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**Medtronic**

## **Nexus-D System**

### **Instructions for Use in a Research System**

**CAUTION – Investigational device. Limited by Federal (or United States) law to investigational use.**

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## Explanation of symbols on product



Non-ionizing radiation



Consult Instructions for Use



Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations



Type BF applied part (IEC 60601)



Manufacturer



Manufactured At



Serial Number

## Warnings / Precautions

- ⚠Caution:** Remove the batteries from the device when it will not be used for several weeks. A battery left inside the device can start leaking, which can damage the electronic circuitry.
- ⚠Caution:** Replace the batteries after four hours of use.
- ⚠Caution:** Be careful not to allow liquid into any Nexus-D System components.
- ⚠Caution:** If the external antenna is used, only connect and disconnect the antenna to/from the system while the power is off to avoid damaging the Nexus-D System hardware. Do not pull on the cable to disconnect the antenna.
- ⚠Caution:** Do not change the connection between the external antenna and the Nexus-D System during active telemetry sessions. Connecting or disconnecting can damage Nexus-D System electrical components.

## Abbreviations and Definitions

8181	The Model 8181 Activa PC+S Sensing Programmer used to set up the Activa PC+S for waveform sensing and real time data viewing
8840	The Model 8840 Clinician Programmer unit used to set up neurostimulator stimulation functionality
8870	The software used on the Model 8840 to program the non-sensing parameters of the neurostimulator
37642	The Model 37642 DBS Patient Programmer unit used to access and modify the stimulation functions of the Activa family neurostimulators
DBS	Deep brain stimulation
DEC	Decrement
INC	Increment
INS	Implantable neurostimulator
IR	Infrared
NAK	Response code that indicates problems encountered in processing an associated request
STM	Streaming Telemetry Module
USB	Universal serial bus

## Applicable Documents

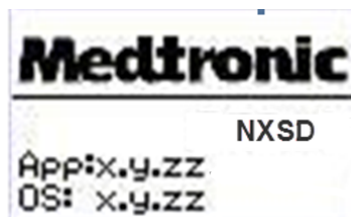
Number	Version	Title
NRP1088-35854	2.0	Nexus-D System USB Driver Installation Guide
NRP1088-35790	8.0	Interface Specification, Nexus-D System

## 1.0 Introduction

The Medtronic Nexus-D System provides a communication conduit between a host computer and an Activa family (Activa PC+S, Activa PC, Activa RC, and Activa SC) implantable neurostimulator (INS). It is intended exclusively for research use.

This user manual is complementary to the Nexus-D System Interface Specification which provides details of the implementation of a host computer application to interface to the Nexus-D System. This user manual provides high-level information while the interface specification provides implementation details.

This user manual applies to both the Nexus-D System and the Nexus-D2 System. All Nexus-D System functionality is incorporated in the Nexus-D2 System. New functionality that is only supported by the Nexus-D2 system will be noted. The Nexus-D family is defined by the application version (see Table 1: Nexus-D System Family Versions). The version is displayed when batteries are replaced in the Streaming Telemetry Module (STM). A “Splash Screen” will display for several seconds after battery replacement with the following information:



**Table 1: Nexus-D System Family Versions**

System Designation	App Version
Nexus-D	App: 2.6
Nexus-D2	App: 2.7

The Activa PC, Activa RC and Activa SC are stimulation-only neurostimulators. The Activa PC+S adds sensing capability to the Activa PC platform. Throughout this system, when functionality pertains to stimulation, it is assumed that the functionality applies to the Activa family neurostimulators. When functionality pertains to sensing, it is assumed that the functionality applies to only the Activa PC+S.

The Nexus-D System must always be used under the direction of a physician (i.e., in an in-clinic environment), with a Model 8840 Clinician Programmer, Model 37642 DBS Patient Programmer, and Model 8181 Activa PC+S Sensing Programmer available for use.

**⚠ Caution:** Availability of the Model 8840 Clinician Programmer and Model 37642 DBS Patient Programmer allows the INS stimulation to be turned off if necessary.

