

Section 5.3 Injection settings

You can control some aspects of your Saizen® injection with easypod® by adjusting the injection settings.

i NOTE: Contact your doctor or nurse for advice on adjusting these settings.

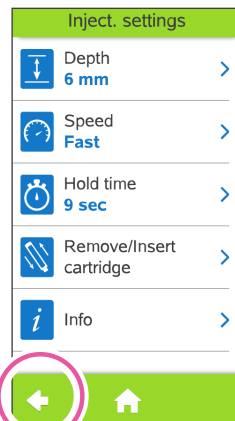
To access the Injection settings menu:

- Open  menu from the home screen.
- Select  Injection settings.

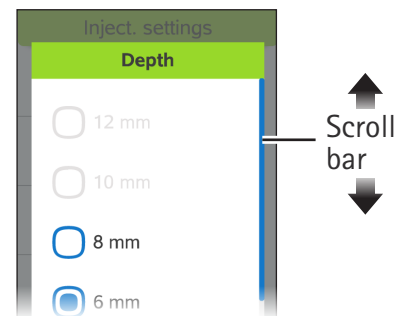


Injection
settings

Press to Exit



Depth



"Depth" is how far the needle goes into the skin when injecting.

- Select  Depth.
- Select 12 mm, 10 mm, 8 mm, 6 mm, or 4 mm.
- Press  to confirm.

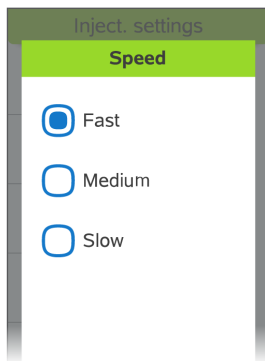
i NOTE: The 12 mm and 10 mm options are only available for the 29G needle. If your easypod® is set to use the 31G needle, then only the 4 mm, 6 mm and 8 mm options will be displayed on the menu.



Section 5.3 Injection settings (continued)



Speed

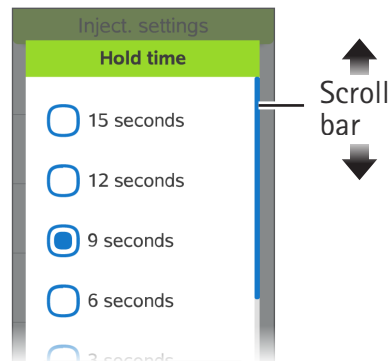


Speed is rate at which medication is delivered during the injection. It can be set to one of three values: Slow, Medium and Fast.

- Select  Speed.
- Select the speed you wish to set.
- Press  to confirm.



Hold time

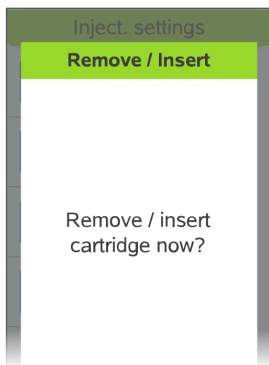


The time the needle remains in the skin after medication has been delivered. The needle will retract after this time (between 3 – 15 seconds, default is 6 seconds).

- Select  Hold time.
- Select the time you wish to set.
- Press  to confirm.



Remove/Insert cartridge



Unlock cartridge door to remove the cartridge:

- Select  Remove / Insert cartridge.
- Press  to unlock cartridge door.



Info

Info
Dose 1.50 mg
Frequency 6 inject. / week
Needle 29G Serofine

Provides an overview of your treatment (e.g. dose, frequency and needle).

- Select  Info.
- Press arrow  to close the treatment overview.



Section 5.4 Device settings

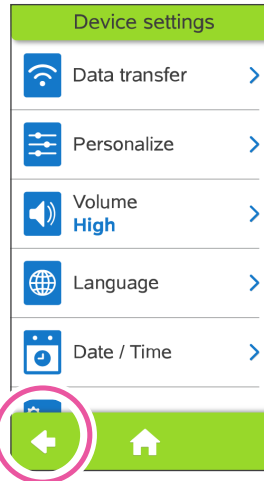
Use the Device settings screen to adjust the settings of the device, such as color use, volume, language, date and time, and connectivity.

To access the Device settings menu:

- Open  menu from the home screen.
- Select  Device settings.



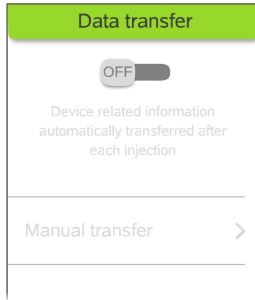
Device
settings



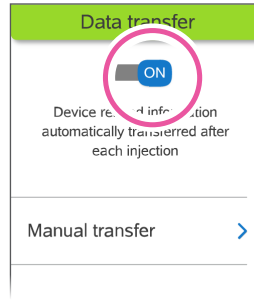
Press to Exit



Data transfer

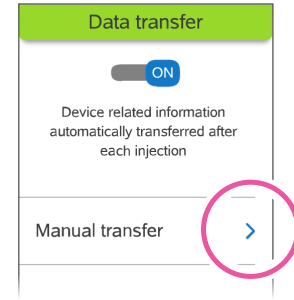


You can set easypod® to transmit your injection history to a database accessible by your doctor or nurse.



To automatically transfer device related information after each injection:

- Select  data transfer.
- Press  button to ON.



To manually transfer device related information (e.g., on demand):

- Press "Manual transfer"
- Wait until data has been shared.
- Press  to confirm.

