



bipendiq 2.0

User Manual

CE
0068
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Introduction

The digital insulin pen pendiq 2.0 is designed to deliver insulin for the insulin-required diabetes mellitus. With this pen you can adjust every dose up to increments as small as 0.1 U (0.001ml) and with the memory function you can review your injection history with the date, time and amount of insulin delivered. The Bluetooth function lets you transfer data from your pendiq 2.0 to a Diabetes Management Solution.

This manual gives you instructions on how to use and maintain your pendiq 2.0.

Please read this manual thoroughly and familiarize yourself with the information before using the pen. We advise you to keep this manual for your reference.

Safety Guidelines pendiq 2.0



Consult a healthcare professional regarding your condition before using the pendiq 2.0, and carefully read the safety guidelines provided in this user manual.



Consult your healthcare professional, if you encounter abnormal blood glucose levels.




Do not share this pen with other people to prevent infection.





Inject only into the body areas suggested by the official national endocrinologist association, your healthcare professional or your physician.





You should change the injection area for each injection. After discussing the injection areas with your healthcare professional, follow the instructions given at all times.


 Before using the pendiq 2.0 for the first time, make sure to set the correct date and time, and to change the Bluetooth PIN number.


 Before every injection, make sure that the body of the pendiq 2.0 and the cartridge holder are firmly screwed together.


 Always remove possible air bubbles before each injection.

 The pendiq 2.0 is a technical, medical device. Use the pendiq 2.0 properly.

 Always check the remaining insulin amount before each injection to ensure that there are enough units left for your dose.

 Always remove the pen needle before changing the cartridge.

 Do not modify or disassemble the pendiq 2.0. Do not use the pendiq 2.0 if any part of your pendiq 2.0 looks broken or damaged. Contact your local supplier or your healthcare professional.

 Do not forcefully remove the USB cover.



The manufacturer shall not be held liable for any problems, damages or malfunctions arising from a Force Majeure or other events beyond the control of the manufacturer.



Do not remove the cartridge holder before the plunger is fully rewound when changing a cartridge.



Do not throw your pen on purpose as shocks and impacts may damage the pen.




The pen is not designed for the blind or visually impaired without a trained assistant.





Make sure the insulin cartridge in the setting matches the insulin cartridge manufacturer (Novo, Lilly, Sanofi...) you are using.


If they do not match the pen cannot recognize the exact residual amount of insulin in the cartridge and the amount of units displayed may then differ from the real residual amount.


This can result in the injection of an incorrect dose.


 Do not expose the pendiq 2.0 to high temperature and/or humidity. The pendiq 2.0 is not water-proof and holds no protection against the ingress of water or moisture. When exposed to water or moisture the pen may suffer damages and not function properly.

 Do not store the pendiq 2.0 in a refrigerator.

 Do not expose the pen to heat or direct sun light.

 Do not expose the pendiq 2.0 to flammable and/or combustible mixtures.

 Do not expose the pendiq 2.0 to any electromagnetic waves and/or frequency (CT, MRI, X-ray, etc.). The pen may suffer damages when exposed to electromagnetic waves.

 Always make sure that the battery is fully charged. It is recommended to fully charge the battery as often as possible to extend the duration of battery life.



Only one type of insulin cartridge (Basal/Bolus) can be used with one pendiq 2.0. Do not use different insulin cartridges (Basal/Bolus) for one device.



Compatibility: The pendiq 2.0 pen is only suitable for the use of 3ml insulin cartridges (300 Units, U 100 insulin) of the manufacturers Novo Nordisk®, Lilly®, Sanofi-Aventis® and Berlin-Chemie®. Do not use insulin cartridges from manufacturers other than the manufacturers stated above.



Do not use NPH or premix insulin with the pendiq 2.0.



Do not use a non-sterilized or damaged pen needle. Healthcare professionals strongly recommend not reusing a pen needle. Using a new needle for each injection will minimize the risk of infections and a pen needle blockage.



Do not keep the needle attached to the pen after the injection. Always safely withdraw and dispose the used needle. Always follow general safety measures for the removal and disposal of needles in order to minimize the risk of unintended needle penetration and transmission of infectious diseases. Otherwise, it may cause incorrect insulin delivery, leakage of insulin and unintended needle injury, etc.



Please follow the instructions and the safety guidelines of the pen needle manufacturer, as disregard may cause infection and/or damage in the injection area.



The manufacturer is not responsible for any problems caused by the malfunction of the Bluetooth connection between the pendiq 2.0 and a smartphone app.



We recommend not using the device if you are an individual with hypersensitive reactions to insulin.



We recommend not using the device if you suffer from mental and/or developmental disabilities, or have impaired dexterity.



The motor function is limited while the pen is charging. It is not possible to make an injection while the battery is charging.



The manufacturer is not responsible for the safety, dosage accuracy and functionality as well as any damages caused by the usage of insulin cartridges that are not adequate for the pendiq 2.0.



We recommend not using the device if you are an individual who has not been prescribed by a doctor to inject insulin.



All users under the age of 14 must be under supervision of their parents or a healthcare professional when injecting insulin.



We recommend not using the device if you are an individual with no diabetes.

Emergency Kit (Recommended)

Please carry an emergency kit with you at all times, containing the following components in case of emergencies.

Make sure to inform your family, friends and colleagues where to find the kit.

Emergency kit should include:

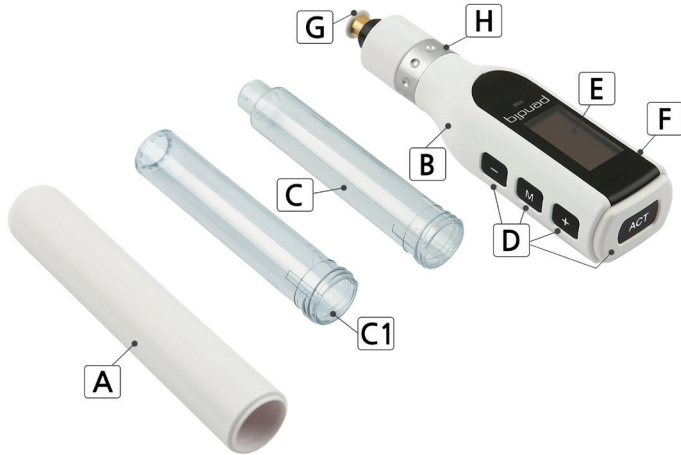
- Blood glucose meter and strips
- Blood or urine ketone meter and strips
- Spare insulin cartridge prescribed by doctor
- Insulin injection syringe
- Alcohol swab
- Emergency food for hypoglycemia
- Diabetic patient identity card with all necessary info
- Micro USB cable for charging the battery of the pendiq 2.0





Contents product box

Check if all the following components are included in the pendiq 2.0 box:

- Digital insulin pen pendiq 2.0
- User Manual English
- User Manual German
- USB cable
- USB adapter
- Cartridge holder Novo Nordisk
- Warranty card

Components



- A** Pen cap
- B** Product body (D~G)
- C** Cartridge holder
- C1** Cartridge holder (for Novo Nordisk cartridge)
- D** Operation buttons    
- E** OLED screen
- F** Micro USB port
- G** Plunger

Operation buttons



ACT button is used

- to turn on the pen
- to confirm an operation or setting
- to inject a dose

- button is used

- to decrease a number
- to select a setting
- to go back in the menu

+ button is used

- to increase a number
- to select a setting
- to go forward in the menu

M button is used

- to enter the menu
- to return to previous screen
- to cancel an operation or setting

Please visit our homepage www.pendiq.com/downloads
to see a menu tree of the pendiq 2.0.

Getting started with your pendiq 2.0

When you use your pendiq 2.0 for the first time, follow the steps below to get started. Before you use your pendiq 2.0 for the first time, you need to charge the battery. Read the chapter „Battery“ for more information.

The pendiq 2.0 has no OFF button. The screen turns itself off after 60 seconds when no button is pressed. When going through the menu, you can always return to the home screen by pressing **M**.

The device will come with factory default settings. Before you can use your pendiq 2.0 for injection, you need to complete the initial setup. Follow the next steps to get started.

Step 1 – Language

Press **ACT** for 3 seconds to turn on the display for the first time.

The initial language setting screen appears. The factory language is German.



Press **ACT** to start. You will see the word, “Deutsch” flashing on the screen. Press **+** or **-** to select the language you wish to use. You can choose between German (1) and English (2).



Select language and press **ACT**. “Done” will appear on the display.



The initial setup will automatically continue to “Date/Time” setting.

Step 2 – Date/Time

Injections in the injection history are displayed with date and time.

Therefore, it is important to set a correct Date/Time before making the first injection.

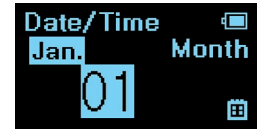


After you have completed the initial language setting, the setup will continue with the initial “Date/Time” setting.



Press **ACT** to start with setting the year. The year starts flashing.

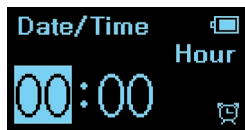
Press **+** or **-** to adjust the year and confirm with **ACT**.



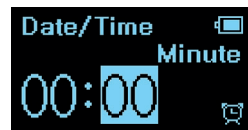
Press **+** or **-** to select the month and confirm with **ACT**.



Press **+** or **-** to set the day and confirm with **ACT**.

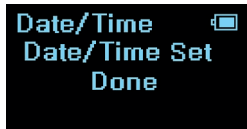


Press **+** or **-** to set the hour and confirm with **ACT**.



Press **+** or **-** to set the minute.

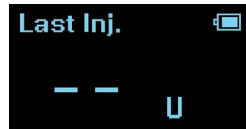
Press and hold **+** or **-** to increase number by 10.



Press **ACT**.

“Date/Time Set. Done”
will appear on the display.

“Done” will flash three
times.



Initial setup is now complete.
The display will show the home
display “Last Inj.”.

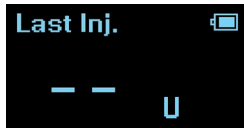
As there is no injection history
saved yet “--” will be displayed
on the home screen.



Step 3 – Cartridge settings

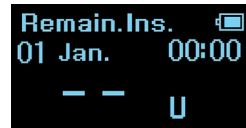
Before you can use your pendiq 2.0 for injection, you need to setup the cartridge settings and insert a cartridge. You can first use the pendiq 2.0 for injection after completing the cartridge settings.

Follow the next steps when you insert a cartridge for the first time or want to replace a cartridge. Always have the new cartridge ready at hand.



Press **ACT** for 3 seconds to turn on the power in case the display is turned off.

The home screen “Last Inj.” will appear on the screen.



Press **M** and “Remain. Ins.” screen will appear.

At initial setup “--” will be displayed.



Press **+** once and "Replace Cart." will appear.

Press **ACT** to enter.



"New cartridge" will appear and the name of the cartridge manufacturer flashes.

Press **+** or **-** to select the insulin cartridge manufacturer of the insulin cartridge you wish to insert.

You can select between Novo Nordisk, Sanofi, Lilly and Berlin-Chemie. Select an insulin cartridge manufacturer and press **ACT**.



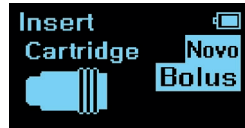
Press **+** or **-** to select the insulin type (Basal/Bolus).

