



These instructions are intended for use only by a Medtronic representative.

*Model 9767/9767L*

*Installation  
Instructions*

*About These Instructions*

## About These Instructions

These instructions explain how to install The Medtronic® Model 9767/9767L for a Medtronic® Model 9790 series programmer ("programmer").

**Note:** Please return the **Model 9766A/9766AL programming head** to Medtronic Instrument Service in the pre-labeled box provided in the **Model 9767/9767L** package.

## Contents of Package

- Model 9767/9767L programming head and TEM (Telemetry Electronics Module)
- Screwdriver (packaged with the Model 9767/9767L)
- Packaging materials for return of Model 9766A/9766AL programming head (included with 9767 packaging)
- Product Literature

## Installation Instructions

If your programmer does not have an Analyzer module installed, follow the instructions in the "Installing Programming Head Without Analyzer" section.

If your programmer does have an Analyzer module installed, follow the instructions in the "Installing Programming Head With Analyzer" section.

*Installing Programming Head Without Analyzer*

## **Installing Programming Head Without Analyzer**

The following instructions describe the steps involved to install the Model 9767/9767L to a Model 9790/9790C programmer with no Analyzer module installed.

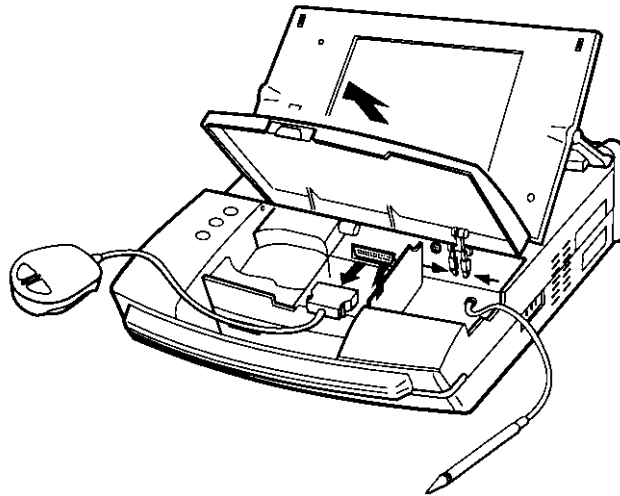
### ***Preparing the programmer:***

1. Turn off the programmer. Do not install the programming head while the programmer is turned on.
2. Remove any cables or accessories from the storage compartment under the lid of the programmer. Place the touch pen outside of the compartment as shown in Figure 1.

**Note:** Do not disconnect the touch pen from the programmer.

3. Remove the lid of the programmer by:
  - a. Squeezing together the tips of the prongs on the right underside of the lid and push them up, out of the slots they are in, as shown in Figure 1.
  - b. Sliding the lid off, disengaging the pin on the left side of the lid from the socket on the programmer.
4. Remove the partition from the compartment by lifting up on the front edge of the partition and rocking it back and forth until it loosens. Discard the partition once it is removed.
5. Disconnect the **Model 9766A/9766AL programming head** from the telemetry port in the compartment as shown in Figure 1.

*Installing Programming Head Without Analyzer*



**Figure 1.** *Preparing a programmer with no Analyzer.*

**Installing the TEM:**

1. Remove the small screw next to the partition slot located on the back wall.
2. Place the TEM in the programmer compartment by:
  - a. Holding the TEM such that the connector jack is facing to the right in the compartment.
  - b. Inserting the TEM so that the raised fin on the top slides under the programming head's storage space.
3. Insert the small screw, and secure the TEM in place.
4. Connect the TEM to the programmer's telemetry port.

**Connecting the Model 9767/9767L programming head:**

1. Connect the **Model 9767/9767L programming head** to the telemetry port on the TEM.
2. Re-install the programmer lid.

*Installing Programming Head With an Analyzer*

## **Installing Programming Head With an Analyzer**

The following instructions describe the steps involved to install the Model 9767/9767L to a Model 9790/9790C programmer with a Medtronic Model 8090 Analyzer.

