Section 5 Indications and Use - Treatment Procedures

Indications and Use - Treatment Procedures

This section contains information concerning patient and applicator selection guidelines and pretreatment setup procedures. All operators and clinicians using the BSD-500 System and system applicators must be thoroughly familiar with this information prior to use of the equipment with patients. Applicator information is contained in individual applicator manuals sent with the BSD-500 System purchased.

NOTE
The Patient Selection Guidelines, which include Contraindications, Restrictions, Patient Warnings, and Precautions, should be adhered to for all hyperthermia treatments.

Device Description

The BSD-500 Hyperthermia System delivers therapeutic heat (hyperthermia) to certain surface or subsurface malignant tumors, *i.e*., melanoma, squamous-or basal-cell carcinoma, adenocarcinoma, or sarcoma, by external or interstitial application of electromagnetic energy, and monitors the temperature of target and surrounding tissues by means of invasive temperature sensors. In response to an operator-designated control sensor, the BSD-500 System automatically adjusts power to maintain the operator-set therapeutic temperature, which typically is 42°C to 44°C. The BSD-500 System also automatically limits RF power to prevent any detected temperature from exceeding the operator-set maximum temperature, which cannot be greater than 59.9°C without special measures.

"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. For a given absorbed power, the reduced ability to dissipate heat causes tumor tissue to reach higher temperatures than normal tissue. Therefore, absorbed electromagnetic radiation will preferentially heat tumors that are present in normal tissue and cause them to reach higher temperatures than the surrounding normal tissue. Tumors heated repeatedly 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 applicators which are used to apply therapeutic heat for standard systems available in the U.S. Other multichannel applicators, such as spiral arrays, are available outside the U.S.:

Table 5-1: Local Microwave Applicators Used with the BSD-500 System

Applicator	Model No.	Recommended Frequency (MHz)	Typical Power in Watts (W)
Side-loaded Waveguide	MA-100	915	100
Mini Dual-ridge Waveguide	MA-151	915	40
Interstitial Coaxial	MA-251	915	20 (each)
Side-loaded Waveguide	MA-120	915	250

Other BSD-500 Components include:

[1] A set of microwave applicators for local therapy, as listed in the following table, where 'MHz' signifies Megahertz and 'W' signifies Watts.

[2] A set of non-perturbing, temperature sensors which are insensitive to electromagnetic fields.

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

[4] Various accessories, including blind-end catheters for insertion of sensors, Thermal Mapping, a sensor calibration system, a coupling and cooling water bolus system, a radiation leakage monitor, and various patient and treatment monitoring support.

Indications and Use

The BSD-500 System and PMA Approved external local applicators (MA-100, MA-120, MA-151) and Microwave Interstitial Applicators are 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 ten (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, should be achieved. A desired total thermal dose over the entire course of treatment is 600 minutes, expressed in Thermal Equivalent Minutes (TEM) equal to 42.5°C.This is equivalent to a thermal dose of 300 minutes expressed in Thermal Equivalent Minutes (TEM) equal to 43.0°C, as calculated during treatment by the BSD-500 Hyperthermia System. When hyperthermia is combined with brachytherapy, it is common to treat between one and five times in combination with the internal radiation therapy treatments.

Patient Selection Guidelines

When selecting patients for hyperthermia treatments, consideration should be given to the accessibility of the tumor(s) to be treated and the potential benefit to the patient by treating the tumor(s). There are certain contraindications, restrictions, patient warnings, and precautions specified in FDA approved labeling that must be adhered to when selecting patients for hyperthermia treatment.

Contraindications

There are certain conditions that either limit or prevent the use of hyperthermia as a treatment for cancer. When choosing a patient for treatment, consider each of these conditions before recommending or proceeding with a hyperthermia treatment.

Does the patient have adequate pain perception?

The patient's ability to detect pain is an essential safety mechanism. Hyperthermia is contraindicated in patients whose pain response has been ***significantly*** decreased, both in the treatment area and in the immediate surrounding tissue, by any means—disease, previous surgery, ionizing radiation therapy, regional or general anesthetic, or other conditions. The unimpaired ability of the patient to sense pain is the most effective and all encompassing temperature monitoring system available to clinicians.

