SmartPilot
User Manual

**This User Manual contains information about how
to set up and use the SmartPilot with the autoinjector.
Read this User Manual completely before use.**

YPSOMED
SELFCARE SOLUTIONS

Table of Contents

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$\mathbb{R}$*Only*

Caution: Federal law restricts this device
to sale by or on the order of a physician

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About the SmartPilot

- The SmartPilot is an optional, single-patient use, reusable accessory for the defined compatible autoinjector. It assists patients by providing visual and audible feedback during injections, and it records, stores, and transfers the injection data and device data to the Companion App (provided by the pharmaceutical company).

- The SmartPilot is not intended to guarantee the medicine quantity nor serve as a dose counter.

- The SmartPilot is intended to be used either in a professional healthcare facility environment or home environment.

- The SmartPilot can digitally read the label of the autoinjector if the autoinjector has a Smart NFC-based Label.

Indications for Use

The SmartPilot is indicated for use with the compatible disposable autoinjector to capture and record injection information that provides feedback to the user. The following autoinjector is compatible:

Drug Manufacturer	Brand Name (Drug Name)	Compatible Autoinjector	SmartPilot for Compatible Autoinjector
Novartis/Sandoz	Cosentyx (Secukinumab)	Cosentyx UnoReady pen	

Hereafter we refer to the compatible autoinjector as "autoinjector" and for its corresponding SmartPilot as "SmartPilot".

Do not use your SmartPilot with an incompatible autoinjector.

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Important Information

Please read this important information carefully before use:

- Read this user manual completely before use.

- Only use your SmartPilot as described in this user manual.

- In case of questions concerning the use of the SmartPilot ask your healthcare professional or contact our customer service at any time. Phone number: 1-800-930-0321

- Misuse of the SmartPilot may lead to injection of incorrect drug, injection of a degraded or expired drug, or under or over dosage of drug. Talk to your healthcare provider about these risks.

⚠ **Warnings**

- Check the medicine name on the autoinjector's label to make sure it is correct. **Do not** use if the autoinjector contains the wrong medicine.

- Check the expiration date on the autoinjector's label. **Do not** use if the expiration date has passed.

- Check the appearance of the medicine. **Do not** use if the appearance of the medicine does not look as described in the autoinjector's Instructions for Use.

- Keep the SmartPilot out of reach of children.

⚠ **Cautions**

- **Do not** use your SmartPilot with an incompatible autoinjector.

- **Do not** share the SmartPilot with others.

- **Do not** expose the SmartPilot to extreme temperatures below 41 °F (5 °C) or above 95 °F (35 °C).

- **Do not** leave the SmartPilot in direct sunlight.

- **Do not** store your SmartPilot in the refrigerator or freezer.

- **Do not** get your SmartPilot wet.

- **Do not** throw away (dispose of) your SmartPilot device after the injection. The SmartPilot device is reusable.

- Throw away (dispose of) the SmartPilot according to your local regulations.

- **Do not** modify the SmartPilot or any of the system components without authorization of the manufacturer.

- If you are unsure of the status or progress of the injection based on the information provided by the SmartPilot, check the autoinjector's visual and audible feedback. Refer to the autoinjector's Instructions for Use for more information.

- **Do not** use the SmartPilot on patients with active implants (implanted medical devices requiring external power to operate, e.g. pacemaker, neurostimulator).

- **Do not** use the SmartPilot within 12 inches (30 cm) of electric medical equipment.

MRI safety information:

- **Do not** use the SmartPilot near surgical or magnetic resonance imaging (MRI) equipment, or in areas where electromagnetic disturbance is high.

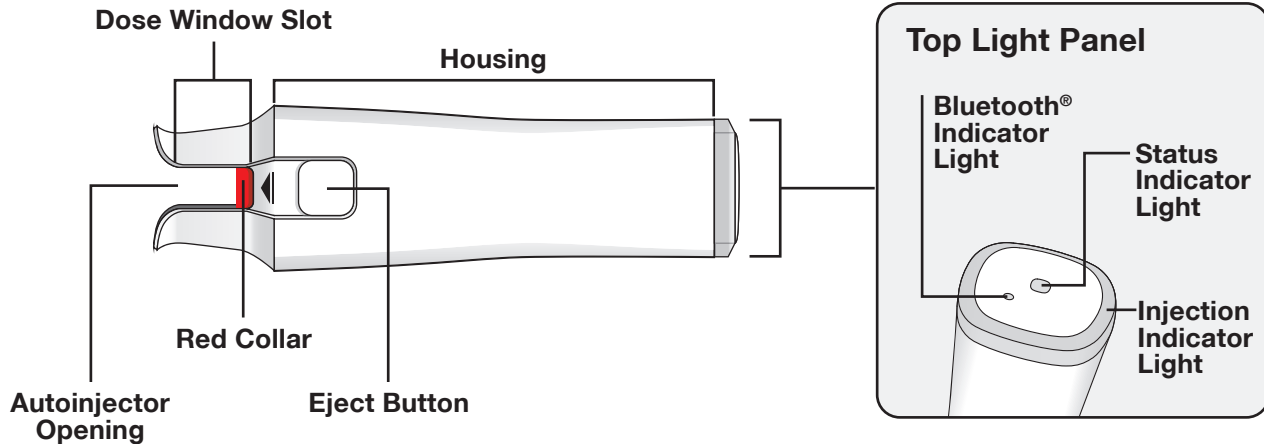# Overview of the SmartPilot Parts (Figure A)

Dose Window Slot

Housing

Top Light Panel

Bluetooth® Indicator Light

Status Indicator Light

Red Collar

Injection Indicator Light

Autoinjector Opening

Eject Button

Figure A

Overview of the SmartPilot Features

- **Data Recording:** For each injection, the SmartPilot collects a set of data:
  – Date, time and result of the injection (complete or incomplete injection)
  – Device related data of the SmartPilot including battery status, connection status and potential device error information
  – The information from the autoinjector's Smart NFC-based Label, if it is provided and enabled

- **Data Transfer:** When the SmartPilot is connected via Bluetooth® to the Companion App, the data can be transferred to the Companion App.

- **User Feedback:** The SmartPilot provides visual and audible feedback to guide the user through the injection process of the autoinjector.

Indicator Light Quick Reference

Blinking blue

New SmartPilot was Woken Up

The SmartPilot has been woken up as part of setting the SmartPilot up for the first time and needs to be paired with your smartphone.

Flashing blue

Bluetooth® Not Paired

The SmartPilot is not paired to the Companion App and is attempting to pair.

Solid blue

Bluetooth® Paired

The SmartPilot is paired to and connected with the Companion App on your smartphone.

Pulsing amber

◀)) Beeps

Reminder to Eject and Dispose of the Used Autoinjector

If the SmartPilot has just been used and still has the autoinjector inside, eject the autoinjector so the SmartPilot is empty for storage.

OR

SmartPilot is not Ready to Record an Injection

If the autoinjector has not been used, eject the autoinjector, wait 10 minutes and then reinsert.

Solid amber

5 Seconds

Battery is low

If the Status Indicator light is solid yellow for 5 seconds before the SmartPilot shows it is ready for injection, the SmartPilot battery is low. The SmartPilot can only be used for a few more injections and will need to be replaced soon.

Ready for Injection

Pulsing green

🔊 Beeps

The autoinjector is inserted into the SmartPilot and ready for the injection.

Injection in Progress

Blinking green

Continue holding down against the skin until the Injection Indicator Light turns solid green and the SmartPilot "Beeps".

Injection is Complete

Solid green

🔊 Beeps

Your injection, including the holding time, is now complete and you can lift the autoinjector from the site.

Incomplete Injection

Quickly Pulsing red

🔊 Beeps

If the Injection Indicator Light quickly pulses red **after injecting**, the autoinjector was not held down long enough to give the full injection. **Do not** start over or repeat the injection. Contact your healthcare provider for information about what to do next.

OR

Expired Autoinjector or Incorrect Medicine

If the Injection Indicator Light quickly pulses red **before injecting**, the autoinjector has expired or contains the wrong medicine.
Do not inject the medicine.

Device Error or Empty Battery

No light or sound

There has been a device error or an empty battery. Eject the autoinjector and reinsert it. If the SmartPilot continues to show no lights or sound, follow the instructions in the Disposal Information on page 56.

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Using the SmartPilot: Inserting the Autoinjector

Step 1: Gather Devices

➡ Gather the Following Devices (Figure B):

- Your SmartPilot,
- Your autoinjector,
- Your smartphone (only required when setting up a new SmartPilot for the first time).

Do not modify the SmartPilot or any of the system components without authorization of the manufacturer.
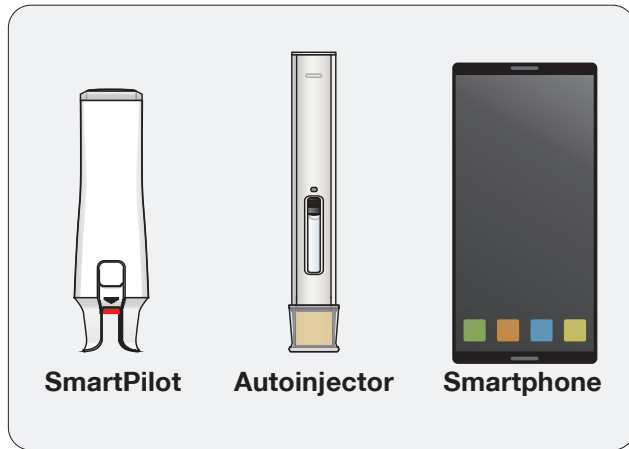

SmartPilot   **Autoinjector**   **Smartphone**

Figure B

Step 2: Check Devices

➡️ **2.1 Check the SmartPilot Before Use (Figure C)**

● **Check the SmartPilot for damage.**

Do not use the SmartPilot if it is damaged.

