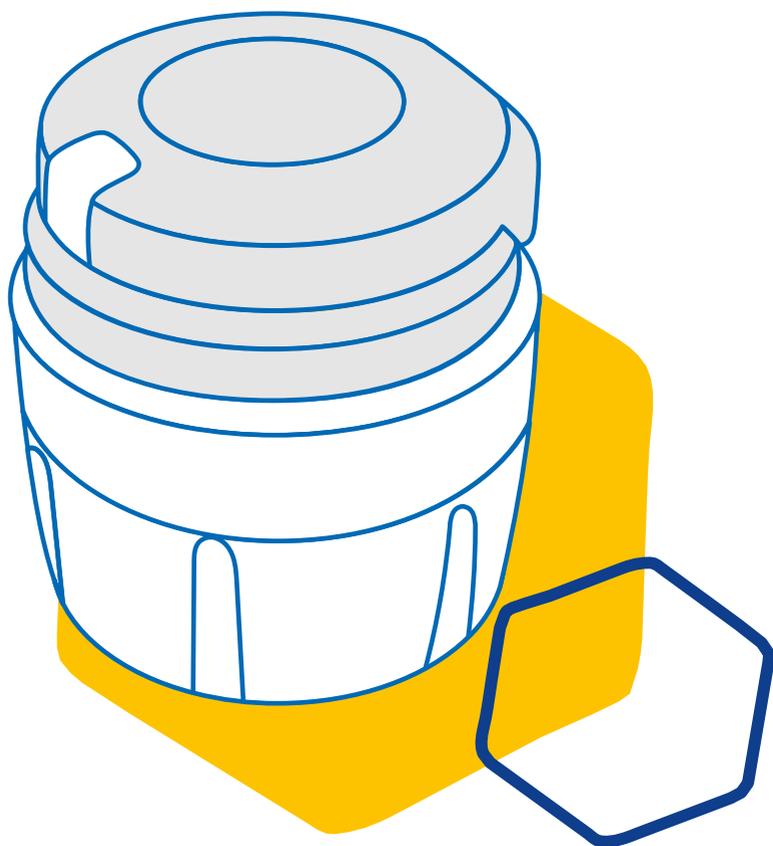# Instructions for Use

smartdot™ transmitter

for aluetta™ pen injectors 6, 12 and 20

- The smartdot™ transmitter can only be used with the aluetta™ pen injector (6, 12, 20).

- The purpose of the smartdot™ transmitter is to store and transfer injection data when administering Saizen® (somatropin) injections with the aluetta™ pen injector.

- Injection data are transferred to the growlink™ compatible mobile application (app) via Bluetooth® technology. Your healthcare provider 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 aluetta™ pen user only.

- The smartdot™ transmitter does not change the aluetta™ pen injection process. Please read your aluetta™ pen injector instructions before starting to use the transmitter.

- Keep your transmitter out of the reach of children. Small parts could be inhaled or swallowed and may lead to choking. If smartdot™ is being used by a child, they should be supervised by an adult.

⚠️ **Please read all the instructions in this manual before using the smartdot™ transmitter.**
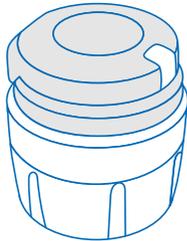
To preserve the performance and lifespan of the smartdot™ transmitter, please adhere to the following environmental conditions:

- Do not use in an environment containing flammable substances or oxygen.

- Store the smartdot™ transmitter in a safe place. Do not leave it unattended in the presence of children due to the risk of serious injury (swallowing or choking), or damage to the device.

- Do not use smartdot™ while it is charging.

- Do not use smartdot™ in the case of visible damage. Contact your healthcare professional for further assistance.

