Performance comparison of electro-hyperthermia devices: EHY-2000plus and EHY-2030

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Performance comparison of Electro-hyperthermia Devices: EHY2000plus and EHY-2030

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Abstract
To assess to the effect of a medical device on the patients is critical for clinical users and device developers. The effect of the device on the patient, the physical characteristics that generate it and the way in which these features are regulated are of decisive importance when evaluate the performance of a medical device.
The aim of our study we would like to introduce was to determine the magnitude of energy transmitted via electromagnetic field to the patient at EHY-2000plus and EHY-2030 types of Oncotherm electro-hyperthermia devices by using experimental methods, investigate the depth distribution of the absorption in order to compare the essential characteristic of the two devices and describe a technically relevant dose measurement device for hyperthermia.
As the first step of the study, we identified the variable set (outputs) whose representative to the performance of the devices (TS1 … TS12) then the environmental conditions that could have a significant effect on these monitored outputs (Tamb, ctarget, Ztarget) . In order to mimic the intended use and the human anatomy as well as possible during the measurements we have developed and utilized an artificial target which can be a valid replacement of the average patient from electromagnetic, thermal and macrostructural point of view (thermally well isolated DIA200mm, 200mm high polymer tube filled with mixed pork tissue) even though the vascular system and the inhomogeneity of the human body where not taken into account.
During measurements we utilized the most commonly used applied parts (electrodes) which are at the same size (DIA200mm) but structurally significantly different on the two evaluated device. We selected the maximum output power (Set Power: 150W) allowed for the DIA200mm electrodes. To continuously monitor temperature TM-300 series thermometers where chosen which has comprehensive immunity to the frequency used by the evaluated devices (13.56MHz) and a recent development of the Oncotherm Kft. Our study pointed out that both of the evaluated devices transmit energy to the tissues in a highly effective way even in larger depths (minimum 0.15°C/minute thermal gradient) and the method which was elaborated is able to measure output parameters in a consistent and reproducible manner. It was clearly demonstrated that the new developments had a positive effect on the quality of the application of the technology, both the average temperature gradient and the temperature distribution as a function of anatomic depth, including skin surface temperature control have been improved significantly.

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General description of the devicesre

EHY-2000plus electro-hyperthermyia device

EHY-2000plus

Main features

- 150W rated output power
- 13.56MHz output carrier frequency
- 0-5 kHz modulating frequency
- D100, D200 and D300 size applicators
- Water bed with active temperature control

General description of the devicesre

EHY-2030 electro-hyperthermyia device

EHY-2030

Improvements

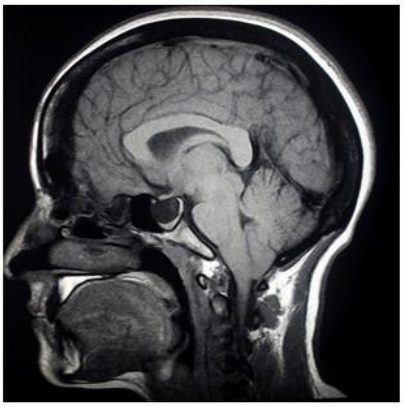
- New smart electrode design, flexible, conductive material
- 250W rated output power
- 0-10 kHz modulating frequency
- Easy to use graphic interface
- Compact design

Challenge identification

Evaluation of effective energy through temperature measurement

Parameters have influence

- Electrical properties of the target and surrounding tissues
- Thermal properties of the target and surrounding tissues
- Anatomic dimensions
- Vascularization
- Homogeneity / inhomogeneity



› Study design

Control of input parameters

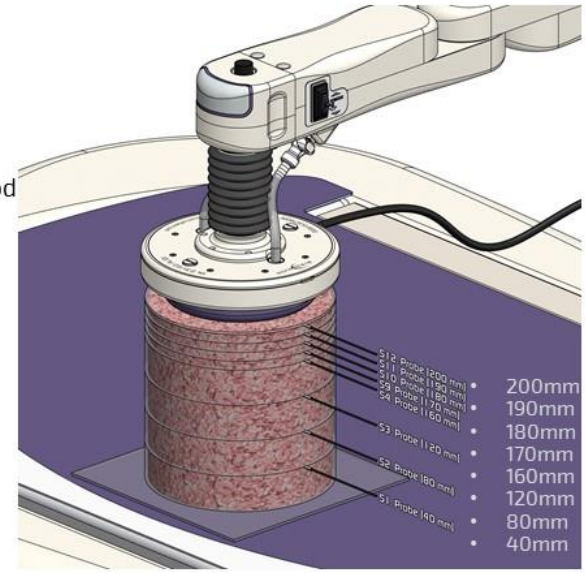
- Electrical properties of the target and surrounding tissues → Utilization of tissues from animal source to mach impedance
- Thermal properties of the target and surrounding tissues → Utilization of tissues from animal source and measure /calculate thermal coefficiencies
- Anatomic dimensions → Mimic the human body cross-section lay between the two electrodes
- Homogeneity / inhomogeneity → Simplification the system and test in homogenous system

