

Operation

Disposing of the product











Dispose of the product in accordance with your local waste management policy.

Safety Precautions

- WARNING**
- Do not use if the package is damaged.
 - Always use **Mul-T-Pad** products with an approved temperature controller. Using this product with other controllers has not been tested.
 - Do not reuse this product on another patient to avoid the risk of cross-contamination and infection.
 - Do not use this product to position or transfer a patient.
 - Do not allow hoses to fold, kink, or to wrap around a patient.
 - Always pre-fill the pad before applying to the patient.
 - Always check the patient's skin condition of areas in contact with the pad at a minimum of 30 minutes or as directed by a physician.
 - Always consult the controller operations manual before connecting this product.

- CAUTION**
- US Federal Law restricts this device to sale by or on the order of a licensed physician.
 - Do not use sharp objects or pins with this product.
 - Do not clean this product. If soiled, dispose of product according to hospital protocol. This is a single patient use product.
 - Always inspect the product for tears, cuts, holes, stains, or any other damage before use. Always monitor more frequently pediatric patients and patients with impaired circulation.
 - Always use minimal layers of sheeting and incontinence pads. Too many layers between the patient's skin and the pad will reduce the cooling or warming capabilities of the system.

Symbols

	General warning		Caution
	Consult instructions for use		Do not puncture
	Quantity		Single patient use
	Batch code		Catalogue number
	Date of manufacturer		Manufacturer

Warranty

C2Dx, Inc. warrants that its models 8002-062-612, 8002-062-622, and 8002-062-626 **Mul-T-Pad** products will be free from defects in manufacturing and workmanship for maximum of 30 day use period. "Use" period begins when such devices individual package is opened. C2Dx's obligation under this warranty is expressly limited to supplying a product replacement, at its option, any product which is, in the sole discretion of C2Dx, found to be defective. If requested by C2Dx, products of which a claim is made shall be returned prepaid to the factory. Any improper use or any alterations or repair by others in such manner as in C2Dx's judgement affects the product materially and adversely shall void this warranty. No employee or representative of C2Dx is authorized to change this warranty in any way.

Warranty exclusion and damage limitations

The express warranty set forth herein is the only warranty applicable to the product. **Any and all other warranties, whether express or implied, including any implied warranty of merchantability or fitness for a particular purpose are expressly excluded by C2Dx.** In no event shall C2Dx be liable for incidental or consequential damages.

Return authorization

Product cannot be returned without prior approval from the C2Dx Customer Service Department. An authorization number will be provided which must be printed on the returned product. C2Dx reserves the right to charge shipping and restocking fees on returned product. Special, modified, or discontinued products are not subject to return.

Damaged merchandise

ICC Regulations require that claims for damaged product must be made with within fifteen (15) days of receipt of the product. Do not accept damaged shipments unless such damage is noted on the delivery receipt at the time of receipt. Upon prompt notification, C2Dx will file a freight claim with the appropriate carrier for damages incurred. Claims will be limited in amount to the actual replacement cost. In the event that this information is not received by C2Dx within the fifteen (15) day period following the delivery of the product, or the damage was not noted on the delivery receipt at the time of receipt, the customer will be responsible for payment of the original invoice in full within thirty (30) days of receipt. Claims for any incomplete shipments must be made within thirty (30) days of invoice.

International warranty clause

This warranty reflects U.S. domestic policy. Warranty outside the U.S. may vary by country. Please contact your local C2Dx Inc. representative for extra information.

Mul-T-Pad

8002-062-612

REF 8002-062-622

8002-062-626

C2Dx[®]

Operations Manual



Manufactured For:
C2Dx Inc.
555 E. Eliza St. | Ste. A
Schoolcraft, MI 49087 USA

C2Dx[®]

Introduction

This manual assists you with the operation of the C2Dx Model 8002-062-612, 8002-062-622, and 8002-062-626 **Mul-T-Pad®**. Read this manual before operating this product and keep a copy on file. Set methods and procedures to educate and train your staff on the safe operation of this product.

Intended use

The **T/Pump®** localized therapy system supplies warm or cold water at controlled temperatures. Delivery of the water is through the thermal transfer devices (**Mul-T-Pad**) for localized temperature therapy. The **T/Pump®** is for use in situations where temperature therapy is necessary or desired.

Localized temperature therapy is of particular benefit in treating the following:

- Orthopedic conditions such as acute injuries, chronic pain, lower back pain, muscle spasm, and strains;
- Skin trauma such as abscesses, boils, bruises, burns and contusions;
- Other medical conditions such as chronic arthritis, neuritis, phlebitis, tendonitis, and IV infiltration; and symptoms such as infections and localized pain.

Product description

The **Mul-T-Pad** is a lightweight polymer. The colder style connectors provide the means to connect to the temperature controller. The button design allows water to flow when the pad is folded to form a customized fit.

Expected life

These Mul-T-Pad products have a 30 day single patient use expected life upon first use and under normal use conditions.