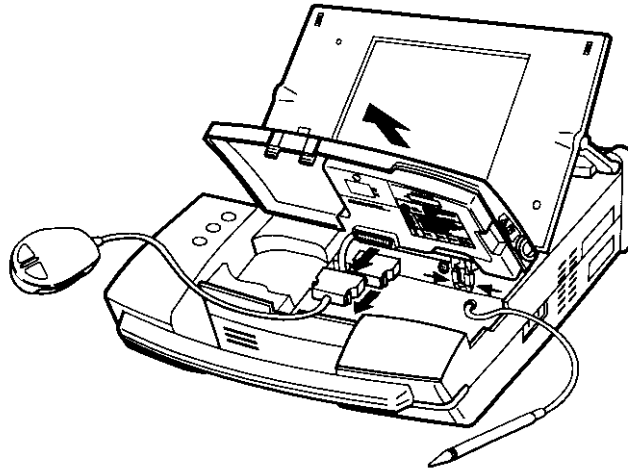
### ***Preparing the programmer:***

1. Turn off the programmer. Do not install the programming head while the programmer is turned on.
2. Remove any cables or accessories from the storage compartment under the lid of the programmer. Place the touch pen outside of the compartment as shown in Figure 2.

**Note:** Do not disconnect the touch pen from the programmer

3. Disconnect the **Model 9766A/9766AL programming head** from the telemetry port on the underside of the Analyzer module (see Figure 2).
4. Remove the lid of the programmer by:
  - a. Disconnecting the Analyzer module from the programmer.
  - b. Releasing the locking bar.
  - c. Squeezing together the tips of the prongs on the right underside of the lid and push them up, out of the slots they are in.
  - d. Sliding the lid off, disengaging the pin on the left side of the lid from the socket on the programmer.

*Installing Programming Head With an Analyzer*



**Figure 2.** *Preparing a programmer with an Analyzer.*

**Installing the TEM and connecting the 9767/9767L Programming Head:**

1. Remove the small screw next to the partition slot located on the back wall.
2. Place the TEM in the programmer compartment by:
  - a. Holding the TEM such that the connector jack is facing to the right in the compartment.
  - b. Inserting the TEM so that the raised fin on the top slides under the programming head's storage space.
3. Insert the small screw, and secure the TEM in place.
4. Connect the **Model 9767/9767L programming head** to the telemetry port on the TEM.
5. Reconnect the Analyzer module to the programmer.
6. Replace the Analyzer lid.
7. Connect the TEM to the telemetry port on the underside of the Analyzer module.

*Installing Programming Head With an Analyzer*

This completes the Model 9767/9767L programming head and TEM installation procedure. The programming head and TEM are now prepared for use as described in the Model 9767/9767L Technical Manual.

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**9767**  
**9767L**      *Technical manual*

**Programming head**

*Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.*

*Investigational device*



Part# 197372-001

Rev A



**MEDTRONIC CONFIDENTIAL ACCR6ML.FR5**

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*Caution: Investigational device. Limited by  
Federal Law (USA) to investigational use.*

*This product is not shipped in a sterile state.*

*Exclusively for Clinical Investigations*

Part# 197372-001

Rev A

**EXPLANATION OF SYMBOLS ON  
PACKAGE LABELING**



Read instruction manual  
prior to use



Type BF Equipment.



This symbol means that the  
device is listed to applicable  
U.S. and Canadian safety  
standards by Underwriters  
Laboratories Inc.



Manufacturing Date



Serial Number



**CAUTION: THIS CONTAINS  
A STRONG MAGNET.  
PROXIMITY TO MAGNETIC  
RECORDING TAPE AND  
DISKS SHOULD BE  
AVOIDED.**



**CAUTION: DO NOT  
UNPLUG DEVICE WHILE  
THE POWER IS ON.**



Part# 197372-001



Rev A



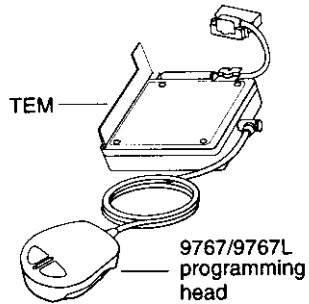
**Description/Intended Use**

The Medtronic®/Vitatron® Model 9767/9767L consists of two components: the programming head and the Telemetry Electronics Module (TEM).

The use of the Model 9767/9767L is necessary for all programmer functions that require programming or interrogating operations. The Model 9767/9767L provides the communication link between the Medtronic/Vitatron Model 9790/9790c™ programmer and a Medtronic or Vitatron implantable device.

