

Medical Regulatory Policy Department Post Market Surveillance Section

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Date: 9th August 2024

Ref: MRAA-9127

Dear Customer,

Field Safety Notice

Affected Products:

SIL-40C XR CL, SIL-40C X3 CL

Description of issue (Reason):

There have been cases of failure of the main board due to condensation water occurring in the gap between thermal insulation material on the underside of the main base dropping onto the main board. The symptoms and errors differ depending on the position where the water drops adhere. To date there have been examples of reports of inter-board communication errors (NOT CONNECT [Board name]), HOME POSITION error or SLIP error of XYZ drive units and valves when the instrument was started up.

There have been no reports of it occurring on Clinical model, SIL-40C XR CL and SIL-40C X3 CL till now.

How to identify the affected products:

The Serial Numbers of Instruments below are not applied countermeasure in factory. You will be contacted by Shimadzu's local representative to determine whether your system requires the above corrective action

Corrective action plan by Shimadzu:

We prepared the cover of part (Electrical ASSY Cover Kit) on the main board and the updated firmware for SIL-40C XR CL and SIL-40C X3 CL.

The corrective actions to be taken to affective products are

- (1) Add a cover part to the main board.
- (2) Update the SIL-40 firmware to Ver. 1.16 or above.

Actions to be taken by customer:

Please check the Serial Number and F/W version of SIL-40C XR CL and SIL-40C X3 CL, and if the instruments is affected by this issue, contact your sales representitive or distributor.