CIRCUL8® ONE

Mobile **Blood Clot Prevention**

Instructions for Use

Revision Date: April, 2021

Vascular Therapy System

(Compressible Limb Sleeve Device)

Model No. 08-0030

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DESIGN PHILOSOPHY

Pneumatic compression is a clinically proven modality for reducing the risks associated with deep vein thrombosis (DVT[1]). The Circul8 One Vascular Therapy System is a self-contained, compact DVT therapy device that is tubeless, portable, lightweight and battery-operated. Due to Circul8 One'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 One incorporates asymmetric compression for the superior emptying of veins[2] and concurrent compression 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 One provides potentially life-saving mechanical DVT prophylaxis to patients with a continuum of DVT preventative care in acute care environments, in the pre-, intra-, and post-surgery phases, expertly designed to provide increased compliance with breathable cuffs that enhance patient experiences.

PURPOSE OF THIS DEVICE

The purpose of the Circul8 One 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. Internal rechargeable batteries allow the Circul8 One to be completely portable, thus preventing interruptions in treatment.

INDICATIONS FOR USE

Circul8 One is an easy to use system prescribed by healthcare professionals for stimulating blood flow in the legs (simulating muscle contractions) that aids in the prevention of DVT, enhances blood circulation, diminishes post-operative pain and swelling, reduces wound healing time, and aids in the treatment and healing of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency, and reduction of edema in the lower limbs. The design allows patients to wear the device during many clinical related activities, such as physical therapy sessions, wheelchair transportation, cafeteria sittings, and during general mobility throughout the clinic.

CONTRAINDICATIONS

The Circul8 One 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, dermatitis, 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.

1. Labropoulos N, OH D.S, Golts, E, et al: Improved Venous Return By Elliptical, Sequential and Seamless Air-cell Compression. Loyola University Medical Center, January 2003.

2. Kamm R: Unsteady Venous Blood Flow Resulting From Different Modes of External Compression Cambridge, MIT, 1996

Features & Benefits

Portable
Fully ambulatory design allowing better compliance with increased patient mobility.

Easy One-Touch Operation
Control all functions with just the power button.

Infection Control
Cuffs are impervious to liquid strike-through which can help to reduce bacterial transfer and subsequent contamination.

No External Tubes or Hoses
Other devices require tubing, which present a tripping hazard and are inconvenient to use and manage. Additionally, such devices usually lack true portability.

Lightweight
Circul8 One weighs less than a pound and is portable while improving patient discomfort.

Battery Operated
Self-Contained, Lithium Ion powered pneumatic compression device that allows for better compliance with increased patient mobility.

Single Patient Use
Improved compliance and patient safety

Concurrent Compression
Provides sequential, gradient, concurrent lateral and medial compression duplicating the blood flow of an ambulating patient.

Compliance Monitor
Downloadable for detailed patient device use time.

Symbols


Power button


Battery indicator


No Scissors


Power Supply


Manufacturer with 4-digit year of manufacture printed underneath


Keep dry


Class II medical electrical equipment


Warning or Caution


Battery operated


Refer to Instruction Manual/Booklet


Atmospheric pressure range


Not made with natural rubber latex


The patient cuff(s) are intended for single patient use. Use on more than one patient may cause cross-contamination.


Temperature range


Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.


The use of accessories, power supplies and cables other than those specified, with the exception of components sold by the manufacturer of the VenaOne as replacement parts, may result in increased emissions or decreased immunity of the VenaOne


This symbol designates the degree of protection against electrical shock from the wrap as being a type BF applied part


Humidity range


Idle pulse between compression cycles


Low pressure indicator


"CO" on LED Display "confirms proper USB Connection."


High pressure indicator


Battery event


Battery low


System failure


System failure reset


End of life indicator

System Contents

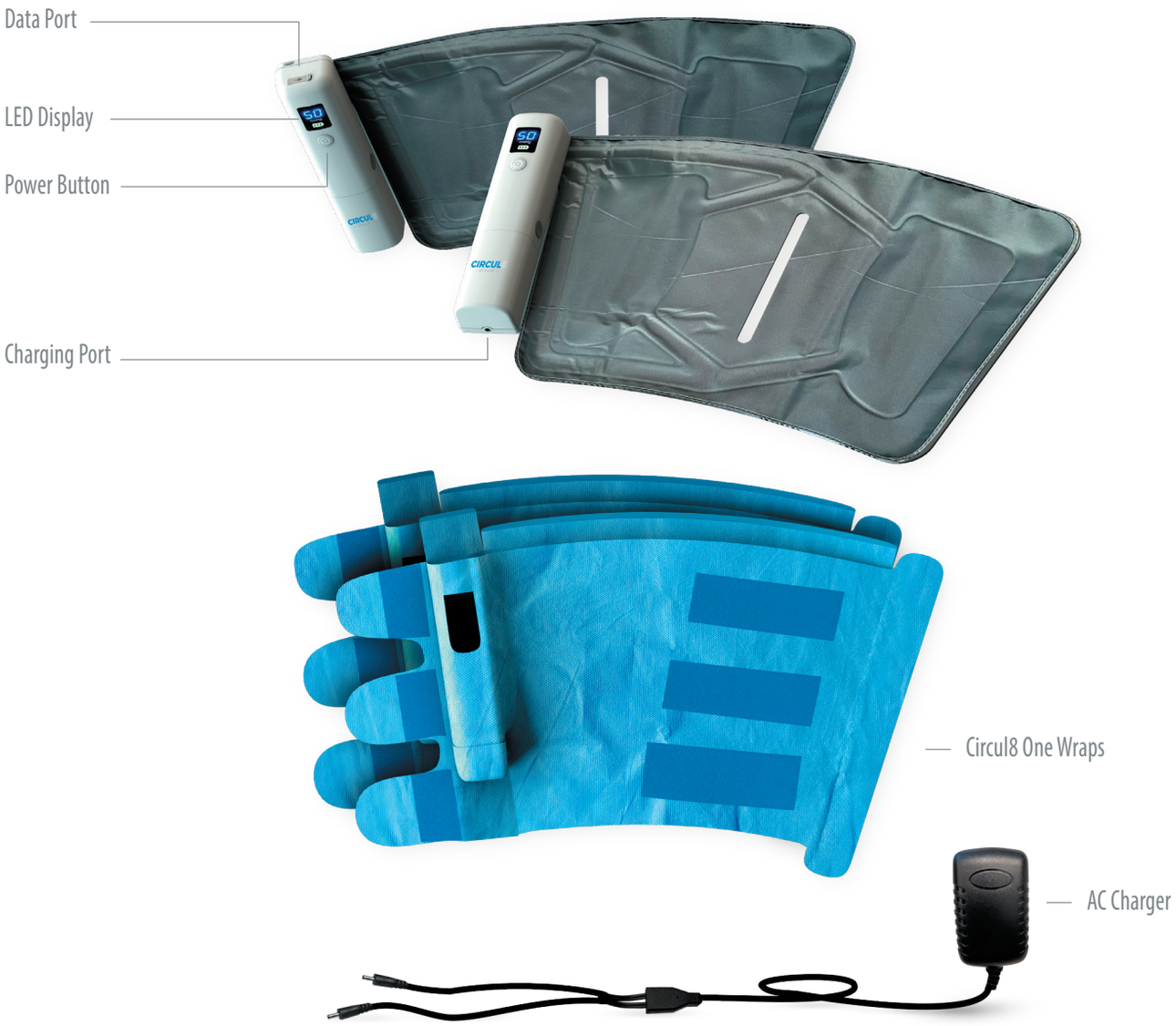
Each package contains:

One right compression device
One left compression device
One AC adapter and battery charger
One Circul8 One operator's manual

Separate package contains:

One right compression wrap
One left compression wrap

⚠ **Warning:** ONLY USE WRAP(S) PROVIDED BY Circul8 One



Instructions

SYSTEM OVERVIEW

If necessary, contact your local Customer Service representative for assistance setting-up, using or maintaining the device, or to report unexpected operation or events.

POWER OFF

The device is in “sleep” mode. No visible illumination. To turn the device off, press the power button THREE times.

POWER ON

Press the power button THREE times, and the device will turn on. When the device is powered on the audible alarm beeps twice, the LED display illuminates, and the battery icon stays on (refer to the battery indicator section for battery life expectancy). Note: The power button light will be OFF to save battery life and will only illuminate if an alarm is triggered. After a four-second delay, the pumps will inflate the cuff(s) to a pre-determined pressure of 55 mmHg. Once the pressure reaches the proper level, the pump will turn OFF for a 50-second “rest” period, and the cuff deflates. After the “rest” period, the cuff is again inflated, and repeats this cycle every 50 seconds.

After the device is powered on, the LED display will always remain on. The device applies compression to the leg(s) in cycles. During each cycle, the device inflates the cuff to 55mmHg pressure, holds the pressure for four seconds, and then releases the pressure.

Cuff inflation occurs in 6 to 8 seconds. During cuff inflation, the device will display dynamic pressure in five-degree increments 00-05-10-15-20-25-30-35-40-45-50-55. During hold, the device will display “55” and applies pressure for four seconds. Afterwards, the pressure is released. The cycle repeats after 50 seconds of idle time. During the 50 seconds of idle time between compression cycles, the display pulses a lower right dash for 48 seconds, and will Fast Flash “00” for the remaining two seconds before the next inflation of pump activation.

BATTERY INDICATOR

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

Battery icon: Remains illuminated at all times during operation

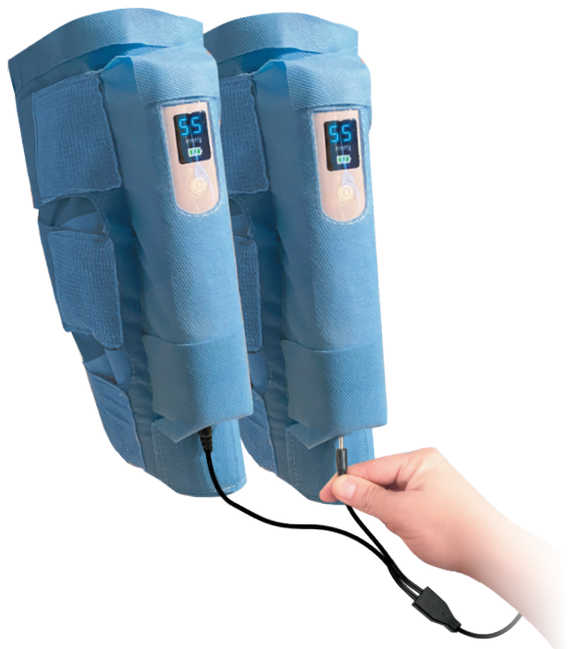
Solid Green all three Bars: 100% battery life remaining

Solid Green Two Bars: 31% to 60% battery life remaining, third bar pulses until fully charged.

Solid Green One Bar: 30% battery life remaining, second and third bar pulses alternately until 31% charged.

Solid Yellow One Bar: Battery will last 30 minutes or less. Alarm ONE (refer to page 9 for alarm description) sounds three times every two minutes, and simultaneously “BL” quickly flashes on the LED display three times every two minutes.

Flashing RED One Bar: Battery will last five minutes or less. “BL” quickly flashes on the LED display until the auto shut down or the device(s) are connected to the power supply. Alarm ONE (refer to page 9 for alarm description) sounds three times every ten seconds.



USING THE AC ADAPTER/BATTERY CHARGER

The Device Powered OFF

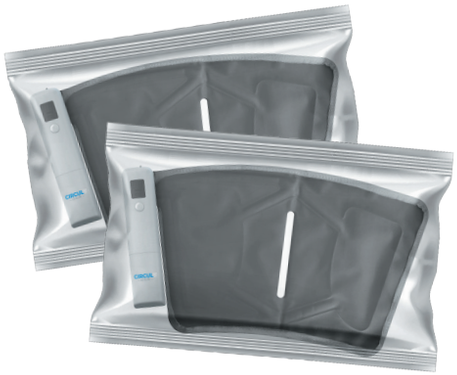
Insert the supplied power supply plug into the port(s) at the bottom end of each device and connect the power supply adapter to the wall socket. The battery indicator icon on the LED Display will illuminate three flashing green bars and provide the current charge status. Once the device is fully charged, all three bars will be solid green.

The Device Powered ON

Insert the supplied power supply plug into the port(s) 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 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.

