High frequency e low potency medical equipment for physiotherapy, rehabilitation and pain management - Model PRONEXIBUS™, Patent Application n. PD2011A000318

User's Manual

User's Manual
Instructions for the use and maintenance of Medical Equipment
PRONEXIBUS®

CE 0476

FOCUSMED S.r.l. *Largo Traiano n.4 – Montegrotto Terme (PD) - P.IVA 04590310282*
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Introduction

This document provides information for the implementation and for the correct use of Pronexibus® medical device.
This document is an essential guide for the user: before the installation and use of the medical device, it is essential to read the Manual carefully and to keep it always handy for a quick reference.
The non-compliance - even if partial – of all that is contained in the Manual, may lead to malfunctions, damages to the medical device and invalidation of the warranty.

Safety information

,
To reduce the risk of fire or electric shock, do not expose the medical device to rain or to a relative humidity that exceeds 85% with condensation.

Make sure before use that these conditions are not present.
In case of these conditions would be present, it is recommended not to open the suitcase that contains the medical device and consequently, not switching it on.

WARNING: to reduce the risk of fire or electric shock, do not remove the panel of the device. In case of problems, please contact exclusively the qualified service personnel of Focusmed srl.

 The lightning symbol within an equilateral triangle alerts the user of dangerous voltage inside the medical device and danger of electric shock.

ELECTRICAL SCHOCK HAZARD This writing reminds the user the importance of the previous symbol.

 This symbol reminds the user that the User's Manual contains

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important information regarding safety

 - This symbol warns the user that the device emits radio frequency but does not emit ionizing radiation.

 - This symbol warns the user to store and use medical device in a dry place, away from water.

CE 0476 This symbol refers to the certification obtained for the medical device according to directives CE 93/42 and CEE 07/47, by CERMET.

 This symbol indicates applied parts of the medical device as type BF (floating)

<u>In addition to the normal safety precautions, please take out the following steps to protect your and the patient's safety, and that of the product and its accessories.</u>

- Do not overload the socket by plugging double or triple plugs or multi sockets. This medical device needs to be connected by one single wall outlet.

- Do not use not protected power outlets, it can be dangerous
- Always control that electrical connections are correct; there should not be any exposed wires. In case, you are invited to contact a qualified technician
- Make sure that the wall socket has the right ground connection that must be controlled according to current standards.
- Do not use electrical outlets near water containers, swimming pools, bathtubs, showers, washing machines, sinks etc.
- Do not place the equipment over unstable objects, this can cause serious injury or damage to the equipment
- Do not place the device near stoves, heaters, furnaces, fans, audio amplifiers and / or TV, this can cause malfunctions
- Always disconnect the appliance from the electrical outlet before cleaning
- Do not try to insert the current plug in old-type plugs or forcing it. In case, contact a qualified electrician.

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- Do not step on or place any kind of objects on the power cord. In case the cord is ruined, replace it with a new one.
- Disconnect the device from the wall outlet in case of storms or long absence.
- Do not attempt to open the system and do not touch the contained components. These operations can be done only by qualified and trained personnel for the maintenance / repair.
- Do not tamper PRONEXIBUS® medical device. In case the device should be opened and / or tampered with by unauthorized staff, the warranty should be void and the medical device can not be put into service.
- Install the device in a place with good air circulation. Do not block the vent slots on the device.
- Do not place in any case glasses, bottles, cosmetic products, gels or any kind of containers of various products etc.. over the inner cover of the device
- Do not pull the cables
- Do not press the touch screen..
- In case the medical device does not emit signals or a malfunction is present, switch off immediately PRONEXIBUS, remove the power and contact the technical support.

Warning: *PRONEXIBUS® emits, through the handpiece, controlled high frequency electromagnetic fields which, in case of direct contact with the patient, are closed by the insulating mat. This must be connected to the bushing of PRONEXIBUS® and be positioned under the patient. (no skin contact or use of creams or conductor gels are required. In case of direct contact with the patient, for hygienic and sanitary reasons, it is advised the isolation with a cloth or a tissue).*

PRONEXIBUS® may interfere with other medical equipments. Do not use PRONEXIBUS® in surgical environment or near life support equipment (Critical Care). In case treatment would occur at the home of the patient and the device would interfere with appliances such as television, radio, CD/DVD players or wireless devices, normally it is sufficient to interrupt treatment and change room. Possibly switch off the device before restarting the treatment. Pay also attention to the indications on the display of the device and on the following label inside the cover:

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Montegrotto Terme (PD)
Tel. 389.0666696

In case of treatment at the patient's home, healthcare professional must verify that the electrical system of the location possesses regular conformity certifications required by law and is regularly tested by qualified personnel.

