1 LAB SETUP

a. Open tank valve

b. Connect scavenging line

c. Connect foot switch and ICB to console

d. Connect console to wall power

e. Connect HDMI slave cable to boom monitor

f. Turn on power switch located in rear/top of console

g. Press Cryo Therapy on screen and log in with username and password
2 PATIENT SETUP

a (Optional) Connect Esophagus Temperature Sensor (ETS) and Diaphragm Movement Sensor (DMS) to ICB

Note: ETS does not currently accept multi-sensor probes.

b Optimal DMS placement varies by patient, but right sub-costal or ~4cm sub-xiphoid may be appropriate

c Enter patient information on screen

3 PREPARE FOR ABLATION

a Verify tank status on Therapy screen

Note: If tank weight is <1.6kg (3.5lb), case start is not recommended. If <1.1kg (2.5lb), a notification is displayed, and case start is not allowed. Exit to main screen and press Change Tank to follow on-screen video instructions.

b Connect electrical umbilical to catheter and ICB

c Connect Cryo-Cable to catheter and to front of console

d Press Vacuum On and Confirm Catheter in ‘Ready’ state
**ABLECTION SETTINGS**

**Fixed Timer**
- Select fixed time to ablate in 30 seconds increments
- May stop at any time

**TTI Fixed Timer**
System logic depends on marking of TTI (programmable)
- If TTI < 60 seconds, then Ablation Timer extends 180 seconds
- If TTI ≥ 60 seconds, then Ablation Timer extends to 240 seconds

**TTI + Duration**
System logic depends on marking of TTI (programmable)
- If TTI < 60 seconds, adds “x” seconds to time at which TTI marked
- If TTI ≥ 60 seconds, adds “x” seconds to time at which TTI marked
- A maximum of 240 seconds is allowed

**POSITION & INFLATE**

a. Wire target vessel using POLARMAP™ Circular Mapping Catheter

b. Start Inflation *(3 options)*
   - Press Start button on front of console
   - Press green Foot Pedal
   - Press Inflate on Therapy screen
**SMARTFREEZE™ Console Operator Guide**

for use with **POLARx™** Cryoablation Catheter

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### 6 OCCLUDE

- **a** Verify occlusion
- **b** Designate vein
  - Touch Other on Therapy screen
  - Select PV

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### 7 ABLATE

- **a** Use programmed Ablation Timer or manually select duration
- **b** Start Ablation (3 options)
  - Press Start button on front of console
  - Press green Foot Pedal

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### 8 MONITOR

- **a** Temperature and mark TTI (Time to Isolation)
  - Press and hold green Foot Pedal for 3 seconds
  - OR
  - Press on Therapy screen
- **b** Monitor DMS and ETS
  - NOTE: DMS Monitoring is an adjunct diagnostic tool and should not replace standard monitoring for PNP.

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### 9 STOP

- **a** Automatic Stop: Allow Console to stop ablation by reaching end of the Ablation Duration Timer, and allow Catheter to thaw to automatic deflation temperature (+20°C)
- **b** Manual Stop: (3 options)
  - Press Stop button on front of console
  - Press orange Foot Pedal
  - Press Stop button on Therapy screen

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**For Emergency Stop:** Double Tap on any of the stop options to rapidly cease ablation and deflate the balloon.

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CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations. Information not intended for use or distribution in France.