# **Gymna Care 300**

**USER MANUAL** 

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## 1. INTRODUCTION

# 1.1 Diathermy

Heat has been used to treat a wide range of disorders for a great many years: it provides relief in chronic, traumatic and inflammatory conditions; it increases the blood flow, thereby improving cell nutrition and oxygenation and speeding up the elimination of toxins; it improves the elasticity of the connective tissue; it reduces joint stiffness, pain and muscle spasms; and it facilitates the reabsorption of haematoma and oedema.

A variety of energy forms are described in physics: thermal, kinetic, electrical, electromagnetic, etc., which can be transformed from one form to another, for example, electrical energy can be transformed into thermal or mechanical energy and vice versa. The application to biological tissue of a field of electrical currents of appropriate power, frequency and wavelength, supplies energy to the underlying layers, restoring the chemical and electrical balance that have been negatively affected by the disorder being treated. This is the theory behind its use in physiotherapy. Every single individual cell is involved in the regenerative function of the tissue as a result of morphological, chemical and electrical interactions.

The new Gymna Care 300® (Powered by Fisiowarm®) devices are capable of supplying energy by utilising a different form of interaction between electrical field, inspired by the physical model of the condenser <u>but without using high voltage</u>. There are multiple transfer modes characterised by the fact that the heat is generated directly within the tissues, thus succeeding in treating disorders that were previously inaccessible.

Results are achieved deep inside the body, without any form of energy being projected directly through the skin.

Gymna Care 300

# 1.2 Gymna Care 300® - Presentation

The Gymna Care 300<sup>®</sup> (Powered by Fisiowarm<sup>®</sup>) is a new generation of devices.

The Gymna Care 300® technological approach is unique. For the first time in this sector, we provide machines equipped with our dedicated Gymna Care 300® iOS app supplied on iPad. Gymna Care 300® devices are equipped with supports integrating the iPad perfectly into the design. The main functions can also be managed without using the iPad, via a new front panel incorporating a new-generation OLED display.

The design features advanced encoders and processors ensuring fast, intuitive control of functions.

Its overall visual impact is strong and versatile.

Gymna Care 300® (Powered by Fisiowarm®) is designed to meet the most wide-ranging requirements of professionals in the sector.

Two different energy transfer modes are available:

✓ Capacitive mode uses special electrodes that enable the equipment to provide a capacitive treatment using a low-voltage output only (below 200 V). This means that the system is very stable and offers improved levels of safety for both the operator and the patient.

In comparison, the voltage can exceed 1000 V in the conventional devices available on the market. With this application, the passage of current, which occurs in proximity to the dielectric barrier inside the electrode, produces a significant temperature increase in the tissue beneath the applicator, without particular distinctions in terms of resistivity. Because of this, capacitive treatment is particularly suitable for soft tissues.

Resistive Mode uses a conductive electrode applied directly to the body: the current travels through the area of the body in question, dispersing towards the neutral electrode. On its journey it generates heat due to the resistance of the organic tissue to its passage. The charges build up in the most resistive areas of tissue between the active and neutral electrodes, producing a biological effect in these areas. These resistive points are made up of bone, tendons, ligaments and fascia which, subjected to the treatment, act like the dielectric in a capacitive electrode. A current is therefore created that transfers the charges inside the biological tissue, affecting the innermost layers and, as a result, standardising the deep-down endothermal response.

# 1.3 Distinctive features of the Gymna Care 300<sup>®</sup> series

#### 1.3.1 The Gymna Care 300® system

The Gymna Care 300® system was inspired by the idea of offering physiotherapists all the advantages of a truly dynamic application.

Tecar therapy is always associated with massage and kinetic therapy. It is therefore important to ensure the greatest possible freedom of action for therapists (who have to keep a constant eye on the treatment parameters and controls while working), as well as an extensive and innovative range of dedicated accessories.

For the first time in our sector, the operator-machine interface is managed using an iPad and dedicated software app. The interface takes advantage of all current technological advances, including **wifi and Bluetooth connection**, with availability of software updates and possibilities of further supplementing the applications. The interface is simple and intuitive, providing a rich and complete range of controls.

The Gymna Care 300® system guarantees the same readability and usability that we've become accustomed to in the technologies of everyday life. All the important functions and utilities are now accessible via the most recent generation of iPad, with all its advantages and potentials, making operation easy to learn.

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#### 1.3.2 Methods of application

#### **BIPOLAR**

During normal use of tecartherapy equipment, therapists often have to apply treatment to a much larger area of the body than is really necessary. This increases the size of the treated area, involving tissues that do not really require any stimulation. Above all, this entails the use of higher power, a delay in the perception of the thermal increase with a consequent increase in application times and, occasionally, difficulty identifying the exact treatment area. Bipolar treatment offers a significant improvement in application terms, effectively overcoming these problems.

The structure of the handpiece encompasses a neutral electrode and an active electrode (resistive or capacitive) within a limited area. The current therefore tends to circulate within the underlying tissue, migrating from one electrode to the other and involving medium-depth tissue, while the typical characteristics of the capacitive or resistive transfer remain unchanged.

#### **STATIC AUTOMATIC**

**Static Automatic** mode permits application without requiring the constant presence of the therapist. Having identified the application zone and parameters, the electrodes provided can be positioned so as to treat the area of body concerned. In this treatment, the device automatically limits the output power.

#### **NEUTRO DINAMICO®**

This new application mode sums up the essence of the treatment in its name, which literally translates as *Neutral Dynamic*. The use of the **Neutro Dinamico®** system makes it possible to channel energy in different directions within the same application. Various accessories in the Neutro Dinamico® range allow therapists to move around the patient's body, giving the active electrode different geometric reference points, and channelling the energy with their own hands to create alternative routes.

#### 1.3.3 Emission

In addition to the classic continuous emission mode, Gymna Care 300 now offers three progressive modes of "Athermic" emission, ensuring optimal application in different states of inflammation. In addition, the "Superpulsed" athermic mode (available only on Model 400W) transmits high energy values with almost no thermal increase: highly useful for treatments in acute phase and for immediate intervention following a trauma.

Choosing the "Sensitive" emission mode, the sophisticated algorithms of Gymna Care 300 allow highly regulated optimized energy transfer: ideal for treatment of the most delicate body areas.

#### 1.3.4 Multi-frequency and automatic scanning

Using the new app the operator can choose different frequency settings, of both resistive and captive energy transfer. This allows the treatment to reach different depths and extents, given the varying behaviours of body tissues under the different applications of signal frequencies.

Choosing the AUTOMATIC SCAN mode, the physiotherapist automatically draws on a range of preset frequencies (varying with the model of instrument): energy transmission reaches the tissue throughout its depth, evenly and uniformly.

#### 1.3.5 Guideline and Customized Protocols

The operator can select from more than 50 predefined protocols, divided in categories (Muscles, Nervous system, Physio-aesthetics, Post-operative, ...).

Practical suggestions are provided, for standard and advanced applications. An assortment of customisable protocols offer the possibility of creating treatments comprised of several operating steps (up to three separate phases).

For further details on these Gymna Care 300 features, please refer to section 6.2 of this manual

# 1.4 Intended use and CE marking

Gymna Care 300® devices are designed for physiotherapy, rehabilitation therapy and pain therapy applications.

They are intended for use under the supervision of a doctor or a professionally qualified rehabilitation therapist (or equivalent), with adequate expertise in the methods employed.

The treatments provided by this machine, together with the application times and modes, should only be prescribed by a doctor.

The devices must be installed by authorised personnel in premises equipped for medical use and compliant with all legal requirements.

Do not carry out treatments in conjunction with examinations or treatments using other electrical equipment.

Gymna Care 300® is an active therapeutic medical device, which performs its function by transmitting energy to the human body. Therefore, Rule 9 of Annex IX to Directive 93/42/EC as subsequently amended, applies in full. This device is rated as class IIb, in accordance with Directive 93/42/EC as subsequently amended, and is identified by the following CE marking



# 1.5 General Safety Terms

- The device should only be used by personnel trained in the application of the treatments.
- Do not attempt to repair any internal parts. Only authorised technicians can intervene in the event of a fault in the device or its accessories.
- Follow the instructions and directions provided in this manual.
- Place the device on an appropriate work surface, in the operating position that provides the best view of the control panel. It is advisable to use a stable and practical support.
- Keep the bottom and rear vents on the unit free of all obstacles.
- Do not insert objects in the vents.
- Do not expose the device to direct sunlight or place it close to a heat source.
- Do not use the device if it has been exposed to excessive damp.
- Do not allow the device to come into contact with liquids.
- Do not disinfect or sterilise the device.
- The European Commission Directive on Medical Devices (93/42/EC) requires the use of safe devices. It is recommended that the device be inspected for safety by authorised technical personnel, at least once per year.
- Keep these user instructions with the device at all times.
- If the device starts smoking or produces a burning smell, unplug it immediately.
- Only move the device when the machine is not plugged in.
- Do not operate the device near equipment that may produce strong electromagnetic fields.
- Do not use the device in the presence of gas or inflammable vapours.
- Switch the device off when it is not in use.
- Use only original accessories.

# 1.6 Liability

The manufacturer declines all liability for injuries to the therapist, the patient or third parties, or for damage caused by or to the device, in the event of:

- an incorrect diagnosis
- incorrect use of the device or the accessories
- incorrect interpretation of the instructions for use or failure to follow them
- the device not being properly maintained
- maintenance or repairs by unauthorised persons
- attempted modifications to the device or accessories
- installation of the device in unsuitable environments

## 2. DEVICE DESCRIPTION

# 2.1 Gymna Care 300®: the device and standard accessories

Gymna Care 300® takes a unique, innovative approach within the panorama of Tecartherapy.

Our new equipment boasts modern and minimal design. Drawing on the most advanced technologies we obtain truly compact dimensions and weight, finally allowing ease of handling and simplicity in transport. Both machines can be provided with an optional carry bag, complete with accessory holder.

The operator interfaces with the machine via the dedicated Gymna Care 300® software app, installed in an Apple® iPad with iOS operating system: an absolute first in our sector, drawing on all the potential advantages of this technology, including interactivity, automatic access to new releases, updates, and new supplementary apps. The interface is simple, intuitive, complete, and rich with utilities.

The screen displays the settings, information on the treatment in progress and feedback to support its successful outcome. It is simple and intuitive to use and easy to read. Both models are designed with the output connections at the rear, achieving a front panel with clean lines and easy-to-clean surfaces.

Conformity with regulatory standards is essential. Gymna Care 300® equipment is manufactured to the maximum specifications, using components rated for higher applications in completely shielded and protected circuits.

The device also has a smart protection system that carries out constant safety checks on various levels.

**Gymna Care 300**® stands out on the market for its design, which uses the highest standards of technology available today. It is a real gem in terms of innovation, strength and functionality, offering the added peace of mind of purchasing a Gymna product entirely <u>designed and made</u> in Italy by Golden Star.

## 2.2 Front view



- 1) Apple® iPad
- 2) Mobile support\* for iPad
- 3) Encoder knob with multi-function pushbutton
- 4) 4 lines x 20 characters OLED display
- 5) START/PAUSE LED indicator
- 6) Failure, error or fault LED signals
- 7) PATIENT CONTACT LED indicator

<sup>\*</sup> The iPad support has a magnetic holder to guarantee stability. The special shape allows free rotation, with "catch" points at 45 degrees. The support can also be removed and positioned as desired for convenience in use.

# 2.3 The rear panel



- 1) IEC socket for mains cable, fuses, on/off switch
- 2) Jack type power receptacles for special accessories
- 3) USB charging port, compatible with iPad
- 4) Cooling fan
- 5) LED indicating ready USB charge
- 6) Unipolar output connector
- 7) Bipolar output connector
- 8) Static Automatic/Neutro Dinamico output connector

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# 2.4 Technical characteristics

# 2.4.1 Features table

Product	Gymna Care 300®
INTERFACE	- Gymna Care 300 iPad App (included) - OLED display and rotary encoder with multi-function button
Nominal Power	400 Watt
OPERATING FREQUENCY	Preset frequencies: 300, 400, 450, 500 kHz, 1MHz AUTO (automatic scanning of the preset frequencies)
EMISSION	- Continuous - Sensitive - Athermia 1/2/3
OPERATING MODE	Unipolar Bipolar Neutro Dinamico Static Automatic Fascial Full
COMPATIBLE ACCESSORIES	The whole range
ENERGY TRANSFER	Capacitive Resistive
PRESET PROGRAMS	56 guidelines that can be integrated into the new releases of the app and advanced modes

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# 2.5 The Gymna Care 300® app for iOS® operating system

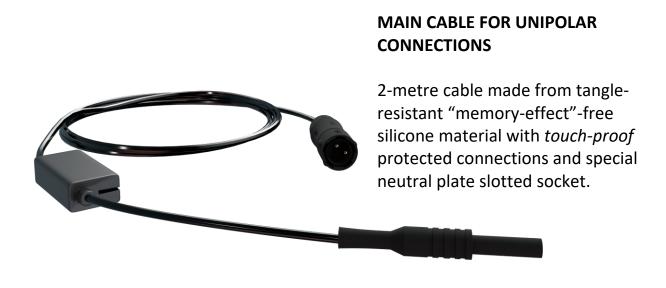
The Gymna Care 300 system is managed via a dedicated interface operating on Apple iPad (available from AppStore), which simplifies operation and achieves a rich, optimal physiotherapist-equipment interaction. Operating in remote control via Bluetooth, the operator achieves a truly dynamic user experience, with full freedom of movement. Treatment sessions now become reliable and comfortable, for both patient and operator.

