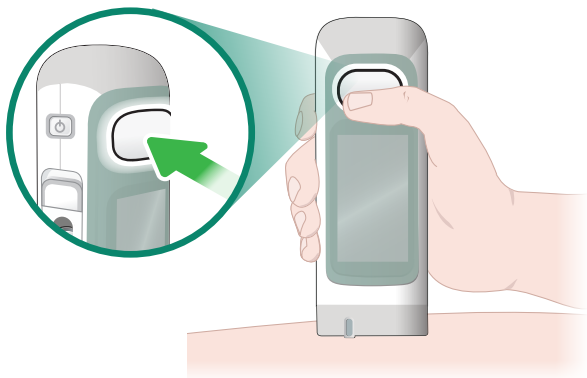


## 2 Inject medication



- Press injection button once to begin injecting. The injection button light flashes white during the injection.
- Keep RebiSmart® 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 RebiSmart®

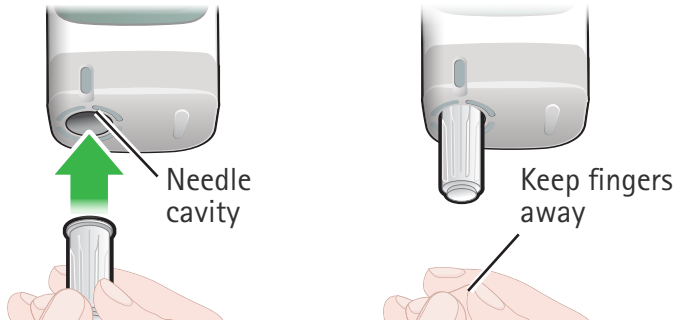


- When the injection is complete, RebiSmart® plays a chime sound and the injection button light will stop flashing and turn off.
- Lift RebiSmart® from your skin.
- If some medication remains on the skin after the injection, gently apply a cotton ball on the injection site to avoid skin reaction.



## Section 3.4 Detach needle and confirm injection

### 1 Insert needle cap, let go



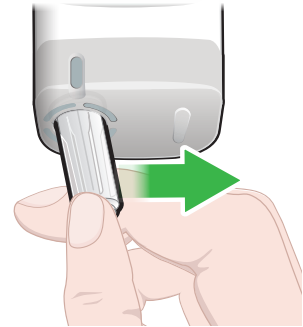
When RebiSmart® screen tells you "Insert needle cap":

- 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 RebiSmart® screen tells to, push the needle cap sideways to remove it.

 **WARNING: DO NOT** pull needle cap straight down. This might damage RebiSmart®.

### 3 Dispose needle

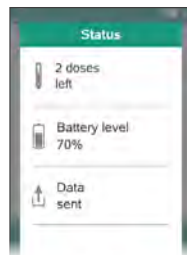



Dispose of cap with needle in a sharps container.

#### 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 RebiSmart® upright in its storage box, and as required by the Rebif® Patient Information Leaflet if cartridge is inside.

See "Section 4.1 Storing device and cartridges".

Section 4


Caring for  
the device



This section gives you instructions on how to take care of RebiSmart® when traveling, storing, replacing RebiSmart®, 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

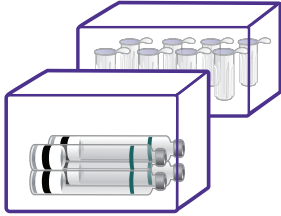
## Reminders and tips to care for your RebiSmart®

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

## Section 4.1 Storing device and cartridges

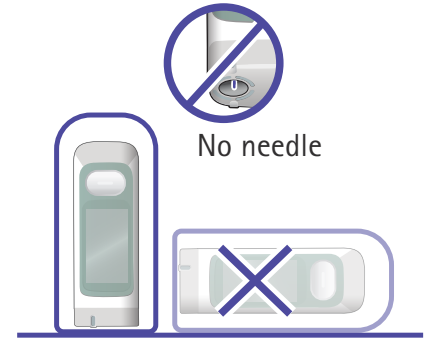
### General storage instructions



- Keep the unused Rebi® cartridges and Serofine® needles in their original packaging until you need them.
- Rebi® cartridges should be stored according to the Patient Information Leaflet (PIL).



