



Instructions For Use



Questions about
easypod™?

connections
for growth
800-582-7989

www.easypodus.com

exclusively for use with

saizen®

[somatropin (rDNA origin) for injection]

click.easy® cartridges 8.8 mg



Quick Contacts

For additional Serofine™ needles

Call Connections for Growth®.....800-582-7989

If easypod™ does not work properly

Call Connections for Growth.....800-582-7989

Default Settings Table

Your easypod comes programmed with the following default settings. These settings may be changed to suit your individual preference.

Note: Clinical settings should be changed only under guidance from your healthcare provider.



<u>Comfort settings</u>	<u>Default</u>	<u>Clinical settings</u>	<u>Default</u>
Needle speed	Medium	Dose settings	
Injection speed	Medium	Daily dose	0.15 mg
Injection depth	6 mm	Weight	1 kg
Injection time	5 seconds	Height	1 cm
		Posology (Pos)	0.025 mg/kg/day or 0.7 mg/m ² /day
<u>Device settings</u>	<u>Default</u>	Frequency	7 days/week
Date & Time	day/month/year	Dose adjustment	Off
Sound	On	Cartridge	B (5.83 mg/mL)
Name	easypod	Needle type	29 G x 12 mm
Welcome picture	easypod	Cartridge expiration	28 days
Language	English	Dose log	On
		PIN code	0000

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A Message about easypod™ to Saizen® [somatropin (rDNA origin) for injection] Patients and their Caregivers

- easypod is a smart injector, which means it automatically inserts a needle and delivers a preset dose of Saizen®. Your easypod is a personal device; for use by one person only.
- easypod should only be used according to this instruction manual and only after proper training from a healthcare provider. For children, an adult should supervise the use of easypod.

The “Teach me” section (see page 24) may be used to review the formal training you received.

- easypod is to be used exclusively with Saizen click.easy® cartridges, in accordance with the prescription written by your healthcare provider. Prior to delivery with easypod, Saizen must be reconstituted (mixed) using click.easy. Be sure to write the date of reconstitution on the transparent inner label on the click.easy cartridge. easypod is not designed for use with any other cartridges.

Detailed information about reconstitution and administration of Saizen is provided in the Saizen Package Insert and the click.easy Instructions for Use.

- easypod is compatible with Saizen click.easy cartridges in the following concentrations: (a) 8 mg/mL; (b) 5.83 mg/mL; and, (c) 1.5 mg/mL. You should check the expiration date printed on the click.easy carton prior to use.
- easypod should be handled with care. When possible, store easypod in the storage case provided, which limits exposure to dirt, dust, liquid, and other substances.

- As needed, clean easypod™ with a damp cloth and mild soap solution.

Do not use harsh chemicals, cleaning solvents, strong detergents, or alcohol solutions, as these could damage easypod. Remove dirt and dust from your easypod with a soft brush.

CAUTION: Never rinse or immerse easypod or any of its parts in water.

- easypod contains no harmful components.
- easypod should be replaced after three years of use. A new easypod can be obtained through your healthcare provider, or through Connections for Growth® (CFG), the patient-support program provided by EMD Serono. Call CFG toll-free at 800-582-7989.
- easypod should only be used with Serofine™ single-use, disposable sterile needles, 0.33 x 12 mm (29 G x 1/2") or 0.30 x 8 mm (30 G x 5/16"). Call Connections for Growth at 800-582-7989 to refill your supply of needles. Dispose of used needles safely and appropriately as recommended by your healthcare provider. easypod is not designed for use with other needles.

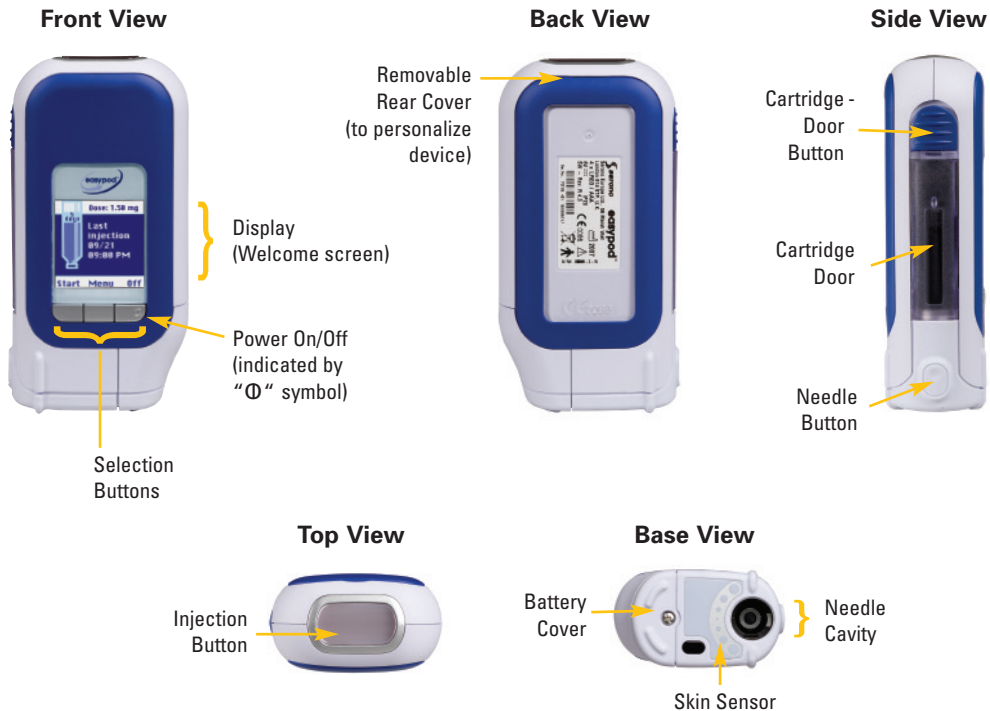
When a needle is attached, and prior to injection, keep the needle and the base of easypod pointing down.

WARNING:

- **easypod is an electromechanical device and should be handled with care. Do not use easypod if it does not work properly and do not attempt to repair a faulty easypod.**
- **easypod should not be turned on near strong electromagnetic sources like an x-ray machine in a medical facility or a security machine at an airport. Use of easypod near common-household electronic devices should not be a problem.**

Section 1. Getting Started

Getting to know easypod™



Section 1. Getting Started

First-time use of easypod™

1. Open the storage case by pushing the sliding-release button to the left (5a).
2. Install four new 'AAA' batteries into easypod by unscrewing the battery cover and placing the batteries as shown inside the cover.
3. Turn on easypod by holding down the power "Ⓞ" button (5b) until the Welcome screen appears.
4. You will be prompted to change the date and time using the international-standard settings (day/month/year). Once reset, you may change the date and time settings to US format. See "Date & Time", page 11.
5. The default-language setting is English. If you prefer another language, see "Language", page 13.
6. Saizen® [somatropin (rDNA origin) for injection] click.easy® cartridges have a 21-day expiration after reconstitution (mixing). Follow the directions under "Cartridge expiration", page 23, to change the setting to 21 days. easypod will automatically notify you when the cartridge has been in use for 21 days.
7. Make sure the cartridge setting is correct according to your prescription (see "Cartridge", page 21). Then insert a new click.easy cartridge (see "Insertion of a new cartridge or change of an empty/expired cartridge", page 32).



