

# OPERATOR'S MANUAL



**cryosurgery at your fingertips®**



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OM-CT1010-01-R1 Revised 07.31.08

## OPERATOR'S MANUAL

(Minimally invasive cryosurgical unit and accessories for physician use only)

- **Caution: "Federal law restricts this device to sale by or on the order of a Physician".**

Model number: CT-CT1000

Model number: CT-CT1010

<p><b>Manufactured and Distributed by:</b> CryoPen, Inc. 1301 McKinney, Suite 3150 Houston, TX 77010 p: 1.888.246.3928 713.600.5010 efax: 1.281.754.4359 www.cryopen.com</p>
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**Disclaimer: Items may vary according to model number**

<b>CONTENTS:</b>	<b>ITEM NUMBER:</b>
CryoPen <sup>®</sup> Cooling System Assembly (1ea.)	CT-CT1000
CryoPen <sup>®</sup> Cooling System Assembly (1ea.)	CT-CT1010
Non-Sterile re-usable CryoPen <sup>®</sup> tip (3ea.) 3mm	CT-TA5003
Non-Sterile re-usable CryoPen <sup>®</sup> tip (3ea.) 5mm	CT-TA5005
Non-Sterile re-usable CryoPen <sup>®</sup> tip (3ea.) 7mm	CT-TA5007
Non-Sterile re-usable CryoPen <sup>®</sup> tip (3ea.) 10mm	CT-TA5010
CryoPen <sup>®</sup> Module Assembly (2ea.) 10mm (0.4 in.)	CT-PA1000-10
CryoPen <sup>®</sup> Module Assembly (2ea.) 7mm (0.25 in.)	CT-PA1000-7
CryoPen <sup>®</sup> Module Assembly (2ea.) 5mm (0.19 in.)	CT-PA1000-5
CryoPen <sup>®</sup> Temperature indicator (1ea.)	CT-TI1000
CryoPen <sup>®</sup> Reservoir Solution 500ml (1ea.)	CT-AL1000
CryoPen <sup>®</sup> Swabs (6)	CT-SW1000
CryoPen <sup>®</sup> Cotton Towel	CT-TO1000
CryoPen <sup>®</sup> Operators Packet	CT-OP1000

### Indications For Use:

- Intended use: Cryosurgical unit used for ablative type surgical technique
- Indications for use: Multiple organ systems, wide range of disease, viral, premalignant and malignant tissue.

### Contraindications:

The CryoPen<sup>®</sup> is contraindicated in patients with recurrent basal cell cancers; lesions on the lower extremities (i.e. feet, ankles, lower legs) when circulation is in question, especially in patients with diabetes; lesions in the nasolabial fold or preauricular area (basal cells often are more extensive in this area); lesions in the immediate periorbital area; port-wine stains, lesions in areas in which hair loss or pigmentary changes are critical to the patient. Cryosurgery is not recommended for Melanomas.

**WARNING: Do NOT use the CryoPen<sup>®</sup> when the above listed conditions are present. The use of cryosurgical procedures in the treatment of the above listed conditions may cause serious injury to the patient.**

## **WARNINGS:**

**WARNING (Model Number CT-CT1010): Do not Autoclave re-usable tips**

**WARNING (Model Number CT-CT1010): If re-usable tip gets stuck on skin, remove handheld module from tip and allow to thaw.**

**WARNING: Never leave the chilling wells open. Doing so will render your unit inoperable.**

**WARNING: Do not use the electrical charging unit near or in water. Doing so may cause electrical shock resulting in serious injury or death to the user.**

**WARNING: Do not use an extension cord. Use of extension cords may present potential fire hazards.**

**WARNING: Explosion hazard! Do not use in presence of flammable anesthetics. Unit contains 1oz. of an ethanol based proprietary solution.**

**WARNING: Ethanol is poisonous! May be fatal if swallowed. Harmful if inhaled or absorbed through skin. Please refer to Material Safety Data Sheet regarding the ethanol based reservoir solution.**

