Section 4 Computer Software Operation

Section 4 provides information for initial power-up procedures and software operation instructions for the BSD-500 Hyperthermia System (BSD-500 System).

Initial Power-Up Sequence

The BSD-500 System is designed so that all power to the console can be turned ON by the power switch located on the front of the monitor support pole.

The following sequence must be followed when powering up the BSD-500 System:
- Verify that the AC power cord for the system is connected to an AC outlet.
- Verify that the POWER SWITCH located on the front of the monitor pole, is turned **ON**
- Verify that the POWER SWITCH for the MONITOR is turned **ON.**
- Verify that the MICROWAVE GENERATOR POWER SWITCH is turned **ON** (located inside the MAIN OPERATOR CONSOLE panel doors. This need only be turned ON when entering into a treatment procedure.).

> **NOTE**
> The MICROWAVE AND THERMOMETRY INTERFACE PANEL will stabilize within fifteen seconds after the power is turned to ON. This enables temperature monitoring to be performed almost immediately. The CALIBRATION WELL requires about 5 minutes after AC power is turned on to stabilize to 42°C

Software Operation

The MAIN POWER SWITCH on the front of the monitor support pole controls the power to the COMPUTER, the MONITOR, and the CONTROL CONSOLE UNIT. Power is applied to the computer and the monitor when this main power switch is turned to ON. If the computer does not automatically turn on when the MAIN POWER SWITCH is turned to ON, press the COMPUTER POWER SWITCH on the front panel of the COMPUTER. The system software will automatically load as the COMPUTER powers to ON and the **PASSWORD PROMPT** will appear (Figure 4-1).

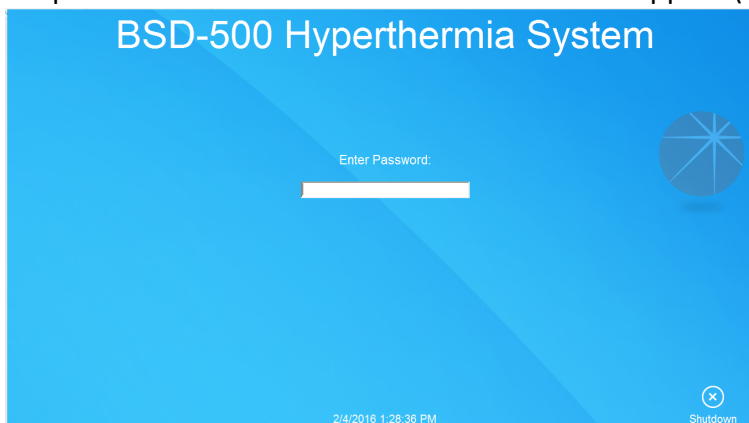BSD-500 Hyperthermia System

Enter Password:

2/4/2016 1:28:36 PM   Shutdown

Figure 4-1: Password Prompt

To select any of the software options, the operator can simply touch the screen directly over the desired option or using the touchpad mouse, move the cursor to the desired option and click the left mouse button. Clicking selects and opens the functions of the program*.*

The operator should select the password entry window and use the keyboard to enter the password provided by the facility administrator.

Main Menu (Function Selection Menu)

The Main Menu for the BSD-500 System has also been referred to in other Pyrexar equipment manuals as the FUNCTION SELECTION MENU. For purposes of this manual, the first screen to appear after the initial password screen is referred to as the Main Menu. This menu is illustrated in Figure 4-2*.* The operator can select one of the following options from the Main Menu:

- o Hyperthermia Treatment
- o Planning (Microwave Interstitial Pretreatment Planning)
- o Recall (Treatment Recall / Thermal Mapping Recall)
- o Sensor Setup (Sensor Calibration / Sensor Verification)
- o Utilities
- o Shut Down

Each of these options will be discussed in the order they appear in the list above, with the sub-options to each selection discussed in the order they appear on the various software screens. These options, and all associated sub-options, can be selected in any order.
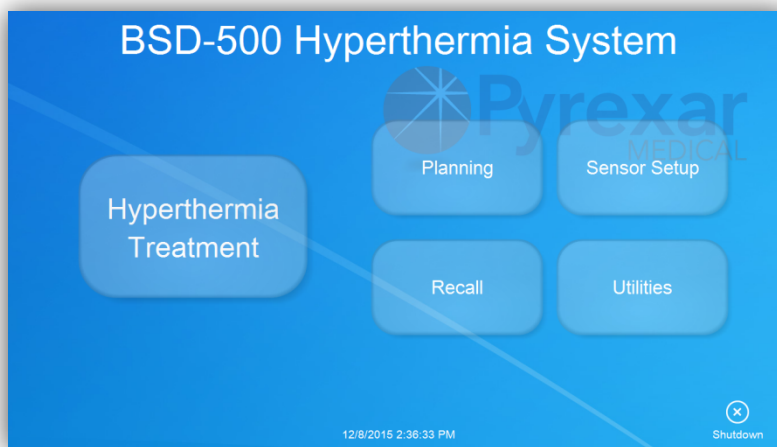

Figure 4-2: *Main Menu*

NOTE
The software version appears on the Version Information utility screen.

Pyrexar recommends performing a Sᴇɴsᴏʀ Vᴇʀɪғɪᴄᴀᴛɪᴏɴ procedure as the first step each day that the BSD-500 System is to be used. In order to perform this procedure, the operator must connect the ᴛᴇᴍᴘᴇʀᴀᴛᴜʀᴇ sᴇɴsᴏʀs to the ᴍɪᴄʀᴏᴡᴀᴠᴇ ᴀɴᴅ ᴛʜᴇʀᴍᴏᴍᴇᴛʀʏ ɪɴᴛᴇʀғᴀᴄᴇ ᴘᴀɴᴇʟ as illustrated in Figure 4-3.

Figure 4-3: *Temperature Sensor connection to Microwave and Thermometry Interface Panel*

After the ᴛᴇᴍᴘᴇʀᴀᴛᴜʀᴇ sᴇɴsᴏʀs are connected, select Sᴇɴsᴏʀ Sᴇᴛᴜᴘ from the Mᴀɪɴ Mᴇɴᴜ, then select Sᴇɴsᴏʀ Vᴇʀɪғɪᴄᴀᴛɪᴏɴ (refer to Sᴇɴsᴏʀ Vᴇʀɪғɪᴄᴀᴛɪᴏɴ in this manual for details on how to operate the software.) This verification procedure displays the calibrated temperature of the current sensors and the temperature of the Reference Sensor in the Calibration Well.

HYPERTHERMIA TREATMENT

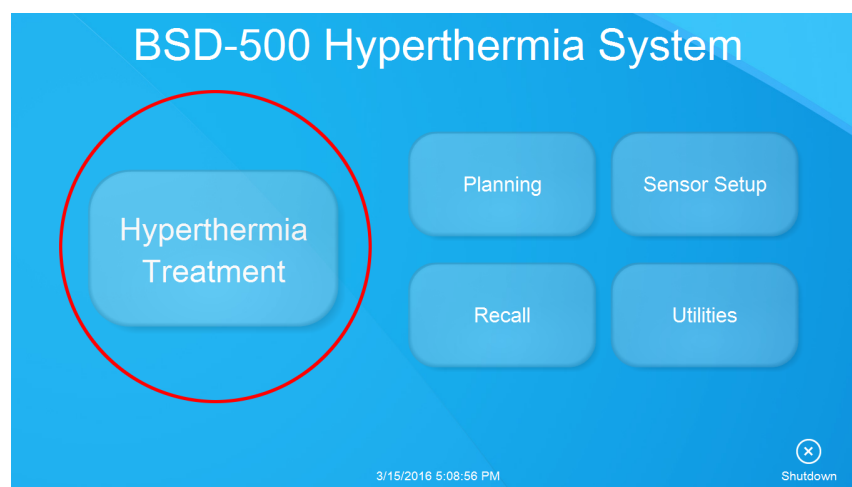Hʏᴘᴇʀᴛʜᴇʀᴍɪᴀ Tʀᴇᴀᴛᴍᴇɴᴛ is the large selection option on the Mᴀɪɴ Mᴇɴᴜ. (Figure 4-4)

Figure 4-4: *Hyperthermia Treatment Selection on Main Menu.*

When this option is selected, the next display to appear will be the Pᴀᴛɪᴇɴᴛ Sᴇʟᴇᴄᴛɪᴏɴ menu illustrated in Figure 4-5 The operator can select from two tabs 'ᴀᴄᴛɪᴠᴇ' patients or 'ᴀʟʟ' patients. The default menu is 'ᴀᴄᴛɪᴠᴇ' patients (Figure 4-5). This screen displays a list of all active patients in the system.
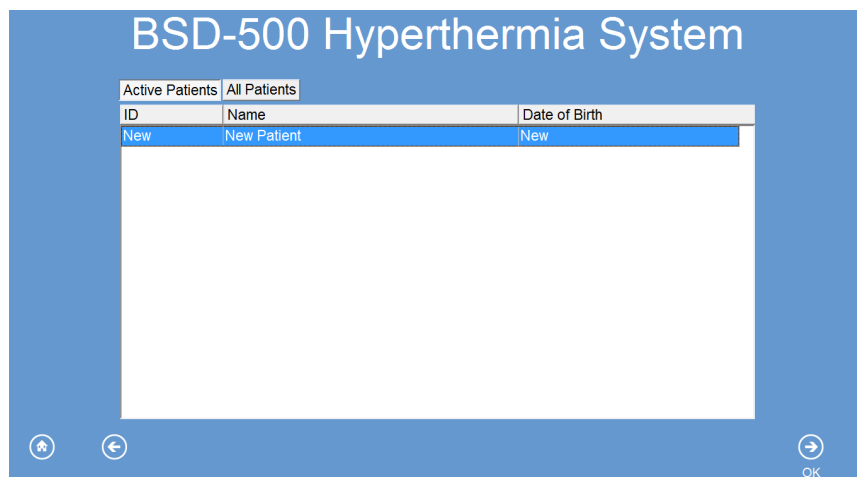
Figure 4-5: *Patient Selection – active patients tab.*

Figure 4-6 illustrates the '**all**' patients screen. From the '**all**' patients screen, the operator can change the status of a patient from 'active' to 'inactive' or from 'inactive' to 'active'. To change a patient's status, click once on the patient's name to highlight the patient information and then click the **Patient Status** button. The 'status' of the patient will be indicated in the Status field. The operator can also select the **Change Patient Status** button from the '**active**' patients screen to display the '**all**' patients screen.
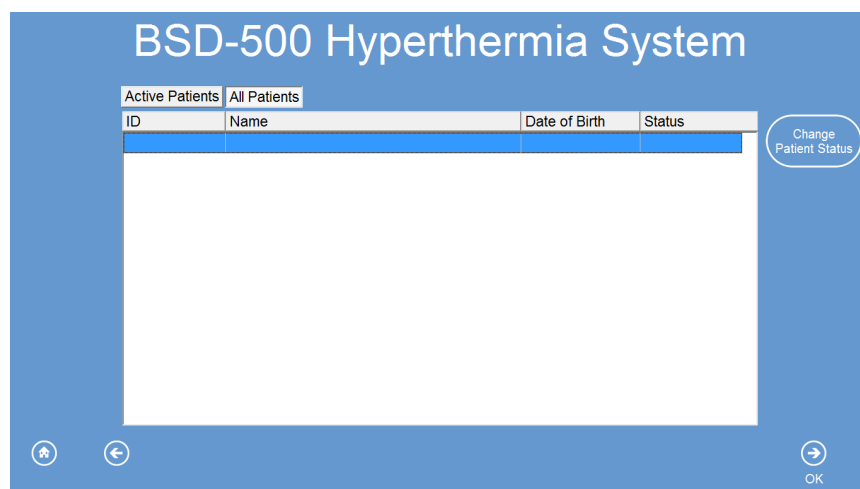

Figure 4-6: *Patient Selection – all patients tab.*

From the '**active**' patient screen (default screen), the first item highlighted is **New Patient**. With the **New Patient** selection highlighted, select the **OK** button on the bottom of the display and the **Patient Information** screen will appear (Figure 4-7)

After the correct patient has been selected or entered, the operator should select **OK** to proceed with the remaining parameter settings. Selecting **OK** allows the operator to proceed to the next sequence of the **Hyperthermia Treatment** procedure.   Selecting the Back arrow icon button returns the operator to the previous page. Any time the Home icon button option is selected, the software will return to the **Main Menu**.