The Model 9767/9767L programming head and TEM are under clinical investigation. The procedures for using the lead, as well as its safety and efficacy, will be evaluated during this investigational study according to the clinical investigational protocol. Therefore, the "Instructions for Use" section is based on Medtronic's experience with similar devices. No claims for safety and effectiveness can be made for the Model 9767/9767L programming head and TEM during clinical evaluation. Patients should be advised by their physician that the Model 9767/9767L programming head and TEM are under clinical investigation.

The programming head and TEM (see Figure 1) fit inside the Model 9790/9790c front storage compartment.



**Figure 1.** Model 9767/9767L programming head and TEM

**Note:** The 9767/9767L programming head can be used only with the TEM.

The programming head contains a permanent magnet, a radio frequency (RF) transmitter and receiver, and a light array. The programming head must be held over the implantable device during a programming or interrogating operation.

The TEM is connected to the programmer by a cable and resides inside the programmer's front compartment.

The Model 9767/9767L is compatible with all versions of the Model 9790/9790c programmer.

#### Package Contents

Model 9767 (standard cable length) and Model 9767L (long cable length):

- One Model 9767 programming head
- One Telemetry Electronics Module
- One Phillips screwdriver
- Documentation

#### Precautions

Check the package prior to use. Damaged devices should be returned to Medtronic.

- Do not expose the programming head or the TEM to storage temperatures above 70 °C (158 °F) or below -40 °C (-40 °F).
- Do not position the programming head over an implanted device during electrocautery or external defibrillation procedures.
- Do not autoclave the programming head or the TEM.

- Keep the programming head away from any device or material that will be damaged by their magnetic fields.
- The TEM cannot be sterilized.
- The programming head contains a magnet. Proximity to magnetic recording tape and disks should be avoided.
- This device has been tested for compliance to FCC regulations. Changes or modifications of any kind not expressly approved by Medtronic, Inc. or Vitatron Inc. could void the user's authority to operate this device.

#### **Sterilization**

**Caution:** To sterilize the programming head, disconnect it from the TEM by pulling its connecting cable out of the jack on the right side of the TEM unit.

The programming head may be sterilized by a validated ethylene oxide gas sterilization method at temperatures not to exceed 55 °C (130 °F). Biological controls should be used to ensure that proper sterilization standards have been met.

Due to the variability between sterilizers, precise sterilization instructions cannot be provided. Contact your sterilizer manufacturer for more information regarding sterilization procedures.

**Cleaning the Programming Head**

Use a brush and a mild detergent, enzymatic cleaner, or 70% isopropyl alcohol to remove all visible contaminants. Completely dry the programming head.

**Caution:** The programming head must not be autoclaved.

**Instructions For Use**

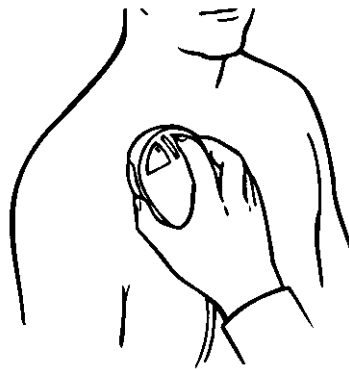
Verify that the Model 9767/9767L programming head and TEM have been connected to the programmer by pulling lightly on the TEM cable's metal connecting head. The connecting head should not move at all. Once connected, the TEM cable cannot be removed without squeezing in the studs on the two sides of the metal connecting head.

For an implantable device, the programming head should be held directly against the patient's skin. The face of the programming head must be parallel to and typically within two inches (5 mm) of the implanted device. The optimum position of the programming head may not be directly centered over the implantable device.

Position the programming head over the implantable device (see Figure 2) before initiating a programming transmission, a data transmission from the implantable device, or a measurement function.

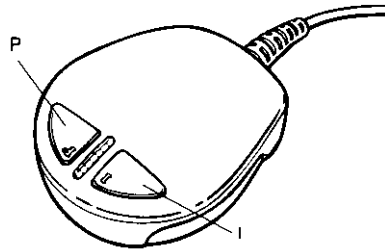
Positioning the programming head is required for any interaction between the programmer and the implantable device. The programming head should be held in this position until the operation is completed.





