Medtronic

Activa® SC, Activa® RC and Activa® PC

NEUROSTIMULATORS FOR DBS

PROGRAMMING GUIDE

OVERVIEW

This guide describes many key functions of the Activa® SC, Activa® RC and Activa® PC neurostimulation systems and software for the Model 8840 N'Vision® Programmer. This guide does not replace the product technical manuals. For complete instructions, contraindications, warnings, and precautions, consult the product technical manuals.

The following products are referenced:

1. Activa® SC Neurostimulator (Model 37602 and 37603)
2. Activa® RC Neurostimulator (Model 37612)
3. Activa® PC Neurostimulator (Model 37601)
4. Medtronic DBS Patient Programmer (Model 37642)
5. External Neurostimulator (ENS) (Model 37022)
6. N'Vision® Clinician Programmer (Model 8840)
7. Recharging System (Model 37651)

TABLE OF CONTENTS

Information Icon—Refers to Additional Information.

PROGRAMMING FEATURES

The advanced programming system is used for patient management through a menu-driven navigation system.

Guided Profile

Steps the user through the capture of a standard set of patient and system information, including:

- Lead Configuration
- Patient Data
- Lead Data
- Baseline
- Device Data

Guided Programming

Offers a systematic, step-by-step approach to programming basic therapy parameters. On-screen prompts guide you through each of the basic steps, from the initial electrode selection, to testing and recording the effects of various amplitudes, to programming the final selections *(refer to pages 36–59)*.

Manual Programming

Offers flexibility in programming basic and advanced therapy settings *(refer to pages 61–93)*.

Voltage Mode & Current Mode Options

Offers an opportunity to choose the desired operating mode using the N'Vision Clinician programmer. The programmed values are automatically displayed in either volts (voltage mode) or mA (current mode) *(refer to page 45)*.

External Neurostimulator (ENS)

Used to deliver stimulation during interoperative screening or postoperative test stimulation. Programmed with the N'Vision clinician programmer. *(refer to pages 8–15)*.

Medtronic DBS Patient Programmer

Used to check device status and adjust parameters. Using an icon-based LCD screen, patients can choose from up to four stimulation groups, increasing their ability to control their therapy within clinician-defined limits *(refer to pages 82-87)*.

INTRAOPERATIVE TESTING SEQUENCE

Prepare for the Intraoperative Test Stimulation Process:

1. Turn the N'Vision programmer ON.
2. Select the neurostimulator icon to navigate to the NEUROSTIMULATION DESKTOP screen.
3. Interrogate the ENS by holding the programming head steady over the neurostimulator and pressing the PROGRAMMING button.
4. Select a therapy on the CONFIGURE TEST STIM screen.
5. Select the test stimulation option. Options include: New or Follow-up.

Configure the Lead and Check System Performance:

1. Follow the prompts on the GUIDED PROFILE screen.
2. Check electrode impedance, if desired.

Set Stimulation Parameters:

1. Ensure the neurostimulator is ON.
2. Set electrode polarities.

   Note: *This step is not applicable if alligator clips are used.*
3. Set rate and pulse width.
4. Set amplitude resolution and amplitude.
5. If desired, set stimulation parameters for a second program.

   Note: *This step is not applicable if alligator clips are used.*
6. Check therapy impedance, if desired.

Complete the test stimulation process:

1. Exit application.

EXTERNAL NEUROSTIMULATOR (ENS)

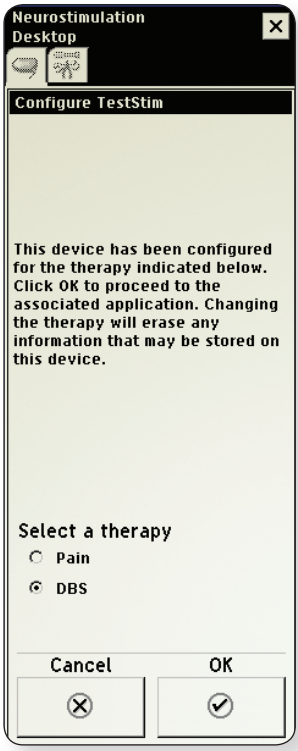
To program for intraoperative screening, the Model 37022 External Neurostimulator (ENS) is connected to the Model 8840 Clinician Programmer. The Model 8870 application card provides the software to program the ENS for this procedure.

When the external neurostimulator is interrogated, the programmer identifies the neurostimulator model and reads the current neurostimulator configuration.

Therapy automatically turns OFF when:

- The screening cable is disconnected from the ENS.
- Moisture is detected.
- The battery door is opened.

Note: *Therapy can be manually turned OFF using the red Therapy Stop button on the external neurostimulator.*


Neurostimulation
Desktop
Configure TestStim
This device has been configured for the therapy indicated below. Click OK to proceed to the associated application. Changing the therapy will erase any information that may be stored on this device.
Select a therapy
Pain
DBS
Cancel
OK

TEST STIM

Use intraoperative test stimulation to determine the optimal site of stimulation.

New and follow-up options are available from the TESTSTIM SELECTION screen after initial interrogation and ENS identification.

Note: *When using the ENS for intraoperative screening, the N'Vision programmer software takes approximately 60 seconds to load.*

1 **New**

Select for new test stimulation session with full programming capabilities:

- Previous session information will be cleared
- Used to determine optimal placement of the test lead

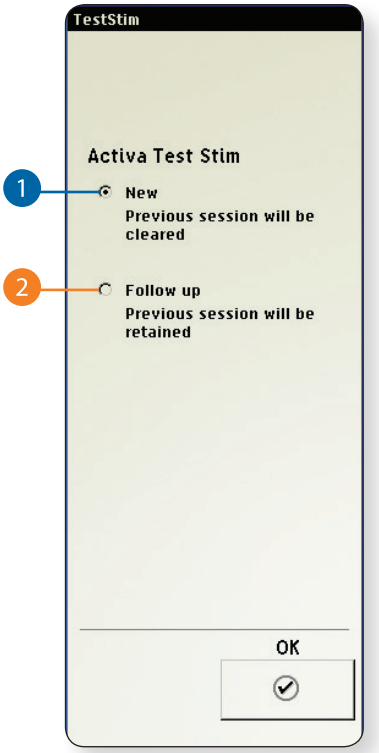
2 **Follow-up**

Select for test stimulation session follow-up or continuation with full programming capabilities:

- After one hour of inactivity, choose the Follow up option to resume your test stimulation session (previous session information is retained)
- Used to re-establish the target site for the Medtronic DBS lead and continue intraoperative testing

Note: *Use the lowest effective amplitude and pulse width values. High amplitude and pulse width combinations can result in excessive charge density.*

When changing therapy parameter settings, increase or decrease in small increments while evaluating the patient's response.


TestStim
Activa Test Stim
1
New
Previous session will be cleared
2
Follow up
Previous session will be retained
OK

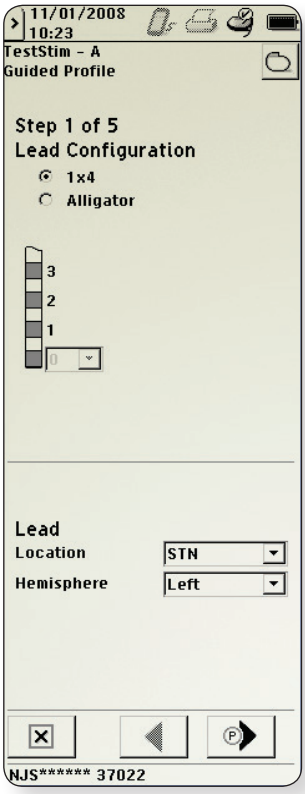
SCREENING CABLES

Two screening cables are available for intraoperative screening:

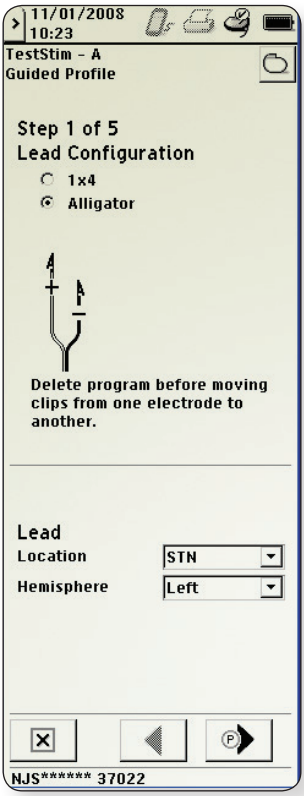
1. 1 x 4 Twistlock screening cable (Model 3550-68), used for:
   - One or two programs (one hemisphere)
   - Rates up to 250 Hz or 125 Hz with two programs
   - Pulse widths from 60–450 µs
   - Amplitude from 0–10.5 V or 0–25.5 mA

2. Alligator clip screening cable (Model 3550-67), used for:
   - One program (one hemisphere)
   - Rates up to 250 Hz
   - Pulse widths from 60–450 µs
   - Amplitude from 0–10.5 V or 0–25.5 mA

The Lead Configuration screen will reflect the screening cable selected.



1 1 x 4 Twistlock Screening Cable



2 Alligator Clip Screening Cable

LEAD CONNECTION CHECK (LCC)

The Lead Connection Check feature is available when using the diagnostic screens of the Activa DBS Model 37642 patient programmer and is available for use during the implant of an Activa SC, Activa RC or Activa PC neurostimulator.

The Medtronic DBS patient programmer may be used to quickly check connections between the leads, extensions, and INS.

This Patient Programmer feature:

- Counts the number of "OK" electrodes
- Does not check for short circuits
- Tests at 1.5 V, 80 µs, 100 Hz
- Does not test all electrodes, but only selected specific pairs

Using Lead Connection Check (LCC)

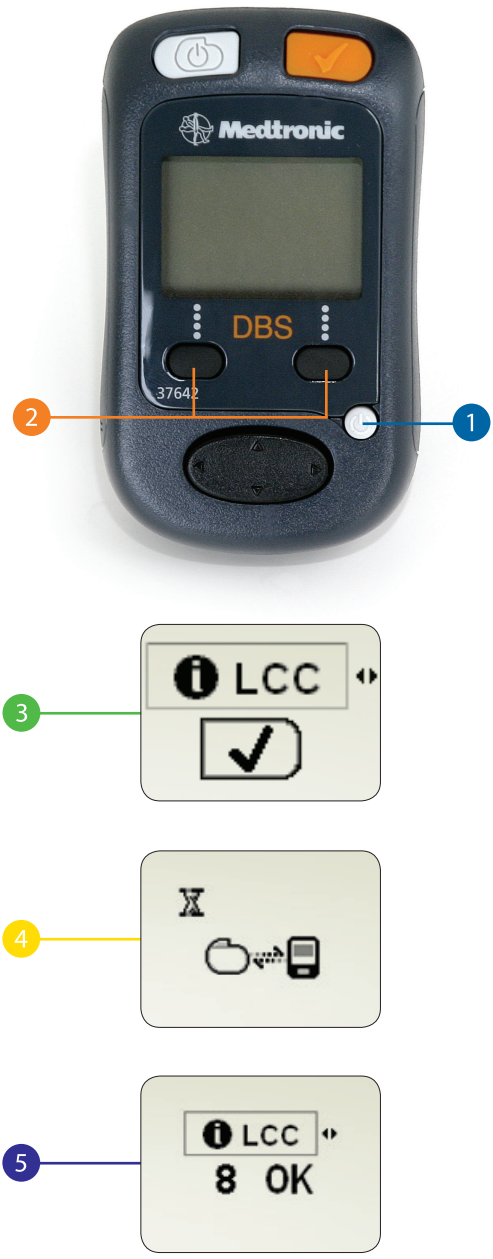
1. Turn the Activa DBS patient programmer ON.
2. Simultaneously press and hold the SELECTION keys.
3. The Lead Connection Check screen will display.
4. In a clear sterile bag, place the Medtronic DBS patient programmer over the INS and press the Check key () to initiate the lead connection check.

   Note: *The Communication screen will be displayed while the LCC screen is in progress*

5. When the Lead Connection Check is complete, the number of connected electrodes will be displayed.

   Note: *If the number of electrodes shown does not correspond with the number expected or to check the impedance of these connections, use the N'Vision Clinician Programmer.*

   Note: *The maximum number of connected electrodes for Activa SC is four. The maximum number of connected electrodes for Activa RC and PC is eight.*


Medtronic
DBS
37642
2
1
3
LCC
4
5
LCC
8 OK

POSTIMPLANT GENERAL PROGRAMMING SEQUENCE—INITIAL PROGRAMMING

Prepare for the Programming Session

1. Turn the N'Vision programmer ON.
2. Select the neurostimulator icon to navigate to the NEUROSTIMULATION DESKTOP screen.
3. Interrogate the Neurostimulator by holding the programming head steady over the neurostimulator and pressing the PROGRAMMING button.

Configure Leads

4. Access the PROFILE menu and enter the lead configuration.
5. Enter the lead location and hemisphere.
6. Follow the prompts in the GUIDED PROFILE to enter additional information, as desired.
7. If desired, perform programming using GUIDED PROGRAMMING.

POSTIMPLANT GENERAL PROGRAMMING SEQUENCE—FOLLOW-UP PROGRAMMING

1. Access the PROFILE menu and Review/Update Profile information
   - Patient Data
   - Lead Configuration
   - Lead Data
   - Baseline Diagnosis Information
   - Neurostimulator and Implant Information
2. Access the START SESSION menu and review neurostimulation system information, including battery information and active program settings.
3. Review patient use data, if applicable.
4. **Check System Integrity**
   Access the MEASUREMENT menu and check electrode impedance.
   - During the initial programming session, the focus is typically on the patient's dominant symptom(s). These are recorded using the baseline diagnosis feature.

5 Review/Modify Stimulation Parameters

Access the PROGRAMMING menu and select Manual Programming. Use Manual Programming to:

- Select a group and a program.
- Review/modify electrode polarities.
- Review/modify rate and pulse width.
- Review/modify amplitude resolution and amplitude.
- Record screening results.
- If desired, review/select screening history results.
- If desired, review stimulation parameters for all programs in each group.

Note: *Once impedances have been checked, amplitude settings are gradually increased to determine the thresholds for therapeutic and side effects and to define the therapeutic window for each electrode.*

Note: *Results may be recorded using the screening history feature. The optimal electrode(s) and final stimulation parameters may be selected from the screening history results.*

6 Check System Performance

- Access the MEASUREMENT menu and check Therapy Impedance.

Note: *Under some conditions, such as low amplitudes (less than 0.25 V or 0.4 mA) or narrow pulse widths, a measurement cannot be obtained.*

7 Program Neurostimulation for Patient Control (optional)

Access the END SESSION menu and select Patient Programmer.

- Review/modify patient control limits.
- Program patient reminder.

8 Customize Device Settings (optional)

- Access the PROGRAMMING menu and select Manual Programming.
- Review/modify SoftStart/Stop®.
- Access the PROGRAMMING menu and select Manual Programming.
- Review/modify Cycling.

9 Complete the Programming Session

- Access the END SESSION menu and select End Session.
- Review programmed settings.
- If desired, enter clinician notes.
- Print report(s).
- Exit application.

NOTES

Guided Profile

GUIDED PROFILE

Upon successful interrogation of the neurostimulator for the first time or prior to programming the lead configuration, Guided Profile will be displayed.

