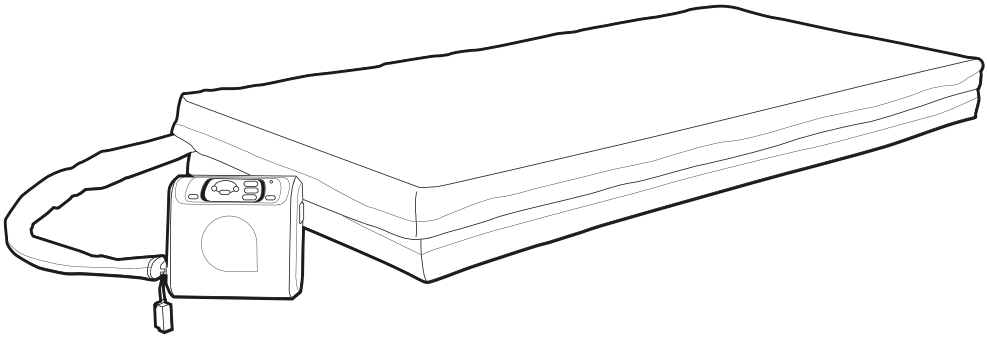
EN

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

Technical manual



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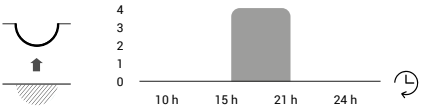
CE

Version 7 31/10/2024

Axtair One® Plus

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



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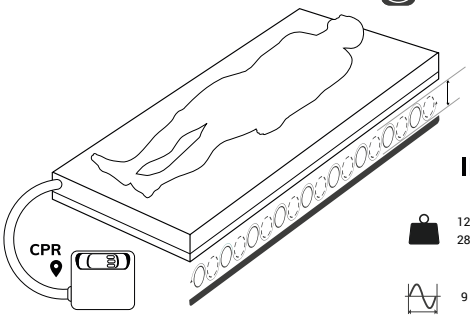


30-165 Kg
67-364 Lb

210 kg - 463 Lb

<35 dBA

12 cm

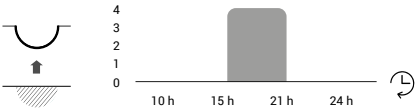
IP42

12,7 Kg
28 Lb

9 - 14 min

Axtair Automorpho® Plus

	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



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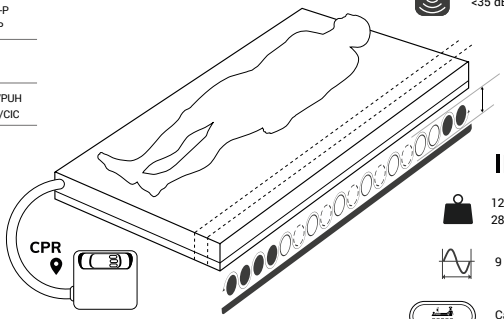


30-180 Kg
67-397 Lb

225 Kg - 496 Lb

<35 dBA

12 cm

IP42

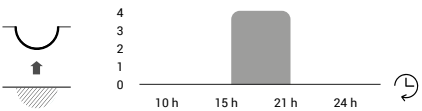
12,7 < 16 Kg
28 < 35,3 Lb

9 - 15 min

Care mode

Axtair Axensor® AT12

	VAXT6/AUTO-S	VAXT6/AUTO-80-S
	VAXT6/POMPE/AUTO-S	
	VAXT6/MA/AUTO	VAXT6/MA/AUTO-80



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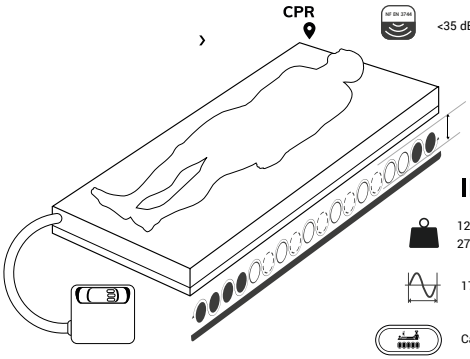


