CTU mega 20

DIAMAGNETIC PUMP

DEVICE FOR DIAMAGNETIC THERAPY


CTU mega
PERISO
CTU mega

Index

1. INTRODUCTION

1.1 Introduction to the CTU Mega 20 device

CTU Mega 20 Diamagnetic Pump is a device for physiotherapy and rehabilitation, moreover effective in the field of orthopedics, neurology, aesthetic and sports medicine, that allows you to perform Diamagnetic Therapy. The methodology applies the physical principle of the magnetic repulsion, or diamagnetic effect, that concerns the behavior of water and most of the biological substances once exposed to the effects of High Intensity Pulsed Magnetic Fields. Also called Diamagnetic Molecular Accelerator, along with the Magnetic Field source the system includes a particular RF generator of diathermy which works in combination with the diamagnetic effect, to assist and improve the outcome of the treatments.

The treatments are painless and parameterization procedures are simple and intuitive.
The action mechanisms induced by Diamagnetic Therapy are:

- Movement of liquids
- Endogenous biostimulation
- Pain control

1.2 Introduction to the manual

This manual is an integral part of the equipment supplied with the CTU Mega 20 Diamagnetic Pump, it constitutes documentation and support for use and is not intended for sale.
The reproduction, even partial, without the express consent of the Manufacturer is prohibited.
It is produced by the Manufacturer's Technical Department for exclusive use with the Diamagnetic Pump CTU Mega 20 equipment.

We guarantee that the present manual is related to the equipment supplied. The possible and eventual corrections or updates will be included in new editions.

All information may be subject, without notice, to change by the Manufacturer for purposes and reasons related to technical or business improvements.

The use of the CTU Mega 20 Diamagnetic Pump implies knowledge of this manual in all its parts. Usage not conform to the Manual automatically invalidates the warranty and liability by the Manufacturer.

1.3 Safety precautions and warnings

- Before connecting the CTU Mega 20 Diamagnetic Pump device to the power supply you must ensure that it has the following characteristics:
  - Mains voltage 230 Volt (+/- 10%)
  - Mains frequency 50-60 Hz
  - Network Consumption 2200 VA (800 W) 9,5 A

- It is also necessary that the surrounding conditions are the following:
  - Room temperature from 10 °C to 30 °C
  - Relative humidity from 30% to 75% non-condensing
  - Atmospheric pressure from 700 to 1032 hPa

- The environmental storage conditions must instead be the following:
  - Room temperature from 0 °C to 40 °C
  - Relative humidity from 10% to 80%

- It should be avoided the installation of the equipment in the following cases:
  - Near heat sources
  - Exposed to rain or humidity
  - Exposed to direct sunlight

- The Manufacturer accepts no responsibility for damage or malfunction resulting from:
  - Supply mains do not conform to the above
  - Unsuitable environmental conditions

- Do not use the device:
  - In the presence of combustible gases, flammable vapors, in rooms with oxygen or detonating atmosphere
  - In the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide
  - Near equipment with strong electromagnetic emissions or sensitive to electromagnetic emissions
  - Near to or over other equipment

- Keep the device away from splashing water, even accidental.

- Avoid using the device in combination with monitoring devices.
- Portable and mobile communications equipment can affect the operation of the device.
- In the diamagnetic pump mode the handpiece can be used between 4/5 cm away from the skin of the patient.
- **ATTENTION:** only distilled water should be used in the tank.

Connection to the power supply

Connecting the device to the power supply is simple and immediate, and must be made by the use of the power cable following the instructions below (Chapter 3).

- To avoid the risk of electric shock, this device must be connected only to mains supplies with a protective ground connection
- If the power cable is damaged, it must be replaced only by the manufacturer Periso or by personnel appropriately qualified by Periso.
- Any repair work on the CTU Mega 20 product must be carried out by the manufacturer Periso or by personnel appropriately qualified by Periso.
- The device is not permanently installed and uses the power plug for separation and isolation from the mains voltage.
- The distance between the device and the power cable should be almost equal to 90 cm in order to unplugging the device if needed.

Moving the device

The device is equipped with wheels to facilitate moving in various environments. While moving the device, it is advisable to hold the device to the outer metal frame making sure that the wheel brakes are unlocked, as shown in figure.

- Check that the wheels are unlocked before moving the device.
- Check that the wheel brakes are locked every time you start a treatment.
- Make sure before starting a treatment that the device is blocked on a flat floor.
- It is forbidden to push the device on its side since it can cause it to tip over.

- It is recommended to use gloves to handle the handles of the power module as they may be slightly sharpened.

1.4 Shipping damage

The equipment and all its components and accessories are subjected to careful and accurate testing by our quality control department, which certifies the integrity and proper functioning. Any damage and/or the failure or malfunction, must be promptly reported to the Manufacturer, especially if entirely attributable to the negligence of the carrier. The original packaging must be stored in order to send the device back it to the Manufacturer, for whatever reason.

1.5 Contents of the package

CTU Mega 20 device will be shipped carefully packed in a casing that also contains all the accessories and the manual, provided with the basic equipment. Below is a list of items included in the casing of delivery.

Quantity	Description
1	User and Maintenance Manual
1	Service and Warranty Booklet
1	Declaration of Conformity CE
1	Method of Working
1	Power module
1	Control module
1	Trolley
1	RS232 cable
1	Operating handpiece
2	Return Plates
1	Kit coated electrodes 3 pcs. (50 mm – 75 mm – 80 mm)
1	Kit uncoated electrodes 3 pcs. (50 mm – 75 mm – 80 mm)
1	Conic shaped electrode
1	Shelf
1	Arm with electric piston
1	Plastic water bottle for tank refilling
1	Fork spanner
1	Hexagonal key 3 mm
1	Hexagonal key 5 mm
2	Ignition keys
1	Handpiece spring
1	Diamagnetic Complex Cream

1.6 Warranty Conditions

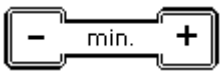
Refer to the Service and Warranty Booklet provided in the shipping wrap. Service life expected for CTU Mega 20 device is 10 years.

1.7 Area of Jurisdiction

For any dispute regarding these conditions the exclusive jurisdiction is the one in Lugano (CH), in Italian Language.

2. GLOSSARY AND WRITING CONVENTIONS

2.1 Glossary of symbols

	Press “Enter” to move to the next screen after the initial one.
	Press “Start” to start.
	Press “Exit” to exit the current screen and to return to the previous one.
	Increase or decrease of the relative activity.
	Increase or decrease the activity time.
	Press “Start” to start the treatment.
	Press “Stop” to interrupt the treatment.
	Press “Sel” to select a determined option or program.
	Press “Reset” to return to initial settings.
	Only one plate in use.
	Two plates in use.
	Caution: high value.

periodically checks the level of water

remember to do the annual service
check that the cables are not damaged
clean the electrodes after each treatment
for the therapy uses only the cream supplied
if the light is red, contact your service!

Service messages that appear at the top of the screen.

Label symbols

	CE mark.		Temperature Limitation.
	Indicates the Name and Address of the Manufacturer.		Humidity Limitation.
	Consult the Instruction Manual.		Atmospheric pressure limitation.
	Applied Component type BF.		Keep away from sunlight.
	Non Ionizing Emissions.		Keep dry.
	Obligatory to read the Instruction Manual.		Forbidden to Push the Device on its side.
	Serial Number.		Batch code.
	ESD sensitive.		Waste Electrical and Electronic Equipment

2.2 Writing Conventions

Abc	Highlighted	Highlights certain parts of the document, where important and particular attention is necessary.
	Note	Notes that put in highlight important instructions for specific uses.
	Caution	These messages appear before the description of operations which, if not observed, may cause damage to the equipment or its accessories, and to people.
	Forbidden	This message is placed before operations that must never be carried out.

