KOYA MEDICAL ®

Koya

Dayspring®

Directions for Use

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Getting Started with Dayspring

Read this entire guide before using your device.

The Dayspring active wearable compression system is designed for the treatment of lymphedema, chronic edema, venous insufficiency, and the reduction of wound healing time. The system can be used in a home or clinical setting and is designed to allow mobility during treatment.

The optional Koya app allows you to work with your provider to individualize your treatment settings and track your usage.

Contact Koya Medical

- By phone: **+1 (415) 209-5035**
  Monday–Friday, 8 a.m.–6 p.m. PT

- By email: **support@koyamedical.com**

Indications for Use

U.S. federal law restricts this device to sale by or on the order of a licensed healthcare professional.

Consult your physician or healthcare provider for recommendations regarding your treatment plan duration and frequency of use. Use this product only in a manner consistent with the directions provided.

Dayspring is a prescription-only wearable compression system that is intended for use in a clinic or home setting by medical professionals and patients who are under medical supervision to increase lymphatic flow in the treatment of many conditions such as:

- Lymphedema
- Primary lymphedema
- Post mastectomy edema
- Edema following trauma and sports injuries
- Post immobilization edema
- Venous insufficiency
- Reducing wound healing time
- Treatment and assistance in healing stasis dermatitis, venous stasis ulcers, or arterial and diabetic leg ulcers
- Lipedema
- Phlebolymphedema

Dayspring delivers active compression, designed to provide mobility and movement for patients.

Contraindications & Warnings

The Dayspring system should not be used if you have one or more of the following conditions:

- Pulmonary edema
- Thrombophlebitis
- Congestive heart failure
- Deep vein thrombosis
- Episodes of pulmonary embolism
- Infections and inflammations
- Uncontrolled systemic disease
- Severe peripheral artery disease
- Conditions in which increased venous and lymphatic return is undesirable

⚠ WARNING: Risk of Electric Shock

- Do not touch metal contacts on the connectors.
- Do not use the device near water, while bathing, or in a wet environment.
- Unplug the Charging Cable when not in use.
- Do not attempt to open, tamper with, disassemble, or service the device.

⚠ WARNING: Risk of Personal Injury

- Always wear the provided liner or lightweight, loose-fitting clothing when using this device.
- Only apply the device in a manner consistent with the directions in this document.
- Do not use the device while driving, operating machinery, or during any activity that may put the device user at undue risk of injury.
- Persistent use of the device in the presence of skin irritation may cause injury.
- Keep all components away from wet and hot surfaces.
- Strangulation hazard: Cables should never be placed near or around children or around a person's neck.
- Do not use the device if it is not working properly, if it is damaged, or if it has been dropped in water.
- Do not place device within reach of children.
- Do not use the device outside of the specified temperature, humidity, and atmospheric pressure ranges.
- Never place Garments in direct contact with open wounds.
- Keep cables out of your walking path to prevent tripping

⚠ CAUTION: Risk of Device Damage

- Do not use devices that can generate high heat such as irons or blow dryers near the Dayspring system.
- Do not attempt to wash the Garment.
- Do not place objects more than five pounds in weight onto the carrying case.

- Do not attempt to forcibly bend your limb when wearing the Garment.

Introduction

Dayspring is a calibrated non-pneumatic active compression system designed to stimulate the body's superficial and deep lymphatic system and provide mobility and portability while helping you manage your chronic condition.

The system consists of a Controller and a Garment with programmable compression segments. When properly used, the Dayspring system creates a calibrated pressure gradient that compresses sequentially in distal (away from the center of the body) to proximal (nearer to the center of the body) directions to help you move and drain excess lymph fluid.

Your Dayspring system comes with the following:

- One Directions for Use
- One Quick Start Guide
- One Programmable Controller
- One Segmented Garment, sized to measure
- Accessories (static compression liners and Charging Cable)
- An optional Koya app, which can be downloaded from the Apple App Store or Google Play Store
- One Carrying Case

For the most up to date directions for use, visit **www.koyamedical.com/dayspring-directions**

Controller

Charging the Controller

Before using the system for the first time, fully charge the Controller. Plug the Charging Cable into a wall outlet and into the Controller. A full charge takes approximately three (3) hours. The battery indicator light on the Controller will flash orange when charging and turn to solid green when fully charged. Unplug the Charging Cable from the Controller after it has fully charged.

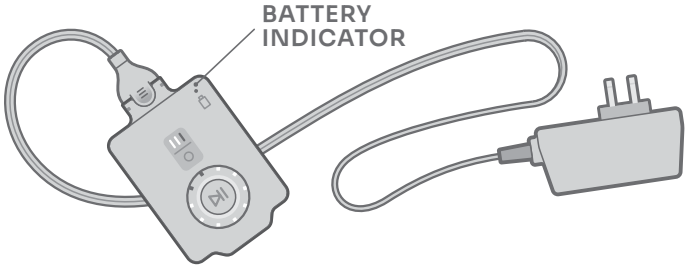


Figure 1. Connecting Controller to Charging Cable.

