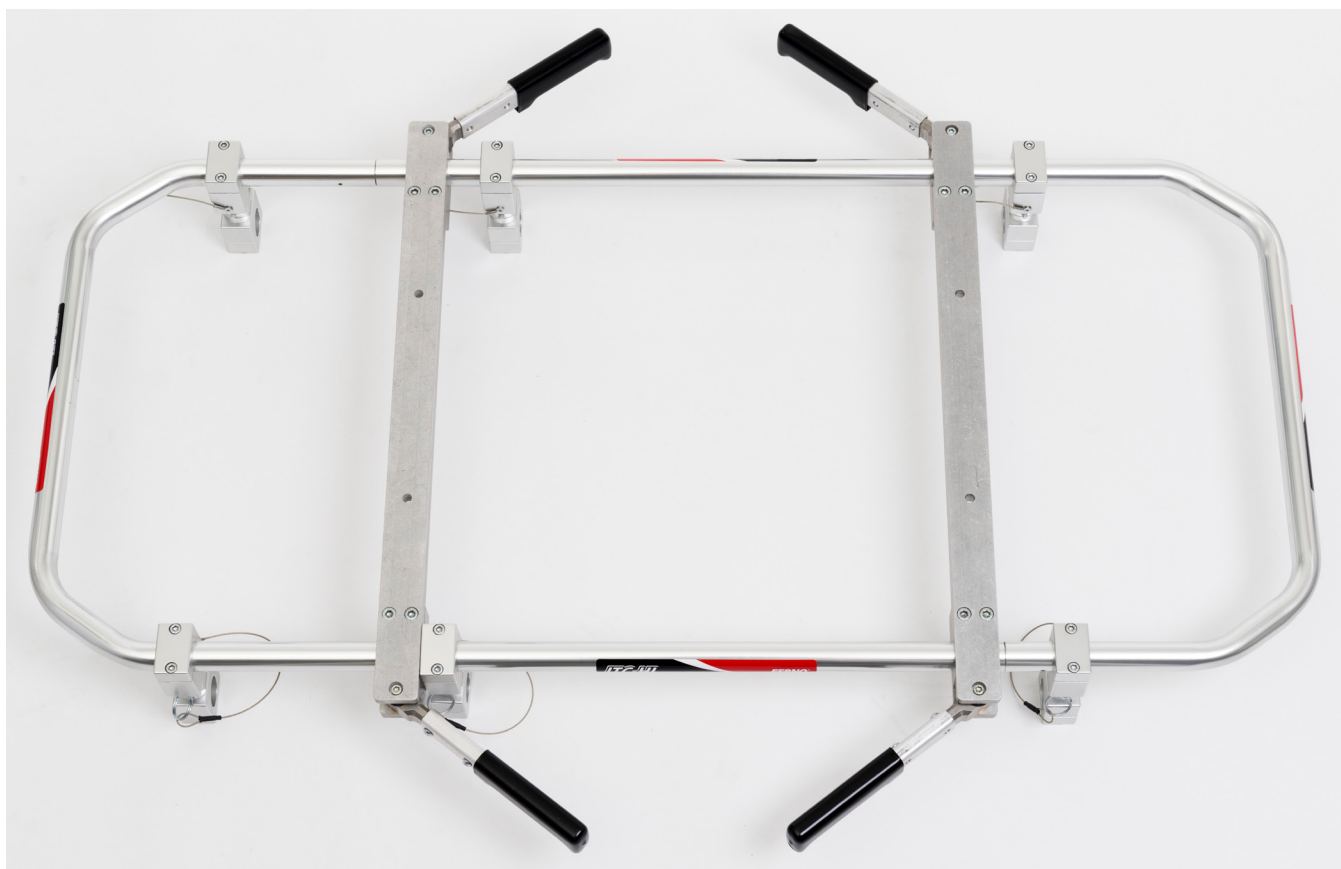




ITC-HL Locking system for incubator

Rel.260717 English



*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

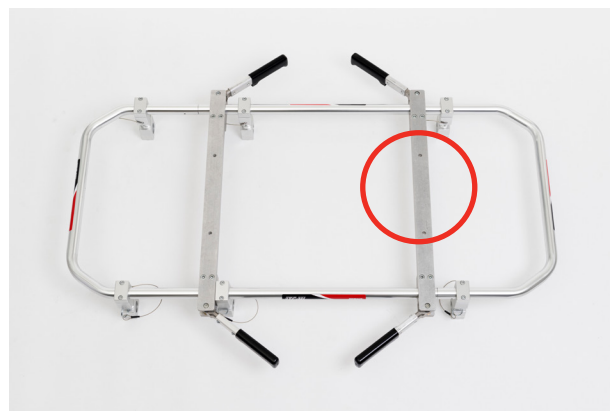
Ferno Customer Service

For assistance and further information, contact Ferno Washington Italia s.r.l.'s:

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



Serial number: _____

Placement: Main label placed on the locking device upper bar.



**USER AND MAINTENANCE
MANUAL**

To request additional free copies of the instruction manual, please contact Ferno Washington Italia's Customer Service.

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 Washington Italia'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 rights, construction, reproduction, use and sale 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*

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*

In order to avoid infections and/or bacterial contaminations, follow what indicated in sections 5.2 and 5.3, *Disinfection* and *Cleaning*.

Warning

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



WARNING

Improper use of the locking device may cause damage and/or injury. Install and use the locking device as described in this manual.