- Do not attempt to modify or repair smartdot™. It may damage the transmitter or cause you harm. Please note, smartdot™ does not require any special maintenance during its lifespan.
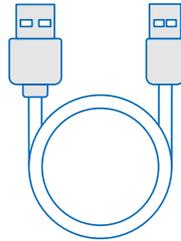
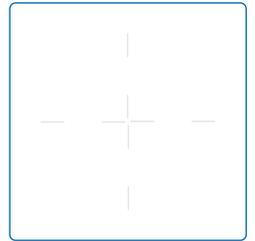- smartdot™ is an electronic product. Do not dispose of it as household waste.
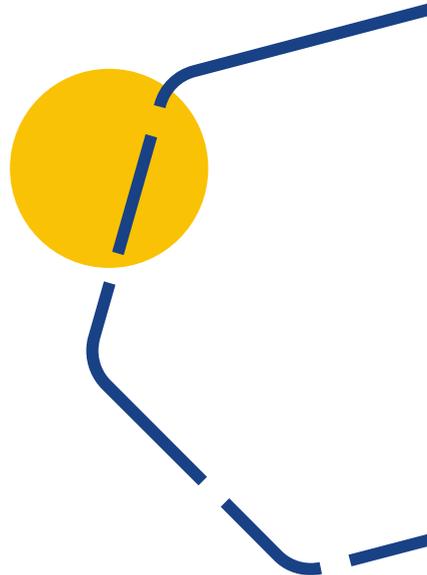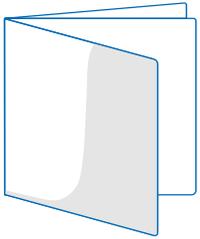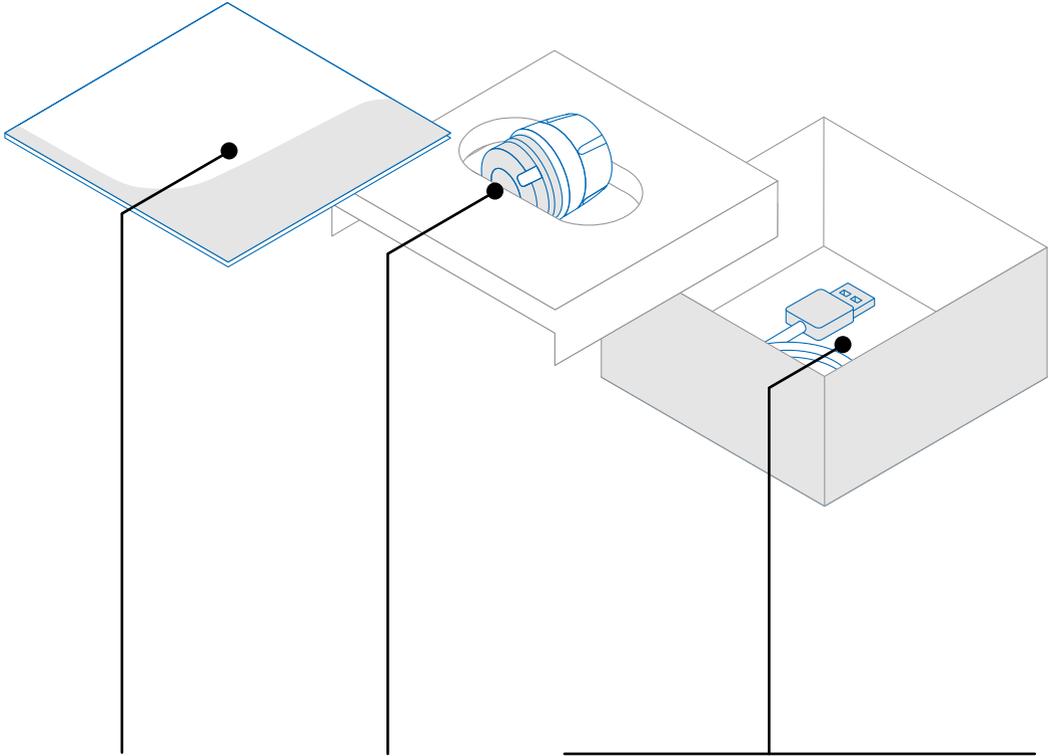
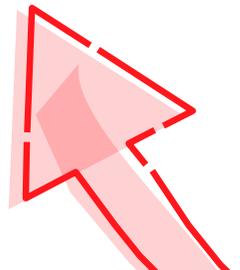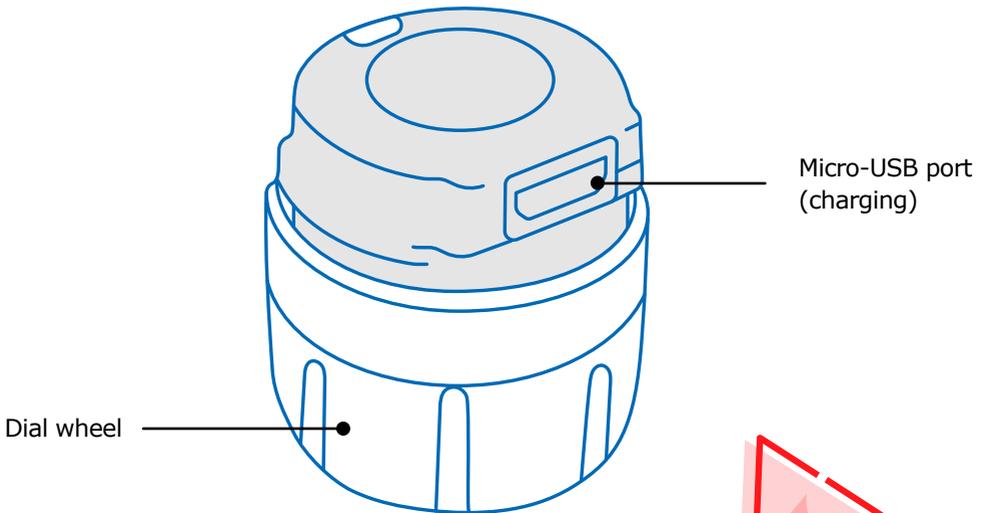Quick Start Guide   smartdot™   USB cable   Compliance information

Injection button

Light signal

Micro-USB port (charging)

