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www.medtronic.co.uk
Telephone: 01923 212213
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Urgent Field Safety Notice

Potential for Over or Under Delivery of Insulin if Insulin or Other Fluids Contact the Inside of Medtronic Paradigm Tubing connectors

June, 2013

Medtronic Reference: FA577

Dear Healthcare Professional,

The purpose of this letter is to notify you that Medtronic Diabetes has become aware of a potential safety issue that can occur if insulin or other fluids come in contact with the inside of the connector on Medtronic Paradigm infusion sets. This letter also provides information on how to prevent this from occurring.

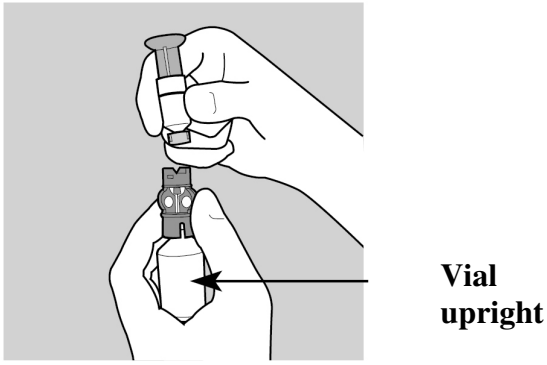
Medtronic kindly ask you to inform Paradigm pump users using the enclosed letter.

Exposure of the inside of the tubing connector to fluid is most likely to occur if insulin is spilled on the top of insulin reservoir when the reservoir is removed from the transfer guard after filling the reservoir from a vial of insulin. If this occurs, the insulin can temporarily block the vents in the connector that allow the pump to properly prime. If these vents are blocked, this can potentially result in too much or too little insulin being delivered, which may cause hypoglycemia or hyperglycemia, which, in extreme cases, may cause loss of consciousness or death.

The information in this letter applies to all Medtronic infusion sets designed for use with Medtronic Paradigm family infusion pumps. The specific model numbers affected are listed at the end of this letter. Please note that the potential for temporary blocking of the infusion set vents can be avoided by not applying liquid to make contact with the inside of the tubing connector and following the recommended reservoir filling procedure with careful attention to the information provided below.

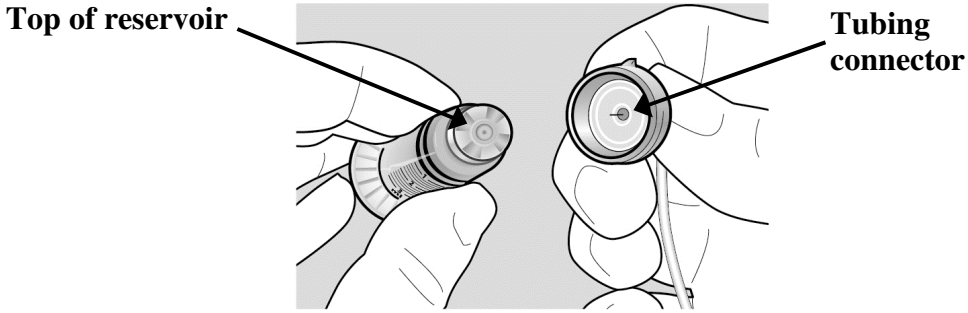
Below are the recommendations to patients to prevent fluid from blocking the connector vents:

1. After filling the reservoir, make sure the vial of insulin is held upright when removing the reservoir from the blue transfer guard. This prevents insulin from accidentally getting on the top of the reservoir, which could transfer liquid into the tubing connector.



Hold insulin vial upright when removing reservoir.

2. If any liquid (such as insulin, isopropyl alcohol, or water) gets on the top of the reservoir or inside the tubing connector, start over with a new reservoir and infusion set.



Make sure these are dry when connecting.

How to recognize that the infusion set vents may be blocked

If you notice anything unusual during the infusion set prime process such as the insulin continuing to drip from the infusion set cannula when the manual prime has been completed, this may indicate that the connector vents are not working properly. If this occurs, do not insert the infusion set and call the HelpLine immediately for additional assistance.

In addition to providing this communication to current users of Medtronic Paradigm insulin pumps, we are also updating the instructions for use to include this information on how to avoid temporary blocking of the infusion set vent membranes due to exposure to fluid.

The Medicines and Healthcare products Regulatory Agency (MHRA) has been notified of this action.

