

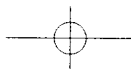
Medtronic

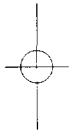
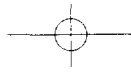
N'VISION™

Clinician Programmer

8840

Technical Manual





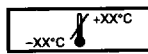
Explanation of Symbols



Conformité Européenne (European Conformity).
This symbol means that the device fully complies with European Directive AIMD 90/385/EEC.



Lot number



Storage temperature



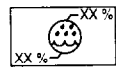
Attention. See accompanying documents



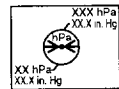
IEC 60601-1, Type BF Equipment



Caution



Relative Humidity



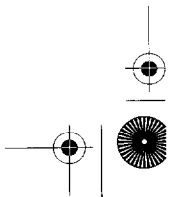
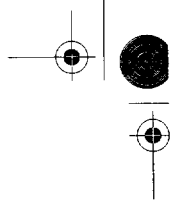
Atmospheric Pressure

The following is communications regulation information on the Model 8840 N'Vision Clinician Programmer.

FCC ID: LF58840

This device complies with Part 15 Rules. Operation is subject to the following two condition: (1) This device may not cause harmful interference an (2) this device must accept any interference received, including interference that may cause undesired operation.

Important: Changes or modifications to this product not authorized by Medtronic, Inc., could void FCC Certification and negate your authority to operate this product.

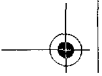


How to Use This Guide

About the Model 8840 N'Vision Clinician Programmer Guide

This guide presents information for users of the N'Vision Clinician Programmer:

- Programmer overview
- Programmer description
- Programmer use
- Programmer maintenance



How to Use This Guide

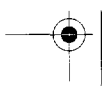
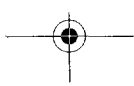


Table of contents

Explanation of Symbols i

How to Use This Guide iii

1. Programmer Overview

Device Description 1-2

Supply and Accessories 1-2

Indications for Use 1-2

Warnings and Precautions 1-3

Warnings 1-3

Precautions 1-4

2. Programmer Description

Component Identification 2-2

Interactive Features 2-5

Graphical Display 2-5

Display Feature 2-10

Hard Keys 2-10

Scroll Wheel 2-10

Connection Ports and Other Features 2-11

Application Card Port 2-11

Telemetry Module 2-12

IR Port 2-12

Audio Speaker 2-12

3. How to Use the N'Vision Programmer

Powering Up the Programmer 3-2

Inserting the Application Card 3-5

Stand-by Mode 3-7

Navigating Menu Options 3-8

The Programmer Display 3-8

Using the Display 3-9

Display Calibration 3-9

Using the Scroll Wheel and Program Key 3-9

Programmer Operation 3-11

Start-up and Self-test Sequence 3-11

Programmer Status Bar 3-11

Status Bar Icons 3-12

Software Application Selection 3-13

Using the Slider Bar 3-14

Activating the Slider Bar 3-14

Slider Bar Icons 3-14

Table of contents

- Platform Session Data Management 3-20
- Navigation Tab Bar 3-21
- Programmer Connections 3-22
 - Communicating with a Printer 3-22
 - Printing 3-22
- Telemetry Module Use 3-23
 - Using the Telemetry Module Attached to the Programmer 3-23
 - Using the Telemetry Module Detached from the Programmer 3-23
 - Positioning the Telemetry Head 3-24
 - Reeling in the Telemetry Head 3-26
 - Connecting the Magnet to the Telemetry Module 3-28
- 4. Programmer Maintenance**
 - Changing the Programmer Batteries 4-2
 - Battery Replacement 4-3
 - Back-up Battery 4-3
 - Cleaning the Display 4-3
 - Display Calibration 4-4
 - Cleaning the Telemetry Module 4-5
 - Safety and Technical Checks 4-5
- 5. Troubleshooting**
 - Troubleshooting Reference Guide 5-2
- 6. Specifications**
 - N'Vision Programmer Specifications 6-2
 - Electrical and Operating Characteristics 6-2
 - Programmer Storage and Operating Conditions 6-3
- A. Glossary**

Programmer Overview

1

Device Description 1-2

Supply and Accessories 1-2

Indications for Use 1-2

Warnings and Precautions 1-3

Medtronic N'Vision Clinician Programmer Guide 1-1

Programmer Overview
Device Description

Device Description

The Model 8840 N'Vision™ Clinician Programmer is a small, portable device that offers a single programming platform for Medtronic Neurological implantable therapy devices. The programmer is equipped with a touchscreen display for data entry, telemetry head for device programming, and an infrared port through which communications can be established with compatible printers.

A therapy application card that contains application-specific software is supplied separately.

Supply and Accessories

The following accessories are used in conjunction with the N'Vision Programmer:

- therapy software on an application card (supplied separately)
- a compatible printer (optional)
- a magnet (optional)

Indications for Use

The N'Vision Programmer is indicated for use with Medtronic Neurological therapies and devices as provided on Medtronic application cards. Refer to specific application manuals and information sheets to determine card compatibility.

Warnings and Precautions

Warnings

- Refer to the appropriate implanted/device manual for instructions on specific therapy applications and a complete listing of warnings, precautions, contraindications and instructions for use for applications.
- The N'Vision Programmer can only be used to program Medtronic Neurological devices that correspond with therapy application software on the application card within the programmer.
- Use only fresh batteries (four "AA" alkaline batteries).
- Do not immerse the N'Vision Programmer in water or other fluids. Do not expose the programmer to excessive amounts of water or other fluids. This may damage the programmer.
- Do not connect the N'Vision Programmer to any equipment not specifically listed in this technical manual. Connection to non-specified equipment may result in damage to the programmer, or patient injury.
- Do not use the N'Vision Programmer if it is damaged.
- Peripheral equipment connected to the N'Vision Programmer must be certified according to the respective IEC standards (e.g., IEC 950 for data processing equipment and IEC 60601 for medical equipment). Furthermore, the system formed by the N'Vision Programmer and any connected peripherals must comply with the requirements of IEC 60601-1-1, Safety requirements for medical electrical systems. Such compliance is the responsibility of the person who connects the peripheral. If in doubt, consult the technical services department or your local representative.

For all peripherals certified to IEC 950, it is the responsibility of the user to keep the peripheral at least 2 meters from the patient. This will satisfy the requirements of IEC 60601-1-1.

- The magnet is for use with Medtronic pumps only. Remove the magnet before using the N'Vision Programmer with Medtronic neurostimulators.
- Return devices for disposal to Medtronic when the devices are no longer functional.
- If the display is inactive, inadvertent programming may occur.

Programmer Overview

Warnings and Precautions

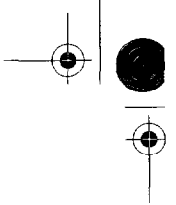
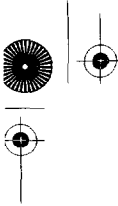
- If the display is not working, do not use the N'Vision Programmer. Return the device to Medtronic for repair.
- The N'Vision Programmer is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

Precautions

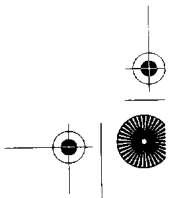
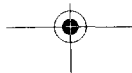
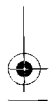
- Power failures during programmer use will reinitialize the programmer, and application state data will be lost.
- Do not remove the application card while a therapy is active, because these circumstances may cause programming operations to cease.
- Do not drop the device, because the display may break, causing injury to the user.
- Telemetry failures will result in loss of communication between the programmer and the device. To ensure that telemetry is established and maintained, keep the telemetry head as close as practical to the implantable device. Do not move the telemetry head once telemetry has been established.
- Do not insert nonMedtronic, generic compact flash cards into the N'Vision Programmer.
- Do not use the N'Vision Programmer in the proximity of equipment that generates electromagnetic interference (EMI). EMI may cause a disruption in programmer function. Examples of common medical sources of EMI are magnetic resonance imaging (MRI) and lithotripsy. Powerful computer monitors, cell phones, x-ray equipment, and other monitoring equipment may also generate EMI.
- Medtronic neurostimulators controlled by the N'Vision Programmer may affect the operation of other implanted devices, such as cardiac pacemakers and ICDs. Physical proximity of implanted neurostimulators to other implanted devices may cause sensing problems and inappropriate responses by these other implanted devices. If the patient requires concurrent implantable pacemaker and/or defibrillation therapy, evaluation of any potential interference problems and careful programming of each system may be necessary to optimize the patient's benefit from each device.
- The N'Vision Programmer is not sterile and cannot be sterilized. Sterilization will cause damage to the programmer.

Programmer Overview
Warnings and Precautions

- The THERAPY-STOP function does not operate unless an application card is in place in the programmer and a therapy has been selected.



Programmer Overview
Warnings and Precautions



Programmer Description

2

Component Identification 2-2

Interactive Features 2-5

*Connection Ports and Other
Features 2-11*

Medtronic N'Vision Clinician Programmer Guide 2-1

Programmer Description
Component Identification

Component Identification

The front of the Model 8840 N'Vision Clinician Programmer is equipped with a touchscreen display and a THERAPY-STOP "hard key" (Figure 2-1). The left side of the programmer includes an application card port, two "hard" keys (to initiate power or programming functions), a scroll wheel used during programming, and a button used to eject application cards from the programmer. An infrared transceiver (IR port) is located at the top of the programmer.

Note: Serial number information for N'Vision Programmer is displayed:

- inside the programmer battery compartment
- on the programmer Information Screen (Figure 3-11)

Programmer Description
Component Identification

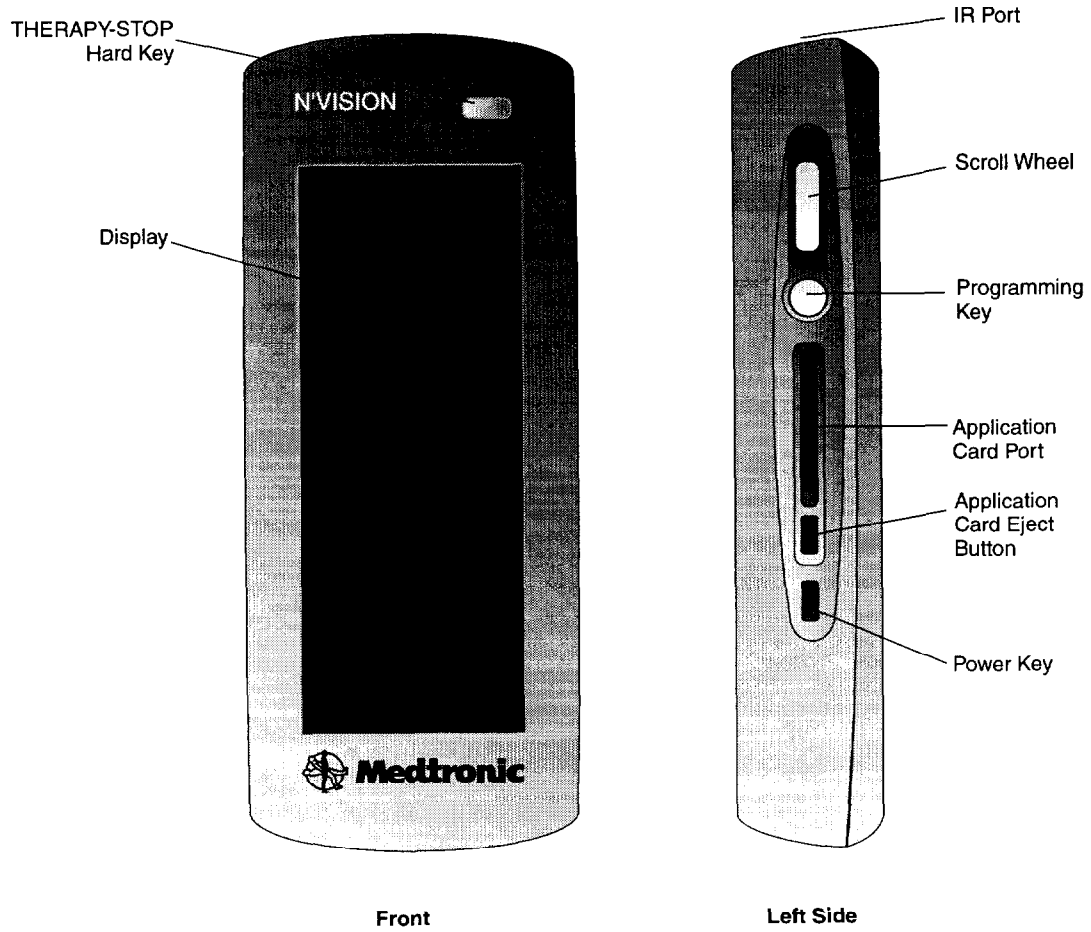


Figure 2-1. N'Vision Programmer Front and Left Side

Programmer Description
Component Identification

On the back of the N'Vision Programmer are the telemetry module and magnet (optional), cable reel for the telemetry module, audio speaker, and battery compartment (Figure 2-2). The stylus is stored in a recessed area on the right side of the device.

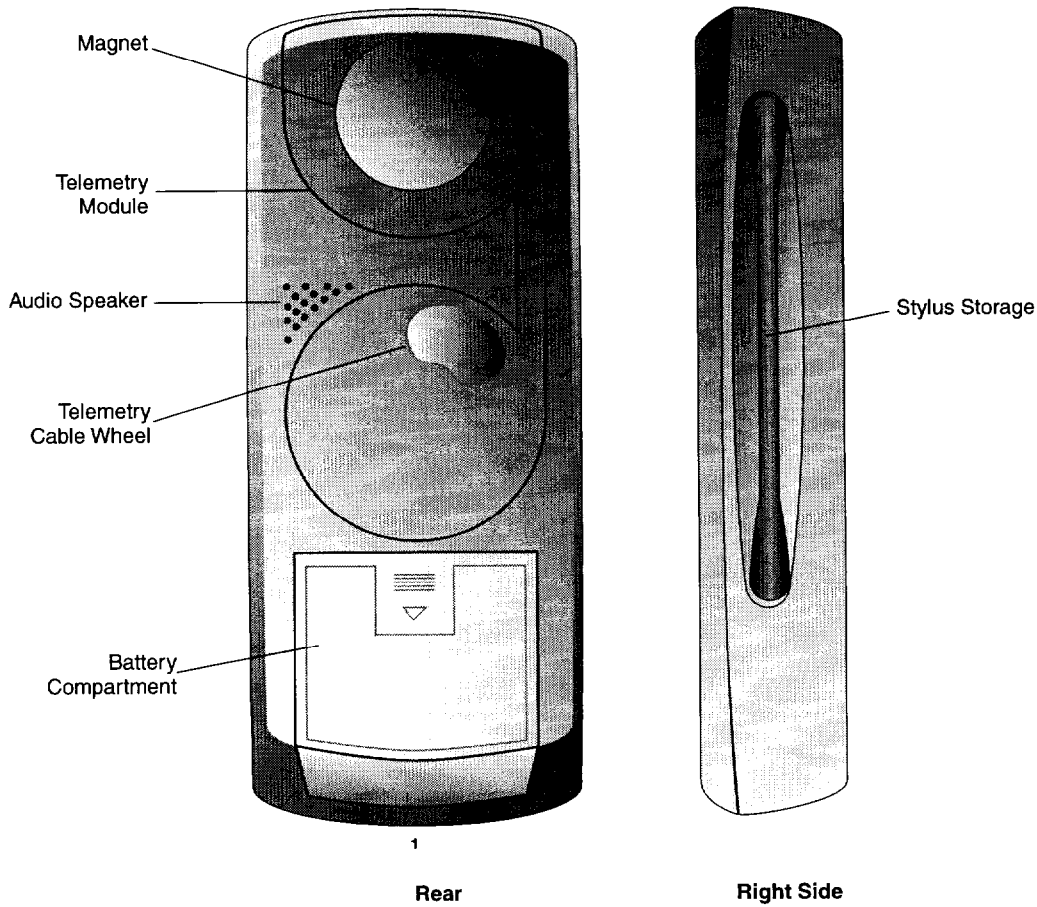


Figure 2-2. N'Vision Programmer Back and Right Side Views

¹ **Note:** The connection port housed near the battery compartment is used by Medtronic for test purposes only.

Interactive Features

Graphical Display

The touchscreen of the programmer displays text and graphical messages that guide the user through all programmer functions. The display is divided into five sectors:

- Programmer status bar
- Title bar
- Application tabs
- Primary application area
- Secondary application area


The significance of each sector is unique.


Icons have been placed on these sectors, and these icons represent either access to status information ("inactive" icons) or links to another function within the program ("active" icons).


Inactive icons appear as empty, outlined graphics. Active icons appear as selectable "buttons" on the screen.


Programmer Description
Interactive Features

- **Programmer Status Bar:**
The programmer status bar provides information on the status of various programmer functions (Figure 2-3). The following “inactive” icons present information on the status of the:

 connection;

 printer;

 telemetry function;

 and battery.

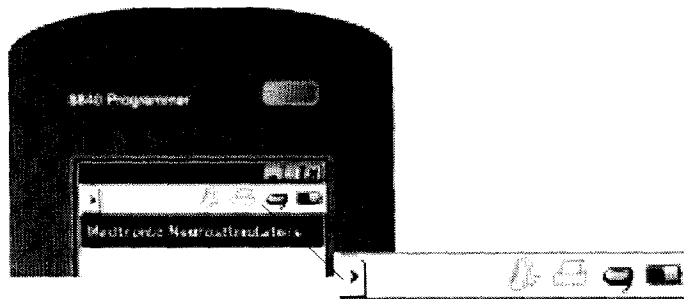


Figure 2-3. Programmer Status Bar

*Programmer Description
Interactive Features*

▪ **Title Bar and Application Tabs:**

When an application is active on the N'Vision Programmer, the Title Bar identifies the application tab in use, along with the print and close program icons (Figure 2-4). Application tabs are application-specific "active" icons, each representing a separate function of the application in use.

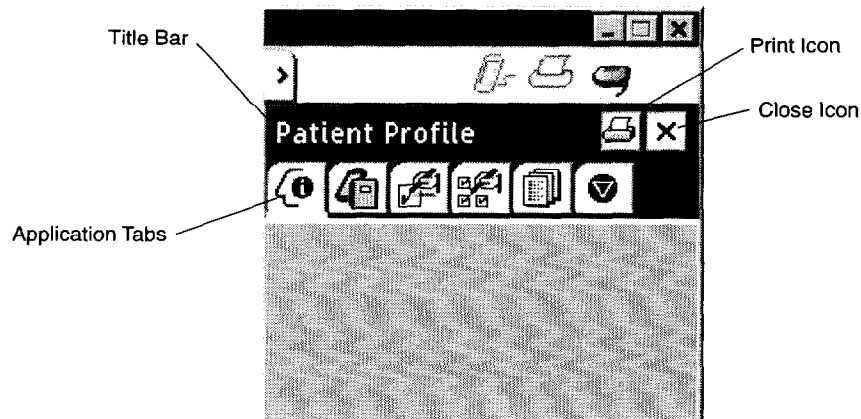


Figure 2-4. Title Bar and Application Tabs

Print and close icons on the title bar are "active" icons. Proper contact of the stylus with these "active" icons results in the action associated with the icon. For example, on the Title Bar, contact of the stylus with the "close" icon results in termination of the current application.

Programmer Description
Interactive Features

- **Primary Application Area:**
Active application information comprises the largest area of the display screen (Figure 2-5).

Note: The parameters displayed in Figure 2-5 are generic and do not represent data from any specific pump or neurostimulator.

