Pyrexar MEDICAL

BSD-500 - Superficial/Interstitial Hyperthermia System

915 MHz Eight-Channel Power Amplifier

Multi-channel solid-state amplifier producing an available 480 Watts maximum RF power with independently adjustable phase and amplitude.

24" Medical Grade Touch Screen Monitor

High-resolution monitor providing easy access to user control systems for improved patient monitoring and system control.

Interchangeable Superficial Applicators

Applicators are available in multiple configurations to treat a range of tumor sizes and locations. The base model includes the MA-100 waveguide, as shown.

5-Point Pneumatic Applicator Arm

Provides rock-steady placement of Hyperthermia applicators at any angle with a total reach of 41".

Brachytherapy Treatment Support

Interstitial hyperthermia delivers heat directly to the site of the tumor via brachytherapy catheters. 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.

8-port Temperature Monitoring

Track up to 8 independent temperature probes for accurate thermal dosing. An integrated temperature well ensures easy and precise temperature calibration.

Water Circulation System

Provides constant volume water supply to the Applicator Bolus with a temperature range of 5°C to 45°C.

ASSEMBLED IN THE USA · EU-MDR · Product is CE Marked · ISO 13485:2016 CERTIFICATION intertek · TÜV · RoHS COMPLIANT

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What are you doing for your recurrent Cancer patients?

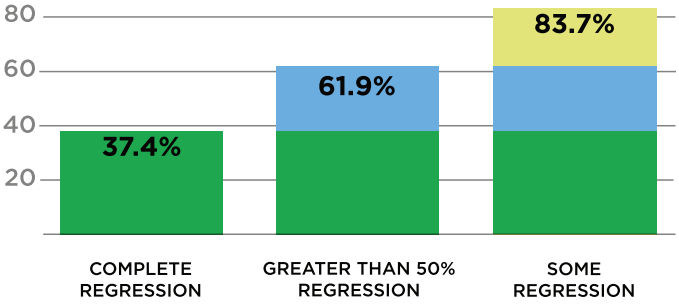
BSD-500

- Portable, No shielding room needed.
- Indications include Melanoma, Cancers of the Head and Neck, Soft Tissue Sarcomas, Breast Cancer (including Recurrent Chest Wall tumors), and Prostate Cancer.
- FDA PMA for palliative treatment of certain tumors
- Delivers both superficial and interstitial hyperthermia

Hyperthermia is a therapy used to heat tumors. Research has shown that heat can damage cancer cells while also increasing radiation therapy's effectiveness in treating recurrent or progressive tumors.

While it has been known for hundreds of years that fevers attack disease, only recently has technology existed to control and focus heat specifically on cancer tumors. As a result, hyperthermia treatments are typically given in Radiation Oncology departments between one to three times a week, either before or after radiation therapy. Each treatment session lasts approximately one hour.

Hyperthermia in conjunction with radiotherapy



Indications for Use

The BSD-500 is indicated for use alone or in conjunction with radiation therapy in the palliative management of certain solid surface or subsurface malignant tumors (i.e., melanoma, squamous or basal cell carcinoma, adenocarcinoma, or sarcoma) that are progressive or recurrent despite conventional therapy. A complete list of indications for use and description of all adverse effects are included in the appendix.

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Phase II/III Clinical Studies have demonstrated that using hyperthermia is both safe and effective. In addition, hyperthermia increases the complete, partial, and objective tumor response compared to radiotherapy alone.

The primary types of tumors included in this study were recurrent chest wall, recurrent head and neck, recurrent melanoma, and recurrent sarcoma.

Although hyperthermia has the potential for producing a variety of adverse effects, those regularly observed during clinical studies have been limited to the direct impact of heating upon tissue . Reported toxicity is generally low and treatable and any adverse effects are generally outweighed the outcomes

Hyperthermia and Brachytherapy

The BSD-500 hyperthermia system can be used for combined therapy with a brachytherapy system. Interstitial antennas fit into certain brachytherapy catheters. The operator inserts antennas to heat the tumor before or after the afterloading process (usually within 30 minutes before or after the treatment). A typical heat treatment might achieve an intratumoral temperature of 42.5°c, sustained for 60 minutes or equivalent.

