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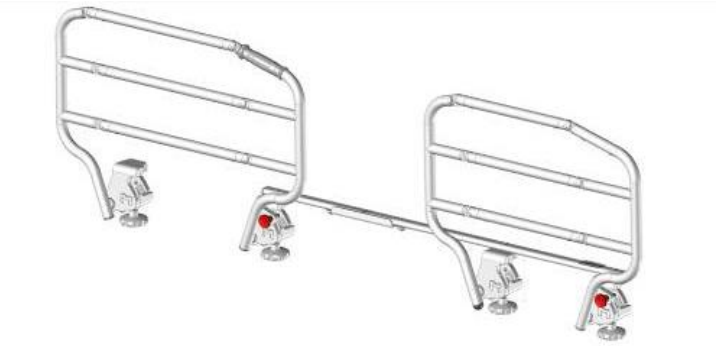
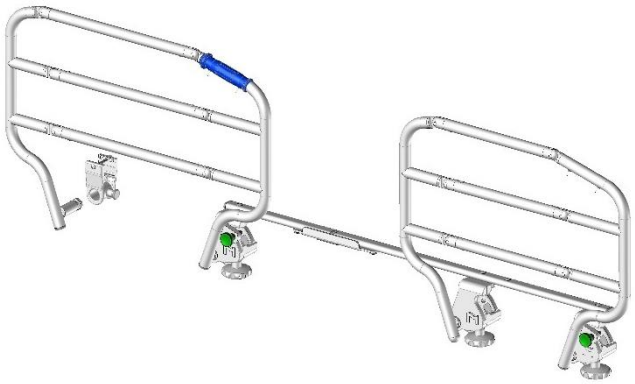
USER'S MANUAL
Mobility Support Systems

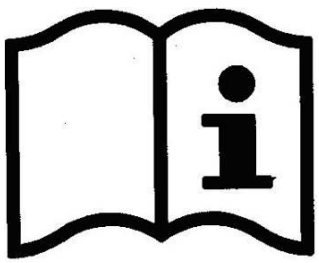
A611-00 / A612-00 SAM Evolution



A613-00
SAM Block

A645-00 / A646-00 SAM Evolution





Dear Sir/Madam,

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

Our medical support systems (MSSs) and their accessories are designed and manufactured in compliance with the essential requirements applicable thereto of European Directives 2007/47/EC.

They are tested in conformity with standard EN 60601-2-52 (2009) 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 boards and accessories, which also guarantees you safe use of the medical MSS and its accessories.

1. TRANSPORT CONDITIONS

During transport, the mobility support system must be strapped and protected by plastic packaging.

NB: stacking packages on the mobility support systems is strictly prohibited.

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

2. STORAGE CONDITIONS

The mobility support system 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

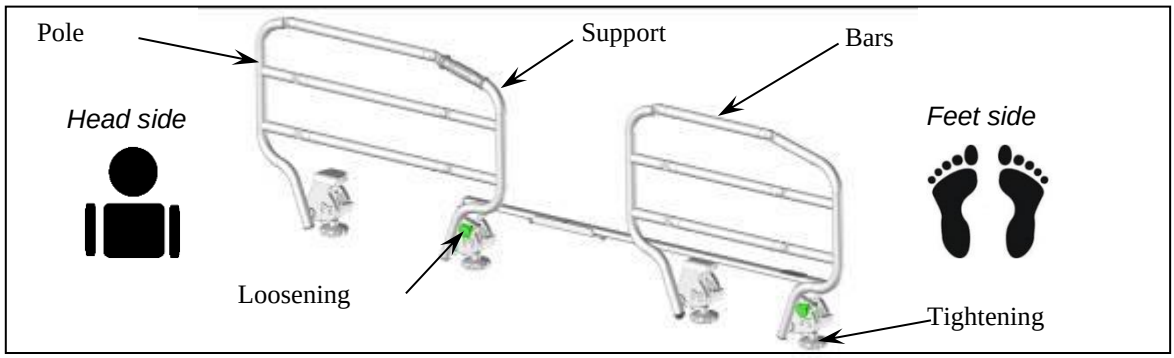
Only WINNCARE beds listed below are compatible with SAMs :

