OPERATOR MANUAL

CSA Medical

truFreeze® System

Model Number: CC3-01

Freeze Disease.®

CSA Medical
1101 E. 33rd Street, E305
Baltimore, MD 21218 USA

CAUTION--Investigational device. Limited by Federal law to investigational use.

15-00127-D09

Revision	Revision History
D00	Initial development release.
D01	Updated Section 1.4.1 (Symbols), based on DR-10-017, and TCR-10-0070, to include more ISO Symbols. Updated Sections 2.1-2.4 (Specifications) updated based on TCR10-0110 to comply with Specs noted in PPS-02-00024. Updated Section 5 (Troubleshooting) based on TCR-10-0088 and DR-10-024 to include more trouble shooting solutions for users. Made general updates to Section 3 (Station Description and Console Description) to add clarity and detail.
D02	Updated Pictures to reflect hardware changes. Updated Table of Contents including hyperlinks. Updated Workflow, Troubleshooting, and System Description to reflect changes to hardware and software. Removed numerous ISO symbols and references to symbols on GUI buttons (changed to text).
D03	Section 1.2 added “Federal law (USA) restricts this device to sale by or on the order of a physician Section 1.4-updated new timer start button on RC, removed keyboard symbol (not used), removed fragile symbol (not used), updated usage column based to reflect where symbols are used and combined redundancies. Section 2.0- removed measurement in cm and updated dimensions, humidity, operating pressure, cryogen capacity and burst disc. Removed environmental requirements for remote control since redundant with console Section 3.0- added description of auxiliary connector (missing), added note to remove batteries to save lifespan, added introducer description (missing), changed PREP to COOL, changed two translucent buttons on left and right to one translucent button in center (to reveal data and service) and general clarifications of descriptions. Section 4.0-added general clarifications to existing information Section 5.0-BIT-Estop, write directions more clearly, Scan-note tag positioning, change PREP to COOL Updated photo on first page and figure 2 General formatting as needed
D04	Added description (Section 3) and instructions (Section 4) for use of control panel covers (USB, Fill Port, and Auxiliary Ports)
D05	Added Section 1.3 Accessories and Materials Provided Added Section 1.4 Installation Added Section 1.7 Summary of Safety Guidelines and Information to include FCC statement in English and French, RSS102 warning, service information, and general warnings Modified the location of the status indicator on Home screen to under the module access buttons Changed description from translucent blue dot to CSA logo to access hidden module buttons Removed reference to cancel scan box; limited to 5-10 second timeout period Modified instructions to select flow, suction, sound using radio buttons Updated pictures and formatting as needed
D06	Section 1.7 - Added Class B digital device to the FCC / IC section and compliance statement to Canadian ICES-003 in English and French and EMC / EMI guidance statements. Section 3.0 - Added explanation of E-Stop, description of suction canister holder and port, clarification of auxiliary covers, modification of fill hose insertion into fill port, COOL alert when foot pedal depressed (low bong), accessing HOME button from Set-Up screen, automatic precool with tag scan, note for normal and low suction combination, suction indicator background, and note when moving from low to normal cryogen. Section 4.0 – added modification of fill hose insertion into fill port, default for normal suction, note for normal and low suction combination, scan prior to treatment, and clarification around COOL feature (i.e., automatically engaged when tag is scanned, COOL alert when foot pedal depressed, automatic time-out). Section 5.0 - Added cryogen and suction states and indicators for Run screen.
D07	Symbols - added ESD label and description; corrected success BIT symbol from green check mark to plus System Description – added note about ESD warning to foot pedal storage box Workflow – added ESD symbol with warning to avoid touching pins of connectors
D08	Added statement to remove batteries from remote control if stored for extended periods of time.
D09	Added pressure sensing.

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1 INTRODUCTION

1.1 INDICATIONS FOR USE

The CSA Medical truFreeze CryoSpray System is intended to be used as a cryosurgical tool in the field of general surgery.

1.2 INSTRUCTIONS FOR USE

This Operator Manual contains essential information regarding the safe and effective operation of the CSA Medical truFreeze System. Before use, thoroughly review this Manual and the Instructions for Use (IFU) included with the truFreeze Spray Kit.

1.3 ACCESSORIES AND MATERIALS PROVIDED

Model / Part Number	Item
CC3-04	truFreeze Remote Control
CC3-01	truFreeze Fill Kit
14-02102	Foot Pedal
15-00127	Operators Manual
CD3-001	truFreeze Spray Kit (Provided Separately)
15-00133	Instructions for Use (Provided with Spray Kit)

1.4 INSTALLATION

The truFreeze System is to be installed by CSA Medical representatives only.
Reference Install and Removal Work Instruction (08-00025) for installation details.

1.5 SYSTEM OVERVIEW

The truFreeze System components and accessories are briefly explained below. Additional information, including how to use this System, is detailed throughout this Manual.

SYSTEM OVERVIEW	
Item	**Brief Description**
Console	The console provides thermal (cryogen), suction, pressure sensing and timer functions. Users interact with the console through a dual foot pedal and a large touch panel graphical user interface on a rotating monitor head. A controller and associated software manages cryogen level sensing, filling, pressure, cooling, defrosting, suction, timing and data management. Ergonomic features include a flat top work space, storage on sides and rear with a compact nitrogen tank and swiveling/locking casters for ease of movement. A wireless remote control provides alternative timer control from a distance of approximately 15 feet. A fill kit, stored on the rear of the console, allows for liquid nitrogen transfer from the source tank to the console.
Spray Kit	A sterile, single use, single patient 7 French catheter transports cryogen from the console to the treatment area. The catheter is flexible and durable and capable of retroflex in a scope. A bull-nosed (atraumatic) tip helps protect the patient. An insulated sheath and handle helps protect the user. A tapered introducer is used to reduce stress on the catheter where it enters a scope. A sterile, single use 20 French dual lumen CryoDecompression Tube (CDT) and accessory tubes are also included for use with the onboard suction system. The two CDT lumens are coupled by ports for gas evacuation through both the on-board suction pump and through passive vents to ambient.
Suction Canister	Bemis disposable high flow, high pressure canisters are purchased independently and used with the system.
Cryogen Source	A low pressure, medical grade liquid nitrogen (LN2) source is used to fill the console.
Freezing	Freezing techniques are monitored by direct visualization using the appropriate scope.

1.6 SYMBOLS

The following symbols are used on the truFreeze System and packaging and in this manual.

SYMBOLS		
Symbol	**Meaning**	**Usage**
	On (power)	Console (Rear)
	Off (power)	Console (Rear)
	Serial Number	Console (Rear) Remote Control
	Stepping prohibited. Do not step on foot pedal storage space.	Console (Front)
	Site Decrement	Remote Control
	Cycle Decrement	Remote Control
	Cryogen Timer Start/Stop	Remote Control
	Site Increment	Remote Control
	Cycle Increment	Remote Control
	Clear	Remote Control
	Successful	Console GUI (Built-In Test)

SYMBOLS		
Symbol	**Meaning**	**Usage**
	Unsuccessful	Console GUI (Built-In Test)
	Increment	Console GUI (Timer)
	Decrement	Console GUI (Timer)
	Authorized Representative in the European Community	Instructions for Use
	European Conformity (CE Marking)	Instructions for Use
	Keep Dry (Keep Away from Rain)	Instructions for Use and Disposable
	Use By	Instructions for Use and Disposable
	Sterilized Using Ethylene Oxide	Instructions for Use and Disposable
	Sufficient For Number of Procedures	Instructions for Use and Disposable
	Latex Free	Instructions for Use and Disposable
Rx ONLY	Federal law (USA) restricts this device to sale by or on the order of a physician.	Instructions for Use and Disposable
	Catalog Number	Instructions for Use and Disposable
	Lot Number/ Batch Code	Instructions for Use and Disposable

SYMBOLS		
Symbol	**Meaning**	**Usage**
	Date of Manufacture	Instructions for Use and Disposable
	Consult Instructions for Use	Instructions for Use and Disposable
	Manufacturer	Instructions for Use, Disposable and Manual
	Single Use. Use only once. Do not Re-use. Single patient	Instructions for Use, Disposable and Manual
	Do Not Use if Package is Opened or Damaged	Instructions for Use, Disposable and Manual
	Do Not Re-sterilize	Instructions for Use, Disposable and Manual
	Caution	Instructions for Use, Disposable, Console (Front) and Manual
	Warning; Dangerous voltage	Instructions for Use and Manual
	Contents Under Pressure	Instructions for Use and Manual
	Do Not Stack Sticker or Cone	Crate Packaging
	Emergency Stop	Manual

SYMBOLS		
Symbol	**Meaning**	**Usage**
	Warning: Low Temperature/ Freezing Conditions	Manual
	Wear Safety Gloves Appropriate for Cryogenic Conditions	Manual
	Wear Protection Goggles Appropriate for Cryogenic Conditions	Manual
	Type BF Applied Part	Manual Console (Front and Rear)
DANGER	Indicates an imminently hazardous situation, which, if not avoided, will result in death or serious injury.	General Safety Precautions
 **DANGER**	Never expose the truFreeze System to liquid. If any liquid is spilled into 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.	General Safety Precautions
WARNING	Indicates a potentially hazardous situation, which, if not avoided, could result in death or serious injury.	General Safety Precautions

SYMBOLS		
Symbol	**Meaning**	**Usage**
 **WARNING:**	Ensure that the cryogen does not unintentionally come in contact with 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 must be worn when filling the truFreeze Console to prevent damage to the skin. Protective eyewear must be worn when filling the truFreeze Console.	General Safety Precautions
 **WARNING** **Asphyxiation Hazard**	Always use equipment in a ventilated area. Nitrogen may act as an asphyxiation hazard by displacing oxygen from a confined space[1]. High concentrations of nitrogen in the air cause a deficiency of oxygen with the risk of unconsciousness or death. On loss of containment this liquid evaporates very quickly, causing super saturation of the air with serious risk of suffocation when in confined areas. Use of an oxygen monitoring device is recommended.	General Safety Precautions
 **WARNING**	The cryogen tank in the console is under pressure.	General Safety Precautions

[1] A confined space is defined by the U.S. Occupational Safety and Health Administration (OSHA) as a space that is large enough for a person to enter, has limited means for entry or exit, and is not designed for continuous occupancy.

