

Regulatory Operations
 Insert: 2010-508x462-029
 Current 1.0

USA
 Demonstration Pen

Colour: PMS 280C +
 PMS 185C

**Demonstration Pen
 for FlexTouch®**

2U increment pens

**▲ For demonstration and training of
 2U increment pens only.**

Not for injection into humans.

Does not contain insulin.

Not for treatment of any disease.

**Only for demonstration by representatives
 of Novo Nordisk or healthcare
 professionals educated in the use of the
 Demonstration Pen.**

Demonstration Pen for FlexTouch contains
 Test Medium and is a Service Product for
 demonstration purposes only.

Demonstration Pen does not contain insulin
 and consequently must not be administered
 for the treatment of Diabetes Mellitus.
 Demonstration Pen must not be injected
 into patients.

**Use of Service Products must comply
 with national regulations and is the
 responsibility of the healthcare
 professionals requesting the medium.
 This includes assuming full responsibility
 for appropriate instructions if usage is
 intended by a third party.**

Ingredients

Glycerol, metacresol, sodium hydroxide,
 hydrochloric acid, and water for injection.

Pharmaceutical form and contents

Test Medium is a colorless, clear solution
 contained in 3 mL prefilled Demonstration Pens.

Produced by

Novo Nordisk A/S
 DK-2880 Bagsvaerd, Denmark

Intended use

Demonstration Pen is used to demonstrate the
 use of FlexTouch 2U increment pens.

**What has to be checked before
 demonstration?**

Make sure you have the needle and a test
 object that you plan to use to inject the
 Test Medium into. Check the label to
 ensure demonstration of the correct
 Test Medium FlexTouch.

How to handle this Demonstration Pen

Prefilled Demonstration Pens for FlexTouch
 should be used with NovoFine®, NovoFine® Plus
 or NovoTwist® needles for demonstration
 purposes and to practice an appropriate dosing
 and injection technique. Each Demonstration
 Pen contains a total of 3 mL (600 units) of Test
 Medium solution. This Demonstration Pen can
 deliver up to a maximum of 160 units per
 a single injection in 2-unit increments.

When using a Demonstration Pen, the needle
 should be removed after each injection. Take
 care not to drop or knock the Pen.

Expiration date

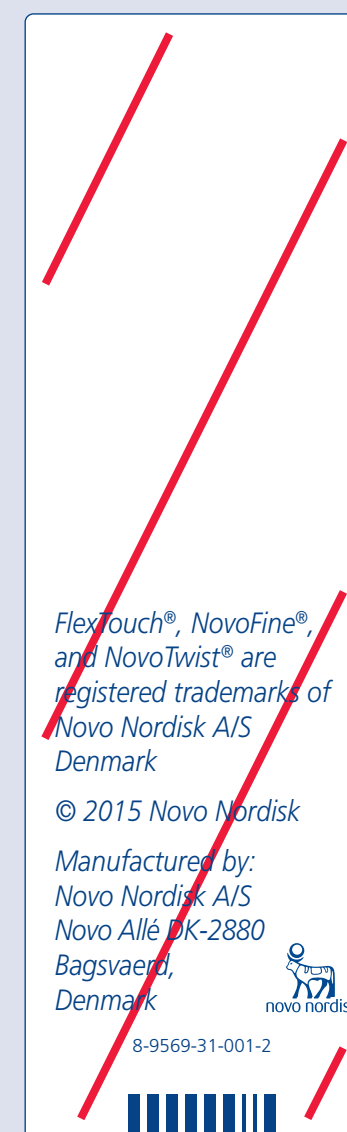
Do not use Demonstration Pen after the
 expiration date printed on the carton.

Storage

Keep unused Demonstration Pens at room
 temperature until the expiration date on the
 carton. Keep the Pens out of the reach and
 sight of children.

Disposal

Dispose of used Demonstration Pens carefully
 without the needle attached after use.



