



Medtronic

SYSTEM ELIGIBILITY
BATTERY LONGEVITY

Neurostimulation systems for deep brain stimulation

Reference manual

! USA Rx Only



Explanation of symbols on product and package labeling for non-USA audiences.



For USA audiences only



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



Manufacturer



Authorized representative in the European community

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Refer to the indications sheet for indications and related information.

Refer to the device implant manual for device description, package contents, device specifications, and instruction for use.

Refer to the Information for Prescribers booklet for contraindications, warnings, precautions, adverse events summary, patient selection, resterilization, and component disposal.

 Refer to the Clinical Summary booklet for information on the clinical study results of the neurostimulation system, individualization of treatment, and use in specific populations.

Introduction

This manual is divided into two parts:

- **System eligibility:** For movement disorder therapies, this part describes how to use test stimulation to aid in neurostimulator selection.
- **Battery longevity and maintenance:** This part describes how to:
 - maximize recharge intervals for rechargeable neurostimulators, and
 - maximize battery longevity and estimate battery longevity based on programmed settings for nonrechargeable neurostimulators.

Device Selection

Remember that the use of higher settings with the Activa RC Neurostimulator results in the need for more frequent recharging.

Refer to the battery longevity sections for a comparison of therapeutic programming available for the neurostimulators discussed in this manual.

System Eligibility

Neurostimulator selection

For movement disorder therapies, you can use test stimulation results to guide you in selecting an appropriate implantable neurostimulator for your patient. When you find maximum settings that, during test stimulation, provide safe symptom suppression to your patient, identify the implantable neurostimulator that can most closely approximate those parameters. Remember to take into account the fact that not all neurostimulators have identical capabilities. For example, some neurostimulators will accommodate two leads, while others will not.

Prior to test stimulation and implant, the following should also be considered:

- Patient capability (eg, can the patient effectively use the recharger and/or the patient programmer associated with the neurostimulator considered for use)
- Cosmetics (eg, is the neurostimulator too large to be comfortable for the patient)
- Body type/physique

Different implantable neurostimulators have different limitations for various combinations of pulse width, rate, and amplitude. You might find that a specific combination of these parameters is accepted during test stimulation, but cannot be duplicated by all available implantable neurostimulators.

Neurostimulator replacement

Replacement of one type of neurostimulator with another can result in required parameter changes. For example, replacement of a Soletra neurostimulator with a Kinetra neurostimulator typically requires an increase of 25% in programmed voltage to maintain equivalent symptom suppression.

When replacing one model of neurostimulator with another, begin screening with low level therapeutic parameters and titrate (increase) parameters as needed.

Finally, remember that not all implantable neurostimulators offer identical expanded features.

Test stimulation devices

The Model 37022 External Neurostimulator and Model 3625 Test Stimulator can be used to assess the suitability of the following neurostimulators:

- Activa PC Model 37601
- Activa RC Model 37612

- Activa SC Model 37602
- Activa SC Model 37603
- Kinetra Model 7428
- Soletra Model 7426

Refer to Table 1 to identify:

- which implantable neurostimulators to consider based on the number of programs that successful test stimulation results require.
- when to use the test stimulation maximum amplitude tables.

Table 1. Test stimulation devices and implantable neurostimulators

Test stimulation device	Test stimulation parameter settings compared to implantable neurostimulators parameter settings
Model 37022 External Neurostimulator	For voltage mode, not all parameter settings available on the external neurostimulator during test stimulation can be duplicated with an Activa PC, Activa SC, Kinetra, or Soletra implantable neurostimulator. Refer to Table 2 for Activa PC voltage mode eligibility data. Refer to Table 4 for Activa SC voltage mode eligibility data. Refer to Table 5 for Kinetra eligibility data. Refer to Table 6 for Soletra eligibility data. The Activa RC implantable neurostimulator is capable of duplicating all programming parameters available on the external neurostimulator. For current mode, parameter settings available on the external neurostimulator during test stimulation are identical to those available on Activa PC, Activa RC, and Activa SC implantable neurostimulators.
Model 3625 Test Stimulator	Not all parameter settings available on the test stimulator during test stimulation can be duplicated with all available implantable neurostimulators. Refer to the programming parameter information for specific neurostimulators in the appropriate neurostimulator implant manual and in the Model 3625 Test Stimulator manual.

Programming instructions for the Model 37022 External Neurostimulator are located in the Activa PC, Activa RC, and Activa SC Model 8870 programming guide and the Kinetra, Soletra, and Itrel II Model 8870 programming guide.

Test stimulation using the Model 3625 Test Stimulator

When using a Model 3625 Test Stimulator:

- If the test stimulation amplitude exceeds the maximum amplitude for a specific rate and pulse width, reduce the rate until you are at or below a rate/pulse width/amplitude displayed in Table 2, Table 3, Table 4, Table 5 or Table 6.
- If the test stimulation pulse width is greater than 450 microseconds, reduce the pulse width to 450 microseconds and gradually increase the amplitude to confirm safe and satisfactory symptom suppression. A five to ten percent increase in amplitude should be expected.
- If the test stimulation rate is greater than 250 Hz, reduce the rate to 250 Hz and gradually increase the amplitude to confirm safe and satisfactory symptom suppression. Note that the Soletra neurostimulator cannot be programmed to rates greater than 185 Hz.

Test stimulation using the Model 37022 External Neurostimulator

Implantable neurostimulation systems may have limited stimulation adjustments available with certain combinations of high amplitude, pulse width, and rate settings. If a desired parameter value is unavailable, try lowering another parameter and then increasing the original parameter. For example, if amplitude cannot be increased, try lowering the rate or pulse width first, and then increase the amplitude. Alternatively, therapy efficacy might be achieved at lower amplitude with a higher pulse width. In addition, you might try changing the selected electrode(s) or repositioning the lead(s).

Screening for patient eligibility for Activa PC, Activa RC, and Activa SC

Refer to Table 2, Table 3, or Table 4 for a presentation of specific parameter combinations that will be accepted when you program the Activa PC Model 37601, Activa RC Model 37612, Activa SC Model 37602, or Activa SC Model 37603 Neurostimulator.

Note: Because testing with the Model 37022 External Neurostimulator and the Model 3625 Test Stimulator is performed one hemisphere at a time, you might see acceptable test stimulation with single-hemisphere testing but still encounter limited available programming parameters during bilateral use. Refer to Table 2, Table 3, and Table 4 for information on parameter limits for programs.

Remember that the amplitude available with one program on the external neurostimulator might be greater than the amplitude available on the implantable neurostimulator when all programs are taken into consideration.

If safe and satisfactory symptom suppression cannot be achieved within the parameters provided in the test stimulation maximum amplitude tables, that neurostimulator is not an appropriate device for the patient.

