

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 Tempo Smart Button (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).



WARNING: When using your Tempo Smart Button, 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 healthcare practitioner.



WARNING: Consult with your healthcare practitioner to make sure you have a backup diabetes management plan if your Tempo Smart Button or App stops working. Having a backup plan and supplies can help you avoid severe low or high blood glucose.

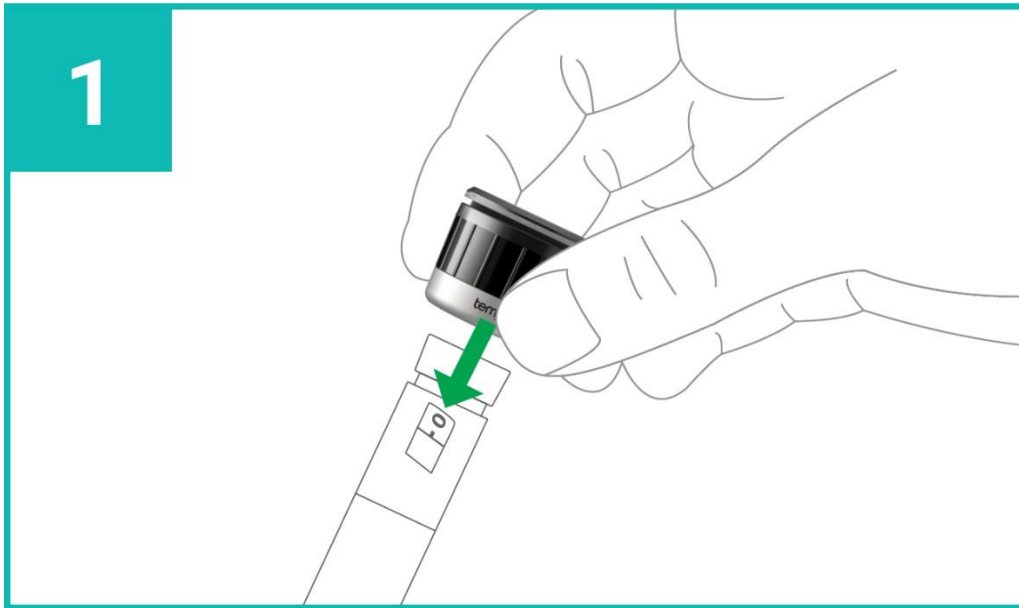
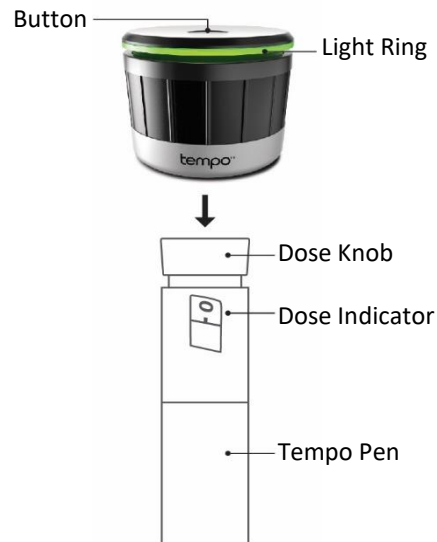


WARNING: The Tempo Smart Button is intended to help support the management of your diabetes. You must continue to independently manage your blood glucose values and your prescribed regimen with support from your healthcare practitioner.



CAUTION: Keep your Smart Button away from children. The Smart Button represents a choking hazard. The Smart Button could be swallowed or inhaled which could lead to choking or injury.

Parts of the Tempo Smart Button



Attach to Tempo Pen

Your Smart Button must be attached to a Tempo Pen to record or transfer insulin dose-related data.

- 1) Check your pen label to make sure that you have a Tempo Pen.



- 2) Make sure your dose indicator on your Tempo Pen is at "0".
- 3) Push the Smart Button straight down on the dose knob until you hear a snap or feel the Smart Button snap into place.