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

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

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 Washington Italia.

Unauthorised repairs, and repairs carried out by technicians not authorised by Ferno Washington Italia, will render all warranties null and void and may compromise the safety of the stretcher.

Non-original spare parts and inadequate repairs may cause damage and/or injury. Use only original Ferno parts and refer exclusively to Ferno Washington Italia Customer Support.

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.

Compatibility

The ITC-HL system is compatible with FERNO stretchers of the Proflexx 26B and 35P, 35A, 5126, 5126EL, 26S, Mondial, INX series and with the intra-hospital transporter 147. It allows fastening incubators with an overall weight not exceeding 140 kg, including accessories, and compatible with the 4 anchorages (see diagram in section 4.1 of parts "A"), with centre distance of 218 mm x 525 mm (the latter centre distance can be slightly changed by moving the two incubator support bars, paying attention to always balance the weight of the incubator correctly on the ITC-HL frame).

Ferno recommends using Ferno stretchers exclusively with Ferno locking devices, and using Ferno locking devices exclusively with Ferno stretchers.

Glossary of symbols

The symbols used in this manual and/or on the locking device's labels are defined below. The CE mark is present on the locking device and in this manual.

Important

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

Important



Read the user manual
carefully



This product meets
European Union
Standards

Labels and product identification

Carefully read and follow the instructions for use; replace any damaged or worn label immediately. To obtain replacement labels, contact Ferno's Customer Service.

The ITC-HL system is identified by the Part Number (PN) and by the Serial Number (SN) permanently printed on the label applied to the product.

CE Compliance

MEDICAL DEVICES DIRECTIVE

Ferno's products meet the requirements of European Directive 93/42/EEC concerning medical devices. The locking device is a Class I device.

The ITC-HL system is designed and manufactured by Ferno in compliance with the safety requirements provided for by the Directive 93/42/EEC (class I) on medical devices and certified according to standard EN1789 on medical vehicles and their equipment (test report "10G" No. 0139\ME\PCA\08 of 23/01/2009).

All materials used, duly sized to work correctly within the load limits appearing in the technical specifications, are flame-resistant, do not release toxic or polluting substances, and are protected to ensure high resistance to wear and corrosion.



ITC-HL FRAME

Description

The ITC-HL system consists of a frame and a set of six rapid anchorages. This device, in addition to the incubator, allows for a safe newborn transport in accordance with current regulations. If prearranged with the additional specific blocks (code 082-1942/ITC-HL), the ITC-HL system is interchangeable with different Ferno stretchers and intra-hospital transporters. The interchange manoeuvre is quick, safe and made easy by 4 additional lifting handles. Stretchers prearranged with 6-pin fasteners in the Proflexx series may be fitted with accessories for bariatric patients and still be used for all standard uses.

The ITC-HL system is compatible with:

- Series 26S - 26P - 26B;
- Series 5126 EL, Custom M;
- Series Mondial
- Series 35
- Series Inx

Features

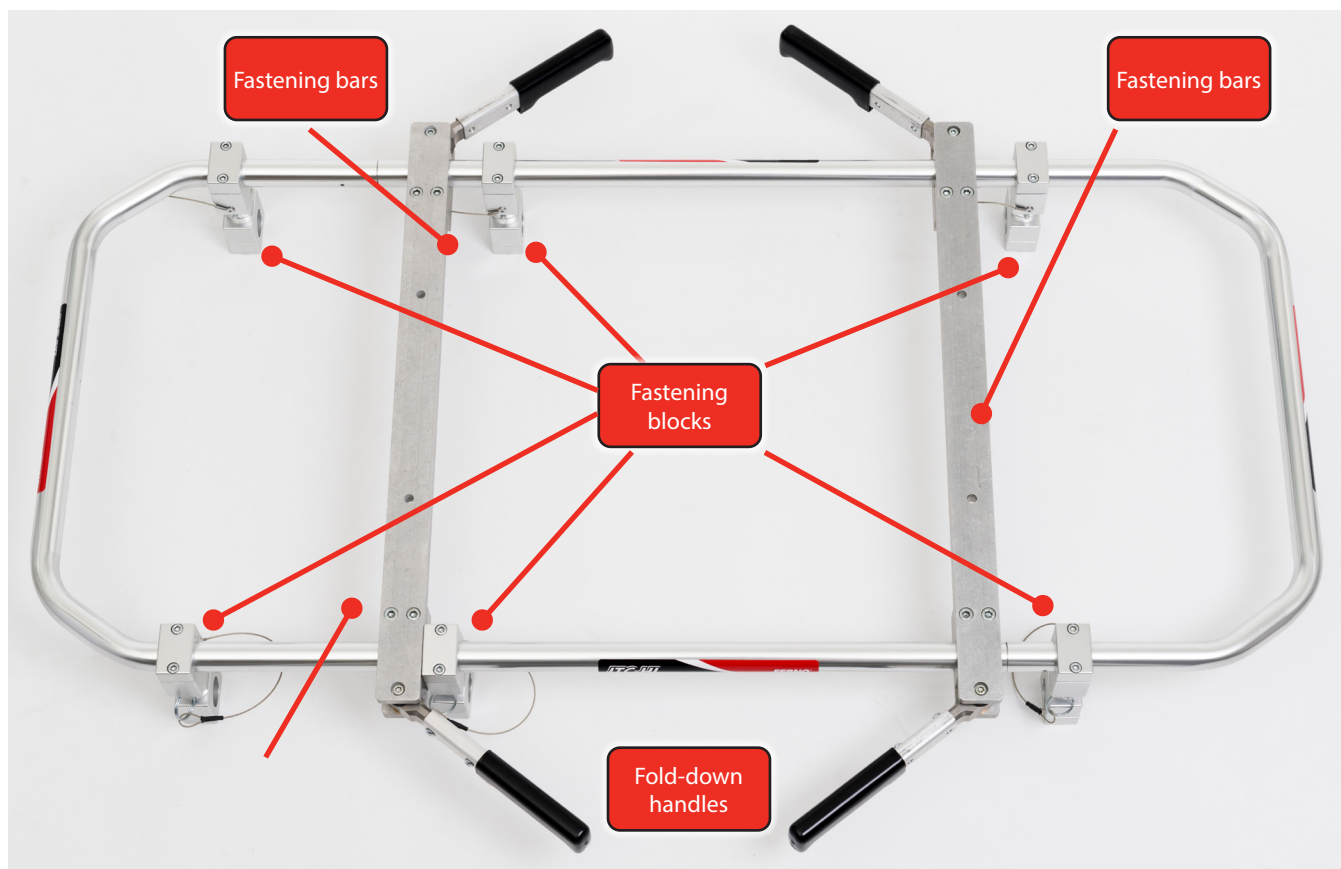
- High resistance aluminium alloy frame.
- 6-pin fastener with quick coupling.
- 4 lifting handles.
- Maximum load capacity: 140 kg.



WARNING

Anchoring systems/blocks must be assembled only by trained and qualified Ferno operators. All screws must also be tightened correctly, with the threaded part dampened with medium type threadlocker.

Components (Locking)



Technical Data

The following figures are rounded off to the nearest whole number. For further details, please contact Ferno Customer Service. Ferno reserves the right to change the specifications without notice.

Size without incubator:

Length	120 cm
Width	62 cm
Maximum width (with open handles)	103 cm
Height	13.5 cm
Weight	10 kg



WARNING

Anchoring systems/blocks must be assembled only by trained and qualified operators. All screws must also be tightened correctly, with the threaded part dampened with medium type threadlocker.

OPERATOR TRAINING AND SKILLS

Operators' skills

Operators authorised to use the locking system must:

- know the procedures for moving the patient;
- be able to assist the patient;
- have understood the procedures described in this manual;
- have attended a suitable training course on the correct use of the device;
- know the device, its features and all accessories used.

- scrupulously record the training sessions performed with the locking system on the form attached to this manual "Training record".

Operators' knowledge

- Operators must be able to ensure the safety of both themselves and their patients while using the product. Operators must be able to safely use the device and all the components of the system.

Training

For proper training it is necessary to:

- read this manual carefully (for additional copies contact the Customer Service of Ferno s.r.l.);
- attend a training course for the safe and correct use of the locking system;
- practice with the ITC-HL device and its accessories before using it in real situations;

DESCRIPTION OF THE ITC-HL LOCKING SYSTEM

General information

The ITC-HL device is a locking system for incubators to be installed on the main frame of the stretchers. It is supplied in different configurations so that it can be adapted to several stretchers and loading systems.

The available models are the following:

- ITC-HL (for 26-S, 26P, 26-B stretchers, series 5026 and 5126 CUSTOM-M, 35A, 35P and transporter 147);
- ITC-HL-INX (for INX stretcher and Mondial Monobloc)
- ITC-HL-BML (for Mondial with little stretcher)

Declination of responsibility for the ITC-HL locking system

The ITC-HL locking system, in the available configurations, is designed only for use with stretchers and transporters listed in section "General information". No warranty is provided on the adaptability of the ITC-HL locking system with transporters or stretchers other than those indicated. For warranty conditions, please refer to section "Warranty".



WARNING

Improper use of the ITC-HL locking system may cause damage and/or injury. Use the locking system according to the intended use as described in this manual.

A locking system that is assembled in a way that is not conforming with the instructions contained in this manual may cause serious accidents, damage and/or injuries to operators and/or patients.

INSTALLATION

Locking device installation

The ITC-HL frame is delivered already assembled with all 6 blocks as shown in the diagram below; minor adjustments to the position of the blocks may be necessary if the different stretchers are not perfectly interchangeable.

For any installation of the ITC-HL system on Ferno stretchers, contact the Ferno s.r.l. Customer Service.

