

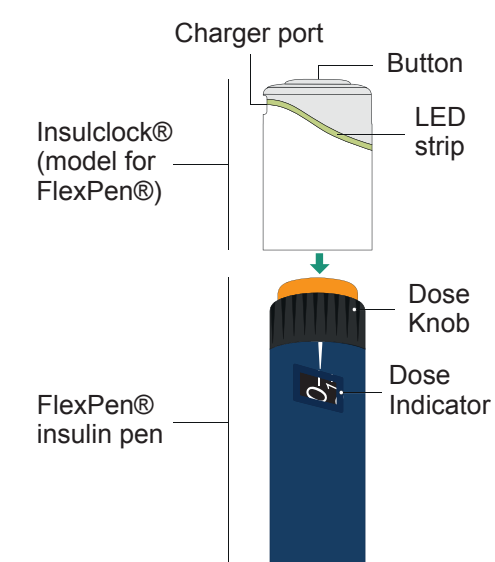
Insulclock
Model for FlexPen®

Instructions For Use



Before you use Insulclock® v2.0 pro (hereinafter Insulclock®), read all the information and carefully follow all the step-by-step instructions.

Parts of the Insulclock®



Storage & handling

⚠ Appropriate storage conditions

	TEMPERATURE	ATMOSPHERIC PRESSURE	RELATIVE HUMIDITY
STORAGE & HANDLING	32°F to 104°F	0.7 to 1.2 atm	5% to 95%

⚠ Keep your Insulclock® away from children and pets.



⚠ Insulclock® is a single-patient multiple use device. Do not share your Insulclock® with other patients.



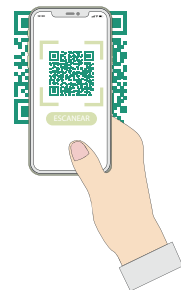
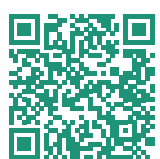
Discard or do not use the device in case it was exposed to weight or mechanical stress.

Discard Insulclock® after 1 year from first use.

PREPARATION FOR USE

1 Check pen compatibility

Scan the QR code to check for FlexPen® compatibility:



⚠ Your Insulclock® only works with a compatible FlexPen® disposable insulin pen.

2 Read pen instructions



Read the Instructions For Use of your FlexPen® disposable insulin pen (manufactured by Novo Nordisk A/S®).

3 Check for damage

Check your Insulclock® for damage before every use. Discard it if exposed to hazardous situations.

4 Check for battery

Check your Insulclock® for battery* before every use. Insulclock® is supplied with a wall charger and an USB-C cable.

*Go to point 6 of "Indications on your Insulclock®" section on the reverse page.

5 Check for cleaning

Make sure your Insulclock® is clean* before every use.

*Go to point 1 of "About your Insulclock®" section on the reverse page.

6 Check App compatibility

Make sure you are using a compatible mobile application (App) (see "8. Pair with an App").

7 Attach Insulclock® to FlexPen®

A) Insert your Insulclock® onto the disposable insulin pen as shown in the picture, fully covering the dose knob.

B) ⚠ Make sure you can turn the dose knob normally.

⚠ - Check your pen label to make sure that you have a FlexPen® disposable insulin pen.
- Check that Insulclock® is firmly attached: the dose knob must be fully inserted into the Insulclock®.
- Make sure you can turn the dose knob normally.

⚠ - Make sure that the dose indicator on your pen is at "0" (zero) while attaching your Insulclock®.
- Do not twist your Insulclock® while attaching to the disposable insulin pen.

8 Pair with an App



A) Scan the QR code to download a compatible App:



⚠ Required operating systems: iOS (version 15.0 or later); Android (version 8.0 or later).

B) Place your smartphone near your Insulclock®. There should be no more than 9 feet between them. ⚠ Your smartphone's bluetooth must be on.

C) ⚠ Open the App and follow the App's prompts to successfully finish pairing your Insulclock®. If the data transfer of your Insulclock® takes more than 5 minutes, you should contact the manufacturer.

Pairing means linking your Insulclock® with a compatible App. Note: You should only have to pair your Insulclock® to the App once.

Connecting/synchronizing means there is data transfer between your Insulclock® and a compatible App.

