Recall Exposure & Inventory Quality Report

SAMPLE - Sample City Clinic (fictional) · source: sample-free-audit.csv · recall window 2024-11-10 to 2026-11-10 · generated 2026-11-10

28 assets reviewed	**16** assets with potential recall matches	**46** matches to recalls still open
2 likely duplicate asset records	**5** models with inconsistent naming	**1** records missing mfr/model/serial

Potential recall matches

Asset	Device	Serial	Recall	Status	Match	Reason / action
10004 ICU	CAREFUSION 8100 BD / ALARIS 8100	23456781	Z-2179-2025 Class I 2025-07-08	Open, Classified	All serials of model in scope Device	Infusion pump module used with compatible pump infusion sets may perform outside the established performance ranges for flow rate and bolus accuracy, downstream and upstream occlusion time to alarm, and post-occlusion bolos volume. BD Alaris Pump Module Model, 8100 with Guardrails, Suite MX software versions BD Alaris" Pump Module Model 8100- All Serial Numbers/ UDI(s): 10885403222054, 10885403517723, 10885403810015, 10885403810039, 10885403810046 On December 12, 2025, CareFusion 303, Inc. (BD) issued a updated "Urgent Medical device Recall Notice via E-Mail and physical mail. The updated notice includes important information on infusion sets as well as labeling updates. Previous notifications were sent on July 8,2025, July 17, 2025, September 11, 2025 and September 12, 2025. CareFusion ask consignees to take the following actions: 1. Review your inventory for the catalog numbers included in the updated letter. Remove and discard any remaining inventory per your facility guidelines. 2.To receive credit or replacement product, please return the completed customer response form attached to this notice. 3.Please contact your BD Clinical Consultants and Account Executives for alternative sets information. 4. Review the updated

Asset	Device	Serial	Recall	Status	Match	Reason / action
10005 Med/Surg	BD Alaris LVP BD / ALARIS 8100	23456782	Z-2179-2025 Class I 2025-07-08	Open, Classified	All serials of model in scope Device	Infusion pump module used with compatible pump infusion sets may perform outside the established performance ranges for flow rate and bolus accuracy, downstream and upstream occlusion time to alarm, and post-occlusion bolos volume. BD Alaris Pump Module Model, 8100 with Guardrails, Suite MX software versions BD Alaris" Pump Module Model 8100- All Serial Numbers/ UDI(s): 10885403222054, 10885403517723, 10885403810015, 10885403810039, 10885403810046 On December 12, 2025, CareFusion 303, Inc. (BD) issued a updated "Urgent Medical device Recall Notice via E-Mail and physical mail. The updated notice includes important information on infusion sets as well as labeling updates. Previous notifications were sent on July 8,2025, July 17, 2025, September 11, 2025 and September 12, 2025. CareFusion ask consignees to take the following actions: 1. Review your inventory for the catalog numbers included in the updated letter. Remove and discard any remaining inventory per your facility guidelines. 2.To receive credit or replacement product, please return the completed customer response form attached to this notice. 3.Please contact your BD Clinical Consultants and Account Executives for alternative sets information. 4. Review the updated

Asset	Device	Serial	Recall	Status	Match	Reason / action
10018 Respiratory	Philips Respironics Trilogy Evo PHILIPS / TRILOGY EVO	TV0123456789	Z-1614-2026 Class I 2026-03-02	Open, Classified	All serials of model in scope Device	Using non-pneumatic nebulizers with Trilogy Evo Platform ventilators may result in a discrepancy between the set tidal volume and the tidal volume received by the patient. Philips Respironics Trilogy Evo, Software Version 1.05.15.00. Continuous home-use ventilator device. All Model No.; All UDI; All Serial No. An UPDATED: "URGENT FIELD SAFETY NOTICE" dated 3/2/26 was mailed to consignees containing recall information for three different failure modes that can be experienced in all Trilogy Evo, Trilogy EVO O2, Trilogy Evo Universal, and Trilogy EV300 devices. The firm identified that using non-pneumatic nebulizers with Trilogy Evo Platform ventilators may result in a discrepancy between the set tidal volume and the tidal volume received by the patient. This can lead to under-delivery of therapy to the patient. Consignees are being instructed to update all devices with software version 1.05.15.00 through the My Philips for Professionals and In Center websites. The provided Appendix B contains the required instructions. Consignees are also instructed to review the latest version of the Us

Asset	Device	Serial	Recall	Status	Match	Reason / action
10018 Respiratory	Philips Respironics Trilogy Evo PHILIPS / TRILOGY EVO	TV0123456789	Z-1615-2026 Class I 2026-03-02	Open, Classified	All serials of model in scope Device	Using non-pneumatic nebulizers with Trilogy Evo Platform ventilators may result in a discrepancy between the set tidal volume and the tidal volume received by the patient. Philips Respironics Trilogy Evo O2, Software Version 1.05.15.00. Continuous home-use ventilator device. All Model No.; All UDI; All Serial No. An UPDATED: "URGENT FIELD SAFETY NOTICE" dated 3/2/26 was mailed to consignees containing recall information for three different failure modes that can be experienced in all Trilogy Evo, Trilogy EVO O2, Trilogy Evo Universal, and Trilogy EV300 devices. The firm identified that using non-pneumatic nebulizers with Trilogy Evo Platform ventilators may result in a discrepancy between the set tidal volume and the tidal volume received by the patient. This can lead to under-delivery of therapy to the patient. Consignees are being instructed to update all devices with software version 1.05.15.00 through the My Philips for Professionals and In Center websites. The provided Appendix B contains the required instructions. Consignees are also instructed to review the latest version of the Us

Asset	Device	Serial	Recall	Status	Match	Reason / action
10018 Respiratory	Philips Respironics Trilogy Evo PHILIPS / TRILOGY EVO	TV0123456789	Z-1617-2026 Class I 2026-03-02	Open, Classified	All serials of model in scope Device	Using non-pneumatic nebulizers with Trilogy Evo Platform ventilators may result in a discrepancy between the set tidal volume and the tidal volume received by the patient. Philips Respironics Trilogy Evo Universal, Software Version 1.05.15.00. Continuous home-use ventilator device. All Model No.; All UDI; All Serial No. An UPDATED: "URGENT FIELD SAFETY NOTICE" dated 3/2/26 was mailed to consignees containing recall information for three different failure modes that can be experienced in all Trilogy Evo, Trilogy EVO O2, Trilogy Evo Universal, and Trilogy EV300 devices. The firm identified that using non-pneumatic nebulizers with Trilogy Evo Platform ventilators may result in a discrepancy between the set tidal volume and the tidal volume received by the patient. This can lead to under-delivery of therapy to the patient. Consignees are being instructed to update all devices with software version 1.05.15.00 through the My Philips for Professionals and In Center websites. The provided Appendix B contains the required instructions. Consignees are also instructed to review the latest version of the Us

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10018 Respiratory	Philips Respironics Trilogy Evo PHILIPS / TRILOGY EVO	TV0123456789	Z-1646-2026 Class I 2026-03-02	Open, Classified	All serials of model in scope Device	In some situations, the Obstruction Alarm does not trigger within the timeframe dictated by the relevant standards and may take up to four breaths. Philips Respironics Trilogy Evo, Software Version 1.05.15.00. Continuous home-use ventilator device. All Model No.; All UDI; All Serial No. An IMPORTANT PRODUCT NOTICE was mailed to consignees 6/5/24 about obstruction alarm compliance failure in Trilogy Evo devices. Refer to the most current version of the IFU in the event of an obstruction. A software update to correct this issue is pending. An UPDATED: URGENT FIELD SAFETY NOTICE was mailed 3/2/26 with recall information for three failure modes possible in all Trilogy Evo, Trilogy EVO O2, Trilogy Evo Universal, and Trilogy EV300. Using non-pneumatic nebulizers with Trilogy Evo Platform ventilators may result in a discrepancy between the set tidal volume and the tidal volume received by the patient. This can lead to under-delivery of therapy to the patient. Update all devices with software version 1.05.15.00 through the My Philips for Professionals and InCenter websites. Stop

Asset	Device	Serial	Recall	Status	Match	Reason / action
10018 Respiratory	Philips Respironics Trilogy Evo PHILIPS / TRILOGY EVO	TV0123456789	Z-1647-2026 Class I 2026-03-02	Open, Classified	All serials of model in scope Device	In some situations, the Obstruction Alarm does not trigger within the timeframe dictated by the relevant standards and may take up to four breaths. Philips Respironics Trilogy Evo O2, Software Version 1.05.15.00. Continuous home-use ventilator device. All Model No.; All UDI; All Serial No. An IMPORTANT PRODUCT NOTICE was mailed to consignees 6/5/24 about obstruction alarm compliance failure in Trilogy Evo devices. Refer to the most current version of the IFU in the event of an obstruction. A software update to correct this issue is pending. An UPDATED: URGENT FIELD SAFETY NOTICE was mailed 3/2/26 with recall information for three failure modes possible in all Trilogy Evo, Trilogy EVO O2, Trilogy Evo Universal, and Trilogy EV300. Using non-pneumatic nebulizers with Trilogy Evo Platform ventilators may result in a discrepancy between the set tidal volume and the tidal volume received by the patient. This can lead to under-delivery of therapy to the patient. Update all devices with software version 1.05.15.00 through the My Philips for Professionals and InCenter websites. Stop

Asset	Device	Serial	Recall	Status	Match	Reason / action
10018 Respiratory	Philips Respironics Trilogy Evo PHILIPS / TRILOGY EVO	TV0123456789	Z-1649-2026 Class I 2026-03-02	Open, Classified	All serials of model in scope Device	In some situations, the Obstruction Alarm does not trigger within the timeframe dictated by the relevant standards and may take up to four breaths. Philips Respironics Trilogy Evo Universal, Software Version 1.05.15.00. Continuous home-use ventilator device. All Model No.; All UDI; All Serial No. An IMPORTANT PRODUCT NOTICE was mailed to consignees 6/5/24 about obstruction alarm compliance failure in Trilogy Evo devices. Refer to the most current version of the IFU in the event of an obstruction. A software update to correct this issue is pending. An UPDATED: URGENT FIELD SAFETY NOTICE was mailed 3/2/26 with recall information for three failure modes possible in all Trilogy Evo, Trilogy EVO O2, Trilogy Evo Universal, and Trilogy EV300. Using non-pneumatic nebulizers with Trilogy Evo Platform ventilators may result in a discrepancy between the set tidal volume and the tidal volume received by the patient. This can lead to under-delivery of therapy to the patient. Update all devices with software version 1.05.15.00 through the My Philips for Professionals and InCenter websites. Stop

Asset	Device	Serial	Recall	Status	Match	Reason / action
10010 ICU	Philips Medical Systems IntelliVue MX450 PHILIPS / INTELLIVUE MX450	DE81234567	Z-0863-2026 Class II 2025-10-31	Open, Classified	All serials of model in scope Device	Potential issue where the IntelliVue monitors did not alarm. IntelliVue Patient Monitor MX450. Product Number: 866062. Product Number: 866062; UDI-DI: 00884838038769; All Serial No. An URGENT Medical Device Correction notice, dated 10/31/25, was mailed to customers and distributors. Distributors were notified of this correction and instructed to forward the provided recall notification to all consignees. Additionally, distributors are asked to include their contact information for consignees in the provided response form and perform a good faith effort for each customer to obtain a completed response form. Consignees are instructed to notify all users of this recall notification and forward the notice to all who need to be aware within their organization or where affected devices were potentially transferred. Consignees are to re-evaluate and reconfigure device configuration per the provided instructions. Once recall actions have been completed, consignees are to
10011 ICU	PHILIPS MX450 PHILIPS / INTELLIVUE MX450	DE81234568	Z-0863-2026 Class II 2025-10-31	Open, Classified	All serials of model in scope Device	Potential issue where the IntelliVue monitors did not alarm. IntelliVue Patient Monitor MX450. Product Number: 866062. Product Number: 866062; UDI-DI: 00884838038769; All Serial No. An URGENT Medical Device Correction notice, dated 10/31/25, was mailed to customers and distributors. Distributors were notified of this correction and instructed to forward the provided recall notification to all consignees. Additionally, distributors are asked to include their contact information for consignees in the provided response form and perform a good faith effort for each customer to obtain a completed response form. Consignees are instructed to notify all users of this recall notification and forward the notice to all who need to be aware within their organization or where affected devices were potentially transferred. Consignees are to re-evaluate and reconfigure device configuration per the provided instructions. Once recall actions have been completed, consignees are to