**WARNING: End of CryoPen<sup>®</sup> is extremely cold. Accidental contact with tip end of CryoPen<sup>®</sup> may result in frostbite.**

**WARNING: Clean CryoPens<sup>®</sup> with soap and water or with standard solutions such as glutaraldehyde or isopropyl alcohol. Clean only when the CryoPens<sup>®</sup> have reached room temperature. Do not submerge CryoPens. Doing so will render them inoperable.**

**WARNING: Do not use hand-held CryoPen<sup>®</sup> without a sterile tip. Doing so will expose your patients to non-sterile conditions and may cause cross patient contamination.**

**WARNING: Use of the hand-held CryoPens<sup>®</sup> without a sterile tip may cause the CryoPen<sup>®</sup> to become stuck on patient's skin thereby causing injury to the patient.**

## **PRECAUTIONS:**

- **CAUTION: (Model Number CT-CT1010) Do not Autoclave re-usable tips (doing so will melt the plastic)**
- **CAUTION: (Model Number CT-CT1010) Do not replace CryoPens<sup>®</sup> hand-held modules in chilling well with re-usable tip attached. If re-usable tip accidentally gets lodged in chilling well, turn unit off. When warm, dislodge tip with hemostats.**
- **CAUTION: This device should be used with caution on patients with diabetes, peripheral vascular disease or cold intolerance problems.**
- **CAUTION: Use of CryoPen<sup>®</sup> on lesions with hair, may cause patient to lose hair.**
- **CAUTION: Use of CryoPen<sup>®</sup> on lesions in areas where pigment is critical to patient, patient should be made aware that change in pigment may result.**
- **CAUTION: Federal Law restricts this device to sale, distribution and use by or on the order of a physician.**

- **CAUTION: Do not replace CryoPens<sup>®</sup> hand-held modules in chilling well with a tip attached. If tip accidentally gets lodged in chilling well, turn unit off. When warm, dislodge tip with hemostats.**
- **CAUTION: Reservoir solution contains alcohol (ethanol) Avoid skin contact with the reservoir solution on persons taking the medication ANTABUSE<sup>®</sup>.**

### **POWER OUTAGE**

- **Step one:** Turn unit off
- **Step two:** After unit has reached room temperature, approximately 8 hours, remove handheld modules from the chilling wells.
- **Step three:** Using the double sided swab that is provided, remove all reservoir solution and water from the chilling wells. Wells should be completely dry.
- **Step four:** Remove lid and reservoir cup from the unit and discard old solution and refill.
- **Step five:** Dry all handheld modules with cotton towel. Using the supplied plastic Pipette, fill each chilling well with reservoir solution. (one Pipette full per well) Place 1 pen of your choice into each of the three chilling wells. Place remaining three pens in the holding wells.
- **Step six:** Turn unit on. System will be ready for use in approximately 90 minutes. Test handheld modules (pens) for readiness using the temperature indicator.

**The above steps should be followed each time you have a power outage.**

### **POWER SURGE**

- **Step one:** Turn unit off, wait 3-5 minutes then turn system back on. This will allow your system to reset.
- **Step two:** If unit does not chill properly after this process, turn unit off and follow the steps for a Power Outage and/or call Technical Support.

**Note: We recommend using a line surge protector to protect your investment.**

**DESCRIPTION:**

The CryoPen<sup>®</sup> system provides a means of freezing tissue without the use of cryogenic gases or liquids. The system consists of six hand-held freezing modules, a refrigeration unit, re-usable tips in (4) four sizes and a temperature indicator. When used properly, the system will deliver effective temperatures for tissue ablation.

