Medtronic International Ltd.
49 Changi South Avenue 2
Singapore 486056
Tel. +65 6436 5000
Fax +65 6776 6355
www.medtronic.com

Medical Device Recall Notification Letter
Medtronic MiniMed Infusion Sets
Potential Over-Delivery of Insulin

12 September 2017

Dear Health Care Provider:

The purpose of this letter is to notify you that we are voluntarily recalling specific lots of infusion sets used with Medtronic insulin pumps.

Medtronic has become aware of recent reports of potential over-delivery of insulin shortly after an infusion set change that have required medical intervention. Our investigation has shown this can be caused by fluid blocking the infusion set membrane during the priming/fill-tubing process. A membrane blocked by fluid most likely occurs if insulin, alcohol, or water is spilled on the top of the insulin reservoir which then could prevent the infusion set from working properly. Infusion sets currently being shipped by Medtronic contain an enhanced membrane material that significantly reduces this risk.

We are informing your patients of this recall via email and/or registered mail and have asked them to do the following:

A. Patients have been instructed to go to https://checklots.medtronicdiabetes.com and determine if they have recalled infusion sets. The website will prompt them to enter the REF and LOT numbers for all infusion sets in their possession. The website will then tell them which infusion sets are part of this recall and which are not.

   The REF and LOT numbers are listed on the labels as shown in the below examples:

BOX LABEL

POUCH LABEL

B. Medtronic recommends that the recalled infusion sets are not used by patients.
   i. If they have new and enhanced infusion sets that are not part of this recall, they should use only those sets starting with their next set change. As a reminder, we have enclosed Key Steps regarding the priming/fill-tubing process.

   ii. If they only have recalled infusion sets right now, it is very important that they carefully follow the Key Steps.

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C. Patients have been instructed to return their recalled infusion sets and Medtronic will replace the recalled infusion sets free of charge.

Follow the process on the website at https://checklots.medtronicdiabetes.com. If you have additional questions, please refer to the enclosed Frequently Asked Questions. You can also contact your Medtronic representative or call us at (+65) 6439-6893.

Please complete and return the Physician/HCP Reply Form to your Medtronic representative or fax it to (+65) 6776 6355.

Medtronic considers patient safety and customer satisfaction our top priorities. We appreciate your time and attention in reading this important notification.

Sincerely,

[redacted]

Eunice Lee
Business Leader, South East Asia
Medtronic Diabetes

Enclosed:
Appendix A: KEY STEPS Infusion Set Priming / Fill-tubing Process
Appendix B: Physician/HCP Reply Form
Appendix C: Affected REF and LOT Numbers supplied in Singapore

CC: Chairman of Medical Board and relevant HoDs

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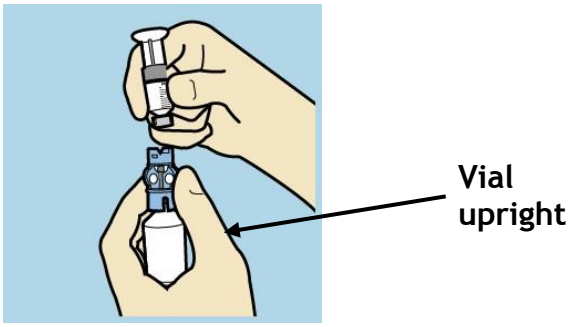
Appendix A: KEY STEPS
Infusion Set Priming / Fill-tubing Process

