User Manual

ava™

User Manual

Ref: q-011957 v. 4.0, June 2016

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Immunity test	Test level	Compliance level / performance criterion	Electromagnetic environment - guidance
Conducted RF ETSI EN 301 489-1 ETSI EN 301 489-3 IEC 60601-1-2 IEC 61000-4-6	$10V_{rms}$ 150kHz - 80 MHz (AM, modulation depth 80%, sinusoidal audio signal of 1 kHz)	$10V_{rms}$ CT for transmitters, CR for receivers	None
Radiated RF ETSI EN 301 489-1 ETSI EN 301 489-3 IEC 60601-1-2 ISO 11608-1 ISO 11608-4 IEC 61000-4-3	10 V/m 26 MHz -2700 MHz (1 kHz, modulation depth 80%)	10 V/m CT for transmitters, CR for receivers	None

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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Chapter 1:

Important information about ava

This section contains important information you must be aware of before starting to use ava.

1

Important information

Make sure you read and understand these ava instructions.

Read these instructions for use before you start using ava to inject. However, only use ava to inject your medication after you, or someone you know, has received training from your healthcare provider.

ava must only be used in the way described in these instructions.

Always follow the warnings and cautions in the instructions or on the device itself.

ava is an electromechanical device and should be handled with care.

WARNING: ava is an injection device for delivering a fixed dose of CIMZIA. It is for use by one person only. **DO NOT** share the device or allow anyone else to inject themselves with it, as doing so may result in injury. **DO NOT** use ava if it does not appear to be working properly and **DO NOT** attempt to repair a faulty ava.

ava must only be used with pre-filled cassettes of CIMZIA as prescribed by your healthcare provider.

CIMZIA medication cassettes are single-use only and must be discarded in a biohazards (sharps) container immediately after use. **DO NOT** re-use a cassette.

Contact your healthcare provider when you need more CIMZIA medication cassettes.

Be sure to store the CIMZIA medication cassettes properly:

- Store CIMZIA medication cassettes in the refrigerator between 36ºF to 46ºF (2ºC to 8ºC).
- Keep this medication out of sight and reach of children.
- **DO NOT** freeze CIMZIA.
- Protect CIMZIA medication cassettes from light. Store CIMZIA medication cassettes in the carton they came in.
- The CIMZIA medication cassette contains a glass syringe. **DO NOT** drop or crush the cassette.

DO NOT use CIMZIA medication cassette if:

- Any name other than CIMZIA is on the carton and/or cassette label.
- The expiration date on each cassette or its outer carton has passed.
- The carton is torn or the tamper evident seal is missing or broken when you receive it.
- The cassette has been frozen or if it has been left in direct sunlight.
- The CIMZIA solution in the cassette is not clear to colorless to light yellow, if it looks cloudy, or if it has large or colored particles in it.
- The red medication level indicator is not right at the top of the cassette.

DO NOT shake the cassette before use.

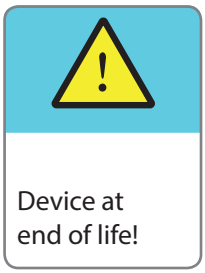
Keep your ava and CIMZIA medication cassettes out of the sight and reach of children.

Be sure to store ava properly:

- Store ava in its closed storage case to limit exposure to dirt, dust, liquid and other substances.
- Keep ava at room temperature between 68ºF to 77ºF (20ºC to 25ºC).
- **DO NOT** freeze ava or place it in the refrigerator.

WARNING: Do not operate ava near strong electromagnetic sources like an x-ray machine in a medical facility or a security machine at an airport. However, using your ava near common-household electronic devices should not be a problem.

The expected lifetime for ava under normal use is up to 3 years, after which it must be replaced. When it is nearing its end of life, ava will automatically show the message **'Device is nearing end of life!'**. As soon as you see this message, contact your healthcare provider or local helpline for a replacement device.



After another 10 injections when the message above first appears, ava will stop working and display the warning **'Device at end of life!'**.

ava contains no harmful or toxic components. The device does not contain any personal information.

However, ava is considered biohazardous waste and must not be disposed of in household waste.

Dispose of your used ava according to your community guidelines, observing all Federal, State and local regulations or contact the helpline for information on safe disposal of ava.

WARNING: ava should be handled with care. **DO NOT** drop. If ava is dropped, check that no broken parts are visible. Turn ava on. If you see an **'Error! Do not use. Helpline code'** warning message - **DO NOT** use it. Make a note of the four digit Helpline Code number and contact your local helpline for support.

CAUTION: Avoid spilling liquid on your ava. Never rinse or put ava under water. If ava has been exposed to liquid, wipe it with a clean, dry cloth, turn it on and check for error messages.

ava set up

Your new ava device needs to be set up by your healthcare provider. Please make sure to schedule an appointment with your healthcare provider to have your medication dose set up in ava. You should also receive training on the correct use at the same time.

DO NOT forget to bring ava to your appointment.

You can practice using ava even before your healthcare provider has set up ava for you. The training cassette can be used at any time before or after the medication dose has been set up.

Additional important information

The use of ava is not approved or recommended for the following circumstances:

- users less than 18 years of age
- users who are legally blind
- users who are unable to self-inject as determined by a health care provider

Your healthcare provider will determine if you are able to use ava. Ask your health care provider if you are not sure.

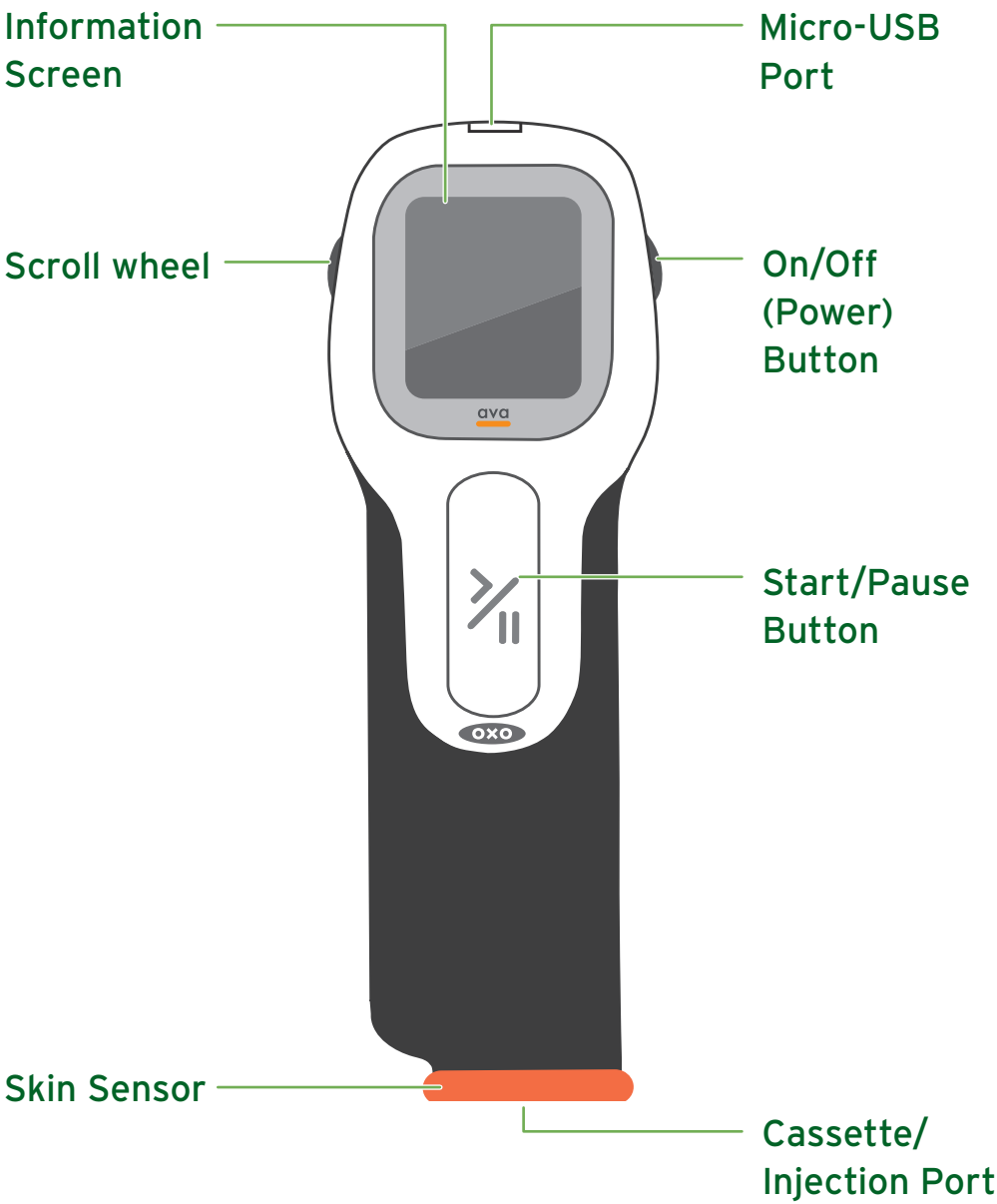
Chapter 2:
Getting to know ava

This section is a guide to ava and CIMZIA medication cassettes, showing the controls and the names of the main parts. You will also find information on how to take care of your ava and CIMZIA medication cassettes.

2

ava

Use this illustration to identify the controls and the names of ava's parts.



Information screen

ava's screen will display step-by-step instructions and any advice or warning messages.

Scroll wheel

This wheel lets you adjust the speed of your injection.

Skin sensor

The skin sensor detects when the injection port is fully in contact with your skin.

Micro-USB Port

This is where you connect the battery charger or your computer to view your injection log.

On/Off (Power) Button

Use this button to turn ava on or off.

Start/Pause button

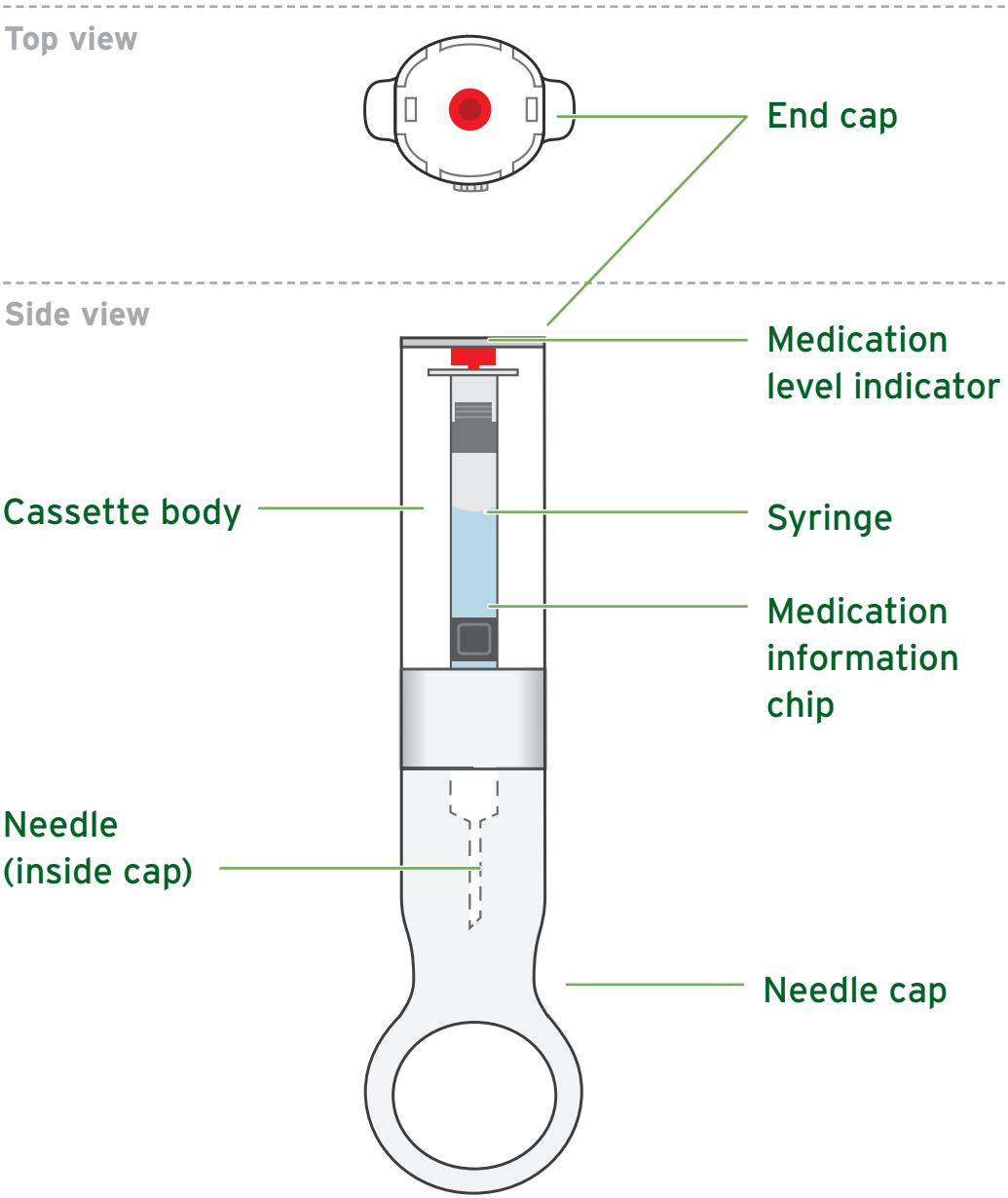
Pressing this button will begin administering an injection. It can also be used to pause and re-start the delivery of CIMZIA during an injection.

