OPERATING INSTRUCTIONS K-0 SERIES

K-0 Elite

ALTERNATING PRESSURE WITH ON-DEMAND LOW AIR LOSS SYSTEM



& K-0*0em* ALTERNATING PRESSURE SYSTEM



ALL K-0 Elite & K-00em MODELS including Foam Aire Mattress & Chair Overlay Systems

> Please read this manual before using this product. Do not discard, save for future reference.

> This manual MUST be given to the user of this product.





A FDA registered company. Products are FDA listed.

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MADE IN USA

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GENERAL INFORMATION

Danger indicates an imminently hazardous situation, which if not avoided, will result in death or serious injury.

♦ EXPLOSION HAZARD ♦

DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS OR AN OXYGEN TENT AROUND THE CONTROL UNIT

Caution indicates a potentially hazardous situation which, if not avoided, may result in property damage or minor injury or both.

- There is no known risk of adverse effects on the KAP Medical control unit/pump caused by other electromagnetic devices, present at the time of treatment, or vice-versa.
- Refer servicing to qualified service personnel.

Warning indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

- Never drop or insert objects into any opening of the control unit.
- 4 Risk of electrical shock. Do not remove control unit cover.
- DO NOT SMOKE while using this product and do not use in the presence of smoking materials or open flame. Smoking by visitors in the room will contaminate the system. Therefore, visitor smoking is NOT permitted. Air flowing through air mattress will support combustion. Failure to observe this warning can result in severe fire, property damage and cause physical injury or death.
- Entrapment may occur. Patient entrapment with bed side rails and mattress may cause injury or death. Mattress MUST fit bed frame and side rails snugly to prevent patient entrapment. Follow the manufacturer's instructions and monitor patient frequently. Proper patient assessment and monitoring, and proper maintenance and use of equipment is required to reduce the risk of entrapment. Variations in bed rail dimensions, and mattress thickness, size, or density could increase the risk of entrapment. Visit the FDA website at http://www.fda.gov to learn about the risks of entrapment. Refer to the owner's manual for beds and rails for additional product and safety information. Mattress MUST fit bed frame and bed rails snugly to reduce the risk of entrapment.

- To avoid risk of electric shock, this equipment must only be connected to a supply main with a protective earth using the supplied 14-foot (427cm) hospital-grade power cord provided with the product.
- Do not spill liquids or food on or into the control unit. In the event of any spillage, immediately turn off the control unit and disconnect it from the power source. Return the control unit for servicing to a factory authorized service center.
- Care should be taken such that the power cord of the control unit is not pinched or has any objects placed upon it. Make certain the unit is not located where it can be stepped on or tripped over.
- Do not modify this equipment without authorization of the manufacturer.
- Not for use in oxygen-rich environments.
- Before opening or cleaning the control unit enclosure, make certain that the unit is turned off and unplugged from its power source. The control unit enclosure should only be opened by factory authorized qualified technical service personnel.
- Do not heat, steam autoclave, or immerse the control unit in liquids.
- Please read this manual before operating any of KAP Medical's Air Therapy systems. If you are unable to understand the manual, please contact your dealer or the manufacturer before attempting to use this equipment. Otherwise personal injury or property damage may result.

<u>NOTE:</u> INFORMATION CONTAINED IN THIS OPERATING INSTRUCTION MANUAL IS SUBJECT TO CHANGE WITHOUT PRIOR NOTICE.

MANUFACTURER'S LIABILITY

KAP MEDICAL'S original warranty on the K-0/K-00em ALTERNATING PRESSURE SYSTEMS will remain in effect during the warranty period provided any changes, readjustments, or repairs have been carried out by a factory authorized service center or a technician of KAP MEDICAL, or whenever the control unit and mattress system has been used according to the following operating instructions.

KAP MEDICAL'S liability under the warranty is the repair or replacement provided and, in no event, shall KAP MEDICAL'S liability exceed the purchase price paid by the customer for the product. Under no circumstances shall KAP MEDICAL be liable for any loss, direct, indirect, incidental, or special damages arising out of or in connection with the use of this product.

AIR THERAPY SUPPORT SYSTEMS

These Air Therapy Systems are designed to provide continuous air therapy support and are used to inflate a mattress replacement system or seating surface. The control unit is designed to provide continuous air therapy support at required patient comfort levels. The ABS/PVC blended enclosure houses a pump, a quick-disconnect coupling connector, 14-foot detachable hospital-grade power cord, display panel, and a CPR label. The mattress replace system (B) is comprised of a durable Cordura base (C) with a safety 2" convoluted foam or air base, 5" or 8" (inflated) detachable air cushions (T), and covered with a vapor permeable, waterproof, low friction and low shear nylon quilted top sheet (E) with zipper to fasten the top sheet to the mattress base. The complete mattress system has 10 straps (F) in several areas so it can be easily fastened to any size hospital bed.

Intended Use:

The KAP Air Therapy Systems are intended to be used for the prevention and treatment of decubitus ulcers.

K-0 SERIES WEIGHT CAPACITY

NOTE: K-0 SERIES systems are used for patients who weigh between 35 lbs. and 450 lbs. (15 Kg. and 205 Kg.) All Overlay Mattresses, Pediatric Mattresses, and Geri Chair Pads: 35~450 lbs. (15~205 Kg.).

Replacement Mattress Systems: 32"/36" wide 35~450 lbs. (15~205 Kg.). Foam Aire Mattress: 360 lbs. (163 Kg.)

EXPLANATION OF SYMBOLS USED ON THIS DEVICE Not all features included with each model.

Not all features included with each model.		
FUNCTION	SYMBOL	EXPLANATION
POWER	ون	Turns unit On/Off.
SOFT / FIRM		Up or Down key adjusts patient comfort pressure levels.
THERAPY	E	Selects Static or A/P Time (Alternating Pressure (A/P) therapy time). A/P times may be set to 5, 10, 15, or 20 minutes. (K-0 ELITE only)
STATIC	m	Static Therapy on.
LOW AIR LOSS (K-0 ELITE)		Static Therapy with Low Air Loss on.
MAX INFLATE	m	Inflates mattress to Max pressure. (45 minute timer).
FOWLER		Boosts 15~25% more air pressure in the mattress
(K-0 ELITE)		during fowler position to avoid patient bottoming out.
LOCK		Locks out all control unit functions to prevent patient settings tampering.
O POWER FAIL	~	In the event of power failure or if the hose is disconnected an audio/visual alarm will sound.
O LOW PRESSURE		
ALARM SILENCE		Mutes audio alarm.
\checkmark	Indicates the point of attachment of the equipment to earth (Grounding Point).	
\triangle	Attention: Instructs end user / care giver / operator to refer to the manual.	
i	Indicates that the degree of protection against electrical shock is TYPE BF.	
Ø	Not for use in presence of flammable anesthetics.	
i	Consult Instructions for Use	
X	Waste electrical and electronic equipment (recycle). Marketed after 2005	
4	Risk of electrical	shock. Do not remove back cover.

TECHNICAL SPECIFICATIONS

ELECTRICAL SPECIFICATIONS

Note: The control unit Power Inlet is used as the means of isolating the equipment from the supply mains on all poles simultaneously.

	<u>U.S. / INTL.</u>
Input Voltage AC:	90 / 240 V
Input Frequency:	60 / 50 Hz
Current:	1A
Maximum Power	
Consumption:	8 watts ± 2
Circuit Protection:	Dual fused, 250V, 1A slow
	blow fuses.
Fuse Type:	Bussmann #GMD-1-R
Breaking Capacity:	@125 VAC is 10kA
(BRK.CAP.)	@250 VAC is 35A

Mode Of Operation: Continuous

PERFORMANCE SPECIFICATIONS

K-0, K-00em, & K-0FAMS, K-00emFAMS

Weight Capacity:

K-0COS and K-0oemCOS =	Overlay: 360 Lb. (160 Kg.) maximum.
K-0MS and K-0oemMS =	Standard Mattress: 450 Lb. (205 Kg.) maximum.
K-0FAMS and K-0oemFAMS =	Standard Mattress: 360 Lb. (163 Kg.) maximum.
Pressure Zones:	2
Max Flow:	8 ± 4 LPM
Max Inflate Pressure:	35 ± 5 mmHg
Max Flow Timer:	45 minutes
K-0MS and K-0oemMS =	Support Surface Inflation Time: 20~45 minutes.
K-0FAMS and K-0oemFAMS =	Support Surface Inflation Time: 5~15 minutes.
Patient Comfort Control Pressures	
Soft Pressure:	7 ± 5 mmHg
Firm Pressure:	32 ± 5 mmHg
AP Times (K-0):	5, 10, 15, 20 Min Variable
AP Time (K-0oem):	10 Min Fixed
AP Low Pressure:	0%, 25%, 50% and 75% of High Pressure

K-0CS/K-0oemCS

K-0CS/K-0oemCS = Chair Overlay Inflation Time: 10~15 minutes.

K-0CS/K-00emCS = Standard Chair Overlay (20" or 51 cm) is 250 Lb. (114 Kg.), and wider Chair Overlay (28" or 71 cm) is 450 lb. (205 Kg.).

Pressure Zones:	2
Max Flow:	8 ± 4 LPM
Max Inflate Pressure:	$120 \pm 10 \text{ mmHg}$
Max Flow Timer:	45 minutes

Patient Comfort Control Pressures

Soft Pressure:	10 ± 5 mmHg	
Firm Pressure:	110 ±10 mmHg	
AP Times (K-0):	5, 10, 15, 20 Min	Variable
AP Time (K-0oem):	10 Min Fixed	
AP Low Pressure:	50% and 75% of High	n Pressure

Patient Contact

Control unit and mattress have lead free, mercury free, and latex free components.

MECHANICAL SPECIFICATIONS

Control Unit (A)

Dimensions, LxWxH:	10" x 5 " x 5" (25cm x 13cm x 13cm)
Weight:	5 lbs. (2.2 Kg.)
Power Cord:	14' (427 cm) long detachable 16~18 AWG hospital grade.
Connection:	1/4" flow plastic quick couplings
Packaging:	1~3 Piece per Box.

Air Filter:

Internal, non-replaceable.

Support Surface (B)

Optional 1632 & 1633 compliant mattresses are available.

Standard Support Surface

<u>Air cushions</u>: 70 denier urethane coated nylon, R.F. welded, liquid proof and washable. Cal.117 pass.

<u>Base:</u> 1000 denier cordura or non-skid material, embossed PVC / Nylon / Polyester Knit, liquid proof and washable. Cal.117 pass. Optional 1632 & 1633 compliant mattresses are available.

<u>Top Sheet:</u> 70 denier urethane coated nylon, low friction, low shear force producing, breathable, liquid resistant and highly vapor permeable or 4-way stretch Derma-plush Urethane coated, low friction, low shear force producing, breathable, liquid resistant and highly vapor permeable. Cal.117 pass. <u>Optional PATENTED Low Air Loss top sheet</u> has 3 layers: Top layer is breathable nylon or 4-way stretch Derma plush, air distribution special spacer material for middle layer, and the bottom layer is water resistant nylon.

Description	Inflated Dim. LxWxH	Weight
Overlay:	80" x 36" x 5"	8 lbs.
	(203cm x 89cm x 13cm)	3.6 Kg.
Mattress:	80" x 36" x 8" or 10" high	23 lb. (38 lbs. for Foam Aire Mattresses)
	(203cm x 91cm x 20cm or 25 cm)	10.5 Kg. (17 Kg. Foam Aire Mattresses)
Chair Pad		
Standard:	69"x20"x1"/3"	8 Lbs
	(175x51x5/7.5 cm)	3.6 Kg.
Chair Pad		
Special Size:	69"x28"x1"/3"	9 Lbs.
	(175x51x5/7.5 cm)	4 Kg.
Packaging:	1 piece per box	

ENVIRONMENTAL SPECIFICATIONS

Operating Conditions:

Ambient Temperature:	50° ~ 104° F 10° ~ 40° C
Relative Humidity:	30% ~ 75% Non-Condensing
Atmospheric Pressure:	70 kPa to 106 kPa

Storage And Shipping Conditions:

Ambient Temperature:	-40° ~ 158° F
	-40° ~ 70° C
Relative Humidity:	10% ~ 100%
Atmospheric Pressure:	50 kPa to 106 kPa

Protection Against Harmful Ingress Of Liquids:

Ordinary Protection (IPXO)

Mattress Sanitation:

Complete support surface is made of superior quality materials and is modular in construction. All components such as manifold, hose assembly, air cushions, top sheet, and foam base are interchangeable and can be easily cleaned or detached for laundry. The Foam Aire Mattresses (K-0FAMS and K-00emFAMS) have a Kevlar fire barrier sock inside the cover and care should be taken if removing the cover for cleaning.