- Discard each cartridge within **28 days after first injection** to avoid expired medication. RebiSmart® will inform you if 28 days have passed (however, in most cases, a cartridge will be used up within a week).



- Before storing RebiSmart®, make sure there is no needle in the device. Always store device upright, in its storage box, to avoid drops of Rebi® causing malfunction.
- If a cartridge is in the device, also refer to the storing conditions in the Rebi® PIL.

## Section 4.2 Taking care of your device

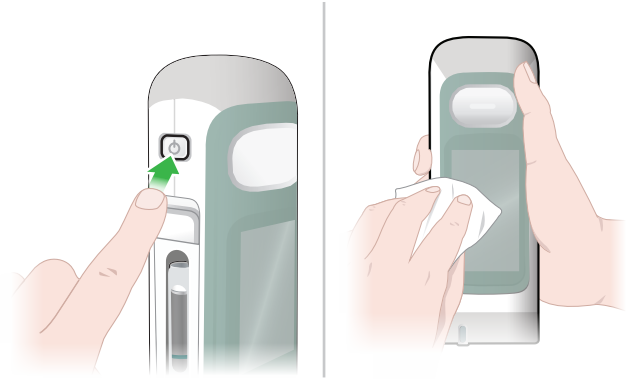
If the device is dirty and you would like to wipe it, perform the following steps on the right.

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

### 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 RebiSmart® in water or any liquid.
- **DO NOT** wipe RebiSmart® more than once per week.

### To wipe the device



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



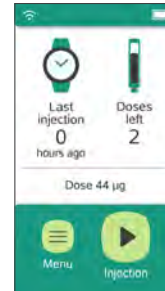
## Section 4.3 Changing cartridge

Only change the cartridge inside RebiSmart® if:

- You did not store the Rebif® cartridges according to the Patient Information Leaflet.
- RebiSmart® displays "Cartridge expired" because the cartridge is expired (28 days after first use).
- RebiSmart® displays the message "Cartridge empty" because the cartridge is empty or does not have enough medication for a full injection.
- You dropped RebiSmart®, the cartridge might be damaged and needs to be replaced.

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

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



2 doses left



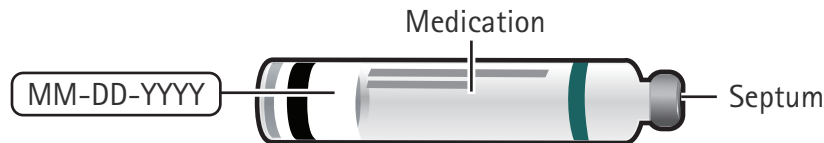
Cartridge is empty

### **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:

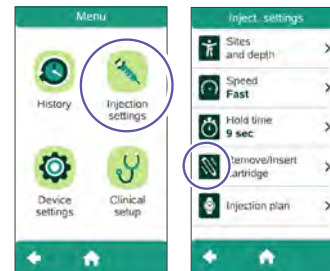
- Packaging and cartridge label have the medication and dosage of Rebif® (132 or 66 µg).
- Cartridge's expiration date has not passed.
- Cartridge is not cracked.
- Cartridge and medication correspond to the description in the Rebif® Patient Information Leaflet (PIL).






### 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 Rebif® PIL for detailed information.
- **DO NOT** touch the cartridge's septum to avoid risks of injection site reactions.

## 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.

## Section 4.3 Changing cartridge (continued)

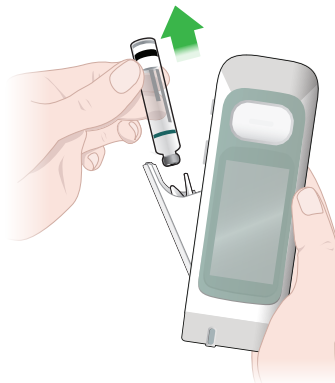
### 3 Open cartridge door



- 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.

