this mode, the operation is reduced to selection of disease entity from the list.



The values of the preset treatment programs parameters are based on the available literature data and they are determined as average values. Parameters should be treated exclusively as indications. The user is solely responsible for the application of the preset treatment programs.



Pressing the button 🗓 after program / sequence selection results in appearing information which contains:

- description of electrodes placement, ultrasound heads application,
- · illustrations with highlighted points or areas of the body covered by the treatment,
- · suggested number of procedures, the frequency of repetition,
- impact on the patient,
- notes,
- treatment parameters.

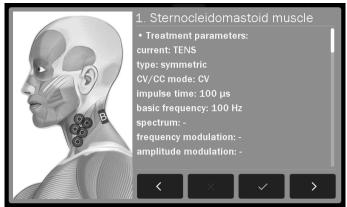


Figure 7-8. Information screen sample view



# Information mode navigation:

Description
Approval of the program / sequence and return to the list (the current position)
Back to the list of preset programs / sequences on a position from which there was an encyclopedia entry
Go to the next program / sequence
Go to the previous program / sequence
Model of the human body – go to the previous / next illustration for the program / sequence



Use keys or a bar located on the right side of the display to scroll the information.

If it is necessary to interrupt the treatment procedure (pause), press | key. To resume the treatment procedure, it is recommended to follow the instructions shown on the display.

Schematic procedures for therapies are presented below. In continuous operation, it is recommended to start the treatment procedure from step 3 of the schemes.

Schematic procedure for electrotherapy treatments:

Step	Description
1.	Connect patient's cables.
2.	Switch the unit on.
3.	Select the tab 1 or 2 depending on needs or availability. Select the therapy A B A+B
4.	Press the field Program mode
5.	Select the option <b>Preset programs</b> or <b>Preset sequences</b> from <b>Program modes</b> menu. Confirm your choice by pressing the selected field again.
6.	Select the program / sequence from the list.
7.	Prepare the patient for the treatment according to indications in point 7.1
8.	Press the key ■/▶
9.	Using the keys set the current or voltage amplitude.

Schematic procedure for ultrasound therapy treatments:

Step	Description
1.	Connect the appropriate ultrasound heads.
2.	Switch on the unit.
3.	If two heads are connected, select the head which is going to be used. If the SnG head is connected, select the operating mode.
4.	Press the field Program modes
5.	Select the option <b>Preset programs</b> from <b>Program modes</b> menu. Confirm your choice by pressing the selected field again.
6.	Select the program from the list.
7.	Prepare the patient for the treatment according to indications in point 7.1.
8.	Press the key ■/►.
9.	Using the keys optionally adjust power density of the ultrasound head.

Schematic procedure for combined therapy treatments:

Step	Description
1.	Connect the patient's cable to B socket. Connect a standard ultrasound head for combined therapy to socket A or B.
2.	Switch on the unit.
3.	Select the tab no 2. Select the combined therapy B Aor B B
4.	Press the field Program modes
5.	Select the option <b>Preset programs</b> from <b>Program modes</b> menu. Confirm your choice by pressing the selected field again.
6.	Select the program from the list.
7.	Prepare the patient for the treatment according to indications in point 7.1.
8.	Press the key ■/►.
9.	Using the keys set the amplitude of current or voltage, or optionally adjust the power density of the ultrasound head.



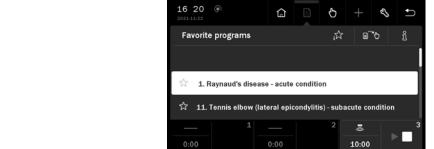
## 7.7 Favorite programs

The function offers quick access to frequently used **preset programs and sequences** without browsing the entire

list.	
To add o	r remove the program from the favorite list, follow the instructions:
Step	Description
1.	Prepare the unit to work with preset treatment programs and sequences (see section <b>7.6</b> ).
	Select program / sequence.
	16:19 (P) (C) (C) (C) (C) (C) (C) (C) (C) (C) (C
	Preset programs 🛱 📵 ්ර 🐧
2.	10. Tennis elbow (lateral epicondylitis) - acute condition
	☆ 11. Tennis elbow (lateral epicondylitis) - subacute condition
	12. Tennis elbow (lateral epicondylitis) - chronic condition
	0:00 0:00 10:00
	add remove
	Press the symbol $\stackrel{\bigstar}{\lambda}$ next to the name of the Press the symbol $\stackrel{\bigstar}{\lambda}$ next to the name of the
	program / sequence Symbol color changes to program / sequence Symbol color changes to

program / sequence. Symbol color changes to yellow and the program / sequence is inserted on the favorite list.

program / sequence. Symbol color changes to blue and the program / sequence is deleted from the favorite list.



You can also remove the item from the favorite 4. list, if you press the symbol

3.



If no item from the preset treatment program or sequences list is selected as a "favorite", then after entering the option, the list will be empty.

**NOTE: Favorite** option is not available when you set the view of preset treatment programs or sequences by medical fields. See point 6.2.4.2.

## 7.8 Manual mode operation

Step	Description
1.	Connect proper accessory and/or detachable parts.
2.	Switch the unit on.
3.	Select the tab 1. 2 or 3 depending on needs or availability. Select the therapy according to point 7.3.
4.	Press the filed Manual mode
5.	In the case of electrotherapy and combined therapy select the current type. In the case of ultrasound therapy, if two heads are connected, select the head which is going to be used. If the SnG head is connected, select the operating mode.
6.	Select the parameter for edition, using the keys set its value.
7.	Prepare the patient for the treatment according to indications in point 7.1
8.	Press the key ■/►
9.	Using the keys set the amplitude of output signal.



If it is necessary to interrupt the treatment procedure (pause), press key. To resume the treatment procedure, it is recommended to follow the instructions shown on the display.

# 7.9 User programs

The User has the possibility to save in to the device memory own sets of treatment parameters in the form of programs.

Saving of user program:

Step	Description
1.	Prepare the unit to work in manual mode (steps 1 – 5 see section 7.8).
2.	Set the program parameters.
3.	Press the button + from main menu.
4.	Select the item number under which the program will be saved. Confirm your choice by pressing the selected field again.
5.	Enter the program name. Press the button <

The user-defined programs are selected in the same way as preset treatment programs. In **Program modes** menu select the option **User programs.** 

Edition of user program:

Step	Description
1.	Prepare the unit to work in the program mode (see section 7.6).
2.	Select the option <b>User programs</b> from <b>Program modes</b> menu. Confirm your choice by pressing the selected field again.
3.	Select the program for edition.

Step	Description
4.	Press the button + from main menu.
5.	Select the action – <b>Edit</b> .
6.	Correct the parameters.
7.	Press the button + from main menu.
8.	Select the item number under which the program will be saved. Confirm your choice with $\checkmark$ .
9.	Enter or edit the program name. Press the button $\checkmark$ .

### Removal of user program:

Step	Description
1.	Prepare the unit to work in the program mode (see section 7.6).
2.	Select the option <b>User programs</b> from <b>Program modes</b> menu. Confirm your choice by pressing the selected field again.
3.	Select the program which will be deleted.
4.	Press the button + from main menu.
5.	Select the action – <b>Remove</b> .
6.	Confirm by pressing $\checkmark$ or resign using $×$ .

### User program parameter view:

Step	Description
1.	Prepare the unit to work in the program mode (see section 7.6).
2.	Select the option <b>User programs</b> from <b>Program modes</b> menu. Confirm your choice by pressing the selected field again.
3.	Select the program which parameters will be checked.
4.	Press button 1.
5.	Press the button , to return to the user-defined treatment program list.

# 7.10 User sequences

The unit is equipped with an advanced editor which allows you to create electrotherapy treatment sequences. A single sequence may consist of up to four stages. The sequence may be created from previously saved user-defined programs.

The user sequences are selected in the same way as preset treatment programs. In **Program modes** menu select the option **User sequences.** 

Step	Description
1.	Connect patient's cables.
2.	Switch the unit on.
3.	Select the tab 1 or 2 depending on needs or availability. Select the therapy A B A+B
4.	Press the filed Program mode
5.	Select the option <b>User sequences</b> from <b>Program modes</b> menu. Confirm by pressing the selected field once again.
6.	Select the sequence from the list.
7.	Prepare the patient for the treatment according to indications in point 7.1

### Step Description

8. Press the key -/-

Select the amplitude control mode.

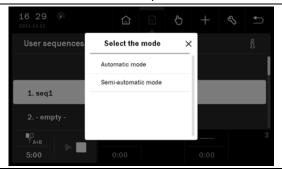
### **Automatic mode**

The sequence is performed continuously. Between the steps, the current or voltage amplitude is reduced to the safe level. Therefore, there is a need for its upregulation in order to ensure the proper feelings of the patient.

### Semi-automatic mode

The sequence is performed continuously. Between the steps, the current or voltage amplitude is reduced to the minimum level. Therefore, there is a need for its upregulation in order to ensure the proper feelings of the patient.

9.



10. If it is necessary, during treatment procedure, using the keys set the amplitude.



If it is necessary to interrupt the treatment procedure (pause), press the key . To resume the treatment procedure, it is recommended to follow the instructions shown on the display.

### Creation of user sequence:

Step	Description			
1.	Prepare the unit to work in the program mode (see section 7.6).			
2.	Select the option <b>User sequences</b> from <b>Program modes</b> menu. Confirm by pressing the selected field once again.			
3.	Press the button  from main menu. This opens the user's sequence editor. Select the item to be saved. Press	User sequences editor  User sequences:  Sequence stagles:  L. engly - 2. engly - 3. engly -		
4.	From the list of user programs, select the program and press The Repeat the action for additional items. The sequence may consist of up to 4 programs.	User sequences editor User programs Sequence stages:  1.596 1 2.396 2 3.599 3  C\$\tilde{\rightarrow}^{\bar{\text{t}}} \tilde{\rightarrow}^{\bar{\text{t}}} \til		
5.	Use the sequence edition tools described below to make changes in the created sequence.			
6.	Press the button to save the sequence. Enter the name. Then press			
7.	Press the button X to escape from the sequence editor	or.		

### User sequence edition:

Step	Description			
1.	Prepare the unit to work in the program mode (see section 7.6).			
2.	Select the option <b>User sequences</b> from <b>Program modes</b> menu. Confirm by pressing the selected field once again.			
3.	Press the button + from main menu. This opens the user's sequence editor.			
4.	Select the sequence. Press			
5.	Use the tools described below.			
6.	Press the button to save the sequence. Enter or modified the name. Then press			

### **Sequence edition tools:**

Button	Explanation				
<u></u>	Select the user-defined program – left side of the edition screen.				
<b>└</b> 〉	2. Press , selected item will be added as a new step of the sequence.				
-/-	1. Select the sequence step – right side of the edition screen.				
<b>√</b>	2. Press T. Step will be deleted.				
$\wedge$	1. Select the sequence step – right side of the edition screen.				
<u>'</u>	2. Press 1. Step will be moved up one level.				
	1. Select the sequence step – right side of the edition screen.				
$\checkmark$	2. Press . Step will be moved down one level.				

### Removal of user sequences:

Step	Description		
1.	Prepare the unit to work in the program mode (see section 7.6).		
2.	Select the option <b>User sequences</b> from <b>Program modes</b> menu. Confirm by pressing the selected field once again.		
3.	Press the button + from main menu.		
4.	Select the sequence. Press		
5.	Confirm by pressing $\checkmark$ or resign using $×$		

# 7.11 I/t curve

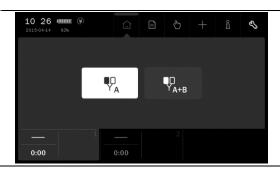


It is recommended to use the results obtained by determining I/t curve to create a program of electrostimulation of flaccid muscles treatment program that will be executed exclusively with the PhysioGo.Lite Combo unit.

# Step Description

1. Switch the unit on.

Choose the tab 1. mode YA
 Confirm by pressing the selected field once again.



3. If the unit is in manual mode, press

4. Using keys or by touch set the position of **I/t curve**. Confirm by pressing the selected field once again.

5. Prepare the patient for the treatment according to indications in point 7.1. It is recommended to use the point electrode (cathode, black plug) as an active electrode.

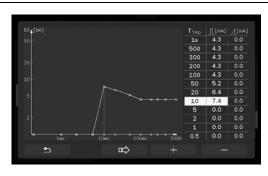
6. Press key for button. The unit is in stimulation mode.

Using the keys or buttons increase the output current for the pulse duration of 1000 ms until reaching value, at which minimum muscle contraction is observed. The current value is automatically applied to the chart.

The pulses appear at 2 seconds intervals.

Using the button , move one position to the right to the value under 500 ms pulse duration. Again, set the current at such a value at which minimum muscle contraction occurs, then mark it on the diagram (setting starts with value).

on the diagram (setting starts with value measured for the previous pulse width time, you can reduce the current and start your observation from zero value of the output current). Repeat the procedure for all rectangular and triangular pulse time values.



Upon completion of stimulation, press the button  $\Box\Box$ , the unit will automatically display:

- rheobase, chronaxie, accommodation threshold value,
- accommodation factor value along with commentary and visual evaluation on the scale.
  - quotient accommodation value with commentary and visual evaluation on the scale.



10. Press to see again the graph. Press to save the curve. Enter the name and press

11. Press the X key to escape from the I/t curve mode.



8.

9.

It may happen that the muscle reaction is not observed for triangular pulses of 1 s pulse duration. Then you should interrupt the procedure and start it again from 500 ms pulse duration. For the time value of 1 s should be set 0 mA value. In this case, parameters are determined on the base of signal amplitude for 300 ms and 200 ms pulse duration.

There is a possibility to view the saved results of I/t curves. In order to open the list of saved I/t curves press L. Then select the item to be loaded by pressing its name.

You can also delete the saved results of I/t curves. In order to delete the entry, press . Then select the entry to delete it by pressing its name and confirm the deletion by pressing the button .



# 7.12 Safe shutdown procedure

The work flow for the safe termination of the operation:

Step	Description				
1.	Click the UNIT ON / OFF (STANDBY) key on the front panel .				
	After clicking the button, a message will appear on the display as it is shown on the screen below.				
	△ CAUTION				
2.	Are you sure to switch off the unit?				
3.	If you want to confirm the operation, select the $\checkmark$ button, pressing of which will switch the unit				
Э.	off properly. If you quit turning the unit off, select $ imes$ .				
4.	After closing the system, you can disconnect the unit from the power supply network by means of				
٦.	power switch. If you want to charge the battery, leave the device connected to the mains.				

# 8. Definitions and parameters

## Electrotherapy

### 8.1.1 Terminology

The carrier frequency is a parameter of medium frequency alternative current, the so called carrier wave of interferential fourpolar and bipolar currents (4000 Hz), Kotz' current (2500 Hz) and medium frequency unipolar currents modulated by low frequency current. As the current carrier frequency increases, the capacitive resistance of the tissues decreases.

**Base frequency** is a parameter of low frequency alternative current, which is produced in course of amplitude modulation of carrier wave creating a low frequency sine curve (5÷100 Hz). The sine wave of base frequency constitutes an envelope circumscribed on the carrier wave, which enables its deep penetration into human body tissues, is often referred to as AMF – amplitude modulated frequency.

Basic frequency **spectrum** determines scope of modulation of this parameter as function of time. This parameter determines the frequency added to basic frequency, and the sum of them is the highest base frequency value that occurs during modulation.

Example: Base frequency is at 60 Hz, spectrum 40 Hz. That means that the base frequency will vary within the limits 60 to 100 Hz (60+40=100) in timely dependence determined by the FM program.

The base frequency of Kotz' current determines the number of bipolar "bursts" in the 2500 Hz carrier wave. **TENS pulse frequency** determines frequency of occurring pulses, where the pulse duration time is a value set separately between 25 and 300  $\mu$ s.

### 8.1.2 Output signal modulations

**Frequency modulation program FM** determines how the frequency of the signal changes, depending on the settings of the base frequency and the spectrum over a given time interval. Program parameters define:

- duration of the lowest frequency,
- time of increase to the highest frequency,
- duration of the highest frequency, and
- falling time to the lowest frequency.

If SPECTRUM value is set up at 0 Hz, it is not possible to use frequency modulation program. And when nonzero SPECTRUM value is selected, default settings of frequency modulation program are 3 s rise time and 3 s fall time.

**Amplitude modulation program AM** determines in what time spans therapeutic signal amplitude change and how deep that change goes. Such modulation aims at delaying process of adaptation to the set value of the therapeutic signal and alleviation of adverse treatment results with patients badly tolerating electrotherapy. Amplitude is modulated within the range 70% to 100% of set up output signal.

**Training program** controls occurrence of muscle contraction and rest phases. Voltage and amperage, which will be applied during electrostimulation, should be determined when no training program is set. This program includes an active phase only, enabling comfortable setup of appropriate value of output signal. This program shall not be applied in therapy. Set value of output signal shall be remembered and set up during session of the selected treatment program.

