SHAW SCALPEL

Shaw Scalpel System Model SG6 Controller

Instructions for Use

Part Number 7013-0006

For use with the Model 9050 Disposable Scalpel Handles

℞ ONLY

C2Dx

3439300-RevB

Introduction

Shaw scalpel blades are similar in size, shape, and sharpness to traditional steel scalpel blades; however, Shaw 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 Shaw 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 Shaw 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 Shaw 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 Shaw 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 Shaw 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 Shaw 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.

Notice To Users And/Or Patients

Any serious incident that occurs in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

System Warnings

1. EXPLOSION HAZARD – The Shaw 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 SG6 unit to avoid electrical shock.
5. Ensure the sound volume is adequately adjusted so that audio indications and alerts are clearly heard.
6. To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.
7. This equipment has been tested and found to comply with the limits for medical devices to the IEC60601-1-2:20 {ed 4.1}. 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 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.

8. Any attempt to plug non-Shaw equipment into the output connectors may result in damage to the SG6 unit thereby terminating any warranties and may result in an unsafe electrical condition, increased electrical emissions, or decreased immunity of the Shaw system. Anyone who connects additional equipment via the output connectors 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

System Precautions

1. It is important that the Shaw Scalpel System (SG6) 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 SG6 unit to make it difficult to remove and insert the unit's separable power cord plug.
3. There are hazardous electrical and thermal outputs. This equipment should be used only by qualified medical personnel
4. Disconnect power to the SG6 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 SG6 unit to hospital grade receptacles only, using a hospital grade AC power cord.
6. The SG6 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the SG6 should be observed to verify normal operation in the configuration in which it will be used.
7. Do not operate the SG6 in the presence of Magnetic Resonance Imaging Equipment.
8. If choosing to mount to an IV Pole, follow the recommendations on page 10. Failure to comply could result in an injury to the user or the patient.
9. 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. If you'd like to cut with a heated blade, use lower temperature settings for skin incisions (70° C - 110°C).

10. 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.

11. Care should be taken when using the Shaw to dissect around nerves and other delicate structures to avoid thermal injury to these structures.

12. The Shaw 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. Portable and RF communications equipment can affect the operation of the product.

13. All service must be performed by C2Dx, Inc. personnel only.

14. Repair and/or modification of the SG6 by anyone other than qualified service personnel may significantly compromise the unit's ability to perform effectively and/or void the equipment warranty.

15. Opening the SG6 unit and/or breaking the tamper-proof seal will void the equipment warranty.

16. Shaw Scalpel handles are single-use devices.

17. Lists of all compatible components of the Shaw Scalpel System are provided on page 12 of this manual.

18. In the unlikely event that the handle is unable to be turned off normally due to a mechanical failure or due to debris in the handle, the controller should be turned off and the disposable replaced.

19. The Handle and Footswitch connector ports on the front of the SG6 controller are not to be utilized for any other purpose than to connect to specified compatible components designed by C2Dx.

20. 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.

21. 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).

22. USE WITH ELECTROSURGICAL UNITS – DO NOT touch the Shaw Scalpel blade to any electrosurgical (e.g., Bovie) tip as significant damage to the SG6 controller unit will result. Keep at least 1cm between the blade and the electrosurgical tip. The Shaw Scalpel System CANNOT BE USED to conduct electrosurgical current through clamps.

23. AVOIDING INADVERTENT PATIENT BURNS – DO NOT rest the Shaw Scalpel handle and/or blade on surgical drapes or on the patient during use. When activated, the blade is sufficiently hot such that patient burns can result from inadvertent patient contact. When the Shaw 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 MAX TEMP mode by inadvertently depressing the MAX TEMP button or foot pedal.

Warning: The scalpel can stay hot for up to 2 minutes after de-activation.

24. GROUNDING – Reliability can only be achieved when the equipment is connected to a properly equivalent receptacle marked “Hospital Grade”.