Considerations on the vehicle

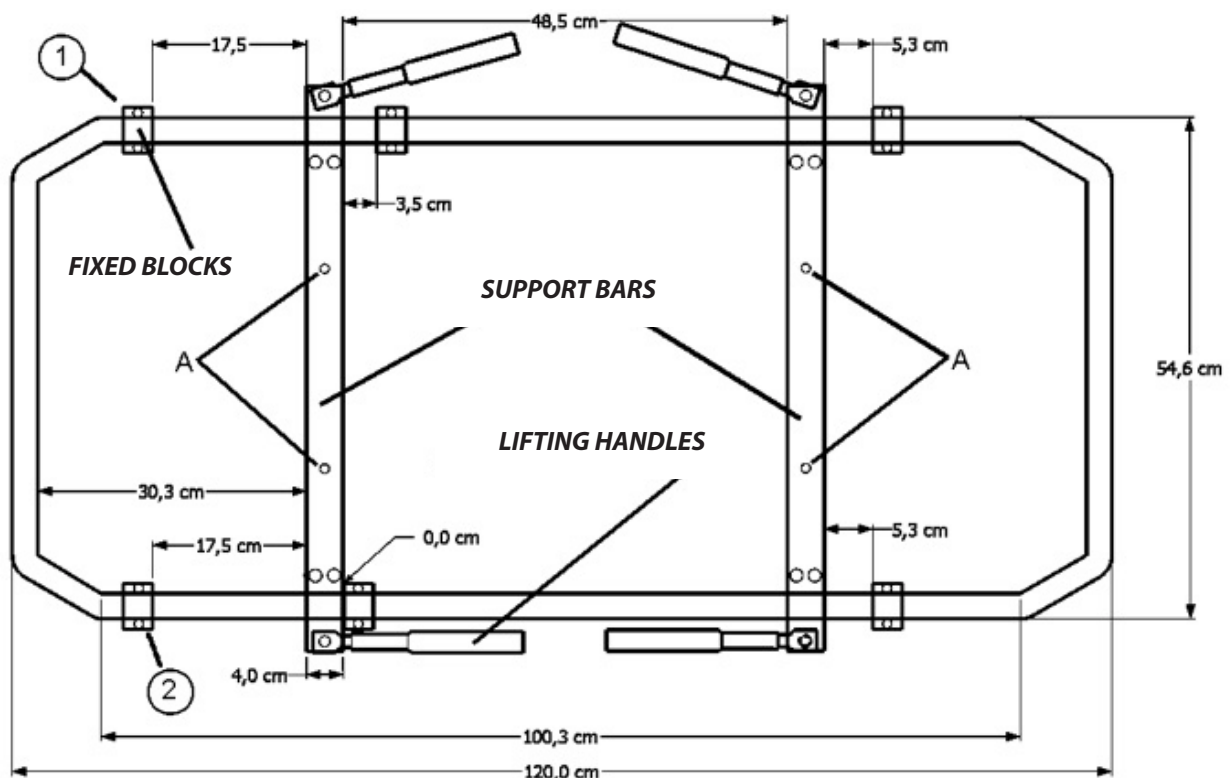
If the locking system is assembled on the ambulance floor, make sure that it is not installed in correspondence of the oxygen and fuel lines or that, during installation, holes are not carried out in the structural parts of the vehicle.

1. Every available model is equipped with ITC-HL locking system and front anchorage.
2. Please refer to the "Description of the ITC-HL locking system".

ITC-HL system anchoring

1. To perform this operation remove the stretcher mattress.
2. Remove the safety restraints
3. Position the 6 "blocks" without fully tightening them
4. Position the ITC-HL system so that it is centred and making the blocks match
5. Fix the 6 "blocks" with the "pin" system
6. Fully tighten using a suitable wrench

Included parts



WARNING

Follow this assembly diagram to ensure interchangeability between the different FERNO stretchers. Anchoring systems/blocks must be assembled only by trained and qualified operators. All screws must also be tightened correctly, with the threaded part smeared with medium type threadlocker.

Assembly details

To assemble rotating blocks, position the plastic spacers (code 2042729) on the frame, opening them up sufficiently (figure 1); then proceed to lock them in place definitively using the lower part of the block and the two respective hexagon head screws (figure 4). Check that all the rotating blocks have the pin aligned with the relevant seats on the fixed blocks on the ITC-HL frame.

Components

For ITC-HL system, series 26/5126/35



Figure 1: Assembly of plastic spacer (code 2042729).



Figure 2: Detail of the rotating block (Male) with Pin to be installed on the various stretchers.

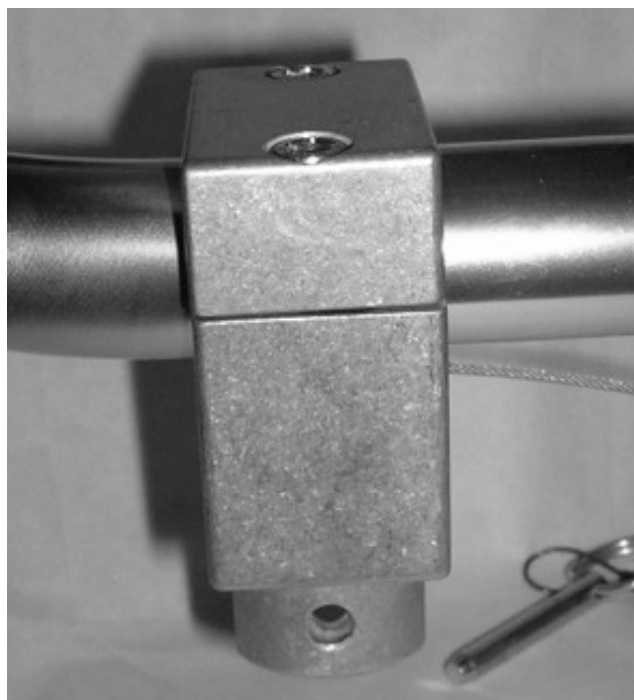


Figure 3: Detail of the fixed block (Female) installed on the ITC-HL frame.



Figure 4: Assembly of fixed block on ITC-HL frame.



Figure 5: Assembly of rotating block on stretcher.



