

06-2022

Instructions For Use



Embedded software version 3.7 and above

BIGCORP

CE 0459

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SYMBOLS USED IN THIS MANUAL


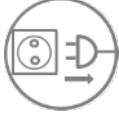
Symbol	Meaning	Explanation
	WARNING	Improper operation may result in serious injury* ¹ or death to the user, patient
	CAUTION	Improper operation may result in bodily injury* ² or property damage* ³
	CAUTION	Disconnect the device from power supply before servicing/cleaning
	NOTE	Important information for operation

Table 1 - Symbols used in IFU

*1 Serious injury means electrical shock or poisoning that causes a subsequent complication or requires hospitalization or long-term outpatient treatment.

*2 Bodily injury means an injury, burn, electrical shock and so on that will not necessitate hospitalization or long-term outpatient treatment.

*3 Damage to property means extensive damage to a house and/or household goods as well as a domestic animal and pet.

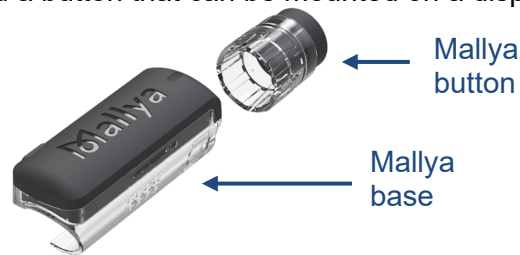
ABBREVIATIONS LIST

Abbreviation	Definition
PN	Part Number
SN	Serial Number
LED	Light indicator (Light Emitting Diode)
IP	Ingress Protection
BLE	Bluetooth Low Energy

Table 2 - Abbreviations list

Device features

Mallya is composed of a base and a button that can be mounted on a disposable insulin pen.



Mallya allows you to:

- Record the injected selected increment (insulin dose),
- Record the day and time when each insulin dose was injected,
- Transmit the dose, day/time when each insulin dose was injected to a compatible mobile app. on a bluetooth paired mobile device (smartphone).

The compatible mobile application is then able to display the injected Insulin Selected Dose (ISD) by day/time.

The Mallya System aims to help patients keep accurate records of their insulin injections (without providing specific treatment or treatment suggestions). The device's purpose is to help patients improve adherence to their treatment and share data with healthcare professionals.

Intended use

Mallya is intended to be used for the capture and wireless transmission of dosing information from compatible pen injectors.

Intended users

The intended users of the Mallya device are patients with type I and II diabetes. Mallya is a reusable device intended for a single patient.

Usage environment

The Mallya device is intended for use in a medical office or at home.

Healthcare data protection

The terms of the regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 may apply to the interactions between Biocorp Production and users of its products.

To this end, Biocorp Production agrees to comply with its obligations in accordance with the regulation applicable to Personal data protection and makes every effort to guarantee the security, confidentiality, and integrity of the Personal data that it may process.

A user has the right to access their data, rectify them, request their deletion, or exercise their right to limit the processing of such data. They may withdraw their consent to the processing of such data at any time; they may also object to the processing of their data and exercise their right to the portability of such data. To exercise these rights, please contact: gdpr@biocorp.fr

If a user considers, after having contacted Biocorp Production, that their Data Protection and Privacy rights have not been respected or that the access control provision does not comply with data protection rules, such user may file a claim online or by mail with the relevant national data protection authority.

1. GENERAL INFORMATION



BIOCORP PRODUCTION
ZI LAVAUUR LA BECHADE
63500 ISSOIRE
CEDEX – FRANCE

DISTRIBUTOR:

See list at the end of leaflet

The user manual must be accessible to you at all times. You must read all instructions carefully before using the device.

If you have technical problems with our product, please contact a BIOCORP PRODUCTION authorized dealer.

The following information will be needed in order to provide you with the necessary assistance:

- **Serial Number of your Mallya unit** (this **SN** number can be found on the device label)

2. MALLYA COMPATIBILITIES – MOLECULES AND CONCENTRATIONS



WARNING

Make sure Mallya is compatible with your pen (insulin type and concentration).

The molecules and associated concentrations compatible with the Mallya device are listed in the table below:

MALLYA MODEL	INSULINE INN	CONCENTRATION
Mallya designed for KWIKPEN® ELI LILLY insulin pen	GLARGINE	100 IU/mL
	LISPRO	100 IU/mL
		200 IU/mL
	LISPRO AND PROTAMINE	100 IU/mL
	HUMAN ISOPHANE	100 IU/mL
	REGULAR HUMAN USP	100 IU/mL
Mallya designed for FLEXPEN® NOVO NORDISK insulin pen	REGULAR HUMAN AND HUMAN ISOPHANE	100 IU/mL
	DETEMIR	100 IU/mL
	ASPART	100 IU/mL
	ASPART AND PROTAMINE	100 IU/mL
Mallya designed for SOLOSTAR® SANOFI insulin pen	HUMAN ISOPHANE	100 IU/mL
	GLARGINE	100 IU/mL
		300 IU/mL
	LISPRO	100 IU/mL
	GLULISINE	100 IU/mL
GLARGINE AND LIXISENATIDE	100 IU/mL	
		+33 mcg/mL

Table 3 - Mallya compatibilities – Molecules and concentrations



CAUTION

Mallya is only compatible with insulin pens allowing selection of unitary doses (1 unit increments).

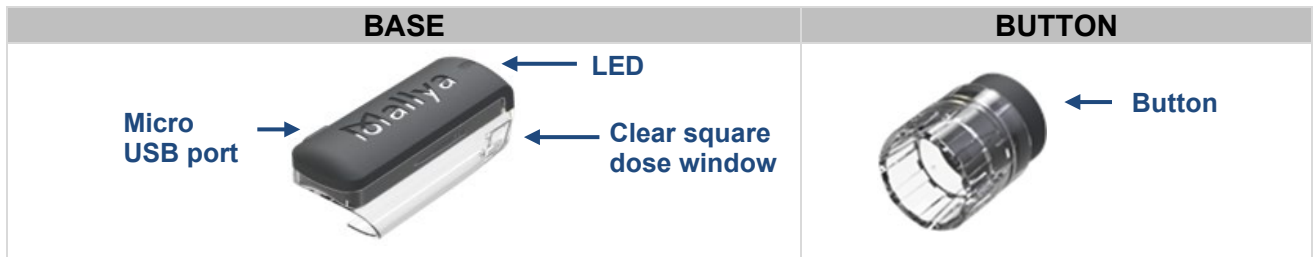
It is, for instance, not compatible with Kwikpen Junior (0.5 unit increments) or Max Solostar/Doublestar (2 unit increments).

3. DEVICE DESCRIPTION AND EXAM ENVIRONMENT

3.1 DEVICE DESCRIPTION

3.1.1 MALLYA CHARACTERISTICS

The Mallya device is composed of a base and a button:



3.1.2 ESSENTIAL PERFORMANCES OF THE SYSTEM (SIGNIFICANT OPERATING CHARACTERISTICS)

The essential performance for the Mallya device has been defined as follows:

Provide reliable data dosage parameters of a drug to the patient and caregivers.

The device sends treatment information via Bluetooth (BLE) to the patient's smartphone:

- Injected Insulin Dosage (UI)
- Injection Date
- Injection Hour

The compatible Mallya mobile application allows the patient to securely display treatment information. This improves the patient's therapeutic adherence.

3.1.3 MALLYA PARTS REFERENCES

The references (Part Numbers) vary depending on the Mallya model:

MALLYA MODEL	MALLYA BASE <i>APPLIED PART</i>	MALLYA BUTTON <i>APPLIED PART</i>
Mallya designed for FLEXPEN® NOVO NORDISK insulin pen	 PN : 0273778	 PN : 0273727
Mallya designed for KWIKPEN® ELI LILLY insulin pen	 PN : 0273694	 PN : 0273698
Mallya designed for SOLOSTAR® SANOFI insulin pen	 PN : 0273777	 PN: 0273710

Table 4 - Mallya parts numbers

The following parts are necessary to operate the Mallya device:



USB CABLE	RESET KEY
	
PN: 0373707	PN: 0373708

Table 5 - Parts necessary for operation

NOTE:

To upload the Mallya application, please refer to **section 5.4.1. Installing the “Mallya” application.**

3.2 WEIGHT AND SIZE OF THE MAIN ELEMENTS

ELEMENT	WEIGHT	INSULIN PEN	SIZE
Mallya base	0,016 kg	KWIKPEN®	(60.8x28.9x21.3) mm
		FLEXPEN®	(60.8x26.9x21.3) mm
		SOLOSTAR®	
Mallya button	0,006 kg	KWIKPEN®	(11.6 x Ø22) mm
		FLEXPEN®	(26.3 x Ø19.3) mm
		SOLOSTAR®	(24.4 x Ø20) mm
Mallya total weight	0,022 kg	-	-

Table 6 - Weight and size of the main elements

4. SAFETY INFORMATION

4.1 SYMBOLS ON THE DEVICE AND / OR ITS PACKAGING









SYMBOL	LOCATION	DESCRIPTION
	DEVICE AND PACKAGING	Refer to the instructions for use
	DEVICE AND PACKAGING	Manufacturer
	DEVICE AND PACKAGING	CE marking: product conform to CE regulations
	DEVICE AND PACKAGING	Serial Number
	DEVICE AND PACKAGING	Date of manufacture and country of manufacture
	PACKAGING	Batch Number
	PACKAGING	Unique Device Identification
	PACKAGING	International and unique item code (Global Trade Item Number)

Table 7 - Symbols on the device and its packaging













SYMBOL	LOCATION	DESCRIPTION
	DEVICE AND PACKAGING	Product reference
	PACKAGING	Distributor reference
	PACKAGING	Class II device (double isolation)
	PACKAGING	Type BF applied part
IP 22	PACKAGING	Protection index IP22 (see section 10.4.: maintain water, dust and light resistance)
	PACKAGING	For indoor use only
	PACKAGING	Moisture sensitive device
	PACKAGING	Temperature limits to which the device can be safely exposed.
	PACKAGING	Humidity limits to which the device can be safely exposed.
	PACKAGING	Pressure limits to which the device can be safely exposed.
	PACKAGING	Do not use if the packaging is damaged
	PACKAGING	Management of electrical and electronic waste.
	PACKAGING	Single patient, multiple use

Table 8 - Symbols on the device and its packaging (next)

4.2 WARNINGS AND CAUTIONS

NOTES:

- Mallya must only be used for the **intended use** described in this manual.
- **Read these instructions before you use Mallya** for the first time. Keep these instructions in a safe place.
- The device must be used in the **specified ambient conditions** (do not expose the device to temperatures above 40°C (104°F) or flames).
- When Mallya is used at a high temperature that exceeds our recommendations, the surface of the device can reach temperatures above 41 °C (maximum temperature of 44.5 ° C). In this case, the duration of use should be limited to 10 minutes in order to avoid any risk of burns.
- If the device experiences an external **mechanical impact** (knocking, bumping, dropping, etc.), this may cause malfunctioning of the device. In case of malfunctioning, please contact a BIOCORP PRODUCTION authorized dealer for technical support.

- Never install a mobile application from **unofficial stores** on your phone.
- Using a phone of **unknown origin** causes risk and will invalidate the Mallya warranty.
- Protect your **personal health data** by using a password on your smartphone.
- Periodic maintenance of Mallya is not required, only **daily inspection** is recommended. Maintenance of the Mallya is required when the device does not pass its functional testing. If the functional testing is not successful, you are prompted to contact a BIOCORP PRODUCTION authorized dealer.
- The **Cybersecurity nomenclature** corresponding to the embedded software version is available in the technical notice of the device. Please contact a BIOCORP PRODUCTION authorized dealer if you wish to consult it.

