PamMobility

VARIABLE-HEIGHT STRETCHERS
7285RT51

CE

USE AND MAINTENANCE INSTRUCTIONS

Translation of the original instructions

REVISIONS TABLE		
Revision	**Date**	**Notes**
0.0	05/04/2023	First edition

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UE declaration of conformity

The manufacturer:

Company: Pam Mobility s.r.l.

Address: Via Verdi, 39 - 42043 Gattatico (RE) – Italy

SRN: IT-MF-000027951

Declares, under its own and exclusive responsibility, that the device(s)

Code	Model	ID BD/RDM	Basic UDI-DI
7285RT51	Variable-height stretcher	2322462/R	8055774207285RT51YE

Intended use: The device is intended to be used exclusively as a stretcher for the transportation, diagnosis, treatment and monitoring of patients under the close supervision and surveillance of medical personnel.
The device cannot be used for inpatient purposes.
Environment of use: within healthcare and health facilities.
The device cannot be used in a potentially explosive or flammable atmosphere.
Personnel intended for use of the product: specialist operators and doctors.

Risk class: Class I (according to Rule 1, Annex VIII of Regulation (EU) 2017/745)

It complies with the following European Union legislative acts:

2017/745/EU Regulation (EU) 2017/745 of the European Parliament and of the Council, of 5 April 2017, relating to medical devices, which amends directive 2001/83/EC, regulation (EC) no. 178/2002 and regulation (EC) no. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

The device is subject to the conformity assessment procedure provided for in article 52, section 7 of Regulation 2017/745/EU

Gattatico,
05 April 2023

Managing Director

Andrea Muzzini

1. GENERAL PROVISIONS

1.1 Presentation of the manual

This manual is intended to provide the user with all the necessary information so that, in addition to suitable use of the device, they are able to manage it as autonomously and as safely as possible.
It includes information concerning the technical aspect, operation, maintenance, spare parts and safety.
Read carefully the warnings and instructions contained in this manual as they provide important indications regarding SAFETY, USE AND MAINTENANCE. Before carrying out any operation on the device, operators and qualified technicians must carefully read the instructions contained in this publication.
In the event of any uncertainty about the correct interpretation of the instructions, please consult our office to obtain the necessary clarifications.
The descriptions and illustrations provided in this publication are non-binding. Pam Mobility reserves the right to make any changes it deems appropriate for the purpose of improvement, without undertaking to update this documentation.
The illustrations and images contained in this manual are intended only as examples and may differ from practical situations.
This manual is an integral part of the device and must be kept with the utmost care by the purchaser. It must be placed in the immediate vicinity of the device, inside a dedicated container and, above all, protected from liquids and anything else that could compromise its readability.
The manual must accompany the device if it is transferred to a new user.
The content of this manual complies with regulation (EU) 2017/745 dated 05.04.17 (class I), concerning medical devices.
It is forbidden for anyone to disclose, modify or use this manual for their own purposes. The operator and patient safety and efficient operation depend on compliance with and exact observance of the instructions described here.

1.2 Customer assistance service

Customer Service and product support are important aspects of the Pam Mobility s.r.l. company structure.
Customer Service is available for further information on the use, maintenance and support of this product.

1.3 Conventions

The following graphic symbols have been adopted in this manual:

ATTENTION! Placed before certain procedures. Failure to do so may result in damage to the item.

WARNING! Placed before certain procedures. Failure to do so may cause damage to the operator or patient and to the item.

2. GENERAL WARNINGS

2.1 Manufacturer

The item described in this manual is manufactured by:

Pam Mobility s.r.l.
Via Verdi 39 – 42043 Gattatico (RE) - Italy
Tel. 0522 473859 - Fax 0522 1548244
E-mail: info@pammobility.com
http: www.pammobility.com

2.2 Intended use

The device is intended to be used exclusively as a stretcher for the transportation, diagnosis, treatment and monitoring of patients under the close supervision and surveillance of medical personnel.
The device cannot be used for inpatient purposes
Environment of use: within healthcare and health facilities.
The device cannot be used in a potentially explosive or flammable atmosphere.
Personnel intended for use of the product: specialist operators and doctors

2.3 Environmental limits of use

WARNING! The stretcher cannot be used in a potentially explosive or flammable atmosphere.

The environmental working conditions of the stretcher must respect these indications:

- Temperature: 0°C ÷ +40°C
- Humidity: 10% ÷ 70% (non-condensing).

The device must be placed in an absolutely dry environment.
Environmental conditions other than those indicated may cause serious damage to the stretcher. Positioning of the stretcher in environments that do not correspond to what is indicated will invalidate the warranty.

2.4 Expected lifespan

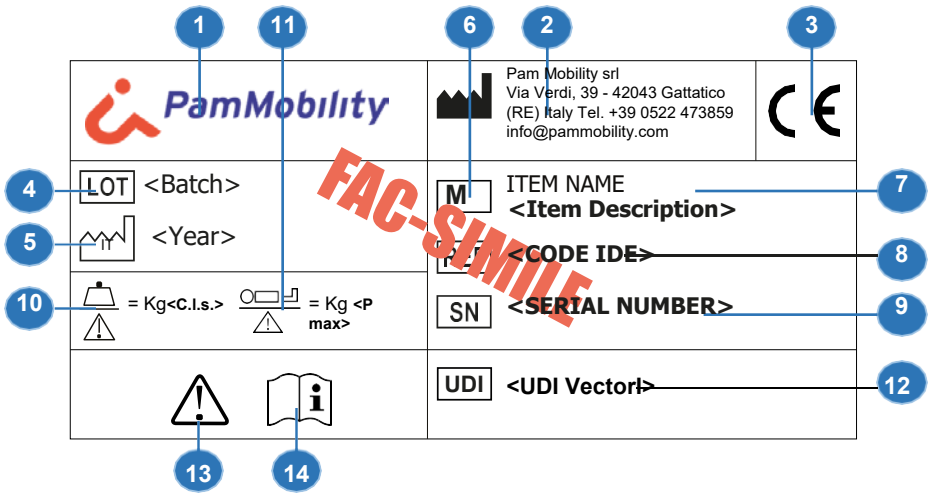
The stretcher has been designed and built to operate without risk to property and persons under the ordinary conditions of use defined in this manual for 10 years. However, this duration can only be achieved by complying with the requirements set out in this manual and by contacting Pam Mobility s.r.l. assistance whenever a malfunction occurs on the stretcher. After 10 years of use it is advisable to replace the entire stretcher.

2.5 Identification

ATTENTION! It is forbidden to remove the label from the device for any reason.

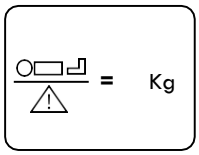
The item is identifiable by the plate on the base on which the following data are reported:

1. Company logo;
2. Name and address of the manufacturer;
3. CE marking;
4. Batch number;
5. Date and country of manufacture;
6. Medical device;
7. Item name
8. Item code;
9. Serial number;
10. Safe workload;
11. Maximum patient weight;
12. Unique device identifier (UDI);
13. Attention: be careful when using the medical device;
14. Read the user instructions.

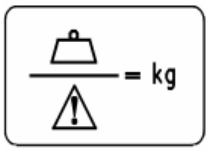


2.6 Identification of the controls

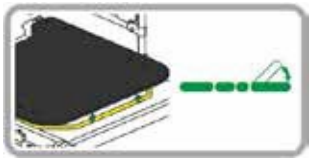
The controls and devices are identified by labels placed near or on the devices themselves.



MAXIMUM PATIENT WEIGHT



SAFE WORK LOAD



BACKREST ADJUSTMENT

TRENDELENBURG ADJUSTMENT

DANGER CRUSHING

BRAKE LOCKING AND UNLOCKING

3. SAFETY

3.1 General provisions

WARNING! Improper use and maintenance can cause damage to persons and property.

WARNING! WARNING FOR BLOOD-BORNE DISEASES: To reduce the risk of exposure during use of the stretcher, follow the maintenance instructions in this manual, in addition to the instructions on personnel safety prepared by the Emergency Medical Service Manager.

Operators must carefully read this manual, follow the instructions contained therein and familiarise themselves with the correct procedures for use and maintenance of the stretcher.
Use and perform maintenance on the item only as prescribed in this manual and use only Pam Mobility s.r.l. spare parts and assistance.
The stretcher, on flat routes and with patients and operators of average height, can be moved by one single operator. Unusual circumstances or the excessive weight of the patient may require the intervention of other personnel to ensure comfort and safety of the patient.
Do not use the stretcher for purposes other than those for which it was conceived and designed.
Always notify the patient before making any adjustments to the stretcher.
Always lock the stretcher with the brakes when it is not in transit.
Never leave the stretcher unattended when the patient is on it.
Keep this manual for reference and to support personnel training. Transfer it together with the product in case of sale or transfer to new users.

4. GENERAL DESCRIPTION

4.1 Stretcher description

The variable-height stretcher is the Pam Mobility solution dedicated to first aid, radiology, intensive care, surgery and endoscopy areas. Thanks to the wide range of accessories, suitably chosen, it is possible to use the stretchers in full compliance with the needs of the destination areas.

4.1.1 Name of the main parts

1. Backrest section;
2. Foldable push handle;
3. Pelvis section;
4. Mesh frame;
5. Columns;
6. Descent/Trendelenburg pedal;
7. Reverse trendelenburg descent pedal;
8. Bumpers;
9. Ascent pedal;
10. Backrest adjustment handle;
11. Collapsible sides;
12. Leg section;
13. Mattress stopper;
14. Brake pedal/directional wheel control;
15. Wheels;
16. Push bar/ IV pole accessory insertion.

4.2 Technical characteristics

VARIABLE-HEIGHT STRETCHER		7285RT51
Sections	no.	3
Surface length	mm	1950 ÷ 2010
Surface width	mm	580 ÷ 650
Height	mm	550 ÷ 850
Overall dimensions	mm	2060x820
Backrest section length	mm	728
Pelvis section length	mm	270
Leg section length	mm	941
Backrest adjustment	deg	0 ÷ 71 (90)
Leg section adjustment	deg	0 ÷ 20
Trendelenburg Angle	deg	0 ÷ -18
Reverse-trendelenburg angle	deg	0 ÷ 18
Safe work load[1]	kg	320
Patient weight	kg	260
Standard wheel diameter	mm	200
Weight	kg	100

*the surface dimensions may vary according to customer needs: width from 580 to 650 mm, length from 1950 to 2010 mm.

1 WORK LOAD is defined as the sum of the following: patient (260 Kg), mattress (15 Kg) and accessories (45 Kg).

5. INSTALLATION

The handling activities described in this chapter must be carried out exclusively by qualified personnel specially trained to perform in complete safety the operations of loading, unloading and handling of packs by means of lifting tools such as cranes or forklift trucks. Local staff should be aware of the accident-prevention rules.

5.1 Transportation and delivery

Transportation can be carried out by the following means of communication: road, rail, sea, air.
The weight of the item can be ascertained from the technical characteristics and packaging.
Movement of the individual item must be performed using means suitable for handling such as the self-propelled forklift truck or the manual forklift truck.
The precautions for safety at work remain valid.
The device is delivered assembled wrapped in a shockproof bubble wrap film.

ATTENTION! Upon receipt of the device, check with the carrier that the material is intact, that it has not been damaged during transportation or has not been opened intentionally to remove parts inside. Check that the supply corresponds to the specifications of the order and verify with the shipping documents that the delivery is complete.

If the packaging is damaged externally, open it in the presence of the carrier and check that the stretcher has not been damaged.
Note any damage on the shipping documents and immediately inform the Company Pam Mobility s.r.l.
If the packaging does not show anomalies, check the stretcher externally within 24 hours of delivery.
In case of visible damage due to transportation, immediately inform the carrier and the insurer, as well as the Company Pam Mobility s.r.l.

5.2 Lifting

WARNING! Lifting and handling operations must be carried out by specialist personnel trained in these types of manoeuvres.

ATTENTION! When lifting, slowly tension the straps and check that no components are involved that are not intended to support the weight of the unit.

ATTENTION! During the manoeuvre, check that no part of the stretcher remains compressed against the lifting equipment.

In order to ensure safe handling of the stretcher, strictly follow these instructions:

- make sure that the lifting equipment is suitable for the weight of the stretcher.
- use only flat lifting straps.
- place the lifting straps near the trolley frame and not near the mesh.
- if forklift trucks are being used, place the stretcher on a suitable platform, locking the four wheels.
- lift the stretcher off the ground as little as possible.

5.3 Storage

In case of prolonged storage, leave the stretcher protected from rain and wind and in a dry place. Protect the hydraulic parts and all parts very sensitive to humidity and low temperatures particularly well.
The stretcher can be stored in dry rooms with a temperature of between -10°C and +50°C; and relative humidity 20% ÷ 90% without condensation.

5.4 Installation

Installation takes place under the direction and responsibility of a qualified technician of Pam Mobility s.r.l.

