

OptiClik™

INSTRUCTION LEAFLET

OptiClik™ is a reusable insulin delivery device (insulin Pen) for use with 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 all 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™.

You will find further useful information on the back side of this leaflet in the chapters:

- (A.) General Notes
- (B.) Troubleshooting
- (C.) Storage Instructions
- (D.) Other Information

Please read this Instruction Leaflet carefully and completely before using OptiClik™ for the first time. Keep this leaflet for future reference for each time you use OptiClik™.

Talk with your healthcare provider before using OptiClik™ about proper injection technique.

If you have visual problems, use OptiClik™ only if you have help from a trained person with good vision.

Additional items needed for use with OptiClik™

- Alcohol swabs
- Appropriate needles
- Cartridge System, at room temperature

If you have any questions about OptiClik™ or about diabetes, ask your healthcare professional, go to www.opticlik.com or call Aventis at 1-800-633-1610.

General Warnings and Precautions

Needles

You must use a new sterile needle (intact protective seal) for each injection. This prevents a blocked needle and air bubbles. In order to avoid injuries, replace Outer Needle Cap before removing and disposing of used needles.

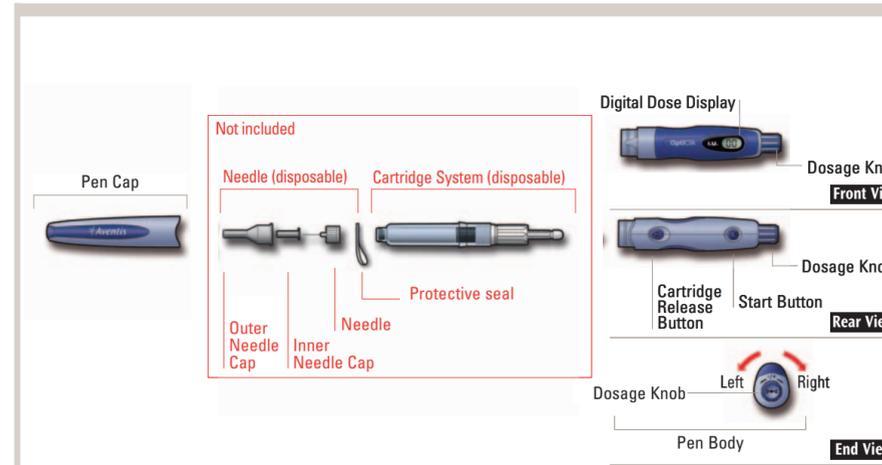
Safety test

Before each injection, carry out the Safety Test (Step 3). If you do not follow the instructions completely, you may get too much or too little insulin. Injecting too much or too little insulin dose may lead to unwanted blood sugar changes (see the package leaflet for your insulin). Do not perform the safety test without the needle attached.

Damage to OptiClik™

OptiClik™ may become damaged by rough handling, dropping, or turning of the Dosage Knob by force. Make sure that no dirt gets in contact with the mechanical parts. You should always make sure that:

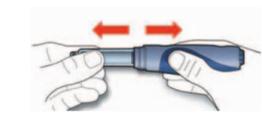
- a) The Cartridge System is undamaged.
 - b) The Start Button, Dosage Knob, and Digital Dose Display operate properly.
- Do not use tools on OptiClik™. If you are not sure whether or not your OptiClik™ is damaged, contact your healthcare professional or call 1-800-633-1610. If damaged, it is no longer safe to use. In an emergency, you can draw up the insulin from the Cartridge System using a U-100 insulin syringe.** OptiClik™ should not be used near electrical and electronic equipment.



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Step 1 Inserting the Cartridge System

Do not shake the cartridge system before use. You should look at the solution in the cartridge system before inserting it into OptiClik™. If the solution is cloudy, slightly colored, or has particles in it, do not use the cartridge.



- C** To make sure that the Cartridge System clicked in place properly, gently try pulling out the Cartridge System. The Cartridge System should not come out. Make sure you do not press the Cartridge Release button during or after this check.

OptiClik™ is now ready for Step 2 (Attaching the needle), or it can be stored with the attached Pen Cap.

DO NOT STORE YOUR OPTICLIK™ IN A REFRIGERATOR AFTER CARTRIDGE SYSTEM IS INSERTED IN OPTICLIK™



- A** Make sure the Dosage Knob is pushed in.



- B** Hold the Pen Body with the release button facing up. Insert the Cartridge System straight into the Pen Body. If you meet resistance, slightly raise and rotate the Cartridge System while inserting it. Make sure that it clicks in. Do not use force.