In case of unsuitable circumstances the treatment MUST NOT be performed.

The use of PRONEXIBUS® is dedicated to physicians, physiotherapists and nurses, always under medical supervision.

PRONEXIBUS® can not be used independently by the patient. PRONEXIBUS® can be used in any environment with an electrical system in accordance with current legislation and in possess of required authorizations.
The device is designed and certified also for home use.

Keep the medical device away from children and always close it with the appropriate supplied keys.

Attention to cables! Danger of strangulation!

Do not use the medical device in explosive environment and/or areas saturated with oxygen (f. e. hyperbaric chambers)

The fuses are of 2,5 Ampere and are positioned within the filtered socket, as indicated by the front screen printing.

In case of any malfunction, contact immediately the technical support.

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General information

PRONEXIBUS® is a therapeutic type medical device that, by the application of low power and high frequency via two types of handpieces, causes the stimulation of connective and muscle tissues, as well as having an anti-inflammatory and anti-oedema effect. There is the possibility to select three types of high frequency:

- LF of 2 Mhz;
- MF of 4 Mhz;
- HF of 8 Mhz;

Besides this, there is the possibility to select the power, the number of cycles, timings and sound volume.

Contents of the packaging

- Suitcase with the medical device;
- User's manual;
- Safety test sheet.

The upper compartment of the suitcase contains:

- n° 1 handpiece with head (plate/discoid) with application diameter of 40 mm
- n° 1 handpiece with head (plate/discoid) with application diameter of 50 mm
- n° 1 power cord with plug of 10 Amp and ground socket
- n° 1 cable with two "banana" terminations to connect the suitcase with the isolating mat that blocks the return currents
- n° 1 Isolating mat that allows to block the return of high-frequency currents

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Technical specifications

1 Joule, the symbol "J" is the measurement unit of energy and coincides with "Watt per second" J = W * s = N * m = K * m/ s2

Parameters	Values
Commercial denomination	**ProNexibus®**
Aims and function of use	High-frequency device 2, 4, 8 MHz from 8 J /cm2 max Physioterapic and antalgic therapies
Weight	< 10,5 Kg
Power supply	From single-phase system 110 - 220 V ± 10% - 50/60 Hz, by a plug with protective conductor and no voltage change Connectorised cable IEC detachable by plug / socket
Power absorbed by the net	250 VA (max)
Output power	100 Joule (max)
Frequencies	LF = 2 MHz MF= 4 MHz HF= 8 MHz
Environmental condition requirements	Temperature: +10 ÷ +35 °C; Relative humidity: 30 ÷ 85 %

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	Atmospheric pressure: 70 ÷ 106 kPa
Storage and transport conditions	Temperature: –25 ÷ +70 °C; Relative humidity: 10 ÷ 100 %, condensation included; Atmospheric pressure: 50 ÷ 106 kPa
No. handpieces	2
Emission mode	Continuous 100 Joule max on 100 Ohm Reflected power control 15 Joule max
Maximum effective intensity in case of normal use and first malfunction	14,2 J cm q on handpiece of 30 mm 8 J cm q on handpiece of 40 mm 5 J cm q on handpiece of 50 mm 3,5 J cm q on handpiece of 60 mm
Time for each emission cycle: no. Max. cycles:	1 / 30 min. 20 cycles
Safety class:	 I type BF (CEI EN 60601-1, CEI EN 60601-2-3).
Internal power source:	+ 48V, 4 A e +24 V 3 amp
Fuse value:	2,5 Ampère
Level of protection for the medical device	IP20

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Regulations

Active therapeutical device class I and type BF, class IIb according to CEE 93/42 and CE 07/47, being intended to supply energy to the human body in a non-potentially hazardous way, taking in consideration the nature, the density and the place where the energy is applied (Rule 09 Annex 09 Directive 93/42/CE).

Regarding home use we highlight that the device is not a B-classed. This fact however, is an acceptable limitation in accordance to the benefits both from a health / therapeutic point of view and for the collective economy. Disorders due to eventual interferences with home appliances in case of home use, are absolutely not dangerous neither for the patient and nor for the operator and cause no damage to the appliances.

Discoids must be properly cleaned and disinfected before and after each application.

WARNING! DO NOT use the medical device near children, they could get hurt or damage the device. Pay special attention to the handling of cables for the risk of strangulation.

WARNING! KEEP THE DEVICE AWAY FROM CHILDREN!

WARNING! Always lock the suitcase after use, in order to avoid the use of the device by unauthorized persons or children. Pay attention in handling the cables, risk of strangulation!

IN CASE OF ANY KIND OF ANOMALIES (f.e. problems with set-up, no energy supply, low energy supply, led off…) INTERRUPT THERAPY,SWITCH OFF DEVICE AND CALL ASSISTANCE.