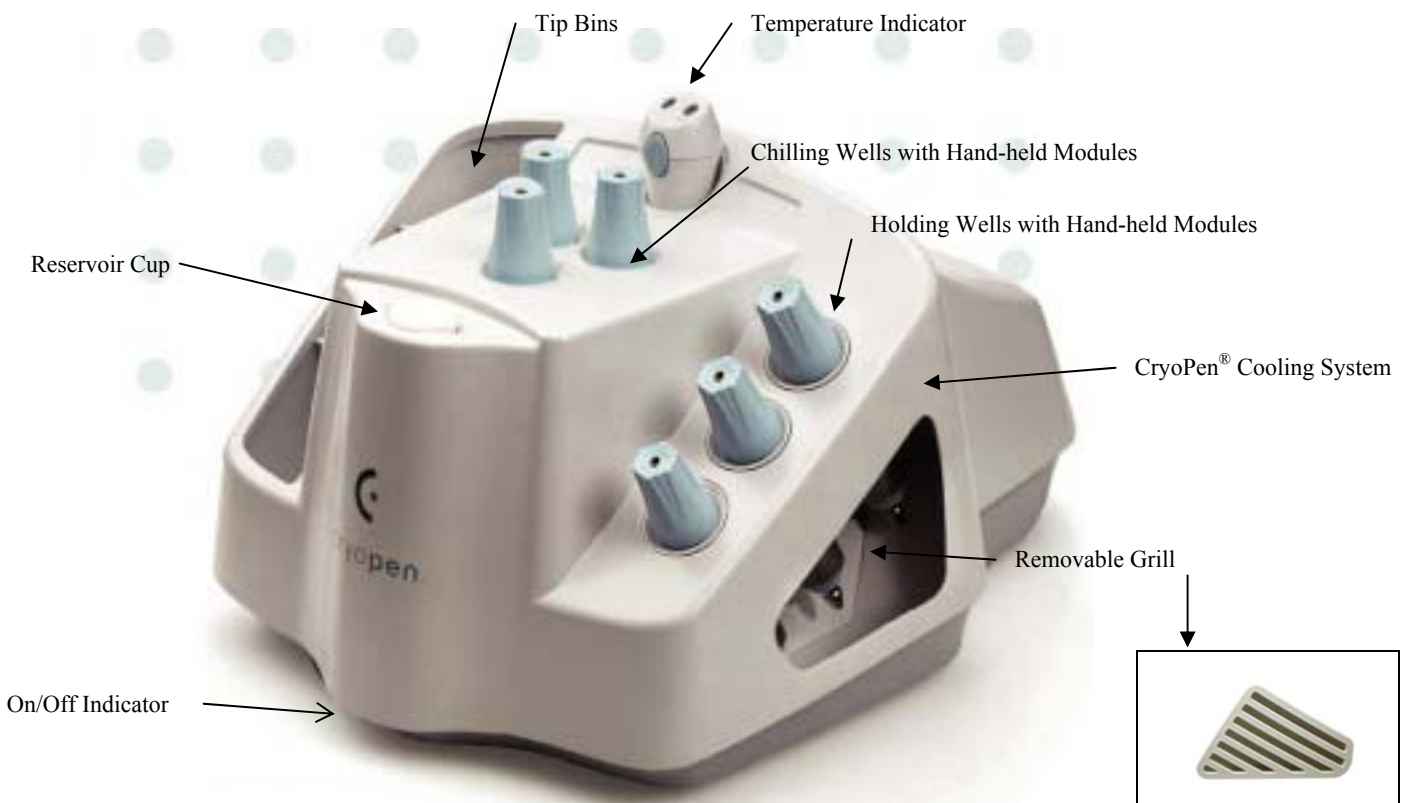
The CryoPen<sup>®</sup> Cooling System: The unit is a refrigeration component that operates on 115 volt AC obtained from conventional convenience outlets. It is used to lower the temperature of the CryoPen<sup>®</sup> units to temperatures of -95°C.

The CryoPen<sup>®</sup> Module (handheld): It consists of a heat sink that has been shaped at one end to form a treatment surface. A connection for proper temperature indication is on the top of the module.

The CryoPen<sup>®</sup> Re-usable Tips: (Model#CT-CT1010) Tips consist of resilient medical grade plastic that contains an aluminum tip. When surgery is complete, remove the tip and re-sterilize.