Figure 6 Detail of safety pin to be removed when ITC-HL frame is to be separated from the stretcher

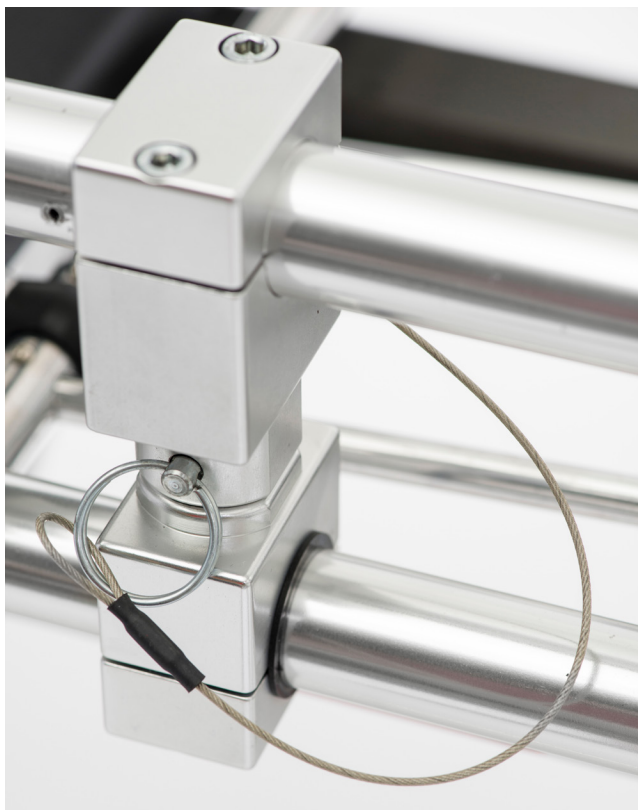


Figure 7: Coupling of fixed and rotating blocks with safety pin.



Figure 8: Figure 8: Lifting handle OPEN.



Figure 9: Lifting handle CLOSED.

The use of the ITC-HL system requires a minimum of four trained operators. To remove the ITC-HL system with incubator, remove all the safety pins holding the anchoring blocks between the ITC-HL frame and the stretcher together (see figure 6 and figure 7), open the four lifting handles (see figure 8), and lift the ITC-HL frame with the incubator, keeping it parallel to the ground. Always put the handles back in the starting position when connecting the system to the stretcher again, as shown in figure 9. If the pins on the blocks fixed onto the stretcher get in the way, they can easily be turned by 180°.

NOTE: Slightly loose one of the two fastening screws if the block cannot be easily moved, as indicated in figure 10.



Figure 10

WARNING

The installation of the incubator must be carried out exclusively by staff authorised and certified by the Manufacturer.

WARNING

For the assembly of the anchoring blocks, drive screws fully home using a 5 mm hexagonal head wrench, as indicated in the figures below.

Incubator Installation

The incubator is anchored to the ITC-HL frame in accordance with the manufacturer's guidelines, using the 4 anchorages provided on the ITC-HL frame, which have the following centre distances, 218 mm and approx. 525 mm (the latter centre distance may be slightly changed by moving the two bars that support the incubator, ensuring that the incubator weight is correctly balanced on the ITC-HL frame). The incubator frame must be provided with holes with diameter equal to 13 mm, with the same centre distance of the anchorages mentioned above.

If it is necessary to adapt the centre distance of the anchorages of the ITC-HL frame with those of the incubators, slightly loosen the 12 screws of the clamps holding the two brackets supporting the incubator onto the ITC-HL frame, move the two brackets symmetrically to balance the weight and fully tighten the screws on each bracket.



WARNING

Always apply threadlocker when indicated in this user manual.

Follow the installation instructions contained in this user manual, supplied with the product, to guarantee that the safety requirements are met. The declaration of conformity of the locking system released by Ferno Washington Italia concerns the product installed in compliance with the correct installation instructions; Ferno Washing Italia will not be held responsible for an incorrect installation.

INSTALLATION OF ITC-HL FRAME ON FERNO 5126 / 5126EL STRETCHER

Warning: to assemble the ITC-HL system on 5126 series stretchers, make a slot in the ABS central panel with a cutter or small saw in order to fix the relevant blocks onto the frame, as shown by the two RED arrows in figure 13.

