

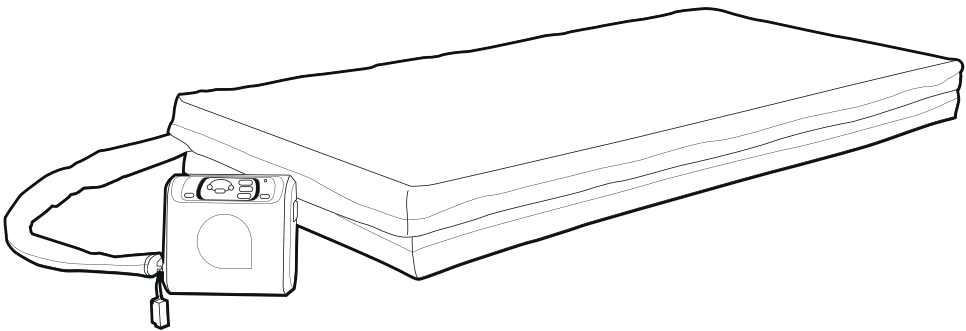
GB

Axtair One®Plus

Axtair Automorpho®Plus

Axtair Axensor® AT12/AT15/AT20

Axtair XXL®



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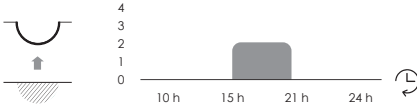


Version 5




22/11/2023

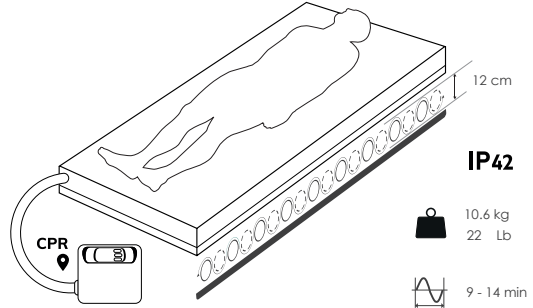
# Axtair One<sup>®</sup>Plus

UDI	03664897001013	
	VAXT2/ONE-P	VAXT2/ONE/CIC-P
	VAXT/PONEP	
	VAXT/MONEP90/PUL	VAXT/MONEP90/CIC



Alternating cycle frequency: 1 cell out of 2

-  = 30-165 Kg  
67-364 Lb
-  = 210 Kg - 463 Lb
-  < 35 dBA

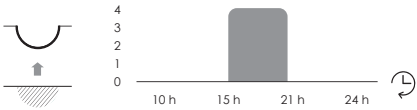


 10.6 kg  
22 Lb




 9 - 14 min

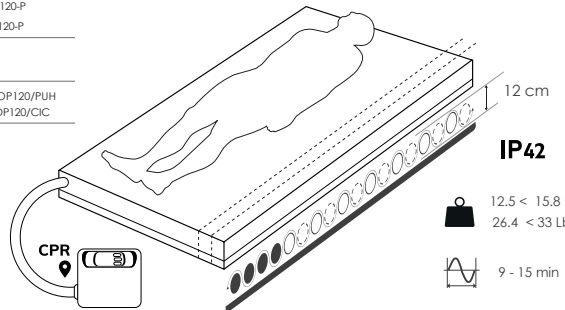
# Axtair Automorpho<sup>®</sup>Plus


UDI	03664897000832		
	VAXT4/AUTO-P	VAXT4/AUTO100-P	VAXT4/AUTO120-P
	VAXT4/CIC-P	VAXT4/CIC100-P	VAXT4/CIC120-P
	VAXT/PAUTOP		
	VAXT/MAUTOP90/PUH VAXT/MAUTOP90/CIC	VAXT/MAUTOP100/PUH VAXT/MAUTOP100/CIC	VAXT/MAUTOP120/PUH VAXT/MAUTOP120/CIC




