



July 2, 2013

Medtronic Reference: FA586

Dear Medtronic Paradigm Insulin Infusion Pump User:

This letter is to notify you that Medtronic MiniMed is voluntarily recalling certain manufacturing lots of model MMT-326A and MMT-332A insulin reservoirs used with our Paradigm insulin pumps. We are recalling these reservoirs due to the potential that reservoirs from these lots are at increased risk for leaking. A leak in the reservoir may result in delivery of less insulin than intended and, if there is an occlusion in the infusion set, the pump may not alarm.

Our investigation has indicated that this increased potential for reservoir leakage is related to abnormal wear of a manufacturing tool involved in the production of a component used in the affected lots of reservoirs. We have implemented additional testing and inspection steps to ensure that currently produced reservoirs will not be subject to this problem.

Recommended Actions

It is important that you check the lot numbers of any MMT-326A and MMT-332A reservoirs in your possession against the lot numbers listed on the page attached to this letter. For your convenience, you may also enter reservoir lot numbers at the following website (<http://www.medtronic-diabetes.info>) to confirm whether or not your reservoirs are included in this recall.

- If you only have reservoirs with a lot number listed on the page attached to this letter, do not use these reservoirs. We recommend that you switch to your back-up insulin injection plan according to the direction of your health care provider until you receive new reservoirs. We would like to emphasize the importance of testing your blood glucose levels at least four times per day as stated in the recommendation of the pump user guide.
- If you do have reservoirs with a lot number **not listed** on the page attached to this letter, then you should only use these reservoirs because these are not affected by this recall.
- Any unused reservoirs included in this recall should be returned to your supplier or, if it is easier for you, you should return the part of the box showing the barcode lot number as shown in the below picture and discard the affected reservoirs.
- Please note that we will replace all reservoirs from the affected lots at no cost to you. Please contact your supplier /and or Medtronic Representative : Tel 00 966 1 4646955 to ensure receiving replacement once you return them

A full list of questions and answers is included with this letter.



Risk to Health

Under-delivery of insulin can cause high blood sugar, which if untreated can lead to diabetic ketoacidosis. DKA is a serious condition that can cause severe health impact, including death. Symptoms of diabetic ketoacidosis may include nausea, vomiting, shortness of breath and excess thirst/urination. Contact your healthcare professional immediately if you are experiencing any of these symptoms.

In most cases, the impact of a leaking reservoir is limited to a temporary increase in glucose levels. We have received a small number of reports of patients being hospitalized for diabetic ketoacidosis as a result of insulin under-delivery due to the reservoir leaking.

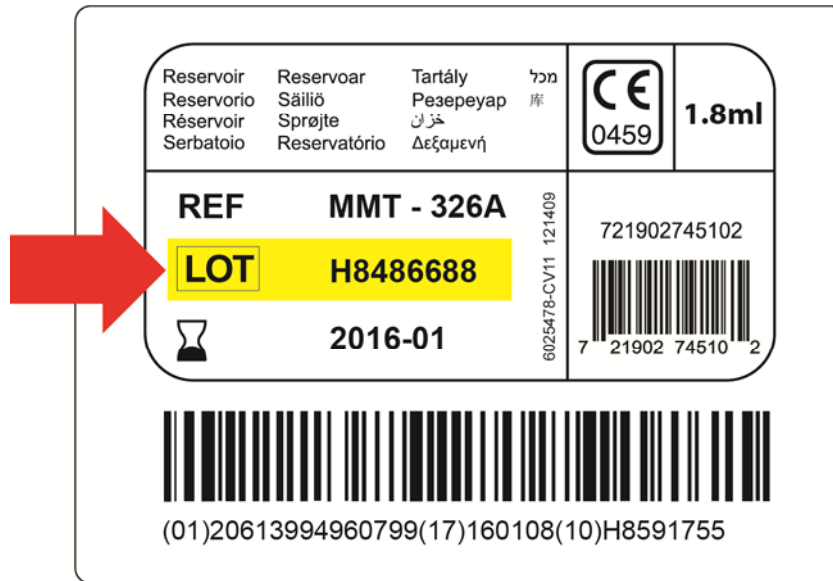
We apologize for any inconvenience this recall may cause you and we are here to assist you with any questions or concerns you may have. Medtronic has also sent a letter to your healthcare provider to inform him or her of this issue. If you would like more information, please contact Medtronic Representative . We appreciate your time and attention to this important notification.




