





## **Universal Therapy System**

(UTS)

Handset : HS-NBE

### **USER MANUAL**

Manufactured for:
Great Life Healthcare, Inc.
www.greatlifehealthcare.com



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#### 1. IMPORTANT SAFEGUARDS

When using electrical products, especially when children are present, basic safety precautions should always be followed, including the following:

——This device can be used in home healthcare and professional healthcare environment. ——

#### DANGER - READ ALL INSTRUCTIONS BEFORE USING THE APPLIANCE

#### **DANGER** – To reduce the risk of electrocution:

- 1. Always unplug this product immediately after use.
- 2. Do not use while bathing.
- 3. Do not place or store product where it can fall or be pulled into a tub or sink.
- 4. Do not place in, or drop into, water or other liquids, unless following specific manufacturers guidelines.
- 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. This product should never be left unattended when plugged into a power outlet.
- 2. Close supervision is necessary when this product is used by, on, or near children or physically challenged individuals.
- 3. Only use this product for its intended purpose, as described in this manual.
- 4. Never use attachments with this system that have not been recommended or approved by the manufacturer.
- 5. Never connect this product to a power supply or operate it if:
  - A. The system shows any signs of having a damaged cord or plug.
  - B. It does not appear to work properly or makes any abnormal noise.
  - C. The products have been dropped, damaged, or dropped into water.

Should any of the above be relevant, return the product to a service center for examination and repair.

- 6. Keep the electrical cord away from heated surfaces, open flames, liquids and sharp objects.
- 7. Never drop or insert any object into any openings.
- 8. Do not use outdoors, operate where aerosol (spray) products are being used, or where oxygen is being administered.
- 9. ALWAYS disconnect from power supply before opening up the mattress.
- 10. If pain, irritation, numbness, swelling, or redness occurs discontinue use and contact a healthcare professional.

### 2. The Purpose of this Manual

This operation manual is mainly focused on the set-up, cleaning and routine maintenance of the **Universal Therapy System (UTS)**. We recommend that you keep this manual in a safe location to help answer any questions that may arise relating to the system.

### 3. Product Description - Intended Use

The **Universal Therapy System (UTS)** is an alternating air replacement system designed to prevent and treat pressure ulcers. The **Universal Therapy System (UTS)** works on the principle of actively encouraging tissue blood flow by gently increasing and decreasing pressure within the support surface over a 10-minute cycle. This results in the reduction of surface pressures helping to prevent tissue breakdown and encourage healing.

Contraindications: Patient conditions for which the application of pressure therapy on the Universal Therapy System (UTS) systems. Contraindications include:

\*Instable spinal cord injury

\*Cervical traction

Intended Care Setting will be in Aged care and Home care.

Intended User Profile:

- At least fifteen years old
- Language understanding:
  - Read and understand 'Westernized Arabic' numerals when written in Arial font
  - Understands hygiene
- Experience Requirement: Have nursing facilities
- Permissible impairments: Except for contraindications

For added durability, and longer working life, the **Universal Therapy System (UTS)** has been constructed using high strength components and premium grade materials. The mattress features a heavy-duty base layer and a water resistant, multi-stretch vapor permeable PU cover to reduce risks of friction and shear.

### 4. General Safety

It is important to read the information in this user manual before you use your **Universal Therapy System (UTS)**.

Please follow the guidelines below for your safety and maintaining of system performance.

- Maximum patient weight is 350 lbs. and minimum user weight is 66 LBS.
- Avoid exposing pump to liquids.
- When cleaning do not use of Phenol based substances.
- This Universal Therapy System (UTS) must be used on top of a bed frame

### 5. SYSTEM CONTROL

### Item Description

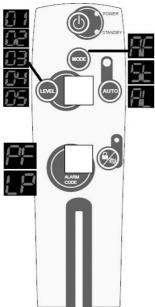
2

- 1 **POWER** Switch Power On (Green LED), Standby (Amber LED)
- comfort level according to patient's weight. **NOTE:** The "AUTO" detection mode will be disabled when comfort level is manually adjusted. Press "AUTO" again to re-activate the automatic weight detection when needed. It will detect around 10 minutes to achieve suggested comfort level based on patient's weight.