Dial wheel
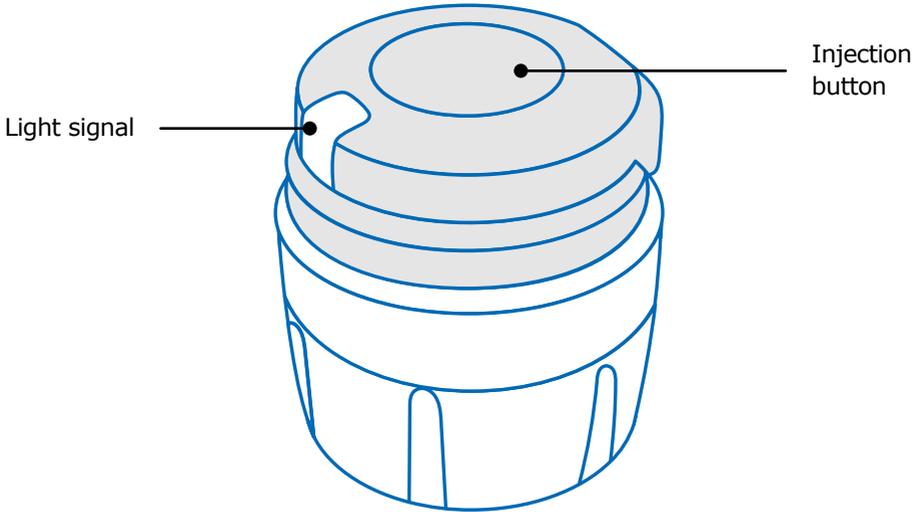
White

The white light shows that smartdot™ is ready to use.

Orange

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

Red

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

Blinking red

The blinking red light means that a reset is in progress.

Purple

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

Blinking blue

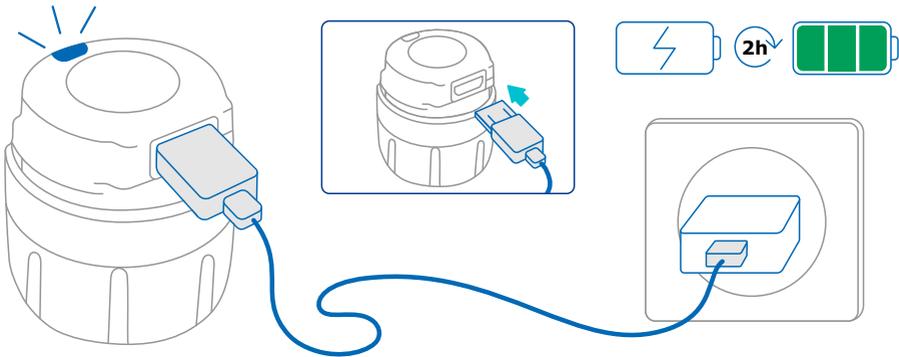The blinking blue light shows that smartdot™ is charging.
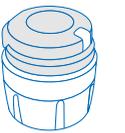
No signal

No light is displayed when smartdot™ is sleeping, or the battery is empty. You can check the status of smartdot™ by pressing the injection button. See 'Part 9: Troubleshooting guide <no light' for more details.

A   Charging your smartdot™ transmitter

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

1. Connect smartdot™ 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 smartdot™ is fully charged, the **blinking blue** light will disappear, and no light is shown.

5. Remove the charging cable. smartdot™ is now ready to be paired.

Do not use smartdot™ while it is charging.

> **Note:**
> There will be no light signal until the pairing process has finished.

B **Downloading the growlink™ app**

1. Your healthcare provider will create an account for you in the growlink™ app. You will receive an email with instructions to complete the registration process.

2. When you complete the registration, you will receive a second email to activate your account and a link to download the growlink™ app. You can also download the app by scanning the QR code below. You can also find this QR code in the Quick Start Guide.

PLACEHOLDER

Install the growlink™ app on your smartphone and log in with your details.

