

NovoPen 3 PenMate Instruction Manual Page 2

FDA revision #4 (final)

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NovoPen® 3

previous page for graphic

PenMate_®

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Instruction Manual

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- 9 Read this carefully
- 10 before you use
- NovoPen® 3 PenMate® 11
- 12 and NovoPen® 3

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INTRODUCTION

- 18 NovoPen® 3 PenMate® is a replacement component specifically designed to be used
- 19 with the NovoPen 3 insulin pen. NovoPen 3 PenMate helps you to insert the needle and
- 20 to give injections quickly and easily. With NovoPen 3 and NovoPen 3 PenMate, you can
- 21 dial doses in units of one from 2 to 70 units.
- 22 NovoPen 3 PenMate should only be used in combination with products that are
- 23 compatible and allow the device to function safely and effectively.
- 24 NovoPen 3 PenMate is designed to be used with:
- 25 ■ NovoPen® 3
- 26 PenFill® 3 mL cartridges
- 27 NovoFine® 30G/8 mm and NovoFine® 31G/6 mm needles.
- 28 NovoFine disposable needles are for single-use only.

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- 30 The NovoPen 3 PenMate can be used the same way as the NovoPen 3 insulin pen. Its 31 design allows you to use the same recommended injection technique as for the NovoPen
- 3 insulin pen. 32

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- 34 This booklet contains instructions for using, storing, and cleaning NovoPen 3 PenMate in
- 35 combination with NovoPen 3. Please follow them carefully. You should read these
- 36 instructions even if you have used NovoPen 3, or NovoPen 3 in combination with the
- NovoPen 3 PenMate before. The two following pages provide illustrations of both the 37
- 38 NovoPen 3 and the NovoPen 3 PenMate.

- 40 Always check that the PenFill® cartridge you use contains the correct type of insulin.
- 41 If you are treated with more than one type of insulin in PenFill cartridges, you should use
- 42 a separate NovoPen 3 PenMate and NovoPen 3 for each type of insulin.
- 43
- 44 If you have any questions about your NovoPen 3 PenMate or your NovoPen 3 insulin
- delivery device, please call Novo Nordisk Pharmaceuticals, Inc. at 1-800-727-6500.
- 46 Please complete and return the NovoPen 3 PenMate Warranty Card.
- 47 Thank you for choosing the NovoPen 3 PenMate and NovoPen 3 insulin delivery device.

Look at the diagram

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NovoFine® NovoPen_® 3 NovoPen_® 3 **Insulin Delivery** PenMate_® **Disposable Needle** Device (For single-use only. Discard immediately after use.) Cap Outer needle cap Inspection window Insulin scale window Pen cap Inner Insulin scale needle cap Control line Needle Yellow push button Protective tab



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Barrel

window

Dose indicator

Push button

Dial-a-dose selector



Barrel

Dose indicator

window

selector

Dial-a-dose

Push button

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HOW TO USE THIS BOOKLET

This booklet gives you step-by-stepinstructions for using the NovoPen 3 PenMate in combination with the NovoPen 3.

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- Begin by reviewing the illustration layout of the parts of the NovoPen 3, NovoPen 3
- 59 PenMate, 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 an illustration on the right with numbered instructions to the left of
- 62 the illustration.
- 63 Important additional information is given below the illustration.
- We suggest that you **read the text and look at the illustrations** to make sure that you
- 65 understand each step thoroughly.
- Also included is a diagram showing a side-by-side comparison of the NovoPen 3 and the
- NovoPen 3 PenMate. This illustration allows you to see which part of the NovoPen 3 the
- NovoPen 3 PenMate replaces.

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- 70 The main differences between the NovoPen 3 and the NovoPen 3 PenMate are as
- 71 follows:
- The PenFill cartridge holder and the Pen cap of the NovoPen 3 are replaced by the
- 73 NovoPen 3 PenMate.
- NovoPen 3 PenMate allows for automatic insertion of the NovoFine needle under the
- skin; NovoPen 3 requires manual needle insertion.
- NovoPen 3 PenMate allows for the NovoFine needle to be completely hidden prior to
- needle insertion; the needle is visible on the NovoPen 3 prior to needle insertion.

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Look at the diagram inside the front cover for the names of the different parts of NovoPen 3 and NovoPen 3 PenMate. You can unfold the diagram to help you while you follow the instructions.

