

Federal law restricts this device to sale and use by, or on the order of, a licensed medical practitioner.

### Special Considerations

#### Congestive heart failure

Decompensated cardiac failure (CHF) is a contraindication to pump use. Patients who have had recent hospitalization for CHF should receive physician clearance prior to pump use. Patients with a history of CHF should be monitored for symptoms of shortness of breath, increased rate or labored breathing, lung crackles, cardiac gallop, and jugular vein distension. Patients with CHF who avoid lying flat due to shortness of breath should have close physician monitoring if they use pneumatic compression.

Monitor symptoms during and after treatment. Start treatment at low pressure (<35 mmHg) and short (<30 minute) treatment and gradually increase pressure and time according to tolerance and treatment response. For initial leg treatments in patients with CHF, start by using pump on one leg, and then follow up with the second leg the next day or treatment session. If after pumping there is no worsening in symptoms, simultaneous bilateral treatment can be applied. If pants-type appliance garments are used, treat bilaterally at low pressures for short periods of time (30 minutes, <35 mmHg) and increase time and pressure gradually per treatment session, according to tolerance.

Patients undergoing treatment in hospital can receive IV diuretics prior to treatment. Start treatment after urine output is established. Pulse oximetry can be used to monitor lung function.

#### Mixed venous and arterial disease

Some patients with venous stasis ulcers may have arterial insufficiency as well as venous insufficiency. Use Lympha Press® and The Petite Basic System™ with caution (lower pressures, frequent inspection of skin) on patients with ABI from 0.6 to 0.8. Lympha Press® and The Petite Basic System™ pumps should not be used on patients with ABI <0.6.

#### Deep vein thrombosis (DVT)

Patients with a history of DVT should have a Doppler ultrasound to rule out DVT prior to initiating treatment.

#### Cellulitis infection

Patients should avoid pneumatic compression treatment during an acute infection; treatment may be resumed 48-72 hours after beginning antibiotics.

#### Patient disability

Patients who are unable to operate pump, don, doff, or adjust the appliance garments should have an appropriate family member or other caregiver available to assist throughout the treatment session.

### Modifications for Special Situations

#### Calibrated gradient pressure (Lympha Press Optimal® and 201Max™ models)

Allows selection of different pressures in specific areas of the appliance garment. For example, this can be used to set lower pressures over the torso and higher pressures as needed over the extremity.

#### Pretherapy™ (Lympha Press Optimal® models)

Decongests proximal areas before the main treatment. It applies extra treatment to the proximal thigh/hip, torso and upper arm areas.

#### Peristaltic (Lympha Press Optimal® models)

This compression mode releases pressure over the distal areas as the pressure wave moves proximally. It is very relaxing and can be an alternative for patients who experience discomfort with the longer distal compression of the Sequential compression mode.

#### Pause time adjustment (The Petite Basic System™)

Selects the length of intermission between inflation cycles.

#### Disconnection of individual chambers

Use to prevent pressure application to a specific area.  
Contact Lympha Press USA for instructions.



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## Protocols for Lympha Press® Therapy:

### A Guide for Medical Professionals



Treatment for lymphedema, venous insufficiency, venous stasis ulcers, and dysfunction of the “muscle pump.”

This document offers guidance for the licensed medical practitioner in selection of treatment parameters. These treatment parameters (pressure, frequency, and duration of treatment) should be selected according to individual patient characteristics, including edema, fibrosis, wound status, body mass and response to a trial treatment session.

### Patient Evaluation

Obtain medical history: Surgeries, co-morbidities; pain/sensation levels, functional ability/mobility, edema, and skin condition including fibrosis, scars and wounds. Obtain baseline (pre-treatment) edema measurements.

Rule out general contraindications to pump use: Known or suspected deep vein thrombosis or pulmonary embolism; inflammatory phlebitis process; acute infection of the affected limb; decompensated cardiac failure; severe arteriosclerosis or other ischemic vascular disease; any circumstance where increased venous and lymphatic return is undesirable. Due to movement of fluids in the body when using the device, be careful with patients who have heart disease. High pressure is not recommended for patients with peripheral vascular disease. The abdominal area should not be treated during pregnancy.