Why choose Apple iOS®? Gymna Care 300 has developed important technical and functional advances in its main systems. Combining these with low- energy Bluetooth native to iOS, we offer a more incisive user experience, guaranteeing the best in the Tecar sector combined with the latest technologies available via iPad.

#### 2.6 Accessories

Because of the important role they play, particular attention has been paid to the applicators. Made from lightweight materials, with an ergonomic and innovative shape, they guarantee high standards of comfort for both the therapist and the patient.

## **2.6.1 UNIPOLAR Accessories**



#### HANDPIECE FOR UNIPOLAR APPLICATIONS

The new handpieces with 90° grip make the treatment process more comfortable for the therapist and ensure even more natural movement of the electrode on the patient. The accessory cable will be connected to the main cable for unipolar applications.





Available diameters: 44 mm, 64 mm, 80 mm

#### **CAPACITIVE ELECTRODE SERIES**

A new design and new materials make the capacitive electrodes even lighter and more resilient. The galvanised contact surface is coated with a 1-micron layer of gold. The part that comes into contact with the patient is perfectly smooth and even, ensuring a pleasant massage sensation during treatment, while the isolated top part of the electrode offers added protection for the therapist.



#### **RESISTIVE ELECTRODE SERIES**

Mirror-polished steel conductive surface and fully isolated top.

Available diameters: 44 mm, 64 mm, 80 mm



Available diameters: 44 mm, 64 mm, 80 mm

# "UNIQ" RESISTIVE/CAPACITIVE UNIPOLAR ELECTRODE SERIES

"UNIQ" is a sophisticated and innovative series of electrodes for difficult unipolar treatments. The electrode features a central zone operating in resistive mode and an outer ring in capacitive mode, permitting significant gains in extent and depth of penetration for the treated area.



#### **NEUTRAL ELECTRODE**

Steel electrode with slot connection, available in 19x26 cm and 14x20 cm sizes.

#### 2.6.2 BIPOLAR accessories

#### **RESISTIVE/CAPACITIVE BIPOLAR HANDPIECE**

The new handpieces with 90° grip feature an ergonomic, lightweight design, making the treatment process more comfortable for the therapist and ensuring even more natural movement of the electrode on the patient. The cable connects directly to the machine via a safety connector.





# CAPACITIVE BIPOLAR ELECTRODE SERIES

Both the capacitive and resistive bipolar electrodes are designed using the same technology. The electrode features the neutral and active poles in the form of two concentric rings.

Available diameters: 44 mm, 64 mm, 80 mm

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#### **RESISTIVE BIPOLAR ELECTRODE**

Electrode with mirror-finished steel plates, suited for treatments on limited body surfaces and in delicate areas.

#### **PROFILE** BIPOLAR RESISTIVE ELECTRODE WITH MOVABLE HEADS

The new Gymna Care 300® bipolar resistive electrode with movable heads: the PROFILE electrode offers important innovations, replacing products which were often unusable in difficult applications.

The heads can be attached at different distances, enabling treatment of varying extensions of body areas.



#### 2.6.3 NEUTRO DINAMICO® Accessories

#### HANDHELD NEUTRODINAMICO®

A special handheld electrode, with a larger surface area than the electrodes provided as standard, allows the operator to move around the patient's body, with the "mobile" neutral offering the active electrode a range of different geometric reference points. Therapists can finally channel energy with their own hands, creating customised routes



#### **NEUTRO DINAMICO®**

The Neutro Dinamico handpiece has an ergonomic grip. It can be used with electrodes of three different sizes, in combination with the unipolar handpiece for facilitating bipolar transarticular treatments, or preserving the classic active/neutral arrangement.

The various accessories from the Neutro Dinamico range offer an impressive array of application options.



#### **2.6.4 STATIC AUTOMATIC Accessories**

#### STATIC AUTOMATIC KIT

The accessory consists of a series of 4 electrodes that can be freely positioned on the body, at differing distances from a self-adhesive electrode made of conductive material (with safety power connection). This enables the therapist to select the best area or direction for treatment according to individual treatment patterns. Each active electrode will refer to a single earth electrode, permitting an application with standardised charge transfer, without the intervention of the operator.

The accessory can be used in a partial manner, using only the electrodes needed for the treatment to be provided (for example, two electrodes may be sufficient when treating limited areas of the body).





#### **2.6.5 PHYSIO-AESTHETIC Accessories**

#### **FACELIFT BIPOLAR FACIAL ELECTRODE**



for treatment and improvement of facial blemishes, with a mirror-finish surgical steel surface and a shape making contact with the skin particularly pleasant. The concentration of energy between the two heads allows safe and targeted treatment in all delicate areas, including the contours of the eye, mouth, neck and forehead.

FACELIFT this is especially suited for treatment and reduction of age wrinkles and expression lines. Applications using Facelift are non-invasive, fast and effective.

#### **UNIPOINTER UNIPOLAR ELECTRODE**

This electrode features a perfectly polished surgical steel head mounted at the tip of a specifically designed light and ergonomic handpiece.

UNIPOINTER allows a range of operations in different body areas and for different application aims.

The shape and size allow the operator to direct treatment to any very small body zone, such as trigger points, nerve lines and small skin imperfections.

UNIPOINTER is especially useful in treatment of the hands and feet. The electrode is used in combination with the neutral return plate, meaning that besides being highly precise, the treatment can also be deep.



#### **2.6.6 INTIMITY Accessories**

Electrodes dedicated to treatment of diseases and disorders of the pelvic region. Some examples of therapeutic applications are:

- postpartum scarring
- pelvic pain
- urinary problems
- haemorrhoids
- prostatitis.

#### **ENDOPROBE UNIPOLAR - UNIPOLAR ELECTRODE**



The anatomically shaped handpiece and electrode of perfectly polished surgical steel allow internal application in a safe, non-traumatic manner. The UNIPOLAR Endoprobe is used in combination with the neutral plate, placed externally to the target area, and thus allows precise, deep application, useful in treatments of the pelvic region and all its related pathologies.

#### **ENDOPROBE BIPOLAR - BIPOLAR ELECTRODE**



The anatomically shaped handpiece and electrode of perfectly polished surgical steel allow internal application in a safe, non-traumatic manner. Given the construction incorporating both active and neutral electrodes, the BIPOLAR Endoprobe can be used without the neutral return plate.

Application is very precise and can be targeted specifically on the treatment area, allowing greater effectiveness where the pathology is superficial or not particularly deep.

#### 2.6.7 MYOFASCIAL Accessories

Fascial Full® for Gymna Care 300® is a multi-purpose tool that combines, in a single instrument, the benefits of myofascial manual therapy and Tecar therapy.

#### Mechanical action

- on the adhesion between fibres that limits movement in the different sliding planes;
- on the fibrous nodules deposited in the intermuscular septa that cause adhesion between sliding planes, often resulting from hematomas.

#### **Circulatory action**

- hyperaemia and vasodilatation
- thermo-mechanical stimulation
- histamine release

#### **Reflex Action**

- trigger points
- dermatomes
- gate control (reflected inhibition mechanism)



Fascial Full® for Gymna Care 300

Fascial Full® for Gymna Care 300® is provided with three different tips, designed for the different operating modes and the body areas subject to treatment.

The two curved faces, of larger radius and smaller radius, are specifically designed for acupressure therapy and localized ischemic compressions.

#### Useful for:

- all accepted methods of fascial manipulation
- trigger points
- deep transverse massage
- Shiatsu
- acupressure
- reflexology
- palper-rouler (subdermal tissue massage)

The spatula is designed for complete muscular and connective tissue myofascial treatment. Very useful for:

- soft-tissue fibrolysis
- fascial manipulation
- kinesio taping (adjuvant treatment and pre-event)

# 3. TECHNICAL INFORMATION

### 3.1 General

Supply voltage 100 - 240 Vac Mains frequency 50 - 60 Hz

Power consumption 500 W full load; 50 W standby

Safety classification 1 type BF

Medical rating IIb

Serviceable fuses 2x 5A size 5x20 mm

Operating temp.erature from 0°C to 40°C (32°F to 104°F)
Storage and transport temperature from -10°C to 60°C (14°F to 140°F)

### 3.2 Technical characteristics

#### **Unipolar output**

Power available in RESISTIVE mode 360 W rms @ nominal impedance

Maximum power in RESISTIVE mode 400 W rms

Power available in CAPACITIVE mode 500 VA rms @ nominal impedance

Maximum power in CAPACITIVE mode 600 VA rms

Maximum output voltage 200 V rms

Maximum output current 2 A rms

Nominal load 100 Ohm

#### **Accessory outputs**

Maximum power100 W rmsMaximum output voltage100 V rmsMaximum output current1 A rmsNominal load100 Ohm

# 3.4 Symbols and labels

(Exxxx	Ministerial Decree pursuant to Directive 93/42/EEC as subsequently amended
	Name or corporate name and address of the manufacturer
SN	Serial number (information designed to identify the device and the contents of the packaging)
Ţ	Caution! See the accompanying documents/Caution! See the user instructions (warnings, contraindications)
	Production date
<b>†</b>	Type BF electrical protection rating
	Separate collection of waste electrical and electronic equipment
(((•)))	You are in the presence of a device able to emit non-ionising radiation (RF)

# 4. THERAPEUTIC INDICATIONS

# 4.1 Therapeutic indications

Heat provides relief in chronic, traumatic and inflammatory conditions, it increases the blood flow thereby improving cell nutrition and oxygenation and speeding up the elimination of toxins, and it improves the elasticity of the connective tissue.

The vasodilation achieved with the heat causes an increase in the exchanges of substances that encourage the drainage of the inflamed site and the local influx of cells responsible for repair processes.

It can be applied in the following circumstances:

- Contusive or distorting traumas
- Post-surgical rehabilitation
- Sports traumatology
- Muscle and tendon pathologies
- Scarring
- Pathologies of the spine and peripheral joints
- Pathologies of the vascular and lymphatic systems
- Pathologies of the peripheral nervous system of orthopaedic origin
- Pelvic floor rehabilitation

Please consult a doctor for diagnosis and therapeutic advice.

#### 4.2 Contraindications

- Always consider general contraindications for heat application, such as infections, loss of sensation (meaning that the patient is unable to perceive or report pain) and specific contraindications for electromagnetic diathermy, such as clotting disorders, arterial diseases and thrombophlebitis.
- Other contraindications for short-wave diathermy, such as the presence of metal prostheses, can be avoided, under strict medical supervision, by means of capacitive energy transfer.
- Do not perform applications on pregnant women, patients with pacemakers or other active implantable life aids, Parkinson's disease, or cancer.
- For patients with metal prostheses, application is possible where approved by the doctor who performed the operation or specialists in the same field.
- Caution should be taken in treatments in the region of the cervical spine, where changes to blood circulation could cause slight dizziness.
- The application could cause temporary low blood pressure during treatment. Assess whether or not to ask the patient to wait a few minutes before leaving the facility.
- The pain could become acute once again during treatment, which could be a normal phenomenon. If this occurs, reduce the output power and the length of the application. If the problem persists, stop applications and consult the doctor who prescribed the treatment.
- In the case of skin irritations attributed to the application, stop treatment and consult a doctor.

#### 4.2.1 Contraindications for radio-frequency (RF) treatments of the pelvic floor

- neoplastic and infectious prostate diseases
- inflammatory, vascular and neoplastic diseases of the anorectal wall (ulcerative rectocolitis, Crohn's disease, etc.)
- implanted sacral stimulators
- mucosal lesions and local infectious conditions (rashes, abscesses, fistulas, etc.)
- vaginal mechanical contraceptive methods, including intrauterine spirals (IUDs)

#### 4.3 Limitations of use

Certain precautions need to be taken in the following specific cases:

- Take due care when treating patients with loss of sensation and poor heat tolerance
- Oedema, joint effusions and the presence of metal prostheses can be treated with the capacitive energy transfer system. Local bipolar treatment is also possible in combination with athermic emission.
- Avoid applications in the region of the cervical spine in patients with low blood pressure.
- In cases of trauma associated with oedema and effusion, it is best to begin tecar therapy at least 24–48 hours after the accident, when deemed appropriate by the doctor.

The information provided is of a general nature. Operators are advised to consult a physician concerning specific contraindications.

## 5. SAFETY

# 5.1 Safety features

The device has a smart protection system that carries out constant safety checks on various levels:

- 1) Gymna Care 300® instruments feature a circuit design providing for constant monitoring of the RF power modules, ensuring that energy supply corresponds to the set values at all times. In case of even a slight misalignment from the monitored values the device automatically suspends the supply, providing an alarm signal on the front panel.
- 2) If the electrodes are inadvertently left unattended and connected to the device during treatment, the safety feature will automatically cut off the supply after thirty seconds, reporting the event by means of an alert on the front panel.
- 3) After 4 minutes in PAUSE state the treatment will be automatically terminated, for safety reasons.
- 4) If the electrodes accidentally come into contact, creating a short circuit, the machine will automatically limit the current delivered without suspending the treatment in progress. If the short circuit lasts a significant amount of time the protection device will automatically terminate the supply, signalling the event by an alarm on the front panel.
- 5) To ensure that the accessory applied to the body remains "floating", the equipment is constructed with a device that constantly monitors the current-patient circuit. In case of even a minimum leakage towards ground the protective device automatically suspends the supply, signalling this event by an alarm on the front panel.

# 5.2 Soft-start system

The device only releases energy after checking that effective contact has been made between the electrodes and the patient. The increase of power towards the set value takes place gradually.

