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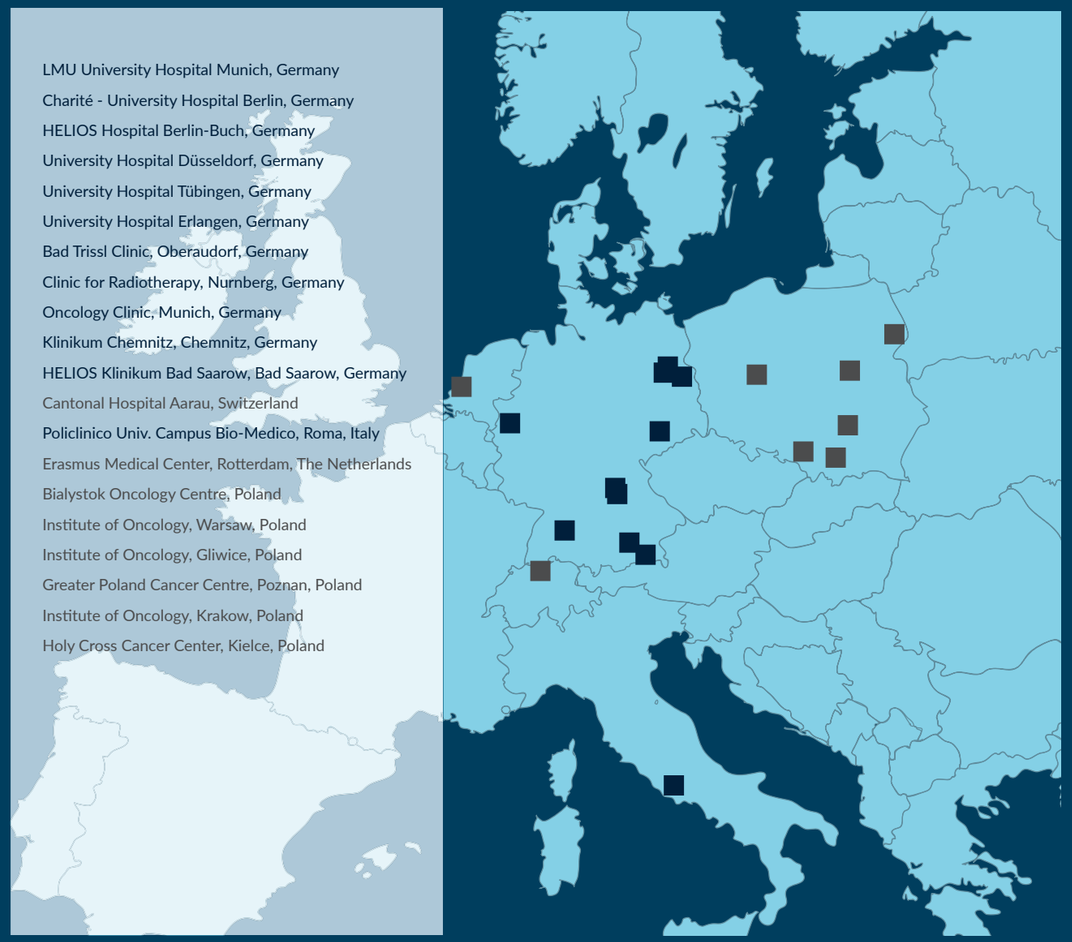
BSD-2000 3D
CONFORMAL HYPERTHERMIA

PYREXAR HYPERTHERMIA SYSTEMS IN EUROPE



LMU University Hospital Munich, Germany
Charité - University Hospital Berlin, Germany
HELIOS Hospital Berlin-Buch, Germany
University Hospital Düsseldorf, Germany
University Hospital Tübingen, Germany
University Hospital Erlangen, Germany
Bad Trissl Clinic, Oberaudorf, Germany
Clinic for Radiotherapy, Nurnberg, Germany
Oncology Clinic, Munich, Germany
Klinikum Chemnitz, Chemnitz, Germany
HELIOS Klinikum Bad Saarow, Bad Saarow, Germany
Cantonal Hospital Aarau, Switzerland
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Erasmus Medical Center, Rotterdam, The Netherlands
Bialystok Oncology Centre, Poland
Institute of Oncology, Warsaw, Poland
Institute of Oncology, Gliwice, Poland
Greater Poland Cancer Centre, Poznan, Poland
Institute of Oncology, Krakow, Poland
Holy Cross Cancer Center, Kielce, Poland