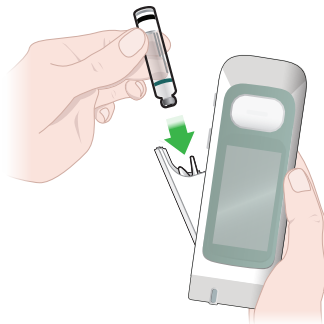
**⚠ WARNING: DO NOT** use RebiSmart® if a cartridge has broken inside the device. A broken cartridge and any remaining liquid may harm the user or damage the device.

## 5 Discard cartridge



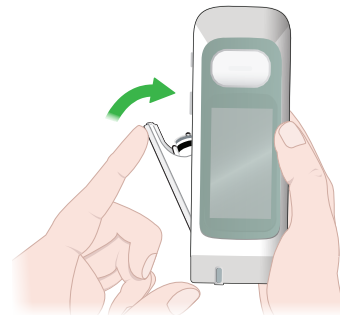
Discard the empty, expired or broken cartridge in a sharps container.

## 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.

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



## Section 4.4 Replacing device

The expiration date is printed on the device label.  
The device does not require any special maintenance.  
Starting 6 months before the expiration date,  
RebiSmart® will regularly present messages to  
remind you of the expiration date.

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



### CAUTION

- **DO NOT** use RebiSmart® if the expiration date has passed or 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 RebiSmart®, 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 RebiSmart® 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 Rebif® medication at the appropriate temperature according to the Rebif® Patient Information Leaflet, whether the cartridge is inserted in the device or not. Consider using a travel cooling bag that will keep within Rebif® cartridges and your device at the correct temperature.
- The device is safe to pass through X-ray airport security gates with the Rebif® 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.
- RebiSmart® will search for a cellular network to transmit data if you have turned this feature on when setting up RebiSmart®. First-time connection from another country might take longer.



## Section 5


# Settings



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



5.1 Menu overview	54
5.2 History	55
5.3 Injection settings	57
5.4 Device settings	62
5.5 Battery status	68

## Reminders and tips to change RebiSmart® settings

 **CAUTION: DO NOT** change the injection settings on RebiSmart® 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 your mobile application includes only injection data and technical data related to your RebiSmart® 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
- Injection site



### Device settings

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



### Injection settings

- Sites and depth
- Speed
- Hold time
- Remove/Insert cartridge
- Injection plan



### 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 four ways to view your injection history: Calendar, List, Clinical summary, and Injection site.

To access the History menu:

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



History

Press to Exit



### Clinical summary

Clinical summary	
Last 6 months	
Planned (injections)	Actual (Injections)
72	68 (95%)
Last 12 months	
Planned (injections)	Actual (injections)
144	136

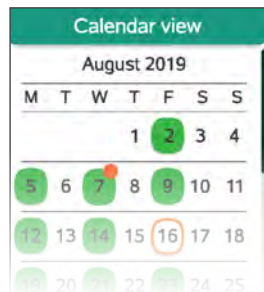
The clinical summary is for your doctor or nurse to review. It shows your dosing patterns over multiple months, which your doctor or nurse can use to give you further guidance.



## Section 5.2 History (continued)



### Calendar view

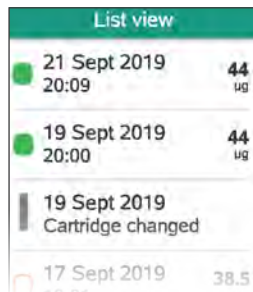


Swipe  
scroll bar

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



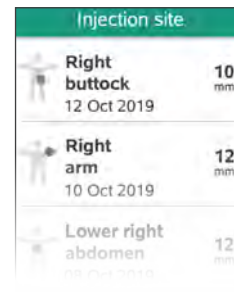
### Injection List view



List view shows a chronological list of events.



### Injection site



Injection site shows your injection site history over multiple months.



### Calendar and List icons



Full dose delivered



Cartridge changed



Interrupted injection





Orange dot: Notable event  
(e.g., more than one full dose  
in one day)

## Section 5.3 Injection settings

You can control some aspects of your RebiF® injection with RebiSmart® by adjusting the injection settings.

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

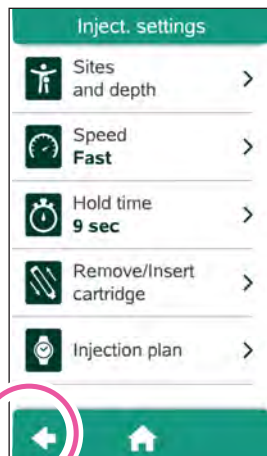
To access the Injection settings menu:

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

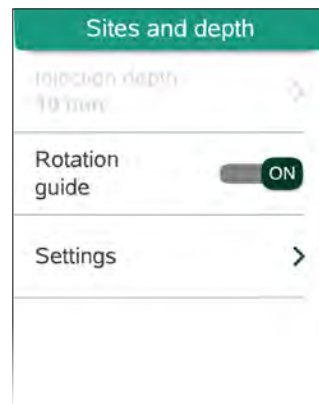


Injection  
settings



Press to Exit



### Sites and depth

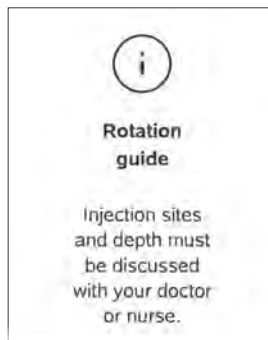


"Site" is the location of the injection and "Depth" is how far the needle goes into the skin when injecting.

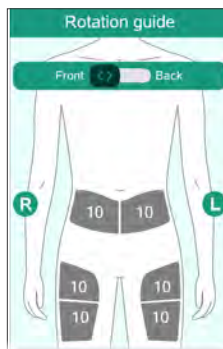
- Select  Sites and depth.
- Press  to turn on rotation guide.
- Press Settings.



## Section 5.3 Injection settings (continued)



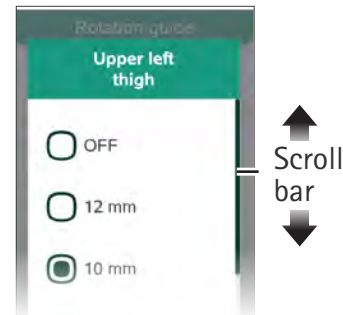
Press  to continue to rotation guide setup.




By default, all injection sites are selected and have an injection depth of 10 mm.

You can switch between Front and Back using the button at the top of the screen.

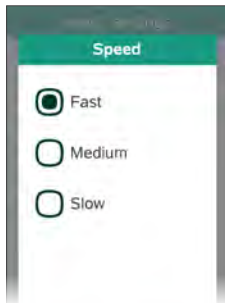
**i NOTE:** Remove the sites you don't want to inject by clicking on it. At least 4 sites should be kept selected.





- Select the appropriate depth for the injection site or select OFF if you do not want that site to be used.
- Press  to confirm.



## Speed

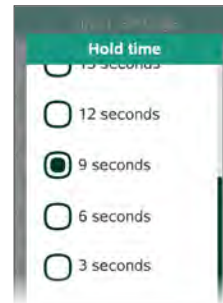


Speed is rate at which medication is delivered during the injection. It can be set to one of three values: Slow, Medium and Fast.



- 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 – 21 seconds, default is 6 seconds).

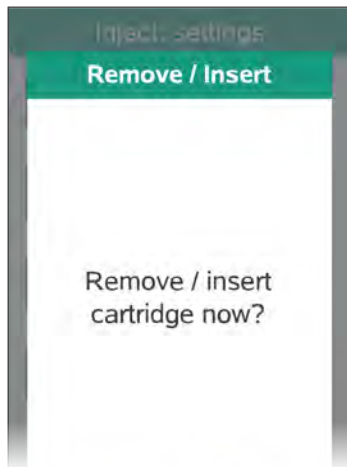
- Select  Hold time.
- Select the time you wish to set.
- Press  to confirm.





