

4 Le Pas du Château 85670 SAINT PAUL MONT PENIT

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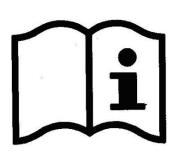
USER'S MANUAL WOODEN BARRIERS

A579-00 / A580-00 / A581-00 A676-00



A680-00







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Dear Sir/Madam,

You have acquired a WINNCARE medical accessory, and we thank you for your custom.

This class 1 medical device complies with Regulation (EU) 2017/745 relating to medical devices

They are tested in conformity with standard EN 60601-2-52 (2010) in their commercial configurations, including the boards and accessories that we manufacture, so as to ensure you maximum safety and performance.

As a result, maintenance of the contracted good's warranty depends on compliance with the conditions for use recommended by WINNCARE and the use of original accessories, which also guarantees you safe use of the medical bed and its accessories.

1. TRANSPORT CONDITIONS

During transport, the side rails must be strapped and protected by plastic packaging.

NB: stacking packages on the side rails is strictly prohibited.



Stacking packages weighing over 60kg/m² is strictly prohibited, irrespective of their position.

2. STORAGE CONDITIONS

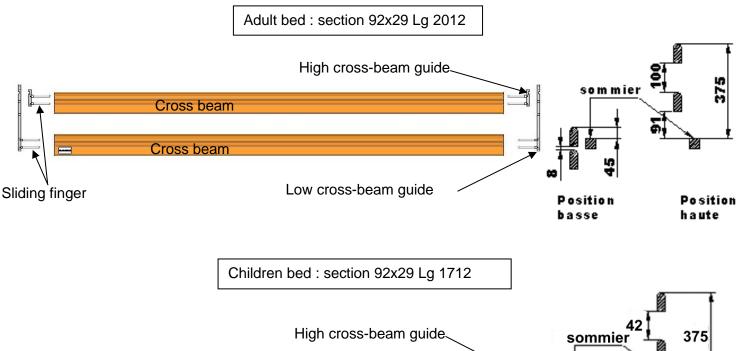
The side rails must be stored at a room temperature of between -10°C and +50°C, and relative humidity of between 30% and 75%.

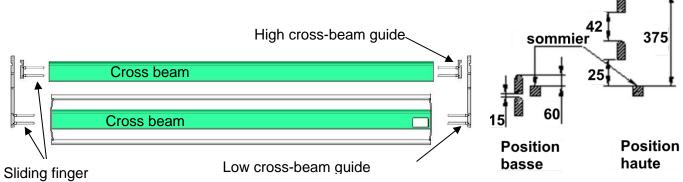
Atmospheric pressure between 700hPa and 1060hPa under the same conditions as for transporting.



3. ASSEMBLY CONDITIONS

3.1. General description







Be sure to check the position of the panels and the correct sliding of the barrier.

4. CONDITIONS FOR USE

4.1. Function

The side rails are designed to prevent patients from falling while asleep or being transported BUT are not designed to prevent a patient from leaving his or her bed voluntarily. Many accidents happen when the patient tries to leave his or her bed despite the side rails being in place. In some cases, the side rails helps to prevent falls, BUT it can pose a hazard: injuries, falling after trapping a

limb in the side rails, suffocation after trapping the head, neck or chest. A risk/benefit assessment should preferably be carried out of the side rails to decide whether or not to use it.



These barriers must be provided if specified in the medical prescription. The benefit/risk ratio must be reassessed every 24 hours.

Barriers that go from the patient's feet to their head are recommended for children who have lost their autonomy.

This assessment must take the following into account:

- the department's surveillance capacities: A standardized protocol of the establishment for using the side rails may be drawn up.
- the physical and mental condition of the patient: his/her needs, capacities, lucidity, size, agitation. This assessment should be repeated at regular intervals.

4.2. .Assembly of wooden barriers for junior bed A680-00 and adult beds A579-/A580-00 and A581-00

WINNCARE wooden barriers are designed to be used on all WINNCARE beds that have panels with recesses needed for their assembly



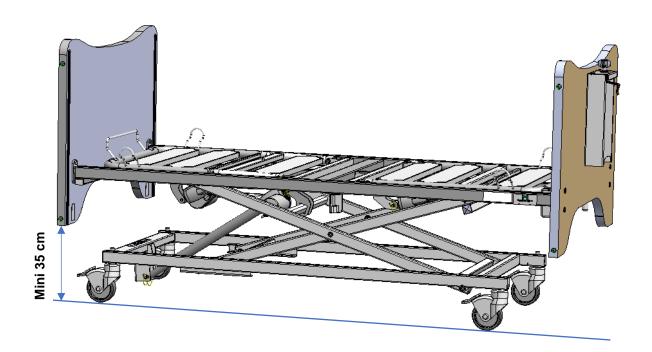
INCOMPATIBLE SIDE BARRIERS CAN CREATE HAZARDS.

