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THERMAL SCALPEL SYSTEM
MODEL PRECISION 8400 CONTROLLER

Part Number 7013-8400

OPERATING MANUAL

℞ ONLY

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INTRODUCTION

HEMOSTATIX THERMAL SCALPEL BLADES are similar in size, shape, and sharpness to traditional steel scalpel blades; however, Hemostatix blades can be heated to a user-selected temperature appropriate for sealing small vessels as they are cut.

To cut and simultaneously seal blood vessels effectively with minimum tissue damage, the sharp steel cutting edge of a heated scalpel blade must be uniformly maintained at the desired temperature within narrow limits. The Hemostatix Thermal Scalpel System utilizes micro-circuitry incorporated within the blade itself to maintain the cutting edge temperature within the necessary tolerance, selectively delivering additional thermal energy only to those regions of the blade using heat due to tissue contact. By so doing, the Hemostatix Thermal Scalpel System automatically compensates for the varying degrees of heat loss that occur during surgical procedures (depending on the type of tissue being incised and the rate at which cutting is carried out), maintaining the cutting edge in the desired temperature range.

In contrast with electrosurgical devices, the Hemostatix Thermal Scalpel System passes no electrical current through the patient, and there is no sparking or electrical arcing to the tissue. Electrosurgical devices "cut" and/or cauterize using electrical currents which pass through the patient vaporizing tissue at the point of contact and generating heat and tissue damage down the path of the electrical current. The Hemostatix Thermal Scalpel System cuts tissue with a sharpened steel edge, like a conventional cold-steel scalpel blade, and simultaneously seals blood vessels using heat thermally conducted to the tissue from an elevated-temperature blade which is electrically insulated from the patient. By thermally transferring heat from a uniformly- controlled, essentially constant temperature blade, the amount of tissue damage associated with hemostatic cutting is minimized.

INDICATIONS FOR USE

The Hemostatix Thermal Scalpel System is a surgical instrument designed to retain the precise, clean cutting characteristics of the traditional steel scalpel while minimizing blood loss by simultaneously sealing blood vessels as they are cut, with minimum damage to surrounding tissue and virtually no muscle stimulation, using heat thermally conducted to the tissue from an elevated-temperature blade.

Rx Only – CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

CONTRAINDICATIONS

The Hemostatix Thermal Scalpel System is contraindicated in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or OXYGEN or NITROUS OXIDE.

POTENTIAL ADVERSE EFFECTS

Known potential adverse effects include, but are not limited to, thermal injury to tissue, including nerves or other delicate tissues, and inability to effectively provide hemostasis of larger vessels.

SYSTEM WARNINGS

1. EXPLOSION HAZARD – The Hemostatix Thermal Scalpel System is contraindicated in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or OXYGEN or NITROUS OXIDE.
2. NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED.
3. Electrical shock hazard. Do not remove cover. Refer to manufacturer for service.
4. Do not attach unapproved components to the HTSS unit to avoid electrical shock.
5. To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
6. Do not place the HTSS controller unit in direct contact with or within 1 m of any type of electro-surgical equipment. This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment radiates electromagnetic fields and, if not installed and used in accordance with the instructions, may cause harmful interference. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, or is affected by interference

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from other devices, the user is encouraged to try to correct the interference by one or more of the following measures:
- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer.

7. The HTSS's maintenance port is to be used by Hemostatix personnel only. The port is not to be accessed, for any purpose, by the customer. Any attempt to connect via the maintenance port will result in a termination of any warranties that may exist and may damage the unit.
8. The HTSS's auxiliary port is not to be utilized for any other purpose other than to power equipment specifically designed by Hemostatix. Any attempt to plug, non Hemostatix equipment into the output connector may result in damage to the Hemostatix unit thereby terminating any warranties and may result in an unsafe electrical condition, increased electrical emissions, or decreased immunity of the Hemostatix system. Anyone who connects additional equipment via the auxiliary output terminal is therefore responsible for configuring a medical system and is responsible that the newly configured system complies with the requirements of the system standards IEC 60601-1 and IEC 60601-1-2. If the user has questions regarding any connections to the AUX output port, they should contact Hemostatix Medical Technologies.

SYSTEM PRECAUTIONS

1. It is important that the Hemostatix Thermal Scalpel System (HTSS) operator be familiar with the System's Operator's Manual, its precautions, procedures, and safety issues. Read the complete operators manual before using this equipment.
2. Do not position the HTSS unit to make it difficult to remove and insert the unit's separable power cord plug.
3. Hazardous electrical and thermal outputs. This equipment to be used only by qualified medical personnel.
4. Disconnect power to the HTSS before cleaning the unit to avoid electrical shock.
5. To avoid the risk of electrical shock, achieve electrical grounding reliability with proper connections. Connect the HTSS unit to hospital grade receptacles only.
6. Do not touch handle or blade with an active electro cautery electrode.
7. The HTSS should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the HTSS should be observed to verify normal operation in the configuration in which it will be used.
8. Do not attempt to use the HTSS handle immediately after autoclaving. Allow the handle to "cool down" to room temperature prior to use.
9. Medical Electrical Equipment needs special Precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Manual.
10. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
11. Do not operate the HTSS in the presence of Magnetic Resonance Imaging Equipment.
12. The recommended temperature setting for skin incisions is 70° C. For minimal scarring, make the initial skin incision with the scalpel handle in the OFF position. Cutting with the blade unheated will eliminate the possibility of superficial skin scars due to contact with a heated blade.
13. User should select the lowest set point temperature that will afford adequate hemostasis for the maximum anticipated rate of tissue cutting, thereby minimizing unnecessary (thermal) necrosis of tissue.
14. Care should be taken when using the HTSS to dissect around nerves and other delicate structures to avoid thermal injury to these structures.
15. The Model P8400 Hemostatix Thermal Scalpel System needs special precautions regarding EMC and needs to be installed and operated according to the information in the tables presented at the back of this manual and portable and RF communications equipment can affect the operation of the product.
16. All service must be performed by Hemostatix Medical Technology personnel only.
17. Repair and/or modification the HTSS by anyone other than qualified service personnel may significantly compromise the unit's ability to perform effectively and/or void the equipment warranty.
18. Opening the HTSS unit and/or breaking the tamper-proof seal will void the equipment warranty.
19. Hemostatix Thermal Scalpel handles are limited-use, reusable devices. **However, the handles are warranted to be free from**

defects in materials and workmanship only for their first use, NOT any subsequent reuse. With proper care, the multi-use, disposable handle can be cleaned and sterilized for re-use. Some users report they are able to use the handles up to 10 times before replacing, others replace the handles after each use. Reuse is highly dependent on the care afforded the handle during use and any subsequent reprocessing.