## Section 5.3 Injection settings (continued)



### Remove/Insert cartridge

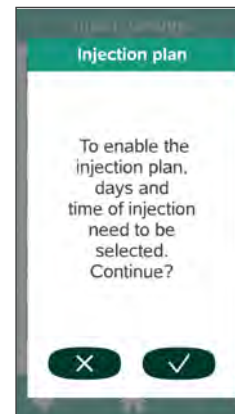


Unlock cartridge door to remove the cartridge:



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



### Injection plan



Set up a schedule on which days and times you will inject. After setting up this injection plan, RebiSmart® will display the time until the next injection.


- Select  Injection plan.
- Press  to set up injection plan.
- Press Set days.

Set days

Select 3 non-consecutive days

M T W T F S S


Legend:

- d. Select three days on which you will inject.
- e. Press  to continue.

**i NOTE:** Selecting consecutive days is not allowed. A minimum of 48 hours is recommended between each injection.

Set time

05 12  
06 13  
07 14  
08 15  
09 16  
10 17  
11 18  
12 19  
13 20



- f. Select the time for the injections.
- g. Press  to continue.



## Section 5.4 Device settings

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

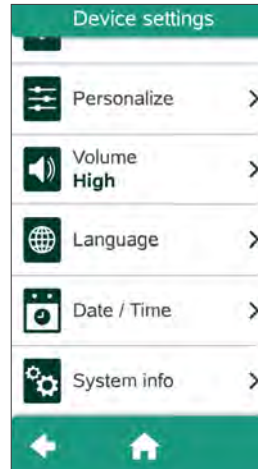
To access the Device settings menu:

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



Device settings

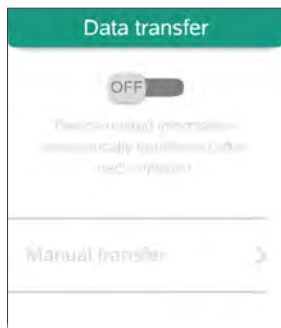
Press to Exit



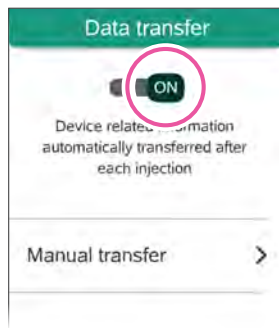




## Data transfer

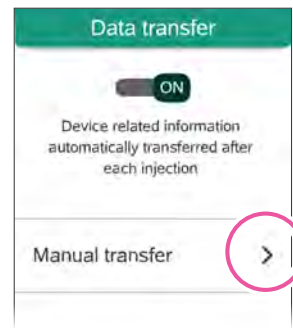


You can set RebiSmart® to transmit your injection history to a mobile application accessible by you.




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 mobile application is not available in all countries. Contact your doctor or nurse to get more information.



## Section 5.4 Device settings (continued)

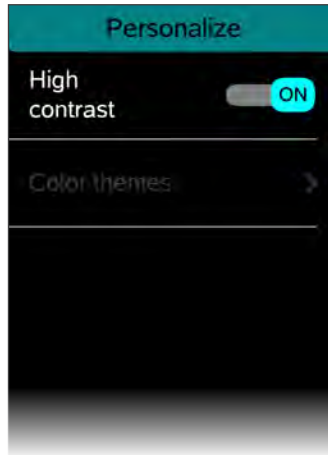


### Personalize




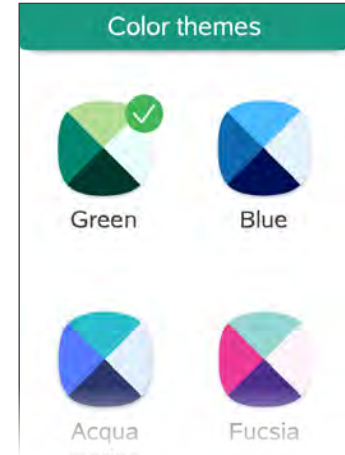
"Personalize" provides two ways to modify the way screens look.

