WINCARE group by ASKLÉSANTÉ

User manual

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INTRODUCTION

NECESSARY INFORMATION FOR PATIENTS AND THEIR FAMILIES

This product helps to prevent and treat pressure ulcers.

Why have you been prescribed this support?

Your health condition reduces your mobility and exposes you to the risk of pressure ulcers.

What is a pressure ulcer?

A pressure ulcer is a lesion of varying depth on the skin, associated with excessive and prolonged compression of tissue between the body and a support surface. This excessive pressure can prevent blood circulation and cause pressure ulcers.

A pressure ulcer can have several forms: a simple persistent rash for more than a day, hardening of the skin, a wound of varying depth that can in severe cases affect muscles or under-lying bone.

A pressure ulcer can be related to a lack of mobility and/or a chronic disease.

How does the support work?

The support reduces support pressure and enables better blood circulation in skin with the aim of helping to prevent pressure ulcers.

INSTRUCTIONS FOR USE

⚠ A support in itself is not enough to prevent pressure ulcers; other preventive measures are also essential:

- change position frequently (at least every 2 to 3 hours)
- maintain skin hygiene and avoid maceration
- in the event of incontinence, change protection regularly
- check (or have checked) skin condition daily
- ensure a sufficient and appropriate diet
- drink regularly and in sufficient quantities.

If any of these measures cannot be followed, your doctor or nurse must be informed as quickly as possible.

Tell your doctor or nurse about any abnormal event such as fever, pain or even a rash or whitening of support points (head, shoulder, back, hip, shoulder blade, pelvis, heel, etc.).

It is important to limit over-thickness between the body and the support as much as possible, with the exception of a cover for a bed support, clothing and a potential complete change. Favour loose cotton clothing and if possible without stitching in the support zone. Do not insert: folded towel or sheet, additional cushion, etc.

Ensure there are no foreign objects such as: tubes, crumbs, fat, etc.

For hygiene reasons, each pressure ulcer prevention support must be restricted to a single person.

INDICATIONS

According to the opinion of the National Commission for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS) dated 22 December 2009 and in accordance with the expert opinions of clinicians:
Prevention and support for treatment of stage 1 to 4 pressure ulcers (according to medical advice) for patients up during the day, confined to bed for over 15 hours and with a "moderate" to "high" risk of pressure ulcer evaluated according to a validated scale and clinical judgement. Treatment support: combine with a positioning system and auxiliary medical intervention or intervention from a close relative at least 3 times a day.

CONTRAINDICATIONS

- Patient weight over 165 kg for the **AUTOMORPHO® PLUS** (VAXT4/AUTO-P and VAXT4/AUTO100-P)
- Use in decompression chamber
- Use on a stretcher.

PRECAUTIONS

- Non-stabilized bone and/or muscle injuries in contact with the support.
- Initial days for post-surgery pressure ulcer (skin transplant or flap) [→ Use the low pressure static mode].
- Patient treated at home with no possibility for auxiliary medical intervention.
- For a patient confined to bed with weight over 135 kg in semi-seated position at 45° at least.
  Check by a "guess work" test by placing the palm of the hand towards the top between the buttock area and the support that there is no risk of injury by checking there is a sufficient volume of air. If applicable, the "comfort" setting can be used to add air.
- Also check the condition of exposed skin at each treatment and change of position.

WARNING

- In accordance with appendix 1 of the 93/42/CEE directive regarding essential requirements applicable to medical devices, only the compatibility between systems assembled by the manufacturer ASKLÉSANTÉ, ensures a safe combination with the use of AXTAIR AUTOMORPHO PLUS motorized air support.
- The characteristics and performance of the motorized air support will be maintained exclusively through the use of the pump [see references on page 18], combined with mattress topper type supports [see references on page 18] with no modification and optionally, with an inflation/deflation kit [see references on page 18]
- The national authority responsible for the safety of health products can at any time check marketing conditions for products and take the necessary steps in the event of danger or breach of regulations. Should the conditions for use outlined above not be followed, the user's responsibility is likely to be implicated in the event of an accident.