GET IT ON
Google Play

Download on the
App Store

C **Pairing your smartdot™ with the growlink™ app**

1. Activate Bluetooth ⚹ on your smartphone.

2. Place the smartdot™ transmitter near your smartphone. You can do this while the transmitter is charging.

3. Open the growlink™ app and follow the onscreen instructions to pair it with your smartdot™.

4. After successful pairing, smartdot™ will display a **white light**. Your growlink™ app will also confirm that the pairing was successful.
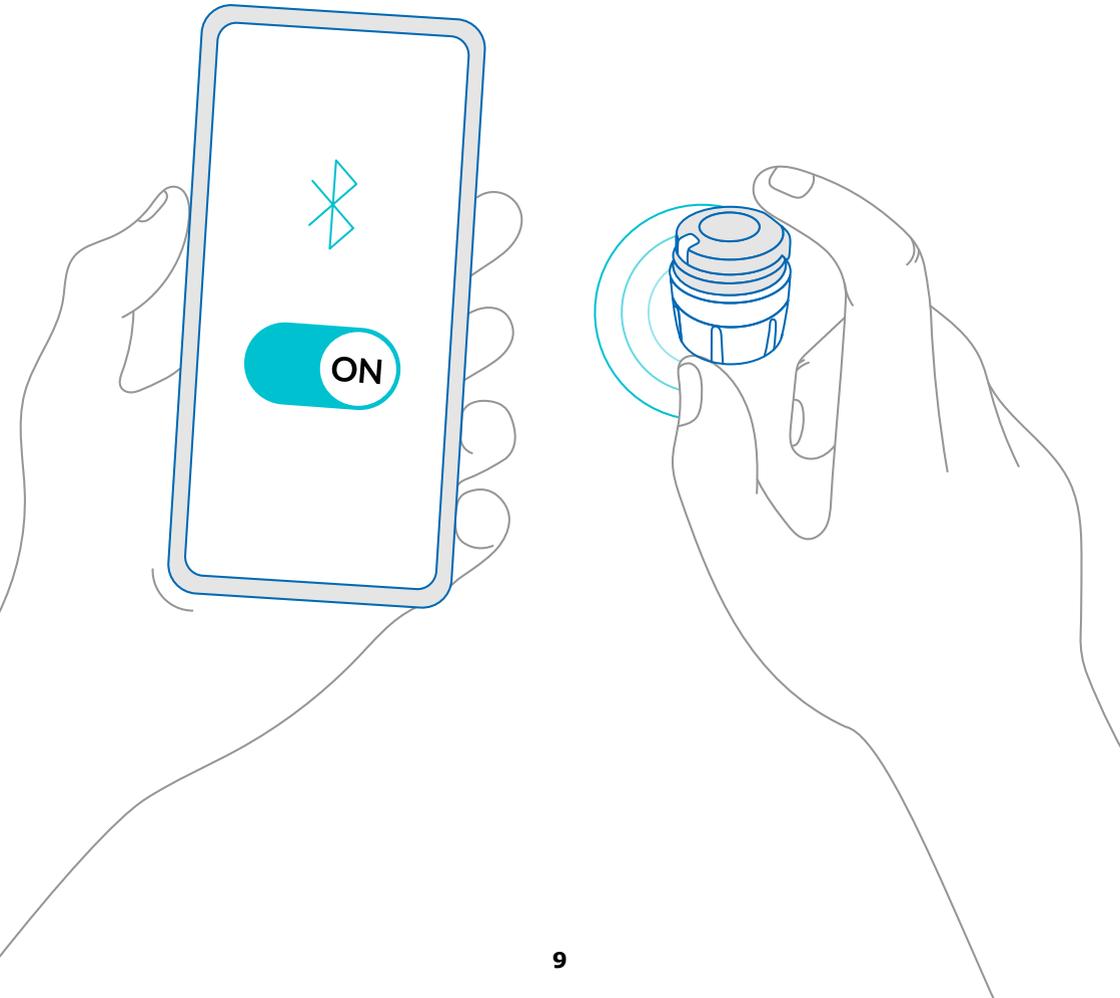
D Placing smartdot™ on your aluetta™ pen

1. Hold the aluetta™ pen in one hand, so that you can see the aluetta™ dose knob.

2. In your other hand, hold the smartdot™ transmitter by the dial wheel.

3. Place the transmitter onto the aluetta™ dose knob and push the dial wheel down until the aluetta™ knob is completely covered by smartdot™, and you cannot push anymore.

Do not hold or push the injection button when placing it onto the aluetta™ pen.
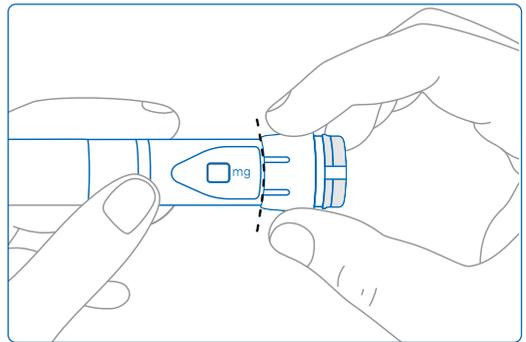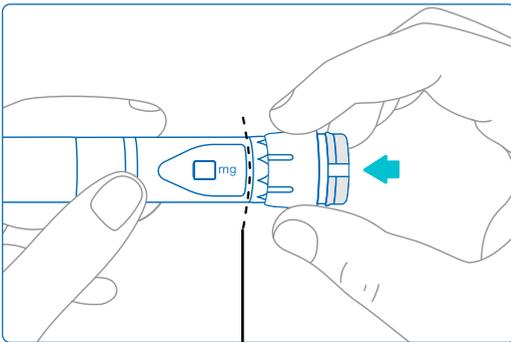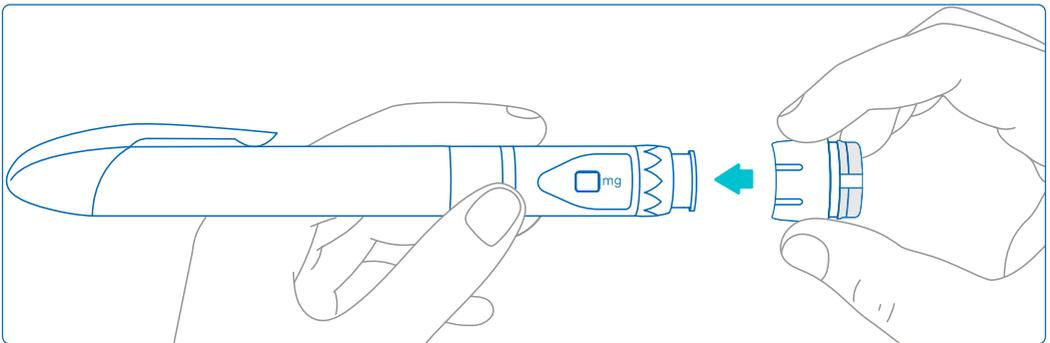
smartdot™ transmitter should cover the pen button entirely

E Activating your smartdot™ transmitter

> **Note:**
> You need to activate smartdot™ to use it. This will allow your transmitter to record injection data when you perform your injection.

1. Press the smartdot™ injection button, until you see a **purple light**.

2. Now release the button. smartdot™ will display a white light. When the **white light** turns off, smartdot™ has been successfully activated.