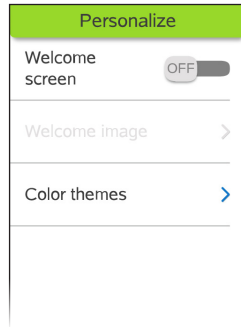
i NOTE: In some countries, due to local regulations, data transmission is automatically disabled. In this case do not turn data transfer on. The web application is not available in all countries. Contact your doctor or nurse to get more information.



Section 5.4 Device settings (continued)

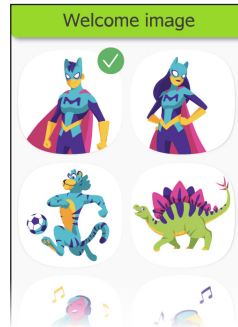


Personalize



"Personalize" provides two ways to modify the way screens look.

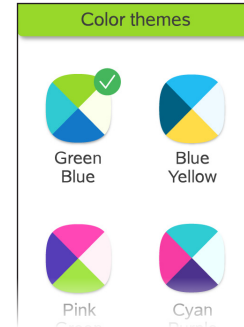
Select  Personalize to access options.



Welcome screen

To have a welcome image appear when you turn on the device:

- Press  button to ON.
- Press "Welcome image".
- Select the image you prefer.



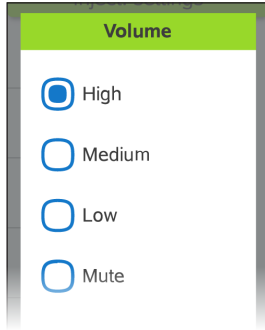
Color themes

To change the colors of the screens:

- Press "Color themes".
- Select a specific color theme.



Volume



The default sound setting is "High", to change:

- Select  Volume.
- Select the volume you prefer, or "Mute" to turn sounds off.
- Press  to confirm.

i NOTE: Sounds for warning messages, ready for injection, and injection finished cannot be muted.



Language



The language is set during the device set up the first time you turn on easypod®. To change:

- Select  Language.
- Select the language you prefer.
- Press  in the next screen to confirm.



Section 5.4 Device settings (continued)



Date / time

Date / Time

Set date
17 Oct 2019 >

Set time
09:16 >

Set format
Day Month Year
24H >

"Date / Time" provides the option to change the date, time and the formatting of those.

Select  Date / Time to access options.

When you select "Set date":

- Scroll up or down and press to select the current date.
- On the next screen, press  to confirm.

Set date

October 2019

M	T	W	T	F	S	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27

When you select "Set time":

- Scroll up or down to select the current time.
- Press  to confirm.

Set time

05 12
06 13
07 14
08 15

09 : 16

10 17
11 18

When you select time and date "Set format":

- Select the date and time format you prefer.
- Scroll down and press  to confirm.

Set format

Date

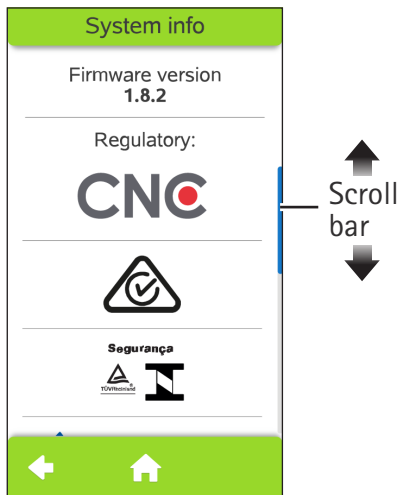
☒ Day Month Year

☐ Month Day Year

☐ Year Month Day



System info



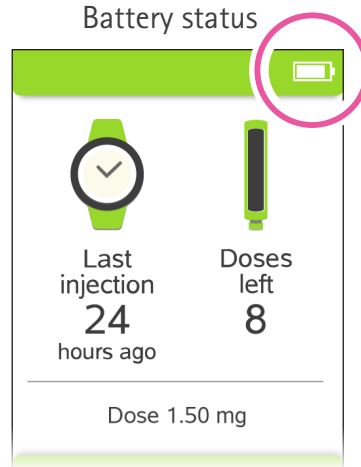
"System info" displays compliance to local regulations. See Section 8.2 for the symbols chart.



Section 5.5 Battery status

You can check the battery level of the device at any time. The battery status is displayed on the right side at the top of the home screen.

A fully-charged battery can power the device for about 30 days.



Battery status icons:



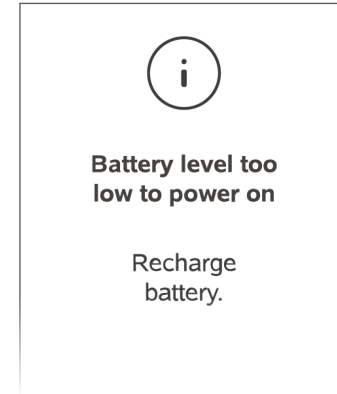
Battery fully charged



Battery partly used



Red - Battery is nearly empty. Charge your battery now, see *"Section 2.1 Charging the device"*.



When the device displays the "Battery level too low to..." message, refer to *"Section 6.3 Warning and information messages"*.

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Section 6

Troubleshooting



This section provides an overview of warning and information messages that may be displayed on easypod®, frequently asked questions, and what to do if you have dropped the device, or interrupted an injection.

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Reminders and tips when troubleshooting your easypod®



CAUTION

- **DO NOT** use easypod® if it is not working properly.
- **DO NOT** modify or attempt to repair easypod®, to avoid risk of incorrect dosing.
- If you have any questions or concerns, or if the steps provided in this section do not correct the issue, contact your doctor or nurse.