5.4.1 Preparing the installation area

The place of installation must have a rigid, horizontal, flat floor.
Check that the installation surface is sufficient considering the additional space necessary for assembly.
Make sure that the space left next to the stretcher is sufficient for a person to pass by.
Ensure that the specific capacity of the floor is sufficiently strong to bear the weight of the stretcher.

5.5 Checking the equipment

The packaging contains:
- Variable-height stretcher or variable-height Plus (ordered version);
- additional accessories ordered;
- the user instruction manual.

5.6 Assembly

ATTENTION! The assembly area must be clean and clear; it must be at least 4x3 m to allow assembly operations.

The place of assembly must have the following characteristics:
- flat, non-yielding floor;
- 400 LUX lighting.

5.7 Functional test

ATTENTION! The following check must be repeated periodically to verify the efficiency of the product.

Before putting the item into use:
- perform the "periodic check" provided for in the maintenance chapter;
- if the check is successful, the item is ready to be put into regular service, otherwise contact Pam Mobility Customer Service immediately.

6. OPERATION AND USE

6.1 Warnings

Sanitise the stretcher as described in the SANITISATION chapter. Notify the patient whenever stretcher adjustments are to be made.

Always raise the collapsible sides of the stretcher when a patient is on it. Always lock the stretcher when it is not in transit by applying the brakes.

When the patient's conditions (such as disorientation due to medicines or particular clinical conditions) can lead to patient entrapment with the sides/edges, the mattress support platform must be left in a safe position with the mesh surface horizontal and lowered when the patient is left alone (except when requested otherwise by the medical staff in the case of special or particular circumstances).

Do not use the device for purposes other than those for which it was intended and for which it was designed.

6.2 Safe position

The stretcher is in a safe position when the mesh surface is in the horizontal position in the lowest position with the sides raised and the brake engaged.

6.3 Brake and release the stretcher/directional wheel insertion

Use the feet side pedals (optional head zone pedals) as follows:

- Pedal all the way down: braked wheels.
- Horizontal pedal: free wheels.
- Pedal fully up: directional wheel insertion.

6.4 Moving the stretcher

WARNING! Always notify the patient before moving the stretcher.

WARNING! Movement must only take place on flat, rigid surfaces and with the sides raised. Always lock the stretcher at the end of handling.

To move the stretcher proceed as follows:
- release the brakes using the dedicated pedal (14);
- make sure that the sides (11) are raised;
- push or pull the stretcher by holding it by the push handles (2);
- at the end of the journey, lock the stretcher.

6.5 Raise and lower the stretcher

WARNING! Before adjusting the height of the stretcher, make sure that the brakes are locked and the sides are raised; always warn the patient before making any adjustments.

Height adjustment of the stretcher is obtained by means of two hydraulic pistons controlled by a bilateral pedal.

To **raise** the stretcher, proceed as follows:
- press the pedal (**9**) repeatedly until the desired position is reached.

To **lower** the stretcher, proceed as follows:
- press the two pedals (**6**) and (**7**) simultaneously until they stop; release when the desired position is reached.

6.6 Raise and lower the backrest section

WARNING! Always notify the patient before adjusting the stretcher backrest.

Adjustment of the back section of the stretcher is obtained by means of two gas springs controlled by a lever (**10**).

WARNING! Do not place hands or objects between the backrest and the frame of the mesh surface. Do not manually intervene on the moving parts and follow the instructions.

To **raise** the backrest section proceed as follows:

- grip the backrest section with one hand using the handle (**10**) accompanying the upward movement;
- once the desired position has been reached, release the handle (**10**).

To **lower** the backrest section proceed as follows:

- grip the backrest section with one hand using the handle (**10**);
- push the backrest section down until the desired position is reached and release the handle.

6.7 Raising and lowering the leg section

WARNING! Always notify the patient before adjusting the leg section.

Adjustment of the leg section of the stretcher is obtained by means of a rack mechanism.

WARNING! Do not place hands or objects between the leg section and the frame of the mesh surface. Do not manually intervene on the moving parts and follow the instructions.

To **raise** the leg section proceed as follows:
- grip the leg section (12) with both hands and pull it upwards until the desired position is reached (see figure below).

