

ITC Heated Cot Anchorage System

April 2012 Pub. N° MU-074-C



Warning

This users' manual contains general specifications on the use, operation and maintenance of this product. The general guidelines contained in this manual should not be considered to cover all possible applications and operations.

Safe, proper use of this product is at the user's discretion.

Safety information is provided as an aid to the user, and simply guarantees the minimum level of safety necessary to prevent accidents to operators and patients. Appropriate training of operators using the product is recommended prior to actual application.

Keep this users' manual for future reference and make sure new users have access to it. You may request additional copies from Ferno Washington Italia s.r.l.'s Customer Service Center.

ATTENZIONE

Before beginning regular use of the product, operators must read this manual carefully, following the general guidelines contained in it and familiarizing themselves with correct use and maintenance procedures.

Rights

The information contained in this users' 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 the rights to all images and drawings.

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

© Copyright Ferno Washington Italia s.r.l.. All rights reserved.

Ferno Washington Italia s.r.l. Via Benedetto Zallone 26 40066 Pieve di Cento (BO) - Italy

Internet	<u>www.ferno.1t</u>
E-mail	info@ferno.it
Telephone	+39 0516860028

TABLE OF CONTENTS

1. SAFE	ETY INFORMATION	4
1.1. 1.2. 1.3. 1.4. 1.5. 1.6. 2. 2.1. 2.2.	SAFETY WARNINGS COMPATIBILITY SAFETY LABELS CONFORMITY WITH CURRENT SAFETY LEGISLATION WARNING REGARDING DISEASES CARRIED THROUGH THE BLOOD PRODUCT IDENTIFICATION OPERATORS' CAPACITY AND TRAINING OPERATORS' CAPACITY TRAINING ITC SYSTEM	4 5 5 5 5 6 6 6 6
3.1. 3.2.	DESCRIPTION TECHNICAL DATA	7 7
4.	INSTALLATION AND PREPARATION FOR USE	8
4.1. 4.2. 4.3.	INSTALLATION COMPONENTS GENERAL GUIDE TO USE	8 9 11
5.	INSTALLATIONS	12
5.1. 5.2. 5.3. 5.4. 5.5. 5.6. 5.7.	HEATED COT INSTALLATION INSTALLING THE ITC FRAME ON THE FERNO 26P STRETCHER INSTALLING THE ITC FRAME ON THE FERNO 5126 E 5126EL STRETCHER. INSTALLING THE ITC FRAME ON THE FERNO 35A STRETCHER INSTALLING THE ITC FRAME ON THE FERNO 35P PROFLEXX STRETCHER INSTALLING THE ITC FRAME ON THE FERNO 26S STRETCHER INSTALLING THE ITC FRAME ON THE INTRA-HOSPITAL TRANSPORTER FERNO 147	12 13 14 15 16 17
6.	MAINTENANCE	19
6.1. 6.2. 6.3. 6.4. 6.5.	MAINTENANCE PROGRAM DISINFECTION AND CLEANING INSPECTION LUBRICATION TECHNICAL SAFETY CHECK	19 19 19 20 20
7.	ACCESSORIES	20
8.	REPLACEMENT PARTS AND ASSISTANCE SERVICE	21
9.	GUARANTEE	22
9.1. 9.2. 9.3. 9.4. 9.5.	GUARANTEE CONDITIONS LIMITATIONS ON LIABILITY REQUESTS UNDER THE GUARANTEE CLAIMS AUTHORIZATION TO RETURN	22 23 23 23 23
10.	TRAINING RECORD	24
11.	MAINTENANCE RECORD	24

1. SAFETY INFORMATION

1.1. Safety warnings

"Warnings" such as the one shown below identify a hazard which, if not prevented, could cause injury to the patient and/or operator.

This manual contains the following safety warnings:

ATTENZIONE

Untrained operators could cause injury to themselves or others. Allow only trained operators to use the system.

Improper use of the system may cause damage or injury. Use the system only as described in this users' manual.