SYMBOLS		
Symbol	**Meaning**	**Usage**
 **WARNING**	Do not use the system if the system has indicated an alarm; user or patient injury or device damage may result. Investigate the alarm and contact CSA Medical if the cause cannot be determined or corrected.	General Safety Precautions
 **WARNING**	The defrost function uses warm nitrogen gas. Adequate venting of this gas from patient should be ensured.	General Safety Precautions
 **WARNING**	Inspect the catheter for damage prior to use and do not use the catheter if it is damaged in any way.	General Safety Precautions
 **WARNING**	Never use the catheter if the outer packaging is punctured or open, as the product is no longer sterile and patient injury may result. Do not re-use the catheter; do not resterilize catheter; it is a single-use single patient device.	General Safety Precautions
 **WARNING**	Cutting or otherwise altering catheters may impact (increase) the flow of liquid nitrogen though the catheter, resulting in an increased risk of perforation, stricture, or other damage to the treatment area.	General Safety Precautions
 **WARNING**	Electrostatic Discharge Warning: Avoid touching electrical pins of the foot pedal connector, unless properly trained and using ESD procedures.	Manual Console (Foot Pedal Storage)
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.	General Safety Precautions

SYMBOLS		
Symbol	**Meaning**	**Usage**
 **Caution: Emergency Stop**	Depressing the emergency stop button on the front of the console halts the cryogenic delivery system and releases the pressure in the cryogen tank.	General Safety Precautions
 **CAUTION**	Liquid nitrogen expands more than 700 times when changing from a liquid to a gaseous state. It is imperative for patient safety that adequate ventilation is ensured to remove gas created during the treatment session.	General Safety Precautions
 **CAUTION**	The console is designed for use in the upright position and should not be laid on its side. Do not attempt to lift.	General Safety Precautions
 **CAUTION**	Disconnect the console from the electrical source when performing repairs.	General Safety Precautions
NOTE	Indicates additional helpful information.	General Safety Precautions
CONDITIONS TO AVOID DURING USE	In the presence of large magnetic fields, the wireless communication of the remote control may be disrupted; however, the controls on the console should not be affected.	General Safety Precautions

1.7 SUMMARY OF SAFETY GUIDELINES AND INFORMATION

Federal Communications Commission (FCC)
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.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radioexempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

This equipment has been tested and found to comply with the limits for a Class A (console) and Class B (remote control) 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/her own expense.

Industry Canada RSS210
This Class B digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de la Classe B est conforme à la norme NMB-003 du Canada.

The installer of this radio equipment must ensure that the antenna is located or pointed such that it does not emit RF field in excess of Health Canada limits for the general population; consult Safety Code 6, obtainable from Health Canada's website www.hc-sc.gc.ca/rpb

Service Information
Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

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

This manual contains important information on the proper use and maintenance of the CSA Medical truFreeze 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 truFreeze System and should be retained in a conveniently accessible area for quick reference.

General Warnings

WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING: No modification of this equipment is allowed.

Guidance and manufacturer's declaration – electromagnetic emissions		
The truFreeze Console and Remote Control are intended for use in the electromagnetic environment specified below. The customer or the user of the truFreeze Console and Remote Control should assure that it is used in such an environment.		
Emissions test	**Compliance level**	**Electromagnetic environment – guidance**
RF Emissions CISPR 11	Group 2	The truFreeze Console and Remote Control use RF energy and emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class B	The truFreeze Console is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network power supply that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations / flicker emissions	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The truFreeze Console and Remote Control are intended for use in the electromagnetic environment specified below. The customer or the user of the truFreeze Console and Remote Control should assure that it is used in such an environment. (* indicates affects both the truFreeze Console and Remote Control; all others apply strictly to the truFreeze Console)			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD)IEC 61000-4-2*	±6kV Contact ±8kV Air	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Radiated RF IEC 61000-4-3*	3 V/m 80MHz to 2.5GHz	Complies	Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic sit survey, should be less than 3 V/m. Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted RF IEC 61000-4-6	3Vrms 150kHz to80MHz	Complies	
Electrical fast transient IEC 61000-4-4	±2kV power line ±1kV I/O lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential ±2kV common	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
Power frequency magnetic field IEC 61000-4-8*	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interrupts and voltage variations on power supply input lines IEC 61000-4-11	>95% dip 0.5 cycle 60% dip 5 cycles 70% dip 25 cycles 95% dip 5 sec.	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the truFreeze Console requires continued operation during power mains interruptions, it is recommended that the truFreeze Console be powered from an uninterruptible power supply or battery.

2 SPECIFICATIONS

Some truFreeze System Specifications are provided below.

CONSOLE SPECIFICATIONS	
Type	Class I Equipment in Accordance with EN 60601-1 Type BF Applied Part
Applied Parts	Catheter and CryoDecompression Tube (CDT) (Optional Pressure Sense Tube)
Size	Width: 16 in Height: 65 in Depth: 27 in
Weight	Empty: 250 lb Full: 300 lb
Cryogen Capacity	13 L (Minimum)
Cryogen Operating Pressure	Up to 24 PSI (Nominal) (Accuracy +/- 2.4 PSI)
Cryogen Storage Pressure	35 PSI (Nominal) (Accuracy +/- 4 PSI)
Cryogen Safety Burst Disk	98 PSI (Nominal) (Accuracy +/- 10 PSI)
Vacuum Pressure	Up to 20 inHg (Nominal) (Accuracy +/- 3 inHg)
Power Requirements	100-240 VAC, 10 A, 50/60 Hz
Fuse Requirements	250 VAC, 10 A
Environment	Operating Temperature: 15-30 C Relative Humidity: 20-90%, Non-Condensing Shipping: -20-50 C
REMOTE CONTROL SPECIFICATIONS	
Type	Dedicated Radio Frequency Remote Control Device
Size	Width: 3 in Height: 5 in Depth: 1.2 in
Power Requirements	Two (2) AA Batteries (Alkaline)

3 SYSTEM DESCRIPTION

A description of the truFreeze system and individual components is provided below.

CONSOLE	
Console	The console is the main component of the truFreeze System and controls delivery of cryogen to the patient through a disposable catheter. The console is made up of the cart and panel personal computer (PC) where the user interfaces with the software. Accessories such as the remote control and fill kit are also included as part of the system. A controller and associated software manages cryogen level sensing, filling, pressure, cooling, defrosting, suction, timing and data management. Console features include a flat top work space, storage on sides and rear, four (4) rotating casters for ease of movement, nitrogen holding tank, large color monitor at eye level with rotating monitor head, onboard suction pump with variable speed and an interactive color touch screen (user interface) for operation.
CONSOLE CART (Figure 1)	
Mobility	The console is packaged in a mobile cart with four freely rotating, large casters. The two (2) front casters may be locked by moving the lock lever to left or right of center; the cart is free to roll when the lock lever is in the center position. A handle located on the front makes it easy to maneuver the console and protects key components including the catheter.
CONSOLE FRONT PANEL (Figure 1)	
Foot Pedal Storage Compartment	The foot pedal storage compartment is located in the bottom middle portion of the front panel and provides housing for the foot pedal control unit. A cord spool for the foot pedal cord is located directly above the compartment. **NOTE:** A warning label indicates stepping is prohibited on foot pedal storage area. **WARNING** (Electrostatic Discharge): Avoid touching electrical pins of the foot pedal connector, unless properly trained and using ESD procedures.

Control Panel	The blue control panel is located in the upper middle portion of the console front panel. It contains the EMERGENCY STOP (E-Stop) button, catheter port, auxiliary panel, auxiliary connector, fill port, and USB port. Covers are provided to protect control panel features from damage.
Emergency Stop Button (E-Stop)	An EMERGENCY STOP button is located on the upper left portion of the control panel. It is a large red button with a yellow shroud surrounding the E-Stop button to prevent accidental activation. Pressing the button stops cryogen transfer and releases pressure in the cryogen tank. If E-Stop remains engaged, all cryogen will be evacuated from the console. When the button is pressed (activated), the red E-Stop light will be illuminated. To disengage (turn off) E-Stop button in the event of accidental activation, twist red button to the right (light will not be illuminated)
Catheter Port	The catheter port is located on the upper middle portion of the control panel. The catheter port is the insertion point of the catheter hub (white handle on the end of the catheter), and connects the catheter to the console's cryogenic delivery system. The catheter port contains a small white catheter switch which is activated when the catheter is inserted.
Auxiliary Ports and Connector	The auxiliary ports are located on the upper right portion of the control panel. The auxiliary connector is located on the lower right portion of the control panel, below the auxiliary ports. The auxiliary pressure port connects the pressure sense tube to pressure sensor. The auxiliary thermocouple port and control ports, are not currently implemented (white, red, and blue ports). A tethered cover is provided to protect from debris and damage, and should remain in place when not in use.
Fill Port	The fill port is located on the lower middle portion of the control panel. The fill port is the insertion point for the fill hose bayonet. The transfer of liquid nitrogen from the source tank to the console is via the fill hose.

	Using the handle, the fill hose should be inserted into the fill port at the 12 o'clock position. Rotate the handle counterclockwise until the fill hose pin aligns with the fill port slot. Once aligned, rotate handle clockwise until the hose clicks into place. A tethered cover is provided to protect fill port from debris. Cover should only be removed for filling the console or downloading data.
USB Port	A USB port is located in the lower left portion of the control panel. The USB port is used to download log files from the console to a USB stick (not provided). The USB port may also be used by authorized CSA Medical personnel to perform service activities. A tethered cover is provided to protect USB port from damage. Cover should only be removed for downloading data or filling console.
Canister Holder	The canister holder is located on the lower left portion of the front panel. The canister holder consists of the canister holder reservoir, and the suction port. The assembled Bemis canister will reside inside the canister holder reservoir. The suction port is located on the underside of the canister holder reservoir. The short section of accessory tubing connects the suction port to the Bemis canister
CONSOLE PANEL PC AND USER CONTROLS (Figure 1)	
Panel PC	A touch panel personal computer is mounted to the top of the console at eye level. The mount allows rotation side-to-side and up-and-down (via knob on back of PC) for optimum viewing and touch screen access. The user interfaces with the touch screen display on the Panel PC, known as the graphical user interface (GUI), by touching buttons on the screen.
Remote Control	The remote control allows the user to control certain functions remotely. All buttons on the remote control are redundant with the RUN screen.

	The remote control contains the following buttons: site increment () site decrement () cycle increment () cycle decrement () time start/stop () clear () When selecting a button from the remote control, press it firmly and then release pressure on the button.
Remote, Electronics and Batteries	The remote control sends signals via a standard IEEE 804 wireless communication (Zigbee). The remote control runs on two (2) AA batteries. The battery compartment is located in the back of the remote control. Batteries may be removed after each procedure to preserve lifespan. **NOTE:** If the remote control will not be used for an extended period of time the batteries should be removed.
Foot Pedal Control	The foot pedal control provides control of the cryogen spray & suction. Pressing the grey foot pedal activates suction. Pressing the grey foot pedal again de-activates suction (toggle pedal). Depressing the blue foot pedal starts the spray of cryogen. Releasing the pedal stops the flow of cryogen (momentary pedal). **NOTE**: if COOL has not been engaged prior to spraying cryogen, depressing the footpedal will activate COOL automatically. The user will know the system is cooling by a low bong sound emitted upon depression of the foot pedal (see Treatment Panel, COOL Button section for more details).
CONSOLE REAR PANEL (Figure 2)	
Label	The console label is located on the upper center of the rear panel and indicates the product name, model and serial numbers, the input voltage and input frequency, the manufacturer address and logo, and appropriate certifications.