Cassette/Injection port

This is where the CIMZIA, or training cassette, is loaded and where the needle comes out during a CIMZIA injection.

CIMZIA medication cassette

This illustration shows a CIMZIA medication cassette for use with ava.



Cassette body

This plastic cassette body contains the glass syringe of CIMZIA.

Needle (inside cap)

The single-use needle is safely covered by the needle cap until you are ready to inject.

Medication level indicator

This red plastic indicator enables you to see the level of CIMZIA in a cassette. When the syringe is full the indicator is at the top of the syringe. When the syringe is empty the indicator is at the bottom of the syringe.

Medication information chip

This microchip enables ava to identify the type of cassette and check other information about it.

Needle cap

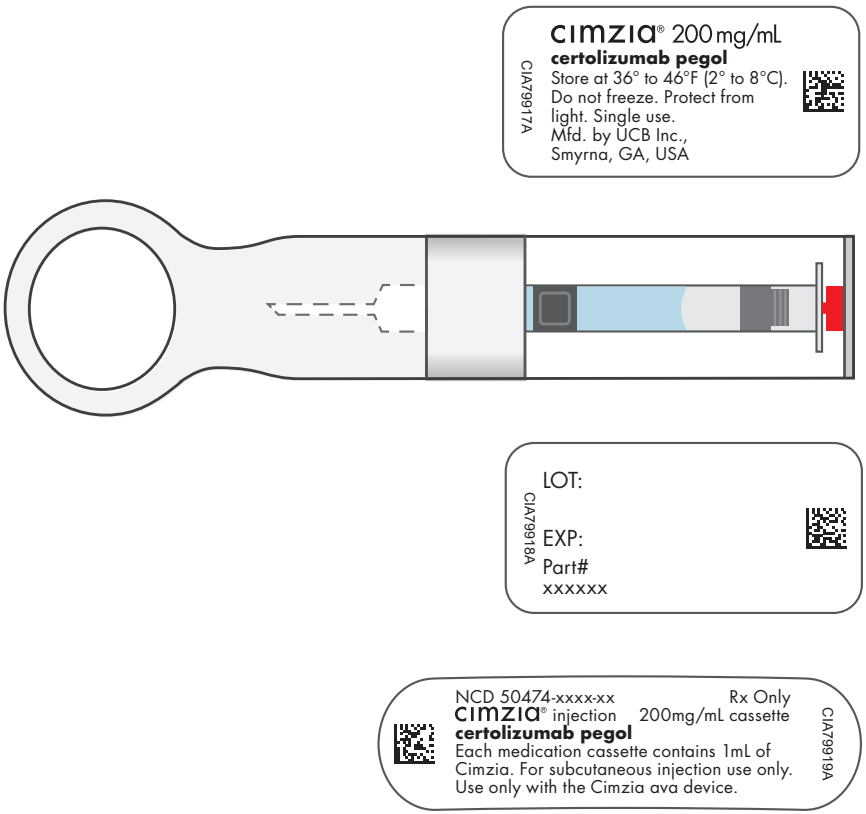
This part covers the needle whenever it is not inside ava ready for an injection.

Keep the needle cap to remove the cassette after an injection.

ava's medication dosing

ava delivers your medication from CIMZIA medication cassettes as shown below.

This illustration also shows the labels you will see on your CIMZIA medication cassettes.



ava can only be used with CIMZIA medication cassettes. However, before ava accepts CIMZIA medication cassettes it must be set up by your healthcare provider according to your prescribed dose of CIMZIA. This is indicated by the following screen.

If you have not done so already, take an appointment with your healthcare provider to have your new ava set up for you. Remember to bring ava to your appointment.

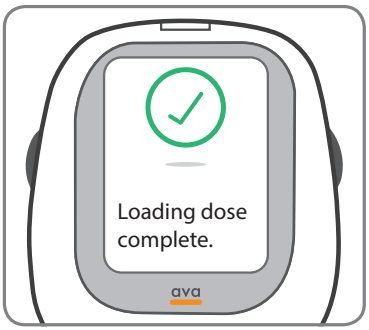
In the meantime, you can practice using ava with the training cassette that is provided in your ava storage case. See Chapter 3 for more information.

Your healthcare provider will set up ava according to your prescription.

If your healthcare provider prescribes the loading doses, ava is programmed to deliver your loading dose injections at weeks 0, 2 and 4 and then automatically switches to the maintenance dosing regimen which has been selected by your healthcare provider for you.

The loading dose regimen consists of two injections given every 2 weeks at the start of your CIMZIA treatment (week 0) and then at week 2 and the final loading dose injections are given at week 4.

Once the last injection of your loading dose has been delivered at week 4, ava indicates this by displaying the message **'Loading dose complete.'**.



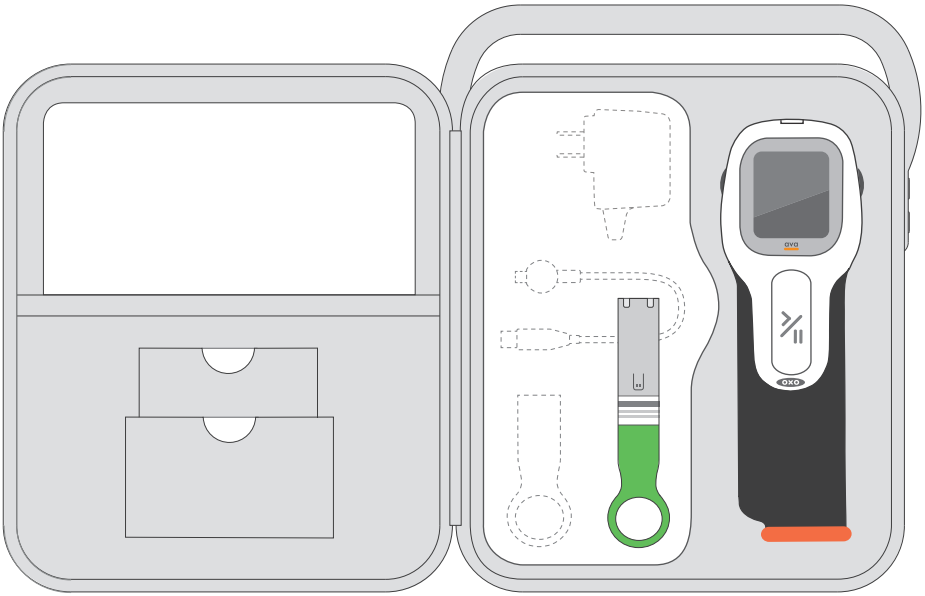
This message will be followed by either **'You are on maintenance dose 1 inj. every 2 weeks.'** or **'You are on maintenance dose 2 inj. every 4 weeks.'** depending on which maintenance dose has been selected for you.

Changing your CIMZIA dosing

In case your healthcare provider needs to change your dose, ava will need to be set up again. Please make sure you bring ava to your next appointment where your healthcare provider will set up ava for your new medication dosing.

ava accessories

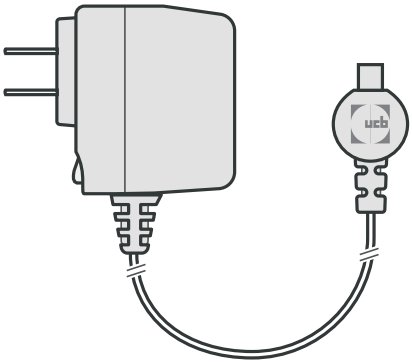
ava is supplied with a storage case containing additional items you will find useful. When not in use, keep ava and accessories securely inside the storage case to protect them from dust or accidental damage. Keep ava with all accessories out of the sight and reach of children. All of ava's accessories are designed for the life of the product.



Storage Case

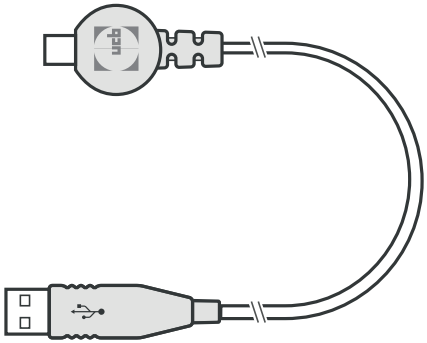
The storage case has an internal compartment which is covered by a lid. To open the lid, slide a finger under the small lever and lift. The charger, USB cable and spare needle caps are placed under this internal lid.

The Storage Case contains



An electrical battery charger

Charge ava only with this battery charger. When charging ava make sure to keep the cable out of reach of children and keep it secure to avoid the risk of tripping over it.

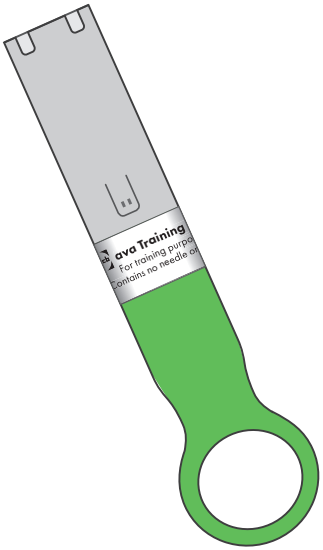


A USB cable

Use this USB cable to connect ava to your computer to view your injection log. When viewing the injection log make sure to keep the cable out of reach of children and keep it secure to avoid the risk of tripping over it.

ava welcome booklet

A booklet introducing you to ava.



A training cassette

Use this training cassette to help you practice injections with ava. The training cassette is reuseable and does not contain a needle or medication. It can be used at any time and as often as you like, even before ava has been set up for your medication dose.

CAUTION: Never replace the training cassette by a CIMZIA medication cassette! Your medication cassettes must be stored between 36°F to 46°F (2°C - 8°C) and must never be transported inside of the storage case.

Two spare needle caps

These are extra caps to remove used cassettes from ava in case you dispose of the needle cap from the medication cassette.

The helpline support number is 1-800-xxx-xxxx.

ava operating environment

When operating ava make sure you observe the following environmental requirements.

Operating temperature	41°F to 104°F (5°C to 40°C)
Humidity	15 – 90% relative humidity, non-condensing
Atmospheric Pressure	700 hPa to 1060 hPa

It is recommended to avoid using ava in direct sunlight as the display may be more difficult to read.

WARNING: This medical equipment is not intended for use in oxygen-rich environments.

Storing ava

When you are not using ava or you are travelling, it is recommended that you store it, together with the accessories, inside the storage case. This will help prevent ava from being exposed to dust and dirt and getting damaged. Use the handle to carry the storage case.

Be sure to store ava properly:

- Store ava in its closed storage case to limit exposure to dirt, dust, liquid and other substances.
- Keep ava at room temperature between 68°F to 77°F (20°C to 25°C).
- **DO NOT** freeze ava or place it in the refrigerator.

Cleaning ava

If needed, you may clean the exterior surface of ava with a solution of mild soap and water using a damp cloth. You may also clean it with a commercially available, alcohol based, colorless disinfectant.

CAUTION: Do not use a scouring powder or an abrasive sponge as it will damage the surface.

DO NOT attempt to clean the inside of the cassette port.

DO NOT insert your finger or any objects other than a cassette into the cassette port.

DO NOT clean ava while there is a cassette inserted into the cassette port.

CAUTION: Avoid spilling liquid on your ava. Never rinse or put ava under water. If ava has been exposed to liquid, wipe it with a clean, dry cloth, turn it on and check for error messages.

The helpline support Number is 1800-xxx-xxx.

Battery saving mode

If ava is inactive for 60 seconds, the screen will dim automatically to preserve battery. Pressing any button will restore the normal screen brightness and you can continue the procedure.

If left inactive for 3 minutes, ava will automatically turn off, unless you have not completed your injection. You will need to re-start any procedure from the beginning, if the device turns off.