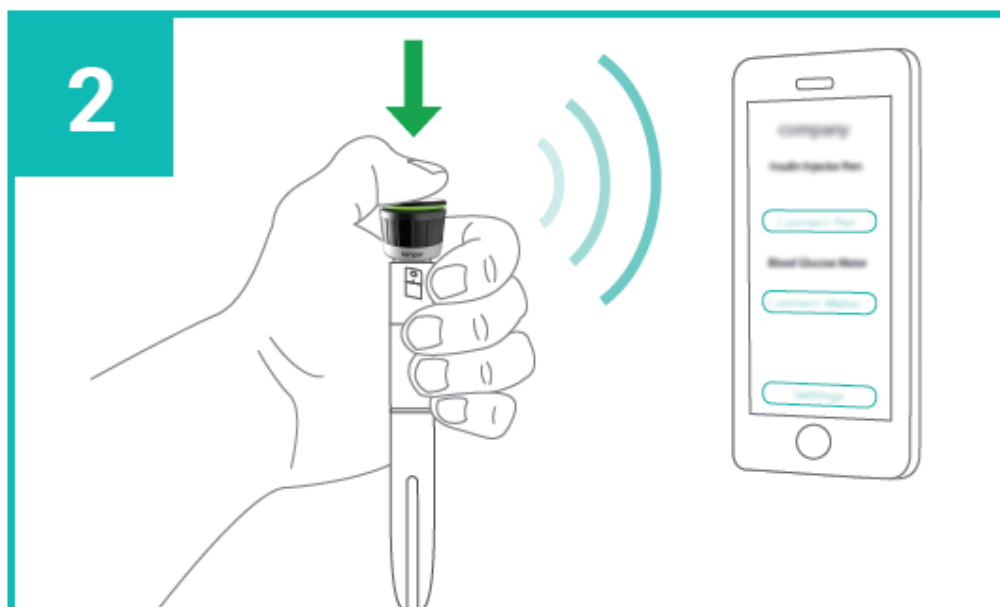
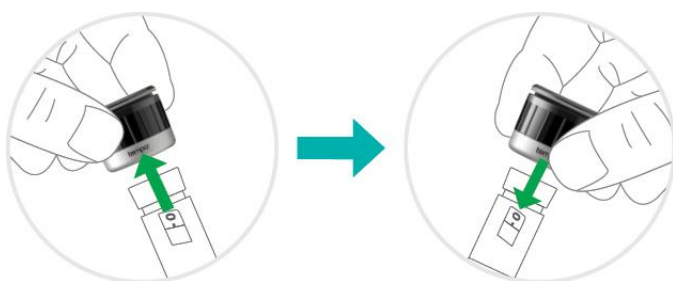
Note: Do not twist the Smart Button while attaching to the Tempo Pen. Push the Smart Button straight down.

Switching your Tempo Smart Button between Tempo Pens

You can switch your Smart Button between Tempo Pens (for example if your Tempo Pen runs out of insulin or if you are using two types of insulin).

To remove: Pull the Smart Button straight away from your current Tempo Pen. Avoid twisting while removing the Smart Button from your Tempo Pen.

To attach: Follow the instructions in the section “Attach to Tempo Pen.” Avoid twisting while attaching the Smart Button to your Tempo Pen.



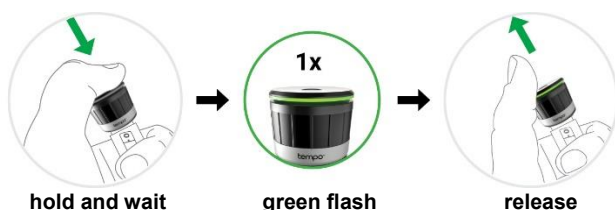
Connect to an App

Your Smart Button must connect (pair) to an App before it transfers your insulin dose-related data.

