Specifications

- UL Classification: Class 1
- FDA Classification: Class 2
- Polar Wand is a Type CF Defibrillation Proof System with a 10 second recovery time.
- Operating temperature: Up to 80°F
- Operating humidity: Up to 90%
- Operating altitude: No effect on the function
- The degree of protection provided by the Polar Wand System is IPX1.
- Polar Wand is considered to be continuous operation and not intermittent.
- Polar Wand is not suitable for use in the presence of flammable anesthetics.
- System electrical ratings 100-135V 2A or 185-250V 1A VAC, 1 Phase, 50-60 Hz, 2 Amps.
- Fuse – 250V T2AL, 20 mm
- Suction Canister, standard 1200cc
- CO2, 5 lb tank
- Plastic washers – flat 11/16 od, 1/4 id

polarwand

Manufactered at 150 Hopper Avenue, Waldwick NJ 07463

If you have any questions about this device, please contact:

GI Supply
Customer Service
200 Grandview Ave • Camp Hill, PA 17011-1706
(P) 717-761-1170 • 1-800-451-5797 • (F) 717-761-0216

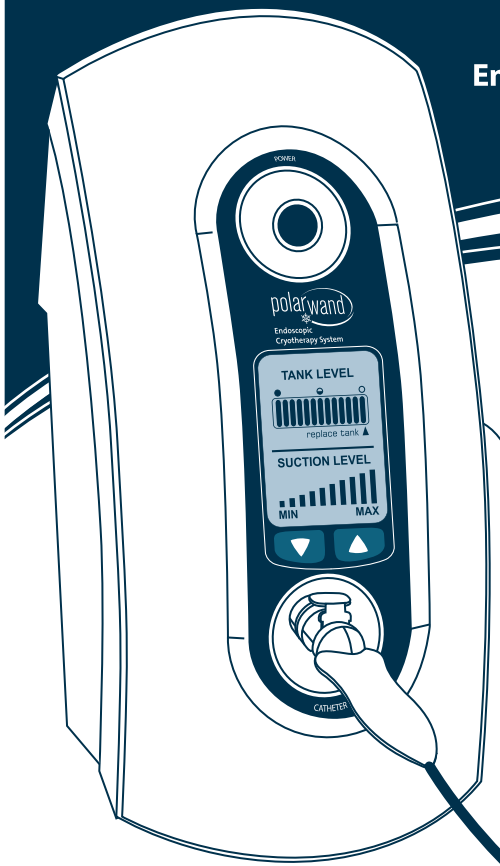
CE 0086

EC REP Diagmed Healthcare Ltd. • Lumley Close
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Rev.10

polarwand

Endoscopic Cryotherapy System



A portable cryosurgical device developed for endoscopic tissue ablation of the GI tract.

User Manual

GI Supply

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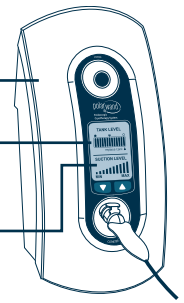
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Icon Definitions

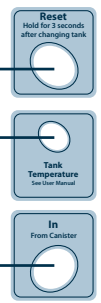
A guide to the markings that appear on the Polar Wand Endoscopic Cryotherapy System

- Power On & Off
- Protection of Defibrillation-Proof Applied Parts
- Attention
- Disposal Alert

Controls & Indicators



- Power On & Off
- Indicates that the Cryogen Tank is Running Low
- Indicates Suction Level



- Reset Button
- Indicates that the Cryogen (liquid CO2) Tank is Too Warm for Use.
- From Canister

polarwand

Intended Use and Function

The Polar Wand System consists of a portable cryogen containing unit, a single-use flexible cryogen spray catheter and a CO2 evacuation tubing set. The cryogen is delivered to the probe via a foot pedal.
The Polar Wand System is specifically designed for use with CO2 (Carbon Dioxide) in standard 5-lb. cylinders or tanks and can only be used with Polar Wand Cryotherapy catheter sets .

Indication for Use

The Polar Wand Cryotherapy System is indicated for the endoscopic ablation of tissue in the gastrointestinal tract. The treatment protocols are case specific, determined by the physician, based on multiple variables including the patient, condition and area of treatment.

Cryogen Unit Set-Up

1 The Polar Wand System is designed for use with a standard 5-lb. cylinder of CO2.

2 Attach the cryogen supply line (tank hose assembly) to the cryogen source (CO2 tank) by turning the nut in a clockwise direction making sure the plastic washer is in place. DO NOT TIGHTEN.