› Study design

Test setup

INPUTS

- Applicator size: 200mm diameter electrod
- Impedance of the test analogue
- Set power: 150W
- Height of the test analogue: 200mm
- Tissue type: pork ribs
- Weight of tissue: 6.6kg

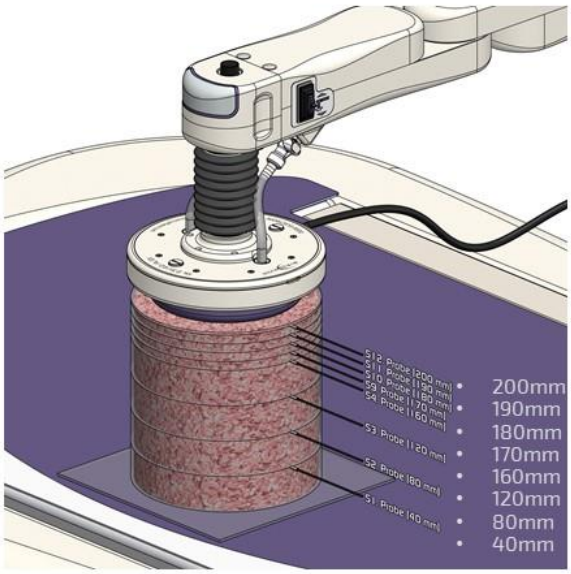


› Study design

Test setup

OUTPUTS

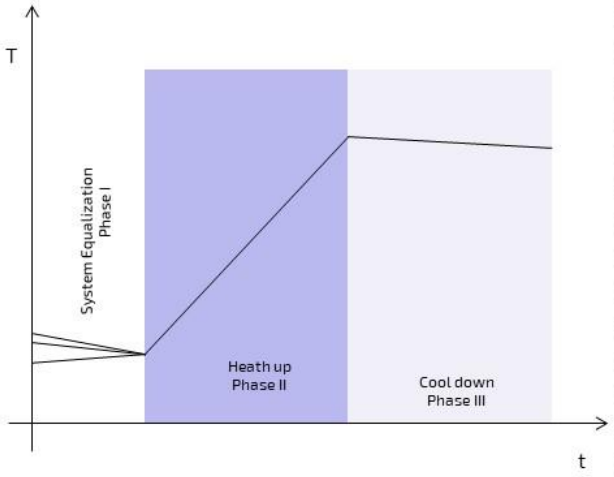
Thermal probes in 8 different heights of the tissue column. The thermal probes were introduced through side holes. The probes were placed in the middle of the tissue column **40** mm, **80** mm, **120** mm, **160**mm, **170**mm, **180**mm, **190**mm and **200**mm away from the bottom plate of the test analogue.



