

# VISUAL<sup>®</sup>ICE

CRYOABLATION SYSTEM



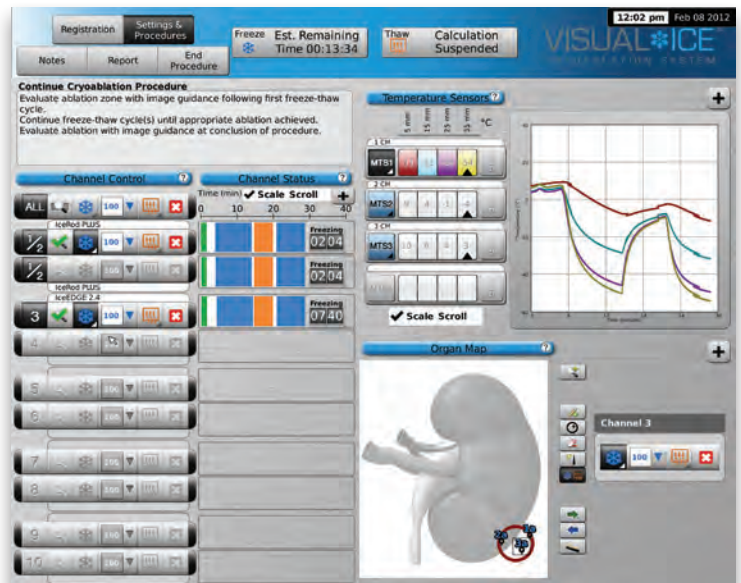
## Cryoablation Made Smarter

- Intuitive and Simplified Operation
- Enhanced for Procedural Control and Flexibility
- Latest Cryoablation Technology
- Platform for All Future Needle Development

# Intuitive and Simplified Operation

## Single screen for operational display of procedure status

- Customizable screen to meet your clinical needs
- Ability to focus on relevant data