3. INSTALLATION

3.1 Installation Instructions

The CTU Mega 20 device must be extracted from the front of the box after removing the safety locks. Then remove all accessories and check its integrity.
The device comes partially assembled, the only operations to be performed are:

- Mount the arm
- Assemble the electrodes shelf
- Connect the cables

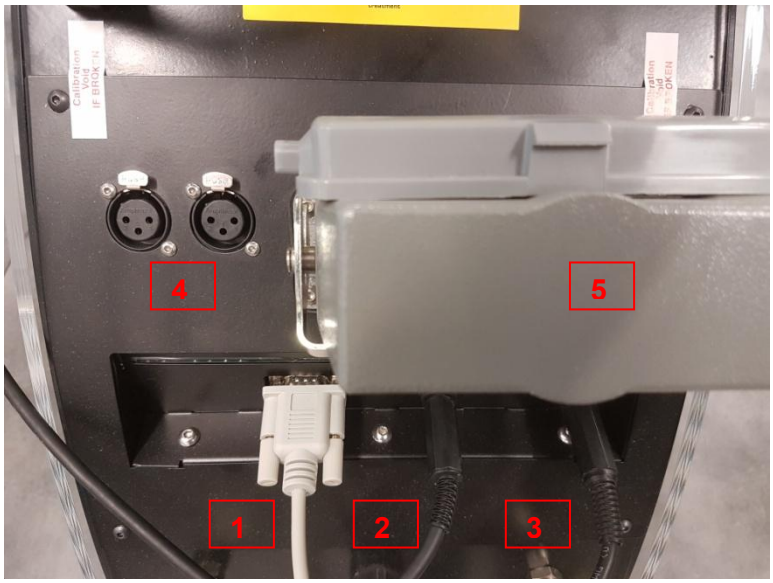
Attach the arm with the supplied screws: two to attach it to the trolley (a) and one to secure it to the electric motor (b).

Assemble and secure the shelf with appropriate and supplied screws.

Fix the control module on the trolley with four supplied screws.

Button to move up the arm.

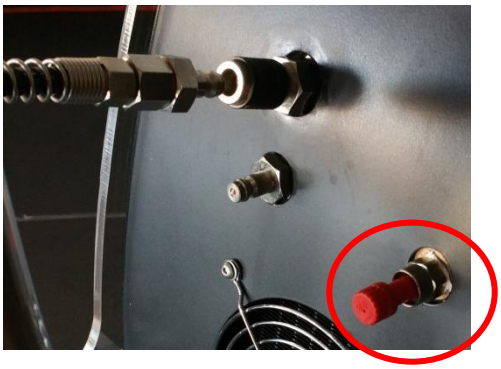
Button to move down the arm.



1) Connect the female DB9 pin connector to its male connector on the back of the power module.
2) Connect the plug of the control module to the socket.
3) Connect the motor plug of the arm to the connector.
4) Connect the plugs of the neutral plates to connectors.
5) Connect the handpiece connector to its socket.

CAUTION: Connect the handpiece to the connector of the power module always when the device is disconnected to the power supply.

6) Connect the female DB9 pin connector to its male connector on the back of the control module.



7) Plug the connectors of the water pipes of the handpiece to the respective sockets, applying slight pressure.

Removable cap for topping up with dematerialized water.

8) Connect the device to the power network.

- It is always advisable not to use extension cords and/or multiple sockets between the wall outlet and power card, since possible malfunctions and system damage could result from this type of connection. If however, it becomes necessary to use this type of connection, make sure that those components are fully functional and equipped with a grounding conductor.

- The device must be positioned in such a way that it is feasible to operate on the plug or on the switch if it is necessary to interrupt the connection with the mains.

Turning ON and OFF the device

To turn on the device, turn the key on the front of the power module clockwise; to turn it the device, turn the key counterclockwise.

Emergency Button

If it is necessary to IMMEDIATELY block the device push the red button shown in the figure.

To unlock the device, rotate the button in the direction of the arrow.

- No modification of this equipment is allowed.
- Never turn off the device by unplugging the power cable in order to avoid software damage or anomalies.
- The machine stops when a red light in the back switch on the back of the module; it indicates a low level of cooling water, meaning that the head of the handpiece is not cooled adequately. In this case, top up the cooling water with the supplied bottle.
- If the problem persists, contact PERISO Technical Support:

  Email: assistancemed@periso.ch
  Telephone: +41 919359400

3.2 Operating handpiece

The CTU Mega 20 Diamagnetic Pump device is equipped with a moveable operating handpiece. Inside the handpiece there is a coil for the generation of the magnetic field. This coil is equipped with a liquid cooling system.

The mobile hand piece must be connected to the device by means of the relative 3 connectors. In particular, it should be performed in the following sequence:

1) Connect the two cooling tubes, paying particular attention to the direction of insertion;
2) Connect the power cord.

- The handpiece must never fall on the ground. It should be always clean, after each treatment exclusively with mild liquid detergent.
- Do not leave the handpiece for too long on the same area of the body being treated, as it may cause burns.
- Periso SA recommends to carry out treatments lasting 20/30 minutes and leave the CTU MEGA 20 device on standby without performing any treatment for at least 10 minutes, to avoid overheating of the handpiece.

Replacing of the operating handpiece

The replacement of the operating handpiece is easy to perform and should be done by following the procedure below:

1) Disconnect the power supply first;
2) Disconnect the hydraulic joints, pressing lightly on the sealing ring (the sealing rings are self-locking to prevent accidental refrigerant leakage);
3) Slide the cables out of the mechanical arm guide;
4) Detach the cables from the retaining clips in the mechanical arm;
5) For the installation of the new hand piece repeat the operations in reverse.

4. OPERATING INSTRUCTIONS

4.1 Required skills

The CTU Mega 20 Diamagnetic Pump is a device intended to be used by medical staff and/or physiotherapist. It can be used in:

- Physiotherapy Clinics and Centers
- Hospital Rehabilitation Clinic
- Aesthetic Medicine

4.2 Side effects

The CTU Mega 20 Diamagnetic Pump equipment does not cause any kind of intolerance or unpleasant events following the treatment sessions. Problems may arise as the result of a combination of factors involving the inappropriate use of the device in extent and in modality of treatment. The use of the device is operator-dependent (doctor or physiotherapist and in any case qualified). Treatments contrary to the characteristics of the pathology and of the subject being treated may, theoretically, cause cell damage as well as non-thermal effects of unknown nature.

- The manufacturing company is not liable for the misuse of medicines, over/under doses or of inappropriate designation to the pathology being treated.

4.3 Operating Section

Turn on the device using the power key located on the front of the power module and unlock the emergency button. When the device is on, the following screen will appear:

Press the ENTER button to move to the next screen.

The system will then go to the selection of the operating mode screen, allowing you to

select from three possible applications:

- Movement of liquids;
- Endogenous biostimulation;
- Pain Control.

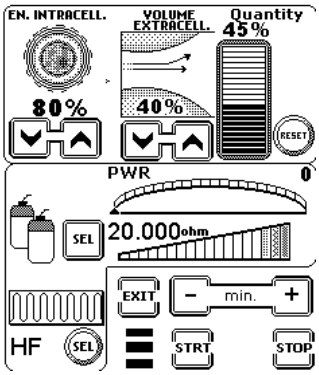
Select one of the operating modes among those displayed.