Disposal Requirements:

This equipment should be disposed of at your local recycling center (non-hazardous waste) when it has reached the end of its service life.

Contraindications:

ALWAYS consult the patients' physician before using any of KAP Medical's Air Therapy Systems.

SAFETY AGENCY APPROVALS

ETL Listed: 2nd Edition



The standard for safety of Medical Electrical Equipment

Conforms To: UL STD 60601-1 with respect to Electrical Shock, Fire and Mechanical Hazards

Certified To: CAN/CSA STD C22.2 No. 601.1

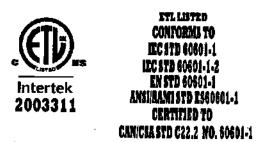
CE Mark:

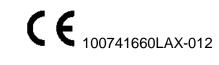
3143628MPK-001

Class 1 equipment

OPTIONAL 3rd EDITION COMPLAINT SYSTEMS AVAILABLE

ETL Listed: 3rd Edition





3rd Edition CE Mark:

Flame Resistance:

Unit components meet UL 94V-0. Mattress components pass California117.

Optional 1632 & 1633 compliant mattresses are available.

FDA REGISTRATION

FDA registered company as a manufacturer and as a contract manufacturer.

KAP MEDICAL'S quality system meets the requirements of <u>FDA 21 CFR, PART 820- QSR-Current</u> <u>Good Manufacturing Practices (CGMP) for medical devices.</u>

Products are FDA listed.

PATENTS

Optional Low Air Loss Top Sheet.

CERTIFICATE OF ORIGIN:

All products are manufactured in Corona, CA, USA.





FDA registered company.





California FDA



Medicare coded (SADMERC).



h Santé da Canada

Health Canada Medical Device Licensed.



ISO 13485 certified company.





SAFETY INSTRUCTIONS

- Always consult the patient's physician before using the K-0 series system.
- <u>An Andrew Construction</u> <u>Andrew Construct</u>
- 2^{1} To avoid electric shock, always plug the power cord of the control unit into a properly grounded power source.
- 27 Do not insert items into any openings of the control unit. Doing so may cause fire or electrical shock by shorting internal components.
- <u>Z</u> Do not spill liquids or food on or into the control unit. In the event of any spillage, immediately turn off the control unit and disconnect it form the power source. Return the control unit for servicing to a factory authorized service center.
- <u>ZIN</u> Care should be taken such that the controls on the footboard of the bed frames are not obstructed by the K-0 series control unit.
- A Care should be taken such that the power cord of the control unit is not pinched, or has any objects placed on it. Make certain it is not located where it can be stepped on or tripped over.
- A Do not attempt to service the control unit except as explained in this operating instruction manual. Contact factory for servicing instructions. Always follow operating and service instructions closely.
- <u>A</u>Do not place the patient directly on the mattress without the top sheet. The breathable nylon top sheet is water repellent; highly vapor permeable, anti-microbial, low friction and low shear, quilted and reusable.

• **WARNING:** Before opening the control unit enclosure, make sure the control unit is turned off and unplugged from its power source. The control unit enclosure should only be opened by a factory authorized qualified service technician.

• Zhanking by the patient or anyone else around or on the K-0 series system is prohibited. K-0 series system uses room air for circulation through the mattress. Smoking will contaminate the system.

UNPACKING THE SYSTEM

 \triangle Note: When opening the large system box or the small control unit box, ensure that the object used to open the box does not penetrate and damage the components inside.

Components Supplied:

K-0 / K-00em series System Box 1 Control Unit and Mattress Box

Control Unit Box

1 Control Unit

- 1 Operating Instruction Manual
- 1 Power Cord

Foam Aire Mattress Box

- 1 Foam Aire Mattress
- 1 Control Unit (if ordered with Mattress)
- 1 Hose Assembly (if ordered with Mattress)

Chair Overlay System Box

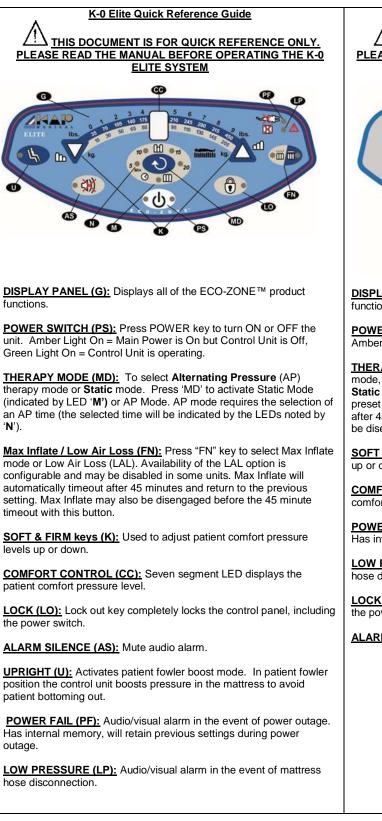
1 Control Unit

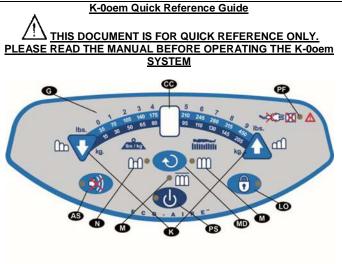
1 Chair Overlay

1 Operating Instruction Manual

Unpacking and Inspection

Before accepting and signing for your shipment, please inspect the box or boxes for external and internal damages. Verify that the number of boxes listed on the packing list matches the number boxes received. Verify that no components in your shipment are damaged or missing. Report any missing boxes, components and or damages to the transportation carrier immediately.





DISPLAY PANEL (G): Displays all of the ECO-AIRE[™] product functions.