Can the tumor be heated without damaging surrounding normal tissue?

Excessive heating of normal tissue is primarily limited by normal blood perfusion; therefore, it is imperative that adequate circulation be present and maintained in all non-malignant tissues within the heating field. Treatment with the BSD-500 System is contraindicated in patients having a known decrease in circulation in normal tissues located within the heated area produced by any means, *i.e*., vasoconstrictive drugs, DIC, ischemia, previous surgery and resultant scar tissue, or any other cause.

Does the patient have any metallic implants?

Metallic implants, *e.g*., cardiac pacemaker, joint prosthesis, or dental braces in the treatment area and tissues near these metal objects might be overheated, lose function, or be adversely affected by EM/microwave radiation. Cardiac pacemakers may become temporarily or permanently disabled by the RF power of the BSD-500 System. Because electromagnetic radiation from the applicators of the BSD-500 System may interfere with the operation of an electronic device, hyperthermia treatments are contraindicated in patients with cardiac pacemakers.

Restrictions

The following are restrictions for use of the BSD-500 System in treating patients and must be adhered to:

- 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

The following warnings indicate possible dangers that could result from a hyperthermia treatment.

- Hyperthermia treatments can be safely and effectively administered only after careful placement of TEMPERATURE SENSORS, as described in this manual, the specific applicator manuals, 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 (EM) from microwave applicators may interfere with the operation of 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 tissue 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

Previous to and during a hyperthermia treatment the operator should observe the following precautions:

- Adhere to the recommended procedures for TEMPERATURE SENSOR placement and selection of CONTROL SENSOR. This will minimize the probability of excessive temperature in normal tissue or of inadequate treatment temperature in the tumor.

- Observe strict adherence to aseptic techniques during the invasive placement of catheters. This will help to avoid infections. The operator should also instruct all patients in the daily care of indwelling catheter sites to prevent sepsis.

- Verify calibration of TEMPERATURE SENSORS daily or as used to ensure accurate temperature monitoring during treatments.

- 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, cardiac pacemakers, joint prostheses, dental braces, etc., during treatment. Such metal objects and tissues near these metal objects may be excessively and preferentially heated.

Adverse Reactions to Treatment

Although hyperthermia has the potential for producing a variety of adverse effects, the adverse effects actually observed have been limited to direct effects of heating upon tissue and indirect effects related to tumor necrosis. Statistical analysis of clinical data obtained from 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 from local microwave applicators used with Pyrexar's Hyperthermia Systems. Adherence to recommended applicator placement techniques and bolusing practices greatly reduces the number of these 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 from local microwave applicators used with Pyrexar's Hyperthermia Systems. The use of surface cooling techniques can diminish this pain.

Infection

Patients have experienced, in 1.8% of tumor sites studied, local and systemic infections resulting from the placement of TEMPERATURE SENSORS used with Pyrexar's Hyperthermia Systems and from the ulceration related to rapid tumor necrosis. These infections have generally been local.

Ulceration

Patients have experienced, in 3.6% of tumor sites studied, ulceration from rapid tumor necrosis following successful hyperthermia treatment with Pyrexar's Hyperthermia Systems.

Such ulceration may produce both fever through toxemia and patient discomfort through drainage and bleeding.

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 of exposure to electromagnetic (EM) radiation. However, none of these adverse reactions were observed during the clinical investigation of local hyperthermia.

Cataracts

Inadvertent heating of the eye may occur during treatment of tumors in the head or neck. A single high dose of microwave radiation or repeated exposure over a long period of time may result in cataract formation, which may not be observable for several weeks.
[Cleary, 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. Feris, 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, DC, 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 systemic 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 of local brain overheating may appear after several (up to 24) hours.

Patient Setup

Since treatments, including setup, induction, and washout time, may require a patient to be immobilized for 45 to 75 minutes; it is important that the patient be comfortably positioned. The operator should have a good assortment of pillows, foam wedges, and bolsters.

