

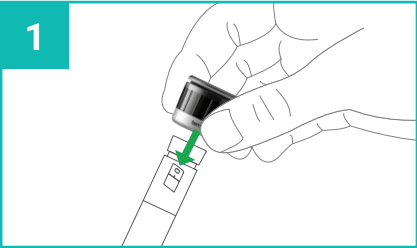
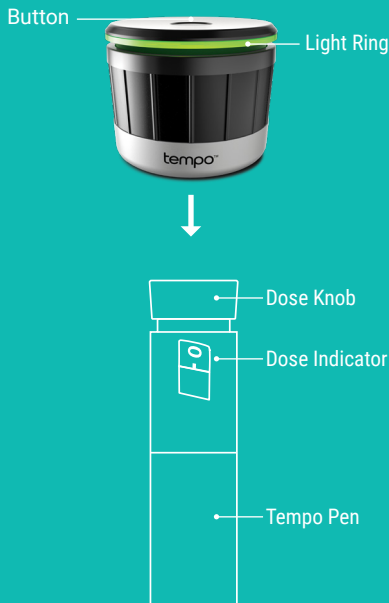
Instructions for Use

Before you use the Tempo Smart Button,™ read all the information and carefully follow all the step-by-step instructions.

Before Using your Smart Button

- 1) Check that you have your Tempo Pen™ and your Smart Button. Your Smart Button will only work with a Tempo Pen.
- 2) Check your Smart Button for physical damage before every use. Do not use if damaged.
- 3) Make sure your Smart Button is clean before every use.
- 4) Make sure you are using a compatible application (App).

Parts of the Tempo Smart Button (Smart Button)

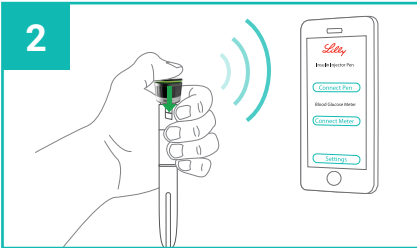


Attach to Tempo Pen

Push the Smart Button straight down on to the dose knob until you hear a snap or feel the Smart Button snap into place.

Need help attaching the Tempo Smart Button?

- Check your pen label to make sure that you have a Tempo Pen.
- Check that your Dose Indicator is at “0”.
- Push the Smart Button straight down.
- Push the Smart Button all the way down until you hear a snap or feel the Smart Button snap into place.



Connect to an App

Open the App in a private location, away from other mobile devices. Make sure the Dose Indicator is at “0”. Press and hold the Smart Button down until the green light flashes once at 10 seconds. Release the Smart Button. Follow your in App instruction. Your Smart Button will flash green three times when pairing is done.

Need help connecting (pairing) to an App?

Note: You should only have to connect (pair) your Smart Button to your App during setup.

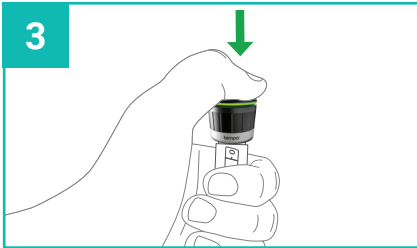
Follow these detailed steps to connect (pair) your Smart Button to an App. Your Smart Button must connect with an App before it transfers your dose data.

- 1) Make sure the Dose Indicator on your Tempo Pen is at “0”.
- 2) Open your App.
- 3) Follow the instructions of your App to connect the Smart Button.
- 4) Press and hold the Smart Button down for 10 seconds to allow for a Bluetooth® connection to your App.
- 5) Release the Smart Button after you see the green flash at 10 seconds.



Single green flash after 10 seconds= release the Smart Button.

- 6) Follow your App’s onscreen prompts to finish pairing your Smart Button.
- 7) The light ring on the Smart Button will flash green three times when the Smart Button is connected (paired) with your App.



Give Your Insulin Dose

Give your insulin dose as described in the Tempo Pen Instructions for Use. Be sure to push the Smart Button straight down when injecting the dose. **The Smart Button will flash green three times when it stores your insulin dose data.**

Need help giving your insulin dose?

- IMPORTANT NOTE: If you are not sure if you injected your insulin, do not start over or repeat your injection. Monitor your blood glucose as instructed by your healthcare practitioner.
- IMPORTANT NOTE: If you have a problem with your Smart Button, you should still give your insulin dose as instructed by your healthcare practitioner.
- Refer to the Instructions for Use that came with your Tempo Pen.

Need help with sending your dose-related data?

REMINDER: Your Smart Button must be attached to the Tempo Pen to record doses. See Attach to Tempo Pen (Section 1) to attach the Smart Button.