POWER SWITCH (PS): Press POWER key to turn ON or OFF the unit. Amber Light On = Main Power is On.

THERAPY MODE (MD): To select Alternating Pressure (AP) therapy mode, Static mode or Max inflate mode. Press 'MD' key to activate Static Mode (M), Max Inflate (W) or AP Mode (N). AP mode has a preset time of 10 minutes AP time. Max inflate will automatically timeout after 45 minutes and return to the previous setting. Max Inflate may also be disengaged before the 45 minute timeout with this button.

SOFT & FIRM keys (K): Used to adjust patient comfort pressure levels up or down.

<u>COMFORT CONTROL (CC):</u> Seven segment LED displays the patient comfort pressure level.

<u>POWER FAIL (PF):</u> Audio/visual alarm in the event of power outage. Has internal memory, will retain previous settings during power outage.

LOW PRESSURE (PF): Audio/visual alarm in the event of mattress hose disconnection.

LOCK (LO): Lock out key completely locks the control panel, including the power switch.

ALARM SILENCE (AS): Mute audio alarm.

◆ QUICK OPERATING INSTRUCTIONS ◆

- Unroll the K-0 series air mattress, Foam Aire mattress, or chair overlay and place it on the bed frame or a chair and attach it firmly with straps (straps are present only on air mattress and the chair overlay). Hang the K-0 series control unit on the footboard of the bed frame or place it in the pocket on the back of the chair overlay and make sure that the mattress hose assembly is connected securely to the control unit.
- Place patient on the mattress or chair overlay. Plug the hospital grade power cord provided with the unit into a three pronged hospital socket, the amber "STANDBY" LED will light up. Press power switch, green LED lights up, and then press MAX FLOW. The pump will come on and inflate the mattress.
- 3. Using "SOFT" / "FIRM" keys set patient comfort pressure level. Seven segment LED will display the patient comfort pressure level.
- 4. To set Alternating Pressure therapy mode press the Mode key and select appropriate AP time from 4 different AP times (K-0 Elite has variable AP times, K-00em has fixed 10 min AP time). An AP time LED will light up. To change AP time simply press Mode key to light up appropriate AP time LED. In this mode every other air cell in the mattress will change pressure from high to low or low to high. Note: AP time is only adjustable on K-0 Elite units.
- 5. To set THERAPY (STATIC) mode press MODE key until STATIC LED lights up. In this mode constant pressures are maintained in each of the 2 zones of the mattress.
- To set UPRIGHT (K-0 Elite only) mode press <u>Manual Upright (U)</u> (patient's fowler position). When upright is activated the control unit inflates the mattress to higher pressures to eliminate patient bottoming.
- 7. For CPR or quick deflation, disconnect mattress hose connector from the control unit by simply squeezing both buttons of the large body couplings and pulling them away from the control unit. If OPTIONAL CPR valve is present on the mattress/pad, twist the CPR valve to the open position. CPR valve is located at the foot end of the mattress. On the Foam Aire Mattress disconnect the "DEFLATE" connector which is attached to the DEFLATE tag.
- 8. The Air Mattress has a 2" safety convoluted foam pad or optional 2" air pad to provide support to the patient during transportation or power failure.

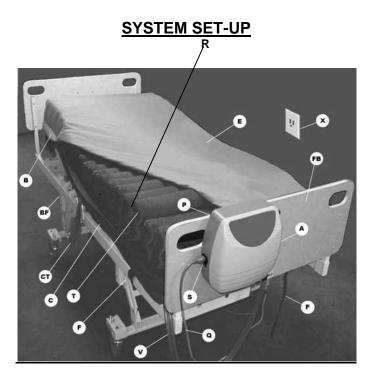


Figure –1

WARNING:

It is highly recommended that the K-0 series SYSTEMS always be installed on medical bed frames that are equipped with standard hospital side rails or assist rails. Please raise all 4 side rails on the bed and lock them in position after the patient is on the mattress. Health care professionals assigned to each case should make the final determination whether side or assist rails are warranted after assessing patient risks of entrapment and falls in accordance with State patient restraint legislation or facility interpretation of such legislation.

<u>Check that all air hoses and power cord are clear of moving bed components before</u> placing a patient on the bed. Operate all bed frame motorized functions through their full range of motion to be certain that there is no pulling, interference or pinching.

Mattress MUST fit bed frame and side rails snugly to prevent patient entrapment.



CONTROL UNIT DISPLAY PANEL (K-0 ELITE)

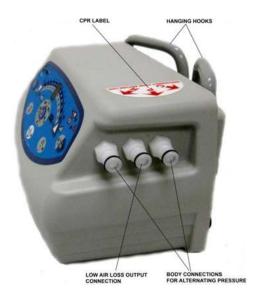


CONTROL UNIT DISPLAY PANEL (K-00em)



CHAIR OVERLAY CONTROL UNIT DISPLAY PANEL (K-0 Elite)

CONTROL UNIT RIGHT SIDE (K-0 ELITE)



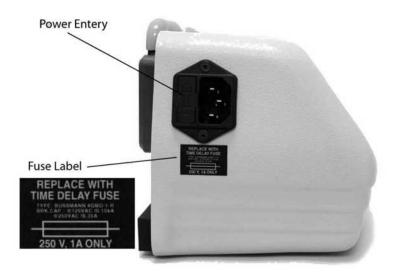
CONTROL UNIT RIGHT SIDE (K-00em)



Alternating Pressure Connectors

Figure – 3

CONTROL UNIT LEFT SIDE



<u>Figure – 4</u>

CONTROL UNIT REAR



<u>Figure – 5</u>



CHAIR OVERLAY UNIT

n)

VARIOUS MATTRESSES



<u>FIGURE 5 A</u>

- 1. <u>Replacement Mattress</u>
- 2. Foam Aire Mattress
- 3. Bolstered Mattress
- 4. Overlay Mattress



Figure 5B FOAM AIRE MATTRESS



Figure 5C FOAM AIRE MATTRESS CONNECTORS



- 1. A PLEASE NOTE: Before using the K-0 and K-00em Series systems including chair overlay system and the FOAM AIRE ALTERNATING PRESSURE mattress replacement systems, remove any non K-0 mattress or chair systems from the bed frame (BF) and the chair.
- 2. <u>K-0 Overlay system</u>: When using a K-0 Overlay mattress, care should be taken such that the overlay is placed directly on an existing 3" to 5" foam mattress.
- 3. <u>Overlay System:</u> There are two elastic straps, one at the head and the other at the foot section. Two long straps on one side and two short straps with buckles on the other side of the overlay. Insert head and foot elastic straps around the foam mattress. Loop each long side strap around the foam mattress and fasten it securely to the foam mattress using the buckle.
- K-0 Mattress Replacement system: When using a K-0 mattress replacement system or a K-00em mattress system or a K-0FAMS or a K-00emFAMS FOAM AIRE mattress system, unroll the K-0 series mattress (B) system and place it on the bed frame (BF).

