OptiClik™ is a reusable insulin delivery device (prescription use) for use with a 3 mL LANTUS cartridge (U-100) system.

OptiClik™ allows you to dial the dose in one-unit step increments between one unit and a maximum of 80 units per injection.

This instruction leaflet explains how to use OptiClik™. It is important for you to read and follow the instructions in this leaflet carefully. If you do not follow these instructions completely, you may get too much or too little insulin. Keep this leaflet for future reference for each time you use OptiClik™.

General Warnings and Precautions

You should use a new sterile needle (intact protective seal) for each injection. This prevents a blocked needle and air bubbles. OptiClik™ allows you to dial the dose in one-unit step increments with 3 mL LANTUS cartridge (U-100) system.

Step 1

Make sure the Dosage Knob is pushed in.

Step 2

Attach the cartridge.

A. Peel off the Protective Seal on the needle.

B. Use an alcohol swab to wipe the rubber seal on the end of the cartridge.

C. Hold the Pen Body with the release button facing you and insert the cartridge system directly into the Pen Body. If you meet resistance, slightly raise and retake the Cartridge System while inserting it. Make sure that it clicks in. Do not use the cartridge system before use.

Step 3

Safety Test

A. Inject insulin to check.

B. The Dosage Knob must come out. “0” appears in the Digital Dose Display.

C. Turn the Dosage Knob to the right (clockwise) until it clicks. “1” appears in the Digital Dose Display.

Step 4

Press the Start Button.

A. The Cartridge Release Button is pressed.

B. Turn the Dosage Knob slowly to the right (clockwise) until you reach your required dosage. You must feel and hear a click.

Step 5

Injecting the dose

A. Press the Start Button. Do not press the Cartridge Release Button during the injection. See (C.) STORAGE INSTRUCTIONS.

B. If you have selected a dose that is too high, simply turn the Dosage Knob back to the left. If you have selected a dose that is too low, (B) TROUBLESHOOTING, Dose-setting on the back of this manual.

Step 6

Removing the needle

A. Replace Outer Needle Cap carefully.

B. Remove the needle after the injection. For safe disposal of needles see (A.) GENERAL NOTES, Needles for OptiClik™ on the back of this manual. Always replace Pen Cap on the Pen Body after use.

Step 7

Replacing an empty Cartridge System

A. Make sure the Dosage Knob is pushed in.

B. Press the Cartridge Release Button or the Start Button. See (C.) STORAGE INSTRUCTIONS.

C. The Cartridge System is undamaged. Insert the new sterile needle (intact protective seal) for each injection. This prevents a blocked needle and air bubbles. OptiClik™ allows you to dial the dose in one-unit step increments with 3 mL LANTUS cartridge (U-100) system.

Additional information needed for use with OptiClik™:

• Alcohol swabs:
• Appropriate needle:
• Cartridge System, at room temperature:
• Do not use tools on OptiClik™. If you are not sure whether or not your OptiClik™ has been damaged, contact your healthcare professional or call 1-800-633-1610. If damaged, do not use in your emergency. You could draw the insulin from the Cartridge System using a 3 mL insulin syringe. OptiClik™ should not be used near mobile and electronic equipment.

D. Other Information

1. Fill the Digital Dose Display.

2. Safety Test

A. The Cartridge System is undamaged.

B. The Cartridge System is not damaged by rough handling, dropping, or turning of the Dosage Knob too hard. Make sure that the unit is in contact with the mechanical parts. You should always make sure that:

C. If you have dials past 80 units, see (B) TROUBLESHOOTING, Dose-setting on the back of this manual.

D. The Cartridge System is not damaged, contact your healthcare professional or call 1-800-633-1610. If damaged, do not use in your emergency. You could draw the insulin from the Cartridge System using a 3 mL insulin syringe. OptiClik™ should not be used near mobile and electronic equipment.

E. The Cartridge System is at room temperature.

F. Do not insert the needle into the Cartridge System. The Cartridge System may become damaged by rough handling, dropping, or turning of the Dosage Knob too hard.

