

easypod[®]

Instructions for Use

Model: 3

easypod[®] autoinjector delivers a pre-set dose of Saizen[®].



MERCK

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Section 1

Introduction to easypod[®]



This section introduces you to easypod[®] and provides important safety information about using easypod[®] to deliver Saizen[®] medication.

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Section 1.1 About the device

easypod® is an electromechanical autoinjector which delivers a pre-set dose of Saizen® (somatropin [rDNA origin] for injection).

- easypod® keeps track of your injections. You can review up to 12 months of injections in the History screen (from the current month and previous 11 months).
- 24 hours or more (6 or 7 injections per week) are recommended between injections. To prevent from injecting too often, easypod® warns you if a new injection is attempted **less than 18 hours after the previous one.**
- easypod® contains no harmful or toxic materials.

- easypod® will not save or transfer any personal information.
- If you have any questions, talk to your doctor or nurse.
- By turning on the "Data transfer" feature in easypod®, you can share your injection history with your doctor or nurse.

Data means device injection data and technical log. It does not contain any personal identifiable information. It is anonymous.



Section 1.2 Indications and contraindications

Indications for use:

easypod® is a reusable, electromechanical software-controlled autoinjector intended for subcutaneous (under the skin) injection of Saizen® medication (recombinant human growth hormone).

easypod® is indicated for use by patients treated with recombinant human growth hormone (Saizen®). The patient population is comprised predominantly of pediatric patients (treatment of children with growth failure due to growth hormone deficiency (GHD)) but also adult patients with GHD (treatment of adults with either adult onset or childhood onset GHD). Intended users of the product also include the patient's parents and caregivers, as well as their nurse, doctor and medical support staff. easypod® can be operated for self injection by patients who are at least seven years old.

easypod® facilitates the administration of Saizen® treatment, including self-administration for patients at home. In addition, easypod® supports adherence management by allowing the review

of automatically recorded date, time and dose of injections.

Contraindications for use:

Your doctor or nurse will advise if you need support from a caregiver for your injections.

For contraindications related to Saizen® medication, please read the Saizen® Patient Information Leaflet.

Section 1.3 Safety precautions

This section provides general precautions related to using easypod®. Additional warnings and cautions related to specific instructions are highlighted throughout this booklet. If you have any questions after reading this section, do not hesitate to ask your doctor or nurse.



Before you proceed, review these general warning and cautions.

- Carefully read all instructions in this booklet before using easypod® and follow these Instructions for Use while using easypod®. These Instructions for Use provide important safety information about easypod®.
- **DO NOT** discard these Instructions for Use. Keep this booklet in a safe place for future reference.
- You must be trained by a qualified doctor or nurse before using easypod®. If you have not received training, please contact your doctor or nurse.
- easypod® is a personal device for use by only one patient. **DO NOT** share easypod® with anyone else because other users might have a different treatment.



General warning and cautions (continued)



- Children using easypod® must be supervised by adults at all times.
- **DO NOT** change the injection settings on easypod® until you have discussed it with your doctor or nurse.
- Take care not to drop easypod®. easypod® should be handled with care.
- **DO NOT** use easypod® if it is not working properly.
- **DO NOT** attempt to modify, or repair the device, or an incorrect dose might be delivered. Contact your doctor or nurse in case of device malfunction.
- **DO NOT** insert any foreign object into the needle cavity.
- Use Saizen® in accordance with the Patient Information Leaflet.
- **DO NOT** load non-Saizen® cartridges into easypod®. Only use original Saizen® cartridges.
- **DO NOT** use a cartridge if the label is missing or damaged.
- To avoid administration of non-sterile medication:
 - DO NOT** use a Saizen® cartridge if it shows any signs of damage.
 - DO NOT** reuse a cartridge rejected by easypod®.
- To avoid risks of injury caused by a broken cartridge, **DO NOT** try to remove broken glass from your easypod®.
- **DO NOT** touch or use the battery charger if it shows signs of damage or is broken.
- Make sure the charging cable does not cause a hazard of tripping or other injury.
- **DO NOT** allow children to play with the charging cable.
- **Report any serious incidents involving your easypod® to the easypod® local representative and your national competent authority for medical devices.**

Section 1.4 Device and supplies

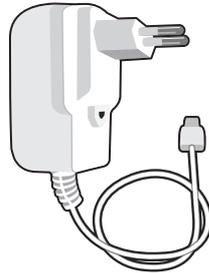
Items provided in device packaging:



1 easypod® autoinjector



1 Battery



1 Battery charger*



1 Storage box



Instructions for Use**

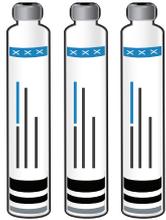
i NOTE: Contact your doctor or nurse for information on the supply of medication cartridges and needles, or if you need replacements for easypod® or any supplies.

* Number of plug adapters may vary (included for different regions)

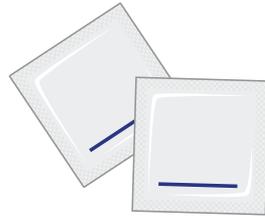
** Number of Instructions for Use booklets may vary (included for different languages).

A distributor list is part of device packaging.

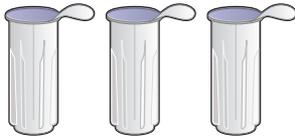
Other supplies needed:



Saizen® cartridges



Alcohol wipes



Serofine® needles



Biohazard (sharps) container

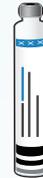
Not all cartridges, needles, or supplies are approved or available for use in all countries.

The following pages include details about each of the main components:

- **easypod® autoinjector** delivers Saizen® medication



- **Saizen® cartridge** containing Saizen® medication



- **Serofine® needle** (29G or 31G) for every injection. Use a new needle for each injection.

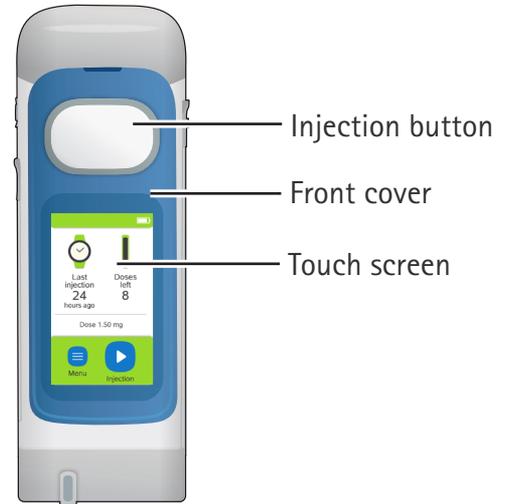


Section 1.4 Device and supplies (continued)