Table 2. Model 37601 Activa PC Nonrechargeable Neurostimulator
Maximum programmable amplitude at high rate/pulse width combinations using voltage mode

No. of programs intended for use	Rate (Hz)	Pulse width (µsec)					
		60	120	180	240	330	450
1 ^a	50	10.5V	10.5V	10.5V	10.5V	10.5V	10.5V
1	70	10.5V	10.5V	10.5V	10.5V	10.5V	10.0V
1	100	10.5V	10.5V	10.5V	10.5V	10.5V	9.3V
1	125	10.5V	10.5V	10.5V	10.5V	10.15V	8.75V
1	160	10.5V	10.5V	10.5V	10.5V	9.5V	8.1V
1	180	10.5V	10.5V	10.5V	10.4V	9.15V	7.75V
1	200	10.5V	10.5V	10.5V	10.05V	8.85V	7.4V
1	220	10.5V	10.5V	10.5V	9.75V	8.55V	7.1V
1	250	10.5V	10.5V	10.3V	9.35V	8.1V	6.7V
2 ^b	25	10.5V	10.5V	10.5V	10.5V	10.5V	10.5V
2	35	10.5V	10.5V	10.5V	10.5V	10.5V	10.0V
2	50	10.5V	10.5V	10.5V	10.5V	10.5V	9.3V
2	80	10.5V	10.5V	10.5V	10.5V	9.5V	8.1V
2	100	10.5V	10.5V	10.5V	10.05V	8.85V	7.4V
2	120	10.5V	10.5V	10.45V	9.45V	8.25V	6.8V
2	125	10.5V	10.5V	10.3V	9.35V	8.1V	6.7V
2	140	10.5V	10.5V	9.85V	8.9V	7.65V	6.25V
2	160	10.5V	10.5V	9.35V	8.4V	7.15V	5.75V
2	180	10.5V	10V	8.85V	7.9V	6.65V	5.25V
2	200	10.5V	9.55V	8.4V	7.45V	6.2V	4.8V
2	220	10.5V	9.1V	7.95V	7V	5.75V	4.35V
2	250	10V	8.5V	7.35V	6.4V	5.15V	3.75V
3 or 4 ^c	10	10.5V	10.5V	10.5V	10.5V	10.5V	10.5V
3 or 4	20	10.5V	10.5V	10.5V	10.5V	10.5V	9.75V
3 or 4	40	10.5V	10.5V	10.5V	10.5V	9.5V	8.1V
3 or 4	60	10.5V	10.5V	10.45V	9.45V	8.25V	6.8V
3 or 4	80	10.5V	10.5V	9.35V	8.4V	7.15V	5.75V
3 or 4	100	10.5V	9.55V	8.4V	7.45V	6.2V	4.8V
3 or 4	120	10.2V	8.7V	7.55V	6.6V	5.35V	3.95V

Table 2. Model 37601 Activa PC Nonrechargeable Neurostimulator
Maximum programmable amplitude at high rate/pulse width combinations using voltage mode (continued)

No. of programs intended for use	Rate (Hz)	Pulse width (µsec)					
		60	120	180	240	330	450
3 or 4	125	10V	8.5V	7.35V	6.4V	5.15V	3.75V

^a In this instance, the lead configuration is 1X4 and only one program is defined.

^b In this instance, the lead configuration is 2X4, and one program is defined per lead/hemisphere.

^c In this instance, the lead configuration is 2X4, and a second program is in use on one or both leads or in one or both hemispheres.

Table 3. Model 37612 Activa RC Rechargeable Neurostimulator
Maximum programmable amplitude at high rate/pulse width combinations

No. of programs intended for use	Rate (Hz)	Pulse width (µsec)					
		60	120	180	240	330	450
1 ^a	160	10.5 V	10.5 V	10.5 V	10.5 V	10.5 V	10.5 V
1	180	10.5 V	10.5 V	10.5 V	10.5 V	10.5 V	10.35 V
1	200	10.5 V	10.5 V	10.5 V	10.5 V	10.5 V	10.25 V
1	220	10.5 V	10.5 V	10.5 V	10.5 V	10.5 V	10.1 V
1	250	10.5 V	10.5 V	10.5 V	10.5 V	10.4 V	9.9 V
2 ^b	80	10.5 V	10.5 V	10.5 V	10.5 V	10.15 V	10.5 V
2	100	10.5 V	10.5 V	10.5 V	10.5 V	10.5 V	10.25 V
2	120	10.5 V	10.5 V	10.5 V	10.5 V	10.5 V	9.95 V
2	125	10.5 V	10.5 V	10.5 V	10.5 V	10.5 V	9.9 V
2	140	10.5 V	10.5 V	10.5 V	10.5 V	10.5 V	9.7 V
2	160	10.5 V	10.5 V	10.5 V	10.5 V	10.4 V	9.45 V
2	180	10.5 V	10.5 V	10.5 V	10.5 V	10.15 V	9.20 V
2	200	10.5 V	10.5 V	10.5 V	10.5 V	9.9 V	8.95 V
2	220	10.5 V	10.5 V	10.5 V	10.5 V	9.65 V	8.7 V
2	250	10.5 V	10.5 V	10.5 V	10.35 V	9.25 V	8.3 V
3 or 4 ^c	40	10.5 V	10.5 V	10.5 V	10.5 V	10.5 V	10.5 V
3 or 4	60	10.5 V	10.5 V	10.5 V	10.5 V	10.5 V	9.95 V
3 or 4	80	10.5 V	10.5 V	10.5 V	10.5 V	10.5 V	9.45 V
3 or 4	100	10.5 V	10.5 V	10.5 V	10.5 V	9.90 V	8.95 V
3 or 4	120	10.5 V	10.5 V	10.5 V	10.45 V	9.35 V	8.45 V

Table 3. Model 37612 Activa RC Rechargeable Neurostimulator
Maximum programmable amplitude at high rate/pulse width combinations (continued)

No. of programs intended for use	Rate (Hz)	Pulse width (µsec)					
		60	120	180	240	330	450
3 or 4	125	10.5 V	10.5 V	10.5 V	9.95 V	9.25 V	8.3 V

^a In this instance, the lead configuration is 1X4 and only one program is defined.

^b In this instance, the lead configuration is 2X4, and one program is defined per lead/hemisphere.

^c In this instance, the lead configuration is 2X4, and a second program is in use on one or both leads or in one or both hemispheres.

Table 4. Activa SC Model 37602 and Activa SC Model 37603 Nonrechargeable Neurostimulator
Maximum programmable amplitude at high rate/pulse width combinations using voltage mode

No. of programs intended for use	Rate (Hz)	Pulse width (µsec)					
		60	120	180	240	330	450
1 ^a	50	10.5V	10.5V	10.5V	10.5V	10.5V	10.5V
1	70	10.5V	10.5V	10.5V	10.5V	10.5V	10.0V
1	100	10.5V	10.5V	10.5V	10.5V	10.5V	9.3V
1	125	10.5V	10.5V	10.5V	10.5V	10.15V	8.75V
1	160	10.5V	10.5V	10.5V	10.5V	9.5V	8.1V
1	180	10.5V	10.5V	10.5V	10.4V	9.15V	7.75V
1	200	10.5V	10.5V	10.5V	10.05V	8.85V	7.4V
1	220	10.5V	10.5V	10.5V	9.75V	8.55V	7.1V
1	250	10.5V	10.5V	10.3V	9.35V	8.1V	6.7V
2 ^b	25	10.5V	10.5V	10.5V	10.5V	10.5V	10.5V
2	35	10.5V	10.5V	10.5V	10.5V	10.5V	10.0V
2	50	10.5V	10.5V	10.5V	10.5V	10.5V	9.3V
2	80	10.5V	10.5V	10.5V	10.5V	9.5V	8.1V
2	100	10.5V	10.5V	10.5V	10.05V	8.85V	7.4V
2	120	10.5V	10.5V	10.45V	9.45V	8.25V	6.8V
2	125	10.5V	10.5V	10.3V	9.35V	8.1V	6.7V

^a In this instance, only one program is defined.

^b In this instance, a second program is in use.

Screening for patient eligibility for Kinetra or Soletra

For Kinetra and Soletra Neurostimulators, when performing test stimulation with either the Model 37022 External Neurostimulator or the Model 3625 Test Stimulator, verify that the screening parameters do not exceed the maximum amplitude and pulse width combinations shown in Table 5 and Table 6.