25. The controller can be removed from Mains only by disconnecting the AC power cord from the Power Inlet.

26. STERILIZATION – The Shaw Scalpel Handle is provided STERILE, provided the primary sterile packaging is unopened and undamaged. In the event that the sterile barrier has been compromised, discard the handle and obtain a new one. The handle cannot be re-sterilized.

27. Remove and discard of used disposables following local regulations for proper disposal of contaminated material.

28. Electrical shock hazard. Do not remove cover. Refer to manufacturer for service.

29. If the user has any questions regarding compatibility of accessories or cables they should contact C2Dx, Inc.

Component Precautions

1. Shaw 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 grasp the insulated plastic hub when handling the blade and take care as this may also be hot to the touch.

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 Shaw 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, using the insulated plastic hub.

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 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.

10. The handle must be activated (ON) for the MAX TEMP button to work.

11. The handle contains a strong earth magnet. Take care of placement near electronic implantable devices.

12. 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.

13. External cleaning is the only controller maintenance that can be performed by the user. The unit should be wiped down with alcohol, mild soap, or detergent.

14. The SG6 controller requires cleaning after each use. The Touch-Panel display should not be exposed to caustic chemicals used during this process. This includes Chlorine Dioxide, Sodium Hypochlorite (Bleach), Ethyl Alcohol, Alconox, Liquinox, Cidex, Chlorides, or similar. EPA studies have shown these chemicals cause damage to electronic devices.

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

16. DO NOT immerse the controller.

17. DO NOT use an abrasive cloth or cleaners, especially on the display screen.

18. Servicing the controller unit by anyone other than a qualified service personnel approved by C2Dx, Inc renders the warranty void.

19. DO NOT dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations.

System Description

MODEL SG6 Shaw Scalpel System

The Shaw Scalpel System consists of four components:

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

2. **SINGLE-USE, DISPOSABLE HANDLE –** A single-use, disposable handle connected to the controller unit with a light-weight, flexible electrical cable. Disposable scalpel blades are inserted into the disposable handle. The user is able to control blade temperature, on/off and MAX TEMP modes directly from the handle.

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 Shaw 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 the scalpel or MAX TEMP mode. The footswitch has two modes: (1) ACTIVATE/MAX TEMP 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 black pedal will decrease the set point temperature by 10° C; whereas, depressing and releasing the right red pedal will increase the set point temperature by 10° C. When in the ACTIVATE/MAX TEMP mode, depressing and holding the left black pedal will activate the scalpel blade to come to the selected temperature. Similarly, depressing and holding the right red pedal will activate the scalpel blade to come to the MAX TEMP temperature of 300° C.

Important Features

SURGICAL FEATURES

1. **Retains the Precision of Surgical Steel** – Shaw 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 Shaw Scalpel conducts heat from 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 Shaw 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.

4. **Minimizes Tissue Damage –** Hemostatic incisions made with the Shaw 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 Shaw 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 Shaw Scalpel.

6. **Eliminates Patient Currents and Muscle Stimulation –** Since no electrical current passes through the patient when using the Shaw 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 –** Shaw 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 Shaw Scalpel System automatically calibrates each blade, typically within 6 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° C using the touchscreen "Temperature Up" + or

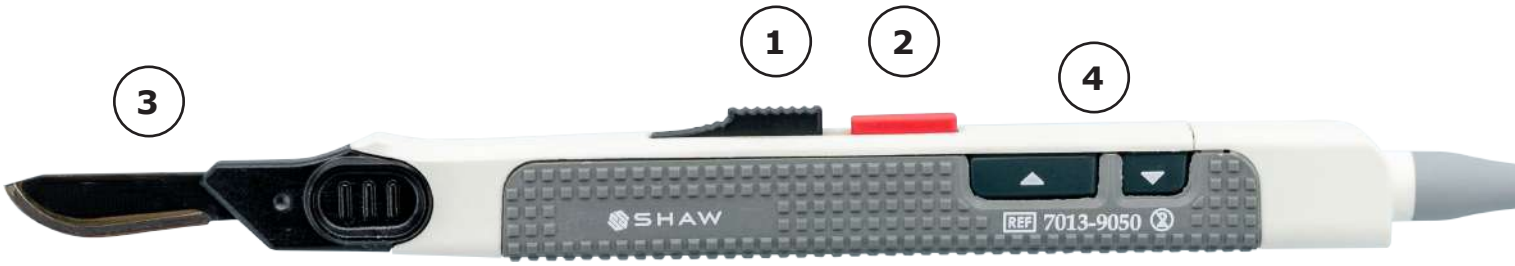
"Temperature Down" - buttons OR by using the UP/DOWN arrows on the handle. The Shaw Scalpel System provides a high temperature MAX TEMP Mode, suitable for sealing vessels. The MAX TEMP Mode is preset to 300° C.