- **If you are having problems sending your dose data, make sure that you have:**
 - o Your Smart Button connected (paired) to your App. See “Connect to an App” (Section 2)
 - o Your mobile device next to you
 - o Your mobile device on with Bluetooth enabled
 - o Push the Smart Button straight down while giving the insulin dose



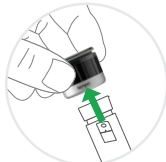
After Your Injection

You can leave your **REUSABLE** Smart Button on your Tempo Pen between uses. Your Smart Button should remain connected to your App between uses.

- 1) Follow the “After your injection” section of the Instructions for Use included with your Tempo Pen.
- 2) If your App disconnects from your Smart Button, follow section 2, “Connect to an App”.

Removing your Tempo Smart Button

- 1) Remove your Smart Button before disposing your Tempo Pen.
- 2) Remove the Smart Button by pulling straight away from the Tempo Pen.



IMPORTANT NOTE: Your Tempo Smart Button is **REUSABLE** and you can switch your Smart Button between your Tempo Pens. Your Tempo Smart Button is designed to work for about 1 year.

Disposal of your Smart Button

Due to the electronic components in the Smart Button, do not throw in household trash.



Dispose of your Smart Button in accordance with applicable federal, state, and local regulations.

Error Flashes on your Smart Button

Important Note: If you are not sure if you injected your insulin, do not start over or repeat your injection. Monitor your blood glucose as instructed by your healthcare practitioner.

When you: Have made your device “ready to pair” during the Connect to an App step and you are waiting for your Smart Button to pair to your app.

Light Ring Flashes



Three Amber Flashes

Meaning: Your Smart Button had a problem during pairing. See Commonly Asked Questions or call 1-855-LILLY-TEMPO (1-855-545-5983).

Important Note: If you are not sure if you injected your insulin, do not start over or repeat your injection. Monitor your blood glucose as instructed by your healthcare practitioner.

When you: Push the Smart Button down

Light Ring Flashes



Blinking Amber and Green Flashes

Meaning: Your Smart Button has less than 2 weeks of battery life left. Your Smart Button will blink amber and green after every use until the battery no longer works.

Important Note: If you are not sure if you injected your insulin, do not start over or repeat your injection. Monitor your blood glucose as instructed by your healthcare practitioner.

When you: Push the Smart Button down

No Light Ring Flashes



No Flash

Meaning: There is no light ring flash after use while attached to your Tempo Pen. Your Smart Button is not working. Your Smart Button will only flash if it is attached to a Tempo Pen. Make sure your Smart Button is fully attached to a Tempo Pen. You may need to replace your Smart Button or call 1-855-LILLY-TEMPO (1-855-545-5983) for help.

The Smart Button will not transfer your dose info. Continue to dose insulin as instructed by your healthcare practitioner.

Important Note: If you are not sure if you injected your insulin, do not start over or repeat your injection. Monitor your blood glucose as instructed by your healthcare practitioner.

Reminder: If you have questions about the meaning of green flashes on the light ring display, please see the steps in this Instructions for Use or call 1-855-LILLY-TEMPO (1-855-545-5983).



User Guide
TEMPO SMART BUTTON™



Read the entire User Guide before you use your Tempo Smart Button (Smart Button) and each time you get a new Smart Button. There may be new information. This information does not take the place of talking to your healthcare practitioner about your medical condition or treatment.

About Your Tempo Smart Button

Intended Use

- The Smart Button is intended to store and transfer insulin dose-related data from a Tempo Pen.

Indications for Use

- The Smart Button is for use by people 18 years or older.
- The Smart Button works with a Tempo™ compatible application (App).
- The Smart Button automatically transfers insulin dose-related data you would put in a dose logbook.
 - Dose-related data includes the type of insulin, dose amount, date and time.

Important Information

- Only use Smart Button with your Lilly Tempo Pens™.
- Your Smart Button is reusable.
- Each Smart Button is for single-patient use only.
- Do not try to repair or replace the Smart Button battery. This may cause you harm or damage the Smart Button.
- Press the Smart Button down only when using your Smart Button. Repeated pressing while not using the Smart Button for dosing may reduce the battery life.
- Keep your Smart Button out of the reach of children. Small parts could be inhaled or swallowed and lead to choking.

Cleaning Instructions

- Use a clean dry cloth to wipe the outer surface of the Smart Button.
- Avoid the use of cleaning or disinfecting fluids to clean your Smart Button.



Storage and Handling

- Store your Smart Button at room temperature below 86°F (30°C). Do not store your Smart Button in the refrigerator.
- You may keep the Smart Button attached to your Tempo Pen in between doses.
- Keep your Smart Button away from excessive light, including sunlight.
- Keep your Smart Button away from strong electromagnetic fields, such as Magnetic Resonance Imaging (MRI). This may cause you harm or damage your Smart Button.
- Avoid getting the Smart Button wet.
- Store in-use insulin pen injectors as described in the Tempo Pen Instructions for Use.