IMPORTANT INFORMATION:

- **Clinical settings should be changed only under guidance from your healthcare provider.**
- **Do not use the window on the cartridge door to gauge the amount of remaining solution in the cartridge.**

Explanation of easypod symbols



Refer to accompanying documents



Power on/off



Dispose of safely according to your local regulations



Do not freeze



DC



Applied part type B (electrical isolation)



Refrigerate device after use

Section 1. Getting Started

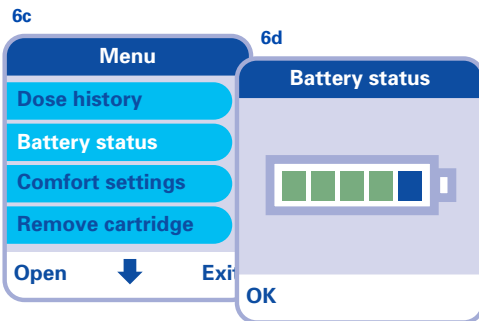
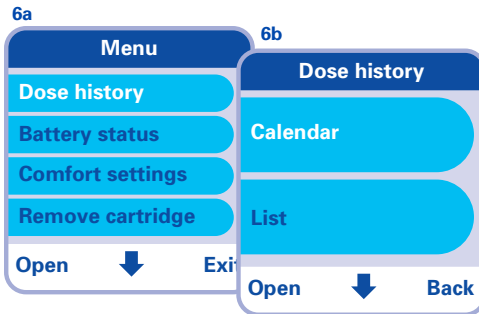
Dose history and Battery status settings

Dose history

1. Select "Menu". "Dose history" will be highlighted (6a).
2. Select "Open". "Calendar" will be highlighted.
3. Use the "↓" key to select a display of Dose history in either "Calendar" or "List" format (6b).
4. Select "Open" to see the dose history.
5. Select "Exit" and then "Back" to return to the Menu.
6. Select "Exit" to return to the Welcome screen.

Battery status

1. Select "Menu".
2. Use the "↓" key to highlight "Battery status" (6c).
3. Select "Open" to see the battery status.
4. Select "OK" to return to the Menu (6d).
5. Select "Exit" to return to the Welcome screen.



Section 1. Getting Started

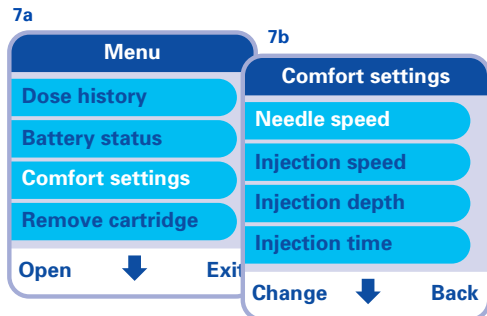
Comfort settings

There are four Comfort settings for easypod™:

- Needle speed
- Injection speed
- Injection depth
- Injection time

To change a Comfort setting:

1. Select “Menu”.
2. Use the “↓” key to highlight “Comfort settings” (7a).
3. Select “Open”.
4. Follow the instructions on pages 8 and 9 for the Comfort setting you would like to change (7b).
5. Once your setting is changed, select “Back” and then “Exit” to return to the Welcome screen.

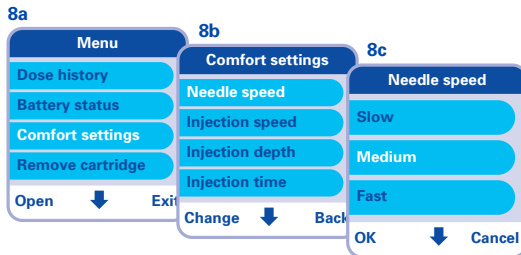


Section 1. Getting Started

Comfort settings

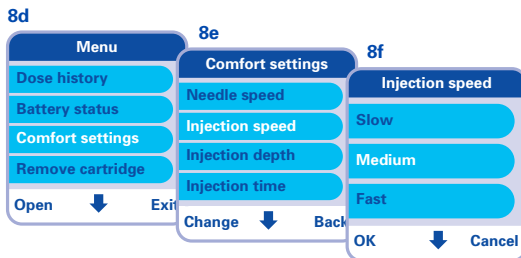
Needle speed – controls how fast the needle is inserted into your skin.

1. Open the “Comfort settings” menu (8a), “Needle speed” will be highlighted.
2. Select “Change” (8b) to open the “Needle speed” menu. The current setting will be highlighted.
3. Use the “↓” key to select Slow, Medium, or Fast (8c).
4. Select “OK”.



Injection speed – controls how fast your Saizen® [somatropin (rDNA origin) for injection] is delivered.

1. Open the “Comfort settings” menu (8d).
2. Use the “↓” key to highlight “Injection Speed” (8e).
3. Select “Change” to open the “Injection speed” menu. The current setting will be highlighted.
4. Use the “↓” key to select Slow, Medium, or Fast (8f).
5. Select “OK”.

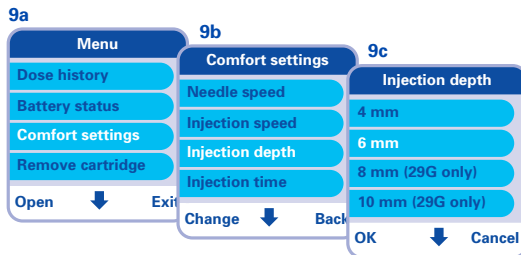


Section 1. Getting Started

Comfort settings

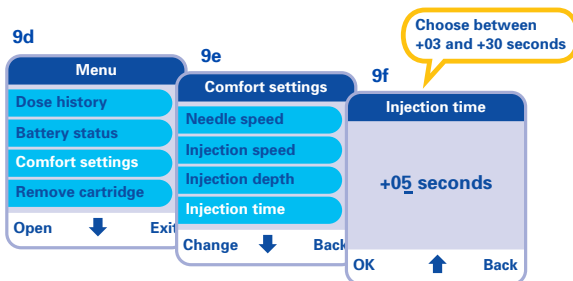
Injection depth – controls how deep the needle is inserted into your skin.

1. Open the “Comfort settings” menu (9a).
2. Use the “↓” key to highlight “Injection depth” (9b).
3. Select “Change” to open the “Injection depth” menu. The current setting will be highlighted.
4. Use the “↓” key to select 4 mm, 6 mm, 8 mm, or 10 mm (8 mm and 10 mm available for 29 G needles only) (9c).
5. Select “OK”.



Injection time – controls how long the needle stays in your skin.

1. Open the “Comfort settings” menu (9d).
2. Use the “↓” key to highlight “Injection time” (9e).
3. Select “Change” to open “Injection time”. The current setting will be highlighted. Recommended setting is 5 to 10 seconds.
4. Use the “OK” key to move the cursor under the number you would like to change and use the “↑” key to change the number (9f).
5. When the correct number appears, select “OK” to move to the next number.
6. Select “OK”.