Select  Personalize to access options.



### High contrast

To turn on high contrast, press  button to ON.



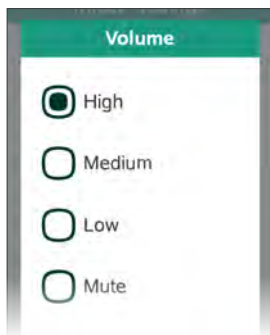
### Color themes

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 RebiSmart®. To change:

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



## Section 5.4 Device settings (continued)




### Date / Time

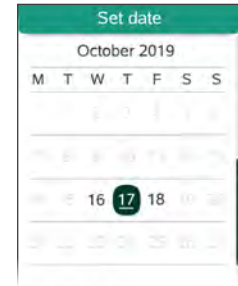


"Date / Time" provides the option to change the date, time and the formatting of those.


Select  Date / Time to access options.

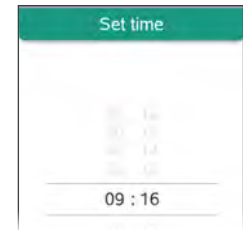
When you select "Set date":

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




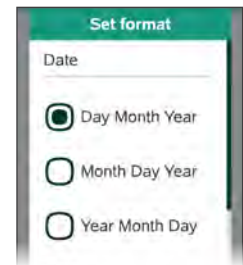
When you select "Set time":

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



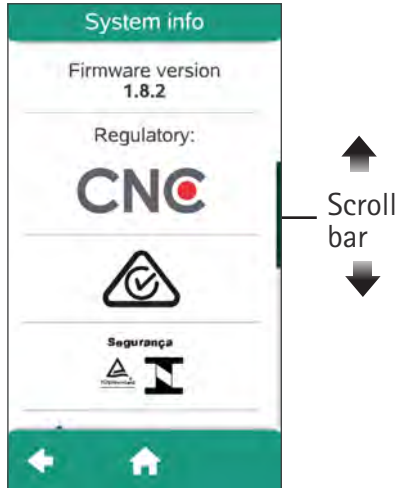
When you select time and date "Set format":

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





## System info



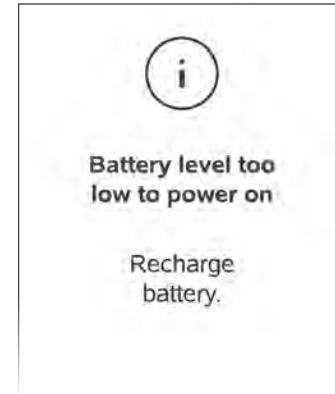
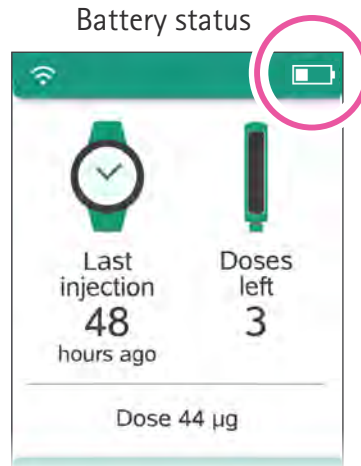
"System info" displays compliance to local regulations. See Section 8.2 for the symbols chart.



## 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 RebiSmart®, frequently asked questions, and what to do if you have dropped the device, or interrupted an injection.

6.1 Interrupted injection	72
6.2 Dropped device	74
6.3 Warning and information messages	76
6.4 Frequently asked questions	84



## Reminders and tips when troubleshooting your RebiSmart®

### CAUTION

- **DO NOT** use RebiSmart® if it is not working properly.
- **DO NOT** modify or attempt to repair RebiSmart®, 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

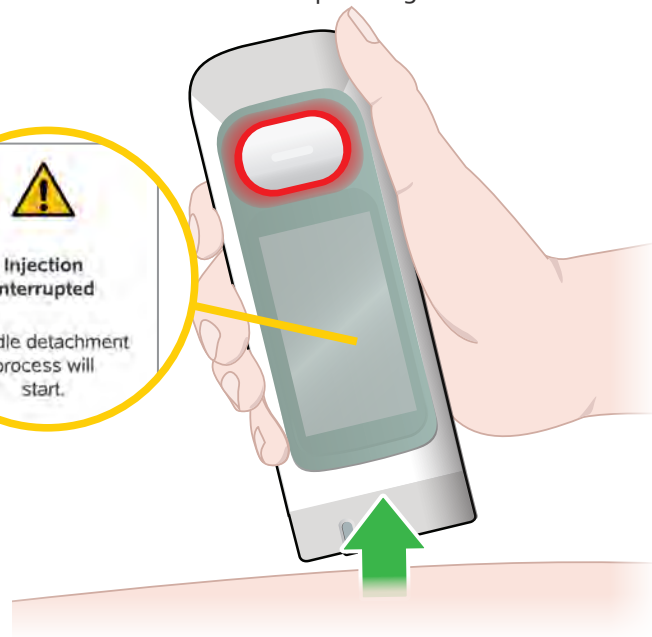
If RebiSmart® is lifted off of your skin during an injection, RebiSmart® will stop the medication flow and retract the needle. This is called an "interrupted injection" and means you did not receive your complete dose.

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

You can complete your dose by delivering a second injection of the remaining dose. You need to use a new needle to deliver the second injection. Follow the on-screen instructions and steps on the next page.



Red interruption light




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

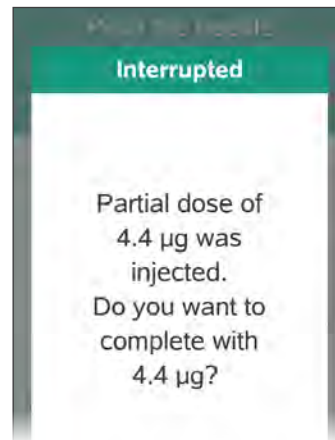
- If you cancel the second partial dose injection, the next injection will be a full dose.
- After two consecutively interrupted injections, the device will return back to the home screen and will not deliver the remaining dose. The next injection will deliver a complete full dose.

## 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.

**i NOTE:** Keep RebiSmart® steady and in contact with your skin for the entire injection. Remove RebiSmart® from the skin after RebiSmart® 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

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

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 RebiSmart® 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 RebiSmart® if it is not working properly.
- **DO NOT** modify or attempt to repair RebiSmart®, 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:

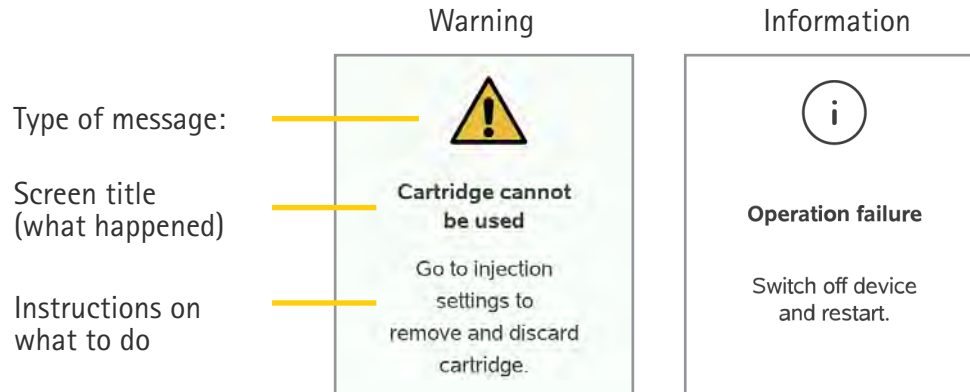
- Cartridge is not cracked or damage.
- Medication is clear and **does not** contain particles. Inspect according to the Rebif® Patient Information Leaflet.

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.