*FlexTouch®, NovoFine®,
 and NovoTwist® are
 registered trademarks of
 Novo Nordisk A/S
 Denmark*

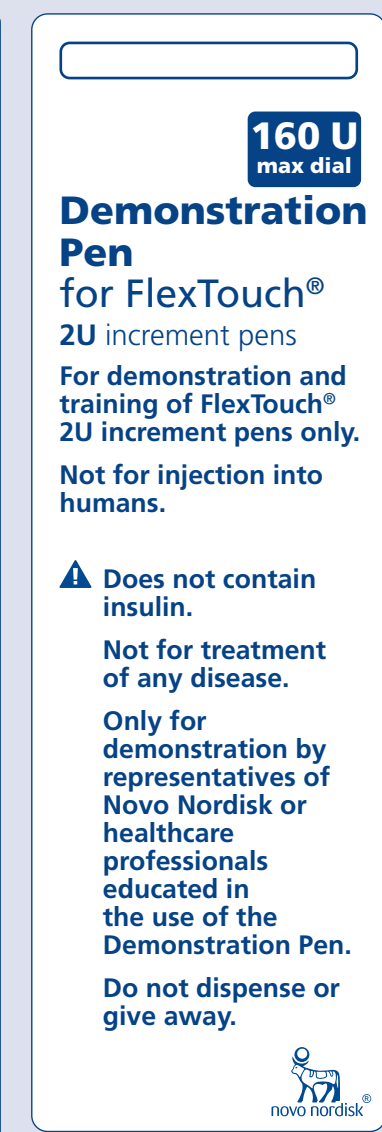
© 2015 Novo Nordisk

*Manufactured by:
 Novo Nordisk A/S
 Novo Allé DK-2880
 Bagsvaerd,
 Denmark*

8-9569-31-001-2



Length: Max. 20 mm (100%)
 Code: 100% Direction →
 Code centered



160 U
 max dial

**Demonstration
 Pen
 for FlexTouch®**

2U increment pens

**For demonstration and
 training of FlexTouch®
 2U increment pens only.**

**Not for injection into
 humans.**

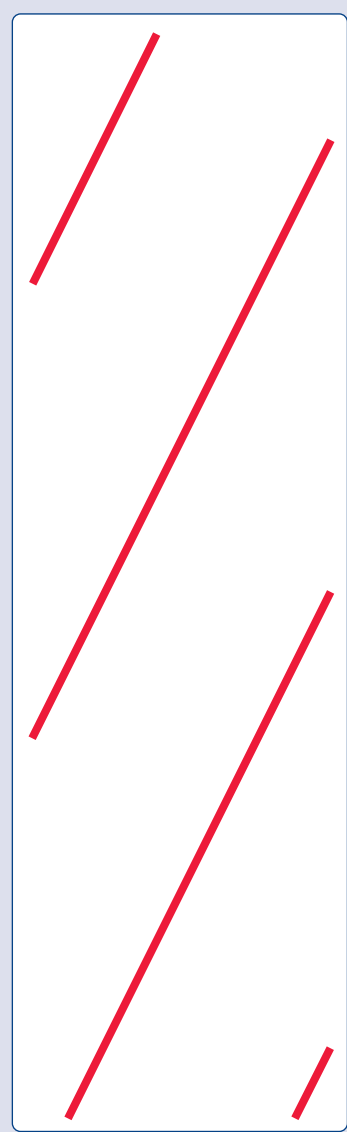
**▲ Does not contain
 insulin.**

**Not for treatment
 of any disease.**

**Only for
 demonstration by
 representatives of
 Novo Nordisk or
 healthcare
 professionals
 educated in
 the use of the
 Demonstration Pen.**

