Section 3 Equipment Description and Function

This section provides a description of each equipment control and unit that comprises the BSD-500 System and information about the specific function of each of these controls and units. For instructions on how these controls and units are used in conjunction with a treatment, refer to Section 5, *Indications for Use and Treatment Procedures*. The BSD-500 System uses applicators designed for specific types of hyperthermia treatments. A manual for each applicator is included with the applicator.

The operating controls for the BSD-500 System are found in the **MAIN OPERATING CONSOLE**. This console provides controls for the 915 MHz GENERATOR and Computer. Independent self-contained controls are used for the WATER CIRCULATION SYSTEM (WCS). Water systems are only provided with systems that include external water-cooled bolus applicators. The front of the console opens to provide access to a storage drawer, the computer access panel, and the MW GENERATOR. Storage slots for interstitial applicators and temperature sensors are provided in the vertical slots behind the doors.

Main Operating Console

The MAIN OPERATING CONSOLE provides structural support for the BSD-500 System control panel assembly, computer, monitor, temperature sensor interface module, and specific treatment applicators. This console is mounted on locking casters that provide the ability to position the equipment for specific needs.

Figure 3-1: *Main Operator Control Panel Assembly*

MAIN OPERATOR CONTROL ASSEMBLY

The **MAIN OPERATOR CONTROL PANEL ASSEMBLY** (Figure 3-1) contains: the main power ON/OFF switch, USB computer connector, and mouse/keyboard connector. The touch-screen, color monitor displays the RF ON indicator, RF ON/OFF controls, sensor temperatures, and power level amplitude and phase control.

The **MAIN POWER ON/OFF SWITCH** is located on the front side as the operator faces the panel doors of the MAIN OPERATOR CONTROL PANEL ASSEMBLY. This switch is a circuit breaker that controls **all** power to the BSD-500 SYSTEM.

RF ON INDICATOR is a software display that indicates when the system is using EM energy. (Refer to *Section 4: Computer Software Operation*.)

RF ON/OFF SWITCH is an alternate action icon that, in the OFF position, immediately disables the oscillator in the 915 MHz generator and switches the internal oscillator power to OFF, which blocks the generator's EM energy output. (Refer to *Section 4: Computer Software Operation*.)

Microwave power levels for each individual channel are selected using the computer software. The selected power levels manually control the EM function of the 8-channel 915 MHz GENERATOR. (Refer to *Eight-Channel Generator information* in Section 4: *Computer Software Operation* section of this manual.)

The COMPUTER is located behind the MAIN OPERATOR CONTROL ASSEMBLY access doors. The computer hard drive has been pre-programmed with all the necessary software to perform hyperthermia treatments, calibrate temperature sensors, and perform treatment recall.