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Chapter 3:

Learning to use ava

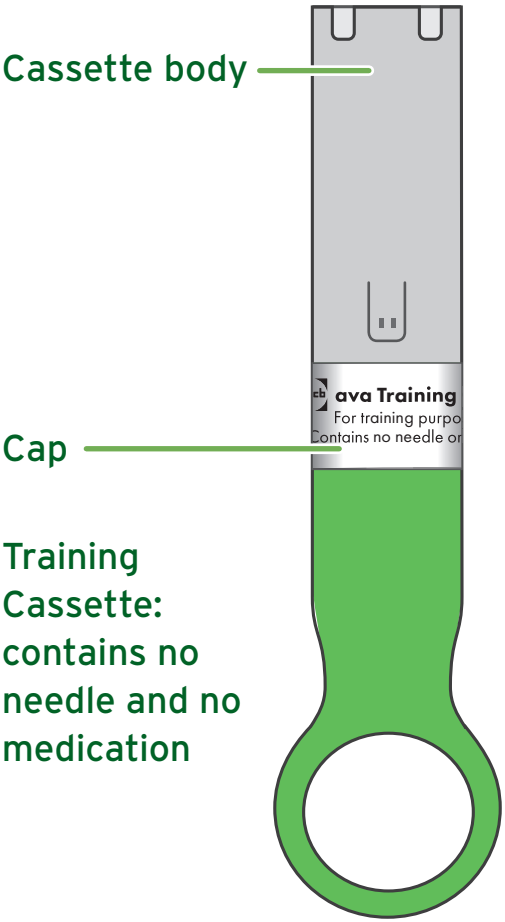
This section teaches you how to use ava with a training cassette that does not contain a needle or medication.

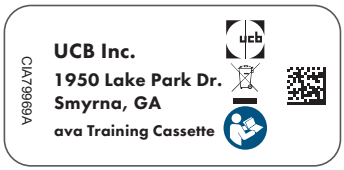
By using a **'training cassette'**, you can get used to operating ava.

This section does not cover the safety precautions you have to take when injecting CIMZIA. You can find that information in Chapter 4, **"Injecting CIMZIA with ava"**.

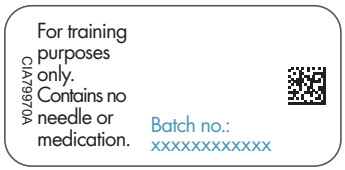
Training cassette

There is a training cassette included in your ava kit to help you practice injections. **The training cassette has no needle or medicine.** When it is time to inject your medicine, use the CIMZIA medication cassettes only, not the training cassette.

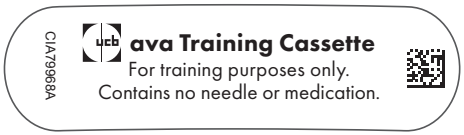




Body label 1



Body label 2



Cap label

NOTE: The training cassette is reuseable. **DO NOT** discard.

Your training cassette has

- no needle
- no medicine inside.

You can use it to practice injecting with ava. It can be used

- before your healthcare provider has set up your medication dose on ava
- after your medication dose has been set up
- as often as you would like
- Make sure you keep the training cassette. **DO NOT** throw it away.

NOTE: When using the training cassette you are practicing the injection steps without actually injecting any medication. The screens you will see on the display when using the training cassette are the same you will see when using your cassettes containing medication.

Using this training cassette will teach you how ava guides you through the injection process.

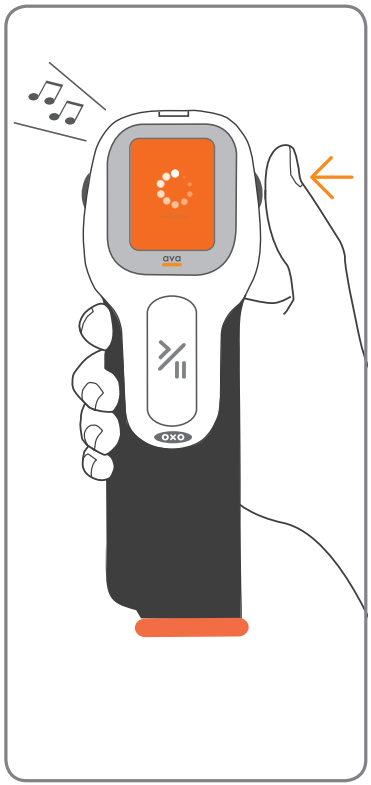
The training cassette cap is colored bright green and the cassette body is gray.

WARNING: See Chapter 4 for full injection instructions using a CIMZIA medication cassette.

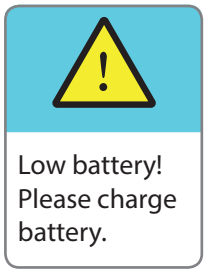
If you drop the training cassette, check the cassette to make sure there are no broken parts before inserting into ava.

Using the training cassette

1. Turn on ava by holding down the **'On/Off '** button for 1 second, or until the screen lights up and you hear a sound.



NOTE: ava should arrive with the battery charged, but, if ava does not turn on, or it displays the message **'Low battery. Please charge battery.'**, the battery will need charging before you start. See Chapter 5 for instructions on how to re-charge the battery.

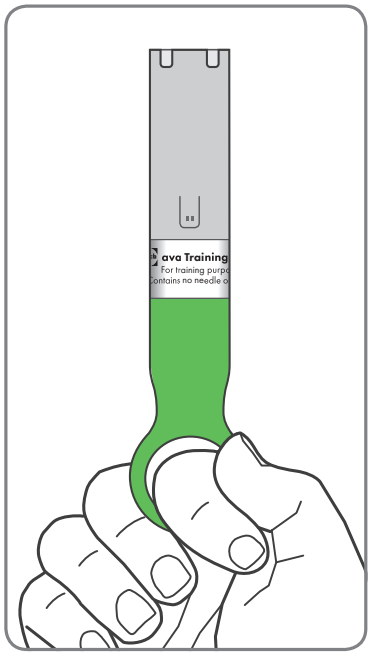


If your healthcare provider has not set up your device, you will see the following message.

You can still insert the training cassette to practice the injection process.

The message **'Inspect and then insert medication.'** will be displayed. If ava has been used before it will also briefly show your current dose and schedule. For example, if you are on the loading dose you will see the following messages.

2 Take the training cassette from the storage case. **DO NOT** try to remove the green cap

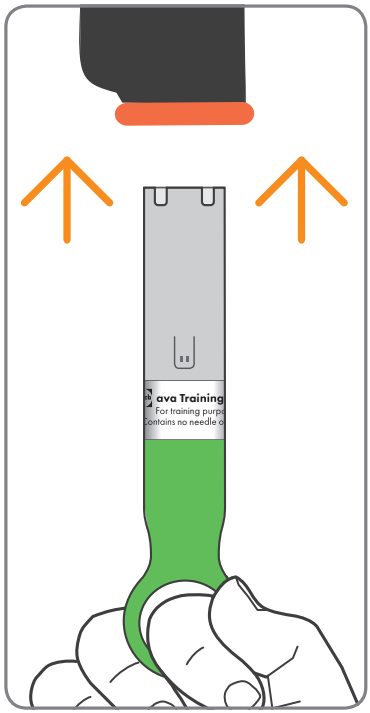


③ Push the flat end of the training cassette firmly into the cassette port of ava until you hear a click.

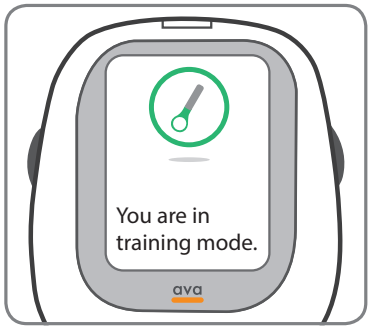
DO NOT twist the training cassette; it is shaped so that it can only be inserted the correct way.

DO NOT keep any other medication cassettes near ava while using the training cassette.

Let go of the cap.



ava will now check the training cassette and will display the message **'You are in training mode'**.



WARNING: If you do not see this message turn off ava by holding down the power button and remove the cassette. Make sure you are using a training cassette. Go back to Step 1 on page 30.

NOTE: You are now in training mode. ava will behave as if you had inserted a real medication cassette.

ava will now check the cassette and display **'Medication cassette accepted'**.

After a short pause, ava will automatically pull the cassette further in.

4 The currently selected injection speed is briefly displayed. You can change this setting using the **'scroll wheel'** on the side of ava to any of the four available settings.

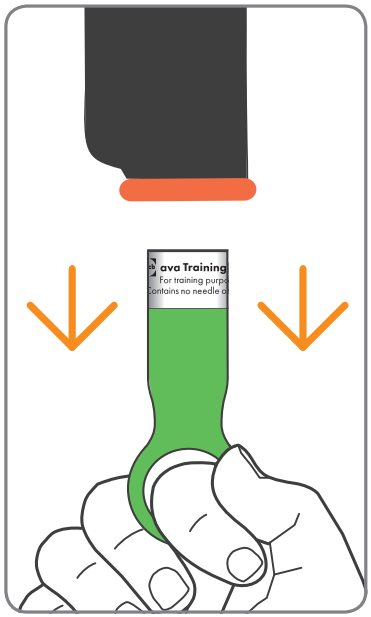
NOTE: The injection speed can only be changed when a cassette is inserted into the cassette/injection port. You can only adjust the injection speed before performing or when pausing your injection.

This setting controls the speed at which medication is injected. This setting does not change the speed of the needle being inserted, just the speed at which CIMZIA is injected.

You can practice changing the speed by rotating the scroll wheel on the side of the device. The screen will update to show the four available speeds. Rotate the wheel to see how the highlighting moves from one speed to another. If you want to change the speed, scroll until the highlight shows the new speed and leave it there for five seconds. The new speed has been set and will be kept for future injections, or until you choose to change it again.

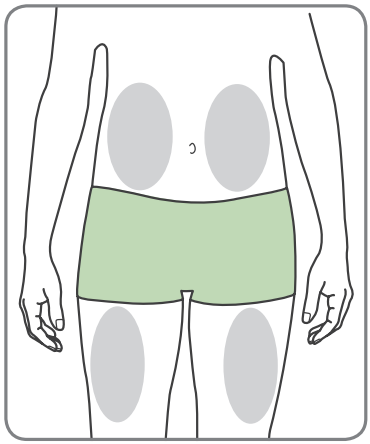
5 The **'Remove and save the needle cap.'** message is displayed.

6 When you are ready, remove the cap by pulling it firmly downwards.



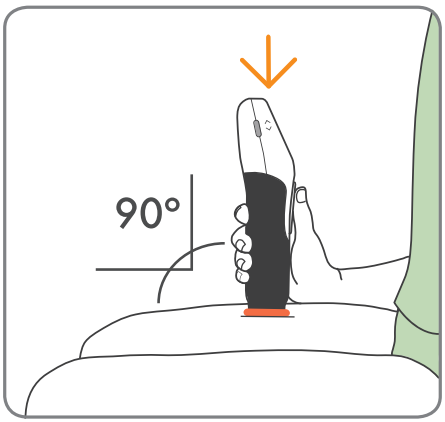
NOTE: KEEP THE CAP. This is important as you will need it to remove the Training cassette after the simulated injection. **DO NOT** throw the green cap into the sharps container.

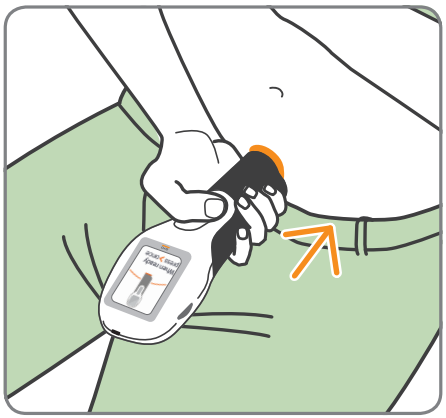
7 Choose a place on your stomach or your upper thighs (as shown in the diagram) to practice using ava. Your healthcare provider will help you identify suitable sites to inject.



Find a comfortable position sitting down to give your injection. Try to relax the muscles around the injection site as this will make injecting more comfortable.

Place the orange skin sensor against your skin at the cleaned injection site, with ava's screen facing you so you can see it. The **'Start/Pause'** button must be in a position where you can use it comfortably without moving your ava. These diagrams show how to position ava.

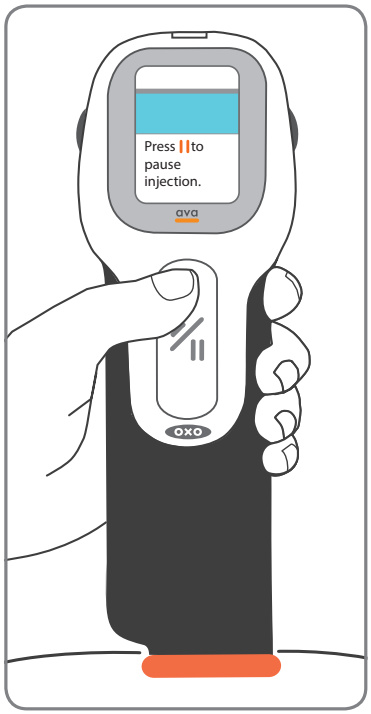




Position ava at a right angle on your skin to ensure the injection is done correctly

When ava senses contact with your skin the message **'When ready press > once'** is displayed.

