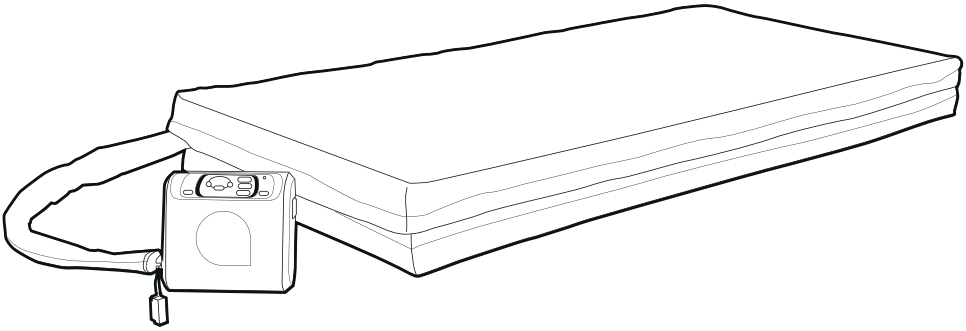
GB

Axtair One®Plus
Axtair Automorpho®Plus
Axtair Axensor® AT12/AT15/AT20
Axtair XXL®



FR

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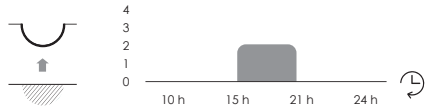
CE