› Study design

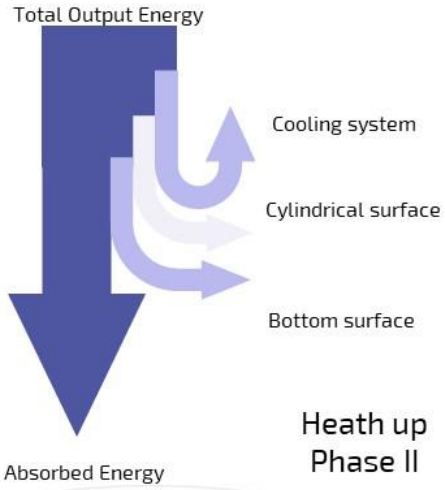
Methodology

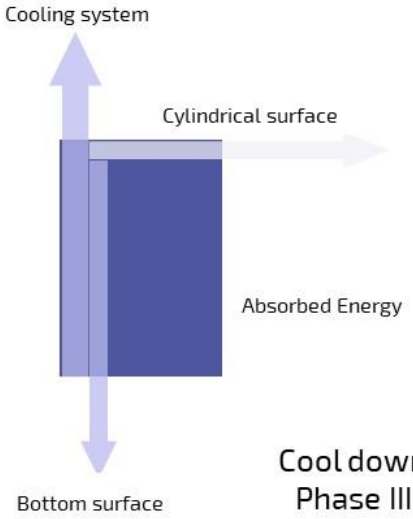
- Test analogue placement to device
- Equalisation of the system (Phase I)
- Treatment initiation using 150W set power
- Treatment, energy transfer for about an hour (Phase II)
- Treatment ends but maintains electrode cooling
- Cools down in about an hour (Phase III)



Study design

Methodology

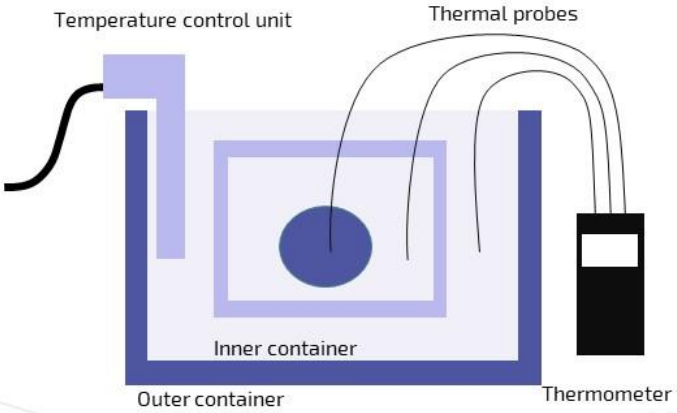




Specific heat capacity

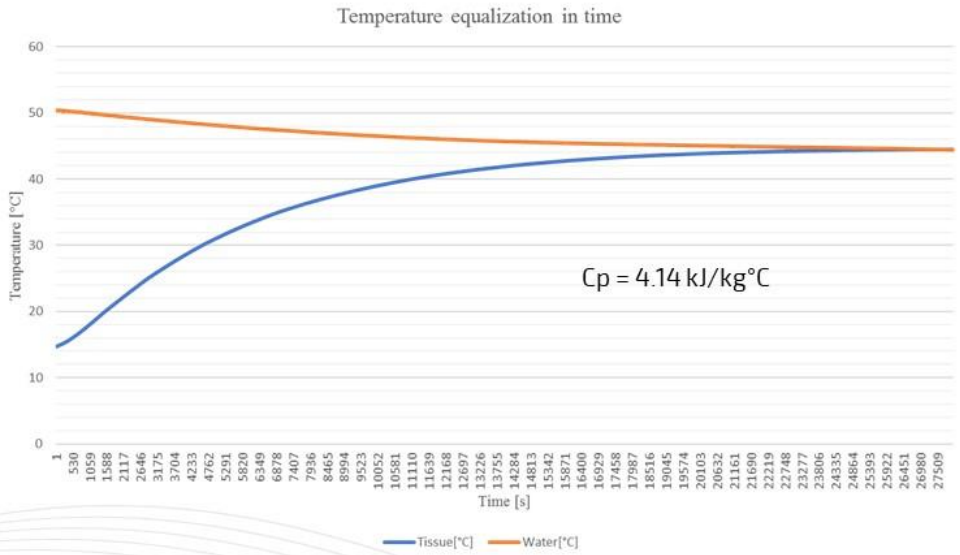
Experimental evaluation

- Environmental control for test volume
- Cold pork rib tissue
- Hot water
- Temperature monitoring until the equalization
- C_p calculation using initial and final temperatures



