

press release

UPDATE

Additional information to help clarify affected device lot numbers for NovoPen 5®

Important safety information for people with diabetes using NovoPen Echo® or NovoPen® 5

MISSISSAUGA, ON, July 10, 2017 – Novo Nordisk A/S has detected that the insulin cartridge holder used in a select number of NovoPen Echo® and NovoPen® 5 lots may crack or break if exposed to certain chemicals, for example certain cleaning agents. NovoPen Echo® and NovoPen® 5 are used for insulin treatment by people with diabetes.

Novo Nordisk urges people with diabetes using a NovoPen Echo® and/or NovoPen® 5 from one of the affected lots to replace the cartridge holder as some could be damaged or subject to damage in the future if not changed. The lot numbers of the affected lots are listed below.

A picture of the cartridge holder is shown below



Using a device with a cracked/broken cartridge holder can result in the device delivering a smaller dose of insulin than expected and may lead to high blood sugar. The risk of experiencing high blood sugar with the use of a device with an affected cartridge holder is evaluated to be less than 0.1 per cent, i.e. one in 1,000 patients will experience high blood sugar due to an affected cartridge holder.

The warning symptoms of high blood sugar (hyperglycaemia) normally appear gradually and can be flushed, dry skin; feeling sleepy or tired; dry mouth, fruity (acetone) breath; urinating more often, feeling thirsty; losing your appetite, feeling or being sick (nausea

or vomiting)!. You might not experience any physical signs of high blood sugar, but only be able to see it in your blood sugar measurements.

The lot numbers printed on the affected NovoPen Echo® and NovoPen® 5 devices distributed in Canada are shown in below tables:

NovoPen Echo®:

Device Lot Number	Package Lot Number
DUG2373	DUG2373-5
DVG1368	DVG1368-B
EVG2915	EVG2915-7
EVG3010	EVG3010-2
EVG4252	EVG4252-6
EVG5699	EVG5699-6
EVG5946	EVG5946-7
EVG5963	EVG5963-1
FVG7337	FVG7337-2
FVG7561	FVG7561-1
FVG8131	FVG8131-5
FVG8132	FVG8132-6
FVG8212	FVG8212-1
FVG8414	FVG8414-9
FVG8994	FVG8994-1
FVG8997	FVG8997-1

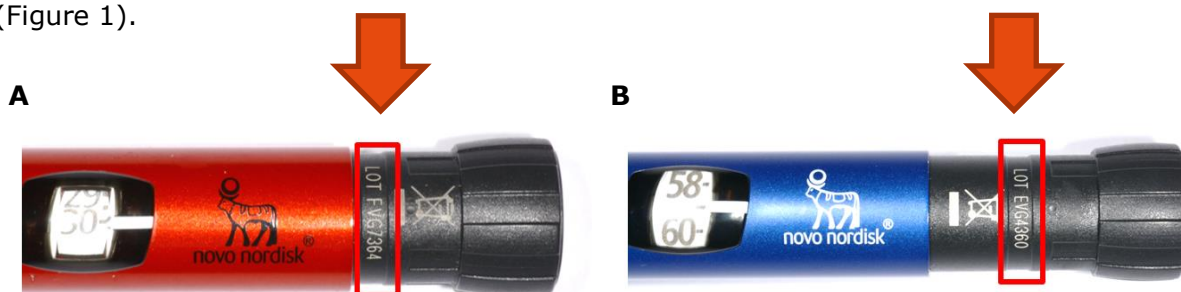
Table 1. List of affected NovoPen Echo® lots in Canada.

NovoPen® 5:

Device Lot Number	Package Lot Number
EVG5564	EVG6240
EVG3337	EVG6241
EVG5564	FVG6867
EVG0915	FVG6868
FVG7336	FVG7469
FVG7377	FVG7568

Table 2. List of affected NovoPen® 5 in Canada.

The lot numbers are printed on NovoPen Echo® and NovoPen® 5 as indicated below (Figure 1).



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Figure 1. Arrows show where the lot number is located on A) NovoPen Echo® and B) NovoPen® 5. E.g. the lot number on the NovoPen Echo® to the left is FVG7364.

If patients are in possession of a NovoPen Echo® and/or a NovoPen® 5 device with a lot number which is **not** mentioned above there is no reason for concern and they can be confident that the pen will work as intended.

What to do if you are using a NovoPen Echo® and/or NovoPen® 5 with one of the above-mentioned lot numbers:

- Do not stop treatment without consulting your doctor.
- Register contact details (name, address, phone number, email and number of affected cartridge holders) either at the local affiliate website Novo Nordisk Canada (www.novonordisk.ca) or at Novo Nordisk's corporate website (www.novonordisk.com) or contact the local Novo Nordisk Customer Service team (nnci_customercare@novonordisk.com or 1-800-465-4334) in order to receive an unaffected cartridge holder for your NovoPen Echo® and/or NovoPen® 5, which you should attach and use as stated in User Guide.
- You should measure your blood sugar levels as instructed by your healthcare professional and more frequently if symptoms of high or low blood sugar develop unexpectedly.
- In the event that you experience symptoms of high blood sugar involving this product, contact your healthcare professional for advice.
- Report any adverse events or complaints to Novo Nordisk's Customer Service, which can be reached at 1-800-465-4334.

If you have any questions or concerns, please contact your healthcare professional or Novo Nordisk Customer Service at 1-800-465-4334.

Novo Nordisk is committed to delivering high-quality products and sincerely apologizes for this unfortunate situation and the concerns and inconvenience it may cause patients and health care professionals. We are working closely with Health Canada to ensure patient safety and minimise the disruption this situation causes.

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: haemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 42,000 people in 77 countries and markets its products in more than 165 countries. For more information, visit novonordisk.com, [Facebook](#), [Twitter](#), [LinkedIn](#), [YouTube](#)

Further information

www.novonordisk.ca

Customer Service

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ⁱ Diabetes Canada. Lows & Highs: Blood Sugar Levels. Accessed on June 28, 2017 at www.diabetescanada.ca/diabetes-and-you/healthy-living-resources/blood-glucose-insulin/lows-highs-blood-sugar-levels.

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