


NovoPen® 3

Dial-A-Dose
Insulin Delivery System

Instructions For Use



**Open this flap
for photos of the
NovoPen® 3 insulin
injection system**



NovoPen® 3 Insulin Delivery Device

NovoFine® Disposable Needle



Pen cap



Outer needle cap



Inner needle cap



Needle



Inspection window

Insulin scale

Cartridge holder

Insulin scale window



Protective tab

PenFill® Cartridge (3 mL)



Piston rod

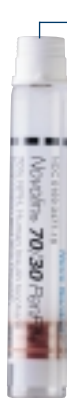
Reset mechanism

Barrel

Dose indicator window

Dial-a-dose selector

Push button



Front rubber stopper

Threaded plastic cap

Rear rubber stopper

Need Help?
Call 1-800-727-6500

Welcome to Your NovoPen® 3

Dial-A-Dose
Insulin Delivery System

INTRODUCTION

Dear NovoPen® 3 User:
Congratulations! You have selected an accurate, discreet, convenient and comfortable way to deliver from 2 to 70 units of insulin with the NovoPen 3 insulin delivery system. This booklet includes everything you need to know about using the NovoPen 3. Please read it carefully before using your NovoPen 3 for the first time.

The NovoPen 3 is designed for use with:

- PenFill® 3 mL cartridges.
- NovoFine® disposable needles.

You will also need alcohol swabs.

Customer service and satisfaction are our top priority. If you have any questions about your NovoPen 3 insulin delivery system, please call Novo Nordisk Pharmaceuticals, Inc. at 1-800-727-6500.

Please complete and return the NovoPen 3 warranty card. Upon receipt of your warranty card, we will send you a free gift if you would like one. See the enclosed warranty card.

Thank you for choosing the NovoPen 3 insulin delivery system.

(See **Important Things to Know** and **Important Notes** on pages 33-35.)

HOW TO USE THIS BOOKLET

This booklet gives you step-by-step instructions for using the NovoPen 3.

Begin by reviewing the photo layout of the parts of the NovoPen 3, PenFill 3 mL cartridge and NovoFine disposable needle. The inside front cover opens out so you have a handy reference while you read the rest of the booklet. Most pages contain a photo on the right with numbered instructions to the left of the photo. **Important additional information is given below the photo.**

We suggest that you **read the text and look at the photos** to make sure that you understand each step thoroughly.

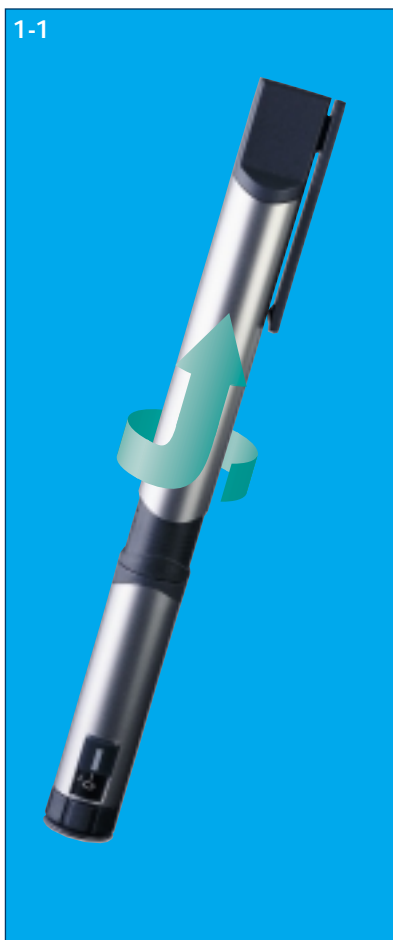
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Remove the device cap:

- 1** Remove the NovoPen 3 from the case, by pressing down on the flat part of the pen cap.
- 2** Gently twist the pen cap until the cap separates from the barrel.
- 3** Pull the pen cap straight up to remove it.