Use of Medication

The patient's ability to detect pain is an essential safety mechanism; the use of the BSD-500 System is contraindicated in patients whose pain response has been decreased by the use of regional or general anesthetics. (If necessary, a tranquilizer, such as Valium, can be used in small quantities.) Elevated temperatures may be expected to affect the pharmacologic activity of some drugs with unpredictable results. A patient who is awake with good pain sensibility is a safeguard against thermal burns, especially since it is never possible to have as many temperature sensors as the patient has nerve endings.

Treatment Setup

This section provides guidelines for catheter insertion, external local and interstitial applicator selection, and recommended use of the bolus.

Insertion and Placement of Temperature Sensors

Temperature sensors can be used to monitor tumor tissues by insertion into the tumor using closed-tip plastic catheters. Temperature sensors can also be placed on a thin layer of plastic film, such as Tegaderm, that is placed on the skin surface of the area to be treated to monitor both surface temperatures of the target tissue zone and surrounding normal tissues. The temperature sensors used with the system are not sterile and must be inserted into tissue using a standard, sterile, 16 gauge or 5 French size, sealed (closed-tip), plastic catheter (not supplied by Pyrexar). Skin surface sensors should be placed on top of a thin plastic film that is placed on the skin or placed on intact skin to prevent infection. If sensors are placed on intact skin surfaces, they should be cleaned using sterile wipes before and following use. The placement of and number of temperature sensors used is at the discretion of the physician, based on the tumor being treated and the individual patient characteristics. Pyrexar recommends that a sufficient number of temperature sensors be used to provide the operator with adequate data on the distributed heat pattern.

Closed-tip catheters for insertion of temperature sensors into tissue are commercially available from a number of companies. The required specifications for the insertion catheters are provided below. Any catheter that meets these specifications is acceptable for use as an insertion catheter for Pyrexar's temperature sensors.

Specifications for Insertion Catheter for Temperature Sensors Inserted into Tissue

The catheter must have a 1.09mm (0.043inch) minimum and 1.27mm (0.050inch) maximum Inner Diameter (ID) and a 1.40mm (0.055inch) minimum and 5mm (0.20inch) maximum Outer Diameter (OD). The catheter must be constructed of a plastic or silicone and must meet applicable biocompatibility standards for a part that contacts a patient. The catheter material needs to be classified as an electrical insulator; i.e., non-electrically conductive. Note that if a Foley catheter is used as an insertion catheter for a temperature sensor, the catheter track should have a slick inner surface for ease of insertion of the temperature sensor. Some suppliers of catheters that meet these requirements are: Nucletron (www.nucletron.com), Best Medical (www.teambest.com), Cook Medical

(www.cookmedical.com), Somatex Medical Technologies GmbH, (www.somatex.com) and the N6.0 CE Series manufactured by William Cook Europe ApS (http://www.cookgroup.com), Bjaeverskov, Denmark. Catheters can also be obtained from Dr. Sennewald Medizintechnik GmbH, Munich, Germany (www.sennewald.de).

For pre-sterilized closed-tip insertion catheters, do not use if the integrity of the catheter package has been broken. For closed-tip insertion catheters supplied without pre-sterilization, follow the manufacturer's sterilization recommendations.

WARNING
Temperature sensors and interstitial applicators must never be inserted directly into the tissue or inserted using open-tip catheters.

WARNING
Do not use sterile catheters if the integrity of the sterile catheter package has been compromised.

NOTE
Catheter insertion must be performed by a physician.

CAUTION
Soaking the sensors in sterilization solution is not recommended.

CAUTION
Do not touch the temperature sensor connector with swab, fingers, or other objects. Contamination will degrade the accuracy of the sensor readings.

CAUTION
Inserting the sensor into the calibration well will contaminate the sensor.

CAUTION
Always check the fit of the temperature sensor in the catheter before inserting the sensor. Do not force the insertion of temperature sensor. Damage to the temperature sensor may occur if the sensor is forced into a catheter that is smaller in diameter than the temperature sensor.

CAUTION
All catheters used must meet the EEC 9342 standard.

Stylette Insertion Catheters

Figure 5-1 and 5-2 provide illustrations of the stylette insertion, closed-end catheter that is suitable for use with Pyrexar's temperature sensors. This catheter consists of a plastic sheath that is sharply pointed, and closed at the tissue insertion end; open and wider at the sensor insertion end. This catheter is available in several lengths from Best Industries.

