USER'S MANUAL

EHY-3010ML

OncoTherm Kft.

Both the hardware and software are specially developed for the OncoTherm systems.
Copyrights belong to OncoTherm Kft.

User's manual

EHY-3010 ML

Oncotherm Kft.

Date: 2017.03.13.

Version: 29

Content

Introduction

The EHY-3010 ML

Congratulations 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.

EHY-3010ML is a German product, certified by the TÜV SÜD Product Service GmbH (Munich, Germany), certified by the German law according to the European Medical Device Directive.

The production is controlled also by the rigorous production standards of EU, 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 the EHY-3010 ML 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-3010 ML, you can continue with the technical and theoretical background. On the base of this knowledge, you can learn the treatment process with EHY-3010 ML. The device control parts should be used as a guideline for treatments.

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 about production and management:

Oncotherm Group
Dr. Olivér Szász
CEO Hungary/ Germany
Belgische Allee 9, D-53842 Troisdorf, Germany
Phone: +49-2241-319-920
Fax: +49-2241-319-9211
Email: info@oncotherm.de
and
Gyár utca 2., H-2040 Budaörs, Hungary
Phone: +36-23-555-510
Fax: +36-23-555-515
E-mail: info@oncotherm.org

Questions about research and development:

Prof. Dr. András Szász
Chief Scientific Officer
E-mail: ProfSzasz@oncotherm.org

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 that 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 operating 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 and must be collected separately. Please contact the authorized representative of Oncotherm Group for information concerning the decommissioning of your equipment.
CLASS II	EQUIPMENT having a durable and substantially continuous ENCLOSURE of insulating 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.

	Stop button: Stop the treatment
	Start button: Start the treatment
 + 	Turn on the device

Installation

General

The device has to be installed by a qualified technician/engineer on behalf of 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, please 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 for which it was expressly designed. Any other use is considered improper and consequently dangerous. The manufacturer declines all responsibility for damage resulting from improper and irresponsible use.

Electrical connection

Connect the equipment to 230 V A/C socket with ground only. Ensure that the socket is properly installed.

Observe that a minimum 16 Ampere fuse protects the socket.

Make sure that the device uses the single phase independently from other appliances. Let an independent phase for the device and others for the applied electric appliances (e.g. air-conditioning, diagnostics systems, computers, sterilization equipment, etc.) in the room.

(Our service team controls these conditions and the pre-installation discussions will be also taken into consideration 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 shall have normal climate conditions (e.g. temperature humidity, pollution, etc.) at all times.
    - Temperature range: 15 – 30 °C
    - Humidity range: 20 – 60 %, non-condensing.
    - No aggressive pollution (e.g. chemicals, fibres, 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 subject to vibration.
6. Avoid using the equipment near appliances generating strong electro-magnetic fields (e.g. motors, transformers, etc.).
7. In the room there has to be a safe place for treatment accessories.
8. Examine the device carefully when it is delivered and wait for the authorized service for the installation.
9. If your device looks damaged, do not use it. When you have any doubts, please ask the Oncotherm service team for advice.
10. To move the device into another room or into any other place from the place where it was installed originally, please ask for the assistance of the Oncotherm service team. The unauthorized relocation is strictly prohibited 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. The unit should be kept away from heat registers, radiators, stoves or other appliances that produce heat. Also windy places or the vicinity of windows should be avoided.
13. For 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 wall and/or grounded surface has to be minimum 1.5 meter away from the treatment bed, so that the patient cannot reach any surface independent from the device which could cause electric shock.

14. **The EHY-3010 ML unit must be located in a suitable place, where the emergency switch of the device can be accessible for anybody in case of a dangerous situation. This emergency switch cuts off the mains voltage of the EHY-3010 ML device itself. This button does not affect the web based PCs.**
15. Good air circulation around the device is essential to prevent internal overheat of the electronic parts.
16. Take care of not breaking the power and optical cables.
17. Electrical safety of the appliance is only guaranteed if the grounding system of the building is in accordance with local electricity board regulations. The Oncotherm service team checks the proper electric conditions at the regular services, but it remains the liability of the customer. Avoid the mains and grounding discrepancies as they increase the risk of potential electric shock.
18. Only an authorized service personnel should carry out repairs and any other work on the device. The approval must be in written form from Oncotherm Group. The relocation and/or using mains-socket other than the originally installed must be done only by Oncotherm or its authorized service-representatives. Only the Oncotherm service personnel, should service the unit when it does not operate normally or shows marked change in its performance.
19. Devices, which are to be discarded, should be made unusable. Pull out the plug from the mains socket and remove the cable.

Safety

1. The device is only suitable for normal treatment use and for the purposes and intended use stated in these operating instructions.
2. Do not use any extension- and radio-frequency-cables, only those which are provided by the authorized service and/or by 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 for an extended period of time.
5. Do not plug in or unplug the mains lead with wet hands.
6. Do not use the device when you are barefoot.
7. Take care that objects do not fall and liquids are not spilled into the interior of the device through ventilation openings. If liquid is spilt into the equipment, disconnect it from the mains and consult a qualified service technician.

8. Do not allow children to operate and/or control the equipment.
9. **Do not allow untrained/inexperienced personnel to operate and/or control the equipment.**
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 'periodical safety testing instruction.'**
12. **The mattress surface must not be damp. After cleaning the surface the user has to wait until it is dry.**
13. Do not use other surgical or endocardial devices while the patient is being treated.
14. Dangerous voltage inside. Do not open the cabinet. There are no user-serviceable parts inside. Only qualified service personnel should carry out repairs.

General description

Intended use

- The EHY-3010 ML 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 distinguish among therm. The main effect is the multi-local overheating of the tumor, but additionally other electric effects are also in use.

Effects

- generates all effects of hyperthermia; heat dependent distortions, acidosis, chemo- and radio-sensitizing etc.
- stops both the chemical and physical positive feedback loops in malignant proliferation
- promotes Ca++ influx and Na+ efflux in malignant cells,
- acts on the collective states by noise modulation, enhances the contrast of the malignant area.

Side effects

- The EHY-treatment can have a side effect (about 3% of the cases). In cases the treatment area is covered by a considerable adipose tissue, subcutane fat-burn may occur and the skin may become red (slight burn) as well.

Main 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 gynaecological cases, sexual organs

Contra indication

- Cannot be used when the patient is under deep-sedation or anesthesia. Application of analgesics in the treated area is prohibited.
- Cannot be used when the patient is unconscious.
- Cannot be used when 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 for person with organ-transplants or for patients who is suffering of consequences of organ-transplant.
- Cannot be used for patients who are not able to operate the emergency button.

Important medical notices

1. **The intended user** of this device is a **trained physician** and/or **trained clinical staff** under a physician's control.

2. **Permanent monitoring** of the treatment by medical staff is necessary. Check the patient and ask about their feelings frequently.

3. The treatment needs extra care, when the patient has **reduced thermal sensitivity** on the treated area.

4. It is suggested to remove extra fluid (ascites, pleural liquid) before the treatment. Furthermore, it is suggested to **empty the urinary bladder, stomach**, rectum before treatments in the area.

5. **Special care is necessary concerning the patient's hair in the treated area** (e.g. pubic hair or at head-hair or hair on breast [for men]), because burning and mistreating is very likely. Please do a shaving on the treated area before treatment if necessary or at least 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.

6. **The tissue electrode must smoothly cover the patient's skin**. Any humps or irregular cover could cause burn on the patient's skin. Please put a water-weighted pillow on the top if necessary.

7. **Check the position of the electrode** to keep it as smooth on the skin as possible. The applicator (electrode) is flexible to have the best contact with the skin.

8. **Staff in pregnancy is not recommended** to operate the EHY-3010 device.

9. Extra care is necessary when patient has surgery clips in the treated volume.

10. Extra care is necessary when the patient has a diathesis of convulsion (epileptic).

11. Attention is necessary when patient is allergic to the electric field or electromagnetic effects.

12. Stop the treatment immediately if anything unusual happens (eg. eritema, burning, etc.) and ask help of a trained doctor if it is needed.

13. **Before rearranging and/or repositioning the applicator, please pause/stop the treatment**. Also in case of any necessary medical aid

(injection, infusion, etc.) please pause/stop the treatment. **Do not touch the electrode during the treatment process.**

14. Be careful with temperature measurements and the other controlling units. Any metallic part could be an antenna. **Using any non-Oncotherm product for controlling the process is prohibited.** Do not use any system-independent electric device during the treatment. It can cause electric shock due to the broken safety isolation.

15. Credit-cards and/or any other magnetically sensitive products (diskettes, tapes etc.) should be kept away from the treatment. There is no guarantee of data integrity of these storage media.

16. **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 in one of the Oncotherm reference clinics.

17. Do not clean the electrodes while the RF radiation is on! Do not use wet textile-tissue that could release water to penetrate into any part of the equipment!

18. The patient must be positioned between the electrode and the counter electrode. The optimal placement of the applicator is as horizontal as possible. Such 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-horizontal arrangement. **Do not let the electrode and counter electrode touch each other!**

19. During the treatment relaxing (so called 'alpha') music is suggested for psychological reasons (faster recovery is possible).

20. This kind of **radio-frequency treatment has an effect on the surroundings**. This is why some attention should be taken on how to set up the treatment system and how to furnish the room in which treatments will take place. Do not install the machine in the vicinity of RF-sensitive equipments (ECG, EEG, intensive-care control-monitor, ultra-sound, video-rectoscopy and/or other sensitive imaging systems) without shielding. It should be noted that microwave sources can influence the Oncotherm device in the treatment room and vice-versa. Make sure that those devices are well shielded.

21. It is optimal if the **device is separated from the web-computer**. The web-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.

22. **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.

23. 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 you have any doubts, consult the technical service department or your local representative.

24. **Use medical hygienic paper** (See detailed description in Accessories and Appendix 8 for datasheet) – **or other medical hygienic paper with CE mark - between the bare skin and the electrodes**. Any other material is not allowed to be used!

25. Special care is necessary in case of head treatment, because of the very efficient power transmission of the device. The patient has to be supervised continuously.

26. Oncothermia does not substitute the conventional therapies only support those.

The EHY3010 ML's electrode (multilayer coatings with definite sheet-current compensation; patented structure) has more superior efficacy than the classical oncothermia bolus system.

Because of that, we suggest setting the lowest available dose at the start and increasing it slowly depending on how the patient can tolerate it. Take extra attention on the patient's well-being. Special extra care is necessary to treat sensitive organs like the brain. Start with very low power (10-15 W) and increase it carefully. Power increase could be in subsequent sessions only.

Resident risk: 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 an average calculation. Take in consideration that the temperature of some points of the heated local area can be considerably higher than the average. This effect in the Literature 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 is the equivalent 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.

Due to the intensive heat-delivery to the body, the heat can have effects on the heart-function like in general hyperthermia cases (e.g. hot car effect on children or hot bath effect on sensitive people etc.) The general sign of the problem is the heart arrhythmia, which must be checked when

the heat delivery is too intensive (large area is treated or huge power is applied). The heart arrhythmia could happen to patients having rare "electrosmog" sensitivity or psychological indisposition against electric field radiation. Note that the field is delivered in low frequency, about 1/10 of the regular radiobroadcasts frequencies.

Please remember: the patient's feeling is the best safety alarm for any unwanted, unexpected events. Do not ignore it, react immediately. This kind of oncothermia has extremely highly effective power transfer; its mismanagement could be dangerous!

Written consent for the treatment

In such countries, where it is necessary or mandatory, 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:

- Clear capacity (or ability) to make the decision.
- 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.
- The patient must comprehend the relevant information.
- The patient must voluntarily grant consent without coercion or duress.

The doctor must give information to the patient about a particular treatment or test so that the patient can decide whether or not they wish to undergo such a treatment or test. This process of understanding the risks and benefits of the treatment is known as informed consent. It is based on the moral and legal premise of the patient's autonomy: The patient has to have the right to make decisions about his/her own health and medical conditions.

