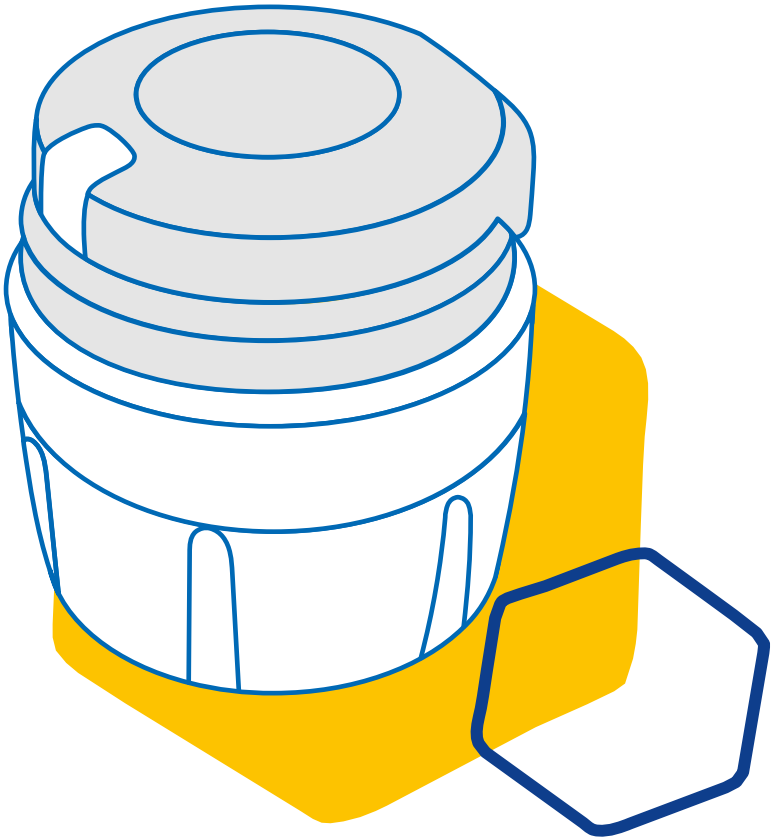
smartdot™

Instructions for Use



MERCK

SUMMARY

Part 1 · Safety information 3

Part 2 · What's in the box 5

Part 3 · Your smartdot™ transmitter 6

Part 4 · smartdot™ light signals 7

Part 5 · Preparing 8

Part 6 · Injecting 13

Part 7 · Storing 16

Part 8 · Frequently asked questions 17

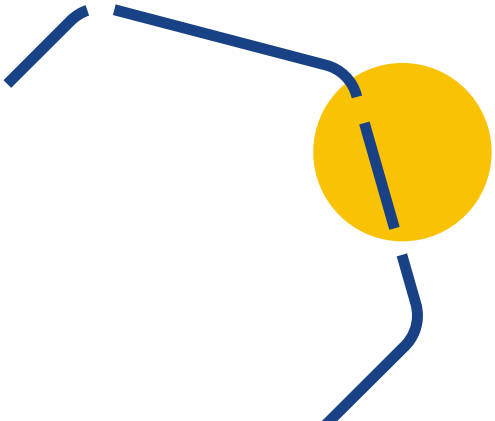
Part 9 · Troubleshooting guide 21

Part 10 · Regulatory information on radio communication 26

Part 11 · Regulatory information on electronic waste 27

Part 12 · Technical specifications 28

Part 13 · Symbols and information on the packaging 32



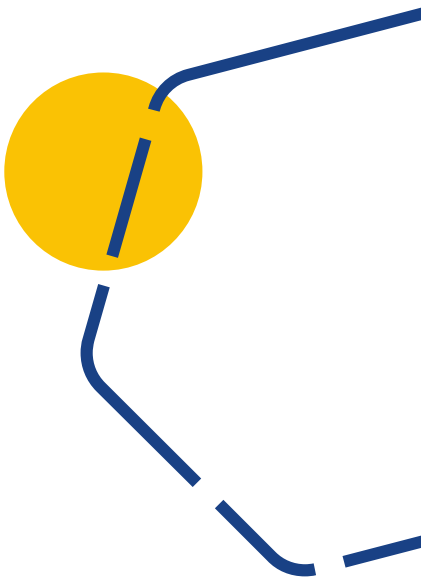
Part 1 Safety information

- The purpose of the smartdot™ transmitter is to store and transfer injection data when administering growth hormone treatment.
- The smartdot™ transmitter can only be used when injecting Saizen® (somatropin) with the Merck pen injector.
- Injection data are transferred to the smartdot™ compatible mobile Application (App) via Bluetooth® technology. Your healthcare professional has access to those data.
- The smartdot™ transmitter is reusable and has a rechargeable battery.
- **Do not** share your transmitter with any other person. smartdot™ is intended for use at home by one pen user only.
- The smartdot™ transmitter does not change the pen injection process. Please read your pen injector instructions before starting to use the transmitter.
- Keep your transmitter out of the reach of small children. Small parts could be inhaled or swallowed and may lead to choking. If the smartdot™ transmitter is being used by a child, they should be supervised by an adult.

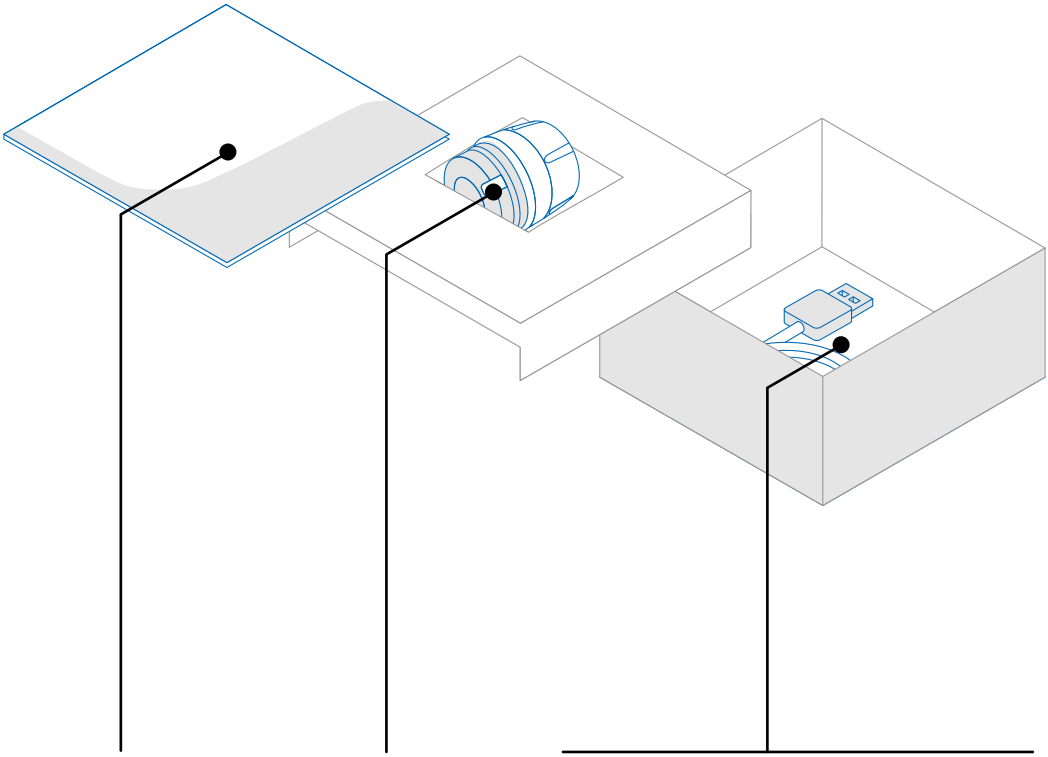
IMPORTANT:
Please read all the instructions in this manual before using the smartdot™ transmitter.