Section 6.1 Interrupted injection

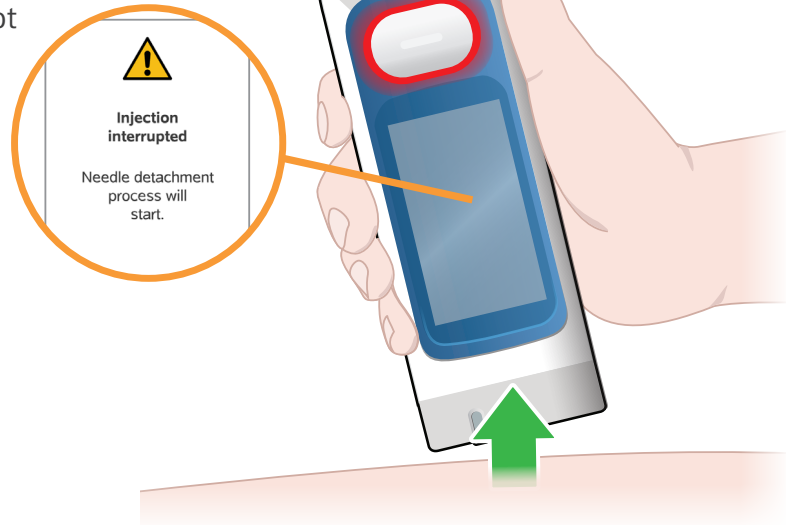
If easypod® is lifted off of your skin during an injection, easypod® will stop the medication flow and retract the needle. This is called an "interrupted injection" and means you did not receive your complete dose.

- easypod® will display an "Injection interrupted" message on screen
- The injection button turns red

You can complete your dose by delivering a second injection of the remaining dose. You need to use a new needle to deliver the second injection.

Follow the on-screen instructions and steps on the next page.

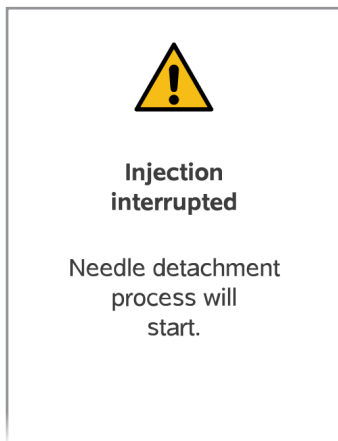
Red interruption light



i NOTE: Discuss with your doctor or nurse what you should do in case of an interrupted injection, before using easypod® for the first time.

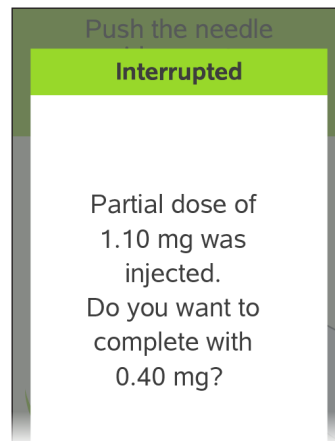
- If you cancel the second partial dose injection, the next injection will be a full dose.
- After two consecutively interrupted injections, the device will return back to the home screen and will not deliver the remaining dose. The next injection will deliver a complete full dose.

Injection has been interrupted, inject remaining dose



Injection interrupted warning

- Press  to detach the used needle and to complete the partial dose injection.



Partial dose message

- Press  to attach a new needle and to complete the partial dose injection.

 **NOTE:** Keep easypod® steady and in contact with your skin for the entire injection. Remove easypod® from the skin after easypod® plays a chime sound and the injection button light stops flashing and turns off. This signals the injection is done.



Section 6.2 Dropped device

easypod® should be handled with care. Take care not to drop easypod®.

If you have dropped the device, you need to check the needle, cartridge and device for signs of cracks or damages, according to the directions on the next page.



WARNING

- **DO NOT** use easypod® if a cartridge has broken inside the device. A broken cartridge and any remaining liquid may harm the user or damage the device.
- **DO NOT** use easypod® if it is not working properly.
- **DO NOT** modify or attempt to repair easypod®, to avoid risk of incorrect dosing.
- **DO NOT** use the needle from the dropped device to conduct next injection.

Check needle:

First, if the needle is bent or exposed, you may use small pliers to carefully remove the needle and discard it safely.

Check cartridge and device:

Then, look through the cartridge door's window to check if the cartridge is cracked or damaged.

If the cartridge is broken inside the device:

- a. Watch out for broken glass and do not touch the broken cartridge.





b. Contact your doctor or nurse to replace the device.

If the cartridge is not broken inside the device:

c. Turn on device. The drop might have caused a device failure.

d. If device functions normally, unlock cartridge door:

- Open  menu.
- Select  injection settings.
- Select  remove cartridge.
- Press  to remove cartridge.

e. Carefully remove cartridge and check cartridge to make sure:

- Cartridge is not cracked or damaged
- Medication is clear and **does not** contain particles. Inspect according to the Saizen® Patient Information Leaflet.

f. If there are no signs of damage, put cartridge back into device and close cartridge door. Contact your doctor or nurse if you have any doubts.

Section 6.3 Warning and information messages

Warning and Information message screens tell you if an error or issue is detected, and what you should do about it. The table in this section lists the main message screens for your reference, in addition to the instructions provided on the screen.

easypod® can display warning messages related to the cartridge, device, or needle. The message screens can come in two types, but will have the same basic elements:

	Warning	Information
Type of message:		
Screen title (what happened)	Cartridge cannot be used	Operation failure
Instructions on what to do	Go to injection settings to remove and discard cartridge.	Switch off device and restart.

i NOTE: If you have any questions or concerns, or if the steps provided in this section do not correct the issue, contact your doctor or nurse.