Improper use may cause damage, injury and/or serious accidents. Use only as described in this users' manual.

Helpers can cause accidents and/or be injured. Always ensure that you are in control of the system and are working the commands and coordinating helpers.

Improper maintenance could cause accidents. Perform system maintenance as described in this users' manual.

Use of inappropriate replacement parts or services could cause damage. User only Ferno parts.

Application of improper accessories not approved by Ferno could cause accidents. Use only Ferno approved accessories.

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

The heated cot must be installed only by authorized operators certified by the manufacturer.

Follow this assembly diagram to ensure interchangeability of various FERNO stretchers.

The owner of the stretcher is responsible for tightening the blocks on the stretcher frame. Always contact an authorized Ferno operator if you require any kind of repair work.

1.2. Compatibility

The ITC system is compatible with FERNO Proflexx 26P and 35P, 35A, 5126, 5126EL, 26S series stretchers and with intra-hospital transporter 147. Permits anchorage of heated cots with a total weight, including accessories, of no more than 80 kg compatible with the 4 anchorage points (refer to diagram in paragraph 4.1, detail "A"), with a center-to-center distance of 218 mm x 525 mm (the latter center-to-center distance may by varied slightly by shifting the two bars supporting the heated cot, being careful always to ensure correct balancing of the heated cot on the ITC frame). For further information refer to figure 11 in section 5.1.

Ferno Washington recommends use of Ferno stretchers exclusively with Ferno locking devices, and use of Ferno locking devices exclusively with Ferno stretchers.

1.3. Safety labels

Carefully read and follow the general guidelines; replace worn or damaged labels immediately. Contact Ferno Washington Italia Customer Service to request a replacement label.

1.4. Conformity with current safety legislation

Ferno Washington Italia has designed and built the ITC system in compliance with the safety requirements of directive 93/42/EEC (class I) concerning medical devices and certified by CSI according to EN1789 standards for medical vehicles and their equipment (test report "10G" N° 0139\ME\PCA\08 of 23/01/2009).

All materials used, scaled to work correctly within the load limits appearing in the technical specifications, are flame-resistant, do not give off any toxins or pollutants, and are protected to ensure high resistance to wear and corrosion.

1.5. Warning regarding diseases carried through the blood

To reduce risk of exposure to infectious diseases carried through the blood, such as HIV-1 or hepatitis, scrupulously following the general guidelines appearing in this users' manual during use of the ITC system and subject the device to a hygienizing treatment.

1.6. Product identification

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

Sample product identification label



2. OPERATORS' CAPACITY AND TRAINING

2.1. Operators' capacity

Operators using the device must:

- be familiar with procedures for moving the patient;
- be capable of assisting the patient;
- have understood the procedures described in this users' manual;
- have attended a special training course in correct use of the device;
- be familiar with the device, its features and all accessories used.

ATTENZIONE

Untrained operators could cause injury to themselves or others. Allow only trained operators to use the ITC system.

2.2. Training

To ensure correct training, it is necessary to:

- read this users' manual carefully (for additional copies contact the Ferno Washington Italia s.r.l. Customer Service Center);
- attend a training course in safe, correct use;
- practice using the device and its accessories before using it in a real emergency;
- keep proper record of training sessions with the device using the form attached to this users' manual (see chapter 10, "Recording training").

3. ITC SYSTEM

3.1. Description

The ITC system consists of a frame and a set of six rapid anchorage points made of high quality material. This device, in addition to the heated cot, permits safe transport of newborns in accordance with current regulations. If prepared with the supplementary blocks supplied (code 082-1942/ITC), the ITC system is interchangeable with various different Ferno stretchers and in-hospital transporters. The interchange movement is quick, safe and made easy by 4 additional lifting handles. Stretchers prepared with 6-pin anchorages in the Proflexx series may be fitted with accessories for bariatric patients and still be usable for all standard uses.