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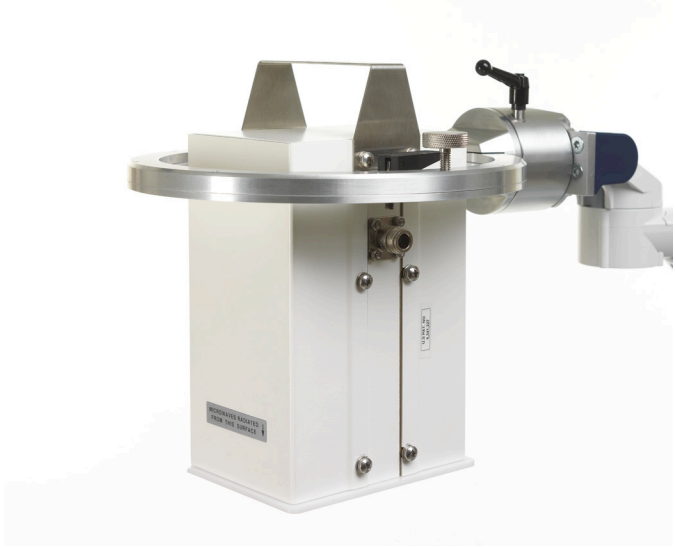
Superficial Applicators

Applicator Type	Model Number	Recommended Freq (MHz)	Typical Power(W)
Side-loaded waveguide	MA-100	915	100
Mini dual-ridge waveguide	MA-151	915	40
Side-loaded waveguide	MA-120	915	250

MA-151: mini-dual ridge waveguide applicators have an aperture of 4 x 5 cm and individual heating patterns approximately 2.5 x 2.5 cm by 2 cm deep. Advanced annular phased array principles create a central focusing of energy, which significantly overcomes the penetration losses of the energy radiated into the body.



MA-100: side loaded waveguide applicators have a 10 x 13 cm aperture and a heating pattern approximately 8 x 10 cm by 2.5 cm deep.

MA-120: side-loaded waveguide applicator has an 18 x 24 cm aperture and a heating pattern of approximately 12.5 x 19.5 cm by 2.5 cm deep.

Interstitial Applicators

Applicator Type	Model Number	Recommended Freq (MHz)	Typical Power(W)
Interstitial antenna	MA-251	915	10
Temperature sensor	TP-100		

MA-251: Semi-rigid microwave interstitial applicator 1.2 mm diameter x 33cm length

Interstitial Applicators

The semi-rigid MA-251 microwave interstitial applicators are 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.

Different heating patterns can be achieved using arrays of up to 24 applicators with eight independent microwave power channels. In addition, asynchronous and electronically controlled synchronous phase modes are provided.

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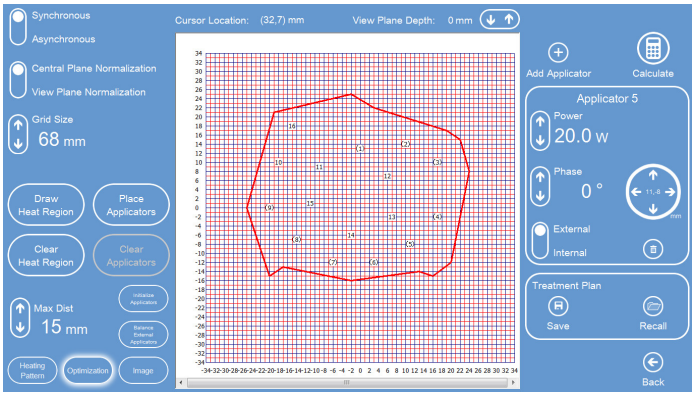
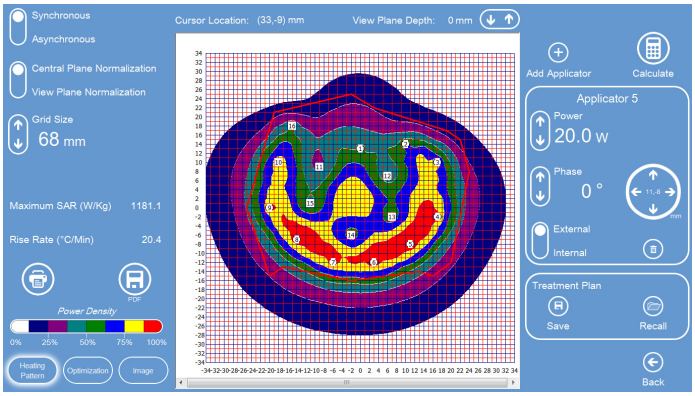
Treatment Planning Software

