WIN CARE group by ASKLÉSANTÉ

User manual

PA0010085

MAJ 18/09/2014 UK

afaq ISO 13485 Santé Médical AFNOR CERTIFICATION

afaq QSE Qualité Sécurité Environnement AFNOR CERTIFICATION

AXTAIR

AXTAIR

A CONTENTS OF THE PACKAGING

- 1 mattress, rolled in a transport bag
- 1 integrated compressor in rolled-up mattress
- 1 electric power cable which has 2 ways of being attached to the bed.
- 1 user manual

B MEANINGS OF THE COMPRESSOR PICTOGRAMS

	Caution, read the user manual and/or instructions for use
	Keep dry
	Class II appliance (double-insulated)
	Caution electrical and electronic equipment - only to be disposed of in a special waste collection
	Type BF electrical appliance
	Compliant with the essential criteria in European Directive 93/42/CEE applicable to medical devices
	Alternating current

C DESCRIPTION

The mattress consists of 18 air cells 12 cm in height placed on a 5 cm foam base.
The cells are inflated alternately (one out of two) except for the 3 head cells, which remain static.
The whole is protected by an integral, removable, waterproof and breathing cushion, incorporating a pillow.

D HOW IT WORKS

- The alternating pressures prevent prolonged vascular compression which may lead to histohypoxia.
- The low pressure static mode enables you to handle patients who need to be immobilised (fractures, neurological trauma, etc.) in order to reduce to a minimum local trauma, helping the patient to rest or carrying out transfer preparations before setting up a static mattress (…).
- The care mode helps with the ergonomics of some care procedures.
- The inflation level can be adjusted automatically. You use the pressure adjustment to adapt the mattress to the patient's morphology and position. Pressure should be calculated when the patient is lying down and calm.

E INDICATIONS

In the opinion of the Committee for Evaluation of Goods and Services published in the *Journal Officiel* on 21 July 2005 and in the opinion of clinical experts:

Prevention and aid to treatment of eschars from stages 1 to 4 (according to medical opinion) in patients confined to bed for more than 15 hours, presenting with a risk of eschars assessed against a validated scale and clinical judgment.
Patients whose weight cannot be determined.

F PRECAUTIONS

Non-stabilised and/or muscular trauma in contact with the support;
Days immediately following surgical intervention on eschar (skin graft or pedicled graft) [→ prefer static mode];
Patient monitored at home without the possibility of intervention by medical auxiliaries;
The device must not be used in a hyperbaric chamber.

⚠ **WARNING:**
According to appendix 1 to European Directive 93/42/CEE relating to the essential criteria applicable to medical devices, only compatibility between systems assembled by the manufacturer, **ASKLE**SANTE, guarantees a safe combination when using the AXTAIR motorised air mattress.
The specification and performance of the motorised air support will only be maintained by using the AXTAIR pump [ref. VAXT4/POMPE/AUTO], associated with the AXTAIR mattress [ref. VAXT4/MA/AUTO or VAXT4/MA/XL] and, optionally, the inflation/deflation kit [ref. VKIT/AXT].
The national authority responsible for health and safety and health products can at any time institute audits of the conditions under which said products are marketed and take the measures necessary if there is danger or a breach of the rules. In the event of failure to comply with the abovementioned conditions of use, the user's liability may be committed if there is an accident.

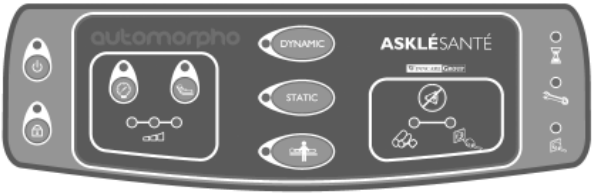
⚠ **PLEASE NOTE**: **The compressor and the mattress are still compatible with the products with equivalent references from previous ranges**

G SPECIFICATION

MATTRESS SPECIFICATION		
	AUTOMORPHO	**AUTOMORPHO XL**
Tested user weight:	30 – 135 kg	
Weight of the support:	8 Kg	9.5 Kg
Dimensions of the support:	195 x 87 x 17 cm	195 x 117 x 17 cm
Air cell height:	12 cm	
Rapid deflation (CPR valve)	less than 15 seconds	
Cell material:	Polyurethane ether 300 µm	
Foam base material:	Polyether -18 kg/m^3 (detachable)	
Cushion material (upper section)	PROMUST PU HD (Jersey/Polyurethane)	
Cushion material (lower section)	Non-slip PU/PVC	
Operation with transport plug:	> 8 hours	
Fire standards	EN 597-1&2 and GPEM D1-90 & D1-89a	
Guarantee:	2 years against any manufacturing defect	
Working life:	5 years	
High speed inflation pump	Compatible (ref. VKIT/AXT)	