To avoid potential over-delivery of insulin shortly after an infusion set change

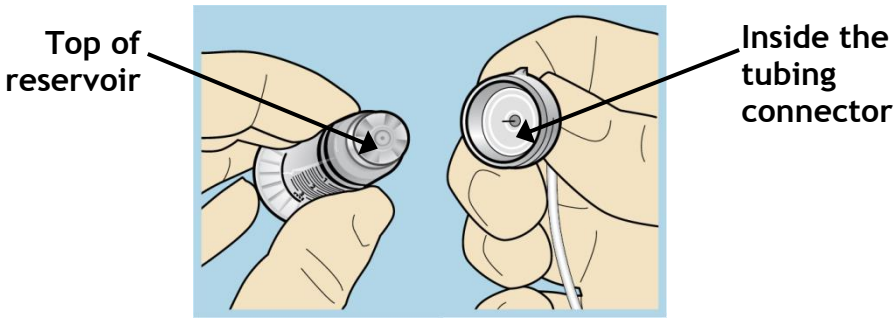
It is very important to follow the steps below to prevent fluid from getting on the infusion set membrane during the priming/fill-tubing process:

a) 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 be transferred onto the infusion set membrane.



Hold insulin vial upright when removing reservoir.

b) If any liquid (such as insulin, isopropyl alcohol, or water) gets on the top of the reservoir or inside the tubing connector, it can block the infusion set membrane. This may lead to increased pressure inside the pump's reservoir chamber during the priming/fill-tubing process. This may potentially lead to over-delivery of insulin shortly after the infusion set change. If liquid is visible on 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.

If you notice anything unusual after the priming/fill-tubing process, such as insulin continuing to drip or squirt from the infusion set cannula, do not insert. Start over with a new reservoir and infusion set.

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Best Practices for Changing Your Infusion Set Include:

- Do not change your infusion set before going to sleep so that you are able to monitor your glucose levels.
- As an extra precaution, check your blood glucose at 1 hour after your infusion set change in addition to your routine monitoring.

Following these best practices will allow you to identify potential hypoglycemia and hyperglycemia so you can take necessary action.

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Appendix B: PHYSICIAN / HCP REPLY FORM

Important information regarding the Recall of Medtronic MiniMed Infusion Sets

Potential Over-Delivery of Insulin

September 2017

Dear Physician / Healthcare Professional,

According to our records, you are currently managing physician for patients who are affected by the recall of Medtronic MiniMed Infusion Sets.

Should you have the affected lots in your possession, please complete the table below and return them to your Medtronic Representative:

REF	LOT numbers	# of Products Returned

Medtronic requires confirmation that you have received and understand the attached information regarding the Medtronic MiniMed Infusion Sets.

_____ _____

Confirm physician name (please print) ***Facility Name and Stamp***

_____ _____

Physician signature and stamp ***Date***

Please sign and date this form and return it to Medtronic immediately, providing any corrections to your contact information. Thank you.

Return this form (keep a copy for your records) to:

POSTAL MAIL: Medtronic International Ltd., 49 Changi South Avenue 2, Singapore 486056

FAX: +65 6776 6355

REF	LOT
MMT-864	5007430
MMT-381	5011173
MMT-864	5013807
MMT-866	5017113
MMT-864	5020537
MMT-864	5020539
MMT-864	5022231
MMT-866	5028964
MMT-864	5028965
MMT-864	5030899
MMT-864	5030944
MMT-864	5032625
MMT-866	5033395
MMT-876	5033401
MMT-864	5034326
MMT-864	5034331
MMT-381	5035645
MMT-381	5035708
MMT-864	5036354
MMT-864	5039579
MMT-866	5039879
MMT-864	5040158
MMT-381	5040167
MMT-381	5041853
MMT-381	5042472
MMT-381	5042473
MMT-377	5042575
MMT-864	5042580
MMT-377	5042715
MMT-864	5043094
MMT-864	5043095
MMT-381	5043407
MMT-876	5043426
MMT-381	5044102
MMT-377	5046462
MMT-864	5046640
MMT-876	5047179
MMT-381	5047504
MMT-866	5047583
MMT-381	5048109
MMT-866	5049124
MMT-381	5049552
MMT-381	5051363
MMT-382	5051365
MMT-866	5051563
MMT-378	5055347
MMT-381	5056652
MMT-381	5057788
MMT-876	5059553
MMT-864	5060206
MMT-381	5060844
MMT-864	5060948
MMT-381	5061645
MMT-394	5063644
MMT-378	5064853
MMT-378	5066631