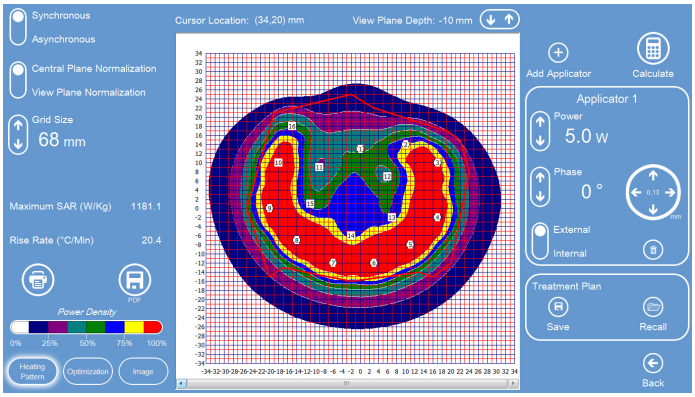
Performing interstitial hyperthermia requires the use of the BSD-500 built-in treatment planning program. The size and shape of the tumor is traced on a grid on the computer screen. Treatment plans can then be made by simulating the placement of antennae in and around the tumor. The power and phase of each channel can be set and adjusted on the screen. Each change in placement, power, or phase will display the new simulated heating pattern.



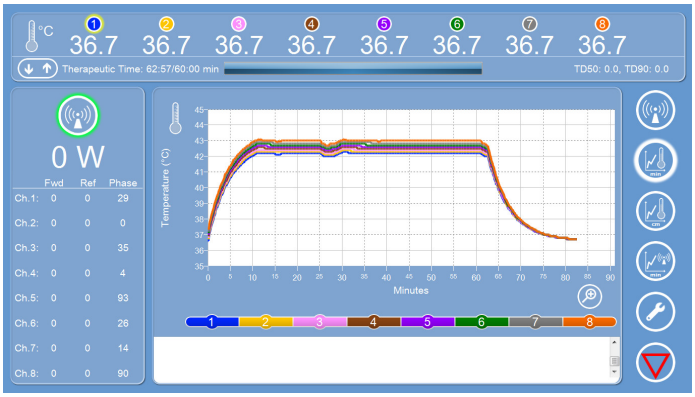
Trace tumor and position applicators



Calculate energy distribution pattern



Adjust phase and power to achieve desired heating pattern



Monitor temperature throughout treatment

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Indications and Use of the BSD-500 Hyperthermia System

The BSD-500 Hyperthermia System delivers therapeutic heat (hyperthermia) to specifc surface or subsurface malignant tumors (i.e., melanoma, squamous or basal cell carcinoma, adenocarcinoma, or sarcoma) by the external or interstitial application of electromagnetic energy and monitors the temperature of the target and surrounding tissues employing temperature probes. In response to an operator-designated control probe, the BSD-500 Hyperthermia System automatically adjusts power to maintain the operator-set therapeutic temperature, typically is 42-44°C. The BSD-500 Hyperthermia System also automatically limits power to prevent any detected temperature exceeding the operator-set maximum.

Tissue absorption of electromagnetic energy causes heating by molecular excitation. Living tissue dissipates accumulated thermal energy principally through transport by blood perfusing the tissue. Solid malignant tumors of significant size have less blood perfusion than surrounding normal tissue. The reduced ability to dissipate heat causes tumor tissue to reach higher temperatures than normal tissue for a given absorbed thermal dose. Therefore, absorbed electromagnetic radiation will preferentially heat tumors present in normal tissue and cause them to reach higher temperatures than the normal surrounding tissue. Tumors repeatedly heated to higher temperatures (hyperthermia) for times approaching an hour sometimes exhibit regression and necrosis [Song, C.W., "Physiological Factors in Hyperthermia of Tumors" in Physical Aspects of Hyperthermia, G.H. Nussbaum, ed. American Institute of Physics (American Association of Physicists in Medicine, Medical Physics Monograph No. 8). New York, NY: 1982, p.43].

