



Head Immobilizer 365-E

Rel.111615
English



Ferno Technical Support

Customer relations and technical support are important aspects of each Ferno product. Please have the product serial number available when calling, and include it in all written communications. For technical support questions, contact Ferno Washington Italia s.r.l.:

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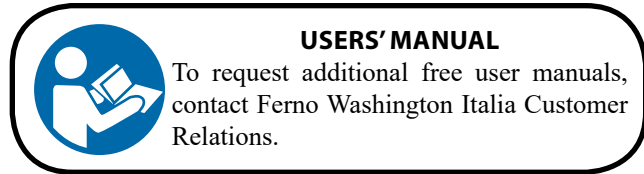
Ferno Customer Relations

For service or further information, contact Customer Relations, Ferno Washington Italia s.r.l.:

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Disclaimer

This manual contains general instructions for the use, operation and care of this product. These instructions do not cover all possible applications and operations. Safe and proper use of this product is solely at the user's discretion. Safety information is provided for the user and only ensures the minimum level necessary to avoid injury to operators and patients. All other safety measures taken by the user should be within and under consideration of applicable regulations. Operators must be trained before using this product. Retain this manual for future reference. Include the manual with the product in the event of transfer to a new user. Additional free copies are available upon request from Ferno Washington Italia Customer Relations.

Proprietary Notice

The information disclosed in this manual is the property of Ferno Washington Italia s.r.l. - Via Benedetto Zallone 26, 40066 Pieve di Cento (BO). Ferno Washington Italia s.r.l. reserves all patent rights, proprietary design rights, manufacturing rights, reproduction use rights, and sales use rights related to any article in this manual, except to the extent that those rights are expressly granted to others or where not applicable to vendor proprietary parts.

This manual may not be reproduced in whole or part without the express authorization of Ferno Washington Italia s.r.l.

Limited Warranty Statement

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

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1 – SAFETY INFORMATION

Read this User Manual carefully. It is an integral part of the device and must always be readily available. For your own personal safety and that of the patient, please observe the following:

– Before each use, inspect the device carefully to ensure it is not worn, damaged or malfunctioning. See *Inspection* paragraph, page 11.

– To avoid infection or bacterial contamination, follow instructions in *Disinfection* and *Cleaning*, page 11.

1.1 Warning

Warning notices indicate a potentially hazardous situation which, if underestimated, could result in accident, damage or injury.

! WARNING

Untrained operators may injure themselves and/or cause damage or injury. Only trained, qualified operators should be allowed to use the head immobilizer.

Improper use of the head immobilizer may cause damage or injury. Use the head immobilizer as shown in this manual.

Unauthorized modifications may cause serious damage, injury or unforeseen operative problems. Do not modify or alter the head immobilizer in any way.

Any damage to the head immobilizer components or the whole system may affect its performance and safety. Inspect the head immobilizer frequently and especially before and after each use. Do not use the head immobilizer if it appears worn or damaged.

Unattended patients may injure themselves. Never leave a patient in the head immobilizer unattended. Always attend to the patient during rescue operations.

Untrained helpers may cause damage and/or injury or hurt themselves. Do not allow untrained helpers to prepare the head immobilizer. Take the utmost care while using the head immobilizer and coordinating helpers.

Inadequate maintenance may cause serious damage or injury. Carry out maintenance as described in this manual.

The use of improper or unauthorized devices may cause accidents, damage or injury. Use only devices approved and authorized by Ferno Washington Italia.

Repairs carried out by technicians not authorized by Ferno Washington Italia will render any type of warranty void and may make any operation involving the head immobilizer dangerous.

Non-original parts and inadequate technical support may cause damage or injury. Only use original Ferno parts and contact Ferno Washington Italia Technical Support.

1.2 Important

Boxes with the word “Important” contain important information on the use and maintenance of this device.

Important

1.3 Bloodborne Diseases Notice

To reduce the risk of infective bloodborne diseases, like HIV-1 or hepatitis, scrupulously follow the disinfecting and cleaning instructions in this manual.

1.4 Compatibility

The head immobilizer 365-E can be used with the Ferno SCOPEXL™ stretcher. It should be used with Ferno Wizloc cervical collar.

Use only Ferno-approved and authorized accessories. Any other combination is not compatible with the specifics and instructions in this manual.

Ferno Washington Italia will not be held responsible for injury to operators or third parties caused by improper use of head immobilizer 365-E.

1.5 Symbol Glossary

The symbols defined below appear in this user manual. The head immobilizer and this manual both carry the CE marking.



Read the user manual carefully



The head immobilizer requires at least two qualified operators



This product meets European Union Standards



Do not clean with high pressure water

2 - OPERATOR SKILLS AND TRAINING

2.1 Skills

Operators using the head immobilizer need:

- specific experience of patient-handling procedures.
- the ability to assist the patient.

2.2 Training

Operators need to:

- carefully read and understand the information in this manual.
- undergo adequate training in the use of the head immobilizer.
- practice with the head immobilizer before using it in an actual situation with a patient.

- record training sessions. An example of the training session record form is shown on page 16.

! WARNING

Untrained operators may injure themselves and/or cause damage or injury. Only trained, qualified operators should be allowed to use the head immobilizer 365-E.

3 – THE HEAD IMMOBILIZER

3.1 Description

The head immobilizer 365-E (known simply as the “head immobilizer” in this manual) is a device that immobilizes the head and neck of the patient.

The head immobilizer is designed to be used by a minimum of two trained and qualified operators. A third operator may be required according to local protocols and an additional helper may be needed for heavy patients.

The head immobilizer has a base plate to support the head, ensuring necessary protection from the ground, as well as two support pads fastened to the base with Velcro, two straps (for the forehead and chin) and an “H” Velcro strap for patient handling on the scoop stretcher.

HEAD IMMOBILIZER FEATURES

- Base Plate (1)
- Support pads (2)
- Forehead and chin strap (2)
- “H” Velcro strap (1)

! WARNING

Improper use of the head immobilizer may cause damage or injury. Use the head immobilizer 365-E as described in this manual.

3.2 CE Conformity

MEDICAL DEVICES DIRECTIVE

Ferno products meet the requirements of European Directive 93/42/EEC concerning medical devices.

More informations: www.ferno.it



3.3 Components (Head Immobilizer)



FRONT VIEW

USERS' MANUAL



To request additional free user manuals, contact Ferno Washington Italia Customer Relations.

3.4 General Technical Specifications

Ferno reserves the right to change specifications without notice. For further information, contact Ferno Customer Relations (page 2).

Material	
Head immobilizer	vinyl coating
Length	250 mm
Width	300 mm
Weight	0.620 kg

WARNING

Untrained operators may injure themselves and/or cause damage or injury. Only trained, qualified operators should be allowed to use the head immobilizer.

4 – USING THE HEAD IMMOBILIZER

4.1 Before Using the Head Immobilizer

Operators using the head immobilizer must have carefully read and understood the information in this manual.

- Before any use of the head immobilizer ensure that the base plate, support pads, forehead and chin straps and “H” Velcro strap are present and ready for use.
- Check that the head immobilizer has no sign of damage or wear and is working perfectly. See *Inspection*, page 11.

4.2 Instructions for Use

- This manual does not provide any medical advice.
- It is responsibility of the users to ensure correct and safe practices for the patient and themselves.
- This manual illustrates use of the head immobilizer in an ideal setting and should be considered as a guideline only.
- A minimum of two trained and qualified operators are needed to use the head immobilizer.
- **Operators must work together and cooperate correctly during all operations.**
- Follow standard protocol procedures for emergency patient handling.
- Operators must work together by communicating and cooperate correctly when using the head immobilizer.
- During application of the head immobilizer, one operator should manually stabilize the patient’s head and neck while the other applies the head immobilizer.
- The head immobilizer must always be used together with a cervical collar, as it is not a substitute for the latter.
- Always follow guidelines and local medical protocols.
- Always attend to the patient and never leave him alone when using the head immobilizer.