Commonly Asked Questions

Q. Will my data automatically transfer to my App?

- A. Your Smart Button stores and will automatically transfer data to your App when:
- Your Smart Button is connected (paired) to your App. See “Connect to an App” (Section 2) of this instructions for use.
 - Your mobile device is next to you.
 - Your mobile device is on with *Bluetooth* enabled.
 - You push the Smart Button straight down while giving the insulin dose.

Q. My dose data is not appearing in my App. What should I do?

- A. You should try to sync your dose data as directed in “How do I sync dose data from my Smart Button to my App?” of the Commonly Asked Questions.

Q. How do I sync dose data from my Smart Button to my App?

- A. Place your Smart Button within 9 feet of the application device. Turn on the mobile device’s *Bluetooth*. With the Dose Indicator at “0” press and hold the Smart Button down for 5 seconds.

If your dose data still does not appear, wait 30 seconds and try to sync again.

If your dose data still does not appear, contact Lilly at 1-855-LILLY-TEMPO (1-855-545-5983) or call your healthcare practitioner for help.

Q. The underside of my Smart Button is dirty. What should I do?

- A. You should try cleaning the underside of the Smart Button with a dry, lint-free cloth. Refer to the “Cleaning Instructions” section in the User Guide.

Q. Can I use the Smart Button with any insulin pen?

- A. No, you may only use the Smart Button with Tempo Pens.

Q. How long will my Smart Button work?

- A. Your Tempo Smart Button is designed to work for about 1 year.

Q. Who do I call if I need help with my Smart Button?

- A. Contact Lilly at 1-855-LILLY-TEMPO (1-855-545-5983) or call your healthcare practitioner for help.

Q. How will I know when to get a new Smart Button?

- A. You will know by the Smart Button blinking amber and green flashes about 2 weeks before the end of the battery life. You should replace your Smart Button before it runs out of battery life. If your Tempo Smart Button stops working, the light ring will no longer light up while attached to your Tempo Pen. The Smart Button will not transfer dose data.

Q. Can I repair or change my battery?

- A. Do not try to replace or change the battery. Trying to repair or change the battery could cause you harm or damage your Smart Button. If the battery is no longer working, you should replace your Smart Button.

If you have any questions or problems with your Smart Button, contact Lilly at 1-855-LILLY-TEMPO (1-855-545-5983) or call your healthcare practitioner for help. For more information on Smart Button, go to www.lillytempo.com.

Marketed by: Lilly USA, LLC

Eli Lilly and Company
Pharmaceutical Delivery Systems
Lilly Corporate Center
Indianapolis, IN 46285, USA

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Date: 8 AUGUST 2019



Read instructions before use.



Keep Dry.



The Smart Button uses *Bluetooth* low energy.



Keep away from heat and sunlight.



Manufactured for:
Eli Lilly and Company
Pharmaceutical Delivery Systems
Indianapolis, IN 46285, USA

1 General Properties

- Name: Tempo Smart Button
- Manufacturer: Eli Lilly and Company; Manufactured at Flex on behalf of Eli Lilly and Company
- Compatibility
 - Mobile Medical Applications
 - MyTempo Apps
 - Pen Injectors
 - Tempo Pens
- Dose Measurement
 - Increment: 1 Pen Injector Dial Click
 - Accuracy: +/- 1 Dial Click
- Tempo Smart Button Life: 1 year (nominal)
- Approximate Size
 - Height: 21 mm
 - Diameter: 25 mm

2 Electrical Properties

- Mode of Operation: Continuous Operation
- Communication: Wireless Bluetooth Low Energy (BLE)
 - Frequency: 2.40 GHz – 2.48 GHz
 - Range: 3 meters (nominal)
- Memory: 5840 dose records; where a single dose record includes Injection time, increments, and dose knob color.
- Battery:
 - Type: Manganese Dioxide Lithium Battery
 - Model Number: CR1616
 - Voltage: 3 V
 - Non-replaceable; non-rechargeable

3 Degree of Protection

- Ingress: IPX2 – The Tempo Smart Button is not waterproof; keep dry.

4 Storage and Handling for the Smart Button

- Temperature: 5C to 40C; for maximum Tempo Smart Button life, store Smart Button at room temperature
- Humidity: 15% to 90%
- Atmospheric Pressure: 700 hPa to 1060 hPa

Note: Store in-use insulin pen injectors as described in the patient Information Leaflet.

Portable RF (radio frequency) communications equipment should be used no closer than 30cm to any part of the device or system; otherwise, degradation of the performance of the device could result.

5 Compliance

- Title 47 Part 15
 - 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.
- FCC ID: 2AS69LLY00043845100
- Changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.
- WARNING: This product contains a chemical known to the State of California to cause cancer.
- WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

6 Symbols

Manufacturer	
Consult Accompanying Documents	
Lot Number	
Do not dispose in household waste	
Temperature limitation (5C to 40C)	
Keep dry	
Keep away from heat and sunlight	
Bluetooth Low Energy	