

Aria Free™ pneumatic compression system



Brought to you by
Aria Health,
a ResMed company



Aria™: Lymphedema Management



Welcome

The Aria Free System is an ultra-compact air pump, slim-profile garment, and mobile phone app by Aria Health.



WARNING

Read this entire guide before using the system.

Do not use the system if your affected leg has open wounds. The system is only intended for use on legs with intact skin.



CAUTION

In the US, federal law restricts this system to sale by or on the order of a physician.

Indications for use

The Aria Free system by Aria Health is intended for use by medical professionals and patients at home for the treatment of the following conditions:

- Lymphedema
- Chronic edema
- Venous insufficiency
- Wound healing

The Aria Free system is for single-patient use only. It is only intended for adult patients (≥ 18 years).

Contraindications

Use of pneumatic compression may be contraindicated in some patients with the following pre-existing conditions:

- Congestive heart failure
- Any condition where increased lymphatic and venous return is undesirable

Adverse effects

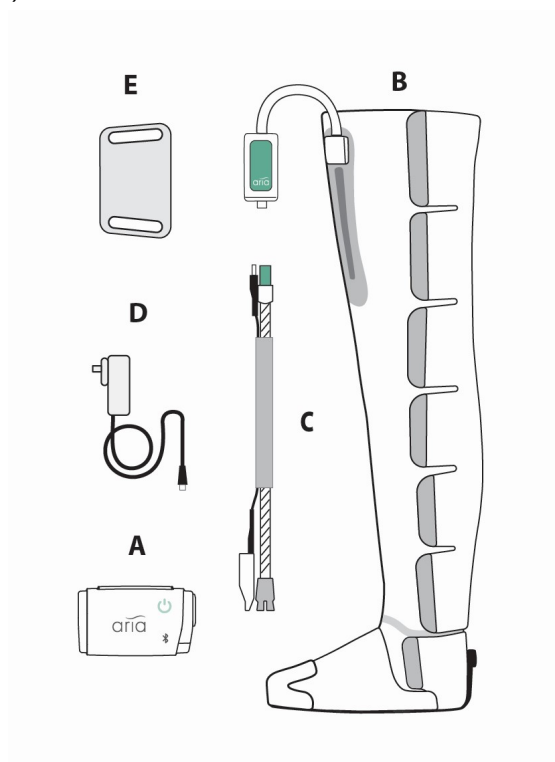
The following side effects may arise during the course of using the system:

- Mild to moderate pain and/or discomfort
- Skin irritation
- Minor skin breaks
- Anxiety
- Nausea/dizziness

Your Aria Free system at a glance

The Aria Free system includes the following:

- A. Air pump
- B. Pneumatic garment
- C. Connector tube
- D. Power supply unit
- E. Adjusters (x7)



For accessories available for use with the Aria Free system, please contact us or visit our website: AriaHealth.com

Your Aria Free system in detail

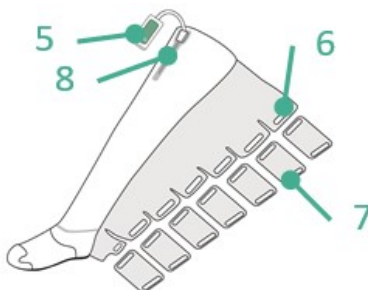
A Air pump

- 1 Start/Stop button
- 2 Air pump connection point
- 3 *Bluetooth®* button
- 4 Air filter cover



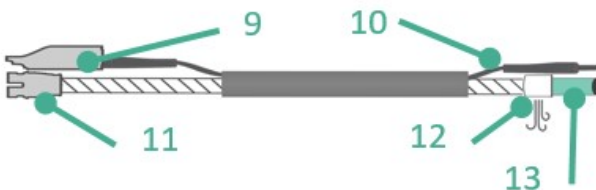
B Pneumatic garment

- 5 Garment connection point
- 6 Self-fastening tabs
- 7 Adjusters (x7)
- 8 Connector strip



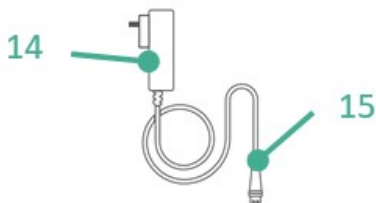
C Connector tube

- 9 Power connection point
- 10 Electrical line
- 11 Air line grey end
- 12 Vent module
- 13 Air line green end



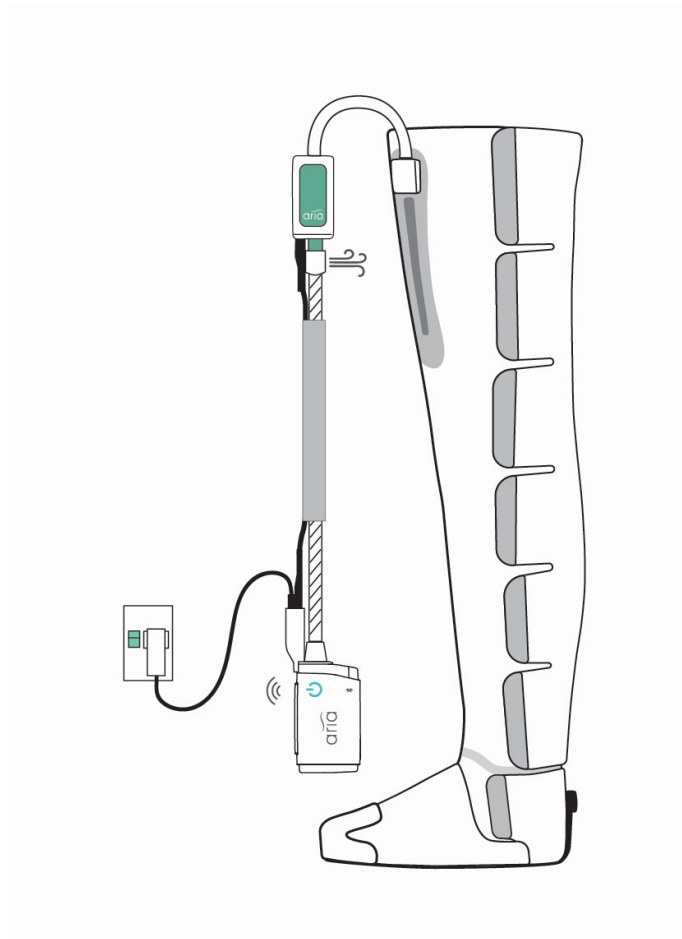
D Power supply unit

- 14 Wall plug
- 15 Power line



Your assembled system

Your fully assembled system will look similar to below. Detailed assembly instructions can be found in the section *Setting up and starting therapy*.



Note: The adjusters are not represented as they are not necessary for use. Refer to the section *Using Your Garment Adjusters* within this manual.

Aria: Lymphedema Management app

Your Aria Free system is designed to work with the **Aria: Lymphedema Management** app. However, the app is not required to operate the system. For more information, refer to the section *Connecting your Aria Free system and smart device* within this manual or *Help Bar* within the app.

Setting up and starting therapy

If the app has been downloaded, open it and follow the step-by-step instructions. You will also find helpful videos to assist you in your first time setup.

Use your Aria Free system only as directed by your physician or healthcare provider.

If you are unable to or do not wish to download the app, follow these instructions.

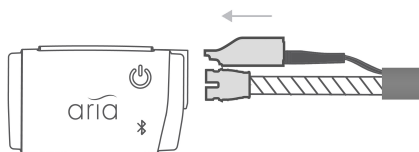
Location for use

Before setting up, find a comfortable place for therapy. Ideally, you would want your leg stretched out either on a sofa or bed during therapy.

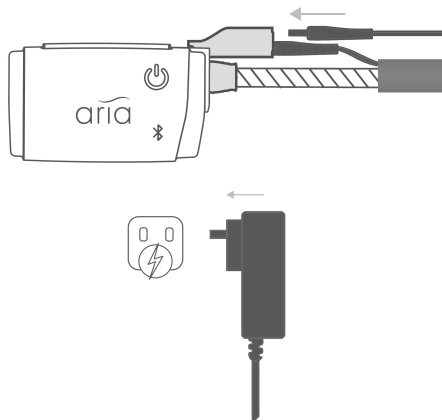
Set up your pump

1. Connect the connector tube to the air pump by:

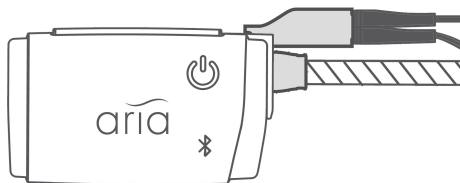
- a. Inserting the power connection point.
- b. Inserting the grey end of the air line.



2. Plug the power line of the power supply unit into the remaining port on the power connection point. Plug the other end of the power supply unit into the power outlet on your wall.



3. After following these steps, your air pump connections should look like this.



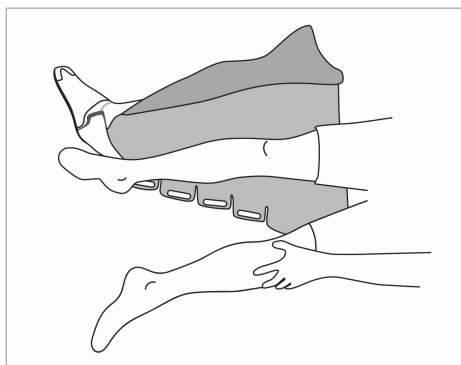
Wearing your garment

WARNING

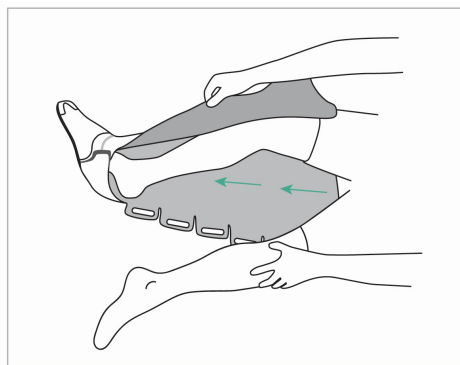
Do not put on the garment if your affected leg has open wounds. The system is only intended to contact intact skin. Ensure any wounds are adequately covered with wound dressing prior to use.

Prepare the garment by loosening the self-fastening tabs, **except the tabs around the foot and ankle**. The self-fastening tabs on the foot and ankle are only there for minor adjustments to achieve a good fit, after initially putting the garment on.

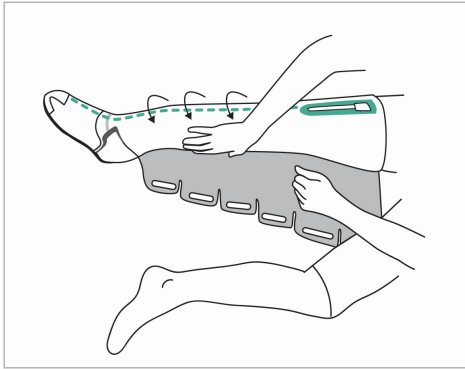
Follow the below step-by-step instructions to fit your garment.



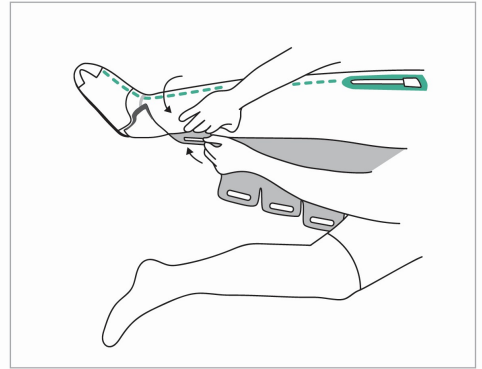
Lay garment out flat and place your leg on top of it.



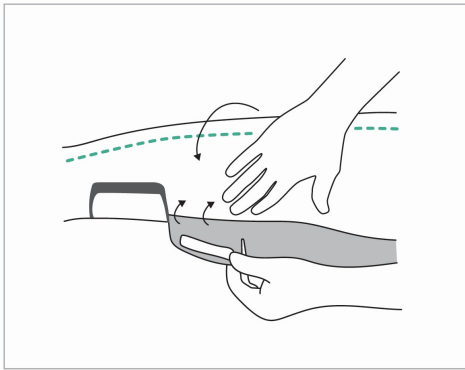
Place foot into the garment and wrap it around your leg. Keep your leg straight in the garment.



