Pyrexar MEDICAL

HT SYSTEMS

BSD-2000 2D
BSD-2000 3D

Deep tissue local hyperthermia

Hyperthermia as another weapon in the fight against cancer

What is hyperthermia?

Hyperthermia used in oncology consists in heating the tumor tissue up to the temperature of 38-43°C.
Increased temperatures acts on different levels:
• on the one hand, it has cytotoxic properties in itself, as it adversely affects the metabolism of neoplastic cells, which partially undergo apoptosis in the highest temperature ranges. Healthy cells show much greater tolerance to elevated temperature and remain intact;

• on the other hand hyperthermia, by stimulating circulation in the tumor area, increasing oxygen supply, and the homologous recombination pathway (HRR) inhibitor effect (HRR) has a chemo- and radiotherapy sensitizing function, thereby increasing the efficacy of these standard oncology therapies;

• an additional beneficial effect is the stimulation of a number of immunological processes in which heat shock proteins play a key role.

A treatment combined with radiotherapy and chemotherapy

Achieving a sensitization effect is possible by the use of one of the many existing treatment protocols in which hyperthermia is performed at specified intervals. In combination with chemotherapy, the most common hyperthermia procedure is performed up to 48 hours after the administration of the cytostatics. On the other hand, combining hyperthermia with radical radiotherapy usually involves performing from 1 to 3 hyperthermia treatments per week parallel to the radiotherapy program, always at an interval of at least Two days.

Indications to deep tissue HT

Most of the malignant neoplastic lesions located deep in the body, with particular emphasis on the following diseases:
• gynecological tumors
• tumors in the pelvic area
• pancreas cancer
• liver cancer
• germinal tumors in children and adolescents
• soft tissue sarcomas

Phased array radio frequency

BSD-2000 devices emit directional phased array radio waves (RF) in the frequency range from 75 to 140 MHz. Dipole antennas, two for each channel, are arranged in pairs symmetrically around the circumference of the annular applicator, inside which the patient is placed. Power, phase and frequency control enables precise delivery of energy to the target area of heating.
The main advantage of this technology is its ability to deliver energy to tissues at any depth in the patient's body.

www.pyrexar.pl

Pyrexar MEDICAL

Hyperthermia systems BSD-2000

System description

Each of the BSD-2000 devices consists of the following components:

- RF power amplifier
- Proprietary, thermistor-based, thermometry subsystems
- Patient support system „Sigma Base"
- Computer system for treatment planning & control
- Set of applicators
- Various accessories, including a tissue equivalent QA lamp phantom that provides verification of the energy focus, pattern steering, and system operations.

Amplifier

- Depending on model, 4 or 12 RF channels
- Phase accuracy within a 10° tolerance
- Computer automatically monitors and controls forward and reflected power, phase, and power on each channel
- Solid-state construction made in USA

Thermometry Subsystem

- Ceiling mount above the treatment unit
- 8 independent and electromagnetically insensitive temperature sensors with only 0.9 mm thickness, passing to the flexible catheters for non-invasive, invasive and intracavitary temperature measurement.
- Accuracy of ±0.2°C
- „Thermal mapping" systems with a mechanism of continuous movement of selected probes along the catheter in order to obtain data in the form of a temperature distribution map

Computer Control System

User friendly, intuitive, color graphics interface with a touch screen

Step-by-step guide for setup and treatment procedure

Closed -loop feedback system provides automatic monitoring and control of treatment parameters, including power output, frequency, amplitude and phase, tissue temperatures, core temperature, and treatment time

Steady monitoring of tissue temperature of tissue according to the ESHO guidelines. Data regarding temperatures, RF power level, and RF power control updated every 2 seconds.

SAFETY CONTROL – The computer automatically performs numerous safety checks to ensure proper operation of the system and ensure safety for the patient and the operator.

Sigma base

The patient support system Sigma Base is basically the same for BSD-2000 2D and 3D. Sigma Base supports the patient and the applicator. The patient lays on a sling stretched on two fiberglass beams, which are connected to a hydraulic elevator, allowing for precise positioning in the vertical axis.

The applicator is placed over the tumor area and connected to the RF power supply and the water conditioning system.

The water conditioning system installed in the treatment unit keeps the water in the bolus of the applicator at the desired temperature throughout the treatment, and its design allows for instant discharge of water: patient release takes up to 15 seconds and complete emptying of the bolus within 30 seconds.