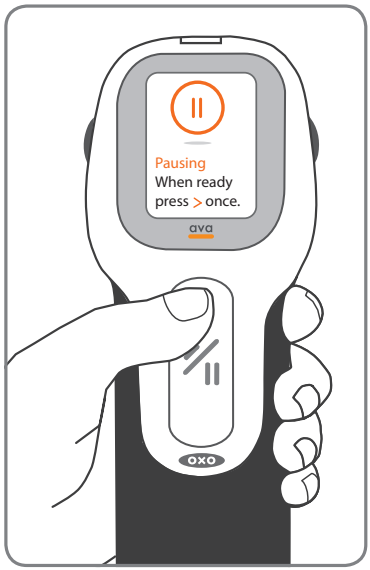
⑧ Press the **'Start/Pause'** button; you will hear the motor inside ava move the cassette and the simulated training injection will begin. The screen will display an indicator to show the progress of the injection. Hold ava firmly against your skin the entire time.



If you need to pause during an injection, for example to change the injection speed, press the **'Start/Pause'** button at any time, **DO NOT** remove ava from your skin. If this were a CIMZIA medication cassette , pressing the **'Start/Pause'** button would pause the flow of medication, but it would leave the needle in the skin.

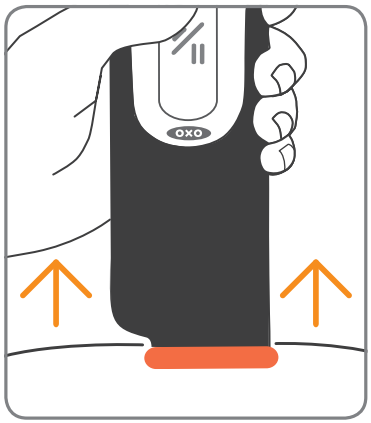
The message **'Pausing. When ready press > once'** will be displayed.

When you are ready to re-start, press the **'Start/Pause'** button again to complete the injection.

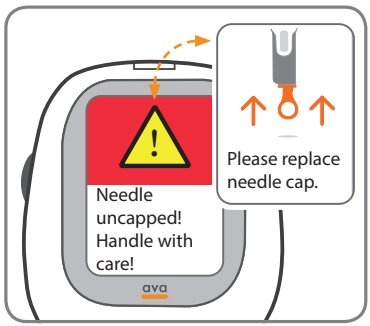


When the training injection is complete, the message **'Injection complete. Please remove from skin.'** will be shown on the screen.

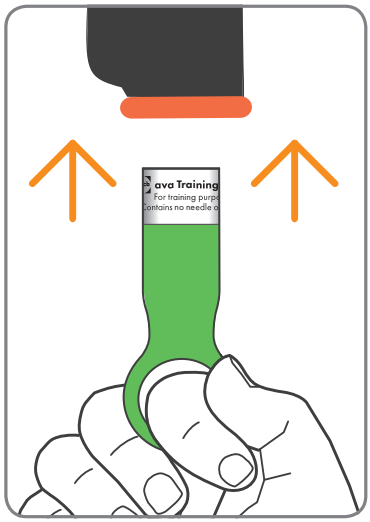
9 Remove ava from your skin.



The messages **'Needle uncapped! Handle with care!'** and **'Please replace needle cap.'** will be displayed until the cap is replaced.



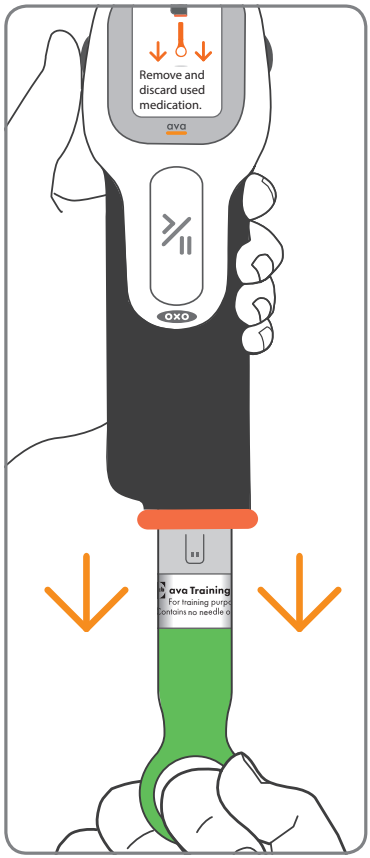
⑩ Insert the cap.



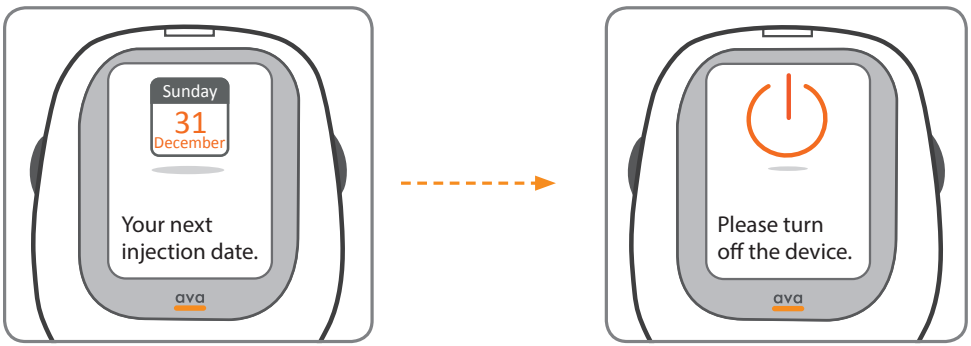
⑪ Let go of the cap while ava will release and eject the training cassette.

⑫ When the message **'Remove and discard used cassette.'** appears on the information screen, pull out the training cassette.

NOTE: Unlike medication cassettes, the training cassette can be re-used at any time.



ava will show your next injection date unless it is a new device which has never injected any medication, followed by a **'Please turn off the device.'**.



NOTE: Your next injection date will only be shown if you have already completed an injection with a medication cassette.

Press the **'On/Off'** power button until ava turns off.

You have successfully completed a training injection.

If you want to use the training cassette again for more practice, re-start ava and repeat the training.

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Chapter 4:

Injecting CIMZIA with ava

This section is a step-by-step guide to injecting CIMZIA with ava, from preparation to completion.

Read through the whole chapter before injecting CIMZIA with ava.

Preparing your CIMZIA medication cassette

NOTE: ava will have to be set up by your healthcare provider for your medication dosing before you can inject CIMZIA.

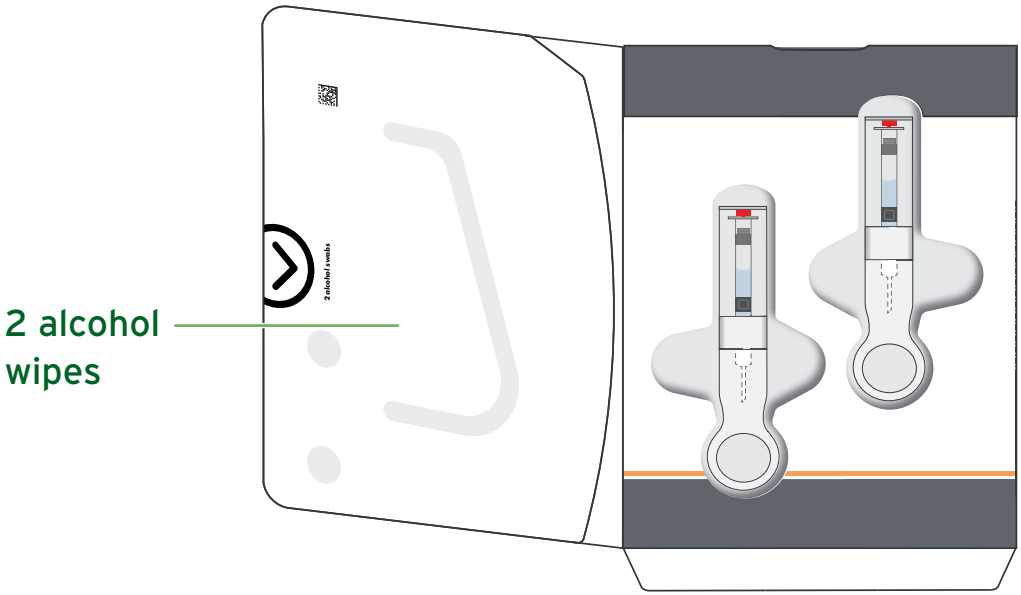
Make sure that you also have received injection training by your healthcare provider before injecting CIMZIA on your own.

The following are the supplies you will need to give your CIMZIA injection:

- ava device.
- 1 CIMZIA medication cassette. You may need 2 CIMZIA medication cassettes to give higher doses.
- 1 or 2 alcohol wipes (located in your CIMZIA pack).
- 1 or 2 clean cotton balls or gauze pads.
- 1 puncture-resistant sharps disposal container. See Step 19 **"Disposal of Used Medication Cassettes" on page 59.**

If you do not have everything you need, ask your healthcare provider.

CIMZIA comes in a carton containing 2 medication cassettes. Use a new medication cassette for each injection.



These instructions are for 1 injection only. Your healthcare provider will have prescribed a particular dose of CIMZIA for you. This may mean that you may need more than one injection at a time to deliver your prescribed dose. If required, ava will tell you if you need to perform a second injection and will guide you through this process.

Setting up for your CIMZIA injection

1. Take the carton containing CIMZIA medication cassettes out of the refrigerator. Check the expiration date on the medication cassette carton and label.

   If the expiration date has passed, do not use the cassette. Call your pharmacist for questions about the expiration date.

   DO NOT use if the tamper evident seal is missing or broken on the carton when you receive it. If this is the case, contact your pharmacist.

2. Remove the medication cassette from the box and let it warm to room temperature. This will take 30 to 45 minutes. **DO NOT** warm the medication cassette in any other way. If you are not using the second medication cassette, put the carton containing the remaining medication cassette back in the refrigerator.

   30 to 45 minutes

   If any condensation appears on the outside of the cassette, wipe it off with a clean dry cloth to avoid getting moisture into ava.

   DO NOT try to remove the needle cap.

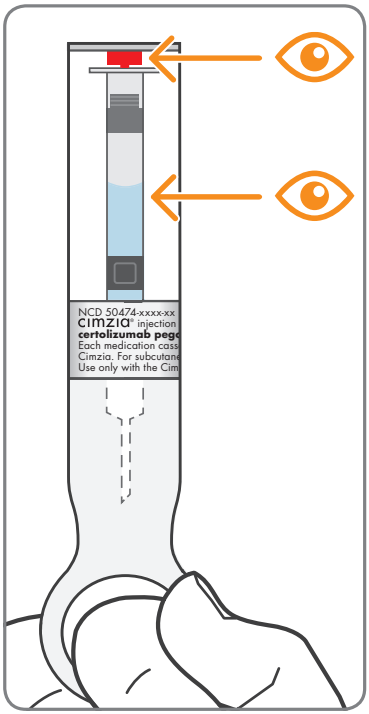
   DO NOT try to remove the syringe that is inside the medication casette.

3. Find a clean, flat work surface, such as a table.

4. Inspect the liquid in the medication cassette to check that it is clear to pale yellow and free from particles. **DO NOT** inject the medicine if it is cloudy or discolored. Call your healthcare provider or pharmacist if you have any questions about your CIMZIA medication cassette.

Inspect the cassette and make sure that the red medication level indicator is at the top of the syringe within the cassette body, as shown here.

The cassette may contain air bubbles. This is normal. **DO NOT** try to remove air bubbles before injection. Injecting CIMZIA which contains air bubbles is harmless.

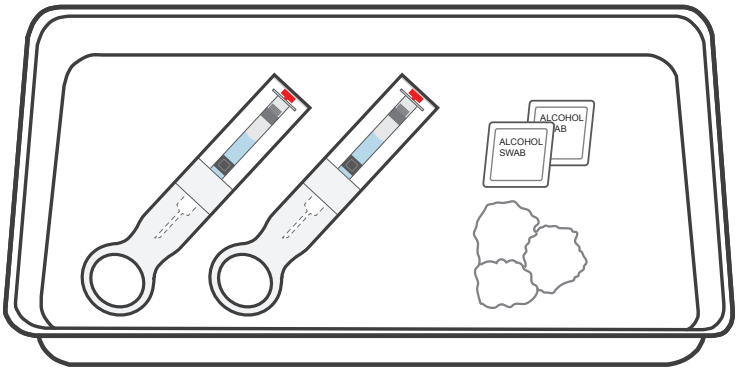


5. Gather all the supplies you will need for an injection.

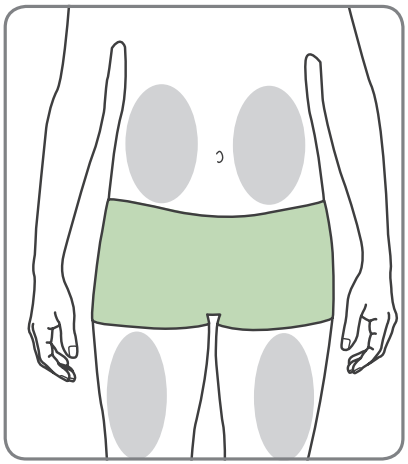
6. Wash your hands with soap and warm water and dry thoroughly with a clean towel.