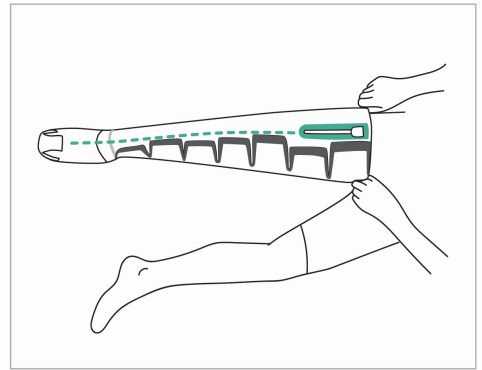
Make sure it's tucked into the underside of your leg securely. Align the connector strip on the front and center of the leg (shown by the green dotted line) when fitting.



Secure the bottom tab first.



As you move your way up the garment and secure each tab, pull the garment up and tuck into the underside of your leg for a tight fit before securing the next tab.

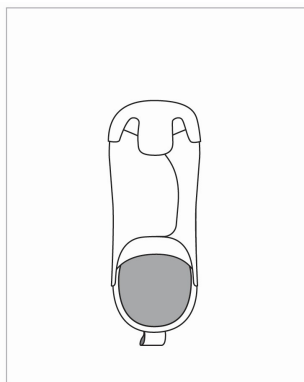


Once all tabs are secured, you are ready for therapy.

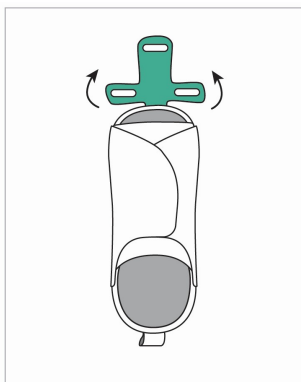
Your garment should have a tight but not restrictive fit, like a yoga pant. It is important to avoid wearing anything underneath your garment that may hamper the lymph flow. These items include: pants with heavy seams, compression stockings, zippers. You may wear loose-fitting, non-elastic clothes, sheer liners or place the garment directly on intact skin.

If the foot area requires adjustment (for the first time use or if your foot size has changed), follow the step-by-step instructions below after first following the step-by-step instructions above.

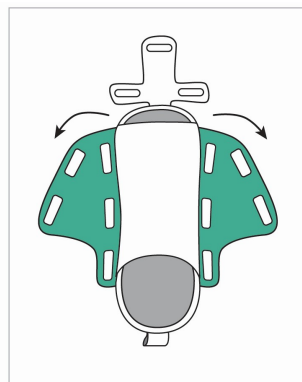
Note: To reach and adjust the foot, it can be helpful to temporarily loosen the self-fastening tabs above the knee.



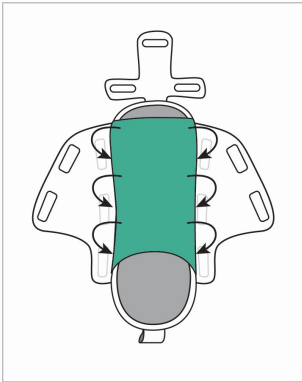
Place your foot on a flat surface and bend the knee to reach your foot. Ensure that the heel is against the back of the garment.



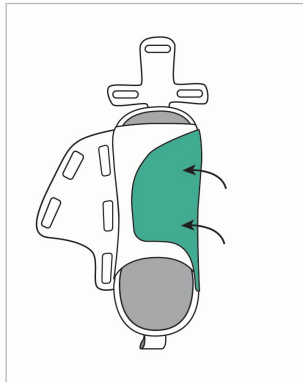
Start by undoing the toe tab.



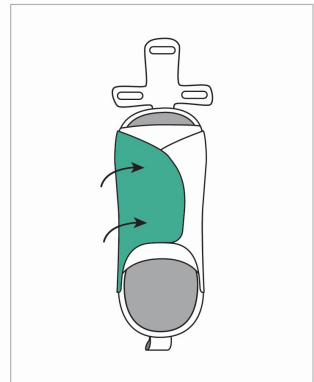
Followed by the side tabs.



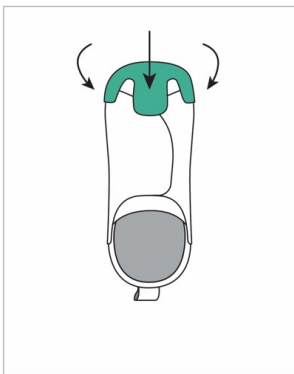
Adjust the foot wrap by evenly tucking the material around the foot to create a close fitting wrap. Remove any bunching that might be present.



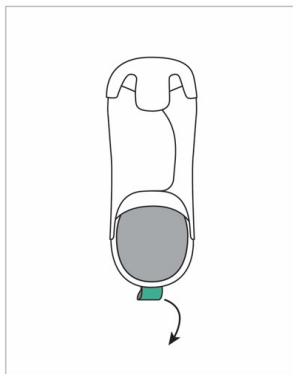
Re-secure starting with the right side tab.



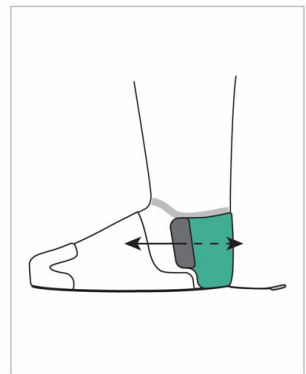
Followed by the left side tab.



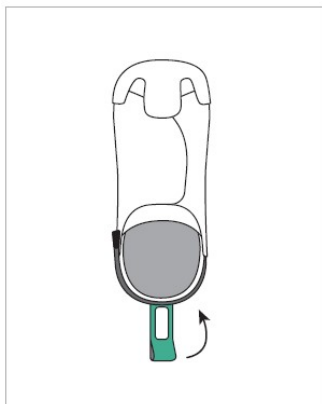
Bring the toe tab over the top.



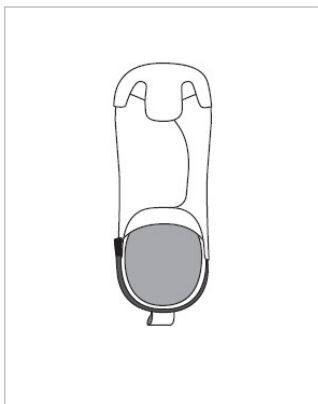
Pull heel tab away from ankle.