Applicator

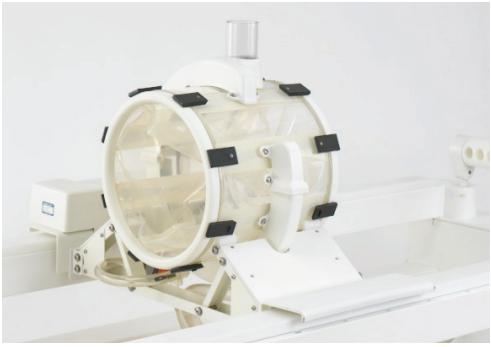
Sigma applicators have the form of rings, more or less cylindrical and consist of a composite housing, a subsystem of radio-emitting antennas and a water bolus.

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, be cause the demineralized water filling it is a neutral medium for radio waves.

The dipole antennas are arranged symmetrically on the circumference of the applicator, eight antennas in one ring.

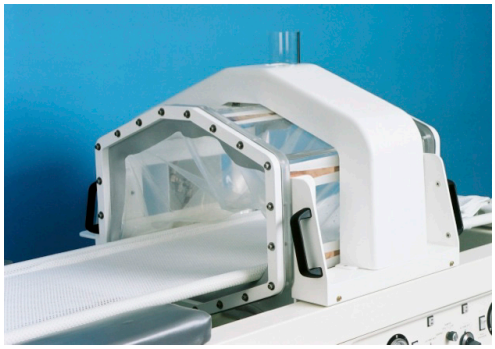
The BSD-2000 2D uses the 8 antennas applicators Sigma 30, Sigma Ellipse oraz Sigma 60.

Sigma 30

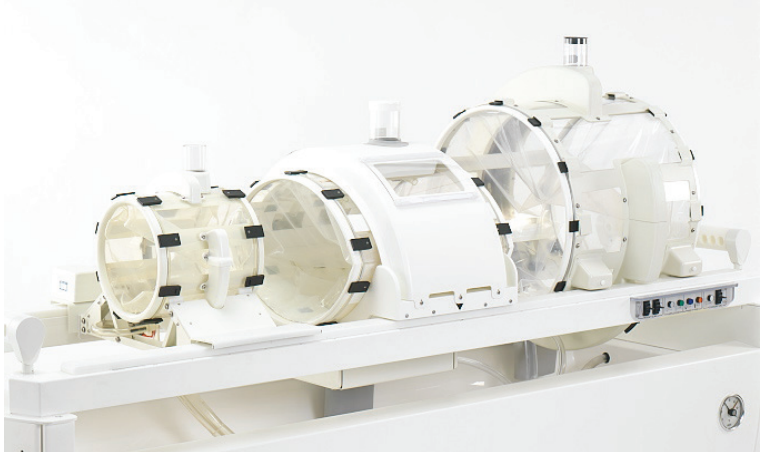


# of antennas	8
shape	circular
application	limbs or child (Ø 30 cm)

Sigma Ellipse



# of antennas	8
shape	octagonal
application	standard patient



Sigma 60

# of antennas	8
shape	circular
application	patients XXL (Ø 60 cm)

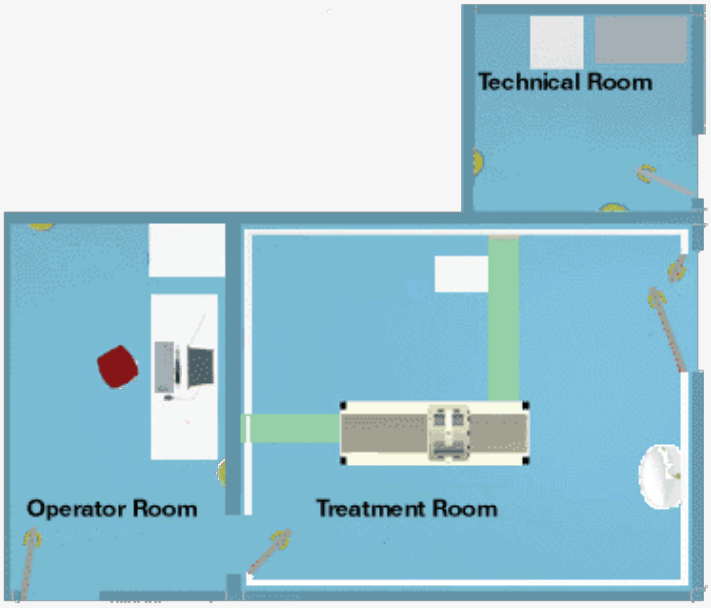
Sigma Eye

The BSD-2000 3D uses additionally a specially designed Sigma Eye applicator, which is equipped with three antenna rings, which gives a total of 24 antennas and allows you to plan the procedure in 3D