Section 1. Getting Started

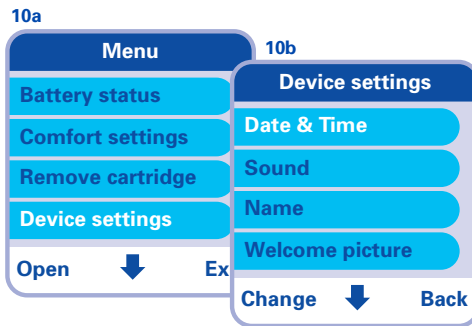
Device settings

There are five Device settings for easypod™:

- Date & Time
- Sound
- Name
- Welcome picture
- Language

To change a Device setting:

1. Select “Menu”.
2. Use the “↓” key to highlight “Device settings” (10a).
3. Select “Open” to view the Device settings menu.
4. Follow the instructions on pages 11–13 for the Device setting you would like to change (10b).
5. Once your setting is changed, select “Back” and then “Exit” to return to the Welcome screen.



Section 1. Getting Started

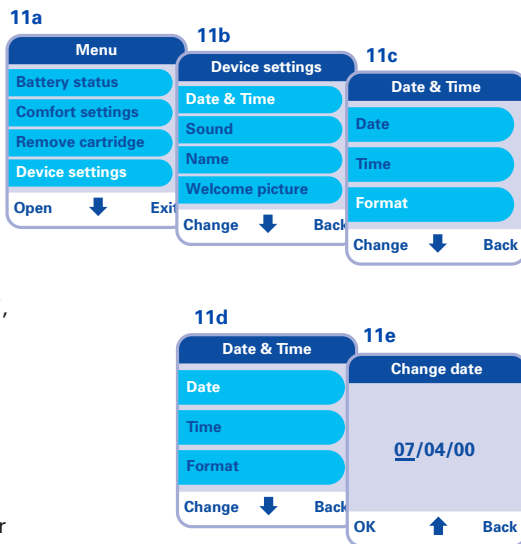
Device settings

Date & Time

1. Open the “Device settings” menu (11a). “Date & Time” will be highlighted.
2. Select “Change” to open the “Date & Time” menu (11b).
3. To change the appearance of the date and time, use the “↓” key to highlight “Format” (11c).
4. Select “Change”.
5. Use the “↓” key to highlight “dd/mm/yy 24h”, “mm/dd/yy am/pm” (US standard format), or “yy/mm/dd 24h”.
6. Select “OK”.
7. To change the date, use the “↓” key to highlight “Date” (11d).
8. Select “Change”.
9. Use the “OK” button to move the cursor under the part of the date you would like to change, and use the “↑” key to change the numbers (11e).
10. When the correct number appears, select “OK” to move to the next number.
11. Continue pressing “OK” until you return to the “Date & Time” menu.

To change the time, use the “↓” key to highlight “Time”. Select “Change”. Use the same steps to change the time as you used to change the date.

Note: Each time the batteries are removed, easypod will prompt you to change the date and time.

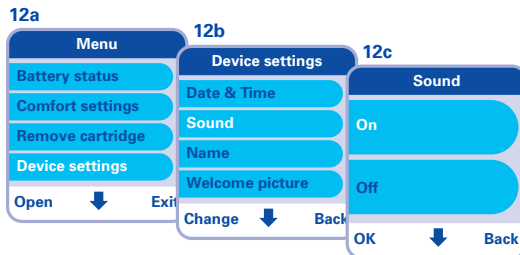


Section 1. Getting Started

Device settings

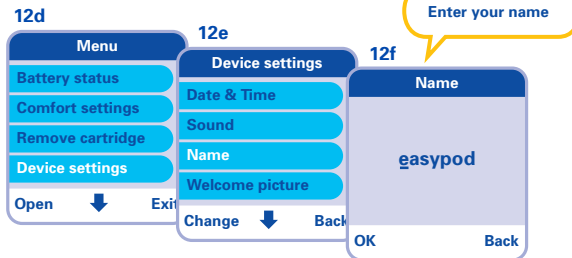
Sound

1. Open the “Device settings” menu (12a).
2. Use the “↓” key to highlight “Sound” (12b).
3. Select “Change” to open the “Sound” menu. The current setting will be highlighted.
4. Use the “↓” key to choose “On” or “Off” (12c).
5. Select “OK”.



Name

1. Open the “Device settings” menu (12d).
2. Use the “↓” key to highlight “Name” (12e).
3. Select “Change” to open “Name”.
4. Use the “OK” key to move the cursor under the letter you would like to change, and use the “↑” key to scroll through the alphabet (12f).
5. When the correct letter appears, select “OK” to move to the next letter.
6. Continue pressing “OK” until you return to the “Device settings” menu.

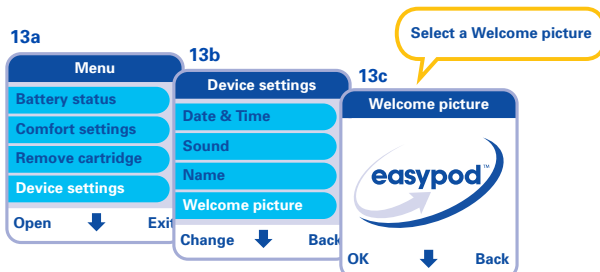


Section 1. Getting Started

Device settings

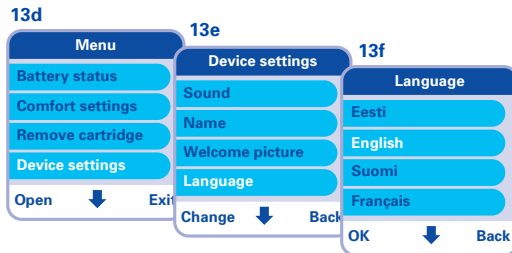
Welcome picture

1. Open the “Device settings” menu (13a).
2. Use the “↓” key to highlight “Welcome picture” (13b).
3. Select “Change” to open “Welcome picture”. The current Welcome picture will appear.
4. Use the “↓” key to scroll through the pictures (13c).
5. Select “OK” when your choice appears.



Language

1. Open the “Device settings” menu (13d).
2. Use the “↓” key to highlight “Language” (13e).
3. Select “Change” to open the “Language” menu. The current setting will be highlighted.
4. Use the “↓” key to scroll through the language options (13f).
5. Select “OK” when your language choice is highlighted.