REF	LOT
MMT-378	5066632
MMT-381	5067489
MMT-876	5070667
MMT-975	5072864
MMT-876	5076353
MMT-397	5077085
MMT-864	5077107
MMT-876	5077117
MMT-396	5078043
MMT-975	5078351
MMT-399	5079001
MMT-921	5079674
MMT-925	5079703
MMT-941	5079704
MMT-965	5079712
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MMT-975	5082275
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MMT-866	5084137
MMT-975	5084640
MMT-397	5084719
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MMT-399	5084744
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MMT-378	5085604
MMT-394	5085665
MMT-394	5085667
MMT-396	5086237
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MMT-399	5086919
MMT-965	5086977
MMT-965	5087592
MMT-396	5087785
MMT-397	5087815
MMT-397	5087823
MMT-941	5088389
MMT-397	5088652
MMT-397	5088653
MMT-381	5088662
MMT-866	5088976
MMT-876	5088979
MMT-876	5088980
MMT-378	5089246
MMT-864	5089777
MMT-975	5093162
MMT-399	5093727
MMT-399	5093730
MMT-399	5093736
MMT-397	5093777
MMT-876	5095007
MMT-921	5095068
MMT-866	5095230

REF	LOT
MMT-396	5095596
MMT-396	5095598
MMT-396	5095599
MMT-874	5095827
MMT-862	5096973
MMT-398	5097954
MMT-975	5097966
MMT-397	5098534
MMT-397	5098545
MMT-397	5098546
MMT-397	5098552
MMT-923	5099489
MMT-378	5099494
MMT-864	5099714
MMT-399	5100637
MMT-399	5100640
MMT-399	5100643
MMT-398	5103300
MMT-975	5103324
MMT-396	5103398
MMT-965	5103887
MMT-864	5105140
MMT-876	5105362
MMT-923	5105363
MMT-965	5105460
MMT-399	5105462
MMT-399	5105473
MMT-399	5105477
MMT-396	5108158
MMT-397	5108207
MMT-397	5108216
MMT-397	5108217
MMT-397	5108220
MMT-397	5108232
MMT-397	5108234
MMT-398	5108301
MMT-398	5108311
MMT-399	5108371
MMT-399	5108373
MMT-399	5108375
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MMT-381	5113201
MMT-397	5114141
MMT-876	5114176
MMT-941	5115443
MMT-396	5117839
MMT-862	5117946
MMT-876	5117948
MMT-866	5118920
MMT-975	5118933
MMT-975	5118945
MMT-866	5119225
MMT-381	5119288
MMT-876	5119918

REF	LOT
MMT-923	5119934
MMT-397	5122087
MMT-397	5122091
MMT-381	5122169
MMT-965	5123232
MMT-921	5123254
MMT-398	5123273
MMT-399	5123282
MMT-399	5123283
MMT-399	5123288
MMT-862	5127927
MMT-876	5127930
MMT-921	5127932
MMT-874	5129157
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MMT-381	5130780
MMT-396	5130894
MMT-398	5130957
MMT-398	5130963
MMT-397	5131560
MMT-397	5131565
MMT-399	5131629
MMT-399	5131631
MMT-399	5131632
MMT-399	5131637
MMT-876	5131852
MMT-965	5131868
MMT-382	5132364
MMT-397	5132578
MMT-864	5132945
MMT-923	5132952
MMT-923	5134550
MMT-965	5135142
MMT-943	5137371
MMT-382	5137383
MMT-864	5137410
MMT-975	5137568
MMT-397	5139911
MMT-397	5139913
MMT-397	5139917
MMT-397	5139918
MMT-864	5140267
MMT-399	5140423
MMT-381	5140434
MMT-925	5141470
MMT-399	5141482
MMT-399	5141485
MMT-398	5141521
MMT-975	5143135
MMT-397	5143522
MMT-397	5143547
MMT-397	5143549
MMT-397	5143551
MMT-397	5143552
MMT-397	5144227
MMT-397	5144228