Patient Information

After selecting a patient from the **Patient Selection** screen, the **Patient Information** screen will be displayed. (Figure 4-7).

A vertical line cursor (text cursor) will appear in the 'Patient Name' block. The arrow keys or the tab key on the keyboard can be used to move the insertion point of the text cursor from one field to another. Use the keyboard to type patient data. After all information has been entered, reviewed and/or changed, select **OK** to proceed to the next software section.

Figure 4-7: *Patient Information screen*

NOTE
The 'Height' and 'Weight' selections are not designated as decimal or metric. The operator can enter numbers in units that are consistent with the hospital or clinic data collection system.

Select Applicator Type Menu

After selecting **OK** from the **Patient Information** display (Figure 4-7), the **Select Applicator** display illustrated in Figure 4-8 will appear on the monitor. There are various options available with each icon representing an available applicator that can be used and was purchased with the BSD-500 System. The MA-100, MA-120, MA-151 (Mini-Dual Ridge), and Microwave Interstitials (MA- 251 Series) are standard applicators in the U.S. (see Table 1-2) used with the BSD-500 System. As other applicators are developed and approved for use, an icon representing these applicators (when purchased) will be available. (*Refer to the individual applicator manuals for specific operational features for each applicator.*)

The operator must select an applicator before proceeding.
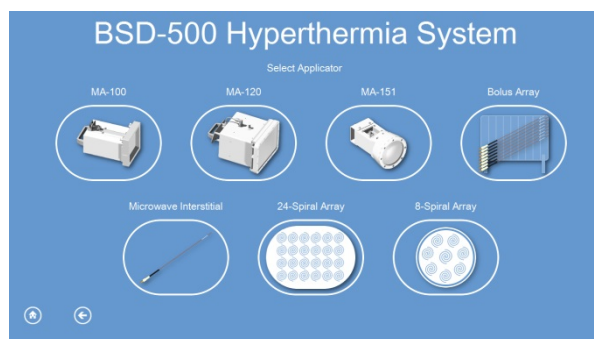

Figure 4-8: *Applicator Selection Menu*

To change the applicator selection, simply select *(using the mouse cursor or touch the screen)* another applicator icon; the previous applicator selection will be deselected and the newly selected applicator will be highlighted, indicating that it has been selected. After selecting an applicator, the OK icon button will appear. Select OK to proceed.

The power source and the power range for the superficial applicators; e.g., the MA-100, MA-120, or MA-151 APPLICATORS are pre-established by the software. The RF power range cannot be changed.

When superficial single channel applicators are selected, the software will automatically switch to the single channel mode, which directs RF power to the coaxial connector on the top of the monitor support arm.

When the **Microwave Interstitial** icon or another multiple channel applicator is selected, the 915 MHz generator 8-Channel mode will automatically be selected. The specific portion of the software that applies to multiple channel applicators is discussed in this section under '*Multiple Channel Applicator Selections*'.

NOTE
Once an applicator has been selected and the Treatment Control screen is showing, the operator cannot change the applicator type without ending the treatment (End TX) and repeating the setup procedure starting at the Main Menu.

NOTE
Transparencies that contain grid, applicator footprint and SAR contours can be created from templates provided by Pyrexar Medical. These transparencies match the screen grid and can be used to mark sensor and tumor locations and can then be transferred to these sensor placement screens.

Temperature Sensor Placement Screen
After the applicator and power channels (multi-channel applicators only) have been selected, the **Temperature Sensor Placement Screen** is displayed. (NOTE: The Temperature Sensor Placement Screen has to be enabled prior to display – Treatment Configuration Utility). The SAR pattern and label for each screen differs according to the applicator and configuration selection; thus, the operator should select the Temperature Sensor Placement Screen that most closely represents the applicator setup that will be used in the treatment.

The grid is one centimeter squares and can be used with templates provided by Pyrexar to assist in marking the sensor and tumor locations. These templates can be printed on transparencies for easier use. The Transparency can be used to mark the locations of the temperature sensors and can then be overlaid on the Temperature Placement screen for record data storage.
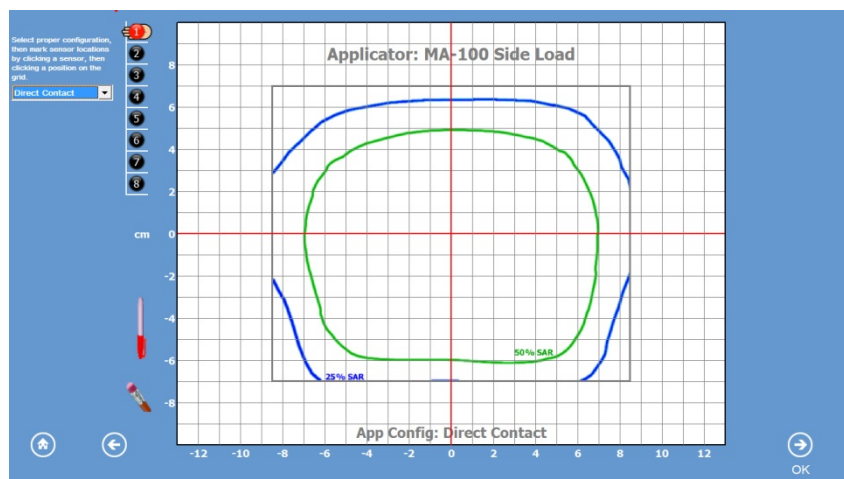
To place the temperature sensors, touch or click on a sensor. The hand icon will then move beneath that sensor. The hand icon is used to indicate temperature sensor location by touching an intersection on the grid that is closest to the actual physical location of that sensor. As long as the hand icon is underneath the sensor, you can reposition it by touching any grid intersection. If a sensor will not be used and it is on the grid, you can select it and click the sensor rack (upper left side of the grid) and the sensor will return to the rack.
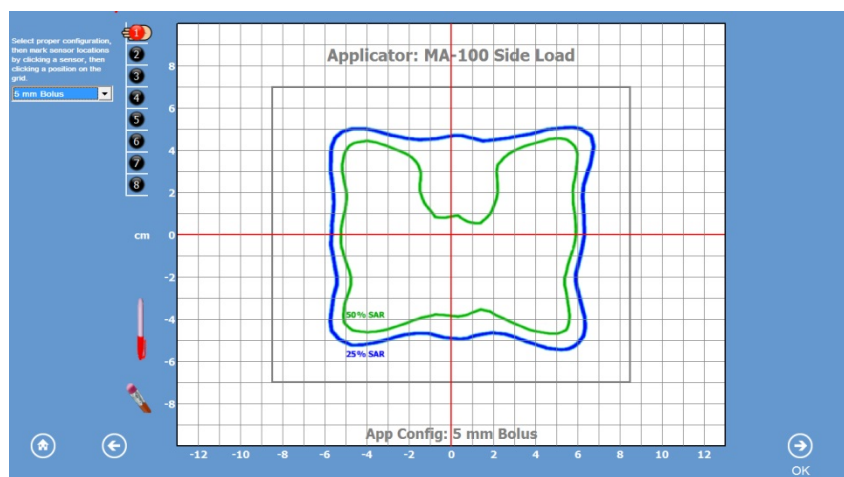
To draw a tumor boundary, select the tumor marker to the left of the grid by touching the marker. You will notice that the cap of the marker will transfer to the other end of the marker and the hand icon will be beneath the marker. You can now draw one continuous region by touching anywhere inside the grid in a clockwise direction. Each touch will place a point in the boundary polygon. When the boundary is near where you started, you can then touch the tumor marker to complete the polygon's boundary line. This will also return the hand icon back to a selected sensor.

When complete this will represent a treatment configuration record. The use of this screen is only to aid in the documentation and record keeping of the temperature sensor orientation relative to the tumor location and the applicator placement. This screen does not affect the treatment and will not alter the treatment process. The SAR patterns shown are from the Operator Manual of the respective applicators and these patterns are based on laboratory testing only and may not be indicative of expected clinical heating patterns. Clinical heating patterns can be altered by many variables, including blood flow, different spacing between the applicator and the surface, and curvature of the treatment surface.
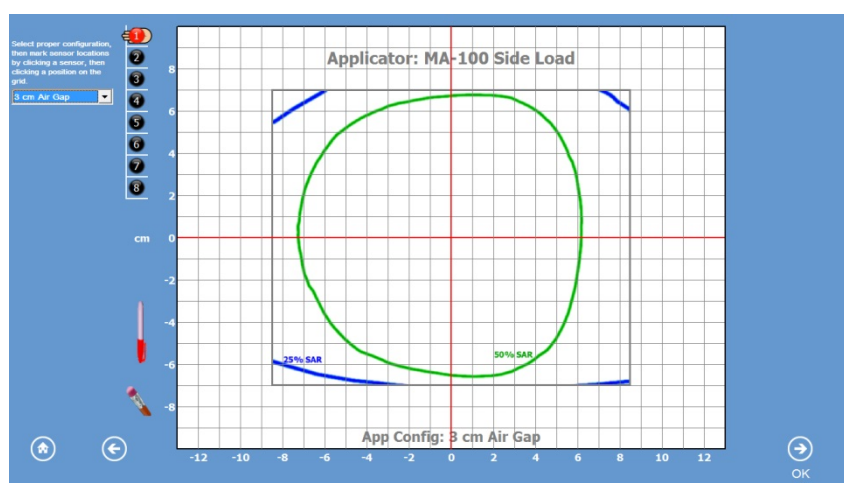
The SAR pattern and sensor position(s) are selected and input prior to starting a treatment procedure. This screen information is then saved in the active computer memory during the treatment. This screen can only be created before starting the treatment and can only be printed or electronically exported to an external memory device immediately after the treatment is ended. A manual tracing on a transparent plastic sheet of the sensor locations can also be placed as an overlay on the system monitor for use during treatment.

Screen 1 - *Temperature Sensor Placement Screen – MA-100 Direct Contact SAR Pattern*
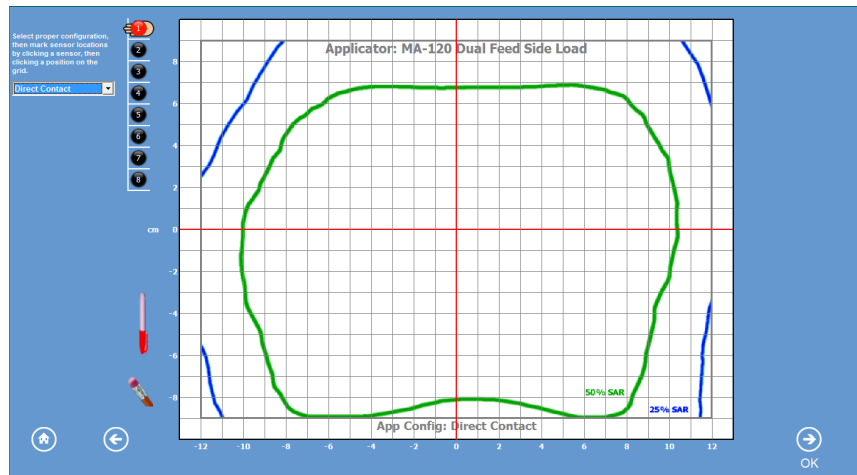

Screen 2 - *Temperature Sensor Placement Screen – MA-100 5 mm Bolus SAR Pattern*

Screen 3 - *Temperature Sensor Placement Screen – MA-100 3 cm Air Gap SAR Pattern*

Screen 4 - *Temperature Sensor Placement Screen – MA-120 Direct Contact SAR Pattern*

