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Field Safety Notice
Fenom Pro® Asthma Monitor

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CAIRE Diagnostics is performing a voluntary recall involving the Fenom Pro Asthma Monitor. This recall is being conducted with the knowledge of the Food and Drug Administration in the United States, our European Authorised Representative, and our Australian Sponsor.

Issue Description:

CAIRE Diagnostics Inc. is initiating a voluntary recall to repair two calibration errors in the Fenom Pro® Asthma Monitor. First, we have discovered drift in our calibration gases, which has now been corrected by the supplier. Second, we found a software error that requires an update to correct. Each of these issues can cause FeNO scores to be erroneously high.

Risk to Health:

A high reading may falsely indicate that therapeutic action should be taken. This may result in prescription of unneeded medication to the patient. Risks of injury from that medication are unlikely, but possible.

Which units are affected?

All units sold before 23 February 2021 are affected (serial numbers 100107 to 100651).

What actions are required?

1. Discontinue use of the device. Make all personnel who use it aware of this recall.

2. Contact CAIRE Diagnostics or your distributor. You can reach us at +1-888-609-4839 or customerservice.cdx@caireinc.com. We will arrange for shipment of the device back to the factory for a software update and re-calibration. If you purchased Fenom Pro from a distributor, please contact them to arrange shipment.

3. Distributors: Please cease distribution of the device and contact CAIRE Diagnostics to arrange for return of your existing inventory to CAIRE Diagnostics for a software update and re-calibration, or device replacement. Please immediately forward this notice to all Fenom Pro customers and request they comply with the recall process.

Thank you for your immediate attention to this important matter. We appreciate your cooperation.