(DynaLaL III)

User Manual

Dynamic True Low Air Loss Mattress Replacement System

Alternating +
True Low Air Loss Pressure Relief System

Manufactured by: Caremed Supply, Inc.
Distributed by: Quart Healthcare Inc.
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Toronto, ON
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WARNING

- Connect the Master Control unit to a proper power source
- Do not use the system in the presence of any flammable gases (such as Anesthetic Agents)
- Keep the pump and mattress away from sources of liquid and open flames
- Keep mattress away from sharp objects
- The device is not AP/APG protected
- Keep mattress system away from heating devices
- No modification of this equipment is allowed

CAUTION

- Consult a clinical professional before use of mattress
- Support surfaces should always be used in conjunction with a care plan that includes the turning/repositioning of the patient over a 24 hour period
- The control unit should only be repaired by an authorized vendor/distributor
- Do not drop the control unit and avoid direct sunlight or extreme cold conditions
- Operation Temp: 5℃ ~ 35℃, Relative Humidity: 30% ~75 %
- During operations, cellular devices with output power over 2W shall be kept at least 3.3 meters away

Contraindications

- The system should not be applied to patients suffering from polytrauma with fractures of spine, pelvis, extremities and skull. Patients with neurological impairments and missing body perception should require a physician's prescription. Alternating pressure should not be applied to patients that are experiencing pain or pain sensitive patients. In these cases we recommend the application of static mode or other suitable foam overlays or other materials which can be found in the Quart Healthcare product range

- People who may be allergic to any materials/substances used for the mattress and cells should not be positioned on the mattress.

Intended Use

The DynaLaL Ⅲ system is a unique and innovative specialized 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. The advanced 3:1 alternating function also provides an active prevention for pressure relief, especially for those in acute care and long term care settings (the cells inflate and deflate in a 3:1 cycle, meaning 2/3rds of the body is always supported at any given time). The soft to firm adjustment allows the patient to adjust the firmness or softness of the surface for optimal comfort. The surface also includes a 2 inch enclosed convoluted foam to provide extra protection and comfort for the patient in case of power failure and or in the case of mattress deflation.

Control Unit Features (Blower)

- There are 8 digital pressure settings for individual preferences. The control unit is set to default at P4 (150lb) setting per initial power-up. The control unit also includes a memory function. Starting from the 2nd power-up, control unit will resume to the previous pressure setting before it was turned off.
- The control unit has three therapy modes to chose from:
  (1) ALTERNATION - allows the system to operate 3:1 alternating function, with selectable cycle time setting from 5, 10, 15 or 20 minutes.
  (2) STATIC - stopping the alternating functions, providing only true low-air-loss therapy.
  (3) PULSATION - pressure in the cells will pulsate in an alternating 3: 1 pattern without complete offload.
- MAX function: Max inflation provides a uniform firmness for nursing procedures. Uniformed firmness will last for 30 minutes; after 30 minutes, control unit will resume to its previous therapy mode and pressure setting.
- FOWLER function: When Fowler is selected, system's pressure and firmness will increase to support patient at chair position, preventing patient bottom-out. Fowler mode will last for 30 minutes, after 30 minutes the pump will resume to its previous therapy mode and pressure setting.
- AUTO function: DynaLaL III system is equipped with an auto-sensor technology. Plug in the sensor cable to air outlet and activate Auto mode. Under Auto mode, system is able to detect when/if the patient leaves the bed, system bottom out, and activate Fowler upon detection of bed head section's angular change over 30 degrees.
- BARI function: DynaLaL III system can used with different bariatric size mattresses. When bariatric size mattress is used, set the control unit at BARI mode for appropriate pressure setting.

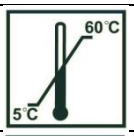
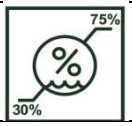
Master Control Unit

Model No.	DynaLaL Ⅲ
Part No.	FC-QHI0003
Size (cm)	28.5(L)x19.5 (W)x33.5(H)
Weight (Kg)	5 Kg
Cycle Time (min)	5, 10, 15, 20 minutes.
Min/Max Pressure	10-45 mmHg +/- 6mmHg
Max Flow-rate	1200 liter per minute
Rated Voltage	AC 110-120V
Rated Frequency	60 Hz
Fuse Rating	T5AH / 250V
Current	5A max.
Classification	Class I, Type BF Not AP or AGP Type 
Classification to Health Canada	Class 2
Mode of Operation	Continuous

Mattress Features

Model No	FM-QHI0014
Size (cm)	89(W)x203(L)x24(H)
Weight (Kg)	21 Kg
Cells Material	Pure PU
Cover Material	Nylon fabric w/ PU coating finish, quilting included
Base Material	Polyester fabric w/ PVC coating
Number of Cells	18 cells

