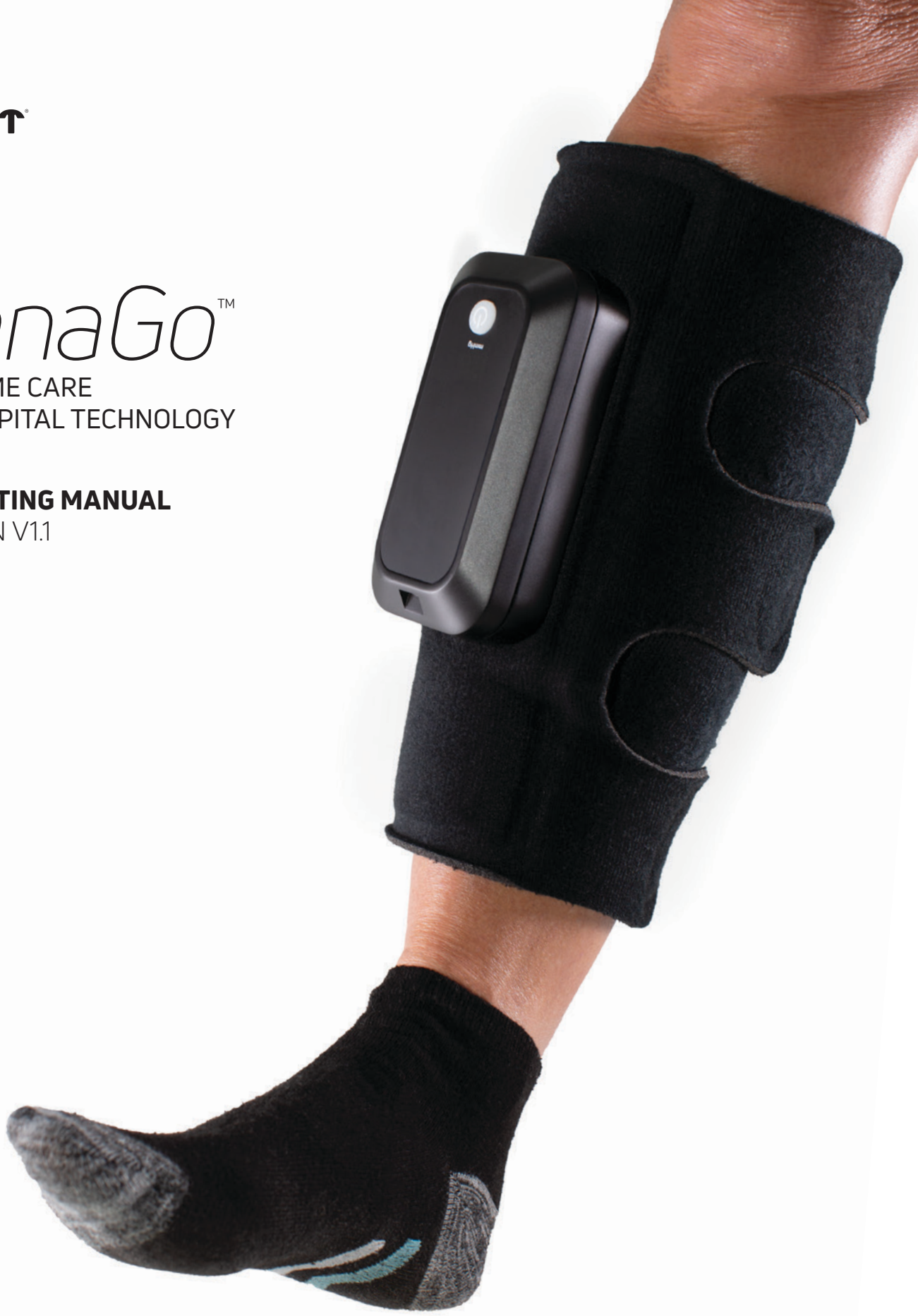
AIRCAST®

VenaGo™

AT-HOME CARE
IN-HOSPITAL TECHNOLOGY

OPERATING MANUAL
EDITION V1.1



READ THE MANUAL BEFORE OPERATING THIS PRODUCT

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER

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INTRODUCTION

The purpose of the VenaGo is to help prevent DVT (Deep Vein Thrombosis) by stimulating blood flow in the legs. The electronically controlled pump delivers a preset amount of air to the leg cuffs that, in turn, compress the calf to help blood flow out of the lower extremities.

INDICATIONS FOR USE

The VenaGo 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). The device can be used to:

- Help prevent DVT
- Enhance blood circulation
- Diminish post-operative pain and swelling
- Help in the treatment and healing of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency, and reduction of lower limb edema

The unit can also be used to help DVT prophylaxis for individuals expecting to be stationary for long periods of time.

SAFETY WARNING

CONTRAINDICATIONS

The device 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 leg deformity.
- On any neuropathy.
- On extremities that are insensitive to pain.
- Where increased venous or lymphatic return is undesirable.