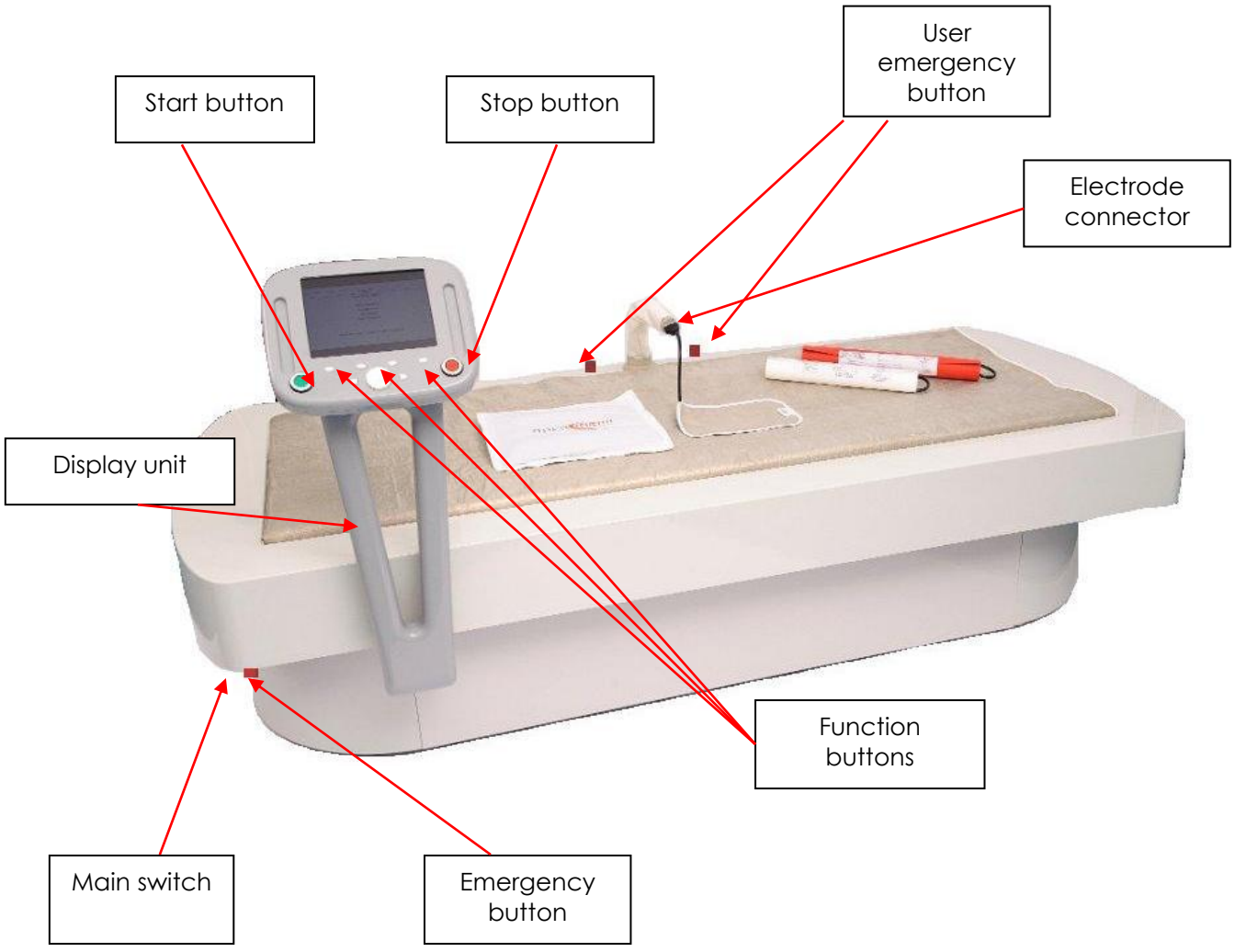
- The patient must give his/her voluntary informed consent for treatment and for most medical tests and procedures.
- For many types of interactions (for example a physical exam with your doctor), implied consent is assumed.
- For more invasive tests or for those tests or treatments with significant risks or alternatives, the patient will be asked to give his/her explicit (written) consent.
- Under certain circumstances, there are exceptions to the informed consent rule. The most common exceptions are these:
    - An emergency in which medical care is needed immediately to prevent serious or irreversible harm.
    - 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.

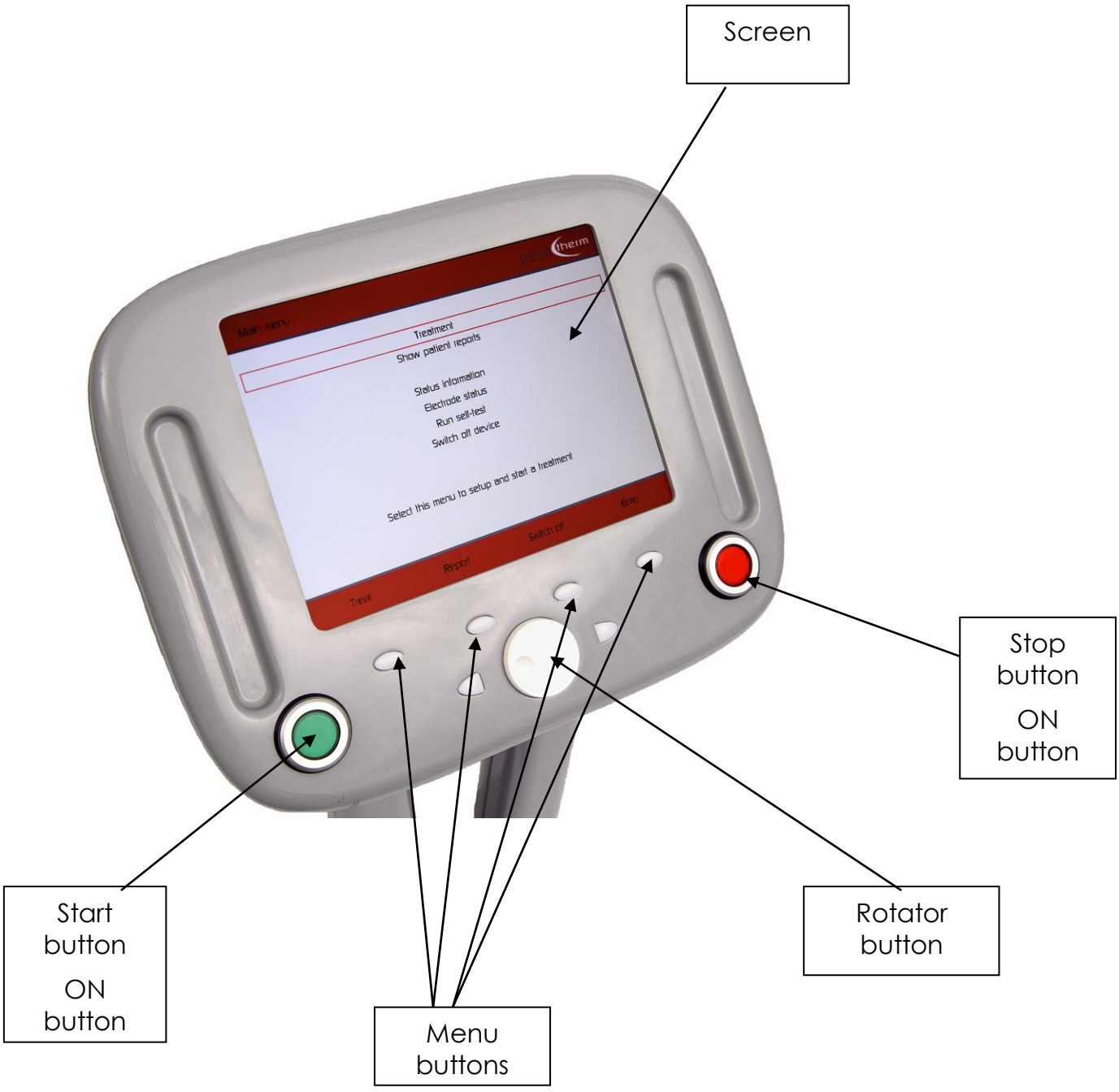
Device control

The Oncotherm EHY-3010 ML is devoted to the high level requirements of modern medical practice. The equipment, for safety purposes, is isolated from the common power-network and supported by a specially developed software.

Controls on the device



Controls on the display panel



Function of the buttons

Main switch

You can switch on and off the device by pushing the main switch.

You can also switch on the device by pushing Start and Stop button at the same time.

Emergency button

The supervisor may press this button to stop any running function of the device in case of emergency. If the button is pushed, the device cannot be started, but makes an alarm signal. To start the device, the emergency stop button must be pulled out into its original position.

User emergency button

The patient may press this button to stop any running function of the device in case of emergency. If the button is pushed, the device cannot be started, but makes an alarm signal. To start the device the emergency stop button must be pulled out into its original position.

Start button

The treatment can be started by pressing this button. Pressing simultaneously Start and Stop buttons is changing the status of the device from standby to active.

Stop button

With this button you can pause or stop the treatment. Pressing simultaneously Start and Stop buttons is changing the status of the device from standby to active.

Menu buttons

Below the screen of the display, there are the four menu buttons. The actual function of the buttons can be found right above the buttons on the screen.

Rotator button

Turn the rotator button to the left or right direction to tune the active parameter on the screen quicker, which can be a value (temperature, power, date, etc.) or a specification in a list (like name).

Tuning

Goal

The EHY-3010 ML has a special radio frequency generator, which must be carefully tuned to the patient. If this 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 available 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 part of the resonant electronic circuit. (Reflected power is minimal and useful power is near to the forwarded power.)

Automatic tuning

The automatic tuning tries to set the tuner into a position where the reflected power is minimal, while the forwarded is maximal. In this position the SWR value is calculated (SWR (Standing Wave Ratio)=(forwarded + reflected power)/(forwarded - reflected power)). The ideal SWR value is SWR=1.0. The device accepts values only below 3.5, but normally this value should go below 2.0.

If the machine is not able to get into a correct position, up to a specified time, 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. The device has a built-in protective system. In case of improper tuning a watchdog will limit the incorrect high (depending on the connected electrode but maximum 600W) outgoing power.

Treatment preparation

Allow the device to warm up for about 15 minutes before the treatment. This is a reasonable amount of time in most cases. The device starts the self-test process. The self-test lasts for about one minute.

All metal objects, parts (necklaces, rings, jewels, watches, pipes, coins, phones etc.) must be far away from the electrode and the machine while the treatment is running.

Also before the treatment give the patient the necessary medical aids (injections, infusions) as needed and ordered by the doctor. (Please note that the infusion can only be given before or after the treatment, while under the RF conditions no metal needle should be in the patient.)

The electrodes have to be positioned on the tumor area with best overlapping. Do not wrap the electrode into any textile material for the treatment. Reduce the thickness of textile material to minimum between the electrode and patient's skin. Textile quality has an effect on the tuning frequency that can lead to system error in tuning under the given circumstances. It is necessary to isolate the patient's skin from the electrode surface, it is suggested to use medical hygienic paper (see detailed description in Accessories and Appendix 8 for datasheet) – or other medical hygienic paper with CE mark - between the bare skin and the electrodes. Any other material is not allowed to use! Please note the list of optimal electrodes for the various tumors in Appendix 1

When the patient breathes the electrode must always be on the patient. (Typical case is the breast cancer treatment when the electrode moves continuously because of the breathing.) Note that pushing the electrode too strongly can be uncomfortable for the patient.

Take care of the cables, do not break them. Check proper connection of the RF cable.