Guided Profile takes the user through the Profile menu items:

- Lead Configuration
- Lead Data
- Patient and Physician Data
- Baseline
- Device Data

LEAD CONFIGURATION

1 **Lead Configuration drop-down list**

Touch (▼) to select the appropriate lead configuration.

Note: *The lead configuration must be selected in order to proceed. Once the lead configuration, lead location(s) and hemisphere(s) are entered, you may opt to exit the Guided Profile feature. Select (☒) to exit the Guided Profile and program the lead configuration.*

2 **Lead 1 (▼) Location drop-down list**

Touch (▼) to select the location for lead #1. Location options include: STN, Vim, GPi, and Other.

3 **Lead 1 Hemisphere drop-down list**

Touch (▼) to select the appropriate hemisphere for lead #1. Left and Right options are available.

4 **Lead 2 Location drop-down list**

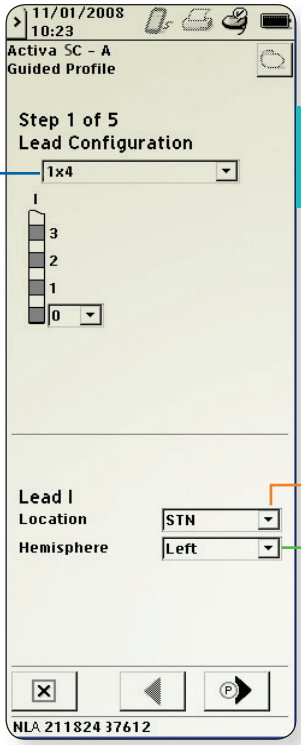
Touch (▼) to select the appropriate location for lead #2. Location options include: STN, Vim, GPi, and Other.

5 **Lead 2 Hemisphere drop-down list**

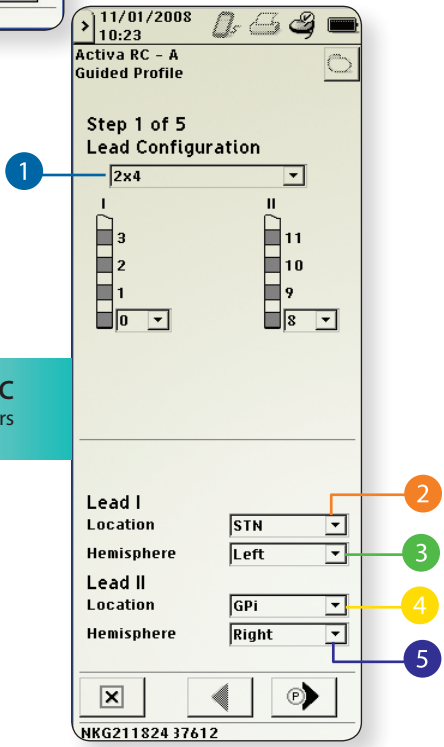
Touch (▼) to select the appropriate hemisphere for lead #2. Left and Right options are available.

Note: *You cannot select both leads as left, or both as right.*

Note: *Steps 4 and 5 apply to Activa RC and Activa PC only.*



Activa SC
Neurostimulator

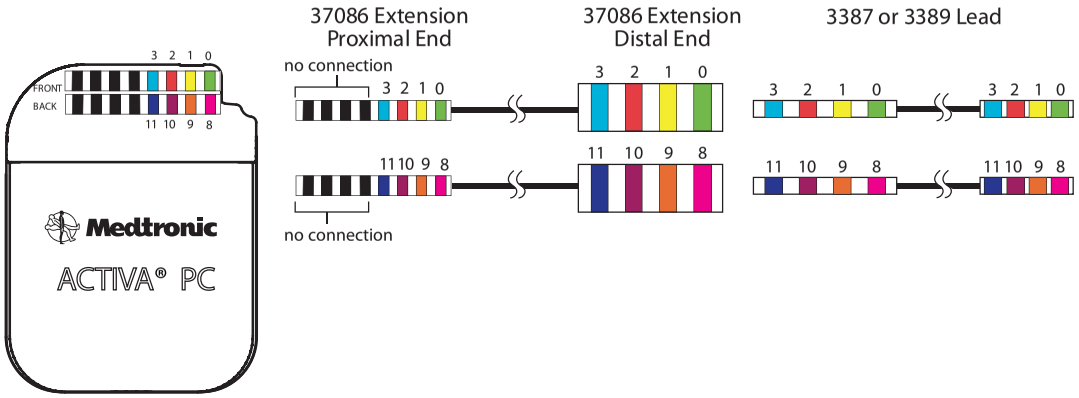


Activa RC and Activa PC
Neurostimulators

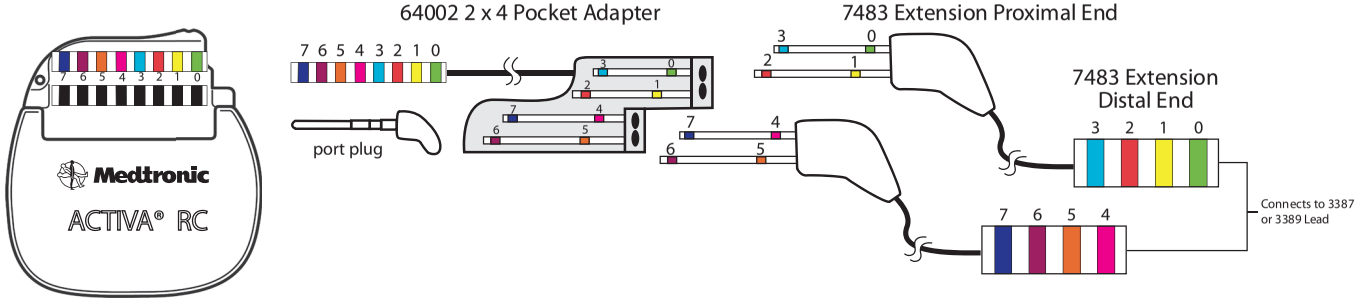
LEAD CONFIGURATION *(continued)*

The Model 37086 extension is used to connect a four-contact lead to an eight-contact channel in the neurostimulator. Connection is made to the first four contacts in the neurostimulator channel.

ACTIVA RC AND ACTIVA PC CONNECTION DIAGRAM



ACTIVA® RC AND ACTIVA® PC WITH 2X4 POCKET ADAPTOR CONNECTION DIAGRAM



LEAD MODEL NUMBER

1 **Lead 1 drop-down list**

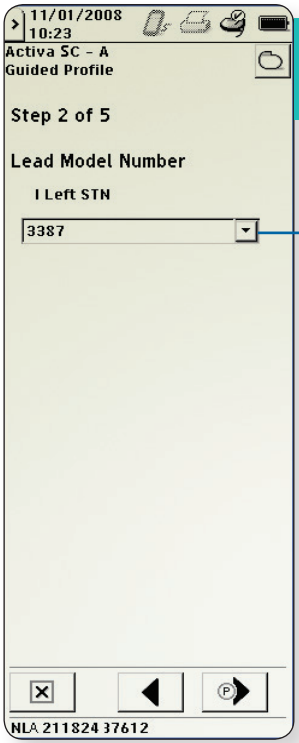
Touch (▼) to select the appropriate lead model number for the specified location.

2 **Lead 2 drop-down list**

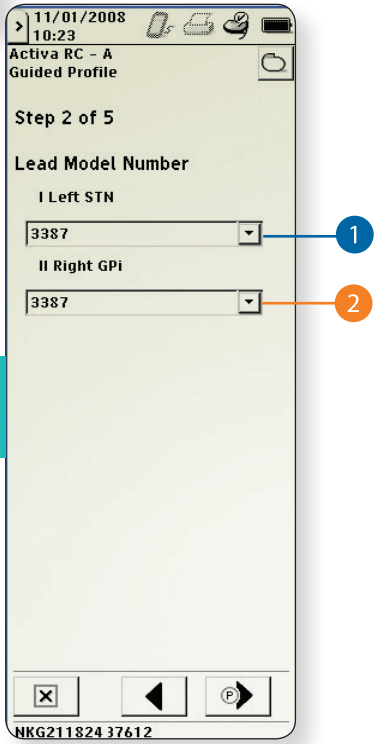
Touch (▼) to select the appropriate lead model number for the specified location (if used).

Note: *Step 2 applies to Activa RC and Activa PC only.*

Activa SC
Neurostimulator



Activa RC and Activa PC
Neurostimulators



PATIENT DATA

1 **Patient ID**

Select to enter patient name, ID number, or any other appropriate information.

2 **Patient Diagnosis**

Touch (▼) to select patient diagnosis from the drop-down list or select the field to enter another diagnosis. Options include Parkinson's Disease, Essential Tremor, Dystonia, or Other.

3 **Physician Information fields**

Select to enter physician name, phone number, or any other appropriate information.

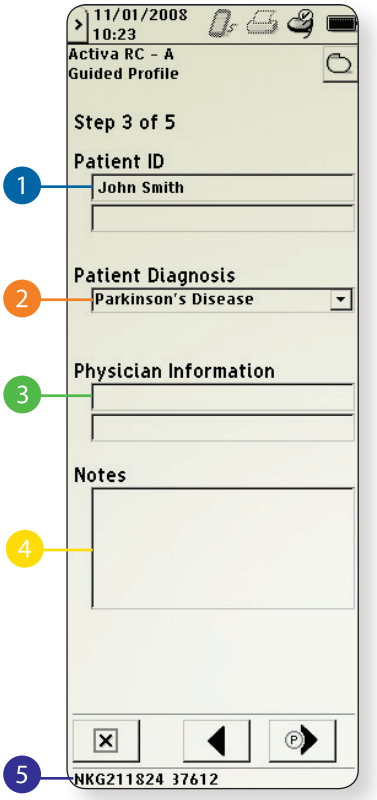
4 **Notes field**

Select to enter any desired information.

5 **Patient Session Name**

Displays neurostimulator serial number. Also displays patient name if entered on the Patient Data screen.

Note: *The patient session name will appear at the bottom of every screen and on session reports.*


11/01/2008
10:23
Activa RC - A
Guided Profile
Step 3 of 5
Patient ID
John Smith
Patient Diagnosis
Parkinson's Disease
Physician Information
Notes
NKG211824 37612
1
2
3
4
5

BASELINE

Use to evaluate the potential effectiveness of selected stimulation parameter settings. Enter the patient's diagnosis and the predominant disease symptoms that will be monitored for response to changes in stimulation.

1 **Diagnosis List**

This information is populated from diagnosis selected in previous step. Select to enter patient diagnosis, if necessary.

2 **Symptom drop-down list**

Touch (▼) to select the predominant disease symptoms to be assessed for changes in stimulation.

3 **Location drop-down list**

Touch (▼) to select the location of the symptom.

4 **Rating drop-down list**

Touch (▼) to select the severity of the symptom. Rating options include: None/Normal, Mild, Moderate, or Severe.

5 **Add button**

Select the Add button to add the symptom. The symptom will be displayed in the area below.

Note: *Maximum of five entries allowed.*

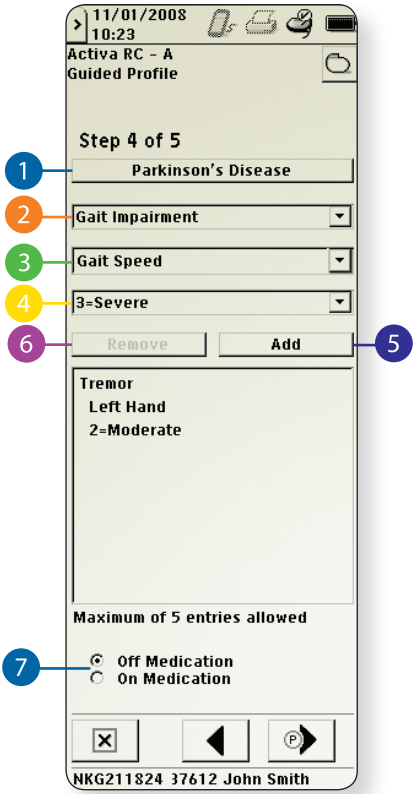
6 **Remove button**

Select the Remove button to remove a selected symptom.

7 **Off/On Medication radio buttons**

Select the appropriate radio button to record if the patient is currently on or off medication at the time of the test.

Note: *This medication information will not be present on reports.*


11/01/2008
10:23
Activa RC - A
Guided Profile
Step 4 of 5
1
Parkinson's Disease
2
Gait Impairment
3
Gait Speed
4
3=Severe
6
Remove
Add
5
Tremor
Left Hand
2=Moderate
Maximum of 5 entries allowed
7
Off Medication
On Medication
NKG211824 37612 John Smith

DEVICE DATA

1 Date and Time input fields

View the current system date and time stored in the neurostimulator. To set the date and time, select the input box and use the Increase and Decrease buttons or select the Match N'Vision button on the Date and Time screen to set the neurostimulation system to the N'Vision programmer date and time.

2 Location drop-down list

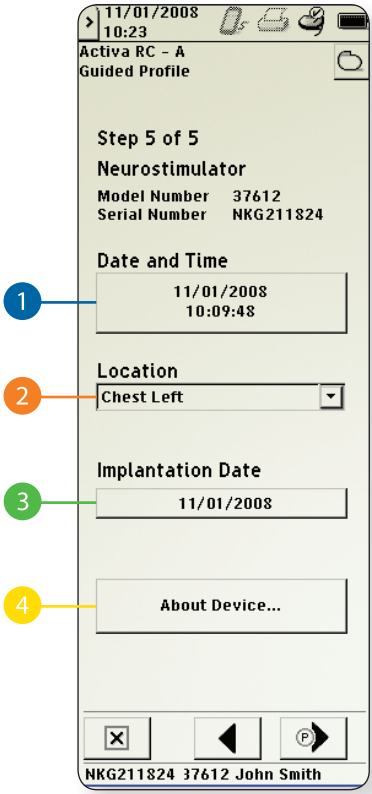
Touch (▼) to select the neurostimulator implant location from the Location drop-down list or to enter another location.

3 Implantation Date input field

Select to enter the date the neurostimulator was implanted.

4 About Device button

Select to view information about the N'Vision programmer and the neurostimulator.


11/01/2008
10:23
Activa RC - A
Guided Profile
Step 5 of 5
Neurostimulator
Model Number 37612
Serial Number NKG211824
Date and Time
11/01/2008
10:09:48
Location
Chest Left
Implantation Date
11/01/2008
About Device...
NKG211824 37612 John Smith
1
2
3
4

UNILATERAL VS. BILATERAL STIMULATION

Stimulation can be applied unilaterally or bilaterally. In unilateral stimulation, targeted structures in only one side of the brain (one hemisphere) are stimulated, using one lead. In bilateral stimulation, targets in both sides of the brain are stimulated (using two leads).

PROGRAMS AND GROUPS

Programs

A Program is a specific combination of amplitude, pulse width and rate parameters, acting on a specific electrode set. Each hemisphere can have up to two programs.

When using more than one program, the pulses are delivered sequentially—first a pulse from one program, then a pulse from the next program, and so on.

- In bilateral stimulation, pulses alternate between hemispheres when one neurostimulator is used for bilateral therapy.
- When two programs are assigned to a single lead, pulses are delivered sequentially.
- Pulses from different programs are never delivered simultaneously.

