User's manual

ChemoBooster

Version: v7
(Oct. 2010)

Both the hardware and software are specially developed for the Oncotherm systems.

Content

Introduction

The ChemoBooster

Congratulations 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.

ChemoBooster 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.

How to use this manual

The user's manual of ChemoBooster 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 ChemoBooster, you can continue with the technical and theoretical background. On the base of this knowledge, you can learn the treatment process with ChemoBooster. Device control part should be used as a guideline to treatments.

Intended use

1. The ChemoBooster device is devoted to support the chemotherapy treatments by intensifying the effects of the chemotherapy by several ways. The first is, that the Booster increases the blood-volume, which is proportional with the drug concentracion in the selected part of the body. Another effect is, that the use of the Booster increases the pO2 (oxygen concentration) in the given volume, which helps the drug metabolism. The third useful effect of the Booster is, that extra drug-concentration in the desired volume decreases the drug in the non-targeted volumes.

Contacts

In case of any question, we are happy to serve you:

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Safety Warning

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

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

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

A special training is required to operate the equipment! For this procedure, 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 service refer only to the Oncotherm qualified personnel.

Symbols and their definitions

Please refer to the below symbols 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.
	Reads it before a usage the **User's manual.**
	This symbol informs the user, 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 Ltd. for information concerning the decommissioning of your equipment.
CLASS I	EQUIPMENT having a durable and substantially continuous ENCLOSURE of conductive, grounded material Not grounded parts of the enclosure are isolated from LIVE parts by insulation at least equivalent to REINFORCED INSULATION.;

Installation

General

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.

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

1. Connect the equipment only to grounded 230 V A/C socket. Ensure that the socket is properly installed.
2. Notice that a minimum 1 Ampere fuse shall protect the socket.
3. Make sure that the device uses a single phase, independent from other appliances (e.g. air-conditioning, diagnostics systems, computers, sterilization equipment.)

Pre-installation notices

1. The room shall have normal climate conditions (e.g. temperature humidity, pollution, etc.) throughout its lifetime. Temperature range: 15 – 30 °C, humidity range: 20 – 60 %, non-condensing.
2. 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. Avoid using your equipment immediately after sudden changes of the ambient temperature, due to the moisture damage in the electronic components.

9. 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.
10. Good air circulation around the device is essential to prevent internal overheat of the electronic parts.
11. Take care of not braking the power cables.
12. Electrical safety of the appliance is only guaranteed if the grounding system of the building is in accordance with local electricity board regulations. Avoid the mains and grounding discrepancies as they increase the risk of potential electric shock.
13. Devices, which are to be discarded, shall 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 itself.
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 barefoot.
7. Take care that objects do not fall and liquids are not spilled into the interior of the device. If liquid is spilt into the equipment, disconnect it from the mains and consult a qualified service technician.
8. Do not allow untrained/inexperienced personnel to operate and/or control the equipment.
9. Never leave the device exposed to environmental effects (rain, sun etc.).
10. The patient's surface must not be damp. After cleaning the surface the user have to wait until it is dry.
11. Do not use other surgical or endocardial devices while patient is being treated.
12. Dangerous voltage inside. Do not open the cabinet. There are no user serviceable parts inside. Only qualified service personnel should carry out repairs.

Resident risks:

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

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General description

Intended use

The Booster device is devoted to support the chemotherapy and/or radiotherapy treatments by localizing, personalizing and intensifying the effects of the applied therapy by several ways.

The Booster is not intended and not capable to be used for any separate treatments. Its intended use is only for complementary application, helping, extending (boosting) of treatment of arts!

Effects

- Increases the oxygenation and decreases acidity of the tissues.
- The drug metabolism is promoted drastically.
- Increases the venous drainage with greater re-absorption of catabolites and decreases of the oedema in areas with inflammatory processes.
- Speeds healing of wounds.
- Stimulates the immune system and decreases of free radicals

Side effects

- skin can become red (slight burn)
- overdose in the local area where ChemoBooster is used

Main indications

Applicable for most of the pharmaceutical products taken by

- orally,
- intravenous infusion, (i.v.),
- muscular injection,
- rectal suppository,
- skin-addicted,
- heath bathes,
- inhalations

Available applicators

- electrode

Contra indication

- Treatment is **strictly prohibited** when the patient is **unconscious!**
- Can not be used for treating patients who have pacemaker or other type of electrical implants
- Can not be used for treating patients with any metallic lead or implanted system (e.g implanted deep brain stimulator (DBS))
- Especial care is requested with continuous patient feedback at treating patients who have joint-support, who have surgery clips, who have bone-replacement, or have insensitive surface area at the treatment region (due to the surgery of other.)
- Can not be used under the age of 6
- Use is prohibited under pregnancy