**WARNING**

- If you are not certain that you injected your insulin, do not start or repeat your injection. Monitor your blood glucose as instructed by your healthcare provider.



- **Disconnect the USB cable from the USB charging port and disconnect Mallya from the USB cable before using it.**

- Mallya is supplied with a **USB cable**. Do not use any other cable. Use the cable supplied with the device to connect it to a USB power port.
- Do not attach or tighten cable to or around the head or neck. Cable can cause **strangulation**.
- Avoid using near **PACEMAKERS and DEFIBRILLATORS**.
- Mallya contains a **magnet**, avoid contact with metallic parts during use.
- This device is not recommended for use by the **blind** or **visually impaired** without the help of someone trained to use the device.
- Do not disassemble, modify or repair the device by yourself. Otherwise, it may cause fire, electrical shock, bodily injury, or device malfunction. Refer all **servicing** to your authorized BIOCORP PRODUCTION dealer. The instrument disassembled, modified or repaired by anyone other than a BIOCORP PRODUCTION designated repair facility will invalidate the warranty.
- If there is any abnormal smell, sound, heat, or smoke when using the device, stop using Mallya. Continued use may cause **fire** or device malfunction. Contact your authorized BIOCORP PRODUCTION dealer for inspection.
- Mallya is **not waterproof** and will not be protected against the infiltration of water or moisture:
 - ✓ Do not immerse the device in water and do not clean it under running water.
 - ✓ Do not expose the device to moisture.
- Do not place Mallya in a **microwave**.
- Do not operate the device in a hazardous environment: presenting a **risk of explosion**, or containing volatile solvents (alcohol, etc.) or flammable substances (anaesthetics, etc.); or do not place it in the vicinity of an environment rich in OXYGEN.
- **Small Children:** Do not leave your Mallya and its accessories within the reach of small children or allow them to play with it. They could hurt themselves or others or could accidentally damage the device. Your Mallya contains small parts with edges that may cause injuries or may detach and create a **choking** hazard.
- **Animals or insects:** Do not leave your Mallya and its accessories within the reach of animals or insects. After use, your device must then be put away in its original packaging.
- The use of accessories other than those specified for the device is not recommended. They may result in increased emissions or decreased **electromagnetic immunity** of the device.

4.3 ELECTRICAL SAFETY

Mallya is supplied with a USB cable. Do not use any other cable. Use the cable supplied with the device to connect it to a USB power port.

**CAUTION**

Connect the Mallya USB cable to a power source compliant with the **IEC 60601-1**.

4.4 COMPLIANCE WITH STANDARDS / REGULATION AND CLASSIFICATIONS

COMPLIANT STANDARDS	DESCRIPTION	CLASSIFICATION
IEC 60601-1	• Protection type against electric shock	Class II (double isolation)
	• Degree of protection against electric shock	Type BF
	• Mode of operation	Continuous operation
IEC 60601-1-2	• Electromagnetic compatibility	* Refer to EMC section 12
IEC 60529	• Type of protection against the access to hazardous parts and the infiltration of water as detailed in the current edition of IEC	IP22

Table 9 - Mains standards & classification

4.5 MALLYA BASE LABELING

MALLYA type	BASE LABELING	BUTTON MARKINGS (INSIDE)
Mallya designed for FLEXPEN® NOVO NORDISK insulin pen		
Mallya designed for KWIKPEN® ELI LILLY insulin pen		
Mallya designed for SOLOSTAR® SANOFI insulin pen		

Table 10 - Mallya base and button labeling

NOTE:

The part number and serial number of the device can also be found on the packaging accompanying the device.

4.6 TRANSPORT AND STORAGE CONDITIONS

	Temperature	Atmospheric pressure	Relative humidity
Transport	-10°C to +40°C (14°F < T° < 104°F)	500 hPa to 1060 hPa	10% to 90%
Storage	-10°C to +40°C (14°F < T° < 104°F)	800 hPa to 1060 hPa	10% to 90%

Table 11 – Transport and storage conditions



CAUTION

- The device must be transported and stored in its original packaging designed to protect it from damage.
- Storage and transport conditions must meet conditions described in the above table.

4.7 USAGE CONDITIONS

	Temperature	Atmospheric pressure	Relative humidity
Operating	+15°C to +35°C (59°F < T° < 95°F)	800 hPa to 1060 hPa	30% to 70%

Table 12 - Usage conditions



CAUTION

- Leave the device in a room for 30 minutes before unpacking to ensure there is no condensation.

4.8 DISPOSAL

Dispose of Mallya according to your local guidelines.

According to Directives **2012/19/UE WEEE** and **2011/65/UE RoHS II** on the restriction of hazardous substances in electrical and electronic equipment on their disposal:

Public authorities adopt adequate measures to make sure that users, distributors and manufacturers contribute to the collection of electrical and electronic equipment, setting legal requirements to reuse, recover or recycle the said equipment.



CAUTION

You must take into account the potentially harmful effects to the environment or human health due to the improper disposal of the equipment or of parts of it.

The following graphic symbol is applied on the label of the equipment:



It reminds that all electrical and electronic equipment must be collected and disposed of separately from domestic waste at the end of life.



CAUTION

Before disposing of Mallya: reset the device to delete all your personal health data (see **section 9.3.**)

5. UNPACKING AND INSTALLING MALLYA (CHARGING / CALIBRATING / ASSEMBLING / PAIRING)

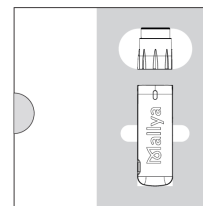


CAUTION

- Mallya can only be paired with a compatible mobile application.
- Mallya is only compatible with insulin pens allowing selection of unitary doses (1 unit increments). It is, for instance, not compatible with Kwikpen Junior (0.5 unit increments) or Max Solostar/Doublestar (2 unit increments).
Refer to section 2 – Mallya compatibilities – Molecules and concentrations

5.1 UNPACKING YOUR MALLYA AND ITS ACCESSORIES

5.1.1 PACKAGE CONTENTS







Mallya base (x1)		Mallya button (x 2)	
USB Cable (x 1)		Reset Key (x 1)	
Quick Start Guide with reference: QSG_MAL_AN (x 1)			

Table 13 - Package content

5.1.2 UNPACKING

➤ **STEP 1 – Open the Mallya shipping box**

Mallya is packed for shipping / transportation in a cardboard box:



The internal cardboard housing with special shaped forms and cardboard parts supports the Mallya base and the button.

NOTES:

- After opening, keep all the original packaging for future use (in case of return or transport of the device). The device must always be transported in its original packaging, which has been specially designed to protect it from damage.
- Check whether the packaging is damaged. If damage is found, the device may also have been damaged. Please contact your distributor.

➤ STEP 2 – Remove from the box: the base, the button and the accessories

You can get Mallya free support @ my-mallya.com

5.2 CHARGING AND CALIBRATING YOUR MALLYA**5.2.1 CHARGING YOUR MALLYA****NOTE:**

Mallya must be charged before first-time use.

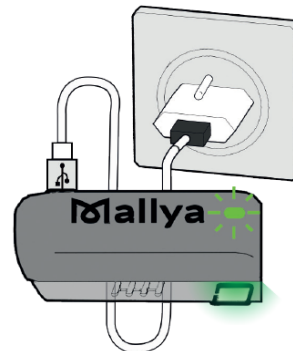
**CAUTION**

- Mallya is supplied with a USB cable. Do not use any other cable. Use the cable supplied with the device to connect it to a USB power port.
- Never use your Mallya for an injection while it is connected to a USB power port and charging.

5.2.1.1 Plug the powered USB cable into the Mallya micro-USB port.

5.2.1.2 Check that the Mallya LED is slowly flashing **green**.

5.2.1.3 Let the battery charge for **at least 10 minutes**.

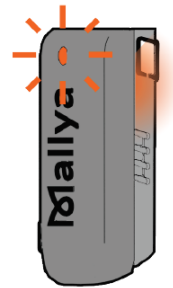
**NOTES:**

- Fully recharging the battery takes approximately 2 hours. When the battery is fully charged, the **green** LED will turn off. You can then unplug the USB power cable.
- Optimal autonomy is reached when Mallya's battery is fully charged. You can then use Mallya for at least 2 weeks.

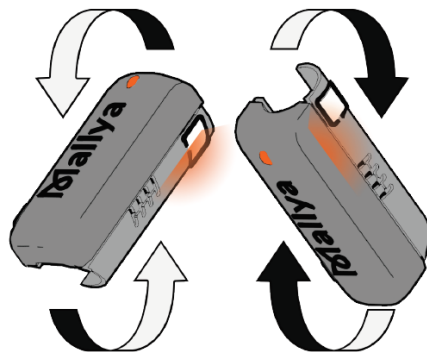
5.2.2 CALIBRATING YOUR MALLYA

5.2.2.1 Disconnect the USB cable from the Mallya base.

5.2.2.2 Check that the Mallya LED is flashing **orange**.

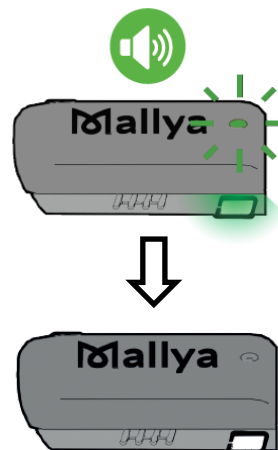


5.2.2.3 **Slowly** tilt the Mallya base side to side to **CALIBRATE**.



5.2.2.4 **Continue tilting until:**

- ✓ The base beeps and the LED light turns **green**.
- ✓ Then the light will turn off.



NOTE:

If the **orange** LED does not light up after disconnecting the USB cable from the Mallya base, it means that the calibration was done automatically. You can go directly to the next section: **Section 5.3. Assembling your Mallya to the insulin pen.**

5.3 ASSEMBLING YOUR MALLYA TO THE INSULIN PEN



CAUTION

The Mallya base and button must be correctly attached onto the pen, otherwise, data will not be transferred.

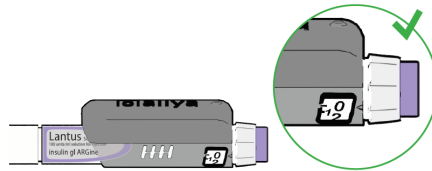
5.3.1 ATTACHING BASE TO PEN

5.3.1.1 Hold the Mallya base so that the clear square plastic window is facing you

5.3.1.2 Align the Mallya base clear square plastic window with the pen dose window, then snap the base onto the pen.



5.3.1.3 Make sure the Mallya base window is perfectly aligned with the pen dose window.



NOTE:

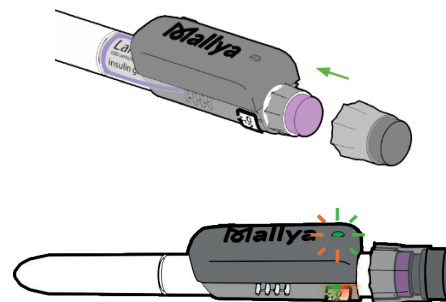
A pen symbol is represented on the side of the Mallya base to help you position the pen in the correct orientation (square window oriented toward the top of the pen).



5.3.2 ATTACHING BUTTON TO PEN

5.3.2.1 Align the Mallya button's grooves with the dose injection button's notches, then insert the Mallya button onto the pen injection button. Make sure the button is properly attached and fully inserted.

5.3.2.2 The Mallya base LED will flash **orange** and **green** when the button and base are properly mounted onto the pen and when the Mallya device is not yet paired.



5.4 PAIRING MALLYA WITH YOUR SMARTPHONE

5.4.1 INSTALLING THE “MALLYA” MOBILE APPLICATION

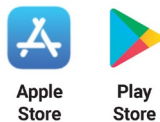
Mallya connects your insulin pen to your smartphone!
Use the Mallya smartphone application to keep track of your insulin doses.

5.4.1.1 *Technical compatibilities*

The list of smartphones compatible with Mallya application is available from your Mallya distributor (contact information at the bottom of the box).

5.4.1.2 *Download the Mallya application and get started*

Download the Mallya application from:



Once installed, select the following icon to open up the application:



The first time you open the application, you are prompted to choose the country in which your insulin was prescribed:



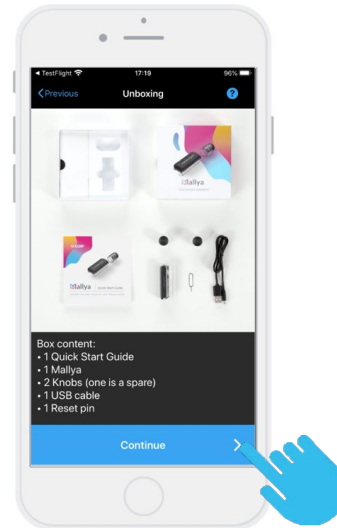
NOTE:

The application is going to be configured with compliant insulins available in the chosen country. A change of this setting would require a complete new installation of the application.

Then:

- the Mallya application General Terms & Conditions of Use (T&Cs) screen is displayed. Please read the terms of use before accepting them and then confirm your choice.
- the Privacy Policy screen is then displayed: make sure you understand it, before accessing the “**Get Started**” screen:



5.4.1.2.1 Select: **"Get started"**:**5.4.1.2.2** A video will guide you through the unboxing steps. Select **"Continue"** to watch the Quick Start video:

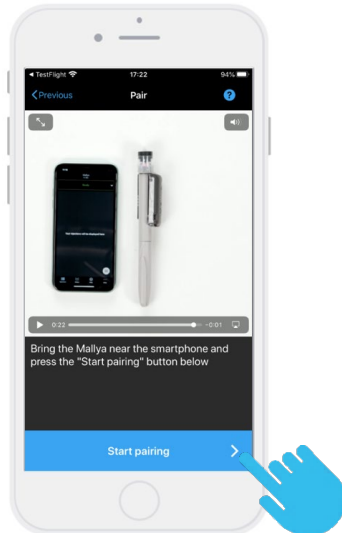
The next screens will guide you through the 4 operations required to start up your Mallya:

- Switch on (as explained in section **5.2.1. Charging your Mallya**)
- Calibrate (as explained in section **5.2.2. Calibrating your Mallya**)
- Assemble (as explained in section **5.3. Assembling your Mallya to the insulin pen**)
- Pair (as explained in the following section **5.4.2. Pairing your Mallya**)

5.4.2 PAIRING

To pair the Mallya device to the BIOCORP Mallya application, follow the steps indicated below:

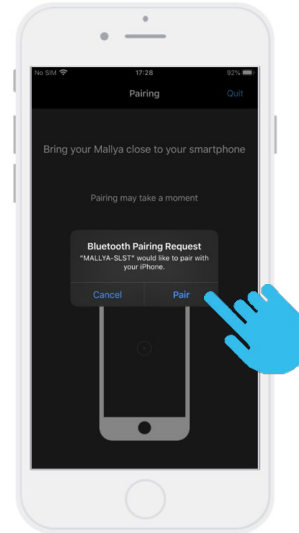
5.4.2.1 Make sure the Mallya base is within 30 cm of your smartphone and select **“Start pairing”**:



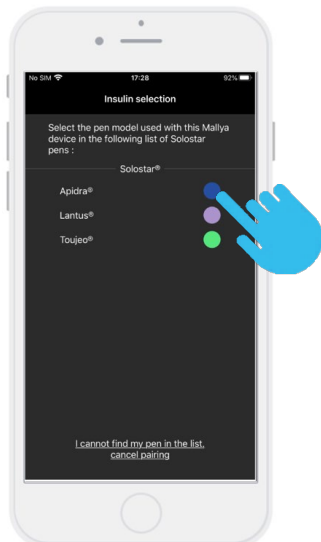
5.4.2.2 Select **“Pair”**

NOTE:

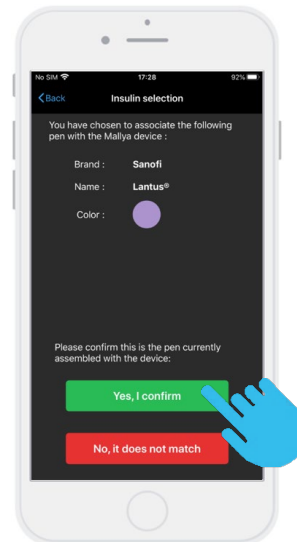
The pairing step may take few seconds.



5.4.2.3 Choose the insulin pen model onto which the Mallya device is assembled from the proposed list.



5.4.2.4 Confirm the pen model currently assembled with the Mallya device.



NOTE:

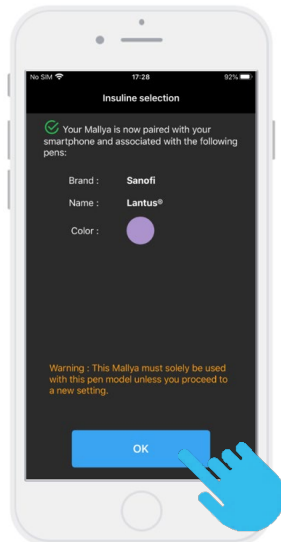
In case you cannot find your pen model in the list: select **“cancel pairing”**. The application will guide you to pair a new Mallya device.

NOTE:

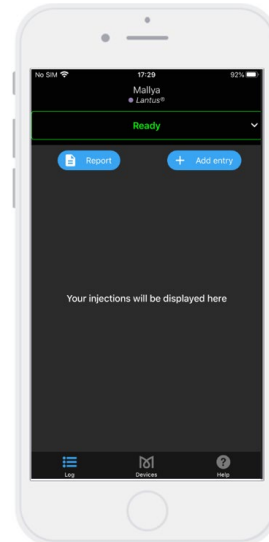
If you select **“No, it does not match”**, the application will return to the previous screen (**section 5.4.2.3.**) to let you choose another pen model.

5.4.2.5 Your Mallya device is now paired with the Mallya application on your smartphone.

Select “OK” to move on to the injection screen.



5.4.2.6 The injection screen is displayed:

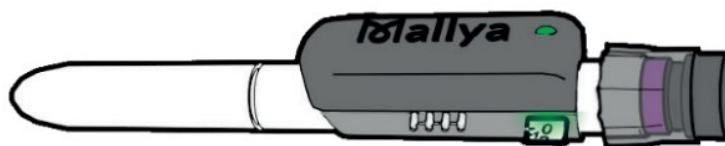


CAUTION

From now on, this Mallya should only be used with this pen model, unless you make a new adjustment.

Your insulin pen can now be used as usual and Mallya will track your insulin intake.

When Mallya is paired to the compatible mobile application and correctly attached to the insulin pen: the Mallya LED is **green**.



NOTE:

The LED of Mallya is **green** when:

- the device is ready for use, or
- the dose setting is in progress, or
- the injection is in progress.

6. OPERATING INSTRUCTIONS

NOTE:

Once Mallya is attached to the insulin pen, the pen should be used just like a normal insulin pen. Refer to the manufacturer's injector pen user manual.

6.1 SECURITY TEST - PRIMING



WARNING

Always perform a priming (safety test) before each injection to ensure that:

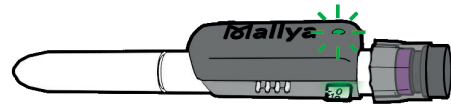
- ✓ Your pen and the needle are working properly,
- ✓ The right dose of insulin will be injected.

If you do NOT perform the priming, you may receive too much or too little insulin (refer to the manufacturer's injector pen user manual).

6.1.1 Follow the injectable insulin pen instructions for use to carry out the priming step.

6.1.2 At the end of the priming step, keep the injection button pressed down:

- While Mallya's **green** LED is flashing,
- Until Mallya emits an audible signal (BEEP) signaling the end of the priming step.



WARNING

If the liquid does not come out of the needle tip during the safety test, do not use the pen and refer to the manufacturer's injector pen user manual for more information to solve the problem.

6.1.3 You can release the pressure on the button when the **green** LED stops flashing and the **"BEEP" signaling the end of priming is emitted.**

The Mallya application will automatically detect a "priming" if:

- **You are priming 1 or 2 unit(s), AND**
- **You perform your insulin injection just after the priming step (within 2 minutes)**

NOTE :

"Priming" will not be displayed in the application right away: it will be displayed once the insulin injection is done, within 2 minutes after priming.



CAUTION

If the time interval between the two consecutive injections exceeds 2 minutes, the application will automatically detect an injection instead of a priming.

NOTE :

You can always change an injection recorded as a "dose" to a "priming", or a "priming" to a "dose" in case it has not been suitably categorized. Please refer to **section 7.2.2.**

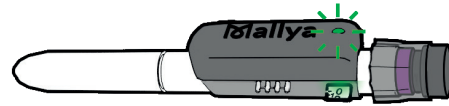
6.2 INJECTION



WARNING

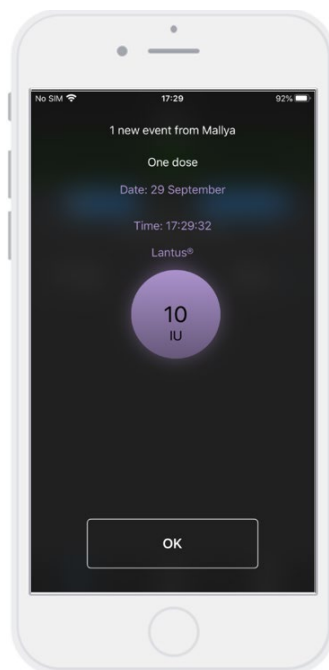
If you are not certain that you injected your insulin, do not start or repeat your injection. Monitor your blood glucose as instructed by your healthcare provider.

- 6.2.1 Check the insulin dose to inject according to the prescription and the type of medication.
- 6.2.2 Turn the button to select the number of units to inject. **The dose indicator should line up with the dose to inject.**
- 6.2.3 Press on the injection button until you return to ZERO (complete dose injection)
- 6.2.4 **Keep the injection button pressed in** and the needle in the skin:
- While the Mallya's **green** LED is flashing,
 - Until Mallya emits an audible signal (BEEP) signaling the end of the injection.
- 6.2.5 You can release the pressure on the button and then remove the needle from the skin when the **green** LED stops flashing and the **"BEEP" signaling the end of injection is emitted.**

**WARNING**

If you do not see ZERO ("0") in the pen dose window: it indicates that the full dose has not been injected.

If the above instructions are followed, the Mallya application will automatically detect an injection:



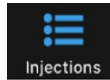
The information corresponding to the injected dose is displayed:
Injected dose, day and time.

7. **MANAGE RECORDED DATA**

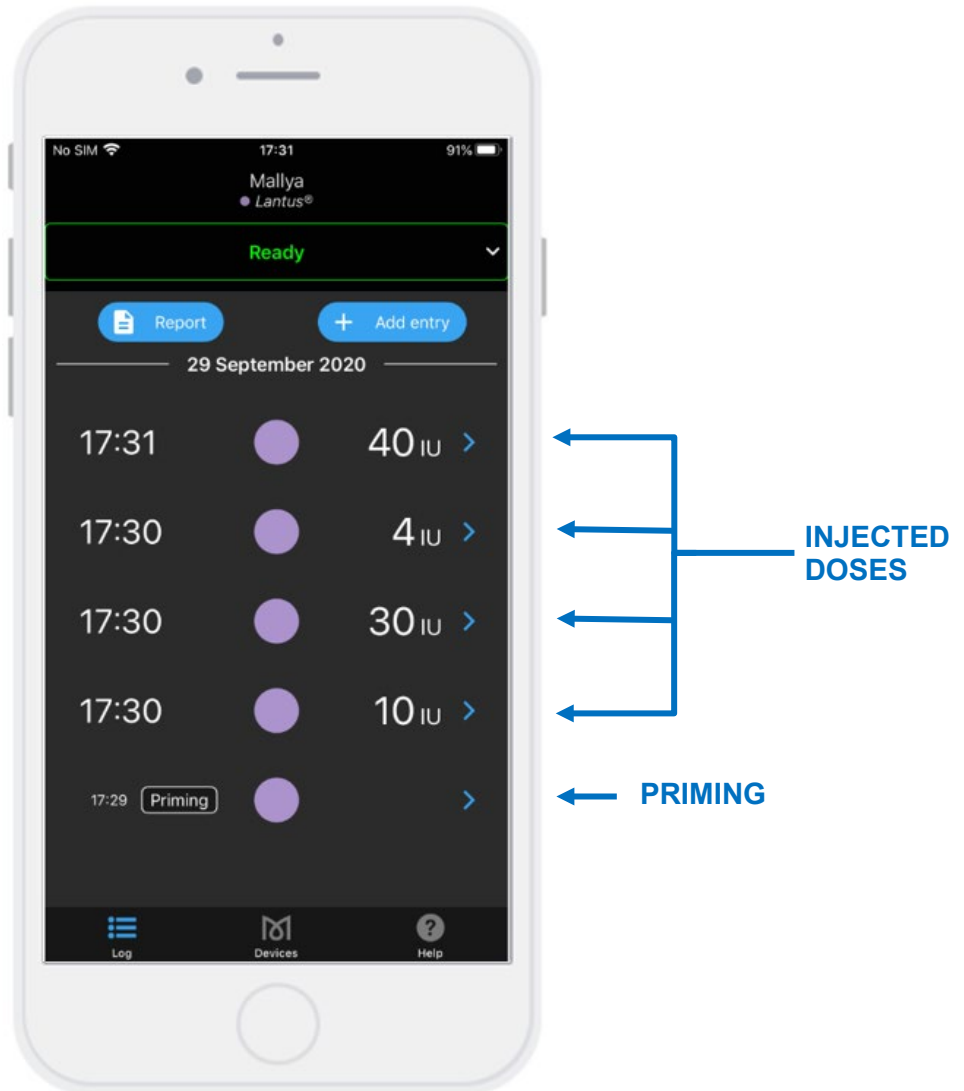
Once data is transferred from a paired compatible Mallya, you can display and manage any recorded data using the Mallya application as follows:

7.1 DISPLAY OF THE RECORDED DATA

Select the **“injections”** icon of the application to display information related to the history of injections:



Injected “doses” or “priming” injections are then displayed as follows:



The Insulin Dose information is displayed:

- Type of injection: **“priming”** or **“dose”**
- Injection **day** and **time**
- Insulin dialed **dose** (in International Unit)
- **Color indicator for the insulin pen used**

7.2 MANAGE YOUR RECORDED DATA

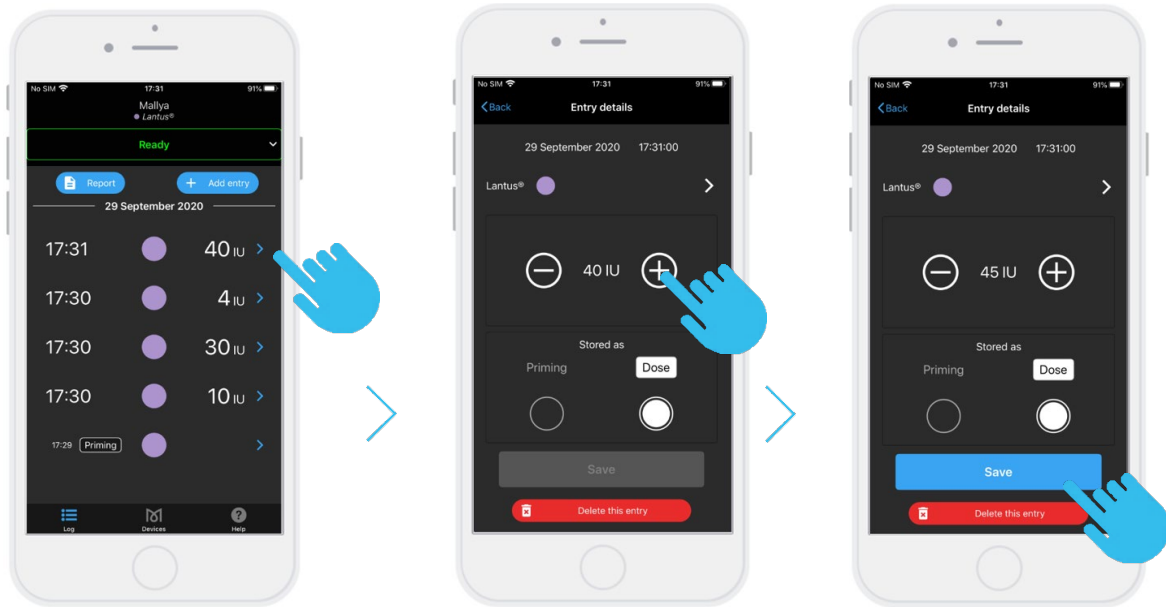
You can manage and edit the following list of items:

- You can change a “priming” or a “dose” quantity (see **section 7.2.1.**),
- You can change an injection recorded as a “dose” to a “priming”, or a “priming” to a “dose” (see **section 7.2.2.**),

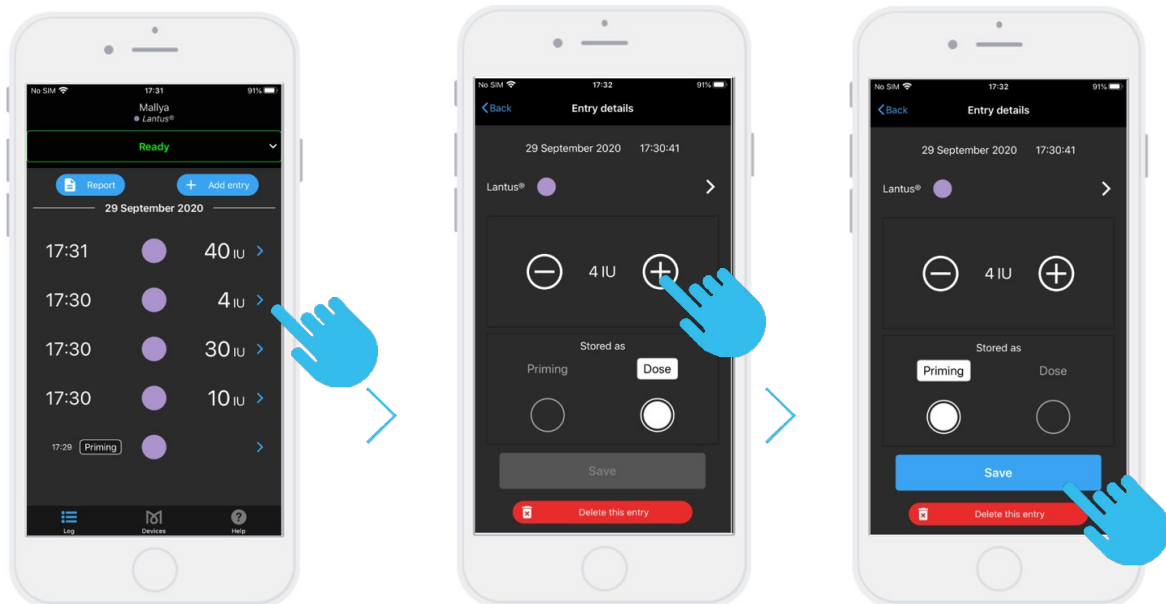
- You can delete a “dose” or a “priming” (see **section 7.2.3.**),
- You can add an injection that was not recorded to the history (see **section 7.2.4.**),
- You can fill in a dose that was not captured by the device (see **section 7.2.5.**).

7.2.1 YOU CAN CHANGE A “PRIMING” OR A “DOSE” QUANTITY

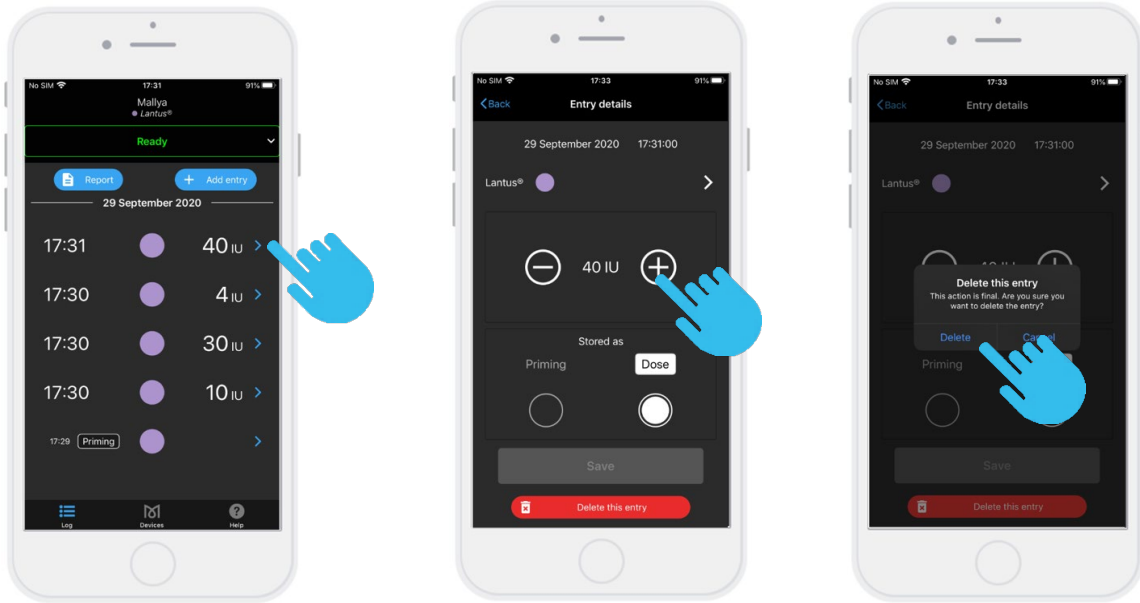
In this example, we want to change the measured dose of 40IU to 45IU:



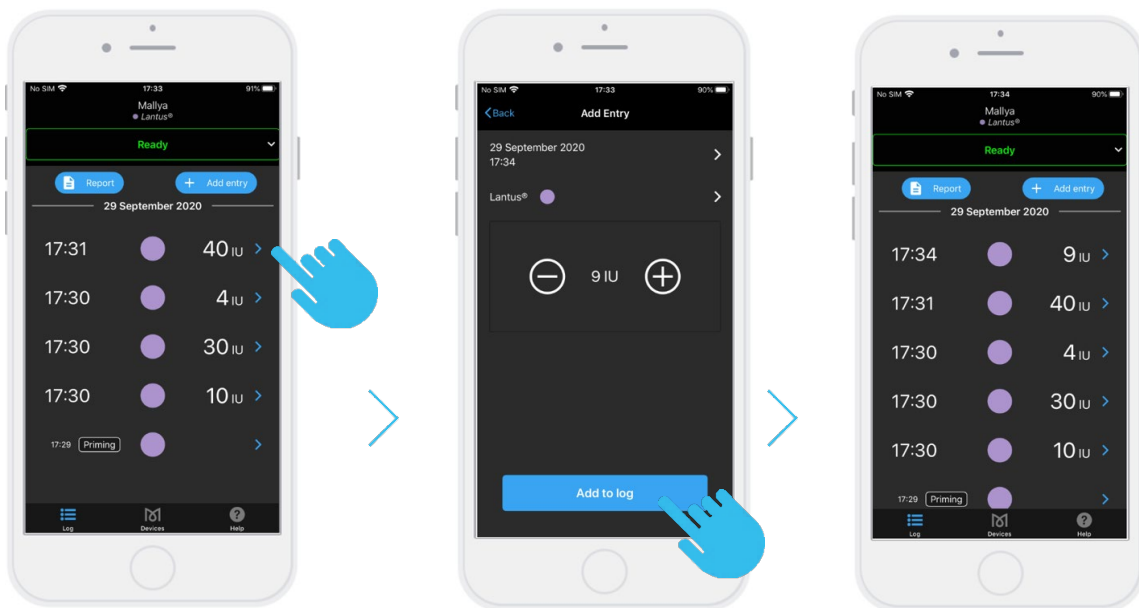
7.2.2 YOU CAN CHANGE AN INJECTION RECORDED AS A “DOSE” TO A “PRIMING”, OR A “PRIMING” TO A “DOSE”



7.2.3 YOU CAN DELETE A “DOSE” OR A “PRIMING”

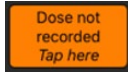


7.2.4 YOU CAN ADD AN INJECTION THAT WAS NOT RECORDED TO THE HISTORY

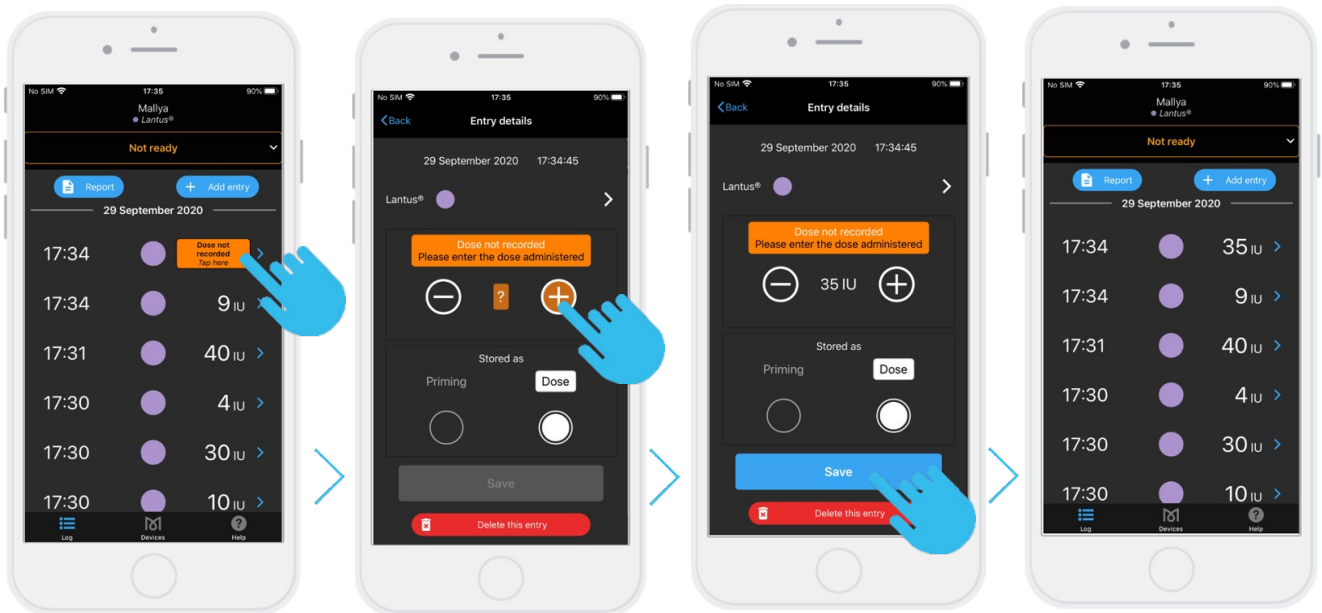


7.2.5 YOU CAN FILL IN A DOSE THAT WAS NOT CAPTURED BY THE DEVICE

The information **“Dose not recorded”** is displayed if a disturbance occurs during the injection. You can add the dose information as follows:

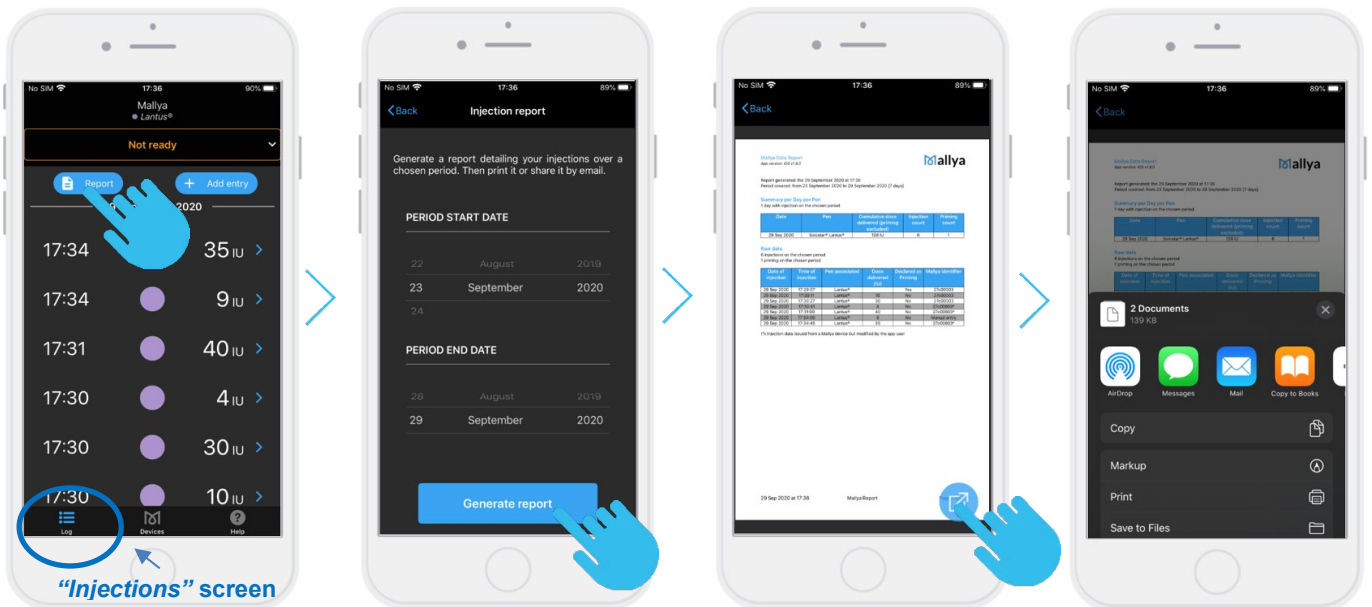


Tap  to modify the information related to the injection:

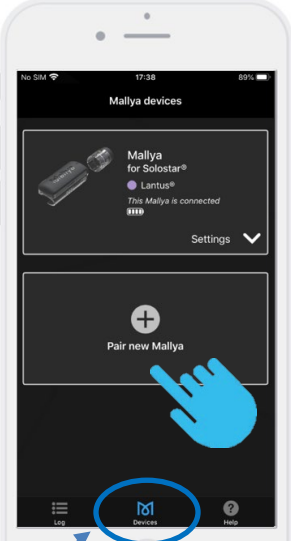
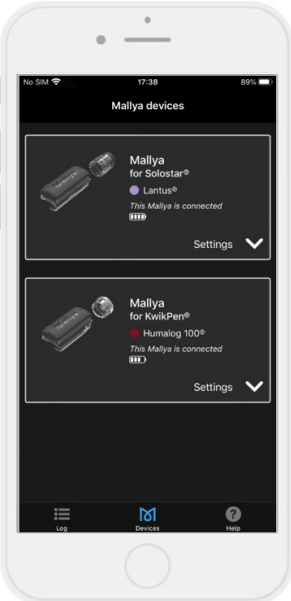
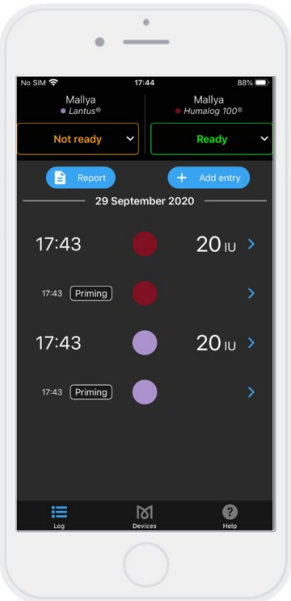



7.3 OTHER FEATURES OF THE MALLYA APPLICATION


7.3.1 GENERATE A REPORT

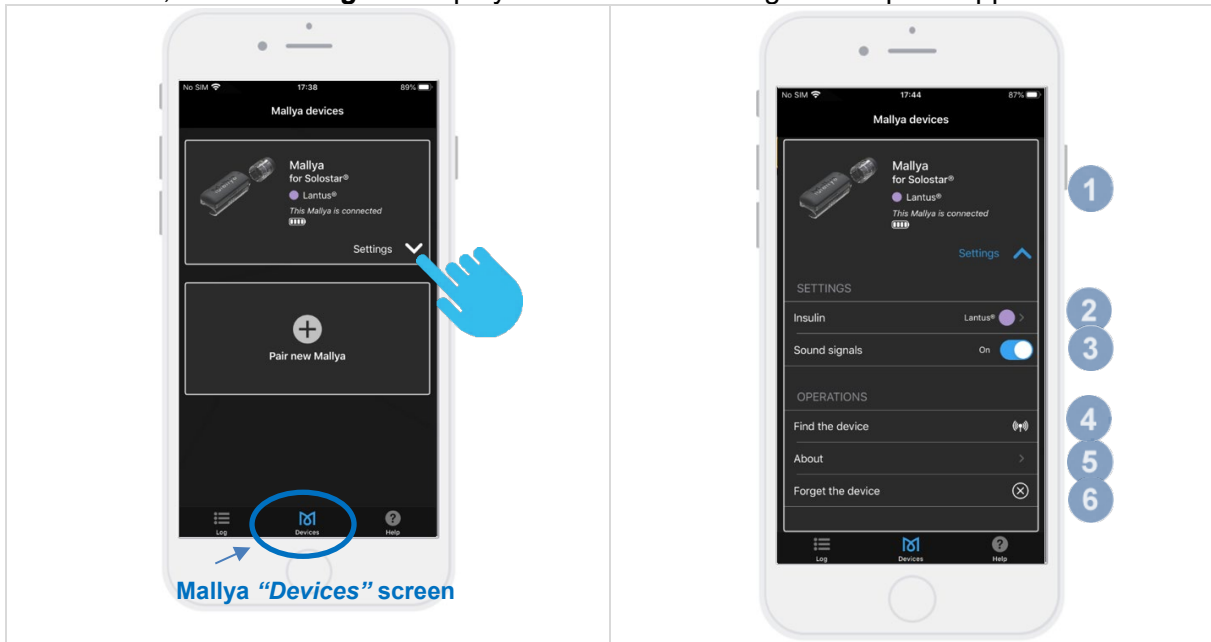




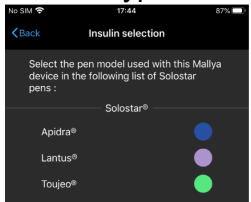
7.3.2 PAIR TWO MALLYA DEVICES TO YOUR MOBILE APPLICATION

 <p>Mallya "Devices" screen</p>	
	<p>Both Mallya devices with associated insulin pens are activated and can be used independently. They both have the status "Ready".</p> <p> WARNING Make sure you do not switch the pens between the two Mallya devices. In case you have any doubt, you can use the "Find the device" functionality to identify the Mallya as explained in the section below (section 7.3.3.)</p>

7.3.3 SETTINGS

Select , then **“Settings”** to display the screens allowing to set up the application:



<p>1</p>	<p>Battery status : </p> <p>When Mallya is fully charged (after approximately 2 hours): 4 bars are displayed</p> <p>Device status: “This Mallya is connected” or “This mallya is disconnected since ...”</p> <p> CAUTION</p> <p>A Bluetooth connection is necessary to transmit the injection data.</p>
<p>2</p>	<p>Tap “Insulin” to select the pen model onto which Mallya is currently assembled.</p> <p>Each color indicator is associated to a type of insulin pen:</p> 

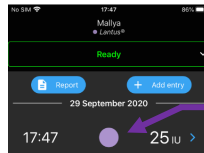


CAUTION

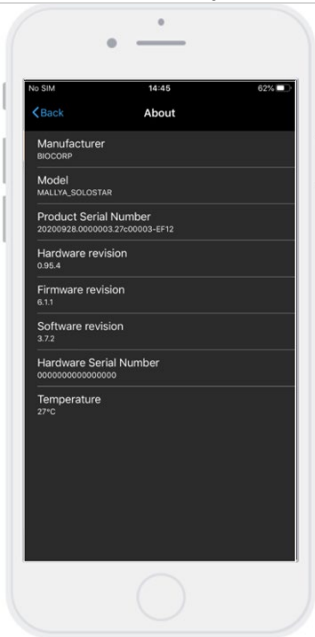

It is important to check, before each injection, that the type of insulin selected in the application corresponds to the type of insulin indicated on the label of your pen.

The color indicators are also displayed in the injections screen so that you can **differentiate between the types of insulin injected** in the injection history.

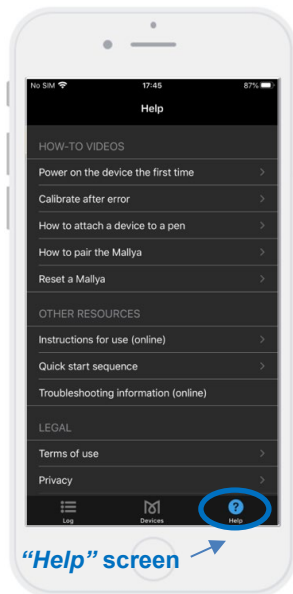
Example:



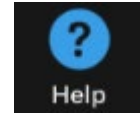
LANTUS (example)

3	Sound signals: you can activate / deactivate the silent mode.
4	Find the device: select this option to make the Mallya ring* in order to identify or locate the device. *Only if the Mallya is on “standby”.
5	<p>“About” Information about Mallya application:</p> <div style="display: flex; align-items: center;"> <div style="flex: 1;">  </div> <div style="flex: 1; padding-left: 20px;"> <ul style="list-style-type: none"> - Manufacturer - Model - Serial number - Hardware revision - Firmware revision - Software revision - Temperature </div> </div>
6	“Forget the device” Select “Forget Mallya” to unpair Mallya.
	<p>CAUTION</p> <ul style="list-style-type: none"> - If you unpair your Mallya while it is out of range, you will have to reset the system before pairing your Mallya again, in accordance with the procedures described in the section 9.3. - Reset Instructions. - Mallya has been designed to work with ONE insulin pen. If you unpair your Mallya base from the insulin pen, you MUST reselect your insulin pen medication.

7.3.4 “HELP” SCREEN

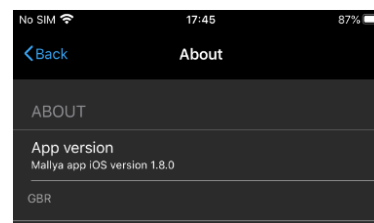


Video tutorials and other resources are available from the **“Help”** screen:



The legal notices concerning the Terms of use, Privacy and licenses and are also available.

The Version of the application is displayed in the **“About”** tab:

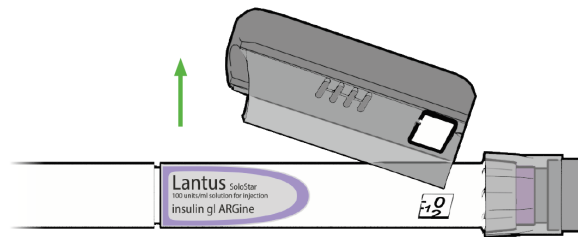


8. TRANSFERRING MALLYA TO A NEW PEN

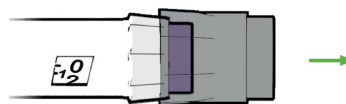
8.1 REMOVE MALLYA FROM THE EMPTY PEN

Follow the procedure indicated below when your insulin pen is empty:

- 8.1.1** Remove the Mallya base from the insulin pen. Use your thumb to press on Mallya and to remove it from the pen.



- 8.1.2** Then, remove the Mallya button from the pen.



8.2 ATTACH YOUR MALLYA TO A NEW PEN

Follow **section 5.3.** on assembling your Mallya to the new insulin pen. Once properly assembled to the new pen, the Mallya LED indicator is **green**.

NOTE :

It is not necessary to pair your Mallya again when changing the pen (unless your system has been reset - **see section 9.3. Reset instructions**).



CAUTION

- Mallya models are only compatible with the disposable insulin pens (Solostar, Kwikpen, Flexpen) they are designed for. Do not attach to, pair or use with any other insulin pen types.
- If you need to inject more than the number of units left in the pen, you may either:
 - 1) inject the amount left in your pen and then use a new pen to deliver the rest of your dose: the Mallya application will then display 2 successive injections, or
 - 2) get a new pen and inject the full dose: the Mallya application will display one full dose injection.

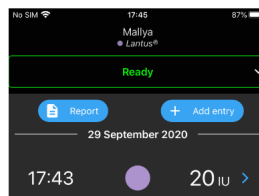


CAUTION

When Mallya is transferred onto a new pen, the application automatically detects a “**mounting event**” (eg.: your base and / or the button have / has been removed from the original pen). In this situation, the application will require a confirmation of the pen currently assembled with Mallya.

Example:

8.2.1 Injection screen before transferring Mallya onto a new pen:



8.2.2 Remove Mallya from the empty pen / attach Mallya onto a new pen (base and / or button)

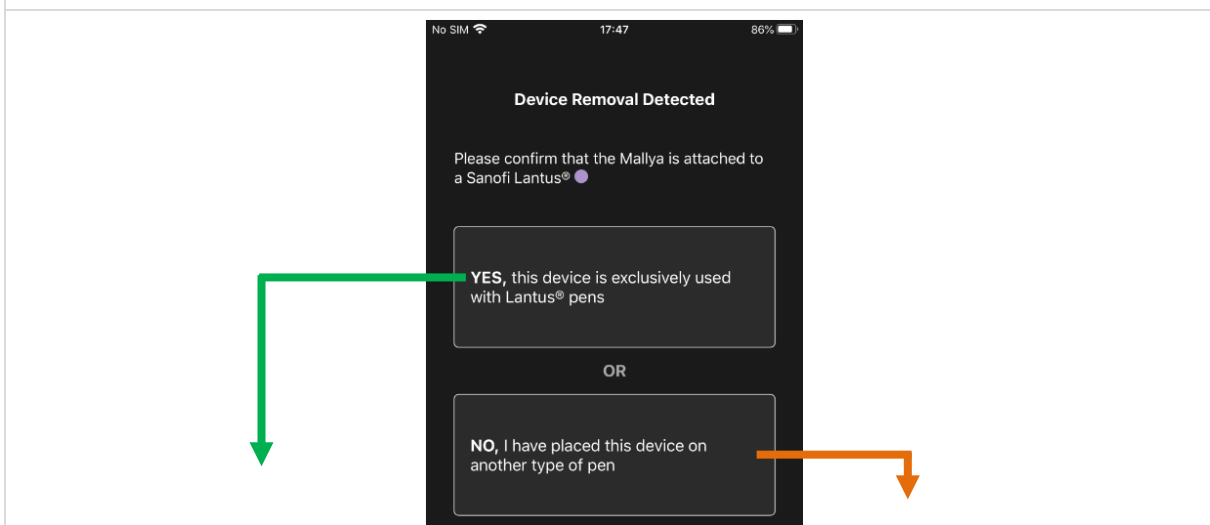


8.2.3 On the next PRIMING or DOSE INJECTION:



A MOUNTING EVENT IS DETECTED!

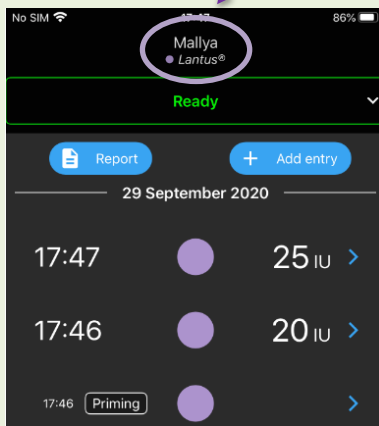
The following screen is displayed with 2 options to choose from:



YES, this device is exclusively used with the same type of pen (same as the original pen).

In this case, the injection dose will be displayed in the injection history as if no mounting event had taken place.

Example with the "LANTUS" pen model (Pen unchanged)

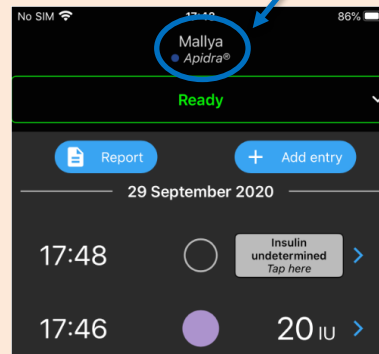


NO, I have placed this device on another type of pen.

1) In this case, the screens in **sections 5.4.2.3., 5.4.2.4., and 5.4.2.5.** are displayed. You have to select the new pen model on which your Mallya is currently assembled.

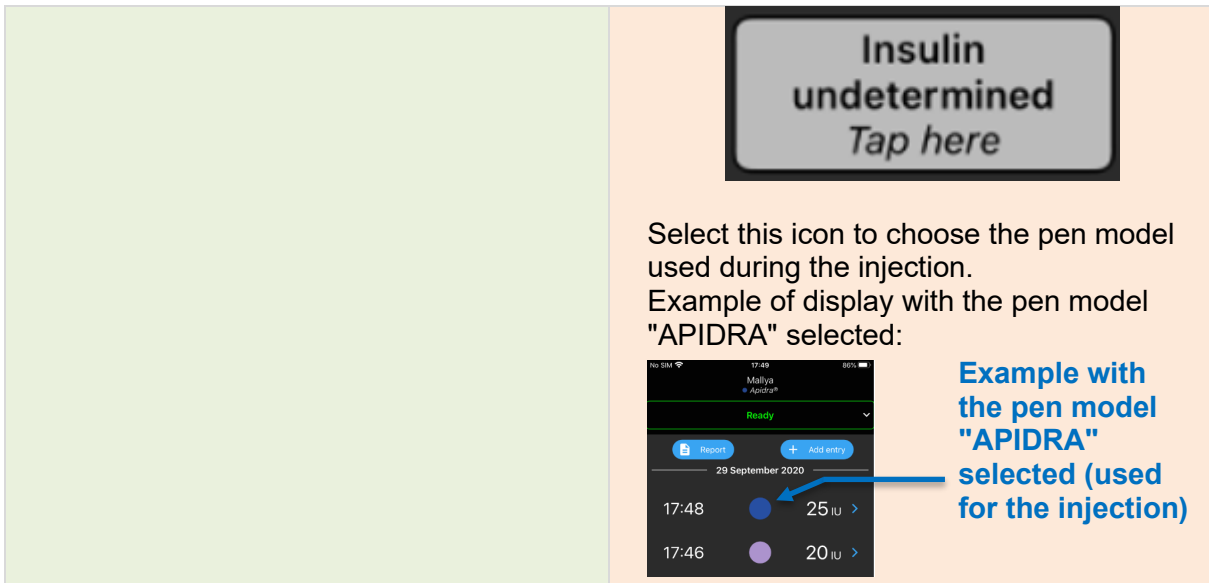
The new pen model currently assembled is then displayed at the top of the screen (Apidra in the example below):

Example with a new "APIDRA" pen model selected (pen model currently assembled to Mallya)



2) Following your change of pen model, some new injections (or primings) are pending confirmation of the insulin type that has been used.

Those injections are displayed in the list above with a grey colored circle and the **"insulin undetermined"** text:



Insulin undetermined
Tap here

Select this icon to choose the pen model used during the injection.
Example of display with the pen model "APIDRA" selected:

Example with the pen model "APIDRA" selected (used for the injection)

8.3 COLLECT YOUR INJECTION DATA FROM MALLYA AFTER SMARTPHONE DISCONNECTION

Your smartphone may disconnect from the Mallya system in case Bluetooth is out of range, or the battery is empty, or for other potential reasons. In this case, you can still use Mallya to record your insulin doses and, on the next connection, data will be automatically transferred from Mallya to your smartphone.

Upon re-connection, 2 options are possible:

- Your Mallya application will display the recorded injections data as usual if no **mounting event** occurred during the disconnection period (eg.: your base and / or the button have / has not been removed from the original pen in the meantime), or
- Your Mallya application will display the 2 options indicated in **section 8.2.4.** if a mounting event occurred (the Mallya base and / or the button have / has been removed from the original pen during the disconnection period).

Follow the instructions in **section 8.2.4.** to indicate:

- ✓ the pen model on which your Mallya is currently assembled, and
- ✓ the pen model used for the injections (or primings) during the disconnection period.



CAUTION

Upon a first injection following a disassembly, make sure you reconnect the device with the application as soon as possible to avoid "Insulin undetermined" doses.

NOTE:

Bluetooth communication limits:

The compatible application can inform you that Bluetooth communication has been interrupted. Indeed, if the compatible application and the Mallya device are used in a noisy environment (in terms of an electromagnetic signal close to 2.4 Ghz), communication will no longer be possible between them and the connection will stop. However, the Mallya device will continue to track the history of all your injections. As soon as the disturbing electromagnetic signals disappear, the compatible application and the Mallya device will be able to communicate again.

9. TROUBLESHOOTING



CAUTION

- Never attempt to access the internal hardware of the device.
- When a functional testing is not successful and if the given recommendations do not solve the issue, you are prompted to contact a BIOCORP PRODUCTION authorized dealer.

9.1 TROUBLESHOOTING MALLYA WITH VISUAL AND AUDITIVE BASE SIGNALS

When a visual or audible signal occurs on your Mallya, check the cause and follow the indications listed below to solve the issue:

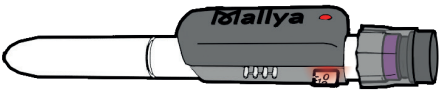

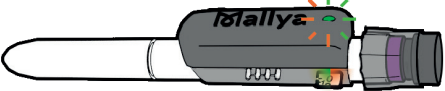

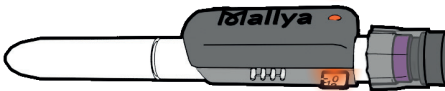
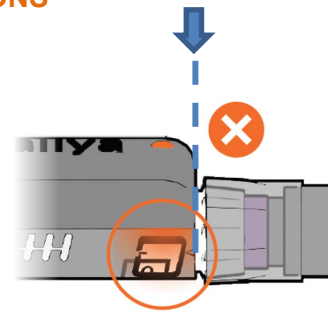
SIGNAL	CAUSE	TROUBLESHOOTING STEPS
<p>Red LED</p> 	Mallya error	<p>Remove Mallya from pen. Re-calibrate Mallya if the light indicator is flashing orange (see section 5.2.2.) If the issue persists and the light is still red: reset the system (see section 9.3.) Then, try to pair Mallya to your smartphone (see section 5.4.2.) If the problem is not solved, please contact a BIOCORP PRODUCTION authorized dealer.</p>
<p>Orange LED (rapid flashing)</p> 	Calibration in progress:	<p>Slowly tilt the Mallya side to side to calibrate (see section 5.2.2.) A green light will appear for 2 seconds upon successful calibration (with a beep, then the green light will turn off).</p>
<p>Alternating orange and green flashing (rapid flashing)</p> 	Mallya device is correctly positioned onto the pen but must be paired.	<p>Pair Mallya to your smartphone (see section 5.4.)</p>
<p>Orange LED (slow flashing) (every 15 seconds)</p> 	Battery is low.	<p>Plug in and charge the Mallya base (see section 5.2.1.)</p>
<p>Orange LED</p> 	<p>Mallya position error on pen, Or The button is not turned back to the dose "0"</p>	<p>Make sure that:</p> <ul style="list-style-type: none"> - the Mallya window and the pen dose window are properly aligned, and - the Mallya button is correctly pushed onto the pen <p>(please see the "cautions recommendations below this table")</p> <p>Or</p> <ul style="list-style-type: none"> - the button is turned back to the dose "0".

Table 14 - Troubleshooting with visual and auditive base signals

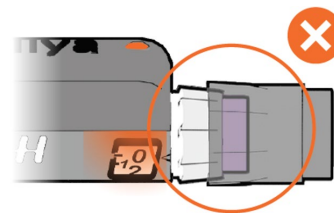
**CAUTION****ORANGE LED – TROUBLESHOOTING RECOMMENDATIONS**

The Mallya base light indicator (LED) remains **orange** if:


- the clear square plastic window of the Mallya base and the dose window of the pen are not correctly aligned, or
- if the base is mounted too low / too high (↓ the top of the Mallya base must be aligned with the top of the pen, at the base of the dose button on the pen),



- or, if the Mallya button is not pushed on enough.



In this case, it is necessary to:

- adjust and align the position of the windows: 
- or to raise or lower the position of the Mallya base on the pen,
- or, to push the Mallya button onto the pen,

until the Mallya base LED flashes **green** and **orange** if Mallya is not paired (if Mallya is paired, the light indicator is **green**).

9.2 TROUBLESHOOTING MALLYA WITH THE APPLICATION

This section describes the troubleshooting procedures you can perform if there is a problem with your Mallya.

Find the problem you are experiencing among those listed in the following list and apply the appropriate solution.

If the recommended solutions do not eliminate the problem or if you encounter an unlisted problem, please contact a BIOCORP PRODUCTION authorized dealer.

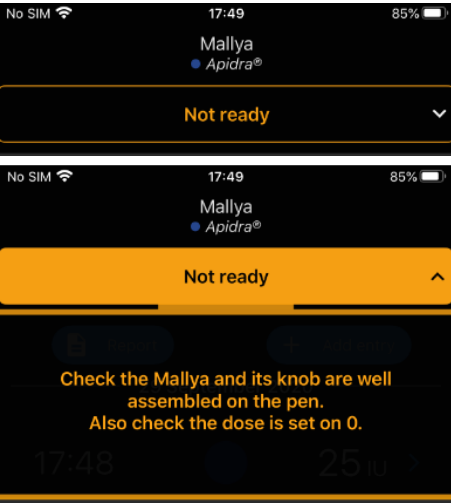
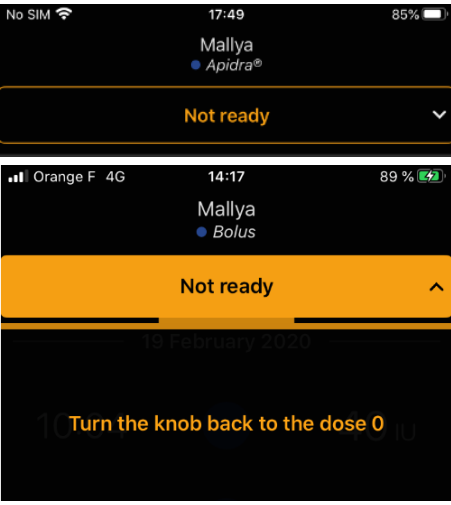
INDICATION	CAUSE	TROUBLESHOOTING STEPS
	<p>Mallya's base not detected</p>	<ol style="list-style-type: none"> ① Select: “Not Ready” ② Check that the Mallya device is correctly assembled on the pen (see section 5.3.)
	<p>Button of the pen not at ZERO</p>	<ol style="list-style-type: none"> ① Select: “Not Ready” ② Turn the button of the pen back to the ZERO position.

Table 15 - Troubleshooting with app.