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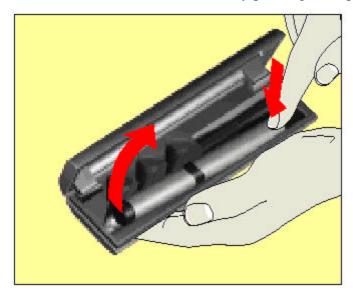
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SECTION 1 Assembly of the NovoPen3 PenMate

115 Assembly of the NovoPen 3 PenMate

1 Take NovoPen 3 out of its case by pressing the top of the pen cap.

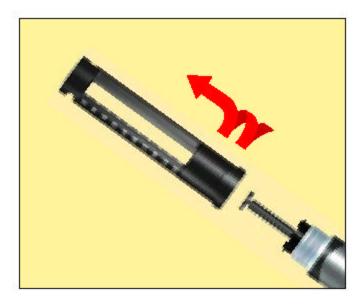


2 Gently twist the pen cap until it separates from the barrel.



3 Pull the pen cap straight up to remove it.

124 4 Unscrew and remove the PenFill holder from the barrel*



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- 126 * See diagram.
- 127 You will not use the pen cap and PenFill holder with the NovoPen 3 PenMate but you
- should store them in the case if you want to use NovoPen 3 without NovoPen 3 PenMate 128
- 129 in the future.

130 SECTION 1 (cont.)

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

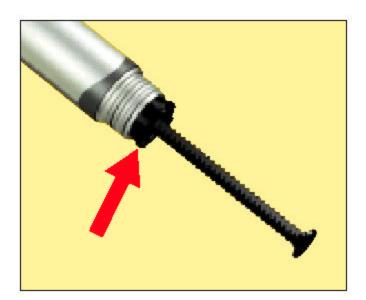
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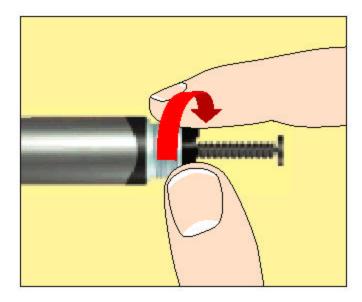
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If the piston rod is sticking out:

- Turn the end of the reset mechanism in a clockwise direction until the piston rod is no 135
- 136 longer sticking out. Never push the piston rod back in.

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Need Help? Call 1-800-727-6500

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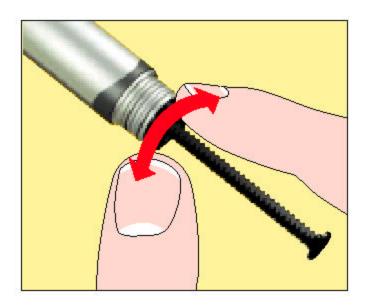
You should not reset the piston rod again until it is time to remove the used PenFill 3 mL cartridge and insert a new one.

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

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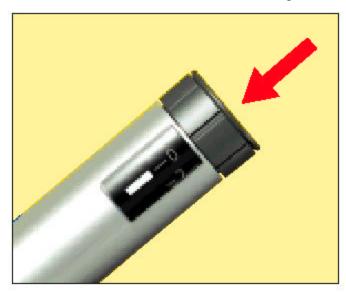
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SECTION 1 (cont.)

- **6** 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.
- 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.



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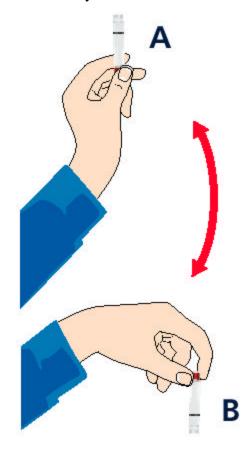
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- 7 If you use Novolin 70/30 [70% NPH, Human Insulin Isophane Suspension and 30% Regular, Human Insulin Injection (recombinant DNA origin)] or Novolin N, NPH [Human Insulin Isophane Suspension (recombinant DNA origin)], mix the insulin: 158
 - a. Turn PenFill cartridge up and down between positions A and B, as shown.
 - b. Repeat this mixing step at least 10 times or until the insulin looks uniformly white and cloudy.



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

Once the cartridge is punctured, it can be used at room temperature for the length of time identified in the storage information section of the Information For The Patient supplied with the PenFill cartridges. *The expiration date on the cartridge is for unused cartridges under refrigeration.*

SECTION 1 (cont.)