WARNING

Improper use of the head immobilizer may cause damage or injury. Use the head immobilizer 365-E as described in this manual.

WARNING

Never leave a patient in the head immobilizer unattended. Always attend to the patient during all rescue operations.



Read the user manual carefully



Two Trained Operators Required (Minimum)

WARNING

The use of improper or unauthorized devices may cause accidents, damage or injury. Use only devices approved and authorized by Ferno Washington Italia.

Important

When not in use, place head immobilizer 365-E in a dry place indoors where it is protected from direct light in storage configuration (*Storage*, page 12).

4.3 Applying the Head Immobilizer

During application of the head immobilizer, one operator should manually stabilize the patient's head and neck while the other applies the head immobilizer.

Before applying the head immobilizer, ensure that the cervical collar has been correctly applied on the patient (Figure 1). For use of the cervical collar, consult the relative user manual.



Figure 1 – Cervical Collar Applied

HOW TO APPLY THE HEAD IMMOBILIZER

It is recommended that two trained, qualified operators are present:

- Operator 1:** raised slightly the patient's head to ensure only the space necessary for the positioning of the base of the head (figure 2A). When doing this make sure you keep aligned with the patient's head.
- Operator 2:** inserts the base plate of the head immobilizer under the patient's head. Ensure that the base is centered correctly during this operation (Figure 2B).



2A



2B

Figure 2 – Applying the base plate

- Operator 2:** apply the side blocks adhering to the patient's head and collarbone, then stop it to the Velcro on the bottom head stop (Figure 3A). Be sure to align the holes with the ear of the patient (Figure 3B). The holes allow the patient to feel the operator and the latter to inspect the auricle.



3A



3B

Figure 3 – Applying the support pads

- Operator 2:** While the operator 1 retains control of the patient's head, the operator 2 apply both front and Chin straps, compress the pillows head stop, before attaching the fascia on the appropriate Velcro straps (Figure 4A- 4B).



4A



4B

Figure 4 – Applying the Forehead and Chin straps



Figure 5 - Head immobilizer applied correctly

- Operator 1:** Collet base lightly with your fingertips to help Scoop Exl to position themselves easily under the patient. (Figure 5)
- Both operators:** once the head immobilizer has been correctly applied, proceed to place the patient onto the scoop stretcher (Figure 6).



Figure 5 - Clamp the base for head



Figure 6 - Placing the patient on the scoop stretcher

7. **Both operators:** before completing the immobilization of the head, ensure that the stretcher restraints have been correctly applied to the patient.
8. **Operator 2:** while operator 1 maintains control of the patient's head, operator 2 applies the "H" Velcro strap (Figure 7) to secure the head immobilizer to the scoop stretcher.
9. **Both operators:** ensure that they have completely immobilized the head and correctly secured the patient to the scoop stretcher before patient handling.



Figure 7 – Applying the "H" Velcro strap



Figure 8 – Head immobilizer correctly applied with the "H" Velcro strap

5 - MAINTENANCE

5.1 Routine Maintenance

The head immobilizer requires regular maintenance. The table on the right shows the minimum maintenance schedule.

Keep a record of maintenance operations. An example of maintenance record is shown on page 17.

Maintenance Schedule	Each Use	As Needed	Each Month
Disinfection (page 11)	•	•	
Cleaning (page 11)		•	
Inspection (page 11)	•	•	•

5.2 Disinfection

Disinfect the entire surface of the head immobilizer with a neutral, non-abrasive disinfectant. If necessary, use a soft brush to remove organic liquids.

Suitable gloves are recommended during disinfection (e.g. disposable gloves or household gloves).

5.3 Cleaning

Wash the head immobilizer with warm water and mild, non-abrasive neutral detergent. Rinse with clean water. Dry with a towel or allow to air-dry.

Do not clean with high pressure water.

