Regulatory Operations

Novo Nordisk template no.:
X0_2010-380x447-001-dev
Current 1

Full laquer on both side

Leaflet

Colour: CMYK +
PMS 280C +
PMS 289C

User guide

How it works

8-0054-X0-003-1

Dialoq® works with FlexTouch® to track your doses

While Dialoq® is attached to your FlexTouch® pen, it records and remembers:

- the drug brand name and strength
- the number of units dosed
- the time and date of your doses.

Dialoq® stores up to 1200 doses including your priming doses. Dialoq® is a medical device.

Read this user guide before you start using Dialoq® to learn how to use Dialoq® correctly.

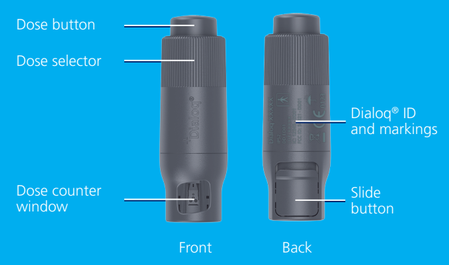
Use Dialoq® with your phone

You can export the doses in your Dialoq® to a compatible app on your phone. That way you can keep a digital insulin log.

Export your doses

Dialoq® sends your injected doses and priming doses to the app when you press and release the dose button. Make sure Bluetooth® on your phone is turned on and that the app is open.

Dialoq® overview



Need help?
Call us at 1-833-4-DIALOQ

novo nordisk®

1. Attach Dialoq®

Figure A

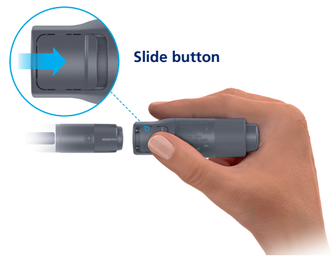
- Look at the back of your FlexTouch® pen to make sure it has a small attachment knob.

ⓘ FlexTouch® pens with this knob can be used with Dialoq® (see a list of compatible FlexTouch® pens at www.mydialoq.com).

Figure B

- Attach Dialoq® to your FlexTouch® pen. Make sure the dose counter window on your FlexTouch® pen lines up with the dose counter window on your Dialoq®.
- Leave it on until your FlexTouch® pen is empty. Remove Dialoq® before you dispose of your FlexTouch® pen.

Figure C



- You can remove Dialoq® from your FlexTouch® pen by using the slide button on the back.

ⓘ Never use excessive force to remove Dialoq®.

2. Download app and pair

Figure D

- Check your phone to make sure you are connected to the internet and Bluetooth is turned on. To ensure a secure connection, avoid pairing your Dialoq® in public places.
- Go to: www.mydialoq.com on your phone to see where you can download a compatible app. You can skip this step if you already have a Dialoq® compatible app on your phone.
- Open the app and follow the instructions to pair your Dialoq® with the app.

Figure E

- To pair your Dialoq® with the app, make sure that the dose selector shows 0 on your FlexTouch® pen.
- Then press and release the dose button on Dialoq®.
- Check that the Dialoq® ID in the app matches the ID you can find on the back of your Dialoq®. (See Dialoq® overview in How it works section of this User guide)
- Follow the instructions in the app to complete pairing.

Figure F

- Dialoq® is now paired with the app, and you are ready to start using Dialoq® with your FlexTouch® pen.

ⓘ Always check the app to see if pairing succeeded. If not, repeat the steps for figures D and E.

When you attach Dialoq® to a new FlexTouch® pen, you do not need to pair your Dialoq® again.

3. Use Dialoq® with your FlexTouch® pen

Figure G

⚠ Always follow the instructions for use that comes with your FlexTouch® pen to ensure you receive the correct dose.

Figure H

- Make sure Dialoq® is paired (see section 2) and is correctly attached to your FlexTouch® pen (see section 1).
- Turn the dose selector on your Dialoq® to select your dose.

Figure I

- Insert the needle into your skin.
- Press and hold down the dose button on your Dialoq® until the dose counter shows 0, then count slowly to 6 before dosing is complete.
- Your Dialoq® records the size, time and date of the injected dose.

ⓘ Dialoq® exports the dose when you inject if you keep the app open, keep your phone within reach of your Dialoq®, and Bluetooth turned on. If you export this way, you can skip the steps in section 4.

4. Export doses to app

Figure J

- Make sure Bluetooth on your phone is turned on and Dialoq® is attached to your FlexTouch® pen.

Figure K

- Open the app on your phone.
- Check that the dose counter on your FlexTouch® pen shows 0, unless you are taking a dose, see section 3.

- Press and release the dose button on your Dialoq® to export your doses to the app.
- Check the app to see if the export was successful.

ⓘ It is recommended to export your doses from Dialoq® whenever you want to consult your dose log and at least once every month.

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Frequently asked questions

Significance of symbols

Caution
Pay special attention to these notes as they are important for safe use of Dialoq®.

Useful information and tips.

Name and address of manufacturer.

Dialoq® will last for 2 years during normal use if used for the first time before the date printed next to this symbol on the package.

Consult instructions for use.

40° C 104° F / 5° C 41° F Temperature range.

The disposal symbol indicates that Dialoq® must not be disposed of with household waste.

Keep dry.

LOT Batch no.

BF Applied Part.

Turn over to see the user guide.

How your Dialoq® works

• What does Dialoq® record?

When Dialoq® is attached to a compatible FlexTouch® pen (see a list of compatible FlexTouch® pens at www.mydialoq.com) it records:

- the drug brand name and strength
- the number of units dosed
- the time and date of all your injected doses and priming doses

Your FlexTouch® pen dose counter always shows the number of units selected for injection or priming.

Always keep Dialoq® attached to your FlexTouch® pen. Please note, Dialoq® only records doses taken while it is attached to a compatible FlexTouch® pen. If you prime a dose or inject a dose without Dialoq® attached, your dose log in the app will not show that dose.

If you are in doubt about how much insulin you need to inject, monitor your blood sugar level as instructed by your doctor or nurse, before selecting the dose for your next injection. Otherwise, you may get too much or too little insulin.

Dialoq® is only for single person use. Never share your Dialoq® with other people. Otherwise, it may record doses from other people.

Do not stop and resume during injection as Dialoq® then may be unable to detect the dose sizes.

Dialoq® records both priming doses and injected doses. All recorded doses will be included in the dose log sent to the app. Check with your app provider for more information on how the doses will be shown.

Dialoq® and its functions are intended to be used by diabetes patients, health care professionals and caregivers.

• Does Dialoq® automatically export my doses to my phone?

When you take your injection, Dialoq® will automatically export your dose if:

- your Dialoq® is paired with the app
- the app is open
- your phone is within reach of Dialoq®
- Bluetooth is turned on

Your dose will then be exported the moment you release the dose button.

If you wish to export your doses at another time, see section 4.

Please note, if you try to export your doses while Dialoq® is not attached to a FlexTouch® pen, the dose log in the app will not be updated.

• What if I do not export my doses regularly?

Dialoq® will always store the most recent 1200 doses including priming doses.

It is recommended that you export your doses at least once every month to ensure that all your doses are contained in your app.

It is recommended that you leave Dialoq® on your FlexTouch® pen until the FlexTouch® pen is empty. This makes sure that all doses with the FlexTouch® pen are recorded.

• Which information is exported to the app?

The information exported to the app includes:

- drug brand name and strength
- number of units dosed
- time and date of all injected doses and priming doses
- Dialoq® status information.

Caring for your Dialoq®

• Where do I keep my Dialoq®?

2° C 36° F / 40° C 104° F Storage:
When Dialoq® is not attached to your FlexTouch® pen, store Dialoq® at temperatures above 36° F (2° C) and below 104° F (40° C).

When Dialoq® is attached to your FlexTouch® pen, follow the instructions for storage conditions that came with your FlexTouch® pen.

5° C 41° F / 40° C 104° F During use:
Dialoq® is intended to be used at home or in a normal public environment at these conditions:
Temperature: 41° F (5° C) to 104° F (40° C)
Humidity: 15% RH to 90% RH
Atmospheric pressure: 700 hPa to 1060 hPa

When Dialoq® is attached to your FlexTouch® pen, follow the instructions for maximum in-use temperature that came with your FlexTouch® pen.

• How do I take care of my Dialoq®?

Do not try to repair your Dialoq® or pull it apart. This will break it.

Keep your Dialoq® away from dust, dirt, and liquid.

Do not attach Dialoq® to a FlexTouch® pen with a visibly scratched, damaged, or dirty dose button. Otherwise, Dialoq® may not be able to identify the drug brand name and strength in your FlexTouch® pen correctly.

Do not modify Dialoq® in any way. Do not try to insert any foreign objects or fingers in your Dialoq®. If you do, Dialoq® may not work as intended.

Do not use your Dialoq® if it is visibly damaged. If you think your Dialoq® is not working the right way, call 1-833-4-DIALOQ.

• How should I clean Dialoq®?

You can only clean the outside of Dialoq®. Use a mild detergent on a moistened cloth. Do not use products containing bleaching agents, such as chlorine, iodine, or alcohol to clean Dialoq® as this may damage it. Do not wash, soak, or lubricate your Dialoq®.

• How long does the battery last?

If Dialoq® is used as described in this user guide, the battery will run out after two years and the app will alert you about 30 days before. The battery may run out sooner, for example if you have more than one app paired with your Dialoq®, or if the dose button on Dialoq® is pressed and released very often, unrelated to injecting or exporting doses.

Remember to export your doses before the battery runs out for when it does, Dialoq® will no longer record your doses or be able to export your doses to the app. Contact your supplier to get a new Dialoq®. You can still use your FlexTouch® pen for injections.

The battery cannot be replaced or recharged.

• How do I dispose of Dialoq®?

Please dispose of electronic equipment separately as according to local regulations.

Dialoq® must not be disposed of as household waste. Please consider the environment when you dispose of Dialoq®, as it contains a lithium battery and electronic parts. The packaging and paper materials can be recycled.

Troubleshooting

• What if Dialoq® does not export my doses to the app?

- Make sure that Dialoq® is properly attached to a compatible FlexTouch® pen, see figure A.
- Keep your phone within reach of your Dialoq®.
- Make sure that Bluetooth on your phone is turned on and that the app is open.
- Keep your phone and Dialoq® at least 12 in (30 cm) away from other mobile phones, tablets, pc's, etc. to avoid interference. If your doses are still not exported, move your phone and Dialoq® even further away from other devices.
- Or check the compatible app to see if there is an alert of low battery in your Dialoq®. The battery may have run out after the alert.

• What if I cannot pair Dialoq® with the app?

Follow the first 4 steps from the section "What if Dialoq® does not export my doses to the app?"

• Why does the app not show the medicine or dose amount I expect?

If you stop and resume during injection, Dialoq® may register the injection as multiple doses without dose sizes.

If you split your dose when transferring to a new FlexTouch® pen, the two doses will be shown as two separate doses.

If Dialoq® registers an error during injection, it will record the injection as one dose of without dose size. You may still have received your full dose, and you do not need to inject again.

If you are in doubt about how much insulin you need to inject, monitor your blood sugar level as instructed by your doctor or nurse, before selecting the dose for your next injection. Otherwise, you may get too much or too little insulin.

• Still need help?

If you are in doubt about how to use Dialoq®, contact your healthcare professional or call 1-833-4-DIALOQ.
If you experience unexpected events or have any questions, please visit our support site: www.mydialoq.com.

Warranty
Dialoq® comes with a two-year warranty.
If you find that your Dialoq® is faulty, Novo Nordisk will replace it. Return it to your supplier for inspection within two years of receiving it.

This warranty will be invalid and Novo Nordisk cannot be held responsible in the case of defects or damages arising from:

- the use of Dialoq® with non-compatible pens (see a list of compatible FlexTouch® pens at www.mydialoq.com)
- the use of Dialoq® not in accordance with the instructions in this user guide
- physical damage to Dialoq® caused by neglect, misuse, unauthorized repair, accident, or other breakage

Classification
Dialoq® is classified according to IP 52, where:

- 5 indicates that Dialoq® is dust-protected.
- 2 indicates that Dialoq® is protected against vertically falling water drops when tilted up to 15 degrees.

Protection against electrical shock
Type: Classified for continuous operation. Internally Powered ME Equipment.

Degree: Type BF Applied Part.

Logging accuracy
Dialoq® registers the dose exactly as selected in more than 99% of all doses. The remaining doses are registered within +/- 1 increment of the selected dose.

Electromagnetic compatibility
Dialoq® lives up to the emissions and immunity requirements from IEC 60601-1-2:2014 for Home Healthcare Environments. See details on tests in technical description at www.mydialoq.com

Dialoq® complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Before you use Dialoq® on an airplane, ask the cabin attendants for instructions for using a Bluetooth connection on the flight. You can also ask the airline you fly with for instructions.

Wireless technology
Frequency Band: 2.4-2.4835 GHz
Technology: Bluetooth low energy
Modulation type: Gaussian Frequency Shift Keying (GFSK)
Output power: 0 dBm

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Dialoq® is classified as a device receiver category 3: noncritical communication.

Dialoq® collects data to enable improvements in device performance. The data can only be reviewed during device maintenance.

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For information about Dialoq® contact:
1-833-4-DIALOQ
Novo Nordisk Inc.
800 Scudders Mill Road
Plainsboro, NJ 08536
Attention: Customer Care

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www.novonordisk.com
Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd, Denmark
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