

Sigma Spectrum Notification: Possible Keypad Errors

Baxter/Sigma has announced that there is a potential for the device keypad to short, which could result in improper programming of pumps. The notification letter outlines guidelines for the handling of Sigma pumps, the correct methodology for pressing keypad buttons, and instructions for testing the keypad.

Baxter/Sigma recommends the keypad be tested every time a pump is seen for service in Biomed. The method for checking the keypad and documentation is slightly different depending on what service the pump is receiving.

Pump Receiving SM:

Testing:

The SM procedure includes a keypad check, so pumps that receive an SM do not require any additional testing. *However, please be sure to follow the SM procedure exactly as all keys are incorporated through performing all steps in the SM procedure.* If you do not follow the procedure and key strikes *exactly*, there is a potential to miss a key press.

Documentation:

Since the SM will be documented in the work order and it includes the keypad check, there is no need to document the keypad check in addition to normal SM documentation.

Pump Receiving Service other than SM:

Testing:

For any pump receiving service other than SM, a keypad check must be performed each time the pump is seen. In addition to whatever service is needed on the pump, you must perform the keypad check. See Appendix A for the keypad check procedure. *Be sure to use the procedure in **Appendix A** and not the procedure in the manual as the SM keypad check does not test every key because the rest are tested during other sections of the SM.*

Documentation:

In addition to the documentation needed for whatever service the pump initially received, you must document the keypad check by performing the following steps:

For a PASSED Keypad Test:

- Complete a 'Performance Verification' service action and note in the comments, '**KEYPAD CHECK PASSED**'
- In 'Summary of Work Done' field, type: '**KEYPAD CHECK COMPLETED AND PASSED**'

For a FAILED Keypad Test:

- In 'Summary of Work Done' field, type: '**KEYPAD CHECK COMPLETED AND FAILED – SEND TO VENDOR**'
- Complete a 'Vendor Service' service action and send to vendor for repair

Appendix A: SPECTRUM Keypad check

Use the following check to evaluate the SPECTRUM keypad and display for proper operation.

1. Plug in the AC Power Adaptor into a working wall outlet or install a Battery Module.
2. Power on the pump by pressing the ON/OFF key.
3. While in the Care Area Screen, press OK.
4. Press the "ABC" key twice then press OK.
5. Press the down arrow soft key to select BASIC and press OK.
The pump is now in BASIC MODE.
6. Press OK to select Primary Bag.
7. Press OK to select mL/hr.
8. Enter "1,2,3,4,5,6" using the keypad.
Verify the numbers (123456) appear in the Rate mL/hr field.
9. Press the "clear" soft key.
10. Enter "7, 8, 9, 0" and [. 1 keys.
Verify numbers and decimal point (7890.) appear in the Rate mL/hr field.
11. Press RUN/STOP.
Message: "UPPER Hard Limit Enter a Value of 999 or lower" will appear.
• NOTE: 5.02 and earlier software versions will display:
Hard limits exceeded (0.5 - 999) Reset value within limits
Press OK.
12. Press the SETUP key.
13. Press clear program soft key.
o NOTE: For software version 5.02 and earlier, press "clr all".
The screen will prompt you to Clear Program? yes/no
Press the yes soft key.
14. The Care Area Selection screen appears.
15. Press ON/OFF key to power off the pump.
16. If keypad malfunctions, repeat the test to verify.
17. If the error repeats, remove the pump from service and send to vendor