NOTE
The protective plastic tube enclosed in the plastic gripper has no function in inserting the catheter.

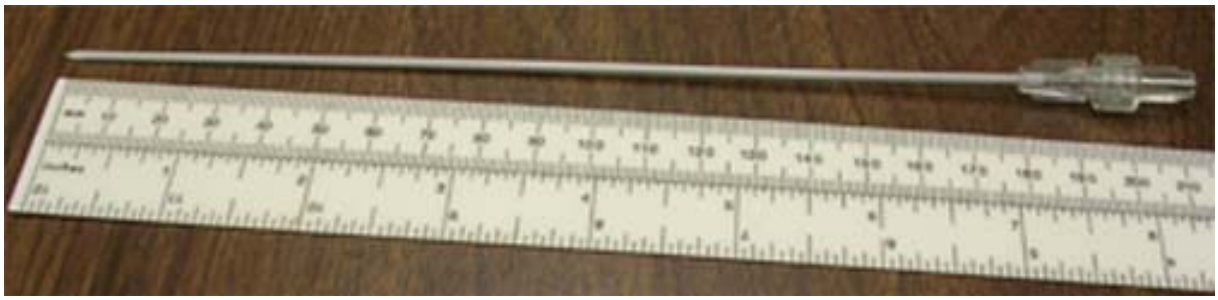


Figure 5-1: *Stylette insertion closed-end catheter*

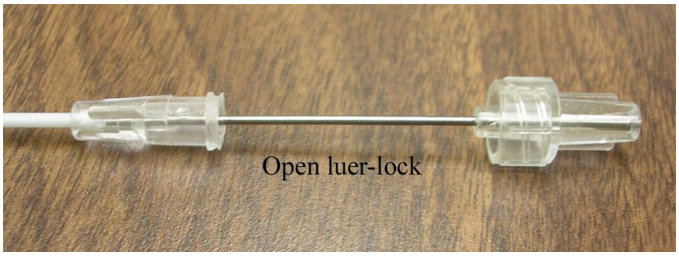


Figure 5-2: *Open luer-lock showing stylette removal.*

Insertion Techniques for Temperature Sensors Inserted Into the Tumor or Tissues

Note that the depths at which temperature sensors must be placed for hyperthermia frequently require that monitoring sites be locally anesthetized prior to catheter insertion.

1. Determine the number of sensors to be used.
2. Check the fit of the temperature sensor in the catheter prior to insertion of the catheter into the patient. If the fit is too snug or too loose, change the gauge or type of catheter to be used.
3. Perform a Calibration or verification of the calibration of the temperature sensors using the Calibration Well prior to insertion.
4. Place the patient in a comfortable position.
5. Prepare the insertion site in accordance with established sterile procedures to ensure sterility of all implanted catheters.
6. Insert the catheters to the desired insertion depth following the Instructions for Use supplied by the catheter manufacturer.

7. Leave at least a 3 cm length of catheter protruding from the tissue surface to help support the sensor after insertion.
8. Secure the catheter to the skin with sutures or tape, if needed to secure the positioning of the temperature sensor during the treatment.
9. Avoid crimping any button clamps around the catheter because this may prevent insertion of the sensor.
10. Insert the temperature sensor or applicator into the catheter prior to the hyperthermia treatment.
11. Removal of the luer-lock hub of the closed-tip catheter may be necessary prior to insertion of the sensor into the catheter if the hub is too tight**.**
12. Insert at least one temperature sensor into the treatment field and designate one sensor as the control sensor. A control sensor should be used during every treatment.
13. Check all temperature readouts after insertion of the temperature sensors into the patient and prior to applying RF power. The initial temperatures from the treatment site allow the operator to make a temperature calibration check using normal body temperature.

After placement of the temperature sensor inside of the insertion catheter, the sensor can be moved along the length of the insertion catheter (mapped) to obtain a temperature distribution along the length of the measurement zone.

Instruct all patients in the daily care of indwelling catheters to prevent sepsis.