FEATURES:

- High quality aluminum alloy frame.
- Snap-together 6-pin anchorage.
- 4 lifting handles.
- Maximum load: 80 kg.

ATTENZIONE

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

3.2. Technical data

The following figures are rounded off to the nearest whole number. Contact Ferno Washington Italia Customer Service for further information. Ferno reserves the right to make changes without advance notice.

Dimensions without heated cot:

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

4. INSTALLATION AND PREPARATION FOR USE

4.1. Installation

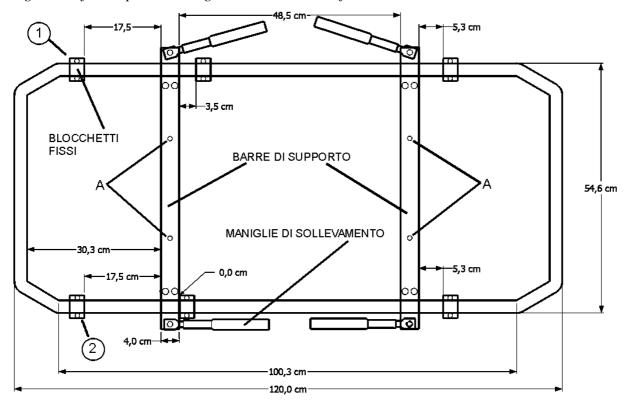
The ITC frame is delivered already assembled with all 6 blocks as shown in the diagram below; minor adjustments to the position of the blocks may be necessary if the various different stretchers are not perfectly interchangeable.

For installation of the ITC system on Ferno stretchers, contact the Ferno Washington Italia s.r.l. Customer Service Center.

ATTENZIONE

The heated cot must be installed exclusively by authorized operators certified by the manufacturer.

Arrangement of the 6 pin anchorage blocks on the ITC frame



A = Anchorage points for heated cot

1-2 = Blocks not used on intra-hospital transporter 147

ATTENZIONE

Follow this assembly diagram to ensure interchangeability of various FERNO stretchers.

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

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 its housing in the block permanently fixed on the ITC frame.



Figure 1: Assembling plastic spacers (code 2042729).

4.2. Components

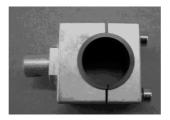


Figure 2: Detail of the rotating block (Male) with Pin for installation on the stretcher.



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

ATTENZIONE

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

To assemble the anchoring blocks, tighten the screws all the way using a 5 mm hexagonal wrench, as shown in the figures below.

Figure 4: Assembling the fixed block on the ITC frame.



Figure 6
Detail of safety
plug for removal when
separating the ITC frame from the stretcher.



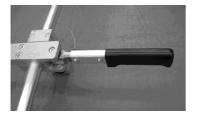


Figure 8: Lifting handle OPEN.



Figure 9: Lifting handle CLOSED.

Figure 5: Assembling the rotating block on the stretcher.



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



4.3. General guide to use

Use of ITC-stretcher and heated cot requires at least four trained operators. To remove the ITC system with the heated cot, remove all the safety plugs which hold the anchorage blocks between the ITC frame and the stretcher together (see *figure 6 and figure 7*), open the four lifting handles provided (see *figure 8*), and lift the ITC frame with the heated cot, 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 permanently fixed onto the stretcher get in the way, they can easily be turned 180° as shown in *figure 10*.

NB: Loosen one of the two anchorage screws slightly if you cannot move the block easily, as shown in figure 10.



Figure 10

! ATTENZIONE

The heated cot must be installed exclusively by authorized operators certified by the manufacturer.

5. INSTALLATIONS

5.1. Heated cot Installation

The heated cot is anchored to the ITC frame in accordance with the manufacturer's guidelines, using the 4 anchorage points provided on the ITC frame, which have the following center-to-center distances, 218 mm and about 525 mm (the latter center-to-center distance may be varied slightly by shifting the two bars supporting the heated cot, ensuring correct balancing of the weight of the heated cot on the ITC frame). Refer to the diagram appearing in section 4.1 detail "A" and figure 11.