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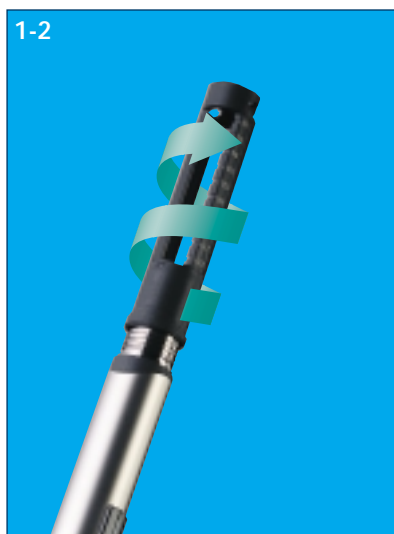


If you use more than one type (N, R or 70/30) of insulin, use a separate NovoPen 3 for each type.

SECTION 1 (cont.)

Separate the cartridge holder from the barrel:

- 4 Unscrew and remove the cartridge holder from the barrel.



Make sure the dose indicator window shows zero:

- 5 Press the push button all the way in until zero (0) appears in the window. The zero should be lined up with the stripe below the dose indicator window.



SECTION 1 (cont.)

The end of the piston rod should be flat against the end of the reset mechanism prior to inserting each new PenFill 3 mL cartridge. It should not be sticking out.

If the piston rod is sticking out:

Turn the end of the reset mechanism in a clockwise direction until it is no longer sticking out. Never push the piston rod back in.

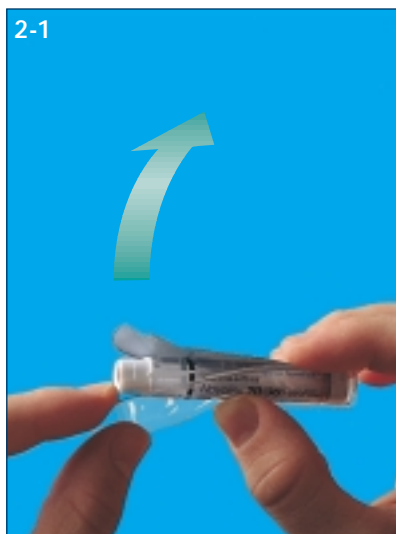
*Need Help?
Call 1-800-727-6500*



You should never reset the piston rod until it is time to remove the used PenFill 3 mL cartridge and insert a new one.

If the reset mechanism locks, it is usually due to improper technique. Gently turn the mechanism side to side until it unlocks. Then call our toll free number (1-800-727-6500) so that we may review your operating technique with you.

- 1 To remove the PenFill cartridge from its wrapper, push the cartridge through the foil side of the packaging. Before use, check that the PenFill cartridge is full and intact. If not, do not use it.



Each PenFill 3 mL cartridge contains a total of 300 units of insulin. There are five cartridges in a box. Make sure you are using the correct type of insulin. On the glass part of the cartridge is the name of the insulin.

Each PenFill cartridge is for single-person use only. **DO NOT** use the same cartridge for more than one person, even though you attach a new disposable needle for each injection. This will prevent the spread of disease.

Use only a new PenFill 3 mL cartridge when loading the NovoPen 3. Never load a partially filled cartridge.

Never try to refill a used PenFill 3 mL cartridge.

SECTION 2 (cont.)

If you use Novolin® 70/30 70% NPH, Human Insulin Isophane Suspension & 30% Regular, Human Insulin Injection (recombinant DNA origin) or Novolin® N, NPH, Human Insulin Isophane Suspension (recombinant DNA origin), mix the insulin:

- Turn the PenFill cartridge up and down between positions **A** and **B**, as shown.
- Repeat this mixing step at least 10 times until the insulin looks uniformly white and cloudy.



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SECTION 2 (cont.)

Insert the PenFill cartridge:

- 2 Hold the cartridge holder so the wider opening is up.
- 3 Drop the PenFill cartridge into the cartridge holder, plastic cap first.



A threaded plastic cap surrounds the end of the PenFill cartridge, like the cap on a bottle. In the center is the front rubber stopper.

