

**USER GUIDE,
CARE & INSTRUCTIONS**



**SURFACE ELECTRICAL STIMULATION
SYSTEM¹**

Indications For Use:

The Axiobionics Wearable Therapy Garments with Cutaneous Electrodes are Intended to be Used to Apply Electrical Stimulation Current to the Patient's Skin via Electroconductive Media Gel.

Examples of Electrical Stimulation Applications of the Garment Are:

1) Transcutaneous Electrical Nerve Stimulation (TENS) for Pain Relief,

2) Neuromuscular Electrical Stimulation (NMES) for:

- Retarding or preventing disuse atrophy
- Maintaining or increasing range of motion
- Re-educating muscles
- Relaxation of muscle spasm
- Increasing local blood circulation
- Prevention of venous thrombosis of the calf muscles immediately after surgery

3) Functional Electrical Stimulation (FES)

¹ Surface Electrical Stimulation System refers to 21 CFR Sec. 882.1320 Cutaneous electrode: (a) Identification. A cutaneous electrode is an electrode that is applied directly to a patient's skin to apply electrical stimulation.

WARNINGS, PRECAUTIONS & ADVERSE REACTIONS

Read this instruction manual as well as the stimulator instruction manual before operation. Be sure to comply with all WARNINGS and CAUTIONS in the manuals. Failure to follow instructions can cause harm to user or device. Before wearing the Wearable Therapy electrode garment it is imperative that you understand all precautions and contraindications. Refer to your stimulator manual for information pertaining to stimulator procedures and safety precautions.

Warnings

Electrical burn to the skin may occur if garment is not securely fit to body.

Never use garment unless all contact points are covered by an electrode.

The garment should be completely dry before wearing. Hazardous electrical shock may occur if garment is moist.

The Wearable Therapy System is to be worn only on the affected body part of the patient for whom it is fitted. It should not be worn by anyone else or on any other part of the body.

Wearable Therapy is not for transthoracic stimulation.

Apply stimulation to normal, intact, clean, healthy skin only.

Always empty the bladder prior to putting on the garment and stimulating. If a bowel or bladder accident occurs at any time during a session, discontinue stimulation immediately and remove the garment.

Only an authorized doctor or clinician should fit and program the Wearable Therapy System.

Do not wear the Wearable Therapy System over swollen, infected, or inflamed areas. Do not wear the system over skin eruptions or varicose veins.

Do not place stimulation electrodes over your neck because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.

Do not place stimulation electrodes across your chest because the introduction of electrical current into the chest may cause rhythm disturbances to your heart, which could be lethal.

Electrical stimulation should never be used on the eye region, over the carotid sinus nerves, over the laryngeal or pharyngeal muscles, over the chest region, transcerebrally, or during pregnancy.

Do not place stimulation electrodes over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).

Do not place stimulation electrodes over, or in proximity to, cancerous lesions.

The size, shape, and type of electrodes may affect the safety and effectiveness of electrical stimulation and recording.

The electrical performance characteristics of electrodes may affect the safety and effectiveness of electrical stimulation and recording.

Using stimulation electrodes that are too small or incorrectly applied could result in discomfort or skin burns.

You should contact the manufacturer of the electrical stimulator or recording device if you do not know if the electrode can be used with the stimulation or recording device.

Do not attempt to repair or modify the Wearable Therapy System.

Modifying, cutting, or in any way altering the garment or electrodes from their original condition may be dangerous and will alter your warranty.

Precautions

Wearable Therapy electrode garments must be utilized in the manner prescribed for you by your doctor or clinician. Severe injury may result if used incorrectly.

The long-term effects of cutaneous electrodes for electrical stimulation and/or recording are unknown.

Do not use the Wearable Therapy System without the electrodes. NEVER use the garment when one or more electrode contacts are exposed.

The Wearable Therapy System electrodes must be saturated with BioGel before use and periodically checked to ensure they are moist with gel.

Turn off the Stimulator before removing, adjusting or replacing the electrodes.

Persistent redness, lesions, or blisters are signs of irritation. Stop using the Wearable Therapy System until any irritation is completely gone.

Since the effects of stimulation of the brain are unknown, stimulation electrodes should not be placed on opposite sides of your head.

Keep electrodes out of the reach of children.

Use caution if electrodes are applied over areas of skin that lack normal sensation.

The Wearable Therapy electrode garment may require some alteration in standard electromedicine methods and this should be discussed with your therapist prior to using Wearable Therapy.

If you notice any change in comfort level of the stimulus or alteration in muscle contraction quality this could indicate a substantial reduction in gel in one or more electrodes. Cease the stimulating program immediately. Steps should be taken to check each electrode. Add gel to those electrodes that are lacking before proceeding.

Adverse Reactions

No known side effects have been reported from wearing the Wearable Therapy electrode garment without electrical stimulation.

Electrical burns to the skin have been reported. You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin.

After removing the Wearable Therapy System, it is normal for the areas under the pocket electrodes to be red and indented. The redness should disappear in approximately one hour. Please consult your physician if irritation continues.

Possible side effects from the Wearable Therapy system are: hypertension, hypotension, nausea, faintness, tachycardia, muscle and/or ligament damage, bone fracture, and an uncomfortable sensation from stimulation.

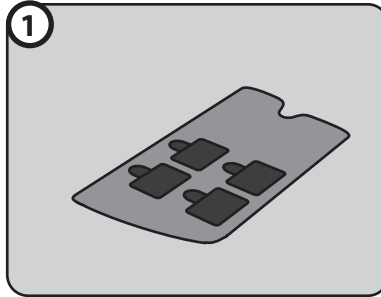
Autonomic dysreflexia has been reported in spinal cord injury patients.

Allergic dermatitis from electrode gel has been known to occur in some patients.

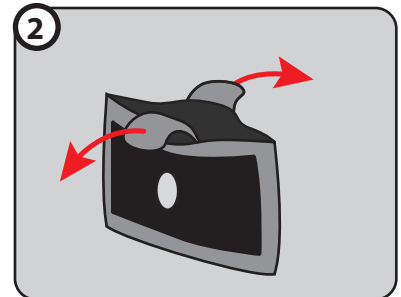
If any of these conditions should occur, discontinue therapy immediately and seek medical attention.

ELECTRODE PREPARATION

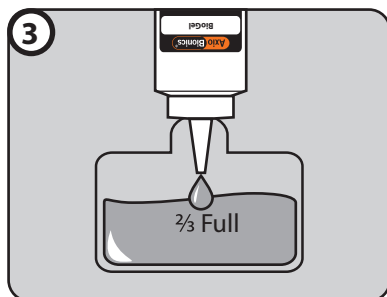
Wearable Therapy electrode garments require BioGel in each electrode pocket for electricity to transmit to the body. Only if the proper amount has been injected will the garment perform as expected and in a safe manner. When filled appropriately, the garment can be worn up to 8 hours. If longer wear time is desired, you may slowly extend this time with caution. This is because BioGel electrodes require a sufficient amount of gel in the pocket to conduct electricity. The gel dissipates throughout the day. The rate of dissipation will vary depending on the patient and other conditions. Therefore, each patient should take special precaution when increasing wear time. It is advisable that this be done under medical supervision.



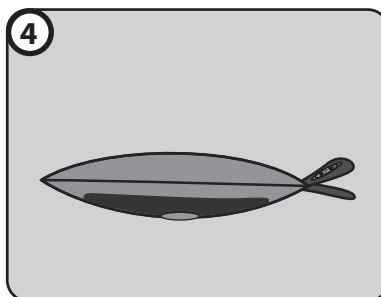
Unfasten garment. Lay it flat, with the inside of the garment facing up. Remove the electrodes from the garment by detaching them from their respective locations.



Each electrode is equipped with two tabs, which when pulled apart, separate the hook and loop closure. Grip both tabs and pull apart.

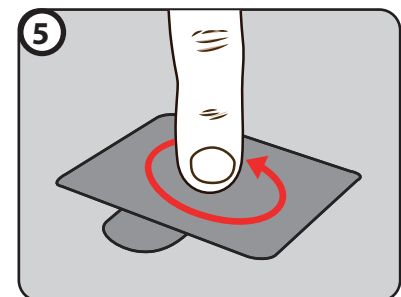


Once the electrode is open, insert the nozzle of the BioGel bottle and squeeze a liberal amount of Gel into the pocket, filling the interior of the electrode until it is approximately $\frac{2}{3}$ full. If necessary, gently shift the electrode back and forth to allow the BioGel to settle in the bottom of the pocket. Repeat this step for each electrode



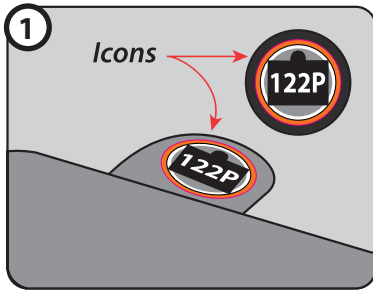
Close the electrode by fastening the hook and loop. When the electrode is properly filled it looks and feels like a pillow. Electrodes filled this way will last for 8 hours or more on the body without refilling.

CAUTION: Patients lacking sensation should not wear garment longer than 4 hours without checking BioGel electrodes to ensure gel is evenly distributed across electrode.

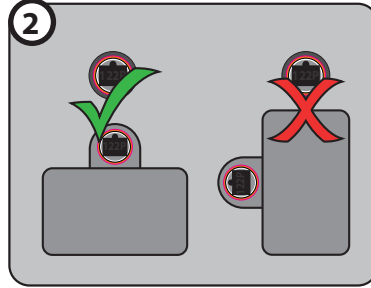


Gently spread the BioGel within the pocket to cover the entire interior surface area. The pocket is properly saturated when the outer surface is moist, but not leaking. Repeat this step for each electrode.

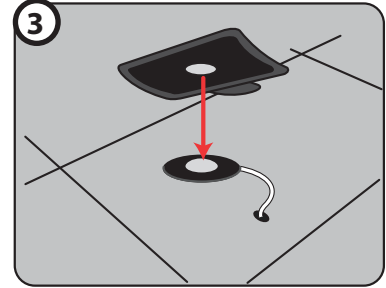
APPLYING ELECTRODES TO THE GARMENT



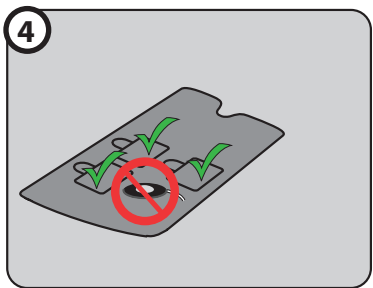
Once the electrode has been prepared, attach it to the garment. Match each numbered electrode to its respective icon.



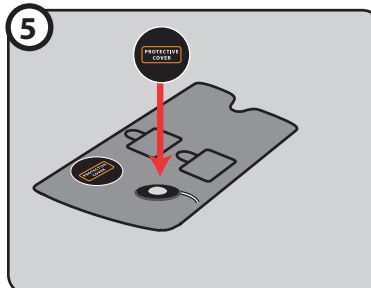
Orient the electrode in the same direction as the nearest icon.



Electrical contact is made by matching the silver dot on the electrode with the silver dot on the garment.



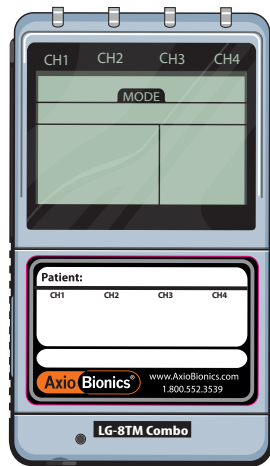
IMPORTANT: Make sure ALL electrodes are affixed to the interior of the garment and that there are no exposed electrode contacts. NEVER use the garment when one or more electrode contacts are exposed. Serious injury may result.



IMPORTANT: Cover all unused domatroides before applying garment.

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PROTOCOLS

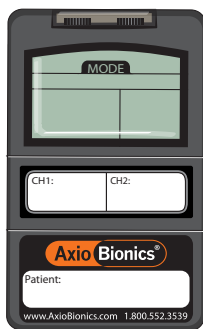


4 Channel Stimulator



Protocol 1

Ramp Up	3 Seconds
On Duration	10 Seconds
Off Duration	10 Seconds
Rate	25 Hz
Width	300 Pulse
Mode	EMS A (Alternate)



2 Channel Stimulator



Protocol 2

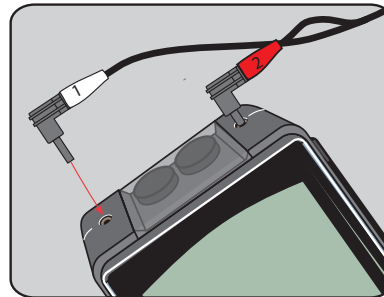
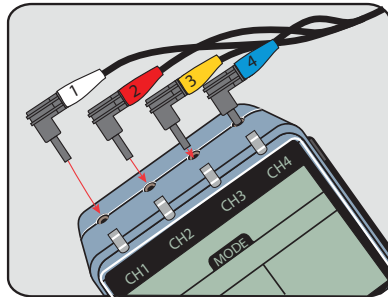
Ramp Up	3 Seconds
On Duration	10 Seconds
Off Duration	10 Seconds
Rate	25 Hz
Width	300 Pulse
Mode	EMS S (Synchronous)



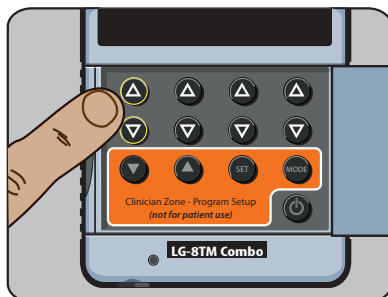
Custom Protocol

Ramp Up	
On Duration	
Off Duration	
Rate	
Width	
Mode	

STIMULATOR SET UP

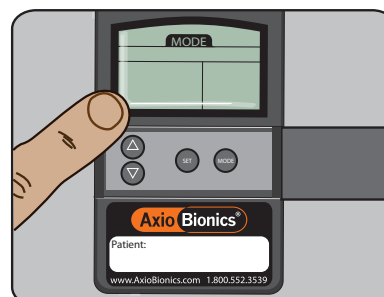


Identify connectors on the end of lead wire (1-4 connections). Identify the corresponding channel ports to insert lead wires. Your stimulator may differ slightly from the one pictured. Connect lead wire cable #1 to its corresponding port of stimulation, as labeled on the Axio stimulator. Do this for subsequent lead wires.



Setting Intensity Levels

Increase the intensity of channel #1 to the level that produces the best result your AxioBionics clinician may have provided you with suggested intensity levels. Use them as a guideline. You may increase or decrease the stimulus to optimize results. Contact your AxioBionics clinician for assistance with stimulator settings.

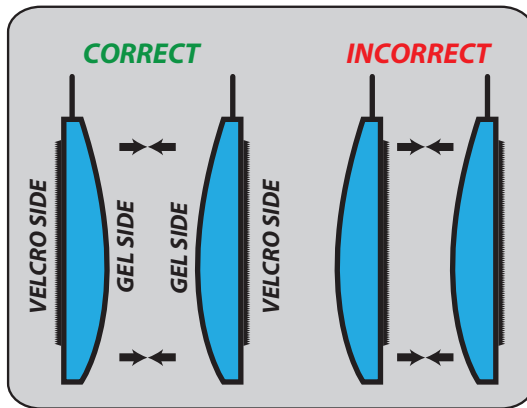


Once on the body, gelled, and connected to the stimulator, the Wearable Therapy electrode garment is ready for operation.

