

Disetronic Medical Systems, Inc.

5151 Program Avenue
St. Paul, MN 55112-1014
800-280-7801
763-795-5200
Fax 763-795-5300
www.disetronic-usa.com



03-123
07/24/03

URGENT!
Product Correction and Removal
On Your D-TRONplus Insulin Pump

Issues

The Food and Drug Administration (FDA) inspected our insulin infusion pump manufacturing facility and determined that our manufacturing processes are not in substantial compliance with the regulations. In the absence of compliance with these regulations, the reliability of devices cannot be assured, which could potentially result in problems with the product leading to over and/or under infusion of insulin. Based on our discussions with the FDA and our evaluation of the observations, we have decided not to ship D-TRONplus insulin pumps to any new customers until we have improved our manufacturing processes to adequately ensure the reliability of our pumps for their intended use. Some of the problems that have been reported include stuck piston rods and punctured buttons. Pumps that do not perform reliably as expected may lead to hypoglycemic or hyperglycemic events, the symptoms and actions for these possible events are described on page three of this letter.

The FDA has asked that we inform you of the problems with this pump so that you can make an informed decision regarding the continued use of your D-TRONplus pump. If you wish to discontinue use of your pump, have your pump replaced, or have questions regarding your pump, please refer to the "Actions" section of this letter.

Important Information

Please review the following information carefully.

Stuck Piston Rod



Warning

A stuck piston rod can cause under delivery of insulin, resulting in hyperglycemia. Anytime you have an unexplained high blood sugar, or with any reading over 300 mg/dL on an insulin pump, take a second reading to confirm the result. If the result is still high, suspect an insulin delivery problem. If there is a clear reason for the high reading, follow the advice of your healthcare provider and recheck your sugar in one hour to ensure it is being corrected.



NOTE

If the piston rod sticks, an "Alert A4:Cartridge/Adapter Alert" or an "Error E6: Mechanical Error" message may be given. If this occurs, you could get a high glucose reading.

over...

 D-TRONplus

Important Information, cont.

If there is no clear reason for the high glucose reading, or the second blood sugar remains high:

1. Check for pump or site-related problems. This can be done by following the procedure in the D-TRONplus Reference Manual, 4.5 Prime the infusion set.
2. Check your blood or urine for ketones. Ketones suggest you have a problem with insulin delivery from your pump or a serious illness. If you have ketones present, contact your healthcare provider. If you suspect a problem with your pump, please call 1-800-688-4578.

Punctured Key(s)

A punctured key is one with a crack or hole in the key pad. Punctured keys can result from using a sharp item or your fingernails when pressing the key pad.

If you decide to continue using your D-TRONplus pump, we would like to make you aware that punctured keys can allow water to enter your pump. You must not use a pump with punctured keys in or around water.



We would like to remind you to never press any key on your pump with a sharp item or with your fingernails. Only use the pad of your finger to prevent puncturing the keys. Punctured keys can allow water to enter the pump.



If your D-TRONplus pump has punctured keys, avoid any contact with water as your pump may or may not alarm if water has entered the pump. If you obtain an “Error E7: Electronic Error” and you detect water in your pump or it has been exposed to water, DO NOT follow the instructions in the D-TRONplus pump reference manual. Instead, call the number on the back of your pump to arrange for a replacement.

For your convenience, we are including pages copied from the D-TRONplus Reference Manual describing the alarms mentioned above and the corrective actions.

Precautions

If your pump has punctured keys avoid contact with water and contact us to arrange for a replacement. If your pump has punctured keys and has been in contact with water or if you detect water in the pump casing, discontinue use of your pump and take the following steps:

- Measure your blood glucose value immediately and correct it, if necessary, using an insulin injection or your backup insulin pump.
- If you are unable to correct your blood glucose value, contact your healthcare provider immediately or get transportation to the nearest emergency room.
- If you are able to correct your blood glucose value, continue therapy with your backup insulin delivery device and follow the instructions for returning your pump. If you are unsure if your blood glucose is correct, call your healthcare provider.
- Call the toll-free number (1-800-688-4578) on the back of your pump for troubleshooting help or to make arrangements to return your D-TRONplus for inspection or replacement.

Backup System

You should always have insulin and syringes on hand as a backup to your insulin pump. If you do not have these supplies, please contact your healthcare provider for a prescription and obtain these supplies. If you purchased a two-pump system and are still awaiting a second pump, we will not be able to ship your second pump until we have completed certain corrective actions in our manufacturing process. When we have pumps available to ship, we will contact you to arrange shipment.

