

Duet

LAL Alternating Anti-Decubitus System



User Manual

Manufactured by: Prius Healthcare USA 160 Scarlet Blvd Oldsmar, FL 34677

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Warning

- Connect the Master Control unit to a proper power source.
- Don't use the system in the presence of any flammable gases.
 (such as Anesthetic Agents)
- ✤ Keep the pump and mattress away from open flame.
- Keep sharp objects away from the mattress.
- The device is not AP/APG protected.
- Do not place a heating device on or close to the mattress system.

\triangle Caution

- The Alternating System should always be used in accordance with your Institutions pressure care guidelines.
- Re-positioning of the patient is always recommended when using an alternating pressure air mattress (APAM).
- ✤ The Control unit can only be repaired by an authorized technician.
- Do not drop the control unit.
- ✤ Do not store the system in direct sunlight or extreme cold conditions
- ◆ Operation Temp: 15-35°C (59-95°F) R.H. : 30-75 %

1. The Purpose of this Manual

This operation manual is mainly focused on the set up, cleaning and routine maintenance of the *Duet LAL Alternating Anti-Decubitus System*. We recommend you keeping this manual handy to answer most of the question related to the system and please read the whole manual before setting up.

2. Product Description

The *Duet LAL Alternating Anti-Decubitus System* is a unique and innovative specialty mattress replacement unit. The system utilizes true low air loss technology with a high flow rate that provides pressure management for the treatment of pressure ulcers. It features continuous lateral rotation therapy in 40 degree, which gently turns the patient from side to side to significantly lower the risk of infection, pneumonia and other pulmonary complications – illnesses that significantly ad to patient care costs and length of stay.

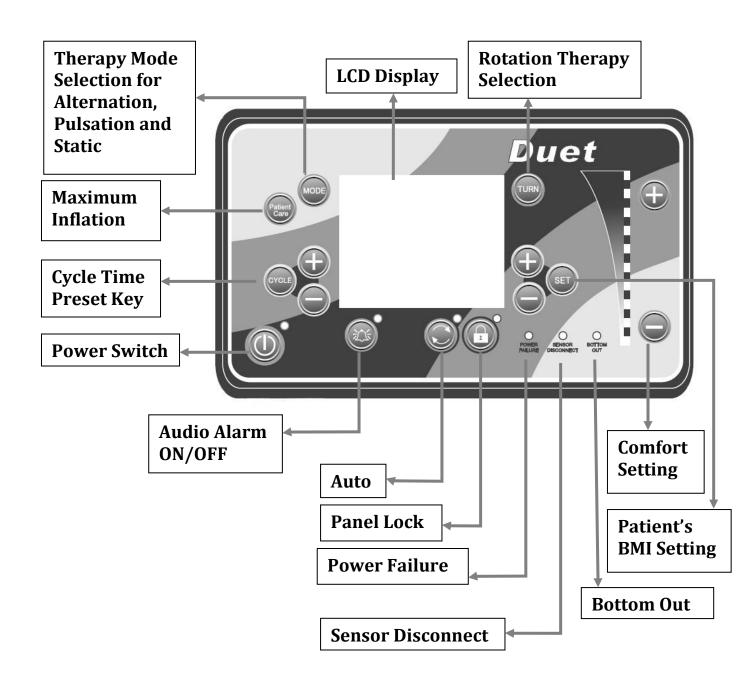
<u>The Duet Features</u>

- User-friendly controls
- Large LCD display on each function status
- Rapid CPR deflation
- Patient Care mode provides quick maximum inflation within seconds to help transfers and nursing procedures
- Incorporate sensor technology with Auto mode to constantly monitoring the mattress pressure based on inputting patient's height and weight
- Lock out function avoids tampering with settings
- Fowler mode gives added support to help prevent bottoming out while patient is in sitting position
- Highly vapor permeable and oversized pliable quilted nylon top cover providing low shear, friction and moisture protection
- Low Air Loss, Pulsation, Alternation, Static and Lateral Rotation for outstanding pressure redistribution outcomes
- 2" convoluted foam base for addition safety support Recommended maximum safe working load as following:

>36": 350lbs
>42": 500lbs
>48": 600lbs

Intended Users

- Healthcare professionals or caregivers who are at least fifteen years in age, with the ability to read and understand English and Westernized Arabic Numerals.
- This device should not be operated by patients.



