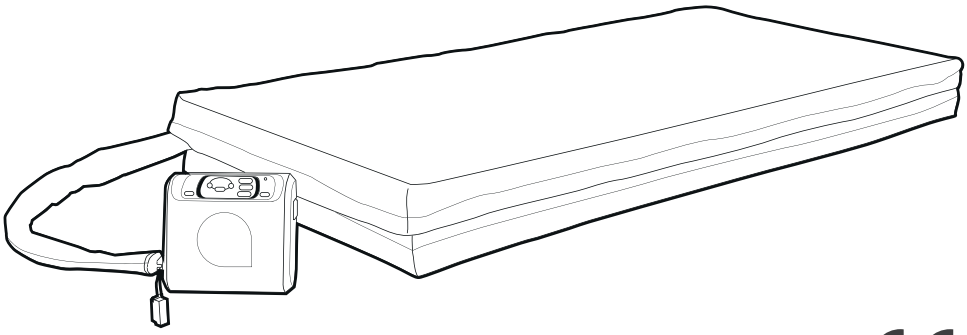
GB

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



CE

WINNCARE FRANCE - Site ASKLÉ SANTÉ
200 Rue Charles Tellier - Actiparc de Grézan
30034 Nîmes Cedex 1
FRANCE

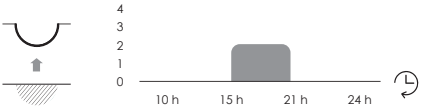
Tél. : +33 (0)4 66 02 15 15
Fax. : 33 (0)4 66 02 15 00
Email : contact@winncare.com
www.winncare.com

PA0010157

MAJ 21/10/2021 GB

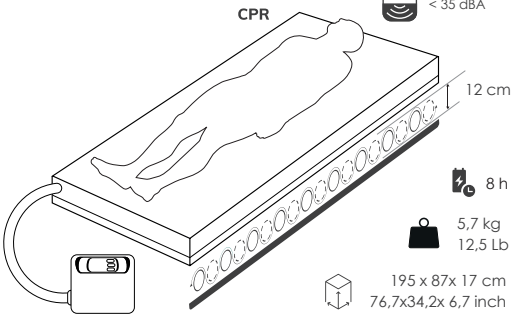
Axtair One®Plus

	VAXT2/ONE-P	VAXT2/ONE/CIC-P
	VAXT/POMPE/ONEP	
	VAXT2/MA/ONE	VAXT2/MA/ONE/CIC



30 ≤ 150 Kg
66 ≤ 330 Lb

< 35 dBA



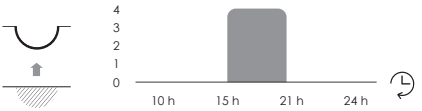
8 h

5,7 kg
12,5 Lb

195 x 87x 17 cm
76,7x34,2x 6,7 inch

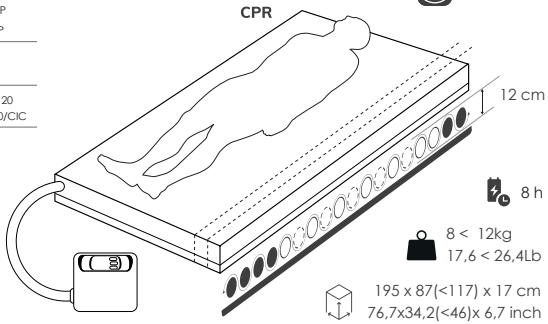
Axtair Automorpho®Plus

	VAXT4/AUTO-P VAXT4/CIC-P	VAXT4/AUTO100-P VAXT4/CIC100-P	VAXT4/AUTO120-P VAXT4/CIC120-P
	VAXT/POMPE/AUTO		
	VAXT/MA/AUTOP VAXT/MA/AUTOP/CIC	VAXT/MA/AUTOP100 VAXT/MA/AUTOP100/CIC	VAXT/MA/AUTOP120 VAXT/MA/AUTOP120/CIC