Step 1a

Middle of
the button

Step 1b

5s

Step 2a

Purple
Light

Step 2b

White
Light
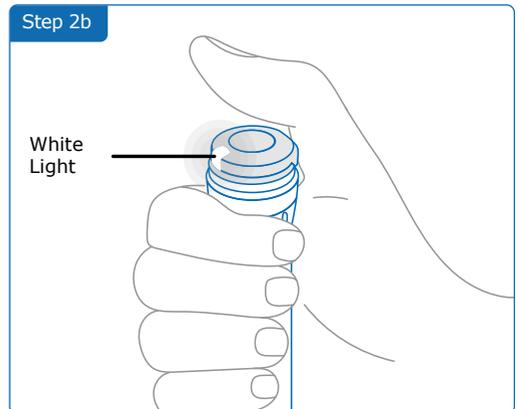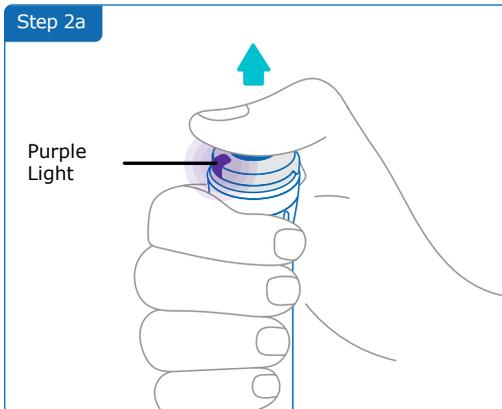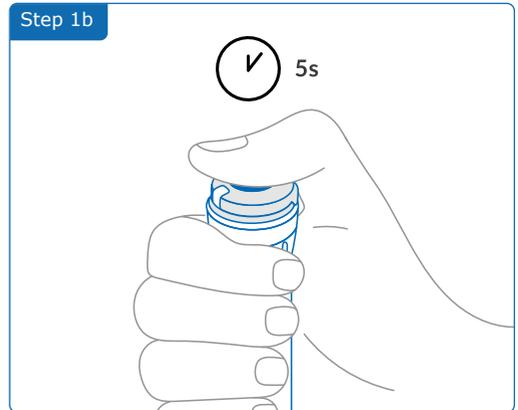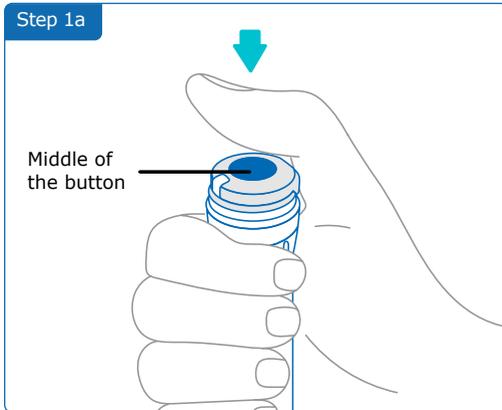
Note:
Your smartdot™ transmitter does not change the injection process for your aluetta™ pen. Please follow the aluetta™ instructions for use to prepare and perform your injection. The steps below only cover the use of smartdot™.

1. Prepare your aluetta™ pen, as shown in the aluetta™ Instructions for Use. If stored in the refrigerator, open the storage box and wait five minutes 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 aluetta™ Instructions for Use. Note: A white light will appear when you are performing your injection. It will disappear when you release the button.

⚠️ **Before removing the aluetta™ pen injector from the skin, make sure you see "0.0" in the dose window to ensure you injected the full dose.**

4. Remove the needle from your skin.

5. Release the button. The white light will stay for few seconds.

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

Step 1

0.0 mg

Always set your dose according to your prescription.
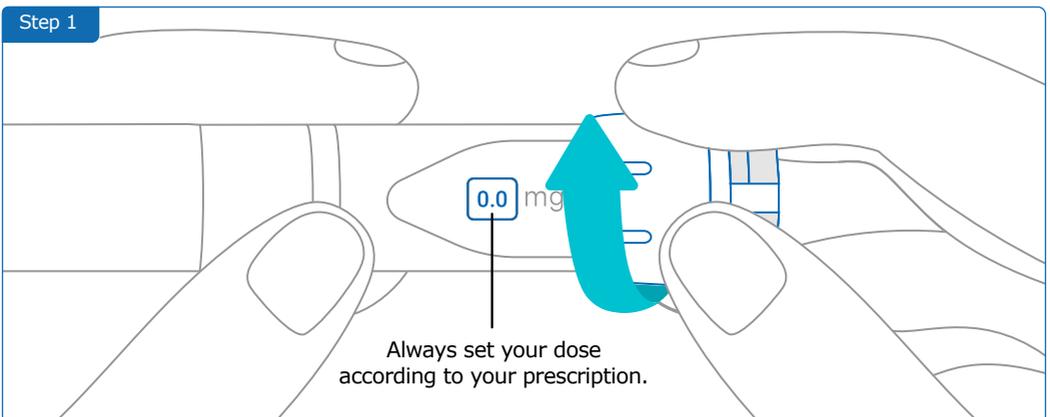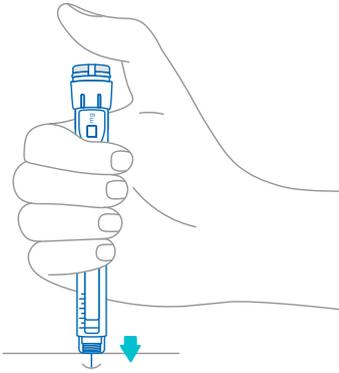
Step 2a

