Intended use

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

Device features

Mallya^G 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^G 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 Mallya⁶ for these

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.

MallyaG

Package contents







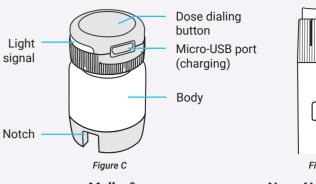


User

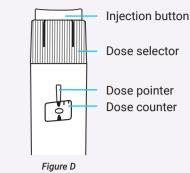
NOTE: the USB charger is not included. Use a Class II USB wall charger. with output 5V and at least 500mA (Figure B).



Getting to know Mallya^G and the pen







Hold until ligh

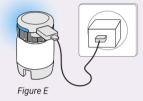
Novo Nordisk® pen injector

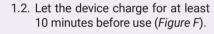
How to setup your Mallya^G

1 Wake up and charge Mallya^G

Mallya^G 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^G to the supplied USB cable and connect the cable to a powered USB wall charger (Figure E). This will wake up the device.





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

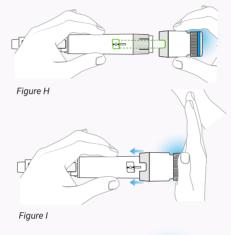


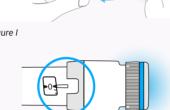


2 Attach Mallya^G to your pen

Mallya⁶ 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^G by the body so your fingers only touch the sides of the device, being careful to not depress
- 2.3. Insert Mallya^G on the pen dose button. aligning the notch of Mallya^G with the pen dose counter (Figure H).
- 2.4. Push Mallya^G 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^G is pushed all the way down on the pen as shown on the picture (Figure J).





3 Download a connectable app and pair with Mallyage

PN: 0274345

Before you can use your Mallya^G, you will need to pair it with a mobile application on your smartphone.

- 3.1. Please refer to Mallya⁶ internet website https://my-mallya.com/us/growthdisorder, 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 Mallya⁶ by following the guidance in the App to: - Turn on your smartphone's Bluetooth® (if not already on).
- Pair the Mallya⁶ with the App.

NOTE: you must keep Mallya^G within 10 centimeters of the smartphone during pairing (Figure M).

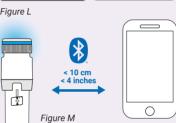
At the end of the pairing step, you may notice the signal light turn green and then turn off (Figure N). Once paired your Mallyage will enter standby mode and the light will turn off.

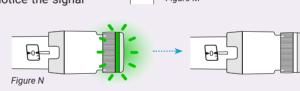
3.4. After pairing, follow the guidance in the application.

Unsure if the dose is delivered









Put Mally⁶ into active mode

To activate Mallyag on the pen:

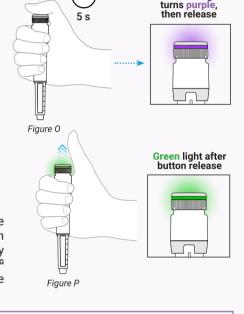
4.1. Firmly press and hold the Mallya^G's button down for at least 5 seconds until the light turns purple (Figure 0).

NOTE: If the light does not turn purple make sure Mallya^G is pushed all the way down (see Figure I in step 2.4).

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^G is now ready for use.

NOTE: Green light will remain on throughout the injection. If green ight does not come on, the injection will not be recorded. Make sure Mallya^G is sufficiently inserted on your pen. Repeat step 2.4 to push Mallya^G 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 Mallya⁶ 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 Mallya⁶. 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.

- 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^G device **black** dose dialing button to select the dose (Figure Q).
- 3. Turn Mallya6's button to select the dose you need. The selected dose should line up in front of the pen Figure Q dose pointer. During a dose selection, MallyaG's light is green (Figure Q).

NOTE: Do not use the transparent body of Mallya^G to select your dose (Figure R).

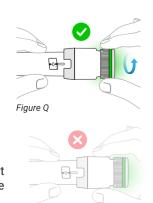


Figure R

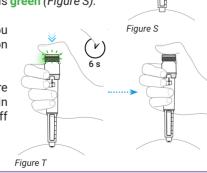
IMPORTANT: If the light does not turn green, Mallya⁶ is not ready and will not record the injection. It needs to be put on active mode before performing an injection. Follow the step 4 in the "How to setup your Mallya" section above to put the device into active mode.

4. Perform the injection as described in the Instructions for Use of your pen injector Press and hold down Mallya^G 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, MallyaG's light is green (Figure S).

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

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

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

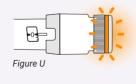


Figure V

Rapid Flashing (Figure U)





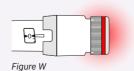


Mallyae's battery is low. Charge your Mallyae following the instructions in the "Charging Mallya" section. Charge the battery for at least 2 hours for a full charge. Do not give an injection with Mallya^G while it is charging. Mallya^G light is orange during injections if the battery is low.

When the pen dose pointer is aligned with the number 0,

press the dose button for 2 seconds until Mallya^G's light turns

The pen dose counter must be set at 0.



Red Solid (Figure W)

Error: the solid red light will come on when Mallya⁶ is in an error state and needs to be reset.

In this state, Mallya^g is not ready to record injections. Follow the instructions in the "Resetting Mallya" section on the back side if these instructions to reset Mallya^G. If the problem persists, contact the Support service. The red signal is not an alarm at meaning of IEC 60601-1-8.

Charging Mallya^G

After a full charge, if you use Mallya^G 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^G by connecting it to

a powered USB wall charger (not supplied) using the supplied USB cable (Figure Y).

Do not use any other cable.

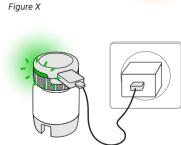
Please connect the supplied USB cable to the USB port of a power adapter (IEC / UL 60950-1 or IEC / UL 62368-1 certified with CE or UL marking) suitable for your region. (Figure Y).

The signal light will slowly flash green when Mallya⁶ is charging.

Do not give an injection with Mallya^G 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
- Liahts Cleaning



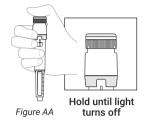


Transferring Mallya^G to another pen

1 Put Mallya⁶ into standby mode

Before transferring Mallva^G to another pen, you must first put it into standby mode so that transferring the device won't cause false doses to be logged in the application.

1.1. Firmly press and hold the Mallya^G button for at least 5 seconds, until the green light turns purple and then turns off. (Figure AA).



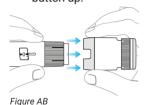
1.2. Then, lift your finger. Mallya^G is deactivated.

2 Remove Mallya^G from the pen

2.1. Hold Mallva^G by the body so your fingers only touch the sides of the device. being careful to not depress the button (Figure AB).

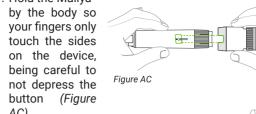
2.2. Pull Mallya^G straight off the pen (Figure

2.3. Set Mallya^G down unright onto a clean flat surface with the button up.



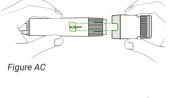
3 Attach Mallya⁶ to the new pen

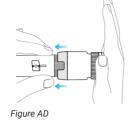
3.1. Hold the Mallya^G your fingers only on the device. button (Figure



3.2. Push Mallya^G 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

3.3. Make sure Mallya^G is properly mounted on the nen as shown on the picture (Figure AE).

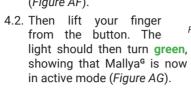




Put Mallya⁶ into active mode

To activate Mallya⁶ on the

4.1. Firmly press and hold the Mallya^G button down for at least 5 seconds. until its light turns purple (Figure AF).



Mallya^G is now ready for use on your new pen

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^G is sufficiently inserted on your pen. Repeat step 3.2 to push Mallya^G onto your pen to fully insert it. Then proceed to activate it, following the instructions in step 4.1.

If the following has occured, Mallya^G may need to be reset

 the Mallya^G signal light is solid red.

Resetting Mallva^G

- you need to unpair your Mallya^G from your phone and pair with a new nhone
- you want to delete your personal health data from Mallva^G.

Remove Mallya^G from the pen

- 1.1. Hold Mallya^G by the body so your fingers only touch the sides on the device, being careful to not depress the button (Figure AH).
- 1.2. Pull Mallya^G straight off the pen (Figure AH).
- 1.3. Set Mallya^G down upright onto a clean flat surface with the button up.

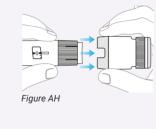
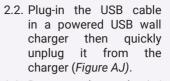


Figure AS

2 Reset Mallya⁶

2.1. Connect Mallya^G to the supplied USB cable (Figure AI).



2.3. Repeat the plug-in/ unplug process at least 4 times until Mallya^G flashes red and then turns off (Figure AJ).

Plug in and unplug 4 times

- 2.4. Disconnect Mallva^G from the USB cable.
- 2.5. Allow Mallya^G to sit on a clean flat surface with the button up for 30 seconds.