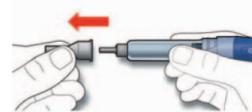
Step 2 Attaching the needle



- A** Peel off the Protective Seal on the needle.



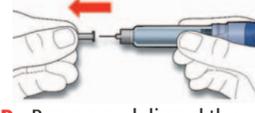
- B** Use an alcohol swab to wipe the rubber seal on the end of the cartridge. Connect a new needle without removing the Outer and Inner Needle Caps straight to the Cartridge System.



- C** Remove Outer Needle Cap from the needle. Save Outer Needle Cap for use later on in discarding the needle.

Step 3 Safety Test

Before each injection, carry out the Safety Test or you may get too much or too little insulin. **Make sure a needle is attached to OptiClik™ before you do the Safety Test.** Do not press the Cartridge Release Button during these steps.



- D** Remove and discard the Inner Needle Cap. Handle the exposed needle carefully.



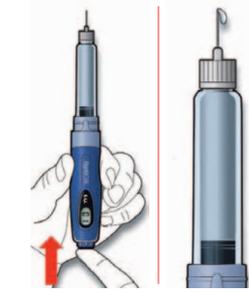
- A** Press the Start Button.



- B** The Dosage Knob must come out. "00" appears in the Digital Dose Display.



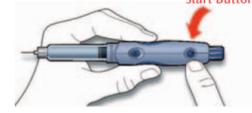
- C** Turn the Dosage Knob to the right (clockwise) until it clicks. "01" appears in the Digital Dose Display.



- E** Hold OptiClik™ with the needle pointing up. Press the Dosage Knob fully until it stays in. Insulin must appear at the tip of the needle. If not, repeat the Safety Test. When replacing an empty cartridge system with a new one, it might require repeating this procedure several times. A Safety Test must be carried out before each injection.

Additional information about "Cartridge System" and "Removing air bubbles" is on the back side of this leaflet.

Step 4 Setting the dose



- A** Press the Start Button.



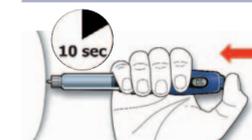
- B** Turn the Dosage Knob slowly to the right (clockwise) until you reach your required dosage. You must feel and hear a click.

If you have selected a dose that is too high, simply turn the Dosage Knob back (to the left). If you have dialed past 80 units, see (B.) TROUBLESHOOTING, Dose-setting on the back of this manual.

Step 5 Injecting the dose



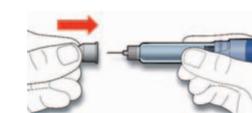
- A** Clean the injection area with alcohol. Insert the needle as recommended by your healthcare professional (e.g., lightly pinch a fold of skin on your stomach, thigh, or buttock). Insert the needle straight into the pinched skin.



- B** Press the Dosage Knob slowly and completely. The Dosage Knob must stay in. Then slowly count to 10 while holding the Dosage Knob down before withdrawing the needle.

Do not press the Cartridge Release Button or the Start Button while injecting.

Step 6 Removing the needle



- A** Replace Outer Needle Cap carefully.



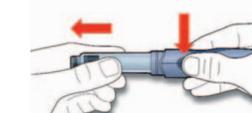
- B** Remove the needle after the injection. For safe disposal of needles see (A.) GENERAL NOTES, Needles for OptiClik™ on the back of this manual. Always replace Pen Cap on the Pen Body after use.

OptiClik™ can be stored with the attached Cartridge System until your next injection. See (C.) STORAGE INSTRUCTIONS.

Step 7 Replacing an empty Cartridge System



- A** Make sure the Dosage Knob is pushed in.



- B** Press the Cartridge Release Button, and remove the entire Cartridge System. Dispose of the Cartridge System.

Start again at Step 1 (Inserting the Cartridge System).

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A. GENERAL NOTES

Cartridge System

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

Before the use of an unopened, refrigerated Cartridge System, take it out of the refrigerator and leave it at room temperature for about 1 to 2 hours. Do not remove the Cartridge System from packaging until ready to use. This will prevent dust or dirt from getting into the mechanical parts of the Cartridge System. Use an alcohol swab to wipe the rubber seal on the end of the cartridge before inserting the needle. 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 there are two types of needles available: one type which needs to be screwed on and another type which only needs to be pushed on ("clicks on"). 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 intend to travel abroad, make sure that you have sufficient needles and insulin with you.

Do not store OptiClik™ with a needle attached. Storing OptiClik™ with the needle attached may allow insulin to leak from OptiClik™ and air bubbles to form in the cartridge.