Selecting and preparing your injection site

Prepare the supplies you need for your injection on a clean surface: medication cassette(s) warmed to room temperature, alcohol wipe (located in the CIMZIA pack) and cotton balls.

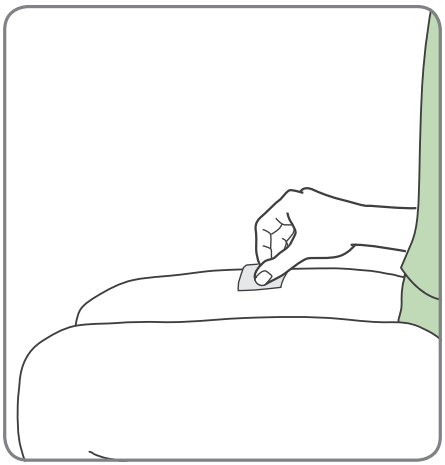


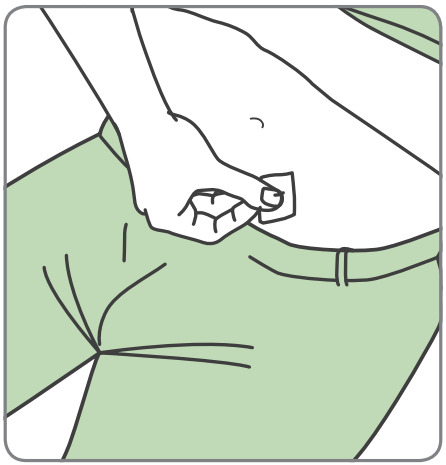
7. Choose your injection site(s) on your stomach or upper thighs (see Figure).
   - Choose a new injection site each time you use a CIMZIA medication cassette.
   - Each new injection should be given at least 1 inch from the site you used before. If you choose your stomach, avoid the 2 inches around your belly button (navel).



- **DO NOT** inject into areas where your skin is tender, bruised, red or hard, or where you have scars or stretch marks.
- Change injection sites between your stomach and upper thighs to reduce the chance of having a skin reaction.
- You may want to write down the site you use for injection to help you remember to use a different site each time you inject.

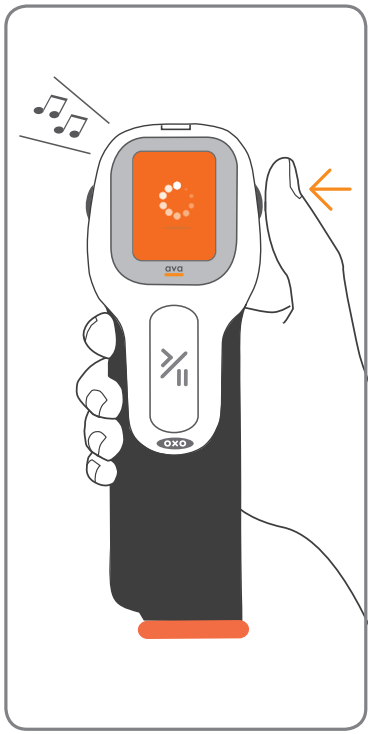
8 Clean your injection site with an alcohol wipe. Let the area dry completely.



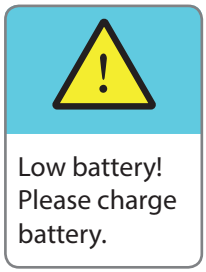


Giving your CIMZIA injection

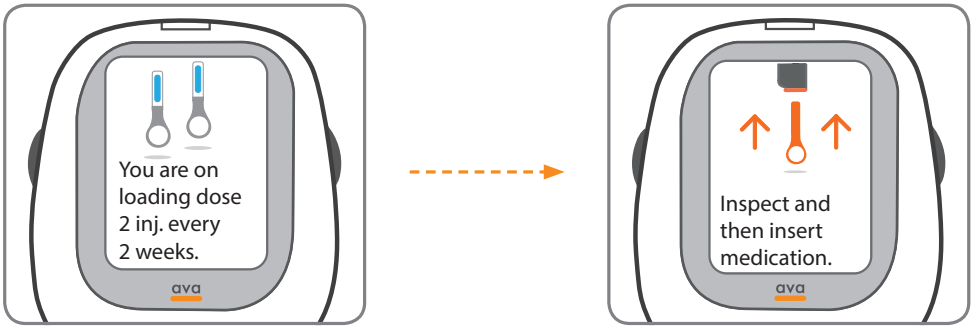
9 Turn on ava by pressing the **'On/Off'** button for 1 second, or until the screen lights up and you hear the sound.



NOTE: ava should arrive with the battery charged, but, if ava does not turn on, or it displays the message **'Low battery. Please charge battery!'**, the battery will need charging before you start. See Chapter 5 for instructions on how to re-charge the battery.



ava will show you your current dose and frequency. Then the message **'Inspect and then insert medication.'** will be shown.

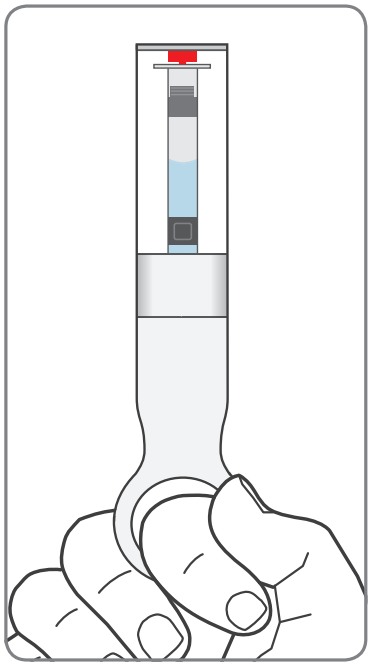


(example screen only.) Your ava may show a different dose.

⑩ Take the CIMZIA medication cassette which you have let warm up to room temperature for 30 to 45 minutes.

If any condensation appears on the outside of the cassette, wipe it off with a clean dry cloth to avoid getting moisture into ava.

DO NOT try to remove the needle cap.

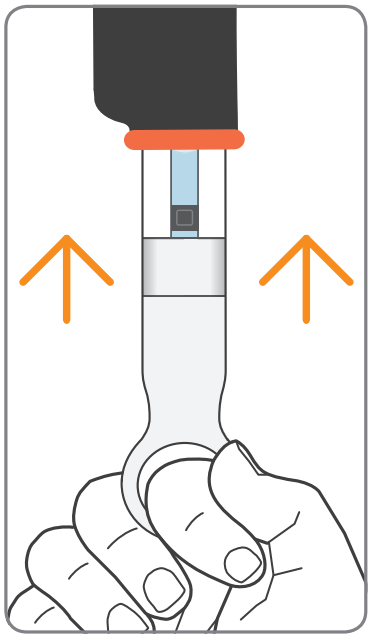


⑪ Push the flat end of the medication cassette firmly into the cassette port of ava until you hear a click.

DO NOT twist the medication cassette; it is specially shaped to ensure it is correctly inserted.

DO NOT keep other other medication cassettes near ava while injecting.

Let go of the needle cap.



ava will check the medication cassette and display the message **'Medication cassette accepted.'** if it is correct.

After a short pause, ava will automatically pull the cassette further in and release the needle cap.

⑫ After ava has pulled in the medication cassette, the currently selected injection speed is briefly displayed. You can change this setting using the **'scroll wheel'** on the side of your ava to any of the four available settings.

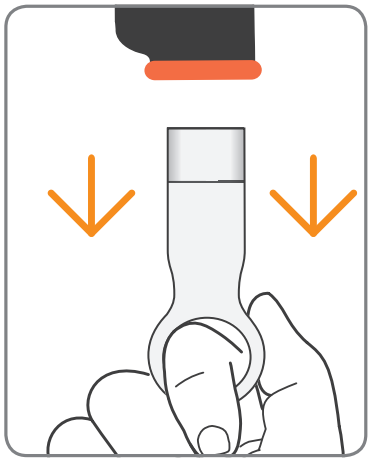
NOTE: The injection speed can only be changed when a cassette is inserted into the cassette/injection port. You can only adjust the injection speed before performing or when pausing your injection.

This setting controls the speed at which medication is injected. This setting does not change the speed of the needle being inserted, just the speed at which CIMZIA is injected. See **"CIMZIA Injection speed settings" on page 63** for more information.

The **'Remove and save needle cap.'** message is displayed.

Only remove the needle cap when you are ready to inject.

13 When you are ready, remove the needle cap by pulling it firmly downwards.



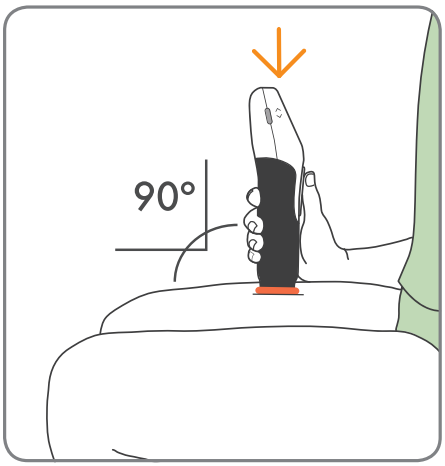
NOTE: KEEP THE NEEDLE CAP. This is important because you will need it to remove the empty medication cassette after injecting.

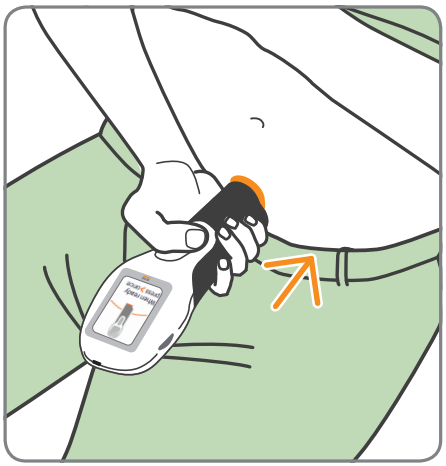
Only remove the needle cap when you are ready to inject. To ensure the sterility of your medication cassette complete your injection within 5 minutes.

However, there is no need to rush your injection; 5 minutes will allow you plenty of time to begin injecting. The remaining time is displayed on the information screen.

⑭ Find a comfortable position sitting down to give your injection. Try to relax the muscles around the injection site as this will make injecting more comfortable.

Place the orange skin sensor against your skin at the cleaned injection site, with ava's screen facing you so you can see it. The **'Start/Pause'** button must be in a position where you can use it comfortably without moving your ava. This diagram shows how to position ava.





Position ava at right angle on your skin to ensure the injection is done correctly.

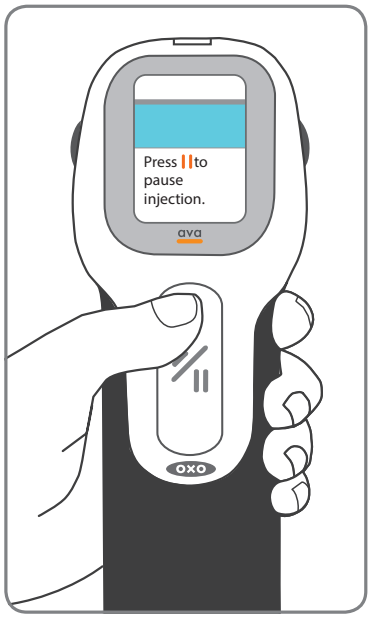
DO NOT try to inject through your clothing. ava must be placed on clean dry skin.

DO NOT try to trigger the skin sensor in any other way other than as instructed above."

When ava senses contact with your skin the message **'When ready press > once'** is displayed.

15 Press the **'Start/Pause'** button.

You will hear the motor inside ava move the cassette and the injection will begin. The screen will display an indicator to show the progress of the injection. Throughout the injection process, continue to hold ava firmly against your skin the entire time.

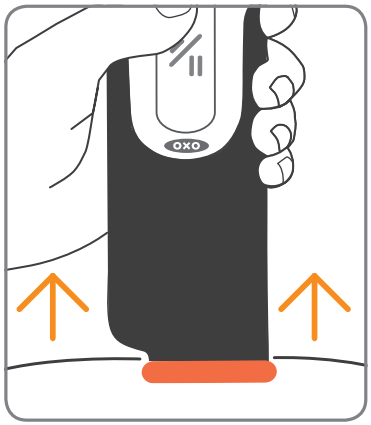


You can temporarily pause the flow of medication by pressing the **'Start/Pause'** . **DO NOT** remove ava from the skin during a pause. Refer to **"Optional Actions During an Injection: Pausing your injection" on page 62** for more information.

