

Protekt™ Seat Relief

Alternating Pressure Seat Cushion System

80120	16"x16" Protekt Seat Relief System
80121	18"x16" Protekt Seat Relief System
80122	20"x16" Protekt Seat Relief System
80123	Protekt Seat Relief Pump Only
80124	16"x16" Protekt Seat Relief Cushion Only
80125	18"x16" Protekt Seat Relief Cushion Only
80126	20"x16" Protekt Seat Relief Cushion Only

Please read the instruction manual before use.

IMPORTANT SAFEGUARDS

READ ALL INSTRUCTIONS BEFORE OPERATING THIS DEVICE.

DANGER - To reduce the risk of electrocution:

1. Always unplug this product immediately after using.
2. Do not use while bathing.
3. Do not place or store this product where it can fall or be pulled into a tub or sink.
4. Do not place in or drop into water or other liquid.
5. Do not reach for a product that has fallen into water. Unplug immediately.

WARNING - To reduce the risk of burns, electrocution, fire, or injury to persons:

1. Evaluate patients for entrapment risk according to facility protocol and monitor patients appropriately.
2. The product may be used for patients with spinal injury, but suggested to consult with physician before use. However, it should not be used for patients with unstable spinal fractures.
3. Close supervision is necessary when this product is used on or near children. Electrical burns or choking accident may result from a child swallowing a small part detached from the device.
4. Use this product only for its intended use as described in this manual. Do not use other mattress not recommended by the manufacturer.
5. Never operate this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water. Return the product to your supplier or Proactive Medical Products for examination and repair.
6. Keep the cord away from heated surfaces.
7. Never block the air openings of this product or place it on a soft surface, such as a bed or couch, where openings may be blocked. Keep the air opening free of lint, hair, and other similar particles.
8. Never drop or insert any object into any opening or hose.
9. Do not modify this equipment without authorization of the manufacturer.
10. Cushion covers have passed skin sensitization and skin irritation test. However, If you suspect that you may have had or are having an allergic reaction, please consult a physician immediately.

⚠ CAUTION: If there is a possibility of electro-magnetic interference with mobile phones, please increase the distance (10 ft) between devices or turn off the mobile phone.

				the compliance level in each frequency ranged. Interference may occur in the vicinity of equipment marked with the following symbol: 
<p>NOTE 1: U_i is the a.c. mains voltage prior to the application of the test level</p> <p>NOTE 2: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people</p>				
<p>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 reorienting or relocating the device.</p> <p>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.</p>				

Recommended separation distances between portable and mobile RF communications equipment and this device:

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this 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 $d = \sqrt{P}$	80 MHz to 800 MHz $d = 0.6\sqrt{P}$	800 MHz to 2.7 GHz $d = 1.2\sqrt{P}$
0.01	0.1	0.06	0.12
0.1	0.31	0.19	0.38
1	1	0.6	1.2
10	3.1	1.9	3.8
100	10	6	12

			line	
Surge IEC61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s)	± 1 kV line(s) to line(s)	Mains power quality should be that of atypical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	Voltage Dips: i) 100% reduction for 0.5 period, ii) 100% reduction for 1 period, iii) 30% reduction for 25/30 period, Voltage Interruptions: 100% reduction for 250/300 period		100-240 V	Mains power quality should be that of a typical commercial or hospital environment. If the user of this 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 (50/60Hz) magnetic field IEC61000-4-8	30 A/m	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.
Conducted RF IEC 61000-4-6	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	6Vrms	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than there commended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF EM Fields IEC61000-4-3	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz 385-6000 MHz, 9-28V/m, 80% AM(1kHz) pulse mode and other modulation	10 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz 385-6000 MHz, 9-28V/m, 80% AM(1kHz) pulse mode and other modulation	10V/m	Recommended separation distance $d = \sqrt{P}$ 150kHz to 80MHz $d = 0.6\sqrt{P}$ 80MHz to 800MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.7GHz 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). ^b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than

NOTE, CAUTION AND WARNING STATEMENTS

NOTE: Indicates some tips.

CAUTION: Indicates correct operating or maintenance procedures in order to prevent damage to or destruction of the equipment or other property

WARNING: Calls attention to a potential danger that requires correct procedures or practices in order to prevent personal injury.

SYMBOLS

	Authorised representative in the European community.
	For equipment with carry bag (protection against nearly vertically falling water drops)
	For equipment without carry bag (protection against solid foreign objects of 12.5mm and greater)
	Class II
	Manufacturer
	Complies with standards protecting against electric shock for type BF equipment.
	Consult operating instructions for use
	Temperature limitation/Temperature Range
	Machine wash, regular/ normal, 95 degree C (203 degrees F)
	Do Not Bleach
	Do Not Iron
	Do Not Dry Clean
	Tumble Dry, Normal, Low Heat
	Attention – Observe proper Disposal of Electrical & Electronic Equipment (WEEE): This product should be handed over to an appropriate collection point for the recycling of electrical and electronic equipment. For more detailed information about the recycling of this product, please contact your local city office, household waste disposal service or the retail store where you purchased this product.

KEEP THIS MANUAL FOR REFERENCE

1. INTRODUCTION

This manual should be used for initial set up of the system and for reference purposes.

1.1 General Information

The device is a high quality, affordable pressure relief seat cushion system for wheelchair users. It helps to decrease the concentrated pressure, distribute the pressure over the entire contact interface and stimulate capillary blood flow for the prevention of pressure ulcers.

The system has been tested and successfully approved to the following standards:



- IEC/EN 60601-1
- IEC/EN 60601-1-2
- IEC/EN 61000-3-2 Class A
- IEC/EN 61000-3-3
- CISPR 11 Group 1, Class B

EMC Warning Statement

This equipment has been tested and found to comply with the limits for medical devices to the EN 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the 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. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

1.2 Intended Use

This product is intended:

- to help and reduce the incidence of pressure ulcers while optimizing patient comfort.
- for long term home care of patients suffering from pressure ulcers.
- for pain management as prescribed by a physician.

The product can only be operated by personnels who are qualified to perform general nursing procedures and has received adequate training in knowledge of prevention and treatment of pressure ulcer.

⚠ NOTE: Equipments are not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Appendix A: EMC Information

Guidance and Manufacturer's Declaration- Electromagnetic Emissions:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions 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 emissions 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
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations / Flicker emissions IEC61000-3-3	Complies	



Warning:

1. The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
2. 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.
3. 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 Pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's Declaration- Electromagnetic Immunity:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Basic EMC standard	Immunity Test Levels		Compliance Levels	Electromagnetic Environment-Guidance
	Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT		
Electrostatic Discharge (ESD) IEC61000-4-2	±8kV contact ±15kV air		±8kV contact ±15kV 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 IEC61000-4-4	±2kV for power supply line ±1kV for input/output line		±2kV for power supply line ±1kV for input/output	Mains power quality should be that of atypical commercial or hospital environment

10. Technical specification

Item		Specification
Power Source		DC12V, 1250 mA by Adaptor
Power consumption		12V DC, 1150 mA
Device Dimension (L x W x H)		25 x 12.2 x 5.7cm or 9.8" x 4.7" x 2.2"
Device Weight		1.0 kg or 2.2lb (battery and adaptor included)
Environment	Atmospheric Pressure	700 hPa to 1013.25 hPa
	Temperature	Operation: 5°C to 40°C (41°F to 104°F) Storage: -10°C to 45°C (14°F to 113°F) Shipping: -10°C to 45°C (14°F to 113°F)
	Humidity	Operation: 30% to 75% non-condensing Storage: 10% to 75% non-condensing Shipping: 10% to 90% non-condensing
Classification		Type BF, Class II, IP2X; IP22 (with carrying bag) Applied part: Air Seat Cushion Not suitable for use in the presence of a flammable anaesthetic mixture (No AP or APG protection)
Pressure Range		Five selectable settings
Cycle Time		10, 15, 20 minutes
Battery Pack		3.78V Li-ion Battery x2 (2.95Ah typical) (recommended type HOVANOX METAL, SDI-30B-2S1P)
Battery Operation Time		Approx. 12 hours
Battery Recharge Time		Approx. 4.5 hours
Cushion		Specification
Dimension (L x W x H)		43 X 43 X 10.2 cm or 17" x 17" x 4"
Weight		1.1 kg or 2.4lb
Max. Weight Capacity		120 kg

⚠ NOTE :

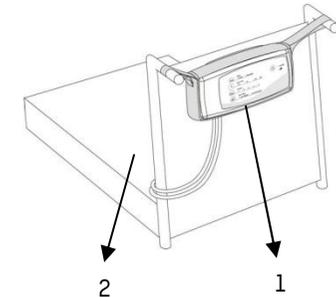
1. The battery performance may be reduced if the device is stored in a hot environment.
2. Consult the distributor or EU representative for other technical documents.
3. Please follow national requirements to dispose of the unit properly
4. The manufacture reserves the right to change product specification without prior notice.

2. Product Description

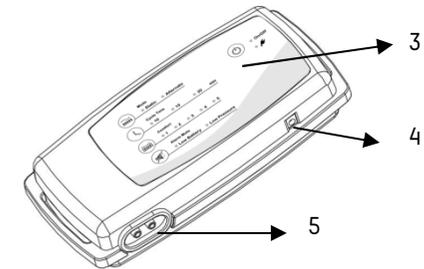
The device is an active alternating pressure seat cushion system and consists of a reliable pump and seat cushion providing the best pressure relief. It comes equipped with a fully digitalized pump and each function mode can be adjusted individually, such as cycle time and comfort range. It provides you with total pressure management control and runs on AC power supply or a Li-ion rechargeable battery.

2.1 Pump and Seat Cushion System

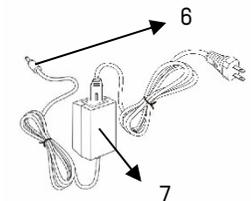
1. Pump Unit
2. Cushion



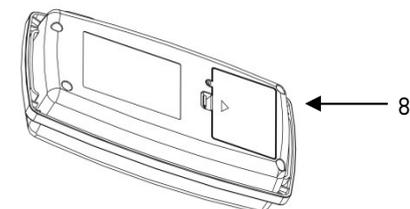
3. Control Panel
4. DC Power Jack
5. Air hose port



6. DC Plug
7. AC/DC Adaptor



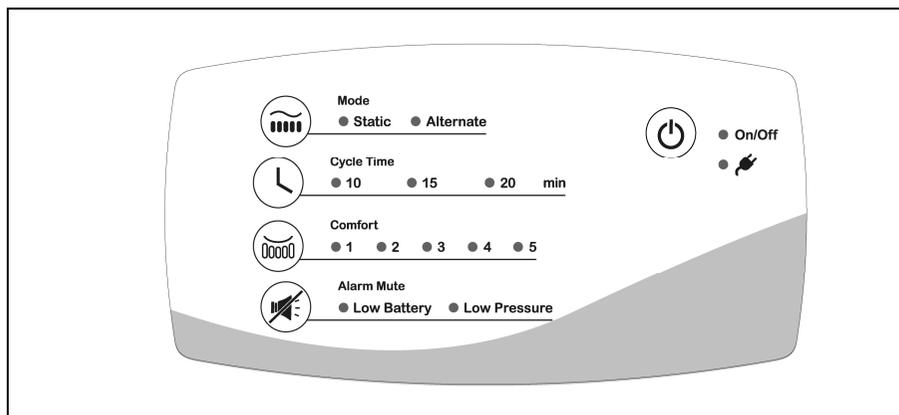
8. Battery pack stored area



CAUTION:

1. Do not drop water on to the device.
2. Do not apply shock to the device.
3. Do not disassemble or modify the device.
4. Do not obstruct the air outlet.
5. Do not use any power adapter and battery pack not provided by the manufacturer.
6. To prevent battery pack damage, please remove the battery pack from the battery compartment when not using the device for a long period.

2.2 Front Panel



1. Therapy Modes

To switch the therapy mode:

A. Alternating Mode

Continuously and sequentially inflate and deflate air cells to remove constant pressure and facilitate improved cellular perfusion.

B. Static Mode

Provides a stable all cell inflated surface at lower pressure when compared to the respective comfort level in alternative mode. The system then redistributes patient weight over a greater surface.

2. Cycle Time

To adjust the pressure alternating cycle time to 10, 15 or 20 minutes..

3. Comfort Setting

To adjust the comfort level according to user's preference or doctor's advice. There are 5 different comfort levels: 1 is the softest & 5 is the firmest. The default setting is at comfort level 1.

9. Trouble Shooting

Q1 Power is not ON

- Check if the plug is connected to mains.
- Check if the power cord is well connected to the pump
- To operate from battery, check if the DC plug is disconnected from the pump unit

Q2 Low Pressure Alarm is on (audible & visual)

- Check if the connection between air tube connector to pump unit is tightly secured.
- Check if all tubing connections along cushion are secured.
- Check if there is any leakage from air cells

Q3 Cushion becomes too firm and pressure can't be lowered

- The pressure is too firm for too long, release some air by disconnecting the air tube connector and change to your preferred setting..

Q4 No air is produced from some air outlet of the air tube connector

- This is normal since it is at alternating mode. Air outlets take turns to produce air during their preset cycle time..

Q5 Low Battery Alarm is on (audio & visual)

- Only approx.1 hour of battery power remain, it is a reminder that user must recharge the battery pack and use AC power source immediately. To mute the alarm, simply press the alarm mute button.
- After the battery is fully charged (about 5 hours), the pump immediately has 12 hours of continuous operation time. If it is unable to operate over 12 hours, the battery pack might need to be replaced.
- If the low battery indicator still lights up after it has been properly recharged for approximately 5 hours, the battery pack might need to be replaced. Replacement required after about 6 months.

If the above information does not solve your problems, please contact your local agent directly. They might require a technician to take care the problem.

 **CAUTION:** It is prohibited to use the battery pack not from the vendor. The charging function of the pump is designed for the battery pack only. The vendor will not warranty any damage from another battery pack not supplied by the vendor

 **NOTE:** Higher temperature will shorten life of the battery pack, please keep the battery in a cold place and avoid direct sunlight

 **NOTE:** The Velcro serves to secure the battery for the purpose of ensuring the stability of battery pack. It's recommended to check if the Velcro is secured before putting the cover back

 **WARNING:** Lithium-ion battery, DO NOT disassemble or remove outer casing, short-circuit, puncture, crush, incinerate or expose to heat source, due to risk of fire and combustion.

8. Expected Service Life:

The products are intended to offer safe and reliable operation when use or installed according to the instructions provided by Proactive Medical Products. Proactive Medical Products recommends that the system be inspected and serviced by authorized technicians if there are any signs of wear or concerns with device function and indication on products. Otherwise, service and inspection of the devices generally should not be required.

 **NOTE:** A hand check is needed to determine if patient is bottoming out. When a patient's condition has significantly changed reassess appropriateness of product and comfort setting level

4. **Alarm Mute**  Press alarm mute button to temporary suspend the alarms. Should the problem continue, the alarms will resound within 10 minutes to notify the caregiver until resolved.

5. **Low Battery Indicator**
A low battery alarm indicates approximately 1 hours of therapy remain; charge batteries IMMEDIATELY to prevent disruption of therapy. When battery is charged, audible and visual alarms will turn off.

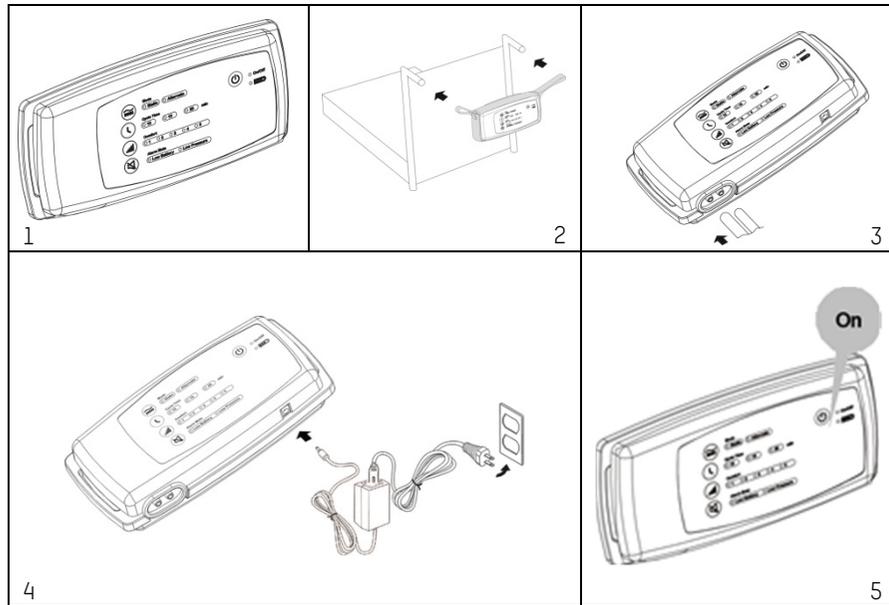
6. **Low Pressure Indicator**
When the pressure is below setting pressure, the Low Pressure indicator will light up along with audio alarm. Please check if all connections are connected properly as per instructions. If the pressure level is consistently low, check for any leakage (tubes or connecting hoses). If necessary, replace any damaged tubes or hoses or contact local qualified dealer for repairment.

 **NOTE:** Even when pressing the Alarm Mute, the indicator light will stay on until the problem is solved.

7. **On/off**  To turn the pump unit on/off.

8. **Battery Charge Indicator**  When the indicator light is on, AC power is charging the battery. The typical charging period is approx.. 4.5 hours. The led light will be off once the battery is full.

3. Installation



⚠ NOTE: Unpack the box to inspect for any damage, which may have occurred during shipping. If there are any damages, please contact your dealer immediately.

3.1 Setting Up

1. Place the seat cushion on top of the (wheel) chair. The slip-resistance mat found at the bottom of cushion will prevent slippage.

⚠ CAUTION: The pump can only be used with the air seat cushion recommended by the manufacturer. Do not use it for any other purpose.

2. Put the pump into the carry bag and hang the pump onto the (wheel) chair handle or frame with the straps of the carry bag.
3. Connect air hose from the seat cushion to the pump unit.

⚠ NOTE: Check and ensure the air tubes have no kinks in them and are not tucked under the cushion.

4. Connect the AC/DC adaptor to DC power jack of the pump unit. Plug into mains electrical outlet..

⚠ NOTE: Use only with original manufacturer's adaptor, improper use of adaptor or charge with adaptors other than supplied from the manufacturer will not be covered under the warranty.

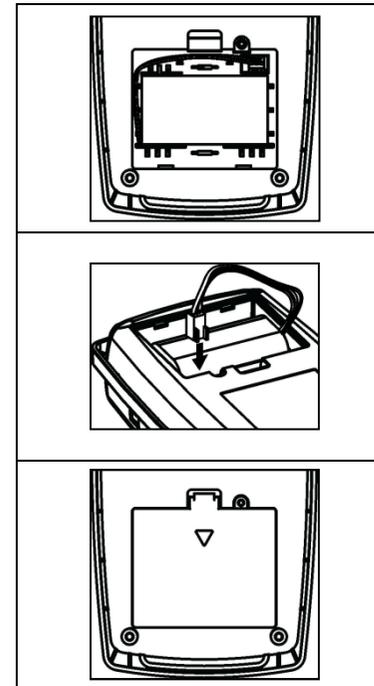
7. Maintenance

7.1 General

1. Check main power cord and plug if there are abrasions or excessive wears.
2. Check mattress cover for signs of wear or damage. Ensure mattress cover and tubes are stubbed together correctly.
3. Check the air hoses for any kink or break. For replacement, please contact your local dealers.

7.2 Battery Pack Replacement

To replace the battery pack, follow the instructions below.



1. Remove the AC power source & disconnect the DC plug.
2. Open the battery cover by removing the screw on the back of the pump unit.
3. Take out the battery pack by pulling the cable connector.
4. Plug in the new battery pack connector and insert the battery pack.
5. Put the cover on and screw back.
6. Connect the pump to a power outlet using the included cable and power adaptor to recharge the battery.

Carrying Bag

The carrying bag should be turned inside out and completely wiped down using disinfectant solutions. Allow it to air-dry thoroughly. Once the inside is dry, turn it back and wipe down the outside of the bag with disinfectant solutions.

⚠ CAUTION: Dry the Seat Cushion in SUNLESS area after cleaning.

6. Storage

1. Disconnect the air hose from the cushion to the pump.
2. Protect the air tube coupler by putting it inside of seat cushion.
3. Place the whole system into a protective bag.

⚠ CAUTION: For storage period more than 3 months, disconnect the Li-ion battery pack from the pump and make sure the battery is partially charged. This will help to keep the performance and life of the battery.

⚠ CAUTION: Do not store the system under direct sunlight, high temperature or moisture area.

⚠ NOTE: The plug also serves to disconnect the device. The system can operate in battery mode only when the DC Plug is disconnected from the pump unit.

5. Press the power button to start the machine. When the pump unit is turned on, the ON/OFF indicator will light up

3.2 Charging Battery Pack

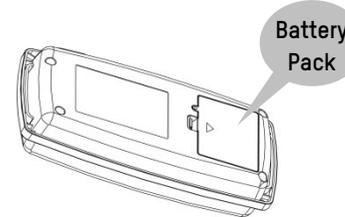
The Sedens 500 Pump Unit is battery-operated to facilitate patient mobility.

1. Depending on how long you store your device, it may be in a low-battery state when you remove it from long-term storage. After it's removed from storage, it may require **4.5 hours** of charging with the original adapter to fully charge the battery.

⚠ CAUTION: It's especially important to avoid charging your device under temperatures higher than 104° F (40° C), which can permanently damage device.

2. When the power in the battery pack becomes low, the low battery indicator flashes to indicate that only approx.1 hour of battery power remain. You must recharge the battery pack by using AC power source.

⚠ NOTE: Replace the battery recommended by the manufacturer, if the performance becomes undesirable. It is suggested that users charge the battery pack fully at night and use the pump during the next day.



3. Please make sure the battery is fully charged as the battery charge indicator light turn off.

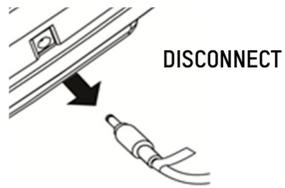
⚠ NOTE: Regularly check the battery indicator on the control panel to determine the status of the rechargeable battery.

⚠ NOTE: When low battery condition occurs, the Low Battery indicator will light up and the pump will set off the audible alarm at the same time. To mute the alarm, simply press the alarm mute button. However, it is a reminder that user must recharge the battery pack or use AC power source immediately.

⚠ CAUTION:

1. Please keep the battery pack out of the reach of children.
2. The battery pack is a Li-ion rechargeable battery, which can explode if not properly replaced, used, handled or disposed of.
3. Dispose of the battery as required by local ordinances or regulations.
4. If you plan to store your device for longer than six months, charge it to 50% every six months.

- After the battery is fully charged, the pump has approx. 12 hours of operation time without the adaptor.



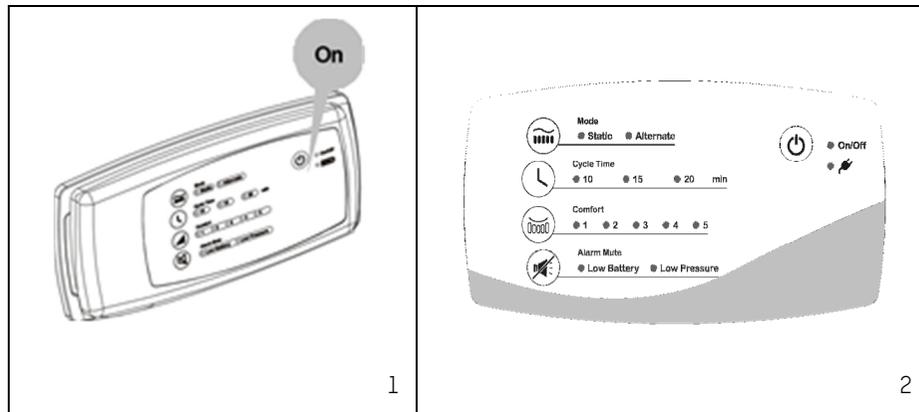
- CAUTION:** If the charging time is over 5 hrs but the battery charge indicator still lights up, please do NOT continue to charge the battery, and disconnect the adapter for safety.

4. Operation

- NOTE:** Always read the operating instruction before use.

4.1 Operating Instructions

- NOTE:** For first time use, please use the AC/DC adaptor to charge the battery while using the system. The typical charging period will be about 4.5 hours. Once the battery is fully charged, the battery charge indicator light will turn off.



- Press the On  button on the display panel to start the system.
- It will take a few minutes to inflate the cushion.
- Before cushion is fully inflated, according to the weight and height of the patient, adjust the mode, cycle time, and comfort setting to the most suitable level without bottoming out.

- NOTE:** Sometimes the Low Pressure indicator will light up and flash temporarily when users leave the cushion. This is normal, as inner pressure of the cushion suddenly changes when load changes.

- NOTE:** Should the battery fail to keep working for 12 hours, please check for air leakage or tubing connections as it might reduce the performance of the battery considerably.

- CAUTION:** Pump unit should always put in carrying bag to prevent drop damage of the equipment.

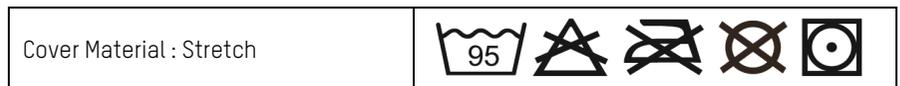
5. Cleaning

It is important to follow the cleaning procedures to avoid cross contamination. Be sure to clean the surface in a dry and dust free environment. Wipe down the pump unit with a damp cloth pre-soaked with a mild detergent. Avoid contact with dust and proximity to dusty areas. Make sure that any cleaning agents you use will not harm or corrode the plastic casing on the pump unit. If your doctor or medical facilities have other special cleaning instruction, please follow the professional instruction.

- CAUTION:** Do not immerse or soak pump unit in liquids.

- WARNING:** Do not remove the housing of the pump to avoid the electrical shock. All disassembly or repair should be done by professional technicians.

- CAUTION:** The pump does not need oil lubrication; please do not disassemble the system.



Wipe-down the cushion unit with a damp cloth pre-soaked with warm water containing a mild detergent, or chlorine bleach followed by an approved intermediate level disinfectant. Also the mattress top cover can be completely removed for laundry with water temperature up to 95°C; however, it is recommended that the user still check with local policy to determine the time/ temperature ratio required to achieve thermal disinfection. The cover may also be cleaned using sodium hypochlorite diluted in water. After cleaning, please avoid dust and proximity to dusty areas and all parts should be air dried thoroughly before use.

- CAUTION:** Do not use phenolic based products for cleaning.

- CAUTION:** After cleaning, dry the mattress without direct exposure of sunlight.