SPECIFICATION OF THE AUTOMORPHO COMPRESSOR
Alternating mode: 1 cell out of 2 (Alternates every 7 minutes)
Low pressure static mode
Automatic pressure control dependent upon the patient's morphology
Manual optimisation in semi-seated position > 50°
Static mode for care (closed plan)
Flow: 8 litres/min
Mattress inflation time: • Less than 20 mins for an Automorpho • Approx. 30 minutes for an Automorpho XL • Approx. 2 minutes with a VKIT/AXT high speed inflation pump
Removable particle filter
Audible output: < 35 dBA (to NF EN ISO 3744: 1995)
Audio-visual alarms
Power supply: 220-240 volts
Length of power cable: 4m
Fusible : 630 mAT
Mean output: 5 watts
Class II protection against electric shock
Compliance certificate IEC 60601-1& 60601-1-2
Guarantee: 2 years against any manufacturing defect
Working life: 5 years

H CONTROL PANEL



Start/stop button

This button starts or stops the compressor. The button is pressed in the normal way to start the compressor and held down to stop it.

Keyboard locking button

This button locks the touchpad; simply hold it down for approximately 4 seconds to avoid accidental selections. The touchpad defaults to locked after it has not been used for 5 minutes.

"Waiting" indicator

This orange indicator flashes when the compressor is in operation. Example: initial inflation

Servicing indicator

This orange indicator lights up continuously if servicing of the compressor is advisable.
The indicator flashing together with an alarm sound indicates a problem with the distributor. In this case please contact your reseller.

(See § L- MAINTENANCE/SERVICING)

Mains indicator

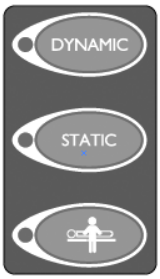
This orange indicator, when on permanently, indicates that the compressor is connected to the mains (source of electrical energy), even if the compressor is not working.

Audio alarm cut-off button

This button cuts off audio alarms.

Each modification or selection (parameters or functions) is signalled by an audible BEEP.
A selection error is signalled by 3 very rapid BEEPS.

Operating modes



This zone selects one of the three possible operating modes. Pressing the button corresponding to the mode enables it. The green light comes on continuously to validate the selection.

Low pressure dynamic mode: enables alternating of one cell out of two (except for the 3 head cells). The cycle change is made every 7 minutes.

Low pressure static mode: inflates all the mattress cells to a constant pressure equal to the lowest internal pressure and allows the patient to sink into the support so as to increase the supporting area and thus reduce the average interface pressures.


Care mode (static): makes the surface of the mattress firm in order to simplify handling of the patient during care or when lifting (e.g. transfer from bed to armchair)

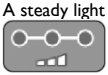
⚠ **WARNING:**

For safety, the care mode is enabled for 30 minutes; after 25 minutes an audio signal (3 BEEPS) warns that the mode is almost ended and the light flashes. At the end of 30 minutes, the compressor reverts automatically to the previous mode.

Settings

This zone is used to set the parameters. Press the corresponding button to adjust the settings. The blue lights come on continuously to validate the selection.


"Pressure" button: this runs a pressure calculation with an AUTOMORPHO compressor at any time.
A steady light means that the calculation is OK.


Pressure level indicator: low, medium or high.


This button adjusts the pressure according to the position of the patient.
It should be selected for a sitting position greater than 30°.

HINT: *In some cases, if the slope of the bed chest elevator is greater than 30°, you may have to increase the pressure inside the cells for the comfort and safety of the user → Press the*  *key and a blue light comes on.*
We recommend that you limit the time in the semi-seated position at 45° to a maximum of 2 hours to reduce the risk of eschar.

Alarms

This zone is devoted to alarms:


Audio-visual alarm indicating abnormal pressure: the indicator flashes and a bell sounds if the pressure is too low or too high and in this way warns of leaks or pump failures.


Audio-visual alarm indicating an electrical fault: the indicator flashes and a bell sounds if the power supply is cut-off or the power lead is disconnected or altered.

I INSTALLATION/USE

1. Unroll the mattress.
2. Position it on the base of the bed, ensuring the cushion "head" and "foot" symbols are placed correctly.
3. Hook the compressor to the bed frame (the foot).
4. Guide the power lead for the compressor along the bed to the nearest power point and connect it.