Release the ankle tab and adjust by either loosening or tightening the fit.



Place heel tab back on the garment.



You are now ready for therapy.

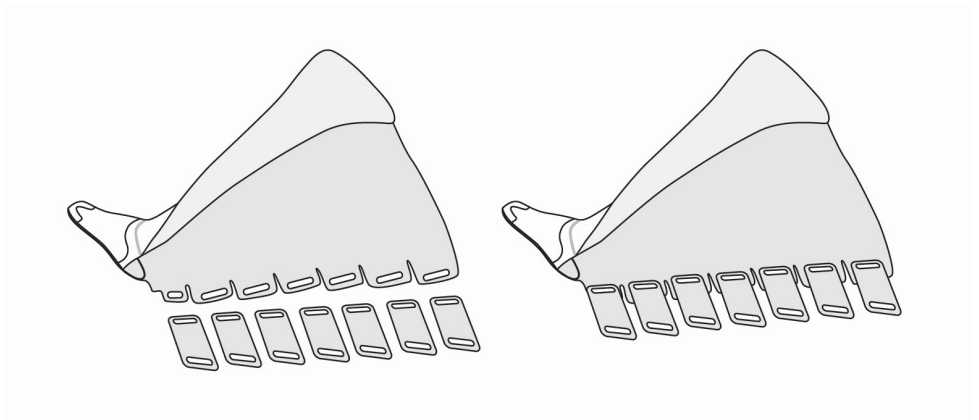
Note: If your toes don't reach the end of the sole, do not pull the toe tab backwards to reduce the length. This might impact the inflation received on the toes and other parts of the foot.

There are different sizes available for the garment. For the sizing chart, visit our website AriaHealth.com and contact customer support if you need a different size.

Using your garment adjusters

Each Aria Free system comes with seven (7) adjusters, one for each tab. There are two reasons to use the adjusters:

1. Extension: To extend the self-fastening tabs in cases where the pneumatic garment does not wrap around the entire leg. See the diagram below. Once you have attached the adjusters, follow the instructions found in the section *Wearing your garment* to achieve a good fit. NOTE: Only attach the adjusters to the tabs which need extension.



2. Tightening: To tighten areas where necessary, two methods can be employed:
 - a. After fitting the garment, simply attach the adjusters on top of the garment where you need a tighter fit; or
 - b. Before fitting the garment, attach the adjusters to the self-fastening tabs as described in the method for extension. NOTE: you can adjust where the adjusters are hooked to control how much fabric is wrapped around the leg.

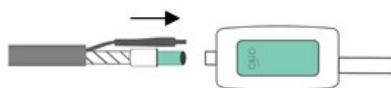
Your adjusters may have covers on one side of the self-fastening tabs:

1. For extension: Keep the cover on to ensure the self-fastening tab does not come into contact with exposed skin.
2. For tightening: Remove the cover to expose both self-fastening tabs if the method 2a is used. Otherwise, keep the cover.

Note: The covers are not designed for repetitive use.

Connect the garment

1. Connect the green end of the air line and the electrical line to the garment connection point as shown on the right.



2. The garment connection point should look as shown on the right.

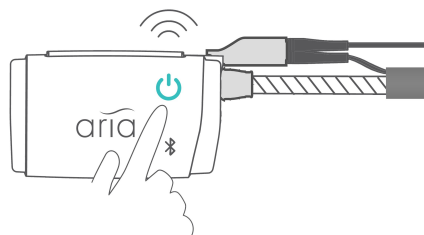


Using therapy

Once all the connections have been made, you are ready for therapy

Start therapy by pressing the Start/Stop button.

Stop therapy by pressing the Start/Stop button or wait until therapy session completes.



Therapy session

One full therapy session will take sixty (60) minutes. Once you press the Start/Stop button, a pre-inflation cycle will commence for around 30 seconds during which different parts of the garment will slightly inflate. After the pre-inflation cycle, therapy will commence. You will feel the garment inflate starting from the foot, and gradually progressing up to the thigh. Once the garment is fully inflated, it will gradually deflate starting from the thigh, and continuing down to the foot. This cycle repeats until the end of the therapy.

Please consult with your therapy provider for recommended therapy treatment schedule.

Using the therapy pause feature

Therapy Pause is a comfort and convenience feature. It is designed to allow you to temporarily pause therapy and disconnect the garment from the air pump. This gives you the freedom to step away from therapy without having to completely remove the garment, and then resume therapy where you left off. This is useful should you need to answer the door, etc.

To use the Therapy Pause feature, simply press the Start/Stop button once or disconnect the green end of the air line from the garment connection point. The device will turn off when you do this. Once the device is stopped, you will be able to disconnect the connector tube from the garment (if not done so already) and walk around freely.

If you return within 30 minutes, reconnect and press the Start/Stop button, to resume therapy from where you left off. Otherwise, it will reset and start again.

Ending therapy

Once your full therapy session is complete, the air pump will stop inflating and a green light will appear on the indicator light above the power button. You can then follow the below steps:

1. Remove the garment from your leg.

2. Leave the garment with the tube and air pump connected for at least 5 minutes. This will allow for some (but not all) air to be removed from your garment.
3. If you would like to store for routine use, simply disconnect the connector tube from the garment and unplug the power supply unit from the air pump.
4. Alternatively, if you would like to store your system for travel, please refer to the *Removing air from your garment* section to make the garment more compact.

CAUTION

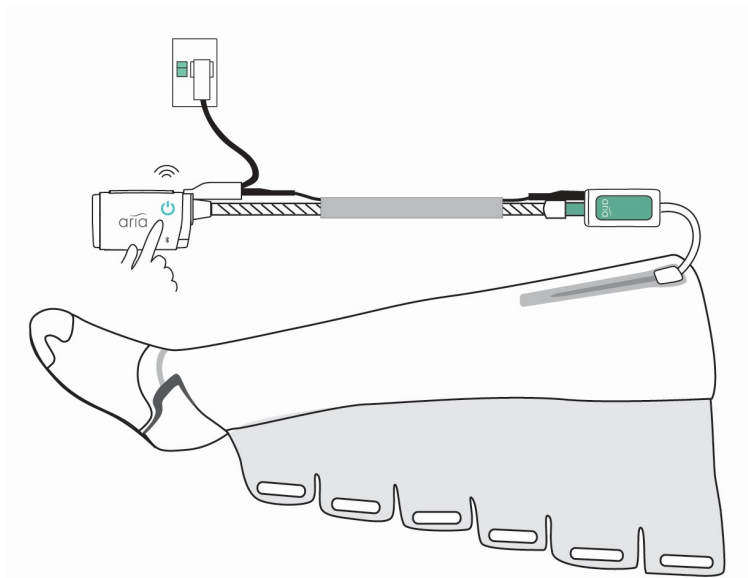
Do not disconnect the electrical line from the power connection point when disconnecting. In the event the cable comes out, insert it back into the same side of the power connection point as illustrated in the below diagram.



Removing air from your garment

A deflation mode is available in your Aria Free system. It is designed to allow you to remove trapped air from the garment. Follow the below steps to enter this mode and use it.

1. Connect your device as you would for therapy. However, leave the garment tabs unfastened.



2. Press the start/stop button and hold for five seconds. Once the LED starts flashing white and green, let your finger off the button.
3. Leave the garment connected for five (5) minutes. Air will gradually escape. The LED on the device will automatically stop flashing once the deflation mode has finished.

NOTE: Not all air will escape from the garment.

Using your system with the **Aria: Lymphedema Management** app



Your Aria Free system can be used with or without the **Aria: Lymphedema Management** app by Aria Health. The app will help keep yourself accountable by providing a timer of your therapy session and tracking your usage against a personal goal over time. It also provides a platform to log how you and your limb feels each day and tracks other aspects of your therapy to understand what works and what doesn't. When you open the app for the first time, you will see instructions on how to pair the app with your system. Data sent via Bluetooth is encrypted to protect your privacy.

Connecting your system and smart device

Before connecting the Aria Free system to a smart device, ensure that the latest version of the **Aria: Lymphedema Management** app is installed on the smart device. If not, download the app from the Apple App Store® or Google Play™ store. The following QR code will take you directly to the app:




1. Ensure your Aria Free pump is set up correctly and plugged in to a power source.
 2. On your smart device, enable Bluetooth.
 3. Open the **Aria: Lymphedema Management** app.
 4. Create an account by selecting "Sign up Now" and fill the requested information.
 5. To use the app, you will need to accept Aria Health's terms of use and privacy policies. You will also have the option to allow Aria Health to use analytics to improve the app experience.
 - a) To accept Aria Health terms of use and privacy notice, select that check box.
 - b) To allow Aria Health to use analytics, select the 'use analytics to improve my experience' and 'I agree to allow the Aria App to upload my data to the cloud'. If you decide not to check these boxes during the first use of the app, you can enable this later from the *Settings* page.
- NOTE: There are links provided that will take you to documents that describe these policies in detail. Links to the privacy policy and terms of use are always available from the *Settings* page.
6. Once selections are complete, tap *Sign Up*.




7. Next you will be provided the option to enroll in a coaching program. If you sign up and provide your email address, we will send you helpful tips for successful therapy. If you decide not to enroll at this time, you can enroll at any time from the *Settings* page. You also have the option to allow Aria Health to use your email address to send you updates on our products. Once you have completed this screen, tap *Next*.
8. You will be taken through a series of short videos that will describe how to connect and power up your Aria Free system, as well as properly fit your garment. If you want to revisit these setup videos later, they are available on the *Help Bar* page under 'Aria Setup'.
9. Now we will establish connection between your smart device and the Aria Free pump.
 - a) On your Aria Free pump, press the Bluetooth button  when prompted by the app.
 - b) When the light starts to flash blue , Bluetooth is enabled on your Aria Free machine and ready to connect.
 - c) On your smart device, tap *Connect*.
 - d) The first time you pair your Aria Free system with your smart device, it will prompt you to allow Aria Free to connect with your phone's Bluetooth, select *Allow*.
 - e) When your Aria Free system is discovered, the system name appears in the system selection list.
 - f) To connect, select the system name from the list.

- g) On your smart device, tap *Connect*.
- h) The first time you pair your Aria Free system with your smart device, you will need to perform the authentication procedure.
- i) When prompted by the app, authenticate by entering the four-digit key located on the back of the Aria Free pump.

10. Tap *Done*.

When successfully connected, the light on your device  will be a solid blue and it will take you to the *Therapy* page.

Bluetooth status indicators

	Bluetooth indicator light is flashing blue.	Your machine is in discoverable mode and ready for pairing.
	Bluetooth indicator light is constantly blue.	Your machine is connected to your smartphone.
	Bluetooth indicator light is constantly white (airplane mode).	Bluetooth on your machine is disabled.
	Bluetooth indicator light is off.	Your machine is not connected to your smartphone.

Note: Once therapy starts, the indicator light will start to fade.

Cleaning and maintenance

It is important that you regularly clean your Aria Free system to make sure you receive optimal therapy. The following sections will help you with disassembly, cleaning and checking your machine.

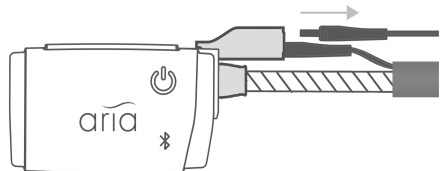
The air pump has an expected life of five years based on normal daily usage. Please contact customer support if any deterioration in air pump performance (e.g. failure to inflate air chambers) is observed.

The garment life will depend largely on your usage and maintenance. For a longer useful life, please ensure the cleaning instructions below are observed.

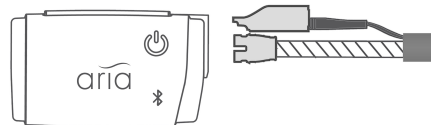
Disassemble your system to prepare for cleaning

Disconnect the air pump

1. Unplug the power supply unit from the wall power outlet and power connection point.

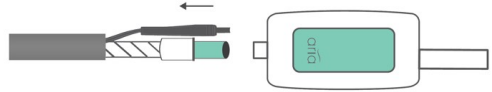


2. Detach the connector tube from the air pump.



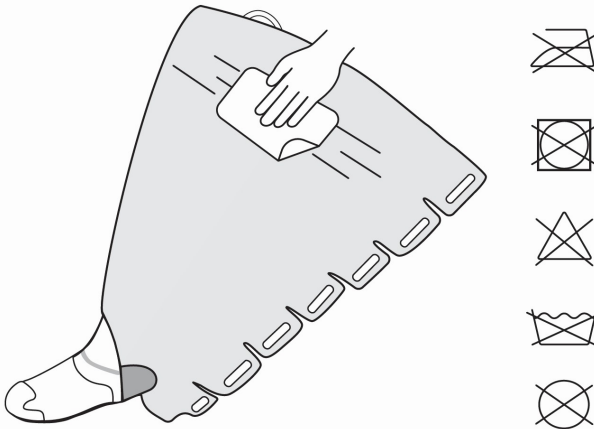
Disconnect the garment

Disconnect the connector tube from the garment connection point.