Section 1. Getting Started

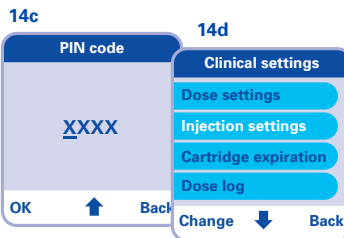
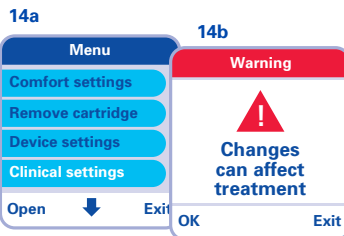
Clinical settings

There are six Clinical settings for easypod™:

- Dose settings
- Cartridge expiration
- Connection
- Injection settings
- Dose log
- PIN code

To change a Clinical setting:

1. Select “Menu”.
2. Use the “↓” key to highlight “Clinical settings” (14a).
3. Select “Open”. The warning message “Changes can affect treatment” will appear (14b) and easypod will beep three times.
4. Select “OK” to continue, or “Exit” to return to the Menu. You will be asked for a **PIN code**, which must be entered to change any Clinical setting.
5. Use the “↑” key and then press “OK” to enter the initial PIN code “0000” (14c). The “Clinical settings” menu will open (14d).
6. Follow the instructions on pages 15–23 for the Clinical setting you would like to change.
7. Once your setting is changed, select “Back” and then “Exit” to return to the Welcome screen.



Information about Clinical settings

- Clinical settings should be changed only under guidance from your healthcare provider.
- The initial PIN code is “0000” and should be changed only by your healthcare provider.
- “Connection” is not an active feature.

Section 1. Getting Started

Clinical settings

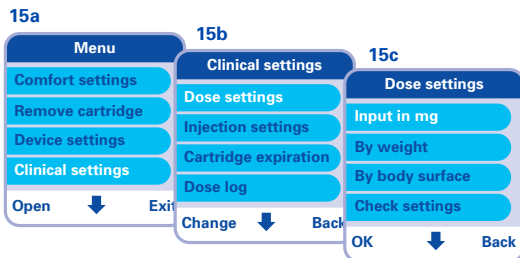
Dose settings

There are three options in easypod™ for setting the dose:

- Input in mg
- By weight
- By body surface

To change a Dose setting:

1. Open the “Clinical settings” menu (15a) and enter the PIN code (see page 14). “Dose settings” will be highlighted (15b).
2. Select “Change” to open the “Dose settings” menu.
3. Follow the instructions on pages 16 and 17 to change the dose by mg, weight, or body surface, and for “Check settings” (15c).
4. Follow the instructions on page 18 to use the Dose adjustment feature, which can reduce medication waste.

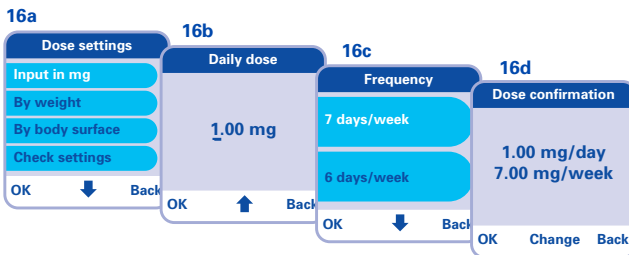


Section 1. Getting Started

Clinical settings

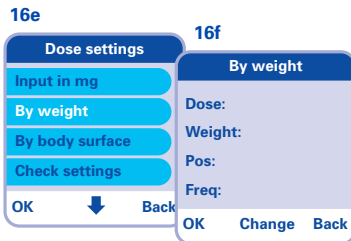
Input in mg – dose in milligrams

1. Open the “Dose settings” menu (16a). “Input in mg” will be highlighted.
2. Select “OK” to open “Daily dose”.
3. Use the “OK” key to move the cursor under any number you would like to change and use the “↑” key to change the number (16b).
4. When the correct number appears, select “OK” to move to the next, until all numbers are correct.
5. Continue pressing “OK” until the “Frequency” menu appears.
6. Use the “↓” key to highlight “7 days/week” or “6 days/week” (16c).
7. Select “OK” and the “Dose confirmation” display will appear.
8. If the dose information is correct, select “OK” (16d), and the “Dose adjustment” menu will appear (see page 18 for instructions). If the dose information is incorrect, select “Change” to return to the “Dose settings” menu and repeat the steps.



By weight – dose per kg of body weight

1. Open the “Dose settings” menu and use the “↓” key to highlight “By weight” (16e).
2. Select “OK” to open the “By weight” menu.
3. Select “OK” if the settings are correct, or select “Change” to change the settings (16f).
4. Repeat steps 3 to 8 above (under “Input in mg”).



Section 1. Getting Started

Clinical settings

By body surface – dose per m² of body surface

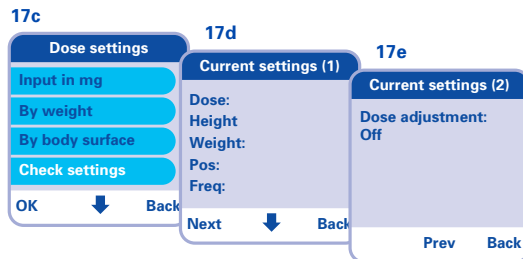
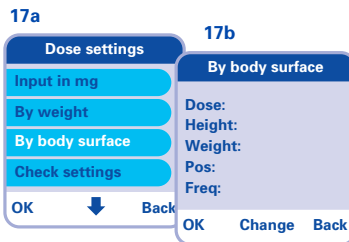
1. Open the “Dose settings” menu and use the “↓” key to highlight “By body surface” (17a).
2. Select “OK” to open the “By body surface” menu.
3. Select “OK” if the settings are correct, or select “Change” to change the settings (17b).
4. Repeat steps 3 to 8 (under “Input in mg”, page 16).

Note: Posology (“Pos”) on (16f) and (17b) is another term used for “dosing” expressed as mg/kg/day or mg/m²/day.

Check settings

This feature allows you to review the Dose settings selected.

1. Use the “↓” key to highlight “Check settings” from the “Dose settings” menu (17c).
2. Select “OK” to open the “Current settings (1)” menu, showing the current Dose settings (17d).
3. Select “Next” (17d) to open “Current settings (2)”, showing the current Dose adjustment setting (17e).
4. Select “Back” to return to the “Dose settings” menu.



Section 1. Getting Started

Clinical settings

Dose adjustment

The Dose adjustment feature can reduce the amount of medication wasted. There are three settings to choose from: “Off”, “>50%”, and “Automatic”.

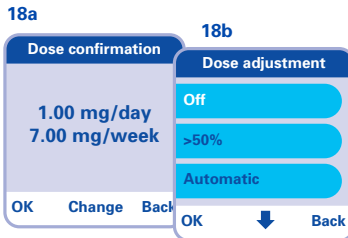
To change the Dose adjustment setting:

1. Follow the instructions on pages 16 and 17 to change the dose by mg, weight, or body surface.
 2. Select “OK” on the “Dose confirmation” menu (18a), which is step 8 under “Dose settings—Input in mg” (see page 16). The “Dose adjustment” menu will open.
 3. Use the “↓” key to highlight “Off”, “>50%”, or “Automatic” (18b).
 4. Select “OK”.
- 5a. **WHEN “OFF” IS SELECTED**, you will be asked to confirm the daily dose.