If the SmartPilot is damaged, throw away (dispose of) the SmartPilot following the instructions in the "Disposal Information" section on page 56. Contact your healthcare provider for further instruction. Contact your supplier to get a new SmartPilot.
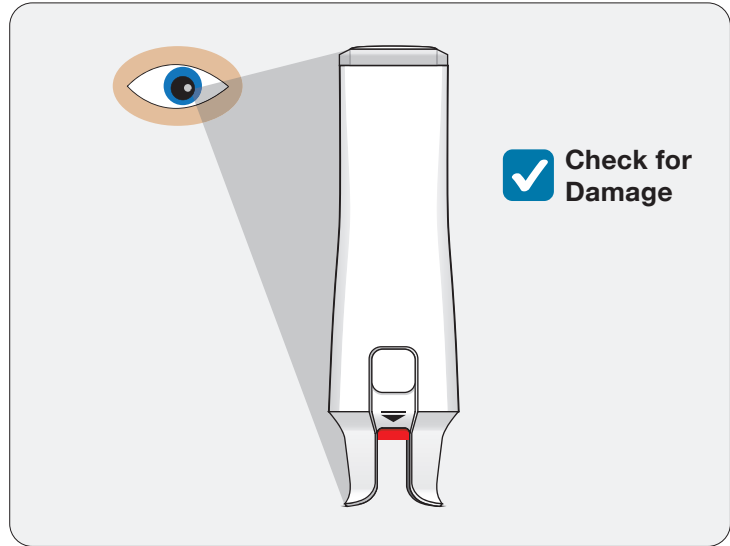

Check for Damage

Figure C

➡️ 2.2 Check the Autoinjector Before Use (Figure D)

- **Check the medicine name** on the autoinjector's label to make sure it is correct.
- **Check the expiration date** on the autoinjector's label.
- **Check the appearance of the medicine.**

Do not use if the autoinjector contains the wrong medicine.
Do not use if the expiration date has passed.
Do not use if the appearance of the medicine does not look as described in the autoinjector's Instructions for Use.
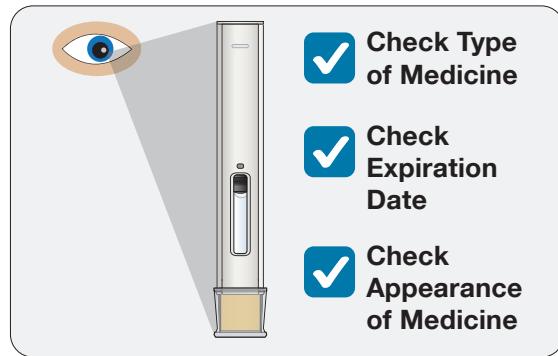

Figure D

ℹ️ **Important:** Only insert autoinjector if all related preparation steps have been performed according to autoinjector's Instructions for Use.

Step 3: Insert the Autoinjector into the SmartPilot

➡ 3.1 Position the SmartPilot and the Autoinjector (Figure E)

- **With one hand, hold the SmartPilot with the Autoinjector Opening pointed down,** so the Eject Button and Dose Window Slot face you.
- **With the other hand, hold the autoinjector with the cap end down** so the Dose Window faces you.

Do not remove the autoinjector cap until after the autoinjector is inserted into the SmartPilot and you are ready to inject.

> **Note:** When shipped, the SmartPilot is in storage mode to preserve battery life. To wake up the SmartPilot, insert an autoinjector into the SmartPilot following the instructions on the next page.
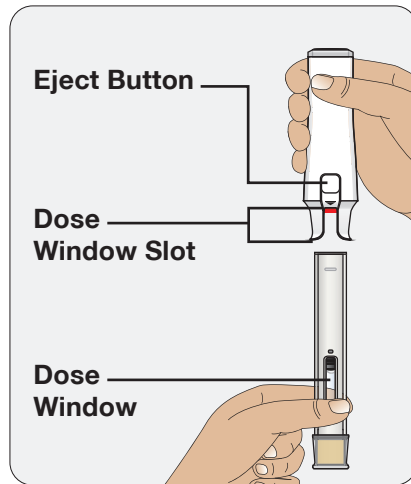

Eject Button

Dose Window Slot

Dose Window

Figure E

→ 3.2 Insert the Autoinjector into the SmartPilot

Insert the body of the autoinjector into the Autoinjector Opening of the SmartPilot until you hear a "Click" (Figure F).

Troubleshooting:
- If the autoinjector does not easily slide into the SmartPilot, press the white Eject Button, and try again.
- If the autoinjector cannot be inserted all the way until it "Clicks", check that the Dose Window on the autoinjector lines up with the Dose Window Slot on the SmartPilot and try again.
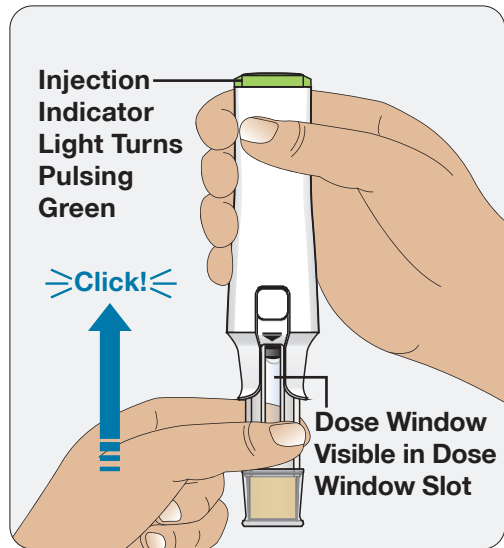
Injection Indicator Light Turns Pulsing Green

⇄Click!⇄

Dose Window Visible in Dose Window Slot

Note: If you are inserting the autoinjector into a new SmartPilot device, the Status Indicator Light will slowly blink blue and the SmartPilot will "Beep" (Figure G) indicating that it needs to be paired with your smartphone.

For any other use, the Injection Indicator Light is pulsing green, the Status Indicator Light is solid green and the SmartPilot is beeping every few seconds.

Beeps

Status Indicator Light Slowly Blinking Blue

Figure G

3.3 Confirm the Autoinjector Is Fully Inserted

- **If the Red Collar is no longer visible,** the autoinjector is fully inserted (Figure H).

- **If the Red Collar is still visible,** the autoinjector is not fully inserted (Figure I).

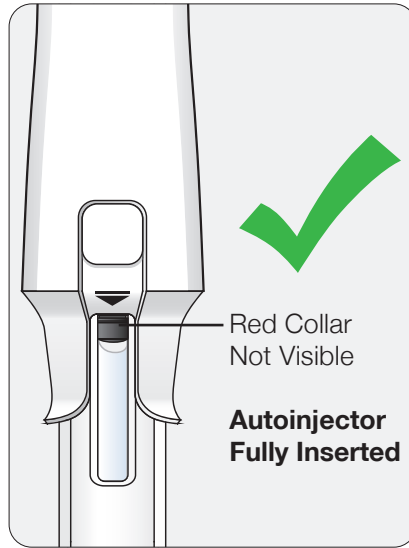**Do not** continue if the Red Collar is still visible. Eject the autoinjector and reattempt to fully insert it.
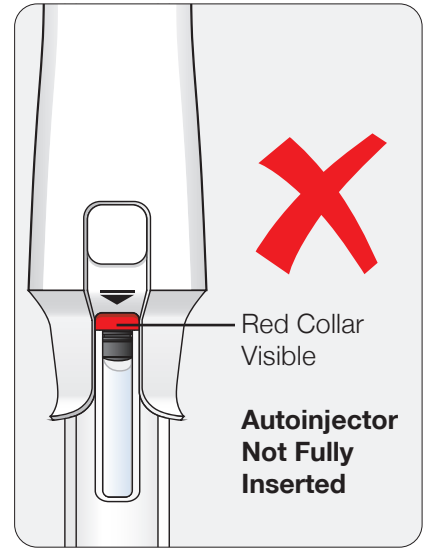

Red Collar Not Visible

Autoinjector Fully Inserted

Figure H

Red Collar Visible

Autoinjector Not Fully Inserted

Figure I

Are You Using A New SmartPilot for the First Time?

If Yes:

Complete Step 4 on page 22 to pair the SmartPilot with the Companion App, **then continue to Step 5.**

Device needs to be paired to the app.

If No:

Skip Step 4 (pairing) and continue to Step 5 on page 28 to prepare for the injection.

Device already paired to the app.

Important: The SmartPilot device only needs to be paired when using it for the first time.
If you are not using the SmartPilot for the first time, skip Step 4 and complete Step 5 on page 28.

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Step 4: Pair the SmartPilot with the Companion App (First Use Only)

ℹ

Important: The SmartPilot device only needs to be paired when using it for the first time. If you are not using the SmartPilot for the first time, skip Step 4 and complete Step 5 on page 28.

Before using the SmartPilot for the first time, always complete this setup procedure to wake up the SmartPilot and to pair it with the Companion App. If the SmartPilot is not fully set up before use, it will not work properly.