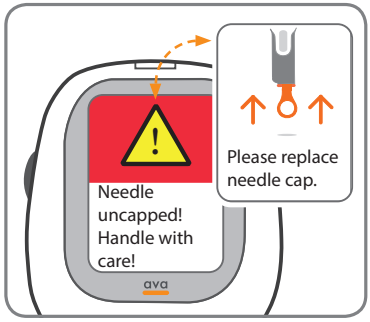
When the injection is complete, the message **'Injection complete. Please remove from skin.'** will be shown on the screen.

16 Remove ava from your skin.

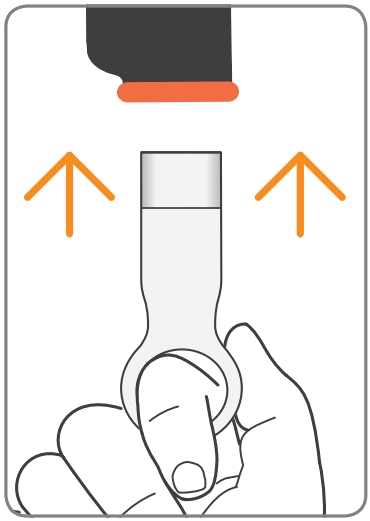
Place a dry cotton ball or gauze pad over the injection site for several seconds. Do not rub the injection site. Do not use an alcohol wipe as it may cause stinging. If there is a little bleeding cover the injection site with a small bandage.



The messages **'Needle uncapped! Handle with care!'** and **'Please replace needle cap'** will be displayed until the cap is replaced.



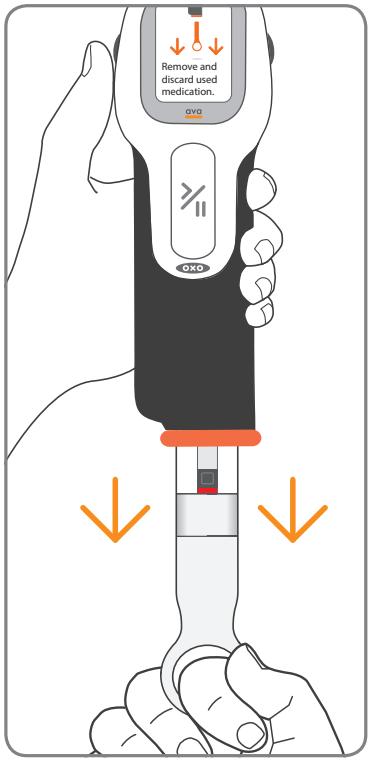
Insert the needle cap.



NOTE: If you threw away your needle cap, you can use one of the spare needle caps that come with your ava.

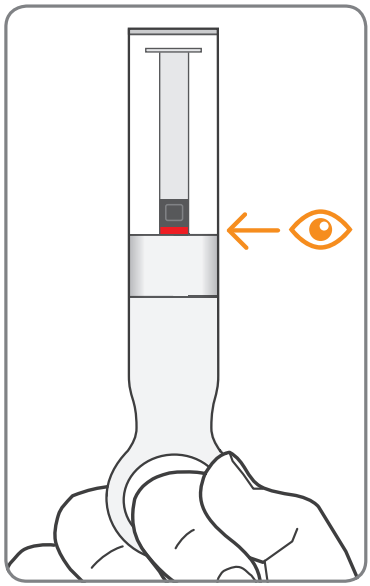
17 Let go of the needle cap. ava will release and eject the empty medication cassette.

When the message **'Remove and discard used cassette.'** appears on the information screen, pull out the CIMZIA medication cassette.

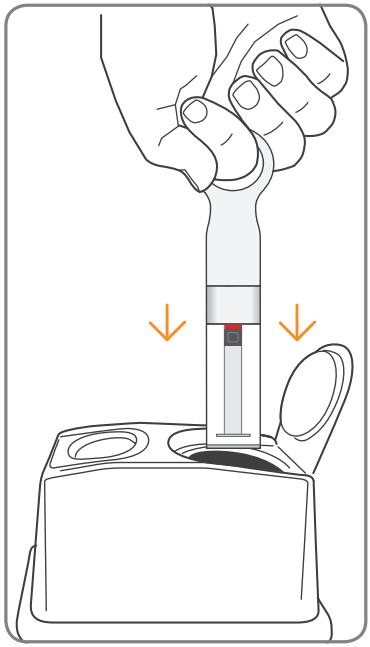


⑱ Inspect the used cassette to make sure that all of the CIMZIA has been injected.

Make sure that the red medication level indicator is at the bottom of the syringe within the cassette body.



Disposal of Used Medication Cassettes



19 Follow these instructions for disposal of your medication cassettes with needles attached:

- Put your used medication cassettes in an FDA-cleared sharps disposal container right away after use.
- **DO NOT** throw away (dispose of) medication cassettes in your household trash.
- If you do not have an FDA-cleared sharps container, you may use a household container that:
  - Is made of heavy duty plastic.
  - Can be closed with a tight fitting, puncture-resistant lid, without sharps being able to come out.
  - Upright and stable during use.
  - Leak-resistant.
  - Properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps

disposal, and for specific information about sharps disposal in the state that you live in go to FDA's website at www.fda.gov/safesharpsdisposal.

- **DO NOT** recycle your used sharps disposal container.

If you have completed all your doses, go to step 20.

If your prescribed dose requires a second injection, go to step 10 on page 51.

20 When you have completed injecting your prescribed full dose of CIMZIA ava will display your next injection date followed by how much battery charge you have left. Finally, ava will notify you to please turn off the device.

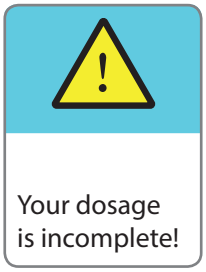
21 Press the **'On/Off '** power button to turn off ava.

If your prescribed dose requires you to administer a second injection, the message **'You have 1 injection left.'** will be displayed.

Repeat the procedure, starting at step 10 on page 51, to deliver a second injection.

NOTE: If you do not do this immediately, the warning message **'Your dosage is incomplete!'** will be displayed.

This is repeated until you administer the second injection.



You have successfully completed the injection.

Optional Actions During an Injection:

Pausing your injection

If you need to pause during an injection of CIMZIA, for example to change the injection speed, press the **'Start/Pause'** button at any time. **DO NOT** remove ava from your skin, because pressing the **'Start/Pause'** button pauses the flow of medication, but it leaves the needle in the skin.

The message **'Pausing. When ready press > once'** will be displayed.

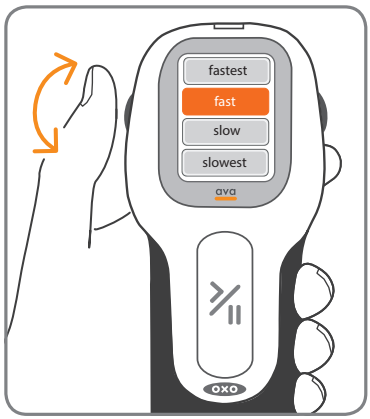
When you are ready to re-start, press the **'Start/Pause'** button again to complete the injection.

CIMZIA Injection speed settings

ava can be set to inject CIMZIA at any one of four different speeds. This setting does not change the speed of the needle being inserted, just the speed at which CIMZIA is injected. Decide on the best setting for your personal preference. The medication injection time varies approximately between 7 to 18 seconds assuming the CIMZIA medication cassette has warmed up to room temperature. By default, the injection speed is set to **'fast'** when you initially receive ava.

NOTE: The injection speed can only be changed while a CIMZIA medication cassette is inserted into the cassette/injection port. You can only adjust the injection speed before performing or when pausing your injection.

When a CIMZIA medication cassette is inserted, the injection speed is briefly displayed. You can change this injection speed setting by rotating the **'scroll wheel'** on the side of ava.



Rotating the scroll wheel highlights each of the four available speed settings. Don't press the wheel, just turn it.

Rotate the wheel until the new speed is highlighted and leave it there for five seconds. The new setting will flash and be kept for future injections, or until you choose to change it again.

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Chapter 5:

More information about ava

The section tells you about viewing your injection log and how to charge the battery.

5

Viewing the injection log

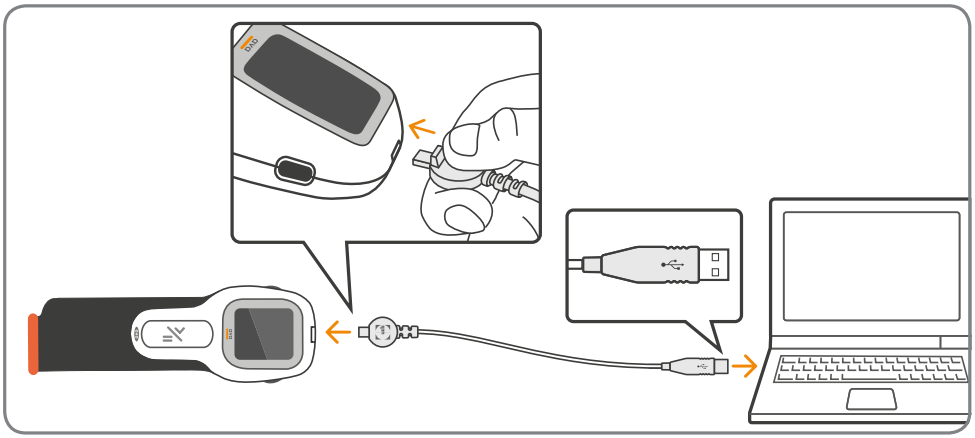
ava automatically records your injection history and this **'injection log'** can be seen by connecting ava to a computer.

NOTE: You can only view your injection log; the information in the injection log file cannot be changed.

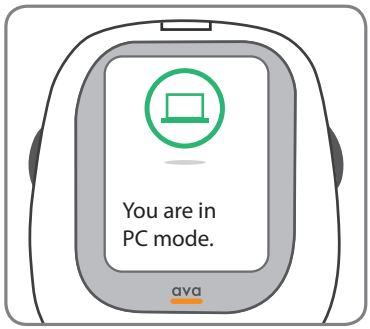
Treatment should not be altered based on the information contained in the injection log. Dosing changes can only be made by your healthcare provider.

Please make sure that you take ava with you every time you see you healthcare provider as it facilitates review of the injection log and is useful in case your healthcare provider decides to change your medication dosing.

① Using the supplied USB cable, plug the smaller end into the micro-USB port on the top of ava. Use the small tab on the micro-USB to orient it correctly for easy insertion to into ava. With the tab and the UCB logo facing the information screen, keep it parallel to the plastic housing. This is the same port that you normally use to charge the battery. **DO NOT** twist or bend the UCB connector once it is plugged into ava. Plug the other end into a free USB port on your computer. When ava is connected to your computer, it will behave like a USB drive.



ava will switch on automatically and display this screen.



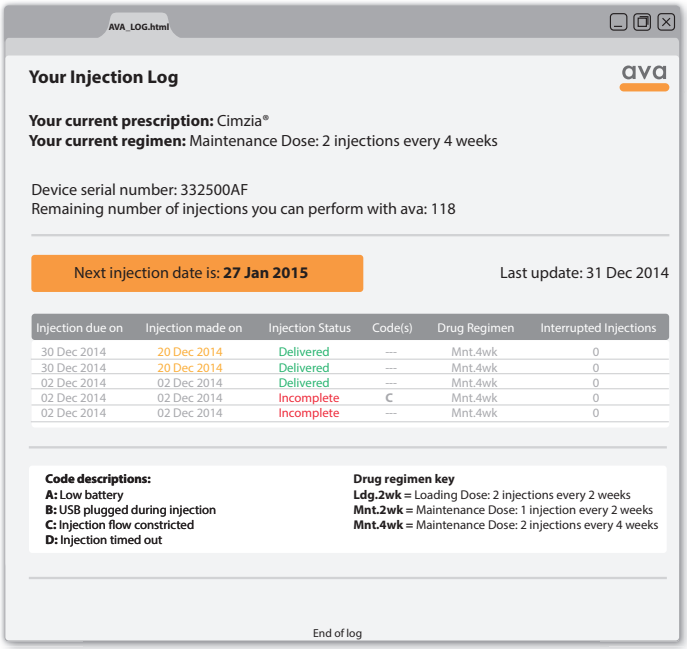
② When you connect ava to a computer for the first time, it may take about a minute to appear as a drive on your computer.

If needed, your computer will automatically install the necessary driver before connecting to ava as a USB drive.