If easypod detects that the cartridge content is less than the daily dose, you will be prompted to change the cartridge. Choose **i.** or **ii.** or **iii.** below:

- i.** inject the full daily dose with a new cartridge; **or**,
- ii.** inject the medication remaining in the current cartridge and count this partial dose as the daily dose; **or**,
- iii.** complete two injections that together total the full daily dose: the first with the remaining medication in the current cartridge; and, the second, with a new cartridge (see “Partial dose”, page 30). easypod will automatically calculate the dose needed for the second injection.

Select “OK”, or “Back” to change the dose settings (18c).



Section 1. Getting Started

Clinical settings

- 5b. WHEN “>50%” IS SELECTED**, the daily dose, the projected date of the last dose, and the left over medication in the cartridge will be displayed.

easypod™ will keep track of the amount of medication remaining in the current cartridge.

- i. if >50% (but less than 100%) of the daily dose is remaining in the current cartridge, easypod will inject this partial dose from the current cartridge and record it as the daily dose;
- ii. if <50% of the daily dose is remaining in the current cartridge, you will be prompted to change the cartridge and easypod will inject the full daily dose from the new cartridge.

Select “OK”, or “Back” to change the dose settings **(19a)**.

19a

Last dose >50%

Dose:
Last dose:
Left over:

OK Back

- 5c. WHEN “AUTOMATIC” IS SELECTED**, the “Dose spread” menu will open.

Use the “↓” key to highlight the “Dose spread” setting you want **(19b)**.

easypod will calculate the dose that optimally uses the cartridge content and remains close to the daily dose. The dose will be adjusted by ± 10%, 25% or 50%, whichever is selected on the Dose spread menu.

Select “OK” to see the Automatic adjustment and view the min/max daily adjusted dose **(19c)**, or “Cancel” to change the dose settings.

19b

Dose spread

<10%
<25%
<50%

OK ↓ Cancel

19c

Automatic adjustment

Dose:
Min:
Max:

OK Back

Section 1. Getting Started

Clinical settings

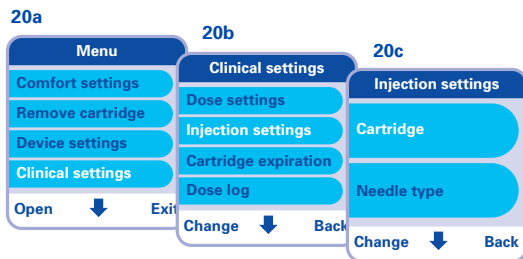
Injection settings

There are two Injection settings for easypod:

- Cartridge
- Needle type

To change an Injection setting:

1. Open the “Clinical settings” menu (20a) and enter the PIN code (see page 14).
2. Use the “↓” key to highlight “Injection settings” (20b).
3. Select “Change” to open the “Injection settings” menu.
4. Follow the instructions on pages 21 and 22 to change an Injection setting (20c).



Section 1. Getting Started

Clinical settings

Cartridge

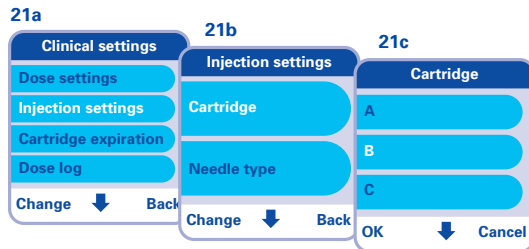
The dose range depends on the type of cartridge selected containing a specified concentration of Saizen® [somatropin (rDNA origin) for injection]. The following click.easy® cartridge concentrations are available:

- Cartridge type A (concentration of 8 mg/mL):
range can vary between 0.5 mg to 6.4 mg in increments of 0.01 mg.
- Cartridge type B (concentration of 5.83 mg/mL):
range can vary between 0.15 mg to 4.66 mg in increments of 0.01 mg.
- Cartridge type C (concentration of 1.5 mg/mL):
range can vary between 0.15 mg to 1.2 mg in increments of 0.01 mg.

IMPORTANT: The cartridge type should be selected according to your prescription.

To change the Cartridge setting:

1. Open the “Clinical settings” menu and enter the PIN code (see page 14) (21a).
2. Use the “↓” key to highlight “Injection settings”.
3. Select “Change” to open the “Injection settings” menu. “Cartridge” will be highlighted.
4. Select “Change” and the “Cartridge” menu will open (21b).
5. Use the “↓” key to highlight Cartridge “A”, “B”, or “C” (21c).
6. Select “OK”.



Section 1. Getting Started

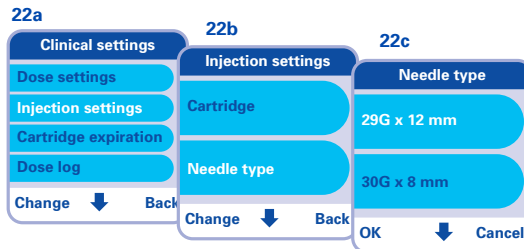
Clinical settings

Needle type

easypod™ should only be used with Serofine™ single-use, disposable sterile needles. Serofine needles are available as a 29 G x 1/2" (12 mm) or a 30 G x 5/16" (8 mm). Choose the appropriate needle type.

To change the Needle type setting:

1. Open the "Clinical settings" menu and enter the PIN code (see page 14) (22a).
2. Use the "↓" key to highlight "Injection settings".
3. Select "Change" to open the "Injection settings" menu.
4. Use the "↓" key to highlight "Needle type" (22b), and the "Needle type" menu will open.
5. Use the "↓" key to highlight "29 G" or "30 G" needles (22c).
6. Select "OK".



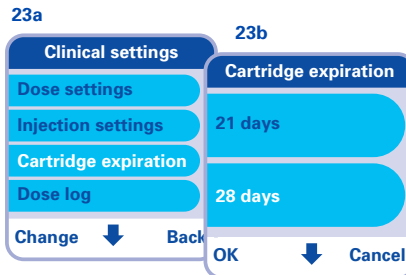
Section 1. Getting Started

Clinical settings

Cartridge expiration

To change the Cartridge expiration setting:

1. Open the “Clinical settings” menu and enter the PIN code (see page 14) (23a).
2. Use the “↓” key to highlight “Cartridge expiration”.
3. Select “Change” to open the “Cartridge expiration” menu.
4. Use the “↓” key to highlight “21 days” (23b).
(The cartridge expires and must be changed after 21 days).
5. Select “OK”.



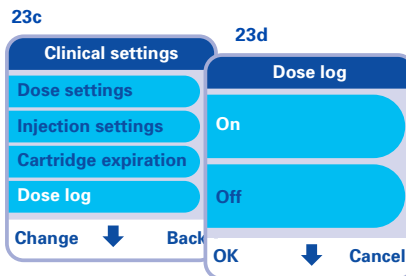
Dose log

The Dose log keeps track of each dose injected.

To change the “Dose log” setting: Open the “Clinical settings” menu → Open “Dose log” → Activate “Dose log” by highlighting “On” and deactivate by highlighting “Off” → Select “OK”.

