IFU_MAL_G_FDA_EN_1.1_2024_06
0374495

Mallya G

USER MANUAL

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.

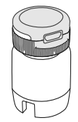
Device features
Mallya^G is able to :
- be assembled with Novo Nordisk® pen injector designed for growth disorder treatment,
- record the amount of dose increments injected by the pen,
- record the timestamp (date & time) of each injection,
- transmit information relating to dose, time, and date of each 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 Mallya^G 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.

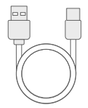
Package contents

Mallya^G x1



PN : 0274345

USB cable x1



PN : 0373707

User instructions x1

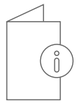


Figure A

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

5V
≥ 500mA
⎓

Figure B

Getting to know Mallya^G and the pen

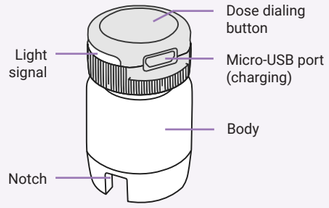


Figure C

Mallya^G

All exterior plastic parts to the device constitutes its applied part

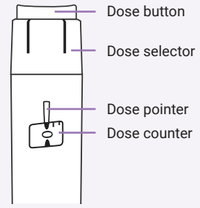


Figure D

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 *(Figure E)*.

1.2. Connect the cable to a powered USB wall charger *(Figure E)*.

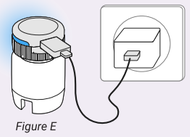


Figure E

1.3. Let the device charge for at least 10 minutes before its first use *(Figure F)*.

Figure F

1.4. Unplug the cable and Mallya^G *(Figure G)* then unplug the charger.

Figure G

The **blue** light signal indicates that the device is not paired yet.

2 Attach Mallya^G to your pen

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, without pressing on its dose dialing button.

2.3. Insert Mallya^G on the pen dose button, aligning the Notch of Mallya^G with the pen Dose counter *(Figure H)*.

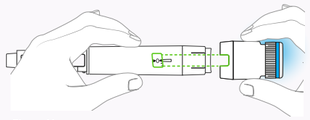


Figure H

2.4. Push Mallya^G fully onto the pen, pressing the button with the palm of your hand. It must be inserted all the way onto the dose selector *(Figure I)*.

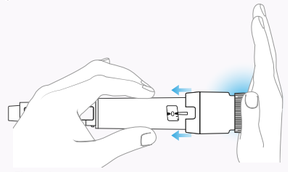


Figure I

2.5. Make sure Mallya^G is properly mounted on the pen as shown on the picture *(Figure J)*.

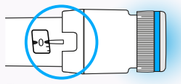


Figure J

3 Download a connectable app and pair with Mallya^G

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 Mallya^G internet website *https://my-mallya.com/us/growth-disorder*, or by scanning this QR Code *(Figure K)*.

Figure K

3.2. Download the mobile application on Google Play™ (Android) or the App Store® (Apple) *(Figure L)*.

GET IT ON Google Play | Download on the App Store

Figure L

3.3. Activate the Bluetooth® on your smartphone, if not already done.

3.4. Keep Mallya^G less than 10 cm away from your smartphone *(Figure M)*.

3.5. Open the App and follow the instructions to pair Mallya^G.
Once paired, Mallya^G's light signal turns **green**, then off *(Figure N)*.

3.6. Once the device is paired, follow the instructions in the connected mobile application.

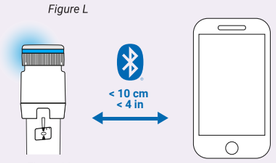


Figure M

Figure N

4 Put Mallya^G into active mode

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

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).

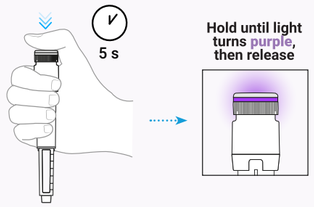


Figure O

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^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.

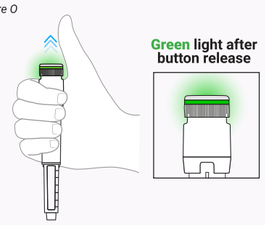


Figure P

IMPORTANT: Follow the ***"Injecting a dose with Mallya^G attached to your pen"*** section below when you give an injection.

Injecting a dose with Mallya^G attached to your pen

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

Monitor your treatment as instructed by your healthcare provider.

If you have any doubts about your treatment, please consult your healthcare provider.

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^G device **black** dose dialing button to select the dose *(Figure Q)*.

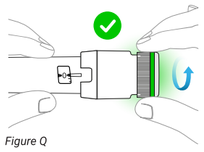


Figure Q

3. Turn Mallya^G'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^G's light is **green** *(Figure Q)*.

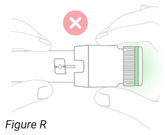


Figure R

IMPORTANT: If the light does not turn **green**, Mallya^G 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^G"*** section above to put the device into active mode.

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

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, Mallya^G's light is **green** *(Figure S)*.

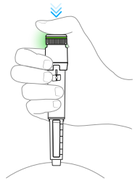


Figure S

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)*.

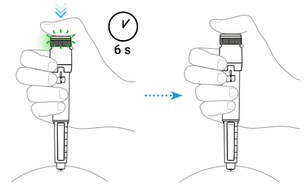


Figure T

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.

NOTE: Safety tests performed to check the flow (priming), will also be automatically detected, and recorded by Mallya^G. Perform the safety test to check the flow as described in the Instructions for Use of your pen injector.

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.

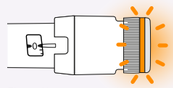


Figure U

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^G's light turns **green**.

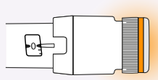


Figure V

Orange
Solid
(Figure V)

Mallya^G's battery is low. Plug-in and charge your Mallya^G (2h for a full charge).
Mallya^G's light is **orange** during injections if the battery is low.

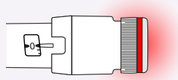


Figure W

Red
Solid
(Figure W)

Mallya^G is in error state. In this state, Mallya^G is not ready to record injections. Reset your Mallya^G and restart it. Refer to section "***Resetting 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

Mallya^G's battery has a 2-weeks minimum autonomy in normal use conditions.
When the battery is low, Mallya^G's light is **orange** *(Figure X)*.

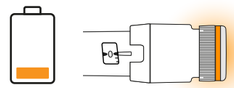


Figure X

Connect Mallya^G to the supplied USB cable, then connect the cable to a powered USB wall charger to charge Mallya^G.
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)*.

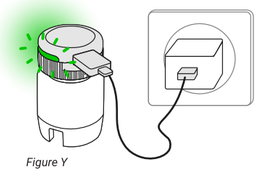


Figure Y

While charging, Mallya^G's light **flashes slowly green**.
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.

Figure Z

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

Transferring Mallya^G to another pen

1 Deactivate Mallya^G

Before transferring Mallya^G to another pen, you must first deactivate it so that transferring the device won't cause false doses to be logged in the application.

1.1. Press firmly on Mallya^G's button for 5 seconds, until its **green** light turns **purple**. Then, lift your finger. Mallya^G's light turns off, indicating that Mallya^G is deactivated *(Figure AA)*.

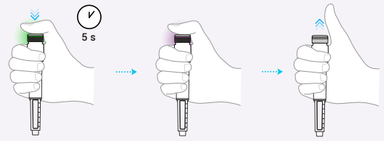


Figure AA

2 Remove Mallya^G from the pen

2.1. Hold Mallya^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 AB)*.

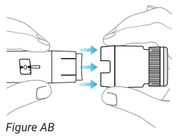


Figure AB

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

3 Attach Mallya^G to the new pen

3.1. Hold the Mallya^G by the body so your fingers only touch the sides on the device, being careful to not depress the button *(Figure AC)*.

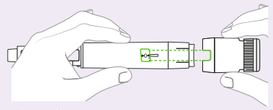


Figure AC

3.2. Push Mallya^G fully onto the pen, pressing the button with the palm of your hand. It must be inserted all the way onto the dose selector *(Figure AD)*.

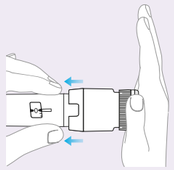


Figure AD

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

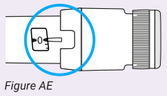


Figure AE

4 Put Mallya^G into activate mode

4.1. Press firmly on Mallya^G's button for 5 seconds, until its light turns **purple** *(Figure AF)*.

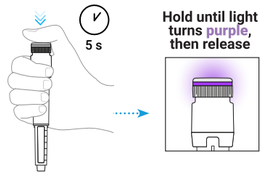


Figure AF

4.2. Lift your finger, Mallya^G's light turns **green**, indicating that Mallya^G is ready to be used *(Figure AG)*.

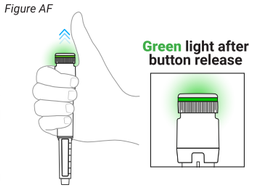


Figure AG

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.

Resetting Mallya^G

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

- Mallya^G's light is red.
- you need to unpair your Mallya^G from your phone and pair with a new phone.
- you want to delete your personal health data from Mallya^G.
- you face time zones or switch between standard and daylight-saving times smartphone malfunction.

1 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)*.

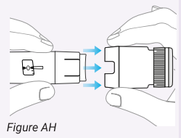


Figure AH

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.

2 Reset Mallya^G

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

Figure AI

2.2. Plug-in the USB cable in a powered USB wall charger and quickly unplug it from the charger.
Repeat the plug-in/unplug process until Mallya^G's light flashes several times and then turns off (it may require at least 4 times) *(Figure AJ)*.

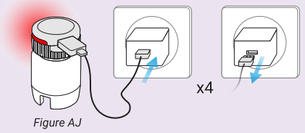


Figure AJ

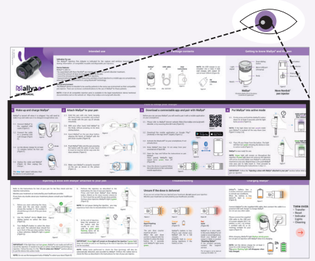
2.3. Disconnect Mallya^G from the USB cable.

2.4. 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 started again.

3 Restart Mallya^G

Please refer to the section "***How to setup your Mallya^G***" to restart your Mallya^G device.



IMPORTANT: You must follow all the steps of the "***How to setup your Mallya^G***" section to restart your Mallya^G device.

Light signals and meaning

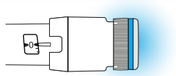


Figure AK

Blue
Solid *(Figure AK)*

Mallya^G is ready to be paired.

Before Mallya^G has been paired, the light is **blue**, regardless of the operation. No data is recorded.

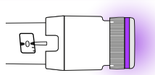


Figure AL

Purple
Solid *(Figure AL)*

Mallya^G is being activated or deactivated.

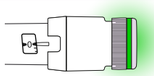


Figure AM

Green
Solid *(Figure AM)*

Mallya^G is, either:

- paired.
- setting a dose.
- injecting a dose.

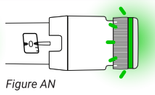


Figure AN

Green
Slow Flashing *(Figure AN)*

Mallya^G is charging and paired.

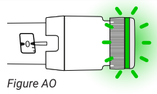


Figure AO

Green
Rapid Flashing *(Figure AO)*

Mallya^G is seeing the end of an injection.

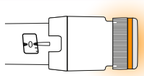


Figure AP

Orange
Solid *(Figure AP)*

Mallya^G's battery is low.
Plug-in and charge your Mallya^G (2h for a full charge). Mallya^G's light is **orange** during injections if the battery is low.

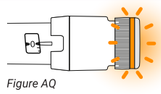


Figure AQ

Orange
Rapid Flashing *(Figure AQ)*

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^G's light turns **green**.

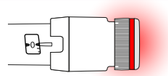


Figure AR

Red
Solid *(Figure AR)*

Mallya^G is in error state.
In this state, Mallya^G is not ready to record injections.
Reset your Mallya^G and restart it. Refer to section "***Resetting Mallya^G***". If the problem persists, contact the Support service.

The red signal is not an alarm at meaning of IEC 60601-1-8.

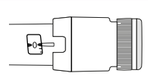


Figure AS

No signal *(Figure AS)*

The light automatically turns off after a period of inactivity (10 seconds).
Press lightly on the Mallya^G's button to activate it and check its status by the light color.
If the light does not turn on, press the button for 5 seconds, Mallya^G may be disactivated.
If the light still does not turn on, despite a long and firm press on the button, the battery might be empty. Charge your Mallya^G.

Cleaning

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

Mallya^G can be cleaned if necessary.

To clean Mallya^G:

- Make sure Mallya^G is unplugged and not connected to the USB charging cable.
- Wipe the external surfaces with a soft lint-free cloth, slightly damped with a small amount of neutral detergent if needed, being careful not to get the micro-USB port wet.
- 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 Mallya^G 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 burning.
• Mallya^G contains a magnet. To guarantee optimal results, avoid contact with metallic parts during use, and avoid using Mallya^G near PACEMAKERS, DEFIBRILLATORS and BODY WORN INFUSION PUMPS or MAGNETIC RESONANCE IMAGING (MRI) ENVIRONMENT.
• 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 damage

• 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 yourself: it may cause fire, electrical shock, bodily injury, or device malfunction. Your device's warranty will be void. Periodic maintenance of Mallya^G 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 Mallya^G and contact BIOCORP PRODUCTION or its authorized dealer for technical support.
• Do not leave your Mallya^G and its accessories next to 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 injectors 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 peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Mallya^G device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
• Electrical 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 a password on your smartphone.
• 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 Mallya^G.
• In case of Bluetooth® transmission disturbance or loss, the Mallya^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® communication is no more possible, and the connection is closed. However, the device continues to track injection. Where perturbing electromagnetic 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 managing your phone. If you suspect an adverse 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 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 Mallya^G 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 settings.
• 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 sure it's working properly.
• Before disposing of Mallya^G: reset the device to delete all your personal health data.

Technical specifications

Intended Patients	Patients using a Novo Nordisk® pen injector 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	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 1.0.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: 2°C - 36°F / 35°C - 95°F; Humidity: 15% - 90%; Pressure: 700hPa - 1060hPa Do not freeze the device between injections (36°F <T° or 2°C < T°C)
Lifetime	2 years

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

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

SYMBOL	DESCRIPTION
	Refer to the instruction manual / booklet. Follow instructions for use
	Manufacturer
SN	Serial Number
	Country and date of manufacture
LOT	Batch number
UDI	Unique Device Identification
#	Model number
	Distributor
REF	Product reference
	Distributor reference
	Use by date
MD	Medical Device
	Type BF applied part (according to IEC 60601-1 continuous mode)
IP 22	Ingress Protection index IP22 (IEC 60529)
	Direct current
	For indoor use only
	Keep away from humidity
	Do not use if the packaging is damaged or opened
	WEEE; waste electrical and electronic equipment
	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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