

# *Endocare Urethral Warming System*

## **Operator Manual**

**Caution:** Federal law (USA) restricts this device to sale, distribution, and use by or on the order of a physician.

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## **System Description**

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The Endocare Urethral Warming system consists of a Fluid Warmer and Circulating Pump mounted to an IV Pole which has a movable base. It is intended supply warm, sterile water or saline to the Endocare Urethral Warming Catheter, which transfers heat to the urethra during prostate cryosurgery.

It is recommended that the Endocare Urethral Warming System be used with the following:

- (1) Endocare Circulating Catheter Kit - (includes (1) heat exchanger cassette, (1) tubing set and (1) urethral catheter).
- (1) One-liter sterile water or saline bag (not supplied by Endocare).

## **System Components**

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The Endocare Urethral Warming System contains:

- (1) Fluid Warmer
- (1) Circulating Pump
- (1) IV Stand

### **FLUID WARMER**

The Fluid Warmer maintains sterile water or saline from an IV bag at a set point temperature. A shut-off feature prevents the temperature from exceeding 45°C. The Fluid Warmer utilizes a heat exchanger in the form of a cassette. This Heat Exchanger Cassette is a component of the Endocare Circulating Catheter Kit, which is supplied separately. The Heat Exchanger Cassette is inserted between the microprocessor controlled heat plates located within the Fluid Warmer housing.

### **CIRCULATING PUMP**

The Circulating Pump is a peristaltic pump which circulates warm, sterile water or saline from the Fluid Warmer through the Endocare Urethral Warming Catheter, returning to the IV bag to form a closed circuit.

### **IV POLE**

The IV Pole consists of a wheeled base with telescoping pole. The Fluid Warmer and Circulating Pump are supplied mounted to the IV Pole. The wheeled base is fitted with castors, two of which are lockable, that allow the Endocare Urethral Warming System to be moved as needed during cryosurgery.

See Figure 1.

## **System Safety**

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### **INTENDED USE**

The Endocare Urethral Warming System is intended to be used to transfer heat to urethral tissue during urological cryosurgery procedures using the CRYOcare™ Cryosurgical System. The System consists of a urethral catheter, tubing set, fluid warmer, IV stand and peristaltic pump. The urethral catheter transfers heat from the warm, sterile water or saline to the urethral tissue. The urethral catheter is inserted into the urethra prior to cryosurgery and is removed immediately after the procedure.

### **CONTRAINDICATIONS**

There are no specific contraindications for the use of this device.

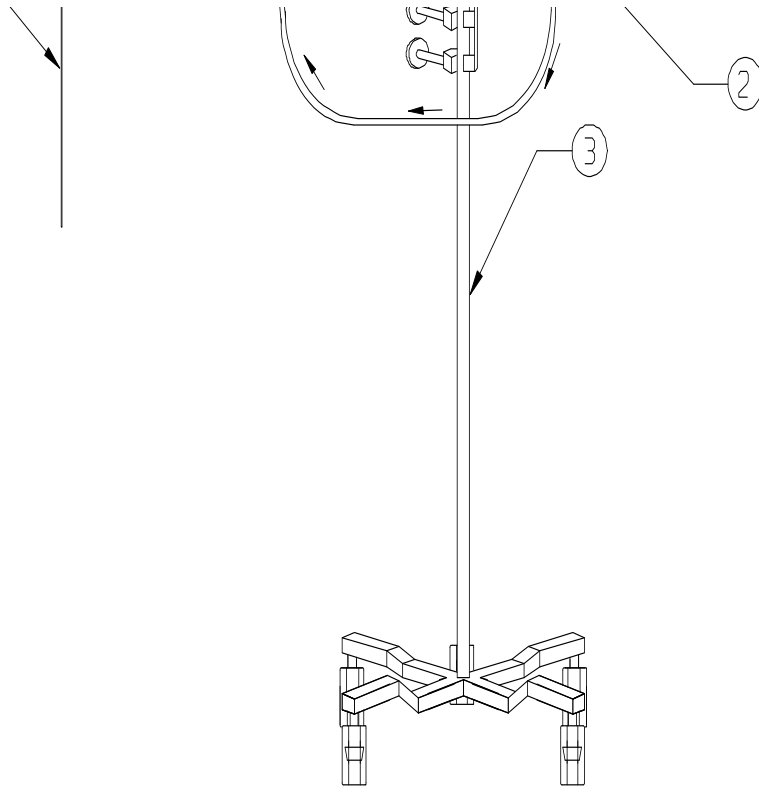
**CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE OF THIS PRODUCT. OBSERVE ALL WARNINGS AND PRECAUTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.**