The Dose history in calendar or list format uses the following color code:

- Green** = injection completed
- Red** = injection missed
- Orange** = partial injection delivered
- Black** = cartridge changed
- Blue** = future days



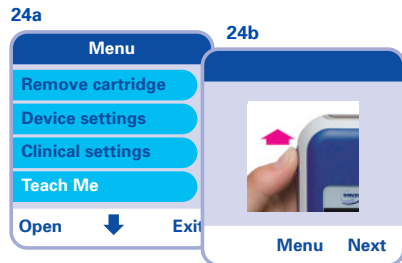
Section 1. Getting Started

“Teach me”— pictorial demonstration built into easyPod™

See the chart below for the easyPod operations demonstrated in “Teach me”.

To watch “Teach me”:

1. Select “Menu” from the Welcome screen.
2. Use the “↓” key to highlight “Teach me” (24a).
3. Select “Open”. The first pictorial step will appear (24b).
4. Select “Next” to scroll through each step shown below.



Manual Removal of empty cartridge and insertion of a new cartridge	
Step 1 Attach the Needle	
Step 2 Inject	
Step 3 Detach the needle	
Storage and Needle Disposal	

Section 2. Delivering Saizen® [somatropin (rDNA origin) for injection] with easypod™

Preparing for your injection

IMPORTANT: Always start by washing your hands thoroughly with antibacterial soap and water. Make sure to use a clean towel when drying your hands.

1. To turn on easypod, press the power button with the “ Φ ” symbol and hold down until the Welcome screen appears (25a).

Note: If your refrigerator is very cold, easypod will be cold. You may want to wait 5 to 10 minutes before turning it on, allowing easypod to adjust to room temperature.

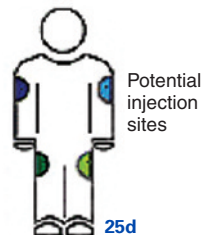
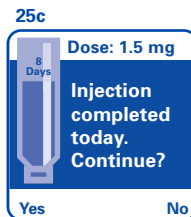
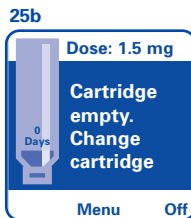
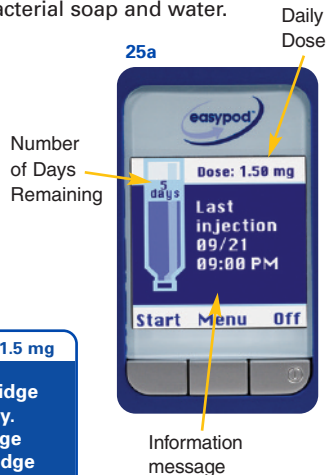
2. Press the Start button. easypod will check the cartridge to determine whether it contains enough medication for your full-dose injection:

- If the cartridge does not contain enough medication for your full-dose injection, or needs to be manually removed, the display will read “Cartridge empty. Change cartridge” (25b), (see “Partial dose”, page 30);
- If there is enough medication in the cartridge for a full dose, the display will read “Insert new needle”.

Note: easypod will display a reminder “Injection completed today. Continue?” if you try to inject within 12 hours of your previous injection (25c). Select “Yes” if you wish to continue.

Note: easypod will beep every 30 seconds for three minutes if an injection is not completed, and it will turn off automatically after 10 minutes.

3. Prepare your injection site according to the instructions given by your healthcare provider (25d).



Section 2. Delivering Saizen® [somatropin (rDNA origin) for injection] with easypod™

Giving your daily injection in three steps

Step 1: Attach the needle

- A. Remove the sterility seal from a new Serofine™ needle cap (26a).

WARNING: Do not use the needle if the sterility seal is damaged or lifting. Make sure to completely remove the sterility seal.

- B. Insert the needle cap into the needle cavity on easypod until it locks into place (26b). When inserted correctly, the needle cap clicks into place and easypod will beep once.

IMPORTANT: Do not continue to hold the needle cap while easypod attaches the needle.

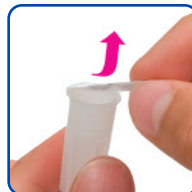
When the needle is attached, the display will read “Needle attached Remove empty cap” (26c) and easypod will beep twice.

Note: If the needle is not attached correctly, a warning message “Check needle” (26d) will be displayed. Follow the prompts to safely detach the needle and replace with a new needle.

- C. Remove the needle cap by pushing the cap sideways (26e).

Note: Do not throw the needle cap away. You will need it to detach the used needle after your injection.

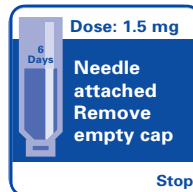
26a



26b



26c



26d



26e



Section 2. Delivering Saizen® [somatropin (rDNA origin) for injection] with easypod™

Giving your daily injection in three steps

Step 2: Inject

- A. When the display reads “Place on skin Press injection button”, place easypod at a right angle (90°) against your skin (27a).

When properly positioned against the skin, easypod will beep once and the injection button on top will turn green, indicating you are ready to inject.

IMPORTANT: Do not pinch your skin at the injection site.

- B. Press the green injection button once to start your injection (27b). It is not necessary to hold down the injection button.

During injection, the injection button will blink and the display will read “Injection in progress” (27c).

When the injection is complete, the injection-button light will go off and easypod will beep twice.

IMPORTANT: During the injection, hold easypod steady and always in contact with your skin. Removing easypod prior to the end of the injection will result in an incomplete injection.

- C. Lift easypod from the skin. The display will read “Injection completed” and show the injected dose (27d). Select “OK” to confirm the injected dose.

27a



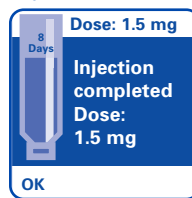
27b



27c



27d



Section 2. Delivering Saizen® [somatropin (rDNA origin) for injection] with easypod™

Giving your daily injection in three steps

Step 3. Detach the needle

- A. When the display reads “Place empty cap”, insert the empty needle cap into the needle cavity until it locks into place (28a). easypod will beep once.

IMPORTANT: Make sure you insert an empty cap. Do not continue to hold the needle cap while easypod detaches the needle.

- B. When the display reads “Press needle button until beep”, press and hold the needle button (28b) until easypod beeps twice. The needle is now detached and inside the needle cap.

IMPORTANT: Releasing the needle button too quickly (before the two beeps) may cause the needle to detach incorrectly and a warning message to appear that reads “Check needle is detached”. In this case, remove the cap and see if the needle is in the cap. If so, select “OK”. If not, place the empty cap back onto easypod, select “Repeat”, and follow the prompts.

- C. When the needle cap is ready to be removed, the display will read “Remove cap”. To remove the used needle and needle cap, push the cap sideways (28c). Dispose of the used needle safely.

IMPORTANT: Remember to dispose of the used needle in a suitable container, as recommended by your healthcare provider.

28a



28b



28c



Section 2. Delivering Saizen® [somatropin (rDNA origin) for injection] with easypod™

After your injection

1. When your injection is complete, the Welcome screen will appear and the date and time of your injection will be displayed (29a).
2. To turn off easypod, press and hold the “Power” (“⏻”) button until the display is blank.