Groups

A Group is a specific combination of programs created by the clinician as a therapeutic option for the patient. Patients may choose among up to four groups using the Medtronic DBS Patient Programmer. A Group can include up to two programs per hemisphere.

- Amplitude, pulse width, and electrode polarity are programmed separately for each program within the group.
- Amplitude limits or pulse width limits are programmed separately for each hemisphere within the group.
- Programmed rate, rate limits, SoftStart/Stop, and Cycling are the same for all programs in a group.

BILATERAL AND UNILATERAL GROUPS

Activa SC, Activa RC and Activa PC neurostimulators have the capacity for up to four groups (A–D).

- Activa RC and Activa PC support two leads, so a total of four programs can be assigned in each group, up to two per lead.
- Activa SC supports one lead, so a total of two programs may be assigned in each group.

Parameter Settings

Amplitude ( ):
Voltage Mode: 0–10.5 V (0.05 V or 0.1 V resolution)
Current Mode: 0–25.5 mA (0.1 mA resolution)

Pulse Width ( ): 60–450 µs (10 µs resolution)

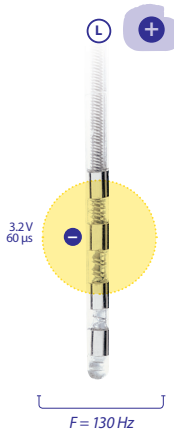
Rate ( ):
Voltage Mode: 2–10 Hz (1 Hz resolution);
10–250 Hz (5 Hz resolution)
Current Mode: 30–250 Hz (5 Hz resolution)

High-Output Interlocks

Certain combinations of high amplitude, pulse width, and rate settings are not allowed by the clinician programmer. High-output interlocks can prevent certain values from being available for programming. If you attempt to program a parameter value (or limit) that will cause the settings to exceed the high output interlock limit, the desired parameter value can only be achieved by reducing one of the other parameter values.

EXAMPLE OF UNILATERAL GROUPS

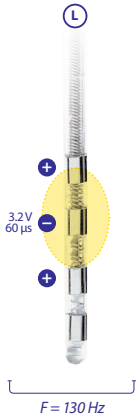
GROUP A



The group shown uses the program on the DBS lead; a single unipolar electrode is shown.

Single unipolar electrode

GROUP B



The group shown uses one program on the DBS lead; the bipolar configuration is shown.

Guarded cathode bipolar configuration

GROUP C

The group shown uses two unipolar programs on the DBS lead.

Unipolar interleaving

GROUP D

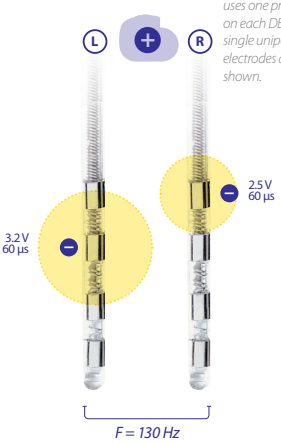
The group shown demonstrates one of the possible uses of the groups feature: depicted are settings that were used in a previous office visit, thus allowing the patient to return back to these by selecting this group.

Return to settings from previous office visit

EXAMPLE OF BILATERAL GROUPS

GROUP A

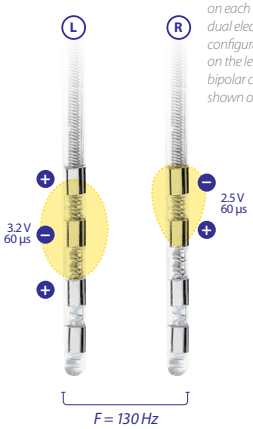
The group shown uses one program on each DBS lead; single unipolar electrodes are shown.



Single unipolar electrode

GROUP B

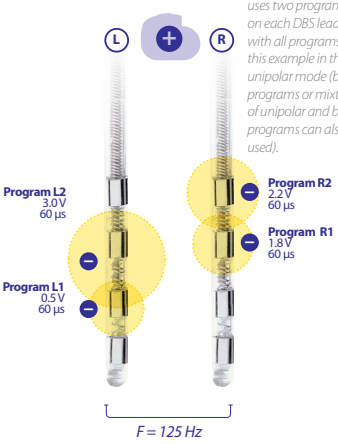
The group shown uses one program on each DBS lead; a dual electrode bipolar configuration is shown on the left and a simple bipolar configuration is shown on the right.



Single and double bipolar

GROUP C

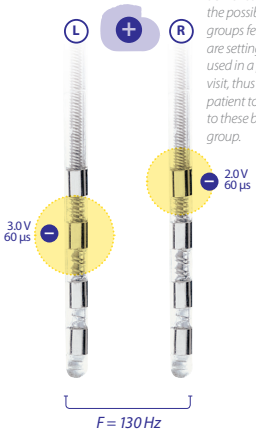
The group shown uses two programs on each DBS lead, with all programs in this example in the unipolar mode (bipolar programs or mixtures of unipolar and bipolar programs can also be used).



Unipolar interleaving on both leads

GROUP D

The group shown demonstrates one of the possible uses of the groups feature: depicted are settings that were used in a previous office visit, thus allowing the patient to return back to these by selecting this group.



Return to settings from previous office visit

GUIDED PROGRAMMING

Guided Programming is available as a programming option when programming a neurostimulator with only one group. It can be used for initial or follow-up programming.

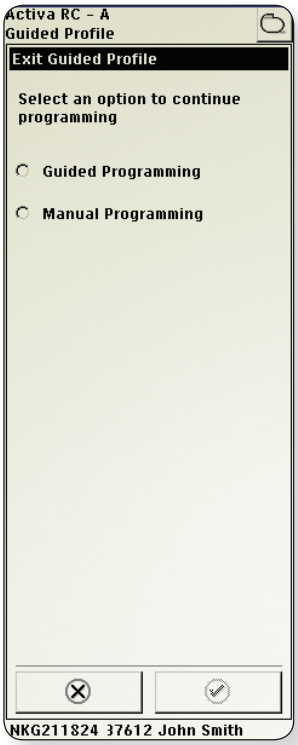
Guided Programming steps the user through the screening process:

- Electrode Impedance Test
- Screening Settings Selection
- Electrode Screening (varying amplitude and recording effects)
- Program Selection
- Program Review
- Final Amplitude Programming

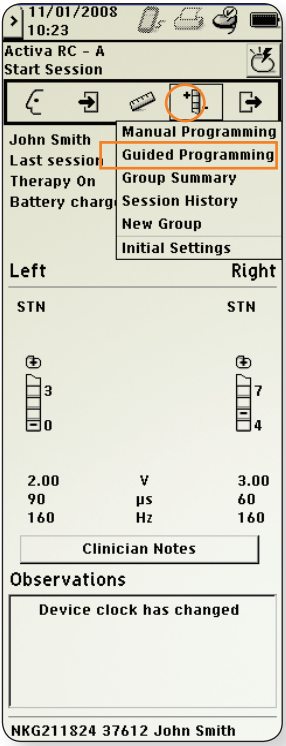
Note: *Guided programming is not available when programming an ENS, when programming multiple groups, or when assigning multiple programs to a single lead.*

Guided Programming can be accessed from the EXIT GUIDED PROFILE screen 1 or from the PROGRAMMING menu 2.

1


Activa RC - A
Guided Profile
Exit Guided Profile
Select an option to continue programming
Guided Programming
Manual Programming
NKG211824 37612 John Smith

2


11/01/2008
10:23
Activa RC - A
Start Session
John Smith
Last session
Therapy On
Battery charg
Manual Programming
Guided Programming
Group Summary
Session History
New Group
Initial Settings
Left
Right
STN
STN
3
0
7
4
2.00
90
160
V
µs
Hz
3.00
60
160
Clinician Notes
Observations
Device clock has changed
NKG211824 37612 John Smith

ELECTRODE IMPEDANCE

This step guides you through the electrode impedance test. During this test, preset rate and pulse width values are used.

1. **Take Measurement button**

   Select to begin electrode impedance test.

2. **Out-of-Range Results window**

   Displays out of range results from the electrode impedance test. Review results to detect potential issues with system integrity (i.e., short circuit, open circuit, etc.).

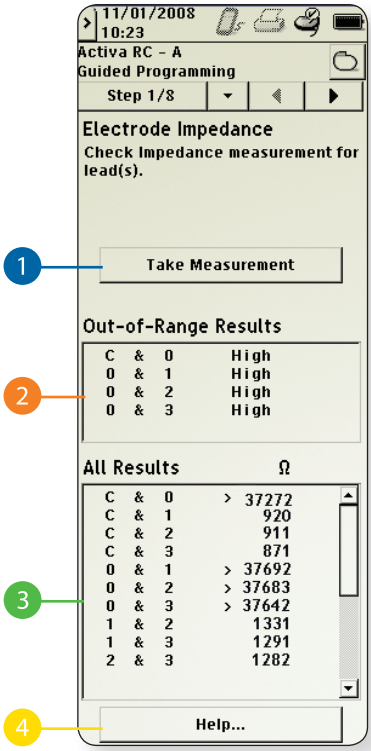
3. **All Results window**

   Displays all electrode impedance results from the impedance test.

4. **Help button**

   Select to display information that will assist in interpreting impedance readings. Information includes:

   - Definition of impedance measurement result
   - Electrode where the terms and ranges were detected
   - Recommendations for correcting the potential issue


11/01/2008
10:23
Activa RC - A
Guided Programming
Step 1/8
Electrode Impedance
Check Impedance measurement for lead(s).
1
Take Measurement
Out-of-Range Results
C & 0 High
0 & 1 High
0 & 2 High
0 & 3 High
2
All Results Ω
C & 0 > 37272
C & 1 920
C & 2 911
C & 3 871
0 & 1 > 37692
0 & 2 > 37683
0 & 3 > 37642
1 & 2 1331
1 & 3 1291
2 & 3 1282
3
4
Help...

CHECKING ELECTRODE IMPEDANCE

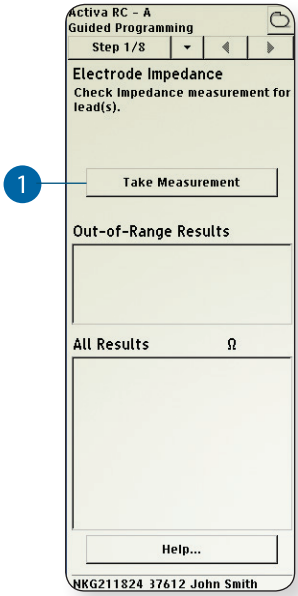
To check electrode impedance measurement:

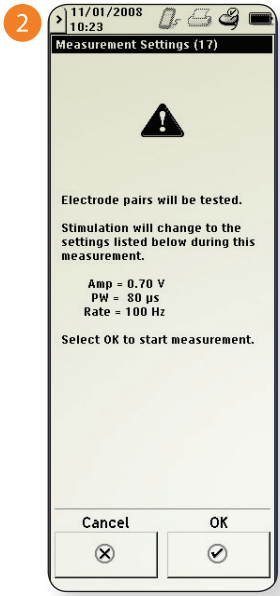
1. Select the Take Measurement button.
2. A warning screen is displayed describing the testing process. To start the measurement process, select the OK button ( ).
3. If a measurement result was above the measurement range, a Possible Open Circuit screen displays and the testing process can be re-run with higher amplitudes (0.7 V, 1.5 V, or 3.0 V) to increase the measurement range range. Select the OK button ( ) to re-run test.

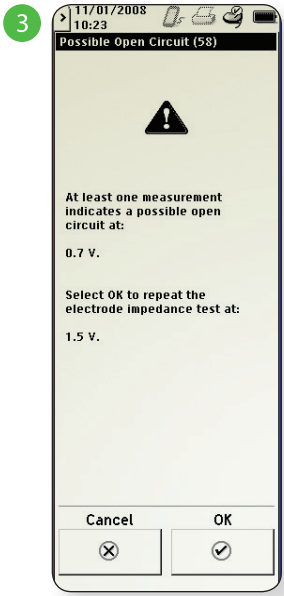
Note: *All values >2000 ohms (unipolar) and >4000 ohms (bipolar) will be labeled as "high" by the software. The user will be prompted to re-run the test for the following impedance values at each measurement output:*

Electrode Impedance		
Measurement Output (V)	Measurement Range	8840 Prompts to Measure at Higher Output
0.25	up to 4000 ohms	value above 4000 ohms
0.7*	up to 10000 ohms	value above 10000 ohms
1.5	up to 20000 ohms	value above 20000 ohms
3.0	up to 40000 ohms	No prompt: highest range already achieved

* default measurement output value


Activa RC - A
Guided Programming
Step 1/8
Electrode Impedance
Check Impedance measurement for lead(s).
1
Take Measurement
Out-of-Range Results
All Results
Ω
Help...
NKG211824 37612 John Smith


2
11/01/2008
10:23
Measurement Settings (17)
Electrode pairs will be tested.
Stimulation will change to the settings listed below during this measurement.
Amp = 0.70 V
PW = 80 µs
Rate = 100 Hz
Select OK to start measurement.
Cancel
OK


3
11/01/2008
10:23
Possible Open Circuit (58)
At least one measurement indicates a possible open circuit at:
0.7 V.
Select OK to repeat the electrode impedance test at:
1.5 V.
Cancel
OK

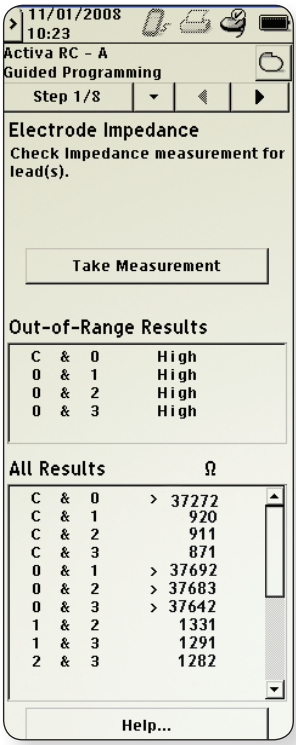
CHECKING ELECTRODE IMPEDANCE *(continued)*

4. Once the measurement tests are complete, results will be displayed on the Electrode Impedance screen.

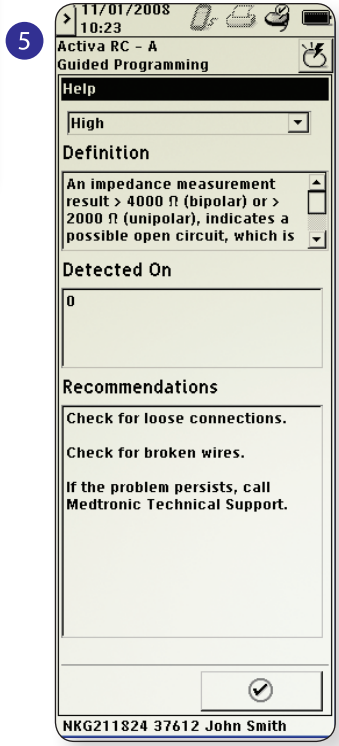
5. Select the Help button (Help...) to display information that will assist in interpreting impedance readings.