Symbols Used

	Refer to Accompanying Documents
	Type BF Applied Part
	Waste Disposal
	Warning
	Alternating Current
	Temperature Limitation
	Humidity Limitation

1. Instructions for Proper Use

i) Remove the existing mattress from the bed frame
ii) Replace the standard mattress with the DynaLaL III mattress replacement system (arrange the mattress so that the air tube is at the foot of the bed)
iii) Secure straps beneath the mattress to the bed frame
iv) Hang the control unit on the foot board of the bed frame
v) Attach the air tube connectors and sensor cable to the socket on the left hand side of the control unit panel
vi) Ensure air hoses are not kinked under the mattress
vii) Attach cover to mattress
viii) Plug in the control unit (the STANDBY LED will illuminate)
ix) Press the STANDBY/OPERATE button on the front panel (OPERATE LED will now be illuminated and the control unit will be in operation)
x) Pressing the MAX button will activate quick inflation; allow 4-7 minutes for full inflation.

xi) After the mattress is fully inflated, the caregiver can transfer patient to the mattress (note: the mattress can also be inflated while a patient is laying on it). Press MAX again to release the fast inflation mode.

xii) Chose the appropriate therapy mode and adjust the system's pressure setting; Alternate mode can select cycle time between 5, 10, 15 or 20 minutes.

xiii) The control unit includes a memory function, and will default to previous setting when powered on.

Static Function:

Press the STATIC button and adjust the comfort setting by pressing the +/- buttons to achieve maximum patient comfort. In STATIC mode the system provides only true low air loss therapy. Perform a hand check by placing hand under the patient's buttocks between the cells and foam. The patient should have at least 4 cm of clearance between the buttocks and the bottom of the mattress.

Alternate Function:

Press the ALTERNATE button to enable 3:1 alternating function.

Pulsation Function:

Press the PULSE button to enable pulsation function.

Lock-out Function:

When lock-out function activates, buttons on the control panel will be non-functional; press and hold the LOCK button for 3 seconds to activate or deactivate lock-out function.

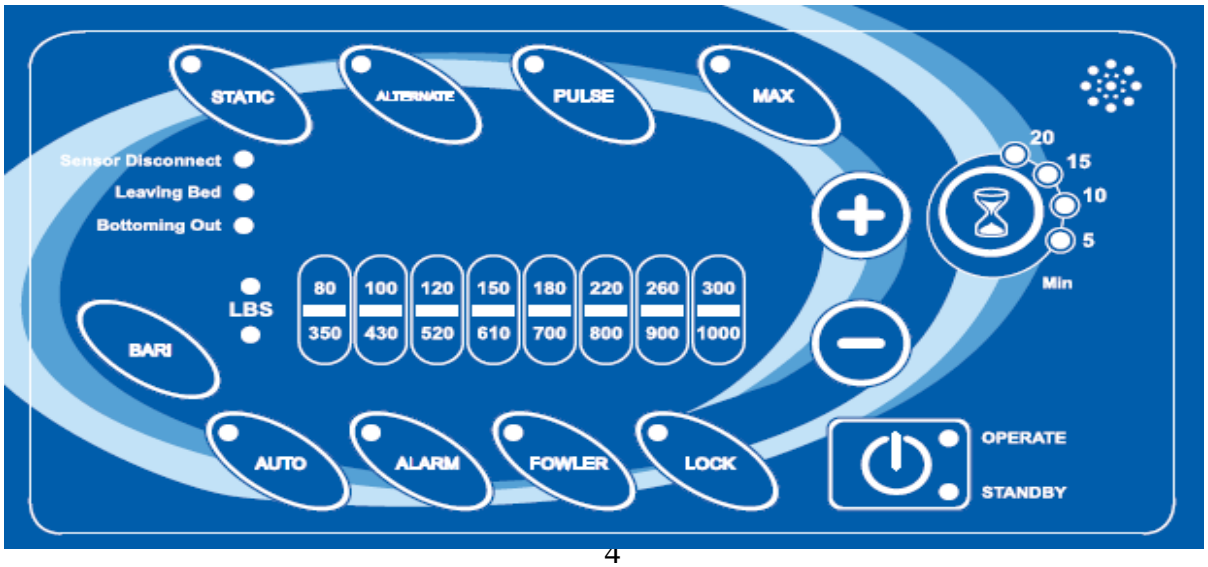
Fowler Function:

Press FOWLER button to enable fowler function.

Auto Function:

When sensor cable is connected to the pump, AUTO mode will activate automatically. Under AUTO mode, system will detect leave-bed, bottom out and fowler.

<u>Illustration of Control Panel</u>



2. Cleaning

Mattress

The mattress should be cleaned on the bed weekly using a damp soft cloth and mild detergent. If top cover or bottom cover becomes severely soiled, put on clean gloves, plastic gown and eye protection before removing top cover or bottom cover and dispose according to standard hospital procedures for contaminated waste. Replace with clean covers.