Note: Make sure easypod is turned off to preserve the batteries.

3. Place easypod, with the cartridge containing your medication, in its storage case.

Do not remove the cartridge from easypod unless traveling (see “Manual removal of an in-use cartridge”, page 31).

4. Immediately place easypod back into the refrigerator (2-8°C / 36-46°F).

WARNING: Never store easypod in the freezer.

29a



Section 2. Delivering Saizen® [somatropin (rDNA origin) for injection] with easypod™

Partial dose

If there is not enough medication in the cartridge for your full dose, the display will read “Inject partial dose?” (30a). Select “Yes” or “No” and follow the instructions below under **A** or **B**, respectively.

A. SELECT “YES” IF YOU WANT A PARTIAL DOSE

Continue your injection of the medication in the current cartridge by following the daily-injection instructions beginning on page 25.

Once the first (partial dose) injection is completed, the display will read “Second injection?” (30b). Select “Yes” or “No” and follow the instructions below under **a** or **b**, respectively.

a. Select “Yes” if you want a second injection, to complete your full dose.

Detach the used needle from your first injection by following the instructions on page 28. Change the cartridge as instructed in the section “Insertion of a new cartridge or change of an empty/expired cartridge” on page 32. Follow the daily-injection instructions beginning on page 25.

easypod automatically calculates the dose needed for the second injection and injects this dose.

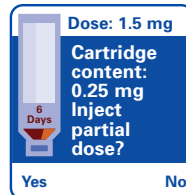
IMPORTANT: The second injection is automatically canceled if not performed within 60 minutes.

- b. Select “No” if you do not want a second injection.** The injection procedure is stopped and the display will read “Place empty cap”. Follow the instructions to detach the needle on page 28.

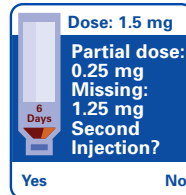
B. SELECT “NO” IF YOU DO NOT WANT A PARTIAL DOSE

Follow the instructions for “Insertion of a new cartridge or change of an empty/expired cartridge” on page 32. Once the cartridge is changed, follow the daily-injection instructions beginning on page 25.

30a



30b



Section 3. Maintenance, Care, and Handling of easypod™

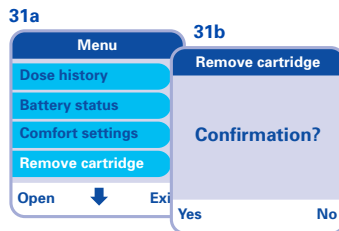
A. Traveling with easypod

Your cartridge of medication needs to be kept at a temperature between 2-8°C / 36-46°F. If possible, always store it in the refrigerator. If you need to travel with your cartridge of medication, then it should be removed from easypod and stored in an appropriate cooling container (see below “Manual removal of an in-use cartridge”).

B. Manual removal of an in-use cartridge (e.g., for traveling)

1. Select “Menu” from the Welcome screen.
2. Use the “↓” key to highlight “Remove cartridge”.
3. Select “Open” (31a).
4. easypod will confirm you want the cartridge removed (31b).
 - a. If you select “Yes”, easypod will beep twice and the message “Open cartridge door” will be displayed.
 - b. If you select “No”, you will return to the Menu.
5. Open the cartridge door by sliding the cartridge-door button up (31c). easypod will display the message “Insert cartridge” (31d).
6. Remove the cartridge and push closed the cartridge door (31e) until a click is heard. The display will read “Continue?”.
7. Select “No”.
8. Select and hold “Off” until the display is blank to turn off easypod.

Note: When travel is over, see “Insertion of a new cartridge or change of an empty/expired cartridge”, page 32, for instructions on reinserting your click.easy® cartridge.



Section 3. Maintenance, Care, and Handling of easypod™

C. Insertion of a new cartridge or change of an empty/expired cartridge

1. If there is no cartridge inside easypod, or no medication left in the cartridge, the display will read “Cartridge empty. Change cartridge” (32a).

If the cartridge is used for longer than 21 days, the warning “Cartridge expired” will be displayed. The injection-button light will turn red and not allow an injection until the cartridge is replaced.

Note: easypod has the ability to keep track of the days a cartridge has been in use, starting from the day it is inserted.

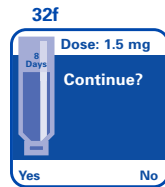
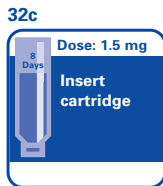
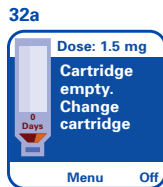
IMPORTANT: easypod must be turned on and the needle detached to change an expired cartridge.

2. Open the cartridge door by sliding the cartridge-door button up (32b). The display will read “Insert cartridge” (32c).

Note: easypod allows you to open the door only when there is no cartridge inside or it is empty. If the door does not open, the cartridge inside is not empty.

3. If there is an empty or expired cartridge inside easypod, remove it. Then insert a new click.easy® cartridge (32d).
4. Push closed the cartridge door until a click is heard (32e).
5. “Continue?” will be displayed each time a new cartridge is loaded (32f).
6. Select “Yes”. easypod will beep once when ready.

WARNING: To ensure a correct dose, make sure the easypod setting is correct for the cartridge type you are using.



Section 3. Maintenance, Care, and Handling of easypod™

D. Replacing the batteries

The battery-power level is shown by bars changing from green (full), to yellow, to red (low). When the battery-power level is very low, easypod will display the warning “Replace battery” (33a).

You will not be able to inject your next dose until the batteries are changed.

To change the batteries, follow the steps below.

1. Turn off easypod.
2. Use a screwdriver to unscrew the battery cover.
3. Remove the used batteries and appropriately discard them.
4. Insert four new ‘AAA’ batteries as shown inside the battery cover. **Lithium batteries*** are strongly recommended and expected to last approximately 10 months (supplied with easypod by EMD Serono).
5. Screw the battery cover back onto easypod.
6. Turn on easypod.
7. Reset the date and time. Each time the batteries are changed, the date and time need to be reset (see “Date & Time”, page 11).

*Alkaline batteries can be used in easypod and are expected to last approximately six months.

E. Storage

When containing a Saizen® [somatropin (rDNA origin) for injection] click.easy® cartridge, easypod should always be placed in its storage case and stored in the refrigerator (2-8°C / 36-46°F). Before storing, the needle should always be detached.

33a



Section 3. Maintenance, Care, and Handling of easypod™

F. Cleaning easypod

As needed, clean easypod with a damp cloth and mild soap solution. Do not use harsh chemicals, cleaning solvents, strong detergents, or alcohol solutions, as these could damage easypod. Remove dirt and dust with a soft brush.

G. Replacement of easypod

easypod should be replaced after three years of use. A new easypod can be obtained through your healthcare provider or by calling Connections For Growth® (CFG), EMD Serono's patient-support program at 800-582-7989. If you experience problems with your easypod, please contact your healthcare provider or CFG. You can record the date you received easypod and its serial number below.