Note: *Repeat Steps 1-5 from pages 40 and 42 if a patient has two neurostimulators.*

4


11/01/2008
10:23
Activa RC - A
Guided Programming
Step 1/8
Electrode Impedance
Check Impedance measurement for lead(s).
Take Measurement
Out-of-Range Results
C & 0 High
0 & 1 High
0 & 2 High
0 & 3 High
All Results Ω
C & 0 > 37272
C & 1 920
C & 2 911
C & 3 871
0 & 1 > 37692
0 & 2 > 37683
0 & 3 > 37642
1 & 2 1331
1 & 3 1291
2 & 3 1282
Help...

5


11/01/2008
10:23
Activa RC - A
Guided Programming
Help
High
Definition
An impedance measurement result > 4000 Ω (bipolar) or > 2000 Ω (unipolar), indicates a possible open circuit, which is
Detected On
0
Recommendations
Check for loose connections.
Check for broken wires.
If the problem persists, call Medtronic Technical Support.
NKG211824 37612 John Smith

REVIEW DEFAULTS

The Review Defaults screen is used to review and modify screening settings.

1. **Pulse Width (µs)**

   Select to set default Pulse Width parameter value.

2. **Rate (Hz)**

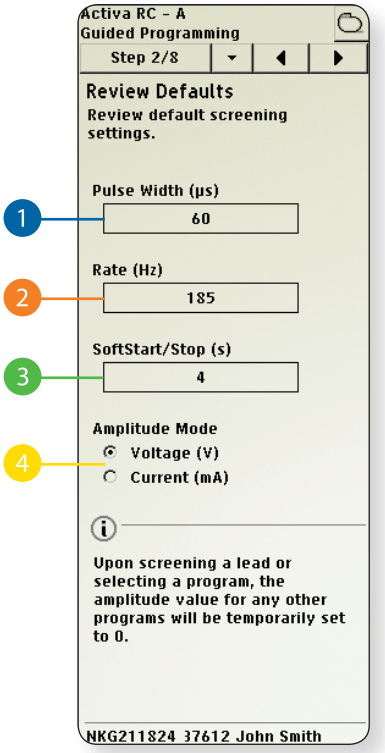
   Select to set default Rate parameter value.

3. **SoftStart/Stop(s)**

   Select to set SoftStart/Stop parameter values.

4. **Amplitude Mode**

   Select to choose between Voltage or Current Mode.


Activa RC - A
Guided Programming
Step 2/8
Review Defaults
Review default screening settings.
Pulse Width (µs)
60
Rate (Hz)
185
SoftStart/Stop (s)
4
Amplitude Mode
Voltage (V)
Current (mA)
Upon screening a lead or selecting a program, the amplitude value for any other programs will be temporarily set to 0.
NKG211824 37612 John Smith
1
2
3
4

ELECTRODE SCREENING

Use to systematically screen all of the electrodes based on the lead configuration selected.

1 **Amplitude Input box**

After choosing the electrode pair, select to adjust amplitudes.

2 **Record Effects button**

Select to record both beneficial effects and side effects.

3 **Beneficial Effects window**

Displays beneficial effects reported from electrode screening.

4 **Side Effects window**

Displays side effects reported from electrode screening.

A **Amplitude Check box ( )**

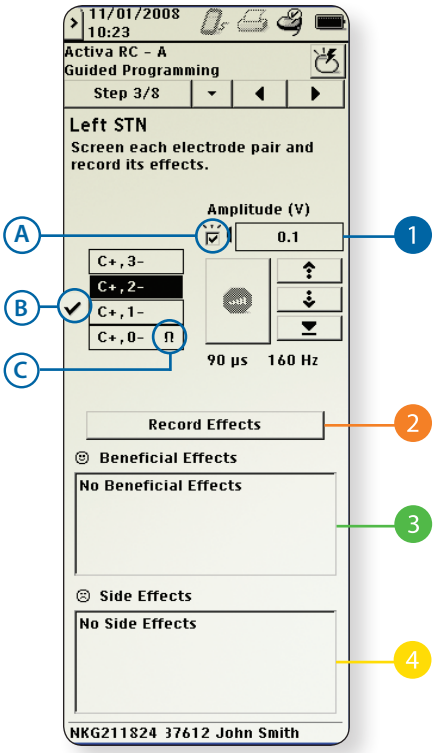
Allows the user to "turn off" the program when unchecked (amplitude will revert to 0.0 V). If the box is rechecked, the amplitude will return to the previously used amplitude value.

B **Check Symbol (✔)**

Indicates an effect has been logged for this electrode pair.

C **Ohm Symbol (Ω)**

Indicates the impedance for this electrode pair was either HIGH or LOW.


11/01/2008
10:23
Activa RC - A
Guided Programming
Step 3/8
Left STN
Screen each electrode pair and record its effects.
Amplitude (V)
0.1
C+,3-
C+,2-
C+,1-
C+,0-
90 µs
160 Hz
Record Effects
Beneficial Effects
No Beneficial Effects
Side Effects
No Side Effects
NKG211824 37612 John Smith
A
B
C
1
2
3
4

RECORDING SCREENING HISTORY

To Record Screening History

1. Select the desired electrode pair.

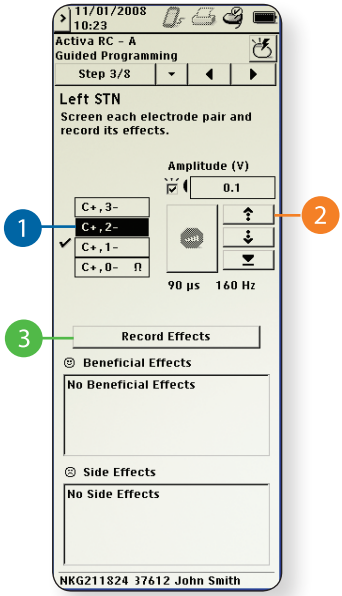
Recording Beneficial Effects

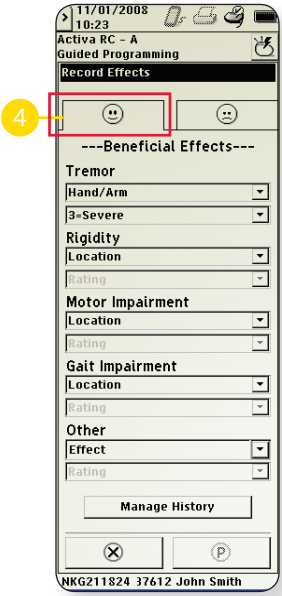
2. While holding the programming head steady over the neurostimulator, gradually increase the amplitude, noting any effects.
3. Select the RECORD EFFECTS button.
4. Record the observed beneficial effects at the selected stimulation parameters using the drop-down lists (symptom and rating) on the Beneficial Effects (☺) tab.

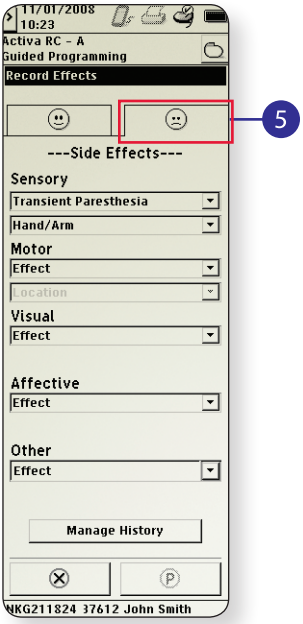
Recording Side Effects

5. Turn stimulation OFF, then record the side effects that were observed at the selected stimulation parameters using the drop-down lists (effect/location) on the Side Effects (☹) tab.

   Continue assessing stimulation settings, observing effects, and recording results as desired for each electrode combination.


11/01/2008
10:23
Activa RC - A
Guided Programming
Step 3/8
Left STN
Screen each electrode pair and record its effects.
Amplitude (V)
0.1
C+,3-
C+,2-
C+,1-
C+,0-
90 µs
160 Hz
Record Effects
Beneficial Effects
No Beneficial Effects
Side Effects
No Side Effects
NKG211824 37612 John Smith
1
2
3


11/01/2008
10:23
Activa RC - A
Guided Programming
Record Effects
---Beneficial Effects---
Tremor
Hand/Arm
3=Severe
Rigidity
Location
Rating
Motor Impairment
Location
Rating
Gait Impairment
Location
Rating
Other
Effect
Rating
Manage History
NKG211824 37612 John Smith
4


11/01/2008
10:23
Activa RC - A
Guided Programming
Record Effects
---Side Effects---
Sensory
Transient Paresthesia
Hand/Arm
Motor
Effect
Location
Visual
Effect
Affective
Effect
Other
Effect
Manage History
NKG211824 37612 John Smith
5

SELECT PROGRAM

Use to sort on various criteria to select the best program based on the screening of the lead.

1. **Electrodes drop-down list**

   Touch (▼) to display electrode pairs.

2. **Symptom drop-down list**

   Touch (▼) to select the symptom to be displayed.

3. **Best Effects display**

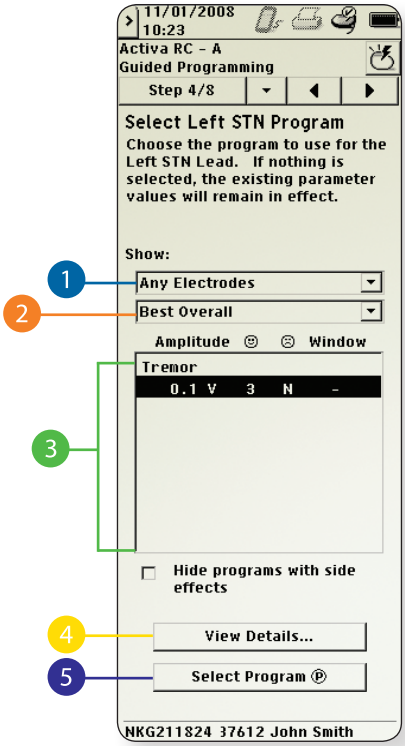
   Displays the rating (0–3) of beneficial effects (with symptom level displayed) and side effects reported during the screening process.

4. **View Details button**

   Select to review information about the program selected.

5. **Select Program button**

   Select to program the highlighted values.


11/01/2008
10:23
Activa RC - A
Guided Programming
Step 4/8
Select Left STN Program
Choose the program to use for the Left STN Lead. If nothing is selected, the existing parameter values will remain in effect.
Show:
Any Electrodes
Best Overall
Amplitude
Window
Tremor
0.1 V 3 N -
Hide programs with side effects
View Details...
Select Program
NKG211824 37612 John Smith
1
2
3
4
5

ELECTRODE SCREENING FOR SECOND LEAD

Repeat the electrode screening process for the second lead (if applicable).

1 **Amplitude Input box**

After choosing the electrode pair, select to adjust amplitudes.

2 **Record Effects button**

Select to record both beneficial effects and side effects.

3 **Beneficial Effects window**

Displays beneficial effects reported from electrode screening.

4 **Side Effects window**

Displays side effects reported from electrode screening.

A **Amplitude Check box ( )**

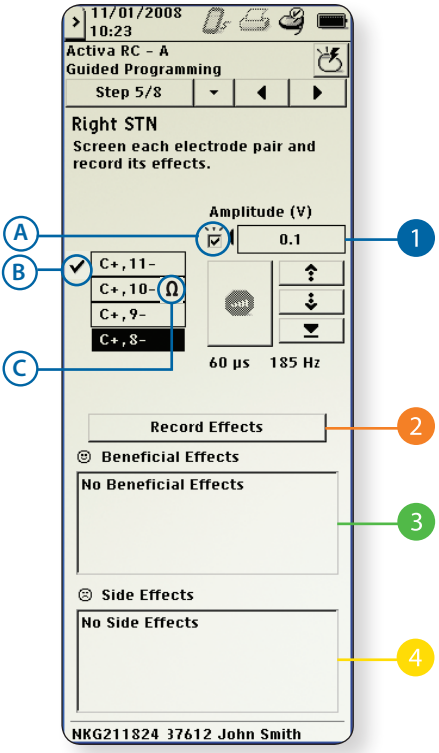
Allows the user to "turn off" the program when unchecked (amplitude will revert to 0.0 V). If the box is rechecked, the amplitude will return to the previously used amplitude value.

B **Check Symbol (✔)**

Indicates an effect has been logged for this electrode pair.

C **Ohm Symbol (Ω)**

Indicates the impedance for this electrode pair was either HIGH or LOW.


11/01/2008
10:23
Activa RC - A
Guided Programming
Step 5/8
Right STN
Screen each electrode pair and record its effects.
Amplitude (V)
0.1
A
B
C
C+,11-
C+,10-
C+,9-
C+,8-
Ω
60 µs
185 Hz
Record Effects
Beneficial Effects
No Beneficial Effects
Side Effects
No Side Effects
NKG211824 37612 John Smith
1
2
3
4

SELECT PROGRAM FOR SECOND LEAD

Select the program to use for the second lead (if applicable).

1. **Electrodes drop-down list**

   Touch (▼) to display electrode pairs.

2. **Symptom drop-down list**

   Touch (▼) to select the symptom to be displayed.

3. **Best Effects display**

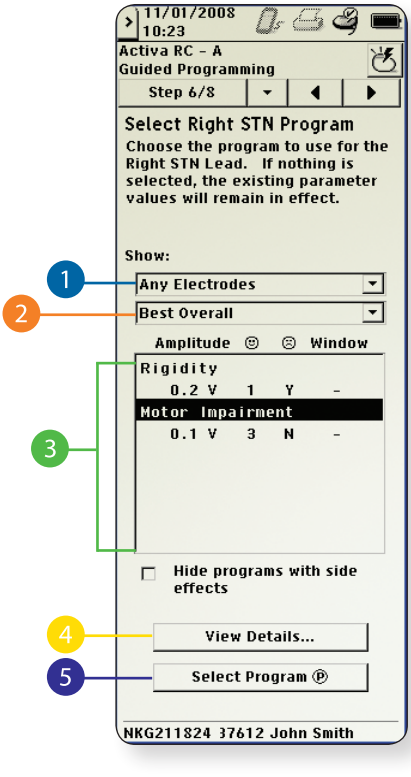
   Displays the rating (0–3) of beneficial effects (with symptom level displayed) and side effects reported during the screening process.

4. **View Details button**

   Select to review information about the program selected.

5. **Select Program button**

   Select to program the highlighted values.


11/01/2008
10:23
Activa RC - A
Guided Programming
Step 6/8
Select Right STN Program
Choose the program to use for the Right STN Lead. If nothing is selected, the existing parameter values will remain in effect.
Show:
1
Any Electrodes
2
Best Overall
Amplitude
Window
3
Rigidity
0.2 V 1 Y -
Motor Impairment
0.1 V 3 N -
Hide programs with side effects
4
View Details...
5
Select Program
NKG211824 37612 John Smith

REVIEW PROGRAMS

Use to review stimulation parameters and modify amplitude settings, if desired.