N.B.: If you have a high-speed inflation pump, after stage 4,

- Connect the power lead for the inflation pump to the mains,
- Blank off the connection to the mattress feed pipe with the attached plug.
- Set the CPR valve to "OPEN",
- Connect the high speed inflation pump as shown in the diagram below,
  (Comment: the pump inflates in one direction and deflates in the other),
- Press the start button until the mattress appears to be fully inflated (approximately 2 minutes)

5. Close the mattress CPR valve (set the dial to "CLOSE")
6. Connect the mattress feed pipes to the compressor connector
7. Press the Start/Stop button. The lights come on for 1 second and a BEEP sounds.
8. Wait until the "Wait" indicator stops flashing, indicating the end of the auto-inflation phase. (Without high speed inflation, this step lasts about 20 minutes for a mattress 87 cm wide and 30 minutes for a mattress 117 cm wide)
9. Lay the patient out flat on the mattress.
10. Start a pressure calculation by pressing the button while the LED is flashing. If you do nothing, the calculation will start automatically after a 5 minute pause.
During the calculation, the pressure button indicator stays on and the pressure indicators come on alternately. (For a precise calculation, the patient should not move excessively). The calculation lasts a maximum of 6 minutes.
When the calculation is finished, the pressure button indicator goes out and the pressure indicators are lit continuously to indicate that the pressure is now matched to the patient's morphology.
The compressor then starts DYNAMIC mode automatically.
11. Selecting the position corresponding to that of the patient. (see § CONTROL PANEL)

⚠ COMMENTS:

- Unlock the keypad before making selections by holding the button down for a little while (Example: to change mode)
- To recalculate the inflation pressure, press again on the pressure button and the pressure indicators will come on alternately.
- **If installation was completed without the patient present, you must rerun the calculation once the patient is lying on the mattress.**

- It is possible, exceptionally, to modify the setting obtained by automatic calculation by holding the "pressure" button down.
- The principal information for using the compressor is printed on its side.

- After 30 minutes has passed without selection, the intensity of the indicators reduces in order not to inconvenience the patient during the night. Pressing a key resets maximum intensity for 30 minutes.

⚠ **WARNING:** for a precise pressure calculation, the patient should be lying flat on the bed and should not make any sudden movements.

⚠ **WARNING:**
the power lead should be should be installed so as to avoid any interference with the articulated parts or the wheels of the bed and employees cannot trip over it. There is a risk of physical injury and damage to the equipment. Use the removable hooking systems supplied.

J ALARMS

If there is a **pressure alarm**, the red indicator will flash and an intermittent audio signal will sound. The audio signal can be cancelled by pressing the  button.

1. Check the feed pipe connection to the compressor and that the CPR valve is closed
2. Check that the air lines are positioned and connected correctly and not split
3. Check that there are no leaks in the cells (structure, connection)
4. Replace defective parts if necessary (pipes, cells, etc.)
5. If the problem persists, contact your reseller

When the pressure returns to normal, the compressor will revert to normal operation and the indicator will go out.

If there is an **electrical fault alarm**, the red indicator will flash and a continuous audio signal will sound. The audio signal can be cancelled by pressing the  button.

1. Check that the compressor is still connected (to the pump and to the power point) and that the mains indicator is on.
2. If the problem persists, we advise you strongly to disconnect the air lines, blank them off with the transport plug and move the patient regularly.

When the power supply returns, you must restart the compressor by pressing the Start/Stop button while repeating the INSTALLATION/USE instructions, §.I, starting from step 8, after you have reconnected the mattress feed pipe to the compressor.

⚠ COMMENTS:

- On starting the compressor, there is an initialisation step. If there is a fault, an alarm is indicated by rapid flashing of all the indicators or, depending on the type of problem by the servicing indicator flashing.
- If the compressor is disconnected, even temporarily, there is always an electrical fault alarm to warn against accidental handling.

⚠ WARNING:

After accidental deflation of the mattress due to a prolonged power cut, check at the time of reflation that the patient does not have a limb wedged between the mattress and the bed sidebars.

CPR (Emergency Cardio-Pulmonary Resuscitation)

In case of cardiac arrest:

1. Turn the end of the CPR valve to set the dial to OPEN,
2. The mattress will deflate and the back of the thorax will be in less than 15 seconds on the firm base of the bedframe to allow External Cardiac Massage.