4. **Audible Signals –** The controller provides audible tones to indicate certain system functions and status. The signal volume can be adjusted by selecting the volume icon on the screen and then turning up or down. The audible functions include: pressing any button on the console, handle, or footswitch, blade heating, blade cooling, MAX TEMP, and blade removal. Also, a tone is heard when there are certain problems with the system. Ensure the sound volume is adequately adjusted so that audio indications are clearly heard.

5. **Visual Displays –** The Model SG6 controller has one display on the front of the unit.

6. **IV Pole Mount –** Secure the controller using the clamp on the back. Be sure to tighten snugly, but do not provide excessive force. Care should be taken in selecting a stable IV pole with a wide base (a circular pattern with a diameter of at least 25in) with five locking casters (Pryor Products Model 176G or equivalent). The unit should be mounted such that its top surface is no more than 48in from the floor. Consult your biomedical department in the event there are any questions regarding the stability of the intended IV pole and mounting location.

Handle Controls And Indicators



1. **ON/OFF SWITCH -** Sliding the black ON/OFF switch rearward (toward the cable) mechanically latches the switch and activates the blade. A red dot is visible when switch is in the “ON” position. Sliding the switch forward (toward the blade) deactivates the blade.

2. **MAX TEMP BUTTON -** Depressing the red button on the handle activates the MAX TEMP mode as long as the switch is depressed. Releasing the switch causes the temperature to revert to the original temperature setting. NOTE: MAX TEMP mode can only be activated if the ON/OFF switch is in the ON position.

3. **BLADE -** The blade/hub assembly includes a magnetic interface. The blade/hub should automatically seat fully into the Disposable Handle with zero force required when the blade/hub assembly is placed into the mating portion of the Disposable Handle. 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.

Handle, Blade, And Footswitch Compatibility

1. **HANDLE Compatibility –** SG6 Shaw Scalpel Controller (REF 7013-0006) is compatible with the following Shaw Scalpel handle/cable configurations:

   - REF **7013-9050**–Shaw Handle w/Integral Cable Assembly–Qty 1.
   - REF **7023-9050**–Shaw Handle w/Integral Cable Assembly–Qty 6.

2. **BLADE Compatibility –** The Model SG6 Controller is compatible with the following shaw scalpel blades:

   - REF 7013-5810 – #10 Blade - Sterile Disposable - Quantity 24
   - REF 7023-5810 – #10 Blade - Sterile Disposable - Quantity 10
   - REF 7013-5812 - #12 Blade - Sterile Disposable - Quantity 24
   - REF 7023-5812 – #12 Blade - Sterile Disposable - Quantity 10
   - REF 7013-5815 – #15 Blade - Sterile Disposable - Quantity 24
   - REF 7023-5815 – #15 Blade - Sterile Disposable - Quantity 10

3. **FOOTSWITCH Compatiblity**

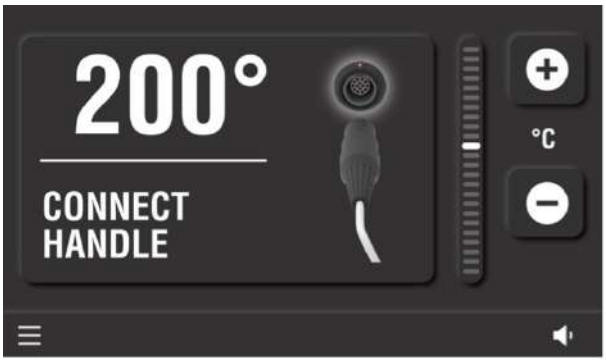
   - The Model SG6 Controller is compatible with the optional Footswitch (REF 7013-8410).

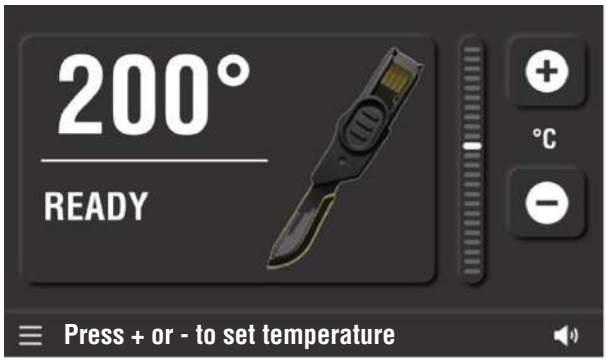
4. SYSTEM CHECKOUTS NOTE: The Model SG6 Controller unit is rated 100-240VAC ± 10%, 50 - 60Hz ± 1Hz.

Graphical User Interface

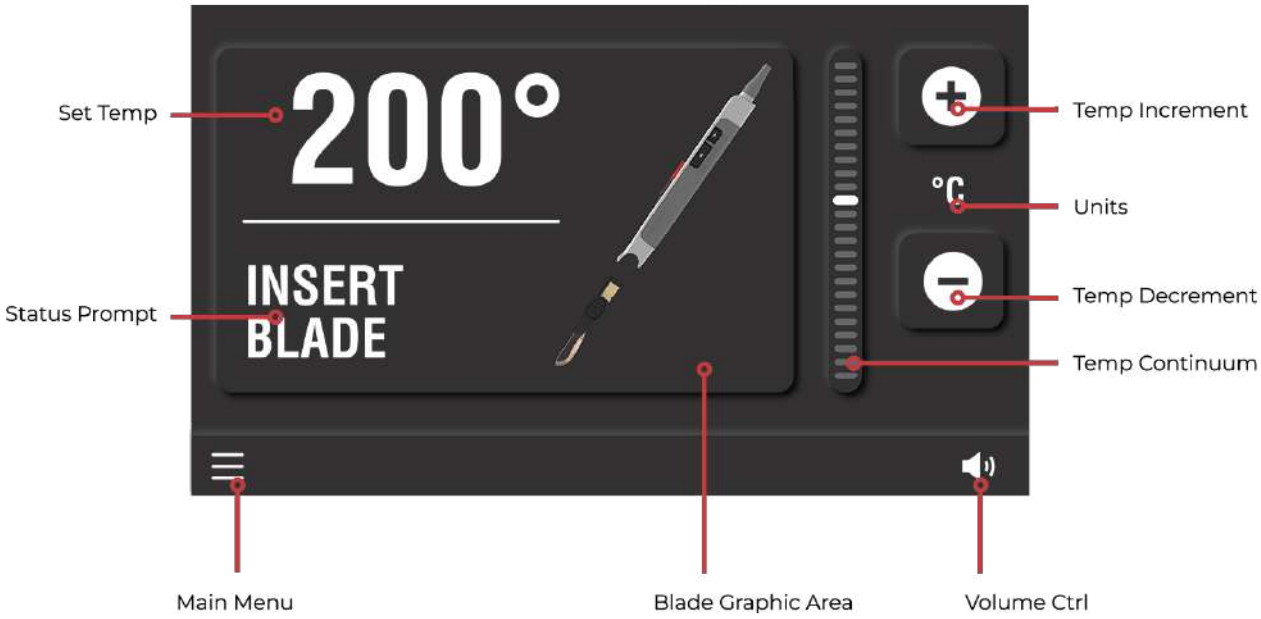
The Model SG6 Controller's touchscreen display provides step-by-step instructions and visual references throughout the operation.

