Shock Impedance Testing at Implant for COGNIS™ CRT-Ds and TELIGEN™ ICDs

SUMMARY
The Shock Impedance Test is a painless, subthreshold/low-energy test that evaluates the integrity of the shock lead system through the programmed Shock Lead Vector. These vectors are programmable for COGNIS™ and TELIGEN™ devices, and the impedance test operates differently in these devices than in other Boston Scientific ICDs and CRT-Ds.

During any implant procedure, it is important to verify the lead **Configuration**, **Connection**, and **Contact** to ensure accurate lead impedance values.

Although the Shock Impedance Test does not detect all possible lead-related issues, it is a useful tool for lead system evaluation.

ICD: Implantable Cardioverter Defibrillator
CRT-D: Cardiac Resynchronization Therapy Defibrillator

CRM PRODUCTS REFERENCED*
COGNIS and TELIGEN

*Products referenced herein may not be approved in all geographies. For comprehensive information on device operation, reference the appropriate product labeling.

CRM CONTACT INFORMATION

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Shock Impedance Testing During Device Implant Procedures

During device implant procedures, shock lead integrity in Boston Scientific's COGNIS™ CRT-Ds and TELIGEN™ ICDs can be evaluated using the Shock Impedance Test. Measurements typically range between 20 and 80 ohms, however if the test yields an out-of-range measurement displayed on the programmer as >125 ohms, <20 ohms, or "Noise," the following troubleshooting techniques can be considered:

Configuration

- **Confirm that the device's programmed Shock Lead Vector matches the configuration of the implanted lead.**

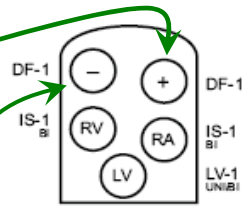
  Example: For single coil leads, **program** the Shock Lead Vector to *RV coil to Can.* If a single coil shock lead is implanted, but the vector is left in the nominal *TRIAD* configuration, the Shock Impedance Test will display an out-of-range impedance measurement or the word "Noise."

Connection

- **Confirm the shock lead's terminal pins are placed in the correct lead ports in the header.**

1) Insert the "DF-1 PROXIMAL (+)" terminal pin into the + (positive) lead port[1]

2) Insert the "DF-1 DISTAL (–)" terminal pin into the – (negative) lead port[2]



IS-1 lead connection ports on COGNIS device header

- **Verify a secure lead connection in the header.[3]**

  Step 1. Verify setscrews are not visible in lead ports.
  Step 2. Insert the torque wrench before the lead, which allows pressure to equalize during lead insertion.
  Step 3. With the torque wrench in place, fully insert the lead and verify terminal pin is beyond connector block.
  Step 4. Keep the torque wrench perpendicular (90º) to the lead connector block while tightening the setscrew. Additional downward force is not necessary.
  Step 5. Remove the torque wrench.
  Step 6. Verify lead connection by applying gentle traction to each lead terminal. If the lead is not secure, reinsert the torque wrench, loosen the setscrew by rotating the wrench counterclockwise, and repeat steps 3-6.

  TIP: If the lead-to-device connection is not optimal, noise may be visible on stored or real-time electrograms.

Contact

- Prior to initiating the Shock Impedance Test, **make sure the device is inside a wet device pocket (irrigated with saline)**, as the device casing may also serve as an active electrode during the test.

  TIP: To increase tissue contact during impedance testing, consider placing a hand over the pocket (with the device inside). However, to prevent the device from sensing external noise, avoid pocket manipulation or device movement during hand placement.

Additional Troubleshooting Techniques During Implant Procedures

If **Configuration, Connection, and Contact** have been verified, but the Shock Impedance Test continues to return an out-of-range measurement or "Noise," consider the following steps:

- **Turn Off or disconnect all equipment connected to the patient such as electrocautery or external electrocardiogram (ECG).**
- **Select a different Shock Lead Vector and test to evaluate impedance measurements.** The Shock Lead Vector in COGNIS and TELIGEN devices can be programmed to one of three configurations (Figure 1).
  - RV Coil to RA Coil and Can (referred to as TRIAD—nominal setting)
  - RV Coil to RA Coil
  - RV Coil to Can

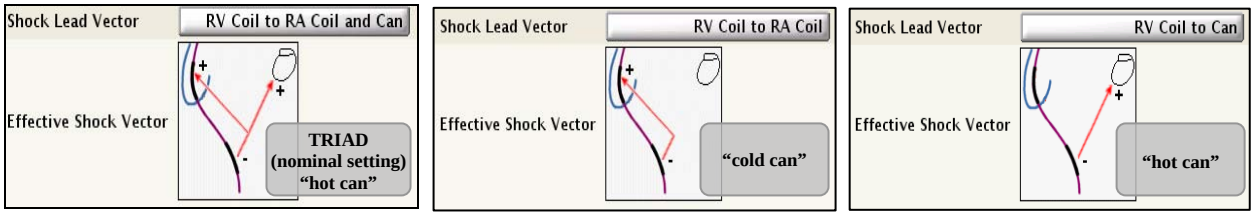


Figure 1. Programmable shock vector configurations for COGNIS and TELIGEN devices.

Contact CRM Technical Services for additional assistance if out-of-range impedance measurements or "Noise" continue to display on the programmer despite using the troubleshooting techniques provided herein. Electrogram analysis, X-ray or fluoroscopic image review, visual inspection, or synchronized commanded shocks may also be useful tools to further assess lead system integrity.

NOTE: *The Shock Impedance Test is a painless, subthreshold/low-energy test that does not identify all forms of potential short circuit conditions. In some cases, commanded shocks may also be a useful tool for lead system evaluation. For additional information, please contact CRM Technical Services, reference device system guides and the* ***A Closer Look*** *article "Shorted Shock Lead Warning Screen," available on www.bostonscientific.com or through CRM Technical Services.*

[1]The DF-1 PROXIMAL pin is often referred to as the SVC coil and/or RA coil.
[2]The DF-1 DISTAL pin is often referred to as the RV coil.
[3]These steps are illustrated in the **A Closer Look** article *Connecting Leads to Boston Scientific ICDs and CRT-Ds with White Seal Plugs* available on www.bostonscientific.com or through CRM Technical Services.