

URGENT DEVICE FIELD CORRECTION

June 12, 2020

ATTN: MATERIALS MANAGEMENT OR STERILE PROCESSING DEPARTMENT

RE: CMAX 3 and CMAX 3-DRIVE Surgical Tables

Dear Valued STERIS Customer:

STERIS is voluntarily implementing a field correction for all CMAX 3 and CMAX 3-DRIVE Surgical Tables manufactured between October 23, 2017 - July 19, 2019. Our records indicate that your facility purchased one or more of the CMAX 3 and CMAX 3-DRIVE 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 and CMAX 3-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 not prevent damage caused by fluid intrusion. The auxiliary control has an incomplete seal around the cursor side of the control which may allow fluid to enter, and over time, cause the circuit board to short, potentially resulting in undesired table movement or the table becoming unresponsive to user inputs.

STERIS Action – A STERIS Service Technician will arrange an onsite inspection of the tables for replacement of the auxiliary control.

User Action – The table should be both visually inspected and functionally tested prior to each use. Additionally, users should follow proper cleaning practices as outlined in the operator manual which will ensure excess fluid does not remain on the auxiliary control.

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

Attachment A

Affected CMAX 3 and CMAX 3-DRIVE Surgical Table Serial Numbers

70552	102250	109136	123195	131400
70553	102251	109137	123196	131401
70554	102252	109138	123197	131402
70555	102253	109139	123198	131406
70556	102254	109140	123199	131407
70557	102255	109607	123200	131408
77484	102256	109608	123599	131409
77485	106692	109609	123600	131410
77486	106693	109610	123601	131411
77487	106694	109611	123602	131412
77491	106695	111163	123603	131413
77492	106696	111164	123604	131414
77493	106697	111165	123605	131415
94650	106698	111166	123606	131416
94651	106707	117283	123607	131417
94652	107004	117284	123608	131418
95584	107005	117849	123609	131419
98573	107006	120816	123610	131420
98574	107007	120817	123611	132067
98575	107008	120818	123612	132068
98576	107009	120819	125491	132069
98577	107010	120820	125493	132070
98578	108223	120821	127298	133548
98579	108224	120822	127299	133549
98580	108225	120823	127300	133550
98581	108226	120824	127301	133551
98582	108227	120825	127302	134276
98582	108228	120826	127303	134277
98583	108229	120827	127304	134278
98585	108230	120828	129386	134279
98586	108231	120829	129387	134280
101673	108232	120830	129388	134281
101674	109126	120831	129389	134282
101675	109127	120832	129390	134283
102218	109128	122243	129391	134284
102219	109129	122244	129392	134285
102220	109130	122245	129393	134286
102221	109131	122246	129394	134287
102222	109132	122247	129395	134288
102247	109133	122248	129396	134289
102248	109134	123192	129397	134290
102249	109135	123193	129398	134291
		123194	131399	134292