Placement Techniques for Temperature Sensors Placed on the Skin Surface

Temperature sensors can also be placed on the skin surface of the area to be treated to monitor both surface temperatures of the target tissue zone and surrounding normal tissues. Temperature sensors are not sterile and should only be placed on intact skin surfaces or on top of a thin layer of plastic film, such as Tegaderm, that has been placed over the surface area, to provide isolation between the skin and the bolus and to provide a surface that can be used to place the temperature sensors. If the sensor is separated from the water bolus by only a thin piece of tape or plastic, the measured temperature will be significantly impacted by the water bolus temperature and thus accuracy may be compromised. Thus, Pyrexar recommends that the tip of the sensor be taped to the skin surface or to a plastic film surface using microfoam surgical tape (approximate size of 5 to 10mm) to provide better thermal insulation from the bolus. If sensors are placed on intact skin surfaces, they should be cleaned using sterile wipes before and following use.

Local Applicator Selection

Local hyperthermia treatments of solid malignant tumors are practically limited to tumors not extending more than about 2.5cm below the skin surface. Three noninvasive, local, external applicators are commonly used with the BSD-500 System -- MA-100, MA-120, and

MA-151. (*Refer to for the individual operator manual for each applicator for specific information on use and heating patterns*.)

The MA-100 and MA-120 Applicators may be expected, under favorable conditions, to reach to a depth of 3.5cm from the tissue surface. The MA-151 Applicator normally reaches to between 2cm and 3cm.

The irradiation and heat volume comparison is indicated in the chart below:

Applicator	Irradiation Area	Volume of Expected Heat
MA-100	10 x 10cm	150cm^3
MA-120	12.5 x 19.5cm	365cm^3
MA-151	2.5 x 2.5cm	20cm^3

Since the BSD-500 System available RF power is approximately 400 Watts, it is usually not practical to use more than a single MA-100 or MA-120 Applicator.

OTHER LOCAL APPLICATOR OPTIONS

The surface contour of the body overlying the tumor may affect the choice of an applicator. Contours that cannot be accommodated by the MA-100 used with the 1cm bolus may require use of the MA-100 with an air gap, the MA-120 Applicator, or an invasive Microwave Interstitial Applicator (MA-251).

It is also possible that an occasional patient will not tolerate the pressure of an MA-100 and water bolus. For complete details on operation, recommended use, and heating patterns, refer to the individual applicator operator manuals.

INVASIVE APPLICATORS

Invasive antenna applicators, MA-251 Microwave Interstitial applicators, are also available for use with the BSD-500 System. For heating volumes larger than about 1cm in diameter, it is customary to use the Microwave Interstitial Applicators in arrays at power levels of about 10 Watts per applicator. For complete details on use and setup of the Microwave Interstitial or other multiple channel applicators, refer to the separate operator manuals provided.

Use of the Bolus and the Water Circulation System (WCS)

Since skin is high-water content tissue and is located closest to the radiating surface of the applicator, it will have a tendency to achieve the highest temperatures if provision is not made to cool the skin surface. For this purpose, water boluses are provided with all external local applicators used with the BSD-500 System. A **WATER CIRCULATION SYSTEM** provides circulating water through the water boluses to maintain the operator specified bolus temperature. The water bolus temperature is usually within the range of 25°C to 40°C and is

kept from exceeding its predetermined limit by circulating cooled water through the bolus of the applicator, as require to maintain the desired temperature.

The bolus also serves as a coupler between the RF energy being emitted from the hyperthermia applicator to the tissue volume being treated. The bolus serves to couple body surfaces of irregular contour to the front surfaces of the radiating applicators. Additional boluses or plastic bags filled with distilled water can be used in those areas where the applicator bolus doesn't give sufficient contact. (Refer to the specific applicator manuals for further information on use of the bolus.)

The following steps describe operations of the WCS. A complete description of the WCS is provided in the Water Circulation System Operator Manual (#10-16348).