Alternating cycle frequency: 1 cell out of 2

-  = 30-180 Kg  
67- 397 Lb
-  = 225 Kg - 496 Lb
-  < 35 dBA






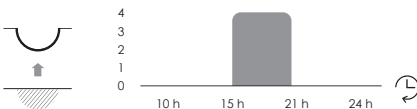
 12.5 < 15.8 kg  
26.4 < 33 Lb

 9 - 15 min




 Care mode

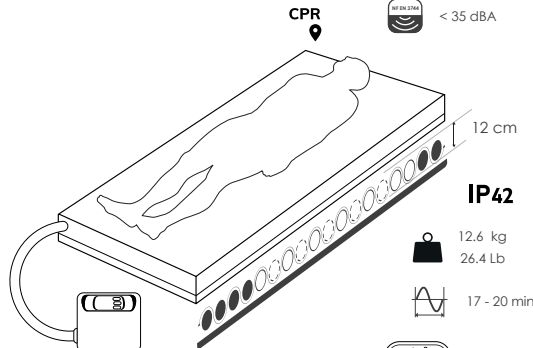
# Axtair Axensor<sup>®</sup> AT12

UDI	03664897001020	
	VAXT6/AUTO-S	
	VAXT6/POMPE/AUTO-S	
	VAXT6/MA/AUTO	



Alternating cycle frequency: 1 cell out of 2

-  = 30-165 Kg  
67- 364 Lb
-  = 210 Kg - 463 Lb
-  < 35 dBA



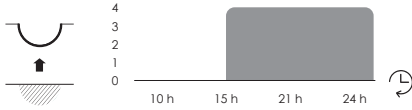
 12.6 kg  
26.4 Lb

 17 - 20 min

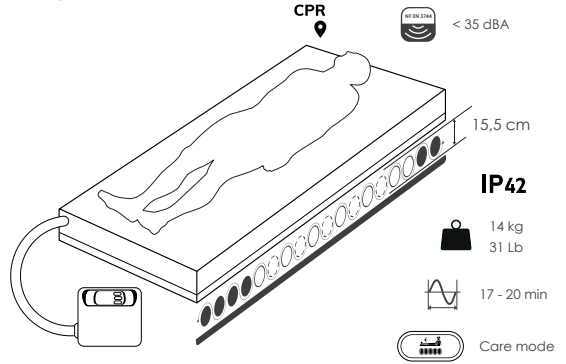
 Care mode

# Axtair Axensor® AT15







	03664897001020
	VAXT6/MAX-S
	VAXT6/POMPE/AUTO-S
	VAXT6/MA/MAX

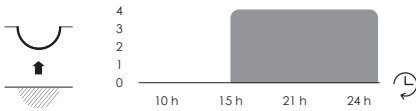


Alternating cycle frequency: 1 cell out of 2

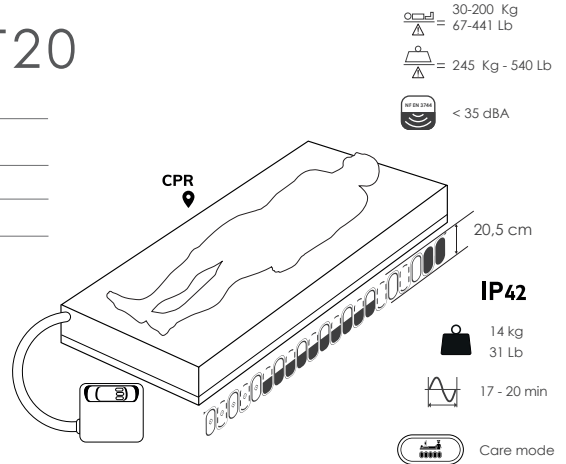


# Axtair Axensor® AT20







	03664897001020
	VAXT6/AT20-80-S
	VAXT6/AT20-90-S
	VAXT6/POMPE/AUTO-S
	VAXT6/MA/AT20-80
	VAXT6/MA/AT20-90

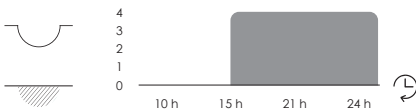


Alternating cycle frequency: 1 cell out of 2

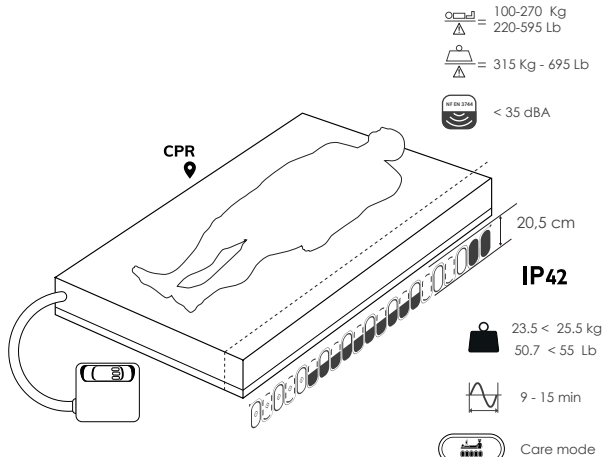





# Axtair XXL®




	03664897022407
	VAXT/XXL120
	VAXT/XXL140
	VAXT/POMPE/XXL
	VAXT/MA/120XXL
	VAXT/MA/140XXL






Alternating cycle frequency: 1 cell out of 2



 = 30-180 Kg  
 67-397 Lb  
 = 225 Kg - 496 Lb  
 < 35 dBA

 = 30-200 Kg  
 67-441 Lb  
 = 245 Kg - 540 Lb  
 < 35 dBA

 = 100-270 Kg  
 220-595 Lb  
 = 315 Kg - 695 Lb  
 < 35 dBA

## 1. INDICATIONS

### Device intended use

This medical device is intended to be used medically in the treatment and prevention of pressure ulcers injuries.

### Indications

Prevention and support for the treatment of stage 1 to 4 pressure ulcers/injuries (according to medical opinion) for patients who may or may not be up during the day and/or have a "moderate to very high" risk of developing a pressure ulcer/injury, assessed according to a proven scale and based on clinical judgement.

(See diagrams on the inside user manual front cover)

### Contraindications

Patient weight Min<Max. Non-stabilized post-traumatic fractures. For use in hyperbaric chambers and on stretchers.

### Target group of patients and users

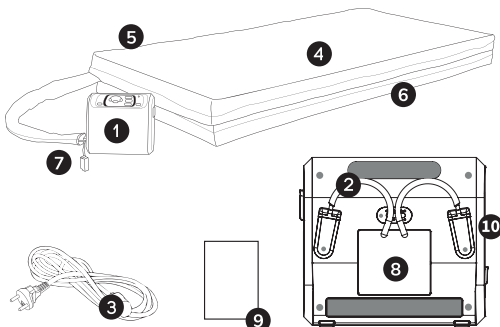
Hospitalized, institutionalized or home-based adults of over 146 cm in height, with one or more pressure ulcers/injuries and/or at risk of developing pressure ulcers/injuries due to the transitory or definitive alteration of their condition. These people are cared for by health professionals, assisted by carers when necessary.

## Identify adverse side effects



Inform the competent authority if you consider or have reason to believe that the device poses a serious risk or has been tampered with. All serious incidents which are related to the device must be notified to the manufacturer and the competent authority of the member state in which the user and/or patient resides.

## 2. COMPOSITION DU DISPOSITIF MÉDICAL



- 1 Compressor.
- 2 Hooks system for hanging up to the medical bed.
- 3 Power supply cable.
- 4 Alternating cell mattress, 2 static cells in the head zone except for ONE PLUS & AUTOMORPHO PLUS.
- 5 4 foot zone cells with individual deflation valve, except ONE PLUS.
- 6 Polyurethane foam base except AXENSOR AT20 and XXL mattresses .
- 7 Pneumatic connector fitted with a plug for rebalancing support pressure when disconnected from the compressor. Automatic on AXENSOR. Provides CPR function on ONE PLUS and AUTO PLUS.
- 8 Regulatory identification labels.
- 9 Instruction for Use
- 10 Simplified instructions attached to the side of the compressor.

## 3. CLINICAL BENEFIT, PERFORMANCE, MECHANISM OF ACTION

### Device performance characteristics

- > Operating principle: "mechanical" effect based on the alternating inflation of the overlay mattress cells and the pneumatic management of the applied pressure.
- > The inflation level adjustment is automatic and based on the patient's morphology. No external intervention is required.

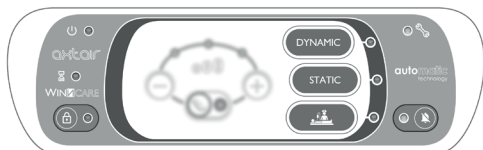
> "Dynamic" mode: alternating pressures prevent prolonged vascular compression that can lead to tissue hypoxia.

> Low pressure "static" mode: immobilization (orthopaedic, neurological trauma), local pain, withdrawal phases. This mode is not active when the compressor is connected to a cushion.

> "Care" mode: handling, performance of certain medical acts and transfers. This mode is not active when the compressor is connected to a cushion.

### Projected clinical benefits

- > Maintenance of tissue oxygenation in the anatomical areas in contact with the surface of the support by decreasing the pressure applied to the cutaneous and subcutaneous tissue.



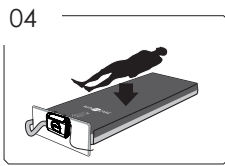
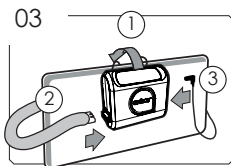
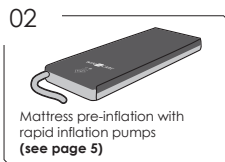
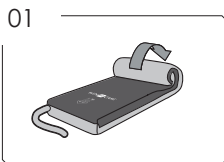
## 4. INSTRUCTIONS FOR USE

### User training and qualification

Users trained by individuals approved by the economic operators, notably in safety and non-compliance reporting aspects

### Device Installation

- › Check compressor and (overlay) mattress compatibility (see "technical specifications" table)



- › In the case of inflation of the mattress via the compressor the self-inflation phase can take 20 min for a 90 cm wide mattress and 30 minutes for a 120 cm wide mattress. Wait for this time before installing the patient.
- › In the case of pre-inflation of the mattress by a rapid inflation pump, the patient can be installed at the end of the installation of the dynamic mattress.

- › Assess the risk of patient entrapment in non-moving parts according to IEC 60601-2-52 (the requirements of figures 201.107, 201.108 and Table 201.101 are excluded)

### Cleaning and disinfection

- › Between each patient.
- › Bio-cleaning or steam process.
- › Surface detergent and disinfectant products conforming to requirements of Regulations (UE) n°648/2004 et n°528/2012.
- › Prohibit the high-pressure jet process.
- › Prohibit colouring, industrial degreasers, abrasive and solvent-based products.
- › Mattresses ONEP and AUTOP are washable (65°C - 750 rpm) Contact Winnicare Services for full protocol

### Preventive maintenance

- › Check the device every 2 years of use or after 17500 hours of operation (Indicator: maintenance key led).
- › Contact the manufacturer or distributor in regard to the AIRCARE maintenance solution (training, software, connection kit, revision kit).
- › Lifespan 6 years.
- › See Technical Manual (Downloadable from [www.winnicare.com](http://www.winnicare.com))



## 5. WARNINGS, PRECAUTIONS FOR USE

### Precautions for use

- › Use static low pressure mode in the case of non-stabilized bone and/or muscle injuries in contact with the support, and in initial days of post pressure ulcer/injury surgery (skin graft or flap).
- › Identify a caregiver who can intervene in the event of a technical or medical problem in the patient's home.
- › For patients weighing more than 135 kg in a semi-seated position (> 45°), check that there is no contact between the gluteal area and the base of the bed by means of a "trial and error" test, with the hand placed palm upwards between the gluteal area and the base.
- › Place a sheet between the mattress protection cover and the patient.

### Warning

- › If the device alarm LED is flashing or fixed contact your maintenance department as quickly as possible in order to carry out the appropriate troubleshooting.
- › Installation and commissioning according to the EMC information provided by WINNCARE FRANCE on request.
- › Only use accessories and cables supplied and/or specified by WINNCARE FRANCE.
- › Observe the storage and operating conditions specified by WINNCARE FRANCE.
- › Associate the compressor reference with its support.

### Action required

#### The support alone is not enough to prevent bedsores:

- › Change position at least every 2 to 3 hours,
- › Maintain skin hygiene and avoid maceration,
- › In case of incontinence, change protection regularly,
- › Ensure a sufficient and appropriate diet,
- › Drink regularly and in sufficient quantities,
- › Avoid unnecessary thickness and foreign objects between the body and support.

### Notify your doctor or nurse

- › Of any abnormal event (fever, pain, redness, or whitening of the support points of your body with the support)
- › If the required measures for use of the medical device cannot be observed.





Indicates the compressor is switched on.



Flashes to indicate inflation of the support.  
After switch-off, the patient can be installed.



Indicator light on: keypad automatically locked after 5 minutes of continuous 4 second press.  
Unlocking: continuous 4 second press.



Care mode (static): mode duration limited to 30 minutes.  
Idle mode when the compressor is connected to a cushion.