Bed reference	SAMs reference	Bed reference	SAMs reference
IAL1L*	A611-00/A612-00 A613-00	IEX1L	A611-00/A612-00 A613-00
IAL2L*	A611-00/A612-00 A613-00	IEX2L	A611-00/A612-00 A613-00
IAL3L*	A611-00/A612-00 A613-00	IEX3L	A611-00/A612-00 A613-00
IAL4L*	A611-00/A612-00 A613-00	IEX4L	A611-00/A612-00 A613-00
IAL5L / AL5*	A645-00/A646-00 A613-00	IEX5L	A645-00/A646-00 A613-00
IXS1L	A611-00/A612-00 A613-00	IMS1L-IMSL2	A611-00/A612-00 A613-00
IXS2L	A611-00/A612-00 A613-00	IMS3L / MS3	A645-00/A646-00 A613-00
IXS3L	A611-00/A612-00 A613-00	MS4	A645-00/A646-00 A613-00
IXP1L	A611-00/A612-00 A613-00	IML1L	A611-00/A612-00 A613-00
IXP2L	A611-00/A612-00 A613-00	IML2L / ML2	A645-00/A646-00 A613-00
IXP3L	A611-00/A612-00 A613-00	IAE1L	A611-00/A612-00 A613-00
IXP4L	A645-00/A646-00 A613-00	IAE2L / AE2	A645-00/A646-00 A613-00
IXX1L	A611-00/A612-00 A613-00	IAE3L / AE3	A645-00/A646-00 A613-00
IXX2L	A611-00/A612-00 A613-00	IAF1L / AF1	A645-00/A646-00 A613-00
IXX3L	A645-00/A646-00 A613-00	IAF2L / AF2	A645-00/A646-00 A613-00
IXA1L / XA1	A645-00/A646-00 A613-00	IAX1L / AX1	A645-00/A646-00 A613-00
IXB1L / XB1	A645-00/A646-00 A613-00	IDO1L	A611-00/A612-00 A613-00
IXL1L	A611-00/A612-00 A613-00	IDO2L	A611-00/A612-00 A613-00
IXL2L	A611-00/A612-00 A613-00	IDO3L	A611-00/A612-00 A613-00
IXL3L	A611-00/A612-00 A613-00	IDO4L	A611-00/A612-00 A613-00
IXL4L	A645-00/A646-00 A613-00	IDO5L	A645-00/A646-00 A613-00
IXN1L / XN1	A645-00/A646-00 A613-00	IDO6L	A645-00/A646-00 A613-00
IXO1L	A611-00/A612-00 A613-00	IDO7L	A645-00/A646-00 A613-00
IXO2L	A611-00/A612-00 A613-00	IDO8L / DO8	A645-00/A646-00 A613-00
IXO3L / XO3	A645-00/A646-00 A613-00	AG1	A645-00/A646-00 A613-00
		AH1	A645-00/A646-00 A613-00

* ≥ if height less than 240 mm

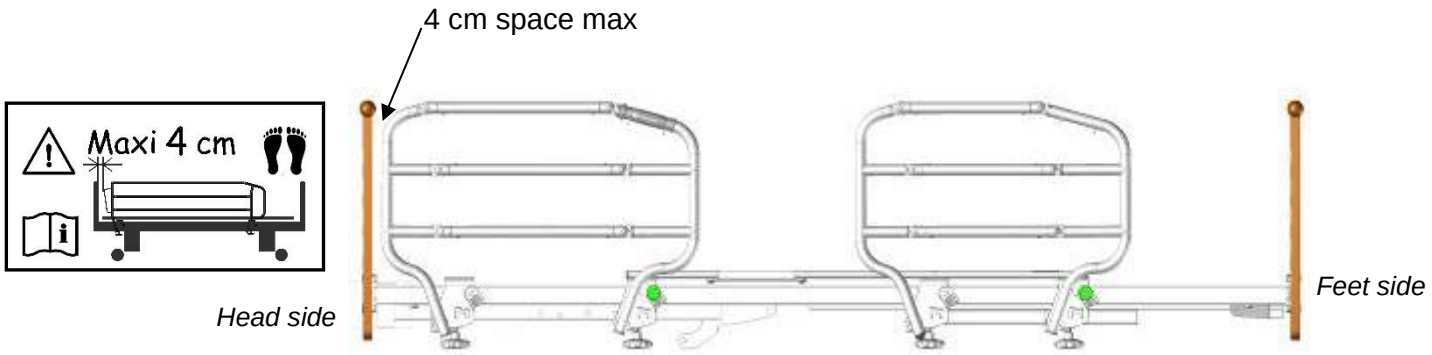
MSSs are delivered folded up.