Step 2b

Press and hold the button
all the way down

Middle of
the button
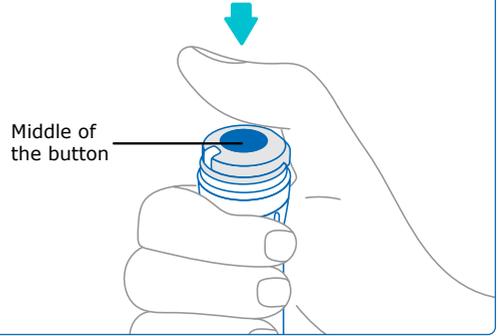
Step 2c

Hold while slowly
counting to 10
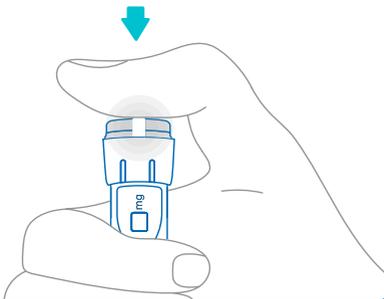
Step 3a

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

0.0 mg

Step 3b

Step 3c

13

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

A ## How do I check the status of my smartdot™ transmitter?
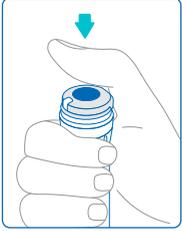
Once smartdot™ has been connected to the growlink™ app, you can press the injection button at any time. This will wake up the transmitter and a light will switch on for few seconds. This light can be white, orange or red. See 'Part 9: Troubleshooting guide' if you see a red or orange light, or no light at all.

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

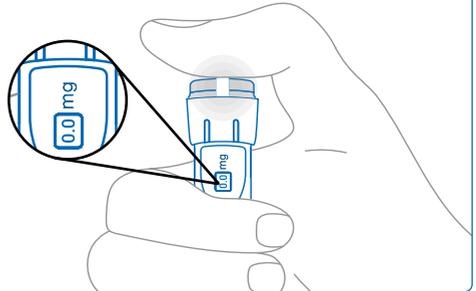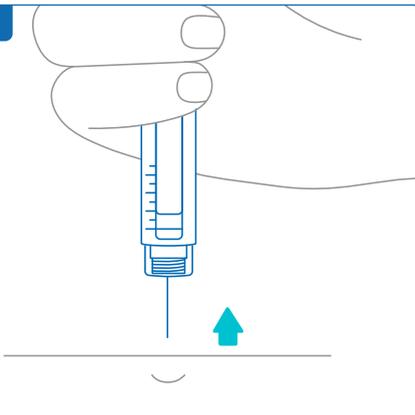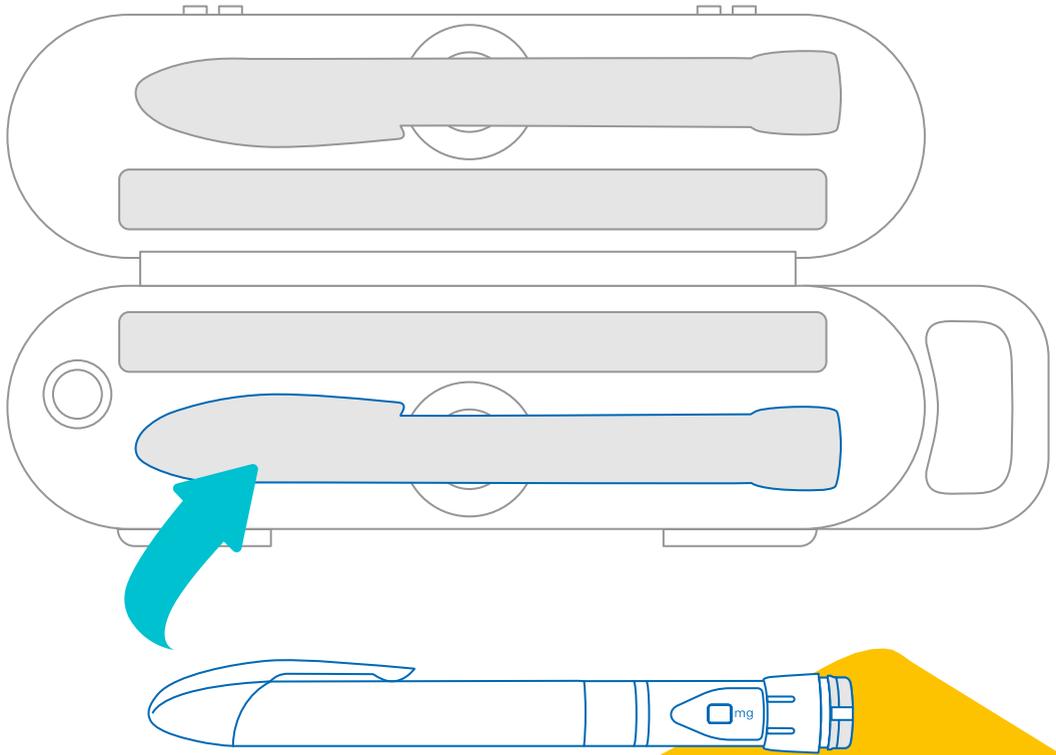**B** ## How do I clean my smartdot™ transmitter?

