Shorted Shock Lead Warning Screen

SUMMARY
Current Boston Scientific implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) measure shock lead impedance during every shock delivered to the patient. In the rare event that a yellow shorted shock lead warning screen is observed, thoroughly evaluate lead integrity. Consider whether or not pulse generator and lead components require replacement, based on lead evaluation and patient-specific risk/benefit factors. For assistance with warning screens or any product performance observations, contact your local Boston Scientific CRM representative or CRM Technical Services.

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CRM PRODUCTS REFERENCED*
All ICDs and CRT-Ds

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

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Boston Scientific ICDs and CRT-Ds measure shock lead impedance during every therapeutic or commanded shock. This diagnostic tool is designed to detect out-of-range shock lead impedance values and initiate appropriate warning screens and tones.

When a **shorted** lead condition is identified during shock delivery, audible tones (16 beeps every six hours) are sounded, prompting the patient to return to his/her follow-up clinic for system evaluation. At the first post-shock interrogation, a yellow warning screen (Figure 1) is displayed on the programmer confirming that a shorted lead condition was detected within the lead or pulse generator circuitry during delivery of a recent shock. The user is prompted to print the warning screen (*Print Fault* button), and then reset/close the warning screen message (*Close Warning Screen* button). Although clearing the programmer message enables continued interaction between the programmer and the pulse generator, it does not alleviate the shorted lead condition, and further lead evaluation is required.

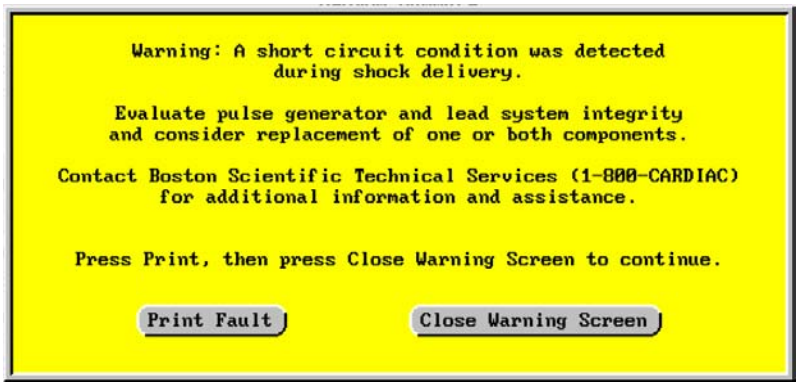

Figure 1. Sample warning screen for short circuit condition.
(Programmer screen wording will vary by device family.)

Several useful techniques are available to assess lead integrity:

- Standard lead troubleshooting tests, including electrogram analysis, x-ray or fluoroscopic image review, additional maximum-energy shocks, and invasive visual inspection can be used to assess lead system integrity.
- Some physicians have reportedly conducted one or more low-energy (subthreshold/painless) shock lead impedance tests, in an effort to validate a shorted lead warning message. A low-energy test can be a useful follow-up tool for viewing session-to-session shock lead impedance changes.

  However, it is important to understand that a low-energy lead impedance test does not expose all forms of potential shorted lead conditions. A low-energy impedance test(s) may appear normal in the presence of a potential shorted lead condition. A maximum-energy shock is a more robust tool for identifying/verifying a potential shorted shocking lead condition.

On rare occasion, a shorted shock lead warning screen may be displayed as the result of decreased shocking circuit impedance within the pulse generator. Pulse generator circuitry is designed to resist damage when confronted with a shorted condition. However, if a device has already delivered a high-energy shock into a shorted condition, normal pulse generator function cannot be guaranteed.

Following detailed lead evaluation, consider whether or not pulse generator and lead components require replacement, based on lead evaluation results and patient-specific risk/benefit review.

For Further Information
For assistance with warning screens or any product performance observations, please contact your local Boston Scientific CRM representative or CRM Technical Services.