Remove the garment

1. Loosen the self-fastening straps.
2. Remove your limb from the garment.
3. Flatten the garment for cleaning by opening all of the self-fastening straps and placing the garment on a flat surface (with the side you want to clean facing up).



WARNING

- As part of good hygiene, always follow cleaning instructions. Some cleaning products may damage the equipment and affect its function, or leave harmful residue that could irritate the skin.
- Regularly clean, *but do not launder*, your Aria Free garment, following the detailed instructions provided below. This ensures you receive optimal therapy, prevents the growth of germs that can adversely affect your health, and avoids damaging the electronics embedded within the garment.

CAUTION

- If any visible deterioration of a system component is apparent (cracking, discoloration, tears, breaks in tubing etc.), the component should be replaced.
- If the garment is damaged (rips, tears in fabric or tubing) or has become excessively soiled and the soiling cannot be cleaned, it is recommended that the garment be replaced. Please contact customer support for a replacement garment.

Cleaning and replacing parts

Cleaning the air pump, garment connection point and connector tube

Wipe the exterior of the components with a dry cloth as necessary. If there are stains or marks on the connector tube and/or the garment connection point, you may wipe with a damp cloth using water and a mild liquid detergent (for example Ultra Joy™ Dishwashing Liquid), immediately followed by a dry cloth to remove any dampness.

Cleaning the garment and adjusters (including cover)

- Wipe clean the interior of the garment and adjusters with a damp cloth each week:
 - Using a clean cloth, lightly moisten it with warm water to dampen. Mild liquid detergent may be used to address difficult soiling (for example Ultra Joy Dishwashing Liquid).
 - Wipe clean the interior surface of the garment and adjusters using the lightly dampened cloth.
 - Leave to dry completely before reusing.
- Do not use bleach, chlorine, alcohol, cleaners or solvents as these may damage the garment and adjusters.
- Spot clean the grey cable connecting the garment connection point and garment, as well as outside of the garment periodically using a similar process.



CAUTION

Do not put the garment and adjusters through the washing machine or dryer cycle.

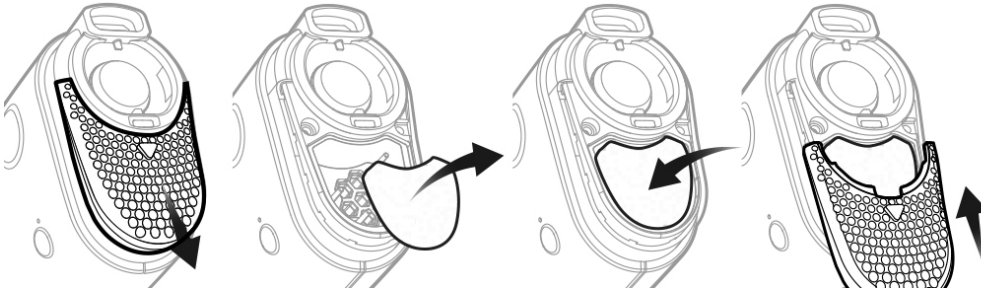
Change the Air pump filter

Replace the filter at least every 6 months. It cannot be washed.

Check and replace it more often if there are any holes or blockages caused by dirt or dust.

To change the filter:

1. Slide the filter cover off and remove the old filter.
2. Insert a new filter and replace the filter cover.



Notes:

- Make sure the filter cover is fitted at all times to prevent water and dust from entering the machine.

Traveling



You can take your Aria Free system with you wherever you go. It has a universal power supply that will accept voltage standards across the world. However, make sure you have the appropriate power plug adapter for the region where you will be traveling. Please contact us or visit our website for official Aria Free travel accessories.

Traveling by air

For some airlines, medical devices do not count toward carry-on luggage limits. Please check with your airline for their policy regarding medical equipment.

You can use your Aria Free system on a plane as it meets the Federal Aviation Administration (FAA) requirements. An air travel compliance letter can be downloaded and printed from AriaHealth.com.

If your air carrier does not allow for Bluetooth devices during flight, you can take the following steps to still receive therapy:

1. Connect the air pump to power.
2. Disable Bluetooth (enter airplane mode) by pressing and holding the Bluetooth button  for at least ten seconds, until the indicator light is white.
3. Use the Start/Stop button  on your machine to start therapy.
4. To reconnect Bluetooth (exit airplane mode), press the Bluetooth button.

Troubleshooting

If you have any problems, consult the following troubleshooting topics. If you are not able to fix the problem, contact customer support. Do not try to open the machine.

Problem/possible cause	Solution
Air pressure in my garment seems too low / It feels like I am not getting enough air.	
Initial air pressure is still building.	At the start of therapy, the garment takes a few minutes to fill with air. After 1-2 minutes, therapy should begin at the prescribed pressure.
Air pump filter might be blocked.	Inspect the air pump filter for blockages or damage. Refer to Cleaning and Maintenance section for more information.
Air line may be kinked.	Inspect the air line of the connector tube, and the connector from the garment connection point to the garment. Remove any kinks and try starting the air pump again.
Size of the garment may be too big.	Please contact customer support, several sizes are available for the garment.