The heated cot frame must have holes with a diameter of 13 mm, with the same center-to-center distance as the anchorage points described above.

If it is necessary to adapt the center-to-center distance of the anchorage points of the ITC frame with those of the heated cot, slacken the 12 screws on the clamps holding the two brackets supporting the heated cot onto the ITC frame slightly, move the two brackets symmetrically to balance the weight and screw in the screws on each bracket all the way.

ATTENZIONE

The heated cot must be installed exclusively by authorized operators certified by the manufacturer.

! ATTENZIONE

Following the heated cot manufacturer's guidelines for use of the heated cot and anchorage to the ITC frame.

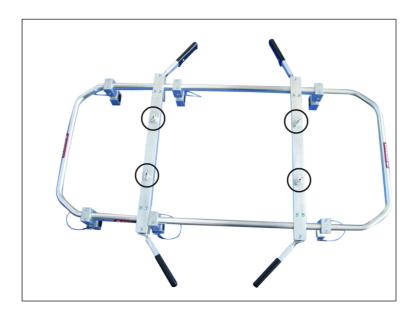


Figure 11: The four circles indicate the anchorage points for the heated cot.

5.2. Installing the ITC frame on the Ferno 26P stretcher



Figure 12: Installing the ITC frame on the Ferno 26P stretcher.

5.3. Installing the ITC frame on the Ferno 5126 e 5126EL stretcher.

<u>Caution</u>: to assemble the ITC system on stretchers in series 5126, make a slot in the ABS central panel with a knife or small saw so that you can anchor the corresponding blocks onto the frame, as shown by the two white arrows in *figure 13*.

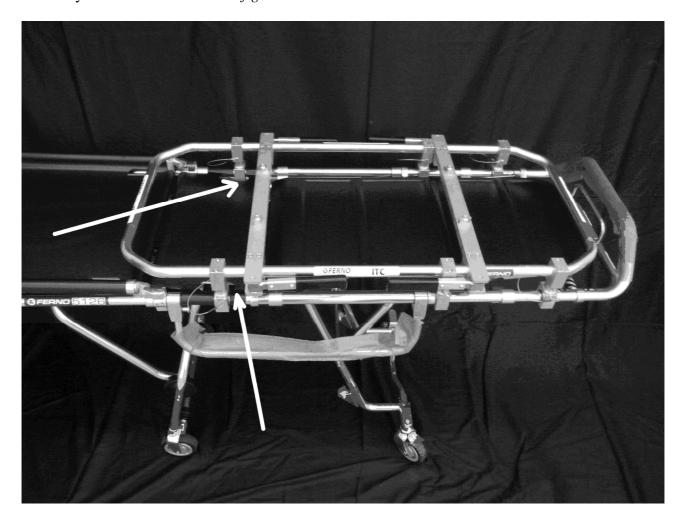


Figure 13: Installing the ITC frame on the Ferno 5126 and 5126EL Stretcher.

5.4. Installing the ITC frame on the Ferno 35A stretcher

<u>Caution:</u> to ensure interchangeability of the ITC system with other Ferno stretchers, remove the mobile backrest on the stretcher.

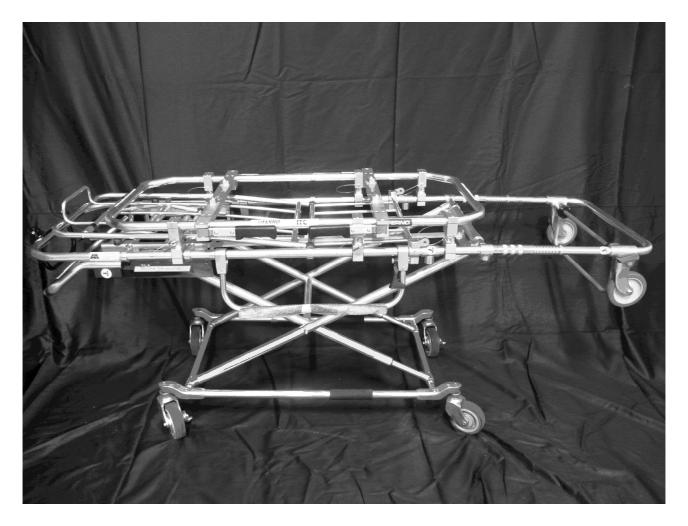


Figure 14: Installing the ITC frame on the Ferno 35A stretcher.

