**PURPOSE OF THIS DEVICE**

The purpose of the Circul8 Max is to aid in the prevention of DVT by helping to stimulate blood flow in the legs. This is accomplished by an electronically controlled pump delivering a set amount of air to the leg cuffs that, in turn, compress the calf or calves to aid blood flow out of the lower extremities. The pump will inflate each leg cuff to a preset pressure of 55 mmHg and deflate once the pressure is reached. The cycles are repeated on each device until the power is turned off.

**Indications for Use**

The Circul8 Max Vascular Therapy System, model 08-0036, is intended to be an easy to use portable system prescribed by a physician for use in the home or clinical setting to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions).

**This device can be used to:**
- Aid in the prevention of DVT
- Enhance blood circulation
- Diminish post-operative pain and swelling
- Reduce wound healing time
- Aid in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and ischemic vascular disease, severe arteriosclerosis, pulmonary edema, severe congestive heart failure, thrombophlebitis, or an active infection.
- As prophylaxis for Deep Vein Thrombosis (DVT) by persons expecting to be stationary for long periods of time

**CONTRAINDICATIONS**

The Circul8 Max Vascular Therapy System MUST NOT be used to treat the following conditions:
- Persons with suspected, active, or untreated: deep vein thrombosis, ischemic vascular disease, severe arteriosclerosis, pulmonary edema, severe congestive heart failure, thrombophlebitis, or an active infection.
- On the legs where cuffs would interfere with the following conditions: vein ligation, gangrene, dermattich, open wounds, a recent skin graft, massive edema, or extreme deformity of the leg.
- On any neuropathy.
- On extremities that are insensitive to pain.
- Where increased venous or lymphatic return is undesirable.

**USER MAINTENANCE**

Contains no serviceable parts. Contact Ortho8 Inc. Customer Service at (800) 604-2487

Inspect the unit and all components for any damage that may have occurred during shipping or general handling prior to each use (for example, faulty or cut charging cord, cracked plastic housings, torn cuffs, etc.). Refer to image of Circul8 Max for description of all components.

Do not attempt to connect the wall supply if any damage is noticed.

Avoid subjecting the units to shocks, such as dropping the pumps. Do not handle the leg cuffs with any sharp objects. If a bladder is punctured or you notice a leak, do not attempt to repair the unit or cuffs. Replacement units are available through customer service.

Avoid folding or creasing the bladder during use and transportation of the units.

Battery is not replaceable, replacement units are available through customer service.

Contact Ortho8 Inc. to receive replacements instructions for any damaged items.

**STORAGE**

Store in a dry location between -25°C (13°F) and +70°C (158°F).

Do not expose to heat exceeding +70°C (158°F).

Do not store items in direct sunlight.

**TECHNICAL DATA**

**Specifications:**

- **Main Unit:**
  - Dims: 1.12” x 2.75” x 3.25” (29 X 69.9 X 82.6 mm)
  - Weight: 2.7 lb (1235g)
  - Mode of Operation: Cyclic
  - Source of Power: 3.7 volt Li-Ion battery

- **Output:**
  - Mode of Operation: Continuous

- **SYSTEM OPERATING ENVIRONMENT:**
  - Temperature: +5 Degrees C to +40 Degrees C (41 Degrees F to +104 Degrees F)
  - Humidity: 30% - 75%

- **Power Supply:**
  - Input: 100 - 240 vac, 50 - 60 Hz, output: 5 vac @ 2.0 Amp
  - Use only UL listed power supplies from Ortho8 Inc. for use in hospital settings.

- **DEFAULT SETTINGS:**
  - Low pressure (not adjustable)
  - Steady Cycle Time: 10 Seconds

- **TOLERANCES:**
  - Pressure: ± 10%

- **BATTERY CHARGE:**
  - Single Charge approximately 4 Hours (Ships depleted state).
  - Store in a dry location between -25°C (-13°F) and +70°C (158°F).
  - Do not expose to heat exceeding +70°C (158°F).
  - Do not store items in direct sunlight.

**User Maintenance**

- Charge batteries using only the power supply provided by Ortho8 Inc.

**Service:**

- Single Patient - Multiple Use

**Contraindications**

- Persons with suspected, active, or untreated: deep vein thrombosis, ischemic vascular disease, severe arteriosclerosis, pulmonary edema, severe congestive heart failure, thrombophlebitis, or an active infection.

**Design Philosophy**

Pneumatic compression is a clinically proven modality for reducing the risks associated with deep vein thrombosis. The Circul8 Max Vascular Therapy System is a self-contained, compact DVT therapy device that is tubeless, portable, lightweight, and battery-operated. Due to Circul8 Max's portability, with no separate pumps and hoses, patients can use it at all times, ensuring maximum mobility during any phase of care. Additionally, Circul8 Max incorporates asymmetric compression for the superior emptying of veins that consists of an intermittent pneumatic compression device with sequential, asymmetrical, gradient, graduated, compression distal to proximal, duplicating the blood flow of an ambulating patient. Circul8 Max provides potentially life-saving mechanical DVT prophylaxis to patients with a continuum of DVT preventative care in the pre-, intra-, and post-surgery phases, expertly designed to provide increased compliance with breathable cuffs that enhance patient experiences.