Press **ACT** to confirm.



“Rewinding” screen will appear and the plunger will be automatically rewound.

NOTE: You can stop the plunger by pressing **M** anytime. The screen will return to “Remain. Ins.” screen and you can start over.



“Insert cartridge” screen will appear after the plunger is fully rewound.

Now you can insert a new cartridge.

Step 4 – Insert new cartridge



Pull off the cartridge holder cover.



Unscrew the cartridge holder from the body. If you are replacing a cartridge, remove the empty cartridge and dispose of it carefully.



Insert a new insulin cartridge into the cartridge holder. When inserting a cartridge, make sure the insulin cartridge you are inserting matches the insulin cartridge manufacturer you selected in the cartridge setting.



Screw the cartridge holder and the body firmly together.



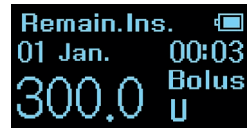
After inserting the cartridge, press **ACT**.

The plunger will now move forward until it makes contact with the rubber of the insulin cartridge.



When the plunger stops moving forward, "Completed!" will flash three times on the display.

The screen will automatically return to "Replace Cart." menu.



Press **M** once and the remaining amount of insulin will be displayed.

Injection

Healthcare professionals strongly recommend not to reuse a pen needle. When a pen needle is reused, a blockage in the pen needle can occur and the flow of the medicine is obstructed.

In case of a blockage during the injection or priming of the pen, the pendiq 2.0 will display a warning message and sound an audible warning tone.

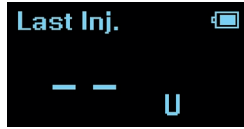


Attaching a pen Needle

- Take a new pen needle and remove the protective seal.
- Attach the needle by firmly screwing it onto the threads at the end of the cartridge holder.
- Remove the outer protective cap and the inner needle cap from the needle.

Prime

Press **ACT** for 3 seconds to turn on the power in case the pen is turned off.



Press **ACT** from the home screen "Last Inj." to start.



The word "Prime" will appear on the screen and start flashing.

Hold the peniq 2.0 with the needle pointing up in order to remove any air bubbles.

Press **-** until you see bubbles of insulin appearing at the tip of the needle.

Dose setting



When you have finished the priming process, press **ACT** to enter dose setting.




The factory setting for a dose is 0.5U. The minimum dosage for an injection is 0.5U.



Press **+** or **-** to adjust the dose. The default dose limit for a single injection is 60.0U. You can increase the dose limit in the “Settings Menu”.

Press **+** or **-** to increase/decrease the number by 0.1U.
Press and hold **+** or **-** to increase/decrease the number by 1.

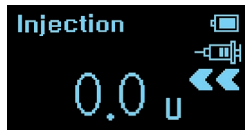
Press **M** to cancel the dose setting and return to the “Remain. Ins.” screen.

 If you cancel the injection after priming by pressing the  button, a prime dose of 0.5U for every time you pressed  will be subtracted from the remaining insulin amount.

*Firmly hold your pen*diq* 2.0 and insert the needle into the injection area using the injection technique recommended by your healthcare professional.*



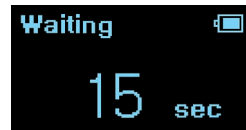
Press **ACT** to start the injection.



The number on the display will count down from the dose you have set to 0.0U.

The pen will then sound one short beep to indicate the end of the injection.

Injecting your dose



The display will count down from 15 seconds to 0 second.

This is how long it is recommended to keep the needle inserted in the injection area.



After the 15 seconds the pen will sound two short beeps to indicate the end of the countdown.

The pen needle can now be removed from the injection area.



After the injection the remaining amount of insulin in the cartridge will be displayed on the screen.



If you believe you have set an incorrect dose, pull out the needle from the injection site immediately.



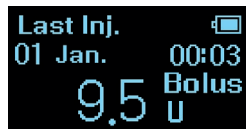
After the injection

- Carefully place the outer cap back on the pen needle and unscrew it from the cartridge holder.
- Dispose of the used needle as advised by your healthcare professional or according to local regulations.

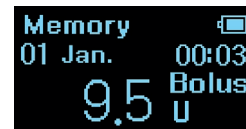
Memory function


With the pendiq 2.0, users are able to check their injection history with the date, time and the amount of insulin delivered.

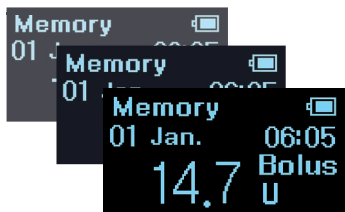
The details of your last injection are always displayed on the home screen “Last Inj.” when you turn on the power.



The “Last Inj.” home screen displays the dose, date & time and insulin type of the last injection.



From the home screen “Last Inj.” press  and “Memory” menu will appear.



Press **-** to go through your injection history and check the details of previous injections.
Press **+** to move forward.



Press **M** to return to home display “Last Inj.”.

Press **ACT** in the “Memory” menu if you want to jump to injection mode (Prime).

Settings

In the “Settings Menu” of the pendiq 2.0 pen, you can turn the Bluetooth on and off, change the language, Date/Time, volume of the speaker, set TimeBlocks and dose limits, reset the pen to factory settings and review the software version of the pen.





The pendiq 2.0 is equipped with Bluetooth Smart which makes it possible to transfer data from your pendiq 2.0 to a smartphone app. It is only possible to transfer data when the Bluetooth is activated on the pendiq 2.0 pen, and the pendiq 2.0 is connected to the smartphone app.

To activate Bluetooth on your pendiq 2.0 pen follow the next steps.

Turn Bluetooth ON/OFF



Press **ACT** for 3 seconds to turn on the power in case the pen is turned off.

The home screen "Last Inj." will appear on the screen.

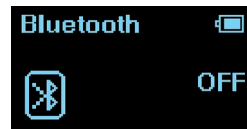


Press **M** and "Remain. Ins." screen will appear.

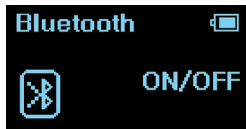


Press **+** or **-** button until you reach "Settings Menu" screen.

Press **ACT** to enter.

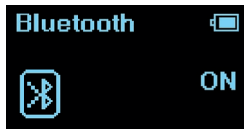


Bluetooth menu will appear.



Press **ACT** and “ON/OFF” will start flashing.

Press **ACT** again and “OFF” will start flashing.



Press **+** or **-** to select Bluetooth “ON”, and press **ACT** to confirm.



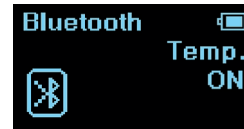
The word “Always” will start flashing.

Press **+** or **-** to select “Always” or “Temp.”.



Always: Even when the pendiq 2.0 is turned off, the Bluetooth connection between the pendiq 2.0 and the smartphone app is always active.

The advantage of this setting is that you can change/edit settings on the pendiq 2.0 via the smartphone app even when the pen is not in nearby reach. Be aware that the battery consumption is high in “Always” mode.



Temp. (Temporarily): Only when the pendiq 2.0 is turned on, the Bluetooth connection between the pendiq 2.0 and the smartphone app is active.

The advantage of this setting is that it will save battery.



Press **ACT** and “Done” will flash thrice.

The screen will automatically change to Bluetooth setting menu.

Press **M** several times to return to home screen.



If Bluetooth is set to “Temp.”, the message “Bluetooth loading...” will appear when you turn on the pen whilst Bluetooth is activated.



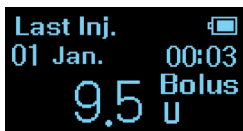
When the Bluetooth is activated a little Bluetooth icon will be displayed at the bottom right corner.

Bluetooth PIN

The pendiq 2.0 will come with a factory PIN number for the Bluetooth connection.

When you receive the pendiq 2.0 it is important that you change and choose a personal PIN number for your pendiq 2.0 pen.

With a personal PIN number for the Bluetooth connection only you can access your pendiq 2.0 pen via the smartphone app.



Press **ACT** for 3 seconds to turn on the power in case the pen is turned off.

The home screen "Last Inj." will appear on the screen.

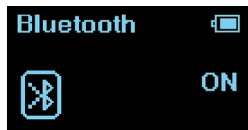


Press **M** and "Remain. Ins." screen will appear.



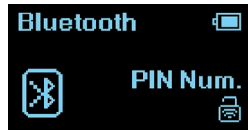
Press **+** or **-** button until you reach “Settings Menu” screen.

Press **ACT** to enter.



The Bluetooth setting will appear.

Press **ACT** again to enter Bluetooth setting.



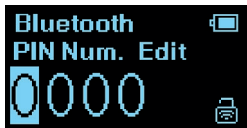
Press **+** and “PIN Num.” will start flashing.

Press **ACT**.



The factory default PIN number (0000) will be displayed.

Press **ACT** to confirm.



The screen will now display the word “Edit”. You can enter a 4 digit personal PIN number.

Press **+** to change the number from 0 to 9. Press **-** to move the cursor from right to left.


Press **ACT** to confirm your personal PIN number.



Your personal PIN number and the word “Done” will flash thrice.

The screen will automatically change to “Bluetooth PIN” setting menu.

To return to home screen “Last Inj.” press **M** several times.

 *Please keep your personal PIN number safe at all times.*

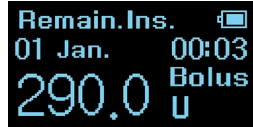
Forgot your PIN number? Restore the pendiq 2.0 to factory settings.

Speaker



Press **ACT** for 3 seconds to turn on the power in case the pen is turned off.

The home screen "Last Inj." will appear on the screen.



Press **M** and "Remain. Ins." screen will appear.



Press **+** or **-** button until you reach "Settings Menu" screen.

Press **ACT** to enter.



Press **+** or **-** to reach "Speaker".

Press **ACT** and "Vol." will start flashing (Factory setting: Vol.3).



Press **+** or **-** to adjust the volume (0~4). You will hear the sound of the volume.



Press **ACT** and “Done” will flash thrice. The screen will automatically change back to “Speaker” setting menu.

Press **M** several times to return to home screen “Last Inj.”.

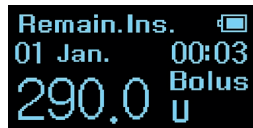


Even though the volume is set to zero (mute), you will hear an audible alarm for warnings.



Press **ACT** for 3 seconds to turn on the power in case the pen is turned off.

The home screen "Last Inj." will appear on the screen.



Press **M** and "Remain. Ins." screen will appear.



Press **+** or **-** button until you reach "Settings Menu" screen.

Press **ACT** to enter.

Language



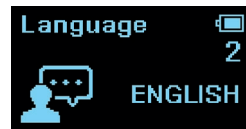
Press **+** or **-** until you reach the language setting.

Press **ACT** to enter.



Press **+** or **-** to select the language you wish to use. Confirm with **ACT**.

“Done” will flash thrice on the display.



The screen will automatically change back to “Language” setting.

Press **M** several times to return to home screen.

Date / Time

In case you are travelling or need to adjust the time due to summer/winter time changeover, follow the next steps.



Press **ACT** for 3 seconds to turn on the power in case the pen is turned off.

The home screen "Last Inj." will appear on the screen.

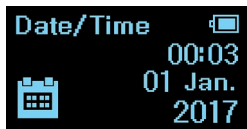


Press **M** and "Remain. Ins." screen will appear.