After system initialization, a home or default screen is presented to system users. This main screen serves as a landing and overview screen to communicate basic device status and information such as current temperature, handle/blade attachment status, device state (activated-deactivated), messaging, and navigation elements.





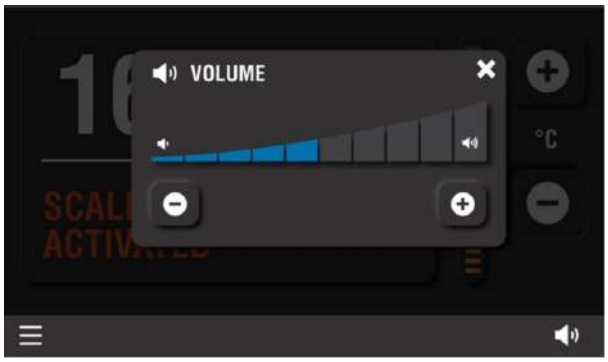
Screen Organization



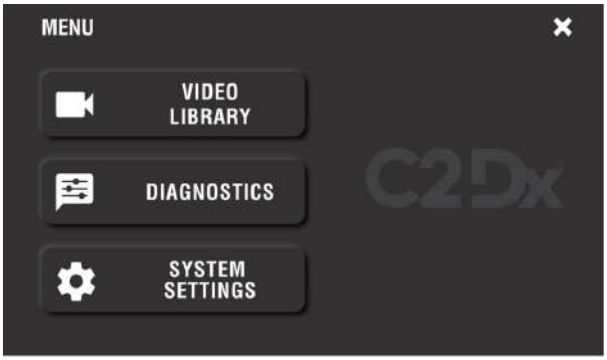
Screen Controls

1. **Set Temperature –** Press the temperature + or – buttons to adjust the set point temperature. Temperature increases in increments of 10° C.
   NOTE: Temperature can only be adjusted if hande is OFF/De-activated.

2. **Adjust Volume -** Press the volume control icon on the display and adjust to your desired volume using the + or – buttons. A tone will sound to indicate what the volume will be.



3. **Access Menu -** Press the hamburger icon on the display to access menu options including: video library, diagnostic information, and system settings.
   NOTE: The menu can only be accessed if hande is OFF/De-activated.



Operating Instructions

1. **POWER ON**

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

   The unit will briefly undergo a self-test (less than 10 - 15 seconds). Once the self-test is completed, the display will illuminate with the default set-point temperature setting (200˚ C) and prompt the user to connect the handle.

2. **POWER OFF**

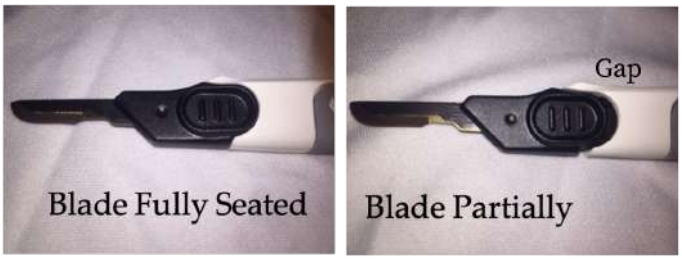
   Turn off POWER to the system by pushing the POWER SWITCH located at the front lower left side of the controller in the DOWN or '0' position.

3. **HANDLE INSERTION**

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

4. **BLADE INSERTION AND CALIBRATION**

   The sterile, disposable blade/hub assembly includes a magnetic interface. The blade/hub should automatically seat fully into the Disposable Handle with zero force required when the blade/hub assembly is placed into the mating portion of the Disposable Handle. In the unlikely event that the hub does not fully seat, simply manually press the hub into handle until the blade is firmly seated as shown. NOTE: The handle should be in the "OFF" position before inserting the blade.