REF	LOT
MMT-378	5144277
MMT-368	5144318
MMT-398	5146763
MMT-381	5147470
MMT-381	5148814
MMT-921	5148887
MMT-965	5148890
MMT-399	5149811
MMT-399	5149812
MMT-864	5149836
MMT-399	5149930
MMT-399	5149945
MMT-399	5149947
MMT-399	5149953
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MMT-965	5150484
MMT-975	5150486
MMT-864	5150585
MMT-864	5150586
MMT-941	5151276
MMT-965	5151306
MMT-381	5151822
MMT-876	5151828
MMT-397	5152576
MMT-862	5152957
MMT-941	5154656
MMT-874	5155459
MMT-876	5155460
MMT-965	5155467
MMT-876	5156262
MMT-381	5156830
MMT-381	5157191
MMT-975	5158204
MMT-378	5158221
MMT-378	5158222
MMT-864	5158841
MMT-396	5162132
MMT-399	5162186
MMT-876	5162196
MMT-943	5162236
MMT-399	5164624
MMT-399	5164626
MMT-394	5164691
MMT-394	5164692
MMT-397	5165447
MMT-397	5165449
MMT-381	5166041
MMT-397	5170632
MMT-397	5170721
MMT-399	5170741
MMT-399	5170742
MMT-399	5170747
MMT-399	5170750
MMT-381	5173070
MMT-381	5174428
MMT-381	5175268

REF	LOT
MMT-381	5175691
MMT-965	5177293
MMT-864	5178113

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Medical Device Recall Notification Letter
Medtronic MiniMed Infusion Sets
Potential Over-Delivery of Insulin

12 September 2017

Dear Valued Customer:

Because the safety of our customers is our top priority, we are voluntarily recalling specific lots of infusion sets used with Medtronic insulin pumps.

Explanation of the Issue

Medtronic has become aware of recent reports of potential over-delivery of insulin shortly after an infusion set change. Over-delivery of insulin can cause hypoglycaemia and in extreme cases, death. Medtronic has received reports of hypoglycaemia requiring medical intervention potentially related to this issue.

Our investigation has shown this can be caused by fluid blocking the infusion set membrane during the priming/fill-tubing process. A membrane blocked by fluid most likely occurs if insulin, alcohol, or water is spilled on top of the insulin reservoir which then could prevent the infusion set from working properly. Infusion sets currently being shipped by Medtronic contain a new and enhanced membrane material that significantly reduces this risk.

Actions Required by You

A. Go to https://checklots.medtronicdiabetes.com to determine if you have recalled infusion sets. You will be prompted to enter the **REF** and **LOT** numbers for all infusion sets in your possession. The website will then tell you which infusion sets are part of this recall and which are not.

Your **REF** and **LOT** numbers are listed on the labels as shown in the examples below:

BOX LABEL

POUCH LABEL

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B. Medtronic recommends you not use recalled infusion sets.
   i. If you have new and enhanced infusion sets that are not part of this recall, use only those sets starting with your next set change. As a reminder, we have enclosed Key Steps regarding the priming/fill-tubing process.

   ii. If you only have recalled infusion sets right now, **it is very important that you carefully follow the Key Steps.**

C. Return your recalled infusion sets within the next four weeks. Medtronic will replace the recalled infusion sets free of charge. For detailed information on returns, please refer to the following steps.

After identifying your recalled **REF** and **LOT** numbers:

Please send an email to rs.mdtdibsgsalesandsupport@medtronic.com or call us at (+65) 6439-6893 between 9am to 5pm on weekdays with the following information:

1. Your Name
2. Your Contact number
3. Product related information as below

REF	LOT Number	# of Products to be Returned

4. Preferred delivery date (weekdays)
5. Preferred delivery time (10am – 12pm or 2pm – 5pm)

We will respond with a delivery confirmation within one working day.

What if I have more questions?