Quick Start Guide

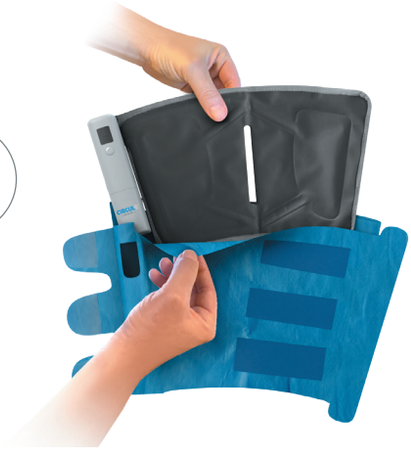
1



REMOVE THE DEVICES

Remove the devices from the plastic packaging.
Note: the devices will come in separate packaging.

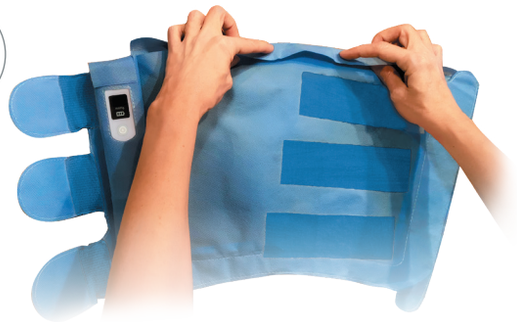
2



PLACE THE DEVICE IN THE WRAP

The device and bladder will slide to the bottom of the wrap.

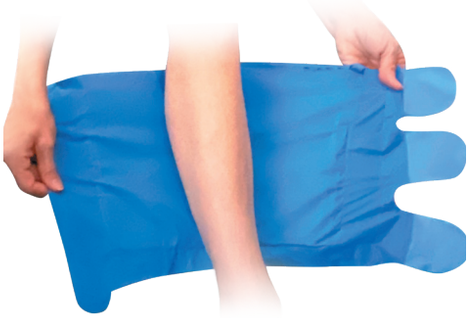
3



SEALING THE WRAP(S)

Once the device is placed inside the cuff, peel off the backing on the adhesive strip. Then simply fold over and press to seal the wrap.

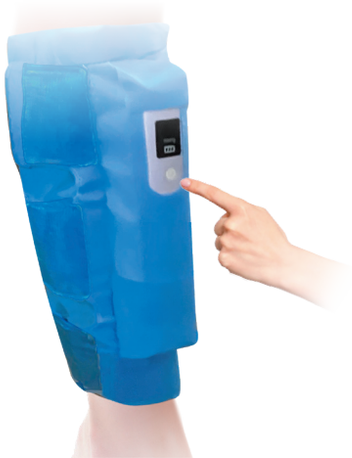
4



CALF CUFF APPLICATION

Wrap the cuff around the calf and secure the Velcro to hold it in place. Make sure the wrap is snug, but not too tight. When one or both wrap(s) are secured on the leg(s), the device(s) are ready for operation.

5



TURNING THE DEVICE ON

When the wrap(s) are secured on the leg(s) PRESS the Power Button on both devices THREE TIMES, and the LED display illuminates, and the Battery Icon stays ON. When one or both wrap(s) are secured on the leg(s), the device(s) are ready for operation.

USING THE DEVICE

The device will make a quiet “humming” sound when inflating to pressure. THIS IS NORMAL. The wraps inflate once each minute during the therapy.

Pump Alarm Legend

If the device is turned on after an Alarm event, the LED displays the previous alarm.

High Pressure "HP" is displayed flashing quickly following a High-Pressure event. After a four-second delay, the solenoid closes, the pump starts, and the dynamic pressure is displayed.

Low Pressure "LP" is displayed flashing quickly following a Low-Pressure event. After a four-second delay, the solenoid closes, the pump starts, and the dynamic pressure is displayed.

Battery Event "BE" is displayed flashing quickly following a Battery event. After a four-second delay, the solenoid closes, the pump starts, and the dynamic pressure is displayed.

Battery Low "BL" is displayed when the battery is low.

System Failure "SF" is displayed flashing quickly following a System event. The device is in ALARM THREE. The SF Fast Flash continues to display until the device is turned off or the System Failure is reset.

End of Life "EL" is displayed flashing quickly following an End of Life event. The pump does NOT start, and ALARM 3 is activated. The EL continues to Fast Flash until the device is turned off or End of Life is Reset.

Reset "RS" is displayed during a system failure reset.

ALARM ONE: Audible alarm for 0.25 Seconds

ALARM TWO: Audible alarm for 0.25 Seconds repeats every three seconds, and the power button will flash. If alarm two is activated, after two minutes, the device will turn off automatically, and the solenoid will open. Alarm two CAN be SILENCED without turning off the device, and the device will continuously work as instructed below.