- Products in the AXTAIR motorized air range are therapeutic supports in the context of the CEI standard 60601-2-52 regarding the evaluation of protection against mechanical danger from Electro-Mechanical devices (EM) and EM systems, particularly against trapping of the patient in non-mobile parts. The requirements in figures 201.107, 201.108 and table 201.101 involving Axtair type therapeutic mattress are excluded.
- To satisfy the risk analysis according to the ISO 14971 standard, the evaluation was conducted on "medical bed-therapeutic support (AXTAIR) units - accessories". The risk assessment demonstrates that there could be a risk of bodily entrapment in the case of a person confined to bed who has a confusion and/or anxiety disorder. The use of the device was approved for improved service provided in terms of therapeutic support and/or pressure ulcer prevention.
- Attention must be paid when using a patient contention system. See the manufacturer's instruction leaflet.
- Keep the packaging, transport bag and the support out of reach of children to avoid the risk of suffocation.
- In order to avoid any risk, any modification to this product, or use of non specified accessories is forbidden.

- Meaning of symbols

	Note, see user manual and (or) instruction leaflet
	Category II device (Dual insulation)
	BF type electrical device (applied to aids)
CE	Complies with essential requirements of European directive 93/42/CEE applicable to medical devices (amended 2007/47/CEE)
	Note, electrical and electronic equipment subject to selective waste collection
	Manufacturer
SN	Serial number
LOT	Batch number
	Patient weight range
	Warning

USE

CONTENT OF PACKAGING FOR MATTRESS TOPPER AND MATTRESS TYPE SUPPORTS

- 1 rolled support in a transport bag
- 1 dirty/clean label
- 1 identification label
- 1 integrated compressor in a rolled support
- 1 electrical power supply cable with 2 attachment systems to long sides of a medical bed
- 1 user manual

OPERATING PRINCIPLE

- The dynamic mode enables alternation of pressure to avoid extended vascular compression likely to result in tissue hypoxia.
- The low pressure static mode enables the treatment of people requiring immobilization (fractures, neurological injury, etc.), reduces secondary pain from a local injury to a minimum, encourages patient rest, enables weaning before the installation of a static support (...).
- The "treatment" (firm surface) mode facilitates handling during certain treatment and transfer procedures.
- The inflation pressure calculation is automatic and continuous according to a patient's morphology. No external intervention is needed.
- The seated position function adjusts the pressure when the chest relief is over 30°.
- The comfort setting adjusts the pressure irrespective of mode of operation and position.

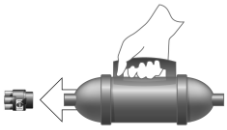
⚠ NOTES:

- Contact the shop or service provider where the product was purchased for any assistance with assembly, use or repair of the product.

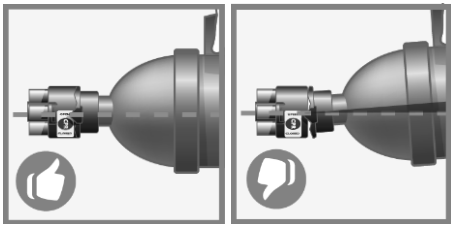
INSTALLATION OF SUPPORTS

1. Unroll the support.
2. Position it on the bed base in accordance with the location of the "head" and "foot" symbols for the cover.
3. Hang the compressor on the bed panel (foot side) using the hooks.
4. Guide the power supply cable for the compressor along the bed to the closest socket, attach it to long side of bed using 2 connectors on the cable and connect the socket: All the LEDs come on for a few seconds and a BEEP is heard.
5. If you have a rapid inflation kit, follow these steps, otherwise go to step 9.
6. Open the CPR valve by positioning the index finger on OPEN, 

. Block the power supply pipe using the "transport" stopper.



7. Connect the rapid inflation pump to the CPR.
Keep the CPR and pump in the same axis in order to avoid arching the CPR by the weight of the pump. Incorrect use could cause a water tightness defect for the CPR.



8. Press the ON button for the rapid inflation pump until the support is inflated (approx. 1 minute) - Note: The level of inflation has no significance because it will be adjusted automatically by the compressor.

9. Close the CPR valve by positioning the index finger on CLOSED,  .

10. Connect the support to the compressor.

11. After the hourglass LED has gone off, the patient can be installed on the support.

⚠ **NOTES:**

- The information needed to use the compressor is on the side of it: simplified leaflet.
- After 5 minutes without a selection, the brightness of the LEDs is lessened to avoid disturbing the user at night. Pressing the key reactivates maximum brightness for 5 minutes.
- The pneumatic connector has a stopper to re-equilibrate pressure of the support when it is disconnected from the compressor.

⚠ **WARNING:**

- The electrical cable must be installed in such a way as to avoid any severing with the articulated parts or the wheels of the bed and prevent staff from stumbling. Risk of physical injury and equipment damage. Use the removable attachment systems provided.
- The power supply cable is the severing system for the machine.
- The compressor keyboard, the power supply cable, the pneumatic connector and the CPR valve must be permanently visible and accessible.

Use:

	Shows that the compressor is switched on
	Flashes to indicate inflation of the support After it goes off, the patient can be installed
	The on LED shows that the keyboard is locked: it is not possible to change mode. Continuously pressing for 4 seconds unlocks the keyboard. Locking is automatic after 5 minutes or it can be controlled by continuously pressing for 4 seconds.
	Low pressure dynamic mode: triggers the alternation of one cell out of two (except for 2 cells for static head).
	Treatment mode: makes the support surface firm in order to facilitate handling of patient during treatment or lifting (e.g. Bed-chair transfer). The duration of this mode is limited to 30 minutes.
	Securization of treatment mode: the flashing of the treatment mode LED means that the mode is almost finished. It is triggered 5 minutes before the end. A sound signal is emitted when it is triggered. At the end of 30 minutes, the compressor automatically switches to the previously used mode.
	Low pressure static mode: inflates all cells in the support at a constant pressure dependent on the morphology of the patient and encourages its immersion in the support to increase the support surface and thereby reduce average interface pressure.
	Enables comfort to be adjusted for the patient. It is applicable in the 3 modes of operation (DYNAMIC, STATIC and TREATMENT) and in seated position. By default, the LED is in the central position, which is the calculated nominal position.
	The seated position function can be selected when the chest relief is over 30°. When the function is set, dynamic cycles are accelerated for greater comfort and restricts the risk of injury. NOTE: It is preferable to press this function before tilting the chest relief rather than the other way round. NOTE: Don't forget to come out of the function if the patient returns to the lying down position.
	FIXED LED: Compressor revision recommended (17500 hours of operation)
	Fixed LED: Low priority alarm. (See alarms chapter)
	Flashing LED: Medium priority alarm. (See alarms chapter)

	Key press: stops sound alarm In the event of a medium priority alarm, the sound alarm is reactivated after 3 minutes.

The following conditions of use must be followed:

- Temperature: between +15°C and + 40°C
- Hygrometry level: between 30% and 95%
- Altitude: under 2000 m

EMERGENCY CARDIO-PULMONARY RESUSCITATION: CPR (SUPPORTS)

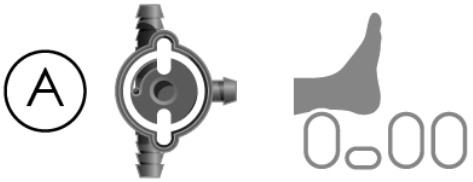
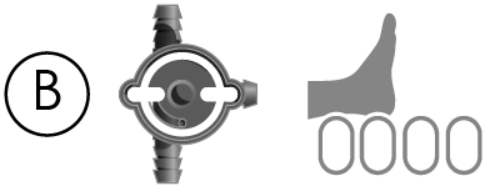
<u>In the event of a cardiac arrest</u>:

1. Turn the nozzle of the CPR valve to position the index finger on the "OPEN" position.

2. The support deflates and the back part of the thorax is on the firm surface of the bed base in less than 20 seconds to enable External Cardiac Massage to be performed.

PRESSURE RELIEF VALVES (SUPPORTS)

Supports in the AUTOMORPHO PLUS range are equipped with 4 independent pressure relief discharges in the foot cells.

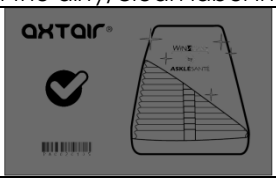
	**In position A** The cell, put in open air, deflates.
	**In position B** the cell re-inflates.