4.1 Get the Smartphone Ready (Figure J)

- **Make sure the Companion App is installed on the smartphone.** The Companion App is provided by the pharmaceutical company.
- **Make sure to turn on in the smartphone settings** the Wi-Fi/Internet Connection, Bluetooth® and NFC (Android only).
- **Open the Companion App** on your smartphone and follow the in-app instructions.
- When asked for, **allow the Companion App access** to Wi-Fi/Internet Connection, NFC and Bluetooth® within your smartphone. Access to these functions is needed to pair the SmartPilot with the Companion App.
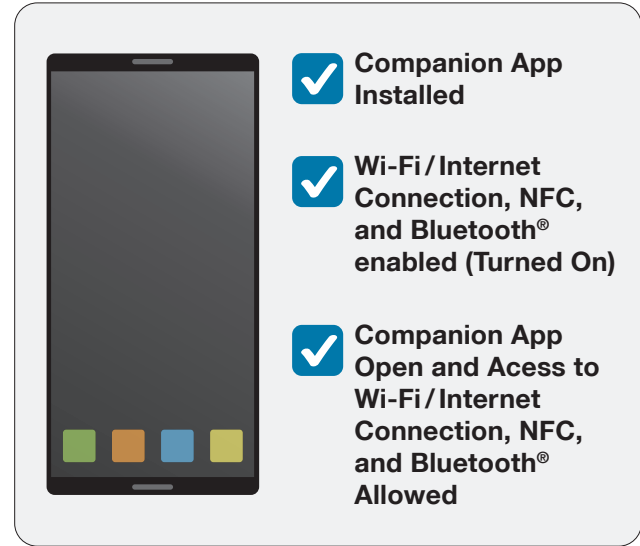

✅ **Companion App Installed**

✅ **Wi-Fi/Internet Connection, NFC, and Bluetooth® enabled (Turned On)**

✅ **Companion App Open and Acess to Wi-Fi/Internet Connection, NFC, and Bluetooth® Allowed**

Figure J

4.2 Make Sure the SmartPilot is Ready to Pair

- **Make sure the SmartPilot Status Indicator light is slowly blinking blue** (Figure K). This means that the SmartPilot is on and ready to pair.

ℹ️

Important: If the Status Indicator Light is off, the SmartPilot has turned off as a result of inactivity. Eject the autoinjector and reinsert it.

4.3 Touch the SmartPilot with the smartphone

- **Place the Top Light Panel of the SmartPilot against the back of your smartphone.** The Top Light Panel of the SmartPilot should sit flat against the back of the smartphone at a 90-degree angle (Figure K).
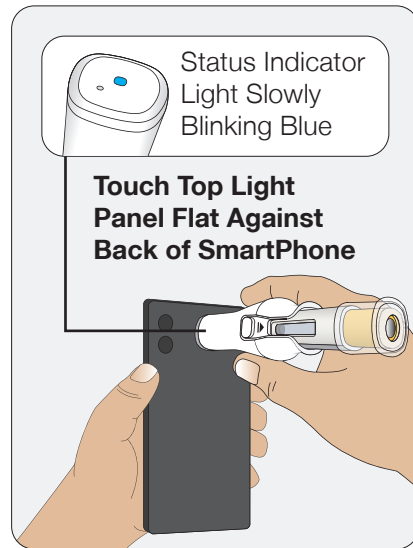

Status Indicator Light Slowly Blinking Blue

Touch Top Light Panel Flat Against Back of SmartPhone

Figure K

➡ 4.4 Slowly Slide the SmartPilot Up and Down to Pair

● Keeping the Top Light Panel of the SmartPilot flat against the back of the smartphone, **slowly slide the SmartPilot up and down** on the back of the smartphone **from top edge to bottom edge** until the device pairs with the Companion App (Figure L). This may take about 30 seconds.

ℹ

Important:
- ● Make sure the Top Light Panel of the SmartPilot is touching or resting against the back of the smartphone. If it is not touching, pairing may not occur.
- ● Make sure you slide the SmartPilot slowly all the way from top edge to bottom edge of the phone.
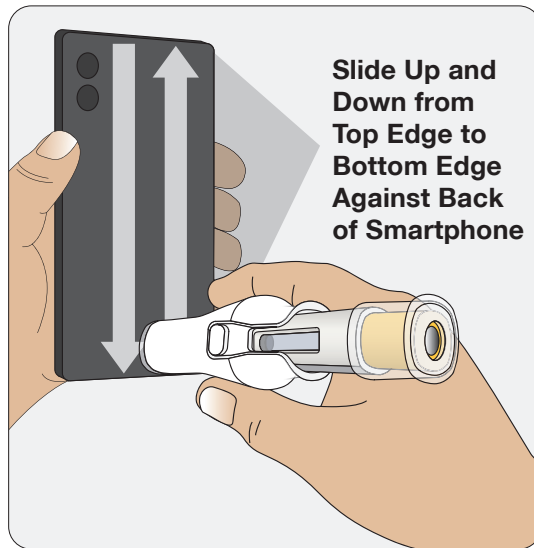

Slide Up and Down from Top Edge to Bottom Edge Against Back of Smartphone

Figure L

➡️ 4.5 Confirm the SmartPilot is Paired

- **Take the SmartPilot away from the back of the phone and check to see if the Bluetooth® Indicator Light is showing a solid blue light.** If the Bluetooth® Indicator Light is showing solid blue, the SmartPilot is paired (Figure M).

ℹ️

Important: If the Bluetooth® Indicator Light is not lit or is flashing blue, repeat steps 4.1–4.4.

💡

Troubleshooting: If after several attempts, the Bluetooth® Indicator Light is not solid blue, refer to the "Troubleshooting" section on page 45.

SmartPilot is Paired
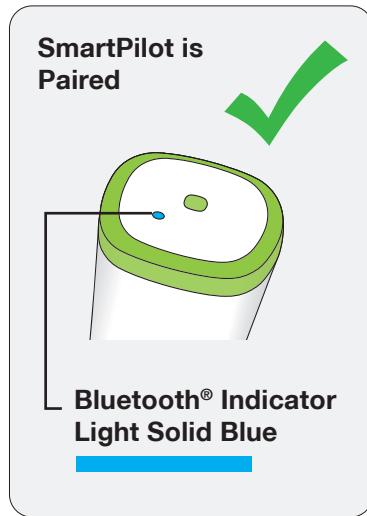
Bluetooth® Indicator Light Solid Blue

Figure M

Your SmartPilot is now paired with the Companion App.

Note: If you do not plan to give an injection after pairing the SmartPilot with the Companion App: Eject the autoinjector by pressing the white Eject Button and store for later use.

If you leave the autoinjector inside the SmartPilot, it will drain the battery more quickly.

Important: You only need to pair the SmartPilot with the Companion App one time. After this initial pairing, the SmartPilot will automatically connect to the Companion App on your smartphone when Bluetooth® is enabled. Continue to Step 5 to give an injection.

Using the SmartPilot: Giving the Injection

Step 5: Prepare for Injection

➡️ **When ready to inject**, the SmartPilot will beep and the Injection Indicator Light will slowly pulse green, while the Status Indicator Light will show solid green (Figure N).

ℹ️

Important:
- The autoinjector should already be inserted into the SmartPilot. If it is not already inserted, start with Step 1 on page 14.
- Give the injection as instructed in the Instructions for Use provided with your autoinjector.
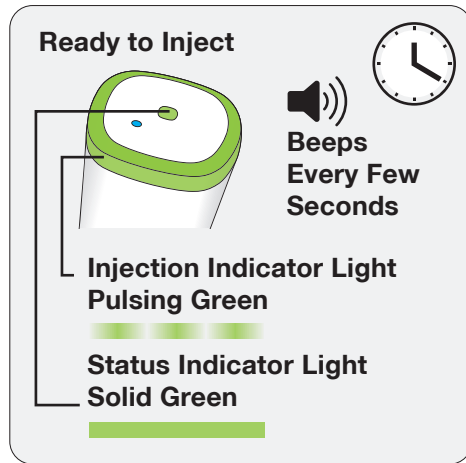- **Do not** press the white Eject Button of the SmartPilot during the injection. This will eject the autoinjector.

Ready to Inject

Beeps Every Few Seconds

Injection Indicator Light Pulsing Green

Status Indicator Light Solid Green

Figure N

Step 6: Give the Injection

ℹ️

Important: Read all of Step 6 (Steps 6.1–6.6) very carefully before giving the injection and then follow along step-by-step when giving the injection.

➡️ **6.1 Pull the Autoinjector Cap Straight Off (Figure O)**

➡️ **6.2 Throw Away (dispose of) the Autoinjector Cap Immediately Into a FDA-Cleared Sharps Disposal Container**

Do not put the cap back onto the autoinjector. Throw the cap away into the FDA-cleared sharps disposal container.
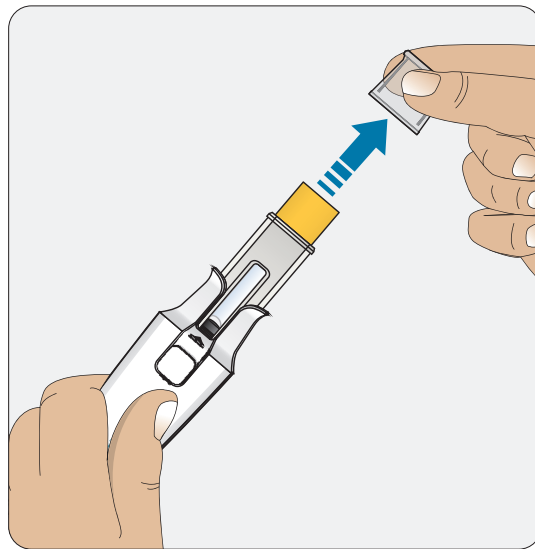

Figure O

6.3 Position the Autoinjector

- Hold the SmartPilot as shown and **position the autoinjector straight on the injection site (90 degrees)** with the needle guard resting on the skin and the Dose Window facing you (Figure P).

