



Mallya[®]

USER MANUAL

Intended use

Indication for use

The Mallya[®] Injection Pen Adapter is indicated for the capture and wireless transmission of dosing information of compatible reusable and disposable pen injectors.

Device features

- Mallya[®] is able to :
- be assembled with Novo Nordisk[®] pen injector designed for growth disorder treatment,
 - record the amount of dose increments injected by the pen,
 - record the timestamp (date & time) of each injection,
 - transmit information relating to dose, time, and date of each injection to a mobile app on a smartphone, when the device is connected to it, using Bluetooth[®] technology.

Clinical environment

The Mallya[®] device is intended to be used by patients in the same use environment as their compatible pen injector. There are no known contraindications to the use of Mallya[®] for these patients.

NOTE: A list of all compatible injection pens is available in the legal manufacturer device technical documentation and on the website at: <https://my-mallya.com/us/growth-disorder>.

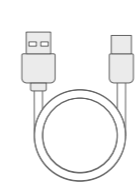
Package contents

Mallya[®]
x1



PN : 0274345

USB cable
x1



PN : 0373707

User instructions
x1

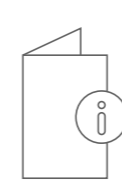


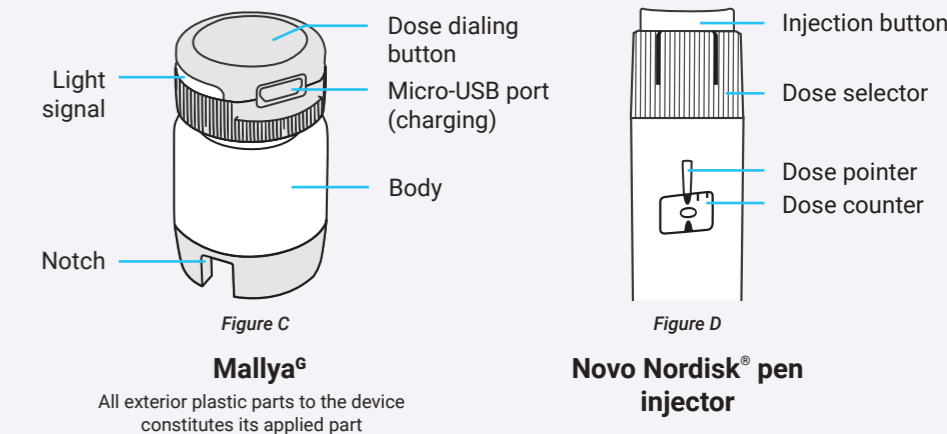
Figure A

NOTE: the USB charger is not included. Use a Class II USB wall charger, with output 5V and at least 500mA (Figure B).



Figure B

Getting to know Mallya[®] and the pen

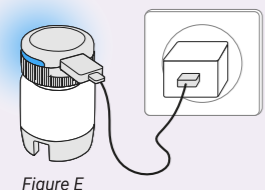


How to setup your Mallya[®]

1 Wake up and charge Mallya[®]

Mallya[®] is turned off when it is shipped. You will need to wake it up and make sure it is charged enough before use.

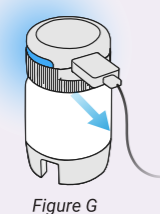
- 1.1. Connect Mallya[®] to the supplied USB cable and connect the cable to a powered USB wall charger (Figure E). This will wake up the device.



- 1.2. Let the device charge for at least 10 minutes before use (Figure F).



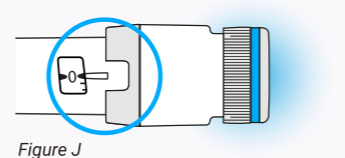
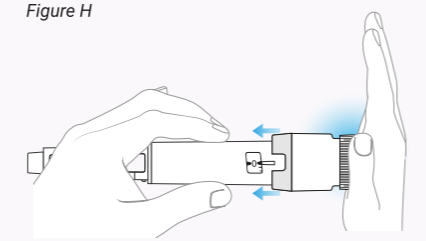
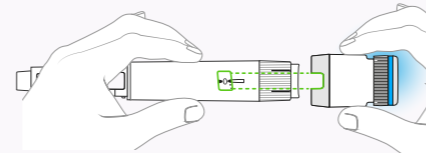
- 1.3. Unplug Mallya[®] from the USB cable (Figure G) and then unplug the wall charger. When you are done, Mallya[®] signal light will turn blue indicating that the device is in pairing mode but not yet paired.