AUTO Weight Detection function – Enabled by pressing the "Auto" button and will self-adjust the

- MODE Cycle through Auto Firm (AF), Alternating (AL) and Static (ST) therapy modes by repeatedly pressing the "Mode" button the pump is set to alternating mode by default with "AL" display on LED window. UTS is programmed to default back to alternating mode after 30 minutes of usage. Auto Firm (AF)- Fast inflates the mattress to maximum pressure in static mode to perform nursing procedures. It is programmed to return to alternating mode after 30 minutes of usage by default. Alternating (AL) To inflate mattress in alternating mode

  Static (ST) To inflate the mattress to a static surface. The pump will default back to alternating mode after 30 minutes.
- 4 **LEVEL** Allows for manual adjustment, by repeatedly pressing "LEVEL" button to accommodate an individual's comfort if needed. Default manual setting will be the level detected during "Auto" mode, or at Level 02 if Auto detection is incomplete. Display of "LEVEL" will automatically go back to "MODE" when not in operation for 10 seconds.
- Alarm Codes Display Window "PF" stands for Power Failure, displayed in LED window with an audio alarm to indicate a power outage situation. "LP" stands for Low Pressure, where the system will alert user with a visual alarm displayed in LED display window, and an audible alarm triggered 5 minutes after visual alarm. (Check)
- 6 Lock/Unlock/ Alarm Mute Button Lock/Unlock button allows user to manually lock (3 seconds) /unlock (3 seconds) the control panel to safeguard against any undesired/accidental changes to the settings. Control panel will auto lock when system is not in operation for 5 minutes. Alarm Mute Press to mute the audio alarm. The alarm will re-activate after 20 minutes if the problem is not resolved. (Check)



### 6. **Installation Guide:**

- Place the Universal Therapy System (UTS) directly on to bed frame and ensure CPR valve is at the head end of the bed. Secure and check that the bed straps on the underside of mattress are fastened to the bed frame correctly (Check moving sections on the bed frame to make sure that they are not encumbered by the straps and can continue to operate normally).
- Hang the handset on the bed rail or mattress platform and plug the power cord into mains outlet. Ensure that electrical cables are safe, tidy, free of obstruction and are not able to be caught in the bed frame. The power LED will be at standby mode with amber light illuminating.
- CAUTION: it is important to routinely inspect power cable to ensure it is not obstructing or causing a tripping hazard. Check and make sure that the power cable is not under strain or damaged.
- 3. Ensure that the CPR valve is set to "CLOSE" position (Fig. 1).



Fig. 1 Turn the dial to **CLOSE** position to inflate air mattress.

- 4. Turn the power on from handset (Green LED will illuminate).
- 5. When the **Universal Therapy System (UTS)** is turned on, the pump will start to inflate the mattress for around 30 minutes in auto firm mode. During this inflation period, the "AF" LED will be displayed on LED window to indicate the mattress is not ready to use. When "AF" switches to "AL" with display on LED window, bed sheet can be added (NOT tucked under mattress, left to hang freely) and the patient can be placed and positioned on the mattress surface. The audible alarm is disabled during the inflation period and will resume its function when "AF" LED goes off.
- 6. Once the mattress is properly inflated, system will switch to alternating mode. Press "Auto" button to enable auto detection feature and the system will automatically set to an optimum pressure according to patient's weight.
  - The **Universal Therapy System (UTS)** also allows the caregiver the flexibility to disable "Auto" feature and switch to manual adjustment, by repeatedly pressing "LEVEL" button to accommodate an individual's comfort need. Default manual setting will be the level detected during "Auto" mode, or at Level 2 (02 displayed on LED window) if Auto detection is incomplete.

Please Note: "Auto Firm (AF)" and "STATIC (St)" mode is designed to return to "Alternating (AL)" mode after 30 minutes of activation.

This mattress features a Cardio Pulmonary Resuscitation (CPR) valve at **right side head end** of the patient.

In the event of an emergency, turn the CPR valves to the OPEN position for fast deflation the air mattress. (Fig. 2)



Fig. 2 Turn the dial to **OPEN** position to release air.

IMPORTANT: Please ensure that all care staff are trained and familiarized with the mattress and this function.

CAUTION: During power failure/outage, the Universal Therapy System (UTS) will stop functioning and PF (Power Failure) alarm codes will be displayed on LED window with audio alarm. The pump will return to its normal operation when power is resumed.