⚠ - Your Insulclock® must be paired and connected to an App before it transfers the recorded information.
- Your smartphone's bluetooth must be on to pair/connect/synchronize your Insulclock® and the App. Use your smartphone's instructions to switch on the bluetooth.
- Your Insulclock® must be charged to pair/connect/synchronize your Insulclock® and the App.
- Wireless connection might take some time to complete.
- Open the App and follow the App's prompts to successfully finish pairing your Insulclock®.
- A blue light will appear in the LED strip of your Insulclock® once your Insulclock® and the App are correctly paired/ connected/synchronized. Any doubt you might have, please check the App guide.
- Insulclock® is designed to be used together with an associated compatible App which allows for data transfer and Insulclock® setup and updating. Any time you use Insulclock® without the App, Insulclock®'s functionalities may be limited:
- There is a risk of data loss if the Insulclock®'s internal memory is full (maximum storage capacity of 35 injections/primings).
- You can not check the battery level.
- The alarm setting will not work.
- You can not check the Insulclock®'s specific temperature exposure.
- You can not specify if you are using a short or long-acting insulin type.

PRIME THE PEN

Priming means removing the air from the needle and pen cartridge that may be collected during normal use.

IMPORTANT

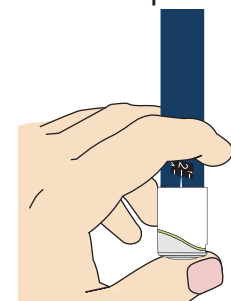
Scan the QR code to watch how to correctly hold the pen while priming:



⚠ Remove the needle caps prior to priming.

1) Turn the dose knob to select 2 units at least.

2) Hold the pen vertically with the needle pointing upwards as shown in the picture below:



90°

3) Continue holding your pen vertically with the needle pointing up as you firmly press and hold the Insulclock®'s button down (for about 3 seconds) until you see a white light in the LED strip and a sound is played for 1 second.



white light + 1second sound

IMPORTANT: Priming angle and pressing time are requirements for App registration.

4) Make sure some insulin comes out of the needle.

5) ⚠ If no insulin comes out, repeat the process until it does*.

6) ⚠ Check the dose indicator on your pen has returned to "0" (zero) after priming.

7) ⚠ Check that the data transferred to the App is correct and you clearly see the priming information in the App.

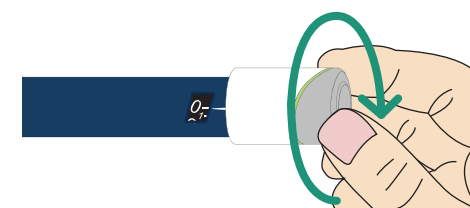
⚠ *If this issue remains, use a new needle, check that your Insulclock® is correctly placed and repeat the steps mentioned above.
- If it is still not working, you may need to use a new FlexPen®.

⚠ - Ensure that your Insulclock® has enough battery. If you are not sure if your Insulclock® has battery power, open the compatible App to check the battery level and charge the Insulclock® if the battery level is less than 20%.
- Make sure your Insulclock® is disconnected from power.
- Check the Insulclock® is correctly attached to a FlexPen® disposable insulin pen.
- Check that you correctly orient the pen while priming.
- The white light in the LED strip and sound for 1 second will tell you that the prime has been successfully recorded.

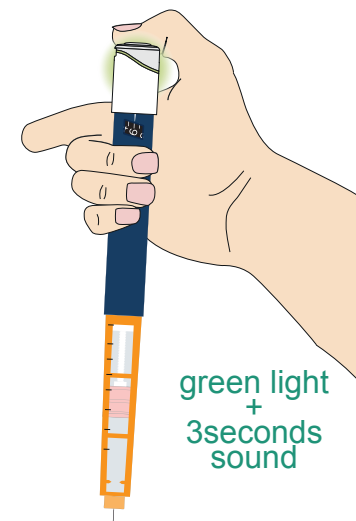
GIVE YOUR INSULIN DOSE

1) ⚠ It is highly recommended to double-click the Insulclock®'s button as a first step before selecting the desired insulin dose*.

2) Looking at the dose indicator on your FlexPen®, turn the Insulclock® on the pen to select the desired insulin dose.