# 5.3 Safety regulations

- 1) Particular attention should be paid when positioning the neutral electrode, so as to ensure that as large a surface area as possible makes contact with the patient. Failure to comply with this safety regulation could cause burns to the patient corresponding to the passive plate when the device is operating.
- 2) The handpiece connectors must always be engaged before starting treatment.
- 3) Do not disengage the handpiece connectors during operation.
- 4) The equipment must be placed in PAUSE or STOP prior to changing the handpiece electrodes.
- 5) Do not leave the handpieces unattended while they are connected and the device is operating.
- 6) Never rest an "active" electrode (inserted in the handpiece) on the passive plate when the equipment is in operation.
- 7) Never perform applications without conductive cream on the two electrodes.
- 8) During treatment, ensure that the patient does not come into contact with other conductors (metal parts of massage tables, chairs, other furniture).
- 9) If the device starts smoking or produces a burning smell, unplug it immediately.
- 10) Do not operate the device near equipment that may produce strong electromagnetic fields, such as radar therapy or shortwave therapy devices.
- 11) Avoid the operation of other electronic devices that could be sensitive to radiated electromagnetic fields (e.g. electrotherapy, diagnostic imaging instruments).

# 5.4 Before starting

Before programming the device and starting treatment, it is advisable to check that the patient has an appropriate medical prescription and that a number of simple but fundamental conditions are met:

- 1) read this user manual in its entirety. contact your authorised dealer for any clarification necessary;
- 2) before starting treatment, always check the patient's general state of health;
- 3) check that all the components supplied as standard are present when opening the packaging;
- 4) place the device on an appropriate work surface, in the operating position that provides the best view of the control panel. it is advisable to use a stable and practical support;
- 5) ensure air circulation around the equipment. keep the rear of the machine away from heat sources and at least 10-15 cm away from any wall;
- 6) Gymna Care 300® is a medical device and must be used in accordance with a medical prescription;
- 7) Gymna Care 300® must be used by qualified personnel, trained in the use of the equipment and only for the purposes indicated in this manual.

#### **ADVISORY**

This device may expose the operator to the irradiated electromagnetic field as a byproduct of treatment. Minimise exposure by limiting contact with the conductive parts of the electrodes; use only the original cables.

## 6. PRELIMINARY INFORMATION

#### 6.1 Thermal effect

Energy transfer by capacitive or resistive contact has different effects in biological tissues depending on the mode and level of the power delivered:

• Effects at a low energy level (heat-free): when power is supplied at very low levels, cellular biostimulation is produced due to an increase in energy transformations, boosting oxygen consumption and producing a greater demand for blood. This indirectly activates the arterial and venolymphatic microcirculation without dilating the larger vessels, as well as producing a slight analgesic effect.

Key words: mechanical biostimulation, increased oxygen demand, analgesia.

• Effects at a medium energy level (moderate heat): in addition to biostimulating effects, this level also produces capillary and pre-capillary vasodilation due to the demand for oxygen in the tissues. The increased endogenous temperature is closely related to the displacement currents, which run from the peripheral zones to build up in the application areas in direct proportion to the intensity of the treatment.

Key words: micro-hyperaemia, faster blood flow, higher endogenous temperature, intracellular oxygenation, accelerated cellular metabolism

• Effects at a high energy level (very hot): in the treated areas, the cellular biostimulation effect tends to diminish, while the endothermal effect is increased significantly, leading to a large influx of blood, vasodilation and increased lymphatic drainage.

The injured tissues are therefore subjected to rapid re-oxygenation and accelerated defence and repair system activation times.

Key words: mechanical vasodilation, large influx of blood, lymphatic drainage, deep heat

# 6.2 Additional Information

# 6.2.1 Emission

The equipment provides for different types of emission: Continuous, Sensitive, and various levels of Athermy.

**CONTINUOUS:** used in standard applications.

**SENSITIVE:** selecting this mode, the sophisticated Gymna Care 300 algorithm allows highly regulated power supply and optimizes the energy transferred to the patient.

The **ATHERMY** mode is suitable for all cases in which treatment should avoid excessive thermal increase in the intended body part (i.e. athermic or homothermic treatment), for example in cases of an acute pathology, when treatment in continuous mode would require operation at such low powers as to jeopardize the therapeutic effect.

The Athermic mode provides an emission of high power during a timed period, followed by a pause during which the body can dissipate the absorbed heat. When using this mode it can be useful to increase the application time.

There are 3 levels of Athermic application:

ATHERMY 1: moderately athermic effect

ATHERMY 2: athermic effect

ATHERMY 3: pronounced athermic effect

#### **6.2.2** Mode

Gymna Care 300® offers a variety of application modes.

In **UNIPOLAR mode** the direction of the energy is defined by the position of the active/neutral electrodes. The transfer that takes place will depend on whether a capacitive or resistive electrode is chosen. It is indicated for standard treatment, and is also suitable for treating large areas of the body.

The **BIPOLAR** mode allows operation using maximum power within a limited area. The small surface of the bipolar electrode contains both the neutral and the active electrode (resistive or capacitive), making it possible to apply energy without connection to the classic neutral plate electrode. In this way the current circulates in the underlying tissue, migrating from one electrode to another and interacting with the tissues to a medium depth, maintaining the typical characteristics of capacitive or resistive transfer.

This mode is particularly useful for very localized applications. It allows to the operator to direct the energy charges to the treated area as desired, without affecting the adjacent body parts.

The **STATIC AUTOMATIC mode** enables the application of treatment without requiring continuous operator action. After identifying the body area and choosing the application parameters the operator fixes the electrodes in the positions for the desired treatment. In this mode, to ensure patient safety, the equipment automatically limits the maximum power output. The accessory for static automatic applications consists of a series of four resistive electrodes that can be positioned freely on the body at a variable distance.

This enables the therapist to select the best area or direction for treatment according to individual treatment patterns.

**Neutro Dinamico**® technology can be combined with the freedom of movement offered by the static automatic mode ("automatic dynamic"), making it possible to include strengthening and stretching exercises in the treatment.

### 6.2.3 Neutro Dinamico®

The key to a heat-based physiotherapy treatment is the **CONTROL** over the temperature increase in the deep tissues, while the key to rehabilitation therapy is "movement and kinetic therapy".

**Neutro Dinamico**® technology offers the interesting possibility of combining heat-based treatment of a small area with therapeutic exercise.

Mobile electrodes can be used to restrict the action of the heat therapy to the treatment area – without dispersing the energy developed by the tecar therapy and without interfering more than necessary with blood vessels, nerves and internal organs – channelling the energy as required.

## **6.2.4 Frequency**

The operating frequency is set to 500 KHz for standard applications.

Using the new Gymna Care 300 App, the operator can now set the working frequency choosing from the range of available values.

This allows the depth and diffusion of the transmitted energy to be varied without altering the type of transfer (resistive or capacitive), thanks to the variable nature of tissues. Low frequencies are used for deeper treatment and high frequencies for more superficial and localized treatment near the active electrode.

The automatic scan mode (AUTO) allows the operator to use the full range of available frequencies, consistently and uniformly treating the full depth of the tissue.

# 6.3 Fisiowarm® conductive Cream

Conductive cream is a fundamental element when it comes to correct and effective application. Its composition has been studied to ensure excellent electrical conductivity, maintaining the right level of density throughout the course of the treatment, limiting excessive absorption by the body and softening the skin without being sticky.

Its delicate scent makes it pleasant for both the operator and patient to use.

The treatment zone must always be covered in cream so as to permit the electrode to slide over it smoothly, while maintaining optimal contact with the treated surface throughout the duration of the treatment.

If the cream develops a pasty texture during treatment (due to the length of the application or excessive dryness of the patient's skin), it is essential to add more cream or, better still, to clean off the old cream and then apply new cream.

The use of insufficient or poor quality cream can cause (especially during capacitive treatment) an annoying pins-and-needles sensation underneath the electrode.

Once used, it is essential to close the cream container properly so as to prevent alterations to its principal characteristics. If this condition is not met and the surface of the cream becomes altered, it is advisable to remove it.

The use of products other than Fisiowarm Cream may not guarantee adequate conditions for the successful outcome of the application. To avoid any forms of allergy, it is always advisable to test a small amount of the product on a small area of the body and wait a few minutes before application.

Fisiowarm® Cream is a Class I medical device, an accessory to Gymna Care 300® equipment and a fundamental part for its proper function, ensuring safety in application and compatibility with accessories. The use of creams other than Fisiowarm® Cream can damage the parts to which it is applied and will invalidate the warranty of the accessories (electrodes, cables, handpieces).

# 7. OPERATION

# 7.1 Using the front panel

The device can also be controlled without connecting to the iPad, using the front display. This provides a basic working mode, enabling application of Tecar therapy in CONTINUOUS emission, and using all the advantages of the equipment with the exclusion of those offered by the Gymna Care 300 App.

The front panel of the device features a 20 characters x 4 lines OLED display, LED indicators and a knob with rotary encoder and button, used to impose all the necessary the settings.



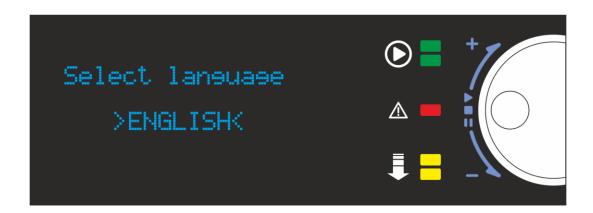
- 1) 20 characters x 4 lines OLED display
- 2) Encoder knob
- 3) LEDs signalling START and PAUSE
- 4) LEDs signalling error, fault and anomaly
- 5) LED signalling PATIENT CONTACT
- 6) Multifunction encoder button (push at the knob center)

### 7.1.1 Initial setup

Connect the power cable to the power socket and turn on the equipment using the main switch on the back panel, marked "0/1". The start-up stage lasts a few seconds, during which the system carries out a general check of all functions, accompanied by an acoustic signal and the sequential switching on of all the LED indicators.

As the display activates it shows the model of the device and the software version installed.

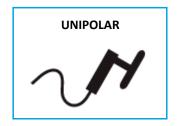
During this display you can change the interface language by briefly pressing the encoder button. The display will show:

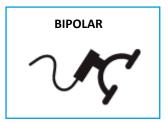


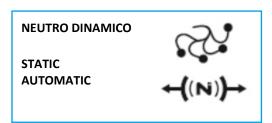
Turn the multifunction encoder knob to select the desired language; confirm the choice by briefly pressing the encoder button.

The machine will continue to use the selected language until a further change in the settings.

Connect the cable for unipolar/bipolar/neutro dinamico/static automatic applications to the appropriate dedicated socket on the rear panel of the equipment, identified by the symbols:





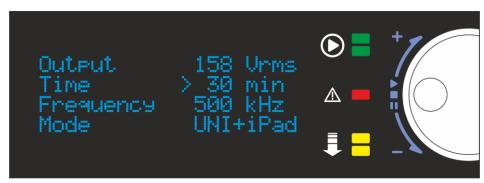


Proceed with connection of the accessories required for the planned application.

## 7.1.2 Setting up a work session

To access the parameter settings, turn the encoder knob gradually. The display will show an arrow indicating the different parameters open to change:

- Turn the encoder to select the desired parameter.
- Briefly press the knob to activate the parameter the arrow will change appearance.
- Turn the knob in either direction until the desired value is displayed.
- Briefly press the knob to confirm the setting the arrow will turn off.



Note: "+iPad" next to Mode means the iPad is connected and ready to use.

### **Set the Time of treatment**

Select the TIME parameter as described above; activate with a brief press; turn the knob to select the desired duration of treatment (1 to 30 minutes); store the selection with a further brief press.

#### **Set the Output frequency**

Select the FREQUENCY parameter; activate with a brief press; turn the knob to select from the preset values; store the selection with a further brief press.

#### **Set the treatment Mode**

Select the MODE parameter; activate with a brief press; turn the knob to select the desired mode, **(UNI)** unipolar, **(BIP)** bipolar, **(STA)** static automatic or **(NED)** neutro dinamico; store the selection with a further brief press.

#### Set the Output level

Select the OUTPUT parameter; activate with a brief press; turn the knob to select the desired value (expressed in Volt RMS) and store the selection with a further brief press.

The presetting of this value requires an excellent knowledge of the method, equipment, the patient and their response to treatment and is therefore limited to 50%. For safety, we recommend setting this parameter only after starting the therapy and correctly positioning the electrodes in contact with the patient.



**Start the treatment:** after quickly checking the parameters just set on the display, keep the multifunction encoder button pressed until an acoustic signal sounds and both green LED indicators turn on, showing that the device is running.

<u>After positioning</u> the electrodes on the patient, the operator can control the **OUTPUT LEVEL** by turning the encoder knob directly, without any other operation, gradually increasing or decreasing the output emission.

No other parameters can be changed after starting the application.



<u>Patient contact indicator:</u> rapidly communicates information on the quality of energy transfer to the patient.

- both indicators on: optimal transfer;
- only one indicator flashing: low transfer;
- one indicator flashing with an audible "tic": no transfer.

If contact between the electrodes and the patient is not detected for thirty seconds, the device will enter into pause (see Pause).



<u>Pause</u>: during the treatment the device can be placed in PAUSE by briefly pressing the multifunction button. The energy supply is immediately suspended; the green led indicators will blink and the yellow ones will turn off.

For safety, if a PAUSE state lasts more than four minutes, the equipment will automatically enter into STOP mode and terminate the session.



**Stop:** the operator can interrupt the treatment at any time by keeping the encoder multifunction button pressed; the device will immediately stop RF supply, the green and yellow LEDs will turn off and the device will reset to the initial parameters, ready for a new treatment. Any previous settings will be deleted.

<u>The treatment ends</u> when the time imposed expires: the machine enters into STOP mode with an acoustic signal and the green LEDs turn off. You can now set up a new treatment.