Asset	Device	Serial	Recall	Status	Match	Reason / action
10008 ED	Baxter Spectrum IQ BAXTER / SPECTRUM IQ	BX770012	Z-1253-2025 Class I 2025-02-05	Open, Classified	Model match - confirm serial/lot/software version Units serviced/repaired by mfr only	There is the potential for missing motor mounting screws, which may have occurred during the servicing process. Baxter Sigma Spectrum Infusion System (V6 Platform), Product Code 35700BAX UDI/DI 00085412091570, Serial Numbers: 704198, 728888, 751492, 758399, 758614, 761662, 763197, 766291, 772611, 773302, 775486, 778837, 785425, 793453, 795240, 798065, 814485, 818850, 826637, 850214, 850854, 851500, 854157, 855803, 863354, 870307, 873114, 876483, 877014, 877102, 889153, 896292, 900181, 906422, 907176, 912242, 913562, 927864, 938265, 958176, 962828, 963975, 965158, 974676, 981605, 982459, 984154, 986132, 986634, 989053, 993087, 994417, 994842, 995538, 997153, 1006359, 1011058, 1013925, 1014064, 1014529, 1014856, 1017150, 1017546, 1018229, 1018703, 1024109 Baxter issued an "URGENT MEDICAL DEVICE RECAL" notice to its consignees on 02/05/2025 via US Mail. The notice explained the issue, hazard involved, and requested the following actions be taken: "1. Immediately locate, isolate, and cease all use of Spectrum pumps with the affected serial numbers. The product code and serial number can be found on the bottom of the infusion pump. 2. Contact Baxter to arrange for the return of the affected pumps for inspection and reservicing as applicable. 3. If you received this communication directly from Baxter, acknowledge receipt on the enclosed reply form even if you have no remaining inventory. If you do not complete the acknowledgement, you will receive a phone call from OnProcess Technology on behalf of Baxter to confirm your re

Asset	Device	Serial	Recall	Status	Match	Reason / action
10008 ED	Baxter Spectrum IQ BAXTER / SPECTRUM IQ	BX770012	Z-1254-2025 Class I 2025-02-05	Open, Classified	Model match - confirm serial/lot/software version Units serviced/repaired by mfr only	There is the potential for missing motor mounting screws, which may have occurred during the servicing process. Baxter Spectrum IQ Infusion System with Dose IQ Safety Software, Product Code 3570009 UDI/DI 00085412610900, Serial Numbers: 3020290, 3020992, 3020996, 3021929, 3023080, 3023183, 3023537, 3023758, 3500529, 3502799, 3502864, 3510806, 3511639, 3512647, 3514801, 3516888, 3517399, 3517517, 3518558, 3519053, 3564064, 3564818, 3565462, 3565620, 3566022, 3566254, 3567145, 3567218, 3567998, 3568527, 3568922, 3570910, 3571100, 3571598, 3571972, 3573147, 3573504, 3574293, 3575033, 3575107, 3576026, 3576443, 3656732, 3657316, 3657541, 3657814, 3657821, 3657995, 3659259, 3660176, 3660244, 3662986, 3664495, 3665624, 3721608, 3721910, 3721946, 3722620, 3723725, 3724211, 3730270, 3730408, 3732309, 3732476, 3734858, 3735010, 3735261, 3735734, 3738122, 3744219, 3744455, 3746159, 3746749, 3749111, 3749929, 3764591, 3767418, 3519969, 3520138, 3520706, 3520746, 3520829, 3521120, 3521338, 3606099, 3607097, 3607681, 3608730, 3609223, 3610668, 3610820, 3611120, 3611140, 3611650, 3612298, 3612886, 3613052, 3614035, 3615599, 3615816, 3616449, 3666443, 3666451, 3667116, 3668076, 3668654, 3668851, 3669058, 3669126, 3669307, 3670942, 3671444, 3672061, 3672846, 3676099, 3677241, 3679511, 3680542, 3681596, 3681981, 3686743, 3689421, 3691453, 3691496, 3693341, 3696268, 3618354, 3619039, 3619876, 3620296, 3620427, 3620631, 3620643, 3620757, 3621068, 3621252, 3621777, 3623915, 3623963, 3624131, 3624546, 3627519, 3628177, 3630964, 3632085, 3632710, 3632830, 3633267, 3634729, 3634792, 3699321, 3699388, 3699822, 3699917, 3700350, 3700551, 3701785, 3703127, 3703425, 3703513, 3703840, 3704056, 37 Baxter issued an "URGENT MEDICAL DEVICE RECAL" notice to its

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10008 ED	Baxter Spectrum IQ BAXTER / SPECTRUM IQ	BX770012	Z-2095-2025 Class I 2025-06-20	Open, Classified	Model match - confirm serial/lot/software version Device	Certain Spectrum infusion pumps may have an incorrect version of software. Baxter SIGMA Spectrum Infusion Pump V6, Model Number 35700BAX UDI-DI: 00085412091570; Serial Numbers: 765100 , 772744 , 789742 , 841197 , 867753 , 920606 , 1024015 770164 788724 , 793079 , 842498 , 918342 , 962810 , 1027523 An URGENT MEDICAL DEVICE RECALL notification letter dated 6/20/25 was sent to customers. Actions to be Taken by Customers 1. Immediately locate Spectrum pumps with the affected serial numbers and remove them from service. The product code and serial number can be found on the bottom of the infusion pump. 2. Check and record the software version installed on the pump. The software on a V6 pump should begin with the number 6 and the software on a V8 pump should begin with the number 8. The software version is located on the startup screen upon powering up the pump as pictured on the next page. Additionally, the software version is indicated in the pump menu which can be accessed by following the steps. For V6: From the Pump Information screen, press the sw info soft key to display the so

Asset	Device	Serial	Recall	Status	Match	Reason / action
10008 ED	Baxter Spectrum IQ BAXTER / SPECTRUM IQ	BX770012	Z-2096-2025 Class I 2025-06-20	Open, Classified	Model match - confirm serial/lot/software version Device	Certain Spectrum infusion pumps may have an incorrect version of software. Baxter SIGMA Spectrum Infusion Pump V8, Model Number 35700BAX2 UDI-DI: 00085412498683; Serial Numbers: 2006307 , 2052091 , 2093765 , 2095360 , 2104302 , 2119236 , 2141815 , 2025925 , 2067699 , 2094483 , 2095541 , 2105238 , 2119436 , 2143406 , 2034297 , 2074097 , 2094580 , 2096351 , 2105769 , 2135482 , 2143684 , 2051591 , 2090658 , 2095202 , 2096856 , 2118940 , 2137976 , 2156201 An URGENT MEDICAL DEVICE RECALL notification letter dated 6/20/25 was sent to customers. Actions to be Taken by Customers 1. Immediately locate Spectrum pumps with the affected serial numbers and remove them from service. The product code and serial number can be found on the bottom of the infusion pump. 2. Check and record the software version installed on the pump. The software on a V6 pump should begin with the number 6 and the software on a V8 pump should begin with the number 8. The software version is located on the startup screen upon powering up the pump as pictured on the next page. Additionally, the software version is indicated in the pump menu which can be accessed by following the steps. For V6: From the Pump Information screen, press the sw info soft key to display the so

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10019 ED	Hamilton Medical Hamilton-C1 HAMILTON MEDICAL / HAMILTON-C1	7001234	Z-2167-2025 Class I 2025-06-26	Open, Classified	Model match - confirm serial/lot/software version Possibly accessory/consumable	Ventilator coaxial breathing circuit may have a crack in blue tubing, which is used to deliver fresh gas to the patient. The crack will compromise inspiratory and expiratory flows, leading to partial or complete rebreathing of exhaled gases, which could lead to acute hypercapnia, respiratory acidosis, and if unrecognized organ dysfunction. Breathing circuit set, coaxial, 1.80 m, with flow sensor and expiratory valve set, REF: 260128, used with HAMILTON-C1, HAMILTON-T1 and HAMILTON-MR1 ventilators. UDI-DI: 07630002802963, Lots: 199675, 199676 Starting on 6/26/2025, recall notices were emailed to customers who were asked to do the following: Return affected devices. If one of the affected breathing circuits would be already in use with a patient, it is requested to exchange it and discard the product after replacement. If you are a distributor, please forward to any organization where potentially affected product has been transferred. Complete and return the acknowledgement form via email to complaints@hamiltonmedical.com If you have any questions contact firm at: complaints@hamiltonmedical.com and 800-426-6331

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10004 ICU	CAREFUSION 8100 BD / ALARIS 8100	23456781	Z-0430-2026 Class I 2025-10-17	Open, Classified	Model match - confirm serial/lot/software version Device	If infusion pump is dropped or severely jarred this may damage the pump module bezel assembly, which can cause under-infusion, over-infusion, unregulated flow, or pump module failure to calibrate; so dropped/jarred pumps should be removed from use, tested, and inspected by qualified service personnel prior to reuse; tip sheet, cleaning and disinfecting procedure and reference guide updated. BD Alaris infusion Pump Module 8100, REF: 8100; KIT, BEZEL ASSY 8100BD, REF: 49000437; KIT ASSY ONE PIECE BEZEL 8100, REF: 49000270. Used with the following new and updated documents: BD Alaris Infusion System Inspection Safety Reminder, Part: BD-163124, Revision: 00; Cleaning and Disinfecting Procedure, Part: P00000864; Cleaning and Disinfecting Quick Reference Guide All Alaris Pump Modules distributed after June 19, 2004. REF/UDI-DI: 8100/10885403810015, 10885403810046, 10885403810039, 10885403222054, 10885403517723, 10885403213212, 10885403211423; 49000437/10885403471018; 49000270/10885403247743 On 10/17/2025, correction notices were mailed and emailed: Distribute notice to clinical and non-clinical users. Safety Reminder: https://academy.bd.com/en-us/home. Provide notice to any facilities you may have sold or transferred devices to. Use only BD-authorized companies when renting infusion devices. Complete and return response form to bdrc55@bd.com If dropped, biomedical engineering should perform testing as specified in Level of Testing Guidelines, including rate accuracy verification testing. If any test fails see troubleshooting section, see Technical Service Manual, Chapter 5 and 6. User Manuals: https://bd.com/self-service. Firm contacts: Technical Support 888-812-3229, DL-US-INF-TechSupport@bd.com . Product Complaints: ProductComplaints@bd.com BD Alaris Infusion System S

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10005 Med/Surg	BD Alaris LVP BD / ALARIS 8100	23456782	Z-0430-2026 Class I 2025-10-17	Open, Classified	Model match - confirm serial/lot/software version Device	If infusion pump is dropped or severely jarred this may damage the pump module bezel assembly, which can cause under-infusion, over-infusion, unregulated flow, or pump module failure to calibrate; so dropped/jarred pumps should be removed from use, tested, and inspected by qualified service personnel prior to reuse; tip sheet, cleaning and disinfecting procedure and reference guide updated. BD Alaris infusion Pump Module 8100, REF: 8100; KIT, BEZEL ASSY 8100BD, REF: 49000437; KIT ASSY ONE PIECE BEZEL 8100, REF: 49000270. Used with the following new and updated documents: BD Alaris Infusion System Inspection Safety Reminder, Part: BD-163124, Revision: 00; Cleaning and Disinfecting Procedure, Part: P00000864; Cleaning and Disinfecting Quick Reference Guide All Alaris Pump Modules distributed after June 19, 2004. REF/UDI-DI: 8100/10885403810015, 10885403810046, 10885403810039, 10885403222054, 10885403517723, 10885403213212, 10885403211423; 49000437/10885403471018; 49000270/10885403247743 On 10/17/2025, correction notices were mailed and emailed: Distribute notice to clinical and non-clinical users. Safety Reminder: https://academy.bd.com/en-us/home. Provide notice to any facilities you may have sold or transferred devices to. Use only BD-authorized companies when renting infusion devices. Complete and return response form to bdrc55@bd.com If dropped, biomedical engineering should perform testing as specified in Level of Testing Guidelines, including rate accuracy verification testing. If any test fails see troubleshooting section, see Technical Service Manual, Chapter 5 and 6. User Manuals: https://bd.com/self-service. Firm contacts: Technical Support 888-812-3229, DL-US-INF-TechSupport@bd.com . Product Complaints: ProductComplaints@bd.com BD Alaris Infusion System S

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10019 ED	Hamilton Medical Hamilton-C1 HAMILTON MEDICAL / HAMILTON-C1	7001234	Z-2463-2026 Class I 2026-05-29	Open, Classified	Model match - confirm serial/lot/software version Possibly accessory/consumable	Ventilator coaxial breathing circuit may have, expiratory valve sets with membranes sticking to valve body, not detectable during pre-operative test, which will result in "exhalation obstructed " alarm, which may result in inadequate ventilation, oxygen desaturation. Advising: Prior to use, test lung action. If alarm occurs, expiratory valve set removal to overcome membrane adhesion or r Breathing circuit set, coaxial: REF: 260127, 260128, 260167, 260168 used with HAMILTON-C1, HAMILTON-T1 and HAMILTON-MR1 ventilators. REF/UDI-DI: 260127/07630002802956, 17630002802953; 260128/07630002802963, 17630002802960; 260167/07630002802970, 17630002802977; 260168/07630002802987, 17630002802984. Lot numbers between 200379 and 205050 (including both.) On 5/29/2026, correction notices were emailed to customers who were asked to do the following: 1) Inform all potential users of affected devices within your facility about this issue. 2) Inform all affected end users and/or sub-distributors and provide them with this notice. 5) Post this notice to ensure all personnel are informed. 6) Complete and return Facility Reply Form via email to complaints@hamiltonmedical.com Customers with questions can contact the firm at the email above. Initially customers were informed to continue use and perform actions to mitigate risk, but later the updated notice called for affected device removal. On 7/8/2026, updated recall notices were emailed and mailed to healthcare facilities, physicians and end users who were informed of the following: 1) Disc