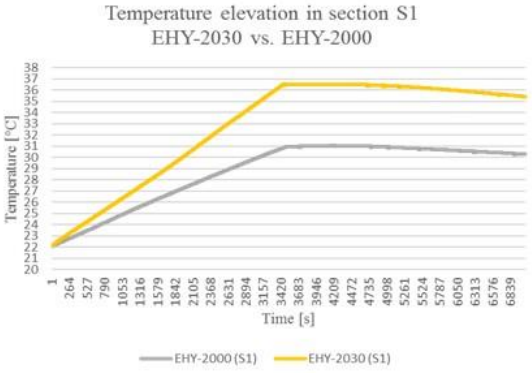
Specific heat capacity

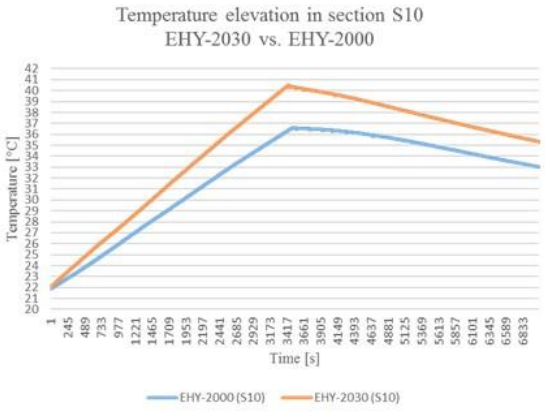
Experimental evaluation

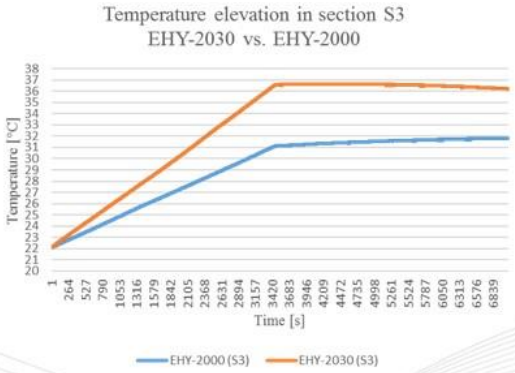


Results

Temperature data from sections

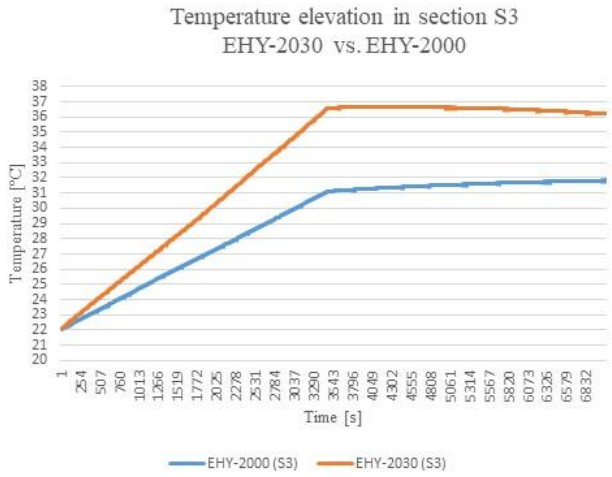


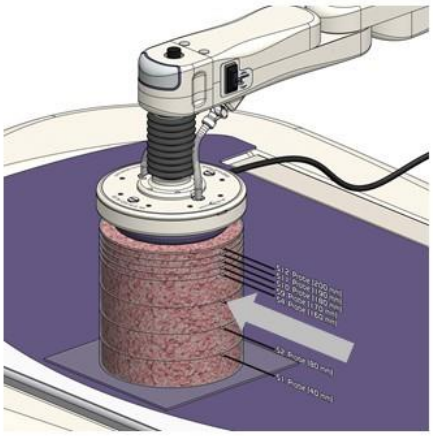




Results

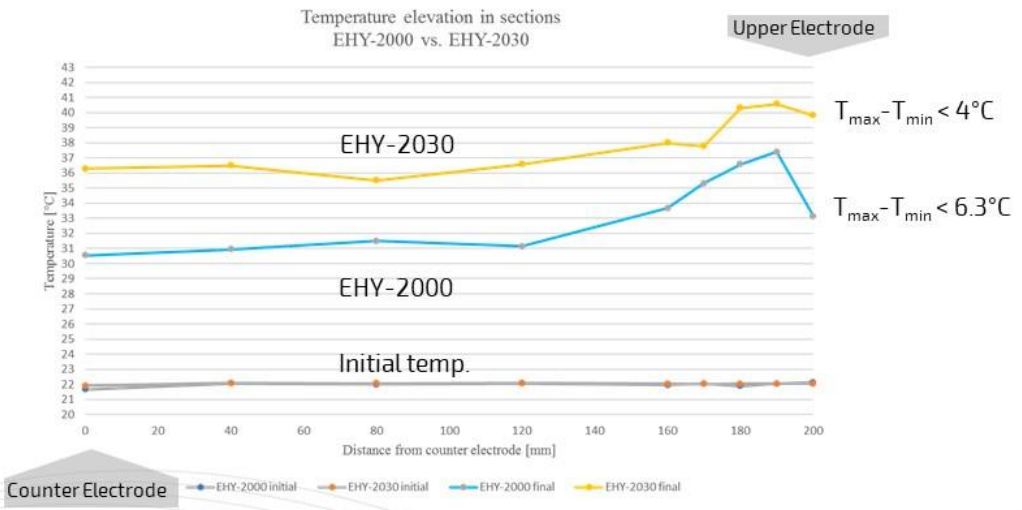
Temperature elevation in section S3





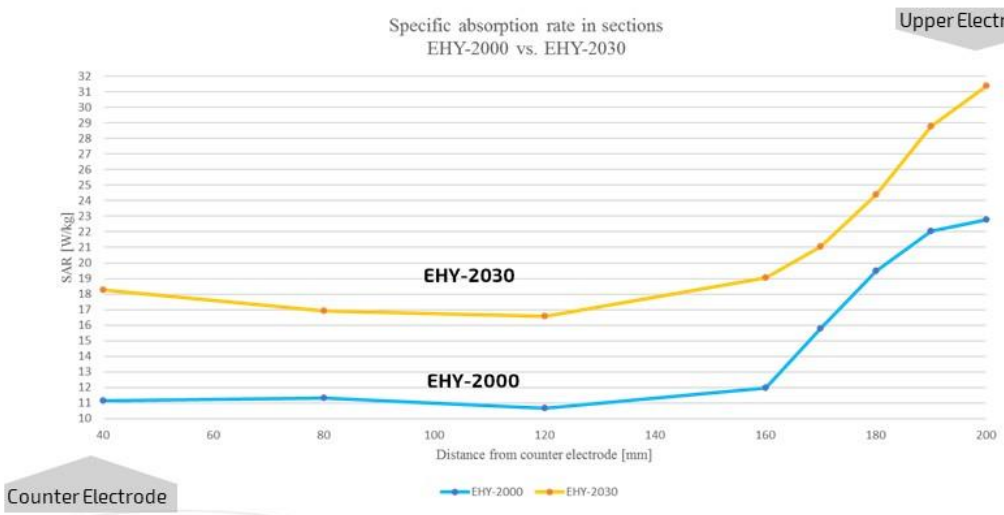
