USER'S MANUAL

EHY-2000plus

OncoTherm Kft.

User's Manual

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Oncotherm Kft.

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Contents

Introduction

Congratulation on your excellent choice!

You are the owner of a high-tech medical product, developed and produced by

Oncotherm Kft.

on the basis of the latest bio-engineering and medical knowledge.

The design and production of EHY-2000plus is controlled by the rigorous EU standards, certified for ISO 13485 and ISO 9001, certified also by the German TÜV SÜD Product Service GmbH (Munich). The product is completely manufactured in the European Union.

How to use this manual

The user's manual of EHY-2000plus explains the proper use and maintenance of the device. We recommend you to follow the content order first time you study the manual. After you are familiar with the safe operation of the EHY-2000plus, you can continue with the technical and theoretical background. On the base of this knowledge, you can learn the treatment process with EHY-2000plus. The device control part should be used as a guideline for treatments. We recommend to keep this manual close at hand since you may need to refer to it in the future.

You can find the latest valid version of the User's Manual on our website **(www.oncotherm.org/for Specialists (please login)/User's Manuals).**

Contacts

Please do not hesitate to contact us if you have any questions:
Questions in connection with production and management:

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Your local distributor:

Safety Warning

Please read these installation- and operating-instructions carefully before using your device. These instructions contain important notes regarding safe installation, use and maintenance of your appliance.

Please keep these instructions in a safe place you can always access and, if you sell the appliance, hand them over to the new owner.

The manufacturer cannot accept liability if these instructions are not adhered to.

A technical training is required to operate the equipment! For this procedure, please ask the manufacturer or the distributor.

To reduce the risk of fire or electric shock, do not expose this appliance to rain or moisture. Due to dangerous high voltage, do not open the cabinet. For technical support please contact the qualified personnel of Oncotherm.

Symbols and their definitions

Please note the symbols below for correct usage of the equipment:

	This symbol is intended to inform the user about the ground independent (body floating) construction. Do not rearrange the professional installation.
	This symbol is intended to alert the user to the presence of important operation and maintenance instructions in the literature accompanying this product.
	This symbol warns the user to read the relevant part in the User's manual.
	This symbol informs the user that the device is intended to emit non-ionizing radiation.
	This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste but has to be collected separately. Please contact the authorized representative of Oncotherm Group for information concerning the decommissioning of your equipment.
CLASS I	Conductive-enclosed CLASS I EQUIPMENT: EQUIPMENT having a durable and substantially continuous ENCLOSURE of conductive material which envelops all conductive parts with the exception of small parts, such as nameplates, screws and rivets, which are isolated from LIVE parts by insulation at least equivalent to REINFORCED INSULATION. The ENCLOSURE of insulation-enclosed CLASS II EQUIPMENT may form a part or the whole of the SUPPLEMENTARY INSULATION.

Installation

General

The device must be installed by a qualified technician/engineer on behalf of the Oncotherm Group in compliance with the instructions provided. The manufacturer declines all responsibility for improper installation which may harm people and damage property.

When the packing is removed, check that the appliance is not damaged. If you have any doubts, do not use the appliance, but call for a qualified technician.

The packaging items (plastic bags, foamed polystyrene, nails, etc.) are potential sources of danger. Never leave them within the reach of children.

This device shall be used for the purpose it was expressly designed for. Any other use is considered improper and consequently dangerous. The manufacturer declines all responsibility for damage resulting from improper and irresponsible use.

Electrical connection

1. Connect the equipment to 230/110V A/C socket with ground only. Ensure that the socket is properly installed.
2. Observe that a min. 16 Ampere fuse protects the socket.
3. Make sure that the device uses the single-phase independently from other appliances. Use an independent phase for the device and others for the other applied electric appliances (for example: air-conditioning, diagnostics systems, computers, sterilization equipment, etc.) in the room.

(Our service team controls these conditions, and we will be taken into consideration during installation to satisfy these requests.)

Pre-installation notices

1. Put the device into a quiet, independent room, devoted only to the Oncotherm device and treatment procedure.
2. The room must have normal conditions (e.g. temperature humidity, pollution, etc.) at all times.
    - temperature range: 15 – 23 °C
    - humidity range: 20 – 60 %
    - No aggressive pollution (e.g. chemicals, fibers, dust, smoke, etc.) is allowed in the room where the device is installed
3. Let the room have enough natural and/or artificial light for the proper handling of the treatment.
4. Do not install the device on textile carpet. Avoid using the equipment on soft surfaces.
5. Do not use the equipment where it may be exposed to vibrations.
6. Avoid using the equipment near appliances generating strong electro-magnetic fields (e.g. motors, transformers, etc.).
7. There has to be a safe place for treatment accessories in the room.
8. On delivery, observe the device carefully and wait for the authorized Service for the installation.
9. If your device looks damaged, do not use it. In case of any questions ask the Oncotherm service team for advice.
10. To move the device into another room and/or into any other place from the place where it was installed originally please ask for the assistance of the Oncotherm service. The unauthorized relocation is strictly prohibited in order to avoid the mains and grounding discrepancies and the possible electric shock.
11. Avoid using your equipment immediately after sudden changes of the outside temperature, due to the moisture damage in the electronics.
12. Ensure that no objects fall or no fluid passes through the ventilation openings. If liquid is spilt into the equipment, disconnect it from the mains and consult a qualified service technician.
13. Dangerous voltage inside. Do not open the cabinet. There are no user serviceable parts inside. Only qualified service personnel should carry out repairs.

Installation notices

1. This unit should be kept away from heat registers, radiators, stoves or other appliances that produce heat. Windy places or the vicinity of windows should also be avoided.
2. For the best performance and safety, please place this unit in the middle of the room. Make it possible for the operator to access the device from any direction. Any walls and/or grounded surface have to be minimum 1.5 meter away from the treatment bed, so that the patient cannot reach any surfaces independent from the device, which could cause an electric shock for them.
3. **The EHY unit must be located in a suitable place, where the emergency switches of the device are accessible for everybody in case of a dangerous situation. This emergency switch cuts off the mains voltage of EHY device itself, but this button does not affect the waterbed and the PC.**
4. Good air circulation around the device is essential to prevent internal overheat of the electronic parts.
5. Choose a dust-free, well-ventilated position. Do the everyday cleaning by washing up the floor, as it is usual in medical institutions.
6. Take care of the intactness of cables and water pipes. Do not break them, or obstruct the free flow of the cooling water.
7. Electrical safety of the appliance is only guaranteed if the grounding system of the building is in accordance with the local electricity board regulations. The OncoTherm service team controls it at the regular services. The proper electric conditions are the liability of the customer.
8. Only authorized service personnel should carry out repairs and any other work on the device. The approval must be in written form from the Oncotherm Group. The relocation and/or using mains-socket other than the originally installed, must be done only by the Oncotherm or its authorized service-representative. Only the qualified and authorised Oncotherm personnel should service the unit when it does not operate normally or shows marked change in its performance.
9. Devices, which are to be discarded, must be made unusable. Pull out the plug and remove the cable.

Safety

1. The device is only suitable for normal treatment use and for the purposes and intended uses stated in the operating instructions.
2. Do not use any extension- and radio-frequency-cables, only those which are provided by the authorized service and/or by the Oncotherm.
3. Before starting any cleaning work on the device it must be disconnected from the electric supply by removing the plug from the socket. Do not pull the cable!
4. The mains lead of the unit should be unplugged when the unit is not in use.
5. Do not plug in or unplug the mains lead with wet hands.
6. Do not use the device when you are barefoot.
7. Make sure that objects do not fall and liquids are not spilled into the interior of the device through openings.
8. Do not allow children to operate and/or control the equipment.
9. Do not allow people who are not experienced nor trained in operating the equipment to use it without supervision.
10. Never leave the device exposed to environmental effects (rain, sun etc.).
11. Every six months the service team has to check the device according to the 'regular safety testing instruction'.
12. Never use the waterbed without the mattress. Touching the heating surface directly can cause burn!
13. Never use the mattress without water (only distilled water can be used.) as the patient can compress it and can touch heating surface almost directly! (Check of filling up: Push the middle of one half of the mattress with one hand till reaching bottom. Then push the middle of the other half with the other hand - minimum ½ meter from the first point. It should not reach the bottom.)
14. Water leakage is shown on display (sensed electronically in wastewater tank). In case of water-loss failure, treatment should be stopped immediately and the service team should be called for help. If water flows quickly, treatment must be stopped, switch off the bed and pull out the mains plug.

15. In case of noticing water in the plastic tray or on the surface of the mattress, please check the water level in mattress and presence of possible mechanical damage. Do not use damaged mattress in order to avoid an electric shock.
16. The patient's surface must not be damp. After cleaning the surface the user has to wait until it is dry.
17. Using EHY-2000plus without a heated waterbed may decrease the temperature of the body of the patient. In case of everyday use, keep the bed switched on permanently. (Heating up the water from room temperature to treating temperature level requires about 12 -16 hours.)
18. Check the temperature settings before each treatment! Recommended temperature setting is 30-32°C, because the treatment itself also heats and the patient will have sweaty skin which is not suitable for correct EHY-2000plus treatment.
19. Check the alarm system daily during continuous use. Switch the device off for a short time. When you switch on the waterbed, a self-test is implemented, and a warning is shown until the user sets the desired temperature again.
20. Do not use other surgical or endocardial devices while the patient is on the waterbed.

Resident risks:

The user has to follow the instructions mentioned above, otherwise burning or overheating of the tissue can occur.

General description

Intended use

The EHY-2000plus device is devoted to the non-invasive treatment of malignant tissues. The difference between the complex dielectric constant (complex impedance) of the malignant and healthy tissues makes it possible to select them. The main effect is the local overheating of the tumor, but additionally other electric effects are also in use.

Target group

Cancer patients, adults and children over 6 years.

Side effects

When the treatment area is covered by a considerable adipose tissue, subcutane fat-burn might occur and the skin can become red (slight burn) as well.

Indications

- deep-seated primer tumors and metastasizes in organs (incl. liver, pancreas, kidney, lung, brain, etc.)
- gastro-enterological tumors, including small and large intestine, stomach, esophagus, etc
- deep-seated gynecological cases, sexual organs

Available applicators

- Waterbed electrode (permanent part of the device)
- Bolus electrode, standard (20 cm diameter)

- Bolus electrode, small (10 cm diameter)
- Bolus electrode, large (30 cm diameter)

Contra indication

- Cannot be used when the patient is under deep-sedation or anesthesia (missing thermal sensitivity). Application of analgesics in the treated area is prohibited.
- Cannot be used when the patient is unconscious.
- Cannot be used when the patient is not able to communicate with the physician.
- Do not use the electrodes in the vicinity of the patient's metallic/prosthesis (bone-replacement, joint support, etc.). The distance between the implanted metal and the circumflex of the upper electrode shall be more than the radius of the electrode.
- Do not use the electrodes in the vicinity of the patient's silicone prosthesis (breast implant.). The distance between the implanted prosthesis and the circumflex of the upper electrode shall be more than the radius of the electrode.
- Before the treatment all metallic pieces (necklaces, rings, jewels, watches, pipes, coins, phones, hairpins, pens, etc.) have to be left far away from the treatment bed. Do not treat patients who have earphones, hearing-aid, music devices (Walkman, walk-watch, etc.) and or/any wire-connected instruments.
- Cannot be used for treating patients who have pacemaker or any other type of electrical implants (e.g. implanted. deep brain stimulator (DBS), implanted hearing-aids, implanted erectile function stimulator, etc.).
- Must not be used in case of tendency to hemorrhage, including menstruation or open wound (e.g. newly operated patients).
- Do not apply on person with organ-transplants.

Important medical notices

Please remember:

1. The user of this device has to be a physician and/or a trained clinical staff under the physician's control.
2. The treatment has to be permanently monitored by the staff.
3. The treatment needs extra care, when the patient has reduced thermal sensitivity on the treated area.
4. Check the position of the electrode to keep it as parallel to the bed surface as possible (try to avoid the electrode being placed on an inclined angle). The applicator (electrode) has a flexible water-bolus to enable the best interface with the patient. Please note that positioning of the electrode is to be carefully controlled because some temperature increase can occur at the skin's surface. This will not be a sudden effect and is can be controlled with patient feedback during the treatment. In addition, users are advised to place medical hygienic paper (see detailed description in Accessories and Appendix 9 for datasheet) between the electrode and the patient to avoid direct skin contact. Also, when positioning the electrode, avoid direct patient contact with the black plastic border of the electrode during the treatment to eliminate the risk of burning.
5. Do not use the equipment improperly: it can be dangerous. Always check the user's manual.
6. The EHY device should not operated by staff during pregnancy and also not advised to treat pregnant patients. It can cause abortion.
7. It is suggested to remove extra fluid (e.g. ascites, pleural liquid, etc.) from the treated area before the treatment. Furthermore, it is suggested to empty the urinary bladder, stomach, rectum before treatments in the area.
8. Extra care is necessary when patient has surgery clips in the treated volume.
9. Extra care is necessary when the patient has a diathesis of convulsion (epileptic).
10. Attention is necessary when the patient is allergic to the electric field or electromagnetic effects.

11. Special care is necessary concerning the patient's hair in the treated area if the patient has hair (e.g. pubic hair or at head-hair or hair on breast (for men)), because the burning and the mistreating is very likely. Please shave the treated area before treatment if necessary, or at least please make very tight control of the treatment, using small power for a longer time. If you are not able to shave the treated area, please put ultrasound/ECG gel on the hair for better contact. Please ask the patient about their cavities (bladder, stomach, pleural cavity, etc.) sensing. Stop the treatment immediately if anything unusual happens near the cavities, and continue it only when the hair is removed.
12. Check the patient and ask about their feelings frequently.
13. Check the water-cooling of the electrode before positioning it.
14. At rearranging and/or positioning the applicator, please pause/stop the treatment.
15. In case of any necessary medical aid (injection, infusion, etc.) please pause/stop the treatment.
16. Stop the treatment immediately if anything unusual happens (eg. eritema, burning, etc.) and ask help of a trained doctor if it is needed.
17. Be careful with temperature measurements and other controlling units. Any metallic part could be an antenna. Using any non-Oncotherm product to control is prohibited. Do not use any system-independent electric device during the treatment. It can cause electric shock due to the broken safety isolation.
18. Credit-cards and/or any other magnetically sensitive products (diskettes, tapes, etc.) are recommended not to be kept near the treatment. No guarantee of not losing the information from the data-carriers.
19. Do not treat near the eyes of the patient. The direct RF-radiation can cause temporary or permanent blindness. The treatment of the head requires special training at one of the OncoTherm reference clinics. For brain treatment, please follow the protocol detailed in Appendix 8 of the User's manual.
20. Do not clean the electrodes while the equipment is on! Do not use such wet textile-tissue that could release water which might penetrate into any part of the equipment!

21. The optimal placement of the applicators is parallel to each other. Such an arrangement gives the most effective heating power. Note that in many cases only a small power is required for the treatment (for example when treating a brain tumour) which can be regulated by the output power control or by placing the electrodes in a non-parallel arrangement. The patient must be between the electrode and counter electrode placed into the waterbed.
22. Do not wrap the electrode into any textile material for the treatment. Reduce the thickness of any textile material to minimum between the electrode and the patient's skin. Textile quality has an effect on the tuning frequency which can lead to system error in tuning under the given circumstances. Ideally, isolate the patient's skin from the electrode surface using medical hygienic paper (see detailed description in Accessories and Appendix 9 for datasheet) – or other medical hygienic paper with CE mark, between the bare skin and the electrodes. Any other material can have an impact on the device tuning.
23. During treatment, relaxing (so called 'alpha') music is suggested for psychological reasons (faster recovery is possible).
23. This kind of radio-frequency treatment has an effect on the surroundings. This is why it is important to pay attention to setting up the treatment system and the furnishing of the treatment room - in which treatments will take place. Do not install the machine in the vicinity of any sensitive equipment (ECG, EEG, intensive-care control-monitor, ultra-sound, video-rectoscopy and/or other sensitive imaging systems, etc.) without shielding. Shielding is also required to protect the EHY-2000plus in the vicinity of large electro-magnetic sources and/or high-power machines (power transformer, X-ray units, NMR, CT, etc. It should be noted that microwaves could influence the Oncotherm device in the treatment room and vice-versa. Make sure that these machines are well shielded.
24. It is optimal if the device is separated from the control-computer. The central computer should be placed outside the treatment room. An observation room has to be arranged from where the personnel can control the patient's treatment.
25. The personnel, responsible for the treatment/equipment, should check the cables before each treatment. At any doubt about the intact isolation, stop the treatment and call for an immediate service check-up.
26. Clean the electrodes before each treatment. Follow the procedure written in the "disinfecting the accessories" part of this user's manual. Alcohol (or its substitute) has to be used for disinfecting.

27. Before the treatment any sharp objects (knives, scissors, needles, pens pencils, glasses etc.) have to be left far away from the **waterbed**.
28. Using **waterbed mattress** without checking its sufficient amount of water can be dangerous, the patient could be burnt.
29. The water in the mattress must be heated up before the treatment. You can find its detailed description in the 'Preparation before treatment' section of this user's manual.
30. Accessory equipment connected to the analogue and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, consult the technical service department or your local representative.
31. Oncothermia does not substitute the conventional therapies only supports those.

Resident risks:

The user has to follow the instructions mentioned above otherwise burning or overheating of the tissue can occur.

The temperature calculation (displayed temperature) is only a calculation. Note, Bear in mind that the temperature of some points of the heated local area can be considerably higher than the average. This effect is called "hot spots" in the literature. This inaccuracy can cause overheating of the tissue.

The calculation however is based on the so-called "equivalent temperature" idea. This means that Electro-Hyperthermia heats up the tissue by a dynamic, gradient method. The calculated temperature - has the same distortion ability of the cells as the static overheating. This temperature (due to the dynamical effects) in reality could be lower than the statically measurable one. Tolerated accuracy of forwarded and reflected power (±30%) is checked at the start but is not checked continuously during the treatment. This can cause overheating of the tissue.

Written consent for the treatment

According to medical regulation in some countries, a written consent has to be signed by the patient before the start of the first treatment. This consent has to contain the following points:

a. Clear capacity (or ability) to make the decision.

b. The medical provider must disclose information on the treatment, test, or procedure in questions, including the expected benefits and risks, and the likelihood (or probability) that the benefits and risks will occur.

c. The patient must comprehend the relevant information.

d. The patient must voluntarily grant consent, without coercion or duress.

Doctors must give information to the patients about a particular treatment or test so that the patient can decide whether or not they wish to undergo the treatment or the test. This process of understanding the risks and benefits of treatment is known as informed consent. It is based on the moral and legal premise of patient autonomy: Patients have the right to make decisions about their own health and medical conditions.

- The patient must give their voluntary, informed consent for the treatment and for most medical tests and procedures. The legal term for failing to obtain informed consent before performing a test or procedure on a patient is called battery (a form of assault).
- For many types of interactions (for example, a physical exam with your doctor), the implied consent is assumed.
- For more invasive tests or for those tests or treatments with significant risks or alternatives, you will be asked to give explicit (written) consent.
- Under certain circumstances, there are exceptions to the informed consent rule. The most common exceptions are these:

  I. An emergency in which medical care is needed immediately to prevent serious or irreversible harm.

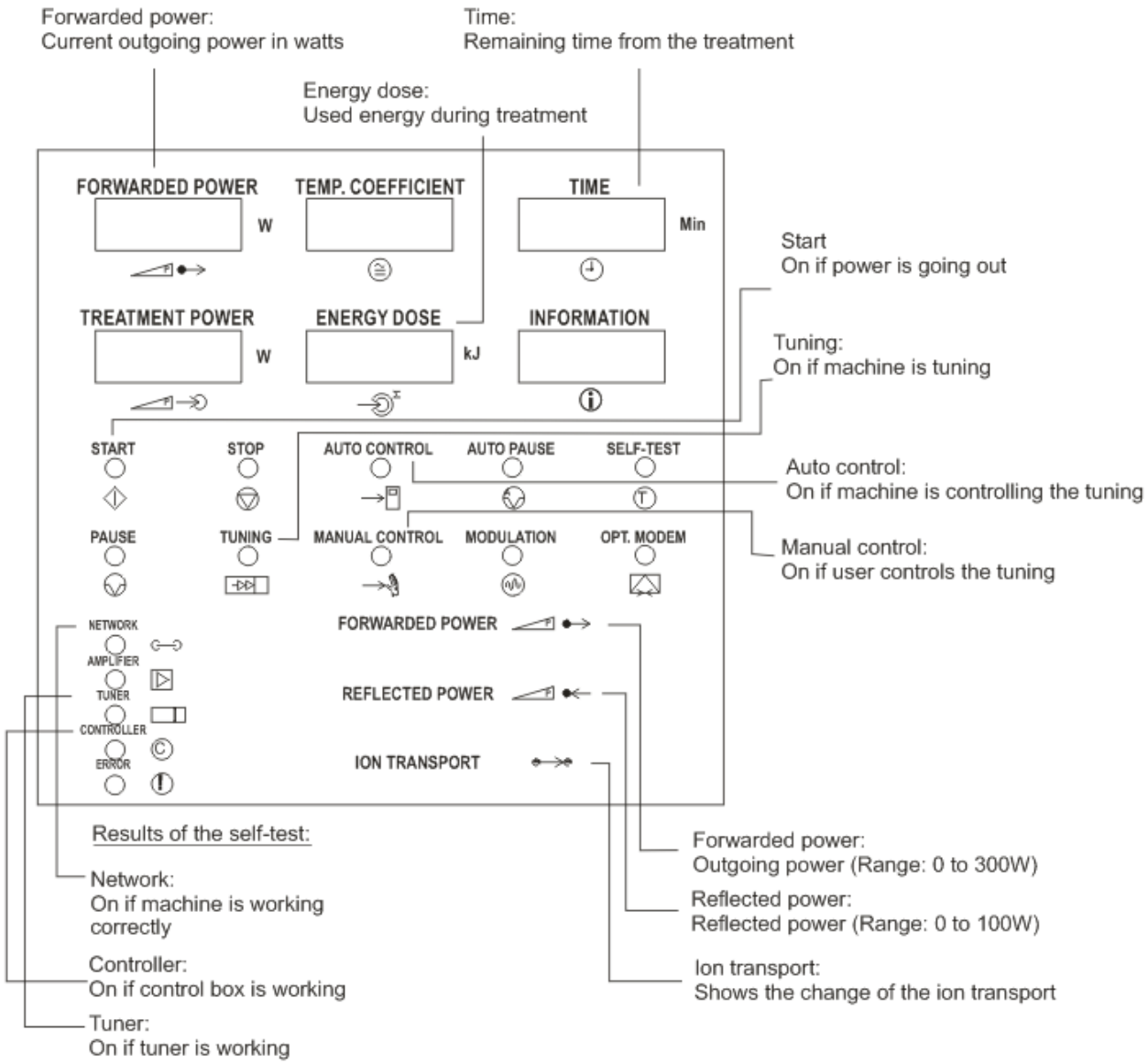
  II. Legal incompetence in which someone is unable to give permission (or to refuse permission) for testing or treatment.

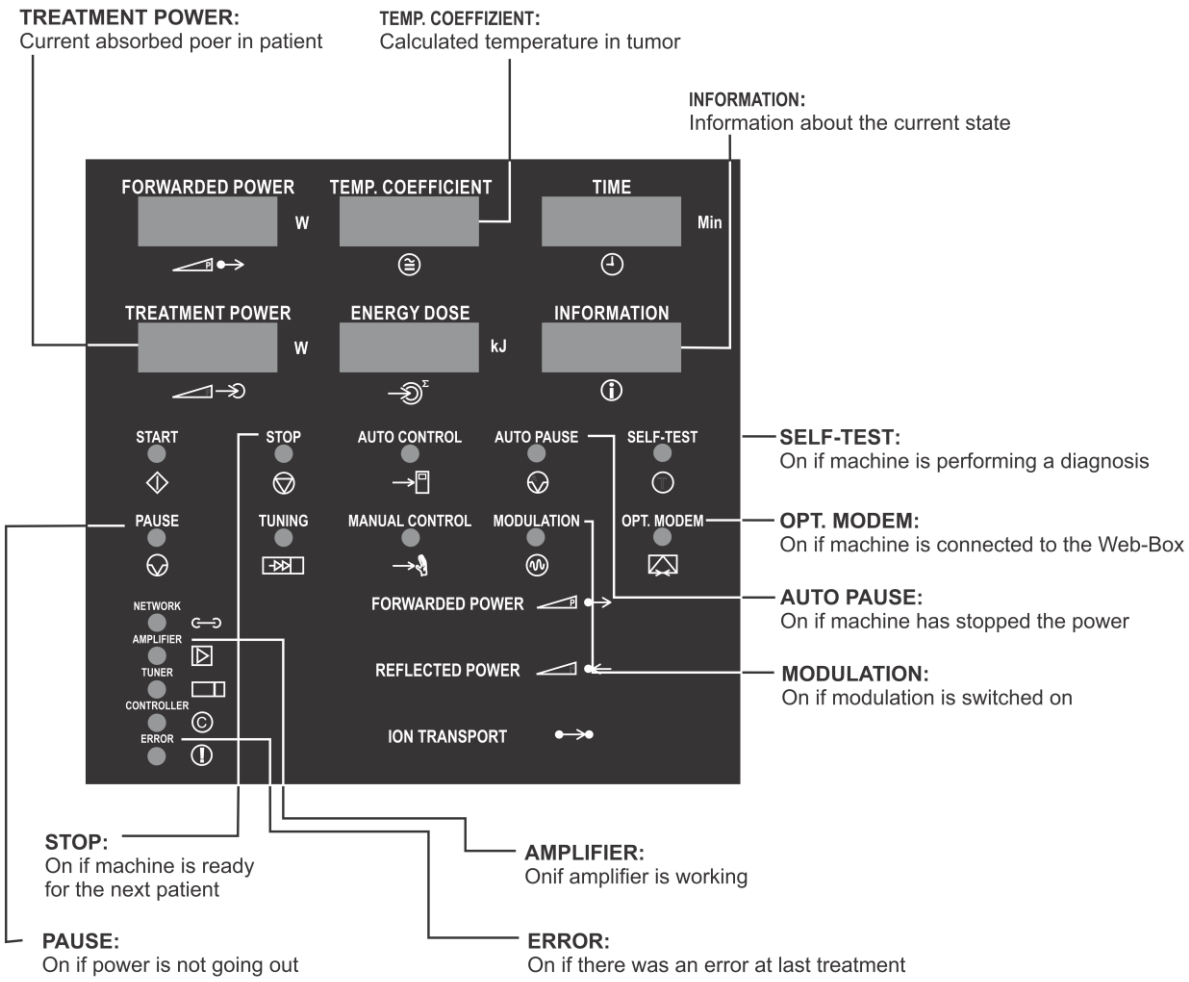
For clear orientation the FDA (USA) and MHRA (UK) guidelines for written consent are attached in Appendix 7.

Device control

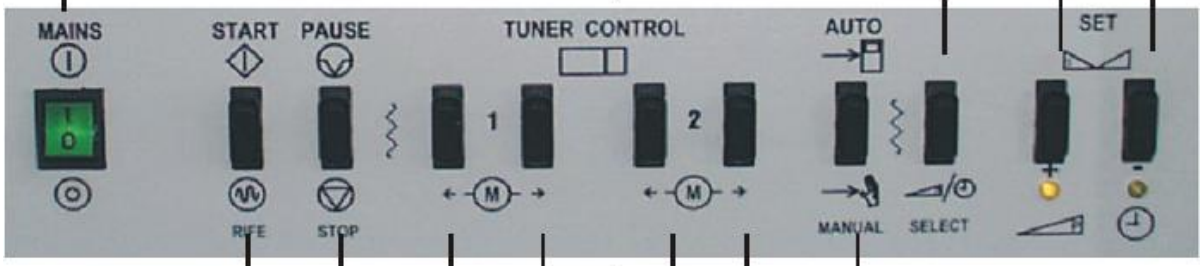
The Oncotherm EHY-2000plus is devoted to the high level requirements of modern medical practice. The equipment is isolated from the common power-network for safety purposes and supported by a specially developed software.

Display-EHY-2000plus





The "temperature coefficient" s equivalent with the static temperature, which does the same distortion which is the actual distortion rate in the tissue. In this meaning the temperature coefficient is the parameterization of the actual distortion rate in the tumor.



Select
Time/Power select switch

Up
Increase time/power

Down
Decrease time/power

Mains:
Power switch

Stop
Pause switch
Long: Stop switch

Start
Start/continue switch
Long: modulation
on/off switch

Automatic/Mute:
Automatic mode switch
Long: Manual mode switch
On alarm: mute

Tuning:
Motor 2 anti-clockwise

Tuning:
Motor 2 clockwise

Tuning:
Motor 1 anti-clockwise

Tuning:
Motor 1 clockwise

The actual denotations are:

German:

English		German		English		German
Forwarded Power		Leistungsabgabe		Manual Control		Manual mode
Reflected Power		Leistungsreflexion		Opt. Modem		Opt. Modem
Treatment Power		Leistungaufnahme		Network		Netz
Temp. Coefficient		Temp. Koeffizient		Amplifier		Verstärker
Energy dose		Energiemenge		Controller		Controller
Time		Zeit		Error		Fehler
Information		Information		Tuner		Tuner
Self-test		Test		Iontransport		Ionen transport
Stop		Stop		Tuner		Tuner
Pause		Pause		Mains		Netz
Auto Pause		Pause		Mains Off		Netz aus
Start		Start		Set		Einstellung
Tuning		Tuning		Select Time/Power		Zeit/Leistung Wahl
Auto Control		Auto mode		Power		Leistung

Hungarian:

English		Hungarian		English		Hungarian
Forwarded Power		Kiadott teljesítmény		Manual Control		Kézi vezérlés
Reflected Power		Visszavert teljesítmény		Opt. Modem		Optikai Modem
Treatment Power		Kezelési teljesítmény		Network		Belső hálózat
Temp. Coefficient		ECM hőmérséklet		Amplifier		Erősítő
Energy dose		Energia mennyiség		Controller		Vezérlő
Time		Idő		Error		Hiba
Information		Információ		Tuner		Kézi hangolás
Self-test		Belső teszt		Iontransport		Ion transzportáció
Stop		Leállítás		Tuner Motor		Hangoló motor
Pause		Szünet		Mains On		Hálózat be
Auto Pause		Automatikus szünet		Mains Off		Hálózat ki
Start		Indítás		Set		Beállítás
Tuning		Automatikus hangolás		Select Time/Power		Idő/teljesítmény választás
Auto Control		Automatikus vezérlés		Power		Teljesítmény

Keyboard

Some keys may have many functions depending on the actual mode of the device.