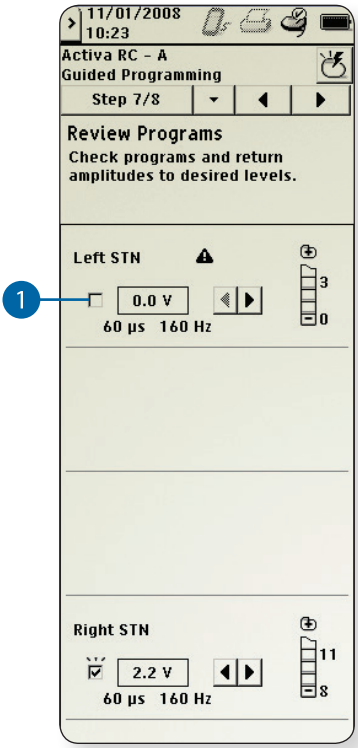
1. **Program checkbox**

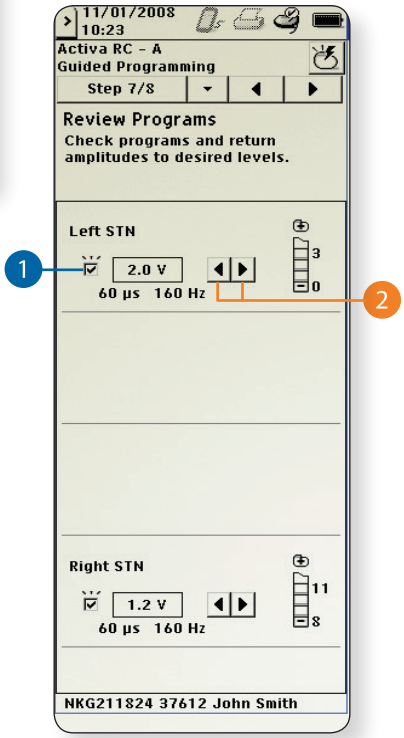
   Select to activate or deactivate a program.

   Note: *An exclamation point (⚠) next to the program description indicates the amplitude is currently at 0.0 V, but a stored amplitude exists.*

2. **Amplitude Adjust buttons**

   Select to modify the amplitude value.


11/01/2008
10:23
Activa RC - A
Guided Programming
Step 7/8
Review Programs
Check programs and return amplitudes to desired levels.
Left STN
0.0 V
60 µs 160 Hz
3
0
Right STN
2.2 V
60 µs 160 Hz
11
8
1

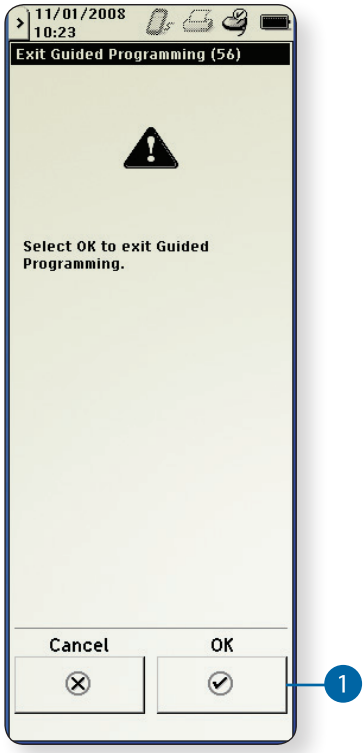

11/01/2008
10:23
Activa RC - A
Guided Programming
Step 7/8
Review Programs
Check programs and return amplitudes to desired levels.
Left STN
2.0 V
60 µs 160 Hz
3
0
Right STN
1.2 V
60 µs 160 Hz
11
8
NKG211824 37612 John Smith
1
2

EXIT GUIDED PROGRAMMING

1 **OK button**

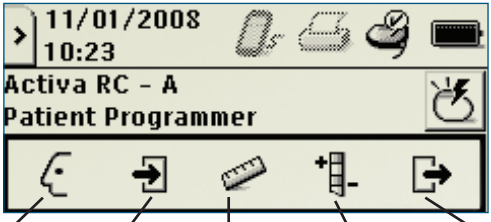
Select to exit Guided Programming.

This is the final screen for the Guided Programming feature, which will appear upon exiting the feature. The user will be taken to the Patient Programmer Set-up panel upon selecting OK ( ). If the user selects Cancel ( ), they will be taken to the screen previously displayed.


11/01/2008
10:23
Exit Guided Programming (56)
Select OK to exit Guided Programming.
Cancel
OK
1

NOTES

NAVIGATION

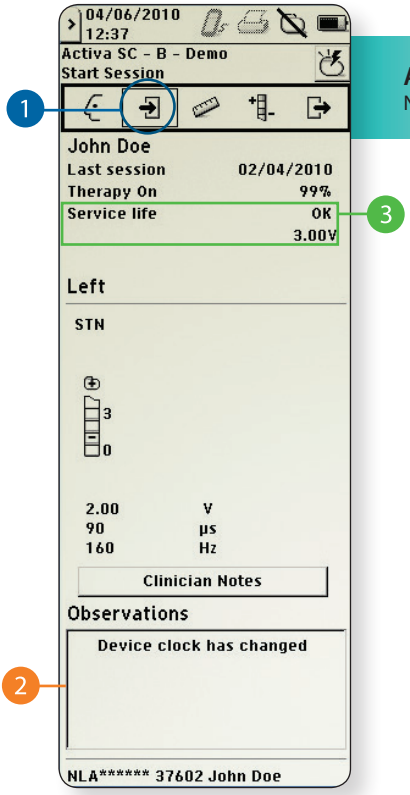


Profile	Start Session	Measurement	Programming	End Session
Patient Data	Start Session	Electrode Impedance	Manual Programming	Print Reports
Lead Configuration	Device Usage	Therapy Impedance	Guided Programming	Print Screen
Lead Data	Group Usage	Battery	Group Summary	Patient Programmer
Baseline			Session History	End Session
Device Data			New Group	Exit
			Initial Settings	

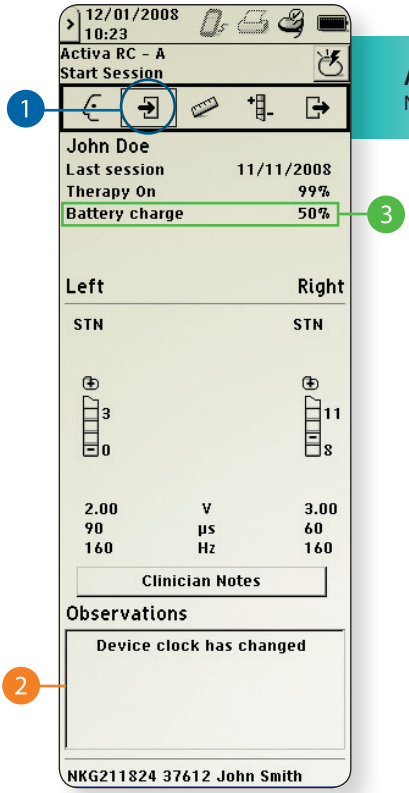
REVIEWING NEUROSTIMULATION SYSTEM INFORMATION

To Review Neurostimulation System Information

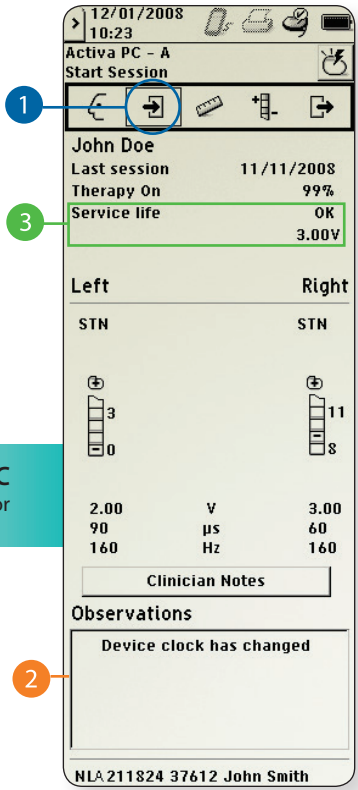
1. Access the START SESSION menu ( ) and select Start Session.
2. Review the Observations box for significant system events that have occurred. The observations are brief notifications (e.g., Check INS clock, Stimulation off) that need to be investigated.
3. Check Battery charge level for a rechargeable neurostimulator or the Service Life and battery voltage for a nonrechargeable neurostimulator.



Activa SC
Neurostimulator



Activa RC
Neurostimulator



Activa PC
Neurostimulator

DEVICE USAGE

Use to review patient data collected between sessions.

Note: *"No Data Available" will be displayed if there is no diary information available.*

1. **Month drop-down list**

   Select the month to view patient use data.

2. **Recharge Date information** (for Activa RC Rechargeable neurostimulator only).

   Note: *A square around the date field indicates that the device has been recharged. A black bar in the date field indicates that therapy was ON.*

3. **To view more detailed patient use data for a specific day, select the day on the calendar.**

4. **Day Details Screen**

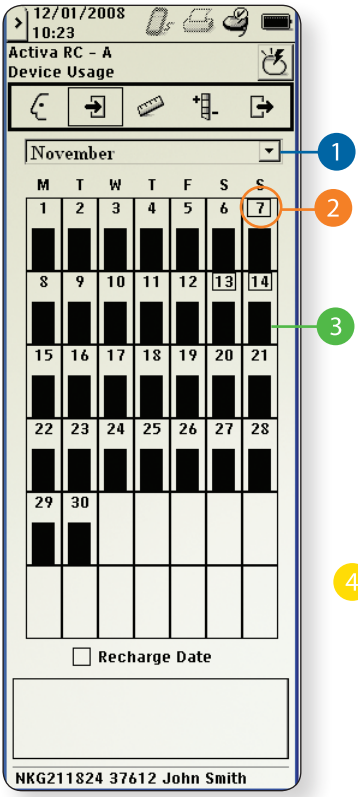
   Displayed when specific day is selected. Used to review active groups and stimulation ON periods for specific times of the day.

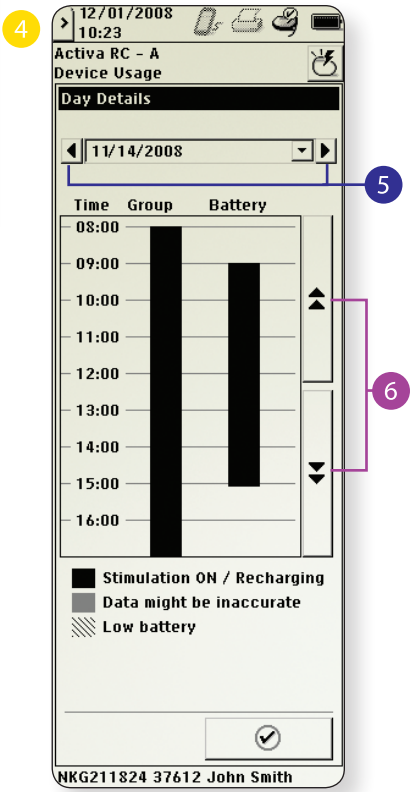
5. **Previous and Next buttons (date)**

   Select to view patient use data for the previous or next calendar day.

6. **Previous and Next buttons (time)**

   Select to view patient use data for an earlier or later time.


12/01/2008
10:23
Activa RC - A
Device Usage
November
M T W T F S S
1 2 3 4 5 6 7
8 9 10 11 12 13 14
15 16 17 18 19 20 21
22 23 24 25 26 27 28
29 30
Recharge Date
NKG211824 37612 John Smith
1
2
3

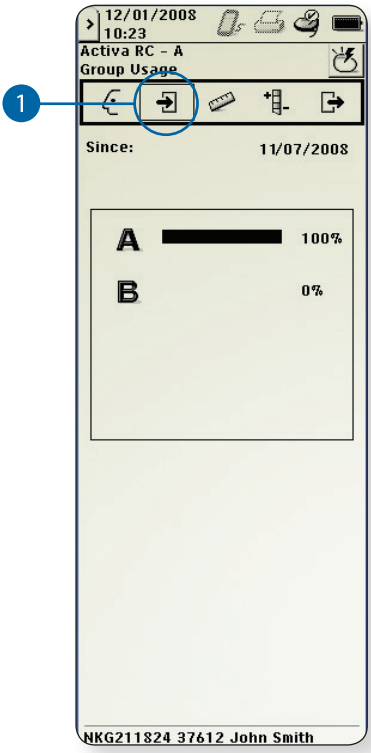

4
12/01/2008
10:23
Activa RC - A
Device Usage
Day Details
11/14/2008
5
Time Group Battery
08:00
09:00
10:00
11:00
12:00
13:00
14:00
15:00
16:00
6
Stimulation ON / Recharging
Data might be inaccurate
Low battery
NKG211824 37612 John Smith

GROUP USAGE

Use to show percentage of time each group is used.

Note: *This feature is only available if more than one group has been programmed.*

1. Access the START SESSION menu () and select Group Usage.


12/01/2008
10:23
Activa RC - A
Group Usage
1
Since:
11/07/2008
A
100%
B
0%
NKG211824 37612 John Smith

REVIEWING NEUROSTIMULATOR BATTERY INFORMATION

To Review Neurostimulator Battery Information
Activa RC—Rechargeable Neurostimulator

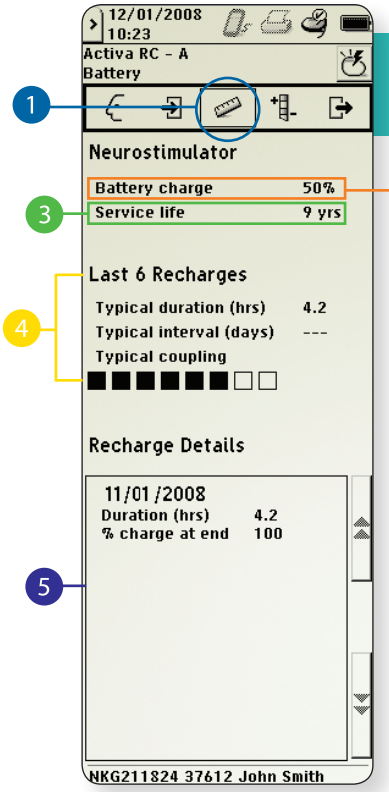
1. Access the MEASUREMENT menu () and select Battery.
2. Check the battery charge level.
3. Review the implanted neurostimulator service life.
4. Review the implanted neurostimulator battery recharge information for the last six recharging sessions:
   - Typical duration (hrs)
   - Typical interval (days)
   - Typical coupling
5. Review the details of the last six charging sessions:
   - Date of the charging session
   - Duration of the charging session (an extended duration may indicate coupling problems)
   - Battery charge level at the end of the charging session.

   Note: *At the start of a session, the programmer will check the neurostimulator battery status and the information stored in the device and if appropriate, it will display the following messages in the Observations box:*

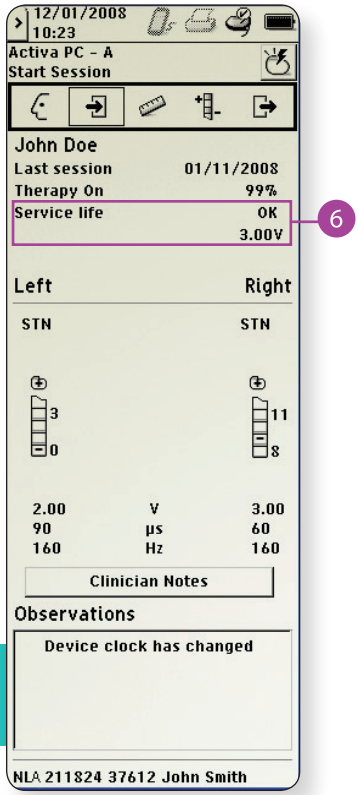
   - *Charge Sooner—Indicates that the patient didn't recharge soon enough and the neurostimulator dropped to a low battery level since the last follow-up.*
   - *Charge Soon—Indicates that the neurostimulator is presently at the 0-10% charge level.*

To Review Neurostimulation Battery Information
Activa SC and Activa PC—Nonrechargeable Neurostimulators

6. Review the Start Session screen for the neurostimulator service life and battery voltage:
   - Elective Replacement Indicator (ERI) and measured battery voltage will appear under Service Life in a nonrechargeable neurostimulator with a low battery status, typically starting at 3 months before the neurostimulator reaches end of life.