Asset	Device	Serial	Recall	Status	Match	Reason / action
10008 ED	Baxter Spectrum IQ BAXTER / SPECTRUM IQ	BX770012	Z-0775-2025 Class II 2024-11-19	Open, Classified	Model match - confirm serial/lot/software version Units serviced/repaired by mfr only	Devices were identified as released after repair without full testing being performed, which includes flow testing. Baxter SIGMA Spectrum Infusion Pump with Master Drug Library (Version 6), Product Code 35700BAX GTIN 00085412091570; Serial Number: 779515 Customers were contacted via telephone beginning 11/19/24. Baxter Healthcare is calling to notify you of a potential issue with the Spectrum infusion pump. One of your devices has been identified as released after repair without full testing being performed, which includes flow testing. Baxter is requesting the return of the impacted infusion pump to perform all tests required and confirm that the infusion pump performs as expected. As part of this process, we need to make you aware of the potential hazard associated with flow related issues. Flow issues may cause excessive therapy, free-flow condition, insufficient therapy or interruption of therapy. These may lead to serious adverse health consequences, including permanent injury and death. Send signed form to Global CORP Service Qual

Asset	Device	Serial	Recall	Status	Match	Reason / action
10008 ED	Baxter Spectrum IQ BAXTER / SPECTRUM IQ	BX770012	Z-0776-2025 Class II 2024-11-19	Open, Classified	Model match - confirm serial/lot/software version Units serviced/repaired by mfr only	Devices were identified as released after repair without full testing being performed, which includes flow testing. Baxter SIGMA Spectrum Infusion Pump with Master Drug Library (Version 8), Product Code 35700BAX2 GTIN 00085412498683; Serial Number: 2153638 Customers were contacted via telephone beginning 11/19/24. Baxter Healthcare is calling to notify you of a potential issue with the Spectrum infusion pump. One of your devices has been identified as released after repair without full testing being performed, which includes flow testing. Baxter is requesting the return of the impacted infusion pump to perform all tests required and confirm that the infusion pump performs as expected. As part of this process, we need to make you aware of the potential hazard associated with flow related issues. Flow issues may cause excessive therapy, free-flow condition, insufficient therapy or interruption of therapy. These may lead to serious adverse health consequences, including permanent injury and death. Send signed form to Global CORP Service Qual

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10010 ICU	Philips Medical Systems IntelliVue MX450 PHILIPS / INTELLIVUE MX450	DE81234567	Z-1108-2025 Class II 2025-01-15	Open, Classified	Model match - confirm serial/lot/software version Device	Potential failure to alarm for "No Device Data" INOP. The device to alarm after a Hamilton ventilator is disconnected from the EC10 Module or IntelliBridge I/O board. IntelliVue Patient Monitor MX450. Model Number: 866062 Model Number: 866062. UDI-DI: (01)00884838038769(21); Serial Numbers: DE35169761, DE671V3903, DE671V3885, DE671V7898, DE7770DC1L. UDI-DI: 884838045859; Serial Numbers: DE32303399, DE32302479, DE32302480, DE32306956, DE35131294, DE35114613, DE35114612, DE671T9641, DE7770C86L, DE7770C86K, DE7770C86J, DE7770C86H, DE7770C86G, DE35120431, DE671K3731, DE671K3729, DE671K3706, DE671K3796, DE671K3816, DE671K3737, DE671K3773, DE671L0436, DE671L0462, DE671L0406, DE671L5214, DE671L5207, DE671L5206, DE671L5181, DE671L5169, DE671M3993, DE671M4048, DE671M4036, DE671M4037, DE671M4053, DE671M7009, DE671M7012, DE671M9968, DE671M9972, DE671M9963, DE671N0009, DE671N0010, DE671N0092, DE671N0008, DE671N0001, DE671N0002, DE671M9985, DE671M9999, DE671N0000, DE671P0411, DE671P1094, DE671P2457, DE671P2537, DE32306016, DE32306017, DE32306018, DE7580B4PC, DE7580B4PB, DE7580B4PA, DE7770C6ZP, DE7770C74Y, DE7770C74Z, DE7770C750, DE7770C74W, DE7770C74V, DE7770C78E, DE7770C78D, DE7770D6LH, DE7770D6LG, DE7770D6LF, DE7770D6LE, DE35142704, DE35142703, DE35142705, DE35142702, DE35142706, DE35182894, DE32301491, DE32301476, DE32301477, DE32301478, DE32301479, DE32301480, DE32301481, DE32301482, DE32301483, DE32301484, DE32301485, DE32301486, DE32301487, DE32301488, DE32301489, DE32301490, DE32301506. Philips began notifying consignees on about 01/15/2025 via certified letters titled URGENT Field Safety Notice and URGENT Medical Device Correction letters. Consignees were instructed to ensure that there is no interruption of

Asset	Device	Serial	Recall	Status	Match	Reason / action
						the cable connection between the Hamilton ventilator and the EC10 Module or IntelliBridge I/O board before use, provide the notification to all affected personnel and customers if the devices have been further distributed, and to complete and return the response form provided. A Philips representative will contact you to schedule a visit from a Philips Field Service Engineer who will upgrade your ED245 Driver from revision A.0 to revision A.1. Distributors were instructed to return the Response Form attached your contact information, send the attached URGENT Fiel

Asset	Device	Serial	Recall	Status	Match	Reason / action
10011 ICU	PHILIPS MX450 PHILIPS / INTELLIVUE MX450	DE81234568	Z-1108-2025 Class II 2025-01-15	Open, Classified	Model match - confirm serial/lot/software version Device	Potential failure to alarm for "No Device Data" INOP. The device to alarm after a Hamilton ventilator is disconnected from the EC10 Module or IntelliBridge I/O board. IntelliVue Patient Monitor MX450. Model Number: 866062 Model Number: 866062. UDI-DI: (01)00884838038769(21); Serial Numbers: DE35169761, DE671V3903, DE671V3885, DE671V7898, DE7770DC1L. UDI-DI: 884838045859; Serial Numbers: DE32303399, DE32302479, DE32302480, DE32306956, DE35131294, DE35114613, DE35114612, DE671T9641, DE7770C86L, DE7770C86K, DE7770C86J, DE7770C86H, DE7770C86G, DE35120431, DE671K3731, DE671K3729, DE671K3706, DE671K3796, DE671K3816, DE671K3737, DE671K3773, DE671L0436, DE671L0462, DE671L0406, DE671L5214, DE671L5207, DE671L5206, DE671L5181, DE671L5169, DE671M3993, DE671M4048, DE671M4036, DE671M4037, DE671M4053, DE671M7009, DE671M7012, DE671M9968, DE671M9972, DE671M9963, DE671N0009, DE671N0010, DE671N0092, DE671N0008, DE671N0001, DE671N0002, DE671M9985, DE671M9999, DE671N0000, DE671P0411, DE671P1094, DE671P2457, DE671P2537, DE32306016, DE32306017, DE32306018, DE7580B4PC, DE7580B4PB, DE7580B4PA, DE7770C6ZP, DE7770C74Y, DE7770C74Z, DE7770C750, DE7770C74W, DE7770C74V, DE7770C78E, DE7770C78D, DE7770D6LH, DE7770D6LG, DE7770D6LF, DE7770D6LE, DE35142704, DE35142703, DE35142705, DE35142702, DE35142706, DE35182894, DE32301491, DE32301476, DE32301477, DE32301478, DE32301479, DE32301480, DE32301481, DE32301482, DE32301483, DE32301484, DE32301485, DE32301486, DE32301487, DE32301488, DE32301489, DE32301490, DE32301506. Philips began notifying consignees on about 01/15/2025 via certified letters titled URGENT Field Safety Notice and URGENT Medical Device Correction letters. Consignees were instructed to ensure that there is no interruption of

Asset	Device	Serial	Recall	Status	Match	Reason / action
						the cable connection between the Hamilton ventilator and the EC10 Module or IntelliBridge I/O board before use, provide the notification to all affected personnel and customers if the devices have been further distributed, and to complete and return the response form provided. A Philips representative will contact you to schedule a visit from a Philips Field Service Engineer who will upgrade your ED245 Driver from revision A.0 to revision A.1. Distributors were instructed to return the Response Form attached your contact information, send the attached URGENT Fiel

Asset	Device	Serial	Recall	Status	Match	Reason / action
10012 ED	Physio-Control LIFEPAK 15 STRYKER / LIFEPAK 15	44120033	Z-1184-2025 Class II 2025-01-21	Open, Classified	Model match - confirm serial/lot/software version Device	Due to an error message that prevents users from utilizing carboxyhemoglobin saturation and methemoglobin saturation sensors on their monitor/defibrillator system. LIFEPAK 15 V4/Masimo Rainbow Sensors: Masimo RD rainbow Adt 8 SpCO, SpO2, and SpMet, Adult Adhesive Sensors REF 11996-000515 Masimo LNCS-II rainbow DCI 8 SpCO, Adult Reusable Sensor REF 11996-000519 Masimo LNCS-II rainbow DCI 8 SpCO, Pediatric Reusable Sensor REF 11996-000520 The LIFEPAK 15 Monitor/Defibrillator (LP15) is a complete acute cardiac care response system designed for basic life support (BLS) and advanced life support (ALS) patient management protocols. RD rainbow" 8 SpCO sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), and methemoglobin saturation (SpMet) for use with adult, pediatric, infant, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments. Catalog Number: 11996-000515 UDI-DI/GTIN code: 00843997010863 Lot Number: 23G79 Catalog Number: 11996-000519 UDI-DI/GTIN code: 00843997015608 Lot Numbers: 23HER 23HPT 23JBN 23JTA Catalog Number: 11996-000520 UDI-DI/GTIN code: 00843997015615 Lot Numbers: 23HNV 23JBP On 1/21/2025, the firm send an "URGENT: MEDICAL DEVICE RECALL" Letter via UPS 2-Day mail to customers to inform them that the LIFEPAK 15 V4 displays an error where "SpO2: Sensor does not support SpCO or SpMET". The error results in preventing users from utilizing LIFEPAK 15 V4 SpCO and SpMet functionalities when connected to specific lots of Masimo Rainbow Sensors. Customers are instructed to: 1. Immediately check your internal inventory to locate the product listed on the attached business reply form and remove them from their point of use. 2. Return the enclosed business reply form by email to RSRecall@Stryker.com to confirm receipt of this notification. 3. Upon receipt of the completed business reply form, Stryker will contact you to arrange for the return and repl

Asset	Device	Serial	Recall	Status	Match	Reason / action

Asset	Device	Serial	Recall	Status	Match	Reason / action
10013 OR	Stryker LP15 STRYKER / LIFEPAK 15	44120034	Z-1184-2025 Class II 2025-01-21	Open, Classified	Model match - confirm serial/lot/software version Device	Due to an error message that prevents users from utilizing carboxyhemoglobin saturation and methemoglobin saturation sensors on their monitor/defibrillator system. LIFEPAK 15 V4/Masimo Rainbow Sensors: Masimo RD rainbow Adt 8 SpCO, SpO2, and SpMet, Adult Adhesive Sensors REF 11996-000515 Masimo LNCS-II rainbow DCI 8 SpCO, Adult Reusable Sensor REF 11996-000519 Masimo LNCS-II rainbow DCI 8 SpCO, Pediatric Reusable Sensor REF 11996-000520 The LIFEPAK 15 Monitor/Defibrillator (LP15) is a complete acute cardiac care response system designed for basic life support (BLS) and advanced life support (ALS) patient management protocols. RD rainbow" 8 SpCO sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), and methemoglobin saturation (SpMet) for use with adult, pediatric, infant, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments. Catalog Number: 11996-000515 UDI-DI/GTIN code: 00843997010863 Lot Number: 23G79 Catalog Number: 11996-000519 UDI-DI/GTIN code: 00843997015608 Lot Numbers: 23HER 23HPT 23JBN 23JTA Catalog Number: 11996-000520 UDI-DI/GTIN code: 00843997015615 Lot Numbers: 23HNV 23JBP On 1/21/2025, the firm send an "URGENT: MEDICAL DEVICE RECALL" Letter via UPS 2-Day mail to customers to inform them that the LIFEPAK 15 V4 displays an error where "SpO2: Sensor does not support SpCO or SpMET". The error results in preventing users from utilizing LIFEPAK 15 V4 SpCO and SpMet functionalities when connected to specific lots of Masimo Rainbow Sensors. Customers are instructed to: 1. Immediately check your internal inventory to locate the product listed on the attached business reply form and remove them from their point of use. 2. Return the enclosed business reply form by email to RSRecall@Stryker.com to confirm receipt of this notification. 3. Upon receipt of the completed business reply form, Stryker will contact you to arrange for the return and repl