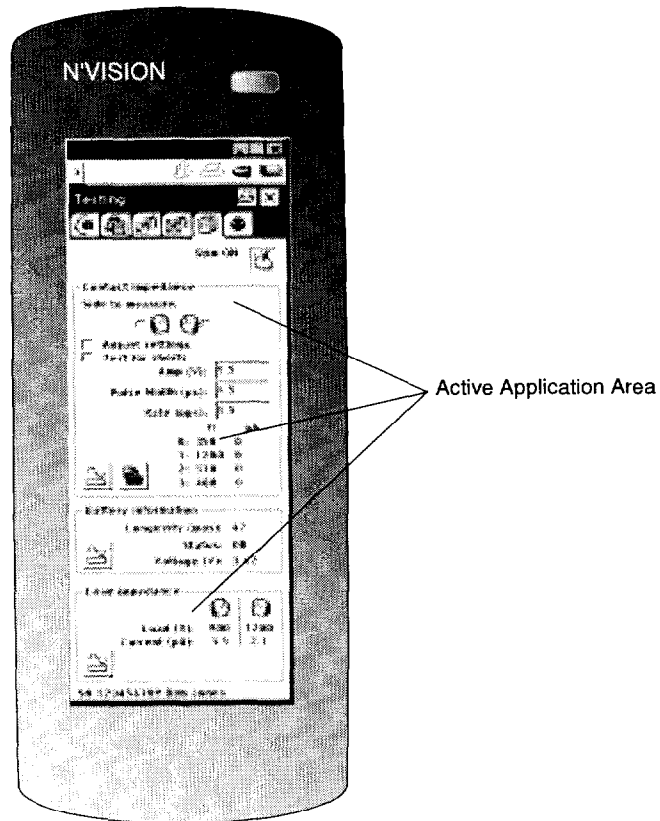


Figure 2-5. Active Application Area of the Display

*Programmer Description
Interactive Features*

- **Secondary Application Area:**
A secondary window at the bottom of the display houses the calculator function that is accessed through the Slider Bar (Figure 2-6). The secondary application area may at times be covered by these tools.

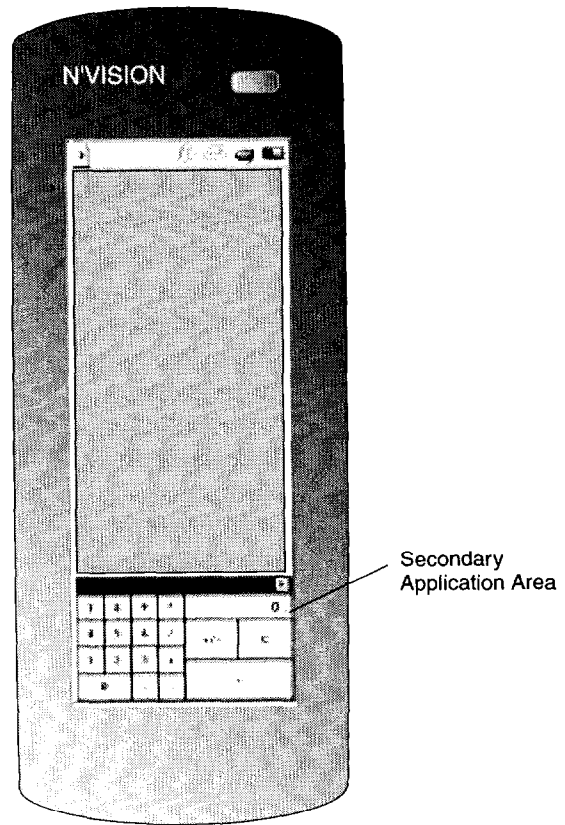


Figure 2-6. Secondary Application Area

Programmer Description

Interactive Features

Display Feature

The entire area of the display is functional. Each operative sector of the display can be activated by stylus (provided with the N'Vision Programmer) or fingertip. All therapy applications available for use with this device can be selected through use of the display, as can programmer parameters such as date, time, and language.



Caution: If stylus contact with the display results in a different function, action, or therapy than expected, the display must be calibrated. Display calibration is described in detail in "Chapter 4, Programmer Maintenance."

Note: Do not use sharp objects (i.e., pencils, pens, paperclips) on the display. Use only the stylus provided with the programmer, or your fingertip.

Hard Keys

Three "hard keys" on the N'Vision Programmer correspond with three specific functions: power key, application of power; programming key, programming; and THERAPY-STOP key, immediate stop therapy functions. Figure 2-1 shows the location of the keys on the programmer.

Scroll Wheel

The scroll wheel is positioned on the left side panel of the programmer (Figure 2-1). The scroll wheel is used when programmer input requires continuous variation of parameters or when the user needs to operate the programmer with one hand. The scroll wheel spins in both directions (up/down) for parameter variation and depresses inward for parameter selection. Scroll wheel functions are application specific and may vary from one therapy to another. Refer to the device-specific programming guide for more detailed information on the use of the scroll wheel.

Connection Ports and Other Features

Application Card Port

Therapy applications hosted on the N'Vision Programmer are stored on application cards. The interface between the programmer and the application card is contained within the application card port (Figure 2-7).

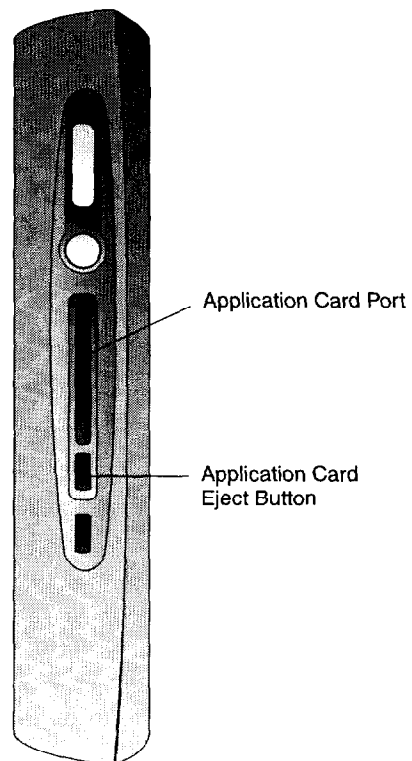


Figure 2-7. Application Card Port Location

Programmer Description

Connection Ports and Other Features

Telemetry Module

The N'Vision Programmer is comprised of a base module and a telemetry module (TM). The telemetry module is attached to the base module by a 1-meter long cable that retracts onto a spool in the back of the base module. The telemetry module can be used while extended or while housed on the device.

IR Port

An IR port located on the front of the N'Vision Programmer allows the device to communicate with IR-capable printers without physical connections (Figure 2-1).

Audio Speaker

An audio speaker located in the back of the N'Vision Programmer provides audible signals to the user during various programming conditions and events. Successful completion of an event, failed event completion, and system errors will be identified by a series of unique tones:

- Success (two tones in rapid succession, the second a higher pitch than the first)
- Error (two tones in rapid succession, the second a lower pitch than the first)
- Alert (two tones in rapid succession, both the same pitch)
- Failure (five flat tones in rapid succession)

The volume of these tones is user adjustable, and they can be turned off.

Additionally, successful contact of the stylus with an icon on the display is confirmed with the sound of a click. This sound can be turned off, but the volume is not adjustable.

How to Use the N'Vision Programmer

3

The first few pages of this chapter present basic information on use of the N'Vision Programmer. Specific operational instructions begin on page 3-11.

<i>Powering Up the Programmer</i>	3-2
<i>Inserting the Application Card</i>	3-5
<i>Navigating Menu Options</i>	3-8
<i>Programmer Operation</i>	3-11
<i>Programmer Connections</i>	3-22
<i>Telemetry Module Use</i>	3-23

How to Use the N'Vision Programmer
Powering Up the Programmer

Powering Up the Programmer

The power key for the Model 8840 N'Vision Clinician Programmer is located on the left side of the device, toward the bottom (Figure 3-1). The power key toggles the power on or off. Slide the key backward and hold in position momentarily to apply power or to shut off the programmer.

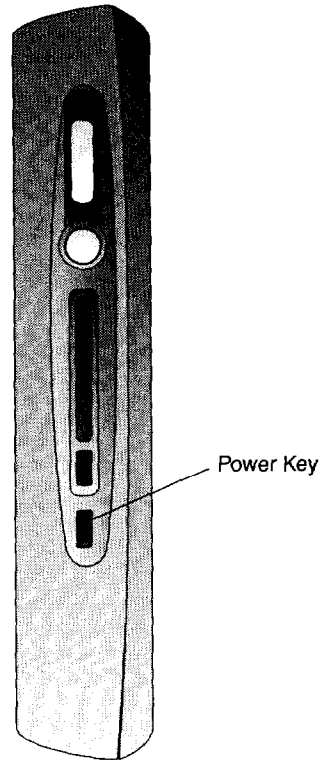


Figure 3-1. Power Key Location

Note: If the programmer is powered up prior to insertion of an application card, the selection screen will present an icon for a missing application card.

How to Use the N'Vision Programmer
Powering Up the Programmer

The first time that the programmer is turned on, the user will be directed to choose localization parameters for date, time, and number format (Figure 3-2). These parameters appear automatically only the first time the programmer is powered up, or when the back-up lithium battery is changed. During normal operation, localization parameters may be accessed through the Slider Bar (refer to page 3-14).

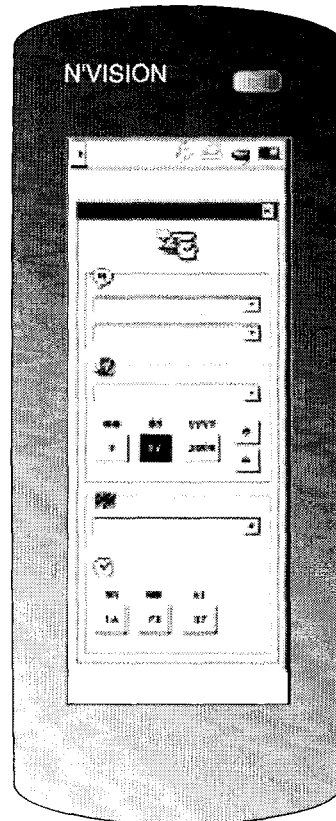


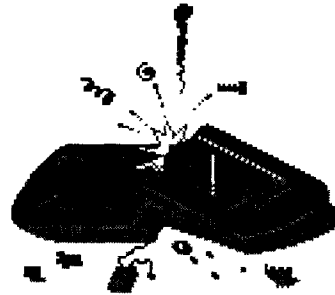
Figure 3-2. Localization Options

The Information Screen displays only when selected from the Slider Bar. On start up, a different screen displays momentarily.