2 Attach Mallya[®] to your pen

Mallya[®] attaches over the dose selector and injection button of your pen. To attach, carefully follow these steps.

- 2.1. Hold the pen with one hand, keeping the dose button accessible, and protect the needle with the pen cap (if already mounted).
- 2.2. With your other hand, hold Mallya[®] by the body so your fingers only touch the sides of the device, being careful not to depress the button.
- 2.3. Insert Mallya[®] on the pen dose button, aligning the notch of Mallya[®] with the pen dose counter (Figure H).
- 2.4. Push Mallya[®] fully over the pen, pressing the button with the palm of your hand. It must be inserted all the way onto the dose selector (Figure I).
- 2.5. Check that Mallya[®] is pushed all the way down on the pen as shown on the picture (Figure J).



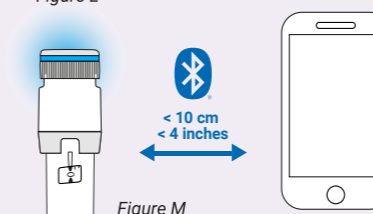
3 Download a connectable app and pair with Mallya[®]

Before you can use your Mallya[®], you will need to pair it with a mobile application on your smartphone.

- 3.1. Please refer to Mallya[®] internet website <https://my-mallya.com/us/growth-disorder>, or by scanning this QR Code (Figure K).
- 3.2. Download the application from Google Play™ (Android) or the App Store® (Apple) (Figure L).
- 3.3. Pair Mallya[®] by following the guidance in the App to :
- Turn on your smartphone's Bluetooth® (if not already on).
- Pair the Mallya[®] with the App.



NOTE: you must keep Mallya[®] within 10 centimeters of the smartphone during pairing (Figure M).



At the end of the pairing step, you may notice the signal light turn green and then turn off (Figure N). Once paired your Mallya[®] will enter standby mode and the light will turn off.

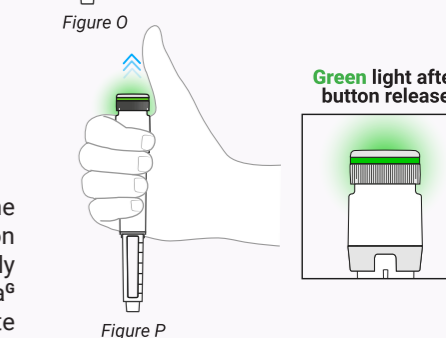
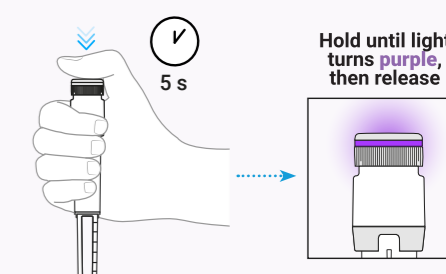


- 3.4. After pairing, follow the guidance in the application.

4 Put Mallya[®] into active mode

To activate Mallya[®] on the pen:

- 4.1. Firmly press and hold the Mallya[®]'s button down for at least 5 seconds until the light turns purple (Figure O).
- 4.2. Then, lift your finger from the button. The light will then turn green showing the device is now in active mode (Figure P).



Mallya[®] is now ready for use.

NOTE: Green light will remain on throughout the injection. If green light does not come on, the injection will not be recorded. Make sure Mallya[®] is sufficiently inserted on your pen. Repeat step 2.4 to push Mallya[®] onto your pen to fully insert it. Then proceed to activate it, following the instructions in step 4.1.

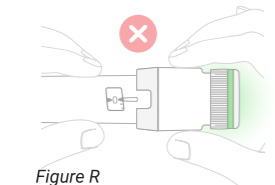
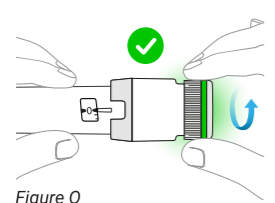
IMPORTANT: Follow the "Injecting a dose with Mallya[®] attached to your pen" section below when you give an injection.

Injecting a dose with Mallya[®] attached to your pen

Refer to the Instructions for Use of your pen for the flow check and the injection instructions.

NOTE: Safety tests performed to check the flow (priming), will also be automatically detected, and recorded by Mallya[®]. Perform the safety test to check the flow as described in the Instructions for Use of your pen injector. Check your mobile application for correct identification of the flow check performed.