Power: Here you can switch on and off the device. If the device is switched on the switch should lighten up. Note: if an emergency button is pressed – that is indicated by a red light on the front panel – then the device cannot be switched on.

Start/ReTune: The treatment can be started by pressing this button. By doing it, the treatment starts and an automatic tuning also starts to set the correct

parameters for the treatment. Pressing this button during the treatment will start the retuning algorithm, to find a new tuner position.

Pressing the Start-button for a longer time changes the Modulation-mode. (If it was off, then it will turn on, and if it was on, it will turn off.) Modulation does not have any effect on temperature.

Stop: With this button you can pause or stop the treatment. If you only pause the treatment, you can continue it later at where you left it, no parameters will be changed. But if you stop it, then all the parameters will be reset to their default value. The actual information will be stored only on the computer (if any).

Press for a longer period to stop the RF power (treatment).

Pause: Press only for a short time to pause the treatment. RF power is stopped.

Motor 1 clockwise: Rotate the first tuning motor clockwise. You should use this only if you are an advanced user.

Motor 1 anticlockwise: Rotate the first tuning motor anticlockwise. You should use this only if you are an advanced user.

Motor 2 clockwise: Rotate the second tuning motor clockwise. You should use this only if you are an advanced user.

Motor 2 anticlockwise: Rotate the second tuning motor anticlockwise. You should use this only if you are an advanced user.

Automatic/Manual selection

Automatic: Press for a short period of time to set automatic mode. In automatic mode all limits are checked, and power is managed by the attached computer. In automatic mode you can press this button shortly when you reach 46°C-47°C on the E.C.M temperature and the alarm sound will disappear. You can continue the treatment carefully.

- **Manual:** Press it for a long period of time to set manual mode. In manual mode a lot of things are not controlled by the microcontroller.

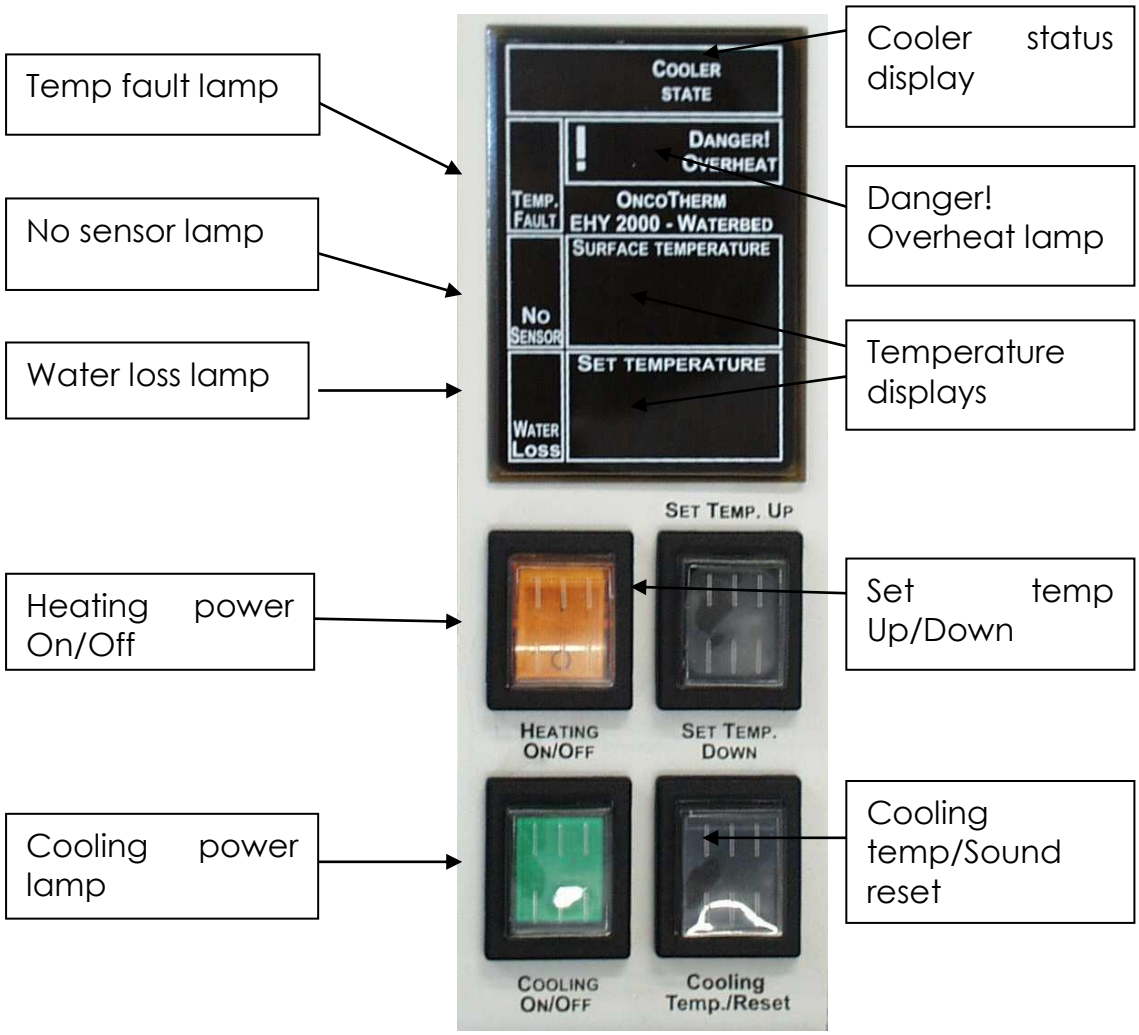
Mute: Mute the device with this button if there is an alarm for high temperature and temperature display flashes.

Power / Time selection: To select the function of the up/down buttons. This will change from time to power or from power to time settings. The actual Mode is indicated by a yellow Light at the Up/Down- Buttons

Up (+): You can change the actual time limit or power setting upward with this button. The one you change depends on the power/time selection button.

Down (-): You can change the current time limit or power setting downward with this button. The one you change depends on the power/time selection button.

Display-WEY-2000plus waterbed



Control panel of waterbed

"Temp. fault" lamp: 1 yellow lamp shows if the temperature is not correct. It alerts the user if the surface temperature differs with more than +/-1 °C from the setting in stabilized state.

"No sensor" lamp: 1 yellow lamp alerts the user if one or more sensors do not function correctly. It can occur if the mattress is pulled out of its place.

"Water loss" lamp: It lights up if water flows into the wastewater tank (approx. 3 liters) from mattress. This tank is at the foot-end of the waterbed. The tank's capacity is 20 liters. If flowing is not stopped, water will appear around the mattress. With wet mattress the treatment cannot be continued. It can be dangerous for the patient. (Danger of burn)

"Heating power On/Off" button: To turn off and on waterbed heating. The lamp is yellow when the operating power is on.

“Cooling power” lamp: It lights up when the EHY power is on and cooling unit is working.

“Cooler state” display: It warns the user if there is a problem with the cooling unit. If the display does not show any code (--), there is no error.

“Danger! Overheat!”: 1 red lamp alerts the user if the mattress temperature is over 38 °C.

“Temperature displays”: 3 digits for actual surface temperature + 3 digits for set temperature (xx.x°C)

“Set temp.” “Up” and “Down”: One push of a button changes temperature with only an unnoticeable fraction of a degree, so push the button longer to see the change on the display. You can also use this button for “sound reset” after switching on the device.

“Cooling temp./ Sound reset” button: By pressing this button the display shows the actual temperature of the cooling water. In case of error, this button clears sound warning for maximum 8 minutes if the error is simple one. In case of serious errors, when treatment could be dangerous, the sound cannot be muted.

Tuning

The EHY-2000plus has a special radio frequency generator, which must be carefully tuned to the patient. If it is not done, the energy released from the device (in the form of radio frequency) will not heat the patient, but will be lost in the air, cables, and in the internal electronic parts. The tuning is the most important way of the personalization of the device and guarantees the best achievable effect for the patient.

A good tuning means that the outgoing power from the device is mostly absorbed by the patient and not reflected. In case of proper tuning the patient becomes a part of the resonant electronic circuit. (Reflected power is minimal and useful power is near the forwarded power.)

If the machine is not able to get into a correct position, up to a specified time, then it will restart the tuning from a given position. This is done three times. If during this procedure the proper tuning cannot be established, the device stops and resets the parameters. In this case please try to change the position of the electrode and then restart the tuning again.

Preparation before treatment

The treatment starts with the preparation of the patient for the actual treatment through medicine and psychological attention. After the treatment immunology support is suggested.

The most optimal electrode has to be chosen for the treatment. For the suggested electrodes see Appendix 3. For smaller solid tumors, a small applicator is suggested. Note that a small electrode with the same output power has proportionally larger electric field surface. Do not forget about the disinfecting the electrode before every treatment. *For disinfection see instructions in the technical description part.*

The electrodes have to be positioned on the tumor area with the best overlapping.

The waterbed offers comfortable feeling only if its temperature suits the patient's sensitivity. For this reason the water is preheated. It needs a few hours to warm up such an amount of water, so switch on the heating minimum 12 hours before starting the treatment, but it is better to keep the heating continuously on. To comply with the room temperature better, the heating levels can be set to adjust the comfort. The required temperature of the surface of the waterbed is adjustable with the buttons placed on the display from the Menu. Follow the instructions displayed in the appropriate menu point. The actual setting is displayed continuously.

Between treatments - for a few hours – do not switch off the waterbed heating. For a longer period – 10…30 hours – set a low temperature, but do not switch it off. If the equipment is not in use for a longer time period – e.g. to store – do switch off the heating.

Please check before every treatment:

- water in bed: by pushing the mattress, it must be filled correctly
- vapor/water wet surfaces: sides and bottom of the mattress must be dry (some moisture is possible)
- water in the cooling system: as well as with the other bed, the electrode's cooling water tube must be filled with water.

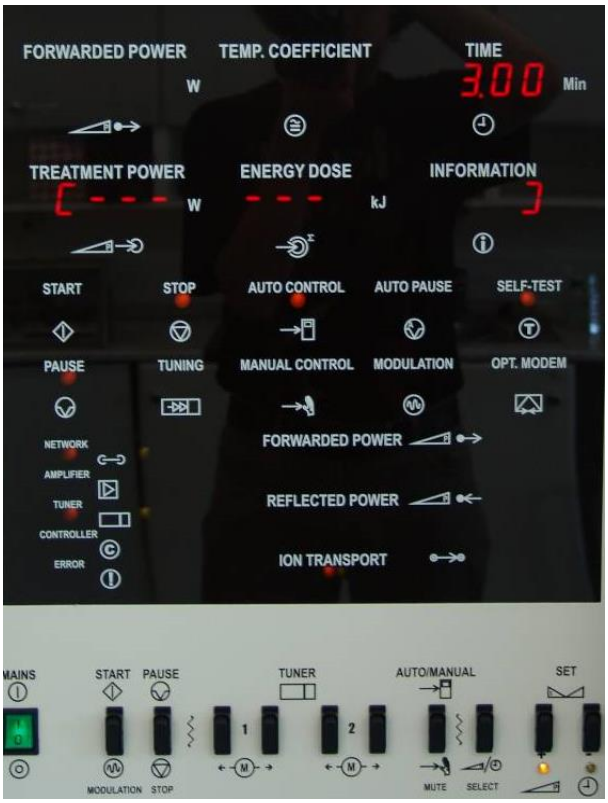
After half a year of use the water should be changed in the bed. If water-loss is observable, call the service.

Device use

Starting the device

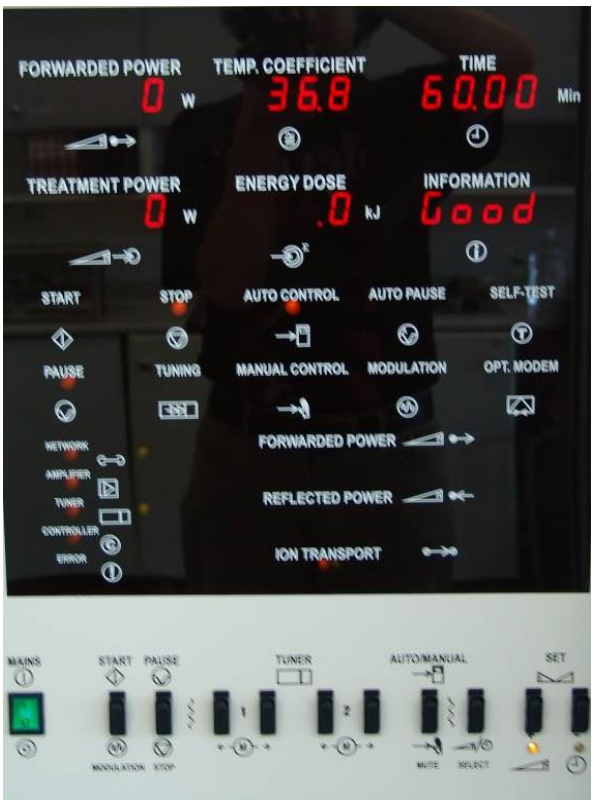
Switch on the device (power switch). If the Emergency Stop was pressed before, you have to free the emergency stop button first from its fixed position by pulling it out entirely, because as long as it is fixed you are not able to turn the power on. The emergency blocking status is indicated by a light in the center of the front of the device. Emergency blocking status is also indicated with an alarm signal.

After switching the power on, the machine will start a self-test procedure and to positionauto-matching to the calibrated start (reference) position. During the self-test a line can be seen on the displayindicating the progress of the self-test.



During the self-test procedure the emergency buzzers will give sound signals (all the three main units must give the signal) for testing purposes. If you cannot hear these testing sound signals, please report it to the OncoTherm service team.

After the self-test procedure you will get the "GOOD"- message in the info window.



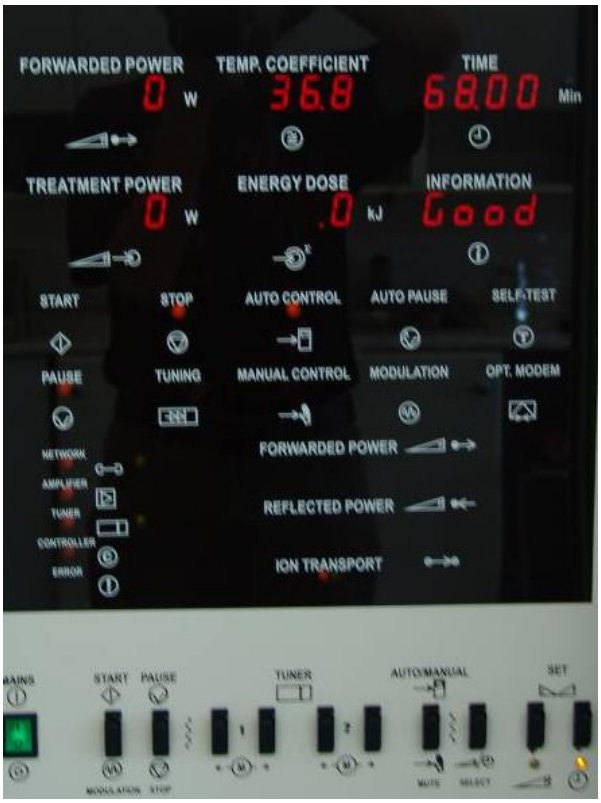
Now the device is ready for use. (Remark: The waterbed for proper treatment must be on heated state.)

