CSA medical

OPERATOR MANUAL

CryoSpray Ablation System

Model #: CTI-G2-50L

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This manual contains important information on proper use and maintenance of the SprayGenix™ Cryo Ablation System. **ALL PERSONNEL INVOLVED IN THE USE AND MAINTENANCE OF THIS EQUIPMENT MUST CAREFULLY REVIEW AND COMPLY WITH THE WARNINGS, CAUTIONS, AND INSTRUCTIONS CONTAINED IN THIS MANUAL.** These instructions are important to protect the health and safety of patients and personnel operating the Cryo-Ablator System and should be retained in a conveniently accessible area for quick reference.

Complete instructions for setting up the device are presented in Chapter Three of this manual.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Indications for Use

The CryoSpray Ablation™ System is intended to be used as a cryosurgical tool for destruction of unwanted tissue gastroenterology, including the eradication of Barrett's esophagus, with or without dysplasia.

Service Information

A thorough preventive maintenance program is essential to safe and proper system operation. This manual contains maintenance schedules and procedures that should be followed for satisfactory equipment performance.

Advisory

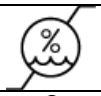
A summary of safety precautions to be observed when operating and servicing this system can be found in Chapter One of this manual. Do not operate or service the equipment until you have become familiar with this information.

TABLE OF CONTENTS

LIST OF FIGURES

DEFINITION OF SYMBOLS

The following symbols are used within this manual, or on the CryoSpray Ablation™ System and its packaging:

Symbol	Meaning
	Caution; Caution, see notes in Operator's Instructions
	Electrical shock hazard
	Wear Safety Gloves appropriate for Cryogenic Conditions
	Wear Protection Goggles appropriate for Cryogenic Conditions
	Contents under Pressure
	Serial number
	Fragile, Handle with care
	TYPE BF Applied Part
	Date of Manufacture
	Keep dry
	Humidity Range (with inclusive upper and lower limits)
	Temperature Range (with inclusive upper and lower limits)
	**Emergency Stop**

The following signal words are used throughout this manual.

DANGER Indicates an imminently hazardous situation, which, if not avoided, will result in death or serious injury.

WARNING Indicates a potentially hazardous situation, which, if not avoided, could result in death or serious injury.

CAUTION Indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

NOTE Indicates additional helpful information.

Follow the dangers, warnings and cautions described below when handling this device. This information is supplemented by the dangers, warnings and cautions described in each chapter.

DANGER

Note
Never expose the CryoSpray Ablation™ System to liquid. If any liquid is spilled into the display of the Console or down the back panel of the console, stop using immediately, unplug from the AC power source and contact CSA Medical to perform comprehensive cleaning and safety testing. Failure to do so may result in electrical shock to the patient, physician, or maintenance person.

WARNING

The valves, fittings, and hose will become extremely cold and frosted as liquid nitrogen passes through them. Cryogenic gloves and goggles should be worn when filling the cryogenic Tank to prevent injury.

WARNING

Do not use the CryoSpray Ablation™ System if the System has indicated an alarm mode; user or patient injury or device damage may result. Investigate the alarm and contact CSA Medical if the cause cannot be determined or corrected.

Caution: Emergency Stop

Depressing the emergency stop button will halt the cryogenic delivery system and release the pressure in the cryogenic tank. It will prevent any other operator control with the exception of the HEAT to remove the CSATM Cryocatheter from the endoscope.

Note

WARNING

Never bend a flexible endoscope distal tip towards the patient's tissue while the end of the CSA™ Cryocatheter is exiting the endoscope distal tip. Doing so may result in patient injury. Gently pull the CSA™ Cryocatheter tip inwards prior to re-adjusting the endoscope tip.

WARNING

Inspect CSA™ Cryocatheter for damage prior to use and do not use the CSA™ Cryocatheter if is damaged in any way.

This device contains no user-serviceable parts. Do not disassemble, modify, or attempt to repair the device. Patient or user injury and equipment damage can result.

WARNING

Never use the CSA™ Cryocatheter if the outer packaging is punctured or open, as the product is no longer sterile. Patient injury may result.

CAUTION

Do not bend or kink the flexible tubing of the CSA™ Cryocatheter. It is fragile and can be mechanically damaged. Do not use the CSA™ Cryocatheter if is damaged in any way.

CAUTION

Do not re-use the CSA™ Cryocatheter. It is a single use device.

CAUTION

Do not use the CSA™ CDT if any cuts are identified. Do not use the CSA™ CDT if is damaged in any way.

CAUTION

Do not re-use the CSA™ CDT. It is a single use device.

WARNING
Asphyxiation Hazard

Always use equipment in a ventilated area. Nitrogen may act as an asphyxiation hazard by displacing oxygen from a confined space. High concentrations of Nitrogen in the air cause a deficiency of oxygen with the risk of unconsciousness or death.

WARNING
Asphyxiation Hazard

On loss of containment this liquid evaporates very quickly causing super saturation of the air with serious risk of suffocation when in confined areas.

WARNING

Wear protective gear when filling the nitrogen tank. The liquid nitrogen may cause frostbite.

The nitrogen tank is under pressure.

WARNING

INDICATIONS FOR USE

The CryoSpray Ablation™ System is intended to be used to destroy unwanted tissue by application of extreme cold to a selected site. Liquid Nitrogen is stored in a tank and then propelled through a CSA™ Cryocatheter to perform the cryo-ablation procedure. The CSA™ Cryocatheter is placed in the appropriate position through the use of visual observation. The CSA™ Cryocatheter applies the cryogen to a selected area and freezes the unwanted tissue. Cryosurgical procedures are used when surgical resection is not indicated, and may also provide an alternative to typical resection in certain cases.

The CryoSpray Ablation™ System is intended to be used as a cryosurgical tool for destruction of unwanted gastrointestinal lesions.

Federal (USA) law restricts this device to sale by or on the order of a physician.

INSTRUCTION FOR USE

This instruction manual contains essential information on using this device safely and effectively. Before use, thoroughly review this manual and the manuals of all equipment which will be used during the procedure and use the instruments as instructed. Only approved CSA Medical accessories are designated for use with the system.

USER REQUIREMENTS

The CryoSpray Ablation™ System must be operated by a physician certified by CSA Medical

CONDITIONS TO AVOID DURING USE

In the presence of large magnetic fields, the wireless communication may be disrupted; however, the controls on the main console will not be affected.

