NovoPen Echo

URGENT MEDICAL DEVICE RECALL

ISSUE	Novo Nordisk A/S has detected that the insulin cartridge holder used in a small number of NovoPen® Echo® batches may crack or break if exposed to certain chemicals, for example certain cleaning agents. • The reason for the cracking is that the plastic materials used for the cartridge holders in the affected batches can be weakened if exposed to certain chemicals found, for example, in some cleaning products.
IMPACT	• Using a device with a cracked/broken cartridge holder can result in the device delivering a smaller dose of insulin than expected leading to high blood sugar levels. • Using a device with a cracked/broken cartridge holder can result in the device delivering a smaller dose of insulin than expected leading to high blood sugar levels. The risk of experiencing high blood sugar levels with the use of a device with an affected cartridge holder is evaluated to be less than 0.1 %, i.e. only 1 in 1000 patients will experience high blood sugar levels due to an affected cartridge holder. • When cleaning the pen as described in the User Guide, there is no reason to believe that cracking of the cartridge holder will occur. All other batches include cartridge holders of a type where the issue with cracked and broken cartridge holders was not seen.
ACTION	• Novo Nordisk is recalling all pens in the affected batches **not currently issued to a patient**. • Novo Nordisk urges people with diabetes using a NovoPen® Echo® from one of the affected batches to replace the cartridge holder, as some could be damaged. **Please check the device batch number against the list of affected batches as shown in table below**.
PATIENTS	• Where affected pens **have been issued to a patient**, Novo Nordisk urges patients to replace the cartridge holder, as some could be damaged (as per User Guide). • It is important to clean pens only as described in the User Guide. • Be aware of the symptoms of hyperglycaemia. If you note these symptoms, measure your blood sugar levels as instructed by your health care provider and take appropriate action. • In the event that you experience symptoms of too high blood sugar levels involving this product, contact your doctor for advice.

Novo Nordisk
Pharmaceuticals Pty. Ltd.

Level 3
21 Solent Circuit
Baulkham Hills NSW 2153
Australia

Telephone:
1800 668 626

E-mail:
aunrccc@novonordisk.com
Internet:
www.novonordisk.com.au

	• Register your contact details (name, address, phone number, email and number of affected cartridge holders) either at www.novonordisk.com.au or at www.novonordisk.com/novopenecho5.html in order to receive a replacement cartridge holder for your NovoPen® Echo®(after 7 working days, approximately). • Upon receipt you should attach this replacement cartridge holder as stated in the NovoPen® Echo® User Guide, pages 2-4, enclosed in the carton and also available at: http://www.novonordisk.com.au/patients/consumer-medicines-information.html). ○ If your NovoPen® Echo® *is currently loaded* with an insulin cartridge, you must replace the cartridge holder ***the next time*** you load a new insulin cartridge. ○ If your NovoPen® Echo® *is NOT currently loaded* with an insulin cartridge, you must replace the cartridge holder ***as soon as possible***. • Report any adverse events or complaints to the NovoCare® Customer Care Centre, which can be reached at 1800 668 626 or via email at aunrccc@novonordisk.com.
HEALTH CARE PROFESSIONALS	• Please immediately quarantine all affected batches within your possession to prevent further distribution. • Please contact any patients to whom you have supplied NovoPen® Echo® since July 2014 and ask them to check the batch numbers on any product in their possession. • If the patient possesses a pen from an affected batch, provide them with the Patient Information Letter (copies available on request from NovoCare® Customer Care Centre, ph. 1800 668 626) describing how to obtain a replacement cartridge holder and urge the patient to follow the instructions immediately (included below). • Please advise other relevant staff members in your organisation of this recall and safety notice. • Please complete and return the attached Acknowledgment form **even if no affected stock is held**. Please return by email to aurecall@novonordisk.com. • If you have affected stock, **Novo Nordisk will contact you** and arrange for the quarantine product to be returned to us. • Please retain this letter in a prominent position for one month in case stock is in transit. • Whenever the opportunity presents, please reiterate to patients that the cleaning instructions of the NovoPen® Echo® User Guide (page 26) describe that a cloth dampened ONLY with water (and certainly not with bleaching agents such as chlorine, iodine or alcohol) is to be used to clean the insulin pen.