20. Electrical contacts in the handle will wear and become oxidized with repeated use. When handle contacts have degraded, the handle will no longer function properly and should be replaced with a new one. Use of a handle with degraded contacts can result in blades running hotter or cooler than the 'temperature setting' value indicated by the controller unit and may adversely affect surgical performance. It is recommended that the handles be reused no more than 10 times, after which the reliability of the handle begins to greatly diminish.
21. If required by local code, connect the HTSS unit to the hospital equalization connector with an equipotential cable.
22. Lists of all compatible components of the Model P8400 Hemostatix Thermal Scalpel System are provided on pages 14 and 15 of this manual. The Handle and Footswitch connector ports on the front of the Hemostatix controller are not to be utilized for any other purpose than to connect to specified compatible components designed by Hemostatix.
23. DO NOT allow saline, or any other fluid, to enter the handle during use. Saline is highly conductive and will interfere with the circuitry inside the handle causing the handle not to work properly.
24. Rx Only – CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
25. USE WITH PLASTIC ADHESIVE DRAPES – When the skin incisions are to be made through a plastic adhesive skin drape, use the scalpel handle and blade in the OFF position (handle switched OFF).
26. USE WITH ELECTROSURGICAL UNITS – DO NOT touch the Hemostatix Thermal Scalpel blade to any electrosurgical (e.g., Bovie) tip as significant damage to the Hemostatix Thermal Scalpel controller unit will result. Keep at least 1 cm between the blade and the electro surgical tip. The Hemostatix Thermal Scalpel CANNOT BE USED to conduct electro-surgical current through clamps.
27. AVOIDING INADVERTENT PATIENT BURNS – DO NOT rest the Hemostatix Thermal Scalpel handle and/ or blade on surgical drapes or on the patient during use. When energized, the blade is sufficiently hot such that patient burns can result from inadvertent patient contact. When the Hemostatix Thermal Scalpel handle is not being used, it is HIGHLY RECOMMENDED that the handle ON/OFF switch be positioned OFF. Care should be taken to avoid unintended activation of COAG mode by inadvertently depressing the COAG switch or foot pedal.
28. GROUNDING – Reliability can only be achieved when the equipment is connected to a properly equivalent receptacle marked "Hospital Grade".
29. STERILIZATION – The Model P8400 Hemostatix Thermal Scalpel Handle is provided STERILE provided the primary sterile packaging is unopened and undamaged. Prior to any subsequent REUSE, the handle MUST BE STERILIZED.
30. Remove and discard of used disposables following local regulations for proper disposal of contaminated material.
31. Electrical shock hazard. Do not remove cover. Refer to manufacturer for service.
32. If the user has any questions regarding compatibility of accessories or cables they should contact Hemostatix Medical Technologies, LLC.

COMPONENT PRECAUTIONS

1. Model P8400 Hemostatix Thermal Scalpel System Blades are provided sterile and ARE NOT intended for reuse.
2. Blades are surgically sharp and used blades may be extremely hot to the touch. Always use a sponge, clamp or hemostat to grasp the used blade. Always follow proper sharps precautions when handling a blade and biohazard disposal techniques when discarding a used blade.
3. DO NOT BEND THE BLADE – Care should be taken not to bend the blade while cleaning, insertion, or reinsertion as the heater leads may become broken and the blade stop working.
4. The HTSS blade's non-stick coating cleans most effectively when hot. Best results are obtained using dry 4x4 gauze when the blade is hot.
5. Accurate calibration can only be achieved if the blade is at room temperature when it is inserted into the handle. If the blade becomes accidentally dislodged from the handle, turn the handle OFF, dip the blade in sterile water to cool it to room

temperature, and then reinsert it.

6. Never use any type of abrasive pad to clean the blades. The abrasives will damage the circuit and render the blade unusable.
7. To remove a blade from the handle, pull the blade straight out of the handle. Bending, twisting or flexing the blade could damage the blade contacts and retainers within the handle causing it to no longer function.
8. If you are getting multiple error messages during blade insertion, try inserting the blade into the handle BEFORE plugging the handle into the controller unit.
9. DO NOT allow saline, or any other fluid, to enter the handle during use. Saline is highly conductive and will interfere with the circuitry inside the handle causing the handle not to work properly.
10. DO NOT use any type of instrument (e.g. hemostats) to insert the blade into the handle as this would damage the blade's imprinted circuitry and render it inoperable.
11. The handle must be energized for the COAG switch to work.
12. DO NOT reuse a handle or cable without first cleaning and re-sterilizing the device(s).
13. DO NOT immerse the handle in liquid of ANY KIND. The handle contains electronic contacts and moisture sensitive electrical components which can be damaged and fail to function if immersed in liquids of any kind. DO NOT allow any solution to penetrate to the interior of the handle.
14. DO NOT use ultrasonic cleaning. Manual cleaning is the recommended (and tested) method of cleaning for the Model P8400 handle and cable.
15. Do not sterilize the handle using the Steris® method or Sterrad® method of sterilization. These sterilization methods are contraindicated for this product and the sensitive electrical components within the handle are damaged by the process.
16. Repeated exposures to steam autoclave temperatures of 132° C (270° F) and above in an "unwrapped" for "flash" steam autoclave cycle may result in discoloration and/or deformation of the handle parts, cable, or connectors; thereby, reducing the life of the devices.
17. Handles can only be re-sterilized using the steam autoclave parameters contained in this Manual. For steam autoclaving, the handles are to be "wrapped" during steam autoclaving.
18. External Cleaning is the only controller maintenance that can be performed by the user.
19. Servicing the controller unit by other than and qualified service personnel approved by Hemostatix Medical Technologies, LLC renders the Warranty void.
20. Before cleaning the controller, detach the controller unit from the AC power source.
21. DO NOT immerse the console.
22. DO NOT use an abrasive cloth or cleaners, especially on the display screen.
23. DO NOT dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations.

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SYSTEM DESCRIPTION

MODEL P8400 HEMOSTATIX THERMAL SCALPEL SYSTEM

The Model P8400 Hemostatix Thermal Scalpel System consists of four components:

1. **CONTROLLER** – An electronic power supply/controller that energizes the blade and provides various automatic calibrations, sensing, and control functions. It has user controls with visual and audible indications of instrument status.

2. **MULTI-USE, DISPOSABLE HANDLE** – A multi-use, disposable handle connected to the instrument with a light-weight, flexible electrical cable for holding the disposable scalpel blades. The handle can be used to set the temperature of the blade and to provide a COAG mode when necessary. With proper care, the multi-use, disposable handle can be cleaned and sterilized for re-use. Some users report they are able to use the handles up to 10 times before replacing, others replace the handles after each use. Reuse is highly dependent on the care afforded the handle during use and any subsequent reprocessing. NOTE: Electrical contacts in the handle will wear and become oxidized with repeated use. When handle contacts have degraded, the handle will no longer function properly and should be replaced with a new one. Use of a handle with degraded contacts can result in blades running hotter or cooler than the 'temperature setting' value indicated by the controller unit and may adversely affect surgical performance. It is recommended that the handles be reused no more than 10 times, after which the reliability of the handle begins to greatly diminish.