Depending on the operating mode required, select the working parameters related to the section Magnetic Field and relative to the section Radio Frequencies.

Press the ESC button to return to the home screen.

Movement of Liquids

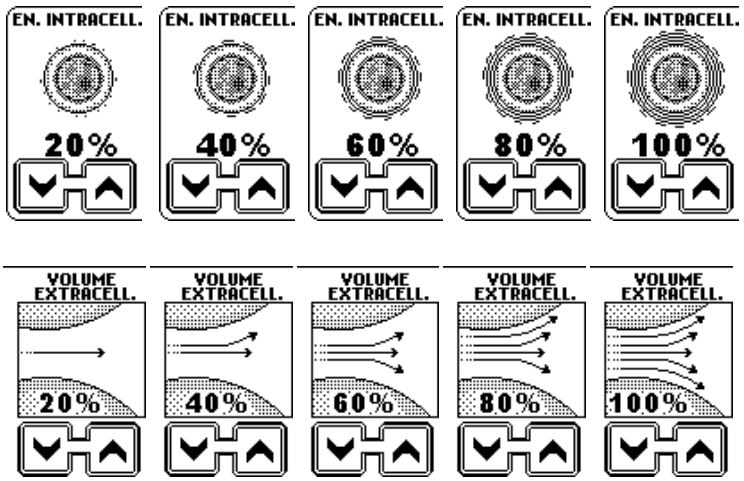
Action on intracellular and extracellular fluid



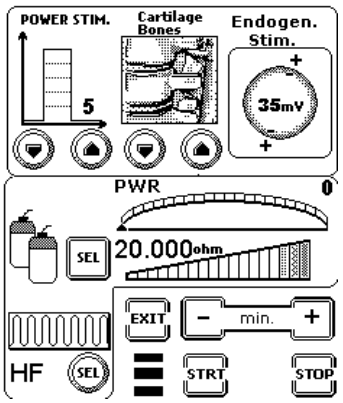
In treatments aimed at movement of liquids, it is possible to select the greater or lesser activity on intracellular liquid than those extra- cellular, or vice versa, by selecting the percentage of activity.

The movement of liquids mode is used every time you need drainage of the extracellular matrix or metabolic stimulation of the cells. This mode can be performed alone or alternating the endogenous stimulation.

The intracellular liquid movement mechanism supports the reconstitution and the regeneration of damaged tissues. Acting on the keys, you can select a higher or lower activity/application on intracellular liquid in respect to the extracellular:



Endogenous Biostimulation



Biostimulation

It corresponds to the amplitude of electrical stimulation induced within the tissues.

You can operate selectively, for each specific tissue, choosing the parameter corresponding to the activity that is intended to get on at cellular and sub-cellular level.

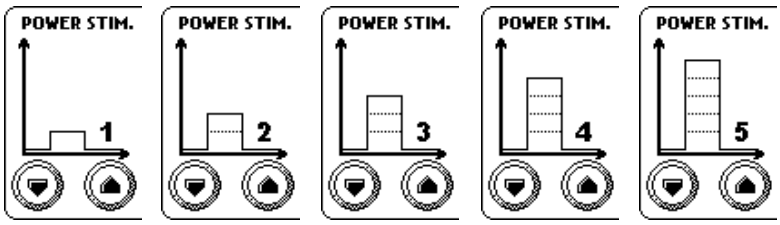
With this mode you can create a particular tissue biostimulation:

- endogenous type, developed directly within the tissue;
- isotropic type, that is homogeneous throughout the tissue invested by the magnetic field;
- cell type, allowing you to restore the metabolic activities of the cells.

For this operating mode you can select two parameters:

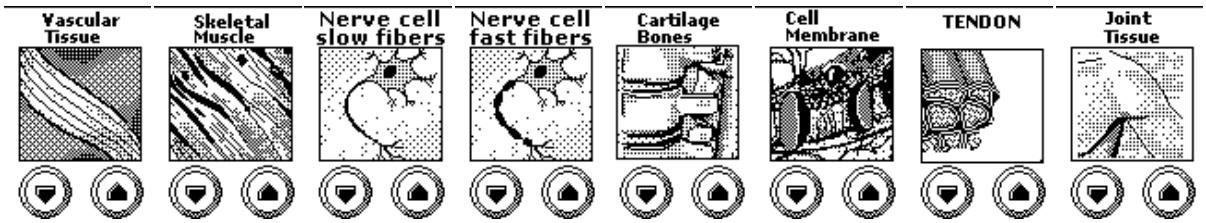
- Stimulation Power

  This parameter corresponds to the magnetic field gradient used and allows you to select a greater or lesser intensity of tissue stimulation.



- Treatment Target

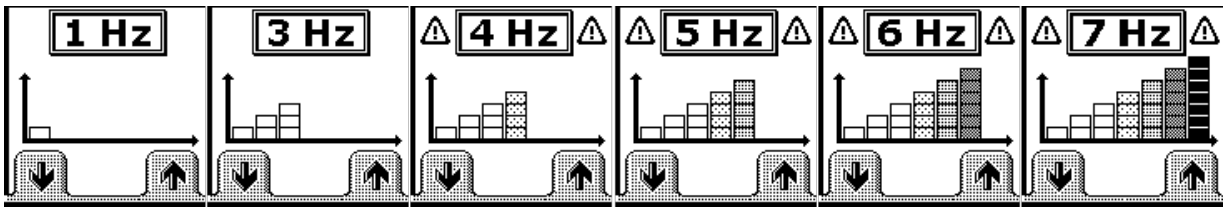
  Thanks to variations of the intrinsic frequency rate managed by the machine, it is possible to select the tissue to be stimulated touching the corresponding icon.



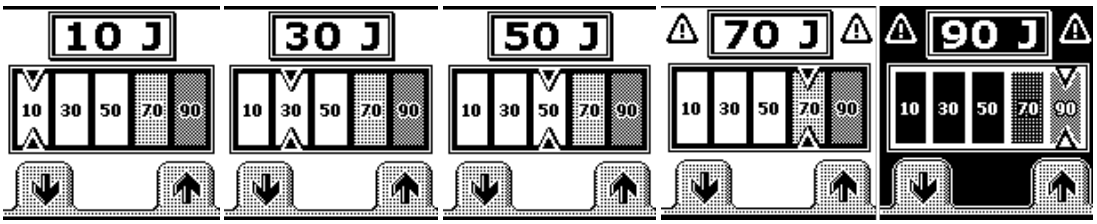
Pain Control

In this operating mode you can treat acute or chronic pain.

The parameters on which to interact are Joule and Hz.
The Hz represent the repetition frequency of the pulses generated by the magnetic field. By pressing the buttons with the arrow keys you can increase or decrease the frequency. It ranges from a minimum of 1 Hz to a maximum of 7 Hz.



The Joule represents the strength of the magnetic field generated. By pressing the buttons with the arrow keys you can increase or decrease the power. The possibilities are: 10J, 30J, 50 J, 70 J, and 90 J.



4.4 Radiofrequency for capacitive and resistive diathermy

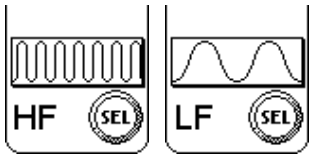
Parameterization of capacitive and resistive diathermy

Radiofrequencies have as primary therapeutic purpose the analgesic effect and the oxygenation of the tissues due to vascular effects. The capacitive energy transfer allows greater activity on soft tissues (muscle, skin, etc.) while the resistive energy transfer allows an increased activity on the hard tissues (bones, tendons, etc.).