WARNINGS AND PRECAUTIONS

- The device wraps 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.
- Wraps used in combination with warming device may cause skin irritation. Regularly check f or patent 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 wraps.
- Do not open or remove covers. No user serviceable parts inside. Direct all unit issues to the manufacturer or seller.
- If pulsations or throbbing occur, the wrap 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 device is turn 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 wraps to warm to room temperature if exposed to temperatures below 5°C (41°F).
- Do not subject the device to extreme shocks (such as dropping the device).
- 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.

CONDITION OF WORKING, STORAGE AND TRANSPORTATION

- Normal working ambient temperature: 5~40°C
- Normal working ambient humidity: 15~90%
- Store and transport ambient temperature: -25~70°C
- Store and transport ambient humidity: 0~90%
- Atmospheric pressure: 70~106kPa

SYMBOL INTERPRETATION

Information essential for proper use shall be indicated by using the corresponding symbols. The following symbols may be seen on the device and labeling.

SYMBOL	TITLE
	ON/OFF button
	Refer to instructions for use
IP22	IP code of the device
	Unrecyclable
	This way up
	Date of manufacture
LOT	Batch code
SN	Serial number
	Manufacturer
	Type BF applied part
EC REP	Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"
	Fragile, handle with care
	Keep the product in a dry place Away from water and rain.
	Product packaging is able to be recycled

ELECTROMAGNETIC COMPATIBILITY

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.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSION		
The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should assure that it is used in such an environment**.**		
EMISSION TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT – GUIDANCE**
RF emissions CISPR 11	Group 1	The device 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 emission CISPR 11	Class B	The device 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 device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	±1 kV differential 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% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1,2\sqrt{p}$ $d = 1,2\sqrt{p}$ 80 MHz to 800 MHz $d = 2,3\sqrt{p}$ 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. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

B. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE DEVICE.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device 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	80 MHZ TO 800 MHZ	800 MHZ TO 2.5 GHZ
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.

PRODUCT SPECIFICATIONS

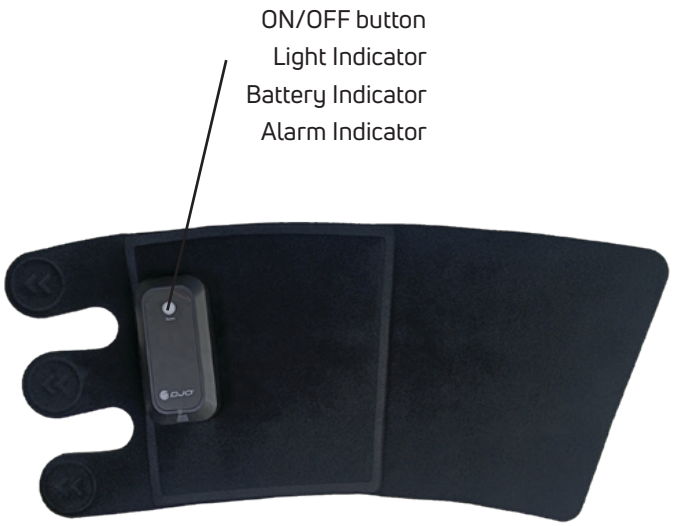
ACCESSORIES INCLUDED IN THE PACKAGE.

1. Device * 1 pair
2. Manual *1 piece
3. IEC 60601-1 compliant Charger *1 piece (Input: AC100-240V, output: DC5.0V--1A)

TECHNICAL INFORMATION

Model/type	VenaGo	**Weight**	378g±20g
Power supply	Powered by internal 3.7V li-ion battery	**Degree of protection against electric shock**	Type BF applied part
Leg Pressure	0--50mmHg	**Type of protection against electric shock**	Class and built-in battery
Warranty	6 months	**Grade of waterproof**	IP22
Recommended Treatment time	prescribed by a physician	**Software version**	A0
Modes	1 auto mode	**Mode of operation**	Continuous operation
The time required for equipment to warm from the minimum storage temperature between uses until it is ready for intended use	30 minutes	**The time required for equipment to cool from the maximum storage temperature between uses until it is ready for intended use**	15 minutes
Typical service life of Battery	300 times of recharging	**Adapter for charging**	Please use the adapter of output DC5V and 1A for charging
Note: Not intended to be sterilized.			
Not for use in an OXYGEN RICH ENVIRONMENT			

OPERATING INSTRUCTIONS



INSTRUCTION

WRAP APPLICATION

Wrap the device-operated wrap around your calf and secure the hook and loop to hold it in place. Make sure the wrap is snug, but not too tight. When both wraps are secured on your legs, they should look like the picture below. Note: The wrap may be placed directly against the skin or over a light dressing.

POWER ON

Hold the On/Off button for approximately 1.5 seconds to turn on the device. The buzzer will sound once when the device is powered on, the digital display shows the accumulated working time for 2 seconds, and the green indicator under the ON/OFF button power lights up (when the battery is low, the light indicator is changed to orange).

