BSD-2000 3D
Conformal Hyperthermia
Definition of Hyperthermia

3D tumor conformal hyperthermia

The battle against cancer is also a race against time. The hyperthermia systems from Pyrexar help the human body win this fight giving physicians the edge over monotherapies. We offer a range of complete solutions allowing for individualized treatment.

What is the benefit of hyperthermia?

Hyperthermia – heating the tumor to 40 - 45 °C – combined with radiation and/or chemotherapy is a proven treatment for malignant tumors. Randomized clinical trials have shown that hyperthermia used in conjunction with other therapies improves relapse-free survival and local tumor control – without any significant increase in toxicity.

What is deep regional hyperthermia?

Deep regional hyperthermia goes one step further by supplying therapeutic heat to those tumors seated more than 3 - 5 cm below the skin surface. Here, the tumor region is raised to the desired temperature using targeted electromagnetic energy radiating at around 100 MHz (radio frequency). Antenna arrays, mounted in applicators of varying shapes placed around the body, focus this energy onto specific tumor locations. The amplitude and phase of the radio frequency (RF) energy can be adjusted to provide the most suitable heating pattern for the individual tumor shape and size.

The BSD-2000 Deep Regional Hyperthermia System is FDA Approved under HDE exemption for the treatment of cervical cancer.
The Advantage

3D tumor conformal hyperthermia

What is the advantage of 3D hyperthermia?

3D hyperthermia allows for optimum results, since the heating zone is targeted specifically towards the tumor region. This is achieved by focusing the electromagnetic power onto the target volume. The focus is not fixed at the center of the applicator but may be targeted at any specific area, providing the system operator with significantly more freedom in positioning the applicator. The BSD-2000 3D hyperthermia system is designed particularly for treating tumors in hard-to-reach locations.
Improved treatment with targeted heating

How is 3D hyperthermia applied?

To begin with, part of the patient’s body is enclosed by an eye-shaped applicator. Phase and amplitude steering can be used to determine the heating focus within the applicator. The 3D technology makes use of 24 dipole antennas driven by RF power channels. These dipoles are arranged in three rings of eight antennas each. By varying the phase and amplitude of each of the 12 input channels, the operator creates a constructive interference at the tumor zone. The dedicated treatment-planning software, SigmaHyperPlan, calculates the best possible settings for each channel.
Combined Treatments

Combined treatments with hyperthermia

Clinical studies have revealed that the addition of hyperthermia to radiotherapy can double the efficacy of the treatment.

This is because the temperatures attained through hyperthermia increase blood flow to the tumor, accentuating the formation of the oxygen radicals required to attack cancer cell DNA through radiotherapy. Heat shock through hyperthermia is also an effective agent in inhibiting DNA repair in cancer cells after double-strand breaks occur from ionizing radiation. Further, hyperthermia kills radiation-resistant hypoxic cancer cells by forcing a rise in their anaerobic metabolism, causing them to weaken as they deplete their energy supply and become toxically acidic as their consumption exceeds their ability to expel waste.

Hyperthermia and Chemotherapy

Hyperthermia used in combination with chemotherapy increases the drug concentration in the tumor region due to increased blood flow, thus raising the effectiveness of cytostatic drugs. In addition, hyperthermia has been proven to enhance drug toxicity in cells resistant to many drugs.

Hyperthermia can, therefore, be employed synergistically with chemotherapy in strategies to treat high-risk tumors with a view towards total tumor eradication.
For Whom is Hyperthermia Suitable?