Care mode indicator flashes 5 minutes before the end.  
Audible signal emitted when triggered.  
After 30 minutes: switches to the previously used mode.



Fixed LED: Low priority alarm. Contact the maintenance department.



Flashing LED: Medium priority alarm. Remove the patient.  
Contact the maintenance department.

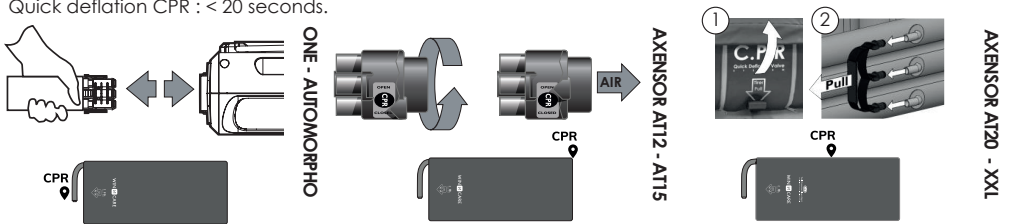


Press button: stops sound alarm.  
Moderate alarm: reactivation after 3 minutes.

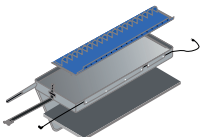
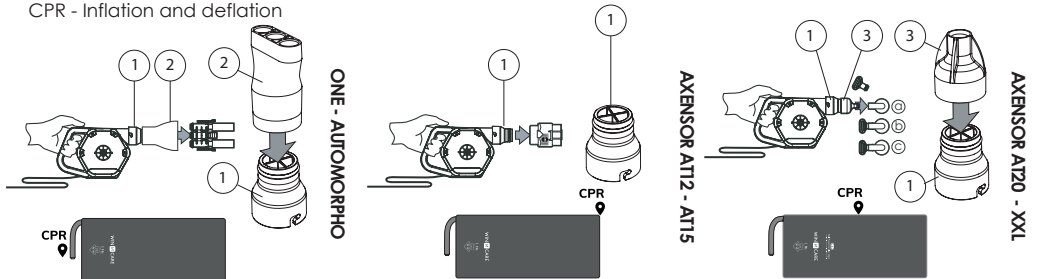


See Technical Manual (Downloadable on [www.winncare.com](http://www.winncare.com))

CPR - Emergency: CPR opening depending on mattress type - Warning: Closed position during use.  
Quick deflation CPR : < 20 seconds.



CPR - Inflation and deflation



Cable holder available as standard on AUTOP - AT20 and XXL mattresses.  
Available as an option on all other mattresses, except for the ONEP model.



Caution, read the user manual and (or) the technical manual.



Category II device (Dual insulation)



BF type electrical device (applied to supports)



Complies with the general requirements of Regulation (EU) 2017/745 relating to medical devices



Caution, electrical and electronic equipment subject to selective waste collection



Manufacturer



Manufacture country - France



Serial number



Batch number



Medical Device



Unique ID of the device



Patient weight range



Maximum load

**IP42**

Protection class IP42 according to IEC 60529



**Applicable to top cover only**

Wash with water, T° max 90°C, reduced mechanical action, reduced temperature rinsing, reduced spin.



**Applicable to the complete mattress ( compatible machine washing)**

Machine wash, max. temperature 65°C, reduced mechanical action, rinsing at decreasing temperature, reduced spinning (750 rpm)



**Applicable to the complete mattress ( compatible machine washing) and Cover.**

Tumble drying allowed, moderate temperatures (60°C)



Bleaching possible, chlorination at 5000 ppm allowed.

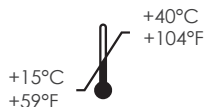


Ironing excluded.



Dry cleaning not allowed, use of solvent-based stain remover not allowed.

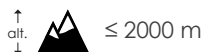
## Use



Temperature range



Hydrometric range



Maximum Altitude

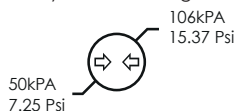
## Storage



Temperature range



Hydrometric range



Atmospheric pressure range

**P.max**  
User



mmHg

165 Kg	min.	0	15	13
364 Lb	max.	29	51	42

**P.max**  
User



mmHg

180 Kg	min.	4	12	24
397 Lb	max.	37	63	57

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Distributor