The programs which feature relatively long rest time in relation to contraction phase give appropriate conditions for muscle fiber regeneration. The programs which have decisively shorter rest phase shall only be applied to electro-gymnastics with healthy persons or to cause tonolitic effect.

### 8.1.3 TENS pulse current



The TENS method (Transcutaneous Electrical Nerve Stimulation) was developed in the 1960s as an alternative to the then modern analgesic stimulation conducted with electrodes implanted adjacent to posterior horns of spinal cord. According to the check gate theory of Wall and Melzack, stimulation of fast-conducting nerve fibers of the A type inhibits the conductivity of slow-conducting fibers of the C type, responsible for connection of pain receptors with posterior horns of spinal cord. The check gate constitutes here the common synaptic system, loaded with the burden of A type fiber pulses, which inhibits pain transmission. Additional phenomenon accompanying the TENS stimulation is increase in endorphin production in Central Nervous System centers. TENS are used mainly for prolonged analgesic therapy and for stimulation of skeleton muscles.

The pulse current used with this method consists of rectangular bipolar pulses, symmetrical, asymmetrical or asymmetrical with alternately changing polarization. The choice of pulse shape is at the discretion of the patient's preferences. Symmetric and asymmetric pulses have similar biophysical properties. The pulse duration is short, whereas the amplitude is relatively high. The pulse frequency occurs within the range from several to more than one hundred Hertz. The TENS pulse current is frequency and amplitude modulated, which aims at delay in adaptation and creation of relax phases during session.

The BURST 7/2 program consist of 7 pulse sequences (timp =  $100 \mu s$ ) generated every 10 ms, occurring with 2 Hz frequency.

The BURST 7/4 program consist of 7 pulse sequences (timp =  $100 \mu s$ ) generated every 10 ms, occurring with 4 Hz frequency.

The BURST 9/2 program consist of 9 pulse sequences (timp =  $100 \mu s$ ) generated every 10 ms, occurring with 2 Hz frequency.

The BURST 9/4 program consist of 9 pulse sequences (timp =  $100 \mu s$ ) generated every 10 ms, occurring with 4 Hz frequency.

Parameters description:

Symbol	Description	Symbol on the treatment screen	Available parameters	
	Treatment time	-	1 – 60 minutes, 1 minute step	
		SYM	Symmetric Symmetric	
	Shape of the current	ASYM	Asymmetric	
		ALT	Alternating asymmetric	
<b>*</b>	TENS pulse duration	t_imp	Possible settings: 25 $\mu$ s, 50 $\mu$ s, 75 $\mu$ s, 100 $\mu$ s, 150 $\mu$ s, 200 $\mu$ s, 250 $\mu$ s, 300 $\mu$ s, 400 $\mu$ s, 500 $\mu$ s  Note: pulses longer than 200 $\mu$ s are available only for the sum of the frequencies (basic and spectrum) < 150Hz	
++++	Basic frequency	f_bas	Regulation in the range of 1 Hz – 200 Hz (variable step)	
<b>+   </b>	Frequency spectrum	f_spec	Regulation in the range of 0 Hz – 200 Hz (variable step)	
	Frequency modulation program	FM	Frequency modulation program is switched off	
FM			Frequency rise time 1 s  Hold time of maximum frequency 2 s  Frequency fall time 1 s  Hold time of basic frequency 3 s	
			Frequency rise time 3 s Frequency fall time 3 s	

Symbol	Description	Symbol on the treatment screen	Available parameters	
			6 6	Frequency rise time 6 s Frequency fall time 6 s
			6 6 6 /	Frequency rise time 6 s Hold time of maximum frequency 6 s Frequency fall time 6 s Hold time of basic frequency 6 s
			12 12	Frequency rise time 12 s Frequency fall time 12 s
	_		RAND	Random pulse generation
				Amplitude modulation program is switched off
АВЛ	Amplitude modulation program	АМ	3 3	Amplitude rise time 3 s Hold time of maximum amplitude 3 s Amplitude fall time 3 s
AM			6 6	Amplitude rise time 6 s Amplitude fall time 6 s
			6 6	Amplitude rise time 6 s Hold time of maximum amplitude 12 s Amplitude fall time 6 s
	BURST mode	FM = BURST		7 pulse sequences, 2 Hz
\\\				7 pulse sequences, 4 Hz
∕#			9/2Hz	9 pulse sequences, 2 Hz
-00 :				9 pulse sequences, 4 Hz
CC	Amplifier operation mode	-	CC – stabilized output current CV – stabilized output voltage  1 – 140 mA in CC mode  Regulation step:  • 0.5 mA in the range of 1-140 mA  2 – 140 V in CV mode, max. 140 mA  Regulation step:  • 0.5 V in the range of 2-140 V	
	Maximum amplitude	-		

### 8.1.4 Interferential currents



Interferential current is a two-channel sine wave current with carrier frequency with modulated amplitude to the basic frequency. Most frequently basic frequency is modulated, i.e. it changes with the time within the preset spectrum. In modern electrotherapy devices, the carrier frequency can be from 2 to 10 kHz.

As opposed to the classic technique of generating interferential currents within patient's tissue (frequency interference), the internal modulation process has been transferred to the inside of the unit. This technology causes generation of interference field occupying much space (the therapeutic current passes larger tissue space than with the classic method), interference occurs even in case of not very precise electrode application, which simplifies the treatment method.

In case of **dynamic interferential current** additional amplitude and phase modulation of both channels was introduced, which causes the area of most effective therapeutic current operation to sweep in cycles the area between the electrodes (vector scanning). This effect increases additionally the volume capacity exposed to stimulation and continuous change of interference field location delays the adaptation process.

**Isoplanar interferential current** — its properties are similar to the current resulting from the classical interference, generated by the older unit versions. The unit has the additional amplitude modulation causing that the treatment covers the entire area between the electrodes and not just a small part on bisector of angles formed by lines connecting the electrodes centers from both circuits. This simplifies the placement of electrodes and improves the spatiality of the current therapeutic effect.

**Bipolar interference current** is applied with two electrodes (one channel). Its biophysical properties are the same as in the case of standard interference, however, it features somewhat lesser penetration range. It is recommended for electrotherapy applied onto a small area or in places, which are not easily accessible. Because of the similarity to the interferential current it is determined as the IF-2P on the list of treatment programs.

**Static interferential current** – is not directly available. In order to apply this current you should choose **AMF** current working in **A+B mode** and use both channels while placing the electrodes.

Parameters description:

Symbol	Description	Symbol on the treatment screen	Available para	ameters
	Treatment time	-	1 – 60 minutes, 1 minute step	
F0.0.0		-		Diadynamic interferential current
	Shape of the current			Isoplanar interferential current
			▊╶╢╢╸	One-channel AMF current
$\overline{\ \ }$	Carrier frequency	c_freq	Possible settir	ngs: 2 kHz, 4 kHz, 6 kHz, 8 kHz, 10 kHz
	Basic frequency	f_bas	Regulation in	the range of 1 Hz – 200 Hz (variable step)
	Frequency spectrum	f_spec	Regulation in the range of 0 Hz – 200 Hz (variable step)	
$\bigcirc$	Pulse duration	pd	Regulation in	the range of 0 – 10 s
FM	Frequency modulation program	FM	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	Frequency modulation program is switched off  Frequency rise time 1 s  Hold time of maximum frequency 2 s  Frequency fall time 1 s  Hold time of basic frequency 3 s  Frequency rise time 3 s  Frequency fall time 3 s  Frequency rise time 6 s  Frequency fall time 6 s  Frequency rise time 6 s  Frequency rise time 6 s  Hold time of maximum frequency 6 s  Frequency fall time 6 s  Hold time of basic frequency 6 s  Frequency rise time 12 s  Frequency fall time 12 s
AM	Amplitude modulation program	AM	3 3 3	Amplitude modulation program is switched off  Amplitude rise time 3 s  Hold time of maximum amplitude 3 s  Amplitude fall time 3 s  Amplitude rise time 6 s  Amplitude fall time 6 s

Symbol	Description	Symbol on the treatment screen	Available parameters	
			Amplitude rise time 6 s  Hold time of maximum amplitude 12 s  Amplitude fall time 6 s	
CC	Amplifier operation mode	-	CC – stabilized output current CV – stabilized output voltage	
	Maximum amplitude	-	0.5 – 140 mA in CC mode  Regulation step:  ■ 0.5 mA in the range of 0.5-140 mA  1.5 – 100 V in CV mode, max. 140 mA  Regulation step:	
			• 0.5 V in the range of 1.5-100 V	

### 8.1.5 Kotz' current (Russian stimulation)



Kotz' current is a medium frequency sinusoidal alternating current. For the stimulation a relatively complicated current train is here applied. Current of 2500 Hz frequency is joined to form rectangular trains or "bursts" with length equal to the pause time (e.g. pulse current with 20 Hz frequency consists of bursts lasting 25 ms and pauses of equal length).

The bipolar pulse current of such duty cycle is subjected to amplitude modulation to obtain smooth increase and reduction of output current within patient circuit (by the use of a training program), which results in mild muscle contraction and relaxation effect with determined activity and rest phase. The training program is selected depending on the purpose of therapy and the patient's needs. Kotz describes stimulations using frequency within the above range, suggesting that by using the 2500 Hz frequency the deeper located muscle layers are excited. The stimulation methodic is similar to the classic method utilizing unipolar rectangular or triangular impulses. Most frequently the bipolar method is used by applying small, flat electrodes above extreme segments of muscle belly. Stimulation involves the parts of muscle groups that perform the same movement.

The Kotz' stimulation influences correctly innervated skeletal muscles. The method is useful for stimulation of hypotrophic muscles disappearing due to immobilization and for exercise of healthy muscles. It can also be used to treat tissue injuries to achieve an analgesic or hyperemic effect. This method does not enable stimulation of partially and totally denervated muscles. It is worth remarking here that the method is practically painless.

Parameters description:

Symbol	Description	Symbol on the treatment screen	Available parameters	
	Treatment time	-	1 – 60 minutes, 1 minute step	
-	Carrier frequency	-	2500 Hz – default parameter	
	Basic frequency	f_bas	Regulation in the range of 3 Hz – 100 Hz (variable step)	
			No training program	
PT	Training program	PT	Rise time 1 s  Contraction phase 2 s  Fall time 1 s  Rest phase 2 s	

Symbol	Description	Symbol on the treatment screen	Available pa	arameters
			1/3/1 8 /	Rise time 1 s Contraction phase 3 s Fall time 1 s Rest phase 8 s
			1,5,1,	Rise time 1 s Contraction phase 5 s Fall time 1 s Rest phase 5 s
			1/5 1 10/	Rise time 1 s Contraction phase 5 s Fall time 1 s Rest phase 10 s
			2 10 2 10 /	Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 10 s
			2 10 2 20 /	Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 20 s
			2 10 2 30 /	Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 30 s
			2 10 2 40 /	Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 40 s
			2 10 2 50 /	Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 50 s
			3/15/3/30/	Rise time 3 s Contraction phase 15 s Fall time 3 s Rest phase 30 s
			3 15 3 50 /	Rise time 3 s Contraction phase 15 s Fall time 3 s Rest phase 50 s
CC	Amplifier operation mode	-		ed output current ed output voltage
<b>4</b>	Maximum amplitude	-	Regula • 1.5 – 100 V Regula	A in CC mode tion step: 0.5 mA in the range of 0.5-140 mA in CV mode, max. 140 mA tion step: 0.5 V in the range of 1.5-100 V

## 8.1.6 Medium frequency currents



The idea of using medium frequency currents is similar to the use of Russian stimulation, but with other carrier frequencies available. This enables the choice of stimulation depth.

Parameters description:					
Symbol	Description	Symbol on the treatment screen	Available parameters		
	Treatment time	-	1 – 60 minutes, 1 minute step		
$\overline{\mathbb{W}}$	Carrier frequency	c_freq	Possible settings: 2 kHz, 4 kHz, 8 kHz		
	Basic frequency	f_bas	Regulation in the range of 5 Hz – 100 Hz (variable step)		
			No training program  Rise time 1 s		
			Contraction phase 2 s Fall time 1 s Rest phase 2 s		
			Rise time 1 s  Contraction phase 3 s  Fall time 1 s  Rest phase 8 s		
			Rise time 1 s  Contraction phase 5 s  Fall time 1 s  Rest phase 5 s		
			Rise time 1 s  Contraction phase 5 s  Fall time 1 s  Rest phase 10 s		
PT	Training program	PT	Rise time 2 s  Contraction phase 10 s  Fall time 2 s  Rest phase 10 s		
			Rise time 2 s  Contraction phase 10 s  Fall time 2 s  Rest phase 20 s		
			Rise time 2 s  Contraction phase 10 s  Fall time 2 s  Rest phase 30 s		
			Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 40 s		
			Rise time 2 s  Contraction phase 10 s  Fall time 2 s  Rest phase 50 s		

Symbol	Description	Symbol on the treatment screen	Available parameters		
			3 <sup>15</sup> 3 30 /	Rise time 3 s Contraction phase 15 s Fall time 3 s Rest phase 30 s	
			3 15 3 50 /	Rise time 3 s Contraction phase 15 s Fall time 3 s Rest phase 50 s	
CC	Amplifier operation mode	-		d output current d output voltage	
	Maximum amplitude	-	<b>1.5 – 100 V in</b> Regulation	on step: .5 mA in the range of 0.5-140 mA CV mode, max. 140 mA	

### 8.1.7 SP-TENS pulse current

On the basis of classical TENS pulse currents, SP-TENS currents were created, intended for spastic paralysis treatments. Stimulation may be performed by using one- or two-channels simultaneously. While two-channel operation, during the stimulation phase in one channel, in the second channel the rest phase occurs, then there is a change.

Symbol	Description	Symbol on the treatment screen	Available para	meters
	Treatment time	-	1 – 60 minutes	s, 1 minute step
-8-8-8-			-0-0-0-	One-channel
	SP-TENS current	-		Sequence, available only in $\frac{1}{2} \frac{4}{1} \frac{1}{6}$
₽ A	TENS pulses type in	SYM	1-1-	Symmetric
B B	A and B circuits	ASYM		Asymmetric
→ F <sub>A</sub>	TENS pulses duration time in A and B circuits	t_imp		gs: 25 μs, 50 μs, 75 μs, 100 μs, 125 μs, 150 μs, 250 μs, 300 μs
+++ <sub>A</sub>	Basic frequency in A and B circuits	f_bas	Regulation in t	he range of 30 Hz – 100 Hz (step 10 Hz)
PT	Training program	PT	0,202/ 0,204/	Stimulation phase 2 s Rest phase 2 s Stimulation phase 2 s Rest phase 4 s

Symbol	Description	Symbol on the treatment screen	Available para	ameters
			0 2 0 6	Stimulation phase 2 s Rest phase 6 s
			0/2 0 10/	Stimulation phase 2 s Rest phase 10 s
			.5, 3, 5, 4	Rise time 0.5 s Stimulation phase 3 s Fall time 0.5 s Rest phase 4 s
			.5/3.58	Rise time 0.5 s Stimulation phase 3 s Fall time 0.5 s Rest phase 8 s
			1/4/16/	Rise time 1 s Stimulation phase 4 s Fall time 1 s Rest phase 6 s
			1/4 1 10/	Rise time 1 s Stimulation phase 4 s Fall time 1 s Rest phase 10 s
			2/6/2 10/	Rise time 2 s Stimulation phase 6 s Fall time 2 s Rest phase 10 s
CC	Amplifier operation mode	-		output current I output voltage
	Maximum amplitude	-	1 – 140 mA in Regulatio • 0 2 – 140 V in CV Regulatio	CC mode on step: 5 mA in the range of 1-140 mA V mode, max. 140 mA

### 8.1.8 Diadynamic currents



The device generates unipolar low-frequency currents or a medium-frequency carrier currents, whose envelope corresponds to the traditional diadynamic currents. There are no significant therapeutic differences between such an approach to diadynamic currents generation and traditional method. However, because of applying medium frequency current, the unpleasant patient's sensations during the procedure and the electrochemical effect are reduced. With this method of signal generation, it should be taken into consideration that a higher amplitude has to be set in order to evoke a certain level of patient's sensation, in comparison to traditional diadynamic currents.

Parameters	description:			
Symbol	Description	Symbol on the treatment screen	Available parameters	
	Treatment time	-	1 – 60 minutes, 1 minute step	
	Shape of the current	MF / DF / CP / CP_ISO / LP / RS / MM	<ul> <li>DF – direct diphase</li> <li>CP – short periods</li> <li>CP_ISO – MF phase modification (reduction of 12%)</li> <li>LP – long periods</li> <li>RS – syncopated rhythm</li> <li>MM – modulated monophase</li> <li>MF – direct monophase</li> </ul>	
	Continuous or interrupted shape of the current	c_shape	Continuous  Pulse frequency is 4 kHz  Duty factor 80%  Pulse frequency is 8 kHz  Duty factor 90%	
	Polarization	NOR	For such polarization setting red plug is a positive electrode, and black plug is a negative electrode.	
<b>₩</b> -⁄4		REV	For such polarization setting red plug is a negative electrode and black plug is a positive electrode. Warning means that such a setting is the reverse of commonly accepted way of marking polarity.	
		ALT	Automatic polarization switch in the half performed treatment.	
	0.3 – 70 mA in CC mode			
	Maximum		Regulation step:	
	amplitude	-	<ul> <li>0.1 mA in the range of 0.3-10 mA</li> </ul>	
			0.5 mA in the range of 10-70 mA	

### 8.1.9 Galvanic current



Galvanic current is a direct current or a medium frequency unipolar current, not modulated. There are no significant therapeutic differences between this type of current and traditional direct current. However, because of applying medium frequency current, the unpleasant patient's sensations during the procedure and the electrochemical effect are reduced. It should be taken into consideration that set up amplitude, which determines certain degree of sensation, will be higher than amplitude of traditional direct current, which causes the same degree of sensation.

With this method of signal generation, it should be taken into consideration that a higher amplitude has to be set in order to evoke a certain level of patient's sensation, in comparison to traditional direct current.

**Parameters description:** 

Symbol	Description	Symbol on the treatment screen	Available par	ameters	
	Treatment time	-	1 – 60 minute	es, 1 minute step	
	Continuous or interrupted shape	c shane	∭ 4kHz	Continuous  • Pulse frequency is 4 kHz	
/m 	of the current	c_shape	SkHz	<ul><li>Duty factor 80%</li><li>Pulse frequency is 8 kHz</li><li>Duty factor 90%</li></ul>	
		NOR		For such polarization setting red plug is a positive electrode, and black plug is a negative electrode.	
<b>P</b> -/+	Polarization	REV	<u>A</u>	For such polarization setting red plug is a negative electrode and black plug is a positive electrode. Warning means that such a setting is the reverse of commonly accepted way of marking polarity.	
		ALT	0,00,0	Automatic polarization switch in the half performed treatment.	
			0.3 – 80 mA ii	n CC mode	
	Maximum amplitude	_	Regulation step:		
				.1 mA in the range of 0.3-10 mA .5 mA in the range of 10-80 mA	

### 8.1.10 Ultra Reiz current (Träbert's current)



The Ultra Reiz current (Träbert's current) is a special case of rectangular pulse current. This is a current with rectangular shape, pulse duration 2 ms and pause duration 5 ms. These settings are not adjustable. Ultra Reiz current is used in segmentary and local applications.

Symbol	Description	Symbol on the treatment screen	Available parameters
	Treatment time	-	1 – 60 minutes, 1 minute step
	Shape of the current	-	Rectangular pulse current according to Träbert (Ultra Reiz)
<u></u>	Continuous or interrupted shape of the current	c_shape	Continuous  Pulse frequency is 4 kHz  Duty factor 80%  Pulse frequency is 8 kHz  Duty factor 90%
	Pulse duration	-	Constant 2 ms
	Pause duration	-	Constant, 5 ms

Symbol	Description	Symbol on the treatment screen	Available parameters	
F	Basic pulse frequency	-	Constant, 143	3 Hz
PT	Training program	PT		No training program, non-editable parameter
		NOR		For such polarization setting red plug is a positive electrode, and black plug is a negative electrode.
Y-/+	Polarization	REV	<b>∆€ô</b>	For such polarization setting red plug is a negative electrode and black plug is a positive electrode. Warning means that such a setting is the reverse of commonly accepted way of marking polarity.
		ALT	0,00,0	Automatic polarization switch in the half performed treatment.
CC CV	Amplifier operation mode	-	CC – stabilized output current CV – stabilized output voltage	
	Maximum amplitude	-	0.3 – 140 mA in CC mode  Regulation step:  • 0.1 mA in the range of 0.3-10 mA  • 0.5 mA in the range of 10-140 mA  1.5 – 100 V in CV mode, max. 80 mA  Regulation step:  • 0.5 V in the range of 1.5-100 V	

### 8.1.11 Unipolar and bipolar sine surge



Sine surge current is an average frequency current with modulated amplitude. The shape of the generated wave is similar to the interferential current. In the case of a unipolar sine surge current under the electrodes electrochemical changes occur, as in constant current. Therefore, you must pay special attention to safety during treatment. It is recommended to use thick pads and it is possible to change the polarity while the treatment is performed.

Compared to low frequency pulse current and direct current, the sine surge is better tolerated by patients, it also creates proper conditions for affecting tissues located deeper. The unipolar current can also be used to perform iontophoresis treatments. Properly selected training programs facilitate the adjustment of signal parameters to the purpose of therapy and the patient's needs.

Symbol	Description	Symbol on the treatment screen	Available parameters	
	Treatment time	-	1 – 60 minute	es, 1 minute step
-	Carrier frequency	-	Rectangular	signal with 4 kHz frequency and duty factor of 50%
	Current type	UNI		Unipolar
/ 🖤	current type	ВІ		Bipolar

Symbol	Description	Symbol on the treatment screen	Available parameters		
	Basic frequency	f_bas	Regulation in the range of 1 Hz – 100 Hz, variable step		
	Frequency spectrum	f_spec	Regulation in the range of 0 Hz – 200 Hz, variable step		
FM	Frequency modulation program	FM	Frequency modulation program is switched off  Frequency rise time 1 s  Hold time of maximum frequency 2 s  Frequency fall time 1 s  Hold time of basic frequency 3 s  Frequency rise time 3 s  Frequency fall time 3 s		
			Frequency rise time 6 s Frequency fall time 6 s  Frequency rise time 6 s  Frequency rise time 6 s  Hold time of maximum frequency 6 s  Frequency fall time 6 s  Hold time of basic frequency 6 s  Frequency rise time 12 s  Frequency fall time 12 s		
			Amplitude modulation program is switched off  Amplitude rise time 3 s  Hold time of maximum amplitude 3 s  Amplitude fall time 3 s  Amplitude fall time 6 s  Amplitude fall time 6 s  Amplitude fall time 6 s  Amplitude rise time 6 s  Amplitude fall time 6 s  Amplitude fall time 6 s  Contraction phase 2 s  Fall time 1 s  Rest phase 2 s		
AM	Amplitude modulation program or training program	AM / PT	Rise time 1 s  Contraction phase 3 s  Fall time 1 s  Rest phase 8 s  Rise time 1 s  Contraction phase 5 s  Fall time 1 s  Rest phase 5 s  Rest phase 5 s  Rise time 1 s  Contraction phase 5 s  Fall time 1 s  Rest phase 5 s  Fall time 1 s  Contraction phase 5 s  Fall time 1 s		
			Rest phase 10 s  Rise time 2 s  Contraction phase 10 s  Fall time 2 s  Rest phase 10 s  Rest phase 10 s  Rest phase 10 s  Rise time 2 s  Contraction phase 10 s  Fall time 2 s  Rest phase 20 s  Rest phase 20 s		

Symbol	Description	Symbol on the treatment screen	Available pa	rameters
			2 10 2 30 /	Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 30 s
			2 10 2 40 /	Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 40 s
			2 10 2 50 /	Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 50 s
			3 15 3 30 /	Rise time 3 s Contraction phase 15 s Fall time 3 s Rest phase 30 s
			3 <sup>15</sup> 3 50 /	Rise time 3 s Contraction phase 15 s Fall time 3 s Rest phase 50 s
		NOR		For such polarization setting red plug is a positive electrode, and black plug is a negative electrode.
<b>₹</b> -/4	Polarization	plarization REV	<b>Æ</b>	For such polarization setting red plug is a negative electrode and black plug is a positive electrode. Warning means that such a setting is the reverse of commonly accepted way of marking polarity.
		ALT	0,00,0	Automatic polarization switch in the half performed treatment.
CC	Amplifier operation mode			ed output current ed output voltage
	Maximum		Unipolar current	0.3 – 30 mA in CC mode  Regulation step:  • 0.1 mA in the range of 0.3-10 mA  • 0.5 mA in the range of 10-30 mA  1.5 – 100 V in CV mode, max. 30 mA  Regulation step:  • 0.5 V in the range of 1.5-100 V
	amplitude	Maximum amplitude	Bipolar current	O.5 – 100 mA in CC mode  Regulation step:  O.5 mA in the range of 0.5-10 mA  O.5 mA in the range of 10-100 mA  1.5 – 100 V in CV mode, max. 100 mA  Regulation step:  O.5 V in the range of 1.5-100 V

### 8.1.12 Leduc's current



Another are Leduc's current is a special case of rectangular pulse currents with pulse duration 1 ms and pause duration 9 ms.

Parameters d	escription:	Symbol on		
Symbol	Description	the treatment	Available parameters	
		screen		
	Treatment time	-	1 – 60 minutes	, 1 minute step
	Shape of the current	-	1-9	Rectangular pulse current according to Leduc
	Continuous or interrupted	c_shape	4kHz	Ontinuous     Pulse frequency is 4 kHz     Data factor 800%
	shape of the current		3 8kHz	<ul><li>Duty factor 80%</li><li>Pulse frequency is 8 kHz</li><li>Duty factor 90%</li></ul>
	Pulse duration	-	Constant, 1 ms	3
	Pause duration	-	Constant, 9 ms	-
F	Basic pulse frequency	-	Constant, 100	Hz
PT	Training program	PT		No training program, non-editable parameter
		NOR		For such polarization setting red plug is a positive electrode, and black plug is a negative electrode.
<b>P</b> -/4	Polarization	REV	<u></u>	For such polarization setting red plug is a negative electrode and black plug is a positive electrode. Warning means that such a setting is the reverse of commonly accepted way of marking polarity.
		ALT	0,00,0	Automatic polarization switch in the half performed treatment.
CC	Amplifier operation mode	-	CC – stabilized output current CV – stabilized output voltage	
	Maximum amplitude		0.3 – 140 mA in CC mode  Regulation step:  • 0.1 mA in the range of 0.3-10 mA  • 0.5 mA in the range of 10-140 mA  1.5 – 100 V in CV mode, max. 80 mA  Regulation step:  • 0.5 V in the range of 1.5-100 V	

### 8.1.13 Rectangular pulse currents



Rectangular pulse current consists of pulse sequence of rectangular shape and independently adjusted times of pulse and pause. It may consist of a series of pulses with amplitude modulation, where the intensity of consecutive pulses in the series gradually increases and decreases (training program). As a result, electrostimulation parameters can be individually adjusted, depending on the patient's condition and the purpose of the treatment.

This current is used to stimulate properly innervated muscles. It is also applied in electrodiagnostics to determine the I/t curve.

Symbol	Description	Symbol on the treatment screen	Available parameters	
	Treatment time	-	1 – 60 minutes, 1 minute step	
	Shape of the current	-	Rectangular pulse current	
<u></u>	Continuous or interrupted shape of the current	c_shape	Continuous  Pulse frequency is 4 kHz  Duty factor 80%  Pulse time values of 100 μs and 200 μs do not have pause  Pulse frequency is 8 kHz  Duty factor 90%	
	Pulse duration	t_imp	<ul> <li>Pulse time values of 100 μs and 200 μs do not have pause</li> <li>Regulation in the range of 100 μs – 1 s (variable step)</li> <li>Regulation in the range of 100 μs – 200 ms for the operation of training program PT (variable step)</li> </ul>	
	Pause duration	t_pause	<ul> <li>Max. regulation in the range of 1 ms – 5 s (variable step, range depends on pulse duration)</li> <li>Regulation in the range of 1 ms – 200 ms for the operation of training program PT (variable step)</li> </ul>	
F	Basic pulse frequency	f_bas	<ul> <li>calculated from the formula f_bas=1 / (t_imp + t_pause)</li> <li>changing the parameter means a change of t_pause</li> </ul>	
			No training program  Rise time 1 s Contraction phase 2 s Fall time 1 s Rest phase 2 s	
PT	Training program	PT	Rise time 1 s  Contraction phase 3 s Fall time 1 s  Rest phase 8 s	
			Rise time 1 s  Contraction phase 5 s  Fall time 1 s  Rest phase 5 s	

Symbol	Description	Symbol on the treatment screen	Available parameters	
			1 10 /	Rise time 1 s Contraction phase 5 s Fall time 1 s Rest phase 10 s
			<sup>2</sup> /10 2 10 /	Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 10 s
			2 10 2 20 /	Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 20 s
			2 10 2 30 /	Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 30 s
			2 10 2 40	Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 40 s
			2 <sup>10</sup> 2 50 /	Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 50 s
			<sup>3</sup> / <sub>3 30</sub> /	Rise time 3 s Contraction phase 15 s Fall time 3 s Rest phase 30 s
			3 15 3 50 /	Rise time 3 s Contraction phase 15 s Fall time 3 s Rest phase 50 s
		NOR	0,5	For such polarization setting red plug is a positive electrode, and black plug is a negative electrode.
<b>₽</b>	Polarization	REV	<b>Æ</b>	For such polarization setting red plug is a negative electrode and black plug is a positive electrode. Warning means that such a setting is the reverse of commonly accepted way of marking polarity.
		ALT	موق	Automatic polarization switch in the half performed treatment.
CC	Amplifier operation mode	-		output current output voltage
	Maximum amplitude	-	• • 1.5 – 100 V in	lation step:  0.1 mA in the range of 0.3-10 mA  0.5 mA in the range of 10-140 mA  CV mode, max. 80 mA  lation step:  0.5 V in the range of 1.5-100 V

Due to the limitations arising from IEC 60601-2-10. the value of the maximum amplitude depends on the pulse duration. Permissible values are presented in the table.

Table 8-1. Permitted amplitude values in relation to pulse duration

Pulse duration [ms]	Maximum amplitude [mA]
≤ 30	140
40	120
50	110
60	100
70	90
80	85
≥ 90	80

### 8.1.14 Triangular pulse currents



Triangular pulse current consists of a sequence of saw-shaped pulses and independently adjusted times of pulse and pause. It is used to stimulate denervated muscles (struck by flaccid paralysis) and smooth muscles. It is also applied in electrodiagnostics to determine the I/t curve.

Parameters d	description:			
Symbol	Description	Symbol on the treatment screen	Available parameters	
	Treatment time	-	1 – 60 minutes	, 1 minute step
	Shape of the	ASYM	$\Lambda\Lambda\Lambda$	Asymmetric triangular pulse current (unipolar)
_ <del></del>	current	SYM	1/1/	Symmetric triangular pulse current (bipolar)
			_/_	Continuous
<u></u>	Continuous or interrupted shape of the current	c_shape	4kHz	<ul> <li>Pulse frequency is 4 kHz</li> <li>Duty factor 80%</li> <li>Pulse time values of 100 μs and 200 μs do not have pause</li> </ul>
			8kHz	<ul> <li>Pulse frequency is 8 kHz</li> <li>Duty factor 90%</li> <li>Pulse time values of 100 μs and 200 μs do not have pause</li> </ul>
<b>→</b> [+ []	Pulse duration	t_imp	Regulation in the range of 100 $\mu$ s – 1 s (variable step)	
	Pause duration	t_pause	Regulation in the range of max. 1 ms – 5 s (variable step, range depends on pulse duration)	
F	Basic pulse frequency	f_bas	<ul> <li>calculated from the formula:         f_bas=1 / (t_imp + t_pause) for ASYM and         f_bas=1 / (2*t_imp + t_pause) form SYM</li> <li>changing the parameter means a change of t_pause</li> </ul>	
PT	Training program	PT		No training program, non-editable parameter
<b>P</b> _/+	Polarization	NOR		For such polarization setting red plug is a positive electrode, and black plug is a negative electrode.

Symbol	Description	Symbol on the treatment screen	Available pa	Available parameters	
		REV	<b>A</b>	For such polarization setting red plug is a negative electrode and black plug is a positive electrode. Warning means that such a setting is the reverse of commonly accepted way of marking polarity.	
		ALT	0,00,0	Automatic polarization switch in the half performed treatment.	
CC	Amplifier operation mode	-		ed output current ed output voltage	
	Maximum		Unipolar current	<ul> <li>0.3 – 140 mA in CC mode</li></ul>	
	amplitude		Bipolar current	0.5 – 140 mA in CC mode  Regulation step:  0.1 mA in the range of 0.5-10 mA  0.5 mA in the range of 10-140 mA  1.5 – 100 V in CV mode, max. 80 mA  Regulation step:  0.5 V in the range of 1.5-100 V	

### 8.1.15 Neofaradic pulse currents



The neofaradic current is a low frequency pulse current, which is a modern version of the faradic current. It consists of positive rectangular or triangular pulses with a duration of 1 ms and a variable frequency (and therefore a variable pause time).

The neofaradic current is used to stimulate properly innervated muscles in order to stimulate the muscle to contract, re-educate and train new muscle actions.

Symbol	Description	Symbol on the treatment screen	Available parameters	
	Treatment time	-	1 – 60 minutes, 1	minute step
	Shape of the	TRI	$\bot$	Neofaradic triangular pulse current
	current	REC		Neofaradic rectangular pulse current
	Continuous or		or _/_	Continuous
<u></u>	interrupted shape of the current	c_shape	4kHz	<ul><li>Pulse frequency is 4 kHz</li><li>Duty factor 80%</li></ul>

Symbol	Description	Symbol on the treatment screen	Available parameter	rs
			8kHz or 8kHz	Pulse frequency is 8 kHz Duty factor 90%
<u>-</u> 1-1	Pulse duration	-	Constant, 1 ms	
	Pause duration	-	Constant, it results fr	rom the basic frequency
F	Basic pulse frequency	f_imp	Regulation in the ran	nge of 1 Hz – 100 Hz (variable step)
PT	Training program	PT		No training program, non-editable parameter
		NOR	<b>G</b> ↓ <b>□</b> p	or such polarization setting red plug is a positive electrode, and black plug is a pegative electrode.
Y-/4	Polarization	REV	n <b>∱≙ib</b> p s	or such polarization setting red plug is a negative electrode and black plug is a positive electrode. Warning means that such a setting is the reverse of commonly accepted way of marking polarity.
		ALT		utomatic polarization switch in the half erformed treatment.
CC	Amplifier operation mode	-	CC – stabilized output current CV – stabilized output voltage	
	Maximum amplitude	-	0.3 – 140 mA in CC mode  Regulation step:  • 0.1 mA in the range of 0.3-10 mA  • 0.5 mA in the range of 10-140 mA  1.5 – 100 V in CV mode, max. 80 mA  Regulation step:  • 0.5 V in the range of 1.5-100 V	

### 8.1.16 Microcurrents



Microcurrents characterize significantly lower values of amplitudes in comparison with traditional currents used in electrotherapy. Unipolar and bipolar currents are used in a therapy. The applied amplitudes are so low that they are not felt by the patient, and the signal is a subliminal stimulation (it does not stimulate the nerves). There is also significantly reduced risk of side effects like irritation, skin burns and damages as well as discomfort of current flow felt by some patients.

Microcurrent restores the biological, electrical balance of tissues, which is necessary to stimulate healing processes.

Parameters d	lescription:		
		Symbol on	
Symbol	Description	the treatment	Available p
		screen	

POS

NEG

ALT

t\_imp

f\_bas

FM

Treatment time

Shape of the

Pulse duration

current

Available p	arameters
1 – 60 minu	ites, 1 minute step
	Positive
$\overline{\mathcal{M}}$	Negative
<u> </u>	Alternating
Regulation	in the range of 1 ms – 500 ms
Regulation	in the range of 0.3 Hz – 500 Hz

++++	Basic frequency
<del> </del>	Frequency
<b>←</b>	spectrum

Frequency	f spec
spectrum	i_spec

	Frequency modulation progr
Regulation	in the range of 0 Hz – 500 Hz

1_1_1_	<b>3</b> _/	

ulation program is switched Frequency rise time 1 s

Hold time of maximum frequency 2 s Frequency fall time 1 s Hold time of basic frequency 3 s

Frequency rise time 3 s Frequency fall time 3 s Frequency rise time 6 s



Frequency fall time 6 s Frequency rise time 6 s Hold time of maximum frequency 6 s

Frequency fall time 6 s Hold time of basic frequency 6 s Frequency rise time 12 s

Frequency fall time 12 s



Maximum amplitude

Frequency

modulation

program

 $0 - 1000 \mu A$  in CC mode Regulation step:

 $50\;\mu\text{A}$  within the range

### 8.1.17 IG pulses



IG pulses are triangular unipolar or bipolar pulse currents. Depending on the type used, the IG current has an analgesic effect, improves circulation or reduces muscle tension.

Symbol	Description	Symbol on the treatment screen	Available parameters	
	Treatment time	-	1 – 60 minutes, 1 minute s	tep
	Shape of the	IG30-UNI	_/_ IG 30 unipo	olar
	current	IG30-BI	√ IG 30 IG 30 bipol	ar

Symbol	Description	Symbol on the treatment screen	Available parameters		
		IG50-UNI	√_ IG 50 IG 50 unipolar		
		IG50-BI	-√ IG 50 IG 50 bipolar		
		IG100-UNI	√ IG 100 IG 100 unipolar		
		IG100-BI	√ IG 100 IG 100 bipolar		
		IG150-UNI	√ IG 150 IG 150 unipolar		
		IG150-BI	√ IG 150 IG 150 bipolar		
		NOR	For such polarization setting red plug is a positive electrode, and black plug is a negative electrode.		
<b>P</b> -/4	Polarization	REV	For such polarization setting red plug is a negative electrode and black plug is a positive electrode. Warning means that such a setting is the reverse of commonly accepted way of marking polarity.		
		ALT	Automatic polarization switch in the half performed treatment.		
CC	Amplifier operation mode	-	CC – stabilized output current CV – stabilized output voltage		
F	Basic pulse frequency	f	Constant:  • 8,33 Hz – IG30-UNI  • 6,25 Hz – IG30-BI  • 185 Hz – IG50-UNI, IG100-UNI, IG150-UNI  • 172 Hz – IG50-BI, IG100-BI, IG150-BI		
	Pause duration	t_idle	Constant:  • 80 ms – IG30-UNI, IG30-BI  • 5 ms – IG50-UNI, IG50-BI, IG100-UNI, IG100-BI, IG150-UNI, IG150-BI		
£	Pulse edge rise time	t_r	Constant:  • 30 ms – IG30-UNI, IG30-BI  • 300 µs – IG50-UNI, IG50-BI, IG100-UNI, IG100-BI, IG150-UNI, IG150-BI		
F	Pulse edge fall time	t_f	Constant:  • 10 ms – IG30-UNI, IG30-BI  • 100 µs – IG50-UNI, IG50-BI, IG100-UNI, IG100-BI, IG150-UNI, IG150-BI		
PT	Training program	РТ	No training program, non-editable parameter  Rise time 25 s Contraction phase 15 s Fall time 10 s Rest phase 100 s non-editable parameter  Rise time 25 s Contraction phase 65 s Fall time 10 s Rest phase 150 s non-editable parameter		

Symbol	Description	Symbol on the treatment screen	Available pa	arameters
			25 10 200	Rise time 25 s Contraction phase 115 s Fall time 10 s Rest phase 200 s non-editable parameter
	<b>■</b> Maximum		Unipolar current	<ul> <li>0.3 – 80 mA in CC mode Regulation step: <ul> <li>0.1 mA in the range of 0.3-10 mA</li> <li>0.5 mA in the range of 10-80 mA</li> </ul> </li> <li>1.5 – 100 V in CV mode, max. 60 mA <ul> <li>Regulation step:</li> <li>0.5 V in the range of 1.5 -100 V</li> </ul> </li> </ul>
	amplitude	-	Bipolar current	0.5 – 80 mA in CC mode  Regulation step:  • 0.1 mA in the range of 0.5-10 mA  • 0.5 mA in the range of 10-80 mA  1.5 – 100 V in CV mode, max. 60 mA  Regulation step:  • 0.5 V in the range of 1.5-100 V

### 8.1.18 EMS



EMS i.e. electrostimulation of properly innervated muscles is based on generating a contraction of selected muscles with the appropriately selected rectangular symmetric impulses. Its aim is to maintain the contraction ability of the properly innervated muscle, to prevent muscle atrophy and to restore muscle strength and mass.

Symbol	Description	Symbol on the treatment screen	Available parameters	
	Treatment time	-	1 – 60 minutes, 1 minute step	
	Shape of the current	-	Symmetric	
	Pulse duration	t_imp	Possible settings: 25 μs, 50 μs, 75 μs, 100 μs, 150 μs, 200 μs, 250 μs, 300 μs, 400 μs, 500 μs	
	Basic frequency	f_bas	Regulation in the range of 1 Hz – 250 Hz (variable step)	
<del>       </del>	Frequency spectrum	f_spec	Regulation in the range of 0 Hz – 250 Hz (variable step)	
			Frequency modulation program is switched off	
FM	Frequency modulation FM program	Frequency rise time 1 s  Hold time of maximum frequency 2 s  Frequency fall time 1 s  Hold time of basic frequency 3 s		
		Frequency rise time 3 s Frequency fall time 3 s		

Symbol	Description	Symbol on the treatment screen	Available pa	arameters
			3/3/3/3/	Frequency rise time 3 s Hold time of maximum frequency 3 s Frequency fall time 3 s Hold time of basic frequency 3 s
			3 6 3 6	Frequency rise time 3 s Hold time of maximum frequency 6 s Frequency fall time 3 s Hold time of basic frequency 6 s
			3/6/3 12/	Frequency rise time 3 s Hold time of maximum frequency 6 s Frequency fall time 3 s Hold time of basic frequency 12 s
			3 12 3 6	Frequency rise time 3 s Hold time of maximum frequency 12 s Frequency fall time 3 s Hold time of basic frequency 6 s
			6 6	Frequency rise time 6 s Frequency fall time 6 s
			6 6 6	Frequency rise time 6 s Hold time of maximum frequency 6 s Frequency fall time 6 s Hold time of basic frequency 6 s
			12 12	Frequency rise time 12 s Frequency fall time 12 s
				Amplitude modulation program is switched off
			1/3/18/	Rise time 1 s Contraction phase 3 s Fall time 1 s Rest phase 8 s
			1 5 1 5	Rise time 1 s Contraction phase 5 s Fall time 1 s Rest phase 5 s
	Amplitude modulation program		1 10	Rise time 1 s Contraction phase 5 s Fall time 1 s Rest phase 10 s
AM		AM	2 10 2 10 /	Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 10 s
			2 10 2 20 /	Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 20 s
			2 10 2 30 /	Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 30 s
			2 10 2 40	Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 40 s

Symbol	Description	Symbol on the treatment screen	Available pa	rameters
			2 10 2 50 /	Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 50 s
			3 15 3 30 /	Rise time 3 s Contraction phase 15 s Fall time 3 s Rest phase 30 s
		-	3 15 3 50 /	Rise time 3 s Contraction phase 15 s Fall time 3 s Rest phase 50 s
CC	Amplifier operation mode	-		ed output current ed output voltage
	Maximum amplitude	-	1 – 140 mA in CC mode  Regulation step:  • 0.5 mA in the range of 1-140 mA  2 – 140 V in CV mode, max. 140 mA  Regulation step:  • 0.5 V in the range of 2-140 V	

### 8.1.19 H-waves



H-waves are rectangular, bidirectional current with a constant pulse duration that uses a low frequency (level of 2 Hz) to stimulate the muscles and a higher frequency (level of 60 Hz) to effectively relieve pain.

Low frequency increases the lymph and blood flow, accelerates toxin outflow and reduces swelling. In the higher frequency mode, the H-waves work by their influence on the sodium pump function within the nerve and thus produce a profound anaesthetic / analgesic effect.

rarameters u	escription.		
Symbol	Definition	Symbol on the treatment screen	Available parameters
	Treatment time	-	1 – 60 minutes, 1 minute step
	Shape of the current	-	Symmetric
<u></u> →11	Pulse duration	t_imp	Constant, 11.2 ms
	Pause duration	t_pause	Non-editable parameter, calculated from the formula (1/f_bas)-11.2
++++	Basic frequency	f_bas	Regulation in the range of 0.1-87,7 Hz (variable step)
CC/	Amplifier		CC – stabilized output current
/cv	operation mode	-	CV – stabilized output voltage

Symbol	Definition	Symbol on the treatment screen	Available parameters
			0.5 – 140 mA in CC mode  Regulation step:
	Maximum - amplitude		<ul> <li>0.5 mA in the range of 0.5-140 mA</li> </ul>
		-	2 – 140 V in CV mode, max. 140 mA
			Regulation step:
			<ul> <li>0.5 V in the range of 2-140 V</li> </ul>

### 8.1.20 Exponential pulses



Exponential currents belong to the group of low-frequency currents, they are made up of triangular pulses, whose intensity increases exponentially.

They are used to stimulate denervated, struck by flaccid paralysis muscles.

Symbol	Description	Symbol on the treatment screen	Available para	nmeters
	Treatment time	-	1 – 60 minutes	s, 1 minute step
<u> </u>	Shape of the	SYM	-\\\	Symmetric triangular pulse current (bipolar)
	current	ASYM	$\mathcal{I}\mathcal{I}\mathcal{I}$	Asymmetric triangular pulse current (unipolar)
				Continuous
<u></u>	Continuous or interrupted shape of the current	c_shape	4kHz	<ul> <li>Pulse frequency is 4 kHz</li> <li>Duty factor 80%</li> <li>Pulse time values of 100 μs and 200 μs do not have pause</li> </ul>
			8kHz	<ul> <li>Pulse frequency is 8 kHz</li> <li>Duty factor 90%</li> <li>Pulse time values of 100 μs and 200 μs do not have pause</li> </ul>
<u>-1-1</u>	Pulse duration	t_imp	Regulation in t	he range of 1 ms – 500 ms (variable step)
	Pause duration	t_pause	Non-editable parameter, calculated from the formula:  • ASYM: (1/f_bas)-t_imp  • SYM: (1/f_bas)-2*t_imp	
F	Basic pulse frequency	f_bas	Remark: the n	the range of 0.1 Hz – 500 Hz (variable step).  naximum frequency value depends on the  n, see Table 8-2.
AM	Amplitude modulation program	РТ	2 10 /	Amplitude modulation program is switched off Rise time 2 s Contraction phase 10 s Fall time 2 s Rest phase 10 s

Symbol	Description	Symbol on the treatment screen	Available pa	arameters
		NOR	6,5	For such polarization setting red plug is a positive electrode, and black plug is a negative electrode.
<b>P</b> -/4	Polarization	REV	<b>∆♠</b>	For such polarization setting red plug is a negative electrode and black plug is a positive electrode. Warning means that such a setting is the reverse of commonly accepted way of marking polarity.
		ALT		Automatic polarization switch in the half performed treatment.
CC	Amplifier operation mode	-	CC – stabilized output current CV – stabilized output voltage	
	Maximum		Unipolar current	0.3 – 140 mA in CC mode  Regulation step:  0.1 mA in the range of 0.3-10 mA  0.5 mA in the range of 10-140 mA  1.5 – 100 V in CV mode, max. 80 mA  Regulation step:  0.5 V in the range of 1.5-100 V
	amplitude		Bipolar current	0.5 – 140 mA in CC mode  Regulation step:  0.1 mA in the range of 0.5-10 mA  0.5 mA in the range of 10-140 mA  1.5 – 100 V in CV mode, max. 80 mA  Regulation step:  0.5 V in the range of 1.5-100 V

Table 8-2. Available frequency values in relation to pulse duration

Pulse duration [ms]	Asymmetric shape – basic pulse frequency	Maximum basic pulse frequency possible to set	Symmetric shape – basic pulse frequency	Maximum basic pulse frequency possible to set
1	857,1 Hz	500 Hz	461.5 Hz	333 Hz
3	285,7 Hz	100 Hz	153,8 Hz	100 Hz
5	171.4 Hz	100 Hz	92,3 Hz	50 Hz
10	85,7 Hz	50 Hz	46,2 Hz	30 Hz
30	28,6 Hz	10 Hz	15,4 Hz	10 Hz
50	17,1 Hz	10 Hz	9,2 Hz	5 Hz
100	8,6 Hz	5 Hz	4,6 Hz	3 Hz
300	2,8 Hz	1 Hz	1.5 Hz	1 Hz
500	1.7 Hz	1 Hz	0.9 Hz	0.5 Hz

### 8.1.21 Hufschmidt stimulation



Hufschmidt stimulation is a method of two-channel alternating electrostimulation of spastic and antagonistic muscles. In the therapy, a single rectangular pulse is applied to the spastic muscle, then the antagonistic muscle is stimulated with a single rectangular pulse (with a certain delay, during rest of spastic muscle).

Parameters description:				
Symbol	Description	Symbol on the treatment screen	Available par	ameters
	Treatment time	-	1 – 60 minute	es, 1 minute step
	Trigger pulse shape (channel A)	-	R	ectangular
*T*	Trigger pulse duration (channel A)	t_trig	Regulation in	the range of 100μs-1s (variable step)
r-	Stimulating pulse duration (channel B)	t_stim	Regulation in	the range of 100μs-1s (variable step)
ŢŢ,	Time lag between channels	t_del	Regulation in	the range of 10ms-3s (variable step)
		NOR / NOR		For such polarization setting, the red plugs of <b>channels A and B</b> of the patient's cables are positive electrodes, and the black plugs are negative electrodes.
		NOR / REV		For such polarization setting the red plug of <b>channel A</b> of the patient's cable is a positive electrode, and the black plug is a negative electrode. The red plug of <b>channel B</b> of the patient's cable is a negative electrode and the black plug is a positive electrode. Warning means that such a setting in <b>channel B</b> is the reverse of commonly accepted way of polarity marking.
A/B 7+	Polarization	REV / NOR		For such polarization setting the red plug of <b>channel A</b> of the patient's cable is a negative electrode, and the black plug is a positive electrode. The red plug of <b>channel B</b> of the patient's cable is a positive electrode and the black plug is a negative electrode. Warning means that such a setting in <b>channel A</b> is the reverse of commonly accepted way of polarity marking.
		REV / REV		For such polarization setting, the red plugs of <b>channels A and B</b> of the patient's cable are negative electrodes, and the black plugs are positive electrodes. Warning means that such a setting is the reverse of commonly accepted way of polarity marking.
cc cv	Amplifier operation mode	-		d output current d output voltage

Symbol	Description	Symbol on the treatment screen	Available parameters
			CC mode:
			0.3 – 100 mA for trigger and stimulating pulses
			(channel A and B)
			Regulation step:
			<ul> <li>0.1 mA in the range of 0.3-10 mA</li> </ul>
	Maximum amplitude	-	<ul> <li>0.5 mA in the range of 10-100 mA</li> </ul>
	·		CV mode:
			1.5 – 100 V, max. 100 mA for trigger pulses (channel
			A) and bipolar stimulating pulses (channel B)
			Regulation step:
			<ul> <li>0.5 V in the range of 1.5-100 V</li> </ul>

### 8.1.22 Tonolysis



Tonolysis is a method of two-channel alternating electrostimulation, which through proprioreceptive facilitation of impulse transmission along nervous pathways aims at restoration of physiological balance of nerve fiber stimulation. With tonolysis spastically paralyzed muscles are stimulated with short triangular or rectangular impulse of high output current. In this way their strong contraction is evoked, which is followed by their relaxation. In the phase of relaxation of spastic muscles, antagonistic muscles are stimulated with a sequence of amplitude modulated impulses.

Symbol Symbol	Description	Symbol on the treatment screen	Available parameters
	Treatment time	-	1 – 60 minutes, 1 minute step
$\overline{\Lambda}$	Trigger pulse shape	REC	Rectangular pulse
_ / ] L	(channel A)	TRI	/ Triangular pulse
<b>→</b> E	Trigger pulse duration	t_trig	Regulation in the range of 100 $\mu s$ – 10 ms
	Stimulating pulse envelope shape (channel B)	SIN-BI	Sinusoidal bipolar Frequency and current shape:  Rectangular 4 kHz
^/-		TRI-UNI	Triangular unipolar Frequency and current shape:  • 40 kHz modulated by rectangular pulses with 4 kHz frequency  • Duty factor 50%
		TRI-BI	Triangular bipolar  Frequency and current shape:  Rectangular 4 kHz
		SIN-UNI	Sinusoidal unipolar Frequency and current shape:  • 40 kHz modulated by rectangular pulses with 4 kHz frequency  • Duty factor 50%

Symbol	Description	Symbol on the treatment screen	Available para	meters
	Pocket frequency	f_trig	Regulation in t	he range of 0.2 Hz – 10 Hz
	Time lag between channels	t_del	Regulation in t	he range of 5 ms – 300 ms
**************************************	Stimulating pulse width (Stimulation duration)	t_stim	Regulation in t	he range of 5 ms – 1 s
		NOR / NOR	<b>+,=</b> <sub>A</sub>   <sub>B</sub> <b>+,=</b>	For such polarization setting, the red plugs of <b>channels A and B</b> of the patient's cables are positive electrodes, and the black plugs are negative electrodes.
	Polarization	NOR / REV		For such polarization setting the red plug of channel A of the patient's cable is a positive electrode, and the black plug of the patient's cable is a negative electrode. The red plug of channel B of the patient's cable is a negative electrode and the black plug is a positive electrode. Warning means that such a setting in channel B is the reverse of commonly accepted way of polarity marking.
Y-/4		REV / NOR		For such polarization setting the red plug of <b>channel A</b> of the patient's cable is a negative electrode, and the black plug is a positive electrode. The red plug of <b>channel B</b> of the patient's cable is a positive electrode and the black plug is a negative electrode. Warning means that such a setting in <b>channel A</b> is the reverse of commonly accepted way of polarity marking.
		REV / REV		For such polarization setting, the red plugs of <b>channels A and B</b> of the patient's cables are negative electrodes, and the black plugs are positive electrodes. Warning means that such a setting is the reverse of commonly accepted way of polarity marking.
cc cv	Amplifier operation mode	-		output current output voltage

Symbol	Description	Symbol on the treatment screen	Available parameters
	Maximum amplitude	-	CC mode:  0.3 – 140 mA for unipolar trigger and stimulating pulses (channel A and B)  Regulation step:  • 0.2 mA in the range of 0.3-0.5 mA  • 0.5 mA in the range of 0.5-140 mA  0.5 – 140 mA for bipolar stimulating pulses (channel B)  Regulation step:  • 0.5 mA in the range of 0.5-140 mA  CV mode:  1.5 – 100 V, max. 100 mA for trigger pulses (channel A) and bipolar stimulating pulses (channel B)  Regulation step:  • 0.5 V in the range of 1.5-100 V  1.5 – 100 V, max. 80 mA for unipolar stimulating pulses (channel B)  Regulation step:  • 0.5 V in the range of 1.5-100 V

### 8.2 Ultrasound therapy

The term ultrasounds applies to mechanical vibrations with frequency that exceeds the upper limit of human hearing (above 20 kHz). Electromechanically active substances, that are distorted as a result of an external electric field, are used for generation of ultrasounds used in physical therapy. In physical medicine, sound waves are generated by electroacoustic transducers using the reverse piezoelectric effect. Mechanical vibrations of the piezoelectric element are conducted to the surface of the ultrasound head. Particles adjacent to the vibrating surface of the ultrasonic transducer begin to oscillate around their equilibrium position. The vibrations are transferred to the next particles causing the formation of a mechanical wave that propagates in space and time. When the ultrasound head comes into contact with the patient's body, the ultrasound waves propagate in the form of longitudinal waves, which cause parallel movement of particles in the same direction as the energy flow. The frequencies used in physiotherapy are typically between 0.8 and 3.5 MHz.

Absorption of the energy by tissues to which it is applied produces the therapeutic effects. The greatest amount of ultrasound energy is absorbed in human tissues with a high content of proteins, such as tendons and articular cartilage.

In tissues, the ultrasound produces:

- thermal effects,
- mechanical effects,
- physicochemical changes.

The thermal effect is based on the increase in the temperature of the tissues, that results from the conversion of kinetic and potential energy (molecules oscillation around the equilibrium position) into thermal energy. The physiological responses to the rise of the temperature include:

- increase in collagen flexibility,
- acceleration of blood flow,
- changes in the peripheral nerves conduction velocity,
- increase of pain threshold,
- acceleration of enzymes activity,
- changes in skeletal muscles contractile activity.

The non-thermal ultrasound mechanisms include:

- mechanical changes (micromassage),
- cavitation (formation of cavities penetrated by vapors of liquids, that are result of overcoming cohesive forces and breaking the water bonds in the emerging areas of negative pressure),
- chemical changes.

Under the influence of the mechanical energy of the ultrasounds, the following physiological effects occur:

- increase of the intracellular calcium level,
- degranulation of mastocytes,
- stimulation of fibroblasts activity,
- increase of the permeability of vascular walls,
- increase of angiogenesis,
- increase of the tensile strength of collagen fibers.

Because of the mechanical and thermal effects, the ultrasounds cause physicochemical changes in tissues, including:

- acceleration of conventional reactions as well as oxidation and reduction in aqueous solutions,
- degradation of polymers,
- lysis and reactions in organic solvents.

The biological effect of ultrasounds is the resultant of thermal, mechanical and physicochemical effects and includes:

- · agitation of fibroblast activity,
- stimulation of collagen synthesis,
- stimulation of synthesis of non-collagen proteins in fibroblasts (albumin and globulin),
- acceleration of DNA synthesis,
- vasodilation and hyperemia of organs,
- intracellular increase of calcium synthesis,
- degranulation of mastocytes,
- acceleration of angiogenesis,
- agitation of cellular oxidation processes,
- change of cell membrane functions,
- change of nerve fibers conduction rates.

Ultrasounds, due to their biological effects in tissues, are used to:

- treat inflammation,
- reduce pain and swelling,
- increase the flexibility of connective tissue,
- reduce muscle tension,
- accelerate tissue healing, including bone fusion,
- reconstruct and improve circulation.

A low intensity ultrasounds therapy (LIPUS) is a special type of ultrasonic wave incorporated in the device. Generally, they are emitted in pulsed mode with average power density up to 0.1 W/cm² (100mW/cm²), low frequency (most often 1.5 MHz), short duty cycles (20%), pulse repetition frequency around 1kHz. The low intensity ultrasounds do not cause thermal and destructive effects, they accelerate the healing of open wounds, as well as tendons, nerves and bones.

The ultrasounds in LIPUS mode are used to:

- stimulate bone fusion, tendons and nerve repair,
- support the healing processes in acute and subacute inflammation.

### 8.2.1 Standard ultrasound heads (GU-5, GU-1)

Parameters description:

Acoustic working frequency  1 MHz  3 MHz  1/3 MHz – switching frequency every 8 seconds	
Acoustic working frequency  Acoustic working frequency  Acoustic working 1 MHz  3 MHz  1/3 MHz – switching frequency every 8 seconds	
Acoustic working frequency  • 1 MHz • 3 MHz • 1/3 MHz – switching frequency every 8 seconds	
Acoustic working frequency	
• 3 MHz • 1/3 MHz – switching frequency every 8 seconds	
1/3 MHz – switching frequency every 8 seconds	
LIDIG II I II C CANALL	
LIPUS – operation only with a frequency of 1 MHz	
Setting – power density [W/cm <sup>2</sup> ]:	
• 0.1 – 3 W/cm <sup>2</sup> – pulse mode	
• 0.1 – 2.5 W/cm² – continuous mode	
• 0.1 – 0.5 W/cm <sup>2</sup> – LIPUS	
Regulation step:	
• 0.1 W/cm <sup>2</sup>	
Available settings:	
Pulse operation • 10 Hz – 150 Hz, variable step	
frequency • LIPUS – 1 kHz	
• cont – continuous mode	
Available settings:	
Pulse operation • 5 – 75%, 5% step – pulse mode	
duty factor • LIPUS – 20%	
• cont – 100%	
30 seconds – 30 minutes, 30 seconds step (manual adjustme possible by "holding" the time field by means of a pen / finge	
Treatment time possible by "holding" the time field by means of a pen / finge increments of 1 s, chapter 7.5Figure 7-7)	er – m
Non-adjustable parameter, the result of power density and e	effective
radiating area.	FITECTIVE
8 5 W GH-5	
Power $\frac{3,3}{1.75}$ W $\frac{30.5}{\text{GU-1}}$ Maximum output power in continuou	us mode
10.2 W GII-5	
$\frac{10.2 \text{ W}}{2.1 \text{ W}} = \frac{30.3 \text{ Temporal maximum output power in}}{\text{GU-1}}$	pulse mode
A Effective 3,4 cm² for GU-5	
Fig. 1 Page 1 Pa	
2 VFC active	
LIPUS mode  • YES – active  • NO – disabled	

### 8.2.2 SnG head – single-transducer mode

Symbol	Description	Available parameters	
	Operating mode	Non-adjustable parameter, one transducer active	
· · · · · · · · · · · · · · · · · · ·	Acoustic working frequency	<ul> <li>Available settings:</li> <li>1 MHz</li> <li>3 MHz</li> <li>1/3 MHz – switching frequency every 8 seconds</li> <li>LIPUS – operation only with a frequency of 1 MHz</li> </ul>	

Symbol	Description	Available parameters
	Amplitude	Setting – temporal power density [W/cm²]:  • 0.1 – 2 W/cm²  • 0.1 – 0.5 W/cm² – LIPUS  Regulation step:  • 0.1 W/cm²
		Amplitude change in the range of 75 – 100% of the setting in the 5s-5s cycle (rise-fall).
*: . <del>*</del>	Pulse operation frequency	Available settings:  • 10 Hz – 150 Hz, variable step  • LIPUS – 1 kHz
<b>→</b> : , <b>←</b>	Pulse operation duty factor	Available settings:  10-60%, 5s-5s cycle (rise-fall).  LIPUS – 20%
	Treatment time	30 seconds – 30 minutes, 30 seconds step (manual adjustment is possible by "holding" the time field by means of a pen / finger – in increments of 1 s, chapter 7.5Figure 7-7)
Р	Power	Non-adjustable parameter, the result of power density and effective radiating area.  6 W Temporal maximum output power in pulse mode
$A_{\scriptscriptstyleER}$	Effective radiating area	3 cm <sup>2</sup>
LIPUS	LIPUS mode	<ul><li>YES – active</li><li>NO – disabled</li></ul>

### 8.2.3 SnG head – dual-transducer mode

Symbol	Description	Available parameters
	Operating mode	Non-adjustable parameter, two transducers active
		Available settings:
$\Lambda \Lambda \Lambda$	Acoustic working	• 1 MHz
. ۸ ۸ ۸	frequency	• 3 MHz
		<ul> <li>1/3 MHz – switching frequency every 8 seconds</li> </ul>
		Setting – temporal power density [W/cm²]:
		• 0.1 – 3 W/cm <sup>2</sup>
		Regulation step:
		• 0.1 W/cm <sup>2</sup>
	Amplitude	The transducer is switched every 1 second. Emission control cycle of single ultrasonic wave transducer:
		<ul> <li>increase of power – 0.25s</li> </ul>
		<ul> <li>phase of full emission – 0.5s</li> </ul>
		• decrease of power – 0.25s
<del></del>	Pulse operation	Available settings:
<del></del>	frequency	• 10 Hz – 150 Hz, variable step
		Available settings:
<b>→</b> ; <b>←</b>	Pulse operation	• 10-60%, 0.5s-0.5s cycle (rise-fall)
<del>         </del>	duty factor	• 20-80%, 0.5s-0.5s cycle (rise-fall)
ш ш	duty factor	• 50-80%, 0.5s-0.5s cycle (rise-fall)
		<ul> <li>80-100%, 0.5s-0.5s cycle (rise-fall)</li> </ul>

Symbol	Description	Available parameters		
<b>(</b>	Treatment time	30 seconds – 30 minutes, 30 seconds step (manual adjustment is possible by "holding" the time field by means of a pen / finger – in increments of 1 s, chapter 7.5Figure 7-7)		
Р	Power	Non-adjustable parameter, the result of power density and effective radiating area.		
		9 W Temporal maximum output power in pulse mode		
$A_{ER}$	Effective radiating area	3 cm <sup>2</sup> for every transducer		

### 8.2.4 SnG head – quadruple-transducer mode

Symbol	Description	Available parameters
	Operating mode	Non-adjustable parameter, four transducers active
<b>W</b>	Acoustic working frequency	Available settings:  • 1 MHz  • 3 MHz  • 1/3 MHz – switching frequency every 8 seconds
		Setting – power density [W/cm²]:  • 0.1 – 3 W/cm² – continuous mode  Regulation step:  • 0.1 W/cm²
	Amplitude	The transducer is switched every 1 second. Emission control cycle of single ultrasonic wave transducer:  • increase of power – 0.25s  • phase of full emission – 0.5s  • decrease of power – 0.25s
* *	Pulse operation	Available settings:
<u> </u>	Pulse operation duty factor	<ul> <li>10 Hz – 150 Hz, variable step</li> <li>Available settings:         <ul> <li>10-60%, 0.5s-0.5s cycle (rise-fall)</li> <li>20-80%, 0.5s-0.5s cycle (rise-fall)</li> <li>50-80%, 0.5s-0.5s cycle (rise-fall)</li> </ul> </li> <li>80-100%, 0.5s-0.5s cycle (rise-fall)</li> </ul>
	Treatment time	30 seconds – 30 minutes, 30 seconds step (manual adjustment is possible by "holding" the time field by means of a pen / finger – in increments of 1 s, chapter 7.5Figure 7-7)
Р	Power	Non-adjustable parameter, the result of power density and effective radiating area.  9 W Temporal maximum output power in pulse mode
A <sub>ER</sub>	Effective radiating area	3 cm <sup>2</sup> for every transducer

### 8.2.5 Characteristics of pulse parameters

The pulse durations depending on the set frequency and duty factor are presented in Table 8-3. For the LIPUS mode, the parameter is non-adjustable – for the frequency of 1 kHz it is 1 ms. In pulse mode, the output power is equal to the product of the duty factor and the set power.

- DF duty factor, percentage and division value,
- prp [ms] pulse repetition period (inverse of frequency),
- pd [ms] pulse duration.

Table 8-3. Pulse duration depending on the duty factor and pulse repetition period (GU-5, GU-1)

* *			5%	10%	15%	20%	25%	30%	35%	40%	45%	50%	55%	60%	65%	70%	75%
	prp L	DF	1:20	1:10	1:6.67	1:5	1:4	1:3.33	1:2.86	1:2.5	1:2.22	1:2	1:1.82	1:1.66	1:1.54	1:1.43	1:1.33
шш			pd [ms]														
10 Hz	100 m	ıs	5.00	10.00	15.00	20.00	25.00	30.00	35.00	40.00	45.00	50.00	55.00	60.00	65.00	70.00	75.00
16 Hz	62.5 m	ıs	3.13	6.25	9.38	12.50	15.63	18.75	21.88	25.00	28.13	31.25	34.38	37.50	40.63	43.75	46.88
20 Hz	50 ms	S	2.50	5.00	7.50	10.00	12.50	15.00	17.50	20.00	22.50	25.00	27.50	30.00	32.50	35.00	37.50
30 Hz	33.3 m	ıs	1.67	3.33	5.00	6.66	8.33	9.99	11.66	13.32	14.99	16.65	18.32	19.98	21.65	23.31	24.98
40 Hz	25 ms	S	1.25	2.50	3.75	5.00	6.25	7.50	8.75	10.00	11.25	12.50	13.75	15.00	16.25	17.50	18.75
48 Hz	20.8 m	ıs	1.04	2.08	3.12	4.16	5.20	6.24	7.28	8.32	9.36	10.40	11.44	12.48	13.52	14.56	15.60
50 Hz	20 ms	S	1.00	2.00	3.00	4.00	5.00	6.00	7.00	8.00	9.00	10.00	11.00	12.00	13.00	14.00	15.00
60 Hz	16.7 m	ıs	0.84	1.67	2.51	3.34	4.18	5.01	5.85	6.68	7.52	8.35	9.19	10.02	10.86	11.69	12.53
70 Hz	14.3 m	ıs	0.72	1.43	2.15	2.86	3.58	4.29	5.01	5.72	6.44	7.15	7.87	8.58	9.30	10.01	10.73
80 Hz	12.5 m	ıs	0.63	1.25	1.88	2.50	3.13	3.75	4.38	5.00	5.63	6.25	6.88	7.50	8.13	8.75	9.38
90 Hz	11.1 m	าร	0.56	1.11	1.67	2.22	2.78	3.33	3.89	4.44	5.00	5.55	6.11	6.66	7.22	7.77	8.33
100 Hz	10 ms	S	0.50	1.00	1.50	2.00	2.50	3.00	4.00	4.00	4.50	5.00	5.50	6.00	6.50	7.00	7.50
110 Hz	9.1 m	S	0.46	0.91	1.37	1.82	2.28	2.73	3.19	3.64	4.10	4.55	5.01	5.46	5.92	6.37	6.83
120 Hz	8.3 m	s	0.42	0.83	1.25	1.66	2.08	2.49	2.91	3.32	3.74	4.15	4.57	4.98	5.40	5.81	6.23
130 Hz	7.7 m	s	0.39	0.77	1.16	1.54	1.93	2.31	2.70	3.08	3.47	3.85	4.24	4.62	5.01	5.39	5.78
140 Hz	7.1 m	s	0.36	0.71	1.07	1.42	1.78	2.13	2.84	2.84	3.20	3.55	3.91	4.26	4.62	4.97	5.33
150 Hz	6.7 m	s	0.34	0.67	1.01	1.34	1.68	2.01	2.68	2.68	3.02	3.35	3.69	4.02	4.36	4.69	5.03

## 8.3 Combined therapy



Combined therapy joins electrotherapy and ultrasound therapy into one treatment. The current in this type of treatment is generated in channel B. The active electrode is a front ultrasound head (connected to socket A or B), the passive electrode is the red plug connected to socket B. The number of currents is limited, there are available only unidirectional (unipolar) currents according to the following chart.

Therapy	Available parameters							
Ultrasound therapy	All parameters are consistent with chapter 8.2							
	TENS pulse currents	TENS						
	AMF current	<b>■</b> # 2p IF						
Electrotherapy	Kotz' current	RS	All parameters are consistent with chapter 8.1					
	Medium frequency currents	#### #### MF						
	EMS	EMS						
	Treatment time	30 seconds -	– 30 minutes, 30 seconds step					

### 8.4 Intended clinical benefits of the therapies

#### Clinical benefits description:

### Intended clinical benefits - electrotherapy

### **TENS and SP-TENS pulse current**

Pain reduction, circulation improvement, muscle stimulation, stimulation of nerve fibers of different thickness depending on the frequency range, pulse width and type of modulation:

- pulse duration 50-100 μs, frequency 50-150 Hz, intensity above the sensory threshold and below the motor threshold - inhibition of pain transmission at the level of the spinal cord
- pulse duration 100-300 μs, frequency 1-10 Hz, intensity above the motor threshold stimulation of endorphin synthesis, facilitation of impulse transmission along nervous pathways in afferent fibers, stimulation in electroacupuncture
- pulse duration 200-300 μs, frequency 5-50 Hz, intensity above the motor threshold stimulation of motor units
- BURST, intensity above the motor threshold strong analgesic effect, increasing the production of endorphins
- SP-TENS, intensity above the motor threshold for the treatment of spastic paralysis

# Interference current and AMF current They act mainly on deeper tissues, showing different

biological effects depending on the range of fundamental frequency and the intensity of current:

- 1-10 Hz, intensity above the sensory threshold and below the motor threshold - stimulation of postganglionic sympathetic fibers
- 1-10 Hz, intensity above the motor threshold, stimulation of endorphin production - single muscle contractions
- 10-20 Hz, intensity above the sensory threshold and below the motor threshold stimulation of postganglionic parasympathetic fibers
- 10-20 Hz, intensity above the motor threshold incomplete tetanus contractions
- 20-80 Hz, intensity above the motor threshold complete tetanic contractions
- 50-100 Hz, intensity above sensory threshold and below motor threshold - inhibition of pain conduction on the principle of gate control theory
- 80-150 Hz, intensity above the sensory threshold and below the motor threshold inhibition of the preganglionic fibers of the sympathetic system
- 90-200 Hz, intensity above the sensory threshold and below the motor threshold muscle relaxation, increasing local hyperemia

#### **Kotz current - Russian stimulation**

- improvement of trophics and muscle tone
- prevention of atrophy
- a counterweight to the side effects of connective tissue formation (fibrosis)
- · muscle strengthening
- muscle re-education (after operations, restoration of normal functions)
- in sports medicine as training techniques aimed at increasing muscle strength and mass as well as economizing muscle work in order to increase resistance to fatigue

#### Medium frequency currents MF

They act mainly on deeper tissues, showing different biological effects depending on the range of the fundamental frequency and the intensity of current:

- 1-10 Hz, intensity above the sensory threshold and below the motor threshold - stimulation of postganglionic sympathetic fibers
- 1-10 Hz, intensity above the motor threshold stimulation of endorphin production, single muscle contractions
- 10-20 Hz, intensity above the sensory threshold and below the motor threshold stimulation of postganglionic parasympathetic fibers
- 10-20 Hz, intensity above the motor threshold incomplete tetanus contractions
- 20-80 Hz, intensity above the motor threshold complete tetanic contractions
- 50-100 Hz, intensity above sensory threshold and below motor threshold - inhibition of pain conduction on the principle of the gate control theory.
- 80-150 Hz, intensity above the sensory threshold and below the motor threshold -

Diadynamic currents	inhibition of the pre-ganglionic fibers of the sympathetic system  • 90-200 Hz, intensity above the sensory threshold and below the motor threshold - muscle relaxation, increasing local hyperemia  Galvanic current
• pain relief,	Electrochemical and electrokinetic phenomena
improvement of peripheral circulation,	which lead to:
normalization of the activity of the vegetative	pain relief
system,	dilatation of peripheral blood vessels
muscle relaxation,	introduction of healing ions into tissues by the
acceleration of hematoma and edema	forces of an electric field
resorption	
Träbert current	Wave current
Segmental and local action that leads to:	Unipolar, bipolar:
reduction of the increased activity of the	restoration of the electrical balance of cells and
sympathetic system	tissues
reduction of muscle tension locally and	improvement of circulation in the capillaries
segmentally	supporting the processes of cell and tissue
pain relief	regeneration
improvement of peripheral circulation	acceleration of breakdown and elimination of
	lactic acid and pain substances
Leduc current	Rectangular pulses
Pain reduction	Stimulation of properly innervated muscles and nerves
Triangular pulses Stimulation of muscles with impaired nerve	Neofaradic pulse current Pain reduction or triggering skeletal striated muscle
conductivity	contraction in order to:
Microcurrents	IG pulses
restoring the electrical balance of cells and	analgesic effect
tissues	circulation improvement
<ul> <li>improving circulation in the capillaries</li> </ul>	reduction of increased muscle tension
supporting the processes of cell and tissue	reduction of increased muscle tension
regeneration	
accelerating the breakdown and elimination of	
lactic acid and pain substances	
EMS	H waves
Triggering of skeletal striated muscle contractions in	reduction of acute and chronic pain
order to:	increasing the lymph and blood flow to speed
increase muscle strength	up the drainage of toxins
<ul> <li>increase metabolism and blood supply in the</li> </ul>	reduction of swelling
muscle	
improve circulation	
re-educate muscles (after operations,	
restoration of normal functions)	
relax muscles	
prevent atrophy	
change the structure of a muscle	
maintain or increase the range of motion in the	
	1

facilitate volitional movements					
Exponential pulses	Hufschmidt stimulation, tonolysis				
<ul> <li>in diagnostics: to determine the I/t curve and the accommodation coefficient,</li> <li>in therapy: for excitability disorders, to obtain contractions of denervated muscles (flaccid paralysis) and to stimulate smooth muscles</li> </ul>	<ul> <li>restoring the physiological balance of excitation of spastic paralyzed muscle fibers</li> <li>normalizing spastic muscle tone</li> </ul>				
Intended clinical benefits – ultrasound therapy					
Standard and SnG heads therapy					
The biological effects in the tissues, under the influence of the ultrasound energy absorption, include:  • agitation of fibroblast activity,  • stimulation of collagen synthesis,  • vasodilation and hyperemia of organs,  • agitation of cellular oxidation processes,  • change of cell membrane functions,	<ul> <li>Therapeutic effects include:</li> <li>pain relief,</li> <li>acceleration of angiogenesis,</li> <li>increase the flexibility of connective tissue,</li> <li>acceleration of bone fusion,</li> <li>reducing the tension of muscles, tendons and ligaments,</li> <li>improving the quality of scar tissue,</li> </ul>				

### LIPUS therapy

reducing of the ulceration area,

the tissue healing process,

injuries.

normalization the rate of repair processes in

shortening the recovery period in sports

• stimulation of bone fusion, tendons and nerve repair,

change of nerve fibers conduction rates

causing the therapeutic effects described on the right.

• supporting the healing processes in acute and subacute inflammation.

### Intended clinical benefits - combined therapy

- the sum of the effects of electrotherapy and ultrasound therapy,
- greater effectiveness of treatments achieved in a shorter time and with a smaller number of treatments

### 9. Indications and contraindications

### 9.1 Indications

### 9.1.1 Electrotherapy

#### 9.1.1.1 TENS and SP-TENS current

**biological impact:** pain relief, improvement of blood circulation, stimulation of muscles, stimulation of nerve fibers with varying effect depending on frequency range, pulse width and modulation type:

- t<sub>imp</sub> 50÷100 μs, f 50÷150 Hz inhibition of pain conduction through a gate control mechanism
- t<sub>imp</sub> 100÷300 μs, f 1÷10 Hz stimulation of endorphins synthesis, stimulation in electroacupuncture
- t<sub>imp</sub> 200÷300 μs, f 5÷50 Hz stimulation of neuromotoric units
- BURST strong analgesic effect
- SP-TENS for spastic paralysis of the nervous muscle system

#### therapeutic application:

- discopathy
- degenerative joint diseases
- arthralgias and pain syndromes of rheumatoid arthritis and spondylitis
- neuralgias and compression syndromes
- periarthritic inflammation
- zoster
- post-surgical pain
- other pain syndromes (except for tumor related pain, details are presented in 9.2)
- partial damage of afferent nerve fibers (facilitation of impulse transmission)
- atrophy of immobilization
- acceleration of bone consolidation
- wound healing

### 9.1.1.2 Interferential and AMF currents

**biological impact:** interferential and AMF currents affect mainly tissues located deeper inside human body showing different biological impact based on the range of basic frequency and intensity:

- f 5÷50 Hz stimulation of muscles, intensity above motor threshold
- f 40÷90 Hz improvement of local circulation, acceleration of resorption
- f 50÷150 Hz relief of pain and relaxation of muscles
- f 90÷150 Hz relief of pain
- f 100÷150 Hz normalization of vegetative system functions, intensity above sensory threshold

#### therapeutic application:

- pain syndromes in the course of osteoarthritis of the spine
- discopathy
- degenerative joint diseases
- pains in rheumatoid arthritis and spondylitis
- neuralgias and compression syndromes
- periarthritic inflammation
- vascular syndromes
- post-traumatic conditions after movement apparatus injuries
- syndromes with increased muscular tone
- vegetative disorders
- oedemas, subcutaneous and intramuscular extravasations

#### 9.1.1.3 Kotz' current – Russian stimulation

biological impact: contraction of skeleton muscles

#### therapeutic application:

- muscle atrophy of immobilization
- muscle re-education
- reduction of gynoid lipodystrophy symptoms

#### 9.1.1.4 Medium frequency currents

#### biological impact:

- pain relief
- increasing muscle strength
- circulation improvement

#### therapeutic application:

- acute / chronic pain of known etiology
- circulation disorder
- oedemas
- hematomas
- muscle strength training

#### 9.1.1.5 Diadynamic currents

#### biological impact:

- pain relief
- improvement of peripheral circulation
- normalization of vegetative system functions
- muscle relaxation
- acceleration of resorption

#### therapeutic application:

- pain syndromes in the course of osteoarthritis of the spine
- discopathy
- degenerative joint diseases
- neuralgias and compression syndromes
- periarthritic inflammation
- vascular syndromes
- post-traumatic conditions after movement apparatus injuries
- syndromes with increased muscle tone
- vegetative disorders
- chilblains
- oedemas, subcutaneous and intramuscular extravasations
- emphysema, subcutaneous emphysema

#### 9.1.1.6 Galvanic current

#### biological impact:

- dilatation of peripheral vessels
- ion movement within tissues

#### therapeutic application:

- drug administration (iontophoresis)
- circulation disorder
- diagnostics of internal inflammatory focuses (galvano-palpation)

#### 9.1.1.7 Ultra Reiz current

#### biological impact:

- reduction of increased activity of the sympathetic system
- decrease in paraspinal muscle tone
- pain relief
- improvement of peripheral circulation

#### therapeutic application:

- degenerative joint diseases
- neuralgias
- peripheral circulation disorders
- spinal pain syndromes
- radicular pains (sciatic neuralgia)
- post-traumatic states

#### **9.1.1.8** Sine Surge

#### biological impact:

- pain relief
- · increasing muscle strength
- circulation improvement

#### therapeutic application:

- acute / chronic pain of known etiology
- drug administration (iontophoresis) only unipolar current
- circulation disorder
- oedemas
- hematomas
- muscle strength training

#### 9.1.1.9 Leduc's current

biological impact: pain relief, stimulation of muscles

#### therapeutic application:

- discopathy
- degenerative joint diseases

#### 9.1.1.10 Rectangular impulses

biological impact: muscle and nerve stimulation

#### therapeutic application:

- electrostimulation of nerves
- electrostimulation of correctly innervated muscles
- electro diagnostics, plotting the I/t curve

#### 9.1.1.11 Triangular impulses

biological impact: muscle stimulation

## therapeutic application:

- electrostimulation of smooth muscular coat, e.g. electro-stimulation in case of post-surgical atonia of bladder and intestines, treatment of spastic and atonic constipation
- electrostimulation of denervated skeleton muscles
- electro diagnostics, plotting the I/t curve

#### 9.1.1.12 Neofaradic currents

#### biological impact:

- activation of muscles through unimpaired peripheral nerves to increase contraction force and sensory consciousness
- obtaining correct movement patterns
- support of the central nervous system in adapting new patterns

#### therapeutic application:

- prevention of muscle atrophy
- muscle training (increase in strength and endurance)
- muscle reeducation
- maintaining or increasing the range of movement
- increasing local blood flow in the muscle
- muscle relaxation
- preventing thrombosis after surgeries

#### 9.1.1.13 Microcurrents

#### biological impact:

- restoring the electric equilibrium of cells and tissues
- improving blood circulation in capillaries
- supporting cells and tissues recovery process
- acceleration of lactic acid and pain substances decomposition and elimination

#### therapeutic application:

- acute / chronic pain of known etiology
- extremities osteoarthritis / spine joint disease
- difficult bone consolidation
- wounds which are difficult to heal
- traumas of periarticular soft tissues
- decubitus ulcers
- ulceration