The mobility support system is intended to be used on 2,000 mm long WINNCARE beds with a square tube frame of no more than 40 mm.

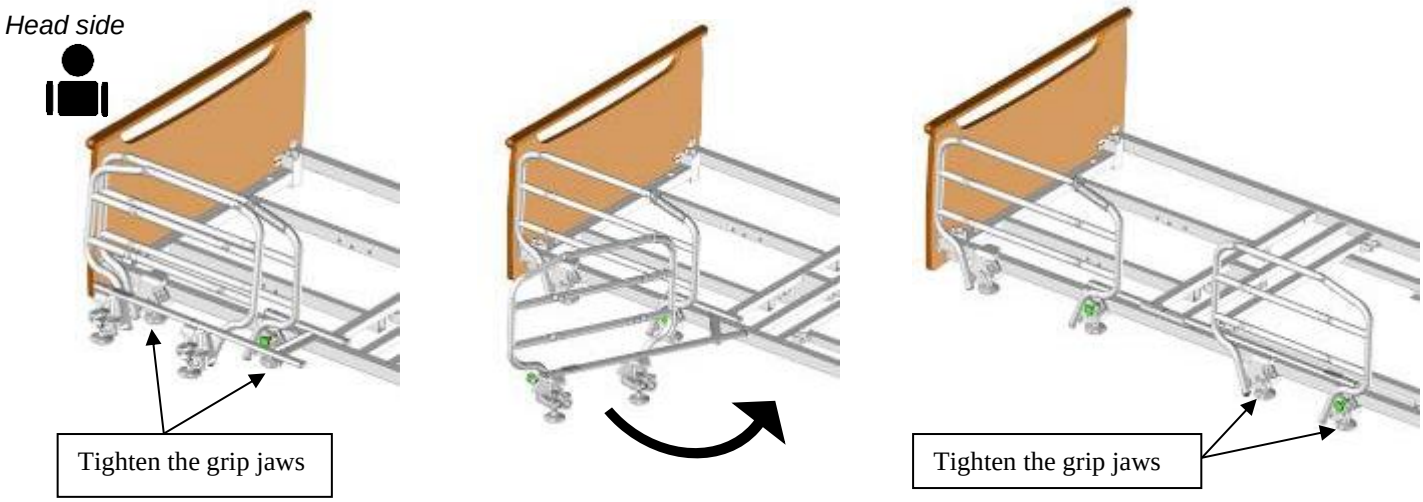


3.1. Assembling of the side rails A611-00 / A612-00

The mobility support system is marked left and right by the grip jaws. Position the grip jaws as shown in the diagrams below.

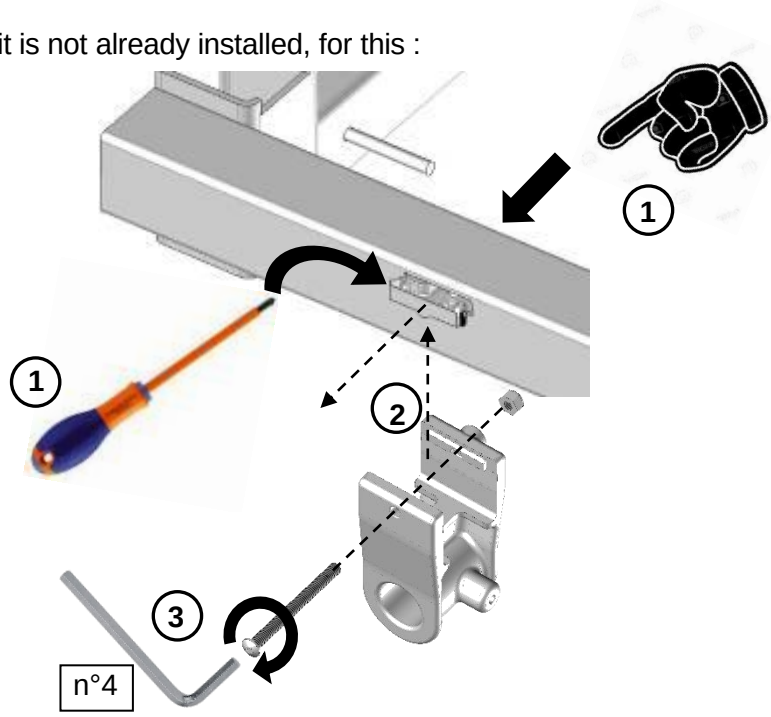


In order to assemble them on the bed, the longest section on the head end must be positioned by tightening the two adjustment knobs under the grip jaws. Then unfold the last one towards the foot end and tighten the knobs. Check that they are well locked.