Mallya^G is now reset. After reset, Mallya^G is powered off and must be setup again.

3 Restart Mallva^G

Please refer to the section "How to setup vour MallyaG" section on the front page of these instructions, starting with step 1 (Figure AK), to restart your Mallyage device.

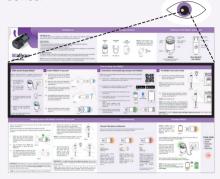


Figure AK

IMPORTANT: You must complete all steps in the "How to setup your Mallya6" section to restart your Mallyage device.

Light signals and meaning

Blue Solid (Figure AL)



During setup and when charging, a blue light will turn on when Mallya^G is ready to be paired or is not paired

During the selection of the dose and injection, if a blue light turns on, Mallya^G is not paired with your phone and is not recording injection information.

hilo2 (Figure AM)

> When changing Mallya⁶ modes, a purple light will turn on after Mallya^G is put into standby mode.

Then a purple light will turn on and off followed by a green light to show that active mode is turned on (see the "Transferring Mallyage to another pen" section and the "How to setup your MallyaG" section).

Figure AM

Solid (Figure AN) During setup, a green

solid light means that the Mallya^G is properly installed and paired.

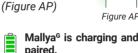
During the selection of the dose and the injection, a green solid light will turn on

Figure AN

Rapid Flashing (Figure AO)

During an injection. a rapidly flashing green light will turn on when Mallya^G is sensing the end of an injection. Keep your finger on the button until the light is done flashing to ensure the full dose is delivered.

Figure AO



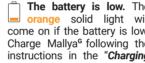
Slow Flashing

The green slow flashing light will turn off when the battery is fully charged.

Charge the battery for at least 2 hours for a full charge

Do not give an injection with Mallya^G when it is charging.

Solid



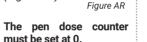
Charge the battery for at least 2 hours for a full charge.

Mallya^G light is orange during

(Figure AQ)

The battery is low. The orange solid light will come on if the battery is low. Charge Mallya^G following the instructions in the "Charging Mallva^G" section.

injections if the battery is low.



When the pen dose pointer is aligned with the number 0, press the dose button for 2 seconds until Mallya^G light turns green

Rapid Flashing

(Figure AR)

Hold until light

turns purple, then release

Green light after

5 s

Figure AG

Figure AC

Figure AF

Solid (Figure AS)

Error: the red solid light will come on when Mallya^G is in an error state and needs to be reset. Follow the instructions in the Resetting Mallya^{6"} section to reset Mallya⁶ If the problem persists, contact the Support service. The red signal is not an alarm at meaning of IEC 60601-1-8.

IMPORTANT: In case of injection, if the device lights red, the dose will not be recorded.

No signal (Figure AT)

The light automatically turns off after 10 seconds of inactivity. To check the status of Mallya^G, press lightly on the button to wake it up.

If the light does not turn on, press firmly on the button for several seconds to remove it from standby mode and put it into active mode (see step 4 of the "How to Setup Your Mallyag" section)

If the light still does not turn on despite a long and firm press, the battery may be empty. Charge Mallya^G following the instructions in the "Charging Mallya6" section. Charge the battery for 2 hours for a full charge. The green slowly flashing light will turn off when charged

IMPORTANT: If there is no light, the device is off, and injections will not be recorded.

Cleaning

Figure AI

x4

Figure AJ

Mallya^G is not sterile and can be reused for a single patient only

Mallya^G can be cleaned if necessary. To clean Mallva^G:

- Make sure Mallya⁶ is unplugged and not connected to the USB charging cable.
- Wipe the external surfaces with a soft lintfree cloth, slightly damped with a small amount of neutral detergent if needed being careful not to get the micro-USB port
- Dry the surfaces with a soft cloth.

IMPORTANT: Mallya^G is not waterproof, never wet the micro-USB port.

Technical safety information

In case of side effects or incident, please contact the manufacturer and the competent Health Authority.

Improper operation may result in serious injury or death • If you are not certain that you injected your medication, do not start, or repeat your injection. Monitor your treatment as instructed by your healthcare provider.