Type	Screen title	What happened and what to do
	Battery removed during operation	The battery has been removed while using the device. This action may cause harm to the device.
	Cartridge cannot be used	Cartridge cannot be used with device. Go to injection settings to remove and discard the cartridge. Replace it with a new cartridge.
	Cartridge expired	This screen will appear if: - The cartridge has been in use for 28 days and is now expired. Do not inject. Go to injection settings to insert new cartridge. OR - The device has just been turned on again after you have received the warning titled "Cartridge will soon be rejected due to inactivity". This appears when the sterility of the cartridge is compromised. Go to injection settings to insert new cartridge.
	Cartridge status is unknown	Device is not able to determine the cartridge's status. If cartridge is not new, make sure the cartridge is within 28 days after first injection. Or, if the cartridge has been in use for 28 days, it is expired, do not inject, replace the cartridge.



Section 6.3 Warning and information messages (continued)



Cartridge will soon be rejected due to inactivity

Device detected a needle still attached to the cartridge without a needle cap. Immediately insert an empty needle cap to start the needle detachment process. For sterility reasons, the device will automatically reject a cartridge if the needle is not removed after 30 minutes. The device will not allow that a rejected cartridge is used for injections and will force you to replace (and waste) the cartridge.



Charging cable attached

The device cannot conduct injection while USB-charging cable is connected. Please remove the charging cable to resume the injection process.



Check settings

Device turned off while modifying settings. To confirm settings, contact your doctor or nurse.



Clinical setup

Clinical setup can only be changed by your doctor or nurse. Contact your doctor or nurse if you would like to make any changes to the clinical setup of your device.

	Data transfer failed	This screen will appear if: • The network in your current location is too weak. You can try to transfer manually in another location. Manual transfer will transmit your injection history. Otherwise the data will be transmitted automatically after your next injection. OR • The device tries to transmit data in a country where data transmission is restricted. Turn off the data transfer to optimize battery consumption.
	Demonstration cartridge detected	The cartridge inserted is not intended for human use. Remove demonstration cartridge and replace with a new cartridge.
	Device error	The device encountered an error. Turn the device off and then on again. After you turn on the device, select  Menu >  Injection settings >  Remove/Insert cartridge>, then take out the cartridge and insert back the cartridge to let the device recognize the cartridge.
	Device expired	The device has expired and cannot be used anymore. Contact your doctor or nurse to replace the device.



Section 6.3 Warning and information messages (continued)



Device failure

The device has malfunctioned and cannot be used anymore. Contact your doctor or nurse to replace the device.



Device settings lost

All settings have been lost. Device will start the first time set up wizard. Contact your doctor or nurse to check the settings.



Device temperature out of range

Allow device to reach normal operating temperature, 5 - 40°C (41 - 104 °F).
Do not put the device into the microwave to warm it up.



Injection depth changed

Current injection depth not compatible with the needle type.



Injection interrupted

Injection procedure was interrupted. This occurs when the device leaves the skin during an injection. You did not receive your complete dose. The device will lead you through the steps to remove the needle.

	Last injection	The last injection was less than 24 hours ago. A 24 hour period between injections is recommended.
	Needle attached at power on	A needle was detected during power on (you did not complete the needle removal from the last injection). The device will lead you through the steps to remove the needle.
	Needle attachment failure	Check the on-screen instructions, and these two options: • You inserted an empty needle cap. Remove this needle cap and insert a new needle cap with a needle inside. OR • Device is not able to detect and retract the needle. Carefully remove the needle cap and check if the needle is inside. If the needle is not in the cap but inside the device, you may use small pliers to carefully remove the needle and discard it safely. Alternatively, contact your doctor or nurse.
	Needle cap attached	The needle cap is attached to the device. Remove the needle cap. Only attach the needle cap when prompted by the device.



Section 6.3 Warning and information messages (continued)

	Needle cap removed unexpectedly	Needle cap was removed at the wrong time. Only remove the cap when prompted by the device. The device will lead you through the steps to remove the needle again.
	Needle detachment failure	You inserted a needle cap that was not empty. Discard this needle cap and insert an empty needle cap to remove needle.
	Needle expired due to inactivity	Needle has been exposed to air for more than 10 minutes, which compromises needle sterility. The device will lead you through the steps to remove the needle.
	New cartridge concentration detected	A new cartridge concentration detected. If the drug concentration is different from the previous one, the injection time will automatically be adjusted.
	No valid cartridge detected	No cartridge is inside the device, or the device detected an invalid or incompatible cartridge. Go to injection settings to insert a valid cartridge.

**Service mode**

You have entered the service mode and must restart the device to exit this mode. Power off the device, then power it back on again.

**Selected dose incompatible with cartridge**

The dose selected in the clinical setup is not compatible with this cartridge. Contact your doctor or nurse to correct clinical setup or to receive the correct cartridge.

**Unexpected needle detachment**

The device cannot sense the needle. Check the needle cavity to see if the needle is in the cavity. If the needle is visible, contact your local support. Otherwise dispose of the needle properly.



Section 6.4 Frequently asked questions

Using easypod®

What if I cannot turn my easypod® on?

Make sure that when you turn on easypod®, you hold down the selection button on the right (power on) until the home screen appears. Make sure that the battery is charged and properly connected.

