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Boule Diagnostics – Field corrective action

During recent routine internal quality processes, Boule identified a potential risk of malfunction that can occur during certain specific conditions with the Autoloader version of its hematology analyzers. In accordance with the company's improved Quality System and in compliance with international regulations Boule has submitted a corrections and removal report to the FDA and affected US customers as well as a Field Safety Notice to other markets.

As part of these notifications, revised instructions for use have been provided to customers to ensure operation of the instrument meets the stated specifications. Boule is actively investigating to determine a corrective action. The issue relates to four (4) percent of Boules total installed base since 2006. Less than one (1) percent will need physical modifications. No material impact on company performance is expected.

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About Boule Diagnostics AB (publ)

Boule Diagnostics AB is a global diagnostics company that develops, manufactures and markets instruments and consumable products for blood diagnostics. The company serves hospitals, clinics, laboratories and companies within blood diagnostics, in both human and veterinary hematology. The company operates via subsidiaries in Sweden, the USA, Mexico and Russia. The company products are sold globally primarily through distributors, supported by Boule's own local sales and support personnel. The Boule shares are listed on Nasdaq Stockholm since 2011. www.boule.com

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