6.4 Push and Hold the Autoinjector Down Against the Skin

- **Push and hold the autoinjector down against the skin** to start the injection. After the injection is started, the SmartPilot Injection Indicator Light will be slowly blinking green (Figure P).

Do not press the white Eject Button of the SmartPilot during the injection. This will eject the autoinjector.
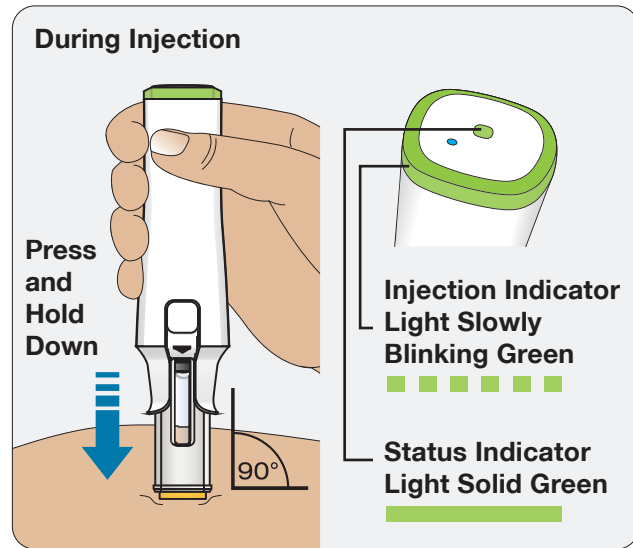

During Injection

Press and Hold Down

90°

Injection Indicator Light Slowly Blinking Green

Status Indicator Light Solid Green

Figure P

➡️ 6.5 Keep Holding the Autoinjector Down Against the Skin

- **Continue holding down against the skin** until the Injection Indicator Light turns solid green and the SmartPilot "Beeps" (Figure Q).
  Do not lift the SmartPilot from the injection site before the Injection Indicator Light turns solid green and the SmartPilot "Beeps".

💡

Troubleshooting: If the Injection Indicator Light flashes red, you did not hold the device down long enough to give the full injection.
Do not start over or repeat the injection. Contact your healthcare provider for further instruction and continue to Step 7 on page 33.
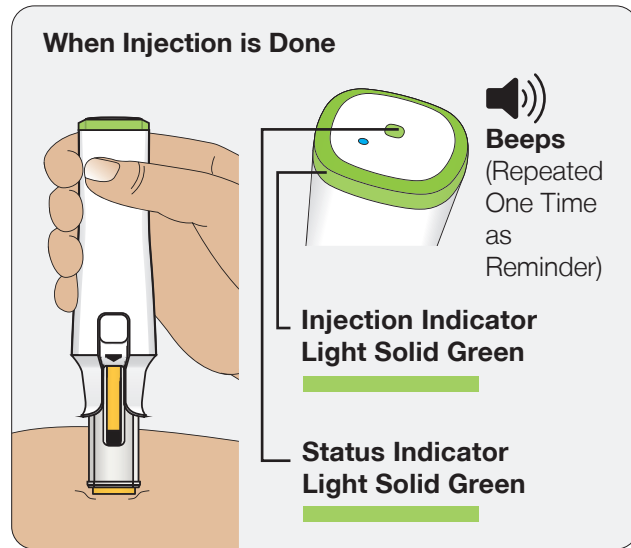

When Injection is Done

🔊)) **Beeps** (Repeated One Time as Reminder)

Injection Indicator Light Solid Green

Status Indicator Light Solid Green

Figure Q

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➡️ 6.6 Lift the Autoinjector from the Site

● The injection is now complete, and you can lift the autoinjector straight from the site (90 degrees) (Figure R).

Note: The Indicator Lights on the SmartPilot will fade and turn off about 20 seconds after the injection.
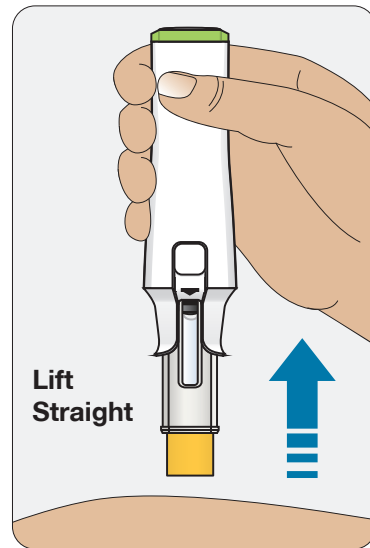

Figure R

Lift Straight

Step 7: Eject and Dispose of the Autoinjector

➡️ Press the white Eject Button to **eject the used autoinjector into a FDA-Cleared sharps disposal container** (Figure S).

Do not throw away (dispose of) your SmartPilot device. The SmartPilot device is reusable.

> **Note:**
> - For additional information about disposing of the used autoinjector refer to the autoinjector's Instructions for Use.
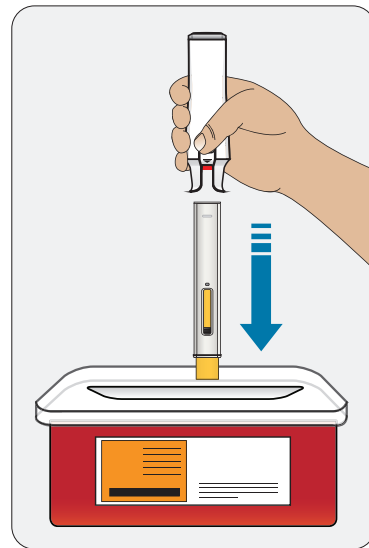> - If you leave the autoinjector inside the SmartPilot, it will drain the battery more quickly.

Figure S

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Step 8: Store the SmartPilot After Use

➡️ **Store the SmartPilot at room temperature in a clean dry place (Figure T).** Store the SmartPilot in a home environment or professional healthcare facility environment.

   For more information on storing the SmartPilot, refer to "Storage Information" section on page 54.

● **If needed,** clean the SmartPilot before storing with an alcohol-based surface disinfectant wipe following the instructions in the "Cleaning Information" section on page 55.

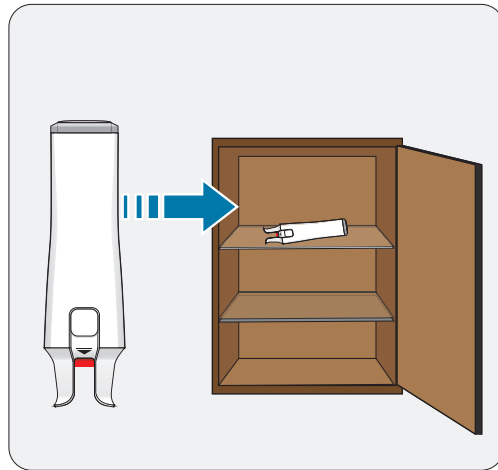The only maintenance required for the SmartPilot is to clean the SmartPilot if needed.

Figure T

Beeps

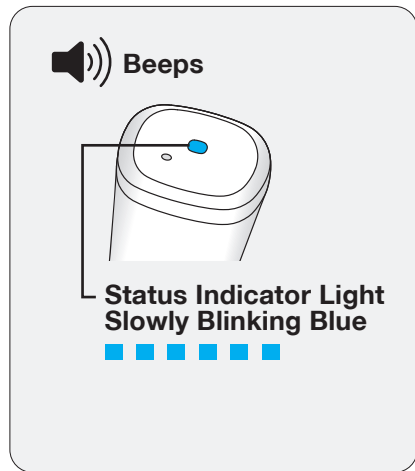**Status Indicator Light Slowly Blinking Blue**

Figure U

New SmartPilot was Woken Up and is Attempting to Pair (Figure U):

The SmartPilot has been woken up as part of setting the SmartPilot up for the first time and is attempting to pair to the Companion App. Follow the instructions in the section "Using the SmartPilot: Pair the SmartPilot with the Compantion App" starting on page 22.

Important: Before using the SmartPilot for the first time, always complete the setup procedure to wake up the SmartPilot and to pair it with the Companion App. If the SmartPilot is not fully set up before use, it will not work properly.

Bluetooth® Indicator Light Solid Blue

Figure V

Bluetooth® Pairing Successful – The SmartPilot is Connected to the Companion App (Figure V):

The SmartPilot is paired to and connected with the Companion App on your smartphone.

Bluetooth® Indicator Light Quickly Flashing Blue

Figure W

The SmartPilot is Attempting to Pair with a New Smartphone (Figure W):

If you are pairing the SmartPilot to the Companion App on a different smartphone, follow the instruction in the section "Using the SmartPilot: Pairing the SmartPilot with the Companion App" starting on page 22.
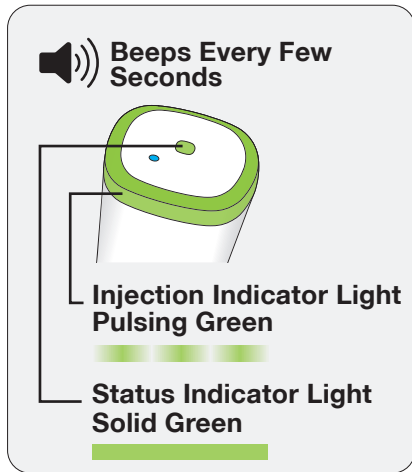
Beeps Every Few Seconds

Injection Indicator Light Pulsing Green

Status Indicator Light Solid Green

Figure X

Ready to Inject (Figure X):

The autoinjector is inserted into the SmartPilot and ready for the injection.

Refer to Step 5 on page 28 for more information.