Important medical notices

1. **Intended user** of this device is a **trained physician** and/or a **trained clinical staff**.
2. In the case of **reduced thermal sensitivity** the use of the device needs extra care.
3. Treatment is **strictly prohibited** when the patient is **unconscious!**
4. It is **prohibited to treat patient with permanent electric stimulators** (e.g. pace-maker, deep brain stimulator, etc.).
5. Treatment is **prohibited** when the patient is **under deep-sedation** or anesthesia!
6. Treatment is **strictly prohibited** in case of children, who are not able to communicate with the physician!
7. **Inclination to epilepsy** needs extra attention!
8. **Special care is necessary if the patient has hairs** at the treatment location (e.g. pubic hair or at head-hair or hair on breast [for men]), because the burning and the mistreating is very likely. Please do a saving before treatment if necessary, or at least please make very tight control of the treatment, use small power longer time. If you are not able to save, please ultrasound/ECG gel on the hair for better contact, or at least please make the hair wet by infusion solution. Please ask the patient about his/her cavities (bladder, stomach, pleural cavity, etc.) sensing. Stop the treatment

immediately if any unusual happen near the cavities, and continue it only when the hair is removed.

9. **The tissue electrode must be smoothly cover the patient's skin**. Any humps or irregular cover could cause burn on the patient's skin.
10. **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.
11. **Staff in pregnancy is not recommended** to operate the ChemoBooster device.
12. Do not use the electrodes in the vicinity of the patient's **metallic/prothesis/implant** (bone-replacement, pacemaker, joint-support, surgery clips, etc.) (The distance has to be laterally the same from the outside circumflex of the electrode tissue, as the diameter of the electrode itself.)
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 to control any non-Oncotherm product 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. **Before the treatment** any metallic pieces (necklaces, rings, jeweller, watches, pipes, coins, phones, hairpins, pens, etc.) have to be removed from the patient and kept away from the treatment bed. Do not treat patients who have earphones, hearing-aid, music devices (walkman, mp3 player, etc.) and/or any wire-connected instruments. Also, please keep away any sharp objects (knives, scissors, needles, pens pencils, glasses etc.). Also credit-cards and/or any other magnetically sensitive products (diskettes, tapes, etc.) should be kept away from the treatment. There is no guarantee of losing data from these 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 at 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 parts of the equipment!**
18. **The selected part of the body –where the drug is wanted to be concentrated – must be between the two electrodes! Any metallic object or infusion needle can not be between the electrodes !**
19. 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 could influence the Oncotherm device in the treatment room and vice-versa. Make sure that those devices are well shielded.

20. The personnel, responsible for the treatment/equipment, **should check the cables before each treatment**. At any doubt about the intact isolation, stop the use of the device and call for an immediate service check-up.
21. If it is possible, use the **electrodes personally** for the given patient. Another cases thin paper tissue (like a simple paper-towel or medical hygienic paper) can be used between the bare skin and the electrode for hygienic reasons.
22. The ChemoBooster 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
23. Take care, that the cables to the electrode as far as possible placed from the patient, while they can burn the patient.

24. **Resident risk:** Due to the intensive heat-delivery to the body, effect of the heat on the heart-function could happen, like in general hyperthermia cases (e.g. hot car effect on children or hot bath effect on some sensitive person, etc.) The general sign of the problem is the heart arrhythmia, which you must check when the heat delivery is too intensive (large area is treated or huge power is applied). The heart arrhythmia could happen for patients having rare “electrosmog” sensitivity or psychological indisposition against electric field radiation. Note, the field is delivered in low frequency, about 1/10 of the regular radiobroadcasts frequencies.

Do remember: the patient’s sensing is the best safety alarm for any unwanted, not expected events. Do not ignore it, react immediately.

Written consent to treatment

A written, signed consent to treatment is mandatory before start of the first treatment for the given patient. This consent has to contain:

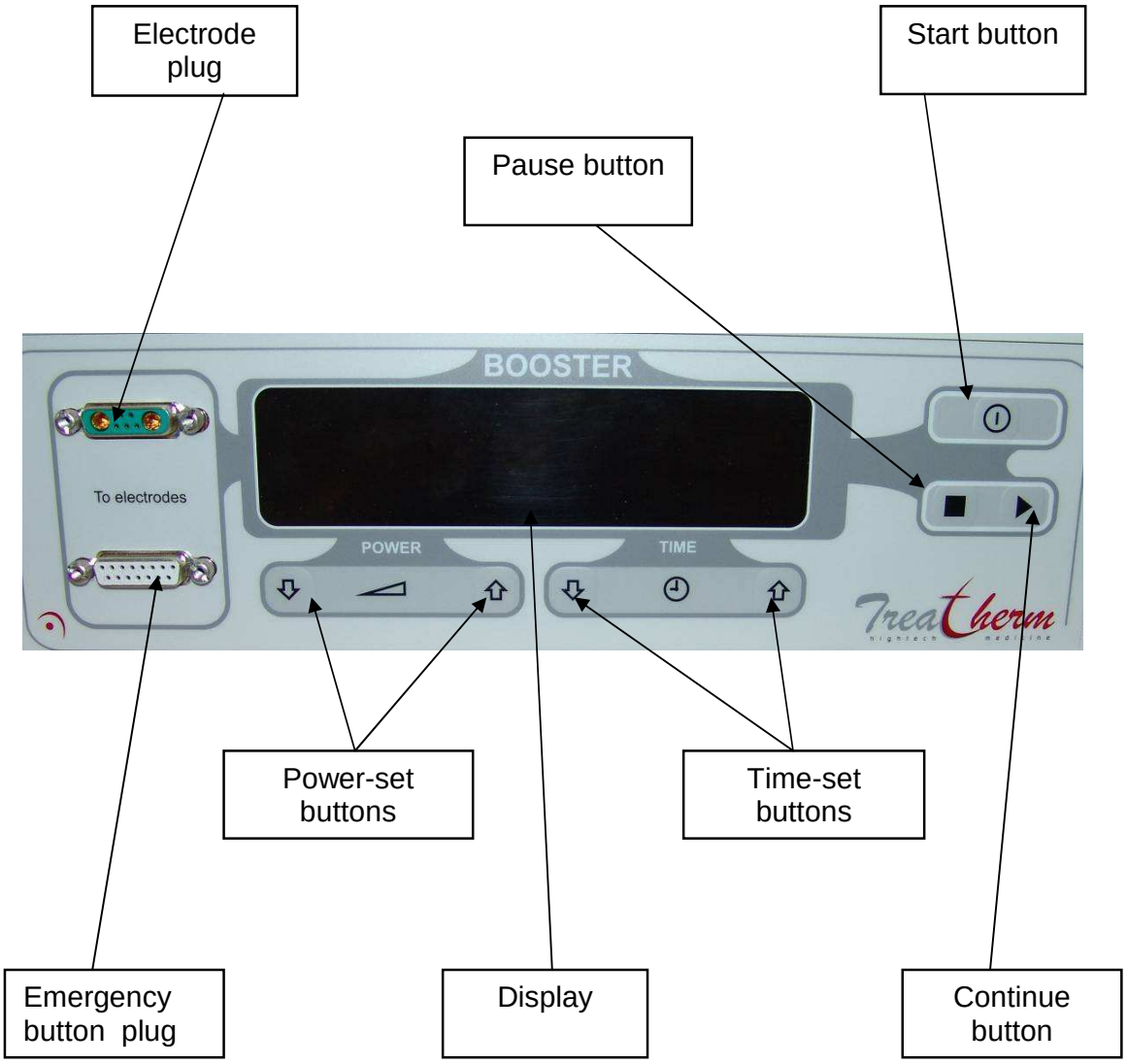
- Clear capacity (or ability) to make the decision.
- The medical provider must disclose information on the treatment, test, or procedure in question, including the expected benefits and risks, and the likelihood (or probability) that the benefits and risks will occur.
- Patient must comprehend the relevant information.
- Patient must voluntarily grant consent, without coercion or duress

Doctors must give information to the patient about a particular treatment or test in order for the patient to decide whether or not you wish to undergo such treatment or test. This process of understanding the risks and benefits of treatment is known as informed consent. It is based on the moral and legal premise of patient autonomy: Patient have the right to make decisions about your own health and medical conditions.

- Patient must give your voluntary, informed consent for treatment and for most medical tests and procedures. The legal term for failing to obtain informed consent before performing a test or procedure on a patient is called battery (a form of assault).
- For many types of interactions (for example, a physical exam with your doctor), implied consent is assumed.
- For more invasive tests or for those tests or treatments with significant risks or alternatives, you will be asked to give explicit (written) consent.
- Under certain circumstances, there are exceptions to the informed consent rule. The most common exceptions are these:
- An emergency in which medical care is needed immediately to prevent serious or irreversible harm.
- Incompetence in which someone is unable to give permission (or to refuse permission) for testing or treatment.

Technical description

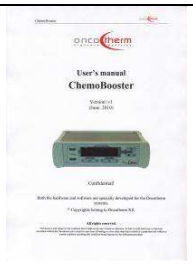
Technical details



The device

Device height (mm)	110 mm
Device width (mm)	380 mm
Device depth (mm)	330 mm
Device weight (kg)	7,6 kg
Electrical input (V)	230 (1 phase)
Electrical max. load (A)	1
Electrical avg. load (A)	0.8
RF output forwarded (W)	80
RF output useful (W)	1 → 80
RF frequency (MHz)	13.56
Medical device class: II/B	

Accessories

Accessories	Description	Photo	Order number
User's manual	This user's manual in printed form.		
Electrode	28x22 cm		

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

Transportation and storage

Oncotherm service is responsible for transportation and storage.

The following transportation and storage conditions apply:

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

The following operating condition values apply:

Temperature:	+15℃ → +30℃
Relative humidity:	20% → 60% (non condensing)
Air pressure:	700hPa → 1060hPa

Storage: only in closed room.

Before use

Check the electrode before each use of the device for broken insulation or damage of the surface of the electrode. Electrodes with damaged surface are dangerous for the patient, so do not use this electrode, but call the service.

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

Cleaning

Maintenance of external surfaces:

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

Disinfecting the accessories

Electrode: It is very important to disinfect the electrode before each treatment. Suggested solution is **Isopropanol 70% (V/V)** or **ethanol** according to user instructions on the bottle. Use only damp textile. If the textile is too wet, liquid can penetrate into any part of the equipment. Use disposable paper bandage to fix the electrode.

Disposal

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). Price of transportation and packaging is subject to discussion.

Device control

The Oncotherm ChemoBooster 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.

General instructions

It's strongly recommended to disinfect the electrodes with antiseptic solution or alcohol. Use only damp textile. If the textile is too wet, liquid can penetrate into any part of the equipment.

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

The best placement of the electrode, when it is placed directly on the skin, without any isolation material.

You could place special paper on the treated area of the patient in case the patient is sensible to silver, and the electrode can be placed on this paper. The electrode must always be on the patient, so they have to be fixed Note that the too strongly fixing f the electrodes can be uncomfortable for the patient.

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

Correct tuning is very important for the correct and effective operation of the machine. Correct tuning must be checked after the process. There are some possibilities of checking the result.

When the treatment has been started, let the treatment run until the required time limit.

There is no continuous supervision is needed during the use of the device, intervention is necessary only in special situations, such as:

- The electrode's position has been changed because of the patient's movements. In some of this cases the machine must be stopped and the tuning procedure must be repeated.
- The set power is too high (or too small) and treatment values must be changed. In this case the machine does not need to be stopped, only values must be changed.
- The patient feels heat on his/her skin. In this case the electrode is not laid onto the body of the patient properly. As much portion of the electrode surface needs to be in direct contact with the patient as possible to ensure power distribution.
- Also the tuning parameters can be changed during the treatment.

To finish the treatment, (before removing the electrode), the device RF supply must be stopped! Do not remove the applicator when the RF power is on.

Tuning

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

Preparation for use

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

Please control before using the device:

- Electrode cables shall not be broken,
- Electrode material shall not be torn or damaged,
- Electrode needs to be cleaned and disinfected to prevent infection,
- Electrodes can be used until significant damage on the electrode surfaces can't be observed

Turning on the device

The switch-on of the device can be made by the main switch placed on the back-plate of the device. After the turn-on you can see the name of the manufacturer and the type of the device for a short time, then the opening screen appears on the display of the device.

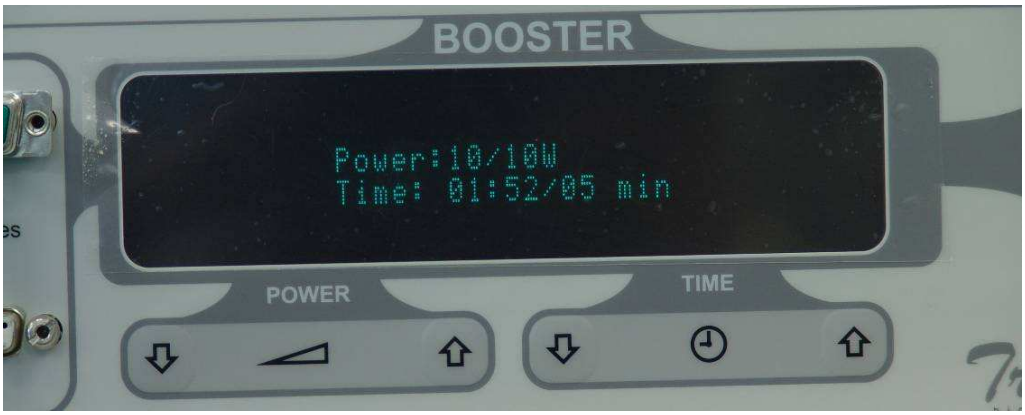
Here the parameters of action can be set by the Power-set and the Time-set buttons. After that the action can be started by pushing the Start button. In this case the device will use the last saved tuning position (see next point).

Action

On the opening screen you can set the parameters of the action by the Power-set and Time-set buttons. After that the action can be started by pushing the Start button. At the beginning of the action the device checks if the last-saved tuning position is optimal for the actual action (actual patient). If not, the device starts the tuning method and saves the optimal tuning position automatically.

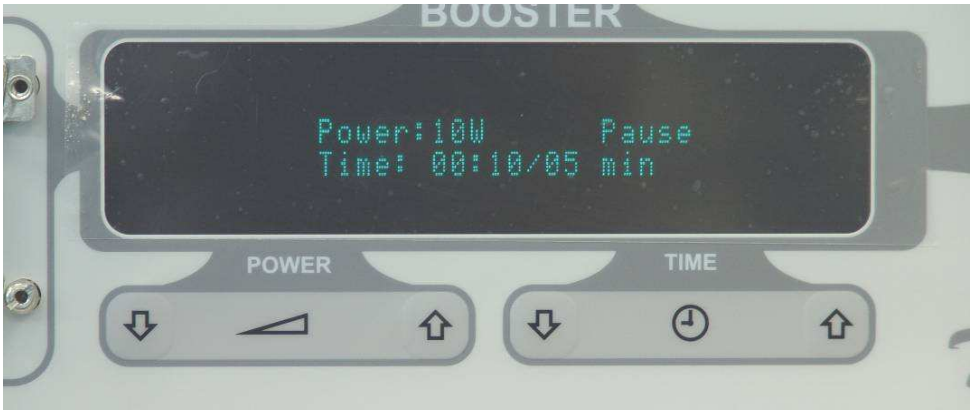
During the action the following information can be found on the display:

- Actual output power/Set power
- Elapsed time



Both the time and power values can be changed during the operation by the Power-set and Time-set buttons.

The operation of the device can be paused by pushing the Pause button. On the display the similar text appears.



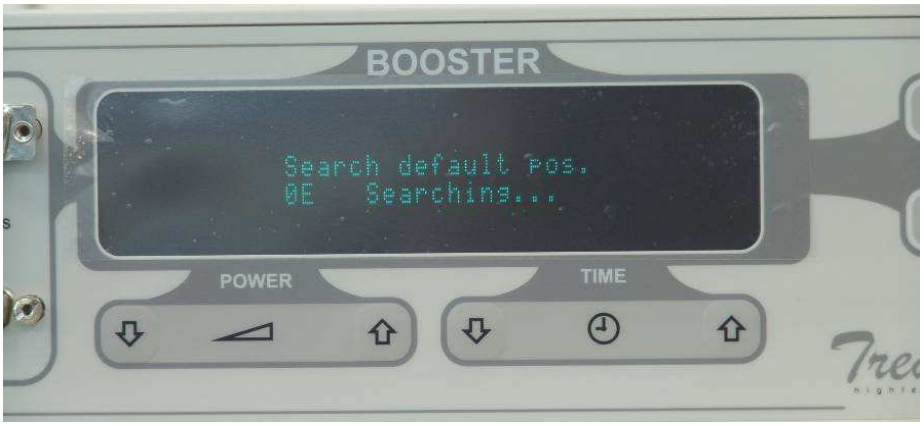
The operation can be continued by pushing the Start or the Continue button and can be aborted by pushing the Pause button. After the abort another treatment can be set and started.

Saving tuning positions

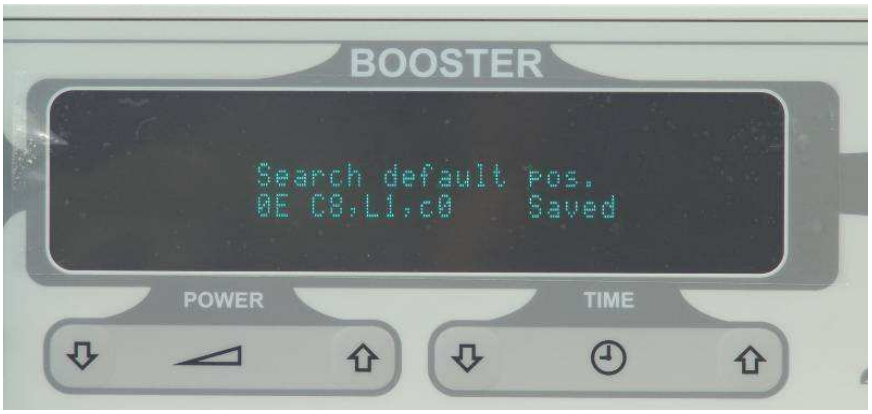
To reach the optimal power-transmission into the patient, the device must be tuned. The device tunes itself at the beginning of action, but sometimes you need to start the tuning manually.

First the electrodes must be placed onto the patient, then all the four Power-set and Time-set buttons have to be pushed on the same time. The display will change to the tuning mode.

To start the tuning push the Start button. During the tuning you will see the next on the display:



When the optimal tuning position has been found, the position will be showed on the display and the device automatically saves it. The saving is confirmed by the display.



After the tuning you can step back to the opening screen by pushing the Pause button.

Emergency stop

In emergency situations (for example, if the patient feels burn) the patient can stop the device by a separated emergency button. The push of the button stops the action and restarts the device. So an emergency stop will lead back to the action screen, where a new action can be started.

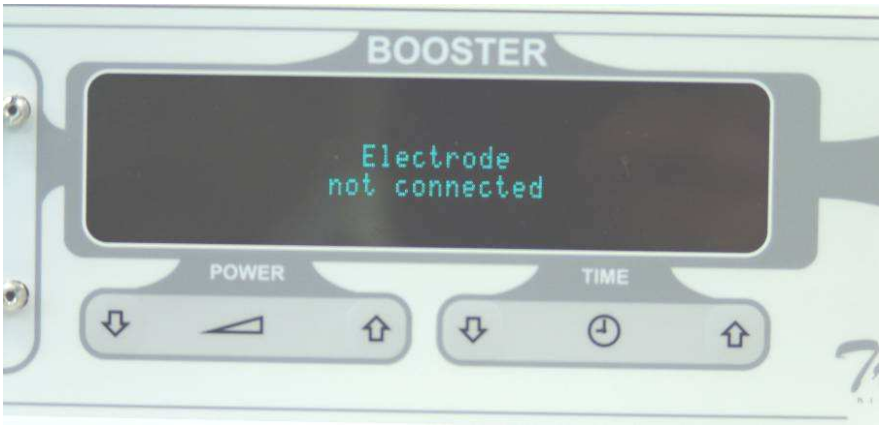
Take care about, that the patient could reach the emergency button in every situation.

Switching off the device

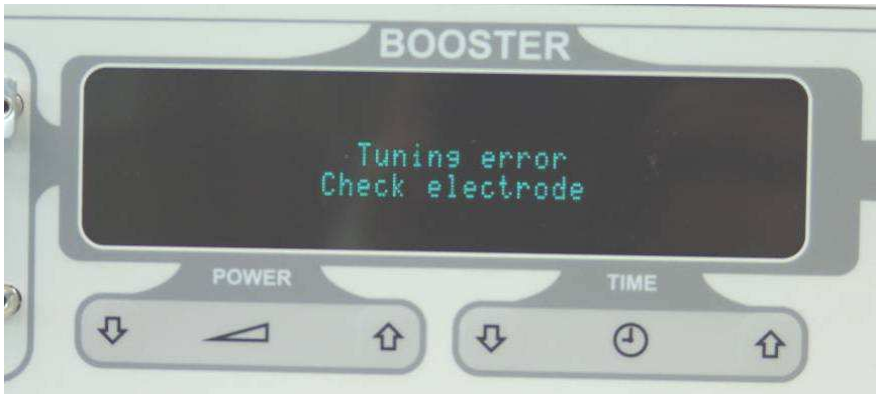
The turn-off of the device can be made by the main switch placed on the back-plate of the device.