What if I cannot open the cartridge door?

The cartridge door can only be opened, and the cartridge removed, at certain times. When the cartridge is empty the device will walk you through the steps to replace the empty cartridge with a new one. Or, you can remove the cartridge at any time by selecting  Menu >  Injection settings >  Remove/Insert cartridge > then,  on the device screen. Do not use any tools to force the cartridge door open.

What if I accidentally press the injection button before I am ready?

The injection button will not work unless the device is in contact with your skin, so pressing it accidentally while preparing will have no effect.



What if I remove easypod® from my skin during an injection?

If you remove easypod® from your skin during an injection (while the injection button light is flashing white), the injection will stop, the needle will retract and easypod® will display a warning message:

- Select Yes to insert a new needle and take the remaining dose with a second injection.
- Select No to stop now. Only a partial dose will have been injected. easypod® will re-set and the option for a partial dose injection will no longer be available.

Can I make the injections more comfortable?

Always discuss injection pain with your doctor or nurse first. easypod® allows you to change settings for injection depth, speed and hold time, and use a 29G or 31G needle (which is thinner and shorter). Discuss with your doctor or nurse how these options may impact injection pain.

Section 6.4 Frequently asked questions (continued)

What if I notice a drop of Saizen® on my skin after the injection?

If you notice a drop of Saizen® on your skin when you remove easypod®, you may need to:

- Reduce the injection speed, and/or
- Increase the injection depth, and/or
- Increase the hold time.

Please discuss with your doctor or nurse on how to best adjust these settings in the device  Menu >  Injection settings.

Needles and Cartridges

Can I choose another needle type?

Before injection, you need to ask your doctor or nurse to update the needle type in the Clinical setup of easypod®. Furthermore, you CANNOT use another needle. The only needles compatible with easypod® are Serofine® Needles 29G and 31G.

What if I cannot detach a needle from my easypod®?

Make sure the needle cap does not contain a needle or anything else, then try again to push the empty needle cap into the needle cavity until it clicks into place and remove the needle. If you still cannot detach the needle, you may use small pliers to carefully remove the needle and discard it safely. Alternatively, contact your doctor or nurse.

What if I cannot insert a new needle or needle cap into my easypod®?

If you cannot insert the needle cap, check if there is any foreign object in the needle cavity. If there is foreign object in the needle cavity:

- Select  Menu >  Injection settings >  Remove/Insert cartridge > then,  on the device screen.
- The cartridge door will open to allow the object to fall.
- If the foreign object is still inside the needle cavity, please consult your doctor or nurse.

What if I lose or discard the empty needle cap prematurely?

The empty cap is necessary to detach the needle. If you cannot find it, or you don't have a spare needle cap, please consult your doctor or nurse for help.

How do I dispose of empty or discarded cartridges and used needles?

You should discard the empty, expired or broken cartridges, as well as used needles, in a biohazard (sharps) container, always complying with your local regulations. Contact your doctor or nurse for more information.



Section 6.4 Frequently asked questions (continued)

Settings

What should I do when my doctor prescribes a new dose?

Consult your doctor or nurse to update your dose setting in easypod®. Once your new prescribed dose is entered easypod® will automatically detect the cartridge type and adjust accordingly. However, if your prescribed daily dose is very high then it may not be possible to change to other cartridge types.

When I change the date or time, what happens to the Injection history?

The date and time setting in the device will be reflected in the dose history. If the date and time in the device is incorrect, the dose history will not show the actual date and time of injection. You can adjust the date or time on the device by going to the Device settings option on the menu. Changing the date or time will not affect the previous dose history.



Connectivity

How is my device data processed? How do I share my injection history?

Sharing any log data firstly requires you to activate the data transfer functionality in your device. If activated, your device can send anonymous device logs and information, injection and technical data, error reports, and generally information that helps us understand how our devices are being used or to identify potential improvements.

To ensure patient confidentiality, this information is by default anonymous (i.e., it is not associated to an individual patient profile). Device data is sent automatically after each injection, and typically, a transfer will be completed within 25 seconds. A given data transfer can also be aborted by pressing the Cancel button. Data will then only be transferred as from your next injection.

easypod® will automatically search the most appropriate cellular network, although the first transmission from your device will take more time than subsequent ones. Transfers may also take longer when you are travelling, transmitting from another country, or depending to available networks and connectivity. Any transmission or processing of device data is robustly protected (including being generally anonymized) to ensure compliance with applicable privacy law.

An additional offering may also be available (depending on your location) whereby data from your device (including injection history) can be made available through a connected web application to your treating doctor, nurse or treating healthcare professional. This additional service however requires your prior and express consent (obtained by your treating healthcare professional). This includes providing you with all relevant information on the relevant processing so you can make an informed decision. Once your consent has been given, your healthcare professional can activate your profile in the web application, allowing them to better view and track your injection history and treatment results. The same injection data can also be displayed on a dedicated mobile application for patients and/or their parents or caregivers. You must also provide your express consent for this by means of a similar information and consent process.

You may reach out to your doctor, nurse or health professional for more information on these services, including whether they are available in your location.

Section 6.4 Frequently asked questions (continued)

Storage and maintenance

How should I store cartridge?

You should refer to the Saizen® Patient Information Leaflet.

Should I remove the battery if I keep easypod® in the refrigerator?

There is no need to remove the battery if you keep easypod® in the refrigerator. However, if you want to charge the battery, you should remove the battery to charge it outside of the refrigerator.

How should I store my device?