#### **Quick commands**

#### **Setting the Time**

To change the TIME simply activate the function with a brief press, turn the knob to the desired value (1 to 30 minutes) and store the selection with a further brief press.

#### **Automatic insertion of selection**

Any setting will be automatically stored if you do not confirm the selected value within a few seconds.

**Set the Output Level** with the machine in START or PAUSE.

During the START/PAUSE phases, only the Output level can be changed:

- in **START** mode, simply turn the Encoder knob to increase or decrease the level, the change in effective output will be immediate; beyond a certain value the increase will be slowed for safety.
- the procedure in **PAUSE** is the same except that the change in output will be faster and the effect will take place when the knob turn will stop, up to a safety limit of 50%.

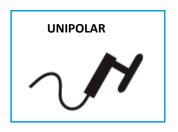
# 7.2 Using iPad

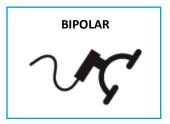
## **7.2.1** Introductory steps

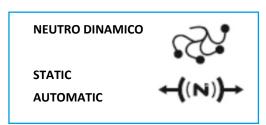
#### Switch on the equipment

Connect the power cable to the IEC socket and turn on the Gymna Care 300 equipment using the main switch on the back panel identified with 0/1; an acoustic signal will be emitted and the display will turn on.

Connect the cables for Unipolar, Bipolar, Neutro Dinamico/Static Automatic applications to the dedicated sockets on the rear panel of the equipment identified by the respective symbols and proceed with the connection of the relative handpieces and electrodes.







## 7.2.2 Connecting the iPad

Place the iPad on the Gymna Care 300 dedicated support. When not using the iPad we recommend that you connect it to the Gymna Care 300 device using the original iPad cable, to maintain battery charge at all times. Prior to "dynamic" use of the iPad, for example positioned near the patient on the massage table, check that the battery charge is sufficient for the expected treatment time.

**NOTE:** the "low battery" signal indicates that the iPad battery is almost flat. Recharge the iPad by connecting it the Gymna Care 300 device (with the power turned on), using the USB cable. The iPad must be recharged for at least 20 minutes before returning to cordless mode.

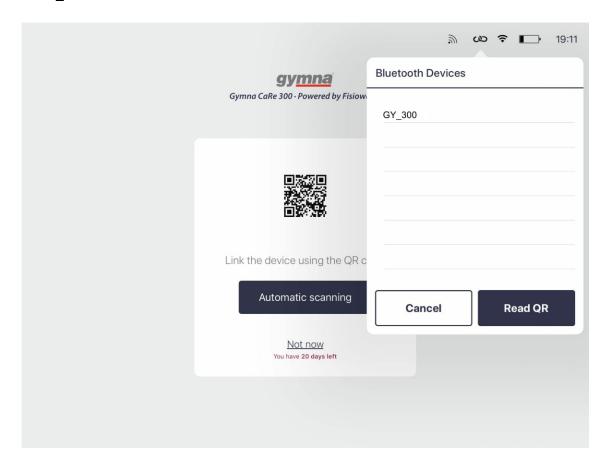
- ✓ Use only the original equipment power cable/transformer.
- ✓ For reliability in operation, recharge the iPad before the charge drops below 20%.
- ✓ To preserve battery life, avoid using the iPad while charging.

Any deposits of conductive cream on the iPad touchscreen should be removed immediately to avoid imprecision in controls.

# 7.2.3 Bluetooth connection

Turn on your iPad and if necessary, configure it according to the manufacturer's instructions (see the online user manual at help.apple.com/iPad). Next, download the Gymna Care 300 App from the App Store.

Launch the Gymna Care 300® app, touch the "open link" symbol and select the item with "GY 300" from the list of available devices.



The "closed link" symbol indicates correct Bluetooth pairing between the Gymna Care 300 device and iPad.



# 7.2.4 Product registration via the Gymna Care 300® app

Follow the guidelines provided by the App for registering your Gymna Care 300 product, starting with scanning the <u>QR code</u> on the body of the equipment.





You can postpone the registration of your Gymna Care 300 product up to a maximum of 20 days by selecting "not now".

The app will indicate the number of days remaining every time you switch it on.

After 20 days it will no longer respond without first completing the registration.

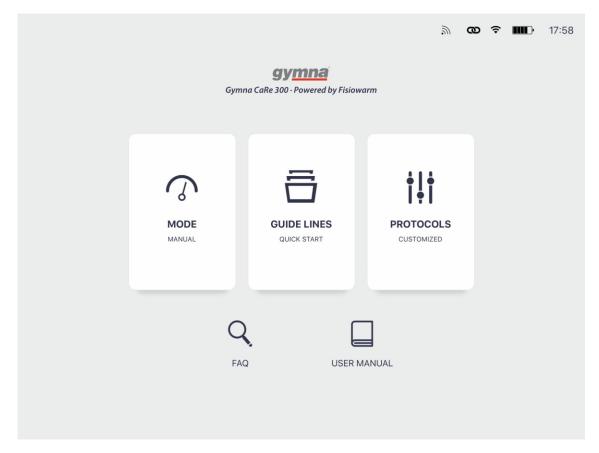
The documentation supplied in the original Gymna Care 300 packaging includes a Quick-start Guide.

# 7.3 The Gymna Care 300® app

The Gymna Care 300® app serves as an all-inclusive practical assistant to the physiotherapist. When connected in wifi you will be informed as new versions and related software releases become available on the App Store.

You will also receive technical and commercial notifications concerning important Gymna Care 300 news.

## 7.3.1 Homepage



The user menu consists of:

Operating sections: Support sections:

Manual mode FAQ

Guideline protocols User's manual

**Customized protocols** 

The user menu consists of:

# **Operating sections:**

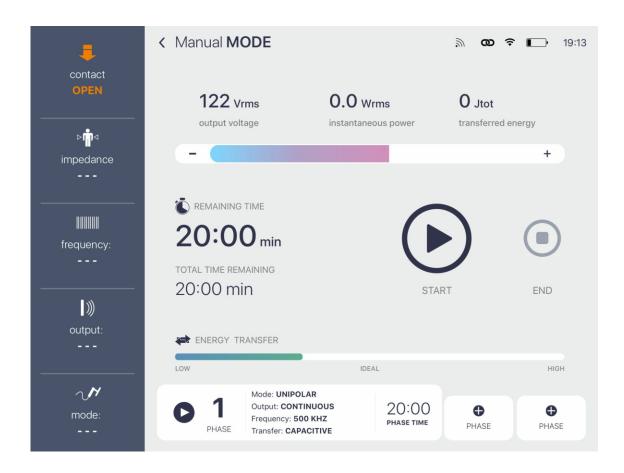
- Manual mode
- Guideline protocols
- Custom protocols

# **Support sections:**

- FAQ
- User's manual

# 7.3.2 Operating sections: MANUAL mode

Select "MANUAL mode" on the homepage to go directly to the work screen.



The Gymna Care 300 app proposes a default work session consisting of a single phase with the following characteristics:

✓ Mode: UNIPOLAR

✓ Emission: CONTINUOUS

✓ Frequency: 500 kHz

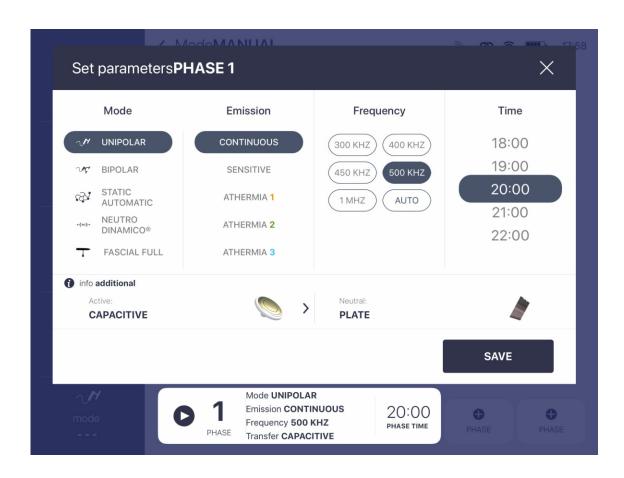
✓ Time: 20 MINUTES

If desired, press START to proceed directly to the default treatment session.

### Setting up a work session

You can also change the parameters of Phase 1 and/or add further phases to prepare a work program for your specific needs.

Touch the "PHASE 1" button in the lower part of the screen to modify the standard parameters; touch "+ PHASE" to add successive PHASES to the treatment session.



### **Select parameters**

**Mode** Unipolar, Bipolar, Neutro Dinamico, Static Automatic

**Emission** Continuous, Sensitive (only with "Unipolar" mode), Athermy 1,

Athermy 2; Athermy 3

Frequency 300 - 400 - 450 - 500 KHz - 1MHz, AUTO (automatic scanning from preset

values)

**Time** Duration of application in minutes (maximum 30 minutes per phase)

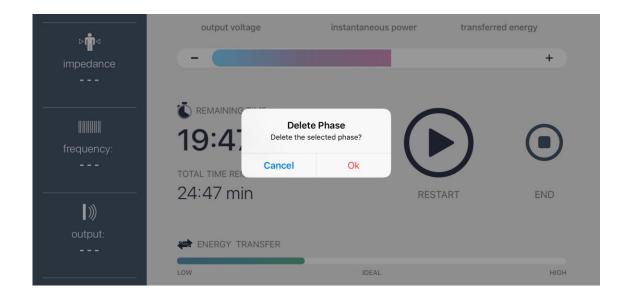
#### **Additional Info**

This section shows the potential combinations of active/neutral electrodes and allows the operator to add notes on their applications. This is very useful in the event that the operator chooses to save a newly created protocol. The "save" option is re-proposed as a reminder at the beginning of every phase and at the end of the overall treatment.

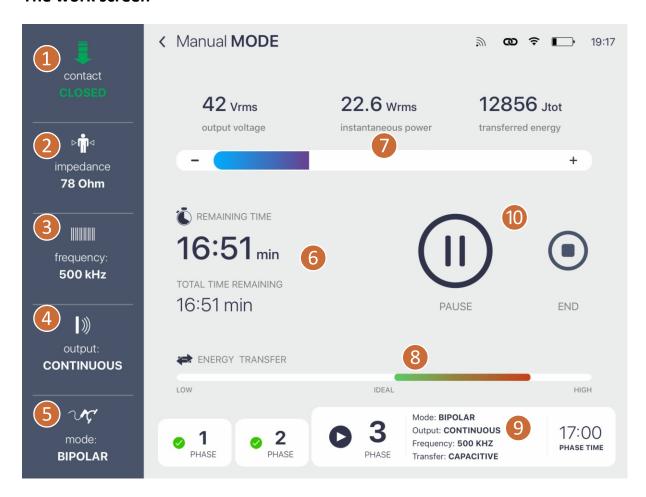
The "Added info" section serves simply as a record, without direct effect on the values of dispensing parameters.



During the treatment, the operator can preview of the settings of the subsequent phases. A phase already created can be deleted by pressing continuously on its symbol.



#### The work screen



The work screen is designed to provide full information and control over the true operating parameters. The precision and clarity of the information allow the operator to develop greater awareness and deeper knowledge of the processes underlying Tecar therapy.

#### Elements of the work screen:

- 1) **Contact:** OPEN (orange) indicates little or no patient contact, minimal delivery. CLOSED (green) indicates good patient contact, delivery in progress.
- 2) **Impedance:** shows the average impedance measured between the two electrodes, expressed in Ohm.
- 3) **Frequency:** the selected frequency expressed in kHz or MHz.
- 4) **Emission:** the type of emission selected.
- 5) Mode: the mode selected.

- 6) Time: dual display of the duration of the phase in progress and total accumulated duration of the treatment.
- 7) Area for setting and controlling the Output Level Operation of the Output level "bar" controls the real output value being applied, indicated in volts RMS. This parameter is an absolute value, unrelated to frequency, mode, type of transfer, and above all independent of the impedance presented by the patient's body.

This value serves as the basis for development of treatment protocols. The increase in output level is gradual in the first half of the scale, allowing better management of the supply, and becomes more pronounced in the second half.

Beyond a certain value, for safety reasons, any further increase in the Output level will be slowed and/or subject to a request for operator confirmation. Starting from STOP mode the pre-set value will always limited to 50%.

**Output voltage** - Shows the output value in volts RMS, set by the control bar.

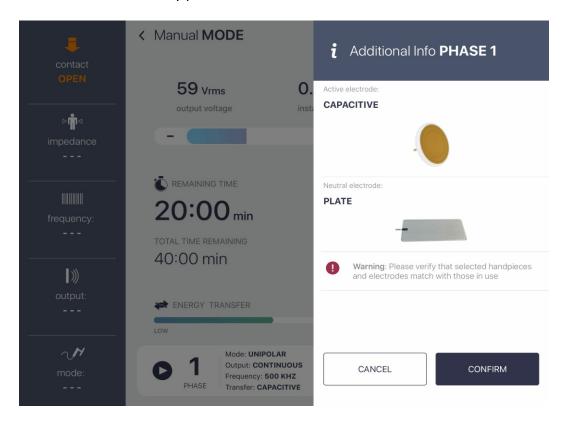
**Instantaneous power** - This quadrant shows the real time reading of the power effectively delivered and transferred to the patient, expressed in Watt RMS. This value, calculated directly from the voltage applied and the detected body impedance, offers a reliable parameter for evaluation and management of the different therapies applied.

