



MiniMed® Personal Pump Communicator	
REF MMT-3150	Personal Pump Communicator (English)

**** 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 Personal Pump Communicator is intended to be used with the Medtronic MiniMed Implantable Pump. Specific indications for use of the Implantable Pump System are provided in the Implantable Pump Package Insert.

CONTRAINDICATIONS

The Medtronic 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. 3-3 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

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

DEVICE PACKAGING

The Medtronic MiniMed Personal Pump Communicator (PPC) is packaged in a specially prepared carton to secure the product from damage. A 1.5v battery (replaceable power source) has been included in the carton. The Personal Pump Communicator should not be used if there are obvious signs of damage to the device.

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.

Medtronic Minimed Manual

Arturo Cuomo



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Table of Contents **Medtronic Minimed Manual**

1. Understanding the eBook **Medtronic Minimed Manual**
 - The Rise of Digital Reading **Medtronic Minimed Manual**
 - Advantages of eBooks Over Traditional Books
2. Identifying **Medtronic Minimed Manual**
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an **Medtronic Minimed Manual**
 - User-Friendly Interface
4. Exploring eBook Recommendations from **Medtronic Minimed Manual**
 - Personalized Recommendations
 - **Medtronic Minimed Manual** User Reviews and Ratings
 - **Medtronic Minimed Manual** and Bestseller Lists

5. Accessing Medtronic Minimed Manual Free and Paid eBooks
 - Medtronic Minimed Manual Public Domain eBooks
 - Medtronic Minimed Manual eBook Subscription Services
 - Medtronic Minimed Manual Budget-Friendly Options
6. Navigating Medtronic Minimed Manual eBook Formats
 - ePub, PDF, MOBI, and More
 - Medtronic Minimed Manual Compatibility with Devices
 - Medtronic Minimed Manual Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Medtronic Minimed Manual
 - Highlighting and Note-Taking Medtronic Minimed Manual
 - Interactive Elements Medtronic Minimed Manual
8. Staying Engaged with Medtronic Minimed Manual
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Medtronic Minimed Manual
9. Balancing eBooks and Physical Books Medtronic Minimed Manual
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Medtronic Minimed Manual
10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
11. Cultivating a Reading Routine Medtronic Minimed Manual
 - Setting Reading Goals Medtronic Minimed Manual
 - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Medtronic Minimed Manual
 - Fact-Checking eBook Content of Medtronic Minimed Manual
 - Distinguishing Credible Sources
13. Promoting Lifelong Learning

- Utilizing eBooks for Skill Development
- Exploring Educational eBooks

14. Embracing eBook Trends

- Integration of Multimedia Elements
- Interactive and Gamified eBooks

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