Asset	Device	Serial	Recall	Status	Match	Reason / action

Asset	Device	Serial	Recall	Status	Match	Reason / action
10023 Biomed Shop	Physio Control LIFEPAK 15 STRYKER / LIFEPAK 15	44120033	Z-1184-2025 Class II 2025-01-21	Open, Classified	Model match - confirm serial/lot/software version Device	Due to an error message that prevents users from utilizing carboxyhemoglobin saturation and methemoglobin saturation sensors on their monitor/defibrillator system. LIFEPAK 15 V4/Masimo Rainbow Sensors: Masimo RD rainbow Adt 8 SpCO, SpO2, and SpMet, Adult Adhesive Sensors REF 11996-000515 Masimo LNCS-II rainbow DCI 8 SpCO, Adult Reusable Sensor REF 11996-000519 Masimo LNCS-II rainbow DCI 8 SpCO, Pediatric Reusable Sensor REF 11996-000520 The LIFEPAK 15 Monitor/Defibrillator (LP15) is a complete acute cardiac care response system designed for basic life support (BLS) and advanced life support (ALS) patient management protocols. RD rainbow" 8 SpCO sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), and methemoglobin saturation (SpMet) for use with adult, pediatric, infant, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments. Catalog Number: 11996-000515 UDI-DI/GTIN code: 00843997010863 Lot Number: 23G79 Catalog Number: 11996-000519 UDI-DI/GTIN code: 00843997015608 Lot Numbers: 23HER 23HPT 23JBN 23JTA Catalog Number: 11996-000520 UDI-DI/GTIN code: 00843997015615 Lot Numbers: 23HNV 23JBP On 1/21/2025, the firm send an "URGENT: MEDICAL DEVICE RECALL" Letter via UPS 2-Day mail to customers to inform them that the LIFEPAK 15 V4 displays an error where "SpO2: Sensor does not support SpCO or SpMET". The error results in preventing users from utilizing LIFEPAK 15 V4 SpCO and SpMet functionalities when connected to specific lots of Masimo Rainbow Sensors. Customers are instructed to: 1. Immediately check your internal inventory to locate the product listed on the attached business reply form and remove them from their point of use. 2. Return the enclosed business reply form by email to RSRecall@Stryker.com to confirm receipt of this notification. 3. Upon receipt of the completed business reply form, Stryker will contact you to arrange for the return and repl

Asset	Device	Serial	Recall	Status	Match	Reason / action
10004 ICU	CAREFUSION 8100 BD / ALARIS 8100	23456781	Z-1231-2025 Class II 2025-01-23	Open, Classified	Model match - confirm serial/lot/software version Labeling/IFU	Due to User Manual/Direction for Use incorrectly instructing user to leave the safety clamp in the open position when reloading an infusion set. This issue potentially could result in an accidental over infusion if the roller clamp is left open. BD Alaris Pump Module REF 8100 The BD Alaris System with Guardrails Suite MX is a modular infusion pump and monitoring system for the continuous or intermittent administration of fluids to adult, pediatric, and neonatal patients through clinically accepted routes of administration Catalog Number: 8100 UDI-DI codes: 10885403810046 10885403517723 Software Version: 12.1.2 Serial/Lot Numbers: Pending On 01/23/2025, the firm sent via FedEx, 2-day mail and email an "URGENT MEDICAL DEVICE LABELING CORRECTION" Letter to customers informing them that Through an internal review, BD has identified that in the BD Alaris" System User Manual v 12.3.1 (p/n #P00000455), 12.3.2 (p/n# P00000827) and 12.4 (p/n# P00000828), there is an incorrect note on the Pump Module Set Loading instructions. The manuals incorrectly instruct users to leave the safety clamp in the open position when reloading an infusion set. The correct procedure is to leave the safety clamp in the closed position. Following the incorrect note could potentially disable a safety feature that could result in an accidental over-infusion if the roller clamp is left open. Customers are instructed to: 1. Post the Customer

Asset	Device	Serial	Recall	Status	Match	Reason / action
10005 Med/Surg	BD Alaris LVP BD / ALARIS 8100	23456782	Z-1231-2025 Class II 2025-01-23	Open, Classified	Model match - confirm serial/lot/software version Labeling/IFU	Due to User Manual/Direction for Use incorrectly instructing user to leave the safety clamp in the open position when reloading an infusion set. This issue potentially could result in an accidental over infusion if the roller clamp is left open. BD Alaris Pump Module REF 8100 The BD Alaris System with Guardrails Suite MX is a modular infusion pump and monitoring system for the continuous or intermittent administration of fluids to adult, pediatric, and neonatal patients through clinically accepted routes of administration Catalog Number: 8100 UDI-DI codes: 10885403810046 10885403517723 Software Version: 12.1.2 Serial/Lot Numbers: Pending On 01/23/2025, the firm sent via FedEx, 2-day mail and email an "URGENT MEDICAL DEVICE LABELING CORRECTION" Letter to customers informing them that Through an internal review, BD has identified that in the BD Alaris" System User Manual v 12.3.1 (p/n #P00000455), 12.3.2 (p/n# P00000827) and 12.4 (p/n# P00000828), there is an incorrect note on the Pump Module Set Loading instructions. The manuals incorrectly instruct users to leave the safety clamp in the open position when reloading an infusion set. The correct procedure is to leave the safety clamp in the closed position. Following the incorrect note could potentially disable a safety feature that could result in an accidental over-infusion if the roller clamp is left open. Customers are instructed to: 1. Post the Customer

Asset	Device	Serial	Recall	Status	Match	Reason / action
10004 ICU	CAREFUSION 8100 BD / ALARIS 8100	23456781	Z-2477-2025 Class II 2025-05-08	Open, Classified	Model match - confirm serial/lot/software version Device	Antivirus software was not consistently installed on impacted devices during the implementation process. BD Pyxis Product Name / UDI-DI code / Catalog No. BD Pyxis" MedStation" 4000 Main / 10885403512629 / 303 BD Pyxis" MedStation" ES Tower / 10885403512674 / 352 BD Pyxis" Anesthesia Station ES / 10885403477836 / 327 BD Pyxis" MedStation" ES (Main) / 10885403512667 / 323 BD Pyxis" CII Safe ES / 10885403512605 / 1116-00 BD Pyxis" Enterprise Server / 10885403518348 and 10885403520341 / 1115-00 BD Pyxis" CIISafe, V9.X, SGL IM, BIO, / 10885403512520 / 111-221 BD Pyxis" CIISafe, V7.X, DBL INTG MAIN, BIO, SOLID DO / N/A / 111-194 BD Pyxis" MedBank Tower / 10885403512568 / 169-29 BD Pyxis" CIISafe, V8.X Desktop PC, Bio / N/A / 107-245-01 Supply Server / N/A / N/A CCE Enterprise SW Site License (2-5) / N/A / N/A BD Pyxis" Logistics / N/A / 806 BD Pyxis" SupplyStation" V9 / N/A / 317 Security Module / N/A / 139698-01 Supply itParActive RF V11 / N/A / 138566-01 BD Knowledge Portal for Medication Technologies / N/A / 136607-01 STOCKSTN V10.X WRD/WL SCANNERS / N/A / 132-53-02 PRS STOCKSTN V10.X WRD/WL SCANNERS / N/A / 132-53-01 STOCKSTN V10.X WIRED SCANNER / N/A / 132-52-02 PRS STOCKSTN V10.X WIRED SCANNER / N/A / 132-52-01 BD Pyxis" CII Safe ES, Desktop PC / N/A / 1156-00 BD Pyxis" SupplyStation" Panel PC V11 / N/A / 1132-00 Pyxis" SupplyRoller V11 / N/A / 1127-00 Dell 640 Server / N/A / 1128-00 BD Pyxis" SupplyStation" System V11 / N/A / 1123-00 BD Pyxis" SupplyRoller V10 / N/A / 1101-00 BD Pyxis" SupplyStation" System V10 / **** / 347 BD Pyxis CII Safe,V9.X DESKTOP PC / **** / 107-252-01 BD Pyxis CII Safe,V7.X,DBL INTG MAIN,BIO,CLEAR DO 111-191 BD Pyxis CII Safe, V9.X, DBL IM, BIO, SLD DOORS / **** / 111-215 BD Care Coordination Engine (CCE) / **** / 134056-01 The Pyxis devices are automated medication dispensing cabinet that is intended to securely store and dispense medications to a qualified and authorized healthcare provider. BD Pyxis Product Name / UDI-DI code / Catalog No. BD Pyxis" MedStation" 4000 Main / 10885403512629 / 303 Atlas Key / Computer Name: DF36449C-9896-4A27-BC18-

Asset	Device	Serial	Recall	Status	Match	Reason / action
						481981535F84 OR2 993BA58F-B5FB-49E8-AE94-BC81E0A93C2A ER-PED FF9AD713-320E-4317-94C0-1A7F57F1AA63 K3 25845A1C-20A3-44BA-8D78-9C9DC001F5B8 PYXH5SASC 2BFA94A6-6192-4ACA-B495-06BA07DC2D73 ESC-WARD1 38404D6B-8356-476A-970F-E4F9CE5731DB WC A9EF86BC-6DF5-4F7F-AE54-6F51773D343E THEATRE12W 1B194D06-1F1A-4930-AA42-57BBDF1E72EE OAKTON B7F75FB9-7480-4C2F-8E91-66D5AF2C0607 MEDSURG 390D8BC7-36E3-4D8D-8CB6-E9360C197DE5 W15 D83C62B5-8D53-4A6B-85AD-E0119DF3E186 THEATRE6 63605AE3-DC21-45BB-A882-F40E22EF811E MEDSHIP 1D2BA923-E0B0-4DE4-BFDB-69247B773273 ED-1 4D0B213F-D42B-4829-9431-1C4D482B1D67 THEATRE 3482ADD7-D610-4FD7-B561-2CC85D4028D4 4K102713S1 214209FD-6AD2-48CE-A15F-8252209D60EF HAMPDENFC_pyx 0B8D0E14-7E8E-4AE7-B492-726887F4411C W5-AUX CF5045AE-86EE-4698-ACEA-3581C9EC7CD1 THEATRE7 92F5A739-E0CA-4C9B-AD3D-27CF3921F944 ACARE 00AAEB97-9E1B-4738-B7EF-93A1EA43A46C LD 4A431A7F-5476-4EA3-899B-71CBDD82799E ADU-DIAG FC072559-E041-41F4-8879-40C03F076484 PXJAXMHC 95A507B9-D859-4622-916B-1C41935BFC55 MEDSHIP 791A5DA7-CC98-4061-8FE5-6065E0CB3A1F PXJAXPROC1 C5EA0AEC-0917-4350-A0C0-5C926F04CF2E MS_SIM 693763A3-0D4A-4CFC-8037-9972131A8924 MS_SKILL 1204B120-1B79-4C7B-824E-ED0A35A07F4D ADU-ASSESS 7FAF82BF-8C1E-4CB3-95A8-9427E78AD973 ECCW-RESUS D50DF9EB-62BB-4FBA-890B-A4245C1C770B EL_D430 88F6239C-2EE3-486A-A29E-CEA9D1F7F6C8 W8 376EFDC5-52C7-4 On 05/08/2025, the firm sent via mail and email an "URGENT MEDICAL DEVICE PRODUCT CORRECTION" Letter informing customers of two issues. For this recall the issue pertains to technicians failing to install (ESET) antivirus software on affected devices. This can potentially result in a malicious actor that could exploit a cybersecurity weakness on a device that is configured without antivirus protection within a hospital network. Customer are instructed and/or informed: For Clinical Users: -to utilize user facility policies and procedures for cybersecurity issues or disaster recovery. -to remove devices

Asset	Device	Serial	Recall	Status	Match	Reason / action
						from network and continue to use operational devices in critical override per the BD Pyxis" MedStation" ES user guide DME 10000430667, version 00 (pages 74-75). For IT,