The rear rubber stopper is at the other end of the PenFill cartridge.

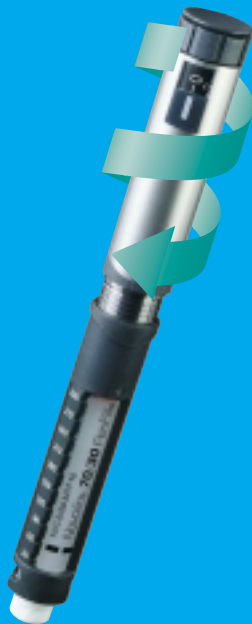
SECTION 2 (cont.)

Re-attach the cartridge holder:

- 4 Screw the barrel into the cartridge holder completely until it is tight.

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2-4



You can see the cartridge in the insulin scale window. For your convenience, the cartridge holder has a scale with marks showing approximately how much insulin is left in the PenFill cartridge.

SECTION 3 Attaching the NovoFine Disposable Needle

At the end of the cartridge holder are two inspection windows. You can see the cartridge through these windows.

If you use Novolin 70/30 or Novolin N insulin, use the windows to check if there is enough insulin left for proper mixing.

Check the amount of insulin remaining:

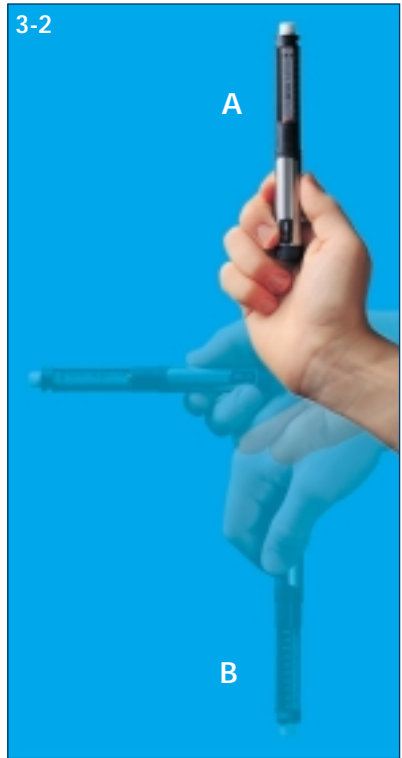
- If the rear rubber stopper cannot be seen in the inspection window, you have enough insulin for mixing left in the cartridge.
- If the rear rubber stopper can be seen in the inspection window, you do not have enough insulin left in the cartridge and must insert a new PenFill 3 mL cartridge. (See Section 7 for instructions on removing a PenFill cartridge and Section 2 for inserting a new one.)



SECTION 3 (cont.)

**For users of Novolin 70/30
or Novolin N insulin:
Always remix the insulin.**

To remix the insulin, turn the NovoPen 3 up and down between positions **A** and **B** 10 times or until the insulin looks uniformly white and cloudy.



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SECTION 3 (cont.)

- 1 Wipe the front rubber stopper with an alcohol swab.

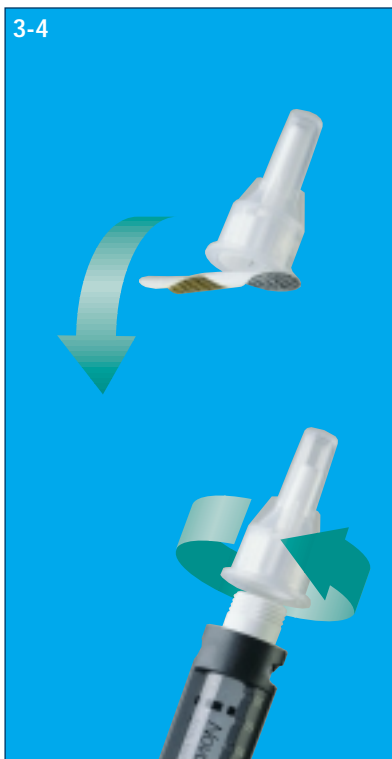


You must wipe the front rubber stopper with an alcohol swab before each injection, even if you are using the same PenFill cartridge.