OVERVIEW

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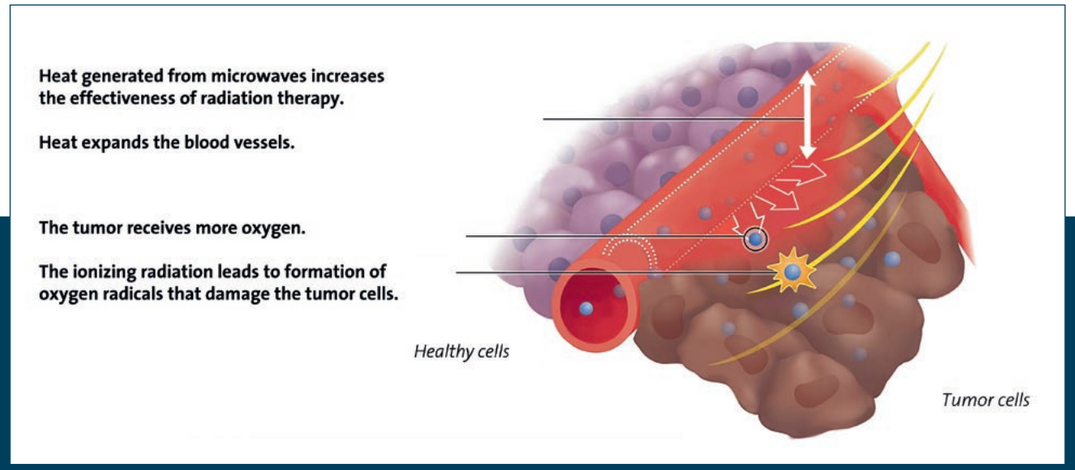
HYPERTHERMIA

WHAT IS HYPERTHERMIA?

Hyperthermia is a treatment method in cancer therapy that has proved effective in combination with the classic standard therapies, namely radiation therapy and/or chemotherapy. It involves heating the tumor to 42°C, using focused electromagnetic waves, without damaging the surrounding tissue.

Hyperthermia is mainly used for tumors that have so far been resistant to treatment or that have relapsed. Clinical studies have proven that hyperthermia in combination with conventional therapies clearly improves the prognosis of patients with certain types of tumor.

Primarily inoperable tumors are another indication. Hyperthermia treatment in combination with radiation therapy can reduce the size of the tumor and/or separate the tumor from surrounding tissue and thus enable its successful surgical removal.



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?

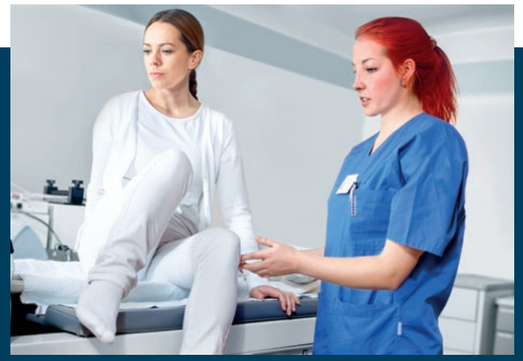
Deep regional hyperthermia goes one step further by supplying therapeutic heat to those tumors seated more than 3 - 5 cm below the skin surface. Here, the tumor region is raised to the desired temperature using targeted electromagnetic energy radiating at around 100 MHz (radio frequency). Antenna arrays, 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.

3D TUMOR CONFORMAL HYPERTHERMIA

WHAT IS THE ADVANTAGE OF 3D HYPERTHERMIA?