**Figure 2. Positioning the Model 9767/  
9767L**

The P and I buttons on the programming head correspond to commands that appear on the display screen of the 9790/9790c programmer. Refer to the appropriate software manual to determine which commands the buttons correspond to (see Figure 3).



**Figure 3. P and I buttons**

Any temporarily programmed state or function will remain in effect as long as the programming head is held in place over the implanted device. Lifting the programming head cancels a temporary program and terminates any continuous telemetry (such as Marker Channel telemetry or EGM waveforms). Upon removal of the programming head, the implantable device reverts to permanently programmed values.

Be aware that the magnet in the programming head may attract metal instruments or attach itself to metal surfaces.

**The following Limited Warranty<sup>1</sup>  
Applies to United States Customers  
Only:**

A. This Limited Warranty provides the following assurance to the purchaser of the Model 9767 or 9767L programming head, hereafter referred to as the "Equipment":

1. Should the Equipment fail to function within normal tolerances due to a defect in materials or workmanship within a period of one year, commencing with the delivery of the Equipment to the purchaser, Medtronic will at its option: (a) repair or replace any part or parts of the Equipment; (b) issue a credit to the purchaser equal to the Purchase Price, as defined in Subsection A(2), against the purchase of the replacement Equipment or (c) provide a functionally comparable replacement Equipment at no charge.

<sup>1</sup> This Limited Warranty is provided by Medtronic, Inc., 7000 Central Avenue N.E., Minneapolis, MN 55432. It applies only in the United States. Areas outside the United States should contact their local Medtronic representative for exact terms of the Limited Warranty.

2. As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original, or current functionally comparable, or replacement Equipment.

**B.** To qualify for the repair, replacement or credit set forth in Section A, the following conditions must be met:

1. The Equipment must be returned to Medtronic within 60 days after discovery of the defect, (Medtronic may, at its option, repair the Equipment on site).

2. The Equipment must not have been repaired or altered outside of Medtronic's factory in any way which, in the judgment of Medtronic, affects its stability and reliability. The Equipment must not have been subjected to misuse, abuse or accident.

**C.** This Limited Warranty is limited to its express terms. In particular:

1. Except as expressly provided by this Limited Warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE OR MALFUNCTION OF THE EQUIPMENT, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.
2. This Limited Warranty is made only to the purchaser of the Equipment. AS TO ALL OTHERS, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN A(1) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.

3. The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid. This Limited Warranty gives the purchaser specific legal rights. The purchaser may also have other rights which vary from state to state.
4. No person has any authority to bind Medtronic to any representation, condition or warranty except this Limited Warranty.

**The following Limited Warranty Applies to Customers Outside the United States:**

- A. This LIMITED WARRANTY provides the following assurance to the purchaser of the Model 9767 or 9767L programming head, hereafter referred to as the "Equipment", that should the Equipment fail to function within normal tolerances due to a defect in materials or workmanship within a period of one year, commencing with the delivery of the Equipment to the purchaser, Medtronic or Vitatron will at their option: (a) repair or replace any defective part or parts of the Equipment; (b) issue a credit equal to the original Equipment purchase price (but not to exceed the value of the replacement Equipment), against the purchase of replacement Equipment, or (c) provide functionally comparable replacement Equipment at no charge.
- B. To qualify for this repair, replacement or credit. The following conditions must be met:
1. The Equipment must be returned to Medtronic or Vitatron within thirty (30) days after discovery of the defect. (Medtronic or Vitatron may, at their option, repair the Equipment on site).

2. The Equipment must not have been repaired or altered by someone other than Medtronic or Vitatron in any way which, in the judgment of Medtronic or Vitatron, affects its stability and reliability.
  3. The Equipment must not have been subjected to misuse, abuse or accident.
- C.** This LIMITED WARRANTY is limited to its express terms. In particular, Medtronic or Vitatron is not responsible for any incidental or consequential damages based on any use, defect or failure of the Equipment, whether the claim is based on warranty, contract, tort or otherwise.
- D.** The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. If any part or term of this LIMITED WARRANTY is held by any court of competent jurisdiction to be illegal, unenforceable or in conflict with applicable law, the validity of the remaining portion of the LIMITED WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this LIMITED WARRANTY did not contain the particular part or term held to be invalid.