DEVICE DESCRIPTION

The CryoSpray Ablation™ System is a cryosurgical device utilizing a spray tip CSA™ Cryocatheter. Medical Grade liquid nitrogen is the cryogen used in the device. The device is used to destroy unwanted tissue by the application of

extreme cold with the focused application to select tissue. The cryogen is stored in a liquid nitrogen holding tank.

The liquid Nitrogen is propelled through a spray CSA™ Cryocatheter to the selected site by head pressure in the holding tank (approximately 22 psi holding pressure). Freezing techniques are monitored by the use of direct visualization with an endoscope. Once the freezing is completed, the cryogen flow is terminated and the thawing system may be engaged to allow accessory removal. The console enables the physician to control the start and stop of flow and the duration of the cryogen spray.

The CryoSpray Ablation™ System consists of the following components:

MAIN CONSOLE

- **Cryogenic Delivery System**
  - Cryogenic Tank
  - Catheter Connection Port
  - CSA™ Cryocatheter
- **User Interface**
  - Display
  - Operator Controls
  - Error Indicators and Alarms
- **Suction System**
  - Cryogenic Decompression Tube (CDT)
  - Collection Canister
  - Suction Port
- **Catheter Removal System / Active Heat**
- **Power System**
- **Emergency Stop**

FOOT PEDAL CONTROLS

HAND HELD REMOTE CONTROL

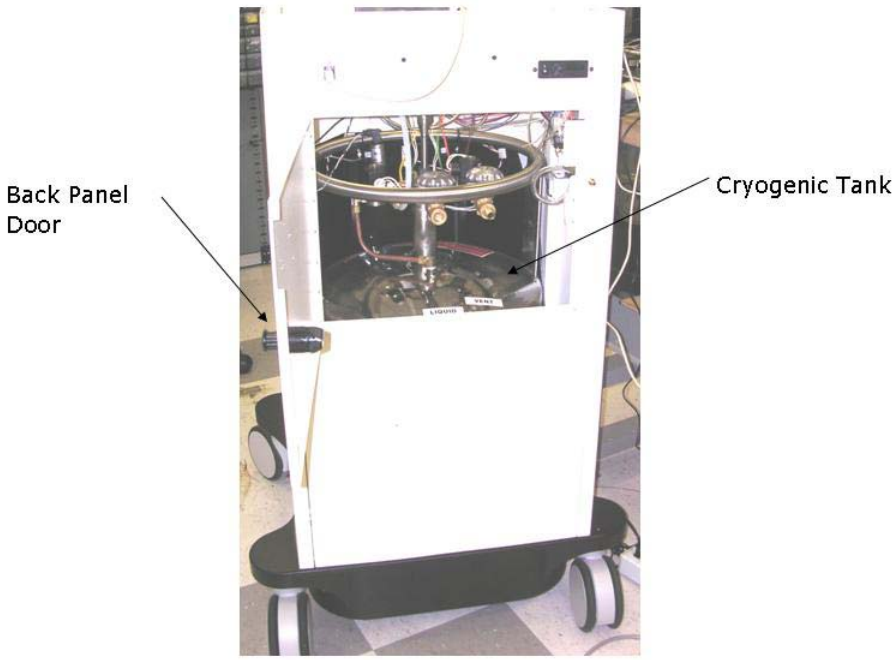
REMOTE DISPLAY

CRYOGENIC DELIVERY SYSTEM

Cryogenic Tank

Each cryogenic delivery system includes one cryogenic tank that is housed within the main console, capable of containing a minimum of 35 liters total liquid volume. The tank is a double jacketed, vacuum insulated, stainless steel cryogenic tank (Figure 1). The tank is equipped with a rupture disc and venting means for releasing excessive vapor pressure.

Figure 1: Back Panel Access to the Cryogenic Tank



An active delivery control system maintains the desired operating pressure. An electrically controlled pressure regulator and venting device prevents the buildup of excess pressure.

CSA™ Cryocatheter

The CSA™ Cryocatheter attaches to the catheter connection port, Figure 2. The distal end of the CSA™ Cryocatheter is inserted into and passed through the working channel of a diagnostic gastroscope. The CSA™ Cryocatheter is a sterile, single use, disposable device. Only approved CSA Medical accessories are designated for use with the system.

Figure 2: Catheter Connection Port

The catheter tube is packaged to protect it from damage in handling and shipping. (Figure 3)

Figure 3: CSA™ Cryocatheter

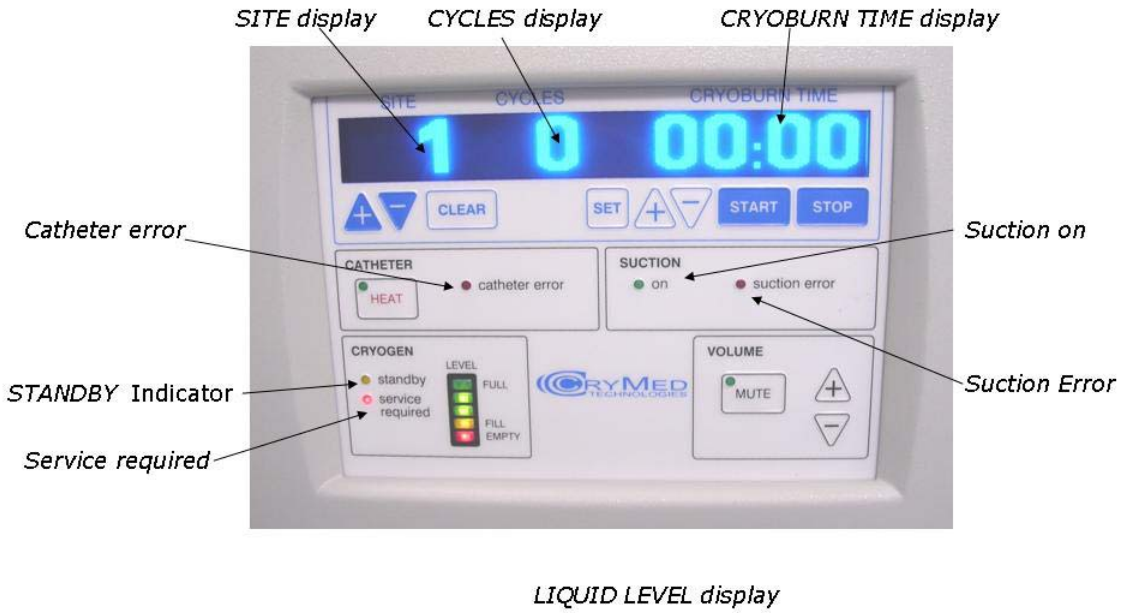
Catheter Connection Port

The catheter connection port connects the CSA™ Cryocatheter to the cryogenic delivery system. Additionally, this connection serves to perform certain quality assurance checks on the CSA™ Cryocatheter prior to use.

