Pyrexar MEDICAL

HT SYSTEMS

BSD-2000 3D MRI

hyperthermia with MR image guided thermometry

A decisive breakthrough in oncological hyperthermia

Quality assurance fully under control

Maintaining a target temperature while treating a patient is essential to the quality of hyperthermia as a cancer therapy. Traditionally, temperature probes are placed into the natural orifices of the body near the tumor or invasively directly into the tumor. The additional use of the "thermal mapping" technique - the mechanism of continuous movement of selected probes along the catheter in order to obtain data in the form of a temperature distribution map - provides much more information about the temperature in the tumor and the surrounding healthy tissue.

The breakthrough, however, is the addition of **MRI** as another method of measuring temperature. Now the clinician can obtain detailed, three-dimensional temperature and perfusion information during hyperthermia treatment in almost real time.

Comfort for patient and operator

The operator can control the heating zone in the X, Y and Z axes by using phase and amplitude adjustments on each of the RF channels. Controlling energy and focusing it on the tumor area is both precise and dynamic without the need for corrective changes in patient positioning.

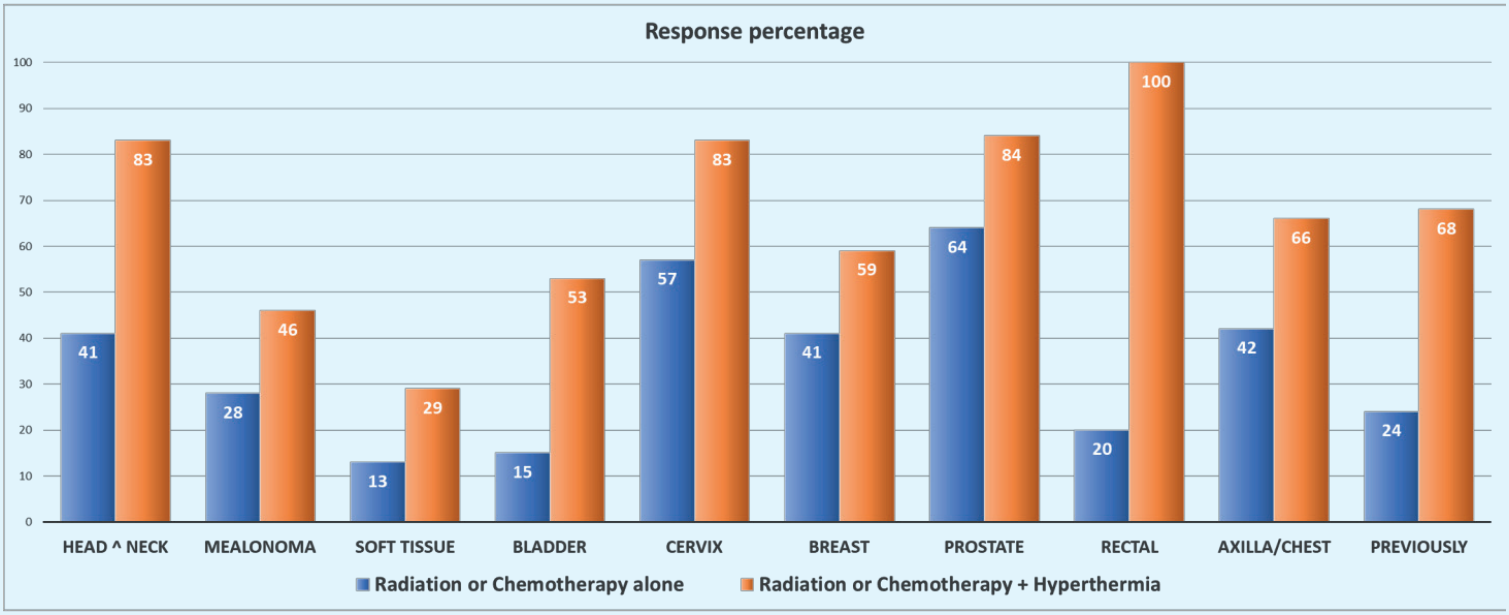
Clinical data are supporting the effectiveness of hyperthermia

Hyperthermia combined with radiotherapy

Hyperthermia increases the effectiveness of radiotherapy both because of its independent cytotoxic effect and its radiation sensitizing effect. Heat increases blood flow and thus the level of tissue oxygenation, which enhances the effect of radiation. The temperature in range of 42-43°C also blocks the natural mechanism of rebuilding DNA damaged by radiation.

Hyperthermia combined with chemotherapy

Hyperthermia increases the effectiveness of chemotherapy by increasing blood flow and perfusion around the tumor. This results in a higher concentration of the drug in the tumor. According to a recently completed phase III clinical trial in 341 patients suffering from sarcoma, the addition of hyperthermia to chemotherapy protocol significantly improved treatment outcomes.



Source: Pyrexar Medical report based on selected clinical trials.

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BSD-2000 3D MRI

The BSD-2000 3D MRI system operates at a constant frequency of 100 MHz, providing local hyperthermia at any depth of the body.

The main components of the BSD-2000 3D MRI systems are:

- Fiber optic thermometry
- Integrated calibration well
- Universal applicator
- External applicator bolus water circulation system
- RF power amplifier
- Therapy planning and control software
- Integration with Magnetic Resonance Systems

Thermistor thermometry system

The use of magnetic resonance for image temperature measurement does not mean resignation from the classic fiber-optic thermometry system used in the BSD-2000 since always.

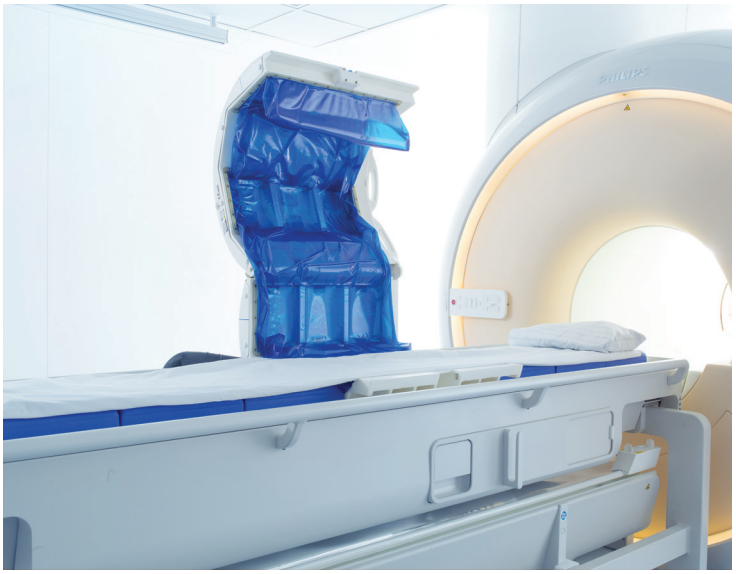
- Ceiling mounting above the treatment table.
- 8 independent, electromagnetically insensitive fiber optic probes with a cross section of only 0.9 mm, suitable for flexible catheters for non-invasive as well as invasive and intracavitary measurements.
- Measurement accuracy ±0.2°C,

- "Thermal mapping" system with the mechanism of continuous movement of selected probes along the catheter in order to obtain data in the form of a temperature distribution map.

Sigma Eye MR applicator

The universal applicator Sigma Eye MR is adapted to the treatment of patients within the overall dimensions covering 95% of the society (according to global averaged data). It is a 12-channel applicator with 24 dipole antennas for radio wave emission in phased array, arranged in three rows of 8 antennas to allow for 3D heating field control.

Unlike other BSD-2000 models, the Sigma Eye MR applicator opens wide, which radically facilitates patient positioning and increases both the operator's comfort and the patient's comfort.
After the applicator is closed, the bolus is filled with water. In addition to the function of regulating the temperature on the skin, the water bolus in the applicator acts as a stabilizer of radio waves in terms of their direction and phase, because the demineralized water is a perfect neutral medium for radio waves.



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Software

Basic – SigmaHyperPlan

- Intuitive and user-friendly graphic interface with touch screen.
- Transparent steps for setting up the treatment procedure.
- Closed feedback system with automatic monitoring and control of parameters during treatment, including power output, amplitude and phase.
- Constant control of tissue temperature according to ESHO guidelines. Temperature data is updated every 2 seconds.
- SECURITY CHECKS - The computer performs automatic security checks. In the event of a system malfunction, the system automatically shuts down to protect the patient and operator.

Enhanced - SigmaVision® Advanced

SigmaVision® Advanced creates a completely new visual concept of hybrid hyperthermia: the combination of hyperthermia with an MRI system provides a non-invasive, three-dimensional temperature measurement in any area of the body and during treatment, leading to optimal therapeutic effects.