3. When the computer recognizes ava, the name 'ava' will appear automatically in the list of connected devices.

4. Wait for AVA_LOG.html file to appear in the directory, then open it by double clicking on it.

5. Your injection log will open in your internet browser, and will show an overview of your injection history (in date order) like this example.



AVA_LOG.html

Your Injection Log

ava

Your current prescription: Cimzia®
Your current regimen: Maintenance Dose: 2 injections every 4 weeks

Device serial number: 332500AF
Remaining number of injections you can perform with ava: 118

Next injection date is: **27 Jan 2015**

Last update: 31 Dec 2014

Injection due on	Injection made on	Injection Status	Code(s)	Drug Regimen	Interrupted Injections
30 Dec 2014	20 Dec 2014	Delivered	---	Mnt.4wk	0
30 Dec 2014	20 Dec 2014	Delivered	---	Mnt.4wk	0
02 Dec 2014	02 Dec 2014	Delivered	---	Mnt.4wk	0
02 Dec 2014	02 Dec 2014	Incomplete	C	Mnt.4wk	0
02 Dec 2014	02 Dec 2014	Incomplete	---	Mnt.4wk	0

Code descriptions:
A: Low battery
B: USB plugged during injection
C: Injection flow constricted
D: Injection timed out

Drug regimen key
Ldg.2wk = Loading Dose: 2 injections every 2 weeks
Mnt.2wk = Maintenance Dose: 1 injection every 2 weeks
Mnt.4wk = Maintenance Dose: 2 injections every 4 weeks

End of log

Your computer does not have to be connected to the internet to access your injection log. Without an internet connection, your injection log will simply not show the ava logo in the top right corner.

When you are finished, close your web browser and unplug ava from your computer.

ava will turn off automatically. The injection log provides information regarding your next injection date and lists your previously administered injections.

An explanation of the different columns of the injection log is provided below.

Injection due on

This is the date when you should be making your next injection.

Injection made on

ava records the actual date when you make your next injection. Injection dates which are more than 3 days before your scheduled injection due date or 3 days after this date are displayed in orange instead of black font.

Injection status

Delivered: This means that the entire content of your CIMZIA medication cassette has been injected successfully.

Incomplete: This means that not the entire content of the CIMZIA syringe has been injected. You only have received a partial dose.

If applicable, ava may add a code to an injection entry depending on whether during an injection the battery was low (A) or the USB cable was plugged in (B), there was a problem with the flow of medication (C) or the injection was not performed within the allotted time of 5 minutes and has timed out (D).

Charging the battery

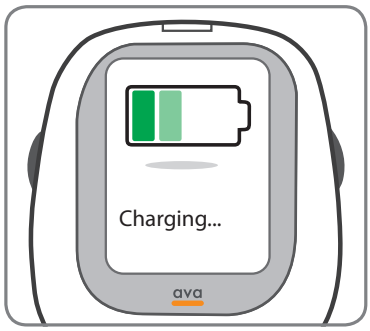
ava is powered by a rechargeable battery and it is important that you always have enough charge to complete an injection. Do not try to replace the battery. The battery does not need replacing during the lifetime of ava.

If ava's battery does not have sufficient charge to complete an injection the message **'Low battery! Please charge battery.'** will be displayed. You will not be allowed to start an injection until the battery has been charged.

If ava does not turn on, the battery probably needs to be charged.

If at the end of injecting the battery is completely empty, ava will show **'Low battery! Please charge battery.'**.

1. To charge ava, plug the provided charger into a power outlet and connect the other end to the micro-USB port on the top of ava.



DO NOT twist or bend the USB connector once it is plugged into ava.

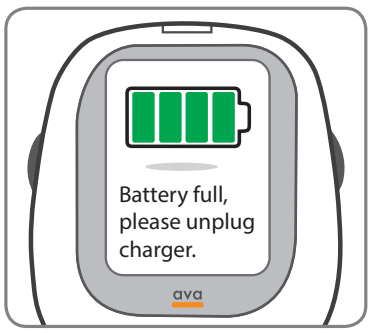
ava will turn on and show the status of the battery and begin charging. If possible, **DO NOT** disconnect the charger before the battery is fully charged.

Only use the provided charger to charge ava.

In case ava does not display the **"Charging..."** screen, make sure the charger is connected to a live electrical outlet and the micro-USB plug is connected to ava. If ava still does not charge, call your local helpline for a replacement charger.

It takes approximately 2-3 hours to fully charge.

2. When the battery is fully charged, the message **'Battery full. Please unplug charger.'** will be displayed.



Unplug the charger. ava will turn off automatically.

NOTE: ava will show the battery status every time an injection is completed. It will display the message **'Enough battery for next injection.'** or, if you need to charge ava before your next injection, the message **'Not enough battery to inject.'** will be displayed.

At the end of injecting, if your battery is completely empty, ava will show **'Low battery! Please charge battery.'**.

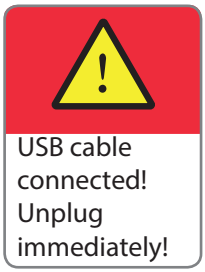
Enough battery for next injection.

Not enough battery to inject.

Low battery! Please charge battery.

If you charge the battery and ava still doesn't turn on, call helpline at 1-800-xxxxx

WARNING: DO NOT try to charge ava during an injection. If you connect ava to charge during the injection process ava will stop the injection and will display the message **'USB cable connected! Unplug immediately!'**. You will not be able to progress with the injection until you unplug the charger.



Chapter 6:
Troubleshooting

In this section you can find information on how to troubleshoot problems and you can find an explanation of all the warnings and cautions which ava may display.

6

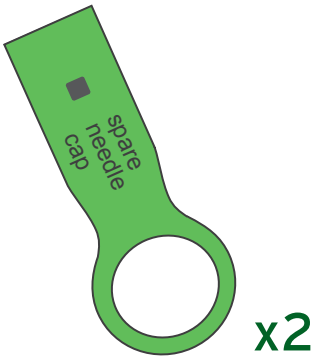
Removing a cassette if the needle cap is lost or if needle is severely bent

Following an injection the needle cap is required to remove the used cassette from ava. If you have accidentally lost the original needle cap of your cassette you can use one of the spare needle caps. There are two green spare needle caps which you can find in the storage case.

You can also use the spare needle cap to remove a medication cassette in case the needle is bent and is not allowing you to use the original medication cassette cap.

DO NOT attempt to remove a cassette by any other means due to the risk of an acccidental needle stick injury.

NEVER insert any foreign objects such as tools or fingers into the cassette port.



Spare needle cap

What to do if ava has problems identifying a cassette by the Radio Frequency Identification (RFID)

If you have a problem with ava identifying an inserted cassette, make sure you do not have any other cassettes (medication cassette or training cassette) immediately next to ava. You may also find it helpful to use ava away from or temporarily turn off household appliances which might cause interference such as television sets, radios, microwaves or mobile phones etc. Generally, a distance of a few feet from potentially interfering appliances should be sufficient to avoid any problems.

Always make sure you are not using ava near strong sources of magnetic and electromagnetic radiation such as x-ray machines at airports or hospital equipment.

Warning message priority

When using ava you may see warning messages displayed. To help you to understand importance of these messages the following symbols have been used:

Messages with this symbol are High Priority Alarms and may represent a danger and must be acted upon immediately.

Messages with this symbol are Medium Priority Alarms and in most cases require you to consult with your physician before proceeding.

Messages with this symbol are Low Priority Alarms providing instructions of important next steps which need to be performed.

Messages with this symbol are instructions which must be completed.

Messages with this symbol indicate medication cassette actions which are not possible or allowed.

These symbols indicate the alarm priority and will be shown together with additional instructions.

High priority alarms

MESSAGE	EXPLANATION
Entering dose setting mode. Only for physician!	As a patient you should never attempt to enter this menu nor try to modify the setting of your medication dose. If you encounter this message by error, simply turn off ava by pressing the power button for 3 seconds. This message signifies that you are about to enter the dose setting mode on ava. This set up menu is intended only for your healthcare provider and is used to set up your specific medication dose in ava. If you accessed this message by mistake, press the On/Off (Power) button until ava turns off
Error! Do not use. Helpline code xxxx	ava has a self-test procedure to make sure it is working properly before use. This warning shows that an error was detected during this test. For your own safety ava will not allow you to proceed. A four digit **'error helpline code'** will be displayed. Contact your local helpline for support and tell them the 4-digit error code.

MESSAGE	EXPLANATION
Needle uncapped! Handle with care!	Following a partial or completed injection the needle cap has not yet been replaced. Although the needle is safely retracted inside ava, it remains exposed inside the device until the needle cap is replaced. Handle with care, until you have replaced the needle cap to avoid accidental needle stick injury. **DO NOT** attempt to insert a finger inside of the cassette port. If you have interrupted an injection and delivered only a partial dose, you should try to complete your injection before replacing the needle cap.
USB cable connected! Unplug immediately!	This warning will be displayed if you connect ava to the electrical charger or to your PC during an injection. You must immediately unplug the micro-USB cable from the charging port before proceeding to minimize the risk of electric shock. You cannot finish your injection while ava is connected to the charger or a computer. Unplug the micro-USB cable and then finish your injection.

Medium priority alarms

MESSAGE	EXPLANATION
Incorrect medication dosing interval!	If for some reason during your loading dose regimen you have not been using ava for more than 70 days to inject CIMZIA, you will see this message. Consult with your physician how to proceed with your CIMZIA injections.
Injecting ahead of scheduled date!	ava uses an internal calendar to keep track of when your next injection is due. If you turn on ava more than 3 days before your next injection is due, ava will display this message to warn you that it is too soon to inject and performing an injection now may result in an overdose of CIMZIA. This warning does not stop you from injecting; however, you should always consult with your physician before performing an out-of-schedule injection.

Low priority alarms

MESSAGE	EXPLANATION
Cassette error! Refer to user manual!	This message indicates that ava has detected a **'needle injection error'**. This may be due to a blocked needle, frozen CIMZIA or other reason. **DO NOT** try to inject using this cassette. Replace the needle cap and remove the cassette. Dispose of it in your biohazard (sharps) container. You can inject with a different cassette.
Consult your physician to set device dosage!	When you first receive ava the medication dose corresponding to your specific prescription has not been set up yet in ava. Contact your healthcare provider to have ava set up for the exact amount of CIMZIA you should take. When you see your healthcare provider make sure you bring ava along. You should also receive injection training at the same time. In the meantime, to practice the injection process with ava you can proceed to insert the training cassette. However, you will not be able to inject your medication until your specific medication dose has been set.

MESSAGE	EXPLANATION
Device at end of life!	When this warning is displayed ava must be replaced and no more injections can be made with this device. ava has been designed to be used for up to 3 years and it has been programmed to prevent use after this time. Contact your healthcare provider or local helpline for a replacement device.
Device is out of temperature range!	ava can operate within the temperature range of 5°C – 40°C (41°F – 104°F) at 15 – 90% relative humidity. Outside of these temperatures ava will display this message. If you see this message store ava at the appropriate operating temperature. Allow enough time until ava has reached the normal operating temperature. This can be checked by turning ava on. This message should not be displayed before proceeding.

MESSAGE	EXPLANATION
Device is nearing end of life!	When ava first displays this warning it can still be used for another 10 injections (plus any use of the training cassette) before it must be replaced. ava has been designed to be used for up to 3 years and it has been programmed to prevent use after this time. To ensure your safety and reduce the risk of device failure, ava will soon have to be replaced. You may also see the warning **'Please replace device by calling helpline'**. After another 10 injections ava will stop working and display the warning **'Device at end of life. Please do not use'**. Contact your healthcare provider or local helpline for a replacement device.
Early medication insertion!	ava displays this message if you insert a cassette too soon after you have turned ava on.

MESSAGE	EXPLANATION
Injection not complete! Reposition on skin.	If skin contact is lost during an injection, ava automatically stops the injection and withdraws the needle. Not all the CIMZIA will have been injected and this warning indicates that your injection is not complete. If an injection is interrupted due to loss of skin contact, small amounts of medication may be lost. Multiple interrupted injections may lead to a medication underdose. To complete your injection, choose a new injection site and follow the instructions given in **"Chapter 4: Injecting CIMZIA with ava" on page 43**.
Insertion error! Refer to user manual.	This warning indicates that ava has found a technical problem with the cassette. Replace the needle cap and remove the cassette from ava. Once the cassette has been removed ava will automatically carry out a self-test. In case there is a problem with ava, the high-priority alarm message **'Error! Do not use. Helpline code'** will be shown. Provide the error code to the helpline. If ava does not show an error code, ask the helpline for instructions how to proceed.