To **lower** the leg section proceed as follows:
- assume a position at the foot of the stretcher;
- grip the leg section (12) with both hands and lift it completely in such a way as to unlock the rack mechanism;
- lower the leg section until it rests completely on the frame of the mesh surface

6.8 Trendelenburg and Reverse-trendelenburg

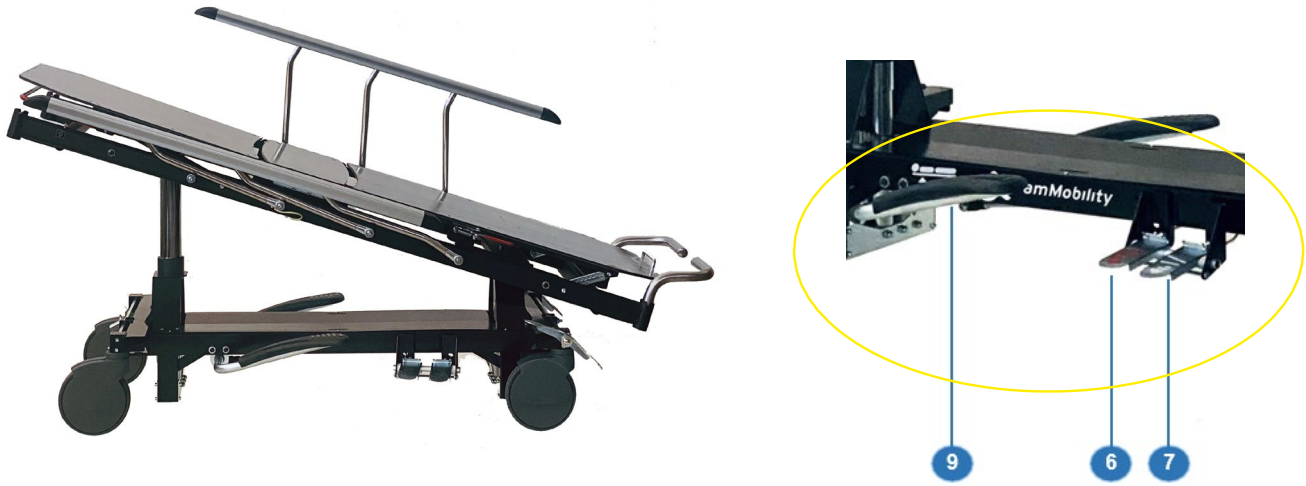
WARNING! Before adjusting the Trendelenburg / Reverse-Trendelenburg position of the stretcher, make sure that the brakes are locked and the sides are raised; always warn the patient before making any adjustments.

The adjustments of the trendelenburg and reverse-trendelenburg movements of the stretcher are obtained by means of two hydraulic pistons controlled by a pedal.
To adjust the trendelenburg position proceed as follows:

- fully raise the stretcher by repeatedly pressing the pedal (**9**) until reaching the maximum height;
- press the pedal (**6**) adjusting the trendelenburg position.

To adjust the reverse-Trendelenburg position, proceed as follows:

- fully raise the stretcher by repeatedly pressing the pedal (**9**) until reaching the maximum height;
- press the pedal (**7**) to adjust the reverse-trendelenburg position.



6.9 Handling the sides

WARNING! Always notify the patient before making any adjustments.

To **lower the sides (11)**, proceed as follows;

- pull the red lever (17) and accompany the side as far as it will go.

To **raise the sides (11)** proceed as follows:

- raise the side (11) up to the safety lock.

6.10 Push handles movement (only if available)

To **move the handles**, proceed as follows;

- pull the handle upwards and rotate it downwards or upwards according to the desired position;
- if necessary, repeat the operation to return to the initial handle position

6.11 Use of stretcher for radiographic examinations (where provided)

The stretchers can have a box placed on the back of the backrest which allows insertion of the digital detector to perform the radiographic examination.

7. SANITISATION

7.1 Sanitising products

ATTENTION! Sanitising agents are corrosive.

The best sanitizing and disinfecting agents are those most commonly used in the industrial field. Follow the manufacturer's instructions for the specific application during use. If possible, ask the manufacturer for guarantees on the degree of corrosivity of the solutions used.
Any changes to these characteristics may damage the item.
It is very important to follow the specifications regarding concentration, temperature and reaction times. Any change to these characteristics may damage the device.

During the sanitisation phases, only use:
- cold water;
- hot water max. 95°C;
- alkaline solutions max. 80°C;
- disinfectant solutions.

Do not use sulphuric acids or mineral acids such as HCl, H_2SO_4, HNO_3 and H_2SO_3.