Note: If you leave the autoinjector inserted in the SmartPilot without using it, the SmartPilot will go to standby mode after 2 minutes. To leave the standby mode, move the SmartPilot. The SmartPilot will go to sleep mode after being in standby mode for 4 hours. To leave the sleep mode, insert an autoinjector.
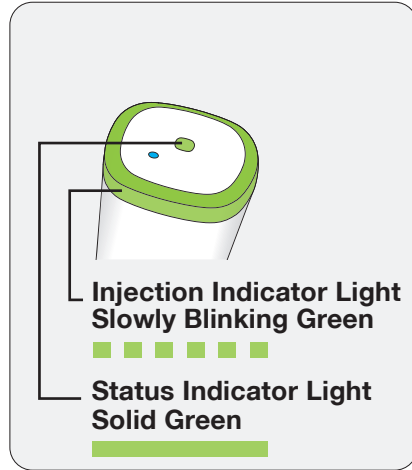
**Injection Indicator Light
Slowly Blinking Green**

**Status Indicator Light
Solid Green**

Figure Y

Injection In Progress (Figure Y):

After the injection is started by pushing the autoinjector against the skin, continue holding down the SmartPilot while the injection is in progress.

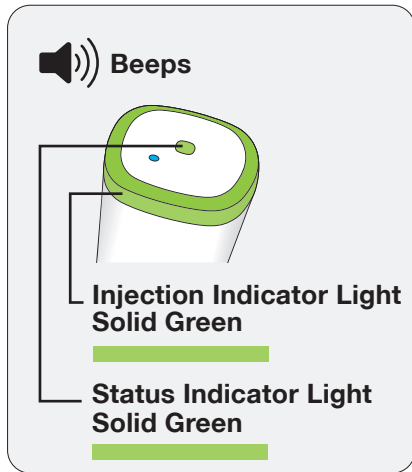Refer to Step 6 on page 29 for more information.

Beeps

Injection Indicator Light Solid Green

Status Indicator Light Solid Green

Figure Z

Injection Is Complete (Figure Z):

Your injection, including the holding time, is now complete and you can lift the autoinjector from the site.

Refer to Step 6 on page 29 for more information.

Note: The Injection Indicator Light will fade and turn off about 20 seconds after the injection.
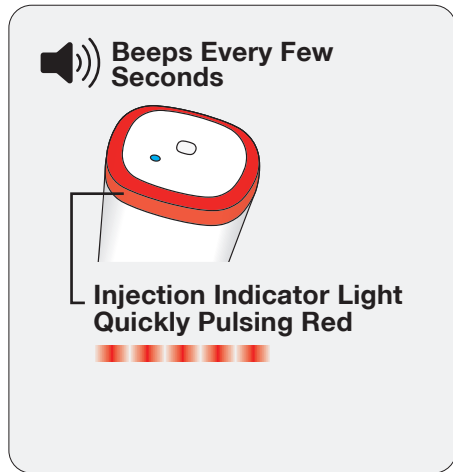
Beeps Every Few Seconds

Injection Indicator Light Quickly Pulsing Red

Figure AA

Incomplete Injection (Figure AA):

If the Injection Indicator Light quickly pulses red **after injecting**, the autoinjector was not held down long enough to give the full injection.

Do not start over or repeat the injection. Contact your healthcare provider for information about what to do next.
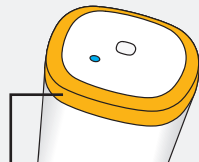
OR

Expired Autoinjector or Incorrect Medicine if Smart NFC-based Label provided and enabled (Figure AA):

If the Injection Indicator Light quickly pulses red **before injecting**, the autoinjector has expired or contains the wrong medicine.

Do not inject the medicine.

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Beeps (Repeats if Not Ejected)

Injection Indicator Light Pulsing Amber

Figure AB

Reminder to Eject and Dispose of the Used Autoinjector (Figure AB):

If the SmartPilot has just been used and still has the autoinjector inside, eject the autoinjector so the SmartPilot is empty for storage.

If you leave the autoinjector inside the SmartPilot, it will drain the battery more quickly.

OR

The SmartPilot is not Ready to Record an Injection (Figure AB):

If the autoinjector has not been used, eject the autoinjector, wait **10 minutes** and then reinsert.
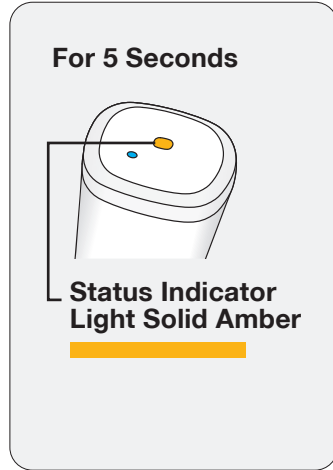
For 5 Seconds

**Status Indicator
Light Solid Amber**

Figure AC

Then

Ready to Inject

◀))) **Beeps
Every
Few
Seconds**

**Injection Indicator Light
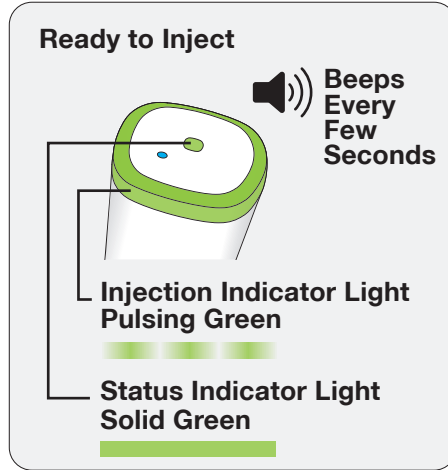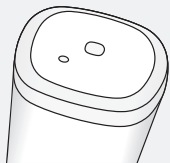Pulsing Green**

**Status Indicator Light
Solid Green**

Figure AD

Battery Low (Figure AC and Figure AD):

If the Status Indicator light is solid amber for 5 seconds before the SmartPilot shows it is ready to inject, the SmartPilot battery is low.

The SmartPilot can only be used for a few more injections and will need to be replaced soon.

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No Lights or Sound

Figure AE

Device Error or Empty Battery (Figure AE):

If the SmartPilot does not make a sound and the indicator lights do not light up after inserting an autoinjector, there has been a device error or an empty battery.

Eject (remove) the autoinjector and reinsert it.

If the SmartPilot continues to show no lights or sound, the device has an error, is damaged, or the battery is empty. Follow the instructions in the "Disposal Information" section on page 56.

Troubleshooting Information

The Autoinjector Does not Fit into My SmartPilot

- **Press the white Eject Button to eject (remove) the autoinjector and try again.** Refer to "Using the SmartPilot: Inserting the Autoinjector" section on page 14.
- **Check that the Dose Window on the autoinjector lines up with the Dose Window Slot on the SmartPilot and try again** (Figure AF). Refer to "Using the SmartPilot: Inserting the Autoinjector" section on page 14.
- **Check that the autoinjector is compatible with the SmartPilot.** Refer to "Indications for Use" section on page 5 for more information and a list of compatible autoinjectors.
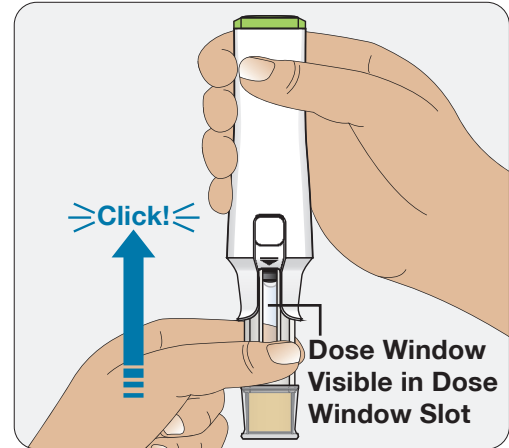

Click!

Dose Window Visible in Dose Window Slot

Figure AF

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My SmartPilot Will Not Pair to the Companion App On My Smartphone

If the SmartPilot will not pair to the Companion App, try the following:
- Eject the autoinjector and reinsert it to make sure the SmartPilot is on and ready to pair. The Status Indicator light should be slowly blinking blue (Figure AG).
- Make sure the Top Light Panel of the SmartPilot is touching or resting against the back of the smartphone.
- Make sure you slide the SmartPilot slowly all the way from top edge to bottom edge of the smartphone until the the device pairs with the Companion App (Figure AH).
- Allow approximately 30 seconds for the pairing to establish while sliding the SmartPilot up and down on the back fo the smartphone.
- On the Smartphone:
  – Make sure the Companion App is installed on the smartphone and the Wi-Fi/Internet Connection, Bluetooth® and NFC (Android only), are turned on (Figure AI).
  – Remove the protective cover from your smartphone, if you have one.
  – Restart the Companion App and your smartphone.