5.5. Installing the ITC frame on the Ferno 35P Proflexx stretcher



Figure 15: Installing the ITC frame on the Ferno 35P Proflexx stretcher.

5.6. Installing the ITC frame on the Ferno 26S stretcher

<u>Caution:</u> to ensure interchangeability of the ITC system with other Ferno stretchers, remove the mobile backrest on the stretcher.

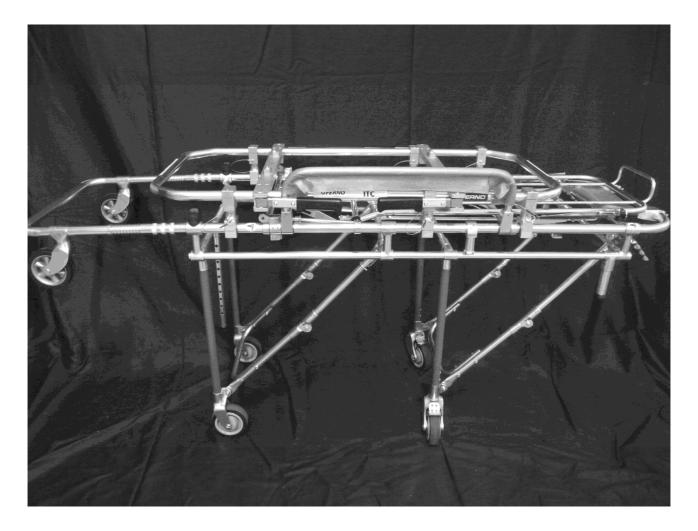


Figure 16: Installing the ITC frame on the Ferno 26S stretcher.

5.7. Installing the ITC frame on the intra-hospital transporter Ferno 147

<u>Caution</u>: do not use rotating blocks 1 and 2 for assembly on transporter 147 (see assembly diagram in section 4.1).

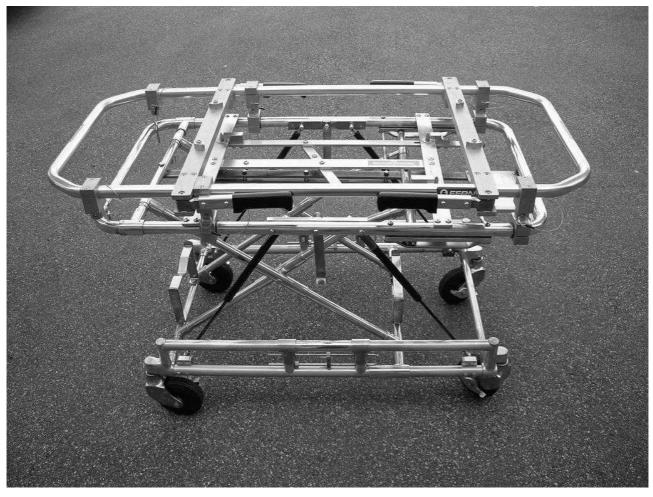


Figure 17: Installing the ITC frame on the intra-hospital transporter Ferno 147

6. MAINTENANCE

6.1. Maintenance program

The ITC system requires regular maintenance. Establish and follow a maintenance program as shown in the table below.

The table below shows the necessary maintenance frequency:

	Before each use	After each use	Every two years
Disinfection and cleaning (section 6.2)	•	•	
Inspection (section 6.3)	•		•
Technical safety check (section 6.5)			•

When using maintenance products, follow the manufacturer's recommendations and read the information appearing in the product's "safety data sheet".

