

FLEXITOUCH® PLUS

ADVANCED PNEUMATIC COMPRESSION SYSTEM

User Guide

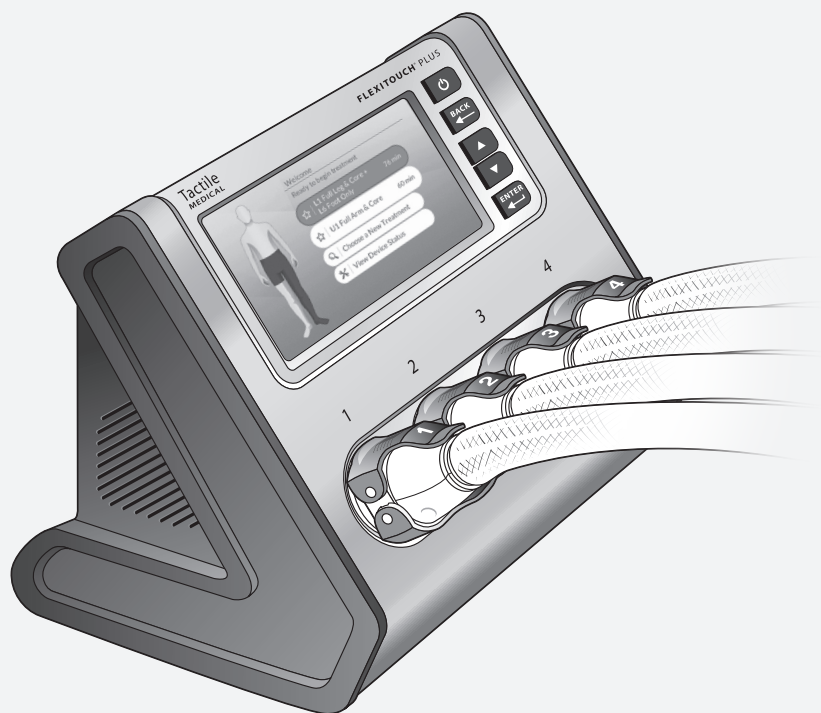


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Before You Get Started

Read the entire guide before attempting to connect or operate this product. Keep this guide for future reference.

The Flexitouch Plus system is designed for at-home treatment of lymphedema, chronic edema and chronic wounds. When used daily, the Flexitouch Plus system can help you manage your condition, improve your health and allow you to enjoy a better quality of life.

This guide provides the information needed to set up and use your Flexitouch Plus system.




1.1 How to Contact Tactile Medical






If you have questions about the Flexitouch Plus system or require service, contact Tactile Medical:

- **By phone:** Customer Service: toll free (U.S. only) at 833.382.2845 (833.3TACTILE), 7 a.m. to 7 p.m. CT, Monday–Friday.
- **By email:** You may also email us at info@tactilemedical.com.

If you have medical questions, please contact your physician or healthcare provider.

1.2 Safety Precautions and Explanation of Symbols

	IMPORTANT: Read Instructions Before Using Before attempting to connect or operate this product, please read the entire guide. Keep this guide available for future reference.
	CAUTION
	MANUFACTURER'S PART NUMBER

Rx Only	 CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed healthcare professional. The device may only be used by individuals for whom it has been prescribed. Consult your physician or other healthcare provider for recommendations regarding your therapy program, treatment cycles and/or duration of treatment. Use this product only at the settings prescribed by your healthcare provider.
	Do NOT Dispose with General Household Waste Tactile Medical complies with the Waste Electric and Electronic Equipment Directive (WEEE) 2002/96/EC. Contact Tactile Medical at 612.355.5100 or toll-free at 866.382.2845 (833.3TACTILE) (U.S. only) to get disposal instructions.
	Type BF Applied Part
	Device Serial Number
	Intertek ETL Mark Product Category: Medical Equipment Product Category CCN: PIDF Class II with respect to electrical shock, fire and mechanical hazards only in accordance with EN60601-1
IP21 Flexitouch Plus system complies with IEC60329 regarding degree of protection against water and particulates.	
WARNING: Risk of Electric Shock <ul style="list-style-type: none"> • Do not attempt to service the controller unit. Such attempts could result in injury or damage to the product, and will void any warranty. • Do not disassemble the controller unit. • Only use the power adapter provided with your Flexitouch Plus system. • Unplug the controller unit when not in use. • The Flexitouch Plus system is to be used indoors only. • Do not use the controller unit near water or while bathing. • Do not reach for the controller unit if it falls into water. Unplug the controller at the electrical outlet immediately. • Do not use the controller or garments if they become wet. Dry them off before use or wait until they become dry. 	

EMC Precautions

The Flexitouch Plus system is Medical Electrical Equipment that has been tested and demonstrated to be compatible with electromagnetic compatibility (EMC) CISPR 11 Class B limits and is therefore suitable for use in hospital, clinic and home care environments.

WARNING: Although the Flexitouch Plus system has no essential performance affected by EMC, use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Power cords can be affected by EMC. Use only the power cord provided by Tactile Medical.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Flexitouch Plus system.

WARNING: Risk of Personal Injury

- Use the controller unit only for its intended purpose, as directed in this guide.
- Use accessories only if recommended or supplied by Tactile Medical.
- Set up the controller unit in a manner that provides easy access to the power cord should it become necessary to unplug quickly.
- Never operate the controller unit if the cord or plug is not working properly, if it has been damaged or if the controller unit has been dropped into water. Return it to Tactile Medical for inspection or repair. Do not modify the cord or plug.
- Keep the power cord away from heated surfaces.
- Never operate the controller unit where the cord or tubing harness will present a strangulation or tripping hazard.
- Strangulation potential: Power cord and tubing bundle should never be placed near or around a person's neck.
- Never smoke while wearing product garments or while operating the product.



CAUTION: Risk of Device Damage

- Never block the ventilation openings on the sides of the controller unit. Keep the ventilation openings free of debris such as lint and hair.
- Never operate the controller unit on a soft surface, such as a bed, couch or pillow, where the ventilation openings may be blocked.
- Never drop or insert any object into any opening of the controller unit.
- Never use sharp objects, such as pins, scissors or clasps on or near the Flexitouch Plus system.
- Never use hot devices such as irons or blow dryers, on or near the Flexitouch Plus system.
- Keep the product free from debris to avoid valve closed or valve open failures.
- Never place the product in a position or location that would allow the tubing harness to become pinch or crushed.



PRECAUTION:

Theoretically, massage and mechanical compression could mobilize dormant tumor cells in some patients; however, this is expected to have limited impact on prognosis such that the benefits of reduction in morbid edema will likely outweigh those theoretical risks.

1.3 Indications for Use

The Flexitouch Plus system and garments for legs, arms, trunk, and chest are intended for use 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
- Phlebolympheidema

The Flexitouch Plus system and garments for the head and neck are intended for use by medical professionals and patients who are under medical supervision for the treatment of head and neck lymphedema.

1.4 Contraindications

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

- Heart failure (acute pulmonary edema, decompensated acute heart failure)
- Acute venous disease (acute thrombophlebitis, acute deep venous thrombosis, acute pulmonary embolism)

- Severe peripheral artery disease (critical limb ischemia including ischemic rest pain, arterial wounds or gangrene)
- Active skin or limb infection/inflammatory disease (acute cellulitis, other uncontrolled skin or untreated inflammatory skin disease)
- Any circumstance where increased lymphatic or venous return is undesirable
- During pregnancy (applies only to the Flexitouch Plus trunk accessory)

The head garment and the vest for head and neck for the Flexitouch Plus system should not be used if you have one or more of the following conditions:

- Uncontrolled hyperthyroidism or parathyroidism (for which an endocrinologist recommends against neck compression)
- Carotid sinus hypersensitivity syndrome
- Symptomatic carotid artery disease, as manifested by a recent transient ischemic attack (within 30 days), ischemic stroke, or amaurosis fugax (monocular visual ischemic symptoms or blindness)
- Symptomatic bradycardia in the absence of a pacemaker
- Internal jugular venous thrombosis (within 3 months)
- Increased intracranial pressure or other contraindication to internal or external jugular venous compression
- Acute radiation dermatitis, unhealed surgical scar, unhealed or open wound(s), surgical flap less than 6–8 week post-operative
- Facial or head and neck dermal metastasis
- Acute facial infection (e.g., facial or parotid gland abscess)
- Any condition in which increased venous and lymphatic return is undesirable

1.5 Unpacking Instructions

When your Flexitouch Plus system arrives, allow the controller unit to reach room temperature for one hour before using. It is important that you carefully unpack the contents and ensure that you have all the equipment required to begin operation.

Included in the box, you should find the following:

- User Guide
- Controller unit
- Garments and accessories needed to treat your condition
- Power adapter

The garments and accessories you receive will depend upon your individual therapy requirements.

If you are missing any of the items listed for your prescribed treatment, please contact Customer Service.

Lower Extremity Treatment

The garments and accessories needed for lower extremity treatment may include the following:

- Full leg garment (short, medium or long)
- Half leg garment (regular or EXT)
- Trunk accessory (small, medium or large)
- EXT trunk–thigh accessory
- Waist extender(s)

Upper Extremity Treatment

The garments and accessories needed for upper extremity treatment may include the following:

- Arm–shoulder garment
- Trunk accessory (small, medium or large)

Head and Neck Treatment

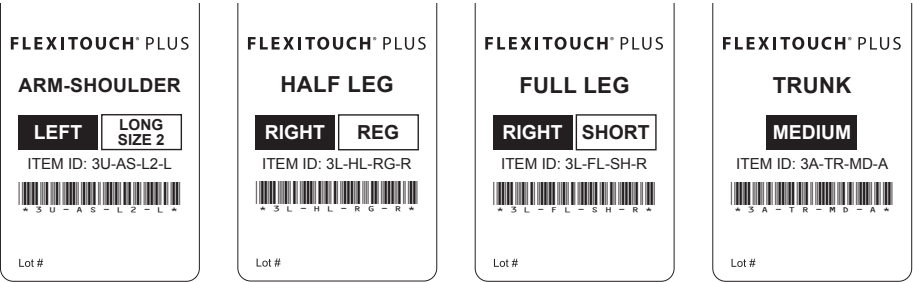
The garments needed for head and neck treatment may include the following:

- Head garment
- Vest for head and neck

Labels

Each label is located where the tubing attaches to the garment or accessory. It indicates the body area where the garment or accessory is to be applied (full leg, half leg, trunk, trunk–thigh, arm–shoulder, head and vest for head and neck) (Figure 1.5.a.).

Figure 1.5.a. Label Examples



The Flexitouch® Plus System

The Flexitouch Plus system is an advanced pneumatic compression device clinically proven to stimulate the lymphatic system. The device helps direct and move excess fluid from an impaired lymphatic region to healthy regions, where fluid can be absorbed and processed naturally by your body.

Flexitouch Plus garment chambers inflate sequentially with each chamber inflating before the adjacent distal chamber fully deflates. This creates a dynamic wave of therapy that directs fluid into the lymphatic capillaries while maintaining distal pressure to prevent distal backflow.

NOTE: No special skills, training or knowledge are required to operate the Flexitouch Plus system.

2.1 System Components

The Flexitouch Plus system consists of two primary components:

Controller Unit

The controller unit is a programmable pneumatic compressor with four connector outlets. Each connector has eight outflow ports that garment hoses plug into. Air passes through the hoses, delivering treatment through the sequential inflation and deflation of up to 32 air chambers in the garments. By selecting the appropriate treatment program, calibrated gradient pressure is delivered to the chambers and assists in moving excess fluid out of the affected limb(s).

Garments and Accessories

The air-chambered garments and accessories are made of soft, pliable fabric. They are designed to fit the contours of your body by wrapping around the limb(s) and attaching with hook and loop fasteners. A variety of upper and lower extremity treatment options are available in order to address your specific needs.

The lower extremity garment(s) and accessories are used to treat the leg(s) and core. Depending on your clinical needs, you may be prescribed a leg garment (or leg garments), or both a leg garment (or leg garments) and a trunk accessory.

The upper extremity garment(s) and accessories are used to treat the arm, or arm and core. Depending on your clinical needs, you may be prescribed an arm–shoulder garment and trunk accessory.

The head garment and the vest for head and neck are used to treat the head, neck and chest. Depending on your clinical needs, you may be prescribed a head garment and a vest for head and neck.

2.2 Programmed Pressure Levels

Programmed pressure levels in each of the air chambers are based on physiological principles of how lymph fluid moves through the system. Your healthcare provider will determine what individual programs are appropriate for you. In certain medical circumstances, your healthcare provider may wish to increase or decrease the pressure settings. The Flexitouch Plus controller unit allows for selection of INCREASED, NORMAL or DECREASED pressure settings. If additional pressure adjustment is needed, individual treatment segments may be adjusted manually.

Refer to *Appendix A: Clinician-Directed Manual Pressure Adjustment* for additional information on how to change pressures

for the various treatment segments.

When using the various pressure modes or manually calibrating segmental pressures, the pressure gradient is maintained throughout each treatment segment and the most distal garment chambers hold a level of sustained pressure which is intended to prevent the distal backflow of lymph fluid. The treatments are designed to only deliver clinically appropriate pressures and to maintain pressure gradients in order to prevent adverse device settings.

NOTE: *Please consult with your healthcare provider before changing the pressure settings.*

Table 1: Treatment Programs and Therapy Times				
Program	Program Display	Body Regions Treated	Treatment Time (min.)	Available Cycles
Lower Extremity—Primary Treatment Programs				
L1	Full Leg & Core	Trunk, thigh, calf and foot	60	1
L4	Full Leg Plus	Thigh, calf and foot	45	1–5
L5	Half Leg Plus	Calf and foot	30	1–5
L7	Half Leg	Calf and foot	30	1–5
L8	Full Leg	Thigh, calf and foot	45	1–5
Lower Extremity—Supplemental Treatment Programs				
L2	Trunk Only	Trunk	16	1–5
L3	Trunk & Thigh	Trunk and thigh	30	1–5
L6	Foot Only	Foot	16	1–5
Upper Extremity—Primary Treatment Programs				
U1	Full Arm & Core	Trunk, chest, shoulder, biceps, forearm and hand	60	1
U4	Arm–Shoulder	Chest, shoulder, biceps, forearm and hand	50	1–5
U7	Full Arm	Arm	30	1–5
Upper Extremity—Supplemental Treatment Programs				
U2	Trunk Only	Trunk	12	1–5
U3	Trunk & Chest	Trunk and chest	30	1–5
U5	Forearm & Hand	Forearm and hand	24	1–5
U6	Hand Only	Hand	12	1–5
Head and Neck—Primary Treatment Program				
H1	Head, Neck & Vest	Head, neck & chest	32	1
Head and Neck—Supplemental Treatment Programs				
H2	Head Only	Head, neck	13	1
H3	Vest Only	Chest	12	1

2.3 Treating the Lower Extremity

Treatment Program L1: Full Leg & Core

This treatment option provides the ability to deliver therapy to both the leg and trunk regions when clinically appropriate. Incremental proximal clearing of lymphatic fluid in the ❶ trunk, ❷ thigh, ❸ calf and ❹ foot regions is followed by delivery of the traditional ❺ full leg and trunk treatment.

Treatment time: 60 minutes.

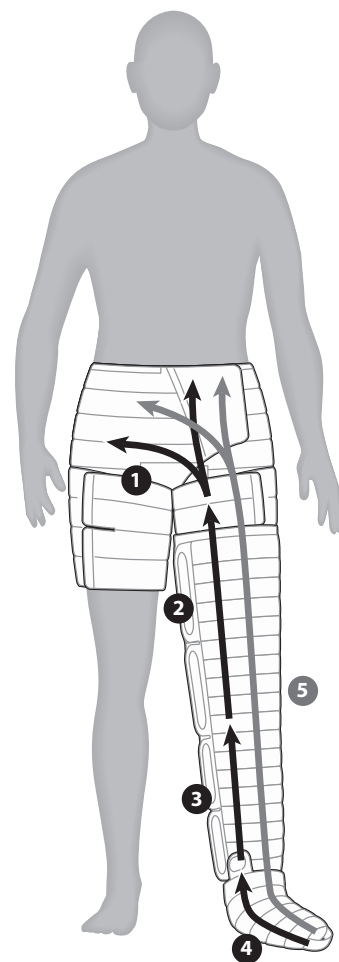


Figure 2.3.a.: Full Leg and Core

- 1. Trunk**
directs fluid from top of the thigh toward waist
- 2. Thigh**
directs fluid from knee toward top of the thigh
- 3. Calf**
directs fluid from ankle toward knee
- 4. Foot**
directs fluid from toes toward ankle
- 5. Full Leg and Trunk**
directs fluid from toes toward top of waist in one continuous motion

2.4 Treating the Upper Extremity

Treatment Program L4: Full Leg Plus

This treatment option provides the ability to deliver therapy to the leg when clinically appropriate. Incremental proximal clearing of lymphatic fluid in the ① thigh, ② calf and ③ foot regions is followed by delivery of the traditional ④ full leg treatment.

Treatment time: 45 minutes.

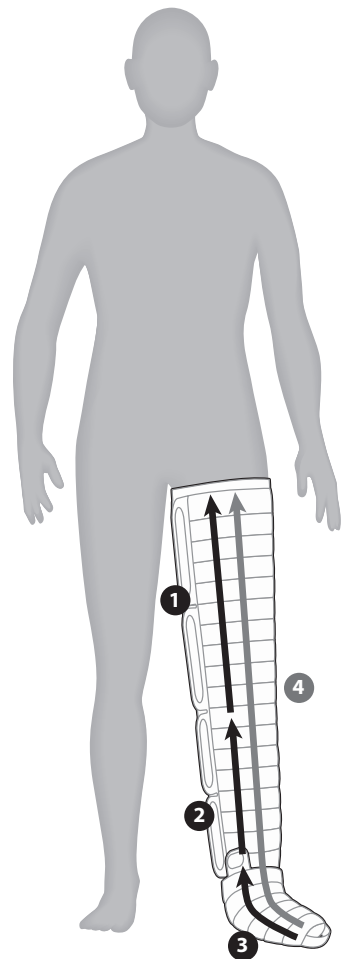


Figure 2.3.b.: Full Leg Plus

- 1. Thigh**
directs fluid from knee toward top of thigh
- 2. Calf**
directs fluid from ankle toward knee
- 3. Foot**
directs fluid from toes toward ankle
- 4. Full Leg**
directs fluid from toes toward top of thigh in one continuous motion

Treatment Program U1: Full Arm & Core

This treatment option provides the ability to deliver therapy to the arm, chest and trunk regions when clinically appropriate. Incremental proximal clearing of lymphatic fluid in the ① trunk, ② chest, ③ biceps, ④ forearm and ⑤ hand regions is followed by delivery of the traditional ⑥ full arm, shoulder, chest and trunk treatment.

Treatment time: 60 minutes.

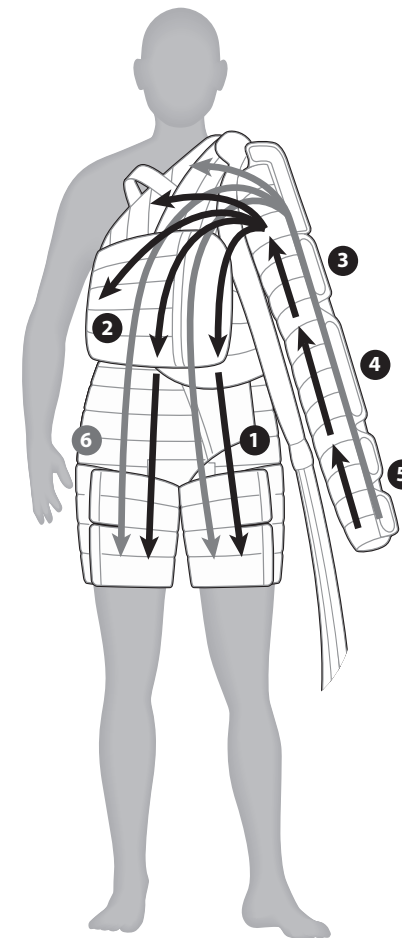


Figure 2.4.a.: Full Arm and Core

- 1. Trunk**
directs fluid from waist toward top of thigh
- 2. Chest**
directs fluid from shoulder toward waist
- 3. Biceps**
directs fluid from elbow toward shoulder
- 4. Forearm**
directs fluid from wrist toward elbow
- 5. Hand**
directs fluid from fingers toward wrist
- 6. Full Arm, Shoulder, Chest and Trunk**
directs fluid from fingers toward the top of thigh in one continuous motion

Treatment Program U4: Arm–Shoulder

This treatment option provides the ability to deliver therapy to the arm and chest regions when clinically appropriate. Incremental proximal clearing of lymphatic fluid in the ❶ chest, ❷ biceps, ❸ forearm and ❹ hand regions is followed by delivery of the traditional ❺ full arm, shoulder and chest treatment.

Treatment time: 50 minutes.

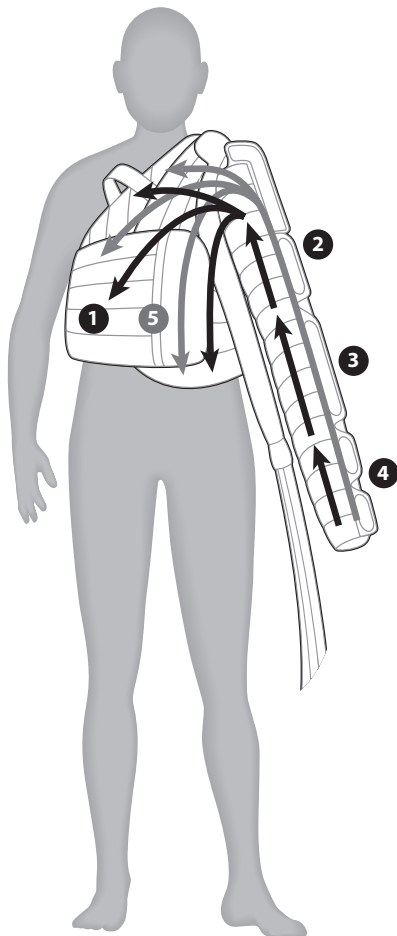


Figure 2.4.b.: Arm–Shoulder

- 1. Chest**
directs fluid from the shoulder toward the waist
- 2. Biceps**
directs fluid from the elbow toward the shoulder
- 3. Forearm**
directs fluid from the wrist toward the elbow
- 4. Hand**
directs fluid from the fingers toward the wrist
- 5. Full Arm, Shoulder and Chest**
directs fluid proximally from the fingers up toward the shoulder, then toward the top of the waist in one continuous motion

2.5 Treating the Head and Neck

Treatment Program H1: Head, Neck & Vest

This treatment option provides the ability to deliver therapy to the head, neck and chest when clinically appropriate. Incremental proximal clearing of lymphatic fluid in the ❶ chest and neck and ❷ head is followed by delivery of the ❸ full head, neck and chest treatment.

Treatment time: 32 minutes.

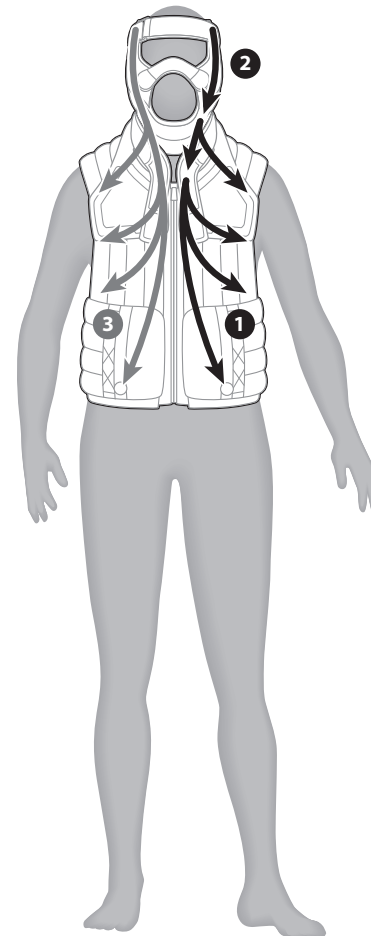


Figure 2.5.a.: Head and Neck

- 1. Chest and Neck**
directs fluid from the neck and the chest toward under arm area
- 2. Head**
directs fluid from head toward neck
- 3. Head, Neck and Chest**
directs fluid from head toward the under arm area in one continuous motion

Controller Unit Setup

The Flexitouch Plus system consists of a controller unit, a garment set and accessories to treat your condition. In this chapter you will learn how to set up the controller unit and select the proper settings prior to receiving therapy. You will learn how to apply the garments in Chapters 5 (lower extremity), 6 (upper extremity) and 7 (head and neck).

3.1 Setting Up the Controller Unit

Follow the steps outlined below:

1. Find an appropriate location for the controller unit. Place the controller unit on a sturdy, flat surface near an electrical outlet. Position the device so you have easy access to the plug.
2. Plug the supplied power adapter into the power adapter inlet on the back of the controller unit. Then, plug the two-pronged plug into an electrical outlet (Figure 3.1.a. on next page).

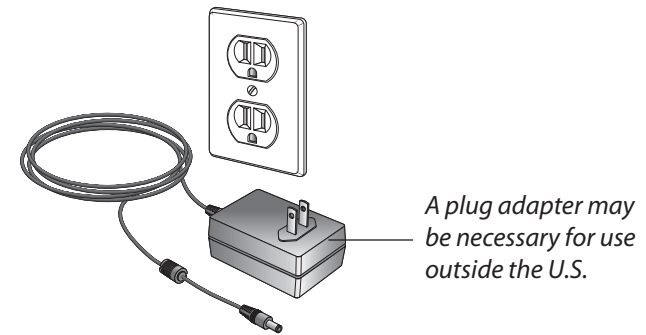
NOTE: There are two 12 VDC power adapter options, so the version shown below may be different from the one you receive. The two versions are:

- Meanwell GSM36U12-P1JNX
- Fuhua UE36LCP1-120300SPA

WARNING: RISK OF ELECTRIC SHOCK

Only use the Meanwell GSM36U12-P1JNX or Fuhua UE36LCP1-120300SPA power adapter with your Flexitouch Plus system. These power adapters are designed for use with either 120 Volt AC or 230 Volt AC outlets.

Figure 3.1.a. Power Adapter




3.2 Select Your Settings

Follow the steps outlined below to select the settings prescribed by your healthcare provider:

NOTE: Your controller unit will arrive programmed with your prescribed treatment saved as the first preset. You may not need to modify the preset program(s) unless instructed by your healthcare provider. The controller unit can, however, store up to three treatment therapies, and will automatically recall and highlight the last performed treatment.

1. Turn the controller unit ON.

Turn the controller unit on by pressing the  button located in the upper right corner on the front panel (see Figure 3.2.a. on next page).

2. Select and start your therapy session.


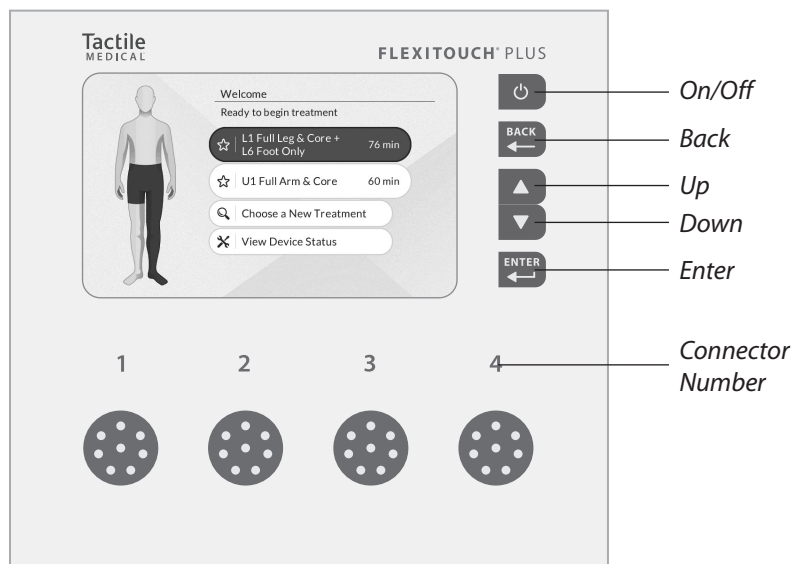
Your prescribed treatment program will be saved as the first preset on the home screen, and will be highlighted in blue when the controller unit is turned ON. To begin your prescribed treatment session, select the  button found on the right-hand side of the controller unit. Your therapy session will begin, and the time remaining will be displayed.

Figure 3.2.a. Controller Unit Front Panel



If you are prescribed a supplemental program, it will be saved as the second preset on your controller unit. To switch to the second preset and run the treatment program, press the ▼ arrow button until the second preset is highlighted in blue. Once highlighted, select the ENTER button to begin the supplemental therapy. Your therapy session will begin, and the time remaining will be displayed.

NOTE: You may PAUSE TREATMENT for up to 15 minutes at any point during a therapy session by pressing the ENTER button. The controller unit will remain paused for up to 15 minutes. After that time, the controller unit will automatically shut off, requiring you to restart your therapy session. To resume your therapy, make sure the RESUME TREATMENT option is highlighted in blue, and press the ENTER button. To stop treatment, press the ▼ arrow button to select STOP TREATMENT and select ENTER.

3. Selecting or programming a new treatment.

On the home screen, press the ▼ arrow button until the CHOOSE A NEW TREATMENT option is highlighted in blue. Once highlighted, select the ENTER button. Using the ▲ / ▼ arrow buttons, and by pressing the ENTER button when the appropriate option is highlighted in blue, complete the following:

1. Select the appropriate TREATMENT REGION.
2. Select the appropriate BODY TREATMENTS.
3. Select the appropriate TREATMENT LOCATION.
4. Select the prescribed TREATMENT PRESSURE.
5. Select the number of TREATMENT CYCLES.
6. Complete the treatment selection. Select DONE WITH SETUP using the ENTER button if the treatment selection is complete. If you would like to string an additional treatment with the existing programmed treatment, select ADD ANOTHER TREATMENT and complete steps 2–5 above.
7. Choose a preset to save the new treatment.

NOTES:

- If you have three saved presets, you will need to overwrite one of them to save the new treatment.
- Please consult your healthcare provider before changing or adding programs to your prescribed treatment.

After you have selected the necessary settings, you are ready to connect the hoses to the controller unit.

Connecting the Hoses to the Controller Unit

The next step before therapy can be delivered is connecting the hoses to the controller unit. The hose latches and the ports on the controller unit/bilateral adapter are numbered 1 through 4. When connected properly, latch number 1 will connect to port number 1, and so on.

4.1 Connecting the Bilateral Adapter

If you are conducting bilateral therapy, you will have received a bilateral adapter that connects to the controller unit (Figure 4.1.a. on next page). The adapter must be connected to the controller unit prior to connecting your garments. To connect the adapter, position it so the paddles on both sides are perpendicular to the adapter and the ports on the back of the adapter align with the ports on the front of the controller unit (Figure 4.1.a. on next page). You will hear two clicks, which confirm the ports have been properly aligned and connected. Once the adapter has been properly connected, move the paddles on both sides in the down direction, so they are positioned in the locked direction (Figure 4.1.b. on next page). You should not be able to remove the bilateral adapter from the controller unit without unlocking it once it has been properly locked.

NOTE: One or more of the ports will be capped if your prescribed therapy does not use the port(s). Do not remove the port cap(s).

Figure 4.1.a.
Bilateral Adapter

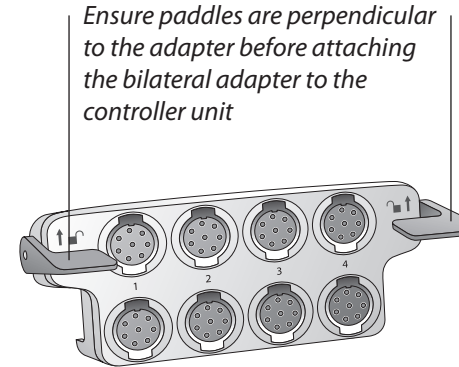
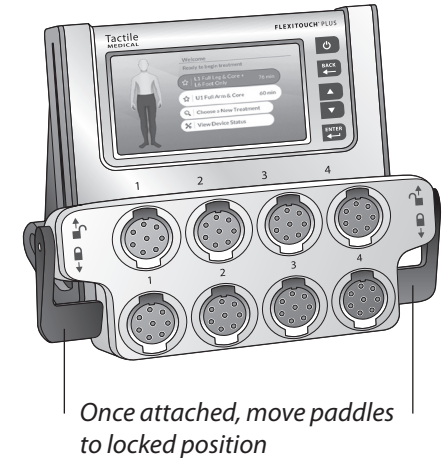
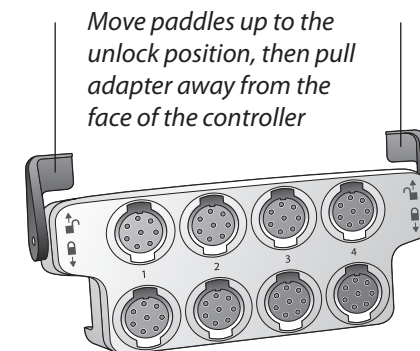


Figure 4.1.b.
Bilateral Adapter Attached to the Controller Unit



To remove the bilateral adapter, move the paddles on both sides all the way up to the unlock position (Figure 4.1.c. below). With the paddles unlocked, pull the bilateral adapter away from the face of the controller to remove it.

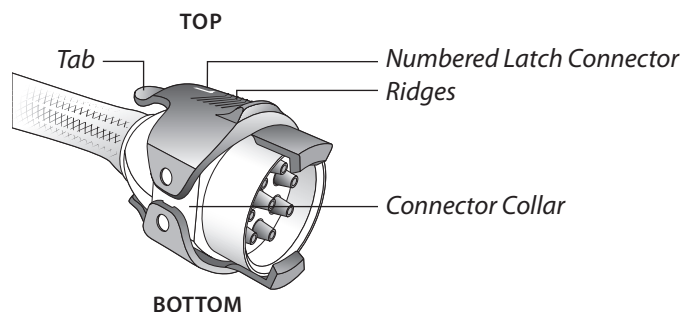
Figure 4.1.c.
Removing the Bilateral Adapter



4.2 Connecting the Hoses to the Controller Unit

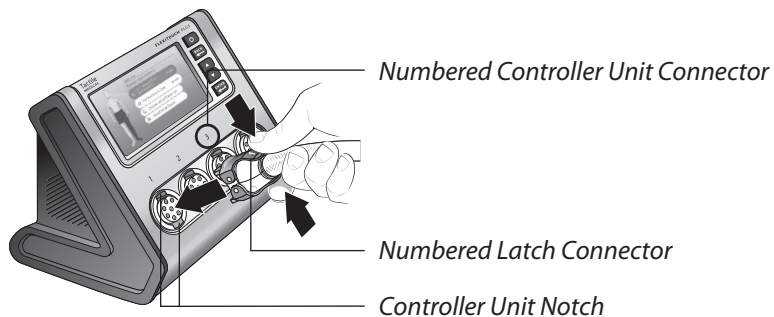
1. Hold the hose connector by the tabs on the back of the latch making sure the numbers are facing up.
2. Gently squeeze the tabs to widen the front end of the hose connector (Figure 4.2.a. below).

Figure 4.2.a. Hose Connector



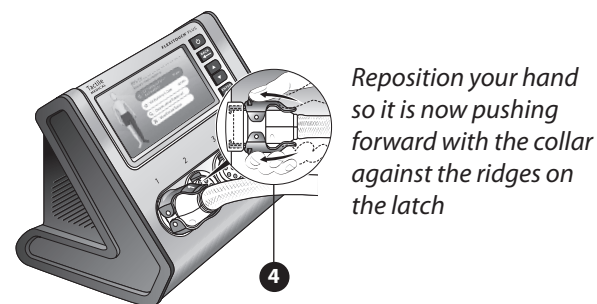
3. Align the numbered latch with the notch on the corresponding controller unit notch (Figure 4.2.b. below).

Figure 4.2.b. Corresponding Hose Connector with Controller Unit Connector



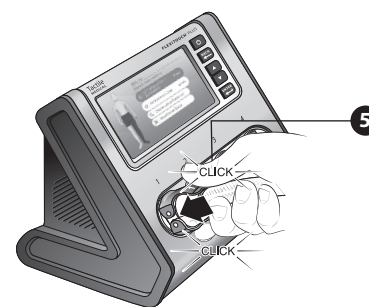
4. Reposition your hand so your thumb and fingers are positioned on the top and bottom latch ridges. This enables you to slide the latch (#4 in Figure 4.2.c. below).

Figure 4.2.c. Proper Handling of the Hose Connector



5. Push the latch forward. It will hook on the top and bottom of the controller unit connector. You should hear a click when each of the latches is properly connected. Two clicks will be heard, one for the top and one for the bottom latch (#5 in Figure 4.2.d. below).

Figure 4.2.d. Properly Connecting the Latches



6. Repeat for all connectors required for your prescribed treatment (Figures 4.2.e., 4.2.f., 4.2.g. and 4.2.h. on next page).

Figure 4.2.e. Fully Attached Hose Connectors When Full Leg and Arm–Shoulder Treatment is Prescribed

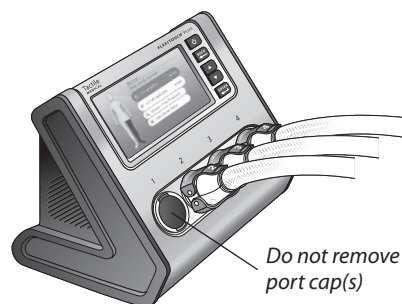


Figure 4.2.f. Fully Attached Hose Connectors When Both Extremity and Core Treatment are Prescribed

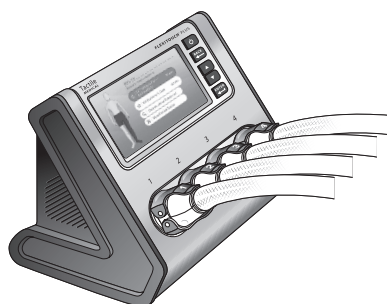


Figure 4.2.g. Fully Attached Hose Connectors When Head and Neck Treatment is Prescribed

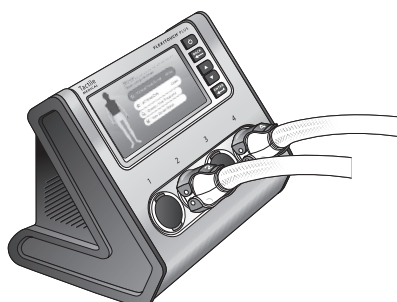
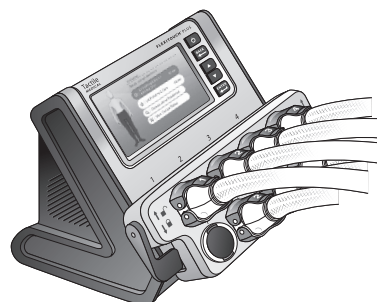


Figure 4.2.h. Fully Attached Hose Connectors When Bilateral Adapter is Attached



NOTES:

- *Holding the back of the controller unit may help to stabilize the unit as you attach the latch connectors. If you are having trouble connecting the latches, try connecting the bottom latch first then tipping the top latch into place.*
- *You may see black numerical markings through the tubing. This is normal and does not affect performance.*

You are now ready to apply your garment set as the final step before treatment can be delivered.

Garment and Accessory Application— Lower Extremity

Prior to starting therapy, it is important to:

1. Be sure you are using the recommended garments and accessories to complete your therapy.
2. Choose a time that will limit interruptions that would require you to pause therapy. The therapy session typically lasts one hour.

If your garment(s) is labeled:

- **Full leg and trunk**, proceed to section **5.1 Applying the Trunk Accessory**.
- **Full leg**, proceed to section **5.2 Applying the Full Leg Garment**.
- **Half leg**, proceed to section **5.3 Applying the Half Leg Garment**.
- **EXT Half leg and trunk–thigh**, proceed to section **5.4 Applying the EXT Half Leg Garment and Trunk–Thigh Accessory**.

CAUTION

To avoid skin irritation that may result from contact with the nylon material, wear lightweight, loose-fitting (non-elastic) cotton clothing (example: scrubs, stockinette); for head and neck garments a face mask or balaclava. If skin irritation develops, consult with your doctor.



Lymph fluid is moved through the vessels in the skin. It is important to avoid wearing anything during therapy that may hamper the lymph flow. These items include:

- **Belts**
- **Jewelry**
- **Restrictive clothing such as:** Elastic-banded underwear, Compression bandaging, Elastic-banded socks, Compression garments, Bra

CAUTION



- The Flexitouch Plus garments should not be placed in direct contact with an open wound. It is recommended that wounds be properly dressed before the garment is applied. Contact your healthcare provider if you have any questions.
- Take care to avoid overheating when donning or doffing garments.

5.1 Applying the Trunk Accessory

NOTE: For EXT Trunk–Thigh, proceed to section 5.4

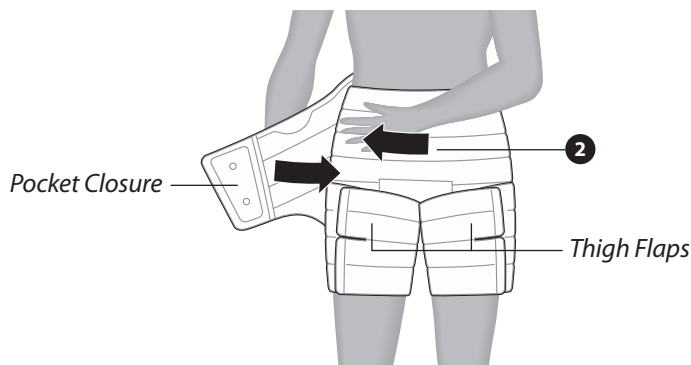
Trunk Accessory Preparation:

1. Unfold and place your trunk accessory on the bed or sofa so the thigh flaps and pocket closure are facing up. This is the front of the trunk accessory. The thigh flaps are located on the thighs. The pocket closure is located on the abdomen (Figure 5.1.a. below).

Trunk Accessory Application:

2. To apply the trunk accessory, sit down, open the pocket closure and slide the trunk accessory on like a pair of shorts. Bring the inside flap of the trunk garment across your waist (#2 in Figure 5.1.a. below).

5.1.a. Trunk Accessory Application

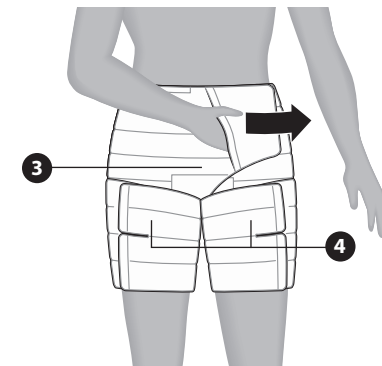


3. Secure the trunk garment using the pocket closure (#3 in Figure 5.1.b. below).
4. To get a well-contoured fit on the thigh, undo the thigh flaps and wrap the garment snugly around your thigh (#4 in Figure 5.1.b. below). Repeat this process on your other thigh.

NOTE: For additional range of motion when applying the leg garment, you may want to keep the abdomen area loose until after the leg garment is fully applied.

You are now ready to proceed to section 5.2.

5.1.b. Securing the Trunk Accessory



5.2 Applying the Full Leg Garment

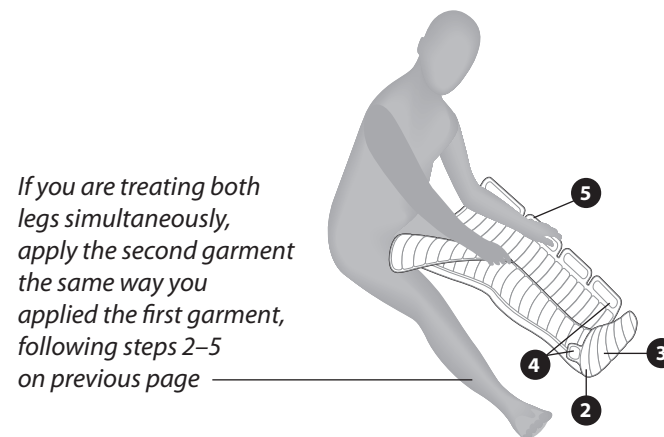
Full Leg Garment Preparation:

1. Unfold and place the full leg garment on the bed or sofa so the foot section is at the bottom, and the tubing cover runs along the back of your leg.

Full Leg Garment Application:

2. Sit down and place your leg on the garment. Center your heel in the heel cup area, where the foot section bends (#2 in Figure 5.2.a. on next page).
3. Contour the ankle section and secure the fabric in place with the hook fasteners (#3 in Figure 5.2.a. on next page).
4. Next, unfasten the small tabs at the ankle section and secure the hook fasteners as you contour the foot section snugly around the arch of your foot and your toes. Continuing up your leg, readjust the ankle section, if necessary, and continue wrapping your lower calf, following its contours. Secure the fabric with the hook fastener tabs (#4 in Figure 5.2.a. on next page).
5. Continue to contour the garment using the hook fasteners for a secure fit up the calf and thigh (#5 in Figure 5.2.a. on next page). When wrapping, try to minimize any bunches or folds in the fabric and adjust the hook fastener tabs as necessary to get a well-contoured fit.

Figure 5.2.a. Applying the Full Leg Garment



6. Finally, place a couple of pillows under your calf and foot to elevate them just above your hips for optimal treatment (#6 in Figures 5.2.b. and 5.2.c. on next page). Place the hoses alongside your body so they are easy to reach when attaching them to the controller unit.

NOTE: You should be able to slide your leg garment on, as you would a boot, after it has been configured the first time. You should only need to open the hook fasteners above the knee when removing and reapplying the garment each time.

You are now ready to begin your therapy session. See Chapter 8 for further instructions.

Figure 5.2.b. Fully Applied Full Leg Garment and Trunk Accessory

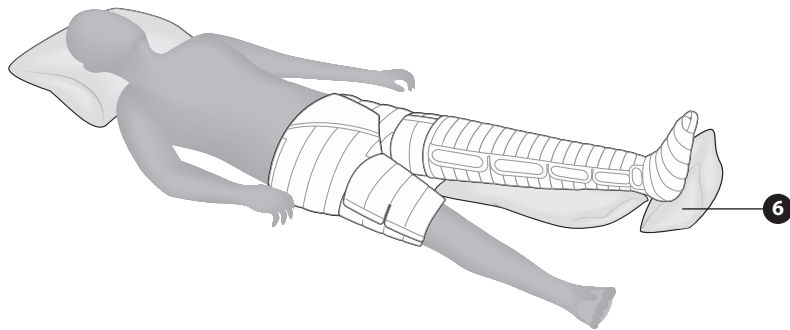
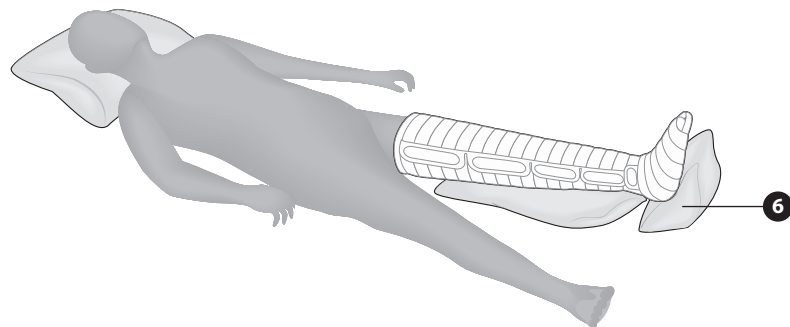


Figure 5.2.c. Fully Applied Full Leg Garment



5.3 Applying the Half Leg Garment

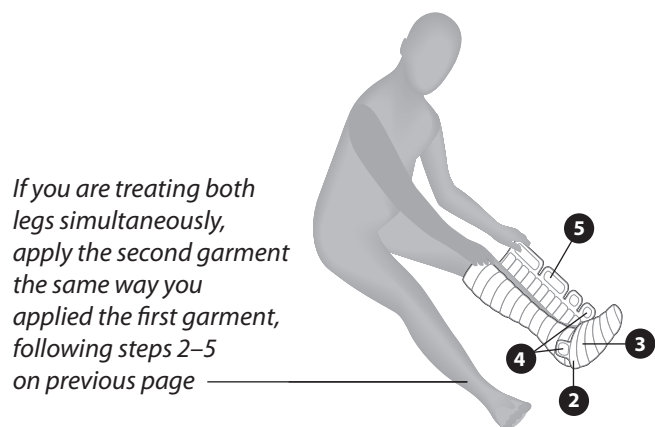
Half Leg Garment Preparation:

1. Unfold and place the half leg garment on the bed or sofa, positioned so the foot section is at the bottom, and the tubing cover runs along the back of your leg.

Half Leg Garment Application:

2. Sit down and place your leg on the garment. Center your heel in the heel cup area, where the foot section bends (#2 in Figure 5.3.a. on next page).
3. Contour the ankle section and secure the fabric in place with the hook fasteners (#3 in Figure 5.3.a. on next page).
4. Next, unfasten the small tabs at the ankle section and secure the hook fasteners as you contour the foot section snugly around the arch of your foot and your toes. Continuing up your leg, readjust the ankle section, if necessary, and continue wrapping your lower calf, following its contours. Secure the fabric with the hook fastener tabs (#4 in Figure 5.3.a. on next page).
5. Continue to contour the garment using the hook fasteners for a secure fit up the calf (#5 in Figure 5.3.a. on next page). You may need to readjust the ankle area before continuing to contour up the calf. When wrapping, try to minimize any bunches or folds in the fabric and adjust the hook fastener tabs as necessary to get a well-contoured fit.

Figure 5.3.a. Applying the Half Leg Garment

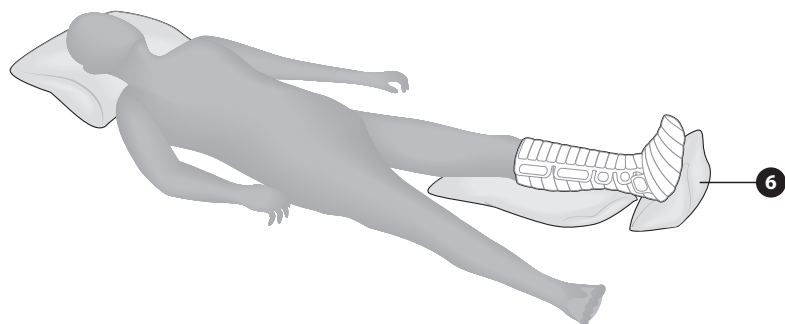


- Finally, place a couple of pillows under your calf and foot to elevate them just above your hips for optimal treatment (#6 in Figure 5.3.b. below). Place the hoses alongside your body so they will be easy to reach when attaching them to the controller unit.

NOTE: You should be able to slide your half leg garment on, as you would a boot, after it has been configured the first time. You should only need to open the top hook fastener when removing and reapplying the garment each time.

You are now ready to begin your therapy session. See Chapter 8 for further instructions.

Figure 5.3.b. Fully Applied Half Leg Garment



5.4 Applying the EXT Half Leg Garment and Trunk–Thigh Accessory

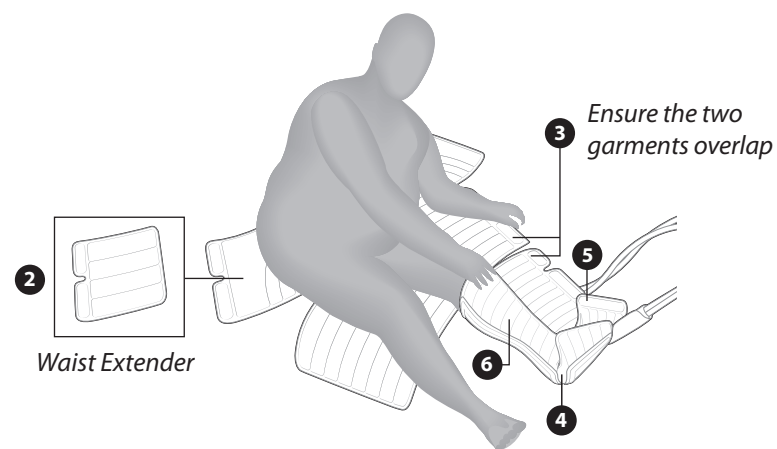
EXT Half Leg Garment and Trunk–Thigh Accessory Preparation:

- Unfold and place the trunk–thigh accessory on the bed or sofa, positioned so when you sit on it, the seam will be along the outside of your leg.
- If you need a waist extender, attach it to the trunk accessory (#2 in Figure 5.4.a. below).
- Place the half leg garment on the bed so that it overlaps the trunk–thigh accessory by a couple of chambers and so the seam runs along the back of your leg (#3 in Figure 5.4.a. below).

EXT Half Leg Garment Application:

- Sit down and place your heel into the heel cup area of the garment (#4 in Figure 5.4.a. below).

Figure 5.4.a. Applying the Half Leg Garment



5. Begin wrapping the foot section with the non-hook fastener side of the fabric. Snugly wrap the arch of the foot and the toes. Secure the fabric with the hook fastener tabs (#5 in Figure 5.4.a. on previous page).
6. Grasp the non-hook fastener side of the calf fabric. Wrap this section by starting mid-calf then move up and down your leg making sure the fabric is smooth and there are no gaps around the toes, ankle and knee. Secure the fabric with the hook fastener tabs, starting at the midpoint of the calf and continuing to attach the hook fasteners up and down your calf (#6 in Figure 5.4.a. on previous page).
7. If necessary, readjust the fasteners to obtain a well-contoured and comfortable fit.
8. Place a couple of pillows under your calf and foot to elevate them just above your hips for optimal treatment (#8 in Figure 5.4.b. on next page). Place the hoses alongside your body so they are easy to reach when you are ready to attach them to the controller unit.

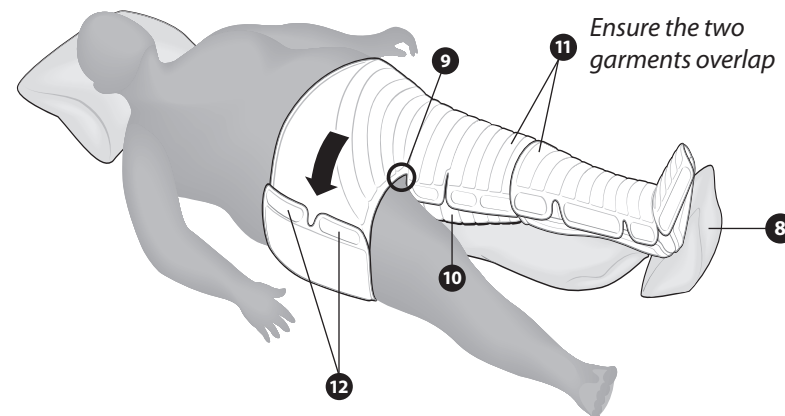
Trunk–Thigh Accessory Application:

9. Check to make sure the U-shaped notch on the trunk thigh accessory will be centered on the groin area when fully applied (#9 in Figure 5.4.b. on next page).
10. Hold the non-hook fastener side of the thigh accessory at the midpoint and bring it up between your thighs (#10 in Figure 5.4.b. on next page). Starting mid-thigh, wrap this section over your thigh so that the fabric is snug and follows the crease where your thigh meets your trunk .

11. Grasp the hook fastener side of the thigh accessory at the midpoint wrapping it over the non-hook fastener fabric. Secure the hook fastener tabs starting at the midpoint and working up and down your thigh. Adjust the hook fastener tabs as necessary to ensure a snug fit without gaps, paying particular attention to where the trunk–thigh accessory and half leg garment meet (#11 in Figure 5.4.b. below).
12. Lay back and snugly wrap the non-hook fastener side of the trunk fabric over your abdomen. Bring the hook fastener side of the fabric as far as you can over your trunk. Secure the hook fastener tabs (#12 in Figure 5.4.b. below).

You are now ready to begin your therapy session. See Chapter 8 for further instructions.

Figure 5.4.b. Fully Applied EXT Lower Extremity Garment Set



Garment and Accessory Application— Upper Extremity

Prior to starting therapy, it is important to:

1. Be sure you are using the recommended garments and accessories to complete your therapy.
2. Choose a time that will limit interruptions that would require you to pause therapy. The therapy session typically lasts one hour.

If your garments and accessories are labeled:

- **Arm–shoulder and trunk**, proceed to section **6.1 Applying the Trunk Accessory**.
- **Arm–shoulder**, proceed to section **6.2 Applying the Arm–Shoulder Garment**.

CAUTION

To avoid skin irritation that may result from contact with the nylon material, wear lightweight, loose-fitting (non-elastic) cotton clothing (example: scrubs, stockinette); for head and neck garments a face mask or balaclava. If skin irritation develops, consult with your doctor.

Lymph fluid is moved through the vessels in the skin. It is important to avoid wearing anything during therapy that may hamper the lymph flow. These items include:

- **Belts**
- **Jewelry**
- **Restrictive clothing such as:** Elastic-banded underwear, Compression bandaging, Elastic-banded socks, Compression garments, Bra

CAUTION

- The Flexitouch Plus garments should not be placed in direct contact with an open wound. It is recommended that wounds be properly dressed before the garment is applied. Contact your healthcare provider if you have any questions.
- Consult your physician before using Flexitouch Plus garments that cover the chest (Arm–Shoulder garment, and Vest for Head & Neck garment) if you have a tissue expander.
- Take care to avoid overheating when donning or doffing garments.



6.1 Applying the Trunk Accessory

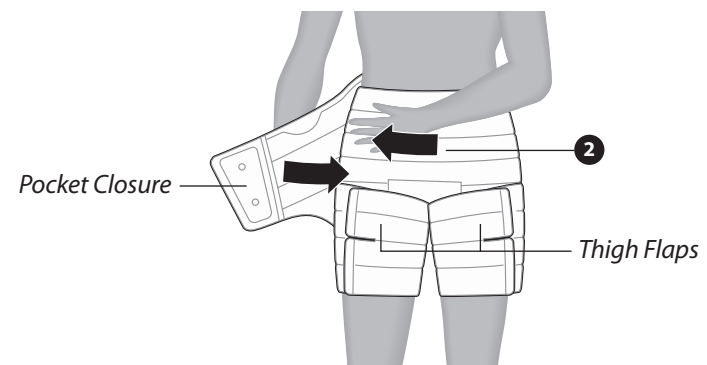
Trunk Accessory Preparation:

1. Unfold and place your trunk garment on the bed or sofa so the thigh flaps and pocket closure are facing up. This is the front of the trunk accessory. The thigh flaps are located on the thighs. The pocket closure is located on the abdomen (Figure 6.1.a. below).

Trunk Accessory Application:

2. To apply the trunk accessory, sit down, open the pocket closure and slide the trunk accessory on like a pair of shorts. Bring the inside flap of the trunk garment across your waist (#2 in Figure 6.1.a. below).

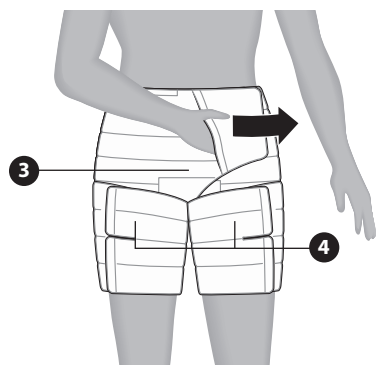
6.1.a. Trunk Accessory Application



3. Secure the trunk garment using the pocket closure (#3 in Figure 6.1.b. below).
4. To get a well-contoured fit on the thigh, undo the thigh flaps and wrap the garment snugly around your thigh (#4 in Figure 6.1.b. below). Repeat this process on your other thigh.

You are now ready to proceed to section 6.2.

6.1.b. Securing the Trunk Accessory



6.2 Applying the Arm–Shoulder Garment

Arm–Shoulder Preparation:

1. In preparation for donning the arm–shoulder garment, loosely form the arm portion of the garment into a cone shape and fasten the hook tabs.

NOTE: *Adjust the tabs around the biceps section so you will be able to slide your affected arm into the garment easily.*

2. Unfasten the chest strap on the front of the garment so you are able to apply the garment.

Arm–Shoulder Application:

3. Slide your arm into the pre-shaped cone, making sure the tabs run along the front of the garment (#3 in Figure 6.2.a. on next page).

NOTE: *Pay particular attention to snugly fitting the contours of the wrist and elbow areas.*

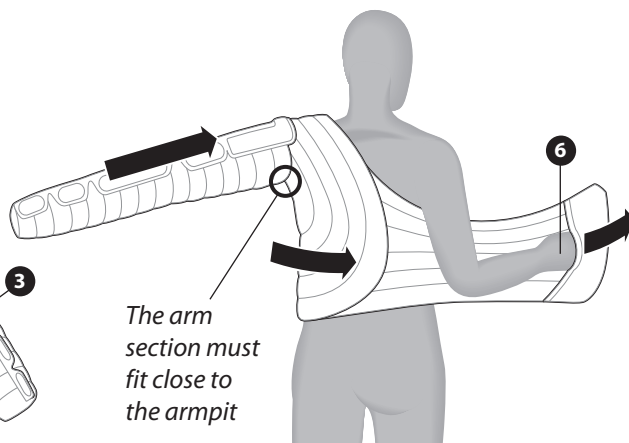
4. Pull the arm portion of the garment up toward your shoulder (#4 in Figure 6.2.a. on next page), making sure your fingertips remain fully enclosed in the garment.
5. Ensure the chest flap attached to the arm piece crosses the center line of your chest and is flat against your chest (#5 in Figure 6.2.a. on next page).
6. Place your free hand (extremity not being treated) in the pocket located at the end of the chest strap (#6 in Figure 6.2.b. on next page) and wrap it around the front of your chest.

7. Readjust and tighten the hook fasteners on the biceps, under the arm and on the arm to obtain a well-contoured fit (#8 in Figure 6.2.c. below).

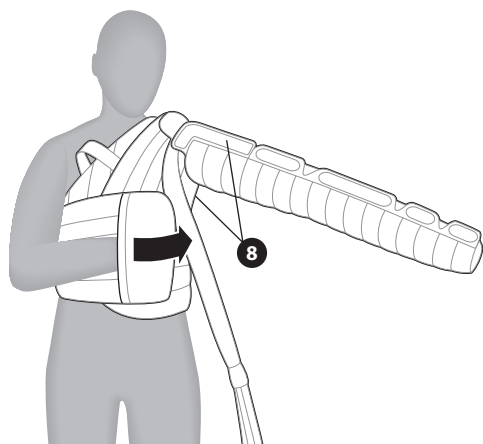
**Figure 6.2.a.
Preparing the Garment**



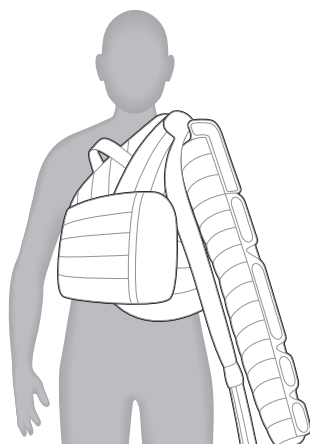
**Figure 6.2.b. Applying the
Arm–Shoulder Garment**



**Figure 6.2.c.
Ensure a Well-Contoured Fit**



**Figure 6.2.d.
Fully Applied Arm–Shoulder Garment**



Fully Applied Arm–Shoulder Garment:

8. Properly applied, the garment and accessories will follow the contours of your body and fit snugly, yet comfortably (Figure 6.2.d. on previous page). Make any necessary adjustments after you lie down to ensure a well-contoured fit.
9. Use a pillow to elevate your arm slightly above your torso during treatment (#10 in Figures 6.2.e. and 6.2.f. below) and angle your arm about 45 degrees out from the side of your body.

You are now ready to begin your therapy session. See Chapter 8 for further instructions.

Figure 6.2.e. Fully Applied Trunk and Arm–Shoulder Garment

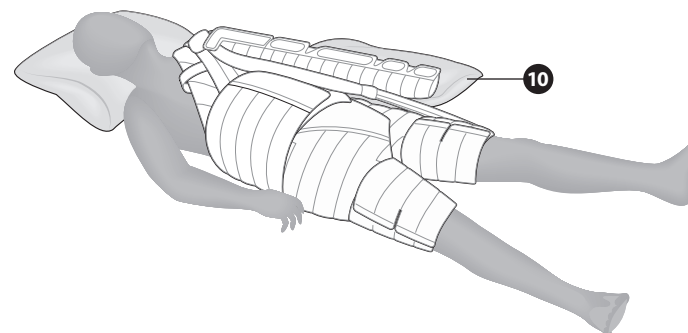
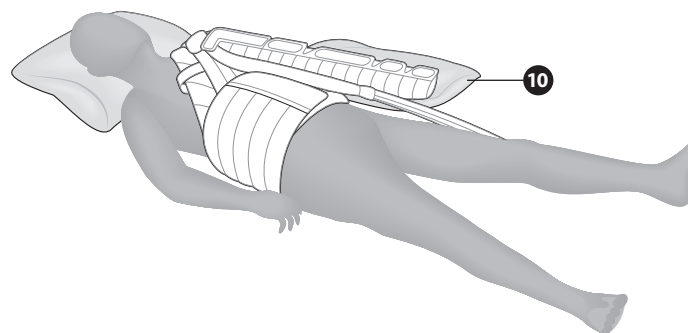


Figure 6.2.f. Fully Applied Arm–Shoulder Garment



Garment Application— Head and Neck

Prior to starting therapy, it is important to:

1. Be sure you are using the recommended garments and accessories to complete your therapy.
2. Choose a time that will limit interruptions that would require you to pause therapy. The therapy session typically lasts 30–40 minutes.

If your garment(s) and accessories are labeled:

- **Head and vest**, proceed to section **7.1 Applying the Head Garment and Vest for Head and Neck**.

CAUTION

To avoid skin irritation that may result from contact with the nylon material, wear lightweight, loose-fitting (non-elastic) cotton clothing (example: scrubs, stockinette); for head and neck garments a face mask or balaclava. If skin irritation develops, consult with your doctor.



Lymph fluid is moved through the vessels in the skin. It is important to avoid wearing anything during therapy that may hamper the lymph flow. These items include:

- **Belts**
- **Jewelry**
- **Restrictive clothing such as:** Elastic-banded underwear, Compression bandaging, Elastic-banded socks, Compression garments, Bra

CAUTION

- The Flexitouch Plus garments should not be placed in direct contact with an open wound. It is recommended that wounds be properly dressed before the garment is applied. Contact your healthcare provider if you have any questions.
- Consult your physician before using Flexitouch Plus garments that cover the chest (Arm–Shoulder garment, and Vest for Head & Neck garment) if you have a tissue expander.
- Take care to avoid overheating when donning or doffing garments.
- Flexitouch Plus garments have been designed to allow use by patients with tracheotomy tubes. Take care when donning or doffing garments to avoid disturbing tracheotomy tubes.
- Remove any hearing aids and/or eyeglasses before donning head and neck garments.



7.1 Applying the Head Garment and the Vest for Head and Neck

Head Garment Preparation:

1. Unfold your head garment so the head strap is facing up and located at the top. This is the front of the head garment. The nose piece will be located with the garment. The chin straps are located at the bottom by the chin (Figure 7.1.a. on next page).

Head Garment Application:

NOTE: A mirror may be helpful for garment placement and fitting when applying the head garment.

2. Place the head garment around the back of the head aligning the top of the garment so the forehead strap runs across the crown of the head.
3. Pull the forehead strap through the plastic loop. Tighten by pulling on the forehead strap and secure by attaching the hook fastener of the forehead strap to the inner head strap (#3 in Figure 7.1.a. on next page).
4. Conform the nose piece across the bridge of the nose and attach the free hook fasteners to the side of the head garment to ensure good contact of garment to the cheeks. Adjust garment so it doesn't come into contact with your eyes (Figure 7.1.b. on next page).
5. Adjust the right inner chin strap to fit snugly under the chin (Figure 7.1.c. on next page).
6. Adjust the left outer chin strap over the top of the right inner chin strap and fasten using the hook fastener (Figure 7.1.d. on next page).

Figure 7.1.a.
Attach Hook Fastener to
Inner Head Strap

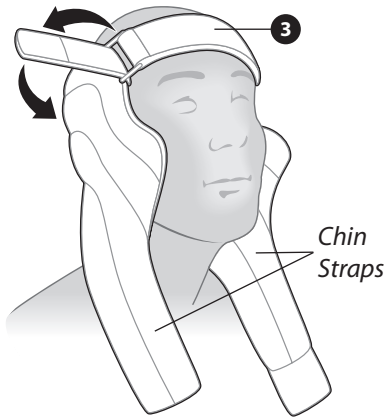


Figure 7.1.b.
Conform Nose Piece Across the
Bridge of the Nose

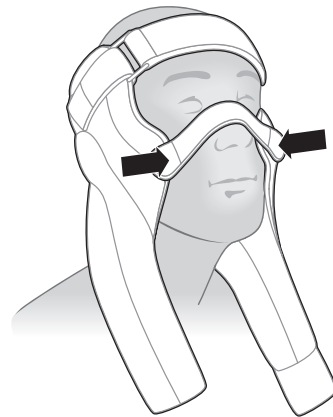


Figure 7.1.c.
Adjust Right Inner Flap
Under Chin



Figure 7.1.d.
Attach Hook Fasteners of
Left Outer Chin Flap



Vest for Head and Neck Preparation:

7. Unfold your vest accessory so the zipper is facing up. This is the front of the vest accessory. The collar tabs are located near the neck of the garment. The pocket and round closure dials are located on the abdomen (Figure 7.1.e. below).

Vest for Head and Neck Application:

8. Attach the back straps to the back flap of the vest garment so it is shaped like a vest.
9. Slide your arms through the arm holes of the vest garment as you would a jacket (#9 in Figure 7.1.e. below).
10. Align both sides of the front zipper at the bottom of the vest garment and zip up the front of the garment to the collar opening.

Figure 7.1.e.
Slide Arms Through
the Holes like a Vest

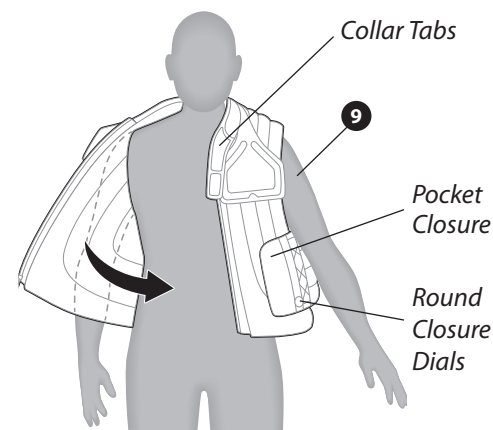
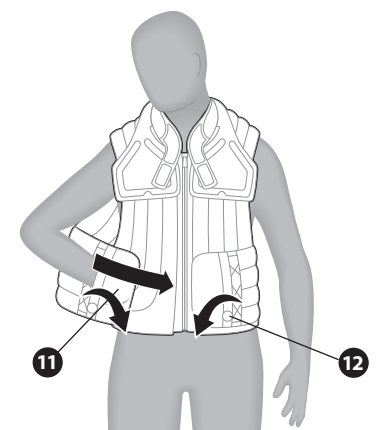


Figure 7.1.f.
Adjust Fit by Adjusting the
Placement of the Hook Fastener Pads
and Round Closure Dials



11. To adjust the fit of the vest garment around the waist, place hands inside the pockets of the waist flaps and adjust the placement of the hook fastener pads on each side of the waist to achieve a snug fit (#11 in Figure 7.1.f. on previous page). To allow for easy garment removal, do not pull the waist flaps across the zipper in the front of the garment.
12. To tighten the vest garment around the waist, rotate the round closure dials on the waist flaps of the garment (#12 in Figure 7.1.f. on previous page, and 7.1.g. below).
13. To loosen the vest garment around the waist, pull out on the round closure dials located on both sides of the garment, extend the closure laces by pulling the back of the garment away from the hook fastener pads on the front of the garment. Push the closure dials in until you hear a “click” to secure them (Figure 7.1.h. below).
14. Pull the vest collar tabs straight down and attach the hook fastener pads to the chest of the vest garment (Figure 7.1.i. on next page). The collar tabs **should not** cross over the zipper, and are designed to help the neck chamber of the garment maintain good contact with your neck during treatment. The collar tabs do not need to be readjusted at the start of each therapy session if you achieve a snug fit when initially contouring the garment.

Figure 7.1.g.
Rotate Closure Dial to Tighten

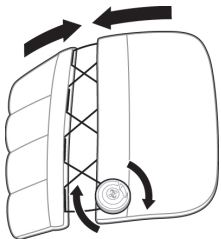


Figure 7.1.h.
Pull Out Closure Dial to Loosen Laces

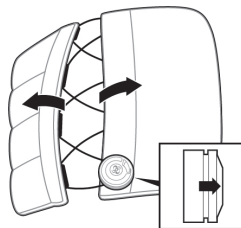
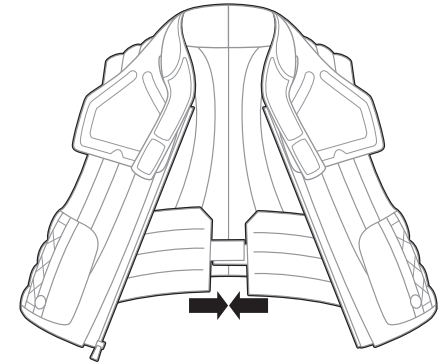


Figure 7.1.i.
Adjust Collar Tabs



Figure 7.1.j.
Adjust Hook Fastener Tabs on Back Panel



15. To achieve additional fit of the garment around the waist, remove the vest garment and adjust the placement of the hook fastener straps on the back panel of the vest. Move the hook fastener straps outwards to make the vest larger or inwards to make the garment smaller (Figure 7.1.j. above).

Fully Applied Head Garments and Vest for Head and Neck:

16. Properly applied garments will follow the contours of your body and fit snugly yet comfortably. To ensure they fit well, you may need to re-adjust when you sit and recline.
17. Sit in a soft-backed chair or recline at up to a 45-degree angle.

You are now ready to begin your therapy session. See Chapter 8 for further instructions.

Conducting a Therapy Session


Now you are ready for your therapy session with the Flexitouch Plus system. Be sure that you have followed the instructions outlined in the previous chapters. Then, begin the process of starting your therapy session using the instructions outlined below.







CAUTION

To achieve maximum benefit from your session, it should be completed without interruption.

8.1 Starting the Therapy Session

1. Prepare yourself for an uninterrupted therapy session.
- 2a: **If treating the upper or lower extremity(ies):** Lay down on your back with your hips and legs positioned straight. Do not sit in a chair or bend your affected limb(s) during the therapy session. Elevate the affected limb(s) on a pillow just above your hips.
- 2b: **If treating the head and neck:** Sit in a soft-backed chair or recline at up to a 45-degree angle.
3. Check your program settings to ensure you have selected the correct program.
4. When properly positioned, press the  button on the controller unit to begin the highlighted therapy session (see Figure 3.2.a. on page 19 for an illustration of the controller unit front panel).
5. For best results, relax and take deep abdominal breaths during the therapy session.


8.2 Pausing the Therapy Session

You may PAUSE TREATMENT for up to 15 minutes at any point during a therapy session by pressing the  button (see Figure 3.2.a. on page 19 for an illustration of the controller unit front panel). The controller unit will remain paused for up to 15 minutes. After that time, the controller unit will automatically shut off, requiring you to restart your therapy session. To resume your therapy, make sure the RESUME TREATMENT option is highlighted in blue and press the  button. To stop treatment, press the  arrow button to select STOP TREATMENT and select .

8.3 Completing the Therapy Session

The therapy program will automatically stop when the treatment has been completed.

8.4 Turning the Controller Unit Off

When your treatment is complete, turn the controller unit off by pressing the  button located in the upper right corner of the controller unit, next to the screen (see Figure 3.2.a. on page 19 for an illustration of the controller unit front panel).

8.5 Storing the Flexitouch Plus System

To store the Flexitouch Plus system, follow the steps outlined below:

1. Unplug the power adapter from the controller unit and from the electrical outlet.

WARNING: RISK OF ELECTRICAL SHOCK

Unplug the power adapter from the electrical outlet prior to cleaning the controller unit. Allow the controller unit to dry completely prior to connecting the power adapter to the electrical outlet.

2. Store the garments and accessories by first coiling the harnesses for each of the supplied garments or accessories. Avoid kinking the tubing. It is preferable to store them by laying them flat. Do not stack anything on top of them.
3. Store the controller unit, garments and accessories in a cool, dry place. Keep them out of excessive heat or cold. Store them away from children and pets.

8.6 Cleaning the Flexitouch Plus System

To clean the controller unit and/or garments and accessories, follow the steps outlined below.

Cleaning the Controller Unit

The controller unit is to be cleaned, as needed, using a damp cloth and mild household cleaner.

1. Unplug the power adapter from the electrical outlet.
2. Wipe all accessible surfaces, including the power adapter.
3. After cleaning, allow the unit to dry completely prior to using.

Cleaning the Garments and Accessories

1. A lint brush or roller may be used to remove particles.
2. The garments and accessories may be spot-cleaned using a damp cloth and a mild detergent.
3. Allow garments and accessories to dry thoroughly prior to using.



CAUTION

- Do not submerge.
- Do not disassemble.
- Do not machine dry.
- Do not iron.
- Do not machine wash.
- Do not dry clean.
- Do not autoclave.

Disinfecting the Flexitouch Plus System

DisCide® Ultra Spray Disinfectant has been demonstrated to effectively disinfect the Flexitouch Plus system. Use DisCide Ultra Spray or similar disinfectant compliant with OSHA's Bloodborne Pathogen Standard (29 CFR 1910.1030) and/or registered with EPA. To disinfect the Flexitouch Plus system, including garments, controller unit or accessories between patient use, or if there are visible biological contaminants or visible stains, the following steps are recommended:

1. Clean any visible blood or body fluids from the surface of the garment.
2. Thoroughly wet surface with DisCide Ultra Disinfecting Spray.
3. Allow surfaces to remain wet for one minute and then allow to air dry.



CAUTION

Follow instructions and warnings as issued by manufacturer of any disinfecting product.

Troubleshooting and Specifications

If you experience a problem with the Flexitouch Plus system, refer to the following information for assistance. If the information in Table 2 does not help solve the problem, call Customer Service toll free at 833.382.2845 (833.3TACTILE) (U.S. only).



CAUTION

The Flexitouch Plus system contains no serviceable parts. Do not attempt to perform any unauthorized maintenance or repairs.

9.1 Troubleshooting

Table 2: Troubleshooting




Issue	Recommended Solution
Controller unit does not function or display does not illuminate	<ol style="list-style-type: none"> 1. Disconnect the power cord from the back of the controller unit and then reconnect. Ensure that the power cord is fully inserted in both the power inlet on the back of the controller unit and the wall outlet. 2. Press the  button. 3. The display's backlight will illuminate and the program options will be displayed.
The chambers do not fill with air (Controller screen may read "The treatment failed with result R3, R4, or R5")	<ol style="list-style-type: none"> 1. Verify the correct program has been selected. 2. Verify the connectors are attached to the correct controller unit connectors. 3. Ensure that both upper and lower connector latches are engaged. 4. If the chambers still do not fill, turn the machine off, detach the connectors and turn the machine on again. 5. Begin a treatment session. <p>NOTE: If you feel air coming out of the connectors, reattach the connectors and check again.</p>

Table 2: Troubleshooting

Issue	Recommended Solution
Hook fasteners do not stay closed	<p>With continued use, the outside of the fabric will become worn and the hook fasteners may become filled with debris.</p> <ol style="list-style-type: none"> 1. Clean debris from the hook fasteners using a stiff brush, such as a toothbrush, lint roller or patting it with tape. 2. If you continue to experience issues with the hook fasteners not adhering to the fabric, Tactile Medical can provide you with a replaceable garment pad which will cover the worn area of fabric and allow the hook fasteners to attach to an unworn surface. Call Customer Service at 833.382.2845 to request replaceable garment pads. 3. To apply the replaceable pad when it is received, place the replaceable pad of fabric on the loop surface of the garment in the location where the hook fastener secures the garment. 4. When applying the garment for treatment, secure the garment hook fastener to the new loop material on the replaceable pad.
Chambers are not filling in the expected pattern	<ol style="list-style-type: none"> 1. Verify that the connectors have been attached to the controller unit, with both the top and bottom latches securely engaged. 2. Verify that the connectors are attached to the correct controller unit connectors by checking corresponding numbers. 3. Verify that the correct program has been selected. <p>NOTE: The first half of many of the available programs have sections that do not inflate adjacent chambers sequentially.</p>
Chambers' pressures are higher or lower than expected	<ol style="list-style-type: none"> 1. Verify the correct program, including correct pressure setting, has been selected. 2. Adjust the fit of the garment, ensuring no folds or kinks are in the fabric. 3. Check to be sure the latches are firmly in place and attached to the correctly numbered port.
Chambers remain inflated	<p>It is normal for a small amount of air to remain in the chambers between inflations, giving the garment or accessory a puffy appearance. If the chambers remain fully inflated:</p> <ol style="list-style-type: none"> 1. Ensure that the tubing is not kinked or pinched. 2. Disconnect the connectors and the chambers should deflate.

Table 2: Troubleshooting	
Issue	Recommended Solution
Controller unit runs longer than expected	<p>The session length is controlled by the specific program selected and the number of therapy cycles chosen.</p> <ol style="list-style-type: none"> 1. Verify that the selected PROGRAM and THERAPY CYCLES are as recommended by your healthcare provider. 2. Upon completion of all treatment sessions, verify that the display indicates the treatment is completed. 3. If the controller unit continues to operate beyond the time when COMPLETED is displayed, or if the TIME REMAINING indicated on the controller unit is incorrect, call Customer Service.*
Latches have broken or become disconnected from garment connectors	<p>Latches can be replaced or reattached. Please call Customer Service* for instructions.</p>
The controller unit makes an abnormal noise	<ol style="list-style-type: none"> 1. Stop the treatment session by pressing the  button. 2. Verify the noise has stopped. 3. Ensure the hoses from your garments are not kinked or pinched. 4. Check the program selection and make sure the program being run corresponds to the garments being used. Make sure the selected garment size matches the garments being used. 5. Check to make sure the correct garment connectors are connected to the correct port in the controller unit (e.g., the #4 garment connector is connected to the #4 port on the controller unit). 6. Restart the treatment by pressing the  button. 7. If the noise continues, contact Customer Service.*

***Tactile Medical Customer Service can be contacted at 833.382.2845 (833.3TACTILE) Monday through Friday, 7:00 a.m.–7:00 p.m. CT.**

9.2 Limited Warranty and Service for Home Use

Tactile Medical provides a warranty for the Flexitouch Plus system. The Flexitouch Plus controller is warranted to be free from defects in material and workmanship for a period of two (2) years from the date of purchase. The Flexitouch Plus garments and garment accessories are warranted to be free from defects in material and workmanship for a period of five (5) years from the date of original purchase. All other accessories and supplies related to the use of the Flexitouch Plus system are warranted to be free from defects in material and workmanship for one (1) year from the date of purchase. Tactile Medical's sole obligation in the event of a breach of this warranty is expressly limited to the replacement of defective parts that cannot, in the sole discretion of Tactile Medical, be repaired. Replacement parts may be new or refurbished parts as solely determined by Tactile Medical. No representation or other affirmation of fact set forth in this agreement, including but not limited to statements regarding suitability for use or performance of the Flexitouch Plus system, shall be deemed to be a warranty or representation by Tactile Medical for any purpose, nor give rise to any liability or obligation of Tactile Medical. EXCEPT FOR THE FOREGOING, TACTILE MEDICAL MAKES NO OTHER WARRANTY. THE WARRANTIES SET FORTH HERE ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, WHICH ARE HEREBY DISCLAIMED AND EXCLUDED BY THE MANUFACTURER, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE AND ALL OBLIGATIONS OR LIABILITIES ON THE PART OF TACTILE MEDICAL FOR DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE USE, REPAIR OR PERFORMANCE OF THE FLEXITOUCH PLUS SYSTEM. IN NO EVENT SHALL TACTILE MEDICAL BE LIABLE FOR ANY SPECIAL, DIRECT, INDIRECT OR CONSEQUENTIAL DAMAGES. Some

states, provinces or countries do not allow exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply. This warranty is available only to the original user if their account is in good standing. This warranty is not transferable. Repairs or alterations to the product not conducted by Tactile Medical shall void these warranties. These warranties do not cover failures due to improper or negligent use of the product.

These warranties provide specific legal rights; there may be other available rights, which may vary by state, province or country.

If you have questions or to obtain warranty service, contact:

Tactile Medical
Product Support Department
833.382.2845 (833.3TACTILE), ext. 4300

9.3 Limited Warranty and Service for Facility Use

Contact Tactile Medical for information regarding the service agreements available to facilities.

9.4 Equipment Lifetime

When used and maintained as instructed, the average expected controller lifetime is five (5) years.

9.5 Return Policy

Refunds are not issued for returned Tactile Medical products; this includes the garments/sleeves, controller or any accessories, once opened.

9.6 Patents

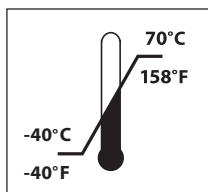
Patents pending.

9.7 Technical Information

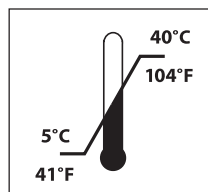
The Flexitouch Plus system has the following characteristics:

Table 3: Flexitouch Plus System—Technical Information	
Model Number	PD32–G3
Power Adapter Input	100–240 VAC 50/60 Hz
Device Input Voltage	12 VDC Nominal
Device Input Current	3.0 A Maximum
Current	1.0 A Maximum
Controller Unit Size	8”H x 10”W x 8”D (203 mm x 254 mm x 203 mm)
Controller Unit Weight	6.2 lbs. (2.8 kgs)
Outer Fabric	100% nylon, not made with natural rubber latex
Therapy Programs	18
Chambers (max)	32
Mode of Operation	Continuous
Calibration	Recalibration not required for the Flexitouch Plus system
Electromagnetic Interference (EMI) Electromagnetic Compatibility (EMC)	The Flexitouch Plus system was designed to minimize the effects of external EMI upon the device and to minimize the effect upon the environment from the device. The device conforms to the appropriate EMC standards. See Table 5.
Operating Atmospheric Pressure	700 to 1060 hPa

Device Transport and Storage Temperature Limits



Device Operating Temperature Limits



Device Operating Humidity Limits

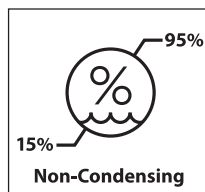


Table 4: Flexitouch Plus System—Classification Information

US FDA Medical Device	Class II per 21CFR 870.5800 & 21 CFR 890.5650
Canada Medical Device	Class II per Canadian Medical Devices Regulations SOR/98-282
Protection Against Electric Shock Hazard	Class II per UL/EN/IEC 60601-1
Protection Against Fluid Ingress	IP21
Applied Part	BF

Table 5: Flexitouch Plus System—Conformance Information

Quality Assurance	FDA 21 CFR 820 QSR ISO 13485
Safety	UL/EN/IEC 60601-1 CAN/CSA C22.2 No. 601.1
Electromagnetic Compatibility (EMC)	EN 60601-1-2
Waste Electrical & Electronic Equipment (WEEE)	Directive 2002/96/EC
Restriction of Hazardous Substances (RoHS)	Directive 2002/95/EC

9.8 Device Label

The device label is found on the back of your device. To read the label, place the device facing away from you at eye level at a distance that maximizes character clarity—generally 20 inches (50 cm) to 40 inches (100 cm) with an illumination of 500 lx minimum.

If label reading issues remain, please call Tactile Medical Customer Service.

NOTES:

- *Device label not to scale.*
- *Device label depiction (Figure 9.8.a. on next page) may be different than that on your device.*
- *See pages 1 and 2 for symbol definitions.*

Tactile MEDICAL®
MEDICAL ELECTRICAL EQUIPMENT
AND DEVICES

3701 Wayzata Blvd, Ste 300
Minneapolis, MN 55416 USA
www.tactilemedical.com
833.382.2845 (833.3TACTILE)

Patented

ETL CLASSIFIED
ETL
c US

Intertek
5000585

REF MODEL: PD32-G3
CAUTION: RxOnly
NO SERVICEABLE PARTS
RATED: 12 VDC @ 3A MAX

PN: 500433-000-00 Rev E

QR Code

(01)00816305021400
(21)319-123456

IP21


Warning Icons: Information, Caution, No Open Flame, No Smoking

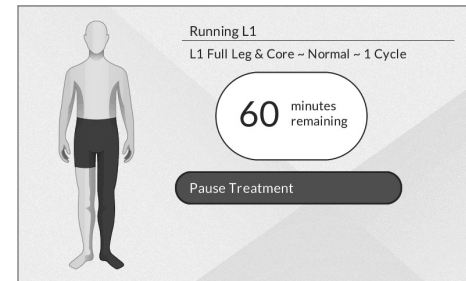
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Clinician-Directed Manual Pressure Adjustment

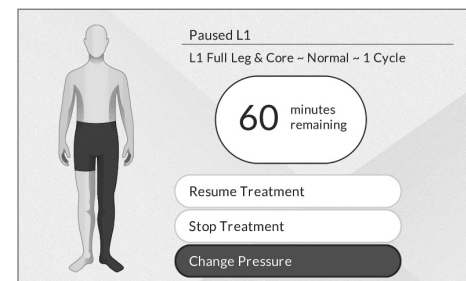
The Flexitouch Plus is designed to allow patients to manually adjust treatment pressures for individual treatment segments in different areas of the body during treatment. Follow the steps outlined below to manually adjust the pressure(s) for the individual treatment segment(s).




NOTE: Please consult with your healthcare provider before changing the pressure settings.

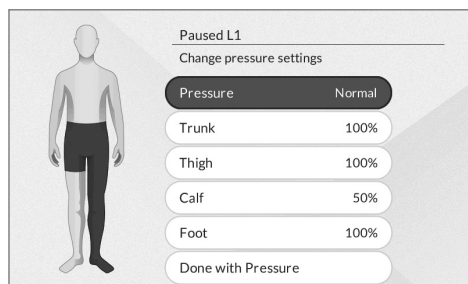
1. Press the  button on the controller during treatment to PAUSE TREATMENT.




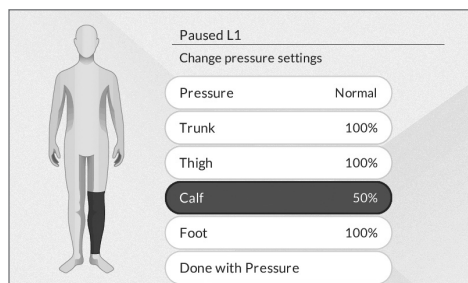
2. Press the  arrow button until the CHANGE PRESSURE option is highlighted in blue. Press the  button to select.





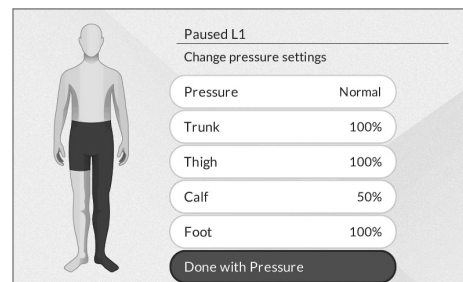
- Press the  button so the PRESSURE option is highlight in blue to select the DECREASED, NORMAL or INCREASED options. To manually adjust treatment pressure(s) for individual segment(s) in different areas of the body, press the  and  arrow buttons to select the area of the body for which you want to change the treatment pressure.





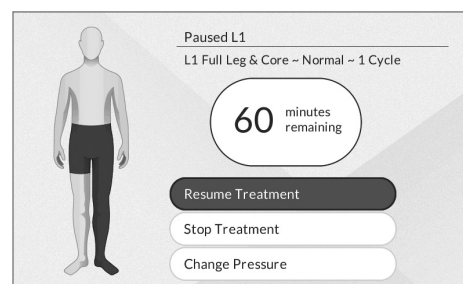
- Press the  button to manually adjust the pressure(s) for the individual treatment segment(s) when the appropriate area(s) is highlighted in blue. You can select 25, 50, 75 or 100 percent of the standard pressure for the treatment area.



- Once you have adjusted the pressure for the desired treatment area(s), use the  arrow button so the DONE WITH PRESSURE option is highlighted in blue. Press the  button to select.



- Use the  arrow button so the RESUME TREATMENT option is highlighted in blue. Press the  button to continue your treatment session. The controller will return with the run screen and resume treatment.



NOTES:

- The selected pressures will be saved for future treatment sessions. To reset the pressures to the prescribed treatment pressures, follow the steps above to set each body treatment area pressure back to 100 percent.
- Please contact Customer Service toll free at 833.382.2845 (833.3TACTILE) if you or your clinician have questions on making individual pressure adjustments for your specific clinical needs.

For Additional Questions

If you have any questions that are not covered by this user guide, contact:

- **By mail:** Tactile Medical, 3701 Wayzata Blvd, Suite 300
Minneapolis, MN 55416 USA
- **By phone:** Toll free: 833.382.2845 (833.3TACTILE) (U.S. only)
Hours: 7 a.m. to 7 p.m. CT, Monday–Friday
- **By fax:** Toll free: 866.435.3949 (U.S. only)
- **By email:** info@tactilemedical.com
- **Visit:** tactilemedical.com

Tactile Medical

3701 Wayzata Blvd, Suite 300
Minneapolis, MN 55416 USA
T: 612.355.5100
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Customer Service

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tactilemedical.com

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