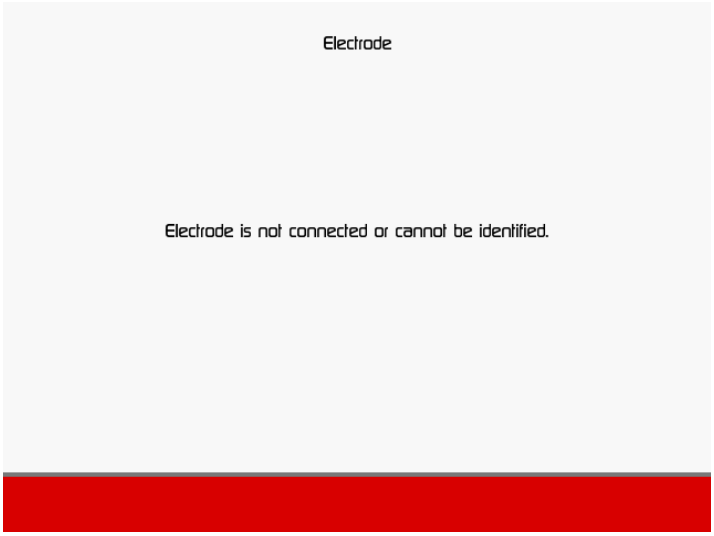
Please periodically control:

- Electrode cables should not be broken
- Electrode material should not be torn or damaged
- Upper electrodes can be used for about 25 treatments
- Bed electrodes can be used for about 400 treatments, but needs to be replaced every ½ year

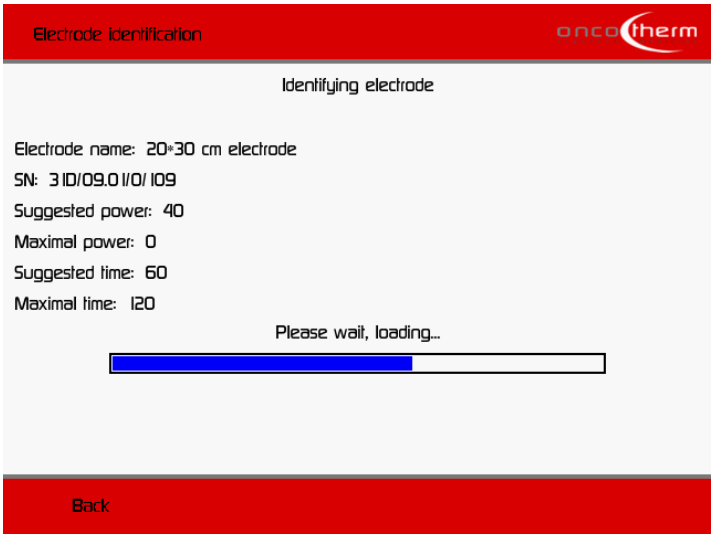
Device use

Switching on the device

To start the device, please turn the main switch on, then push the *'START'* and the *'STOP'* button simultaneously for 3-4 seconds. The device turns on and makes a self-test, which may take a few seconds. After that – if no electrode is connected to the device – you will see the next screen on the display.



After connecting an electrode you will see on the display that the device identifies the connected electrode. The identifying may take a few seconds too.



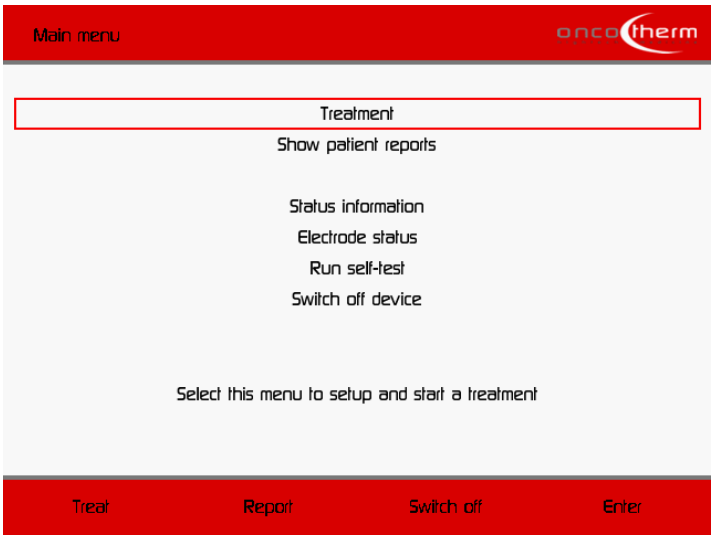
At the end of the identification you can read the electrode data on the display. If an electrode is connected to the device, when the device is switched on, the identifying runs automatically after the self-test. **Do not disconnect the electrode during the identifying process, because it can cause errors.**

After the self-test and the electrode identification the Oncotherm logo appears on the display.

You can enter the main menu by pushing the function button below the main menu screen.

Main menu

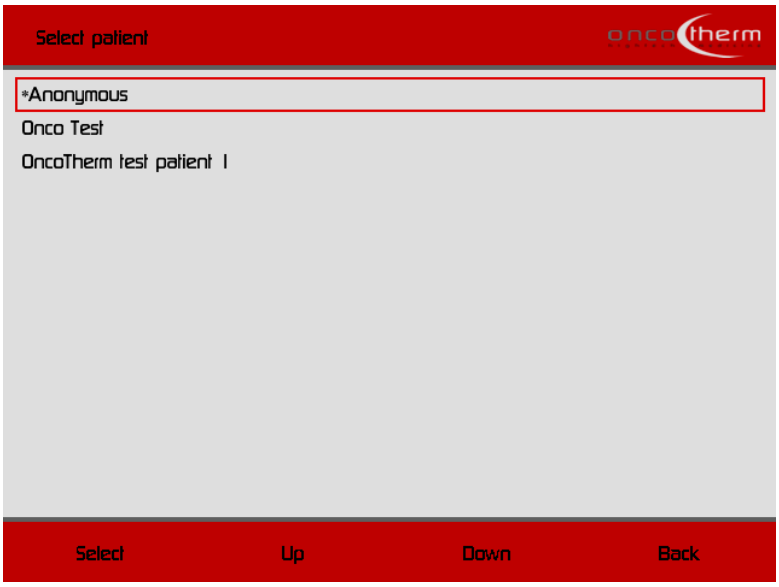
In the main menu you can select various options. You can see the menu on the following picture.



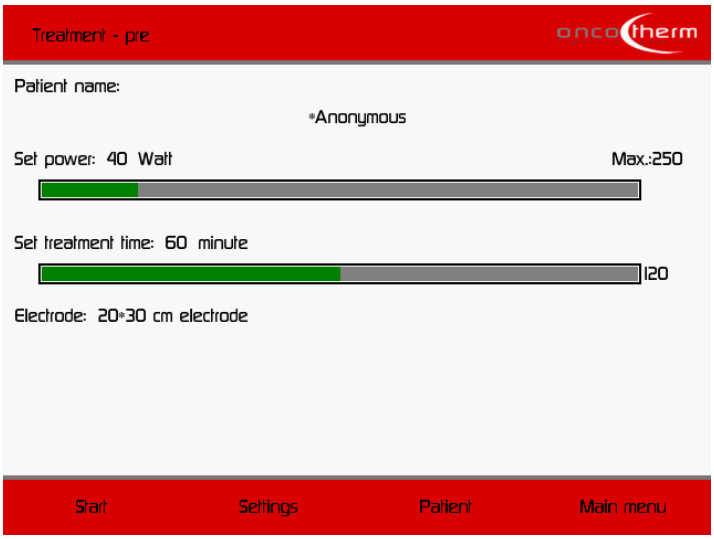
To select of the available options use the rotator button and select the option with the menu button below the ENTER text on the display. Note that all four menu buttons are "softkeys". They do not have a dedicated function. Their actual function depends on the actual screen and is written on the bottom of the screen directly above the buttons. In the following part of the manual we will use these texts written on the display to identify the buttons (except those ones, which have a dedicated function).

Treatment

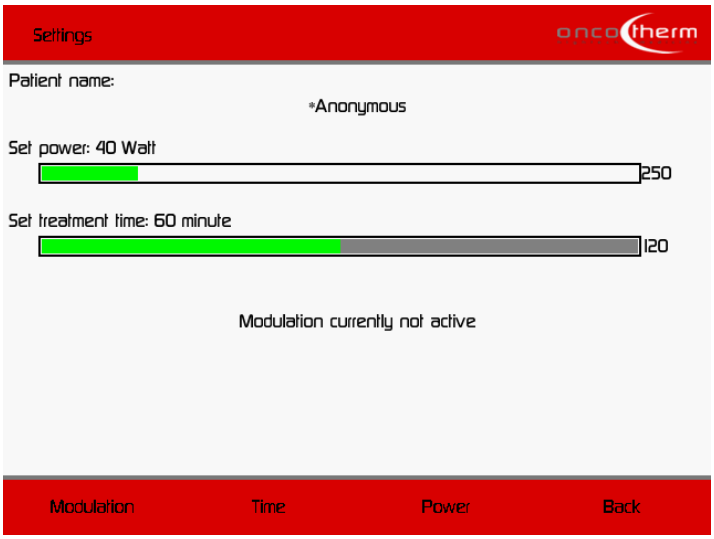
The first – and most important –option in the main menu is the ***Treatment*** option. The first step of the treatment is to select the patient whom you want to treat. You can do it on the following screen by the *Rotator button* and the *Select* buttons. Instead of the *Rotator button* you can also use the *Up* and *Down* buttons too.



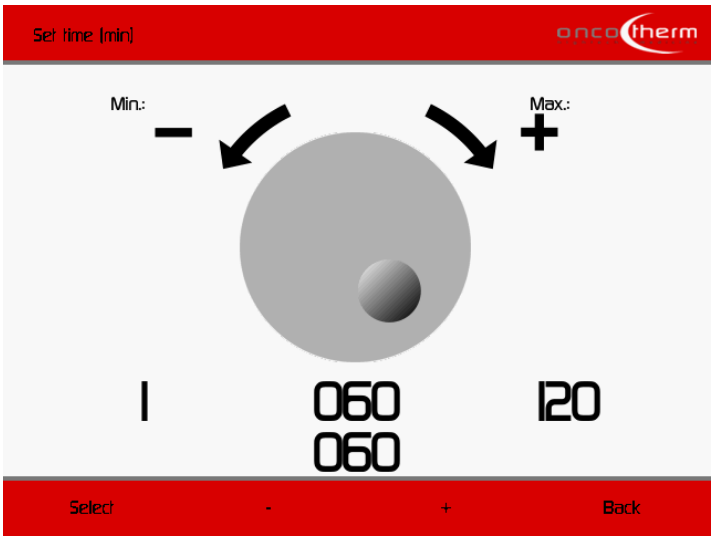
After choosing the patient you will be automatically led to the following ***Treatment – Pre*** screen, where you can start the treatment or change the settings of the treatment.



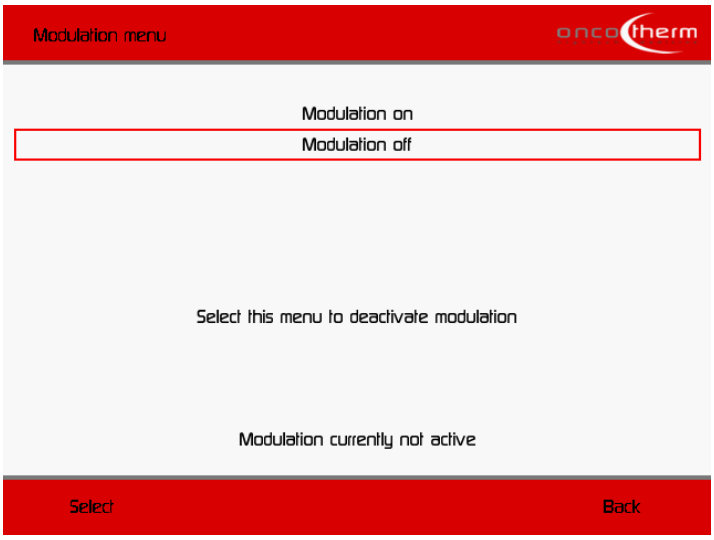
To set the treatment settings (power, time, modulation) choose the *Settings* button. On the following ***Settings*** screen you can choose the parameter which you would like to modify.



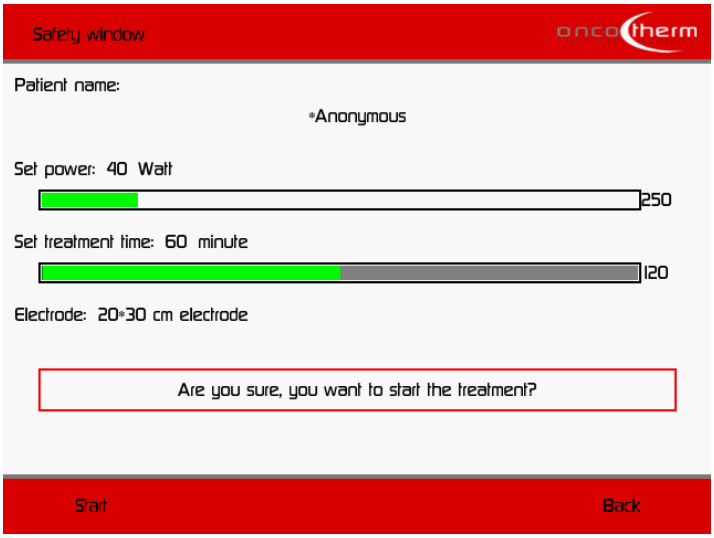
For example, to modify the treatment time push the *Time* button. On the appearing screen you can set the treatment time by the *Rotator button* or **+** and **–** buttons. To apply the modified parameter, use the *Select* button To leave the screen without changes, use the *Back* button.