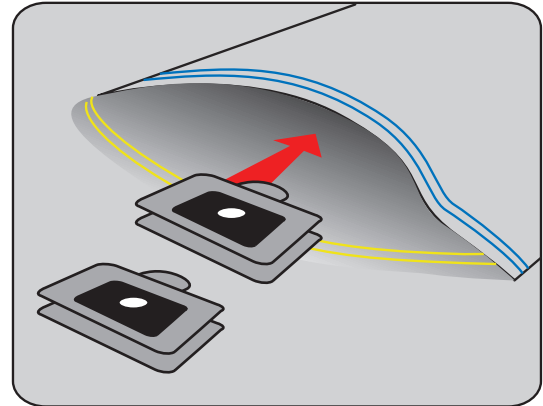
STORING THE ELECTRODES

Storing the Electrodes

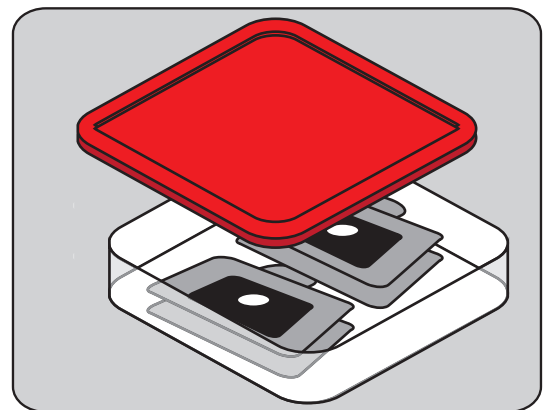
- Step 1.** After using the garment, remove it from your body and lay the garment flat with the electrodes facing upwards.
- Step 2.** Remove electrodes and place the gelled, non-Velcro side of each electrode onto the gelled, non-Velcro side of its mate and place them inside an air-tight container to prevent evaporation of the Gel.



Do not place velcro side of electrode to non-Velcro side. This will cause damage to the electrode surface.



OR



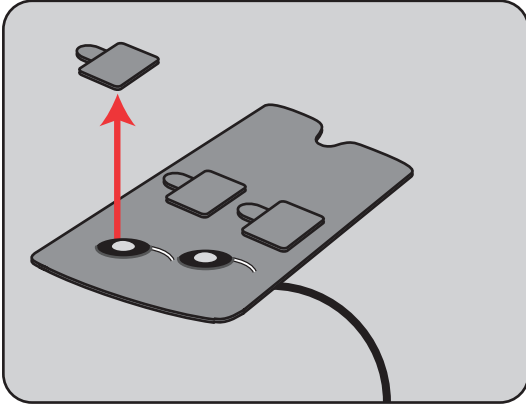
NOTES:

CLEANING THE GARMENT

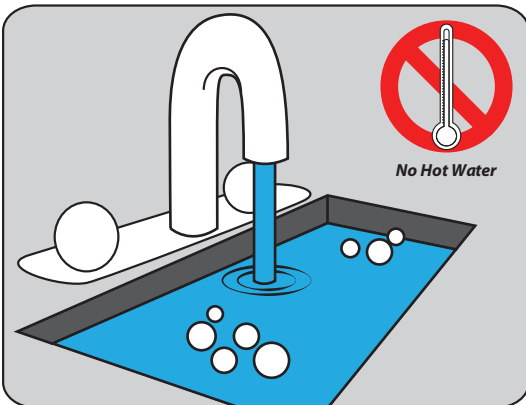
How to Clean the Garment

BioGel Velcro electrode should be washed at least once per week while in use.

Step 1. Remove the electrodes from the garment.



Step 2. Prepare a bath of lukewarm soapy water using Ivory Liquid Hand Soap® (or similar mild hand soap). Add just enough soap to produce a soapy bath. Suggested concentration: 1 tea-spoon per 1 gallon of water.

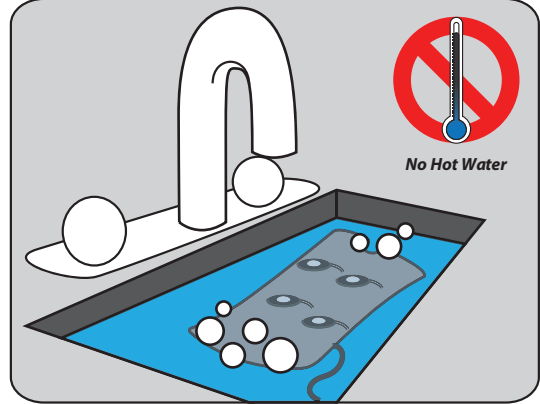


Never use bleach on this product since this will harm the garment and void the warranty.



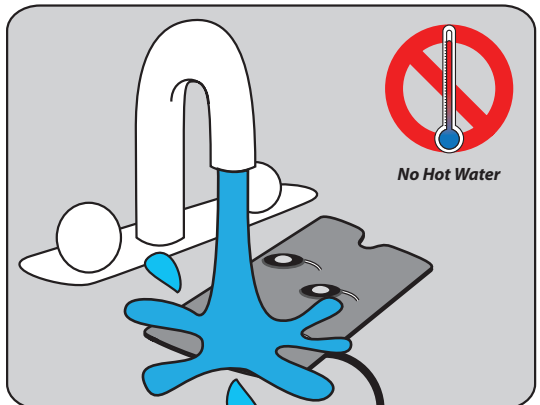
Do not expose the garment to extreme temperatures.

Step 3. Soak garment and its integrated wires and cabling in bath until gel and soil has loosened from the garment. If gel has dried, longer soaking time may be required. No more than 10 minutes.



Do not machine wash or machine dry the garment.

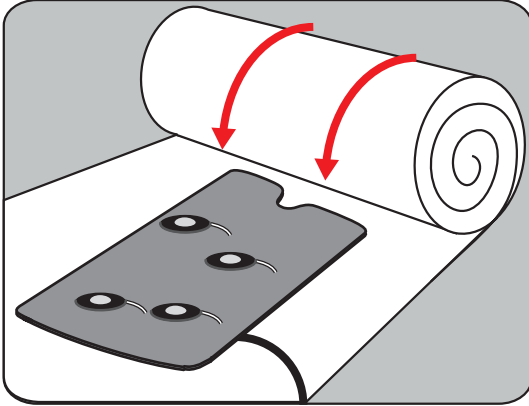
Step 4. Rinse garment thoroughly by hand using cool or lukewarm water until free of soap and gel.



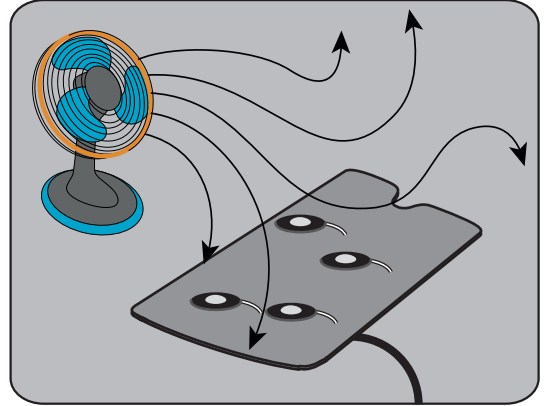
Step 1. Do not soak the garment longer than 10 minutes.

CLEANING THE GARMENT

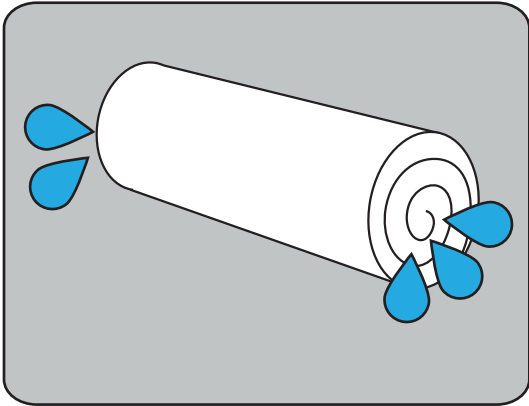
Step 5. Once the washing is complete, lay the garment on a dry towel..



Step 8. For faster drying time, place the garment directly in front of a fan.

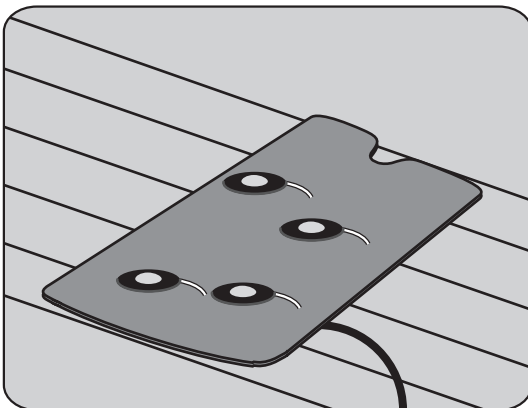


Step 6. Roll the towel up and squeeze out excess water and moisture.

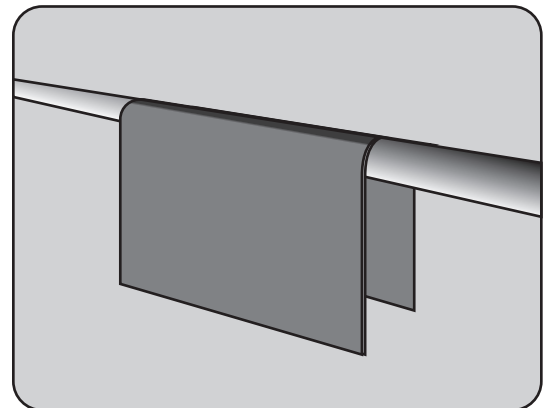


NOTES:

Step 7. Remove the garment from the towel and lay flat on a drying rack until completely dry.



OR

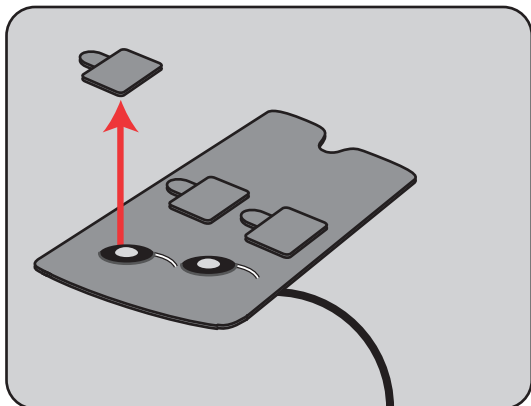


CLEANING THE ELECTRODE

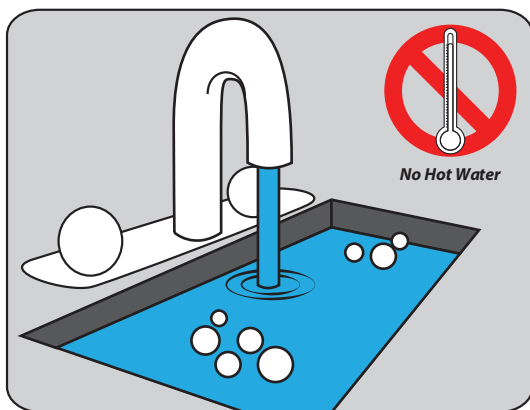
How to Clean the Electrode

BioGel Velcro electrodes should be washed at least once per week while in use.

Step 1. Remove the electrodes from the garment.



Step 2. Prepare a bath of lukewarm soapy water using Ivory Liquid Hand Soap® (or similar mild hand soap). Add just enough soap to produce a soapy bath. Suggested concentration: 1 tea-spoon per 1 gallon of water.

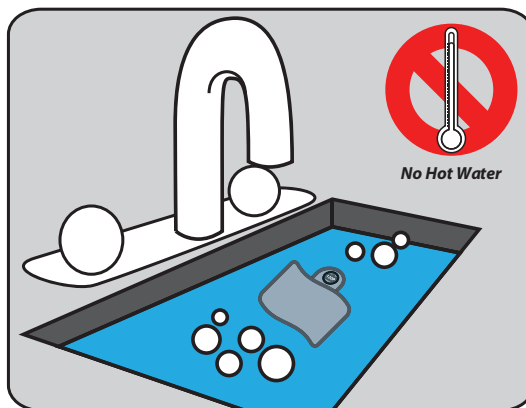


Never use bleach on this product since this will harm the electrode and void the warranty.



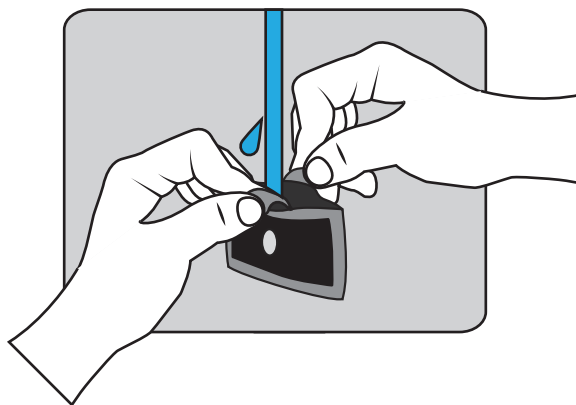
Do not expose the electrodes to extreme temperatures.

Step 3. Soak electrodes in bath until gel has loosened from the interior. If gel has dried, longer soaking time may be required.



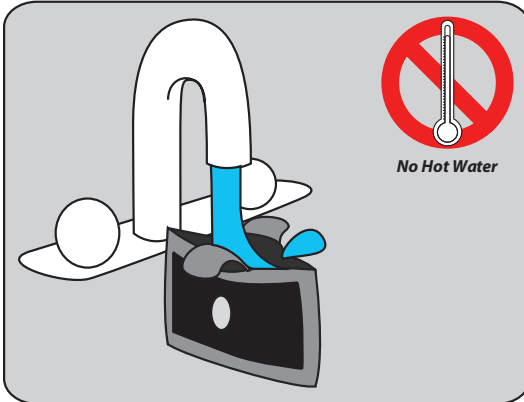
Do not machine wash or machine dry the electrodes.

Step 4. Remove electrodes from soap bath and massage the interior and the exterior of the electrode with your hands while washing under a faucet.

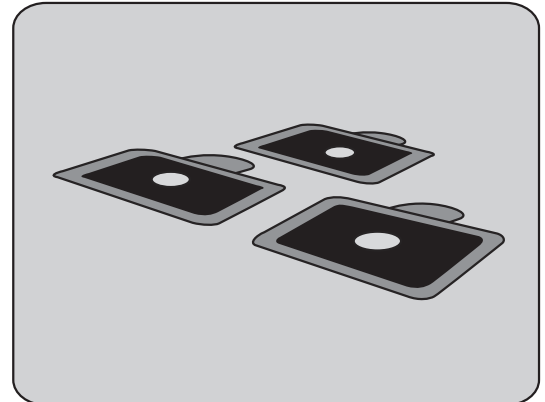


CLEANING THE ELECTRODE

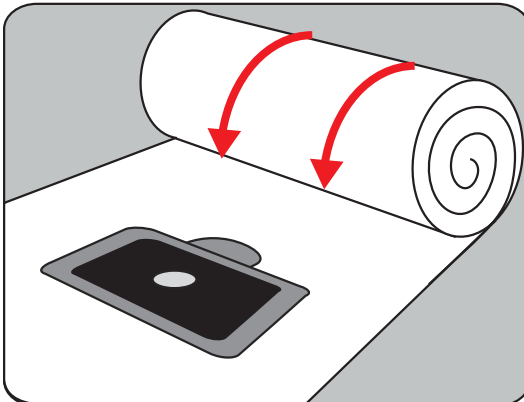
Step 5. Rinse electrodes thoroughly by hand using cool or lukewarm water until they are free of soap and gel.