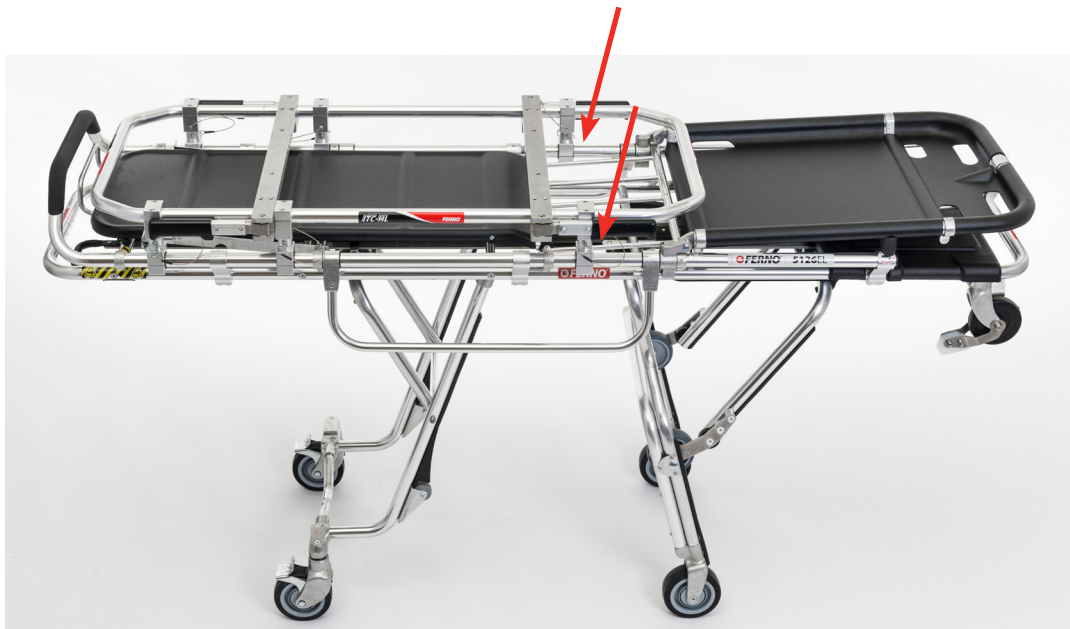


Figure 13: Installation of ITC-HL frame on Ferno 5126 and 5126EL Stretcher.

INSTALLATION OF ITC-HL FRAME ON FERNO 35A AND 36 PROFLEXX STRETCHER

Warning: to ensure interchangeability of the ITC-HL system with other Ferno stretchers, remove the mobile backrest on the stretcher.



Figure 14: Installation of ITC-HL frame on Ferno 35A Stretcher.

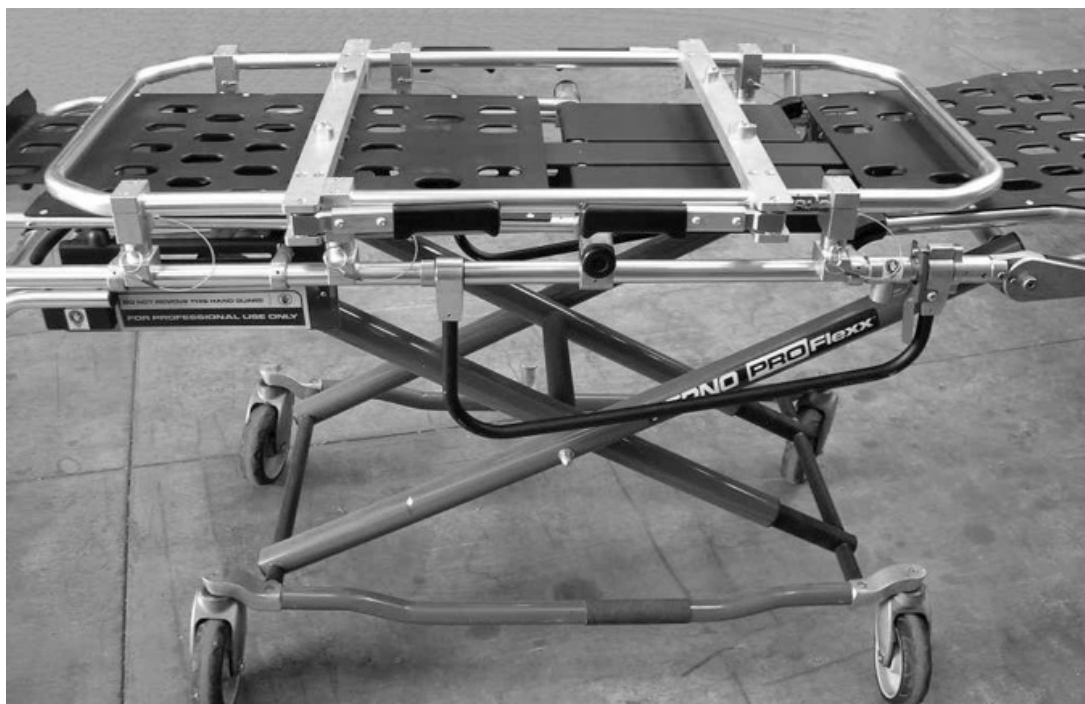


Figure 15: Installation of ITC-HL frame on Ferno 35P Proflexx Stretcher.

INSTALLATION OF ITC-HL FRAME ON FERNO 26S - 26 B STRETCHER

Warning: to ensure interchangeability of the ITC-HL system with other Ferno stretchers, remove the mobile backrest on the stretcher.



Figure 16: Installation of ITC-HL frame on Ferno 26 P - 26 B Stretcher.

INSTALLATION OF ITC-HL FRAME ON FERNO MONDIAL WITH SMALL STRETCHER AND MONDIAL MONOBLOC STRETCHER

Warning: to ensure interchangeability of the ITC-HL system with other Ferno stretchers it may be necessary to remove the mobile backrest on the stretcher.

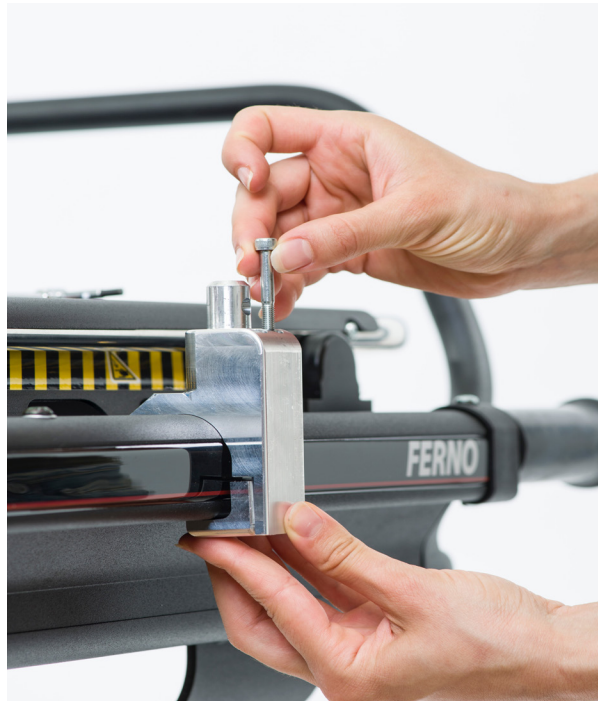
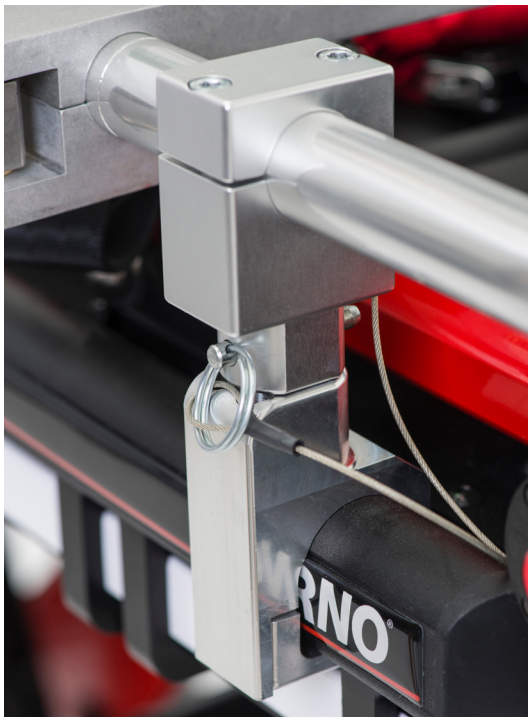


Coupling of fixed and rotating blocks with safety pin for Mondial



Figure 17: Installation of ITC-HL frame on Ferno Mondial Monobloc Stretcher

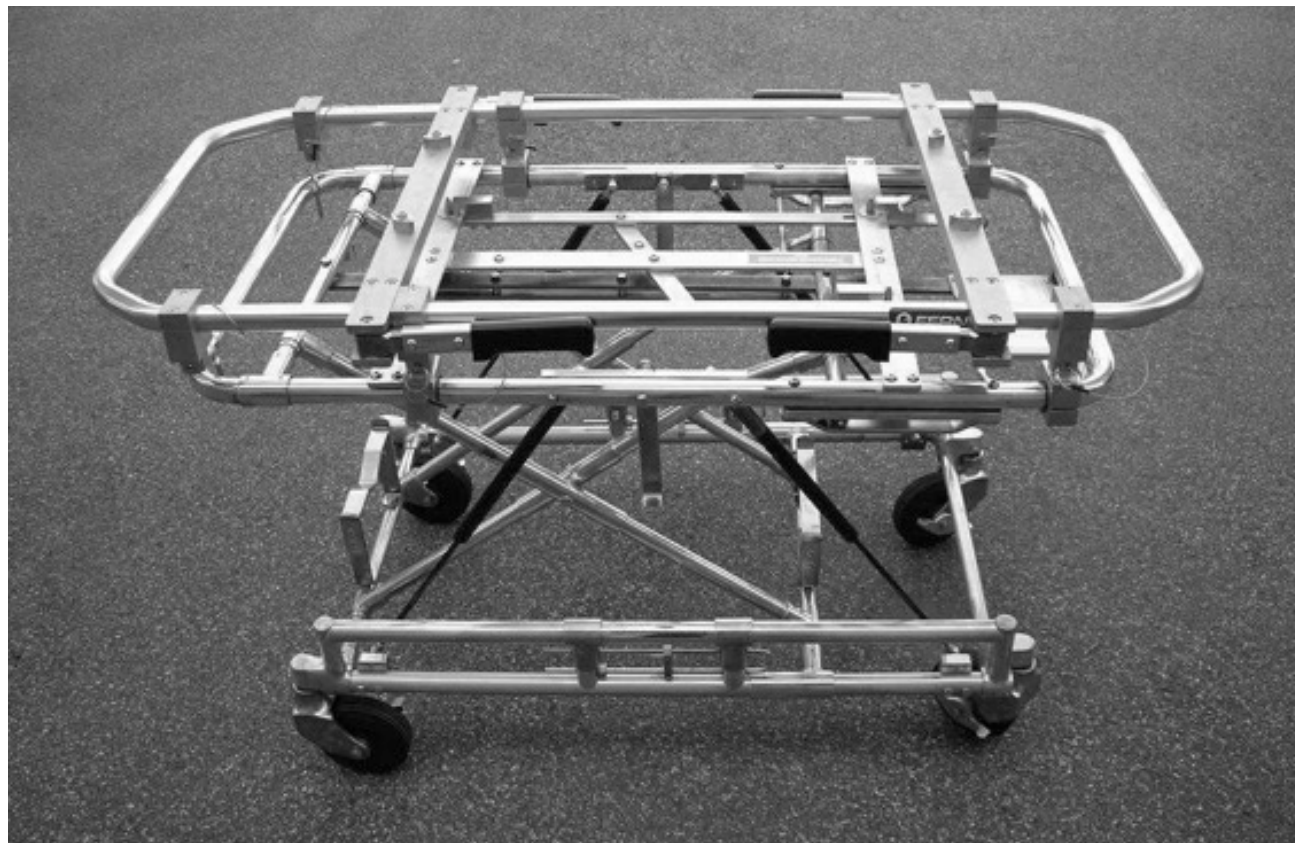
INSTALLATION OF ITC-HL FRAME ON FERNO IN/X STRETCHER



