

Date 15 July 2025

URGENT: FIELD SAFETY NOTICE

<Radiography System RADspeed PRO>
< CEILING TYPE X-RAY TUBE SUPPORT CH-200>
and
< CEILING TYPE X-RAY TUBE SUPPORT CH-200M>

Attention to RADspeed PRO owners and users,

Affected Products:

- RADspeed Pro
- RADspeed Safire
- CEILING TUBE SUPPORT CH-200
- CEILING TUBE SUPPORT CH-200M

(1) Purpose of this letter

The purpose of this letter is to advise you that Shimadzu Corporation is voluntarily carrying out a Field Correction Action (FCA) for RADspeed Safire and RADspeed Pro, which are X-ray general imaging systems that include a ceiling-mounted X-ray tube suspension, and the CH-200 and CH-200M.

(2) Reason for the Corrective Action:

The CEILING TUBE SUPPORT CH-200 and CH-200M, which are components of the equipment described in the Affected Product, consist of a ceiling suspension mechanism and an X-ray Tube Support Section (Hereinafter, the" support") for mounting the X-ray tube assembly.

It also features a rotating mechanism in which the shaft of the X-ray tube support (hereinafter referred to as the shaft) of the ceiling suspension mechanism is inserted into the rotating bearing of the Support Section, allowing the X-ray tube to be rotated for positioning.

In the above equipment, it was found that the shaft for mounting the X-ray tube unit on the support may be prone to breakage. In addition, it was found that the protective parts might not work effectively only when the shaft was broken while being operated in a forward direction during lifting.

We will take countermeasures to address this issue.

(3) Risk to health:

a) If the shaft breaks and the Support Section comes off, the possibility of contact with the patient or operator cannot be denied.

However, due to the structure in which the shaft is fitted to the rotary bearing part of the Support, and the protective parts, the Support does not come off except when the shaft is broken during operation in the forward direction.

Based on the above, no serious health hazard is expected to occur.

We have not received any reports of health hazards.

b) "How to recognize that the device may fail."

Please refer to section 5 below.

(4) Actions to be taken by the customer/user:

Perform the daily inspection described in the CH-200/CH-200M operation manual to check for wobbles or shakes, misalignment of the light irradiation position, etc. If any abnormality is found, discontinue use and contact our service provider.

When rotating the X-ray tube unit, avoid hitting the stopper at the end.

If the stopper is hit hard, in the unlikely event that a crack has already occurred, a significant impact may be applied, which could accelerate the growth of the crack.

In the case of electric rotation, it is controlled by software and does not hit the stopper.

Do not rotate the X-ray tube over or near the patient.

(5) Product and distribution information:

Your authorised Shimadzu local representative can investigate whether your product(s) are affected.

Please contact your local Shimadzu representative for assistance.

(6) Type of action by Shimadzu:

We will take measures to add parts that prevent the X-ray tube holder from coming off, even if the retaining shaft is compromised.

(7) Other information:

a) Contact information for questions.

b) Attachments of Acknowledgement and Receipt Form (separate sheets).

Yours sincerely,



Chopng Yip Kee

Regulatory Affairs



SHIMADZU MALAYSIA SDN. BHD.

Contact person for this notification:

Mr. Ganny Bu

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Acknowledgement of receipt

I hereby confirm that, as the owner / responsible operator of the affected system with the ceiling tube support CH200 / CH200M serial number _____,

I have received the following document.

Field Safety Notice

Affected system with a short description of the malfunction and the correction action.

Date:

Hospital:

Name of Person in Charge:

Signature:

Company stamp: