

Date: February 7th, 2022

Ref: MRBR-22H001

Dear Customer,

Field Safety Notice

Affected Products: Shimadzu XTV system : SONIAOVISION G4, FLUOROspeed**Description of issue (Reason):**

It was found that the following problems may occur when certain operations are performed, in the course of product evaluation in the factory.

- (1) The X-ray irradiation rate (pulse rate) of pulsed fluoroscopy is different from the set value.
- (2) BH filter (Beam Hardening filter) for fluoroscopy is different from the set value.
- (3) The calculated dose displayed on the screen is higher than the actual dose. (The correct dose value is displayed if an area dosimeter is installed.)

How to identify the affected products:

Your authorized Shimadzu local representative or Shimadzu National Technical Support can investigate whether your product(s) is affected or not. Please contact your local Shimadzu representative or contact Shimadzu National Technical Support.

Corrective action plan by Shimadzu:

We will take field corrective action to avoid the problems described in the "Description of issue" section above.

Actions to be taken by customer:

To avoid problems, do not do any of the following until you are completed corrective action:.

- Before study begins (before patient registration), fluoroscopy is done by pressing a foot switch.
- Change from continuous fluoroscopy to pulsed fluoroscopy by the touch panel. (Continuous fluoroscopy is not registered at the time of delivery)
- "Temporary Procedure Edit" is performed during study to change the fluoroscopy mode..
- After general radiographic examination, fluoroscopic examination is performed. (If fluoroscopy is performed after a general radiographic procedure, carry out the procedure selection again after the procedure is started. Reselect to get the correct setting.).
- While the fluoroscopic rate of 30 fps is selected, the visual field size is changed from a small field of view (12/9/6 inches) to a large field of view (17/15 inches), and the setting of the fluoroscopic tube voltage etc. is changed (IBS ON/OFF change, fluoroscopy density change, and manual change of fluoroscope voltage).

You will be contacted by Shimadzu's local representative to determine whether your system requires the above corrective action. If you are not contacted by Shimadzu, please call Shimadzu National Technical Support.

Attachment to MRBR-22H011, List of affected Serial Numbers:

41C350C32001	MP0000C5B005	MP0000C8A001	MP0000DB7003
41C350C32003	MP0000C5B001	MP0000C8B001	MP0000DB8001
41C350C33001	MP0000C5B004	MP0000C8C001	MP0000DB8002
41C350C33002	MP0000C5C004	MP0000D89001	MQ493E1A6001
41C350C32002	MP0000C5C005	MP0000C8C002	
41C350C35001	MP0000C5C008	MP0000C91002	
41C350C34002	MP0000C5C006	MP0000C91003	
41C350C34003	MP0000C5C007	MP0000C91004	
41C350C3A003	MP0000C5C002	MP0000C91005	
41C350C3A002	MP0000C5C009	MP0000C93001	
41C350C39003	MP0000C5C013	MP0000C92004	
41C350C39002	MP0000C61001	MP0000C93002	
41C35643B012	MP0000C5C010	MP0000C93003	
41C356441001	MP0000C5C011	MP0000C93004	
M1C35643C001	MP0000C63001	MP0000C93006	
41C350C41001	MP0000C63003	MP0000C93005	
41C350C43001	MP0000C62003	MP0000C94002	
M1C356442007	MP0000C63002	MP0000C94003	
M1C356443003	MP0000C63005	MP0000C94009	
M1C356443004	MP0000C63004	MP0000C94010	
M1C356443005	MP0000C66002	MP0000C95001	
41C350C44001	MP0000C68009	MP0000C95002	
41C350C44002	MP0001147001	MP0000C96004	
41C350C43005	MP0000C73003	MP0000C96001	
MP0000C45004	MP0000C73004	MP0000C96003	
MP0000C45001	MP0000C75002	MP0000C96002	
MP0000C45005	MP0000C75003	MP0000C96006	
MP0000C45003	MP0000C76004	MP0000C96007	
MP0000C45002	MP0000C76003	MP0000C98002	
MP0000C46001	MP0000C78001	MP0000C98001	
MP0000C45006	MP0000C79002	MP0000C99002	
MP0000C46005	MP0000C79001	MP0000C99004	
M1C356446011	MP0000C7A005	MP0000C99003	
M1C356446012	MP0000C7A006	MP0000C9A004	
MP0000C46006	MP0000C7A004	MP0000C9A006	
MP0000C47002	MP0000C7A003	MP0000C9A001	
MP0000C47003	MP0000C7B001	MP0000C9A003	
MP0000C4A001	MP0000C7A001	MP0000C9A002	
MP0000C48001	MP0000C7B003	MP0000C9C004	
MP0000C4A004	MP0000C7B007	MP0000C9C003	
MP0000C4A005	MP0000C7B004	MP0000C9C005	
MP0000C4A006	MP0000C7B005	MP0000CA4003	
MP0000C4B004	MP0000C7B008	MP0000CB5001	
MP0000C4B005	MP0000C7C006	MP0000D8C001	
MP0000C4B002	MP0000C7B010	MP0000D91003	

