Travel

How do I store my device while traveling?

You can travel with RebiSmart®. It is recommended to store RebiSmart® in the storage box when traveling. The device is safe to pass through X-ray airport security gates with the Rebif® medication inserted. Please 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.

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

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

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Section 7

Additional information for doctors or nurses

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

⚠ CAUTION

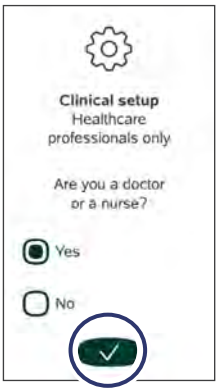
- This section is for doctors and nurses only. As a patient you should not use these instructions.
- Contact your doctor or nurse if you would like to receive information about this section.

Section 7.1 Complete first time setup wizard

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

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

1 Confirm you are a nurse or doctor



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

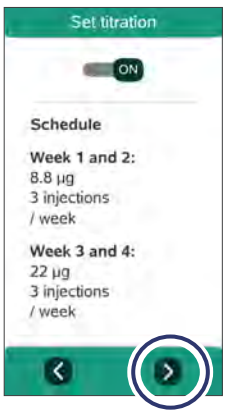
2 Create PIN

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

3 Set dose

- Press checkbox of the prescribed dose.
- Press › arrow to continue.

4 Set titration



- Press button to ON to switch on titration.
- Press › arrow to continue.

5 Confirm settings

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

6 Device data transfer

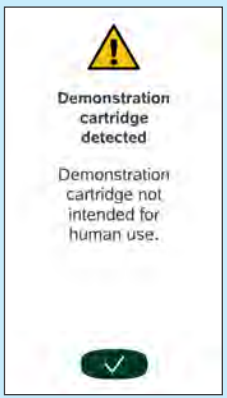
- Press "Yes" checkbox to turn data transfer on. Or, press "No".
- Press ✓ to continue.

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

7 Complete

- Press ✓ to complete the device setup.

NOTE



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

Demo injections can only be done using a demo cartridge.

Section 7.2 Clinical setup

Use the clinical setup screens to adjust the treatment settings, such as dose and titration. In the clinical setup you can also change or turn the PIN code on/off.

To access the Clinical setup menu:

a. Open menu from the home screen.

b. Select Clinical setup.

c. Enter 4-digit PIN, if applicable.

Clinical setup

Press to Exit

NOTE: Before you insert a cartridge with different concentration: go to injection settings to remove cartridge, then update the dose in clinical setup, finally go to injection settings to insert new cartridge.

NOTE

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

After making an adjustment, select ✓ to confirm each new setting. Note that titration and dose reduction cannot be turned ON at the same time.

Dose

The dose defines how much medication is administered during an injection. Press to select a dose.

Dose reduction

This feature automatically reduces doses to minimise side effects of medication. When ON, dose reduction will last for 36 injections, then it will automatically shut off. Dose reduction requires a password - so the PIN code must be set to ON. Dose reduction can only be used with a 132 µg (44 µg/0.5 mL) cartridge.

Titration

Titration is the gradual increase of medication over time. When ON, RebiSmart® will automatically adjust doses. Titration can only be used with a 132 µg (44 µg/0.5 mL) cartridge.

PIN code

Press button to ON to add a PIN code that will prevent patient access to clinical setup. To change PIN code select "Change PIN", enter current pin code, then re-enter the new pin code before confirming.

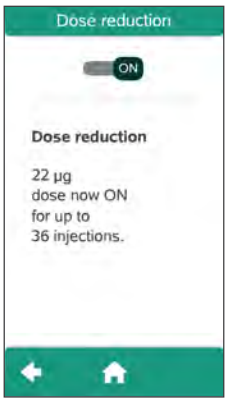
NOTE: Titration and dose reduction cannot be turned ON at the same time.

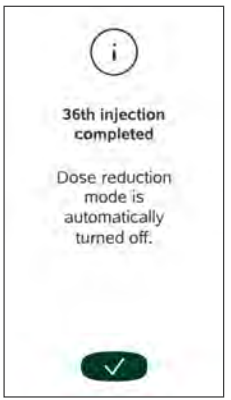
Dose

The dose defines how much medication is administered during an injection.

