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## **Urgent Field Safety Notice**

**Re:** Waters ACQUITY UPLC Sample Organizer, IVD (PN 186015020IVD)

**Correction #** 1218959-04/10/2017-001-C

Recall-Correction

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10April2017

### **Attention: Customer**

#### **Details on affected devices:**

Waters Corporation is initiating a voluntary Medical Device Recall – Correction on the ACQUITY UPLC Sample Organizers (IVD). Only sample organizers with the serial numbers listed on the attached Reply Verification Tracking Form are affected. Our records indicate that you own or lease one or more of these sample organizers.

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

Waters Corporation is initiating this recall because a remote potential exists for an internal fuse shield to combust resulting in a burning odor and instrument failure. Our investigation has concluded that the potential combustion of the fuse shield will be contained within the instrument with no risk of damage to samples or surrounding area.

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

In the unlikely event that burning odor is observed in or around the instrument; immediately power down the unit, discontinue use, and call your local Waters Service organization to report the event. To ensure the continued safety and reliability of our products, Waters recommends that this correction be performed at the earliest opportunity. This correction involves removal of the internal fuse shield by a Waters field service engineer.

Please complete the attached Reply Verification Tracking Form and return it to Waters per the instructions within the form. Completion of this form will expedite the field correction activity and provides evidence that Waters has notified you about this correction. A Waters field service engineer will contact you to schedule the update of your affected instrument(s).

#### **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 devices have been transferred. Please contact me directly if you have any questions or concerns

The undersigned confirms that this notice has been provided to the appropriate Regulatory Agency.

Sincerely,

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**REPLY VERIFICATION TRACKING FORM****Medical Device Recall -- Correction - Waters ACQUITY UPLC Sample Organizers****Customer:****Region:****Contact :****Email:**

<i><b>Name of Product Affected</b></i>	<i><b>Serial Number</b></i>

**INSTRUCTIONS FOR COMPLETING THIS REPLY VERIFICATION TRACKING FORM:**

This completed form is required for tracking purposes. Please check the applicable boxes below. Your signature and date are required.

- ☐ I acknowledge receipt of this letter
- ☐ I have the affected product(s) / Serial Number(s) noted above
- ☐ I DO NOT have the affected product(s) / Serial Number(s) noted above

Name (Print):

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Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
(DD/MM/YYYY)

Please return the completed form via email or Fax to:

(e) E-Mail Address: [waters\\_quality@waters.com](mailto:waters_quality@waters.com)

(f) Fax Number: US: (508) 482-2339 / Outside US: +1 (508) 482 2339