3 Turn the cylinder upside-down and place it in the tank cradle inside the Polar Wand unit. Secure cylinder using the attached retaining strap. Using the wrench provided, (or similar tool), FULLY TIGHTEN NUT.

4 Plug the unit into a grounded outlet with the supplied power cord. Press the power button on the front of the unit. Reset timing and "Tank Level" bars by pressing and holding the red reset button for at least three seconds. The reset button is located on the back of the unit. This turns off the reset indicator light and resets the timer to monitor cryogen usage.

5 Open the cylinder valve by turning it counter-clockwise in relation to the tank. Check and ensure there are no leaks.

Attaching the Cryotherapy Catheter

Use only Polar Wand Cryotherapy Catheters with this system. **Prior to use, inspect the tip of the Polar Wand catheter. Do not use the catheter if the tip does not have a very small hole, barely visible to the naked eye. Do not alter the device in any way.** Press the male fitting of the Polar Wand Catheter into the fitting on the front of the cryogen unit. Make sure the fitting is securely in place. An audible click should be heard. Pull lightly on the catheter to confirm attachment. The fitting on the cryogen unit contains an internal shut-off valve, which will only open if the cryotherapy catheter fitting is in place.

The CO2 Evacuation Tubing Set

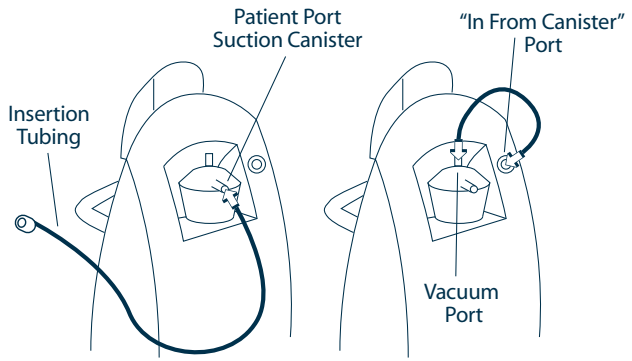
The CO2 evacuation set consists of an insertion tube with a cap on one end that fits over the end of the endoscope.

Attachment and Assembly of the CO2 Evacuation Tubing Set

1 Advance the cap on the end of the insertion tubing onto the tip of the endoscope. The cap will fit endoscopes with OD from 9 - 10mm. Attach the evacuation set of the tubing, after the spray catheter has been primed (see operating instructions), to the patient port of a suction canister (not supplied) on the back of the Polar Wand unit.



2 Connect one end of a suction tube (not supplied) to the vacuum port of the suction canister and the other to the "In From Canister" port on the Polar Wand.



Operating Instructions

1 Make sure the power and foot pedal cords are securely attached to the base of the Polar Wand unit and the power cord is plugged in to a power source. Turn the power on by depressing the power switch on the front of the unit. The power switch will illuminate.

2 The main power connection must be within operator's reach. It must be a grounded outlet, hospital grade, easily accessible.

3 Make sure cryogen source tank (CO2) is open.

4 Attach the cryotherapy catheter per the above instructions.

5 Hold the cryotherapy catheter near its tip, pointing it in a safe direction away from you. Depress the blue foot pedal to prime the system with cryogen and test for leaks at the connection site. This may take up to 30 seconds depending on tank pressure and ambient temperature. The cryotherapy catheter is ready for use when you observe an obvious white spray exiting the catheter. Attach the evacuation set to the suction canister.

6 Advance the cryotherapy catheter through the appropriate channel of the endoscope. Place the tip of the catheter relative to the target tissue according to desired physician technique. Activate freezing by depressing the foot pedal. Stop the flow of cryogenic spray by releasing the foot pedal.

7 Dual foot Pedal - Depression of the BLUE foot pedal activates the flow of CO2 and also the CO2 evacuation system. The range of suction is 4 to 21 liters per minute with each indication bar representing about 2 LPM. It is controlled by pressing the up or down buttons on the front of the unit. Depression of the YELLOW foot pedal activates full suction only and cannot be adjusted using the up and down buttons.

ATTENTION
PATIENT MONITORING RECOMMENDED

Using pressurized gas during some endoscopic procedures could lead to over-insufflation and the risk of tissue perforation. Patient monitoring for significant abdominal distention which may indicate the presence of a pneumo-peritoneum is recommended.