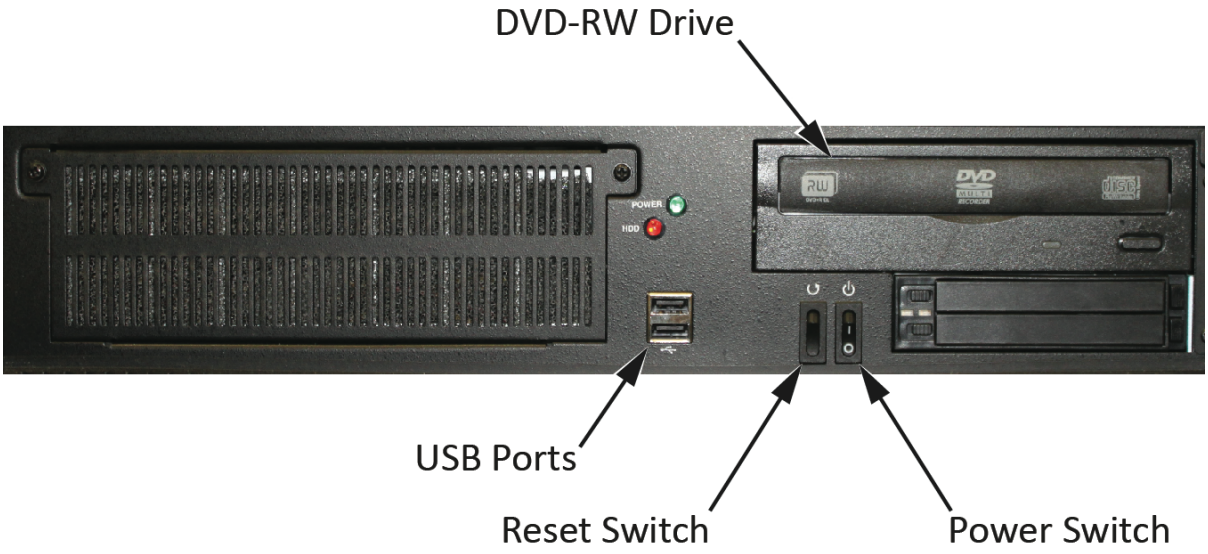


Figure 3-2: *COMPUTER Front Panel*

The BSD-500 System hard drive records and stores patient treatment data. This data can be saved to either a CD-ROM Disk or USB FLASH DRIVE. Two USB ports are available on the side of the MONITOR stand and on the front panel of the COMPUTER for this purpose.

The switches below the DVD-RW Drive on the front panel of the computer include a COMPUTER RESET SWITCH (left) and a COMPUTER POWER SWITCH (right). The COMPUTER RESET SWITCH forces a restart of the COMPUTER and is not normally used by the operator. The COMPUTER normally turns on automatically when the MAIN POWER SWITCH is turned ON. In the case that the COMPUTER does not power up automatically when the system is turned ON, the COMPUTER POWER SWITCH on the front panel of the COMPUTER may be pressed to turn on the COMPUTER. The air foam window to the left is the airflow vent and should be kept clean of dirt and dust.

The COMPUTER controls the following operations of the BSD-500 System.

- *Receives and processes information on sensor temperatures and controls power based on temperature feedback.*
- *Controls data to and from the hard disk drive.*
- *Receives and processes information from the monitor.*
- *Provides control of the displayed information on the monitor.*

Figure 3-3 is a complete view of the inside of the BSD-500 Main Operator Control Assembly. The front doors open to show the MW generator, the computer and the storage drawer.

In the doors are open tubes for safe storage of temperature sensors and Microwave Interstitial Applicators.

Figure 3-3: *Inside view of Main Operator Control Assembly*

MONITOR

The BSD-500 System is equipped with a touch-screen MONITOR to display instructions, software and equipment selections and choices, updated digital displays of temperature sensors, a graphic color plot of the treatment, and the date and time. Many of the system software functions can be set simply by touching the monitor screen display. For example, if the screen has a save option that is active, the operator can touch the monitor display area directly over the save button.

Figure 3-4: *Monitor and stand*

The operator can control the*, brightness, horizontal positioning (HPos), vertical positioning (VPos), and color display* using the monitor's control buttons on the underside of the MONITOR. A vendor manual is supplied that explains the control buttons of the monitor. The **POWER SWITCH** for the MONITOR should be left in the ON position at all times.

Two USB ports for use with USB FLASH DRIVES or other USB components are located on the side of the monitor stand. These ports provide an easy way to save patient treatment data through the use of a USB FLASH DRIVE (*not provided with the BSD-500 System*). Two USB ports are also located on the front panel of the computer, which may also be used for this purpose.

KEYBOARD

Patient data and other software data requirements are entered using the USB Keyboard and touchpad supplied with the BSD-500 System. Because the monitor is a touch screen display, the operator does not need any other selection or data entry components.

MICROWAVE AND THERMOMETRY INTERFACE PANEL

This interface panel (Figure 3-5) contains all of the connection ports for the 8 TEMPERATURE SENSORS and the RF power ports for multiple-channel applicator connection. The 8-channel configuration allows the operator to use all 24 ports; however, applicators should only be connected to the interface panel power ports during use.

All unused cables and applicators must be removed before enabling RF power.

The thermometry portion of the panel contains the connection ports for up to 8 TEMPERATURE SENSORS. The calibration well is in the center of the panel and contains a built-in REFERENCE SENSOR and 4 insertion holes for Temperature Sensor calibration and verification.