3. **DISPOSABLE BLADES** – Various sizes and shapes of sterile disposable scalpel blades are available which are similar in size and shape to conventional cold-steel scalpel blades. Blades are single-use only and should never be reused. The Hemostatix blades incorporate heating and temperature-sensing micro-circuitry which provides heat for hemostasis and sensing feedback to the controller. DO NOT bend the blade – Care should be taken not to bend the blade while cleaning, insertion, or reinsertion as the heater leads may become broken and the blade stop working.

4. **FOOTSWITCH** – An optional footswitch (REF 7013-8410) is available which allows the surgeon to set the desired temperatures of the blades as well as activate CUT or COAG modes. The footswitch has two modes: (1) CUT/COAG and (2) TEMP UP/DOWN. Switching from mode (1) to mode (2) and vice-versa is controlled by depressing the black MODE button on the top of the footswitch. When in the TEMP UP/DOWN mode, depressing and releasing the left (yellow) pedal will decrease the set point temperature by 10° C; whereas, depressing and releasing the right (blue) pedal will increase the set point temperature by 10° C. When in the CUT/COAG mode, depressing and holding the left (yellow) pedal will energize the scalpel blade to come to the selected temperature. Similarly, depressing and holding the right (blue) pedal will energize the scalpel blade to come to the COAG temperature of 300° C.

IMPORTANT FEATURES

SURGICAL FEATURES

1. **Retains the Precision of Surgical Steel** – Thermal Scalpel blades are similar in size and shape to conventional scalpel blades and have the same sharp surgical steel cutting edges to retain the precision and "feel" of the conventional scalpel when cutting.

2. **Reduces blood Loss** – The Thermal Scalpel conducts heat from

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its sharp, heated blade to a thin layer of tissue adjacent to the cutting edge. The heat seals most blood vessels (less than 2mm in diameter) as they are cut, producing near- bloodless incisions with the precision of sharp surgical steel.

3. **Maintains a Clean, Dry Surgical Field** – The Thermal Scalpel seals as it cuts tissue, largely eliminating the flow of blood into the incised area. This clean, clear operative field contributes to improved precision and visibility at the incision site and reduces the need for "mop-up" procedures.

4. **Minimizes Tissue Damage** – Hemostatic incisions made with the Thermal Scalpel result in visibly less tissue damage than when electrosurgical units are used. Independent experiments have shown that the breaking strength and infection resistance of healing wounds made with the Hemostatix Thermal Scalpel were essentially equal to those obtained with conventional cold-steel scalpels and better than those made with electrosurgical units.

5. **Shortens Surgery** – Experience indicates that a net reduction in overall operating time generally results when an appropriate technique is developed and with sufficient experience in the use of the Thermal Scalpel.

6. **Eliminates Patient Currents and Muscle Stimulation** – Since no electrical current passes through the patient when using the Hemostatix Thermal Scalpel System, a grounding pad is not needed and the risk of accidental electrical current burns at grounding sites is eliminated. Muscle stimulation associated with passing electrical currents through the body is also eliminated, improving surgical precision.

SYSTEM FEATURES

1. **Sterile, Disposable Scalpel blades** – Hemostatix Thermal Scalpel blades are individually packaged sterile and ready for use. They are discarded when they become dull, just like conventional cold-steel scalpel blades. Blades are single-use only and should never be reused.

2. **Automatic Calibration** – The Hemostatix Thermal Scalpel System automatically calibrates each blade, typically within 6 – 12 seconds of its insertion into the handle. The blade is ready to be energized as soon as the calibration is complete.

3. **User-Selectable Cutting Temperature** – The user is able to select the desired cutting temperature over a range of 70° C to 300° C in increments of 10° degrees C using the front panel "Temperature Up" ▲ or "Temperature Down" ▼ buttons OR by using the UP/DOWN arrows on the handle. Thermal COAG Mode – The Hemostatix Thermal Scalpel System provides a high temperature Thermal COAG Mode, suitable for sealing vessels not sealed as they are cut. The black bar on the handle provides convenient switching between the selected cutting and Thermal COAG temperatures. The Thermal COAG Mode is preset to 300° C.

4. **Audible Signals** – The controller provides audible tones to indicate certain system functions and status. The signal volume can be turned up or down by the rotating switch on the back of the unit. The audible functions include: pressing any button on the console or handle, blade heating, blade cooling, Thermal COAG, and blade removal. Also, a tone is heard when there are certain problems with the blade(s).

5. **Visual Displays** – The Model P8400 controller has one display on the front of the unit.

6. **Equipotential** – Uniform potential. Means for eliminating noise or interference with sensitive equipment by application of a potential equalization conductor. If required by local code, connect the HTSS unit to the hospital equalization connector with an equipotential cable.

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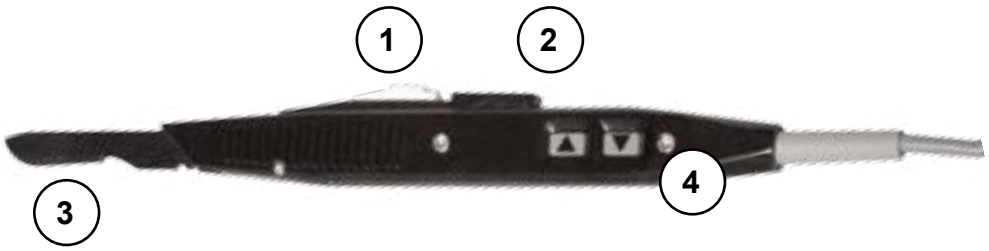
HANDLE CONTROLS AND INDICATORS



1. **ON/OFF SWITCH** - Sliding the white ON/OFF switch rearward (toward the cable) mechanically latches the switch and activates the blade. Tangerine dot is visible when switch is in the "ON" position. Sliding the switch forward (toward the blade) deactivates the blade.

2. **THERMAL COAG SWITCH** - Depressing the rear portion of the black bar activates the Thermal COAG mode as long as the switch is depressed. Releasing the switch causes the temperature to revert to the original temperature setting.

3. **BLADE** - Manually insert connector end of blade into handle until the blade is firmly seated. NOTE: The handle should be in the "OFF" position before inserting the blade.

4. **TEMPERATURE CONTROL SWITCHES** - With the ON/OFF switch in the "OFF" (forward) position, depressing the UP '▲' arrow temperature control switch increases the temperature. Depressing the down '▼' arrow temperature control switch decreases the temperature. The temperature changes as long as the switch is depressed. The temperature remains at the last setting when the switch is released.

OPERATING INSTRUCTIONS

HANDLE, BLADE, AND FOOTSWITCH COMPATIBILITY

1. **HANDLE Compatibility** – The Model P8400 Hemostatix Thermal Scalpel Controller (REF 7013-8400) is compatible with the following Hemostatix Thermal Scalpel handle/cable configurations:

   - REF **7013-8050** – Model P8400 Handle w/ Integral Cable Assembly – Sterile.

