

EHY-2000

h i g h t e c h m e d i c i n e *plus*

USER'S MANUAL

SAFETY, GUARANTEE

OncoTherm Kft.

July 2010

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OncoTherm systems.

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Contents

| | |
|--|-----------|
| CONTENTS | 2 |
| INTRODUCTION | 3 |
| THE PRODUCTION IS CONTROLLED ALSO BY THE RIGOROUS PRODUCTION STANDARDS OF EU, CERTIFIED FOR ISO-13485 AND ISO-9001, APPROVED ALSO BY THE GERMAN TÜV PRODUCT SERVICE (MUNICH). THE PRODUCT IS COMPLETELY MANUFACTURED IN THE EUROPEAN UNION.SAFETY AND | |
| CAUTIONARY NOTES | 4 |
| INSTRUCTIONS | 4 |
| ELECTRICAL CONNECTION | 5 |
| INSTALLATION | 5 |
| <i>Pre-installation notices</i> | 5 |
| <i>Installation notices</i> | 6 |
| SAFETY - UNIT | 7 |
| SAFETY - WATERBED | 8 |
| WARNING | 8 |
| IMPORTANT MEDICAL NOTICES | 10 |
| <i>Operator's table:</i> | 14 |
| GUARANTEE | 15 |
| QUALITY REFERENCES:..... | 15 |
| CONTACTS | 16 |

Introduction

Congratulation on your excellent choice!

You are an 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-2000 is a German product, approved by the TÜV Product Service (Munich, Germany), tested and approved by the German law according to the European Medical Device Directive (called medical CE).

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

Union. Safety and cautionary notes

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

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

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

Instructions

Read the instructions in this user's manual carefully since you will find all the instructions you require to ensure safe installation, use and maintenance. Always keep this manual close at hand since you may need to refer to it in the future.

When the packing is removed, check that the appliance is not damaged. If you have any doubts, do not use the appliance, call for a qualified technician. Since the packing (plastic bags, foamed polystyrene, nails, etc.) are potential sources of danger, never leave them within the reach of children.

The device must be installed by a qualified technician/engineer sent or contracted by OncoTherm Kft in compliance with the instructions provided. The manufacturer declines all responsibility for improper installation which may harm people and damage property.

The user must not replace the supply cable of this appliance. Always call an after-sale-service centre authorised by the manufacturer in case of cable damage or replacement.

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

Electrical connection

1. Connect the equipment to 220-240 V 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. Let 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 the preinstallation discussions will be also taken into consideration to satisfy these requests.)

Installation

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.) throughout its lifetime.
 - 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 subject to vibration.
6. Avoid using the equipment near appliances generating strong electromagnetic fields (e.g. motors, transformers, etc.).
7. In the room there has to be a safe place for treatment accessories.
8. On delivery, observe the device carefully and wait for the authorized Service for the installation.
9. If your device looks damaged, do not attempt to use it, when in doubt ask OncoTherm service team for advice.

10. To move the device into another room and/or into any other place from the place where it originally was installed please ask for the assistance of the OncoTherm service. The unauthorized relocation is strictly prohibited, 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 or fluids pass 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 situated away from heat registers, radiators, stoves or other appliances that produce heat. Also windy places or the near vicinity of the windows should be avoided.
2. 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 walls and/or grounded surfaces have to be minimum 1.5 meter away from the treatment bed, on the way, that the patient could not reach any surfaces independent from the device, which could cause an electric shock for him/her.
3. The EHY unit must be located on a suitable place, where the **emergency switch** of the device can be accessible for anybody in case of a dangerous situation. This emergency switch cut off the mains voltage of EHY device itself, but this button does not affect on the waterbed and 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 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 an authorized service personnel should carry out repairs and any other work on the device. The approval must be on written form from OncoTherm Kft. The relocation and/or using other mains-socket than the originally installed, must be done only by OncoTherm or its authorized service-representative. Only the service personnel, a 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, remove the cable and make the door lock and door catch unusable.