· Do not leave Mallyag or its accessories within the reach of children (injury, choking and strangulation hazard). Do not attach or tighten cable to or around the head or neck. · Do not expose the device to a temperature above

40°C (104°F) or flames. If Mallya^G is used at high temperatures exceeding our recommendations, the surface of the device may reach a maximum temperature of 43°C. In this case, the duration of use should be limited to 10 minutes to avoid any risk of

 Mallya^G contains a magnet. To guarantee optimal results, avoid contact with metallic parts during use, and avoid using Mallya⁶ near PACEMAKERS, DEFIBRILLATORS and BODY WORN INFUSION PUMPS or MAGNETIC RESONANCE IMAGING (MRI)

• Do not operate the device in a hazardous environment: presenting a risk of explosion, or containing volatile solvents (alcohol, etc.) or flammable substances (anesthetics, oxygen-rich environment, etc.).

 Mallya^G can only be used by patients already familiar with the pen injectors. Contact your healthcare provider, or a BIOCORP PRODUCTION authorized dealer to check your usual pen compatibility

Improper use may result in bodily injury or property

• Do not expose the device to moisture. Do not immerse the device in liquids. · Leave the device in a room at room temperature

for 30 minutes before unpacking it to avoid possible

malfunctions due to condensation · Do not disassemble, modify, or repair the device by could result

vourself: it may cause fire, electrical shock, bodily injury. or device malfunction. Your device's warranty will be void. Periodic maintenance of Mallya⁶ is not required. · If there is any abnormal smell, sound, heat, or smoke when using the device, stop using Mallya^G.

· If the device experiences an external mechanical impact (knocking, bumping, dropping, etc.) or excessive stress (inappropriate storage/transport/ use conditions), this may cause malfunctioning of the device. In case of malfunctioning, do not use the device and continue your injection pen treatment. Please contact the BIOCORP PRODUCTION authorized dealer as identified on the outside of the packaging for technical support.

· In case of visible damage, do not use Mallyage and contact BIOCORP PRODUCTION or its authorized dealer for technical support.

 Do not leave your Mallya^G and its accessories next to password on your smartphone. animals/insects or dust/plush. After use, your device must be put away in its packaging. Only use your Mallya^G with Novo Nordisk[®] pen

njectors for growth disorder treatment. Never use Mallya^G with any other pen. • This device is not recommended for use by the blind or visually impaired without the help of someone trained

to use the device. · During handling operations, protect the needle with the pen cap, if it is assembled on the pen.

 Separate collection for waste electric and electronic equipment (WEEE) is required.

Wireless communication safety issues · Portable RF communications equipment (including communication is no more possible, and the peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 to track injection. Where perturbing electromagnetic inches) to any part of the Mallya⁶ device, including cables specified by the manufacturer. Otherwise,

degradation of the performance of this equipment

 Flectrical medical devices and systems are subject. to special measures concerning electromagnetic compatibility (EMC) and must be installed in accordance with the EMC instructions contained in the technical note available online at https://my-mallya. com/us/growth-disorder.

· 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. Use of accessories, transducers and cables other than

those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Protect your personal healthcare data with

· Protect your smartphone by installing antivirus software. · Never install a mobile application from unofficial

stores on your phone. Contact Biocorp Production for list of approved compatible apps & verified phones to be used with Mallva^G

In case of Bluetooth® transmission disturbance

or loss, the Mallva^G device will continue to track and record the history of all your injections. More information is available on the technical note available online at https://my-mallya.com/us/growth-disorder. • In case of use in a noisy environment (in terms of electromagnetic signal near 2.4Ghz), the Bluetooth® connection is closed. However, the device continues signals disappear, communication is possible

The Cybersecurity nomenclature corresponding

to the embedded software version is available on request. Please contact a BIOCORP PRODUCTION authorized dealer if you wish to consult it. You are responsible for properly securing and

cybersecurity event related to the Mallya^G device or related App, contact Customer Service. Make sure that your phone and Mallya^G device are kept in a safe place, under your control. This is important to help prevent anyone from accessing or

managing your phone. If you suspect an adverse

tampering with the System. • The App used with Mallya^G device is not intended for use on a phone that has been altered or customized to remove, replace or circumvent the manufacturer's approved configuration or use restriction, or that

otherwise violates the manufacturer's warranty. • The App used with Mallya⁶ device requires that your phone has the correct date and time for recording your health information. Your phone's date and time should be set to update automatically. You can check

this in your phone settings. When you travel across time zones, save your infusion data and check your smartphone time. In case of local time management malfunction, do not start or repeat your injection, monitor your treatment as instructed by your healthcare provider and use the device reset function to retrieve your Mallya^G factory

• When using the App used with Mallya^G device, you should keep your phone well charged.