**Energy transferred** - This quadrant shows the total amount of energy effectively transferred to the patient, calculated as the product of the effective power transfer and the elapsed time of delivery. The value is expressed in joules (1 joule = 1 watt delivered for 1 second). The measurement of this parameter is particularly useful for creating optimized protocols. The expression of protocols in joules also makes it easier to correlate and integrate the application of laser therapies in conjunction with Tecar therapy.

- 8) **Energy transfer bar** The energy transfer bar indicates the level of energy transferred to the patient in relation to the energy available at output. This is a qualitative parameter, expressing the efficiency of the "machine-electrode-cream-patient" system at a glance. Readings are accurate and realistic, allowing for better evaluation by the therapist.
  - Readings averaging above half of the bar scale indicate optimal function and good contact with the patient.
  - Full scale readings indicate patient impedances well below 100 ohms; in these cases it is advisable to use caution given the increased possibility of hyperthermia.
  - Readings of less than half scale indicate sub-optimal contact between the electrodes and the patient, or passage through areas of bone or poor vascularisation where tissue impedance is well above 100 ohms.
- 9) **Phases area** This area displays the settings of the phase in progress and provides access to information on the subsequent phases.
- 10) **START/PAUSE/STOP controls** These serve as the commands to start/suspend/resume/end a phase or protocol, also showing the current status.

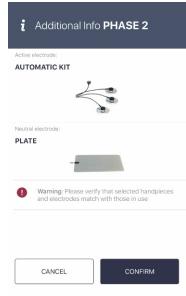
## Starting the treatment session

After pressing the "START" button, a pop-up dialogue box shows the "added information" on the phase (unless the default protocol has been chosen). It notes the settings and electrodes selected by the operator for the phase being started (plus the notes recorded in the "Added info" section of the work screen). The dialogue box serves only as a reminder and cannot be used to influence the delivery parameters.



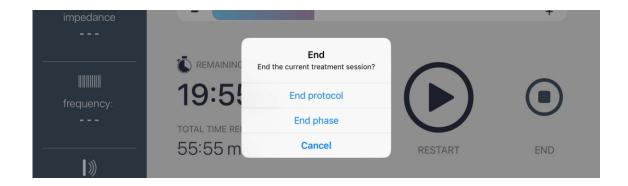
In a work session consisting of more than one phase, the App provides an acoustic signal to alert the operator at the end of the first one. The delivery of that phase is terminated and the device goes into Pause.

To begin the next phase, press the RESUME button: the Added info panel will appear, providing a summary of the settings and electrodes chosen when planning the work session.



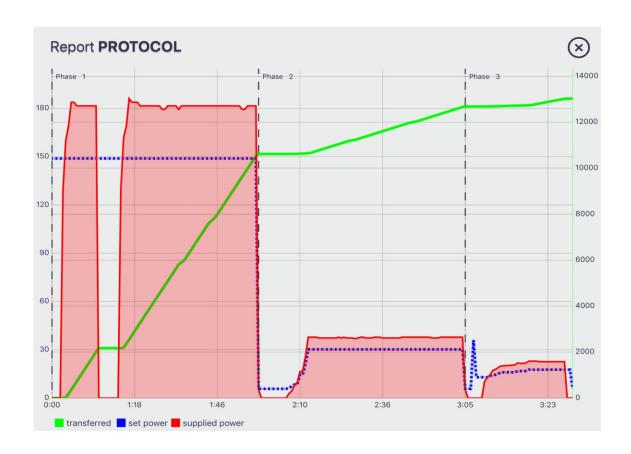
A treatment session can consist of up to three phases.

All the parameters of a phase in progress can be also modified at any time; the device must first be placed in PAUSE. The operator can also skip a programmed work phase (whether in manual mode or part of a Guideline or Custom protocol) using the STOP button.

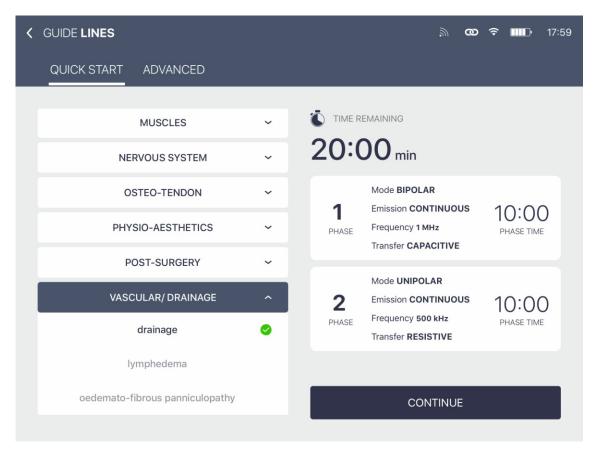


An acoustic signal alerts the operator at the end of the treatment. The Gymna Care 300 app presents a graph summarizing the treatment protocol just performed.

Closing the graph, the app presents a pop-up window offering the option of saving the protocol.



## 7.3.3 Operating sections: predefined GUIDELINE PROTOCOLS



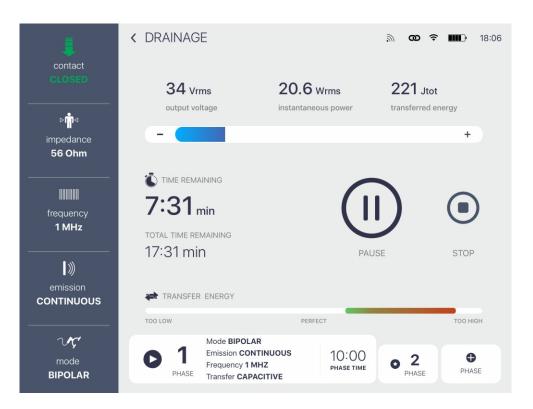
The GUIDELINES section proposes protocols organised in macro-categories:

- 1) NERVOUS SYSTEM
- 2) ARTHROPATHY
- 3) OSTEO-TENDON
- 4) PHYSIO-AESTHETICS
- 5) VASCULAR-DRAINAGE
- 6) POST-SURGICAL
- 7) MUSCLES

On selection of a protocol the App show its composition, divided into phases. The operator can then access a gallery with extensive information and images supporting application of that treatment - to access this information simply press "PROCEED".



Touch the RUN button to go to the work screen.



# **Table of predefined protocols**

NER	vous s	YSTEM								
	MODE	EMISSION	FREQUENCY	TRANSFER	TIME	ELECTRODES	PATIENT DYNAMICS			
BELL'S PA	LSY									
PHASE 1	Bipolar	Contin.	500 kHz	Capacitive	10'	Small Bipolar Capacitive	supine decubitus			
TARGET	Areas where facial nerve function is lost									
CERVICA	LGIA									
PHASE 1	Unipolar	Contin.	300 kHz	Resistive	15'	Small Unipolar Resistive Neutral Electrode	sitting, neutral electrode under hand/forearm ipsilateral to the symptomatology			
TARGET	Interverteb	ral disc/neu	ral root inte	rface, path	of cervica	I nerve roots and trunks				
CARPAL T	UNNEL									
PHASE 1	Bipolar	Contin.	500 kHz	Resistive	15'	<b>Profile</b> Bipolar Resistive	sitting with forearm supported			
TARGET	interface be	etween flex	or retinaculu	ım and med	ian nerve	(osteofibrous channel)				
CUBITAL	TUNNEL									
PHASE 1	Bipolar	Contin.	500 kHz	Resistive	15'	<i>Profile</i> Bipolar Resistive	sitting with forearm supported			
TARGET	interface be	etween the	median nerv	e and the ti	ssues imp	pairing mobility				
TARSAL T	UNNEL									
PHASE 1	Unipolar	Contin.	500 kHz	Resistive	15'	Medium Unipolar Resistive Neutral Electrode	supine decubitus, neutral electrode under the leg			
TARGET	interface be	etween nerv	ve and tissue	es impairing	mobility	•				
STRAIGHT	T BACK SYND	ROME								
PHASE 1	Unipolar	Contin.	300 kHz	Resistive	15'	Small Unipolar Resistive Neutral Electrode	seated, neutral electrode under hand/arm ipsilateral to symptomatology			
TARGET	interface be	etween cerv	rical nerve tr	unks, 1st rib	and ante	erior and middle scalene mu	uscles			
SCIATICA										
PHASE 1	Unipolar	Contin.	300 kHz	Resistive	20'	Medium Unipolar Resistive Neutral Electrode	prone decubitus, neutral electrode under the thigh ipsilateral to the symptom			
TARGET	interverteb	ral disk/neu	ral root inte	rface, cours	e of lumb	ar nerve roots and trunks				
PIRIFORM	IIS SYNDRON	ME								
PHASE 1	Bipolar	Contin.	300 kHz	Resistive	20'	<b>Profile</b> Bipolar Resistive	supine with hip flexed hip to 80/90° in abduction and slight external rotation (piriformis muscle stretch)			
TARGET	interface be	etween the	sciatic nerve	and the tis	sues impa	iring mobility				

ARTI	HROPAT	THIES									
	MODE	EMISSION	FREQUENCY	TRANSFER	TIME	ELECTRODES	PATIENT DYNAMICS				
KNEE - FE	MOROTIBIAL										
PHASE 1	Neutro Dinamico	Contin.	300 kHz	Resistive	15'	Medium Unipolar Resistive Medium Unipolar Resistive	sitting, knee flexed in suspension				
TARGET	tibial femoral joint										
KNEE - PA	E - PATELLOFEMORAL										
PHASE 1	Neutro Dinamico	Contin.	500 kHz	Resistive	15'	Small Unipolar Resistive Medium Unipolar Resistive	supine decubitus, flexed knee				
TARGET	patellofemo	oral joint									
KNEE - PA	TELLOFEMO	RAL									
PHASE 1	Unipolar	Contin.	1 MHz	Resistive	10'	Medium Unipolar Resistive Neutral Electrode	supine decubitus, knee extended				
PHASE 2	Bipolar	Contin.	500 kHz	Resistive	10'	<i>Profile</i> Bipolar Resistive	supine decubitus, knee extended				
TARGET	collateral lig	gaments									
SHOULD	ULDER - ACROMIOCLAVICULAR										
PHASE 1	Bipolar	Contin.	500 kHz	Resistive	15'	<i>Profile</i> Bipolar Resistive	Seated				
TARGET	acromioclav	vicular joint									
SHOULDE	R - HUMERA	L SHOULDE	R								
PHASE 1	Neutro Dinamico	Contin.	300 kHz	Resistive	15'	Medium Unipolar Resistive Neutral Electrode	sitting / standing				
TARGET	humeral sh	oulder joint									
НІР											
PHASE 1	Unipolar	Contin.	300 kHz	Resistive	15'	Medium Unipolar Resistive Neutral Electrode	supine decubitus, neutral electrode under the gluteus				
TARGET	coxo-femor	al joint									
FOOT - TI	BIAL TARSAL										
PHASE 1	Neutro Dinamico	Contin.	500 kHz	Resistive	15'	Medium Unipolar Resistive Medium Unipolar Resistive	supine decubitus, with foot resting on massage table or unstable surface				
TARGET	tibial tarsal	joint									
ELBOW -	COLLATERAL	LIGAMENT	S								
PHASE 1	Bipolar	Contin.	500 kHz	Resistive	15'	<i>Profile</i> Bipolar Resistive	sitting with arm supported / supine decubitus				
TARGET	collateral el	bow ligame	ents								

ARTI	ROPATI	A					
	MODE	EMISSION	FREQUENCY	TRANSFER	TIME	ELECTRODES	PATIENT DYNAMICS
CERVICAL							
PHASE 1	Bipolar	Contin.	300 kHz	Resistive	20'	<b>Profile</b> Bipolar Resistive	seated
TARGET	zygapophys	seal and inte	ersomatic jo	ints			
LUMBAR							
PHASE 1	Bipolar	Contin.	300 kHz	Resistive	15'	<i>Profile</i> Bipolar Resistive	prone decubitus
PHASE 2	Unipolar	Contin.	300 kHz	Resistive	15'	Medium Unipolar Resistive Neutral Electrode	prone decubitus
TARGET	zygapophys	seal and inte	ersomatic jo	ints			
LUMBAR	UNDER LOAI	D					
PHASE 1	Unipolar	Contin.	300 kHz	Resistive	20'	Medium Unipolar Resistive Neutral Electrode	seated
TARGET	zygapophys	seal and inte	ersomatic jo	ints			
WRIST							
PHASE 1	Unipolar	Contin.	500 kHz	Resistive	15'	Medium Unipolar Resistive Neutral Electrode	sitting with arm supported, neutral electrode under the palm of his hand
TARGET	radiocarpal	and interca	rpal joints				