! ATTENZIONE

Improper maintenance could cause accidents. Perform the maintenance procedures described in this manual.

6.2. Disinfection and cleaning

Clean all surfaces with disinfectant. Ferno recommends you inspect the stretcher during disinfection to look for signs of damage or wear.

- 1. Clean all metal surfaces with warm water and a mild detergent.
- 2. If necessary, use a stiff non-metallic brush or a mild solvent to remove stains.
- 3. Rinse with warm water. Dry with a towel or allow to air-dry.

Important

Disinfectants containing chlorine, phenol and iodine can damage the surfaces of the device. Do not use disinfectants containing these chemicals to clean and disinfect the device.

Steam or pressurized water can get into the joints and cause corrosion. Do not use steam or pressurized jets of water to clean the device.

6.3. Inspection

Have the maintenance workers follow the guidelines contained in chapters 4 and 5 and perform the following checks:

© Ferno-Washington Italia s.r.l.. MU-074-C, April 2012

ITC System

- Check that all components are present.
- Check that all screws, nuts, bolts, rivets and elastic plugs are solidly in position.
- Check that all mobile parts move properly in the appropriate manner.
- Check that there are no worn parts.
- Check that all anchorage systems are joined correctly.
- Check that all anchorage blocks are solidly anchored to the frame of the ITC and the stretcher.
- Check that the heated cot is solidly anchored to the ITC frame and all anchorage screws are present.
- Check that the safety plugs are present and correctly inserted in their seats.
- Check that the plastic bushes on the rotating blocks (see *figure 1*) are present and not worn.

If inspection reveals the presence of signs of damage and/or worn parts, do not use the device, and contact the Ferno Washington Italia Technical Assistance Service immediately.

6.4. Lubrication

The ITC system does not require any lubrication.

6.5. Technical safety check

To guarantee the safety of the device and its operators, the ITC system must be subjected to a technical safety check by technical staff or an authorized Ferno service center 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. In the event of doubt or for further clarification, contact Ferno Washington Italia Customer Service.

7. ACCESSORIES

Code Description

082-1942/ITC Set of ITC rotating blocks



Application of improper accessories can cause accidents. Use only FERNO

approved accessories.

8. REPLACEMENT PARTS AND ASSISTANCE SERVICE

The Ferno Washington Italia Technical Assistance Service is at your disposal for more information on use, maintenance and assistance for this product.

Contact:

Ferno Washington Italia s.r.l.

Via B. Zallone n. 26 40066 Pieve di Cento (BO) tel. +39 0516860028

fax. +39 0516861508 e-mail: info@ferno.it

ATTENZIONE

Use of non-original replacement parts or inappropriate service could cause damage. User only original FERNO parts.

9. GUARANTEE

9.1. Guarantee Conditions

Ferno products are guaranteed to be free from defects in manufacture for 24 months starting on the date appearing in the Ferno W. Italia s.r.l. shipping document.

Ferno Washington Italia guarantees replacement parts for 12 months.

While the guarantee remains in effect, it will repair and/or replace all defective parts free of charge provided the defect is proven to be due to faulty manufacture, excluding the cost of labor, travel, shipping and packaging.

The guarantee does not cover consumables or components subject to wear associated with normal product use, all parts typically subject to sliding or rolling friction (bearings, brushes, lubricants, sliding blocks, belts, etc.), parts potentially subject to rust or corrosion (contacts made of copper or metal alloys; electrical, electronic and mechanical equipment) and batteries.

External finishes (gel coat/resin, paint, powder paint, decals, straps, text, etc.) are guaranteed for 90 days.

Repairs are performed by specialized technical staff on Ferno Washington Italia s.r.l.'s premises at Via Zallone 26- 40066 Pieve di Cento (BO) or on the customer's premises in the event of a written agreement with the Ferno Washington Italia Customer Service Center.

