PROMEBA
EMERGENCY & RESCUE

USER GUIDE

PEDIATRIC IMMOBILIZATION SYSTEM PA-190

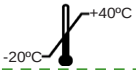
Review 2021/09

01 INTRODUCTION

01.1 Using of manual

The manual provides using and maintenance instructions of the product as well as technical aspects, functioning, spare parts and safety.
It is recommended before the operation of the product to read carefully this manual in order to avoid damages caused by a misuse.
Do not lose this document. It should be accessible to any doubt that could appear by medical personnel. Remember that a good use and maintenance are necessary for the proper operation of the product.

01.2 Legend of Symbols

SYMBOL	EXPLANATION / DESCRIPTION
	MANUFACTURER symbol. This symbol is accompanied by the name and address of the manufacturer, adjacent to the symbol (PRODUCTOS METÁLICOS DEL BAGÉS S.L., Ctra. C-16 Km 59.5, 08650 - Sallent (Barcelona) - Spain).
	Indicates the manufacturer's reference number to identify the medical device. PROMEBA, S.L. uses this symbol to set each internal reference for each configuration and business variant.
	Indicates the manufacturer's serial number to identify a specific medical device.
	Indicates the manufacturing date. The symbol must be accompanied by a manufacturing Date (yyyy-mm), adjacent to the symbol.
	It is placed to inform that the product is a "Medical Device".
	CE symbol without the intervention of a Notified Organism, as a Medical Device classified as Class I according to the EU Regulation 2017/745 on Medical Devices.
	Symbol for the Unique Device Identifier.
	Symbol "See instructions for use or operating instructions".
	Symbol "caution". This symbol is placed to warn of the need for the user to refer to important precautionary information in the operating instructions, such as warnings and cautions not otherwise found on the label.
	Symbol "Caution". For a general warning.
	Warning, crushing of hands
	Indicates the temperature limits. The upper and lower temperature limits should be indicated adja- cent to the horizontal lines.

01.3 Servicing request

For information of the correct interpretation of the instruction manual, the use, maintenance, installation and restoration of the product, please contact Promeba customer service: T. 93 837 12 00, email promeba@promeba.com or write to PROMEBA, S.L. - Ctra C-16 Km 59.5 · 08650 Sallent (Barcelona) · SPAIN.

01.4 Demolition

When the devices are no longer suitable for use, if they have not been contaminated by any particular agent, they can be disposed of as normal solid waste, otherwise, follow the current demolition regulations.

01.5 Labelling

Each product incorporates an identification label, placed on the device itself and/or on the box. It must never be removed or covered. This label includes the serial number and the product code. Please keep these numbers so you can inform the dealer if necessary.

1.6 Contraindications and adverse effects

The use of this device, if used as described in this manual, does not present any contraindications or collateral effects.

01.7 Physical requirements of the operators

Promeba's Pediatric immobilization system PA-190 is destined to professional use only.

The operators must be trained in efficient, effective and safe patient transport.

01.8 Intended purpose

The Model is a device designed to aid in stabilizing and immobilizing a pediatric trauma patient.

01.9 General warnings

1. The product must be used by trained personnel only, having attended specific training for this device and not for similar products.

2. At least every 6 months, is important to verify if updated User Manuals are available or there is any change involving your product. This information is freely available on the website http://www.promeba.com

3. Before carrying out any kind of operation on the appliance (training, installation, use), the operator must carefully read the enclosed instructions, paying particular attention to the correct safety precautions and to the procedures to be followed for installation and for correct use.

4. In the case of any doubts as to the correct interpretation of the instructions, please contact Promeba, S.L. for any necessary clarifications.

5. Do not allow untrained persons to help during the use of the device, because they could cause damage to the patient or to themselves.

6. Periodically check the device, carry out the prescribed maintenance and respect the life span indicated by the manufacturer in this user manual.

7. Before each use of device the perfect operating state of the device must be checked as specified in the instruction manual. If any damage or abnormalities which could in any way influence the correct functioning and the safety of the device, of the patient and/or of the user are detected, the device must be immediately removed from service and the manufacturer must be contacted.

8. If any failure or incorrect functioning of the device is detected, it must be immediately substituted with a similar item so that the rescue procedures are guaranteed without any interruption.

9. Use of the device in anyway other than described in this manual is forbidden.

10. Do not alter or modify in any way the device; any such interference could cause malfunctions and injury to the patient and/or rescuer.

11. The device must not in any way be tampered with (modification, adjustment, addition, replacement). In such cases all responsibility will be denied for any malfunctions or injuries caused by the appliance itself; moreover CE certification and product warranty will be considered void.

12. Handle with care.

13. Ensure that all the necessary precautions are taken in order to avoid the hazards that can arise as the result of contact with blood or body fluids.

14. Register and store with these instructions: lot number, place and date of purchase, first date of use, date of checks, name of users, any comments.

15. When the device is being used, the assistance of qualified staff must be guaranteed.

16. Do not store the device underneath any heavy objects which could cause structural damage.

17. Store in a cool, dry, dark place and do not expose to direct sun.

18. Store and transport device in its original packaging.

19. The device must not be exposed or come into contact with any source of combustion or inflammable agents.

20. Position and adjust the device taking care not to cause any obstruction to rescuers and or any other rescue equipment.

21. Attention: laboratory testing, post production tests and instruction manuals cannot always consider every possible scenario for use. This means that in some cases the performance of the product could be notable different from results to date obtained. Instructions are continually being updated and are under tight surveillance of fully qualified staffs with adequate technical formation.

22. Both public and private operators are obliged to report any accident involving any medical device to the Ministry of Health and the manufacturer as specified and within the time given by European regulations.

23. Both public and private operators are obliged to inform the manufacturer of the measures to be taken to guarantee the safety and health of patients and users of any medical device.

24. As a distributor or end user of the products manufactured and/or distributed by Promeba, S.L., you are strictly obliged to know the legal provisions in force in the country of destination of the goods, applicable to the devices to be supplied (including the regulations relating to technical specifications and/or safety requirements) and, therefore, understand the necessary requirements to ensure compliance of the products themselves with all the legal requirements of the territory.

25. Promptly notify PROMEBA regarding any revisions to be made by manufacturer in order to guarantee the conformity of the product to the territory's legal specifications (including those resulting from rules and/or norms of other nature).

26. Act with all due care and diligence, and contribute to ensure conformity to general safety requirements of all devices marketed in the territory, by providing final users with all necessary information for carrying out periodical checks on their devices, as specified in the relevant user manual.

27. Actively contribute to product safety checks on products sold, by communicating any relevant risk analysis information both to the manufacturer and to any competent authorities so that the necessary actions can be promptly taken.

28. Be aware that in the event of any failure to conform to the above mentioned requirements you will be deemed fully responsible for all damages that might occur. Therefore we expressly disclaim any responsibility and/or liability for your non-compliance with the present "Regulatory provisions".

01.10 Specific warnings

1. Establish a maintenance program and periodic testing, identifying a reference employee. The person to whom the ordinary maintenance of the device is entrusted must ensure the basic requirements foreseen by the manufacturer in the user's manual.

2. Use only accessories/spare parts that are original or approved by Promeba, S.L. , when carrying out any operation, to avoid causing any alteration or modification to the device, otherwise we assume no responsibility for the proper functioning or damage resulting from device to the patient or the operator and warranty will be considered void.

3. Never leave the patient unassisted on the device, because he may be injured.

4. Do not use bleach to disinfect the product. Use a hydroalcoholic based disinfectant and wash with water.

5. The device and all its components, after washing, should be allowed to dry completely before storing.

6. Keep clean as routine (incl. disinfect).

7. Follow procedures approved by Emergency Medical Services for immobilization and transportation of the patient.

8. Follow procedures approved by Emergency Medical Services.

9. Avoid contact with sharp objects.

10. Use the Pediatric immobilization system PA-190 only as described in this user's manual.

01.11 Residual risks

The residual risks listed below have been identified only with reference to the intended use of the device:

1. Use by untrained personnel may result in injury to patient, operator, or third parties.

2. Inappropriate disinfection procedures can create a risk of cross infection.

3. Failure to comply with the warnings for operators can create risks.

4. Failure to read and understand the product instructions can result in injury to the patient and operators.

01.12 Reference standards

REFERENCE	TITLE OF DOCUMENT
(UE) 2017/745	Reglamento UE del 05 de Abril del 2017 sobre productos sanitarios

As a distributor or end user of the products manufactured and/or distributed by Promeba, S.L., you are strictly obliged to know the legal provisions in force in the country of destination of the goods, applicable to the devices to be supplied (including the regulations relating to technical specifications and/or safety requirements) and, therefore, understand the necessary requirements to ensure compliance of the products themselves with all the legal requirements of the territory.