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Instructions for use

a) Environment requirements for the use

PRONEXIBUS® can be used in any environment corresponding to the standards defined by the current legislation, regarding the electrical systems and sanitary authorizations.
The device was designed and certified for home use, but treatments must always be done by physicians, physiotherapists or nursing personnel under medical supervision. Patients must not use independently the device.
In order to avoid any kind of interferences, do not use PRONEXIBUS® on the patient simultaneously with other electromedical devices.

Do not use PRONEXIBUS® in surgical environment or near life support equipment (Critical Care), it may cause interferences.

b) Pre and post treatment indications

It is not necessary to follow specific protocols or particular precautions before the treatment..
Normally the patient, once concluded the therapy, can get back to his normal daily activities. Anyhow, it will be the physician to decide and give the necessary indications thereupon.
It is not required to take any post-treatment precautions.
Anyhow, it will be the physiotherapist or the physician to decide and give the necessary indications thereupon.
In case physician would use the handpiece in a dynamic way, it may cause redness caused by the rubbing. The redness should disappear within an hour.

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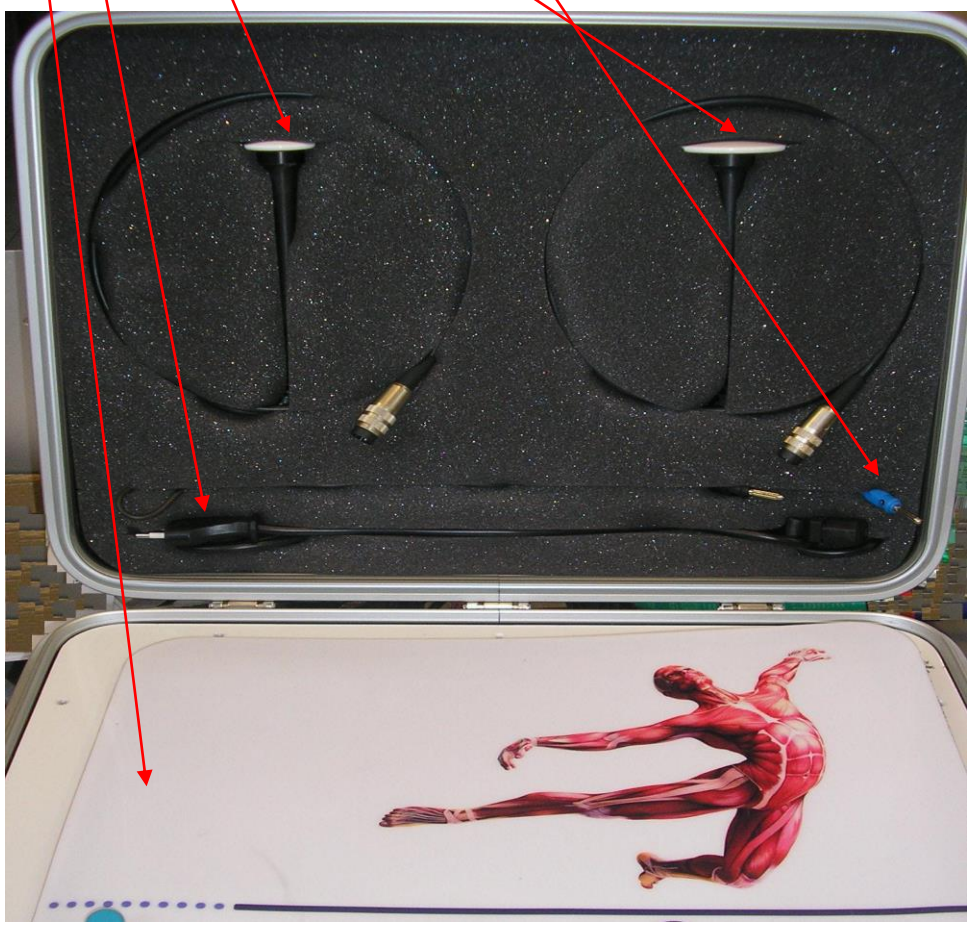
c) Switching, commands and indications

In the suitcase / container PRONEXIBUS® are stored the controlled high frequency generator and the related and necessary accessories for the proper use.