7.2 Sanitisation with halogen-containing products

ATTENTION: Do not use products containing halogens during closed-loop sterilisation as they could damage the stretcher.

If used incorrectly these products can corrode steel especially if the pH is low. Perform thorough checks before using these solutions.
If the device is to be sanitised using halogen containing sanitising products (e.g. chlorine), the following requirements must be followed:
- the pH must be greater than 10;
- the temperature must not exceed 40°C;
- the solution must not remain in contact with the stretcher for more than 20 min.;
- use a concentration of max. 50 ppm of active chlorine;
- after sanitising, rinse thoroughly with water.

7.3 Sanitisation intervals

The sanitisation intervals are defined by the user, according to requirements, taking into account the indications reported in this manual and those stated on the sanitising products being used.

7.4 Automatic sanitisation

The stretcher cannot be sanitised in an autoclave. Danger of damage.

7.5 Manual sanitisation

Manual sanitisation will be defined by the customer, based on requirements, taking into account the indications given in this manual, and those reported by the sanitising products being used.

ATTENTION! Always check the safety data sheets of the materials being used for sanitisation. In case of contact/inhalation and/or ingestion, follow the instructions provided in the prescribed sheets.

8. MAINTENANCE

8.1 Periodic check

The user personnel must inspect the item at least once a year; the inspection must include a visual search for any damage that could compromise the integrity and correct functioning of the item. This inspection could include:

- integrity of sides and brakes functionality;
- integrity of the stretcher structure;
- tightening screws;
- correct insertion and fixing of any accessories;
- wheel and general cleaning of the product.

ATTENTION! If damage is found, immediately take the product out of service until it has been repaired or replaced.

8.2 Technical assistance

Requests for customer service assistance should be sent by fax or e-mail to the following address:

Pam Mobility s.r.l.
Via Verdi 39 – 42043 Gattatico (RE) - Italy
Tel. 0522 473859 - Fax 0522 1548244
E-mail: info@pammobility.com
http: www.pammobility.com

Specifying:

- product code, serial number, production code, year of installation;
- defects found;
- exact address of the place where the stretcher is installed.

ATTENTION! all assistance interventions must be strictly carried out by Pam Mobility personnel. Assistance interventions carried out by unauthorised persons may compromise the operation of the stretcher and could cause damage to property or persons. Pam Mobility s.r.l. assumes no responsibility for damage to property or persons resulting from assistance interventions carried out by unauthorised personnel.

8.3 Long term storage

If the product is set aside for a long period, it is necessary to:

- turn off and/or disconnect the battery;
- position it in a place that is dry and protected from the sun;
- protect it from dust by covering it with a nylon sheet;
- grease the parts that could be oxidised or damaged in the event of drying.

8.4 Demolition and disposal

The component materials of the stretcher essentially consist of:

- painted or galvanised steel;
- plastic abs material;
- elastomers.

Disassemble the stretcher, separating the individual pieces according to the component material. It is mandatory to dispose of the different materials in accordance with the regulations of the country in which the product is to be disposed of.

8.5 Sanitisation products

- Products used for sanitisation must not be discharged into urban pipes.
- Enquire about the provisions in force on disposal procedures with local authorities.

9. WARRANTY

For the entire duration of the warranty period, the manufacturer undertakes to eliminate any faults and/or defects of the stretcher provided that it has been used correctly in compliance with the indications provided in the use and maintenance manual.
The replacement of parts with others that do not comply with the Pam Mobility s.r.l. specifications if commercial, or not supplied by Pam Mobility s.r.l. if according to design, as well as improper use of the stretcher will void the warranty.

10. ACCESSORIES

10.1 4 hook drip pole code 72850032

10.1.1 Technical presentation

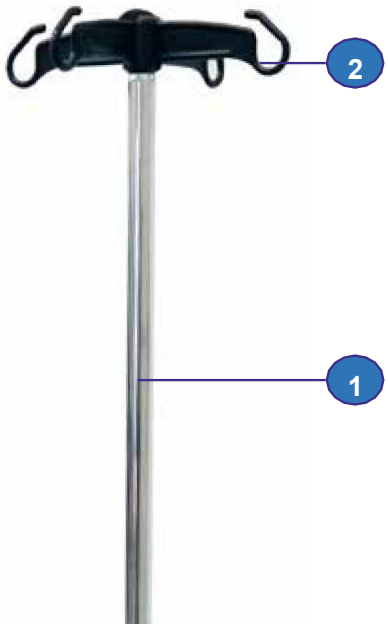
The IV pole consists of a chromed steel pipe, at the end of which there is a support with 4 hooks in resistant plastic material. The pole must be fixed to the stretcher by means of the IV pole-holder bar with clamp (code 4MK00073).