Press **+** or **-** button until you reach "Settings Menu" screen.

Press **ACT** to enter.

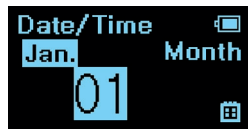


Press **+** or **-** until you reach the Date/Time setting.

Press **ACT** to enter.



The year starts flashing. Press **+** or **-** to adjust the year and confirm with **ACT**.



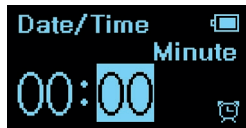
Press **+** or **-** to select the month and confirm with **ACT**.



Press **+** or **-** to set day and confirm with **ACT**.

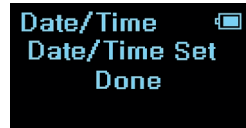


Press **+** or **-** to set the hour and confirm with **ACT**.



Press **+** or **-** to set the minute.

Press and hold **+** or **-** to increase/decrease the number by 10.



Press **ACT**. Date/Time "Done" will flash thrice on the display.

The screen will automatically change back to "Date/Time" Menu.

Press **M** several times to return to home screen.

TimeBlock

TimeBlock means that you can pre-program a fixed dose for a TimeBlock of your choice.

The starting time of a TimeBlock is automatically the ending time of the previous TimeBlock.

The TimeBlocks programmed will automatically be repeated every 24 hours unless the TimeBlocks are deleted.

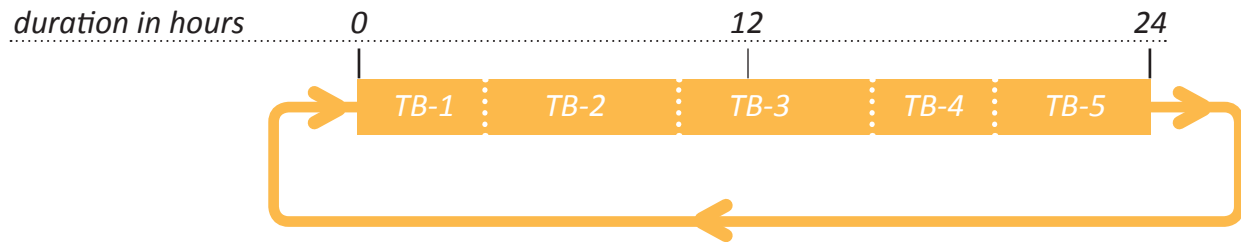
One TimeBlock (TB-1) is preset in the factory (Time: 06:00 AM, Dose: 0.5 U).

If you only use TB-1 with this setting, the TimeBlock lasts 24h and a dose of 0.5 U is presented to you for each injection.

You can add and delete other TimeBlocks but one TimeBlock always remains. Programming TB-1 is convenient in case you generally need to inject more than, for example, 30.0 U for each injection.

You set the dose of TB-1 to 30.0 U and for each injection adjust the dose from there.

Setting TimeBlocks is convenient because you can pre-program up to **5 TimeBlocks** for a day, each TimeBlock delivering a pre-programmed dose.

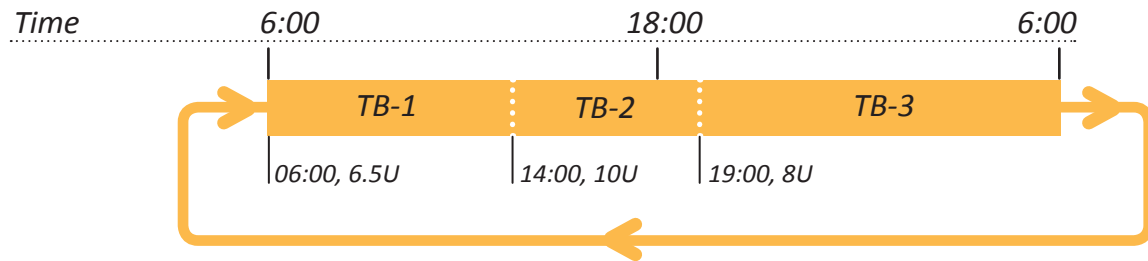


Example for three TimeBlocks:

TB-1 (06:00, 6.5U)

TB-2 (14:00, 10U)

TB-3 (19:00, 8U)



TB-1

TimeBlock 1 starts at 06:00 o'clock and ends with the starting time of TB-2 at 14:00 o'clock. During this time a dose of 6.5U will be preset for your injection.

TB-2

TimeBlock 2 starts at 14:00 o'clock and ends with the starting time of TB-3 at 19:00 o'clock. During this time a dose of 10U will be preset for your injection.

TB-3

TimeBlock 3 starts at 19:00 o'clock and ends with the starting time of TB-1 at 06:00 o'clock. During this time a dose of 8U will be preset for your injection.

With the start of TB-1 all three TimeBlocks will be repeated.

Add a TimeBlock



Press **ACT** for 3 seconds to turn on the power in case the pen is turned off.

The home screen "Last Inj." will appear on the screen.



Press **M**. "Remain. Ins." screen will appear.



Press **+** or **-** button until you reach "Settings Menu" screen.

Press **ACT** to enter.



Press **+** or **-** until the “TimeBlock” menu will appear.



Press **ACT**. “New” will start flashing.

Press **ACT** to confirm adding a TB.



Press **+** or **-** to set the hour.

Press **ACT** to confirm.



Press **+** or **-** to set the minute.

Press and hold **+** or **-** to increase/decrease the number by 10.

Confirm with **ACT**.



Press **+** or **-** to adjust the insulin dose.

Press **+** or **-** to increase/decrease the number by 0.1U.
Press and hold **+** or **-** to increase/decrease the number by 1.



Press **ACT** to confirm.