The self test, approximately 5 seconds in duration, is designed to test various system components (refer to page 3-11).

How to Use the N'Vision Programmer
Powering Up the Programmer

If a failure is encountered during the self test, a failure mode screen may be displayed (Figure 3-3), accompanied by an audible beep. The failure mode screen, if displayed, will indicate the nature of the problem. Contact Medtronic for further instructions.



```
ERR #2
100x
TCB: Error Handling T
X = 100
@ = 800108a
^ = 8000f3c
^^ = a8174ca4
^^^ = 0
^^^^ = 0
```

Figure 3-3. Failure Mode Screen

*How to Use the N'Vision Programmer
Inserting the Application Card*

Inserting the Application Card

The N'Vision Programmer uses only compatible Medtronic application cards through a card slot on the left side of the device (Figure 3-4). Insert the application card into the N'Vision Programmer before turning on the programmer.

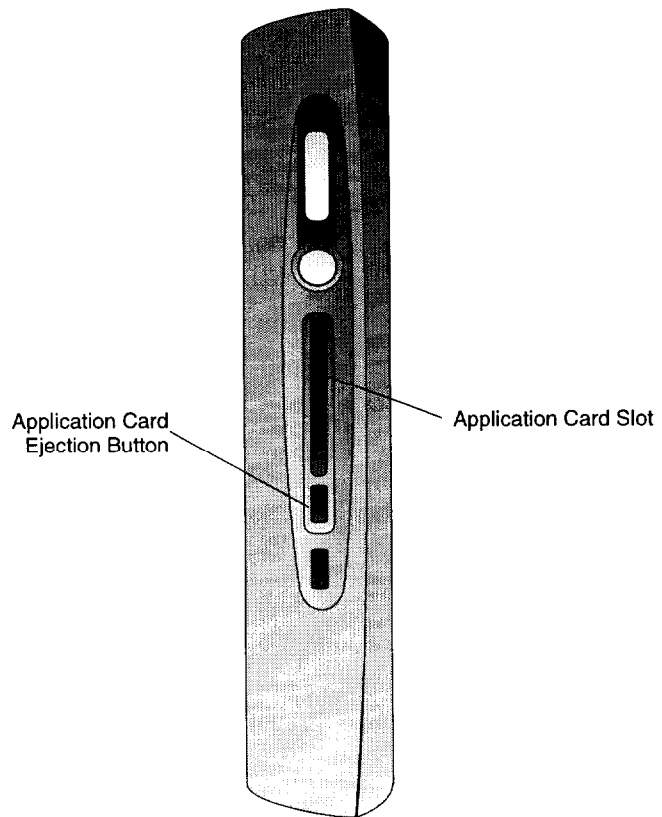


Figure 3-4. Application Card Slot and Ejection Button Locations

How to Use the N'Vision Programmer *Inserting the Application Card*

Insert a single application card into the programmer (Figure 3-5); insertion is complete when the application card “clicks” into place and the ejection button is closed. To eject the application card, depress the ejection button just behind the card slot on the left side of the programmer.

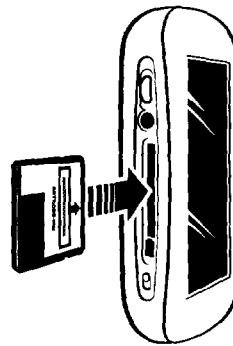


Figure 3-5. *Inserting an Application Card*

Note: Do not remove the application card unless you are replacing it with a new card.



Caution: If the ejection button is depressed while application software is running, the current application will cease to function, and you will lose unsaved data. If the application card is ejected while an application is running, turn the programmer off, reinsert the card, and turn the programmer back on. Leave the application card in place at all times, even when the programmer is turned off.

*How to Use the N'Vision Programmer
Inserting the Application Card*

Stand-by Mode

When the N'Vision Programmer is powered up and in use, the programmer enters Stand-by Mode if no input is received during a continuous 6-minute period of time. During Stand-by Mode, the programmer screen goes blank. The programmer leaves Stand-by Mode and becomes active when the user activates the power button on the programmer (refer to page 3-2).

If an application is running when the programmer goes into Stand-by Mode, and the user activates the power key on the programmer within 1 hour of Stand-by Mode initiation, the programmer returns to the function that was in use at the time of Stand-by Mode onset. If, however, the power switch is not activated within 1 hour of Stand-by Mode initiation, the programmer will shut down. When the power button is activated after the 1-hour period, it reverts to the start-up sequence and self test.



Caution: If the programmer is in Stand-by Mode for more than 1 hour, all data from the application in use at the time of Stand-by Mode onset will be lost.

*How to Use the N'Vision Programmer
Navigating Menu Options*

Navigating Menu Options

The Programmer Display

Figure 3-6 is a representation of the N'Vision Programmer display.

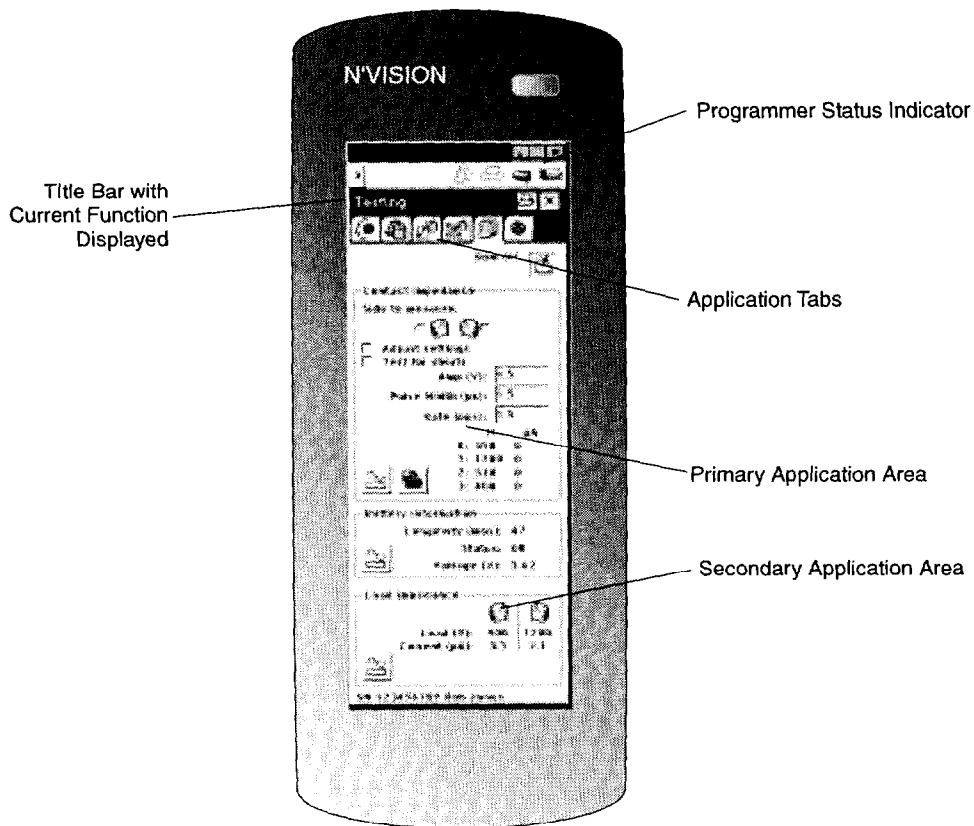


Figure 3-6. N'Vision Programmer Display Sectors

How to Use the N'Vision Programmer Navigating Menu Options

Using the Display

Most user input to the N'Vision Programmer is via the display, which is the preferred mode of access to configure programmer settings and to operate applications housed on the application card. The display responds to stylus or finger tip touch.

A stylus is supplied with the device and can be stored in a groove molded into the right side of the programmer. To remove the stylus from its storage area, slide it down and out of the groove. Use the pointed end of the stylus to make contact with the display screen.

Display Calibration

The display on the N'Vision Programmer may require periodic calibration. For details, refer to "Chapter 4, Programmer Maintenance."



Caution: Use of the N'Vision Programmer while the screen is out of calibration may result in unintended programming or function selection.

Using the Scroll Wheel and Program Key

A scroll wheel located on the left side of the N'Vision Programmer (Figure 3-7) allows the user to select graduated parameters. The wheel turns forward and backward in discrete increments and is positioned on the device to facilitate single-handed use of the programmer. The scroll wheel also can be depressed partially into the programmer, and depression of the wheel communicates an "enter" or "select" function to the device. The scroll wheel functions are application specific and may vary from one therapy to another.

How to Use the N'Vision Programmer
Navigating Menu Options

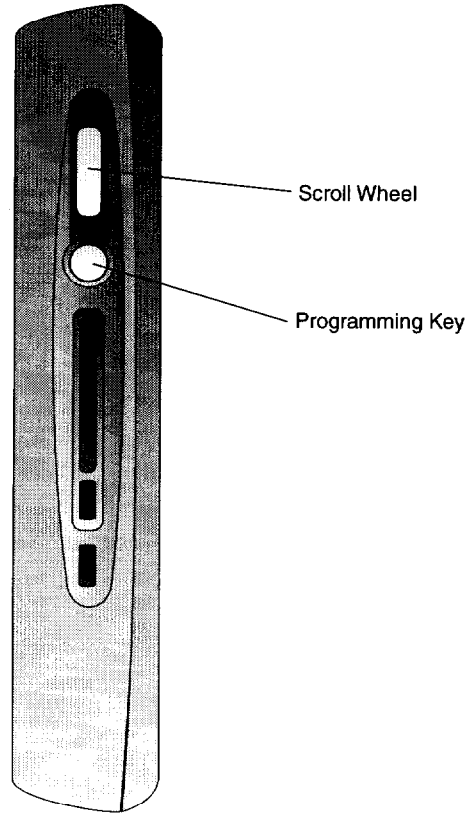


Figure 3-7. Scroll Wheel and Programming Key Locations

The programming key (Figure 3-7) is positioned just below the scroll wheel. Depression of the key initiates a telemetry operation (interrogate and/or program) that is dependent upon the application and the operating context.