USER INTERFACE

A brief operator alert tone is generated whenever a button is pressed on the control console front panel. (Figure 4)

Figure 4: Displays on the User Interface[JBC1]



Display

Site Display

The *SITE* display enables the operator to view the current treatment site information (Figure 4).

SITE: 2-digit display indicates the current treatment site.

When moving between sites, the FREEZETIME TIME will show the last treatment FREEZETIME TIME for that site. If it is a new treatment site, the FREEZETIME TIME will display zeros.

Cycle Display

The *CYCLES* display enables the operator to view the current treatment cycle information for any particular site (Figure 4).

CYCLES: a 2-digit display indicates the treatment cycle for a particular treatment site.

The *CYCLES* display keeps track the number of times the timer has reached its target time (default value: 20 seconds) for a specific treatment site. If the FREEZETIME announcement time exceeded the FREEZETIME set time, the cycle will automatically increment to the next cycle. If the FREEZETIME announcement time did not exceeded the FREEZETIME set time, the CYCLES will flash to imply that either the cycle should be completed or treatment should move to a new site.

FreezeTime Time Display

The *FREEZETIME TIME* display enables the operator to know how long a specific treatment tissue has been frozen. (Figure 4)

FREEZETIME TIME: is displayed in minutes:seconds format.

The *FREEZETIME TIME* displays the elapsed time since the *START* button has been depressed, either from wireless remote control or the control console. The *FREEZETIME TIME* display will continue to count until the *STOP* button is depressed, and will resume without clearing upon the next depression of the *START* button.

Cryogen Level Display: *CRYOGEN LEVEL*

A multi-element display indicates the cryogen level. The display indicates the level in the tank, *FULL*, *FILL*, or *EMPTY*.

Standby Indicator

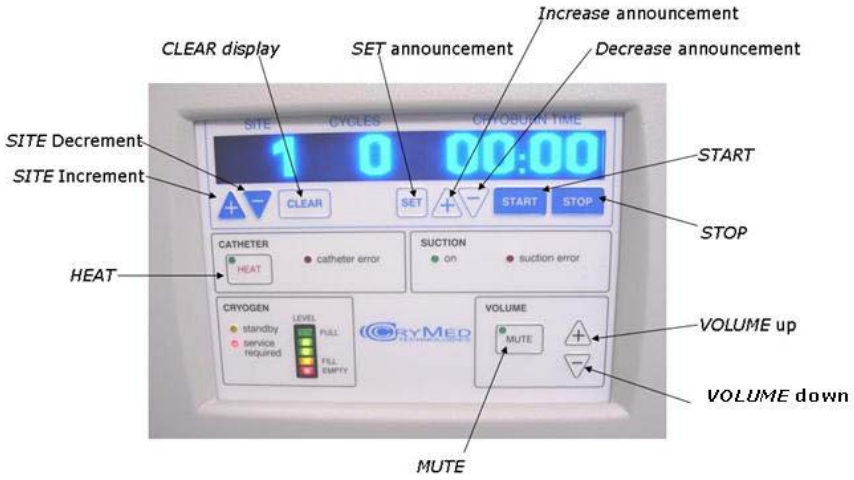
Upon power-up, the control console will initialize and will perform a set of self-tests. During this self-test period, the *STANDBY* indicator will be illuminated. Also, the *STANDBY* indicator will be illuminated while the system adjusts the tank pressure.

USB Port

The USB Port is for authorized CSA Medical Service personnel and should not be used by the end user.

Operator Controls: Main Console

Figure 5: Operator Controls on the User Interface[JBC2]



<u>Volume Management</u>:

Pressing the *MUTE* button while in the un-muted state will mute the timer announcement volume. Pressing the *MUTE* button while in the muted state will restore the timer announcement volume to its previous level. **<u>System Alarm volume is affected by the *MUTE* button.</u>** An LED is continuously illuminated to indicate that the timer announcement volume has been muted. (Figure 5)

<u>Volume Arrows</u>:

Depressing the up and down arrow of the volume will result in adjusting volume of the timer announcement. (Figure 5)

Catheter Removal Management

HEAT: depressing the *HEAT* button on the hand remote or main console will activate the CSA™ Cryocatheter 's active heating cycle. The heating cycle is active for a period of 14 seconds. Additional cycles may be activated by depressing the *HEAT* button on the hand remote or main console until the catheter is thawed. An LED is illuminated while the CSA™ Cryocatheter heater is active. (Figure 5)

FreezeTime Time Management

An announcement tone is generated to alert the operator as the target time is approached. The announcement tones are generated at five-second intervals, and at each of the final four seconds approaching the target time. Once the target time is reached, the announcement tone will be generated continuously until the *STOP* button is pressed (Figure 5).

START: depressing the *START* button, on the hand remote or on the console, begins the *FREEZETIME TIME*.

STOP: depressing the *STOP* button ceases the *FREEZETIME TIME*.

Announcement Management

Three buttons are provided to set the FREEZETIME announcement Time. (Figure 5)

While the set time is depressed, the time display shows the current timer announcement interval, and flashes.

SET Time: allows user to set announcement times.

UP ARROW: allows user to increase the announcement time.

DOWN ARROW Time Decrement: allows user to decrease the announcement time.

If the *UP ARROW* is depressed while the set time is flashing, the timer announcement interval will increment by one second.

If the *DOWN ARROW* is depressed while the set time is flashing, the timer announcement interval will decrement by one second.

If either the *UP ARROW* or *DOWN ARROW* is held down for more than 2 seconds, while set time is flashing, the timer announcement intervals will auto-increment or auto-decrement.

Site Management

UP ARROW Site: allows user to move to the next treatment sites. (Figure 5)

DOWN ARROW Site: allows user to move to the previously treated sites. (Figure 5)

Clear

Pressing the *CLEAR* button resets the Site, Cryo-Cycle, and Cryo Burn Time values on the displays, remote display and main console.

ERROR INDICATORS AND ALARMS

CATHETER ERROR: An LED is continuously flashed to indicate an error in the CSA™ Cryocatheter . See trouble shooting Guide for details on resolving a catheter error. (Figure 5)

- A CSA™ Cryocatheter may be disconnected from the control console for up to 30 minutes without becoming invalid.
- A CSA™ Cryocatheter may be connected to the control console for up to 2 hours before becoming invalid.
- If the CSA™ Cryocatheter is determined to be an invalid device, the control console will illuminate the *CATHETER ERROR* and sound an alarm. The control console will not permit further system operation while an invalid catheter is connected.