1. Disconnect the water lines from the WCS. Ensure all valves are in the "RUN" position.

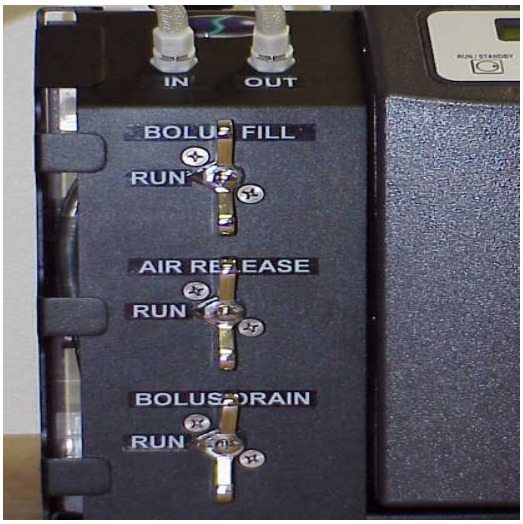


Figure 5-3: *Picture of Manual Control Valves in RUN position*

2. Remove the white cap from main reservoir. Add additional water, if needed to completely fill the reservoir.

Figure 5-4: *Picture of Main Water Tank White Cap.*

3. Replace the white cap on the main reservoir and tighten securely by hand.

4. Turn the middle valve to “AIR RELEASE” and leave in this position until the bottom reservoir is full. Verify that the auxiliary (top) reservoir is approximately half full. **Do not turn the middle valve to “AIR RELEASE” while the pump is operating.**

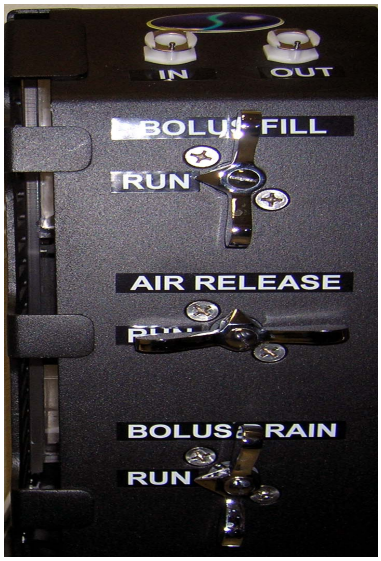


Figure 5-5: *AIR RELEASE Valve in RELEASE position*

5. Turn all valves to “RUN”.

Figure 5-6: *All Valves in RUN position.*

6. Attach the bolus water lines to the “IN” and “OUT” connectors.

7. Turn the Main Power Switch on the lower right side of the system to ON.

8. Set the chiller temperature by pressing the “MENU” button and using the up and down arrows to scroll to the desired temperature. Temperature should not be set below 15°C

or above 45°C. Press the “MENU” button again to return to the “coolant temperature” screen.

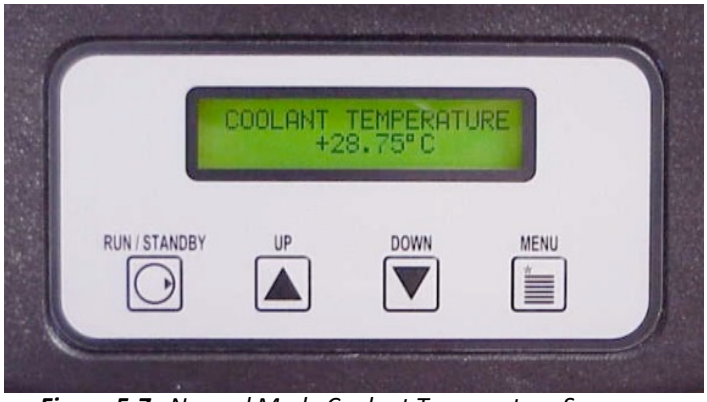


Figure 5-7: *Normal Mode Coolant Temperature Screen*

9. Water flow can be stopped and restarted by repeatedly pressing the “RUN/STANDBY” button.

Figure 5-8: *Standby Screen*

10. To add water to the bolus turn the top valve to “FILL”, once the bolus contains the desired amount of water, turn the valve to “RUN”. **Do not leave the bolus fill operation unattended, as the bolus may rupture.**

***Figure 5-9**: Valve in FILL Position*

11. To remove water from the bolus, turn the bottom valve to “DRAIN”. Once the bolus is empty or has the desired amount of water for storage, turn the valve to “RUN”. Do not leave the bolus drain operation unattended, as the auxiliary tank may be over filled, allowing water to leak past the black cap.

