



B-lock head immobiliser

Rel.08042022
English (UK)



*Read this manual
carefully and keep it
for future reference*

Ferno Technical Support

Customer Service and Technical Support are important aspects of every Ferno product. Before contacting us, note the serial number of the product and specify it in all written communications. For all queries concerning technical support, contact Ferno s.r.l.:

| | |
|--------------------------------|----------------|
| Telephone (toll-free in Italy) | 800.501.711 |
| Fax | +39 0516861508 |
| E-mail | info@ferno.it |

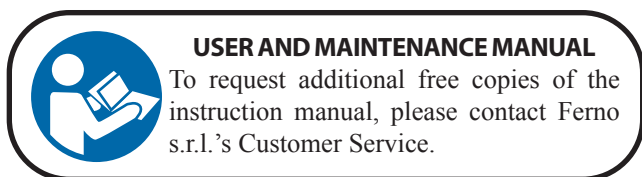
Ferno Customer Service

For assistance and further information, contact Ferno s.r.l.'s Customer Services:

MANUFACTURER

Ferno s.r.l., Via Benedetto Zallone 26
40066 - Pieve di Cento (BO) - ITALY

| | |
|--------------------------------|----------------|
| Telephone (toll-free in Italy) | 800.501.711 |
| Phone | +39 0516860028 |
| Fax | +39 0516861508 |
| Website | www.ferno.it |



Limitation of liability

This manual contains general instructions on the use and maintenance of the product. The instructions do not cover all possible applications and operations. The user is solely responsible for proper and safe use of the product. The safety information is provided as a service to the user and ensures only the minimum required level of safety to prevent injury to operators and patients. Any other safety measure implemented by the user must comply with applicable regulations. Before using the product, it is strongly recommended that staff be trained in its correct usage. Retain this manual for future reference. In case of change of ownership, ensure that the manual remains with the product. Additional free copies can be obtained from Ferno s.r.l.'s Customer Service.

Intellectual property declaration

The information in this manual is the property of Ferno s.r.l. - Via Benedetto Zallone 26, 40066 Pieve di Cento (Bologna) Italy. All patent rights, design, construction, reproduction, use and sale rights relating to any item covered in this manual are the confidential and exclusive property of Ferno s.r.l., except for rights expressly transferred to third parties or not attributable to parties owned by the supplier.

It is prohibited to reproduce this manual, either in full or in part, without the prior consent of Ferno s.r.l..

Limited warranty

Ferno products are covered by a 24-month warranty against manufacturing defects. For the full terms and conditions of warranty and liability, see chapter *Warranty*, page 14.

Reporting accidents

(MDR 745/17 Att. I, chapter III sect. 23.4)

In the event of a serious accident occurring in relation to the device, immediately contact Ferno S.r.l. and the competent authority of the member state in which the user has its main office.

E-mail: eu-regulatory@ferno.it

Website dedicated to support - Ferno SOS www.fernosos.it

Phone +39 051 6860028

Fax +39 0518681508

TABLE OF CONTENTS

| Chapter/Section | Page | Chapter/Section | Page |
|---|-----------|---|-----------|
| Ferno Customer Service _____ | 2 | 8 - Warranty _____ | 13 |
| Ferno Technical Support _____ | 2 | 8.1 Warranty Terms and Conditions _____ | 13 |
| 1 - Safety information _____ | 4 | 8.2 Limitation of liability _____ | 13 |
| 1.1 Warning _____ | 4 | 8.3 Warranty claims _____ | 14 |
| 1.2 Important _____ | 4 | 8.4 Complaints _____ | 14 |
| 1.3 Blood-borne diseases _____ | 4 | 8.5 Return authorisation _____ | 14 |
| 1.4 Compatibility _____ | 4 | Training record _____ | 15 |
| 1.5 Glossary of symbols _____ | 4 | | |
| 2- Operator training and skills _____ | 5 | | |
| 2.1 Skills _____ | 5 | | |
| 2.2 Training _____ | 5 | | |
| 3 - The head immobiliser _____ | 5 | | |
| 3.1 Description and intended use _____ | 5 | | |
| 3.2 CE Marking _____ | 5 | | |
| 3.3 Components (Head immobiliser) _____ | 6 | | |
| 3.4 General specifications _____ | 6 | | |
| 4 - Use of the head immobiliser _____ | 7 | | |
| 4.1 Instructions for Use _____ | 7 | | |
| 4.2 - Head immobiliser application _____ | 8 | | |
| 5 - Maintenance _____ | 10 | | |
| 5.1 Routine maintenance _____ | 10 | | |
| 5.2 Sanitisation and disinfection procedure _____ | 10 | | |
| 5.3 Disinfection _____ | 10 | | |
| 5.4 Cleaning _____ | 11 | | |
| 5.5 Storage _____ | 11 | | |
| 6 - SPARE PARTS _____ | 12 | | |
| 6.1 B-lock head immobiliser spare parts _____ | 12 | | |
| 6.2 B-lock head immobiliser accessories _____ | 12 | | |
| 7 - Technical support _____ | 12 | | |
| 7.1 Technical Support Service _____ | 12 | | |