Asset	Device	Serial	Recall	Status	Match	Reason / action
10005 Med/Surg	BD Alaris LVP BD / ALARIS 8100	23456782	Z-2477-2025 Class II 2025-05-08	Open, Classified	Model match - confirm serial/lot/software version Device	Antivirus software was not consistently installed on impacted devices during the implementation process. BD Pyxis Product Name / UDI-DI code / Catalog No. BD Pyxis" MedStation" 4000 Main / 10885403512629 / 303 BD Pyxis" MedStation" ES Tower / 10885403512674 / 352 BD Pyxis" Anesthesia Station ES / 10885403477836 / 327 BD Pyxis" MedStation" ES (Main) / 10885403512667 / 323 BD Pyxis" CII Safe ES / 10885403512605 / 1116-00 BD Pyxis" Enterprise Server / 10885403518348 and 10885403520341 / 1115-00 BD Pyxis" CIISafe, V9.X, SGL IM, BIO, / 10885403512520 / 111-221 BD Pyxis" CIISafe, V7.X, DBL INTG MAIN, BIO, SOLID DO / N/A / 111-194 BD Pyxis" MedBank Tower / 10885403512568 / 169-29 BD Pyxis" CIISafe, V8.X Desktop PC, Bio / N/A / 107-245-01 Supply Server / N/A / N/A CCE Enterprise SW Site License (2-5) / N/A / N/A BD Pyxis" Logistics / N/A / 806 BD Pyxis" SupplyStation" V9 / N/A / 317 Security Module / N/A / 139698-01 Supply itParActive RF V11 / N/A / 138566-01 BD Knowledge Portal for Medication Technologies / N/A / 136607-01 STOCKSTN V10.X WRD/WL SCANNERS / N/A / 132-53-02 PRS STOCKSTN V10.X WRD/WL SCANNERS / N/A / 132-53-01 STOCKSTN V10.X WIRED SCANNER / N/A / 132-52-02 PRS STOCKSTN V10.X WIRED SCANNER / N/A / 132-52-01 BD Pyxis" CII Safe ES, Desktop PC / N/A / 1156-00 BD Pyxis" SupplyStation" Panel PC V11 / N/A / 1132-00 Pyxis" SupplyRoller V11 / N/A / 1127-00 Dell 640 Server / N/A / 1128-00 BD Pyxis" SupplyStation" System V11 / N/A / 1123-00 BD Pyxis" SupplyRoller V10 / N/A / 1101-00 BD Pyxis" SupplyStation" System V10 / **** / 347 BD Pyxis CII Safe,V9.X DESKTOP PC / **** / 107-252-01 BD Pyxis CII Safe,V7.X,DBL INTG MAIN,BIO,CLEAR DO 111-191 BD Pyxis CII Safe, V9.X, DBL IM, BIO, SLD DOORS / **** / 111-215 BD Care Coordination Engine (CCE) / **** / 134056-01 The Pyxis devices are automated medication dispensing cabinet that is intended to securely store and dispense medications to a qualified and authorized healthcare provider. BD Pyxis Product Name / UDI-DI code / Catalog No. BD Pyxis" MedStation" 4000 Main / 10885403512629 / 303 Atlas Key / Computer Name: DF36449C-9896-4A27-BC18-

Asset	Device	Serial	Recall	Status	Match	Reason / action
						481981535F84 OR2 993BA58F-B5FB-49E8-AE94-BC81E0A93C2A ER-PED FF9AD713-320E-4317-94C0-1A7F57F1AA63 K3 25845A1C-20A3-44BA-8D78-9C9DC001F5B8 PYXH5SASC 2BFA94A6-6192-4ACA-B495-06BA07DC2D73 ESC-WARD1 38404D6B-8356-476A-970F-E4F9CE5731DB WC A9EF86BC-6DF5-4F7F-AE54-6F51773D343E THEATRE12W 1B194D06-1F1A-4930-AA42-57BBDF1E72EE OAKTON B7F75FB9-7480-4C2F-8E91-66D5AF2C0607 MEDSURG 390D8BC7-36E3-4D8D-8CB6-E9360C197DE5 W15 D83C62B5-8D53-4A6B-85AD-E0119DF3E186 THEATRE6 63605AE3-DC21-45BB-A882-F40E22EF811E MEDSHIP 1D2BA923-E0B0-4DE4-BFDB-69247B773273 ED-1 4D0B213F-D42B-4829-9431-1C4D482B1D67 THEATRE 3482ADD7-D610-4FD7-B561-2CC85D4028D4 4K102713S1 214209FD-6AD2-48CE-A15F-8252209D60EF HAMPDENFC_pyx 0B8D0E14-7E8E-4AE7-B492-726887F4411C W5-AUX CF5045AE-86EE-4698-ACEA-3581C9EC7CD1 THEATRE7 92F5A739-E0CA-4C9B-AD3D-27CF3921F944 ACARE 00AAEB97-9E1B-4738-B7EF-93A1EA43A46C LD 4A431A7F-5476-4EA3-899B-71CBDD82799E ADU-DIAG FC072559-E041-41F4-8879-40C03F076484 PXJAXMHC 95A507B9-D859-4622-916B-1C41935BFC55 MEDSHIP 791A5DA7-CC98-4061-8FE5-6065E0CB3A1F PXJAXPROC1 C5EA0AEC-0917-4350-A0C0-5C926F04CF2E MS_SIM 693763A3-0D4A-4CFC-8037-9972131A8924 MS_SKILL 1204B120-1B79-4C7B-824E-ED0A35A07F4D ADU-ASSESS 7FAF82BF-8C1E-4CB3-95A8-9427E78AD973 ECCW-RESUS D50DF9EB-62BB-4FBA-890B-A4245C1C770B EL_D430 88F6239C-2EE3-486A-A29E-CEA9D1F7F6C8 W8 376EFDC5-52C7-4 On 05/08/2025, the firm sent via mail and email an "URGENT MEDICAL DEVICE PRODUCT CORRECTION" Letter informing customers of two issues. For this recall the issue pertains to technicians failing to install (ESET) antivirus software on affected devices. This can potentially result in a malicious actor that could exploit a cybersecurity weakness on a device that is configured without antivirus protection within a hospital network. Customer are instructed and/or informed: For Clinical Users: -to utilize user facility policies and procedures for cybersecurity issues or disaster recovery. -to remove devices

Asset	Device	Serial	Recall	Status	Match	Reason / action
						from network and continue to use operational devices in critical override per the BD Pyxis" MedStation" ES user guide DME 10000430667, version 00 (pages 74-75). For IT,
10008 ED	Baxter Spectrum IQ BAXTER / SPECTRUM IQ	BX770012	Z-2415-2025 Class II 2025-07-14	Open, Classified	Model match - confirm serial/lot/software version Device	Baxter has identified that certain pumps have potentially been released with the grease applied to the cam and motor gears that will break down quickly. The breakdown of the grease will lead to the device having insufficient or ineffective grease applied to the cam, which could lead to premature wear of the mechanism assembly, resulting in excessive therapy. Spectrum IQ Infusion Pump, Product Code 3570009 UDI-DI: 00085412610900; Serial Numbers: 3815255 3815261 3815265 3815266 3815267 3815271 Customers were contacted via telephone beginning 7/14/25. The included information about the product, the issue and the action to be taken by the customers. Baxter Healthcare is requesting the return of the impacted product to perform all tests required and confirm that the product perform as expected. If you have any questions, phone (Toll Free): 800-422-9837 or 847-948-4770; hours of operation: Monday through Friday from 8:00 am to 5:00 pm CST

Asset	Device	Serial	Recall	Status	Match	Reason / action
10012 ED	Physio-Control LIFEPAK 15 STRYKER / LIFEPAK 15	44120033	Z-2497-2025 Class II 2025-07-22	Open, Classified	Model match - confirm serial/lot/software version Units serviced/repaired by mfr only	Due to required inspections not being performed on products/units that have gone through servicing. LIFEPAK 15 Part / Catalog Numbers / UDI-DI code: V15-7-000022 / 99577-001957 / 883873871690 V15-2-000051 / 99577-000046 / 883873988022 V15-2-000099 / 99577-000093 / 883873979020 V15-2-001603 / 99577-001256 / 883873911631 LIFEPAK 15: The LP15 is intended for use by trained medical personnel in out-of-doors and indoor emergency care settings within the environmental conditions specified in the Operating Instructions. The LP15 is designed to be used during ground transportation except when specified otherwise. Manual mode monitoring and therapy functions are intended for use on adult and pediatric patients. Automated external defibrillation mode is intended for use on patients eight years of age and older. Part / Catalog Numbers / UDI-DI code / Serial Number: V15-7-000022 / 99577-001957 / 883873871690 / 49085553 V15-2-000051 / 99577-000046 / 883873988022 / 38154524 V15-2-000099 / 99577-000093 / 883873979020 / 39059475 V15-2-001603 / 99577-001256 / 883873911631 / 40973093 On 07/22/2025, the firm sent via certified mail an "URGENT: Medical device recall" Letter to customers informing them that, Stryker discovered a subset of work orders performed between August 10th 2022 and October 30th 2023 with Performance Inspection Procedures (PIP) recorded as PASS without the corresponding objective evidence properly documented in the work order to ensure the devices are performing as intended. Customers are instructed to: 1. Immediately check their inventory to locate the affected product as listed in the letter. 2. On the business reply form, customer need to indicate if their devices have been serviced since October 30th 2023 (after that time, if affected device have undergone Preventative Maintenance through Stryker, Stryker has verified that the PIPs we

Asset	Device	Serial	Recall	Status	Match	Reason / action
10013 OR	Stryker LP15 STRYKER / LIFEPAK 15	44120034	Z-2497-2025 Class II 2025-07-22	Open, Classified	Model match - confirm serial/lot/software version Units serviced/repaired by mfr only	Due to required inspections not being performed on products/units that have gone through servicing. LIFEPAK 15 Part / Catalog Numbers / UDI-DI code: V15-7-000022 / 99577-001957 / 883873871690 V15-2-000051 / 99577-000046 / 883873988022 V15-2-000099 / 99577-000093 / 883873979020 V15-2-001603 / 99577-001256 / 883873911631 LIFEPAK 15: The LP15 is intended for use by trained medical personnel in out-of-doors and indoor emergency care settings within the environmental conditions specified in the Operating Instructions. The LP15 is designed to be used during ground transportation except when specified otherwise. Manual mode monitoring and therapy functions are intended for use on adult and pediatric patients. Automated external defibrillation mode is intended for use on patients eight years of age and older. Part / Catalog Numbers / UDI-DI code / Serial Number: V15-7-000022 / 99577-001957 / 883873871690 / 49085553 V15-2-000051 / 99577-000046 / 883873988022 / 38154524 V15-2-000099 / 99577-000093 / 883873979020 / 39059475 V15-2-001603 / 99577-001256 / 883873911631 / 40973093 On 07/22/2025, the firm sent via certified mail an "URGENT: Medical device recall" Letter to customers informing them that, Stryker discovered a subset of work orders performed between August 10th 2022 and October 30th 2023 with Performance Inspection Procedures (PIP) recorded as PASS without the corresponding objective evidence properly documented in the work order to ensure the devices are performing as intended. Customers are instructed to: 1. Immediately check their inventory to locate the affected product as listed in the letter. 2. On the business reply form, customer need to indicate if their devices have been serviced since October 30th 2023 (after that time, if affected device have undergone Preventative Maintenance through Stryker, Stryker has verified that the PIPs we

Asset	Device	Serial	Recall	Status	Match	Reason / action
10023 Biomed Shop	Physio Control LIFEPAK 15 STRYKER / LIFEPAK 15	44120033	Z-2497-2025 Class II 2025-07-22	Open, Classified	Model match - confirm serial/lot/software version Units serviced/repaired by mfr only	Due to required inspections not being performed on products/units that have gone through servicing. LIFEPAK 15 Part / Catalog Numbers / UDI-DI code: V15-7-000022 / 99577-001957 / 883873871690 V15-2-000051 / 99577-000046 / 883873988022 V15-2-000099 / 99577-000093 / 883873979020 V15-2-001603 / 99577-001256 / 883873911631 LIFEPAK 15: The LP15 is intended for use by trained medical personnel in out-of-doors and indoor emergency care settings within the environmental conditions specified in the Operating Instructions. The LP15 is designed to be used during ground transportation except when specified otherwise. Manual mode monitoring and therapy functions are intended for use on adult and pediatric patients. Automated external defibrillation mode is intended for use on patients eight years of age and older. Part / Catalog Numbers / UDI-DI code / Serial Number: V15-7-000022 / 99577-001957 / 883873871690 / 49085553 V15-2-000051 / 99577-000046 / 883873988022 / 38154524 V15-2-000099 / 99577-000093 / 883873979020 / 39059475 V15-2-001603 / 99577-001256 / 883873911631 / 40973093 On 07/22/2025, the firm sent via certified mail an "URGENT: Medical device recall" Letter to customers informing them that, Stryker discovered a subset of work orders performed between August 10th 2022 and October 30th 2023 with Performance Inspection Procedures (PIP) recorded as PASS without the corresponding objective evidence properly documented in the work order to ensure the devices are performing as intended. Customers are instructed to: 1. Immediately check their inventory to locate the affected product as listed in the letter. 2. On the business reply form, customer need to indicate if their devices have been serviced since October 30th 2023 (after that time, if affected device have undergone Preventative Maintenance through Stryker, Stryker has verified that the PIPs we