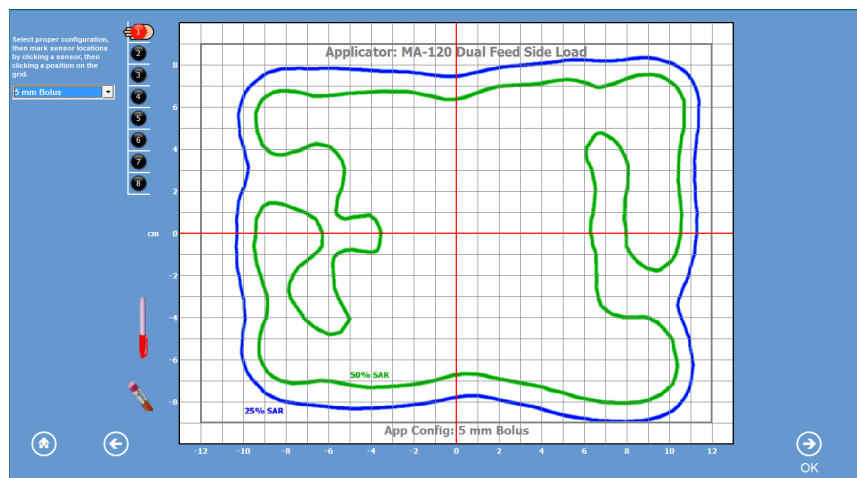**Screen 5** - *Temperature Sensor Placement Screen – MA-120 5 mm Bolus SAR Pattern*

Screen 6 - *Temperature Sensor Placement Screen – MA-120 3 cm Air Gap SAR Pattern*
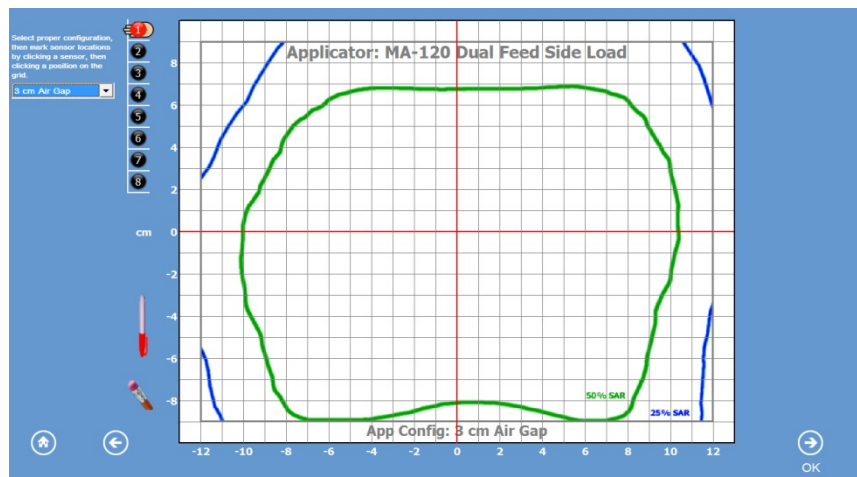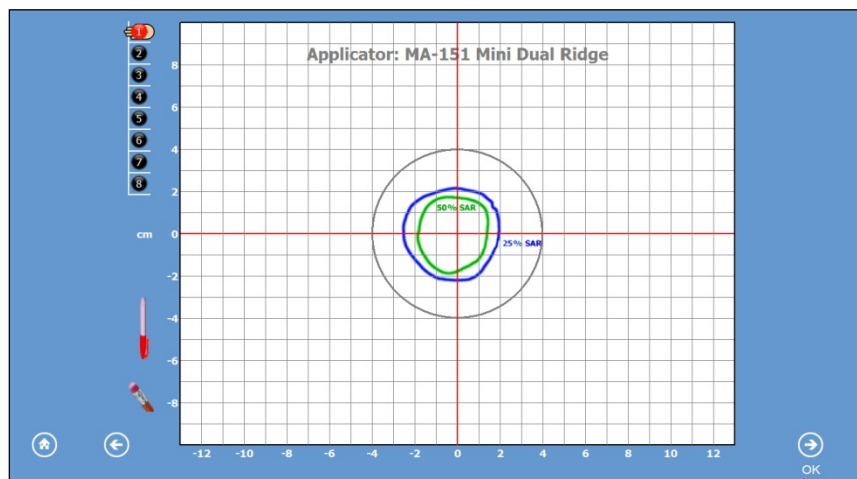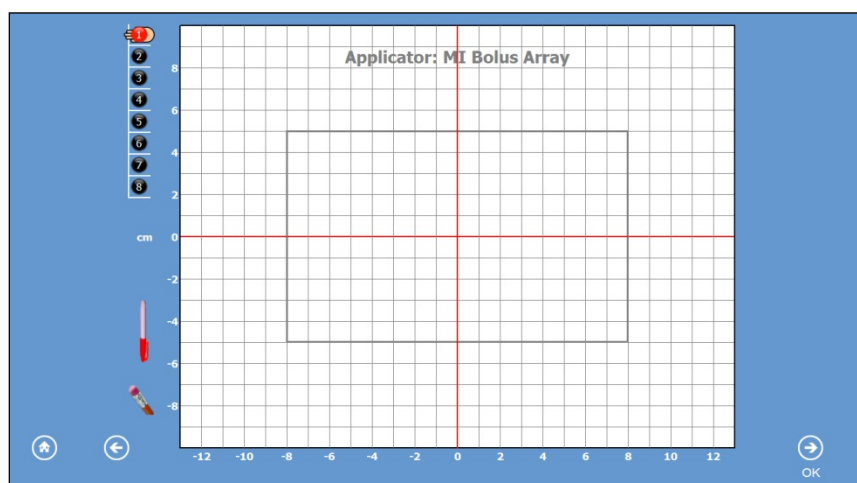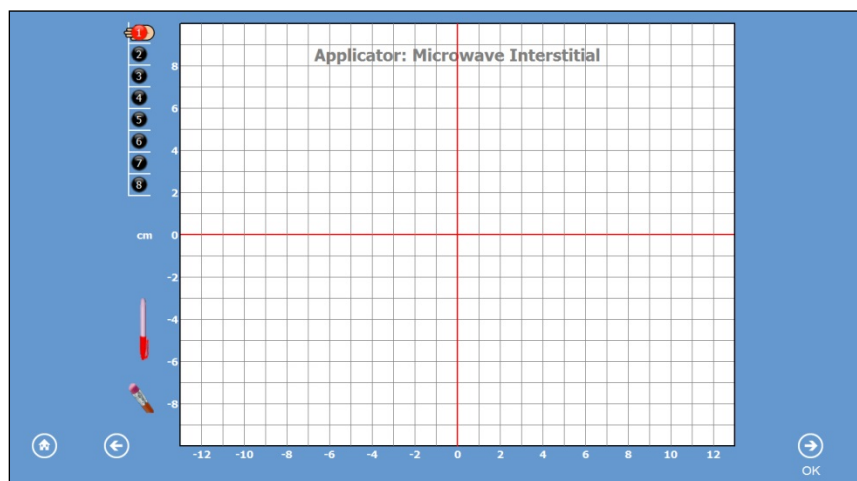
Screen 7 - *Temperature Sensor Placement Screen – MA-151 Bolus SAR Pattern*

Screen 8 - *Temperature Sensor Placement Screen – Microwave Interstitial Bolus Array*

Screen 9 - *Temperature Sensor Placement Screen – Microwave Interstitial*

Treatment Control

After an applicator is selected and **OK** is selected, the **Treatment Control Screen** will be displayed. This screen visually displays all aspects of the treatment. The default view differs slightly for a single channel applicator (Figure 4-9) and a multiple channel applicator (Figure 4-10).

Figure 4-9: *Treatment Control screen – Single Channel Applicator*
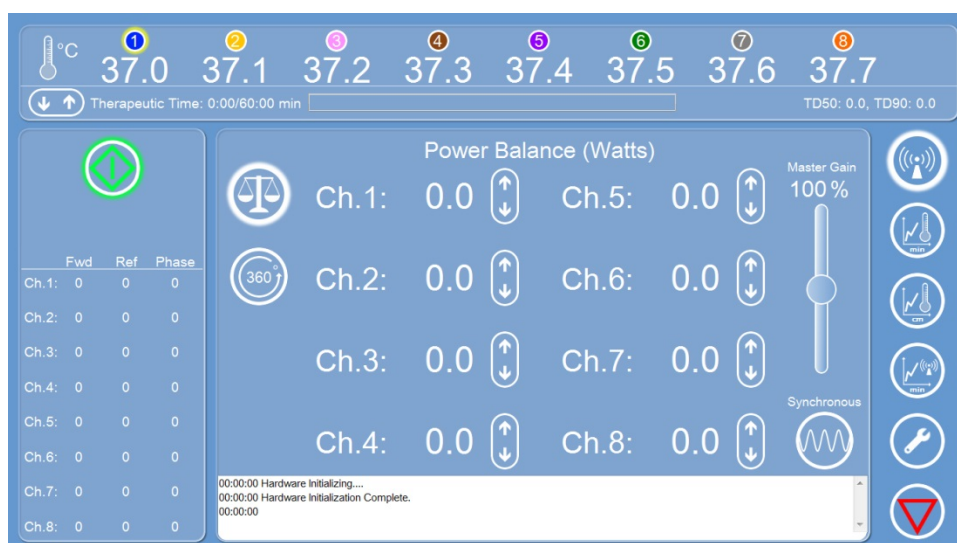

Figure 4-10: *Treatment Control screen – Multiple Channel Applicator*

The various options and settings displayed on this screen will be discussed as follows:

Top of the screen

> Colored, numeric TEMPERATURE SENSOR selection buttons, measured temperatures, therapeutic time display and adjustment controls, and the TD50 / TD90 thermal dose calculations are displayed.

<u>Left side of the screen</u>

Numeric display labels for measured power and phase are displayed. Note, phase measurements are only displayed for multiple channel applicators.

Also, the Start Treatment icon button is available after the hardware completes its initialization steps. When the Start Treatment icon button is selected, it will change into the RF Disabled state of the RF Enable/Disable Icon Button, illustrated below.

START TREATMENT ICON BUTTON   RF ENABLE/DISABLE ICON BUTTON   RF ENABLE/DISABLE ICON BUTTON
(RF DISABLED)   (RF ENABLED)

Single channel applicators always have their Maximum Power and Maximum Gain controls accessible on the left of the screen.

<u>Center of the screen</u>

Graphs for **Time@Temp. Power Plot, Current Thermal Map and Thermal Map History** are displayed in the center of the screen, as well as **RF Power / Phase Controls** for multiple channel applicators. These are selectable by using the icon buttons along the right side of the screen. Also, a message box is included at the bottom-center of the screen to provide additional status information to the operator.

<u>Right side of the screen</u> – Treatment Control / Monitoring Icon Buttons

RF Power / Phase Controls Icon Button
Displays RF Power and Phase Controls in the center of the screen.
(Multiple channel applicators only)

Temperature vs. Time Chart Icon Button
Displays the Temperature vs. Time Chart in the center of the screen.

Temperature vs. Distance Chart Icon Button

Displays the Temperature vs. Distance Chart in the center of the screen.

Power vs. Time Chart Icon Button

Displays the Power vs. Time Chart in the center of the screen.

Treatment Setup Tools Icon Button

Displays the Treatment Setup tools in the center of the screen.

End Treatment Icon Button

These buttons do not need to be selected in any designated order.