**Do not dispense or
 give away.**

novo nordisk



8 mm
 1 mm

Instructions on how to use Demonstration Pen for FlexTouch® 2U increment pens

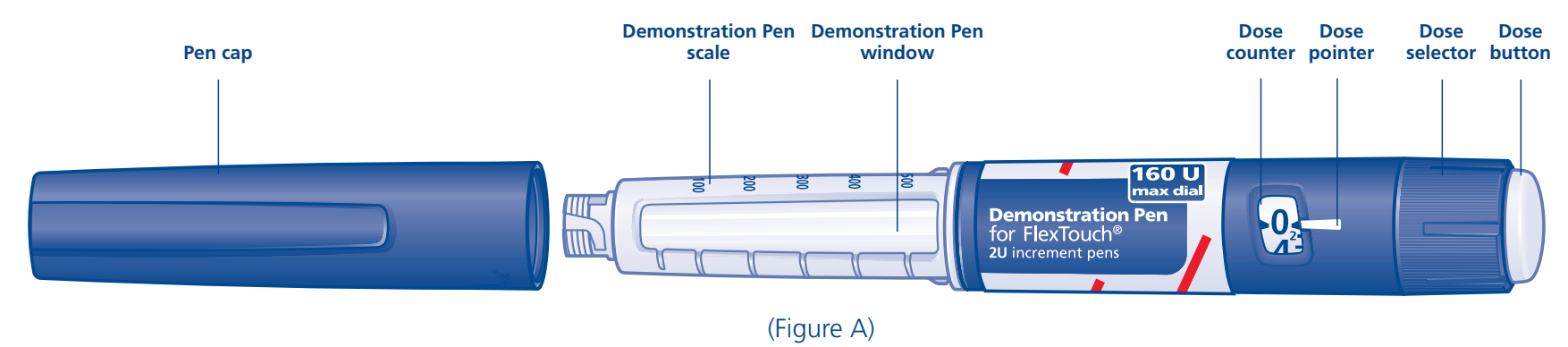
For demonstration and training of 2U increment pens only. Not for injection into humans.
Demonstration Pen for FlexTouch 2U increments ("Demonstration Pen" and "Pen") is a prefilled disposable pen, which contains 3 mL (600 units) of Test Medium and delivers from 2 to 160 units in a single injection.

Supplies you will need to demonstrate the use of the Pen:

- Demonstration Pen
- a new NovoFine, NovoFine Plus or NovoTwist needle
- an alcohol swab
- a test object, e.g. a sponge or other suitable prop
- a sharps container for throwing away used Pens and needles. See "After the demonstration:" at the end of these instructions.

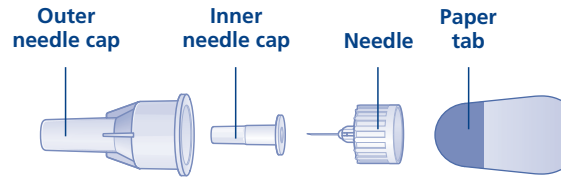
Read these instructions carefully before demonstrating the use of the Pen. Keep these instructions with the Pen – you may need to read them again. Always instruct patients to read the instructions that come with their specific Pen before use. Instruct patients not to share the Pen with another person. They may give an infection to them or get an infection from them. Tell patients that this Pen is not recommended for use by the blind or visually impaired without the assistance of a person trained in the proper use of the product.

In the following, you will instruct patients on how to use the Demonstration Pen. Test Medium is the term used when referring to the drug.

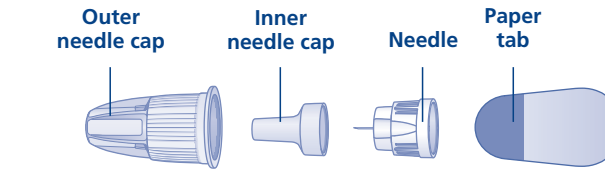


(Figure A)

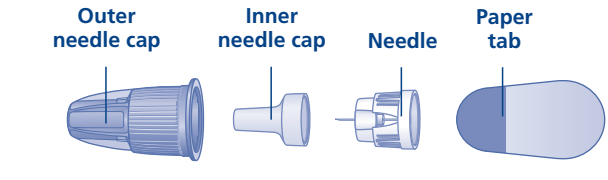
NovoFine®



NovoFine® Plus



NovoTwist®

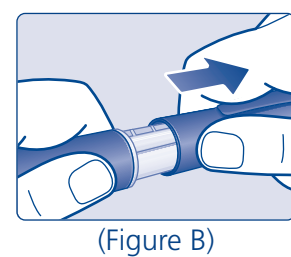


Preparing your Demonstration Pen:

- Wash your hands with soap and water.
- **Before you start to prepare your injection, check the Pen label to make sure you are injecting with the right Pen. This is especially important if you take more than 1 type of insulin.**
- Test Medium should look clear and colorless. **Do not** use Test Medium if it is cloudy or colored.
- **Do not** use Demonstration Pen past the expiration date printed on the label.
- **Always use a new needle for each injection to help ensure sterility and prevent blocked needles. Do not reuse or share needles with another person.**

Step 1:

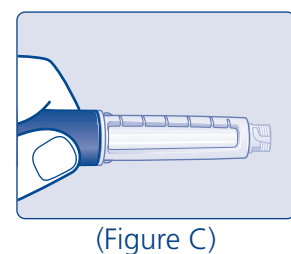
- Pull Pen cap straight off (See Figure B).



(Figure B)

Step 2:

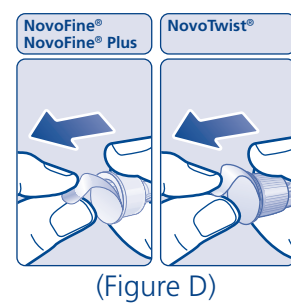
- **Check the liquid in the Pen** (See Figure C). Test Medium should look clear and colorless. **Do not** use it if it looks cloudy or colored.



(Figure C)

Step 3:

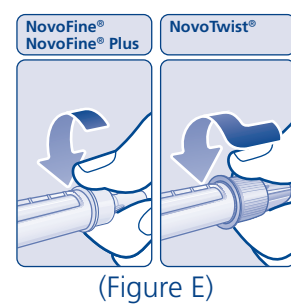
- **Select a new needle.**
- Pull off the paper tab from the outer needle cap (See Figure D).



(Figure D)

Step 4:

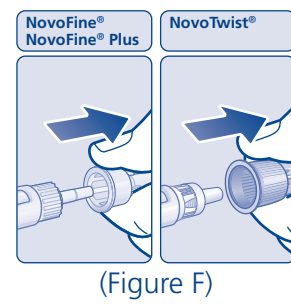
- Push the capped needle straight onto the Pen and twist the needle on until it is tight (See Figure E).



(Figure E)

Step 5:

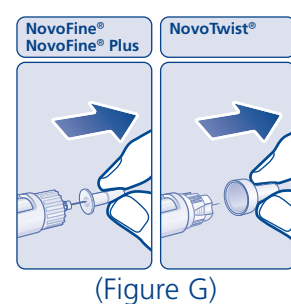
- Pull off the outer needle cap. **Do not** throw it away (See Figure F).



(Figure F)

Step 6:

- Pull off the inner needle cap and throw it away (See Figure G).

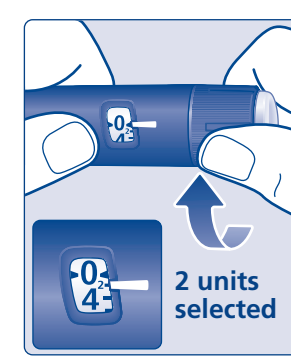


(Figure G)

Priming your Demonstration Pen:

Step 7:

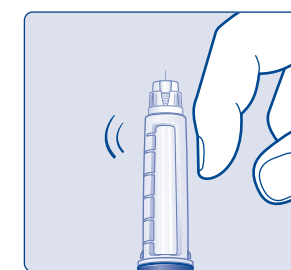
- Turn the dose selector to **select 2 units** (See Figure H).



(Figure H)

Step 8:

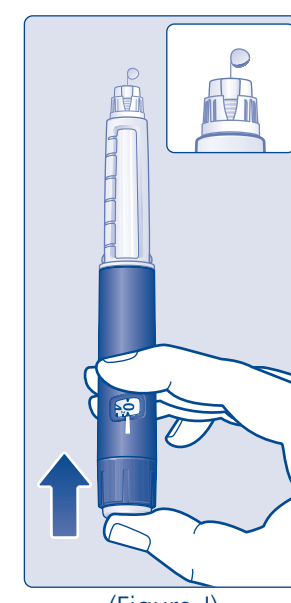
- Hold the Pen with the needle pointing up. Tap the top of the Pen gently a few times to let any air bubbles rise to the top (See Figure I).