Press **+** or **-** to turn the alarm for the TimeBlock “On” or “Off.”

This means that the pen will sound a beep at the start of a TimeBlock.



Press **ACT** and “Done” will flash thrice on the screen.



The screen will change back to TimeBlock “Add” menu. To set more TimeBlocks follow the steps 5 to 11.

You can set up to 5 TimeBlocks.

Press **M** several times to return to home screen.

Change a TimeBlock



Press **ACT** for 3 seconds to turn on the power in case the pen is turned off.

The home screen "Last Inj." will appear on the screen.



Press **M**. "Remain. Ins." screen will appear.



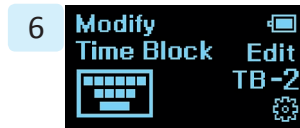
Press **+** or **-** button until you reach "Settings Menu" screen. Press **ACT** to enter.



Press **+** or **-** until the “TimeBlock” menu will appear.



Press **ACT**. “New” will start flashing.



Press **+**. The screen will change to “Modify” setting and “Edit” will start flashing.

With the **+** or **-** button you can switch between the “Modify” and “Add” screen.



Choose “Modify” and press **ACT** to see the TimeBlocks (TB 1 ~ TB 5).

Press **+** to select the TimeBlock (TB 1 ~ TB 5) you wish to modify.



Press **ACT** to enter the TimeBlock and “Edit” will start flashing. Press **ACT** again to confirm. Press **M** to cancel.

Follow the steps 6-10 in chapter “Add a TimeBlock” on how to set the time and dose.

Delete a TimeBlock

Follow the steps 1-6 in the chapter “Change a TimeBlock”.



Press **ACT** in the “Modify” setting to see the set TimeBlocks.

Press **+** to select the TimeBlock (TB 1 ~ TB 5) you wish to delete.



Press **ACT** to enter the TimeBlock and “Edit” will start flashing.



Press **+** or **-** once and “Delete” will start flashing.

Press **ACT**.

4

Time Block 2
Delete ?



Press **ACT** again to confirm deletion of TimeBlock.

5

Time Block 2
Delete Done



“Done” will flash thrice. The TimeBlock is now deleted.

The screen will automatically change back to “Modify” screen.

Press **M** several times to return to home screen “Last Inj.”.



Dose limit

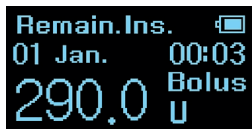
The default dose limit is 60.0U for each injection and 80.0U for one day. It is possible to change the dose limit for the day and for each injection to avoid overdose.

Dose limit for a day (1 Day) & Dose limit for injections (1 Time)



Press **ACT** for 3 seconds to turn on the power in case the pen is turned off.

The home screen "Last Inj." will appear on the screen.



Press **M** and "Remain. Ins." screen will appear.



Press **+** or **-** button until you reach "Settings Menu" screen.



Press **ACT** to enter and then press **+** or **-** until you reach "Dose Limit" screen.

Press **ACT** to enter.



With **+** or **-** you can choose between setting a dose limit for a day (1 day) or for injections (1 time).

Choose and press **ACT** to confirm.



1 day dose limit can be set between 80.0U and 160.0U.

1 time dose limit can be set between 60.0U and 100.0U.

Press **+** or **-** to adjust dose limit.

Press **+** or **-** to increase/decrease the number by 0.1U.

Press and hold **+** or **-** to increase/decrease the number by 1.



Press **ACT** and “Done” will flash thrice on the screen.

The screen will automatically change back to “Dose limit” menu.

Press **M** to go back in the menu and return to home screen “Last Inj.”



Press **ACT** for 3 seconds to turn on the power in case the pen is turned off.

The home screen "Last Inj." will appear on the screen.

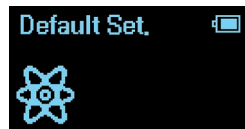


Press **M** and "Remain. Ins." screen will appear.



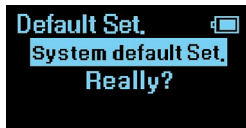
Press **+** or **-** button until you reach "Settings Menu" screen.

Default setting

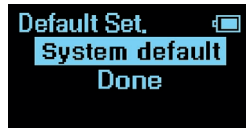


Press **ACT** to enter and then press **+** or **-** until you reach "Default Set." screen.

Press **ACT** to enter.





Press **ACT** and “Really?” will start flashing.



Press **ACT** to confirm and “Done” will flash thrice. The screen will automatically change back to “Default” setting menu.

Press **M** to go back in the menu and return to home screen “Last Inj.”.

 After the system of the pendiq 2.0 is restored back to factory default settings, the language will be switched back to the factory setting (German).

 After the system of the pendiq 2.0 is restored back to factory default settings, the language, Date/Time, TimeBlock, 1 day dose limit, 1 time dose limit, Speaker and Bluetooth PIN Number settings must be set again.



Press **ACT** for 3 seconds to turn on the power in case the pen is turned off.

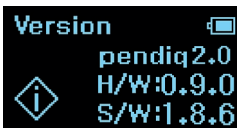
The home screen “Last Inj.” will appear on the screen.



Press **M** and “Remain. Ins.” screen will appear.



Press **+** or **-** button until you reach “Settings Menu” screen.



Press **ACT** to enter and then press **+** or **-** until you reach “Version” screen.

The software and hardware version information is displayed on the screen.

Version

Battery

Open the USB port cover on the side of your pen. Take the micro USB cable that was delivered with the pendiq 2.0 box and plug in the end of the USB connection into the USB port of the pen.

Connect USB cable with your computer or with the USB adapter to charge your pen.

While the pen is charging, the LED light will show a flashing green light.

When your pen is completely charged, the LED light shows a consistent green light and you can remove the charger from your pen. If not removed the green LED light turns itself off.