You can select the following activities:

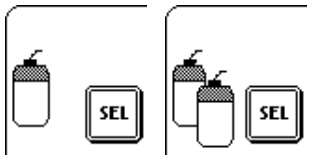
- Frequency

  You can select the emission frequency, High Frequency (HF) or Low Frequency (LF), for the depth of action on tissues. In particular, HF allows more surface activity; LF promotes deeper action in the tissues.



- Neutral plates

  Depending on the area of the body to be treated, you can select "single plate" or "double plate".



- Radiofrequency power

  The power adjustment from 0% to 100%, favors biostimulation processes and re-energizing of tissues.

The procedure for the correct adjustment of the power is as follows:

1) Select the area of the body being treated. Prepare the patient in the most appropriate position.

2) Place the neutral plate in position perpendicular to the CTU Mega 20 handpiece. Apply on neutral plate the right amount of the specific cream, such as to entirely cover the surface of the plate.

3) Choose the capacitive or resistive electrode to be mounted at the tip to the CTU Mega 20 handpiece, depending on the region and the pathology to be treated.

4) Select the emission frequency HF (High Frequency) or LF (Low Frequency).

5) Spread on the area to be treated an adequate amount of proper cream, to facilitate the sliding of the CTU Mega 20 handpiece during treatment.

6) Place the CTU Mega 20 handpiece on the treatment area and slowly raise the power by using the gray power meter on the front of the display.

It is important to remember that with the CTU Mega 20 there is the automatic recognition of the capacitive and/or resistive electrode, so it must not be preselected on the display.

Reading and recording of skin impedance system

This particular feature allows you to track the changes in skin impedance, with respect to energy delivered, allowing you to monitor the progress of treatment sessions.

5. INDICATIONS, CONTRAINDICATIONS AND PRECAUTIONS

5.1 Clinical indications

The use of CTU Mega 20 is indicated for the following scopes:

- Acceleration of the healing process (formation of the bone callus) in the treatment of the fractures of the long bones (fracture gap < 1 cm).
- Reduction of pain and inflammation in musculoskeletal disorders (e.g. pubalgia, tendinitis, sprains, contractures and muscle hematomas)
-Liquids drainage in post -traumatic edema and in lymphedema.

Below, are reported some examples of suggested treatments (these are only suggested treatments, the choice of the treatment protocol is solely responsibility of the medical/paramedical personnel in charge):

• **Reduction of pain and localized inflammation - Knee Osteoarthritis**
PROTOCOL
Magnetic Field=2 Tesla; Intensity=90 J; frequency of impulses=7Hz; duration=30minutes/session and 1 session/day for a maximum period of 3 weeks.

EXCLUSION CRITERIA
Before performing the treatments with PEMF CTU Medical Device – PERISO SA, all the patients received a clinical evaluation to exclude patients with: open physis, inflammatory joint disease. Acromegaly, Charcot's arthropathy, Haemochromatosis, Wilson's disease, Ochronosis, terminal illnesses/malignancies, pregnancy or lack of contraception use in women of childbearing age, use of pacemaker or any electrical device and ferromagnetic implants in the area of treatment

• **Reduction of pain and localized inflammation - Chronic Low Back pain**
PROTOCOL

Magnetic Field=2 Tesla; Intensity=90 J; frequency of impulses=7Hz; duration=30minutes/session and 3 session/week for a maximum period of 3 weeks.

EXCLUSION CRITERIA

Before performing the treatments with PEMF CTU Medical Device – PERISO SA, all the patients received a clinical evaluation to detect: unsuitable physiological states (pregnancy or lack of contraception use in women of childbearing age), open physis, terminal illnesses/malignancies, , use of pacemaker or any implanted electrical device, ferromagnetic implants in the area of the treatment.

• Reduction of pain and localized inflammation - Ankle sprain

PROTOCOL

Magnetic Field=2 Tesla; Intensity=90 J; frequency of impulses=7Hz; duration=30minutes/session and only 1 session).

EXCLUSION CRITERIA

Before performing the treatments with PEMF CTU Medical Device – PERISO SA, all the patients received a clinical evaluation to detect: Patients younger than 18 years (open physis), severe instability as sign of a third-degree of the lesion, chronic ankle injury on the contralateral side, unsuitable physiological states (pregnancy), use of pacemaker or any electrical device, ferromagnetic implants in the treatment area .

• Formation of bone callus – Treatment of delayed unions of fractures of the long-bone

PROTOCOL

Magnetic Field=2 Tesla; Intensity=90 J; frequency of impulses=7Hz; duration=30minutes/session and 1 session/day for a maximum period of 4 – 6 weeks).

EXCLUSION CRITERIA: Implant loosening or failure, infection, nonunion (healing failure after more than 9 months or without any clinical or radiographic sign of progression to union within the last 3 months), a fracture gap greater than 5 mm, presence of ferromagnetic implants within the fracture gap. Before performing the treatments with PEMF CTU Medical Device – PERISO SA, all the patients received a clinical evaluation to detect: Unsuitable physiological states (pregnancy or lack of contraception use in women of childbearing age). In addition the patients with metabolic disorders were excluded as were those patients who received medications that could affect fracture healing. Patients with Open Physis, terminal illnesses/malignancies, use of pacemaker or any implanted electrical device.

• Liquid drainage - Treatment of the Lymphedema

PROTOCOL

Executive procedure: the application of diamagnetic therapy was performed according to the scheme: PEMF (Magnetic Field=2 Tesla; Intensity=90 J; frequency of impulses=7Hz; duration=30minutes/session), plus diathermia with resistive system, electrical resistance of 500-1000 Ohm according to the measured impedance (the device is provided with an

impedance detector that permits to highlight tissue areas with high resistance to magnetic fields, where it is necessary to increase the electrical resistance up to 1000 Ohm) plus compression.
The treatment was performed following the lymphatic draining directions, in this way combining the advantage of the hand-made lymphatic drainage with the energy developed by the machinery.
The duration of diathermia application was 30-40 minutes and it was repeated three times per week for about two months (for a total of 20 applications).

EXCLUSION CRITERIA

Before performing the treatments with PEMF CTU Medical Device – PERISO SA, all the patients received a clinical evaluation to detect: unsuitable physiological states (pregnancy or lack of contraception use in women of childbearing age), patients with open physis, terminal illnesses/malignancies, pregnancy or lack of contraception use in women of childbearing age, and use of pacemaker or any implanted electrical device were excluded, and ferromagnetic implants.

5.2 Contraindications

IMPORTANT

Before performing one or more treatments with the CTU Mega 20 Diamagnetic Pump device, you must submit the patient to a medical screening in order to detect:

- Unsuitable physiological states;
- Presence of ferromagnetic material within the areas of the body to be treated.

The application is limited to the treated area, and is then will sent back to the clinical evaluation of the physician, in case of :

- Shrapnel, metal fragments, ferromagnetic substances
- Clips of previous surgery
- Clips on aneurysms (blood vessels), aorta, brain
- Heart valves
- Distractors spine
- Infusion pump for insulin or other medications
- Cardiac pacemaker and other electronic devices
- Neuro stimulators, electrodes, systems of the brain or subdural
- Spinal or ventricular derivation
- Crystalline lens prosthetics
- Ferromagnetic prosthetics

The application is absolutely prohibited on patients/subjects with:

- Serious Heart disease
- Tumors
- Fertile epiphysis
- Pregnancies

Hypotension: For people with low blood pressure (hypotension): the arterial pressure should be checked before and after treatment and, if necessary, the duration of the session should be decreased and the time between two sessions should be increased.