Power	The power switch is located on the upper left of the rear panel. The console is ON when the switch is in the “I” position, indicated by a green light; console is OFF when the switch is in the “O” position, green light will no longer be illuminated. A detachable power cord has a female end that plugs into the power entry module (PEM) on the lower left rear panel and a male end that plugs into standard wall power. The power cord storage spool is located on the lower center of the rear panel. A compartment directly under the power entry module (PEM) houses the PEM fuse. Labeling above the PEM indicates the proper fuse rating.
Fill Kit and Storage	Storage for the fill kit items (hose, wrench, gloves and goggles) is located on the console rear panel. A 6 ft fill hose is provided for transferring LN2 from the source tank to the console; the hose is partially insulated, and has a handle for gripping. The hose is designed for liquid nitrogen (CGA-295 fitting), and cannot be used with other types of gases; the non-handle end of the fill hose will be connected to the LIQUID valve of a low pressure, medical grade LN2 source tank. The handled end of the fill hose has a bayonet which will be inserted into the transfer port on the console. A wrench is provided to fully secure the connection between the fill hose and the LIQUID valve of the source tank. Protective eyewear and cryogenic gloves are provided to prevent damage to skin and eyes during the filling process. **NOTE**: The valves, fittings, and hose will become extremely cold and frosted as liquid nitrogen passes through them. **WARNING**: Special gloves must be worn when filling the console to prevent damage to the skin. **WARNING:** Protective eyewear must be worn when filling the console; liquid nitrogen and gas are extremely cold and may cause serious eye injury if protective eyewear is not worn.
CONSOLE SIDE PANELS AND STORAGE (Figures 3 & 4)	
Storage Compartment	Large storage compartments are located on both side panels for storage of manuals, instructions and disposable catheter spray kits.

	A smaller storage compartment is located on the upper left side for remote control and other procedure items. **NOTE:** Side panels should only be removed by authorized service personnel and are protected by coin-lock latches.
Scan Pad	The right side panel contains a blue scan pad for the Radio Frequency Identification (RFID) scanner. The RFID scan tag on the catheter pouch should be held up against the scan pad and held slightly forward of center for 2-3 seconds (avoid waving the tag). Tag side of the catheter pouch should be facing the scan pad for optimal results.
CONSOLE CRYOGEN MODULE	
Cryogen Tank	The console contains a 15L vacuum insulated stainless steel cryogen tank for liquid nitrogen storage. The tank has operating pressures up to 24 PSI and storage pressure up to 35 PSI.
Cryogen Tank Filter	A 200 µm stainless steel filter is located on the fill port to prevent debris from the source tank or the fill hose from entering the console tank.
Cryogen Tank Level Sense	A load cell built into the front mount of the tank senses the weight of the tank to determine its fill level (level sense).
Pressure Control	The tank builds pressure passively by the natural evaporation of the liquid nitrogen. A mechanical relief valve regulates the liquid nitrogen pressure during storage (power off) and use (power on). When necessary (e.g., following a fill), the tank quickly builds pressure using a pressure build coil (PBC) located in the tank vacuum insulation jacket. A PBC valve controls the flow through the PBC. A pressure relief burst disc provides backup protection. A pressure sensor and switch provide pressure feedback for the controller.
Transfer Valve	The transfer valve is controlled by both the controller and E-Stop switch. The transfer solenoid valve provides on/off control to the console.

Electronics Module	The electronics module is located inside the upper rear of the cart. The electronics module includes a 24 VDC medical grade power supply, data acquisition and control modules, inner wiring interconnect board, and level sense conditioning module. Data acquisition and control hardware have input to sense system pressure, temperature and tank level, and provides on/off output to various control valves.
DISPOSABLE KIT (Figure 5)	
Spray Kit	Spray Kits include one box of five (5) individually packaged, single use, single patient catheter pouches (Catheter Kit), and one box of (5) individually packaged, single use, single patient tubing pouches (CryoDecompression Kit). Spray Kits must be ordered from CSA Medical in advance of a procedure to ensure on time arrival. Only CSA Medical Spray Kits are approved for use with the truFreeze System.
Catheter Kit (Catheter and Introducer)	The catheter is a sterile, single-use, single patient, disposable device. The catheter is packaged in a rigid, plastic tube to protect it from damage in handling and shipping. The catheter connection hub connects the catheter to the cryogenic delivery system via the catheter connection port. The catheter transports the liquid nitrogen from the console to the treatment site. The introducer is a flexible spring that will be inserted tapered end first approximately 1.5cm in the cap of the working channel of a scope. The introducer provides reinforcement for the catheter to help prevent kinking during use.
Decompression Kit (CDT and Accessory Tubes)	The CryoDecompression Tube (CDT) and accessory tubes are sterile, single-use, single patient, disposable devices. The CDT and long section of accessory tubing are divided by a separator. The short section of accessory tubing is packaged individually within the pouch. The CDT and tubing are connected to the console and Bemis canister to transport gas from the treatment area.
SYSTEM ACCESSORIES	
Cryogen	A low pressure (<50PSI), medical grade liquid nitrogen source must

Source	be used to fill the console.
Bemis Canisters	Bemis Canisters are not manufactured by CSA Medical, but may be ordered through CSA Medical when purchasing spray kits. Only high flow, high pressure canisters may be used with the truFreeze System. Other canister types may crack and are not recommended.
CONSOLE HOME SOFTWARE MODULE (Figures 6A and 6B)	
Home	The main menu of the console is referred to as the HOME screen. From the HOME screen, the user may access all interface control modules (various screens that allow the user to perform many functions). The HOME screen consists of the status indicator (sometimes hidden) and module access buttons.
Status Indicator	The status indicator is located under the module access buttons and will be hidden except during an error condition. If the built-in test (BIT) passes, the user will be taken to the HOME screen, and the status indicator will be hidden (not visible). If any built-in test (BIT) fails, the status indicator will display the failure message on the HOME screen. For example, if the tank is empty, the status indicator will display the message “Fill Required” on the HOME screen.
Buttons	Three (3) buttons located in the center of the HOME screen allow access to the three main modules: FILL, TEST (BIT), and RUN. Touching the CSA logo will reveal two (2) hidden module buttons, DATA and SERVICE. Additional information on all modules is provided below.
CONSOLE FILL SOFTWARE MODULE *(*Figure 7*)*	
FILL	Access the FILL screen by selecting the FILL button from the HOME screen. The FILL screen consists of a graphic of the cryogen tank, fill hose, state and action indicators, as well as the START/ABORT (toggles between start & abort) and HOME buttons. Filling the console cryogen tank is a semi-automatic process. Refer to the workflow section (Console, Fill) of this manual for filling instructions.

Level Indicator	The console cryogen tank graphic is located to the left of the screen. The cryogen tank graphic alerts the user to the amount of LN2 in the tank. When the tank graphic is green, there is a normal to full amount of LN2 in the tank. A yellow indicator signals that there is sufficient LN2 to start and complete at least one additional standard procedure. However, it is recommended the console is filled at the next opportunity. When red, the tank is empty or near empty and no additional procedures may be started until the tank is filled. However, a procedure currently in progress may be completed. **NOTE:** The average procedure uses approximately 2-3 L of liquid nitrogen.
Fill Indicator	A fill hose graphic with red and green boxes is connected to the top of cryogen tank graphic. When all boxes turn green, transfer of LN2 from the source tank to the cryogen tank will occur. Left to right, the boxes on the fill hose graphic represent the vent valve, transfer valve, fill switch and source tank valve, respectively.
State and Action Indicators	The state indicator is displayed directly below the fill hose graphic. It describes the state that the console is in. The action indicator is displayed directly below the state indicator. It describes the action that the operator needs to perform in order for transfer to occur. **NOTE:** A table of the fill states and actions is located in the troubleshooting section of this manual.
START/ABORT Button	The START/ABORT button is located below the action indicator and is used to start the fill process. While a fill is in process, the START button transforms to the ABORT button; select the ABORT button at any time to stop the fill process.
HOME Button	The HOME button is located below the action indicator and should be selected to return to the HOME module. While a fill is in process, the HOME button is disabled (grayed out) until the fill is completed or aborted.
CONSOLE BUILT-IN TEST (BIT) SOFTWARE MODULE *(*Figures 8A & 8B*)*	

TEST (BIT)	Access the TEST screen by selecting the TEST button from the HOME screen. The TEST screen displays the results of the built-in tests (BIT), a series of self-checks to assess the status of the system. BIT runs automatically upon power-up of the console, but can be re-run at any time by selecting the TEST button from the HOME screen. The TEST screen consists of the BIT table, the status indicator, and the START/ABORT and HOME buttons.
Results Table	The BIT table occupies the majority of the BIT screen. It displays all the diagnostic tests that will be performed automatically, as well as the results of each individual test. There are four (4) columns that make up the BIT table: Column 1 displays the name of the test Column 2 displays the criteria/parameters needed to pass each test Column 3 displays the test result Column 4 graphically displays if the result value in column 3 met the test criteria A green plus '+' indicates the test passed. A red 'x' indicates the test failed. A question mark '?' indicates the test has not been run.
Status Indicator	The BIT status indicator is below the BIT table. The status indicator displays the test that is running and the test value in real time or the previous test result if a test is not currently in progress. **NOTE:** If BIT fails, see the troubleshooting section of this manual.
START/ABORT Button	The START button re-starts testing after abort or failure. The START button transforms to ABORT while running. Select ABORT at any time during the BIT to stop the test.
HOME Button	The HOME button may be pressed to return to the HOME screen. Once the BIT has started to run, the HOME button will be grayed out and will not be functional until the BIT is completed or aborted.
TEST Protocol	If the BIT passes (on start-up or manual run), the user will be taken to the HOME screen.

	If the BIT fails, the user will be taken to the HOME screen, and the failure message will be displayed in the results indicator. The user will be unable to open the RUN Screen until BIT is re-run and passes. **NOTE:** If BIT fails, see the Troubleshooting section of this manual.
CONSOLE RUN (PROCEDURE) SOFTWARE MODULE: SETUP TAB (Figure 9*)*	
RUN	Access the RUN screen by selecting the RUN button from the HOME screen. RUN is comprised of the HOME button and two (2) tabs: Set-up and Run.
SET-UP Tab	The SET-UP tab contains five (5) panels (clockwise): scan, tank level, pressure, thermal, and treatment. From the SET-UP tab, the HOME button may be selected to return to the HOME screen.
Scan Panel	The upper left portion of the SET-UP tab contains the scan panel. The indicators on the scan panel will not become active until a catheter is scanned.
Scan Panel, Catheter Indicator	When a catheter is successfully inserted, the catheter indicator will turn green.
Scan Panel, Procedure Number Indicator	When a catheter is successfully scanned, the background will be green and the procedure number indicator will display a unique integer between 000 and 999.
Scan Panel, Model and Lot Number Indicators	When a catheter is successfully scanned, the background will be green, the model number indicator will display the model number, and the lot number indicator will display the lot number.
Scan Panel, SCAN Button	The SCAN button should be selected when the user wants to scan in a new catheter. When the SCAN button is selected, the scanning window will pop up. Hold the catheter pouch (do not wave) with the scan tag slightly forward of center, up against the blue scan panel on right side of console. Scan can be canceled by waiting 5-10 seconds for the scan feature