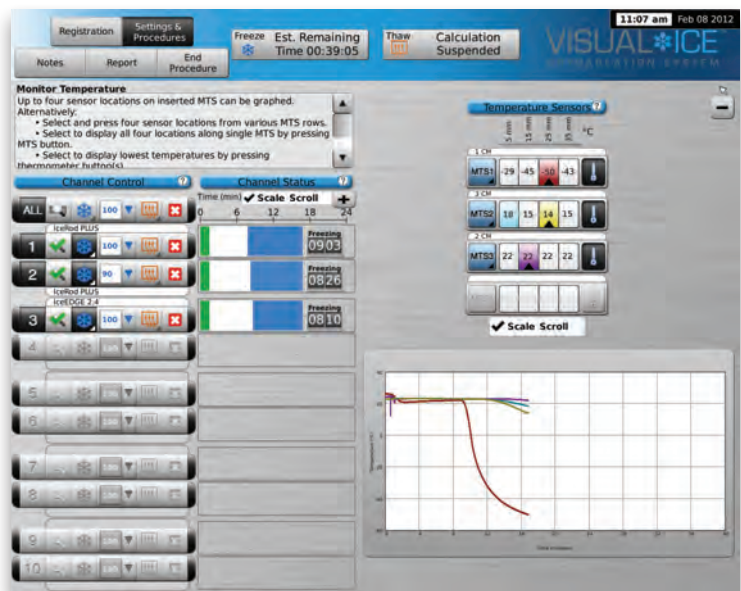
Procedure Status

## Large HD screen for monitoring procedure status

- Monitor procedure from a distance with the enlarged timers



Enlarged Timer



Customized Screen

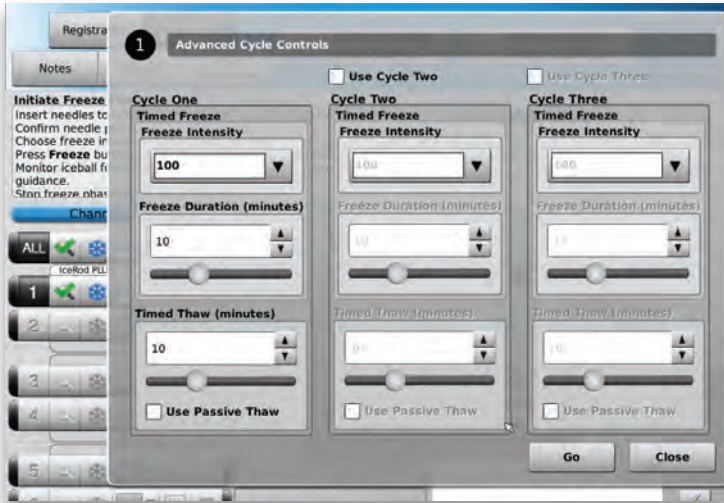
## Active Thawing without helium

- No helium cylinders, reduced procedure cost and faster setup
- i-Thaw Technology, Galil Medical's proprietary argon-only needle technology



i-Thaw Mode

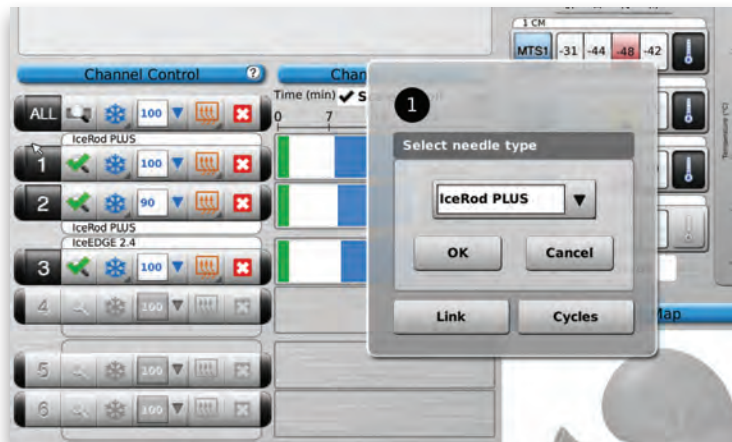
## Enhanced for Procedural Control and Flexibility



Advanced Channel Controls

### Precise control to shape and manage iceball growth

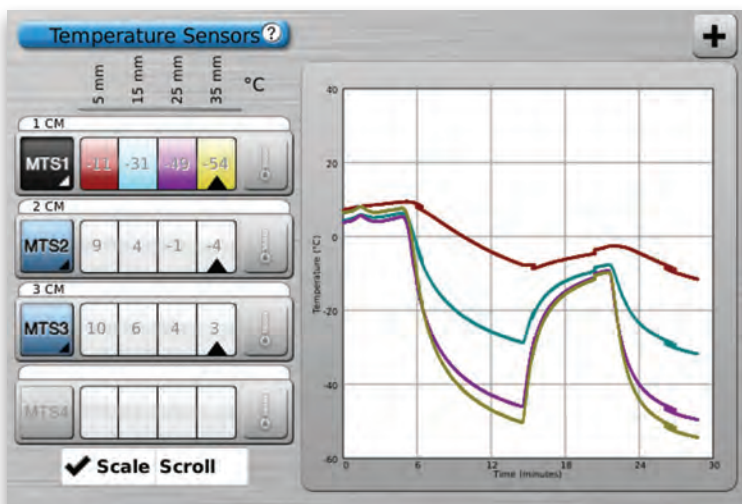
- Freeze intensity adjustable in 5% increments
- Ability to program freeze and thaw phases
- Independent control and operation of needles with 10 independent channels
- Potential to operate 20 needles (2 needles per channel)
- Ability to mix needle types for a procedure
- Ability to treat multiple tumors and different tumor sizes during a single procedure



Select Needle Type Menu

### Real-time temperature monitoring to manage iceball growth near critical structures

- Proprietary Multi-Point Thermal sensor technology
- Ability to set temperature warnings for each thermal sensor based on either a minimum temperature limit or a maximum rate of temperature drop