Sincerely,

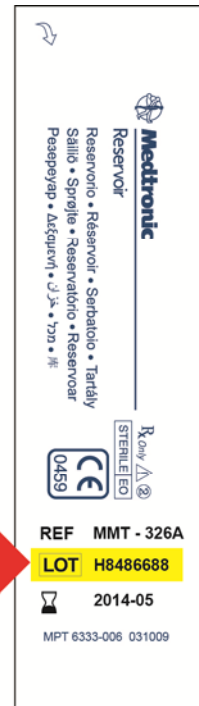
Lina Haffar
Business Manager, Middle East
Medtronic Diabetes


Lot Numbers of Recalled MMT-326A and MMT-332A Reservoirs


H8416432	H8461538	H8489386	H8512826
H8420977	H8463297	H8491921	H8515317
H8422490	H8464121	H8492449	H8517079
H8424676	H8467888	H8494645	H8521052
H8437486	H8469703	H8496561	H8539013
H8441420	H8471745	H8500423	H8541843
H8442973	H8473106	H8500472	H8584244
H8451531	H8473271	H8503372	H8627745
H8452933	H8476270	H8503728	H8603292
H8455959	H8478398	H8509305	H8604958
H8457716	H8485398	H8510440	H8635301
H8459557	H8486688	H8512566	




Reservoir Reservorio R�servoir Serbatoio	Reservoar S�illi� Spr�jtte Reservat�rio	Tart�ly Pezepayap ﺧﺰن Δεξαμεν�	מכל 库	 0459	1.8ml
REF MMT - 326A		6025478-CV11 121409		721902745102	
LOT H8486688		2016-01			
					
(01)20613994960799(17)160108(10)H8591755					




Reservoir
 Reservorio • Reservoir • Serbatoio • Tartaly
 S illi  • Spr jtte • Reservat rio • Reservoar
 Pezepayap • Δεξαμεν  • ﺧﺰن • 库 • #


 0459

REF MMT - 326A
LOT H8486688
 2014-05
 MPT 6333-006 031009

QUESTIONS AND ANSWERS REGARDING THE RESERVOIR RECALL

Q1. Why is Medtronic recalling certain manufacturing lots of model MMT-326A and MMT-332A insulin reservoirs?

- A. We are recalling these reservoirs due to the potential that reservoirs from these lots are at increased risk for leaking. A leak in the reservoir may result in delivery of less insulin than intended and, if there is an occlusion in the infusion set, the pump may not alarm.

Q2. Has Medtronic stopped shipping affected lots of reservoirs?

- A. Yes, we are no longer shipping reservoirs with the affected lot numbers.

Q3. Does this recall affect all Medtronic reservoirs?

- A. No. Only the reservoirs with the lot numbers listed in this letter are affected by the recall. All Medtronic reservoirs other than these impacted lot numbers are fine and safe to use.

Q4. What solution is Medtronic providing to its customers?

- A. Medtronic will exchange all reservoirs with the unused lots for customers who have received them at no cost to you, and will make that process as easy as possible for you.

Q5. Are the replacement reservoirs safe to use?

- A. Yes! We have implemented additional testing and inspection steps to ensure that currently produced reservoirs will not be subject to this problem. So you can feel perfectly comfortable using your replacement reservoirs.

Q6. May I wait a few days to change my reservoir? I just started using a reservoir from the affected lot and have a full insulin reservoir. I would prefer to use my insulin so I don't waste it.

- A. We recommend that you stop using your reservoir with the affected lot right away, even if you need to discard some insulin. Please know that we are making this recommendation for your safety. We recognize that there will be some insulin waste and deeply apologize for this situation.

PROCESS QUESTIONS

Q7. Should I return my unused reservoirs with the affected lot numbers?

- A. **yes please return the products with the affected lot numbers to your supplier and request replacements units or if it easier , you can discard the affected reservoir and return only the part of the box showing the barcorde /LOT Number and request replacement units .**

Q8. I have reservoirs from the affected lots. How do I get replacements for these reservoirs?

- A. Step 1) Stop using the reservoirs with affected lot numbers right away.
Step 2) Notify your supplier / provider and request replacement reservoirs:



Q9. Now that I've notified Medtronic that I need replacement reservoirs, how will I know when I will receive them?

- A. Please call your supplier or Medtronic Representative to know the status of your next replacement box.

Q10. Can I just throw away my unused reservoirs with the affected lot numbers?

- A. You need to notify Medtronic in order to process your replacement reservoirs. Refer to Q8 to get replacement for your unused reservoirs.

Q11. What if I don't have any unused reservoirs with the affected lot numbers?

- A. Please take a moment to notify us even if you don't have any unused reservoirs with the affected lot numbers. We need to confirm that you've received this notification because your safety is our top priority.