   If there is a pause during blade insertion, an error message may appear. Simply remove the blade assembly and reinsert. Once the blade is successfully inserted into the handle, the controller unit will begin calibrating the blade. If calibration is successful, the controller unit will display the Ready Screen.

   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.

   NOTE: 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.

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.

5. USING THE SHAW SCALPEL

With the controller powered ON, the handle attached and a blade inserted into the handle, VERIFY that the controller display reads 200° 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 screen 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 black handle ON/OFF switch to the ON position to expose the red-colored dot. The handle is now activated and the blade will be heated to the displayed temperature setting.

To activate the MAX TEMP mode, depress and hold the red MAX TEMP button on the top of the handle. The blade temperature will be approximately 300° C in the MAX TEMP mode.

NOTE: The handle must be activated for the MAX TEMP button to work.

6. USING THE OPTIONAL FOOTSWITCH

The footswitch has two modes: (1) ACTIVATE/MAX TEMP 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 black pedal will decrease the set point temperature by 10° C; whereas, depressing and releasing the right red pedal will increase the set point temperature by 10° C.

When in the ACTIVATE/MAX TEMP mode, depressing and holding the left black pedal will activate the scalpel blade to come to the selected temperature. Similarly, depressing and holding the right red pedal will activate the scalpel blade to come to the MAX TEMP temperature of 300° C.

Upgrade Features

1. **MAINTENANCE PORT –** Located on the rear of the unit, this port allows easy diagnostic access for C2Dx personnel as well as future software upgrade access via a USB port. The maintenance port is covered with a maintenance port cover.

WARNING: The maintenance port is to be used by C2Dx 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.

Surgical Use & Techniques

1. **CUTTING TEMPERATURES**

- The 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.
- **SKIN** – Cutting with the blade unheated will eliminate the possibility of superficial skin scars due to contact with a heated blade. For minimal scarring, make the initial skin incision with the scalpel handle in the OFF position. If you'd like to cut with a heated blade, use lower temperature settings for skin incisions (70° C - 110° C).

  (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 determined by the surgeon by raising the set point temperature until adequate hemostasis is achieved. Alternatively, the surgeon can, at any selected temperature, modulate the speed of tissue cutting according to the vascularity of the tissue being incised.

3. SEALING BLEEDERS

- The heat from the Shaw 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 MAX TEMP mode by depressing and holding down the red MAX TEMP button (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 Shaw Scalpel thermal energy is to have bleeding 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 Shaw 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 BLUE 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, grab the plastic hub and 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 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.

Maintenance

The SG6 controller requires cleaning after each use. The Touch-Panel display should not be exposed to caustic chemicals used during this process. This includes Chlorine Dioxide, Sodium Hypochlorite (Bleach), Ethyl Alcohol, Alconox, Liquinox, Cidex, Chlorides, or similar. EPA studies have shown these chemicals cause damage to electronic devices.

- The controller 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 controller.
- **DO NOT** use an abrasive cloth or cleaners, especially on the display screen.

NOTE: Servicing the controller unit by anyone other than a qualified service personnel approved by C2Dx, Inc. renders the Warranty void. For any service or warranty questions, please call C2Dx, Inc.

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

Servicing

The Shaw 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 anyone other than a qualified service personnel approved by C2Dx, Inc. renders the Warranty void. Before returning a controller unit for servicing, please call C2Dx, Inc. to obtain a Return Material Authorization (RMA) and instructions as to how and where to send the controller unit and accessories.

To ensure the SG6 controller unit is operating as intended, it is recommended to have C2Dx perform a functional check annually. Software upgrades should also be completed when they become available.

Warranty

C2Dx, Inc. warrants to the original purchaser that reasonable care has been used in the manufacture of the MODEL SG6 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 C2Dx or any of its authorized distributors.