1 - SAFETY INFORMATION

Read this user manual carefully. It is an integral part of the device and must always be stored close at hand. For your personal safety and for that of patients, please observe the following points:

- Before every use, make sure that there are no signs of wear, damage and/or malfunctioning. Refer to section *Inspection*, page 11.
- In order to avoid infections and/or bacterial contaminations, follow the indications in sections *Disinfection* and *Cleaning*, page 11.

1.1 Warning

The danger symbols draw attention to potentially dangerous situations that, if disregarded, may result in accidents, damage and/or injury.



WARNING

Untrained users may injure themselves, cause damage and/or physical harm. Allow only trained and qualified staff to use the head immobiliser.

Improper use of the head immobiliser may cause damage and/or injury. Use the head immobiliser as described in this manual.

Unauthorised modifications of the head immobiliser could cause serious damage, injury and/or unforeseeable operating problems. Do not modify or alter the head immobiliser in any way.

Any damage to the components of the head immobiliser or to the entire system may affect its performance and safety. Inspect the head immobiliser frequently, especially before and after each use. Place the head immobiliser out of service if it shows signs of wear or damage.

An unassisted patient is at risk of injury. Never leave the patient alone while tied to the head immobiliser. Assist the patient throughout all rescue operations.

Occasional assistants may cause damage and/or physical harm, or injure themselves. Do not allow occasional assistants to carry out the preparation of the head immobiliser. Take extreme care when using the device and coordinate any assistants.

Improper maintenance may cause serious accidents and/or damage. Perform maintenance as instructed in this user manual.

The use of improper and/or unauthorised devices may cause accidents, damage, and/or injury. Use only devices that have been approved and authorised by Ferno s.r.l.

Unauthorised repairs carried out by people not approved by Ferno s.r.l. will render all warranties null and void and may compromise the safety of the head immobiliser.

Non-original spare parts and inadequate repairs may cause damage and/or injury. Use only original Ferno spare parts and refer exclusively to Ferno s.r.l.'s Customer Support.

1.2 Important

Boxes labelled "Important" contain important information on use and/or maintenance of the device.

Important

1.3 Blood-borne diseases

To reduce risks of exposure to infectious diseases that may be transmitted by blood, such as HIV-1 or Hepatitis, follow the instructions on disinfection and cleaning in this manual carefully.

1.4 Compatibility

The B-lock head immobiliser system can be used also on other spinal supports such as:

Millennia Spinal Board and the entire Najo series.

1.5 Glossary of symbols

The symbols used in this manual are defined below. The CE mark is present on the head immobiliser and in this manual.



Read the user manual carefully



The head immobiliser requires at least two qualified operators for correct use



This product meets European Union Standards



Do not wash with high pressure water



Medical Device

2- OPERATOR TRAINING AND SKILLS

2.1 Skills

Operators who use the head immobiliser must:

- Have specific experience in patient handling procedures.
- Possess the appropriate skills to assist the patient.



WARNING

Untrained users may injure themselves, cause damage and/or physical harm. Allow only trained and qualified staff to use the B-lock head immobiliser.

2.2 Training

Operators are required to:

- Carefully read and understand all information in this manual.
- Attend a suitable training course on the use of the head immobiliser.
- Practice with the head immobiliser before using it in real situations with patients.

3 - THE HEAD IMMOBILISER

3.1 Description and intended use

The B-lock head immobiliser (more simply referred to as “head immobiliser” in this manual) is a device designed to immobilise the patient's head and neck.

The head immobiliser must be used according to the local regulations.

The head immobiliser is equipped with a head base, two side blocks that can be fixed to the base by Velcro, two straps (forehead and chin) and an “H”-shaped Velcro strap for final immobilisation on the atraumatic stretcher.