***Figure 5-10:** Valve in DRAIN Position*

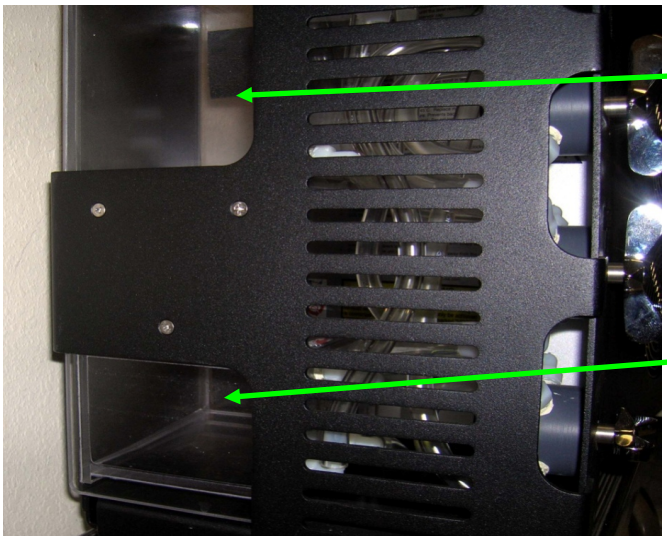
CAUTION

If the FILL or DRAIN Valve is open when a bolus is connected to the water system, it is possible to overfill the applicator's water bolus and cause it to burst or to overfill the Water Reservoir. Ensure that these valves are closed, by being placed in the RUN position, before connecting an applicator and only turn the FILL or DRAIN valve away from the RUN position for the short time required to activate the FILL or DRAIN functions.

12. During treatment, all valves should be in the "RUN" position.

Figure 5-11: *Normal RUN position for all valves*

Figure 5-12 shows the "Auxiliary" tank, which should be about ½ full prior to filling bolus, and the "Air Trap" tank, which should be full prior to turning on the WCS. (See step 4).



Auxiliary tank - should be about ½ full prior to filling bolus and should not be empty during treatment.

Air Trap tank - should be full prior to turning on the WCS and should have minimal air during treatment.

Figure 5-12: *Two Side Water Tanks*

CARE PROCEDURES FOR MA-100, MA-120 AND MA-151 APPLICATOR BOLUS

The flexible bolus membrane of the MA-100, MA-120 and MA-151 Applicators is fragile and special care in handling must be taken to avoid any damage. When the bolus is not being used, place a thin layer of plastic film on the membrane to keep it clean and to prevent damage.

WARNING
The bolus membrane may rupture while in use.

Pyrexar recommends that the treatment site or bolus membrane be wrapped with one or two layers of plastic or rubber film sheeting that is water resistant, such as Tegaderm, to prevent contact of the bolus membrane with the treatment site, particularly if the treatment area is near an open wound or orifice that could be affected by water leakage; *i.e.*, tracheotomy area. The material used should total no more than .002 inches thick and should have a dielectric constant between 2 and 10 at RF frequencies. (All plastic and rubber materials fall within this range.) A drape can also be used and the edges of the drape can be positioned to direct water away from any open wounds. The physician should ensure the sterility of the sheeting or drape, if necessary.

NOTE
Stiff facial hair should be removed prior to treatment to prevent bolus puncture.

Pyrexar supplies a protective cover that should be placed over applicators with flexible bolus membranes when they are not in use. It is also advisable to store any applicators with integral bolus membranes with a small amount of water remaining inside the applicator to prevent any unnecessary stretching of the membrane while not in use. Impacts, puncturing, and localized stress to membrane surfaces should be avoided.

Concomitant Procedures

If the tumor site is located adjacent to the eye, it may be desirable to uncouple the RF energy from the normal tissues near the eye by using air-filled foam to cover the sensitive areas. The air-filled foam will prevent the bolus from coming into close contact with the eye. Wrapping the foam in thin, impervious plastic film prevents saturation with coupling fluids such as sweat or tears.

WARNING
Extreme caution should be exercised when performing a treatment near the eyes. The eyes have low blood flow and may excessively heat. Treatment near the eyes may cause cataract formation.