Note: The Controller will be in a deep sleep mode when you first receive it, and you must charge it prior to first use.

Selecting Treatment Intensity

If the Controller is off, press any button to wake it. Press the intensity button to toggle between preprogrammed treatment pressure settings. A single lit left dot indicates low intensity, a double dot indicates medium intensity (default), and a triple dot indicates high intensity.

Figure 2. Toggle between pressure settings with the intensity button.

Note: Your healthcare provider will determine what intensity setting is appropriate for you.

Starting Treatment

Your Dayspring system comes with a Garment that is sized for you. Once the Garment is properly donned, connect the Garment to the Controller. For donning instructions see Upper Extremity or Lower Extremity Care sections.

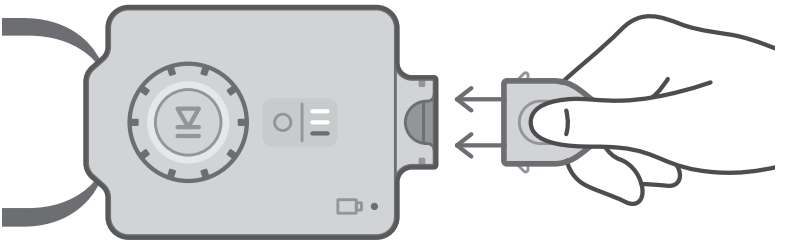


Figure 3. Connecting Controller to the Garment.

If the Controller is off, press any button to wake it. Press the button marked with the play/pause symbol once to start treatment. An illuminated light ring will appear, indicating that the treatment has started and is delivering active compression. The light ring counts down to reflect how much time is remaining for the current treatment session.

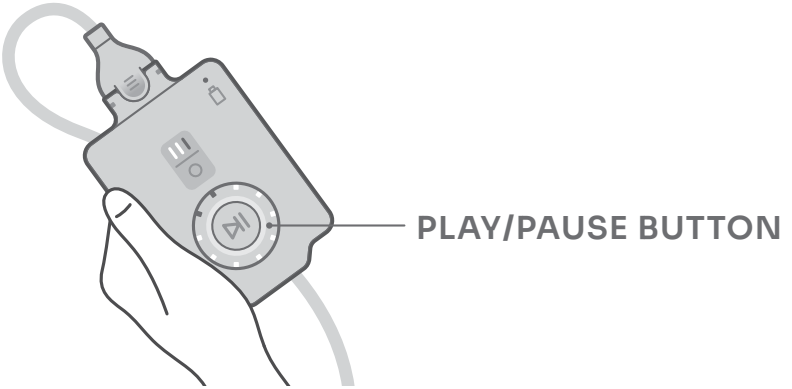


Figure 4. Start, pause, and end treatment using the play/pause button.

Note: If you attempt to start treatment but the Garment is not attached to the Controller, the status indicator light will flash orange and the Controller will vibrate. Ensure the Garment is properly attached to the Controller prior to starting treatment.

Note: There is a decongestion phase at the start of each session so that your limb is ready to receive treatment. This phase lasts 3 minutes, and you will feel compression only in the proximal portion of your limb during that time.

Pausing & Resuming Treatment

When a treatment session is active, press the play/pause button to pause the treatment at any time. While treatment is paused, the pressure intensity can be changed by pressing the intensity button or through the Koya app. Press play/pause button again to resume treatment.

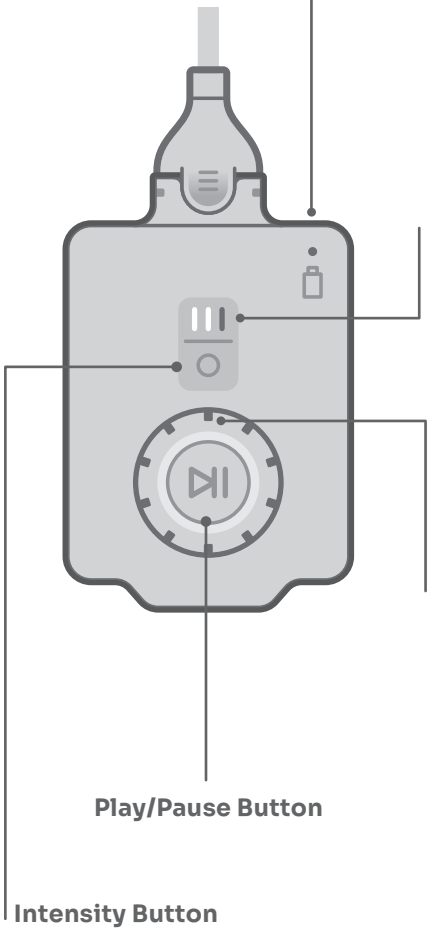
Note: The system will remain paused for a maximum of ten (10) minutes before it turns off.