SILENCE ALARM: Press and hold POWER BUTTON FOR ONE SECOND.

ALARM THREE: Audible alarm for 0.25 Seconds, the power button will flash and repeats every TEN SECONDS until the device is TURNED OFF. The device must be turned off manually to silence the ALARM. Once activated, the device will turn off automatically, and the solenoid will open. ALARM THREE CANNOT be silenced.

SYSTEM FAILURE: If a System Failure event has occurred, the only way to make the device work again is to do a System Failure reset.

1. You must start with the device off.

2. When you turn on the device from a System Failure event, it should turn on as described in the "Turning on and off" specification section. The "SF" will be flashing quickly.

3. With the "SF" flashing quickly, now press and hold the power button for THREE seconds. The display will switch to flashing quickly "RS" for reset. The device will remain in the "RS" mode for 30 seconds.

4. To confirm reset, press the power button and hold for three seconds. The quickly flashing "RS" will go away, and the device will begin a normal turn-on mode. If the device is turned off or nothing is done for the 30-second reset mode, the device turns off and remains in "SF" mode.

A System Failure Reset can only be done ONE time on a device; a System Failure Reset for the SECOND time will cause the LED DISPLAY to quickly flash "SF" and the pump will stop, the solenoid will open and ALARM THREE will be active. The device must be turned off.

HIGH-PRESSURE EVENTS

High-Pressure Type ONE: Sensor reading above 65mmHg AND below 85mmHg, with the pump running, is a Type ONE High-Pressure event. The pump will turn off, and the solenoid will open. After the first Type ONE High-Pressure event, the device cycles normally to idle for 50 seconds. If a second consecutive Type ONE High-Pressure event occurs, the LED Display flashes “HP” quickly and ALARM TWO is activated. If the ALARM TWO is silenced after the second event, the device will idle for 50 seconds and cycle through a “turned on” from a previous High-Pressure event. A third consecutive Type ONE High-Pressure event will be considered a System Failure event. The LED Display will quickly flash “SF.” The pump will stop, and the solenoid will open, and ALARM THREE will be active. The device must be turned off.

High Pressure Type TWO: Pressure sensor senses above 81mmHg sustained for five seconds with or without the pump running is a Type TWO High-Pressure event. With the first Type TWO High-Pressure event, the pump will stop, and the solenoid will open. The LED Display will quickly flash “HP” and ALARM TWO will be active. If the ALARM TWO is silenced after the first event, the device will idle for 50 seconds and cycle through a “turned on” from a previous HP event. If a second consecutive Type TWO High-Pressure event occurs, it will be considered a System Failure event. The LED Display will quickly flash “SF.” The pump will stop, and the solenoid will open, and ALARM THREE will be active. The device must be turned off.

High Pressure Type THREE: Immediately prior to “pump restarts inflation cycle after 50 seconds idle,” the pressure sensor senses above 30mmHg is a Type THREE High-Pressure Event. With the first Type THREE High-Pressure Event, the pump stops, the solenoid opens, and the device goes through the normal 50 seconds idle period. With the second consecutive Type THREE High-Pressure Event the pump stops, the solenoid opens, and the LED Display Fast Flashes “HP” and ALARM TWO activates. If the Alarm TWO is not silenced, it will shut down in two minutes. If the Alarm TWO is silenced, the device will follow the normal “turn on” process for an “HP” previous event. A third consecutive Type THREE High-Pressure Event is considered a System Failure event. The LED Display will flash “SF” quickly. The pump will stop, and the solenoid will open, and ALARM THREE will be active. The device must be turned off.

ALARMS: LOW-PRESSURE EVENT

If the pressure sensor fails to register 55mmHg after 20 seconds, then the pump will turn off, and the solenoid will open. The 20-second timeout of the pump is considered a Low-Pressure event. If the device has three consecutive Low-Pressure events in a row, the LED Display will quickly flash “LP” and ALARM TWO will be activated. If the ALARM TWO is not silenced within a two-minute interval, the device will shut down as per a normal ALARM TWO specification.

If the Low-Pressure ALARM TWO is silenced within two-minutes, the device will follow the normal “turn on” process for an “LP” previous event.