Batch no. as shown on NovoPen® Echo® carton	Batch no. as shown on NovoPen® Echo® pen
EVG3310-6	EVG3310
EVG4252-2	EVG4252
EVG4253-2	EVG4253
FVG8218-4	FVG8218
FVG8412-3	FVG8412
FVG8415-1	FVG8415

A picture of the cartridge holder is shown below (figure 1)

Figure 1. Picture of cartridge holder used for NovoPen® Echo®.

How do I check if I have a NovoPen® Echo® from one of the six affected batches listed in the table above?

1. Batch numbers are printed on NovoPen® Echo® as indicated below (Figure 1).
2. If the dose button is not already out, pull it out and turn the dial on the pen to '30 units' so that the batch number becomes visible (Figure 2, below).

Figure 2. Red square shows where the batch number is located on NovoPen® Echo® E.g. the batch number on the NovoPen® Echo® shown in the image is FVG7364 (this is an example only and this batch has not been distributed in Australia).

3. Write down the batch number printed on your NovoPen® Echo® and check to see if it is in the list of affected batches.

   If your NovoPen® Echo® has not yet been removed from the original carton it came in, please check the batch number printed on the carton (figure 3).

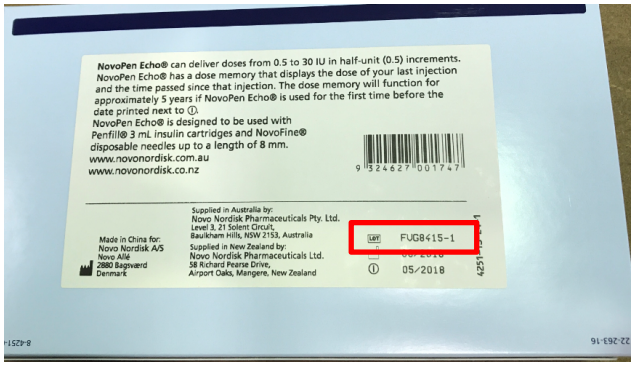

Figure 3. Red squares shows where the batch number is located on the NovoPen® Echo® carton

What do I do if the batch number on my NovoPen® Echo® is different to one of the six affected batches in the table above?

Importantly, if you are in possession of NovoPen Echo® with batch numbers **NOT** mentioned above, or a NovoPen® 3 or NovoPen® 4 product, there is **NO** concern and you can be confident that the products will work as intended. It is important to clean pens only as described in the NovoPen® Echo® User Guide.

This action has been undertaken following consultation with the Therapeutic Goods Administration (TGA).

Yours sincerely,

Dr. Shaun O'Mara

Director-Diabetes and Biopharm Marketing,
Novo Nordisk Australia & New Zealand

ACKNOWLEDGEMENT FORM/ INVENTORY OF RETURNED MEDICINES

Please complete and email to aurecall@novnordisk.com within 7 days of its receipt.

Note: This form must be completed and returned even if no stock is held

Product	Batch No.	No. of packs
NovoPen® Echo®	EVG3310-6	
NovoPen® Echo®	EVG4252-2	
NovoPen® Echo®	EVG4253-2	
NovoPen® Echo®	FVG8218-4	
NovoPen® Echo®	FVG8412-3	
NovoPen® Echo®	FVG8415-1	

IF NO STOCK IS HELD, TICK THIS BOX ☐

Organisation			
Name		**Date**	
Position		**Telephone No.**	
Email		**Fax No.**	

AU/DV/0717/0067a 10Jul2017

RETURNED GOODS FORM

Please complete this form, and <u>upon receipt of instructions from Novo Nordisk</u>, send back with stock returns.

Please take spare copies of this blank form for subsequent returns

Product	Batch No.	No. of packs
NovoPen® Echo®	EVG3310-6	
NovoPen® Echo®	EVG4252-2	
NovoPen® Echo®	EVG4253-2	
NovoPen® Echo®	FVG8218-4	
NovoPen® Echo®	FVG8412-3	
NovoPen® Echo®	FVG8415-1	

Organisation			
Name		**Date of Dispatch**	
Position		**Telephone No.**	
Email		**Fax No.**	

Please include a copy of this form with any product you are returning.

AU/DV/0717/0067a 10Jul2017