⚠ **WARNING:**

- Do not simultaneously discharge more than 2 cells out of 4 in order to ensure patient comfort and safety.
- Do not leave a pressure relief discharge in an intermediate position between A and B. A notch on positions A or B ensures correct positioning.

UN-INSTALLING THE SUPPORT

1. Disconnect the compressor from the mains
2. Open the CPR valve to deflate the support. Complete removal of air from the support can be facilitated by using the inflation/deflation kit connected to the CPR, and obstructing the power supply pipe.,
3. Position the compressor in the middle of the support.
4. Roll the support starting with the feet
5. Strap up the support
6. Insert the support in the transport bag supplied with the product.
7. Position the dirty/clean label in order to make the yellow side visible.

	
Blue label: the support is clean Use of blue transport bag	Yellow label: the support is dirty (risk of contamination) Use of red transport bag (sold as an option)

⚠ WARNING:

- Accidental deflation of the mattress (power cut or accidental cut of the air circuit): Should the patient have to be kept in the continuous seated position and/or the patient is unable to get up alone or assisted and/or the patient lives alone and/or the patient is hard of hearing, the patient must be lifted to replace the mattress of the medical bed as soon as possible. Should the patient be able to get up alone and intervention is possible within less than 8 hours, he/she must lower the chest relief at least.

STORAGE AND TRANSPORT

There is a label on the transport bag to enable rapid identification of the device from the AXTAIR range contained in the bag. This label must be visible when the product is stored.

The following storage and transport conditions must be followed:

- Temperature: between -25°C and + 70°C
- Hygrometry level: between 30% and 95%
- Atmospheric pressure: between 50 kPa and 106 kPa

⚠ **WARNING:**

- Keep the device away from humidity, direct sunlight, continuous heat source.
- Prevent the risk of shock or alteration from sharp objects.

⚠ **NOTE:**

- The MANUFACTURER will provide, upon request, the circuit schemas, list of components, descriptions, calibration instructions or any other relevant information to MAINTENANCE STAFF to perform authorized repairs in accordance with the contract that binds the requester to the manufacturer ASKLÉ SANTÉ.

MAINTENANCE/DISINFECTION

The method used depends on the required level of disinfection: Techniques and products will be applied according to validated good practice recommendations.
The compressor and supports are compatible with SANIVAP type steam processes (Contact us for further information)
See the diagram at the end of the section.

⚡ - Daily upkeep of the compressor is done in operation with the connector for the support to the connector.

- For all other maintenance, it is essential to disconnect the mains socket from the electrical cable attached to the compressor and ensure the transport stopper is put on the mattress topper. The "mains present" LED must be off - Do not use high pressure jet to clean an Axtair AUTOMORPHO PLUS compressor.

- Do not put the compressor on the ground. Hang it at a distance ≥ 60 cm from a water point.

⚠ Do not allow abrasive cleaning products such as commercial detergents, acetone type solvents, ether and colouring products (iodized alcohol, potassium permanganate, silver nitrate etc.). Do not allow abrasive materials such as steel wool or "scotch brite".

AUTOMORPHO PLUS COMPRESSOR:

Use a cloth soaked in a detergent product solution or CE* labelled surface detergent/disinfectant at the usage concentrations recommended by the manufacturer. Adhere to the remanence times.
Attention: do not project liquid to avoid any damage to the compressor through penetration of liquid inside the box.

MACRO-PARTICLE FILTER:

The filter must be replaced once per year or more frequently depending on environmental conditions (dust, smoke, etc.).
This filter is on the back of the compressor, protected by a removable cover.

SUPPORTS:

On the support, two zippers inside the cover at the head and foot of the support are used to separate the elements quickly.
All the cells and the maintenance sheet remain together and must be manually disinfected: use a cloth soaked in a detergent solution or CE* labelled surface detergent/disinfectant at usage concentrations recommended by the manufacturer. Adhere to the remanence times.

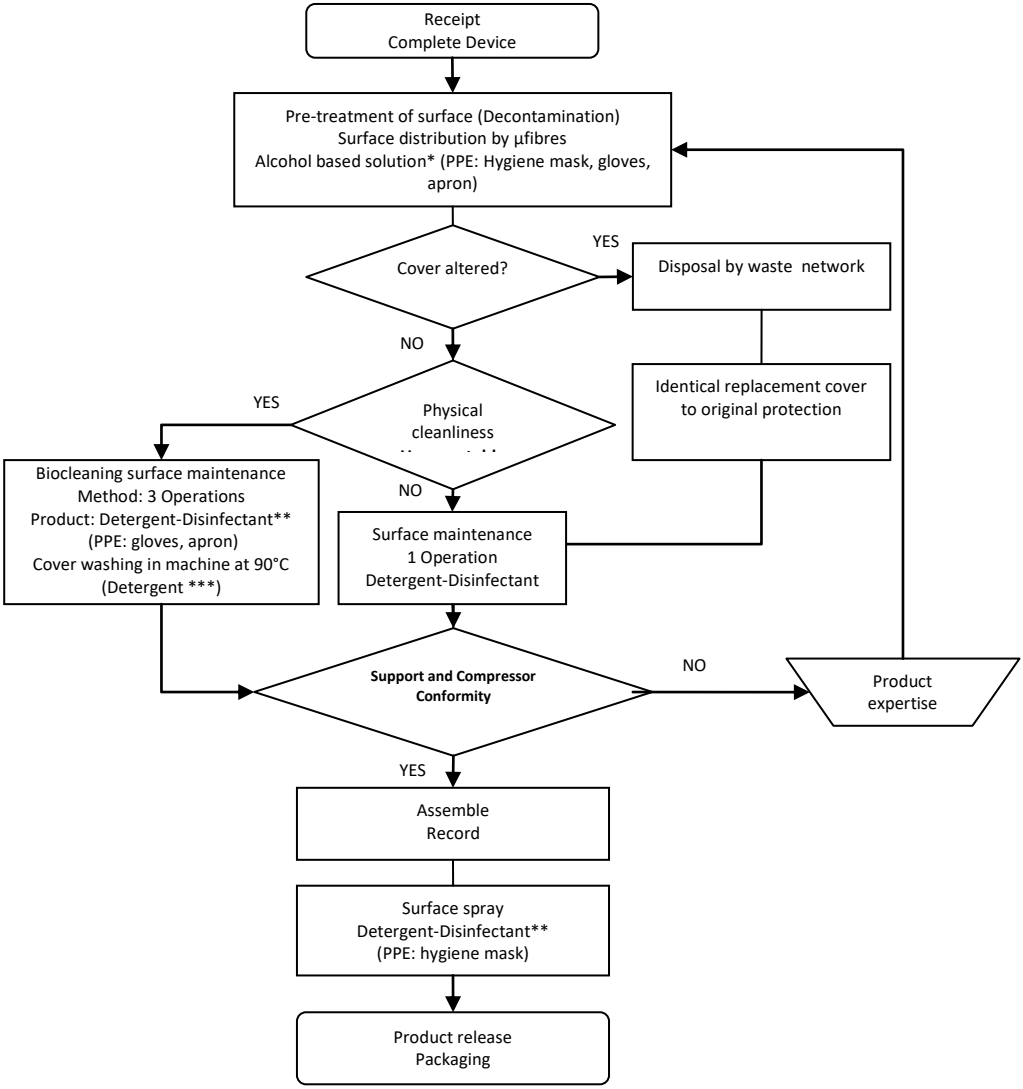
** CE labelling obligatory in the context of directive 93/42/CEE for products claiming use on surfaces for Medical Devices.*

For the cover and base, the following maintenance recommendations must be respected:

	Wash in water, maximum temperature 90°C, reduced mechanical action, rinsing at decreasing temperature, reduced spinning.
	Bleaching possible, chlorination at 5000 ppm authorized.
	Ironing excluded.
	Dry cleaning excluded, use of solvent-based stain remover excluded.
	Drum drying authorized, moderate temperatures

Item treated with biocide substance at no risk to users. www.winncare.fr

MAINTENANCE DIAGRAM AND RECOMMENDED DISINFECTION



* Broad spectrum, alcohol-based Disinfectant Detergent, standardized: bactericide EN1040, EN13727, Fungicide EN1275, EN13624, NF T72-190, Sporicide EN13697, EN14561, Polyvirus EN14476, HBV, HCV, EN 14347 (clostridium difficile)
Restrict spraying to mattress topper. Damp wiping of compressor.

** Detergent-Disinfectant for maintenance of floors and surfaces (Positive list of Disinfectants)

*** Neutral detergent (domestic washing product)

ALARMS AND REPAIR

The following table shows all the alarms for the device, their triggering conditions, their priority as well as possible repair.

Description	Priority	Trigger		Possible repair
		Condition	Time frame	
Alarm LED flashing and mains present LED off  + sound signal	Medium	Electrical fault: the compressor is not powered by the mains	0 min	1 - Re-connect the compressor 2 - Check the status of the electrical network 3 - Replace the fuse 4- Disconnect the support from the compressor. 5 - Contact your maintenance department
Alarm LED flashing and mains present LED on  + sound signal	Medium	Compressor system problem	0 to 1 min	1 - Check that the support is properly connected to the compressor 2 - Check that the CPR is well sealed 3 - Remove the patient from the support 4 - Contact your maintenance department
		The compressor measures a nil pressure whereas it pumps	1 min	
		The compressor measures an over-pressure	1 min	
		Inflation impossible	40 min	
		The compressor detects a pneumatic problem	1 min	
Fixed alarm LED  + sound signal	Low	Initial inflation impossible	40 min	1 - Check that the support is properly connected to the compressor 2 - Check that the CPR is well sealed 3 - Contact your maintenance department

⚠ NOTES:

- At start up of the compressor, there is an initialization step. In the event of malfunction, an alarm is indicated by rapid flashing of all the LEDs or by the flashing of the revision LED or by the flashing of the alarm LED.
- When the compressor is disconnected, even voluntarily, there is systematically an electrical fault alarm to prevent involuntary action.
- The triggering conditions in the table above are classified according to their priority.
- The sound and visual alarms are designed to be noticed 2 metres from the compressor.

⚠ **WARNING:**
After accidental deflation of the support due to an extended power cut, at re-inflation, ensure that the patient has no limbs stuck between the support and the bed barriers.

MAINTENANCE - REVISION

FREQUENCY OF REVISIONS:

it is recommended revising the AUTOMORPHO PLUS compressor at least every 2 years of use.
To facilitate the management and scheduling of these revisions running time counters show the compressor usage time. To see this information, specific equipment is necessary, contact your retailer for more information.

⚠ **WARNING:**
Revisions can only be made by authorized individuals trained by ASKLÉ SANTÉ. **Contact your retailer.**

need for revision		Meaning
	FIXED LED	Means product revision is required (17500 hours of operation).

DISPOSAL OF MEDICAL DEVICE

PROTECTION OF THE ENVIRONMENT

This device contains multiple recyclable materials.
This symbol shows you that this equipment is recyclable and that used devices must not be mixed with other waste.
The recycling of devices will therefore be done under the best safety conditions to limit effects on the environment and human health in the event of the existence of hazardous substances, in accordance with European directive 2002/96/CE for obsolete electrical and electronic equipment.
You can return your obsolete compressor to your closest waste reception centre. The device should be placed in the container for mixed small devices.
You can contact the shop or service provider from whom the product was purchased to find out the details of used device collection points closest to your home.
The DEEE collection applies to the complete medical device: compressor + associated mattress or associated cushion. Log on to www.eco-systemes.fr and search for your closest collection point.

Your DEEE waste can be dropped off there free of charge. For further information log on to www.winncare.fr where you will find information about this in each of the product sections.
Prior to any disposal, the device should be cleaned according to the instructions in the MAINTENANCE-DISINFECTION chapter to avoid any risk of contamination.

Thank you for your public citizen contribution to protecting the environment.

GUARANTEE

The compressor and its supports are guaranteed for 2 years against any manufacturing defect from the date of purchase and under the recommended usage conditions outlined in the usage leaflet. This guarantee cannot substitute legal guarantees.
To avail of this, **the purchase invoice for the product must be retained.**
In the event of a manufacturing defect and if the product is still under guarantee, please contact your service provider showing him the relevant product. He/she will start the necessary steps with our company to proceed with repair.

⚠ WARNING:
A guarantee seal is placed under the simplified leaflet stuck on the side of the compressor. This seal ensures that the compressor has passed all the control tests successfully as well as its tamper resistance.
In the event of removal of this label by the user or an unauthorized third person, the integrity of the compressor is no longer guaranteed: ASKLÉ SANTÉ could refuse to cover the repair under guarantee, and authorize the right to end this.

TRACEABILITY

Traceability by serial number or batch number according to product types enables ASKLÉSANTÉ to ensure traceability of raw materials and assembly operations for these products.
In the Axtair range, compressors are managed by serial number. The serial number is on the product and its packaging.

SN: **AASSTXXX**	AA: Year of Manufacture
	SS: Week of Manufacture
	T: Type
	XXX: Incremental number

In the Axtair range, mattress toppers are managed by batch number except for Axensor mattresses which are managed by serial number. The batch number is on the product and its packaging.

BATCH: **AASS**	AA: Year of Manufacture
	SS: Week of Manufacture

TECHNICAL CHARACTERISTICS

CHARACTERISTICS OF:	MATTRESS TOPPER SUPPORTS	
References	Supports from KITS **VAXT4/AUTO-P** **VAXT4/CIC-P**	Supports from KITS **VAXT4/CIC100-P** **VAXT4/AUTO100-P** **VAXT4/AUTO120-P**
Validated user weight	30 – 165 kg	30 – 165 kg
Support weight	8 Kg	10 kg
Support size	195 x 87 x 17 cm	195 x 87 x 17 cm 195 x 97 x 17 cm 195 x 117 x 17 cm
Therapeutic air cells (AT)	Number: 18 Height: 12 cm Material: Polyurethane ether	Number: 18 Height: 12 cm Material: Polyurethane ether
Head cells	2 static cells	
Rapid deflation (CPR valve)	less than 20 seconds.	
Foam mattress	Polyether foam (removable) - Height + 5 cm	
Outer cover	- Removable - Material impermeable to liquids and permeable to water vapour. Polyurethane/Polycarbonate on a mesh enriched with silver ions. Welded assembly - Housing for comfort pillow	
Inner cover	- Removable - Material: non slip PU/PVC	
Support standby disconnected	> 8 hours	
Fire standards	EN 597-1&2 and GPEM D1-89bis and D1-90 Class D	
Guarantee	2 years against manufacturing defects	
Service life	5 years	
Rapid inflation pump	Compatibility (ref. VKIT/AXT and VAXT/PGR)	
Cable channel	Compatible (ref. VAXT/PC)	

CHARACTERISTICS OF:	**COMPRESSOR**
Reference:	Compressor from KITS **VAXT4/AUTO-P VAXT4/CIC-P** **VAXT4/AUTO100-P VAXT4/CIC100-P** **VAXT4/AUTO120-P**
Modes of operation	- Alternative: 1 cell out of 2 - Static low pressure - Treatment: duration 30 minutes that can be repeated
Compressor weight	2.7 Kg
Compressor size	22 x 25 x 11.5 cm
Pressure setting	Automatic
Complete cycle time	Between 9 and 14 min
Pump speed (indicative value)	> 7 litres / min
Support inflation time	- approx. 20 minutes - less than 1 minute with a rapid inflation pump
Acoustic pressure As per NF EN3744	< 35 dBA
Alarms	visual and sound
Electricity supply	220-240 volts – 50 Hertz
Power supply cable length	4.5 m
Fuse	T 0,63A H 250 V
Max consumed visible power	13 VA
Average consumption seen	5 Wh
Electric shock protection	class II. BF type insulation applied to compressor
Box material	Fire-retardant plastic material
Guarantee	2 years against manufacturing defects
Service life	5 years
Standards	IEC 60601-1 ; IEC 60601-1-2

ELECTROMAGNETIC COMPATIBILITY

The Axtair AUTOMORPHO PLUS complies with applicable electromagnetic compatibility standards (CEM).
The Axtair AUTOMORPHO PLUS requires special precautions with respect to CEM and it must be installed and serviced according to CEM information provided upon request from ASKLE SANTE and available on their website.
The use of accessories, and cables other than those supplied and specified by ASKLE SANTE can result in increased emissions from the Axtair AUTOMORPHO PLUS or reduced immunity, affecting its operation, as well as its performance.

WINNCARE group by ASKLÉSANTÉ

DISTRIBUTED BY

papiers Avec Ecofolio tous les papiers se recyclent.

CE

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