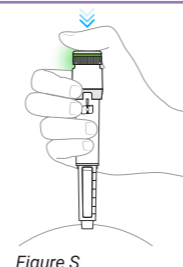
1. Before you start selecting the dose, make sure the pen dose counter shows the number 0. The number 0 should line up in front of the pen dose pointer.
2. Use the Mallya[®] device black dose dialing button to select the dose (Figure Q).
3. Turn Mallya[®]'s button to select the dose you need. The selected dose should line up in front of the pen dose pointer. During a dose selection, Mallya[®]'s light is green (Figure Q).



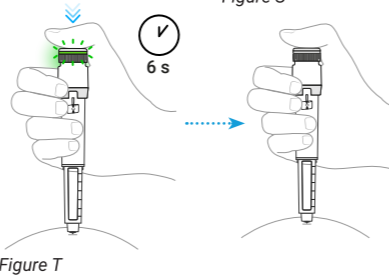
NOTE: Do not use the transparent body of Mallya[®] to select your dose (Figure R).

IMPORTANT: If the light does not turn green, Mallya[®] is not ready and will not record the injection. It needs to be put on active mode before performing an injection. Follow the step 4 in the "How to setup your Mallya[®]" section above to put the device into active mode.

4. Perform the injection as described in the Instructions for Use of your pen injector. Press and hold down Mallya[®] dose dialing button. Watch as the dose counter returns to 0. The 0 must line up with the pen dose pointer. During a dose injection, Mallya[®]'s light is green (Figure S).



NOTE: Do not pause during the injection, you may experience harm due to miscalculation of doses.



5. At the end of injection, keep the pressure on the button and the needle in your skin until the green rapid flashing turns off (6 seconds) (Figure T).

IMPORTANT: Green light will remain on throughout the injection if green light does not come on and is not flashing at the end of injection, the injection will not be recorded.

Troubleshooting

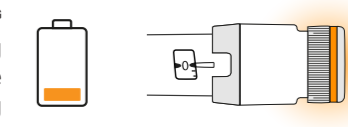
Unsure if the dose is delivered

If you are not certain that you injected your treatment, do not repeat your injection. Monitor your treatment as instructed by your healthcare provider.

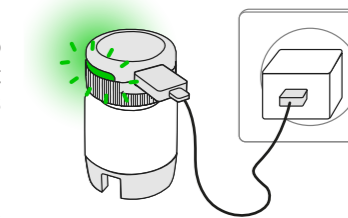
- Orange Rapid Flashing (Figure U)**
The pen dose counter must be set at 0. When the pen dose pointer is aligned with the number 0, press the dose button for 2 seconds until Mallya[®]'s light turns green.
- Orange Solid (Figure V)**
Mallya[®]'s battery is low. Charge your Mallya[®] following the instructions in the "Charging Mallya[®]" section. Charge the battery for at least 2 hours for a full charge. Do not give an injection with Mallya[®] while it is charging. Mallya[®] light is orange during injections if the battery is low.
- Red Solid (Figure W)**
Error: the solid red light will come on when Mallya[®] is in an error state and needs to be reset. In this state, Mallya[®] is not ready to record injections. Follow the instructions in the "Resetting Mallya[®]" section on the back side if these instructions to reset Mallya[®]. If the problem persists, contact the Support service. The red signal is not an alarm at meaning of IEC 60601-1-8.

Charging Mallya[®]

After a full charge, if you use Mallya[®] every day, it will only need recharging once every 2 weeks. If you use it once a week, it will only need recharging once a month. When the battery is low, the orange light will show (Figure X).



Charge Mallya[®] by connecting it to a powered USB wall charger (not supplied) using the supplied USB cable (Figure Y).



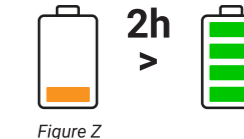
Do not use any other cable.

Please connect the supplied USB cable to the USB port of a power adapter (IEC / UL 60950-1 or IEC / UL 62368-1 certified with CE or UL marking) suitable for your region. (Figure Y).

The signal light will slowly flash green when Mallya[®] is charging.

Do not give an injection with Mallya[®] when it is charging.

NOTE: Let the device charge for at least 2 hours for a full charge (Figure Z).



The green flashing light will disappear when fully charged.

- TURN OVER:**
- Transfer
 - Reset
 - Indicator Lights
 - Cleaning



