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# INTERSTITIAL HYPERTHERMIA AND BRACHYTHERAPY

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## HYPERTHERMIA & BRACHYTHERAPY

### WHAT IS HYPERTHERMIA?

Hyperthermia – heating the tumor to 42.5 °C – combined with radiation and/or chemotherapy is a proven treatment for malignant tumors. Randomized clinical trials have shown improved disease-free survival and local tumor control without an increase in toxicity for the combined treatment.

### WHAT IS INTERSTITIAL HYPERTHERMIA?

Interstitial hyperthermia delivers the heat directly at the site of the tumor. Its delivery is compatible with brachytherapy. A combination of both modalities is therefore easy to deliver and effective for the treatment of malignant tumors.

Interstitial hyperthermia uses up to 24 small microwave antennas (1.2 mm in diameter) placed in the tumor volume. Temperature sensors (up to 8) of the same diameter measure the temperatures for treatment control.

### HYPERTHERMIA AND BRACHYTHERAPY

The combination of hyperthermia and HDR-brachytherapy increases the treatment results of HDR-brachytherapy alone.

The BSD-500 hyperthermia system is ideally suited for combined use with a brachytherapy system. Interstitial antennas fit neatly into brachytherapy catheters. The operator simply inserts antennas and heats the tumor after or before afterloading.

HDR-brachytherapy isodose calculations are easily imported into the hyperthermia planning system.

## HYPERTHERMIA CLINICAL STUDIES

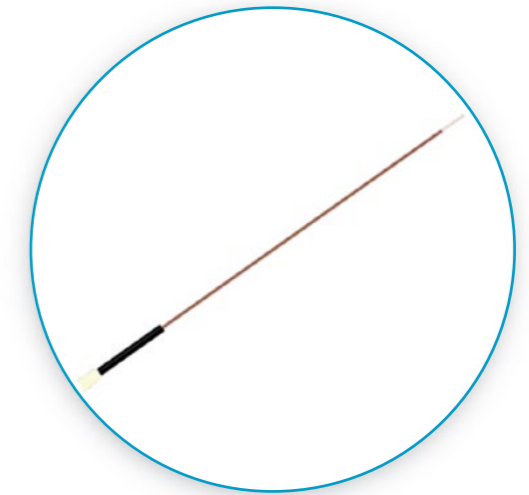
### BENEFITS OF HYPERTHERMIA

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

# BSD-500 BY PYREXAR MEDICAL

# FEATURES



## MA-251 MICROWAVE INTERSTITIAL ANTENNA

The semi-rigid MA-251 microwave interstitial applicators can be inserted into 15.5-gauge (5 French) radiation implant catheters. The heating pattern is ellipsoidal and approximately 4.5 cm in length along the applicator shaft with heating to the applicator tip.

## BRACHYTHERAPY



## BRACHYTHERAPY TREATMENT SUPPORT

Interstitial hyperthermia delivers heat directly to the site of the tumor via brachytherapy catheter. The microwave power delivered to the antennas (available as an optional kit) can be adjusted in amplitude and phase to conform the heating pattern to the tumor.

## VERSATILITY

# TREATMENT PLANNING

# INTERSTITIAL HYPERTHERMIA

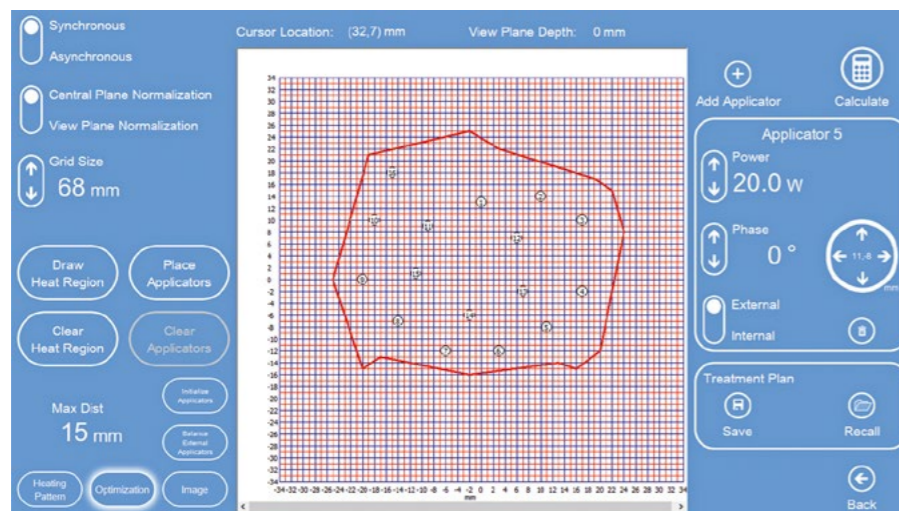
## APPLICATOR POSITIONING AND ENERGY CALCULATION