The currently active button is designated by a white glow around the button, as illustrated below:

TREATMENT SETUP TOOLS ICON BUTTON
ACTIVE / SELECTED

TREATMENT SETUP TOOLS ICON BUTTON
INACTIVE / NOT SELECTED

Treatment Charts

TEMPERATURE VS. TIME GRAPH

Selecting the **Temperature vs. Time** icon button displays the corresponding graph in the center of the screen. The base temperature of the graph can be adjusted by dragging the chart area up and down. The range of temperatures on the graph can be adjusted by dragging up and down on the vertical temperature axis labels.
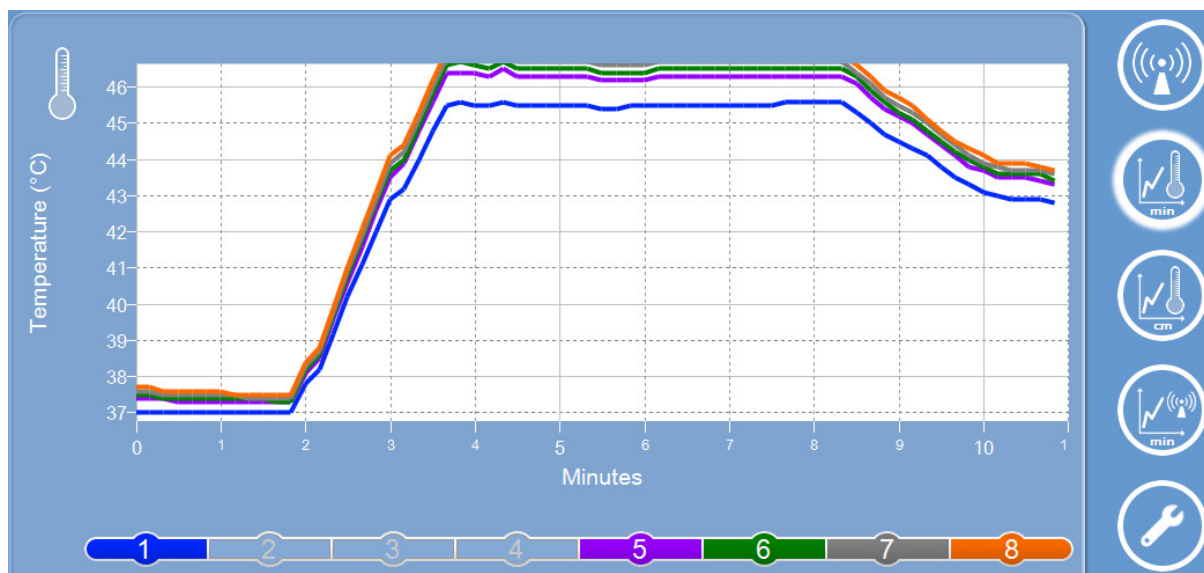

Figure 4-11: *Temperature vs. Time Graph*

After enough time has elapsed to span the default range of minutes on the graph, the displayed range of time will automatically begin to scroll along with new temperature measurements that are added to the graph. At this point, a **Zoom In/Out** icon button will appear which can be used to toggle between viewing the whole duration of the treatment or just the last ten minutes. When zoomed in, the displayed range of time can be adjusted by dragging the chart area left and right.

ZOOM IN ICON BUTTON

ZOOM OUT ICON BUTTON

The colored legend shown beneath the graph may be used to adjust which TEMPERATURE SENSORS are plotted on the graph. To select or deselect a TEMPERATURE SENSOR from the graph, click on or touch the numbered section in the legend corresponding to that sensor. In Figure 4-11, sensors 2, 3 and 4 have been deselected from plotting on the graph, while the other sensors are selected for plotting. As a default, all sensors which were enabled on the top of the screen when first entering Treatment Control are automatically selected to be plotted.

POWER VS. TIME GRAPH

Selecting the **Power vs. Time** icon button displays the **Power vs. Time** graph in the center of the screen (Figure 4-12). The controls to adjust the display range for this graph are identical to those described above for the **Temperature vs. Time** graph. For multiple channel applicators, a colored legend beneath the graph may be used to adjust which POWER CHANNELS are plotted on the graph. As a default, all power channels which were enabled on the top of the screen when first entering Treatment Control are automatically selected to be plotted.
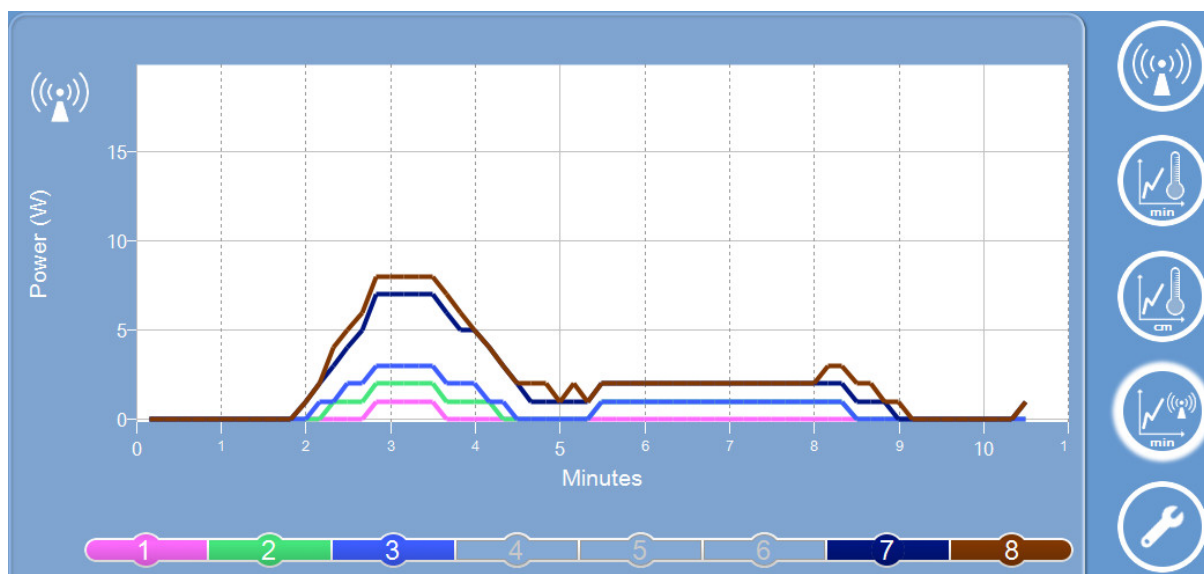

Figure 4-12*: Power vs. Time Graph (Channels 4-6 are deselected from plotting)*

THERMAL MAPPING GRAPHS

The **Thermal Mapping Graphs** are viewed by selecting the **Temperature vs. Distance** icon button on the right side of the screen, as shown in Figure 4-13.
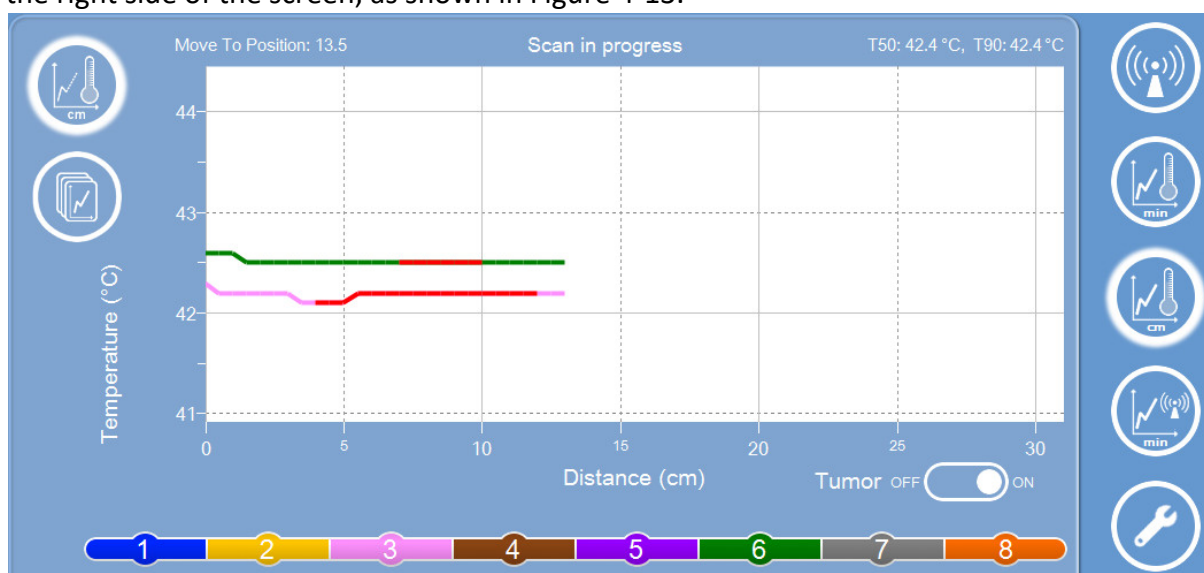

Figure 4-13*: Temperature vs. Distance Graph (Current Map Option)*

Thermal Mapping Graphs provide a visual representation of the mapped temperatures vs. distance (dwell positions in centimeters) along the catheter track, as well as the stop and start positions of the mapping scans. A label above the Thermal Mapping chart instructs the operator when to move the sensor to the next dwell position. Multiple sensors may be mapped at the same time, as is illustrated in Figure 4-13 where sensor 3 and sensor 6 are both being mapped. Tumor locations along each catheter track can be highlighted in red by selecting the Tumor switch icon below the graph area, changing the Tumor switch position from OFF to ON.

Two graph types are available, the **Current Map** and the **Historical Map**. The **Current Map** view is enabled by selecting the **Current Map** icon button, the topmost icon button to the left of the graph. The **Historical Map** view is enabled by selecting the **Historical Map** icon button, the lower icon button to the left of the graph.

CURRENT MAP ICON BUTTON   HISTORICAL MAP ICON BUTTON

The **Current Map** graph provides a 'real-time' display during the Thermal Mapping procedure and displays the results of the most recent scan.

The **Historical Map** graph shows previous **Thermal Mapping** scans from the current treatment. Use the left/right arrow buttons to select the sensor number to plot. The graph will be updated with the six most recent Thermal Mapping scans for that sensor. The scan start times are given above the colored legend beneath the graph. This legend may also be used to select which scans are plotted on the graph. To select or deselect a scan from the graph, click on or touch the colored section in the legend below the indicated timestamp. In Figure 4-14, the scan with a start time of 05:59 has been deselected from plotting on the graph.
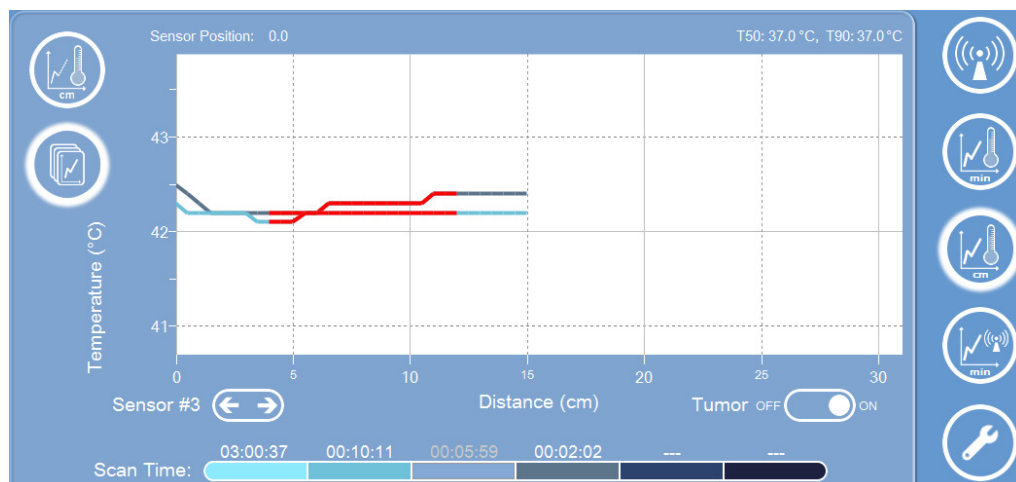

Figure 4-14*: Temperature vs. Distance Graph (Historical Map Option)*

Treatment Setup

Therapeutic Time

Therapeutic Time (Figure 4-15) is set to be the time that any sensor is over 40°C. The RF Power will automatically turn OFF when the measured Therapeutic Time reaches its set limit. The displayed value of Therapeutic Time at the top of the display screen is incremented when any sensor is above 40°C and represents the time at which therapeutic temperatures were measured from any sensor.

The factory default value is 60 minutes, but the default can be changed through the Treatment Configuration Screen in the Utilities Menu. The maximum time is 240 minutes. Use the arrow buttons by the **Therapeutic Time** label to set this time limit.