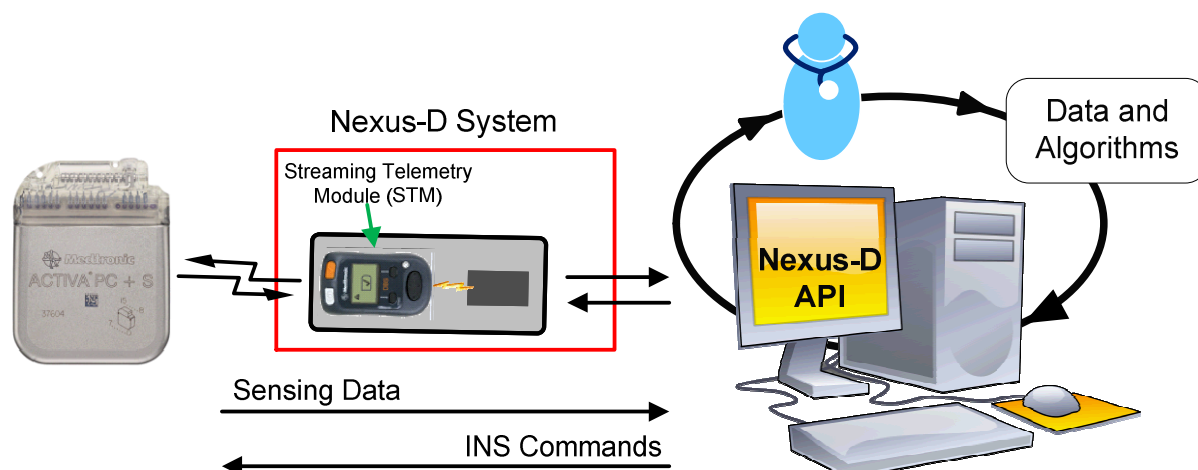
## 2.0 Nexus-D System Description

The Nexus-D System shown in Figure 1 is a bidirectional telemetry system component that facilitates exploration of generic closed-loop therapy algorithms. In operation, the host computer sends commands to the Nexus-D System through a USB port to request data and update stimulation parameters of the INS. Throughout this document, the “host” refers to the computer system that is connected to the Nexus-D system.

The Nexus-D System is designed to function in a similar manner as a patient programmer. In this light, all Nexus-D stimulation control will be bound by the limits and interlocks set forth by the Model 8840 Clinician Programmer.

The Nexus-D System consists of two components housed in a sleeve: the Streaming Telemetry Module (STM) that communicates with the INS and a USB-to-IR adaptor that interfaces the STM to the host computer through a USB port.

The Interface Specification for the Nexus-D System is a separate document that describes in detail the message sequencing requirements for connection establishment, link management, and status reporting. This user guide provides a high-level description of Nexus-D System operations, and refers to the Interface Specification when detailed information is needed.



**Figure 1: Nexus-D System run-time system components**

## 2.1 Host Computer Requirements

The host computer performance requirements are as follows:

- Windows based operating system
- USB port

## 3.0 Setup

### 3.1 Installing the STM Batteries

The STM operates on two AAA alkaline batteries. Use only alkaline batteries or telemetry communication may be degraded.

1. Confirm that there is no telemetry session active and unplug the external antenna (if used), open the top flap from the sleeve and remove the STM from the sleeve.
2. Open the battery compartment cover by sliding the cover forward and lifting as shown in Figure 2. Install the two AAA batteries in the proper polarity shown in Figure 2.



**Figure 2: STM battery compartment and splash screen**

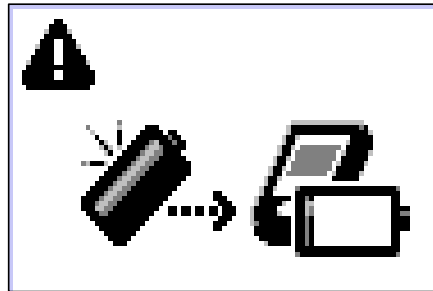


3. Upon installing the batteries, the splash screen displays for eight seconds, identifying the Nexus-D System and showing its application and operating system version numbers. x.y.zz represents the version of the latest software installed.
4. Press any key to exit the splash screen before the eight-second timeout.
5. Turn the STM off, slide the STM back into the sleeve, fasten the Velcro strap, and connect the external antenna (if used).

**⚠ Caution:** Remove the batteries from the device when it will not be used for several weeks. A battery left inside the device can start leaking, which can damage the electronic circuitry.

### 3.2 Replacing Batteries

Battery status is shown on the display. When the battery level is depleted, the indication shown in Figure 3 is displayed, commands are not executed, and a NAK (unsuccessful communication - battery depleted) code is returned when commands are received by the Nexus-D System.



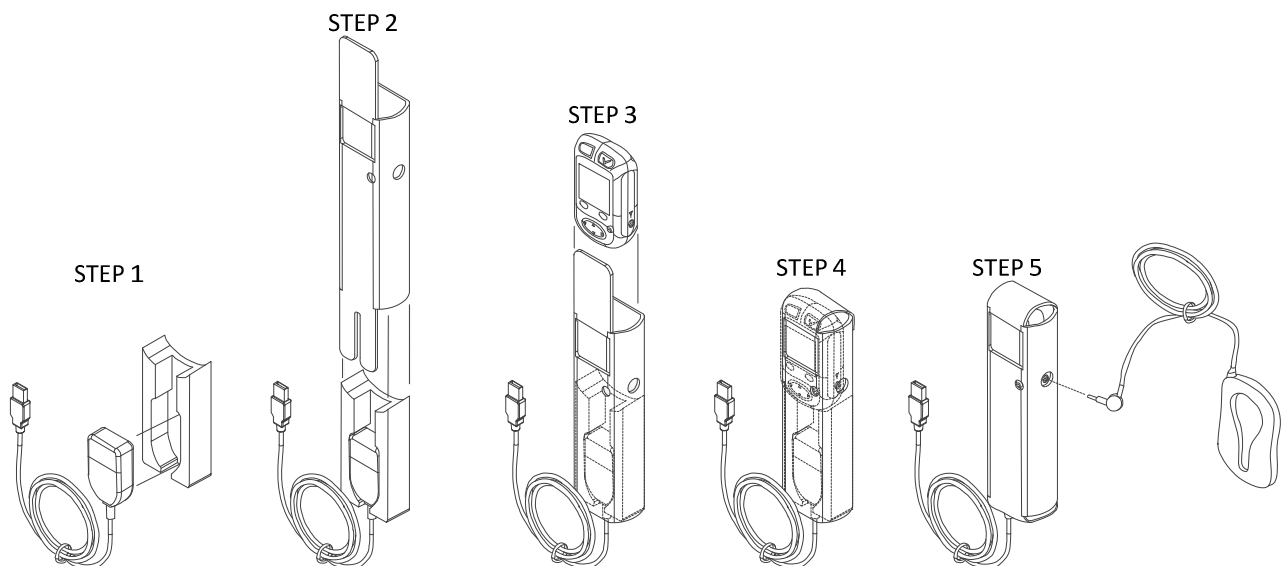
**Figure 3: Screen shows that battery is depleted**

**⚠ Caution:** Replace the batteries after four hours of use.

To change batteries, open the battery compartment cover by sliding the cover forward and lifting, and replace the batteries as shown in Figure 2.

### 3.3 Assembling the Nexus-D System Components

Figure 4, below, shows how the components of the Nexus-D System are assembled.



**Figure 4: Assembling the Nexus-D system components**

1. Place the USB-to-IR adapter (Actisys IR Wireless Interface) into the foam cradle. (Step 1)

2. Slide the cradle into the sleeve and fasten the Velcro straps to hold it in place. (Step 2)
3. Open the top flap and slide the STM into the sleeve and fasten the Velcro strap to hold it in place. (Step 3)
4. Step 4 shows the completed Nexus-D System assembly.
5. If an external antenna is used, insert the antenna connector into the jack on the side of the Nexus-D System. (Step 5)

**Note:** Use of the external antenna is optional.

**⚠ Caution:** If the external antenna is used, only connect and disconnect the antenna to/from the system while power is off to avoid disabling the telemetry antenna. Do not pull on the cable to disconnect the antenna.