SUCTION ERROR: An LED is continuously flashed to indicate that the suction system is occluded. (Figure 5)

***SERVICE REQUIRED*:** An LED is continuously flashed to indicate that the device requires service, unplug the device and call CSA Medical for service. See Maintenance section for contact information. (Figure 5)

AUDIBLE ALARMS

Cryogen pressure low (*STANDBY* indicator flashes)

Cryogen volume low *ALARM* (*STANDBY* indicator flashes)

Cryogen volume empty *ALARM* (*STANDBY* indicator flashes)

Invalid catheter detected *ALARM* (catheter error indicator flashes)

SUCTION SYSTEM

Cryogenic Decompression Tube (CDT)

The cryogenic decompression tube (CDT) is a sterile, single use, disposable device. The physician places the CDT in the patient per physician training certification protocol. The port indicator band on the CDT is placed just proximal to the targeted treatment site, while the distal end of the CDT is placed into the atrium of the stomach. The proximal end of the CDT connects to the vacuum tubing by means of the CDT connector. (Figure 6) Only approved CSA Medical accessories are designated for use with the system.

Figure 6: CDT System

Collection Canister

The collection canister is an 800ml, disposable canister for the accumulation of fluids. One end of the vacuum tubing connects to the CDT and the other end connects to the inlet port on the collection canister. (Figure 7)

Figure 7: Suction Canister

Suction Port

The suction port is found on the back panel of the main console. One end of vacuum tubing connects to this port and the other end connects to the wall vacuum or appropriate free-standing suction system. The setting of the wall vacuum must be on High or Full.

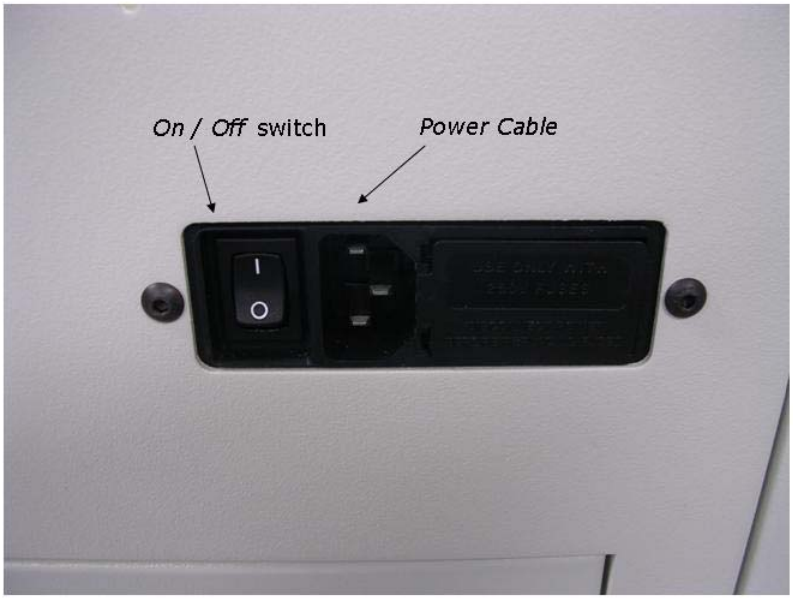
CATHETER REMOVAL SYSTEM / ACTIVE HEAT

An active heating mechanism works to defrost the catheter/gastroscope interface to facilitate removal of the catheter from the gastroscope.

POWER SYSTEM

Power *On/Off* is located on the back panel (Figure 8). The display on the main console is illuminated to indicate that the power is connected and functioning when the device is in the *ON* position.

Figure 8: ON/OFF Switch on the Back Panel

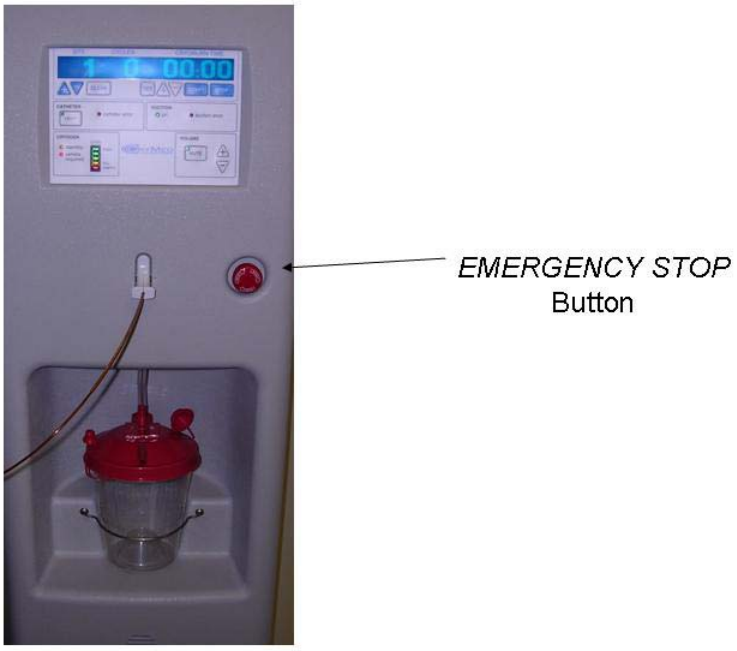


EMERGENCY STOP

The EMERGENCY STOP button is located on the front panel of the main console (Figure 9). Depressing it will stop the cryogenic delivery system and release the pressure in the cryogenic tank. It will also prevent any other operator control with the exception of the HEAT to remove the CSA™ Cryocatheter from the endoscope.