- **WARNING:** A thorough understanding of the technical principles, clinical applications, and risk associated with cryosurgery is necessary before using this product. Use of this device should be restricted to use by or under the supervision of physicians trained in cryosurgical procedures.
- **WARNING:** Excessive heating of the urethra could result in damage to the urethral and periurethral tissues. Always monitor the system temperature display to ensure temperatures do not exceed 42°C.
- **WARNING:** To protect against shock hazard, connect the warmer and pump to hospital-grade outlets **ONLY**. The electrical components are not explosion proof. Do not use this equipment in an area where flammable vapors are present.
- **WARNING:** The Urethral Catheter must be removed from the patient while the Warming System is still operating. **DO NOT** turn off Endocare Urethral Warming System prior to removal of Endocare Urethral Warming Catheter. If the System is turned off prior to the catheter being removed, the catheter may freeze in the urethra, be difficult to remove and may result in injury to the patient. **DO NOT** attempt to remove the Endocare Urethral Warming Catheter if Endocare Urethral Warming System has been turned off. If this occurs, turn on Urethral Warming System and circulate warm sterile water or saline through the catheter until it can be safely removed.
- **CAUTION:** Fluids pre-heated above 42°C will cause the Fluid Warmer safety mechanism to activate, disabling the Fluid Warmer.
- **CAUTION:** The Endocare Urethral Warming system is supplied mounted to an IV Pole and should not be used with any other pole.
- **CAUTION:** There are no user-serviceable parts with the Endocare Urethral Warming System. Refer all service issues to Endocare Customer Service.
- **NOTE:** Read the Endocare Urethral Warming System Operators Manual and become familiar with the System and all controls before operation.

## Figure 1: Urethral Warming System Configuration

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1. Fluid Warmer
2. Circulating Pump
3. IV Stand Pole
4. Heat Exchanger Cassette
5. Heat Exchanger Inflow Tube
6. Catheter Inflow Tube
7. Urethral Warming Catheter
8. Catheter Outflow Tube
9. Tube Retainers
10. IV Bag
11. Heat Exchanger Cassette Inflow Tube
12. Heat Exchanger Cassette Outflow Tube



Note: Items 4,5,6,7,and 8 are components of the Endocare Circulating Catheter Kit. Items 11 and 12 are components of the Heat Exchanger Cassette.

## Installation Procedures & Requirements

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Upon receipt the Endocare Urethral Warming System should be visually examined for damage. The System must be assembled as described in “System Set-up”. See also Figure 1. Refer all service issues to Endocare Customer Service.

### System Set-up

1. Open latches on both ends of shipping crate; remove crate lid and set aside.
2. Remove retainer blocks on top of Fluid Warmer and Circulating Pump.  
**NOTE:** Fluid Warmer and Circulating Pump are supplied mounted to an IV Pole.
3. Remove IV Pole with attached Fluid Warmer and Circulating Pump. Set aside and lock casters.  
**CAUTION:** Warming System weighs approximately 49 pounds (22 kg). Use caution when moving.
5. Plug main power cords from Fluid Warmer and Circulating Pump into a hospital-grade power strip or outlet
6. Turn ON power switch located on Circulating Pump.
7. The Endocare Urethral Warming System is now ready to use.

### Operating Instructions

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#### Prior to Use

1. Connect the Endocare Circulating Catheter Kit to the Urethral Warming System. Refer to the Circulating Catheter Kit Directions for Use.
2. Ensure that the Heat Exchanger Cassette is correctly inserted into the Fluid Warmer. To verify proper insertion of Heat Exchanger Cassette into Fluid Warmer, gently pull on Cassette to confirm heater plates are securely seated on Cassette.
3. Check Fluid Warmer and Circulating Pump power cords to ensure they are securely plugged into a hospital-grade outlet.
4. Place a one liter bag of sterile water or saline on the IV pole.
5. Turn Fluid Warmer power switch ON.
6. Open hose clamps. Turn Circulating Pump speed to “2” and prime lines. Lack of presence of air bubbles indicates the System has been primed.
7. Rotate speed control knob on Circulating Pump knob to the “0” position to ensure rollers are not moving.

#### Instructions For Use

1. Insert the Endocare Urethral Warming Catheter into the patient's urethra. Immobilize patient's penis to prevent distal migration of the catheter.
2. Confirm position of the Endocare Urethral Warming Catheter by transrectal ultrasound.
3. Confirm Fluid Warmer and Circulating Pump main power switches have been turned ON.
4. Increase the Circulating Pump speed to setting number "3". Visually confirm flow by examining the flow indicator.  
**CAUTION:** If the Catheter Inflow Tubing begins to migrate in the pump head, turn off the pump, reinsert the Catheter Inflow Tubing and check tube retainers on both sides of the pump head. Tube retainers should set firmly against the Catheter Inflow Tubing. Reposition to securely hold tubing, if necessary. (See Figure 1.)
5. Set temperature to 37.5°C using the UP or DOWN arrow keys on the Fluid Warmer faceplate. Watch the LCD display until the recommended temperature is reached.
6. Prior to cryosurgical procedure, confirm air has been bled out of the Endocare Urethral Warming System by watching fluid flow through the Catheter Outflow Tubing. Lack of presence of air bubbles indicates System has been properly bled of air.
7. During cryosurgical procedure, monitor the fluid level in the IV bag at all times.  
**CAUTION:** Drop in fluid level and bladder distention may indicate a Endocare Urethral Warming Catheter leak. Replace the Catheter if a leak is detected.
8. At the end of the cryosurgical procedure, remove the Endocare Urethral Warming Catheter **before** turning off the Urethral Warming System.
9. Turn off the Fluid Warmer and Circulating Pump after the Urethral Catheter has been removed from the patient.
  - **WARNING:** The Urethral Catheter must be removed from the patient while the warming system is still operating. **DO NOT** turn off Endocare Urethral Warming System prior to removal of Endocare Urethral Warming Catheter. If the system is turned off prior to the catheter being removed, the catheter may freeze in the urethra, be difficult to remove and may result in injury to the patient. **DO NOT** attempt to remove the Endocare Urethral Warming Catheter if Endocare Urethral Warming System has been turned off. If this occurs, turn on Urethral Warming System and circulate warm sterile water or saline through the catheter until it can be safely removed.

## Care of Equipment

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The Endocare Urethral Warming System has been designed to require little or no daily maintenance. The Fluid Warmer and Circulating Pump should be wiped down as appropriate with only mild detergent and water, using a soft cloth. **DO NOT** immerse Fluid Warmer and Circulating Pump in liquids. **DO NOT** autoclave or ETO gas sterilize.

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# Troubleshooting Guide

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## **Leaks:**

- Replace Endocare Urethral Warming Catheter if leaks are detected.
- Replace any or all components of tubing set if leaks are detected.

## **No/Low Flow: (Flow Indicator is not rotating.)**

- Ensure tubing clamps are open.
- Ensure Circulating Pump power switch is turned ON and pump speed is set above 0.
- Check all tubing for kinks. Straighten tubing and reevaluate flow indicator.
- Check all tubing connections.
- Ensure Catheter Inflow Tube is properly installed in pump head.
- Ensure there is fluid in IV bag.
- If Flow Indicator is still not rotating, immediately remove Endocare Urethral Warming Catheter and replace all tubing.

## **LCD screen is dark.**

- Turn power switch ON.
- Ensure power cords are securely plugged into hospital-grade outlet.

## **Heat Exchanger Cassette Door Will Not Latch Closed.**

- Lift door up firmly until door is latched. Green band on top of Door Latch Button should be visible.
- Prime tubing only after cassette if fully installed. If cassette is pressurized, close red clamp at heat exchanger to release fluid pressure on cassette and release fluid downstream.

## **Heat Exchanger Cassette Door Will Not Open.**

- Press Door Latch Button firmly.
- Prime tubing only after cassette if fully installed. If cassette is pressurized, close red clamp at heat exchanger to release fluid pressure on cassette and release fluid downstream.

## **Fluid temperature is too low.**

- Increase set point temperature to no greater than 39.5°C using UP arrow key on Fluid Warmer faceplate.
- Ensure all clamps are open.

## **High Temperature Alarm.**

- Do not use pre-warmed fluids.
- Turn unit off, allow to cool for 5 minutes and turn on again. If alarm is not cleared, call Endocare for service.

## **Low Temperature Alarm.**

- Ensure that the pump flow rate is correctly set.
- Turn unit off, allow to cool for 5 minutes and turn on again. If alarm is not cleared, call Endocare for service.

## **FAULT CODE No. “01” through “17” is displayed on LED screen.**

- Make note of code number and call Endocare for service.

## **FAULT CODE No. “20” through “44” is displayed on LED screen.**

- Turn power off unit. Allow to cool for 5 minutes and restart unit.
- If problem persists, make note of code number and call Endocare for service.

**FAULT CODE No. “45” is displayed on LED screen.**

- Make note of code number and call Endocare for service.