Note: If test stimulation is unsuccessful, the system should not be implanted.

You may be required to program a greater voltage on the Kinetra neurostimulator than that used during screening with the Model 37022 External Neurostimulator in order to achieve comparable symptom suppression. Review the information in Table 5 and Figure 1 before screening.

Table 5. Maximum amplitude (volts) available for specific rate/pulse width combinations on the Model 7428 Kinetra Neurostimulator^a

		Pulse width (µseconds)					
		60	90	120	150	180	210 ^b
Rate (Hz)	130	8.2V	8.1V	8.0V	7.6V	6.9V	6.4V
	140	8.1V	8.1V	7.8V	7.3V	6.7V	6.3V
	150	8.1V	8.0V	7.6V	7.1V	6.5V	6.1V
	160	8.0V	8.0V	7.4V	6.8V	6.3V	5.8V
	170	8.0V	7.8V	7.2V	6.5V	6.0V	5.6V
	185	7.9V	7.6V	6.8V	6.2V	5.6V	5.2V
	200	7.8V	7.3V	6.5V	5.9V	5.4V	4.9V
	220	7.7V	6.8V	6.1V	5.4V	4.9V	4.4V
	250	7.3V	6.4V	5.7V	4.9V	4.4V	3.8V

^a This table is based on data collected with a 1000-ohm resistive load. If the screening rate is between table settings, use the higher rate.

^b The Kinetra neurostimulator can be programmed to pulse widths up to 450µsec.

Table 6. Maximum amplitude (volts) available for specific rate/pulse width combinations on the Model 7426 Soletra Neurostimulator^a

		Pulse width (µseconds)					
		60	90	120	150	180	210 ^b
Rate (Hz)	130	8.7V	8.6V	8.5V	8.4V	8.4V	8.3V
	135	8.6V	8.5V	8.5V	8.4V	8.3V	8.2V
	145	8.6V	8.5V	8.4V	8.3V	8.2V	8.1V
	160	8.5V	8.4V	8.3V	8.1V	8.0V	7.9V
	170	8.5V	8.3V	8.1V	7.9V	7.7V	7.6V
	185	8.3V	8.0V	7.7V	7.5V	7.1V	6.7V

^a This table is based on data collected with a 1000-ohm resistive load. If the screening rate is between table settings, use the higher rate.

^b The Soletra neurostimulator can be programmed to pulse widths up to 450µsec.

When assessing the suitability of a neurostimulation system, ensure parameter settings used to achieve symptom suppression are not within the charge density warning area shown in Figure 1.

Note: The amplitude and pulse width limits in Figure 1 were computed for impedances ranging from 500 to 2000 ohms, lead surface areas of 0.06 cm², and a charge density threshold of 30 microcoulombs/cm²/phase.

Charge Density

A survey of literature regarding electrical stimulation of neural tissue suggests that damage may occur above 30 microcoulombs/cm²/phase. The Medtronic DBS System is capable of producing charge densities in excess of 30 microcoulombs/cm²/phase on an electrode surface area of 0.06cm² (for the DBS Model 3387 and Model 3389 Leads). If the maximum charge density threshold is reached, the **Charge Density** warning message appears.

Charge density depends on the delivered current:

- In voltage mode, the delivered current depends on the therapy impedance.
- In current mode, the delivered current remains constant regardless of therapy impedance.

Charge density in voltage mode

When programming parameters using voltage mode, there are two charge density thresholds to be considered:

- First threshold is based on the assumed conservative 500-ohm impedance
- Second threshold is based on the actual therapy impedance measurement

Charge density is first calculated using the programmed settings and the conservative impedance of 500 ohms. If parameter limits are programmed, the upper limit settings for amplitude and pulse width are always used in the charge density calculation.

The first time the programmed therapy settings result in a charge density that exceeds the default threshold (30 microcoulombs/cm²/phase at 500 ohms), the following charge density warning appears:

Charge density may be high enough to cause tissue damage. Consult the technical manual. Select OK to continue and use the selected value.

Note: A parameter setting that exceeds the default threshold would fall in the area above the solid line in Figure 1.

After the warning appears, you can select **Cancel** and continue to use the previously programmed parameter settings or select **OK** to use the new parameter settings. Refer to the appropriate neurostimulator programming guide for additional programming instructions related to charge density warnings.

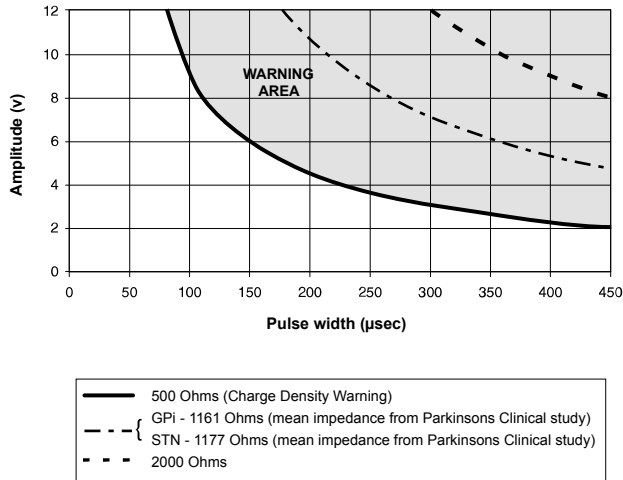


Figure 1. Charge density with Parkinson's disease clinical mean impedance.

Note: Amplitude and pulse width combinations that fall below the plotted line are safe for use.

Charge density in current mode

If the Medtronic DBS System is programmed with the amplitude in current mode:

- If parameter limits are programmed, the upper limit settings for amplitude and pulse width are used.
- If the charge density exceeds 30 microcoulombs/cm²/phase, the following warning message appears:

Charge density may be high enough to cause tissue damage. Consult the technical manual. Select OK to continue and use the selected value.

Refer to the appropriate programming guide for additional programming instructions related to charge density warnings.

Battery longevity and maintenance

To maximize the battery longevity of a non-rechargeable implantable neurostimulator or the recharge interval of a rechargeable implantable neurostimulator, follow these tips:

- Use fewer programs, if applicable.
- Use the minimum number of electrodes necessary for effective symptom suppression.
Note: Adhere to the guidelines in the Model 7426 Soletra Neurostimulator literature for programming cycling.
- Use the lowest effective settings for amplitude, rate, and pulse width.
- Unipolar stimulation may allow for lower amplitude levels to achieve equivalent therapies, resulting in longer battery life.

Note: The use of cycling may cause a reduction in longevity or time between recharge sessions on Activa RC, Activa PC, and Activa SC devices. Consult the appropriate section for the device in question for additional information.

Activa RC Neurostimulator battery longevity

The Activa RC Neurostimulator rechargeable battery requires that a minimum charge be maintained in order for the battery to reach maximum longevity.

The Activa RC Neurostimulator battery may provide 9 years of operation. Over time, the neurostimulator battery will need more frequent recharges. Like all rechargeable batteries, use over time and repeated recharge cycles reduce the maximum charge capacity of the neurostimulator battery.

When the neurostimulator battery reaches 8 years of operation, the elective replacement indicator (ERI) message is displayed in the Observations box on the clinician programmer screen and on the patient programmer screen. A replacement neurostimulator is needed within 12 months. At 9 years, the end of service (EOS) message is displayed in the Observations box on the clinician programmer screen, the patient programmer screen, and the recharger screen. At this time, the neurostimulator may no longer provide effective stimulation and a replacement neurostimulator is needed.