If your cartridge is inserted in the device, refer to the storing conditions in the Saizen® Patient Information Leaflet. If the device is stored in the refrigerator, store it in the front section to avoid lower temperatures.

How long does the battery last?

It will take up to 2.5 hours to fully charge the battery. A fully charged battery can power the device for about 30 days. If you need to frequently charge the battery, the battery may be degraded. Please contact your doctor or nurse for a new battery.

What if the battery status light flashes red when charging the device?

When the status light of the battery flashes red it is not recharging. Make sure the battery charger and cable are connected properly. If the status light continues to flash red, you might need a new battery charger, contact your doctor or nurse.

If the device is in its end life, what should I do?

When the device is reaching its expiry date, you should contact your doctor or nurse to return it and replace it with a new device. A message will appear on easypod® 6 months ahead of its expiry date.



Section 6.4 Frequently asked questions (continued)

Travel

How do I store my device while traveling?

You can travel with easypod®. It is recommended to store easypod® in the storage box when traveling. The device is safe to pass through X-ray airport security gates with the Saizen® medication inserted. Please make sure to store your Saizen® medication at the appropriate temperature according to the Saizen® Patient Information Leaflet, whether the cartridge is inserted in the device or not.

What should I do if my planned injection coincides with a time I will be in a moving vehicle (e.g., airplane, train, car)?

It is not recommended to inject in a moving vehicle. If you anticipate a planned injection will happen while you are traveling in a moving vehicle, please discuss it with your doctor or nurse to update your injection schedule. Do not turn the device on while in the airplane.



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Section 7

Additional information for doctors or nurses



This section is for doctor or nurse only and describes how to setup easypod® for first time use, enter clinical settings, and train people to use easypod®.

7.1 Complete first time setup wizard	94
7.2 Clinical setup	98

 CAUTION

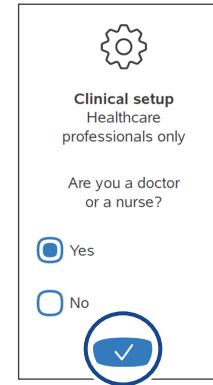
- This section is for doctors and nurses only. As a patient you should not use these instructions.
- Contact your doctor or nurse if you would like to receive information about this section.

Section 7.1 Complete first time setup wizard

As a doctor or nurse you will need to complete the Clinical setup portion of the first time setup wizard. These are settings following the basic device settings in *"Section 2.2 Enter device settings"*.

Follow the steps in this section and make sure the clinical settings are set according to the patient prescription.

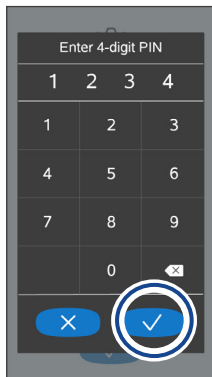
1 Confirm you are a nurse or doctor



The screenshot shows a screen titled "Clinical setup" with the subtitle "Healthcare professionals only". Below the title is a gear icon. The main question is "Are you a doctor or a nurse?". There are two radio button options: "Yes" and "No". The "Yes" option is selected, and a blue circle with a white checkmark is overlaid on the "Yes" radio button.

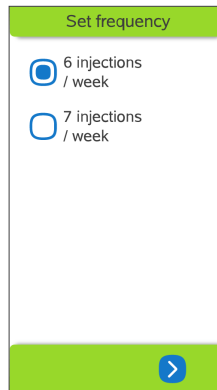
- After completing the initial device settings (see section 2.2), press checkbox next to "Yes" to confirm you are a nurse or doctor.
- Press  to continue.

2 Create PIN



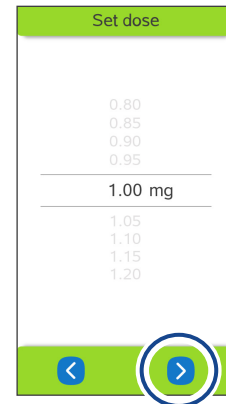
- Type in a 4-digit PIN code if you want to lock access to the clinical settings.
- Press  to continue and confirm the PIN code.

3 Set frequency



- Press checkbox of the prescribed injection frequency.
- Press  arrow to continue.

4 Set dose



- Swipe down or up to select prescribed dose.
- Press  arrow to continue.

i Dose range in 0.05mg increments:

- 0.1mg to 4.6mg with 6mg cartridge
- 0.1mg to 6.3mg with 12mg, 20mg cartridge



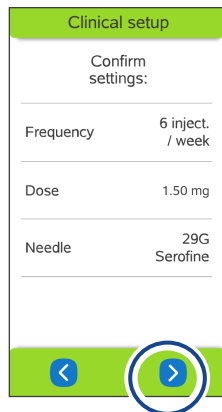
Section 7.1 Complete first time setup wizard (continued)

5 Set needle



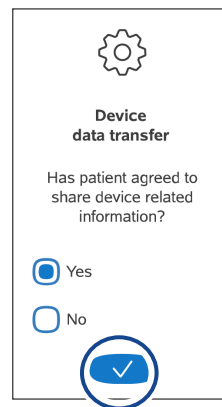
- Press checkbox of the prescribed needle gauge.
- Press  arrow to continue.

6 Confirm settings



- Review the clinical settings.
- Press  to confirm, or press  if you need to go back and make changes.

7 Device data transfer



- Press "Yes" checkbox to turn data transfer on. Or, press "No".
- Press  to continue.

In some countries, due to local regulations, data transmission is automatically disabled. In this case do not turn data transfer on.