2. **BLADE Compatibility** – The Model P8400 Hemostatix Thermal Scalpel Controller is compatible with the following thermal scalpel blades:

   - REF **7013-5710** – #10 Blade - Sterile Disposable - Quantity 24
   - REF **7023-5710** – #10 Blade - Sterile Disposable - Quantity 10
   - REF **7023-5712** – #12 Blade - Sterile Disposable - Quantity 10
   - REF **7013-5715** – #15 Blade - Sterile Disposable - Quantity 24
   - REF **7023-5715** – #15 Blade - Sterile Disposable - Quantity 10

3. **FOOTSWITCH Compatiblity**

   - The Model P8400 Hemostatix Thermal Scalpel Controller is compatible with the optional Footswitch (REF **7013-8410**).

4. **SYSTEM CHECKOUTS NOTE**: The Model P8400 controller unit is rated 100-240 VAC ± 10%, 50 - 60 Hz ± 1 Hz.

5. **POWER ON**

   Turn on POWER to the system by placing the POWER SWITCH located at the front lower left side of the controller console in the UP or 'I' position.

   The unit will briefly (less than 10 seconds) undergo a self-test.

   Once the self-test is completed, the display will illuminate with the default set-point temperature setting (70° C) and prompt the user to connect the handle.

6. **POWER OFF**

   Turn off POWER to the system by placing the POWER SWITCH located at the front lower left side of the controller console in the DOWN or '0' position.

7. **HANDLE INSERTION**

   With the console powered ON and the handle ON/OFF switch in the OFF position, attach the handle cable to the

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controller console by aligning the arrow on the handle cable connector with the arrow on the mating front panel connector and inserting it into the front panel receptacle.

The Model P8400 controller unit is designed to count the number of times a particular handle has been energized. When a handle is detected by the unit, the unit reads the handle cycle count stored in the handle's memory. If a new handle (first time use) is detected, the console will increment the handle use counter value by one and write the new value to the handle's memory. If a reprocessed handle is detected, meaning that there has been a console power OFF- ON cycle since the last count increment, the unit will increment the handle use counter value by one and write the new value to the handle's memory.

NOTE: Hemostatix Thermal Scalpel handles are limited- use, reusable devices. **However, the handles are warranted to be free from defects in materials and workmanship only for their first use, NOT any subsequent reuse.** With proper care, the multi-use, disposable handle can be cleaned and sterilized for re-use. Some users report they are able to use the handles up to 10 times before replacing, others replace the handles after each use. Reuse is highly dependent on the care afforded the handle during use and any subsequent reprocessing.

NOTE: Electrical contacts in the handle will wear and become oxidized with repeated use. When handle contacts have degraded, the handle will no longer function properly and should be replaced with a new one. Use of a handle with degraded contacts can result in blades running hotter or cooler than the 'temperature setting' value indicated by the controller unit and may adversely affect surgical performance. It is recommended that the handles be reused no more than 10 times, after which the reliability of the handle begins to greatly diminish.

Beginning with the 5th reuse, the controller unit will display the number of uses on the controller unit display screen. Once the number of uses has reaches 10, the controller unit will display a message indicating that the maximum number of recommend uses for that particular handle has been reached and that the handle should be discarded after use and replaced with a new handle. If the same handle is used again, the controller unit will alert the user that the maximum number of recommended uses has been exceeded and the handle should be replaced.

8. BLADE INSERTION AND CALIBRATION

Manually insert the squared-off end of a new blade into the handle in one continuous motion until the blade is firmly seated in the handle. If there is a pause during blade insertion, an error message may appear. Once the blade is successfully inserted into the handle, the controller unit will begin calibrating the blade. Calibration should be completed within 10 seconds. If calibration is successful, the controller unit will display a message indicating that the blade has been calibrated.

NOTE: If you are getting multiple error messages during blade insertion, try inserting the blade into the handle BEFORE plugging the handle into the controller unit.

NOTE: DO NOT use any type of instrument (e.g. hemostats) to insert the blade into the handle as this would damage the blade's imprinted circuitry and render it inoperable.

If calibration is not successful, an error message will appear on the controller unit's display. In that case, remove the blade and re-insert it into the handle in one continuous motion. If the controller unit continues to display an error message that the blade is not calibrated, insert another new blade repeating steps.

If calibration with a second blade is not successful, then the controller unit is unable to read the blade via the handle. Replace the handle and reinsert a blade.

9. USING THE HEMOSTATIX THERMAL SCALPEL

With the console powered ON, the handle attached and a blade inserted into the handle, VERIFY that the console display reads 70° C.

With the handle switched OFF, the blade temperature can be elevated or lowered in increments of 10° C by using the UP '▲' or DOWN '▼' arrows on the side of the handle, or the front of the controller unit, or by using the optional footswitch pedals (See Optional Footswitch Controls). The handle temperature controls work only when the handle is switched OFF.

Slide the handle ON/OFF switch to the ON position to expose the tangerine-colored dot. The handle is now activated and the blade will be heated to the displayed temperature setting.

To activate the thermal COAG mode, depress the Thermal COAG switch on the top of the handle. The blade temperature will approximate 300° C in the thermal COAG mode.

NOTE: The handle must be energized for the COAG switch to work.

10. USING THE OPTIONAL FOOTSWITCH

The footswitch has two modes: (1) CUT/COAG and (2) TEMP UP/DOWN. Switching from mode (1) to mode (2) and vice-versa is controlled by depressing the black MODE button on the top of the footswitch.

When in the TEMP UP/DOWN mode, depressing and releasing

the left (yellow) pedal will decrease the set point temperature by 10° C; whereas, depressing and releasing the right (blue) pedal will increase the set point temperature by 10° C.

When in the CUT/COAG mode, depressing and holding the left (yellow) pedal will energize the scalpel blade to come to the selected temperature. Similarly, depressing and holding the right (blue) pedal will energize the scalpel blade to come to the COAG temperature of 300° C.

UPGRADE FEATURES

1. **MAINTENANCE PORT** – Located on the rear of the unit, this port allows easy diagnostic access for Hemostatix personnel as well as easy future software upgrade access via a RS232 computer port. The maintenance port is covered with a maintenance port cover.

WARNING: **The maintenance port is to be used by Hemostatix personnel only. The port is not to be accessed, for any purpose, by the customer. Any attempt to connect via the maintenance port will result in a termination of any warranties that may exist and may damage the unit.**

2. **AUXILIARY OUTPUT** – Also located on the rear of the unit, this port is designed to power future Hemostatix add on modules. The purpose of the auxiliary output connector is to potentially offer other modules (i.e. irrigation, suction, etc.) that would complement the existing Hemostatix technology.