If the problem persists, the SmartPilot may need to be exchanged. Contact the help line: 1-800-930-0321

Injection Indicator Light Turns Green

Insert Autoinjector

⋛**Click!**⋚

Dose Window Visible in Dose Window Slot

Figure AG

Slide from Top Edge to Bottom Edge Against Back of Smartphone

Figure AH

☑ **Companion App Installed**
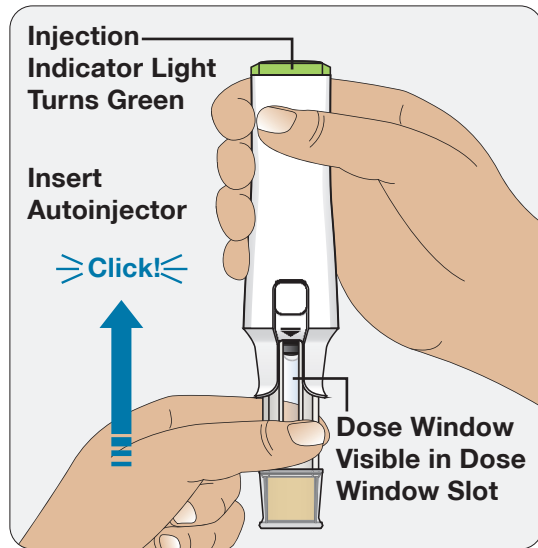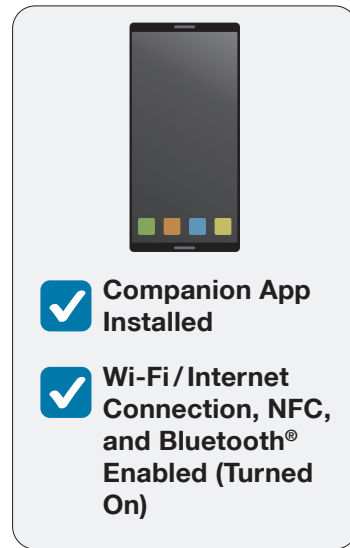
☑ **Wi-Fi / Internet Connection, NFC, and Bluetooth® Enabled (Turned On)**

Figure AI

My Autoinjector is Inserted into the SmartPilot and the Injection Indicator Light is Pulsing Amber (Figure AJ).

Beeps (Repeats if Not Removed)

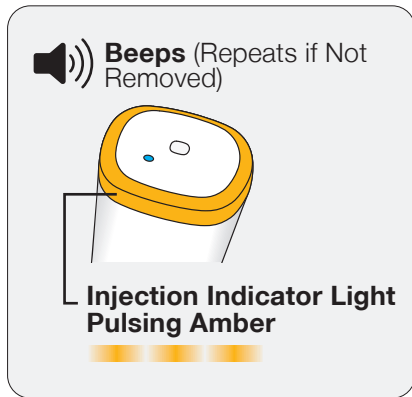**Injection Indicator Light Pulsing Amber**

Figure AJ

Reminder to Eject and Dispose of the Used Autoinjector (Figure AJ):

- If the SmartPilot has just been used and still has the autoinjector inside, eject the autoinjector so the SmartPilot is empty for storage.

  If you leave the autoinjector inside the SmartPilot, it will drain the battery more quickly.

OR

The SmartPilot is not Ready to Record an Injection (Figure AJ):

- If the autoinjector has not been used, eject the autoinjector, wait **10 minutes** and then reinsert.

My Injection is Completed and the Injection Indicator Light is Quickly Pulsing Red (Figure AK).

Beeps Every Few Seconds

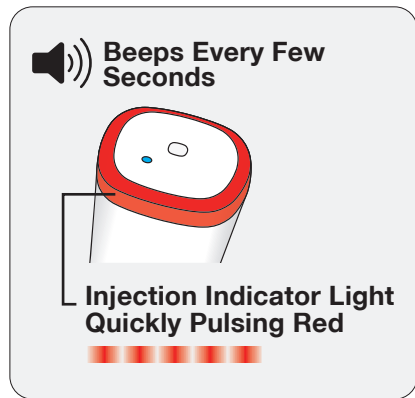**Injection Indicator Light Quickly Pulsing Red**

Figure AK

Incomplete Injection (Figure AK):

- If the Injection Indicator Light quickly pulses red **after injecting**, the autoinjector was not held down long enough to give the full injection.

Do not start over or repeat the injection. Contact your healthcare provider for information about what to do next.

OR

Expired Autoinjector or Incorrect Medicine if Smart NFC-based Label provided and enabled (Figure AK):

- If the Injection Indicator Light quickly pulses red **before injecting**, the autoinjector has expired or contains the wrong medicine.

Do not inject the medicine.

I Don't Think I Got My Full Injection

- **Do not** start over or repeat the injection. Contact your healthcare provider for further instruction.

My SmartPilot shows an unexpected behavior

- Press the Eject Button to eject the autoinjector. Wait 5 minutes before reinserting the autoinjector.
- Restart the Companion App.

My SmartPilot is damaged

- If the SmartPilot is damaged, throw away (dispose of) the SmartPilot according to your local regulations. Contact your healthcare provider for further instruction. Contact your supplier to get a new SmartPilot.

Frequently Asked Questions (FAQs)

Who should use your SmartPilot?
- The SmartPilot may only be used by or for a single patient. **Do not** share the SmartPilot with others. Keep the SmartPilot out of reach of children.

Can the SmartPilot be modified?
- **Do not** modify the SmartPilot or any of the system components without authorization of the manufacturer.

When should you avoid using the SmartPilot?
- **Do not** use the SmartPilot on patients with active implants (implanted medical devices requiring external power to operate, e.g. pacemaker, neurostimulator).
- **Do not** use the SmartPilot within 12 inches (30 cm) of medical electric equipment.
- **Do not** use the SmartPilot near surgical or magnetic resonance imaging (MRI) equipment, or in areas at which electromagnetic disturbance is high.

What do the lights on the SmartPilot mean?

- For information about the meaning of the indicator lights on SmartPilot, **refer to the "Indicator Lights Status and Meaning (Pages 35–44)"**.

How should the SmartPilot be stored and cleaned?

- For information about how to store or clean the SmartPilot, **refer to the "Storage Information" section on page 54 and the "Cleaning Information" section on page 55.**

Which checks should be done before using the SmartPilot?

- Check the SmartPilot for damage.
- Check on the autoinjector if it has the correct medicine name, the expiry date and the appearance of the medicine.
- If something is not as expected, refer to pages 15 and 16.

How should the SmartPilot be disposed of (thrown away)?

- The SmartPilot should be disposed of (thrown away) following the instructions in the "Disposal Information" section on page 56.

Pairing the SmartPilot After the First Use

- **If your SmartPilot has been unpaired from your Companion App or if you are pairing the SmartPilot to the Companion App on a different smartphone,** follow the instructions in the "Using the SmartPilot: Pair the SmartPilot with the Compantion App" section starting on page 22.

Storage Information

- **Store the SmartPilot at room temperature in a clean dry place (Figure AL). Store the SmartPilot in a home environment or professional healthcare facility environment.**

Do not store the SmartPilot with the autoinjector inserted. If you leave the autoinjector inside the SmartPilot, it will drain the battery more quickly.
Do not store the SmartPilot in the refrigerator or freezer.
Do not expose the SmartPilot to extreme temperatures below 41 °F (5 °C) or above 95 °F (35 °C).
Do not leave the SmartPilot in direct sunlight.
Do not get your SmartPilot wet.

Keep the SmartPilot out of reach of children.

Figure AL

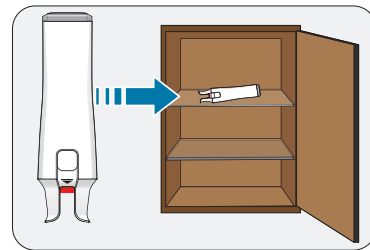See the Product Specifications within "Technical Information" section on page 62 for more information.

Cleaning Information

- **If needed,** use only alcohol-based surface disinfectant wipes to thoroughly clean the exterior of your SmartPilot to remove soil or contaminants. The SmartPilot can withstand up to 30 seconds of cleaning after each use.
- After the cleaning, visually inspect the SmartPilot for residual soil. If there is any residual soil visible, repeat the cleaning process.

Do not get your SmartPilot wet.
Do not wash, soak, or submerge your SmartPilot.

Only clean the SmartPilot if it is not in use.

Disposal Information

- **The SmartPilot cannot be recharged** and is designed to last about 2 years or 120 injections (whichever comes first).

ℹ️

Important: Please do not throw away (dispose of) the SmartPilot if your SmartPilot has an empty battery, is damaged or you do not need your SmartPilot anymore. SmartPilot should be returned to the manufacturer. Contact your supplier to get a new SmartPilot. In case of questions ask your healthcare provider or contact our customer service at any time. Phone number: 1-800-930-0321

SmartPilot Software Update Information

The SmartPilot receives software updates periodically when connected to the Companion App.
The software updates will be installed automatically.

Symbols

Symbol	Standard Reference	Symbol Title	Description
(MR)	ASTM F2503	MR Unsafe	Is an item that is known to pose hazards in all MRI environments.
▲	21 CFR 801.1	Manufacturer	Indicates the medical device manufacturer.
⌖ yyyy-mm-dd	ISO 15223-1, Symbol 5.1.11	Date of manufacture	Indicates the date when the medical device was manufactured.
		Country of manufacture	To identify the country of product manufacturing.
℞ *Only*	21 CFR 801.109	Prescription use only	Caution: Federal (USA) Law restricts this device to sale by or on order of a licensed practitioner.
⚠	ISO 15223-1, Symbol 5.4.4 IEC 60601-1 Table D.1, Symbol 10	Caution	Indicates the need for the user to consult the user manual for important cautionary information such as warnings and cautions that cannot, for a variety of reasons, be presented on the medical device itself.
⟳	ISO 15223-1, Symbol 5.4.12	Single patient multiple use	Indicates a medical device that may be used multiple times (multiple procedures) on a single patient.

Symbol	Standard Reference	Symbol Title	Description
✷	Trademarks of Bluetooth® Special Interest Group (SIG)	Bluetooth® wireless or enabled technology	The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Ypsomed AG is under license. Other trademarks and trade names are those of their respective owners.
SN	ISO 15223-1, Symbol 5.1.7	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
✷	IEC 60601-1, Table D.2, Symbol 10	Refer to instruction manual/booklet	Indicates the need for the user to consult the user manual.
☂	ISO 15223-1, Symbol 5.3.4	Keep dry	Indicates a medical device that needs to be protected from moisture.
IP20	IEC 60601-1, Table D.3, Symbol 2	Degree of Ingress Protection Provided by Enclosure	Protected against solid foreign objects of 12,5 mm and greater. Not-protected against water.