Activa RC
Rechargeable Neurostimulator

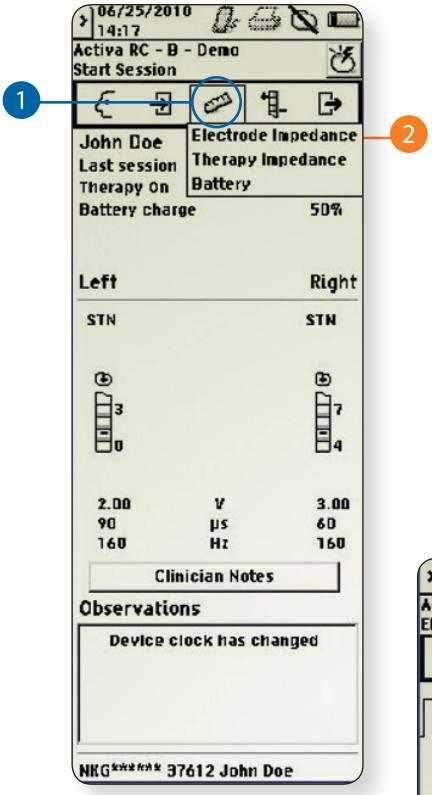


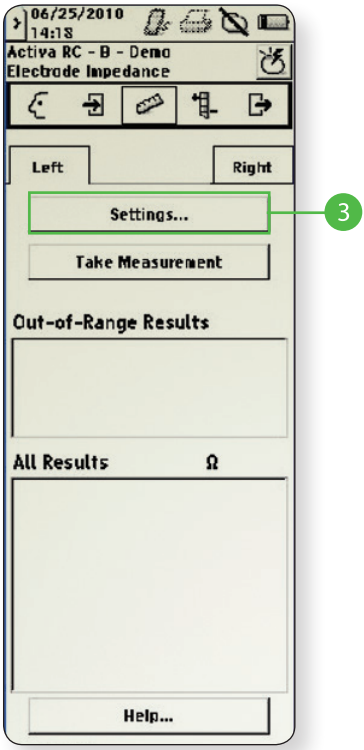
Activa SC and Activa PC
Nonrechargeable Neurostimulators

CHECKING ELECTRODE IMPEDANCE

To Determine Impedance Values for Electrode Pairs

1. Access the MEASUREMENT menu () .
2. Select electrode impedance.
3. Click on settings.

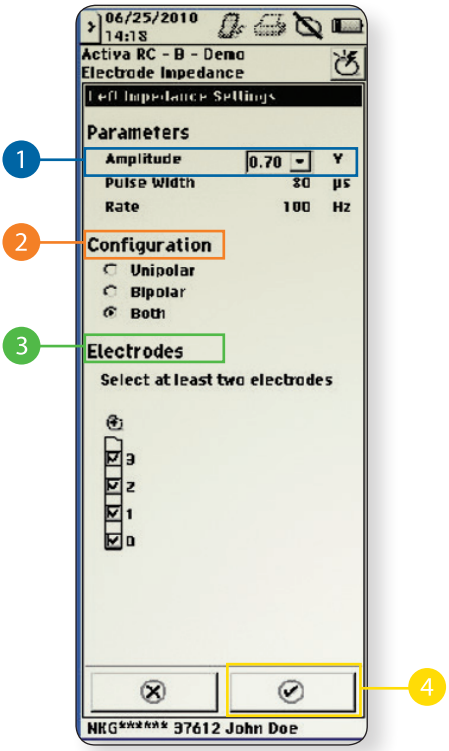

06/25/2010
14:17
Activa RC - B - Demo
Start Session
1
2
John Doe
Last session
Therapy on
Electrode Impedance
Therapy Impedance
Battery
Battery charge
50%
Left
Right
STN
STN
3
0
7
4
2.00
90
160
V
µs
Hz
3.00
60
160
Clinician Notes
Observations
Device clock has changed
NKG***** 37612 John Doe


06/25/2010
14:18
Activa RC - B - Demo
Electrode Impedance
Left
Right
Settings...
3
Take Measurement
Out-of-Range Results
All Results
Ω
Help...

CHECKING ELECTRODE IMPEDANCE *(continued)*

Determine Settings to Be Used for Impedance Measurement

1. Select an amplitude value (default is 0.70).
2. Select electrode configuration option.
3. Select electrodes to test.
4. Click OK to exit settings.


06/25/2010
14:18
Activa RC - B - Demo
Electrode Impedance
Lead Impedance Settings
Parameters
Amplitude
0.70
V
Pulse Width
90
µs
Rate
100
Hz
Configuration
Unipolar
Bipolar
Both
Electrodes
Select at least two electrodes
3
2
1
0
NKG****** 37612 John Doe
1
2
3
4

CHECKING ELECTRODE IMPEDANCE *(continued)*

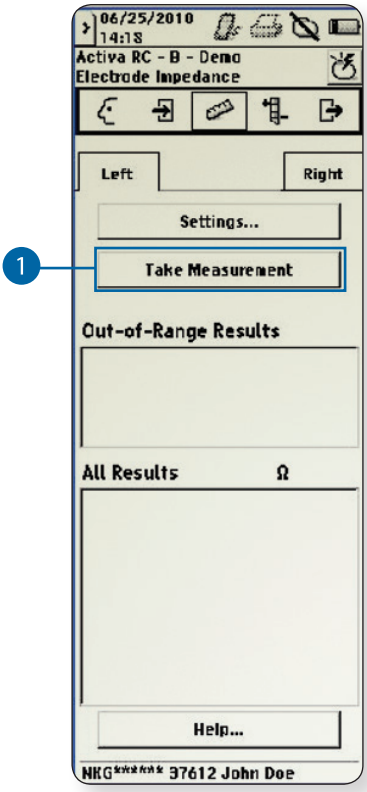
1. Select take Measurement.

Note: *Ensure telemetry head is over neurostimulator for the duration of the measurement.*

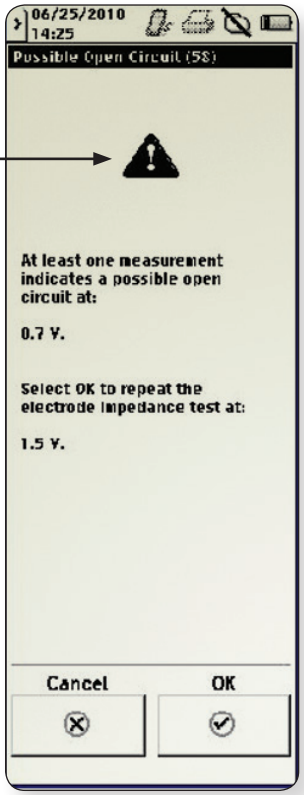
Note: *All values >2000 ohms (unipolar) and >4000 ohms (bipolar) will be labeled as "high" by the software. The user will be prompted to re-run the test for the following impedance values at each measurement output:*

Electrode Impedance		
Measurement Output (V)	Measurement Range	8840 Prompts to Measure at Higher Output
0.25	up to 4000 ohms	value above 4000 ohms
0.7*	up to 10000 ohms	value above 10000 ohms
1.5	up to 20000 ohms	value above 20000 ohms
3.0	up to 40000 ohms	No prompt: highest range already achieved

* default measurement output value



If any measurement is out of range, a prompt appears to repeat measurement at the next higher amplitude.



SELECTING AND ACTIVATING A GROUP

To program stimulation parameters, a group must be selected and activated:

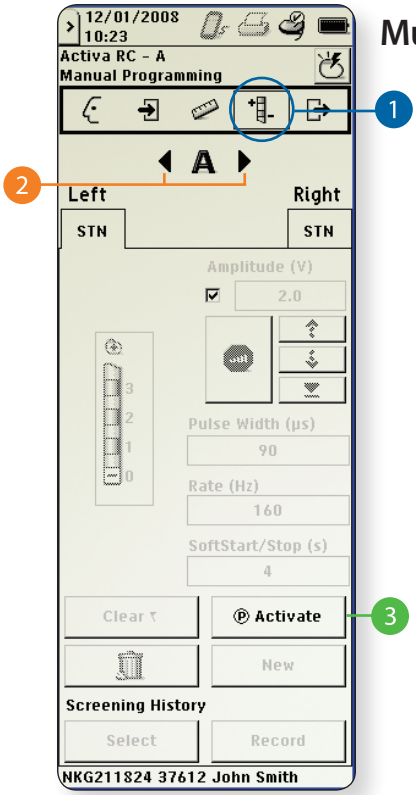
- Up to two programs of stimulation per hemisphere may be programmed for a total of two programs per group for Activa SC and four programs per group for Activa RC and Activa PC.
- The program name that appears on the program tab includes the hemisphere and location entered on the Lead Configuration screen.

To Select and Activate a Group

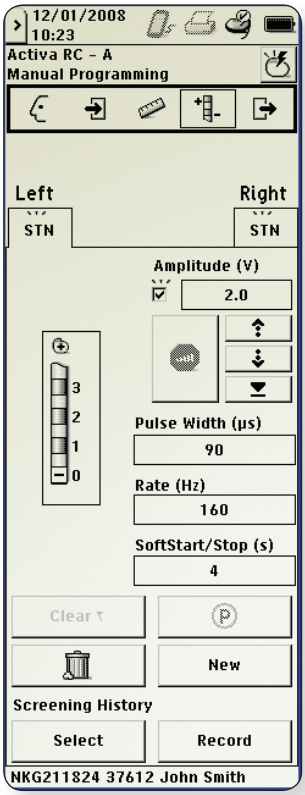
1. Access the PROGRAMMING menu () and select Manual Programming.
2. If more than one group is defined, use the GROUP SELECTION SCROLL buttons to select a group.

   Note: *If only one group is defined, the group is automatically active and no letter or scroll buttons are displayed.*
3. To activate the group, hold the programming head steady over the neurostimulator, then press the PROGRAMMING (P) key or select the ACTIVATE button on the programmer screen.

Multiple Groups



One Group



ADDING GROUPS AND PROGRAMS

To add groups and programs

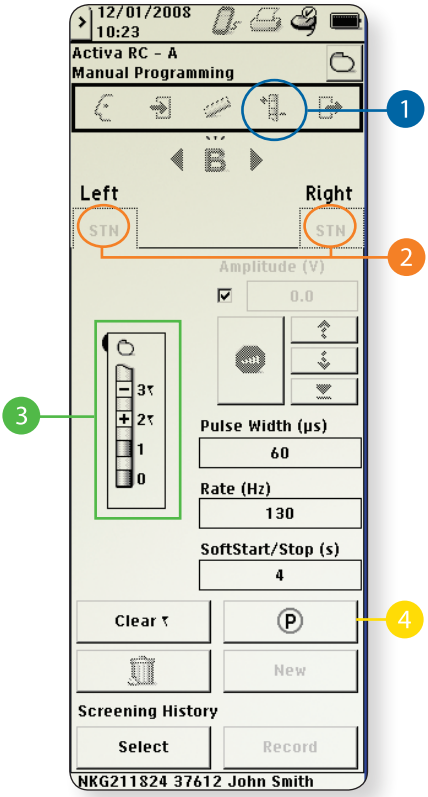
1. Access the PROGRAMMING menu ( ) and select New Group.

   Note: *Alternatively, select Group Summary, then scroll to an undefined group and select the CREATE NEW GROUP button.*

2. Select a program in the new group.

3. Select electrode polarities.

4. Hold the programming head steady over the neurostimulator, then press the Programming Ⓟ key or select the Program (Ⓟ) button on the programmer screen.


12/01/2008
10:23
Activa RC - A
Manual Programming
B
Left
Right
STN
STN
Amplitude (V)
0.0
3
2
1
0
Pulse Width (µs)
60
Rate (Hz)
130
SoftStart/Stop (s)
4
Clear
P
New
Screening History
Select
Record
NKG211824 37612 John Smith
1
2
3
4

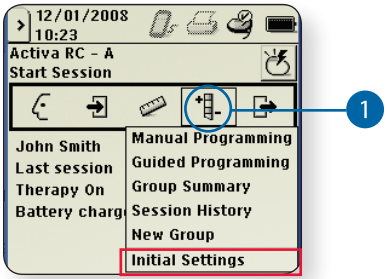
INITIAL SETTINGS

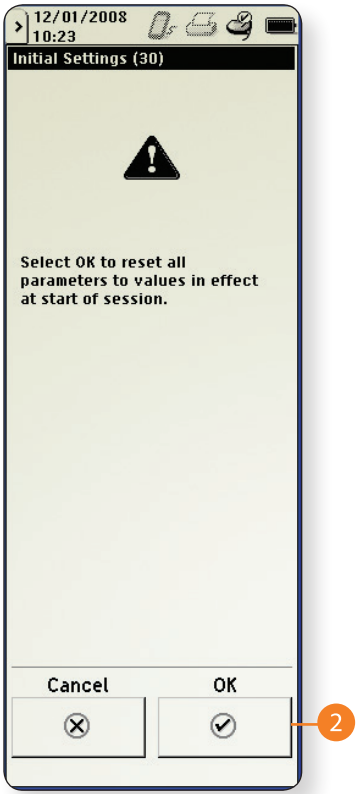
During a programming session, you can reset all parameters to values in effect at the start of the session. If you return to initial settings, however, you will lose all changes made to group and program parameters during the session.

Note: *You will not be able to retrieve initial settings if you have changed the lead configuration during the session.*

To return to initial settings:

1. Access the PROGRAMMING menu () and select Initial Settings.
2. Hold the programming head steady over the neurostimulator, then select the OK () button.


12/01/2008
10:23
Activa RC - A
Start Session
John Smith
Last session
Therapy On
Battery charg
Manual Programming
Guided Programming
Group Summary
Session History
New Group
Initial Settings
1


12/01/2008
10:23
Initial Settings (30)
Select OK to reset all
parameters to values in effect
at start of session.
Cancel
OK
2

PATIENT PROGRAMMER

Patient control limits for amplitude, pulse width, or rate are set by the clinician and programmed to the neurostimulator before the patient leaves the clinic. The patient uses a patient programmer to adjust the stimulation parameter values within the clinician-set limits.

There are two patient programmer modes:

1. Simple Mode—Allows the patient to view battery status, adjust the preferences of the patient programmer, and turn stimulation ON or OFF, but not access other stimulation settings.

2. Advanced Mode—Allows the patient to do everything that Simple Mode does and, in addition, access their stimulation settings. There are two options within Advanced Mode:

   - View—Allows the patient to only view their stimulation settings
   - View and Adjust—Allows the patient to also make adjustments to their stimulation settings.