	to timeout. NOTE: When a tag is scanned, it automatically pre-cools the system (see Treatment Panel, COOL Button section for more details).
Scan Panel, Time Remaining Indicator	When a catheter is successfully scanned, the time remaining indicator will turn green, and display 3:00. As time elapses, the time remaining indicator will decrement. When there are 30 minutes left before the catheter expires, the time remaining indicator will turn orange. When there are 0 minutes left before the catheter expires, the time remaining indicator will turn red.
Tank Panel	The upper right portion of the SET-UP tab displays the LN2 tank level graphic. The graphic scale is displayed in percentage (0-100%). If the tank graphic level is high (green), the console has enough LN2 for several standard procedures If the tank level graphic is moderate (yellow), the console has enough LN2 for approximately one standard procedure If the tank graphic level is low (red), the console must be filled before performing a procedure.
Pressure Panel	The middle right hand portion of the SET-UP tab contains the pressure panel; this panel contains informational indicators only, and cannot be changed by the user. The pressure indicator will illuminate green when sufficient pressure is in the tank. The pressure indicator displays the current pressure numerically in pounds per square inch (PSI) units. The venting indicator will be illuminated when the system is releasing pressure (for example, if the flow has been changed from NORMAL to LOW). The building indicator will be illuminated when the system is building pressure (for example, if the flow has been changed from LOW to NORMAL).
Thermal Panel	The lower right hand portion of the SET-UP tab contains the thermal panel; this panel contains informational indicators only, and cannot be changed by the user. The thermal control indicator displays the manifold temperature numerically in °C. The thermal control indicator will illuminate green when the manifold temperature is sufficiently cooled prior to

	a procedure. When the system is cooling (for example, the COOL button has been selected) the cooling indicator will be illuminated.
Treatment Panel	The lower left portion of the SET-UP tab contains the treatment panel which consists of the flow, suction and sound indicators. To change the level of any indicator, select the desired radio button on the touch screen.
Treatment Panel, FLOW Level Control	Flow refers to the pressure and volume at which LN2 is transported through the catheter to the treatment area. The default setting is NORMAL flow (approximately 24 PSI) and the alternate setting is LOW flow (approximately 12 PSI).
Treatment Panel, SUCTION Level Control	Suction refers to the capacity of the device to evacuate gas from the treatment area. Two settings are available: NORMAL (default) and LOW. **NOTE**: Normal cryogen and low suction may result in increased pressure in the treatment area.
Treatment Panel, SOUND Level Control	Sound refers to the decibel level at which alarm and alert tones are audible. Two settings are available: NORMAL (default) and LOW.
CONSOLE RUN (PROCEDURE) SOFTWARE MODULE: RUN TAB *(*Figure 10*)*	
RUN Tab	The RUN tab contains two (2) panels: timer and treatment. **NOTE**: while in the RUN tab, the HOME button is grayed out and may not be selected. To select the HOME button, first select the SET UP tab.
Timer Panel	The timer panel is located on the top half of the RUN tab.
Timer Panel, Time Clock & Time Progress Bar	The time clock is located in the upper left of the timer panel and is displayed in a minutes:seconds (0:00) format. A progress bar is displayed below the timer once the timer has been started either by pressing the TIME START button on the screen or remote control. Audible tones are generated in conjunction with the progress bar. The tones are generated at five-second intervals and at each second of the final five seconds approaching the target set time when the cryogen pedal is engaged.
Timer Panel, Time Start/Stop	The TIME START/STOP and TIME CLEAR buttons are located

and Time Clear	below the time clock and progress bar. Selecting the TIME START button on the console or on the remote control begins the time based upon the physician's observation of frozen tissue. The time clock should start once the area being treated is completely covered in cryofrost (i.e., freeze time). Selecting the TIME STOP button ceases the time. Selecting the TIME CLEAR button clears the time and returns the timer to zero. **NOTE:** Reaching the target time DOES NOT stop cryogen flow. Cryogen flow is controlled by the physician via the foot pedal.
Timer Panel, Target Time and Time Reset	The time management default time is 20 sec and increments and decrements in units of 5 sec (range 5-60 sec). To increase or decrease the programmed time, use the INCREMENT (⬆) or DECREMENT (⬇) buttons, respectively, until the desired time is reached. To reset the time to 20 sec, select the TIME RESET button.
Timer Panel, Cycle Counter	The cycle management default is 1 and increments up and down in intervals of 1 (range 1-99). During treatment, the cycles can be incremented or decremented using the ⬆ or ⬇ buttons, respectively. To clear/reset the cycles, select the CYCLE CLEAR button. **NOTE:** Cycles do not automatically increment with treatment.
Timer Panel, Site Counter	The site management default is 1 and increments up and down in intervals of 1 (range 1-99). During treatment, the site can be incremented or decremented using the ⬆ or ⬇ buttons, respectively. To clear the sites, select the SITE CLEAR button. **NOTE:** Site Definition: A treatment site is an area of tissue that the physician has chosen to treat with cryogen. A site is typically the area that a physician can comfortably keep frozen without intermittent or interspersed thawing. **NOTE:** Sites do not automatically increment with treatment.
Treatment Panel	The treatment panel is located on the lower half of the RUN tab. Thermal information is on the left and venting information is on the right. The left, thermal, half contains the state indicator, COOL and

	DEFROST buttons. The right, venting, half contains the indicators for the suction state ,suction status, and pressure sense status.
Treatment Panel, State Indicator	The state indicator displays the state of the system as referenced in the Procedure Run Screen Cryogen States and Indicator table. If a thermocouple is inserted, the temperature from the auxiliary thermal port is displayed in the state indicator when applicable.
Treatment Panel, COOL Button	The COOL button allows the user to pre-cool the system before spraying. If the COOL button is not selected before activating spray via the foot pedal, the system will automatically engage COOL when the foot pedal is depressed. The user will know the system is cooling by a low bong sound (alert). When the COOL button is engaged, the indicator will display *COOL* while the system is cooling to -25 C, and *VALID* when ready to spray. **NOTE:** The COOL button will be grayed out until pressure is within the allowed range (~22PSI)
Treatment Panel, DEFROST Button	To the right of the COOL button is the DEFROST button. The defrost mechanism works to facilitate removal of the catheter from a scope or other manipulation tool, if applicable. To engage DEFROST, select the button. When the DEFROST button is engaged, the indicator will display the elapsed defrost time. The preset defrost time is 30 seconds and will automatically turn off. If desired, press the DEFROST button again to disengage the defrost mechanism before 30 seconds has elapsed. **WARNING:** The DEFROST function uses warm nitrogen gas. Adequate venting from the patient should be ensured.
Treatment Panel, Suction State and Status Indicators	On the far right of the treatment panel is the suction state indicator (top) and the suction status indicator (bottom). Suction is engaged by pressing and releasing the suction foot pedal (gray). Suction State Indicator (On/Off and Level): When the suction pump is on, the status indicator will display either SUCTION ON (NORM or LOW) against a green or orange background.

	When the suction pump is off, the status indicator will display either SUCTION OFF (NORM or LOW) against a red background. Suction Status Indicator (Pressure): During normal operation, the suction status indicator will display the pressure in X inHg against a gray background. In the event of a suction error, the suction status indicator will display the pressure as either XX inHg (HIGH) or XX inHg (LOW). A suction status of HIGH will be displayed against an orange background. **NOTE**: When moving from LOW cryogen to NORMAL cryogen, the Suction setting will automatically default to normal. This can be over-ridden by selecting the LOW suction radio button. However, normal cryogen flow with low suction may result in increased pressure in the treatment area. **NOTE**: When operating in NORMAL cryogen and LOW suction, the suction indicator will be orange. ⚠ **WARNING:** The combination of normal cryogen flow with low suction level may result in increased pressure in the treatment area.
Treatment Panel, Pressure Sensing Indicator	Located below the suction state and status indicator is the pressure sense status indicator. During normal operation, the indicator will display the pressure in XX cmH2O against a gray background. The indicator contains the value and a color coded warning as described in the Pressure Sensing Performance Indicator table.
CONSOLE DATA SOFTWARE MODULE *(*Figure 11*)*	
Data Screen	Access the DATA screen by selecting the DATA button from the HOME screen. The DATA button is hidden and can be selected by pressing the CSA logo on the HOME screen. The DATA screen contains a log table, a drop-down menu to choose the type of log file to download, and an UP, DOWN, USB and HOME buttons.
Log Table	There are three (3) columns that make up the log table: Column 1 displays the timestamp of the event Column 2 displays the action

	Column 3 displays the data The most recent files are at the top of the table, and can be viewed by selecting either the UP or DOWN button to scroll through the log entries.
Log Files	The DATA screen has a drop-down menu to select the type of log file to view and/or download (fill, test, procedure, system, error, and service).
USB Button	The fill, test, procedure, system, error, and service log files can be downloaded by selecting the USB button. Follow the prompts.
Home Button	The HOME button may be pressed to return to the HOME screen.
CONSOLE SERVICE SOFTWARE MODULE	
SERVICE	The SERVICE screen provides authenticated access for CSA Medical service personnel. The screen is not accessible for non-CSA Medical service personnel.

4. SYSTEM OPERATION (WORKFLOW)

A description of the truFreeze System Operation (workflow) from filling to clean up is provided below.

CONSOLE FILL	
Manual Section	**Workflow**
Fill, General	The console must be filled with the power on as filling is a semi-automated process and must be initiated from the FILL screen on the console graphical user interface (GUI). Standard wall power may be used to plug in the console. If the storage room where the source tank is kept does not have a wall outlet, arrangements must be made to temporarily move the source tank to another location to fill the console. Read Cautions and Warnings below before filling console. ⚠ **CAUTION**: The fill hose may contain residual LN2 after filling; use caution when removing it from the console.  **WARNING:** Ensure that the cryogen does not come in contact with persons 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 and protective eyewear must be worn when filling the console to prevent damage to the skin. ⚠ **WARNING:** 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. ⚠⚠  **DANGER:** Never expose the truFreeze System to liquid. If any liquid is spilled into 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, user or maintenance personnel.

CONSOLE FILL	
Manual Section	**Workflow**
Fill, Set-Up	Position console in desired location, and lock console wheels by moving the lever right or left of center (remember to leave ample room in front of the console for the source tank). Remove power cord from the storage spool on the back of the console, and plug the female end of the power cord into the lower left rear panel of the console. Plug the male end of the cord into standard wall power. Turn 'ON' (⏽) the power switch located on the upper left, rear panel of the console. Built-In Tests (BIT) will run automatically on power-up, and may take up to three minutes to complete. If the console needs to be filled, BIT may fail upon power-up. The message *Fill required (130)* will be displayed. Alternatively, the BIT test may be aborted to go directly to the HOME screen to access the Fill module. Remove the lower control panel cover. Position a source tank of low pressure (22 psi), medical grade LN2 in front of the console, with the liquid valve of the source tank facing the console. Remove the fill hose from the rear panel of the console. Connect the thread end of the fill hose to the LIQUID valve of the low pressure, medical grade LN2 source tank. Use the wrench (stored in the rear panel of the console) to make sure the connection is snug. Proper PPE should be worn throughout the fill process and are provided in the storage compartment on the rear panel of the console (gloves, glasses, etc.).

