

September 20, 2024

URGENT: MEDICAL DEVICE CORRECTION

Product Name	Model/Catalog Number	Serial Number	UDI DI
Gastrointestinal Videoscope	GIF-1100	See Attachment	04953170420191

Attention: Endoscopy Department, Risk Management Department

Dear Healthcare Professional / Provider:

Olympus is writing to inform you of a Medical Device Correction pertaining to the attached list of scopes and serial numbers of Olympus EVIS X1™ GIF-1100 Gastrointestinal Videoscope. This videoscope works in conjunction with the Olympus video system, light sources, monitors, etc. for visualization during endoscopy and endoscopic surgery.

Reason for Action:

It was discovered during device performance testing that the CCD imaging sensors were programmed with the incorrect color correction data and therefore, specifications are not met. The overall effect on the device is a slightly less intense or faded representation when compared to the desired color, and in addition the color blue is slightly shifted to a more purple shade. See images below.

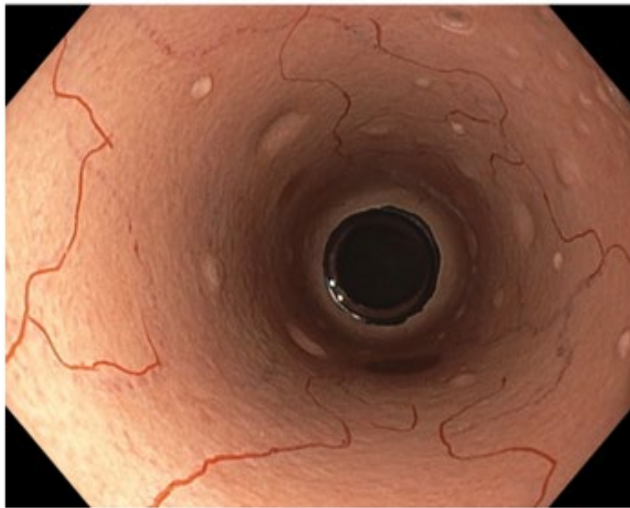
Incorrect color correction data



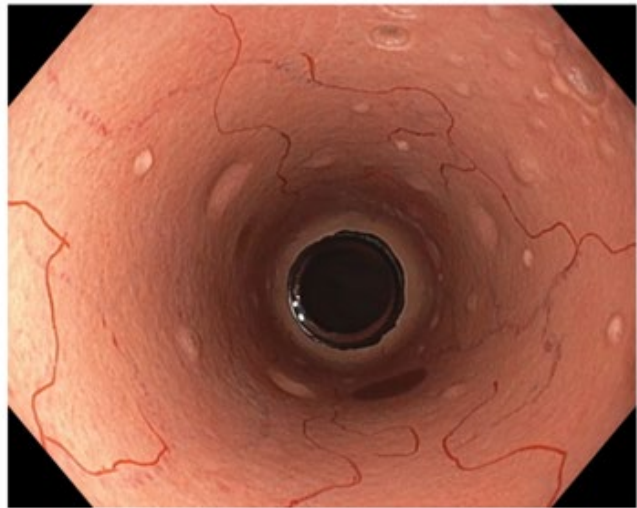
Correct color correction data



Incorrect color correction data



Correct color correction data



Olympus has not received any reported injuries relating this matter.

Risk to Health:

Imaging color is an important factor in endoscopic procedures which assists clinicians in recognizing relevant anatomical features for diagnostic or therapeutic treatment. When image discoloration is detected, clinicians are frequently able to adjust the monitors for desired effects. If the discoloration is noted prior to a procedure (during procedure pre-check), a replacement device may be desired which may potentially result in a minor delay in patient treatment. If the issue is encountered during the procedure, the clinician may opt to adjust the colors via the monitors, or if color adjustment is not to the clinician's preference, a replacement device may need to be obtained, resulting in a prolonged procedure.

Actions Required:

Our records indicate that your facility has purchased one or more of the affected products. Therefore, Olympus requires you to take the following actions:

1. Carefully read the content of this notification.
2. Examine your inventory and identify the above-listed device with the affected serial number.
3. Beginning October 28, 2024, please call Olympus Customer Service at 1-800-848-9024, option 3, to request a "CCD Color Adjustment". Olympus will arrange for the return of your device to our Olympus Repair Center at a mutually convenient time. Olympus Repair will perform a color adjustment.
4. If you have further distributed this product, identify your customers, and forward them this notification.
5. Olympus requests that you acknowledge receipt of this letter through the Olympus web portal:
 - a. Go to <https://olympusamerica.com/recall>
 - b. Enter the recall number "0454"
 - c. Complete the form as instructed.

Olympus requests that you report any complaints, including any imaging issues, to the Olympus 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 email at Cynthia.Ow@Olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow,
Field Corrective Actions Lead, Americas

URGENT: MEDICAL DEVICE CORRECTIVE ACTION
Gastrointestinal Videoscope, GIF-1100
Attachment (1 of 4)

2304049	2404596	2404637	2404699	2404739	2404779	2404823	2404863	2404903	2404945
2404300	2404597	2404638	2404700	2404740	2404780	2404824	2404864	2404904	2404946
2404333	2404598	2404640	2404701	2404741	2404781	2404825	2404865	2404905	2404947
2404537	2404599	2404641	2404702	2404742	2404782	2404826	2404866	2404906	2404948
2404541	2404600	2404642	2404703	2404743	2404783	2404827	2404867	2404907	2404949
2404547	2404601	2404643	2404704	2404744	2404784	2404828	2404868	2404908	2404950
2404550	2404602	2404644	2404705	2404745	2404785	2404829	2404869	2404909	2404951
2404551	2404603	2404647	2404706	2404746	2404786	2404830	2404870	2404910	2404952
2404552	2404604	2404649	2404707	2404747	2404787	2404831	2404871	2404911	2404954
2404559	2404605	2404653	2404708	2404748	2404788	2404832	2404872	2404912	2404955
2404560	2404606	2404655	2404709	2404749	2404789	2404833	2404873	2404913	2404956
2404561	2404607	2404656	2404710	2404750	2404790	2404834	2404874	2404914	2404957
2404562	2404608	2404657	2404711	2404751	2404791	2404835	2404875	2404915	2404958
2404563	2404609	2404660	2404712	2404752	2404792	2404836	2404876	2404916	2404959
2404564	2404610	2404665	2404713	2404753	2404793	2404837	2404877	2404917	2404960
2404565	2404611	2404672	2404714	2404754	2404794	2404838	2404878	2404918	2404961
2404566	2404612	2404673	2404715	2404755	2404795	2404839	2404879	2404919	2404962
2404567	2404613	2404674	2404716	2404756	2404796	2404840	2404880	2404921	2404963
2404568	2404614	2404675	2404717	2404757	2404797	2404841	2404881	2404922	2404964
2404569	2404615	2404676	2404718	2404758	2404798	2404842	2404882	2404923	2404965
2404570	2404616	2404677	2404719	2404759	2404799	2404843	2404883	2404924	2404966
2404571	2404617	2404678	2404720	2404760	2404800	2404844	2404884	2404925	2404967
2404573	2404618	2404679	2404721	2404761	2404801	2404845	2404885	2404926	2404969
2404574	2404619	2404680	2404722	2404762	2404803	2404846	2404886	2404927	2404970
2404576	2404620	2404681	2404723	2404763	2404804	2404847	2404887	2404928	2404971
2404577	2404621	2404683	2404724	2404764	2404805	2404848	2404888	2404929	2404972
2404580	2404623	2404684	2404725	2404765	2404806	2404849	2404889	2404930	2404973
2404581	2404624	2404685	2404726	2404766	2404808	2404850	2404890	2404931	2404974
2404582	2404625	2404686	2404727	2404767	2404810	2404851	2404891	2404932	2404975
2404584	2404626	2404687	2404728	2404768	2404811	2404852	2404892	2404934	2404976
2404585	2404627	2404688	2404729	2404769	2404812	2404853	2404893	2404935	2404977
2404586	2404628	2404689	2404730	2404770	2404813	2404854	2404894	2404936	2404978
2404587	2404629	2404690	2404731	2404771	2404814	2404855	2404895	2404937	2404979
2404588	2404630	2404691	2404732	2404772	2404816	2404856	2404896	2404938	2404980
2404589	2404631	2404692	2404733	2404773	2404817	2404857	2404897	2404939	2404981
2404590	2404632	2404693	2404734	2404774	2404818	2404858	2404898	2404940	2404982
2404591	2404633	2404694	2404735	2404775	2404819	2404859	2404899	2404941	2404983
2404592	2404634	2404696	2404736	2404776	2404820	2404860	2404900	2404942	2404984
2404594	2404635	2404697	2404737	2404777	2404821	2404861	2404901	2404943	2404985
2404595	2404636	2404698	2404738	2404778	2404822	2404862	2404902	2404944	2404986

URGENT: MEDICAL DEVICE CORRECTIVE ACTION
Gastrointestinal Videoscope, GIF-1100
Attachment (2 of 4)

2404987	2405031	2405077	2405140	2405197	2405250	2405304	2405359	2405405	2405451
2404988	2405032	2405078	2405141	2405199	2405251	2405305	2405361	2405406	2405452
2404989	2405034	2405079	2405142	2405200	2405252	2405307	2405362	2405407	2405453
2404990	2405035	2405081	2405143	2405201	2405253	2405308	2405364	2405408	2405454
2404991	2405036	2405084	2405144	2405202	2405254	2405309	2405365	2405409	2405455
2404992	2405037	2405085	2405145	2405203	2405255	2405313	2405366	2405410	2405456
2404993	2405038	2405094	2405146	2405204	2405256	2405314	2405367	2405411	2405457
2404994	2405039	2405100	2405147	2405205	2405259	2405315	2405368	2405414	2405458
2404995	2405040	2405101	2405148	2405206	2405260	2405316	2405369	2405415	2405459
2404996	2405041	2405106	2405149	2405207	2405264	2405317	2405370	2405416	2405460
2404997	2405042	2405107	2405150	2405208	2405265	2405321	2405371	2405417	2405461
2404998	2405043	2405108	2405151	2405211	2405266	2405322	2405372	2405418	2405462
2404999	2405044	2405109	2405152	2405212	2405267	2405323	2405373	2405419	2405463
2405000	2405045	2405110	2405153	2405213	2405268	2405324	2405374	2405420	2405464
2405001	2405046	2405111	2405154	2405214	2405269	2405325	2405375	2405421	2405466
2405002	2405047	2405112	2405155	2405215	2405270	2405326	2405376	2405422	2405467
2405003	2405048	2405113	2405156	2405216	2405271	2405327	2405377	2405423	2405468
2405004	2405049	2405114	2405158	2405217	2405272	2405330	2405379	2405424	2405469
2405005	2405050	2405115	2405159	2405221	2405273	2405331	2405381	2405425	2405470
2405006	2405051	2405116	2405160	2405222	2405274	2405333	2405382	2405426	2405471
2405007	2405052	2405117	2405161	2405224	2405276	2405335	2405383	2405427	2405472
2405008	2405053	2405118	2405162	2405225	2405279	2405336	2405384	2405428	2405473
2405009	2405056	2405119	2405163	2405226	2405280	2405339	2405385	2405429	2405474
2405010	2405057	2405120	2405164	2405227	2405281	2405340	2405386	2405432	2405475
2405011	2405059	2405121	2405165	2405228	2405282	2405341	2405387	2405433	2405476
2405012	2405060	2405122	2405166	2405229	2405283	2405342	2405388	2405434	2405477
2405013	2405061	2405124	2405167	2405230	2405284	2405343	2405389	2405435	2405478
2405014	2405062	2405125	2405168	2405232	2405286	2405344	2405390	2405436	2405479
2405015	2405063	2405126	2405169	2405233	2405287	2405345	2405391	2405437	2405480
2405016	2405064	2405127	2405176	2405235	2405288	2405347	2405392	2405438	2405481
2405017	2405065	2405129	2405180	2405237	2405289	2405348	2405393	2405439	2405483
2405018	2405066	2405130	2405184	2405238	2405290	2405349	2405394	2405440	2405484
2405019	2405067	2405131	2405185	2405239	2405291	2405351	2405395	2405441	2405485
2405020	2405068	2405132	2405186	2405240	2405294	2405352	2405397	2405442	2405486
2405021	2405069	2405133	2405187	2405241	2405295	2405353	2405399	2405443	2405487
2405022	2405070	2405134	2405189	2405242	2405296	2405354	2405400	2405444	2405488
2405026	2405071	2405135	2405190	2405243	2405297	2405355	2405401	2405445	2405489
2405027	2405072	2405136	2405192	2405244	2405299	2405356	2405402	2405446	2405490
2405028	2405073	2405138	2405193	2405247	2405300	2405357	2405403	2405447	2405491
2405029	2405074	2405139	2405196	2405248	2405301	2405358	2405404	2405449	2405492

URGENT: MEDICAL DEVICE CORRECTIVE ACTION
Gastrointestinal Videoscope, GIF-1100
Attachment (3 of 4)

2405493	2405536	2405578	2405624	2405671	2405730	2405786	2405833	2405883	2405928
2405494	2405537	2405579	2405625	2405672	2405731	2405787	2405834	2405884	2405929
2405495	2405538	2405581	2405626	2405673	2405732	2405790	2405836	2405886	2405930
2405496	2405539	2405582	2405627	2405674	2405734	2405792	2405837	2405889	2405932
2405497	2405540	2405583	2405628	2405675	2405735	2405793	2405838	2405890	2405933
2405498	2405541	2405584	2405629	2405676	2405736	2405794	2405839	2405891	2405938
2405499	2405542	2405587	2405631	2405677	2405737	2405795	2405840	2405892	2405939
2405500	2405543	2405588	2405632	2405678	2405738	2405796	2405841	2405893	2405940
2405501	2405544	2405589	2405633	2405681	2405739	2405797	2405843	2405894	2405941
2405502	2405545	2405590	2405634	2405682	2405740	2405798	2405844	2405895	2405942
2405504	2405546	2405591	2405635	2405683	2405741	2405799	2405845	2405896	2405943
2405505	2405547	2405592	2405637	2405684	2405742	2405801	2405846	2405897	2405944
2405506	2405548	2405593	2405638	2405685	2405744	2405802	2405848	2405898	2405945
2405507	2405550	2405595	2405639	2405686	2405745	2405803	2405849	2405899	2405946
2405508	2405551	2405596	2405640	2405687	2405747	2405804	2405850	2405900	2405950
2405509	2405552	2405597	2405642	2405688	2405750	2405806	2405851	2405901	2405951
2405510	2405553	2405598	2405643	2405689	2405753	2405807	2405852	2405902	2405952
2405511	2405554	2405599	2405644	2405690	2405754	2405808	2405853	2405903	2405954
2405513	2405555	2405600	2405645	2405691	2405757	2405809	2405854	2405904	2405955
2405515	2405556	2405601	2405646	2405692	2405758	2405810	2405856	2405905	2405960
2405516	2405557	2405602	2405647	2405694	2405759	2405811	2405858	2405906	2405961
2405517	2405558	2405604	2405648	2405698	2405760	2405812	2405859	2405907	2405969
2405518	2405559	2405605	2405649	2405699	2405761	2405813	2405860	2405908	2405971
2405519	2405560	2405606	2405650	2405700	2405762	2405814	2405861	2405910	2405973
2405520	2405561	2405607	2405651	2405702	2405763	2405815	2405862	2405911	2405975
2405521	2405562	2405609	2405652	2405703	2405764	2405818	2405863	2405912	2405977
2405522	2405563	2405610	2405653	2405707	2405765	2405819	2405866	2405914	2405979
2405523	2405565	2405611	2405654	2405708	2405767	2405820	2405867	2405915	2405980
2405524	2405566	2405612	2405655	2405710	2405768	2405821	2405868	2405916	2405983
2405525	2405567	2405613	2405656	2405712	2405769	2405822	2405869	2405917	2405984
2405526	2405568	2405614	2405657	2405713	2405773	2405823	2405871	2405918	2405987
2405527	2405569	2405615	2405658	2405715	2405774	2405824	2405873	2405919	2405988
2405528	2405570	2405616	2405659	2405716	2405776	2405825	2405874	2405920	2405989
2405529	2405571	2405617	2405661	2405719	2405778	2405826	2405875	2405921	2405991
2405530	2405572	2405618	2405665	2405721	2405779	2405827	2405876	2405922	2405992
2405531	2405573	2405619	2405666	2405722	2405780	2405828	2405877	2405923	2405993
2405532	2405574	2405620	2405667	2405723	2405781	2405829	2405878	2405924	2405994
2405533	2405575	2405621	2405668	2405727	2405782	2405830	2405879	2405925	2405995
2405534	2405576	2405622	2405669	2405728	2405783	2405831	2405880	2405926	2405996
2405535	2405577	2405623	2405670	2405729	2405785	2405832	2405881	2405927	2405997

URGENT: MEDICAL DEVICE CORRECTIVE ACTION
Gastrointestinal Videoscope, GIF-1100
Attachment (4 of 4)

2405998	2406062	2406116	2406174	2406234	2406289				
2405999	2406063	2406117	2406175	2406235	2406290				
2406000	2406064	2406118	2406176	2406237	2406292				
2406001	2406065	2406119	2406177	2406241	2406293				
2406005	2406066	2406120	2406178	2406242	2406294				
2406008	2406069	2406121	2406179	2406243	2406295				
2406009	2406070	2406122	2406180	2406244	2406298				
2406010	2406072	2406125	2406181	2406245					
2406012	2406073	2406126	2406188	2406246					
2406013	2406074	2406127	2406189	2406247					
2406015	2406075	2406128	2406190	2406248					
2406025	2406076	2406129	2406191	2406249					
2406026	2406077	2406130	2406192	2406250					
2406027	2406078	2406131	2406193	2406251					
2406028	2406079	2406132	2406195	2406252					
2406029	2406080	2406135	2406196	2406253					
2406030	2406081	2406136	2406198	2406255					
2406031	2406082	2406140	2406199	2406257					
2406033	2406087	2406142	2406200	2406259					
2406034	2406089	2406143	2406201	2406261					
2406035	2406090	2406145	2406202	2406263					
2406036	2406091	2406146	2406206	2406264					
2406037	2406092	2406147	2406207	2406265					
2406038	2406093	2406149	2406209	2406266					
2406039	2406094	2406150	2406213	2406267					
2406040	2406095	2406151	2406216	2406268					
2406041	2406096	2406152	2406217	2406269					
2406042	2406097	2406153	2406218	2406271					
2406044	2406098	2406154	2406219	2406272					
2406048	2406099	2406155	2406220	2406273					
2406049	2406100	2406157	2406221	2406274					
2406051	2406101	2406158	2406223	2406275					
2406052	2406102	2406162	2406224	2406276					
2406053	2406103	2406164	2406226	2406278					
2406054	2406104	2406166	2406227	2406281					
2406055	2406105	2406167	2406228	2406283					
2406057	2406106	2406168	2406229	2406284					
2406059	2406110	2406169	2406230	2406285					
2406060	2406111	2406170	2406231	2406287					
2406061	2406113	2406173	2406233	2406288					