

Deep Brain Stimulation Programming

Site Applicability

VGH Deep Brain Stimulator Clinic Only

Practice Level

Profession	Basic Skill	Specialized Skill (requiring additional education)
RN		Must have additional specific education, knowledge and expertise in the programming of deep brain stimulators and have completed additional training (i.e. Deep Brain Stimulator training offered through Medtronic and Boston Scientific).

Policy Statements

- A physician order is required for any medication changes.
- A physician order is required to initiate and titrate deep brain stimulation see PPO information to be completed once the PPO completed.

Need to Know

Deep Brain Stimulation (DBS) is a surgical procedure that uses an implanted electrode to deliver high frequency electrical stimulation to a region of the brain.

Common brain regions that are stimulated using DBS include:

- The Subthalamic Nucleus (STN) used to treat Parkinson's disease symptoms.
- The Globus Palladium Interna (GPi) used to treat dystonia and dyskinesias related to Parkinson's disease.
- The Thalamus (VIM) used to treat tremor.

These brain regions are involved with the control of movement. Electrical stimulation of one of these regions of the brain overrides abnormal neuronal activity within the targeted brain region to bring motor controlling circuits into a more normal state of function, thereby reducing movement disorder symptoms.

The system consists of one or two electrodes and an extension wire(s) connected to an internal neurostimulator (INS).

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Adjustment of the following parameters maximizes the therapeutic effect:

- Contact(s) on the DBS electrode(s) selected to deliver stimulation
- Polarity
- Amplitude
- Pulse Width
- Rate

Effects of deep brain stimulation depend on:

- Location of the stimulating electrode
- Stimulation parameters

Common Side Effects of Deep Brain Stimulation

STN	GPi	Thalamus
Dysarthria Paresthesia	Muscular Contraction	Dysarthria
Muscular Contraction Visual Disturbance Disequilibrium Dyskinesia	Phosphenes Gait Impairment	Paresthesia Muscular Contraction Gait Impairment

Adverse effects will cease when deep brain stimulation is stopped

Programming Goals

STN GPi		Thalamus			
Delive	Deliver stimulation to appropriate target.				
	Maximize therapy benefits.				
Minimize stimulation of s	urrounding structures that may i	nduce adverse events.			
Improve quality of life.					
Increase ON Time.	Decrease severity of dystonia				
Decrease ON/OFF fluctuations.	and associated pain.				
Decrease duration and severity of levodopa induced dyskinesia.	Decrease duration and severity of levodopa induced dyskinesia.	Decrease severity of tremor.			

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Key Definitions

Amplitude	Is the intensity of stimulation that is delivered to the targeted area of the		
	brain and is measured in volts (V) or milliamperes (mA).		
Pulse Width	Is measured in microseconds (µs); determines coverage of stimulation.		
Rate	Represents the number of times per second that a stimulation pulse is		
	delivered and is measured in pulses per second (pps) or Hertz (Hz);		
	determines the frequency of stimulation.		
Charge Density	The amount of electrical charge delivered to the cathode (-) or absorbed by		
	the anode (+) phase of the stimulation pulse divided by the surface area of		
	the electrical contact.		
Anode	The electrically positive contact.		
Cathode	The electrically negative contact.		
Electrode	ctrode The resistance to the flow of electrical charge with each monopolar and		
Impedance	bipolar configuration; used primarily to check the electrical integrity of the		
	system and is measured in Ohms.		
Therapy	nerapy The resistance to electrical flow for those stimulation parameters and		
Impedance	electrode configurations that are currently in use to treat the patient.		
Closed Circuit	A complete electrical circuit or path the electrical impulses follow as they		
	travel from the negative to the positive pole.		
Open Circuit	Occurs if there is a break in the lead wire. It may result in loss of stimulation.		
Short Circuit	Occurs when wires lose their insulation in places other than at the electrode.		
	May result in shocking or jolting sensations when the current flows along an		
	unintended path.		

Guideline

Medication Adjustment for Patients with STN DBS

Medication adjustment for patients with STN DBS is patient-specific depending on patient age, response to medication and stimulation. Too aggressive dopaminergic reduction has been associated with neuroleptic malignant syndrome. The following table is a guide to how medications may be weaned for a patient with STN DBS by a Physician. A Physician order is required for any changes in medications.

Medication	Reason to Wean	Titration Range	Weaning Guideline
Carbidopa- Levodapa IR	Fast acting medication. May induce peak dose dyskinesias. May induce peak dose dyskinesias.	Can wean 25 to 100%	May consider reducing all tablets by half or halving every other tablet.
Carbidopa- Levodapa CR		Can wean 25 to 100%	May consider reducing all tablets by half or halving every other tablet.
Anti-Cholinergics	May induce peak dose dyskinesias.	Can wean 25 to 100%	Slow wean of 1mg every 2 weeks if tolerated until discontinued.