### Perform a trial to determine response to treatment time and pressure

Follow the guidelines for pressure selection provided in **Tables 1-3**. Begin with the lower pressure ranges, and adjust pressure upward within the recommended ranges according to patient tolerance and response. Increase pressure if no adequate response is seen. The patient should feel comfortable during treatment. If patients are insensate or have fragile skin, begin at conservative levels of compression and observe for skin changes. If using an appliance garment that covers the abdomen, set the pressure at this level below 40 mmHg.

If patient feels discomfort, investigate source. Reducing the compression level may alleviate discomfort. If discomfort persists, stop treatment and determine whether pump treatment should be continued.

Stop treatment and assess patient if the patient experiences dizziness, numbness, tingling, cramping, coldness, extremity or chest pain, or shortness of breath during or immediately following treatment. After assessment, if treatment is continued, compression levels and/or treatment time should be resumed at a reduced level.

After completion of the trial treatment session, check for edema reduction, softening and tissue extensibility changes. Inspect the skin to ensure there are no adverse effects.

### Quick Reference Guide

1. Rule out contraindications.
2. Trial pump on patient, starting with lower pressure and increasing pressure if no adequate response seen. Patient should feel comfortable during treatment. If patient feels discomfort, investigate source. Reducing the compression level may alleviate discomfort.
3. After the pumping session, inspect for edema reduction, softening and tissue extensibility changes. Assess the skin for any adverse effects (skin breakdown, irritation, or other).

| Table 1: Venous Ulcer/Venous Stasis                   |            |  |   |
|---|------------|--|---|
| Compression Level                                     | Pressure   | Appropriate for:   | Frequency/Duration  |
| Low compression                                       | <40 mmHg   | Patients with wounds, insensate, or fragile tissue (can increase with monitoring if no adverse response seen)  | 60 minutes once or twice per day. Shorter, more frequent sessions may be helpful for patients who can comply. Evening or afternoon sessions will provide the most response. |
| Moderate compression                                  | 40-60 mmHg | Most patients  |   |
| High compression                                      | >60mmHg    | Extreme fibrotic changes; lipodermatosclerosis   |   |
| Table 2: Lower Extremity Lymphedema                   |            |  |   |
| Compression Level                                     | Pressure   | Appropriate for:   | Frequency/Duration  |
| Low to moderate compression                           | 30-60 mmHg | Low to normal body mass, Stage 1 or Stage 2 lymphedema, patients with wounds, insensate or fragile tissue (can increase with monitoring if no adverse response seen) | 60 minutes once or twice per day. Shorter, more frequent sessions may be helpful for patients who can comply. Evening or afternoon sessions will provide the most response. |
| Moderate to high compression                          | >60 mmHg   | Stage 3 lymphedema, heavy fibrosis and/or high body mass. Use <40 mmHg compression over abdomen for comfort.   |   |
| Table 3: Upper Extremity / Post-Mastectomy Lymphedema |            |  |   |
| Compression Level                                     | Pressure   | Appropriate for:   | Frequency/Duration  |
| Low to moderate compression                           | 30-50 mmHg | Low to normal body mass, Stage 1 or Stage 2 lymphedema, patients with wounds, insensate or fragile tissue (can increase with monitoring if no adverse response seen) | 60 minutes once or twice per day.   |
| Moderate to high compression                          | 40-60 mmHg | Stage 2 or Stage 3 lymphedema, heavy fibrosis, or high body mass. Use <40 mmHg compression over torso for comfort  |   |

### Prepare a home therapy program

**Educate patient** to recognize signs of infection and development of contraindications to pump use and compression.

**Educate patient** in the operation of the pump system and appliance garments.

**Instruct patient** in elements of a home edema management program, including pumping schedule, positioning during treatment, limb elevation, skin and wound care, infection prevention, self-massage, and appropriate exercise.

**Static compression garments** should be worn between pumping sessions to maintain reduction.

**Establish a maintenance program** when symptoms are adequately resolved.