(Figure I)

Step 9:

- **Hold the Pen with the needle pointing up.** Press and hold in the dose button until the dose counter shows "0". The "0" must line up with the dose pointer.
- A drop of Test Medium should be seen at the needle tip (See Figure J).
- If you **do not** see a drop of Test Medium, repeat steps 7 to 9, no more than 6 times.
- If you **still do not** see a drop of Test Medium, change the needle and repeat steps 7 to 9.

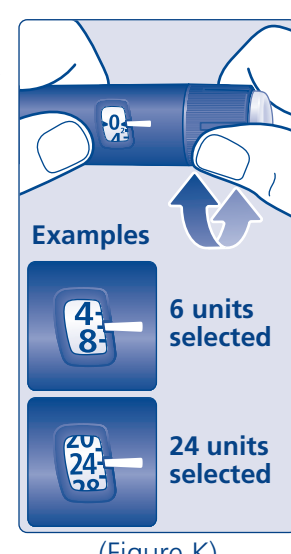


(Figure J)

Selecting your dose:

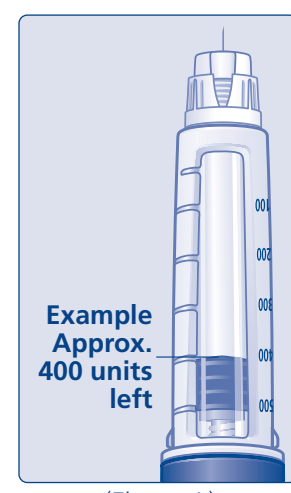
Step 10:

- This 2-unit increment Pen is designed to deliver the number of units dialed. **Do not perform any dose conversions.**
- **Turn the dose selector to select the number of units you need to inject.** The dose pointer should line up with your dose (See Figure K).
- If you select the wrong dose, you can turn the dose selector forwards or backwards to the correct dose.
- Each line on the dial represents even numbers.



(Figure K)

- The Demonstration Pen scale will show you how much Test Medium is left in your Pen (See Figure L).



(Figure L)

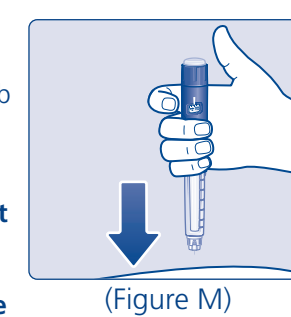
- **To see how much Test Medium is left in your Demonstration Pen:**

- Turn the dose selector until it stops. The dose counter will line up with the number of units of Test Medium that is left in your Pen. If the dose counter shows 160, there are **at least 160** units left in your Pen.
- If the dose counter shows **less than 160**, the number shown in the dose counter is the number of units left in your Pen.

Demonstrating your injection:

Step 11:

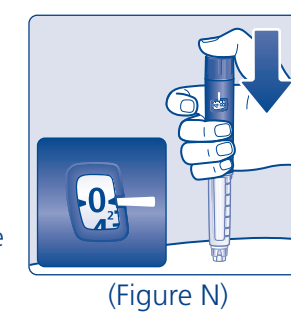
- Wipe the test object with an alcohol swab **to simulate an injection site.**
- **Insert the needle into the test object** (See Figure M).
- **Make sure you can see the dose counter.** **Do not** cover it with your fingers, this can stop your injection.



(Figure M)

Step 12:

- **Press and hold down the dose button until the dose counter shows "0"** (See Figure N).
- The "0" must line up with the dose pointer. You may then hear or feel a click.



(Figure N)

- **Keep the needle in the test object after the dose counter has returned to "0" and slowly count to 6** (See Figure O).



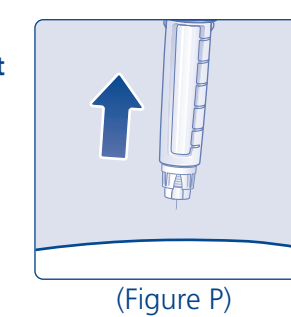
(Figure O)

Pay special attention to ...