CONSOLE FILL	
Manual Section	**Workflow**
Fill, LN2 Transfer	Choose the FILL button from the HOME screen. Follow the prompts on the screen: Using the handle, Insert the bayonet end of the fill hose into the fill port on the front of the console at the 12 o'clock position. Rotate the handle counterclockwise until the fill hose pin aligns with the fill port slot. Once aligned, rotate handle clockwise until the hose clicks into place. Once the hose is connected, the FILL screen will display *Ready* and prompt the user to press the START button. Once the START button has been pushed, the console will regulate pressure in preparation for filling. This may take a few minutes (the console must reach 5 PSI) before filling can commence. The FILL screen will display *Transfer* and prompt the user to open the source tank LIQUID valve. Fully open the LIQUID valve of the source tank by turning it all the way to the left to initiate LN2 flow (Note: the fill hose will start to get "frosty" soon after the LIQUID valve is opened. This is normal). Once the source tank valve is open, the filling will begin. Approximately 10-15 minutes is required to fill an empty console. When the console tank is full, the FILL screen will prompt the user to close the LIQUID valve on the source tank. Close the LIQUID valve on the source tank by turning all the way to the right (make sure valve is securely closed). A large red reminder button (SOURCE CLOSED?) will be displayed on the FILL screen. Push the reminder button to acknowledge the source tank has been closed. Allow hose to vent. When Fill is complete, *Console Full* will be displayed. Press the "HOME" button to return to the Home screen. User may choose the TEST button to verify the console passes all tests. Upon successful completion of BIT, the console will automatically transfer to the HOME screen. Consult Troubleshooting Section of this manual if the automatic BIT fails on power-up. **NOTE:** See Console Fill Indicator Codes in the Troubleshooting Section (5) for fill problems.

CONSOLE FILL	
Manual Section	**Workflow**
Fill, Clean-Up	Allow a minimum of 15 seconds for the hose to vent before removing from the transfer interface. Remove the fill hose from the console by turning it counterclockwise and pulling outward. Note that some residual LN2 may be in the fill line when removing the fill hose. Using a wrench, remove the hose from the source tank (remember to wear gloves, the hose is VERY cold). Return the hose, wrench, and associated PPE to storage on the rear panel of the console. Return the source tank to its original location, and power down the console (turn power button on rear panel of console to OFF) and unplug for transport, if applicable. Insert lower control panel cover into fill port and secure.

PROCEDURE SET UP	
Manual Section	**Workflow**
Overview	Procedure set up operations include: • Console Set Up • Foot Pedal Set Up • Remote Control Set Up • Treatment Plan Development • Cryogen Flow Rate Selection • Suction Level Selection • Sound Level Selection • Spray Set Time Selection • System Prep

PROCEDURE SET UP	
Manual Section	**Workflow**
Console Set-Up	Position Console as desired for procedure. Lock wheels by moving lever to the right or left of center. Remove power cord from rear cord wrap. Plug male end of power cord to standard wall power. Verify female end of power cord is connected to console (lower left back panel). Turn on the power switch located on the upper back panel. Allow automatic BIT to run (Built In Test). Upon successful completion of BIT, the console will automatically transfer to the HOME screen (if BIT fails, the results indicator will display the failed test. Consult Troubleshooting Section of this manual if the automatic BIT fails on power-up). Select the RUN button. The RUN screen has two tabs at the bottom, SETUP and RUN. The SETUP tab is the default. In the SETUP tab, verify that there is adequate LN2 in tank by using the tank graphic in the upper right corner of the SETUP tab. If the graphic is yellow or red, the console should be filled prior to using for treatments. See Workflow, Console Fill Section for filling instructions. **NOTE:** On power up, BIT will run automatically. The tests can be rerun at any time by selecting TEST from HOME screen. **NOTE:** The BIT must pass all conditions to enter the RUN screen. ⚠ **CAUTION:** Ensure power cord is dry or it may result in electrical shock to the user.
Foot Pedal Set Up	Remove the foot pedal from the front lower storage compartment and position as desired. Confirm the foot pedal is connected to the console (connection is in the foot pedal storage compartment on the right side). WARNING (Electrostatic Discharge): Avoid touching electrical pins of the foot pedal connector, unless properly trained and using ESD procedures.

PROCEDURE SET UP	
Manual Section	**Workflow**
Remote Control Set-Up (Optional)	Select “Run” Tab. Remove remote control from compartment on left side of console. Add batteries if necessary. Select site increment button to confirm communication with console. Site should increment on console GUI display. Decrement Site back to 1. Position remote control as desired.
Develop Treatment Plan	Physician should survey treatment area of patient and develop a treatment plan. Treatment plan includes: spray time, flow setting, suction setting and vent method based on patient presentation and medical indications as well the number of freeze thaw cycles and the number of sites to be treated.
Cryogen Flow Rate	Select “Set Up” Tab. Cryogen flow rate may be selected between NORMAL and LOW (default is NORMAL). To change the setting, select the radio button directly to the left of the desired flow rate on the setup tab. The selected flow rate will be displayed.
Suction Level	Suction level refers to the suction system pump power level that is used during active venting. Two suction levels (NORMAL or LOW) are available using the radio buttons on the setup tab (default is NORMAL). Data regarding suction performance at each level is included with the Instructions for Use (IFU) included in each spray kit. Refer to the troubleshooting section for the state indicators and colors. ⚠ **WARNING:** Normal cryogen flow with low suction level may result in increased pressure in the treatment area.
Sound Level	Sound refers to the decibel level at which alarms and alerts are audible. Sound level may be adjusted, if necessary, using the radio buttons on the setup tab. It is recommended that sound be set to the highest (normal) level except under special circumstances requiring a quieter environment.

PROCEDURE SET UP	
Manual Section	**Workflow**
Spray Time	After verifying the spray time with the physician (see Procedure Set Up, Treatment Plan,) select the RUN tab to program the spray time. In the upper right hand portion of the screen is the spray time set. The default for spray time is 20 sec. To change the time from 20 sec, use the INCREMENT (⬆) or DECREMENT (⬇) buttons until the desired time is reached. **NOTE:** The spray time increments (⬆) and decrements (⬇) in multiples of five seconds.

PROCEDURE	
Manual Section	**Workflow**

Overview	Procedure operations include the following functions, described below:
	• Venting Method
	  ○ Active Venting (Suction)
	  ○ Passive Venting
	• Scan Catheter
	• Position Pressure Sense Tube (if applicable)
	• Position Catheter
	• Parameter Verification
	• Spray Initiation
	• Timer
	• Monitor Gas Evacuation
	• Stop Spray
	• Repeat as Necessary

Venting Method	Venting of nitrogen gas from the treatment area can be done actively (suction) or passively (no suction). In all cases, the physician should determine the appropriate venting method. **NOTE:** See Instructions for Use (IFU) 15-00133 for additional information **NOTE:** Patient must be monitored for distention during the procedure, if applicable. ⚠ **CAUTION:** Liquid nitrogen expands more than 700 times when changing to a gaseous state. It is imperative for patient safety that adequate ventilation is ensured to remove gas created during the treatment session.
Gather Disposables for Vent Method	After the proper venting method has been determined, gather the necessary disposables (CDT and accessory tubing, or passive vent tube) including the catheter. Place these sealed disposables in the holder provided on the side(s) of the console.

PROCEDURE	
Manual Section	**Workflow**
Active Venting (Suction)	Place suction canister in the recessed canister holder in the front of the console. Open a CDT Kit pouch. Remove the connector (short tube). Connect blue end of the connector to the top port of the suction canister and the clear end to the suction port on the underside of the canister holder on the console. Canister port should face forward to allow tubing connection. Remove the suction tubing (long tube with no vent holes). Connect the blue end of the suction tubing to the front port on the suction canister residing in the front holder of the console. Leave the CDT in the packaging until the physician is ready to place it for treatment (prior to cryospray). Depress the SUCTION (grey) foot pedal to verify that the tubing draws suction. After verification that suction is working, depress the SUCTION pedal again to disengage suction until ready to treat. A guide wire may be used to aid in CDT placement. Double black bands should be approximately 1 cm below the GEJ (if treating in the esophagus). After placement, attach the free end of the suction tubing to the CDT. During treatment, a “distention monitor” should physically monitor the patient for distention.

PROCEDURE	
Manual Section	**Workflow**
Passive Venting	Physician must ensure adequate venting of nitrogen gas is attained by ensuring a sufficient passive channel is available (natural or artificial) in accordance with the Instructions for Use. If a passive vent tube is not used (i.e., dermatologically), ensure area is sufficiently open to atmospheric pressure. If a passive vent tube is used, physician must determine proper passive vent tube size, if needed. Refer to the IFU for tube diameter guidelines. Place distal end of the passive vent tube in an unobstructed cavity near the procedure area. The proximal end of the passive vent tube should be positioned outside the body where the pressure is atmospheric. **NOTE**: See Instructions for Use (IFU) 15-00133 for additional information. **NOTE:** Patient must be monitored for distention during the procedure, if applicable. ⚠ **CAUTION:** Ensure that the passive tube is not kinked during placement. It is imperative for patient safety that the passive tube removes the gas created during the treatment session ⚠ **CAUTION:** Liquid nitrogen expands more than 700 times when changing to a gaseous state. It is imperative for patient safety that adequate ventilation is ensured to remove gas created during the treatment session.

PROCEDURE	
Manual Section	**Workflow**
Scan Catheter	Choose the SETUP tab on the RUN screen. In the upper Left portion of the screen, select the SCAN button and the scanning window will pop up. Hold the catheter package with the scan tag up against the blue scan panel on right side of console (do not wave catheter package around, hold package steady). When the tag is scanned, the scanning window will disappear, and the scan indicators will be populated (the scan number will be incremented, the time remaining for the disposable will be displayed as 3:00, the model and lot number will be displayed, and indicators will be green). See Troubleshooting Section of this manual if scan fails. A tag should be scanned immediately before treatment (approximately 3-4 minutes in order to maximize your tag time and system preparation). When a tag is scanned, the COOL feature will automatically be engaged to pre-cool the system (see System Preparation, below). **NOTE:** Scan can be canceled by waiting 5-10 seconds for the scan feature to timeout. **NOTE:** Only CSA Medical catheter kits are approved for the system.
System Preparation	The system must be pre-cooled so it is ready for treatment. This will be done automatically when a valid tag is scanned. COOL takes approximately 1-2 minutes to reach the desired precool temperature. Monitor the system cooling via the blue progress bar directly above the COOL button. It will display *Cool* and the temperature while the system is cooling. Once the system reaches -25 C, the progress bar will display *Ready*. COOL will automatically time out after 5 minutes in order to conserve cryogen. If this occurs, select the COOL button on the bottom left portion of the RUN screen. If COOL times out and is not re-engaged before spraying, activation of the footpedal will automatically engage COOL. The user will be alerted that the device is cooling by a low bong (alert). **NOTE:** When the COOL button is engaged, it will automatically cycle to keep the unit cold and ready for spray. To prevent loss of cryogen in the event of a procedure delay, turn the COOL button off until ready to spray. COOL must be run again immediately before spray.

