California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

CareFusion 303, Inc. BD Pyxis Medstation CII Safe ES, ES 7 Drawer Auxiliary Tower, ES, 4000, ES AUX Tower, 4000 AUX Tower, MedFlex, Medbank Mini, Tower, MedPass, and CUBIE

Recall Date	Product Description	Recalling Firm	Recall Reason
12/11/2024	BD Pyxis CII Safe ES REF: 1116-00 BD Pyxis MedStation ES 7 Drawer Auxiliary Tower REF: 324 BD Pyxis MedStation ES REF: 323	CareFusion 303, Inc.	Due to a software issue, automated dispensing cabinet devices may open the wrong cubie pocket or position, which can lead to: 1) Unintended and incorrect medication removal, or 2) Potential for a different medication (medication pulled in error) to be refilled/loaded, which may lead to may lead to low inventory or a stockout.
01/30/2025	BD Pyxis MedStation ES AUX Tower REF 343 BD Pyxis " MedStation 4000 AUX Tower REF 314 The BD Pyxis "MedStation ES and Pyxis" MedStation 4000 are automated dispensing cabinets (ADC) that are intended to securely store and dispense medications to a	CareFusion 303, Inc.	Due to an increase in complaints of door latch assembly failures that may cause the doors to be left in an open state potentially causing inventory discrepancies, a delay in access to medication and/or diversion of

	qualified and authorized healthcare provider.		medication.
02/11/2025	BD Pyxis MedStation 4000 REF: 303 Intended to securely store and dispense medications to a qualified and authorized healthcare provider.	CareFusion 303, Inc.	Retroactive-Due to an increase in complaints, their is a potential for drawer and/or door failures of the medication cabinet which could result in delay in accessing medications.
04/09/2025	BD Pyxis MedBank Mini and BD Pyxis MedBank Tower, BD Pyxis MedFlex, BD Pyxis MedBank MedPass are automated dispensing cabinets (ADC) intended to securely store and dispense medications to a qualified and authorized user in a clinical settings. BD Pyxis MedBank CUBIE Replenishment Station The BD Pyxis MedBank CUBIE Replenishment Station is an Automated Dispensing Cabinet (ADC) that is intended to be used by a qualified and authorized user to replenish medications and supplies to a BD Pyxis" MedBank" cabinet.	CareFusion 303, Inc.	Due to a software bug, automated dispensing cabinet is unable to calculate countback discrepancies during the issue process, which causes incorrect transaction quantity to be recorded. This bug can also result in the CUBIE opening more times than needed for the transaction to be completed, which may result in a patient receiving more than the intended dose of medication.

Recall Class	Product Identification	Distribution	Affected Dates
II	All software versions. REF: 1116-00 UDI-DI: 10885403512605 Serial Numbers: 15938609 - 16907911	13,662 units in California	November 2024 and prior

	All software versions. REF: 324 UDI-DI: 10885403512681 Serial Numbers: 12440840 - 16937679 All software versions. REF: 323 UDI-DI: 10885403512667 Serial Numbers: 12441103 - 14538143		
II	BD Pyxis MedStation ES AUX Tower Catalog Number: 343 UDI-DI code: 10885403512698 Serial Number/Equipment Number: 14535900 - 16187542 BD Pyxis MedStation 4000 AUX Tower Catalog Number: 314 UDI-DI code: 10885403512650 Serial Numbers/Equipment Numbers: 13347095 - 15955591	33,589 systems nationwide	February 2023 and prior
II	BD Pyxis MedStation 4000 REF: 303 UDI: 10885403512629 Serial Numbers: 16153360 - 16283947	Unavailable units	February 2024 and prior
II	REF: 169-143 - 1145-00 UDI-DI: 10885403512568 - 10885403517167 Software Version: 2.4, 1.2.3.23 UDI-DI: 10885403504440 - 10885403512568	7,761 units nationwide	March 2025 and prior

For additional information, please visit: FDA Website (CII Safe ES), FDA Website (MedStation ES 7), FDA Website (MedStation ES),.FDA Website (01/30), FDA Website (02/11), FDA Website (MedBank Mini, etc.) and FDA Website (MedBank Cubie)..