The design of the system does allow the safe support of a patient even in the case of a power failure and loss of air from within the mattress. Please do not use any other cables or accessories not approved by the manufacturer in this manual to avoid negative influence on electromagnetic compatibility

In the event of product failure, unless the mattress has been 'set' to operate as a standard, non-powered system, return the product to a service center for examination and repair as soon as possible.

**Attention:** If the airflow output varies unstably or stops erratically, it might be caused from EMC disturbance or unstable power socket. Be sure to use the device with a stable power supply or in connection with Uninterruptible Power Supplies and repress the power ON button to activate the air mattress system.

### 7. Maintenance & Troubleshooting

No daily maintenance is required. It is intended this equipment should only be serviced by qualified and authorized technical personnel. It is suggested that professional healthcare and caregivers to check patients' conditions and settings every two hours to prevent any emergency or misuse situation.

Fault/Problem Description	Troubleshooting	Solution
No indication that the pump is on.	Check <b>Universal Therapy System (UTS)</b> is connected to the mains power supply.	Check the power is switched on.
	Check for loose connection on plug and main power is switched on.	Secure plug connection and turn on power from main.
	Check if mains socket is faulty.	Try another socket.
Low pressure in mattress/mattress is not inflating.  Check Universal Therapy System (UTS) is connected to the mains power supply.		Ensure the main power is turned on and Universal Therapy System (UTS) is plugging into main.
	Check <b>Universal Therapy System (UTS)</b> air connections are fitted securely. Ensure airflow is coming out from pump.	Ensure connectors are securely fastened and reconnect pump air hoses if loose. Ensure pump is turned on.
	Check CPR valve is set to CLOSE position and is not leaking.	Ensure CPR valve is set to CLOSE position. Replace a new CPR valve if an air leak is found.
	Check the connector tubes for kinks, obstructions or damage.	Undo any kinks and obstructions.
	Check air intake from filter is not blocked by linen/dust.	Replace with new filter.
Pump Controls lock up 'freeze'.	Turn off and unplug Universal Therapy System (UTS)	Rest Universal Therapy System (UTS) for a few seconds and plug the back in to main and turn on the pump.

If problem is not resolved, please contact your sales representative for advice.

**CAUTION:** Please ensure the system is connected to a stable power or in connection with Uninterruptible Power Supplies.

### 8. Cleaning & Disinfection Protocol

It is very important to have a strict cross infection, cleaning and disinfection policy in line with current Hospital/Nursing Home infection control guidelines. A daily routine check should be carried out & the following steps should be taken:

- 1. Remove the bedding.
- 2. If necessary, inflate the mattress.
- 3. Ensure that the power unit is off.
- 4. Unplug the power cord from the wall outlet.
- 5. Unzip the top cover & check for signs of soiling or damage. Note, if signs of soiling on the underside of the top cover is present this means the cover is no longer water resistant & should be replaced immediately.
- 6. Check all areas of the inner cells & any inner covers or foam sections. Note, any signs of soiling on foam sections means the foam section must be replaced.
- 7. Ensure that the underside of the mattress is clear of all sharp objects.
- 8. Perform one of the following:
  - If blood is present, decontaminate the whole mattress product in line with current hospital or Nursing Home Guidelines.
  - If blood is not present, remove any soil from the cover with paper towels.

### NOTE: If grossly soiled, the cover should be removed, cleaned and decontaminated.

- 9. Using a clean sponge or paper towel, wipe down the cover surface and cells with a diluted detergent solution, recommended cleaner disinfectant or other germicidal detergent solution.
- 10. Cleaning and disinfection may be carried out on the cover with hand hot water and a neutral detergent or with a sodium hypochlorite solution (0.1% or 1000 parts per million available chlorine).
- 11. Alternatively remove the cover and launder, 95° C (203° F), using normal detergents. It is essential that articles be thoroughly dried after all cleaning procedures and before storage.
- 12. Perform the following steps to clean the power unit and hose fittings:
  - Open the system and expose the pump which is housed in the corner at the foot end of the mattress.
  - Wipe all controls, chassis and hose fittings with a damp cloth and a mild detergent.
  - Using a nylon brush, gently clean all crevices as they can harbor microorganisms.
  - Air dry all treated surfaces.