Contraindications

For heating:

- Application to a body surface with compromised blood flow (Ischemia, area under pressure, arterial insufficiency).
- Application to a patient with an increased tendency to bleeding (aggravates potential for hemorrhage).
- Application to a body surface with possibility of malignancy (tissue metabolism is increased and therefore, the growth potential of the malignant tissues).
- Treatment of hematoma within first 24-48 hours (potential for re-bleeding and hemorrhage). Recent sprain or fracture (acute inflammatory response).
- In combination with topical solutions whose toxicity may be affected by the application of heat.
- In combination with other heat sources.

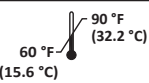
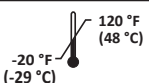


For cooling:

- Application to body surface with compromised blood flow (Ischemia, area under pressure, arterial insufficiency)
- Application to body surface with known vascular impairment such as frostbite, arteriosclerosis or ischemia
- Application to body surface in people with hypersensitivity to cold, such as people with Raynaud's phenomenon, cold urticaria, cryoglobulinemia, and paroxysmal cold hemoglobinuria
- Application to body surface in people with impaired sensation
- In combination with topical solutions whose toxicity may be affected by the application

Introduction

Specifications

Material	rayon, ethylene vinyl acetate (EVA), polypropylene, polyethylene					
Model	8002-062-612		8002-062-622		8002-062-626	
Length	18 in.	46 cm	22 in.	56 cm	26 in.	66 cm
Width	13 in.	33 cm	15 in.	38 cm	18 in.	46 cm
Compatible controllers	T/Pump series temperature controllers					

Environmental conditions	Operating	Storage and transportation
Temperature	 60 °F (15.6 °C) 90 °F (32.2 °C)	 -20 °F (-29 °C) 120 °F (48 °C)
Relative humidity	 30% 75%	 10% 95%

C2Dx reserves the right to change specifications without notice.

Contact information

Contact C2Dx Customer Service at 1-888-902-2239.

C2Dx, Inc.
555 E. Eliza St. | Ste. A
Schoolcraft, MI 49087 USA

Have the Lot batch code of your C2Dx product available when calling C2Dx Customer Service or Technical Support. Include the Lot batch code in all written communication.

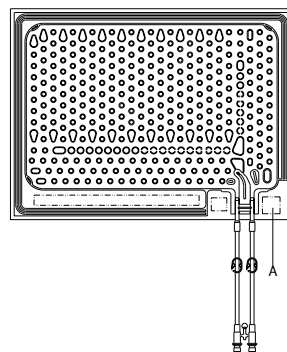


Figure 1: Batch lot code

Operation

Assessing the patient's skin condition

Note: Follow your facilities skin care protocol. The following instructions are recommendations.

1. Document initial skin assessment.
2. Check for any foreign items such as medical patches, IV's, sutures.
3. Check for fluids such as moisture or gels.
4. Verify the pad size is correct before applying to the patient.

Note: Apply the pad directly to the skin or add minimal layers.

Connecting the pad (colder style connectors)

1. Close the pinch clamps on the connector hose and pad (Figure 2).
2. Insert the male coupling of pad into the female coupling of hose. Press until you hear a click (Figure 3).
3. With a light pull, make sure that you locked the connectors.
4. Open all clamps on the connector hose and the pad (Figure 4).
5. Insert the power cord into a wall outlet.
6. Press the power button to turn on the controller. See the controller instructions for use.
7. Check that the pad fills with water.

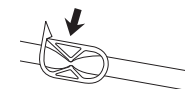


Figure 2: Close

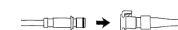


Figure 3: Connect

Note:

- Iodine based disinfectants will stain the product. Staining does not affect the patient nor the use of the product.
- Do not use pins or sharp objects with this product.
- If you fold the pad, place the end of the pad that contains the tubing away from the patient.

Rechecking the patient's skin condition

Check the patient at regular intervals as directed by hospital protocol. Note any change in the skin integrity that relates to:

- Excessive moisture - dry the skin surface by wiping away the moisture
- Color of the epidermis
- Skin texture
- Patient's skin condition is acceptable to continue therapy

Check the pad

Check the pad at regular intervals as directed by hospital protocol.

- position
- water status
- dry surface
- leaks
- cracks

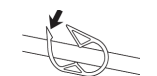


Figure 4: Open

Defibrillation considerations

1. Remove the pad to expose patient's chest.
2. Remove excess moisture.

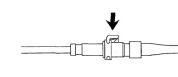


Figure 5: Disconnect

Disconnecting the pad from the hoses

1. Power off the controller.
2. Close pad clamps (Figure 2).
3. Press down on the thumb tab of the female coupling. Pull the male coupling out to disconnect (Figure 5).
4. Discard pad after use per facility protocol.

Note: Do not discard the controller connector hose after use, save for next use.

1. Fold as shown in Picture A, keeping title page (page 1) facing front.



Picture A: Fold Example

NOTE: This portion of the document should not appear on produced Labels or IFUs

C2Dx Inc.
1-888-902-2293

Dimensions:

11-inch (width) x
8.5-inch folded to
3 5/8 x 8 1/2 per
folding
instructions.

Color/Material/Finish:

Color graphics on
white background.

20# bond or
equivalent

Label Stock:

N/A

Description/Type:

Instructions For Use

Part Number:

8002-009-131

Rev.

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