Estimating how frequently the battery requires charging

The amount of time before the battery requires charging is affected by patient use, the number of programs, stimulation settings in each program, and the use of cycling. All these factors are variable and may result in reduced time between recharge sessions. Monitor your patient's battery charge level frequently. Higher stimulation settings will require more frequent recharging sessions. Patients should

define a recharge schedule that meets their individual needs while maintaining a charge level that is capable of sustaining programmed stimulation settings.

△ **Caution:** Stimulation settings for systems implanted in the internal globus pallidus (GPi) may be higher than stimulation settings for systems implanted in the subthalamic nucleus (STN). Consequently, when implanted in the GPi, rechargeable systems may need to be charged more frequently and nonrechargeable systems may have reduced battery longevity compared to systems implanted in the STN.

Table 7 and Table 8 provide data on expected recharge intervals based on typical usage parameters.

Table 7. Activa RC voltage mode recharge intervals

Amplitude (V)	Rate (Hz)	Pulse (microsec)	Load (ohms)	Recharge interval (days)
2	130	60	800	33.8
2	130	90	800	29.2
2	130	120	800	25.8
2	130	210	800	19.2
2	185	60	800	26.3
2	185	90	800	22.5
2	185	120	800	19.7
2	185	210	800	14.5
2	250	60	800	20.9
2	250	90	800	17.7
2	250	120	800	15.4
2	250	210	800	11.4
2	130	60	1200	37.4
2	130	90	1200	33.4
2	130	120	1200	30.2
2	130	210	1200	23.7
2	185	60	1200	29.5
2	185	90	1200	26.1
2	185	120	1200	23.4
2	185	210	1200	18.1
2	250	60	1200	23.6
2	250	90	1200	20.7
2	250	120	1200	18.5
2	250	210	1200	14.2

Table 7. Activa RC voltage mode recharge intervals (continued)

Amplitude (V)	Rate (Hz)	Pulse (microsec)	Load (ohms)	Recharge interval (days)
2	130	60	1600	39.6
2	130	90	1600	36.1
2	130	120	1600	33.2
2	130	210	1600	26.8
2	185	60	1600	31.4
2	185	90	1600	28.3
2	185	120	1600	25.8
2	185	210	1600	20.7
2	250	60	1600	25.2
2	250	90	1600	22.6
2	250	120	1600	20.5
2	250	210	1600	16.3
3	130	60	800	28.9
3	130	90	800	24.2
3	130	120	800	20.8
3	130	210	800	14.8
3	185	60	800	22.2
3	185	90	800	18.4
3	185	120	800	15.7
3	185	210	800	11.1
3	250	60	800	17.5
3	250	90	800	14.3
3	250	120	800	12.2
3	250	210	800	8.6
3	130	60	1200	33.1
3	130	90	1200	28.7
3	130	120	1200	25.4
3	130	210	1200	18.9
3	185	60	1200	25.8
3	185	90	1200	22.1
3	185	120	1200	19.3

Table 7. Active RC voltage mode recharge intervals (continued)

Amplitude (V)	Rate (Hz)	Pulse (microsec)	Load (ohms)	Recharge interval (days)
3	185	210	1200	14.3
3	250	60	1200	20.4
3	250	90	1200	17.4
3	250	120	1200	15.2
3	250	210	1200	11.2
3	130	60	1600	35.8
3	130	90	1600	31.7
3	130	120	1600	28.5
3	130	210	1600	22.1
3	185	60	1600	28.0
3	185	90	1600	24.6
3	185	120	1600	21.9
3	185	210	1600	16.8
3	250	60	1600	22.3
3	250	90	1600	19.4
3	250	120	1600	17.3
3	250	210	1600	13.2
4	130	60	800	18.1
4	130	90	800	14.6
4	130	120	800	12.2
4	130	210	800	8.3
4	185	60	800	13.5
4	185	90	800	10.8
4	185	120	800	9.0
4	185	210	800	6.1
4	250	60	800	10.4
4	250	90	800	8.3
4	250	120	800	6.9
4	250	210	800	4.7
4	130	60	1200	21.5

Table 7. Activa RC voltage mode recharge intervals (continued)

Amplitude (V)	Rate (Hz)	Pulse (microsec)	Load (ohms)	Recharge interval (days)
4	130	90	1200	18.0
4	130	120	1200	15.5
4	130	210	1200	11.0
4	185	60	1200	16.2
4	185	90	1200	13.4
4	185	120	1200	11.5
4	185	210	1200	8.2
4	250	60	1200	12.5
4	250	90	1200	10.3
4	250	120	1200	8.9
4	250	210	1200	6.3
4	130	60	1600	23.8
4	130	90	1600	20.4
4	130	120	1600	17.9
4	130	210	1600	13.2
4	185	60	1600	18.0
4	185	90	1600	15.3
4	185	120	1600	13.4
4	185	210	1600	9.8
4	250	60	1600	14.0
4	250	90	1600	11.9
4	250	120	1600	10.3
4	250	210	1600	7.6
5	130	60	800	16.0
5	130	90	800	12.6
5	130	120	800	10.5
5	130	210	800	7.0
5	185	60	800	11.9
5	185	90	800	9.3
5	185	120	800	7.7
5	185	210	800	5.1

Table 7. Activa RC voltage mode recharge intervals (continued)

Amplitude (V)	Rate (Hz)	Pulse (microsec)	Load (ohms)	Recharge interval (days)
5	250	60	800	9.1
5	250	90	800	7.1
5	250	120	800	5.9
5	250	210	800	3.9
5	130	60	1200	19.5
5	130	90	1200	15.9
5	130	120	1200	13.5
5	130	210	1200	9.4
5	185	60	1200	14.5
5	185	90	1200	11.8
5	185	120	1200	10.0
5	185	210	1200	6.9
5	250	60	1200	11.2
5	250	90	1200	9.1
5	250	120	1200	7.7
5	250	210	1200	5.4
5	130	60	1600	21.8
5	130	90	1600	18.3
5	130	120	1600	15.9
5	130	210	1600	11.4
5	185	60	1600	16.4
5	185	90	1600	13.7
5	185	120	1600	11.8
5	185	210	1600	8.5
5	250	60	1600	12.7
5	250	90	1600	10.6
5	250	120	1600	9.1
5	250	210	1600	6.5

Table 8. Activa RC current mode recharge intervals

Amplitude (V)	Rate (Hz)	Pulse (microsec)	Load (ohms)	Recharge interval (days)
2	130	60	800	42.7
2	130	90	800	35.8
2	130	120	800	30.9
2	130	210	800	21.8
2	185	60	800	34.9
2	185	90	800	28.5
2	185	120	800	24.1
2	185	210	800	16.5
2	250	60	800	28.6
2	250	90	800	22.9
2	250	120	800	19.2
2	250	210	800	12.8
2	130	60	1200	42.6
2	130	90	1200	35.8
2	130	120	1200	30.8
2	130	210	1200	21.8
2	185	60	1200	34.8
2	185	90	1200	28.5
2	185	120	1200	24.1
2	185	210	1200	16.5
2	250	60	1200	28.6
2	250	90	1200	22.9
2	250	120	1200	19.1
2	250	210	1200	12.8
2	130	60	1600	41.6
2	130	90	1600	34.9
2	130	120	1600	29.3
2	130	210	1600	16.8
2	185	60	1600	33.9
2	185	90	1600	26.9
2	185	120	1600	20.1

Table 8. Activa RC current mode recharge intervals (continued)