▲ `aution

Alternating pressure therapy is not recommended to patient who has serious pain or pain-sensitive symptom. In this case, we recommend the application of foam mattress which can be found in **MOXI ENTERPRISES, LLC** product range.

			AA JUDD MODE TURN MIN.				
			LCD Displa	y introduction	<u> </u>		
	LOCK		STATIC	FULL	FULL TURN		ALTERNATION CYCLE TIME
A))	MUTE	AA	PULSATION	LEFT	LEFT TURN		TURNING CYCLE TIME
~	FOWLER		ALTERNATION	RIGHT	RIGHT TURN		HEIGHT
()	AUTO		PATIENT CARE	REST	NO TURNING FUNCTION	888 lb kg	WEIGHT
	BOTTOM OUT						

3. Technical Data

Master Control Unit

Model No.	FC-MOX0027		
Model Name	Duet		
Size (inch) LxWxH	12.2" x 6.7" x 13.2"		
Weight	14.3lbs		
Cycle Time (min)	3 - 95		
Min Operating Pressure	8 +/- 5mmHg		
Max Operating Pressure	33 +/- 5mmHg		
Rated Voltage	AC 110-120V		
Max Current	5 Amp		
Fuse Rating	T5AH 250V		
Rated Frequency	60 Hz		
Classification	Class I, Type BF Not AP/APG type		
Mode of Operation	Continuous		
Environment	Operation: 15°C to 35°C (59°F to 95°F)		
(Temperature)	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			
	IEC 60601-1,		
Standard	CAN/CSA C22.2 No. 60601-1,		
	IEC 60601-1-2		

Mattress Replacement

	FM-MOX0009(36")	
Model No	FM-MOX0044(42")	
	FM-MOX0045(48")	
	36"(W)x80"(L)x10"(H)	
Size (inch)	42" (W)x80"(L)x10"(H)	
	48" (W)x80"(L)x10"(H)	
Weight (lbs)	39.6	
Cells Number	18 cells	
Cells Material	Nylon coated with PU	
Cover Material	Nylon woven fabric w/ PU coating finish	
Base Material	Woven Polyester fabric w/ PVC backing	

i	Refer to Accompanying Documents	
X	Waste Disposal	
Ŕ	Type BF Applied Part	
\sim	Alternating Current	
\triangle	Caution	
Ť	Keep Dry	
	Manufacturer	

4. Operation Instruction

1. Power On/Stand-By



Plug the power cord to the socket and switch on the power at control panel, the orange LED will illuminate, it means Stand-By. Press the button Power On/Stand-By button, the LED light will turn to green, and the control unit will start to operate.

2. Mode Selection

Under normal operating, press mode button switches to select therapies. Each mode needs manually switch. Please must have healthcare professionals or caregivers to check the setting every two hours.

2.1 Static Mode



The system will only provide low air loss therapy.

2.2 Alternate Mode



The system will provide 3-1 alternation. Press "CYCLE" button and adjust the alternation cycle time by pressing the +/- button. The cycle can be set from 3 to 95 minutes.

2.3 Pulsation Mode

The system will provide pulsation pressure-relieving therapy.



3. Patient Care

- 3.1 Patient Care provides quick maximum inflation within seconds to help transfers and nursing procedures.
- 3.2 Press the Patient Care button for fast inflation.



- 3.3 When the mattress is fully inflated, the caregiver can transfer the patient onto the mattress.
- 3.4 Press Patient Care button again to return previous setting.
- 3.5 When Patient Care function is activated for over 30 minutes, the system will default back to previous setting automatically.

4. Turning Function

- 4.1 Press the TURN button to select from LEFT/RIGHT/FULL TURN to enable rotation pressure-relieving therapy.
- 4.2 Press CYCLE button to set for rotation cycle time from 3 to 95 minutes and hold postion "Hd".



