
Any Changes in Agenda - CE Files Review

DB3 risk analysis - Continuous 1Hz function

Issue ID #18651

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Issued To: Steve Nixon

Completed Status: 15 Feb 2010

Notes:

Added by steve nixon sent to steve nixon

Some end users in Canada would like the following additional functions:

- a) Continuous twitch mode (1 Hz) without having to keep button depressed.
- b) Display of output current.

Continuous twitch mode - Easiest solution with current model would be to replace the lower mode switch with a MOMENTARY ON - OFF - ON switch. This would enable the switch to be latched in the 1 Hz position. A different coloured actuator could be fitted i.e. green to differentiate between standard units. The part number inside the battery compartment would also be changed.

The above was discussed with Derek and John. It was suggested that it may be better to add pad printing text i.e. the word CONTINUOUS below or adjacent to 1Hz.

Risk analysis. If left in the continuous mode there are the following risks:

- a) Battery would deplete.
- b) Danger of inadvertent stimulus to operators or patients.

31 Mar 2009 steve nixon

Next Action Changed From steve nixon To Steve Nixon

In addition to the above the PIC could be reprogrammed so that the unit resets after say 10 minutes. Could also amend the pad printing in terms of model number and add warning triangle symbol to advise, refer to operating manual.

Risks:

- a) Battery would still deplete, although slower.
- b) Still danger of inadvertent stimulus, although now minimized.
- c) Confusion to operators, would have to centre the switch to reset.

15 Feb 2010 steve nixon

10 modified supplied to Dyna Medical.

Notes have been added to the packaging and the manual.

Unit is easily identified - has green switches instead of the standard red switches:

Functionality of the stimulation is as follows:

T.O.F. Now latching switch - Continuous cyclic output, T.O.F. which repeats after a pause

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of 8 seconds - for a total period of 5 minutes.

D.B.S. Momentary switch - Functionality as with standard DB3

P.T.C. Momentary switch - Functionality as with standard DB3

1 Hz . Now latching switch - Continuous output repeats for a total period of 5 minutes.

NOTE: With either of the revised T.O.F. and 1Hz functions the latching switches need to be reset to the middle position otherwise another function cannot be selected.

After use - if either of the T.O.F and 1 Hz switches are left in the latched (On) position there is still a small current drain even after the five minute time-out period. This current consumption will drain the battery unless the switches are returned to the middle (Off) position.