In the upper compartment of the suitcase you can find (see pic. 1):

- n° 1 handpiece with head (piaster/discoid) with application diameter of 40 mm
- n° 1 handpiece with head (piaster/discoid) with application diameter of 50 mm
- n° 1 power cable with a 10 Amp plug and ground socket
- n° 1 cable with two "banana" terminations to connect the suitcase with the isolating mat that blocks returning currents
- n° 1 isolating mat allowing to block the returning high frequency currents



PICTURE 1

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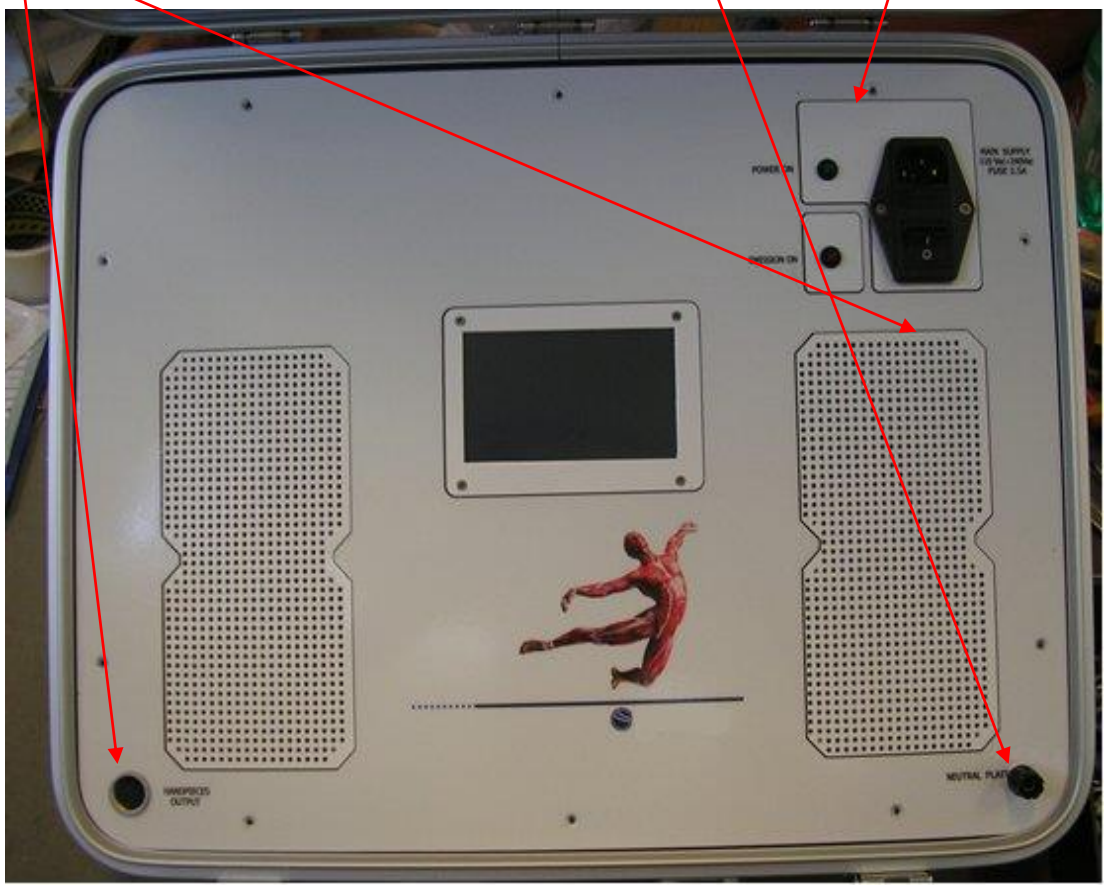
In the lower compartment of the suitcase you can find the high frequency generator to which the above mentioned accessories must be connected.
The power switch is to be placed into the socket in the upper right.

- Connect the power cord to the dedicated socket of the generator (lower case of suitcase)
- Make sure that ON/OFF switch is positioned OFF
- At this point connect the 10 Amp plug to the wall jack
- Place the chair or bed where the patient will have to sit or lie down close to PRONEXIBUS®
- Place the isolating mat on the chair or bed and connect it using the right cable – the one with "banana" termination – to PRONEXIBUS® on the top of the generator
- Connect the free connector of the chosen handpiece to the plug of the generator, screwing it carefully.



- At this point switch on Pronexibus® and verify that the green "ON" Led near the input jack is lightning

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PICTURE 2

- Verify that the display shows the following figure (pic. 3)

d) Description of displays of the touch screen

PRONEXIBUS™ has one display, allowing the operator to select the operating and emitting mode of the device. The display is touch-screen type, and by graphic buttons allows:

- Select the operating frequency (LF. MF, HF)
- Select the output power (shown in W, corresponding to 1 second for 1 Joule/cmq) power is expressed as a percentage of the maximum power possible
- Select the singular emission cycle length
- Select the reps of output cycle that you want to program