HEAD IMMOBILISER COMPONENTS

- Head immobiliser base (1)
- Side blocks (2)
- Forehead strap and chin guard (2)
- “H”-shaped Velcro strap (1)



WARNING

Improper use of the head immobiliser may cause damage and/or injury. Use the B-lock head immobiliser as described in this manual.

3.2 CE Marking

Ferno's products meet the requirements of European Regulation (EU) 2017/745 (MDR) concerning medical devices.



3.3 - Components (Head immobiliser)



3.4 General specifications

Materials

| | |
|------------------------------|-------------------------|
| Head immobiliser | Thermoplastic elastomer |
| "H"-shaped Velcro strap | Polypropylene |
| Forehead/chin strap | Neoprene |
| Dimensions (assembly) | 240x300x140mm |
| Weight | 0.970 kg |

USER AND MAINTENANCE MANUAL



To request additional free copies of the instruction manual, please contact Ferno s.r.l. Customer Service. (page 2).

4 - USE OF THE HEAD IMMOBILISER

4.1 Instructions for Use

- This manual does not provide any medical instructions.
- It is the responsibility of the operators to follow correct procedures and ensure the safety of both the patient and themselves.
- This manual explains the use of the head immobiliser under ideal conditions and is purely indicative.
- Follow procedures while complying with standard regulations for moving the patient in an emergency.
- In any case, always observe local healthcare instructions and regulations.



Read the user
manual carefully



At least two
qualified
operators

Important

When not in use, store the B-lock head immobiliser indoors, in a dry location protected from direct sunlight and in the storage configuration (*Storage*, page 12).

4.2 - Head immobiliser application

1. Slightly lift the patient's head to position the head immobiliser base (Figure 2A). During this operation, make sure to keep the patient's head aligned.
2. Place the head immobiliser base under the patient's head. During this operation, make sure that the base is correctly centred.

Figure 1 - Base application



2A

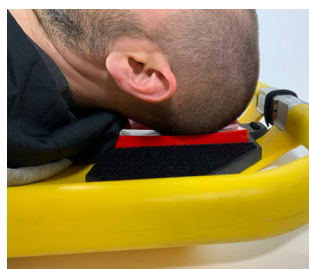


Figure 3 - Side blocks application

3. Apply the side blocks on the clavicle, making them adhere to the patient's head.



3A



3B

4. Apply both forehead and chin straps.

Figure 4 - Forehead and chin straps application



4A



4B

5. Apply the “H”-shaped Velcro strap securing the B-lock head immobiliser to the atraumatic stretcher (Figure 7-8).



Figure 7 - “H”-shaped Velcro strap application



Figure 8 - Head immobiliser correctly applied with “H”-shaped Velcro strap

5 - MAINTENANCE

5.1 Routine maintenance

The head immobiliser requires regular maintenance. The table on the right shows the minimum maintenance intervals.

Keep track of maintenance operations. An example list for recording maintenance operations can be found on page 18.

5.2 Sanitisation and disinfection procedure

WARNINGS

- Chemical agents can be toxic.
- Take necessary precautions before use. Use suitable gloves and PPE.
- Follow the instructions and warnings on the package labels and on the safety data sheets of each chemical agent.
- Do not mix disinfectants or descaling agents of different composition.
- It is recommended to disinfect the device after each use.
- Cleaning and any descaling operation must be performed after disinfection.
- Do not immerse the head immobiliser directly in disinfectant.
- During disinfection, ensure there are no signs of wear and/or damage.
- Dry with a cloth. Ensure all the components of the device are completely dry before reusing them.
- After cleaning, be sure to refit on the device the straps and/or any other accessory that was removed.

5.3 Disinfection

Disinfect the entire surface of the head immobiliser with a proven disinfectant.

WARNINGS

Rifraxan C is a detergent/disinfectant, commonly used in medical facilities, which has not caused any alteration or damage to Ferno products.

This product is therefore recommended.

If different products are used, follow local disinfection procedures.

| Maintenance intervals | After each use | Whenever necessary | Every month |
|-------------------------------|----------------|--------------------|-------------|
| Disinfection (page 11) | • | • | |
| Cleaning (page 11) | | • | |
| Inspection (page 11) | • | • | • |



WARNING

Improper maintenance may cause serious accidents and/or damage. Perform maintenance as instructed in this user manual.