#### **WARNING:**

- Switch off the electrical supply to the pump and disconnect the power cable from the mains before cleaning and inspection.
- Protective clothing should be worn when performing cleaning procedures.
- Do not use Phenol based cleaning solutions.

All equipment should be inspected. Any item that is visibly soiled with the patient's blood or other body fluids should be properly cleaned or removed. It is recommended that the system is clean regularly and after each patient use.

In many cases it will be only be necessary to remove the mattress cover for cleaning. If there is obvious soiling a complete cleaning or decontamination will be required.

# 9. Specification

Model Name:	Universal Therapy System (UTS)		
Size in CM (L x W x H):	80" x 36" x 8" cm		
Weight of system:	33 lbs.		
Cycle Time (min):	10 min		
Max User weight	350 lbs.		
Minimum User Weight	66 lbs.		
Min/Max Pressure:	20 ~ 60 mmHg +/- 6mmHg		
Max Flow Rate:	≥6 L/min		
Rated Voltage:	AC115Vac / 60Hz		
Max Current:	0.2-0.1A		
Protection Type:	Class II Type BF		
Ingress of Water Protection:	IP22		
Mode of Operation:	Continuous		
Environment (Temperature)	Operation: 15°C to 35° C (59°F to 95°F)		
	Storage:5°C to 60°C (41°F to 140°F)		
Environment (Humidity)	Operation: 30% to 75% non-condensing		
	Storage: 30% to 90% non-condensing		
Operation Atmospheric Pressure Range	700 hPa to 1060 hPa		
Operation altitude	-1017 feet to 9,843 feet (-310 meters to 3000 meters)		
Test Standard:	IEC60601-1, IEC60601-1-2 and IEC60601-1-11		
Mattress Material	Top Cover: Two way stretch, PU laminated Nylon Base Cover: PVC laminated Polyester		
Packaging in CM (L x W x H):	67x 27 x 98CM		

### Accessories

Item	Model	Material
Handset	HS-NBE	ABS

### 10. EMC Related Notification

**Warning:** Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to the EMC information provided. Careful consideration of this information is essential when stacking or collocating equipment and when routing cables and accessories.

Warning: RF mobile communications equipment can affect medical electrical equipment.

Manufacturer's declaration-electromagnetic emissions						
The <u>Universal Therapy System (UTS)</u> is intended for use in the electromagnetic						
environment (for home and professional healthcare) specified below.						
The customer or the user of the <b>Universal Therapy System (UTS)</b> should assure that it is						
used in such an environme	ent.					
Emission test Compliance Electromagnetic environment-						
		guidance				
		(for home and professional				
		healthcare environment)				
RF emissions CISPR 11 Group 1		The <b>Universal Therapy System (UTS)</b>				
		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 <b>Universal Therapy System (UTS)</b>				
Harmonic emissions	Not applicable (120V)	is suitable for use in all				
IEC 61000-3-2	Class A (230V)	establishments, including domestic				
		establishments and those directly				
Voltage fluctuations	Not applicable (120V)	connected to the public low-voltage				
/flicker emissions IEC	Compliance (220V)	power supply network that supplies				
61000-3-3 Compliance (230V)		buildings used for domestic purposes.				

During test, the wired control box signal display flashed but could return to normal status after the test was not affected so there is no concern with the basic safety.

Please refer to Risk management Report for the detail.