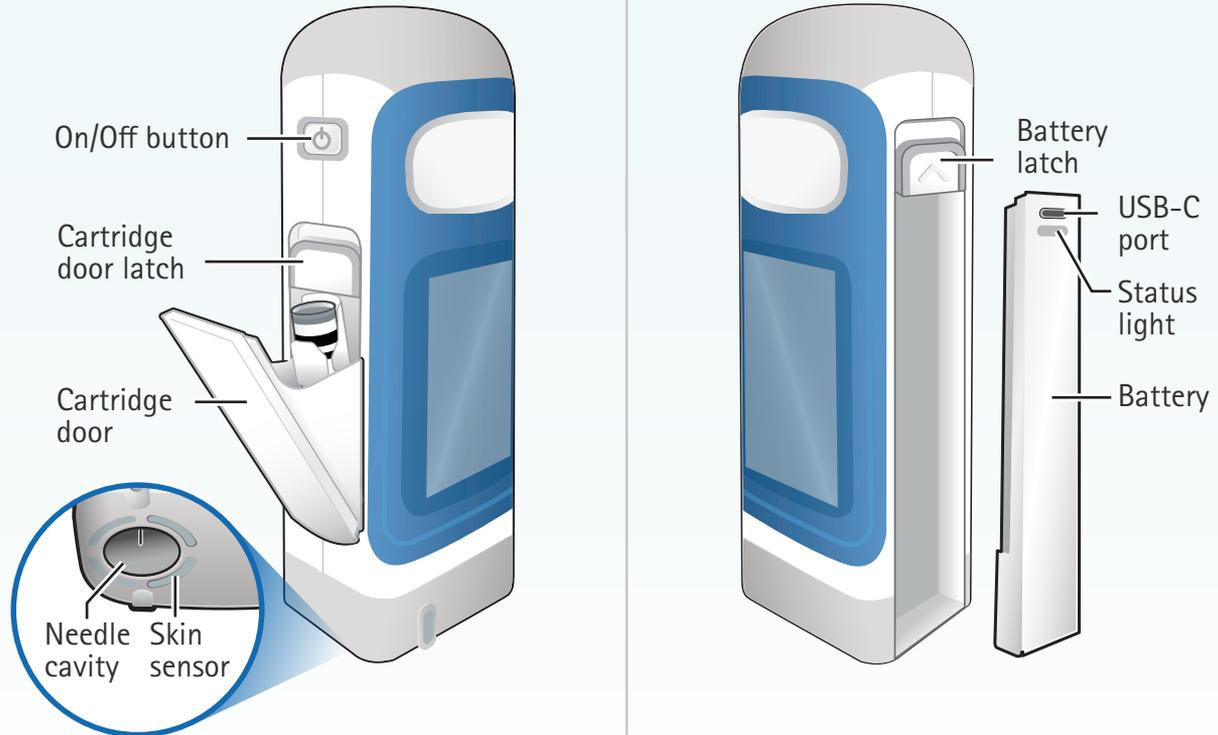
easypod[®] autoinjector

easypod[®] is an electromechanical device that automatically injects the set dose of medication through single-use needles it inserts and retracts on each injection.

- The skin sensors around the needle cavity detect if the device is positioned correctly onto your skin.
- You can remove the battery to charge it or charge the battery while it is in easypod[®].
- Store easypod[®] in the storage box to keep it clean and avoid contamination from food and dust.



Side views



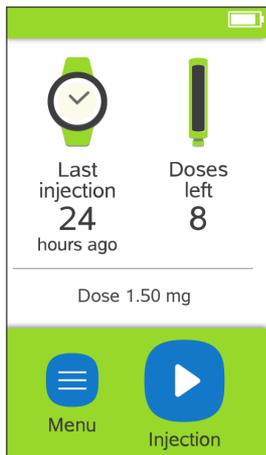
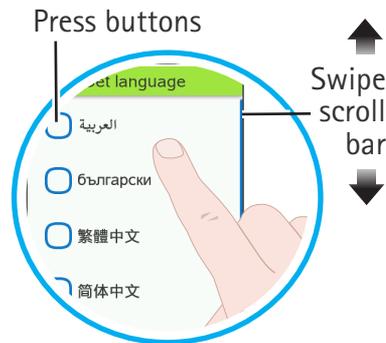
Section 1.4 Device and supplies (continued)

Touch screen

The touch screen provides current information, settings, and instructions on how to administer an injection. You can press buttons, or swipe up and down on lists to navigate the screens and make selections.

You can change the colors of the screen (the screen colors in this booklet might be different then the colors you have chosen).

Buttons on the home screen:



Menu button: provides access to the Injection settings, Clinical setup, Device settings, and History (overview of previous injections) menus



On-screen injection button: begins the guided injection process



Last injection

Last injection: shows how many hours ago you administered the previous injection



Doses left

Doses left: shows how many doses are left in the Saizen® cartridge

Saizen[®] cartridges

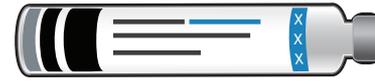
There are three Saizen[®] cartridge types compatible with easypod[®]:

- 6 mg (concentration: 5.83 mg/mL)
- 12 mg (concentration: 8.00 mg/mL)
- 20 mg (concentration: 8.00 mg/mL)

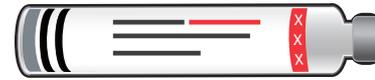
Carefully check the Saizen[®] medication packaging and cartridge label to ensure that you have the correct medication and cartridge type.

Saizen[®] cartridges have a **28-day expiration** after first use. Discard the cartridge if **28 days have passed since the first injection**.

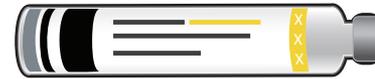
Detailed drug information and the administration of Saizen[®] is provided in the Saizen[®] Patient Information Leaflet.



6 mg (5.83 mg/mL)



12 mg (8 mg/mL)



20 mg (8 mg/mL)

⚠ WARNING: Make sure to use the correct Saizen[®] cartridge with your easypod[®]. Using the wrong cartridge can cause serious harm.

i NOTE: DO NOT remove cartridge label. Otherwise easypod[®] will reject the cartridge.

Section 1.4 Device and supplies (continued)

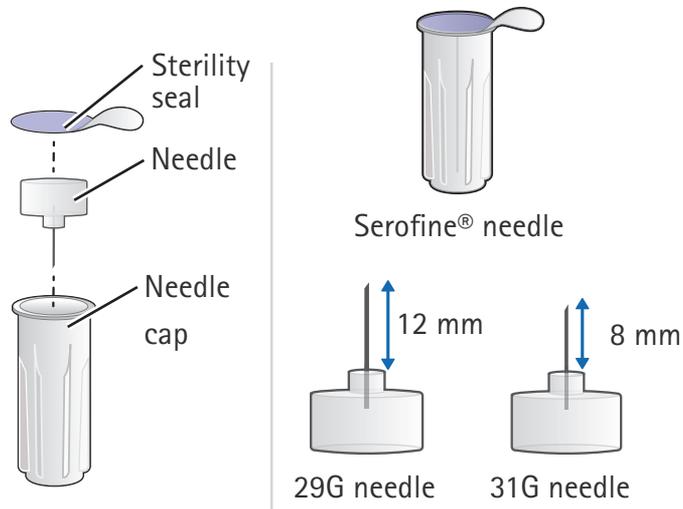
Serofine® needles

There are two Serofine® needle types compatible with easypod®:

- **29G × 1/2"**
(thickness: 0.33 mm × length: 12 mm)
- **31G × 5/16"**
(thickness: 0.25 mm × length: 8 mm)

Carefully check the size (or gauge "G") on the needle carton and the sterility seal of each individual needle to ensure if you have the correct needle, prescribed by your doctor or nurse.

Dispose of used needles safely in a biohazard (sharps) container after each injection.



WARNING

- **DO NOT** re-use needles to avoid risks of infection.
- easypod® must be used with **Serofine® single-use, disposable, sterile** needles only.
- Keep needles away from children 3 years old and younger to avoid risks of needle stick injury of third party.



Discard supplies and device

Use a biohazard (sharps) container to dispose of used needles after each injection and to dispose of used cartridges.

Dispose of needles in the biohazard (sharps) container if the expiration date has passed.

Refer to Saizen® Patient Information Leaflet for cartridge disposal. Dispose of cartridges in the biohazard (sharps) container if:

- it is cracked
- the expiration date has passed
- the medication is discolored or contains particles.

When your biohazard (sharps) container is full, dispose of it in accordance with your local community guidelines. If you are not sure about the local disposal guidelines, ask your doctor or nurse.

If you no longer use easypod®, dispose of it in accordance with your local regulation. Contact your doctor, nurse, or pharmacist for more information.



! **WARNING: DO NOT** insert your hands into the biohazard (sharps) container for any reason to avoid needle stick injury.

Section 2

Getting started

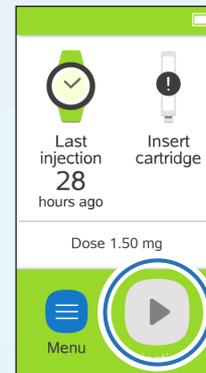


This section provides instructions for setting up the device before administering a first injection.

2.1 Charging the device	22
2.2 Enter device settings	24
2.3 Inserting cartridge	27

Reminders and tips for getting started with easypod®

- You must receive appropriate training from your doctor or nurse before changing any settings and before using easypod®.
- Some device settings can only be changed by a doctor or nurse. If device set up is not complete, the  on-screen injection button will remain disabled. To complete setting up the device for injecting, contact your doctor or nurse.



Injection
button
disabled

Section 2.1 Charging the device

Confirm the battery is fully charged before using the device for the first time. If the battery is not charged, use the battery charger supplied with the device. You cannot inject medication when the battery is charging.

Fully charging the battery will take about 2.5 hours. A fully-charged battery can power the device for about 30 days.

The battery level of the device is displayed at the top of the home screen.



⚠ WARNING: To prevent electric shock, **DO NOT** touch or use the battery charger if it shows signs of damage or is broken.

i NOTE: There are two ways to charge the battery:

Charge the battery while it is in the device.



OR

Remove the battery to charge it. Slide and hold the battery latch up, then slide the battery down to remove.

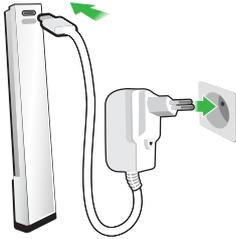


In the latter case, store the device with Saizen® medication according to the Saizen® Patient Information Leaflet.



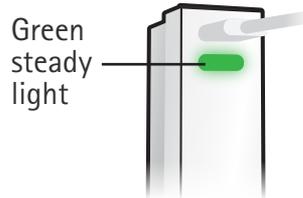
The socket-outlet must be easily accessible.

1 Connect battery to power source



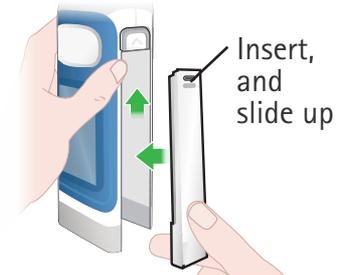
- Plug the battery charger's USB-C plug into the battery port.
- Plug the battery charger into a wall outlet.
- When the status light flashes green, battery is charging.

2 Confirm battery is fully charged



- Check the status light. If light is steady green, battery is fully charged.
- When battery is fully charged, unplug USB cable from battery and power source.

3 Insert battery into device



Insert and slide battery back up until it clicks in place.

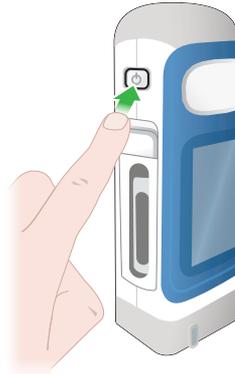
Now that the battery is charged, you can continue with *"Section 2.2 Enter device settings"*



Section 2.2 Enter device settings

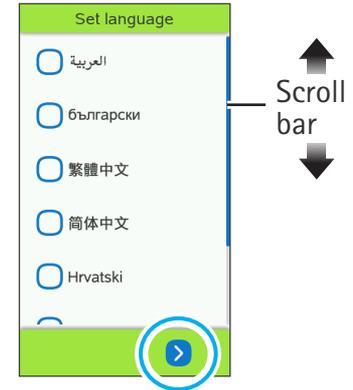
easypod® contains device and injection settings that will need to be set up before you can use the device. These settings can be changed later on at any time as well.

1 Turn on device



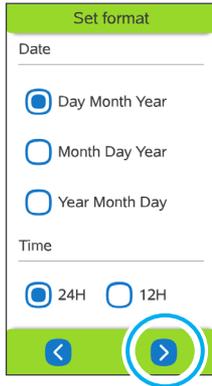
Press and hold on/off button until the display switches on. After a few seconds the "Set language" screen appears. Press  to continue.

2 Set language



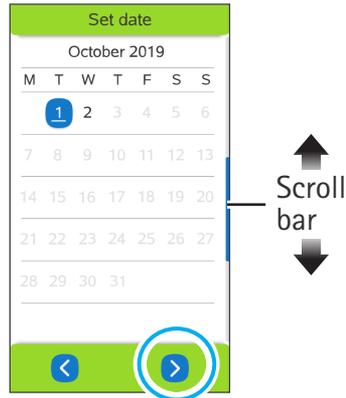
- Swipe up or down and press checkbox to select language you prefer.
- Press  arrow to continue.

3 Set date format



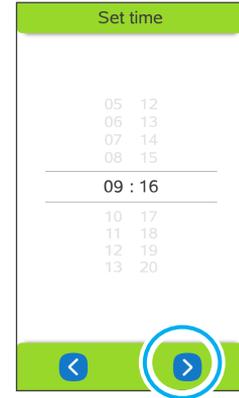
- Press checkbox to select the date format you prefer.
- Press  arrow to continue.

4 Set date



- Swipe down or up across screen to go the right month and select current date.
- Press  arrow to continue.

5 Set time



- Swipe down or up to select current time
- Press  to continue.



Section 2.2 Enter device settings (continued)

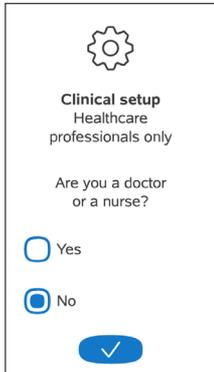
6 Your doctor or nurse must enter clinical settings



Your doctor or nurse must enter the clinical settings that control your dosing and treatment delivery. The  on-screen injection button will remain disabled until the set-up is completed.

If your doctor or nurse is not with you to do it, press "No" when the screen asks, "Are you a nurse or a doctor?"

If you are a doctor or nurse, see *"Section 7.1 Complete first time setup wizard"* for details on entering clinical settings.



 **WARNING:** DO NOT enter clinical settings yourself. Your doctor or nurse must always do this.

 **NOTE:** The PIN code for your easypod® clinical settings is provided to doctors or nurses separately from this Instructions for Use. Clinical settings should only be changed by a doctor or nurse. If the PIN code is lost or forgotten, your doctor or nurse can get another PIN code from the local easypod® representative (refer to the distributor list provided with the device).

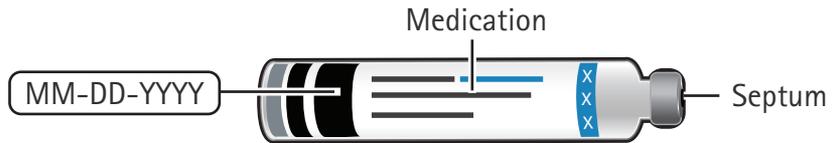
Section 2.3 Inserting cartridge

Before injecting medication (as instructed in Section 3), you must first insert a new Saizen® cartridge. When handling the cartridge, handle with care.

i NOTE

- You can only use the Saizen® cartridges you have been prescribed.
- **DO NOT** remove cartridge label. Otherwise easypod® will reject the cartridge.

1 Get a new cartridge and inspect



Check that the:

- Packaging and cartridge label have the medication and dosage of Saizen® (6, 12, or 20 mg).
- Cartridge's expiration date has not passed.
- Cartridge is not cracked.
- Cartridge and medication correspond to the description in the Saizen® Patient Information Leaflet (PIL).



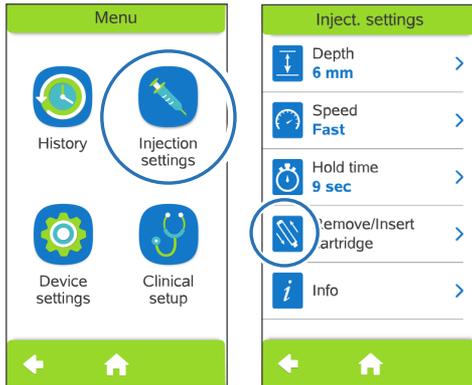
WARNING

- **DO NOT** use cartridge if it is cracked, if expiration date has passed, or if medication is not clear, contains particles or is not the correct one. Refer to Saizen® PIL for detailed information.
- **DO NOT** touch the cartridge's septum to avoid risks of injection site reactions.



Section 2.3 Inserting cartridge (continued)

2 Unlock cartridge door



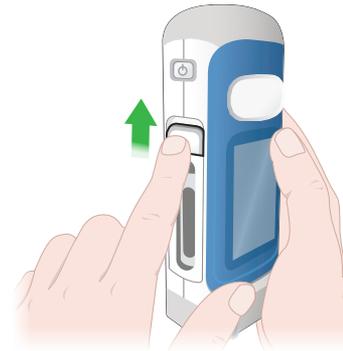
To unlock the cartridge door:

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

i NOTE: A screen might appear during first use prompting you to insert a cartridge.

DO NOT force open the cartridge door, this might damage the cartridge door.