The BSD-500 Hyperthermia System consists of the following components:

(1) A set of microwave applicators for local therapy, as listed in the following table, where "MHz: signifies Megahertz and :W" signifies Watts:

Applicator Type	Model Number	Recommended Freq (MHz)	Typical Power(W)
Side-loaded waveguide	MA-100	915	100
Mini dual-ridge waveguide	MA-151	915	40
Flexible interstitial coaxial	MA-251	915	10
Side-loaded waveguide	MA-120	915	250

(2) A set of non-perturbing, electromagnetically insensitive temperature probes.

(3) An operator console containing computer controls to obtain and display data from the temperature probes and to condition the power output of the applicators, and means to display and record relevant patient treatment parameters.

(4) Various accessories, including a coupling and cooling water bolus system, a radiation leakage monitor, and various patient equipment.

INDICATIONS FOR USE

The BSD-500 Hyperthermia System is indicated for use alone or in conjunction with radiation therapy in the palliative management of certain solid surface and subsurface malignant tumors (i.e., melanoma, squamous or basal cell carcinoma, adenocarcinoma, or sarcoma) that are progressive or recurrent despite conventional therapy.

PROCEDURE FOR ADMINISTRATION OF HYPERTHERMIA IN CONJUNCTION WITH IONIZING RADIATION THERAPY

The standard therapy regimen for hyperthermia in conjunction with ionizing radiation therapy is a total of 10 hyperthermia treatments delivered two times per week at 72-hour intervals, with each heat treatment preceded or followed by a standard prescribed dose of ionizing radiation within 30 minutes of the heat treatment. During each heat treatment, an intratumoral temperature of 42.5°C sustained for 60 minutes, or the equivalent thereof, the entire course of treatment is 600, expressed in Thermal Equivalent Minutes (TEM) equal to 42.5°C, as calculated during treatment by the BSD-500 Hyperthermia System.

Because the patient's ability to detect pain is an essential safety mechanism, hyperthermia is contraindicated in patients whose pain response has been significantly decreased by any means (previous surgery or ionizing radiation therapy, regional or general anesthetic, or other condition).

Since excessive heating of normal tissue is prevented by normal blood perfusion, it is imperative that adequate circulation be present and maintained in all tissues within the heating field. Treatment with the BSD-500 Hyperthermia System is contraindicated in patients having a known decrease in circulation in the heated area produced by any means (i.e., vasoconstrictive drugs, DIC, ischemia, or other cause).

Because electromagnetic radiation from the applicators of the BSD-500 Hyperthermia System may interfere with the operation of an electronic device, hyperthermia treatments are contraindicated in patients with cardiac pacemakers.

RESTRICTIONS

The sale, distribution, and use of the BSD-500 Hyperthermia System are restricted to prescription use.

The BSD-500 Hyperthermia System is to be used only by qualified operators upon the prescription and under the supervision of a physician who is experienced in clinical hyperthermia.

WARNINGS

Hyperthermia treatment can be safely and effectively administered only after careful placement of temperature probes as described in the Reference Manual and with alert monitoring of tissue temperatures during treatment.

Hyperthermia treatment presents a potential safety hazard in patients whose pain response has been decreased because of disease, previous surgery, ionizing radiation therapy, chemotherapy, or general or regional anesthesia.

The electromagnetic energy from microwave applicators may interfere with the operation of the cardiac pacemakers or other implanted electronic devices.

Large thermal doses (a continued elevation of moderately high temperature or a short extreme elevation of temperature) in normal tissues situated in the vicinity of the treated tumor or between the tumor and the body surface may result in regions of thermal aseptic necrosis that require medical intervention and that may not be apparent on inspection of the skin.

Treatment of tumors located in the neck and head may cause inadvertent heating of thermoregulatory centers located in the brain stem and induce general thermoregulatory response exceeding the patient's compensatory capabilities.

PRECAUTIONS

Adhere to recommended procedures for temperature probe placement and selection of control probe to minimize the probability of excessive temperature in normal tissue or of inadequate temperature in the tumor.

Observe strict adherence to aseptic techniques during the placement of catheters to avoid localized infections, and instruct patients in the daily care of indwelling catheters and probe sites to prevent sepsis.

To ensure accurate temperature monitoring during treatments, verify calibration of temperature probes daily or as used.

