



DISCLAIMER STATEMENTS

Users assume responsibility for approving the acceptable condition of this product before it is used, and for ensuring that the product is only used in the manner described in these instructions for use, including, but not limited to, ensuring that the product is not re-used.

Under no circumstances will AtriCure, Inc. be responsible for any incidental, special or consequential loss, damage, or expense, which is the result of the deliberate misuse or re-use of this product, including any loss, damage, or expense which is related to personal injury or damage to property.

TROUBLESHOOTING






















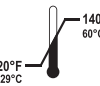

PROBLEM	POTENTIAL CAUSE	SOLUTION
PROBE does not reach desired defrost temperature after freeze.	Plugged gas supply path.	Manually defrost by applying warm saline to tissue and probe as necessary.
PROBE does not reach the proper temperature.	Empty or low N <sub>2</sub> O cylinder.	Replace low or empty N <sub>2</sub> O cylinder.
	Gas not flowing, tubing is restricted.	Verify PROBE tubing is not pinched.
	Gas leak in PROBE Shaft or tubing.	Replace PROBE.
	N <sub>2</sub> O tank valve closed.	Fully open N <sub>2</sub> O tank valve.
CONSOLE displays “—”.	Thermocouple Connectors not fully plugged into the CONSOLE.	Plug Thermocouple Connectors all the way into the CONSOLE ports.
	PROBE internal wires are broken.	Replace PROBE.
CONSOLE reads positive temperature during ablation.	Thermocouple Connectors are plugged in reversed (red-to-black).	Plug Thermocouple Connectors into the matching colored CONSOLE Ports.
CONSOLE displays fault code, error code, maintenance needed, or low cylinder pressure light.	See CONSOLE User’s Manual.	

CLINICAL STUDY REFERENCES FOR NERVE BLOCK INDICATION

- Graves C, Idowu O, Lee S, Padilla B and Kim S. Intraoperative cryoanalgesia for managing pain after the Nuss procedure. J Pediatr Surg. 2017;52:920-924.
- Graves CE, Moyer J, Zobel MJ, Mora R, Smith D, O’Day M and Padilla BE. Intraoperative intercostal nerve cryoablation during the Nuss procedure reduces length of stay and opioid requirement: A randomized clinical trial. J Pediatr Surg. 2019.
- Harbaugh CM, Johnson KN, Kein CE, Jarboe MD, Hirschl RB, Geiger JD and Gadepalli SK.vComparing outcomes with thoracic epidural and intercostal nerve cryoablation after Nuss procedure. J Surg Res. 2018;231:217-223.
- Keller BA, Kabagambe SK, Becker JC, Chen YJ, Goodman LF, Clark-Wronski JM, Furukawa K, Stark RA, Rahm AL, Hirose S and Raff GW. Intercostal nerve cryoablation versus thoracic epidural catheters for postoperative analgesia following pectus excavatum repair: Preliminary outcomes in twenty-six cryoablation patients. J Pediatr Surg. 2016;51:2033-2038.
- Kim S, Idowu O, Palmer B and Lee SH. Use of transthoracic cryoanalgesia during the Nuss procedure. J Thorac Cardiovasc Surg. 2016;151:887-888.
- Morikawa N, Laferriere N, Koo S, Johnson S, Woo R and Puapong D. Cryoanalgesia in Patients Undergoing Nuss Repair of Pectus Excavatum: Technique Modification and Early Results. J Laparoendosc Adv Surg Tech A. 2018;28:1148-1151.
- Parrado R, Lee J, McMahon LE, Clay C, Powell J, Kang P, Notrica DM, Ostlie DJ and Bae JO. The Use of Cryoanalgesia in Minimally Invasive Repair of Pectus Excavatum: Lessons Learned. J Laparoendosc Adv Surg Tech A. 2019;29:1244-1251.
- Pilkington M, Harbaugh CM, Hirschl RB, Geiger JD and Gadepalli SK. Use of Cryoanalgesia for Pain Management for the Modified Ravitch Procedure in Children. J Pediatr Surg. 2019.
- Sujka J, Benedict LA, Fraser JD, Aguayo P, Millspaugh DL and St Peter SD. Outcomes Using Cryoablation for Postoperative Pain Control in Children Following Minimally Invasive Pectus Excavatum Repair. J Laparoendosc Adv Surg Tech A. 2018;28:1383-1386.
- Dekonenko C, Dorman RM, Duran Y, Juang D, Aguayo P, Fraser JD, Oyetunji TA, Snyder CL, Holcomb GW, Millspaugh DL and St Peter SD. Post-Operative Pain Control Modalities for Pectus Excavatum Repair: a Prospective Observational Study of Cryoablation Compared to Results of a Randomized Trial of Epidural Vs Patient-Controlled Analgesia. J Pediatr Surg. 2019.
- Zobel MJ, Ewbank C, Mora R, Idowu O, Kim S and Padilla BE. The incidence of neuropathic pain after intercostal cryoablation during the Nuss procedure. Pediatr Surg Int. 2019.

EXPLANATION OF SYMBOLS ON PACKAGE LABELING

REFER TO THE OUTER PACKAGE LABEL TO SEE WHICH SYMBOLS APPLY TO THIS PRODUCT.

	Manufacturer		Country And Date of Manufacture
	Keep dry		Caution
	Catalogue Number		Batch Code
	Model Number		Unique Device Identifier
<b>Rx ONLY</b>	Prescription use only		Medical Device
	Use-by date		Do Not Resterilize
	Do Not Re-use		Do Not Use if Package is Damaged
	Single Sterile Barrier System with protective packaging inside		Single Sterile Barrier System with protective packaging outside
	Sterilized using irradiation		Follow instructions for use
	Waste Electrical and Electronic Equipment		Not made with natural rubber latex
	Non-pyrogenic		Does not contain Phthalates
 -20°F -29°C 140°F 60°C Transit/Storage Temperature limit		 85% 30% Transit/Storage Humidity limit	