Follow the process on the website at https://checklots.medtronicdiabetes.com. If you have additional questions, please refer to the enclosed Frequently Asked Questions or call Medtronic at (+65) 6439-6893.

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Medtronic considers patient safety and customer satisfaction our top priorities. We appreciate your time and attention in reading this important notification.

Sincerely,

[redacted]

Eunice Lee
Business Leader, South East Asia
Medtronic Diabetes

Enclosed:
Appendix A: KEY STEPS Infusion Set Priming/Fill-tubing Process
Appendix B: Frequently Asked Questions
Appendix C: Affected REF and LOT Numbers supplied in Singapore

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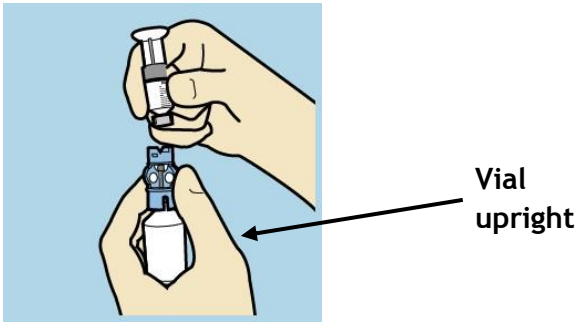
Appendix A: KEY STEPS
Infusion Set Priming / Fill-tubing Process

To avoid potential over-delivery of insulin shortly after an infusion set change

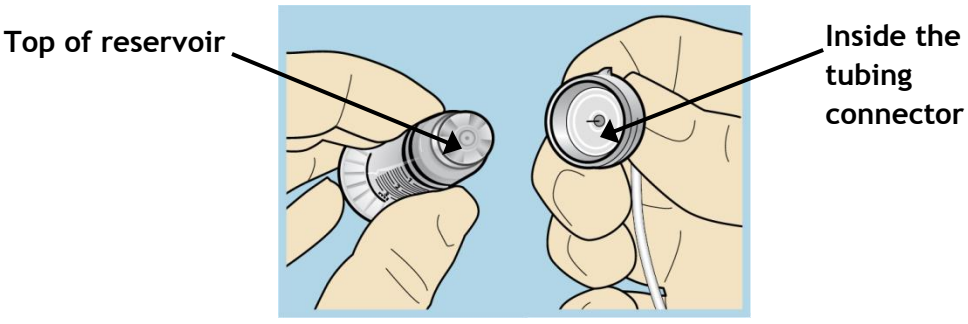
It is very important to follow the steps below to prevent fluid from getting on the infusion set membrane during the priming/fill-tubing process:

a) 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 be transferred onto the infusion set membrane.



Hold insulin vial upright when removing reservoir.

b) If any liquid (such as insulin, isopropyl alcohol, or water) gets on the top of the reservoir or inside the tubing connector, it can block the infusion set membrane. This may lead to increased pressure inside the pump's reservoir chamber during the priming/fill-tubing process. This may potentially lead to over-delivery of insulin shortly after the infusion set change. If liquid is visible on 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.

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If you notice anything unusual after the priming/fill-tubing process, such as insulin continuing to drip or squirt from the infusion set cannula, do not insert. Start over with a new reservoir and infusion set.

Best Practices for Changing Your Infusion Set Include:

- Do not change your infusion set before going to sleep so that you are able to monitor your glucose levels.
- As an extra precaution, check your blood glucose at 1 hour after your infusion set change in addition to your routine monitoring.

Following these best practices will allow you to identify potential hypoglycemia and hyperglycemia so you can take necessary action.

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Appendix B: Frequently Asked Questions

Q1. **Is this a recall?**

Yes, this is a voluntary recall because your safety is our top priority. We are notifying all customers along with their corresponding healthcare providers. You can check to see if your infusion sets are part of the recall by visiting https://checklots.medtronicdiabetes.com

Medtronic recommends that customers do not use and return any recalled infusion sets they have. Medtronic will replace the recalled infusion sets free of charge. Please be aware that the exchange process will take some time, as we need to build the necessary inventory while ensuring supply for ongoing use.

