CLIPSULIN® UNIVERSAL INSULIN PENS RECORDER

ABOUT

The CLIPSULIN® is a removable memory recorder designed to be used with the following insulin pens: Lilly KwikPen®, Lilly HumaPen®, Novo Nordisk FlexPen®, Novo Nordisk FlexTouch®, Sanofi SoloStar®, and Sanofi ClikStar®. (The CLIPSULIN® is currently only intended to be used with 1.0–unit insulin pens.)
The dose, date, and time of injection are stored in the CLIPSULIN®, and through a Bluetooth/NFC connection, this information can be transmitted to the DIABNEXT® APP on your smartphone/tablet for easy access and review.

PRECAUTION

▲ **BEFORE USING CLIPSULIN®, CAREFULLY READ ALL INSTRUCTIONS AND THE "TERMS OF USE" ON THE MOBILE APP.**

▲ The CLIPSULIN® is currently only intended to be used with 1.0–unit insulin pens.

▲ Check CLIPSULIN® for any physical damage each time before use.

▲ If you have any questions, please contact customer service for more information.

▲ If you regularly use two different insulin pens, please pair each pen with two separate CLIPSULIN® devices to avoid unidentifiable data.

▲ **DO NOT** use your CLIPSULIN® without previously pairing it.

⚠ CAUTION

Data recording malfunction may occur if there is excessive bodily movement or vibration of the CLIPSULIN® and insulin pen during use.

Transfer your records to the DIABNEXT® app regularly to avoid losing data stored in CLIPSULIN®.

After replacing the battery, sync the CLIPSULIN® with the DIABNEXT® app to allow the CLIPSULIN® to adjust its time.

Each CLIPSULIN® should only be used on one insulin pen model only. Sharing the CLIPSULIN® may lead to unidentifiable data.

Always select the correct pen in the APP. If you change pen or insulin type, modify the pen selection in the APP list accordingly.

CLEANING INSTRUCTIONS
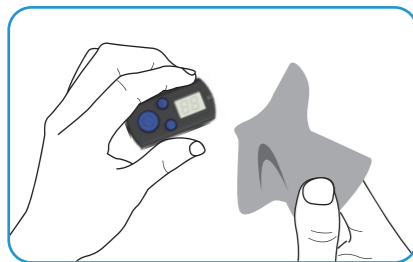
Use a dry cloth to wipe the outer surface of the CLIPSULIN®.

⚠ **DO NOT** immerse CLIPSULIN® in any fluids.

⚠ **DO NOT** spray any fluids at or into CLIPSULIN®.

⚠ **DO NOT** use CLIPSULIN® with any acid or alkaline solutions.

⚠ Cleaning, disinfecting, or testing liquid may damage CLIPSULIN®.

⚠ WARNING

DO NOT use on insulin pens that are not dosed with single unit increments.

DO NOT use if any part of your CLIPSULIN® appears damaged.

DO NOT operate or store CLIPSULIN® under improper environmental conditions.
* refer to the "CLIPSULIN® Description" and "Storage & Transportation" sections

Data within CLIPSULIN® will be overwritten if you do not transfer your records to the DIABNEXT® APP regularly. (Device memory: 200 injections)
The NFC connection can only transmit the lastest 50 records in your CLIPSULIN®.

If CLIPSULIN® is not synced with the APP to adjust its time after battery replacement, incorrect timestamps of the records may occur.

Keep out of reach of children, as small parts may be swallowed and pose a choking hazard.

If any physical irritation or discomfort occurs during the use of CLIPSULIN®, please stop using the device immediately, and contact your healthcare provider or customer service.