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COMT Inhibitors	May induce peak dose	Can weap 25 to 100%	May reduce all tablets by half or halving every other	
	COIVIT INNIBITORS	dyskinesias.	Can wean 25 to 100%	tablet.
	Dopamine Agonists	May induce peak dose dyskinesias. Patient may be suffering	Can wean 25 to100% slowly over several	May consider a gradual wean of 0.25mg-1mg every
		from behavioral side effects as a result of the agonist.	weeks	week if tolerated until discontinued.
	Amantadine	Consult Neurologist	No titration by RN	Consult Neurologist.
	Rasagiline	Consult Neurologist	No titration by RN	Discontinued prior to surgery by Neurologist. *See Note below*

Note: Rasagiline should be discontinued at least 2 weeks prior to surgery by neurologist due to numerous interactions with anesthetic agents. Neurologists may re-initiate Rasagiline post-operatively at their discretion

Deep Brain Stimulation Programming

Prior to programming ensure the micro-lesioning effect has worn off. This may take 4-6 weeks.

Pre-Programming

Prior to starting programing it is important to know the following:

- Electrode type.
- Surgeon's estimation of optimal contact(s) on electrode(s).
- Intra-operative physiology.
- Intra-operative DBS electrode testing.

For patients with STN DBS:

- Patients are scheduled for a morning appointment.
- Medications are stopped after 2000hr the evening prior to the initial programming session.
- Patients should be in the OFF state prior to the initial programming session. This is required to effectively gauge stimulation parameters.

Programming

See Appendix A: DBS Programming Guidelines and Troubleshooting

Expected Outcome

Patients will have the maximum possible benefit from deep brain stimulation with minimal side effects.

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Patient Education

- Goals and limitations of deep brain stimulation
- Precautions associated with DBS
- How to adjust DBS therapy and familiarization of remote access controller
- When to seek medical assistance and follow up

Documentation

- Print out the session data file and place in patients chart
- Dictate on patient after each session being sure to include the following:
 - Presenting Problem
 - Current Medication Schedule
 - Assessments
 - Settings Trialed/Adjustments made
 - Possible side effects of stimulation
 - Future follow up
- A dictated note is sent to all healthcare providers involved in patient's care

Related Documents

- Initial programming DBS Forms.
- Deep Brain Stimulator (DBS) Precautions (FA.200.D44)
- Consent for Notification of Behavioral Changes (STN patients).
- Patient Medication Schedule.
- Patient Diary (STN patients).

References

Medtronic (2017) Neuromodulation Products and Therapies/Healthcare Professionals https://www.medtronic.com/us-en/businesses/restorative-therapies-group.html

Boston Scientific (2015) Bionic Navigator http://www.bostonscientific.com/en-US/404-page.html

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Effective Date:	07-March-2019		
Posted Date:	07-March-2019		
Last Revised:	01-March-2019		
Last Reviewed:	01-March-2019		
Approved By:	VCH		
(committee or position)	Medical Director, Deep Brain Stimulation Clinic Interim Patient Services Manager, Neurosciences, Vancouver Acute Professional Practice Director, Nursing & Allied Health, Professional Practice Admin, Vancouver Acute		
Owners: VCH			
(optional)	Clinical Resource Nurse, DBS Clinic, Vancouver Acute Clinical Resource Nurse, DBS Clinic, Vancouver Acute		

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Appendix A – DBS Programming Guidelines and Troubleshooting

Programming

- 1. Check all surgical incisions (initial programming and post INS replacements).
- 2. Perform a baseline assessment and examination of the patient as per appropriate patient assessment form.
- 3. Check impedances at all programing sessions. **Note:** Normal impedance values verify the integrity of each electrode connection with the electrical system end to end. Without this integrity, all programming efforts are futile and will be of not benefit to patients. See table "Impedances for Possible Short or Open Circuit."

Normal Impedance Values:

Medtronic System

Normal impedances are 600 to 1300 Ohms and normal current drain is 10 to 30 mA.

Soletra and Kinetra: Amp 1.5 V, PW 210 µsec, Rate 30 Hz

It is recommended to adjust the amplitude setting in the Kinetra to 4 V to achieve accurate impedance results.

Activa: RC/PC/SC: Amp 0.7 V, PW 80 µsec, Rate 100 Hz

The amplitude in the Activa RC/PC/SC may be decreased to 0.25 V if the patient experience unpleasant effects at 0.7 V.

You will be prompted to retest the impedances at 1.5 V and 3 V in the Activa RC/PC/SC if the results indicate a possible open circuit.