Safety - Unit

1. The device is only suitable for normal treatment use and for the purposes and intended use 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 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 barefoot.
7. Take care 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 'Periodical safety testing instruction' (see User's manual / Technical part / Appendix 1).






Safety - Waterbed

1. Never use waterbed without the mattress. Touching pure copper heating surface can cause burn!
2. Never use the mattress without water (Only distilled water can be used.) as the patient can compress it and can touch copper 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 with other hand the middle of the other half - minimum ½ meter from the first point. It must not reach the bottom.)
3. Water leakage is shown on display (sensed electronically in wastewater tank). In case of waterloss failure, treatment can be finished, but call for service soon. If water flows quickly, treatment must be stopped, switch off the bed and pull out mains plug.
4. In case of noticing water in the plastic tray or on the surface of the mattress, please check water level in mattress and presence of possible mechanical damage. Do not use damaged mattress, avoid electric shock.
5. The patient's surface must not be damp. After cleaning the surface the user have to wait until it is dry.
6. Using EHY2000plus with not heated waterbed may decrease the temperature of the body of a 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.)
7. Check the temperature settings before each treatment! Recommended temperature setting is 32°C, because the treatment itself is heats also, so patient will have sweaty skin which is not suitable for correct EHY2000plus treatment.
8. Check the alarm system daily during continuous use. Switch off for a short time. Switching on the waterbed, a self-test is implemented, and a warning is going on, till user sets the desired temperature again.
9. Do not use other surgical or endocardial devices while patient is on the waterbed.

Warning

**A SPECIAL TRAINING IS REQUIRED TO OPERATE THE EQUIPMENT!
FOR THIS PROCEDURE ASK THE MANUFACTURER.**

**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
SERVICE REFER ONLY TO THE ONCOTHERM QUALIFIED
PERSONNEL.**

| | |
|---|---|
|  | <p>This symbol is intended to inform the user about the ground independent (body floating) construction. Do not rearrange the professional installation.</p> |
|  | <p>This symbol is intended to alert the user to the presence of important operating and maintenance instructions in the literature accompanying this product.</p> |
|  | <p>Reads it before a usage the User's manual.</p> |
|  | <p>This symbol informs the user, the device is intended to emit non-ionizing radiation.</p> |
|  | <p>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 Ltd. for information concerning the decommissioning of your equipment.</p> |
| <p><u>CLASS</u> <u>II</u></p> | <p>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;</p> |

Important medical notices

Please remember:

1. Intended user of this device is 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 over the treated area.
4. Treatment is strictly **prohibited** when the patient is unconscious!
5. Treatment is **prohibited** when the patient is under deep-sedation or anesthesia!
6. Treatment is strictly **prohibited** in case of children, who aren't able to communicate with physician!
7. If the patient has inclination to epilepsy, the physician has to take extra attention!
8. Check the position of the electrode to keep it **as smooth on the skin as possible**. The applicator (electrode) has water-bolus, a flexible surface to have the best contact with the skin. Note that the direct-contact placement of electrodes on the skin has to be controlled carefully, because some temperature-increase on the skin can occur. It will not be a sudden effect and can be indicated by the patient. Be careful because of the touching of electrode black border to the skin. Because of the special feature of RF field the contact the black border with the skin on a small part of the body can cause burning.
9. Do not use the equipment improperly: it can be dangerous. Always check the user's manual.
10. Operating the EHY device is not suggested for a staff during pregnancy.
11. Do not use the electrodes in the vicinity of the patient's metallic/prosthesis implantat (bone-replacement, pacemaker, joint-support, surgery clips, etc.) Please consult the supervisor immediately before treating such a person.
12. Check the patient, ask about her/his feelings frequently.
13. Check the good water-cooling of the electrode before positioning it.
14. After setting up treatment parameters, the door (made of glass) has to be locked to avoid the unauthorized use or misuse.
15. At rearranging and/or positioning the applicator, please pause/stop the treatment.
16. In case of any necessary medical aid (injection, infusion, etc.) please pause/stop the treatment.