PROCEDURE	
Manual Section	**Workflow**
Position Pressure Sense Tube (Optional)	If using a scope, insert scope near desired treatment location. Feed tipped end of pressure sense tube through biopsy channel and position near treatment area. Remove scope, leaving pressure sense tube in place. Secure pressure sense tube in place (tape to patient or bed). Attach free end of pressure sense tube to connection tube assembly on console control panel.
Position Catheter	Remove the catheter from the pouch. Carefully inspect for damage, such as cracks or breaks. Do not insert the CSA catheter if it appears damaged. Insert catheter into catheter port on front of console. The catheter insertion indicator on the top left of the SETUP tab of the RUN module will turn green when the catheter is properly inserted Care should be taken to avoid kinking or fracturing the catheter during handling and insertion into the catheter Introducer. If using a scope, place catheter through the introducer provided in the catheter kit. Make provisions for holding and manipulating the catheter if a scope is not used. Place the catheter near the target treatment area according to the desired surgical technique. **NOTE:** Only CSA Medical catheters kits are approved for the system. ⚠ **CAUTION:** At atmospheric pressure, nitrogen liquefies at −195.8°C. Avoid directly touching the catheter without sufficient protection during use; it gets very cold. Additionally, care should be taken to ensure that the patient and other health care professionals do not come in incidental contact with the catheter and/or the liquid nitrogen cryogen while the system is in use. **WARNING:** Cutting or otherwise altering the truFreeze Catheter may increase the flow of liquid nitrogen though the catheter, resulting in an increased risk of perforation, stricture, or other damage to the treatment area.

PROCEDURE	
Manual Section	**Workflow**
Parameter Verification	Select RUN Tab. Verify the site number, cycles, and flow parameters are correct in the upper right hand section of the system panel. Verify the vent path has been chosen and implemented. Verify the system is cooled by confirming the state indicator is VALID with green background. If state is not VALID, press the COOL button again. Allow COOL to complete if necessary.
Spray Initiation	The system is ready to begin spray when the state indicator displays *Valid.* If active venting is used, engage SUCTION pedal (grey). To initiate cryogen, press and HOLD the cryogen (blue) foot pedal. The state indicator will display *Freeze*. **NOTE:** Active or Passive Venting is necessary when spray is initiated, as is distention monitoring where applicable.
Timer	The TIMER button () on the remote control, or “Time Start” button on the Run Screen should be pressed when the treatment area displays a uniform white frost. When the TIMER button has been pressed a single beep will be audible. **NOTE:** The TIMER button may be selected on the console screen or the remote control. **NOTE:** System will beep once every 5 seconds and at each of the final 5 seconds of programmed time when the cryogen pedal is engaged.
Monitor Gas Evacuation	Gas evacuation should be closely monitored while spray (cryogen pedal) is engaged. If reduced venting is observed, immediately stop spray and monitor the patient.
Monitor Pressure (Optional)	If using the pressure sense tube, pressure in the patient should be monitored on the Run tab. **NOTE:** Patient must be monitored for distention during the procedure, if applicable.

PROCEDURE	
Manual Section	**Workflow**
Stop Spray	Spray is stopped by releasing blue cryogen foot pedal. Spray may be restarted by depressing blue cryogen foot pedal. **NOTE:** Patient must be monitored for distention during the procedure, if applicable.
Repeat	Repeat steps in Procedure Section as needed for additional cycles (for the purpose of this testing, Spray Initiation through Stop Spray). If active venting is used, turn off SUCTION at end of procedure.

CLEAN UP / MAINTENANCE	
Manual Section	**Workflow**
Overview	Clean Up operations include the following functions, described below: • Catheter Removal/Defrost • Remove Disposable(s) • Discard Disposable(s) • Data View and Download (If Desired) • Power Down • Clean Instrument(s) • Store Accessories • Store Console
Catheter Removal/Defrost	If the catheter is frozen in the console or scope (if applicable), the defrost feature may be used to aid in the removal of the catheter. Select DEFROST button from RUN tab. State indicator will display *Defrost* and show time remaining. Defrost automatically stops after 30 seconds. To stop defrost before completion, select the DEFROST button. ⚠ **WARNING:** The DEFROST function uses warm nitrogen gas. Adequate venting from patient should be ensured.
Remove Disposable(s)	Remove catheter and introducer from scope. Remove catheter from the console by gently pulling handle. Remove vent tubes, if applicable, from patient and console. Remove pressure sense tube, if applicable, from patient and console.
Discard Disposable(s)	Discard disposables including suction canister in accordance with facility and local policies and regulations. **NOTE:** The catheter, vent tubes, and pressure sense tubes are single-use devices. They should be considered clinical waste at the completion of a procedure.

CLEAN UP / MAINTENANCE	
Manual Section	**Workflow**
Data View and Download (If Desired)	Navigate to SETUP tab and then to HOME screen. Select CSA logo on top of HOME screen. DATA button will appear. Select this button. Data screen will load. Remove lower control panel cover to gain access to USB port. Press the drop down menu to select the desired log file (last 100 lines only). To download data, insert USB stick into port on front control panel. Select USB button on screen. Logs will download; a dialog will confirm download is complete. Select the ✓ button. Remove USB stick. Insert lower control panel cover into fill port and secure.
Power Down	Select HOME button. Turn power switch OFF (○, upper rear panel of console). Unplug console from wall power.
Clean Instrument(s)	Clean console and remote control by wiping down the surfaces, including the unplugged power cord and foot pedal. Standard hospital cleaning agents are recommended (mild detergent, alcohol, CIDEX, or a 10% bleach solution). **NOTE:** Do not drench the console with liquids. ⚠⚠ **DANGER:** Never expose the truFreeze System to liquid. If any liquid is spilled into the front panel of the console or down the rear 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 patient, physician, or maintenance person.
Store Accessories	Wrap power cord around the spool on back of console. Store foot pedal in compartment on lower front of console. Wrap the foot pedal cord around spool on front of console. Place the remote control in compartment on left side of console (remove batteries if necessary).

CLEAN UP / MAINTENANCE	
Manual Section	**Workflow**
Store Console	Unlock the wheels of the console. Move console to storage location and re-lock wheels.

5 TROUBLESHOOTING

Listed below are troubleshooting tips that may be helpful when using the truFreeze System. If troubleshooting assistance is required, please contact CSA Medical.

TROUBLESHOOTING		
Symptom	**Cause**	**Solution**
Console		
Not Rolling	Wheels are locked.	Ensure red lever on both front wheels is in the center position (right or left of center is locked).
No Power	Power switch off.	Verify power switch is on (switch will be illuminated green).
	Power cord not connected to console or wall.	Connect power cord to console rear panel (female end) and wall power outlet (male end).
	Wall outlet not functional.	Connect console to wall power outlet known to be functioning properly.
BIT Failure--General	Any BIT failure including user aborted or incomplete tests.	Restart BIT and confirm failure. If failure repeats and is not listed below, contact CSA Medical.
BIT Failure--Level	Cryogen level is low or empty.	Check level indicator and fill console if necessary (Fill module).
BIT Failure--Pressure or Thermal	Cryogen level is low or empty.	Check level indicator and fill console if necessary (Fill module).
BIT Error--ESTOP	E-Stop is engaged (red light on and state indicator reads ESTOP).	Reset E-Stop (twist and pull outward). Indicator will display IDLE. Press START button (restart built-in test).

TROUBLESHOOTING		
Symptom	**Cause**	**Solution**
Scan Fails	Scanner cannot sense tag.	Move disposable package up against the scan pad.
		Hold disposable still for 3-5 seconds slightly forward of center of scan pad (do not wave around).
		Verify the tag side of the catheter pouch is facing the scan pad.
Scan Not Activating	Console in LN2 empty or in pressure build state.	Cancel scan if applicable. Check LN2 level and allow pressure to build. Fill tank if necessary. Scan is not allowed with low LN2 level or pressure to prevent using a catheter if there is insufficient LN2 to perform a procedure.
Cryogen Not Spraying	Cryogen level low or empty.	Check level indicator and fill console if necessary (Fill module).
	Pressure not in range.	Check pressure indicator and verify pressure is building or venting as necessary (see setup tab).
	Temperature not in range.	Select the COOL button (run tab) and verify temperature is cooling into range (see setup tab).
	E-Stop engaged (red light on).	Reset E-Stop (twist and pull outward) and then allow pressure to build and start COOL (precool).
	Catheter switch not engaged.	Re-insert catheter and confirm catheter indicator is green (setup tab).
	Catheter clogged.	Use DEFROST button to dislodge any frozen excretions in catheter. If ineffective, repeat DEFROST or replace catheter.
	Catheter damaged.	Replace catheter.
	Catheter scan not valid (or not scanned).	SCAN catheter pouch using blue scan pad on the right side of the console. Verify that the scan indicator turns green

TROUBLESHOOTING		
Symptom	**Cause**	**Solution**
		and time remaining resets to 3 hours.
	Catheter time limit elapsed (3 hours).	SCAN new catheter pouch. Verify that the scan indicator turns green and time remaining resets to 3 hours.
	Foot pedal malfunction.	Check foot pedal connection inside foot pedal storage on lower front panel of console. Ensure foot pedal is clean and free of any debris that may impair its operation.
Defrost Not Activating	Catheter switch not engaged.	Re-insert catheter and confirm catheter indicator is green.
	Cryogen level empty (EMPTY displayed on indicator).	Check level indicator and fill console (Fill module).
Remote Control		
Remote Not Responding	Dead batteries.	Replace batteries (2 AA alkaline).
	Incorrect battery orientation.	Align batteries with +/- indicators on remote control case.
	Out of range (5 m) or signal path obstructed.	Move remote control closer and in a direct, non-obstructed path to the console.

CONSOLE FILL – INDICATOR CODES		
State	**State Indicator (Background Color)**	**Action Indicator**
IDLE	IDLE (black)	CONNECT FILL HOSE
READY	READY (black)	PRESS START
CONSOLE_VENT	CONSOLE VENT XX PSI (black)	OPEN SOURCE VALVE
TRANSFER	TRANSFER (blue)	OPEN SOURVE VALVE
HOSE _VENT	HOSE VENT (orange)	CLOSE SOURVE VALVE
CONSOLE_FULL	CONSOLE FULL (green)	---
ERROR	ERROR (red)	(blank)
ESTOP	ESTOP (red)	(blank)

PROCEDURE-RUN SCREEN CRYOGEN STATES AND INDICATOR		
State	**State Color**	**Action Required to Spray**
EMPTY	RED	Fill with liquid nitrogen.
PRESSURE	YELLOW	Wait for pressure to reach range.
IDLE	GREY	Press COOL button or depress CRYOGEN PEDAL to start system pre-cooling.
COOL	BLUE	Allow system pre-cooling to complete automatically (transitions to READY).
READY	BLUE	Scan a catheter (Note: system may display READY after scan until catheter inserted. After scan and catheter inserted transitions to VALID).
VALID	GREEN	Depress CRYOGEN PEDAL.
FREEZE	BLUE	Release CRYOGEN PEDAL to stop spray and return to VALID.
DEFROST	ORANGE	Allow defrost to automatically stop or press DEFROST button to abort.
ESTOP	RED	Deactivate ESTOP (twist button to the right, light OFF).
ERROR	RED	Clear error or exit to HOME and run BIT to diagnose.