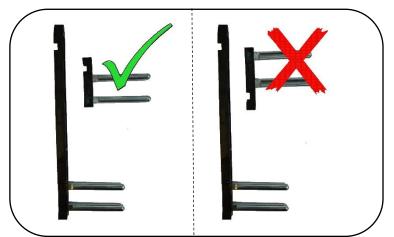
The wooden barriers are designed to be used on WINNCARE beds with a bed frame length of 1,700 mm for junior beds and 2,000 mm for adult beds that have panels with recesses needed for their assembly and that are not equipped with bed frame extensions.

The barrier has been tested in accordance with the test method of standards NF EN 50637 and NF EN 60601-2-52. These barriers must be combined with mattresses whose technical characteristics are included in the bed's instructions.

For installation of the wooden fence, refer to the attached installation instructions.

To facilitate the installation of the barrier, use the variable height of the bed up to a minimum height of 35 cm between the ground and the underside of the foot or head panel.

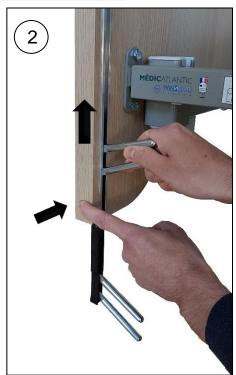






Make sure that the high cross-beam guide is engaged in the correct direction in the low cross-bar guide.





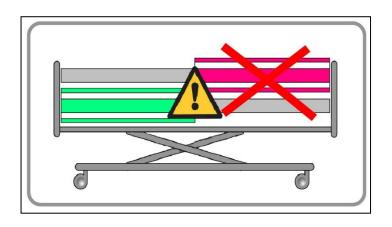




The assembly is identical for all full length wooden barriers and only

the barrier of the A680-00 junior bed is composed of a low wood / metal cross member to respect the standard spacings.

Respect the direction and the position of this element.

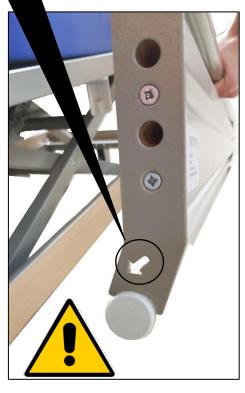




The element composed of the wood and metal bar is always placed in the lower part. The arrow down and to the inside of the bed



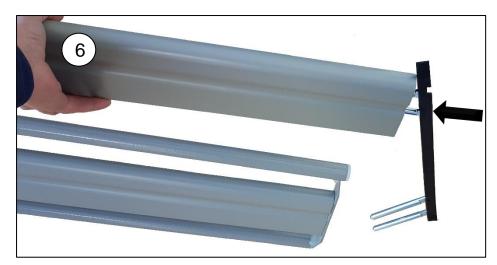




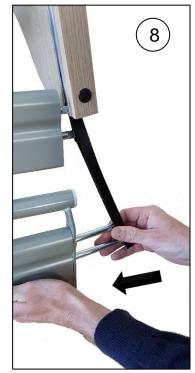














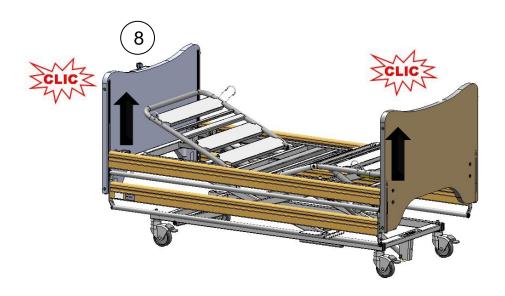




4.3. Use of the barrier

➤ To lower the side rail :

Take the upper bar and lift it up to its locking at the top of the panel. Check if it is properly engaged.



- > To lower the side rail:
- 1) I Lift the upper bar
- 2) Press the locking buttons of each panel.