01.13 Life span

If used as described in the following instructions, this device has a useful life of 10 years from the date of purchase.
This useful life can be extended with annual reviews carried out by the manufacturer, which uses specialized and authorized internal and external technicians.
In case these annual checks are not carried out, the device must be disposed of according to the information in paragraph 01.4 and the manufacturer must be notified.
Only the manufacturer or an authorized center can extend the life of the device, if it meets the safety requirements.
Promeba, S.L. will not accept any responsibility for malfunction or damage caused by the use of devices that have not been checked by the manufacturer or authorized center, or that have exceeded the maximum allowed useful life.

02 PRODUCT DESCRIPTION

02.1 Product Features

The Model is a device designed to aid in stabilizing and immobilizing a pediatric trauma patient.

The Pediatric Immobilization System is for professional use by a minimum of two trained operators.

02.2 Components

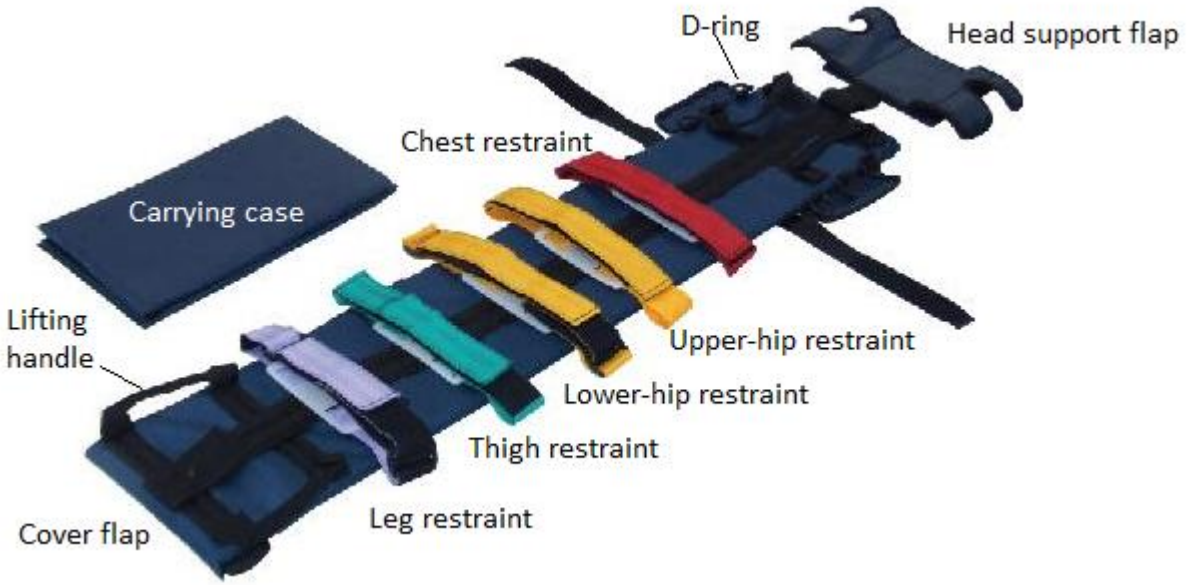
The Pediatric Immobilization System features include:

1. A plywood backboard with a removable nylon cover

2. An adjustable, color-coded restraint system

3. A head support, lifting handle, and cot attachment loops.

4. Included a carrying case, a Pediatric Immobilization System, and two head restraints.



02.3. Use Method

02.3.1 Set up the Pediatric Immobilization System

1. Remove the Pediatric Immobilization System from its carrying case

2. Lay the Pediatric Immobilization System besides the patient.

3. Position the top of the shoulder restraints in line with the top of the patient's shoulders

4. Unfasten and lay the restraints aside.

5. Align the slots in the head support with the patient's ears.

6. Open the head support.

7. Align the color-coded restraints with the patients as follows:

Restraint	Colour-coded	Area
Chest restraint	Red	Even with patient's armpits.
Upper-hip restraint	Yellow	Just above the patient's hips
Lower-hip restraint	Yellow	Just below the patient's hips.
Thigh restraint	Green	Just above patient's knees
Leg restraint	Blue	Even with patient's ankles.