PICTURE 3

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e) Choice of the handpiece

As already mentioned, PRONEXIBUS® has two handpieces that differ only by the dimensions of the application of the plates with diameters of 40 mm or 50 mm, or 30 and 60 mm eventually.
We note that equal emitted power is distributed on the two different surfaces. In case of application of the 40 mm discoid the operating power will be slightly less than twice of the operating power with the application of the 50 mm diameter discoid.
The two discoids are screwed on the handpiece. After use we recommend to store it as soon as possible in the cover's foam insert. Handle carefully, do not hit it, so it does not lose the isolation needed for the proper use.
The white colour of the glaze on the surface allows its easy inspection.
If you note scratches or the colour may not be pure white anymore, change the application plate
In case of the transmission plate of the handpiece would damage and/or have scratches, it must be changed immediately, particularly for the safety of the patient in treatment.
The handpiece can be slid on the skin of the patient or kept stationary, it will be the physician to decide.
In order to make the discoid slide easier on the patient's skin, you can use neutral skin creams. The handpiece is to be chosen by the dimensions of the area to treat, by the energy that should be dispensed (power) and by the pathology to treat.

f) Treatment parameters

As fundamental guideline for the choice of treatment parameters, **the patient's sensational feedbacks must be taken in consideration.** In order to optimize the results of the treatment, it is particularly important that the patient must feel a **nice warmth during each cycle treatment, but not reaching the limit of tolerance.**
The sensation of the heat experienced by the patient should be slight and never excessive.
It is also very important to take in consideration that the sensitivity to pain and/or heat could be different from patient to patient. Therefore, the sensation referred by the patients during the treatment can show also significant differences even in case of identical treatment parameters.
It will be always the physician or physiotherapist to decide for the parameters to adopt, after a precise evaluation based on the pathology, the patient and the body area to treat. (setting the power, duration, number of cycles, choice

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of the handpiece and of the frequencies, number of needed treatments)

WARNING! In case the erogated energy should result excessive, the patient could feel a light burn. In this case remove immediately the discoid of the handpiece from the patient's skin, place the handpiece on a flat surface and press the START button (which becomes button PAUSE colour yellow). At this point recalibrate the power and get back to work pressing the yellow PAUSE button.

It is always recommended that you start the treatment under the threshold of 50% of the power, paying always attention to what the patient perceives.

An average treatment should last around 20 minutes, anyhow it is recommended not to exceed 40 minutes per treatment session.

The duration of the treatment will be always determined by the physician or physiotherapist, based on the width of the area to treat, the pathology and the patient.

In case of degenerative diseases it is recommended to treat the patient once in 72-120 hours (each 3-5 days) , while in case of traumatic diseases treatments could be run once in even 24 or 48 hours.

However it will be up to the your physician to decide for the frequency, the power, the number and duration of the single cycles to adopt and for the number of treatments to run.

g) Antalgic -and physiotherapies

PRONEXIBUS™ can be used with extreme efficacy for the treatment of pain caused by a wide range of diseases.

We remind you to the extraordinary anti-inflammatory and anti-oedema effect.

Therefore among many others, you can treat:
Joint distortions, muscle strains, spasms, contusions, inflammations etc..

h) Contraindications

The application of the electric currents is absolutely contraindicated in cases of:

- **Pace-maker**
- Cancer
- Pregnancy
- **Presence of brain stimulating electrodes**

Some of the above mentioned contraindications make part of the list for not having available case studies in relation.

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i) Protection measures

The treatment cycle can not begin in the following cases:

- The handpiece's connecting cable is unplugged
- Start button (on touch screen) is not pressed

The treatment cycle begins but with power educed to minimum:

- In case the mat is not connected properly by an appropriate cable to the socket of the device, located in the right bottom corner
- In case the mat is not positioned below the patient's body
- In case the plate/discoid of the handpiece is not in direct contact with the patient's skin

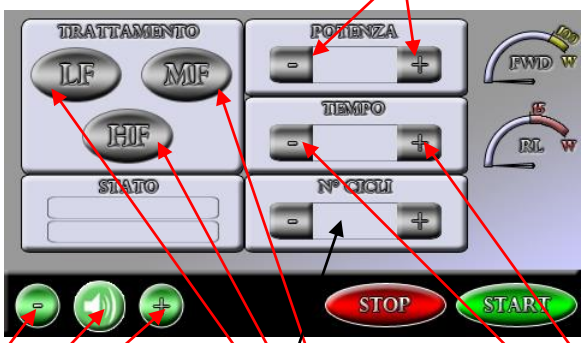
The treatment cycle is suspended under the following conditions:

- If delivery circuits of output power would be out of control
- If absorption of the power terminals exceed the maximum permissible current
- If the plug of the handpiece should disconnect