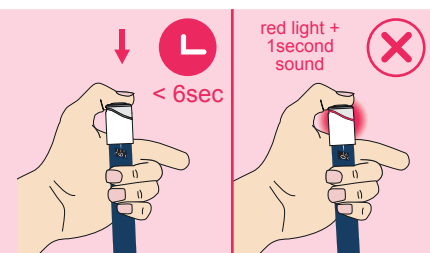


3) Inject yourself by firmly pressing and holding the Insulclock®'s button down (for about 6 seconds) until you see a green light in the LED strip and a sound is played for 3 seconds**.

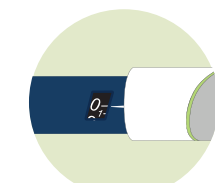


green light + 3seconds sound

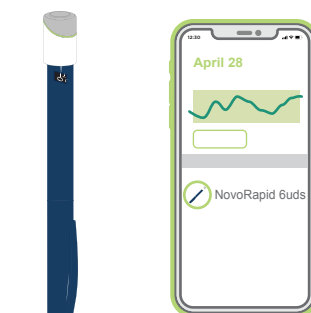
Red light and sound for 1 second after an injection means insufficient time pressing the button during injection.



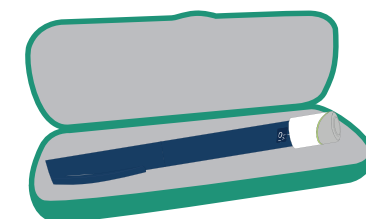
4) ⚠ Check the dose indicator on your pen has returned to "0" (zero) after the injection.



5) ⚠ Confirm that you clearly see the injection information in the App.



6) You should keep your Insulclock® attached to the disposable insulin pen you are using until your disposable insulin pen is empty and/or you have to dispose of it.



⚠ *For more information about indication meanings, see "Indications on your Insulclock®". Before giving your insulin dose, make sure you prime the FlexPen® disposable insulin pen according to the previous section.

⚠ **After the injection, if you see a red light instead of a green one and a sound is played for 1 second, you may not have pressed your Insulclock®'s button long enough during injection.
- When using your Insulclock®, do not repeat or skip your insulin dose which may result in severe low or high glucose. Monitor your blood glucose and consult with your HP.
- Dose Measurement accuracy: 99%.
- There might be potential Insulclock® design limitations which could lead to inaccurate or missing data. It is highly recommended to double-click the Insulclock®'s button as a first step before selecting the desired insulin dose. For more information about indication meanings, see "Indications on your Insulclock®".
- Give your insulin dose as described in the Instructions For Use of your FlexPen® disposable insulin pen and always follow the indications of your HP.
- Ensure that your Insulclock® has enough battery. If you are not sure if your Insulclock® has battery power, open the compatible App to check the battery levels and charge the Insulclock® if the battery level is less than 20%.
- Make sure your Insulclock® is disconnected from power.
- Check the Insulclock® is correctly attached to a FlexPen® disposable insulin pen.
- Be sure to push the Insulclock® straight down when injecting the dose. If you do not push your Insulclock® straight down, you may get more or less insulin than was dialed.
- Pay attention to using your Insulclock® in a quiet place while giving your insulin dose.
- You must handle your Insulclock® firmly when selecting your insulin dose and injecting yourself. Any rotation or movement of the disposable insulin pen could cause an error in the process.
- Do not use Insulclock® in conditions of significant vibrations (such as in a moving vehicle), since registered insulin doses may have some margin of error.

Indications on your Insulclock®

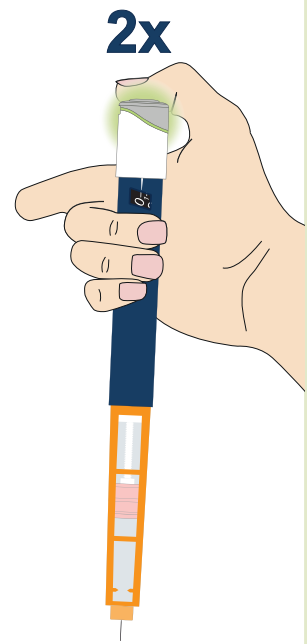
1 WHEN: you double-click the Insulclock®'s button.