Performing interstitial hyperthermia requires the use for the BSD-500 built-in treatment planning program. Using this software, the size and shape of the tumor can be traced on a grid on the computer's screen. Treatment plans can then be made by simulating the placement of antennae in and around the tumor.

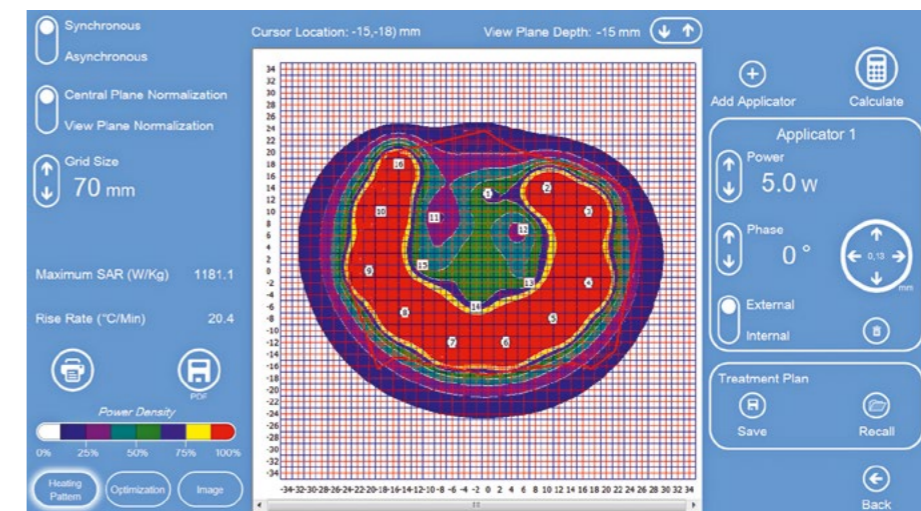
## ADJUSTMENTS AND TRANSFERS

The power and phase of each channel can be set and adjusted on the screen. Each change in placement, power or phase will display the new simulated heating pattern.

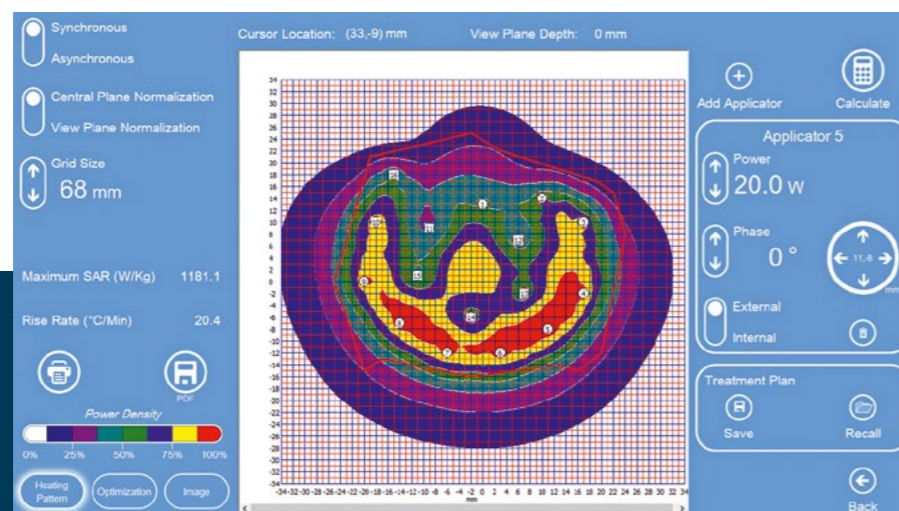
### 1. TRACE TUMOR AND POSITION APPLICATORS



### 3. ADJUST PHASE AND POWER TO ACHIEVE DESIRED HEATING PATTERN



### 2. CALCULATE ENERGY DISTRIBUTION PATTERN



### 4. TRANSFER SETTINGS TO HYPERTHERMIA TREATMENT SCREEN



## FULL COMPLIANCE

### QUALITY ASSURANCE

In keeping with the quality assurance requirements for optimized treatment, all of the Pyrexar hyperthermia systems not only have CE approval, but also comply with the guidelines of the German Society for Radiation Oncology (DEGRO) and the European Society for Hyperthermic Oncology (ESHO).