CAUTION:	**Depressing the EMERGENCY STOP button will stop the cryogenic delivery system release the pressure in the cryogenic tank.**

Figure 9: Emergency Stop Button

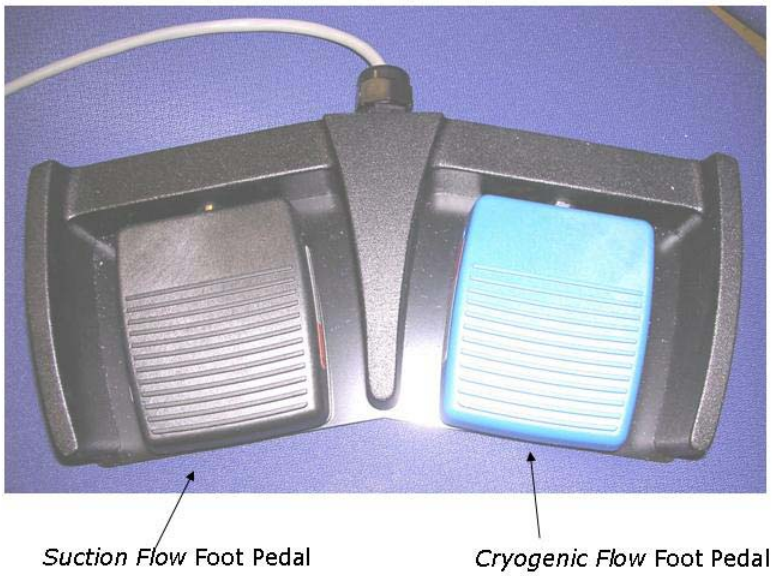


FOOT PEDAL CONTROLS

Cryogen Flow Management

The blue foot pedal activates and deactivates the cryogen flow (Figure 10).

Figure 10: Foot Pedal Controls



Suction System Management

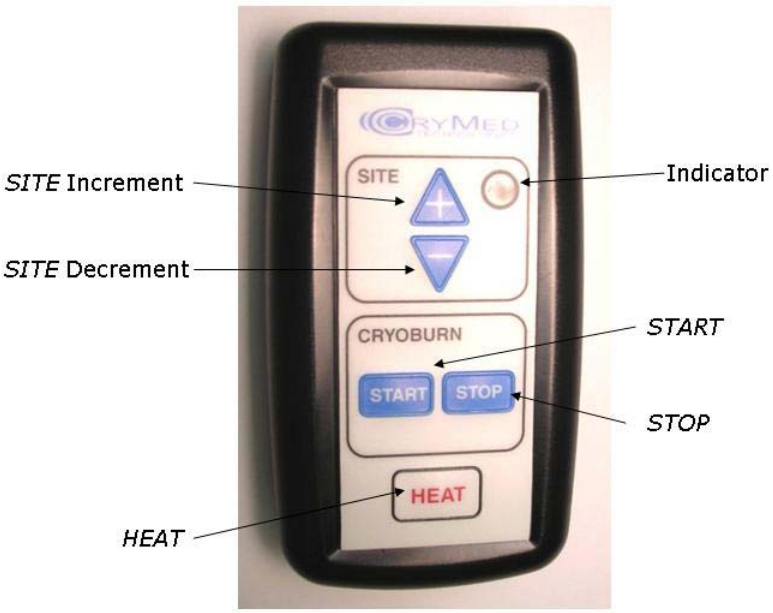
The black foot pedal activates and deactivates the suction flow (Figure 10).

HAND HELD REMOTE CONTROL

Some of the operator controls found on the main console are duplicated on the hand held remote control. This allows the operator to operate the system from a distance. The wireless remote control is powered by 2 "AAA" alkaline batteries. Under normal use, the batteries provide power for approximately one year of use. Only approved CSA Medical accessories are designated for use with the system. The console and remote control transmitters operate at a very low power and are intrinsically compliant to RF exposure requirements.

Caution: changes or modifications to this equipment not expressly approved by CSA Medical could void the user's authority to operate the equipment. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Figure 11: Hand Held Remote[JBC3]



An indicator flashes briefly while any button is pressed to indicate that the wireless remote control is functioning properly (Figure 11).

The wireless remote control contains isolation to preclude the possibility of data cross-transmission between multiple systems in close proximity with each other.

If the Hand held remote should become lost, please contact CSA Medical. The contact information is located on page 30 under the Repair and Modification Section of this User's Manual.

Site Management

UP ARROW Site: allows user to Increment between sites. (Figure 11)

DOWN ARROW Site: allows user to decrement between sites. (Figure 11)

FreezeTime Time Management

A timer announcement tone is generated to alert the operator as the timer approaches its target time. Timer announcement tones are generated at five-second intervals, and at each of the final four seconds approaching the target time. Once the target time is reached, the timer announcement tone is generated continuously until a Stop Timer event occurs. (Figure 11)

START: depressing the *START* button, on the hand remote or on the console, begins the *FREEZETIME TIME* incrementing. (Figure 11)

STOP: depressing the *STOP* button ceases the *FREEZETIME TIME* from incrementing. (Figure 11)

Catheter Removal Management / Active Heat

HEAT: depressing the *HEAT* button on the hand remote or main console will activate the CSA™ Cryocatheter's active heating cycle (Figure 11). The heating cycle will be active for a period of 14 seconds. Additional cycles may be activated by depressing the *HEAT* button on the hand remote or main console until the catheter is thawed.

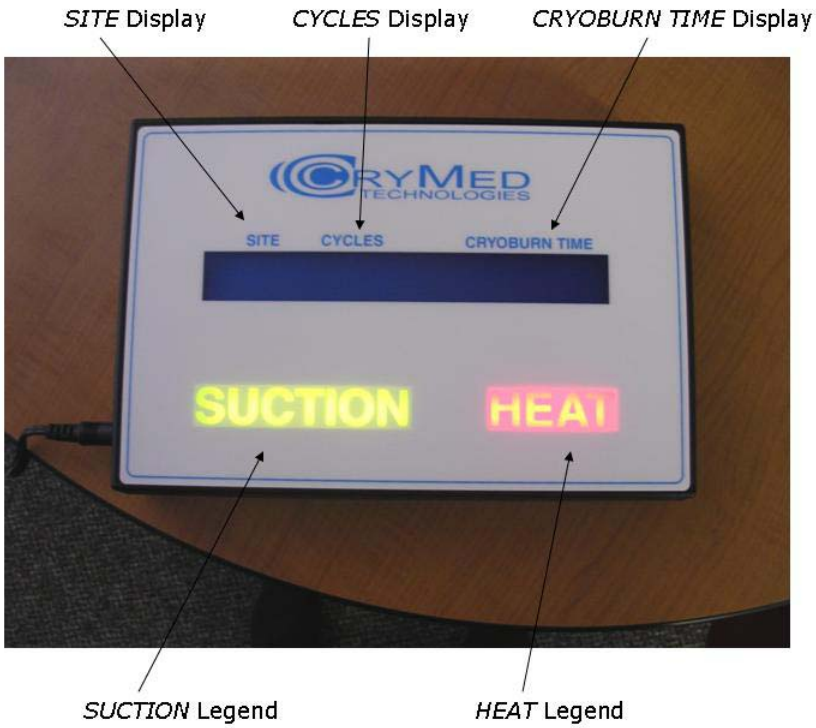
REMOTE DISPLAY

The control console communicates with the remote display device via a dedicated radio frequency link. The console and remote control transmitters operate at a very low power and are intrinsically compliant to RF exposure requirements. Caution: changes or modifications to this equipment not expressly approved by CSA Medical could void the user's authority to operate the equipment. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Means are provided to prevent unintended communication between multiple systems in close proximity to one another.