**⚠ Caution:** Do not change the connection between the external antenna and the Nexus-D System during active telemetry sessions. Connecting or disconnecting can damage Nexus-D System electrical components.

## 3.4 Setting up the INS

### 3.4.1 Stimulation Setup

Before using the Nexus-D System, set up the INS using the Model 8840 Clinician Programmer unit to define leads, amplitudes, pulse width, and rate at the group level. Refer to the "8840/8870 N'Vision Programming Guide for Activa PC, RC and SC" for details.

The Nexus-D System is only capable of changing stimulation settings within the limits set by the 8840 programmer. Use the "Patient Programmer" menu selection to specify which parameters can be changed. See Figure 5 (representative only).

The Nexus-D System provides a Restore Clinician Settings command which can be used to restore individual or all groups that were programmed by the Model 8840 Clinician Programmer. Refer to the "8840/8870 N'Vision Programming Guide for Activa PC, RC and SC" for details of programming the INS groups. To enable the use of the Restore Clinician Settings command, be sure to use "End Session" and "Exit" from the 8840 menu which stores the currently programmed groups to a memory location in the INS so they can be restored if desired. You must explicitly end the 8840 session (See Figure 6 – representative only). Then you can use the Restore Clinician Settings command to revert to the initial settings after modifying them with the Nexus-D System. Refer to the Interface Specification for more details about the Restore Clinician Settings command.

**Note:** Therapy must be off to restore all clinician settings. If therapy is on, the Restore Clinician Settings command will turn therapy off. The Nexus-D System's host computer is responsible to return stimulation to the desired state after performing a "restore."

**⚠ Caution:** The Model 8840 Clinician Programmer should be used to verify the patient's stimulation parameter state after using the Nexus-D System.

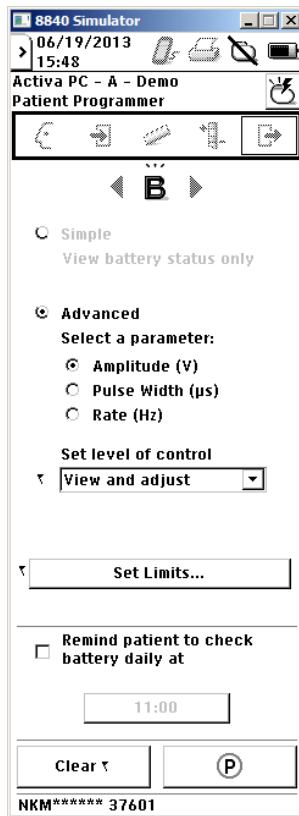


Figure 5: Set view and adjust parameters

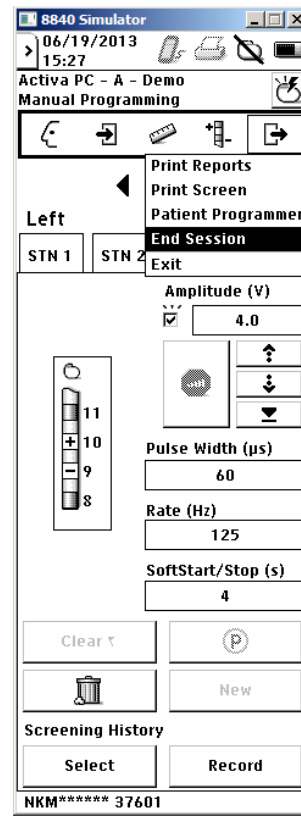


Figure 6: Exit menu

### 3.4.2 Sensing Setup

Use the Sensing Programmer to set up the Activa PC+S waveform sensing configuration. Refer to the 8180 Sensing Software Guide for details. Nexus-D System does not have the ability to change any of the sensing parameters.