- The majority of the contraindications listed above are based on a series of non-existing official results but only on hypothetic or potentially of patients treated with these conditions. In any case, in the presence uncertainty or of undefined symptoms, if in doubt, the patient should consult the doctor.

5.3 Precautions

- Begin treatment only if the patient has no ferromagnetic deposit/objects or similar materials in the area to be treated and focus on knowing the health condition of the subject to be treated.
- Ensure that both the operator and the patient do not wear any metallic object.
- The device must be operated only by personnel trained and qualified to use the device.
- In case of absence of personnel trained in the use of the machine, turn off the device by the general switch on the system.
- Handle with care the CTU Mega 20 handpiece, making sure not to cause damage (scratches, drops, bumps, etc.).
- After each use, please check the integrity of the connection cables and associated connectors, and all moving or fixed parts to assure good working order.
- In case of damage or deterioration of the cables or power supply, contact support.
- The use of accessories, transducers and cables other than those supplied by the manufacturer, is prohibited. It could result in increased or decreased emissions or other compromising the optimal operating/performance of the device.
- Set best working temperature level.
- Make sure that the CTU Mega 20 has no contact with liquids.
- In the event of malfunctions, stop the treatment and notify the technical service.
- In the case of smoke emission, excessive heat or noise from the device it must be stopped immediately.
- In case of irregular temperature increase of the operating handpiece, you must stop the treatment immediately, since this is an index of malfunction.
- You must not use the device in presence of fuel gases, flammable steams, in room with oxygen or detonating atmosphere.
- In case of falling from a height exceeding 30 cm of the insulated capacitive electrode, avoid the further use of this electrode.
- The patient must not come into contact with earthed metal parts during treatment, or with an appreciable ground capacity.
- A low level of dispensing, or incorrect operation, can be caused by a faulty application of the neutral plate. In this case, check the connections.
- The power of electrodes can change during use.

- In the event of contemporary use of radiofrequency:
  - Make sure that the neutral return plate has been placed.
  - Ensure that the neutral plate is totally in contact with the skin on the whole surface to be treated.
  - Ensure that the neutral plate is not placed in direct contact with open wounds or damaged skin.
  - Ensure that the neutral electrode is at position 0 when placed or withdrawn from the body.
  - The device must be used only on patients with intact skin or with the interposition of a suitable protection means.
- The device will have to be disposed of in accordance with standards for the disposal of WEEE.

All devices from PERISO SA are marked with the following symbol:

According to art. 13, paragraph 4 of the Legislative Decree no. 151/2005, all electrical and electronic equipment shall include, under the responsibility of the manufacturer, in a clear, visible and indelible mode, an indication enabling identification of the same manufacturer and the symbol indicating that the product must be disposed of separately.

Disposal of RAEE waste and disposal rules in EU countries outside Italy or outside the EU

As required by national regulations, this equipment cannot be disposed of as municipal waste. Therefore, at the end of its life cycle, after performing and following all the necessary operations for a proper disposal, the equipment must be deposited at one of the recycling centers for waste from AEE. Refer to the appropriate collection centers of the City of reference/belonging, which assures the functionality, accessibility and adequacy of separate collection systems, thus allowing final holders and distributors to give the waste free of charge to the collection center in their territory. This equipment can be returned to the distributor, to be discarded in accordance with current regulations. In regards to disposal in countries outside of Switzerland , the user and the distributor must comply with local regulations in the country of use of the device.

6. MAINTENANCE AND TROUBLE SHOOTING

6.1 Cleaning and disinfection

The cleaning of the device's frame must be done with a damp cloth using neutral and non-aggressive detergents.

Do not use alcohol for cleaning.

The electrodes and the neutral plates should be cleaned and disinfected with a damp cloth, warm water and a non-aggressive detergent after each use in order to prevent any deposits from solidifying and difficult to remove as well as potentially damage the accessories and the handpiece.

After cleaning the electrodes and the neutral plates make sure to dry them completely.

Clean the handpiece, the electrodes and the neutral plates on first use.

- Make sure that the device is disconnected from the power supply when cleaning it.
- Before cleaning the neutral plates, disconnect them from the device.
- Only use the cream produced by Periso SA for treatments with the CTU Mega 20 Diamagnetic Pump.

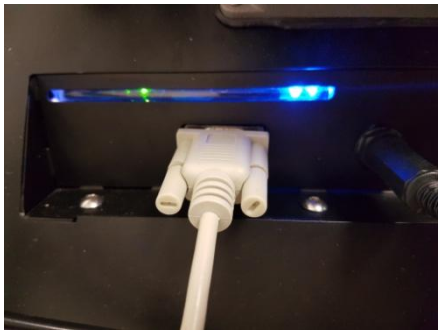
6.2 Guide to the correct maintenance

- The device must be subjected to annual review and must be carried out by the Periso manufacturer or by qualified personnel from Periso.
- The device must be installed and put into service in accordance with the information contained in this manual.
- Make sure that it is disconnected from the mains during maintenance of the device.
- Do not leave the equipment exposed to humidity, rain, direct sunlight.
- Do not spill liquids on the equipment and device and do not place any objects on the device. Do not leave voltage cables in tension in points of passage, to prevent accidental damages.
- Connect the device only to a system that complies with national standards of the user's Country.
- In case of water flow interruption the pump stops and the magnetic field is interrupted. A beep sounds and a red light comes on at the back of the device.

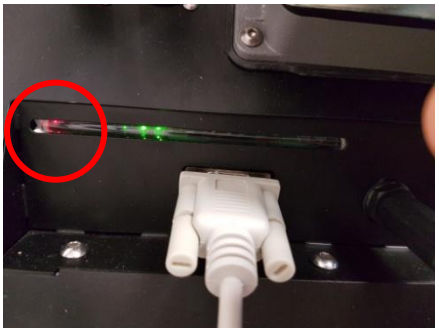
Check with each use that the red light on the back of the power module is not on (insufficient radiator water level) and that blue / green lights are on. If the red light is on, remove the red cap and fill the tank using only demineralised water and the supplied bottle.

If the red light is on, only after having disconnected the device from the mains, open the red cap of the tank (indicated in the image above) and fill the tank using only demineralised water and the supplied bottle. Close the cap and reconnect the device to the mains, leaving the handpiece lying on the floor. Restart the device and let it run for about 10-15 minutes and check that the light is blue / green again.

Turn off the device, reposition the handpiece on the arm and restart.
Check that the magnetic field output is correct.



Blue / green light: correct water level in the radiator.



Red light: insufficient water level in the radiator. It is necessary to fill the tank.

Type of Verification	Frequency	Connection to the mains supply
Power on	Daily	Yes
Integrity of neutral plates cables	Daily	No
Integrity of the handpiece cables	Daily	No
Integrity of the power supply cable	Daily	No
Integrity of power connection cable – controller module	Monthly	No
Integrity of neutral plates	Each use	No
Integrity of the handpiece	Each use	No
Integrity of the electrodes	Each use	No
Level of water in the tank	Each use	No

6.3Troubleshooting

Problem	Potential Solution
Power source	
The device does not switch on.	Is the power cable connected to 230V 50 / 60Hz? Has the key been turned to the ON position? Check that the emergency button it is not pressed.
The display does not switch on.	Has the key been turned to the ON position? The green LED, on the back of the power module, are turned on but nothing is shown on the display? Make sure the cable connections between the device controller and the power module are correct and

The arm does not work.	properly plugged. - Check that the emergency button it is not pressed. - The motor plug of the arm is regularly pushed forward and well connected, on the back of the power module? - The plug of the control shelf is regularly pushed forward, on the back of the power module? - The CTU Mega 20 is connected to a 230V 50 / 60 Hz power source? - The key has been turned to the ON position? - Check that it is not pressed the emergency button.

Visualization

With the device on you cannot select some or all items from the display menu when entering the work templates.	- Is the cable between the device controller and the power module is connected properly? - Check the display of the same functionality in different points. - Ensure that the display is not greasy or dirty and that there is no cover film.
The device turns on but the display is not clearly visible.	- Is the cable between the device controller and the power module is connected properly? - Try adjusting the contrast of the display using the trimmer on the back of the control module by turning the same, very slowly, first to the right and then to the left.
When the device is on, the words written on the screen disappears.	- Make sure the USB cable between the control module and the power module is connected correctly.

- Make sure there are no devices that emit strong electromagnetic fields nearby.
- Turn off the device, disconnect all connection cables, reinsert them, switch the device back on.

On the display of the horizontal or vertical lines are shown that make partial reading of the information.

- Is the cable between the device controller and the power module connected properly?
- Check the display of the same functionality in different points.
- Ensure that the display is not greasy or dirty and that there is no cover film.

Emission

The device turns on, but the handpiece does not supply the magnetic field output.

- Has a work program been set and has been pressed START on the display?
- The handpiece is properly connected to the power module? Check the integrity of the cable. Check the integrity of the connector.
- The connection cable is connected correctly to the power module/controller?
- Check the correct amount of water in the radiator, making sure that the indicator light is green/blue color. The red light indicates missing water or below the necessary level. If the light is red: turn off the device by unplugging it from the mains; open the tank cap and top up the water in adequate quantities, using the filler special tool provided with the device; close the cap; place the dispenser handle lying on the ground; restart the device by pressing start on the display; to

	operate the device for about 10-15 minutes and then verify that the light is green/blue again; again off the device; reposition the handpiece on the arm; reboot the device and try that the flow of the magnetic field is correct.
The device turns on, but the handpiece does not emit radio frequencies.	- The hand piece is properly connected to the power module? - The connection cable is connected correctly to the power module/controller? - Are the electrodes, neutral plates and the cables of the neutral plates intact? Verify its integrity by performing the tests with the various electrodes or the second return plate. - Check the correct amount of water in the radiator, making sure that the indicator light is green/blue color. The red light indicates missing water or below the necessary level. If the light is red: Turn off the device by unplugging it from the mains; Open the tank cap and top up the water in adequate quantities, using the filler special tool provided with the device; close the cap; place the dispenser handle lying on the ground; restart the device by pressing start on the display; to operate the device for about 10-15 minutes and then verify that the light is green/blue again; again off the device; reposition the handpiece on the arm; reboot the device and try that the provision of frequencies is correct.
The device turns on, but the handpiece does not emit.	- Are the cables between the controller and the power module correctly connected? - Is the handpiece and its connection

cable intact?

- If the handpiece cable is intact, check that all the connection connectors are also correct.

If the problem persists, please contact PERISO SA Service and support to send the device to the service center. It is obligatory to make a careful description of the problem by sending a written communication to the service center to the following e-mail address:

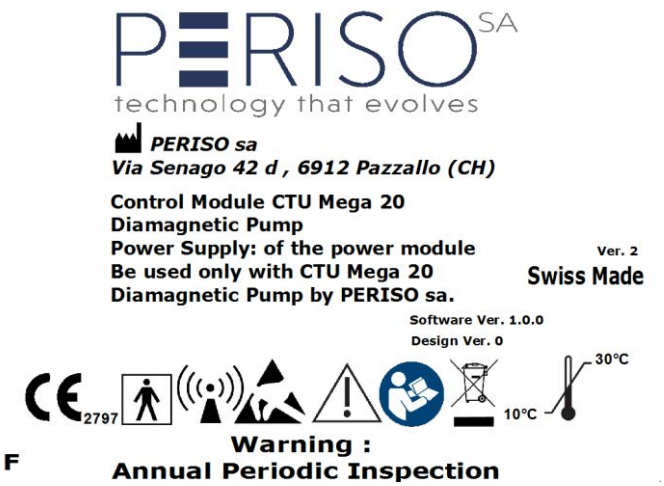
E-mail: assistancemed@periso.ch

7. TECHNICAL SPECIFICATIONS

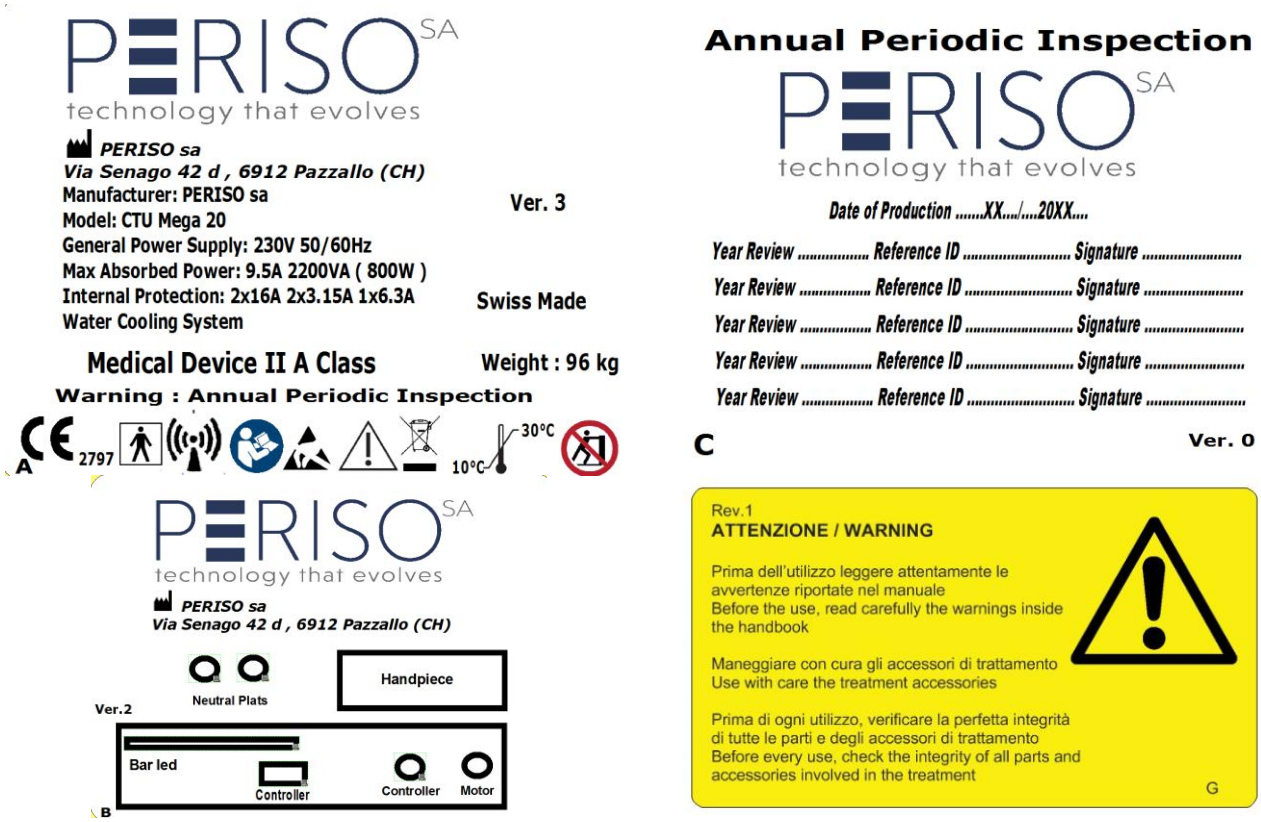
Model	CTU Mega 20
Commercial Denomination	Diamagnetic Pump
General power supply	50/60 Hz 230 Vac
Current Consumption	9.5 A
Power Absorption	2200 VA (800 W)
Conversion factor	0.36
Working frequency	1 Hz – 7 Hz
Emission type	Pulsed
Magnetic Field Generator	Electromagnetic Coil
Internal Protection	2 fuses of 16 A + 2 fuses of 3,15 A + 1 fuse of 6,3 A + 1 thermal magnetic breaker of 10 A **Not replaceable by the operator**
Diathermy Frequency	425 kHz (+/- 5%)
Diathermy power	50 W (+/- 20%)
Cooling system	Liquid
Display	Digital Touch Screen display
Manufacturer	PERISO SA Via Senago 42d 6912 Pazzallo Switzerland CHE-101.514.101 IVA
Medical class	II A
Size	80 x 75 ×160 cm
Weight	96 kg approx
Working temperature	From 10 °C to 30 °C
Storage temperature	From 0 °C to 40 °C
Working Humidity	From 30% to 75% non condensing
Storage Humidity	From 10% to 80% non condensing
Atmospheric pressure	From 700 to 1032 hPa

8. INFORMATION PROVIDED BY THE MANUFACTURER

Label of the control module



Label of the power module



Label of the mobile arm

Label of the handpiece

Serial number label

Label on the connector of the handpiece

Label on the trolley

Applied parts connections labels (neutral plates (M) – handpiece (N))

Packaging label

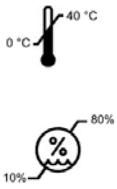
Model: **CTU MEGA 20**
ID PERISO: **30.00.001**
HS Code: **9018.9084**
Dimensions: ***80x60x158cm***
Weight: **144 kg +/- 5%**

PERISO SA
technology that evolves
Via Senago 42 d 6912 Pazzallo
Switzerland

PERISO CODE	DESCRIPTION
A388.019	○ 1 User and Maintenance Manual
A388.021	○ 1 Service and Warranty Booklet
A388.020	○ 1 Declaration of Conformity CE
A388.023	○ 1 Method of Working
30.01.001	○ 1 Power module
30.03.002	○ 1 Control module
30.04.005	○ 1 Trolley
A155.556	○ 1 RS232 cable
30.01.002	○ 1 Operating handpiece
30.04.016	○ 2 Return plates
30.04.018	○ 1 Coated electrode kit 3 pcs. (Ø 50 - Ø 75 - Ø 80)
30.10.005	○ 1 Uncoated electrode kit 3 pcs. (Ø 50 - Ø 75 - Ø 80)
A2000.013	○ 1 Cone electrode
30.04.003	○ 1 Shelf
30.04.004	○ 1 Arm with electric piston
A206.016	○ 1 Plastic water bottle for tank refilling
A102.179	○ 1 Fork panner
A102.176	○ 1 Hexagonal key 3 mm
A102.220	○ 1 Hexagonal key 5 mm
A512.069	○ 2 Ignition keys
A353.163	○ 1 Handpiece spring
A716.004	○ 1 Diamagnetic Complex Cream

Environmental conditions of operation:

Environmental conditions storage:



Avoid storage in the following cases:

Medical device class IIA

Eti. imb. Rev. 5 del 28/08/2019

Tables of electromagnetic emissions, electromagnetic immunity, recommended separation distances

TABELLA 1 TABLE 1		
GUIDA E DICHIARAZIONE DEL COSTRUTTORE – EMISSIONI ELETTROMAGNETICHE – PER TUTTI GLI APPARECCHI ED I SISTEMI GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS – FOR ALL EQUIPMENT AND SYSTEMS		
L' apparecchio CTU MEGA 20 è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore dell'apparecchio CTU MEGA 20 deve garantire che esso venga usato in tale ambiente. The Equipment CTU MEGA 20 is intended for use in the electromagnetic environment specified below. The customer or the user of the Equipment CTU MEGA 20 should assure that it is used in such an environment.		
Prova di emissione Emissions Test	Conformità Compliance	Ambiente elettromagnetico – Guida Electromagnetic environment - Guidance
Emissioni RF RF emissions CISPR 11	Gruppo 1 Group 1	L' apparecchio CTU MEGA 20 utilizza energia RF solo per il suo funzionamento interno. Perciò le sue emissioni RF sono molto basse e verosimilmente non causano nessuna interferenza negli apparecchi elettronici vicini. The equipment CTU MEGA 20 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Emissioni RF RF emissions CISPR 11	Classe B Class B	L' apparecchio CTU MEGA 20 è adatto per l'uso in tutti i locali compresi quelli domestici e quelli collegati direttamente ad un'alimentazione di rete pubblica a bassa tensione che alimenta edifici usati per scopi domestici. The equipment CTU MEGA 20 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Emissioni armoniche Harmonics emissions IEC 61000-3-2	Classe A Class A	
Emissioni di fluttuazioni di tensione/flicker Voltage fluctuation/flicker emissions IEC 61000-3-3	Conforme Complies	

TABELLA 2
TABLE 2

GUIDA E DICHIARAZIONE DEL COSTRUTTORE – IMMUNITÀ ELETTROMAGNETICA – PER TUTTI GLI APPARECCHI ED I SISTEMI GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY – FOR ALL EQUIPMENT AND SYSTEMS			
L'apparecchio CTU MEGA 20 è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore dell'apparecchio CTU MEGA 20 deve garantire che esso venga usato in tale ambiente. The equipment CTU MEGA 20 is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment CTU MEGA 20 should assure that it is used in such an environment.			
Prova di immunità Immunity Test	Livello di prova IEC 60601 IEC 60601 test level	Livello di conformità Compliance level	Ambiente elettromagnetico – Guida Electromagnetic environment - Guidance
Scarica elettrostatica (ESD) Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV a contatto_contact ±8 kV in aria_air	±6 kV a contatto_contact ±8 kV in aria_air La prova non è stata eseguita sul connettore del display poiché è presente il simbolo IEC 60417-5134 di sensibilità alle scariche elettrostatiche. The test is not been performed on display connector because the device is provided with IEC 60417-5134 symbol for ESD sensitivity.	I pavimenti devono essere in legno, calcestruzzo o in ceramica. Se i pavimenti sono ricoperti di materiale sintetico, l'umidità relativa dovrebbe essere almeno 30%. The floors must be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Transitori/treni elettrici veloci Electrical fast transient/burst IEC 61000-4-4	±2 kV per le linee di alimentazione di potenza_for power supply lines ±1 kV per le linee di ingresso/uscita_for input/output lines	±2 kV per le linee di alimentazione di potenza_for power supply lines ±1 kV per le linee di ingresso/uscita_for input/output lines	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. The mains voltage quality should be that of a typical commercial or hospital environment.
Sovratensioni Surge IEC 61000-4-5	±1 kV linea – linea line-line ±2 kV linea - terra line – earth	±1 kV linea – linea line-line ±2 kV linea - terra line - earth	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. The mains voltage quality should be that of a typical commercial or hospital environment.
Buchi di tensione, brevi interruzioni e variazioni di	<5% U_T	<5% U_T	La qualità della tensione di rete dovrebbe essere quella di un tipico