This notice needs to be passed on all those who need to be aware within your organization.

We deeply apologize for any disruption this may cause your practice. Please know, patient safety is our top priority. Feel free to contact your local Medtronic Health Care Professional or phone Medtronic Product Support on 01923 205 167 option 1 if you have any questions or concerns. We appreciate your time and attention to this important notification, and thank you for continuing to put your trust in Medtronic.

Yours sincerely,

LJ Bridge

Lezlie Bridge BSc. DMS
Regulatory Affairs Manager – UK & Ireland

Enclosure: - Letter: Dear Paradigm Insulin Pump User

This field notification involves models MMT-317, MMT-318, MMT-324, MMT-325, MMT-312S, MMT-312L, MMT-386, MMT-387, MMT-394, MMT-396, MMT-397, MMT-398, MMT-399, MMT-377, MMT-378, MMT-381, MMT-382, MMT-383, MMT-384, MMT-368, MMT-862, MMT-864, MMT-866, MMT-874, MMT-876, MMT-884, MMT-886, MMT-921, MMT-923, MMT-925, MMT-941, MMT-943, MMT-945, MMT-961, MMT-963, MMT-965, & MMT-975 Paradigm infusion sets.

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Urgent Field Safety Notice

Recall of Certain Lots of Medtronic MiniMed Model MMT-326A and MMT-332A Insulin Reservoirs

July 2013

Medtronic Reference: FA586

Dear Distributor Partner /Dear Health Care Institutions:

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.

We have confirmed that any affected lots that were sold to distributor partners were shipped between 31 October 2012 through 17 June 2013.

Letters describing this potential safety issue have to be sent to Healthcare Professionals (HCP), Certified Product Trainers (CPT) and Paradigm insulin infusion pump users for which Medtronic knows the address.

As a distributor of our Medtronic Paradigm insulin infusion pumps and accessories, we request that you assist us with this important effort by sending this notification to all your Paradigm pump users.

Required actions:

It is important that you check the lot numbers of any MMT-326A and MMT-332A reservoirs in your inventory 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.

- **Check your current on stock inventory for any reservoirs with an affected lot number,** the list of affected lot numbers is included in the attached Dear Pump User Letter. Please immediately separate these from your other inventory; do not send these to customers. We will provide a credit to your account for these affected products on hand.

- **Information to Paradigm pump users:**

    - For Paradigm pumps users that received as their last shipment an affected lot, we recommend that you send them a new box of reservoirs together with the letter. Use the attached Dear Pump User letter V1 to inform those pump users. **Only use this option if you have full traceability to pump user level.**
    - For all other pumps users, please inform them by using the attached Dear Pump User letter V2 and using registered mail.
    - If you have not yet informed Paradigm pump users and HCP of our previous Field Safety Corrective Action (FSCA) our ref. FA577, please consider to combine both communications. In this case, a cover letter needs to be included in to the envelope referring to the two FSCA. See attached.

- **Information to HCP letter and CPT:** use the attached Dear HCP Letter to inform them of the issue as a courtesy.
- **Return of affected reservoirs: contact your local sales office for the return of all affected reservoirs from your inventory**
- **Confirm completion of the above actions by returning the attached Field Action Confirmation Sheet to**: Lisa.stanley@medtronic.com or fax to 01923 225 273.

In the event you have not distributed these devices directly to pump users or Healthcare Professionals but to another distributor, please forward this information to said distributor.

The Medicines and Healthcare products Regulatory Agency (MHRA) has been notified of this action. This notice needs to be passed on all those who need to be aware within your organization.

Thank you in advance for your cooperation. If you have any additional questions, please do not hesitate to contact 01923 205 167, option 1.

Yours sincerely,

LJ Bridge

Lezlie Bridge BSc. DMS
Regulatory Affairs Manager – UK & Ireland

Enclosures
Dear Pump User Letter V1
Dear Pump User Letter V2
Dear Healthcare Professionals Letter
Cover Letter combining FA577 and FA586 for Pump User
Cover Letter combining FA577 and FA586 for HCP
Field Action Confirmation Sheet

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July, 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.

Enclosed, please find a box of new unaffected reservoirs free of charges that you should use.

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 discarded.

- Instructions how to obtain replacement reservoirs are provided on the following pages, and is also explained on our website at http://www.medtronic-diabetes.info. Please note that we will replace all reservoirs from the affected lots at no cost to you.