NOTE: Shaw 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

The sole and exclusive remedy with respect to any MODEL SG6 or any portion thereof found within its warranty period not to meet these standards is that after return to and examination by C2Dx, C2Dx will without charge at its option either repair or replace that portion of the MODEL SG6 found to be defective. This warranty shall not apply (a) if that portion of the MODEL SG6 has been repaired or altered by anyone other than qualified service personnel approved by C2Dx or altered in any way which, in C2Dx'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 electrosurgical (e.g., Bovie) electrode; 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, C2Dx's determination will prevail and any repairs or replacements, if requested, will be billed at C2Dx's prevailing normal rates. If so requested, estimates will be submitted before work is started.

NOTE: An RMA# issued by C2Dx must be obtained before any part of the MODEL SG6 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 C2Dx. 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. C2Dx shall not be liable for any incidental or consequential loss, damage, expense or liability direct or indirect with respect to this product. C2Dx 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 SG6 Controller Unit

NOTE: The MODEL SG6 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 display as TEMPERATURE SETTING ranging from 70° C to 300° C in 10° C increments.
Room Operating Environment	• 15° C to 30° C (Note: Blade temperature is indexed from room temperature • 30% - 75% Relative Humidity - Non-condensing • 700 to 1060 hPA
Transport & Storage Environment	• -29° C to +50° C • 10% - 85% Relative Humidity • 570 to 1060 hPA
Moisture Protection	• 7013-0006 Controller Unit - IPX1 Rating • 7013-8410 Foot pedal - IPX8
Console Size	• Approximately 8.0 in x 10.9 in
Controller Weight	• Approximately 10 lbs. (4.5 kg) without power cord
Mobility	• Mounted to an IV pole with five casters with a diameter of at least 23in
Power Requirements	• 100-240VAC± 10% • 50 - 60 Hz ± 1 Hz
Power Input	• < 2 A
Power Output	• 100 W
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
Shaw Scalpel System is classified as a Type BF Applied Part, Class I electrical device and is certified to the following:	• IEC60601-1 Ed. 3.2 (2020) • EC 60601-1-2 ED. 4.1 (2020), • CAN/CSA-C22.2 No. 60601-1:14; A2:2022
The Shaw Scalpel System uses a Type BF Applied Part	• The Type BF Applied Parts include the Handle Assembly and the corresponding disposable blade.

Specifications

Shaw Scalpel System Handle - Model 9050

Shaw Scalpel System BLADES - SERIES 5810, 5812, and 5815.

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

Shaw Scalpel System Disposables are provided sterile and ARE NOT intended for reuse.

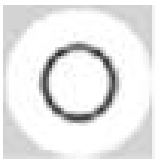
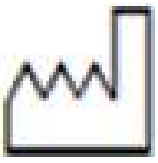
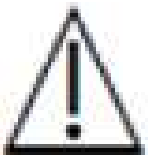
Handle Switches:	Latching On/Off, momentary MAX TEMP & Temperature switches
Initial Sterilization	Ethylene Oxide Gas

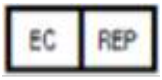
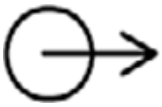
Training Requirements

This device is intended for use by physicians, or appropriate staff, trained in the procedures described in the indications for use. In addition to the information provided in the Instructions for Use Manual, training and troubleshooting videos are available as a menu choice on the SG6 controller.

Essential Performance

The SG6 controller shall be capable of providing the appropriate amount of energy to maintain the temperature of the scalpel blade at a target temperature of between 70C° and 300C° at 10C° increments and shall provide a User Interface that informs the User of the system status, and allows the User to control the application of blade heating.

	Type BF applied Part
	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
	Speaker volume
	Menu
	Maintenance USB 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

	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: IEC60601-1 Ed. 3.2 (2020), IEC 60601-1-2 ED. 4.1 (2020), CAN/CSA-C22.2 No. 60601-1:14; A2:2022

Guidance And Manufacturer's Declarations

The Model SG6 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 SG6 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model SG6 should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environmental guidance
RF emissions	Group 1	The device uses RF energy only for 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.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY
The Model SG6 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model SG6 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	± 8 kV Contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air	± 8 kV Contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 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	± 2 kV for mains	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 volt- age 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 25/30 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 25/30 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.

