

URGENT: VOLUNTARY MEDICAL DEVICE CORRECTION

O-arm™ O2 Imaging System Detector Panel Firmware Update

20 Tháng Năm 2026 | 03:43 CDT

Attention: Risk Management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

Dear Customer:

The purpose of this letter is to advise you that Medtronic is implementing an update to the firmware of the detector panel of the O-arm™ O2 Imaging System (O2) serial numbers listed in Appendix A of this notification. You may continue use of the system prior to the service visit by Medtronic to update the firmware. The issue is intermittent and may not present, however if it does it can be resolved by power cycling (rebooting) the system.

Issue Description:

Medtronic has identified the potential for image artifacts caused by an anomaly in the O-arm O2 Imaging System's detector panel firmware.

The issue presents as an artifact in both 2D and 3D images and can be resolved by power cycling (rebooting) the system. If the artifact is present in a 2D image and the user proceeds to a 3D scan without rebooting the system, the artifact will persist in the 3D images as shown in the images in Figure 1 below.

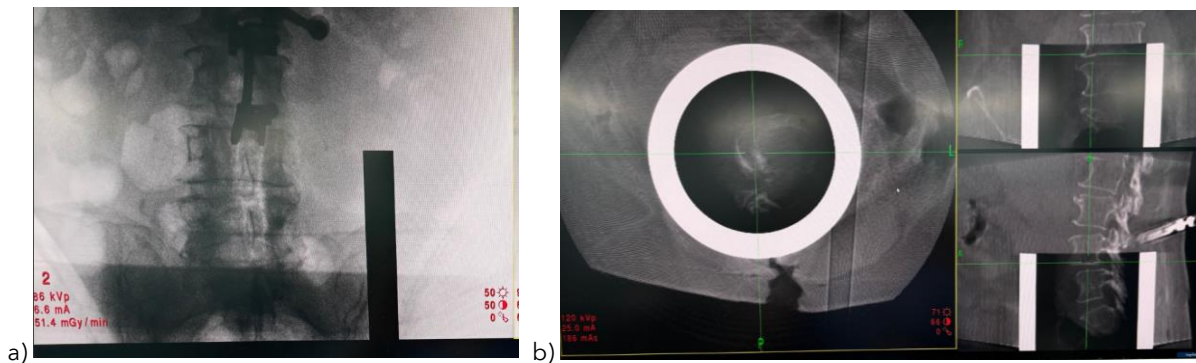


Figure 1. Example of ASIC image artifacts. (a) 2D scan with rectangular artifact (b) 3D Scan with ring artifact

Medtronic has received 69 complaints related to the occurrence of this issue with no reports of patient injury. These reported occurrences have resulted in surgical delays and additional imaging. While not reported in the complaints received, the image artifacts may result in a decision to cancel surgery, or to complete surgery without the benefit of image guidance. This issue is intermittent, has a low occurrence rate and can be resolved with a system reboot.

Product Scope:

A full list of impacted systems is included in Appendix A at the end of this letter.

Actions:

- Please complete and return the Customer Confirmation Form enclosed with this letter, acknowledging that you have received this information. A digital Customer Confirmation Form may also be completed using the QR code or link below.
- You may continue use of the system prior to service by Medtronic to update the firmware. The issue is intermittent and may not present, however if it does it can be resolved by power cycling (rebooting) the system.
- A Medtronic Field Service Engineer will contact your facility to schedule time to update the firmware on your system to permanently resolve this issue.
- This notice should be passed on to those who need to be aware within your organization or to any organization where the affected devices have been transferred.
- Please maintain a copy of this notice in your records.

Digital Customer Confirmation Form:



Link: <https://na3.docusign.net/Member/PowerFormSigning.aspx?PowerFormId=938047da-91e0-4705-8759-574f16a86f2e&env=na3&acct=7a9c79df-7f8a-4520-aa76-f95b30782a76&v=2>




Regulatory notification:

Medtronic is communicating this information to the appropriate regulatory agencies, in accordance with applicable local regulatory requirements. Adverse reactions or quality problems experienced with this product should be reported to your local Medtronic representative.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your local Medtronic Field Service Engineer or email us at rs.navtechsupport@medtronic.com.

Sincerely,

Signed by:
Tra Tran

 Signer Name: Tra Tran
Signing Reason: I approve this document
Signing Time: 20 May 2026 | 01:39 PDT
3EA71AFF83BA46359976CA93556D897A

Quality and Regulatory Affairs Lead

Southeast Asia



Appendix A - List of Impacted Serial Numbers

Product Name	Model #/ CFN	Serial #									
O-arm™ O2 Imaging System (O2)	BI70002000	C1640	C3837	C3903	C3964	C4026	C4087	C4148	C4210	C4271	C4339
		C2096	C3838	C3904	C3965	C4027	C4088	C4149	C4211	C4272	C4340
		C2187	C3839	C3905	C3966	C4028	C4089	C4150	C4212	C4273	C4341
		C2768	C3840	C3906	C3967	C4029	C4090	C4151	C4213	C4274	C4342
		C3316	C3841	C3907	C3968	C4031	C4092	C4152	C4214	C4278	C4343
		C3735	C3842	C3908	C3969	C4032	C4093	C4153	C4215	C4279	C4344
		C3777	C3843	C3909	C3970	C4033	C4094	C4154	C4216	C4280	C4345
		C3778	C3844	C3910	C3971	C4034	C4095	C4155	C4217	C4281	C4346
		C3779	C3845	C3911	C3972	C4035	C4096	C4156	C4218	C4282	C4347
		C3780	C3848	C3912	C3973	C4036	C4097	C4157	C4219	C4283	C4348
		C3781	C3849	C3913	C3974	C4037	C4098	C4158	C4220	C4284	C4349
		C3783	C3850	C3914	C3975	C4038	C4100	C4159	C4221	C4285	C4350
		C3784	C3851	C3915	C3976	C4039	C4101	C4160	C4222	C4286	C4351
		C3786	C3852	C3916	C3977	C4040	C4102	C4161	C4223	C4287	C4352
		C3787	C3853	C3918	C3978	C4041	C4103	C4162	C4224	C4288	C4353
		C3789	C3854	C3919	C3979	C4043	C4104	C4163	C4225	C4289	C4354
		C3790	C3855	C3920	C3980	C4044	C4105	C4164	C4226	C4290	C4356
		C3791	C3856	C3921	C3982	C4045	C4106	C4165	C4227	C4292	C4357
		C3792	C3857	C3922	C3983	C4046	C4107	C4166	C4228	C4293	C4360
		C3793	C3858	C3923	C3984	C4047	C4108	C4167	C4229	C4294	C4361
		C3794	C3859	C3924	C3985	C4048	C4109	C4168	C4230	C4295	C4362
		C3795	C3860	C3925	C3986	C4049	C4110	C4169	C4231	C4296	C4363
		C3796	C3861	C3926	C3987	C4050	C4111	C4170	C4232	C4298	C4364
		C3797	C3862	C3927	C3988	C4051	C4112	C4171	C4233	C4299	C4365
		C3798	C3863	C3928	C3989	C4052	C4113	C4172	C4234	C4300	C4366
		C3799	C3864	C3929	C3990	C4053	C4114	C4173	C4235	C4301	C4368
		C3800	C3865	C3930	C3991	C4054	C4115	C4174	C4236	C4302	C4369
		C3801	C3866	C3931	C3992	C4055	C4116	C4175	C4237	C4303	C4370
		C3802	C3867	C3932	C3993	C4056	C4117	C4176	C4238	C4304	C4372
		C3804	C3868	C3933	C3994	C4057	C4118	C4177	C4239	C4306	C4373
		C3805	C3869	C3934	C3995	C4058	C4119	C4178	C4240	C4307	C4374
		C3806	C3870	C3935	C3996	C4059	C4120	C4179	C4241	C4308	C4375
C3807	C3871	C3936	C3997	C4060	C4121	C4180	C4242	C4309	C4377		
C3808	C3872	C3937	C3998	C4061	C4122	C4181	C4243	C4310	C4378		
C3809	C3873	C3938	C3999	C4062	C4123	C4182	C4244	C4311	C4382		
C3811	C3874	C3939	C4001	C4063	C4124	C4183	C4245	C4312	C4383		
C3812	C3875	C3940	C4002	C4064	C4125	C4184	C4246	C4313	C4384		
C3813	C3876	C3941	C4003	C4065	C4126	C4185	C4247	C4314	C4385		
C3814	C3878	C3942	C4004	C4066	C4127	C4186	C4248	C4315	C4386		