### Manufacturer's declaration-electromagnetic immunity

The <u>Universal Therapy System (UTS)</u> is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the <u>Universal Therapy System (UTS)</u> should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home and professional healthcare environment)
Electrostatic discharge (ESD) IEC 61000-4-2 Electrical fast	Contact: ±8 kV Air±2 kV, ±4 kV, ±8 kV, ±15 kV  ± 2kV for power supply	Contact: ±8 kV Air±2 kV, ±4 kV, ±8 kV, ±15 kV  ± 2kV for power supply	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%  Mains power quality should
transient/burst IEC 61000-4-4	lines <u>+</u> 1kV for input/output lines	lines  Not applicable	be that of a typical home healthcare environment.
Surge IEC 61000-4- 5	<u>+</u> 0.5kV, <u>+</u> 1kV line(s) to line(s) <u>+</u> 0.5kV, <u>+</u> 1kV, <u>+</u> 2kV line(s) to earth	± 0.5kV, ±1kV line(s) to line(s)  Not applicable	Mains power quality should be that of a typical home healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips:  0 % UT; 0,5 cycle  0 % UT; 1 cycle  70 % UT; 25/30 cycles  Voltage interruptions:  0 % UT; 250/300 cycle	Voltage dips:  0 % UT; 0,5 cycle  0 % UT; 1 cycle  70 % UT; 25/30 cycles  Voltage interruptions:  0 % UT; 250/300 cycle	Mains power quality should be that of a typical home healthcare environment. If the user of the <u>Universal Therapy System (UTS)</u> requires continued operation during power mains interruptions, it is recommended that the <u>Universal Therapy System (UTS)</u> be powered from an uninterruptible power supply or a battery.
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz  mains voltage prior to app	30 A/m 50 Hz and 60 Hz	The <u>Universal Therapy</u> <u>System (UTS)</u> power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.

### Manufacturer's declaration-electromagnetic immunity

The <u>Universal Therapy System (UTS)</u> is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the <u>Universal Therapy System (UTS)</u> should assure that it is used in such and environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home and professional healthcare environment)
Conducted RF	3 Vrms:	3 Vrms:	Portable and mobile RF communications
IEC 61000-4-6	0,15 MHz – 80 MHz	0,15 MHz – 80 MHz	equipment should be used no closer to
	6 Vrms:	6 Vrms:	any part of the Universal Therapy System
	in ISM and amateur	in ISM and amateur	(UTS) including cables, than the
	radio bands between	radio bands between	recommended separation distance
	0,15 MHz and 80 MHz	0,15 MHz and 80 MHz	calculated from the equation applicable
			to the frequency of the transmitter.
	80 % AM at 1 kHz	80 % AM at 1 kHz	
Radiated RF	10 V/m	10 V/m	
IEC 61000-4-3	80 MHz – 2,7 GHz	80 MHz – 2,7 GHz	Recommended separation distance:
	80 % AM at 1 kHz	80 % AM at 1 kHz	d = 1,2 <i>VP</i>
			d = 1,2 <i>VP</i> 80MHz to 800 MHz
			d = 2,3 <i>VP</i> 800MHz to 2,7 GHz
			Where Ris the maximum output newer
			Where <i>P</i> is the maximum output power rating of the transmitter in watts (W)
			according to the transmitter
			manufacturer and <i>d</i> is the recommended
			separation distance in meters (m).
			separation distance in meters (m).
			Interference may occur in the vicinity of
			equipment marked with the following
			symbol:
			((,,))
			(( <b>な</b> ))
			. •

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

# Recommended separation distance between portable and mobile RF communications equipment and the Universal Therapy System (UTS)

The <u>Universal Therapy System (UTS)</u> is intended for use in an electromagnetic environment (for home and professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the <u>Universal Therapy System (UTS)</u> can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <u>Universal Therapy System (UTS)</u> as recommended below, according to the maximum output power of the communications equipment.

Rated maximum	Separation distance according to frequency of transmitter				
output power of	m				
transmitter	150 kHz to 80 MHz 80 MHz to 800 MHz		800 MHz to 2,7 GHz		
W	d =1,2√P	d =1,2√ <i>P</i>	d =2,3 <i>√P</i>		
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.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

### Manufacturer's declaration-electromagnetic immunity

### Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

<u>Universal Therapy System (UTS)</u> is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the <u>Universal Therapy System (UTS)</u> should assure that it is used in such an environment.

Test frequency (MHz)	Band <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	Maximum power (W)	<b>Distance</b> (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home and professional healthcare)
385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ②±5 kHz deviation 1 kHz sine	2	0,3	28	28
710		LTC D 1 4 2	Pulse				
745	704 – 787	LTE Band 13, 17	modulation b) 217 Hz	0,2	0,3	9	9
780							
810		GSM 800/900, TETRA 800, Pulse 200 – 960 iDEN 820, modulation b)		2	0,3	28	28
870	_800 – 960						
930		CDMA 850, LTE Band 5	18 Hz				
1 720		GSM 1800;		2	0,3	28	
1 845	1 700 -	CDMA 1900; GSM 1900;	Pulse modulation b)				28
1 970	1 990	DECT; LTE Band 1, 3, 4, 25; UMTS	217 Hz				
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240 5 500 5 785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9

NOTE If necessary, to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

- a) For some services, only the uplink frequencies are included.
- b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
- c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

During power outage, pump will stop functioning. It is suggested to be use with a stable power source or an uninterruptable power supply source. The pump will return to its normal operation when power is resumed.