Immunity Test	Test Level	Compliance Level	Electromagnetic Environmental Guidance
RFID Immunity AIM 7351731:2021 Methods: IEC61000-4-39:2017 Magnetic Field Immunity – RFID IEC61000-4-3:2020 Radiated Immunity - RFID	 65A/m @ 134.2kHz 7.5A/m @ 13.56MHz 3V/m @ 433.92MHz 54V/m @ 860MHz 54 V/m @ 2450MHz	 65A/m @ 134.2kHz 7.5A/m @ 13.56MHz 3V/m @ 433.92MHz 54V/m @ 860MHz 54 V/m @ 2450MHz	 RFID methods typically used in a commercial or hospital environment should be acceptable.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The Model SG6 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model SG6 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) tele- phones 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 SG6 Shaw Scalpel System is used exceeds the applicable rf compliance level above, the model SG6 Shaw 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 SG6 Shaw 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 SG6

The Model SG6 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model SG6 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model SG6.

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 / Handle Error Messages

Condition	Description	Visual Indication	IFU Instructions
Handle Usage Warning	The handle has been used previously and must be replaced to continue.		Discard the handle being used and replace it.
Defective Handle	When performing a handle diagnostic check, the console identified a problem with the handle.		Ensure that the handle is fully connected. If the problem persists, replace handle.
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 persists, replace blade. • If problem persists with new blade, then the handle contacts may be damaged. • Replace handle.
Hot Blade	The system is attempting to calibrate a hot blade.		Remove the blade and allow it to cool before continuing calibration or replace it.
Button Pressed	Console has detected that a button on the handle or footswitch is pressed during the detection mode.		Released all buttons on the handle before continuing.

Insert Blade	Console is unable to detect blade circuits.	Insert Blade	• Replace blade. • If problem persists with a new blade, then the handle contacts may be damaged. Replace handle.
Insufficient Power Fault	The console has not been able to achieve the set point temperature within a time frame of 15 seconds.	 In addition to the fault symbol, the system displays information about the source of the fault.	• Normally not a problem with the unit. • If message does not clear, replace blade. If replacing the blade does not resolve the error, unit must be returned for service.

Troubleshooting Controller Fault Messages

Condition	Description	Visual Indication	IFU Instructions
POST Failure or hardware failure	The FAULT signal is an indication that a hardware fault has been detected. The system will not function until the fault is corrected. The fault tone can be silenced by pressing anywhere on the pop-up or any button. It includes both audio and visual indications.	In addition to the fault symbol, the system displays information about the source of the fault.	• Cycle power to the unit using the switch on the front panel. • If message does not clear, then unit must be returned for service.
Power Supply Fault	The software detected that the internal Power Supply is out of tolerance.	 In addition to the fault symbol, the system displays information about the source of the fault.	• Cycle power to the unit using the switch on the front panel. • If message does not clear, then unit must be returned for service.
Ambient Temperature Fault	The controller's internal temperature is outside of the operating temperature range.	 In addition to the fault symbol, the system displays information about the source of the fault.	• Normally not a problem with the unit. • Turn power off and wait until console reaches room temperature power on console. • If message does not clear, then unit must be returned for service.

Condition	Description	Visual Indication	IFU instructions
Heel or Tip Temperature Fault	The software detected that the heel or tip portion of the console circuit is out of tolerance.	  In addition to the fault symbol, the system displays information about the source of the fault.	• Cycle power to the unit using the switch on the front panel. • If message does not clear, then unit must be returned for service.
Cooling Fan Failure	The cooling fan has stopped rotating.		• Cycle power to the unit using the switch on the front panel. • If message does not clear, then unit must be returned for service.

C2Dx, Inc.
8400 Wolf Lake Drive, STE 109
Bartlett, TN 38133 USA
Telephone: +1 888-902-2239