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URGENT – PRODUCT RECALL

Nipro Diagnostics

TRUEbalance and TRUEtrack Blood Glucose Meters

Certain meters have an incorrect factory-set unit of measure that displays the glucose result in mmol/L rather than mg/dL

Independence Medical TrueBalance Item Numbers	67H4H0181, 67H4H0183, 67H4H0183PCP, 67H4H0181F, 67H4H0183F, 67H4H0181CM, 67ISG1723941CM, 67ISG1724368
Lot Numbers	KK0468, KL01079, KM0337TI, KN1834TI, KN1973TI, KN2074TI, KN2089TI, KN2090TI, KN2102TI, KP0047TI, KP0076TI, KP0128TI, KP0925TI,
Independence Medical TrueTrack Item Numbers	ISG172200, 67A4H0187, 67A4H0187F, 67A4H0181F, 67A4H0181, 67A4H0181CM, 67A4H0187CM, 67ISG172200CM
Lot Numbers	KJ0731, KK0964, KL01213, KL01233-3TI, KL0267-10, KL0381-14, KL0637-2TI, KL0716TI, KL0860TI, KP0074TI

January 8, 2014

Dear Valued Customer:

This letter is to make you aware of an urgent product recall from Nipro Diagnostics regarding certain lots of TRUEbalance and TRUEtrack Blood Glucose Meters. These meters 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.

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.

Our records indicate that we may have shipped you affected product. Please read the enclosed notification from the manufacturer in its entirety. Please check your stock immediately for the items and lot numbers listed above. **If you find you have affected product, please discontinue distribution and contact Independence Medical Customer Service at 1-800-860-8027 to request a return authorization. If you have further distributed this product, please notify your customers of this product recall.**

Thank you for your assistance in this matter.

Sincerely,
Independence Medical

URGENT: MEDICAL DEVICE VOLUNTARY RECALL CERTAIN TRUEbalance™ & TRUEtrack® BLOOD GLUCOSE METERS

December 31, 2013

Dear Valued Customer:

The purpose of this letter is to inform you that Nipro Diagnostics, Inc. has announced a voluntary product recall of a limited number of TRUEbalance™ & TRUEtrack® blood glucose meters. The company has determined that certain isolated TRUEbalance and TRUEtrack Blood Glucose Meters distributed both inside and outside the United States have an incorrect factory-set unit of measure. In the United States, the meter 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. We have not received any reports of patient injuries or adverse events related to this recall.

Replacement meters are available at no charge by following the instructions provided below:

- **People with Diabetes:** Determine whether you 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**. Stericycle can verify affected meters by serial number and will expedite return and replacement of these TRUEbalance and TRUEtrack meters at no charge to you. Discontinue use of any affected meter. You may continue to test blood glucose using any other Nipro Diagnostics blood glucose meter not included in this recall while waiting for your replacement meter to arrive. Only use test strips that are intended for use with your meter.
- **Health Care Professionals:** Determine whether you may have affected TRUEbalance or TRUEtrack meters in inventory by examining the lot number printed on the outer case/shipper label or on the side of the meter box. The affected serial numbers are contained within the lots in the attached Appendix. If you have any product in these lots, you may have an affected product and should return the product. Please contact **Stericycle toll-free at 1-866-236-4518** to expedite return and replacement of these TRUEbalance and TRUEtrack meters. Please advise any patients with recalled product to contact Stericycle toll-free at 1-866-236-4518. Note that patients may continue to test blood glucose using any other Nipro Diagnostics blood glucose meter not included in this recall while waiting for replacement meters to arrive. However, patients should only use test strips that are intended for use with their meters.
- **Pharmacists/DME Providers:** Determine whether you may have affected TRUEbalance or TRUEtrack meters in inventory by examining the lot number printed on the outer case/shipper label or on the side of the meter box. The affected serial numbers are contained within the lots in the attached Appendix. If you have any product in these lots, you may have an affected product and should return the product per your normal return

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procedures. Please advise any patients with recalled product to contact **Stericycle toll-free at 1-866-236-4518**. Note that patients may continue to test blood glucose using any other Nipro Diagnostics blood glucose meter not included in this recall while waiting for replacement meters to arrive. However, patients should only use test strips that are intended for use with their meters. If you receive inquiries from health care professionals or meter users, please reference the above instructions.

- **Distributors:** Determine whether you may have affected TRUEbalance or TRUEtrack meters in inventory by examining the lot number printed on the outer case/shipper label or on the side of the meter box. The affected serial numbers are contained within the lots in the attached Appendix. If you have any product in these lots, you may have an affected product. In addition, please notify your customers of this product recall. Request that they return only the product in the indicated lot numbers per your normal return procedures. Once you have received all TRUEbalance and TRUEtrack meters to be returned, please call **Stericycle at 1-866-236-4518** to obtain prepaid return labels.

This recall is being made with the knowledge of the Food and Drug Administration. Please complete and return the enclosed response form as soon as possible via fax at 1-888-358-7294 or email to niprodiagnostics5172@stericycle.com. If you have any questions, please call **Stericycle toll free at 1-866-236-4518**.

Patient safety is a top priority at Nipro Diagnostics and we apologize for any inconvenience this recall may cause you.

Sincerely,
Nipro Diagnostics

Appendix: Meter Lot Numbers

Product Name	TRUEbalance	TRUEtrack
Finished Goods Lot Numbers	KK0468	KJ0731
	KL01079	KK0964
	KM0337TI	KL01213
	KN1834TI	KL01233-3TI
	KN1973TI	KL0267-10
	KN2074TI	KL0381-14
	KN2089TI	KL0637-2TI
	KN2090TI	KL0716TI
	KN2102TI	KL0860TI
	KP0047TI	KP0074TI
	KP0076TI	
	KP0128TI	
	KP0925TI	