Used needles should be placed in sharps containers (such as red biohazard containers), hard plastic containers (such as detergent bottles), or metal containers (such as an empty coffee can). Such containers should be sealed and disposed of properly.

Removing air bubbles

Air bubbles must be removed before each injection during the Safety Test (Step 3 for Safety Test). If air bubbles still remain, repeat the Safety Test, turning the Dosage Knob to the right until "02" appears on the display. Gently tap the Cartridge System until the air rises to the top of the Cartridge System tip. Then press the Dosage Knob until it stays in. If necessary, keep repeating the Safety Test until insulin appears at the tip of the needle.

Setting the dose and Display feature

To set the dose, hold OptiClik™ as shown in Step 4 for setting the dose. The printed "I.U." must be legible left of the Digital Dose Display. The Digital Dose Display shows the delivered dose for 2 minutes after every injection. After 30 minutes the display will go off to conserve battery power. With the Dosage Knob released the display switches off after 2 minutes.

How long will OptiClik™ last

The expected lifetime of OptiClik™ is 3 years.

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

OptiClik™ is reaching the end of its expected lifetime (3 years). The Digital Dose Display will continue to operate for about 4 more weeks. Please obtain a new OptiClik™.

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

OptiClik™ has reached the end of its lifetime. When you continue to turn the Dosage Knob, the display still shows . Please obtain a new OptiClik™.

B. TROUBLESHOOTING

Safety test

No insulin appears at the needle tip during Step 3 (Safety Test): Repeat 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 **Dosage Knob** has been set correctly (always turn the Dosage Knob to the right/clockwise to preselect the dose). Turn the Dosage Knob one click to the right, equal to one unit.
3. The **Cartridge System** has been inserted correctly. Check by trying to pull the Cartridge System gently out. If the Cartridge System comes out, reinsert it completely, see Step 1 (Inserting the Cartridge System). Repeat Step 3 (Safety Test).
4. The Cartridge System is not empty. If it is empty, insert a new one. Repeat Step 3 (Safety Test).

You hear no clicking sound during dose-setting:

The Cartridge System may have been inserted incorrectly. Check by trying to pull the Cartridge System gently out. If the Cartridge System comes out, reinsert it completely, see Step 1 (Inserting the Cartridge System). Repeat Step 3 (Safety Test).

If you still hear no clicking sound, try a new Cartridge System and listen for clicking sound. In case there is still no clicking sound, obtain a new OptiClik™.

Dose-setting

Insulin drips from the needle tip during dose-setting:

The maximum dose of OptiClik™ is 80 units. If you continue to dial after reaching 80 units, insulin will drip from the needle and the display will continue to show "80". In such a case, DO NOT turn back to the required dose, instead dial back (to the left) to "00". Press the Dosage Knob to expel excess insulin and to reset OptiClik™. OptiClik™ is now again ready for dose setting. If you need a dose greater than 80 units, you should give it as more than one injection.

You feel resistance during dose-setting and the Dosage Knob will not turn further forward (to the right):

- a) You are turning to the left and trying to dial down below zero. Turn the Dosage Knob to the right to dial your dose.
- b) The Cartridge System is almost empty and no longer contains a sufficient amount of insulin for the dose you need. For example, if there are only 20 units left in the cartridge and you need 25 units, the dosage knob will stop at 20 units. You can choose to do one of the following:
 - 1) Do not force the Dosage Knob any further (to the right). Inject the partial dose (20 units in the example), and replace the empty Cartridge System with a new one. Perform the Safety Test as described in Step 3, then inject the remainder of the dose to equal your total prescribed dose. In the above example, the remaining dose is 5 units. OR
 - 2) Dial back (to the left) to "00". Follow Step 2 (Replacing an empty Cartridge System), Step 1 (Inserting the Cartridge System), Step 2 (Attaching the needle), and Step 3 (Safety Test).
- c) You have dialed (to the right) past the maximum dose of 80 units and have no needle (or a clogged needle) mounted. Dial completely back (to the left) to "00", and perform Step 2 (Attaching the needle) and Step 3 (Safety Test). Do not force the Dosage Knob to turn further.

The Dosage Knob does not stop at "00":

When turned back completely, the Dosage Knob should stop at "00", however, sometimes it may stop at "02" or "01". Make sure that a needle is attached; then press the Dosage Knob down (insulin will appear at the tip of the needle). OptiClik™ is now ready for dose setting.

The Dosage Knob no longer turns after a new Cartridge System has been inserted:

Check that the Cartridge System is firmly clicked in. Reseat the Cartridge System and try again. If it still does not work, try again with a new Cartridge System, see Step 1 (Inserting the Cartridge System). Otherwise, get a new OptiClik™.