### DR. OLIVER OTT, RADIATION THERAPY CLINIC, UNIVERSITY OF ERLANGEN

“Only the tumor cells actually heated can respond more sensitively to the radiation treatment or chemotherapy. For this reason, quality assurance, especially measurement of the temperatures in the tumor region and in normal tissue, is an indispensable aspect of hyperthermia treatment.”

## AT A GLANCE

### PYREXAR BSD-500

- ▶ 8 channels, each 60 watts
- ▶ Up to 24 channels by a 3-way power splitter, e.g. for interstitial hyperthermia
- ▶ Large range of applicators
- ▶ Individual temperature distribution and continuous monitoring (Bowmann sensors)
- ▶ Leading supplier of hyperthermia systems for over 30 years
- ▶ As used in clinical studies (cervix, bladder, rectum, head & neck)
- ▶ Experienced service team

### NEW AND IN THE PIPELINE

- ▶ Improved calibration of temperature probes (dry well)
- ▶ Operating noise reduced to below 65 dB (A)
- ▶ DICOM integration and connection to PACS
- ▶ 61 cm medical-grade touchscreen
- ▶ New GUI with user administration and more secure user log-in based on Windows 10

## SYSTEM OVERVIEW (PART 1)

The BSD-500 interstitial microwave hyperthermia system is equipped with a 915 MHz power generator. The solid state generator has 8 channels (BSD 500-8i) which can be independently adjusted in phase and amplitude. The 8 channel generator feeds into a 3-way power splitter. Therefore, up to 24 applicators can be connected.

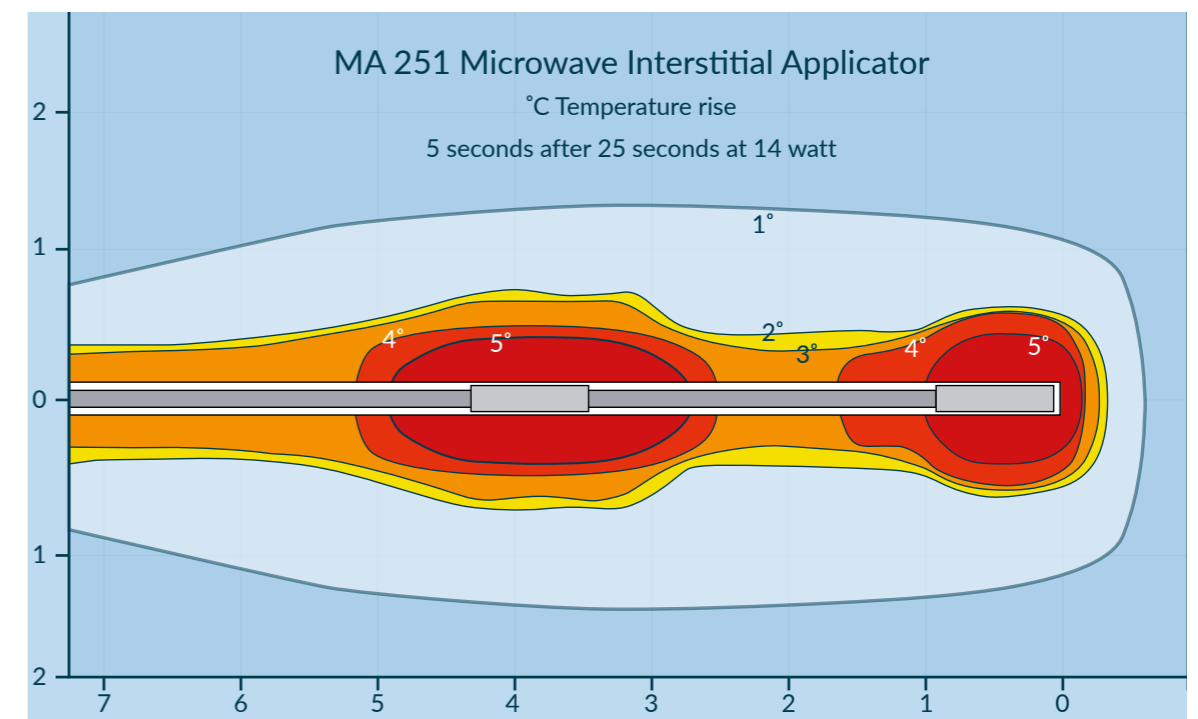
### SOLID STATE MICROWAVE POWER GENERATOR