WARNING: **The auxiliary port is not to be utilized for any other purpose other than to power equipment specifically designed by Hemostatix. Any attempt to plug, non Hemostatix equipment into the output connector may result in damage to the Hemostatix unit thereby terminating any warranties and may result in an unsafe electrical condition, increased electrical emissions, or decreased immunity of the Hemostatix system. Anyone who connects additional equipment via the auxiliary output terminal is therefore responsible for configuring a medical system and is responsible that the newly configured system complies with the requirements of the system standards IEC 60601-1 and IEC 60601-1-2. If the user has questions regarding any connections to the AUX output port, they should contact Hemostatix Medical Technologies.**

SURGICAL USE & TECHNIQUES

1. CUTTING TEMPERATURES

- **SKIN** – The recommended temperature setting for skin incisions is 70° C. For minimal scarring, make the initial skin incision with the scalpel handle in the OFF position. Cutting with the blade unheated will eliminate the possibility of superficial skin scars due to contact with a heated blade (See WARNINGS and PRECAUTIONS).

- **OTHER TISSUES** – For other tissues, the appropriate temperature setting is typically between 180° C and 300° C.

2. INFLUENCE OF CUTTING SPEED ON HEMOSTASIS

In practice, the surgeon generally selects the lowest set point temperature that will afford adequate hemostasis for the

maximum anticipated rate of tissue cutting, thereby minimizing unnecessary (thermal) necrosis of tissue. The determination of the appropriate set point temperature is usually determined by the surgeon by raising the set point temperature adequate hemostasis is achieved. Alternatively, the surgeon can, at any selected point temperature, modulate the speed of tissue cutting according to the vascularity of the tissue being incised.

3. SEALING BLEEDERS

- The heat from the Hemostatix Thermal Scalpel blade will seal most (less than 2mm in diameter) blood vessels as they are cut.
- For a vessel not sealed as it is cut, promptly use the blade's heat to seal it by exerting light pressure on the bleeder with the flat side of the blade.
- For larger bleeders, activate the Thermal COAG mode by depressing and holding down the Thermal COAG switch (or optional footswitch pedal) and holding the flat side of the blade on the bleeder until hemostasis is achieved.

4. MAINTAIN A DRY OPERATIVE FIELD

- The most effective use of the Hemostatix Thermal Scalpel thermal energy such that bleeding does not begin. This is done by making incisions using long, relatively slow, authoritative strokes (rather than short, "choppy" strokes) to maintain constant and meticulous hemostasis at every step, and prevent the onset of bleeding.
- Bleeding vessels are sealed by the direct contact of the hot blade to tissue, thus providing heat transfer to the tissue at the bleeding site. Accordingly, if pools of blood occur from vessels not sealed as they are cut, suction or sponge the area before applying the Hemostatix Thermal Scalpel blade to seal the bleeders. Heat from the blade dissipates in pools of blood and cannot get through these pools to reach the tissue to seal the bleeder. Pools of blood simply coagulate on the blade, thermally insulating it.

5. CHANGING THE BLADE

If the blade becomes dull or the change blade message appears on the controller display, switch the handle ON/OFF switch to off and wait for the temperature display to turn Green indicating the blade is safe to handle. Replace the dull or damaged blade with a new blade.

CAUTION: To remove a blade from the handle, pull the blade straight out of the handle. Bending, twisting or flexing the blade could damage the blade contacts and retainers within the handle causing it to no longer function.

CAUTION: Used blades are surgically sharp and may be extremely hot to the touch. Always use a sponge, clamp or hemostat to grasp the used blade. Always follow proper sharps precautions when handling a blade and biohazard disposal techniques when discarding a used blade.

6. CLEANING THE BLADE DURING USE

Clean any coagulated blood or tissue debris from a HOT blade by LIGHTLY wiping the blade using DRY 4x4 gauze. Using WET gauze will cool the blade causing the blood and coagulum to adhere to the surface of the blade. Only light pressure is needed. Excess pressure will result in the bending of the blade and the subsequent damage to the blade electrical circuit.

NOTE: The Teflon non-stick coating cleans most effectively when hot. Best results are obtained using dry 4x4 gauze when the blade is hot.

NOTE: If the blade becomes accidentally dislodged from the handle, turn the handle OFF, dip the blade in sterile water or saline solution to cool it to room temperature, and then reinsert it. Accurate calibration can only be achieved if the blade is at room temperature when it is inserted into the handle.

CAUTION: Care should be taken not to bend the blade while cleaning, insertion, or reinsertion as the heater leads may become broken and the blade stop working.

CAUTION: Never use any type of abrasive pad to clean the blades. The abrasives will damage the circuit and render the blade unusable.

HANDLE REPROCESSING

1. HANDLE / CABLE CLEANING

- **NOTE: Hemostatix handles are warranted to be free from defects in materials and workmanship only for their first use, NOT any subsequent reuse.**
- **DO NOT reuse a handle or cable without first cleaning and re- sterilizing the device(s).**
- **DO NOT immerse the handle in liquid of ANY KIND. The handle contains electronic contacts and moisture sensitive electrical components which can be damaged and fail to function if immersed in liquids of any kind.**
- **DO NOT allow any solution to penetrate to the interior of the handle.**
- **DO NOT use ultrasonic cleaning. Manual cleaning is the recommended (and tested) method of cleaning for the Model P8400 handle and cable.**

SINCE THE DEVICES CANNOT BE IMMERSED, IT IS IMPORTANT TO ADHERE TO THE FOLLOWING INSTRUCTIONS:

Cleaning should begin as soon as possible following a procedure. Prepare an enzyme solution (e.g., Klenzyme™) and a detergent solution (e.g., Manu-Klenz™) as recommended by the manufacturer. An enzyme solution is not a cleaner. An enzyme solution is intended to break down blood and bodily fluids (i.e., protein), and thus facilitate cleaning. Detergents contain wetting and emulsifying agents that suspend soil and prevent the formation of insoluble compounds on the device or on the surface of the cleaning solution.

a. Gently wipe the surface of the device with a sponge or towel that has been moistened with the enzyme solution.

b. Rinse the blade receptacle of the handle thoroughly with the enzyme solution and use a soft bristle brush to remove any gross soil, paying attention to crevices and other hard-to-clean areas. The use of pipe cleaners or cotton swabs should be avoided since they tend to fray, leaving behind particles inside the blade receptacle. Enzyme solutions are themselves protein substances and must be thoroughly removed with a detergent.

c. Gently wipe the surface of the device with a sponge or towel that has been moistened with a detergent solution and clean the blade receptacle with a soft bristle brush and the detergent solution. Rinsing with lukewarm water is necessary to remove all traces of detergents and extraneous debris.

d. Carefully examine the device for any adherent visible soil (e.g., blood, protein).

e. Following cleaning, shake the device to remove excess water and wipe the handle and cable with a dry cloth.

2. HANDLE / CABLE STERILIZATION

Before re-sterilization:

a. Inspect to ensure there are not breaks in the cable and there is no foreign material in the blade receptacle or the handle / cable connectors.

b. Ensure that the handle On/Off switch is in the ON or OFF position (not in between).

c. Loop the cable cord assembly into approximately seven inch diameter circles and place in appropriate packaging material for the type of sterilization to be performed.

3. STEAM AUTOCLAVE PARAMETERS FOR HANDLES / CABLES

The Hemostatix Thermal Scalpel handle and/or cable can only be sterilized using the following method: STEAM AUTOCLAVE.