Amplitude (V)	Rate (Hz)	Pulse (microsec)	Load (ohms)	Recharge interval (days)
2	185	210	1600	12.2
2	250	60	1600	27.7
2	250	90	1600	19.0
2	250	120	1600	14.8
2	250	210	1600	9.4
3	130	60	800	35.9
3	130	90	800	29.0
3	130	120	800	24.3
3	130	210	800	16.3
3	185	60	800	28.6
3	185	90	800	22.5
3	185	120	800	18.5
3	185	210	800	12.1
3	250	60	800	23.0
3	250	90	800	17.8
3	250	120	800	14.5
3	250	210	800	9.3
3	130	60	1200	27.1
3	130	90	1200	21.5
3	130	120	1200	17.7
3	130	210	1200	11.7
3	185	60	1200	21.0
3	185	90	1200	16.2
3	185	120	1200	13.3
3	185	210	1200	8.6
3	250	60	1200	16.5
3	250	90	1200	12.6
3	250	120	1200	10.2
3	250	210	1200	6.5
3	130	60	1600	26.6

Table 8. Activa RC current mode recharge intervals (continued)

Amplitude (V)	Rate (Hz)	Pulse (microsec)	Load (ohms)	Recharge interval (days)
3	130	90	1600	21.0
3	130	120	1600	17.1
3	130	210	1600	9.6
3	185	60	1600	20.5
3	185	90	1600	15.6
3	185	120	1600	12.0
3	185	210	1600	6.9
3	250	60	1600	15.8
3	250	90	1600	11.4
3	250	120	1600	8.3
3	250	210	1600	5.0
4	130	60	800	25.3
4	130	90	800	18.8
4	130	120	800	15.0
4	130	210	800	9.3
4	185	60	800	18.6
4	185	90	800	13.8
4	185	120	800	10.9
4	185	210	800	6.7
4	250	60	800	14.6
4	250	90	800	10.7
4	250	120	800	8.2
4	250	210	800	5.1
4	130	60	1200	22.3
4	130	90	1200	16.5
4	130	120	1200	12.9
4	130	210	1200	7.3
4	185	60	1200	16.6
4	185	90	1200	11.9
4	185	120	1200	8.7
4	185	210	1200	5.2

Table 8. Activa RC current mode recharge intervals (continued)

Amplitude (V)	Rate (Hz)	Pulse (microsec)	Load (ohms)	Recharge interval (days)
4	250	60	1200	12.2
4	250	90	1200	8.5
4	250	120	1200	6.5
4	250	210	1200	3.9
4	130	60	1600	18.6
4	130	90	1600	14.1
4	130	120	1600	10.8
4	130	210	1600	6.1
4	185	60	1600	14.0
4	185	90	1600	10.0
4	185	120	1600	7.6
4	185	210	1600	4.3
4	250	60	1600	10.6
4	250	90	1600	7.1
4	250	120	1600	5.4
4	250	210	1600	3.1
5	130	60	800	20.1
5	130	90	800	15.2
5	130	120	800	12.2
5	130	210	800	7.7
5	185	60	800	15.2
5	185	90	800	11.3
5	185	120	800	8.9
5	185	210	800	5.5
5	250	60	800	11.7
5	250	90	800	8.6
5	250	120	800	6.8
5	250	210	800	4.2
5	130	60	1200	16.1
5	130	90	1200	12.0

Table 8. *Activa RC current mode recharge intervals (continued)*

Amplitude (V)	Rate (Hz)	Pulse (microsec)	Load (ohms)	Recharge interval (days)
5	130	120	1200	9.6
5	130	210	1200	5.7
5	185	60	1200	12.0
5	185	90	1200	8.8
5	185	120	1200	7.0
5	185	210	1200	3.8
5	250	60	1200	9.2
5	250	90	1200	6.7
5	250	120	1200	5.1
5	250	210	1200	2.6
5	130	60	1600	12.8
5	130	90	1600	9.6
5	130	120	1600	7.7
5	130	210	1600	4.8
5	185	60	1600	9.4
5	185	90	1600	7.0
5	185	120	1600	5.5
5	185	210	1600	3.5
5	250	60	1600	7.2
5	250	90	1600	5.3
5	250	120	1600	4.2
5	250	210	1600	2.6

Activa PC and Activa SC Neurostimulator battery longevity

The battery of an Activa PC or Activa SC Neurostimulator can last for months or years, depending on the following factors:

- Programmed parameters (ie, amplitude, rate, pulse width, number of active electrodes used, number of programs per lead)

- System impedance
- Hours per day of stimulation
- The degree of patient control over programmable stimulation parameters

Note: The use of cycling may cause a reduction in longevity depending on programmed settings. Refer to steps on estimating battery longevity and the Adjusted Energy Use graph (Figure 2) for additional information.

Estimating battery longevity for the Activa PC and Activa SC Neurostimulators

The following formula estimates the approximate period of time that a new Activa PC and Activa SC Neurostimulator battery will last. The estimation is based on the settings for one group. Programs 3 and 4 are available in Activa PC only.

Expected values

1. The estimation formula is based on expected programmed values, the modes of operation, the measured impedance, and how often the therapy is used:

Program 1	Program 2	Program 3 ^a	Program 4 ^a
Amplitude: $\frac{\text{_____}}{\text{V/mA}}$	Amplitude: $\frac{\text{_____}}{\text{V/mA}}$	Amplitude: $\frac{\text{_____}}{\text{V/mA}}$	Amplitude: $\frac{\text{_____}}{\text{V/mA}}$
Rate ^b : _____ Hz	Rate ^b : _____ Hz	Rate ^b : _____ Hz	Rate ^b : _____ Hz
Pulse width: _____ μsec	Pulse width: _____ μsec	Pulse width: _____ μsec	Pulse width: _____ μsec
Impedance: $\frac{\text{_____}}{\text{ohms}}$	Impedance: $\frac{\text{_____}}{\text{ohms}}$	Impedance: $\frac{\text{_____}}{\text{ohms}}$	Impedance: $\frac{\text{_____}}{\text{ohms}}$

Modes of operation and use

Stimulation/day: _____ Hours/day

^a Programs 3 and 4 are available in Activa PC only.

^b Rates for Programs 1, 2, 3, and 4 are the same.

Program 1 (P1)

2. Using the amplitude, rate, and pulse width, locate the energy use (EU) for Program 1 from Table 9 (if voltage mode is applied) or from Table 11 (if current mode is applied): _____
3. Locate the Impedance Correction Factor (ICF) for Program 1 based on the measured impedance from Table 10 (voltage mode) or Table 12 (current mode): _____.
4. Compute the Program 1 Factor (P1F):

$$\text{P1EU } \underline{\hspace{1cm}} \times \text{P1ICF } \underline{\hspace{1cm}} = \text{P1F } \underline{\hspace{1cm}}$$

Program 2 (P2)

5. For a second program, repeat steps 1–3 to obtain the Program 2 Factor (P2F):
 $P2EU \text{ ______} \times P2ICF \text{ ______} = P2F$

Program 3 (P3) Activa PC only

6. For a third program, repeat steps 1–3 to obtain the Program 3 Factor (P3F):
 $P3EU \text{ ______} \times P3ICF \text{ ______} = P3F$

Program 4 (P4) Activa PC only

7. For a fourth program, repeat steps 1–3 to obtain the Program 4 Factor (P4F):
 $P4EU \text{ ______} \times P4ICF \text{ ______} = P4F$

Computing the multi-program factor (MPF)

8. Compute the MPF (use 0 for unused programs):
 $P1F \text{ ______} + P2F \text{ ______} + P3F \text{ ______} + P4F \text{ ______} = MPF \text{ ______}$
9. Determine the Usage Correction Factor (UCF) using the hours of stimulation per day:
 $UCF = \text{hours of stimulation per day} \div 24 \text{ hours}$
10. Compute the adjusted Energy Use value:
 $MPF \text{ ______} \times UCF \text{ ______} + [24.4 \times (1 - UCF \text{ ______})] = \text{______} \text{ Adjusted Energy Use}$
11. Use the adjusted Energy Use value and determine the battery longevity from Figure 2 and Figure 3.