Temperature Sensor Selection

To enable a TEMPERATURE SENSOR:

- Attach a TEMPERATURE SENSOR (or multiple sensors when using a multiple channel applicator) to the TEMPERATURE SENSOR portion of the MICROWAVE AND THERMOMETRY INTERFACE PANEL.
- Select the colored, numeric TEMPERATURE SENSOR selection button at the top of the screen corresponding to the channel number (1 thru 8) to which the TEMPERATURE SENSOR(S) was/were connected. When the TEMPERATURE SENSOR is enabled, the colored, numeric TEMPERATURE SENSOR selection button will be filled in with the color the matches the colored indicator on the TEMPERATURE SENSOR.

Figure 4-15: All Temperature Sensors Enabled

Figure 4-16: Temperature Sensors 2 – 8 Disabled

One TEMPERATURE SENSOR must be selected as the CONTROL SENSOR. The default channel for the CONTROL SENSOR is '1'. The control sensor channel can be changed by selecting the **Treatment Setup Tools** icon button, and then selecting **Temperature Controls**. The CONTROL SENSOR will have its colored, numeric TEMPERATURE SENSOR selection button highlighted with a yellow glow (Figure 4-17).

Figure 4-17: *Control Sensor indicated by yellow glow.*

A minimum of one channel must be assigned and a TEMPERATURE SENSOR properly connected before the RF power will start.

RF Controls

Figure 4-18 illustrates the **RF Controls** for a single channel applicator such as the MA-151, MA-100 or MA-120. For multiple channel applicators, refer to *Multiple Channel Applicators* in this section. The operator will set the **Maximum Power** for the treatment, and the **Master Gain**.

MAXIMUM POWER

The maximum power setting is the allowed maximum RF power the generator can supply as long as the TEMPERATURE SENSORS have not achieved their set target temperature to be used during the treatment. The **Maximum power** is set by the operator and cannot exceed the maximum watts defined for the selected applicator.

Figure 4-18: *RF Controls - single channel applicator.*

MASTER GAIN

The **Master Gain** allows the operator to raise or lower the RF power maximum setting in increments of 5% either up and down. The operator may choose to set the intended maximum power with the **Maximum Power** value and then choose to manually change the **Master Gain**, but the **Master Gain** does not go any higher than 200%.

Treatment Setup Tools

Selecting the **Treatment Setup Tools** icon button displays a set of additional controls categorized as follows:

- Temperature Controls
- Sensor Location
- Thermal Mapping
- Notes
- Patient Information

The currently active button is designated by a white glow around the button. For example, in Figure 4-19, **Temperature Controls** is the current selection.
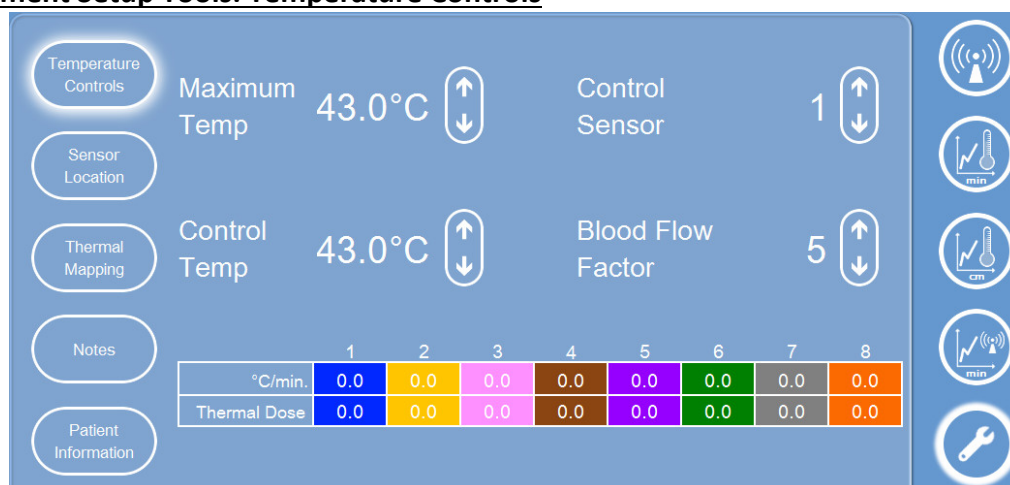
Treatment Setup Tools: Temperature Controls

Figure 4-19: *Temperature Controls Display*

Four settings must be set from the **Temperature Controls** selection: **Control Sensor, Control Temp, Maximum Temp**, and **Blood Flow Factor**. Default values are shown in Figure 4-19.

To change any of these settings, use the mouse to move the cursor over the up and down arrows (bumper arrows). Use the left mouse button and click the arrow -- the up arrow increases the number; the down arrow decreases the number. One click moves the number one numeric place. The operator will need to click several times on an arrow to increase or decrease numbers to the desired setting.

CONTROL SENSOR SETTINGS

The CONTROL SENSOR is a Pyrexar thermistor sensor assigned to monitor the temperature of the target tissue. The CONTROL SENSOR controls the **Total Power** of all channels and maintains the **Control Temperature**. A CONTROL SENSOR **must** be assigned before a treatment can be started. The system will automatically select the lowest channel number enabled as the CONTROL SENSOR if another sensor is not designated by the operator as the CONTROL SENSOR.

To set a channel for the CONTROL SENSOR, use the arrows to the right of **Control Sensor** and select a number between 1 and 8 (refer to Figure 4-19). A sensor must be attached to the selected channel on the MICROWAVE AND THERMOMETRY INTERFACE panel. If no sensor has been attached, attach a sensor. If no sensor has been assigned as the CONTROL SENSOR, select **Temperature Controls** and assign a TEMPERATURE SENSOR.

NOTE
The computer does not know if the correct sensor is connected to the correct port on the Microwave and Thermometry Interface Panel. The operator must verify the temperature accuracy of the sensor in each port to be used.

The CONTROL SENSOR is usually located in the tumor but can be in a normal tissue to be protected by a lower control temperature. The CONTROL SENSOR designation can be changed at any time during the treatment. TEMPERATURE SENSORS should be placed in the deepest possible tumor zone, other sites within the tumor, and peripherally located in sensitive normal tissues. The temperature for the CONTROL SENSOR can be set lower than maximum temperature, but it cannot be set higher than the maximum temperature.

The CONTROL SENSOR will be more useful in some patients if placed in sensitive normal tissue. For example, if the control temperature is exceeded in the sensitive normal tissues, RF power will be controlled to limit the temperature in these tissues to below the selected target maximum for the tumor tissue. If any of the TEMPERATURE SENSORS, other than the CONTROL SENSOR, reach the maximum temperature, power is controlled to maintain this temperature until one of the other sensors exceeds the designated limit. Full control is maintained for all TEMPERATURE SENSORS at all times.

As the respective temperature limitation of the CONTROL SENSOR is reached, the system will decrease the RF power to maintain the temperature at the selected temperature limit, unless another sensor begins to exceed its limit. If this happens, the power control is transferred to the sensor exceeding the limit. Any of the two temperature limits – CONTROL TEMP or MAXIMUM TEMP for any sensor exceeding its limit -can act as the limiting parameter for RF power.

As long as the temperature of the sensors is below the selected temperature limit, the maximum RF power set by the operator will be sent from the generator. If the temperature of any sensor *exceeds* the selected temperature limit by 0.1°C to 0.3°C, the computer will begin to evenly reduce the RF power.

If the temperature of any TEMPERATURE SENSOR exceeds the limiting temperature by 0.4°C or more the RF power will be turned **OFF** until the limiting temperature sensor falls below the limiting temperature. Once the limiting temperature has been attained the computer will control the RF power to maintain the limiting sensor at the selected limiting temperature.

> **WARNING**
> **For safety and precise control, a Pyrexar Thermistor Sensor must be designated as the CONTROL SENSOR.**

CONTROL TEMP SETTING
The range of the **Control Temp** setting is from 29.1°C to 60.0°C. Even though the **Control Temp** setting can be set to 60.0°C, at no time can the **Control Temp** be set higher than the **Maximum Temp** setting. Therefore, if the operator wants to change the **Control Temp** to a higher temperature, the **Maximum Temp** setting must be changed to a higher setting. The **Control** and **Maximum** temperature factory default settings are 43.0°C. These default settings can be changed in the Treatment Configuration Screen.

The **Control Temp** setting defines the temperature monitored by the CONTROL SENSOR and affects all channels of the generator by incrementally decreasing the power uniformly to each channel. If the temperatures exceed the assigned set value, the RF power will be reduced on all channels. When the temperature is exceeded by 0.4°C or more, the RF power will be discontinued until the temperature cools to less than the maximum temperature setting.

MAXIMUM TEMP

The **Maximum Temp** setting controls the highest temperature any sensor can reach before power is decreased. The maximum temperature can be set higher or equal to the **Control Temp**. If any TEMPERATURE SENSOR, other than the CONTROL SENSOR, reaches the maximum temperature, that sensor then controls the **Total Power** of all channels based on this **Maximum Temp** setting.

When a multiple channel applicator is in use, *e.g.*, Microwave Interstitials, and the temperature of an enabled TEMPERATURE SENSOR, other than the CONTROL SENSOR, exceeds the set **Maximum Temp** setting, all eight channels of the generator will be reduced to limit the temperature to that of the **Maximum Temp**.

If a TEMPERATURE SENSOR exceeds the **Maximum Temp** by 0.4°C or more, the RF power will be discontinued until the temperature cools to less than the maximum temperature setting. The range of the **Maximum Temp** setting can be from 29.1°C to 60°C.

BLOOD FLOW FACTOR

The BLOOD FLOW FACTOR is not a critical parameter and is used to adjust temperatures for slight under or over shoot. The range selection is from 0 to 9. This is a fine-tuning power adjustment that defaults to a value of 5.

The number represented by the blood flow factor relates to the degree of blood perfusion in the treatment area. If the rate of perfusion is high, a higher number would be selected; if perfusion is low, a lower number would be selected. The rate at which the computer will respond to changes in the temperature after the control temperature has been reached is determined by the blood flow setting. As the control temperature is reached by any TEMPERATURE SENSOR, a higher blood flow factor will reduce undershoot of target temperature and a lower blood flow factor will reduce temperature overshoot.

Initially, the normal value of '5' should always be used for a treatment. It should be changed only if control overshoot or undershoot of temperature is observed during treatment which is typically when less than a 0.3°C variation is observed while the computer is controlling the temperatures.

> **NOTE**
> Low blood flow factor numbers input by the operator will cause the power to decrease quickly to prevent overshoot in temperature control. High blood flow factor numbers will cause the power to decrease slowly to prevent rapid tissue cooling during temperature control. Normal blood flow value is set at 5.

Treatment Setup Tools: Sensor Location

Figure 4-20: Sensor Location Tools

The **Sensor Location** settings are designed to assist with treatment data collection and information set here is NOT used during the actual treatment. The data obtained from these settings will assist the institution in gathering statistical data for analysis and in tracking the temperature sensor data needed when performing a manual **Thermal Mapping** procedure.

The information gathered from the **Sensor Location** settings is equivalent to treatment notes. It is a visual tracking of the treatment. Figure 4-20 is an illustration of the screen display and the various setting options – Temp Sensors, Location Code, Description, Depth, Insertion Length, and Deepest Point. TEMPERATURE SENSORS which have been enabled at the top of the screen can be selected here to assign these options. Upon selecting a sensor, the **Sensor Location** options for the selected sensor will become visible.

Location Codes are Normal Tissue, Tumor Tissue, Thermal Mapping, and Core. Each of these options has reference to where the selected sensor is located. Next, the operator should enter a brief description about the sensor setup and other unique information pertaining to the selected sensor. This data is entered in the **Description** area provided. The depth of the sensor into the tumor will be recorded in centimeters in the area designated **Depth**. The sensor insertion length will be recorded, in centimeters, in the **Insertion Length** area, and the deepest point of insertion for the sensor will be recorded in the **Deepest Point** area.