K MAINTENANCE/DISINFECTION

⚠ RISK OF ELECTRIC SHOCK:

- Before any maintenance, disconnect the equipment from its power supply in order to avoid any risk of physical injury or damage to equipment.
- Never expose the equipment to sprayed water.

⚠ RISK OF DAMAGE TO THE EQUIPMENT:

- You must not use corrosive cleaning products such as industrial degreasing agents, solvents of the acetone type and ether.
- You must not use abrasive materials such as steel wool or "*ScotchBrite*".

Compressor:

Use a cloth lightly soaked with a detergent or surface detergent/disinfectant solution marked CE* at the concentrations for use recommended by the manufacturer. Observe the remanence time.
Please note: In order to prevent any damage to the compressor through liquid getting inside the casing, please do not spray the product

"The filter should be changed 1 time per year or more frequently depending on environmental conditions (dust, smoke, ...). "

Mattress:

Disinfection by hand: use a cloth impregnated with a solution of detergent or surface detergent/disinfectant marked CE* at the concentrations for use recommended by the manufacturer. Observe the remanence time.
The removable foam base can be replaced in case of alteration [Ref. VAXT3/MS "support x4 Base>5cm"]

** CE marking compulsory under directive 93/42/CEE for products claiming that they are suitable for the surfaces of Medical Devices.*

Cover:
Observe the following washing conditions:

Wash in water, maximum temperature 90°C, reduced mechanical action, rinsing in decreasing temperature, spin drying.

Bleaching possible, chlorination at 1000 ppm permitted.


Do not iron.


Do not dry clean or use solvent-based stain removers.


Tumble drying permitted, moderate temperatures

Item treated with a biocidal substance that is safe for the user. www.winncare.fr

The MANUFACTURER will provide on request wiring diagrams, lists of components, descriptions, calibration instructions or any other relevant information to SERVICING and MAINTENANCE STAFF in order to carry out permitted repairs in accordance with the contract between the applicant and ASKLE, the manufacturer.

