01-2021

Instructions For Use

Mallya®

*Designed for Flexpen® **Novo Nordisk***	*Designed for Kwikpen® **Eli Lilly***	*Designed for Solostar® **Sanofi***

Embedded software versions 3.6. and over

BIOCORP

Helping you keep track of your insulin doses

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SYMBOLS IN THESE INSTRUCTIONS FOR USE

Symbol	Meaning	Signification
	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
	CAUTION	Consult the Instructions for Use documents
	CAUTION	Do not use if the packaging is damaged

Table 1 - Symbols used in these IFU (Instructions for Use)

*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.

STORAGE

Store Mallya at room temperature between 59°F to 95°F (15°C to 35°C).
Keep Mallya away from:

- Water
- Pacemakers and defibrillators
- Metallic parts
- Small children. Your Mallya contains small parts that may cause injury or become a choking hazard.

WARNINGS & CAUTIONS

NOTES:

- Mallya must only be used for the intended use described in this Instructions for Use document.
- Read the Quick Start Guide and these Instructions for Use before you use Mallya for the first time. Keep these instructions in a safe place.
- Warning and Caution statements are included throughout this document.

WARNING: improper operation may result in serious injury or death

- **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 not waterproof and holds no protection 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.

- Avoid using Mallya near PACEMAKERS and DEFIBRILLATORS.
- Mallya contains a magnet, avoid contact with metallic parts during use.
- Do not disassemble, modify or repair the instrument by yourself. Refer all servicing to the BIOCORP PRODUCTION authorized dealer.
- Do not expose the device to temperatures above 40°C (104°F) or flames.
- Never try to access the internal hardware of your device.
- **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 sharp edges that may cause injuries or that may detach and create a choking hazard.
- Mallya must only be paired with a compatible mobile application.
- 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.
- Never install a mobile application from unofficial stores on your phone.
- Jailbreak or rooted phone exposes it to dangers and will invalidate the Mallya warranty.

CAUTION: improper operation may result in bodily injury or property damage

- The Instructions for Use should be accessible to you at all times and you should consider all instructions carefully before using the device.
- Mallya is intended for **Over the Counter use** and is not a prescription device.
- Protect your personal health data by using a password on your smartphone (protection with the phone password).
- Do not wipe the surface of Mallya with chemical products or solvents (e.g. acetone) (other than those specified in the cleaning procedure – *see **step 10.3.)*** as it could lead to discoloration or deterioration.
- 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.
- 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. Other cables may create problems or interfere with other electronic devices.

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

FCC STATEMENTS

MALLYA
Models: 0273694-KWKP, 0273778-FLXP, 0273777-SLST
FCC ID: 2AYCW-EZL

CAUTION:

- 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.
- The user that 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.

NOTE:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception which can be determined by turning the equipment off and on, the user is encouraged to try to correct interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

0. DIRECTIONS FOR USE

0.1 FEATURES

Mallya is composed of a base and a knob 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.

0.2 INTENDED USE

Indications for use:
Mallya can be used either for **type I or type II diabetes**.
The device is intended **to assist patients maintain accurate records of their insulin usage.**

WARNING
The device should not be used by children and women with gestational diabetes.

Contraindications:
There are no known contraindications to the use of Mallya.

Intended Patient population:
Intended users are **patients and medical professionals.**
Mallya can only be used by patients already familiar with the pen injectors: **Kwikpen®** (Eli Lilly), **Solostar®** (Sanofi) or **Flexpen®** (Novo Nordisk).

Over the Counter (OTC) Medical Device:
Mallya is intended for **Over the Counter use** and is not a prescription device.

Sterility information:
Mallya is intended to be non-sterile.

Adverse reaction information:
There are no known adverse reactions to the use of Mallya.

Intended use location:
The device is intended for use in a **medical office or at home.**

1. MALLYA COMPATIBILITIES WITH PENS

WARNING

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

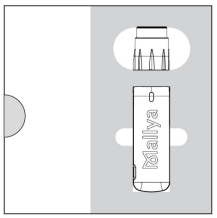
The molecules and associated concentrations compatible with the Mallya device are listed in the table below:

MALLYA MODEL	INSULINE INN	CONCENTRATION	WARNING EXCLUDED VERSIONS MALLYA IS NOT COMPATIBLE WITH THE FOLLOWING INSULIN PENS:
Mallya designed for **KWIKPEN® ELI LILLY** insulin pen	GLARGINE	100 IU/mL	
	LISPRO	100 IU/mL	Humalog Junior
		200 IU/mL	
	LISPRO AND PROTAMINE	100 IU/mL	
	HUMAN ISOPHANE	100 IU/mL	
	REGULAR HUMAN USP	100 IU/mL	
	REGULAR HUMAN AND HUMAN ISOPHANE	100 IU/mL	
Mallya designed for **FLEXPEN® NOVO NORDISK** insulin pen	DETEMIR	100 IU/mL	
	ASPART	100 IU/mL	
	ASPART AND PROTAMINE	100 IU/mL	
	HUMAN ISOPHANE	100 IU/mL	
Mallya designed for **SOLOSTAR® SANOFI** insulin pen	GLARGINE	100 IU/mL	
		300 IU/mL	Toujeo Max Toujeo Doublestar
	LISPRO	100 IU/mL	
	GLULISINE	100 IU/mL	
	GLARGINE AND LIXISENATIDE	100 IU/mL +33 mcg/mL	

Table 2 - Mallya compatibilities – Molecules and concentrations

2. GETTING TO KNOW YOUR MALLYA DEVICE

2.1 GETTING STARTED



The shipment box contains the following items. The Part Numbers (PN) vary depending on the Mallya model (Mallya designed for FLEXPEN or KWIKPEN or SOLOSTAR):

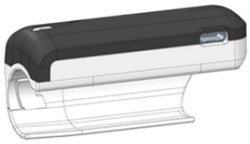
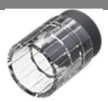
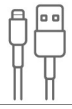
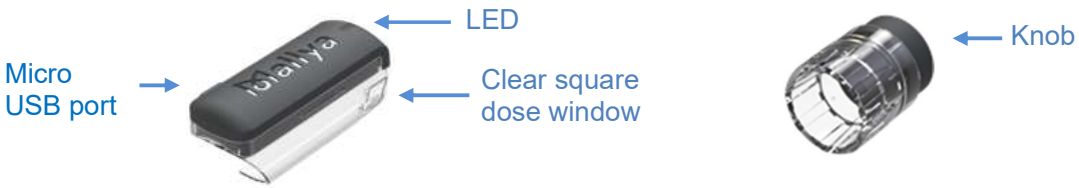
Mallya DEVICE:	
1 X Mallya BASE	
 *Applied part*	For the insulin pen **FLEXPEN® NOVO NORDISK:** PN: 0273778 For the insulin pen **KWIKPEN® ELI LILLY**: PN: 0273694 For the insulin pen **SOLOSTAR® SANOFI**: PN: 0273777
2 X Mallya KNOBS	
 *Applied part*	For the insulin pen **FLEXPEN® NOVO NORDISK:** PN : 0273727
Applied part	For the insulin pen **KWIKPEN® ELI LILLY**: PN : 0273698
Applied part	For the insulin pen **SOLOSTAR® SANOFI**: PN: 0273710
Mallya ACCESSORIES:	
1 x USB CABLE	**1 x RESET KEY** / **1 x QUICK START GUIDE**
	**Quick Start Guide with reference: QSG_MAL_US**
Part Number: B014JOOZFS	Model: B004OQOQQ0 Manufacturer: Bright Sea Industrial. Co
	CAUTION **Consult the Instructions For Use documents:** Reference: IFU_MAL_US

Table 3 - Mallya box contents

NOTE :
Before you use your Mallya for the first time, you have to charge it. Use the provided USB cable to connect the Mallya base to a USB port or outlet. Let it charge for at least 10 minutes.