The Dosage Knob does not come out after you pressed the Start Button:

Do not pull out the Dosage Knob. Check that the Cartridge System is firmly clicked in, see Step 1-Inserting the Cartridge System.

Insulin injection

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

1. In setting the dose, you have turned the Dosage Knob so that it is between two dose steps. Turn the Dosage Knob to the right or the left to the desired dose.
2. The needle may be blocked or defective. Use a new needle.
3. Avoid pushing the Start Button and Dosage Knob at the same time.

After withdrawing the needle from your skin, more than one drop of insulin drips from the needle:

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 (otherwise you will be at risk for low blood sugar). Please check your blood sugar and consult with your healthcare professional.

You can avoid the problem next time by taking the following steps:

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.

Cartridge System replacement

The Cartridge System and Pen Body do not click back together properly:

1. Check that the Dosage Knob is pushed in.
2. Check that you have put the Cartridge System correctly into the Pen Body. Take the Cartridge System out and insert it again (see under Step 2 for replacing an empty cartridge and Step 1 for inserting the cartridge). Repeat Step 2 for attaching the needle and Step 3 for Safety Test.

Digital Dose Display functions

 **is displayed:**

1. When turned back completely (to the left), the Dosage Knob should stop at "00", in some cases it stops at "-". Perform a Safety Test (Step 3).
2. The Dosage Knob has been forced into the negative range with excessive force. The Cartridge System might be damaged and needs to be replaced. Follow the instructions under Step 2 to replace the cartridge and dispose of the damaged Cartridge System. Repeat Step 1 for inserting the cartridge, Step 2 for attaching the needle, and Step 3 for Safety Test.

 and  **flash alternately:**

a) The Dosage Knob has been forced into the negative range and was pushed in. The Cartridge System might be damaged and needs to be replaced. Repeat Step 2 for replacing an empty cartridge and dispose of the damaged Cartridge System. Repeat Step 1 for inserting the cartridge system, Step 2 for attaching the needle, and Step 3 for Safety Test.

b) The Dosage Knob has been turned too quickly. You can choose to do one of the following:

- 1) Dispose of the unknown pre-set dose by pressing the Dosage Knob. Set your dose (Step 4) and inject your dose (Step 5). OR
- 2) Turn the Dosage Knob slowly backward (to the left) until it stops, and then push the Dosage Knob in. Restart OptiClik™ and dial your dose.

No numbers appear on the Digital Dose Display when the Start Button is pressed or when the Dosage Knob is released:

Press the Dosage Knob. Start with a Safety Test (Step 3).

If there are still no numbers on Digital Dose Display, you should obtain a new OptiClik™.

The Digital Dose Display goes blank during dose setting (e.g., if you are interrupted in the middle of your injection preparations):

The energy save function has automatically come into operation. Turn the Dosage Knob one click further (to the right). OptiClik™ should now be ready to use again; check the Digital Dose Display and adjust for the right dose if needed.

Battery Information

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

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

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

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

C. STORAGE INSTRUCTIONS

Do not store OptiClik™, with or without cartridge system, in a refrigerator at any time. Always store OptiClik™ (without the needle attached) with or without Cartridge System inserted at room temperature below 86°F (30°C). Protect OptiClik™ from moisture and direct heat. When OptiClik™ is not in use, push the Dosage Knob in to conserve the battery and to ensure OptiClik™ functions throughout its expected lifetime.

To avoid dust or dirt from getting into OptiClik™, always replace the Pen Cap.

Once the Cartridge System is used with OptiClik™, the Cartridge System can be used for up to 28 days under normal carrying conditions (at room temperature below 86°F/30°C). See "Patient Information" for 3 mL cartridge for cartridge storage information.

D. OTHER INFORMATION

Care, cleaning, and maintenance instructions

Handle OptiClik™ carefully. To keep it clean, use a clean damp cloth. Clean it once a week. Dirt can impede the operation. DO NOT use cleaning agents. Use an alcohol swab only for cleaning the Cartridge System's rubber seal.

Lifetime

OptiClik™ has a lifetime of 3 years. See "(A.) GENERAL NOTES, How long will OptiClik™ last" for details.

Manufactured for and distributed by:

Aventis Pharmaceuticals Inc.,
Kansas City, MO 64137 USA

Made in Switzerland

OptiClik™ is a trademark and Lantus® is a registered trademark of Aventis Pharmaceuticals Inc.

For more information call toll free 1-800-633-1610 or please visit www.lantus.com or www.opticlik.com

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