 Keep your phone well charged and turned on. Disable your phone's automatic operating system updates. After an operating system update, open your App and check your device settings to make

Before disposing of Mallya^G: reset the device to delete all your personal health data.

sure it's working properly.

Technical specifications

Patients	designed for growth disorder	
Intended Users	Users aged from 13 to 80 years old	
Intended Environment	Home use	
Accuracy of recorded doses	99% ±1 increment on test bench	
Charge and autonomy	Charge by USB connector. Full charge in 2h, 2 weeks-autonomy for daily injection / 4 weeks-autonomy for weekly injection. USB AC adaptor (not provided): IEC/UL 60950-1 or IEC/UL 62368-1 certified with CE or UL marking, external module with automatic adaptation of the voltage, 90-264V input voltage range.	
Electrical consumption	5V DC, ≥ 500mA	
Battery	Li-ion 3.6V 25mAh	
Storage of recorded doses	The last 100 recorded increments are stored in the device's internal memory (including flow checks)	
Communication	Bluetooth® Low Energy v4.2 operating in the frequency band of 2400 MHz to 2483.5 MHz. 40 channels, 2MHz spacing channel, 1 MHz channel bandwidth, 4dBm (2.5119 mW) max transmission power, -8dBm max EIRP (Equivalent Isotropic Radiated Power).	
Model	EFA2	
Software version	Firmware 1.2.x	
Dimensions	40,1 mm (h) x Ø 25,8 mm / 1,58 in (h) x Ø 1,01 in	
Weight	11 g / 0,39 oz	
Operating conditions	Temperature Humidity Pressure	

Further information is included in the Technical Note, available online at https://mv-mallya.com/us/growth-disorder

Symbols and information on the device and/or its packaging and labels

Patients using a Novo Nordisk® pen injector designed for growth disorder	SYMBOL	DESCRIPTION
Users aged from 13 to 80 years old	&	Refer to the instruction manual / booklet. Follow instructions for use
Home use	<u>l</u>	Manufacturer
99% ±1 increment on test bench	SN	Serial Number
Charge by USB connector. Full charge in 2h, 2	(FR	Country and date of manufacture
weeks-autonomy for daily injection / 4 weeks-autonomy for weekly injection. USB AC adaptor (not	LOT	Batch number
provided): IEC/UL 60950-1 or IEC/UL 62368-1 certified with CE or UL marking, external module	UDI	Unique Device Identification
with automatic adaptation of the voltage, 90-264V input voltage range.	#	Model number
5V DC, ≥ 500mA		Distributor
Li-ion 3.6V 25mAh	REF	Product reference
The last 100 recorded increments are stored in the	REF	Distributor reference
device's internal memory (including flow checks)	Ω	Use by date
Bluetooth® Low Energy v4.2 operating in the frequency band of 2400 MHz to 2483.5 MHz.	MD	Medical Device
40 channels, 2MHz spacing channel, 1 MHz channel bandwidth, 4dBm (2.5119 mW) max transmission power, -8dBm max EIRP (Equivalent	<u>*</u>	Type BF applied part (according to IEC 60601-1 continuous mode)
Isotropic Radiated Power).	IP 22	Ingress Protection index IP22 (IEC 60529)
Firmware 1.2.x	===	Direct current
40,1 mm (h) x Ø 25,8 mm / 1,58 in (h) x Ø 1,01 in	$\langle \rangle$	For indoor use only
11 g / 0,39 oz		Keep away from humidity
Temperature Humidity Pressure	J	
2°C 36°F 15% 700hPa	•	Do not use if the packaging is damaged or opened
Do not freeze the device between injections (36°F $^{\circ}\text{C}$ or 2°C $^{\circ}\text{C})$	Ā	WEEE; waste electrical and electronic equipment
2 years	<i>c.</i>	

Single patient multiple use

Radio-communication statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This device complies with FCC radiation exposure limits set forth for general population. This device must not be co-located or operating in conjunction with any other antenna or transmitter

FCC ID: 2AYCW-MALLYANN

General information and contact information

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Address of Novo Nordisk affiliate distributing in USA - To be edited

In case of questions, problems or assistance, please contact BIOCORP PRODUCTION authorized dealer for technical support as identified on the outside of the packaging.