Shut Down

1 At the end of the procedure, turn off power to unit by depressing the power switch on the front of the unit.

2 Disconnect the cryotherapy catheter from the unit by pressing the metal lever of the fitting on the front of the cryogen control unit.

3 Dispose of catheter set according to healthcare facility guidelines.

4 Close the valve on the CO2 tank.

5 Unplug power cord and wrap around one set of attached brackets. Store the foot pedal by wrapping it around the other set of brackets and place the pedal in its storage bracket.

Replacing Cryogen Tank

The Polar Wand cryotherapy system monitors the amount of cryogen (liquid CO2) in the tank by timing foot pedal depression time. The tank level indicator on the front of the unit advances as cryogen is used. When the level of cryogen approaches approximately 2 minutes of spray time left (indicated by the Replace Tank arrow) the tank should be changed. When 1 minute of spray remains, a beep will sound at 30 second intervals.

1 Lock the two front wheels.

2 Close the valve on the tank by turning it clockwise and loosen the brass fitting. Release the fabric straps around tank.

3 Remove the tank from its cradle and stand it right-side up.

4 Unscrew brass hose fitting from tank using the wrench provided (or similar tool).

5 Replace the plastic washer located in the brass fitting of the Polar Wand hose. Washers are located in the base of the Polar Wand, and are available from your tank supplier.

6 Screw brass hose fitting on to the new tank. DO NOT TIGHTEN.

7 Turn the tank upside down and place it into the tank cradle inside of the unit. Snap the tank straps together.

8 Fully tighten brass hose fitting using the wrench provided (or similar tool).

9 Fully open the tank valve by turning it counter-clockwise.

10 Listen for leaks around brass hose fitting and tighten further, if needed, to eliminate leaks. If leaking continues, close tank and replace plastic washer in brass fitting and re-tighten.

11 Make sure POWER is on. (The green button on the front of the Polar Wand is illuminated)

12 Press and hold the RESET BUTTON for at least three seconds until the red RESET BUTTON light goes out. The RESET BUTTON is located on the back of the Polar Wand. (Never press the reset button unless you are replacing the tank)

13 Make sure the TANK LEVEL is reset to full.

14 Unlock the front wheels to move Polar Wand.

Unit Cleaning & Maintenance

- Wipe down with a damp cloth and mild detergent.
- Check the power cord regularly for damage.
- Check TANK LOW light regularly and replace tank if light is on.
- Consumable or replaceable components within the PolarWand Cryotherapy unit are the cryogen tanks, suction canister, fuses and the plastic washer within the cryogen tank fitting. Ensure that an adequate supply of plastic washers are available.

Warning: For continued protection against fire hazard, replace fuses only with the same type and rating shown.

Trouble Shooting

1 TANK TEMPERATURE: If the Tank Temperature light is on, the cryogen tank is too warm for use. The Polar Wand Cryotherapy System uses CO2 in liquid form as its cryogen source and if the CO2 tank temperature is above 80°F the liquid turns into gas and proper freezing will not take place. If this occurs, the tank must be left to cool below 80°F before use. Once the Tank Temperature light is off, the tank has cooled down.

2 IF UNIT WILL NOT TURN ON: Make sure the power and foot pedal cords are securely attached to the base of the Polar Wand unit. Also, make sure the power cord is plugged in to a working electrical outlet. If unit will still not turn on, unplug unit from electrical outlet, remove the power cord from the base of the unit and inspect the fuses that are located in the female socket. Replace, if necessary, with 250V 2A.

Warranty

GI Supply warrants this product to be free from defects in material and workmanship for a period of ninety (90) days from the date of shipment. If repair or adjustment is necessary within the warranty period which has not been the result of mishandling or abuse, you may return the unit freight prepaid, providing a return authorization has been obtained. Tampering with the unit will void the warranty.

Servicing

For questions on servicing, contact GI Supply at 717-761-1170 or 1-800-451-5797. If unit requires repair, a return authorization must be obtained for it to be sent back to manufacturer. GI Supply will make available, upon request, items such as circuit diagrams and component parts list to a qualified technician for repairs as needed.

Transportation & Storage

Environmental requirements for transportation and storage: 10 - 60°C, 25 - 90% relative humidity. Polar Wand is a mobile system that should be moved on its own wheels when possible. When lifting is required, lift Polar Wand by holding both sides of the handle where it connects to the front of the unit.