

Troubleshooting in Implanted Neurostimulators - A technical approach

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The basics:

- Patients with implanted devices can be complex situations
 - Sometimes we cannot explain clinical observations
- Our experience and skill is technical
 - Often our job is to prove the stimulator is working correctly
 - We can ask for expert medical opinion from our advisors
 - Logical process to eliminate possible cause
- The 'ideal' process is not always possible

The Process:

- **Step #1**
 - Patient history
- **Step #2**
 - Investigate possible technical causes
 - Impedance tests
 - Battery voltage
 - Present the technical data
- **Step #3**
 - Suggest possible cause
 - If technical, suggest next step
 - Participate in surgical intervention/revision

Step #1a - Patient History

- **May be confidential**
- **Key Information - medical:**
 - Disease and treatment
 - Symptoms prior to implant
 - Symptoms post implant
 - Symptoms now
 - Symptom pattern over time
 - Changes of drug, behaviour, disease state or other
 - Patient behaviour at time of symptom return

Step #1b - Device History

- **Key Information - technical:**
 - Device(s) implanted
 - Battery level and date of implant
 - Sudden failure or gradual decline?
 - If sudden, behaviour at the time

Using impedance

- **Impedance readings can be misleading if not interpreted correctly.**
- **Some points:**
 - system impedance is dependent on time and voltage* (refer 'Eng Note - High impedance')
 - Check for bad connections during implant (refer 'Tech Note: Restore - High Impedances During Screening')
 - Understand the variability of impedance measurements
 - If $C+0- = 2750$ $C+1- = 2550\Omega$ and $0-1+ = >4000\Omega$, all electrodes are OK

The impedance test

- **Automated tests**
 - Test all possible, 2-electrode combinations
 - More combinations are sometimes needed
 - Standard testing parameters
 - May not be enough to make a measurement
 - Send out 2-3 pulses for each combination
 - Therefore rate is irrelevant

The impedance test cont'd

- **Therapy impedance test**
 - Only tests the settings and electrodes as programmed for the patient
 - More relevant than auto test
 - Must be used for advanced troubleshooting
 - Can add electrodes to test for 'expected' results (i.e. more electrodes = impedance down and current up)

The impedance test cont'd

- **Limitations and considerations**
 - Impedance numbers do not 'prove' anything, they only indicate (with varying levels of reliability)
 - Uni-polar (Case+ -ve) tests are more reliable for open circuits
 - Bi-polar (+ve, -ve) tests are more reliable for short circuits
 - Current flow is more important
 - iBat level is significant ('heartbeat' of INS)
 - Synergy/Kinetra = 15 μ A
 - Itrel III/Soletra = 7 μ A
 - Restore and Activa systems use a different measuring system so the iBat is not shown (\sim 53 μ A).
 - Restore and Activa systems measure patient current flow in mA

Case Study #1

- **DBS patient with PD symptoms not responding to stimulation**
- **Patient history**
 - Initially good post implant but 12 months later not responding as before
 - Now getting bad dyskinesia and right-side symptoms not as well controlled
 - Dr performs impedance test

Case Study #1 cont'd

- **Current programmes:**
 - Left brain: 1-, 2+ 2.4V, 90PW, 130Hz
 - Right brain: 1-, C+ 1.1V, 90PW, 130Hz
- **Therapy impedance tests:**
 - Left brain: Out of range (high impedance, low current)
 - $>4000\Omega$ $<15\mu A$
 - Uses 2.4V for the test
 - Right brain: nominal
 - Choice now to raise the voltage of the test but patient declines.....
 - What to do?

Case Study #1 cont'd

- **Consider the issues surrounding the impedance measurements**
 - Patient observations:
 - Dyskinesia increase may be drug, disease or stimulation related.
 - If stim related, the systems is working – test
 - Device observations:
 - Impedance is high on left side but should re-test
 - Bi-polar tests are not reliable for open-circuits
 - Bi-polar configurations will have higher impedance than uni-polar
 - The test voltage may be too low
 - Could raise voltage to induce side-effects

Case Study #1 cont'd

- **Raise voltage of therapy and observe effects:**
 - Left side:
 - Dyskinesia gets worse
 - Symptoms same
 - Therapy impedance test now in range
 - 1- 2+, 2950Ω, 19μA
 - Conclusion:
 - Stimulator is working but due to side-effects is not at sufficient voltage to control symptoms or give a reliable impedance reading
 - It may be possible to adjust the programming, but cannot be sure

Case Study #2

- **DBS patient with PD. Kinetra, bilateral**
 - Good effect for 3 years, now effect is poor
 - Patient fell 3 months ago and symptoms returned
 - Drug has been increased causing dyskinesia
 - Impedance test performed and indicates high impedance low current
 - Auto test showing all combinations >4000
 - both leads are broken??
- **Current programmes:**
 - Left brain: 1-, C+ 1.4V, 90PW, 130Hz
 - Right brain: 1-, C+ 1.1V, 90PW, 130Hz