**CAUTION:**

- Do not use on the legs where cuffs would interfere with the following conditions: vein ligation, gangrene, dermattich, open wounds, a recent skin graft, massive edema, or extreme deformity of the leg.
- Do not store items in direct sunlight.
- Do not expose to heat exceeding +70°C (158°F).
- Do not store items in direct sunlight.

**Quick Start Guide**

1. Left Leg Pictured.
2. When both wraps are secured on your legs, they should look like the picture above.
3. When the wraps are secured on your legs, PRESS and HOLD the White button until the device is illuminated. This is a function of the device to keep your legs cool.
4. Continue to PRESS and HOLD the White button until the following tones sound: BEEP 2 BEEP 2 BEEP. This indicates the anti-embolus function of the device is engaged.

5. Press and Hold the White button to turn the device on or off. The device must be turned off for 15 minutes before it can be turned on again.

6. The device should be used for 2-4 hours per day, or as directed by your physician.

7. The device is not intended for use in the hospital setting.

8. The device is not designed to be used by children or untrained personnel.

**User Maintenance**

Contains no serviceable parts. Contact Ortho8 Inc. Customer Service at (800) 604-2487

Inspect the unit and all components for any damage that may have occurred during shipping or general handling prior to each use (for example, faulty or cut charging cord, cracked plastic housings, torn cuffs, etc.). Refer to image of Circul8 Max for description of all components.

Do not attempt to connect the wall supply if any damage is noticed.

Avoid subjecting the units to shocks, such as dropping the pumps. Do not handle the leg cuffs with any sharp objects. If a bladder is punctured or you notice a leak, do not attempt to repair the unit or cuffs. Replacement units are available through customer service.

Avoid folding or creasing the bladder during use and transportation of the units.

Battery is not replaceable, replacement units are available through customer service.

Contact Ortho8 Inc. to receive replacements instructions for any damaged items.

**STORAGE**

Store in a dry location between -25°C (-13°F) and +70°C (158°F).

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Do not store items in direct sunlight.
INSTRUCTIONS

POWER ON
Press and hold the power button for One Second, and the device will turn on. When the device is powered on, C8 is displayed followed by a double digit number, audible alarm beeps twice. Refer to the battery indicator section on below for battery life expectancy.

After a four-second delay, the device is on, and the LED display will remain on (unless in night mode). The device applies compression to the legs) in cycles. During each cycle, the device inflates the cuff to 55 mmHg pressure, holds the pressure for four seconds, and then releases the pressure.

Cuff inflation occurs in 6 to 12 seconds. During cuff inflation, the device will display dynamic pressure in five-degree increments 0-65-70-15-20-25-30-35-40-45-50-55. During hold, the device will display “SS” and applies pressure for four seconds. Afterward, the pressure is released. The cycle repeats after 50 seconds of idle time. During the 50 seconds of idle time between compression cycles, the device pulses a lower right dash for 48 seconds and will Flash “00” for the remaining two seconds before the next inflation of pump activation.

POWER OFF
When the Device is operating, Press and Hold the power button on top of the device for One Second
The device is in “sleep” mode—no visible illumination.

SYSTEM COMPONENTS

BATTERY INDICATOR
To correctly identify the state of the battery and charger, there are SIX stages of the BATTERY INDICATOR as follows:

- **Battery icon:** Remains illuminated at all times during operation.
- **Solid Green All Three Bars:** 100% battery life remaining.
- **Solid Green Two Bars:** 67% to 100% battery life remaining, when charging in use or sleep mode, third bar pulses until fully charged.
- **Solid Green One Bar:** 33% battery life remaining, second and third bar pulses alternately until 100% charged when charging in use or sleep mode.
- **Flashing Yellow Bar:** Power Button will flash Yellow, and “BL” quickly flashes on the LED display. The battery will last 30-60 minutes or less.
- **Flashing RED Bar:** Battery will last five minutes or less. “BC” quickly flashes on the LED display until auto shut down or the device(s) are connected to the power supply. Audible alarm will continuously sound until the device powers down, or the power supply adapter is plugged into a wall socket.

USING THE AC ADAPTER / BATTERY CHARGER

CHARGING THE BATTERY: USE ONLY THE CHARGER PROVIDED BY ORTHO 8 INC.
Use of the wrong charger can cause excessive heat, damage to the charging circuit, and shorten the life of the battery.

THE DEVICE POWERED OFF
Insert the supplied power supply plug into the two ports at the bottom end of the device and connect the power supply adapter to the wall socket. The battery indicator icon on the LED Display will illuminate three flashing green bars and provide the current charge status. Once the device is fully charged, all three bars will be solid green. A full charge of a depleted battery may take approximately four hours. Refer to the battery indicator on the this page for battery life expectancy.