Results

Temperature elevation in sections



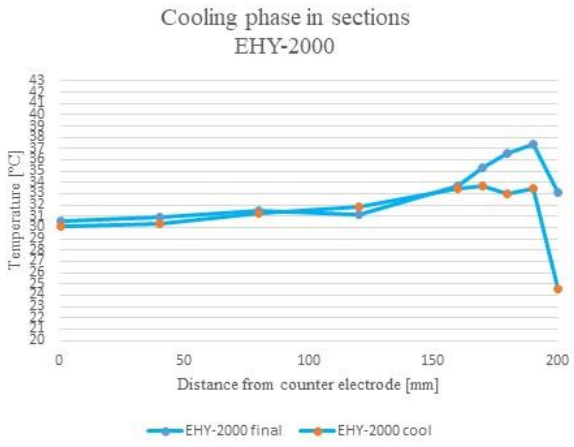
SAR in sections

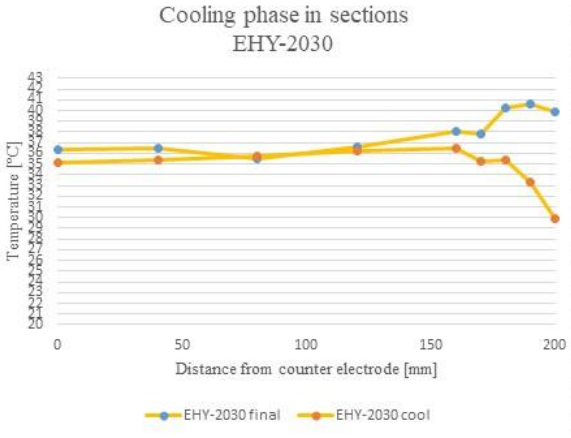
Specific absorption rate calculation



Results

Heat conduction





Conclusions

Improvements at EHY-2030

- Better energy distribution
- Higher Specific Absorption Rate
- Intuitive user interface
- Compact design
- Intelligent features

THANK YOU!