Suitable gloves are recommended during cleaning (e.g. disposable gloves or household gloves).

Be extremely careful of Velcro fastenings when disinfecting and cleaning. Ensure that they hold and work properly.

5.4 Inspection

To guarantee optimal use of the head immobilizer, all components must be in good condition, free from dirt, residue and body fluids. The head immobilizer must be inspected and disinfected after every use. If not used, it must be stored indoors in a dry place and be inspected at least once a month.

Equipment maintenance personnel should inspect the head immobilizer at regular intervals. Carry out the checks listed on page 12.

Do not use the head immobilizer if you see signs of wear or damage during inspection and contact Ferno Customer Relations immediately.

! WARNING

Inadequate maintenance may cause serious damage or injury. Carry out maintenance as described in this manual.

Important

When not in use, place head immobilizer 365-E in a dry place indoors where it is protected from direct light in storage configuration (*Storage*, page 12).

Important

DO NOT CLEAN WITH HIGH PRESSURE WATER



Do not clean the head immobilizer with high pressure water.

Important

Products containing phenol or iodine may damage the head immobilizer. Do not use products containing phenol or iodine to clean/disinfect the head immobilizer.

INSPECTION CHECKLIST	
FOR THE HEAD IMMOBILIZER	
•	Are all head immobilizer components present?
•	Does the head immobilizer show signs of damage or wear?
•	Are there any tears in the head immobilizer or is any of the internal material coming out?
•	Are the forehead and chin strap and the “H” Velcro strap in good condition, with no cuts or frayed edges?
•	Does the Velcro work properly?
•	Does the Velcro show signs of wear? Does the Velcro hold properly?

ADAPTABILITY TO OTHER SPINAL SUPPORT

The system head stop 365-E, can also be used on other spinal media as:

Spinal board Millennia and all the Najo series.

5.5 Storage

The head immobilizer should be cleaned and stored in a dry place indoors, away from direct sunlight. It should be stored as shown when not in use (Figure 9).



Figure 9 - Storage

6 - SPARE PARTS

Ferno supplies original approved parts for head immobilizer 365-E. Always follow the instructions in this user manual.

For further product information, contact Ferno Customer Relations (page 2).

6.1 Head Immobilizer 365-E Spare Parts

Description	Code
Base Plate	25-0057-001
Support pads (pair)	25-0061-000
Forehead and chin straps	25-0062-000
“H” Velcro strap	25-0059-002

WARNING

The use of improper or unauthorized devices may cause accidents, damage or injury. Use only devices approved and authorized by Ferno Washington Italia.

6.2 Head Immobilizer 365-E Accessories

Description	Code
Transport/storage bag for head immobilizer 365-E	10-9900-005

7 – TECHNICAL SUPPORT

7.1 Technical Support

For product technical support, contact Ferno Washington Italia Technical Support.

Telephone (Freephone)	800 501 711
Telephone	+39 051 686 00 28
Fax	+39 051 686 15 08
E-mail	info@ferno.it
Internet	www.ferno.it

For information on the correct use of head immobilizer 365-E and to organize training courses on the correct use of the device, contact Ferno Washington Italia Customer Relations.

WARNING

Non-original parts and inadequate technical support may cause damage or injury. Use only original Ferno parts and Ferno Washington Italia technical support.

WARNING

Unauthorized modifications to the head immobilizer 365-E may cause serious damage, injury or unforeseen operative problems. Do not modify or alter the head immobilizer in any way.

8 - WARRANTY

8.1 Warranty Conditions

Ferno products are guaranteed free from manufacturing defects for 24 months from the date shown on the Ferno Washington Italia s.r.l. delivery note.

Ferno Washington Italia parts have a 12-month warranty.

During the warranty period all parts with properly ascertained manufacturing defects will be repaired and/or replaced, not including labor costs or transfer, transport and packaging costs.

