



**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Baxter Healthcare Recalls Baxter Epiphany Cardio Server E3 ECG Management System Servers for Becoming Nonresponsive**

| Recall Date | Product Description   | Recalling Firm  | Recall Reason   |
|-------------|---|---|---|
| 10/4/2023   | <b>Baxter Epiphany Cardio Server E3 ECG Management System Servers With Software Versions</b><br>A) v6.1.x, b) v6.2.x, c) v7.0.x | <b>BAXTER HEALTHCARE CORPORATION</b><br>Deerfield, Illinois | Epiphany, now a Baxter Healthcare company, is issuing an Urgent Medical Device Correction for the Cardio Server E3 ECG Management System software listed below due to a report of the caliper tool becoming non-responsive, preventing the caliper function from being used temporarily on software versions v6.1.x, v6.2.x, and v7.0.x of the E3 user interface. |

| Recall Class | Product Identification   | Distribution                                | Affected Dates           |
|--------------|--|---|--------------------------|
| II           | <b>Baxter Epiphany Cardio Server E3 ECG Management System Servers with software versions</b><br>A) v6.1.x, UDI/DI 00860991000355, all serial numbers, b) v6.2.x, UDI/DI 00860991000362, all serial numbers, c) v7.0.x, UDI/DI 00860991000379, all serial numbers | 89 Units<br>Nationwide including California | 10 August 2023 and prior |

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