Universal Therapy System

(UTS) Pad System

Handset：HS-NBE

USER MANUAL

Manufactured for:
Prius Healthcare USA
www.priushcusa.com

Contents

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) Pad System Pad System**. 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) Pad System** is an alternating air replacement system designed to prevent and treat pressure ulcers. The **Universal Therapy System (UTS) Pad System** 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) Pad System 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

4. General Safety

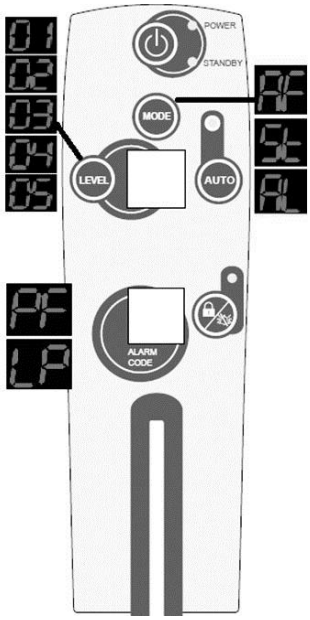
It is important to read the information in this user manual before you use your **Universal Therapy System (UTS) Pad System**.

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

- Maximum patient weight is 440 lbs (200Kg) for Long ver. and 220lbs for short ver. Sacrum area.
- Avoid exposing pump to liquids.
- When cleaning do not use of Phenol based substances.
- This **Universal Therapy System (UTS) Pad System** must be used on top of a bed frame

5. SYSTEM CONTROL

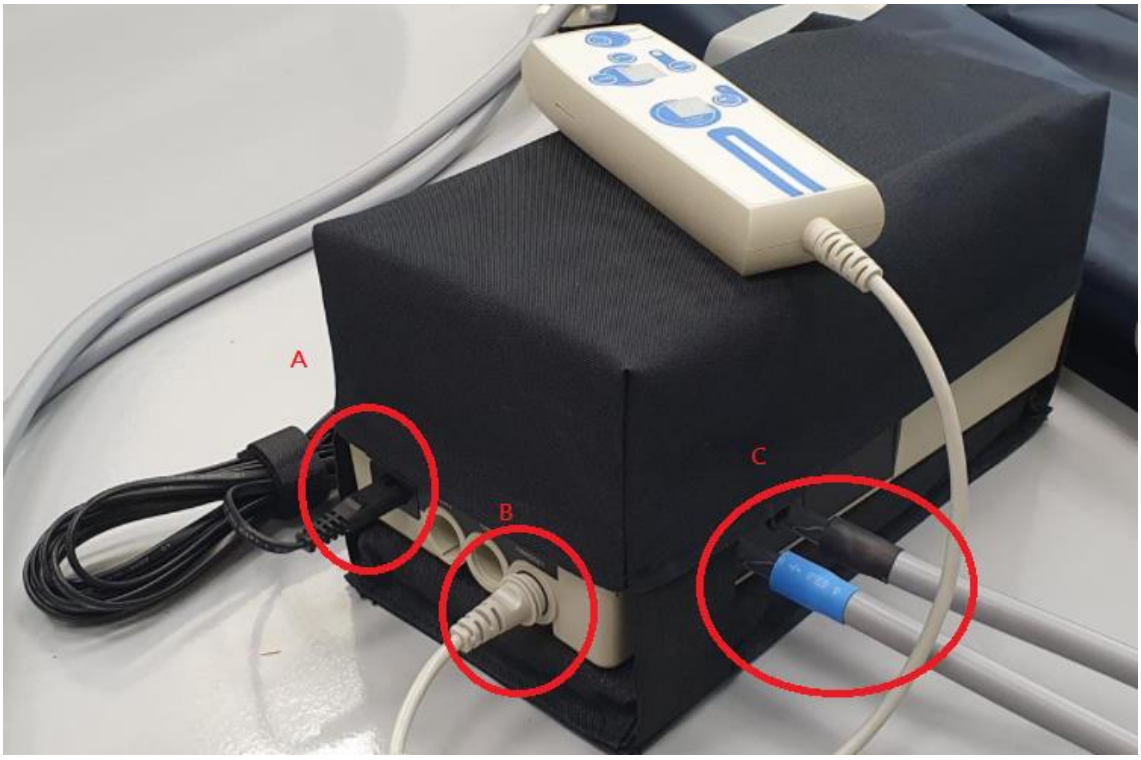
Item	Description
1	**POWER** Switch – Power On (Green LED), Standby (Amber LED)
2	**AUTO** Weight Detection function – Enabled by pressing the "Auto" button and will self-adjust the comfort level according to patient's weight. **NOTE:** The "AUTO" detection mode will be disabled when comfort level is 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.
3	**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.
5	**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:

1. Place the **Universal Therapy System (UTS) Pad** directly on bed frame and place control unit on the floor.
2. Insert control unit for long ver. Pad into Pump Cover (No cover for control unit for Short ver. Pad)

   Insert power cable into power outlet of control unit (“A” Location in below photo) and handset into location B. Then plug air hoses into side of control unit in “C” Location (Blue head hose on left hand side and black head hose on the right side)



3. Make sure control unit marked with orange dot on product label connects with short ver. of Pad. Control unit without orange dot marked connect with long ver. of Pad.

4. 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.

5. Turn the power on from handset (Green LED will illuminate).
6. When the **Universal Therapy System (UTS) Pad System** 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.
7. 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) Pad System** 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.

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) Pad System 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 **Universal Therapy System (UTS) Pad System** 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) Pad System** is connected to the mains power supply.	Ensure the main power is turned on and **Universal Therapy System (UTS) Pad System** is plugging into main.
	Check **Universal Therapy System (UTS) Pad System** 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 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) Pad System**	Rest **Universal Therapy System (UTS) Pad System** 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. 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.
6. Ensure that the underside of the mattress is clear of all sharp objects.
7. 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.

8. 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.
9. 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).
10. 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.

9. Specification

Model Name:	**Universal Therapy System (UTS) Pad System**
Size in CM (L x W x H):	80” x 35” x 8” (Long ver.)
	80” x 28” x 8” (Long ver.)
	40” x 35” x 8” (Short ver., Sacrum area)
	40” x 28” x 8” (Short ver., Sacrum area)
Cycle Time (min):	10 min
Max User weight	440 lbs. for Long ver. and 220 lbs for Short ver..
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

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.

<table>
<tr><th colspan="3">Manufacturer's declaration-electromagnetic emissions</th></tr>
<tr><td colspan="3">The <u>Universal Therapy System (UTS) Pad System</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) Pad System</u> should assure that it is used in such an environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment-guidance
(for home and professional healthcare environment)</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The <u>Universal Therapy System (UTS) Pad System</u> 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.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class B</td><td rowspan="3">The <u>Universal Therapy System (UTS) Pad System</u> 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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Not applicable (120V)
Class A (230V)</td></tr>
<tr><td>Voltage fluctuations /flicker emissions IEC 61000-3-3</td><td>Not applicable (120V)
Compliance (230V)</td></tr>
</table>

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 Universal Therapy System (UTS) Pad System is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the Universal Therapy System (UTS) Pad System 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	Contact: ±8 kV Air±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact: ±8 kV Air±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines Not applicable	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	± 0.5kV, ±1kV line(s) to line(s) ± 0.5kV, ±1kV, ± 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 % *U*T; 0,5 cycle 0 % *U*T; 1 cycle 70 % *U*T; 25/30 cycles Voltage interruptions: 0 % *U*T; 250/300 cycle	Voltage dips: 0 % *U*T; 0,5 cycle 0 % *U*T; 1 cycle 70 % *U*T; 25/30 cycles Voltage interruptions: 0 % *U*T; 250/300 cycle	Mains power quality should be that of a typical home healthcare environment. If the user of the Universal Therapy System (UTS) Pad System requires continued operation during power mains interruptions, it is recommended that the Universal Therapy System (UTS) Pad System 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	30 A/m 50 Hz and 60 Hz	The Universal Therapy System (UTS) Pad System power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Manufacturer's declaration-electromagnetic immunity			
The Universal Therapy System (UTS) Pad System is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the Universal Therapy System (UTS) Pad System 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 IEC 61000-4-6	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	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	**Portable and mobile RF communications equipment should be used no closer to any part of the** Universal Therapy System (UTS) Pad System including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	**Recommended separation distance:** d = 1,2 $\sqrt{P}$ d = 1,2 $\sqrt{P}$ 80MHz to 800 MHz d = 2,3 $\sqrt{P}$ 800MHz to 2,7 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). Interference may occur in the vicinity of equipment marked with the following symbol: 
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) Pad System

The Universal Therapy System (UTS) Pad System 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 Universal Therapy System (UTS) Pad System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Universal Therapy System (UTS) Pad System 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 =1,2$\sqrt{P}$	**80 MHz to 800 MHz** d =1,2$\sqrt{P}$	**800 MHz to 2,7 GHz** d =2,3$\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

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

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

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

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

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Distance** (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) ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
1 845							
1 970							
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	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5 500							
5 785							

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°C (41°F) ~ 60°C (140°F)
Relative Humidity 30% ~90%

13. Symbols Used

	Type BF Protection Against Electronic Shock		Class II Equipment
	Operating Instructions		Waste Disposal
	Caution, Consult accompanying documents		Manufacturer

14. Expected Service Life

The **Universal Therapy System (UTS) Pad System** 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 Prius Healthcare USA. Do NOT use unapproved accessories or attempt to modify, disassemble or otherwise misuse the **Universal Therapy System (UTS) Pad System**.

15. Warranty

- Prius Healthcare USA 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 Prius 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. Prius Healthcare USA 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. Prius Healthcare USA support surfaces should be seen as an aid to care and DO NOT replace the need for good nursing care and intervention. All Prius 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 Prius 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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UTS™
Universal Therapy System