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

Industrial	Break washes	Cold	10 minutes
	Main washes	60° C	6 minutes
	Main washes	70° C	10 minutes
	Extraction		2 minutes
	3 Cold Rinses		
	Extraction		5 minutes
Domestic	Pre-wash	Cold	
	Main Wash	70° C	10 minutes
	Extraction		2 minutes
	Cold Rinses		
	Extraction		5 minutes

TUMBLE DRYING OR TUNNEL DRYING IS NOT RECOMMENDED

Mattress cells can be wiped with a solution of sodium hypochlorite 1000ppm or any other non-phenolic germicidal solution.

Master Control Unit

TURN OFF THE ELECTRICAL SUPPLY TO THE CONTROL UNIT AND DISCONNECT THE POWER CORD FROM THE MAIN SUPPLY BEFORE CLEANING AND INSPECTION

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

The air filter should also be checked and replaced as often as possible at a minimum of every six months. Remove the filter cap and then take out unclean filter. Replace with new filter.

3. Storage and Care

Control Unit

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

Mattress Replacement System

- Check the air manifold for kinks or breaks. Replace if necessary
- Disconnect the air tubing; all of the air will be expelled. Starting at the head of the mattress roll towards the foot of the bed. Use the base mounted straps to secure.
- Place the system in a plastic bag for storage.

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

Temperature limitations 5°C ~ 60°C
Relative humidity 30% ~ 75%

4. 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 the end of its life.

5. Maintenance and Troubleshooting

No daily maintenance is required. This equipment should only be serviced by authorized technical personnel. Use only original spare parts and consumables. In case of minor problems refer to the following:

Symptom	Inspection Procedure	Possible Solution
The air is flowing out from the control unit but the mattress is not inflating	1. Are all tubes allowing smooth airflow? Is an air tube kinked? 2. Is there any air leakage from the air cells? 3. Is there any air leakage from air tube between mattress and control unit? 4. Has the air tube connector been connected properly?	1. Adjust the air tubes to enable smooth air flow. 2. Replace with new air cells 3. Replace with new air tubes 4. Re-connect the air tubes.
The Control Unit is not working	1.Check the fuse 2.Check the power cord and power voltage	1.Replace with a new fuse. Fuses may only be exchanged by qualified and authorized personnel. 2. Use a power regulator
Some air cells have abnormal low air pressure while the air pressure for other air cells is normal	1. Is the connection between air cells and the manifold kinked? 2. Is there any air leakage from the air cells?	1.Adjust the connection between cells and manifold 2. Replace with a new air cell.

6. Maintenance / inspection

Maintenance at regular intervals (mandatory each year) is necessary to preserve the function of the control unit. Maintenance at regular intervals may only be performed by qualified and authorized personnel. Filters must be exchanged within this period.

Maintenance and/or inspection should be performed by an authorized dealer or a distributor at the client's expense.

7. Warranty

- Quart Healthcare guarantees that this equipment is free from defects in materials and workmanship. Our obligation under this warranty is limited to the repair of equipment returned to the place of purchase within 24 months of delivery date
- We agree to service/adjust any equipment returned, and to replace or repair any part that is proven to be a warranty defect, at no charge
- This warranty excludes equipment damage through shipping, tampering, improper maintenance, carelessness, accident, negligence or misuse, or products that 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 Quart Healthcare be liable for any direct, indirect or consequential damages or losses resulting from the use of equipment

8. EMC related notifications

Guidance and manufacturer's declaration – electromagnetic emissions		
DynaLaL III is intended for use in the electromagnetic environment specified below. The customer or the user of the DynaLaL III should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	DynaLaL III 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	DynaLaL III 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity
DynaLaL III is intended for use in the electromagnetic environment specified below. The customer or the user of DynaLaL III should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	□6 kV contact □8 kV air	□6 kV contact □8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	□2 kV for power supply lines □1 kV for input/output lines	□2 kV for power supply lines □1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	□1 kV line(s) to line(s) □2 kV line(s) to earth	□1 kV line(s) to line(s) □2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of DynaLaL III requires continued operation during power mains interruption, it is recommended that DynaLaL III be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *U*T is the a.c. main voltage prior to application of the test level.			
Guidance and manufacturer's declaration – electromagnetic immunity			
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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of DynaLaL III, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2,5 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: 

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 DynaLaL III is used exceeds the applicable RF compliance level above, DynaLaL III should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating DynaLaL III.

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

Recommended separation distances between portable and mobile RF communications equipment and DynaLaL III

DynaLaL III is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of DynaLaL III can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and DynaLaL III 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 2,5 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.