Version 4 12/10/2023

Axtair One®Plus

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

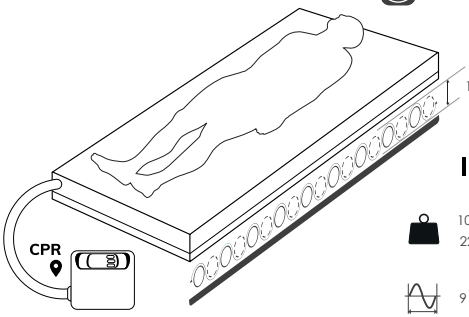


Alternating cycle frequency: 1 cell out of 2

30-165 Kg
67-364 Lb

= 210 Kg - 463 Lb

< 35 dBA



12 cm

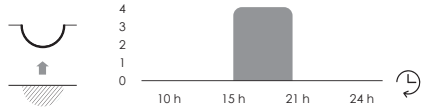
IP42

10.6 kg
22 Lb

9 - 14 mn

Axtair Automorpho®Plus

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

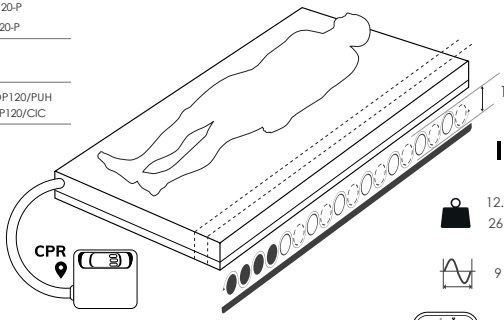


Alternating cycle frequency: 1 cell out of 2

30-180 Kg
67- 397 Lb

= 225 Kg - 496 Lb

< 35 dBA



12 cm

IP42

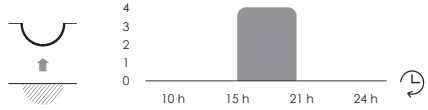
12.5 < 15.8 kg
26.4 < 33 Lb

9 - 15 mn

Care mode

Axtair Axensor® AT12

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

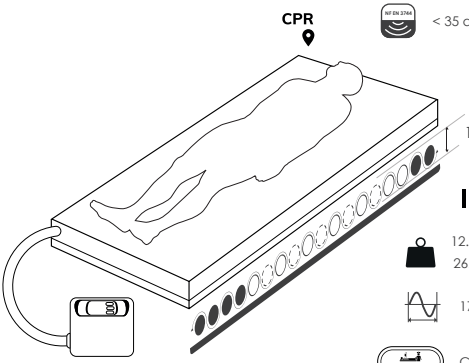


Alternating cycle frequency: 1 cell out of 2

30-165 Kg
67- 364 Lb

= 210 Kg - 463 Lb

< 35 dBA



12 cm

IP42

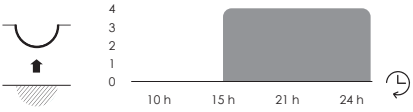
12.6 kg
26.4 Lb

17 - 20 mn

Care mode

Axtair Axensor® AT15

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



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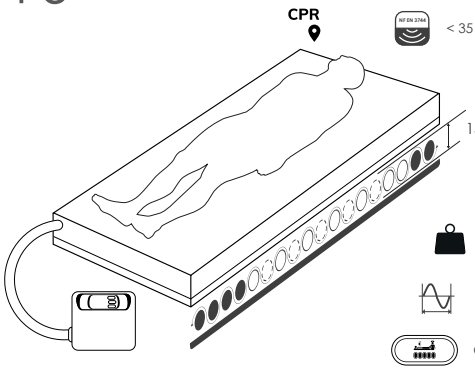


30-180 Kg
67-397 Lb

= 225 Kg - 496 Lb

< 35 dBA

IP42

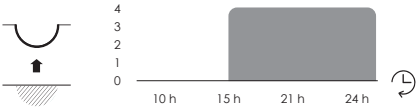
14 kg
31 Lb

17 - 20 mn

Care mode

Axtair Axensor® AT20

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



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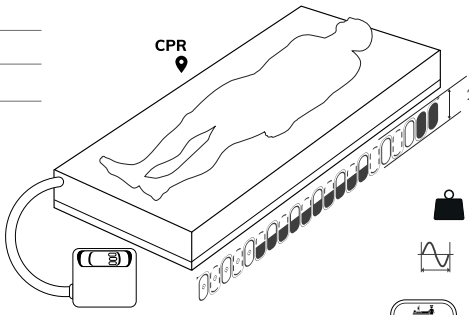


30-200 Kg
67-441 Lb

= 245 Kg - 540 Lb

< 35 dBA

IP42

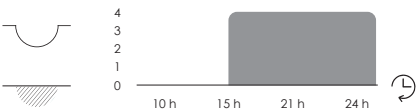
14 kg
31 Lb

17 - 20 mn

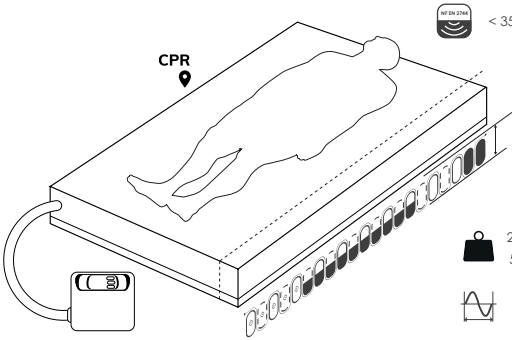
Care mode

Axtair XXL®

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



Alternating cycle frequency: 1 cell out of 2



100-270 Kg
220-595 Lb

= 315 Kg - 695 Lb

< 35 dBA

IP42

23.5 < 25.5 kg
50.7 < 55 Lb

9 - 15 mn

Care mode

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/injurie, 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.

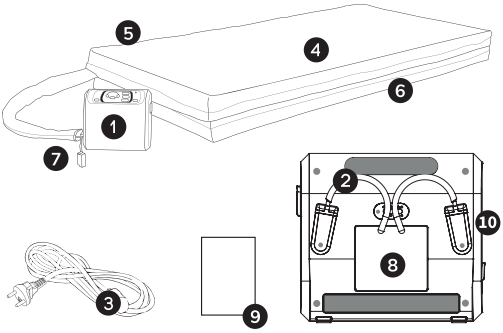
Target group of patients and users

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



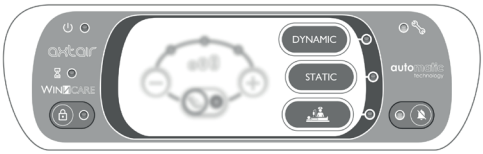
1. Compressor.
2. Hooks system for hanging up to the medical bed.
3. Power supply cable.
4. Alternating cell mattress, 2 static cells in the head zone except for ONE PLUS & AUTOMORPHO PLUS.
5. 4 foot zone cells with individual deflation valve, except ONE PLUS.
6. Polyurethane foam base except AXENSOR AT20.
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. User manual.
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