Hyperthermia is used for the following types of tumor:

- cancer of the colon (i.e. the large bowel or intestine) that is locally advanced or has recurred
- recurring breast cancer on the chest wall
- cancer of the uterine cervix (cervical carcinoma)
- soft-tissue sarcomas
- recurring skin cancer (malignant melanoma)
- locally advanced head-neck tumors
- locally advanced or recurring bladder cancer
- cancer of the pancreas (pancreatic carcinoma)
- locally advanced or recurring anal carcinoma (cancer of the anus)

Hyperthermia is not suitable for

- patients with serious heart disease or with a heart pacemaker
- when there are artificial joints in the area of treatment
- pregnant patients
Benefits of Hyperthermia

The benefits of hyperthermia treatments

Important national and international peer-reviewed studies have clearly proven the effectiveness of hyperthermia in combination with chemotherapy or radiotherapy.

- Improvement and extension of medical tumor control
- Significantly higher success rates for treatment with chemotherapy and radiotherapy
- Reduction of the tumor size enables removal by surgery
- Destruction of tumor cells, especially in cases of previously treatment-resistant tumors
- Increased remission rates and improvement to the quality of life
- Long-term improvement of the course of the illness
- Reduced risk of metastases
Study Results – Overview

All results are statistically significant

We thank Prof. Dr. med. N. R. Datta at Kantonsspital Aarau for his kind permission to show this overview.

<table>
<thead>
<tr>
<th>Site</th>
<th>Trials</th>
<th>RT alone</th>
<th>RT + HT</th>
<th>Odds ratio (CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td>6</td>
<td>88 / 181 (48.6%)</td>
<td>122 / 198 (61.6%)</td>
<td>2.10 (1.34 – 3.30)</td>
<td>0.001</td>
</tr>
<tr>
<td>Cervix</td>
<td>6</td>
<td>173 / 263 (65.7%)</td>
<td>200 / 251 (79.6%)</td>
<td>2.19 (1.45 – 3.32)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Head Neck</td>
<td>9</td>
<td>183 / 364 (65.7%)</td>
<td>266 / 353 (75.3%)</td>
<td>3.71 (2.55 – 5.38)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Rectum</td>
<td>4</td>
<td>16 / 205 (7.8%)</td>
<td>36 / 208 (17.3%)</td>
<td>2.15 (1.10 – 4.20)</td>
<td>0.025</td>
</tr>
<tr>
<td>Ur. Bladder</td>
<td>3</td>
<td>35 / 86 (40.6%)</td>
<td>69 / 118 (58.4%)</td>
<td>2.40 (1.25 – 4.62)</td>
<td>0.009</td>
</tr>
<tr>
<td>Esophagus</td>
<td>2</td>
<td>24 / 132 (18.2%)</td>
<td>47 / 162 (29%)</td>
<td>2.64 (1.34 – 5.20)</td>
<td>0.005</td>
</tr>
<tr>
<td>Lung</td>
<td>2</td>
<td>2 / 70 (2.8%)</td>
<td>7 / 59 (11.8%)</td>
<td>2.69 (0.51 – 14.22)</td>
<td>0.243</td>
</tr>
<tr>
<td>Superficial tumours</td>
<td>2</td>
<td>57 / 169 (33.7%)</td>
<td>75 / 175 (42.8%)</td>
<td>1.48 (0.94 – 2.32)</td>
<td>0.091</td>
</tr>
<tr>
<td>Melanoma</td>
<td>1</td>
<td>23 / 65 (35.3%)</td>
<td>39 / 63 (61.9%)</td>
<td>2.97 (1.45 – 6.09)</td>
<td>0.003</td>
</tr>
<tr>
<td>Anal Canal</td>
<td>1</td>
<td>17 / 25 (68%)</td>
<td>23 / 24 (95.8%)</td>
<td>10.82 (1.23 – 94.92)</td>
<td>0.032</td>
</tr>
<tr>
<td>Choroidal melanoma</td>
<td>1</td>
<td>20 / 70 (28.5%)</td>
<td>33 / 63 (52.3%)</td>
<td>2.75 (1.34 – 5.63)</td>
<td>0.006</td>
</tr>
<tr>
<td>Others (Miscl.)</td>
<td>1</td>
<td>47 / 87 (54%)</td>
<td>50 / 87 (57.4%)</td>
<td>1.15 (0.63 – 2.09)</td>
<td>0.647</td>
</tr>
<tr>
<td><strong>All sites</strong></td>
<td>38</td>
<td><strong>685 / 1717 (39.8%)</strong></td>
<td><strong>967 / 1761 (54.9%)</strong></td>
<td><strong>2.30 (1.95 – 2.72)</strong></td>
<td><strong>&lt;0.001</strong></td>
</tr>
</tbody>
</table>