### 11. Waste Disposal



This Product has been supplied from an environmentally aware manufacturer that complies with the WEEE.

This product may contain substances that could be harmful to the environment if disposed of in places (landfills) that are not appropriate according the legislation. Please be environmentally responsible and recycle this product through your recycling facility at its end of life.

### 12. Storage and Care

### Control unit (Air Pump) & Mattress:

- Check the power cord and plug for abrasions or excessive wear.
- Plug in the unit and verify air flows from the unit's hose connection ports.
- Ensure the system is clean and free from infection.
- Place in plastic bag for storage.

It is recommended the following guidelines are used whenever this system is being stored or transported another location:

Temperature limitations:  $5^{\circ}\text{C} (41^{\circ}\text{F}) \sim 60^{\circ}\text{C} (140^{\circ}\text{F})$ 

Relative Humidity 30% ~90%

### 13. Symbols Used

<b>†</b>	Type BF Protection Against Electronic Shock		Class II Equipment
Ţį	Operating Instructions	7	Waste Disposal
$\triangle$	Caution, Consult accompanying documents		Manufacturer

### 14. Expected Service Life

The **Universal Therapy System (UTS)** has an expected service life of 2 years. To maintain the condition of the pump, have the pump serviced regularly according to the schedule recommended by Comet. Do NOT use unapproved accessories or attempt to modify, disassemble or otherwise misuse the **Universal Therapy System (UTS)**.

### 15. Warranty

- Comet warrants this equipment to be free from defects in material and workmanship from the date of delivery.
- At manufacturers discretion we agree to service, repair or replace any equipment or part found to be defective at no charge.
- This warranty excludes equipment damaged through shipping, tampering, improper maintenance, carelessness, accident, negligence, misuse, or which has been altered, repaired or dismantled other than with the manufacture's written authorization, following its approved procedures and by properly qualified technicians.
- In no event shall Comet be liable for any direct, indirect or consequential damage or loss resulting from the use of equipment.

### 16. Disclaimer

WARNING: The use of side rails and other restraints can result in injury or death - through potential entrapment and potential patient falls. Please see MHRA Device Bulletin DB 2006(06) for details.

WARNING: Risk of electrical shock, serious injury or death. Only authorized technicians should open the pump unit for servicing and maintenance procedures. Electrical equipment can be extremely dangerous if damage or misused.

WARNING: Before any cleaning or disinfection procedure, ensure that the pump system is switched off and unplugged from the mains power supply.

### 17. Legal Disclaimer

- A. Terms such as 'Medium Risk', 'High Risk' and 'Very High Risk' are a description of a person's risk levels, these persons may be at danger of developing a pressure sore at the higher risk status level. These risk levels are assessed by nurses and as there is a variability between nurse measurements/observations. Descriptive risk levels should only be used as guideline for the risk assessment methods being used.
- B. Comet uses these factors and terms based on the existing market research and internal research to show the suitability and effectiveness of the pressure care systems provided. Internal and external research is and will always be ongoing. These risk factors should not be taken as prescriptive criteria.
- C. Comet support surfaces should be seen as an aid to care and DO NOT replace the need for good nursing care and intervention. All Comet products must be used as part of an individualized care plan which include proper nursing practices i.e. turning/re-positioning, and regular patient skin assessments.
- D. Pressure relieving equipment alone will not prevent pressure ulcers. Pressure ulcers are multi factorial and many external and internal factors cause them to develop. It is up to the professional judgement of the nurse to assess the risk and develop a care plan which prescribes suitable pressure reducing/relieving equipment and external care. Some pressure sores are inevitable due to falls and periods of immobility these sores can develop hours after the injury, in these instances a pressure ulcer can develop and Comet cannot guarantee the use of the equipment alone will prevent pressure ulcer formation.
- E. The mattress usage guidance within this user guide in relation to clinical guidance, should always be operated in accordance with best clinical practice outlined by the care giver.

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