SECTION 3 (cont.)

- 2 Remove the protective tab from the NovoFine disposable needle.
- 3 Screw the NovoFine disposable needle firmly onto the PenFill 3 mL cartridge until it is tight.

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Never place a NovoFine disposable needle on your NovoPen 3 until you are ready to do an air shot and give an injection.

If the NovoFine needle is “left on,” some liquid may leak out of the PenFill cartridge. This may cause a change in the strength of Novolin 70/30 or Novolin N insulin.

To prevent the injection of air and make certain insulin is delivered, **you must do an air shot before each injection.**

Before starting the air shot procedure, the dose indicator window must show zero (0).

If you use Novolin 70/30 or Novolin N insulin and have used the Novolin PenFill cartridge for previous injections, make sure there is enough insulin left in the PenFill cartridge to properly mix the insulin (see page 12). If there is enough insulin left in the PenFill cartridge, see the next page for instructions.

SECTION 4 (cont.)

Set the NovoPen 3 for the air shot:

- 1 Turn the dial-a-dose selector to 2 units.

The even numbers are shown. The odd numbers are indicated by the long lines between the even numbers.

4-1



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Call 1-800-727-6500

If you dial more than 2 units, DO NOT turn the dial back to zero (0). If you do, the extra insulin will squirt out of the needle. You may complete the air shot with the number of units you have dialed or refer to page 21 for instructions on how to reset the dose to zero.

SECTION 4 (cont.)

Uncap the NovoFine needle:

- 2** Pull off the outer needle cap and set aside.
- 3** Pull off the inner needle cap and discard.

4-2



- 4** Hold the NovoPen 3 with the NovoFine needle pointing upward.
- 5** Tap the cartridge holder with your finger a few times to raise any air bubbles that may be present to the top of the cartridge.

4-3



SECTION 4 (cont.)

Do the air shot:

- 6 Press the push button all the way in. Insulin should appear at the needle tip.

If no insulin appears, repeat the following steps, until insulin appears:

- a. Make sure the NovoFine needle is securely attached.
- b. Dial 2 units.
- c. Tap the cartridge holder with your finger.
- d. Press the push button all the way in.

There still may be an air bubble in the PenFill cartridge after this step but it will not be injected.

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Call 1-800-727-6500



When you press the push button, the piston rod presses against the rear rubber stopper. This moves the rear rubber stopper and pushes the correct amount of insulin up through the needle.

Be sure to do an air shot before giving an injection (see pages 16-19).

Select the dose:

- 1 Check that the dial-a-dose selector is set to zero. If not, follow the instructions on the next page. Turn the dial-a-dose selector until you see the correct number of units in the dose indicator window.

DO NOT use the clicking sounds as a guide for selecting your dose.



The NovoPen 3 can deliver from 2 to 70 units of insulin, in 1-unit increments.

If you dial more than your dose, DO NOT turn the dial back to zero (0). If you do, the extra insulin will squirt out of the needle. For instructions on how to reset the dose to zero (0) so you can start again, see the next page.

SECTION 5 (cont.)

To reset to zero (0) if you set the wrong dose:

- a. Grasp the cartridge holder with your thumb and forefinger.
- b. Grasp the barrel between your thumb and middle finger.
- c. Pull the cartridge holder down from the barrel as far as it will go (arrow #1).
- d. Press the push button down with your index finger to reset the dose to zero (0) (arrow #2).
- e. Check the dose indicator window to make sure you have reset it all the way to zero (0). If you have not, repeat steps **a** through **e**.



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SECTION 5 (cont.)