Symptoms of Hypoglycemia and Hyperglycemia

Symptoms of hypoglycemia include:

- Shakiness
- Dizziness
- Sweating
- Hunger
- Headache
- Pale skin color
- Seizure
- Difficulty paying attention
- Confusion
- Clumsy or jerky movements
- Tingling around mouth
- Sudden moodiness or behavior changes, such as crying for no apparent reason

Symptoms of hyperglycemia include:

- Fatigue/drowsiness
- High levels of sugar in the urine
- Increased thirst
- Frequent urination

Actions

- You should always have insulin and syringes on hand as a backup to your insulin pump.
- If you are experiencing any of the symptoms described above, please contact your healthcare provider.
- Review this information carefully.
- Inspect your pump for punctured keys and the presence of water.
- If water is present refer to the Precautions section of this communication for the appropriate course of action.
- If you find punctured keys, call the number on the back of your pump to arrange for a replacement.
- We will continue to provide you with any pump service you may require, as well as all of your infusion set and other disposable needs.
- If you experience any problem with your pump, promptly inform us by calling 1-800-688-4578, available 24 hours a day.
- **Continue your daily regimen of blood glucose monitoring and insulin dosage per your healthcare provider's orders.**
- **If you wish to discontinue use of your pump, have your pump replaced, or have questions or concerns regarding the continued use of your pump or about this letter, please call 1-800-281-1986, Monday through Friday, 7:00 AM to 7:00 PM CDT (8:00 AM to 8:00 PM EDT).**
- We have also included answers to frequently asked questions on our website (www.disetronic-usa.com).

Questions

We deeply regret any inconvenience this situation may cause. This notification is being made with the knowledge of the Food and Drug Administration (FDA). Please contact us at 1-800-281-1986 if you have questions about the information contained in this communication.

7.1.4 Alert A4: Cartridge/Adapter Alert

The unique pressure sensor of your D-TRONplus continuously measures the pressure on the cartridge plunger. This feature determines whether a cartridge is present in the cartridge compartment and whether the adapter is properly connected. The adapter itself features a valve which prevents uncontrolled delivery of insulin. If this valve is damaged, an "Alert A4: Cartridge/Adapter Alert" occurs.

If the insulin delivery is impaired by a leak in the cartridge or in the adapter, an "Alert A4: Cartridge/Adapter Alert" occurs.




This alert also occurs when your D-TRONplus is started and no cartridge is in the cartridge compartment, when the adapter is connected incorrectly, the piston rod is not in contact with the cartridge plunger or the piston rod is accidentally returned.



Warning: If an "Alert A4: Cartridge/Adapter Alert" occurs, check your blood glucose level, because insulin delivery may have been interrupted for several hours. If your blood glucose level is high, take the appropriate actions according to your health care team's instructions.



With a disconnectable infusion set do the following:





1. Silence and confirm the alert by pressing  twice.
2. **Check your blood glucose level. If it is high, take the appropriate actions according to your health care team's instructions.**
3. Disconnect the infusion set from the site.
4. *If no cartridge is in the cartridge compartment:*
Remove the adapter and infusion set tubing from your D-TRONplus.
Set up your D-TRONplus with a new cartridge, adapter and infusion set tubing. Be sure to prime the infusion set.
Please refer to section 4 "Prepare the cartridge and attach the adapter and infusion set" for further information.
When finished, reconnect the infusion set tubing and put your D-TRONplus into **RUN** (press  and ).
5. *If the adapter is connected incorrectly (with inserted cartridge):*
Remove the adapter and infusion set tubing from your D-TRONplus.

Set up your D-TRONplus with a new adapter and infusion set tubing. Be sure to prime the infusion set.

Please refer to section 4 "Prepare the cartridge and attach the adapter and infusion set" for further information.

When finished, reconnect the infusion set tubing and put your D-TRONplus into **RUN** (press  and ).

6. *If the piston rod is accidentally returned or not in contact with the cartridge plunger (with correctly connected adapter):*
Prime until the piston rod reaches the cartridge plunger, reconnect your infusion set tubing and put your D-TRONplus into **RUN** (press  and ).



7. *If the cartridge is leaking (with piston rod in position):*
Remove the cartridge, adapter and infusion set tubing from your D-TRONplus.

If the cartridge is broken or leaking, clean and dry the cartridge compartment of your D-TRONplus.

Please refer to section 10.2.2. "Your D-TRONplus" for further information.

Set up your D-TRONplus with a new cartridge, adapter and infusion set tubing. Be sure to prime the infusion set.

Please refer to section 4 "Prepare the cartridge and attach the adapter and infusion set" for further information.

When finished, reconnect the infusion set tubing and put your D-TRONplus into **RUN** (press  and ).





Caution: Broken cartridges can cause injury (glass splinters).










Insulin is recognizable by its unique smell due to its preservatives, therefore, a defective cartridge may be recognized by smelling for leaking insulin in the cartridge compartment.



8. *If the adapter is leaking (with undamaged cartridge):*
Remove the adapter and infusion set tubing from your D-TRONplus.

Set up your D-TRONplus with a new adapter and infusion set tubing. Be sure to prime the infusion set.
Please refer to section 4 "Prepare the cartridge and attach the adapter and infusion set" for further information.
When finished, reconnect the infusion set tubing and put your D-TRONplus into **RUN** (press  and .