4.3 Hold function is only engaged in Left and Right Turn

5. Auto Function



- 5.1 When Auto Function is activated, control unit is automatically optimizing patient's comfort setting base on patient's BMI input. The BMI setting is the guideline and the proper adjustment of the pressure level will be applied according to individual patient.
- 5.2 Press SET button, when both the height and weight indication flash, press +/- to adjust the metric or imperial unit.

- 5.3 Press SET button, when the height indication flash, press +/- to adjust the height of the patient.
- 5.4 Press SET button, when the weight indication flash, press +/- to adjust the weight of the patient.
- 5.5 Press SET to exit menu when finish.

6. Alarm On/Off



Press Alarm on/off to switch on/off the audio alarm

7. Lock Button



When th pump has been activated, the pump will automatically lock on after 2 minutes no operation, and press the lock On/Off button for 3 seconds to unlock.

8. CPR



The air hose connectors can be disconnected from the controller to quick release the air when in an emergency situation where CPR is to be performed.

9. Fowler mode



While the patient is in sitting position over 30 degrees, the fowler mode will be activated automatically.

10. Comfort Level Setting

Press the +/- to adjust the comfort level. The following steps are the suggested pressure level settings when the mattress in alternation mode only.

- Make sure the mattress already fully inflated and connected to the control unit.
- With the patient on the bed, healthcare professionals or caregivers press the SET button to set auto detect function finding the best matching level based on the user weight and height.
- Suggested comfort level can be adjusted according to patients' requirements with no less or more than 2 levels based on the auto detected level setting.
- Suggested weight for 36" mattress is no more than 350 lbs; 42" mattress is no more than 500 lbs and 48" mattress is no more than 600 lbs.
- Suggeseted cycle time is no more than 15 minutes

Please be aware that once patients have any uncomfortable feelings or symptoms, patients must notify healthcare professionals or caregivers to change product settings suit for patients' condition.

5. Cleaning

<u>The Mattress</u>

The mattress should be cleaned on the bed weekly using a damp soft cloth and mild detergent. If top cover or base cover becomes grossly soiled, put on clean gloves, plastic gown and eye protection before removing top and base covers and disposing according to standard hospital procedures for contaminated waste and replace with clean covers. The mattress should check and clean each time before use or once a week.

Covers can be washed and thermally disinfected in a washing machine by following below procedure: **(Never use phenol based cleaning solutions)**.

Industrial	Break washes Main washes Main washes Extraction Cold Rinses	Cold 60°C (140°F) 70°C (158°F)	10 minutes 6 minutes 10 minutes 2 minutes
Domestic	Extraction Pre-wash	Cold	5 minutes
Domestic	Main Wash	70°C (158°F)	10 minutes
	Extraction Cold Rinses	/0.0(1501)	2 minutes
	Extraction		5 minutes

Tumble Drying or Tunnel Drying is not recommended.

Mattress Cells can be wiped over with a solution of sodium hypochlorite1000ppm or any other non-phenolic germicidal solution.

<u>The Master Control Unit</u>

▲ Caution

SWITCH OFF THE ELECTRICAL SUPPLY TO THE PUMP AND DISCONNECT THE POWER CORD FROM THE MAIN SUPPLY BEFORE CLEANING AND INSPECTION

The pump unit should also be cleaned weekly using a damp soft cloth and mild detergent.

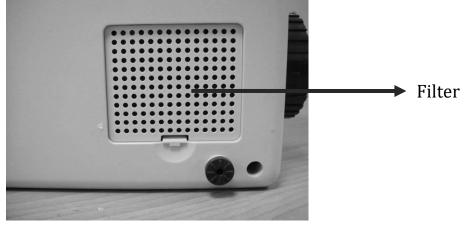
The pump casing is manufactured from ABS plastic and if the case is soiled the pump can be wiped down with a sodium hypochlorite solution to dilution of 1000ppm or any EPA- approved hospital grade disinfectant. **(Do not use phenol based cleaning solution)**.

The air filter should also be cleaned and checked as often as possible at a minimum of every six months. Air Filter can be removed by pinching center of the filter and pulling outward from the back of the control unit.