2.2 FEATURES OF YOUR MALLYA



2.3 WEIGHT AND SIZE OF THE MAIN ELEMENTS

Element	Weight	Size
Mallya base	0.016 kg	KWIKPEN® base: **(60.8x28.9x21.3) mm** FLEXPEN® and SOLOSTAR® bases: **(60.8x26.9x21.3) mm**
Mallya knob	0.006 kg	KWIKPEN® knob: **(11.6 x Ø22) mm** SOLOSTAR® knob: **(24.4 x Ø20) mm** FLEXPEN® knob: **(26.3 x Ø19.3) mm**
Mallya total weight	0.022 kg	

Table 4 - Weight and size of the main elements

2.4 STORAGE INFORMATION

	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%
Operating	+15°C to +35°C **(59°F < T° < 95°F)**	800 hPa to 1060 hPa	30% to 70%

Table 5 - Storage information

2.5 TRANSPORT AND PACKAGING

- The device must be transported and stored in its original packaging. Storage and transport conditions need to meet conditions described in the previous ***step 2.4.***
- Keep the original packaging in case of return or transport of device.
- Check if there is any damage to the packaging. If the packaging is damaged, there is a possibility that the device is also damaged. Please notify the carrier if any damage is found and report it to the manufacturer.

CAUTION:
Do not use Mallya if the packaging is damaged.

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

NOTE :
Keep all original packaging for future use. The system must always be transported in its original packaging specially designed to protect it against damage.

3. INSTALLING THE MALLYA APPLICATION

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

3.1 TECHNICAL COMPATIBILITIES

The list of smartphones validated by BIOCORP and compatible with the Mallya application Version 1.7. is shown below:

SMARTPHONE MODEL	COMPATIBLE OPERATING SYSTEM
Samsung Galaxy S9	Android 10.0
Samsung Galaxy S8 Plus	Android 9.0
Samsung Galaxy S6	Android 7.0
Honor 10	Android 8.1
Huawei P20 Lite	Android 8.0
Huawei Mate 10 Lite	Android 8.0
LG V30	Android 8.0
iPhone SE iPhone 6s iPhone 6s Plus iPhone 7 iPhone 7 Plus iPhone 8 iPhone 8 Plus iPhone X iPhone XR iPhone 11	iOS13

Table 4 - Mallya application technical compatibilities

CAUTION
This list represents the list of smartphones and associated operating systems that have been tested and validated by BIOCORP. This list is not exhaustive.

3.2 DOWNLOAD THE MALLYA APPLICATION AND GET STARTED

Download the Mallya application from:

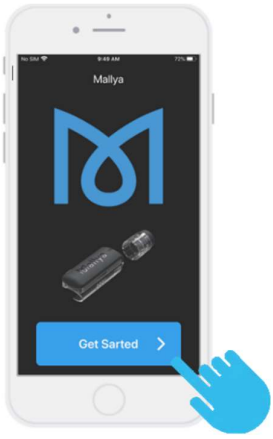
Apple Store Play Store

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

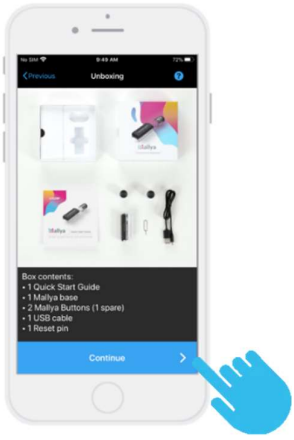
The first time you open the application, the Mallya application terms of service screen is displayed. Please read the Mallya application terms of use before accepting them and confirming your choice.
before accepting them and confirming your choice.

The privacy policy screen is then displayed: make sure you understand it before accessing the ***"Get Started"*** screen.

3.2.1. Select "Get started":



3.2.2. 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 step ***4.1. Charging your Mallya***)
- Calibrate (as explained in step ***4.2. Calibrating your Mallya***)
- Assemble (as explained in step ***4.3. Attaching your Mallya to pen***)
- Pair (as explained in the following step ***4.4. Pairing your Mallya***)

4. CARING FOR YOUR MALLYA

4.1 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.
- You cannot use your Mallya for an injection while it is connected to a USB power port and charging.

4.1.1.
Plug the powered USB cable into the Mallya micro-USB port.

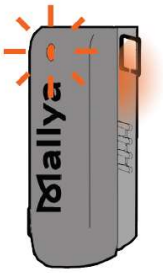
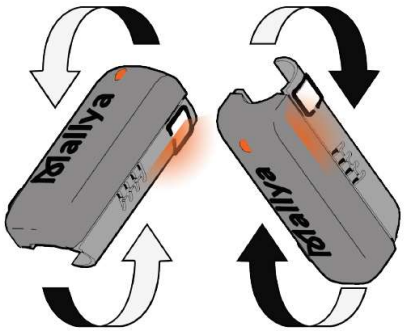
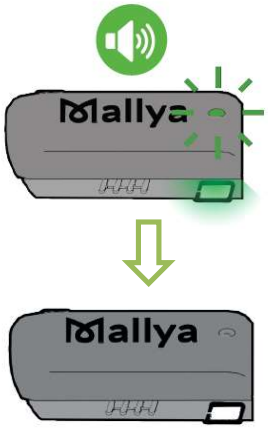
4.1.2.
Check that the Mallya LED is slowly flashing green.

4.1.3.
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.
- Optimal autonomy is reached when Mallya's battery is fully charged. You can then use Mallya for at least 2 weeks.

4.2 CALIBRATING YOUR MALLYA

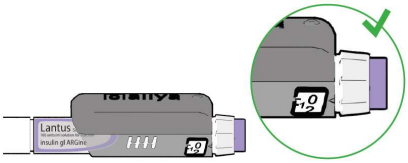
4.2.1. Unplug the Mallya base from the USB cable.	
4.2.2. Check that the Mallya LED is flashing orange.	
4.2.3. Slowly tilt the Mallya base side to side to CALIBRATE.	
4.3.3. Continue tilting until: ✓ The base beeps and the LED light turns **green**. ✓ Then the light will turn off.	

4.3 ATTACHING YOUR MALLYA TO PEN

CAUTION

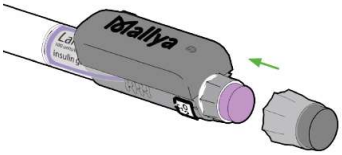
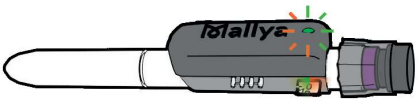
The Mallya base and knob must be correctly attached onto the pen, otherwise, data will not be transferred.

4.3.1 ATTACHING BASE TO PEN

4.3.1.1. Hold the Mallya base so that the clear square plastic window is facing you	
4.3.1.2. Align the Mallya base clear square plastic window with the pen dose window, then snap the base onto the pen.	
4.3.1.3. Make sure the Mallya base window is 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.

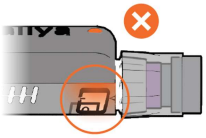
4.3.2 ATTACHING KNOB TO PEN

4.3.2.1 Place and insert the Mallya knob over your pen injection knob. Make sure the knob is properly attached.	
4.3.2.2 The Mallya base LED will flash orange and green when the knob and base are properly mounted onto the pen.	

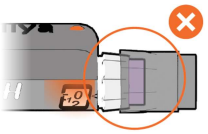
CAUTION

The Mallya base 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, the Mallya knob is not pushed on enough.



In this case, it is necessary to:

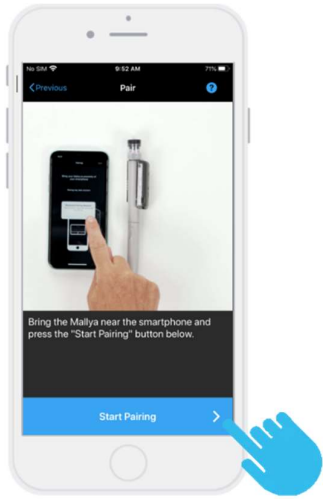
- Re-adjust (re-align) the windows,
- or, push on the knob,

until the Mallya base LED flashes **green** and **orange**.

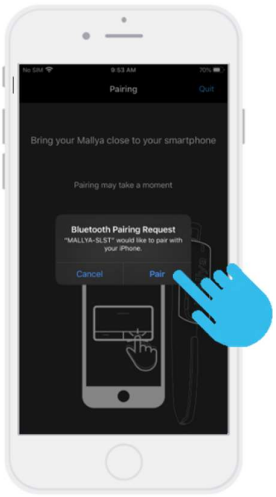
4.4 PAIRING YOUR MALLYA

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

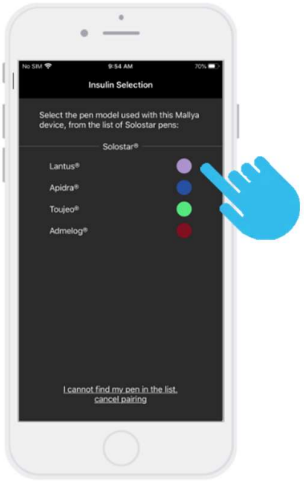
4.4.1.
Make sure the Mallya base is within 12 inches of your smartphone and select *"Start pairing"*:



4.4.2.
Select "Pair"
NOTE:
The pairing step may take few seconds.

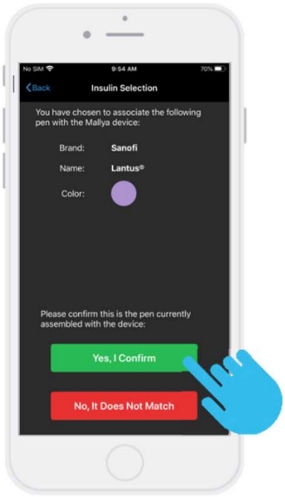


4.4.3.
Choose the insulin pen model onto which the Mallya device is assembled.

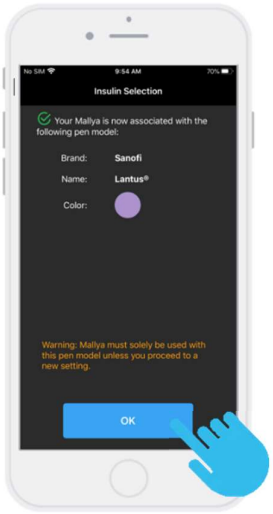
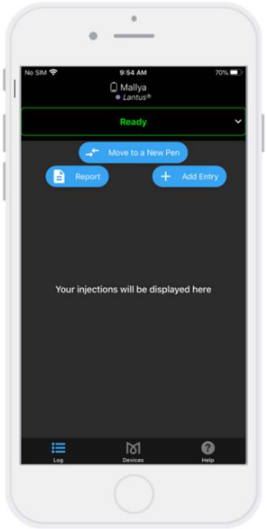


NOTE:
In case you cannot find your pen model in the list: select ***"cancel pairing"***. The application will guide you to pair a new Mallya.

4.4.4.
Confirm the pen model currently assembled with the Mallya device.

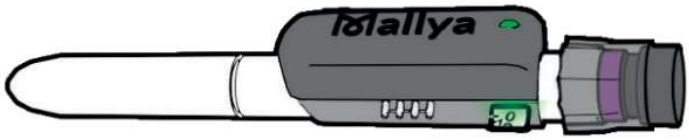


NOTE:
If you select ***"No, it does not match",*** the application will return to the previous screen (***step 4.4.3.)*** to let you choose another pen model.

4.4.5. Well done! Your Mallya device is now paired with the Mallya application on your smartphone. Select “OK” to move on to the injection screen.	**4.4.6.** 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.

NOTE:
When Mallya is paired and correctly attached to the injection pen: the LED is **green.**



5. USING YOUR INSULIN PEN WITH MALLYA

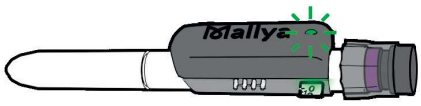
NOTE :
Once Mallya is attached to the insulin pen, the pen should be used just like a normal insulin pen. Refer to the manufacturer's injector pen Instructions for Use.

5.1 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 Instructions for Use).

5.1.1.
Follow the injectable insulin pen Instructions for Use to carry out the priming step.

5.1.2.
At the end of the priming step, keep the injection knob 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 Instructions for Use for more information to solve the problem.

5.1.3.
You can release the pressure on the knob 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)**

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 ***step 6.2.2.***

5.2 INJECTION

WARNING

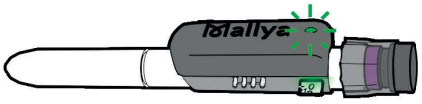
If you are not certain that you injected your insulin, do not start or repeat your injection. Monitor your blood glucose as instructed by your healthcare provider.

5.2.1.
Check the insulin dose to inject as requested by the drug manufacturer's requirements.

5.2.2.
Turn the dose knob to select the number of units to inject. The dose indicator should line up with the dose to inject.

5.2.3.
Press on the injection knob with your thumb until you return to ZERO (complete dose injection)

5.2.4.
Keep the injection knob 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.



5.2.5.
You can release the pressure on the knob 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.

The Mallya application will automatically detect an injection:

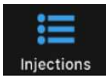
The information corresponding to the injected dose is displayed: **dose**, **day** and **time**.

6. MANAGING 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:

6.1 DISPLAY OF THE RECORDED DATA

Select the injection screen:



"Doses" or "Priming" injections are then displayed as follows:

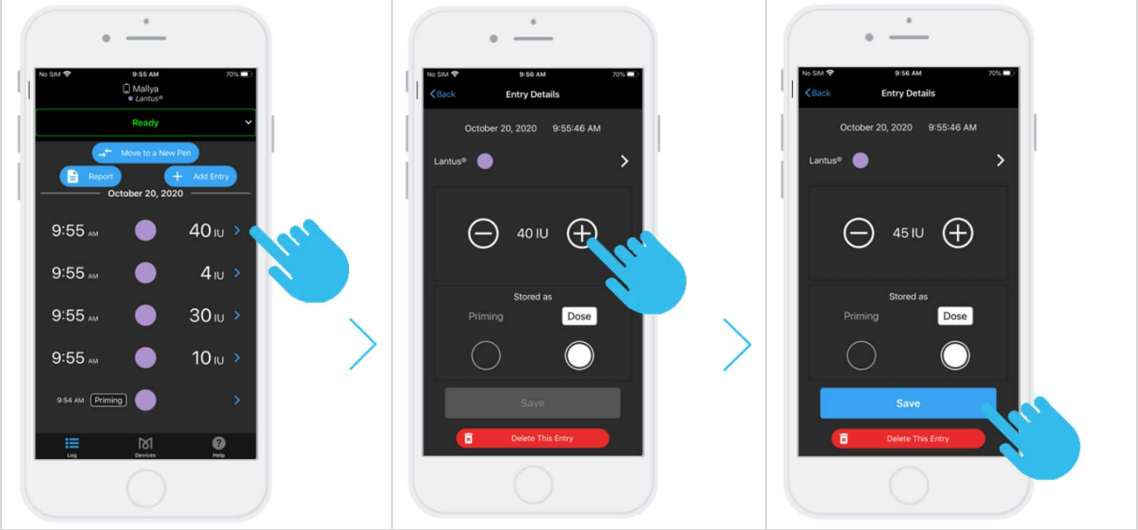
The Insulin Dose information is displayed:

- Type of injection: **"priming"** or **"dose"**
- Injection **day** and **time**
- Insulin dialed **dose** (in International Unit)
- **Color indicator** of the injected insulin type or concentration

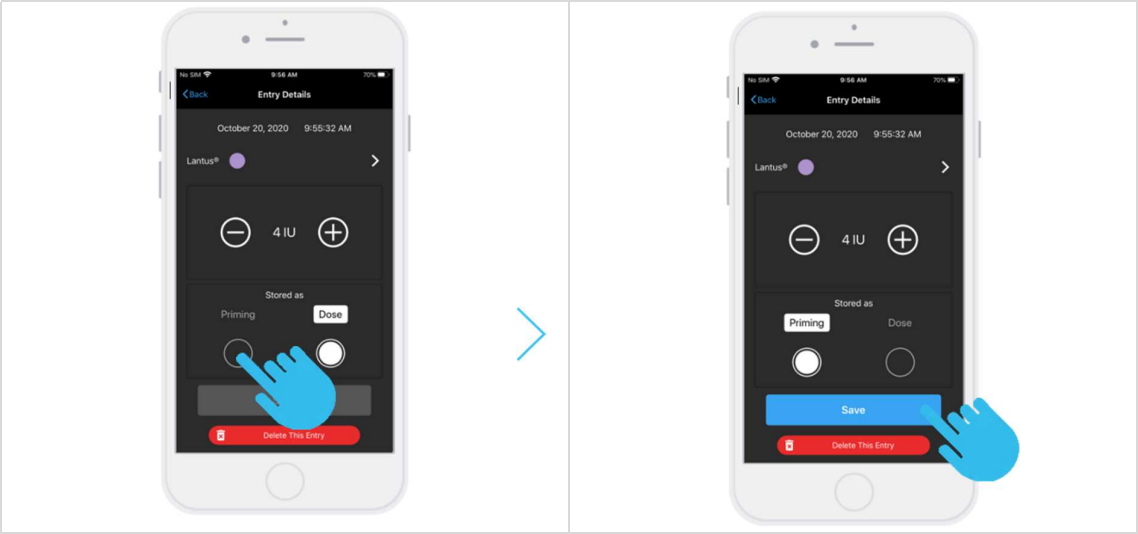
6.2 MANAGE YOUR RECORDED DATA

You can manage and edit the following list of items:
- You can change a “priming” or a “dose” quantity (see ***step 6.2.1.***),
- You can change an injection recorded as a “dose” to a “priming”, or a “priming” to a “dose” (see ***step 6.2.2.***),
- You can delete a “dose” or a “priming” (see ***step 6.2.3.***),
- You can add an injection that was not recorded to the history (see ***step 6.2.4.***),
- You can fill in a dose that was not captured by the device (see ***step 6.2.5.***).

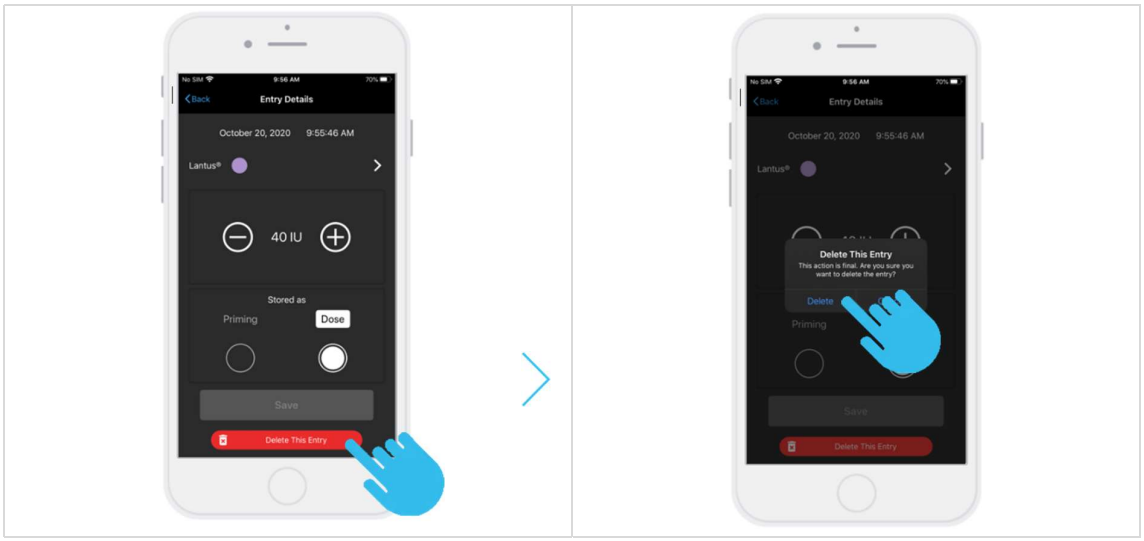
6.2.1 You can change a «priming» or a «dose» quantity already recorded



6.2.2 You can change an injection recorded as a «dose» to a «priming», or a «priming» to a «dose»

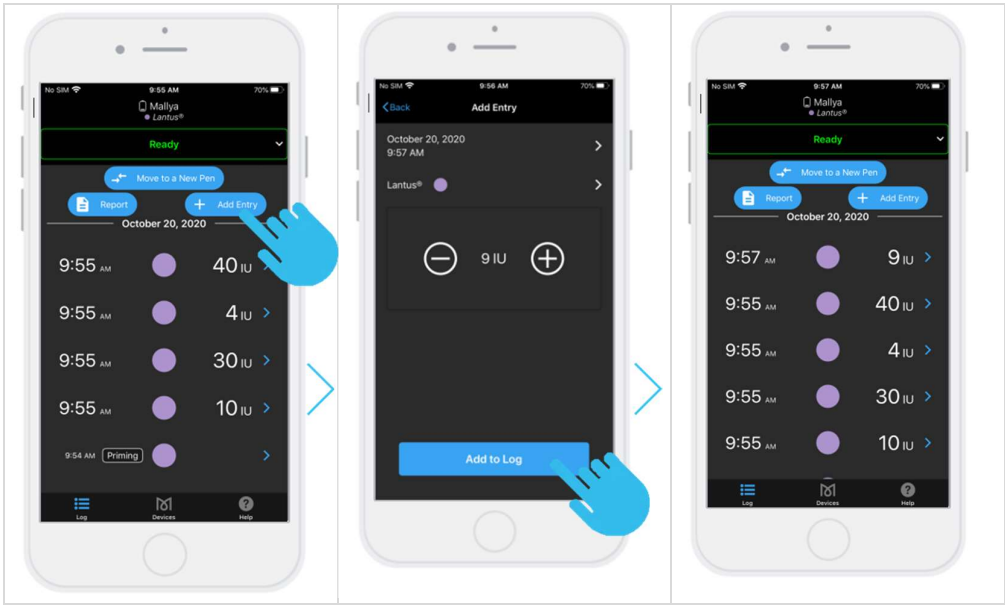


6.2.3 You can delete a «dose» or a «priming»



6.2.4 You can add an injection that was not recorded to the history

To add an unrecorded dose, select “Add to log”:

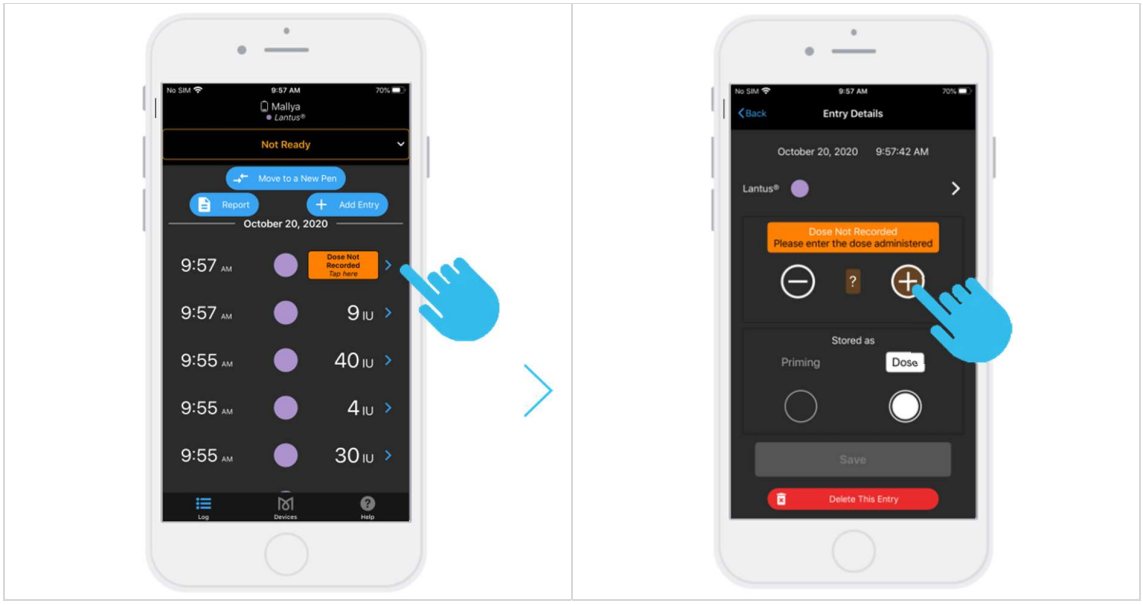


6.2.5 You can fill in a dose that was not captured by the device

If a dose was not captured, you will see the message “Dose not recorded”. You can add the dose information as follows:

Tap

to modify the information related to the injection:

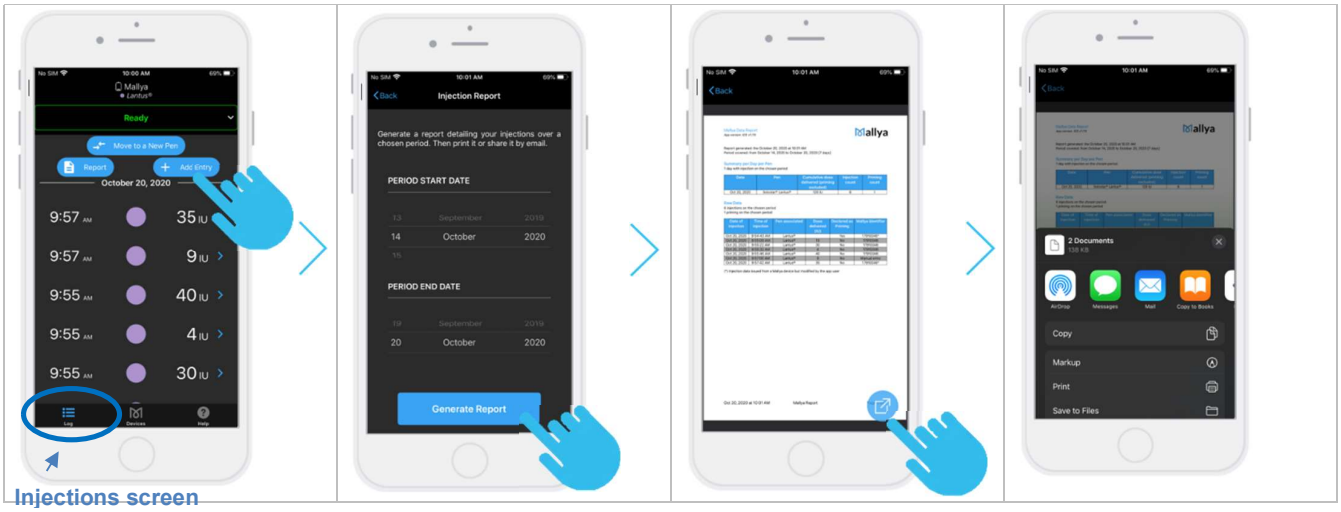


7. OTHER FEATURES OF THE MALLYA APPLICATION

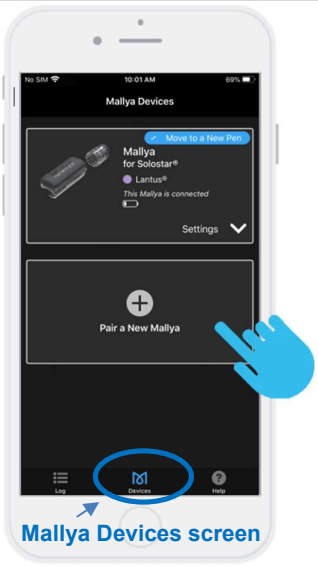
7.1 GENERATE A REPORT

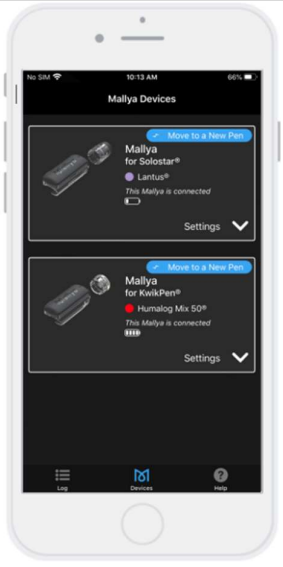
In the **“Injections”** screen, select the icon

to display the window that allows you to **generate a report**:

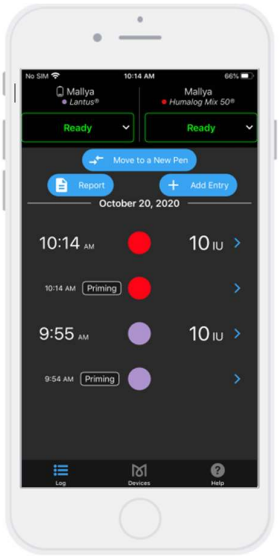


7.2 PAIR TWO MALLYA TO YOUR MOBILE APP.





Both Mallya devices and associated insulin pens can be used independently. They both have the status “Ready for use”:



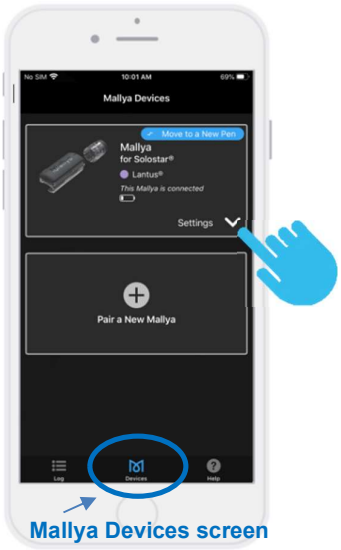
WARNING

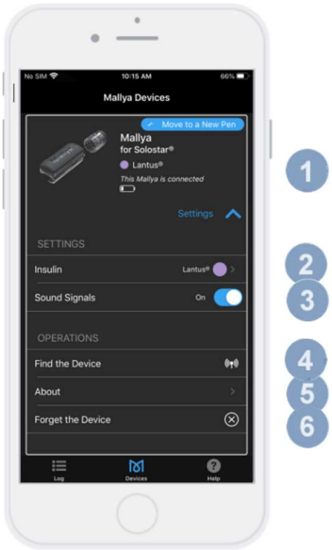
Make sure you do not switch the pens between the two Mallya devices.
In case you have any doubt, you can use the “Find the device” functionality to identify the Mallya as explained in the step below ***(step 7.3.)***

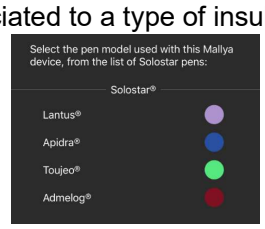
7.3 SETTINGS

Select

, then **"Settings"** to diplay the screens allowing to set up the application:





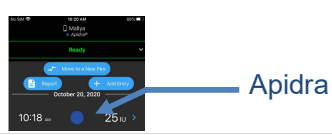
1	**Battery** status : When Mallya is fully charged (after approximately 2 hours) : 4 bars are displayed **Device** status: *Mallya is connected / Disconnected since …* **CAUTION** A Bluetooth connection is necessary to transmit the injection data.
2	Tap **"Insulin"** to select the pen model onto which Mallya is currently assembled. Each color indicator is associated to a type of insulin pen: 

CAUTION

<u>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.</u>

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

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 in STANDBY mode.
5	**"About"** Information about Mallya application:

- Manufacturer
- Model
- Serial number
- Hardware revision
- Firmware revision
- Software revision
- Temperature

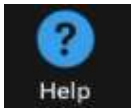
6	**"Forget the device"** Select "Forget Mallya" to unpair Mallya.

CAUTION

- 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 ***step 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.

7.4 "HELP" SCREEN

Video tutorials and other resources are available from the "Help" screen:



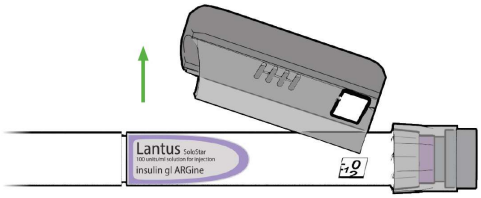
The legal notices concerning the Terms of use, the Privacy, Copyright and Version of the application (About) are also available.

8. TRANSFERRING MALLYA TO A NEW PEN

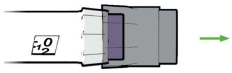
8.1 REMOVING MALLYA FROM THE EMPTY PEN

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 knob knob from the pen.



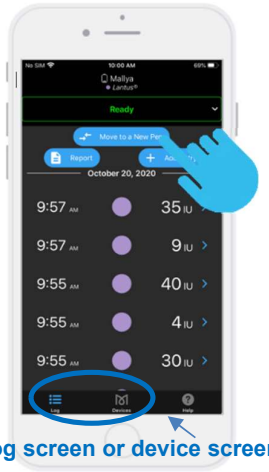
8.2 TRANSFERRING MALLYA TO A NEW PEN WITH SELECTING THE "MOVE MALLYA TO A NEW PEN" BUTTON

When your pen is out of insulin and you want to switch to a new pen, follow the steps below:

8.2.1.
Select the Move to a New Pen button on the log screen or devices screen.

8.2.2.
Follow the app instructions or the steps indicated below to:

- ✓ Remove the Mallya base and Mallya knob from the current pen (see step ***8.1. Removing Mallya from the empty pen***)
- ✓ Assemble the Mallya base and Mallya knob to the new insulin pen (see step ***4.3. Attaching your Mallya to pen***): the Mallya should show a **green** light. If not, check the position of the Mallya knob and Mallya base.



Log screen or device screen

CAUTION

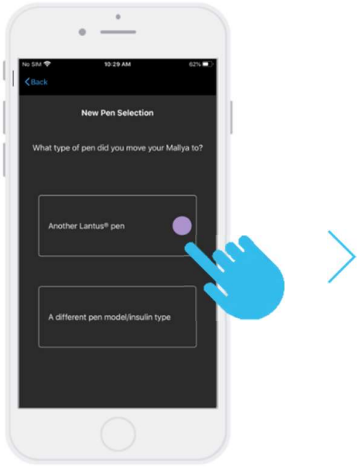
- Mallya models are only compatible with the disposable insulin pens (Solostar, Kwikpen, Flexpen) they are designed for. Do not attach to, pair or use with any other insulin pen types.
- If you need to inject more than the number of units left in the pen, you may either:
  1) inject the amount left in 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.

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

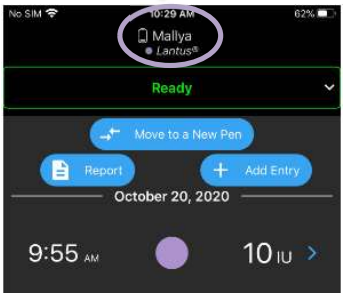
8.2.3.
Moving Mallya to the same pen model or to a different pen model

8.2.3.1
Moving mallya to the same pen model

If you choose to move MALLYA to the same pen model, select:



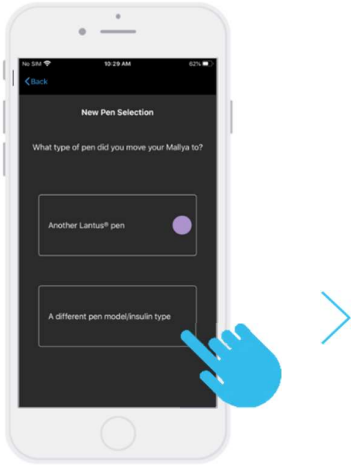
The same pen model, currently assembled, is then displayed at the top of the screen. ("LANTUS" in the example)



On the next injection, the injection dose will be displayed in the injection history as if no Mallya transfer had taken place.

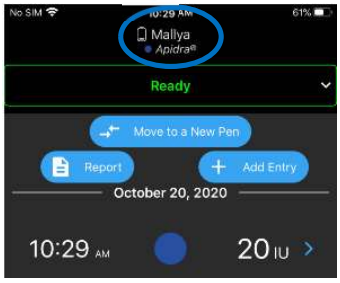
8.2.3.2
Moving mallya to a different pen model

If you choose to move MALLYA to a different pen model, select:



In this case, the screens in ***steps 4.4.3., 4.4.4., and 4.4.5.*** are displayed. You have to select the new pen model on which your Mallya is currently assembled.

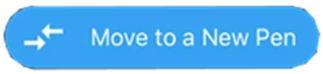
The new pen model, currently assembled, is then displayed at the top of the screen. ("APIDRA" in the example)



On the next injection, the injection dose will be displayed in the injection history with the new model of pen (APIDRA in the example above)

8.3 TRANSFERRING MALLYA TO A NEW PEN WITHOUT SELECTING THE "MOVE MALLYA TO A NEW PEN" BUTTON

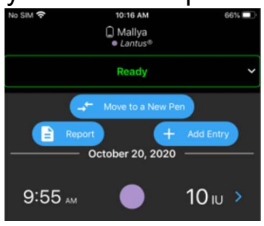
CAUTION

When Mallya is transferred onto a new pen without selecting the 

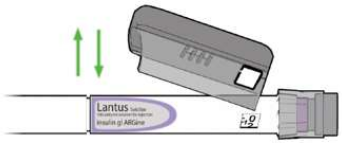
button, the application automatically detects a ***"device removal event"*** (eg.: your base and / or the knob have / has been removed from the original pen).
In this situation, the application will require a confirmation of the pen currently assembled with Mallya.

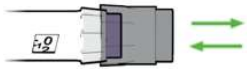
EXAMPLE:

8.3.1.
Log screen before transferring Mallya onto a new pen:



8.3.2.
Remove Mallya from the empty pen / attach Mallya onto a new pen (base and / or knob)

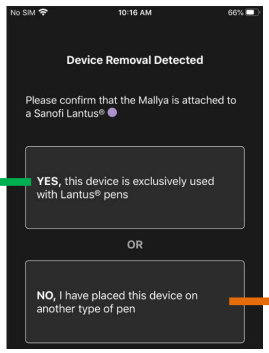


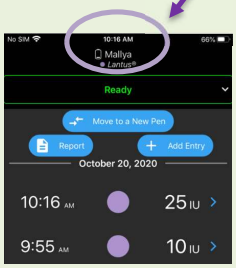
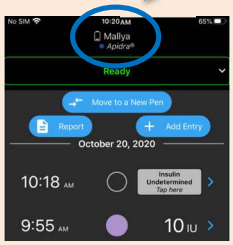
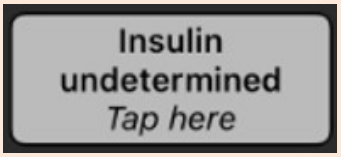


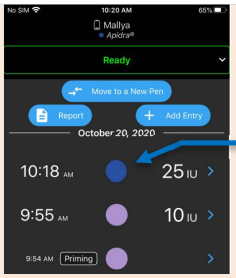
8.3.3.
On the next PRIMING or an INJECTION:

A DEVICE REMOVAL 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).	**NO, I have placed this device on another type of pen.**
In this case, the injection dose will be displayed in the injection history as if no removal event had taken place. **Example with the "LANTUS" pen model (Pen unchanged)**  	1) In this case, the screens in ***steps 4.4.3., 4.4.4., and 4.4.5.*** 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 pen model selected ("APIDRA" 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:  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)

8.4 COLLECT YOUR INJECTION DATA FROM MALLYA AFTER SMARTPHONE DISCONNECTION

Your smartphone may disconnect from the Mallya system if 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 **removal event** occurred during the disconnection period (eg.: your base and / or the knob have / has not been removed from the original pen in the meantime), or
- Your Mallya application will display the 2 options indicated in ***step 8.3.3.*** if a removal event occurred (the Mallya base and / or the knob have / has been removed from the original pen during the disconnection period).
  Follow the instructions in ***step 8.3.3.*** 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.

9. TROUBLESHOOTING

CAUTION

- Never attempt to access the internal hardware for any purpose including maintenance in all circumstances.
- When a function check is not successful and if the recommendations given in this ***step 9.*** do not solve the issue, you are prompted to contact a BIOCORP PRODUCTION authorized dealer.

9.1 TROUBLESHOOTING MALLYA WITH 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:

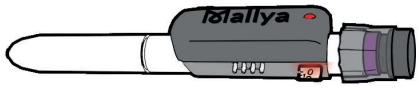
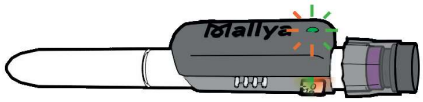
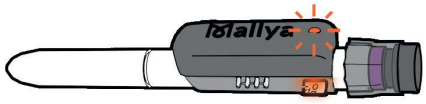
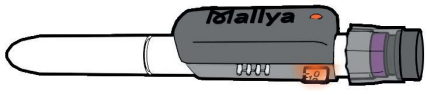
SIGNAL	CAUSE	TROUBLESHOOTING STEPS
Red LED 	Mallya error	Remove Mallya from pen. Re-calibrate Mallya (*see **step 4.2.***) If the issue persists: reset the system (*see **step 9.3.***) Then, try to pair Mallya to your smartphone (see ***step 4.4***.) If the problem is not solved, please contact a BIOCORP PRODUCTION authorized dealer.
Orange LED (rapid flashing)	Calibration in progress: A green light will appear for 2 seconds upon successful calibration (with a beep, then the green light will turn off).	**Slowly** tilt the Mallya side to side to calibrate (*see **step 4.2.***)
Alternating **orange** and **green** flashing (rapid flashing) 	Mallya device is correctly positioned onto the pen but must be paired.	Pair Mallya to your smartphone (see ***step 4.4***.)
Orange LED (slow flashing) (every 15 seconds) 	Battery is low.	Plug in and charge the Mallya base (see ***step 4.1.***)
Orange LED 	- Mallya position error on pen: the knob is not turned back to the dose “0” or - Assembling error: Mallya (base or knob) is not correctly positioned on pen.	Make sure that: - the knob is turned back to the dose “0” or - the Mallya window and the pen dose window are properly aligned, and - the Mallya knob is correctly pushed onto the pen (see ***step 4.3.***)

Table 7 - Troubleshooting with signals

CAUTION

ORANGE LED – TROUBLESHOOTING RECOMMENDATIONS

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

a) The clear square plastic window of the Mallya base and the dose window of the pen are not correctly aligned, or

b) The Mallya base is mounted too high / too low on the pen,

c) Or, if the Mallya knob is not pushed on enough.

In this case, it is necessary to:

a) Check that the Mallya window outline lines up with the pen dose window EXACTLY:
-The pen pointer should fit into the slot on the Mallya base.
-The notch in the pen dose window should line up with the notch on the Mallya window outline.

b) Check that the top edge of the Mallya base lines up with the edge of the pen body, so that it does not sit below or above the edge. The Mallya base should not cover any of the pen dose dial.

c) Press the Mallya knob onto the pen dose dial so that it almost touches the Mallya base.

When the positions of the Mallya knob and button are correct:
- the Mallya base LED flashes **green** and **orange** if Mallya is not paired,
- the Mallya base LED is **green** if Mallya is paired.

INFORMATIONS REGARDING OTHER SIGNALS:

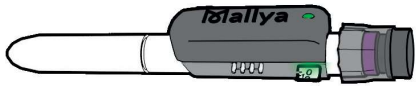
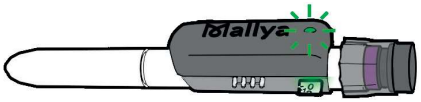
SIGNAL	CAUSE	TROUBLESHOOTING STEPS
Green LED (slow flashing)	Mallya is charging.	*(See **step 4.1.**)*
Green LED 	Mallya is properly assembled onto the pen. It is: - either ready for use, or - the dose setting is in progress, or - the injection is in progress	N/A
Green LED (rapid flashing) 	Mallya is at the end of an injection.	Keep the needle in the skin: - During the whole time Mallya's green LED is flashing, - Until Mallya emits an audible signal (BEEP) signaling the end of the injection.

Table 7 - Troubleshooting with signals (next)

9.2 TROUBLESHOOTING MALLYA WITH THE APPLICATION

This step 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.

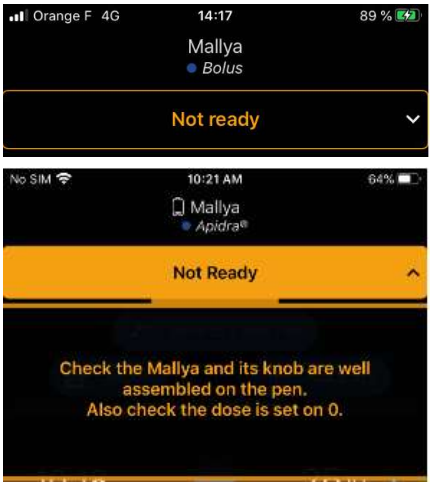
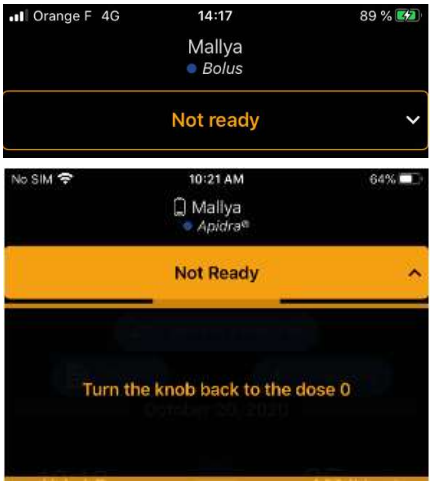
INDICATION	CAUSE	TROUBLESHOOTING STEPS
	Mallya's base not detected	① Select: **"Not Ready"** ② Check that the Mallya device is correctly assembled on the pen (see ***step 4.3.***)
	Knob of the pen not at ZERO	① Select: "**Not Ready**" ② Turn the knob of the pen back to the ZERO position.

Table 8 - Troubleshooting with app.

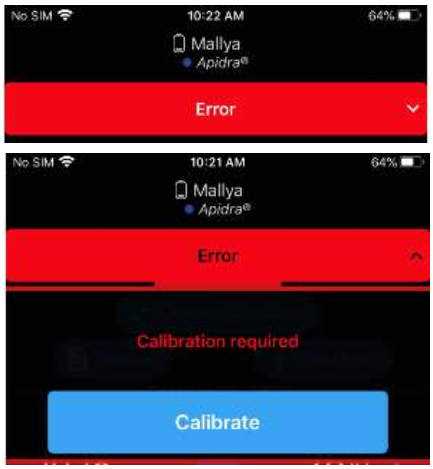
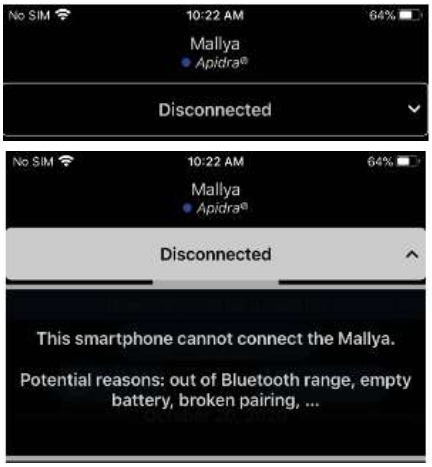
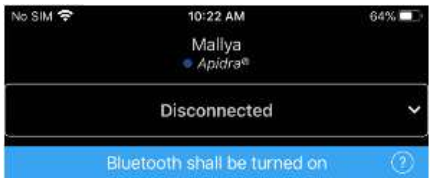
INDICATION	CAUSE	TROUBLESHOOTING STEPS
	Calibration error	① Select "**Error**" ② Perform the calibration as indicated in the Mallya device Instructions for Use (see ***step 4.2.***)
	Mallya is maybe too far away from your smartphone and therefore disconnected *Or*	① Move your Mallya device and your smartphone closer to one another.
	A communication error occurred	① Select "**Disconnected**" ② Reset Mallya as explained in the Mallya device Instructions for Use (see ***step 9.3.***)
	Bluetooth issue or signal lost	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. If the problem is not solved, please contact a BIOCORP PRODUCTION authorized dealer.

Table 8 - 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 *step 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.

3 BEEPS

9.3.5.
Then follow *step 4.* to prepare your device for a new operation.

10. MAINTENANCE AND INSPECTION

10.1 MALLYA DEVICE LIFETIME

Mallya and accessories lifetime is 2 YEARS.

10.2 MALLYA APPLICATION UPDATES

Check each week on your smartphone (in the Apple store / Play store) if a Mallya application update is available, and update when 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 soapy water.
✓ Dry with a clean, dry cloth.

- Disconnect the USB cable before cleaning Mallya.

WARNING

The device is intended to be non-sterile

CAUTION

- Avoid getting moisture into the micro-USB opening.
- 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.
- Remember that 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

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 not at all 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

11.1 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	According to EN 55011 / CISPR 11 the device is classified as a group 1 device with class B emission limits.
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 for the base

Table 9 - Compliance with standards / regulations and classifications

11.2 MALLYA BASE LABELLING

MALLYA SENSOR TYPE	LABELING
Mallya base for insulin pen: **FLEXPEN® NOVO NORDISK**	
Mallya base for insulin pen: **KWIKPEN® ELI LILLY**	
Mallya base for insulin pen: **SOLOSTAR® SANOFI**	

Table 10 - Base labelling

11.3 SYMBOLS ON THE DEVICE AND ITS PACKAGING

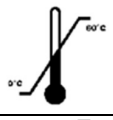
SYMBOL	STANDARDS	DESCRIPTION
	IEC60417-5840	Applied part Type BF
	ISO7010-M002	Please refer to the Instructions for Use document
	ISO 15223-1	Consult the Instructions for Use documents
	ISO 15223-1	Do not use if the packaging is damaged
	ISO 15223-1	Manufacturer
	ISO 15223-1	Manufacturing date
	Symbol 5.3.4 (ISO 7000-0626) of ISO 15223-1:2012	Moisture sensitive device
	The device, packing and accessories must be disposed of separately from domestic waste in accordance with WEEE provisions for EU member countries, and with local recycling provisions and national laws.	
SN	ISO 15223-1	Serial Number
REF		Product reference
FC	This device complies with part 15 of the FCC Rules.	Operation is subject to the following 2 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.
	IEC 60417-5172	Class II device (in compliance with EN 60601-1 standards)
	IEC 60417-5957	For indoor use only
IP 22	IEC 60529	Protection index: Protects persons against access to hazardous parts with fingers and against the harmful effects due to water vertically dripping against the enclosure.
	Symbol 5.3.7 (ISO 7000-0632) of ISO 15223-1:2012	Temperature limits within which the device can be safely exposed
	Symbol 5.3.8 (ISO 7000-2620) of ISO 15223-1:2012	Humidity limits within which the device can be safely exposed

Table 11 - Symbols on the device and its packaging

SYMBOL	STANDARDS	DESCRIPTION
	Symbol 5.3.9 (ISO 7000-2621) of ISO 15223-1:2012	Pressure limits within which the device can be safely exposed

Table 12 - Symbols on the device and its packaging (next)

11.4 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 Voltage	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 at 4,2 V for 2,5 hours

Table 13 - Electrical ratings

It is possible to connect the provided USB cable to the USB port of your PC or AC adaptor with the following characteristics:

AC ADAPTOR (NOT PROVIDED)	
Power supply	External Module with automatic adaptation of the voltage: no selection is required.
Input voltage range	90-264 Vac
Frequency range	47-63 Hz
Current input	0,5 A @ 90 VA
Category	II (double insulation)

Table 13 – Electrical ratings (next)

11.5 MATERIALS

MATERIALS	
Mallya base	PC/ABS (cover)
	Copolyester (body)
Mallya knob	Polypropylene (body)
	POM (knob)

Table 14 - Materials

11.6 ACCURACY

MEASUREMENT ACCURACY	99%

Table 15 – Accuracy

CAUTION
External factors may affect the dose measurement accuracy.

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

Table 16 - External factors and measurement accuracy

To display accurate doses, make sure to use the device as recommended in this Instructions for Use document:
- Follow the Warning and Caution recommendations to avoid magnetic disturbance
- Follow the information given ***step 4.3.2***. to adjust the dose knob position on the pen

11.7 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 ***step 9.3.***)

12. GENERAL INFORMATION

BIOCORP PRODUCTION
ZI LAVAUR LA BECHADE
63500 ISSOIRE
CEDEX – FRANCE
Tel : +33 4 73 55 70 50
www.biocorpsys.com

DISTRIBUTORS (authorized dealers):
See list and contact information at the end of leaflet

The Instructions for Use 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)

13. DISCLAIMER

The warranty is valid twelve months from the date of purchase.

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 recommendations described in this Instructions for Use document.
- 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 Instructions for Use by BIOCORP PRODUCTION.

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.