With a non-disconnectable infusion set do the following:



1. Silence and confirm the alert by pressing  twice.
2. **Check your blood glucose level. If it is high, take the appropriate actions according to your health care team's instructions.**
3. Remove the infusion set from the site.
4. *If no cartridge is in the cartridge compartment:*
Remove the adapter and infusion set from your D-TRONplus. Set up your D-TRONplus with a new cartridge, adapter and infusion set. Be sure to prime the infusion set.
Please refer to section 4 "Prepare the cartridge and attach the adapter and infusion set" for further information.
When finished, put your D-TRONplus into **RUN** (press  and .
5. *If the adapter is connected incorrectly (with inserted cartridge):*
Remove the adapter and infusion set from your D-TRONplus. Set up your D-TRONplus with a new adapter and infusion set. Be sure to prime the infusion set.
Please refer to section 4 "Prepare the cartridge and attach the adapter and infusion set" for further information.
When finished, put your D-TRONplus into **RUN** (press  and .
6. *If the piston rod is accidentally returned or not in contact with the cartridge plunger (with correctly connected adapter):*
Remove the infusion set from your D-TRONplus. Set up your D-TRONplus with a new infusion set. Be sure to prime the infusion set.
Please refer to section 4 "Prepare the cartridge and attach the adapter and infusion set" for further information.
When finished, put your D-TRONplus into **RUN** (press  and .



7. *If the cartridge is leaking (with piston rod in position):*
Remove the cartridge, adapter and infusion set from your D-TRONplus.
If the cartridge is broken or leaking, clean and dry the cartridge compartment of your D-TRONplus.
Please refer to section 10.2.2 "Your D-TRONplus" for further information.
Set up your D-TRONplus with a new cartridge, adapter and infusion set. Be sure to prime the infusion set.
Please refer to section 4 "Prepare the cartridge and attach the adapter and infusion set" for further information.
When finished, put your D-TRONplus into **RUN** (press  and .



Caution: Broken cartridges can cause injury (glass splinters).



Insulin is recognizable by its unique smell due to its preservatives, therefore, a defective cartridge may be recognized by smelling for leaking insulin in the cartridge compartment.

8. *If the adapter is leaking (with undamaged cartridge):*
Remove the adapter and infusion set from your D-TRONplus. Set up your D-TRONplus with a new adapter and infusion set. Be sure to prime the infusion set.
Please refer to section 4 "Prepare the cartridge and attach the adapter and infusion set" for further information.
When finished, put your D-TRONplus into **RUN** (press  and .

If the "Alert A4: Cartridge/Adapter Alert" occurs again, repeat the process and only use new disposables (cartridge, adapter, infusion set). If the "Alert A4: Cartridge/Adapter Alert" occurs again despite the use of new components, please contact Disetronic Pump Support.

7.2.6 Error E6: Mechanical Error

With every insulin delivery (every 3 minutes), with every change of operating status and with each return of the piston rod, the safety system of your D-TRONplus reviews all mechanical parameters. If a mechanical error is discovered during this process, the insulin delivery is stopped and an "Error E6: Mechanical Error" occurs.

Do the following:



1. Silence and confirm the error by pressing twice.
2. Remove or disconnect your infusion set from the site.
3. Remove the cartridge, adapter and infusion set (tubing) from your D-TRONplus.
4. Return the piston rod.
Make sure that the piston rod has returned completely. If it has not, perform this function again.
5. Set up your D-TRONplus with a new cartridge, adapter and infusion set (tubing).
Please refer to section 4 "Prepare the cartridge and attach the adapter and infusion set" for further information.
6. When finished, (reconnect the infusion set tubing and) put your D-TRONplus into **RUN** (press and).

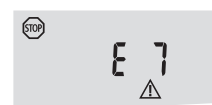
Repeat these steps if "Error E6: Mechanical Error" occurs again. Should "Error E6: Mechanical Error" occur a third time in spite of these actions, contact your doctor or health care team for an alternate therapy plan. Contact Disetronic Pump Support for further assistance.

7.2.7 Error E7: Electronic Error

The safety system of your D-TRONplus continuously monitors the functioning of your D-TRONplus. If an error is discovered, the insulin delivery is stopped and an "Error E7: Electronic Error" occurs.

If the display is damaged, it may not show the error code, however, your D-TRONplus beeps and vibrates.

Do the following:



1. Remove or disconnect your infusion set from the site.
2. Remove the PowerPack, insert it again after a few seconds.
Please refer to section 3.1.1 "Insert the PowerPack" for further information.
3. Reconnect your infusion set or insert a new one.
Please refer to section 5.5 "Change the infusion set " for further information.
4. When finished, put your D-TRONplus into **RUN** (press and .



Caution: The piston rod may return after the insertion of the PowerPack. If this occurs and you are using a disconnectable infusion set, disconnect your infusion set, prime and reconnect. If this occurs and you are using a non-disconnectable infusion set, change the infusion set. Please refer to section 5.5 "Change the infusion set" for further information.

If "Error E7: Electronic Error" occurs during programming (i. e. basal rate, time and date) check your parameters after changing the PowerPack.

If "Error E7: Electronic Error" occurs again, contact your doctor or health care team for an alternate therapy plan. Contact Disetronic Pump Support for further assistance.