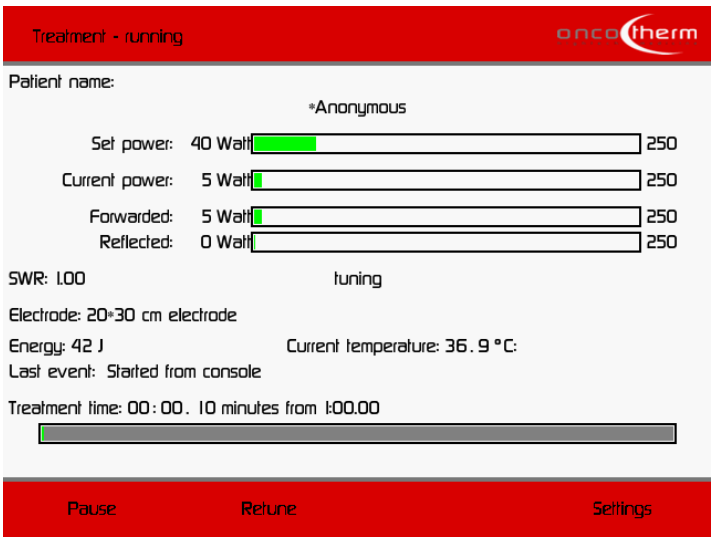
You can set the power in a similar way. The modulation setting is different. You can only switch it on or off on the following screen.



After setting all parameters, please go back to the ***Treatment – Pre*** screen, where you can start the treatment with.the *START* button. Then the following screen appears and you have to reconfirm the start by pushing the *START* button once again.



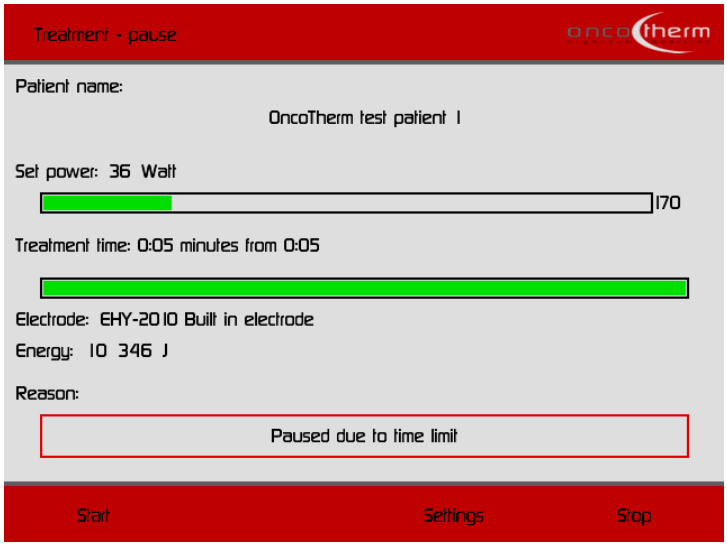
After the reconfirmation, the treatment starts and the ***Treatment – running*** screen appears.



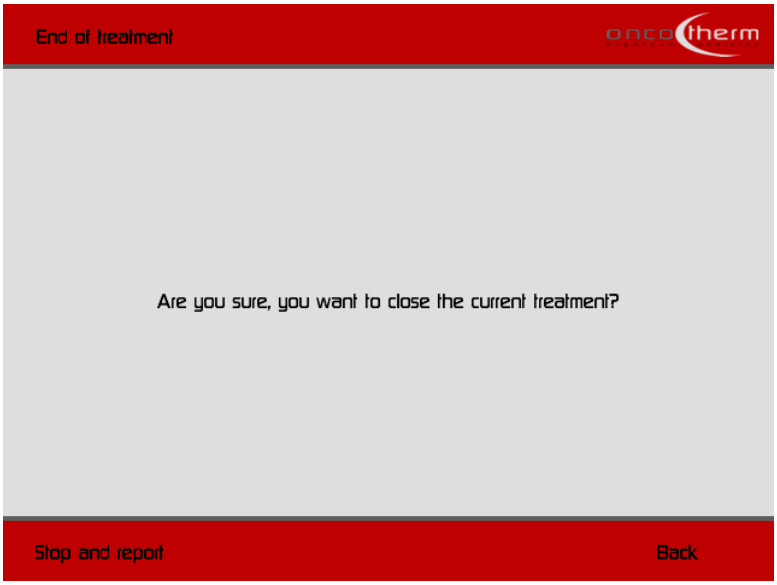
During the treatment, you can see the following parameters on the screen:

- Set power
- Current output power
- Forwarded power
- Reflected power
- SWR (which indicates the effectiveness of the tuning, the perfect is 1.00, but below 1.5 is correct)
- Treatment time

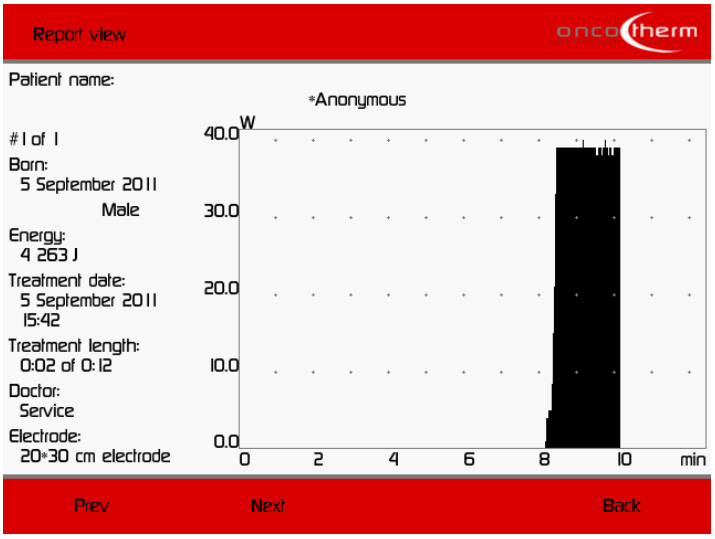
You can modify the treatment setting during the treatment by using the *Settings* button, which leads you back to the *Settings* screen. To pause the treatment, you can use both the *Pause* menu button and the dedicated *STOP* button. The *'Paused from console'* text indicates that the treatment is paused.



You can restart the treatment by both the *'Start'* and the START button. Of course, you have to reconfirm the start, too. **To stop the treatment you can only use the *'Stop'* menu button, not the dedicated STOP button.** On the appearing ***End of treatment*** screen you have to reconfirm the stop of the treatment.

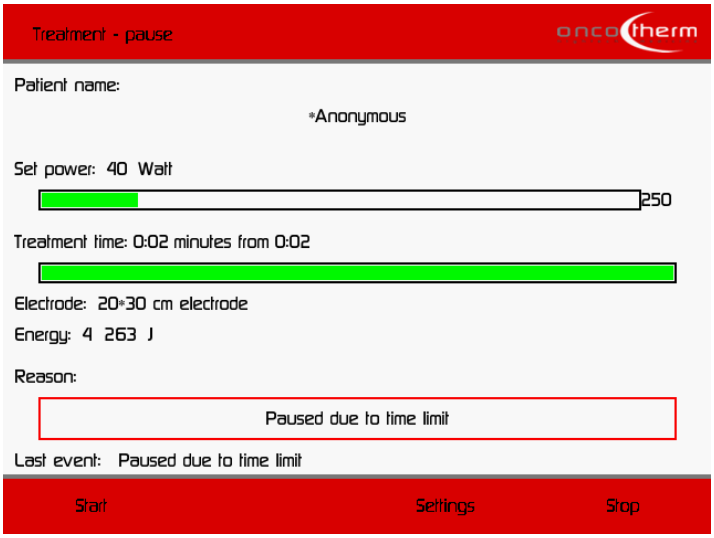


After the reconfirmation, the device saves the treatment data and automatically shows it on the display.



By pressing the *'Back'* button you will get back into the main menu.

If the set time is over, the treatment stops automatically. In this case, the device makes a sound signal and the following screen appears on the display.



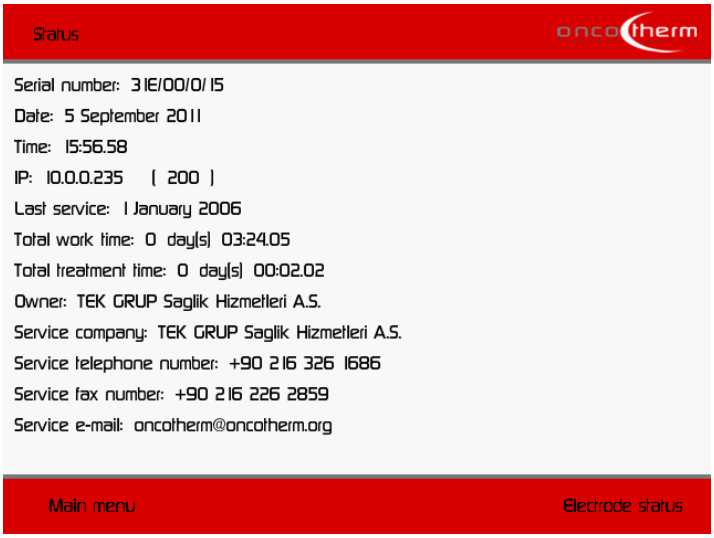
You can finish the treatment and save the treatment data by pressing the *Stop* button.

Show patient report

In this option, you can view the data of the treatments. Similar to the treatment, you have to choose the patient whose treatment data you would like to check first. Afterwards you will see the same screen as after. stopping/finishing the treatment. You can check the data of another treatment of the chosen patient by the *Prev* and *_Next* buttons.

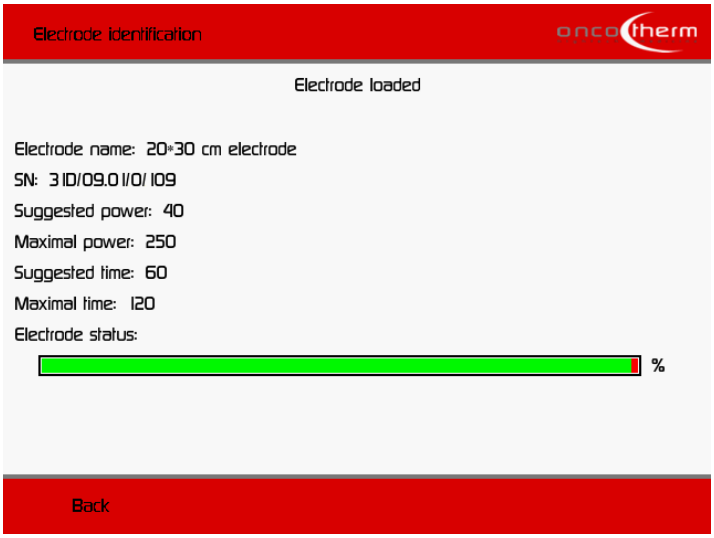
Status information

In the ***Status information*** screen some parameters of the device and the contacts of the manufacturer are shown.



Electrode status

On the electrode status screen the data of the actually connected electrode is shown, like the serial number of the electrode and the remaining time of use.



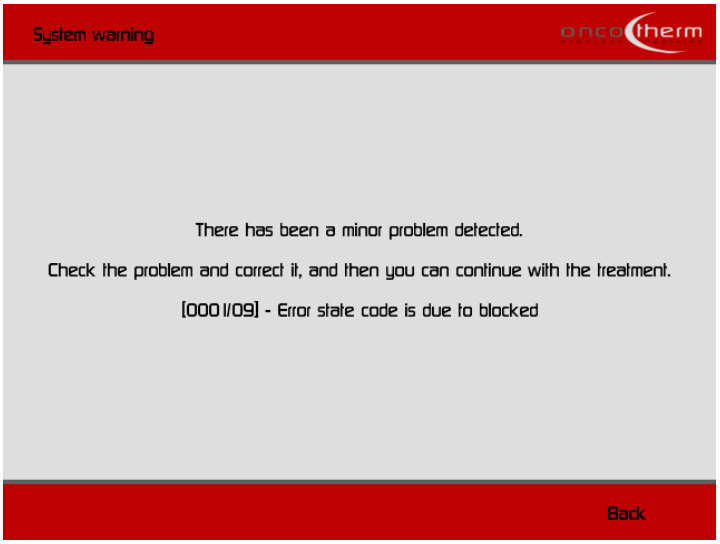
Other options in the main menu

By choosing the ***Run self-test*** button, the device runs the self-test again. This option can be useful when an error occurs.