17. Be careful with temperature measurements and the 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. Before the treatment any metallic pieces (necklaces, rings, jeweller, watches, pipes, coins, phones, hairpins, pens, etc.) has 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.
19. 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 loosing the information from the data-carriers
20. 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.
21. Do not clean the electrodes while the equipment is on! Do not use such wet textile-tissue that could release water to penetrate into any parts of the equipment!
22. The optimal placement of the applicators is to position them 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. Patient must be between the electrode and counter electrode placed into the waterbed.
23. Do not wrap the electrode into any textile material for the treatment. Reduce the thickness of textile material to a minimum between the electrode and patient's skin. Textile quality has an effect on tuning frequency which can lead to system error in tuning under the given circumstances.
24. During treatment, relaxing (so called 'alpha') music is suggested for psychological reasons (faster recovery is possible).
25. 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. Note, do not install the machine in the vicinity of sensitive equipments (ECG, EEG, intensive-care control-monitor, ultra-sound, video-rectoscopy and/or other sensitive imaging systems, etc.) without shielding. Shielding is also required to defend 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.

26. 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.
27. 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.
28. Clean the electrodes before each treatment. Follow the procedure written in the maintenance part (see above). Alcohol (or its substitute) has to be used for disinfecting.
29. Before the treatment any sharp objects (knives, scissors, needles, pens pencils, glasses etc.) have to be left far away from the treatment bed in case of using **waterbed**.
30. Using **waterbed mattress** without checking of its sufficient amount of water can be dangerous, the patient can suffer a burn.
31. The EHY treatment can have a side effect (about 3% of the cases). In cases when the treatment area is covered by a considerable adipose tissue, subcutane fat-burn could create. Also red-skin (slight burn) could happen.
32. The water in the mattress must be heated up before the treatment.(See in detail the Treatment information-Preparation section)
33. Accessory equipment connected to the analog 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.

Resident risks:

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. 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”. 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 such one that has the equivalent distortion ability of the cells as the static overheating. This temperature (due to the dynamical effects) in reality could be smaller than the statically measurable.

Tolerated accuracy of forwarded and reflected power ($\pm 30\%$) is checked at start-up but will not be checked continuously under the treatment. This can cause overheating of the tissue.

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 | 100-130 |
| Liver | large | 0 | 60 | 120-140 |
| Stomach | standard | 0 | 60 | 120-130 |
| Pancreas | standard | 0 | 90 | 100-120 |
| Lymph nodes | standard | 0 | 60 | 80-110 |
| Superficial | small | 0 | 60 | 80-90 |
| Cole-rectal region | standard | 0 | 90 | 100-130 |
| Breast | standard | 0 | 60 | 80-100 |
| Prostate*** | standard | 0 | 60 | 60-80 |
| Oesophagus | large | 0 | 90 | 100-120 |
| Head-neck | small | 0 | 60 | 80-100 |

* Please carefully monitor the patient, and do not exceed Her/His personal tolerance. Patient must not feel any burning or too much hot.

** Always be sure, the electrode bolus tightly touches the skin of the patient in a largest available surface.

*** take extra care on the testes.

**** could be variable, depending on the area of the actual tumor.

Electrode dimensions:

Small: Ø10cm

Standard: Ø20cm

Large: Ø30cm

Guarantee

The manufacturer guarantees service for the whole instrument (hardware and software). The guarantee is free of charge for one year. After one year 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 the field, 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) that the date of claim is within guarantee period.


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

Service (during and after 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.

Quality references:

EHY2000plus and WEY 2000 are ⁰¹²³ marked, TÜV Product Service (Munich) has given the EC Certificate. The device is constructed and produced to satisfy the IEC 601-1 standard and the 93/42/EEC MDD (Medical Device Directive).

The equipment has passed an EMC (Electro-Magnetic Compatibility) check (MIKES Product Service, Strasskirchen).

EHY2000plus has a Technical Report concerning conformity according to MSZ 16260-86 Safety levels of high frequency electromagnetic fields. Rep. No.: 2000/19/112/2 issued by ORKI

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 certificates invalid!

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