PROCEDURE-RUN SCREEN SUCTION INDICATORS			
State	**Level**	**Color**	**System Configuration/State**
OFF	NORMAL	RED	Suction is off (but radio button is in NORMAL state)
	LOW	RED	Suction is off (but radio button is in LOW state)
ON	NORMAL	GREEN	Suction is on and NORMAL suction is selected
	LOW	GREEN	Suction is on and LOW suction is selected in combination with LOW cryogen.
	LOW	ORANGE	Suction is on and LOW suction is selected in combination with NORMAL cryogen.
Suction Performance Indicator Procedure Suction States			
State	**Pressure**	**Color**	**System Configuration/State**
ON/OFF	XX inHg	GREY	Normal reading/Suction not engaged

PROCEDURE-RUN SCREEN SUCTION INDICATORS			
State	**Level**	**Color**	**System Configuration/State**
ON	XX inHg	ORANGE	Indicates higher than normal reading (potential occlusion).

Pressure Sense Performance Indicators		
Pressure	**Display**	**Color**
Normal	XX cmH2O	GREY
Warning Level 1	XX cmH2O	YELLOW
Warning Level 2	XX cmH2O	ORANGE
Warning Upper Limit	> XX cmH2O	ORANGE

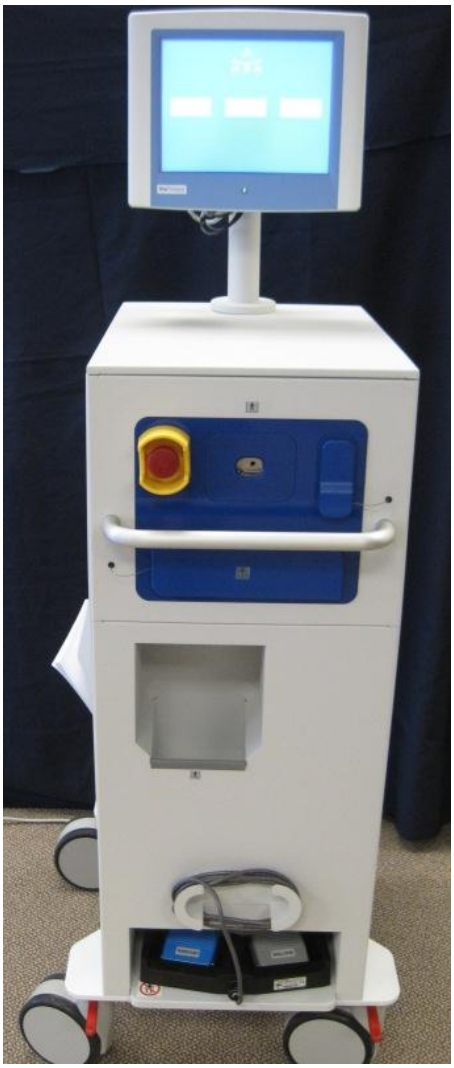

Figure 1. Console (Front)

Figure 2. Console (Rear) with Fill Kit

Figure 3. Console (Right)

Figure 4. Console (Left)

Figure 5. Spray Kit

Figure 6A. . Home Screen (Status Indicator Displayed, Data and Service Button Hidden)

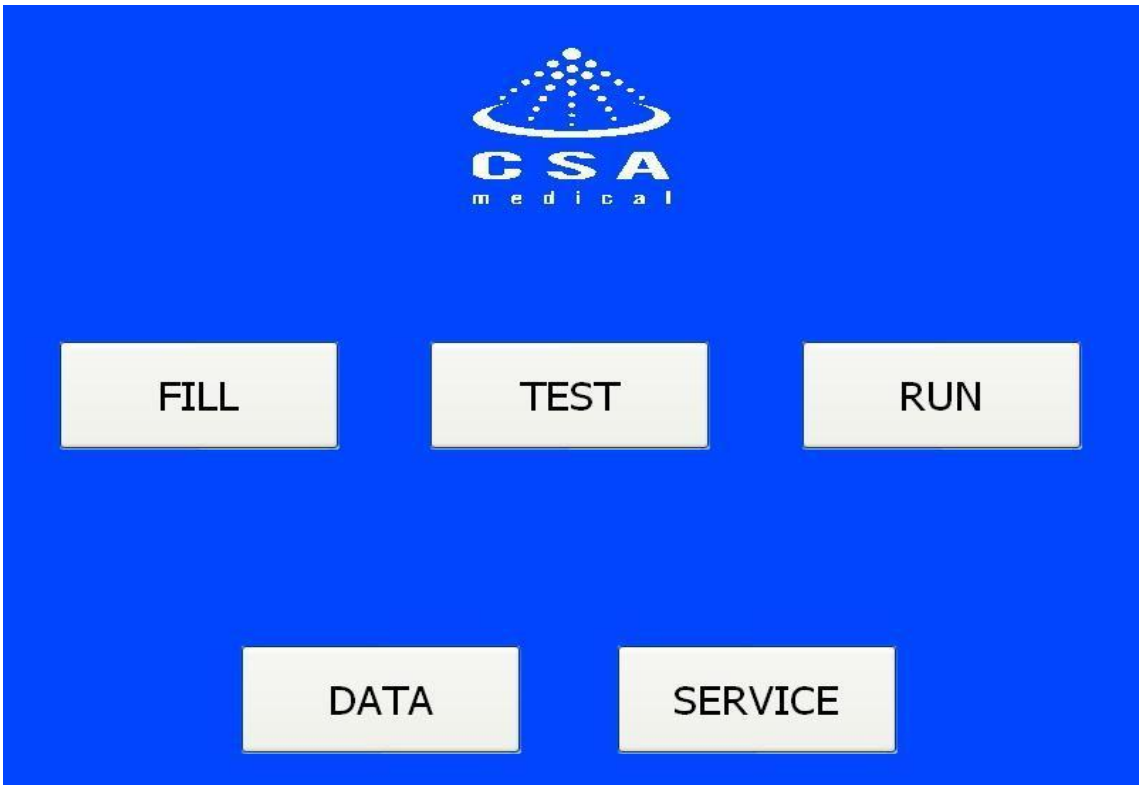

Figure 6B. Home Screen (with Data and Service Buttons Enabled)

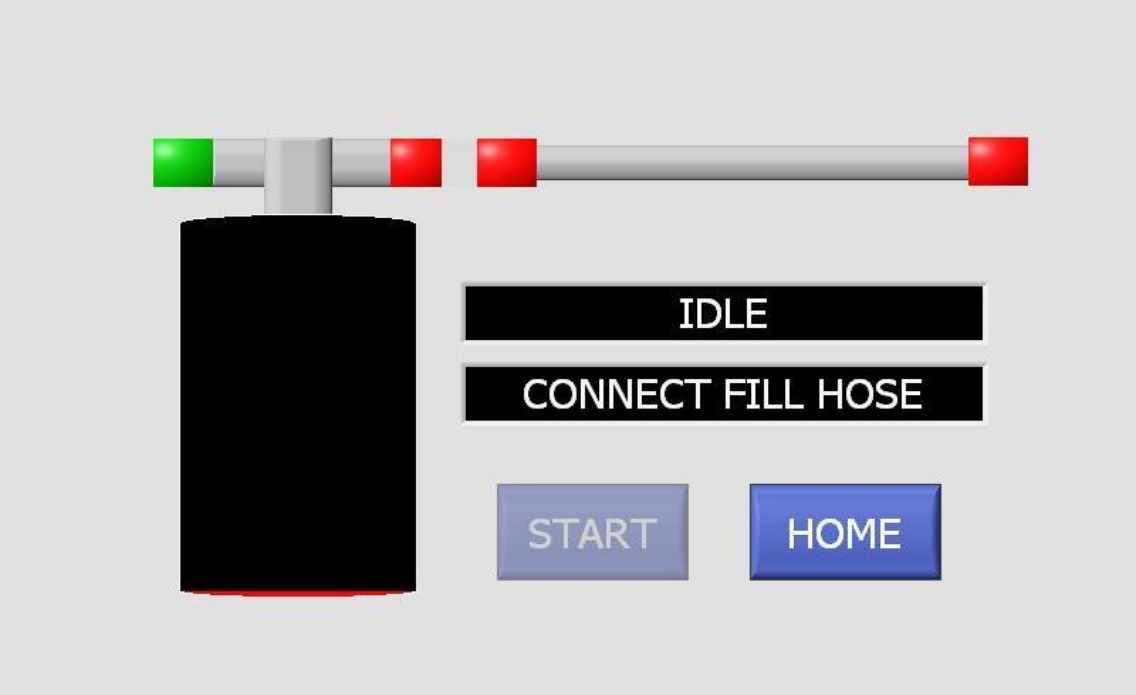

Figure 7. Fill Screen

Figure 8A. Built-In-Test Screen (Test In-Process)

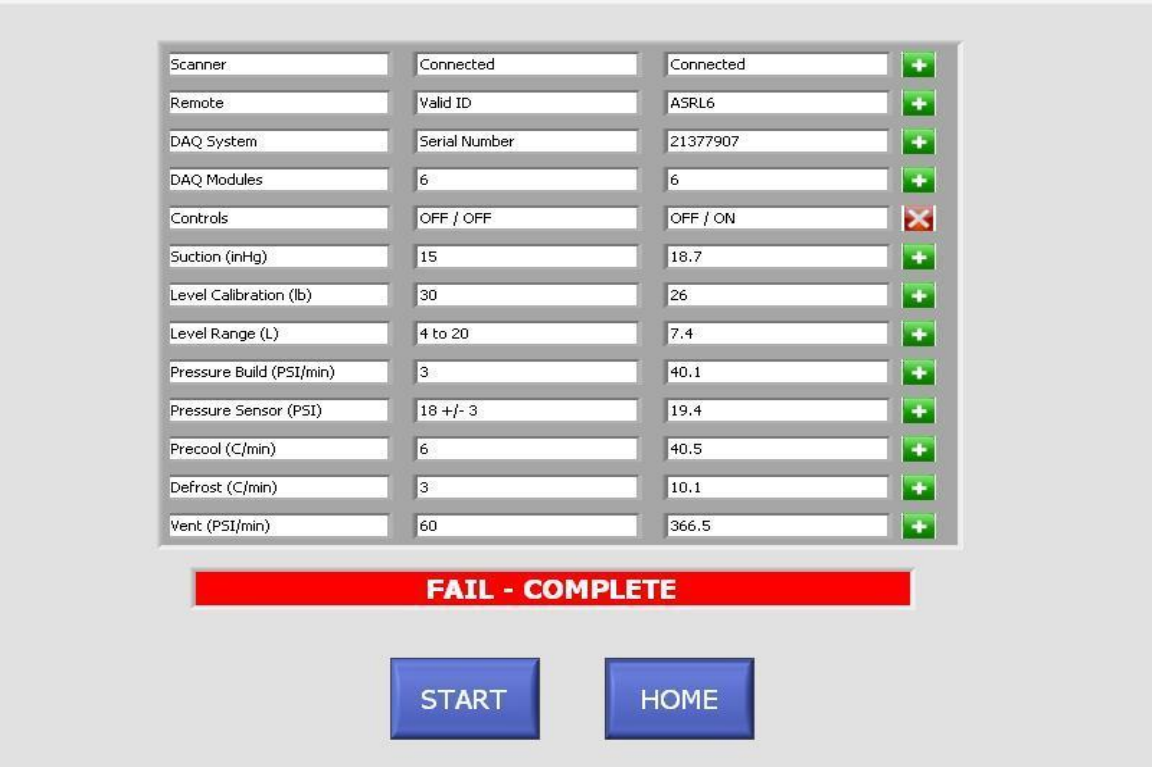

Figure 8B. Built-In Test Screen (Failed View)

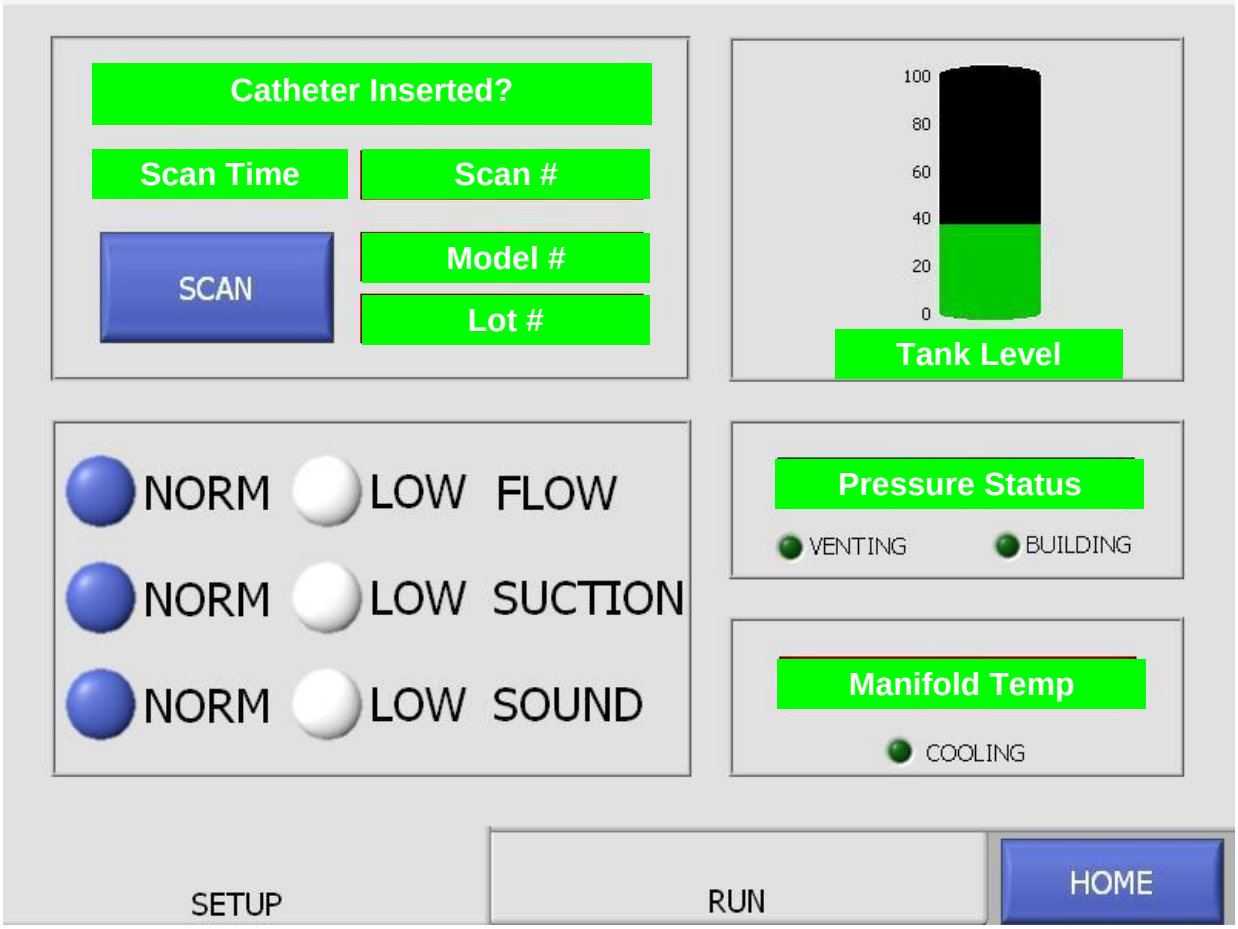

Figure 9. Procedure Screen (Setup)

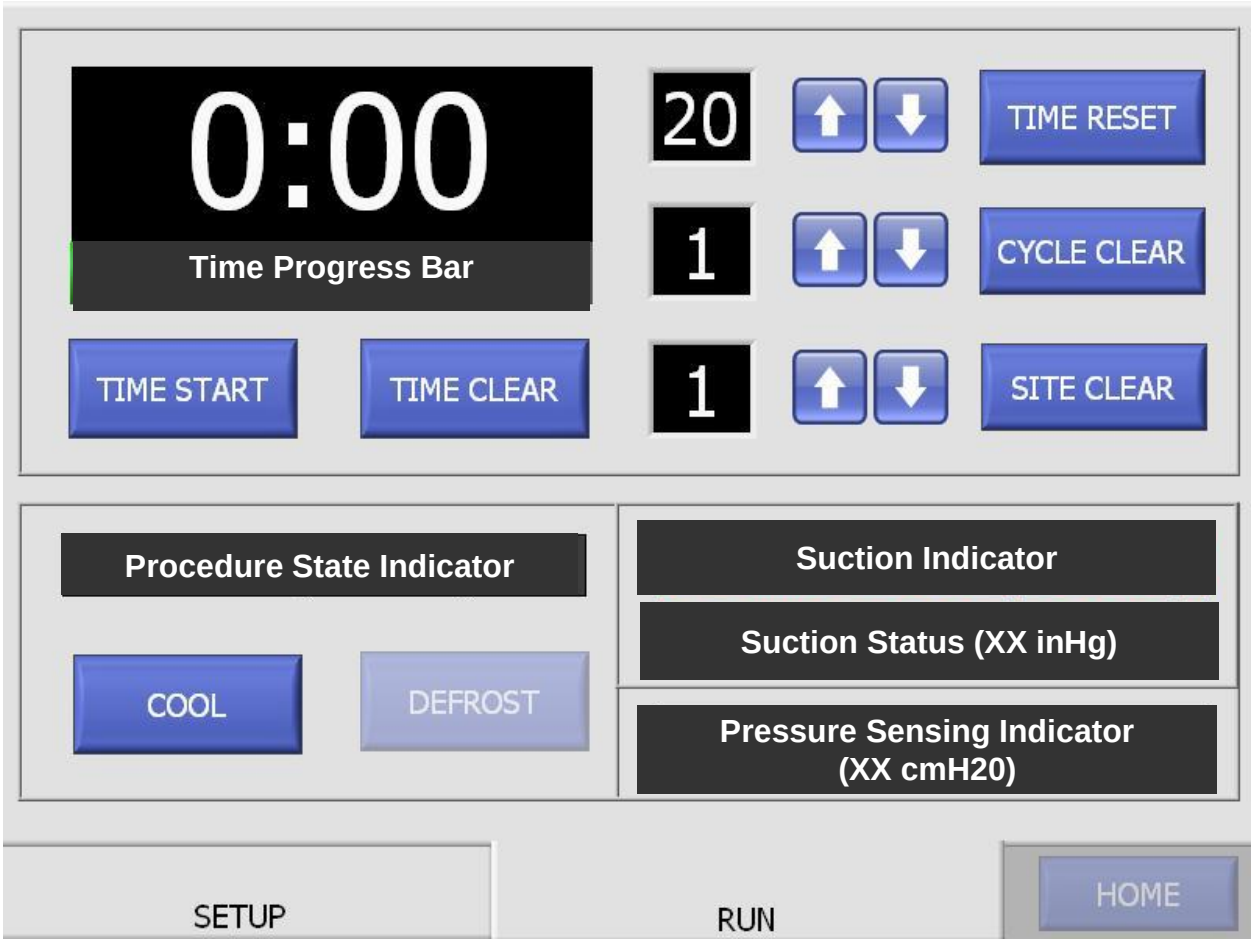

Figure 10. Procedure Screen (Run)

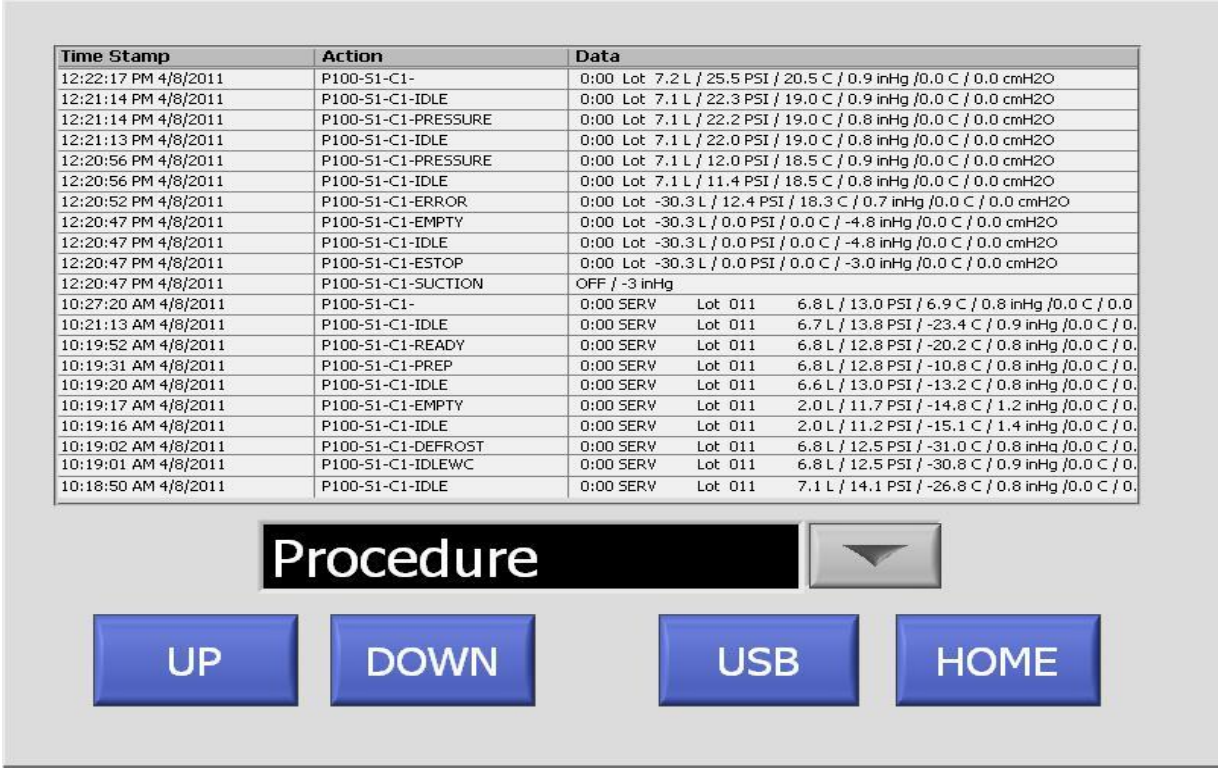

Figure 11. Data Screen

6 APPENDIX

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