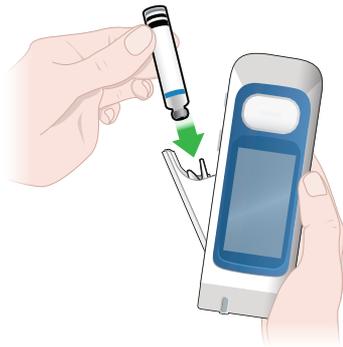
3 Open cartridge door



Slide cartridge door latch up to open door.

i NOTE: If device contains a cartridge that is not empty, you will need to unlock the cartridge door on the touchscreen first, then replace the cartridge. See "Section 4.3 Changing cartridge".

4 Insert cartridge



Insert cartridge into cartridge holder with metal tip pointing down.

5 Close cartridge door



Push cartridge door to close it.

i NOTE: easypod® may take up to 20 seconds to recognize the cartridge and go back into the menu.



Section 3

Injecting medication with easypod®



This section is a step-by-step guide for injecting medication with easypod®.

3.1 Prepare for injection	32
3.2 Attach needle	34
3.3 Administer the injection	36
3.4 Detach needle and confirm injection	38
3.5 Partial dose injection	40

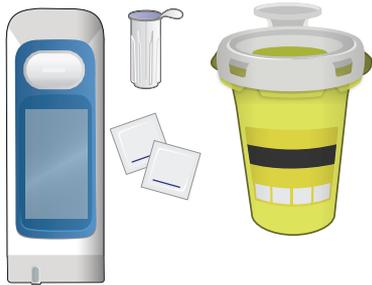
Reminders and tips for injecting with easypod®

CAUTION

- DO NOT use easypod® if it is not working properly.
 - DO NOT attempt to modify, or repair the device, or an incorrect dose might be delivered. Contact your doctor or nurse in case of device malfunction.
 - DO NOT put the device or medication into the microwave to warm it up.
 - Adolescents must be supervised by a caregiver.
-
- If easypod® is stored in the refrigerator, it might be very cold, you may want to take out the device from the storage box and put it on a stable surface. Wait at least 30 minutes to let the device and the medication warm up to room temperature.
 - If condensation appears on easypod®, wipe it off with a clean cloth.
 - If the remaining content of the Saizen® cartridge is not enough for a full dose, easypod® will let you know (you can also see "*Section 3.5 Partial dose injection*").
 - There is no need to pinch skin at injection site.
 - easypod® will let you know if you try to inject too soon. You can also check the History menu to ensure you are taking your Saizen® injections about 18 hours apart.

Section 3.1 Prepare for injection

1 Gather supplies



Place all items listed below on a stable surface (e.g., a table) within easy reach:

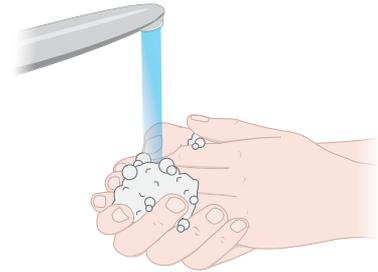
- easypod® containing a cartridge (6, 12, or 20 mg)
- Serofine® needle (29G or 31G)
- Alcohol wipes
- Sharps container

2 Check device



Before each injection, check the device. Make sure the cartridge and medication correspond to the Saizen® Patient Information Leaflet, and there are no signs of damage.

3 Wash hands



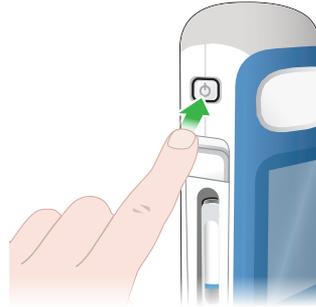
Wash your hands well with soap and water and dry them with a clean towel.

4 Prepare injection site



Select and prepare your injection site as discussed with your doctor or nurse.

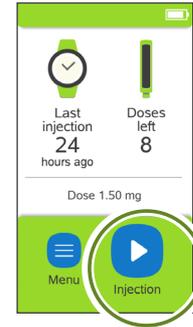
5 Turn on device



Press and hold on/off button until the display switches on.

After a few seconds the welcome screen will appear briefly, followed by the home screen.

6 Press injection



Press  on-screen injection button to start the injection process. easypod® will guide you step-by-step to administer an injection.

If easypod® displays "Less than 1 dose left" message, refer to "Section 3.5 Partial dose injection" to proceed.



Section 3.2 Attach needle

1 Get a new needle



- Get a new Serofine® needle.
- Check that needle size (gauge "G") on the needle cap's sterility seal is the same as the needle size on easyPod® screen.
- Check that the needle's expiration date has not passed.

2 Remove seal

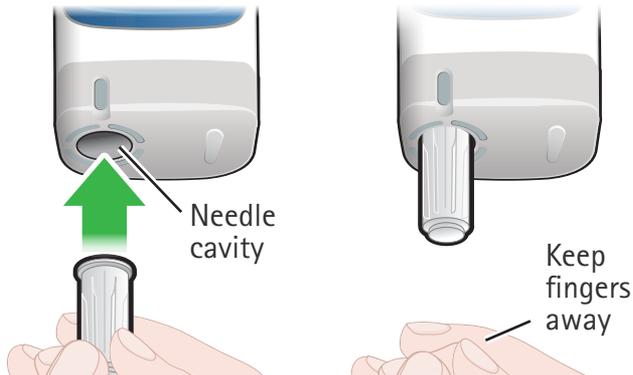


Pull flap and fully remove sterility seal.

WARNING

- Handle needles carefully to avoid injury.
- To avoid risks of injury or infection, **DO NOT** use needle if sterility seal is damaged or detached, the needle is expired or the needle gauge is wrong.

3 Insert needle, let go

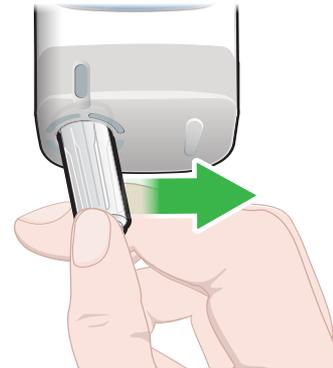


When easypod® screen tells you "Insert new needle":

- Push needle cap with needle straight into the needle cavity until it clicks.
- Let go of the cap while the needle attaches.

 **WARNING:** NEVER insert fingers into the needle cavity to avoid needle stick injury.

4 Remove cap



When easypod® screen tells you to do so, push the needle cap sideways to remove it.

DO NOT inspect the needle cavity when the device is ready for injection.

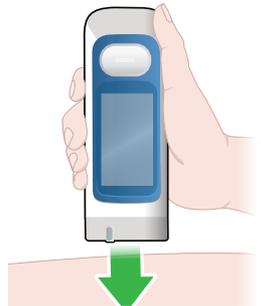
WARNING

- **DO NOT** pull needle cap straight down. This might damage easypod®.
- Save the needle cap to safely remove and dispose the needle after injecting.



Section 3.3 Administer the injection

1 Hold device against skin



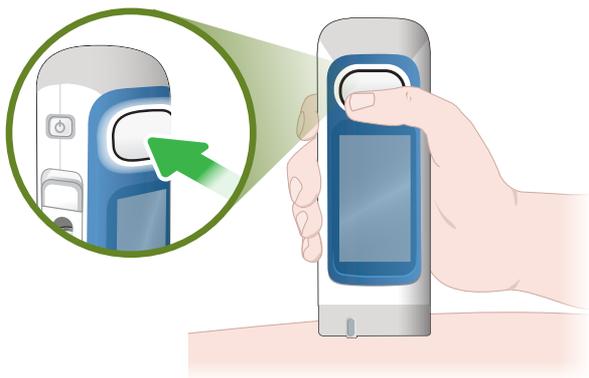
Your doctor or nurse will show you how to inject:

- Hold easypod® as straight as possible firmly against injection site, so the skin sensor fully touches your skin (there is no need to pinch the skin at the injection site).
- When easypod® is in correct position and ready to inject, easypod® plays a chime sound and the injection button light will turn white.

i NOTE: If you **DO NOT** inject right away easypod® will give you instructions to:

- After 60 seconds – continue or cancel injection
- After 10 minutes – insert an empty needle cap to unload the expired needle. A new needle will have to be used to continue with the injection.
- After 30 minutes – the device will shut down and the cartridge will be rejected. When turned on, the device will ask you to replace the needle and cartridge.

2 Inject medication



- Press injection button once to begin injecting. The injection button light flashes white during the injection.
- Keep easypod[®] steady and in contact with your skin for the entire injection.

! **WARNING:** DO NOT move during the injection to avoid a needle stick injury.

3 Remove easypod[®]

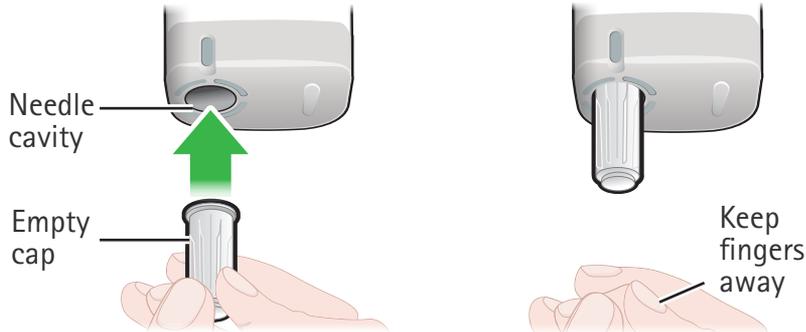


- When the injection is complete, easypod[®] plays a chime sound and the injection button light will stop flashing and turn off.
- Lift easypod[®] from your skin.
- If some medication remains on the skin after the injection, clean injection site.



Section 3.4 Detach needle and confirm injection

1 Insert needle cap, let go



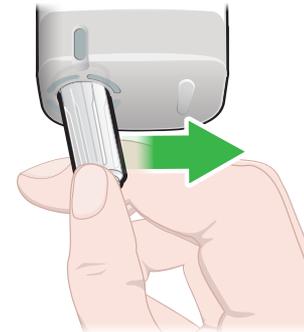
When easypod® screen tells you "Insert needle cap":

- Push empty needle cap straight into the needle cavity until it clicks.
- Let go of the cap while the needle detaches.

WARNING

- Always detach needle after injection using empty needle cap.
- **NEVER** insert fingers into the needle cavity to avoid needle stick injury.

2 Remove needle



When easypod® screen tells to, push the needle cap sideways to remove it.

WARNING: DO NOT

pull needle cap straight down. This might damage easypod®.

3 Dispose needle

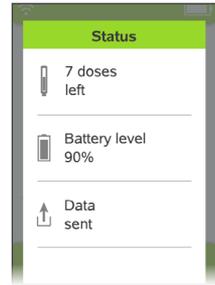


Dispose of cap with needle in a biohazard (sharps) container.

WARNING

- Improper disposal may result in a needle stick injury to you and others.
- **DO NOT** re-use needles to avoid risks of infection.

4 Confirm injection



- Review the amount of doses left and battery charge on the screen.
- Press  to confirm the injection.

5 Power off and store device



- Press and hold the on/off button until the display switches off.
- Store easypod® upright in its storage box, and with cartridge inside as required by the Saizen® Patient Information Leaflet.

See "Section 4.1 Storing device and cartridges".



Section 3.5 Partial dose injection

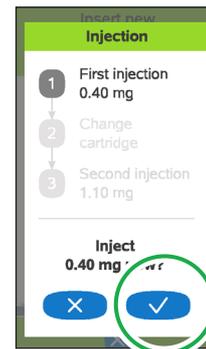
easypod® can deliver a partial dose injection if your current cartridge does not contain enough medication for a full injection.

i NOTE

If the medication left in the current Saizen® cartridge is not sufficient for a full dose, easypod® will display "Less than 1 dose left".

You can use the remaining medication to deliver a partial dose, or you can insert a new cartridge.

1 Inject a partial dose



Continue to next steps

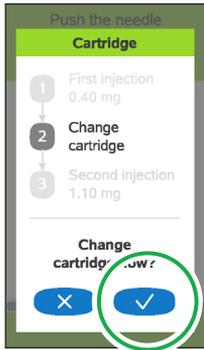
- Press  to start the injection process.
- Press  to confirm you want to take steps to use the rest of the cartridge for a partial dose.

Or, you can press  and go to the Device settings to change the cartridge now, then inject a full daily dose at once.

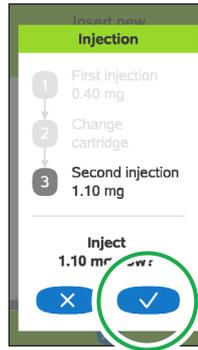
- Attach a new needle and deliver a partial dose.

See "Sections 3.1 to 3.4" for full injection instructions.

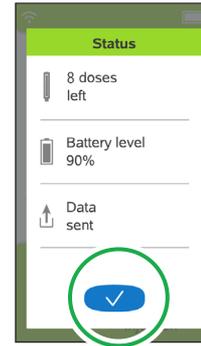
2 Change cartridge, then change needle and inject remaining dose



a. Press  to change cartridge now.



b. Press  to change needle and deliver the remaining dose.



c. Press  to confirm and complete the dose.

See "Sections 3.1 to 3.4" for full injection instructions. Or, you can press  to exit and record only the partial dose.

 **CAUTION:** Administer second partial dose injection (calculated by easypod®) directly after the first injection to complete the full daily dose. If you cancel the second partial dose injection, the next injection will be a full dose.



Section 4

Caring for the device



This section gives you instructions on how to take care of easypod[®] when traveling, storing, replacing easypod[®], or changing a cartridge.

4.1 Storing device and cartridges	44
4.2 Taking care of your device	45
4.3 Changing cartridge	46
4.4 Replacing device	50
4.5 Travel with device	51

Reminders and tips to care for your easypod®

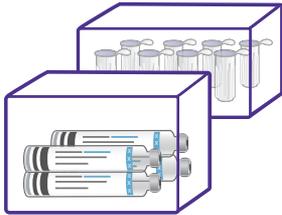


CAUTION: DO NOT attempt to modify, or repair it, or an incorrect dose might be delivered. Contact your doctor or nurse in case of device malfunction.

- Only use Saizen® cartridges with easypod® that are stated in your prescription. easypod® will reject a wrong cartridge.
- easypod® containing a Saizen® cartridge should be stored according to the Saizen® Patient Information Leaflet.
- **DO NOT** remove cartridge label. easypod® will reject a wrong cartridge.

Section 4.1 Storing device and cartridges

General storage instructions



- Keep the unused Saizen[®] cartridges and Serofine[®] needles in their original packaging until you need them.
- Saizen[®] cartridges should be stored according to the Patient Information Leaflet (PIL).
- Discard each cartridge within **28 days after first injection** to avoid expired medication. easypod[®] will inform you when 28 days have passed.
- Before storing easypod[®], make sure there is no needle in the device. Always store device upright, in its storage box, to avoid drops of Saizen[®] causing malfunction.
- If a cartridge is in the device, also refer to the storing conditions in the Saizen[®] PIL.

Section 4.2 Taking care of your device

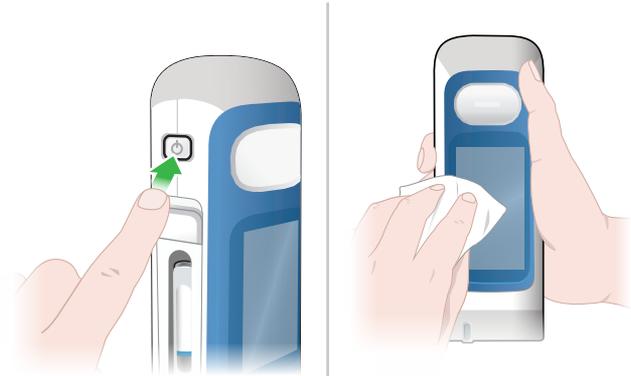
If the device is dirty and you would like to wipe it, perform the following steps on the right.

If easypod® has been exposed to liquid, wipe it with a clean, dry or slightly damp cloth, then check for error messages (see section 6).

i NOTE

- **DO NOT** use any chemicals, cleaning solvents, detergents, or alcohol solutions, because this can damage the device.
- **DO NOT** rinse or immerse any part of easypod® in water or any liquid.
- **DO NOT** wipe easypod® more than once per week

To wipe the device



- a. Make sure easypod® is turned off. If easypod® is on, press and hold on/off button to turn it off.
- b. Wipe it with a dry or slightly damp cloth.