OSTE	O-TEN	DON									
	MODE	EMISSION	FREQUENCY	TRANSFER	TIME	ELECTRODES	PATIENT DYNAMICS				
DEEP BON	NE OEDEMA										
PHASE 1	Neutro Dinamico	Athermia	300 kHz	Resistive	10'	Medium Unipolar Resistive Medium Unipolar Resistive	depending on the site to be treated				
TARGET	Bone										
SUPERFIC	RFICIAL BONE OEDEMA										
PHASE 1	Bipolar	Contin.	300 kHz	Resistive	15'	<i>Profile</i> Bipolar Resistive	depending on the site to be treated				
TARGET	Bone										
SHOULDE	R TENDONO	PATHIES									
PHASE 1	Bipolar	Contin.	300 kHz	Resistive	10'	<i>Profile</i> Bipolar Resistive	Seated				
PHASE 2	Neutro Dinamico	Contin.	500 kHz	Resistive	10'	Medium Unipolar Resistive Medium Unipolar Resistive	Jeuted				
TARGET	GET ligamentous compartment										
KNEE TEN	IDONOPATH	IES									
PHASE 1	Neutro Dinamico	Contin.	500 kHz	Resistive	15'	Medium Unipolar Resistive Medium Unipolar Resistive	Supine decubitus Seated				
TARGET	patellar liga	iment and q	uadriceps te	endon							
FOOT TE	NDONOPATI	HIES									
PHASE 1	Bipolar	Contin.	500 kHz	Resistive	15'	<b>Profile</b> Bipolar Resistive	Supine decubitus				
TARGET	tendons, e	xtensor, tibi	al peroneal	muscles							
ACHILLES	TENDONOP	АТНҮ									
PHASE 1	Neutro Dinamico	Contin.	500 kHz	Resistive	15'	Small Unipolar Resistive Small Unipolar Resistive	prone decubitus				
TARGET	tendons, ex	tensor, tibia	al peroneal r	nuscles							
ELBOW T	ENDONOPAT	HIES									
PHASE 1	Bipolar	Contin.	500 kHz	Resistive	10'	<i>Profile</i> Bipolar Resistive	sitting with forearm supported				
PHASE 2	Bipolar	Contin.	500 kHz	Capacitive	10'	Medium Bipolar Capacitive	sitting with forearm supported				

PHYSIO-AESTHETIC										
	MODE	EMISSION	FREQUENCY	TRANSFER	TIME	ELECTRODES	PATIENT DYNAMICS			
SCARRIN	G									
PHASE 1	Bipolar	Contin.	1 MHz	Resistive	10'	<i>Profile</i> Bipolar Resistive	appropriate to the tissue area to be treated			
TARGET	post-surgical/trauma scars (after removal of stiches and without skin disruption)									
SKIN ELAS	STICITY									
PHASE 1	Bipolar	Contin.	1 MHz	Capacitive	20'	Capacitive Bipolar (size appropriate to the area to be treated)	appropriate to the tissue area to be treated			
TARGET	surface tissues with loss of elasticity and consequent local stasis									
OEDEMA	TO-FIBROUS	PANNICULO	ОРАТНҮ							
PHASE 1	Bipolar	Contin.	500 kHz	Capacitive	30'	Capacitive Bipolar (size appropriate to the area to be treated)	supine/prone decubitus, depending on the area to be treated			
TARGET	"orange-pe	el" skin imp	erfections w	ith or witho	ut associa	ited oedemato-fibrous app	pearance			
A CINIC (V	GING (WRINKLES)									
AGING (V	VKIINKLES)									
PHASE	Bipolar	Contin.	1 MHz	Capacitive	10'	Small Bipolar Capacitive	Supine decubitus			
PHASE		Contin.	1 MHz	Capacitive Resistive	10'	Small Bipolar Capacitive  Bipèolare Resistive  Face-Lift	Supine decubitus  Supine decubitus			

VAS	VASCULAR / DRAINAGE										
	MODE	EMISSION	FREQUENCY	TRANSFER	TIME	ELECTRODES	PATIENT DYNAMICS				
LYMPHE	DEMA										
PHASE 1	Unipolar	Athermia	1 MHz	Capacitive	20'	Medium Unipolar Resistive Neutral Electrode	Supine/prone decubitus				
TARGET	primary and	d secondary	lympheden	na in the lim	bs						
DRAINAG	E										
PHASE 1	Bipolar	Contin.	1 MHz	Capacitive	10'	Capacitive Bipolar (size appropriate to the area to be treated)	appropriate to the tissue area to				
PHASE 2	Unipolar	Contin.	500 kHz	Resistive	10'	Resistive Unipolar (size appropriate to the area to be treated)	be treated				
TARGET	surface tiss	ues with los	s of elasticit	y and conse	quent loc	al stasis					
OEDEMA	TO-FIBROUS	PANNICULO	PATHY								
PHASE 1	Bipolar	Contin.	500 kHz	Capacitive	30'	Capacitive Bipolar (size appropriate to the area to be treated)	supine/prone decubitus depending on the area to be treated				
TARGET	"orange-pe	el" skin imp	erfections w	ith or witho	ut associa	nted oedemato-fibrous app	pearance				

POS	T-SURG	ICAL									
	MODE	EMISSION	FREQUENCY	TRANSFER	TIME	ELECTRODES	PATIENT DYNAMICS				
SHOULDE	R										
PHASE 1	Unipolar	Sensitive	500 kHz	Capacitive	15'	Medium Unipolar Capacitive Neutral Electrode	supine decubitus, neutral electrode under the scapula				
TARGET	TARGET glenohumeral joint (periarticular soft tissue)										
ELBOW											
PHASE 1	Unipolar	Sensitive	500 kHz	Capacitive	15'	Medium Unipolar Capacitive Neutral Electrode	supine / seated decubitus with arm supported, neutral electrode under the forearm				
TARGET	humerouln	ar / humero	radial /radio	oulnar joint (	(periarticu	ılar soft tissue)					
HIP											
PHASE 1	Unipolar	Sensitive	500 kHz	Capacitive	15'	Medium Unipolar Capacitive Neutral Electrode	supine / prone decubitus, neutral electrode under the gluteus / quadriceps				
TARGET	coxofemora	al joint (peri	articular sof	t tissue)							
KNEE											
PHASE 1	Unipolar	Sensitive	500 kHz	Capacitive	15'	Medium Unipolar Capacitive Neutral Electrode	supine decubitus, neutral electrode under the thigh				
TARGET	femoral-tib	ial / patellof	emoral join	t (periarticu	lar soft tis	sue)					
FOOT / A	NKLE										
PHASE 1	Unipolar	Sensitive	500 kHz	Capacitive	15'	Medium Unipolar Capacitive Neutral Electrode	supine decubitus, neutral electrode under the leg				
TARGET	tibiotarsal j	oint, interta	rsal joint, so	oft tissues of	the foot						
WRIST / I	HAND										
PHASE 1	Unipolar	Sensitive	500 kHz	Capacitive	15'	Medium Unipolar Capacitive Neutral Electrode	supine decubitus, sitting with limb supported, neutral electrode under hand				
TARGET	radiocarpal	joint, interd	arpals, soft	tissues of th	ne hand						

MUS	CLES						
	MODE	EMISSION	FREQUENCY	TRANSFER	TIME	ELECTRODES	PATIENT DYNAMICS
TRIGGER	POINTS						
PHASE 1	Neutro Dinamico	Contin.	500 kHz	Resistive	10'	<i>Unipointer</i> Neutral Electrode	Depending on the muscle to be treated, on tissues in both relaxed and stretching state. Five minutes for each trigger point
TARGET	trigger Poir	nts					
MUSCLE I	LESION						
PHASE 1	Unipolar	Athermia	1 MHz	Resistive	10'	Medium Unipolar Resistive Neutral Electrode	depending on the muscle to be
PHASE 2	Bipolar	Athermia	300 kHz	Capacitive	10'	Medium Bipolar Capacitive	treated, on tissues in both relaxed and stretching state
TARGET	Muscolo						
PRE-RACE	/ POST-RAC	E TREATME	NT				
PHASE 1	Neutro Dinamico	Contin.	500 kHz	Capacitive	20'	Medium Unipolar Capacitive Medium Unipolar Resistive	depending on the muscle to be treated, on tissues in both relaxed and stretching state
TARGET	muscle						
NALICOLE A	CONTRACTIC						
MUSCLE	CONTRACTIC	)N					
PHASE 1	Unipolar	Contin.	500 kHz	Capacitive	10'	Capacitive Unipolar (size appropriate to the area to be treated) Neutral Electrode	depending on the muscle to be treated, on tissues in both relaxed and stretching state
TARGET	Muscle						

INTII	MITY						
	MODE	EMISSION	FREQUENCY	TRANSFER	TIME	ELECTRODES	PATIENT DYNAMICS
DYSPARE	UNIA						
PHASE 1	Statico Automatico	Contin.	500 kHz	Resistive	15'	Static Automatic kit + Neutral Electrode	accompany application with manual treatment in homothermia
PHASE 2	Neutro Dinamico	Contin.	500 kHz	Resistive	15'	<i>Endoprobe</i> + Neutral Electrode	accompany application with abdominal massage in homothermia
TARGET	pain reduct	ion					
PELVIC PA	AIN						
PHASE 1	Statico Automatico	Contin.	500 kHz	Resistive	10'	Static Automatic kit + Neutral Electrode	Supine decubitus
PHASE 2	Neutro Dinamico	Athermia	500 kHz	Capacitive	10'	Capacitive Electrode + Neutral Electrode	Supine decubitus
PHASE 3	Neutro Dinamico	Contin.	500 kHz	Resistive	10'	Endoprobe + Neutral Electrode	Supine decubitus
TARGET	pain reduct	ion, tissue h	ealing				
HEMORR	HOIDS						
PHASE 1	Neutro Dinamico	Athermia	1 MHz	Resistive	15'	<i>Endoprobe</i> + Neutral Electrode	prone decubitus
TARGET	pain reduct	ion, improv	ed blood cir	culation			
URINARY	INCONTINE	NCE - ACUTE	PHASE				
PHASE 1	Statico Automatico	Contin.	500 kHz	Resistive	10'	Static Automatic kit + Neutral Electrode	Supine decubitus
PHASE 2	Neutro Dinamico	Athermia	500 kHz	Resistive	10'	Endoprobe + Neutral Electrode	Supine decubitus
TARGET	increase ela	asticity and p	propriocepti	on			
URINARY	INCONTINE	NCE - SUBAC	CUTE PHASE				
PHASE 1	Statico Automatico	Contin.	500 kHz	Resistive	10'	Static Automatic kit + Neutral Electrode	Supine decubitus
PHASE 2	Neutro Dinamico	Athermia	500 kHz	Resistive	10'	Endoprobe + Neutral Electrode	Supine decubitus
TARGET	prepare tiss	sues for mus	scle strength	nening and p	hysiother	apy treatment, increase el	asticity and proprioception

LACERATI	IONS AND EP	ISIOTOMY -	ACUTE PHA	ASE										
PHASE 1	Neutro Dinamico	Athermia	1 MHz	Capacitive	5'	Capacitive Electrode + Neutral Electrode	Supine decubitus							
PHASE 2	Statico Automatico	Contin.	500 kHz	Resistive	10'	Static Automatic kit + Neutral Electrode	Supine decubitus							
PHASE 3	Neutro Dinamico	Athermia	500 kHz	Resistive	10'	Endoprobe + Neutral Electrode	Supine decubitus							
TARGET	reduction o	of pain and in	nflammation	n; increase e	lasticity a	nd proprioception								
LACERATI	IONS AND EP	ISIOTOMY -	SUBACUTE	PHASE										
PHASE 1	Neutro Dinamico	Contin.	1 MHz	Capacitive	5'	Capacitive Electrode + Neutral Electrode	Supine decubitus							
PHASE 2	Statico Automatico	Contin.	500 kHz	Resistive	10'	Static Automatic kit + Neutral Electrode	Supine decubitus							
PHASE 3	Neutro Dinamico	Contin.	500 kHz	Resistive	10'	Endoprobe + Neutral Electrode	Supine decubitus							
TARGET	reduction o	f pain and ir	nflammation	n; increase e	lasticity a	nd proprioception								
POSTPAR	TUM RECOV	ERY - ACUTE	PHASE											
PHASE 1	Neutro Dinamico	Athermia	1 MHz	Capacitive	5'	Capacitive Electrode + Neutral Electrode	Supine decubitus							
PHASE 2	Statico Automatico	Contin.	500 kHz	Resistive	10'	Static Automatic kit + Neutral Electrode	Supine decubitus							
PHASE 3	Neutro Dinamico	Athermia	500 kHz	Resistive	10'	Endoprobe + Neutral Electrode	Supine decubitus							
TARGET	reduction o	f pain and ir	nflammation	n; increase e	lasticity a	nd proprioception								
POSTPAR	TUM RECOV	ERY - SUBAC	CUTE PHASE											
PHASE 1	Neutro Dinamico	Contin.	1 MHz	Capacitive	5'	Capacitive Electrode + Neutral Electrode	Supine decubitus							
PHASE 2	Statico Automatico	Contin.	500 kHz	Resistive	10'	Static Automatic kit + Neutral Electrode	Supine decubitus							
						Endoprobe + Neutral								
PHASE 3	Neutro Dinamico	Contin.	500 kHz	Resistive	CONTIN SUID KHZ RESISTIVE 10" SUDINE DECUDITUS									

PROSTAT	ITIS									
PHASE 1	Statico Automatico	Contin.	500 kHz	Resistive	10'	Static Automatic kit + Neutral Electrode	Supine decubitus			
PHASE 2	Neutro Dinamico	Contin.	500 kHz	Resistive	10'	Resistive Electrode + Neutral Electrode	Supine decubitus			
PHASE 3	Neutro Dinamico	Athermia	500 kHz	Resistive	10'	Resistive Electrode + Neutral Electrode	Supine decubitus			
TARGET	reduction o	f pain and ir	nflammation	n; increase e	lasticity a	nd proprioception				
VAGINAL	VAGINAL DRYNESS									
PHASE 1	Statico Automatico	Contin.	500 kHz	Resistive	10'	Static Automatic kit + Neutral Electrode	Supine decubitus			
PHASE 2	Neutro Dinamico	Contin.	500 kHz	Resistive	20'	Endoprobe + Neutral Electrode	Supine decubitus			
TARGET	increased lu	ubrication				-				
VULVODY	/NIA									
PHASE 1	Statico Automatico	Contin.	500 kHz	Resistive	15'	Static Automatic kit + Neutral Electrode	Supine decubitus			
PHASE 2	Neutro Dinamico	Contin.	500 kHz	Resistive	15'	Endoprobe + Neutral Electrode	Supine decubitus			
TARGET	pain reduct	ion								

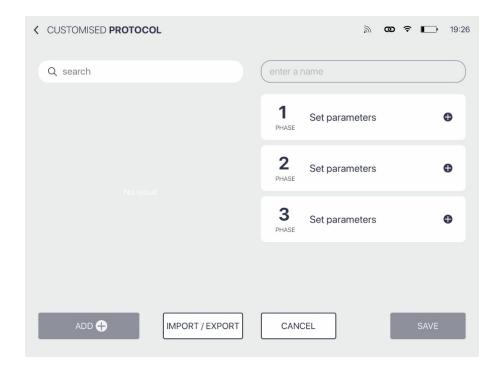
### Warnings:

The application table and the operating information contained in this manual should only be used as a guide.