GREEN LIGHT,
NO SOUND



⚠ Meaning: no insulin dose recorded within:

- The last 2 hours (for short-acting insulin type selected in the App).
- Or the last 8 hours (for long-acting insulin type selected in the App).



RED LIGHT,
NO SOUND



Meaning: at least an insulin dose recorded during:

- the last 2 hours (for short-acting insulin type selected in the App).
- or the last 8 hours (for long-acting insulin type selected in the App).

2 WHEN: you set up an alert in the App.

BLUE LIGHT,
NO SOUND



⚠ Meaning: the alert has been successfully set up in your Insulclock® and synchronized with the App.



3 WHEN: it is time to the reminder alert previously set up in the App.

BLUE LIGHT,
5 SECONDS
SOUND



⚠ Meaning: the alert comes up at the scheduled time previously set in the App.



⚠ May you have any doubts about the meaning of the Insulclock®'s indications, both lights and/or sounds, please review all the step-by-step instructions from the very beginning or contact the manufacturer.

⚠ If you are not sure whether you have injected yourself or not, do not start over or repeat your injection. If you did not specify the insulin type while pairing your Insulclock® to the App, the default parameter is set up for short-acting insulin. Remember to specify the insulin type on the App every time you change the FlexPen® insulin type you are using with your Insulclock®.

4 WHEN: you look for your Insulclock® by using this App feature

BLUE LIGHT,
6 SECONDS
SOUND



⚠ Meaning: the Insulclock® signals are helping you to find it.

5 WHEN: Insulclock® has been exposed to less than 35.6°F or more than 86°F.

FLASHING RED LIGHT,
NO SOUND



Meaning: Insulclock® has been exposed to temperatures out of less than 35.6°F or more than 86°F.

To turn off this alert, double-click the Insulclock®'s button or start the priming process.

6 WHEN: During battery charging, with your Insulclock® connected to the grid.

WHITE LIGHT,
NO SOUND



Meaning: Insulclock® is charging the battery. Description: To avoid mistakes while battery charging, a white light in the LED strip will warn you that your Insulclock® is properly connected to the USB wire and to the wall charger.

GREEN LIGHT,
NO SOUND



Meaning: The battery of your Insulclock® is 100% charged. Description: To prevent battery charging errors, when Insulclock® is still connected to the USB cable and wall charger, a green light in the LED strip will advise you that your Insulclock® is fully charged.

⚠ Refer to the Instructions For Use of the FlexPen® disposable insulin pen to see if any action is necessary when the pen is exposed out of these temperature limits.

About your Insulclock®

This information does not take the place of talking to your HP about your medical condition or treatment. Any doubt may arise regarding your treatment, please ask your HP.

Device description

Insulclock® allows you to detect, store the primes and insulin doses, the day and time of injection and the ambient temperature and transmit all this information to a compatible mobile App.

Intended Use

Insulclock® v2.0 pro is a reusable data transmitter that detects and stores insulin dose-related data when attached to a FlexPen® insulin pen, and then transfers information to a compatible mobile application via Bluetooth® wireless technology to a mobile app via integrated SDK. The insulin dose-related data is used by the mobile application which can display the type of insulin, dose, date and time.

Indications for Use

- Insulclock® is for use by patients using disposable insulin diagnosed with type I or type II diabetes mellitus.
- Insulclock® is for use by people from 18 to 65 years old. Out of this age range, the Insulclock® must be used under supervision.
- Insulclock® is designed for use in any home environment.
- Using a compatible App. Check compatible Apps in step 8 of PREPARATION FOR USE.

Essential performance

The essential performance of Insulclock® is to record the insulin usage of patients prescribed a disposable insulin pen and transmit the data, via Bluetooth Low Energy (BLE), to a mobile platform.

Usage environment

Insulclock® is designed for use in any home environment.

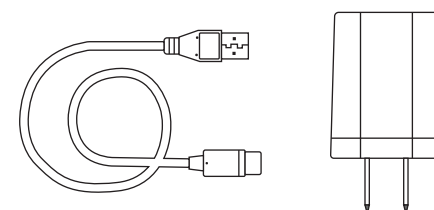
If you have any questions about your treatment, please ask your HP.