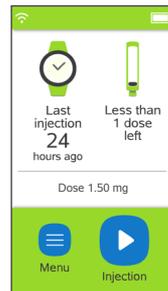
Section 4.3 Changing cartridge

Only change the cartridge inside easypod® if:

- You did not store the Saizen® cartridges according to the Patient Information Leaflet.
- The cartridge is empty or expired (28 days after first use). easypod® will display "Cartridge empty" or "Cartridge expired" message (see right image).
- easypod® displays the "Less than 1 dose left" message (see left image) and you do not want to administer a partial dose injection.
- You dropped easypod®, the cartridge might be damaged and needs to be replaced.

After inserting a new cartridge you can start *"Section 3 Injecting medication with easypod®"*.

easypod® displays the cartridge status in the top right corner:



Less than 1 dose left
(You might not want
to do a partial dose)

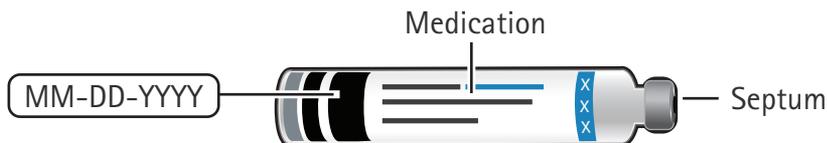


Cartridge is
empty

i NOTE

- **DO NOT** force open the cartridge door, this might damage the cartridge door.
- Contact your doctor or nurse if the cartridge is different from what you have been prescribed.

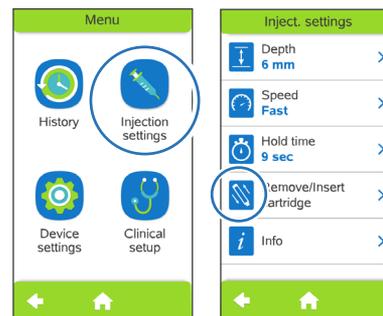
1 Get a new cartridge and inspect



Check that the:

- Packaging and cartridge label have the medication and dosage of Saizen® (6, 12, or 20 mg).
- Cartridge's expiration date has not passed.
- Cartridge is not cracked.
- Cartridge and medication correspond to the description in the Saizen® Patient Information Leaflet (PIL).

2 Unlock cartridge door



To unlock the cartridge door:

- a. Open  menu.
- b. Select  injection settings.
- c. Select  remove cartridge.

i NOTE: You can only remove and insert cartridge by clicking Remove/Insert Cartridge on the screen to unlock and open the cartridge door.

WARNING

- **DO NOT** use cartridge if it is cracked, if expiration date has passed, or if medication is discolored, contains particles or is not the correct one. Refer to Saizen® PIL for detailed information.
- **DO NOT** touch the cartridge's septum to avoid risks of injection site reactions.

Section 4.3 Changing cartridge (continued)

3 Open cartridge door



- Make sure there is no needle inside. If there is see section 3.4 for instructions to detach needle.
- Slide cartridge door button up to open door.

If the cartridge door button is locked, see step 2.

4 Remove cartridge



Remove cartridge from cartridge holder.

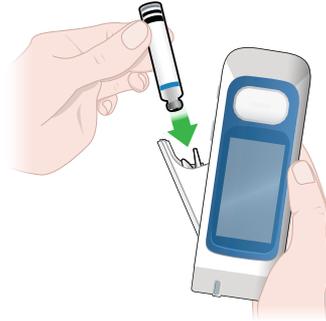
⚠ WARNING: DO NOT use easypod® if a cartridge has broken inside the device. A broken cartridge and any remaining liquid may harm the user or damage the device.

5 Discard cartridge



Discard the empty, expired or broken cartridge in a biohazard (sharps) container.

6 Insert new cartridge



Insert new cartridge into cartridge holder with metal tip pointing down.

7 Close cartridge door



Push cartridge door to close it.



Section 4.4 Replacing device

easypod® has been built to last 5 years. The expiration date is printed on the device label. The device does not require any special maintenance. Starting 6 months before the expiration date, easypod® will regularly present messages to remind you of the expiration date.

Contact your doctor or nurse when it is time to replace your easypod®.



CAUTION

- **DO NOT** use easypod® if it is not working properly and do not attempt to repair it, or an incorrect dose may be delivered.
- Contact your doctor or nurse in case of device malfunction.

Section 4.5 Travel with device

You are allowed to travel with the device.



If you are going to travel with easypod®, remember:

- Travel with the device in your carry-on luggage. **DO NOT** travel with the device in your check-in luggage. It is recommended to store easypod® in the storage box when traveling.
- Ask your doctor or nurse for documentation, if applicable, that will ensure you are allowed to keep the device with you as carry-on luggage.
- 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. Consider using a travel cooling bag that will keep within Saizen® cartridges and your device at the correct temperature.
- The device is safe to pass through X-ray airport security gates with the Saizen® medication inserted.
- Do not turn the device on while in the airplane.
- It is not recommended to inject while in a moving vehicle. If a planned injection will happen while you are in a moving vehicle, please contact in advance your doctor or nurse to update your injection schedule.
- easypod® will search for a cellular network to transmit data if you have turned this feature on when setting up easypod®. First-time connection from another country might take longer.



Section 5

Settings



This section instructs you on how to change easypod® settings.

5.1 Menu overview	54
5.2 History	55
5.3 Injection settings	57
5.4 Device settings	60
5.5 Battery status	66

Reminders and tips to change your easypod® settings



CAUTION: DO NOT change the injection settings on easypod® until you have discussed it with your doctor or nurse.

- Clinical setup features can only be changed by your doctor or nurse. Contact your doctor or nurse if you want to change any of these items.
- Data transfer to the database accessible by your doctor or nurse includes only injection data and technical data related to your easypod® autoinjector device, such as version and serial number. No personal identifiable information such as your name or address are transferred. The data transfer is anonymous.
- The transfer of your data is protected by applying well established security standards as mutual authentication, and encryption. Local data protection laws and directives are strictly followed.
- **DO NOT** remove the battery or power off the device while changing settings without saving. This may cause unsaved changes or loss of data.

Section 5.1 Menu overview

Press the  button on the home screen to access the main menu. You can press the  button to return to the home screen.



The main menu contains:

- History
- Injection settings
- Device settings
- Clinical setup

Each section provides access to a number of feature and settings.



History

- Calendar view
- List view
- Clinical summary



Device settings

- Data transfer
- Personalize
- Volume
- Language
- Date/Time
- System info



Injection settings

- Depth
- Speed
- Hold time
- Remove/Insert cartridge
- Info



Clinical setup (Doctor or nurse only)

Section 5.2 History

Use the history menu to review your total number of injections including the time, date, dose injected and number of times you have changed the cartridge.

There are three ways to view your injection history: Calendar, List, and Clinical summary.

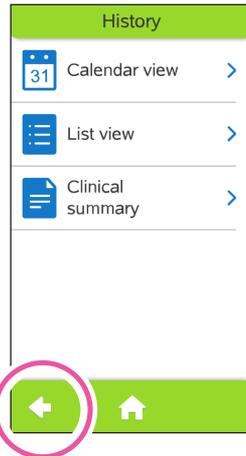
To access the History menu:

- Open  menu from the home screen.
- Select  History.



History

Press to Exit



Clinical summary

Clinical summary	
Last month	
Planned (mg)	Actual (mg)
35.90	32.60 (91%)
Last 3 months	
Planned (mg)	Actual (mg)
102.50	97.30 (95%)

The clinical summary is for your doctor or nurse to review. It shows your dosing patterns over multiple months, which your doctor or nurse can use to give you further guidance.



Section 5.2 History (continued)

Event icons in each view

-  Full dose delivered
-  Interrupted injection
-  Partial dose delivered
-  Cartridge change
-  Orange dot: Notable event (e.g., more than one full dose in one day)



Calendar view



Calendar view shows your daily injections one month at a time. For details on injection days, click the date on the calendar.



Injection List view

List view	
 30 Aug 2019 21:05	1.50 mg
 29 Aug 2019 21:18	1.00 mg
 29 Aug 2019 Cartridge change	
 29 Aug 2019 21:04	0.50 mg
 28 Aug 2019	1.50

List view shows a chronological list of events.

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.