Programmer Operation

Start-up and Self-test Sequence

When the power key is activated on the N'Vision Programmer, a series of self-tests are initiated. These self-tests are designed to ensure the programmer is functioning properly. During the time the programmer is in the self-test mode (approximately 5 seconds), the following parameters are checked:

- Power supply
- Battery power levels
- Memory
- Other hardware

If one or more of the self-tests fail, the programmer alerts the user graphically and with a failure sound (five flat tones in rapid succession). The programmer then displays instructions on how to proceed.

Following successful completion of the self-test, the programmer displays a menu that allows selection of the desired program, along with a Programmer Status Bar that allows the user to select and monitor various programmer functions.

Programmer Status Bar

The status of several functions can be monitored by user selection of an icon on the Programmer Status Bar (refer to Chapter 2, "Programmer Description").

The icons on the Programmer Status Bar are "inactive" (designed to give only information on the performance of the various parameters graphically represented by the icons).

Status Bar icons are presented on page 3-12 and page 3-13.

*How to Use the N'Vision Programmer
Programmer Operation*

Status Bar Icons

Telemetry Status








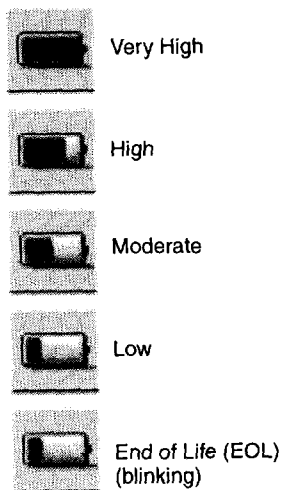
	Telemetry inactive
	Telemetry present
	Telemetry present (Telemetry status is successful)
	Telemetry present (Telemetry status is not successful)
	Telemetry (magnet present)
	Telemetry (magnet present) (Telemetry status is successful)
	Telemetry (magnet present) (Telemetry status is not successful)

Figure 3-8. Status Bar Icons--Telemetry Status

*How to Use the N'Vision Programmer
Programmer Operation*

Battery Status



Printer Status

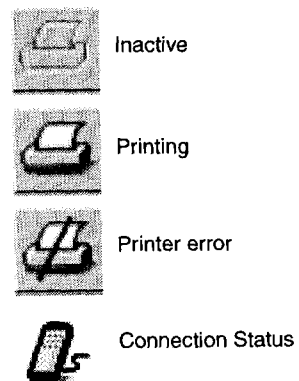


Figure 3-9. Status Bar Icons--Printer, Connection, and Battery Status

Software Application Selection

On the selection menu of the N'Vision Programmer, a list of available applications is displayed. The programmer will list all therapies available on the application card.



Caution: Do not remove the application card while therapy is active, because these circumstances may cause programming operations to cease.

The list of available therapies is dependent upon the application card inserted in the programmer. Once a therapy "family" (group) is selected for use, the therapy selection screen initiates, and the programmer offers the user the software functions available with the application chosen.

How to Use the N'Vision Programmer
Programmer Operation

Using the Slider Bar

At times, the user may choose to interrupt a software application to reconfigure settings on the N'Vision Programmer. The Slider Bar function allows an application to be put on hold in order to perform other tasks.

Activating the Slider Bar

Access the Slider Bar on the touch screen from the Programmer Status Bar. The Slider Bar icon is a "toggle" icon and is activated and deactivated by stylus contact.

Slider Bar Icons

Various functions are accessible through the icons (Figure 3-10) on the Slider Bar.

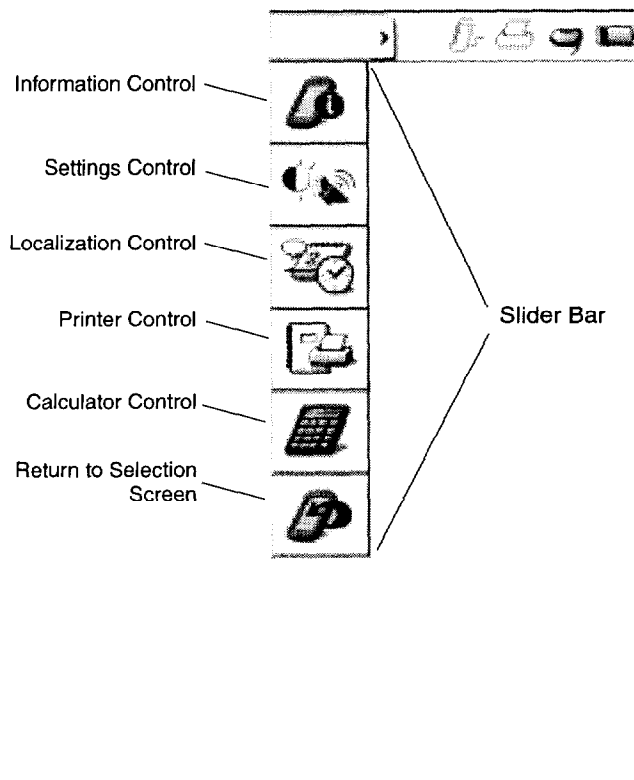


Figure 3-10. Slider Bar Icons

*How to Use the N'Vision Programmer
Programmer Operation*

- The **Information Control** icon gives information about the device, including: model number; hardware version; platform firmware version; telemetry module model number; telemetry module hardware version; telemetry module firmware version; application names and versions; and printer driver names and versions.

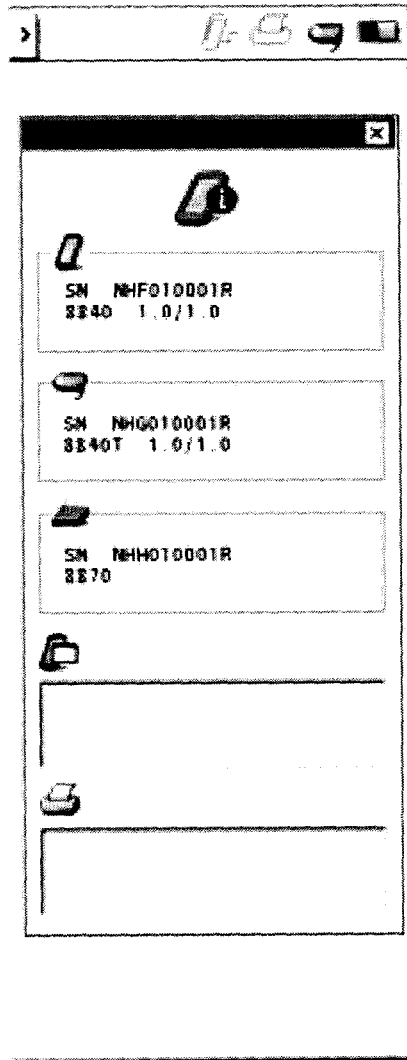


Figure 3-11. Information screen

How to Use the N'Vision Programmer
Programmer Operation

- The **Settings Control** icon allows adjustment of the display contrast, speaker volume and display calibration. Use the stylus to slide the contrast and volume bars to the desired settings. Touch the key click icon to turn the key click sound off or on. To initiate display calibration, select the calibrate button with the stylus.

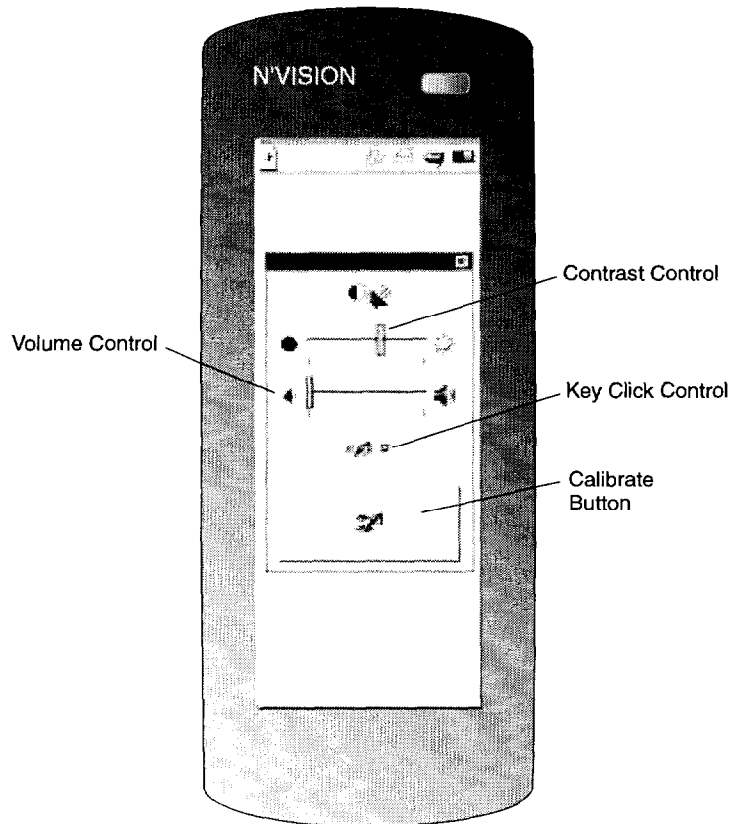


Figure 3-12. *Programmer settings options*

*How to Use the N'Vision Programmer
Programmer Operation*

- The **Localization Control** function allows changes to language preference and date and time formats. Select the desired options using the stylus.

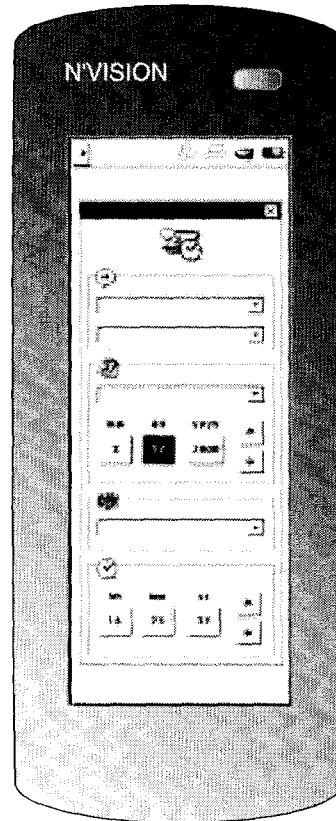


Figure 3-13. Localization options

How to Use the N'Vision Programmer
Programmer Operation

- The **Printer Control** icon gives access to printer options. Using the stylus, select the appropriate printer from the available list (Figure 3-14). The N'Vision Programmer interfaces with the Seiko™ Model DPU 3445. Other printers with IR capability may be supported, also.