POWER OFF

Hold the On/Off button for approximately 1.5 seconds to turn off the device. The buzzer will sound twice when the device is shut down, the digital display turns off, and the light indicator under the ON/OFF button turns off.

WORKING MODE

After being turned on, the device first displays the accumulated working time for 2 seconds. Afterward, the device starts inflating, and meanwhile the display shows the real-time inflation pressure in order of 00-10-20-30-40-50. After reaching the maximum pressure of 50mmHg, the device remains at 50mmHg for 0-4 seconds and then starts deflating. During deflation, the display of pressure is changed from "50" to "00", and keeps flashing until the next cycle starts (Note: A complete circle of inflation, deflation, and rest takes approximately 60 seconds).

CHARGE/DISCHARGE

The green light under the On/Off button will keep flashing when the device is being charged, and become solid when the device is fully charged.

Note:

1. The device can work normally during the period of charging. Use only the charger provided by DJO, LLC. The use of the wrong charger can cause damage and even danger to the device and patient.
2. The light color under the ON/OFF button of the turned-on device is used to represent the battery level of the device: The green light means the device is fully charged or has sufficient power; the light will turn to orange when the battery is consumed to the medium level; when the battery level is low, the red light will appear.
3. When the battery power drops below a critical level, the red light under the ON/OFF button keeps flashing quickly. Meanwhile, the device stops working, the digital display shows "LO", and the buzzer keeps beeping for 10 seconds. Unless the device is connected to the charger within 10 seconds, the device turns off automatically.

ALARM

Low battery voltage: When the battery voltage is severely low (3.3V), the device stops working, the red light under the ON/OFF button keeps flashing quickly, the digital display shows "LO", and the buzzer keeps beeping for 10 seconds. Afterward, the device turns off automatically.

Low pressure and air leakage: When the inflation time exceeds approximately 21 seconds and the inflated air pressure has not reached 50mmHg, the device stops inflating, the red light under the ON/OFF button keeps flashing quickly, the display shows "LP", and the buzzer keeps beeping for 10 seconds. Afterward, the device automatically shuts down.

USE DATA (By Prescribing Physician Only)

The device use time in hour(s) may be viewed directly on the digital display of the device. In addition, the prescribing physician may track the device use hours on the computer: Connect the data transfer cable provided separately to the computer and the device, and then wait for the computer to read the use data. When the data cable is connected between the device and computer, the green light under the ON/OFF button of the device keeps flashing slowly, and the digital display of device shows "CO" (CO represents Connection, which means successful connection). The prescribing physician can download the device use time unidirectionally into Microsoft Excel via the data cable provided separately. There are no bidirectional communications supported by this data cable.

CLEANING AND DISINFECTING

NOTE: Inspect the device 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 DEVICE IN ANY LIQUID FOR ANY REASON.

Clean the outer surface of the device using a soft cloth, moistened with soapy water or 70% isopropyl alcohol.

Do not use abrasive or volatile cleaners.

Do not place the device and wraps in dryer or microwave.

NEVER remove the device from the wrap.

Hand wash the exterior of the wraps using a soft cloth, moistened with soapy water (or 70% isopropyl alcohol), and let air dry.

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

TROUBLESHOOTING

If your device is not operating properly, please check below for the common problems and suggested solutions. If the recommended action does not solve the problem, please contact the seller.

PROBLEM	POSSIBLE CAUSE	SOLUTION
The skin turns red or the skin feels irritated	The use time may be too long	Reduce the use time
No display shown on the device	The battery capacity is depleted	Charge the battery
Power cuts off during use	The battery runs out	Charge the battery

MAINTENANCE AND DISPOSAL

The device contains no serviceable parts. Direct all device issues to the manufacturer or seller at (888) 405-3251.

Inspect the device and all components for any damage that may have occurred prior to each use (for example, frayed or cut charging cord, cracked plastic housings, torn wraps, etc). Refer to this manual for description of all components.

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

Avoid subjecting the device to shocks, such as dropping the device.

Do not handle the wrap that contains air bladders with any sharp objects. If the air bladder is punctured or you notice a leak, do not attempt to repair the device or wrap. Replacement devices are available through customer service.

Avoid folding or creasing the air bladder during use and transportation of the device. Battery is not replaceable; replacement devices are available through customer service. Contact the manufacturer or seller to receive replacement instructions for any damaged item.

This device is an electromechanical device that includes printed circuit boards and rechargeable batteries. Dispose of the battery-containing device according to the local, state, or federal laws. Do not discard in landfill. Do not discard the device in regular waste.

WARRANTY

This device carries a limited warranty of 6 months from the date of delivery. The warranty applies to the device only, and the accessories are not covered by this warranty.

During the warranty period, defective items will be repaired or replaced at no charge. Any evidence of misuse, abuse, alternation, or externally caused damage invalidate this warranty.

For more information, please contact the manufacturer or seller.

CONTACT INFORMATION

Manufactured by DJO, LLC
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Carlsbad, CA 92010
United States

Customer Care: 1-800-336-6569
Product Support: 1-888-405-3251

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