- Take the NovoPen 3 PenMate out of its case.
- Pull off the pen cap and put it to one side.

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Put the PenFill cartridge into the NovoPen 3 PenMate.

The threaded plastic cap goes in first.



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8 Tightly screw the barrel of the NovoPen 3 into the NovoPen 3 PenMate. Make sure that the dose indicator window on the mechanical section is aligned with the yellow push button on NovoPen 3 PenMate.

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187 188 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. The name of the insulin is on the glass part of the cartridge.

Each PenFill cartridge is for single-person use only.

DO NOT share the cartridge with anyone even if you attach a new disposable needle for each injection. This will prevent the spread of disease.

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Use only a new PenFill 3 mL cartridge when loading the NovoPen 3 PenMate. Never load a partially filled cartridge. Never try to refill a used PenFill 3 mL cartridge.

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SECTION 1 (cont.)

9 Clean the front rubber stopper on the PenFill cartridge 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.

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10 Remove the protective tab from the NovoFine® disposable needle.

Screw the NovoFine needle firmly onto the threaded plastic cap until it is tight. Pull off the outer and inner needle caps.

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For users of Novolin 70/30 or Novolin N insulin: Always remix the insulin before each injection.

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To remix the insulin, turn the NovoPen 3 PenMate up and down between positions A and B, as on page 4, 10 times or until the insulin looks uniformly white and cloudy.



strength of Novolin 70/30 or Novolin N insulin.

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SECTION 2

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Air shot before each injection

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

Air shot before each injection

- 11 The PenFill cartridge may contain an air bubble, and small amounts of air may collect in the needle and PenFill cartridge when you use them. To avoid the injection of air and ensure proper dosing, you must perform an air shot prior to each injection.
 - Check that the dial-a-dose selector is set at zero.

A drop of insulin should appear at the needle tip.

- Dial 2 units. Hold the NovoPen 3 PenMate with the needle upwards and tap gently near the window of NovoPen 3 PenMate with your finger a few times.
- Press the push button at the end of the barrel all the way in.

If not, repeat the procedure until a drop of insulin appears. There may still be some small

air bubble(s) in the PenFill cartridge after this, but they will not affect your dose and they will not be injected.

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 the instructions on how to reset the dose to zero in step 14.

239 **SECTION 3**

Choosing your dose

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Choosing your dose

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12 NovoPen 3 PenMate has an insulin scale with marks showing the approximate number of units left in the PenFill cartridge. Always check that there is enough insulin left for the injection. To activate, grip the barrel and the NovoPen 3 PenMate and firmly pull in opposite directions until you hear a click.

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Important: Do not pull the dial-a-dose selector.

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Check that the dial-a-dose selector is set at zero. If zero does not appear, follow the instructions on page 11.

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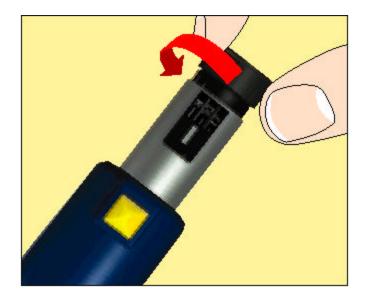
13 Dial the number of units you need to inject.

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The odd numbers are shown as full lines between the even numbers.

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Do not use the clicking sound as a guide for selecting your dose.



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The NovoPen 3 PenMate can deliver from 2 to 70 units of insulin in one 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.

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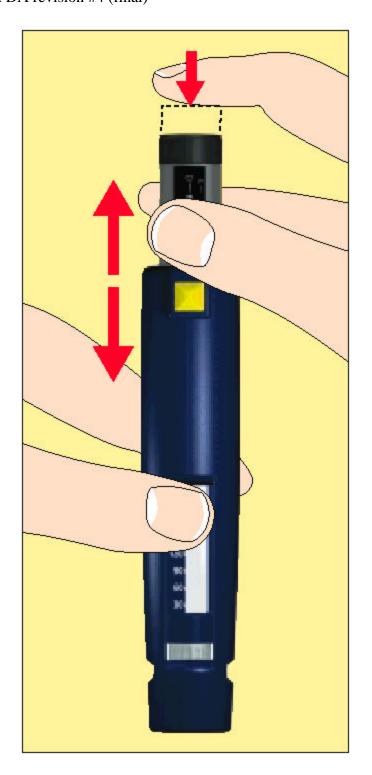
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SECTION 3 (cont.)

- 264 **14** If you dial a larger dose than you need, you need to reset your NovoPen 3 PenMate to zero.
- To reset to zero (0) if you set the wrong dose:
 - a. Pull the barrel and the NovoPen 3 PenMate in opposite directions and keep hold of them (see picture).
 - b. Press the push button on the barrel back to zero (0).
- c. Release your grip and the barrel section will slide back into place.
- d. You can now dial the correct units of insulin.

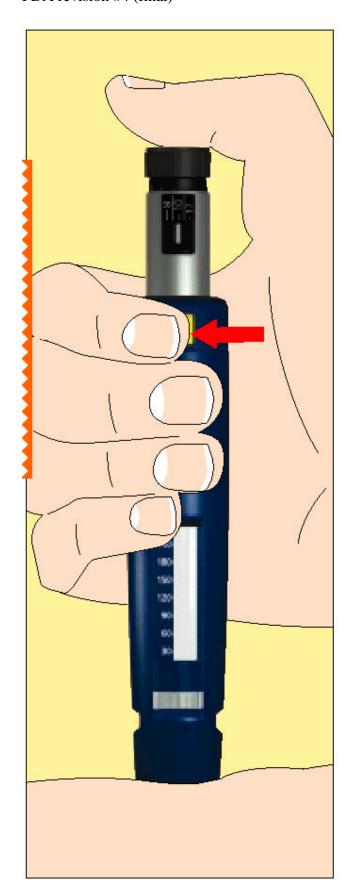
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276 277 278	SECTION 4	Giving the injection
279	Giving the injection	
280 281	15 Before injecting always chailed the correct number	heck the dose indicator window to make sure you have of units.
282	After the airshot (see page	e 9) and choosing your dose, hold the NovoPen 3 PenMate
283	at the correct site on the b	body for an injection. Use the injection technique
284	recommended by your hea	althcare professional. The PenMate is designed with a cut-
285	away on one side. This cu	nt-away allows injections at various angles other than 90°.
286	Press the yellow push-but	tton on the NovoPen 3 PenMate with your finger (see arrow
287	in diagram). The needle w	vill automatically enter the skin.

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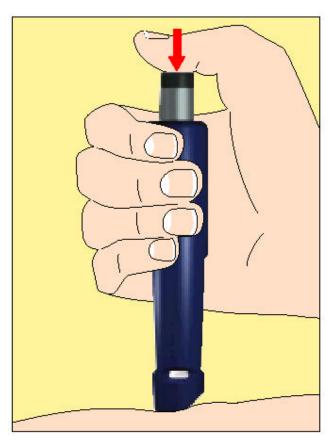


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290 **SECTION 4 (cont.)**

291	16 To inject your dose, press the push button of the barrel section as far as it will go.
292	Do not force it (see arrow in diagram).
293	
294	After injection, the needle should remain under the skin for several seconds. Keep the
295	push button fully depressed until the needle has been withdrawn from the skin.
296	If there is not enough insulin in the PenFill cartridge for the whole dose, you will be
297	able to see the number of units you still need to inject in the dose indicator window.
298	You must always check this after you have given the injection.
299	
300	Important: Never turn the dial-a-dose selector to inject the insulin.

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Page 23 FDA revision #4 (final) 303 When you press the push button, the piston rod presses against the rear rubber stopper of 304 305 the cartridge. This moves the rear rubber stopper and pushes the correct amount of 306 insulin out through the needle. 307 308 309 **SECTION 4 (cont.)** 310 Check that the dose indicator window shows zero. If it does not show zero, you did not 311 receive your full dose. For example: If you dial 25 units and there are only 20 units left in the PenFill cartridge, 312 313 the number 5 will appear in the window following the injection (25-20=5). If this occurs, 314 proceed with the following steps: 315 To get the remaining part of your dose: 316 a. Note the number of units in the dose indicator window. 317 b. Remove the NovoFine needle (see Section 5). 318 c. Remove the empty Novolin PenFill 3 mL cartridge (see Section 8). 319 d. Insert a new Novolin PenFill 3 mL cartridge (see Section 1). 320 e. Attach a new NovoFine needle (see Section 1). 321 f. Do an air shot (see Section 2). 322 g. Dial the number of units noted in step a. 323 h. Give the injection. 324 325 SECTION 4 (cont.) 326 To make sure that the insulin has been injected, do the following to be certain that 327 the needle advanced and penetrated the skin: 328 Check that you can see the control line (solid white line) at the top of the insulin scale 329 (above the number 300). 330 Check to see if your skin is wet where you gave the injection.