8. When individual leg immobilization is needed, fasten the leg restraint.

02.3.2 Apply the Pediatric Immobilization System

1. Transfer the patient onto the System.

2. Maintain stabilization of the patient's head and neck during the transfer and while applying the Pediatric Immobilization System.

3. Fasten the color-coded restraints over the patient in a progressive sequence.

4. Fasten the wrist restraints.

5. Tighten the restraints to limit movement but not to impair circulation.

6. Bring the shoulder restraints over the patient's shoulders, and fasten the shoulder restraints to the chest restraint.

7. Fasten the ankle restraints for individual leg immobilization, if needed.

8. Place a forehead restraint on the patient's forehead.

9. Press the forehead restraint against the fastening strips on the sides of the head-support flaps.

10. Thread each end of the forehead restraint through a D-ring.

11. Fasten the end of the forehead restraint to the fastening strip on the top of the forehead restraint. Tighten the forehead restraint snugly.

12. Use the second forehead strap is to secure the patient's chin, if needed.

13. Wrap the head-support around the patient's head. The slots in the head support should be in line with the patient's ears.

02.3.3 Transport the Patient

1. Use an ambulance stretcher equipped with three restraints.

2. Unfasten the restraints on the stretcher.

3. Use the lifting handles to lift the patient immobilized in a Pediatric Immobilization System onto the stretcher.

4. To secure the Pediatric Immobilization System to the stretcher, thread the head-end stretcher restraint through the stretcher-attachment loop at the head end of the Pediatric Immobilization System.

5. Fasten the head-end stretcher restraint.

02.3.4 Remove the Patient from the Pediatric Immobilization System

1. Unfasten the restraints.

2. Transfer the patient off of the Pediatric Immobilization System.

Note: Inform the emergency room personnel that cutting the restraints is not necessary.

3. Shoulder restraints and stretcher-attachment loops are not replaceable.

4. If the color-coded restraints are cut or damaged, replacement restraints are available.

03. OPERATION

03.1. Transport

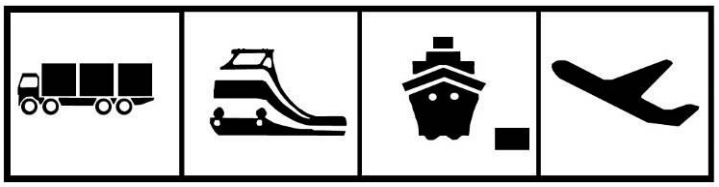
1. Be transferred by common transporting tools: plane, ship or road.

2. The Pediatric immobilization system can be manually handling

3. The Pediatric immobilization system should be kept away from cutter or sharp objects in order to avoid damage.

4. Nylon bag covered and packed in high-durable carton.

5. Attachments: certificate, user's manual.



03.2. Storage

1. Store this Pediatric immobilization system, in the place of damp proof and non-corrosion environment.

2. The Pediatric Immobilization System should be completely dry before being packed.

3. Insert the backboard into the cover, and close the cover flap.

4. Attach the head support and the Pediatric Immobilization System, and fasten the restraints.

5. Slide the Pediatric Immobilization System into its carrying case.

03.3. Maintenance

1. Inappropriate use and lack of maintenance can cause damage to people and objects.

2. The Pediatric immobilization system has no moving parts, and therefore do not require elaborate controls. However, it is recommended that you check the surface of the Pediatric immobilization system.

3. If any parts are damaged or broken, we advise rapid replacement by a new one.

4. Always be kept clean (including disinfection):

- Disinfect the Pediatric Immobilization after each use.

- Remove the head support and the Pediatric Immobilization System.

- Open the cover flap, and remove the backboard.

