



*USER GUIDE*

UNIVERSAL HEAD IMMOBILISER PA-11

Review 2021/09



01	INTRODUCTION	05
01.1	Using this manual	05
01.2	Legend of symbols	05
01.3	Servicing request	05
01.4	Demolition	06
01.5	Labelling	06
01.6	Contraindications and adverse effects	06
01.7	Physical requirements of the operators	06
01.8	Intended purpose	06
01.9	General warnings	06
01.10	Specific warnings	09
01.11	Residual risk	09
01.12	Reference standards	10
01.13	Life span	10
02	PRODUCT DESCRIPTION	10
02.1	Product Features	10
02.2	Technical parameters	10
02.3	Use Method	10
03	OPERATION	12
03.1	Transport	12
03.2	Storage	12
03.3	Maintenance	12
04	MAINTENANCE REGISTER	13
05	LEGAL NOTICES	15
06	PRODUCT WARRANTY	16



# 01 INTRODUCTION

## 01.1 Using of manual












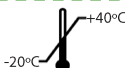
The manual provides using and maintenance instructions of the product as well as technical aspects, functioning, spare parts and safety.

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 adjacent 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](mailto: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 Head immobilizer is destined to professional use only.

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

## 01.8 Intended purpose

It is mainly used for hospitals, sports, rescue activities, ambulance and battle fields for fixed the head and neck of a person.

## 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 Head immobilizer 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

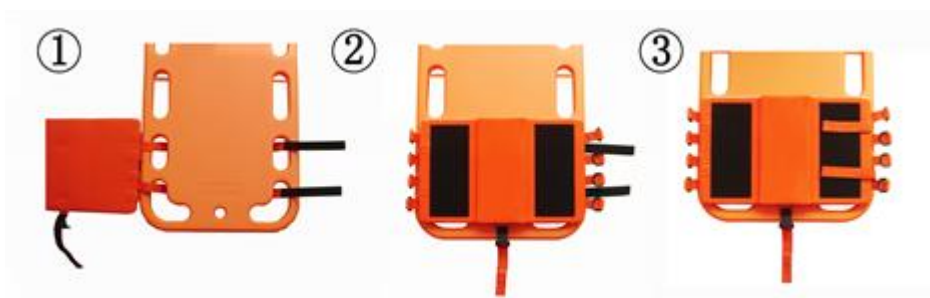
1. It is made of high-density plastic material, large ear holes for monitoring the patient's ear canal.
2. The product can be used with scoop stretcher and spine board together.
3. Minimal interference with X-ray, MRI, or CT scanning procedure
4. Waterproof plastic coating makes it easy to clean and prevents bacterial growth on it.
5. This product is used for adult.

## 02.2 Technical parameters (Tolerance $\pm 5\%$ )

Model	PA-11
Unfolded Size(L×W×H)	40×26×16cm

## 02.3. Use Method

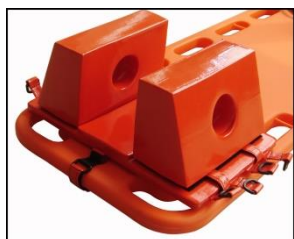
1. Put the head immobilizer lay on the stretcher head section, assembling the safety belts at the bottom of stretcher and fixed by the bristle together.



2. The top of head immobilizer fixed on the stretcher. The belt through the hole of stretcher and then fixed by the bristle together.



3. Fixed the two cushions on the head immobilizer by the bristle. Make sure put the patient's head at the center of two cushions and adjust the size for comfortable.



4. Fixed belt like following:



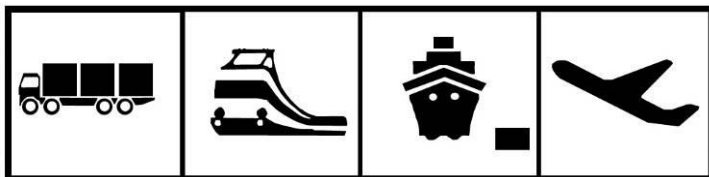
5. Assembling finished as picture:



## 03. OPERATION

### 03.1. Transport

1. Be transferred by common transporting tools: plane, ship or road.
2. Head immobilizer can be manually handling
3. Nylon bag plus a whole carton packaging
4. Attachments: certificate, user's manual.



### 03.2. Storage

1. Store this Head immobilizer in the place of damp proof and non-corrosion environment.
2. Storage, transportation, as shown by the box stacking.

### 03.3. Maintenance

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

#### 03.3.1 Safety Checks

Head Immobilizer has no moving parts and therefore does not require elaborate controls. However, it is recommended that you check the velcro straps and belts for possible damage before using the set.

Should any faults occur, do not use the head immobilizer and contact customer support.

#### 03.3.2 Cleaning Recommendation

Clean the surface using a moist sponge, water and neutral soap. Then rinse and dry thoroughly. Do not use aggressive cleaning agents (bleach, ammonia, etc. ).

Do not use abrasive materials (scrubs, steel wool, knives) to remove stains.

#### 03.3.3 Disinfection Recommendation

After cleaning with an appropriate surface disinfectant (tested with Incidur, Incidin Foam, Mikrozyd AF Liquid, Bacillol AF (for example), disinfect using the spray and wipe method following the manufacturers recommendations.



## 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 OPERATOR	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.

[illegible]



## 05. LEGAL NOTICE

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## 06. PRODUCT WARRANTY

Promeba, 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. Promeba, 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 product to and from Promeba, 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, superficial or appearance changes of the product.
- Installation, use or storage of the product in a way that does not respect the instructions described by Promeba, S.L.
- Maintenance of the product in a way that does not respect the instructions of Promeba, 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.

is used or incorporated with the exception of other products Promeba, 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 Promeba, 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, Promeba, 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, Promeba, S.L. will limit or exclude your warranties only to the extent permitted by applicable law.

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

Promeba, 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 Promeba, S.L., which has caused downtime, loss of user time or business interruption.

In cases where the law prohibits or limits these liability exclusions, Promeba, 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 Promeba, 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.

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