**Pump head rollers not rotating:**

- Ensure Circulating Pump power switch is turned ON.
- Ensure Circulating Pump speed control knob is set to setting number “3”.
- If Circulating Pump rollers are still not rotating, discontinue the procedure and immediately remove the Urethral Warming Catheter to prevent it from freezing in place. If Catheter becomes frozen in place, circulate warm water or saline until the catheter can be safely removed.

## **Service Information**

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There are no user serviceable parts in the Endocare Urethral Warming System. Contact Endocare Customer Service for all support and service issues.

## Technical Data and Specifications (120 VAC)

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### **Fluid Warmer:**

#### **Physical Specifications**

Dimensions 4.75" H x 5.75" W x 11" D  
(12 cm H) x (14.5 cm W) x (28 cm D)

Weight : 8 lbs. (3.6 kg.)

#### **Electrical Specifications**

Supply Voltage 115 VAC  
Operating Frequency 50-60 Hz  
Maximum Operating Current 12 Amps  
Maximum Heating Power 1,440 Watts  
Warmer Circuit Breaker Rating 12 Amps  
Heat Exchanger Dry heat  
Primary Temperature Control Electronic  
Temperature Control Range 28.0 – 42.0°C (NOTE: Default temperature = 38.0°C)  
(Set Point Temperature)  
Low Temperature Alarm Flashing display, 3.0°C below set point  
High Temperature Alarm 44.5°C  
Secondary Heater Disable 45.0°C  
Display Screen 4 digit LED

### **Pump:**

Flow Range 1.2 to 2300 ml/min  
Pump Head Type Roller type peristaltic pump  
Drive 20 - 600 rpm  
Drive Speed Accuracy ± 5%  
Weight 9 lb./ 4.1 kg  
Dimensions (L x W x H) 8 11/16" x 7 1/8" x 5 5/16"  
Voltage 90-130 VAC (50/60Hz)

### **IV Pole:**

Dimensions 68" compressed height (99" extended height) x 22" diameter  
(173 cm compressed to 252 cm extended x 56 cm diameter)

Weight 32 lb. (14.5 kg)

### **Warming System Overall:**

Dimensions H x W x D  
68-99" 22" x 22"  
(173-252 cm) (56 cm) (56 cm)

Weight 49 lb. (22.3 kg.)

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## Technical Data and Specifications (240 VAC)

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### **Fluid Warmer:**

#### **Physical Specifications**

Dimensions 4.75" H x 5.75" W x 11" D  
(12 cm H) x (14.5 cm W) x (28 cm D)

Weight : 8 lbs. (3.6 kg.)

#### **Electrical Specifications**

Supply Voltage 230 VAC  
Operating Frequency 50-60 Hz  
Maximum Operating Current 6 Amps  
Maximum Heating Power 1,440 Watts  
Warmer Circuit Breaker Rating 6 Amps  
Heat Exchanger Dry heat  
Primary Temperature Control Electronic  
Temperature Control Range 28.0 – 42.0°C (NOTE: Default temperature = 38.0°C)  
(Set Point Temperature)  
Low Temperature Alarm Flashing display, 3.0°C below set point  
High Temperature Alarm 44.5°C  
Secondary Heater Disable 45.0°C  
Display Screen 4 digit LED

### **Pump:**

Flow Range 1.2 to 2300 ml/min  
Pump Head Type Roller type peristaltic pump  
Drive 20 - 600 rpm  
Drive Speed Accuracy ± 5%  
Weight 9 lb./ 4.1 kg  
Dimensions (L x W x H) 8 11/16" x 7 1/8" x 5 5/16"  
Voltage 90-130 VAC (50/60Hz)

### **IV Pole:**

Dimensions 68" compressed height (99" extended height) x 22" diameter  
(173 cm compressed to 252 cm extended x 56 cm diameter)

Weight 32 lb. (14.5 kg)

### **Warming System Overall:**

Dimensions H x W x D  
68-99" 22" x 22"  
(173-252 cm) (56 cm) (56 cm)

Weight 49 lb. (22.3 kg.)

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## Warranty and Return Policy

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Endocare warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling, storage, cleaning and sterilization of this instrument as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and others matters beyond ENDOCARE's control directly affect the instrument and the results obtained from its use. ENDOCARE's obligation under this warranty is limited to the repair or replacement of this instrument and ENDOCARE shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. ENDOCARE neither assumes, nor authorizes any other person to assume for it, any other additional liability or responsibility in connection with this instrument.

Price, models and availability are subject to change without notice.

CRYOCARE Cryosurgical System™ is a trademark of ENDOCare.

### Manufacturer



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