Asset	Device	Serial	Recall	Status	Match	Reason / action
10021 PACU	GE B450 GE HEALTHCARE / CARESCAPE B450	SJL12345678GA	Z-0453-2026 Class II 2025-09-26	Open, Classified	Model match - confirm serial/lot/software version Possibly accessory/consumable	Potential loss of monitoring on affected monitors when powered by certain batteries. Affected batteries can lose capability to hold charge and provide back up power. If this situation occurs, it will cause loss of patient monitoring and potentially delay recognizing patient status changes requiring treatment. Carescape B450, Model no. 5805686 - shipped with potentially affected batteries or affected batteries installed as a spare part Monitor, Physiological, Patient (With Arrhythmia Detection or Alarms Record updated 3/19/26 to include: CARESCAPE B450 MBA313 2095800-001 CARESCAPE MONITOR B450 (ATO MODEL) 2068491-002 CARESCAPE MONITOR B450 B1 2107633-001 CARESCAPE MONITOR B450-GS (V2.0.8) 2094080-001 UDI-DI 00840682146135 Serial numbers SNT25079613SA SNT25079608SA SNT25079622SA SNT25079618SA SNT25079619SA SNT25079614SA SNT25079611SA SNT25079621SA SNT25079620SA SNT25079603SA SNT25079616SA SNT25079612SA SNT25079602SA SNT25079615SA SNT25079663SA SNT25079664SA SNT25079677SA SNT25079662SA SNT25079667SA SNT25079678SA SNT25079680SA SNT25079666SA SNT25079695SA SNT25079694SA SNT25079697SA SNT25079688SA SNT25079687SA SNT25079685SA SNT25079676SA SNT25079674SA SNT25079671SA SNT25079691SA SNT25079689SA SNT25079679SA SNT25079681SA SNT25079684SA SNT25079672SA SNT25079668SA SNT25079665SA SNT25079675SA SNT25079693SA SNT25069004SA SNT25069001SA SNT25069002SA SNT25069003SA SNT25069013SA SNT25069007SA SNT25069015SA SNT25069012SA SNT25069014SA SNT25069016SA SNT25069017SA SNT25069021SA SNT25069019SA SNT25069006SA SNT25069020SA SNT25069005SA SNT25069008SA SNT25069009SA SNT25069018SA SNT25069023SA SNT25259594SA SNT25259577SA SNT25259590SA SNT25069508SA SNT25069564SA SNT25219502SA SNT25219501SA SNT25219504SA SNT25219503SA SNT25079536SA SNT25079537SA SNT25079558SA SNT25079532SA SNT25079569SA SNT25079539SA SNT25079526SA SNT25079571SA SNT25079575SA SNT25079576SA SNT25079572SA SNT25079574SA SNT25079533SA SNT25079524SA SNT25079573SA

Asset	Device	Serial	Recall	Status	Match	Reason / action
						SNT24429994SA SNT25149512SA SNT25149514SA SNT25109580SA SNT25109578SA SNT25109576SA SNT25109579SA SNT25109577SA SNT25109574SA SNT25109575SA SNT25109581SA SNT25109573SA SNT25179587SA SNT25179583SA SNT25179577SA SNT25179573SA SNT25179574SA SNT25019477SA SNT24529475SA SNT245 On September 26, 2025, the recalling firm began notifying affected customers. A second letter was issued on October 3, 2025 which addressed a correction to Affected Product Details information. The customer letter advised users to use a monitor with a battery that is not within the affected battery population. However, pending correction by GE HealthCare, users may continue to use a monitor with affected batteries by following instructions included in the letter. These instructions include having mains power connected whenever possible, confirming appropriate battery status prior to use, and being aware that the monitor may still shut down during patient transport. Users are advised to be prepared to provide alternate methods of assessing the clinical status of the patient, bring a mains

Asset	Device	Serial	Recall	Status	Match	Reason / action
10004 ICU	CAREFUSION 8100 BD / ALARIS 8100	23456781	Z-1217-2026 Class II 2025-11-06	Open, Classified	Model match - confirm serial/lot/software version Device	Due to a number of modules flashed with a date and time associated with the daylight savings time (DST) adjustment that may cause connectivity issue with hospital networks. This issue only affects the Interoperability workflow for devices with a DST invalid timestamp, impacting connectivity of the PCU to the hospital network BD Alaris" Pump Module model 8100 UDI-DI code: 10885403810046 The BD AlarisTM System with Guardrails" Suite MX is a modular infusion pump and monitoring system for the continuous or intermittent administration of fluids to adult, pediatric, and neonatal patients through clinically accepted routes of administration: intravenous (IV), intra-arterial (IA), subcutaneous, epidural, or irrigation of fluid spaces. The BD AlarisTM System includes the PC Unit (PCU) and one or more of the following: Pump Module, Syringe Module, end-tidal CO2 (EtCO2) Module, Auto-ID Module, patient-controlled analgesia (PCA) Module, and associated software applications. Catalog Number: 8100 Material Number: 8100BDBDXEN1212 UDI-DI code: 10885403810046 Equipment/Software Version: 8100BD PUMP MODULE V12.1.2 DOM V12.1.2 Serial Numbers: 17377484 17377907 17377935 17377939 17377942 17377946 17377948 17377952 17377959 17377961 17377965 17377970 17377972 17377973 17377976 17377978 17377980 17377987 17377992 17377993 17378071 17378072 17378073 17378074 17378075 17378079 17378081 17378082 17378084 17378085 17378086 17378087 17378088 17378089 17378090 17378091 17378092 17378093 17378094 17378095 17378096 17378098 17378099 17378101 17378102 17378103 17378124 17378125 17378126 17378127 17378145 17378147 17378149 17378153 17378154 17378156 17378157 17378158 17378163 17378164 17378166 17378167 17378168 17378170 17378172 17378176 17378178 17378179 17378180 17378181 17378182 17378183 17378184 17378185 17378186 17378187 17378188 17378189 17378190 17378193 17378194 17378196 17378198 17378199 17378201 17378203 17378205 17378207 17378209 17378221 17378222 17378223 17378224 17378225 17378226

Asset	Device	Serial	Recall	Status	Match	Reason / action
						17378227 17378236 17378239 17378240 17378241 17378242 17378243 17378244 17378245 17378246 17378247 17378248 17378249 17378267 17378268 17378269 17378270 17378271 17378272 17378279 17378281 17378282 17378286 17378287 17378288 17378289 17378290 17378293 17378296 17378298 17378303 17378305 17378309 17378310 17378312 17378314 17378315 17378316 17378317 17378318 17378319 17378320 17378321 17378333 17378334 17378335 17378336 17378337 17378338 17378339 17378347 17378349 17378363 173 On 11/06/2025, the firm sent via mail and email an "URGENT MEDICAL DEVICE PRODUCT CORRECTION" Letter informing customers that during an electronic medical record interoperability workflow, a BD Alaris" PCU (Point of Care Unit) connected to an affected BD Alaris" Pump Module may disconnect from the hospital network. The connectivity issue relates to an unrecognized date and time (datetime) stored within the affected BD Alaris" Pump Module software. The software that was loaded onto the affected pump modules has a datetime that falls within the Daylight Savings Time (DST) adjustment. The Alaris" System Manager software that mediates connectivity between the PCU module and the hospital network does not recognize this DST datetime as valid, resulting in loss of

Asset	Device	Serial	Recall	Status	Match	Reason / action
10005 Med/Surg	BD Alaris LVP BD / ALARIS 8100	23456782	Z-1217-2026 Class II 2025-11-06	Open, Classified	Model match - confirm serial/lot/software version Device	Due to a number of modules flashed with a date and time associated with the daylight savings time (DST) adjustment that may cause connectivity issue with hospital networks. This issue only affects the Interoperability workflow for devices with a DST invalid timestamp, impacting connectivity of the PCU to the hospital network BD Alaris" Pump Module model 8100 UDI-DI code: 10885403810046 The BD AlarisTM System with Guardrails" Suite MX is a modular infusion pump and monitoring system for the continuous or intermittent administration of fluids to adult, pediatric, and neonatal patients through clinically accepted routes of administration: intravenous (IV), intra-arterial (IA), subcutaneous, epidural, or irrigation of fluid spaces. The BD AlarisTM System includes the PC Unit (PCU) and one or more of the following: Pump Module, Syringe Module, end-tidal CO2 (EtCO2) Module, Auto-ID Module, patient-controlled analgesia (PCA) Module, and associated software applications. Catalog Number: 8100 Material Number: 8100BDBDXEN1212 UDI-DI code: 10885403810046 Equipment/Software Version: 8100BD PUMP MODULE V12.1.2 DOM V12.1.2 Serial Numbers: 17377484 17377907 17377935 17377939 17377942 17377946 17377948 17377952 17377959 17377961 17377965 17377970 17377972 17377973 17377976 17377978 17377980 17377987 17377992 17377993 17378071 17378072 17378073 17378074 17378075 17378079 17378081 17378082 17378084 17378085 17378086 17378087 17378088 17378089 17378090 17378091 17378092 17378093 17378094 17378095 17378096 17378098 17378099 17378101 17378102 17378103 17378124 17378125 17378126 17378127 17378145 17378147 17378149 17378153 17378154 17378156 17378157 17378158 17378163 17378164 17378166 17378167 17378168 17378170 17378172 17378176 17378178 17378179 17378180 17378181 17378182 17378183 17378184 17378185 17378186 17378187 17378188 17378189 17378190 17378193 17378194 17378196 17378198 17378199 17378201 17378203 17378205 17378207 17378209 17378221 17378222 17378223 17378224 17378225 17378226

Asset	Device	Serial	Recall	Status	Match	Reason / action
						17378227 17378236 17378239 17378240 17378241 17378242 17378243 17378244 17378245 17378246 17378247 17378248 17378249 17378267 17378268 17378269 17378270 17378271 17378272 17378279 17378281 17378282 17378286 17378287 17378288 17378289 17378290 17378293 17378296 17378298 17378303 17378305 17378309 17378310 17378312 17378314 17378315 17378316 17378317 17378318 17378319 17378320 17378321 17378333 17378334 17378335 17378336 17378337 17378338 17378339 17378347 17378349 17378363 173 On 11/06/2025, the firm sent via mail and email an "URGENT MEDICAL DEVICE PRODUCT CORRECTION" Letter informing customers that during an electronic medical record interoperability workflow, a BD Alaris" PCU (Point of Care Unit) connected to an affected BD Alaris" Pump Module may disconnect from the hospital network. The connectivity issue relates to an unrecognized date and time (datetime) stored within the affected BD Alaris" Pump Module software. The software that was loaded onto the affected pump modules has a datetime that falls within the Daylight Savings Time (DST) adjustment. The Alaris" System Manager software that mediates connectivity between the PCU module and the hospital network does not recognize this DST datetime as valid, resulting in loss of

Asset	Device	Serial	Recall	Status	Match	Reason / action
10008 ED	Baxter Spectrum IQ BAXTER / SPECTRUM IQ	BX770012	Z-1121-2026 Class II 2025-11-28	Open, Classified	Model match - confirm serial/lot/software version Units serviced/repaired by mfr only	Certain pumps have potentially been released from service with defective grease applied to the cam and motor gears. Due to its low viscosity, the defective grease may lead to the device having insufficient lubrication on the cam, which could lead to premature wear of the mechanism assembly, resulting in over-infusion or a free-flow situation. SIGMA Spectrum Infusion Pump, Model/Catalog Number: 35700BAX2 GTIN 00085412498683; Serial Numbers: 2119054 2135735 2132190 2154666 2154656 2096922 2107882 2115820 2116236 2123750 2124467 2142165 2145693 2146570 2135601 2150159 2019614 2030571 2064474 2065875 2007842 2077077 2110000 2139163 2152387 2090011 2150576 2006741 2090877 2091360 2115605 2136756 2145367 2145911 2144366 2147107 2005818 2036444 2040404 2064488 2054317 2064576 2065380 2064711 2055127 2066486 2065852 2065982 2041955 2081026 2023286 2088106 2089908 2089953 2090012 2096271 2106362 2114760 2114275 2116368 2116054 2117183 2118056 2112866 2136545 2139711 2142076 2161326 2112386 2127356 2161111 2003644 2042815 2089901 2026384 2157334 2004602 2093902 2134816 2155520 2156545 2107252 2136765 2152712 2027178 2135072 2081009 2145203 2156837 2124901 2077354 2077117 2122684 2118643 2106472 2145820 2009374 2115158 2090446 2125551 2150237 2004798 2013799 2023938 2092704 2148207 2096246 2007553 2014364 2089297 2089770 2089790 2119778 2105983 2088857 2140961 2119801 2075390 2013353 2014754 2115703 2105569 2106297 2108307 2107928 2107024 2094331 2010527 2108679 2133529 2133609 2091040 2105718 2138210 2106084 2062517 2022721 2106575 2106357 2106667 2026959 2105921 2098876 2106666 2104788 2106441 2020080 2106646 2106571 2020358 2102437 2106458 2106975 2104537 2026270 2021619 2104636 2105332 2106348 2106213 2019141 2023340 2106243 2100062 2106694 2106468 2106652 2106644 2106687 2104780 2106781 2105011 2105920 2105399 2106661 2106657 2104225 2101214 2020660 2106401 2014906 2104935 2105761 An URGENT MEDICAL DEVICE RECALL notification letter dated 11/28/25 was sent to customers. Actions to be Taken by Customers 1. Immediately locate, isolate, and cease all use of the impacted product (see

Asset	Device	Serial	Recall	Status	Match	Reason / action
						Attachment A for complete list of affected serial numbers). The product code and serial number can be found on the bottom of the infusion pump. 2. If you received this communication directly from Baxter, please acknowledge receipt of this notification by following the instructions on the enclosed reply instruction sheet, even if you have no remaining inventory. Acknowledging receipt will prevent you from receiving repeat notices. If you do not complete the acknowledgement, you will receive a phone call from Accenture LLP on behalf of Baxter to confirm your receipt of this notification. 3. I
10008 ED	Baxter Spectrum IQ BAXTER / SPECTRUM IQ	BX770012	Z-1368-2026 Class II 2026-01-13	Open, Classified	Model match - confirm serial/lot/software version Units serviced/repaired by mfr only	Pumps were released without full testing being performed, including occlusion alarm testing. Brand Name: Spectrum IQ Product Name: Infusion Pump Model/Catalog Number: 3570009 Software Version: N/A Product Description: Infusion Pump, one unit per carton Component: N/A Lot Code: GTIN 00085412610900, Serial Numbers 3815663, 3823468, 3824743, 3825234, and 3825599 Firm notified the single customer on 1/13/26 via phone call. Customer was asked to work with on-site service technician to coordinate return of affected product.

Asset	Device	Serial	Recall	Status	Match	Reason / action
10001 ICU	CareFusion Alaris 8015 BD / ALARIS 8015	12345678	Z-1645-2026 Class II 2026-02-11	Open, Classified	Model match - confirm serial/lot/software version Labeling/IFU	Due to product labeling not indicating which Transport Layer Security (TLS) version that must be enabled on hospital network to ensure secure Wi-Fi communication with Point-of-Care Units BD Alaris" System with Guardrails" Suite MX with Point of Care Unit Catalog Number: 8015 UDI-DI codes: 10885403210747 10885403210754 10885403210891 10885403212048 10885403222108 10885403224614 10885403515231 10885403516023 10885403519215 10885403519284 10885403519291 10885403801518 10885403801532 10885403801549 Serial Numbers: 12360968 12360983 12360985 12360986 12360987 12360988 12360989 12360990 12360991 12360992 12360993 12360994 12360995 12360996 12360997 12360998 12360999 12361000 12361001 12361002 12361003 12361004 12361005 12361006 12361008 12361010 12361013 12361017 12361018 12361019 12361020 12361021 12361022 12361024 12361026 12361027 12361028 12361029 12361030 12361031 12383470 12383471 12383472 12386884 12386885 12388269 12389653 12389660 12389680 12389683 12389691 12389698 12389715 12389727 12389730 12389734 12389738 12389740 12389741 12390061 12390104 12390107 12390118 12390133 12390155 12390184 12390187 12390199 12390219 12390236 12390239 12390257 12390258 12390271 12390274 12390290 12390293 12390300 12390301 12390302 12390558 12390560 12390578 12390597 12390603 12390619 12390620 12390634 12390635 12390654 12390662 12390666 12390670 12390678 12390701 12390721 12390722 12390729 12390731 12390736 12390738 12393833 12393834 12393836 12393843 12393870 12393916 12393922 12393929 12393953 12393954 12394011 12394012 12394013 12394015 12394040 12394066 12394105 12394106 12394126 12394171 12394179 12394209 12394219 12394222 12394283 12394284 12394290 12394293 12394298 12394301 12394596 12394619 12394643 12394646 12394659 12394672 12394 On 02/11/2026, the firm sent via US Postal mail, an "URGENT MEDICAL DEVICE PRODUCT CORRECTION"

Asset	Device	Serial	Recall	Status	Match	Reason / action
						letter to customers informing them that labeling does not indicate which Transport Layer Security (TLS) versions must be enabled on the hospital network to ensure secure Wi-Fi communication with the Alaris and BD Alaris Point-of-Care Unit (PCU) when using enterprise-level Wi-Fi security. Without clear labeling, hospitals may unknowingly disable TLS 1.0, resulting in network connectivity failure and memory leaks which could lead to potential System Error. Customers/clinicians are instructed to: 1. Ensure the PCU is connected to the hospital network by viewing the wireless indicator icon on the front of the PCU. If the icon is illuminated or blinking, the PCU is connected. If it is not i

Asset	Device	Serial	Recall	Status	Match	Reason / action
10002 ICU	BD 8015 BD / ALARIS 8015	12345679	Z-1645-2026 Class II 2026-02-11	Open, Classified	Model match - confirm serial/lot/software version Labeling/IFU	Due to product labeling not indicating which Transport Layer Security (TLS) version that must be enabled on hospital network to ensure secure Wi-Fi communication with Point-of-Care Units BD Alaris" System with Guardrails" Suite MX with Point of Care Unit Catalog Number: 8015 UDI-DI codes: 10885403210747 10885403210754 10885403210891 10885403212048 10885403222108 10885403224614 10885403515231 10885403516023 10885403519215 10885403519284 10885403519291 10885403801518 10885403801532 10885403801549 Serial Numbers: 12360968 12360983 12360985 12360986 12360987 12360988 12360989 12360990 12360991 12360992 12360993 12360994 12360995 12360996 12360997 12360998 12360999 12361000 12361001 12361002 12361003 12361004 12361005 12361006 12361008 12361010 12361013 12361017 12361018 12361019 12361020 12361021 12361022 12361024 12361026 12361027 12361028 12361029 12361030 12361031 12383470 12383471 12383472 12386884 12386885 12388269 12389653 12389660 12389680 12389683 12389691 12389698 12389715 12389727 12389730 12389734 12389738 12389740 12389741 12390061 12390104 12390107 12390118 12390133 12390155 12390184 12390187 12390199 12390219 12390236 12390239 12390257 12390258 12390271 12390274 12390290 12390293 12390300 12390301 12390302 12390558 12390560 12390578 12390597 12390603 12390619 12390620 12390634 12390635 12390654 12390662 12390666 12390670 12390678 12390701 12390721 12390722 12390729 12390731 12390736 12390738 12393833 12393834 12393836 12393843 12393870 12393916 12393922 12393929 12393953 12393954 12394011 12394012 12394013 12394015 12394040 12394066 12394105 12394106 12394126 12394171 12394179 12394209 12394219 12394222 12394283 12394284 12394290 12394293 12394298 12394301 12394596 12394619 12394643 12394646 12394659 12394672 12394 On 02/11/2026, the firm sent via US Postal mail, an "URGENT MEDICAL DEVICE PRODUCT CORRECTION"

Asset	Device	Serial	Recall	Status	Match	Reason / action
						letter to customers informing them that labeling does not indicate which Transport Layer Security (TLS) versions must be enabled on the hospital network to ensure secure Wi-Fi communication with the Alaris and BD Alaris Point-of-Care Unit (PCU) when using enterprise-level Wi-Fi security. Without clear labeling, hospitals may unknowingly disable TLS 1.0, resulting in network connectivity failure and memory leaks which could lead to potential System Error. Customers/clinicians are instructed to: 1. Ensure the PCU is connected to the hospital network by viewing the wireless indicator icon on the front of the PCU. If the icon is illuminated or blinking, the PCU is connected. If it is not i

Asset	Device	Serial	Recall	Status	Match	Reason / action
10003 Med/Surg	Becton Dickinson ALARIS PC UNIT BD / ALARIS 8015	12345680	Z-1645-2026 Class II 2026-02-11	Open, Classified	Model match - confirm serial/lot/software version Labeling/IFU	Due to product labeling not indicating which Transport Layer Security (TLS) version that must be enabled on hospital network to ensure secure Wi-Fi communication with Point-of-Care Units BD Alaris" System with Guardrails" Suite MX with Point of Care Unit Catalog Number: 8015 UDI-DI codes: 10885403210747 10885403210754 10885403210891 10885403212048 10885403222108 10885403224614 10885403515231 10885403516023 10885403519215 10885403519284 10885403519291 10885403801518 10885403801532 10885403801549 Serial Numbers: 12360968 12360983 12360985 12360986 12360987 12360988 12360989 12360990 12360991 12360992 12360993 12360994 12360995 12360996 12360997 12360998 12360999 12361000 12361001 12361002 12361003 12361004 12361005 12361006 12361008 12361010 12361013 12361017 12361018 12361019 12361020 12361021 12361022 12361024 12361026 12361027 12361028 12361029 12361030 12361031 12383470 12383471 12383472 12386884 12386885 12388269 12389653 12389660 12389680 12389683 12389691 12389698 12389715 12389727 12389730 12389734 12389738 12389740 12389741 12390061 12390104 12390107 12390118 12390133 12390155 12390184 12390187 12390199 12390219 12390236 12390239 12390257 12390258 12390271 12390274 12390290 12390293 12390300 12390301 12390302 12390558 12390560 12390578 12390597 12390603 12390619 12390620 12390634 12390635 12390654 12390662 12390666 12390670 12390678 12390701 12390721 12390722 12390729 12390731 12390736 12390738 12393833 12393834 12393836 12393843 12393870 12393916 12393922 12393929 12393953 12393954 12394011 12394012 12394013 12394015 12394040 12394066 12394105 12394106 12394126 12394171 12394179 12394209 12394219 12394222 12394283 12394284 12394290 12394293 12394298 12394301 12394596 12394619 12394643 12394646 12394659 12394672 12394 On 02/11/2026, the firm sent via US Postal mail, an "URGENT MEDICAL DEVICE PRODUCT CORRECTION"

Asset	Device	Serial	Recall	Status	Match	Reason / action
						letter to customers informing them that labeling does not indicate which Transport Layer Security (TLS) versions must be enabled on the hospital network to ensure secure Wi-Fi communication with the Alaris and BD Alaris Point-of-Care Unit (PCU) when using enterprise-level Wi-Fi security. Without clear labeling, hospitals may unknowingly disable TLS 1.0, resulting in network connectivity failure and memory leaks which could lead to potential System Error. Customers/clinicians are instructed to: 1. Ensure the PCU is connected to the hospital network by viewing the wireless indicator icon on the front of the PCU. If the icon is illuminated or blinking, the PCU is connected. If it is not i

Asset	Device	Serial	Recall	Status	Match	Reason / action
10024 Storage	CareFusion Alaris PC BD / ALARIS 8015	12345678	Z-1645-2026 Class II 2026-02-11	Open, Classified	Model match - confirm serial/lot/software version Labeling/IFU	Due to product labeling not indicating which Transport Layer Security (TLS) version that must be enabled on hospital network to ensure secure Wi-Fi communication with Point-of-Care Units BD Alaris" System with Guardrails" Suite MX with Point of Care Unit Catalog Number: 8015 UDI-DI codes: 10885403210747 10885403210754 10885403210891 10885403212048 10885403222108 10885403224614 10885403515231 10885403516023 10885403519215 10885403519284 10885403519291 10885403801518 10885403801532 10885403801549 Serial Numbers: 12360968 12360983 12360985 12360986 12360987 12360988 12360989 12360990 12360991 12360992 12360993 12360994 12360995 12360996 12360997 12360998 12360999 12361000 12361001 12361002 12361003 12361004 12361005 12361006 12361008 12361010 12361013 12361017 12361018 12361019 12361020 12361021 12361022 12361024 12361026 12361027 12361028 12361029 12361030 12361031 12383470 12383471 12383472 12386884 12386885 12388269 12389653 12389660 12389680 12389683 12389691 12389698 12389715 12389727 12389730 12389734 12389738 12389740 12389741 12390061 12390104 12390107 12390118 12390133 12390155 12390184 12390187 12390199 12390219 12390236 12390239 12390257 12390258 12390271 12390274 12390290 12390293 12390300 12390301 12390302 12390558 12390560 12390578 12390597 12390603 12390619 12390620 12390634 12390635 12390654 12390662 12390666 12390670 12390678 12390701 12390721 12390722 12390729 12390731 12390736 12390738 12393833 12393834 12393836 12393843 12393870 12393916 12393922 12393929 12393953 12393954 12394011 12394012 12394013 12394015 12394040 12394066 12394105 12394106 12394126 12394171 12394179 12394209 12394219 12394222 12394283 12394284 12394290 12394293 12394298 12394301 12394596 12394619 12394643 12394646 12394659 12394672 12394 On 02/11/2026, the firm sent via US Postal mail, an "URGENT MEDICAL DEVICE PRODUCT CORRECTION"

Asset	Device	Serial	Recall	Status	Match	Reason / action
						letter to customers informing them that labeling does not indicate which Transport Layer Security (TLS) versions must be enabled on the hospital network to ensure secure Wi-Fi communication with the Alaris and BD Alaris Point-of-Care Unit (PCU) when using enterprise-level Wi-Fi security. Without clear labeling, hospitals may unknowingly disable TLS 1.0, resulting in network connectivity failure and memory leaks which could lead to potential System Error. Customers/clinicians are instructed to: 1. Ensure the PCU is connected to the hospital network by viewing the wireless indicator icon on the front of the PCU. If the icon is illuminated or blinking, the PCU is connected. If it is not i