# of antennas	24
shape	oval
application	standard patient

Site planning’

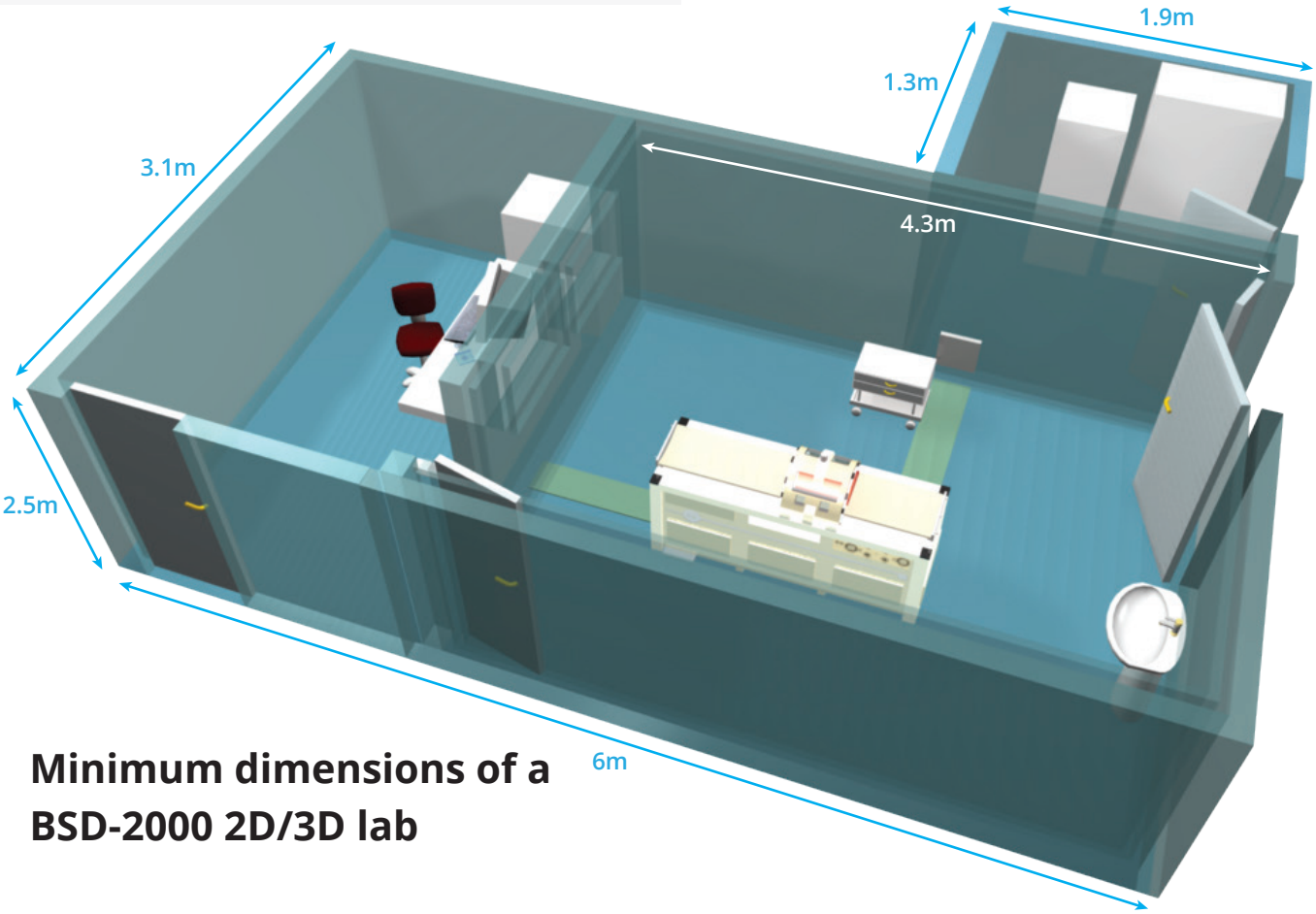
BSD-2000 devices require shielding (the so-called "Faraday cage") due to international regulations on radio frequency. The standard BSD-2000 hyperthermia laboratory consists of a shielded treatment room and non-shielded rooms for the operator and for the RF amplifier, which must be air-conditioned.