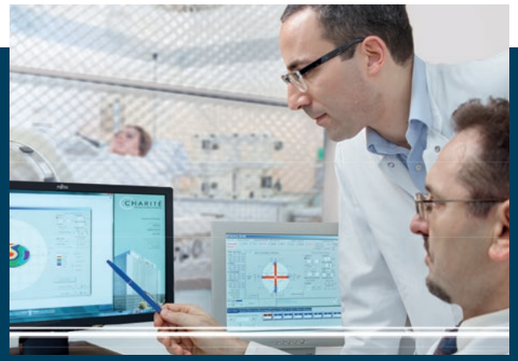
3D hyperthermia allows for improved results, since the heating zone is targeted specifically towards the tumor region. This is achieved by focusing the electromagnetic power onto the target volume. The focus is not fixed at the center of the applicator but may be targeted at any specific area, providing 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 settings for each channel. The software is currently in the final development phase and the relaunch, including certification, is planned for mid-2025.



COMBINED WITH RADIOTHERAPY

COMBINED TREATMENTS WITH HYPERTHERMIA

CLINICAL STUDIES* HAVE REVEALED THAT THE ADDITION OF HYPERTHERMIA TO RADIOTHERAPY CAN ALMOST 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.

* References to clinical studies can be found on our website under Clinical Evidence.

COMBINED WITH CHEMOTHERAPY

HYPERTHERMIA IN COMBINATION WITH CHEMOTHERAPY

Hyperthermia used in combination with chemotherapyincreases 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 metallic implants in the area of treatment
- Pregnant patients

CLINICAL EVIDENCE

HYPERTHERMIA CLINICAL STUDIES

BENEFITS OF HYPERTHERMIA

On our website you will find hyperthermia clinical studies from the past three decades on the effectiveness of adding superficial and regional hyperthermia to radiation therapy and/or chemotherapy. The successes of hyperthermia treatment can be summarized as follows*:

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

* References to clinical studies can be found on our website under Clinical Evidence.

SYSTEM SPECIFICATIONS

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 ± 0.2 °C and are non-perturbing to radio-frequency fields, which ensures precise, continuous temperature monitoring during treatment without the need to switch off power.

TECHNICAL DETAILS

THERMAL MAPPING

Thermal mapping is an automated thermometry system that periodically shifts temperature probes to multiple locations within the 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 10 IoT operation 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.

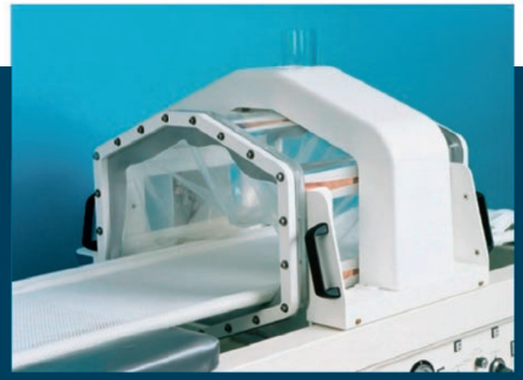
DESIGNED TO MEET EVERY CLINICAL NEED

APPLICATOR SUBSYSTEM

SIGMA TREATMENT BASE UNIT

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 to support the same components used in the **Sigma 60**. The **Sigma Ellipse** provides improved comfort for smaller size patients.

- 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.

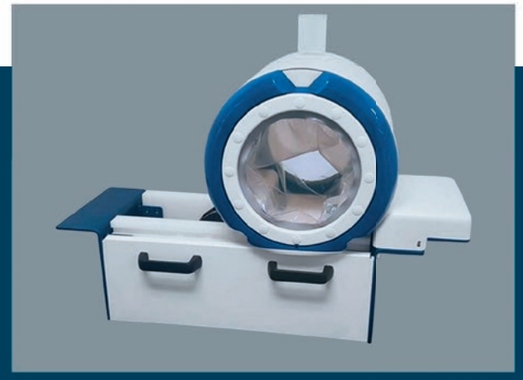


SIGMA EYE AND SIGMA 30 – ADULT EXTREMITIES, CHILDREN

The **Sigma Eye** applicator is the standard for 3D conformal treatments by Pyrexar Medical. It is based on the 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 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.

The **Sigma 30** is a cylinder applicator with a diameter of 30 cm for deep hyperthermia of extremities and small children, with 8 dipole antennas fed in pairs and with a cylindrical water bolus for skin surface cooling and for optimal coupling to the patient. Two-dimensional target zone focusing in the axial plane through control of frequency, phase and amplitude via the operating computer system.