If you cannot see the control line after the injection or your skin is wet, see SECTION 5

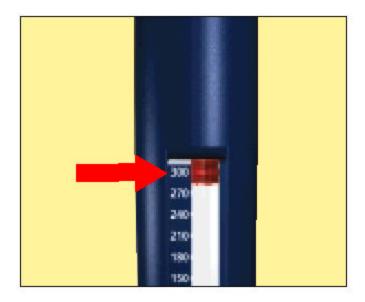
Call (800) 727-6500 or your healthcare professional if you have any questions.

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to perform a mechanical function check.

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SECTION 4 (cont.)

17 After the injection, remove the needle without recapping it. Hold the NovoPen 3 PenMate firmly while you unscrew the NovoFine disposable needle. Place the NovoFine disposable needle in a puncture-resistant disposable container.

Health care professionals, relatives, and other caregivers should follow precautionary measures for removal and disposal of needles to eliminate the risk of unintended needle penetration.

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Graphic to be changed

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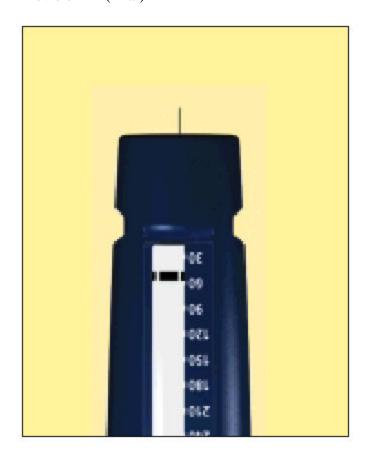
348	The NovoFine disposable needle must be removed immediately after each injection
349	without recapping. Put the NovoPen 3 PenMate cap back on. If the NovoFine
350	disposable needle is not removed, some liquid may leak out of the PenFill cartridge. The
351	may cause a change in the strength of Novolin 70/30 or Novolin N insulin.
352	For information on how to properly dispose of needle containers, call your local trash
353	disposal authorities.
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355	SECTION 5 Mechanical function check
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357	Mechanical function check of NovoPen 3 PenMate
358	18 Hold the NovoPen 3 PenMate with the needle pointing upwards.
359	To activate, grip the barrel and the PenFill holder of the NovoPen 3 PenMate and
360	firmly pull in opposite directions until you hear a click. If you do not hear a click,
361	contact Customer Relations at our toll free number 1-800-727-6500. Never use a
362	NovoPen 3 PenMate unless you are sure that it is working properly.
363	Important: Do not pull the dial-a-dose selector.
364	Check that the dial-a-dose selector is set to zero. If not, press the push button all the
365	way in.



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369 370 371 19 Push the yellow push button and the needle should appear. You should now be able to see the needle and the control line. If you cannot see the needle, do not use the NovoPen 3 PenMate. Never use the NovoPen 3 PenMate unless you are sure that it is working properly.

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Need Help? Call 1-800-727-6500

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SECTION 6

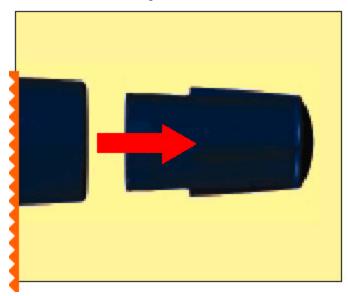
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For subsequent injections

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For subsequent injections

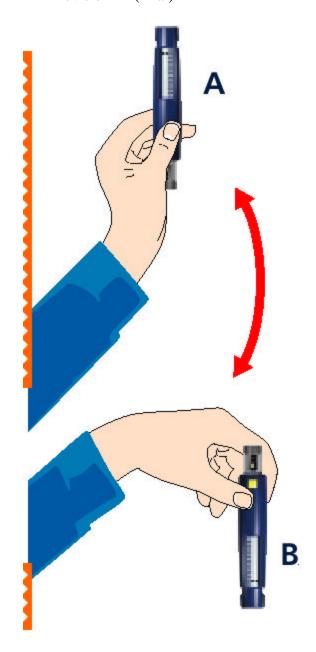
Pull off the NovoPen 3 PenMate cap. **Check that the needle has been removed since your last injection.** Check that NovoPen 3 PenMate contains the type of insulin you want to inject. If the PenFill holder of your NovoPen 3 PenMate contains a clear insulin PenFill cartridge such as Novolin R, follow steps 9 to 17.



