SUPPLEMENTAL PROGRAMMER SOFTWARE INFORMATION

COGNIS™ CRT-D, TELIGEN™ ICD, PUNCTUA™, ENERGEN™, INCEPTA™, DYNAGEN™, INOGEN™, ORIGEN™ ICDs and CRT-Ds

Boston Scientific has released Model 2868 software application in support of COGNIS, TELIGEN, PUNCTUA, ENERGEN, INCEPTA, DYNAGEN, INOGEN and ORIGEN ICD and CRT-D devices and is providing this supplemental information to clarify unintended and unlikely programmer software behavior.

Programmer Software Interruption

If the Coupling Interval, Burst Cycle Length, or Onset parameter and its associated unit of measure (ms or percentage) are both changed in rapid succession, a mismatch between the parameter value and unit could occur. If a mismatch occurs, it will result in an internal software interruption within the programmer. The programmer will display a black screen with white text indicating a software error has occurred. In all cases involving this software interruption, the PG is not affected. To clear the software error and continue with device follow-up, recycle power to the programmer and restart the application as directed on the programmer screen.

If you have any questions regarding these issues, please contact your local Boston Scientific representative or Boston Scientific Technical Services at 1.800.CARDIAC (227.3422) or worldwide at 1.651.582.4000.

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