REV	DESCRIPTION	DATE	DRAWN	CHECKED	APPROVED
A	SEE SHEET 1				

Medtronic MINIMED

MiniMed® Implantable Pump System

REF MMT-2007C	Implantable Pump Unit

**** NOTE ****
Please refer to the physician and patient manual for instructions for use and detailed information regarding the Medtronic MiniMed Implantable Pump System.

INTRODUCTION
The Medtronic MiniMed Implantable Pump System is a sophisticated combination of technologies developed to address the requirements of continuous intraperitoneal insulin delivery for patients with Insulin Dependent Diabetes Mellitus (IDDM). The system is comprised of: Implantable Pump, Side Port Catheter, Personal Pump Communicator, and accessory syringe, needle, template, and pipette. The pump and catheter are designed for implantation. The Personal Pump Communicator is designed to provide the patient a variety of insulin delivery options. The accessory items are specifically designed to facilitate refill of the implanted pump and pump functions.

INDICATIONS FOR USE
The Medtronic MiniMed Implantable Pump System is indicated for intraperitoneal administration of exogenous insulin in patients with diabetes mellitus who are able to actively participate in their treatment program.

CONTRAINDICATIONS
The MiniMed Implantable Pump System is contraindicated in patients who:

- Are unwilling or unable to monitor their blood glucose level at least four times per day.
- Are unwilling or unable to make programming modifications to the pump based on glucose level readings.
- Are unable or unwilling to administer insulin by other means if necessary.
- Are unable or unwilling to comply with the guidance and advice of the treating physician and other healthcare providers.
- Reside at or travel (other than by commercial aircraft) at elevations above 8000 feet.
- Have other medical or mental conditions which may place the patient at risk.
- Are unwilling or unable to return for routine insulin refill (approx. 2-3 months) according to dosage.
- Present current or history of sensitivity to titanium alloy or silicone materials used in the manufacture of system implanted components.

PRECAUTIONS
Patients should always maintain conventional insulin supplies in the event of pump and or Personal Pump Communicator (PPC) failure. Delivery of insulin can become impaired due to pump failure or catheter occlusion. In the event of impaired insulin delivery, replacement of the pump or catheter may be required. Physicians should review Physicians Manual for full description of Pump replacement procedure and catheter clearing procedures. The Medtronic MiniMed Pump and Catheter Implants should NOT be used if damaged prior to or during implantation procedures. The pump should not be placed in contact with other metal implants.

WARNINGS
**** NOTE ****
The MMT-2007C pump can only be used with the MMT 4021A-4028A Side Port Catheters

Physicians should be completely familiar with the function of the pump, catheter, and personal pump communicator prior to use of this device. Patients should be provided a complete copy of the Patient Manual and have demonstrated the ability to program the Personal Pump Communicator (PPC), recognize and respond to safety alarms, and care of the device prior to discharge.

The Medtronic MiniMed Implantable Pump System should not be exposed to therapeutic ultrasound. Exposure to ultrasound therapy may cause damage to the pump that may not be apparent.

Only special-U400 insulins may be used in the Medtronic MiniMed Implantable Pump System. Use of other insulin types may cause damage to the pump mechanism resulting in impaired insulin delivery or pump failure.

Any unauthorized changes or modifications made to any component of the system may prevent effective use of that and other components.

POSSIBLE ADVERSE EFFECTS
The Medtronic MiniMed Implantable Pump System has undergone an extensive clinical evaluation. Evaluation of the system spanned a period of ten years and involved over 600 subjects in the United States and Europe. Though over delivery of insulin did not occur during the ten year evaluation period, there is a potential for such occurrence. The following are specific adverse effects which should be understood by the physician and explained to the patient. These do not include all adverse effects which can occur with surgery in general or with the use of this device, but are important considerations particularly in the treatment of people with diabetes. The general surgical risks as well as operative site cosmetic risks should be explained to the patient prior to surgery.

Abdominal Pain	Foreign Body Reaction
Abnormal Healing	Skin Disorder
Infection	Urinary Disorder
Necrosis	Psychiatric Decompensation
Retinal Disorder	Skin Erosion
Abnormal Liver Function	Kidney Disorder
Ileus	Pocket Lymph Edema
Inflammation at Refill Site	Pump Failure
Hyperglycemia	Catheter Occlusion/
Hypoglycemia	Encapsulation
Ketoacidosis	Battery depletion
	PPC Failure

STERILE DEVICE
The Medtronic MiniMed Implantable Pump is EO sterilized and packaged sterile in tamper evident package. Do not use if package has been opened or damaged.

PRESCRIPTION DEVICE
Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

FCC Notice
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference and (2) This device must accept any interference received, including interference that may cause undesirable operation.

CAUTION: Any changes or modifications not expressly approved by Medtronic MiniMed could void your ability to operate the equipment.

SIDE A

Medtronic MiniMed® 2007C
Implantable Pump System
Limited Warranty

The Medtronic MiniMed 2007 Implantable Pump and Personal Pump Communicator are components of the Medtronic MiniMed Implantable Pump System designed for the long-term, intraperitoneal infusion of insulin in the intensive treatment of insulin dependent diabetes mellitus (IDDM) with the use of a peritoneal catheter, also a component of the system. Pumps include an exhaustible power source which will ultimately cease to function, requiring replacement of the entire pump. No representation is made regarding the longevity of the power supply. Causes of pump or catheter failure include but are not limited to: premature battery failure; changes in product performance characteristics; medical complications; catheter occlusion. The improper handling or filling of pumps, the use of drugs other than special U-400, or other intervening acts may also result in pump or catheter failure, despite all due care in design, manufacture and testing prior to sale. Therefore, no representation or warranty is made that cessation of pump or catheter function will not occur. Moreover, because the implantation of any device is always subject to inherent risks, no representation can be made that the human body will not react adversely to the implantation or presence of the pump and/or catheter.