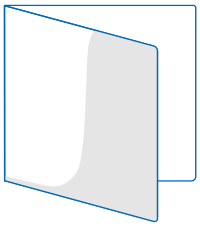
To preserve the performance and lifespan of the smartdot™ transmitter, please adhere to the following environmental conditions:

- **Do not** use in an environment containing flammable substances or oxygen.
- **Do not** use smartdot™ transmitter while it is charging.
- **Do not** use smartdot™ transmitter in the case of visible damage. Contact your healthcare professional for further assistance.
- **Do not** attempt to modify or repair smartdot™ transmitter. It may damage the transmitter or cause you harm. Please note, the smartdot™ transmitter does not require any special maintenance during its lifespan.
- The smartdot™ transmitter is an electronic product. **Do not** throw it away as household waste. Dispose of it in accordance with local regulations.

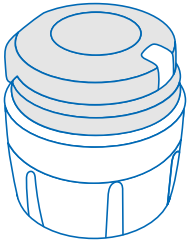


Part 2 What's in the box

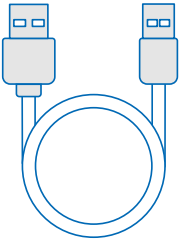




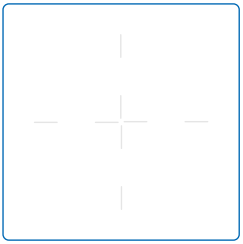
Quick Start Guide



smartdot™ transmitter



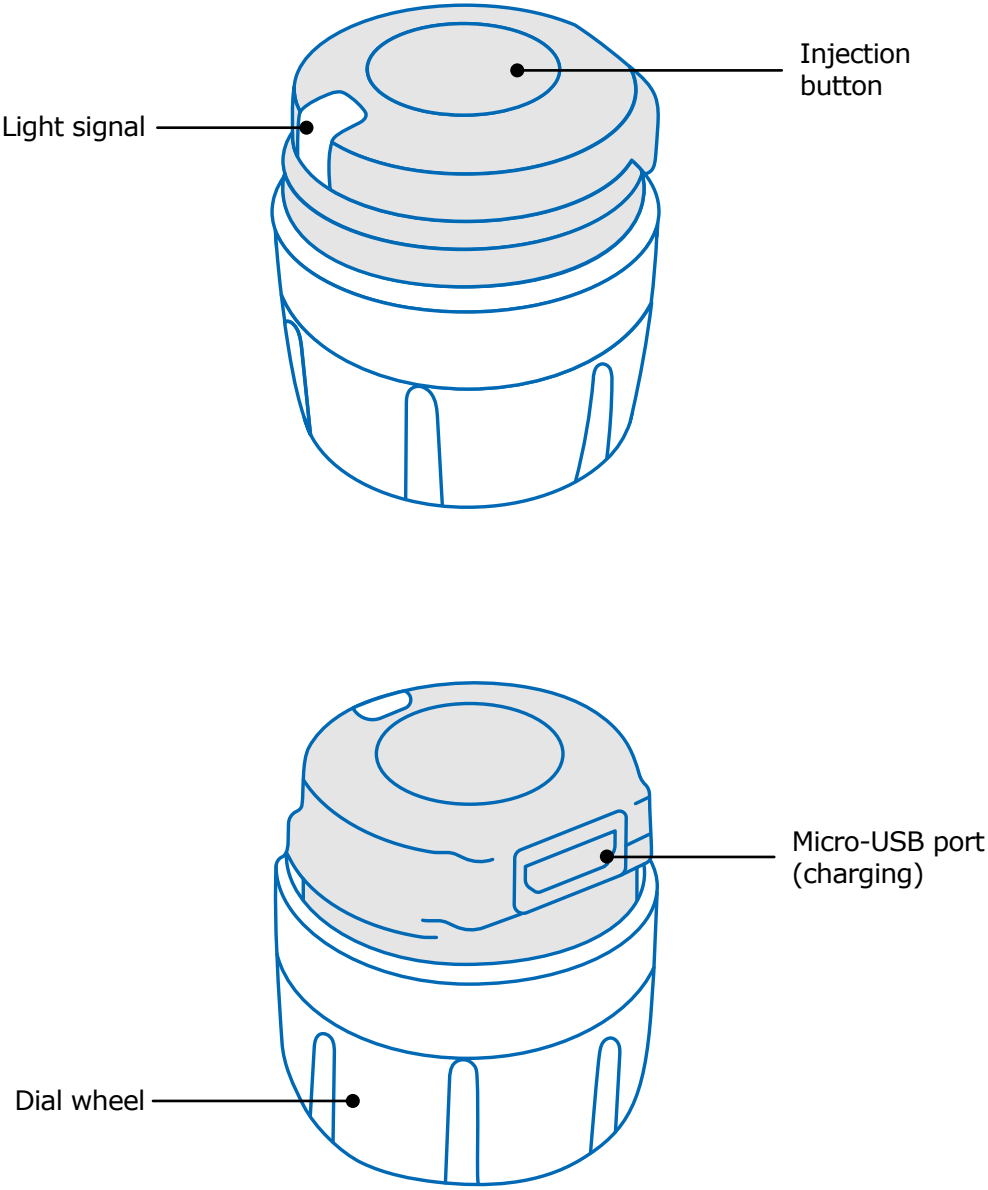
USB cable



Compliance information

Note:
USB charger is not included.

Part 3 Your smartdot™ transmitter

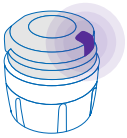


Part 4 smartdot™ light signals



Blinking blue

The blinking blue light shows that smartdot™ transmitter is charging. The smartdot™ transmitter will show no light after it is fully charged and before it is activated. See 'Part 5: Preparing <A. Charging your smardot™ transmitter.'



Purple

The purple light appears when activation or deactivation is in progress. See 'Part 5: Preparing <E. Activating your smartdot™ transmitter'.



Green

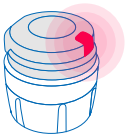
The green light shows that smartdot™ transmitter is successfully activated and ready to use. The green light will disappear after few seconds of inactivity. To see the light again, press the injection button. See 'Part 5: Preparing <E. Activating your smartdot™ transmitter.'