SUPPORT INFORMATION

CLIPSULIN® DESCRIPTION

- LED (Red/Green)
- LCD
- (+1) Button
- (−1) Button
- Power Button
- Data Validation Button
- Data Transmission Button

CE FC

Model No: C3

Size	L 46mm X W 25mm X H 23mm
Weight	9 grams
Battery type	Lithium Coin Cell Battery (CR2032)
Battery life	1800 injections
Shelf life	2 years
Device memory	200 injections
Data transmission	Bluetooth: latest 200 records
	NFC: latest 50 records
Operating temerature	5°C ~ 40°C (41°F ~ 104°F)
Relative humidity	10% ~ 90% R.H.
Wireless connection	Bluetooth Smart/NFC
APP operating system	iOS/Android
Frequency range	2.402GHz ~ 2.480GHz
Maximum allowed RF output power	+4 ~ −40 dBm

DEVICE LED SIGNAL DESCRIPTION

Green light blinks	Data recorded
Red light blinks	Battery level low

⚠ After you see the low battery LED indication for the first time, the device will allow you to perform one additional week of injections. Replace the battery CR2032 as soon as possible to avoid loss of data storage.

STORAGE & TRANSPORTATION

▲ Store this device in −20°C ~ 70°C (−4°F ~ 158°F)   ▲ Relative Humidity: 10% ~ 90% R.H.

▲ Avoid storing the device under direct sunlight.   ▲ Keep out of reach of children.

DISPOSAL

• This product contains a button battery CR2032.
• Recycle or dispose of the device and the battery separately, in accordance with applicable federal, state, and local regulations.

🌡	Temperature Limit: −20°C ~70°C (−4°F ~158°F)	☀	Keep Away From Sunlight
🏭	Manufacturer	EC REP	Authorized Representative in the European Community

HOW TO OPERATE YOUR CLIPSULIN®

1. SETUP

A Install a new battery.
- Battery type: CR2032.
- Refer to "Battery Replacement" section.

B Clip the CLIPSULIN® onto your insulin pen in a way that allows you to see the LCD screen next to the unit window of your insulin pen.
- Attach the CLIPSULIN® near the dosage window.
- Ensure that your CLIPSULIN® is tightly fitted onto your insulin pen.
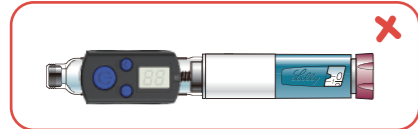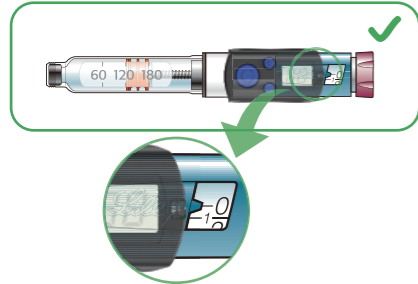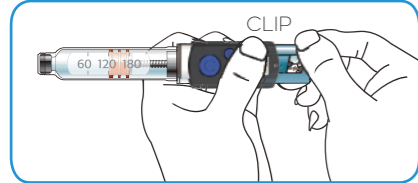
2. BEFORE FIRST USE

**A** Go to www.diabnext.com/app and install the DIABNEXT® APP on your mobile device.

DIABNEXT

B Turn on the Bluetooth function of your mobile device and open the DIABNEXT® APP.

C Enter the menu, select "My Tools" and click "Add Tools".

D Click "Insulin Pens" and select your insulin pen type.

E Follow the instructions on the APP. (Press and hold down the power button of CLIPSULIN®, until you see the double dash "– –" blinking on the LCD screen, to pair with the APP.)

- It will take a few seconds to connect.
- "– –" will be displayed on the screen of CLIPSULIN®.

3. USING THE CLIPSULIN®

A Remove the cap of your insulin pen and install the needle. Click the power button to turn on the CLIPSULIN®.
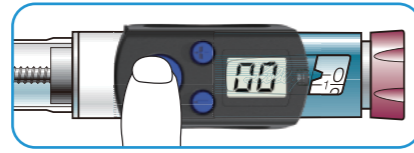
- "00" will be displayed on the CLIPSULIN® screen.
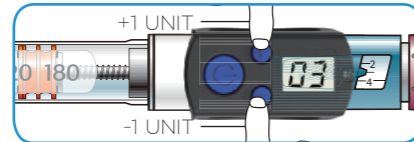
B Select your injection dose on the insulin pen.