Symbol	Standard Reference	Symbol Title	Description
⍟	IEC 60601-1, Table D.1, Symbol 20	Type BF applied part	n.a.
◀‖	n.a.	Eject button indicator	Indicates the eject button on the SmartPilot to eject the autoinjector.
REF	ISO 15223-1, Symbol 5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
LOT	ISO 15223-1, Symbol 5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
GTIN	GS1 standard	Global Trade Item Number	Custom symbol denoting global trade item number.

Symbol	Standard Reference	Symbol Title	Description
	ISO 15223-1, Symbol 5.3.2	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	ISO 15223-1, Symbol 5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1, Symbol 5.3.8	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 15223-1, Symbol 5.2.8	Do not use if package is damaged and consult Instructions for Use	Indicates a medical device that should not be used if the package has been damaged or opened when the user should consult the Instructions for Use for additional information.
	n.a.	Do not open box with sharp tools	Do not open box with sharp tools.

Technical Information

Product Specifications

Characteristic	Description
SmartPilot Dimensions	5.3 × 1.6 × 1.6 inches or 134.5 × 39.5 × 40.4 mm
Weight	Approx. 60 g or 0.13 lb
Operating and storage temperature range	41 °F to 95 °F or + 5 °C to + 35 °C
Operating and storage humidity range	15–90 % relative humidity non-condensing
Operating and storage atmospheric pressure range	700–1060 hPa
Ingress protection classification	IP 20 as defined by IEC 60529
Communication interfaces	Bluetooth® Low Energy 5.1 and NFC
Batteries	1 × CR 2032 Li-manganese dioxide; 1 × lithium-ion polymer
Use environment	Home use healthcare environment, professional healthcare facility environment

Product Specifications

Characteristic	Description
Activation time	Less than 1 s on insertion of an autoninjector
Deactivation time	Less than 1 s on removal of the inserted autoinjector. Note: before the SmartPilot enters the sleep mode it may need to exchange data with the Companion App, which can take longer to complete
Service life	2 years or 120 injections, whichever occurs first

Battery

The SmartPilot contains built-in battery that cannot be replaced nor recharged.

Bluetooth® Low Energy Interface

Characteristic	Description
Function	Enables bidirectional data exchange between the SmartPilot and the Companion App on the smartphone
Protocol	Bluetooth® Low Energy 5.1
Frequency band	2.4 GHz ISM-Band
Modulation	GFSK (Gaussian Frequency Shift Keying)
Effective Radiated Power (ERP)	≤ −8 dBm
Quality of Service (QoS)	No user QoS settings

Bluetooth® Low Energy Interface

Characteristic	Description
Configuration and Operation	Already configured at the factory
	No other specific operation is necessary for use
Pairing method	Initiated by reading the NFC tag of the SmartPilot with the Companion App on the smartphone
Data Security	Encrypted communication with integrity checks
	Application layer: all messages signed and sensitive data encrypted
	Transport layer: TLS 1.3 secured
	Only authorized and authenticated SmartPilot and Companion App can establish a connection

Bluetooth® Low Energy Interface

Characteristic	Description
Performance	Range: typically 20 m (unobstructed)
	Pairing time: typically ≤ 10 seconds
	(Re-) connection time on next use (i.e. after pairing): ≤ 3 seconds
	Data transmission rate: 1 Mbps or 2 Mbps depending on the smartphone capabilities
Recommended Settings	Ensure that Bluetooth®, Wi-Fi/Mobile Data connection, and NFC are enabled on the smartphone
Limitations, Precautions, and Warnings	Performance may degrade by physical obstructions, nearby RF emitters or metal
	For the pairing, the Companion App/smartphone must have an Internet connection (Wi-Fi or mobile network)
	If BLE disconnects during an injection, the device will continue normal operation and will store data locally
Summary of Verification and Validation	Functional, security, and integrity tests
	EMC compliance tests per IEC/EN 60601-1-2, FCC 47 CFR part 15.225 and ISED RSS-210

NFC Reader Interface

Characteristic	Description
Function	Reads the Smart NFC-based Label from the inserted autoinjector
Protocol	ISO/IEC 15693, read-only
Frequency band	13.56 MHz ISM-Band
Modulation	Downlink: ASK (Amplitude Shift Keying)
	Uplink: Load modulation using ASK
Effective Radiated Power (ERP) ≤ 1W	
Quality of Service (QoS)	The SmartPilot does not have any QoS user settings. To prevent mutual interference in the adjacent frequency band, the SmartPilot is designed so that the NFC reader and the inductive sensor are never operated simultaneously.
Configuration and Operation	Already configured at the factory
	No specific operation required for use
Data security	Integrity and signature checks of the Smart NFC-based Label payload

NFC Reader Interface

Characteristic	Description
Performance	Reading position: the SmartPilot reads the data in both coupling positions of the autoinjector (refer to "Insert the Autoinjector into the SmartPilot" section starting on page 18 for more details)
	Reading range: n.a. (the SmartPilot reads the Smart NFC-based Label from the inserted autoinjector)
	Response time: ≤ 500 ms
	Data transmission rate: ≤ 53 kbps (depending on the NFC tag capabilities)
Limitations, Precautions, and Warnings	Available only for the SmartPilot with enabled Smart NFC-based Label function
	Supports only compatible autoinjectors equipped with Smart NFC-based Label
	NFC performance may degrade near RF emitters or metal
Summary of Verification and Validation	Functional, security, and integrity tests
	EMC compliance tests per IEC/EN 60601-1-2, FCC 47 CFR part 15.225 and ISED RSS-210
	Immunity tests per AIM 7351731

NFC Tag Interface

Characteristic	Description
Function	The NFC TAG interface provides data required for pairing with the SmartPilot. Reading the SmartPilot's NFC tag initiates pairing with the SmartPilot.
Protocol	ISO/IEC 14443 Type A, read-only
Frequency band	13.56 MHz ISM-Band
Modulation	Downlink: ASK (Amplitude Shift Keying)
	Uplink: Load modulation with ASK
Effective Radiated Power (ERP)	n.a. (the NFC Tag is passive and the output power of the NFC field is determined by the smartphone used)
Quality of Service (QoS)	The SmartPilot does not have any QoS user settings. To prevent mutual interference in the same frequency band, the SmartPilot is designed so that the NFC tag interface and the NFC reader are never operated simultaneously.
Configuration and Operation	Already configured at the factory
	Only used for pairing, no other specific operation required for use

NFC Tag Interface

Characteristic	Description
Performance	Reading range: typically less than 1 cm depending on the smartphone
	Response time: ≤ 500 ms
	Data transmission rate: 106 kbps
Recommended Settings	Ensure that Bluetooth®, Wi-Fi/Mobile Data connection, and NFC are enabled on the smartphone
	Ensure the smartphone backside is touching the SmartPilot during the pairing
Limitations, Precautions, and Warnings	NFC performance may degrade near RF emitters or metal
Summary of Verification and Validation	Functional, security, and integrity tests
	EMC compliance tests per IEC/EN 60601-1-2, FCC 47 CFR part 15.225 and ISED RSS-210
	Immunity tests per AIM 7351731

Inductive Sensor Interface to Autoinjector

Characteristic	Description
Function	The interface enables the detection of injection events at the inserted autoinjector
Protocol	Purely analog - detection is based on changes of the resonance frequency
Frequency band	800 kHz to 1.1 MHz
Modulation	Unmodulated
Effective Radiated Power (ERP)	≤ 44 µW
Quality of Service (QoS)	The SmartPilot does not have any QoS user settings. To prevent mutual interference in the adjacent frequency band, the SmartPilot is designed so that the inductive sensor and the NFC reader are never operated simultaneously.
Configuration and Operation	Already configured at the factory
	No specific operation required for use

Inductive Sensor Interface to Autoinjector

Characteristic	Description
Performance	Detection independent on the coupling positions of the autoinjector (refer to "Insert the Autoinjector into the SmartPilot" section starting on page 18 for more details)
	Reading range: n.a. (the SmartPilot detects the injection events only from the inserted autoinjector)
	Response time: ≤ 500 ms
Recommended Settings	Use only compatible autoinjectors
	Ensure the autoinjector is fully inserted
Limitations, Precautions, and Warnings	Performance may be affected by RF emitters or metal
Summary of Verification and Validation	Functional, security and integrity tests
	EMC compliance tests per IEC/EN 60601-1-2, FCC 47 CFR part 15.225 and ISED RSS-210

FCC identification of this device is 2AFJO-B01.

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.

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.
- Consult the dealer or an experienced radio technician for help.

The SmartPilot can withstand exposure to common electrostatic (ESD) and electromagnetic interference (EMI) in the specified environmental conditions.

EMC Separation Distances
WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. WARNING: Portable and mobile RF communications equipment should be used no closer to any part of the SmartPilot, including cables, than the recommended separation distance of approximately 12 inches (30 cm). The use of a smartphone for the Bluetooth® Low Energy (BLE) connection or an NFC Reader used for BLE pairing with the SmartPilot is acceptable.

Wireless Communication and Coexistence
The SmartPilot is designed to work safely and effectively in the presence of nearby wireless devices typically found at home, work, retail stores, offices of healthcare facilities, and places of leisure where daily activities occur, and will not affect their performance. As with all wireless communication technology, certain operating conditions can interrupt communication. For example, electric appliances such as microwave ovens, electric machinery and other network devices (Wi-Fi, mobile phones, walkie-talkies and their base stations) may cause interference. Moving away from, or turning off these other devices, may enable communication.