Boston Scientific System

Normal impedances are within 50 or 100 to 8000 Ohms. Anything below is a short circuit. Anything above is an open circuit.

Vercise/Gevia:

The impedance button is used to verify the electrical integrity. Impedances are measured and displayed for each of the electrode's 16 contacts.

The impedance measurements are 0.35 mA, 20 μsec and 700 μsec for each electrode.

The battery capacity for the RC is 200 mA and for the PC is 7200 mA.

- 4. Start programming with monopolar stimulation. Start with the deepest contact first and work up the electrode systematically.
- 5. For bilateral programming, program one side first, and then program the second side with the first side off.
- 6. Set the neurostimulator to the initial setting provided in Table 1.

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Parameters	Initial Setting	Range/Options	Typical Final Settings
		0 to 10.5 V or 0.1 to 20 mA	1.5 to 3.5 V
Amplitude	0 V or 0 mA	in 0.1 V or mA incremental steps	or equivalent mA based upon impedance
D. L. M.C.III.	60.10.00	10 to 450 μsec	60 1 2 420 2 2 2
Pulse Width	60 to 90 μsec	in 30 μsec steps	60 to 120 μsec
Rate	130 to185 Hz	2 to 255 Hz	130 to185 Hz
Electrode polarity	Monopolar	Monopolar or Bipolar	Either
Mode	Continuous	Continuous or Cycling	Continuous

- 7. Gradually increase amplitude by 0.5 V or 0.3 mA until 2 V or equivalent mA is reached, then increase by 0.1 V or 0.1 mA thereafter until the patient experiences benefit in their symptoms or adverse effects occur. Wait a few minutes to assess the effect of stimulation. Record screening results.
- 8. If there is uncomfortable stimulation or inadequate symptom suppression, select another contact as the anode. Repeat step 7.
- 9. Select the contact that provides the best control of symptoms with the fewest adverse effects. Adjustment of pulse width and rate may be utilized to achieve adequate symptom suppression. The therapeutic window between symptom suppression and occurrence of side effects should be sufficiently wide to allow for future amplitude adjustments.

Note: Symptom suppression is desirable at the lowest possible amplitude, rate, and pulse width in order to improve battery longevity and minimize charge density.

- 10. If a bilateral system has been implanted and the best contact is selected for the initial electrode, return amplitude to 0 V or 0 mA. Repeat above steps for second electrode.
- 11. Additional testing may be required in bipolar mode if the patient experiences adverse effects in monopolar mode.
- 12. Should a Charge Density warning appear during the programming session, please see Charge Density graph to determine if it safe to continue. You may also call Medtronic Technical Services (1-800-707-0933) or Boston Scientific Technical Services (1-888-359-9691) for guidance.

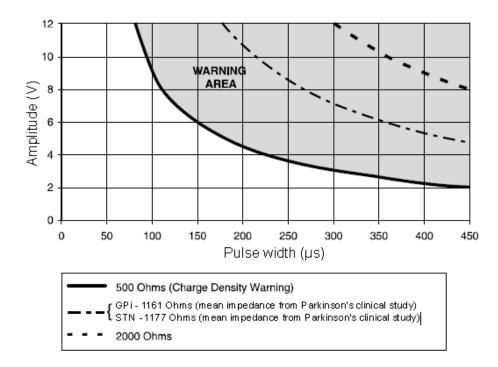
Note: In most dystonia patients, benefit is not seen immediately within the initial programming session. If this is the case, your programming will be based on adverse effect only, rather than beneficial effects. It may take several weeks for the patients to see any benefit from their stimulation

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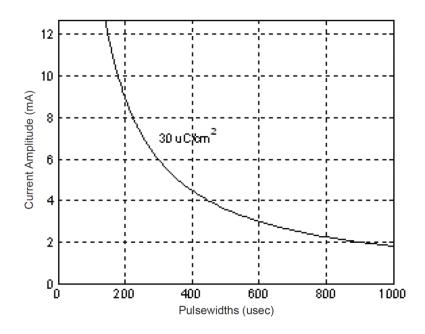
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Charge Density Graph Medtronic