Temperature Indicator: Indicates readiness of CryoPen<sup>®</sup> Module (handheld). When the temperature indicator is plugged into the CryoPen<sup>®</sup> hand held module - a red light means that the CryoPen<sup>®</sup> is not cold enough for procedure. A green light indicates that the CryoPen<sup>®</sup> has reached optimal procedure temperature. Note: The temperature indicator also lights red when not connected to a pen and the button is pushed. If no light is visible, contact CryoPen, L.C. at 1.888.246.3928

Note: Model Shown in diagram CT-CT1010

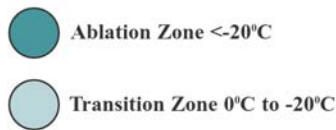
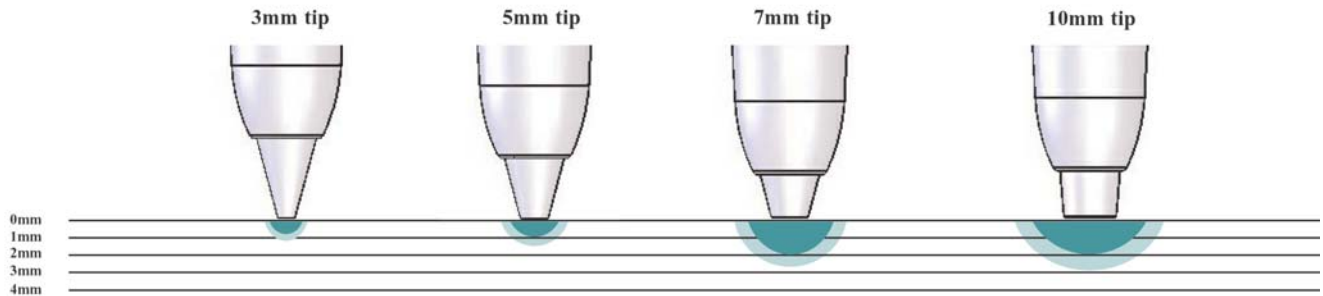


## ABLATION AND TRANSITION ZONES

Ablation and transition zones vary with tip diameter; tip temperature, and tissue temperature. Chart is derived from CryoPen® bench data. Zones will vary with skin thickness and location and lesion types.

Ablation zone is  $<-20^{\circ}\text{C}$ . Transition Zone is  $0^{\circ}\text{C}$  to  $-20^{\circ}\text{C}$ .

### EXAMPLE: 30 second contact duration for various size CryoPens®



- ablation zone  $<-20^{\circ}\text{C}$
- transition zone  $0^{\circ}\text{C}$  to  $-20^{\circ}\text{C}$

When selecting a CryoPen, desired depth of freeze should be considered. As shown in the diagram, the larger the tip, the deeper the ablation zone. A target lesion should be covered completely by the CryoPen tip for proper treatment. If the lesion dictates that a full thickness freeze is needed, an even larger tip size should be chosen.

## INSTRUCTIONS:

**WARNING: SET-UP IS SIMPLE BUT YOU WILL WANT TO CAREFULLY REVIEW THE SET-UP INSTRUCTIONS AND OPERATOR'S MANUAL BEFOREHAND.**