- ▶ Output frequency of  $915 \pm 1.3$  MHz (ISM frequency, requires no RF shielded enclosure)
- ▶ 8 independent channels of 0 to 60 watts
- ▶ Forward and reflected powers of all 8 channels are monitored, controlled and displayed by the computer
- ▶ All 8 channels are driven by a single power signal. The power balance of the channel is software controlled using the touch screen monitor
- ▶ Can be switched to a single output of 0 to 400 watts under computer control. The 8 signals representing forward power are summed and displayed as total power

### ADVANCED MICROWAVE INTERSTITIAL SYSTEM

- ▶ 24 MA-251 semi-rigid interstitial applicators to be inserted into 15.5-gauge (1.2 mm I.D.) closed tip or 15.5-gauge radiation implant catheters. Heating pattern is ellipsoidal and approximately 4.5 cm in length along the applicator shaft, with heating to the applicator tip
- ▶ Different heating patterns can be created by using symmetrical synchronous arrays of up to 24 applicators, with independent control of up to 8 channels split 3 ways

- ▶ Applicator length is 30 cm with a 92 cm extension cable that allows clinical flexibility in patient positioning
- ▶ Applicator diameter is 1.2 mm; typical of a 15.5-gauge closed end catheter commonly used in radiation implants



## SYSTEM OVERVIEW (PART 2)

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### TEMPERATURE PROBES

- ▶ Four probes are provided with the basic system, but the probe interface can accept up to 8 probes
- ▶ A typical treatment set-up would utilize 12 to 15 ports for the microwave interstitial applicators and 1 to 4 ports for connections to the temperature probes
- ▶ Temperatures are displayed to an accuracy of  $\pm 0.1$  °C
- ▶ Inherently stable thermistor type probes with non-metallic leads. Quick calibration method built into the system
- ▶ Non-perturbed by microwave fields
- ▶ The sensor diameter is approximately 1.1 mm and is located at the end of a 33 cm sealed high resistive lead
- ▶ Length approximately 2.1 m
- ▶ Leakage currents guaranteed to be less than 15 micro amps for any type of failure

### OPERATING SYSTEM SOFTWARE

- ▶ Windows 10 operating system
- ▶ Hyperthermia treatment procedures
- ▶ Treatment recall
- ▶ Temperature monitoring procedures
- ▶ User and diagnostic programs
- ▶ Automatic calculation of real time thermal dose
- ▶ Interstitial pre-treatment planning

### COMPUTER SYSTEM

- ▶ 61 cm color touchscreen medical panel PC
- ▶ Fanless, i5 processor, 4 GB RAM, 500 GB HDD
- ▶ Internal battery
- ▶ Audible alert capability
- ▶ Waterproof keyboard and mouse

### SYSTEM CALIBRATION AND COOLING MODULE

- ▶ Integrated thermal well
- ▶ Standard NBS traceable temperature probe, accurate within 0.10 °C
- ▶ Constant volume water supply
- ▶ Bolus temperature controller with a temperature range of 5 °C to 45 °C

### EQUIPMENT RACK

- ▶ Free standing and mobile on swivel-locking casters
- ▶ Operator station and component support arm are mounted on top of the equipment rack
- ▶ Equipment size is 60 x 60 x 90 cm to table top. Approximately 150 cm to top of the monitor

### POWER REQUIREMENTS

- ▶ 115 – 230 VAC  $\pm 10\%$
- ▶ 50 – 60 Hz
- ▶ Current consumption < 15 amps

## DR. SENNEWALD MEDIZINTECHNIK GMBH

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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 is 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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