Troubleshooting signals



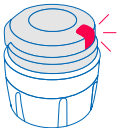
Orange

The orange light appears when the battery is low. See 'Part 9: Troubleshooting guide <orange light.'



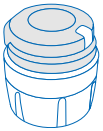
Red

The red light means smartdot™ transmitter is defective. See 'Part 9: Troubleshooting guide <red light.'



Blinking red

The blinking red light means that a reset is in progress. See 'Part 9: Troubleshooting guide <red light <What should I do?'



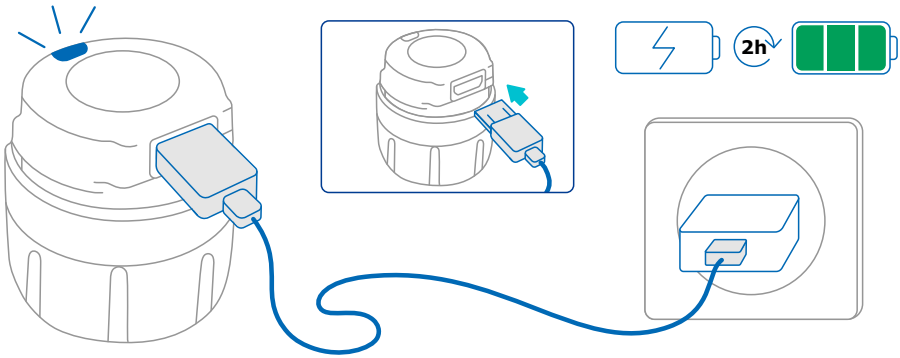
No signal

If the smartdot™ transmitter is paired and activated, a light signal should be shown anytime the injection button is pressed. If no light is shown the battery might be empty. See 'Part 9: Troubleshooting guide <no light' for more details.

Part 5 Preparing

A Charging your smartdot™ transmitter

You must charge your transmitter before using it for the first time.
The smartdot™ transmitter will automatically switch on when you plug in the USB cable.
After initial charging, your transmitter will need to be recharged approximately every 2 weeks.



1. Connect smartdot™ transmitter to the supplied USB cable.
2. Connect the cable to a powered USB wall charger.
3. The transmitter will display a **blinking blue light** to indicate that it is charging. A full charge can take up to 2 hours to complete.
4. When the transmitter is fully charged, the **blinking blue light** will disappear, and no light is shown.
5. Remove the charging cable. smartdot™ transmitter is now ready to be paired.

Do not use smartdot™ transmitter while it is charging.

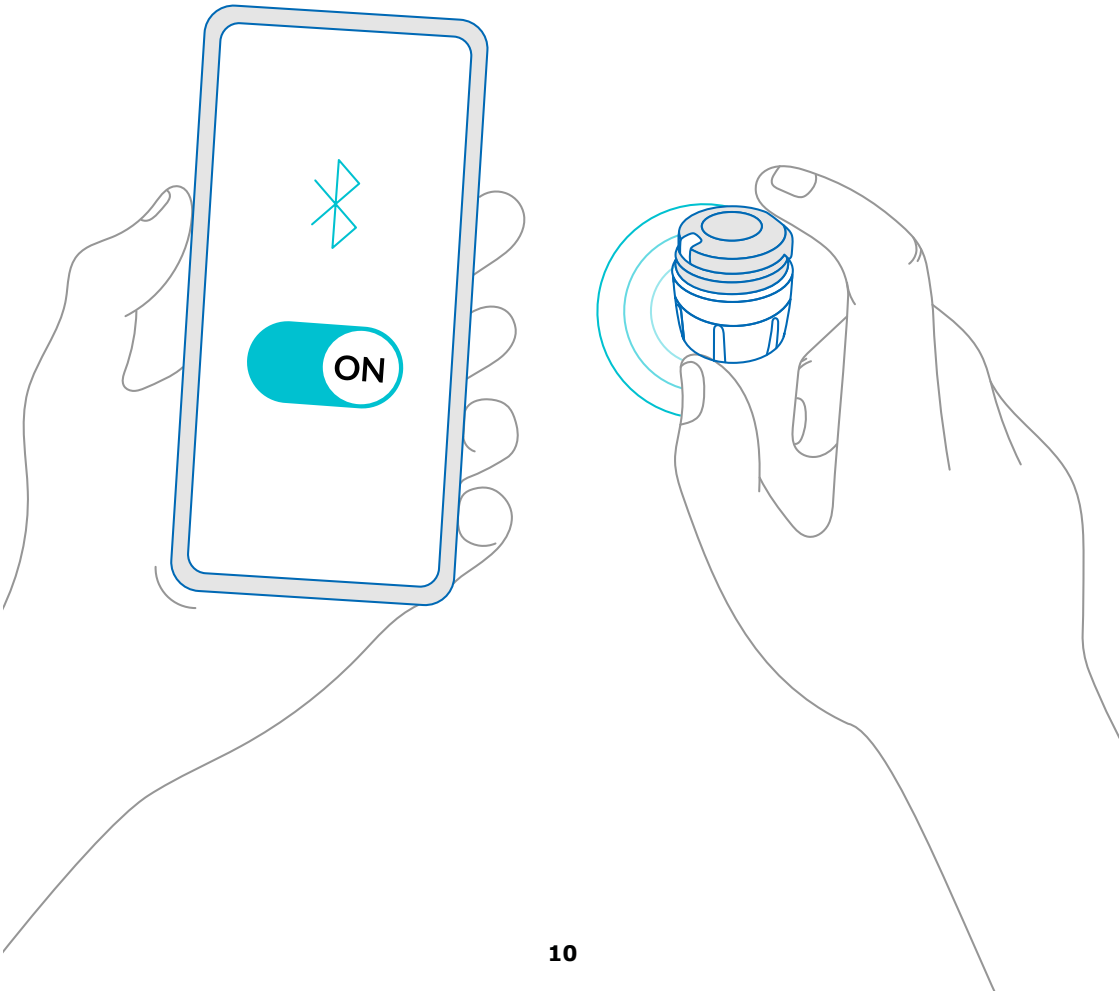
B Downloading the App

1. Your healthcare professional will create an account for you in the associated web-based application. You will receive an invitation email with instructions to download the compatible App.
2. Once installed the compatible App on your smartphone, you can log in with the temporary password shared in the invitation email.

Install the compatible App on your smartphone and log in with your details.

C Pairing your smartdot™ transmitter with the App

1. Activate Bluetooth® on your smartphone.
2. Place the smartdot™ transmitter near your smartphone.
3. Open the App and follow the onscreen instructions to pair it with your transmitter.
4. After successful pairing, smartdot™ transmitter will display a **green light**. Your App will also confirm that the pairing was successful.

