

08 February 2022

[C0031614 Maritim d.o.o]

[Customer Address]

**URGENT: Field Safety Notification – Customer Communication****LUMIRADX PLATFORM INSTRUMENT V5E REMOVAL NOTICE**

Dear [Customer Name],

This notification letter is to inform you of a removal involving the LumiraDx Platform Instrument V5E (Catalogue number L001000303001) with **Serial Number:**

- **30874-20-31-05832**

This removal has been identified due to observations of a manufacturing defect that may lead to reduced effectivity of the instrument control systems. Use of this instrument with D-Dimer or CRP assays may result in artificially reduced quantitative results.

Examine your inventory immediately per the guidance below and quarantine the instrument subject to this removal. We are instructing the affected instruments to be returned immediately to LumiraDx where they will be subject to investigation. Confirmation of any potential impact on test results will be provided following the return and evaluation of the instrument.

Please forward this notice to additional testing sites if these instruments were further distributed.

Your assistance is appreciated and necessary to prevent the risk of incorrect results.

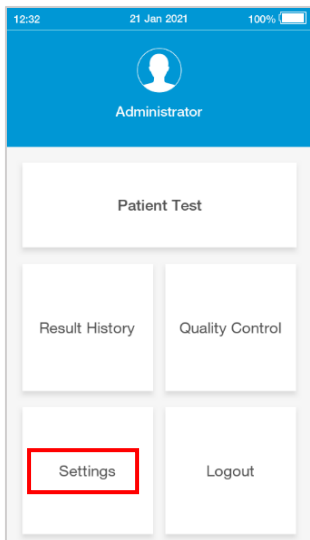
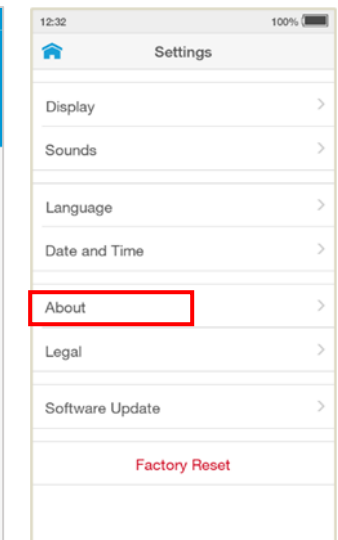
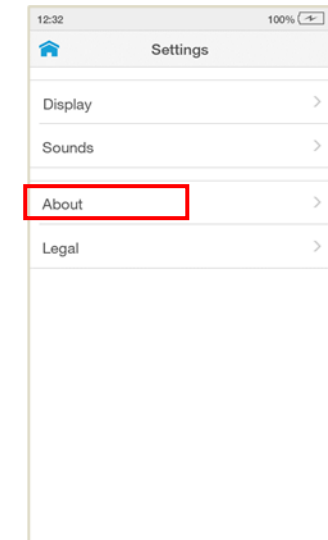
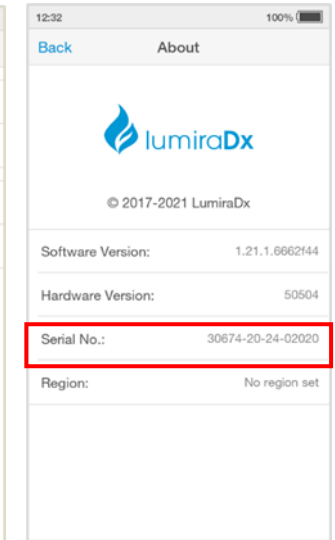
Please complete and return the enclosed customer response form as soon as possible. If you have any questions, contact LumiraDx Customer Services at [customerservices@lumiradx.com](mailto:customerservices@lumiradx.com) or +44(0) 1172 842 535.

See the following guidance for identifying the Instrument Serial Number:

**1) Identifying instrument Serial Number from the instrument label**

The instrument Serial Number can be verified on the label on the underside of the instrument

2) Identifying instrument Serial Number through the user interface:

			
<p>Login to the Instrument then from the home-screen tap the <b>Settings</b> button</p>	<p>Tap the <b>About</b> button (Administrator Settings Menu)</p>	<p>Tap the <b>About</b> button (General User Settings Menu)</p>	<p>Confirm instrument serial number</p>