Completing Treatment

Each session will automatically end after sixty (60) minutes. At the end of treatment, the Controller will vibrate to indicate the session is complete. To manually end treatment at any time press and hold the play/pause button for three (3) seconds.

Note: Perform the treatment for at least sixty (60) minutes a day or as prescribed by your healthcare provider.

Controller Summary



Battery Indicator

- Green: Fully charged
- Orange: Low battery
- Flashing Orange: Charging or critically low battery
- Purple: Charging error (refer to Troubleshooting section)

Intensity Indicator

- 1 Bar: Low Intensity
- 2 Bars: Medium Intensity
- 3 Bars: High Intensity
- Middle Bar Only: Custom settings activated through the Koya app.

Status Indicator

- Light ring counts down remaining treatment time
- Light ring flashes when treatment is paused
- Single blue light means Dayspring is ready to pair to the Koya app via Bluetooth
- Single flashing orange light appears when the Garment is not connected.
- Solid red light appears when there is a system error (refer to Troubleshooting section if this occurs)

Upper Extremity Care

Preparing the Liner

Place the gauntlet on your hand. Then slide your arm through the liner and pull it up toward your shoulder to make sure it's completely unwrapped and smooth, as shown below.

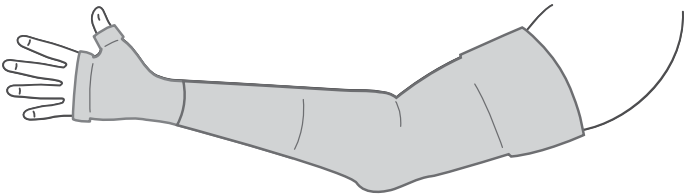


Figure 5. Gauntlet and arm liner are worn on the hand and arm.

Arm Garment

Use the adjustable straps to form the Garment into a loose cone shape. Make sure the smaller wrist end of the cone is facing away from you. Slide your arm through the cone. The Garment should cover your arm completely. Adjust the straps to ensure a tight but comfortable fit from the wrist up to the shoulder. Make sure there are no major gaps in the Garment and adjust as necessary.

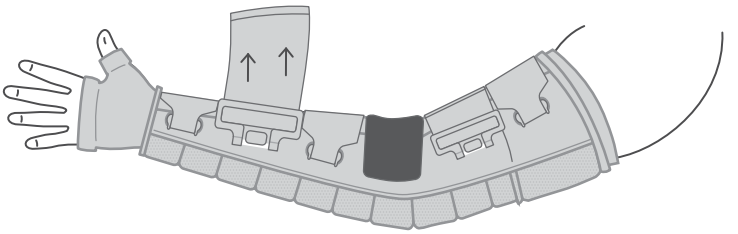


Figure 6. Adjust straps to ensure a snug fit.

When the garment is properly donned, the breathable mesh should be positioned along the outer bend of your elbow, while the straps are on the inner side. Do not forcibly bend your elbow. If additional range of motion is needed the strap at the elbow can be adjusted or loosened.

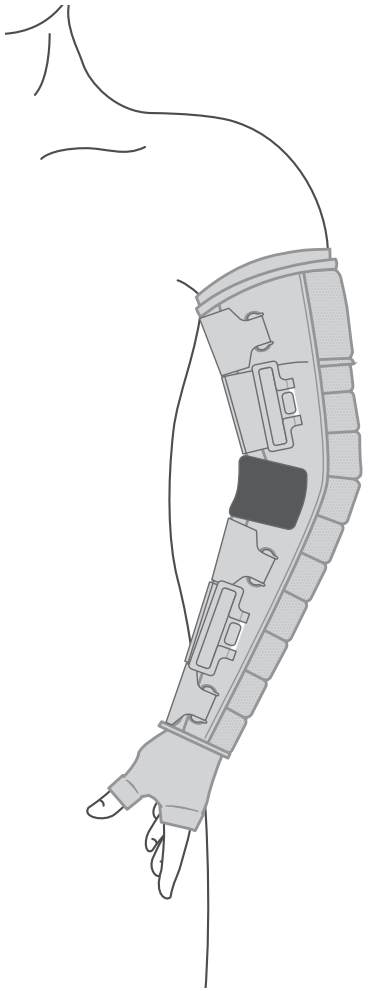


Figure 7. Garment properly donned on arm.

Treatment

The connector that goes to the garment will be connected when you receive it, but is removable. Ensure that this cable is attached before starting treatment.