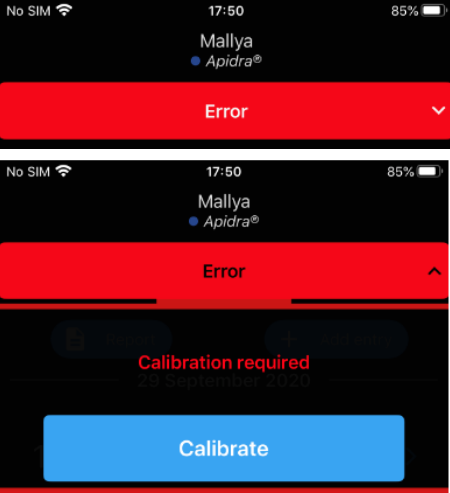
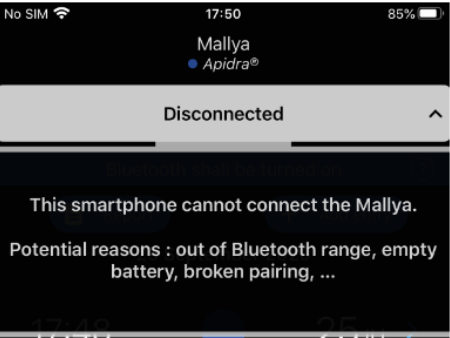
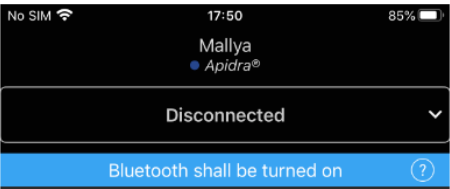
INDICATION	CAUSE	TROUBLESHOOTING STEPS
	<p>Calibration error</p>	<ol style="list-style-type: none"> ① Select “Error” ② Perform the calibration as indicated in the Mallya device instructions for use (see section 5.2.2.)
	<p>Mallya is maybe too far away from your smartphone and therefore disconnected <i>Or</i></p> <p>A communication error occurred</p>	<ol style="list-style-type: none"> ① Move your Mallya device and your smartphone closer to one another. ① Select “Disconnected” ② Reset Mallya as explained in the Mallya device instructions for use (see section 9.3.)
	<p>Bluetooth issue or signal lost</p>	<ol style="list-style-type: none"> ① Check that the Mallya device is powered ON. ② Check that the Mallya device is connected to the App. ③ Check the Bluetooth connection status on your mobile phone. <p>If the problem is not solved, please contact a BIOCORP PRODUCTION authorized dealer.</p>

Table 16 - Troubleshooting with app. (next)

9.3 RESET INSTRUCTIONS

The reset procedure of Mallya may be necessary:

- If Mallya is not working properly (no response, etc...),
- If you need to pair Mallya with another mobile phone (smartphone),
- If you want to delete your personal health data from the device.

PROCEDURE:

9.3.1 Disassemble Mallya as indicated **section 8.1**.

9.3.2 Flip Mallya over so that you can see the following indications:



9.3.3 Take the Reset Key: 

9.3.4 Insert the Reset Key into the hole shown below and WAIT until 3 beeps are emitted before removing the key.



9.3.5 Then follow **section 5**. to prepare your device for a new operation.

10. MAINTENANCE AND INSPECTION

10.1 MALLYA DEVICE LIFETIME

Mallya and accessories' expected lifetime is 2 YEARS.

You are not required to perform a periodic maintenance of the device.

10.2 MALLYA APPLICATION UPDATES

Check each week on your smartphone that there is no Mallya application update available.

10.3 CLEANING YOUR MALLYA

When the surface of Mallya is dirty, follow the steps indicated below to clean it:

- ✓ Disconnect the USB cable from Mallya.
- ✓ Wipe the surface of the device with a slightly damp lint-free cloth.
- ✓ You can wipe off persistent dirt with a soft lint-free cloth slightly moistened: with water containing a small amount of neutral cleaning agent, or with ethanol 95%.
- ✓ Dry with a soft, lint-free cloth.
- ✓ Avoid moisture from reaching the micro-USB opening.

**WARNING**

- Disconnect the USB cable before cleaning Mallya.

**CAUTION**

- Do not wipe the surface of Mallya with chemical products or solvents (e.g. acetone) (other than those specified in this cleaning procedure) as it could lead to discoloration or deterioration.
- Please remember that the Mallya is **not waterproof**:
 - ✓ Do not immerse the device in water and do not clean it under running water.
 - ✓ Do not expose the device to moisture. Do not use the device in the bathroom or in areas with high temperature, humidity, dust or rain.
- Do not share Mallya with other people to prevent infection.

10.4 MAINTAIN WATER, DUST AND LIGHT RESISTANCE

The device is rated **IP22** using the Ingress Protection rating system.

As defined in the IEC standard 60529, the IP code (or Ingress Protection code) classifies and rates the degree of protection provided by mechanical casing and electrical enclosure against the intrusion of solid objects, dust, accidental contact, and water.

Mallya is rated **IP22** using this Ingress Protection rating system: your device has shown to be water and dust resistant in certain circumstances. Despite this classification, your device is no manner impermeable to water damage.

NOTE:

If any liquid is found to have entered your device components (inside the sealed system): your device's warranty will be void.

Follow the next tips carefully to prevent damage to the device (operational or cosmetic issues):

- Whenever your device gets **wet**, dry it thoroughly with a soft, dry and clean cloth. You should dry the inside of the charging port before inserting a power connector to charge your device. If the charging port is not fully dry, your device may operate abnormally. For example, it may charge more slowly or overheat.
- Do not expose the device to direct **sunlight**.
- If the device is dropped or receives an **impact**, its water and dust resistance may be impaired.

11. TECHNICAL SPECIFICATIONS & PERFORMANCES

11.1 ELECTRICAL RATINGS



CAUTION

Make sure you connect the Mallya USB cable to a power source compliant with the IEC 60601-1.

USB CHARACTERISTICS	
Input voltage	5V DC 2A
Min Current	500mA
Ingress Protection	IP 22
BATTERY CHARACTERISTICS	
Battery	Li-ion rechargeable : Li-ion 3,7V-130mAh
Model Number	GEB401730 / FT401235P
Operating time with fully charged battery	2 weeks
Charging time for fully charged battery	Full charge in 2.5 hours

Table 17 - Mallya electrical information

You can connect the supplied USB cable to the USB port of your PC or to an AC adaptor suitable for your region, with the following characteristics:

AC ADAPTOR (NOT PROVIDED)	
External Module with automatic adaptation of the voltage: no selection is required.	
Input voltage range	90-264 V
Frequencies range	47-63 Hz
Category	II (double insulation)
Output voltage	5V DC
Output current	500mA – 2A

Table 18 – Battery charging information

11.2 MATERIALS

MALLYA PART	PEN MODEL	MATERIALS
Mallya base	All	PC/ABS (cover) Copolyester (body)
Mallya button	FLEXPEN® NOVO NORDISK	Polypropylène and
	SOLOSTAR® SANOFI	POM
	KWIKPEN® ELI LILLY	TPE

Table 19 - Materials

11.3 ACCURACY

MEASUREMENT ACCURACY	99%
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Table 20 – Accuracy on test bench



CAUTION

External factors may affect the dose measurement accuracy.

Factors	Affect the measurement	Does not affect the measurement
Ambient Temperature		√
Magnetic disturbance	√	

Table 21 - External factors and accuracy of the displayed value

To display the accurate doses, please follow the recommended conditions of use.

12. ELECTROMAGNETIC COMPATIBILITY

12.1 GENERAL PRECAUTIONS AND WARNINGS



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.
- 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.
- 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 [ME EQUIPMENT or ME SYSTEM], 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 this enclosed document.

12.2 ELECTROMAGNETIC EMISSIONS

EMISSION	
Emissions RF:	CISPR 11 / Groupe 1 Classe B
Distortions Harmoniques IEC 61000-3-2:	Non applicable
Fluctuations de tension et Flicker IEC 61000-3-3:	Non applicable

Table 22 - Emission

12.3 ELECTROMAGNETIC IMMUNITY

IMMUNITY				
Test	Requirements		Conformity Level	
<i>Electrostatic discharges (ESD) IEC 61000-4-2</i>	± 8 kV contact discharges $\pm 2/4/8/15$ kV air discharges		± 8 kV contact discharges $\pm 2/4/8/15$ kV air discharges	
<i>Radiated RF EM fields IEC 61000-4-3</i>	10V/m 80MHz-2.7GHz 80% AM à 1kHz		10V/m 80MHz-2.7GHz 80% AM à 1kHz	
<i>Proximity fields from RF wireless Communications equipment IEC 61000-4-3</i>	<i>Fréquency (MHz)</i>	<i>Modulation</i>	<i>Level (V/m)</i>	<i>CONFORMITY LEVEL (V/m)</i>
	385	Pulse Modulation: 18 Hz	27	27
	450	Pulse Modulation: 18 Hz	28	28
	710 – 745 - 780	Pulse Modulation 217 Hz	9	9
	810 – 870 - 930	Pulse Modulation: 18 Hz	28	28
	1720 – 1845 - 1970	Pulse Modulation 217 Hz	28	28
	2450	Pulse Modulation 217 Hz	28	28
5240 – 5500 - 5785	Pulse Modulation 217 Hz	9	9	
<i>Electrical transients / bursts fast IEC 61000-4-4</i>	Supply: ± 2 kV I/O lines : ± 1 kV Repetition rate : 100 kHz		Supply: ± 2 kV I/O lines : ± 1 kV Repetition rate : 100 kHz	
<i>Surges IEC 61000-4-5</i>	Line-to-line: $\pm 0,5$ kV, ± 1 kV Line-to-ground $\pm 0,5$ kV, ± 1 kV, ± 2 kV		Non applicable	
<i>Conducted disturbances induced by RF fields IEC 61000-4-6</i>	3 V 0,15 MHz – 80 MHz 6 V in ISM and radio-amateur band between 0,15 MHz and 80 MHz 80 % AM à 1 kHz		3 V 0,15 MHz – 80 MHz 6 V in ISM and radio-amateur band between 0,15 MHz and 80 MHz 80 % AM à 1 kHz	
<i>RATED power frequency magnetic fields IEC 61000-4-8</i>	30A/m		30A/m	
<i>Voltage Dips and Interruptions: IEC 61000-4-11</i>	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° et 315° 0 % UT; 1 cycle at 0° 70 % UT; 25/30 cycles at 0° 0 % UT; 250/300 cycles		Non applicable	

Table 23 - immunity

12.4 RADIO MODULE SPECIFICATIONS

Mallya integrates a BLE module with the following characteristics (Reception / Emission):

Bluetooth LE type	BLE
Frequency band	[2400 – 2483.5] MHz
Number of channels	40
Spacing channel	2MHz
Channel bandwidth	1MHz
Max EIRP (Equivalent Isotropic Radiated Power)	-5,5dBm

Table 24 - Electromagnetic immunity

The undersigned BIOCORP PRODUCTION declares that the radio equipment of the Mallya type complies with Directive 2014/53/EU. The full text of the EU Declaration of Conformity is available at the following internet address : my-mallya.com

13. DISCLAIMER

The warranty is valid for twelve months from the date of purchase (unless a more advantageous period has been contractually agreed between the manufacturer and the distributor. Please check with your local distributor for more information).

The warranty covers any fault, material damage or manufacturing defect in products used in accordance with the instructions in this leaflet.

This warranty does not preclude the application of current legal guarantees under national legislation governing the sale of consumer goods.

BIOCORP PRODUCTION is not responsible for:

- Any damage resulting from disregarding the instructions described in this manual.
- Any damage resulting from malfunctioning caused by a combination of connected devices.
- Any damage resulting from transport, improper use or negligence, incorrect handling, modification of the system, poor maintenance, use of incorrect voltage, lightning, infiltration of sand or water, use of parts or accessories not provided or recommended in this manual by BIOCORP PRODUCTION.