

### FDA Recall – Baxter Life2000 Ventilation System

#### **Purpose of this communication:**

We are writing to inform you that Baxter is recalling the Life2000 Ventilation System due to a cybersecurity issue discovered through internal testing. If an unauthorized person were to gain physical access to the device while it is unattended, they could potentially change device therapy settings or access device data. This may lead to the life-supporting air delivery function not working as intended. The use of affected product may cause serious adverse health consequences, including injuries caused by device malfunction or complete failure of vital breathing support and death. As of April 10, 2025, Baxter has reported no serious injuries or deaths associated with this issue.

The affected products include the Life2000 Ventilation System and Life2000 Compressor. Ventilator units include product codes MS-01-0100 and MS-01-0118 with UDI-DI numbers 00815410020278, 00887761978089, and 00815410020537, and shipping carton codes BT-20-0002, BT-20-0002A, BT-20-0002AP, BT-20-0007, BT200007, BT-20-0011, BT200011, and RMS010118CP. Compressor units include product codes MS-01-0093, MS-01-0121, and MS-01-0125 with UDI-DI numbers 00887761978072, 00815410020292, 00887761978041, and 00887761976283, and shipping carton codes BT-80-0004, BT-80-0004A, BT-80-0008, BT-80-0008A, and RMS010093CP. All serial numbers are affected.

#### **What do I need to do?**

- Please review the following recall notice [here](#).
- Notify impacted patients and to facilitate replacement, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

**Thank you in advance for your cooperation and continued partnership.**