Battery status

Remaining battery

Warning signals

< 20%

Battery icon blinking.

< 10%

Battery icon and red LED blinking.

< 5%

Warning “Battery empty” displayed on the screen.

< 1%

Battery icon and red LED blinking.

Battery empty. Only red LED blinking to prevent device malfunction.



Do not use a USB cable other than the USB cable contained in the pendiq 2.0 box.

Do not try to change or remove the battery. It cannot be replaced.

Cleaning & maintenance

- Inappropriate cleaning may damage the pendiq 2.0.
- Do not use any liquid when cleaning the pendiq 2.0. The pendiq 2.0 is not water-proof.
- Do not immerse the pendiq 2.0 into any liquid.
- Do not use any chemicals when cleaning the pendiq 2.0.
- Do not use grease or lubricants.
- Do not expose the pendiq 2.0 to the direct sun light or the dust.
- Carefully wipe the pendiq 2.0 body, the cartridge holder and the cartridge holder cover with a dry or lightly damp cloth.

Diabetes Management App

The pendiq 2.0 is compatible with the Diabetes Management App “dialife” by the company Diamesco Co. Ltd. The smartphone app by Diamesco is an assisting function to make the use of the pendiq 2.0 even more convenient.

The injection history from your pendiq 2.0 will be displayed in the app and you can enter data from your glucometer.

The app can display all data in a diary and in a graph. Also the current status of your pendiq 2.0 will be displayed and it is possible to change the settings of the pendiq 2.0 from the app. Any changes made in the app will be applied to the pendiq 2.0 in real time.

Download the app



1. Search “dialife” in the Google Playstore or Apple Appstore and install it.

2. Turn on the Bluetooth on your smartphone and your pendiq 2.0.

Visit the homepage
www.diamesco.com to download
the user manual of the “dialife”
app.

The application software “dialife” has been / is being developed, further developed, operated, used and distributed exclusively, independently and autonomously by the company Diamesco Co., Ltd., #305, 187, Techno 2-ro, Yuseong-gu, Daejeon, South-Korea (hereinafter referred to as “Diamesco”), and is not a product of Pendiq GmbH.

The liability of pendiq GmbH for damages resulting from the distribution, application, use, use or malfunctions of this application software shall, therefore, in accordance with the conditions set out under <http://www.pendiq.com/en/legal-notes>, be excluded.

Glossary

1 Day	Dose limit for one day
1 Time	Dose limit for single injection
Always	Bluetooth on always
Basal	Long-acting insulin
Berlin	Berlin-Chemie, insulin cartridge manufacturer
Blue LED	Bluetooth working status
Bolus	Regular or rapid-acting insulin
Dose Limit	Injection dose limit

Green LED	Normal operation and charging status
H/W	Pendiq 2.0 hardware version
Last Inj.	Last injection
Lilly	Lilly, insulin cartridge manufacturer
New Inj.	New injection
Novo	Novo Nordisk, insulin cartridge manufacturer
Novo cartridge holder	A cartridge holder for Novo Nordisk insulin cartridges
PIN Num.	Bluetooth PIN number
PIN Num. Change	Bluetooth PIN number change
Prime	Air removal process before injection

Red LED	Abnormal operation, error or warning
Remain. Ins.	Remaining insulin
Replace Cart.	Replace cartridge
Rewinding	The plunger is moved backwards during cartridge replacement
S/W	Pendiq 2.0 software version
Sanofi	Sanofi-Aventis, insulin cartridge manufacturer
Set.	Setting
Default Set.	Factory default setting
Temp.	Bluetooth on temporarily

Specifications

Display symbols

Below a description of the icons that can appear on the pendiq 2.0 screen.



Settings Menu



Bluetooth Menu



Bluetooth ON - Displayed on bottom right corner



Error Bluetooth PIN number



Replace Cartridge Menu



Cartridge



Flashes while rewinding the plunger



Flashes while the plunger moves forward

Prime and injection



Please wait



TimeBlock Menu



Adding a new TimeBlock



Air removal while pressing  button in injection menu



TimeBlock edit Menu



Language Menu



Setting error



Date/Time Menu



Displayed at the bottom right while setting “Year” on Date/Time menu



Displayed at the bottom right while setting “Time” on Date/Time menu



Displayed for a fully charged battery



Flashes when charging the battery



Default Set. Menu



Dose Limit Menu



Bluetooth PIN number



Speaker Menu



Mute in volume setting

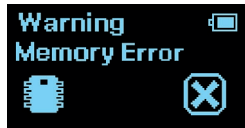


Injection error

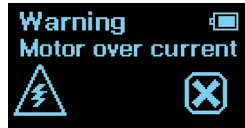
Warning & Errors



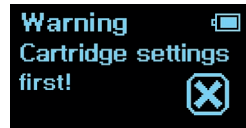
An error occurred with the settings.



An error occurred with the memory function.



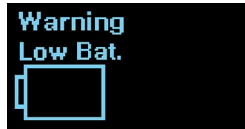
An error occurred during the operation of the motor.



If you try to make an injection before you have set the cartridge settings and with no cartridge inserted in the pendiq 2.0, the display will show this warning with a red LED light blinking.



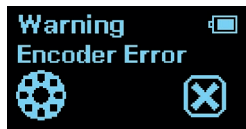
An error occurred during injection.



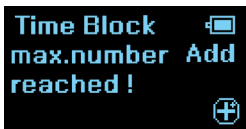
Remaining battery is <5%.



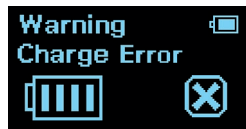
An error occurred during priming.



An error occurred during the operation of the motor.