The odds of achieving a CR with RT+HT is 2.3 times higher than RT alone

(Datta NR et al., Cancer Treat Review, 2015)
Computer-aided hardware

Sigma Treatment Base Unit

The Sigma Treatment Base Unit includes both patient and applicator support systems. The patient support system consists of two fiberglass rods that support a mesh sling, which is connected in turn to the hydraulic lift assembly, located at both ends of the patient support system. The patient is placed on the sling in preparation for the therapy, then the applicator is positioned over the tumor area and the water bolus filled. A large water reservoir mounted in the base unit maintains the bolus water at the desired temperature throughout the treatment.

Dodek Amplifier

The system is powered by a solid-state Dodek amplifier with 12-channel independent amplifier phase and amplitude adjustment. The amplifier operates at a fixed frequency of 75 to 140 MHz and delivers up to 1,800 watts of radio frequency power to the applicator. Each channel is monitored and controlled by computer and can be individually tailored to the requirements of each treatment session. This low maintenance amplifier is located separately from the patient and operator room, and is housed in a 24” mounting rack.

Thermometry

Sophisticated temperature monitoring is carried out by a ceiling-mounted interface box that supports up to eight temperature probes. These each have a diameter of 1.1 mm and an accuracy of ± 0.1 °C and are non-perturbing to radio-frequency fields, which ensures precise, continuous temperature monitoring during treatment without the need to switch off power.
Thermal Mapping

Thermal mapping is an advanced automated thermometry system that periodically shifts temperature probes to multiple locations within the implanted catheter during treatment. The thermal mapping system is integrated into both the hardware and software systems to provide a comprehensive set of parameters, thermal dose calculation, data display, and printout capabilities. Temperatures are automatically recorded throughout this process to provide temperature scans along the entire catheter length. The probes are automatically repositioned after the scans and the temperature scan plots (temperature profiles) are displayed on the system monitor ready for printout.

Computer System

The entire BSD-2000 3D hyperthermia system is controlled by a PC with Windows XP operating system, interfaced to all system modules. A large, user-friendly LCD color monitor, cordless keyboard and cordless mouse create an ergonomic operating environment. The system also includes a high-resolution color inkjet printer for instant hardcopy treatment reports. The system software incorporates a color Graphic User Interface, automatically guiding the operator through the set-up and treatment procedures and featuring menu-driven selection of treatment parameters.
Applicator Subsystem

The Sigma applicators Sigma 60 and Sigma Ellipse are annular phased array applicators that are comprised of a clear plastic shell, 8 radiating dipoles, and a bolus membrane. The Sigma 60 uses a cylindrical shaped plastic shell to support the 8 radiating dipoles. The Sigma Ellipse is an elliptically shaped plastic shell used to support the same components used in the Sigma 60. The Sigma Ellipse provides improved comfort for smaller size patients.

- Advanced annular phased array principles create a central focusing of energy, which significantly overcomes the penetration losses of the energy radiated into the body.
- Phased array applicators allow the operator to shape the heating pattern to the targeted treatment area and achieve selective power targeting at depth for treatment of deep tumors.
- Water filled bolus dielectrically loads the individual antennas and provides an energy-confining medium that directs the RF energy into the body.
- Quick and easy patient setup.
- Plastic shell provides a clear view of the patient’s surface to allow visual verification of the applicator positioning and to facilitate monitoring of any skin color changes, which would be indicative of surface hot spots adapted to the tumor region.
Sigma Eye and Sigma 40 – Adult extremities, children

The **Sigma Eye** applicator is the standard for 3D conformal treatments. It is based on the latest, well-proven phased-array technology and includes an integrated water bolus for energy coupling, surface cooling as well as fast and easy patient setup. It takes its name from the eye-shaped water bolus surface that minimizes the bolus pressure on the patient.