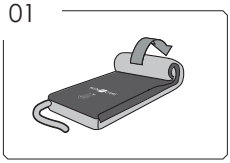
User training and qualification

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

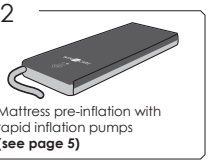
Device Installation

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

01

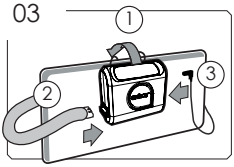


02

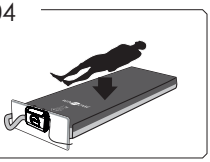


Mattress pre-inflation with rapid inflation pumps **(see page 5)**

03



04



› 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 Winncare 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).

› See Technical Manual (Downloadable from www.winncare.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.

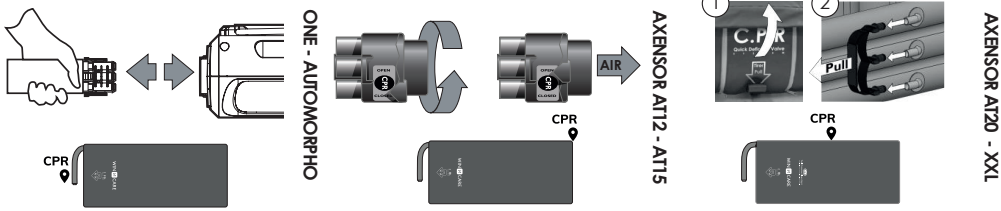
Fixed LED: Low priority alarm. Contact the maintenance department.

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

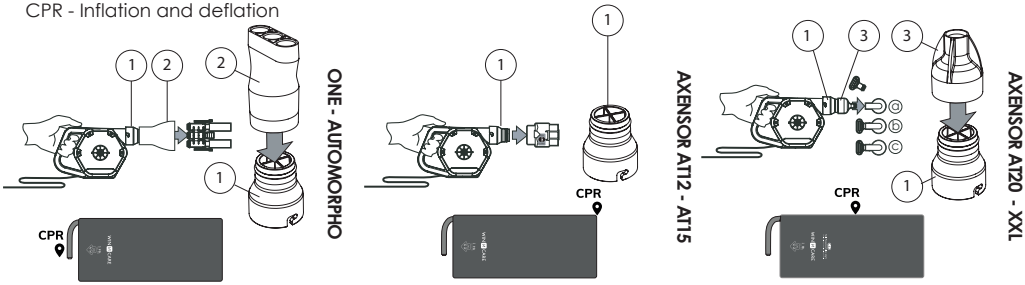
Press button: stops sound alarm.
Moderate alarm: reactivation after 3 minutes.

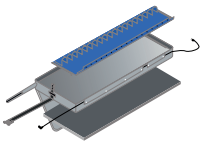
See Technical Manual (Downloadable on www.winncare.com)

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

FR Manufacture country - France

SN Serial number

LOT Batch number

MD Medical Device

UDI Unique ID of the device

Patient weight range

Maximum load

IP42 Protection class IP42 according to IEC 60529

90°

Applicable to top cover only
Wash with water, T° max 90°C, reduced mechanical action, reduced temperature rinsing, reduced spin.

65°

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)

CL
≤5000ppm

Bleaching possible, chlorination at 5000 ppm allowed.

Ironing excluded.

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

Use

+40°C
+104°F
+15°C
+59°F

Temperature range

95%
30%

Hydrometric range

alt. ≤ 2000 m

Maximum Altitude

Storage

+ 70°C
+158°F
- 25°C
-77°F

Temperature range

95%
30%

Hydrometric range

106kPA
15.37 Psi
50kPA
7.25 Psi

Atmospheric pressure range

P.max User		○	▭	⌟ mmHg
165 Kg 364 Lb	min.	0	15	13
	max.	29	51	42

P.max User		○	▭	⌟ mmHg
180 Kg 397 Lb	min.	4	12	24
	max.	37	63	57

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REP

Distributor

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