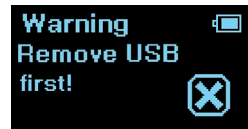
The maximum number of Time Blocks has been reached.



An error occurred during charging the battery.



The maximum dose limit for one day is reached.



The motor function is limited while the pen is charging and no injections can be carried out during.



If Bluetooth is set to “Temp.”, the message “Bluetooth loading...” will appear every time you turn on the pen whilst Bluetooth is activated.



In case that you do not see insulin bubbles at the tip of the needle after you pressed **-** several times, the pen needle may be blocked.

When there is a blockage during the prime process, the screen will display a warning message (Error) with a sound. Press **M** to cancel the warning and return to “Remain. Ins.” menu screen.



Press **M** again to return to “Last Inj.” screen. A syringe with a cross is displayed on the screen. Change the pen needle and press **M**. The syringe will disappear and you can prime again.



When there is a blockage during the injection, the screen will display a warning message (Error) with a sound. The dose deliverance will stop on the display. The injection memory will save the actual dose delivered minus a 0.1U tolerance.

Press **M** to cancel the warning and return to “Remain. Ins.” menu screen. Press **M** again to return to “Last Inj.” screen. A syringe with a cross is displayed on the screen. Change the pen needle and press **M**. The syringe will disappear and you can make a new injection.

Icon description



Manufacturer

SN

Serial number

REF

Reference number



Appointed agent in the EC



Protect from humidity



Specific references regarding storage and/or handling



The date of manufacture



Caution



Recommendation



Prohibition



Type BF applied part



Class II equipment



Direct Current



Electromagnetic compatibility IEC 60601-2-24



Material classification (only GER)



Disposal note (only EU)



Attention, consult accompanying documents



CE- certificate number

0068

Technical Information

Name	pendiq 2.0
Manufacturer	Diamesco Co., Ltd. Daejeon, 34025 Korea
Length	189mm
Weight	65g (Insulin cartridge and pen needle excluded)
Cartridge Capacity	3ml (300.0U)
Increment	0.1U
Dose accuracy	±5%
Dose limit	0.5~60.0U (default), max 1 day 160U, max 1 time 100u (adjust)
Units per second	1.6U/sec.
Battery	3.7V, 190mAh, Lithium Polymer battery

Memory (Injection history)	About 1,000 injections
USB voltage and current	USB 5V, 500mAh
USB charger	Input: 100-240 VAC, 50/60 Hz, 0.5A Output: 5 VDC, 1.5A
Storage conditions	Temperature : -10~40°C / 14~ 104°F Humidity : 10~90%RH Atmospheric Pressure : 66~106kpa
Operation conditions	Temperature : 0~40°C / 32~ 104°F Humidity : 20~70%RH Atmospheric Pressure : 66~106kpa

Life cycle	3 years
Warranty	2 years
Battery duration	10 days (12 injection / 1 day / Bluetooth OFF)
Type of protection against electric shock	Internal powered equipment
Degree of protection against electric shock	Type BF applied part
Degree of protection against the ingress of water	IPX0 (The pendiq 2.0 is not water-proof)
Operating mode	Injection

Factory Default Settings

1 Day dose limit	80.0U
1 Time dose limit	60.0U
Minimum dose per injection	0.5U
Display turns itself off (when no button is pressed) after	60 seconds
Power-on	Press ACT for 3 seconds
Countdown after the injection	15 seconds
Unit	0.1U
Unit display	U(0.01ml)
Cartridge capacity	3ml(300.0U)
Bluetooth PIN number	0000

Product warranty

The statutory warranties shall apply to this product. You are entitled to warranty rights in accordance with the statutory provisions for a period of two years beginning with the date of purchase.

In the unlikely event of failure during the two years of warranty, please fill out the warranty card contained in the product box and send it together with the damaged or defective pendiq 2.0 to the following address:

pendiq GmbH
Customer service
Baerler Strasse 100
47441 Moers, Germany

Please state the reason of your reclamation on the warranty card. The pens send back to us will be recycled after the technical inspection according to legal regulations.

The data on the pendiq 2.0 will be used for inspection but will be deleted when the assessment is completed.

The manufacturer is not responsible for damages caused by the use of unsuitable insulin cartridges or pen needles and for any inappropriate usage of the pendiq 2.0.

General Information

Manufacturer

Diamesco Co., Ltd.
#305, 187, Techno 2-ro,
Yuseong-gu, Daejeon, South-Korea

www.diamesco.com

Distributor in the EU

pendiq GmbH
Baerler Strasse 100
47441 Moers, Germany

info@pendiq.com

www.pendiq.com

pendiq 2.0 meets the requirements of the standards of IEC 60601-2-24 and ISO 13485.

pendiq® is a registered trademark of pendiq GmbH.

Lilly® is a registered trademark of Eli Lilly and Company.

Berlin-Chemie® is a registered trademark of the Berlin-Chemie AG.

Sanofi-Aventis® is a registered trademark of the sanofi-aventis-group.

Novo Nordisk® is a registered trademark of Novo Nordisk A/S.

Bluetooth® is a registered trademark of Bluetooth SIG, Inc. and is used under license agreement.

All trademarks are acknowledged.

- PZN 13231681 Shadow black (black)
- PZN 13231698 Arctic white (white)
- PZN 13231735 Lime green (green)
- PZN 13231706 Funky orange (orange)
- PZN 13231741 Sky blue (blue)



CE 0068

The CE-marking indicates that the product has been subject to an assessment of his conformity with the MDD and that the medical device fulfills the requirements of the Medical Device Directive (93/42/EEC).

Please check our website www.pendiq.com or www.diamesco.com for an updated issue of this manual since issued in March 2017. Technical changes reserved.

DIQ-IFU-02 (Rev.0 2017.03.30)

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