The **Sigma 40•3D** cylindrical applicator is designed specifically for the treatment of children, youths, and smaller-sized adults – its 40 cm opening is ideally suited for smaller patients. The integrated water bolus provides both coupling for the electromagnetic energy and surface cooling for the patient.

The 24 paired antenna arrays are mounted in three rings of 8 dipoles each and are driven by the 12-channel generator. By adjusting the amplitude and phase of each channel, the electromagnetic energy can be focused three-dimensionally onto the tumor region.
SigmaHyperPlan® Advanced

New standard for enhanced quality

SigmaHyperPlan® Advanced is currently the only available clinical planning system for regional deep hyperthermia which has been certified and approved as a medical device. It was designed and developed specifically for deep hyperthermia treatment.

SigmaHyperPlan Advanced sets new standards, particularly in terms of user-friendliness in the clinical setting. Operator guidance adapted to the treatment planning workflow leads the user of SigmaHyperPlan Advanced intuitively through all the necessary planning steps, thus enabling all the relevant phases to be planned efficiently. All the steps are performed quickly, from data import through to optimization of the applicator setting.
The result of interdisciplinary research and development

Raising the bar with hyperthermia software: SigmaHyperPlan® Advanced

Optimal hyperthermia treatment in clinical oncology demands specific planning, in which the patient’s anatomy plays a major role. As a general rule, image data from CT and MRI systems is used to display the tumor precisely in 3D.

The SigmaHyperPlan Advanced software system uses data from medical imaging to enable clearly structured planning and performance of hyperthermia treatments.

A core component of SigmaHyperPlan Advanced is a simulation procedure which calculates and visualizes the optimal heat distribution for the individual patient.

The planning software system SigmaHyperPlan Advanced was developed by Dr. Sennewald Medizintechnik GmbH as an interdisciplinary application, to which scientists at the Zuse Institute Berlin and physicians at the Charité Berlin have also contributed greatly since the beginning of the 1990s.

With SigmaHyperPlan Advanced, the focus is on intuitive operator guidance and maximum precision in data processing.
The Features

The features of SigmaHyperPlan® Advanced at a glance

- Purpose-designed for precise planning, exact simulation and effective implementation with comprehensive documentation of hyperthermia treatments
- The functional design is based on years of interdisciplinary research, studies and user surveys
- Ergonomic, intuitive operation with extensive and tested plausibility checks
- Rapid and precise orientation on the display by means of precise and detailed 3D visualizations of patient models and applicators
- Maximum flexibility with the necessary precision ensured by sophisticated graphical software tools with user-friendly functions
Designed for Deep Hyperthermia Treatment

SigmaHyperPlan® Advanced

Conclusion
Hyperthermia treatment has never been easier or more reliable to perform.
Site Planning

Customized Hyperthermia Suites

The ideal layout for your given environment

A standard hyperthermia suite consists of the treatment room, the operator room plus a small technical room. For convenient patient handling, the treatment room is equipped with electromagnetic shielding and requires floor space of around 24 – 35 m². The adjoining operator room requires floor space of 12 to 16 m² and an observation window looking into the treatment room. A small technical room of 8 to 10 m² is required for installation of the Dodek amplifier. Our site-planning specialists will be happy to assist you in finding the ideal layout for your given environment. The installation manual includes specification parameters for building services, electricity, air conditioning, and other relevant factors.
Floor Space 24 - 35 m²
More information on the topic can be found on the following websites:

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