Medtronic MiniMed hereby warrants solely to the original purchaser of the Pump and Personal Pump Communicator the following:

1. Should the pump fail to function within normal tolerances due to a defect in materials or workmanship within a period of six (6) years, commencing with the date of the implant of the pump, Medtronic MiniMed will issue a credit equal to the percentage purchase price, as defined below, against the purchase of another pump requested as its replacement, or, at the option of Medtronic MiniMed, provide a replacement pump at no charge. The percentage shall be 100% for pumps that fail within four (4) years of implant. The percentage shall be reduced by either (i) 4% for each month beyond the forty-eighth month that the pump functions within normal tolerances, or (ii) 1% for each 1 ml of medication delivered beyond 200 ml of medication, whichever percentage is greater.

2. The credit issued hereunder shall be provided to purchaser of the replacement pump. As used herein, "Purchase Price" shall mean the lesser of the original or replacement pump purchase price, as evidenced by the Medtronic MiniMed invoice, or the purchase price of the currently functionally comparable Medtronic MiniMed pump. In no way shall the Purchase Price include any VAT, sales or other tax paid in relation to the pump.

3. To qualify for this limited warranty, the pump must be implanted before its "use before" date contained in its packaging; replaced pumps must be returned to Medtronic MiniMed and shall be the sole property of Medtronic MiniMed and the use of the pump, including the medication infused thereby, must be in accordance with the manuals shipped with the pump. All explanted pumps returned to Medtronic MiniMed must be prepared and shipped in the manner described in the Physician Manual. Proper preservation of the pump is required for accurate post-implant analysis.

4. Should the Personal Pump Communicator fail to function within normal tolerances due to a defect in materials or workmanship within a period of three (3) years, commencing with the date of implant, Medtronic MiniMed will either repair or replace the Personal Pump Communicator, at the sole discretion of Medtronic MiniMed. For Personal Pump Communicators that have been damaged as a result of abuse or neglect, the owner will be charged for repair or replacement.

The Limited Warranty is limited by its express terms. THE REMEDIES PROVIDED FOR IN THIS WARRANTY ARE THE EXCLUSIVE REMEDIES AND THIS WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES. NEITHER MEDTRONIC MINIMED NOR ITS SUPPLIERS OR DISTRIBUTORS SHALL BE LIABLE FOR ANY GENERAL, SPECIAL PUNITIVE OR CONSEQUENTIAL DAMAGES ARISING OUT OF THE SALE, MANUFACTURE OR USE OF THE PRODUCT SOLD HEREUNDER. MEDTRONIC MINIMED MAKES NO WARRANTIES, EXPRESS OR IMPLIED (INCUDING, BUT NOT LIMITED TO, ANY WARRANTY OF MERCHANTIBILITY OR FITNESS OF THE PRODUCTS FOR ANY PURPOSE OR REASON) WITH RESPECT TO THE PUMP SOLD UNDER THIS WARRANTY, EXCEPT AS CONTAINED IN THIS LIMITED WARRANTY. NO PERSON HAS ANY AUTHORITY TO BIND MEDTRONIC MINIMED TO ANY REPRESENTATION, CONDITION OR WARRANTY, EXCEPT AS SPECIFICALLY SET FORTH HEREIN.

In no event shall this Limited Warranty apply to any Pump or Personal Pump Communicator replaced after the end of the period specified in Paragraphs 1 and 4 above. This Limited Warranty is not applicable to catheters, side ports or other accessories used with the Pump.

Some jurisdictions do not allow the exclusion or limitation of incidental or consequential damages, so the limitations or exclusions herein may not apply. This Limited Warranty gives you specific legal rights, and you may have other rights which vary from jurisdiction to jurisdiction.

Products covered by the Warranty include:
MMT-2007C Implantable Pump
MMT-3150 Personal Pump Communicator

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FAX (33)-(0)1-47-59-76-77
www.minimed.com

These products are covered by one or more of the following U.S. patents:
[U.S.]4,373,527; [U.S.]4,395,259; [U.S.]4,525,165; [U.S.]4,568,250; [U.S.]4,569,641; [U.S.]4,573,994; [U.S.]4,619,653; [U.S.]4,636,150; [U.S.]4,731,051; [U.S.]4,776,842; [U.S.]5,167,633; [U.S.]5,176,644; [U.S.]5,197,322; [U.S.]5,217,442; [U.S.]5,257,971; [U.S.]5,460,618; [U.S.]5,466,218; [U.S.]5,514,103; [U.S.]5,527,307; [U.S.]5,559,828; [U.S.]5,797,733; [U.S.]5,915,929
Patents also exist in a number of foreign countries and other U.S., international, and foreign patent applications are pending.

SYMBOL	MEANING
2	DO NOT RE-USE
	READ INSTRUCTIONS FOR USE
STERILE EO	STERILIZED WITH ETHYLENE OXIDE
REF	REFERENCE/RECORD NUMBER
	STORAGE TEMPERATURE RANGE
	FRAGILE PRODUCT
CE 0459	MARKING AUTHORIZED
	TYPE CF
	OPEN HERE

07/01 6021029-001

SIDE B

-001

XXXXXXX-001 REV: X

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DO NOT SCALE DRAWING				
SCALE 1/1	SHEET 2 OF 3	SIZE D	DWG NO. 6021078	REV A