The warranty does not cover consumables or components subject to wear associated with normal product use, any parts typically subject to sliding or rolling friction (ball bearings, brushes, lubricants, tracks and belts, etc.), parts potentially subject to oxidation or corrosion (copper or metal alloy elements, electrical and mechanical apparatus) and batteries.

External finishes (gel coat/resin, paint, powder coating, decals, ribbons, lettering, etc) are guaranteed for 90 days.

Repairs are carried out by specialized technical staff at the Ferno Washington Italia s.r.l. headquarters in Via Zallone 26-40066 Pieve di Cento (BO) or at the Customer's premises if approved by Ferno Washington Italia Customer Relations.

Technical support carried out at the Customer's premises must be approved and will include partial reimbursement of expenses sustained that will be documented upon request. For info on the cost of technical support contact Ferno Washington Italia L.L.C. Technical Support Department.

Repairs are guaranteed for 6 months from the date of completion. This warranty applies only if the product is used according to the user manual supplied. Improper or careless use will render this warranty void.

The warranty begins on the day on which the product is sent by Ferno Washington Italia s.r.l. and does not cover delivery costs. Ferno Washington Italia s.r.l. is not responsible for damage in transport or for damage caused by improper use of the product.

Products that do not have the original Ferno trademark, sold by Ferno Washington Italia s.r.l., are covered by the product manufacturer's original warranty. Ferno Washington Italia L.L.C will not extend a warranty beyond the product manufacturer's warranty period; Ferno Washington Italia L.L.C will not be held responsible for products manufactured by others.

The warranty will not apply in the case of:

- failure to observe instructions for use,
- wrong usage,
- inappropriate use or handling,
- repairs to the device by unauthorized personnel,
- damage in transport due to improper packaging when returned by the user,
- lack of maintenance,
- failure to use original parts.

In cases not covered by the warranty, Ferno Washington Italia will not be responsible for transport costs for sending and returning the product.

8.2 Disclaimers

If a product is defective, Ferno Washington Italia s.r.l. will repair or replace it, or refund the cost price, at its option. Ferno Washington Italia L.L.C will not be responsible for refunding more than the cost of the product. The buyer accepts these terms in lieu of all damages. Ferno Washington Italia s.r.l. does not make any other express or implicit guarantees, nor does it make any guarantee as to the merchantability or suitability for particular ends of its product or the products

of others. In the case of infraction of the limited warranty, legal procedures must be archived within a year of the date on which an infraction was or should have been discovered. Ferno Washington Italia s.r.l. reserves the right to cancel the warranty on products sold:

- if labels or plates showing the manufacturer's trademark, serial number or registration number have been erased or removed;
- if the product has been altered or repaired or if work has been carried out without authorization by Ferno Washington Italia s.r.l. or its personnel;
- if the product has not been used according to the instructions supplied or for purposes other than that for which it was designed.
- according to paragraph 8.1 "Warranty Conditions".

Under no circumstances will Ferno Washington Italia s.r.l. be held responsible for direct or indirect damage caused by use other than that described in the user manual and for which the product was designed.

8.3 Warranty Requests

If you suspect that you have received a defective product, contact Ferno Customer Relations immediately. A representative will deal with your complaint. Obtain authorization from Ferno Customer Relations before sending products to Ferno Washington Italia s.r.l.

8.4 Complaints

Any complaints must be communicated to the vendor or to Ferno Washington Italia L.L.C Customer Relations within 5 days of receipt of the product or discovery of the alleged defect.

Complaints or controversies regarding a single product do not exonerate the buyer from the obligation of receiving and paying for other products in the same order, unless otherwise agreed with the seller.

8.5 Authorization for Returns

No product will be accepted without prior approval by Ferno Washington Italia s.r.l.

Products returned for commercial reasons, i.e. for reasons that do not derive from defects of conformity, will only be accepted after they have been checked by specialized Ferno Washington Italia s.r.l. staff.

Product user and maintenance manual, needed for the safe operation, efficiency and reliability of the product and to render warranty conditions valid.

**Rel.111615
English**

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