Charge Density Graph Boston Scientific

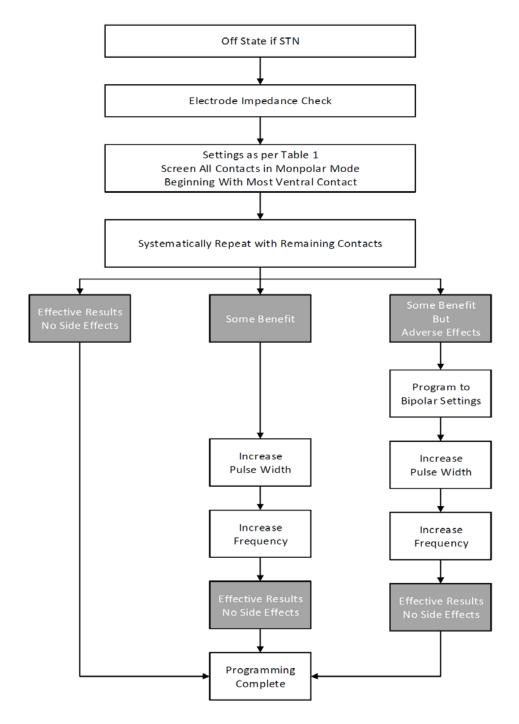


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Deep Brain Stimulation Programming Algorithm



Adpated from Hunka, Suchowersky, Wood, Derwent & Kiss (2005)

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Troubleshooting

1. Loss of or Change in Stimulation

A loss of or change in stimulation can occur as a result of a medical procedure, an accident or trauma, excessive EMI (electrical magnetic interference), or INS depletion.

Assessment:

- When did the change in stimulation occur?
- Was the change sudden or gradual?
- Is there a clear reason for this change in stimulation (medical procedure, fall, etc.)?
- If stimulation is intermittent, ask the patient to place themselves in the position that they feel the loss of stimulation. Run impedances while in this position as it may provide information to confirm the intermittent open or short circuit.

Note: It may be beneficial to develop a time line with the patient to determine what may have attributed to the loss or change in stimulation.

Intervention for suspected short or open circuit:

Note: Short or open circuits may occur in one of the following areas:

- at the connection between the electrode and the extension OR
- at the connection between the extension and the INS.
- Run INS battery check to determine battery life and review patient settings.
- Check impedances (refer to impedance table for possible open or short circuit) to determine
 if within normal range.

Impedances for Possible Short or Open Circuit

Device	Possible Short Circuit	Possible Open Circuit
Soletra	Less than 250 Ohms Greater than 500 mA Current drain less than or equal to 12 mA	
Kinetra	Less than 250 Ohms Greater than 500 mA	Greater than 4,000 Ohms Current drain less than or equal to 15 mA
Activa RC/PC/SC	Less than 250 Ohms	*Greater than 40,000 Ohms (run at 3.0 V)
Vercise/Gevia RC/PC	Less than 50 to 100 Ohms	Greater than 8000 Ohms

If there is an open circuit involving the contact in use, try reprogramming using another
contact where the impedance value is normal. Use this contact only if therapeutic benefit is
achieved.

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• Obtain X-ray (skull and chest AP and lateral) to determine area of potential fracture or break in the hardware.

• Refer to neurosurgeon for possible repair of hardware.

Intervention for change in therapeutic settings:

- Determine if the INS is turned ON.
- Review settings from last programming session.

Note: If a Power on Reset (POR) has occurred with a Soletra or Kinetra the setting will revert back to factory settings and the INS serial number will be deleted.

A POR message will appear upon interrogation of the Activa.

A message will appear on the patient remote indicating the issue with the Vercise.

- Re-enter all neurostimulator parameters that have been deleted.
- Counsel patient to avoid areas with high electromagnetic fields e.g. power lines and substations.

Intervention for low or depleted INS:

- Interrogate INS battery.
- Determine battery life.

Note: Refer to the battery chart below to determine if the battery is approaching end of service (EOS).

For the Soletra and Kinetra call Medtronic Technical Services Technical Services (1-800-707-0933) to obtain battery longevity. This value is based on the assumption the INS is new, therefore you must subtract the number of months the INS has been implanted to determine battery estimate. For the Activa RC the Elective Replacement Indicator (ERI) message will appear at 8 years. At this time, you will have approximately 1 year to extend the battery life of the INS to 15 years using Medtronic software.

For the Vercise/Gevia RC, the remote will not give a warning screen. Schedule replacement surgery at 25 years. For the Vercise/Gevia PC, the ERI screen will be displayed on the remote control 180 days prior to depletion of the battery.

- If battery at ERI complete paperwork to replace neurostimulator.
- If battery at EOS refer patient to neurosurgeon and to the emergency department for urgent replacement.

Battery Life Chart

Device	Shipped	Schedule INS Replacement	Replace INS
Soletra	3.74 V	3.6 V	3.4 V
Kinetra	3.2 V	2.44 V	1.97 V
Activa SC/PC	3.2 V	2.6 V	2.2 V
Activa RC	N/A	ERI (15 Years)	EOS
Vercise/Gevia RC	N/A	25 Years	EOS
Vercise/Gevia PC	N/A	ERI	EOS

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