Q2. **What is better about the new infusion sets that will help prevent this issue?**

The new and enhanced infusion sets being shipped to customers now have a new membrane, and our investigation shows that this significantly reduces the likelihood of a blocked membrane during the priming/fill-tubing process.

Q3. **How common is this problem?**

Out of the millions of infusions sets sold every year, the reported incidence rate requiring medical assistance related to this issue is less than 1 in every 2 million infusion sets. The new and enhanced infusion sets being shipped today are not impacted by this recall. We are voluntarily issuing this recall to ensure that our customers have the best products and a good experience on insulin pump therapy.

Q4. **I am waiting for my replacement units to arrive. Can I continue to use the infusion sets from these recalled lots?**

We recommend that you do not use your recalled infusion sets and use only new and enhanced sets starting with your next infusion set change.

If you only have recalled infusion sets, **it is very important to carefully follow the instructions within the Key Steps** regarding the priming/fill-tubing process.

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Q5. **What do I do if I don't feel comfortable using the recalled infusion sets until the replacement sets arrive?**

You may choose to revert to your back-up injection plan according to your healthcare provider's directions until your new replacement infusion sets arrive.

Q6. **What do I do about ordering supplies?**

It is essential that you continue to order your infusion sets as you usually do, even if you are expecting replacement infusion sets. If you have a current supply order, do not cancel it.

Please note that replacement sets may take longer to receive than your normal shipments. You may not receive all your replacements at once. All infusion sets you receive moving forward will be new and enhanced.

Q7. **I do not have access to the website and I want to handle my returns over the phone.**

You can always call us at (+65) 6439-6893 to speak to a member of our team who can help arrange for your return and replacements.

Q8. **I want to receive training on how to prime my infusion set.**

Important information about how to prime your infusion set properly can be found in the Key Steps instructions included in your recall notification. In addition, Medtronic Diabetes has a host of online educational support that you can access at: https://www.medtronicdiabetes.com

REF	LOT
MMT-864	5007430
MMT-381	5011173
MMT-864	5013807
MMT-866	5017113
MMT-864	5020537
MMT-864	5020539
MMT-864	5022231
MMT-866	5028964
MMT-864	5028965
MMT-864	5030899
MMT-864	5030944
MMT-864	5032625
MMT-866	5033395
MMT-876	5033401
MMT-864	5034326
MMT-864	5034331
MMT-381	5035645
MMT-381	5035708
MMT-864	5036354
MMT-864	5039579
MMT-866	5039879
MMT-864	5040158
MMT-381	5040167
MMT-381	5041853
MMT-381	5042472
MMT-381	5042473
MMT-377	5042575
MMT-864	5042580
MMT-377	5042715
MMT-864	5043094
MMT-864	5043095
MMT-381	5043407
MMT-876	5043426
MMT-381	5044102
MMT-377	5046462
MMT-864	5046640
MMT-876	5047179
MMT-381	5047504
MMT-866	5047583
MMT-381	5048109
MMT-866	5049124
MMT-381	5049552
MMT-381	5051363
MMT-382	5051365
MMT-866	5051563
MMT-378	5055347
MMT-381	5056652
MMT-381	5057788
MMT-876	5059553
MMT-864	5060206
MMT-381	5060844
MMT-864	5060948
MMT-381	5061645
MMT-394	5063644
MMT-378	5064853
MMT-378	5066631

REF	LOT
MMT-378	5066632
MMT-381	5067489
MMT-876	5070667
MMT-975	5072864
MMT-876	5076353
MMT-397	5077085
MMT-864	5077107
MMT-876	5077117
MMT-396	5078043
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MMT-397	5079806
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MMT-975	5082275
MMT-864	5083278
MMT-381	5083738
MMT-381	5083744
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MMT-866	5084137
MMT-975	5084640
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