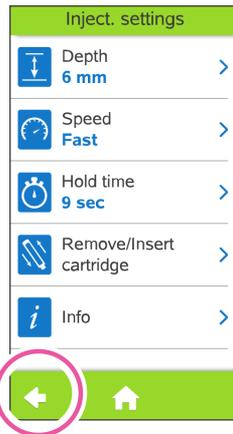
To access the Injection settings menu:

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

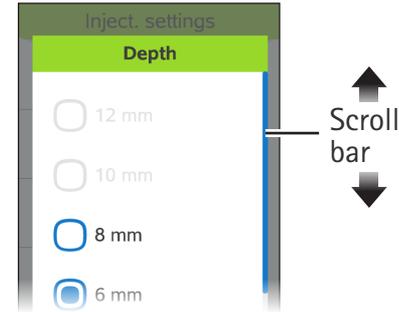


Injection settings

Press to Exit



Depth



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

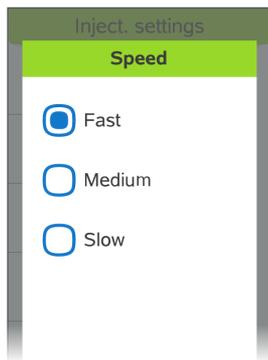
- Select  Depth.
- Select 12 mm, 10 mm, 8 mm, 6 mm, or 4 mm.
- Press  to confirm.

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)

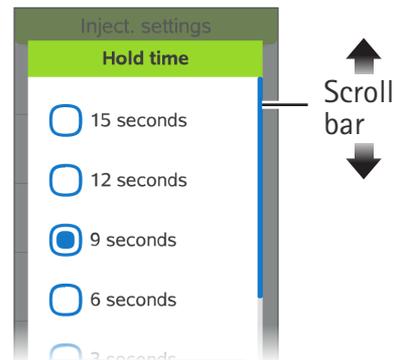
Speed



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

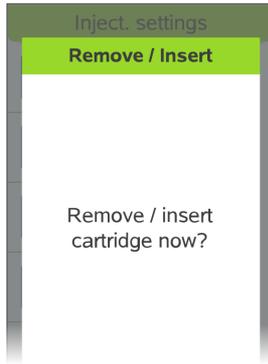


The time the needle remains in the skin after medication has been delivered. The needle will retract after this time (between 3 – 15 seconds, default is 6 seconds).

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



Remove/Insert cartridge

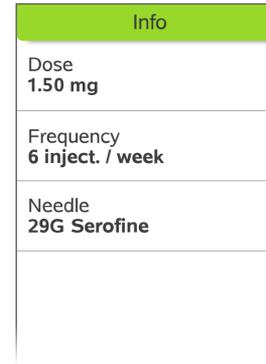


Unlock cartridge door to remove the cartridge:

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



Info



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

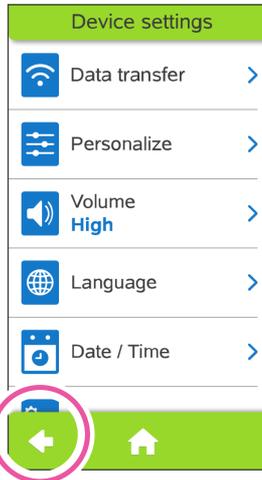
Use the Device settings screen to adjust the settings of the device, such as color use, volume, language, date and time, and connectivity.

To access the Device settings menu:

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



Device settings

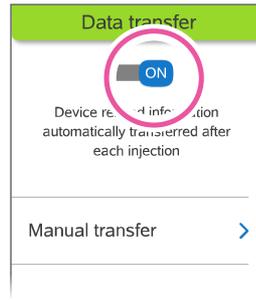


Press to Exit

Data transfer

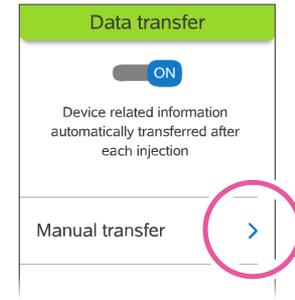


You can set easyPod® to transmit your injection history to a database accessible by your doctor or nurse.



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):

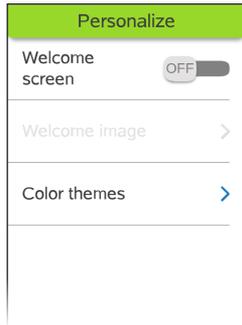
- Press "Manual transfer"
- Wait until data has been shared.
- Press  to confirm.

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.



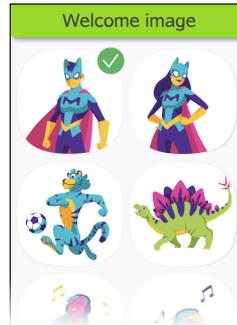
Section 5.4 Device settings (continued)

Personalize



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

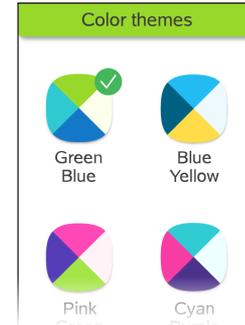
Select  Personalize to access options.



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.

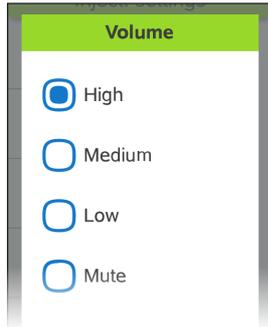


Color themes

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:

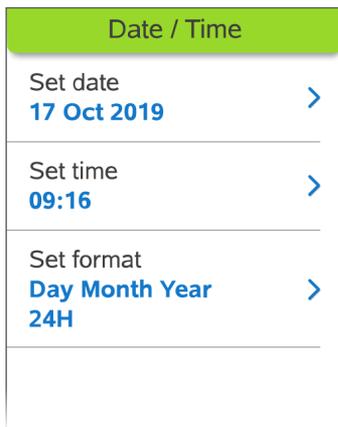
- Select  Language.
- Select the language you prefer.
- Press  in the next screen to confirm.



Section 5.4 Device settings (continued)



Date / time

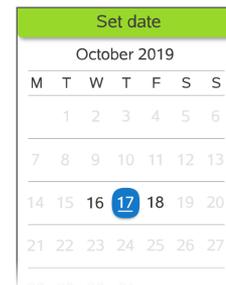


"Date / Time" provides the option to change the date, time and the formatting of those.

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.



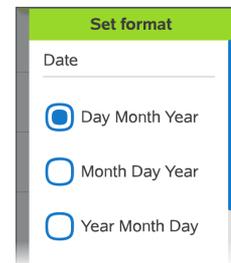
When you select "Set time":

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



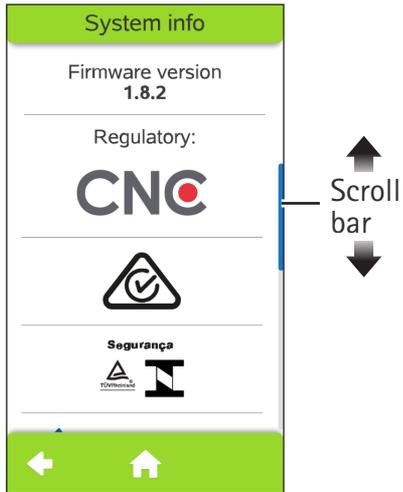
When you select time and date "Set format":

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





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:



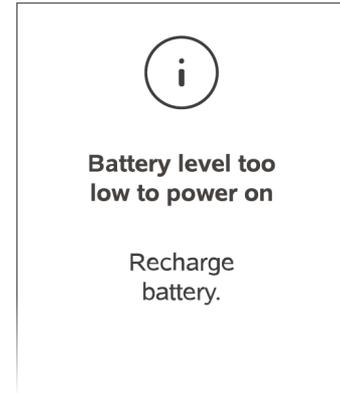
Battery fully charged



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.

6.1 Interrupted injection	70
6.2 Dropped device	72
6.3 Warning and information messages	74
6.4 Frequently asked questions	82

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.