Error and warning messages

If the electrode is not connected, you can see the next message on the display

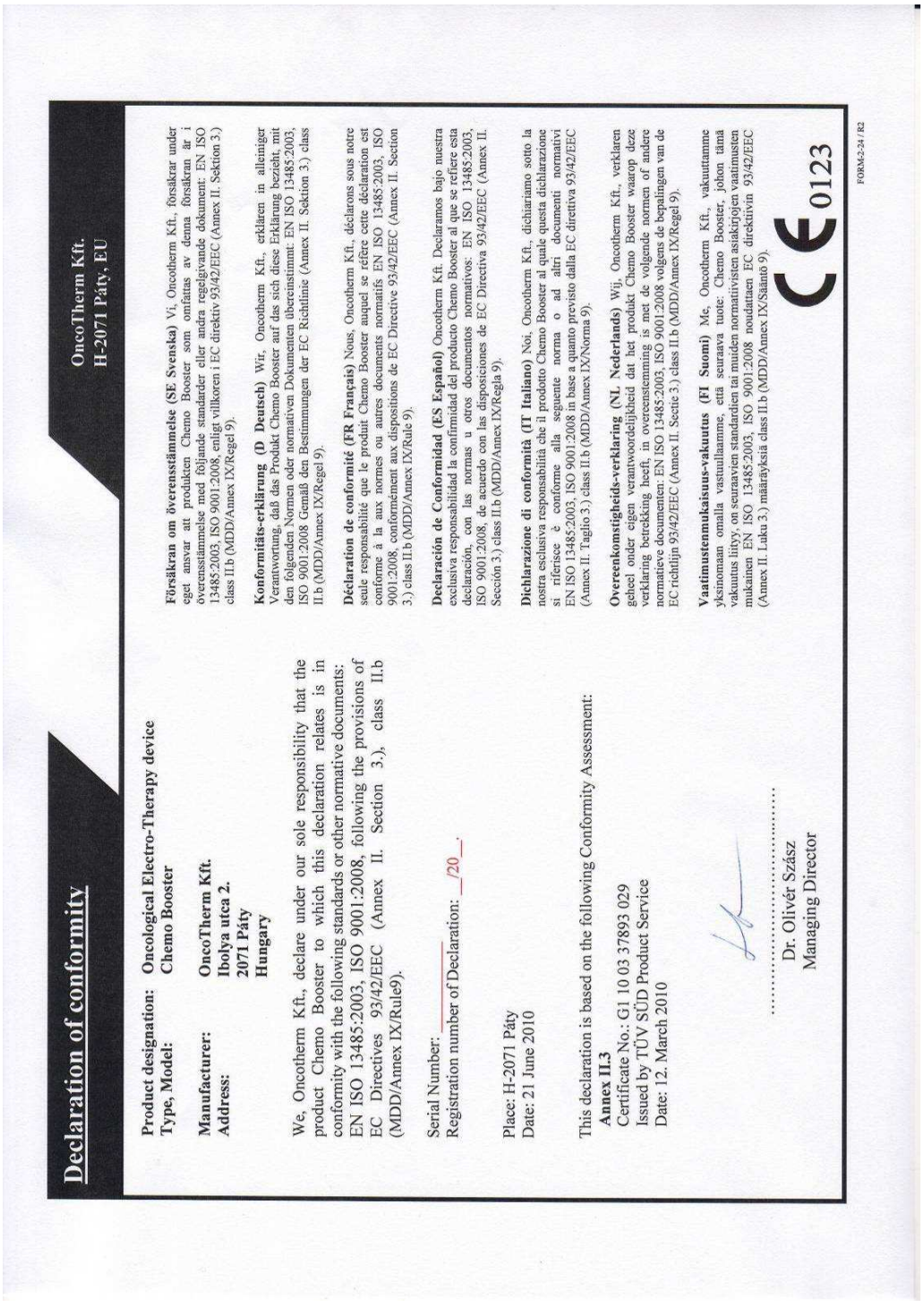


If the electrode is not correctly placed onto the patient or it's seriously damaged, a tuning error can occur.



In this case you must be check the electrode itself and the position of the electrodes on the patient.

Appendix 1: Declaration of conformity



Declaration of conformity

OncoTherm Kft.
H-2071 Páty, EU

Product designation: **Oncological Electro-Therapy device**
Type, Model: **Chemo Booster**

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

We, Oncotherm Kft., declare under our sole responsibility that the product Chemo Booster to which this declaration relates is in conformity with the following standards or other normative documents: EN ISO 13485:2003, ISO 9001:2008, following the provisions of EC Directives 93/42/EEC (Annex II. Section 3.), class II.b (MDD/Annex IX/Rule9).