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

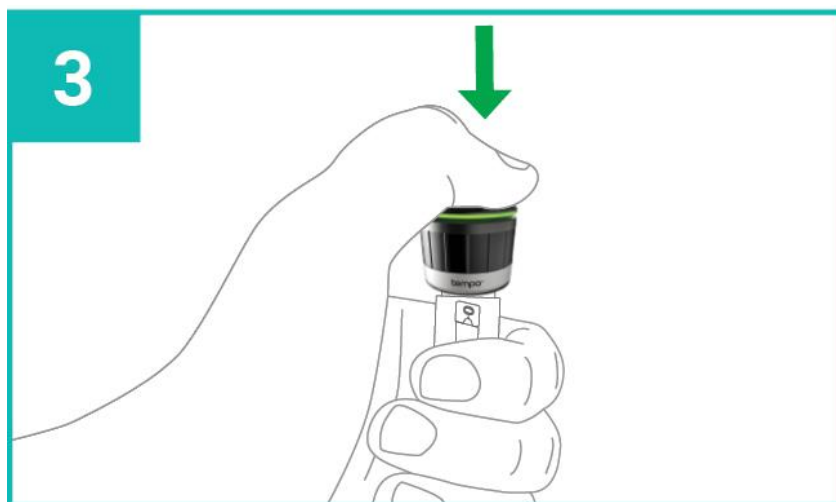


- 1) Make sure the Dose Indicator on your Tempo Pen is at “0”.
- 2) Open the App on your mobile device in a location at least 9 feet (3 meters) away from other mobile devices actively in use. To help prevent others accessing your data or settings do not leave your Smart Button in an area that can be accessed by others.
- 3) Follow the instructions from your App to connect the Smart Button.
- 4) Press and hold the Smart Button down until you see one (1x) green flash (after about 10 seconds). Release the Smart Button after you see one green flash.



The one (1x) green flash will tell you that your Smart Button is ready to pair to your App.

- 5) Follow your App's onscreen prompts to finish pairing your Smart Button.
- 6) The light ring on the Smart Button will flash green three times (3x) when the Smart Button is connected (paired) with your App.
- 7) Check your App to make sure your Smart Button is connected (paired).



Give Your Insulin Dose

Reminder: Your Smart Button must be attached to a Tempo Pen to record or transfer insulin dose-related data.

- 1) Place your mobile device within 9 feet (3 meters) of your Smart Button,
- 2) Make sure that your mobile device's *Bluetooth*® wireless technology is enabled, then
- 3) Give your insulin dose as described in the Instructions for Use that come with your Tempo Pen.

IMPORTANT NOTE: After your insulin dose, the Smart Button will flash green three times (3x) when it stores your insulin dose-related data.



: Be sure to push the Smart Button straight down when injecting the dose. If you do not push the Smart Button straight down, you may get more or less insulin than was dialed.



: If you are not sure if you injected your insulin or the Smart Button does not flash three times (3x), do not repeat your insulin dose or skip your dose which may result in severe low or high glucose. Monitor your blood glucose and consult with your healthcare practitioner.



After Your Injection

Follow the “After your injection” section of the Instructions for Use included with your Tempo Pen. You can leave your Smart Button on your Tempo Pen between uses.

IMPORTANT NOTE: Your Tempo Smart Button is **REUSABLE**. You should remove your Smart Button before disposing of any Tempo Pen.

Need help with pairing your App?

Your Smart Button should remain connected (paired) to your App when switching between Pens. You should not need to pair it to your App again.

If your App disconnects from your Smart Button, follow the section “Connect to an App”.

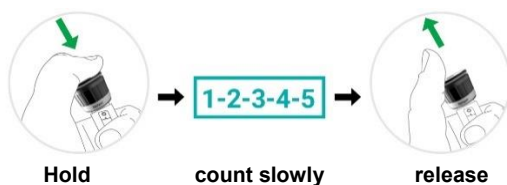
Did you know your Smart Button stores your insulin dose-related data?



: If you are unsure if any App data is inaccurate or missing, do not repeat your insulin dose or skip a dose. This may result in severe low or high blood glucose. Monitor your blood glucose and consult with your healthcare practitioner or Lilly at 1-855-LILLY-TEMPO (1-855-545-5983). There are potential Smart Button design limitations which could lead to inaccurate or missing data.

Your Smart Button can store insulin dose-related data if your phone is not within 9 feet (3 meters) while you are giving your insulin dose. To send this insulin dose-related data to your App, follow these steps:

- 1) Place your mobile device with the App running within 9 feet (3 meters) of your Smart Button.
- 2) Make sure that your mobile device's *Bluetooth*[®] is enabled.
- 3) With the Dose Indicator at "0" press and hold the Smart Button down for 5 seconds. Then, release the Smart Button. You can look at your App to see your data.



If you have questions about your Tempo Pen, refer to the Instructions for Use that came with



your Tempo Pen.

If you have questions about your App, refer to the Instructions for Use that came with your App.



: When using your Tempo Smart Button, 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 healthcare practitioner.

Error Flashes on your Smart Button

When your Smart Button is 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. If your Smart Button is not paired to your App, repeat “Connect to an App” steps. See Commonly Asked Questions or contact Lilly at 1-855-LILLY-TEMPO (1-855-545-5983).

