Unisoft OneTM SINGLE PATIENT USE THERAPEUTIC SUPPORT SYSTEM

UserManual



What's in the box

- 1 x Unisoft One™ Mattress (Single patient use only)
- B 1 x Unisoft One™ Pump (Reusable)
- 1 x Unisoft One™ Tube System (Reusable)



Quick Setup

- 1. Unfold mattress and place on bed deck or box spring.
- 2. Hang Pump on foot or side of bed, or place on a flat surface nearby.
- 3. Attach Tube System to Pump.
- 4. Attach Tube System to Connector Port at the foot of the mattress.
- 5. Plug Pump into a grounded outlet and not a power strip or extension cord.
- 6. Turn Pump dial to 300/Firmer and switch on. The Mattress takes approximately 45 minutes to fully inflate.
- 7. A green light will indicate when the mattress is fully inflated. At this point, adjust the dial to the desired firmness. There should always be at least 2" of air between the patient and the bed deck so the patient doesn't "bottom out."
- 8. Use tie-down straps to secure mattress to bed deck.

Safety Information



Please read all instructions and safety guidelines before operating the product.

IMPORTANT SAFEGUARDS

When using any electrical appliance, some basic safety precautions should always be observed to reduce the risk of fire, electric shock, and/or injury to persons. Read all instructions carefully before using the product. Specifically:

DANGER! Failure to observe any of these warnings may result in life threatening injury by electric shock.

- Do not operate the product with a damaged cord or plug, after faulty operation, or when it has been dropped or damaged in any way. Contact Unisoft Medical Corporation for inspection, electrical or mechanical adjustment, or repair.
- Never position the product where it may fall into a bathtub or come in contact with water. Do not use the product near showers, bathtubs, sinks, swimming pools, etc.
- If the product is located in a room with a bath or shower, always install away from taps, basins, showers, etc.
- **CAUTION: THIS PRODUCT SHOULD NEVER BE USED NEAR** WATER.
- Do not insert or allow foreign objects to get into the air inlet or outlet, as this may cause electric shock or fire, or damage the product.
- Make sure that the plug is fully inserted into the wall outlet. Wall outlets may deteriorate with time, so check the plug periodically for signs of over-heating or deformation. If the wall outlet has deteriorated, stop using it and have it repaired.
- Due to the risk of electric shock, do not attempt to open pump. Please refer any repairs to qualified dealership or service technician.

WARNING! Failure to observe any of these warnings could result in injury to persons or damage to the product.

- This product is not intended for use by persons with reduced physical, sensory or mental capabilities, or lack of experience and knowledge, unless they are in the care of a person responsible for their safety. This product is intended for adults. Children should be supervised to ensure that they do not play on or with the product.
- ALL AIR MATTRESSES CAN BE HAZARDOUS TO INFANTS; INFANTS SHOULD NEVER BE PLACED TO SLEEP OR LEFT UNSUPERVISED ON ANY AIR MATTRESS.
- Always disconnect the plug from the power outlet when the product is not in use.
- Do not use the product outdoors.
- Do not run the power cord under carpeting. Do not cover cord with throw rugs, runners, or the like. Keep the cord away from any passageways where it could be tripped over.
- Do not plug the pump into a wall outlet controlled by a light switch.
- To prevent a possible fire, do not block air intake or outlet in any way. Do not place the pump on soft surfaces, such as a bed, couch or chair, where the openings may become blocked.
- Use this product only as described in this manual. Any other
 use not indicated by the manufacturer may cause fire, electric
 shock, or injury to persons.
- To prevent current overload and blown fuses, make sure that no other appliance is plugged into the same outlet or into another outlet wired into the same circuit.
- If the supply cord is damaged, to reduce the risk of malfunction it must be replaced by the manufacturer, its service agent, or a licensed and qualified professional.
- Do not use this product with an extension cord or outlet strip.
 Connect the product directly to a suitable outlet.
- Keep the cord away from heated surfaces.
- · Never drop or insert any object into any opening or hose
- Do not use outdoors or operate where aerosol (spray) products are being used.
- Connect this product to a properly grounded outlet only. See Grounding Instructions.



GROUNDING

Before the pump is turned on, make certain that it is connected to a protective earth conductor via the three-wire power cord; the three-blade plug should be inserted only into a socket outlet that provides a protective earth contact.

WARNINGS: Use grounded receptacle as shown in photo.

- Do **NOT** plug into a power strip or extension cord.
- Do **NOT** plug into an outlet that is controlled by a wall switch.



TO TRANSPORT PATIENT OR IN THE EVENT OF A POWER OUTAGE:

Quickly disconnect pump tube system from pump and attach cap marked **TRANSPORT** to tube system. The mattress will remain inflated for approximately thirty (30) minutes.

NOTE: Without power the mattress will be unable to provide alternating pressure therapy. If the duration of the power outage is unknown, or likely to extend beyond thirty minutes, remove patient to a different mattress until power is restored and the Unisoft One is re-inflated.

Using the Unisoft OneTM

INDICATIONS FOR USE

The Unisoft One™ Single Patient Use Therapeutic Support System is the first of its kind. Made from sustainable materials, its unique design and structure provide gentle support for the prevention and treatment of pressure ulcers. Because it's designed to be disposed of between patients, the Unisoft One™ eliminates the risk of cross-contamination from dirty mattresses. The Unisoft One™ is suitable for use in healthcare facilities and for personal use.

The Unisoft One[™] is a unique "low pressure alternating pressure" Single-Patient-Use mattress replacement system that is intended to help prevent and treat pressure ulcers while optimizing patient comfort in a cost-effective manner.

The Unisoft One™ is suitable for:

- Patients at risk or suffering from pressure ulcers.
- Patients at risk or suffering from infections.
- Any patient that would benefit from a pressure relief surface and/or protection from mattress-borne pathogens.

The Unisoft One™ is **NOT** suitable for:

- · Patients with unstable spinal cord injuries.
- Patients with skeletal or cervical traction.

We recommend consulting with the patient's attending physician prior to the use of this product.

This product is not a substitute for medical or nursing care. Patients at risk or suffering from pressure ulcers or infections should be under the care of a physician.

Product Features

UNISOFT ONE™ MATTRESS:

- Provides "low pressure alternating pressure" for comfortable pressure redistribution
- Sets up in minutes, no training needed
- Quick Connect / Disconnect Fittings
- Maintenance Free
- Integrated side rails for safe exit
- Eight (8") inch cell depth
- Non-Removable Cover is
 - Soft
 - Stain Resistant
 - Bleach Compatible
 - Breathable: impervious to liquid penetration, vapor permeable.
 - High MVTR
 - · Low friction, low shear
- Lightweight and compact; ships in a 24" x 24" x 6" box, total weight 17 lbs, including shipping materials, 12.7 lbs alone.
- Made from non-toxic, recyclable materials.
- Guaranteed for One Year
- Medicare Approved HCPCS E0277
- Made in the USA

UNISOFT ONE™ PUMP AND TUBE SYSTEM:

- Built in hooks for easy placement on footboard of bed
- User friendly
- Illuminated power switch
- Lightweight
- Quiet operation
- Pressure Control Dial to maximize patient comfort and immersion level
- Six-minute alternating cycle time
- Patent-pending quick connect/disconnect connectors

Instructions

SETUP

- 1. Place the Unisoft ONE Pump on a flat surface or suspend the pump over the bed rails at the foot or side of the bed using the built in hangers. (Do not position in such a manner that it may become a hazard to foot traffic.)
- Place the Unisoft One mattress on top of the bed deck, printed side up, with the Unisoft logos readable from the foot of the bed. (If necessary, first remove standard mattress from bed frame; do not place the Unisoft ONE on top of another mattress.)
- Connect the Unisoft One Tube System to the pump and mattress as shown, ensuring that the tubing isn't twisted.
 Do not tuck the tubing under the mattress. Test the connections by gentle tugging.



CONTINUED ON NEXT PAGE

- 4. Ensure that the power switch is in the OFF position, then plug the AC power cord into a grounded AC outlet. **Do NOT** use an outlet controlled by a wall switch, power strip, or extension cord.
- 5. Switch the power ON. The pump will begin to inflate the mattress. We recommend turning the pump dial to maximum inflation (300) and then adjusting the inflation downward after the patient is in bed, if desired.
- 6. The yellow LED light indicates that the mattress is not yet fully inflated. The green LED light will automatically light up when inflation is complete. Inflation takes approximately 45 minutes.
- 7. Secure the mattress to the bed deck with the tie down strips.
- 8. Adjust the pump to the desired firmness / immersion level. There should always be at least 2" of air between the patient and the bed deck so the patient doesn't "bottom out."