Give the injection:

- 2** Insert the NovoFine needle in the correct site on the body. (Use the injection technique recommended by your health care professional.)
- 3** Press the push button **as far as it will go** to deliver the insulin. Do not force it. To ensure that all the insulin is injected keep the NovoFine needle in the skin for several seconds after injection with your thumb on the push button. Keep the push button fully depressed until after the NovoFine needle has been withdrawn.
- 4** **Check the dose indicator window to make sure it shows zero (0). If zero does not appear, you did not receive the full dose. See the instructions on the next page.**



When you get near the end of a PenFill cartridge, you may need to give yourself two injections to receive your full dose. If, after giving an injection, zero does not appear in the dose indicator window, you did not receive your full dose. See the next page for instructions on how to get the remaining part of your dose.

SECTION 5 (cont.)

If the dose indicator window does not show zero, there were not enough units of insulin in the PenFill cartridge for you to receive the full dose. The dose indicator window shows the number of units that you did not receive.

For example, if you dial **25** units and there are only **20** units left in the PenFill cartridge, after the injection the number in the dose indicator window will be **5** ($25 - 20 = 5$).

To get the remaining part of your dose:

- a. Note the number of units in the dose indicator window.
- b. Remove the NovoFine needle (see Section 6).
- c. Remove the empty PenFill 3 mL cartridge (see Section 7).
- d. Insert a new PenFill 3 mL cartridge (see Section 2).
- e. Attach a NovoFine needle (see Section 3).
- f. Do an air shot (see Section 4).
- g. Dial the number of units noted in step a.
- h. Give the injection.

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Call 1-800-727-6500

SECTION 6 Removing the NovoFine Disposable Needle

Remove the NovoFine disposable needle:

- 1 Carefully replace the outer needle cap.
- 2 Hold the cartridge holder firmly while you unscrew the NovoFine disposable needle.
- 3 Place the NovoFine disposable needle in a puncture-resistant disposable container.



The NovoFine disposable needle must be removed immediately after each injection. If the NovoFine disposable needle is not removed, some liquid may leak out of the PenFill cartridge. This may cause a change in the strength of Novolin 70/30 or Novolin N insulin.

For information on how to properly dispose of needle containers, call your local trash disposal authorities.

SECTION 6 (cont.)

Replace the pen cap:

- 4 Hold the pen cap so that the clip is lined up with the dose indicator window.
- 5 **Gently slide** the pen cap onto the barrel.

6-2



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Call 1-800-727-6500

You will need to remove the PenFill cartridge for the following reasons:

- When the PenFill cartridge is empty.
- **If you use Novolin 70/30 or Novolin N insulin:**
When you see the rear rubber stopper in the inspection window, then you do not have enough insulin left in the PenFill cartridge for proper mixing.

Remove the barrel:

- 1 Remove the pen cap.
- 2 Hold the NovoPen 3 with the dose indicator window at the top.
- 3 Unscrew the barrel from the cartridge holder.



SECTION 7 (cont.)

Remove the PenFill 3 mL cartridge:

- 4 Tip the cartridge holder. The PenFill cartridge will drop out.
- 5 Press the push button all the way in until zero (0) appears in the window.
- 6 Turn the end of the reset mechanism in a clockwise direction until the piston rod is no longer sticking out (refer to figure 1-4 on page 7).
- 7 To insert a new PenFill cartridge please refer to Section 2.

Need Help?
Call 1-800-727-6500

7-2



If the reset mechanism locks, it is usually due to improper technique. Gently turn the mechanism side to side until it unlocks and then call our toll free number (1-800-727-6500) so that we may review your operating technique with you.

FUNCTION CHECK

For your peace of mind, you should regularly check the functioning of your NovoPen 3, (for example, once a month or before starting a new box of PenFill cartridges). The function check is done by delivering 20 units of insulin into the outer needle cap. You will not be injecting insulin into your body.

Always check the functioning of the NovoPen 3 if you suspect it has been damaged or if you are uncertain that it is delivering the correct dose.

To perform the function check:

- 1** Attach a NovoFine disposable needle (pp. 12-15).
- 2** Do an air shot (pp. 16-19).

FUNCTION CHECK (cont.)

- 3 Place the outer needle cap securely over the exposed NovoFine needle. **Do not replace the inner needle cap.**



Expel 20 units into the outer needle cap:

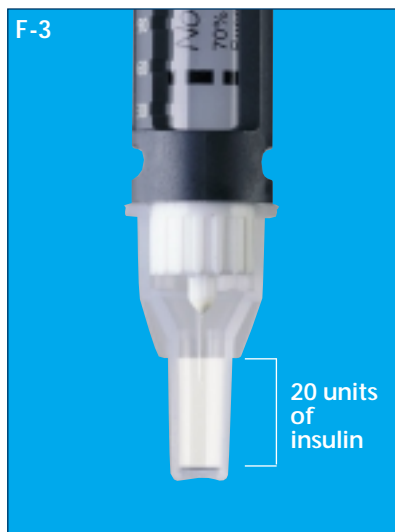
- 4 Turn the dial-a-dose selector so the dose indicator window shows 20.



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FUNCTION CHECK (cont.)

- 5 Hold the NovoPen 3 so the NovoFine disposable needle is pointing downward.
- 6 Slowly press the push button **as far as it will go**.
- 7 Check the dose indicator window to see if it shows zero (0). If it does not, there is not enough insulin in the cartridge for a function check. Insert a new PenFill cartridge (pp. 8-11) and repeat the function check.



The insulin should fill the bottom part of the outer needle cap. This indicates the device is functioning properly.

If the insulin **does not fill or overfills** this part of the cap, review the function check procedure. Then repeat the function check with a new NovoFine disposable needle and outer needle cap.

If the second function check also shows under- or over-filling, do not use your NovoPen 3.

DO NOT try to repair a NovoPen 3 that you think is not working properly.

(See Warranty section for further information.)

STORAGE

Guidelines for storing the NovoPen 3 and PenFill 3 mL cartridges:

- Store the NovoPen 3 (with the PenFill cartridge inside) at room temperature. **Do not store** the NovoPen 3 in a refrigerator or areas where there may be extreme temperatures or moisture, such as your car.
- Store the NovoPen 3 **without** the NovoFine needle attached and **with** the pen cap in position.
- For information on storing PenFill cartridges, see the package insert that comes in the PenFill cartridge box.

MAINTENANCE

Guidelines for maintaining the NovoPen 3.

Be sure to:

- 1 Clean it by wiping with a soft cloth moistened with alcohol.
- 2 Protect it from dust, dirt, and moisture when not in its case.

Make certain you:

- 1 **Do not** soak it in alcohol, wash it in soap and water, or lubricate it, since this may cause damage.
- 2 **Do not** expose it to excessive pressure or blows.
- 3 **Do not** drop it.

IMPORTANT THINGS TO KNOW

- The NovoPen 3 is not recommended for the blind or visually impaired, without the assistance of a sighted individual trained to use it.
- If you use more than one type (N, R or 70/30) of insulin, use a separate NovoPen 3 for each type.
- Use only a new PenFill cartridge when loading the NovoPen 3. Never load the NovoPen 3 with a partially filled PenFill cartridge.
- Always keep a spare insulin delivery system available, in case your NovoPen 3 is lost or damaged.
- Keep the NovoPen 3, PenFill cartridges, and NovoFine needles out of the reach of children.
- The American Diabetes Association recommends that insulin should be self-administered. The proper age for initiating this should be assessed by the adult caregiver.
- Keep the NovoPen 3 away from areas where temperatures may get too hot or too cold such as a car or refrigerator.
- The NovoPen 3 is designed for use with PenFill 3 mL insulin cartridges, NovoFine single-use disposable needles or other products specifically recommended by Novo Nordisk. Novo Nordisk is not responsible for any consequences arising from the use of the NovoPen 3 with products that are not recommended by Novo Nordisk.

IMPORTANT NOTES

The following is a review of some important information about the use and care of your NovoPen 3.