Doing a treatment

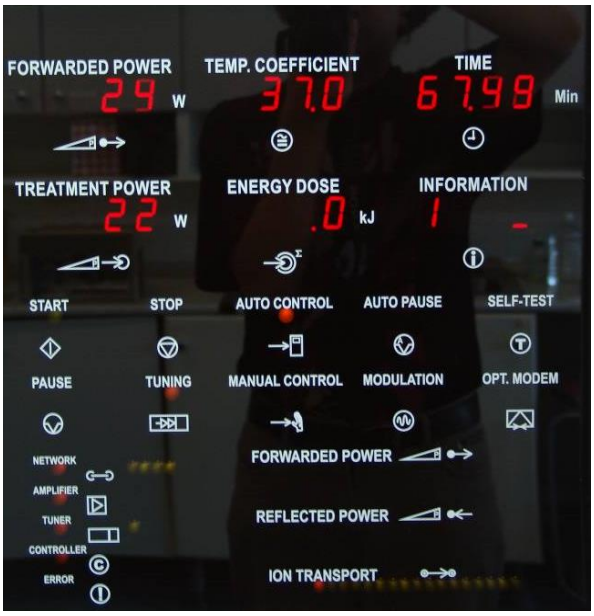
- The patient lies down in the bed in a comfortable position. Note that the patient has to keep this position during the whole treatment process, so please take care of the proper arrangement. Place the applicator on them on the area intended to be treated.

Important: Please remove all the metallic things from the treated patient.

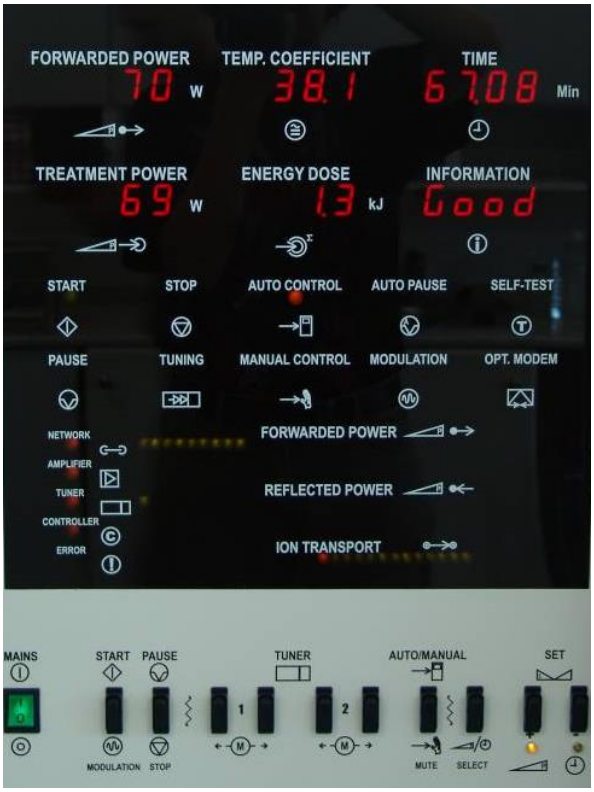
- You have to set the desired treatment parameters, such as treatment time, treatment power and modulation. This can be adjusted by the attached computer, or by the switches on the device. The adjusted parameter can be chosen by the Select button and can be set by the Up and Down buttons. The set time is indicated continuously, but the set power is indicated during the setting process, normally the actual outgoing power is indicated. The following picture is taken during the treatment time setting. Note the LED under the Up/Down buttons, which indicates the currently adjusted parameter.



- To start the RF power output (treatment), just press the START button. After the start the device tunes to the patient at a low power level. The tuning motor movements are indicated on the display in the Information point.



If the tuning is successful, the device increases the power to the set level. The successful tuning is indicated by the small (few watts) difference between the forwarded and treatment power.



If the tuning is not successful within 90 seconds, the device will indicate it with a sound signal and the "Error" LED will be blinking until the tuning is not successful. In this case the electrode should be re-positioned to reach a better electrical contact with the patient.

- To pause the treatment for any reason (for example: to give an injection) press the STOP button for a short period of time. Then you can continue the treatment by pressing the START button again.
- If you have finished the treatment, stop the device by pressing the STOP button for a longer period of time.

Note: Some patients may need some relaxation after the treatment.

Switch off the device

Before you switch off the device it is suggested to finish the treatment completely (stop it and do not pause it). After the complete stop, please wait a few minutes before the complete shut - down to make it possible for the internal cooling to cool down the important electronic parts in order to make their lifetime longer.

After this, switch off the device by the mains switch.

Time-meters

On the front of the device a counter shows the overall running time. This information is for service purposes.

On the front of the device another counter shows the summarized treatment time. This is for controlling of the active time of the device.

Treatment cannot be provided (device is blocked automatically) in case of any manipulation or damage of the time-meters.

Warning and error messages

The treatment cannot be started when an electrode is not connected, the device indicates the lack of electrode by continuous sound alarm and "Disc" text on the display

Note: the electrode must be connected continuously during the self-test procedure. Do not disconnect the electrode during the self-test, because it will cause an error of the self-test.

If the electrode cooling system has an error, the device indicates it by "COOL" text on the display.

The error codes indicating the error exactly can be seen on the waterbed display at the "Cooler state" point. Please forward these error codes to Oncotherm to ease the maintenance of the device.

Note: most of the cooler errors are not critical, that is why the cooling errors do not block the treatment, but then the treatment needs extra care because of the lack of the electrode cooling, and the treatment power should be reduced, especially with the 10 cm electrode.

If the device finds an error during the self-test, it indicates that by continuous alarm signal and an error code will appear on the display.

These errors are critical and the device cannot be used in these cases. If the error remains after a restart, call the Oncotherm service and report the error code to ease the repair of the device.

The Usage of the Web-box

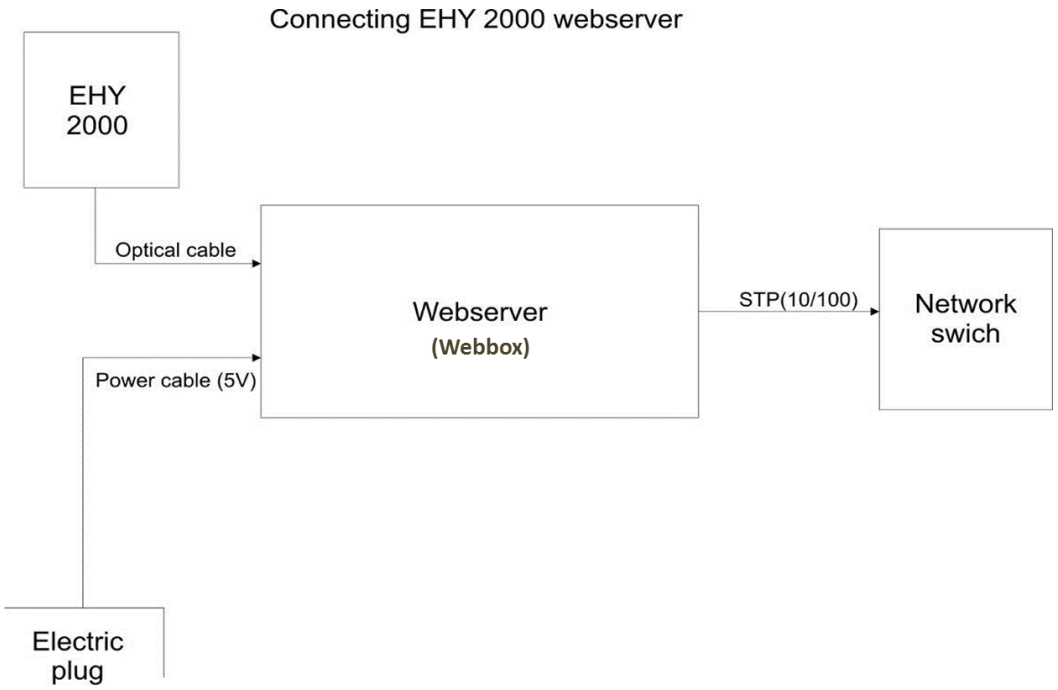
Purpose

The purpose of the Web-box is to have a "database management" in any hospital owned system. Due to the fact that every hospital has its own management system, our system has to support all (or most) of them. This facility has been achieved through the conventional web protocol (HTTP) because nowadays this protocol is supported by every computer and operating system.

This way the physician and the hospital's administration staff have the possibility to control, check and download information from the EHY-2000plus.

System structure

The installation structure of the Web-box for the EHY-2000plus can be represented as shown below:



The Web-box should be placed outside of the patient environment.

Usage

The Web-box is really easy to use. It looks like a common page on the internet. Write the number of the web server (by default it is 10.0.0.235) into the address bar and you are led to the opening page of the web server.

In case your system has a DNS server internally, you can add the IP address to your system and it is possible to refer to the device as a name and not as an IP.

In the following there are some examples how to achieve different major tasks. Later on you will find the description of the different web pages.

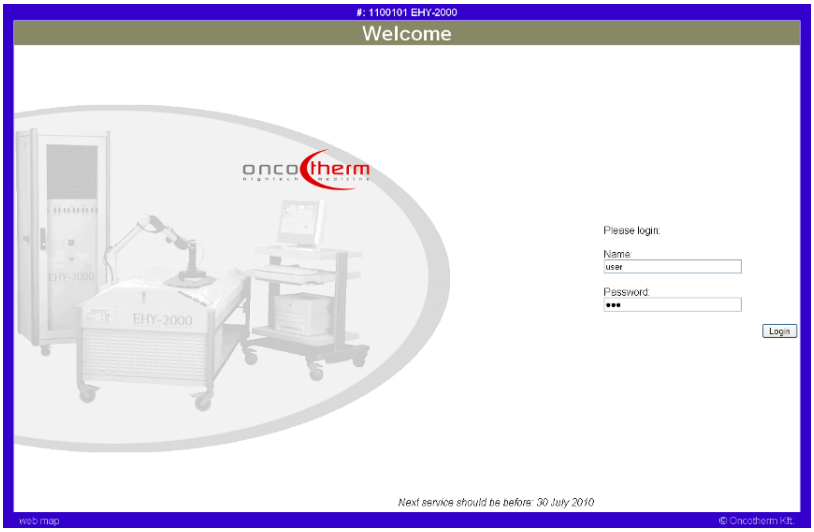
Starting the Web

1. Start your web browser (for example click on the Microsoft Internet Explorer icon, Mozilla Firefox, Google Chrome, …) to enter the web viewing.
2. Type in the IP address of the EHY-2000plus device (by default it is 10.0.0.235) or select the shortcut function to the device if it has already been inserted by our service technician.
3. The EHY-2000plus device opening page should come up in your browser in a few seconds.

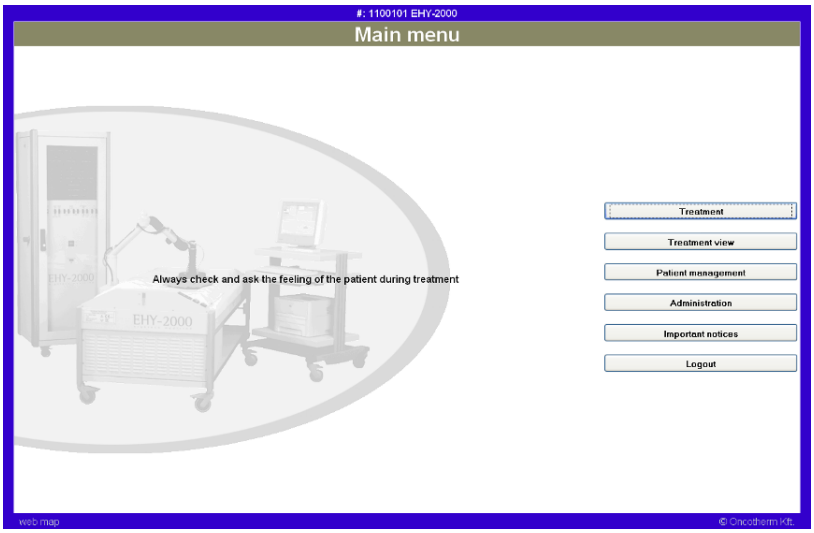
Logging in and the Main menu

1. Click on "*Login*" (or on the Oncotherm logo) on the opening page.
2. Type in your name and password in.
3. In case your name and password are correct and the computer is certified by the web server, you will be allowed to enter the main menu.
4. Note: Every device has its own frame color and serial number. Please always check that you control the device you want to select!

5. By default your user name is *"User"* and the password is *"EHY"*.

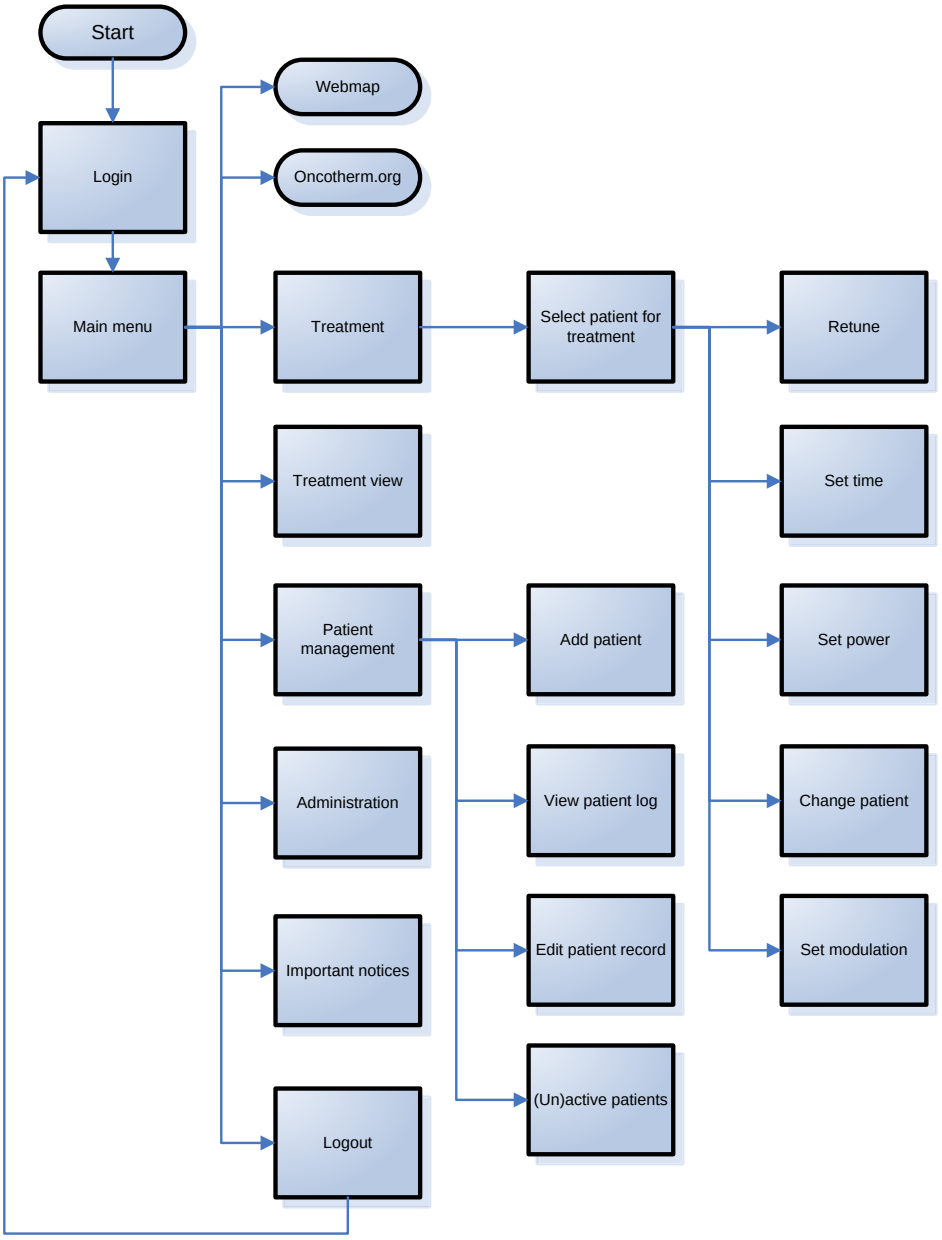


After logging in you will enter the *"Main menu"*.