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Electromagnetic Compatibility (EMC)

Emission Test	Compliance	Electromagnetic Environment – Guidance
CISPR 11: / EN 55011	Group 1	The SmartPilot uses RF energy only for its internal function and communication. Therefore, its RF emissions are very low and are not likely to cause any interference in the nearby electronic equipment.
CISPR 11:2009 / EN 55011	Class B	The SmartPilot is suitable for use in residential establishments, including domestic establishments, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes and professional healthcare environment.
CISPR 16-2-3 / RF Emission FCC 47 CFR Part 15	Class B	
NFC Radiated Emission ETSI EN 300 330	n.a.	
IEC 60601-1 Maximum emission of 10 W/m^2	n.a.	

Electromagnetic Compatibility (EMC)

Immunity Test	Test Level	Electromagnetic Environment – Guidance
Conducted Immunity IEC/EN 61000-4-2	Contact: ±8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	For use in a typical home or professional healthcare environment.
Radiated Immunity IEC/EN 61000-4-3	10 V/m Frequency Range: 80 MHz to 2.7 GHz	
Power Frequency Magnetic Field Immunity IEC/EN 61000-4-8	30 A/m Frequency: 50 Hz and 60 Hz according to 6060112	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or professional healthcare environment.
Radiated fields in close proximity – Immunity test IEC/EN 61000-4-39	60601-1-2 table 11	

Electromagnetic Compatibility (EMC)

Immunity Test	Test Level	Electromagnetic Environment – Guidance
Proximity fields from RF wireless communications equipment EN 60601-1-2, table 9	385 MHz @27 V/m, 18 Hz pulse modulation; 450 MHz @ 28 V/m, 1 kHz sine FM modulation; 710, 745, 780 MHz @ 9 V/m, 217 Hz pulse modulation; 810, 870, 930 MHz @ 28 V/m, 18 Hz pulse modulation; 1720, 1845, 1970 MHz @ 28 V/m, 217 Hz pulse modulation; 2450 MHz @ 28 V/m, 217 Hz pulse modulation; 5240, 5500, 5785 MHz @ 9 V/m, 217 Hz pulse modulation	385 MHz @27 V/m, 18 Hz pulse modulation; 450 MHz @ 28 V/m, 1 kHz sine FM modulation; 710, 745, 780 MHz @ 9 V/m, 217 Hz pulse modulation; 810, 870, 930 MHz @ 28 V/m, 18 Hz pulse modulation; 1720, 1845, 1970 MHz @ 28 V/m, 217 Hz pulse modulation; 2450 MHz @ 28 V/m, 217 Hz pulse modulation; 5240, 5500, 5785 MHz @ 9 V/m, 217 Hz pulse modulation

Compliant standards

Compliant Standards	Description	Classification
IEC 60601-1	Protection type against electric shock	Internally powered ME equipment
	Degree of protection against electric shock	Type BF
IEC 60601-1-2	Electromagnetic compatibility	Refer to EMC section in this user manual
IEC 60529	Type of protection against the access to hazardous parts and the infilitration of water as detailed in the current edition of the standard	IP20

Cybersecurity Precautions

The SmartPilot is designed with security features to help keep the system and the data cyber-secure. The SmartPilot is designed to only accept Bluetooth® communication from authorized and authenticated devices. The SmartPilot ensures data security via encryption and ensures data integrity using error checking processes, such as signature checks. For cybersecurity reasons, it is important to follow instructions with regard to pairing, Wi-Fi/Bluetooth®/NFC connectivity as provided in this user manual. Refer to additional guidance provided in the Companion App's user manual.

System overview, components and connectivity
The SmartPilot (A) is an add-on for an YpsoMate autoinjector (B) intended for use with a personal smartphone (C) running a Companion App connected to cloud services (D) via the smartphone's internet connectivity.

Connections and required open communication ports

Connection between components	Technology	Protocol and port	Purpose
YpsoMate and SmartPilot	NFC	ISO 15693, Type 5, read-only tag to send data	Reading the SmartLabel
SmartPilot and smartphone	NFC	ISO 14443-4, Type A, read-only tag to send data	Pairing
SmartPilot and smartphone	Bluetooth®	Bluetooth® low energy 5.1 or higher, to receive and send data	Communication and firmware updates
Smartphone and cloud services	Internet	HTTPS connections (port 443), to receive and send data	Communication and firmware updates

Cybersecurity Precautions

Connectivity characteristics
- Pairing requires physical contact between SmartPilot and smartphone and confirmation in the authorized Companion App.
- It is recommended to pair the smartphone with SmartPilot in a private and secure location (e.g. at home).
- In addition to BLE encryption, TLS 1.3 for transport and an application security layer (ASL) is used for all data communication. All encryption algorithms comply with the latest NIST requirements (e.g. AES 256 for Bluetooth and ChaCha20 for ASL).
- The SmartPilot applies digital signatures to ensure authenticity when setting up connections.
- Connection timeout occurs after 2 minutes of inactivity.
- No unnecessary open ports or services are activated.

SmartPilot security features
- Bootloader ensures integrity and prevents unauthorized software execution.
- No patient identifying information is stored on SmartPilot.
- Device log entries are encrypted at rest.

Cybersecurity Precautions

Security of the smartphone environment
- A strong password or biometric authentication on the lock screen of the smartphone is recommended to avoid other people accessing the smartphone.
- End-to-end encryption for all data communication between Companion App and cloud services is always applied.
- Injection records are stored locally on a smartphone in an encrypted format.
- Use good cybersecurity practices; keep your smartphone operating system up to date so it can take care of anti-virus/anti-malware measures.
- Do not use a jailbroken or rooted smartphone.
- Always apply Companion App updates as prompted by Apple store or Google Play.

Cybersecurity Precautions

Software update features
- Firmware updates are delivered securely through the authorized Companion App and are digitally signed and verified before installation using strong cryptographic keys and SHA-256 hashes.
- Configuration control prevents downgrade attacks to vulnerable firmware versions.

Software update procedure and notifications
- Always allow software updates for SmartPilot, if you are notified of an update by your Companion App.
- SmartPilot's software updates will be downloaded and applied automatically after you complete your next injection. During software update, keep your SmartPilot within BLE range.
- See also page 57 for usage guidance on software updates.

Cybersecurity Precautions

Secure storage and disposal of SmartPilot
- Store the SmartPilot when not in use as described on page 54.
- Maintain physical control of the SmartPilot during use and report all lost or stolen devices.
- To ensure secure decommissioning of the SmartPilot, follow instructions on p. 56.

Cybersecurity incident response and reporting
- If there is a concern that someone else is trying to connect to or interfere with the SmartPilot, stop using it and contact 24-hour technical support immediately (see page 46, response time within 7 days).
- Contact manufacturer cybersecurity support at pcs-yds@ypsomed.com or report security issues through our website: https://yds.ypsomed.com/en/reporting-security-issues-vulnerability-disclosure-policy.html

Cybersecurity Precautions

Logging
- The SmartPilot and Companion App produce log files of security events (e.g. login attempts, anomalous network traffic, and configuration changes). Ypsomed and the provider of Companion App periodically analyze such logs for incident response and protection against cybersecurity threats.
- Security logs are retained for a period of 1 year to facilitate incident investigations and ensure compliance with regulatory requirements.

Cybersecurity Precautions

Software bill of materials (SBOM)
- SmartPilot, Companion App, and cloud services are using 3rd-party software libraries and components, and they are listed in SBOMs in the industry-standard CycloneDX format for medical device software.
- The SBOMs are available from Ypsomed through our contact at pcs-yds@ypsomed.com and for the Companion App from the respective manufacturer of the App.

Backup, data, and configuration security
- SmartPilot stores injection records in non-volatile memory. Whenever connected to the Companion App and network, these records are automatically backed up to the smartphone and further to the cloud.
- System configurations are restored in case of malfunction automatically. If security issues occur restoring of safe configurations can be performed and guided through the Companion App's user interface.
- Retention of injection records and system configurations is guaranteed for all SmartPilots during their lifetime.

Disclaimer and Warranty

The warranty covers manufacturing and material defects of your SmartPilot for two years of use, from purchase. It is limited to replacement of the SmartPilot. The warranty does not cover damages caused by:
- improper or careless use, handling or cleaning the use contrary to the Instructions for Use.
- the use of the SmartPilot with other autoinjectors, accessories or consumables other than those mentioned in this Instructions for Use
- dropping, impact, application of force, contact with fluids.
- other cases of exposure and wear, not in accordance with the Instructions for Use.

Data Privacy

The terms of data protection regulations may apply to the interactions between the SmartPilot and its users. By registering for the Companion App, and by pairing/connecting your SmartPilot or by sending back your SmartPilot, you consent to the processing of your data in the Companion App, by the pharmaceutical company and by Ypsomed. The information on how your data is processed can be found in the Companion App's Privacy Policy.

If you use your SmartPilot without being connected to the Companion App, all recorded data is only stored locally on the SmartPilot. These data is only transmitted to the Companion App if there is a connection.

Ypsomed agrees to comply with its obligations in accordance with the applicable data protection regulations and makes every effort to guarantee the security, confidentiality, and integrity of the personal data that it may process. Ypsomed processes your personal data exclusively as agreed in the Companion App's Privacy Policy and/or as agreed and/or as instructed with/by the pharmaceutical company. This includes, but is not limited to, handling device complaints and analyses to improve device functions. Ypsomed will never sell your data to third parties.

You may exercise your rights under applicable data protection laws at any time. You can find the contact details in the Companion App's Privacy Policy.