**Caution:** The Sensing Programmer should be used to verify the patient's sensing parameter state after using the Nexus-D System.

## 3.5 Installing the USB Driver on the Host Computer

Install the USB driver on the host computer to enable communication between the computer and the Nexus-D System. See the Nexus-D System USB Driver Installation Guide for details on installation and configuration.

## 4.0 Nexus-D System Operation

### 4.1 Cleanliness

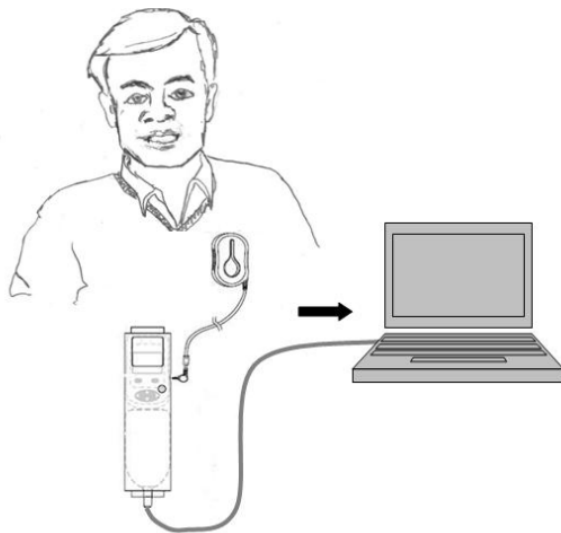
The Nexus-D System should always be cleaned between patient sessions. Wipe patient-contacting components with an antibacterial solution before use. The unit should be bagged when there is a risk of spreading infection.

**Caution:** Be careful not to allow liquid into any Nexus-D System components.

**Caution:** Be careful when using the Nexus-D System with a patient with a pre-existing infection.

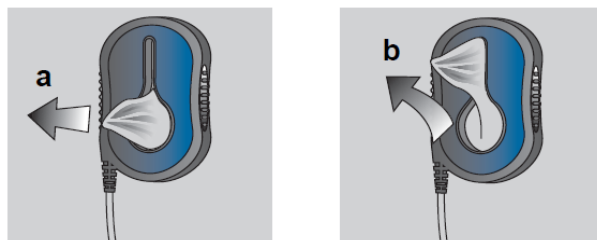
## 4.2 Starting the Nexus-D System

1. Connect the USB connector to the host computer that will be running the user data collection and algorithm development system as shown in Figure 7.
2. Place the Nexus-D System (or the external antenna, if used) over the INS.



**Figure 7: Nexus-D System connection/setup**

3. If you are using the antenna, pull the fabric of the patient's clothing through the large opening in the antenna as shown in Figure 8. Then, wedge the fabric in the narrow slit to secure the antenna in place.



**Figure 8: Pull the fabric through the slit of the antenna (a) and wedge in place (b)**

4. Turn on the Nexus-D System by pressing the white, power-on button under the display window and to the right as shown in Figure 9. The power-on button is the only functional button on the Nexus-D System. The main screen is shown when the Nexus-D System powers on.

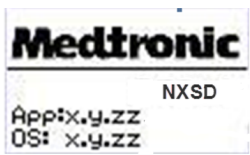



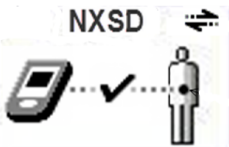


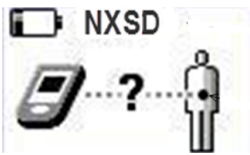

**Figure 9: The Nexus-D System On/Off key and main screen**

**Note:** The Nexus-D System should always be power-cycled (turned off and then on) between sessions with different patients.

The following table shows the types of screens that display the status for the Nexus-D System.