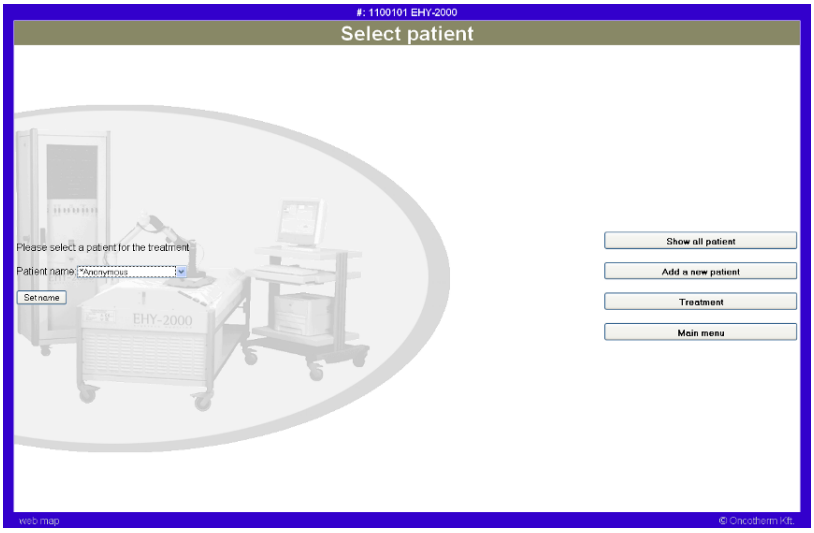
In the menu you can choose from the different tasks which are possible to manage or to see. This menu includes e.g. test results, treatment control, patient management and important medical notes. By clicking on the *"Logout"* button you can end the use of the software.

On the following diagram you can see the structure of the program.

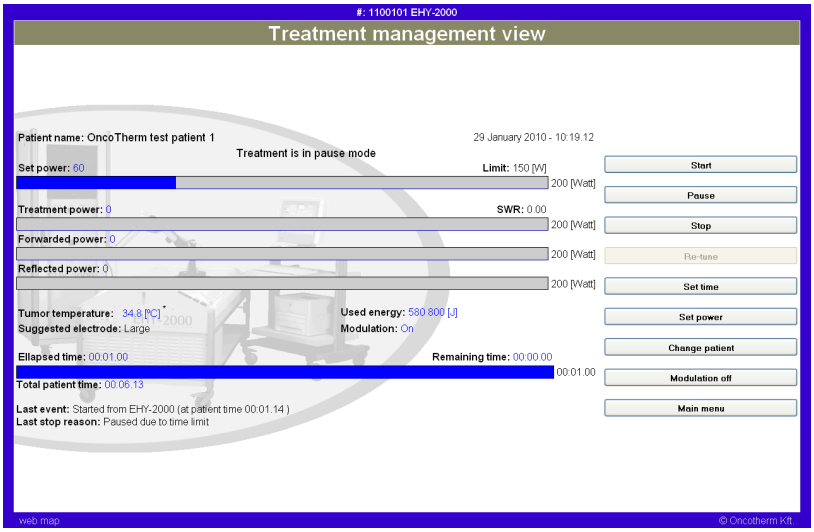


Treatment menu

The main function of the Treatment menu is the control of the device. Entering the treatment menu you will get onto the *„Select patient"* page. Here the patient's name can be set from the predefined list on this screen or add a new patient (this option leads you to the Patient management menu).



By clicking on the *"Set Name"* button you can select the patient and by clicking on the *"Treatment"* button you will enter the *"Treatment management view"* screen.

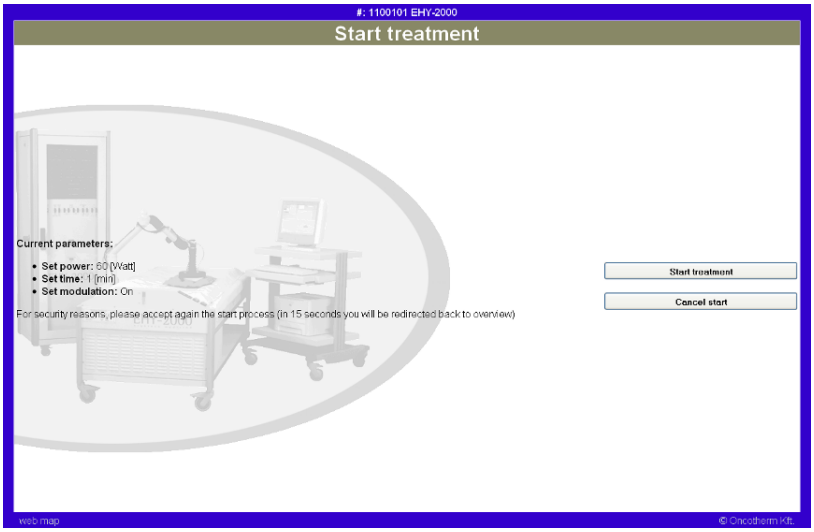


You can set the parameters of the treatment:

- treatment time by the „*Set time*" option
- treatment power by the „*Set power*" option
- turn on or off the modulation of the power by the „*Modulation on/Modulation off*" button (the text of the button depends on the current setting)

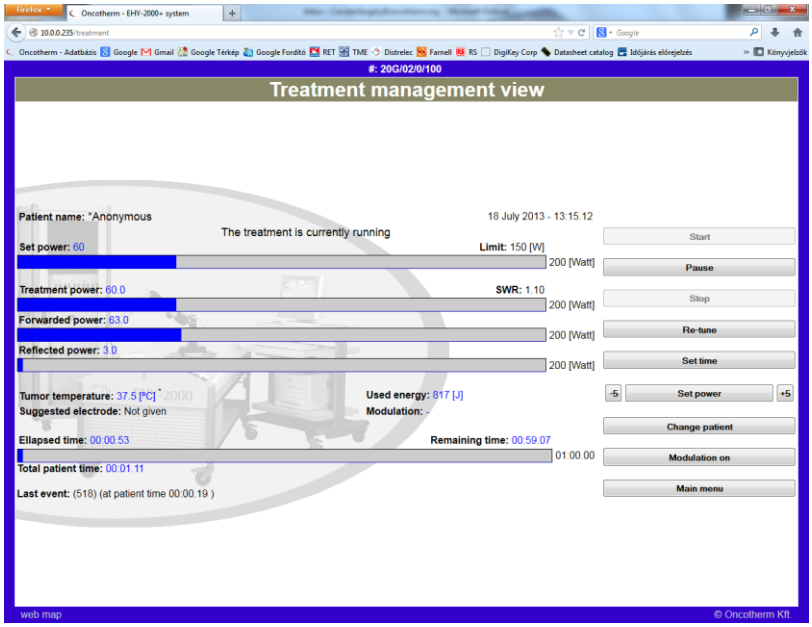
These parameters are changeable during the treatment too.

By clicking on the „Start" button you can start the treatment, but you have to reconfirm it on the automatically appearing *„Start treatment"* page, where you can check the set treatment parameters.



After the reconfirmation you will get back to the *„Treatment management view"* screen (see previous page), where you can check the parameters of the treatment:

- Set power
- Treatment power
- Forwarded power
- Reflected power
- Elapsed time



If the *„Treatment power"* is much less than the *„Forwarded power"* (the Reflected power is more than 25% of the *„Forwarded power"*), use the *„Re-tune"* button to tune the device to the patient. If the re-tuning is not successful, please pause the treatment by the *„Pause"* button, and check the correct placement of the bolus electrode. You can continue the paused treatment by the *„Start"* button. To abort the running treatment you can use the *„Stop"* button. On the appearing of the *„Treatment stop"* screen you can choose to view the logged data of the treatment or get back to the Main menu.

During the treatment the treatment parameters can also be modified. To change the treatment power there are two possibilities. To change the treatment power to a certain value you should click on the *"Set power"* button on the *"Treatment management view"* screen. On the appearing *"Set*

treatment power" page you should type the requested power value into the edit box and confirm the change by clicking on the *"Set power"* button.

If you do not type in a new value, after 30 seconds the software will step back automatically to the *"Treatment management view"* screen.

The treatment power can also be modified with the *"+5"* and *"-5"* buttons on the sides of the *"Set power"* button on the *"Treatment management view"* screen. By clicking on these buttons the power can be increased or decreased with 5 W without the need of confirmation.

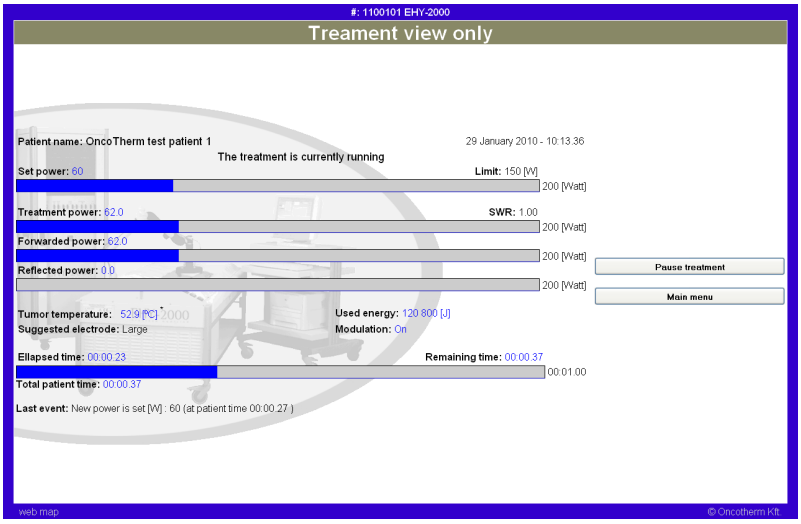
The treatment time can be modified similarly to the power by clicking on the *"Set time"* on the *"Treatment management view"* screen. Confirmation of the new treatment time is needed on the *"Set treatment time"* page.

Modulation can be switched on/off by clicking on the *"Modulation on/Modulation off"* button on the *"Treatment management view"* screen (the text of the button changes by the switching).

All treatment parameters can be changed in the running and paused state of the treatment too.

Treatment view

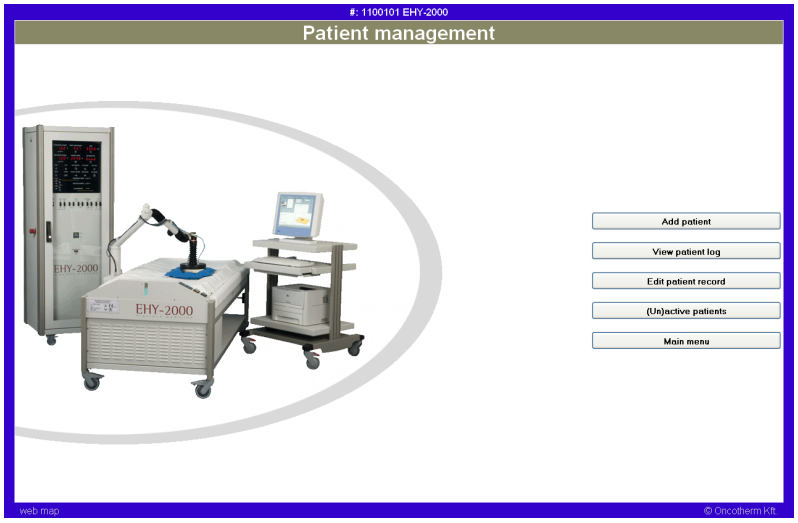
The second option, which you can choose in the main menu, is the treatment view. The *„Treatment view"* screen is very similar to the *„Treatment management view"*, because you can monitor the same parameters, but the difference is that you cannot modify the treatment parameters.



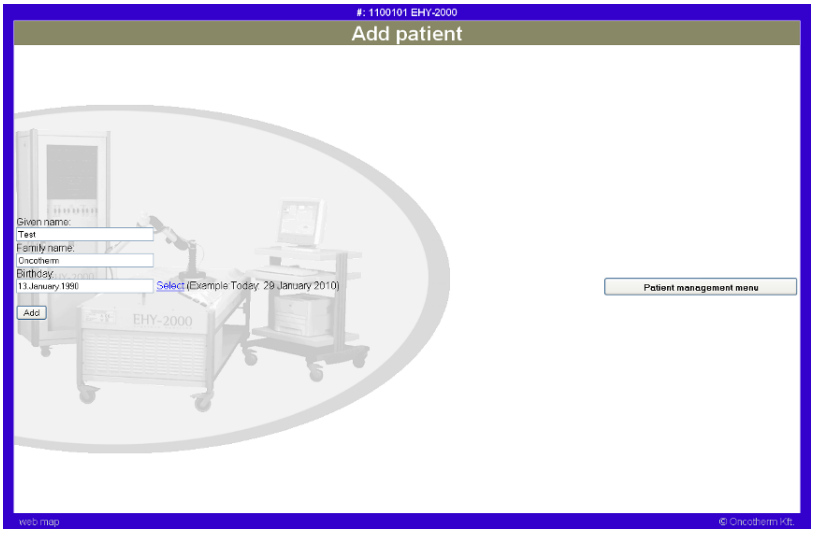
This function is useful if there is a central station – beside the physicians' control – where all devices can be monitored.

Patient management menu

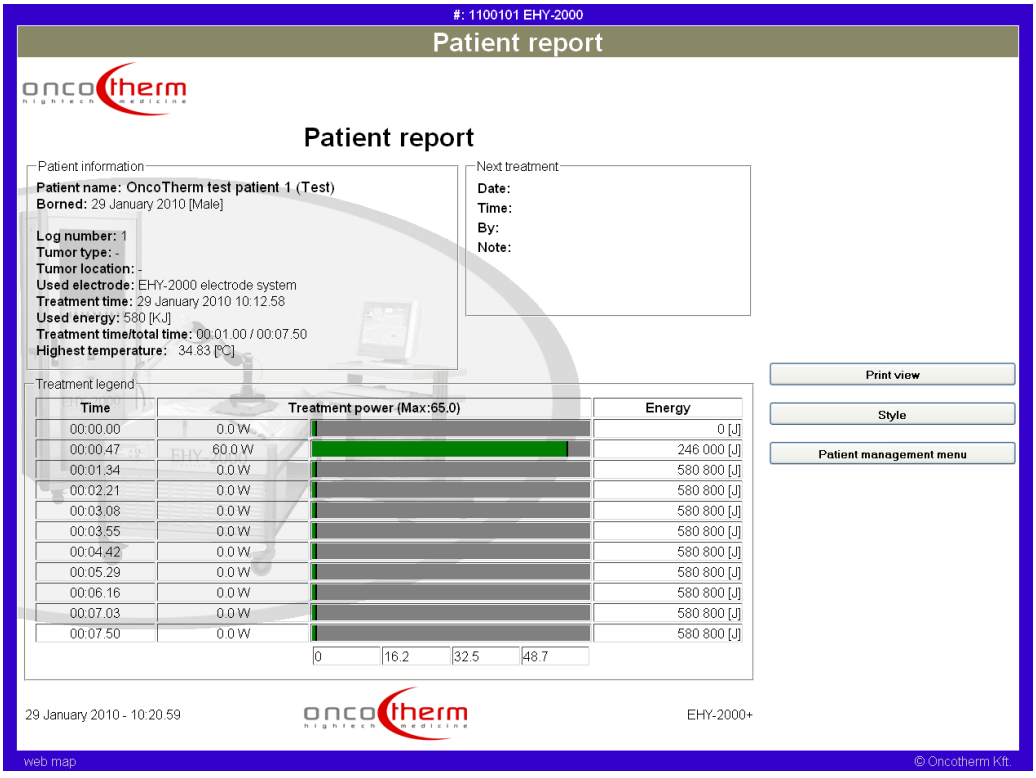
In the *"Patient management"* menu all patient relevant tasks can be performed, like adding new patients, viewing treatment data, etc.