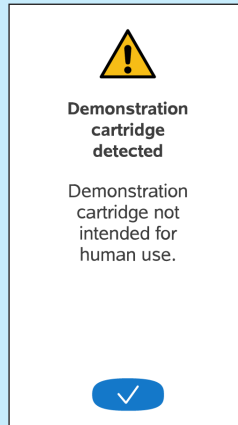


8 Complete



- Press  to complete the device setup.

NOTE



You can demonstrate the injection process without injecting by inserting a demo cartridge. This will prompt the device to enter demonstration mode.

Demo injections can only be done using a demo cartridge.

Section 7.2 Clinical setup

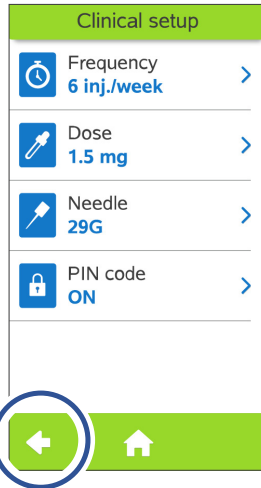
Use the clinical setup screens to adjust the treatment settings, such as the injection frequency, needle type, and dosage. In the clinical setup you can also change or turn the PIN code on/off.

To access the Clinical setup menu:

- Open  menu from the home screen.
- Select  Clinical setup.
- Enter 4-digit PIN.



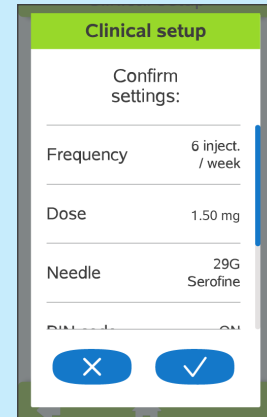
Clinical setup



Press to Exit

NOTE

When you leave the clinical setup screen, review all the clinical settings, then swipe down and select  to confirm.



You can choose any of the following settings and adjust them as you did during the first-time setup wizard (i.e., "Section 7.1 Complete first time setup wizard") . After making an adjustment, select  to confirm each new setting.



Frequency

The frequency determines how often the patient needs to inject. It can be set to 6 or 7 injections per week.



Dose

The dose defines how much medication is administered during an injection. Swipe up or down to select a dose.



Needle

There are two different Serofine® needles you can select: 31G or 29G.



PIN code

You can press  button to ON to add a PIN code that will prevent the patient from modifying the clinical setup.

If you wish to use a different PIN code select "Change PIN", then enter current pin code. Enter, then re-enter the new pin code before confirming.



NOTE

If you prescribe a different needle type, make sure to change the needle type in clinical setup to avoid incorrect injection depth. Inform your patient not to use previous needle type.



Section 8

Technical specifications and appendix



This section provides an overview of easypod®'s technical specifications.

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8.2 Explanation of symbols	104
8.3 Electromagnetic specifications	107

Section 8.1 Technical data

Device specifications

Brand/Product name	easypod®
Model	3
Weight	270 g
Dimensions	H: 155 mm x W: 55 mm X T: 42 mm
Battery charger	Ktec KSA-7A-050150D5, 100-240 V, ~50/60Hz, 0.3A
Power supply	Rechargeable Battery, Li-ion Polymer, Capacity: 3.7V / 1400 mAh, Input: 5VDC / 0.8A
Battery life	Approximatively 5 years, covering >500 discharge cycles
Medical device classification	MDR 2017/745/EU Class IIa
Device's life time	5 years from manufacturing date, refer to device's labelling
Cartridge	EMD Serono Saizen® growth hormone 3 mL cartridges
Maximum injection volume	0.8 mL
Dose accuracy	+/- 5% for dose above 0.250 mL and +/- 0.0125 mL for dose below 0.250 mL
Needles	Serofine® needles: • 29G x 1/2" (thickness: 0.33 mm x height: 12 mm) • 31G x 5/16" (thickness: 0.25 mm x height: 8 mm)



Cellular module	SARA-R412M-02B		
Radio access technology	LTE Cat M1, LTE Cat NB1, 2G GPRS/EGPRS		
Operating frequency bands	LTE B2, B3, B4, B5, B8, B12, B13, B20, B26, B28 GSM 850 MHz, E-GSM 900 MHz, DCS 1800 MHz, PCS 1900 MHz		
Maximum radio-frequency power transmitted in the operating frequency bands	LTE category M1 / NB1: Class 3 (23 dBm) 2G GMSK: Class 4 (33 dBm) in 850/900, Class 1 (30 dBm) in 1800/1900 2G 8-PSK: Class E2 (27 dBm) in 850/900, Class E2 (26 dBm) in 1800/1900		
USB connector	USB 3.0, type C		
Electrical compatibility	in accordance with IEC60601-1-2 (see EMC tables in section "Section 8.3 Electromagnetic specifications")		
Operating environment	5°C to 40°C (41°F to 104°F), 15% to 98% RH (20% to 90% RH during charging), 700 hPa to 1060 hPa		
Transport and storage conditions	Before first use	-20°C to 40°C (-4°F to 104°F) up to 60°C (140°F) during transport, 20% to 90% RH, 700hPa to 1060hPa	
	In between uses	Cartridge is inserted	Refer the Saizen® Patient Information Leaflet.
		Without cartridge	0°C to 40°C (32°F to 104°F), 20% to 90% RH, 700hPa to 1060hPa

Essential performances

The essential performance of the easypod® autoinjector is dose accuracy.