 2^{1} Note: Make sure that the hose end of the mattress is towards the foot of the bed.

- 5. <u>Mattress Replacement System</u>: There are six ~ ten nylon black straps with buckles (F), two straps at the head of the mattress, two on the foot of the mattress, and three on the each side of the mattress shown. Loop each strap around the bed frame and fasten it securely to the bed frame using the buckle.
- 6. Unroll the K-0 and K-00em series replacement Mattress and place it on the bed frame (BF). <u>Note: Make sure that the hose end of the mattress is towards the foot of the bed.</u>

- 7. <u>PLEASE NOTE: On the Foam Aire Mattress System (K-0FAMS and K-00emFAMS)</u> there are no straps, the Foam Aire mattress is placed directly on the bed frame.
- 8. K-0CS Chair Overlay System: A PLEASE NOTE: Before using the K-0CS system, remove any non K-0CS chair systems from the Geri Chair. When using a K-0 Chair Overlay System, care should be taken such that the chair overlay is placed directly on the Geri Chair. There are 3 straps with buckles on the chair pad, one at the top, one in the middle and one at the foot end of the chair pad. Loop each strap around the chair and fasten it securely to the chair using the buckle.
- Make sure the RED CPR valve (present on K-0 and K-00em mattresses only) is in "CLOSED" position, the "DEFLATE" connector(s) are plugged into the deflate valve, if present the optional bottom safety air pad deflate connector is plugged into the air pad deflate connector, and the bolster deflate connectors are also plugged into the bolster deflate valves (bolster deflate connectors are present only on the Bolstered mattresses).
- 10. Open the hooks (P) on the back of the control unit (A) and suspend the control unit from the footboard (FB) of the bed (BF). If the bed you are using does not have a footboard, place the control unit (A) on its base or on its back on a flat surface underneath the bed near the foot of the bed frame (BF). On the K-0CS system, please place the control unit in the pocket which is located at the top of the chair pad and strap it in place. <u>Note: Care should be taken such that the air inlet vent on the control unit is not covered, and the control unit is not placed on the floor in such a manner that it is a hazard for flow of traffic or lowering of bed frame.</u>
- 11. Uncoil the power cord (Q) and plug the cord into the appropriate AC power source (X), which is properly grounded. Plug the other end of the power cord into the control unit and press it in place. Note: Care should be taken such that the power cord of the control unit is not pinched or has any objects placed on it. Ensure it is not located where it can be stepped on or tripped over. Make sure the control units power inlet connection is positioned to easily disconnect the power cord from the unit.
- 12. Connect the mating coupling connectors (R) on the mattress or overlay pad hose assembly (V) into the insert on the control unit connector and lock it in place. Also make sure the CPR tag (CT) insert connector (if present) is securely connected into the mattress manifold body connector on the side of the mattress. <u>Note: Make sure the connectors have a good connection by gently tugging on the hoses. Also, care should be taken such that the mattress or overlay pad hose is freely suspended without being pinched or kinked.</u>

Figure-6



OPERATING INSTRUCTIONS

Refer to figures on pages 18 through 24

1. Make sure the mattress hose assembly (V) is connected securely to the control unit (A). Ensure the CPR Tag (CT) insert connector (if present), is securely connected into the mattress manifold body connector on the side of the mattress.

INITIAL POWER UP

- During initial power up (when power cord (Q) is plugged into the power source), the control unit (A) will be in "STAND BY" with the amber LED on.
- If the unit is in STAND BY mode with the amber LED on, press the POWER key and the green LED will turn on. For the K-00em unit, press Mode (MD); the Max Inflate LED (M) will light up and the pump will turn on at maximum flow. For K-0 Elite unit, press Max Inflate key (W) and the pump will turn on at maximum flow.
- 4. If the power comes on after a power outage, the control unit will go through its system initialization routine for few seconds and then resume the desired function.

MAX INFLATE (W)

- 1. For K-0 Elite unit, press Max Inflate (W) key, the green LED will turn on. For K-0 oem, press the Mode (MD) key to the Max Inflate setting (M). This mode is used to rapidly inflate the mattress. Max Inflate mode will deactivate after 45 minutes. The LED will turn off and the unit will default to previous setting. In this mode the entire mattress will be pressurized to 35 ± 5 mmHg.
- The mattress (B) or Chair pad will inflate to its normal size in 15 ≈ 60 minutes. (Inflation time depends on the size of the mattress). <u>Note:</u> Mattress can be rapidly inflated within 2 minutes using an external Rapid Inflator / Deflator Blower Model # K-39.

THERAPY (STATIC) (MD)

- 1. To set STATIC mode, press (MD) key to "STATIC" position (M), LED lights up.
- 2. In STATIC mode all the air cushions in the mattress will be maintained at a constant pressure according to the desired Patient Comfort Control Level (CC).

ALTERNATING PRESSURE (N)

- To set ALTERNATING PRESSURE (N) mode, press the O(MD) key and light up one of the AP LED's (N). The AP times are 5, 10, 15, or 20 minutes.
 <u>Note</u>: AP time are only adjustable on K-0 Elite units.
- a. In the AP mode the odd numbered air cushions in the mattress will be maintained at a constant set patient comfort pressure, and the even numbered air cushions deflate to 0%, 25%, 50% or 75% of the set patient comfort high pressure in the first half of the AP cycle and vice versa for the second half of the cycle, and continue back and forth. On the K-0CS control unit the low AP can be factory set to 50% or 75% of the high AP pressure.