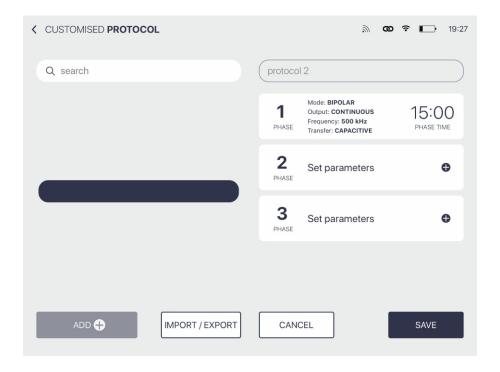
All the information regarding procedures and protocols is provided purely for information purposes and is not intended to replace treatment methods recommended by legally authorised healthcare personnel. The supplier of the device may not be held liable for any consequences deriving from the use of the protocols indicated without adequate verification of their suitability by the healthcare personnel using the device. All the treatments must be carried out under medical supervision.

# 7.3.4 Operating section: CUSTOMISED protocols

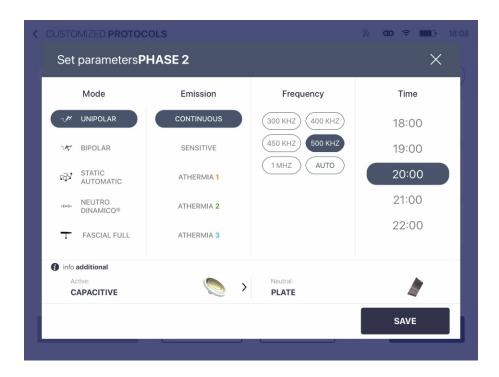
Selecting customised protocols on the homepage takes the user to the following screen



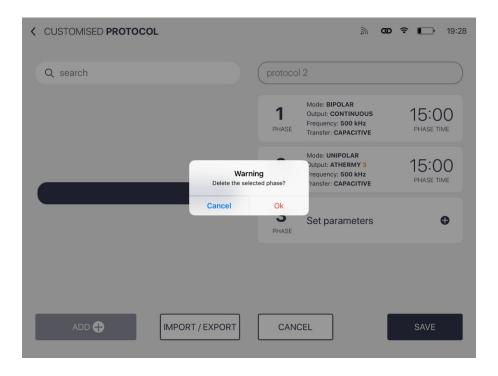
The user can search for a protocol that has already been created by using the **search** function, add a new protocol by setting the parameters for the desired phases, or modify and delete previously stored settings.



The operator can set the parameters of the individual phases ("SET PARAMETERS +" button) to compose a treatment session permitting the specifically required applications. Using the IMPORT/EXPORT function, the operator can add to and back up a folder of customised protocols.

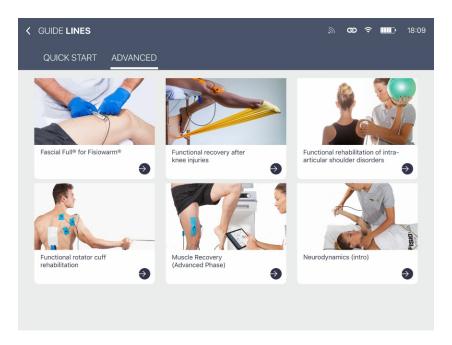


A previously created phase can be deleted by pressing the individual phase concerned and holding it down for a few seconds.



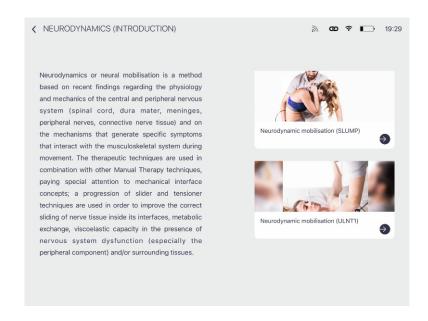
## 7.3.5 Support sections: ADVANCED MODES

The **Advanced Modes** section offers a photo gallery of treatments drawing on the full potentials of the equipment and its special accessories, in combination with the latest methods and techniques of manual therapy.



The examples shown are demonstrative only and not exhaustive, given the great range of applications possible with the Gymna Care 300® device.

The Advanced Modes section is provided with continuous updates. In order to receive these, along with the latest versions of the Gymna Care 300® app, the iPad must be operating in wifi connection.

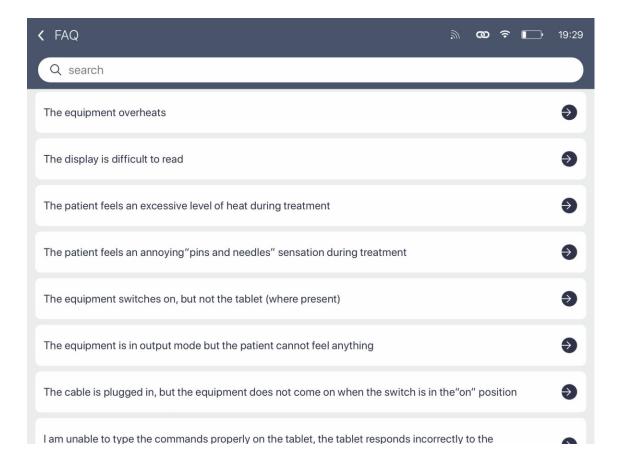


#### 7.3.6 Support sections: Service

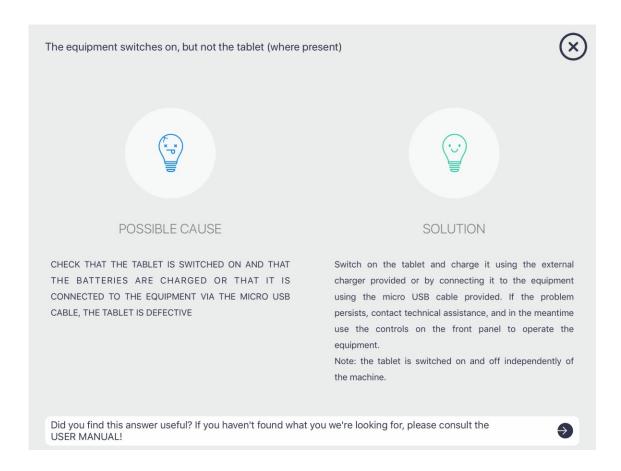
The Assistance section offers two levels of support:

### **Troubleshooting (FAQ)**

Users can either select the problem from the list or use the search tool.



A screen then opens that proposes a simple and immediate solution (see Section 10 Troubleshooting in this manual).



If the proposed resolution does not resolve the actual problem, direct access to the user manual is provided at the bottom of the screen.

#### **User manual**

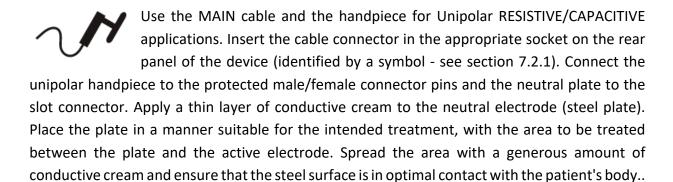
The app is provided with an immediately accessible in-depth interactive user's manual. The manual is updated regularly via the wifi Internet connection.

## 7.4 Application of treatments

#### <u>Proceed with the following preparatory phase before treatment:</u>

- 1) Make sure you have some Fisiowarm® conductive Cream to hand. During treatment it may be necessary to supplement or replace the conductive cream so as to preserve the conductivity and smooth movement of the electrodes used.
- 2) Carefully inspect the patient's skin in the area to be treated. Avoid any damaged areas, scratches, pimples or other similar patches, or protect them with a plaster.

#### 7.4.1 Unipolar applications



#### 7.4.2 Bipolar applications



Use the RESISTIVE/CAPACITIVE handpiece for bipolar applications. Insert the cable connector in the appropriate socket on the rear panel of the device (see section 7.2.1). Output will be limited to 25% of maximum power.

Fit the chosen bipolar electrode, then coat the electrode and the area to be treated with plenty of conductive Fisiowarm® Cream .

### 7.4.3 Neutro Dinamico® applications



Use the cable for STATIC AUTOMATIC/NEUTRO DINAMICO® applications. Insert the connector in the socket on the rear panel of the appliance (see section 7.2.1).

The power output will be limited.



Connect the Unipolar and Neutro Dinamico handpieces to the protected male/female sockets as shown in the image.





Example of Neutro Dinamico + Unipolar handpiece connection

#### 7.4.4 Static automatic applications



Use the cable for STATIC AUTOMATIC/NEUTRO DINAMICO® applications. Insert the connector in the socket on the rear panel of the appliance (identified by the respective symbol). The power output will be limited.



Connect the STATIC AUTOMATIC APPLICATIONS ELECTRODE KIT to the protected male/female sockets and the neutral plate to the slot connector as shown in the image.

After identifying the area and planned type of application, position the electrodes appropriately on the body area.

Apply a thin layer of Fisiowarm® conductive Cream to the electrodes and neutral plate before positioning them. Fix the electrodes in place with the bands supplied.



#### 7.4.5 Applications using Physio-aesthetic accessories



Use the handpiece for BIPOLAR applications and insert the connector in the socket on the rear panel of the device (identified by the respective symbol). Power output will be limited.



Insert the FACELIFT Bipolar Facial electrode in the Bipolar handpiece.

Apply a thin layer of Fisiowarm® Cream to the electrodes and area to be treated before beginning the treatment.



Use the cable for NEUTRAL DYNAMIC applications and insert the connector in the socket on the rear panel of the device (identified by the respective symbol). Power output will be limited.

Connect the UNIPOINTER Unipolar handpiece to the NEUTRO DINAMICO cable.

Connect the neutral plate as for automatic applications.

Apply a thin layer of Fisiowarm® Cream to the electrodes and area to be treated before beginning the treatment.



#### 7.4.6 Applications using Intimity accessories



Insert the connector of the ENDOPROBE BIPOLAR electrode in the socket on the rear panel of the device (identified by the respective symbol). Power output will be limited.

Cover the electrode with a disposable hygienic protection (condom or lubricated vaginal probe cover) before beginning the treatment.





Use the cable for STATIC AUTOMATIC/NEUTRO DINAMICO applications and insert the connector in the socket on the rear panel of the device (identified by the respective symbol). Power output will be limited.

Connect the ENDOPROBE UNIPOLAR electrode to the STATIC AUTOMATIC/NEUTRO DINAMICO cable. Connect the neutral plate as for unipolar applications. Cover the electrode with disposable hygienic protection (vaginal probe cover) before beginning the treatment.



#### 7.4.7 Myofascial applications



Use the cable for STATIC AUTOMATIC/NEUTRAL DYNAMIC applications and insert the connector in the socket on the rear panel of the device (identified by the respective symbol). Power output will be limited.



Insert the Fascial Full® electrode adapter in the Static Automatic/Neutro Dinamico cable.

Connect the electrode to the adapter, using one of the pin sockets on the edge.

Connect the neutral plate as for automatic applications.

Apply a thin layer of Fisiowarm® Cream to the electrodes and area to be treated.

#### **7.4.8 Notes**

Adjust the power via iPad and start the treatment.

The treatment can be suspended (PAUSE) or stopped (STOP) at any time.

In the latter case, the software automatically returns to the home page.

It is difficult to establish a direct link between the power setting on the device and the heat experienced by the patient. This is due to numerous factors such as the zone and surface area treated, tissue moisture levels, diversification of individual disorders, etc.

## 7.5 Switching the device off

Switch Gymna Care 300® off by means of the switch on the back of the device. To preserve the charge, turn off the iPad off when not in use. If the device is inactive for prolonged periods, it is advisable to unplug it from the power supply.

Check the iPad battery level regularly.

## 7.6 Cleaning the accessories

The accessories must be cleaned in order to prevent pathogenic germs being transmitted between objects and surfaces. The accessories must be cleaned carefully before every application. Do not use the accessories until they are completely dry.



Make sure the accessories have been removed from the device before cleaning them



## HANDPIECE FOR UNIPOLAR APPLICATIONS, HANDPIECE FOR CAPACITIVE/RESISTIVE BIPOLAR **APPLICATIONS, NEUTRO DINAMICO HANDPIECE:**

- ✓ The handpiece can be cleaned with a soft clean cloth dampened with water or with a sanitising detergent solution diluted to 10%.
- ✓ Caution! The handpiece is not "watertight", therefore immersing it in water to clean it. could damage the accessory.

#### **ELECTRODES:**

- ✓ Remove all cream residue carefully with a soft cloth;
- ✓ The electrode can be cleaned with a soft clean cloth dampened with water or with a sanitising detergent solution diluted to 10%.
- ✓ Caution! Cleaning by immersion could damage the accessory.
- ✓ Do not steam sterilize the electrodes: this can cause damage.
- ✓ Dry the electrodes with a clean soft cloth.

Electrodes that come into contact with mucous must be disinfected to a high level.