<u>Replace Air Filter</u>

1. Remove air filter and replace with a new one.

2.Use a soft bristle to remove dust and difficult dried-on soil.



NOTE:

- 1. Do not use phenol based cleaning solutions.
- 2. Switch off the electrical supply to the pump and disconnect the power cord from the main supply before cleaning and inspection)

Waste Disposal

This Product has been supplied by an environmentally conscious manufacturer that complies with the WEEE. This product may contain substances that could be harmful to the environment if disposed of in places that are not approved by your state, local or federal laws. Please be environmentally responsible and recycle this product through your recycling facility at its end of life.



6. Storage and Care

Master Control Unit:

- Check the power cord and plug for abrasions or excessive wear.
- Plug in the unit and verify air flows from the units hose connection ports.
- Place in plastic bag for storage.

Mattress:

- Check the air manifold for kinks or breaks. Replace if necessary.
- Twist the CPR plug at the head of the mattress and disconnect the air feed tubes. All the air will now be expelled. Starting at the head end, the mattress can now be rolled. Use the base mounted straps for containment.
- Place in plastic bag of storage.

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

Temperature limitations:	5°C ~ 60°C
Relative Humidity:	30% to 90%

7. Maintenance & Troubleshooting

No daily maintenance is required. It is intended this equipment should only be serviced by properly qualified, authorized technical personnel. In case of minor trouble please refer as following Troubleshooting.

Symptom	Inspection Procedures	Possible Solution
Air is pumping out from the control unit but mattress is not inflating.	 Is the power source correct? Improper voltage may cause the pump to function abnormally and damage the control unit. Is there any kinking tube? Is there any air leakage from air cells? Is there any air leakage from air tube between mattress and control unit? Has the air tube connector been connected properly? 	 Use power regulator Adjust the air tubes to enable smooth air flow. Replace with new air cells. Replace with new air tubes. Re-connect the air tubes.
		6. Refer to service if problem persist.
The control unit is not functioning	 Check the power cord and the power voltage Check the fuse. 	 Use a power regulator. Replace with a new fuse
		3. Refer to service if problem persist.
Some of the air cells are not properly inflated.	 Is the connection between air cells and the manifold kinked? Is there any air leakage from the air cells? 	 Check for any kinking between air cells and manifold. Replace new air cell if faulty. Refer to service if problem persist.
Sensor Disconnect	1. Check the sensor pad to see if the sensor pad connect properly?	 Connect the sensor pad to the properly
	2. Check the sensor pad to see if there is any damage or broken on the sensor	2. Replace a new sensor pad
	pad.	3. Refer to service if problem persist.
Bottom Out	 Check the tubing to see if the mattress connect with the pump propoerly? Check the hardness of the mattress to see if the mattress is too soft? Check the sensor pad to see if there is any damage or broken on the sensor pad. 	 Connect the tubing to the pump properly. Adjust the pressure setting or replace a new mattress. Replace a new sensor pad. Refer to service if problem persist.

8. EMC Related Notifications

Guidance and manufacturer's declaration – electromagnetic emissions				
The Duet control unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Duet control unit should assure that it is used in such an environment.				
Emissions test	Compliance	Electromagnetic environment – guidance		
RF emissions CISPR 11	Group 1	The Duet control unit 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 Duet control unit is suitable for use in all establishments, including domestic		
Harmonic emissions IEC 61000-3-2	Class A	establishments and those directly connected to the public low-voltage power supply network		
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	 that supplies buildings used for domestic purposes. 		

Recommended separation distances between portable and mobile RF communications equipment and the Duet control unit

The Duet control unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Duet control unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Duet control unit as recommended below, according to the maximum output power of the communications equipment.