Adhere to recommended applicator placement and bolusing practices to reduce the likelihood of surface burns and blistering from the subsequent delivery of therapeutic heat.

In patients with severely compromised pain response, monitor closely other physiological indicators of excessive heat delivery.

Monitor closely patients with metallic implants (joint prostheses, dental braces, etc.) during treatment because such metal objects may be excessively (and preferentially) heated.

ADVERSE REACTIONS

SIDE EFFECTS Although hyperthermia has the potential for producing a variety of adverse effects, those observed have been limited to direct impacts of heating upon tissue and indirect effects related to tumor necrosis. Statistical analysis of clinical data obtained in Pyrexar Medical's studies has provided the following approximate figures for hyperthermia in general:

Burns. Patients have experienced in 9.7% of tumor sites studied surface burns and blistering in the area of the delivery of therapeutic heat by local microwave applicators of the BSD-500 Hyperthermia System. Adherence to recommended applicator placement techniques and bolusing practices greatly reduces the number of incidents.

Pain. Patients have experienced, in 8.4% of tumor sites studied, localized and temporary pain in the area of, and during delivery of, therapeutic heat by local microwave applicators of the BSD-500 Hyperthermia System. The use of surface cooling techniques can diminish this pain.

Ulceration. Patients have experienced, in 3.6% of tumor sites studied, ulceration from rapid tumor necrosis following successful hyperthermia treatment with the BSD-500 Hyperthermia System. Such ulceration may produce both fever, through toxemia, and patient discomfort through drainage and bleeding. Infection. Patients have experienced, in 1.8% of tumor sites studied, local and systematic infections resulting from the placement of the temperature probes of the BSD-500 Hyperthermia System and from the ulceration related to rapid tumor necrosis. These infections have generally been local.

POTENTIAL ADVERSE HEALTH EFFECTS OF THE DEVICE

Hyperthermia has the potential for producing the conditions listed below, as a result of the delivery of therapeutic heat or exposure to electromagnetic radiation. However, none of these adverse reactions was observed during the clinical investigation of local hyperthermia.

Cataracts. Inadvertent heating of the eye may occur during the treatment of tumors in the head or neck. A single high dose of microwave radiation or repeated exposure over a long period may result in cataract formation, which may not be observable for several weeks. [Clearly, S. F., "Microwave Cataractogenesis" in Proceedings of the IEEE 68: 4955.]

Male Sterility. A single high dose of microwave radiation to the testes, or testicular heating for a prolonged period of time, may result in temporary or permanent sterility. [Murca, G.J., E.S. Ferris. and F.L. Buchta. " A Study of Microwave Radiation of the Rat Testis" in Biological Effects of Electromagnetic Waves, C.C. Johnson and M. L. Shore, eds. HEW Publ. (FDA 77-8010). Washington, D.C. 1976, pp. 484-494.]

Exacerbation of pre-existing disease. Patients having borderline cardiopulmonary function secondary to coronary atherosclerosis, emphysema, or other conditions, may not be able to tolerate the additional systematic stress of extensive or prolonged hyperthermia.

Enhanced drug activity. Elevated temperatures may be expected to affect the pharmacologic activity of some drugs, with unpredictable results. Altered vascular perfusion may dramatically affect the local tissue effects of systemic or infused drugs.

Thermal Stress. Significantly increasing the core temperature of the body or overheating the thermoregulatory center in the brain may result in thermal stress exceeding the patient's compensatory mechanisms. Reliable prediction of the consequences of thermal stress in patients with cardiovascular impairment is not possible. Signs of consequences of thermal shock or local brain overheating may appear after several (up to 24) hours.

REFERENCES

1. Song, C. W., "Physiological Factors in Hyperthermia of Tumors" in Physical Aspects of Hyperthermia, G. H. Nussbaum, ed. American Institute of Physics (American Association of Physicists in Medicine. Medical Physics Monograph No. 8), New York, NY:

2. Clearly, S. F., "Microwave Cataractogenesis" in Proceedings of the IEEE 68: 4955.

3. Murca, G.J. E.S. Ferris, and F.L Buchta, "A Study of Microwave Radiation of the Rat Testis" in Biological Effects of Electromagnetic Waves, C.C. Johnson and M.L. Shore, eds. HEW P ubl. (FDA 77-8010). Washington. DC, 1976, pp. 484-494.