tensione sulle linee di ingresso dell'alimentazione Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	(>95% buco in_dip in U_T) per_for 0,5 cicli_cycle 40% U_T (60% buco in_dip in U_V) per_for 5 cicli_cycles 70% U_T (30% buco in_dip in U_T) per_for 25 cicli_cycles <5% U_T (>95% buco in_dip in U_T) per_for 5 sec	(>95% buco in_dip in U_T) per_for 0,5 cicli_cycle 40% U_T (60% buco in_dip in U_V) per_for 5 cicli_cycles 70% U_T (30% buco in_dip in U_T) per_for 25 cicli_cycles <5% U_T (>95% buco in_dip in U_T) per_for 5 sec	ambiente commerciale o ospedaliero. Se l'utilizzatore dell'apparecchio CTU MEGA 20 richiede un funzionamento continuato anche durante l'interruzione della tensione di rete, si raccomanda di alimentare l' apparecchio CTU MEGA 20 con un gruppo di continuità (UPS) o con batterie. The mains voltage quality should be that of a typical commercial or hospital environment. If the user of the CTU MEGA 20 device requires continued operation also during the voltage mains interruptions, it is recommended to power the CTU MEGA 20 device with an uninterruptible power supply or a battery.
Campo magnetico a frequenza di rete (50/60 Hz) Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	I campi magnetici a frequenza di rete dovrebbero avere livelli caratteristici di una località tipica in ambiente commerciale o ospedaliero. The mains frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Nota/e U_T è la tensione di rete in c.a. prima dell'applicazione del livello di prova. U_T is the a.c. mains voltage prior to application of the test level.			

TABELLA 3

TABLE 3

GUIDA E DICHIARAZIONE DEL COSTRUTTORE – IMMUNITÀ ELETTROMAGNETICA – PER GLI APPARECCHI ED I SISTEMI CHE NON SONO DI SOSTENTAMENTO DI FUNZIONI VITALI

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY – FOR EQUIPMENT AND SYSTEMS THAT ARE NOT LIFE-SUPPORTING

L'apparecchio CTU Mega 20 è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore dell' apparecchio CTU Mega 20 deve garantire che esso venga usato in tale ambiente.

The equipment CTU Mega 20 is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment CTU Mega 20 should assure that it is used in such an environment.

Prova di immunità **Immunity Test**	**Livello di prova IEC 60601** **IEC 60601 test level**	**Livello di conformità** **Compliance level**	**Ambiente elettromagnetico – Guida** **Electromagnetic environment - Guidance**
RF condotta Conducted RF IEC 61000-4-6	3 Veff_Vrms da 150 kHz a 80 MHz 150 kHz to 80 MHz	3 V	Gli apparecchi di comunicazione a RF portatili e mobili non dovrebbero essere usati più vicino a nessuna parte dell'apparecchio CTU Mega 20 compresi i cavi, della distanza di separazione raccomandata calcolata con l'equazione applicabile alla frequenza del trasmettitore Portable and mobile RF communications equipment should be used no closet to any part of the equipment CTU Mega 20 , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Distanza di separazione raccomandata** **Recommended separation distance** $d = 1{,}17\sqrt{P}$
RF irradiata Radiated RF	3 V/m	3 V/m	

IEC 61000-4-3	da 80 MHz a 2,5 GHz 80MHz to 2,5 GHz		$d = 4\sqrt{P}$ da 80 MHz a 800 MHz 80 MHz to 800 MHz $d = 2{,}33\sqrt{P}$ da 800 MHz a 2,5 GHz 800 MHz to 2,5 GHz Dove P è la potenza massima nominale d'uscita del trasmettitore in Watt (W) secondo il costruttore del trasmettitore e d è la distanza di separazione raccomandata in metri (m). Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Le intensità di campo dei trasmettitori a RF fissi, come determinato da un'indagine elettromagnetica[a] del sito potrebbe essere minore del livello di conformità in ciascun intervallo di frequenza[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Si può verificare interferenza in prossimità di apparecchi contrassegnati dal seguente simbolo: Interference may occur in the vicinity of equipment marked with the following symbol: 

Notes:

(1) A 80 MHz e 800 MHz; si applica l'intervallo di frequenza più alto.

At 80 MHz and 800 MHz, the higher frequency range applies.

(2) Queste linee guida potrebbero non applicarsi in tutte le situazioni. La propagazione elettromagnetica è influenzata dall'assorbimento e dalla riflessione di strutture, oggetti e persone.
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a	Le intensità di campo per trasmettitori fissi come le stazioni base per radiotelefoni (cellulari e cordless) e radiomobili terrestri, apparecchi di radioamatori, trasmettitori radio in AM e FM e trasmettitori TV non possono essere previste teoricamente e con precisione. Per valutare un ambiente elettromagnetico causato da trasmettitori RF fissi, si dovrebbe considerare un'indagine elettromagnetica del sito. Se l'intensità di campo misurata nel luogo in cui si usa un apparecchio CTU Mega 20 , supera il livello di conformità applicabile di cui sopra, si dovrebbe porre sotto osservazione il funzionamento normale dell'apparecchio CTU Mega 20. Se si notano prestazioni anormali, possono essere necessarie misure aggiuntive come un diverso orientamento o posizione dell'apparecchio CTU Mega 20. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment CTU Mega 20 is used exceeds the applicable RF compliance level above, the equipment CTU Mega 20 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment CTU Mega 20.
b	L'intensità di campo nell'intervallo di frequenza da 150 kHz a 80 MHz dovrebbe essere minore di [V_1] V/m. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

TABELLA 4

TABLE 4

DISTANZE DI SEPARAZIONE RACCOMANDATE TRA APPARECCHI DI RADIOCOMUNICAZIONE PORTATILI E MOBILI E L'APPARECCHIO CTU MEGA 20

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE EQUIPMENT CTU MEGA 20

L'apparecchio CTU MEGA 20 è previsto per funzionare in un ambiente elettromagnetico in cui sono sotto controllo i disturbi irradiati RF. Il cliente o l'operatore dell'apparecchio CTU MEGA 20 possono contribuire a prevenire interferenze elettromagnetiche assicurando una distanza minima fra gli apparecchi di comunicazione mobili e portatili a RF (trasmettitori) e l'apparecchio CTU MEGA 20 come sotto raccomandato, in relazione alla potenza di uscita massima degli apparecchi di radiocomunicazione.

The equipment CTU MEGA 20 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment CTU MEGA 20 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment CTU MEGA 20 as recommended below, according to the maximum output power of the communications equipment.

Potenza di uscita massima del trasmettitore specificata Rated maximum output power of transmitter W	Distanza di separazione alla frequenza del trasmettitore (m) Separation distance according to frequency of transmitter (m)		
	Da 150 kHz a_to 80 MHz	Da 80 MHz a_to 800 MHz	Da 800 MHz a_to 2,5 GHz
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,20	1,20	2,30
10	3,80	3,80	7,30
100	12,00	12,00	23,00

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