The remote display is powered by an external, wall-mounted power supply. Only the power supply provided with the device, the Elpac P/N MW1212-760-NC, is designated for use with the system. To turn the remote display off, unplug the display.

Figure 12: Remote Display[JBC4]



Site Display

The *SITE* display enables the operator to view the current treatment site information (Figure 12). *SITE*: 2-digit display indicating the current treatment site.

For a site decrement switch event, the stored *FREEZETIME TIME* will be restored to the display. For a site increment switch event, if the new site has a stored FreezeTime time associated with it, the stored *FREEZETIME TIME* will be restored to the display. If the new site does not have a stored *FREEZETIME TIME* associated with it, the *FREEZETIME TIME* display will be cleared.

Cycle Display

The *CYCLES* display enables the operator to view the current treatment cycle information for any particular site (Figure 12). *CYCLES*: a 2-digit display indicating the treatment cycle for a particular treatment site.

The *CYCLES* display keeps track the number of times the timer has reached its target time (default value: 20 seconds) within an associated *FREEZETIME TIME*. If the FREEZETIME announcement time exceeded the FREEZETIME set time, the cycle will automatically increment to the next cycle. If the FREEZETIME announcement time did not exceeded the FREEZETIME set time, either the cycle should be completed or treatment should move to a new site.

FreezeTime Time Display

The *FREEZETIME TIME* display enables the operator to know how long a specific treatment tissue has been frozen (Figure 12). *FREEZETIME TIME*: will be displayed in minutes:seconds format.

The *FREEZETIME TIME* displays the elapsed *FREEZETIME TIME* since the *START* button has been depressed, either from wireless remote control or the control console. The *FREEZETIME TIME* display will continue to count until the *STOP* button is depressed, and will resume without clearing upon the next depression of the *START* button.

Suction Status

The *SUCTION* legend will be continuously illuminated in *Green* to indicate that suction system is on (Figure 12).

Catheter Removal Status / Heat Status

The *HEAT* legend will be continuously illuminated in *RED* to indicate that heat system is on (Figure 12).

WHEEL LOCK MECHANISM

The wheels may be locked by moving the red lock lever (Figure 13) to the left of center or to the right of center. The wheels are free to roll when in the center position.

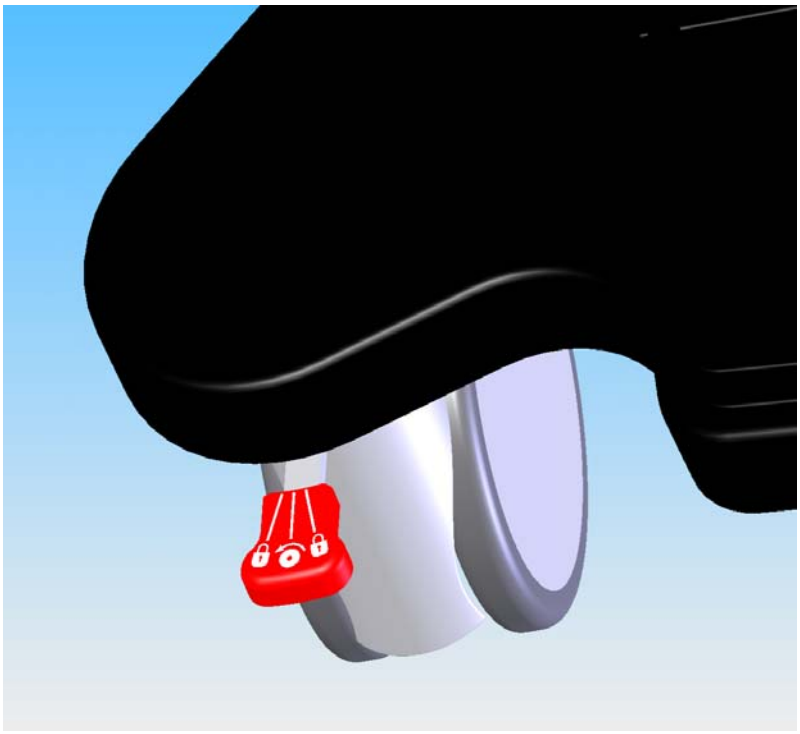


Figure 13: Wheel Lock Mechanism

FILLING INSTRUCTIONS

Prior to use, the Cryogenic tank must be filled with Medical Grade Liquid Nitrogen.

WARNING:

Use medical grade liquid nitrogen (LN2) to fill the cryogenic tank.

WARNING:

Always perform filling in a well ventilated area as nitrogen gas can displace oxygen in a closed area and lead to asphyxiation.

WARNING:

The contents of the Liquid Nitrogen tanks are under pressure.

WARNING:

Ensure that the cryogen does not come in contact with persons or tissue during filling or serious injury may occur. The valves, fittings, and hose will become extremely cold and frosted as liquid nitrogen passes through them. Special gloves should be worn when filling the Cryo Tank to prevent damage to the skin. Protective eye wear should be worn when filling the Cryo Tank. These containers are designed for use in the upright position and should not be laid on their side. Do not attempt to lift the tank.

CAUTION:

FILLING:

These containers can be filled from a pressurized **"medical grade**" liquid Nitrogen Supply Tank using the following procedure:

1) Make sure that all valves are in the closed position before you begin and put the wheel locks into the locked position, by kicking the red lock lever to the right or to the left, and protective eyewear and gloves are worn.

2) Power down the system. Use the key provided with the system to open the door lock on the back panel on the console. Opening the back panel will automatically power down the system.

3) Attach one end of the liquid nitrogen (LN2) transfer hose to the fitting labeled LIQUID on the supply tank. A wrench should be used to make sure that the connection is tight.

4) Attach the other end of the LN2 transfer hose to the fitting labeled LIQUID on the Cryo Tank. A wrench should be used to make sure that the connection is tight.

5) Completely open the VENT valve and then the LIQUID valve on the Cryo Tank.

WARNING: The system will become very cold so LN2 gloves and goggles are necessary!

6) To begin the transfer, open the LIQUID valve on the supply tank. This will start the flow of LN2 through the transfer line into the Cryo Tank.