Declaration of Conformity

Hereby, Ares Trading SA declares that this device complies with Directive 2014/53/EU and UK Radio Equipment Regulations 2017.

The full text of the declarations of conformity is available at the following internet address:
www.aresttradingdevices.com

Section 8.2 Explanation of symbols

The following symbols appear on the easypod® labelling. Reference numbers refer to symbols in standard *ISO 15223-1:2021 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements*.



Refer to instruction manual/booklet.
Reference ISO 7010-M002



Power on/off



Manufacturer. Indicates the device
manufacturer. Reference number 5.1.1.



Use-by date (Expiration date). Indicates
the date after which the medical device is not to
be used. Reference number 5.1.4.



Humidity limitation. Indicates the range
of humidity to which the medical device can be
safely exposed. Reference number 5.3.8.



Catalogue number. Indicates the
manufacturer's catalogue number so that the
medical device can be identified. Reference
number 5.1.6.



Direct current. Reference IEC 60417-5031



Applied part type BF on the whole
device (electrical isolation). Reference IEC
60417-5333



European Conformity marking



Temperature limit. Indicates the temperature
limits to which the medical device can be safely
exposed. Reference number 5.3.7.



Atmospheric pressure limit. Indicates
the range of atmospheric pressure to which the
medical device can be safely exposed. Reference
number 5.3.9.



Batch code (Lot number). Indicates the
manufacturer's batch code so that the batch or
lot can be identified. Reference number 5.1.5.

Section 8.2 Explanation of symbols (continued)



Serial Number. Indicates the manufacturer's serial number so that a specific medical device can be identified. Reference number 5.1.7.



Class II equipment.
Reference IEC 60417-5172



Caution. Indicates that the current situation needs operator awareness or operator action in order to avoid undesirable consequences. Reference number 5.4.4.

IP 52

Protection against dust and dripping water when held in normal position



Medical device. Indicates the item is a medical device. Reference number 5.7.7.



Do not freeze. Refer to the transport and storage conditions in "Section 8.1 Technical data".



Authorized representative in the European Community. Indicates the Authorized representative in the European Community. Reference number 5.1.2.



Date of manufacture. Indicates the date when the medical device was manufactured. Reference number 5.1.3.



Authorized representative in the United Kingdom. Indicates the Authorized representative in the United Kingdom.



Dispose of safely according to your local regulations.
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.

Section 8.2 Explanation of symbols (continued)

Marking showing compliance to local regulations

 RAMATEL

Argentina – Ramatel mark



Korea – KC mark



Thailand – NBTC mark



Australia – RCM mark



Malaysia – MCMC mark



UAE – TRA mark



Brazil – Anatel mark

IFT

Mexico – IFT mark



UK – UKCA mark



Brazil – InMetro mark



NTC

Philippines – NTC mark



Vietnam – ICT mark



Gulf Cooperation Council



Taiwan – NCC mark



Serbia – 3A mark

See “Section 5.4 Device settings”.



Section 8.3 Electromagnetic specifications

easypod® is intended for use in a Home Healthcare environment having the characteristics specified below. User shall ensure that easypod® is used under the following conditions in order to maintain its essential performances. Should easypod® be operated outside of the specified conditions, the device might stop working.

WARNING

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the auto-injector, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result
- Use of easypod® adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, easypod® and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

 **CAUTION:** Changes or modifications made to this equipment not expressly approved by the manufacturer may void the FCC authorization to operate this equipment.

Section 8.3 Electromagnetic specifications (continued)

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 instructions, 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 the 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 a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The radiated output power of the device is far below the FCC and ISED radio frequency exposure limits. Nevertheless, the device should be used in such a manner that the potential for human contact during normal operation is minimized.

Electromagnetic Emissions

Conducted and radiated RF emission according to CISPR 11	Group 1	easypod® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
	Class B	easypod® is suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.



Electromagnetic Immunity

Immunity test	EMC standard	Compliance level
		± 8 kV contact
Electrostatic discharge	IEC 61000-4-2	± 2 kV, ± 4 kV, ± 8 kV air
		± 15 kV air
		10 V/m
Radiated RF EM fields	IEC 61000-4-3	80 MHz to 2.7 GHz
		80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to the following table
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m
		50 Hz or 60 Hz
Electrical fast/transient bursts	IEC 61000-4-4	-
Surges (line-to-line/line-to-ground)	IEC 61000-4-5	-
Conducted disturbances induced by RF fields	IEC 61000-4-6	-
Voltage dips, short interruptions and voltage variations on power supply input lines	IEC 61000-4-11	-
Voltage interruptions	IEC 61000-4-11	-
Electrical transient conduction along supply lines	ISO 7637-2	-

Section 8.3 Electromagnetic specifications (continued)

Immunity to proximity fields from RF wireless communications equipment

Test Frequency (MHz)	Band (MHz)	Service	Modulation*	Max power (W)	Distance (m)	Immunity Test Level (V/m)
385	380–390	TETRA 400	Pulse modulation 18 Kz	1.8	0.3	27
450	430–470	GMRS 460, FRS 460	FM, $\pm$ 5kHz deviation, 1 kHz sine	2	0.3	28
710, 745, 780	704–787	LTE Band, 13,17	Pulse modulation 217 HZ	0.2	0.3	9
810, 870, 930	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
1720, 1845, 1970	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240, 5500, 5785	5100–5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

*carrier modulated using a 50% duty cycle square wave signal

easyPod® will sustain its EMC performances throughout its lifetime without any specific maintenance.



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These instructions for use are also
available electronically at
www.arestadingdevices.com



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