The first option in the menu is *"Add patient"*. On this page you can add new patients to the patient list by typing in the patient's name and their date of birth.



The next option in the *"Patient management"* menu is the *"View patient log"* page. On this page the data of the treatments can be seen and printed. The page is preceded by another one, where you have to choose the patient whose data you want see (like in the *"Treatment"* menu)

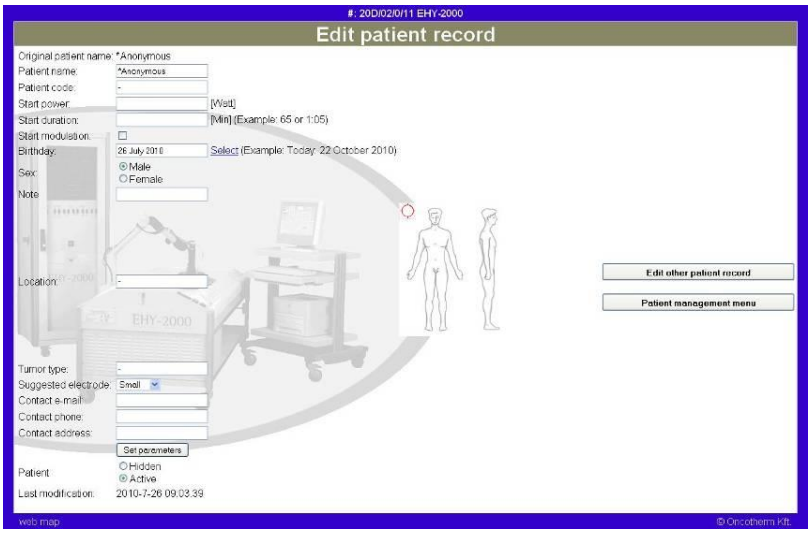


The table shows the major parameters of one treatment of the patient chosen on the previous page. The major parameters are:

- Patient's name
- Treatment date
- Used energy
- Power graph
- Temperature graph
- Event list

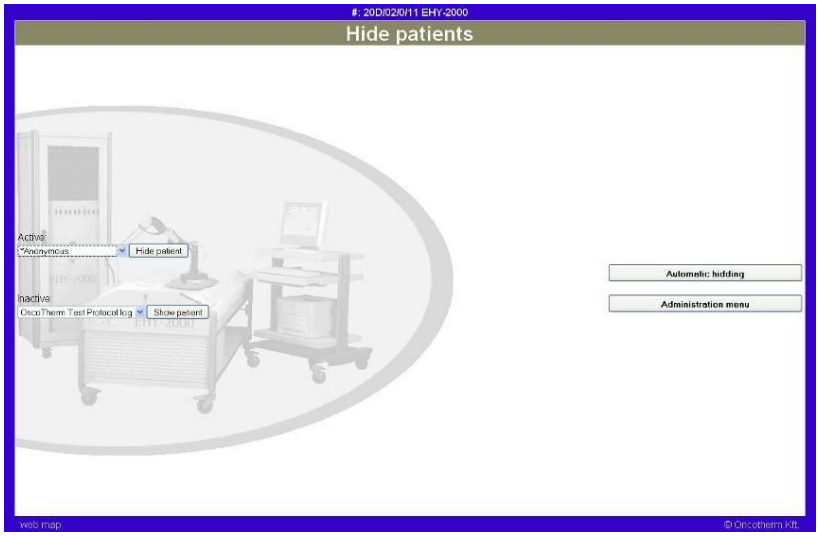
You can check the patient's next, previous, first or last treatment by clicking on the appropriate link. By clicking on the print button, you receive a printable version.

The third option in the *"Patient management"* menu is the *"Edit patient record"* page. The page is followed by another page where you can choose the patient, whose data you want to modify.



On this page you can modify the patient's name, set default treatment parameters for the chosen patient and add notes. In the picture in the middle of the page you can mark the location of the tumor, which is useful for the electrode placement. In the bottom of the page you can hide the not used patients (these patients will not be shown on the patient list).

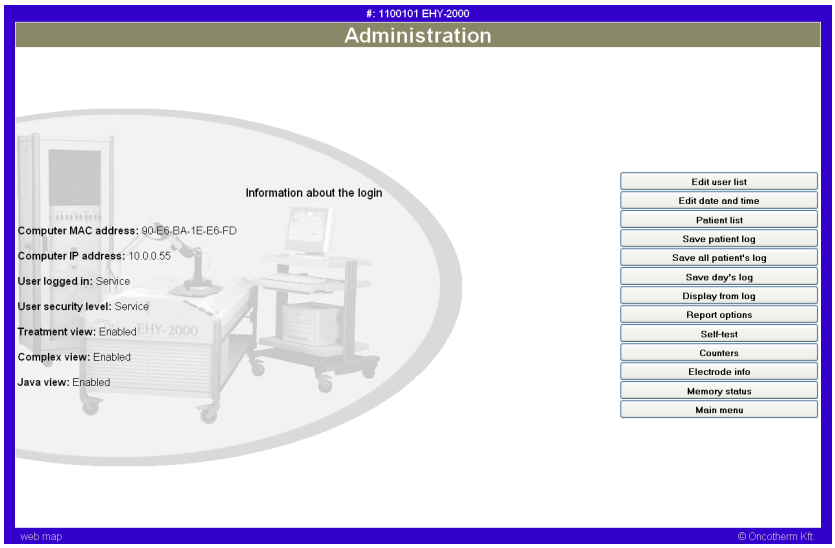
The last option in the *"Patient management"* menu is the *"(Un)active patients"* page.



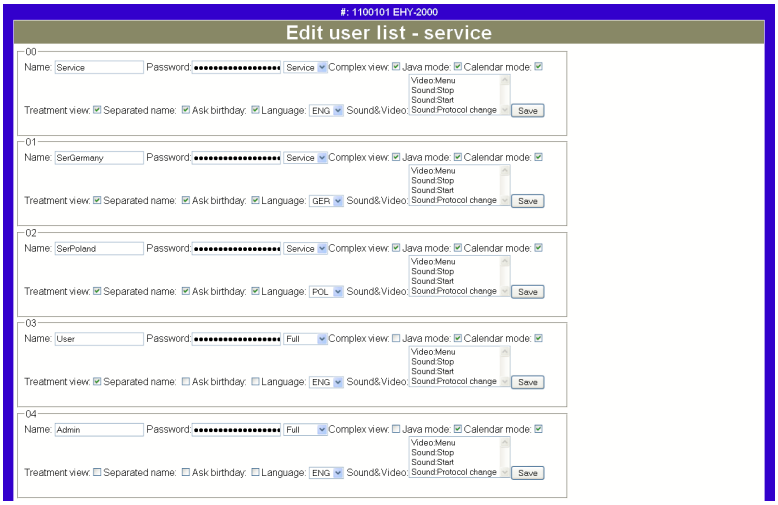
Here you can inactivate the not treated patients (like on the page mentioned before). You can reactivate the hidden patients as well.

Administration menu

In the *"Administration"* menu you can find various support functions like treatment log saving and recovering, user list editing and time and date setting.



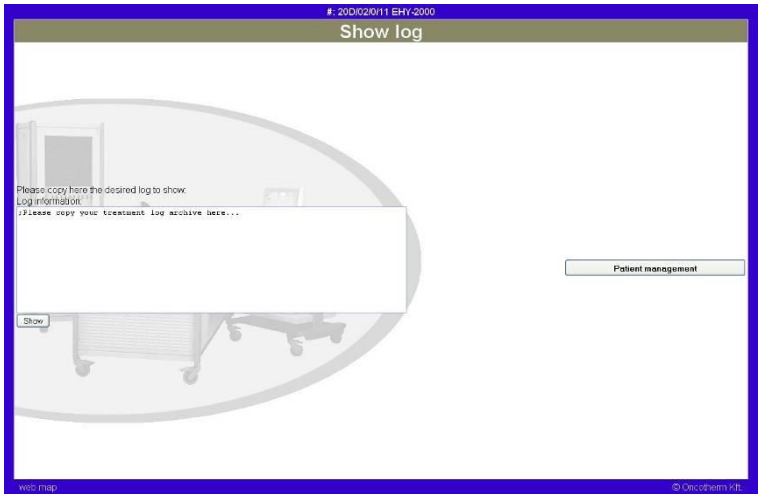
The first option in the menu is the *"Edit user list"* option.



The new and old users can be managed. This is required for logging in into the system. In case you edit your own login name and password, note that you can still log out.

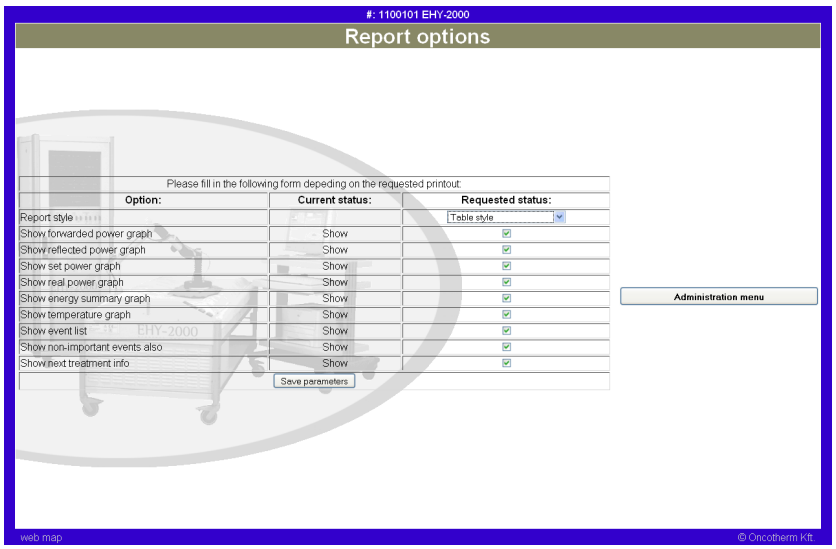
The next options in the menu are *"Edit date and time"* and *"Patient list"*. The time and date can easily be set by synchronizing the time and date of the device with the help of the internet.

With the next three options in the menu (*"Save patient log", "Save all patient's log", "Save day's log"*) the patient logs can be exported from the device in a text form. If the first of the three options is used, you have to choose the patient, whose data you want to export. The exported data will appear in a new window (or tab) of the browser, from where you can save it in a text form. The generated data text is coded, so it cannot be viewed separately from the device. To recover data from the saved coded text, use the Display from log option of the *"Administration menu"*.



To recover the patient logs from the saved data, please copy the saved coded text into the dialog box and then press the "Show" button.

By choosing the *"Report options"* link in the *"Administration"* menu you can select what kind of data will be printed in the Patient report. The first column shows the options, the second: if it is on/off, the third one: checkout box. After all needed options are selected, the settings must be accepted with the Save settings button.



Important notices

Choosing the *"Important notices"* link in the *"Main menu"* you can read the most important notices and warnings about the use of the device.

Important notes for the use of the software

The following notes should be taken into consideration and followed when using the web box.

- The treatment manager view can be used only on a computer from where the patient is within sight.
- The patient should be monitored continuously not only through the web server but in the room as well.
- All warnings mentioned in the EHY-2000plus user's manual have to be considered
- The logged computers must be certified and linked on to the web server by a service technician.
- The treatment view shows the actual time on every new loaded page. It should be checked every time the page is really newly loaded or comes from the cache.
- The device is matched with a colour (and a serial number). In case of every control the web page colour and the serial number written in the border should be checked if the right device is controlled.
- After entering power or time, please check in the treatment window, if the parameter is really set and if is the parameter which is required.
- **The RF radiation emitted by the device may jam the WLAN connections, that is why it is prohibited to use WLAN to connect the device with the controlling computer!**

Supported browsers

The used protocol is the primary HTTP protocol with cookies. This means that any nowadays used common browser should be able to view the pages supported by the web processor. **The suggested browser is Mozilla Firefox.** If Internet Explorer is used, security level of the browser should be set to medium or low.

The following browsers have been tested with the web box:

1. Mozilla Firefox 5.0
2. Microsoft Internet Explorer 7.0

Requested technical background

Client browser

Any kind of computer and browser are suitable and support the HTTP protocol. Our web box does not require any java or flash support but it requires a cookie support.

Your computer also has to be identified by the web server to have a connection allowance with the critical sites. This configuration can be set by our service technician.

Please note that depending on your browser, the look of the screens may differ from each other. (Please check the supported browsers list.)

Network

You are requested to have a UTP network connection to your own network system. It can be 10 or 100 Mb, half or full duplex connection. It is also requested to have your network protected against unwanted intruders. (To have a correct firewall configured.)

Please note that the communication from/to the web processor is not secured. It means that a prepared hacker can read all communication if your network is not protected properly.

Alternative configuration

It is possible to have a sub local network configuration which enables it to connect one (and only one) computer to the web server. In this case a direct contact will be accomplished between the two systems.

Due to this configuration, no external intrusion is possible and the computer cannot connect to the internet either.

Technical description

The main RF-unit

The unit's output power is stable, highly precise and well integrated, containing the following parameters:

The equipment is a high-tech, high-quality unit, having the latest available techniques inside. The device is shown in the figure.

CE 0123

Technical data

Line voltage: AC 230/110 V 50-60Hz

Power input: ≈1600VA/7A

Output RF Voltage (50 Ω) range: 0-130V

Output power by RF generator: max 250W

Output useful power: max 150W

default - 60W

Nominal load is 50 Ω.

Tuning: The auto-matching unit (auto-tuner) always tunes for a calibrated value, a standard 50Ω (fits the impedance), so that the delivered output power is calibrated.

Output carrier frequency: 13.56MHz

(quartz stabilised)

Output modulating frequency: 0-5 kHz,

(experimentally optimised)

Weight (including cables): 175 kg

Height: 1720mm

Electrical safety classification:

Class I, Type BF (according to IEC 60601-1)

Technical data of the waterbed

(WEY: 6DDFFEE)

CE 0123

Line voltage goes through the high frequency control unit	
Surface temperature:	25 … 38°C, adjustable (step 0.1°C)
Display:	Surface temperature, res. 0.1°C
	Set temperature, res. 0.1°C
	4 lamps and 2 buzzers for errors
Warming-up time (24 > 37°C):	approx. 16 hours*
Size:	2100x830x700 mm
Total weight (filled with water):	300kg
Quantity of water:	≈100 l distilled water
Max. weight of the patient	150 kg

Electrical safety classification: Class I., Type BF (according to IEC 60601-1)

*Bed without any covering at 24°C environment - recommended: 24 hours.