1. Read Operators Manual and Quick Set-up Instructions
2. Unpack contents of case: Unit containing (6) Handheld Modules, electrical cord, (1) box containing Temperature Indicator, (1) 500ml Reservoir Bottle, 4 sizes of non-sterile tips (3 of each size), (1) Reservoir Cup (1) Rubber Lid (1) pack of swabs and (1) CryoPen Towel.  
**Note:** Electrical cord is located inside grill on right side of unit. Remove handheld modules from holding wells. Remove grill from unit and pull out electrical cord. Replace grill and handheld modules.
3. Locate unit by the nearest 115-volt outlet. Plug power cord into outlet. Do not turn unit on yet. Unit must be placed at least 1½ inches away from the wall/counter backsplash.  
**WARNING: Do not use an extension cord. Use of extension cords may present potential fire hazard.**
4. Fill Reservoir Cup with 1oz. of the supplied Reservoir Solution. Store remaining solution in a cool dry place. **Note:** The use of any other solution other than that obtained from CryoPen, Inc. will void your warranty. After the Reservoir Cup is filled, remove the (3) pens from the Chilling Wells located on top of unit. Using the supplied transfer pipette, fill each well with (1) one pipette full of reservoir solution from the 1 oz cup.
5. Insert 3 CryoPen® handheld modules fully into the chilling wells. **CryoPens should always be dipped into Reservoir Solution before inserting into chilling wells after initial set-up.** Chilling wells reach -85°C to -95°C. Make sure pens are pushed firmly into chilling wells. Failure to do this will result in pens not reaching optimal temperature. If a CryoPen® is not replaced into a chilling well, freezing of the well will occur and unit defrosting will be necessary. (see #9)
6. Turn on power switch at left side panel of unit. The unit will be operational in approximately 90 minutes. A green light on the front panel will indicate power is on to unit. Unit is designed to remain on unless a problem is encountered or service is needed.
7. After unit has reached the operating temperature, approximately 90 minutes, test the handheld CryoPen® temperature readiness using the temperature indicator. The Temperature Indicator when attached to a CryoPen will indicate GREEN when the CryoPen® is ready to use. A RED light on the temperature indicator means that the CryoPen® is NOT COLD ENOUGH FOR THE PROCEDURE. Re-check in 5 minutes. (If no light is visible, red or green, contact Technical Support at 877-246-3955)

**Note:** The temperature indicator lights red when not connected to a pen and the button is pushed. After initial set-up allow warm CryoPens® to chill in chilling wells for approximately 15 minutes before re-use. **CryoPens should always be dipped into Reservoir Solution before inserting into chilling wells.**

8. To perform cryosurgery
  1. Check temperature readiness of pen from chilling wells using the Temperature Indicator.
  2. Select appropriate re-usable tip (sizes 3mm, 5mm, 7mm, and 10mm)
  3. From Holding Wells (located on right side of unit) remove warm pen, wipe dry, dip pen into reservoir cup.  
**DIP NOTE:** Pens should always be wiped dry before dipping into reservoir cup. Failure to wipe dry, can contaminate solution and may cause failure of unit.
  4. Remove handheld module (pen) from chilling well. Replace with dipped pen.
  5. Place desired tip size on pen before performing procedure.  
(Make sure you have followed step 3 of the **cleaning procedure** for re-usable tips)
  6. After procedure, place tip in a cold soak sterile fluid such as Cidex™ or Wexide™
  7. Replace used pen into holding well.
  8. Warning: Tip end is extremely cold, accidental contact with skin may cause frostbite.
  9. Reservoir Cup should be checked daily and filled as needed.
  10. Pens should be rotated at the end of each day. Rotate from holding wells to chilling wells.  
(Each holding pen should be wiped dry and dipped before placing it into a chilling well)
9. If CryoPen® handheld modules become stuck in chilling wells turn unit OFF and allow unit to defrost. Wells and pens should be wiped dry using the supplied cotton towel and double-sided swabs. (See separate Instructions for Maintenance and Power Outage).
10. System is designed to remain on. Turning the unit on and off will cause the pens in the chilling wells to defrost causing water contamination to the reservoir solution. Chilling wells have to be cleaned and Quick Set-up procedures will be necessary.

**Warning:** Tip end is extremely cold, accidental contact with skin may cause frostbite.

## **CLEANING:**

**The CryoPen® Cooling System:** The main unit, except for the CryoPen® chilling wells, may be cleaned and disinfected as needed. CryoPen® chilling wells may be cleaned periodically as dust and debris may collect in them to the point of making poor contact with the CryoPens®. To clean these chilling wells, use the provided double sided swab. Use a blotting and circular motion to clean out chilling wells. Never place your fingers or hands into the chilling wells, due to the extreme cold. Do not submerge the unit into water; doing so will present an electrical hazard and destroy the unit. It is important **not to** leave chilling wells open for an extended period of time. Swabbing the wells can be completed quickly when rotating pens.

