

URGENT: MEDICAL DEVICE CORRECTIVE ACTION

EasySuite 4K Integrated Operating Room System

Product Name: EasySuite 4K (ES4K)**Serial Number:** See Attachment

Date: May 24, 2024

Attention: Operating Room Director, Biomedical Department

Dear Healthcare Professional:

Olympus is writing to inform you of a Field Corrective Action pertaining to the EasySuite 4K (ES4K). The ES4K is an integrated operating room system intended for routing surgical images to video displays within an operating room and control of room video cameras, surgical cameras, ambient lighting, and surgical lights. An ES4K integrated operating room offers options such as an audio control system, hands-free telephony system, and a single point of entry for querying surgical charts and image archives.

Reason for Action:

Olympus is conducting this field corrective action after determining that a subset of the ES4K systems do not have complete records for earth leakage testing. The earth leakage test is a series of measurements intended to confirm that the amount of electrical current flowing to the earth is within standard limits. Earth leakage testing is performed during device manufacturing and installation, however, to address the absence of adequate records, an Olympus representative will perform this on-site test for the ES4K system(s) at your facility.

Olympus's investigation has identified a total of eighty-six (86) complaints potentially attributable to earth leakage. No serious injuries or reportable malfunctions have been reported in relation to this issue.

Risk to Health:

The user may experience one or more imaging displays suddenly becoming inoperative, the surgical light control on the touch panel user interface may become unusable, or the user may experience a "touch current" sensation (i.e., vibration, slight tingle) when touching a component of the ES4K system as a result of an "earth leakage" issue. These events could lead to a minimal delay in initiating or completing a procedure. As the physician is using a direct source-to-display connection, this issue would not impede their ability to perform a procedure.

Actions Required:

Our records indicate that your facility has purchased one or more of the affected products. A list of affected serial numbers is attached to this letter. The serial number is on a label affixed to the side of the main equipment rack for the system.

An Olympus representative will reach out to you to schedule an on-site service to perform the earth leakage testing on your facility's ES4K system. You may continue to use your ES4K system until an Olympus representative performs the earth leakage test. Additionally, Olympus requires you to take the following actions:

1. Carefully read the content of this notification.
2. If you have further distributed this product, identify your customers, and forward them this notification.
3. Acknowledge receipt of this letter through our Olympus recall portal:
 - a. Go to <https://olympusamerica.com/recall>.
 - b. Enter the recall number "**0446**".
 - c. Complete the form as instructed and include your account ID number.
4. An Olympus representative will contact you to complete the earth leakage test which will serve as the completion of this field corrective action for your facility.

Olympus requests that you report any complaints, including surgical displays becoming inoperable/unusable or "touch current" sensation (i.e., vibration, slight tingle), to the Technical Assistance Center (TAC) at 1- 800-848-9024, option 1, and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me directly by phone at (647) 999-3203 or by e-mail at Cynthia.Ow@olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
FCA Regional Lead, Americas

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Attachment – Affected Serial Numbers

BZ-0000001	BZ-0000059	BZ-0000104	BZ-200011	BZ-300019	EU 4K 1220 TRAINING RACK	FLX-200122
BZ-0000004	BZ-0000060	BZ-0000105	BZ-200012	BZ-300020	FLX-200001	FLX-200123
BZ-0000005	BZ-0000061	BZ-0000106	BZ-200013	BZ-300025	FLX-200003	FLX-200124
BZ-0000007	BZ-0000062	BZ-0000108	BZ-200017	BZ-400001	FLX-200004	FLX-200125
BZ-0000008	BZ-0000063	BZ-0000111	BZ-200018	BZ-400002	FLX-200008	FLX-200126
BZ-0000009	BZ-0000064	BZ-0000112	BZ-200027	BZ-600004	FLX-200013	FLX-200127
BZ-0000010	BZ-0000065	BZ-0000113	BZ-200028	BZ-600050	FLX-200014	FLX-200128
BZ-0000015	BZ-0000066	BZ-0000114	BZ-200029	BZ-600052	FLX-200015	FLX-200129
BZ-0000016	BZ-0000067	BZ-0000116	BZ-200030	BZ-600053	FLX-200016	FLX-200137
BZ-0000017	BZ-0000068	BZ-0000117	BZ-200031	BZ-600055	FLX-200020	FLX-200138
BZ-0000019	BZ-0000069	BZ-0000118	BZ-200032	BZ-600056	FLX-200021	FLX-200139
BZ-0000022	BZ-0000070	BZ-0000120	BZ-200033	BZ-600057	FLX-200022	FLX-200140
BZ-0000030	BZ-0000071	BZ-0000129	BZ-200034	BZ-600060	FLX-200023	FLX-200142
BZ-0000031	BZ-0000072	BZ-0000140	BZ-200037	BZ-600064	FLX-200025	FLX-200155
BZ-0000034	BZ-0000074	BZ-0000141	BZ-200038	BZ-600065	FLX-200026	FLX-200156
BZ-0000035	BZ-0000075	BZ-0000142	BZ-200042	BZ-600066	FLX-200028	FLX-200160
BZ-0000036	BZ-0000076	BZ-0000161	BZ-200064	BZ-600067	FLX-200029	FLX-200172
BZ-0000037	BZ-0000077	BZ-100001	BZ-200065	BZ-600072	FLX-200030	FLX-200175
BZ-0000038	BZ-0000079	BZ-100002	BZ-200070	BZ-600073	FLX-200032	FLX-200184
BZ-0000039	BZ-0000080	BZ-100003	BZ-200071	BZ-600075	FLX-200033	FLX-200188
BZ-0000040	BZ-0000081	BZ-100004	BZ-200132	BZ-600083	FLX-200034	FLX-200191
BZ-0000042	BZ-0000082	BZ-100007	BZ-200184	BZ-600085	FLX-200035	FLX-200194
BZ-0000043	BZ-0000083	BZ-100020	BZ-300001	BZ-600086	FLX-200037	FLX-200197
BZ-0000045	BZ-0000085	BZ-100022	BZ-300002	BZ-600087	FLX-200044	FLX-200198
BZ-0000046	BZ-0000086	BZ-100025	BZ-300003	BZ-600089	FLX-200053	FLX-200205
BZ-0000047	BZ-0000087	BZ-100026	BZ-300004	BZ-600090	FLX-200055	FLX-200206
BZ-0000048	BZ-0000088	BZ-100027	BZ-300005	BZ-600113	FLX-200076	FLX-200210
BZ-0000049	BZ-0000089	BZ-100028	BZ-300006	BZ-600117	FLX-200078	FLX-200212
BZ-0000050	BZ-0000090	BZ-100029	BZ-300008	BZ-600119	FLX-200079	FLX-200213
BZ-0000051	BZ-0000091	BZ-100030	BZ-300009	BZ-600121	FLX-200083	FLX-200214
BZ-0000052	BZ-0000092	BZ-200001	BZ-300011	BZ-600146	FLX-200098	FLX-200215
BZ-0000056	BZ-0000096	BZ-200005	BZ-300012	BZ-600147	FLX-200099	FLX-300002
BZ-0000057	BZ-0000099	BZ-200007	BZ-300013	BZ-700001	FLX-200105	FLX-300003
BZ-0000058	BZ-0000103	BZ-200010	BZ-300014	BZ-700002	FLX-200112	FLX-300005