Contact Medtronic Technical Services at the phone number listed in the back of this manual for a list of compatible printers.

Refer to page 6-3 for the IR-compatible protocol settings to which the programmer complies.

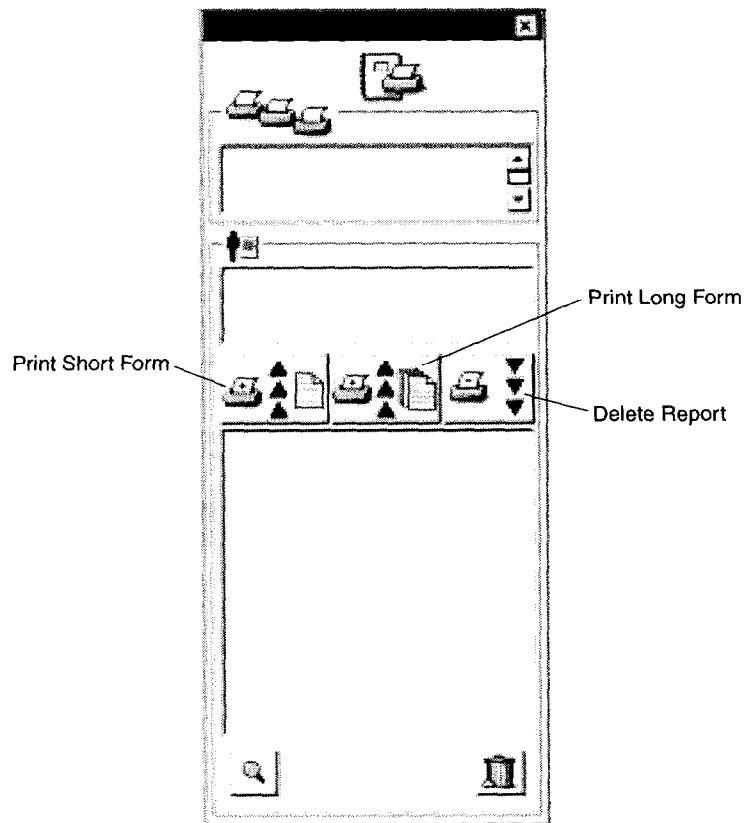


Figure 3-14. Session Data Manager Screen

*How to Use the N'Vision Programmer
Programmer Operation*

- The device calculator is accessed through the **Calculator Control** icon. The calculator is capable of all functions typically available on small, hand-held calculators. Use the stylet to select numbers and functions within the calculator.

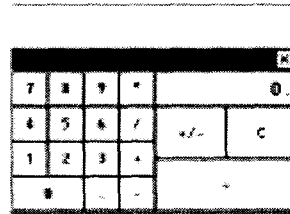



Figure 3-15. Calculator control area

- At any time during programmer use, new applications can be selected by returning to the "home" screen via the **Application Selection Control** (home) icon ().



Caution: Selection of a new application will cause the current application to quit and cause loss of data.

*How to Use the N'Vision Programmer
Programmer Operation*

Platform Session Data Management

The Printer Control icon also gives the user access to patient session reports that have been compiled during previous patient sessions. Information from as many as 100 patient sessions can be stored and accessed.

To retrieve patient data, select the Printer Control icon (Figure 3-10). A list of patient sessions will be displayed in the lower rectangle on the screen. Select a report for viewing using the stylus. To print a report, with the desired report highlighted in the list, touch the printer icon with the "+" on the left for short form or with the "+" in the middle for long form (Figure 3-14). To delete a report from the printer queue, highlight the report in the printer queue list and touch the printer icon with the "-" on the right above the session list.

*How to Use the N'Vision Programmer
Programmer Operation*

Navigation Tab Bar

Each application loaded on the N'Vision Programmer is comprised of various operations and functions that are represented by icons on the Navigation Tab Bar (Figure 3-16). Tabs on the bar contain icons that correspond with application screen selections available to the user.



Figure 3-16. Navigation Tab Bar

The tab for the screen selection in use resides "in front of" tabs corresponding with the other functions.

Note: The icons in Figure 3-16 are a generic representation and do not reflect any specific family of therapies. Each therapy that is used with the N'Vision Programmer will have unique icons. Refer to separate therapy manuals for identification and description of these therapy-specific icons.

How to Use the N'Vision Programmer
Programmer Connections

Programmer Connections

Communicating with a Printer

The N'Vision Programmer supports printing with the Seiko Model DPU 3445 printer and various other desktop printers. The desktop printer must have IR capability or must be fitted with a commercially available IR converter. To connect to a desktop printer, set the desktop printer as the default printer (refer to page 3-14).

For optimal communication between the programmer and the printer, point the programmer IR port directly at the printer IR port from a distance of no more than 1 meter (Figure 3-17).

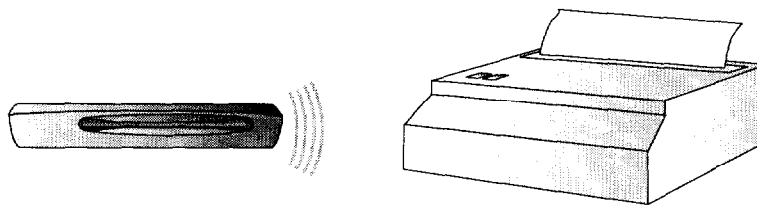


Figure 3-17. Printing using a compatible, IR-capable printer

Printing

The programmer communicates with the Seiko Printer Model DPU 3445 via the infrared port. While in close proximity to the printer (<1 meter), select the print option from the Navigation Tab Bar. After appropriate print parameters are selected, the programmer offers the user the option of executing or canceling the print job.

How to Use the N'Vision Programmer Telemetry Module Use

Telemetry Module Use

The telemetry module located on the back of the N'Vision Programmer may be used while locked in place on the programmer or while extended.

Refer to the appropriate therapy manual for specific device programming and interrogation instructions.



Caution: The programmer, cable, and telemetry head are nonsterile. If used in a sterile field, the programmer and telemetry head should be wrapped in sterile plastic drapes. Do not sterilize the programmer. Sterilization of the programmer may damage the unit.

Using the Telemetry Module Attached to the Programmer

If using the telemetry head while it is locked onto the programmer, position the programmer so that the telemetry head is on the side closest to the implanted device. Prior to the start of interrogation or programming, ensure that the telemetry head is positioned directly over and as close as practical to the implanted device.

Using the Telemetry Module Detached from the Programmer

To unlock the telemetry module from the programmer, press down and forward on the module. After the telemetry head is pushed slightly forward and out of the locked position, grasp the top of the module with one hand, and pull it out to the desired length.

Ensure that the telemetry head is directly over and as close as practical to the implanted device. If the telemetry head is used while extended on the cable, the user will see a green light on the back of the telemetry head, indicating successful interrogation or programming. A red light indicates a failure or error.

*How to Use the N'Vision Programmer
Telemetry Module Use*

Positioning the Telemetry Head

The following graphics demonstrate proper positioning of the programmer and telemetry head in various scenarios:

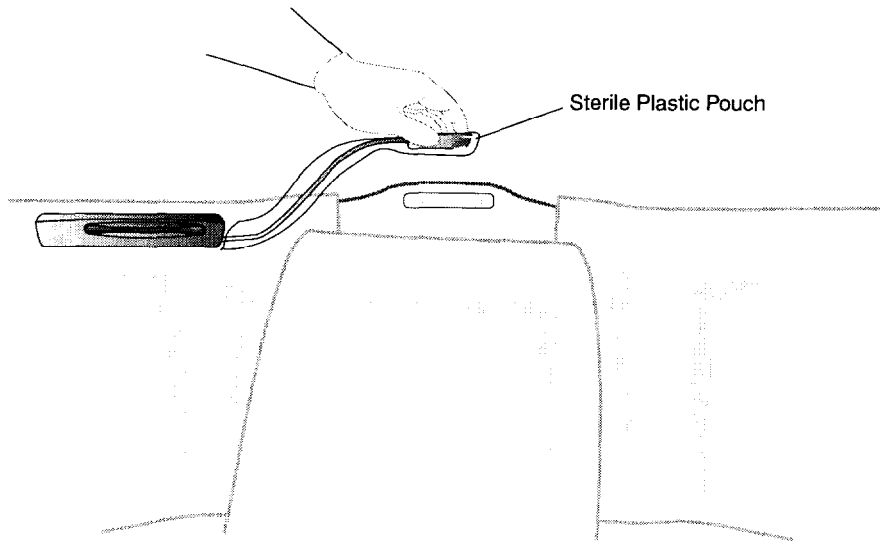


Figure 3-18. Telemetry Head Extended, Patient Supine

**How to Use the N'Vision Programmer
Telemetry Module Use**

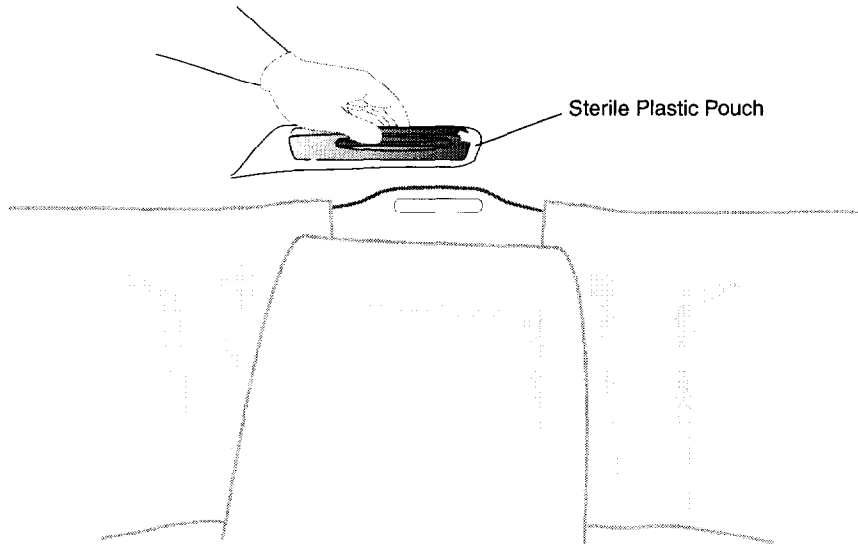


Figure 3-19. Telemetry Head Locked on Programmer, Patient Supine

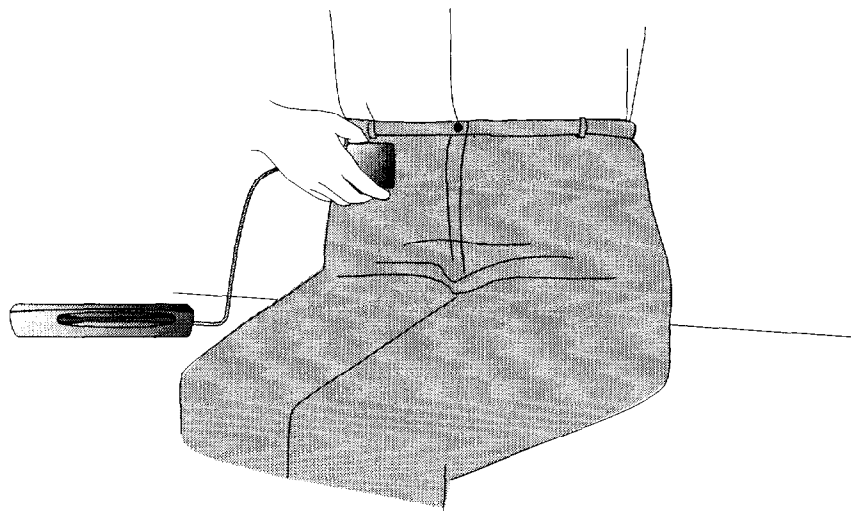


Figure 3-20. Telemetry Head Extended, Patient Upright

How to Use the N'Vision Programmer
Telemetry Module Use

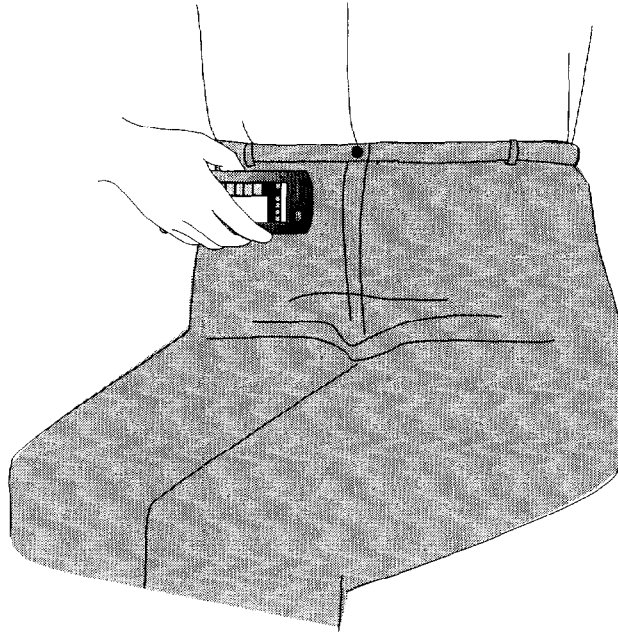


Figure 3-21. Telemetry Head Locked on Programmer, Patient Upright

Reeling in the Telemetry Head

To return the telemetry head to a locked position on the programmer, place one forefinger in the depression on the cable wheel and turn the wheel clockwise until the telemetry head begins to slide onto the back of the programmer (Figure 3-22). Stop turning the cable wheel when the telemetry head pushes against its lock on the programmer. Gently push the telemetry head the rest of the way into its locked position.

△ **Caution:** Do not use excessive force when extending the telemetry head, because the cord may separate from the reel. Do not tangle the cord during extension or retraction of the telemetry module or during use while extended.

△ **Caution:** If the telemetry cable is difficult to reel in, or if it gets caught while you are reeling it in, reextend the telemetry head and begin the process again.

*How to Use the N'Vision Programmer
Telemetry Module Use*

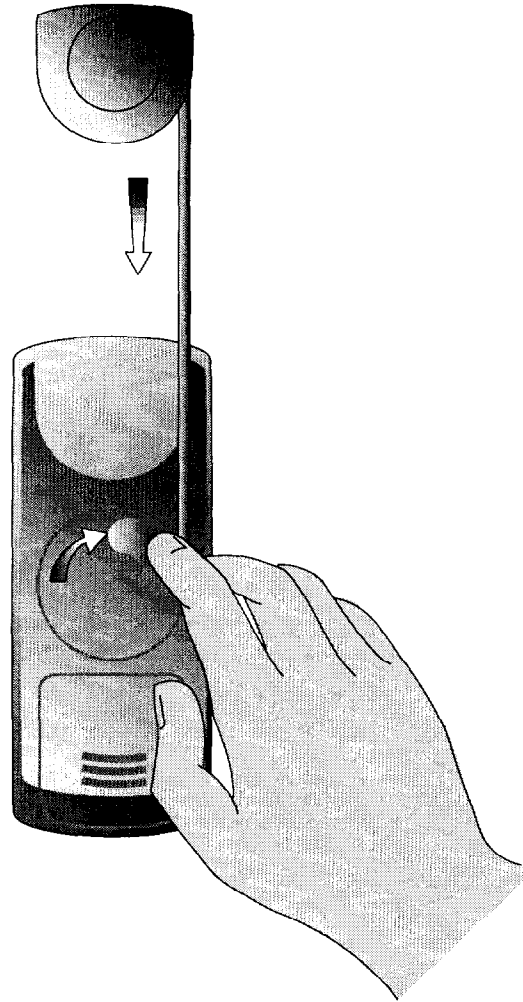


Figure 3-22. Returning the Telemetry Head to its Locked Position

How to Use the N'Vision Programmer
Telemetry Module Use

Connecting the Magnet to the Telemetry Module

The telemetry module includes a molded area for magnet containment, and the magnet “locks” into the telemetry head with a clockwise turn (Figure 3-23). The magnet is device specific. For instructions on magnet use, refer to the technical manual packaged with the patient’s pump.

The programmer carrying case contains a dedicated space for the magnet. Alternatively, the device can be transported with the telemetry magnet affixed to the telemetry module.



Warning: The magnet is for use with Medtronic pumps only. Remove the magnet before using the N'Vision Programmer with Medtronic neurostimulators.

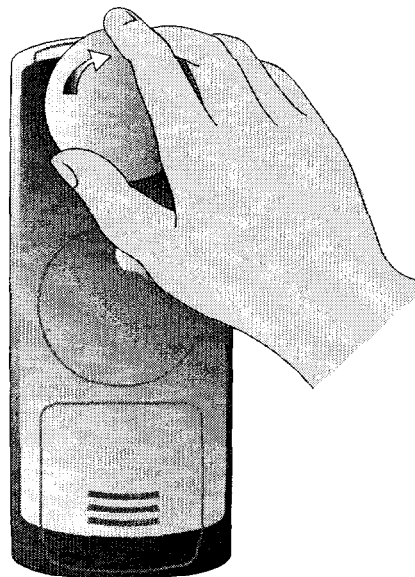


Figure 3-23. Locking the Magnet into the Telemetry Head



Caution: The magnet used in pump programming creates a magnetic field that may affect other implanted programmable medical devices or magnetic storage devices. The physician must identify the other devices and assess the effects of a magnetic field on that device.

How to Use the N'Vision Programmer
Telemetry Module Use

△ **Caution:** Do not allow the magnet to come in contact with magnetic substances. Do not place the magnet on or near computer monitors or magnetic storage devices, disks, or tapes.

***How to Use the N'Vision Programmer
Telemetry Module Use***

Programmer Maintenance

4

*Changing the Programmer
Batteries 4-2*

Cleaning the Display 4-3

Display Calibration 4-4

Medtronic N'Vision Clinician Programmer Guide 4-1

Programmer Maintenance
Changing the Programmer Batteries

Changing the Programmer Batteries

The N'Vision Programmer operates on four "AA" alkaline batteries. (Do not use rechargeable batteries.) Open the battery compartment, located at the bottom rear of the programmer, by pressing down lightly, pushing the lid in the direction of the arrow, and then rotating the cover upwards (Figure 4-1). Correct battery polarity is indicated in the battery wells.

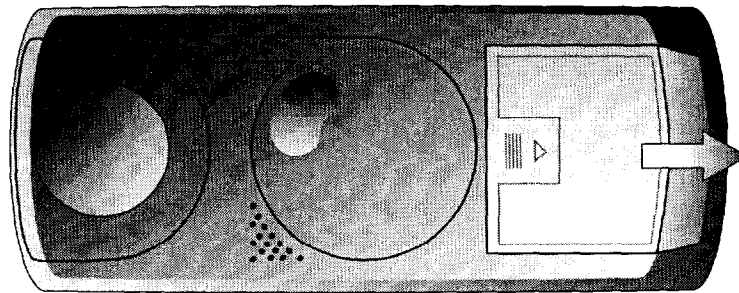


Figure 4-1. Battery Replacement for the N'Vision Programmer

Prior to battery insertion, ensure that the appropriate application card is in place (refer to page 3-5).

Note: If the programmer is powered up prior to insertion of an application card, the selection screen will present an icon for a missing application card.

After the batteries are in place, replace the battery compartment lid by sliding the lid onto the device until it "snaps" into place. Immediately after battery insertion, power up the device to ensure correct battery placement. If the programmer does not power up, check that the batteries have been installed with the correct polarity.

Note: Batteries should be removed from the programmer if the programmer is not likely to be used for an extended period of time.



Caution: Battery depletion may lead to loss of data and/or inability to program. Ensure that fresh "AA" batteries are available as replacements at all times.

Programmer Maintenance

Cleaning the Display

Battery Replacement

Batteries should be replaced after every 40 hours or when the battery status shows low battery. Batteries must be replaced when the battery status indicates EOL (blinking).

- △ **Caution:** Dispose of depleted batteries in accordance with local regulations.

Back-up Battery

A lithium battery supplied with the device runs the programmers internal clock when no main "AA" batteries are installed. The life expectancy of the lithium battery is 3 years, and it can be replaced by the user. The lithium battery compartment is located beneath the "AA" battery compartment. To access the lithium battery compartment, remove the "AA" batteries from the device. The lithium battery in the N'Vision Programmer is a BR1225 standard lithium coin cell. Insert a new lithium battery of the same type (BR1225). Replace the "AA" batteries.

- △ **Caution:** Return worn out devices to the manufacturer.

Cleaning the Display

Do not use abrasive or nonabrasive cleansers on the display. The display should be cleaned only with a soft, dry, lint-free cloth.

- △ **Caution:** Scratches on the display may adversely affect device operation by interfering with display option selection. If scratches are present, the programmer may need to be repaired or replaced.

Programmer Maintenance
Display Calibration

Display Calibration

The display of the N'Vision Programmer may require periodic calibration. To calibrate the display, access the Platform Status Bar, followed by the Slider Bar Mode. On the Slider Bar, select "Programmer Settings" (Figure 4-2) then calibrate button. Alternatively, access the display calibration function by holding in the Program Key for the duration of the power up sequence.

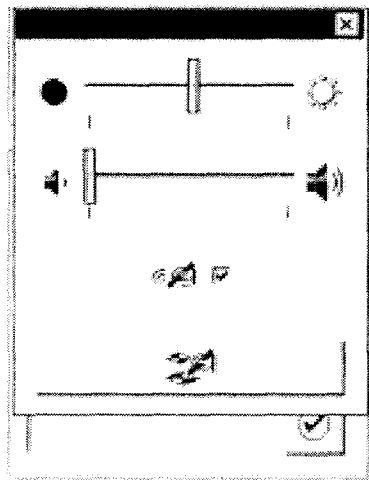


Figure 4-2. *Accessing the calibration option*

During the display calibration procedure, the programmer presents four display calibration targets (refer to Figure 4-3) and instructs the user to touch those locations. With the stylus, touch as close to the center of the locations as possible. Touching away from the center of the target may result in improper display calibration.

Using the input from the touch contacts, the programmer compares the points of contact with known locations and calibrates the display automatically.

Programmer Maintenance
Display Calibration

If display calibration fails, the programmer will reinitiate the calibration procedure until it is successfully completed.

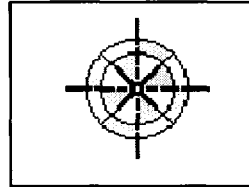


Figure 4-3. Screen calibration target

Cleaning the Telemetry Module

Do not use abrasive or nonabrasive cleansers on the telemetry module. If the module requires cleaning, wipe it with a soft, dry, lint-free cloth.

Safety and Technical Checks

Maintenance

Periodic maintenance of the programmer is not required. Units requiring service or repair should be returned to:

Cardiotron Medizintechnik GmbH
 European Service Center
 Leipziger Chaussee 191
 G-06112 Halle/Saale
 Germany
 Tel. 49-345580-810
 Fax 49-345580-8140

Regular Safety and Technical Checks

Safety and technical checks should be carried out on the 8840 programmer at least once every 12 months by persons who can carry out these checks by reason of their training and skills and the experience which they acquired from practical work and are not subject to any instructions as regards the checking.

1. Visual inspection

- 1.1 Instruction manual
- 1.2 Inscriptions and information signs
- 1.3 Mechanical damage to the programmer, connection cables and programming head

Programmer Maintenance
Display Calibration

2. Testing for operability

- 2.1 Self-test
- 2.2 Programming head
- 2.3 Testing of display
- 2.4 Testing of functional keys
- 2.5 Testing of telemetry

3. Electrical safety in accordance with IEC 60601-1

- 3.1 Patient leakage current max: 0,1 mA



MEDTRONIC CONFIDENTIAL

8840_EN.book Page 1 Tuesday, June 26, 2001 3:37 PM

REF_R18



Troubleshooting

5



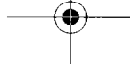
*Troubleshooting Reference
Guide 5-2*



Medtronic N'Vision Clinician Programmer Guide 5-1



198311001
Rev A



Size inches (mm)/CTC
UC200101473 EN xxx
release
Define as desired



Troubleshooting
Troubleshooting Reference Guide

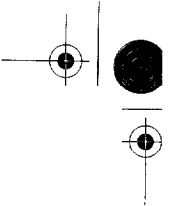
Troubleshooting Reference Guide

Table 5-1. Quick Reference Troubleshooting Guide

Problem	Possible Solution
<ul style="list-style-type: none"> • Power is ON, but there is no self test or display • The programmer cannot be operated • A menu or function is locked 	<ul style="list-style-type: none"> • Turn the programmer off and turn it back on • Check to ensure batteries are installed properly • Install fresh "AA" batteries
<ul style="list-style-type: none"> • Telemetry session is interrupted or not initiated 	<ul style="list-style-type: none"> • Ensure that the application card is correctly in place • Check batteries
<ul style="list-style-type: none"> • Power to programmer is suddenly interrupted 	<ul style="list-style-type: none"> • Replace batteries
<ul style="list-style-type: none"> • Programmer is not communicating with printer 	<ul style="list-style-type: none"> • Clean the IR lens • Check that the correct default printer is selected for use • Contact the printer manufacturer for printer-specific troubleshooting information • Move programmer closer to printer and try again
<ul style="list-style-type: none"> • Telemetry cannot be established 	<ul style="list-style-type: none"> • Reposition the telemetry head over the pump or neurostimulator • Move the telemetry head closer to the patient's device
<ul style="list-style-type: none"> • Programmer is operating erratically 	<ul style="list-style-type: none"> • Ensure no nearby equipment (e.g., MRI, lithotripter, powerful computer monitor) is generating EMI. EMI may cause a disruption in programmer function.

For questions about maintenance of the N'Vision Programmer, call the Medtronic Neurological Division at the phone numbers listed on the back page of this manual.

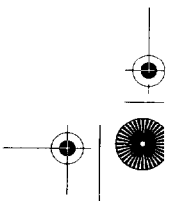
For repairs and returns of the N'Vision Programmer, contact your local Medtronic representative or the Neurological Division.



Specifications **6**



***N'Vision Programmer
Specifications 6-2***



Specifications
N'Vision Programmer Specifications

N'Vision Programmer Specifications

Electrical and Operating Characteristics

Power source: 4 "AA" commercially available alkaline batteries (IEC 86-1)

Battery life (with fresh batteries): Approximately 40 hours

Clock back-up battery: Type BR1225 lithium coin cell

Length: 22 cm (8.75 in)

Width: 10 cm (3.75 in)

Height: 4 cm (1.60 in)

Weight (without batteries): 680 g (24 oz or less)

Case material: Thermoplastic resin and magnesium

Telemetry module cable: 90–100 cm (36–40 in)

Screen:

Color: 4 shades of grey

Screen size: 240X640 pixels

Serial interface: IR communication link (IrdA 1.0)

Operating type: Continuous

Specifications
N'Vision Programmer Specifications

Programmer Storage and Operating Conditions

Table 6-1. Programmer Storage and Operating Conditions

Parameter	Storage	Operating
Minimum temperature	-40°C (-40°F)	9.4°C (49°F)
Maximum temperature	65°C (149°F)	43.3°C (110°F)
Minimum humidity	30% (non-condensing)	30% (non-condensing)
Maximum humidity	75% (non-condensing)	75% (non-condensing)
Minimum Atmospheric pressure	700 hPa (20.7 in. Hg)	700 hPa (20.7 in. Hg)
Maximum Atmospheric pressure	1060 hPa (31.3 in. Hg)	1060 hPa (31.3 in. Hg)

Note: The N'Vision Programmer is IrDa 1.0 compliant at data rates of 9600 and 115200 bits per second.

Specifications
N'Vision Programmer Specifications

Glossary

A

Glossary

Active icon – A graphical representation of a button that, when selected, initiates an operation or action.

Application card – A small computer disk on which Medtronic Neurological therapy applications are housed.

Hard key – A programmer button that, when depressed, initiates an operation or action.

Inactive icon – A graphical representation of a button that offers status information. Use of inactive icons results on no operation or function initiation.

Localization parameters – Options for selecting country-specific formats for date, time, and numbering schemes.

Platform session data management – A feature housed on the N'Vision Programmer that allows collection and storage of patient data information gathered during patient sessions.

Stylus – A pen- or pencil-shaped device used to make contact with a touch screen on a device such as a computer or programmer.



MEDTRONIC CONFIDENTIAL

8840_EN.book Page 3 Tuesday, June 26, 2001 3:37 PM



REFRNCEN.BCV



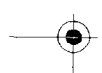
198311001

Blank For Position Only. Do Not Print!

Rev A



Size inches (mm)/CTC
UC200101473 EN xxx release
Define as desired





Manufacturer
Medtronic, Inc.
710 Medtronic Parkway NE
Minneapolis, MN 55432-5604
USA
Internet: www.medtronic.com
Tel. 763-505-5000
Fax 763-505-1000

**Medtronic E.C. Authorized
Representative/Distributed By**
Medtronic B.V.
Wenckebachstraat 10
6466 NC Kerkrade
The Netherlands
Tel. 31-45-566-8000
Fax 31-45-566-8668

**Europe/Africa/Middle East
Headquarters**
Medtronic Europe S.A.
Route du Molliau
1131 Tolochenaz
Switzerland
Internet: www.medtronic.co.uk
Tel. 41-21-802-7000
Fax 41-21-802-7900

UC200101473 EN
PN198311-001 Rev. A
© Medtronic, Inc. 2000
All Rights Reserved