California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Micro-X Ltd. Rover Mobile X-ray System

Recall Date	Product Description	Recalling Firm	Recall Reason
12/12/2024	MICRO-X Rover Mobile X-ray System, # MXU-RV19 MICRO-X Rover Mobile X-ray System, # MXU-RV35 MICRO-X Rover Mobile X-ray System, # MXU-RV35 MICRO-X Rover Mobile X-ray System, # MXU-RV71	Micro-X Ltd.	During internal testing it was found that if the system is Ready to expose and the hand switch is then dropped into the stowage unit such that it lands on the prep/expose switch, the prep switch can be activated for a very short time such that the orange ring of death is displayed in the tube cooling area of the screen. The system then becomes unresponsive to kV/mAs changes, prep/expose presses. The only way to proceed is to suspend the patient, Exit Nexus DR and relogin and continue the exam. Shots were terminated by the mAs integrator; however, the 4 ms exposure time did not

			allow enough tolerance to achieve diagnostic exposures due to variations in hardware and how different timers are started. Mobile x-ray system can report and deliver a lower post-exposure mAs value than what set by the operator.

Recall Class	Product Identification	Distribution	Affected Dates
II	UDI-DI: 09357123000013 Serial Numbers: 262 - 266 UDI-DI: 9357123000037 Serial Numbers: 00334 - 00361 MXU-RV35 UDI-DI: 9357123000037 MXU-RV71 UDI-DI: 935712300005 using Control Board PCBA, 12425-03 (or earlier) Serial Numbers: MSN00334 - MSN00395	3 units in California	October and prior

For additional information, please visit: FDA Website_MXU-RV19 , FDA Website_MXU-RV35 , and FDA Website_MXU-RV35 and MXU-RV71 .