- Wipe all surfaces with disinfectant.

04. MAINTENANCE REGISTER

The product must be used by trained personnel only, having attended specific training for this device and not for similar products.

Keep this document at least 10 years from the end of life of the device.

PLACE AND DATE	NAME OF THE	NAME OF TRAINER	TYPE OF TRAINING

Perform the required maintenance as indicated by the manufacturer in this user's manual. Keep this document at least 10 years from the end of life of the device.

DATE	TYPE OF SERVICE (Maintenance / verification / extension of useful	OPERATIONS OF MAINTENANCE REALIZED	PERSON IN CHARGE OF SERVICE (Operator / Authorized / Center / Manufacturer)

05. LEGAL NOTICE

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06. PRODUCT WARRANTY

Prometa, S.L. guarantees that its products have satisfactorily passed all established quality controls, both functional and material. The duration of the guarantee is 2 years from the date of purchase of the product.

This guarantee will be valid only when it is presented with the original invoice or proof of purchase (indicating the date of purchase, model and the name of the distributor) together with the defective product during the period covered by the guarantee. Prometa, S.L. reserves the right not to offer the free warranty service if the indicated documents are not presented or if the information they contain is incomplete or illegible.

1. This warranty will not apply if the model name or serial number of the product has been altered, erased, disappeared or becomes illegible.

2. This guarantee does not cover transportation costs or risks derived from the transportation of your pro- duct to and from Prometa, S.L.

3. This warranty does not cover any of the following:

a) Periodic maintenance and repair or replacement of parts derived from normal wear and tear.
b) Expendable material (components that are expected to need periodic replacement during the life of the product, such as non-rechargeable batteries, light bulbs, etc.).
c) Damages or defects derived from the improper use, operation or treatment of the product and not due to normal use of the product.
d) Damages derived from:

i. Misuse, including:

- Treatment that results in damages or physical, superfi- cial or appearance changes of the product.
- Installation, use or storage of the product in a way that does not respect the instructions described by Prometa, S.L.
- Maintenance of the product in a way that does not respect the instructions of Prometa, S.L. for proper maintenance.
- Installation or use of the product in a way that does not respect the technical or safety regulations of the country where it is used or installed.

iii. Use of components not provided with the product or incorrect installation of accessory parts not previously tested.

iii. States or defects of the system in which the product is used or incorporated with the exception of other pro- ducts Prometa, S.L. designed for use with the product.

iv. Use of the product with accessories, peripheral units and other products of a type, condition or standards not established by Prometa, S.L.

v. The manufacturer or distributor will be solely responsible for deciding whether to send the parts for repair, or to replace the product in its entirety. In no case will operators be sent to repair or replacement of the product.

Except in the cases mentioned above, Prometa, S.L. will make no warranties in relation to product, performance, accuracy, reliability, or fitness for logic purpose of the equipment or other type. If this exception is not legal or contemplated by current law, Prometa, S.L. will limit or exclude your warranties only to the extent permitted by applicable law.

The only obligation on the part of Prometa, S.L. in connection with this warranty is to repair or replace parts subject to the terms and conditions of this warranty.

Prometa, S.L. is not responsible for loss or damage to products, this warranty or others, including economic loss or non-assessable damage; the price paid for the product; loss of profits, income, information, usufruct or use of the product or associated products or indirect, accidental or critical loss or damage.

This clause refers to whether the loss or damage is due to deterioration or inoperability of the associated product due to defects or unavailability of Prometa, S.L., which has caused downtime, loss of user time or business interruption.

In cases where the law prohibits or limits these liability exclusions, Prometa, S.L. will exclude or limit his liability only to the extent permitted by applicable law. For example, there are countries that prohibit the exclusion or limitation of damages caused by negligence, reckless negligence, willful misconduct, fraud and similar actions. The responsibility of Prometa, S.L. in this guarantee will not exceed, in any case, the price paid for the product, but if the current law allows only limitations of greater responsibilities, these will apply.

SCAN QR CODE

PROMEBA, S.L.

Ctra C-16 Km 59.5 · 08650 Sallent (Barcelona) · SPAIN
T. 00 34 93 837 12 00
promeba@promeba.com · www.promeba.com