Coupling of fixed and rotating blocks with safety pin for Mondial monobloc and IN/x

INSTALLATION OF ITC-HL FRAME ON FERNO INTRA-HOSPITAL TRANSPORTER 147

Warning: to ensure interchangeability of the ITC-HL system with other Ferno stretchers, remove the mobile backrest on the stretcher.



Safety technical check

To guarantee the safety of the device and its operators, the ITC-HL system must be subjected to a technical safety check by technical staff or an authorised Ferno service centre every two years. Contact Ferno Washington Italia Customer Service to set a date for the check. Check once a year or more in the event of heavy-duty or very frequent use, or use under unusual conditions. For any doubt or for further clarifications, contact Ferno Customer Service.

Have the maintenance service staff carry out the instructions contained in the manual.

- Check that all components are present.
- Check that all screws, nuts, bolts, rivets and spring pins are correctly positioned.
- Check that all mobile parts move normally and correctly.
- Check that the system does not feature worn parts.
- Check that all anchoring systems are correctly connected.
- Check that all anchoring blocks are securely fixed to the ITC-HL and stretcher frames.
- Check that the incubator is securely fixed to the ITC-HL frame and that all fastening screws are present.
- Check that the safety pins are present and correctly inserted in the relevant seats.
- Check that the plastic bushings of rotating blocks are present and not worn out.

If signs of wear or damage are found during inspection,

discontinue use of the device and immediately contact Ferno Technical Support Service.

The ITC-HL system does not require any type of lubrication.



WARNING

Steam and high pressure water can penetrate in the joints resulting in corrosion and lubricant elimination. Do not use high pressure water or steam to clean/disinfect the ITC-HL locking system.

MAINTENANCE

Routine and preventive maintenance

The stretcher is a medical device requiring regular maintenance, hence you are recommended to comply with the following schedule:

* **ROUTINE** maintenance: the stretcher has to be subjected to a routine maintenance intervention once a year by Ferno skilled technicians.

* **PREVENTIVE** maintenance: preventive maintenance operations are to be carried out by the user, as specified in the table on the right.

If the device undergoes particularly heavy use, maintenance should preferably be carried out on a more frequent basis. If there are signs of wear and damage, discontinue use of the device and immediately contact Ferno's Technical Support Service.

Ferno directly carries out repair/maintenance operations, without the need of dealers, mechanics or external service centres. You are thus invited to be wary of those who present themselves as Ferno's authorised technician. We suggest you to directly contact our SOS Ferno service.

Disinfection

1. Clean the surfaces of the locking device with a non-abrasive surface disinfectant.
2. Do not immerse the locking device directly in disinfectant.
3. During disinfection, ensure there are no signs of wear and/or damage.
4. Dry with a cloth. Ensure all the components of the device are completely dry before reusing them.

It is advisable to wear suitable gloves (e.g. household or disposable gloves) during disinfection.

Cleaning

1. Clean the surfaces of the locking device with a cloth, water and soap or a mild detergent.
2. Dry with a cloth.

Do not wash with high pressure water.

It is advisable to wear suitable gloves (e.g. household or disposable gloves) during cleaning.

Inspection

To ensure optimal use of the locking device, it is important to keep all the components in good conditions and to remove all traces of dirt, debris and body fluids. When not in use, the

locking device must be stored in a dry, indoor environment and inspected at least once a month.

Inspect the locking system and check that there are no worn, bent, damaged or missing components/parts. If signs of wear or damage are found during inspection, discontinue use of the locking device and immediately contact Ferno's Technical Support Service to request repairs or maintenance. See chapter 6 *Technical Support*.

Routine and preventive maintenance	After each use	Whenever necessary	Every month
Disinfection		•	
Cleaning		•	•
Inspection	•	•	•



WARNING

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

Important

When not in use, store the locking device in an indoor environment that is dry and protected from direct sunlight.

Important

After disinfection/cleaning, ensure that the locking device and its components are completely dry before use.

Important



DO NOT LUBRICATE THE LOCKING DEVICE

The ITC-HL locking system does not require lubrication; do **NOT** lubricate the locking device.

Important



DO NOT WASH WITH HIGH PRESSURE WATER

Do not use high pressure water to clean the locking device.

TECHNICAL SUPPORT

Technical Support Service

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

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

For information on the use of the ITC-HL locking device, and to schedule training courses on the correct use of the device, contact the Ferno Customer Service team.



WARNING

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



WARNING

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

WARRANTY

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), or at the Customer's premises if suitable arrangements with Ferno'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 sustained 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 periods of warranties 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 Washington Italia will not cover the transport costs for sending or returning the product.

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 7.1, "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.

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 Customer Service to request authorisation.

Claims

Any claims 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.

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 of the product, will be accepted only after verification of their condition by Ferno s.r.l. qualified personnel.

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.260717
English (UK)

Ferno s.r.l.

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E-mail	info@ferno.it
Website	www.ferno.it