Problem/possible cause	Solution
I cannot start therapy.	
Power may not be connected.	<p>Connect the power supply unit and make sure the plug is fully inserted. The green indicator light on the power supply unit should be illuminated.</p> <p>Check that the green indicator light above the Start/Stop button on the pump is also illuminated.</p> <p>Check that the connector tube is inserted correctly</p>
My therapy has stopped.	
The air line may be disconnected.	Ensure that the air line is properly connected. Press the Start/Stop button to continue therapy.
There may be damage to the air line.	Inspect the connector tube for any damage (cracks, tears, breaks). If the tubing is damaged, do not attempt to repair it. Please contact customer support for a replacement connector tube.
There may be damage to your garment.	Inspect the garment for damage (rips, tears in fabric). If damage is visually apparent, it is recommended that the garment be replaced. Please contact customer support for a replacement garment.
My garment does not fit properly	
The self-fastening tabs of the garments and/or the adjusters may not stick properly.	If the self-fastening tabs do not stick, it is recommended that the garment and/or the adjusters be replaced. Please contact customer support for a replacement garment and/or replacement adjusters.

Problem/possible cause	Solution
Garment may be the wrong size.	Please contact customer support, several sizes are available for the garment.

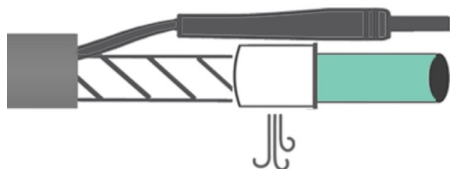
The covers on the adjusters are no longer sticking to the self-fastening tabs.

The covers have been detached too many times from the self-fastening tabs. Please contact customer support.

Noise or airflow coming from the tube.

A small amount of airflow near the green connector is intentional and necessary.

If a large amount of air is coming out from another location, please contact customer support.



The Bluetooth indicator light is constantly white. I cannot pair to my machine.

Bluetooth is disabled.

Press the Bluetooth button for 3 seconds. When the Bluetooth indicator light flashes blue, the machine is ready for pairing.

The light above the Start/Stop button is flashing green.

An error has occurred on the machine.

Unplug your machine. Wait a few seconds and then plug it back in.

If the problem persists, contact customer support. Do not open the machine or attempt to service it on your own.

General warnings and cautions

WARNING

- Keep the power cord and plug away from hot surfaces and make sure it is in good condition and the equipment is not damaged.
- If you notice any unexplained changes in the performance of the system, hear the machine making unusual sounds, you drop or mishandle the machine or the power supply unit, or notice that the enclosure is broken, discontinue use and contact customer support.
- Do not open or modify the system. There are no user-serviceable parts inside. Repairs and servicing should only be performed by an authorized Aria Health service agent.
- Beware of electrocution. Do not immerse the air pump, garment, power supply unit, or power cord in water. If liquids are spilled into or onto the system, unplug the system and let the parts dry. Always unplug the system before cleaning and make sure that all parts are dry before plugging it back in.
- Do not perform any maintenance tasks while the system is in operation.
- The use of accessories other than those specified for the system is not recommended. It may result in increased electromagnetic emissions or decreased immunity of the system and result in improper operation.
- Keep space around the device clear of other equipment. If the device must be used adjacent or stacked on top of other equipment, observe the system to confirm that it is operating normally.
- The system is not intended to be operated by persons with reduced physical, sensory or mental capabilities without adequate supervision by a person responsible for the patient's safety.
- The system is not intended to be operated by children under the age of 18.
- The system has not been tested or certified for use in the vicinity of X-ray, CT or MRI equipment. Do not bring the system within 13' ft (4 m) of X-ray or CT equipment. Never bring the system into

an MR environment.

CAUTION

- Use only Aria Health parts and accessories with the system. Non-Aria Health parts may reduce the effectiveness of the treatment and/or damage the machine.
- Blocking the vent module on the tubing and/or air filter cover of the machine while in operation could lead to overheating of the machine.
- Keep the area around the system dry, clean and clear of anything (e.g. clothes, pillows or bedding) that could block the air filter cover or cover the power supply unit.
- Do not use bleach, chlorine, alcohol, or aromatic-based solutions, moisturizing or antibacterial soaps or scented oils to clean the system. These solutions may cause damage and reduce the life of the products.
- The Aria Free garment is intended for single-patient use. Do not share/exchange garments with another patient.
- Do not insert any USB cable into the system or attempt to plug the power supply unit into a USB device. This may cause damage to the system or USB device.
- Do not operate the device at altitudes, temperatures and humidity levels outside the specified operating environment conditions. Extreme altitudes, temperatures, and humidity levels may compromise the system performance.

Technical specifications

System	
Pressure	At sea level: 0 - 45 mmHG (Single Fault: < 70 mmHG) From 0 to 1250 m: 0 - 35 mmHG From 1250 m to 2591 m: 0 - 32 mmHG <u>Note:</u> up to 2591 m, delivered therapy is still effective.
Materials	Flame-retardant engineering thermoplastic
Operating temperature	+41°F to +95°F (+5°C to +35°C) <u>Note:</u> Under extreme ambient temperature conditions (104°F/40°C) the tubing near the garment may reach temperatures up to 109°F/43°C. These parts of the tubing are not in contact with the user and machine remains safe under these extreme conditions.
Operating humidity	5 to 95% relative humidity, non-condensing
Operating altitude	Sea level to 8,500' (2,591 m); air pressure range 1,013 hPa to 738 hPa
Storage and transport temperature	-4°F to +140°F (-20°C to +60°C)
Storage and transport humidity	5 to 95% relative humidity, non-condensing
Power Supply Unit	
Input range	100-240V, 50-60Hz, 0.5-0.3A or 115V, 400Hz, 0.4A
Output	24 V DC
Typical power consumption	19 W
Power Connection Point	
Materials	Flame retardant thermoplastic
Length	5.9ft (1.8M)
Pump	
Dimensions	5.4" (W) x 3.3" (D) x 2.1"(H) 136 mm (W) x 84 mm (D) x 52 mm (H)
Weight	10.6 oz (300 g)
Air Line	

Materials	Flexible plastic
Length	6.2ft (1.9M)
Garment	
Materials	Textured polyester (outer and inner layer) TPU (air chambers) Dow Corning (silicone tubing to connect with air chambers)
Electromagnetic compatibility	
<p>The Aria Free system complies with all applicable electromagnetic compatibility requirements (EMC) according to IEC60601-1-2:2014, for residential, commercial and light industry environments. Portable and mobile RF communications equipment should be used no closer to any part of the machine, including cables, than the recommended 10cm (3.94in) separation distance. The Aria Free system has been designed to meet EMC standards. However, should you suspect that the machine performance (e.g. pressure or flow) is affected by other equipment, move the machine away from the possible cause of interference.</p> <p>This device complies with the FCC radiation exposure limits set forth in an uncontrolled environment.</p> <p>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:</p> <ul style="list-style-type: none"> • 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. <p>Any change or modification to the product is not expressly approved by Aria Health and could void the user's authority to operate the device.</p> <p>FCC ID: QOQBT121, IC: 5123A-BGTBT121</p>	
Aircraft use	