The Thermal Mapping Track represents locations along the track of a catheter which are designated as being in tumor tissue or in normal tissue. Select the **Locked** icon button

adjacent to the Thermal Mapping Track (Figure 4-21) to unlock the Thermal Mapping Track controls.
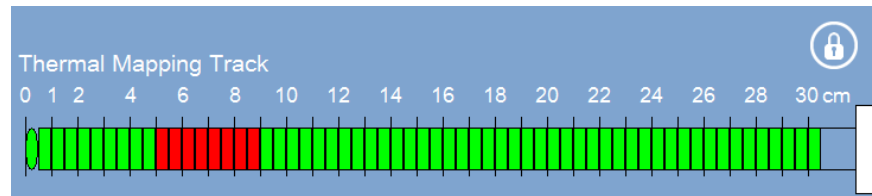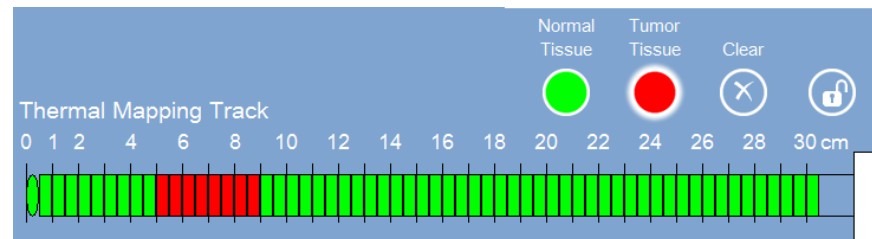

Figure 4-21: Thermal Mapping Track - Locked

Figure 4-22: Thermal Mapping Track – Unlocked (Tumor Tissue selected)

On the Thermal Mapping Track, the color green represents normal tissue, while red represents tumor tissue. To designate a region of the Thermal Mapping Track as "Tumor Tissue", select the red "Tumor Tissue" button (Figure 4-22), then move the mouse cursor over the desired regions to change them from green to red. Alternately, to designate a region of the Thermal Mapping Track as "Normal Tissue", select the green "Normal Tissue" button, then move the mouse cursor over the proper regions to change them from red to green. When Thermal Mapping is performed, the Thermal Mapping Track regions indicated in red will be used to calculate the T50, T90, TD50, and TD90. These values can be used to provide a thermal dose measurement of effectiveness of the treatment.

Treatment Setup Tools: Thermal Mapping
Thermal Mapping provides a method for the operator to manually withdraw a temperature sensor within a catheter for the purpose of collecting temperature data from the catheter's tip to the skin surface.

Before beginning a **Thermal Map,** first start the treatment by selecting the Start Treatment icon button. Next, select the **Treatment Setup Tools** icon button, and then select **Thermal Mapping**. This displays the **Thermal Mapping** controls screen (Figure 4-23). TEMPERATURE SENSORS which have been enabled at the top of the screen will be available to select as THERMAL MAPPING SENSORS. Select the THERMAL MAPPING SENSORS to be manually withdrawn should be selected by clicking on the Thermal Mapping Sensors numbers. The CONTROL SENSOR cannot be used as a Thermal Mapping sensor; this sensor must remain in a position to maintain the proper RF power based on the fixed CONTROL SENSOR temperature. Note that during a Thermal Mapping procedure the RF power may be automatically adjusted lower if one of the mapping sensors exceeds the Maximum Temperature limit.

Figure 4-23*: Thermal Mapping Tools*

The **Rest Position** is that position along the catheter in cm from the tip where the sensor is to be placed between Thermal Mapping procedures.

The **Start Position** indicates the cm location along the catheter where the mapping procedure should start. The 0.0 cm position is normally the tip of the catheter.

The **Stop Position** is the last cm position before the mapping procedure is completed.

The **Step Size** can be set in 0.5 cm increments and represents the distance the sensor will be manually moved between each Step position.

The **Dwell Time** setting is the time between recording each temperature location along the catheter. It sets the time interval at which the computer will prompt the operator to manually pull back and relocate the temperature sensor.

To start the **Thermal Mapping** procedure:
- Select at least one TEMPERATURE SENSOR as a THERMAL MAPPING SENSOR,
- Set the **Dwell Time**, in seconds, to indicate the time between scans,
- Set the **Step Size**, in centimeters, for the distance the sensor is to be pulled for each scan,
- Select the **Temperature vs. Distance Chart** icon button (along the right of the screen) to visually view the scan progress, and to watch for the on-screen prompt to reposition the THERMAL MAPPING SENSOR during the scan.
- Start the treatment by selecting the Start Treatment icon button, if this has not yet occurred.
- A **Start Scan** icon button will appear in the upper-right corner of the screen.
- Select the **Start Scan** icon button in the upper-right corner to the screen to start the scan. The button will change to the **Stop Scan** icon button while the scan is active.

START SCAN ICON BUTTON

STOP SCAN ICON BUTTON

The scan will start and the operator should watch the screen display above the Temperature vs. Distance chart for instructions on when to pull the temperature sensor to the designated distance, in centimeters, from the Start Position to the Stop Position and then return the sensor to the Rest Position. An active scan may be aborted at any time by selecting the **Stop Scan** icon button.

Treatment Setup Tools: Notes

During a treatment the operator can record **Treatment Notes**. The note and the time the note was entered are stored in the patient hard disk file and can be printed at the conclusion of the treatment. If one treatment has been completed for the patient, prior treatment notes from prior treatments can be reviewed using Treatment Recall prior to the treatment START.

New notes are entered in the **Treatment Notes** section. Select the **Save** icon button to save these notes. Previous information is displayed in the **Initial Notes for all Patient's Treatments** display area.

The **Applicator Notes** section allows the operator to record notes about all aspects of the treatment setup. The applicator name is displayed for verification. It is suggested that the operator enter changes that may have been implemented from treatment to treatment pertaining to the applicator setup or treatment setup. These notes are specific to the selected patient. Select the **Save** icon button to retain these notes.

Figure 4-24: *Notes*

Treatment Setup Tools: Patient Info

Figure 4-25: Patient Information

The **Patient Info** screen (Figure 4-25) displays the current patient's information. From this display, the operator can review or change patient information data. Any data displayed can be changed or updated in any order. Changes are automatically saved to the patient's information.

START TREATMENT

After all treatment parameters in the various options, *i.e.*, Sensor Selection, Temperature, RF Controls, and so forth, have been set, the operator must select the green **Start Treatment** icon button, illustrated in Figure 4-26.
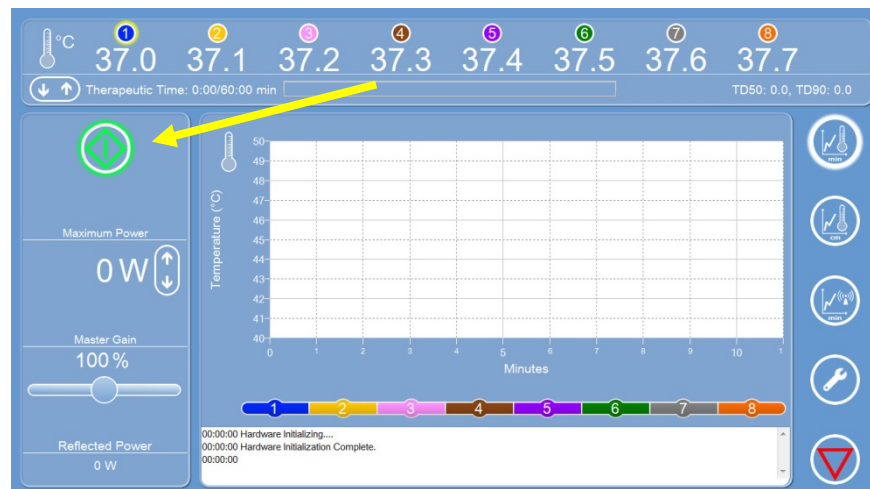

Figure 4-26: Treatment Control Screen – Start Treatment

Selecting the **Start Treatment** icon button will change it into the RF Disabled state of the **RF Enable / Disable** icon button (Figure 4-27). Also, the total measured forward power will appear directly below the **RF Enable / Disable** icon button and the **Elapsed Time** timestamp in the message window will begin to increment.
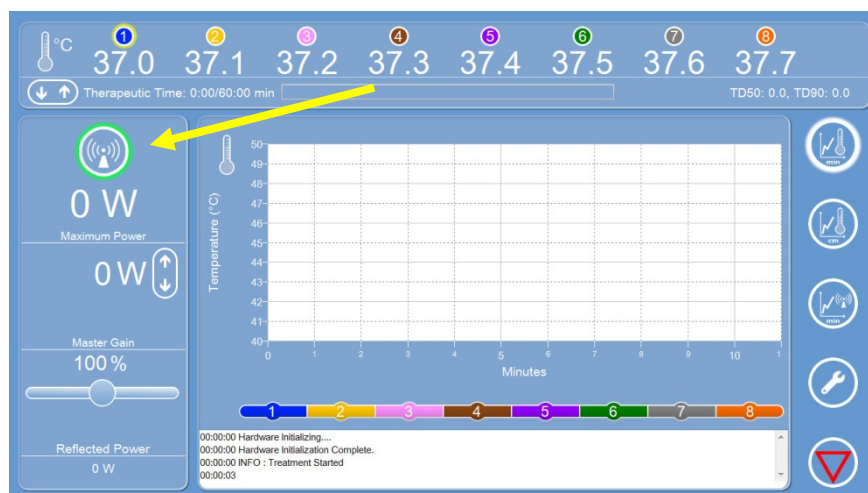

Figure 4-27: *Treatment Control Screen – RF Disabled*

RF ENABLE / DISABLE

The **RF Enable / Disable** icon button must be selected to enable the RF power and begin actual heating of the tumor. RF power can only be enabled after the **Start Treatment** icon button has been selected. If RF power is not enabled, no heat will be sent to the tumor site.

RF ENABLE/DISABLE ICON BUTTON (RF DISABLED)
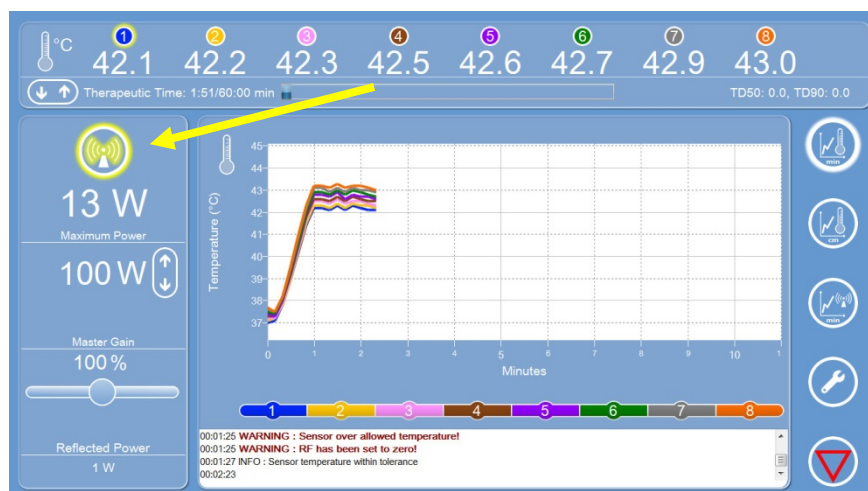

RF ENABLE/DISABLE ICON BUTTON (RF ENABLED)

Figure 4-28: *Treatment Control Screen – RF Enabled*

TEMPERATURE MONITORING

The display of temperatures at the top of the screen is dynamic and active throughout the treatment. The display temperature measurements are updated every 10 seconds.

°C / MINUTE

The **Temperature Controls** screen (Figure 4-29), available by selecting the **Treatment Setup Tools** icon button, includes a display of the rate of temperature change for each TEMPERATURE SENSOR, in °C per minute. This display is updated throughout the treatment. A negative number displayed on the °C/Min. row indicates a decrease in temperature. Pyrexar recommends that, during the treatment induction period, the rise in temperature should not exceed 1.0°C per minute for patient comfort.

The temperature rate of change, in °C per minute, is displayed on the top row of the **Temperature Controls** screen, as shown in Figure 4-29.

THERMAL DOSE

The **Temperature Controls** selection (Figure 4-29), available by selecting the **Treatment Setup Tools** icon button, includes a display of individual thermal dose values for each TEMPERATURE SENSOR. Refer to Appendix C of the *BSD-500 System Operator Manual* for a complete discussion of **Thermal Dose.**

The **Thermal Dose** for each temperature sensor is displayed on the bottom row of the **Temperature Controls** screen, as shown in Figure 4-29.