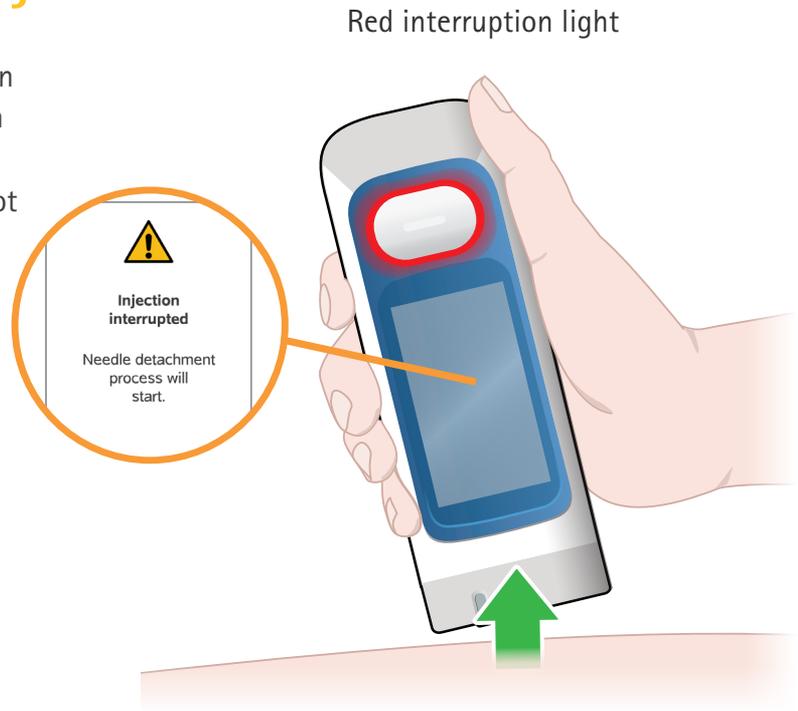
- easypod® will display an "Injection interrupted" message on screen
- The injection button turns red

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.

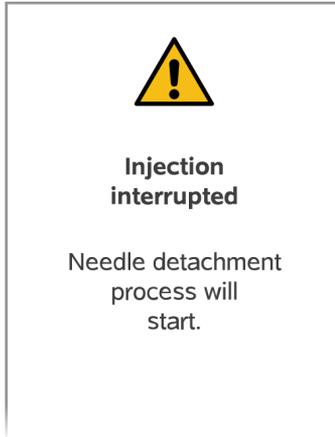
Follow the on-screen instructions and steps on the next page.

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.

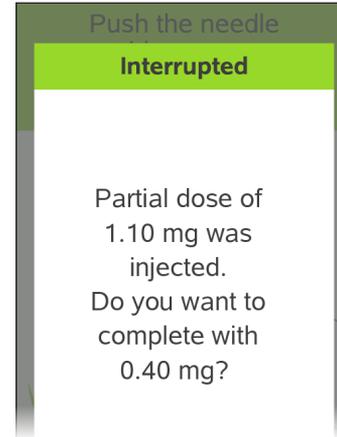


Injection has been interrupted, inject remaining dose



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.

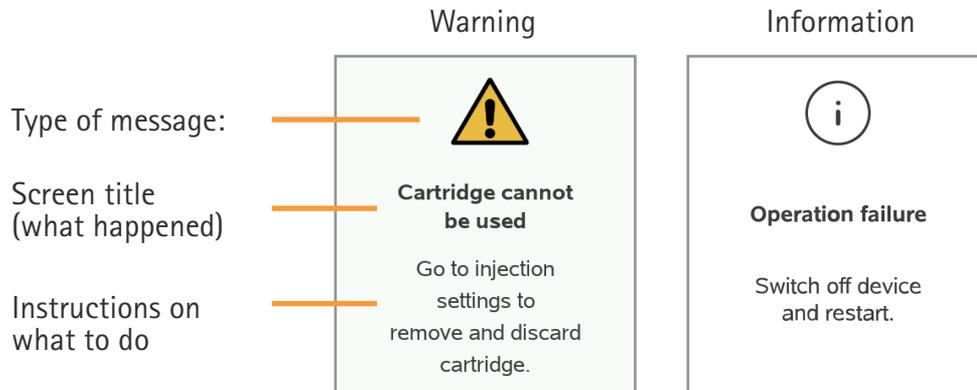
f. If there are no signs of damage, put cartridge back into device and close cartridge door. Contact your doctor or nurse if you have any doubts.



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:



 **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: <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• 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:

- a. Select  Menu >  Injection settings >  Remove/Insert cartridge > then,  on the device screen.
- b. The cartridge door will open to allow the object to fall.
- c. 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**

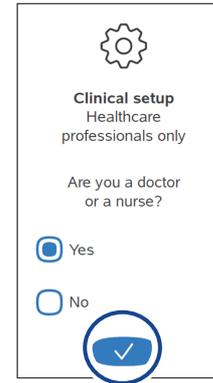
- This section is for doctors and nurses only. As a patient you should not use these instructions.
- Contact your doctor or nurse if you would like to receive information about this section.

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.

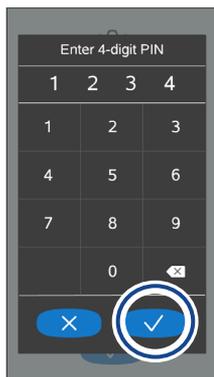
1 Confirm you are a nurse or doctor



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 checkmark icon is visible at the bottom of the screen.

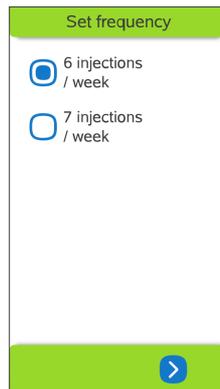
- After completing the initial device settings (see section 2.2), press checkbox next to "Yes" to confirm you are a nurse or doctor.
- Press  to continue.

2 Create PIN



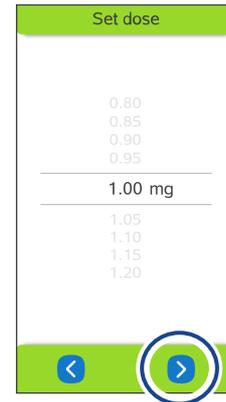
- Type in a 4-digit PIN code if you want to lock access to the clinical settings.
- Press  to continue and confirm the PIN code.

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.

 Dose range in 0.05mg increments:

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



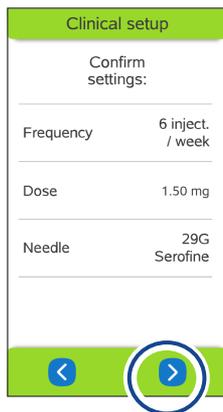
Section 7.1 Complete first time setup wizard (continued)

5 Set needle



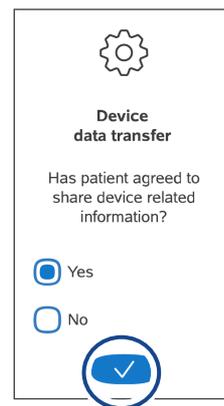
- Press checkbox of the prescribed needle gauge.
- Press  arrow to continue.

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.

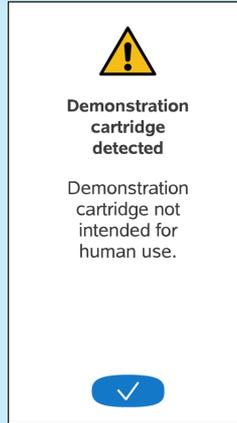
In some countries, due to local regulations, data transmission is automatically disabled. In this case do not turn data transfer on.

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

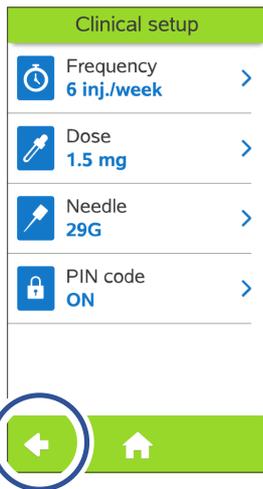
Use the clinical setup screens to adjust the treatment settings, such as the injection frequency, needle type, and dosage. In the clinical setup you can also change or turn the PIN code on/off.

To access the Clinical setup menu:

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



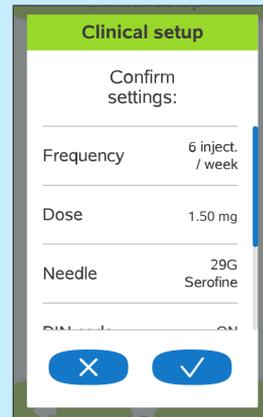
Clinical setup



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	Approximately 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	Merck 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: <ul style="list-style-type: none">• 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
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV air ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	10 V/m 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, ± 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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available electronically at
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