You can clean your transmitter when it is:

- Attached to the aluetta™ pen – to clean the external surfaces

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

Wipe the surfaces with a slightly damp, soft lint-free cloth, with a small amount of neutral detergent if needed.

Dry the surfaces with a soft cloth.

If you removed smartdot™ from the aluetta™ pen:

1. Place your transmitter back on your pen. See 'Part 5: Preparing <D. Placing smartdot™ on your aluetta™ pen'.

2. Reactivate your transmitter. See 'Part 5: Preparing <E. Activating your smartdot™ transmitter'.

Do not clean smartdot™ while it's connected to external power source. Unplug the transmitterbefore cleaning it.

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

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

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

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

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

- Cleaning smartdot™ or your aluetta™ pen
- Charging smartdot™ when the room temperature is above 25°C.
- Moving smartdot™ to a new aluetta™ pen

1. Press smartdot™ for 5s until the white light turns to purple.

2. Release the button as soon as you see the **purple light**.

3. The light will turn off. smartdot™ is now deactivated, and injections will no longer be recorded.

You can now remove the transmitter from the aluetta™ pen.

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

Step 1

White light

5s

Step 2

Purple Light

Step 3

No light
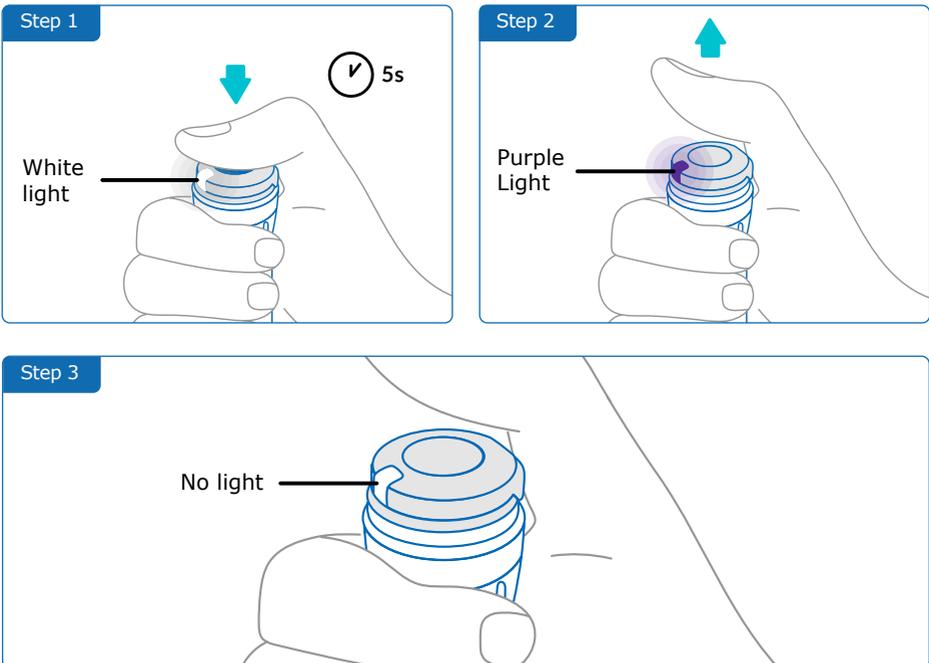
D ## How do I travel with the smartdot™ transmitter?

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

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

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

1. Open the growlink™ app and ensure all your injection data is synchronized. You can manually synchronize your data through the smartdot™ settings page in the app.

2. Reset the transmitter. See 'Part 9: Troubleshooting guide <A. Reset your smartdot™ transmitter'.

3. Download the growlink™ app on your new smartphone. See 'Part 5: Preparing <B. Downloading growlink™ app'.

4. Follow steps A-E in 'Part 5: Preparing'.

F ## How does smartdot™ transfer the injection data?

smartdot™ automatically transfers data to your growlink™ app if your:

- Transmitter is paired with your growlink™ app. See 'Part 5: Preparing <C. Pairing your smartdot™ with the growlink™ app.'

- Smartphone is near the transmitter.

- Smartphone's Bluetooth® is enabled.

- growlink™ app is open.

⚠ **Once paired with growlink™, you can perform 100 injections with smartdot™ without opening the app. The data will synchronize at least once a month, when there is an established connection with the app as specified above.**

G

When would I reset the smartdot™ transmitter?

You need to reset your smartdot™ 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?

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

The smartdot™ 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'.

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?
	smartdot™ 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 smartdot™, deactivates the transmitter and unpairs it from the growlink™ app.

1. Open the growlink™ app and ensure that all your data has been synchronized. You can manually synchronize your data through the smartdot™ settings in the app.

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™ on by plugging in and unplugging the USB cable. Then see steps C-E in 'Part 5: Preparing'.