MP0000C4B001	MP0000C7B009	MP0000D93001
MP0000C4B006	MP0000C7C001	MP0000D93003
MP0000C4B007	MP0000C7C002	MP0000D93002
MP0000C4B008	MP0000C7C003	MP0000D96001
MP0000C4B009	MP0000C81002	MP0000D95002
MP0000C4C004	MP0000C7C010	MP0000D95001
MP0000C51001	MP0000C7C008	MP0000D99002
MP0000C4C001	MP0000C7C009	MP0000D99001
MP0000C4C003	MP0000C81001	MP0000D9B001
MP0000C4C002	MP0000C81004	MP0000D9C003
MP0000C51002	MP0000C81006	MP0000D9C004
MP0000C51003	MP0000C82003	MP0000D9C002
MP0000C52003	MP0000C81005	MP0000D9C001
MP0000C52005	MP0000C81008	MP0000DA4002
MP0000C52007	MP0000C81007	MP0000DA4001
MP0000C52008	MP0000C81010	MP0000DA3004
MP0000C52006	MP0000C81009	MP0000DA3003
MP0000C52002	MP0000C83007	MP0000DA3002
MP0000C56001	MP0000C83008	MP0000DB3001
MP0000C56002	MP0000C83003	MP0000DB3002
MP0000C55004	MP0000C83005	MP0000DB3003
MP0000C55003	MP0000C83006	MP0000DB3004
MP0000C56003	MP0000C84013	MP0000DB4001
MP0000C56005	MP0000C84012	MP0000DB3005
M1C356456004	MP0000C84005	MP0000DB4002
MP0000C56006	MP0000C84004	MP0002A9A001
MP0000C56008	MP0000C84007	MP0002A9A002
MP0000C57002	MP0000C84006	MP0002AA5002
MP0000C57003	MP0000C84011	MP0002AA5001
MP0000C57005	MP0000C84009	MP0002AB7001
MP0000C57007	MP0000C85001	MP0002B9A001
MP0000C58002	MP0000C85002	MP0002BA5001
MP0000C58003	MP0000C85005	MP0002BA8002
MP0000C58006	MP0000C85006	MP0002BA9001
MP0000C58007	MP0000C85004	MP0002BA9002
MP0000C59001	MP0000C85003	MP0002BAA001
MP0000C59009	MP0000C86004	MP0002BAA002
MP0000C59004	MP0000C86001	MP0002BAB001
MP0000C59007	MP0000C85007	MP0002BAB002
MP0000C59006	MP0000C88001	MP0002BAB003
MP0000C59010	MP0000C88003	MP0002BAB004
MP0000C5A006	MP0000C88002	MP0000DB8004
MP0000C5A007	MP0000C89002	MP0000DB8003
MP0000C5A001	MP0000C89005	MP0000DB9003
MP0000C5A002	MP0000C89004	MP0000DB9002
MP0000C5B006	MP0000C89003	MP0000DB9001
MP0000C5B002	MP0000C8A003	MP0000DB7002