30-165 Kg
67-364 Lb

210 Kg - 463 Lb

<35 dBA

12 cm

IP42

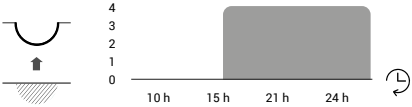
12,6 Kg
27,8 Lb

17 - 20 min

Care mode

Axtair Axensor® AT15

VAXT6/MAX-S	VAXT6/MAX-DV-S
XT6/POMPE/AUTO-S	
VAXT6/MA/MAX	VAXT6/MA/MAX-DV



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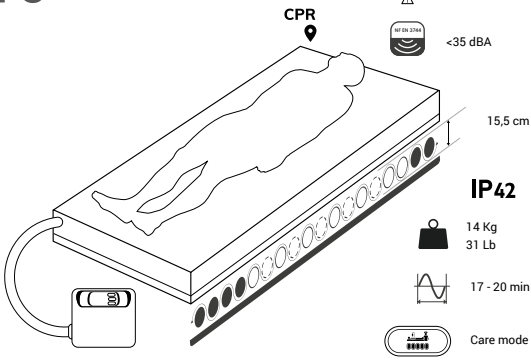


= 30-180 Kg
67-397 Lb

= 225 Kg - 496 Lb

<35 dBA

15,5 cm

IP42

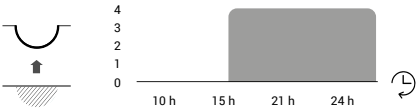
14 Kg
31 Lb

17 - 20 min

Care mode

Axtair Axensor® AT20

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



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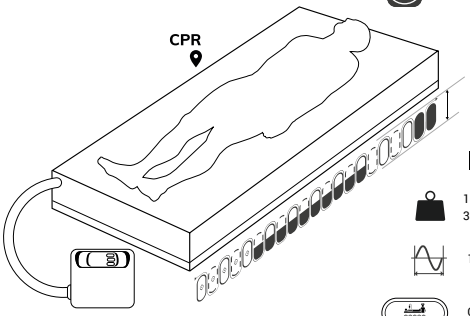


= 30-200 Kg
67-441 Lb

= 245 Kg - 540 Lb

<35 dBA

20 cm

IP42

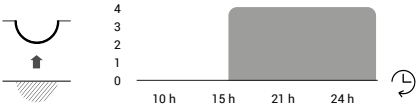
14,2 Kg
31,3 Lb

17 - 20 min

Care mode

Axtair XXL®

VAXT/XXL-120	VAXT/XXL-140
VAXT/POMPE/XXL	
VAXT/MA/120XXL	VAXT/MA/140XXL



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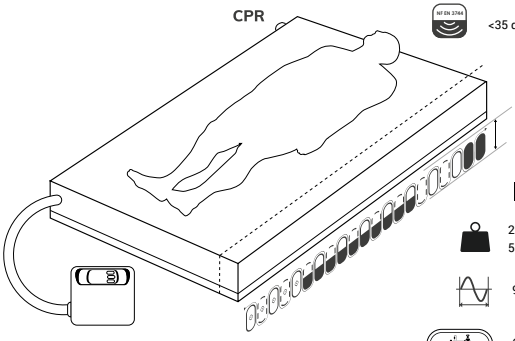


= 100-270 Kg
220-595 Lb

= 315 Kg - 695 Lb

<35 dBA

20 cm

IP42

23,5 < 25,5 Kg
51,8 < 56,2 Lb

9 - 15 min

Care mode

1. INDICATIONS

Device intended use

Pressure area management systems and associated pumps are 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 instructions for use front cover)

Contraindications

Patient with a minimum or maximum weight other than those tolerated by the mattress/cushion. Non-stabilized post-traumatic fractures, with dynamic mode. For use in hyperbaric chambers and on stretchers.

Intended target patient population

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.

Intended target group of users

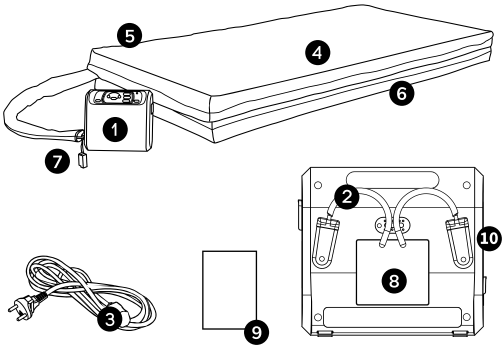
Healthcare professionals, assisted by carers where necessary.

