

## **URGENT FIELD SAFETY NOTICE**

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Control No.: QAD-Z2832R1  
Type of Action: FSCA  
Date of Issue: 16 March 2020

### **Information about UST-2265-2 / 2266-5 Blood-flow Velocity Underestimation**

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#### **Dear customer,**

The purpose of this letter is to advise you that Hitachi, Ltd. Healthcare Business Unit is voluntarily recalling UST-2265-2 / 2266-5 probes. The UST-2265-2 / 2266-5 probe is intended to be used for fluid flow analysis of the human body as Continuous-wave Doppler (CWD) for Cardiac, and Peripheral Vessel.

#### **Details of Affected Devices :**

UST-2265-2 : G3007689, G3007688, G3007687, 206H2628, 206H2629, 206H2630, 206H2620,  
206H2621, 206H2622, 206H2623, 206H2624, 206H2625, 206H2626, 206H2627,  
205X3897, 205X3898, 205X3899, 205X3900, and 20686623  
UST-2266-5 : 20624655, 20624656

#### **Description of the problem :**

1. UST-2265-2 / 2266-5 are potentially underestimating blood peak velocity. The peak velocity readings will be approximately 2 - 7% lower than the specified range. The potentially decreased sensitivity is due to miswiring of inner cables during the manufacturing process.
2. Peak Velocity readings are used along with other test results to determine Aortic Stenosis (AS) severity in patients. The lower peak velocity readings may affect the AS severity grading. AS severity grading ranges from Mild to Moderate to Severe. The lower reading may grade the patient in Mild category rather than Moderate or Moderate rather than Severe.

#### **Possible Health Hazard :**

The grading with other test results are used for diagnosis and treatment purpose. Lower peak velocity reading may lead to delay in diagnosis and potential misdiagnosis.

#### **Advise on action to be taken by the user:**

Please be aware of possible lower peak velocity readings. They may be recognized as suspicious if the readings do not support other clinical evidence. Additionally, we recommend to review the results on performed examinations on patients previously examined with this probe.

#### **Action of manufacturer / distributor:**

Hitachi will provide a replacement probe. The local service organization will contact you regarding the exchange.

#### **Transmission of this Field Safety Notice:**

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected device has been transferred.

#### **Geographic Distribution :**

The Netherlands, Ukraine, USA

#### **Contact reference person:**

Please find your local contact person on the cover letter of our local sales organization to this "Urgent Field Safety Notice". We confirm that this item has been reported to the responsible National Competent Authority.

Yours sincerely  
**Hitachi Ltd.**