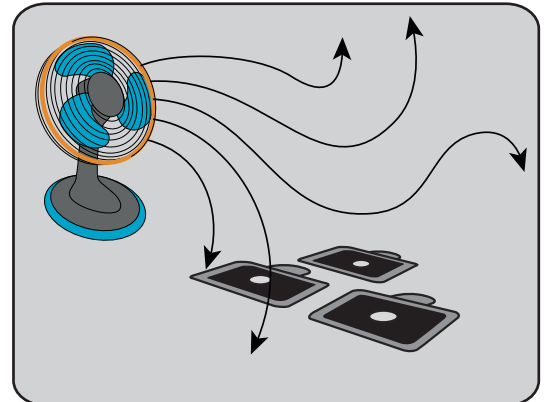
Step 8. Remove the electrodes from the towel and lay flat until completely dry



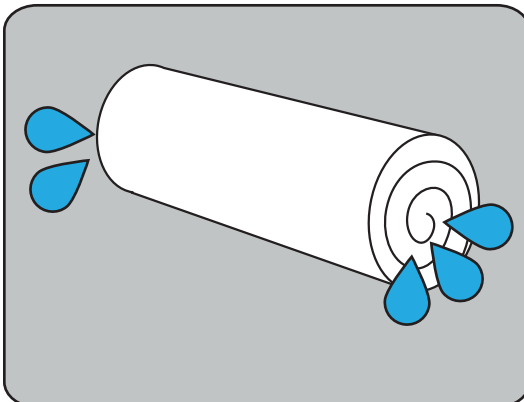
Step 6. Once the washing is complete, lay the electrodes on a dry towel.



Step 9. For faster drying time, place the electrodes directly in front of a fan.



Step 7. Roll the towel up and squeeze out excess water and moisture.



APPLYING THE GARMENT

BioBelt-AB

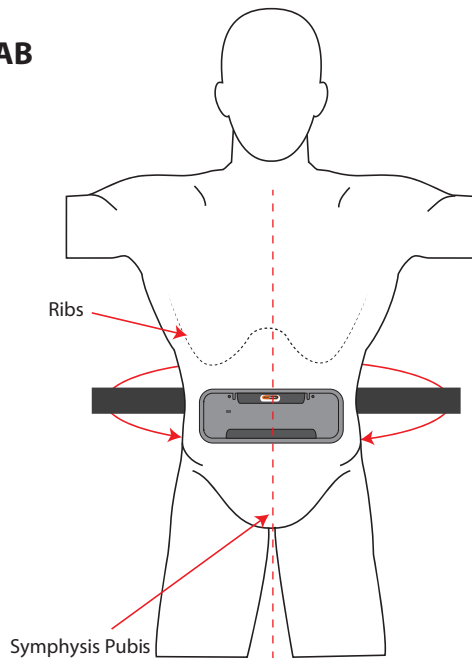
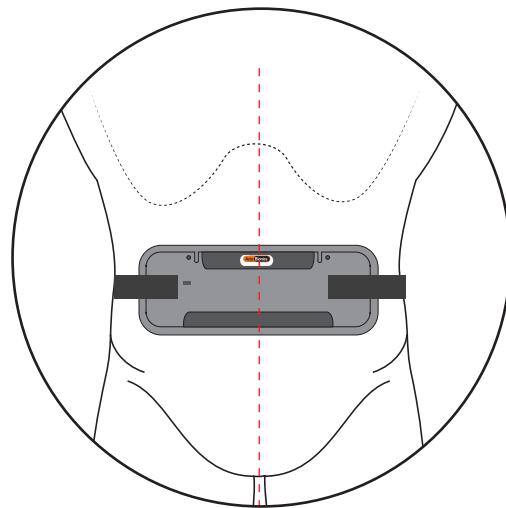
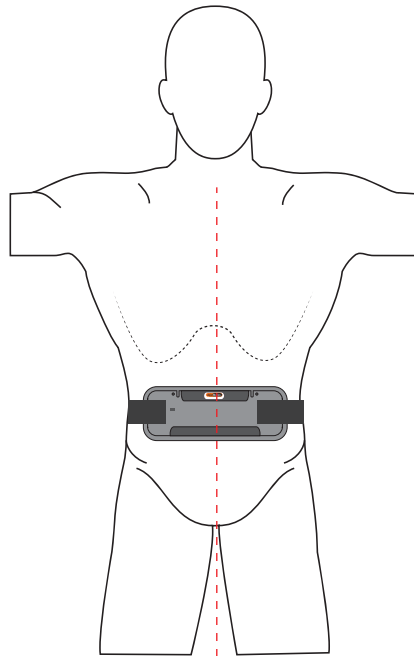
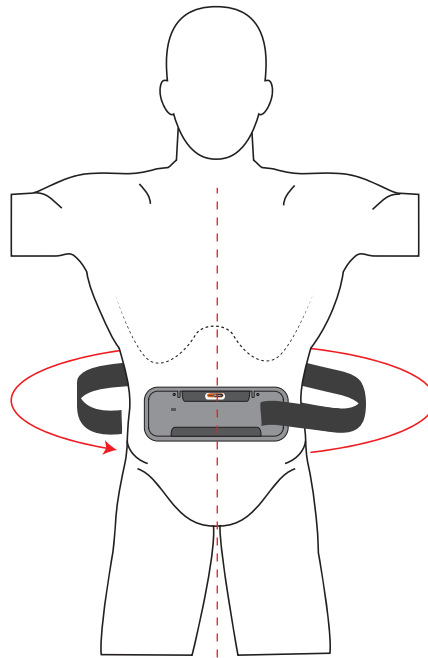


Figure 1

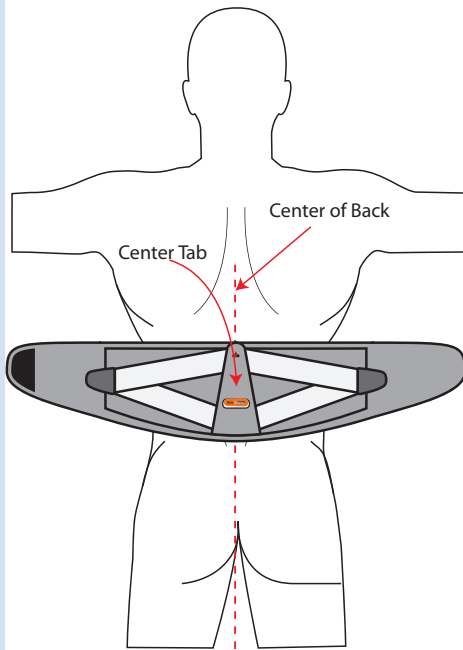


1. Patient should be lying down facing up. Place strap behind back.
2. Place AB panel on the abdomen below the ribs and above the symphysis pubis. (Figure 1)
3. Fasten the strap to one side of the AB panel. (Figure 2)
4. Center the AB Panel with the torso. (Figure 3)
5. Fasten the strap to the other side. Pull firm to snug the fit. (Figure 4)

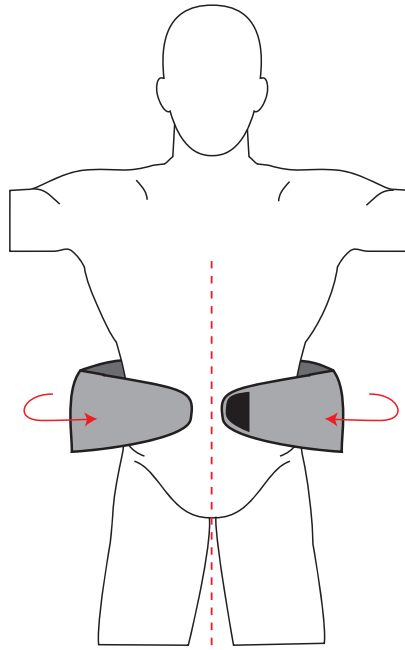
Wearable Therapy electrode garments must be applied directly to skin. No Clothing should intervene between electrode and skin

APPLYING THE GARMENT

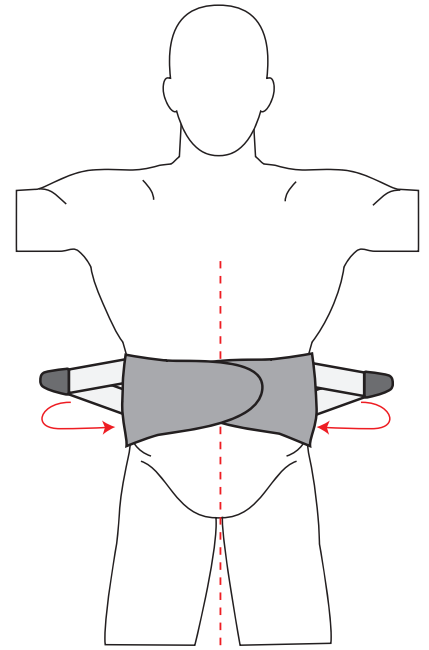
BioBelt–Lumbar



Back
Figure 1



Front
Figure 2



Front
Figure 3

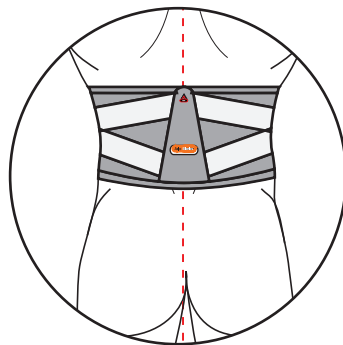


Figure 4- Applied Garment - Back

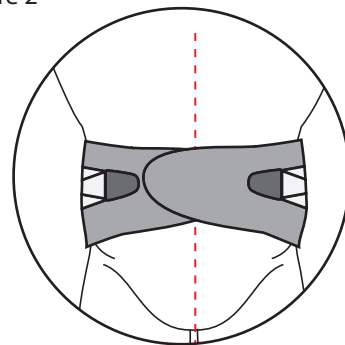


Figure 5- Applied Garment - Front

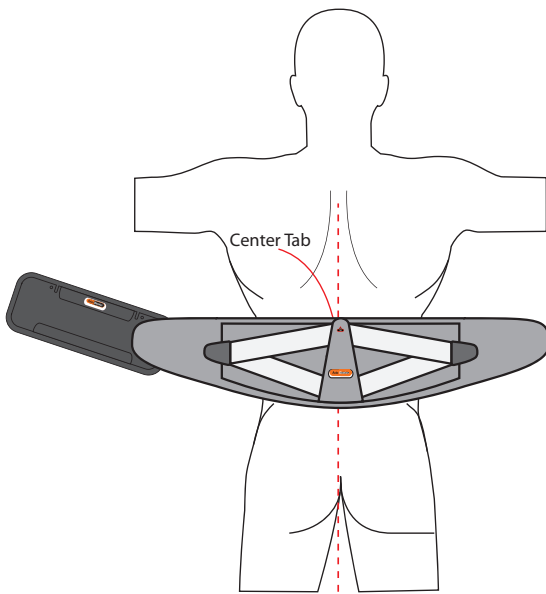
1. Position the BioBelt behind the body and align center tab with the center of the back. (Figure 1 and Figure 4)
2. Wrap BioBelt around the body and fasten the left and right sides together. The BioBelt should be applied with firm pressure. (Figure 2)
3. Grab the outer elastic bands and pull forward. Fasten these two bands to the belt for increased support. (Figure 3)

Wearable Therapy electrode garments must be applied directly to skin. No Clothing should intervene between electrode and skin

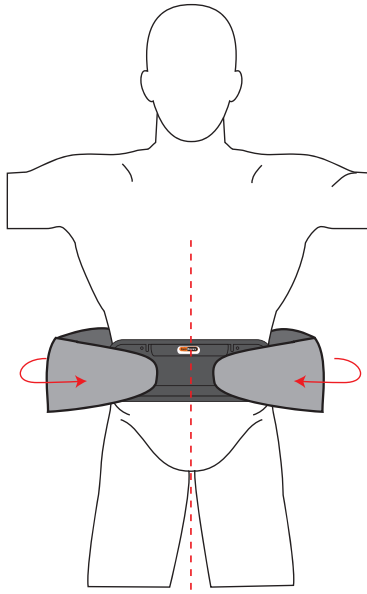
APPLYING THE GARMENT

BioBelt–Lumbar

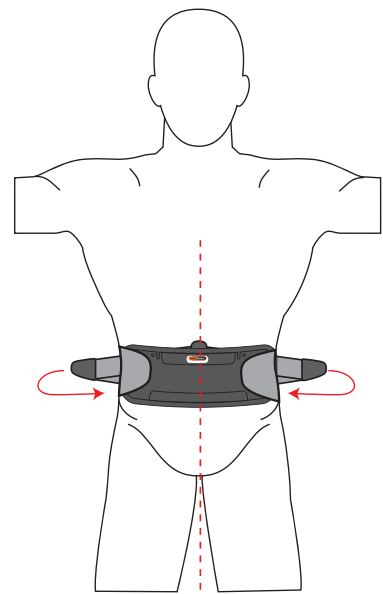
with Ab Panel



Back
Figure 1



Front
Figure 2



Front
Figure 3

1. Fasten the AB Panel to the BioBelt on one side only. (Figure 1)
2. Position the BioBelt behind the body and align center tab with the center of the back. (Figure 1)
3. Wrap BioBelt around the body and fasten the left and right sides together. The BioBelt should be applied with firm pressure. (Figure 2)
4. Grab the outer elastic bands and pull forward. Fasten these two bands to the belt for increased support. (Figure 3)

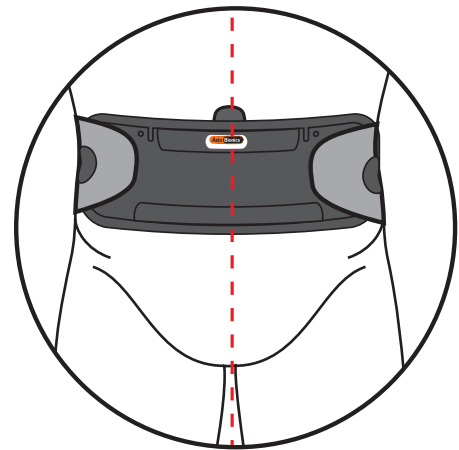
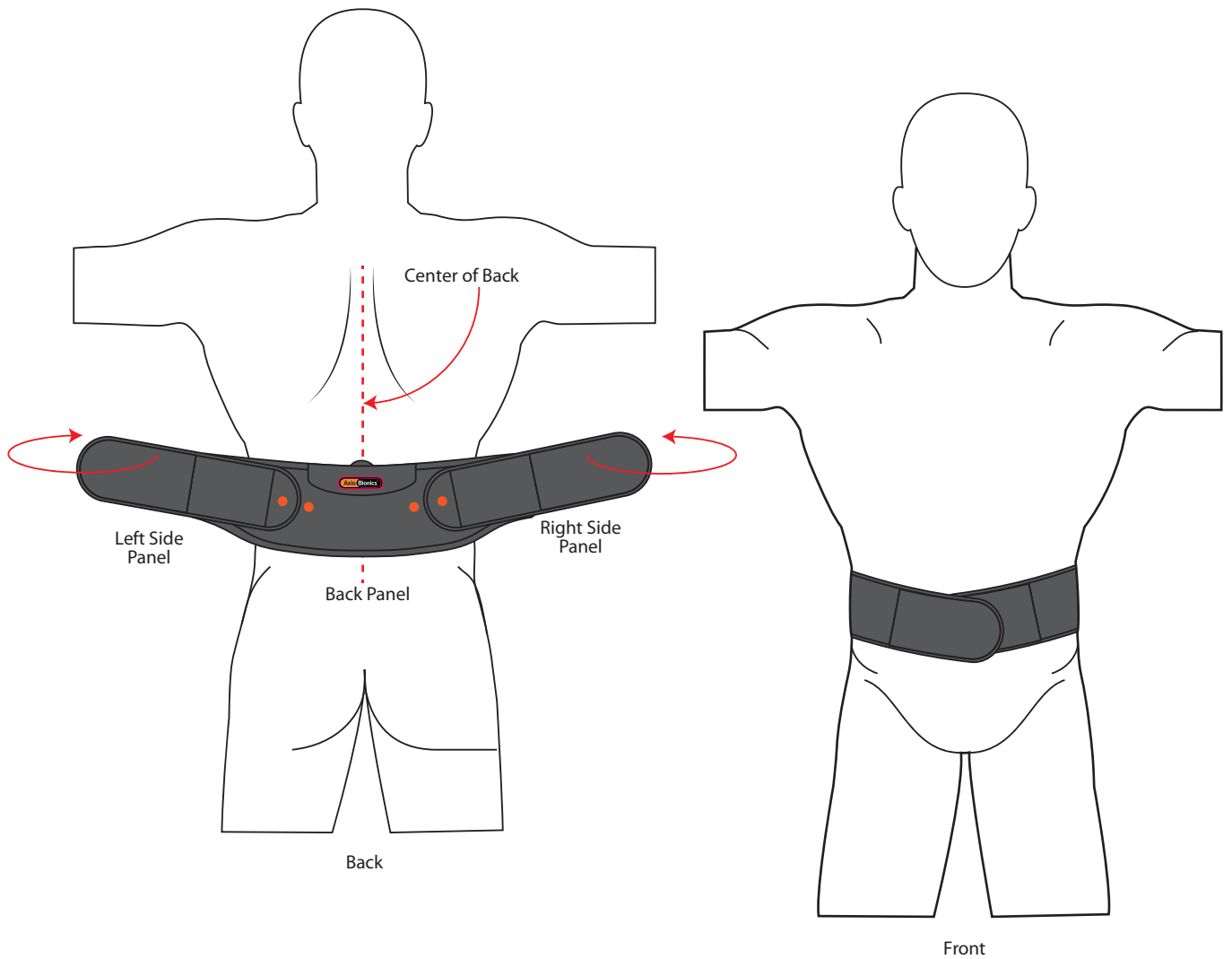


Figure 4 - Applied Garment - Front

Wearable Therapy electrode garments must be applied directly to skin. No Clothing should intervene between electrode and skin

APPLYING THE GARMENT

BioMiniBelt–Lumbar



1. Fasten the left and right side panels to the back panel by aligning the orange dots as noted in the figure above.
2. Align BioMiniBelt center tabs with the center of the back.
3. Wrap BioBelt around the body and fasten securely.