Insulclock® Associated Benefit and Risks

As with any medical device, there are benefits and risks associated with the use of the Insulclock®. Before using the Insulclock®, read all the information including the warnings and cautions to help understand the risks. Consult with your HP if you have any doubts regarding how to safely use your Insulclock®.

Accessories

Insulclock® is supplied with a wall charger and an USB-C cable. It is recommended to charge the device before its first use and, after the first use, frequently before your Insulclock® runs out of battery.



1. Cleaning instructions

Make sure your Insulclock® device is clean before every use.

⚠ - Do not use Insulclock® if it looks dirty. If any substance falls into the device, clean it immediately.

01 Unplug the USB-C cable from Insulclock®, if needed.

02 Use a slightly damp cloth to wipe the surface of Insulclock®.

03 Visually inspect Insulclock® to make sure it is properly clean.

04 If it does not still meet hygiene criteria, please repeat steps 2 and 3.

⚠ - Prevent water from getting into the USB opening.
- Avoid using cleaning or disinfection products such as alcohol wipes to clean Insulclock®.

If the Insulclock® still remains dirty after multiple attempts to clean, contact the manufacturer for help.

2. Technical specifications

Insulclock® electrical properties:

- Input voltage range: 5W
- Maximum power: 1W
- Battery: Li-ion rechargeable: Li-ion 3.7V-122mAh.
 - o Model number: CP 1654 A3.
 - o Operating time with fully charged battery: 14 days.
 - o Charging time for fully charged battery: 1 hour.

- ⚠ - Do not try to repair or replace the Insulclock® battery. This may cause you harm or damage your Insulclock®.
- Only press the Insulclock's® button while in use. Repeated pressing of your Insulclock® can reduce the battery life.

Wall charger electrical properties:

- Input voltage range: 90-264 Vac
- Frequency: 47-63 HZ
- Maximum power: 5 W
- Output voltage: 5 Vdc

Band and Mode

Insulclock® emits 2.4GHz frequency bluetooth radiation with a maximum intensity of 4dBm. Insulclock® passed the following standards:
UNE-EN 60601-1-2:2015 + A1:2021

Emission: (Group 1 Class B)

- UNE-EN 55011:2016 +A1:2017+A2 :2021
- UNE-EN IEC 61000-3-2:2019+A1:2021
- UNE-EN 61000-3-3:2013+A1:2020+AMD2:2021

RF Emission Test	Compliance	Electromagnetic environment guidance
RF emission CISPR 11, IEC 60601-1-2	Group 1, Class B	The device RF emissions are not likely to cause interference in nearby electronic equipment

Portable Radio Frequency communications equipment should be used no closer than 11.8 inches (30 cm) to any part of the Insulclock®; otherwise, essential performance may be lost or degraded due to electromagnetic disturbances.

Electromagnetic environment guidance: the device is suitable for use in domestic and home healthcare environments.			
IMMUNITY TEST	TEST VALUES	RESULTS	ELECTRO-MAGNETIC ENVIRONMENT GUIDANCE
Electrostatic discharge (ESD)	±2, ±4, ±8 and ±15 kV	COMPLIES	IEC 61000-4-2
Radiated RF	10 V/m 80-2700 MHz	COMPLIES	IEC 61000-4-3
Electrical Fast	2kV	COMPLIES	IEC 61000-4-4
Surge	0, 90, 180, 270° 1kV L-N	COMPLIES	IEC 61000-4-5
Disturbances	3 Vrms 0, 15 - 80 MHz 6 Vrms on ISM & amateur bands between 0, 15 - 80 MHz	COMPLIES	IEC 61000-4-6
Power frequency magnetic field	30 A/m	COMPLIES	IEC 61000-4-8
Voltage dips	100-240 V 50 Hz 0% of UN for 0,5 cycles and phase angles of 0°, 45°, 90°, 180°, 225°, 270° and 315° 0% of UN for 1 cycle and phase angles of 0° 70% of UN for 25/30 cycles and phase angles of 0°	COMPLIES	IEC 61000-4-11