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

Place: H-2071 Páty
Date: 21 June 2010

This declaration is based on the following Conformity Assessment:
Annex II.3
Certificate No.: G1 10 03 37893 029
Issued by TÜV SÜD Product Service
Date: 12. March 2010

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Dr. Olivér Szász
Managing Director

Försäkran om överensstämmelse (SE Svenska) Vi, Oncotherm Kft., försäkrar under eget ansvar att produkten Chemo Booster som omfattas av denna försäkran är i överensstämmelse med följande standarder eller andra regelgivande dokument: EN ISO 13485:2003, ISO 9001:2008, enligt villkoren i EC direktiv 93/42/EEC (Annex II. Sektion 3.) class II.b (MDD/Annex IX/Regel 9).

Konformitäts-erklärung (D Deutsch) Wir, Oncotherm Kft., erklären in alleiniger Verantwortung, daß das Produkt Chemo Booster auf das sich diese Erklarung bezieht, mit den folgenden Normen oder normativen Dokumenten übereinstimmt: EN ISO 13485:2003, ISO 9001:2008 Gemäß den Bestimmungen der EC Richtlinie (Annex II. Sektion 3.) class II.b (MDD/Annex IX/Regel 9).

Déclaration de conformité (FR Français) Nous, Oncotherm Kft., déclarons sous notre seule responsabilité que le produit Chemo Booster auquel se réfère cette déclaration est conforme à la aux normes ou autres documents normatifs EN ISO 13485:2003, ISO 9001:2008, conformément aux dispositions de EC Directive 93/42/EEC (Annex II. Section 3.) class II.b (MDD/Annex IX/Rule 9).

Declaración de Conformidad (ES Español) Oncotherm Kft. Declaramos bajo nuestra exclusiva responsabilidad la confirmidad del producto Chemo Booster al que se refiere esta declaración, con las normas u otros documentos normativos: EN ISO 13485:2003, ISO 9001:2008, de acuerdo con las disposiciones de EC Directiva 93/42/EEC (Annex II. Sección 3.) class II.b (MDD/Annex IX/Regla 9).

Dichlarazione di conformità (IT Italiano) Noi, Oncotherm Kft, dichiariamo sotto la nostra esclusiva responsabilità che il prodotto Chemo Booster al quale questa dichlarazione si riferisce è conforme alla seguente norma o ad altri documenti normativi EN ISO 13485:2003, ISO 9001:2008 in base a quanto previsto dalla EC direttiva 93/42/EEC (Annex II. Taglio 3.) class II.b (MDD/Annex IX/Norma 9).

Overeenkomstigheids-verklaring (NL Nederlands) Wij, Oncotherm Kft., verklaren geheel onder eigen verantwoordelijkheid dat het produkt Chemo Booster waarop deze verklaring betrekking heeft, in overeenstemming is met de volgende normen of andere normatieve documenten: EN ISO 13485:2003, ISO 9001:2008 volgens de bepalingen van de EC richtlijn 93/42/EEC (Annex II. Sectie 3.) class II.b (MDD/Annex IX/Regel 9).

Vaatimustenmukaisuus-vakuutus (FI Suomi) Me, Oncotherm Kft., vakuuttamme yksinomaan omalla vastuullamme, että seuraava tuote: Chemo Booster, jolkon tämä vakuutus liittyy, on seuraavien standardien tai muiden normatiivisten asiakirjojen vaatimusten mukainen EN ISO 13485:2003, ISO 9001:2008 noudattaen EC direktiivin 93/42/EEC (Annex II. Luku 3.) määräyksiä class II.b (MDD/Annex IX/Sääntö 9).

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Appendix 2: Guarantee

The manufacturer guarantees service for the whole instrument (hardware and software). The guarantee is free of charge for 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 guarantee period.

Guarantee is valid only in case the problem has been shown, or the failure has been documented (e.g. print out from the failure).

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 voids guarantee.

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.

Appendix 3: Patient Consent

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

IMPORTANT INFORMATION AND WARNING

PATIENT's CONSENT

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

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

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

I now authorize Dr. _____ to 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 have asked the patient if he/she has any questions regarding this treatment or the risks and have answered those questions to the best of my ability. I also acknowledge that I have read and understand the prescribing information listed above.

_____

Physician Date

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

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