



DATE: January 8, 2014
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: *A. Scott Gilliam*
A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
SUBJECT: Nipro Diagnostics, Inc. [Medical Device]

**AFFECTED
PRODUCT:** TRUEbalance™ and TRUEtrack® Blood Glucose Meters

SUMMARY: Unclassified Recall; Certain meters have an incorrect factory-set unit of measure that displays the glucose result in mmol/L rather than mg/dl.

There are 501 affected TRUEbalance meters and 105 affected TRUEtrack meters that were distributed in the United States from September 2008 to May 2013.

**SUGGESTED
ACTION:** For consumer inquiry only. If the consumer has an affected TRUEbalance or TRUEtrack meter, please call Stericycle toll-free at 1-866-236-4518 to verify serial number, and to expedite return and replacement of these affected TRUEbalance and TRUEtrack meters at no charge.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Nipro Diagnostics, Inc. Initiates Voluntary Recall of Certain TRUEbalance and TRUEtrack Blood Glucose Meters

Contact

Consumer:

1-866-236-4518

Media:

Lisa Nardi

800-342-7226, ext. 2183

FOR IMMEDIATE RELEASE - January 2, 2014 - Fort Lauderdale, FL-Nipro Diagnostics, Inc. today announced it is initiating a voluntary recall and replacement of a limited number of TRUEbalance™ and TRUEtrack® Blood Glucose Meters distributed both in the United States and outside the United States.

The company has determined that certain isolated TRUEbalance and TRUEtrack Blood Glucose Meters distributed in the United States have an incorrect factory-set unit of measure that displays the glucose result in mmol/L rather than mg/dl. If a consumer were not to notice the incorrect unit of measure, it is possible that the meter result could be read as a lower than expected blood glucose result.

There are 501 affected TRUEbalance meters and 105 affected TRUEtrack meters that were distributed in the United States from September 2008 to May 2013.

Consumers who have a TRUEbalance or TRUEtrack meter should:

- Check to confirm if they have an affected TRUEbalance or TRUEtrack meter by obtaining the serial number from the serial number label on the back of the meter and visiting www.NiproDiagnostics.com/product-notice or by calling **Stericycle toll-free at 1-866-236-4518**.
- If the consumer has an affected TRUEbalance or TRUEtrack meter, please call Stericycle to verify serial number, and to expedite return and replacement of these affected TRUEbalance and TRUEtrack meters at no charge.

Consumers may continue to test blood glucose using any other Nipro Diagnostics blood glucose meter not included in this recall while waiting for their replacement meter to arrive. Only use test strips that are intended for use with their blood glucose meter.

We have not received any reports of patient injuries or adverse events related to this recall .

The company is sending notifications to pharmacies, durable medical equipment providers, mail order companies and distributors where the TRUEbalance and TRUEtrack meters are recommended or sold in the United States.

Patient safety is a top priority at Nipro Diagnostics. The company has notified the U.S. Food and Drug Administration (FDA) of this voluntary product recall and is working with affiliates in other countries to notify regulatory authorities where the affected products were sold to quickly resolve this matter.

About Nipro Diagnostics, Inc.: Based in Fort Lauderdale, Florida, Nipro Diagnostics, Inc. is a leading developer, manufacturer and marketer of diabetes monitoring and management products. The company offers a portfolio of high-quality blood glucose monitoring systems and diabetes management products available around the world. Nipro Diagnostics is the exclusive supplier of blood glucose monitoring systems, co-branded under the TRUE name, to the world's leading pharmacies, distributors and mail service providers. For more information, please visit: www.niprodiagnostics.com