- Press to select a dose.
- Select ✓ to confirm new setting.

Dose reduction





Press button to ON

When Dose reduction is turned ON, RebiSmart® will administer a 50% dose of Rebif® up to 36 times. Dose reduction can only be used with Rebif® 132 µg (44 µg/0.5 mL) cartridge.

After 36 doses have been administered, the feature is automatically turned OFF. Dose reduction can be used only 2 times for up to 72 injections.

Titration

The titration can only be used with a 132µg (44µg/0.5mL) cartridge. The titration period lasts 4 weeks and during this time 12 injections will be administered using RebiSmart®. The first six injections will deliver a dose of 8.8µg and the next six will be 22µg.

Press button to ON

PIN code

NOTE: If dose reduction is ON, you cannot turn the PIN code OFF.

To add a PIN code that will prevent patient access to clinical setup:

Press button to ON

To change PIN code select "Change PIN", enter current PIN code, then re-enter the new PIN code before confirming.

Section 8

Technical specifications and appendix

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

Section 8.1 Technical data

Device specifications

Brand/Product name	RebiSmart®
Model	3.0
Weight	270 g
Dimensions	H: 155 mm x W: 55 mm x T: 42 mm
Battery charger	Ktec KSA-7A-050150D5, 100-240 V, ~50/60Hz, 0.3A
Power supply	Rechargeable Battery, Li-ion Polymer, Capacity: 3.7V / 1400 mAh, Input: 5VDC / 0.8A
Battery life	Approximatively 5 years, covering >500 discharge cycles
Medical device classification	MDR 2017/745/EU Class IIa
Device's life time	5 years from manufacturing date, refer to device's labelling
Cartridge	EMD Serono Rebif® (interferon beta-1a)
Maximum injection volume	0.8 mL
Dose accuracy	+/- 15%
Needles	Serofine® needle 29G × 1/2" (thickness: 0.33 mm × height: 12 mm)
Cellular module	SARA-R412M-02B
Radio access technology	LTE Cat M1, LTE Cat NB1, 2G GPRS/EGPRS

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

Essential performances

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

Declaration of conformity

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

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

Section 8.2 Explanation of symbols

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

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

Power on/off

Manufacturer. Indicates the device manufacturer. Reference number 5.1.1.

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

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

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

Direct current. Reference IEC 60417-5031

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

European Conformity marking

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

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

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

Section 8.2 Explanation of symbols (continued)

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

Class II equipment.
Reference IEC 60417-5172

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

IP 52

Protection against dust and dripping water when held in normal position

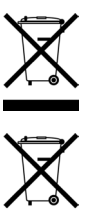
Medical device. Indicates the item is a medical device. Reference number 5.7.7.

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

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

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

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



Dispose of safely according to your local regulations.
Collection and treatment of electrical and electronic equipment*
This symbol indicates that this product should not be disposed with household waste. It has to be returned to a local authorized collection system. By following this procedure you will contribute to the protection of the environment and human health. The recycling of the materials will help to conserve natural resources.
* valid in the EU member states and in any countries with corresponding legislation.

Section 8.2 Explanation of symbols (continued)

Marking showing compliance to local regulations

RAMATEL	Argentina - Ramatel mark
	Australia - RCM mark
	Gulf Cooperation Council
sutel	Costa Rica - SUTEL mark
	Korea - KC mark
IFT	Mexico - IFT mark
	Taiwan - NCC mark
	Serbia - 3A mark
TRA	UAE - TRA mark
UK CA	UK - UKCA mark
FC	USA - FCC mark

See *"Section 5.4 Device settings"*.

Section 8.3 Electromagnetic specifications

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

⚠ WARNING

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

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

Section 8.3 Electromagnetic specifications (continued)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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

Electromagnetic Emissions

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

Electromagnetic Immunity

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

Section 8.3 Electromagnetic specifications (continued)

Immunity to proximity fields from RF wireless communications equipment

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

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

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

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

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