- Ensure that your hands **DO NOT** come into contact with the CLIPSULIN® during dose selection.

C Verify that the number of units displayed on the CLIPSULIN® is the same as the selected dose on the insulin pen.
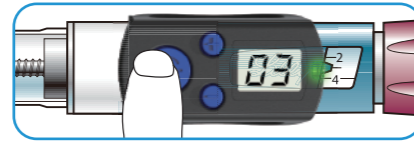

D If the numbers are not the same, use the "+" or "–" button to adjust manually the units on the CLIPSULIN®.


+1 UNIT
-1 UNIT

- You can increase the number gradually by holding down the "+" (plus) button, or decrease the number gradually by holding down the "–" (minus) button.

E Confirm the two numbers are the same, then click the blue button (Power) to validate and send your dosage data.

- The green light and the LCD will blink to signal that the data has been recorded.
- The data will not be recorded if the green light and the LCD have not blinked.
- Your data will be automatically transmitted to your mobile APP after injections. (See the " ★ " part.)
- If you do not want your data to be transferred automatically, please refer to the "Data Transmission" section.

F Perform your injection in your normal manner.
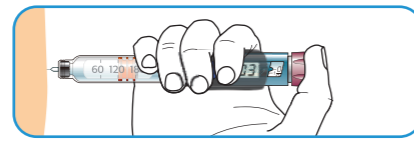
- The device will automatically shut down after 10 seconds of inactivity.

DATA TRANSMISSION

BLUETOOTH

You can use the Bluetooth transmitting function with your mobile phone if you have iOS / Android with BLE 4.0 or higher.
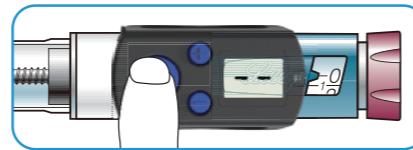
A Enable the Bluetooth function on your mobile device.

B Open the DIABNEXT® APP.

DIABNEXT

C Follow the instructions on the APP.

- Press and hold down the power button of CLIPSULIN®, until you see the double dash "– –" blinking on the LCD screen, to pair with the APP.
- "– –" will be displayed on the screen of CLIPSULIN®.

D Your stored records will be transferred automatically, and can be viewed on your mobile device.

⚠ If you see the "Device error, please contact customer service" message pop up, please refer to the "Troubleshooting" section.

NFC

You can use the NFC transmitting function with your mobile phone if you have:
– iPhone 7 or newer, and have the iOS 11 system updated or newer.
– Android phone with NFC function.

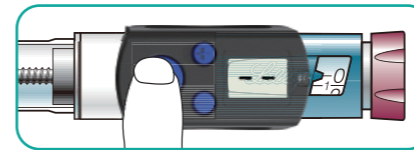**A** Enable the NFC (Near Field Communication) function on your mobile device.
Note: For iPhone users, you may skip this step.

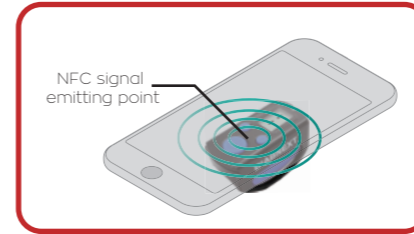**B** Open the DIABNEXT® APP.

DIABNEXT

C Follow the instructions on the APP.

- Press and hold down the power button of CLIPSULIN®, until you see the double dash "– –" blinking on the LCD screen, to pair with the APP.
- "– –" will be displayed on the screen of CLIPSULIN®.

D Your stored records will be transferred automatically, and can be viewed on your mobile device.

NFC signal emitting point

- The NFC transmitter of the CLIPSULIN® is near the power button. Please confirm the NFC transmitter location of your smartphone/tablet, and be sure to have your smartphone/tablet close to your CLIPSULIN® for proper pairing/syncing.

⚠ If you see the "Device error, please contact customer service" message pop up, please refer to the "Troubleshooting" section.

⚠ Only the latest 50 records can be read out via NFC connection. Transfer your records at least once per week to keep track of your injections.

The dose, date, and time of injection will be automatically stored in your CLIPSULIN®.

★ The CLIPSULIN® will automatically transmit the stored injection data under these conditions:
1. You have paired your CLIPSULIN® with the DIABNEXT® APP before.
2. The Bluetooth/NFC function is enabled on your smartphone or tablet.
3. Your smartphone or tablet is nearby with the DIABNEXT® APP open amd connected to your CLIPSULIN®.

Your CLIPSULIN® can store up to 200 records, but the NFC connection can only transmit the latest 50 records in the memory. Transfer your records regularly to your smartphone or tablet to keep track of your injections.

BATTERY

BATTERY REPLACEMENT

A Transfer your stored records before replacing the battery.

B Open the battery compartment.

C Replace the old battery with a new one.

Battery
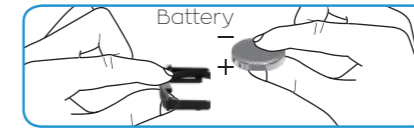
D Push the compartment back into the CLIPSULIN® to close it.

E Click the power button to check the status of CLIPSULIN®.

F Sync your device with the DIABNEXT® APP before using it again, to ensure that the timestamps of the records will be correct.

FCC STATEMENT

This device 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.

NOTE:
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules.
These limits are designed to provide reasonable protection against harmful interference in a residential installation.
This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.
If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
· Reorient or relocate the receiving antenna.
· Increase the separation between the equipment and receiver.
· Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
· Consult the dealer or an experienced radio/TV technician for help.
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

TROUBLESHOOTING

If there is no LCD display and/or LED signal light feedback of CLIPSULIN® , please follow the steps below:

1. Check if there is any physical damage to the CLIPSULIN®. If yes, stop using the device and replace it with a new one. If no, check the LCD and LED functions.
2. If only the LCD display OR the LED signal light is not functioning, stop using the CLIPSULIN® and replace it with a new one.
3. If both the LCD and LED are not functioning properly, replace the battery and check both functions again.
* Caution: After replacing the battery, before using the CLIPSULIN® with your insulin pen, sync the CLIPSULIN® with the DIABNEXT® APP to adjust its time.
4. If the problem persists, go to customer service. (www.diabnext.com/Q&A)

If the CLIPSULIN® cannot connect with the DIABNEXT® APP, please follow the steps below:

1. Check if there is any physical damage to the CLIPSULIN®. If yes, stop using the device and replace it with a new one.
2. If no, reboot the Bluetooth/NFC function on the mobile device, and then try to connect with the CLIPSULIN® again.
3. If rebooting the Bluetooth/NFC function does not resolve the issue, reinstall the DIABNEXT® APP, then try to connect with the CLIPSULIN® again.
4. If the problem persists, go to customer service. (www.diabnext.com/Q&A)

If the injection data cannot be transferred to the DIABNEXT® APP, please follow the steps below:

1. Check if there is any physical damage to the CLIPSULIN®. If yes, stop using the device and replace it with a new one.
2. If no, reboot the Bluetooth/NFC function on the mobile device, and then try to connect with the CLIPSULIN® again.
3. If rebooting the Bluetooth/NFC function does not resolve the issue, reinstall the DIABNEXT® APP, then try to connect with the CLIPSULIN® again.
4. If the problem persists, go to customer service. (www.diabnext.com/Q&A)

If you see the "Device error, please contact customer service" message pop up in your APP, please follow the steps below:

1. When this message pops up, it means that some records in the memory might be damaged.
2. Please confirm the message and go to customer service. (www.diabnext.com/Q&A)