Following are examples for estimating battery longevity for the Activa PC and Activa SC Neurostimulators.

Calculating battery longevity for the Activa PC Neurostimulator in voltage mode

The patient's neurostimulator is programmed with amplitude, rate, and pulse width settings that equate to an energy use figure of 89 for Program 1 and 67 for Program 2 (refer to Table 9 to obtain the energy use figure). The patient uses the neurostimulator 16 hours per day in continuous mode.

The neurostimulator impedance is 1000 ohms for Program 1 and 750 ohms for Program 2. The resulting impedance correction factors (ICFs) from Table 10 are:

Program 1: Impedance = 1000 ohms; ICF = 1.00
Program 2: Impedance = 750 ohms; ICF = 1.20

Program 1 (P1)

P1EU		P1ICF		P1F
89	X	1.00	=	89.00

Program 2 (P2)

$$\begin{array}{rclclcl} \text{P2EU} & & \text{P2ICF} & & \text{P2F} & & \\ 67 & \times & 1.20 & = & 80.40 & & \end{array}$$

Computing the multiprogram factor (use 0 for unused programs)

$$\begin{array}{rclclclclcl} \text{P1F} & & \text{P2F} & & \text{P3F} & & \text{P4F} & & \text{MPF} & \\ 89 & + & 80.40 & + & 0 & + & 0 & = & 169.40 & \end{array}$$

Usage correction factor = 16 hours of stimulation / 24 hours = 0.66

Adjusted energy use value for four programs:

$$\begin{array}{rclclclclcl} \text{MPF} & & \text{UCF} & & \text{UCF} & & \text{AEU} & & & \\ 169.40 & \times & 0.66 & + & [24.4 & \times & (1 & - & 0.66)] & = & 120.1 & \end{array}$$

Use the adjusted energy use to find the battery longevity from the graph in Figure 2.

Calculating battery longevity for the Activa PC Neurostimulator in current mode

The patient's neurostimulator is programmed with amplitude, rate, and pulse width settings that equate to an energy use figure of 65 for Program 1 and 77 for Programs 2, 3, and 4 (refer to Table 11 to obtain the energy use figure). The patient uses the neurostimulator 16 hours per day in continuous mode.

The neurostimulator impedance is 1000 ohms for program 1, 1400 ohms for program 2, 1200 ohms for program 3, and 1100 ohms for program 4. The resulting impedance correction factors (ICFs) from Table 12 are:

Program 1: Impedance = 1000 ohms; ICF = 1.00

Program 2: Impedance = 1400 ohms; ICF = 1.32

Program 3: Impedance = 1200 ohms; ICF = 1.16

Program 4: Impedance = 1100 ohms; ICF = 1.08

Program 1 (P1)

$$\begin{array}{rclclcl} \text{P1EU} & & \text{P1ICF} & & \text{P1F} & & \\ 65 & \times & 1.00 & = & 65.00 & & \end{array}$$

Program 2 (P2)

$$\begin{array}{rclclcl} \text{P2EU} & & \text{P2ICF} & & \text{P2F} & & \\ 77 & \times & 1.32 & = & 101.64 & & \end{array}$$

Program 3 (P3)

$$\begin{array}{rclclcl} \text{P3EU} & & \text{P3ICF} & & \text{P3F} & & \end{array}$$

Program 3 (P3)

$$77 \quad X \quad 1.16 \quad = \quad 89.32$$

Program 4 (P4)

$$\begin{array}{r} P4EU \\ 77 \end{array} \quad X \quad \begin{array}{r} P4ICF \\ 1.08 \end{array} \quad = \quad \begin{array}{r} P4F \\ 83.16 \end{array}$$

Computing the multiprogram factor

$$\begin{array}{r} P1F \\ 65 \end{array} \quad + \quad \begin{array}{r} P2F \\ 101.64 \end{array} \quad + \quad \begin{array}{r} P3F \\ 89.32 \end{array} \quad + \quad \begin{array}{r} P4F \\ 83.16 \end{array} \quad = \quad \begin{array}{r} MPF \\ 339.12 \end{array}$$

Usage correction factor = 16 hours of stimulation / 24 hours = 0.66

Adjusted energy use value for four programs:

$$\begin{array}{r} MPF \\ 339.12 \end{array} \quad X \quad \begin{array}{r} UCF \\ 0.66 \end{array} \quad + \quad [24.4 \quad X \quad (1 \quad - \quad 0.66)] \quad = \quad \begin{array}{r} AEU \\ 232.12 \end{array}$$

Use the adjusted energy use to find the estimated battery longevity from the graph in Figure 2.

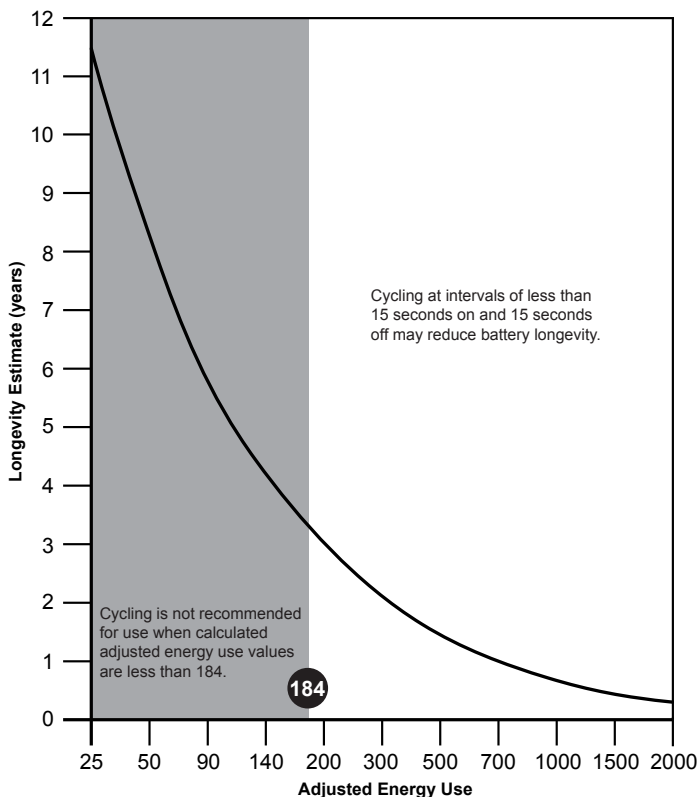


Figure 2. *Activa PC Neurostimulator longevity estimates (years) for energy use.*

Calculating battery longevity for the Activa SC Neurostimulator in voltage mode

The patient's neurostimulator is programmed with amplitude, rate, and pulse width settings that equate to an energy use figure of 89 for Program 1 (refer to Table 9 to obtain the energy use figure). The patient uses the neurostimulator 16 hours per day in continuous mode.

The neurostimulator impedance is 1000 ohms for Program 1. The resulting impedance correction factors (ICFs) from Table 10 are:

Program 1: Impedance = 1000 ohms; ICF = 1.00

Program 1 (P1)

P1EU		P1ICF	=	P1F
89	X	1.00	=	89.00

Computing the multiprogram factor (use 0 for unused programs)

P1F		P2F		P3F		P4F		MPF
89	+	0	+	0	+	0	=	89

Usage correction factor = 16 hours of stimulation / 24 hours = 0.66

Adjusted energy use value:

MPF		UCF		UCF		AEU
89	X	0.66	+	[24.4 X (1 - 0.66)]	=	67.0

Use the adjusted energy use to find the battery longevity from the graph in Figure 3.