**The CryoPens® Handheld Modules:** may be wiped cleaned with soap and water when the CryoPens® are at room temperature (70-75 degrees Fahrenheit) or cleaned (with such standard solutions as glutaraldehyde or isopropyl alcohol) as needed. Do not submerge pens. Doing so will render them inoperable. Before reusing a CryoPen®, it should be thoroughly and completely dry. If placed back in the chilling well when wet, it will become stuck, and thawing of the entire unit will be necessary to remove it. CryoPens® should never be used for a procedure without their single-use tips in place.

### **CryoPen® re-usable non-sterile tips:**

1. Thoroughly clean all surfaces of the CryoPen tip.
2. Place in cold soak sterilant fluid (e.g. glutaraldehyde based solutions) per manufacturer's instructions.
3. Upon removal from fluid, all surfaces must be wiped with CryoPen Reservoir Solution (or an alcohol pad) and allowed to air dry completely.
4. The CryoPen tip is now ready for use.

**Note: Re-usable tips should never be put into a chilling well or Autoclaved**

**Reservoir Solution:** Should be completely changed weekly. Swab and dry out cup completely before refilling. Refill with 1oz. of reservoir solution from 500ml. Bottle. **Note:** The use of any other solution other than that obtained from CryoPen®, L.L.C. will void warranty.

## **DAILY MAINTENANCE:**

Daily maintenance can be done while the unit is on. Rotate pens from the holding wells to the chilling wells at the end of each day. (Make sure all pens from holding wells are wiped dry and dipped before placing into chilling wells) Reservoir cup should be checked daily and filled as needed.

Note: Reservoir solution level should be kept full and checked daily. (Remove Reservoir Cup from unit, discard old solution. Dry cup thoroughly using the supplied cotton towel and double-sided swab, replace cup into unit. Refill the cup with 1oz. of the supplied Reservoir Solution stored in the 500ml bottle. Squeeze reservoir bottle until upper measuring compartment is filled to the 30ml mark (1oz). Open white cap and dispense into reservoir cup. NOTE: When Reservoir Bottle is at 200ml mark, it is time to reorder solution. You may also pour the solution from the larger compartment as well. Clean and disinfect system as needed.

## **QUARTERLY MAINTENANCE:**

The unit must be turned off before quarterly maintenance can be performed. We recommend waiting 8 hours for unit to reach room temperature. Thoroughly dry wells using the supplied double-sided swabs and wipe pens dry. Remove side grill and wipe out inside of unit. Condensation might be visible. Then, follow the initial set-up procedure located on the quick set-up instructions, web-site animation, or Operator's Manual.



**There are no user-serviceable parts contained in the CryoPen® Cryosurgical System. Only CryoPen, Inc. designated personnel are authorized to perform repairs on the CryoPen® Cryosurgical System or accessories. Use of unauthorized personnel will void any and all manufacturer's warranties.**

**FOR GENERAL INFORMATION AND TO ORDER ADDITIONAL SUPPLIES CONTACT  
CRYOPEN, INC.:**

**Call: 1-888-246-3928**

**CryoPen, Inc.**  
1301 McKinney Suite 3150 ▪ Houston, Texas 77010

Toll Free: 1-888-246-3928  
Phone: 713-600-5010  
Fax: 713-600-5050

**TECHNICAL SUPPORT AND/OR SERVICE/REPAIR DEPARTMENT:**

**Call: 1-877-246-3955**

**CryoPen, Inc.**  
Toll Free: 1-877-246-3955  
Fax: 713-600-5050

If your CryoPen® Cryosurgical System becomes inoperable or any device related incidents or problems occur, which are suspected to represent a safety issue should be reported immediately to CryoPen, Inc. at 1-877-246-3928

Our staff will be happy to assist you.

Protected by U.S. Patents 6430956, 6629417, UK Patent GB2392230; other U.S. and Foreign patent(s) pending.

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