#### 9.1.1.14 IG pulses

#### biological impact:

- pain relief
- decrease in muscle tone

#### therapeutic application:

- neuralgias
- muscle pains
- joints degenerative changes
- post-traumatic conditions after joints and muscles injuries
- constipation
- peripheral circulation disorders

#### 9.1.1.15 EMS

#### biological impact:

- activation of muscles through unimpaired peripheral nerves to increase contraction force and sensory consciousness
- obtaining correct movement patterns
- support of the central nervous system in adapting new patterns

#### therapeutic application:

- prevention of muscle atrophy
- muscle training (increase in strength and endurance)
- muscle reeducation
- maintaining or increasing the range of movement
- increasing local blood flow in the muscle
- muscle relaxation
- preventing thrombosis after surgeries

#### 9.1.1.16 H-waves

#### biological impact:

- activation of muscles
- stimulation of blood circulation
- nutrient replenishment
- supporting regeneration
- promoting angiogenesis
- breaking the "vicious circle of pain"

#### therapeutic application:

- acute / chronic pain of known etiology
- post-surgical pain
- post-traumatic soft tissue inflammation
- muscle spasm
- reduced range of movement
- muscle atrophy
- circulatory disorders

#### 9.1.1.17 Exponential currents

biological impact: muscle stimulation

therapeutic application: stimulation of denervated muscles

#### 9.1.1.18 Hufschmidt stimulation and tonolysis

#### biological impact:

reflex transduction of the innervation mechanism and temporary physiological muscles rebalancing

#### therapeutic application:

- stimulation of spastic muscles
- increasing the range of movement and stimulation of any motor control in spastic and antagonistic muscles

#### 9.1.2 Ultrasound therapy

#### impact of ultrasounds application on tissues includes:

- increase in cell membranes permeability
- improvement of tissue respiration and stimulation of cellular metabolism
- changes in tissue colloid structure and their hydration
- changes in tissue ion systems
- change of tissue reading in alkaline direction

#### 9.1.2.1 Standard and SnG heads therapy

#### therapeutic application:

- analgesic effect e.g. in the course of degenerative diseases of the spine and peripheral joints, sciatic and femoral neuralgias, painful shoulder syndrome, muscle pains (myalgia)
- chronic inflammations incl. degenerative diseases of the spine and peripheral joints, rheumatoid arthritis

- contractures of connective tissue (joint capsule, tendons, muscles, skin surface)
- normalization/acceleration of tissues healing and regeneration processes muscles, tendons, ligaments, wounds e.g. ulcerations, bedsores
- improvement of circulation
- muscles strains and calcification
- tendons strains and calcification (e.g. tennis elbow, golfer's elbow)
- neuropathy, e.g. compression of the median nerve (only in an non-thermal dose)
- sympathetic system disorders such as reflex sympathetic dystrophy
- medicine application (phonophoresis)
- combined therapy (except SnG head)

#### 9.1.2.2 LIPUS therapy

#### therapeutic application:

- fractures (of tibia, fibula, carpal bones)
- delayed bone union
- stress fractures
- degeneration disease and intervertebral disc herniation

#### 9.1.3 Combined therapy

Indications as for the electrotherapy and ultrasound therapy.



## 9.2 Contraindications for electrotherapy

- patients with implanted electronic devices (e.g. cardiac pacemakers, cardioverter defibrillator, spinal cord stimulator) procedures on torso and thorax, especially dangerous frequencies 10 60 Hz
- patients with implanted implants (e.g. internal prostheses, bone screws) should consult a physician prior to treatment
- surgical staples in the skin
- tissues protected with dressings or materials containing metal ions (silver, zinc)
- acute infections and inflammatory processes, active tuberculosis
- thrombophlebitis
  - exception: NMES (Neuromuscular Electrical Stimulation) can be beneficial in thrombophlebitis prevention when used prophylactically, e.g. after extensive surgery
- risk of an embolism
- diseases with the possibility of hemorrhages
  - exception: stimulation can be used in patients with bleeding disorders (hemophilia) after administration of a clotting factor and remission of coagulopathy, TENS and NMES can be used to reduce pain and improve muscle strength, without increased bleeding in people with hemophilia
- pregnancy (abdomen and lower part of the spine area)
  - exception: TENS can be safely applied to areas distant from the uterus, TENS is safe during labor to reduce pain
- sensory disturbances
- pain of unknown etiology
- active tumor in the treatment area
  - exception: TENS can be used to treat pain in patients in palliative care, NMES can improve life quality in the final stage of a neoplastic disease
- diseases with pyrexia
- superficial metal implants special attention required
- peripheral artery occlusive disease, II b- IV (Fontaine)
- skin infections and inflammations, cutaneous changes at electrode application places
- cases, when the skin cannot be moistened
- recent surgery, unstable fracture, osteoporosis
- epilepsy
  - exception: TENS applied on limbs can reduce epileptic activity



## 9.3 Contraindications for ultrasound therapy

#### 9.3.1 Absolute

- tumor and state after tumor resection
- areas subjected to radiotherapy in the last few months
- gestation (abdomen and lower part of the spine area)
- active tuberculosis
- hemorrhagic condition
- circulatory failure and arrhythmia
- severe general condition and cachexy
- septic inflammation
- unfinished bone growth in the area of metaphyseal growth cartilage
- neuralgias of unknown etiology
- acute inflammatory process and fever
- diabetes (decrease of glucose in blood)
- thrombophlebitis and varicose veins
- implanted electronic devices (e.g. pacemaker)
- peripheral circulation disorders
- sensory disturbance
- neuropathy (thermal dose)
- intervertebral disc prolapse
- conditions after laminectomy, spina bifida, hernia of the intervertebral disc
- precautions should be taken for implants and endoprostheses (metal, plastic and cement)
- skin conditions and wounds
- peripheral nerves damage

#### 9.3.2 Therapy limitations

- ultrasound must not be applied above the third cervical vertebrae
- avoid application in the area of heart, brain, eyes, facial sinuses, gonads, thyroid and lymph nodes (especially cervical), chest, over the parenchymal organs
- avoid application over bone structures and nerves just below the skin surface



## 9.4 Contraindications for combined therapy

As for the electrotherapy and ultrasound therapy.

## 10. Maintenance, cleaning, disinfection

NOTE: The warranty does not cover any damage due to a failure to adhere to the recommendations stated in this chapter.

NOTE: Before attempting to perform following operations isolate the unit and switch mode power supply from the mains supply!

The activities of maintenance, cleaning and disinfection of device components should be realized at:

- ambient temperature between +15°C to +30°C,
- relative humidity between 30% to 75%,
- atmospheric pressure between 700 hPa and 1060 hPa (70 106 kPa).

These conditions are identical to those defined in chapter 4.2 as operation conditions.

There are no limitations for the number of cleaning and disinfection cycles, procedures should be carried out during the entire device "life time".

# 10.1 Cleaning of the unit, switch mode power supply and mains filter casing

NOTE: Before attempting to perform following operations isolate the unit and switch mode power supply and mains filter from the mains supply!

Cleaning of the unit, switch mode power supply, mains filter and cables shall be performed with lightly humid sponge or soft cloth with delicate soap solution or mild detergent. It is recommended to use a microfiber cloth, preferably designated for cleaning mirrors or electronic equipment.

Do not use solvents for paints and lacquers. Do not use excessively dampened sponges either, which can lead to water penetration inside the unit, switch mode power supply or mains filter.

Then all cleaned cables shall be wiped with dry cloth and left for complete drying.

#### Do not connect wet or moist leads!

Do not disinfect or sterilize unit and switch mode power supply casing. Disinfection of accessories and detachable parts, which are not intended for contact with patient's body (for example cables), shall be carried out at least once a week. It is recommended to use agent based on ethanol and/or isopropyl alcohol e.g. Alpro Minuten Spray or 70% solution of spirit.

All disinfected parts of the device should be completely dry before switching the power on.

It is not recommended to use sanitizers consisting of active oxygen, because it can lead to damage of the unit or its parts.

## 10.2 Cleaning of touchscreen

To clean the touchscreen, we recommend to use a cloth which is standard part of the unit or other made of microfiber, preferably designated for cleaning mirrors or electronic equipment.

The manufacturer recommends to clean regularly the touchscreen display. Gently moisten the cloth with clean water. The cloth should be drained so that there is no dripping water. The screen should be wiped until removal of all dirt and dust.

The manufacturer does not recommend to use any product designated for cleaning screens, because there is no guarantee that the chemicals will not lead to faster wear out of touchscreen layers.



# 10.3 Cleaning and disinfection of the electrotherapy accessories and detachable parts

Leads and electrodes shall be cleaned with water and gentle soap or mild detergent, and then wiped with dry cloth and left for complete drying. Electrodes shall be thoroughly cleaned after each treatment session.

#### Do not use wet or moist leads!

Electrodes shall be disinfected after each treatment session. To disinfect it is recommended to use 70 % alcohol solution. It is recommended to use agent based on ethanol and/or isopropyl alcohol e.g. Alpro Minuten Spray or 70% solution of spirit. After disinfection, accessories and detachable parts must be cleaned to avoid allergic reaction.

After each treatment session viscose electrode pads shall be accurately rinsed in clean water, if necessary it is recommended to add some vinegar to the water to remove calcareous deposit. In this case viscose pads shall be rinsed again in clean water. Viscose electrode covers and Velcro belts may be disinfected with 70 % solution of spirit. It is also premised to use agent based on ethanol and/or isopropyl alcohol e.g. Alpro Minuten Spray.

Viscose electrode covers can be also washed in boiling water by the time of 1 minute, after that it is recommended to soak them in saline solution to improve conducting properties. Before immersion in the boiling water, it is recommended to soak viscose pads in the cool water.

If the viscose covers have a material tear or damage to the seams, replace them with new ones.

NOTE: Used electrodes and viscose pads should be disposed of with hospital waste.

## 10.4 Cleaning and disinfection of the ultrasound heads

Ultrasound heads shall be cleaned with water and gentle soap or mild detergent, and then wiped with dry cloth and left for complete drying. Ultrasound heads shall be thoroughly cleaned after each treatment session.

Ultrasound heads (especially their head fronts) shall be disinfected after each treatment session. To disinfect it is recommended to use 70 % alcohol solution. Wipe disinfected surfaces with clean, lukewarm water to avoid an allergic reaction.

For the SnG head, it is possible to remove the plastic cover from the front side to thoroughly clean the applicator.

#### 10.5 Cable condition control

To check the cable condition you may use the function available in setup mode **Control functions** – **"Electrodes test"**.



Special caution should be exercised due to the possibility of high current flow while testing cables. While performing the test, do not touch the cable plug that is examined!

Step	Description
1.	Switch on the unit.
2.	Press the field 🖏
3.	Select the tab <i>Control functions</i>
4.	Select the tab <i>Electrodes test</i>

Step	Description					
5.	Into socket A connect the patient cable which is going to be tested. Holding the plastic covers, short-circuit the cable plugs. Additionally, you should move the cable near the plugs. Observe the indication shown on the display. Press the button <i>Run the test</i>					
	Evaluate the usage of cable	s according to instructions below:				
6.	<u></u>	Cable in good condition				
	-000					
	-00					
	0000	Reducing the signal level indicates the cable damage				
7.	To escape the test mode or	ess the key . To leave <i>Setup</i> mode, press the key				



Alternative method: cable plug should be inserted into the output socket, and plugs from the side of electrodes should be short-circuited. Then select one-channel interferential current and set 10 mA amplitude. Additionally, you can make movements with the cable, and particularly with the spiral cable glands.

If during current increase the information about high resistance in patient circuit **is not displayed**, the cable shall be deemed in proper working condition.

#### 10.6 Verification of electrodes condition

The unit possesses the function of electrodes test, which allows for checking the status of their usage. To check it, the current circuit A is used, where on its output voltage the signal is given. The unit while measuring the current flow in the circuit determines the level of electrode usage. When the electrode is more consumed, the less current flows in the circuit.



Special caution should be exercised due to the possibility of high current flow while testing cables. While performing the test, do not touch the cable plug that is examined!

Step	Description					
1.	Switch on the unit.	Switch on the unit.				
2.	Press the button					
3.	Select the tab <i>Control functions</i>					
4.	Select the tab <i>Electrodes test</i>	_				
5.	To the patient cables red plug in circuit A connect the electrode that is going to be tested. Press the button <i>Run the test</i> . Black plug press in the corners of the electrode.					
	Evaluate the usage of electrodes according to instructions below:					
6.	New electrode, no signs of usage					

Step	Description	
		Small level of usage
	٥٠٠١	Medium level of usage
		Large level of usage, it is not recommended to perform the treatments with unipolar currents due to the possibility of frequent detection of high resistance in patient circuit.
	ll	Electrode completely consumed, recommended immediate replacement.
7.	To end the test, click <b>Stop</b> button or w	vait to the end.
8.	To escape the test mode press the bu	tton $\stackrel{\clubsuit}{\longrightarrow}$ . To leave <i>Setup</i> mode, press the button $\checkmark$ or $\stackrel{\bigstar}{\searrow}$



Alternative method: Rubber electrodes should be inspected using special "Electrode Tester" or resistance meter. In the case of using a resistance meter, electrodes should be considered to be used, when their resistance measured at the ends (diagonally for rectangular shapes, and diametrically for round shapes) is higher than 1000  $\Omega$ .

In the case of working with used electrodes, the information about detection of high resistance in patient circuit will be shown on the display, while performing treatment procedure.

## 10.7 Special messages

In case of an error occurrence, messages that facilitate error handling are displayed in the edition field. There can also be shown a window that informs user about the need to contact the technical support. By using the visible setup control, it is possible to display the unit logs, in order to pass them to the technical staff (see 6.2.6.4).

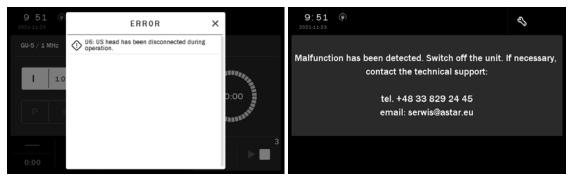


Figure 10-1. The unit error signaling and information visible after closing of the error message

Table 10-1. Signaling special messages

Type of message	Symbol
Errors	<b>①</b>
General information	i
Warnings	$\triangle$

## 10.8 Self-test procedure

Each time the PhysioGo.Lite Combo unit is started, a special self-test procedure is performed during which all modules and functional blocks of the device are tested. If any errors or damage are detected, the relevant information will be presented on the display screen. The module where the irregularity has been detected is blocked and the associated function is not available.

If any mistakes of the hardware nature are detected, the unit will not start. An acoustic signal reminiscent of "tapping" will be emitted. The number of signals ("taps") generated is adequate to the number of the error (see Table 10-2 of error codes). For example, if seven signals are emitted (followed by a short break), this means that the keyboard is damaged or one of the keys is locked.

In this situation, you must disconnect the unit from the mains and contact an authorized service for inspection and a possible repair.

Table 10-2. The "hardware" error coding system

Error code	Error description
12	SDRAM self-test error
13	No communication with the SD card
14	No communication with the TSC controller in the LCD
15	Program defect in the processor FLASH memory (CRC)
17	The keyboard is damaged or a button is pressed (a button short-circuit)
18	Main processor oscillator error

## 10.9 Troubleshooting

Table 10-3.

Symptoms	Undertaking action
The unit does not respond to mains supply	Check fuse. If it is blown, replace it in accordance with indications in point 10.10.  Try to connect different mains cable.  If the problem persists, contact your authorized service.
The unit does not start. Acoustic sounds can be heard	Turn off and on the device.  If the problem persists or occurs frequently, determine the type of error based on chapter 10.8 and contact your authorized service.
Unit Error indication – symbol in the status field or channel tab	Turn off and on the device.  If the problem persists or frequently occurs, note down the error number and contact your authorized service.
Frequent message about detection of a high resistance in the patient circuit. Problems with interconnecting cables or/and electrodes.	Check it in accordance with point 10.5 / 10.6. Follow the instructions described there.
Ultrasound head error indication	Switch the unit off. Disconnect the detachable part. Connect it once again and switch on the mains supply. If the problem persists or frequently occurs, note down the error number and contact your authorized service. If you have another head, connect it in and check if the problem persists.
Message – no ultrasound head contact – appears frequently	Switch on the unit. Enter the setup mode. Modify the US head sensitivity, following point 6.2.4.4.  If the problem repeats, contact your service.