21 If your NovoPen 3 PenMate contains an insulin suspension cartridge, such as Novolin 70/30 or Novolin N mix the insulin by turning the device up and down between positions A and B -as shown in the picture. The movement must be performed so that the glass ball in the cartridge moves from one end to the other. Do this at least ten times until the liquid is white and uniformly cloudy.

 Then continue as shown in steps 9 to 15 and inject immediately.

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SECTION 7 What to do when PenFill is nearly empty

What to do when PenFill is nearly empty

22 Do not start to inject an insulin suspension such as Novolin N or Novolin 70/30 if you can see the rubber piston in the small inspection window. The glass ball must have adequate space to resuspend the insulin. With the NovoPen 3 PenMate, it is possible to select a dose that is larger than the number of units left in the PenFill cartridge. If there is not enough insulin in the PenFill cartridge for the whole dose, you will be able to see the number of units you still need to inject in the dose indicator window after the injection.

To get the remaining part of your dose refer to Section 4, Page 14, a through h.

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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.

SECTION 8

Changing PenFill

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Changing PenFill

- 416 **23** a) Unscrew the barrel from the NovoPen 3 PenMate.
 - b) Press the push button to set the dose indicator to zero.
 - c) Make sure that the piston rod is not out (see Section 1, Page 5). (Twist it gently from side to side, if necessary).

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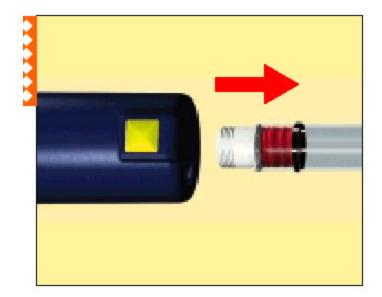
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> 24 Take out the empty PenFill cartridge. Take a new PenFill cartridge and continue as described from steps 6 and 7.

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Need Help? Call 1-800-727-6500

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SECTION 9

Function check

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Function check

25 If you think your NovoPen 3 PenMate is not working properly, follow this procedure:

- a) Check that the barrel and the NovoPen 3 PenMate are screwed together tightly and that the dose indicator window on the barrel is aligned with the yellow push button on the NovoPen 3 PenMate.
- b) Screw on a new NovoFine needle as described in step10.
 - c) Clear the air bubbles as described in step11.
 - d) Put the outer needle cap over the needle.
 - e) Dispense 20 units into the needle cap.

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The insulin should fill the lower part of the outer needle cap. If the pen has delivered too much or too little insulin, repeat the test. If it happens again, do not use the pen. Contact your supplier.

Do not try to repair a faulty NovoPen 3 or a faulty NovoPen 3 PenMate.

Never use NovoPen 3 or NovoPen 3 PenMate unless you are sure that they are working properly.

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449 **IMPORTANT**

- Keep the NovoPen 3 PenMate away from areas where temperatures may get too hot or too cold such as a car or refrigerator.
- Once the cartridge is punctured, it can be kept at room temperature for the length of time identified in the storage information section of the Information For The Patient supplied with the PenFill cartridges.
- Make sure that the piston rod is completely inside the reset mechanism before you screw together the barrel and the NovoPen 3 PenMate. (see step 5).
- 457 Always screw the mechanical section of NovoPen 3 and NovoPen 3 PenMate tightly together.
- Before each injection, make sure that you are using the right insulin preparation.
- 460 Always clear air bubbles with the needle pointing upwards before each injection (see step 11).
- With the NovoPen 3 PenMate, it is possible to select a dose which is larger than the number of units left in the PenFill cartridge. Before you inject, always check on the insulin scale that there is enough insulin left in the PenFill cartridge for your dose.