When you push and release the Smart Button:

Light Ring Flashes



Blinking Amber and Green Flashes

Meaning: Your Smart Button has less than 2 weeks of battery life left. Your Smart Button is not rechargeable. Your Smart Button will blink amber and green after every use until the battery no longer works.

When you push and release the Smart Button:

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 has enough battery life, and 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 contact Lilly at 1-855-LILLY-TEMPO (1-855-545-5983) for help.



: If your Smart Button stops working, 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 healthcare practitioner. Continue to dose your insulin as instructed by your healthcare practitioner.

Reminder: If you have questions about the meaning of the flashes on the light ring display, please see the steps in this Instructions for Use or contact Lilly at 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 detect, store, and transfer insulin dose-related data from a Tempo Pen to a compatible application (App). The Smart Button is indicated for single-patient use by patients 18 years or older who are:

- diagnosed with type 1 or type 2 diabetes mellitus,
- using prefilled insulin Tempo Pens [Basaglar® Tempo Pen (insulin glargine) injection 100 units/mL, Lyumjev® Tempo Pen (insulin lispro-aabc) injection 100 units/mL, Humalog® Tempo Pen (insulin lispro injection) 100 units/mL],
- using a compatible application (App).

Device Description:

The Tempo Smart Button is a reusable data transmitter (or data transfer module) that detects and stores information from a Tempo Pen™ and then transfers insulin dose-related data to a compatible application (App) via Bluetooth® wireless technology.

The insulin dose-related data is used by the App, which can display the brand of insulin, dose amount, date, and time.

Tempo Smart Button Associated Benefit and Risks

As with any medical device, there are benefits and risks associated with the use of the Tempo Smart Button. Before using the Tempo Smart Button, read all the information including the warnings and cautions to help understand the risks. Consult with your healthcare practitioner if you have questions regarding how to safely use your Tempo Smart Button.

Important Information



Only use your Smart Button with your Lilly Tempo Pens. Using any other pens may lead to missing insulin dose-related data.



Keep your Smart Button away from children. The Smart Button represents a choking hazard. If inhaled or ingested, the Smart Button may cause internal injury which could require medical assistance.



Connect (pair) your Smart Button to an App in a private place. This helps keep your Smart Button safe.

- Your Smart Button is reusable.
- Each Smart Button is for single-patient multiple use only.
- Do not try to repair or replace the Smart Button battery. This may cause you harm or damage the Smart Button.
- Only press the Smart Button while in use, such as dosing or transferring insulin dose-related data. Repeated pressing of the Smart Button can reduce the battery life.

Cleaning Instructions

Avoid the use of a dirty-appearing Smart Button. Your Smart Button should be cleaned whenever it looks dirty.

To clean your Smart Button:

1. Use a clean dry cloth to wipe the outer surface of the Smart Button.
2. Inspect the Smart Button to make sure it is clean.
3. If the Smart Button still appears dirty, re-wipe the Smart Button with a clean dry cloth.

If Smart Button still appears dirty after multiple attempts to clean, contact Lilly for help.

IMPORTANT NOTE: Avoid the use of cleaning or disinfecting fluids to clean your Smart Button.



Storage and Handling



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.



- When stored on your Tempo Pen, 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.
- Store in-use insulin pen injectors as described in the Tempo Pen Instructions for Use.
- Keep your Smart Button away from excessive light, including sunlight.
- Your Smart Button is not waterproof.

Disposal of your Smart Button

Your Tempo Smart Button is designed to work for up to 8 months. The Smart Button is REUSABLE and can be changed between your Tempo Pens. When your Smart Button is no longer working, remove your Smart Button and dispose of it in accordance with applicable country, federal, regional, state, and/or local laws and regulations.



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

Record the date the Smart Button was first used here: ___ / ___ / ___

Record the Use-by date from your carton here: ___ / ___ / ___

Do not use your Smart Button for more than 8 months after the first use or past the use-by date on the carton.

Commonly Asked Questions

Q. Will my data automatically transfer to my App?

A. Your Smart Button stores and will automatically transfer insulin dose-related data to your App when:

- Your Smart Button is connected (paired) to your App. See “Connect to an App” of this Instructions for Use,
- Your mobile device with the App running is within (9 feet) 3 meters,
- Your mobile device is on with *Bluetooth*® enabled, and
- You push the Smart Button straight down while giving the insulin dose and then release the Smart Button.

