Datasheet

Gymna Acure 250

The quality solution for electrolysis

The Gymna Acure 250 for Ultrasound-guided Galvanic Electrolysis Therapy and dry-needling

- Offers galvanic electrolysis at $\,$ mid-level range in μA intensity
- Releases trigger point tension with 500 µA intensity
- Offers professionals a modern application technique for treatment of soft tissue injuries, in case of absence of desired outcome from other traditional techniques
- Extremely user-friendly full colour touchscreen operation with an intuitive graphical user interface and comprehensive functionality
- Operates with an ergonomic smart handpiece functioning as a remote control: adjustment of desired intensity, start-stop therapy, immediate visual feedback from colour LED-ring

- Offers a patient database for storage of all treatment information and related therapy result graphs. Analysis of this data is key to more successful treatments
- External medical grade power supply allows to operate mains powered as well as with internal rechargeable batteries

The Gymna Acure 250 is especially developed for physiotherapists and acupuncturists at the forefront of education, innovation and unexcelled patient care.

The patient deserves all attention, while the professional needs to work in all safety.



Main characteristics:



Direct therapy key for µA-level



Direct therapy key for Trigger points



Application protocols via Body Area



Patient database (GDPR-compliant)



Contra indications list



Anatomical library (medical E-book)



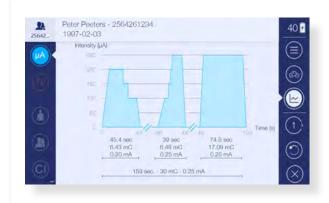
System settings (customize your device)



Graphical user interface characteristics:

- Full colour capacitive touchscreen, 7 inch
- · Intuitive graphical user interface
 - o Colour guided therapy
 - o Use of modern self-explanatory icons and buttons
 - o Quick and easy access to all functionalities
 - o All settings and adjustments directly on the touchscreen
- Self-explanatory therapy screen
 - o Traditional- or in dashboard design
 - o Allows easy parameter adjustments
 - o Shows therapy result graph of administered charge
 - o Visual and auditory feedback (to inform, warn)
- · System settings
 - o Customization of settings to personalize your Acure
 - o Includes accessory testing tool
 - o Manage power savings
- Future proof for software updates via USB



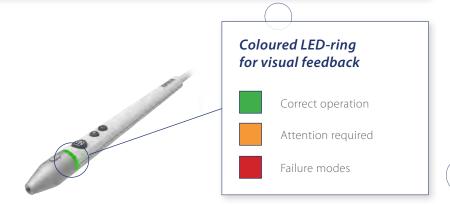


Patient database:

- To manage patients
- · Store treatment sessions linked to a patient
- Store result graph of administered charge
- Supports multiple-sequence treatment
- Access code protected (GDPR compliant)

Smart handpiece:

- Ergonomic modern design
- Ingenious needle grip/release mechanism
- Supports a one-needle electrode
- Functions as a wired remote control allowing:
 - o To Start/Stop the therapy
 - o Adjust the intensity with plus & minus button
- Multi-colour LED-ring for visual feedback
- Connector with lock-function







Handpiece holder:

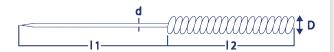
- Magnets allow a secure storage of the handpiece
- Mountable: holder suited for both left and right handed users
- Specifically designed to avoid accidental needle puncture (needle needs to be removed before placement)

Acupuncture needle:



- Purchase acupuncture needles from a local supplier strictly complying with the applicable local legislation
- Only use high quality, single use, sterilized, acupuncture needles
- Needles must have medical CE approval, including Notified Body number
- Needle packaging must state percutaneous electrolysis
- Needle is made of single thread uncoated stainless steel with a braided steel handle without a head

- Dimensions:
 - o Needle diameter (d)
- 0.30mm <-> 0.35mm
- o Handle outer diameter (D)
- 1.25mm <-> 1.45mm
- o Needle body lengths (I1)
- 20mm <-> 100mm
- o Handle length(l2)
- 25mm <-> 30mm





Bracelet electrode:





• Functions as the positive electrode (anode side)

Mains and battery operation:

- Powered with an external medical grade power supply that can remain connected during treatment
- Operates both with mains power and with rechargeable li-ion batteries
- Smart battery management system inside
- Power saving modes





Galvanic Current:

General

Current waveform: Direct continuous current (galvanic)

Output stage type: Constant current source

Channel: 1 Channel for both galvanic electrolysis and dry needling

Polarity: Acupuncture needle is the negative pole

Limitation: 150% of the set value at 10% of the maximum range

decreasing to 110% of this maximum

Accuracy: By a load of 500-1000 Ω the accuracy of the output is \pm 10% of the set value

μA-level in standard mode

Range: $0 < -> 2500 \,\mu\text{A}$

Step size: $50 - 100 - 250 - 500 \; \mu A$ Treatment time: $00:00 <-> 30:00 \; min$

μA-level in advanced mode



Extra specific parameters

Ramp curve time: 2 - 4 - 8 seconds (patient comfort)

Pre-set intensity: $50 < -> 2500 \,\mu\text{A}$

μA- level supported with, Monitoring the closed patient circuit (using an auxiliary current)

guided safety precautions: Warning level for the administered charge Q

TP Trigger points (dry needling)



Range: $0 < -> 1000 \,\mu\text{A}$ Step size: $500 \,\mu\text{A}$

Treatment time: 00:00 <-> 30:00 min

Technical device specifications:

Languages 7

Mains voltage 100-240 V, 50-60 Hz

Current rating 0.6 A - 0.3 A

Maximum power rating 24 W
Power supply voltage 12 VDC
Maximum current rating 2 A

Power supply weight $\sim 0.17 \text{ kg}$

Handpiece (wxdxh) $175 \times 16 \times 16 \text{ mm}$

Handpiece weight $\sim 0.060 \text{ kg}$

Unit (wxdxh) 210 x 160 x 90 mm

Unit weight $\sim 0.85 \text{ kg}$ Weight incl. accessories $\sim 1.00 \text{ kg}$

Operation mode suited for continuous operation

Electrical safety protection Class II

Applied parts Type BF

MDR Classification IIa

Conformity European Medical Device

Regulation (MDR 2017/745)

Notified Body CE0344

Standard accessories

370 601 Acure handpiece369 018 Acure handpiece holder

329 967 1-Pole patient cable; 4mm M to 2 mm F 340 703 Rubber electrode brace, size 6cm x 8cm ; 2 mm

340 681 Sponge for electrode brace, size 6cm x 8cm (2pcs)

108 935 Fixation strap, elastic, size 60 cm369 148 Acure circuit test adaptor

369 006 External medical grade power supply

369 010 Set of power adaptor sockets for other countries 369 014 Rechargeable battery pack 7,4V 5200mAh (li-ion)

Optional accessories

340 714 Rubber electrode brace, size 8cm x 12cm; 2 mm 340 692 Sponge for electrode brace, size 8cm x 12cm (2pcs)

108 934 Fixation strap, elastic, size 30 cm

108 936 Fixation strap, elastic, size 120 cm

368 005 Gymna Mobile Fit

368 027 Gymna Mobile Fit storage tray

Manuals

370 810 Acure quick start manual 370 822 Acure activation quide

370 814 Acure safety instructions, multi language

370 826 Acure instructions for use in English

370 818 USB-stick with instructions for use, multi language