G. OptiClik™ is now ready for use.

H. Do not shake the cartridge system before use. You should look at the solution in the cartridge system before each injection. This prevents a blocked needle and air bubbles.

I. Make sure you do not push the Cartridge Release Button during or after this step. OptiClik™ is now ready for use.

J. Other Information

1. Clean the injection area with alcohol before injecting. Insert the needle as recommended by your Healthcare professional (e.g., tightly pinch a fold of skin on your stomach, thigh, or buttck, insert the needle straight into the pinched area).

2. OptiClik™ should not be used near mobile and electronic equipment.

3. You may become damaged by rough handling, dropping, or turning of the Dosage Knob too hard.

4. The Cartridge System is undamaged.

5. The Start Button, Dosage Knob, and Digital Dose Display operate properly.

6. Do not use tools on OptiClik™. If you are not sure whether or not your OptiClik™ has been damaged, contact your healthcare professional or call 1-800-633-1610. If damaged, do not use in your emergency. You could draw the insulin from the Cartridge System using a 3 mL insulin syringe. OptiClik™ should not be used near mobile and electronic equipment.

7. Make sure you do not push the Cartridge Release Button during or after this step. OptiClik™ is ready for use.

8. Use an alcohol swab to wipe the rubber seal on the end of the cartridge.

9. Correct a new needle without removing the Outer and Inner Needle Caps straight to the Cartridge System.


11. Do not press the Cartridge Release Button during or after this step. OptiClik™ is ready for use.

12. The Cartridge System is not damaged by rough handling, dropping, or turning of the Dosage Knob too hard.

13. Insulin must appear at 80 units, see (C.) STORAGE INSTRUCTIONS.

14. If you have dialed past 80 units, see (B) TROUBLESHOOTING, Dose-setting on the back of this manual.

15. Do not press the Cartridge Release Button during or after this step. OptiClik™ is ready for use.

16. Functional: Date: _____________

17. Regulatory: Date: _____________

18. Signature: ______________________
**A. GENERAL NOTES**

**Cartridge System**

The Cartridge System is sold separately. Before every injection, check the appearance of the Cartridge System and follow the instructions in the patient information booklet for Cartridge. It is important to follow the directions of this Instruction booklet closely to help avoid side effects (e.g., injections, improper dosing). Consult with your personal professional before using OptiClik™.

Before use of any unopened, refrigerated Cartridge System, take out of the refrigerator and leave it at room temperature for about 1 to 2 hours. Do not open or manipulate the Cartridge System in any way.

**Needles for OptiClik™**

Needles are available from BD Consumer Healthcare. Contact your healthcare professional for further information. Please note that these two types of needles differ: a) type whose needle is covered with a different type which needs to be pushed on (“Clicks”). Both needle types can be used. Please consult the manual of the needle package.

Needles may vary from country to country and may not be interchangeable. If you continue to use non-compatible or non-sterile needles, insulin will not be delivered.

Do not store OptiClik™ with a needle attached. Storing OptiClik™ with the needle may allow insulin to leak from OptiClik™ and to be harmful to the patient.

**Setting the dose and Display feature**

The Dose Display may automatically come into operation. The Dose Display may automatically come into operation. If the Dose Display is still flashing, check your batteries. If the Dose Display is still flashing, please consult your healthcare professional.

**Storing OptiClik™**

OptiClik™ is not in use, push the Dosage Knob to release the cartridge system, Step for attaching the needle, and Step for Safety Test.

**B. TROUBLESHOOTING**

**Safety test**

No insulin appears at the needle tip during Step 3 (Safety Test). If no insulin appears this time either, confirm that:

1. The needle is firmly in position. Replace a blocked or defective needle with a new one.
2. The Dose System has been correctly filled and the Dose Knob is turned to the appropriate range to prevent the Dose System from being blocked.
3. The Dose Knob is turned clockwise to the right, equal units. Again, you may try to turn the Dose Knob one click to the right, equal units.
4. The Cartridge System has been incorrectly inserted. Check by trying to pull the Cartridge System gently out. If you hear a clicking sound, remount it correctly, see Step 3 (Inserting the Cartridge System). Repeat step 3 (Safety Test).