NOTE: DO NOT STERILIZE THE HANDLE USING THE STERIS® METHOD OR STERRAD® METHOD OF STERILIZATION. These sterilization methods are contraindicated for this product and the sensitive electrical components within the handle are damaged by the process.

NOTE: Repeated exposures to steam autoclave temperatures of 132° C (270° F) and above in an "unwrapped" for "flash" steam autoclave cycle may result in discoloration and/or deformation of the handle parts, cable, or connectors; thereby, reducing the life of the devices.

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NOTE: For steam autoclaving, the handles are to be "wrapped" and the recommended parameters used as follows:

	GRAVITY DISPLACEMENT CYCLE 1	GRAVITY DISPLACEMENT CYCLE 2	PREVACUUM CYCLE
TEMPERATURE	132° C (270° F)	121° C (250° F)	132° C (270° F)
DWELL TIME	15 MIN	30 MIN	4 MIN
DRYING TIME	30 MIN	30 MIN	30 MIN

A complete drying cycle should be performed to reduce/prevent eventual corrosion from the steam sterilization process.

MAINTENANCE

External Cleaning is the only controller maintenance that can be performed by the user.

- The console may be wiped down with a cloth dampened with alcohol, mild soap, or detergent. Take care not to get liquids into the inside of the controller unit.
- **DO NOT** immerse the console.
- **DO NOT** use an abrasive cloth or cleaners, especially on the display screen.

NOTE: Servicing the controller unit by other than and qualified service personnel approved by Hemostatix Medical Technologies, LLC renders the Warranty void. For any service or warranty questions, please call Hemostatix Medical Technologies, LLC.

NOTE: Before cleaning the controller, detach the controller unit from the AC power source.

SERVICING

The Model P8400 Hemostatix Thermal Scalpel System consists of the controller unit, a handle, and a blade. If a problem is encountered, any of the three may be the cause; therefore, it is important when returning a controller unit for servicing to also return the handle(s) and blade(s) that were in use when the problem occurred.

NOTE: Servicing the controller unit by other than and qualified service personnel approved by Hemostatix Medical Technologies, LLC renders the Warranty void. Before returning a controller unit for servicing, please call, please call Hemostatix Medical Technologies, LLC to obtain a Return Material Authorization (RMA) and instructions as to how and where to send the controller unit and accessories.

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WARRANTY

HEMOSTATIX MEDICAL TECHNOLOGIES, LLC (HMT) warrants to the original purchaser that reasonable care has been used in the manufacture of the MODEL P8400 HEMOSTATIX THERMAL SCALPEL SYSTEM (HTSS) CONTROLLER and that, when properly used, it will be free from defects in material or workmanship for a period of one (1) year after the date of shipment from HMT or any of its authorized distributors.

NOTE: Hemostatix scalpel handles and blades are warranted to be free from defects in materials and workmanship for a period of SIXTY (60) days from the date of shipment and then only for their FIRST (1ST) USE. Because reprocessing of handles is highly variable, we DO NOT warrany Hemostatix handles after reprocessing. Hemostatix blades are indicated for single-use only.

The sole and exclusive remedy with respect to any MODEL P8400 HTSS or any portion thereof found within its warranty period not to meet these standards is that after return to and examination by HMT, HMT will without charge at its option either repair or replace that portion of the MODEL P8400 HTSS found to be defective. This warranty shall not apply (a) if that portion of the MODEL P8400 HTSS has been repaired or altered by anyone other than qualified service personnel approved by HMT or altered in any way which, in HMT's judgment, affects its usability or reliability; or (b) if the sterile lot or serial number has been altered, effaced, or removed; (c) if the fault has been caused by abnormal conditions of operation or misuse including, but not limited to: dropping the controller unit; opening the controller unit; and/or permitting electrical contact with an active electro surgical (e.g., Bovie) electrode; operating the unit within 1 m of another electrosurgical controller unit; or, (d) if in the case of the scalpel blades or handles, the scalpel blades or handles have been reprocessed and reused.

Except for the replacement of fuses, which can be accessed without opening the controller unit's enclosure, any warranty, implied or expressed, is considered void if the tamper-proof seal on the controller unit's enclosure is found to be broken. In all such cases, HMT's determination will prevail and any repairs or replacements, if requested, will be billed at HMT's prevailing normal rates. If so requested, estimates will be submitted before work is started.

NOTE: An RMA# issued by HMT must be obtained before any part of the MODEL P8400 HTSS is returned.

NOTE: Handles and blades being returned must be cleaned, sterilized, and packaged in sterile packaging with labeling which verifies the sterility of the handle and/or blade prior to return to HMT. Any handle and/or blade not properly cleaned, sterilized and packaged as described in this warranty will be disposed of and no warranty will be in effect.

The foregoing express warranty, as conditioned and limited, is in lieu of and excludes all other warranties not expressly set forth herein whether expressed or implied by operation of law or otherwise including, but not limited to, any implied warranties or merchantability or fitness for particular purpose. HMT shall not be liable for any incidental or consequential loss, damage, expense or liability direct or indirect with respect to this product. HMT neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product.

SPECIFICATIONS

Model P8400 Hemostatix Thermal Scalpel Controller Unit

NOTE: The MODEL P8400 HEMOSTATIX THERMAL SCALPEL SYTEM is suitable for continuous operation.

Patient Leakage Current (From Patient Connection to Earth)	≤ 100 microamperes AC – Normal Condition ≤ 500 microamperes AC – Single Fault Condition ≤ 10 microamperes DC – Normal Condition ≤ 50 microamperes DC – Single Fault Condition
Blade Temperature Settings	• VARIABLE, set by USER and displayed on front panel display as TEMPERATURE SETTING ranging from 70° C to 300° C in 10° C increments.
Room Operating Environment	• 10° C to 30° C (Note: Blade temperature is indexed from room temprature • 30% - 75% Relative Humidity - Non-condensing • 700 to 1060 hPA
Transport & Storage Environment	• -20° C to +70° C • 10% - 100% Relative Humidity • 500 to 1060 hPA
Moisture Protection	• 7013-8400 Controller Unit - Ordinary Rating • 7013-8410 Foot pedal - IPX8
Console Size	• Approximately 7.0 in x 10.9 in
Console Weight	• Approximately 7.25 lbs. (3.3 kg) without power cord
Power Requirements	• 100-240VAC± 10% • 50 - 60 Hz ± 1 Hz
Power Input	• 1 A
Power Output	• 60 W dc
Fuses	• T 2A, H 250V (3AB Slo Blo, 2 Amp, glass body, 6.35 x 31.75 mm) (Quantity 2)
Power Cord	• Approx. 10 ft. Hospital Grade
HEMOSTATIX THERMAL SCALPEL SYSTEM is classified as a Type BF Applied Part, Class I electrical device and is certified to the following:	• IEC 60601-1 (3rd Edition): 2005 + CORR. 1 (2006) + CORR. 2 (2007) • CAN/CSA-C22.2 No. 60601-1 (2008) • IEC 60601-1-2:2007 (Mod)

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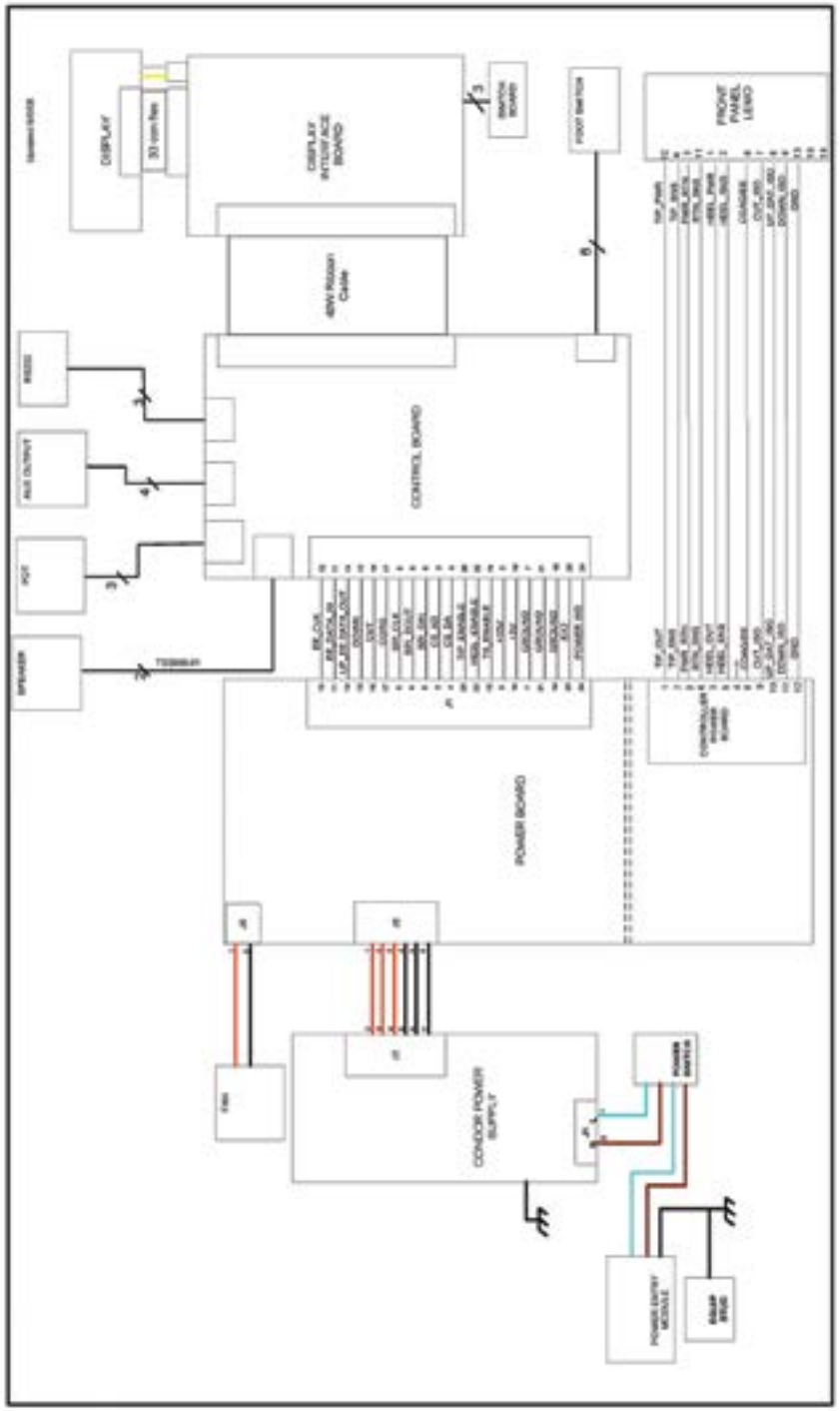

SPECIFICATIONS

Model P8400 Hemostatix Thermal Scalpel System Handle - Model 8050

MODEL P8400 HEMOSTATIX THERMAL SCALPEL SYSTEM BLADES - SERIES 57XX

Model P8400 Hemostatix Thermal Scalpel System Blades are available in the following configurations (similar to cold, stainless steel scalpel blades): No.10, No. 12, and No. 15 blades.

Model P8400 Hemostatix Thermal Scalpel System Blades are provided sterile and ARE NOT intended for reuse.

Handle Switches:	Latching On/Off, momentary Thermal Coag & Temperature switches
Initial Sterilization	Ethylene Oxide Gas
Recommended Re-sterilization Method(s):	Steam Autoclave

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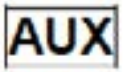
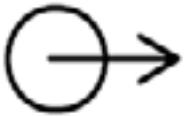
	Type BF applied Part
	Equipotentiality
	On (power connection to mains)
	Off (power disconnection from the mains)
	Alternating current
	Serial number
	Reference number
	Manufacturer
	Manufacturing date
	Maximum DC Output

	Caution

	Authorized Representative in the European Community
	Temperature decrease
	Temperature increase
	Volume increase / decrease
	Auxilliary output port
	Auxilliary serial port
	Output handle connector
	CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
	Fuse
	Foot pedal connector

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	Do not dispose of this product in unsorted municipal waste stream. Dispose of this product according to Local Regulations.
	Follow instructions for use
	Consult instructions for use
	Medical - General Medical Equipment As to electrical shock, fire,and mechanical Hazards only in accordance with: CAN/CSA C22.2 No. 60601-1 (2008) ANSI/AAMI EX 60601-1:2005

GUIDANCE AND MANUFACTURER'S DECLARATIONS

The Model P8400 Hemostatix Thermal Scalpel System needs special precautions regarding EMC and needs to be installed and operated according to the information in the tables given below and portable and RF communications equipment can affect the operation of the product.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS
The Model P8400 Hemostatix Thermal Scalpel System is intended for use in the electromagnetic environment specified below. The customer or the user of the Model P8400 Hemostatix Thermal Scalpel System should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment guidance
RF emissions	Group 1	The device uses RF energy only for is internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby equipment.
RF emissions	Class A	The device is suitable for use in all establishments other than domestic and those connected directly to the public low-voltage power supply network that supplies buildings used for domestic purposes.

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GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The Model P8400 Hemostatix Thermal Scalpel System is intended for use in the electromagnetic environment specified below. The customer or the user of the Model P8400 Hemostatix Thermal Scalpel System should assure that it is used in such an environment.

