FOR IMMEDIATE RELEASE

BAXTER ISSUES URGENT MEDICAL DEVICE CORRECTION REGARDING POTENTIAL RADIO FREQUENCY INTERFERENCE WITH OTHER DEVICES NEAR BEDS INSTALLED WITH WATCHCARE SYSTEM

DEERFIELD, Ill., OCTOBER 21, 2022 – Baxter International Inc. announced today it has issued an Urgent Medical Device Correction for the WatchCare Incontinence Management System due to potential for radio frequency (RF) interference with other medical devices. The WatchCare system is designed to discreetly alert the caregiver of an incontinence event. Although the WatchCare system has been developed to comply with the most recent RF standards, it radiates RF that might affect other devices in the vicinity, including devices on both patients and staff members. This RF interference could result in erroneous readings or additional malfunctions of these other devices and could therefore result in inappropriate medical intervention. Depending on the intended use of the device that malfunctions, there may be different hazardous situations that could occur. This product is manufactured by Hillrom, which was acquired by Baxter in late 2021.

Baxter is also issuing an updated customer notification letter for this correction, replacing the previous letter issued on September 30, 2022.

To date, interference in all cases but two is known to have occurred at distances less than one meter. There is insufficient data about distance on the remaining two reported interferences. Of note, Baxter is informing users of the following potential hazards, though additional devices may be affected:

- Insulin pump/blood glucose sensor: Sensor readings can be affected and result in overdosing of insulin related to incorrect high glucose readings; as a precaution, users should be vigilant of any erratic or incorrect (high or low) glucose level(s) or insulin dosing events
- Fetal monitor/doppler: May cause “phantom” incorrect fetal heart tone readings up to 200 bpm; as a precaution, users should be vigilant of any erratic or incorrect (high or low) fetal heart tones

- Telemetry devices: Could cause telemetry “artifact” of unknown specificity; as a precaution, users should be vigilant of any telemetry rhythm displays that do not match patient’s clinical presentation
- Bladder scanner: May cause interference of unknown specificity; as a precaution, users should be vigilant of any potential false (elevated or low) residual urine volume readings
- Infusion injection pump: May cause interference of unknown specificity; as a precaution, users should be vigilant of any erratic or incorrect dosing events

Since this issue may affect blood glucose sensors, insulin pumps, fetal monitors, and general infusion pumps among other devices, serious harm or death may occur. This issue can affect medical devices on patients as well as staff caring for patients. No serious injuries or deaths have been reported.

Users and facilities should immediately locate all affected devices and stop use of all **WatchCare** system accessories where possible until this functionality is temporarily disabled and while Baxter continues to work to determine the cause of this problem. Baxter will contact users to arrange for **WatchCare** to be temporarily disabled.

Until all RF capabilities are disabled and/or all devices are removed from clinical care areas, be aware that RF emission from a functioning **WatchCare** device may potentially impact other devices (including, but not limited to, insulin pumps/blood glucose sensors, fetal monitor/dopplers, infusion pumps, telemetry devices, and bladder scanners). Please double-check all unexpected or atypical results and monitor infusions closely, if possible. Until this issue is resolved, use standard, non-RF-based, incontinence management pads.

Baxter is monitoring reports of RF interference and validating the impact the **WatchCare** device may have on other devices in the vicinity. Baxter is also investigating improvement opportunities and will provide a follow-up communication to users once available.

This Urgent Medical Device Correction applies to **Centrella** Bed with **WatchCare** product number P7900B; **WatchCare** System for **VersaCare** Bed Rev. A-J product number P00697901; **WatchCare** System for **VersaCare** Bed Rev. K product number P00697902; **WatchCare** System for **Progressa** Bed product number P00697903; and **WatchCare** System for **Centrella** Bed product number P00697905.

The **WatchCare** System is distributed in the United States. Customers with additional questions can contact Hillrom Technical Support by phone at 800-445-3720 or by email at technical.support@hillrom.com. Any adverse events experienced with the use of this product may be reported using one of the following options:

- Calling Baxter Product Surveillance at 800-437-5176 Monday through Friday between 8 a.m. and 5 p.m. Central Time.
- 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 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 Twitter, LinkedIn and Facebook.

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