

To: Managers, Coordinators, Directors, Medical Affairs, and Senior Leadership Committee

From: Quality and Risk Management

Date: November 7, 2023

RE: Baxter Corporation, Novum IQ Large Volume Pump – Potential for Keypad Malfunction

Please be advised that Baxter Corporation has issued a medical device field action for our current intravenous pump, the Novum IQ Large Volume Pump (LVP). This notice has been issued due to the potential for the keypad on these pumps to malfunction, which could result in excessive therapy, insufficient therapy, delay in therapy, or interruption of therapy.

Specifically, when a pump operator presses a single key on the keypad, the pump may incorrectly register multiple keys (e.g. a user presses the number “8” on the keypad, but the pump registers and displays both an “8” and the adjacent “0”). Hearing a “double beep” after a single key press may be an indication that the pump incorrectly registered the keypad entry.

The following mitigation actions have been identified by Baxter:

1. Healthcare providers may continue to safely use the Novum IQ Large Volume Pumps while following the Instructions for Use.
2. Visually verify that entries made on the keypad were correctly registered on the pump display: drug concentration, dose mode, dose rate, and time are correct prior to starting an infusion or initiating a drug titration.
3. Pay additional attention to drug limits, hard, soft and change limits triggered when programming and verify infusion parameters prior to starting an infusion or initiating a drug titration.

If you notice any keypad malfunction of the Novum IQ LVP, please take the following actions:

1. Immediately remove the pump from use and label “out of service”.
2. Complete a biomedical requisition and attach to the pump (include asset number located at the top of each pump, e.g. “2022B10251”).
3. Notify and bring the pump to your Manager.

We appreciate your efforts and cooperation in these extra steps to ensure patient safety is maintained.

Baxter Corporation is working diligently to resolve the issue. Further communication will be provided once the issue is resolved.