Transportation and storage:

The Oncotherm service is responsible for transportation and storage.
The following storage conditions are valid for transportation- and storage time for 15 weeks:

Temperature:	+5°C……+55°C filled with water
	-5°C……+55°C without water!!!
Relative humidity:	10%……75%
Air pressure:	500hPa…..1060hPa

The values of the operating conditions are valid:

Temperature:	+15°C……+23°C filled with water
Relative humidity:	20%……60%
Air pressure:	700hPa…..1060hPa

Storage: only in closed rooms.
After transportation the EHY, WEY and Webbox unit must be installed by the Oncotherm service.

Cleaning

Maintenance of external surfaces:

1. Turn off the power before cleaning the unit.
2. For cleaning use a soft and dry cloth.
3. If the surfaces are extremely dirty, use a soft cloth, dipped into soap and water solution or a weak detergent solution.
4. Wring the cloth well before wiping the unit.
5. Wipe once again with a soft dry cloth.
6. Never use alcohol, paint thinner, benzene or a chemically treated cloth to clean this unit. Such chemicals may damage the surface of your unit.

Disinfecting the accessories

Electrode: It is very important to disinfect the electrode before each treatment. Suggested solution is **Isopropanol 70% (V/V)** Please use it according to the user instructions on the bottle. Once a week the electrode has to be cleaned by a soap-solution. Use only damp textile. If the textile is too wet, the liquid can penetrate into any part of the equipment. Use medical hygenic paper (see detailed description in Accessories and Appendix 9 for datasheet) – or any other medical hygenic paper with CE mark - between the bare skin and the electrodes, to fix the electrode. No other material is allowed to be used!

Treatment bed: Concerning the EHY-bed a cleaning procedure must be done regularly by the user, according to the normal hospital disinfecting rules. The mattress of the bed must be cleaned with a disinfecting solution. Suggested solution is **Incidin plus (Henkel–Ecolab)** according to user instructions on the bottle.

Further recommendations:

Use a special liquid provided by the manufacturer to avoid algae formation in the electrodes. Please check the instructions in the User manual in the Treatment part, APPENDIX 3. (Bolus electrode refilling)

This special liquid is added to the water of the waterbed the water of the waterbed mattress during the installation and on the regular half year services by the Oncotherm service technicians.

Servicing/Maintenance

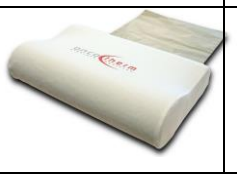
The user is required to have the unit serviced once every half year under normal operating conditions. Only authorized Oncotherm service technicians can do this work. The user must obtain certification concerning to the nature and extent of the work with information on any alteration made to the nominal data or operating range. This certification must also show the date and the name of the firm and a signature.

Disposal

If it is requested, the manufacturer arranges the disposal of the device. In case of disposal, the manufacturer is responsible for organizing the transportation of the unit (with accessories). Price of transportation and packaging will be given to you by our office.

Accessories

Accessories	Photo	Order number
1. User's manual		---
2. Water-cooled bolus asymmetric electrode standard (20 cm) / 6/01/200CO/DD-EE Water-cooled bolus asymmetric electrode large (30 cm) (option) / 6/01/300CO/DD-EE Water-cooled bolus asymmetric electrode small (10 cm) (option)/ 6/01/AABH/DD-EE 3. All: elastosil rubber membrane, flexible holder, plastic		1028 1026 1027
4. Test patient. Devoted for testing of the device and for the exercise of the usage of the device. Can be used for head support at head treatment.		1039
5. Controlling computer (optional)		1004

Other accessories	Photo	Order number
ROLLICELL hygienic paper (optional) type: '3759-50; w:59cm, l:50m (see datasheet in Appendix 9)		1140
Memory foam pillow with metal coated material and cover (optional)		11563

WARNING! To use any accessory ACCESSORIES other than those specified, may result in increased EMISSION or decreased IMMUNITY of the EHY-2000plus device, therefore it is strictly forbidden.

Appendix 1 – Guarantee

The manufacturer guarantees the service for the whole instrument (hardware and software). The guarantee is free of charge for the first two years. After two years, service can be guaranteed in the form of a stand-by agreement. The total upgrading of the system, to keep pace with new developments and knowledge in this field can be included in the stand-by service agreement.

The guarantee covers both spare parts and labour. Service under guarantee is only provided upon presentation of reasonable evidence (e.g. completed guarantee card or purchase receipt) that the date of claim is within the guarantee period.

The guarantee is not valid if the defect is due to accidental damage, misuse or neglect and in case of alterations or repairs carried out by unauthorised persons.

Any change in the hardware and/or software without written permission of the manufacturer is strictly prohibited.

The service (during and after the guarantee period) is available in all countries where the product is officially distributed. For further information, please contact your local distributor.

Any suggestions and/or requests for further development of the system are highly appreciated and very welcomed.

Quality references:

EHY-2000plus are CE 0123 marked, TÜV Product Service (Munich) has given the EC Certificate. The device is constructed and produced to satisfy the IEC 60601-1 standard and the 93/42/EEC MDD (Medical Device Directive).

The equipment has passed an EMC (Electro-Magnetic Compatibility) check (CSA Group Bayern GmbH) according to IEC 60601-1-2 standard requirements.

The rights to this system are the sole property of the manufacturers. Patent is pending.

Not-permitted-change in installed hardware and/or software makes the certificates invalid!

Appendix 2 – Declaration of Conformity sample

Declaration of conformity

OncoTherm Kft.
H-2071 Páty, EU

Product designation: **Oncological Electro-Hyperthermia device**
Type, Model: **EHY-2000plus**

Manufacturer: **OncoTherm Kft.**
Address: **Ibolya utca 2.**
2071 Páty
Hungary

We herewith declare, under our sole responsibility, that above mentioned product in product category class II.b according to Rule 9 of Annex IX of MDD meets the applicable provisions of the EC Directive 93/42/EEC, as stated in Annex II. Section 3 of this directive amended EC Directive 2007/47/EC, by operating a Full Quality Management System following EN ISO 13485:2012 and EN ISO 9001:2008 requirements.

Serial Number: _____
Registration number of Declaration: __/20__.

Place: H-2071 Páty
Date: 24 September 2014

This declaration is based on the following Conformity Assessment:
Annex II.3
Certificate No.: G1 12 07 37893 032
Issued by TÜV SÜD Product Service GmbH
Ridlerstraße 65., 80339-Munich, Germany
Date: 23. July 2012

Konformitäts-erklärung (D Deutsch):
Hiermit versichern wir in alleiniger Verantwortung, dass das oben genannte Produkt der Produktkategorie II.b nach der Regel 9 im Anhang IX des MDD allen Anforderungen der EC Direktive 93/42/EEC, wie genannt in Anhang II. Sektion 3 der Direktive, die in der Direktive 2007/47/EC geändert wurde, entspricht und einem vollständigen Qualitätsmanagementsystem nach EN ISO 13485:2012 und EN ISO 9001:2008 unterworfen ist.

Megfelelőségi nyilatkozat (HU Magyar):
Felelősségünk tudatában kijelentjük, hogy a fent említett, az MDD IX melléklетének 9. szabálya szerint II.b. osztályba sorolt termék megfelel a 93/42/EEC EC direktívában foglalt Annex II 3. szakaszának, kiegészítve a 2007/47/EC EC direktívával, melyet a gyártó által működtetett EN ISO 13485:2012 és EN ISO 9001:2008 szabványok szerinti minőségirányítási rendszer biztosít.

.....
Dr. Olivér Szász
Managing Director

CE 0123

FORM-7-4/186-R4

Appendix 3 – Table of proposed electrodes

Operator's table:

Treated part of the body	Proposed electrode****	Electrode-skin distance ** [cm]	Treatment time [min]	Proposed power* [W]
Lungs	large	0	90	140-150
Kidney	standard	0	60	100-120
Liver	large	0	90	120-140
Stomach	standard	0	60	120
Pancreas	large	0	90	100-120
Lymphatic nodes	standard	0	60	80-100
Superficial	small	0	60	80
Colorectal region	standard	0	90	100-120
Breast	standard	0	60	60-80
Prostate***	standard	0	60	60-80
Esophagus	large	0	90	100-120
Brain	small	0	60	60-80

* Please carefully monitor the patient, and do not exceed their personal tolerance. The patient must not feel any burning or too much hotness.
** Always be sure that the electrode bolus is pressed firmly against the patient on the largest available surface to ensure tuning.
*** Take extra care on the testes.
**** Electrodes could be variable, depending on the area of the actual tumor.

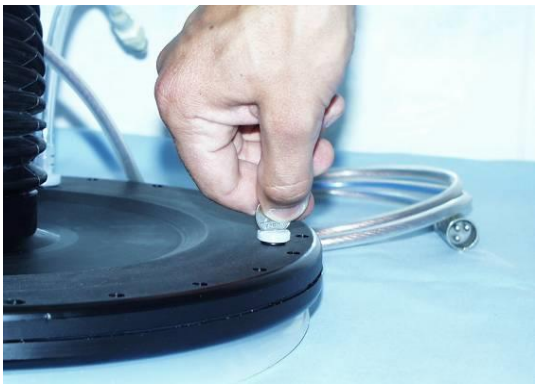
Electrode dimensions:

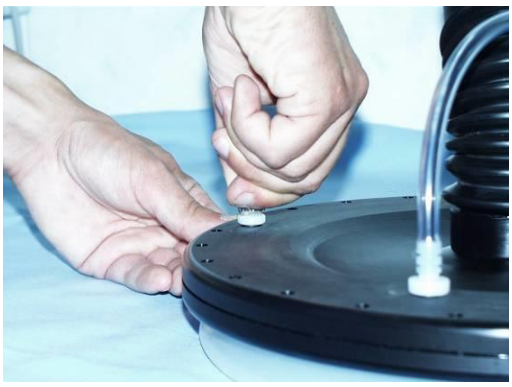
Small: Ø10cm
Standard: Ø20cm
Large: Ø30cm

Appendix 4 – Refilling of the bolus electrode

1. Please, unplug the cooling water quick connectors and the electric cable connector. The fixing safety button of the power plug has to be pressed down before pulling it out and be kept pressed throughout the procedure. Loosen the electrode fixing bolt, screw and pull it out of the electrode-holder arm. Please place the electrode on a clean surface without sharp edges.

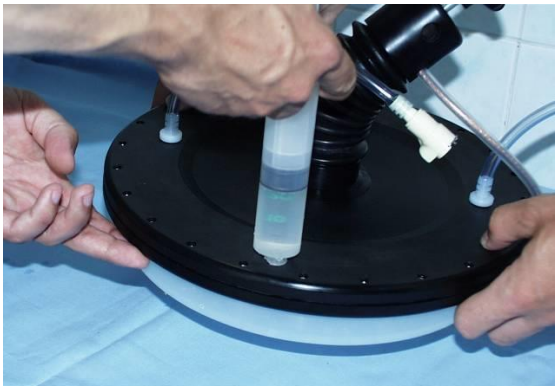
2. Take off both the packing nuts (the method is done by an appropriate coin as shown in the picture below).



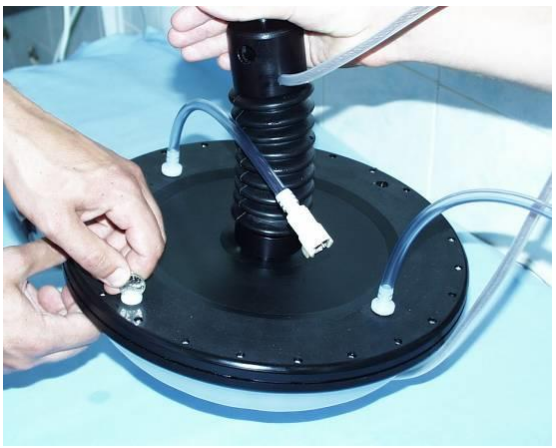


Before the opening of the filling hole, put a tray or absorbing textile below the electrode to avoid the water overflow.

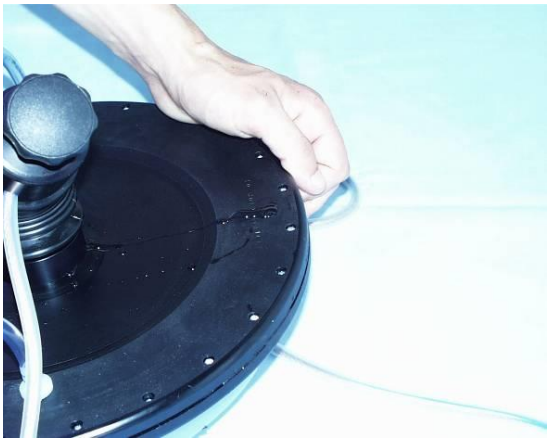
3. Lift up the electrode to such a height that the bolus does not touch the mounting surface. First of all, fill up the electrode with a special liquid provided by Oncotherm to avoid algae formation. Use the small bottle with the label: "Algae control" After this you can fill up the electrode with distilled water in this position. Use a medical syringe for the filling. Ask for help for the process because the action needs more than two hands. (See the picture.)



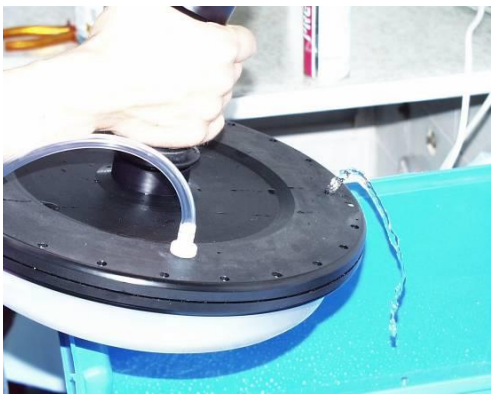
4. Close one of the filling holes with a screw.



5. Tilt the electrode in a small angle so that the open filling up hole must be higher than the closed one. Please press the bolus up until water appears on the open filling up hole. With this process you de-aerated the bolus.

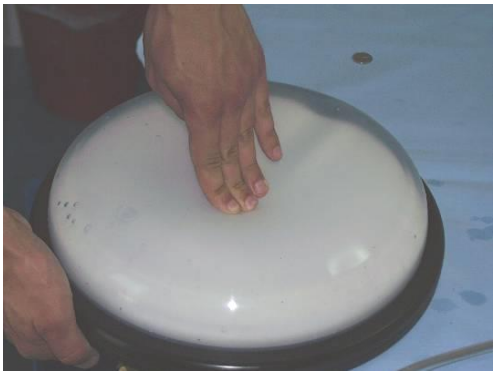


6. Put the electrode in a horizontal position. Ask for help to hold the electrode. Push the bolus up with one of the tip of your fingertips you reach the electrode's metallic plate. The excess water is taken off from the bolus with the shown procedure.



Take care that during this process, air must not get into the bolus. Take care that you can continuously see the water in the filling hole. Now, in this position screw in the packing nut.