Symptoms	Undertaking action
Ultrasound head does not	Switch on the unit. Enter the setup mode. Perform the US head
detect the lack of contact.	calibration procedure, according to point 6.2.5.4.
	If the problem repeats, contact your service.
The unit does not respond	Turn off and on the device. If the problem persists or frequently occurs,
when you press keys	contact your authorized service.
The touch panel is too sensitive	Calibrate the display. To carry out calibration, press the 🗖 🗹 keys
or does not respond to touch	simultaneously during system start-up. The unit then activates the display
The touch panel reacts in a	calibration mode. Follow the messages on the screen. First, touch three
different spot from where it	points, then validate the correctness of operation by touching five points
was touched	on the screen.
	If the problem occurred once, it means the touch panel was touched
Message "A problem in touch	while system start-up. Do not touch the screen during the system start-
panel operation has been	up.
detected."	If the problem occurs after each system start-up, contact your authorized
	service.
Incomprehensible messages	Switch on the unit. Enter the setup mode. Select an appropriate language
Incomprehensible messages	version.
Unclear display	Switch on the unit. Enter the setup mode. Adjust brightness.
Lack of buzzer signals	Switch on the unit. Enter the setup mode. Check the configuration of
Lack of buzzer signals	buzzer volume.
Too silent buzzer volume	Switch on the unit. Enter the setup mode. Set an appropriate buzzer
100 shefft buzzer volume	volume.
Unit equipped with battery	Connect the mains supply. The battery may be discharged.
module – the device does not	To start the operation, please hold on for at least 5 seconds the STANDBY
respond to mains supply	key.
	Contact your authorized service for battery replacement. If the battery
The battery discharges quickly	module has to be dismantled, a stabilizing cartridge should be installed.
	If you change the battery yourself, follow the information included in 5.3
	If I16 error is shown on the display, it means that the backup battery is
Date and time settings cancel	discharged. Its exchange should be directed to an authorized service.
	Type of memory backup battery is a CR2032.



## 10.10 Fuse replacement

NOTE: Before proceeding to the further described operations isolate the unit and switch mode power supply from the mains supply!

In case of burnt the fuse, it must be replaced. Fuse parameters are given in chapter "Specification and parts of the unit" and on the name plate.

To replace the fuse:

	te the ruse.
Step	Description
1.	Switch the power switch to the "0" position.
2.	Disconnect the mains cable from the mains socket. Disconnect the power supply cable from the device socket marked with symbol —.
3.	With flat screwdriver unscrew the fuse socket until the moment of its slipping from the socket.
4.	Remove the socket with your fingers, replace the fuse, install them in the socket again and screw firmly.
5.	Connect the power supply cord to the device socket. Then connect the mains cable to the mains socket.
6.	Switch the power switch on and start the device. Check the device operation.

## 11. Specification and parts of the unit

## 11.1 Technical data

_									
	2	cc	11	ica	1	$\mathbf{a}$	n	c	•
•	a.	33		ıva		v			

Medical device class:

Classification rule:

9 (according to REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017)

Electrical safety class:

Applied part type:

Degree of protection provided by unit enclosure:

Degree of protection provided by ultrasound head enclosure:

IP20

IPX7

#### Mode of operation:

The unit is intended for continuous operation.

#### **Treatment parameters:**

Described in chapter 8 and

Nominal load resistance:  $500 - 750 \Omega$ 

#### Accuracy of operation parameters:

#### **Electrotherapy:**

Output current and voltage amplitude	$\pm 20\%$ for the load resistance: 500 $\Omega$
Microcurrents calibration:	for resistance 22 kΩ
Pulse repetition frequency:	±20%
Pulse duration:	±20%
Accuracy of times of individual phases for AM and FM:	±20%

#### Ultrasound therapy:

Output power / power density:	± 20%
Pulses frequency:	± 20%
Duty factor:	± 20%
Effective radiating area:	$\pm20\%$

#### **Programs and sequences:**

Pre-defined treatment programs for electrotherapy:	71
Pre-defined treatment sequences for electrotherapy:	44
Pre-defined treatment programs for GU-1 head:	7
Pre-defined treatment programs for GU-5 head:	52
Pre-defined treatment programs for SnG head (single-transducer mode):	4
Pre-defined treatment programs for SnG head (dual-transducer mode):	69
Pre-defined treatment programs for SnG head (quadruple-transducer mode):	24
Total	348

#### User defined:

Programs – electrotherapy:	50
Sequences – electrotherapy:	10
Programs – ultrasound therapy:	50 (for every applicator)

#### **Treatment timer:**

Ranges and resolutions:	defined in chapter 8
Time accuracy:	±10%

#### **General:**

Mains supply: 100-240 V; 50/60 Hz
PhysioGo.Lite Combo controller supply: 24VDC; 2,5A
Mains fuses: size 5x20mm, T3,15L250V; 3,15 A, 250 V
Type of memory backup battery: CR2032
Unit weight: max. 3 kg
Ultrasound head weight: max. 0.5 kg
Unit dimensions (WxDxH): 25x27x16.5 cm

#### Switched-mode power supply, type HPU63B-108 by Sinpro:

 Mains supply – input:
 100-240 VAC; 1.62-0.72A; 47-63 Hz

 Output:
 max. 24VDC; 2.62A

 Weight:
 max. 0.38 kg

 Dimensions (WxDxH):
 13.2x5.6x3.7 cm

The power supply cord is equipped with a mains plug that isolates the device from the supply mains on all poles simultaneously.

#### Battery (optional):

 Type:
 Li-lon

 Voltage:
 18 V

 Capacity:
 2,1 Ah

 Charging time:
 max. 6,5 h

 Durability:
 > 700 cycles

 Weight:
 max. 0.45 kg

 Dimensions (WxDxH):
 15x8x3.3 cm

#### Storage conditions:

Temperature range:  $+5\div+45^{\circ}\text{C}$  Relative humidity:  $30\div75\%$  Pressure range:  $700\div1060 \text{ hPa}$  (70-106 kPa)

#### **Operation conditions:**

Temperature range:  $+15\div+30^{\circ}\text{C}$  Relative humidity:  $30\div75\%$  Pressure range:  $700\div1060\text{ hPa}$  (70-106 kPa)

#### **Transport conditions:**

Temperature range:  $-10\div+45^{\circ}\text{C}$  Relative humidity:  $20\div95\%$  Pressure range:  $700\div1060\text{ hPa}$  (70-106 kPa)

#### 11.2 EMC parameters

In compliance with EN 60601-1-2:2015 and EN 60601-1-2:2015/A1:2021 (IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020).

### Guidance and manufacturer's declaration – electromagnetic emissions

Emission test	Compliance	
RF emissions	Group 1	
CISPR 11	Group 1	
RF emissions	Class B	
CISPR 11	Class B	
Harmonic emissions	Class A	
IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions	Complies	_
IEC 61000-3-3	Complies	

#### Guidance and manufacturer's declaration - electromagnetic immunity

Immunity test	IEC60601 test level	Compliance level
Electrostatic discharge (ESD)	±8 kV contact	±8 kV contact
IEC 61000-4-2	±2, ±4, ±8, ±15 kV air	±2, ±4, ±8, ±15 kV air

Recommendation: Floor should be made of wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Immunity test	IEC60601 test level	Compliance level
Radiated RF	10 V/m	10 V/m
IEC 61000-4-3	80MHz do 2,7 GHz	10 V/III

Field strengths from fixed transmitters, such base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PhysioGo.Lite Combo unit is used exceeds the applicable RF compliance level above, the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PhysioGo.Lite Combo unit.

Applied compliance level is suitable for home healthcare environment. It means the device may be connected to the public low-voltage power supply network.

Immunity test	IEC60601 test level	Compliance level
Electric fast transient / burst	±2 kV	±2 kV
IEC 61000-4-4	±Z KV	12 KV

Immunity test	IEC60601 test level	Compliance level
Surges IEC 61000-4-5	±1 kV line-to-line	±1 kV line-to-line

Immunity test	IEC60601 test level	Compliance level
Conducted RF	3 Vrms	3 Vrms
IEC 61000-4-6	150 kHz to 80 MHz	150 kHz to 80 MHz
	6 Vrms in ISM and amateur radio bands between 150 kHz – 80 MHz	6 Vrms in ISM and amateur radio bands between 150 kHz – 80 MHz

Field strengths from fixed transmitters, such base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PhysioGo.Lite Combo unit is used exceeds the applicable RF compliance level above, the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PhysioGo.Lite Combo unit.

Applied compliance level is suitable for home healthcare environment. It means the device may be connected to the public low-voltage power supply network.

Immunity test	IEC60601 test level	Compliance level
Magnetic field power frequency (50 and 60 Hz) IEC 61000-4-8	30 A/m	30 A/m

Immunity test	IEC60601 test level	Compliance level
	$0\%~U_T$ $0.5$ cycle, phase angles of synchronization with AC power supply voltage $0^\circ$ , $45^\circ$ , $90^\circ$ , $135^\circ$ , $180^\circ$ , $225^\circ$ , $270^\circ$ , $315^\circ$	Complies
Voltage dips IEC 61000-4-11	$0\%~U_T1$ cycle, phase angle of synchronization with AC power supply voltage $0^\circ$	Complies
	70% UT for 25 periods, phase angle of synchronisation with supply voltage 0°	Complies
Voltage interruptions IEC 61000-4-11	0% UT for 5 periods	Complies

Immunity test	Compliance level
Proximity fields from RF wireless communications equipment according to the table 9 of IEC 60601-1-2:2014/AMD1:2020	Complies
Immunity to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz according to table 11 of IEC 60601-1-2:2014/AMD1:2020	Complies

## 11.3 Accessories and standard parts of the unit

Multifunctional unit PhysioGo.Lite Combo defined as a medical device contains the controller, accessories and parts of the unit. Accessories are separate medical devices class I. Parts of the unit are not separate medical devices and works only with controllers manufactured by Astar.

Regulatory status of detachable parts and accessories provided with the device:

- Ultrasound heads and patient's cables connected to PhysioGo.Lite Combo are its detachable parts. They are not a separate medical devices and they operate only with controllers manufactured by Astar Sp. z o.o.
- Electrodes for electrotherapy, viscose pads, elastic Velcro belts provided with PhysioGo.Lite Combo are class I medical devices. They are marked with CE mark. They are manufactured by Astar Sp. z o.o.
- USG gel provided with PhysioGo.Lite Combo is class I medical device. It is marked with CE mark.

Standard parts of the PhysioGo.Lite Combo unit

No.	Name	REF	Quantity
1.	PhysioGo.Lite Combo controller	A-UE-AST-PLC	1
2.	Switch mode power supply – type HPU63B-108 by Sinpro	-	1
3.	. Mains cable with filter A-AW-AST-PLMF2A 1		1
4.	Patient's cable:		
	a) Channel A	a) A-AE-AST-KPPL2M_A	2
	b) Channel B	b) A-AE-AST-KPPL2M_B	
5.	Spare fuse – time lag T3,15L250V		1
6.	Pen for a resistive touch screen		1
7.	LCD touch screen cloth	-	1
8.	Masking covers with cutout	-	2
9.	M3x16DK screw	-	4
10.	Instructions for use	-	1
11.	Electrical safety test report		1
12.	PhysioGo.Lite electrotherapy leaflet	-	1

Components and accessories of the set, which are class I medical devices:

No.	Name	REF	Quantity
1.	Electrodes 6x6 cm	A-AE-AST-EL6060R or	4
		A-AE-AST-EL6060RV2	
2.	Electrodes 7,5x9 cm	A-AE-AST-EL7590R or A-AE-	2
		AST-EL7590RV2	
3.	Viscose covers for electrodes 6x6 cm	A-AE-AST-PW8X8	8
4.	Viscose covers for electrodes 7,5x9 cm	A-AE-AST-PW10X10	4
5.	Velcro belt 100x10 cm or 100x9 cm	A-AE-SPM-PR100X10 or A-AE-	2
		AST-PR100X9CA	
6.	Velcro belt 40x10 cm or 40x9 cm	A-AE-SPM-PR40X10 or A-AE-	2
		AST-PR40X9CA	
7.	USG gel	H-AS-CEM-ZEL500G	1

## 11.4 Optional parts of the unit

Parts of the unit and trolleys	
Name	REF
GU-1 ultrasound head	A-AS-AST-GU1
GU-5 ultrasound head	A-AS-AST-GU5
SnG ultrasound head	A-AS-AST-SNG
Standard ultrasound head holder	A-AS-AST-SMSPUCH
SnG head holder	-
Battery	A-AW-AST-LITEAQ
Versa trolley	A-AM-AST-VSA
Versa X trolley	A-AM-AST-VSX
Versa XUVC trolley	A-UI-AST-XUVC55

Other	
Name	
Point electrodes 6, 10. 15, 20 mm	Sand bags 21x14 cm, 21x28 cm
Self-adhesive electrodes	Bag for the unit and parts of the unit
Crocodile clips	Phillips screwdriver

## 12. Appendix A. Symbol description, I(t) curve diagram



Recommendation for the operator's position to ensure the legibility of markings and information on the controller, accessory and detachable parts labels:

- visual distance shall be 30 cm due to the applied technologies,
- lighting 500 lx, which corresponds to normal room lighting conditions.

## 12.1 Controller, parts of the unit, packaging

Symbol	Definition
	Caution, see the ACCOMPANYING DOCUMENTATION, symbol ISO 7000-0434A
	Class II equipment, symbol IEC 60417-5172
<b>†</b>	BF type equipment, symbol IEC 60417-5333
	Date of production: year, symbol ISO 7000-2497
	Manufacturer, symbol ISO 7000-3082
IP20	Degree of protection provided by enclosures (IP code), based on IEC 60529
-	Fuse, symbol IEC 60417-5016
VER	Unit version
SN	Serial number, symbol ISO 7000-2498
LOT	Batch code, symbol ISO 7000-2492
REF	Catalogue number, symbol ISO 7000-2493
MD	Medical device, symbol 5.7.7. of ISO 15223-1 standard

Symbol	Definition
UDI	Unique Device Identifier, symbol 5.7.10. of ISO 15223-1 standard
	Disposal of used devices together with other waste is prohibited, complied with the requirements of WEEE
	General symbol for recovery/recyclable, symbol ISO 7000-1135
[i]	Instructions for use, symbol ISO7000-1641
<u></u>	Caution, risk of electric shock, symbol IEC 60417-6042
	Switch mode power supply socket, direct current, symbol IEC 60417-5031
	Switched-mode power supply and mails filter identification
	Follow Instructions for use, symbol ISO 7010-M002 Background color: blue
	Sitting prohibited, symbol ISO 7010-P018 Background color: white Circular band and slash: red Symbol or text: black
	Stepping prohibited, symbol ISO 7010-P019 Background color: white Circular band and slash: red Symbol or text: black
	Pushing prohibited, symbol ISO 7010-P017 Background color: white Circular band and slash: red Symbol or text: black
	Do not disassemble Background color: white Circular band and slash: red Symbol or text: black
<u> </u>	General warning sign, symbol ISO 7010-W001 Background color: yellow Symbol or text: black
QC Q.C.	The product has passed quality control
2	Keep for further use

Symbol	Definition
Ŝ	Weight
	Packaging size
	Temperature limit, symbol ISO 7000-0632
	Keep away from rain, symbol ISO 7000-0626
	Fragile; handle with care, symbol ISO 7000-0621
<u> </u>	This way up, symbol ISO 7000-0623
<b>(€</b> 0197	The marking of conformity with legal regulations for medical devices applicable in the European Union along with the number of the Notified Body taking part in the conformity assessment.

## Table of ultrasonic parameters of unit:

Symbol	Explanation
F <sub>awf</sub>	Acoustic working frequency
Cont	Continuous mode (continuous emission)
Pulsed	Pulse mode (pulse emission) of standard heads
SnG	Pulse mode (pulse emission) of SnG head
DF	Duty factor of standard heads
DF <sub>SnG</sub>	Duty factor of SnG head
prp	Pulse repetition period
prpLIPUS	Pulse repetition period in LIPUS mode
pr <sub>SnG</sub>	Duration of frequency rise in SnG head pulse mode
pf <sub>SnG</sub>	Duration of frequency fall in SnG head pulse mode
pi	Duration of frequency stabilization in SnG head pulse mode
pd	Pulse duration

## Ultrasound head nameplate symbols:

Symbol	Explanation
f <sub>awf</sub>	Acoustic working frequency
Beam type	Type od the bead (coll. – collimated)
RBN / BNR (max)	Beam non-uniformity ratio
Rated output power	-
AER	Effective radiating area
Head size / Total appl. area	Total contact area (head front)
IPX7	Degree of protection provided by enclosure

# 12.2 Switched-mode power supply – casing

Symbol	Description
TÜVRheinland CERTIFIED	TUV Rheinland conformity mark (the table lists the standards for which compliance has been demonstrated, the ID means the notified body's report number).
CE	Marking of compliance with the requirements of legal regulations in force in the European Union.
c <b>711</b> us	UL+CUL conformity mark (USA, Canada). The alphanumeric string represents the approved UL report number.
Æ	Federal Communications Commission EMC compliance mark (USA)
	For indoor use only, symbol IEC 60417-5957
	Class II equipment, symbol IEC 60417-5172
X	Disposal of used devices together with other waste is prohibited, complied with the requirements of WEEE
V	Energy efficiency level
$\Theta \bigoplus \oplus$	Voltage polarity in the output plug
	Direct current (DC), symbol IEC 60417-5031
F	Alternating current (AC), symbol IEC 60417-5032