Rated maximum	Separation distance according to frequency of transmitter m			
output power of transmitter W	150 kHz to 80 MHz $d = 1, 2 \sqrt{P}$	80 MHz to 800 MHz $d = 1, 2\sqrt{P}$	800 MHz to 2,5 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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration - electromagnetic immunity

The Duet control unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Duet control unit should assure that it is used in such an environment.

customer or the user of the Duet control unit should assure that it is used in such an environment.				
Immunity test	IEC 60601	Compliance level	Electromagnetic environment –	
	test level		guidance	
Electrostatic	± 6 kV contact	± 6 kV contact	Floors should be wood, concrete or	
discharge (ESD)	± 8 kV air	± 8 kV air	ceramic tile. If floors are covered with	
IEC 61000-4-2			synthetic material, the relative humidity should be at least 30 %.	
Electrical fast	± 2 kV for power	± 2 kV for power	Mains power quality should be that of	
transient/burst	supply lines	supply lines	a typical commercial or hospital	
ti ansient, bui st	supply mes	supply lifes	environment.	
IEC 61000-4-4	±1 kV for	± 1 kV for		
	input/output	input/output		
	lines	lines		
Surge	± 1 kV line(s) to	± 1 kV line(s) to	Mains power quality should be that of	
IEC 61000-4-5	line(s)	line(s)	a typical commercial or hospital	
			environment.	
	± 2 kV line(s) to	±2 kV line(s) to		
	earth	earth		
interruptions	<5 % <i>U</i> T	<5 % <i>U</i> T	Mains power quality should be that of	
and	(>95 % dip in <i>U</i> T)	(>95 % dip in <i>U</i> T)	a typical commercial or hospital environment. If the user of the Duet	
voltage variations	for 0,5 cycle	for 0,5 cycle	control unit requires continued	
on power			operation during power	
supply	40 % <i>U</i> T	40 % <i>U</i> T	mains interruptions, it is	
input lines	(60 % dip in <i>U</i> T)	(60 % dip in <i>U</i> T)	recommended that the Duet control	
I	for 5 cycles	for 5 cycles	unit be powered from an	
IEC 61000-4-11	70 % <i>U</i> T	70 % <i>U</i> T	uninterruptible power supply or a battery.	
	(30 % dip in <i>U</i> T)	(30 % dip in <i>U</i> T)	Dattery.	
	for 25 cycles	for 25 cycles		
	<5 % <i>U</i> T	<5 % <i>U</i> T		
	(>95 % dip in <i>U</i> T)	(>95 % dip in <i>U</i> T)		
	for 5 sec	for 5 sec		
Power			Power frequency magnetic fields	
frequency	3 A/m	3 A/m	should be at levels characteristic of a	
(50/60 Hz)			typical location in a typical	
magnetic field			commercial or hospital environment.	
IEC 61000-4-8				
NOTE <i>U</i> T is the a.c. mains voltage prior to application of the test level.				
NOTE OT IS the a.c. mains voltage prior to application of the test level.				

Guidance and manufacturer's declaration – electromagnetic immunity

The Duet control unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Duet control unit is responsible for making sure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Duet control unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF	3 Vrms 150 kHz to 80		Recommended separation distance
IEC 61000- 4-6	MHz	3 Vrms	$d = 1,2 \sqrt{P}$
Radiated RF IEC 61000- 4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,2 \sqrt{P} 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,3 \sqrt{P} 800 \text{ MHz to } 2,5 \text{ GHz}$
			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 metres (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b
			Interference may occur in the vicinity of equipment marked with the following symbol:
			$((\bullet))$

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Duet control unit is used exceeds the applicable RF compliance level above, the Duet control unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Duet control unit.

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

9. Expected Service Life

The Duet control unit has an expected service life of five 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 *Duet LAL Alternating Anti-Decubitus System*.

10. Warranty

- Prius Healthcare USA guarantees that this equipment is free from defects in material and workmanship. Our obligation under this warranty is limited to the repair of equipment returned to the service address given below, transportation charges prepaid, within 12 months after delivery to the original purchaser for all equipment.
- We agree to service and/or adjust any equipment returned for that purpose and to replace or repair any part, which is proven to be defective at no charge.
- This warranty excludes equipment damage through shipping, tampering, improper maintenance, careless, accident, negligence or misuse, or products which have been altered, repaired or dismantled other than with the manufacture's written authorization and by its approved procedures and by properly qualified technicians.
- In no event shall Prius Healthcare USA Products be liable for any direct, indirect of consequential damages or losses resulting from the use of equipment.



Prius Healthcare USA

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