In the ***Switching off device*** menu point, you can switch off the device. You have to reconfirm the switch on an automatically appearing screen.

Warning screen

You get a warning message when there is an error. The treatment can still be continued.



In case you do not know the meaning of the message, your Oncotherm team is ready to help you. Please call them and inform them about the code number between the brackets and the text beside it.

Error screen

In case of receiving an error message, the device has to be turned off. If the error still exists after the restart, do not use the device, but call the service.

Please write down the error number in the brackets and the text beside it and send it to the Oncotherm service team.

From the menu, you can select to switch off the device or you can send a message by E-mail or SMS (optional). In case of sending an e-mail you will need to have an internet access and by SMS you need to have a GSM module installed in the device (the GSM module is an optional part of the device). Some possible error messages are listed in Appendix 2.

Software

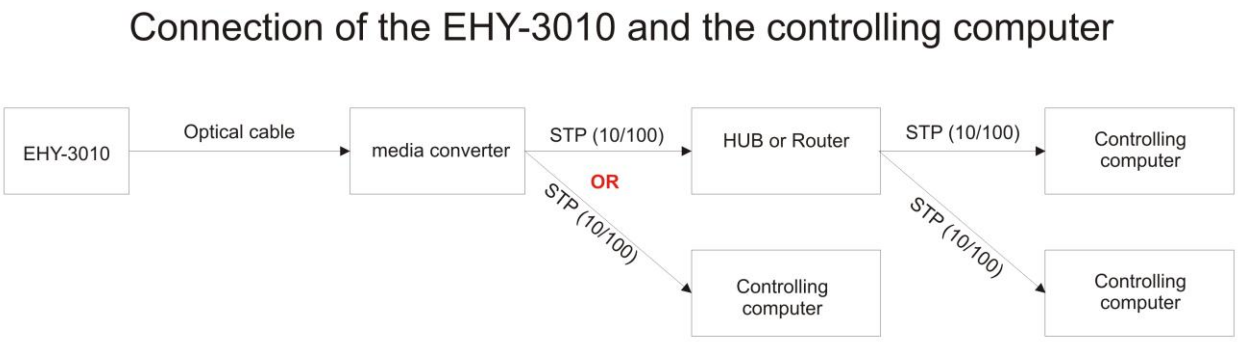
Purpose

The purpose of this additional system 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 this protocol is supported nowadays 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-3010.

System structure

The installation structure of the web box for the EHY-3010 can be represented as shown below:



Usage

The web box is very 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 get to the starting 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.

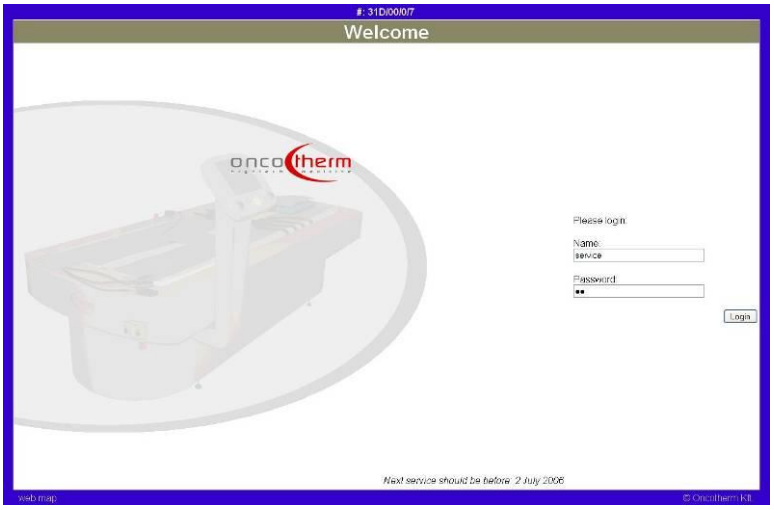
In the following text, there are some examples how to achieve different major tasks. Later on you will find the description of the different web pages.

Starting the web

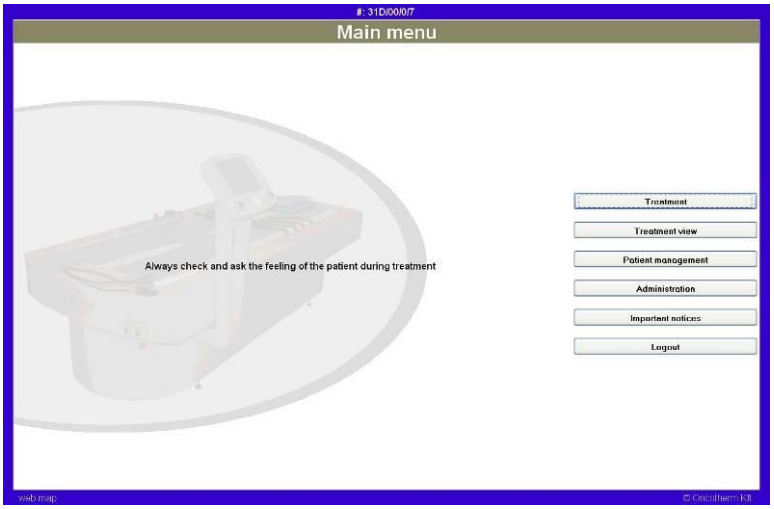
1. Start your web client (for example click on the Microsoft Internet Explorer icon) to enter the web viewing.
2. Type in the IP address of the EHY-3010 device (by default it is 10.0.0.235) or select the shortcut function to the device if it was inserted earlier by our service colleague.
3. The EHY-3010 device starting page should come up in your browser within a few seconds.

Logging in and the Main menu

1. Click on *'Login'* (or on the Oncotherm logo) on the starting page.
2. Type in your name and password.
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 wanted!
5. By default your user name is 'User' and the password is 'EHY'.

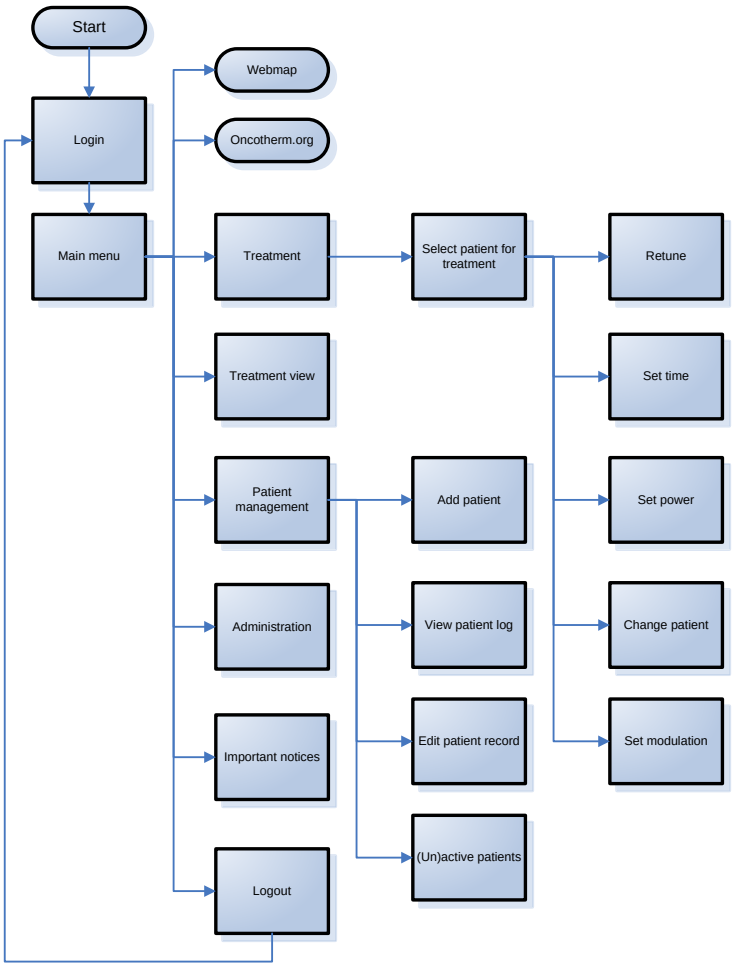


After logging in, you will enter the main menu.



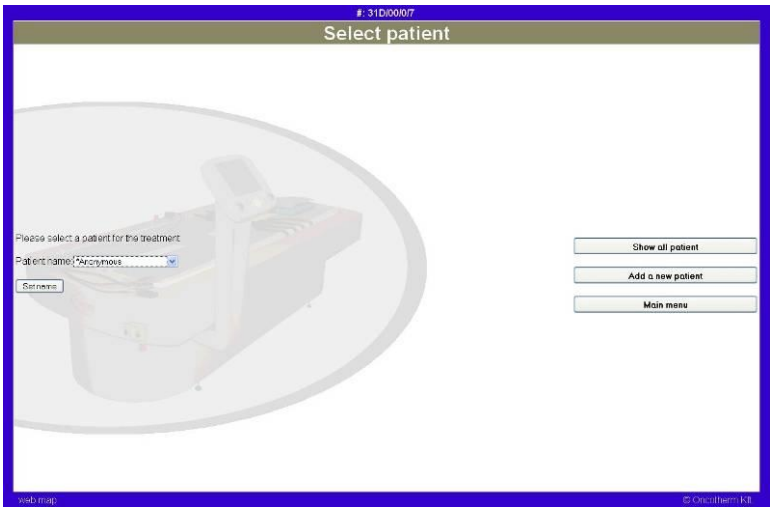
In the menu view you can choose one of the different tasks that can be managed or seen. This menu includes e.g. test results, treatment control, patient management and important medical notes. By the *Logout* button, you can finish the use of the software.

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. When entering the treatment menu you will get to the „*Select patient*" page. Here, the patient's name can be set from a predefined list on this screen or you can add a new patient (this option leads you to the Patient managent menu).



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

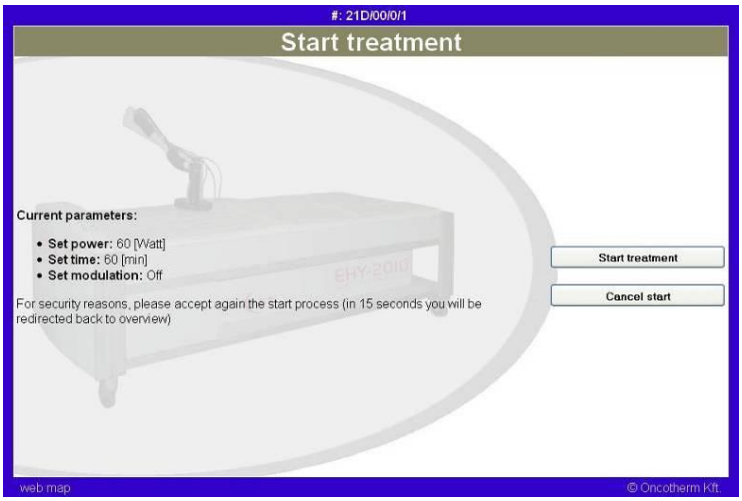
Here you can set the parameters of the treatment:

- treatment time by the „*Set time*" option

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

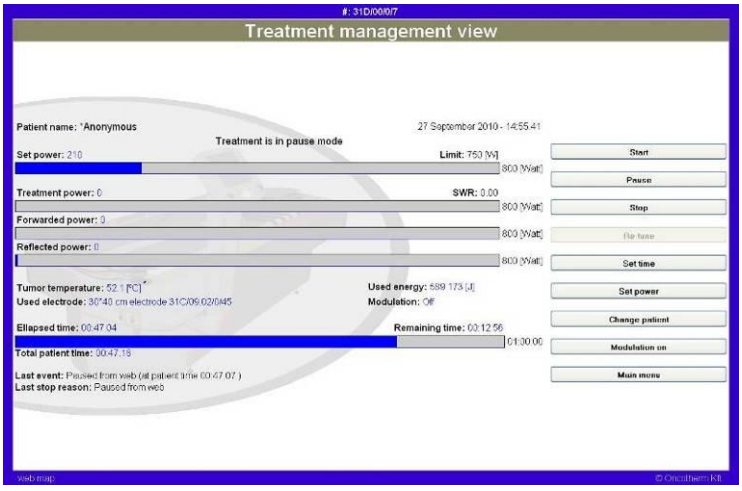
These parameters can be changed during the treatment too.

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*" sreen (see the previous page), where you can check the parameters of the treatment:

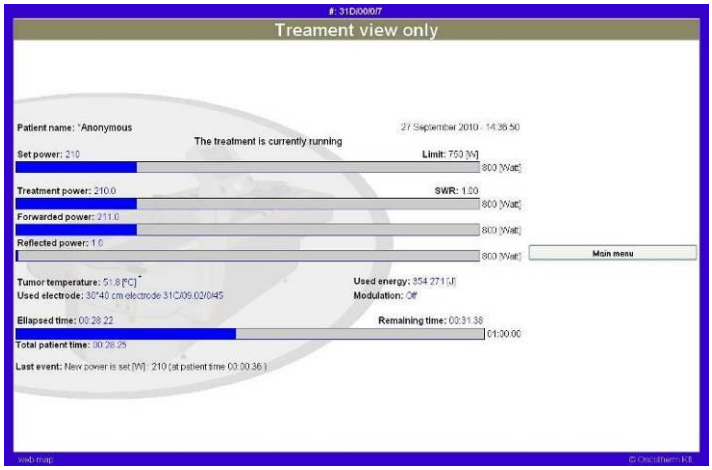
- Set power
- Treatment power
- Forwarded power
- Reflected power
- Elapsed time



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 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 „*Treatment stop*" screen you can choose to view the logged data of the treatment or get back to the Main menu.

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, like on the other screen. The difference is that you cannot modify the treatment parameters.

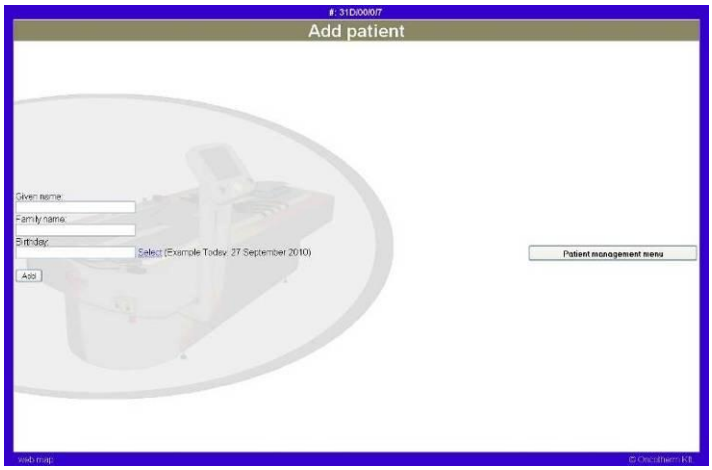


This function is useful if there is a central station – beside the physicians' control – where all devices can be monitored.

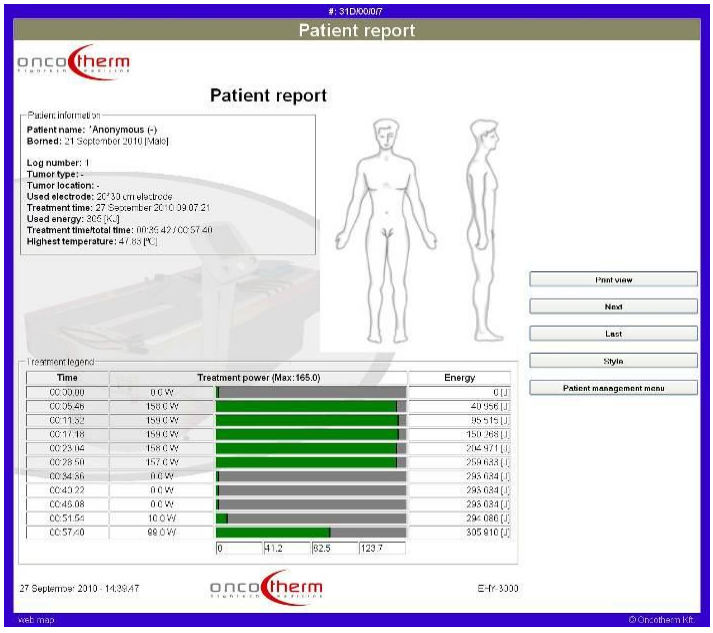
Patient management menu

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 typig in the patient name and 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 shown and printed. The page is preceeded by another one, where you have to choose the patient whose data you want to be shown (like in the *Treatment* menu).



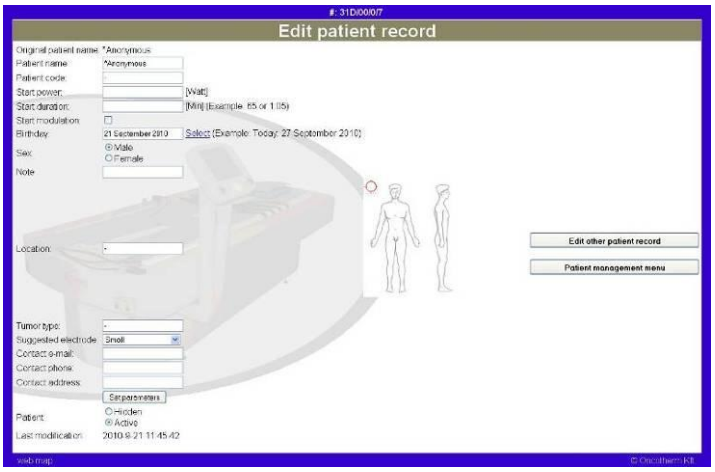
The table shows the major parameters of one treatment of the patient chosen on the page before. The major parameters are:

- Patient's name
- Treatment date
- Used energy
- Power graph

- Temperature graph
- Event list

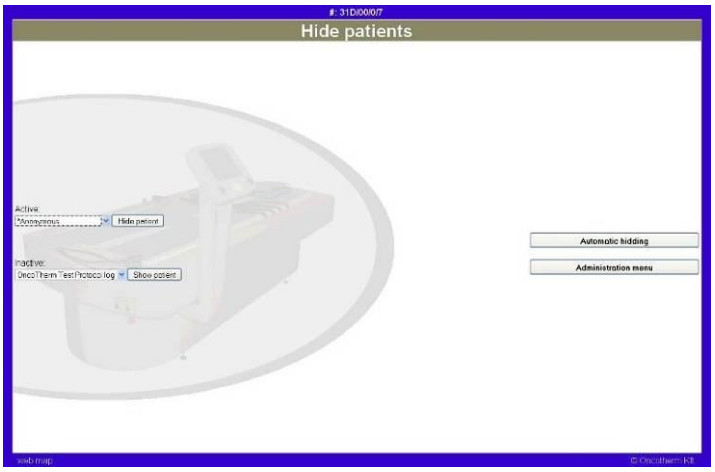
You can check the next, previous, first, last treatment for this patient by clicking on the appropriate link. When you click on the print button a more printer friendly version will be shown, which you can print by the browser.

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



On this page you can modify the patient name, set default treatment parameters for the chosen patient and add notes to the patient. On the image showing a human body you can mark the location of the tumor. This is useful for the electrode placement. At the bottom of the page you can hide the unnecessary patient names (these patients will not be shown on the patient list).

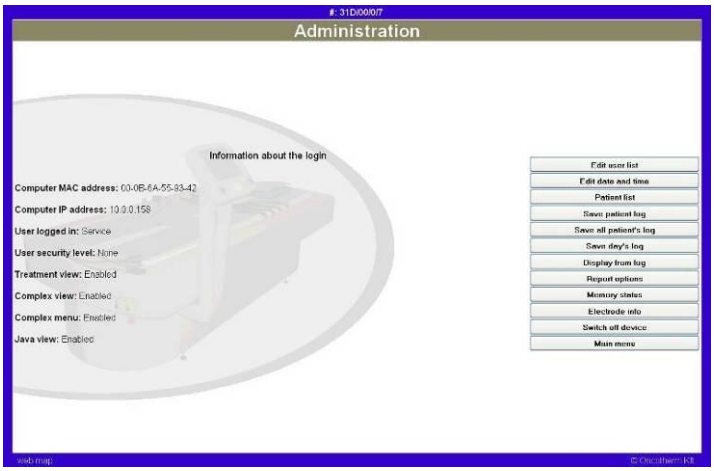
The last option in the *Patient management* menu is the *(In)active patients* page.



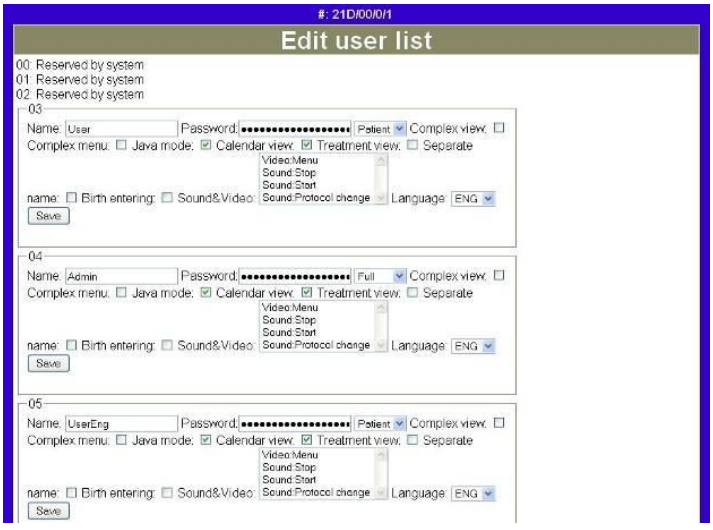
Here you can inactivate the unnecessary patient names (like on the page mentioned before), but on this page you can reactivate the hidden patients, too.

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.



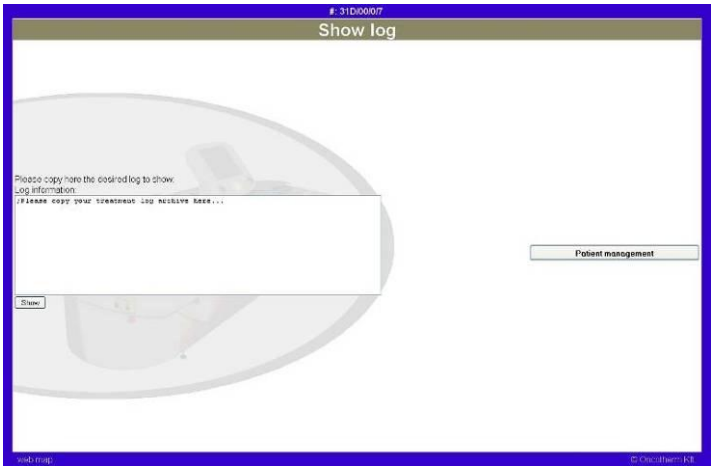
The first option in the menu is the *Edit user list* option.



Here the new and old users can be managed. This is required for the system login. In case you edit your own login name and password, be careful, that you can log out yourself for infinity.

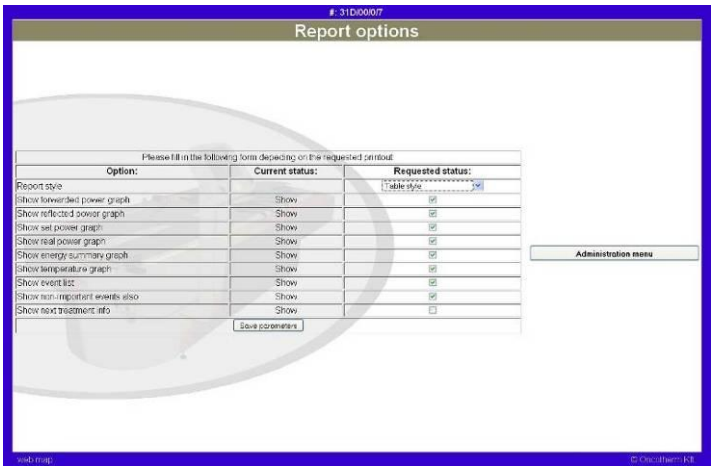
The next options in the menu are *Edit date and time* and *Patient list*. The time and date can be set easily by synchronizing the time and date of the device with the internet.

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 change 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, please 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 the kind of data that will be printed in the Patient report. The first column shows the options, the second: if it's on/off, the third one: checkout box. After all the desired options are selected, the settings must be accepted with the "Save settings" button.



Important notices

By 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 notices 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.
- Monitor the patient continuously, not only through the web server but in the room as well.
- All warnings mentioned in the EHY-3010 user's manual are in force.
- 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, this should be checked every time the page is reloaded or comes from the cache.
- The device matches with a color (and serial number) on the screen. Check the web page color and the serial number written in the border to be sure that the right device is controlled.
- After entering power or time, please check the treatment window again and make sure that the parameter is set, and it is the parameter which is required.

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 following browsers have been tested with the web box:

- Microsoft Internet Explorer 7.0
- Mozilla firefox 5.0

Requested technical background

Client browser

Any kind of computer and browser, which supports the HTTP protocol, is suitable. Our web box does not require any java or flash support but 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 browser 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 that you 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.

The RF radiation emitted by the device may jam the WLAN connections, therefore it is prohibited to use WLAN to connect the device with the controlling computer.

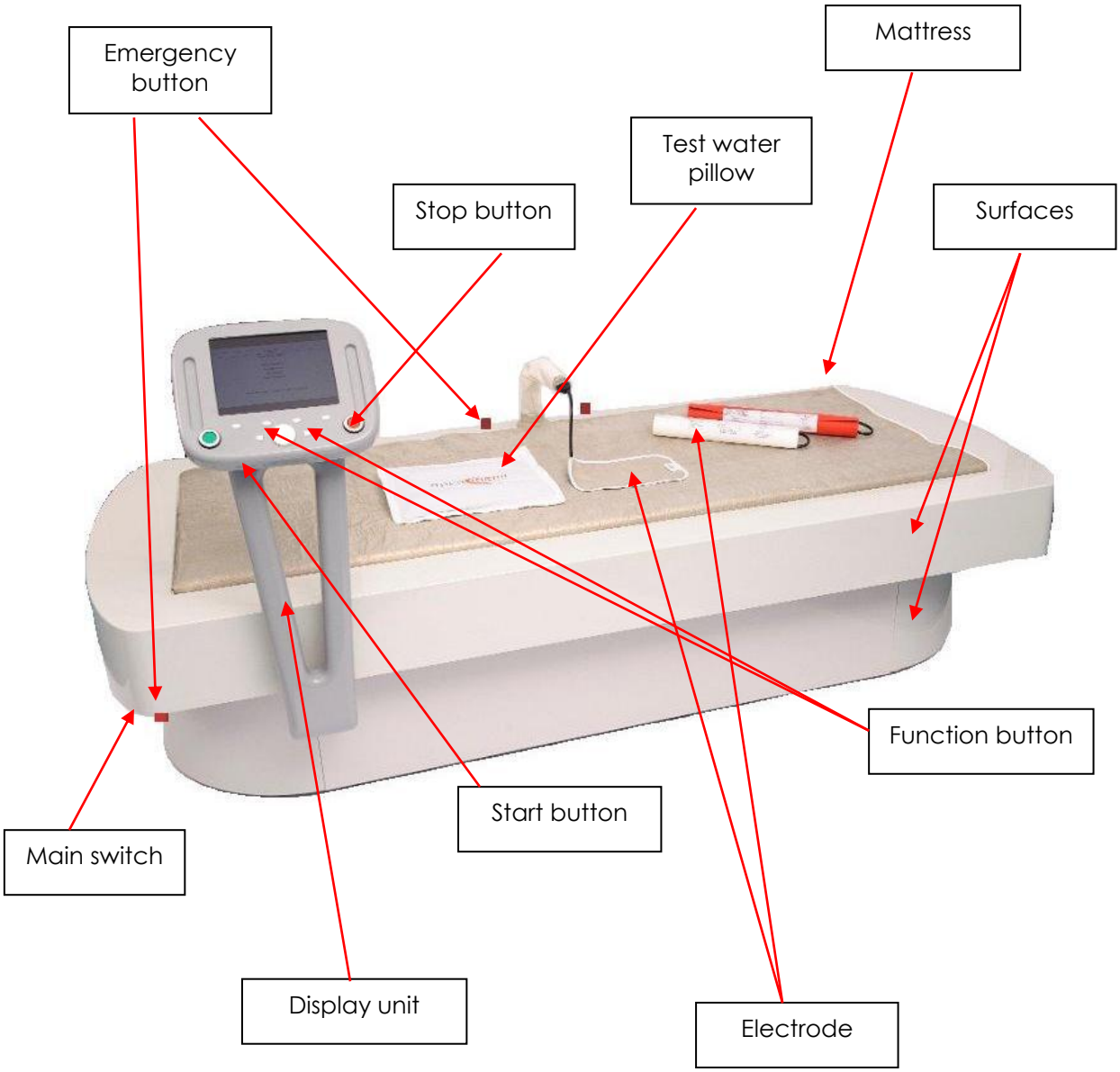
Alternative configuration

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.

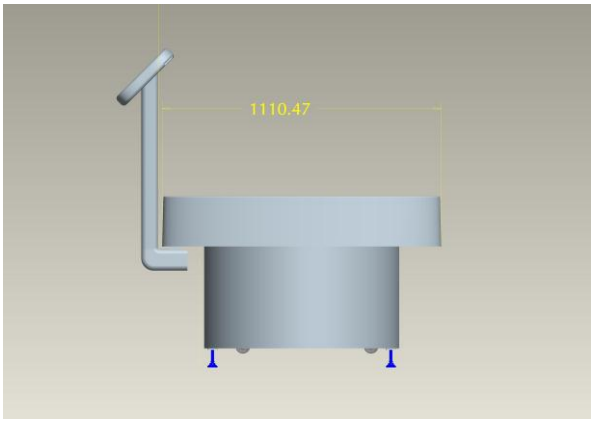
Due to this configuration, no external intrusion is possible, but the computer cannot connect to the internet either.

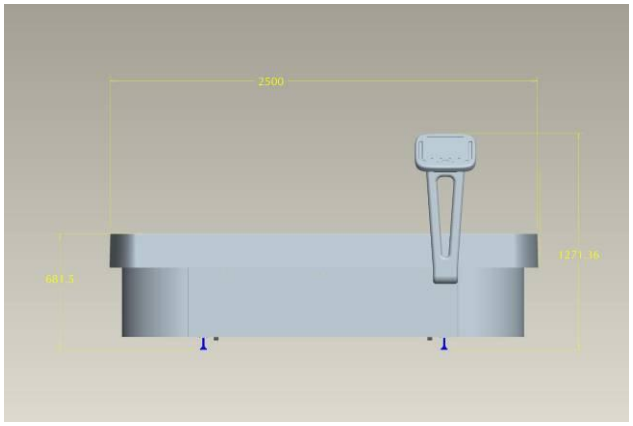
Technical description

Technical details



The device



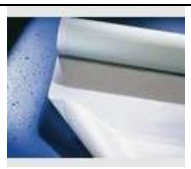


Device height (mm)	1271
Device width (mm)	2500
Device depth (mm)	1300
Device weight (kg)	250
Electrical input (V)	230 (1 phase)/ 50-60Hz
Electrical max. load (A)	16
Electrical avg. load (A)	2.5
Electrical load standby (A)	0.08
RF output forwarded (W)	600
RF output useful (W)	1 → 600
RF frequency (MHz)	13.56

Accuracy of the output power: ±30% of the measured power.

Accessories

Accessories	Description	Photo	Order number
User's manual	This user's manual in printed form.		---
Field tester	It is a small device indicating the RF filed strength.		1117
Test pillow	The test pillow should be used for testing different settings of the device.		1039
Textile electrode	20*30 cm electrode Please mark on your order which connection side your need (left or right)		1226
Textile electrode	30*40 cm electrode (left/right) Please mark on your order which connection side your need (left or right)		1227

Other accessories	Description	Photo	Order number
ROLLICELL hygenic paper	type: '3759-50; w:59cm, l:50m		1140
Textile electrode	10*15 cm oval electrode		1150

Other accessories	Description	Photo	Order number
Textile electrode	10*20 cm electrode Please mark on your order which connection side your need (left or right)		1152
Textile electrode	15*40 cm electrode Please mark on your order which connection side your need (left or right)		1151
Textile electrode	40*50 cm electrode Please mark on your order which connection side your need (left, middle or right)		1228
Textile electrode	40*70 cm electrode (middle)		1156
Textile electrode	40*75 cm electrode Please mark on your order which connection side your need (left, middle or right)		1157
Textile electrode	50*70 cm electrode (middle)		1158
Textile electrode	30*25 "house form-6 angle" textile-electrode for ovary/prostate treatment		1225
Textile electrode	3D C 10*25 cm Head		1154
Textile electrode	3D Oval 8*15 Head		1155

WARNING! The use of ACCESSORIES other than those specified may result in increased EMISSION or decreased IMMUNITY of the EHY-3010 device, therefore it is forbidden.

Transportation and storage

The Oncotherm service is responsible for transportation and storage.

The following transportation and storage conditions apply:

Temperature:	-5°C → +55°C
Relative humidity:	10% → 75% (non-condensing)
Air pressure:	500hPa → 1060hPa

The following operating condition values apply:

Temperature:	+10°C → +40°C
Relative humidity:	20% → 60% (non-condensing)
Air pressure:	700hPa → 1060hPa

Storage: only in closed room.

After transportation, the EHY-3010ML device should be installed by the Oncotherm service.

Before operation

Check the electrode before each treatment for broken insulation. It is dangerous for the patient, so do not use any damaged electrode. Call the service.

During the treatment continuously check that the patient is not able to touch any connection cables associated with the electrode.

Servicing / Maintenance

The user is required to have the unit serviced once every half year under normal operating conditions by the authorized Oncotherm service team. The user shall obtain certification concerning the nature and extent of work with information on any alterations made to the nominal data or operating range. This certification shall also show data and name of the company and signature.

Cleaning

Maintenance of external surfaces:

1. Turn the power off before cleaning the unit.

To clean, use a soft dry cloth.

If the surfaces are extremely dirty, use a soft cloth, dipped into soap and water solution or a weak detergent solution.

Wring the cloth well before wiping the unit.

Wipe once again with a soft dry cloth.

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

Treatment bed: The user shall clean the bed regularly according to the normal hospital disinfecting rules. The mattress of the bed must be cleaned with a disinfecting solution, like the electrode. **IMPORTANT note:** Please use only wet cloth and do not allow the liquid to penetrate into the mattress!

Disposal

Periodical safety test and maintenance (including lifetime check) by Oncotherm service is provided every six month. If it is requested, the manufacturer carries out disposal of the device. In case of disposal, the manufacturer is responsible for organizing the transportation of the unit (with accessories). The price of transportation and packaging is subject to discussion.

Computer control-unit (optional)

If a computer is connected to the EHY-3010 ML, you can check and control treatments and patient data through the PC.

For this purpose, a general computer with intranet access and a web browser with the HTTP standard could be installed.

Oncotherm can deliver you a computer for this purpose, with the following parameters. (Parameters may be changed, without prior notification)

PC:	POC or ONYX
Memory:	256 MB,
Hard disk:	20 GB,
Optical drive:	1 CD drive
Printer:	On request color laser printer
Connection interface:	Ethernet connector,
Input interface:	Keyboard + optical mouse
Operating system:	Microsoft - Windows XP
Control software:	Microsoft - Internet explorer

Minimum Standards for using own PC with the Oncothermia device:

PC:	Tower + computer monitor or Notebook
Attic:	512MB RAM
Drive:	CD/DVD-ROM
Ports:	VGA, LAN, PS/2 Mouse and / or Keyboard
System Software:	starting with Windows-XP
Webbrowser:	Internet Explorer or Mozilla Firefox

Appendix 1: Proposed parameters for different tumors treated with various electrode-sizes

Treated part of the body	Proposed electrode*	Treatment time [min]	Proposed power** [W]
Lung	Larger (40x30cm)	90	90-130
Kidney	Medium (30x20cm)	60	80-90
Liver	Larger (40x30cm)	60	100-120
Stomach	Medium (30x20cm)	60	100-110
Pancreas	Medium (30x20cm)	90	100-110
Lymph nodes	Medium (30x20cm)	60	80-90
Superficial	Special, lesion-dependent	60	60-90
Cole-rectal region	Medium (30x20cm)	90	100-120
Breast	Medium (30x20cm)	60	80-90
Prostate***	Medium (30x20cm)	60	60-80
Esophagus	Larger (40x30cm)	90	90-100
Brain & CNS	Special head/spine	40	special
Head & neck	Special neck	60	60-80

*** Please carefully monitor the patients and do not exceed their personal tolerance. The patient must not feel any burning or severe heat. Always be sure, the electrode bolus tightly touches the skin of the patient on the largest available surface.**

**** It is a general recommendation only. The actual power must be adjusted to the patient's tolerance. It can be different, depending on the area/size of the actual tumor.**

***** Take extra care on the testes.**

The power of the active electrode has to be less than 1 W/^{2}cm, the higher value means a risk of severe burning.

FURTHER proposals:

1. **Please use step-up heating, dynamically increase the power by the acceptance of the patient's tolerance. The above proposed powers are averages.**
2. **In combination with chemotherapy, please use oncothermia in the largest chemo-metabolization period (check the pharmaco-kinetics of the drug).**
3. **In combination with radiotherapy, apply oncothermia before the radiotherapy if the tumor is hypoxic, and after the radio if the tumor is well blood-prefunded.**

Appendix 2: EHY-3010 ML warning and error messages

Code	Description	To do
0001	The warning state is due to error blocking	Call the service
0002	Internal RAM error in the system	Call the service
0003	Internal ROM error in the system	Call the service
0004	Could not stop the device in a pre-specified time	Call the service
0005	Could not start the device in a pre-specified time	Try to restart the treatment.
0006	Time setting is not ACKed in time	Try to re set the time limit.
0007	Power setting is not ACKed in time	Try to reset the treatment power.
0008	Electrode was disconnected	Reconnect the electrode to the device
0009	Web request was not coming in time	Check your browser and restart treatment
000A	Invalid clock base (time base is not correct)	Call the service
000B	Master clock is not enabled	Call the service
000C	External RAM error	Call the service
000D	Register error	Call the service
000E	Flag and jump error	Call the service
000F	External ROM error (1 group)	Call the service
0010	External ROM error (2 group)	Call the service
0011	Command requested block	Call the service
0012	Command request error	Call the service
0013	Command start 1 parameter invalid	Try to restart the treatment
0014	Command start 2 parameter invalid	Try to restart the treatment
0015	In error stop the stop was not ACKed in time	Call the service
0016	In error mode not stopped	Call the service
0017	Blocked bit in communication header	Call the service
0018	Error bit in communication header	Retry your last action

0019	Double variable are mismatch	Call the service
001A	Blocked state cause: CMD_ENTER_BLOCKED_STATE	Call the service
001C	Consistence test of pins failed	Call the service
001D	Self test failed in the module	Call the service
001E	only CMD_TREATMENT_START2 received	Retry to start the treatment
001F	CMD_TREATMENT_START2 received too late	Retry to start the treatment
0020	Invalid CriticalTestPh number	Call the service
0021	Invalid BackGroundTestPh number	Call the service
0024	Setting modulation not responded fast enough	Call the service
0025	Setting energy limit not responded fast enough	Call the service
0026	FPGA download not complete	Call the service
0027		Call the service
0028	URef not in range	Call the service
0029	An. 5V not in range	Call the service
002A	Dig. 5V not in range	Call the service
002B	12V not in range	Call the service
002C	GND not in range	Call the service
002D	Vcc not in range	Call the service
002E	Time out reading AD channel	Call the service
002F	Coax relay not reacting in time	Call the service
0030	Address legs are not correct	Call the service
0040	3 or 4 sensor are damaged	Call the service
0041	3 or 4 sensor are damaged	Call the service
0042	min one water outflow sensor signals error	Call the service
0043	AD->temperature chart error	Call the service
0070	overvoltage	Call the service
0071	too high current	Call the service
0072	too high SWR	Call the service
0073	too high temperature	Call the service
0074	SHUT_DOWN_PIN	Call the service
0075	Contradiction in PowerTable[] values	Call the service
0083	AD->Temperature chart error	Call the service
0084	AD->temperature conversion algorithm error	Call the service

0090	Electrode disconnected	Call the service
00A0	EHY-3010 ML in error state	Call the service
0100	tuner SW in prohibited path	Call the service
0101	tuner relay off during treatment	Call the service
0102	one of the motors did not reach end switch at startup	Call the service
0103	Incorrect serial number module	Call the service
0104	Led state not set fast enough	Call the service

Appendix 3: EMC (Electromagnetic compatibility) information

According to IEC60601-1-2:2001 standard requirements

The EHY-3010 ML 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 the EHY-3010 ML device.

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

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration-electromagnetic emissions (T.201)</th></tr>
<tr><td colspan="3">The EHY-3010 ML device is intended for use in the electromagnetic environment specified below. The customer or the user of the EHY-3010 ML should assure that it is used in such an environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment-guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 2</td><td rowspan="4">The EHY-3010 ML must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
<tr><td colspan="3">The [EQUIPMENT or SYSTEM] is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the [EQUIPMENT or SYSTEM] or shielding the location.</td></tr>
</table>

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-3010 ML is intended for use in the electromagnetic environment specified below. The customer or the user of the EHY-3010 ML 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 EHY-3010 ML requires continued operation during power mains interruptions, it is recommended that the EHY-3010 ML is 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 U_T 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))

<table>
<tr><td colspan="4">Guidance and manufacturer's declaration-electromagnetic immunity (T.204)</td></tr>
<tr><td colspan="4">The EHY-3010 ML device is intended for use in the electromagnetic environment specified below. The customer or the user of the EHY-3010 ML should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6

Radiated RF
IEC 61000-4-3</td><td>3Vrms
150kHz to 80MHz

3V/m
80MHz to 2.5GHz</td><td>3Vrms

3V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the EHY-3010 ML, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
d=1,2√P
d=1,2√P 80MHz to 800MHz
d=2,3√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:  </td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td colspan="4">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-3010 ML is used exceeds the applicable RF compliance level above, the EHY-3010 ML should be observed to verify normal operation. If abnormal performance is observed, additional measurements may be necessary, such as reorienting or relocating the EHY-3010 ML device.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

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-3010 ML (T.206)			
The EHY-3010 ML device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EHY-3010 ML can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EHY-3010 ML 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.			

Appendix 4: Declaration of conformity sample

Declaration of conformity

OncoTherm Kft.
H-2071 Páty, EU

Product designation: Oncological Electro-Hyperthermia device
Type, Model: EHY-3010ML

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:

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 mellékletének 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-7-4118-R4

Appendix 5: 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. Upgrading the system to keep up with new developments and state-of-the-art know-how, can be included in the stand-by service agreement.

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) showing the date of claim is within the guarantee period.

Guarantee is not valid if the defect is due to accidental damage, misuse or negligence and in case of alterations or repairs carried out by unauthorized staff.

Guarantee becomes void if the equipment is not stored, handled, operated or managed in any way according to the User's Manual.

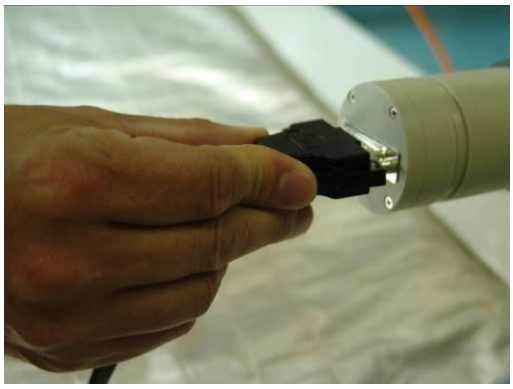
Any changes in the hardware and/or software without written permission of the manufacturer are strictly prohibited and void the guarantee.

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 welcome.

Appendix 6: Treatment in 11 steps

1. Switch on the device by pushing both the START and STOP buttons for 3-4 seconds.
2. Let the self-test run.
3. Choose the proper electrode and disinfect it. (UM: 56. page)
4. Connect the electrode to the holding arm and wait while the electrode is being identified.



5. Lay the patient on the bed and place the electrode on the patient as smooth as possible. Fix the electrode with a water pillow.
6. From the Main menu choose the "Treatment" option, then push the "Enter" button.
7. On the appearing screen select the patient that you want to treat. Use the "Select" button to confirm your choice.
8. On the "Treatment – Pre" screen choose the "Settings" option and set the treatment power and time by choosing the "Time" and "Power" options. Use the "Select" button to confirm the choice.
9. Step back to the "Treatment – Pre" screen and start the treatment by pushing the "Start" button. Press it again to confirm the start.
10. Let the treatment run.
11. After the end of the treatment, choose the "Stop" option and press it again to save the treatment data. After that you can step back to the Main menu.

Appendix 7: Patient Consent

ONCOTHERMIA SHOULD NOT BE USED BY PATIENTS UNTIL THERE HAS BEEN A COMPLETE DISCUSSION OF THE RISKS AND THE 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 begin my treatment with ONCOTHERMIA; OR, if my treatment has already begun with ONCOTHERMIA, to continue such 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 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'S-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: +49-2241-31992-0

Appendix 8: 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

Using the memory foam pillow with EHY-3010ML device

Before the treatment with this device you have to put the pillow on the lower electrode.

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.

REVISION MATRIX			
Ver	When	Who	What
V00	12.12.2007	PP	Finalize first issue
V9	01.15.2008	PA	Picture changes
V10	21.01.2008	SzO	
V11	09.10.2008.	DA	2010 →3010 change
V12	10.02.2009.	SzA	
V13	2009-03-30	CsA	ISO 9001 new date, new pictogram
V14	2009-04-21	CsA	UM new pictogram, all button description
V15	2010.06.09.	SzK	UM restructuring
V16	2010.09.28.	SG	UM restructuring, new photos, patient consent
V17	2010.12.06.	SzK	Text repairer (2010→3010)
V18	2011.03.08.	SzK	New Display Photo (20.Page)
V19	2011.05.18.	SzK	Appropriate TÜV logo 7.Page / TÜV Ø Approval but certified 5.Page / New Declaration of Conformity (Appendix4) / Special training → Technical training 8.Page / / Hygenic paper – Important medical notes 26. point / ROLLICELL Datasheet (Appendix9)
V20	2011.09.12.	JL, SG, PA	Grammar correction / new photos (24-37. Page) / Explanation for the figure about the penetration depth 82. Page (Appendix 6.)
V21	2012.05.30.	GVA, PA	UM latest version in Database 5. Page / Contra indication 15. Page and in Important medical notices (16. Page) / Picture changing in "Device use" chapter 25.o. / deleted Appendix 6: "Principless"
V22	2012.09.19.	SzK	New picture in Accessories (UM Photo –new cover and test pillow) 55. Page / New picture in Appendix 4 (Declaration of Conformity – new Certificate number) 68. Page

V23	2013.06.10.	GVA	Start/stop/on buttons (Page 10) Marking of ON/OFF switch and electrode connector is placed (Page 22-23) Turn on the device (Page 24) Accuracy of the device (Page 56) Electrode types (Page 57-58) Operating temperature was changed (+10 – 40 C) (Page 59) Modification of Table 201 (Page 67)
V24	2014.02.24.	GVA	New Appendix (9) and modified Accessory list (page 57) because of the new memory foam pillow with cover.
V25	2014.06.19	S.G.	New point in Contraindications (page 16) about the prohibition of treatment of silicone implants New point in Important medical notices (page 17)
V26	2014.09.29.	TSz	Declaration of Conformity was changed (Page 71.)
V27	2014.11.04.	TSz	Modification in Important medical notices (Page 17., point 5.) the infusion solution was deleted
V28.	2016.05.31.	TZS	Page 8/ Contacts: address and position change, Page 10/ Symbols: book symbols replaced, Page 78-79/ Appendix 9: Memory foam pillow was deleted -Balázs Ács asked, that is why Page 59/ from other accessories was deleted the memory foam pillow, Page 71/ Appendix 4: Title of appendix 4 was changed to Declaration of Conformity sample, and identification was the header area of User's Manual.
V29	2017.03.13.	TZS	Page 9/ Modified the electrical connection. Page 54/ Electrical input changed.

Oncotherm Group

OncoTherm GmbH
Belgische Allee 9
D-53842 Troisdorf
Tel.: 0049 2241 31992 0

OncoTherm Kft.
Gyár u. 2
HU-2040 Budaörs
Tel.: 0036 23 5555 10

www.oncotherm.com