Q. My data is not appearing in my App. How do I transfer stored insulin dose-related data from my Smart Button to my App?

A. Make sure your Smart Button is attached to your Tempo Pen. Place your mobile device within 9 feet (3 meters) of the Smart Button. Make sure your device is on with *Bluetooth*® enabled. With the Dose Indicator at “0” press and hold the Smart Button down for 5 seconds, then release the Smart Button after 5 seconds.

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

If your 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 prefilled insulin pen?

A. No, you may only use the Smart Button with Tempo Pens (Basaglar® U-100 Tempo Pen, Lyumjev® U-100 Tempo Pen, Humalog® U-100 Tempo Pen).

Q. How long will my Smart Button work?

A. It may be used for up to 8 months if you:

- Do not frequently press the Smart Button without dosing your insulin,
- Do not store the Smart Button with the button pressed,
- Do not use the Smart Button outside of room temperature 59 °F (15 °C) to 86 °F (30 °C),
- Do not store the Smart Button outside the temperature range of 5 °C to 40 °C (41 °F to 104 °F).

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 when you press the Smart Button while attached to your Tempo Pen.

Q. Can I recharge, repair, or change my battery?

A. Your Smart Button battery is not rechargeable. If the Smart Button is no longer working, you should replace your Smart Button. Do not try to recharge, repair or change the battery. Trying to recharge, repair, or change the battery could cause you harm or damage 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. Do not try to repair, perform maintenance, or modify your Smart Button. This could cause you harm or damage your Smart Button. For more information on Smart Button, go to www.lillytempo.com.

Report all MEDICAL DEVICE COMPLAINTS or UNDESIRABLE SIDE EFFECTS, including SUSPECTED SERIOUS INCIDENTS, to Eli Lilly and Company, by contacting them at 1-800-545-5979.

You are also encouraged to report all UNDESIRABLE SIDE EFFECTS, including SUSPECTED SERIOUS INCIDENTS, to the U.S. FOOD & DRUG Administration (US FDA) by:

- Visiting the MedWatch web page on reporting an adverse event or serious problem to FDA at (<https://www.fda.gov/safety/reporting-serious-problems-fda/how-consumers-can-report-adverse-event-or-serious-problem-fda>) or
- Calling FDA's toll-free information line at 1-800-INFO-FDA (1-888-463-6332).

Marketed by: Lilly USA, LLC

**UK
CA****CE**

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Authorized representative in the European community:

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1 General Properties

- 1.1 Name: Tempo Smart Button; Catalogue Number: MS6303
- 1.2 Manufacturer: Eli Lilly and Company Pharmaceutical Delivery System
- 1.3 Compatibility
 - 1.3.1 Mobile Medical Applications
 - Legally marketed Tempo Compatible applications
 - 1.3.2 Prefilled Insulin Pen Injectors
 - Humalog® U-100 Tempo Pen, Lyumjev® U-100 Tempo Pen, Basaglar® U-100 Tempo Pen
- 1.4 Insulin Dose-Related Data Measurement; Data transferred to an App
 - 1.4.1 Increment: 1 Pen Injector Dial Click
 - 1.4.2 Accuracy: +/- 1 Dial Click
 - 1.4.3 Tempo Pen Brand Color Identification: Performed via color detection
- 1.5 Tempo Smart Button Use Life: 8 months, assuming:
 - 4 injections (with priming) per day,
 - Transferring insulin dose-related data after each injection,
 - Use at room temperature, and,
 - The module is attached and detached from the pen no more than twice per day.
- 1.6 Approximate Size: 21 mm (height) x 25 mm (diameter)
- 1.7 Tempo Smart Button Software Version: 3.2.2

2 Electrical Properties

- 2.1 Mode of Operation: Continuous Operation
- 2.2 Communication: Wireless *Bluetooth*® Low Energy (BLE)
 - 2.2.1 Frequency: 2.40 GHz – 2.48 GHz
 - 2.2.2 Range: 3 meters
- 2.3 Memory: 5840 dose records; where a single dose record includes time of dose, dose knob rotation increments, and dose knob color.