At the seventh consecutive “LP” event, a System Failure event will be triggered. The LED DISPLAY will quickly flash “SF.” The pump will stop, and the solenoid will open, and ALARM THREE will be active. The device must be turned off manually to silence the alarm.

END OF LIFE RESET: If an End of Life event has occurred, the only way to make the device work again is to do an End of Life reset.

1. You must start with the device off.
2. When you turn on the device from an End of Life event it should turn on as described in the “Turning on and off” specification section below. The “EL” will be flashing quickly.
3. With the “EL” flashing quickly, now press and hold the power button for three seconds. The display will switch to “RS” flashing quickly for reset. The device will remain in the “RS” mode for 30 seconds.
4. To confirm reset, press the power button and hold for three seconds. The flashing “RS” will go away, and the device will begin a normal flashing. If the device is turned OFF or nothing is done during the 30-second reset mode, the device turns off and remains in EL mode.
5. THE End of Life Reset can only be done one time on a device AND THE BATTERIES SHOULD BE REPLACED. If somebody tries to do the “EL” Reset for a second time, the LED Display will quickly flash “EL.” The pump will stop, and the solenoid will open, and ALARM Three will be active. The device must be turned off.

DEVICE LIFE TIMER

The life timer will be triggered only when the device is used for a total of five hundred hours. After a set amount of cycles, the device will stop working and display “EL” flashing quickly, and ALARM THREE is active. The device must be turned off for the “EL” reset.

The “EL” Reset can only be done ONE time on a device AND BATTERIES SHOULD BE REPLACED. If somebody tries to do the EL Reset for the second time, the LED Display will quickly flash “EL.” The pump will stop, and the solenoid will open, and ALARM THREE will be active. The device must be turned off.

TRACKING PATIENT DEVICE USE TIME

Device use time (amount of time the device is powered ON) is monitored and stored by the MPU. It can be downloaded into Microsoft Excel via the micro USB port located at the top edge of the pump/controller device. DO NOT directly connect this device to a computer with a standard USB cable. To download device use data, use the Circul8 One Data Expander Interface Cable provided by Circul8 One, LLC.

USB CONNECTION TO COMPUTER

Once the patients’ therapy is completed. Make sure the Circul8 One is turned OFF, connect the micro USB cable to the unit, and the regular USB cable port to the computer (PC or Mac). Once connected to a computer, press and hold the power button for three seconds. The device does NOT turn on. The LED will display “CO” to confirm a proper USB connection: The log file containing the patient therapy use time will automatically upload to the connected computer and display on the computer desktop file name “Circul8 One.Log.” The log file will be accessible by opening Microsoft excel on the top command bar, select FILE > OPEN, select Circul8 One.Log from the drop-down “Devices.

PATIENT USE TIME MEMORY RESET

With the USB connected to a computer and confirmed by a display of “CO.” Press and hold the power button for three seconds. The number of patient use time pump cycles will reset to zero, and the LED will display “RS” to confirm reset. YOU MUST RESET THE PATIENT VALUES BEFORE EVERY USE, IF YOU’RE TRACKING USE TIME.

DISCONNECT USB CABLE TO TURN OFF

When you remove the USB cable from the device, the device will turn off automatically.

LIFE EXPECTANCY

When the device reaches the preset pump compression cycles, the LED Display will quickly flash “EL” End of Life. The pump will stop, and the solenoid will open, and ALARM THREE will be active. The device must be turned off for the “EL” reset. The “EL” Reset can only be done ONE time on a device AND BATTERIES SHOULD BE REPLACED. If somebody tries to do the EL Reset for the second time, the LED Display will quickly flash “EL.” The pump will stop, and the solenoid will open, and ALARM THREE will be active. The device must be turned off.

DISASSEMBLY

DO NOT DISPOSE OF THE DEVICE

DISPOSING OF THE WRAP ONLY

All contaminated products or accessories should be disposed of appropriately according to hospital policy and state law taking environmental factors into consideration.

When the therapy is completed, or the patient is discharged, remove the device, and **discard the wrap(s) ONLY**.

DO NOT USE SCISSORS

DO NOT USE ANY SHARP OBJECTS NEAR THE BLADDER.

There is a perforated section at the top of the wrap designed to open the seal easily.

CLEANING AND DISINFECTING

NOTE: Inspect the Circul8 One device and follow the cleaning and disinfecting procedures prior to each use. The device is intended for multiple patients uses.

