FOR IMMEDIATE RELEASE

BAXTER ISSUES URGENT MEDICAL DEVICE CORRECTION FOR NOVUM IQ SYRINGE INFUSION PUMP DUE TO POTENTIAL IMPACT OF DOWNSTREAM OCCLUSIONS ON INFUSION VOLUME

DEERFIELD, Ill., NOVEMBER 29, 2023 – Baxter International Inc. announced today it has issued an Urgent Medical Device Correction for the Novum IQ syringe infusion pump. The Correction is due to the potential for an incomplete infusion following one or more downstream occlusion alarms. Baxter notified impacted customers in October and is developing a software upgrade to resolve the issue. There have been no reports of serious injury associated with this issue to date.

Baxter has identified that after one or more downstream occlusion alarms occur on the Novum IQ syringe pump, the pump may display an "Infusion Complete" alarm despite fluid remaining in the syringe. This could lead to an underdose and/or interruption of therapy. The difference between the remaining volume to be infused displayed on the pump and the volume left in the syringe is dependent on the number of occlusion alarms encountered during an infusion and the size of the syringe being used.

If a patient does not receive the intended dose of a prescribed medication, serious or critical adverse health consequences may occur. Potential health consequences are dependent on multiple patient-specific factors (such as disease state as well as age and weight of the patient involved, and the care area where they are treated), occlusion pressure settings, the number of occlusions that occurred, the size of the syringe used, and the therapy being delivered.

Baxter has contacted affected customers and is developing a software update to resolve the issue. Until the software update is available, customers can continue to use Novum IQ syringe infusion pumps with the following reinforced guidance provided by Baxter:

- As stated in the pump's Operator's Manual, users should choose the smallest compatible syringe size necessary to deliver the fluid or medication.
- Prior to beginning an infusion, users should ensure the downstream occlusion pressure setting is appropriate for the clinical scenario. Consistent with standard clinical practice, users should always check for clamped lines and other sources of downstream occlusion

prior to and during therapy. Pressure setting selection guidelines and instructions for downstream occlusion resolution can be found in section 8.8 of the Operator's Manual.

- Per standard clinical practice, users should continue to monitor the "Volume to be Infused" and the volume delivered while therapy is in progress. This is especially true after a downstream occlusion alarm has occurred. Users should also take note of the initial volume and compare it to the final volume in the syringe. If the total dose is not delivered upon the "Infusion Complete" alarm, users should reprogram the pump and deliver the remaining volume as necessary.

This Urgent Medical Device Correction applies to **Novum IQ** syringe infusion pump with product code 40800BAXUS. This infusion pump is distributed in the United States. Customers with additional questions can contact their Baxter sales representative, or Baxter Global Technical Services at 800-843-7867 Monday through Friday between 6 a.m. and 6 p.m. Central Time. Any adverse events experienced with the use of this product may be reported using one of the following options:

- Emailing Baxter at: corporate_product_complaints_round_lake@baxter.com.
- Reporting to the FDA MedWatch Adverse Event Reporting Program:
    - Online: By completing and submitting the report online at https://www.accessdata.fda.gov/scripts/medwatch/.
    - Regular mail or Fax: Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178.

Baxter is voluntarily issuing this Urgent Medical Device Correction with the knowledge of the U.S. Food and Drug Administration.

About Baxter

Every day, millions of patients, caregivers and healthcare providers rely on Baxter's leading portfolio of diagnostic, critical care, kidney care, nutrition, hospital and surgical products used across patient homes, hospitals, physician offices and other sites of care. For more than 90 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the

healthcare providers who make it happen. With products, digital health solutions and therapies available in more than 100 countries, Baxter's employees worldwide are now building upon the company's rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit www.baxter.com and follow us on X/Twitter, LinkedIn and Facebook.

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