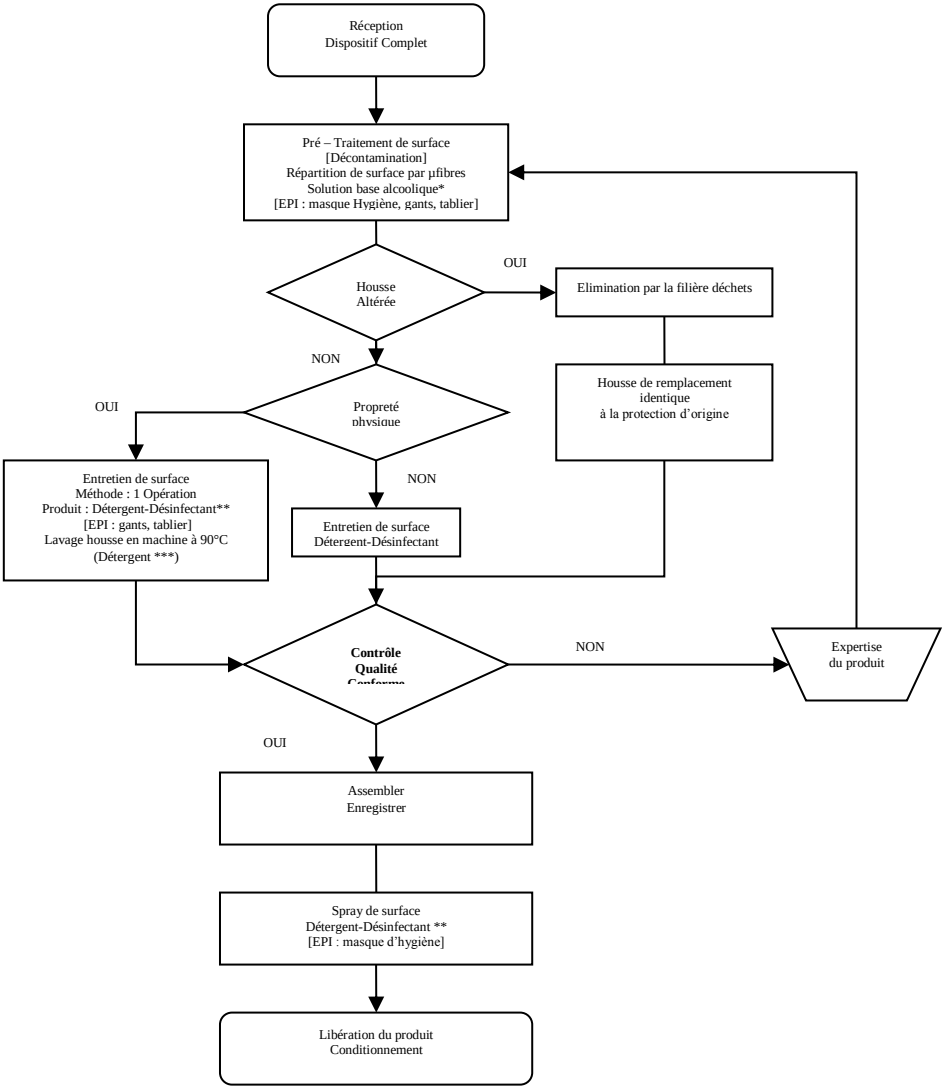
L MAINTENANCE/SERVICING

Periodic servicing of AUTOMORPHO AXTAIR compressors is advised in order to maintain an ideal operating specification.

The periodic servicing interval recommended is indicated by the servicing light on the control panel coming on. 

This servicing can only be carried out by authorised persons; **contact your reseller.**

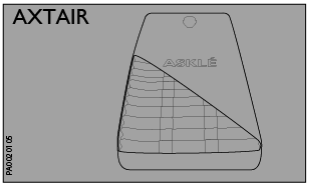
Flow chart of recommended cleaning and disinfection



* Alcohol-based broad-spectrum disinfectant cleaner, standardised: bactericide EN1040, EN13727, Fungicide EN1275, EN13624, NF T72-190, Sporicide EN13697, EN14561, Polyvirus EN14476, HBV, HCV.
Restrict spraying of cells
** Detergent - Disinfectant for cleaning floors and surfaces (Positive list of disinfectants)
*** Neutral detergent (domestic cleaning product)

M STORAGE

A bag is provided for transport and storage of the mattress, which must be rolled. Total deflation of the mattress is easier if you use the inflation/deflation pump connected to the CPR (OPEN position).
The compressor can be placed inside the bag.
The following label identifies the cleaning state of the AXTAIR device:



Blue label when the mattress is clean

Yellow label if there is a risk that the mattress is contaminated

Temperature conditions: minimum: -10°C; maximum: + 40°C
Relative humidity conditions: minimum: 30%; maximum: 95%

⚠ WARNING:

- Keep the devices away from any source of damp, direct sunlight or a source of continuous heat. Risk of damage to the equipment.
- Prevent any risk of impact or damage by sharp or cutting objects. Risk of damage to the equipment.

N DISPOSAL OF THE MEDICAL DEVICE

ENVIRONMENTAL PROTECTION

This appliance contains a variety of recyclable materials.
This symbol indicates that this equipment is recyclable and that worn-out appliances should not be mixed with other waste.
Devices will therefore be recycled under the best possible safety conditions in order to limit effects on the environment and human health if hazardous substances are present, in accordance with European Directive 2002/96/CE concerning electrical and electronic equipment waste at the end of its working life.
You can contact the store, reseller or distributor from whom the product was bought to find out the collection points for worn out devices closest to your home.
Before any disposal, the appliance must be cleaned in accordance with the instructions in § "K- SERVICING/DISINFECTION" to avoid any risk of contamination.
We are grateful for your co-operation in protecting the environment.

O WARRANTY

The compressor and the mattress are guaranteed for 2 years against any manufacturing defect, starting from the date of purchase and subject to use under the conditions recommended in the user manual. This guarantee does not replace the legal guarantees.
In order to claim under the warranty, **it is essential that you keep the bill for the purchase of the product.**
If there is a manufacturing defect and if the product is still under warranty, please contact your distributor and give him the product in question. He will take the necessary steps with our company either to repair it or to make a standard exchange.

⚠ WARNING:

There is a warranty seal under the label on the side of the compressor. The presence is your guarantee that the compressor passed all its inspection tests successfully and that it is tamper-resistant.
If this label is removed by the user or an unauthorised third party, the integrity of the compressor is no longer proven; ASKLE may refuse to repair it under warranty and is entitled to terminate same.

WINNCARE group by ASKLÉSANTÉ

DISTRIBUÉ PAR

papiers Avec Ecofolio tous les papiers se recyclent.

CE

ASKLÉSANTÉ Groupe Winncare – 200, rue Charles Tellier – Actiparc de Grézan – 30 034 Nîmes Cedex 1 (France)
Tél. : +33 (0)4 66 02 15 15 – Fax. : 33 (0)4 66 02 15 00 – Email: contact@askle.com
www.winncare.fr