⚠ **CAUTION: A cold stream of gas and or liquid will exit from the vent valve, so keep clear of the stream!**

7) When the Cryo Tank is filled to maximum capacity, liquid will start to exit from the vent valve; close the LIQUID valve on the supply tank.

⚠ **CAUTION: Only close the valve on the supply tank!**

8) Wait 1 minute until the LN_2 transfer line empties. Slowly, Detach the two ends of the LN2 transfer hose from the supply tank and the Cryo Tank. Use caution because the contents in the transfer hose can have residual LN2 in the hoses.

9) Close the LIQUID valve on the Cryo Tank.

10) Close the VENT valve on the Cryo Tank.

11) Make sure that all the valves are completely closed.

12) Close the back panel.

System Assembly

1. Follow filling instructions in Chapter 3.

2. Connect the Power supply cord to the back panel power fitting labeled *POWER*.

3. Place the Remote display in the field of view of the physician and plug the power cord into an outlet. Attach to the video monitor with the Velcro provided.

4. Install batteries in the hand held remote control.

User Instructions

1) Follow Filling Instructions.

2) Follow Assembly Instructions.

3) Place the Console in close proximity to the physician's work area.

4) Once positioned, lock wheels.

5) Plug the power cable from the back panel of the main console into the electrical outlet.

⚠ **CAUTION:** **Ensure that the power cable is dry or it may result in electrical shock to the user.**

6) Turn the system on by using the ON/OFF power on the back panel of the console.

7) Check the Cryogen Level display and other indicators on the User Interface for any Error readings.

8) Inspect the CDT package for damage. Open the package and connect the CDT to the vacuum tubing be means of the connector provided within the package. The vacuum tubing can be standard 0.30" ID, 6" length Hospital vacuum tubing.

⚠ **CAUTION:** **Prior to installing a CSA™ Cryocatheter or CDT, carefully inspect for damage, such as cracks or breaks. Do not install the CDT if it appears damaged.**

9) Connect the other end of the vacuum tubing to the inlet port on the suction canister. The vacuum tubing can be standard 0.30" ID, 6" length Hospital vacuum tubing.

10) Connect wall suction to the back SUCTION PORT on the back panel of the console with a separate vacuum tube.

NOTE: Ensure that the wall suction setting is on "HIGH" or "FULL".

11) Inspect the CSA™ Cryocatheter package for damage. Open the package and attach the catheter to the catheter port on the front of the console.

⚠ CAUTION: Prior to installing a CSA™ Cryocatheter or CDT, carefully inspect for damage, such as cracks or breaks. Do not install the CSA™ Cryocatheter if it appears damaged.

12) Set the FREEZETIME announcement Time:

An announcement tone is generated to alert the operator as the target time is approached. The announcement tones are generated at five-second intervals, and at each of the final four seconds approaching the target time. Once the target time is reached, the announcement tone will be generated continuously until the *STOP* button is pressed.

To set the announcement time:

While the set time is depressed, the time display shows the current timer announcement interval, and flashes.

SET Time: allows user to set announcement times.

UP ARROW: allows user to increase the announcement time.

DOWN ARROW Time Decrement: allows user to decrease the announcement time.

If the *UP ARROW* is depressed while the set time is flashing, the timer announcement interval will increment by one second.

If the *DOWN ARROW* is depressed while the set time is flashing, the timer announcement interval will decrement by one second.

If either the *UP ARROW* or *DOWN ARROW* is held down for more than 2 seconds, while set time is flashing, the timer announcement intervals will auto-increment or auto-decrement.

NOTE: The *CLEAR* button resets the system to the default value.

13) The system is now ready to run.

14) Place the CDT appropriately relative to the target tissue according to desired surgical technique.

15) Place the CSA™ Cryocatheter through the working channel of the diagnostic endoscope and appropriately relative to the target tissue according to desired surgical technique.

16) Depressing the BLUE foot pedal causes liquid nitrogen to flow out of the catheter. To stop liquid nitrogen flow, depress the BLUE foot pedal again.

17) Depressing the BLACK foot pedal causes a suction to be pulled through the CDT. To stop suction flow, depress the BLACK foot pedal again.

18) Pushing the START button on the console or on the hand remote begins the FREEZETIME TIME. This switch should be depressed when the treated tissue displays a white demarcation.

START: depressing the *START* button, on the hand remote or on the console, will begin the *FREEZETIME TIME* incrementing.

19) Upon hearing the audible announcement, signaling the completion of a CYCLE, depress the BLUE foot pedal to stop the cryogen flow and press the STOP button on the console or on the hand remote to stop the FREEZETIME TIME STOP: depressing the STOP button will cease the FREEZETIME TIME from incrementing.

20) Either move to a new site, or begin a new cycle at the same site. If the FREEZETIME announcement time exceeded the FREEZETIME set time, the cycle automatically increments to the next cycle. If the FREEZETIME announcement time did not exceeded the FREEZETIME set time, either the cycle should be completed or treatment should move to a new site.

21) To remove the catheter, depress the HEAT button on the hand remote or main console actives the CSA™ Cryocatheter's active heating cycle. The heating cycle is active for a period of 14 seconds. Additional cycles may be activated by depressing the HEAT button on the hand remote or main console until the catheter is thawed.

22) Emergency Stop completely shuts down the system, and should only be used in the case of an emergency.

23) Following a single procedure, the CSA™ Cryocatheter and the CDT should be considered clinical waste, and should be disposed of in accordance with facility and local regulations.

SPECIFICATIONS

Main Console

Type:	Class I Equipment in accordance with EN60601-1 TYPE BF Applied Part The system meets the requirements of EN60601-1-2.
Size:	76 cm (30”) in width, 89 cm (35”) in depth, and 134.5 cm (53”) in height
Weight:	182 kg (<400 lb) with tank full
Power requirements:	AC 120V/60Hz with power input switch, maximum power consumption not to exceed 650 W. System operating voltages will be 90 to 132 VAC, 50/60 Hz. System power consumption will not exceed 650 W. Continuous Operation Device IPXO Ordinary Device-console has no protection against water ingression.
Fuse requirements:	(2) 5*20 mm 5 Amp Slo-Blo Fuses
Environment:	Operating temperature range of 15º- 30ºC (59º-86ºF), 10-90% relative humidity, non-condensing. System storage temperatures will be -20 to 50 ºC, humidity 10-90%, non-condensing.
Foot pedal:	9 feet (108 inches) cord length, IPX8 rating

Remote Display

Type:	Dedicated radio frequency remote display device ,
Size:	17 cm (6.7”) in width, 25 cm (9.8”) in depth, and 4 cm (1.6”) in height
Power requirements:	In-line power supply will be designed for operating voltages of 90 to 132 VAC, 50/60 Hz. System power consumption will not exceed 15 W.
Environment:	Operating temperature range of 15º- 30ºC (59º-86ºF), 10-90% relative humidity, non-condensing. System storage temperatures will be -20 to 50 ºC, humidity 10-90%, non-condensing.