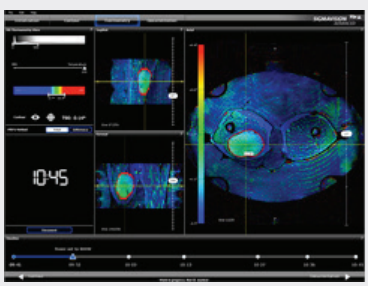
- An intuitive interface supports the user in importing image-acquired patient data

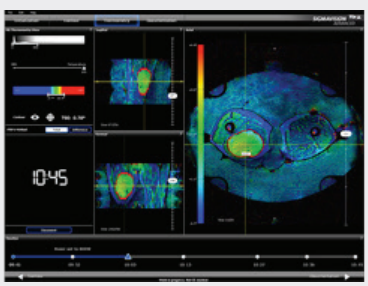
- DICOM input data from the MRI system is automatically recorded and processed by SigmaVision® Advanced. Thanks to three-dimensional images, SigmaVision® Advanced allows you to edit contours in 3D, which translates into the accuracy of planning hyperthermia treatment.

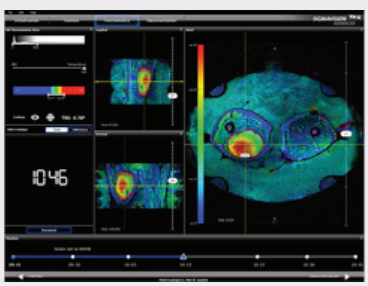
- During the treatment, MRI records at regular intervals a visualization of the axial thermal images, and presents them to the user as computed and color-coded 3D images.

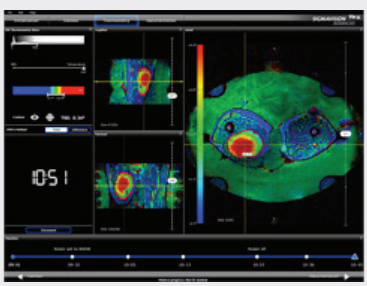
- The gradual changes in temperature in the tumor can be reproduced using a timeline. The user can react to unexpected and unwanted overheating (hot spots) in real time.

SigmaVision® Advanced is a completely new quality in hyperthermia software









Integration with the magnetic resonance system

The BSD-2000 3D MRI Hyperthermia System is designed to work with various 1.5T and 3T magnetic resonance imaging devices.

The basic requirement is that the bore is at least 60 cm. Among the already operating dozens of MRI device models from leading manufacturers, such as Siemens, GE, Philips and Hitachi, fifteen devices with the possibility of integration with BSD-2000 3D MRI have been identified.

A replaceable overlay with a hyperthermia applicator is placed on the MRI treatment table and connected to a panel of connectors mounted near the bore opening. Meanwhile, the MRI device dedicated to hyperthermia fully retains its basic function of diagnostic imaging, at which the overlay with the applicator is removed. The optimal solution for MRI systems with tables in form of mobile carts is to place a secondary cart in the room, which significantly reduces the time needed for a shift.

Other modifications to be taken into account in the adaptation of the room are the suspension of the thermometry system above the table, placing the wiring in the floor and connecting the connector panel.

Integration of the BSD-2000 3D MRI in the MRI lab does not require additional shielding, because the existing one is completely sufficient for radio waves emitted by the hyperthermia antennas.

BSD-2000 DEEP PHASED ARRAY

MOST RELEVANT DIFFERENCES BETWEEN BSD-2000 MODELS

	BSD-2000 2D	BSD-2000 3D	BSD-2000 3D MRI
RF Generator	Tetra	Dodek	Dodek
# of RF Channels	4	12	12
Directional Heat Zone Steering	2 axis (X & Y)	3 axis (X, Y & Z)	3 axis (X, Y & Z)
Frequency (MHz)	75 to 120 MHz	75 to 120 MHz	100 MHz
# of Antennas	8	8 lub 24	24
Maximum Power	1300 W	1800 W	1800 W
Max. Channel Power	325 W	450 W (4 channel) or 135 W (12 channel)	135 W
Forward Pwr & Phase Control	✓	✓	✓
MRI Compatible	✗	✗	✓
Computer Console	included	included	included
Sigma 30 applicator (30cm, 8 ant.)	✓	✓	✗
Sigma 60 applicator (60cm, 8 ant.)	✓	✓	✗
Sigma Ellipse applicator (8 ant.)	✓	✗	✗
Sigma Eye applicator (24 ant.)	✗	✓	✗
Sigma 30MR applicator (24 ant.)	✗	✗	✓
Sigma Eye MR applicator (24 ant.)	✗	✗	✓
Water Heating/Cooling System	Built-in	Built-in	External
Non-invasive thermometry	✗	✗	✓
Integral Deionizer of Water	✓	✓	✗
Room Shielding Required	✓	✓	Uses Existing MRI Shielding

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