NOTES

- A Rapid Inflator pump can be used for faster inflation.
 (Available at box stores or retailers such as Amazon)
- Each time the mattress is inflated, set the pressure dial to "Firmer / 300" first and then adjust after inflation is complete.

DEFLATING THE MATTRESS

Do NOT deflate the mattress while it is in use.

- 1. Switch power to OFF using the switch on the top of the Pump.
- 2. Unplug the Pump from outlet.
- 3. Disconnect the Tube System from the connector at the foot of the mattress by squeezing the blue pressure points on either side and gently pulling.
- 4. Disconnect red CPR port at the head of the mattress by squeezing the handles and gently pulling.

RE-INFLATING THE MATTRESS

Ensure that the mattress is fully inflated before use.

- 1. Ensure that the power switch is in the OFF position, then plug the AC power cord into a grounded AC outlet. Do NOT use an outlet controlled by a wall switch.
- 2. Switch the power ON. The pump will begin to inflate the mattress.
- 3. The yellow LED light indicates that the mattress is not yet fully inflated. The green LED light will automatically light up when inflation is complete.
- 4. Adjust the pump to the desired firmness / immersion level

CPR

To rapidly deflate the mattress in an emergency where CPR is required:

- 1. Disconnect the Tube System from the connector at the foot of the mattress by squeezing the blue pressure points on either side and gently pulling.
- 2. Remove the red CPR port at the head of the mattress by squeezing the red handles and gently pulling.

Cleaning

UNISOFT ONE™ PUMP



WARNING/DANGER: Disconnect the power cord from the wall outlet before cleaning the pump.

Exterior:

- 1. Wipe off dust.
- 2. If necessary, disinfect with bleach or other disinfectant for the recommended contact time. Do NOT immerse the pump or use excessive fluid to clean.
- 3. Wipe with clean water and dry.

Filter:

- 1. Locate filter on back of Unisoft One™ Pump
- 2. Remove filter plate.
- 3. Remove filter. Vacuum to remove dust.
- 4. For excessive dust, rinse filter in warm water. Dry filter completely before reinstalling. 3 replacement filters are included

UNISOFT ONE™ MATTRESS



WARNING/DANGER: It is strongly recommended that disposable gloves and eye protection are worn during cleaning & disinfection.

If the Unisoft One™ mattress becomes soiled, it can be cleaned by using the following procedure:

- 1. Use a damp cloth and mild detergent water solution to clean mattress of any organic material.
- 2. Disinfect with bleach or other disinfectant for the recommended contact time.
- 3. Rinse with clean water and wipe dry. Blotting with paper towels is an effective method of quickly drying the surface.

Storage

UNISOFT ONE™ PUMP AND TUBE SYSTEM

Store in the original box or water tight plastic container.

- 1. Disconnect the Tube System and store in box with Pump.
- 2. Place in a dry, climate-controlled storage area.

Note: The Tube System and Pump MAY be reused if properly cleaned and disinfected.

UNISOFT ONE™ MATTRESS

New/unused Unisoft One™ Mattresses should be stored in their original packaging, away from direct sunlight and extreme temperatures.

Used Unisoft One™ Mattresses should be disposed of by following the directions below.

Mattress Disposal

The Unisoft One™ Mattress is designed for single-patient-use. When no longer needed, it should be deflated completely and disposed of.

Please check your local recycling guidelines before disposal.

The Unisoft One™ mattress is made of thermoplastics. Every component is recyclable. We follow the design guidelines for recycling developed by the Healthcare Plastics Recycling Council. Because healthcare plastics recycling programs vary by facility and locale, we aren't able to provide detailed recycling instructions at this point in time, but hope to in the future

Troubleshooting

Problem

Possible Cause

Remedy

DEFLATION:

Patient bottoms out on mattress, or mattress is too soft.

- Tube System is disconnected from Connector Port.
- CPR Plug (Red) is disconnected from Connector Port.
- 3. Pump is OFF or UNPLUGGED.
- 4. Pressure Control Dial is turned too low.
- 5. There is a leak in the mattress or a pump malfunction.