10.1.2 Intended use

The device is intended to be installed on Pam Mobility stretchers to support IV bags or bottles.
Environment of use: within healthcare and health facilities.
The device cannot be used in a potentially explosive or flammable atmosphere.
Personnel intended for use of the product: specialist operators and doctors.

10.1.3 Name of the parts

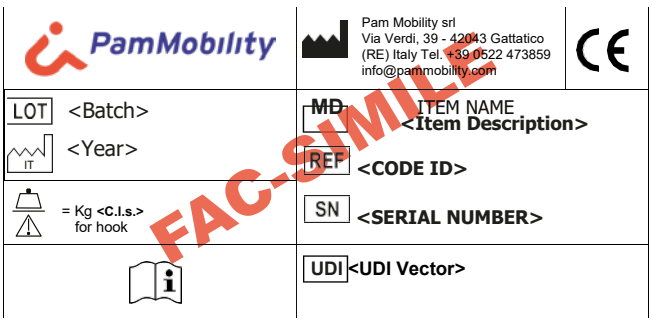
1. Pole;
2. Shaped hooks.



10.1.4 Identification

ATTENTION! It is forbidden to remove the label from the item for any reason.

The following label is affixed to the item:



10.1.5 Preparing the installation area

The IV support pole is installed on the Pam Mobility stretchers by means of the IV pole-holder bar with clamp (code 4MK00073).

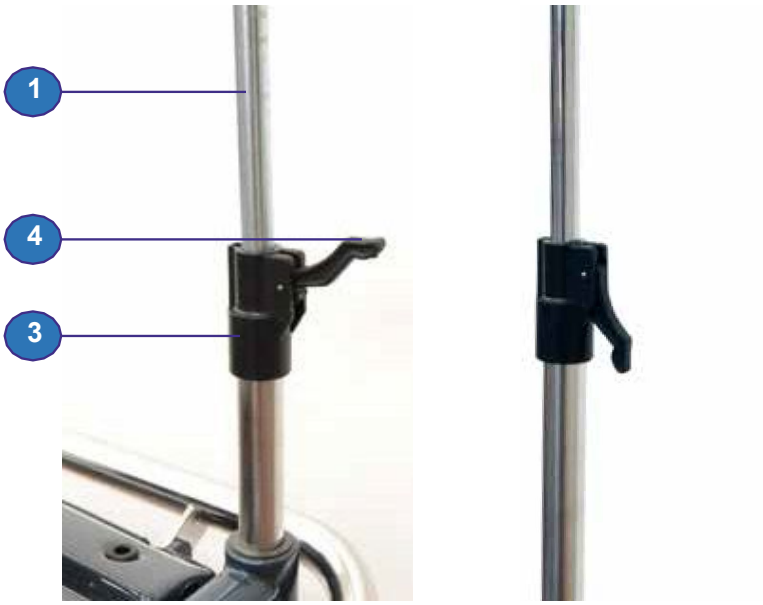
10.1.6 Installing the IV support pole

WARNING! This item must be installed by qualified personnel.

WARNING! Orient the IV support hooks according to the longitudinal axis of the stretcher.

To install the IV pole, proceed as follows:

- lift the pole fixing lever (4) in the clamp (3) of the IV pole-holder bar in the stretcher;
- insert the pole (1) into the clamp (3);
- adjust the height and secure the position by lowering the lever (4).



10.1.7 Functional test

ATTENTION! The following check must be repeated periodically to verify the efficiency of the product.

Before putting the item into use:

- check if it works correctly by referring to the paragraph "Operation and use" of this accessory;
- if the check is successful, the item is ready to be put into regular service, otherwise contact Customer Service immediately.

10.1.8 Operation and use

ATTENTION! Do not use the IV support pole for any other purpose.

WARNING! Always check that the IV support pole is installed correctly before use.

WARNING! Do not exceed the safe work load of the IV support pole.

Hang the IV with its holder on the pole hook (2).

PamMobility
Via Verdi, 39 - 42043 Gattatico (RE)
Tel. +39 0522 473859 - Fax +39 0522 1548244
info@pammobility.com - www.pammobility.com