PATIENT COMFORT CONTROL LEVEL (CC)

The K-0 series system is designed for patients weighing between $35 \approx 450$ lbs. (15 Kg. ≈ 205 Kg.). Using the comfort control:

a. Pressing the SOFT key (K) towards pressure setting 0 position reduces the pressure

setting, pressing the FIRM key (K) towards pressure setting 9 position increases the pressure. The patient comfort pressure ranges from SOFT 8 \pm 5 mmHg to FIRM 32 \pm 5 mmHg on mattress systems, and on the chair pad systems custom pressure ranges from SOFT 10 \pm 5 mmHg to FIRM 110 \pm 10 mmHg. Depending on the desired patient comfort level the micro-controller / sensors will set appropriate air pressure in the mattress, and maintain the desired pressure in the mattress.

b. This procedure can only be checked on the K-0 and the K-00em mattresses systems. Once the mattress is inflated to its normal size with the patient lying on it, set the COMFORT CONTROL SETTING to the desired patient comfort level. Wait for the mattress pressure to stabilize. Verify the appropriate pressure required to support the patient by performing a simple "four finger check".



Ensure that the patient is lying flat on his or her back in the middle of the mattress. Place four fingers between the air cushions directly underneath the sacral region of the patient's body. There should be a minimum of four fingers width clearance between the bottom of the patient and the safety foam base. Repeat this procedure until the desired patient comfort pressure is achieved. (This does not apply to overlay mattress.)

RECOMMENDED PRESSURE SETTINGS

- a. For rapid inflation of the mattress press (Max Inflate) key and activate "Max Inflate" (W) LED.
- b. For extra firm support during patient ingress/egress, patient wound care, patient turning, or patient cleaning, it is recommended to set the mattress pressure to Max Inflate (W).
- c. If a patient's weight to height ratio is above average, it is recommended to set the comfort control to 20% more than the set pressure level.

ON-DEMAND LOW AIR LOSS (K-0 Elite Only)

To activate Low Air Loss mode (AL) please press (FN) key. The Low Air Loss (AL) LED will light up. In this mode the patient will receive low air loss relief. <u>If the mattress</u> contains the optional Low Air Loss Top Sheet the low air loss relief is administered directly underneath the patient in a special multi-chamber air distribution layer in the top sheet.

UPRIGHT (U) (K-0 Elite mattress systems only)

Press UPRIGHT key to light up UPRIGHT LED. In this mode pressures in the entire mattress will be increased to higher than the set comfort pressure level. This enables the patient to be supported without bottoming out.



Control unit functions (including power) can be completely locked out from being tampered with by simply pressing and holding the LOCK key until the light comes on (approximately 3~5 seconds).

ALARM SILENCE (AS)

An audio-visual alarm is sounded in the event of power failure or when the hose is disconnected from the unit. Audio alarm can be muted by pressing Alarm Silence key.



POWER FAIL (PF) (K-0 Elite & K-00em = Power Fail Led light will flash)

In the event of a power outage, the microprocessor will activate an audio/visual signal to alert the caregiver by flashing the amber "POWER FAIL" LED and the buzzer will turn on. Once the power is restored to the control unit, the audio/visual signal will cease and unit resumes operating in its set mode. During power outage the mattress will retain air as long as the mattress is connected to the control unit.

LOW PRESSURE (K-0 Elite = LP will flash on the 7 segment LED & K-00em = Low Pressure Led light will flash)



Power Fail and Low Pressure Led/Led's

In the event of hose disconnection, the microprocessor will activate an audio/visual signal to alert the caregiver by flashing the amber "LOW PRESSURE" LED and the buzzer will turn on. Once the hose(s) are reconnected and the low pressure problem is fixed, the audio/visual signal will cease and the unit resumes operating in its set mode.

HOLDS AIR IN THE AIR MATTRESS DURING POWER OUTAGE

The air mattress will hold air during transportation or power failure as long as the mattress is connected to the control unit.

The air mattress also has a 2" safety convoluted foam pad or optional 2" air pad to provide support to the patient when the mattress is deflated. It is not recommended to keep the patient on the mattress for long periods of time when the mattress is deflated.

BOLSTERED MATTRESS

The left and the right bolsters can be manually deflated by disconnecting the bolster deflate connector which is at the bottom right corner (patient's right) of the mattress.

PLEASE NOTE: Before using the mattress please make sure that the bolster deflate connector is re-connected back into the bolster deflate valve.

BOTTOM SAFETY AIR PAD (OPTIONAL)

The bottom safety air pad can be manually deflated by disconnecting the air pad deflate connector which is at the bottom right corner (patient's right) of the mattress.

PLEASE NOTE: Before using the mattress please make sure that the air pad deflate connector is re-connected back into the air pad deflate valve.

FOAM AIRE MATTRESS AS A NON- POWERED MATTRESS

Foam Aire mattress can be used as a non powered mattress without the control unit. Before using the mattress connect the control unit to the mattress and inflate the mattress by setting

the control unit comfort level to setting 5. Once the control unit fills the mattress to the required setting 5 the unit will stop. Once the control unit stops filling, disconnect the hose assembly from the mattress and store the control unit and the hose assembly in a storage area.

FOAM AIRE MATTRESS AS A POWERED MATTRESS

If need arises the Foam Aire mattress can be converted into a powered mattress by simply connecting the control unit to the mattress using the hose assembly provided with the system. For operating instructions in powered mode please refer to **OPERATING INSTRUCTIONS ABOVE**.

GERI CHAIR OVERLAY

Connect the Geri Chair Overlay into the Chair System Control Unit using the hose assembly provided with the system. For operating instructions please refer to **OPERATING INSTRUCTIONS ABOVE**

CPR FUNCTION (K-0 Elite and K-00em mattress systems only)



Refer to figure 1 on page 18

Figure CPR: Mattress with CPR valve

1. To deflate the mattress / overlay pad or for a CPR procedure, press the quick release buttons on both the coupling bodies and simultaneously pull the hose from the control unit flange connector.

