

Indications on your Insulclock®

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



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



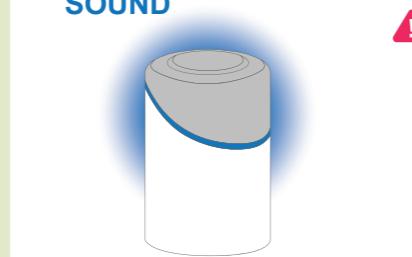
3 WHEN: it is time to the reminder alert previously set up in the App.



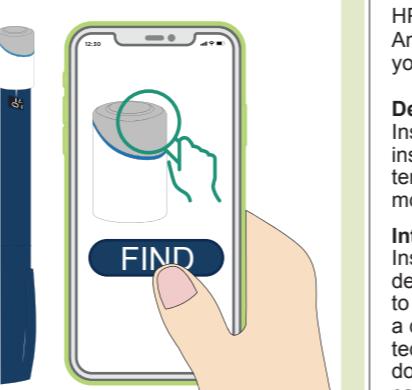
⚠️ May you have any doubts about the meaning of the Insulclock®'s indications, both lights and/or sounds, please review all the step-by-step instructions from the very beginning or contact the manufacturer.
⚠️ If you are not sure whether you have injected yourself or not, do not start over or repeat 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

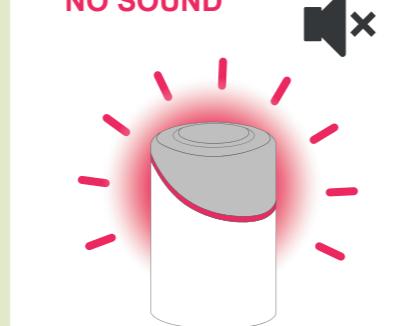


⚠️ Meaning: the Insulclock® signals are helping you to find it.

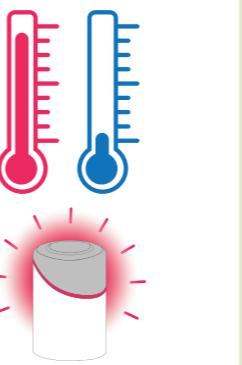


5 WHEN: Insulclock® has been exposed to less than 35.6°F or more than 86°F.

FLASHING RED LIGHT,
NO SOUND

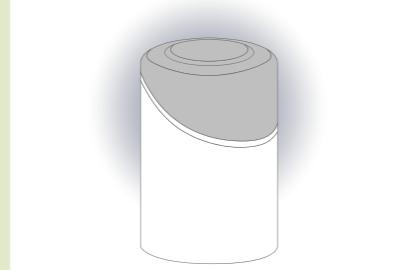


Meaning: Insulclock® has been exposed to temperatures out of less than 35.6°F or more than 86°F.



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

WHITE LIGHT,
NO SOUND

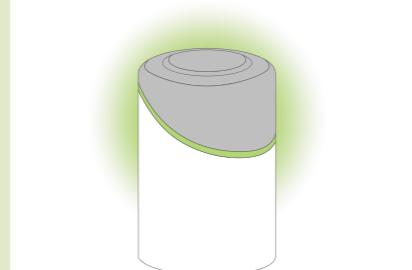


Meaning: Insulclock® is charging the battery.

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.

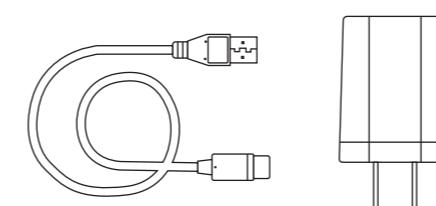
If you have any questions about your treatment, please ask your HP.

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: 5V
- Maximum power: 1W
- Battery: Li-ion rechargeable: Li-ion 3.7V-122mAh.
 - Model number: CP 1654 A3.
 - Operating time with fully charged battery: 14 days.
 - 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 60601-2:2015 + 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.

If you have any questions or problems with your Insulclock®, contact the manufacturer at +34 911 677 677 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.

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October 2024

Manufactured by:



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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.

- Do not place the white light of the LED strip of Insulclock® near your eyes.
- Keep Insulclock® and its accessories dry.

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

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.