

ManaCold® Platinum 2.0

INSTRUCTIONS FOR USE

Circulating Cryotherapy System



DESCRIPTION OF SYMBOLS



Medical Device

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Recovery activated.

ManaCold® Platinum 2.0

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Do not use this product before reading this manual. If you have any questions, please call your physician or email ManaMed at support@manamed.com.

To learn more about ManaMed, visit www.manamed.com



ManaCold® Platinum 2.0

ManaCold® Platinum 2.0 Label Symbol Descriptions



The use of accessories, power supplies and cables other than those specified, with the exception of components sold by the manufacturer of the ManaCold® Platinum 2.0 as replacement parts, may result in increased emissions or decreased immunity of the ManaCold® Platinum 2.0.



Designates Class II medical electrical equipment.



This unit is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Consult local county requirements for proper disposal instructions.



This symbol designates the degree of protection against electrical shock from the wrap as being a Type BF Applied part.



IFU - Consult instructions for use.



CAUTION: Federal Law restricts this device to sale by or on the order of a physician.



Solid particle protection against fingers or similar objects.
Liquid ingress protection against dripping water when tilted at 15°



MR Unsafe – Remove before entering MRI suite

Symbol Glossary

For an explanation of symbols, please refer to <https://www.manamed.com/glossary/symbol-glossary.pdf>

Caution

Federal Law (U.S.A.) restricts this device to sale, distribution or use by or on the order of a physician or properly licensed practitioner. ManaCold® Platinum 2.0 is only intended for the use by the individual for whom it was prescribed. This device is ONLY for a single patient multiple use.

THIS DEVICE IS NON-STERILE. ManaCold® Platinum 2.0 does not require sterilization before use.

Technical Data

Device Box Components

ManaCold® Platinum 2.0 ?
ManaCold® Platinum 2.0 ?

Power Supply

Class II Input: 100 – 240 Vac, 50-60 Hz. Output: 5 V at 1 Amp
Output: Mode of Operation Continuous

Specifications

Rating Voltage: dc6.5V ~ 9.5V
Starting Voltage: 5(v)
Load Current: 630 □ 80(ma)
Highest lift: 500(cm)
Maximum flow: 80-120 (L/h)
Color: Black
Noise: <42 db

System Operating Environment:

Temperature: 41°F (5°C) and 104° (40°C)
Relative Humidity: 15% - 90%. Keep Dry.

Default Settings

Leg Pressure (not adjustable): 55mmHg
Cycle time: 60 Seconds
Mode One: Slow Inflation
Mode Two: Set Up Technology

Tolerance

Pressure 5%



ManaCold® Platinum 2.0 Labeling Information

Product Description

The ManaCold® Platinum 2.0 is a circulating cryotherapy system that includes a spill proof locking lid, hose and the ability to order different style pads.

Indications for Use

The intended use of the ManaCold® Platinum 2.0 is for the temporary reduction of swelling and pain after surgery or injury. This is a non-sterile prescription device for single patient use to provide localized external application of cold therapy. This device may not be used for any other purpose.

Contraindications

Vasospastic disease, cold allergy, cold hypersensitivity, previous cold injury, compromised local circulation, decreased skin sensitivity paroxysmal cold hemoglobinuria and cryoglobulinemia.

Warnings

Warning: Strong supervision when using with children and geriatric patients.

Consumer or patient agrees to the following:

- ManaMed accepts no responsibility for any injury which might occur while using ManaMed products.
- Consult your health care provider for this products indication for use.
- For single patient use only.
- Skin irritation may occur while using this device. If you experience an unusual skin reaction while using this product, consult with your healthcare provider immediately.
- Federal Law restricts this device to sale or by or on the order of a licensed health care practitioner.
- If you do not agree to the above conditions, contact your health care provider before using this product.

Cleaning, Disinfecting, and Reuse

Note: Inspect the device and follow the cleaning and disinfecting procedures prior to use.

Warning: Device must be turned off and disconnected from the wall outlet prior to and during cleaning or disinfecting. DO NOT IMMERSE DEVICE IN ANY LIQUID. DO NOT PLACE DEVICE IN AUTOCLAVE.

The ManaCold Platinum 2.0 may be cleaned by hand using a mild soap and warm water. Air dry only.

Unit must be completely dry prior to use. To ensure unit is completely dry, leave the device in the OFF position and disconnected from the wall outlet for at least 30 minutes (and as long as necessary for the unit to dry completely) after cleaning or disinfecting.

- Do not remove the pump unit from the cuff.
- Do not place cuffs in the dryer or microwave.
- Do not use a hair dryer to accelerate drying.
- Do not place the device on top of or in front of portable or stationary radiators to accelerate drying.
- Do not use abrasive cleans.

After cleaning, inspect the device visually to ensure it is free from soil, discoloration, cracks, or damage. If residual soil is visible, repeat the cleaning process described above until the device is visibly clean. If visual contamination remains after repeated cleaning, do not use the device. Dispose of it per facility protocol. **Note:** Visual inspection ensures that residual biological material is removed before reuse, thereby reducing the risk of cross-contamination and infection.

ManaCold® Platinum 2.0



ManaCold Platinum
Universal Circulating Pad



ManaCold Platinum
Ankle Pad



ManaCold Platinum
Back Pad



ManaCold Platinum
Hip Pad



ManaCold Platinum
Shoulder Pad

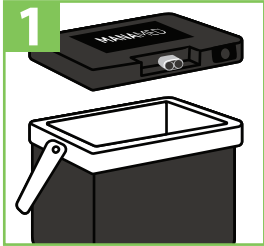
Getting Started

ManaCold® Platinum 2.0 uses a combination of a circulating device and circulating pad. The pad should be connected to the device and then applied to the body. For instructions on your pad, refer to the specific pad packaging for those details.

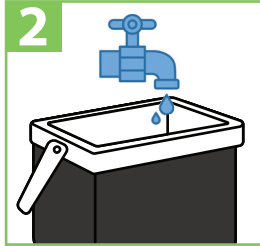
- Use cubed or crushed ice for optimal performance. You may choose to use small frozen water bottles.
- When using the unit, it is recommended to drain the detachable cold therapy pad between uses. To do so, hold the cold therapy pad upright with the hose pointed downward and depress the white plunger to allow the water to drain out of the pad.
- You may disconnect the cold therapy pad from the unit without removing the pad from the affected area by depressing the release buttons on the hose coupling and gently pull the hoses and pad apart. The cold therapy pad and unit will seal themselves and not leak. Some dripping during release is normal.
- Do not pump without water. Running the unit without water will cause permanent damage to the pump.
- Unplug the unit from wall before removing lid.

ManaCold® Platinum 2.0

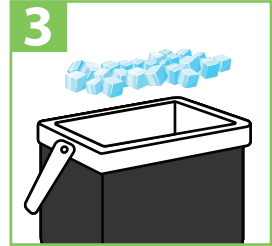
Instructions For Use



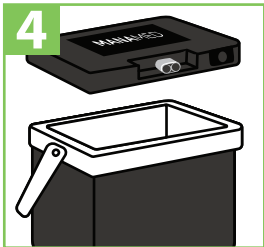
Open the lid off the unit.



Add water to "Water Line" indicator in unit, not exceed maximum line.



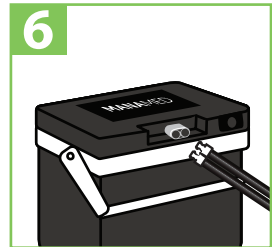
Add ice to "Ice Line" indicator in unit, not exceed maximum line.



Place the lid back on the ManaCold Platinum 2.0.



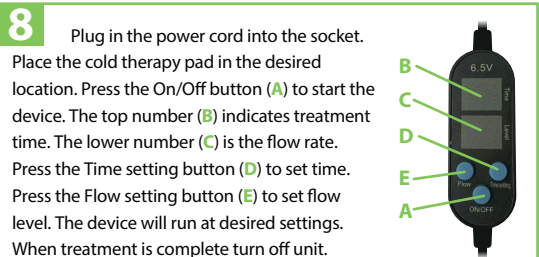
Close the lid and lock it in place by moving the handle to the carrying position.



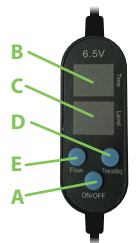
Attach the insulation tubes to the ManaCold Platinum 2 device.



Attach the pad to the tubing by inserting the hose end into the pad coupling. There will be an audible clicking sound when connected. Always use a barrier between the pad and the skin.



Plug in the power cord into the socket. Place the cold therapy pad in the desired location. Press the On/Off button (A) to start the device. The top number (B) indicates treatment time. The lower number (C) is the flow rate. Press the Time setting button (D) to set time. Press the Flow setting button (E) to set flow level. The device will run at desired settings. When treatment is complete turn off unit.



Refilling the Unit

Turn off the unit by unplugging the device or pushing the On/Off button. Disconnect the cold therapy pad and insulation tubes from the device by pressing the release buttons connecting the hose to the device and pulling them gently apart. Repeat from Step 2 above.

ManaCold® Platinum 2.0

Disposal

ManaCold® Platinum 2.0 is an electromechanical device that includes printed circuit boards. Do not discard in landfill. The device and packaging must be disposed of in accordance with respective local or national environmental regulations.

Limited Warranty

ManaMed, LLC warrants to the original purchaser of its ManaCold® Platinum 2.0 purchased by the purchaser directly from ManaMed, LLC that the ManaCold® Platinum 2.0 conforms to ManaMed, LLC's manufacturing specifications. This warranty will be in effect for a period of 120 days from the date of purchase.

In the event of a material breach of this warranty, upon timely written notice, ManaMed, LLC will either repair or replace the ManaCold® Platinum 2.0 or refund the original purchase price. This will constitute the Purchaser's sole remedy. This limited warranty does not extend to any resale or other transfer of the ManaCold® Platinum 2.0 by Purchaser to any other person or entity.

MANAMED, LLC EXPRESSLY DISCLAIMS ANY AND ALL OTHER WARRANTIES, EITHER EXPRESSED OR IMPLIED, RELATING TO THE SYSTEM OR ITS PERFORMANCE, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY AND ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

Customer Service

Manamed is available to answer any questions regarding the use of the ManaCold® Platinum 2.0.

E-mail: support@Manamed.com

For General Information: Visit www.Manamed.com

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