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.

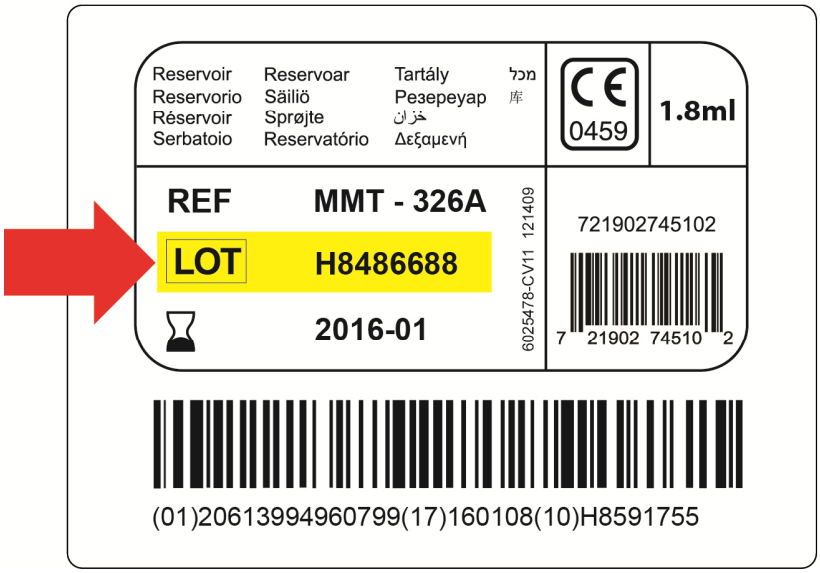
We apologize for any inconvenience this recall may cause you and we are here to assist you with any questions or concerns you may have. Medtronic has also sent a letter to your healthcare provider to inform him or her of this issue. Please feel free to visit our website at http://www.medtronic-diabetes.info or contact our Helpline at 01923 205 167 option 1 if you would like more information. We appreciate your time and attention to this important notification.

Yours sincerely,

Lezlie Bridge BSc. DMS
Regulatory Affairs Manager – UK & Ireland

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	



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. No, you do not need to return the reservoirs with the affected lot numbers. Any unused reservoirs included in this recall should be discarded.

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 01923 205 167 option 1 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.

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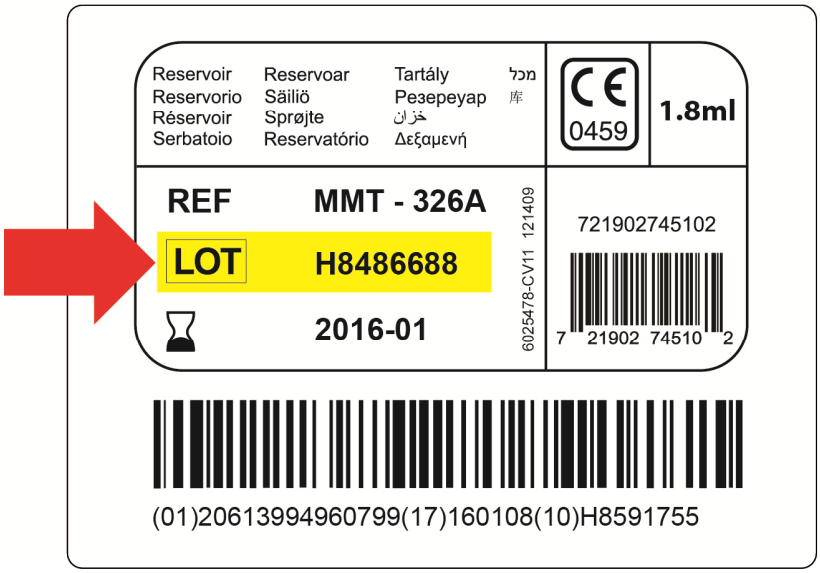
H8437486	H8469703	H8496561	H8539013
H8441420	H8471745	H8500423	H8541843
H8442973	H8473106	H8500472	H8584244
H8451531	H8473271	H8503372	H8627745
H8452933	H8476270	H8503728	H8603292
H8455959	H8478398	H8509305	H8604958
H8457716	H8485398	H8510440	H8635301
H8459557	H8486688	H8512566	



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