RebiSmart® 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:



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

Type	Screen title	What happened and what to do
	<b>Battery removed during operation</b>	The battery has been removed while using the device. This action may cause harm to the device.
	<b>Cartridge cannot be used</b>	Cartridge cannot be used with device. Go to injection settings to remove and discard the cartridge. Replace it with a new cartridge.
	<b>Cartridge expired</b>	<p>This screen will appear if:</p> <ul style="list-style-type: none"><li>• The cartridge has been in use for 28 days and is now expired. Do not inject. Go to injection settings to insert new cartridge.</li></ul> <p>OR</p> <ul style="list-style-type: none"><li>• 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.</li></ul>



## Section 6.3 Warning and information messages (continued)



### **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.



### **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.

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**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 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.

**Demonstration cartridge detected**

The cartridge inserted is not intended for human use. Remove demonstration cartridge and replace with a new cartridge.

## Section 6.3 Warning and information messages (continued)

	<b>Device error</b>	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.
	<b>Device expired</b>	The device has expired and cannot be used anymore. Contact your doctor or nurse to replace the device.
	<b>Device failure</b>	The device has malfunctioned and cannot be used anymore. Contact your doctor or nurse to replace the device.
	<b>Device settings lost</b>	All settings have been lost. Device will start the first time set up wizard. Contact your doctor or nurse to check the settings.
	<b>Device temperature out of range</b>	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 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 48 hours ago. A 48 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.



## Section 6.3 Warning and information messages (continued)

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### **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.



### **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.

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	<b>Needle detachment failure</b>	You inserted a needle cap that was not empty. Discard this needle cap and insert an empty needle cap to remove needle.
	<b>Needle expired due to inactivity</b>	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.
	<b>No valid cartridge detected</b>	No cartridge is inside the device, or the device detected an invalid or incompatible cartridge. Maybe the new cartridge concentration is not compatible with current dose setting. Go to injection settings to insert a valid cartridge or consult your doctor or nurse to check your dose setting.
	<b>Service mode</b>	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.
	<b>Unexpected needle detachment</b>	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.
	<b>Wrong cartridge for selected dose</b>	The dose selected in the clinical setup cannot be used with this cartridge. Contact your doctor or nurse to correct clinical setup or to receive the correct cartridge.







## Section 6.4 Frequently asked questions

### Using RebiSmart®

#### What if I cannot turn my RebiSmart® on?

Make sure that when you turn on RebiSmart®, 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, when the cartridge door is unlocked. 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 RebiSmart® from my skin during an injection?

If you remove RebiSmart® from your skin during an injection (while the injection button light is flashing white), the injection will stop, the needle will retract and RebiSmart® 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. RebiSmart® 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. RebiSmart® allows you to change settings for injection site, injection depth, speed and hold time. 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 Rebif® on my skin after the injection?

If you notice a drop of Rebif® on your skin when you remove RebiSmart®, 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?

No, the only needle compatible with RebiSmart® is Serofine® needle 29G.





### What if I cannot detach a needle from my RebiSmart®?

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 RebiSmart®?

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

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

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

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

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

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



## Section 6.4 Frequently asked questions (continued)

### Settings

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

Consult your doctor or nurse to update your dose setting in RebiSmart®. Once your new prescribed dose is entered, RebiSmart® will automatically detect the cartridge type and adjust accordingly. You may need to insert a cartridge with different concentration: go to injection settings to remove cartridge, consult your doctor or nurse to update the dose in clinical setup, finally go to injection settings to insert new cartridge.

#### **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.

RebiSmart® 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 digital offering may also be available (depending on your location) whereby data from your device (including injection history) can be transmitted through a patient mobile application. This additional service however requires your prior and express consent. 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, you can view and track your injection history in the mobile application.

You may reach out to your doctor, nurse or health professional for more information on this service, including whether it is available in your location.



## Section 6.4 Frequently asked questions (continued)

### Storage and maintenance

#### **How should I store the cartridge?**

You should refer to the Rebi® Patient Information Leaflet.

#### **Should I remove the battery if I keep RebiSmart® in the refrigerator?**

There is no need to remove the battery if you keep RebiSmart® 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 Rebi® 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 RebiSmart® 6 months ahead of its expiry date.