Case Study #2 cont'd

- **Discuss the issues surrounding the impedance measurements**
 - Advisable to do a more exhaustive impedance test.
 - Patient observations:
 - Dyskinesia increase is probably drug
 - Device observations
 - Refer the data shown in table.....

contact	Voltage	Resistance	Current		contact	Voltage	Resistance	Current
C+0-	1.5	>4000	<15		1-0+	1.5	>4000	<15
C+1-	1.5	>4000	<15		1-2+	1.5	>4000	<15
C+2-	1.5	>4000	<15		1-3+	1.5	>4000	<15
C+3-	1.5	>4000	<15		2-0+	1.5	>4000	<15
0-1+	1.5	>4000	<15		2-1+	1.5	>4000	<15
0-2+	1.5	>4000	<15		2-3+	1.5	>4000	<15
0-3+	1.5	>4000	<15		3-0+	1.5	>4000	<15
Test #1					3-1+	1.5	>4000	<15
					3-2+	1.5	>4000	<15

contact	Voltage	Resistance	Current		contact	Voltage	Resistance	Current
C+0-	2	3575	<15		1-0+	2	>4000	<15
C+1-	2	3650	<15		1-2+	2	>4000	<15
C+2-	2	>4000	<15		1-3+	2	>4000	<15
C+3-	2	3550	<15		2-0+	2	>4000	<15
0-1+	2	>4000	<15		2-1+	2	>4000	<15
0-2+	2	>4000	<15		2-3+	2	>4000	<15
0-3+	2	>4000	<15		3-0+	2	>4000	<15
Test #2					3-1+	2	>4000	<15
					3-2+	2	>4000	<15

contact	Voltage	Resistance	Current		contact	Voltage	Resistance	Current
C+0-	3	3575	<15		1-0+	3	1406	<15
C+1-	3	3650	<15		1-2+	3	1406	<15
C+2-	3	>4000	<15		1-3+	3	2815	<15
C+3-	3	3550	<15		2-0+	3	>4000	<15
0-1+	3	1406	<15		2-1+	3	>4000	<15
0-2+	3	2815	<15		2-3+	3	1406	<15
0-3+	3	2815	<15		3-0+	3	2815	<15
Test #3					3-1+	3	2815	<15
					3-2+	3	1406	<15

contact	Voltage	Resistance	Current		contact	Voltage	Resistance	Current
C+0-	5	3575	18		1-0+	5	1250	17
C+1-	5	3650	19		1-2+	5	1350	18
C+2-	5	>4000	17		1-3+	5	2650	17
C+3-	5	3550	20		2-0+	5	2450	18
0-1+	5	1569	19		2-1+	5	1575	20
0-2+	5	2685	19		2-3+	5	1250	18
0-3+	5	3314	<15		3-0+	5	1875	19
Test #4					3-1+	5	2250	19
					3-2+	5	1875	20

Advanced impedance test

- If other tests are inconclusive you can perform an advanced test.
 - Programme different electrode combinations according to following table
 - Conduct therapy test at nominal voltage
 - Repeat at higher voltage if necessary

	2V		3V		4V	
	Ohms (Ω)	mA	Ohms (Ω)	mA	Ohms (Ω)	mA
C+0-	>4000	<15	>4000	<15	>4000	<15
C+1-	>4000	<15	>4000	<15	>4000	<15
C+2-	>4000	<15	>4000	<15	>4000	<15
C+3-	>4000	<15	>4000	<15	>4000	<15
C+0-1-	>4000	<15	>4000	<15	2990	19
C+0-2-	>4000	<15	>4000	<15	3580	17
C+0-3-	>4000	<15	>4000	<15	3250	17
C+1-2-	>4000	<15	>4000	<15	2990	18
C+1-3-	>4000	<15	>4000	<15	3450	18
C+2-3-	>4000	<15	>4000	<15	2990	19
C+0-1-2	>4000	<15	3450	17	2345	23
C+0-1-3	>4000	<15	3580	17	2450	21
C+0-2-3	>4000	<15	3250	17	2650	19
C+1-2-3	>4000	<15	3650	17	2550	18
C+0-1-2-3	>4000	<15	2362	21	1850	32

Case Study #3

- **Synergy patient with left leg pain**
 - Gradual decline of sensation in leg
 - Gradual increase of pain
 - Now cannot feel stimulation at all
 - All electrode combinations with maximum V, PW tested.

Case Study #3 cont'd

- Impedance testing data

- Initial tests all $>4000\Omega$, $<15\ \mu\text{A}$
- Advanced test results.....

Therapy measurement test at PW 210 microsec. Rate 30 Hz

5 volts	Impedance	Current
0-1+	3100	<15
0-2+	>4000	<15
0-3+	>4000	<15
0-1-2+	2450	19
0-1-2-3+	1569	23

**Therapy measurement test at PW 210
microsec. Rate 30 Hz**

7 volts	Impedance	Current
0-1+	2207	21
0-2+	3314	19
0-3+	3314	19
0-1-2+	1651	26
0-1-2-3+	1250	32

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