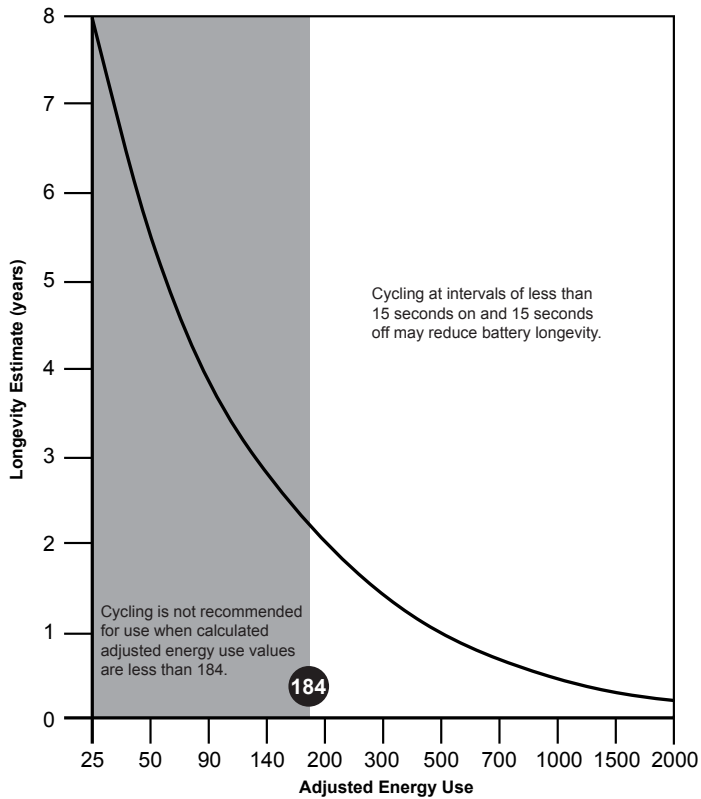


Figure 3. Activa SC Neurostimulator longevity estimates (years) for energy use.

Table 9. Activa PC and Activa SC Neurostimulator energy use for voltage mode^a

Amplitude (V)	Rate	Pulse width			
		60	120	210	450
1.0	130	27	36	48	79
	180	36	47	63	105
	250	48	62	86	141
2.0	130	36	51	74	131
	180	47	67	99	177
	250	63	92	134	239
3.0	130	67	100	149	281
	180	89	135	202	381
	250	122	184	304	513
4.0	130	102	160	251	484
	180	138	218	343	656
	250	188	300	470	883
5.0	130	125	227	380	725
	180	188	330	525	975
	250	268	460	720	1300
6.0	130	176	298	492	975
	180	240	396	630	1294
	250	330	545	862	1790
7.0	130	234	393	633	1300
	180	319	540	867	1678
	250	438	744	1187	NA
8.0	130	318	531	851	1658
	180	436	730	1165	NA
	250	602	1005	1594	NA
9.0	130	372	653	1063	NA
	180	511	896	1454	NA
	250	706	1233	1989	NA

Table 9. *Activa PC and Activa SC Neurostimulator energy use for voltage mode^a (continued)*

Amplitude (V)	Rate	Pulse width			
		60	120	210	450
10.0	130	480	833	1345	NA
	180	666	1143	1840	NA
	250	919	1573	NA	NA

^a Use values that are closest to the expected values (round to the next highest value).

Table 10. *Activa PC and Activa SC Neurostimulator final impedance correction factor (ICF) for voltage mode^a*

Impedance	ICF
500	1.70
750	1.20
1000	1.00
1100	0.91
1200	0.85
1300	0.79
1400	0.76
1500	0.73
2000 ^b	0.65
2500 ^c	0.50

^a Use value closest to the measured impedance value (round to the next lowest impedance value).

^b With a programmed amplitude of 1V, calculated longevity may overestimate actual longevity by 1 to 2 years.

^c Calculated longevity may overestimate actual longevity by 1 to 2 years.

Table 11. Activa PC and Activa SC Neurostimulator energy use for current mode^a

Amplitude (mA)	Rate	Pulse width			
		60	120	210	450
1.0	130	23	30	50	86
	180	28	38	64	114
	250	34	57	83	157
2.0	130	42	65	100	196
	180	53	86	135	291
	250	72	118	187	404
3.0	130	77	127	201	407
	180	103	174	276	562
	250	136	234	382	809
4.0	130	109	180	285	671
	180	140	237	383	927
	250	183	319	521	1352
5.0	130	149	265	444	992
	180	209	366	632	1391
	250	281	507	874	1920
6.0	130	201	356	587	1386
	180	268	481	800	1942
	250	360	656	1099	2843
7.0	130	264	496	833	1721
	180	364	682	1148	NA
	250	518	950	1590	NA
8.0	130	307	597	NA	NA
	180	421	NA	NA	NA
	250	580	NA	NA	NA

^a Use values that are closest to the expected values (round to the next highest value).

Table 12. Activa PC and Activa SC Neurostimulator final impedance correction factor (ICF) for current mode^a

Impedance	ICF
500 ^b	0.75
750 ^b	0.80
1000	1.00
1100	1.08
1200	1.16
1300	1.24
1400	1.32
1500	1.40
2000	1.45
2500	1.80

^a Use value closest to the measured impedance value (round to the next highest impedance value).

^b With a programmed amplitude of 1 mA, calculated longevity may overestimate actual longevity by 1 to 2 years.

Kinetra, Soletra, and Itrel II Neurostimulators

The battery of an implantable neurostimulator can last for months or years, depending on the following factors:

- Programmed parameters (ie, amplitude, rate, pulse width, number of active electrodes used)
- System impedance
- Hours per day of stimulation
- The degree of patient control over programmable stimulation parameters

Tips for maximizing battery longevity

To optimize the battery longevity of an implantable neurostimulator, follow these tips:

- Use fewer programs, if appropriate.
- Program Cycling to provide the shortest amount of time for effective stimulation.
- Use the minimum number of electrodes necessary for effective stimulation.
- Use the lowest effective settings for amplitude, rate, and pulse width.
- Instruct the patient to use the neurostimulator only when needed.

- Unipolar stimulation may allow for lower amplitude levels to achieve equivalent therapies, resulting in longer battery life.
- Stimulation settings for systems implanted in the internal globus pallidus (GPi) may be greater than stimulation settings for systems implanted in the subthalamic nucleus (STN). Consequently, systems implanted in the GPi might have shorter battery life than systems implanted in the STN.

Estimating battery longevity for Kinetra, Soletra, or Itrel II Neurostimulators

The following formula estimates the approximate period of time that a new Kinetra, Soletra, or Itrel II Neurostimulator battery will last.

Note: Only one program of stimulation is available on Soletra and Itrel II Neurostimulators.

Expected values

1. Determine the expected Program 1 operating parameters for the neurostimulator, including amplitude, rate, pulse width, number of active electrodes, cycle ON/OFF times, and hours of stimulation per day.
2. Determine the Program 1 Energy Use (EU) from Table 13 using the expected values for amplitude, rate, and pulse width.