Product Name	Model #/ CFN	Serial #									
		C3815	C3879	C3943	C4005	C4067	C4128	C4187	C4249	C4316	C4388
		C3816	C3881	C3944	C4006	C4068	C4129	C4188	C4250	C4318	C4389
		C3817	C3883	C3945	C4007	C4069	C4130	C4190	C4251	C4319	C4390
		C3818	C3884	C3946	C4008	C4070	C4131	C4191	C4252	C4320	C4394
		C3820	C3885	C3947	C4009	C4071	C4132	C4193	C4253	C4321	C4395
		C3821	C3887	C3948	C4010	C4072	C4133	C4194	C4254	C4322	C4396
		C3822	C3888	C3949	C4011	C4073	C4134	C4195	C4256	C4323	C4397
		C3823	C3889	C3950	C4012	C4074	C4135	C4196	C4257	C4324	C4399
		C3824	C3890	C3951	C4013	C4075	C4136	C4197	C4258	C4325	C4402
		C3825	C3891	C3953	C4014	C4076	C4137	C4198	C4259	C4326	C4403
		C3826	C3892	C3954	C4015	C4077	C4138	C4199	C4260	C4328	C4405
		C3827	C3894	C3955	C4016	C4078	C4139	C4200	C4261	C4329	C4406
		C3828	C3895	C3956	C4017	C4079	C4140	C4201	C4263	C4330	C4407
		C3829	C3896	C3957	C4018	C4080	C4141	C4202	C4264	C4331	C4414
		C3830	C3897	C3958	C4019	C4081	C4142	C4203	C4265	C4332	C4415
		C3831	C3898	C3959	C4020	C4082	C4143	C4204	C4266	C4333	C4416
		C3832	C3899	C3960	C4021	C4083	C4144	C4205	C4267	C4334	C4418
		C3833	C3900	C3961	C4022	C4084	C4145	C4206	C4268	C4335	C4421
		C3834	C3901	C3962	C4023	C4085	C4146	C4208	C4269	C4336	C4422
		C3835	C3902	C3963	C4024	C4086	C4147	C4209	C4270	C4337	



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Customer Confirmation Form

URGENT: VOLUNTARY MEDICAL DEVICE CORRECTION

O-arm™ O2 Imaging System

Detector Panel Firmware Update

For completion by Medtronic Customers Only - Please complete all fields below and return promptly

I have read and understood the Urgent Medical Device Correction Notification Letter, dated 20 Tháng Năm 2026 | 03:43 CD from Medtronic regarding the O-arm O2 Imaging System and have followed the instructions as outlined in the Notification Letter.

Please complete and sign the form as instructed below. If you are submitting the form on behalf of multiple accounts, please ensure that all relevant accounts are clearly listed. If you are completing the form manually, please return the completed form to your local Medtronic representative.

Hospital/Account Name*

Hospital/Account Address*

Country*

First Name of Person Completing the form*

Last Name of Person Completing the form*

Title/ Department*

Signature*

Date*

For questions, contact your local Medtronic Representative.

Note: The addressee may continue to receive reminders of this notice until a response is received.