In addition to the classic permanently built Faraday cages, there are also light and modular constructions made of perforated sheet panels:

Shielding type „PSB”. Details on: www.istracorp.com.

HT Systems specialists will be happy to help you find the optimal technical and financial solution for each interested facility.



Minimum dimensions of a BSD-2000 2D/3D lab

Clinical study results - overview

The last two decades have resulted in numerous clinical studies confirming the benefits of including hyperthermia in an oncological treatment program. The following list, published with the kind consent of prof. Dr. N. R. Datta from the Swiss center Kantonspital Aarau documents the results of selected studies involving hyperthermia.

Source::

Datta, NR, Ordóñez, SG, Gaipl US, Paulides MM, Creeze H, Gellermann J, Marder D, Puric E, Bodis S. Local hyperthermia combined with radiotherapy and /-or chemotherapy: Recent advances and promises for the future. Cancer Treat Rev 2015 Nov;41(9):742-53.

Summary results table HT+RT vs RT alone Odds ratio for: Complete Response

Site	Trials	RT alone	RT+HT	Odds ratio (CI)	p value
Breast	6	88/181 (48.6%)	122/198 (61.6%)	2.10 (1.34-3.30)	0.001
Cervix	6	173/263 (65.7%)	200/251 (79.6%)	2.19 (1.45-3.32)	<0.001
Head & Neck	9	183/364 (65.7%)	266/353 (75.3%)	3.17 (2.55-5.38)	<0.001
Rectum	4	16/205 (7.8%)	36/208 (17.3%)	2.15 (1.10-4.20)	0.025
Ur. Bladder	3	35/86 (40.6%)	69/118 (58.4%)	2.40 (1.25-4.62)	0.009
Esophagus	2	24/132 (18.2%)	47/162 (29%)	2.64 (1.34-5.20)	0.005
Lung	2	2/70 (2.8%)	7/59 (11.8%)	2.69 (0.51-14.22)	0.243
Superficial Tumours	2	57/169 (33.7%)	75/175 (42.8%)	1.48 (0.94-2.32)	0.091
Melanoma	1	23/65 (35.3%)	39/63 (61.9%)	2.97 (1.45-6.09)	0.003
Anal Canal	1	17/25 (68%)	23/24 (95.8%)	10.82 (1.23-94.92)	0.032
Choroidal Melanoma	1	20/70 (28.5%)	33/63 (52.3)	2.75 (1.34-5.63)	0.006
Others (Miscl.)	1	47/87 (54%)	50/87 (57.4%)	1.15 (0.63-2.09)	0.647
All sites	38	685/1717 (39.8%)	967/1761 (54.9)	2,30 (1.95-2.72)	<0.001

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

BSD-2000

Deep tissue local hyperthermia Phased array radio frequency

Comparison of the most relevant features between BSD-2000 models 2D and 3D

	BSD-2000 2D	BSD-2000 3D
RF Generator (name)	Tetra	Dodek
Number of RF channels	4	12
Directional Heat Zone Steering	2 axis (X & Y)	3 axis (X, Y & Z)
Frequency (MHz)	modulated 75 to 120 MHz	modulated 75 to 120 MHz
Number of antennas	8	8 or 24 (depending on applicator in use)
Maximum Power	1300 W	1800 W
Max. Channel Power	325 W	450 W (4 channels) | 135 W (12 channels)
Multiple size applicators	✓	✓
Applicator Sigma 30 (Ø30cm, 8 antennas)	✓	✓
Applicator Sigma 60 (Ø60cm, 8 antennas)	✓	✓
Applicator Sigma Ellipse (8 antennas)	✓	✗
Applicator Sigma Eye (24 antennas)	✗	✓
Number of temperature probes	8	8
Thermal Mapping feature	✓	✓

Authorized distributor on the territory of Poland:

HT System sp. z o.o.

ul. Belgradzka 5 / 02-793 Warszawa

+48 22 300 91 85

info@htsystems.com.pl

Manufacturer:

Pyrexar Medical

1825 West Research Way, Ste. E
Salt Lake City, UT 84119

+1 844 797 3927

info@pyrexar.com

www.htsystems.com.pl