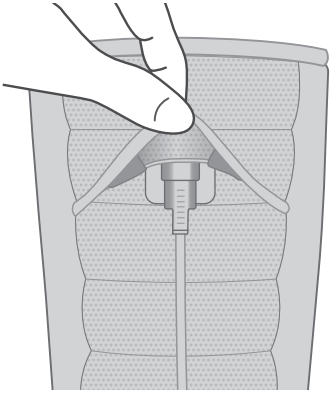


Figure 8. The cable connected to the Garment.

Connect the Garment to the Controller and press the play/pause button to begin treatment.

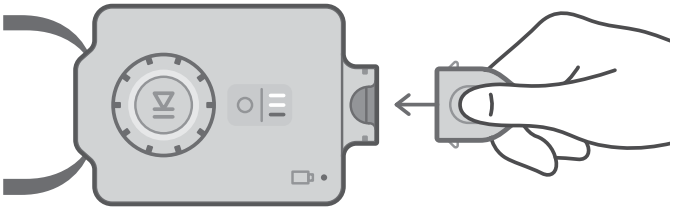


Figure 9. Connecting the Garment to the Controller.

Completing Treatment

Once complete, disconnect the Garment from the Controller. To remove the Garment, loosen all straps and slide the Garment off your arm. You can also detach the buckles to help remove the Garment if needed.

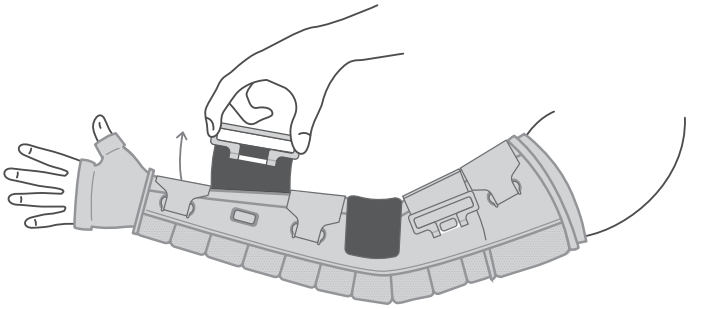


Figure 10. If needed, detach buckles to remove Garment.

Finish by removing the liners. Charge the Controller after each session. When not in use, store components of the Dayspring system in the provided carrying case.

Lower Extremity Care

Preparing the Liner

A compression sock and/or footwrap will be provided with your system. The use of these accessories is optional. Pull the sock over your foot and extend it up until it is fully unrolled and smooth. An additional liner is also included. If using, put your leg through the liner after putting on the sock, and pull it upward toward your hip until it is completely unrolled and smooth. The liner is intended to provide a fabric barrier between the Garment and your skin and can be left off if wearing Dayspring over lightweight pants.

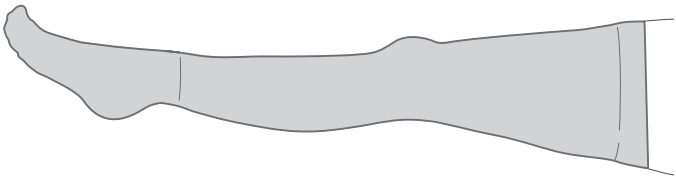


Figure 11. Sock and liner are worn on the foot and leg.

Full Leg Garment

Ready the Garment by ensuring that the smaller end is facing away from you. Align the center of the Garment, where there is a white circle, with your knee cap and wrap the knee strap around your leg to hold the Garment in place. Starting at the ankle, attach the buckle to the hook on the opposite side of Garment. Adjust the straps to ensure a tight but comfortable fit from the ankle up to the hip. Make sure there are no major gaps in the Garment and adjust as necessary.

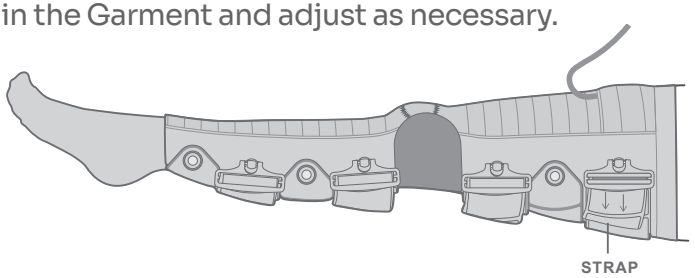


Figure 12. Adjust straps to ensure a snug fit.

Lower Leg Garment

Ready the Garment by ensuring that the smaller end is facing away from you. Align the top of the Garment just below your knee. Starting at the lowest strap, attach the buckle to the hook on the opposite side of Garment. Adjust the straps to ensure a tight but comfortable fit from the ankle up to the knee. Make sure there are no major gaps in the Garment and adjust as necessary.

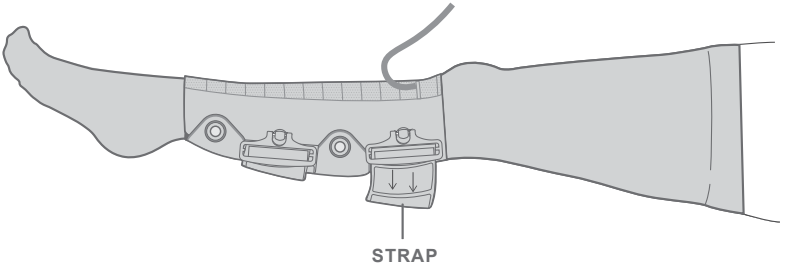


Figure 13. Adjust straps to ensure a snug fit.

Y-Connector

If you have a bilateral prescription and received a y-connector with your garments, you are able to treat both extremities at once. Ensure that the Y-connector is securely connected to the controller and each garment as shown.

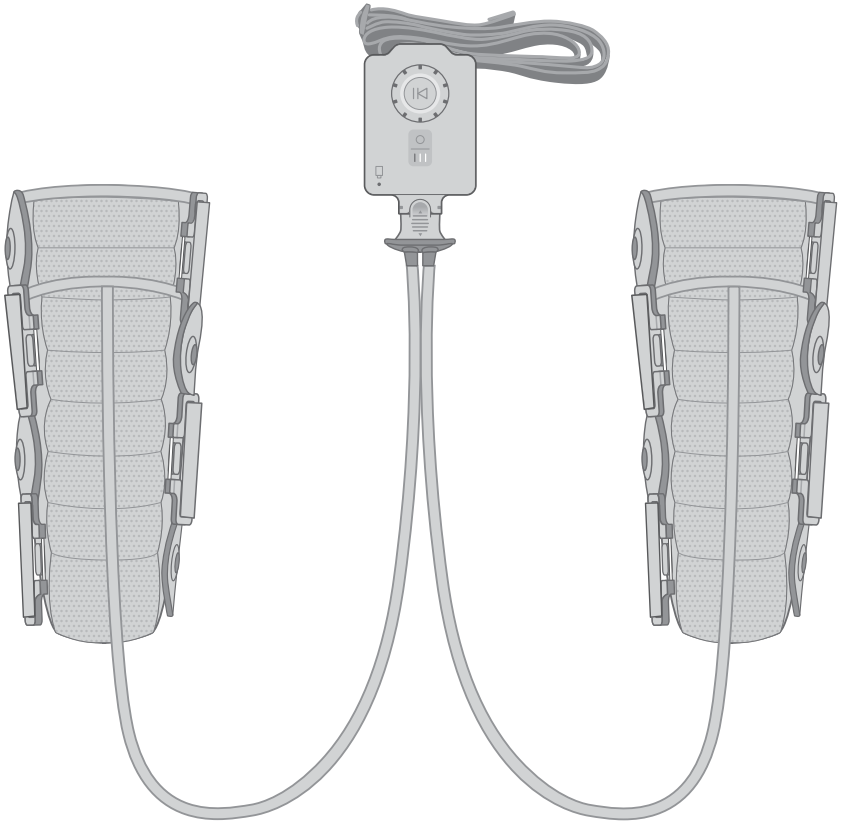


Figure 14. Y-connector connected at three locations.

The cable ties enable adjustment of the y-connector cable length.

To shorten cable length, pull the loops on both sides to extend them.

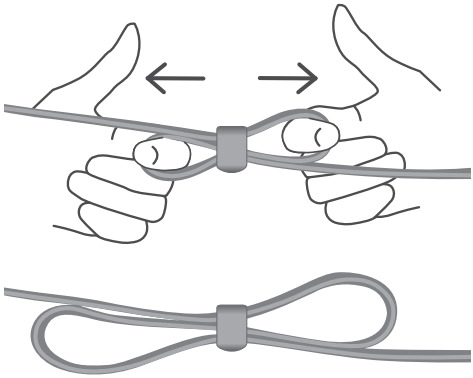


Figure 15. Pull cable ties to adjust y-connector length.

Treatment

The connector that goes to the garment will be connected when you receive it, but is removable. Ensure that this cable is attached before starting treatment.

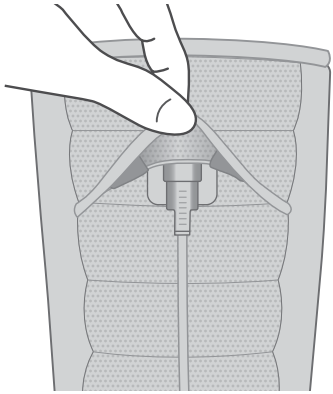


Figure 16. The cable connected to the Garment.

Connect the Garment to the Controller and press the play/pause button to begin treatment.

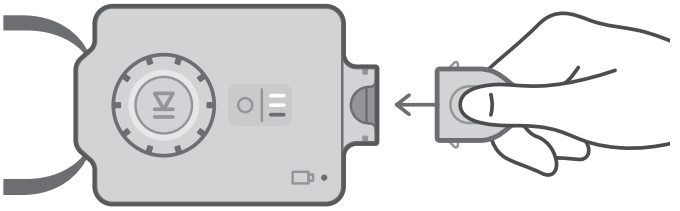


Figure 17. Connecting the Garment to the Controller.

Completing Treatment

Once complete, disconnect the Garment from the Controller. To remove the Garment, loosen and detach all straps from around your leg.

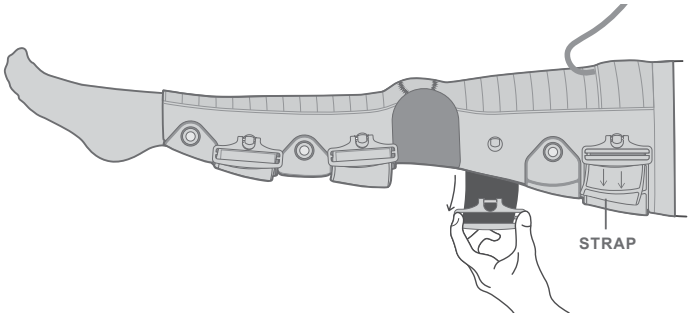
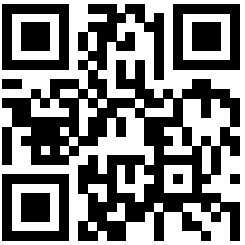


Figure 18. Detach buckles to remove Garment.

Finish by removing the sock or footwrap and liner. Charge the Controller after each session. When not in use, store components of the Dayspring system in the provided carrying case.

Koya App



The Koya app delivers a personalized experience that lets you and your clinician customize your Dayspring system's intensity settings, check your battery life, review your treatment progress, and ensure that your Dayspring device's firmware is always up to date. The app can be downloaded from the Apple App Store or Google Play Store, or by scanning this QR Code.

Connecting to the App

To connect the Dayspring system to the Koya app, turn on Bluetooth and WiFi connectivity on your mobile device. Press and hold the intensity button for two (2) seconds on the Controller until a blue light appears. Once the blue light appears, open the Koya app and follow the prompts on the screen.

Connected Features

The Koya app is the ideal companion to help you track your treatment and stay current with the latest device updates. With the Koya app, you can:

- Customize pressure intensity settings
- Turn on and off decongestion phase
- Start, stop, and pause treatment
- Track session frequency and duration
- View treatment history and your own usage patterns
- Check battery life
- Stay up to date with the latest firmware

Updating Firmware

The Koya app enables you to have the latest firmware on your device so you can ensure the Dayspring system is always up to date. To update the system's firmware, launch the Koya app and tap on the menu button located on the top right of the treatment screen. From the main menu, select "Device." Tap on "Update firmware" if it is available, otherwise your device is already using the latest firmware.

Cleaning & Care

Before cleaning, ensure the Controller is turned off and disconnected from the Garment and Charging Cable. To clean, wipe the Controller and Garment with a clean damp cloth or an alcohol wipe.

After cleaning, visually check that neither component is soiled or damaged. Allow the surfaces to fully dry before starting treatment. Repeat cleaning steps as necessary. Do not attempt to wash the Garment.

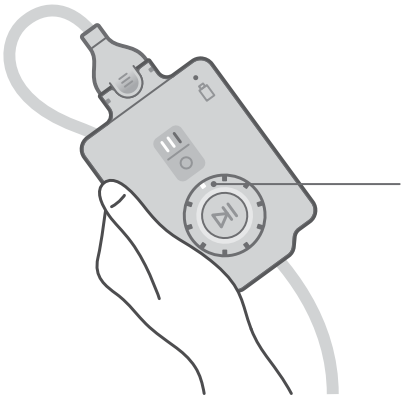
Hand or machine wash the liners with like colors. Only use warm water and mild detergent. Lay flat to dry. Do not wring, iron, dry clean, or bleach. Clean them at least once a week or as needed.

Handle the Dayspring system with care. When not in use, store components of the Dayspring system in the provided carrying case. Store the system in a clean, cool, and dry location. Avoid exposure to extreme temperatures and humidity.

Troubleshooting

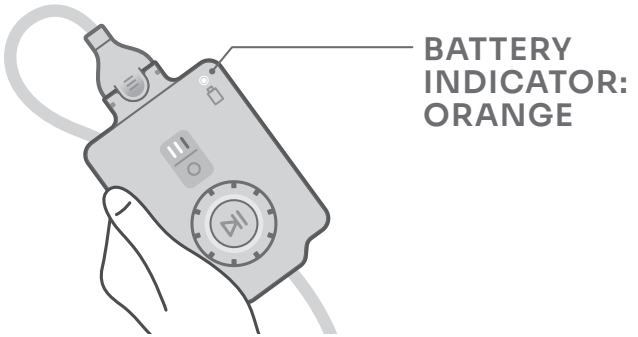
Garment Not Detected:

If you attempt to start treatment but the Garment is not properly attached to the Controller, the status indicator light will flash orange and the Controller will vibrate. Ensure the Garment is properly attached to the Controller prior to starting treatment.



Low Battery:

If the battery level becomes low during treatment, the battery indicator light on the Controller will turn orange. After treatment has ended make sure to fully charge the Controller.



Critically Low Battery:

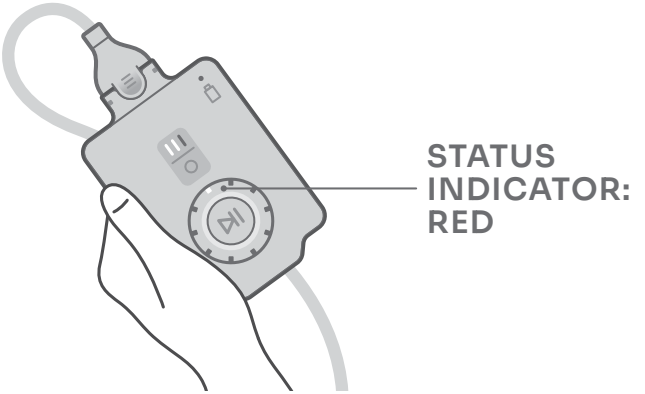
If the battery level is critically low, the battery indicator light will flash orange and the Controller will vibrate if you attempt to use it. Connect the Controller to the Charging Cable and recharge the battery to full before using the device again.

Battery Charging Error:

If the battery indicator shows solid purple while charging, the battery may not be charging correctly. Please contact Koya Medical for assistance.

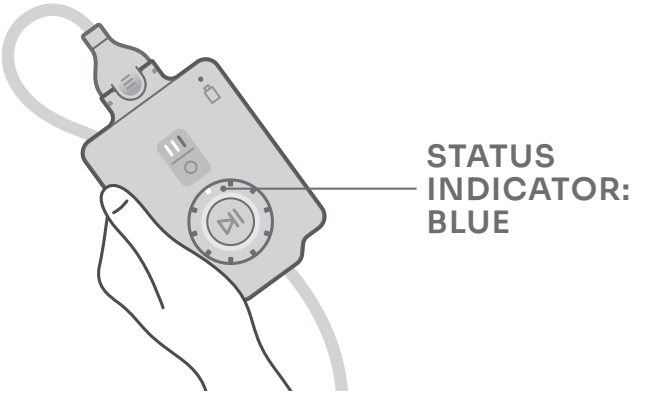
System Error:

If the status indicator light is solid red, please contact Koya Medical for assistance.



Bluetooth®:

If you are having difficulty with the Bluetooth connection between your smartphone and the Controller, reset the connection by going to the Bluetooth settings on your phone and remove the Dayspring from your connected devices. Press and hold the intensity button on the Controller for two (2) seconds until a blue light appears on the status indicator. Once the blue light appears, open the Koya app and follow the prompts on the screen.



Expected Service Life

When used and maintained as instructed, the Controller has an average expected operational life of five (5) years.

Potential Complications & Adverse Events

If you experience any pain or adverse reactions from using Dayspring, stop using the device immediately and consult with your healthcare provider. For other questions or concerns about the Dayspring system, contact the manufacturer, Koya Medical.

Please call:
+1 (415) 209-5035

Send an email to:
support@koyamedical.com

Product Registration

Register your product to receive up-to-date information on your system.
Visit **www.koyamedical.com/register**

Warranty Information

Standard Warranty

Koya Medical warrants to the original purchaser of the Dayspring device that your device is free from defects in materials and workmanship for one (1) year from the date of original purchase. This warranty extends to only the original purchaser and is not transferable. Keep your invoice or receipt safe as this is your proof of purchase and the date marked on it shall be deemed the date of purchase. If during this one (1) year period, the Dayspring device does not function properly because of a defect in materials or workmanship, Koya will repair or replace it with a new device or equivalent product free of charge. The warranty of the replacement Dayspring device will expire on the date of the original warranty expiration. The purchaser's exclusive remedy with respect to the Dayspring device shall be replacement. This warranty covers the original purchaser and cannot be transferred with sale or other transfer of the Dayspring device to any other person or entity.

EXCLUSIONS
This warranty does not apply if the Dayspring device has been:

- Changed or modified by any person or entity other than Koya Medical.
- Serviced or repaired by any person or entity other than Koya Medical.
- Damaged by an act of God, external causes, misuse, abuse, negligence, accident, wear and tear, unreasonable use, use not in accordance with product instructions, failure to perform required maintenance, involvement of parts or components not supplied by Koya Medical or by other causes unrelated to defective materials or workmanship.

Extended Warranty

The original purchaser may contact Koya for information on extended warranty programs and policies. Unless modified in writing and signed by both parties, the standard one (1) year warranty described in the previous section is understood to be the complete and exclusive agreement between the parties, superseding all prior agreements, oral or written, and all other communications between the parties relating to the subject matter of this agreement.

FCC Compliance

This device contains FCC ID: 2AA9B10. This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:
(1) this device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.
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

Bluetooth® Trademark

The Bluetooth word, mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Koya Medical is under license. Other trademarks and trade names are those of respective owners.

Technical Information

Charging Cable	Input	Voltage 90 ~ 264 VAC Current: 800 mA Frequency: 50/60 Hz
	Output	Voltage 18.0 - 24.0 VDC Current: 1500 - 2000 mA
Controller	Input	Voltage 18.0 - 24.0 VDC Current: 2000 mA
	Output	Voltage 25.0 VDC Current: 3000 mA

Additional Technical Information

Garment Material:
Polyester/Spandex blend

Operating Temperature:
5°C to 30°C
41°F to 86°F

Transport & Storage Temperature:
-20°C to 60°C
-4°F to 186°F

Relative Humidity:
15% to 95%

Atmospheric Pressure:
70 to 106 kPa

Protection Against Fluid Ingress
IP22
Applied Part
B

Manufacturer Information:
Koya Medical
2461 Peralta Street
Oakland, CA 94607
+1 (415) 209-5035

support@koyamedical.com

EMC Safety Information
Electromagnetic Compatibility

The Dayspring system has been tested for immunity to electrostatic discharge, radio frequency interference, proximity RF fields from wireless equipment, and power frequency magnetic fields as specified in the table below. Emissions of energy are not likely to cause interference with nearby electrical equipment.

Guidance and Manufacturer's Declaration – Emissions Medical Equipment and Medical Systems

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

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The Dayspring System 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 Dayspring System is suitable for use in all establishments, including domestic establishments and those connected to the public low-voltage power supply 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 – Emissions Medical Equipment and Medical Systems

The Dayspring System contains a fully certified Bluetooth transmitter module. This device complies with Part 15 of the FCC Rules. Operation of the Bluetooth transceiver is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received.

Specification	Description
Standard	Bluetooth® 5 LE
ISM Frequency Band	2.360 – 2.500 GHz
Channels	0-39
Modulation Method	Bluetooth® 5 LE
Transmit Power	+4 dBm
Max Data Rate	2 Mbps

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Immunity Test
ESD IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
EFT IEC 61000-4-4	± 2 kV Mains ± 1 kV I/Os	± 2 kV Mains ± 1 kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV Mains ± 2 kV Common	± 1 kV Mains ± 2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/ Dropouts IEC 61000-4-11	> 95% Dip for 0.5 cycle > 95% Dip for 0.5 cycle 30% Dip for 25 cycle > 95% Dip for 300 cycles	> 95% Dip for 0.5 cycle > 95% Dip for 0.5 cycle 30% Dip for 25 cycle > 95% Dip for 300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Dayspring System requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply.
Power frequency 50/60 Hz Magnetic Field IEC 61000-4-8	30 A/m	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	3V 0.15 MHz-80MHz 6V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1kHz	3V 0.15 MHz-80MHz 6V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1kHz	Home Healthcare Environment Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	

Label Symbols

	Caution
	Do not use if damaged.
	Temperature limits to which the medical device can be safely exposed
	Humidity limits to which the medical device can be safely exposed

	Type B Applied Part
IP22	Controller and Garment are protected against solid foreign objects greater than 12.5 mm. Protection against vertically falling water drops when enclosure tilted up to 15°.
	Product not to be disposed of in normal waste stream.
	Federal law restricts this device to sale by or on the order of a healthcare provider or properly licensed practitioner.
	Bluetooth trademark
	Nonionizing electromagnetic radiation

	Serial Number
	Important information is found in instructions.
	Name of Manufacturer
	Date of Manufacture (YYYY-MM-DD)
	Catalogue Number
	Lot Number

	Do not wash.
	Do not tumble dry.
	Do not iron.
	Do not dry clean.

Koya Medical
2461 Peralta Street
Oakland, CA 94607

+1 (415) 209-5035
support@koyamedical.com
www.koyamedical.com

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