⚠ **WARNING:** Device must be turned off and disconnected from the wall outlet prior to and during cleaning or disinfecting and for storage between uses. See Storage section for instructions on proper storage.

DEVICE CLEANING

DO NOT IMMERSE DEVICE IN ANY LIQUID FOR ANY REASON

Do not use abrasive or volatile cleaners.

NEVER remove the bladder from the device.
The device enclosure can be cleaned with a soft cloth dampened with soapy water or a mild detergent. To sanitize the device, apply cleaning agents with a soft cloth, moistened with 70% isopropyl alcohol. Avoid excessive spraying, especially in the areas of the connection ports on the top and bottom of the device. If any liquid enters the ports, then internal component damage will likely result.

The Circul8 One vascular therapy system cannot be effectively sterilized by liquid immersion, autoclaving, or ETO sterilization, as irreparable damage to the System will occur.

To ensure the device IS completely dry prior to use, leave the device in the OFF condition and disconnected from the wall outlet for 30 minutes after cleaning or disinfecting.

USER MAINTENANCE

The device contains no serviceable parts. Contact your local Customer Service representative.

Inspect the device and all components for any damage that may have occurred during shipping or general handling prior to each use (for example, frayed or cut charging cord, cracked plastic housings, torn cuff(s), and bladders, etc.). Refer to the image of Circul8 One for the description of all components.

Do not attempt to connect the wall supply if any damage is noticed. Avoid subjecting the devices 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 device or cuffs.

Replacement devices are available through customer service.

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

This device is not protected against water.

If you have any issues, please your local customer service representative to receive replacements instructions for any damaged items.

STORAGE AND TRANSPORTATION

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

Relative Humidity: 15% to 93%

Atmospheric Pressure: 525mmHg to 795mmHg

Do not store items in direct sunlight.

DEVICE DISPOSAL

This device is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfills. Consult local country requirements for proper disposal instructions.
Pump control devices contain rechargeable batteries. Do not discard the pump device in regular waste. Bring the device to your local recycling center or contact your local Customer Service representative.

LATEX INFORMATION

All components of the Circul8 One Vascular Therapy System are latex-free. All Circul8 One wraps are latex-free and may be placed directly against the skin or over a light compression dressing.

LITHIUM-ION BATTERY MAINTENANCE GUIDELINES

OVERVIEW

Do not leave batteries unused for extended periods of time because Lithium-Ion batteries continue to slowly discharge (self-discharge) when not in use or while in storage. The typical estimated life of a Lithium-Ion battery is about two to three years or 300 to 500 charge cycles, whichever occurs first. One charge cycle is a period of use from fully charged to fully discharged and fully recharged again. For batteries that do not run through complete charge cycles, there is a two to three-year life expectancy. Rechargeable Lithium-Ion batteries have a limited life and will gradually lose their capacity to hold a charge. This loss of capacity (aging) is irreversible. As the battery loses capacity, the length of time it will power the product (run time) decreases.

BATTERY MAINTENANCE

Always follow the charging instructions provided in your Operator's manual.

CHARGING

Always follow the charging instructions provided in your Operator's manual.

EMC GUIDANCE

⚠ Warning: Don't use near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

⚠ Warning: 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: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 in (30 cm) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

TECHNICAL DESCRIPTION

1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.
2. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS		
The Circul8 One is intended for use in the electromagnetic environment specified below. The customer or the user of the Circul8 One should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment Guidance**
RF Emissions CISPR 11	Group 1	The Circul8 One uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Circul8 One is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations Flicker Emissions IEC 61000-3-3	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The Circl8 One is intended for use in the electromagnetic environment specified below. The customer or the user of the Circl8 One should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/ output lines	±2kV for power supply lines ±1kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Circl8 One requires continued operation during power mains interruptions, it is recommended that the Circl8 One be powered from an uninterrupted power supply or a battery.
Power Frequency (50/60Hz) Magnetic Fields IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c mains voltage prior to application of the test level.			