IN CASE OF ANY KIND OF MALFUNCTION, STOP IMMEDIATELY THE TREATMENT, SWITCH OFF THE DEVICE, UNPLUG POWER AND CALL FOR QUALIFIED ASSISTANCE.

l) Use

1) Set the emission power by the special symbols on the touch screen



2) Select the emission frequency from the 3 available
3) Set the necessary duration for the treatment by the appropriate symbols on the touch screen
4) By pressing the appropriate signals, turn on or turn off the acoustic transmission signal and adjust its volume
5) Set the number of emission cycles

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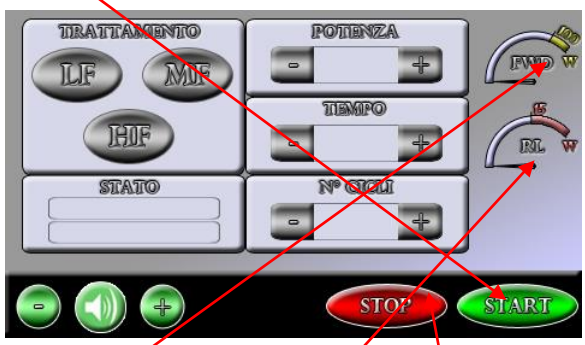
6) Place the blocking mat under the patient (there is no need of skin contact) and connect the mat by the cable with two "banana" terminations, to the socket placed right in bottom of PRONEXIBUS™ (the bush side is positioned in the lower right corner of PRONEXIBUS™, while the pipette blue is located on the blocking mat)
7) Make sure that the chosen handpiece is linked to the appropriate connector (the device reports on touch screen in the STATO section) and that it is well fixed.
8) Press Start button on touch screen and verify that the red LED Tx on the cover of the suitcase is on (near the green Led ON)



9) Place the plate of the handpiece on the skin area to treat and make sure that the FWD signal is going slowly towards the maximum (depending on the power set, the signal will stop at the set point: for example in case of 50% of the power, the signal will stop in the white area ca. at the half), while the RL signal should descend towards the minimum (closer the signal is to the minimum, more the patients absorbs the energy)
10) The power is supplied from the minimum available and is set afterwards according to the adjustments.
11) In case of any kind of anomalies during the absorption of the emitted controlled high frequencies, PRONEXIBUS® ensures an automatic reduction of the power, in order to avoid any injuries to patient or to the operator.
12) During the treatment, in order to obtain a constant delivery of the high frequencies, keep the entire surface of the plate of the handpiece (the white plate/discoid area of the handpiece) in direct and constant contact with the skin area to treat. When the handpiece is in movement and comes lifted or disconnected from the skin, Pronexibus™ reduces immediately the output power and reinitiates then always starting from the half of the power set previously. The emitted power arrives to the requested level in some seconds.
13) At the end of each cycle, PRONEXIBUS™ emits a beep sound and, in case more cycles were set up previously, restarts.

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14) For each cycle, the maximum emission time is 30 minutes that can be repeated max. 20 times (max. number of cycles), that results max. 10 hours of power emission and treatment.

15) To interrupt a treatment cycle, remove the handpiece's plate/discoid from the skin and place it on a flat surface. At this point, pressing **START** button the emission is interrupted and you can change the setting of the parameters. (duration, number of cycles, power, use of handpiece). Press START again – **that, in the meantime, became yellow with PAUSE written on -,** and the treatment will restart from where it was blocked. Contrary as above described, pressing STOP during a treatment will reset all settings, you will have to set each parameter and cycles will start as for a new treatment.

16) The use of any gel or conductive cream is not required neither for the plate/discoid, neither for the blocking mat. To facilitate the sliding of the handpiece, you can use a neutral cream on the patient's skin.

17) The choice of the handpiece is made by the physician, after evaluating the width of the area to treat, the pathology and the power to be dispensed.

K) Precaution for Use

PRONEXIBUS® uses controlled high frequency currents that are blocked by the mat, therefore patient must be seated or lied down on such blocking mat. The blocking mat is connected to the device by the required cable in the appropriate socket placed in the bottom right.
In lack of clinical studies at disposal, avoid the use of the device in the following cases:

a) Pregnancy
b) Patients with heart diseases with cardiac stimulator applied (f.e. pacemaker)

IMPORTANT
Do not use PRONEXIBUS™ in case of patients with AIMD (Active Implantable Medical Devices: pacemaker, hearing aids, electrodes for cerebral stimulation etc.)

PRONEXIBUS™, therefore discoids and plates must not be used on skin wounds or injured skin in general, nor on eyelids or eyes.

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IN CASE OF ANY KIND OF MALFUNCTION (f. e. problems in setup, missing power emission, too low power emission, LED faults..), STOP IMMEDIATELY THE TREATMENT, SWITCH OFF THE DEVICE, DISCONNECT IT FROM THE PLUG AND CALL THE ASSISTANCE.

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Maintenance

a) Generalities

PRONEXIBUS®, as it was designed and built, requires:

1) Annual check up of the output power parameters, by specialized technicians
2) Disinfection of the handpiece's plates/discoids
3) Daily check up of cables and accessories
4) PRONEXIBUS™, therefore plates and discoids, MUST NOT be used on skin wounds, injured skin in general, eyelids or eyes.

b) Annual check up

PRONEXIBUS®, being an electronic instrument, must be submitted to an annual test to verify the calibration of power parameters at different levels of emission and the right functionality of safety checks.
Calibrations and verifies must be performed by authorized personnel in possess of measuring and test equipment suitable for this purpose.
PRONEXIBUS is guaranteed for 24 months only in case the warranty labels attached in factory, remain untouched (ESSENTIAL CONDITION FOR MAINTAINING THE WARRANTY AND COMMISSIONING)
(See warranty section of this document)
Before operating with PRONEXIBUS®, make sure that the annual electronic check up has been made, and from the date of the last calibration no more than 12 months has been passed.

c) Disinfection of handpieces and of related screwed plates and discoids

The handpieces and plates/discoids must be cleaned and disinfected before and after each use.
Handpieces, plates and discoids can be cleaned by normal disinfectants.
However, avoid use under water of:

- Acetone
- Nitro diluents
- Trichlorethylene (benzine)
- Any kind of acids and anyway in case of PH below 6
- Basic components with PH above 8

We recommend the use of the following sterilizing products:

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- appropriately diluted alcohol
- disinfectant and antifungal preparations
- Products diluted with hypochlorite
- Hydrogen peroxide at low/medium volume

DO NOT STERILIZE AT HIGH TEMPERATURES!

d) Daily check up

PRONEXIBUS® must undergo a check up every day and each time you may open the suitcase / container, making sure to check also the conditions of the connecting cables.

e) Handpieces

PRONEXIBUS® must undergo a check up every day and each time you may open the suitcase/container.
Pay attention to the condition of the coating surface of the discoid. Check colour and quality, in case of doubts, replace the plate with a new one (see paragraph dedicated to the handpiece).
Check the attachment of the handpiece you intend to use and its connection to the blocking mat that must be placed under the patient. The blocking mat does not require a skin contact with the patient, nor use of gels or conductive creams.

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Warranty

PRONEXIBUS®, being a generator / suitcase, has a warranty of 24 months only in case that, if controlled, the warranty labels attached in fabric result untouched (ESSENTIAL CONDITION).
In case of any kind of tampering PRONEXIBUS® or its components and/or accessories, the warranty will be void, and the device can not be put in service anymore.
Handpieces have a warranty of 12 months.
Discoids/plates have a warranty of 6 months.
The blocking mat and its connecting cable have a warranty of 6 months.
Warranty covers only manufacturing defects, and do not cover damages or malfunctions from wear or heavy or abnormal use, transport or storage.

Disposal

PRONEXIBUS™, compatibly with operating and safety requirements, have been designed and constructed to minimize the negative impact on the environment.
The criteria were the minimization of waste, toxic materials, noise, undesired radiation and Energy consumption.
A careful study on how to optimize yield of the devices can result reduced consumption, in harmony with the concepts of energy savings.

This symbol indicates that the product should not be disposed with other domestic waste.
The user must dispose of the device by handing it over to a specific collection centre for the recycling of electrical and electronic equipment. In case of problems please, contact us.

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Annex 1: EMC charts

PRONEXIBUS™ was designed and constructed in accordance with the standards regarding electromagnetic compatibility. CE certification proves conformity also regarding this aspect. As for its operating method, PRONEXIBUS™ generates a certain quantity of controlled high frequency energy and has got an appropriate level of immunity to radiating electromagnetic fields (EMF).
In order to not to alter the electromagnetic behaviour of the device, operator must not modify in any way the device itself and/or its accessories and/or any cables.
In order to avoid harmful interferences to radioelectric communications, to other medical equipment used for monitoring, surgery or any kind of therapies, to any electronic equipment such as office computers, printers, copiers, faxes etc. or to any kind of electric or electronic equipment used near to PRONEXIBUS™, considering the characteristics of electromagnetic compatibility, see the following chart in accordance with EN 60601-1-2:

Emission aspects		
Emission test	**Conformity**	**Electromagnetic environment - guidelines**
Emission RF CISPR 11	Class A group 2	PRONEXIBUS™ emits electromagnetic energy to fulfil its therapeutic functions. Equipment near might be influenced by the produced magnetic fields.
Harmonic emissions IEC 61000-3-2	Class A Complies	It is possible to use PRONEXIBUS™ in any kind of buildings including residential and those directly connected to the low voltage public power supply network
Fluctuating emissions of voltage/flicker IEC 61000-3-3	Complies	