**Insulin injection**

The Dose Knob cannot be pressed down for the insulin injection or it does not stay down:

1. As shown in Step for setting the dose, the Dose Knob is turned to the right, equal units. The Dose Knob is turned clockwise to the right, equal units. The Dose Knob is turned clockwise to the right, equal units. The Dose Knob is turned clockwise to the right, equal units.
2. The needle may be blocked or defective. Use a new needle.
3. Avoid pushing the Start Button and Dose Knob at the same time.

The needle from your skin, more than one drop of insulin from inside the Dose System:

It is possible that you may not have injected your full insulin dose. Do not try to make up for the shortfall in your insulin dose by giving a second injection. Again, you may try to turn the Dose Knob one click to the right, equal units. The Dose Knob is turned clockwise to the right, equal units. The Dose Knob is turned clockwise to the right, equal units. The Dose Knob is turned clockwise to the right, equal units.

Your battery has run out. Please obtain a new OptiClik™ as soon as possible.

OptiClik™ is not in use, push the Dosage Knob to release the cartridge system, Step for attaching the needle, and Step for Safety Test.

**Cartridge System replacement**

**Digital Dose Display functions**

The Dose Display automatic will not work back together properly:

1. Check that the Dose Knob is pushed in.
2. Check that you have put the Cartridge System correctly into the Pen Body. Please consult your healthcare professional for further information.
3. Check that you have replaced an empty cartridge and use the Cartridge System with a new one. Perform the Safety Test described in Step 2. Then press the remainder of the dose to equal your total prescribed dose. In the above example, turn the Dose Block to 7 units.
4. Turn back to the left, to “0.”
5. Check that the Dose Button is pushed in. Pressing the Dose Button automatically comes into operation and the Dose Display switches off. After delivering the insulin dose, slowly count to 10 before withdrawing the needle from your skin.

**Removal of air bubbles**

Air bubbles must be removed before each injection during the Safety Test (Step 2 for Safety Test). If air bubbles still remain, repeat the Safety Test, turning the Dose Knob to the right until “0” appears on the display. Then try the Pen Body and Dose System with it if it still gives a “Click”. If the Dose Knob does not stop at 20 units. You can choose to do one of the following:

1. Remove any air bubbles that may be present in the Cartridge System (see "GENERAL NOTES: Removing air bubbles.").
2. After delivering the insulin dose, slowly count to 10 before withdrawing the needle from your skin.

**How long will OptiClik™ last?**

The lifetime of OptiClik™ is 3 years.

**Flashes when the Start Button is pressed:**

Your battery is running out. Please obtain a new OptiClik™ as soon as possible.

**Battery Information**

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4. Turn back to the left, to “0.”
5. Check that the Dose Button is pushed in. Pressing the Dose Button automatically comes into operation and the Dose Display switches off.
6. After delivering the insulin dose, slowly count to 10 before withdrawing the needle from your skin.

**Storage Instructions**

Do not store OptiClik™ with or without cartridge system, in a refrigerator at any time. Always store OptiClik™ out of reach of children. However, sometimes it may stop at “0” or “99” as it will be out of the time. If any problem occurs, consult with your personal professional before using OptiClik™.

If the Dose Display is still flashing, please consult your healthcare professional.

**OTHER INFORMATION**

Care, cleaning, and maintenance instructions

Handle OptiClik™ carefully, to keep it clean, use a damp cloth. Clean it once a day, dirt can resist the operation. Do not store OptiClik™ for more than 3 years. For more information call toll free 1-888-910-1910 or please visit www.bloomberg.com or www.opticlik.com.

**Lifetime**

OptiClik™ is a lifetime of 3 years. For more information call toll free 1-888-910-1910 or please visit www.bloomberg.com or www.opticlik.com.

**Manufactured and distributed by:**

Aventis Pharmaceuticals Inc., Kansas City, MO 64137 USA

OptiClik™ is a trademark and Lanolin is a registered trademark of Aventis Pharma USA Inc.

For more information call toll free 1-888-910-1910 or please visit www.bloomberg.com or www.opticlik.com.

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