Asset	Device	Serial	Recall	Status	Match	Reason / action
10012 ED	Physio-Control LIFEPAK 15 STRYKER / LIFEPAK 15	44120033	Z-2065-2026 Class II 2026-04-13	Open, Classified	Model match - confirm serial/lot/software version Units serviced/repaired by mfr only	Some defibrillators serviced between July 2023 through November 2025 were serviced without objective evidence that a Performance Inspection Procedure (PIP) was conducted, and the inability to perform the device's intended use may result in potential harms such as delays or inability to provide therapy. LIFEPAK 15, REF: 99577-000025, 99577-000047, 99577-001256, 99577-001217, 99577-001241, 99577-001255, 99577-001219, 99577-001957, 99577-001935, 99577-001964, 99577-001955, 99577-001956, 99577-001588, 99577-001958, 99577-001950, 99577-001962, 99577-002178, 99577-001372, 99577-001938, 99577-000045; LIFEPAK 1000, REF: 99425-000025, 99425-000023, 99425-000096; LIFEPAK 35, REF: 99335-000013, 99335-000031; LIFEPAK 20e, REF: 99507-000122 Device/UDI/Serial Number: LIFEPAK 15/00883873911648150115431665 73, 00883873871690150331433948 91, 00883873871690150507435243 60, 00883873871690150928439145 74, 00883873872048150930439151 22, 00883873871690160104441874 47, 00883873871621160120442526 11, 00883873871690160126442627 21, 00883873871690160126442770 82, 00883873871690160127442822 80, 00883873871731160602445743 40, 00883873871731160804448963 29, 00883873871690160831449628 04, 00883873871706170131454472 29, 00883873871690170412457437 86, 00883873871731173050945834 209, 00883873871731170628459981 42, 00883873871731170828461030 43, 00883873871690171010463032 88, 00883873871731171031463030 92, 00883873871621171221465871 30, 00883873871731171226466020 03, 00883873871731171228466087 83, 00883873871731171229466147 88, 00883873871731180222468135 07, 00883873871690180329469662 67, 00883873871731180619473373 96, 00883873871690180705474019 28, 00883873871731180927476114 41, 00883873871690181129477849 31, 00883873871690181129477863 17, 00883873871731181218478476 61, 00883873871731181218478489 50, 00883873877081181219478453 17, 00883873877081181219478553 71, 00883873871690181220478571 72, 00883873871690181220478586 60, 00883873871731181228478728 68, 00883873871731193031248018 370, 00883873871690190612482475 59, 00883873871683190627482987 04,

Asset	Device	Serial	Recall	Status	Match	Reason / action
						00883873871690191008484530 60, 00883873871713191014484558 90, 00883873871713191218485863 51, 00883873871713191219485865 99, 00883873871683200128486515 07, 00883873871713200305487016 89, 00883873877081200428487849 75, 00883873871713200716488 On 04/13/2026, recall notices were sent to customers who were asked to do the following: 1) Return the business reply form by email to RSRecall@Stryker.com to confirm receipt of this notification. 2) Upon receipt of the completed business reply form, firm will contact you to arrange for corrective action on the device if service has not been performed. 3) Continue to follow the Operating Instructions and perform the daily checks and user tests. These tests can be found in the chapter "Maintaining the Equipment" subsection "General Maintenance and Testing". 4) Maintain awareness of this communication internally until all required actions have been completed within your facility. Please ensure this letter is kept with the affected device until the correction has been comp

Asset	Device	Serial	Recall	Status	Match	Reason / action
10013 OR	Stryker LP15 STRYKER / LIFEPAK 15	44120034	Z-2065-2026 Class II 2026-04-13	Open, Classified	Model match - confirm serial/lot/software version Units serviced/repaired by mfr only	Some defibrillators serviced between July 2023 through November 2025 were serviced without objective evidence that a Performance Inspection Procedure (PIP) was conducted, and the inability to perform the device's intended use may result in potential harms such as delays or inability to provide therapy. LIFEPAK 15, REF: 99577-000025, 99577-000047, 99577-001256, 99577-001217, 99577-001241, 99577-001255, 99577-001219, 99577-001957, 99577-001935, 99577-001964, 99577-001955, 99577-001956, 99577-001588, 99577-001958, 99577-001950, 99577-001962, 99577-002178, 99577-001372, 99577-001938, 99577-000045; LIFEPAK 1000, REF: 99425-000025, 99425-000023, 99425-000096; LIFEPAK 35, REF: 99335-000013, 99335-000031; LIFEPAK 20e, REF: 99507-000122 Device/UDI/Serial Number: LIFEPAK 15/00883873911648150115431665 73, 00883873871690150331433948 91, 00883873871690150507435243 60, 00883873871690150928439145 74, 00883873872048150930439151 22, 00883873871690160104441874 47, 00883873871621160120442526 11, 00883873871690160126442627 21, 00883873871690160126442770 82, 00883873871690160127442822 80, 00883873871731160602445743 40, 00883873871731160804448963 29, 00883873871690160831449628 04, 00883873871706170131454472 29, 00883873871690170412457437 86, 00883873871731173050945834 209, 00883873871731170628459981 42, 00883873871731170828461030 43, 00883873871690171010463032 88, 00883873871731171031463030 92, 00883873871621171221465871 30, 00883873871731171227466020 03, 00883873871731171228466087 83, 00883873871731171229466147 88, 00883873871731180222468135 07, 00883873871690180329469662 67, 00883873871731180619473373 96, 00883873871690180705474019 28, 00883873871731180927476114 41, 00883873871690181129477849 31, 00883873871690181129477863 17, 00883873871731181218478476 61, 00883873871731181218478489 50, 00883873877081181219478453 17, 00883873877081181219478553 71, 00883873871690181220478571 72, 00883873871690181220478586 60, 00883873871731181228478728 68, 00883873871731193031248018 370, 00883873871690190612482475 59, 00883873871683190627482987 04,

Asset	Device	Serial	Recall	Status	Match	Reason / action
						00883873871690191008484530 60, 00883873871713191014484558 90, 00883873871713191218485863 51, 00883873871713191219485865 99, 00883873871683200128486515 07, 00883873871713200305487016 89, 00883873877081200428487849 75, 00883873871713200716488 On 04/13/2026, recall notices were sent to customers who were asked to do the following: 1) Return the business reply form by email to RSRecall@Stryker.com to confirm receipt of this notification. 2) Upon receipt of the completed business reply form, firm will contact you to arrange for corrective action on the device if service has not been performed. 3) Continue to follow the Operating Instructions and perform the daily checks and user tests. These tests can be found in the chapter "Maintaining the Equipment" subsection "General Maintenance and Testing". 4) Maintain awareness of this communication internally until all required actions have been completed within your facility. Please ensure this letter is kept with the affected device until the correction has been comp

Asset	Device	Serial	Recall	Status	Match	Reason / action
10023 Biomed Shop	Physio Control LIFEPAK 15 STRYKER / LIFEPAK 15	44120033	Z-2065-2026 Class II 2026-04-13	Open, Classified	Model match - confirm serial/lot/software version Units serviced/repaired by mfr only	Some defibrillators serviced between July 2023 through November 2025 were serviced without objective evidence that a Performance Inspection Procedure (PIP) was conducted, and the inability to perform the device's intended use may result in potential harms such as delays or inability to provide therapy. LIFEPAK 15, REF: 99577-000025, 99577-000047, 99577-001256, 99577-001217, 99577-001241, 99577-001255, 99577-001219, 99577-001957, 99577-001935, 99577-001964, 99577-001955, 99577-001956, 99577-001588, 99577-001958, 99577-001950, 99577-001962, 99577-002178, 99577-001372, 99577-001938, 99577-000045; LIFEPAK 1000, REF: 99425-000025, 99425-000023, 99425-000096; LIFEPAK 35, REF: 99335-000013, 99335-000031; LIFEPAK 20e, REF: 99507-000122 Device/UDI/Serial Number: LIFEPAK 15/00883873911648150115431665 73, 00883873871690150331433948 91, 00883873871690150507435243 60, 00883873871690150928439145 74, 00883873872048150930439151 22, 00883873871690160104441874 47, 00883873871621160120442526 11, 00883873871690160126442627 21, 00883873871690160126442770 82, 00883873871690160127442822 80, 00883873871731606024457434 0, 00883873871731608044489632 9, 00883873871690160831449628 04, 00883873871706170131454472 29, 00883873871690170412457437 86, 00883873871731173050945834 209, 00883873871731170628459981 42, 00883873871731170828461030 43, 00883873871690171010463032 88, 00883873871731171031463030 92, 00883873871621171221465871 30, 00883873871731171226466020 03, 00883873871731171228466087 83, 00883873871731171229466147 88, 00883873871731180222468135 07, 00883873871690180329469662 67, 00883873871731180619473373 96, 00883873871690180705474019 28, 00883873871731180927476114 41, 00883873871690181129477849 31, 00883873871690181129477863 17, 00883873871731181218478476 61, 00883873871731181218478489 50, 00883873877081181219478453 17, 00883873877081181219478553 71, 00883873871690181220478571 72, 00883873871690181220478586 60, 00883873871731181228478728 68, 00883873871731191031248018 370, 00883873871690190612482475 59, 00883873871683190627482987 04,

Asset	Device	Serial	Recall	Status	Match	Reason / action
						00883873871690191008484530 60, 00883873871713191014484558 90, 00883873871713191218485863 51, 00883873871713191219485865 99, 00883873871683200128486515 07, 00883873871713200305487016 89, 00883873877081200428487849 75, 00883873871713200716488 On 04/13/2026, recall notices were sent to customers who were asked to do the following: 1) Return the business reply form by email to RSRecall@Stryker.com to confirm receipt of this notification. 2) Upon receipt of the completed business reply form, firm will contact you to arrange for corrective action on the device if service has not been performed. 3) Continue to follow the Operating Instructions and perform the daily checks and user tests. These tests can be found in the chapter "Maintaining the Equipment" subsection "General Maintenance and Testing". 4) Maintain awareness of this communication internally until all required actions have been completed within your facility. Please ensure this letter is kept with the affected device until the correction has been comp

Asset	Device	Serial	Recall	Status	Match	Reason / action
10025 ED	Mindray ePM 12M MINDRAY / EPM 12M	EP-12345	Z-0109-2027 Class III 2026-08-31	Open, Classified	Model match - confirm serial/lot/software version Labeling/IFU	Certain monitor operator's manuals contain descriptions that may be insufficient or may require clarification regarding selected physiological alarm functions ePM Series Patient Monitor. Patient Monitor Series: ePM 10M/ePM 12M/ePM 12MA/ ePM 15M/ePM 10A Part numbers of ePM Series Patient Monitors Operator's Manuals: 1. Guardian Plus Operator's Manual (OEM, MDPro) up to and including revision 4.0; Part No. 046-026408-00 2. ePM 10A Operator's Manual up to and including revision 12.0; Part No. 046-019796-00 3. ePM 12MA Operator's Manual up to and including revision 13.0; Part No. 046-019797-00 4. ePM 10M, ePM 12M Operator's Manual up to and including revision 13.0; Part No. 046-019798-00 5. ePM 15M Operator's Manual up to and including revision 3.0; Part No. 046-028915-00 Mindray notified consignees on about 08/31/2026 via "URGENT: Medical Device Recall" letter. Consignees were informed that Mindray was providing updated instructions regarding physiological alarms in certain Mindray patient monitoring device Instructions for Use (IFU)/Operator s Manuals. This action is limited to updates to the IFU/Operators Manual content and does not require removal, return, repair, or replacement of the monitors. Consignees were instructed to continue using the Mindray monitors associated with the affected operator s manual, ensure that applicable clinical staff are made aware of the content of this letter and the Operator s Manual Addendum, and if monitors have been distributed or transferred to another organization, please forward this notice to that organ

Likely duplicate records (same manufacturer + serial)

Group	Manufacturer	Serial	Records
D1	BD	12345678	10001: CareFusion | Alaris 8015 | ICU 10024: CareFusion | Alaris PC | Storage
D2	STRYKER	44120033	10012: Physio-Control | LIFEPAK 15 | ED 10023: Physio Control | LIFEPAK 15 | Biomed Shop

Inconsistent naming (same device, different spellings)

Normalized as	Assets	Spellings found
BD / ALARIS 8015	4	BD | 8015 Becton Dickinson | ALARIS PC UNIT CareFusion | Alaris 8015 CareFusion | Alaris PC
BD / ALARIS 8100	2	BD | Alaris LVP CAREFUSION | 8100
ICU MEDICAL / PLUM 360	2	Hospira | PLUM360 ICU Medical | Plum 360
PHILIPS / INTELLIVUE MX450	2	PHILIPS | MX450 Philips Medical Systems | IntelliVue MX450
STRYKER / LIFEPAK 15	3	Physio Control | LIFEPAK 15 Physio-Control | LIFEPAK 15 Stryker | LP15

Incomplete records

Asset	Manufacturer	Model	Serial
10026	Ohio Medical		

Manufacturer names not in the alias dictionary (matched on raw text): Ohio Medical

> **How to read this.** Matches come from FDA's public recall database (openFDA), which can lag the manufacturer's own notice by weeks. 'Serial listed' means the asset's serial number appears in the recall's code information. 'Model match' means the model is named but serial/lot/software-version applicability must be confirmed against the manufacturer's field safety notice. This report is a review aid, not a determination that a device is or is not affected.
