

To: SHIMADZU (ASIA PACIFIC) PTE LTD.

Ref.: MRBR-23H021

Date: 10<sup>th</sup> April 2023

Sub: Recall/Field correction Notification to the regional representative

Dear Sirs,

SHIMADZU CORPORATION has identified a potential issue in RADspeed Pro, RADspeed safire, CH-200 and CH-200M

We have identified potential problems with some of the above Shimadzu products.

The CEILING TUBE SUPPORT for the above device consists of an X-ray Tube Support Pull-up Section and an X-ray Tube Support Section to which an X-ray tube assembly is mounted, and the tube holding section is secured to the column of the X-ray tube X-ray Tube Support Pull-up Section with eight bolts. It turned out that this bolt could come loose.

In use, we think that loosening of the fixed bolt will not occur unless the bolt is repeatedly subjected to strong impact on the mechanical stopper or the like during the vertical axis rotation operation, but if loosening of the bolt increases, the bolt may break.

If all eight bolts break, the X-ray Tube Support Section may eventually come off the column.

Therefore, we will add protective parts so that the X-ray Tube Support Section does not come off the column.

We understood that the notification for the recall or the field correction is required by the regulation in Singapore and Malaysia, and we identified the installed some affected systems in Singapore and Malaysia.

Therefore, could you please notify this recall/ field correction to the national authority instead of us.

We enclosed "FIELD CORRECTIVE ACTION REPORT (draft)" for two countries and related documents.

After notifying the national authority, please send us a copy of the documents you submitted to the national authority.

If notification to the competent authorities is required in a country other than Singapore or Malaysia, please provide the necessary information.

Best Regards,



Naoki Morooka

General Manager of  
Medical Regulatory Policy Department  
Shimadzu Corporation