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The Circul8 One is intended for use in the electromagnetic environment specfied below.The customer or the user of the Circul8 One should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the Circul8 One including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ 150 KHz to 80 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Circul8 One is used exceeds the applicable RF compliance level above, the Circul8 One should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Circul8 One.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE VENAONE

The Circul8 One is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Circul8 One can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Circul8 One as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 KHz to 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

⚠ WARNINGS

- The Circul8 One wraps are designed for single patient use only.
- The device is to be used only by the patient prescribed, and only for its intended use.
- To avoid tripping or falling, do not walk with cuffs on your legs while the device is charging.
- Keep this device out of the reach of children and away from household pets and pests.
- The Circul8 One is a standalone device that uses a Circul8 One AC Adapter and Battery Charger only (see Using the AC Adapter and Battery Charger section). It is not to be used or interconnected to any other device.
- Do not open or remove covers. No user-serviceable parts inside. Direct all device issues to your local Customer Service representative.
- If you experience pain, swelling, sensation changes, or any unusual reactions (including allergic reactions to the materials used in this device) while using this device, stop using this device and consult your medical professional immediately.
- If pulsations or throbbing occur, the cuff may be wrapped too tightly. Loosen Immediately.
- The device is designed to comply with electromagnetic safety standards. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this equipment on and off. Try to correct the interference using one or more of the following:
  - Reorient or relocate the receiving device
  - Increase the separation between the equipment
  - Consult your local Customer Service representative for help
- Care must be taken when operating this equipment around other equipment to avoid reciprocal interference. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with this device.
- Ensure the pump control device is turned off and unplugged from the wall outlet prior to and while cleaning or disinfecting.
- Do not place any items in an autoclave.
- No Service is to be attempted while the device is in use.
- This device is NOT to be altered or modified.
- Contains no user serviceable parts. Contact your local Customer Service representative.

⚠ CAUTIONS

- Medical Electrical Equipment needs special precautions regarding EMC. Portable and mobile RF communication equipment can be affected by other medical electrical devices. If you believe interference is occurring, please consult Electromagnetic Compatibility (EMC) section.
- 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.
- Cuffs used in combination with warming devices may cause skin irritation. Regularly check for patient discomfort, compliance, and skin irritation.
- Allow cuffs to warm to room temperature if exposed to temperatures below 5C (41F).
- Do not immerse in any liquid for any reason.
- Do not operate device in a wet environment.
- Equipment should be used in a lint-free and dust-free environment.
- Do not subject the device to extreme shocks, such as dropping the pump.
- Do not disassemble, crush, or puncture a battery.
- Do not short the external contacts on a battery.
- Do not dispose of a battery in fire or water.
- Do not expose a battery to temperatures above 60 °C (140 °F).
- Keep the battery away from children.
- Avoid exposing the battery to excessive shock or vibration.
- Do not use a damaged battery.
- If a battery pack has leaking fluids, do not touch any fluids.
- Properly dispose of a leaking battery pack.
- In case of eye contact with fluid, do not rub eyes. Immediately flush eyes thoroughly with water for at least 15 minutes, lifting upper and lower lids, until no evidence of the fluid remains. Seek medical attention

CIRCUL8®

ONE

MOBILE BLOOD CLOT PREVENTION

Vascular Therapy System

Compressible Limb Sleeve Device

Model No. 08-0030

TECHNICAL DATA

MAIN DEVICE:
Dimensions: 190 mm X 44 mm X 36.3mm (7.5" X 1.7"X2.5")
Weight: Approx. 0.276.7 kg (0.61 lb)
Mode of Operation: Cyclic
Source of Power: 3.7V 3600mA Lithium-Ion Battery

CAUTION:
Charge batteries using only the power source provided with the device.

POWER SUPPLY:
Class II, input: 100 - 240 Vac, 50 - 60 Hz, output: 12 Vdc @ 2 Amp
Use only UL/60601-1 approved power supplies from Circul8 One for use in hospital settings.

OUTPUT:
Mode of Operation: Continuous

SYSTEM OPERATING ENVIRONMENT:
Temperature: +5C (41F) and +40C (104F)
Relative Humidity: 15%-93%
Atmospheric Pressure: 525mmHg to 795mmHg
Altitude: below 3000 m

DEFAULT SETTINGS:
Leg Pressure (not adjustable) 55 mmHg Cycle time: 60 Seconds

TOLERANCES:
Pressure 10%

BATTERY:
This device is powered by internal Li-ion batteries

BATTERY CHARGE:
Takes approximately 4 hours (from depleted state).

Manufactured for: Ortho8 Inc.

Customer Support: (800) 604-2487 www.Ortho8.com

Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner