

NovoPen® 6))

User guide

Read this user guide carefully before you use your NovoPen® 6 for insulin delivery the first time Find a quick guide at the back of this manual

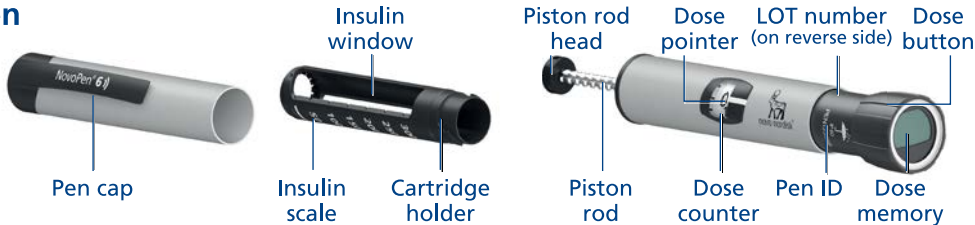


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NovoPen® 6)

Pen



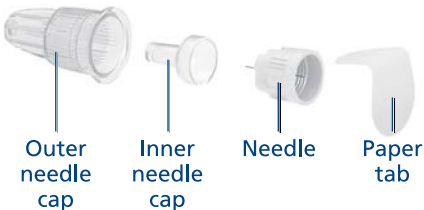
Dose memory



Number of units last injected

Time passed since last injection (hh:mm:ss)

Single-use needle (example)



Insulin cartridge (Penfill® cartridge 3 ml)



Introduction

Thank you for choosing NovoPen® 6.
NovoPen® 6 is a re-usable insulin pen with a dose memory function.

Your NovoPen® 6 package contains one pen, a soft case for storage and this user guide.

You should read this guide carefully before you use your pen – even if you have used NovoPen® 6 or similar Novo Nordisk delivery systems before. It will tell you all you need to know about your pen and how to use it. NovoPen® 6 is a re-usable pen injector designed for single patient use by diabetes patients for the self-injection of insulin in a home healthcare environment. The NovoPen® 6 pen injector should only be used with compatible products that allow it to function accurately and safely. The pen injector uses Penfill® 3 ml cartridges of Novo Nordisk insulin and single-use disposable needles (supplied separately). The pen injector allows the user to dial required doses from 1 to 60 units in 1-unit increments.

The pen has a dose memory that helps you remember the number of units you last injected and the time passed since that injection. The dose memory also saves your injection history for the past three months. See *pages 20-21* in the user guide for more information on how to use this to keep a personal injection log. You can transfer this to, for example, your smartphone to keep a personal injection log.

The pen is durable, which means that you can reuse it. When you have used all the insulin in a cartridge, you simply replace it with a new one. If you use more

than one type of insulin, it is highly recommended that you use a different NovoPen® 6 for each insulin type.

You can get the pen in grey or blue.

Always remember to check the name and colour of the cartridge to make sure it contains the correct type of insulin before every injection.

Mixing up your insulin can have serious medical consequences. It is therefore recommended, that if you use two types of insulin to discuss with your Healthcare Professional how to avoid mix ups.

About this user guide:

Throughout this guide, instructions on how to use your pen are presented step by step. Important information and additional information are clearly marked by the symbols you see below:



Important information

Pay special attention to these notes as they are important for safe use of the pen. If you do not follow the instructions carefully, you may get too little or too much insulin, or no insulin at all.

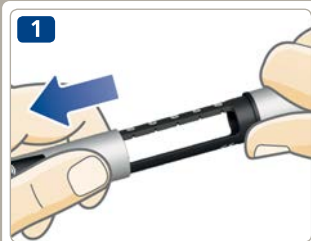


Additional information

Important notes

- **Do not use NovoPen® 6 without proper training** from your doctor or nurse. Make sure you are confident in making an injection with the pen before you start your treatment with it.
 - **If you are blind or have severe visual problems, do not use NovoPen® 6 without help.** Get help from a person with good eyesight who is trained to use NovoPen® 6.
 - **ALWAYS test the insulin flow before each injection.** Do not use the pen if insulin does not squirt from the needle tip when you test the flow. If you do not test the insulin flow, you may get too little insulin, or no insulin at all.
 - **If you drop your pen,** check the insulin cartridge for damages, for example cracks. Replace the cartridge with a new one if necessary.
 - **If you accidentally twist your pen apart** between injections, it is important to test the flow of insulin before your next injection. You may need to do it several times before insulin squirts from the needle tip. If insulin does not appear, you may get no insulin at all.
 - **NovoPen® 6 is designed to be used with Penfill® cartridge 3 ml and NovoFine® Plus, NovoFine® or NovoTwist®** single-use disposable needles up to a length of 8 mm.
- Novo Nordisk is not responsible** for harm due to using NovoPen® 6 with products other than these.
- **Always check the name and colour of the cartridge** to make sure that it contains the type of insulin you need. If you take a wrong type of insulin, your blood sugar level may get too high or too low.
 - **Always carry a spare pen,** extra insulin of the same type(s) you use, and new needles with you in case of loss or damage.
 - **Never share your pen,** insulin cartridges and needles with other people. They are for your use, only.
 - **Always keep your pen,** insulin cartridges and needles **out of sight and reach of others, especially children.**
 - **Always keep your pen with you.** Do not leave it in a car or other place where it can get too hot or too cold.
 - Caregivers must **be very careful when handling used needles** to reduce the risk of needle sticks and cross-infection.

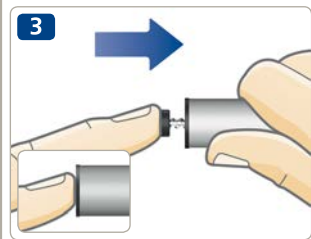
2 Insert an insulin cartridge



- Pull off the pen cap.



- Twist off the cartridge holder. Put it to one side for later use.



- **The piston rod may stick out** of your pen. If so, **push it completely in** until it stops.

i The piston rod and the piston rod head may be loose and move on their own. This is natural and does not affect the function of the pen.

- Take a new insulin cartridge. Hold the cartridge holder and let the cartridge slide in with the **threaded end first** as illustrated. The colour of your cartridge may differ from the one shown in the illustration. It depends on the type of insulin you use.



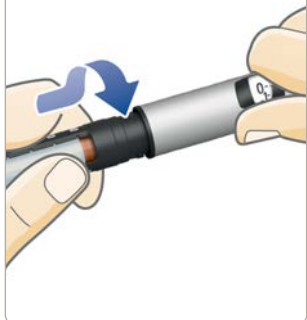
Check the name and colour of the cartridge to make sure that it contains the type of insulin you need. If you take a wrong type of insulin, your blood sugar level may get too high or too low.

Check that the cartridge is not damaged, for example by cracks. See how to do this **in the Penfill® cartridge 3 ml leaflet that comes with the Penfill® cartridge 3 ml package.**

Check that the insulin looks the way it should. The Penfill® cartridge 3 ml leaflet will tell you how your type of insulin should look.

NovoPen® 6 is designed to be used with Penfill® cartridge 3 ml and NovoFine® Plus, NovoFine® or NovoTwist® single-use disposable needles up to a length of 8 mm.

5



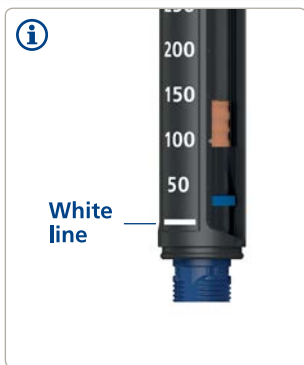
- Twist the cartridge holder back on, as illustrated, until you **hear or feel a click.**

If you use white and cloudy insulin

If you use an insulin cartridge with cloudy-looking insulin (white insulin suspension), **always resuspend this right before injection.** See the *Penfill® cartridge 3 ml leaflet* on how to resuspend your type of insulin.

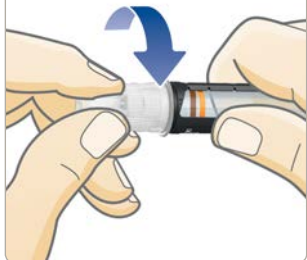
Make sure there is enough space in the cartridge before you resuspend the insulin:

The piston must be **above the white line** on the cartridge holder when you hold the pen as illustrated. This is necessary to allow the glass ball inside the cartridge to move freely to resuspend the insulin. If the piston is below the white line, replace the insulin cartridge with a new one, see *pages 26-27*.



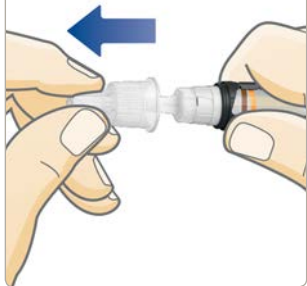
Attach a new needle

1



- Take a new needle, and tear off the paper tab.
- Push the needle **straight** onto the pen. **Turn until it is on tight.**

2



- Pull off the outer needle cap and save it. You will need it after the injection, to safely remove the needle from the pen.

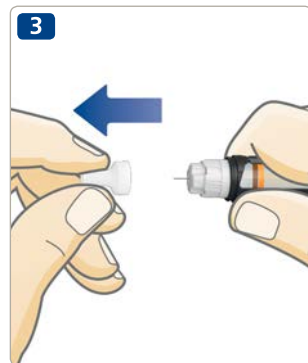


Always use a new needle for each injection. This reduces the risk of blocked needles, contamination, infection and inaccurate dosing.

Never use a bent or damaged needle.

Do not attach a new needle to your pen until you are ready for your next injection.

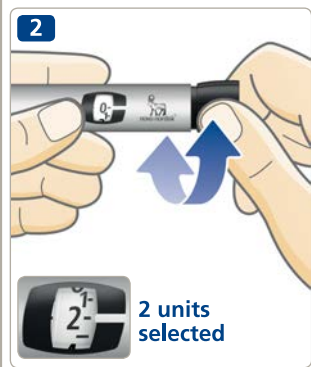
- Pull off the inner needle cap and throw it away.
A drop of insulin may appear at the needle tip. This is normal, but you must **still test the insulin flow**.



The needle is covered by two caps. You must remove both caps. If you forget to remove both caps you will not inject any insulin and your blood sugar level may get too high



NovoPen® 6 is designed to be used with Penfill® cartridge 3 ml and NovoFine® Plus, NovoFine® or NovoTwist® single-use disposable needles up to a length of 8 mm.



ALWAYS test the flow before you inject. Keep testing until insulin squirts from the needle tip. This makes sure that any gap and air bubbles are removed and that insulin is getting through the needle.

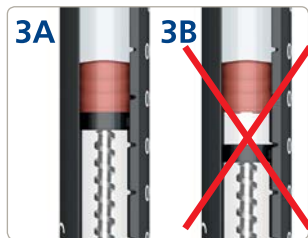
- **Pull out the dose button**, if it is not already out.
- Turn the dose button to select **2 units**.

- **Press the dose button** until the dose counter shows “0”. The “0” must line up with the dose pointer.
- Check that **insulin squirts** from the needle tip.

If no insulin appears, repeat steps 1-3 until insulin squirts from the needle tip.

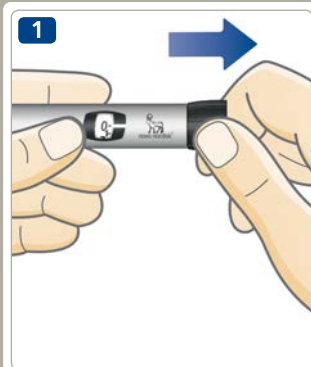
If no insulin appears after several attempts, check the insulin window to see if there is a gap between the black piston rod head and the piston, *see illustrations 3A and 3B*. If you do not see any gap, change the needle and test the insulin flow again.

The insulin flow test is complete when you see insulin squirt from the needle tip.



- !** **Do not try to inject if no insulin appears.** You may not receive any insulin, even though the dose counter may move. This could lead to too high blood sugar (hyperglycaemia). **If insulin does not appear after testing the flow repeatedly**, do not use the pen. Contact your supplier to get a new pen.

10 Select your dose



- **Pull out the dose button**, if it is not already out.
- **Make sure the dose counter shows "0" before you start.**
The "0" must line up with the dose pointer.



- **Turn the dose button to select the dose you need.**
You can turn the dose button **forward or backward**.

i The dose button changes the number of units. Only the dose counter and the dose pointer will show how many units you select per dose.
You can select up to 60 units per dose.



Always look through the insulin window to **make sure that the insulin in your pen looks the way it should.** The Penfill® cartridge 3 ml leaflet will tell you how your type of insulin should look.

Always use the dose counter and the dose pointer to see how many units you select.

Do not use the insulin scale on the cartridge holder. It only shows approximately how much insulin is left in your pen.

Do not count the pen clicks.

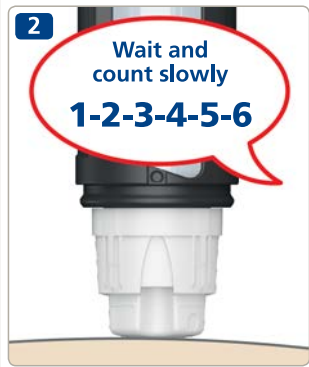
If you select and inject a wrong dose, your blood sugar level may get too high or too low.



The dose button should turn easily. Do not force it to turn.

When your pen contains less than 60 units, the dose counter stops at the number of units left. If you need more insulin than what is left in the cartridge, see *pages 24-25*.

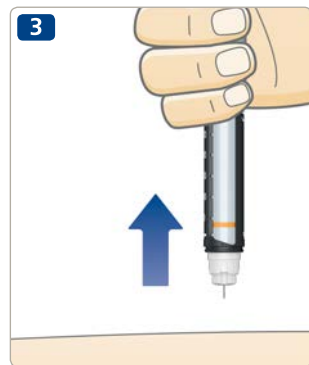
12 Inject your dose



ALWAYS test the flow before you inject.

- **Check the name and colour** of the cartridge to make sure that it contains the type of insulin you need. If you take a wrong type of insulin, your blood sugar level may get too high or too low.
- **Insert the needle into your skin** as your doctor or nurse has shown you.
- **Make sure you can see the dose counter.**
- **Press the dose button** until the dose counter shows "0". The "0" must line up with the dose pointer. You may then hear or feel a click.
- **Keep the needle in your skin after** the dose counter has returned to "0" and **count slowly to 6.**
If the needle is removed earlier, you may see a squirt of insulin coming from the needle tip. If so, the full dose will not be delivered, and you should increase the frequency of checking your blood sugar levels.

- Remove the needle from your skin.



! **Always inject by pressing the dose button. Do not turn it.**

If you turn the dose button, you will **not** inject insulin.

Always watch the dose counter to know how many units you inject. Do not count the pen clicks. The dose counter will show the exact number of units.

If the dose button stops before the dose counter shows "0", the needle may be blocked. Turn the dose counter back to "0" and replace the needle with a new one. Test the insulin flow and inject your full dose.

i You may see a drop of insulin at the needle tip after injecting. This is normal and does not affect your dose.

14 After your injection



- Remove the needle right away by screwing it into a sharps container.



- If you do not have a sharps container, follow a one-handed needle recapping method. **Lead the needle tip into the outer needle cap** on a flat surface without touching the needle.



- Do not touch the outer needle cap before it covers the needle.
- Once the needle is covered, **carefully push the outer needle cap completely on.**




Never try to put the inner needle cap back on the needle.
You may stick yourself with the needle.

- Hold the black cartridge holder and unscrew the needle. Throw it away carefully as your doctor or nurse has instructed you.



- **Put the pen cap on** your pen after each use to protect the insulin from light.
- Store your pen carefully. The pen should be **out of sight and reach of others, especially children**, see *page 31* on how to store the pen.



-  **Always hold the black cartridge holder when you unscrew the needle.** Otherwise you may twist your pen apart. If this happens, twist the pen together again. Replace the needle and test the insulin flow before your next injection to make sure you get your full dose.

Always remove and throw away the used needle safely, for example in a sharps container, as instructed by your doctor or nurse. This reduces the risk of blocked needles, contamination, infection and inaccurate dosing. Do not store your pen with a needle attached.

What is the dose memory?

1

Number of units
last injected



Time passed since
last injection

Your pen has a dose memory that shows **how much** insulin you last injected and the **time passed** since your last injection:

- The number at the top shows the **number of units** last injected.
- The timer below counts the **hours, minutes and seconds (hh:mm:ss)** that have passed since your last injection.

The example on the left shows 5 units injected 3 hours, 45 minutes and 10 seconds ago.

How does it work?

The dose memory records your dose when the dose counter returns to "0" and the dose button is pressed completely in after an injection.

Note that **the dose memory only shows the details of the last injection or insulin flow test**. This means that when you test the insulin flow before a new injection, it will overwrite the details of your last injection.

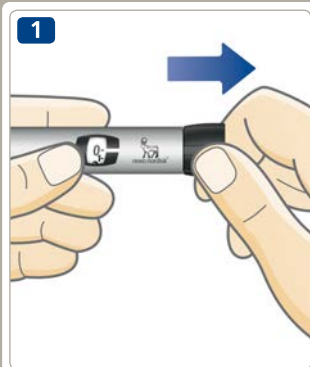
What does it remember?

The dose memory in your pen also **saves your injection history for the past three months**. You can only view this information if you transfer it to, for example, a smartphone, tablet, PC or BG meter. See *pages 20-21* on how to use the information to keep a personal injection log.



The dose memory does **not** tell you how much insulin you need for your next injection. If in doubt about how much insulin you need to inject, check your blood sugar level. Otherwise, you may get too much or too little insulin.

18 How to check your last dose



- Make sure the dose counter shows “0” before you start. The “0” must line up with the dose pointer.
- **Pull out the dose button.**



- **Push the dose button back in.**
The dose memory will now show the details of your last dose. After 15 seconds, it turns off.



If you suspect that the dose memory displays incorrect details, for example if you have handled the pen differently than intended, always check your blood sugar level before you select the dose for your next injection.

Do not turn the dose button when you check your last dose. Turning and then pushing it will overwrite the details of your last dose.

If you turn the dose button by accident, simply turn it back to "0" before you push it in. This will **not** overwrite the details of your last dose.

20 How to keep a personal injection log

The dose memory in your pen supports near field communication (NFC). **If you have a smartphone, tablet, PC, BG meter or another device that also supports NFC**, you can transfer your injection history from your pen to this device to keep a personal injection log. Just make sure your device has a compatible app or other software that can read and display your injection details.

1 Check if your device supports NFC.

Check the user manual for your device to find out if the device supports NFC, and exactly where the NFC spot is located on the device.

2 Check if your device has a compatible app or other software to read your injection details.

If your device does not have a compatible app or other software, locate and download one or contact your Novo Nordisk supplier for information.

3 Check your app or other software to see:

- how to prepare the device for information transfer.
- how to display your injection details.





4 Transfer your injection history to your device.

- **Hold** the dose memory of the pen straight against the NFC spot on your device.
- **Wait** while the details of your latest injections are automatically transferred to your device.



Your pen has a unique pen ID, which is located on the dose button as shown. When you display your personal injection log on your device, the pen ID is linked to your injection details.

If you use different pens for different types of insulin, check the pen ID. It will tell you which of your pens the injection details come from.

22 How to check how much insulin is left



The dose counter will show exactly how much insulin is left in the cartridge, when there is less than 60 units left.

- Turn the dose button until it stops.
- Check the dose counter:
 - If it shows “60”: **60 units or more** are left in the cartridge.
 - If it shows less than “60”: **It is showing the number of units left** in the cartridge.
- Turn the dose button back until the dose counter shows “0”.

- Use the **insulin scale** to see **approximately** how much insulin is left in the insulin cartridge.



-  If you need more insulin than what is left in the cartridge, take your full dose from a new cartridge, see page 24.

24 If you need more insulin than what is left in the cartridge



If you need more insulin than what is left in the cartridge, **take your full dose from a new cartridge.**

- Remove the needle. Twist off the cartridge holder and throw away the used cartridge.
- Insert a new cartridge, see *pages 2-4*.



- Attach a new needle and **test the insulin flow**, see *pages 6-9*.



- Select and inject your **full dose with the new cartridge**, see *pages 10-13*.



Only if trained or advised by your doctor or nurse, you may split your dose between two cartridges.

If you become distracted, make a miscalculation or forget to test the flow, you may get a single under- or overdose which may lead to too high or too low blood sugar levels.

If you feel unwell after splitting the dose, check your blood sugar and/or contact your doctor or nurse.

If you do split your dose:

- 1 Test the insulin flow.**
- 2** Find out exactly how much insulin is left and make a note of it. Turn the dose button until it stops. The dose counter then shows you the number of units left in the cartridge.
- 3** Inject all the insulin left in the cartridge.
- 4** Work out how many more units you need to complete your dose.
- 5** Remove the used needle and cartridge.
- 6** Insert and prepare a new cartridge for injection.
- 7** Attach a new needle and **test the insulin flow.**
- 8** Select and inject the rest of your dose with the new cartridge.



If you split your dose into two injections, the dose memory will only show information about the second injection.

26 How to replace a used insulin cartridge



- **Remove and throw away the needle** from your pen if the needle is still on, see *pages 14-15*.



- Twist off the cartridge holder.

i When you twist off the cartridge holder, the piston rod sticks out of your pen. It may move back or forth on its own. Push it back in *as instructed on page 2*.

- Tilt the cartridge holder and **let the cartridge slide out**. Throw it away as your doctor or nurse has instructed you.
- Push the piston rod back in. Then **insert a new cartridge** and twist the cartridge holder back on. Attach a new needle and test the insulin flow, see *pages 6-9*.





Dose memory inactive or battery flat

Battery is flat or the dose memory has not been activated

What to do?

Pull out the dose button, then push it back in to show the details of your last dose. If the display stays blank, the battery is flat.

Contact your supplier to get a new pen. You can still use your pen for insulin delivery until you get a new one. See page 32 for warranty information.

The dose memory will be activated when you use your NovoPen® 6 for the first time.



Last injection not registered

The dose memory has not registered your last injection.

What to do?

Normally, the dose memory will start working again after your next injection. If not, contact your supplier to get a new pen. You can still use the pen for insulin delivery without using the dose memory. If you are in doubt about how much insulin you injected, check your blood sugar level.



Pen approaching end of life

The battery is running low, and the dose memory is approaching end of life.

What to do?

The pen will last four to five years. When the battery is running low and the dose memory display has shown "End" for a while, the display will turn blank and stop working.

Contact your supplier to get a new pen. You can still use your pen for insulin delivery until you get a new one. See *page 32* for warranty information.

Care

- **Only use your NovoPen® 6** as described in this guide.
 - **Do not drop your pen** or knock it against hard surfaces. If you drop it or suspect a problem, check the insulin cartridge for damages, for example cracks. Replace the cartridge with a new one if necessary.
 - **Keep your pen away** from direct sunlight, and do not expose it to dust, dirt, liquid or extreme temperatures.
 - **Do not try to repair your pen** or pull it apart.
 - Your pen has an internal lithium battery. For your safety it is non-replaceable. When the battery is flat, contact your supplier to get a new pen. You can still use your pen for insulin delivery without using the dose memory.
- ① **The battery lasts for four to five years if used for the first time before the date printed next to this symbol on the outside carton.**

Cleaning

- **Only clean your pen with a mild detergent** on a moistened cloth.
- **Do not wash, soak or lubricate your pen**, and do not use products containing bleaching agents, such as chlorine, iodine or alcohol to clean your pen. This may damage it.
- If there is insulin on the outside of your pen, **clean it before it dries up** with mild detergent on a moistened cloth.



Must be kept dry.

Storage

- With an insulin cartridge inserted, please see the storage instructions in the Penfill® cartridge 3 ml leaflet that comes with the Penfill® cartridge 3 ml package.
- Without an insulin cartridge inserted, store your pen at room temperature.
- **Do not store your pen with a needle attached.**
- **Do not freeze your pen** or store it in a refrigerator or next to a cooling element.
- **Store the insulin cartridges** as instructed in the Penfill® cartridge 3 ml leaflet. There you will also find information about expiry date. The expiry date printed on the cartridge is for unused cartridges under refrigeration. Never use the cartridge after the expiry date on the cartridge or its box.
- **Store your pen in its case** when possible.

Disposal

- **Do not throw the pen out** with your household waste.
- **Throw away your pen as instructed by your doctor, nurse, pharmacist or local authorities.** Consider the environment when you throw away your pen. It contains a lithium battery, electronic parts and recyclable materials. Also make sure to remove the insulin cartridge and needle before you throw away the pen.
- Packaging material can be recycled.



Dispose of electronic equipment separately.

Warranty

NovoPen® 6 comes with a 3-year guarantee, which also includes the dose memory.

If you find that your NovoPen® 6 is faulty, Novo Nordisk will replace it. Return it to your supplier for inspection within three years of receiving it. Enclose the receipt you were given when you received your NovoPen® 6.

For customers in the European Union; if, in the course of use of NovoPen® 6, you have reason to believe that a serious incident occurred, please report it to Novo Nordisk A/S and to your national authority.

The manufacturer cannot be held responsible for any problems with your NovoPen® 6 if the instructions have not been followed.

If you find that the information provided in this user guide is incorrect, contact your supplier to clarify the issue.

If you need your pen's LOT number, you will find it on the dose button as shown in the diagram on the inside cover.

NovoPen®, Penfill®, NovoFine® and NovoTwist® are registered trademarks owned by Novo Nordisk A/S, Denmark.

The N Mark is a trademark or registered trademark of NFC Forum, Inc. in the United States and in other countries.

Technical information

The CE mark on a medical device indicates that the product conforms with the provisions in the EC Directive for Medical Devices 93/42/EEC. Novo Nordisk A/S, hereby declares that the radio equipment type NovoPen® 6 is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: <http://bit.ly/NovoPen6> NovoPen® 6 fulfils the specification limits for dose accuracy (essential performance) according to ISO 11608-1 Pen-Injectors for Medical use, Part 1: Requirements and test methods.

Storage and operational conditions

- Without an insulin cartridge inserted:
Temperature: 5 °C to 40 °C
Humidity: 15% RH to 93% RH
Atmosphere: 700 hPa to 1060 hPa.
- With an insulin cartridge inserted:
See the instructions in the Penfill® cartridge 3 ml leaflet that comes with the Penfill® cartridge 3 ml package.

Mode of operation

Continuous Operation.

Protection against ingress

NovoPen® 6 is marked with IP50, where:

- 5 indicates protection against harmful amounts of dust.
- 0 indicates that the device is not protected against liquid ingress



Protection against electrical shock

Type: Internally Powered ME Equipment.

Degree: Type BF Applied Part.

Electromagnetic compatibility

Although designed to offer protection against harmful interference in a home use environment, NovoPen® 6 generates, uses and can radiate radio frequency (RF) energy. Interference may therefore occur under certain conditions.

Your injection is not controlled by electronics, and dose accuracy will therefore not be affected by electromagnetic disturbance.

Date of issue: 2019/05

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