Temperature Sensor Section



# Platform for the Latest Cryoablation Technology

EZ  **CONNECT2™**  
DUAL CYLINDER ADAPTER

## Designed to Simplify Your Procedure

- Long (8M / 26 Feet), lightweight, flexible pencil-thin gas lines makes system set-up easier in tight spaces
- The option of an extra cylinder allows the maximum depletion of cylinder to lowest working pressure; helps hospitals maximize argon gas and save costs
- Built-in gas regulators enable consistent operating pressures
- Real time indicators provide estimated remaining gas time
- 20% reduction in operational sound
- 33% time reduction in Needle Integrity and Functionality Test
- Online system predictive diagnostics allows technical team to plan for maintenance in advance
- Online software updates and downloads
- Single screen for login and procedure setup
- Start-up, log-in and shut-down simplified
- 50% reduction in start-up time



### Indications for Use

The Galil Medical Cryoablation Systems are intended for cryogenic destruction of tissue during surgical procedures; various Galil Medical ancillary products are required to perform these procedures. Galil Medical Cryoablation Systems are indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ENT, gynecology, oncology, proctology and urology. These Systems are designed to destroy tissue (including prostate and kidney tissue, liver metastases, tumors, skin lesions and warts) by the application of extremely cold temperatures.

A full list of specific indications can be found in the respective Galil Medical Cryoablation System User Manuals.

**Contraindications** There are no known contraindications.

### Warnings / Precautions / Adverse Events

A thorough understanding of the technical principles, clinical applications, and risk associated with cryoablation procedures is necessary before using this product. Use of this device should be restricted to use by or under the supervision of physicians trained in cryoablation procedures with a Galil Medical Cryoablation System.

A full list of the specific indications, warnings, precautions, and adverse events can be found by referencing the respective needle instructions for use or cryoablation system user manual.

**R<sub>x</sub> only** **CAUTION** Federal (USA) law restricts this device to sale by or on the order of physician.



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# VISUAL<sup>®</sup>ICE

CRYOABLATION SYSTEM

## System Specifications



The expected service life of the Visual-ICE Cryoablation System is 5 years. Contact Galil Medical for disposal instructions.

Upon request by a Galil Medical qualified service engineer, a schematic of the system and/or components will be provided.

### Operating Conditions

- Temperature: 10 °C to 40 °C
- Relative Humidity: 30 % to 75 %

### Transportation and Storage Conditions

- Temperature: -15 °C to + 50 °C
- Relative Humidity: 10 % to 90 %

### Mechanical Specifications

- Weight: 100 kg (220 lbs)
- Height: 107 cm (42 inches), monitor down  
157 cm (62 inches), monitor up
- Foot Print: 56 x 66 cm (22 x 26 inches)
- Storage Compartment Weight Capacity: 50 lbs.
- Monitor Storage Basin Weight Capacity: 20 lbs
- Closed Monitor Weight Capacity: 20 lbs

### External Gas Supply

- Argon Cylinder:
  - Purity Level: 99.998 % or higher
  - Solid particle size: < 5 µm
- Helium Cylinder:
  - Purity Level: 99.995 % or higher
  - Solid particle size: < 5 µm

### Gas Cylinder Specifications

- Maximum Pressure: 31 MPa (4500 psi, 310 bar)  
41.4 MPa (6000 psi, 414 bar)  
**USA Only**
- Recommended Volume of Gas Cylinders: 42 – 50 L

### Accuracy of Displayed Values

- Temperature Accuracy:  
± 3 °C over range of -60 °C to +40 °C
- Supplied Gas Pressure Accuracy:  
± 50 psi, over range of 1000 psi to 6000 psi  
± 3.4 bar over range of 69 bar to 414 bar  
± 0.314 MPa over range of 6.9 MPa to 41.4 MPa
- Built-in Regulator Gas Pressure:  
± 50 psi, over range of 1000 psi to 4000 psi  
± 3.4 bar over range of 69 bar to 276 bar  
± 0.314 MPa over range of 6.9 MPa to 27.6 MPa
- Time Intervals:  
± 5 seconds over any 10 minute interval

### Electrical Specifications

- Input Voltage: 100 to 240 VAC, single phase
- Input Frequency: 50 – 60 Hz
- VA Rating: 250 VA
- IP Rating: IP10
- Fuse Rating: T 3.15A
- Electrical Protection: Class I, Type BF protection against shock
- Signal Input/Output Parts: one (1) Ethernet, one (1) USB 2.0 full-speed port, one (1) USB 2.0 low-speed port