30 ≤ 165 Kg
66 ≤ 364 Lb

< 35 dBA



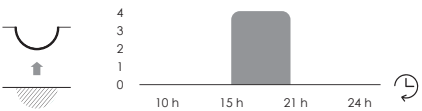
8 h

8 < 12kg
17,6 < 26,4Lb

195 x 87(<117) x 17 cm
76,7x34,2(<46)x 6,7 inch

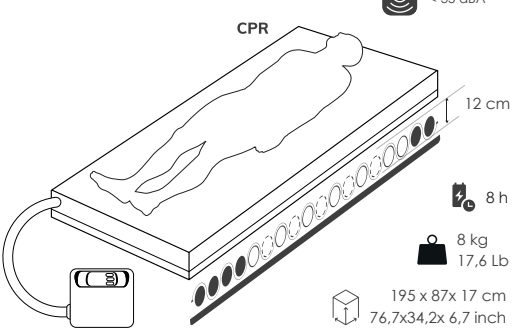
Axtair Axensor® AT12

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



30 ≤ 165 Kg
66 ≤ 364 Lb

< 35 dBA



8 h

8 kg
17,6 Lb

195 x 87x 17 cm
76,7x34,2x 6,7 inch

Axtair Axensor® AT15

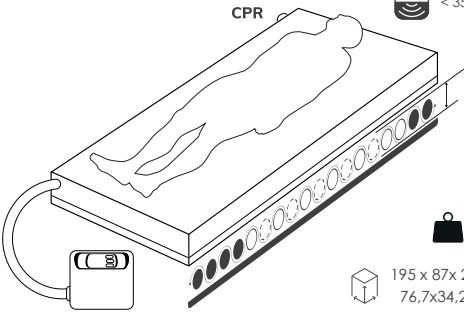
30 ≤ 180 Kg
66 ≤ 396 Lb

< 35 dBA

VAXT6/MAX VAXT6/MAX-S

VAXT6/POMPE/AUTO VAXT6/POMPE/AUTO-S

VAXT6/MA/MAX

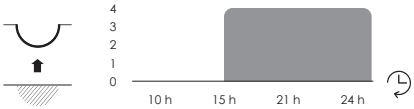


15,5 cm

8 h

10 kg
22 Lb

195 x 87x 20,5 cm
76,7x34,2x8 inch



Axtair Axensor® AT20

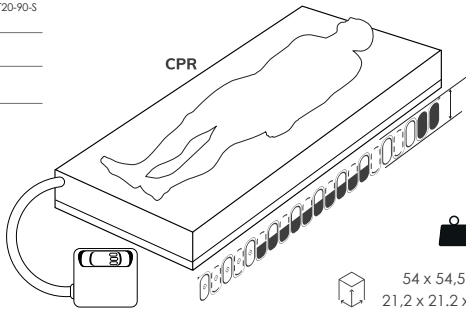
30 ≤ 200 Kg
66 ≤ 440 Lb

< 35 dBA

VAXT6/AT20-80 VAXT6/AT20-90 VAXT6/AT20-80-S VAXT6/AT20-90-S

VAXT6/POMPE/AUTO VAXT6/POMPE/AUTO-S

VAXT6/MA/AT20-80 VAXT6/MA/AT20-90

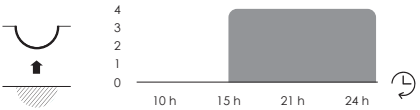


20,5 cm

8 h

10kg
22 Lb

54 x 54,5 x 56 cm
21,2 x 21.2 x 22 inch



Axtair XXL®

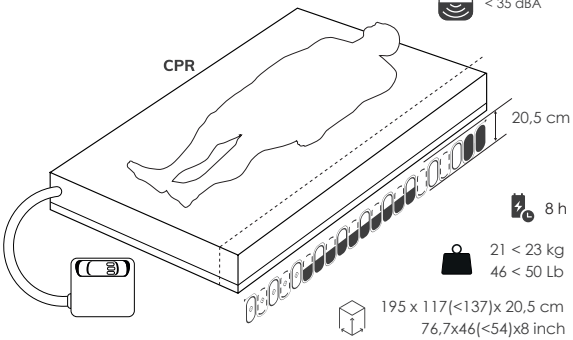
100 ≤ 270 Kg
220 ≤ 595 Lb

< 35 dBA

VAXT/XXL120 VAXT/XXL140

VAXT/POMPE/XXL

VAXT/MA/120XXL VAXT/MA/140XXL

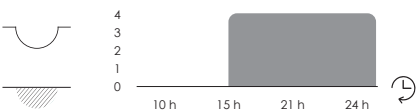


20,5 cm

8 h

21 < 23 kg
46 < 50 Lb

195 x 117(<137)x 20,5 cm
76,7x46(<54)x8 inch



1. INDICATIONS

Device intended use

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

Indications

Prevention and support for the treatment of stage 1 to 4 pressure ulcers (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 sore, assessed according to a proven scale and based on clinical judgement.
(See diagrams on the inside front cover)

Contraindications

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

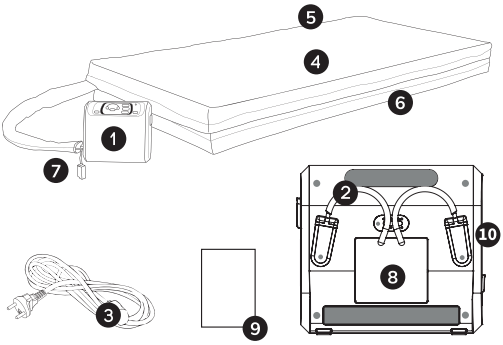
Target group of patients and users

Hospitalized, institutionalized or home-based adults of over 146 cm in height, with one or more pressure sores and/or at risk of developing pressure sores 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.

2. MEDICAL DEVICE COMPOSITION



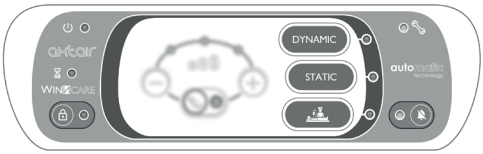
1. Compressor
2. Systems for attaching to the sides of the medical bed
3. Power supply cable
4. Alternating cell mattress,
   2 static cells in the head zone
   4 static cells in the foot zone
5. Individual deflation valve
6. Polyurethane foam base
7. Pneumatic connector fitted with a plug for rebalancing support pressure when disconnected from the compressor.
8. Identification labels, Dirty/clean label,
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

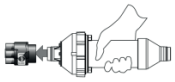
Users trained by individuals approved by the economic operators, notably in safety and non-compliance reporting aspects

Device Installation

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

01

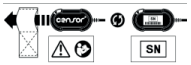
02



03

04

Axensor AT12, AT15, AT20



05

Open Close

06

› 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.

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

› Non-stabilized bone and/or muscle injuries in contact with the support.

› Initial days of post pressure ulcer surgery (skin graft or flap) [Prefer static low pressure mode].

› Home-based care without the possibility of medical assistance.

› Bedridden patient weighing more than 135 kg in a semi-seated position > 45°: check the absence of contact with the bed base via a "judged" test by placing the hand palm upwards between the gluteal area and the support. "Comfort" setting can be used to add air.

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 on request.

› Only use accessories and cables supplied and/or specified by WINNCARE

› Observe the storage and operating conditions specified by Winncare.

› Associate the compressor reference with its support: (technical data tables)

Action required

The support alone is not enough to prevent bed sores:

› 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

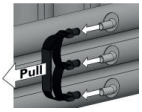
› Of any abnormal event (fever, pain, redness, or whitening of the support points of your body with the support)

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

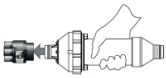
Indicates the compressor is switched on

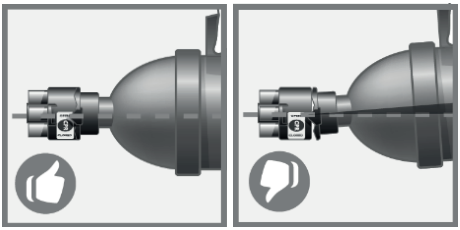
Flashes to indicate inflation of the support
After switch-off, the patient can be installed

CPR (emergency or withdrawal)
Open position for inflation or deflation
Closed position during use.

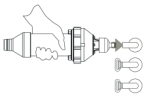


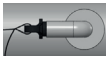
AXENSOR AT20 - XXL





VAXT4 / VAXT6





AXENSOR AT20 - XXL

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

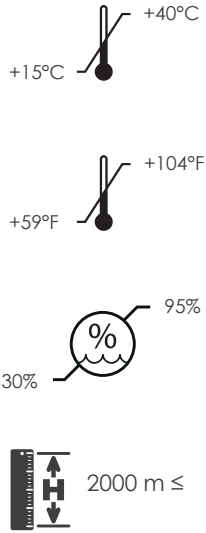
Flashing LED: Medium priority alarm. Remove the patient.
Contact the maintenance department

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

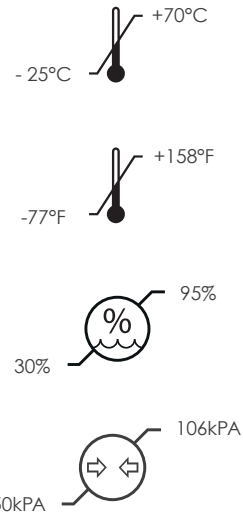
See Technical Manual (Downloadable on www.winncare.com)

	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
	Manufacture date
	Serial number
	Batch number
	Patient weight range
	Warning
	Wash with water, T° max 90°C, reduced mechanical action, reduced temperature rinsing, reduced spin.
	Bleaching possible, chlorination at 5000 ppm allowed.
	Ironing excluded.
	Dry cleaning not allowed, use of solvent-based stain remover not allowed.
	Tumble drying allowed, moderate temperatures (60°C)

Use



Storage



WIN N CARE

FRANCE

4, Le Pas du Château 85670 Saint Paul Mont Penit - FRANCE
Tél : +33 (0)2 51 98 55 64

ESPAGNE

Ctra. Masía del Juez 37b 46909 Torrent Valencia - ESPAGNE
Tél : +34 9 61 56 55 21

POLOGNE

ul. Lubska 17PL 68-320Jasień - POLOGNE
Tél : +48 68 371 10 45

DANEMARK

Tårnborgvej 12C DK-4220 Korsør - DANEMARK
Tél : +45 70 27 37 20

ROYAUME UNI

Unit 15 Gregory Way Stockport, Cheshire, SK5 7ST - UNITED KINGDOM
Tél : +44 161 477 7900

REP

Distributor

www.winncare.com