1) Slide the barrier gently down the bed (make sure that no objects or parts of the patient's body or nursing staff are in the operating area) until the stop is stopped. The upper bar comes to rest on the lower metal / wood bar assembly.



4.4. Precautions for use



Positioning the side rails A579-00 / A580-00 / A581-00 poorly may undermine safety and cause a malfunction. Side rails must not be used when patients are not adults or are ≤ 146 cm tall.



Incorrect positioning of the A680-00 barriers can lead to safety hazards or malfunctions. **These** barriers are used for children with a height of between 125 cm and 145 cm for the "KALIN" junior medical bed.



The user and staff must be trained and aware of the risks associated with using the bed. He must not allow it by children and be vigilant when used by confused or disoriented people.



There must be at least 220 mm between the top of the side rail and uncompressed and no therapeutic mattress surface. It will be advisable to tend towards this specification in the case of the use of a therapeutic mattress.

The side rails must be used by someone outside of the bed, who must ensure that nothing or nobody is situated in the area in which the bed is being used.

Side rails are a medical device, and in this regard we inform you that it must not be modified under any circumstances. You must ensure its traceability. If you assemble different types of medical devices, you are responsible for conducting the risk analysis and making the CE declaration.

We recommend putting the bed in its low position after every use and while the patient is resting, to reduce the height of falls by a confused or agitated person.

For assistance, if necessary, in mounting, operation or maintenance or to report unexpected operation or events, call your supplier or Winncare.

4.5. Residual risks

DANGER	RESULT	REQUIREMENTS FOR THE USER
Trapping	Hands pinched	Handle barrier by the upper bar
Trapping	Crushing body or object	Check before lowering the barrier that the movement area is free

5. MAINTENANCE CONDITIONS

5.1. Identification Warning Manufacturer's address and Medical device) WINNCARE FRANCE MD SITE MEDICATLANTIC 4 LE PAS DU CHATEAU, ST PAUL MT PENIT, contact details 85670, FRANCE, +33(0)2 51 98 55 64 Complies with regulations (EU) Product reference and name REF XXXXX (ZZZZZ) PP Kg SN FR03YYMM/XXXXX Read the instruction manual COLOR : CCCC Product serial number (DDDD) YY: Year of manufacture PP: Product empty weight MM: Month of manufacture XXXXX :Internal numbering Color code and designation

A detailed examination must be carried out on the side rails at least once a year on such parts as: cross-beam guides, cross-beams and unlocking fingers.

5.3. Cleaning

High pressure cleaning, machine cleaning, washing tunnel or jet cleaning is prohibited.

Clean the structure with soapy water and a soft cloth then rinse and wipe dry. All aggressive or scouring products such as detergents, powders, solvents and bleach <u>are prohibited.</u>

5.4. Disinfection

Isolate the side rails in a disinfection room equipped with a particle filtering system and disposal for washing the floors and walls after disinfection.

Use a disinfectant with bactericidal, fungicidal and virucidal properties, either by spraying it evenly onto surfaces, applying it with a disposable cloth or spraying a disinfectant aerosol from a distance of 30 cm.

NB:

Comply with the precautions for using disinfectants indicated on these products.

Leavy to dry and protect the disinfected equipment from other equipment that has not been disinfected by a film and a label indicating the disinfection date.

5.5. Lifetime

The lifetime under normal conditions of use and maintenance is 5 years for accessories, especially for wooden side rails.

5.6. Warranties

- All of our products carry a warranty against any manufacturing defect, provided the normal conditions for use and maintenance are complied with.
- Labour costs due to changes in structures or parts under warranty are not taken into account.
- Please refer to the standard terms of sale for the specific terms of warranty for each product.
- Every time you contact us for possible maintenance, you must quote us the information on the identification label located under the cross-beam.
- Priginal parts shall be supplied for replacement, within the term of warranty, by our customer sales network determining the beginning of the term of warranty.
- Defective parts must be returned to ensure proper application of this warranty and also to avoid any invoicing.

6. CONDITIONS FOR SCRAPPING

- The product must be scrapped if the main requirements are no longer met, particularly when the product no longer has its original characteristics and has not been subject to corrective action during the manufacturing process.
- Measures should therefore be taken to ensure that the product is no longer used for the purpose it was originally intended.
- When scrapping, the current environmental standards must be complied with.



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