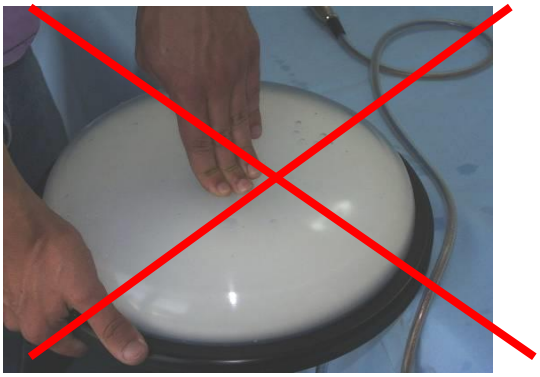
7. Turn up the electrode and check the appropriate volume of the water in the bolus and that it is de-aerated once more.



Attention! In the next pictures we are showing some examples of non-proper filling up of the electrodes and we are also showing how to avoid the mistakes.

Air must not remain in the electrode because this blocks or misleads the tuning and the auto matching procedure and so suppresses the efficacy of the treatment. To correct this mistake, go back to point 5.

By pushing the bolus with your fingertips you cannot reach the metallic plate of the electrode: the electrode is overfilled. In this case the electrode cannot fit well on the patient's treated region, the tuning accuracy decreases. Reduce the amount of water in the bolus! To correct this mistake, go back to point 6.



By pushing the bolus with the entire palm you can reach the metallic electrode plate: not enough water in the electrode. In this case, during the treatment the RF radiator electrode will be too close to the patient and could cause burn. Please fill more water into the electrode. To correct this mistake, go back to point 3.

Appendix 5 - Electromagnetic compatibility information

According to IEC60601-1-2:2001 standard requirements

EHY-2000plus

EHY-2000plus device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.

Portable and mobile RF communications equipment can affect EHY-2000plus device.

Table 201 – Guidance and manufacturer´s declaration – electromagnetic emission– for all EQUIPMENT and SYSTEMS (see 6.8.3.201 a) 3))

Guidance and manufacturer's declaration-electromagnetic emissions (T.201)		
The EHY-2000plus device is intended for use in the electromagnetic environment specified below. The customer or the user of the EHY-2000plus should assure that it is used in such environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 2	The EHY-2000plus must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The EHY-2000plus 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 202- Guidance and manufacturer's declaration-electromagnetic immunity-for all EQUIPMENT and SYSTEMS (see 6.8.3.201 a) 6))

Guidance and manufacturer's declaration-electromagnetic immunity (T.202)			
The EHY-2000plus is intended for use in the electromagnetic environment specified below. The customer or the user of the EHY-2000plus should assure that it is used in such environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/ output lines	±2kV for power supply lines ±1kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of EHY-2000plus requires continued operation during power mains interruptions, it is recommended that the EHY-2000plus be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 204 – Guidance and manufacturer´s declaration – electromagnetic immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING (see 6.8.3.201 b))

Guidance and manufacturer's declaration-electromagnetic immunity (T.204)			
The EHY-2000plus device is intended for use in the electromagnetic environment specified below. The customer or the user of the EHY-2000plus should assure that it is used in such environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	3Vrms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the EHY-2000plus, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1,2\sqrt{P}$ $d=1,2\sqrt{P}$ 80MHz to 800MHz $d=2,3\sqrt{P}$ 800MHz to 2,5GHz 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 meters (m). 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 Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.			
a 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 EHY-2000plus is used exceeds the applicable RF compliance level above, the EHY-2000plus should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EHY-2000plus device. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 206 – Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING (see 6.8.3.201 b))

Recommended separation distances between portable and mobile RF communications equipment and the EHY-2000plus (T.206)			
The EHY-2000plus device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EHY-2000plus can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EHY-2000plus device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150KHz to 80MHz d=1,2√P	**80MHz to 800MHz** d=1,2√P	**800MHz to 2,5GHz** d=2,3√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
For transmitters rated at a maximum output power not listed above the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

WEY-2000plus

Table 201 – Guidance and manufacturer´s declaration – electromagnetic emission– for all EQUIPMENT AND SYSTEMS (see 6.8.3.201 a) 3))

Guidance and manufacturer's declaration-electromagnetic emissions (T.201)		
The WEY-2000plus device is intended for use in the electromagnetic environment specified below. The customer or the user of the WEY-2000plus should assure that it is used in such environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The WEY-2000plus 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.
RF emissions CISPR 11	Class B	The WEY-2000plus 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 202- Guidance and manufacturer's declaration-electromagnetic immunity-for all EQUIPMENT and SYSTEMS (see 6.8.3.201 a) 6))

Guidance and manufacturer's declaration-electromagnetic immunity (T.202)			
The WEY-2000plus device is intended for use in the electromagnetic environment specified below. The customer or the user of the WEY-2000plus should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/ output lines	±2kV for power supply lines ±1kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of WEY-2000plus requires continued operation during power mains interruptions, it is recommended that the WEY-2000plus be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 204 – Guidance and manufacturer´s declaration – electromagnetic immunity– for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING(see 6.8.3.201 b))

Guidance and manufacturer's declaration-electromagnetic immunity (T.204)			
The WEY-2000plus device is intended for use in the electromagnetic environment specified below. The customer or the user of the WEY-2000plus should assure that it is used in such environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	3Vrms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the WEY-2000plus, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1,2\sqrt{P}$ $d=1,2\sqrt{P}$ 80MHz to 800MHz $d=2,3\sqrt{P}$ 800MHz to 2,5GHz 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 meters (m). 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 Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.			
a 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 WEY-2000plus is used exceeds the applicable RF compliance level above, the WEY2000plus should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the WEY-2000plus. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 206 – Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING (see 6.8.3.201 b))

Recommended separation distances between portable and mobile RF communications equipment and the EHY-2000plus (T.206)			
The WEY-2000plus device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the WEY-2000plus can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the WEY-2000plus device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150KHz to 80MHz d=1,2√P		**150KHz to 80MHz** d=1,2√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
For transmitters rated at a maximum output power not listed above the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Appendix 6 - Treatment in 9 steps

The following points contain the steps of a typical treatment. It is suggested to keep a copy of this page near the device.

1. Choose the proper electrode and disinfect it.
2. Fix the electrode on the holding arm and connect the water tubes.


3. Connect the electrode cable to the device and fix the cable on the holding arm on every possible point.


4. Let the self-test run. The self-test takes about 2 minutes.
5. Switch on the device by the Main switch on the front of the device
6. Lay the patient on the waterbed and place the electrode as horizontal as possible on the patient on the identified treatment area.
7. Set the treatment parameters by the Select, Up and Down buttons
8. Start the treatment with the Start button

9. Let the treatment run until the set time runs out. The device signs the end of the treatment by a sound signal. After pushing the Stop button the device makes a self-test automatically, after that you can begin the next treatment.

Appendix 7 - Patient Consent

ONCOTHERMIA SHOULD NOT BE USED BY PATIENTS UNTIL THERE HAS BEEN A COMPLETE DISCUSSION OF THE RISKS AND WRITTEN INFORMED CONSENT HAS BEEN OBTAINED.

IMPORTANT INFORMATION AND WARNING

PATIENT'S CONSENT

My,_____, treatment with ONCOTHERMIA has been personally described to me by Dr. _____.

The following points of information, among others, have been specifically discussed and made clear and I have had the opportunity to ask any questions concerning this information:

1. I, _____(patient's name) understand that ONCOTHERMIA is used to treat certain types of tumors (malignant and benign) and my physician has told me that I am this type of patient.
   Initials: _____
2. I understand that there is a risk of surface or adipose erythematic reaction, sometimes burn-injury, by using ONCOTHERMIA.
   Initials:_____
3. I understand that there are no laboratory tests that will predict the success of the treatment
   Initials:_____
4. I understand that I must immediately report any unusual symptoms to Dr. _____ and be especially aware of persistent nausea, fatigue, lethargy, decreased appetite, itchiness, pain, etc.
   Initials:_____

I now authorize Dr. _____ to start my treatment with ONCOTHERMIA; OR, if my treatment has already begun with ONCOTHERMIA, to continue the treatment.
Patient's Name: _____
Address: _____

_____
Telephone: _____

PHYSICIAN STATEMENT: I have fully explained to the patient, _____, the nature and purpose of the treatment with ONCOTHERMIA and the potential risks associated with that treatment. I have asked the patient if he/she has any questions regarding this treatment or the risks and have answered those questions to the best of my ability. I also acknowledge that I have read and understand the prescribing information listed above.

_____

Physician Date

NOTE TO PHYSICIAN: It is strongly recommended that you retain a signed copy of the informed consent with the patient's medical records.

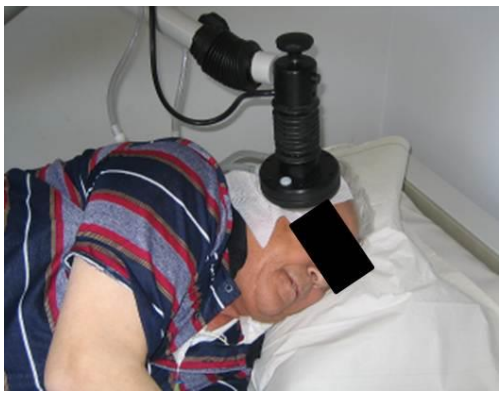
***SUPPLY OF PATIENT CONSENT FORMS**: A supply of "Patient's Consent" forms as printed above, is available, free of charge from Oncotherm GmbH, Belgische Allee 9, D-53842, Troisdorf , Germany (info@oncotherm.de) Phone: +49-2241-319-920*

Appendix 8 - Brain Treatment

The brain treatment needs extra care (at least half year experience of use and a special training at Oncotherm training clinics are also required).

The main points are:

1. Please use the small or the medium size electrode. At the beginning (if you have enough place to position it) please use the medium size, because its energy density is smaller. The high energy density from small electrode needs more expertise.
2. Put a thin paper towel (Use medical hygienic paper (see detailed description in Accessories and Appendix 9 for datasheet) – or any other medical hygienic paper with CE mark - between the bare skin and the electrodes. Any other material is not allowed to use!) under the electrode to avoid free-sweating. When free-sweat appears, please wipe it off to avoid the short circuit of the RF current through the liquid.
3. Please start with 30-40 W for 30 min without modulation!
4. Increase the power at the second treatment from 40 W to 60 W for40 min gradually
5. From the third treatment you may switch on the modulation too and treat the patient in the regime from 40 W to 80 W gradually for 60 min
6. Always control the patient (headache, dizziness, epilepsy, etc.) and ask before the treatment how they were after the last time. In case of adverse effects, do not increase the dose, till the adverse effects continue.
7. Please carefully place the electrode: the electrode frame (black plastic) must not touch the patient's skin, the electrode must be as far as possible from the eye.
8. The patient must lay on the water-bed. When placing any normal pillow under their head, the air in the pillow will prevent the RF-current to flow, and all the current will flow through the neck and shoulder to the waterbed. It could be OK sometimes (depending on the place of the tumor) but sometimes it could be problematic. When you need more positioning, put a water-filled pillow (may be a beach pillow filled with distilled water) under the patient's head



to be sure where the RF- current flows.

9. The patient must be in a relaxed position. Please fix their position with pillows or blankets at the waist or chest, and somehow fix the body so that the patient does not have to keep their body by force.
10. You need very high care during/throughout the whole treatment process. Concentrate- on the patient's complaints and ask their subjective feelings regularly, make regulations, adjustment their needs.
11. Please give some edema-reducing product (usually glycerol-derivatives, Manitol, etc) when the patient makes complaints about the perifocal edema.
12. Please make the protocol for two-three times a week, skip at least one day between the treatments
13. Please remove all the metals- (ear-rings, necklaces, piercings, etc.)
14. Do not allow to use phones, ear-phones, etc.
15. Do not allow the patient to touch anything outside the bed during the treatment.
16. Sometimes the metallic implants in the oral cavity (mainly amalgam fillings) could be slightly painful. In this case adjust the electrode until the feeling is over.
17. Please document everything carefully, because the brain tumor could produce unexpected reactions, which has not got any connection to oncothermia, so you have to be well prepared for any cases.
18. In case of metastatic brain tumor, please treat the primary tumor as well (if it is not operated out completely), avoid any further dissemination supporting the metastasis.
19. Always position the black RF cable behind the patient, and it must be far away from the eyes. (Being exposed to electro smog for a long time could cause eye problems).

Appendix 9 - ROLLICEL datasheet

DATA SHEET „ROLLICEL“

Product Description:

Medical rolls made of virgin pulp
and absorbing tissue
2-layer, perforated
white

Rösner-Mautby Meditrade GmbH
Thierseestr. 196
D-83088 Kiefersfelden – Germany
Telefon: +49 (0)8033/9760-0
Fax: +49 (0)8033/9760-60
E-Mail info@meditrade.de
Internet www.meditrade.de
ILN-Nr. 42 500164 0000 4

Manufacturer:	Rösner-Mautby Meditrade GmbH	
REF:	3739-50 (Width: 39 cm / Length: 50 m) 3750-50 (Width: 50 cm / Length: 50 m) 3755-50 (Width: 55 cm / Length: 50 m) 3759-50 (Width: 59 cm / Length: 50 m)	
Weight:	33 g / m² (+/- 5 %)	
Sheet Length:	380 mm (+/- 5 mm)	
Tensile Strength:	MD (machine direction): CD (cross direction):	410 N/m (+/- 20 %) 240 N/m (+/- 20 %)
Packing:	9 rolls / carton	
Embossment:	Microembossed	
Material:	Virgin pulp	
Certification:	EN ISO 9001 / 12.2000 EN ISO 13485:2003 + AC:2007 Appendix V Section 3 MDD 93/42/EEC CE-Certification: Class I	

Data Sheet Rollicel 2-layer 1/1 26.01.2009

Appendix 10 - Memory foam pillow

Product information

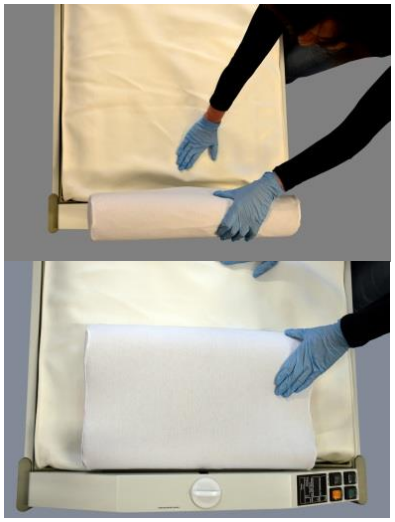
The memory foam pillow can be used as a complementary accessory to treat the head with the EHY-2000, the EHY-2000plus, the EHY-2010 and the EHY-3010ML devices. This instruction is only valid together with the user's manual of the treating device.
The memory pillow can mould the shape of the patient's head and neck and so longer treatments would cause less discomfort to the patient.
The pillow is coated with a special metal fabric which carries well the high frequency current, and in addition it has a special fabric outlet, which has direct connection with the lower electrode so that during the treatment the pillow is used as the lower electrode. This way the treated area (the patient's head) will be exactly between the two electrodes and it increases the efficacy of the treatment.
Additionally, the pillow's cover can be changed and cleaned to preserve its hygiene.

Using memory foam pillow cushion with EHY-2000, EHY-2000plusand EHY-2010 type devices

1. Fold up the waterbed mattress together with the cover.

2. Place the outlet of the memory pillow right on the heating panel.

3. Fold back the waterbed mattress and the cover, and in the meantime place the pillow in its right position.



4. Lay the patient in the desired position.

5. Place the electrode on the treated area.

Cleaning of the memory foam pillow cover

The cover of the pillow can be cleaned. However, when it is removed, or pulled up again, use gloves because of the special metal fabric of the pillow. The metal fabric cannot be washed.

Oncotherm Group

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