 After the injection, always make sure that you have injected the whole dose by checking that the dose indicator window reads 0. If not, see step 22.
- Do not use the insulin scale on the NovoPen 3 PenMate to measure the amount of insulin to be injected.
- Before injecting, always check the dose indicator window to make sure you have dialed the correct number of units.
- After injecting, make sure that NovoPen 3 PenMate was released and that the insulin has been injected (see step16).
- Take the needle off the NovoPen 3 PenMate immediately after each injection. If you do not remove it, temperature changes may cause liquid to leak out of the needle. With Novolin N or Novolin 70/30, this may change the concentration of the insulin.
- Do not inject Novolin N or Novolin 70/30 if the rear rubber stopper can be seen in the small inspection window.
- Always have extra insulin of the same type(s) you use available for alternative administration in case your NovoPen 3 PenMate, NovoPen 3, or PenFill gets lost or damaged.

IMPORTANT (cont.)

- Keep NovoPen 3 PenMate, NovoPen 3, PenFill, and NovoFine out of reach of children.
- 486 Your NovoPen 3 and NovoPen 3 PenMate are for use by the same person only.

- The NovoPen 3 PenMate is not recommended for the blind or visually impaired, without the assistance of a sighted individual who knows how to use NovoPen 3 PenMate.
- If you use more than one type (N, R, or 70/30) of insulin, use a separate NovoPen 3
 PenMate for each type of insulin.
- The American Diabetes Association recommends that insulin should be self-administered. The proper age for initiating this should be assessed by the adult caregiver.
- Use only a new PenFill cartridge when loading the NovoPen 3 PenMate. Never load
 the NovoPen 3 PenMate with a partially filled PenFill cartridge.
- The NovoPen 3 PenMate is designed for use with PenFill 3 mL insulin cartridges and NovoFine single-use disposable needles.
- Novo Nordisk is not responsible for any consequences arising from the use of the NovoPen 3 PenMate with products that are not recommended by Novo Nordisk.

501 **IMPORTANT** (cont.)

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

- Store the NovoPen 3 PenMate (with the PenFill cartridge inside) at room temperature. **Do not store** the NovoPen 3 PenMate in a refrigerator or areas where there may be extreme temperatures or moisture, such as your car. Once the cartridge is punctured, it can be kept at room temperature for the length of time identified in the storage information section of the Information For The Patient supplied with the PenFill cartridges.
- Store the NovoPen 3 PenMate without the NovoFine needle attached and with the pen cap in position. Leaving the needle on can cause the insulin to leak. This will affect the concentration of an insulin suspension.
- For information on storing PenFill cartridges, see the package insert that comes in the PenFill cartridge box. Once the cartridge is punctured, it can be kept at room temperature for the length of time identified in the storage information section of the Information For The Patient supplied with the PenFill cartridges. The *expiration* date on the cartridge is for unused cartridges under refrigeration.

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517 518 519	WHAT TO DO IF
520 521	Here are the answers to some questions you might need to ask when using your NovoPen 3 PenMate.
522	No insulin appears when I try to clear the air bubbles.
523 524 525 526	Check that your NovoPen 3 PenMate was put together correctly when you changed the PenFill cartridge. Make sure that the piston rod is completely inside the reset mechanism. Also make sure that the barrel and the NovoPen 3 PenMate are screwed tightly together (see steps 5 and 25).
527 528	No insulin appears when I try to clear the air bubbles and the push button will not go in.
529 530 531	The needle may be blocked. Change the needle and repeat air shots until insulin appears at the needle tip. Check if the PenFill cartridge is empty.
532 533	The push button will not depress during the injection.
534 535 536 537 538	Do not try to force the push button down. Check if the PenFill cartridge is empty. If there was not enough insulin in PenFill cartridge for the whole dose, you will see the number of units you still need to inject in the dose indicator window. Make a note of this. Change the PenFill cartridge and continue as described from step 23.
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543 544	WHAT TO DO IF (cont.) I cannot press the push button back to zero before I return the piston rod.
J 44	1 cannot press the push button back to zero before 1 return the piston rou.
545 546 547	The reset mechanism may be locked. Gently twist the reset mechanism from side to side until it unlocks. See the picture in step 5. Then you can press the push button down to zero. Never turn the dosage selector back.
548	I cannot get the piston rod back inside the reset mechanism when I change the
549 550 551	PenFill cartridge. The reset mechanism may be locked. Gently twist the reset mechanism from side to side until it unlocks. Then turn the reset mechanism to the right until the piston rod is

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completely inside it. See the picture in step 5.

