

**URGENT MEDICAL DEVICE FIELD CORRECTION**

September 7, 2021

**ATTN: MATERIALS MANAGEMENT OR QUALITY DEPARTMENT**

**RE: CMAX 3, CMAX 3-DRIVE, CMAX 3E, and CMAX 3E-DRIVE Surgical Tables**

Dear Valued STERIS Customer:

STERIS is voluntarily implementing a field correction for all CMAX 3, CMAX 3-DRIVE, CMAX 3E, and CMAX 3E-DRIVE Surgical Tables manufactured between November 24, 2020 – July 5, 2021. Our records indicate that your facility purchased one or more of the Surgical Tables included in this field correction. The complete list of affected serial numbers is included as attachment to this letter.

**Description of the product** – The CMAX 3, CMAX 3-DRIVE, CMAX 3E, and CMAX 3E-DRIVE Surgical Tables are intended to support and position patients during surgical procedures carried out in an operating room, and during transfer to and from the patient’s bed. CMAX surgical tables shall be operated in a controlled environment by a healthcare professional familiar with appropriate techniques with such equipment.

**Description of the problem** – STERIS has identified that the circuit board within the auxiliary (override) control may have been incorrectly manufactured, and over time, may cause the circuit board to short, potentially resulting in undesired table movement or the table becoming unresponsive to user;

**STERIS Action** – A STERIS Service Technician will arrange an onsite inspection of your table(s) for replacement of the auxiliary control.

**User Action** – While the risk of malfunction is low, the table should be both visually inspected and functionally tested prior to each use. Should an issue with table functionality be observed, the table should be removed from service until proper repairs can be conducted.

We apologize for any inconvenience this matter may cause, and as always, STERIS is dedicated to supporting our products and valued Customers. If you have questions regarding this matter, please contact STERIS Customer Service at +33 (0) 5 56 93 94 94 or your local STERIS Representative.

Sincerely,

Veronique Mordelles

Senior Quality Manager

STERIS

List of Affected CMAX 3 and CMAX 3-DRIVE CMAX 3E, and

CMAX 3E-DRIVE Surgical Tables by Serial Number

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| --- | --- | --- | --- |
| 178736 | 182280 | 183828 | 185296 |
| 178829 | 182281 | 183829 | 185572 |
| 179111 | 182354 | 183830 | 185573 |
| 179684 | 183016 | 184389 | 185574 |
| 179685 | 183018 | 184411 | 185576 |
| 179686 | 183019 | 184412 | 185645 |
| 179687 | 183020 | 184413 | 185646 |
| 179688 | 183021 | 184414 | 185647 |
| 179689 | 183022 | 184415 | 185805 |
| 179691 | 183023 | 184416 | 186350 |
| 181458 | 183183 | 184744 | 186351 |
| 182186 | 183184 | 185276 | 186353 |
| 182276 | 183185 | 185293 | 186649 |
| 182277 | 183818 | 185294 | 186650 |
| 182278 | 183827 | 185295 | 188456 |
| 182279 |  |  |  |