Hand Held Remote Control

Type:	Dedicated radio frequency remote control ,DIP switches
Size:	10 cm (3.9”) in width, 6 cm (2.4”) in depth, and 3 cm (1.2”) in height
Power requirements:	2 “AAA” alkaline batteries.
Environment:	Operating temperature range of 15º- 30ºC (59º-86ºF), 10-90% relative humidity, non-condensing. System storage temperatures will be -20 to 50 ºC, humidity 10-90%, non-condensing.

REPAIR AND MAINTAINCE

⚠ **CAUTION:**	Disconnect the Device and Accessories from the electrical source.

Disconnect the Device and Accessories from the electrical source. Fuses may be replaced with identical replacements, (2) 5*20 mm 5 Amp Slo-Blo Fuses. Fuses are located in the fuse box adjacent to the power switch.

⚠ **WARNING**	**This device contains no user-serviceable parts. Do not disassemble, modify or attempt to repair. Patient or user injury and equipment damage can result.**

Refer to Chapter 4, “Troubleshooting” for information about resolving certain problems. If the problem cannot be resolved using the information in Chapter 4, please contact CSA Medical.

CSA Medical, Inc.
Emerging Technology Center
1101 E. 33rd Street, Third Floor - #A305
Baltimore, MD 21218
Phone: 443-921-8053

Internet Address: http://www.CSAmedical.com

SYSTEM START-UP

Upon power-up, the control console initializes all solenoid outputs to the “Off” state, and performs a set of self-tests.

SYSTEM SHUTDOWN

To shut the system down, use the ON/OFF switch on the back panel of the main console. Unplug the power cord from the electric outlet and wrap the cable on the cable storage rack on the back panel of the main console. The System should be powered down at the end of each day of use. The system will vent pressure periodically, both when powered and when it is unplugged.

Place the foot pedal into the foot pedal holster on the back panel of the main console. Wrap the cable around the cable storage rack on the back panel of the main console.

ROUTINE MAINTENANCE

⚠ **WARNING**	**Do not attempt to reprocess the CSA™ Cryocatheter or CSA™ CDT.**

⚠ **CAUTION**	**Do not allow sharp objects, such as scalpels, to touch the CSA™ Cryocatheter or CSA™ CDT.**

SYSTEM CLEANING

Once a day, or more frequently if necessary, use a soft cloth lightly dampened with alcohol, or a 10% solution of bleach, to wipe down the User Interface, exterior of the Main Console, Hand Held Remote and Remote Display.

STORAGE AND TRANSPORT CONDITIONS

The proper storage temperature for the device, CSA™ Cryocatheter and the nasal gastric tube is from -20° to 50°C and a humidity range of 10 – 90%, non-condensing.

The product shall function in the operating temperature range of 15º - 30ºC, and humidity range of 10 – 90%, non-condensing.

Listed below are possible irregularities that may occur with the CSA™ Medical CryoSpray Ablation System. If additional troubleshooting assistance is required, please contact CSA Medical.

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MAIN CONSOLE

Irregularity Description	Possible Cause	Solution
System will not Power-up.	Power supply cord is not connected correctly.	Check the power cord connection.
	On/Off switch is in the *off* position on the back panel.	Turn the power switch to *on* at the rear of the main console.
	Unit is already powered up.	If the displays on the user interface are illuminated, the device is powered up.
CATHETER ERROR Indicator light is illuminated.	The CSA™ Cryocatheter is not connected correctly.	Check catheter connection.
	The CSA™ Cryocatheter has been deemed invalid because the CSA™ Cryocatheter has been disconnected from the control console for more than 30 minutes from its first connection.	Insert a new CSA™ Cryocatheter .
	The CSA™ Cryocatheter has been deemed invalid because the CSATM	Insert a new CSA™ Cryocatheter .

	Cryocatheter has been connected to the control console for more than 2 hours.	
	The CSA™ Cryocatheter has been deemed invalid because the CSA™ Cryocatheter has been used before. The CSA™ Cryocatheter is a single use device.	Insert a new CSA™ Cryocatheter.
The cryogen delivery system is not working.	Foot Pedal is not connected correctly.	Check foot pedal connection on the rear of the main console.
	The CSA™ Cryocatheter is not connected correctly.	Check catheter connection and catheter error indicator LED.
	The emergency stop button has been depressed.	Reset the Emergency Stop Button.
	The system is in the STANDBY mode adjusting pressure and the STANDBY indicator is illuminated.	Wait for the STANDBY function to stop.
	The system low on Liquid nitrogen.	Fill the tank.
The HEAT turns off.	The HEAT is designed to turn off every 14 seconds.	Reengage the HEAT by depressing the button again.
The FREEZETIME TIME announcements can not be heard.	MUTE is engaged.	Press the MUTE button on the User Interface.
The FREEZETIME TIME announcements are not in the correct spacing	Set the announcement time on the User Interface.	Use the SET, UP and DOWN to set the appropriate time.
The FREEZETIME TIME continues to increment.	A STOP input is required.	Depress the STOP on the User Interface or hand remote.
The FREEZETIME TIME does not increment.	A START input is required.	Depress the START on the User Interface or hand remote.

SUCTION SYSTEM

Irregularity Description	Possible Cause	Solution
The suction error is indicated by illumination on the User Interface and the Alarm.	Cryotherapy Decompression Tube is occluded.	Replace the Cryotherapy Decompression Tube.
	The vacuum line is kinked.	Check all of the connection in the vacuum line, and replace if damaged.
	The Cryotherapy Decompression Tube connector is clogged.	Replace the connector.
	The collection canister is full.	Replace the canister.
The suction system is not working.	Foot Pedal is not connected correctly.	Check foot pedal connection on the rear of the main console.

HAND HELD REMOTE CONTROL

Irregularity Description	Possible Cause	Solution
The hand remote will not communicate with the console.	The batteries are dead.	Replace the batteries.

REMOTE DISPLAY

Irregularity Description	Possible Cause	Solution
The remote display will not power up.	Power supply cord is not connected correctly.	Check the power cord connection.