3.2. Assembling of the siderails A645-00 / A646-00

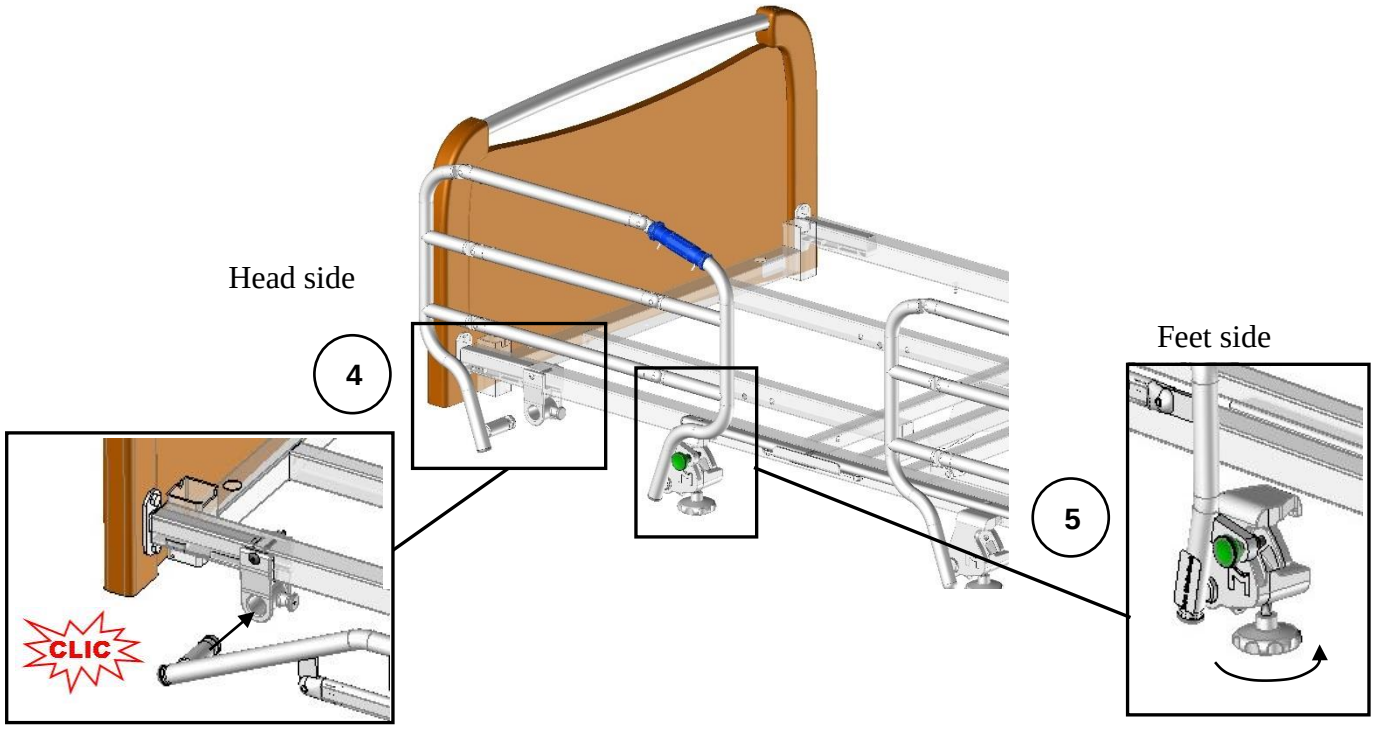
Fixing jaw on the bed if it is not already installed, for this :



①Remove the cap of the siderail by pushing inside or outside (depending on the assembly) then remove it with a screwdriver if necessary.

②Clip the jaw in the slots provided for this purpose, by positioning the nut on the inner side of the bed. Visser la mâchoire avec la vis et l'écrou fournis à l'aide d'une clé Allen n°4.

③Screw the jaw with the screw and nut provided with an Allen wrench n°4



④ Insert pole of the side rail in the jaw on the head side fixed on the bed until to hear the «CLIC».

⑤ Block the jaw on feet side through the clamping rondo and ensure its blocking.

To remove the siderail, loosen the rondo on the feet side ⑤ then disengage the pole without removing it by pulling the index finger on the side of the head side jaw ④. Take the side rail with one hand at each end to remove it completely.

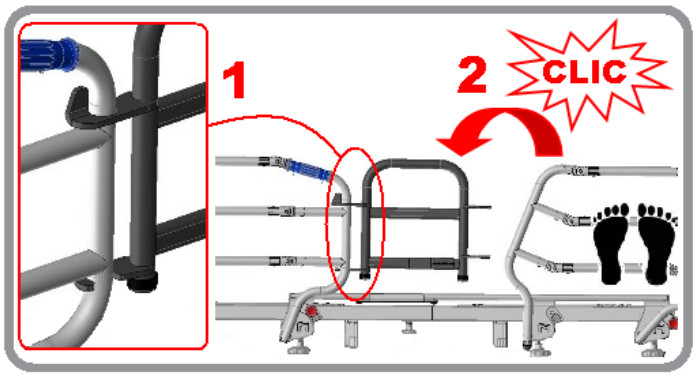
3.3. Assembling of the SAM Block A613-00

The support accessory A613-00 is reversible (left/right side of bed) and adaptable to the mobility support system A611-00 / A612-00 and A645-00 / A646-00 only.
The precautions for using the mobility support system (refer to paragraph 4.2) are also applicable for the support accessory.

- Hook the support accessory to the head end of the mobility support system using the two upside-down hooks.

- Raise the foot end of the mobility support system by slotting it into the two guides of the support accessory until you hear the index pin locking.

- To remove the support system, repeat these operations in reverse order.



4. CONDITIONS FOR USE

4.1. Function

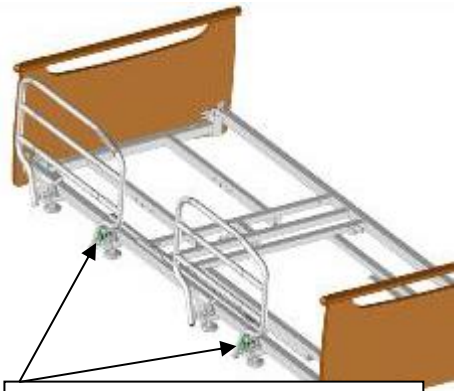
The mobility support system (S.A.M.™) helps people to be independent.

The mobility support system is 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 mobility support system being in place.
In some cases, the mobility support system helps to prevent falls, BUT it can pose a hazard: injuries, falling after trapping a limb in the mobility support system, suffocation after trapping the head, neck or chest. A risk/benefit assessment should preferably be carried out of the mobility support system to decide whether or not to use it.
This assessment must take the following into account:
- the department's surveillance capacities: A standardized protocol of the establishment for using the mobility support system 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.

➢ To lower the mobility support system.

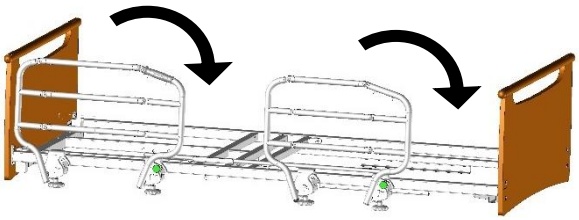
(1) Take hold of the half mobility support system by the top bar.

(2)



Pull on the locking buttons.

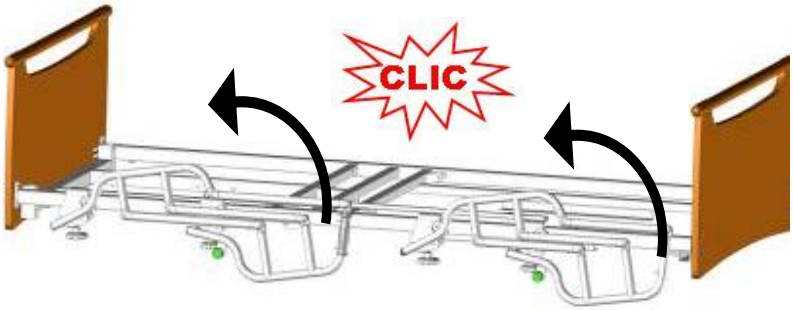
(3)



(4)

➢ To lift the mobility support system.

(1) Take hold of the half mobility support system by the top bar and lift.



Make sure that the barrier is locked properly by attempting to fold it without acting on the unlocking finger

4.2. Precautions for use

Positioning the mobility support system poorly may undermine safety and cause a malfunction. The mobility support system **must not be used when patients are not adults or are ≤ 146 cm tall.**

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.

Use of the mobility support system is not compatible with a bed base extension and does not allow for the use of accessory holders under the bed base.
When the bed is placed in low position, ensure that nothing or no area of the patient's or carer's body is between the bed, boards, accessories and floor.

The mobility support system 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.
The mobility support system is 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.

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

Only use original parts and accessories distributed by **WINNCARE** to guarantee safety and maintain product conformity.

4.3. 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

5.2. Upkeep

A detailed examination must be carried out on the mobility support system at least once a year on such parts as: the adjustment Rondo screws, index pins, pins and rivets.

5.3. Cleaning

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 are prohibited

5.4. Disinfection

The Mobility Support System is a non-critical device justifying “Low-level” disinfection. We draw your attention to the fact that the instructions below are given in compliance with good practice recommendations but do not constitute protocol. Consult the hospital’s hygiene department.

5.4.1. Objective

Return the MSS to its original condition and prevent the transmission of germs from one patient to the next.
Get rid of any organic dirt through:

Mechanical action (cleaning)
Chemical action (disinfection)

5.4.2. Indication

Physical and bacteriological cleanliness of the MSS

5.4.3. Equipment

Microfibre wipes
Detergent or Detergent-Disinfectant (Surface DD° with CE marking and Surface Disinfectant) (Chlorinated derivatives, alcohol base < 30%)

NB: DD products and bleach must not be used neat. Persistence time must be applied according to the disinfectant manufacturer (drying time often equals the persistence time excluding human presence)
SANIVAP type steam device with accessories

5.4.4. Technique

- Daily upkeep using a surface DD product applied in one go.
- Upkeep once the patient leaves or periodically via the *Bio cleaning* process which involves 3 operations:
    - Cleaning is done using a cloth soaked in a detergent solution or surface Detergent-Disinfectant (DD)
    - Rinsing is done using a cloth rinsed in clean water
    - Disinfection is done using a cloth soaked in a surface disinfecting solution.
- Specific upkeep by the service providers once the MSS has been removed from the establishment.
    - Get rid of the packaging after decontamination of the inside by DD solution spray
    - *Bio cleaning* process*,* <u>or</u>,
    - Steam cleaning (accessory with microfibre strip) of the various flat surfaces and bed base slats. Change washing mops at regular intervals to prevent any aqueous build-up. Clean any parts that are difficult to access (casters, joints once they are open, corners, etc.) using a steam nozzle. For the tubes, use the steam nozzle with a microfibre cloth. Do not point the nozzle straight on to electric casing or actuators.
    - Dry joints with compressed air
    - <u>NB</u>: Disinfect jacks, electric casing and remote controls using a microfibre cloth soaked in disinfectant.

Do not rinse or wipe dry.

Inspection that the various functions of the MSS are in good working order.
Repairs if necessary
Packaging of the MSS with heat shrink wrap

NB:

- Apply the measures recommended by the hospital hygiene department in the event of additional precautionary measures (Contact precautions, Drops, Air)
- Use of a bleach solution stronger than 5,000ppm (0.5% of active chlorine) must be justified by microbiological risk and applied for the length of time necessary (Risk of ageing of certain materials over time – particularly colour).
- The concentration of alcohol-based surface disinfecting solutions must be less than 30%.

NB: use of the terminal disinfection procedure is compatible with the medical bed and its accessories.

- Isolate the mobility support system 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.

Product for external use only. Do not swallow. Store in a cool place and avoid contact with eyes.

5.5. Lifetime

The lifetime under normal conditions of use and maintenance is 5 years for accessories, especially for Mobility Support Systems.

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 MSS identification label.

➢ Original 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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