**Table 2: Nexus-D System display screens**

Screen	Description	Comments
	Splash Screen	The splash screen displays when the Nexus-D System's batteries are inserted.  The application and operating system version numbers x.y.zz represent the version of the latest software installed.
	Battery Depleted Screen	When the battery level is depleted, commands are not executed and an NAK (unsuccessful communication – battery depleted) is returned when commands are sent.  Replace the batteries to clear this screen and restore normal operation.
	Main screen in idle state	The lower portion of the main screen is blank when in idle state, unless low battery is indicated.
	Low Battery	When the low battery screen is first displayed, the batteries will function for approximately 30 minutes more.
	Maintenance session screen showing link to neurostimulator and real-time data retrieval	When a maintenance session is active, the battery status does not display because telemetry is continuous; the bi-directional arrows in the top right of the display indicate maintenance state. The display flashes while in real-time data uplink mode  When a supervisory session is active, the battery status does not display if no battery measurement is made for 10 minutes. Battery measurements are made when no

Screen	Description	Comments
		telemetry has been executed for 30 seconds.
	Low battery and neurostimulator is not linked	When the power button is pressed or when the splash screen clears, this screen is displayed. The battery icon shows ¼ full, ½ full, ¾ full or full. The question mark indicates that Nexus-D System could not locate the INS, or that it was not the device that it was expecting, so the Nexus-D System is not linked to the neurostimulator. An audible tone is issued.
	System Error Screen	<p>The System Error Screen is displayed if there is a critical error detected by the Nexus-D System application that prevents the system from continuing operation. The system error screen is a static screen that displays a code indicating the type of error detected. A battery reset (remove the batteries and replace them) is required to clear this screen.</p> <p>This screen should not appear in normal operation, if it does, please contact Medtronic for assistance.</p>

### 4.3 Operation States

The Nexus-D System has three states of operation: active, idle, and sleep.

#### 4.3.1 Active State

The Active state is entered when a command is received by the Nexus-D System from a host computer. Within the Active state, there are two session types: Supervisory and Maintenance (real-time uplink mode). While in the Active state, a Supervisory Session is always running. A Maintenance Session can only be initiated to run when a Supervisory Session is already running. The two types of sessions are described in more detail below.

##### 4.3.1.1 Supervisory Session

In a supervisory session, all commands are initiated by the host computer. Nexus-D System waits for the host to send a command. If no command is received within two minutes, Nexus-D System transitions to sleep state. This no-activity timer value can be changed to any number between 1 and 15 minutes using the Set Nexus Configuration command.

**Note:** If a response to a command is not received, the host computer should not resend the command until the specific command response timeout period has been exceeded to avoid a potential collision between the resent command and the command response from the previous command.

If there is no response to a command within a defined number of milliseconds, a timeout must be implemented by the host computer. Timeout values are listed along with the commands in the Commands table in the Interface Specification.

Nexus-D System commands are used to perform the following types of functions:

- Retrieve INS settings
- Configure Nexus-D System
- Turn sensing On/Off
- Turn real-time mode On/Off
- Retrieve real-time data
- Cycle stimulation
- Reset cycle stimulation
- Turn therapy On/Off

- Change therapy group
- INC/DEC amplitude
- INC/DEC pulse width
- INC/DEC rate
- Restore clinician (8840) settings
- Send external marker
- Output stim window (added in Nexus-D2 System)
- Retrieve sense state (added in Nexus-D2 System)

If the connection between the Nexus-D System and the neurostimulator is lost, the neurostimulator stimulation will continue without change.

**⚠ Caution:** The Nexus-D System does not enforce any delay between commands to simulate patient programmer command timing. The Nexus-D System transfers the commands as fast as possible.

#### 4.3.1.2 Maintenance Session

A Maintenance Session is only allowed when connected to an Activa PC+S device. The host computer initiates the maintenance session by sending the Start Real Time command. In a maintenance session, Nexus-D automatically requests a real-time data packet from the Activa PC+S neurostimulator every 400 ms. The Nexus-D System stores the latest real-time data packet until the host computer requests the data or another data packet from the Activa PC+S neurostimulator is received. If the host computer doesn't request the current data packet before another data packet is received, the current data packet is lost.

To terminate a maintenance session, send a Stop Real Time or Stop Sensing command from the host computer to the Nexus-D System, or press the power key to transition to the sleep state.