- If RED CPR VALVE is present on the mattress / pad (not present on FOAM AIRE mattresses, K-0FAMS, K-00emFAMS and Chair Overlay), {Please REFER TO FIGURE CPR above}. Rotate the red CPR valve to "OPEN" position.
- 3. K-0 overlay pad and the K-0 mattress can also be quickly deflated in case of CPR emergency and for quick deflation of the mattress, by unzipping the top sheet from the foot to the head by pulling the zipper located by the patient's right foot near the exit location of the hose assembly (on some mattresses by unfastening the top sheet straps from the side of the mattress). Disconnect a few air cushions which are directly below the patient's chest from the mattress by pressing the quick release button on the connector with one hand and pulling the air cushion connector with the other.



FOAM AIRE MATTRESS

4. To deflate the FOAM AIRE mattress, disconnect the mattress deflate connector which is attached to the "DEFLATE" tag from the deflate valve. If connected to a control unit, press the quick release buttons on both the coupling bodies and simultaneously pull the hose from the control unit flange connector.

PLEASE NOTE: Before using the mattress please make sure that the mattress deflate connector is re-connected back into the mattress deflate valve.

PATIENT TRANSPORTATION

- 1. To transport a patient without removing the patient off the bed, press mode key to set unit in "STATIC" mode and wait a few minutes for the mattress pressure to stabilize. Turn off the control unit, disconnect the power cord from the power source, and roll it up on the control unit securely.
- 2. To maintain full air pressure in the mattress or overlay, leave the mattress connected to the control unit at all times.

CLEANING PROCEDURE



Mattresses must be cleaned regularly after each patient use.

Because of the potential risk of infectious exposure, cleaning with the patient on the bed is not recommended.

All equipment should be inspected. Any item that is visibly soiled with patient's blood or other body fluids should be properly cleaned or removed.

Staff members should treat all soiled bedding as if it were contaminated with pathogenic microorganisms.

Staff members should wear appropriate protective clothing when cleaning mattresses. All cleaning solutions must be properly diluted according to the manufacturer's instructions. Follow standard institutional wipe down and infection control procedures.

CONTROL UNIT

Before attempting to clean the control unit, turn off and disconnect the control unit power cord from the power source.

- ♦ DO NOT HEAT, STEAM AUTOCLAVE, OR IMMERSE THE CONTROL UNIT IN LIQUIDS ♦
 - 1. Wear eye goggles and protective gloves before starting cleaning procedure.
 - 2. The following germicidal detergents / disinfectants are recommended by the EPA as hospital disinfectants.
 - a. Johnson Wax, Virex 128, EPA Registration Number 47371-130-4822.
 - Quaternary Detergent-Disinfectant by Airkem Professional Products, Division of Ecolab, Inc., Ecolab Center, St. Paul, Minnesota.
 EPA registration number: EPA # 42964-5.
 - c. Hi-Tor Germicidal Detergent by Huntington Laboratories, Inc. Huntington, Indiana. EPA registration number: EPA # 303-91.

<u>Note: A fresh spray bottle of disinfectant / detergent solution should be prepared daily</u> to clean the control unit.

3. By following the preparation instructions provided with the germicidal detergent / disinfectant solution prepare the required amount of solution.

4. Pour required amount into a spray bottle.

5. Use a brush or cloth to wipe off dust. If necessary, spray the exterior of the front and back of control unit, power cord, and the cord plug with the prepared disinfectant / detergent solution. Using a damp cloth, wipe down the sprayed surface cleanly. <u>Note: Do not spray</u> excess amount of solution on the control unit.

6. Once the control unit is clean, wipe the unit, the power cord, cord receptacle, and the cord plug with a clean dry cloth.

7. Place the control unit in a cool and dry area for an hour before operating or storing the unit. If the control unit is not used immediately, place the control unit in a plastic bag and store it in a storage area designated for medical electronic products.

8. After the cleaning operations are completed, remove and dispose the rubber gloves appropriately. Wash your hands thoroughly with antibacterial soap.

AIR MATTRESS, MATTRESS OVERLAY & CHAIR OVERLAY

The complete support surface of the mattress is made of superior quality materials and is modular in construction. All the components such as manifold, hose assembly, air cushions, top sheet, side bolsters, rotation bladders, foam or air pad cover, and mattress base are interchangeable and can be easily cleaned or detached for laundry.

1. Wear eye goggles and protective gloves before starting the cleaning procedure.

2. Follow steps 2 through 4 above to prepare disinfectant solution.

3. Use a damp cloth to wipe down the air cushions and the mattress base. Once the air cushions and the base are clean, wipe them down with a clean dry cloth.

4. Top sheet will require more frequent washing. Set wash cycle to heavy load with warm water. Once the water is full add manufacturer- suggested quantity of laundry detergent and/ or standard hospital disinfectants. If the air cushions or the top sheet becomes soiled with human waste or blood, clean immediately by wiping down. Use hospital recommended laundry detergent and/ or disinfectant per manufacturer's instructions. <u>Note: Use non-</u><u>chlorine bleach detergent.</u>

5. Once the washing cycle is complete, shake cushions gently to remove excess water from inside the air cushions. Dry the cushions/top sheet on the lowest heat settings on the dryer until completely dry.

6. Leave the mattress to dry in a cool, dry area for an hour before using or storing. After drying, if the mattress is not used immediately, roll the mattress and insert it into a plastic bag and store it in a storage area.

7. After the cleaning operations are completed, remove and dispose of the rubber gloves appropriately. Wash your hands thoroughly with antibacterial soap.

FOAM AIRE MATTRESS

Before attempting to clean the mattress, remove the bedding from the mattress. The mattress cover (top sheet) can be cleaned following the steps below.

1. Wear eye goggles and protective gloves before starting the cleaning procedure.

2. Follow steps 2 through 4 in control unit cleaning procedure above to prepare disinfectant solution.

3. Clean the top and bottom mattress cover using the prepared disinfectant solution and refer to step 4 of the above Air Mattress cleaning instructions for washing instructions.

4. Wipe dry with a clean cloth and allow to air dry as needed.

CARE AND STORAGE

1. When the control unit is not in use, turn off the unit, disconnect the power cord from the power source, and wrap the cord around the control unit. Secure the control unit and the power cord in a plastic bag and cable tie to keep the unit dust-free.