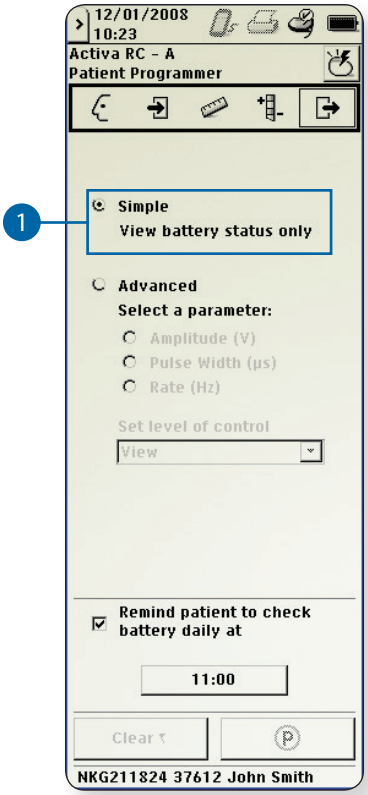
Note: *If more than one group is programmed, only Advanced Mode is available.*

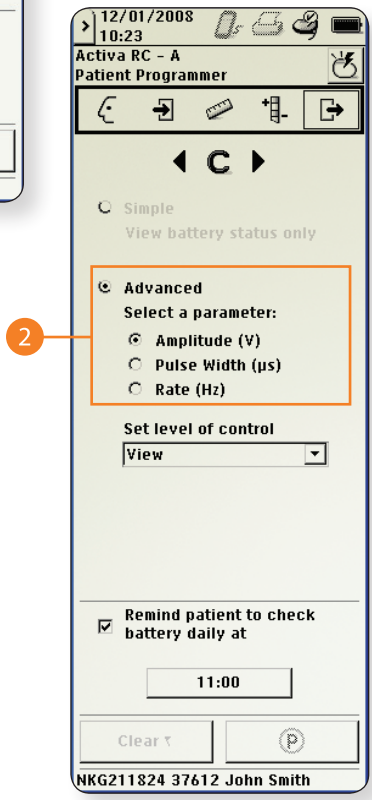
The patient can use the patient programmer to reset stimulation parameters to the most recent clinician settings in effect before any adjustments were made by the patient.

Note: *If the patient has two neurostimulators implanted, the patient programmer can communicate with both neurostimulators, but only one at a time.*

The programmer only displays information about the neurostimulator with which it is presently synchronized.

The programmer must be turned off and then synchronized with the other neurostimulator.


12/01/2008
10:23
Activa RC - A
Patient Programmer
1
Simple
View battery status only
Advanced
Select a parameter:
Amplitude (V)
Pulse Width (µs)
Rate (Hz)
Set level of control
View
Remind patient to check battery daily at
11:00
Clear
NKG211824 37612 John Smith


12/01/2008
10:23
Activa RC - A
Patient Programmer
C
Simple
View battery status only
2
Advanced
Select a parameter:
Amplitude (V)
Pulse Width (µs)
Rate (Hz)
Set level of control
View
Remind patient to check battery daily at
11:00
Clear
NKG211824 37612 John Smith

PROGRAMMING A NEUROSTIMULATOR FOR PATIENT CONTROL

To Set Amplitude, Pulse Width, or Rate Limits

1. Access the END SESSION menu ( ) and select Patient Programmer.
2. Select Advanced Mode.
3. If more than one group is defined, use the GROUP SELECTION SCROLL buttons to select a group.
4. Select a parameter.

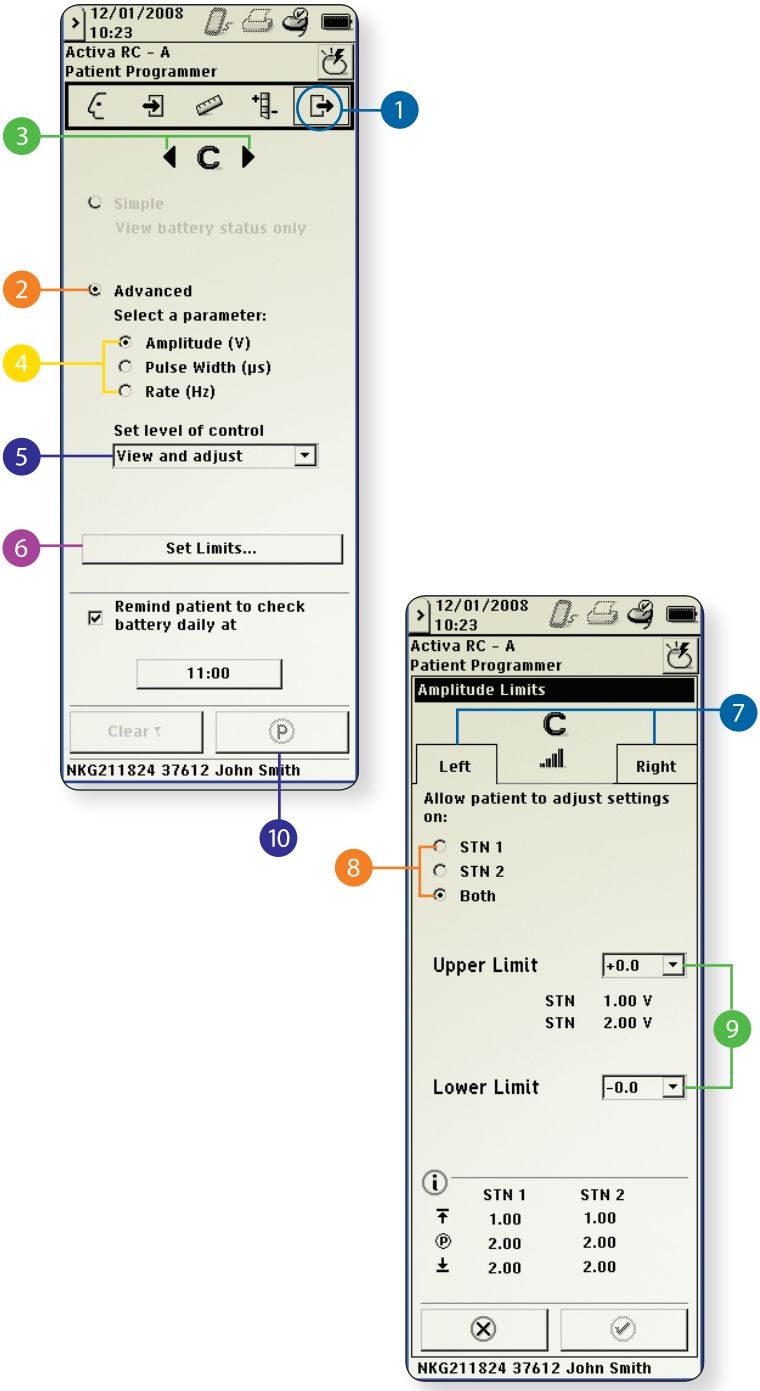
   Note: *The patient is able to adjust or view only one parameter per group. Limits can be programmed for only that parameter.*
5. Touch ( ) to select level of control desired from the drop-down list.
6. Select the SET LIMITS button. The appropriate detail screen is displayed based on the parameter selected.
7. Select a hemisphere for bilateral therapy (not applicable for unilateral therapy)

   Note: *The rate is the same for all programs in a group. Rate or rate limits cannot be programmed for individual programs within a group.*
8. If more than one program is available for that hemisphere, select the appropriate option to allow the patient to adjust settings for a specific program or for both programs.
9. Select the limit value(s) using the drop-down list(s).

   Note: *The calculated limit values (based on the tracking limits selected from the drop-down lists) and the programmed values are displayed in the information area at the bottom of the screen.*

   If available and desired, select the other hemisphere and program limit values (Step 7). Select the OK ( ) button.
10. Hold the programming head steady over the neurostimulator, then press the PROGRAMMING (P) key or select the PROGRAM ( ) button on the programmer screen.

    Note: *Repeat the steps 1-10 above if a patient has two neurostimulators.*


12/01/2008
10:23
Activa RC – A
Patient Programmer
1
3
Simple
View battery status only
2
Advanced
Select a parameter:
4
Amplitude (V)
Pulse Width (µs)
Rate (Hz)
Set level of control
5
View and adjust
6
Set Limits...
Remind patient to check battery daily at
11:00
Clear
NKG211824 37612 John Smith
10
12/01/2008
10:23
Activa RC – A
Patient Programmer
Amplitude Limits
7
Left
Right
Allow patient to adjust settings on:
8
STN 1
STN 2
Both
Upper Limit
+0.0
STN 1.00 V
STN 2.00 V
9
Lower Limit
-0.0
STN 1
STN 2
1.00
1.00
2.00
2.00
2.00
2.00
NKG211824 37612 John Smith

PATIENT REMINDER

Activa RC Rechargeable Neurostimulator

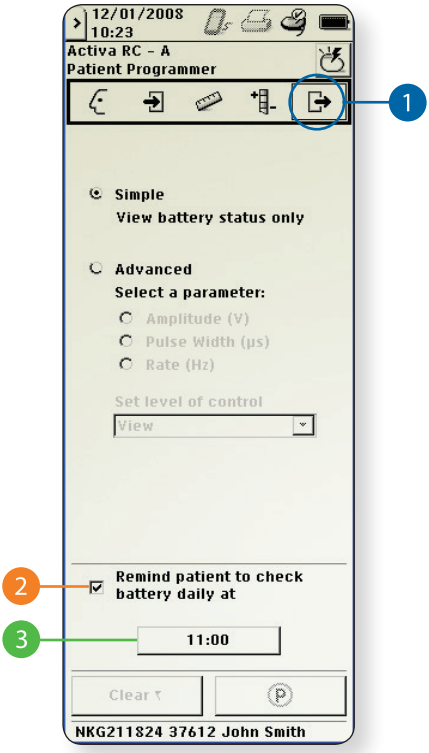
The patient reminder is used to remind the patient to check the neurostimulator battery charge level at a specific time each day:

- If the patient has not checked the neurostimulator battery charge level before the programmed time on a daily basis, the patient programmer alerts the patient with an audible tone.
- If the patient has checked the neurostimulator battery before the programmed time on a daily basis, the patient programmer will not alert the patient that day.

Setting Patient Reminder

1. Access the END SESSION menu ( ) and select Patient Programmer.
2. Select the checkbox next to the patient reminder to turn ON the feature (if it is not active).
3. Using the time input box, set the reminder hour and minute.

Note: *For the alert to function as programmed, the patient must check the neurostimulator with the patient programmer.*


12/01/2008
10:23
Activa RC - A
Patient Programmer
1
Simple
View battery status only
Advanced
Select a parameter:
Amplitude (V)
Pulse Width (µs)
Rate (Hz)
Set level of control
View
2
Remind patient to check battery daily at
3
11:00
Clear
NKG211824 37612 John Smith

PRINT SESSION REPORTS

Session reports contain the settings and patient and system information from patient sessions. You can print reports during and after patient sessions using the Now and Later columns of check boxes.

The following reports can be selected for printing, depending on whether data exist for the report:

- **Session summary report**—Neurostimulator data and history.
- **Measurements report**—Battery information, recharge information, and results from the electrode impedance test and therapy impedance test.

  Note: *This will only print the last impedance measurement done.*
- **History report**—Information on all programs in session and screening histories. There is a maximum of five sessions.
- **Groups report**—Group and program information.
- **Device usage report**—Usage data since the last session.
- **Patient report** (for the patient)—Information on patient settings and available patient limits.
- **MDT Data report**—Data that can be provided to Medtronic Technical Services for troubleshooting. (This report is a separate data file in the Session Data Manager.)
- **All reports**—All reports are selected for printing.

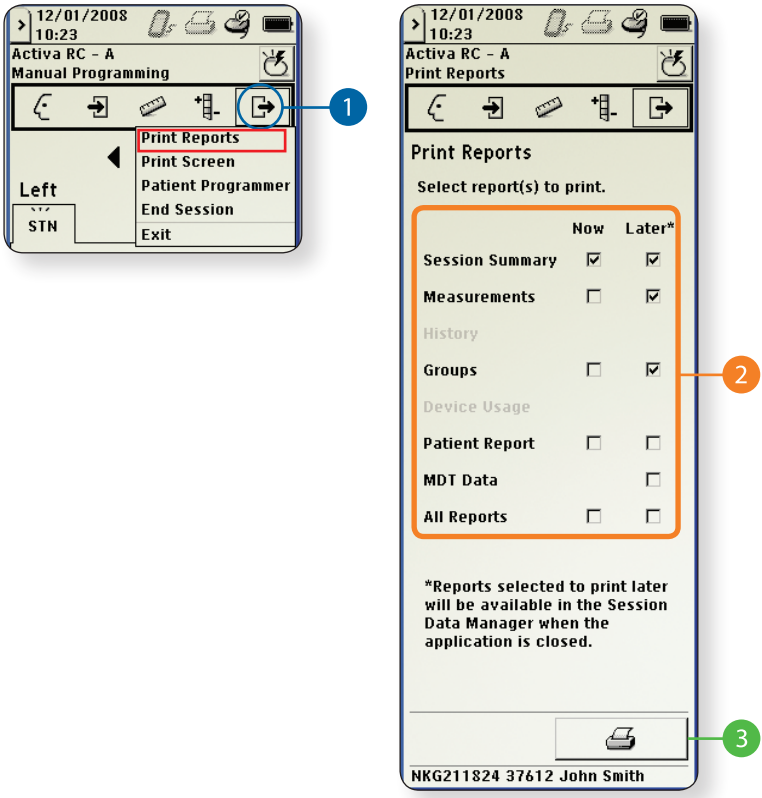
Note: *To receive the same information found in the Kinetra and Soletra long reports, print the Session Summary, Measurements, History, and Groups reports on Activa SC, Activa RC, or Activa PC. Ending parameters from the most recent session can be found in the Groups report, and dates for recent sessions can be found in the History report.*

To print a report during the session:

- Ensure the printer is ON.
- Move the programmer to within 1 meter (3.3 feet) of the printer, with the printer and programmer IR ports directly facing each other.

1. Select Print Reports from the End Session Menu.
2. Select the checkbox next to the desired reports on the list. (Unavailable reports indicated that no data is available.)
3. Select the Print button.

Note: *A printout of the final settings should be placed in the patient file. You can print saved session reports from the Session Data Manager or print current settings any time during the programming session.*



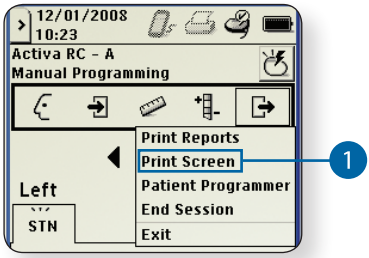
PRINT SCREEN

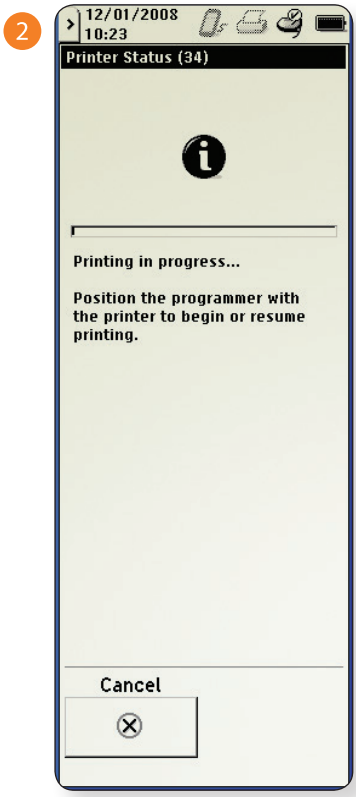
You can print the current screen displayed on the programmer and send the image to a printer.