- 1. Check connections to Connector Ports.
- 2. Check ON /
 OFF Switch on
 Control Module
 (light will be
 illuminated if
 power is on);
 Check the Power
 Cord to ensure it
 is plugged into a
 working outlet.
- Check Pressure Control Dial on Pump and increase firmness.
- 4. Call your Unisoft Medical Sale and / or Service Representative.

ALTERNATING CELL DEFLATION:

ALL or EVERY OTHER horizontal, alternating cell(s) is completely empty of air longer than 10 minutes.

- I. There is a leak in the mattress or a pump malfunction.
- 1. Check Pump.
- Call your Unisoft Medical Sales and / or Service Representative.

System Specifications

MATTRESS

Dimensions:	37" W x 82" L x 8" H
Weight:	6.7 lbs.

PUMP - ELECTRICAL SPECIFICATIONS

Power:	120 VAC
Frequency:	60 Hz
Current:	1 A
Mode of Operation:	Continuous
Circuit Protection:	Fused
Cycle Time:	6 min.

OPERATING CONDITIONS

Ambient Temperature:	+10°C to +40°C
Relative Humidity:	30% to 75% Non-Condensing
Atmospheric Pressure:	700 hPA to 1060 hPa

STORAGE AND SHIPPING CONDITIONS

Ambient Temperature: +10°C to +40°C	
Relative Humidity: 30% to 75% Non-Condensing	
Atmospheric Pressure:	500 hPA to 1060 hPa

PUMP - MECHANICAL SPECIFICATIONS

Dimensions:	11" L x 5" W x 3" H
Weight:	6 lbs.

PUMP - AGENCY APPROVALS

UL Listed	02HG
ANSI/AAMI ES60601-1	2005, 3rd Ed.
CAN/CSA C22.2 No. 60601-2	2008

Warranty

Unisoft Medical Corporation warranties the Unisoft Mattress, Pump, and Tube System for a period of **ONE YEAR** from date of purchase.

Unisoft Medical Corporation's standard warranty is extended to the original buyer purchasing the equipment directly from Unisoft Medical Corporation, or through an authorized dealer. All warranty periods, where applicable, commence on the date of purchase from Unisoft Medical Corporation or an authorized dealer.

Unisoft Medical Corporation's sole obligation and liability under this warranty is limited to repair or replacement by Unisoft Medical Corporation's authorized personnel of any parts or assemblies, which upon test and examination by Unisoft Medical Corporation, prove to be defective. The equipment may be returned prepaid to Unisoft Medical Corporation after notification has been given and approval obtained for return. An authorized return number will be provided. UNDER NO CIRCUMSTANCES WILL A RETURN BE ACCEPTED WITHOUT AN AUTHORIZED RETURN NUMBER.

This warranty does not cover normal maintenance such as cleaning, adjustment, and updating of equipment or parts thereof. This warranty will be null and void if the equipment, including any parts, is modified without Unisoft Medical Corporation's authorizations, is attempted to be repaired by personnel not authorized by Unisoft Medical Corporation, is not maintained in accordance with the prescribed schedule, is used with accessories or parts not authorized, or is damaged due to misuse, mishandling, abuse, negligence, accident, fire, or inadequate packaging by owner for shipment. Unisoft Medical Corporation makes no guarantee of clinical results.

The warranty stated above (including its limitations) is the only warranty made by Unisoft Medical Corporation and is in lieu of all other warranties, whether express or implied, including any warranty of merchantability or fitness for a particular purpose. Unisoft Medical Corporation will not liable for consequential or incidental damages of any kind.

Contact Us

Please call Unisoft Medical Corporation with any questions regarding the Unisoft One or its warranty.

Unisoft Medical Corporation

65 New Litchfield Street Torrington, CT 06790

860.482.6848 customerservice@unisoftmedical.com

Customer Service is available weekdays, 9AM-3PM.

PLEASE FILL OUT AND KEEP FOR YOUR RECORDS.

Mattress Serial No.:
Pump Serial No.:
Date of Purchase: / /
Seller:

REGISTER YOUR MATTRESS ONLINE AT WWW.UNISOFTONE.COM.

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Patent: www.unisoftmedical.com/patents