THE DEVICE POWERED ON
Insert the supplied power supply plug into the two ports at the bottom end of each device and connect the power supply adapter to the wall socket. For extended operation periods or to charge the battery during treatment sessions, the AC adapter CAN be connected while the device is in use.

The Power Button will be illuminated, and the battery indicator icon on the LED Display will illuminate three flashing green bars providing the current charge status. Once the device is fully charged, all three bars will be solid green. Refer to the battery indicator on this page for battery life expectancy.

ALARMS
Low Pressure or Leak “LP” Power button flashes red and display will flash LP simultaneously following a Low-Pressure event. Audible alarm will sound, and the Power Button will flash RED. The alarm will continue for 30 seconds (unless the device is powered OFF) and automatically turn the device OFF.

Make sure the wrap is attached snugly to the leg. Turn the device OFF, and then turn the device back ON. If the device continues to alarm after this step, DO NOT try to fix the device. Call customer service for a replacement device at (800) 604-2487.

High Pressure or Leak “HP” Power button flashes red and display will flash HP simultaneously following a High-Pressure event. Alarm will continue for 30 seconds (unless the device is powered OFF) and automatically turn the device OFF. The pump will turn off, and the solenoid will open, releasing the air in the bladder compressing the leg(s).

Turn the device OFF, and then turn the device back ON. If the device continues to alarm after this step, DO NOT try to fix the device. Call customer service for a replacement device at (800) 604-2487.

Battery Low “BL” – Power button flashes red and display will flash B simultaneously when the battery is low. Plug-in power supply immediately.

Battery Critical “BC” – If the battery voltage drops below a critical level, cycling stops, an audible alarm will sound, display will flash BC and POWER BUTTON WILL FLASH RED. Plug-in power supply immediately.

ALARM RESET:
To reset an alarm, the device must be turned OFF then turned back ON. If not manually turned OFF within 30 seconds of such an alarm condition occurring, the device automatically turns itself OFF. Once the device is turned back on, the alarm is RESET.

OPTIONS

By Prescribing Physician Only
Device use time (amount of time the device is powered ON) is monitored and stored by the MPU (Microprocessor Device) and can be requested by prescribed Physician only.

NIGHT MODE
During normal operation, the device can be turned into night mode by pressing the Power Button Three Times quickly. The light intensity will reduce on the power button, and the LED display will turn off.

To exit night mode press the Power Button Three Times quickly. If the power is turned OFF for any reason, the device will automatically reset and start in normal operation mode.

WARNINGS AND PRECAUTIONS

- The Circu8 Max cuffs are designed for single patient use only.
- Medical Electrical Equipment needs special precautions regarding EMC. Portable and mobile RF Communications Equipment can be affected by other Medical Electrical Devices.
- Cuffs used in combination with warming devices may cause skin irritation. Regularly check for patient discomfort, compliance, and skin irritation.
- To prevent extremity compartment syndrome, special attention should be given to patients who are positioned in the supine lithotomy position for extended lengths of time. This includes patients with or without cuffs.
- Do not open or remove covers. No user serviceable parts inside. Direct all unit issues to Ortho Inc.
- If pulsations or throbbing occur, the cuff may be wrapped too tightly. Loosen immediately.
- Stop using device if swelling occurs; consult a Physician.
- Device is to be used only by the patient prescribed, and only for its intended use.
- Ensure the pump control unit is turned off and unplugged from the wall outlet prior to and while cleaning or disinfecting.
- Equipment should not be used in the presence of any flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- Do not immerse in any liquid for any reason.
- Do not operate device in a wet environment.
- Allow cuffs to warm to room temperature if exposed to temperatures below 5°C or 41°F.
- Do not subject the unit to extreme shocks, such as dropping the pump.
- Do not place any items in an autoclave.
- Operation of this device can be done by the patient.
- No Service is to be attempted while the device is in use.
- This device is NOT to be altered or modified.

CLEANING AND DISINFECTING

NOTE: Inspect the Circu8 Max unit and follow the cleaning and disinfecting procedures prior to each use.

WARNING: Device must be turned off and disconnected from the wall outlet prior to and during cleaning or disinfecting.

DO NOT IMMERSE UNIT IN ANY LIQUID FOR ANY REASON
- Clean the outer surface of the pump unit using a soft cloth, moisturized with soapy water or 70% isopropyl alcohol.
- Do not use abrasive or volatile cleaners.
- Do not place cuffs in dryer.
- NEVER remove the unit from the cuff.
- Hand wash the exterior of the cuffs using a soft cloth, moisturized with soapy water or 70% isopropyl alcohol and lay air dry.
- To ensure the unit is completely dry prior to use, leave unit in the OFF condition and disconnected from the wall outlet for 30 minutes after cleaning or disinfecting.