Wearable Therapy electrode garments must be applied directly to skin. No Clothing should intervene between electrode and skin.

APPLYING THE GARMENT

BioShortX



Figure 1

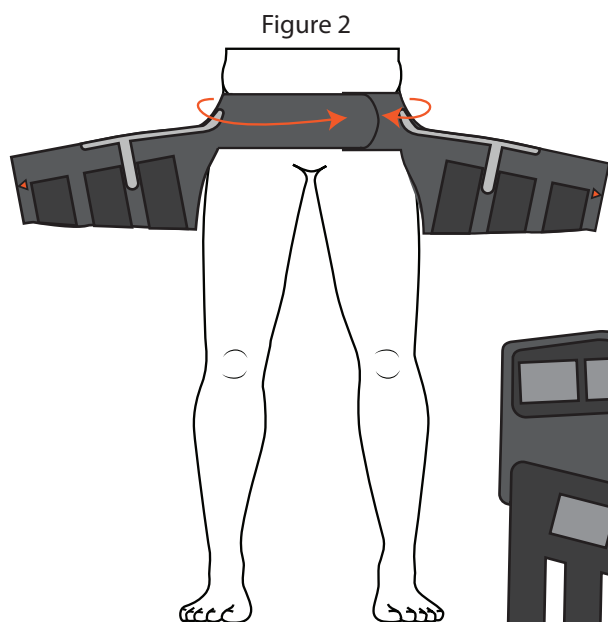


Figure 2

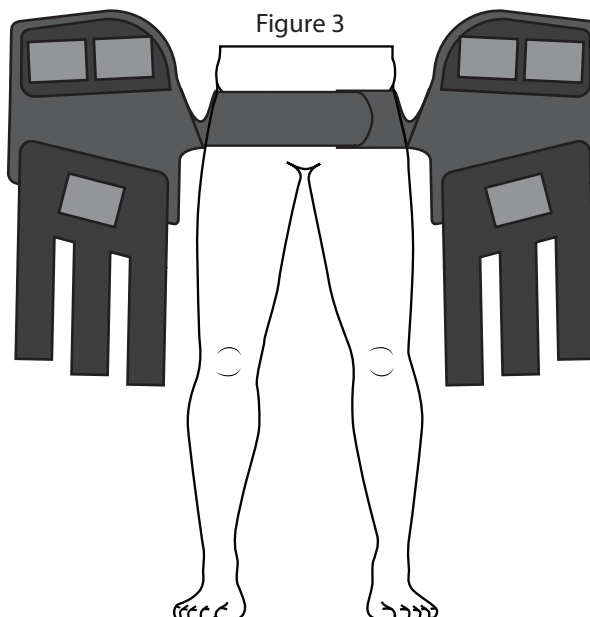


Figure 3

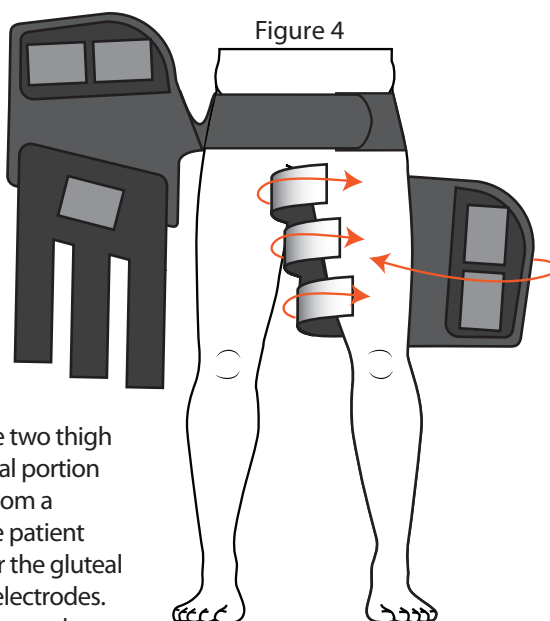


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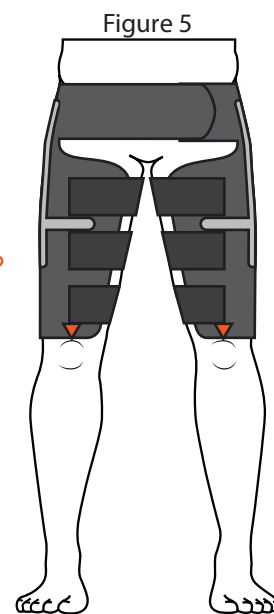


Figure 5

Method 1: BioShortX is Laid Flat on Bed

1. BioShortX is laid out on top of a bed with the two thigh sleeves placed laterally and away from central portion of the belt. (Figure 1) The patient transfers from a wheelchair to a bed and lays on the belt. The patient positions the buttocks (gluteal muscles) over the gluteal electrodes and centers the buttocks on the electrodes. The belt is wrapped around the torso and fastened. (Figure 2)
2. The right thigh sleeve is unfastened and opened up. (Figure 3) The sleeve is placed under the thigh and wrapped around the thigh. (Figure 4) The knee pointer is placed at the center of the knee and the straps are firmly fastened. (Figure 5)
3. The left thigh sleeve is unfastened and opened up. (Figure 3) The sleeve is placed under the thigh and wrapped around the thigh. (Figure 4) The knee pointer is placed at the center of the knee and the straps are firmly fastened. (Figure 5)

Wearable Therapy® electrode garments must be applied directly to skin. No Clothing should intervene between electrode and skin.

APPLYING THE GARMENT

BioShortX

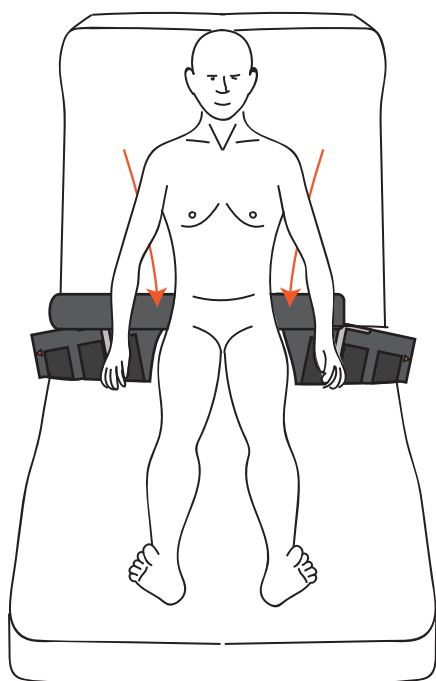


Figure 1

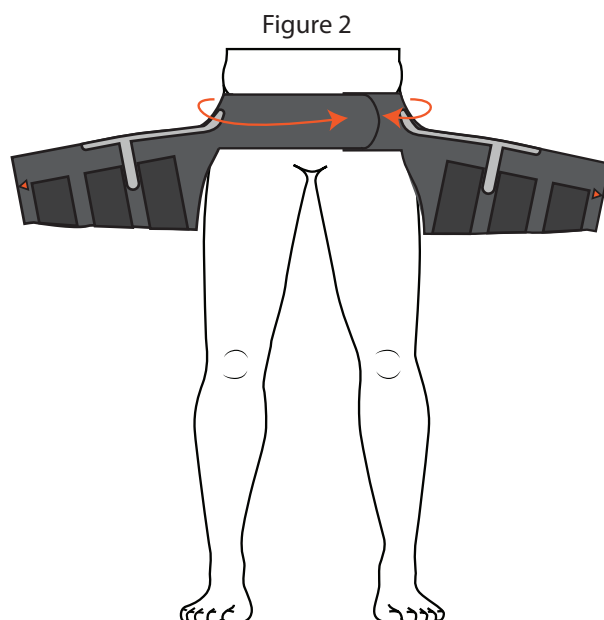


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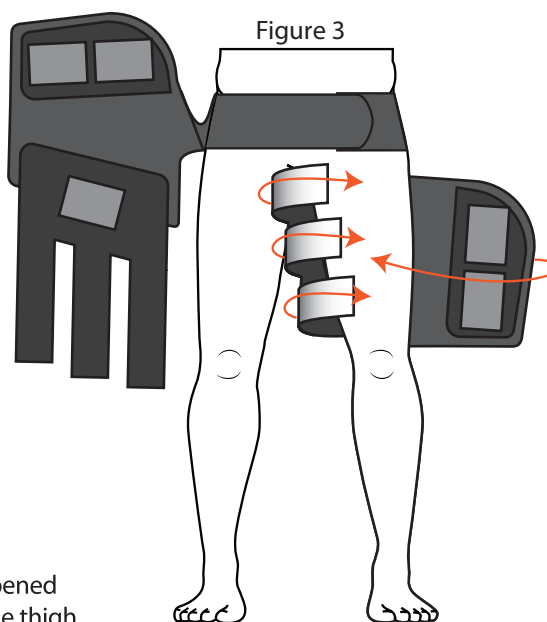


Figure 3

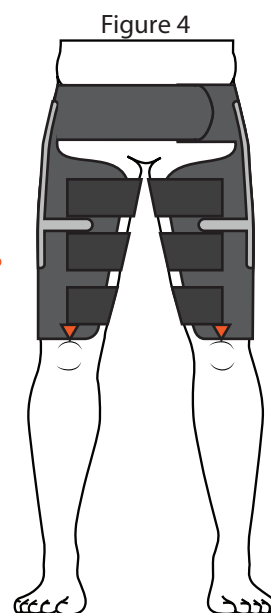


Figure 4

Method 2: BioShort is Placed Behind the Patient's Back (self-application by a paraplegia patient)

1. The patient transfers from a wheelchair to bed. While sitting upright, the BioShort is placed behind the back and shifted down under the buttocks/gluteal muscles. (Figure 2) The buttocks are centered over the gluteal electrodes and the belt is fastened. (Figure 2)
2. The right thigh sleeve is unfastened and opened up. (Figure 3) The sleeve is placed under the thigh and wrapped around the thigh. (Figure 3) The knee pointer is placed at the center of the knee and the straps are firmly fastened. (Figure 4)
3. The left thigh sleeve is unfastened and opened up. (Figure 3) The sleeve is placed under the thigh and wrapped around the thigh. (Figure 3) The knee pointer is placed at the center of the knee and the straps are firmly fastened. (Figure 4)

Wearable Therapy® electrode garments must be applied directly to skin. No Clothing should intervene between electrode and skin.

APPLYING THE GARMENT

BioShorts

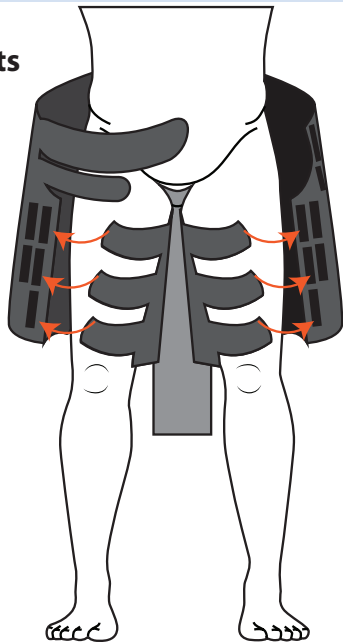


Figure 1

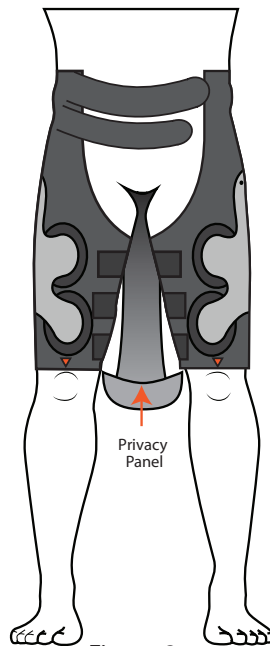


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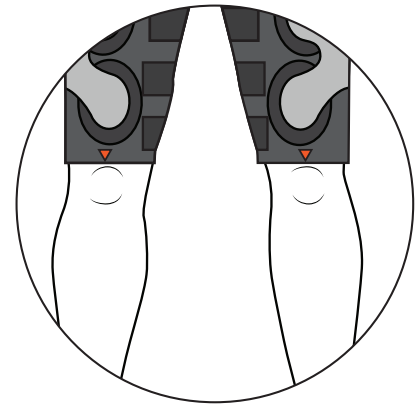


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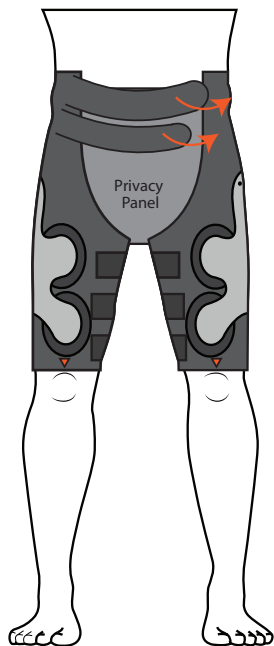


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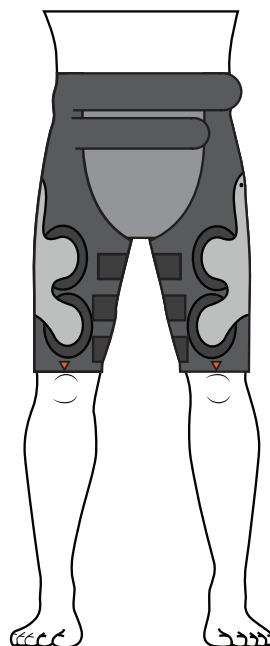


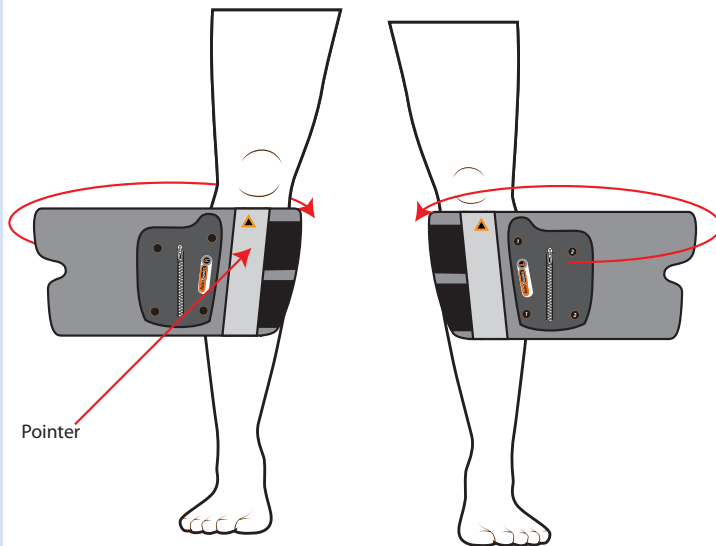
Figure 5

1. Position BioShorts under the body as shown. (Figure 1)
2. Wrap the BioShorts around each leg and fasten securely to the hook opposite the strap. (Figure 2)
3. Be sure to pointer is center on the knee as shown. (Figure 3)
4. Wrap privacy panel as shown. (Figure 2 and 4)
5. Fasten the upper and lower waist straps securely. (Figure 5)

Wearable Therapy electrode garments must be applied directly to skin. No Clothing should intervene between electrode and skin.

APPLYING THE GARMENT

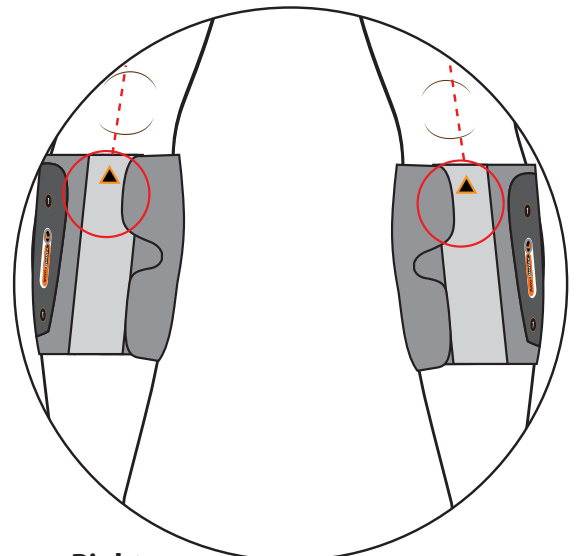
BioSleeve-LE



Right

Figure 1

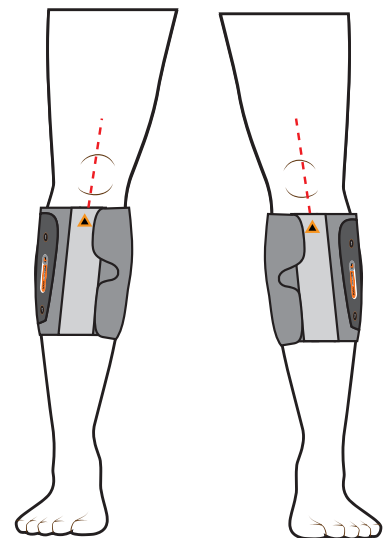
Left



Right

Figure 2

Left



Right

Figure 3

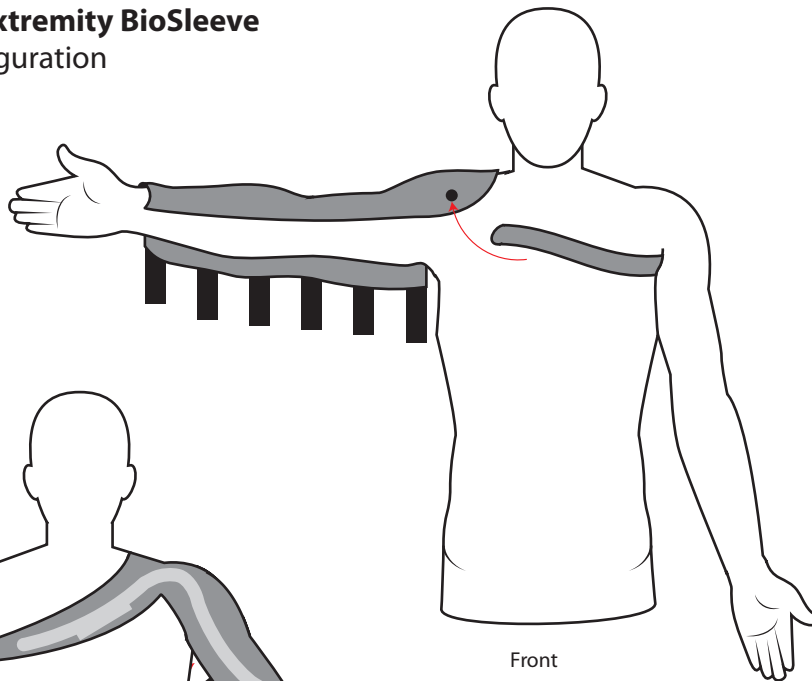
Left

1. Apply the BioSleeve to the lower leg, just below the knee cap. (Figure 1)
2. Align the pointer so it is pointing at the center of the knee. (Figure 2)
3. Wrap the BioSleeve around the leg and fasten it securely. (Figure3)

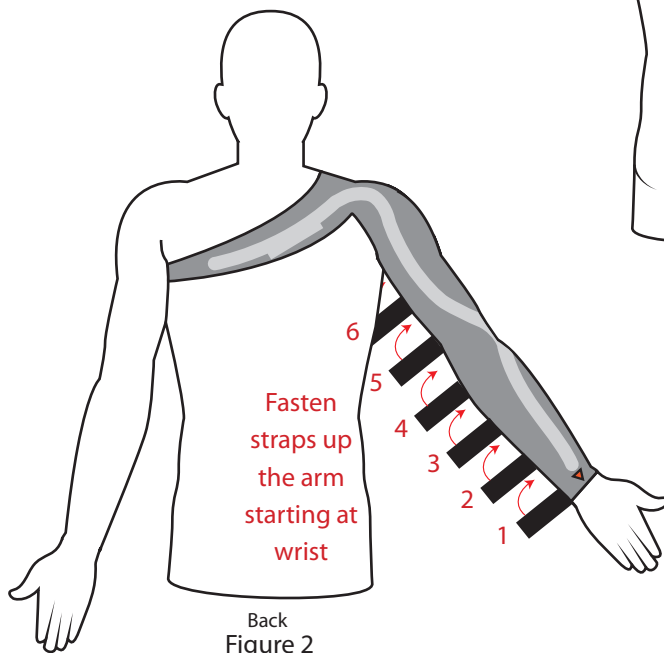
Wearable Therapy electrode garments must be applied directly to skin. No Clothing should intervene between electrode and skin.

APPLYING THE GARMENT

Upper Extremity BioSleeve Ab Configuration



Front
Figure 1



Back
Figure 2

1. Apply BioSleeve to the arm by laying the upper section on the shoulder. (Figure 1)
2. Wrap the chest strap around the body and under the opposite arm as shown. Fasten the chest strap to the sleeve in front. (Figure 1)
3. Align the wrist pointer with the center of wrist as shown. (Figure 2)
4. Fasten each strap securely moving up the arm one strap at a time. (Figure 2)
5. If there is a pointer on the sleeve near the elbow, align this with the center of the front of the elbow crease. (Figure 3)

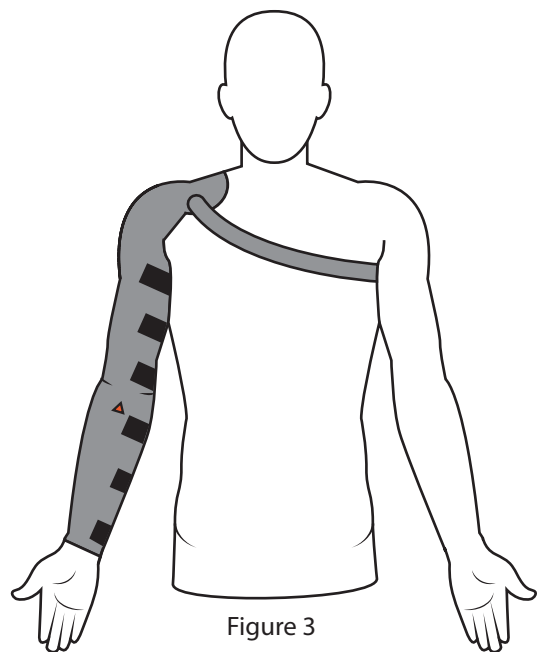


Figure 3
Front

Wearable Therapy electrode garments must be applied directly to skin. No Clothing should intervene between electrode and skin

APPLYING THE GARMENT

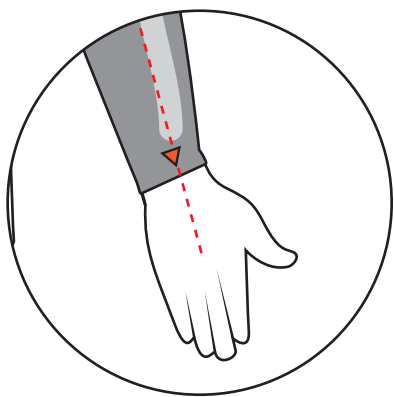


Figure 4: Top of Wrist

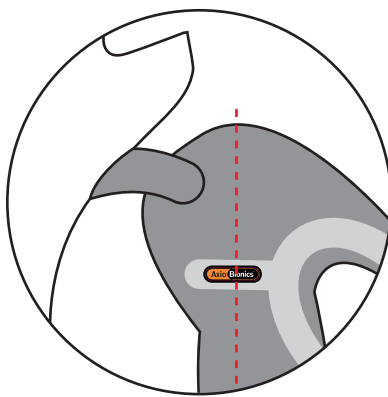


Figure 5: Shoulder

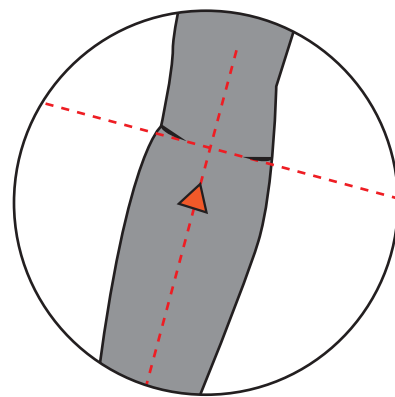
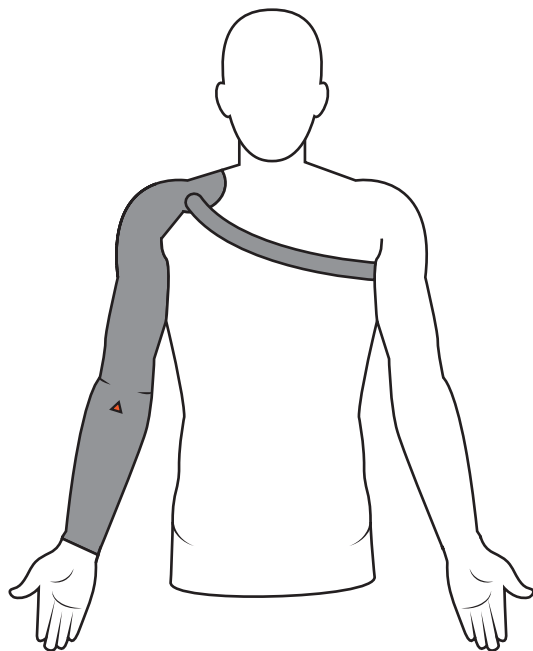
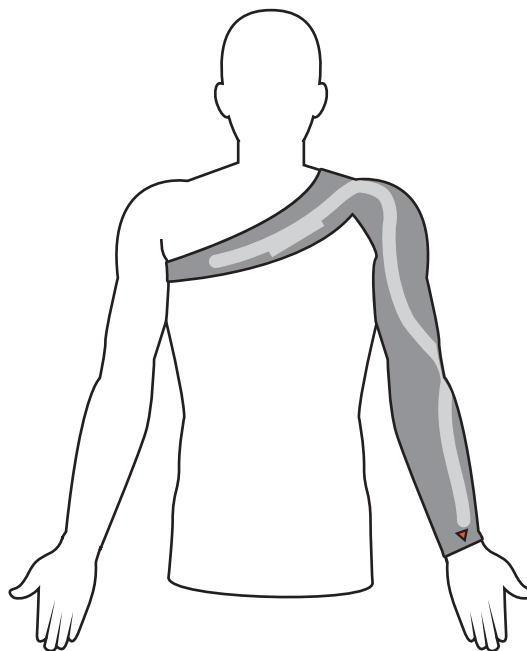


Figure 6: Elbow Crease

Figure 6 :
Fitting of garment



Front



Back



Side

APPLYING THE GARMENT

Upper Extremity BioSleeve AAb Configuration

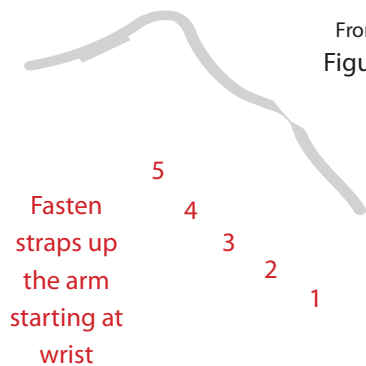
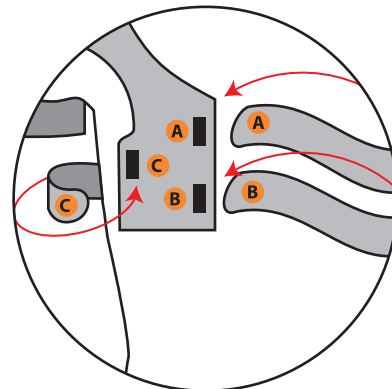
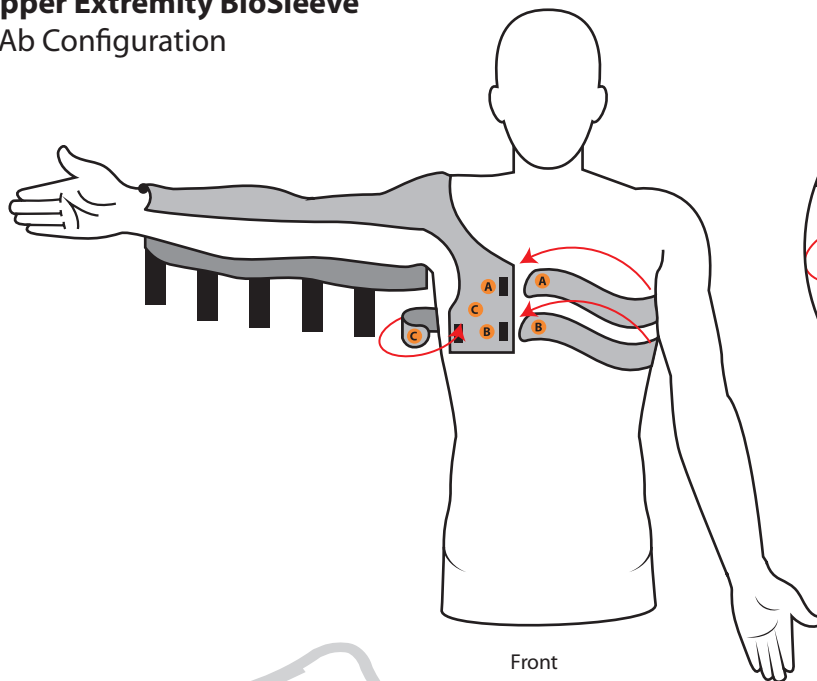
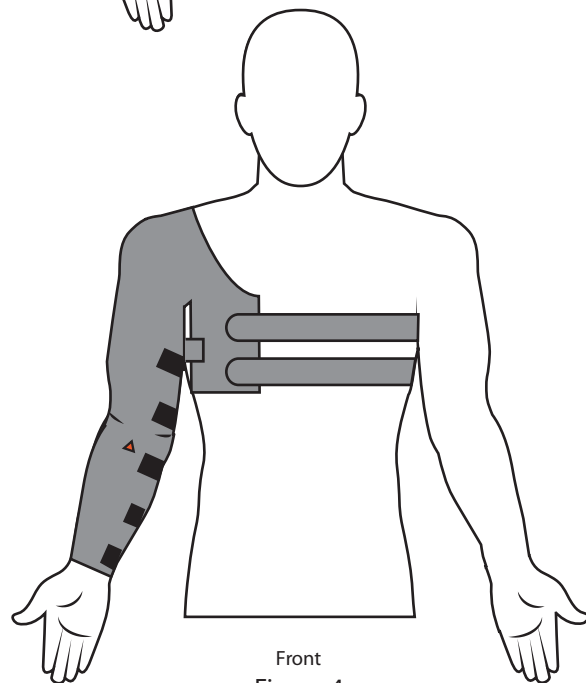


Figure 3

1. Apply BioSleeve to the arm by laying the upper section on the shoulder. (Figure 1)
2. Affix chest and side straps. Align straps with corresponding letters. (Figure 2)
3. Align the wrist pointer with the center of wrist as shown. (Figure 3)
4. Fasten each strap securely moving up the arm one strap at a time. (Figure 3)
5. If there is a pointer on the sleeve near the elbow, align this with the center of the front of the elbow crease. (Figure 4)



Wearable Therapy electrode garments must be applied directly to skin. No Clothing should intervene between electrode and skin

APPLYING THE GARMENT

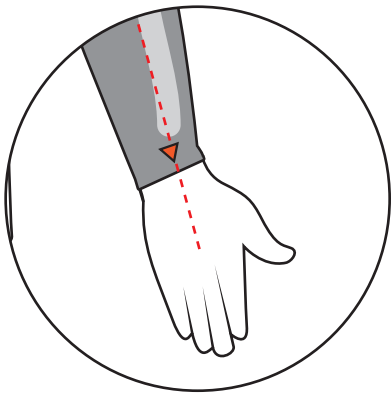


Figure 5: Top of Wrist

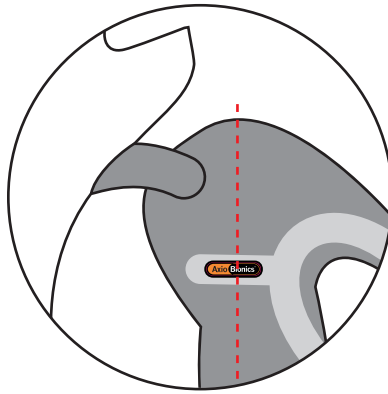


Figure 6: Shoulder

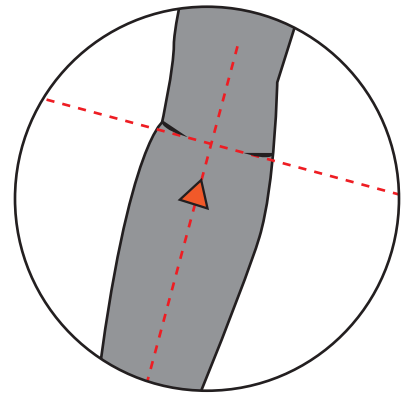
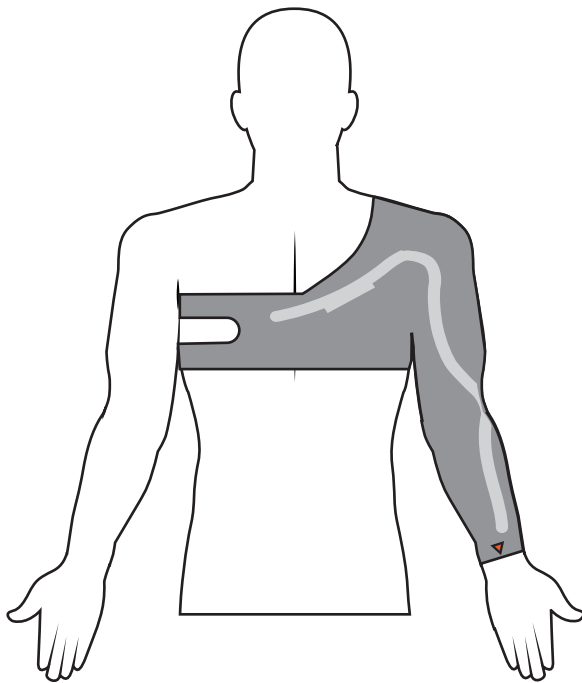
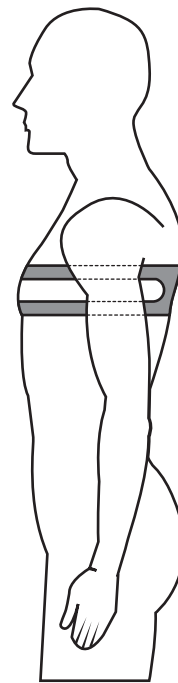


Figure 7: Elbow Crease

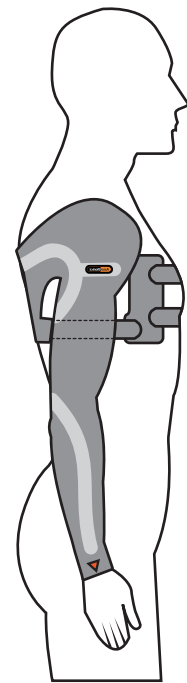
Figure 7:
Fitting of garment



Back



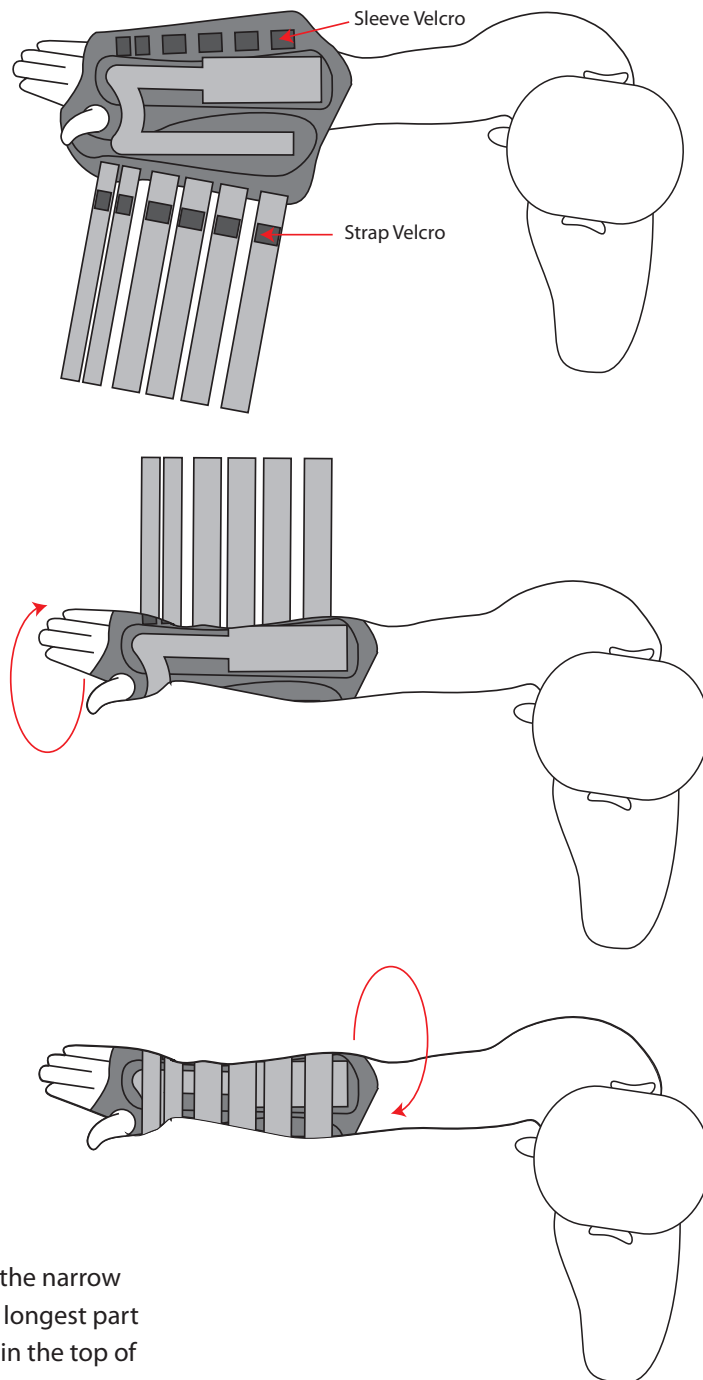
Side



Side

APPLYING THE GARMENT

Upper Extremity BioSleeve bc Configuration



1. Place thumb through the hole in the narrow end of the sleeve. Position so that longest part of the sleeve aligns with muscles in the top of the forearm.
2. Pull straps to tighten around arm. Affix straps to the Velcro on the sleeve.
3. Continue to pull straps around and affix ends of straps to Velcro on the base of the strap.

Wearable Therapy electrode garments must be applied directly to skin. No Clothing should intervene between electrode and skin

APPLYING THE GARMENT

freeSTEP Semi-Rigid Sleeve (with Heel Switch)

Figure 1

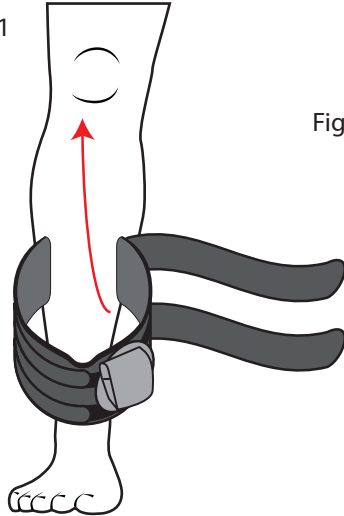


Figure 2

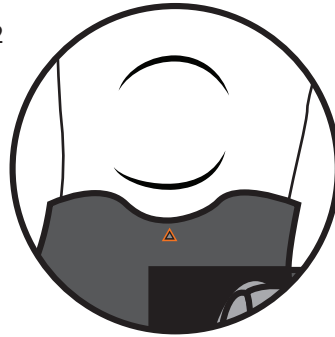


Figure 3

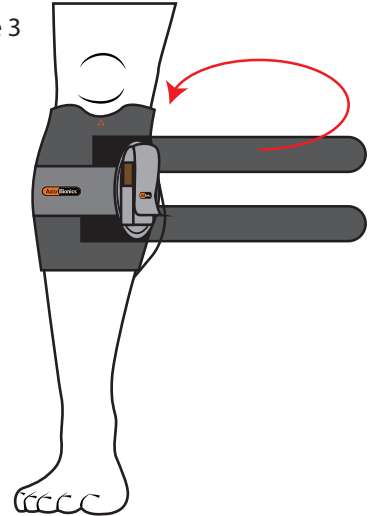


Figure 4

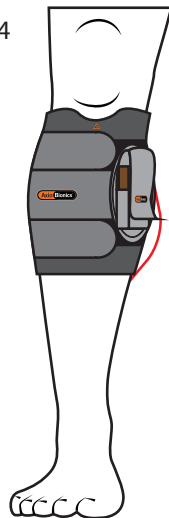


Figure 5

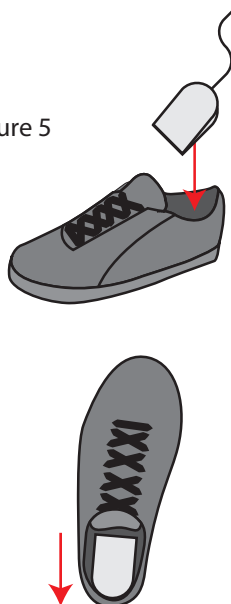


Figure 6

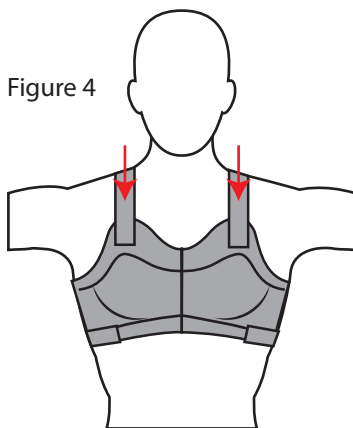
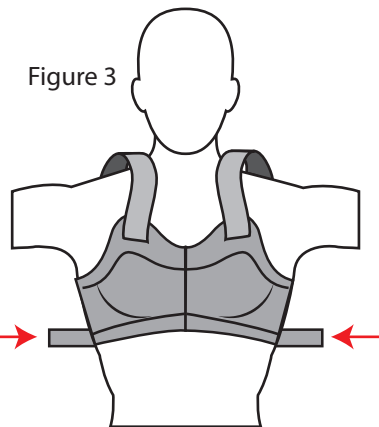
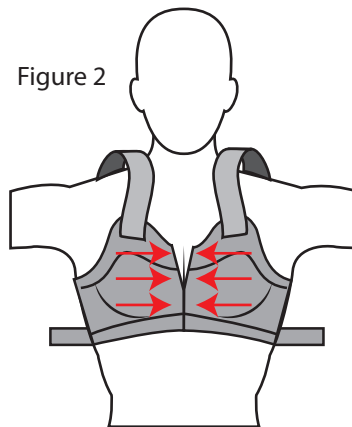
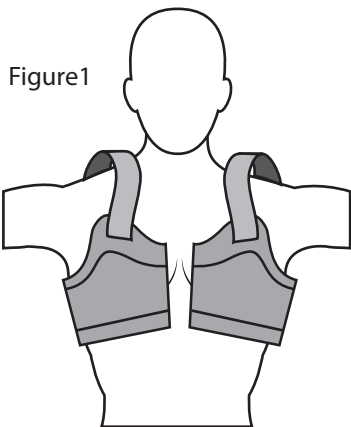


1. Place sleeve over leg just below the knee.
2. Align pointer arrow with center of knee.
3. Pull straps around the back of the leg and affix to the velcro in the front.
4. Continue to pull straps around and affix ends of straps to Velcro on the base of the strap.
5. a. If using with freeSTEP heel switch, place heel switch inside the shoe. Align with the back of the shoe
6. Connect to stimulator on sleeve.

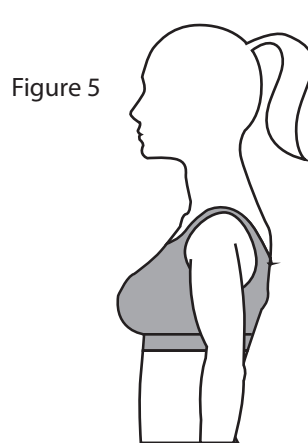
Wearable Therapy electrode garments must be applied directly to skin. No Clothing should intervene between electrode and skin

APPLYING THE GARMENT

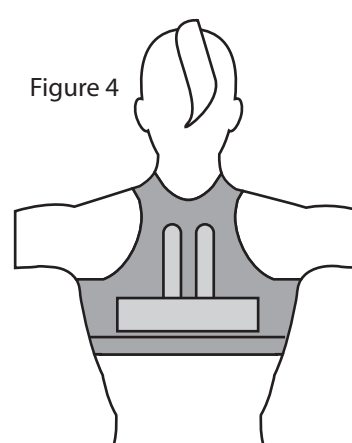
BioMiniVest



Front



Side



Back

1. Leave the front fasteners undone. Affix the over the shoulder straps to the front of the vest loosely. Put the vest on the body one arm at a time. If the vest has hip straps or belt leave them unfastened. (Figure 1)
2. Close the front fasteners. (Figure 2)
3. Tighten the left and right hip straps (if necessary) . (Figure 4)
4. Position the vest on the body where it should be located. Tighten the over the shoulder straps. (Figure 4)

Wearable Therapy electrode garments must be applied directly to skin. No Clothing should intervene between electrode and skin

APPLYING THE GARMENT

BioVest

Figure 1

Over-The-Shoulder Straps

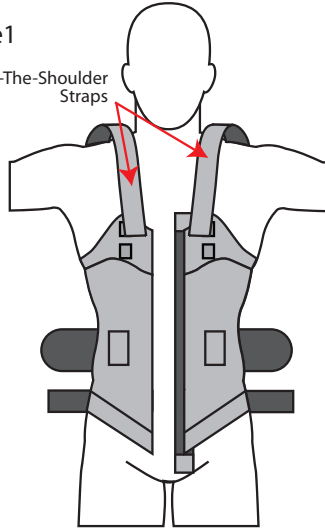


Figure 2

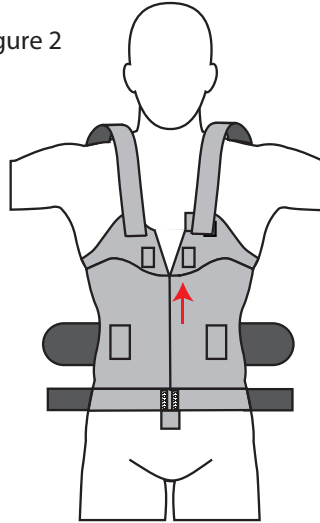


Figure 3

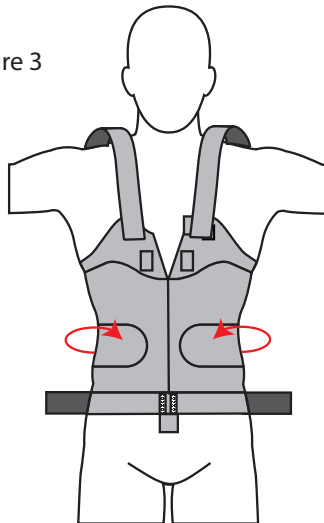
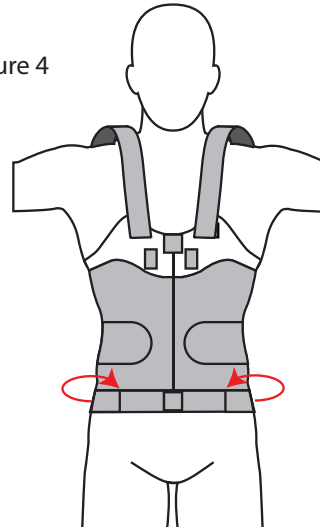


Figure 4



1. Leave zipper unfastened. Afix the over the shoulder straps to the front of the vest loosely. Put the vest on the body one arm at a time. If the vest has side straps or belt leave them unfastened. (Figure 1)
2. Close the front zipper. (Figure 2)
3. Tighten belt around waste. (Figure 3)
4. Tighten the left and right hip straps. (Figure 4)
5. Position the vest on the body where it should be located. Tighten the over the shoulder straps. (Figure 4)

Wearable Therapy electrode garments must be applied directly to skin. No Clothing should intervene between electrode and skin

APPLYING THE GARMENT

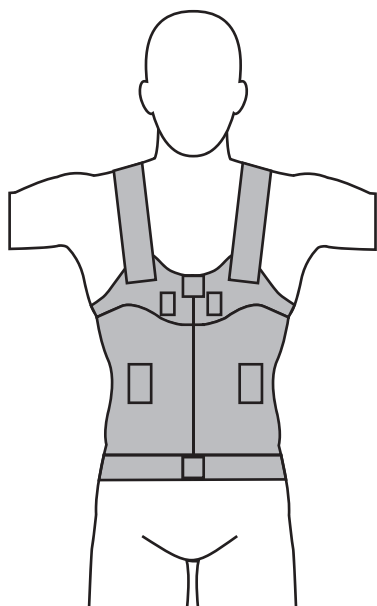


Figure 5

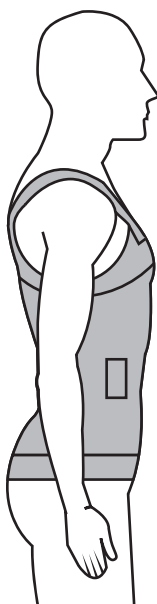


Figure 6

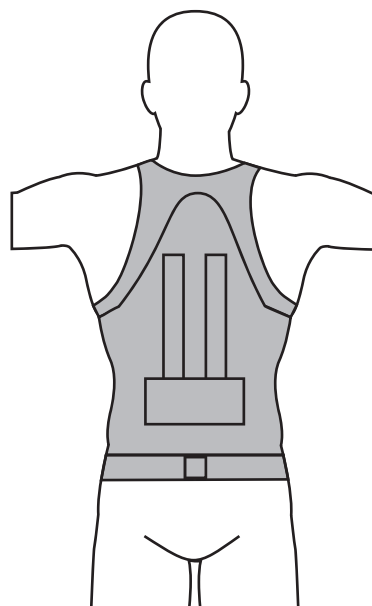
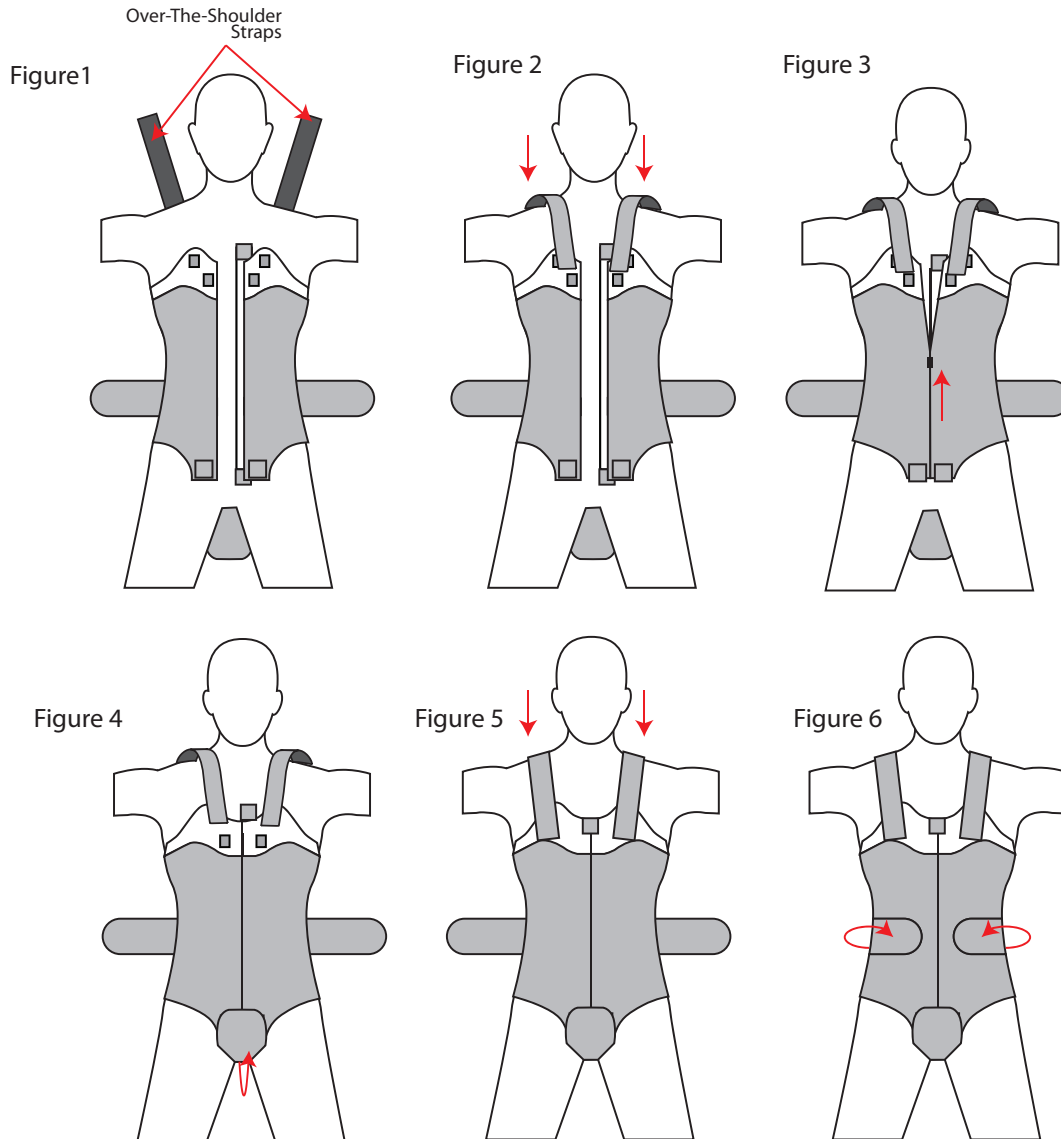


Figure 7

APPLYING THE GARMENT

BioUnitard

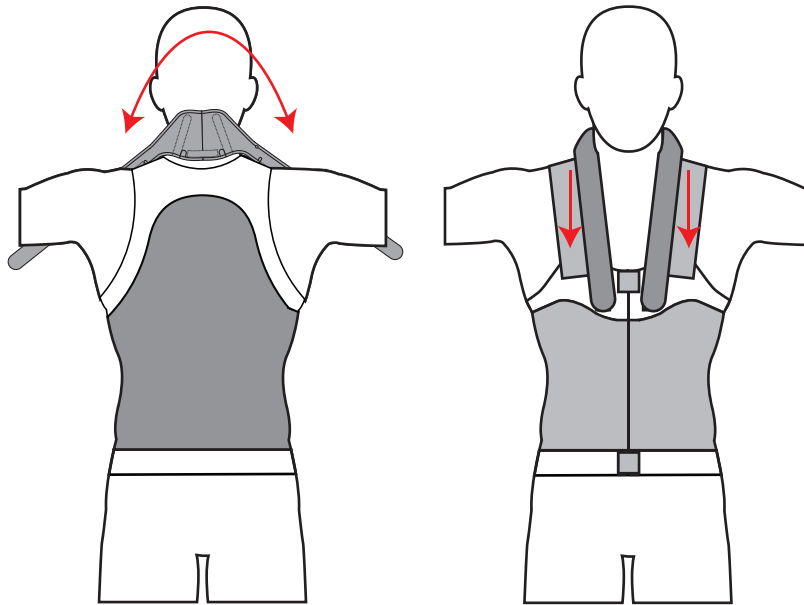


1. With the zipper unfastened and the over the shoulder straps fastened to the front of the vest but loose, put the vest on the body one arm at a time. If the vest has side straps leave them unfastened or belt . (Figures 1 and 2)
2. Close the front zipper. (Figure 3)
3. Fasten privacy panel to front of garment. (Figure 4)
4. Tighten side straps (Figure 5)
5. Position the vest on the body where it should be located. Tighten the over the shoulder straps. (Figure 6)

Wearable Therapy electrode garments must be applied directly to skin. No Clothing should intervene between electrode and skin

APPLYING THE GARMENT

BioCollar



1. Place garment at behind your neck with the pocket facing down.
2. Pull straps until garment is snug.
3. Affix straps to Velcro on BioVest.

Wearable Therapy electrode garments must be applied directly to skin. No Clothing should intervene between electrode and skin

ACCLIMATING TO WEARABLE THERAPY

Suggested Protocols For Acclimating The Body To Muscle Stimulation

Patients using NMES for the first time, or those who have been away from it for a while, should exercise caution. Any form of electrical stimulation that induces muscle contraction, even if that contraction is of low force, may make your muscles sore for a period of time. This soreness may be unavoidable until your body becomes used to the increased activity of the stimulated muscle(s) and surrounding muscle groups. This process may take two or more weeks.

Wearable Therapy Systems are medical devices targeted at patients with medical conditions. As such, you should always follow your physician's prescribed guidelines for activity. You should never exceed these parameters unless given specific instructions by your physician. For example, if your physician has instructed you to not lift more than 20 pounds, you should not lift more than 20 pounds, even if you feel you can do so when wearing your Wearable Therapy System.

To properly acclimate to the Axiobionics Wearable Therapy System, it is best if you follow one of the two provided, structured protocols (1. Slow Acclimation or, 2. Fast Acclimation), or follow a custom protocol provided by your Axiobionics representative, therapist, or physician. As your muscles are activated you may experience muscle soreness. If the soreness becomes excessive or painful, you may want to decrease the usage time or intensity of contraction until your muscles no longer hurt. You should never increase the amount of time you are using the Wearable Therapy System if you have excessive muscle soreness or experience pain.

The Axiobionics Wearable Therapy System can be used as much as 8-14 hours per day. The amount of time the

patient uses the system can be less if the patient is unable to tolerate stimulation beyond a certain duration of time.

General Guidelines For Setting Intensity Levels

Your Axiobionics representative or therapist will assist you with selecting the proper intensity of stimulation for each muscle group targeted by the Wearable Therapy System. As a general rule, muscles should be stimulated with just enough stimulation to make the muscle perform as desired. Any increase in stimulation beyond that point can cause discomfort or pain to the patient and will not provide further benefit. Too little stimulation will either not cause the muscle to contract, or the intensity of contraction will be insufficient to achieve the desired result.

Setting Intensity Levels For Each Muscle

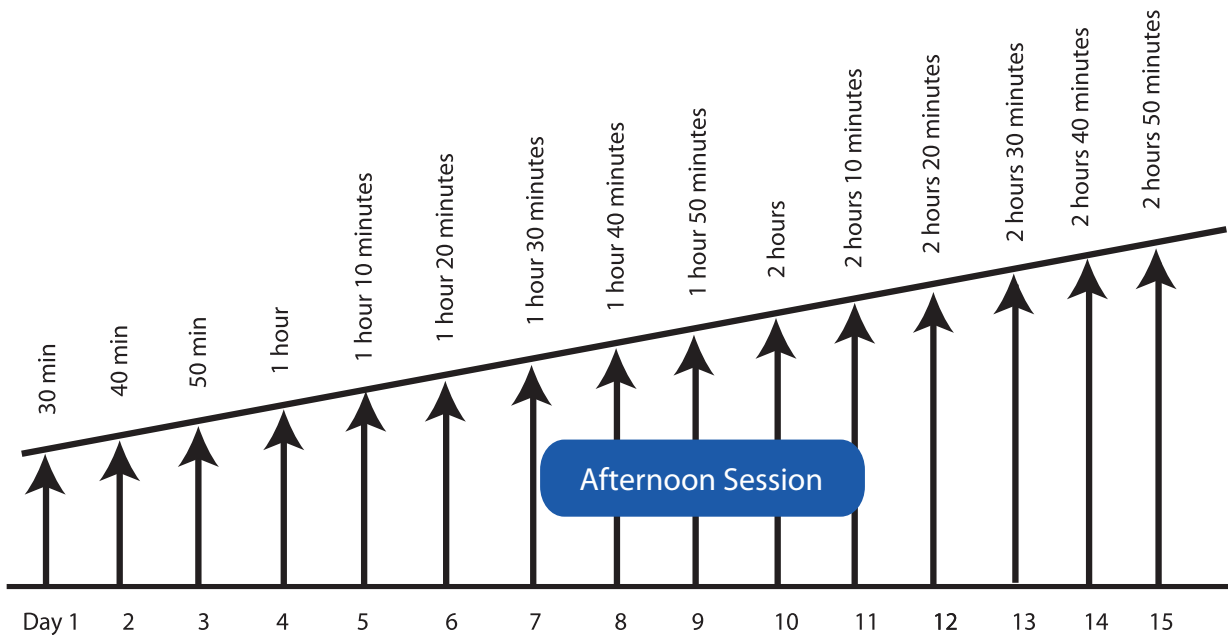
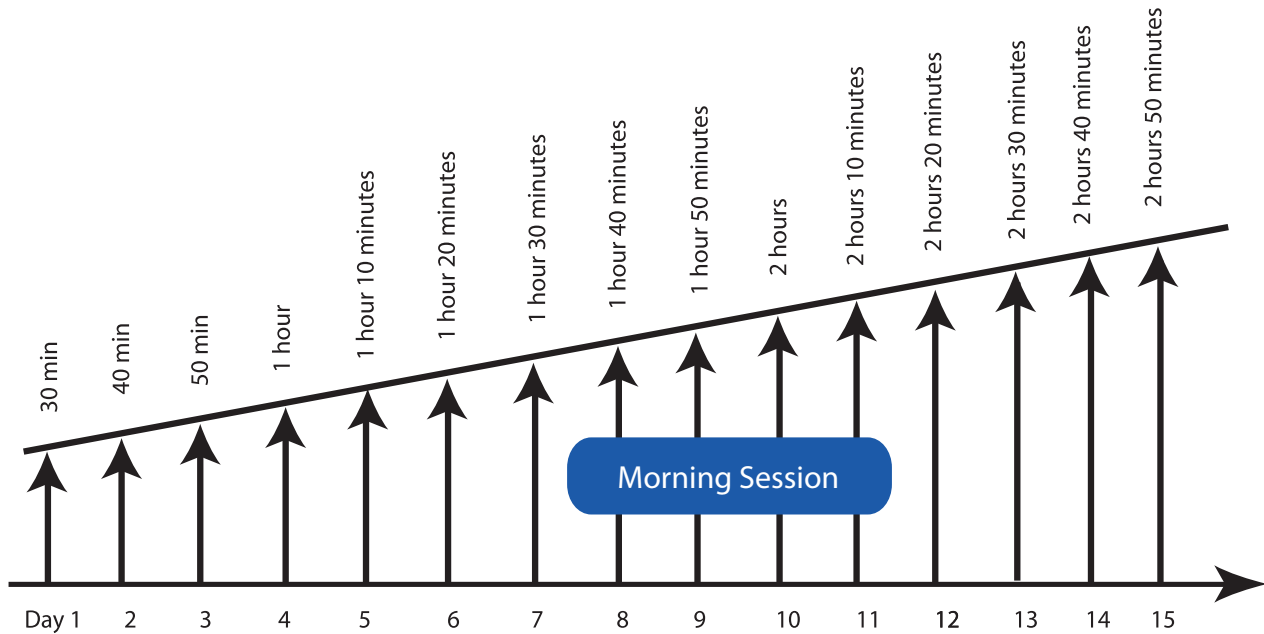
Deltoid: The level of stimulation should cause the deltoid to contract so that any separation or gapping between the shoulder joint and the head of the humerus is eliminated. No further increase in intensity is needed.

Triceps: The level of stimulation should cause the triceps to contract so that it, too, eliminates any gapping between the shoulder joint and the head of the humerus. Additionally, the clinician should increase the stimulation to the triceps so that the elbow fully extends or reaches its endpoint if a contracture at the elbow is present. No further increase in intensity is needed.

Wrist/Finger Extensors: The level of stimulation should cause the fingers to extend at each joint. Hyperextension at the metacarpal-phalangeal joint (MCP) is undesirable, but may be unavoidable if contracture of the flexor group has occurred. Some wrist extension is desirable and sometimes unavoidable. Deviation of the wrist to the ulnar or radial side should be avoided.

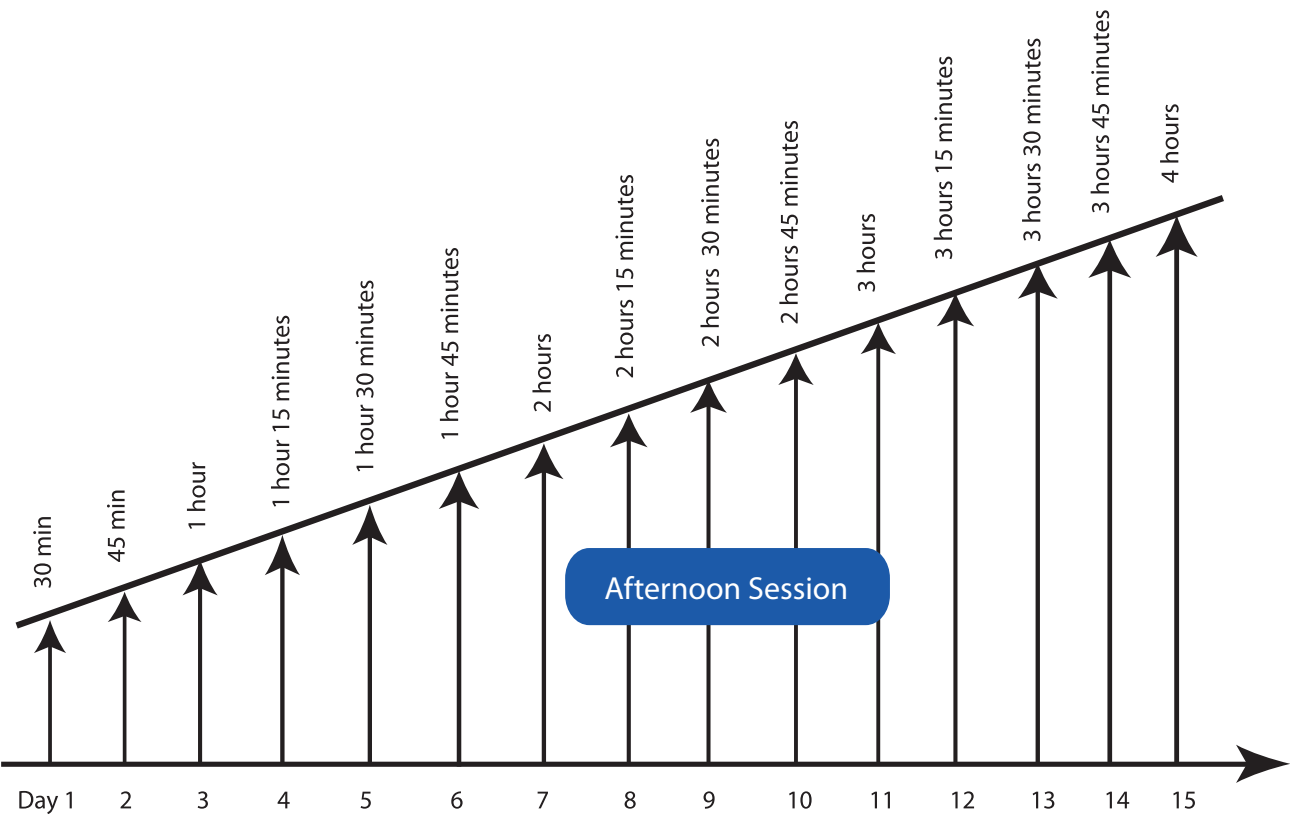
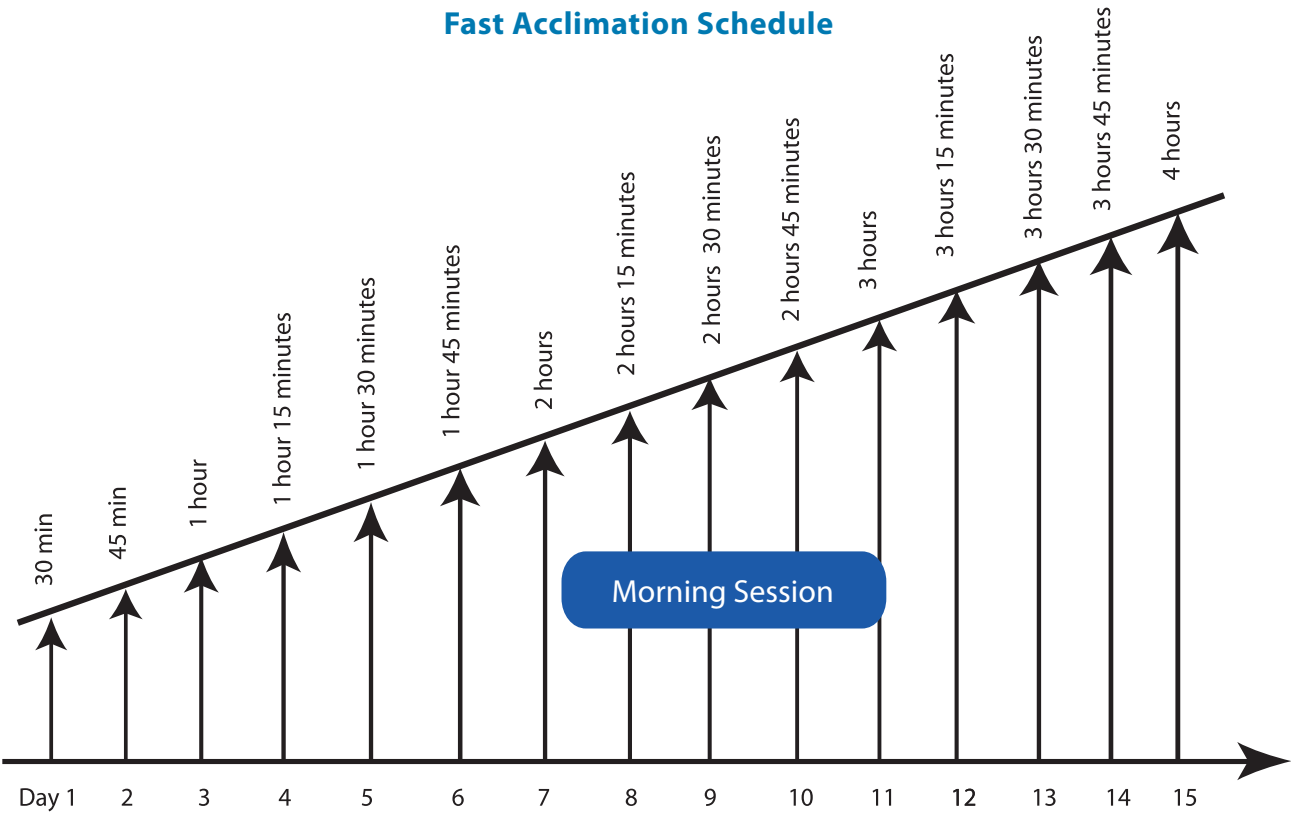
ACCLIMATING TO WEARABLE THERAPY

Slow Acclimation Schedule



ACCLIMATING TO WEARABLE THERAPY

Fast Acclimation Schedule



ACCLIMATION MONITORING FORM

Week 1-2

Morning Session

Day 1	2	3	4	5	6	7	8	9	10	11	12	13	14
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Afternoon Session

Day 1	2	3	4	5	6	7	8	9	10	11	12	13	14
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Week 3-4

Morning Session

Day 1	2	3	4	5	6	7	8	9	10	11	12	13	14
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Afternoon Session

Day 1	2	3	4	5	6	7	8	9	10	11	12	13	14
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Week 5-6

Morning Session

Day 1	2	3	4	5	6	7	8	9	10	11	12	13	14
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Afternoon Session

Day 1	2	3	4	5	6	7	8	9	10	11	12	13	14
-------	---	---	---	---	---	---	---	---	----	----	----	----	----

Week 8-10

Morning Session

Day 1	2	3	4	5	6	7	8	9	10	11	12	13	14
-------	---	---	---	---	---	---	---	---	----	----	----	----	----

Afternoon Session

Day 1	2	3	4	5	6	7	8	9	10	11	12	13	14
-------	---	---	---	---	---	---	---	---	----	----	----	----	----

PARAMETER SETTINGS FORM

Name				Time ON (Sec)	10		Constant		
Date				Time OFF (Sec)	10		Pulse Width (μS)	300	
R P									
Ramp Up (Sec)	3			Synchronous			Frequency (Hz)	25	
Ramp Dn (Sec)	2			Asynchronous	X		Stimulation Time	C	

Ch	Muscle / Area of Body	Intensity		Ch	Muscle / Area of Body	Intensity
	Left Deltoid				Right Deltoid	
	Left Biceps				Right Biceps	
	Left Triceps				Right Triceps	
	Left Wrist / Finger Flexors				Right Wrist / Finger Flexors	
	Left Wrist / Finger Extensors				Right Wrist / Finger Extensors	
	Left Lumbar Paraspinals				Right Lumbar Paraspinals	
	Left Quadratus Lumborum				Right Quadratus Lumborum	
	Left Latissimus Dorsi				Right Latissimus Dorsi	
	Rectus Abdominus					
	Transverse Abdominus					
	Left Quadriceps				Right Quadriceps	
	Left Glut-Hamstrings				Right Glut-Hamstrings	
	Left Dorsiflexors				Right Dorsiflexors	
	Left Plantarflexors				Right Plantarflexors	

WEARABLE THERAPY USAGE LOG

PATIENT _____

Date _____ Indicate the Amount of Time Each Garment is Used (stimulation time),
Time of Day and Protocol Number (NP4 Stim only)

☐ Left UE BioSleeve

Time: _____ Time: _____
Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____

☐ Right UE BioSleeve

Time: _____ Time: _____
Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____

☐ Left LE BioSleeve

Time: _____ Time: _____
Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____

☐ BioShorts

Time: _____ Time: _____ Time: _____ Time: _____
Usage: _____ Usage: _____ Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____ NP4 #: _____ NP4 #: _____

☐ Right LE BioSleeve

Time: _____ Time: _____
Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____

☐ BioBelt-lumbar

Time: _____ Time: _____
Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____

☐ BioBelt-AB

Time: _____ Time: _____
Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____

☐ BioVest

Time: _____ Time: _____
Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____

☐ Other _____

Time: _____ Time: _____
Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____

☐ Other _____

Time: _____ Time: _____
Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____

Person Performing Protocols: _____

Date _____ Indicate the Amount of Time Each Garment is Used (stimulation time),
Time of Day and Protocol Number (NP4 Stim only)

☐ Left UE BioSleeve

Time: _____ Time: _____
Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____

☐ Right UE BioSleeve

Time: _____ Time: _____
Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____

☐ Left LE BioSleeve

Time: _____ Time: _____
Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____

☐ BioShorts

Time: _____ Time: _____ Time: _____ Time: _____
Usage: _____ Usage: _____ Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____ NP4 #: _____ NP4 #: _____

☐ Right LE BioSleeve

Time: _____ Time: _____
Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____

☐ BioBelt-lumbar

Time: _____ Time: _____
Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____

☐ BioBelt-AB

Time: _____ Time: _____
Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____

☐ BioVest

Time: _____ Time: _____
Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____

☐ Other _____

Time: _____ Time: _____
Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____

☐ Other _____

Time: _____ Time: _____
Usage: _____ Usage: _____
NP4 #: _____ NP4 #: _____

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CAUTION: Federal law restricts the device to sale by or on the order of a physician or a practitioner trained in its use.