Technical work to be performed on the customer's premises must be agreed on with refund of documented expenses upon request. For information on the cost of technical work, contact the appropriate Ferno W. Italia s.r.l. office.

Repairs are guaranteed for 6 months from the date of the repair. This guarantee only applies if the product is used as described in the users' manual supplied with the product. Improper use and neglect will invalidate the guarantee.

The guarantee goes into effect on the day on which the product is shipped by Ferno W. Italia s.r.l., and does not cover shipping costs. Ferno W. Italia s.r.l. shall not be held liable for damage due to shipping or damage caused by improper use of the product.

Products not bearing the Ferno trademark which are sold by Ferno W. Italia s.r.l. shall be covered by the product manufacturer's original guarantee. Ferno W. Italia s.r.l. does not offer guarantee extensions for the product manufacturer's guarantee; Ferno W. Italia s.r.l. shall not accept any liability for products manufactured by others.

No guarantee will be provided in the event of:

- failure to follow the guidelines for use,
- incorrect use.
- inappropriate use or handling,
- attempts to repair the device by unauthorized personnel,
- damage during shipping due to improper packaging of products returned by the user,
- lack of maintenance,
- use of non-original replacement parts.

In the cases not covered by the guarantee, Ferno W. Italia shall not accept the cost of shipping and return of the product.

9.2. Limitations on liability

If a product is found to be defective, Ferno W. Italia s.r.l. will choose whether to repair and replace it or refund the purchase price. In no case may Ferno W. Italia s.r.l. be held liable for any amount beyond the sale price of the product. The buyer accepts these conditions for all types of damage. Ferno W. Italia s.r.l. does not provide any other express or implicit guarantees, does not provide any implicit guarantee of salability or suitability for a particular use of its product or products manufactured by others. Any legal measures taken in violation of limited liability must be filed within one year of the date on which the violation is or should have been discovered. Ferno W. Italia s.r.l. reserves the right to cancel the guarantee for products sold:

- if the labels or plates bearing the manufacturer's name, serial number or part number have been deleted or removed;
- if the product has been modified, repaired or worked on without authorization from Ferno W. Italia s.r.l. by people not authorized by Ferno W. Italia;
- if the product has been used in a way which does not conform to the instructions provided or for purposes other than those for which it was designed;
- as stated in section 9.1, "Conditions of Guarantee".

Ferno W. Italia s.r.l. shall in no case be held liable for direct or indirect damage consequent upon use which does not conform to the guidelines in the users' manual and the product's intended use.

9.3. Requests under the Guarantee

Contact Ferno Customer Relations immediately if you receive a product which you suspect to be defective. A representative will help you with the claim procedure. Before shipping a product to Ferno W. Italia s.r.l., request authorization from Ferno Customer Relations.

9.4. Claims

All claims must be presented to the reseller or to Ferno W. Italia s.r.l. Customer Relations within 5 days of the date on which the product is received or the defect in question is discovered.

Claims and complaints regarding an individual product do not exempt the buyer from the obligation to pick up and pay the other products included in the same order, unless otherwise agreed with the seller.

9.5. Authorization to return

Ferno W. Italia s.r.l. will not accept product returns without prior authorization.

Products returned for commercial reasons or for reasons not related to nonconformity will be accepted only following inspection by specialized Ferno W. Italia s.r.l. staff.

10. TRAINING RECORD

Date	Instructor's name	Type of training

11. MAINTENANCE RECORD

Date	Maintenance worker's name	Type of maintenance

Product user and maintenance manual, necessary to work safely and maintain the product's hygiene and dependability and maintain the guarantee.

MU-074-C April 2012

Ferno Washington Italia s.r.l. Via Benedetto Zallone 26 40066 Pieve di Cento (BO) - Italy

Internet	www.ferno.it
E-mail	info@ferno.it
Telephone	+39 0516860028
Fax	+39 0516861508