***Figure 3-5**: Microwave and Thermometry Interface Panel*.

NOTE
Disconnect all unused cables and applicators from the microwave and thermometry interface panel before RF is enabled.

915 MHz GENERATOR

A 915 MHz solid-state generator provides the RF power needed for a successful hyperthermia treatment. This generator contains eight solid-state amplifiers. Power can be applied up to a level of 60 watts per channel or combined into an output of 400 watts for 8-channels.

***Figure 3-6:** 915 MHz Generator front panel.*

The power balance of up to eight channels can be either manually controlled by the clinician or automatically controlled by the computer. (Refer to Section 4: *Computer Software Operation* section of this manual.)

WATER CIRCULATION SYSTEM

The **WATER CIRCULATION SYSTEM** (WCS) part number 21-16348 is used to provide the water that circulates through all Pyrexar applicators that use a water bolus; e.g., MA-100 APPLICATOR. The WCS is fully described in a separate Water Circulation System Operators Manual (10-16348).

TEMPERATURE SENSORS

The BSD-500 system delivers and controls therapeutic heating using a closed loop feedback system. The BSD-500 System software monitors the heated tissue temperature using stable and RF compatible temperature sensors. The system controls the applied power level in accordance with operator inputs and automatically adjusts the level of power to maintain the operator selected temperatures throughout the treatment.

Figure 3-7: *Microwave and Thermometry Interface Panel with sensors connected*

The thermistor TEMPERATURE SENSORS used with the BSD-500 System are neither perturbing to nor perturbed by the EM field. Pyrexar's temperature sensors comply with all industry recognized standards for precision, stability, response time, and diameter.

Each TEMPERATURE SENSOR is 1.1mm diameter and is inserted into the patient using standard disposable blind-end catheters – NOT furnished by Pyrexar. TEMPERATURE SENSORS are used to monitor the temperatures of both tumor and normal tissue.

When in use, the temperature sensors are connected to the Microwave and Thermometry Interface Panel, as illustrated in Figure 3-7.

These sensors can be supported by the storage slots in the black rod, as shown in Figure 3-7, with or without the attached cables. This helps to protect the TEMPERATURE SENSORS when they are connected and before they are used for treatment monitoring.

CAUTION

The TEMPERATURE SENSORS are small and fragile and can be easily damaged in use if they are not protected from sharp objects, sharp bending. Do not crush, smash, or otherwise damage sensors.

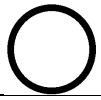
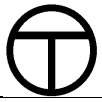
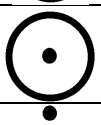
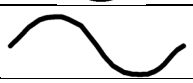
A storage area, located behind the front system doors of the MAIN OPERATOR CONTROL CONSOLE, is provided for storage of the TEMPERATURE SENSORS when not in use.

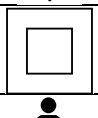
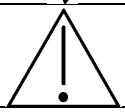
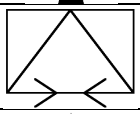
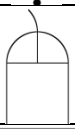
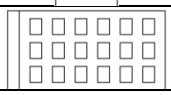
Figure 3-8: *Temperature Sensor storage panel*

Hardware Function and Safety Symbols

The following table provides a description for each universal symbol label bonded to the BSD-500 System.

Table 3-1: Universal hardware and safety symbols

Symbol	*Description*
	**On (Main Power)**
	**Off (Main Power)**
	**On/Off (Push Button)**
	**Stand-by**
	**On (Part of Equipment)**
	**Off (Part of Equipment)**
	**Alternating Current**
3 N 	**Three Phase Alternating Current w/ Neutral Conductor**
N	**Connector Point for Neutral Conductor on Permanently Installed Equipment.**

Symbol	*Description*
	**Protective Earth (Ground)**
	**Earth (Ground)**
	**Hand Held Switch**
	**Class II Equipment**
	**Type B Equipment**
	**Type BF Equipment**
	**Dangerous Voltage**
	**Attention: Consult Documents**
	**Non-ionizing Radiation**
	**Modem (Controls and Terminals)**
	**USB Terminal**
	**Mouse Terminal**
	**Keyboard Terminal**
	**Caution Hot Surface**
	**Start (of action)**

Symbol	*Description*
	**Stop (of action)**