Undesirable effects

Inform the competent authority if you believe or have reason to believe that the device presents a serious risk or that it 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. MEDICAL DEVICE COMPOSITION



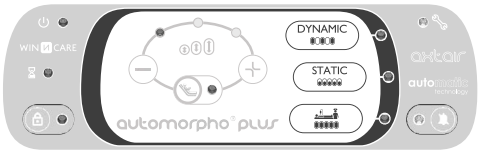
1. Compressor.
2. Hooks system for hanging up to the medical bed.
3. Power supply cable.
4. Alternating-cell mattresses, with two static head cells (except on One Plus).
5. Heel discharge cells with individual deflation valves (4 for Automorpho Plus, AT12, and AT15; 5 for AT20; 0 for One Plus).
6. Polyurethane foam base (except for 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 Automorpho Plus.
8. Regulatory identification labels.
9. Instruction for use (IFU).
10. Simplified instructions attached to the side of the compressor.

3. CLINICAL BENEFIT, PERFORMANCE, MECHANISM OF ACTION

Device performance characteristics

› Operating principle: alternating pressure supports that alternately inflate and deflate the cells.

› The inflation pressure adjustment is automatic thanks to a system that controls the supply and the value of the insufflated air pressure, adapting the inflation pressure to the patient's morphotype at start-up without any external intervention.



› « **Dynamic** » mode: alternating pressure prevent prolonged vascular compression that can lead to tissue hypoxia.

› Low pressure « **Static** » mode: immobilization (orthopaedic, neurological trauma), local pain, withdrawal phases.

› « **Care** » mode: handling, performing of certain medical procedures and transfers.

Expected clinical benefits

› Maintains tissue oxygenation in anatomical areas in contact with the surface of the support by reducing the pressure applied to the skin and subcutaneous tissue.

4. INSTRUCTIONS FOR USE

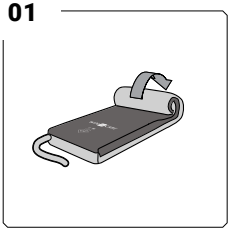
User training and qualification

All users (health professionals or not) must be trained by individuals approved by the economic operators in the use of the functions to which they have access, notably in safety and non-compliance reporting aspects.

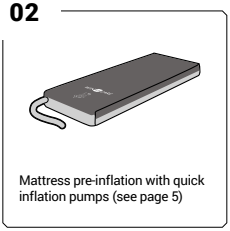
Device Installation

› Check compressor and mattress compatibility.

01

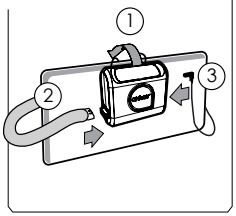


02

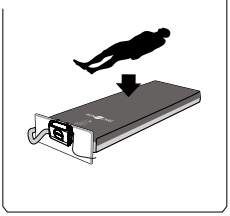


Mattress pre-inflation with quick inflation pumps (see page 5)

03



04



› In the case of inflation of the mattress via the compressor the self-inflation phase can take 20 minutes 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 quick inflation pump, the patient can be installed at the end of the installation of the dynamic mattress.

Cleaning and disinfection

› To be carried out before the first use, and between each patient.

› Refer to WINNCARE Services sheets Cleaning Disinfection Air Mattresses n° 060 (protective cover n° 063).

› Consult the Technical Manual.

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).

› Lifetime: 6 years.

› 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/cushion protection cover and the patient.

Warnings

› 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 (electromagnetic compatibility) information provided by WINNCARE France on request.

› Observe the storage and operating conditions specified by WINNCARE France.

› Only use accessories and cables and cover supplied and/or specified by WINNCARE France to maintain the characteristics of the medical device.

› Associate the compressor reference with its support.

› (Re)assess the risk of patient entrapment in non-moving parts of the medical bed associated with bedrails and therapeutic mattresses (EN 60601-2-52 standard for adults).

› When cleaning and disinfecting, do not use high-pressure jets.

Action required

The support alone is not enough to prevent pressure ulcer/injury:

› Observe the condition of the skin in contact with the support surface several times a day.

› 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.

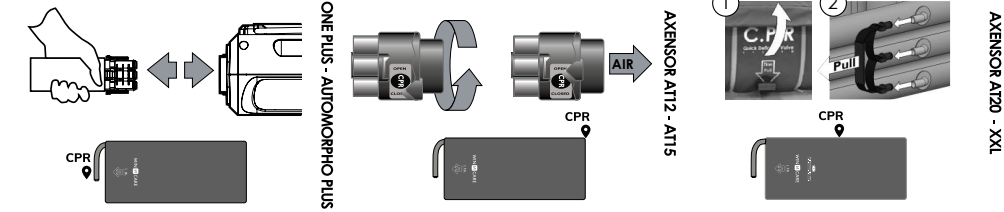
Notify your doctor or nurse

› Of any abnormal event (fever, pain, redness, or whitening of the support points of your body with the support surface).

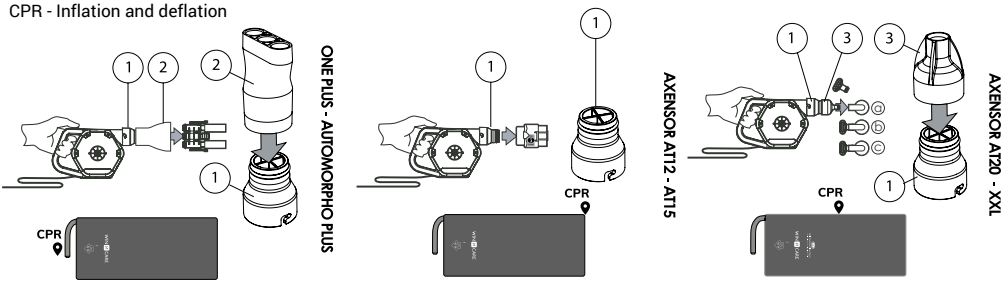
› If the required measures for use of the medical device cannot be observed.

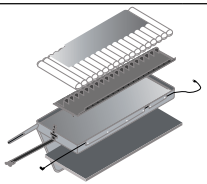
	Indicates the compressor is switched on.
	Flashes to indicate inflation of the support. After switch-off, the patient can be installed.
	Locking system: Indicator light on: keypad automatically locked after 5 minutes of continuous 4 second press. Unlocking: continuous 4 second press.
	Care mode (static): mode duration limited to 30 minutes.
	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





Lateral cable pass available as standard on Automorpho Plus, AT20 and XXL mattresses.
Available as an option on all other mattresses, except for the One Plus model.

Caution, read the instruction for use and/or the technical manual.

Category II device (Dual insulation).

BF type electrical device (applied to supports).

Complies with the general requirements of Medical Devices Regulation (EU) 2017/745.

Caution, electrical and electronic equipment subject to selective waste collection.

Manufacturer

Manufacture country - France

SN Serial number

LOT Batch number

MD Medical Device

UDI Unique device identifier

Patient weight range

Safety working load

IP42 Protection class IP42 according to IEC 60529.

90° **Applicable to top cover only**
Machine wash, T° max 90°C, reduced mechanical action, rinsing at decreasing temperature, reduced spinning.

65° **Applicable to the complete mattress (compatible machine washing)**
Moderate wash up to 65°C.

Applicable to the complete mattress (compatible machine washing) and cover
Tumble dry on low heat, moderate temperatures (60°C).

CL ≤5000ppm Maximum allowable chlorine concentration of 5000 ppm.

Do not iron

Do not dry clean

Use

+40°C +104°F
+15°C +59°F
Temperature limit

95%
30%
Humidity limitation

alt. ≤ 2000 m
Maximum Altitude

Storage

+70°C +158°F
-25°C -13°F
Temperature limit

95%
30%
Humidity limitation

106kPA 15.37 Psi
50kPA 7.25 Psi
Atmospheric pressure limitation

Maximum patient weight		mmHg		
165 kg 364 Lb	max.	29	51	42

Maximum patient weight		mmHg		
180 kg 397 Lb	max.	37	63	57

WIN N CARE

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