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## 8. MANUFACTURER'S INFORMATION

## 8.1 Device maintenance and storage

In order to keep the device in good working order over time, it is essential to follow some simple but important rules:

- ✓ The machine should be cleaned with a soft damp cloth, using water rather than solvents, alcohol or soaps.
- ✓ If the device or its accessories are knocked or dropped, check them immediately to see whether they are still intact; avoid using the equipment in the event of evidence of damage or alteration, contact an authorised service department.
- ✓ Check the patient and network connection cables frequently to make sure they are intact.
- ✓ Check on a daily basis the condition of the accessories applied to the patient.
- ✓ At least once a year, have the equipment and accessories checked by an authorised service laboratory
- ✓ Once per year, in conformity with reference standards CEI62-5 and EN 60601-1, the earth-leakage currents should be checked by an authorised laboratory
- ✓ When not in use, the device should be stored in its packaging, in a dry environment at room temperature
- ✓ When transporting or shipping the device, always use the original packaging to provide optimum protection against any bumps
- ✓ The average life of the Gymna Care 300® medical device is identified as six (6) years
- ✓ The useful life of the electrodes depends on how frequently they are used and how well they are looked after. The average useful life of the capacitive electrode is 500 hours of treatment. The average useful life of the capacitive resistive is estimated to be 1000 hours of treatment.
- ✓ At the end of its working life, the device and its accessories should be disposed of in accordance with local regulations. The device does not contain any harmful substances and is comparable to any other electronic device. See the section entitled "Disposal instructions" in this user manual.

## 8.2 iPad Maintenance and Storage

Follow these general rules for the safe and effective use of the iPad:

- ✓ Do not expose the iPad to extreme temperatures, moisture or dust
- ✓ Prevent spills on the device: this can cause failure or fire
- ✓ Do not clean the iPad using liquids or chemical products
- ✓ Keep foreign bodies away from air intakes and other openings
- ✓ Do not place the device near sources of magnetic fields or heat (e.g. microwave ovens, heat-emitting appliances), or in pressurised containers: the device can overheat and cause a fire
- ✓ Do not disassemble the iPad: technical service should be provided only by a qualified specialist
- ✓ Immediately remove any deposits of conductive cream from the iPad touchscreen to avoid imprecision in controls

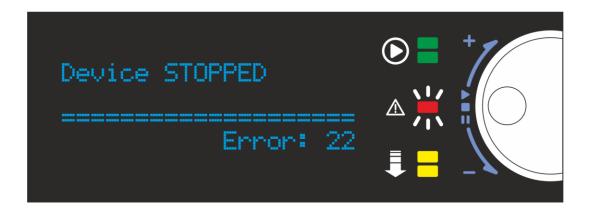
These rules are of a general nature.

Please refer to the product manual for more detailed information

## 8.3 Error codes and messages

The device signals critical situations and faults through the following codes and error messages displayed on the iPad and front display:

CODICI ERRORE	MESSAGGIO UTENTE
02	Main power supply failure  Device blocked. Contact technical assistance
04	RF circuit overheating  Device blocked. Contact technical assistance
05	General overheating  Device blocked. Contact technical assistance
09	Control error  Device blocked. Contact technical assistance
11	RF modules power supply failure  Device blocked. Contact technical assistance
21, 25, 26	RF modules power supply fault  Switch off and restart the equipment. Contact technical assistance if the problem persists
22, 23	RF modules power supply overload  Switch off and restart the equipment. Contact technical assistance if the problem persists
41	Output fault Check electrodes and connections. Contact technical assistance if the problem persists
42	Output overload  Check electrodes and connections. Contact technical assistance if the problem persists



In case of failures, errors or faults, the red LED "alarm" will light up and the display will show the equipment status and error code.

- In case of "Device in STOP", press STOP to restore normal operation and clear the error code
- In case of "Device BLOCKED", switch off the machine, wait 10 seconds and then switch it on again to restore normal operation.

If the error recurs and the machine blocks again, contact an authorised technical service

## 8.4 Warranty - General Terms and Conditions

Golden Star guarantees each device against manufacturing defects for the period iof 24 months, starting from the date of purchase shown on the validly issued sales receipt.

The display with encoder, the device housing and the accessories (handpieces, electrodes, neutral plate, cables, trolley) are guaranteed for 1 year against manufacturing defects, under normal conditions of use.

The iPad is covered by the official Apple® warranty and service network. In the event of failure, malfunction or doubt as to the correct operation of the equipment, refer only to an authorised service centre. This guarantee covers all product material or manufacturing defects, with the exception of the following cases:

- ✓ Products on which the serial number has been deleted, changed or removed.
- ✓ Products with faults due to different causes, including the following:
  - Accidents, transport, negligence, improper use or other mistakes made by the client, its employees or third parties.
  - Damage during transport to the Assistance Centre due to unsuitable packaging.
  - Electric current and/or circuit faults or fluctuations, non-standard operating conditions, or failure to follow the detailed instructions provided in the User Manual.
  - Any damage caused by the use of accessories, products or associated components that are not part of the product covered by this guarantee.
  - All attempts to regulate, modify, repair, install or carry out repairs on the product by not authorised personnel
  - In any of the abovementioned circumstances, or if the fault cannot be attributed to manufacturing defects, Golden Star reserves the right to charge the client for the repair costs.

Golden Star declines all liability for any direct or indirect damage to people or property due to failure to observe the instructions provided in this user manual, particularly the precautions to be taken in terms of the use and maintenance of the device.

## 8.5 Disposal instructions

Information pursuant to Art. 13 of Legislative Decree 15/105 of 25/07/2005 "Implementation of Directives 2002/96/EC and 2003/108/EC, concerning the reduction of hazardous substances in electrical and electronic appliances, as well as waste disposal"



This symbol indicates that, at the end of its working life, this product should not be disposed of with normal domestic waste, but instead disposed of separately.

These devices should be disposed of at waste collection centres in your place of residence, so that the electrical and electronic equipment can be recycled.

Separate collection and recycling of obsolete devices helps to preserve natural resources and ensures that these products are disposed of suitably, protecting the environment and human health. In fact, it is strictly forbidden to dispose of waste electrical and electronic equipment (WEEE) with untreated waste.

Sanctions are applicable in the case of illegal dumping of this product. For further information on collection points please contact your local council, the local waste disposal service or the retailer from whom the product was purchased.

## 8.6 Manufacturer's details



**GOLDEN STAR S.R.L.** 

**VIA ENRICO PALLINI 9** 

00149 ROMA - RM

**ITALIA** 

WEBSITE: www.goldenstar.it

#### 8.7 Manufacturer's note

The illustrations and description of the external appearance, colour and manufacturing details of the device provided in this manual are intended for reference purposes only. The design and technical features of the products may be subject to change without notice.

Contact GOLDEN STAR S.r.l. immediately in the event of any accident; where appropriate, contact the national regulatory authorities

## 9. TRADEMARKS

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- FISIOWARM®, NEUTRO DINAMICO, the NEUTRO DINAMICO logo and the GOLDENSTAR logo are the registered trademarks of Golden Star S.r.l.
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- Wi-Fi® and the Wi-Fi logo are the registered trademarks of Wi-Fi Alliance
- o All the other cited trademarks and copyrights are the property of their respective owners

# 10. TROUBLESHOOTING

N°	WHAT TO DO IF	PROBLEM	SOLUTION
1	The power cable is plugged in but the device does not turn on when the switch is in the "ON" position.	The power cable is damaged or is not plugged in correctly; the electrical outlet is not functioning; the circuit breakers/fuses have opened.	Check that the power cable is properly connected; plug the power cable into a different electrical outlet; reset circuit breakers/replace fuses with others of correct rating; check the power cable for kinks, twists, cuts or bare wires. If the problem continues, contact customer service.
2	The device turns on but the iPad does not.	The iPad battery is not charged or the iPad is not connected to the Gymna Care 300 device; the iPad is broken.	Plug in the iPad using the charger provided (recommended when the battery level is less than 10%), or by connecting it to the Gymna Care 300 device using the cable supplied; check that the battery charge is increasing. If the problem continues contact Apple assistance. Note that most treatments can also be carried out using the front panel. Also note: Switching the iPad and the machine on and off are completely independent functions.
3	The device is turned on, the Gymna Care 300 iPad app is open, but the device does not respond to commands.	There is no Bluetooth connection between the iPad and the device; the app is blocked.	On the Gymna Care 300 for iPad app, check that the Bluetooth connection with the Gymna Care 300 device is active ("closed link" symbol); if the symbol isn't displayed then connect manually by tapping "FW" in the drop-down menu. Switch off the device and iPad, wait a few seconds and then turn them on again. If the problem continues contact customer service.
4	I am unable to connect with the on-line services; I am unable to download the updates for the Gymna Care 300° app that are available on the AppStore°.	There is no Wi-Fi connection to internet.	Check that a Wi-Fi connection with sufficient signal strength is present in the working area, and that the Wi-Fi connection is correctly established. Check that the other iPad functions are working, for example by navigating on the internet. Check that the Apple ID is correctly entered.
5	I am unable to enter the commands on the iPad correctly; the iPad responds incorrectly/ does not respond to commands.	The iPad screen is dirty or greasy; you are wearing latex gloves. You are attempting to operate the iPad while keeping the other hand in contact with the patient.	Clean the iPad screen using mild detergent and a damp cloth. Do not use gloves on the iPad screen. The iPad has a highly sensitive capacitive screen: the correct procedure is to touch the screen only when you are not in contact with the patient.

N°	WHAT TO DO IF	PROBLEM	SOLUTION
6	The device is in operating mode but the patient doesn't feel anything.	The power setting is incorrect; there is no connection between the patient and the device; the output hasn't been set up correctly.	Check that the energy transfer level to the patient has been set correctly; check that the cables, handpieces, and electrodes are correctly connected and undamaged; check the that the back-panel output in use matches the work program selected. Make sure the CONTACT indicator is on during the application.
7	The patient feels annoying "pins and needles" during treatment.	The contact surface between electrode and skin is not clean; there are skin abrasions or growths; the power setting is too high; the size of the electrode isn't sufficient for the treatment.	Before starting treatment check that the skin and electrode contact surfaces are clean. Check that there are no skin abrasions or growths: if these are present, position the handpiece in a way that avoids the area; otherwise suspend the treatment, lower the power, and use an electrode with a surface better suited to the treatment.
8	The patient feels excessive heat during treatment.	There is insufficient or no cream or its quality is poor; the electrode used is unsuitable for the treatment; the dosage setting is too high.	Use the conductive cream supplied in appropriate quantities; check that the electrode in use is suitable for the treatment; reduce the power setting.
9	The iPad screen is difficult to read; after a while the iPad turns off.	The brightness setting is too low; the viewing angle is unsuitable.	Using the iPad settings, change the brightness setting to suit the conditions; bring the iPad closer or change the angle to improve legibility. In the iPad Screen/Auto-Lock settings, choose "NEVER".
10	The device overheats.	The air inlets are blocked or dirty. The cooling fan is not working.	Remove any obstructions from the fan and the cooling fan air inlets on the base of the equipment; clean them using an air jet or soft brush. Position the device with at least 20 cm of space to the rear. Before using the device, remove it from its carry bag and place it on a hard smooth surface. Check that the cooling fan is functioning properly; if it is not then switch off the equipment and call a technical assistance service.
11	The patient feels the current beneath the electrode.	The electrode surface isn't proportional to the application area. The power setting is too high. The skin beneath the electrode is scratched.	Use an electrode proportional to the surface to be treated and suitable for maintaining good contact throughout the therapy. Reduce the power output. Avoid skin areas with scratches or growths; avoid contact between these and the active electrode.

N°	WHAT TO DO IF	PROBLEM	SOLUTION
12	The patient feels heat from the neutral plate.	The plate is positioned near a resistive area, for example near bone surfaces or joints. The cream is not applied evenly. The contact surface is too small to allow the plate to function as neutral. The skin is particularly hairy or dry.	Move the neutral plate to a position on a muscular surface. (It is always advisable to make contact with softer, more conductive surfaces.) Alternatively, use a "bipolar" or "neutral dynamic" working mode. Apply a uniform layer of cream over the entire neutral electrode surface. Maintain the proper positioning necessary for the work: make sure that the contact surface between patient and neutral electrode is substantially greater than the contact between patient and active electrode. It is advisable to depilate the area to be treated, or if not possible then use more cream. If the skin is especially dry then massage it lightly with the conductive cream supplied, prior to applying the electrode: the cream also has a moisturising function.
13	The device often signals "no contact" when using the bipolar electrodes.	The bipolar electrode has much smaller contact surfaces. It is therefore normal for "no contact" indications to show up as the handpieces are moved. However, the "no contact" time is so short that it does not affect the successful outcome of the application	It can be useful to use more cream, or to slightly increase the output power.
14	The electrodes seem to be losing their shiny finish.	This depends on the ways the electrodes are used, on the cleaning methods and products, and the kind of conductive cream used.	Use the conductive cream recommended by the manufacturer and clean the electrodes carefully following the directions in the manual. Gilded electrodes will normally lose their shininess with use, just as happens with gold-plated jewellery, or "white gold" that returns to a natural yellow appearance, however the conductive capacity is not affected.
15	While using the capacitive electrode I sometimes get the impression that the treatment is resistive type.	An electrode with good conduction, even if capacitive, tends to close the circuit with the neutral. This can happen quite easily during treatment if there is a resistive type of tissue between the two electrodes.	Use an electrode of appropriate size, and if possible position the applicators in a manner so as to exclude resistive zones from the treatment.

Gymna Care 300

## 11. NOTES

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