Notes:

- Table 13 assumes neurostimulator usage of 24 hours per day. If neurostimulator usage is different from that, adjustments will be made in later calculations.
 - Use the table values that are closest to the expected values. Be aware that when values do not match, there will be a discrepancy between calculated longevity estimates and actual results.
3. Determine the Program 1 Electrode Correction Factor (ECF) from Table 14 for the number of active electrodes.

Note: If selecting an electrode configuration for this program with only one positive and only one negative electrode (bipolar), you may skip step 3, because the Electrode Correction Factor is 1.0.

4. Multiply the Program 1 Energy Use by the Program 1 Electrode Correction Factor to obtain the Program 1 Factor (P1F).
5. Repeat steps 1 through 4 for Program 2 to obtain the Program 2 Factor (P2F).
6. Add the Program 1 Factor and the Program 2 Factor to obtain the Dual-Program Factor (DPF).
7. Determine the Usage Correction Factor (UCF) from the following formula (the value will be between 0 and 1):

Usage Correction Factor=Usage Ratio X Cycling Ratio

Kinetra: [Usage Ratio = hours of stimulation (per day)/24 hours]

Soletra and Itrel II: [Usage Ratio = hours of stimulation (per day)/16 hours]

[Cycling Ratio = cycle ON/(cycle ON + Cycle OFF)]

Notes:

- If using continuous mode with 24 hours of stimulation, you may skip step 7 because the Usage Correction Factor is 1.0.
 - If cycling is not programmed, the formula becomes: Usage Correction Factor = Usage Ratio.
8. Multiple the results of steps 6 and 7 to obtain the adjusted Energy Use value: DPF X UCF = adjusted Energy Use
 9. Finally, take the adjusted Energy Use value and determine the estimated battery longevity in years from Figure 4.

Table 13. Kinetra Neurostimulator energy use for 2 active bipolar electrodes per program for 24 hours/day usage

Amplitude	Rate	Pulse width			
		60	210	330	450
1.0	130	10	18	29	58
	185	14	26	43	82
	250	19	34	55	103
2.0	130	25	49	84	169
	185	37	71	120	237
	250	49	93	155	300
3.0	130	41	81	137	276
	185	59	114	195	383
	250	77	148	249	481
4.0	130	74	142	241	484
	185	103	200	338	665
	250	134	259	434	NA
5.0	130	25	82	125	163
	185	159	309	522	NA
	250	207	397	666	NA
6.0	130	162	315	536	1073
	185	227	441	743	NA
	250	292	564	NA	NA

Table 13. Kinetra Neurostimulator energy use for 2 active bipolar electrodes per program for 24 hours/day usage (continued)

Amplitude	Rate	Pulse width			
		60	210	330	450
7.0	130	222	432	735	NA
	185	312	603	1020	NA
	250	400	774	NA	NA
8.0	130	293	569	968	NA
	185	409	795	NA	NA
	250	524	1013	NA	NA
9.0	130	376	731	NA	NA
	185	523	1014	NA	NA
	250	664	NA	NA	NA
10.0	130	480	933	NA	NA
	185	673	NA	NA	NA
	250	856	NA	NA	NA

Note: NA in Table 13 refers to values that are not allowed by the clinician programmer.

Table 14. Kinetra Neurostimulator electrode correction factor

Electrode configuration	Electrode correction factor
Bipolar	
1 negative, 1 positive	1.0
1 negative, 2 positive	1.3
1 negative, 3 positive	1.5
2 negative, 1 positive	1.3
2 negative, 2 positive	1.8
3 negative, 1 positive	1.5
Unipolar	
1 negative, case positive	1.8
2 negative, case positive	2.8
3 negative, case positive	3.5
4 negative, case positive	4.2

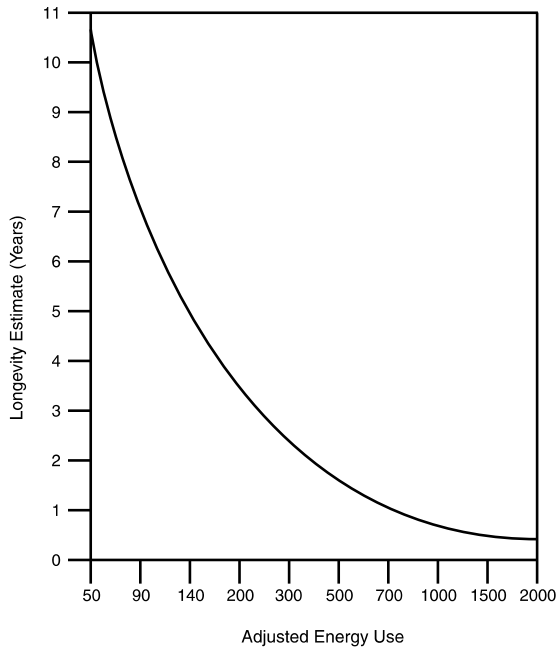


Figure 4. Kinetra Neurostimulator longevity estimates (years) for energy use (EU).

Table 15. Soletra Neurostimulator energy use for single lead with 2 active electrodes for 16 hours/day usage

Amplitude	Rate	Pulse width			
		60	120	210	450
1.0	130	6	11	19	37
	160	8	14	22	41
	185	9	16	24	38
2.0	130	11	21	36	69
	160	14	26	42	77
	185	16	29	45	69
3.0	130	17	33	54	106
	160	21	39	64	117
	185	25	44	68	99
4.0	130	46	86	143	279
	160	56	103	169	302
	185	65	117	179	268

Table 15. *Solettra Neurostimulator energy use for single lead with 2 active electrodes for 16 hours/day usage (continued)*

Amplitude	Rate	Pulse width			
		60	120	210	450
5.0	130	57	108	180	350
	160	69	129	212	385
	185	80	145	225	330
6.0	130	67	127	212	412
	160	82	152	249	451
	185	94	170	262	353
7.0	130	78	148	248	482
	160	95	178	291	523
	185	110	198	303	357
8.0	130	142	262	430	824
	160	173	315	506	890
	185	200	353	525	880
9.0	130	159	293	484	927
	160	194	352	568	1009
	185	223	394	598	922
10.0	130	174	321	530	1017
	160	211	386	623	1086
	185	244	429	644	929

Table 16. *Solettra Neurostimulator Electrode Correction Factor (ECF)*

Electrode correction factor for 1 quadripolar lead	
Electrode configuration	Electrode correction factor
2 Active electrodes	1.0
3 Active electrodes	1.4
4 Active electrodes	2.0
Case +, 1 active electrode	1.6
Case +, 2 active electrodes	2.5
Case +, 3 active electrodes	3.3
Case +, 4 active electrodes	4.0

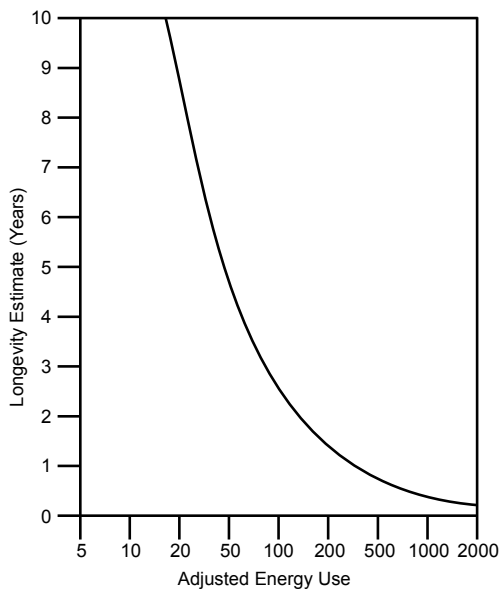


Figure 5. Solettra Neurostimulator longevity estimates (years) for energy use.

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