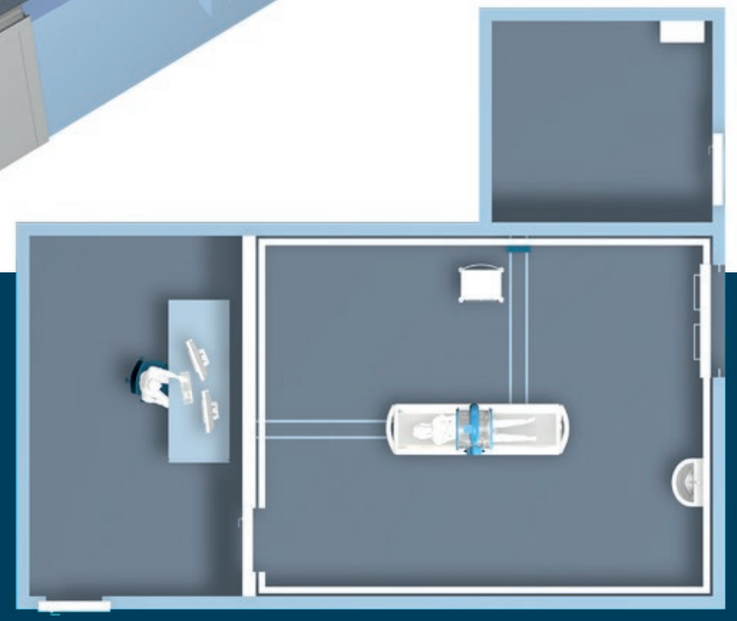


SITE PLANNING

CUSTOMIZED HYPERTHERMIA SUITES (FLOOR SPACE 24-35 m²)

THE IDEAL LAYOUT FOR YOUR GIVEN ENVIRONMENT.

A standard hyperthermia suite consists of the treatment room, the operator room plus a technical room. For convenient patient handling, the treatment room is equipped with electromagnetic shielding and requires floor space of around 24 to 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.



OUR COMPANY

DR. SENNEWALD MEDIZINTECHNIK GMBH

Dr. Sennewald Medizintechnik was founded with the aim of discovering innovative and beneficial cancer therapies and we have since amassed over 30 years of experience in regional and superficial hyperthermia. Our aim is to help improve the range of products on offer, to support the growth of this proven technology and so increase the survival rate among cancer patients.

To help us achieve this goal, we have entered into a long-term partnership with the pioneers and world leaders, Pyrexar Medical, to further develop the manufacture of hyperthermia systems. These high-quality medical devices are designed for maximum efficacy combined with minimum risk for greater patient comfort and are installed in oncology departments, research organizations and leading universities throughout Europe.

Our unrivaled links to the scientific community have led to the acceptance of hyperthermia, the development of dedicated software, reimbursement of hyperthermia and its use in the treatment of children. Strategic partnerships with medical centers have resulted in phase III clinical studies demonstrating that Pyrexar systems offer a significant increase in cancer response rates, and are the only ones to have received FDA approval.

The success of Dr. Sennewald Medizintechnik GmbH is a result of continuity. We are able to draw on our many years of experience for our in-depth knowledge of customers' clinical requirements and of the precise technical specifications for all the hyperthermia systems we offer. In addition, our teams of engineers, technicians and software developers remain as close to customers as possible, offering support in the planning, installation and set-up of the systems, as well as after-sales service.

One example of this is Ludwig-Maximilians University (LMU) of Munich, Germany, which has installed a new image-guided hyperthermia system at Großhadern University Hospital. A pioneer in cancer treatment with hyperthermia, the hospital has carried out over 15,000 patient treatments using this method, many of whom had soft tissue sarcoma tumors.

The facility has been leading a phase III clinical study which illuminated the long-term survival benefits of adding hyperthermia to chemotherapy and LMU was also at the center of the HEAT (Hyperthermia European Adjuvant Trial) study, a randomized, dual-arm trial for pancreatic cancer using chemotherapy plus hyperthermia.

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