- 2.4 Battery:
- 2.4.1 Type: Manganese Dioxide Lithium Battery. Perchlorate Material - special handling may apply. See <http://www.dtsc.ca.gov/hazardouswaste/perchlorate>
- 2.4.2 Model Number: CR1616
- 2.4.3 Voltage: 3 V
- 2.4.4 Non-replaceable; non-rechargeable
- 2.5 Effective Radiated Power (ERP): 0 dBm
- 2.6 Electromagnetic Compatibility

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.

Electromagnetic environment guidance: The device is suitable for use in domestic and home healthcare environments.		
Immunity test	Test level	Compliance level / performance criterion
Electrostatic discharge (ESD) ETSI/EN 301 489-1 ETSI/EN 301 489-17 IEC 60601-1-2 ISO 11608-1 ISO 11608-4	± 2 , ± 4 , and ± 8 kV contact discharge ± 2 , ± 4 , ± 8 , ± 10 , ± 12 and ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge
Power frequency magnetic field IEC 60601-1-2	30 A/m	30 A/m
Radiated RF ETSI/EN 301 489-1 ETSI/EN 301 489-17 EN/IEC 60601-1-2 ISO 11608-4	10 V/m 26 MHz – 6 GHz Immunity to proximity fields from RF wireless communication equipment as defined in Table 9 of IEC60601-1-2	10 V/m CT for transmitters, CR for receivers

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

Smart Button is a *Bluetooth*[®] device using the 2.4GHz transceiver. In review of IEC 60601-1-2, subclause 8.10 the testing requirements in table 9 for the test frequency 2,450 MHz are acceptable for testing Smart Button with the minimum separation distance as 30 cm. There are no foreseeable use cases that would require the Smart Button to be used within the 30 cm separation distance.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

3 Degree of Protection

- 3.1 Ingress: IP22 – The Tempo Smart Button 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.

4 Storage and Handling for the Smart Button

4.1

	Operating conditions	Storage conditions
Temperature	Room Temperature, 59 °F (15 °C) to 86°F (30 °C)	41 °F (5 °C) to 104 °F (40 °C)
Humidity	15% to 90%	
Atmospheric pressure	700 hPa to 1060 hPa	

- 4.2 Store away from pests, pets, and children.

- 4.3 Exposing the Smart Button to environmental conditions outside of those listed in the User Guide may cause damage or the Smart Button to malfunction.

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

No modification of the Smart Button is allowed.

5 Compliance

- Title 47 Part 15

- o 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.








European Union and United Kingdom, compliance with Radio Equipment Directive


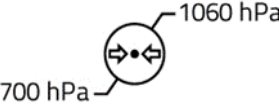

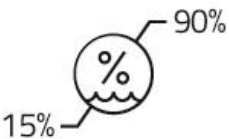










Hereby, Eli Lilly and Company Pharmaceutical Delivery Systems declares that the radio equipment type Tempo Smart Button is in compliance with Directive 2014/53/EU and UK Statutory Instruments 2017 No. 1206, The Radio Equipment Regulations 2017. The full text of the EU and UK declaration of conformity is available at the following internet address:




www.lilly.com/eudeclarations

The Smart Button has no Member State and/or geographical restrictions of use as it relates to the Radio Equipment Directive (Directive 2014/53/EU).

6 Symbols

	Manufacturer
	Batch Code
	Do not dispose in household waste
	Temperature limitation (5 °C to 40 °C)
	Keep away from heat and sunlight
	Serial number
	Authorized representative in the European Community

	Use-by Date
	Atmospheric Pressure Limitations (700 hPa to 1060 hPa)
	Medical Device
	Humidity Limit (15-90%)
	Do not use if package is damaged
	Conformité Européenne (CE) Mark
	UK Conformity Assessed
	Consult instructions for use
	By prescription only
	Caution
	Warning
	Single Patient - multiple use
	Patient information website
	Catalogue number

 A red circle with a diagonal slash over the letters 'MR' in black.	Magnetic Resonance (MR) Unsafe. Keep away from magnetic resonance image equipment.
 A black outline of a factory with a sawtooth roof and the letters 'AT' below it.	Country of Origin: Austria
 A blue circle containing a white icon of a person reading a book.	Refer to instruction manual
IP22	IP22 is protection against finger insertion and will not be damaged or become unsafe when exposed to vertical or near vertical dripping water.

Revised: 29 June 2023

TSB-0002-IFU-20230629