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I think the needle has not entered the skin.

- 555 Check that you can see the control line at the top of the insulin scale.
- Also check if your skin is wet at the injection site. Carry out the mechanical function
- check as described in steps 18 and 19.

558 I think my NovoPen 3 or my NovoPen 3 PenMate is not working properly.

- Carry out the function check described in step 25. Make sure that the lower part of the
- outer needle cap is filled with 20 units of insulin. Also carry out the mechanical function
- check as described in steps18 and 19. Make sure that the control line is visible when
- NovoPen 3 PenMate is released. Never use your NovoPen 3 or your NovoPen 3 PenMate
- unless you are sure that they are working properly.

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MAINTENANCE

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How to store and look after your NovoPen 3 and your NovoPen 3 PenMate

- NovoPen 3 and NovoPen 3 PenMate are designed to work accurately. They should be
- handled with care. Avoid situations where your NovoPen 3 and NovoPen 3 PenMate can
- be damaged. Do not drop. Do not expose to excessive pressure or blows. Keep them in
- 571 the soft case whenever possible.

572

- You can put PenFill cartridges in NovoPen 3 PenMate or carry them with you as spares.
- 574 Please read the Information For The Patient supplied with the PenFill cartridges
- 575 for details of how to store the cartridges and how long to keep them.

576

You can clean your NovoPen 3 and your NovoPen 3 PenMate by wiping them with a cotton swab moistened with ethyl or isopropyl alcohol.

579

- Your NovoPen 3 and your NovoPen 3 PenMate are sturdy products but could still get damaged. So handle them with care and protect them against dust and dirt when they are
- not carried in the case.

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Do not try to repair a faulty NovoPen 3 or a faulty NovoPen 3 PenMate.

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- NovoPen 3 and NovoPen 3 PenMate must only be used in the way described in this
- booklet. The manufacturer will not be responsible for any problems you have with the
- equipment if you have not followed this booklet. If you find your NovoPen 3 or your
- NovoPen 3 PenMate faulty, Novo Nordisk will replace it if:
- You call Novo Nordisk Pharmaceuticals, Inc. at our toll free number 1-800-727-6500 within three years of getting it.

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593 WARRANTY

594

595 Should your NovoPen 3 PenMate device be defective in materials or workmanship within 596 three (3) years of purchase, Novo Nordisk Pharmaceuticals, Inc., will replace it at no 597 charge if you mail the defective unit along with a description of the problem and the sales 598 receipt or other proof of purchase to:

599

- 600 Novo Nordisk Pharmaceuticals, Inc.
- 601 **Customer Relations**
- 602 100 College Road West
- Princeton, New Jersey 08540-7810. 603

604

605 No other warranty is made with respect to NovoPen 3 PenMate. The mechanical section 606 of the NovoPen 3 insulin pen is covered by its own separate warranty, which is described 607 in its instruction manual. This warranty will be invalid and Novo Nordisk A/S, Novo Nordisk Pharmaceuticals, Inc., Bristol-Myers Squibb Co., Nipro Medial Industries Ltd., 608 609 and Bang & Olufsen A/S cannot beheld responsible in the case of defects or damages 610 arising from:

611

612 • The use of the NovoPen 3 PenMate with products other than NovoPen 3, PenFill 3 mL 613 cartridges, and NovoFine single-use disposable needles.

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• The use of the NovoPen 3 PenMate not in accordance with the instructions in this booklet.

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 Physical damage to the NovoPen 3 PenMate caused by neglect, misuse, unauthorized repair, accident, or other breakage.

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Use of the NovoPen 3 PenMate does not extend the warranty of the NovoPen 3 insulin

622 623

- 624 For assistance or further information, write to:
- 625 Novo Nordisk Pharmaceuticals, Inc.
- 626 **Customer Relations**
- 627 100 College Road West
- 628 Princeton, NJ 08540-7810

629

630 Or call: 1-800-727-6500

631

- 632 License under U.S. Patents Nos. 5,462,535; 5,693,02; 5,626,566 and Des. 347,894
- 633 (cartridge) restricted to use with Novo Nordisk insulin cartridges and Novo Nordisk pen needles.
- 634

- 636 Novolin®, NovoPen®, PenFill®, NovoPen® 3 PenMate®, and NovoFine® are
- 637 trademarks owned by Novo Nordisk A/S.

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/s/

David Orloff

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