If no Get Real Time Data command is received within 10 seconds after sending the Start Real Time command, the Nexus-D System transitions from the maintenance session to a supervisory session. **Note:** The timeout value can be changed to any number between 1 and 30 seconds using the Set Nexus Configuration command.

Upon exit from the maintenance session, the neurostimulator sensing state is restored to the state it was in before the maintenance session started. Exception: The Stop Sensing command terminates the maintenance session and disables sensing.

#### 4.3.2 Sleep State

Press the power key from any active state to enter the sleep state. Sleep state is also entered if the no-activity timer expires in a supervisory session. The display is blank while in sleep state.

**Note:** The Nexus-D System reverts to default settings whenever the system enters sleep state.

#### 4.3.3 Idle State

Press the power key from the splash screen or sleep state to enter the idle state. The last-measured battery level is displayed and the Nexus-D System waits for a command from the host computer.

## 5.0 Writing a Host Application

### 5.1 Commands

The Nexus-D System operates with a fixed set of commands and response codes that are listed in the Interface Specification. Command and response formats are defined in the Interface Specification. Every command response will contain a response code. This response code must be checked by the host application to determine the outcome of the command (i.e. success or reject reason).

The timing of sending commands to the Nexus-D System is critical. Commands, responses, and timeout lengths are listed in the Commands table in the Interface Specification. Synchronize the sending of a command

to the reception of the response of the previous command (i.e. – don't use a timer to control the sending of a command).

### 5.1.1 Response Code Handling

Some response codes are generated by the Nexus-D System itself while the others are generated by the INS and passed to the host computer by the Nexus-D. Table 3: Response Codes provides suggestions of how to handle various response codes.

Table 3: Response Codes

Response Code	Description	Suggested Handling
10 – 15, 20 – 27, 51, 54, 59	The INS stimulation parameter sent is invalid, out of range, or reached an upper or lower limit.	Send a valid stimulation parameter. Refer to Interface Specification for details of specific parameter.  Use the 8840 or Sensing Programmer to check current settings
18	Clinician settings are invalid	Reprogram clinician settings with the 8840
29	Out of Regulation (OOR) event	Send the Cycle Stim to reset the OOR condition.
30, 50	A therapy change or transition in the INS is in progress	Resend the command.
32, 110	Device reset	Use an 8840 to clear the power on reset condition. Cycle Nexus-D System power.
101	Nexus-D System not ready to execute command. Nexus-D System is not in the correct state to support the command.	Put Nexus-D System in the appropriate state. For example, if the Nexus-D System is not linked to an INS, the Nexus-D System will respond with this code when Get INS Info command is sent. Refer to the Interface Specification for details.
102 and 103	Invalid Nexus-D System command or data	Refer to the Interface Specification for a valid command or data
105	Real time not active	Send Start Real Time command.
106	Sense configuration error (e.g. – compression is disabled)	Use the Sensing Programmer to resolve the issue (e.g. – enable compression)
107	No telemetry response	Reposition the Nexus-D



		<p>System external antenna over the INS.</p> <p>Remove the external antenna and place the Nexus-D System directly over the INS to allow the use of the internal antenna</p> <p>Reduce environmental electrical interference</p> <p>Possibly trying to communicate to a non-Activa family neurostimulator.</p> <p>Possibly trying to communicate to a different INS, so power cycle the Nexus-D System.</p>
108	Telemetry error	Use the 8840 to check the state of the INS. If this response continues, contact Medtronic.
109	INS Filtering On – real-time will not start.	Use the Sensing Programmer to turn INS filtering off.
111	Activa PC+S responded unexpectedly while uplinking real-time data	Use the 8840 to check the state of the Activa PC+S. If this response continues, contact Medtronic.
112	Activa PC+S responded with null packets for too long while uplinking real-time data.	Resend the Start Real Time command
114	The INS didn't execute all the batch commands.	Check the actual number of executed commands in the command response.
115	The INS Type does not support the command sent.	Do not send any sensing type commands to an Activa PC, RC, or SC.
232 – 234, 241 - 246	Activa PC+S sensing issue	Contact Medtronic
235	Sensing is not configured correctly for the trigger.	Refer to the Set Trigger Command section in the interface specification

## 5.2 Real Time Data

The host application must send a Get Real Time Data command to retrieve each individual data packet from the Nexus-D System. The format and content of a real time data packet is described in detail in the Interface Specification.

### 5.3 Host Priority

While managing a maintenance session, the host computer application must implement one of two approaches: 1) data priority or 2) therapy priority. The approaches differ based on the interleaving of stimulation update commands and data requests.

The data priority approach allows the host computer to request all real time data but requires the host computer application to interleave therapy commands with Get Real Time Data commands, thereby slowing the rate of therapy changes in the Avisa PC+S device.

In the therapy priority approach, the host sends therapy commands one after the other, which will likely result in the loss of some real time data packets. See the Interface Specification for a discussion of these methods.

### 5.4 Latency

It is important to minimize the time between the reception of a real-time data packet and the sending of a stimulation update command. The effect of latency and latency timing (time between data being ready in the neurostimulator and being received by the host computer, or time between a command being sent by the host computer and being received by the neurostimulator) is described in detail in the Interface Specification.

### 5.5 Host Responsibilities

#### 5.5.1 Therapy Updates

When therapy updates are made, the result of the update is returned to the host computer. It is the responsibility of the host computer to manage the stimulation settings. The Nexus-D System assumes no knowledge of the stimulation settings.

#### 5.5.2 Nexus-D Timeout Prevention

The Nexus-D System will timeout after specified time periods of no activity. It is the responsibility of the host computer to periodically send the appropriate commands to the Nexus-D System (e.g. - Get Real Time Data command to continue the maintenance session, Get Status command to continue the supervisory session).

## 6.0 Troubleshooting

Problem	Possible cause	What to do
The power button is pushed but there is no display.	There are no batteries, the batteries are installed backwards or the batteries are dead.	Check for batteries. Check battery polarity. Replace the batteries.

Problem	Possible cause	What to do
The Nexus-D System beeps then displays the telemetry error screen.	<p>If the external antenna is being used, it may not be plugged in all the way.</p> <p>The antenna (internal or external) may not be placed over the device properly.</p> <p>There is EMI interference.</p> <p>The external antenna jack is damaged.</p>	<p>Ensure that the antenna is plugged in.</p> <p>Place the antenna over the device.</p> <p>Move causes of interference (computers, monitors).</p> <p>Remove the external antenna and place Nexus-D System directly over the INS to allow the use of the internal antenna</p> <p>Remove any other telemetry antennae from area</p>
Missing data packets	Host computer not requesting data packets fast enough	<p>Shorten the delay between the Get Real Time Data commands (may need to delay stimulation updates).</p> <p>Refer to the interface specification for more details.</p>
Reception of NAKs	Protocol or Nexus-D System issue	Refer to the NAK code in the interface specification
Cannot establish communication with the Nexus-D System	<p>The communication port on host computer is in use by another application.</p> <p>Incorrectly using Sensing Programmer Telemetry Module instead of Nexus-D System</p>	<p>Terminate the other applications and try again.</p> <p>Use Nexus-D System</p>

Problem	Possible cause	What to do
	Nexus-D System hardware issue	Remove the dongle from sleeve to view the LED indicator on the dongle while attempting to establish communication. If the LED does not blink when a command is sent, contact Medtronic. If it does blink, then verify the host computer port configuration. Refer to Interface Specification for configuration details
	Forming the command header incorrectly	Refer to the Interface Specification for more details.

## **Declaration of Conformity**

Medtronic declares that this product is in conformity with the essential requirements of Directive 1999/5/EC on Radio and Telecommunications Terminal Equipment.

Note: This device is exclusively for clinical investigations according Directive 90/385/EEC on Active Implantable Medical Devices

## Contact Information

For more information about Nexus-D System contact the Medtronic Research Site Contact for your study.

### Manufacturer

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