To print the current screen:

- Ensure the printer is ON.
- Move the programmer to within 1 meter (3.3 feet) of the printer, with the printer and programmer IR ports directly facing each other.

1. Select Print Screen from the End Session menu.
2. Printer Status screen displays.


12/01/2008
10:23
Activa RC - A
Manual Programming
Print Reports
Print Screen
Patient Programmer
End Session
Exit
Left
STN
1


2
12/01/2008
10:23
Printer Status (34)
Printing in progress...
Position the programmer with the printer to begin or resume printing.
Cancel

END SESSION AND EXIT

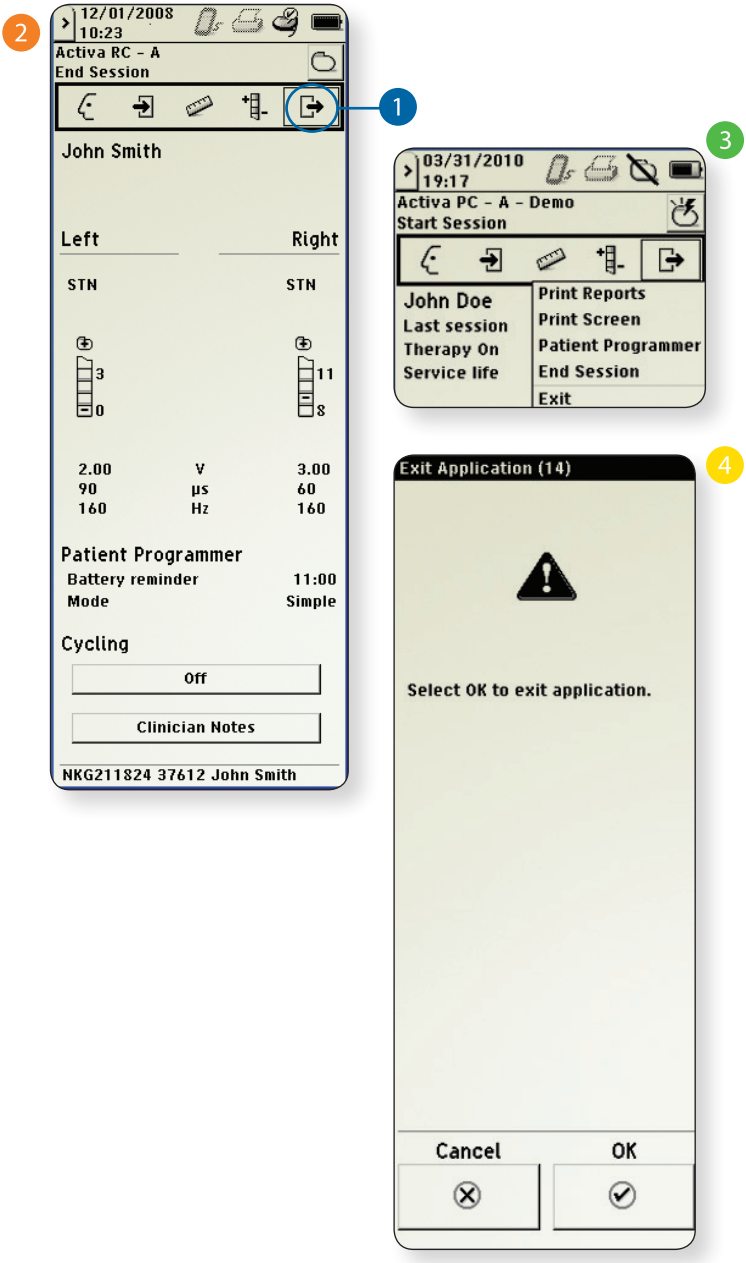
A summary of neurostimulator settings programmed during the programming session are displayed on the END SESSION screen.

To review programmed settings

1. Access the END SESSION menu and select End Session.
2. Review settings on the END SESSION screen.

   Note: *Always check the patient control limit settings on the PATIENT PROGRAMMER screen prior to the patient leaving the office.*

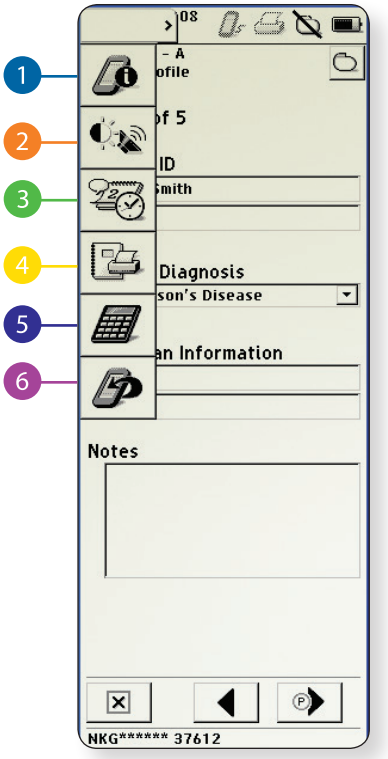
   Note: *To correct settings or make changes, access the PROGRAMMING menu (*  *).*
3. Select Exit from the EXIT menu.
4. Select OK while maintaining the telemetry head over the neurostimulator.


2
12/01/2008
10:23
Activa RC - A
End Session
1
John Smith
Left
Right
STN
STN
3
0
11
8
2.00
90
160
V
µs
Hz
3.00
60
160
Patient Programmer
Battery reminder
11:00
Mode
Simple
Cycling
Off
Clinician Notes
NKG211824 37612 John Smith
3
03/31/2010
19:17
Activa PC - A - Demo
Start Session
John Doe
Last session
Therapy On
Service life
Print Reports
Print Screen
Patient Programmer
End Session
Exit
4
Exit Application (14)
Select OK to exit application.
Cancel
OK

SLIDER BAR

Provides access to programmer information, system settings, and accessories.

1. **Information**—Select to display the names, model numbers, and version numbers for the programmer, application, and associated software and peripheral devices.
2. **Settings**—Select to adjust the display contrast, speaker volume, key click sound and to calibrate the touchscreen.
3. **Localization**—Touch to select the language preference, select/set the date format, select the decimal format, and select/set the the time format.
4. **Session Data Manager**—Select to view, print and delete session reports.
5. **Calculator**—Select to access the calculator.
6. **Exit Application**—Select to return to the Application Selection screen to select a new application.


1
2
3
4
5
6
Diagnosis
Notes
NKG****** 37612

SESSION DATA MANAGER

• To print reports:

Highlight the session data file 1 you would like to print and select the Print Short Report icon 2 or the Print Long Report icon 3 to move a report into the print queue 4.

• The transmission is complete when:

Report is automatically removed from the print queue. On-screen taskbar 9 indicator changes from () to ().

• Printing Tips (prior to queuing report):

- Move the programmer to within 1 meter (3.3 ft) of the printer.
- Ensure that the infrared (IR) port on the programmer and IR port on the printer are directly facing each other.
- Hold the programmer steady until the report transmission has completed.

1 Reports—Select session data files for printing, reviewing or deleting.

2 Print Short Report—Select to print a short version of a report (i.e., summary report only) , if available.

3 Print Long Report—Select to print a long version of a report (i.e. summary, groups, and measurement reports, if available).

4 Print Queue.

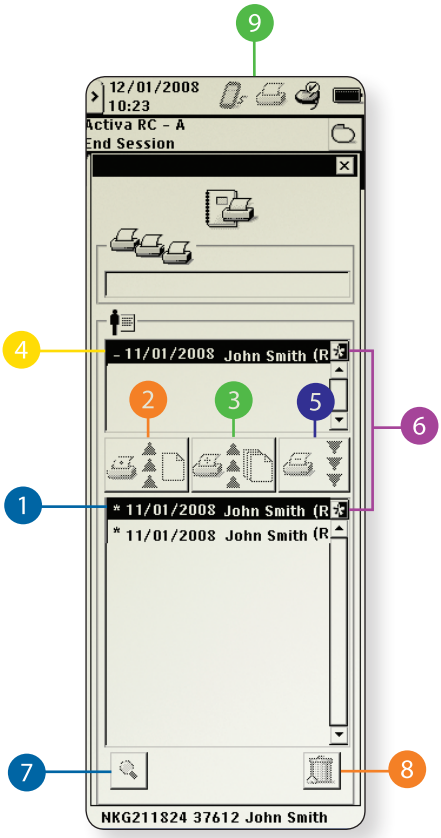
5 Remove From Queue—Select to remove a highlighted report from the print queue.

6 Select or De-Select All—Select to include or exclude all reports shown.

7 View Report—Select to display additional details for your highlighted session on screen.

8 Delete Session File—Select to permanently delete a session from the print queue or reports list.

9 On-Screen Taskbar Indicator—Changes from () to () once a report transmission is complete.


9
12/01/2008
10:23
Activa RC - A
End Session
4
- 11/01/2008 John Smith (R
2
3
5
6
1
* 11/01/2008 John Smith (R
* 11/01/2008 John Smith (R
7
8
NKG211824 37612 John Smith

GLOSSARY

Current Settings—The settings in effect during a patient session.

Cycling Off Time—In cycling, the length of time between stimulation periods; the time of the "resting" period.

Cycling On Time—In cycling, the length of time that stimulation is delivered.

Depleted—Used to refer to the battery status; state of reduced energy of a battery. Condition requires that the external device or the implanted device be replaced.

Discharged—Used to refer to the battery charge level for a rechargeable battery; state of reduced energy of a battery. Condition requires that the battery be charged.

Elective Replacement Indicator (ERI)—Notification that the INS is nearing end of service.

Electrode Impedance Measurement—Measurements of the resistance of the lead(s), extension(s), and body tissue that can provide information about the condition of the implanted system (e.g., short circuit, open circuit).

Electrode Polarity—The state of each electrode for all implanted leads: positive, negative, or off.

End of Service (EOS)—Condition of an implantable device at the time it is no longer able to operate successfully.

Final Settings—Settings in effect at the end of the patient session.

Groups—Collection of programs that work together for a particular effect or area.

Initial settings—Settings in effect at the start of the patient session.

Input Box—An area on the programmer touchscreen that, when activated, initiates the appearance of another screen or an action by the programmer.

Localization Parameters—Options for selecting country-specific formats for date, time, numbering schemes, and language.

Power On Reset (POR)—A neurostimulator safety feature that turns stimulation OFF.

Programs—A specific combination of amplitude, pulse width, and rate parameters acting on a specific electrode set that determines the stimulation pulses that are delivered.

Session Data Manager—A clinician programmer feature that allows collection and storage of patient data information gathered during patient session. Report data from previous sessions can be viewed and printed.

Stylus—A blunt pen-shaped or pencil-shaped device used to make contact with a touchscreen on a device such as a computer or programmer.

Target Value—Before programming, the intended value of a parameter.

Telemetry—Radio-frequency communication between a clinician programmer and an implanted neurostimulator.

Therapy Impedance Measurements—Impedance and stimulation current measurements taken at the programmed settings.

BRIEF SUMMARY DISCLOSURE: MEDTRONIC DBS THERAPY FOR PARKINSON'S DISEASE AND TREMOR

Medtronic DBS Therapy for Parkinson's Disease and Tremor: Product technical manual must be reviewed prior to use for detailed disclosure.

Indications:
Medtronic DBS Therapy for Parkinson's Disease: Bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic DBS Therapy for Parkinson's Disease is indicated for adjunctive therapy in reducing some of the symptoms of advanced, levodopa-responsive Parkinson's disease that are not adequately controlled with medication.

Medtronic DBS Therapy for Tremor: Unilateral thalamic stimulation using Medtronic DBS Therapy for Tremor is indicated for the suppression of tremor in the upper extremity. The system is intended for use in patients who are diagnosed with Essential Tremor or Parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability. The safety or effectiveness of this therapy has not been established for bilateral stimulation.

Contraindications: Contraindications include patients who will be exposed to MRI using a full body radio-frequency (RF) coil or a head transmit coil that extends over the chest area, patients who are unable to properly operate the neurostimulator, or for patients for whom test stimulation is unsuccessful. Diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy) is contraindicated because diathermy's energy can be transferred through the implanted system (or any of the separate implanted components), which can cause neurostimulation system or tissue damage and can result in severe injury or death. Transcranial Magnetic Stimulation (TMS) is contraindicated for patients with an implanted DBS System.

Warnings/ Precautions/Adverse Events: There is a potential risk of tissue damage using stimulation parameter settings of high amplitudes and wide pulse widths. Extreme care should be used with lead implantation in patients with a heightened risk of intracranial hemorrhage. The lead-extension connector should not be placed in the soft tissues of the neck due to an increased incidence of lead fracture. Theft detectors and security screening devices may cause stimulation to switch ON or OFF, and may cause some patients to experience a momentary increase in perceived stimulation. Although some MRI procedures can be performed safely with an implanted DBS System, clinicians should carefully weigh the decision to use MRI in patients with an implanted DBS System. MRI can cause induced voltages in the neurostimulator and/or lead possibly causing uncomfortable, jolting, or shocking levels of stimulation.

The DBS System may be affected by or adversely affect medical equipment such as cardiac pacemakers or therapies, cardioverter/ defibrillators, external defibrillators, ultrasonic equipment, electrocautery, or radiation therapy. Safety and effectiveness has not been established for patients with neurological disease other than Parkinson's disease or Essential Tremor, previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression; or for patients who are pregnant, under 18 years, over 75 years of age (Parkinson's Control Therapy) or over 80 years of age (Tremor Control Therapy). Depression, suicidal ideations and suicide have been reported in patients receiving Medtronic DBS Therapy for Movement Disorders, although no direct cause and effect relationship has been established.

Abrupt cessation of stimulation should be avoided as it may cause a return of disease symptoms, in some cases with an intensity greater than was experienced prior to system implant ("rebound" effect). Adverse events related to the therapy, device, or procedure can include: stimulation not effective, cognitive disorders, pain, dyskinesia, dystonia, speech disorders including dysarthria, infection, paresthesia, intracranial hemorrhage, electromagnetic interference, cardiovascular events, visual disturbances, sensory disturbances, device migration, paresis/asthenia, abnormal gait, incoordination, headaches, lead repositioning, thinking abnormal, device explant, hemiplegia, lead fracture, seizures, respiratory events, and shocking or jolting stimulation. Patients using a rechargeable neurostimulator should check for skin irritation or redness near the neurostimulator during or after recharging, and contact their physician if symptoms persist.

USA Rx only Rev 1212

professional.medtronic.com

United States of America
Medtronic Neuromodulation
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel. 763-505-5000
Toll-free 1-800-328-0810

Europe
Medtronic International Trading Sàrl
Route du Molliau 31
Case Postale
CH-1131 Tolochenaz
Switzerland
Tel. +41-21-802-7000

Asia-Pacific
Medtronic International, Ltd.
Suite 1602 16/F
Manulife Plaza
The Lee Gardens, 33 Hysan Avenue
Causeway Bay
Hong Kong
Tel. 852-2891-4456

Australia
Medtronic Australasia Pty. Ltd.
97 Waterloo Road
North Ryde
NSW 2113
Australia
Tel. +61-2-9857-9000
www.medtronicneuro.com.au

Canada
Medtronic of Canada Ltd.
6733 Kitimat Road
Mississauga, Ontario L5N 1W3
Canada
Tel. 1-905-826-6020

UC200806069c EN Printed in USA.

Medtronic

Innovating for life.