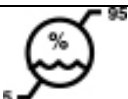
Aria Health confirms that machine meets the Federal Aviation Administration (FAA) requirements (RTCA/DO-160, section 21, category M) for all phases of air travel.	
Wireless technology	
Technology used:	Bluetooth
Connection types:	SPP, iAP2, GATT
Frequency:	2402 to 2480 MHz
Max RF power output:	+4 dBm
Operating range:	33ft (10 m) (Class 2)
It is recommended that the pump is at a minimum distance of 0.43" (1.1cm) from the body during operation. Not applicable to garment, air tubing or accessories.	
IEC 60601-1 (Edition 3.1) classification	
Class II (double insulation), Applied Part Type BF, Ingress protection IP22 (Protected against access to hazardous parts with a finger or solid foreign objects of greater than 12 mm diameter, and protected against vertically falling water drops when tilted up to 15 degrees).	
Design life	
5 years	
<ul style="list-style-type: none"> • Controller/pump: based on daily usage of up to 1 hour per day • Pneumatic Garment: based on continued cleanliness 	
General	
The patient is an intended operator.	
The applied part is the pneumatic garment.	

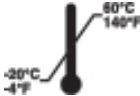











Notes:





- The manufacturer reserves the right to change these specifications without notice.
- This product is not made with natural rubber latex.

Symbols

The following symbols may appear on the product or packaging.

Symbol	Description
	Read instructions before use (IEC 60601-1)
	Indicates a warning or caution (IEC 60601-1)
	Follow instructions before use (IEC 60601-1)
	Manufacturer. (ISO 15223-1)
	European Authorized Representative (ISO 15223-1)
	Batch code (ISO 15223-1)
	Catalog number (ISO 15223-1)
	Serial number (ISO 15223-1)
	Device number
	On / Off. (IEC 60601-1)
IP22	Protected against finger sized objects and against dripping water when tilted up to 15 degrees from specified orientation (IEC 60601-1-11)
	Direct current (IEC 60601-1)
	Type BF applied part(IEC 60601-1)
	Class II equipment (IEC60601-1)
	Humidity limitation (ISO 15223-1)

Symbol	Description
	Temperature limitation (ISO 15223-1)
	Non-ionising radiation (IEC60601-1-2)
	Bluetooth (Bluetooth Brand guide)
Rx Only	Prescription only (In the US, Federal law restricts these devices to sale by or on the order of a physician) (21 CFR 801)
	Operating altitude
	Atmospheric pressure limitation (ISO 15223-1)
	Complies with RTCA DO-160 section 21, category M.
	MR unsafe (do not use in the vicinity of an MRI device) (ASTM F2503)
	Replace 30 days after opening.
	Do not use if package is damaged. (ISO 15223-1).
	Not made with natural rubber latex.
	Do not iron.
	Do not tumble dry.

Symbol	Description
	Do not bleach or treat with chlorine.
	Do not wash.
	Do not dry clean.
	Environmental information (EU directive 2012/19/EE Waste Electrical and Electronic Equipment (WEEE)).

See symbols glossary at [ResMed.com/symbols](https://www.resmed.com/symbols).

If you need information on these disposal systems, please contact your local waste administration. The crossed-bin symbol invites you to use these disposal systems. If you require information on collection and disposal of your Aria Free system please contact customer support.

Servicing

The Aria Free system is intended to provide safe and reliable operation when operated in accordance with the instructions provided by Aria Health. Aria Health recommends that the user contact customer support if there is any sign of wear or concern with device function. Otherwise, service and inspection of the products generally should not be required during their design life.

How to contact Aria Health:

- By phone: 866-647-0691
- By email: support@ariahealth.com

If you have a medical question, please contact your healthcare provider.

Limited warranty

Aria Health warrants that your Aria Free product shall be free from defects in material and workmanship from the date of purchase for the period specified in the following table:

Product	Warranty period
<ul style="list-style-type: none">• Accessories• Adjusters	90 days
<ul style="list-style-type: none">• Air pump (including external power supply unit)• Pneumatic garment• Connector tube	2 years

This warranty is only available to the initial consumer. It is not transferable.

If the product fails under conditions of normal use, Aria Health will repair or replace, at its option, the defective product or any of its components.

This Limited Warranty does not cover: a) any damage caused as a result of improper use, abuse, modification or alteration of the product; b) repairs carried out by any service organization that has not been expressly authorized by Aria Health to perform such repairs; and c) any damage or contamination due to cigarette, pipe, cigar or other smoke.

Warranty is void on product sold, or resold, outside the region of original purchase. Warranty claims on defective product must be made by the initial consumer at the point of purchase.

This warranty replaces all other expressed or implied warranties, including any implied warranty of merchantability or fitness for a particular purpose. Some regions or states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.

Aria Health shall not be responsible for any incidental or consequential damages claimed to have resulted from the sale, installation or use of any Aria Health product. Some regions or states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from region to region. For further information on your warranty rights, customer service.

Guidance and manufacturer's declaration electromagnetic emissions and immunity

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in this document.

Guidance and manufacturer's declaration—electromagnetic emissions

This device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that the device is used in such an environment.

Emissions test	Compliance	Electromagnetic environment — guidance
RF emissions CISPR 11	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	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

This device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that the device is used in such an environment.

Immunity test	Compliance level	Electromagnetic environment — guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	100 V 240 V	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during mains power interruptions, it is recommended that the device be powered from an uninterruptible power source.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Conducted RF IEC 61000-4-6	10 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	9 V/m to 85 V/m at frequencies up to 5.785 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the machine, including cables, than the recommended 10cm (3.94in) separation distance.

Further information

If you have any questions or require additional information on how to use the Aria Free system, contact customer support at:

+1 866-647-0691

MANUFACTURER: Inova Labs Inc.



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TEL: +1 (866) 647-0691
EMAIL: support@ariahealth.com

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