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Immunity aspects			
PRONEXIBUS™ device is designed to operate in the below specified electromagnetic environment. Client or operator should make sure that the device is used in these circumstances.			
Immunity test	**Test level EN 60601-1-2**	**Conformity level**	**Electromagnetic environment - guidelines**
Electrostatic discharge (ESD) EN 61000-4-2	± 6kV at contact ± 8kV in air	± 6kV at contact ± 8kV in air	Floor surfaces should be made of wood, concrete or ceramic tile. In case the floor surface is covered by synthetic material, relative humidity must be at least of 30%.
Transitors/fast electric trains EN 61000-4-4	±2kV Power supply lines	±2kV Power supply lines	Quality of grid voltage should be that of a normal commercial or hospital environment.
Impulses EN 61000-4-5	±1kV Differential mode	±1kV Differential mode	Quality of grid voltage should be that of a normal commercial or hospital environment
Voltage gaps, short interruptions, voltage variations on input lines EN 61000-4-11	< 5% U_T (>95% gap of U_T) for 0,5 cycle 40% U_T (60% gap of U_T) for 5 cycles 70% U_T (30% gap of U_T) for 25 cycles < 5% U_T (>95% gap of U_T) for 5 seconds	< 5% U_T (>95% gap of U_T) for 0,5 cycle 40% U_T (60% gap of U_T) for 5 cycles 70% U_T (30% gap of U_T) for 25 cycles < 5% U_T (>95% gap of U_T) for 5 seconds	Quality of grid voltage should be that of a normal commercial or hospital environment. If user requires continued operation even during the interruption of grid voltage, it is recommended to supply the equipment with an Uninterruptible Power Supply (UPS) or battery.
Magnetic field to the mains frequency EN 61000-4-8	3 A/m	3 A/m	Magnetic fields at grid frequency should have the same characteristics as a normal commercial or hospital environment.

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Immunity aspects a r.f.			
PRONEXIBUS™ device is designed to operate in the below specified electromagnetic environment. Client or operator should make sure that the device is used in these circumstances.			
Immunity test	**Test level EN 60601-1-2**	**Conformity level**	**Electromagnetic environment - guidelines**
RF Behaviour EN 61000-4-6	3 Veff from 150kHz to 80MHz	3 Veff from 150kHz to 80MHz	Mobile and portable RF communication devices should not be used nearby PRONEXIBUS™ including the device itself and its accessories and cables, except in cases they respect the recommended separation distances calculated from the equation applicable to the transmitter's frequency Recommended separation distances $d = 1,2 \cdot \sqrt{P}$ from 150kHz to 80MHz $d = 1,2 \cdot \sqrt{P}$ from 80 MHz to 800 MHz $d = 2,3 \cdot \sqrt{P}$ from 800 MHz to 2,5 GHz where **P** is for maximum nominal output power in Watts (W) declared by the manufacturer and **d** is for recommended separation distance in meters (m).
RF Radiated EN 61000-4-3	3 Veff from 80MHz to 2,5GHz	3 Veff from 80MHz to 2,5GHz	
Field intensity from fixed RF transmitters, as determined by an electromagnetic site survey, may be less than the conformity level in each frequency range. Interference may present near equipment marked with the following symbol: 			

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Recommended separation distances between PRONEXIBUS and mobile and portable radio communication devices

PRONEXIBUS™ is designed to operate in an electromagnetic environment where radiated RF disturbances are under control. The client or the operator, by maintaining the minimum recommended distance between PRONEXIBUS™ and other mobile and portable RF equipment, can contribute to prevent electromagnetic interferences, in relation with the maximum output power of radio communication devices. For the minimum recommended distances see the chart below:

The transmitter's maximum nominal output power (W)	**Separation distance to the transmitter's frequency (m)**		
	From 150kHz to 80MHz $d = 1,2 \cdot \sqrt{P}$	**From 80MHz to 800MHz** $d = 1,2 \cdot \sqrt{P}$	**From 800MHz to 2GHz** $d = 2,3 \cdot \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

In case of transmitters with a nominated maximum output power not listed above, the recommended separation distance in meters, can be calculated using the equation applicable to the transmitter's frequency, where P is for maximum nominal output power in watts (W), declared by the manufacturer.

Note:
(1) At 80 MHz and 800 MHz, the range to apply is that of the higher frequency.
(2) These guidelines may not be applied in all circumstances. Electromagnetic propagation is influenced by the absorption and reflection of various structures, objects and persons.