- Always instruct patients to pay special attention to the following when injecting insulin:
- **When the dose counter returns to "0", the full dose is not completely delivered until 6 seconds later.**
 - **If the needle is removed earlier, you may see a stream of Test Medium coming from the needle tip. If so, the full dose will not be delivered, and you should increase the frequency of checking your blood sugar levels.**
 - **Please note** that if the needle is removed before you count to 6 after the dose counter returns to "0", then under-dosing may occur by as much as 20%, resulting in the need for increasing the frequency of checking your blood sugar levels and possible additional insulin administration.
 - If "0" does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked needle. In this case – you have **not** injected any insulin – even though the dose counter has moved from the original dose that you have set.
 - **If you have a blocked needle**, change the needle as described in step 14 and repeat all steps starting with step 3. **Make sure you select the full dose you need.**

Step 13:

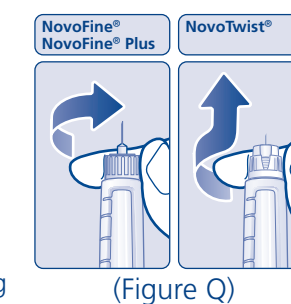
- **Pull the needle out of the test object** (See Figure P).



(Figure P)

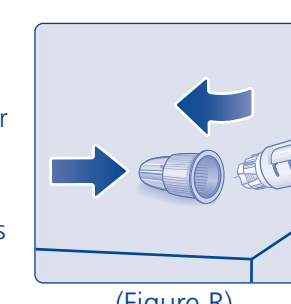
Step 14:

- **Carefully remove the needle from the Pen and throw it away** (See Figure Q).
- **Do not** recap the needle. Recapping the needle can lead to needle stick injury.



(Figure Q)

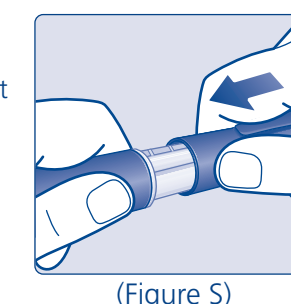
- If you **do not** have a sharps container, carefully slip the needle into the outer needle cap (See Figure R). Safely remove the needle and throw it away as soon as you can.
- **Do not** store the Pen with the needle attached. Storing without the needle attached helps prevent leaking, blocking of the needle, and air from entering the Pen.



(Figure R)

Step 15:

- Replace the Pen cap by pushing it straight on (See Figure S).



(Figure S)

After the demonstration:

- Instruct patients to put used Pens and needles in a FDA-cleared sharps disposal container right away after use. Instruct patients never to throw away (dispose of) loose needles and Pens in household trash.
- If patients do not have a FDA-cleared sharps disposal container, they may use a household container that is:
 - made of a heavy-duty plastic
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
 - upright and stable during use
 - leak-resistant
 - properly labeled to warn of hazardous waste inside the container.
- When a sharps disposal container is almost full, patients will need to follow their community guidelines for the right way to dispose of the sharps disposal container. There may be state or local laws about how they should throw away used needles and syringes. Instruct patients never to reuse or share needles, or syringes with another person. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that they live in, refer patients to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>
- Instruct patients never to dispose of used sharps disposal containers in household trash – unless community guidelines permit this – and never to recycle used sharps disposal containers.

Storage

- Instruct patients to store the Pen they are currently using **according to the storage instructions in the Instructions for Use** that comes with their specific Pen.
- Instruct patients **not** to freeze the Pen, and **not** to use the Pen if it has been frozen.
- Tell patients that unused Pens may be used until the expiration date printed on the label, if kept in the refrigerator.
- Instruct patients to keep the Pen away from heat and light.

General Information about the safe and effective use of the Pen.

- Instruct patients to **keep Pens and needles out of the reach of children.**
- Instruct patients to **always** use a new needle for each injection.
- Instruct patients **not** to share Pens or needles with another person.