Immunity Test	Test Level	Compliance Level	Electromagnetic Environmental Guidance
Electrostatic Discharge IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	± 2 kV for mains ± 1 kV for signal leads	± 2 kV for mains ± 1 kV for signal leads	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV common mode, AC mains ± 2 kV differential mode, AC mains	± 1 kV common mode, AC mains ± 2 kV differential mode, AC mains	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields above those typically found in commercial or hospital environments are acceptable.
Voltage dips, short interruptions and voltage variations on AC mains IEC 61000-4-11	> 5% of nominal voltage for ½ cycle 40% of nominal voltage for 5 cycles 70% of nominal voltage for 25 cycles > 95% of nominal voltage for 5 seconds	> 5% of nominal voltage for ½ cycle 40% of nominal voltage for 5 cycles 70% of nominal voltage for 25 cycles > 95% of nominal voltage for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. For interruptions longer than 10ms, power resets are possible.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The Model P8400 Hemostatix Thermal Scalpel System is intended for use in the electromagnetic environment specified below. The customer or the user of the Model P8400 Hemostatix Thermal Scalpel System should assure that it is used in such an environment.

Immunity Test	Test Level	Compliance Level	Electromagnetic Environmental Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80MHz to 2.5GHz	3 Vrms 3 V/m	Portable and mobile RF communication equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. RECOMMENDED SEPARATION DISTANCE: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.4\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, am and fm radio broadcast and tv broadcast cannot be predicted theoretically with accuracy. to assess the electromagnetic environment due to fixed rf transmitters, an electromagnetic site survey should be considered. if the measured field strength in the location in which the model p8400 hemostatix thermal scalpel system is used exceeds the applicable rf compliance level above, the model p8400 hemostatix thermal scalpel system should be observed to verify normal operation. if abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the model p8400 hemostatix thermal scalpel system.
[b] Over the frequency range 150 khz to 80 mhz, field strengths should be less than 3 v/m.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE MODEL P8400 HEMOSTATIX THERMAL SCALPEL SYSTEM

The Model P8400 Hemostatix Thermal Scalpel System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model P8400 Hemostatix Thermal Scalpel System can
help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model P8400
Hemostatix Thermal Scalpel System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz outside ISM bands d=[3.5/V1]√P	80 kHz to 800 MHz in ISM bands d=[3.5/E1]√P	800 MHz to 2.5 GHz d=[7/E1]√P
0.01	d=[3.5/3]√0.01	d=[3.5/3]√0.01	d=[7/3]√0.01
0.1	d=[3.5/3]√0.1	d=[3.5/3]√0.1	d=[7/3]√0.1
1	d=[3.5/3]√1	d=[3.5/3]√1	d=[7/3]√1
10	d=[3.5/3]√10	d=[3.5/3]√10	d=[7/3]√10
100	d=[3.5/3]√100	d=[3.5/3]√100	d=[7/3]√100

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

TROUBLESHOOTING
BLADE ERROR MESSAGES

BLADE ERROR MESSAGES		
MESSAGE	**REASON**	**TROUBLESHOOTING METHOD**
REPLACE BLADE	CONSOLE CAN NO LONGER READ ONE OF THE TWO CIRCUITS ON THE BLADE OR THE BLADE RESISTANCE HAS BECOME OUT OF SPECIFICATION	• REMOVE BLADE. COOL TO ROOM TEMP. AND REINSERT INTO HANDLE. IF PROBLEM REMAINS: • REPLACE BLADE • IF PROBLEM PERSISTS WITH NEW BLADE THEN THE HANDLE CONTACTS HAVE BEEN DAMAGED AND THE HANDLE NEEDS TO BE REPLACED
INSERT BLADE	CONSOLE DOES NOT RECOGNIZE THAT BLADE IS INSERTED INTO HANDLE. EITHER THE CIRCUIT HAS BECOME DAMAGED ON THE BLADE OR THE BLADE IS NOT MAKING CONTACT WITHIN THE HANDLE	• MAKE SURE BLADE IS FULLY INSERTED INTO THE HANDLE • IF CONSOLE WILL NOT CALIBRATE THE BLADE THEN REPLACE BLADE • IF PROBLEM PERSISTS WITH NEW BLADE THEN THE HANDLE CONTACTS HAVE BEEN DAMAGED AND THE HANDLE NEEDS TO BE REPLACED
REPLACE HANDLE	WHEN PERFORMING HANDLE CHECK, CONSOLE IDENTIFIED A PROBLEM WITH THE HANDLE	• REPLACE HANDLE

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TROUBLESHOOTING
CONSOLE ERROR MESSAGES

CONSOLE ERROR MESSAGES		
MESSAGE	**REASON**	**TROUBLESHOOTING METHOD**
ZERO ADC ERROR	CONSOLE HAS REGISTERED A SIGNAL ACROSS THE ANALOG-TO-DIGITAL CONVERTER THAT IS OUT OF SPECIFICATION	• TURN POWER OFF AND UNPLUG POWER CORD FROM UNIT • REINSERT POWER CORD INTO UNIT AND POWER ON CONSOLE • IF MESSAGE DOES NOT CLEAR, THEN UNIT MUST BE RETUNED FOR SERVICE
AMBIENT TEMPERATURE FAULT	CONSOLE INTERNAL THEROMETER IS OUTSIDE OF NORMAL OPERATING CONDITIONS, MOST OFTEN DUE TO TE FACT THAT THE CONTROLLER HAS BEEN STORED IN A VERY COLD OR HOT ENVIRONMENT	• NO PROBLEM WITH UNIT. SIMPLY WAIT UNTIL ENCLOSURE REACHES ROOM TEMPERATURE AND RESUME NORMAL OPERATION.
INEFFECTIVE POWER FAULT	CONSOLE HAS NOT BEEN ABLE TO ACHIEVE SET POINT TEMPERATURE FOR A PERIOD OF 20 SECONDS	• NORMALLY, NO PROBLEM WITH THE UNIT. CYCLE THE POWER ON/ORR AND RESUME OPERATION. IF PROBLEM PERSISTS, THEN UNIT MUST BE RETURNED FOR SERVICE
HEEL OR TIP-TEMPERATURE FAULT	THE HEEL OR TIP CIRCUIT PORTION OF THE CONSOLE IS OUT OF SPECIFICATION	• TURN POWER OFF AND UNPLUG POWER CORD FROM UNIT • REINSERT POWER CORD INTO UNIT AND POWER ON CONSOLE • IF MESSAGE DOES NOT CLEAR, THEN UNIT MUST BE RETUNED FOR SERVICE
POWER SUPPLY FAULT	CONSOLE POWER SUPPLY IS OUT OF SPECIFICAION	• TURN POWER OFF AND UNPLUG POWER CORD FROM UNIT • REINSERT POWER CORD INTO UNIT AND POWER ON CONSOLE • IF MESSAGE DOES NOT CLEAR, THEN UNIT MUST BE RETUNED FOR SERVICE
SYSTEM FAULT	CONSOLE SELF-CHECK DETERMINED THAT CONSOLE IS NO LONGER FUNCTIONING PROPERLY	• TURN POWER OFF AND UNPLUG POWER CORD FROM UNIT • REINSERT POWER CORD INTO UNIT AND POWER ON CONSOLE • IF MESSAGE DOES NOT CLEAR, THEN UNIT MUST BE RETUNED FOR SERVICE

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