NOTE

43°C equivalent thermal dose minutes are displayed during the treatment.
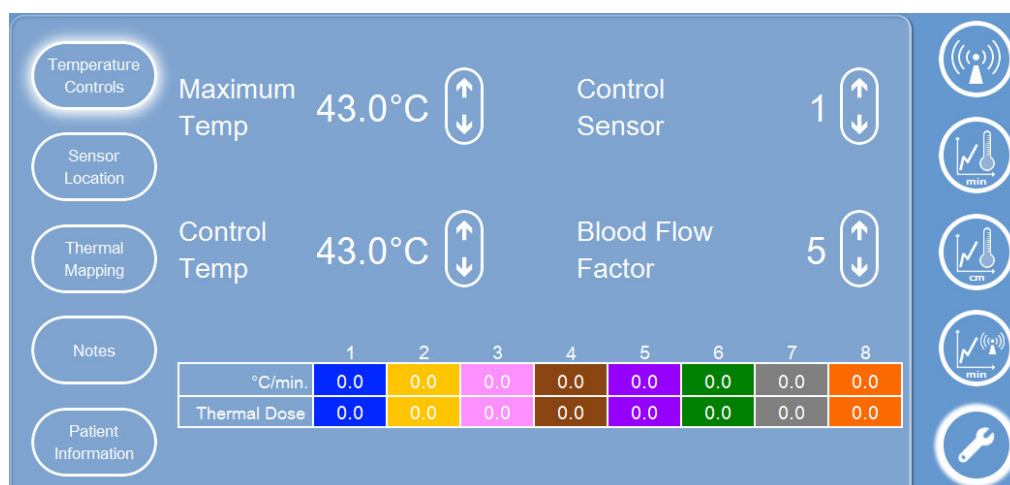

Figure 4-29: Temperature Controls

End Treatment

The operator can end a treatment at any time by selecting the red **End Treatment** icon button at the bottom-right of the screen.
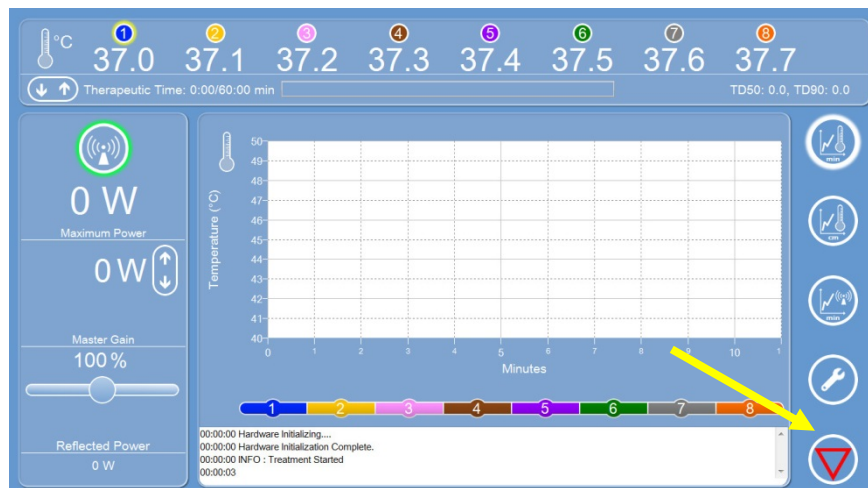

Figure 4-30: *Treatment Control Screen – End Treatment icon button*

The operator can Disable RF prior to selecting the **End Treatment** icon button. At completion of a treatment, the operator will be asked to confirm the end of the treatment and select **YES** or **NO** from the **Confirm** screen (Figure 4-31). When the treatment ends, all data will be saved.
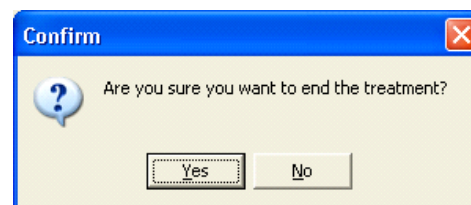

Figure 4-31: *Confirm End Treatment Prompt.*

After stopping the treatment, the RF energy is disabled and the temperature display will stop. The program will return to the **Main Menu** (Figure 4-2) unless the option for the Post Treatment Data Screen is enabled. The **End Treatment** function can also act as an emergency RF power **OFF**. If the operator notices unusual or questionable conditions in either the equipment or the patient, **End Treatment** icon button should be selected and the prompt confirmed to stop the treatment. This method of disabling RF energy should be used only in an emergency situation. Selecting the **RF Enable / Disable** icon button on the **Treatment Control Screen** is the usual method for turning the RF energy **OFF**.

The main AC POWER SWITCH can also be used as an emergency shut off for all RF power.

> **NOTE**
> **The End Treatment icon button should always be selected after a patient treatment. If the BSD-500 computer is turned OFF using the main AC Power Switch while in any of the menus, some treatment data may be lost.**

At the end of the treatment the system will display the Post Treatment Data Export/Print Screen (Figure 4-32). The operator can print or export digital copies of the treatment Data.

Figure 4-32: *Post Treatment Data Export/Print Screen*

The operator can also insert an external storage device; e.g., a USB memory stick, into the computer interface connector and export data files and figures that have been selected to the external storage device. The computer will automatically detect a USB memory device when it is inserted into the USB port. Touch or click on the Save icon button to transfer the selected data files to the external memory device.

The Treatment File, Thermal Mapping File, Statistics File, and Treatment Log File are all text data files that can be opened and viewed using a standard PC computer. The Simulation Image and Thermal Dose Image files are PDF files that can also be opened, viewed, and printed using a standard PC computer. Figure 4-33 shows an example of a Simulation Image file, which is the SAR and temperature sensor placement image selected by the operator at the beginning of the treatment.
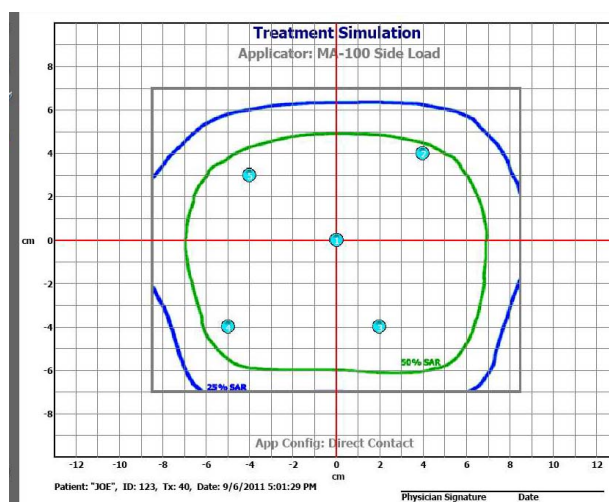

Figure 4-33: *Simulation Image File Example*

Figure 4-34 shows a Thermal Dose Image File, which provides a record of the treatment temperature maximum and the thermal dose for each sensor location. If the operator had graphically drawn the location and shape of the tumor target on the screen at the beginning of the treatment, this graphic would also be displayed on the Simulation Image file and the Thermal Dose Image File shown in Figures 4-33 and 4-34. The Simulation Image and Thermal Dose Image files allow the physician to sign and date the document to provide a hardcopy record of the treatment. The print function also allows the operator to print the plot of Temperature vs. Time and Power vs. Time.
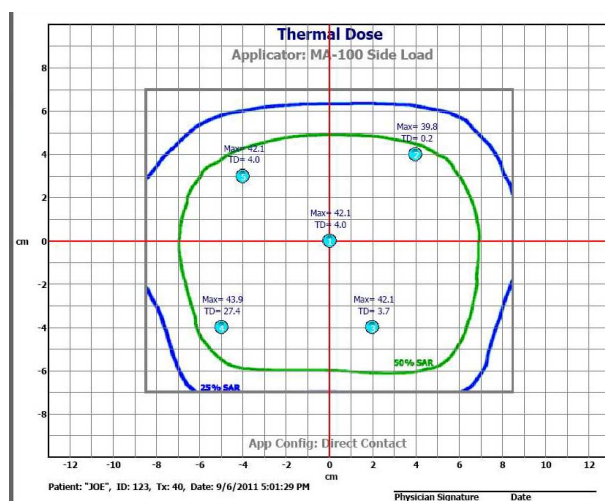

Figure 4-34: *Thermal Dose Image File for Dosimetry Data*

Multiple Channel Applicators

The previous discussion about the treatment setup and various setup options focused on single channel applicators. Most of the treatment settings are the same for multiple channel and single applicators; however, there are some differences. This section discusses only the differences and will refer the reader to previous information when the settings are the similar.

Multiple channel applicators use smaller amounts of RF power from the 8 available power channels of the generator.
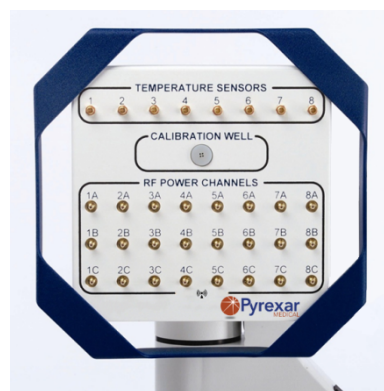

Figure 4-35: *Microwave and Thermometry Interface Panel*

The MICROWAVE AND THERMOMETRY INTERFACE PANEL (Figure 4-35) is used to connect the multiple channel applicator(s) to the RF power. One example of a multiple channel applicator is the MICROWAVE INTERSTITIAL.

Complete the following steps before starting a treatment using a multiple channel applicator.

- Disconnect any cables and applicators that will not be used for treatment.
- Attach the applicator(s) that will be used for treatment to the MICROWAVE AND THERMOMETRY INTERFACE PANEL.
- Attach the TEMPERATURE SENSOR(s) that will be used for treatment to a channel or channels in the temperature sensor port area of the panel.

After the applicators and TEMPERATURE SENSORS are connected, select **Hyperthermia Treatment** from the **Main Menu** (refer to Figure 4-2). Select the patient and verify or change the patient information as illustrated in Figures 4-5, 4-6 and 4-7.

The next screen will be the **Select Applicator** screen (Figure 4-36) is displayed with all available system applicators listed. Select either MICROWAVE INTERSTITIAL or any other multiple channel applicators that are available and are to be used for the specific patient's treatment.
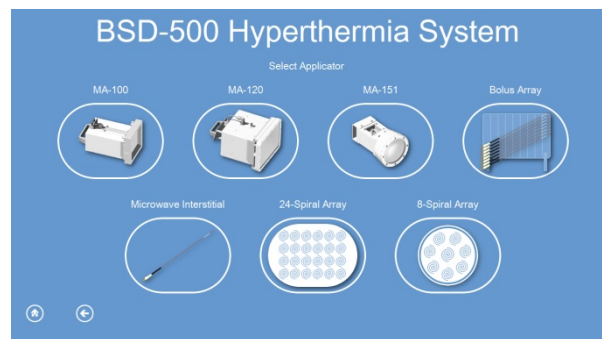

Figure 4-36: *Select Applicator display*

Multiple Channel Applicator RF Power Setup

After selecting a multiple channel applicator, the **RF Power Connection** configuration screen will be displayed (Figure 4-37).
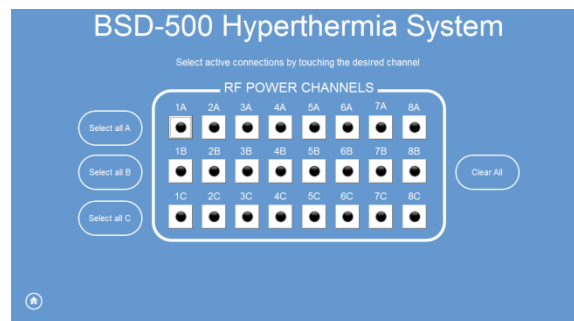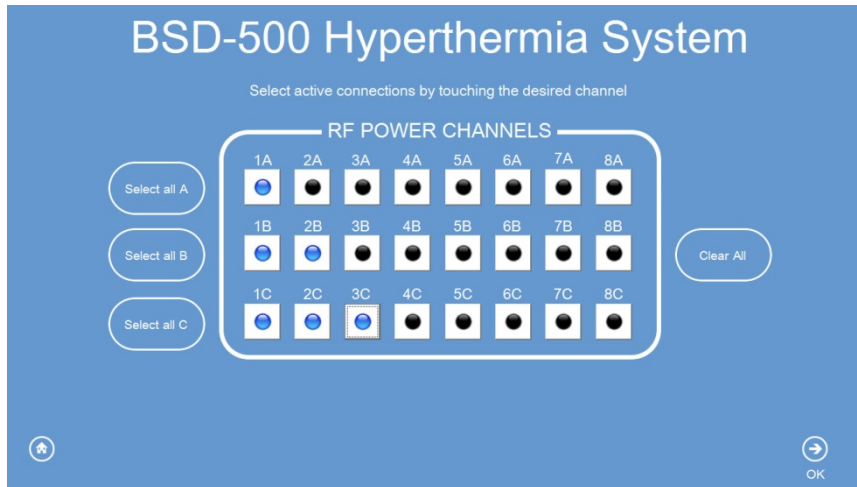

Figure 4-37: *RF Power Channel Selection Screen*

To select the **RF Power Channels**, the operator will either touch the channel number(s) that correspond to the actual channels with connected applicators on the MICROWAVE AND THERMOMETRY INTERFACE PANEL or use the mouse cursor and single, left click on the channel number(s). The active channels are indicated when the LED changes from black (inactive) to light blue (active) below the channel number selected.