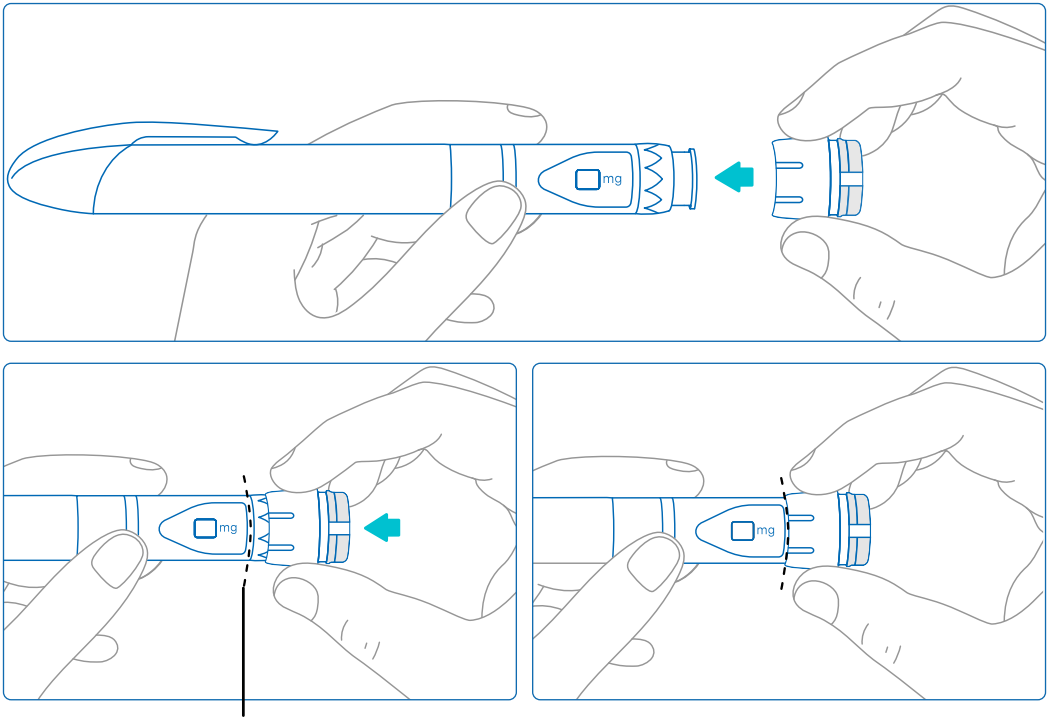


D Placing smartdot™ transmitter on your pen injector

1. Hold the pen in one hand, so that you can see the dose knob.
2. In your other hand, hold the smartdot™ transmitter by the dial wheel.
3. Place the transmitter onto the dose knob and push the dial wheel down until the dose knob is completely covered by smartdot™ transmitter, and you cannot push anymore.

Do not hold or push the injection button when placing it onto the pen injector.

Note:
The smartdot™ transmitter can be placed on the pen in any orientation. The transmitter intended use is to record the injection data, it does not indicate how to inject.

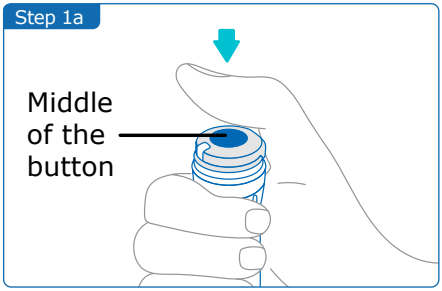


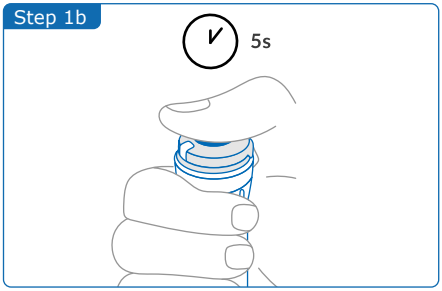
E Activating your smartdot™ transmitter

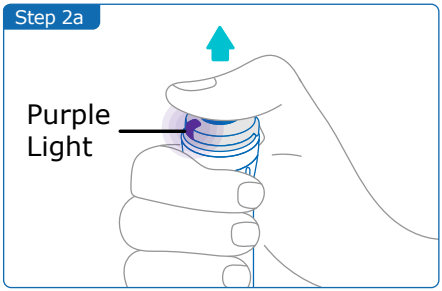
Note:
You need to activate smartdot™ transmitter to use it. This will allow your transmitter to record injection data when you perform your injection.
Learn more about data transmission, see 'Part 8: Frequently asked questions <F. How does smartdot™ transfer the injection data?'

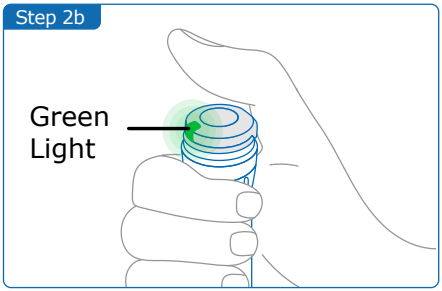
1. Press the smartdot™ injection button, until you see a **purple light**.
2. Now release the button. The transmitter will show a **green light**, it means the smartdot™ transmitter has been successfully activated.

IMPORTANT:
If you do not see a green light when you release the injection button or when you press the button after the activation steps, the activation was not successful. Repeat the steps 1 and 2 and try again.
Do not repeat the activation steps if you see the green light. Repeating the same steps, if the smartdot™ transmitter has been activated, will de-activate it. For more information on when to de-activate the transmitter, see 'Part 8: Frequently asked questions, <C. How do I deactivate and remove the smardot™ transmitter?'.









Part 6 Injecting

Note:
Your smartdot™ transmitter does not change the injection process for your pen injector. Please follow the pen instructions for use to prepare and perform your injection. The steps below only cover the use of smartdot™ transmitter. The green light will show when injection button is pressed, it means that the transmitter is ready to record the injection. During injection, the green light shown means that the injection data is being measured.
Do not watch the green light during injection, it does not indicate how to inject. Always follow the pen injection steps.

1. Prepare your pen injector, as shown in the pen instructions for use. Respect the acclimatation time specified in the pen instructions before use.
2. Turn the smartdot™ dial wheel until your intended dose is visible in the dose window.
3. Perform your injection as described in the pen instructions for use.

IMPORTANT:
Before removing the pen injector from the skin, make sure the number "0.0" appears in the dose window to ensure you injected the full dose.

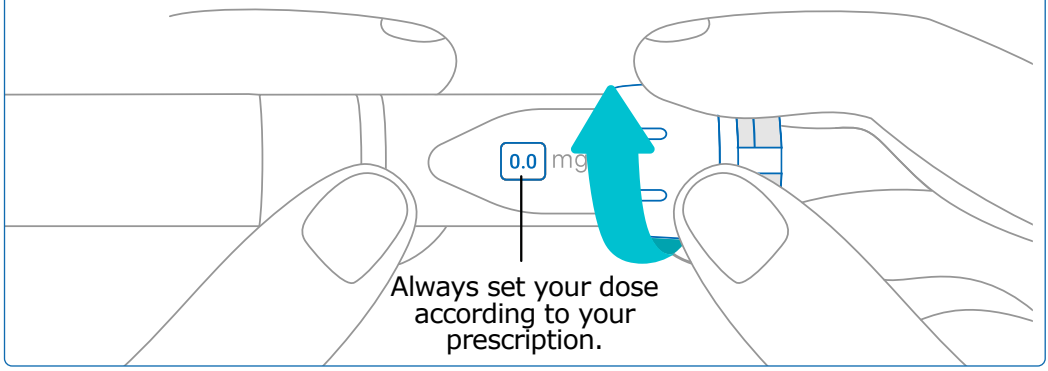
4. Remove the needle from your skin and then release the injection button. The **green light** will stay for few seconds.

Note:
Contact your healthcare professional if you have questions about your pen injector or if you are unsure you have injected your prescribed dose.

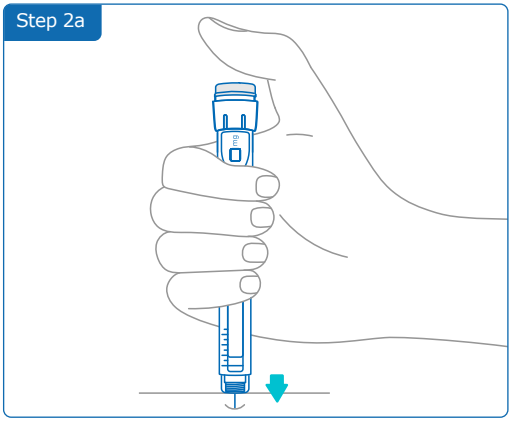
If you have any doubts about the synchronization of the data with the application or with the data displayed please contact your healthcare professional.

Note:
If the smartdot™ battery is low, the green light will turn orange for few seconds after the injection button is released. See 'Part 9: Troubleshooting guide <orange light' for more details.

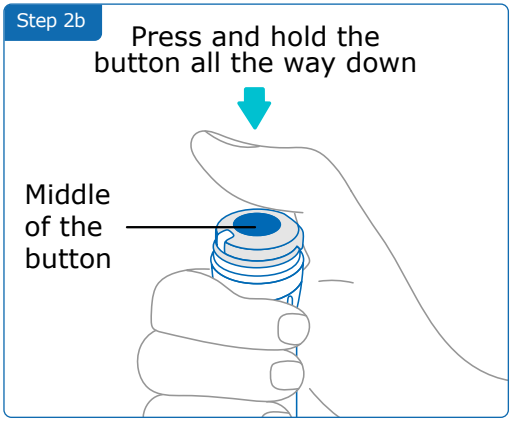
Step 1



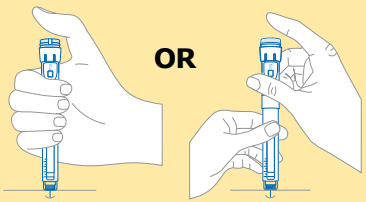
Step 2a



Step 2b

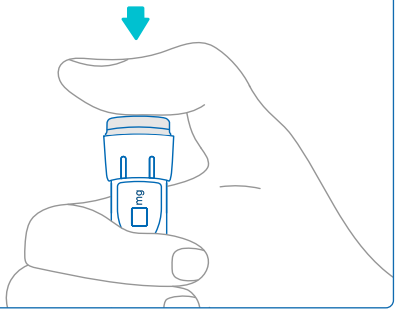


Note:
Adapt your position in order to feel comfortable and be able to inject your dose without changing position or finger during the injection. Use your thumb or index finger. Keep the same position and finger during injection.



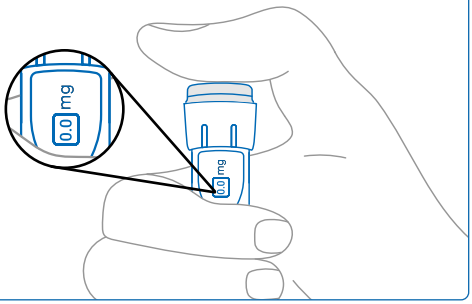
Step 2c

Hold while slowly counting to 10

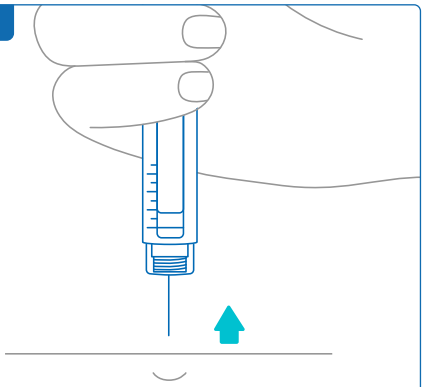


Step 3a

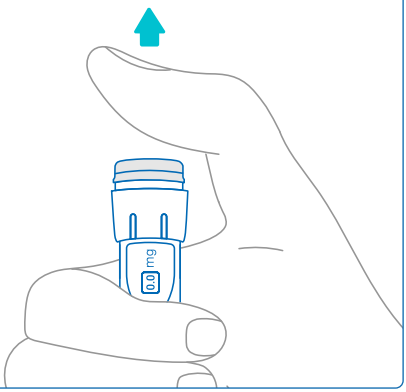
Make sure the number "0.0" appears in the dose window to ensure you injected the full dose.



Step 3b

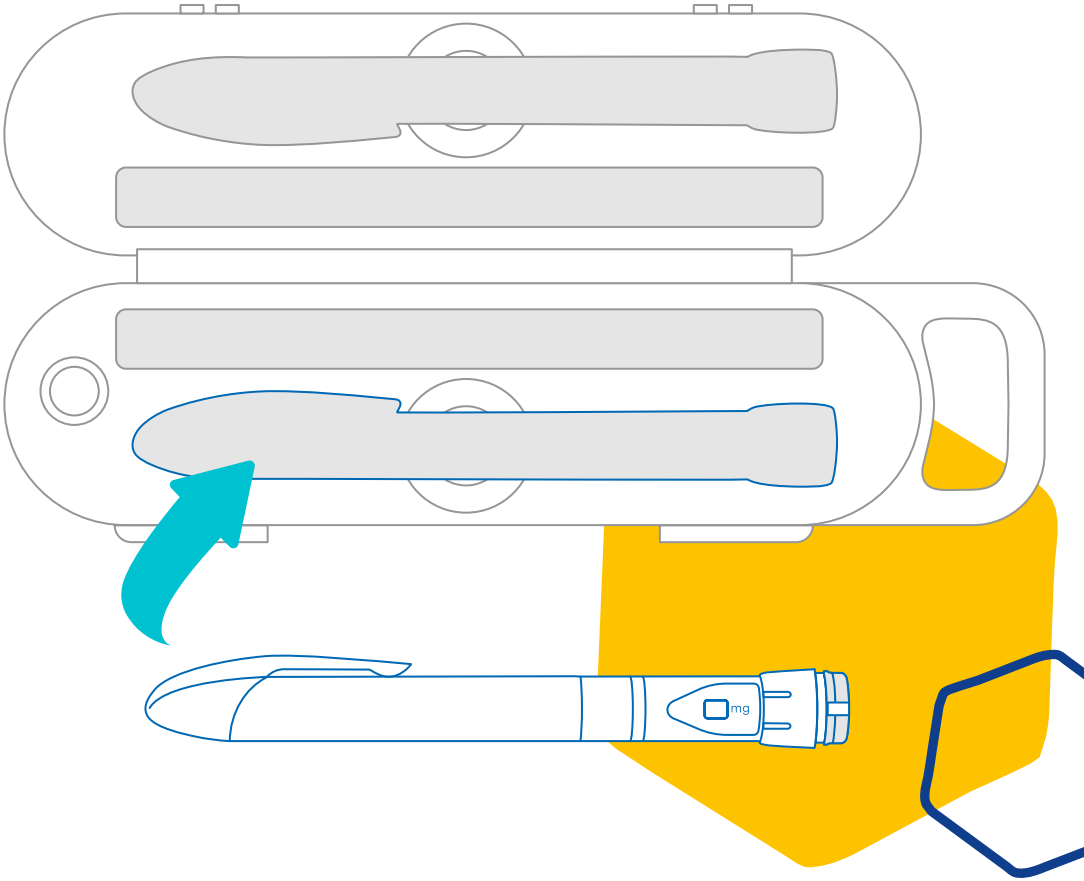


Step 3c



Part 7 Storing

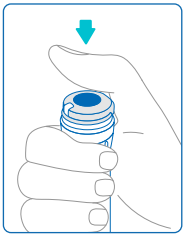
Place your pen injector and attached smartdot™ transmitter in the pen storage case. Store it according to the Saizen® patient information leaflet.



Note:
Your smartdot™ transmitter is designed for storage between 2°C to 40°C.

Part 8 Frequently asked questions

A How do I check the status of my smartdot™ transmitter?



Once smartdot™ transmitter has been connected to the App, you can press the injection button at any time. This will wake up the transmitter and a light will switch on for few seconds. This light can be green, orange or red. See 'Part 9: Troubleshooting guide' if you see a red or orange light, or no light at all.

Do not play with your pen injector or smartdot™ transmitter. Only dial your dose when you are about to perform an injection.

B How do I take care of my smartdot™ transmitter?

You can wipe your transmitter with a clean damp cloth whenever needed, when it is:

- Attached to the pen injector – to wipe the external surfaces
- Removed from the pen injector – to wipe the internal surfaces. In this case, you need to deactivate smartdot™ before removing it from the pen. See 'Part 8: Frequently Asked Questions <C. How do I deactivate and remove the smartdot™ transmitter?'.

If you removed smartdot™ transmitter from the pen:

1. Place your transmitter back on your pen. See 'Part 5: Preparing <D. Placing smartdot™ on your pen injector'.
2. Reactivate your transmitter. See 'Part 5: Preparing <E. Activating your smartdot™ transmitter'.

Do not wipe smartdot™ transmitter while it is connected to external power source. Unplug the transmitter before wiping it.

Do not immerse smartdot™ transmitter in water. It is not waterproof, and you may damage the transmitter.

Do not leave your smartdot™ transmitter or its accessories in a dusty location.

Do not use any cleaning solutions, chemicals or alcohol wipes.

C How do I deactivate and remove the smartdot™ transmitter?

The smartdot™ transmitter must be deactivated before you can remove it from the pen injector. This will prevent data being recorded in error.

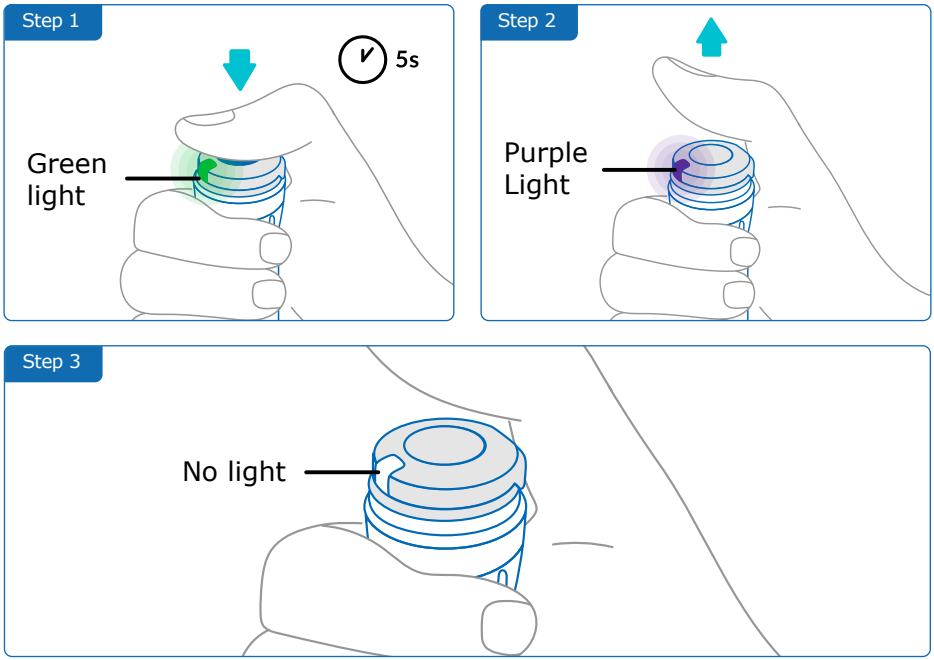
You need to deactivate the transmitter before carrying out the following actions:

- Wiping the internal surfaces of smartdot™ transmitter or your pen injector
- Charging smartdot™ when the room temperature is above 25°C.
- Moving smartdot™ to a new pen injector

1. Press smartdot™ transmitter for 5 seconds until the **green light** turns to **purple**.
2. Release the button as soon as you see the **purple light**.
3. The light will turn off. The transmitter is now deactivated, and injections will no longer be recorded.

You can now remove the transmitter from the pen.

To reactivate smartdot™ transmitter, see 'Part 5: Preparing <E. Activating your smartdot™ transmitter'.



D How do I travel with the smartdot™ transmitter?

Place your pen injector and attached smartdot™ transmitter in the pen storage case. Store it according to the Saizen® patient information leaflet.

E How do I pair smartdot™ transmitter with a new smartphone?

If you want to pair your transmitter with a new smartphone:

1. Open the App and ensure all your injection data is synchronized. See `Part 8: Frequently asked questions <F. How does smartdot™ transfer the injection data?' and refresh the home page by swiping down the screen.
2. Reset the transmitter. See 'Part 9: Troubleshooting guide <A. Reset your smartdot™ transmitter'.
3. Download the App on your new smartphone. See 'Part 5: Preparing <B. Downloading App'.
4. Follow steps A-E in 'Part 5: Preparing'.

F How does smartdot™ transmitter transfer the injection data?

The smartdot™ transmitter automatically transfers data to your App if your:

- Transmitter is paired with your App. See 'Part 5: Preparing <C. Pairing your smartdot™ with the App.'
- Smartphone is near the transmitter.
- Smartphone's Bluetooth® is enabled.
- App is open. Follow the instruction on the application, to see your injections datas.

IMPORTANT:
Once paired with App, you can perform 100 injections with smartdot™ transmitter without opening the App. You should open the App at least once a month to allow data transfer to happen.

G When would I reset the smartdot™ transmitter?

You need to reset your smartdot™ transmitter if:

- It displays a **red light**.
- You want to pair it with a new smartphone.
- You want to delete smartdot™ injection data.

To reset your transmitter, see 'Part 9: Troubleshooting guide <A. Reset your smartdot™ transmitter'.

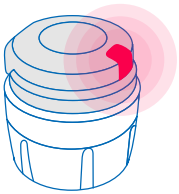
H How do I dispose of the smartdot™ transmitter?

The smartdot™ transmitter has been built to last 3 years after first use.

The transmitter is an electronic product. **Do not** throw it away as household waste. Dispose of it in accordance with local regulations.

Before disposing your smartdot™ transmitter, perform a factory reset to delete your personal medical data. 'Part 9: Troubleshooting guide <A. Reset your smartdot™ transmitter'.

Part 9 Troubleshooting guide

What do I see?	When does this light signal appear?
Red light 	The **red light** can appear when the button is pressed.
	What does it mean?
	The smartdot™ transmitter is defective and cannot record your injections. It needs to be reset.

What should I do?

A. Reset your smartdot™ transmitter.

Please note: Resetting deletes the data stored in the transmitter, deactivates the transmitter and unpairs it from the App. There are two ways to reset your smartdot™ transmitter.

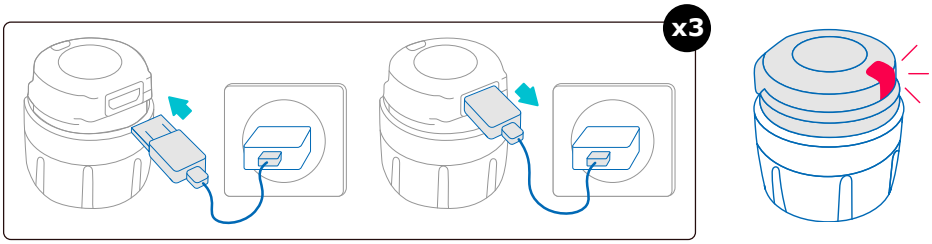
Option 1 - Reset with the App

1. Open the App and ensure that all your data has been synchronized. See `Part 8: Frequently asked questions <F. How does smartdot™ transfer the injection data?' and refresh the home page by swiping down the screen.
2. Open 'smartdot™ settings' in your App and select 'Reset smartdot™'. The transmitter will display a **blinking red light** during the reset.
3. Switch smartdot™ transmitter on by plugging it until you see the **blue light** of charging and then unplug the USB cable. See steps C-E in 'Part 5: Preparing'.

Continued on the next page

Option 2 - Reset with the charging cable

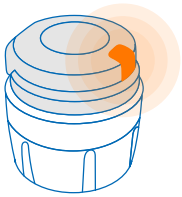
1. Connect the transmitter to a powered USB wall charger through the supplied USB cable.
2. Quickly unplug it from the cable.
3. Repeat this action three times or until you see a **blinking red light**.



4. Switch the smartdot™ transmitter on by plugging it until you see the **blue light** of charging and then unplug the USB cable. See steps C-E in 'Part 5: Preparing'.

If the red light remains, your transmitter is still defective. Remove it from your injection pen and contact your healthcare professional for further assistance.

Note: You can still perform your injections without using your transmitter.

What do I see?	When does this light signal appear?
Orange light 	The **orange light** can appear: • When the button is pressed, and the battery is low • When the button is released at the end of an injection and the battery is low

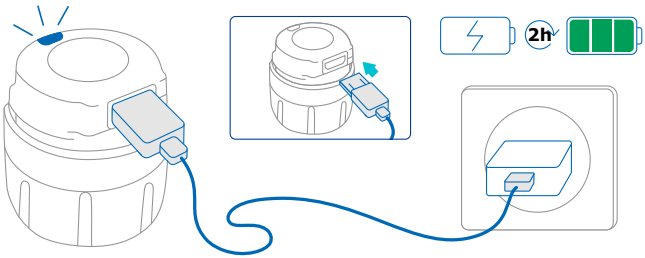
What does it mean?

The smartdot™ transmitter battery is low.
It needs to be charged.

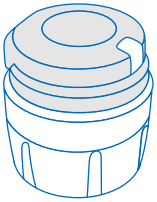
What should I do?

B. Charge your smartdot™ transmitter

1. Connect it to the supplied USB cable.
2. Connect the cable to a powered USB wall charger.
3. During charging, the transmitter will display a blinking **blue light**. A complete charge can take up to 2 hours.
4. When the transmitter is fully charged, the **blinking blue light** will disappear, and you can remove the charging cable.



Note: If you are charging in a room where the temperature is above 25°C, you must deactivate smartdot™ transmitter and remove it from your pen. See 'Part 8: Frequently Asked Questions <C. How do I deactivate and remove the smartdot™ transmitter'.

What do I see?	When does this light signal appear?
No signal 	When the button is pressed, and no light signal appears.
What does it mean?	**What should I do?**
The smartdot™ transmitter is not switched on. It hasn't yet been charged for the first time or it has been reset.	1. Switch on the smartdot™ transmitter by plugging and unplugging it once with the charging cable, when connected to an external power supply. 2. See steps C-E in 'Part 5: Preparing.' 3. Activate your transmitter. See 'Part 5: Preparing <E. Activating your smartdot™ transmitter'.

Continued on the next page

What does it mean?	What should I do?
The battery is out of charge.	Before you can you use your smartdot™ transmitter again, you will need to perform all the following steps: 1. Charge your smartdot™ transmitter until the blue light stops blinking. 2. Open your App, in the home screen, press on the banner that reads: **"smartdot™ is not ready"**. Follow the on-screen, step-by-step instructions to reconnect the smartdot™ transmitter to the mobile App using Bluetooth® and to reactivate the transmitter. 3. Check that the transmitter status banner in the App (home page) reads **"smartdot™ is ready"** before using your smartdot™ transmitter.
smartdot™ transmitter has been deactivated or activation was not successful.	See 'Part 5: Preparing <E Activating your smartdot™ transmitter'.

If there is still no light, remove the smartdot™ transmitter from your pen and contact your healthcare professional for further assistance.

Note: You can still perform your injections without using your transmitter.

If there is problem with your pen injector, please refer to the pen instructions for use.

Part 10 Regulatory information on radio communication

Declaration of conformity 2014/53/EU

- BIOCORP PRODUCTION declares that the radio equipment of smartdot™ transmitter type is in conformity with the Directive 2014/53/EU (RED).
- The full text of the EU Declaration of Conformity is available at the following web address: https://biocorpsys.com/smartdot-certification-red/
- Within Europe you may request a printed copy of these instructions for use, free of charge, by filling the form available on https://biocorpsys.com/ifu/

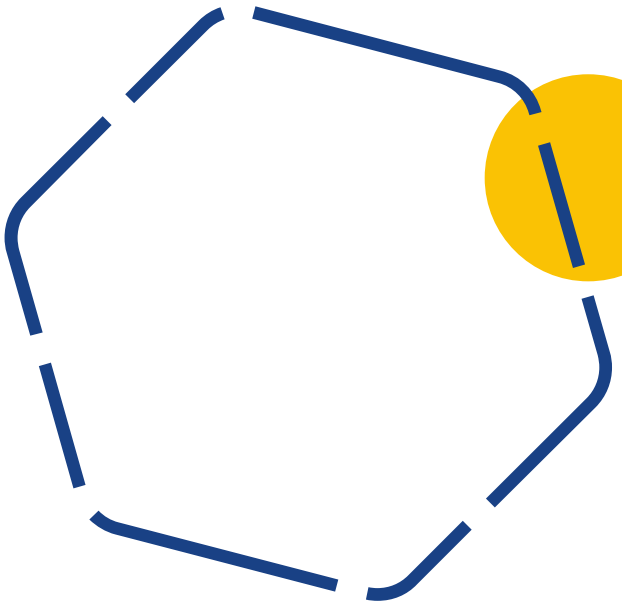
ATTENTION

- Avoid using this transmitter next to or stacked with other devices because it may cause malfunction. If such use is necessary, observe this transmitter and other devices for normal operation.
- The use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment may result in increased electromagnetic emissions or decreased immunity of this equipment and may result in improper operation.
- Portable Radio Frequency (RF) communications devices (including peripherals such as antenna cables and external antennas) should not be operated closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Failure to do so may impair the performance of these devices.

Part 11 Regulatory information on electronic waste

Declaration of conformity 2012/19/EU and 2011/65/EU

- BIOCORP PRODUCTION declares that smartdot™ transmitter radio equipment follows Directive 2012/19/EU (WEEE) and Directive 2011/65/EU (RoHs III) on the restriction of the use of hazardous substances in electrical and electronic equipment going to landfill.
- Public authorities shall adopt appropriate measures for users, distributors, and manufacturers to contribute to the collection of electrical and electronic equipment by establishing legal requirements for the reuse, recovery or recycling of such equipment. Dispose of the smartdot™ transmitter according to local recommendations.



Part 12 Technical specifications

Model number EF36

A Radio module specifications

The smartdot™ transmitter integrates a Bluetooth® module with the following features (Receive / Transmit):

Specification	Value
Bluetooth® Low Energy type	BLE
Frequency band	[2400 - 2483.5] MHz
Number of channels	40
Channel spacing	2MHz
Bandwidth	1MHz
Max EIRP (Effective Isotropic Radiated Power)	-5,5dBm

B Electronical information (1 of 2)

USB Characteristics	
Rated voltage	5V DC
Rated current	2A (min 500 mA)
Model number	0373707
Battery Characteristics	
Battery	Li-ion rechargeable: Li-ion 3,7V-45mAh
Battery life with full charge	2 weeks (once a day use)
Battery charging time	Fully charge after 2 hours

Use an IEC/UL 60950-1 or IEC/UL 62368-1 certified USB charger (with CE or UL mark) to charge the battery via the supplied USB cable.

Disposal of a battery in a fire or hot oven, or mechanical crushing or cutting of a battery, may cause an explosion.

Keeping a battery in a very high temperature environment can cause an explosion or the escape of flammable liquid or gas.

C Electronical information (2 of 2)

Please connect the supplied USB cable to the USB port of an AC adapter suitable for your region with the following specifications:

USB Charger (not included)	
USB charger certified IEC/UL 60950-1 or IEC/UL 62368-1 (with CE or UL mark)	
Adapted external module with automatic voltage adaptation: no selection required.	
Input voltage range	90-264 V
Frequency range	47-63 Hz
Category	II (double isolation)
Output voltage	5V DC
Output current	100mA - 2A - Energy class PS1 for USB power supply

You are responsible for properly securing and managing your smartphone. If you suspect an adverse cybersecurity event related to the smartdot™ transmitter or related App, contact your healthcare professional.

Make sure that your smartphone and the smartdot™ transmitter are kept in a safe place, under your control. This is important to help prevent anyone from accessing or tampering with your smartphone or smartdot™ transmitter.

The App used with the smartdot™ transmitter is not intended for use on a smartphone that has been altered or customised to remove, replace or circumvent the manufacturer's approved configuration or use restriction, or that otherwise violates the manufacturer's warranty.

The App used with the smartdot™ transmitter requires that your smartphone has the correct date and time for recording your injection data. Your smartphone's date and time should be set to update automatically. You can check this in your smartphone settings.

Keep your smartphone well charged and turned on to allow smartdot™ transmitter to transmit your injection data regularly.

Be aware that after an operation system update, there could be unexpected behavior. Open your App, check your smartdot™ transmitter and your App to make sure all is working properly.

Please note that if the App and the smartdot™ transmitter are used in a noisy electromagnetic environment (signal near 2.4GHz), the BLE communication is no more possible and the connection between them is closed. However, the smartdot™ transmitter continues to record injection. When the disturbing electromagnetic signals disappear, the App and the smartdot™ transmitter can communicate again.

Part 13 Symbols and information on the packaging

Symbol	Description and information
	Operator's manual; operating instructions It is necessary to consult instructions for use https://biocorpsys.com/ifu-smartdot/
	Manufacturer
	European Conformity marking
	Serial number
	Date and country of manufacture
	Batch number
	Product reference
	Distributor reference
	Direct current

Part 13: Symbols and information on the packaging

Symbol	Description and information
	For indoor use only
IP32	Ingress Protection index IP32 Protection against solid bodies greater than 2.5 mm Protection against droplets, if the housing is positioned at an angle of 15 degrees from the vertical or less.
	Humidity sensitive device Do not expose the device to moisture
	Temperature limits to which the device can be safely exposed. +2°C to +40°C
	Humidity limits to which the device can be safely exposed. 10% to 90%
	The pressure limits to which the device can be safely exposed. 700 hPa to 1060 hPa
#	Model number : EF36

Part 13: Symbols and information on the packaging

Symbol	Description and information
	Management of electrical and electronic waste. Collection and treatment of electrical and electronic equipment*. This symbol indicates that this product should not be disposed with household waste. It has to be returned to a local authorized collection system. By following this procedure, you will contribute to the protection of the environment and human health. The recycling of the materials will help to conserve natural resources. * Valid in the EU member states and in any countries with corresponding legislation.

BIOCORP

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CE