

## URGENT PRODUCT RECALL

Notification of the New Requirement for increased replacement of the power pack in your D-TRONplus Insulin Pump – Every 2 Weeks

### Disetronic D-TRONplus Power Packs

This notification applies to all Disetronic D-TRONplus Power Packs:

Reference # BAT04697014001 and BAT3000813

---

#### Issue

Disetronic is conducting this recall of Disetronic D-TRONplus Power Packs because the power packs for the D-TRONplus insulin pumps have a potential to shut down the pump without warning. The battery's design was changed by its manufacturer. As a result, the pump does not have enough time to recognize the power supply decrease, and the pump may shut down before the audible and vibrating low power alarms are triggered. This can lead to an interruption of insulin delivery, which may lead to uncontrolled diabetes mellitus, resulting in elevated blood glucose levels (hyperglycemia). In the event that insulin delivery is interrupted, it is possible that patients may experience adverse events, which may result in serious patient injury and/or death. Adverse events may range from nausea and vomiting to diabetic ketoacidosis and coma.

#### Warning

**Until further notice, you must put a new power pack into your insulin pump every two weeks to prevent your pump from turning off without any warning. It is important you do not extend the two week period.**

Disetronic will supply power packs free of charge to all D-TRONplus users until corrective actions have been implemented. Every user is receiving, via Disetronic directly or from their distributor, a power pack together with detailed instructions by UPS Next Day shipment. Disetronic and their distributors will also provide every user with a new power pack and instructions every two weeks until further notice. Distribution of these power packs will begin today, Thursday, July 13, 2006. If you are a physician or a patient who has experienced a problem with any Disetronic D-TRONplus Power Packs, please notify Disetronic at 1-800-688-4578.

If your D-TRONplus insulin pump shuts down without warning please replace your power pack and call Disetronic Medical Systems Pump Support at 1-800-688-4578 as soon as possible.

This is a temporary fix for the power pack problem until adequate supplies of the corrected power pack design are available for shipment. We will notify all users when this situation is resolved and when the new power packs are available. We have performed testing and maintain results to verify a two week power pack life for this temporary fix.

For any questions regarding this recall or this notification you may call Disetronic Medical Systems Pump Support at 1-800-688-4578.

- Actions Required**
- Closely monitor your D-TRONplus insulin pump to ensure that it is adequately delivering insulin.
  - Continue to use your D-TRONplus insulin pump, but remember to put a new power pack into your D-TRONplus insulin pump every two weeks until further notice. Do not use the power pack for more than two weeks.
  - **If you have been using your current power pack for two or more weeks, immediately replace the power pack.**
  - Follow the power pack replacement instructions sent to you with each power pack.
  - If your D-TRONplus insulin pump shuts down without warning please replace your power pack and call Disetronic Medical Systems Pump Support at 1-800-688-4578 as soon as possible.
  - If you experience an interruption of insulin delivery and/or any changes in your medical condition, particularly changes in your glucose levels, please follow your healthcare provider's instructions for alternative insulin delivery methods and blood glucose monitoring. Then, notify your healthcare provider.
  - If you are unable to contact your healthcare provider, contact your local emergency hotline or seek medical attention at an emergency room as soon as possible.
  - File this Urgent Product Recall for future reference.
- 

**Additional Information**

Please check glucose levels throughout the day as instructed by your Healthcare Professional/Provider. Interruption of insulin delivery for this or any other reason may lead to uncontrolled diabetes mellitus, which may result in elevated blood glucose levels (hyperglycemia). Indicative signs and symptoms may include, but are not limited to the following:

- Nausea/Vomiting
- Blurred Vision
- Excessive Thirst or Hunger
- Frequent Urination
- Fatigue/Tiredness/Sleepiness
- Headache
- Fruity acetone breath
- Abdominal Pain
- Diabetic Ketoacidosis
- Coma

If you experience these symptoms, please check your blood glucose to ensure that it is within an acceptable range as defined by your healthcare team. Please notify your healthcare provider and seek medical attention as soon as possible.

---

**Questions**

This Urgent Product Recall is being made with the knowledge of the Food and Drug Administration (FDA). If you have experienced a problem with any of the Disetronic D-TRONplus Power Packs, please send a report to FDA's MedWatch program and to Disetronic. See <http://www.fda.gov/medwatch/> for filing information or call 1-800-FDA-1088 (1-800-332-1088). If you have further questions about the information contained in this Urgent Product Recall, please contact Pump Support at 1-800-688-4578, 24 hours a day, 365 days a year.

---