

MEDTRONIC NAVIGATION, INC.

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URGENT: VOLUNTARY MEDICAL DEVICE CORRECTION

O-arm™ O2 Imaging System Detector Panel Firmware Update

May 2026

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.

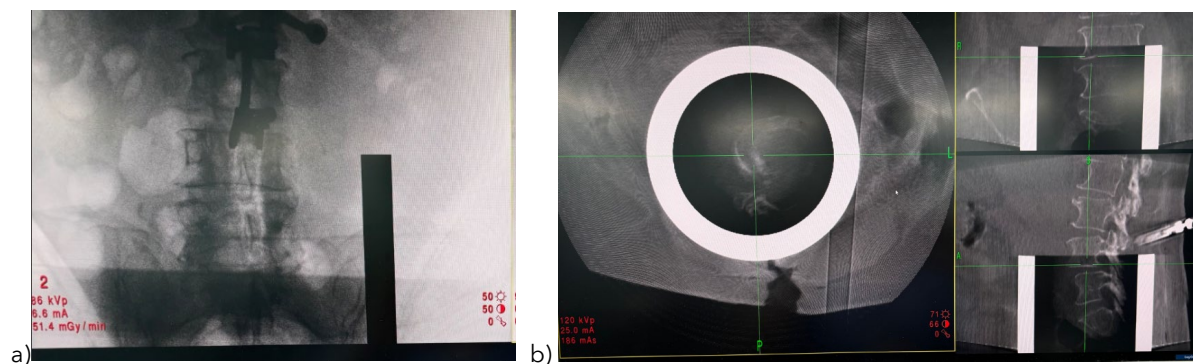


Figure 1. Example of ASIC image artifacts. (a) 2D scan with rectangular artifact (b) 3D Scan with ring artifact

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.

Medtronic

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. The form may be emailed to neuro.quality@medtronic.com.
- 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.

Regulatory notification:

Medtronic is communicating this information to the appropriate regulatory agencies.

Local contact details:

Adverse reactions or quality problems experienced with this product should be reported to FDA and Medtronic:

- Online at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> (form available to fax or mail)
- Call FDA (800) FDA-1088
- Call Medtronic Technical Services at 1-888-826-5603

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 respective Medtronic Field Service Engineer, Technical Services at 1-888-826-5603 or email at rs.navtechsupport@medtronic.com.

Sincerely,



Alison Webster
VP of Quality
Medtronic Cranial & Spinal Technologies

Appendix A-

Product Name	Model #/ CFN	Serial #	Serial #	Serial #	Serial #	Serial #	Serial #	Serial #
O-arm™ O2 Imaging System (O2)	BI70002000	C1640	C3915	C4022	C4190	C4270	C3857	C4143
		C2096	C3916	C4028	C4196	C4271	C3858	C4145
		C2187	C3919	C4045	C4197	C4273	C3859	C4151
		C2768	C3920	C4046	C4198	C4274	C3860	C4152
		C3316	C3924	C4047	C4199	C4278	C3862	C4153
		C3778	C3926	C4048	C4200	C4281	C3866	C4154
		C3779	C3927	C4049	C4210	C4311	C3868	C4155
		C3780	C3928	C4050	C4211	C4312	C3869	C4156
		C3781	C3929	C4051	C4213	C4313	C3872	C4176
		C3786	C3930	C4052	C4214	C4314	C3873	C4181
		C3787	C3931	C4053	C4215	C4315	C3876	C4182
		C3790	C3932	C4075	C4217	C4316	C3918	C4183
		C3792	C3933	C4076	C4218	C4318	C3921	C4184
		C3796	C3934	C4077	C4219	C4319	C3922	C4185
		C3830	C3935	C4078	C4220	C4320	C3923	C4186
		C3831	C3936	C4079	C4226	C4321	C3925	C4187
		C3832	C3937	C4080	C4227	C4322	C3946	C4191
		C3835	C3938	C4082	C4228	C4323	C3947	C4193
		C3837	C3939	C4083	C4229	C4324	C3965	C4194
		C3838	C3940	C4084	C4230	C4325	C3967	C4195
		C3839	C3941	C4085	C4231	C4326	C3968	C4212
		C3840	C3942	C4087	C4232	C4328	C3972	C4265
		C3841	C3943	C4089	C4233	C4329	C3975	C4272
		C3842	C3944	C4093	C4234	C4330	C3976	C4279
		C3844	C3945	C4094	C4235	C4331	C3983	C4332
		C3845	C3948	C4095	C4237	C4333	C3984	C4336
		C3848	C3949	C4101	C4238	C4334	C4014	C4337
		C3849	C3950	C4102	C4239	C4335	C4016	C4339
		C3850	C3951	C4105	C4240	C4342	C4017	C4340
		C3851	C3953	C4132	C4241	C4343	C4018	C4341
		C3852	C3954	C4133	C4242	C4348	C4019	C4344
		C3853	C3955	C4142	C4243	C4349	C4081	C4345
		C3855	C3956	C4144	C4244	C4350	C4090	C4346
C3861	C3957	C4146	C4246	C4382	C4096	C4347		
C3864	C3958	C4157	C4247	C4383	C4097	C4351		
C3867	C3960	C4158	C4251	C4384	C4098	C4385		

		C3870	C3961	C4162	C4252	C4407	C4100	C4386
		C3871	C3962	C4163	C4253	C4418	C4103	C4388
		C3874	C3963	C4168	C4254	C4421	C4104	C4405
		C3875	C3964	C4169	C4256	C4422	C4106	C4406
		C3883	C3966	C4170	C4257	C4280	C4107	C4414
		C3884	C3969	C4171	C4258	C3735	C4108	C4415
		C3885	C3970	C4172	C4259	C3777	C4131	C4416
		C3907	C3971	C4173	C4260	C3791	C4134	
		C3908	C3973	C4174	C4261	C3793	C4135	
		C3909	C3974	C4175	C4263	C3797	C4136	
		C3910	C3977	C4177	C4264	C3798	C4137	
		C3911	C3982	C4178	C4266	C3829	C4138	
		C3912	C4015	C4179	C4267	C3843	C4139	
		C3913	C4020	C4180	C4268	C3854	C4140	
		C3914	C4021	C4188	C4269	C3856	C4141	