2. Fold or roll the mattress and place it in a plastic bag and cable tie to keep the mattress dust-free.

3. Store the control unit and the mattress in a storage area designated for medical electronic product storage.

TROUBLESHOOTING GUIDE

THE FOLLOWING INFORMATION IS FOR FACTORY AUTHORIZED SERVICE FACILITIES AND FACTORY QUALIFIED SERVICE PERSONNEL ONLY.

KAP MEDICAL can provide technical support to factory qualified technical personnel. Contact KAP MEDICAL service department for more information.

PROBLEM	CAUSE	SOLUTION
A. Mattress not inflating / not alternating properly	 Mattress hose disconnected Air hose kinked or split Major leak in the air cushions or overlay pad Kinked or split manifold Has power and fuse is good, control unit does not come on Not alternating, Solenoid malfunction No air, Pump Malfunction 	 Connect hose connectors and lock them in place Un-kink hose or replace split hose Replace leaking air cushions or overlay pad Un-kink manifold or replace split manifold Send unit back for repair Send control unit back to factory for repair Send unit for repair
B. No Power	 Control Unit OFF Power cord disconnected No power in the power source Power outage Blown fuse 	 Check power source and turn on unit Connect power cord to the power source Check power source has power and turn it "ON" Wait till the power source is restored Replace blown fuse with an equivalent fuse

PREVENTIVE MAINTENANCE

It is important to periodically test the control unit to verify its functionality. If the units air pressure reading is out of specification it can result in poor or reduced patient support. There is no filter to change or clean on this system.

<u>NOTE:</u> All preventive maintenance service, performance and electrical tests, or repairs should be performed only by factory authorized and gualified technical personnel.

Filter: Internal filter, no external filter

ACCESSORIES

Model #'s K-0 Series

K-0COS:	K-0 Overlay 5" Cell System
K-0MS8:	K-0 Mattress 8" System
K-0MS:	K-0 Mattress 10" System
K-0RSB:	K-0 Raised Bolstered Mattress System
K-0FAMS:	K-0 Foam Aire Mattress System
K-0CS:	K-0 Chair Overlay System
K-0:	K-0 Control Unit only
K-0CU:	K-0 Chair Control Unit only
K-0CO:	K-0 overlay only
K-0M8:	K-0 8" Mattress only
K-0M:	K-0 10" Mattress only
K-0FAM:	K-0 Foam Aire Mattress only
K-0CP:	K-0 Chair Overlay only

Model #'s K-0oem Series

K-0oemCOS: K-0 Overlay 5" Cell System K-0oemMS8: K-0 Mattress 8" System K-0oemMS: K-0 Mattress 10" System K-0oemRSB: K-0 Raised Bolstered Mattress System K-0oemFAMS: K-0 Foam Aire Mattress System

K-00emCS: K-0 Chair Overlay System

K-00em: K-0 Control Unit only

- K-00emCU: K-0 Chair Control Unit only
- K-0oemCO: K-0 overlay only
- K-00emM8: K-0 8" Mattress only
- K-00emM: K-0 Mattress only
- K-00emFAM: K-0 Foam Aire Mattress only
- K-00emCP: K-0 Chair Overlay only

K-140 (SAC): Foot Support Air Cushion

K-136, K-136FAM, K-136RSB, quilted Top Sheets. K-136CS Chair Overlay top sheet. Add "S" next to the model number for 4 way stretch top sheet, ex.: K-136S.

K-136LAL: Optional standard Low Air Loss Top Sheet. For bariatric, please add LAL next to the model numbers.

K-136SLAL: Standard 4 way stretch top sheet.

SPARE PARTS

Available spare parts are listed below:

Part #'s: 100251-S: Power Cord 14" hospital grade 100255-S: Fuse 1 A 400185-S: Operating Instruction Manual

 <u>Note:</u> To place an order or if you have any questions regarding the K-0 system and its warranties, please call KAP MEDICAL customer service at 951 340 4360. Email: sales@kapmedical.com.

WARRANTY

KAP MEDICAL warrants the K-0 series control unit and the mattress for a period of ONE (1) year from the original date of purchase. The Foam Aire mattress will be repaired or replaced if the measurement of compression is beyond 25% of the mattress thickness.

KAP MEDICAL standard warranty is extended to the original buyer purchasing the equipment directly from KAP MEDICAL or through its authorized dealers. All warranty periods, where applicable, commence on the date of purchase from KAP MEDICAL or its authorized dealers.

KAP MEDICAL'S sole obligation and liability under this warranty is limited to (at KAP MEDICAL'S option) the repair or replacement by KAP MEDICAL'S authorized personnel of any parts or assemblies, which upon test and examination by KAP MEDICAL, prove to be defective. This equipment may be returned prepaid to KAP MEDICAL after notification has been given and approval obtained for the return. Please call your KAP MEDICAL sales representative or customer service at (951) 340 4360 to arrange for warranty services.

KAP MEDICAL'S liability under the warranty is the repair or replacement provided and, in no event, shall KAP MEDICAL'S liability exceed the purchase price paid by the customer for the product. Under no circumstances shall KAP MEDICAL be liable for any loss, direct, indirect, incidental, or special damages arising out of or in connection with the use of this product.

The control unit warranty does not cover normal maintenance such as cleaning, periodic electrical tests, performance tests, and updating of equipment or parts thereof. This warranty shall be void and not apply if the control unit, including any of its parts, is modified without KAP MEDICAL'S written authorization, is attempted to be repaired by personnel not authorized by KAP MEDICAL, is not maintained in accordance with the prescribed preventive maintenance schedule, is used with accessories or parts not authorized by KAP MEDICAL, or is damaged due to misuse, mishandling, abuse, negligence, accident, fire, or inadequate packaging by owner for shipment of the control unit for service, upgrade, repair, retrofit, or product return.

All reasonable freight charges for valid factory approved warranty returns will be reimbursed. KAP MEDICAL makes no guarantee of clinical results.

◆ THE WARRANTY STATED ABOVE (INCLUDING ITS LIMITATIONS) IS THE ONLY WARRANTY MADE BY KAP MEDICAL AND IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. KAP MEDICAL SHALL NOT BE LIABLE FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES OF ANY KIND.

P/N:	Description:	File Name:	Rev:	ECO:
400185	K-0 Operating Manual	400185	F	13-0185