3. Environments

- ⚠ Insulclock® must be used just for the intended use described in this Instructions For Use.
- Check the Insulclock's® packaging for damage the very first time you use it. Discard it if exposed to hazardous situations.
- Insulclock® must be used in the specified ambient conditions.
- Do not transfer Insulclock® from one pen to another, except to replace the pen (p.e. once it is empty or your pen does not work) since your Insulclock® is reusable. The manufacturer strongly recommends using only one Insulclock® for each FlexPen® disposable insulin pen to avoid possible user errors.
- Keep your Insulclock® out of the reach of children and pets. Small parts could be swallowed and lead to choking.
- Do not use or place Insulclock® near heat sources such as radiators, fire, etc.
- Do not place Insulclock® in the microwave.
- Do not use Insulclock® while driving.
- Do not wear gloves when using Insulclock®.
- Do not place the white LED of the device near the eyes. Keep Insulclock® away from materials that might hinder its use, such as hair or loose threads.
- The use of Insulclock® near any other device that may emit electromagnetic disturbances must be avoided. Autonomous use of Insulclock® is not recommended for people with special characteristics, such as:
 - vision problems such as blindness or color blindness.
 - audition problems or deafness
 - disabled people
 - the elderly and children (out of age range for use), who might need assistance by another person to enable the use of Insulclock®.
- No modification of Insulclock® is allowed.
- Do not modify Insulclock® without authorization of the manufacturer.
- If Insulclock® is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
- ⚠ - Do not place the white light of the LED strip of Insulclock® near your eyes.
- Keep Insulclock® and its accessories dry.

4. Cybersecurity safety:



- 01 Never install any App from unofficial stores on your smartphone.
- 02 Using a smartphone of unknown origin causes risk.
- 03 Protect your personal health data by using a password or biometric authentication method (such as fingerprint or facial recognition) on your smartphone. Do not share this information with third parties.
- 04 Connect your Insulclock® to an App in a private place. This helps keep your device safe.
- 05 Use only authorized Apps.
- 06 Connecting to Wi-Fi, use only safe Wi-Fi.
- 07 Keep your smartphone's operating system and Apps up to date.
- 08 Avoid downloading software and files from unknown sources to your smartphone.
- 09 Review and understand the permissions requested by Apps before installing them.
- 10 Stay informed about the latest cybersecurity threats and best practices.
- 11 Update the Insulclock® software only from authorized Apps. Before accepting an Insulclock® software update, ensure that your smartphone is connected to a secure Wi-Fi network.
- 12 Use strong and unique passwords for your App account.
- 13 If your Insulclock® is not working as expected or according to this Instructions For Use, remove it from your pen and contact the manufacturer.

Protection Degree:
The device is not waterproof. IP22 is protection against finger insertion and will not be damaged or become unsafe when exposed to vertical or near vertical dripping water.

If you have any questions or problems with your Insulclock®, contact the manufacturer at +34 911 672 677 or call your HP for help. For more information on Insulclock®, go to www.insulcloud.com/en or send a request through the following contact form: www.insulcloud.com/en/contact

Any serious incident related to Insulclock® must be reported to the manufacturer and the FDA.

Insulclock® is a trademark of Insulcloud S.L.

The FlexPen® brand is a registered trademark owned by Novo Nordisk A/S®. Novo Nordisk A/S® has no agreements or relationship with Insulcloud S.L.

IFU_Insulclockv.2.0 pro_F.rev00.EN
October 2024

Manufactured by:



Insulcloud S.L.
Tax ID: B-87131454
Registered office: Calle Alameda Mazarredo, 25 la, 48009 Bilbao, Bizkaia
Headquarters: 101, Bravo Murillo Street, 2nd floor, 28020 Madrid, Spain.

COMPLIANCE

Title 47 Part 15
Insulclock® 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.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

SYMBOLS

	Manufacturer		Complies with the Federal Communications Commission's rules and regulations for Radio Frequency (RF) emissions and Electromagnetic Interference (EMI)
	Manufacturing date		
	Refer to instruction manual		Protect from heat and radioactivity sources
	Lot Number		Atmospheric pressure limits
	Do not dispose in household waste		Humidity limits
	Protection against solid foreign objects and water.		Temperature limits
	Keep dry		Applicable part BF
	Do not use if package is damaged		Magnetic Resonance (MR) Unsafe. Keep away from magnetic resonance image equipment.
	WARNING		
	CAUTION		By prescription only
	Medical Device		Single-patient multiple use
	Direct current		Lithium-ion battery 3,7V