Entire rows of channels may be selected by pressing one of the buttons to the left of each row. The Clear All button unselects all the channels.

The following is an example of how the **RF Power Channels** selection functions:
Figure 4-38 shows three power ports selected for channel 1 (1A, 1B, and 1C) which means that these three power ports have an applicator connected (MICROWAVE INTERSTITIALS, etc.). This selection and applicator setup will allow the operator the capability of using the full 60 Watts or RF power for the **Max Power** for channel 1 (refer to Figure 4-39). Channel 2 has two selected by the operator so it will set the RF power **Max Power** at 50 Watts. Channel 3 only has one channel selected so only 25 Watts of RF power will be the **Max Power** available for Channel 3.

Figure 4-38: Multiple channel applicator – RF Power Channels example.

With the multiple channel applicators attached to the MICROWAVE AND THERMOMETRY INTERFACE PANEL and the **RF Power Channels** set, the operator will select **OK**. The **Treatment Control** screen will be displayed. The **Power Balance** controls will display in the center of the screen as shown in Figure 4-39.
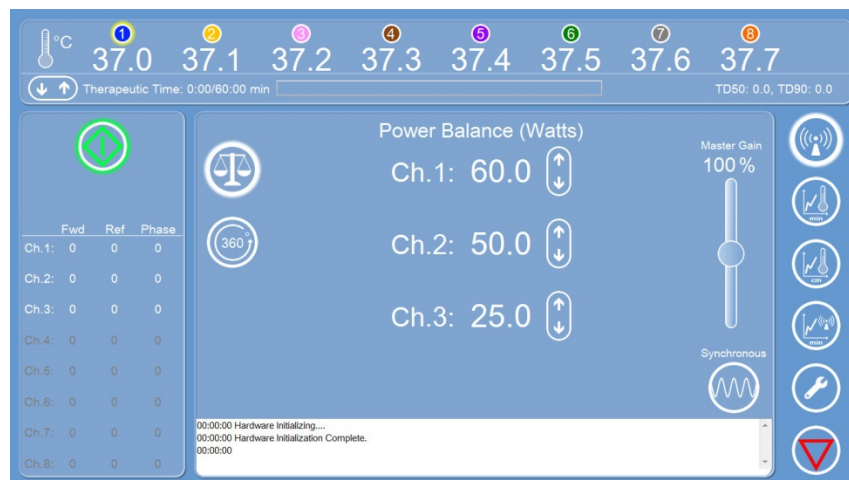

Figure 4-39: Example of RF Controls selection settings and options.

Note that channel 1 has 60 Watts as the **Max watts**, channel 2 has 50 Watts as the **Max watts** and channel 3 has 25 Watts as the **Max watts** based on the channel selection shown in Figure 4-39. The total watts for any channel is 60 Watts when all levels are selected. When one channel and one level within the channel are selected, the total watts available are 25.

When one channel and two levels within the channel are selected, the total watts available are 50.

The total watts available show the maximum setting for the applicator(s) connected to that channel. The **Therapeutic Time** is the total amount of time that any TEMPERATURE SENSOR has been at or above 40°C.

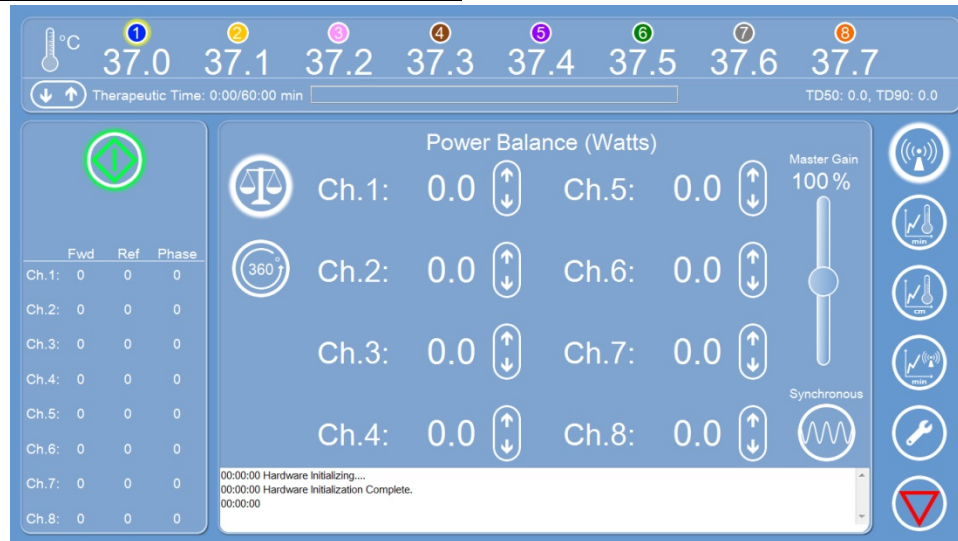### MULTIPLE CHANNEL APPLICATOR TREATMENT SETUP

Figure 4-40: Power Balance Control Screen (Multiple Channel Applicator)

The options and functionality of this screen are the same as previously discussed for the single channel applicator setup. However there are some additional options that are discussed below.

The available treatment setup options for multiple channel applicators are:
- **Therapeutic Time** (refer to Figure 4-15)
- **Temperature Sensor Selection** (refer to Figure 4-15)
- **Treatment Setup Tools: Temperature Controls** (refer to Figure 4-19)
- **Treatment Setup Tools: Sensor Location** (refer to Figure 4-20)
- **Treatment Setup Tools: Thermal Mapping** (refer to Figure 4-23)
- **Treatment Setup Tools: Notes** (refer to Figure 4-24)
- **Treatment Setup Tools: Patient Info** (refer to Figure 4-25)
- **Power Balance Controls:** discussed below (refer to Figure 4-40)
- **Phase Controls:** discussed below (refer to Figure 4-41)

Power Balance and Phase Offsets Icon Buttons – Multiple Channel Applicators

When the **Synchronous Phase Mode** is enabled on the **RF Controls** screen (Figure 4-40), the **Power Balance** and **Phase Offsets** icon buttons will be visible.

POWER BALANCE ICON BUTTON

PHASE OFFSETS ICON BUTTON

The currently active button is designated by a white glow around the button, as illustrated below:

POWER BALANCE ICON BUTTON
ACTIVE / SELECTED

POWER BALANCE ICON BUTTON
INACTIVE / NOT SELECTED

When the **Power Balance** icon button is selected, the **Power Balance** control screen will be displayed (Figure 4-40).

Power Balance Controls– Multiple Channel Applicators

When using multiple channel applicators, each of the microwave power channels previously designated in **RF Channel Power Channel Selection** screen (Figure 4-37) are displayed and a separate power level control for each channel is displayed. The bumper arrows operate the same as previously discussed – the up arrow increases the number and the down arrow decreases the number. The watts per channel can be set equal to or below the allowed maximum. The 8-channel generator system configuration can be set so that each channel can produce a maximum of 60 Watts per channel and a total wattage of 480 Watts. These power levels are set for the output of the generator and a lower amount actually reaches the applicator due to coaxial cable losses in the system.

To preserve the same microwave power balance between the channels, set the **Master Gain**. For example, if the **Master Gain** is being increased and one of the channels reaches the allowed limit of 25 or 50 Watts, the **Master Gain** will not be able to be increased further.

The system computer will automatically control the total allowed power output based on the CONTROL SENSOR setting or the MAXIMUM TEMP setting (refer to **Sensor Selection**).
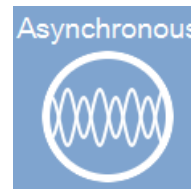
Phase Mode – Multiple Channel Applicators

For multiple channel applicators, the **Synchronous/Asynchronous** icon button permits the control of the relative phase of all of the power channels on the **Phase Offsets** screen (Figure 4-41). When the **Synchronous / Asynchronous** icon button is clicked, it will switch the **Phase Mode**

between **Synchronous** operation and **Asynchronous** operation. The **Phase Mode** can be changed during a treatment.

SYNCHRONOUS MODE ACTIVE

ASYNCHRONOUS MODE ACTIVE

The **Asynchronous Phase Mode** operates the 8 power channels of the generator at slightly different frequencies so that the relative phase between all channels are continually changing. Selecting the **Asynchronous Phase Mode** disables the **Phase Offsets** screen described below. The **Asynchronous Phase Mode** provides simpler operation because overlapping heating fields are simply additive.

The **Synchronous Phase Mode** enables a phased array to have phase control for steering and changing the heating pattern because it changes the physical locations in the patient where the radiated waves are reinforced, causing a location of increased heating. The phase control also causes corresponding regions in the tissue where the heating is decreased. This is explained in greater detail in the multiple channel applicator manuals (such as the MICROWAVE INTERSTITIAL manual).

Phase Offsets (Synchronous Phase Mode Only) – Multiple Channel Applicators

When the **Phase Offsets** icon button is selected, the **Phase Offsets** control screen will be displayed (Figure 4-41). The **Phase Offsets** can be changed during a treatment. When the **Phase Offsets** are all the same, they are called *phase coherent*.

While operating in the **Synchronous Phase Mode**, the RF energy waves radiated from the generator channels are all synchronous with each other, meaning that the same operating frequency is maintained for all of the power channels. When the radiated energy waves from all channels are synchronous and are all set with the same **Phase Offsets** (*Phase Coherent*), they reach their maximum positive voltage at the same instant in time.

When an operator modifies the **Phase Offset** value of any channel on the **Phase Offsets** screen, its phase is no longer coherent with the other channels. This means that the maximum positive voltage for the channel with the unique **Phase Offset** will occur at a slightly different time than that of the other channels which all still have the same **Phase Offset**. All channels will remain synchronous, regardless of the assigned **Phase Offsets**, because all channels in the **Synchronous Phase Mode** will still be operating at a fixed frequency.

Figure 4-41: *Phase Offsets Control Screen (Multiple Channel Applicator) – Synchronous Mode Only*

Starting the Treatment

After setting the **Power Balance** and **Phase Offsets**, the operator will proceed to the remaining setup tools which are the same as previously discussed. At this point, the treatment is ready to begin.

Select the **Start Treatment** icon button and enable the RF power—as previously discussed. This will begin the treatment (Refer to **Start Treatment**).

At the end of the treatment, select the **End Treatment** icon button and the data will be saved, as previously discussed (refer to **RF Enable / Disable** and **End Treatment)**.

NOTE
If at any time during the treatment the operator notices problems or has questions about the screen displays, the operator can select the F12 key. Selecting the F12 key will take a screen shot of the current screen. This screen shot can be retrieved at a later time and sent to Pyrexar Personnel for analysis. (Refer to *Utilities* in this section.)