Date Received _____ Serial Number _____

H. Frequently asked questions

IMPORTANT: In case of a problem with easypod, you should contact your healthcare provider or Connections For Growth at 800-582-7989.

What if I cannot turn on easypod?

Leave easypod at room temperature for 5 to 10 minutes. A very-cold refrigerator can affect the performance of the batteries. Try turning easypod on again.

Make sure you are using the correct type of batteries and they are correctly inserted. Lithium batteries are recommended. Try inserting a new set of batteries. To turn on easypod, you need to press and hold the power button ("⏻") until the Welcome screen appears.

Section 3. Maintenance, Care, and Handling of easypod™

H. Frequently asked questions (continued)

What if easypod turns off unexpectedly or if it remains on the same screen?

Check to see if the batteries need to be changed “Menu” → “Battery status”. If the problem persists, try new batteries or batteries of a different brand.

What if I cannot attach a needle into easypod?

Make sure you are using Serofine™ needles and that the sterility seal on the needle cap has been completely removed. Try reattaching the needle into your easypod. If you still cannot attach the needle, try a new needle.

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

If you remove easypod from your skin during an injection (blinking green light on the injection button), the injection will be interrupted and the needle automatically retracted. You can complete the injection within a time period of five minutes and inject the balance of your dose by replacing easypod onto your skin. Or, you can stop the injection, but only a partial dose will have been delivered.

What if I cannot detach a needle from my easypod?

Make sure you have used an empty needle cap to detach the needle. Try detaching the needle again. Make sure to press and hold the needle button until easypod beeps twice. Be careful not to injure yourself when handling the needle and dispose of it safely. If you still cannot detach the needle, you should contact your healthcare provider or CFG by calling 800-582-7989.

Section 3. Maintenance, Care, and Handling of easypod™

H. Frequently asked questions (continued)

What if I lose the empty needle cap?

The empty cap is necessary to detach the used needle safely. If you no longer have an empty cap, you should contact your healthcare provider or Connections For Growth® at 800-582-7989.

What if I start a new injection within 12 hours of my last injection?

If you try to inject within 12 hours of your last injection your easypod will display a reminder “Injection completed today. Continue?” Select “Yes” if you wish to continue with the injection.

What if I drop my easypod?

easypod has a self-checking mechanism to ensure mechanical problems will not lead to dosing errors. If you have dropped easypod and it still turns on, continue use of easypod. In the event of a mechanical problem, easypod will shut down automatically.

What if I drop my easypod and the cartridge breaks?

If a cartridge breaks inside your easypod, you should stop using it immediately. The electronics or mechanics may be damaged by the liquid or pieces of broken glass. Contact your healthcare provider or CFG by calling 800-582-7989, to replace your easypod.

What if I cannot open the cartridge door?

The cartridge door can only be opened when the cartridge is empty and easypod is turned on. If you need to remove an in-use cartridge (e.g., for traveling), see “Manual removal of an in-use cartridge”, page 31.

What if the date or time is not correct?

You can change the date or time on easypod. See “Date & Time”, page 11.


Section 4. Technical Information about easypod™

Specifications

EMD Serono, Inc.
One Technology Place
Rockland, MA 02370



Model name: easypod™
Weight: 280g (10.3 oz)
Dimensions: H: 128mm x W: 66mm x D: 36mm (H: 5in x W: 2.6in x D: 1.4in)
Voltage supply: 6VDC
Supply: 4 x AAA/LR03; 1.5VDC batteries - Energizer Lithium Ultimate (or e2). (Or high-quality alkaline batteries, recommended brands: Varta Power One, Varta High Energy, Varta Maxitech, Philipps PowerLife, Duracell Procell, Duracell Ultra M3).
Battery life: approx. 10 months with lithium batteries and 6 months with alkaline batteries.
Serial number: number with 16 digits printed below the bar code on the device label (under the rear cover).
Classification: MDD 93/42 CEE Class II
21 CFR 880.58608 Class II
IP20 (easypod not protected against water spillage)

Applied part type B 

Electromagnetic compatibility in accordance with EN60601-1-2 (see EMC tables beginning next page).

Operating environment: 2°C to 30°C (36°F to 86°F), 20%RH to 90%RH, 800hPa to 1060hPa.

Storage condition, (without batteries/cartridge): -20°C to 60°C (-4°F to 140°F), 20%RH to 75%RH, 800hPa to 1060hPa.

Memory: All data (except date and time) is stored permanently in easypod.

Cartridge: Saizen® [somatropin (rDNA origin) for injection] 3mL cartridges.

Maximum injection volume: 0.8mL.

Dose accuracy: +/-10% for dose above 0.25mL and +/-0.025mL for dose below 0.25mL.

Needles: Serofine™ needles 0.33x12mm (29 G x ½") or 0.30x8mm (30 G x 5/16").

Opening easypod will void any guarantee.

Repair to be performed only by authorized companies.

Explanation of easypod symbols



Refer to accompanying documents



Power on/off



Dispose of safely according to your local regulations



Do not freeze



DC



Applied part type B (electrical isolation)



Refrigerate device after use

Section 4. Technical Information about easypod™

Electromagnetic Compatibility Tables

Medical electrical equipment needs special precautions regarding EMC (electromagnetic compatibility) and needs to be used according to the EMC information provided below. Portable or mobile RF communications equipment (e.g., mobile phones, pagers...) can affect easypod.


easypod is intended for use in the electromagnetic environment specified below. The user should ensure that easypod is used in such an environment.

Guidance and manufacturer's declaration – electromagnetic emission		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	easypod uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	easypod is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable	Not applicable
Power frequency (50/60 Hz)	Not applicable	Not applicable	Not applicable

Section 4. Technical Information about easypod™

Electromagnetic Compatibility Tables (continued)

Magnetic field IEC 61000-4-8			
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2,5 GHz</p>	<p>Not applicable</p> <p>10 V/m 26 MHz to 2,5 GHz</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of easypod, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P} \quad 150 \text{ kHz to } 80 \text{ MHz}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ kHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ kHz to } 2,5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).²⁰</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey²¹ should be less than the compliance level in each frequency range.²⁰</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which easypod is used exceeds the applicable RF compliance level above, easypod should be observed to verify normal operation.</p> <p>If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating easypod.</p> <p>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.</p>			

Section 4. Technical Information about easypod™

Electromagnetic Compatibility Tables (continued)

Recommended separation distances between portable and mobile RF communications equipment and easypod			
easypod is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of easypod can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and easypod as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output of transmitter W	Separation distance according to frequency of transmitter (m)		
	$d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 150 kHz to 80 MHz	$d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 kHz to 800 MHz	$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 kHz to 2,5 GHz
0,01	Not applicable	0,04	0,07
0,1	Not applicable	0,11	0,22
1	Not applicable	0,35	0,7
10	Not applicable	1,11	2,21
100	Not applicable	3,5	7
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			





Instructions For Use



Questions about
easypod™?



www.easypodus.com

exclusively for use with

saizen®

[somatropin (rDNA origin) for injection]

click.easy® cartridges 8.8 mg