WARNING

If disinfection procedures other than those specified in this manual are used it is the responsibility of the user to perform efficacy and safety checks to avoid possible risks to the patient.

Important

When not in use, store the B-lock head immobiliser indoors, in a dry location protected from direct sunlight and in the storage configuration (*Storage*, page 12).

Important

DO NOT WASH WITH HIGH PRESSURE WATER



Do not use high pressure water to clean the head immobiliser.

Important

The use of products containing phenol and iodine may damage the head immobiliser. Do not use products containing phenol or iodine for head immobiliser cleaning/disinfection.

5.4 Cleaning

Wash the head immobiliser with water and soap or a mild detergent, wiping it with a non-abrasive sponge.

Rinse with clean water.

Dry with a cloth or allow to air dry.

Do not wash with high pressure water.

When disinfecting and cleaning, pay close attention to Velcro systems.

Make sure they keep their holding properties and work correctly.

CHECK-LIST FOR INSPECTION OF HEAD IMMOBILISER

- Are all the components of the head immobiliser present?
- Does the head immobiliser show any signs of damage and/or wear?
- Are there cuts and leaks of internal material on the head immobiliser?
- Are the forehead strap, the chin guard and the “H”-shaped Velcro strap in good conditions? Do they show cuts or worn edges?
- Do the Velcro systems work properly?
- Do the Velcro systems show signs of wear? Do they have proper holding properties?

5.5 Storage

The head immobiliser must be stored clean, indoors, in a dry place and away from direct sunlight. When not in use, store it in the storage configuration (Figure 9).

Figure 9 - Storage configuration



ADAPTABILITY TO OTHER SPINAL SUPPORTS

The head immobiliser is designed to be used with the Ferno SCOOPEXL™ atraumatic stretcher, with Ferno Millennia spinal board and with the Najo series.

Any other combination that does not include products from the Ferno line must be used only after the user has checked the absolute compatibility with the head immobiliser and the compliance with the standard EN 1865.

Ferno s.r.l. shall not be liable for any damage to users or third parties due to improper use of the B-lock head immobiliser.




6 - SPARE PARTS

Ferno offers original spare parts approved for the B-lock head immobiliser. Always follow the directions in this instruction manual.

For more product information, contact Ferno Customer Service (page 2).

6.1 B-lock head immobiliser spare parts

| Description | Code |
|-------------------------------------|------------------|
| SIDE BLOCKS (pair) | code 25-00059 |
| FOREHEAD/CHIN STRAP (sold in pairs) | code 25-00085 |
| BASE (including mini QHI) | code 25-00058 |
| MINI QHI | code 10-00289 |
| H-SHAPED STRAP | code 25-0059-002 |

| |
|---|
|  WARNING |
| <p>The use of improper and/or unauthorised devices may cause accidents, damage, and/or injury. Use only devices that have been approved and authorised by Ferno s.r.l.</p> |

6.2 B-lock head immobiliser accessories

| Description | Code |
|---|-------------|
| Bag for B-lock head immobiliser transport/storage | 10-9900-005 |

7 - TECHNICAL SUPPORT


7.1 Technical Support Service

For technical support concerning our products, contact the Ferno s.r.l. Technical Support Service.

| | |
|--------------------------------|----------------|
| Telephone (toll-free in Italy) | 800.501.711 |
| Phone | +39 0516860028 |
| Fax | +39 0516861508 |
| E-mail | info@ferno.it |
| Website | www.ferno.it |

For information on the use of the B-lock head immobiliser and to schedule training courses on the correct use of the device, contact the Ferno s.r.l. Customer Service.

| |
|---|
|  WARNING |
| <p>Non-original spare parts and inadequate repairs may cause damage and/or injury. Use only original Ferno spare parts and refer exclusively to Ferno s.r.l. Customer Support.</p> |

| |
|---|
|  WARNING |
| <p>Unauthorised modifications of the B-lock head immobiliser could cause serious damage, injury and/or unforeseeable operating problems. Do not modify or alter the head immobiliser in any way.</p> |

8 - WARRANTY

8.1 Warranty Terms and Conditions

Ferno's products are guaranteed against manufacturing defects for a period of 24 months from the date on the Ferno s.r.l. shipping document.

Ferno guarantees its spare parts for a period of 12 months.

During the warranty period, Ferno will repair and/or replace any parts found to have manufacturing defects free of charge, excluding the costs of labour, travel, transport, and packaging.

The warranty does not cover consumables or parts subject to wear and tear due to normal use of the product, all parts typically subjected to sliding or rolling friction (bearings, brushes, lubricants, shoes, tracks, etc.), parts potentially exposed to oxidation or corrosion (copper or metal alloy contacts, electrical, electronic and mechanical equipment), and batteries.

The surface finishes (gelcoat/resin, paint, powder paint, decals, tape, inscriptions, etc.) are guaranteed for 90 days.

Repairs are performed by trained technical staff at the Ferno s.r.l. site in Via Zallone 26- 40066 Pieve di Cento (BO), Italy or at the Customer's premises if suitable arrangements with Ferno s.r.l.'s Customer Service have been made.

Technical support at the Customer's premises must be arranged beforehand and involves a refund of costs incurred and documented on request. For information on the costs of technical support, please contact the relevant department at Ferno s.r.l..

Repairs are guaranteed for 6 months from the date of repair. This warranty applies only when the product is used according to the instructions in the user manual provided. Misuse and negligence invalidate this warranty.

The warranty is valid from the day the product is shipped from Ferno s.r.l., and the shipping costs are not covered by this warranty. Ferno s.r.l. is not liable for damages incurred during shipment or due to misuse of the product.

Products sold by Ferno s.r.l. that do not bear the Ferno trademark are covered by the warranty of the original manufacturer. Ferno s.r.l. does not extend the warranty periods of other manufacturers; Ferno s.r.l. assumes no responsibility for products manufactured by others.

The warranty is rendered null and void in the case of:

- failure to observe the operating instructions,
- misuse,
- inappropriate use or handling,
- repairs by non-authorised persons,
- damage during transport due to improper packaging of items returned by the user,
- inadequate maintenance,
- failure to use original spare parts.

In cases not covered by the warranty, Ferno will not cover the transport costs for sending or returning the product.

8.2 Limitation of liability

If a product is found to be defective, Ferno s.r.l. will repair and replace it, or, at our own discretion, refund the purchase price. Under no circumstances can Ferno s.r.l. be held liable for more than the selling price of the product. The buyer accepts these conditions for all types of damage. Ferno s.r.l. does not offer other warranties, either express or implied, or any implied warranties of saleability or fitness for a particular purpose for its own products, or those manufactured

by others. In case of infringement of the limited warranty, any legal actions must be filed within one year from the date on which the infringement was, or should have been, discovered. Ferno s.r.l. reserves the right to terminate the warranty of the products sold:

- if the labels or plates bearing the Manufacturer's logo and/or the serial or registration number are rendered illegible or removed;
- if the product has undergone modifications, repairs or treatment not authorised by Ferno s.r.l. and by staff not authorised by Ferno;
- if the product is not used in compliance with the instructions, or for purposes other than those for which it was designed.
- further to the conditions indicated in section 8.1, "Warranty Terms and Conditions".

Ferno s.r.l. cannot, in any event, be held liable for direct or indirect damage due to usage that is non-compliant with the instructions in the user manual or the intended purpose of the product.

8.3 Warranty claims

Contact Ferno's Customer Service immediately if you receive a product that is suspected to be defective. A representative will assist the customer through the complaints procedure. Before returning a product to Ferno s.r.l., contact Ferno's Customer Service to request authorisation.

8.4 Complaints

Any complaints must be communicated to the reseller, or to Ferno s.r.l.'s Customer Service, within 5 days of receipt of the product or of discovery of the alleged defect.

Claims or disputes regarding a single product shall not release the buyer from the obligation to collect and pay for other products in the order, unless otherwise agreed with the seller.

8.5 Return authorisation

No product will be accepted without the prior approval of Ferno s.r.l..

Products returned for business reasons, or for reasons not relating to nonconformity, will be accepted only after verification of their condition by Ferno s.r.l.'s qualified personnel.

[illegible]

*Product User and Maintenance Manual, required to operate the product safely, maintain its efficiency and reliability,
and comply with the terms of the warranty.*

Rel.08042022
English (UK)

Ferno s.r.l.

Via Benedetto Zallone 26
40066 - Pieve di Cento (BO) - ITALY

| | |
|--------------------------------|--|
| Telephone (toll-free in Italy) | 800.501.711 |
| Phone | +39 0516860028 |
| Fax | +39 0516861508 |
| E-mail | info@ferno.it |
| Website | www.ferno.it |