MESSAGE	EXPLANATION
Low battery! Please charge battery.	ava contains a rechargeable battery. This message indicates ava needs recharging. Only use the charger which is supplied with your ava kit to recharge the device. Please refer to **"Chapter 5: More information about ava" on page 65** for more information.
Low battery! Please inject immediately!	This warning indicates that you must complete your injection immediately. ava's battery is almost empty and you must inject before it needs charging.
Scheduled injection date missed!	This message indicates that you have missed your previous scheduled dose. ava automatically records your injection history and when your next dose is due. You need to consult with your healthcare provider how to correct your dosing.
Software error!	In case you see this screen please contact your local helpline for a replacement device.

MESSAGE	EXPLANATION
Your dosage is incomplete!	For patients whose full dose requires two injections, this warning is displayed when you have not yet completed your full dose. You have only injected one of the two required medication cassettes and need to proceed injecting with the remaining medication cassette to complete your prescribed dose.

Instructions

MESSAGE	EXPLANATION
Consult your physician!	This message advises you to contact your healthcare provider.
Follow physician's instructions for dosing!	This message indicates that you have missed your previous scheduled dose. ava automatically records your injection history and when your next dose is due. You need to consult with your healthcare provider how to correct your dosing.
Let go of needle cap!	This message informs you not to hold on to the needle cap of the cassette while inserting or removing the cassette from ava.
Low battery! Please charge battery.	This message indicates that the internal battery is empty and needs to be recharged. ava must be charged before it can be used. Make sure you only use the charger supplied with ava. Refer to **"Charging the battery" on page 70** for help with charging ava.

MESSAGE	EXPLANATION
Contact your physician. Only inject if instructed.	This message is displayed if you turn on ava too far in advance of your next injection due date. ava will also show you your next date for injection. You may want to inject anyway, if your healthcare provider has given you specific instruction to inject your next dose early. **DO NOT** inject unless you have received specific instructions to do so. Otherwise, make a note of the date of your next injection (shown on ava's screen). Next, turn off ava.
Please replace device by calling helpline.	ava has been designed to be used for up to 3 years and it has been programmed to prevent use after this time. To ensure your safety and to reduce the risk of device failure, ava will have to be replaced when this message appears. Contact your healthcare provider or local helpline for a replacement device.

MESSAGE	EXPLANATION
Please read instructions in user manual.	This message advises you to read the relevant information in the user manual.
Please replace needle cap.	This message indicates that the needle cap has been removed. The needle is still retracted inside ava and remains exposed inside the device until the needle cap is replaced. Handle with care, until you have replaced the needle cap.

Cassette Warnings

MESSAGE	EXPLANATION
Medication has expired. Do not use.	This warning indicates that the **CIMZIA** medication cassette has passed its expiration date. ava displays this warning to prevent you from injecting expired medication and will reject the cassette. Remove the cassette and contact your healthcare provider.
This is a used medication. Do not use.	This message indicates that this is a used cassette (for example; the needle cap has been removed before). For your safety, ava will not allow the use of any cassette where the needle cap has been removed before as the needle is no longer sterile. ava will eject the cassette. Remove it and discard it in a sharps container.
This is not your medication. Do not use.	This warning indicates that ava does not recognize the cassette you have loaded as one containing **CIMZIA**. Please contact your healthcare provider to obtain the correct medication for you. ava will reject the cassette. Remove the cassette and return it to your pharmacist.

MESSAGE	EXPLANATION
 Medication not authentic. Do not use.	This message indicates that the cassette which has been inserted is not an authentic **CIMZIA** medication cassette. ava must only be used with genuine **CIMZIA** medication cassettes. Contact your local helpline for advice. The helpline may instruct you to keep the cassette for investigation by the manufacturer. ava will reject the cassette. Remove it from ava.
 Time to inject exceeded. Do not use.	This warning is displayed if ava has been left for more than 5 minutes after the needle cap has been removed and before an injection was started. With the needle cap removed, the needle's sterility seal has been broken and it is important that you inject as soon as possible. ava will no longer accept this cassette. Insert the needle cap and remove the cassette from ava. Put the cassette in your biohazard (sharps) container.

Other Non-Alarm Screens

MESSAGE	EXPLANATION
You are on loading dose 2 inj. every 4 weeks.	When starting ava, one of the following three screens will be displayed to remind you which dose and frequency (regimen) ava is set to use. The first time ava is used you will not see any of these screens because ava still needs to be set up by your healthcare provider. The dose and frequency displayed must correspond to your current prescription. If you believe the displayed dose does not correspond to your current prescription contact your healthcare provider. This particular message is displayed if you are on Loading Dose (2 injections every 2 weeks). **NOTE:** If your healthcare provider prescribed the loading dose to you, ava will automatically transition from the loading dosing when completed to your prescribed maintenance dose.
You are on maintenance dose 1 inj. every 2 weeks.	This particular message is displayed to indicate ava is set to the Maintenance Dose (1 injection every 2 weeks).

MESSAGE	EXPLANATION
You are on maintenance dose 2 inj. every 4 weeks.	This particular message is displayed to indicate ava is set to the Maintenance Dose (2 injections every 4 weeks).
Loading dose complete.	This message is displayed to inform you when your loading dosing is complete. During loading dosing you have administered 2 injections every 2 weeks at weeks 0, 2 and 4. Now your loading dosing has finished and ava automatically transitions to your prescribed maintenance dosing as set up by your healthcare provider.
Please turn off the device.	This message indicates that you have finished injecting and should now turn off ava to preserve battery life. If you do not turn it off, ava will automatically turn off after 3 minutes.

MESSAGE	EXPLANATION
 Your next injection date.	This screen indicates the date that your next injection is due. The date displayed depends on when you last injected and your prescribed dose and dosing frequency. This picture shows a sample date – yours will vary.

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Chapter 7:

Technical Information about ava

7

Technical data

Model Name	ava
Dimensions	H : 203 [mm], W: 68 [mm], D: 56 [mm]; H: 8 [in.], W: 2.68 [in.], D: .2.2 [in.]
Weight	245 g; 8.6 oz.
Serial Number	Unique 8 alphanumeric digit identifying each individual device
Power Supply	Internally powered, rechargeable Lithium Ion Battery, 3.7V DC, 1620 mAh minimum
Battery Charger	Emerson / Artesyn DA12-M, 90 - 264V~ 0.15 A @240V (max), 47 / 63 Hz, output : 5V DC, 2.0 A (max) or Friwo Fox 12 Medical, Type FW8000MUSB/05 100-240V~,0.15 A@ 240V (max), 50-60 Hz, output: 5V DC, 2.2 A (max)
Classification	Ingress Protection IP 52 (ava is protected only against occasional liquid droplets but it is not protected against water spillage) Applied part type BF
Electromagnetic Compatibility	Electromagnetic compatibility in accordance with EN60601-1-2 (see EMC tables)
Operating Environment	5°C – 40°C (41°F – 104°F) at 20 – 90% relative humidity
Pressure Limits	Atmospheric pressure limits: ava can be used between 700 to 1060 hPa, at ambient pressure between 700 to 1060 hPa
Storage Conditions	-20°C – 60°C (-4°F – 140°F) at no humidity requirement
Dose Accuracy	nominal injectable volume 1.0 ml min. volume 0.95 ml
Warranty	ava does not have any user serviceable parts. Opening or attempting to disassemble ava will void any device warranty.

This medical equipment complies with the following international standards:
ISO 60601 and ISO 11608

Explanation of ava symbols

	Manufacturer of ava
	Manufacturing date of ava
SN	Serial number
	Refer to instruction manual
	Applied part type BF (electrical isolation)
⎓	Direct current (d.c.), ava requires 5V direct current to recharge the battery.
RFID	RFID tag ava identifies cassettes via an RFID (radio frequency identification) chip.
	Dispose of safely according to your local regulations
	This symbol denotes the atmospheric pressure limits of ava under which it can be used.
IP52	Level of ingress protection. This rating describes how well ava is protected against dust and liquids entering the interior of the device. The first digit of the IP rating describes the level of protection against solid particles entering through the housing of ava into the device. The rating of 5 means that the ingress of dust is not entirely prevented. The second digit of the IP rating describes the protection against the ingress of liquids into ava. The two (2) rating means that ava is only protected against drops of water. Avoid spilling any liquid onto ava. Make sure you keep ava dry storing it inside the storage case and only use a damp cloth if ava needs cleaning.
℞	Prescription only

Electromagnetic Compatibility Tables

Medical electrical equipment requires special precautions regarding EMC (electromagnetic compatibility) and needs to be used in accordance to the EMC information provided below.

Portable or mobile RF communications equipment (e.g., mobile phones, pagers...) can affect ava.

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

Wireless Functionality	Radio Frequency Identification (RFID) nominal frequency 13.56MHz +/-423,75 kHz subcarriers
Effective Radiofrequency Radiated Power Output	200 mW
Operating Range	< 1 cm outside of ava
Modulation	On-Off Keying (OOK)
Bandwidth of Receiving Section	~ 846 kHz
Wireless Quality of Service Requirement	RFID reader provides Received Signal Strength Indicator (RSSI). In case of single RFID read or write failure ava automatically performs a retry.
Wireless Security Measures	Critical information on the cassette RFID chip is AES128 encrypted with CTR mode of operation.
ava complies with the applicable EMC and telecommunications standards	ETSI EN 300 330-2 V1.6.1 ETSI EN 301 489-1, ETSI EN 301 489-3, FCC Part 15 (10-01-2014 Edition)

Guidance and manufacturer's declaration – electromagnetic emission

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11 ETSI EN 301 489-1 ETSI EN 301 489-3 IEC 60601-1-2 EN 55022	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 ETSI EN 301 489-1 ETSI EN 301 489-3 IEC 60601-1-2:2014 EN 55022	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
FCC Title 47 CFR Part 15, subpart B and C	15B: Class B	This device complies with Part 15 of the Federal Communications Commission (FCC) Rules. The FCC ID for this device is reported on the device label. Operation is subject to the following two conditions: • This device may not cause harmful interference. • This device must accept any interference received, including interference that may cause undesired operation. • Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
Harmonic emissions ETSI EN 301 489-1 ETSI EN 301 489-3 IEC 60601-1-2 EN 61000-3-2	Applicable for the battery charger connected to the device, covered by Telecom Requirements	Battery Charger < 75 watt. No limits apply. Therefore the charger is in compliance with Harmonic requirements.

Emissions test	Compliance	Electromagnetic environment - guidance
Voltage fluctuations and flicker **ETSI EN 301 489-1** **ETSI EN 301 489-3** **IEC 60601-1-2** **EN 61000-3-3**	Applicable for the battery charger connected to the device, covered by Telecom Requirements	Device's charger is assumed not to generate Voltage Fluctuations and Flicker and is therefore deemed to comply without testing. EN 61000-3-3, clause 6.1. "Tests need not be made on equipment which is unlikely to produce significant voltage fluctuation and flicker."
Electromagnetic compatibility and radio spectrum matters **ETSI EN 300 330-2 V1.6.1**	13.56 MHz RFID device Transmitter technical characteristics: Product Class 1 Receiver classification: Receiver Class 3	13.56 MHz RFID device. The device is equipped with a RFID R/W circuit operating on passive tags at a frequency of 13.56 MHz and is therefore classified as an inductive application, of which the parameters to comply with are described in the Electronic Communication Committee recommendation ERC/REC 70-03.

Information to the User (FCC Title 47 CFR Part 15.105 (b))

Note: 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.

Guidance and manufacturer's declaration – electromagnetic immunity

Immunity test	Test level	Compliance level / performance criterion	Electromagnetic environment - guidance
Electrostatic discharge (ESD) ETSI EN 301 489-1 ETSI EN 301 489-3 IEC 60601-1-2 ISO 11608-1 ISO 11608-4 IEC 61000-4-2	±2, ±4, ±6 and ±8 kV contact discharge ±2, ±4, ±8, ±10, ±13 and ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	None
Fast Transient / burst ETSI EN 301 489-1 ETSI EN 301 489-3 IEC 60601-1-2 IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	TT for transmitters, TR for receivers	Mains power quality should be that of a typical commercial or hospital environment.
Surges ETSI EN 301 489-1 ETSI EN 301 489-3 IEC 60601-1-2 IEC 61000-4-4	±1 kV; ±2 kV Common mode	TT for transmitters, TR for receivers	

Immunity test	Test level	Compliance level / performance criterion	Electromagnetic environment - guidance
Voltage dips and interruptions ETSI EN 301 489-1 ETSI EN 301 489-3 IEC 60601-1-2 IEC 61000-4-11	Reduction of the supply voltage of 100% for 20 ms Reduction of the supply voltage of 60% for 200 ms Reduction of the supply voltage of 100% for 5000 ms	CT for transmitters, CR for receivers for ETSI EN 301 489 series CT for SRD class 1 transmitters, CR for SRD class 1 receivers for ETSI EN 301 489 Series TT for SRD class 2 or class 3 transmitters, TR for SRD class 2 or class 3 receivers for ETSI EN 301 489 series TT for transmitters, TR for receivers	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency magnetic field IEC 60601-1-2 IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.