Note: You can also reset smartdot™ without the growlink™ app. To do this:

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. You will see a blinking red light.
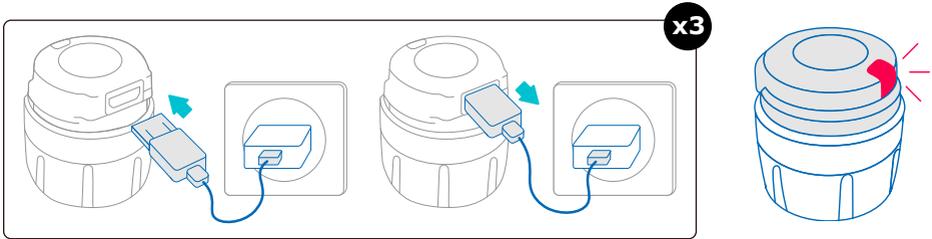
4. Switch smartdot™ on by plugging and unplugging it once. See steps C-E in 'Part 5: Preparing'.

If the red light remains, your smartdot™ is still defective. Remove it from your 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™ battery is low. It needs to be charged.

What should I do?

B. Charge your smartdotTM transmitter

1. Connect it to the supplied USB cable.

2. Connect the cable to a powered USB wall charger.

3. During charging, smartdot™ 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.

21
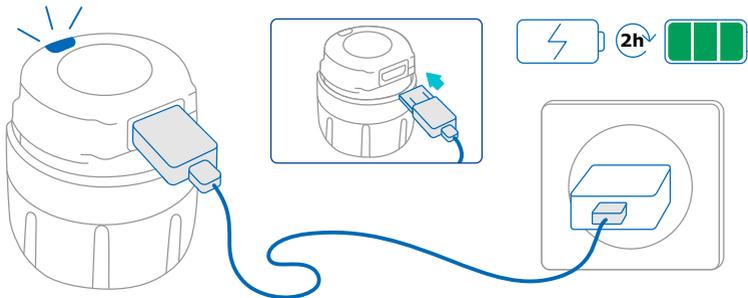
Note: If you are charging in a room where the temperature is above 25°C, you must deactivate Smartdot™ and remove it from your pen. See 'Part 8: Frequently Asked Questions <C. How do I deactivate and remove the smartdot™ transmitter'.

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?
smartdot™ 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'.

What does it mean?	What should I do?
The battery is out of charge.	1. Charge your smartdot™ transmitter. See above for details. 2. Pair smartdot™ with the growlink™ app. See' <u>Part 5: Preparing <C Pairing smartdot™ with the growlink™ app</u>.'
smartdot™ has been deactivated.	See '<u>Part 5: Preparing <E Activating your smartdot™ transmitter</u>'.

If there is still no light, remove smartdot™ 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 aluetta™ pen, please refer to the aluetta™ 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/UE (RED).

- The full text of the EU Declaration of Conformity is available at the following web address: xxxxxxx.com

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 RF communications devices (including peripherals such as antenna cables and externalantennas) should not be operated closer than 30 cm (12 inches) to any part of the [EM DEVICE or SYSTEM], including cables specified by the manufacturer. Failure to do so may impair the performance of these devices.

- Electrical devices are subject to special measures regarding electromagnetic compatibility (EMC) and must be installed in accordance with the EMC instructions in this document.

Regulatory information on electronic waste

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

• BIOCORP PRODUCTION declares that smartdot™ transmitter radio equipment follows Directive 2012/19/EU (WEEE) and Regulation 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
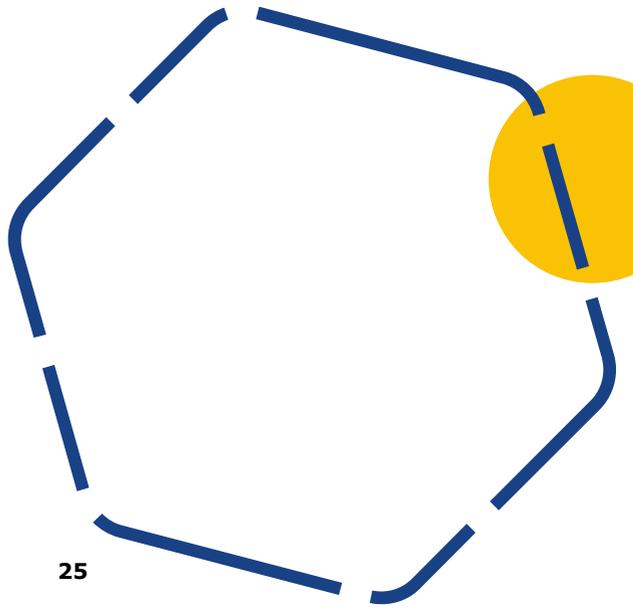
A Radio module specifications

smartdot™ integrates a BLE module with the following features (Receive / Transmit):

Specification	Value
Bluetooth® LE 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)
Battery Characteristics	
Battery	Li-ion rechargeable: Li-ion 3,6V-45mAh
Model number	xxx
Autonomy with a fully charged battery	2 weeks
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.

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

C Electronical information (2 of 2)

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	500mA - 2A

Part 13 Symbols and information on the packaging

Symbol	Description and information
📖ℹ	Operator's manual; operating instructions It is necessary to consult instructions for use [web site]
🏭	Manufacturer
CE	European Conformity marking
SN	Serial number
📅	Date of manufacture
LOT	Batch number
REF	Product reference
REF🚚	Distributor reference
⎓	Direct current

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. 15% to 90%
	The pressure limits to which the device can be safely exposed. 700 hPa to 1060 hPa
MODEL	Model number
#	Unique Device Identification

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

Biocorp Production

ZI de Lavaur La Bechade

63500 Issoire – France

$\mathsf{C}\,\mathsf{E}$