Before each injection, be certain:

- 1** The NovoPen 3 contains the correct insulin cartridge, if you use more than one type of insulin.
- 2** The PenFill cartridge contains enough insulin for mixing, if you use Novolin 70/30 or Novolin N insulin.
- 3** To always do the air shot with the NovoFine needle pointing upward.

Be sure to:

- 1** Check the dose indicator window after each injection to make sure you have received your full dose.
- 2** Remove the NovoFine needle immediately after each injection.
- 3** Select your dose only by using the number in the dose indicator window.
- 4** Perform the function check regularly or if you think your NovoPen 3 is not working properly.

IMPORTANT NOTES (cont.)

Make certain you:

- 1 DO NOT** place a NovoFine needle on the NovoPen 3 until you are ready to do an air shot and give an injection or perform a function check. Remove it immediately after each injection. If the NovoFine needle is not removed, some liquid may leak out of the PenFill cartridge. This may cause a change in the strength of Novolin 70/30 or Novolin N insulin.
- 2 DO NOT** use the clicking sound to set your insulin dose.
- 3 DO NOT** try to refill a PenFill cartridge.
- 4 DO NOT** use the same PenFill cartridge for more than one person, even though you attach a new NovoFine needle for each injection. This will prevent the spread of disease. Each PenFill cartridge is for single-person use only.

Blood glucose levels should be tested frequently to monitor your insulin regimen.

Any change in insulin should be made cautiously and only under medical supervision.

WHAT TO DO IF...

The dose indicator window does not show zero after the injection:

1 You did not receive your full dose.

Follow the steps on page 23 to get the remaining part of your dose.

No insulin appears when you do the air shot:

1 The piston rod is not far enough down the cartridge holder to reach the rear rubber stopper.

Repeat the air shot (pp. 16-19).

2 The NovoFine needle may not be securely attached.

- a. Put the plastic outer cap back on the NovoFine needle.
- b. Turn the plastic outer cap in a clockwise direction to tighten the NovoFine needle.

3 The NovoFine needle may be blocked.

Change the NovoFine needle (pp. 14-15) and continue the air shot (pp. 16-19).

The piston rod is sticking out too far to attach the cartridge holder to the barrel:

- 1** You must screw the piston rod back into the barrel. Never try to push it in or you can damage the mechanism.

The push button will not return to zero or the piston rod will not turn back into the reset mechanism

- 1** The return mechanism may be locked. This is usually due to improper technique. Gently turn the mechanism side to side until it unlocks and then call our toll free number (1-800-727-6500) so that we may review your operating technique with you.

WARRANTY

Should your NovoPen 3 device be defective in materials or workmanship within two (2) years of purchase, Novo Nordisk Pharmaceuticals, Inc. will replace it at no charge if you mail the defective unit along with a description of the problem and the sales receipt or other proof of purchase to:

**Novo Nordisk
Pharmaceuticals, Inc.
Product Safety
100 Overlook Center
Suite 200
Princeton, NJ 08540-7810
License under U.S. Patents
Nos. 5,462,535; 5,693,027;
5,626,566 and Des. 347,894
(cartridge) restricted to use
with Novo Nordisk insulin
cartridges and Novo Nordisk
pen needles.**

No other warranty is made with respect to NovoPen 3. This warranty will be invalid and Novo Nordisk A/S, Novo Nordisk Pharmaceuticals, Inc., Bristol-Myers Squibb Co., Nipro Medical Industries Ltd., and Bang & Olufsen A/S cannot be held responsible in the case of defects or damages arising from:

- The use of the NovoPen 3 with products other than PenFill 3 mL cartridges, NovoFine single-use disposable needles, or other products specifically recommended by Novo Nordisk.
- The use of the NovoPen 3 not in accordance with the instructions in this booklet.
- Physical damage to the NovoPen 3 caused by neglect, misuse, unauthorized repair, accident, or other breakage.

For assistance or further information, write to:

Novo Nordisk Pharmaceuticals, Inc.

Professional Services

100 Overlook Center

Suite 200

Princeton, NJ 08540-7810

Or call: 1-800-727-6500

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8-4244-31-001-4

