



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Skytron Recalls Salus Surgical Table For Lack Of Control Through Bluetooth Mode

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|-------------|--|--|--|
| 9/6/2023 | GS70 Salus Surgical Table Product Code 18-070-70 | SKYTRON, LLC Grand Rapids, Michigan | When the control of the operating table was used in Bluetooth mode, the operating table continued moving even after releasing the button on the control. Originally, the root cause was thought to be confined to Bluetooth/wireless communications between the control pendant and the surgical table. However, during investigation, Mizuho discovered that the failure could be replicated even in wired mode if communication between the pendant and table were somehow interrupted. The root cause appears to be: if communication between the controller and table is interrupted while a button is pressed, the table does not know if/when a button is released. This occurs in wireless or wired mode. |

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|----------|---|--|--|
| 9/6/2023 | GS70H Salus Surgical Table Product Code 18-071-70 | SKYTRON, LLC Grand Rapids, Michigan | When the control of the operating table was used in Bluetooth mode, the operating table continued moving even after releasing the button on the control. Originally, the root cause was thought to be confined to Bluetooth/wireless communications between the control pendant and the surgical table. However, during investigation, Mizuho discovered that the failure could be replicated even in wired mode if communication between the pendant and table were somehow interrupted. The root cause appears to be: if communication between the controller and table is interrupted while a button is pressed, the table does not know if/when a button is released. This occurs in wireless or wired mode. |
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| Recall Class | Product Identification | Distribution | Affected Dates |
|--------------|--|--|-----------------------|
| II | GS70 Salus Surgical Table Serial Numbers: SUC-20207-0006 SUC-20208-0025 SUC-20209-0044 SUC-20212-0063 SUC-20228-0082 ... | 110 Units Nationwide including California | August 2023 and prior |
| II | GS70H Salus Surgical Table Serial Numbers: SUC-20207-0002 SUC-20208-0006 SUC-20209-0010 SUC-2020X-0014 SUC-2022Z-0018 SUC-20233-0022 SUC-20207-0003 SUC-20208-0007 SUC-20209-0011 SUC-2020X-0015 SUC-2022Z-0019 SUC-20233-0023 SUC-20208-0004 SUC-20209-0008 SUC-2020X-0012 SUC-2020X-0016 SUC-2022Z-0020 SUC-20233-0024 SUC-20208-0005 SUC-20209-0009 SUC-2020X-0013 SUC-2022Z-0017 SUC-2022Z-0021 SUC-20233-0025 | 24 Units Nationwide including California | August 2023 and prior |

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](https://www.fda.gov)

CDPH Food and Drug Branch
 MS 7602 • P.O. Box 997435 • Sacramento, CA 95899-7435
 (916) 650-6500 • (916) 650-6650 FAX
 Internet Address: www.cdph.ca.gov

