

## TRAINING STAIRS

# GENERAL SAFETY MANUAL

**RULES, OBLIGATIONS AND INSTRUCTIONS THAT THE OPERATORS AND USERS MUST RESPECT FOR THE INSTALLATION AND USE OF THE FERROX TRAINING STAIRS**



REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017  
THIS MANUAL MUST BE READ BEFORE THE INSTALLATION AND USE OF THE MEDICAL  
DEVICE

**This manual must be kept within reach and available to be consulted whenever necessary.**

**THE DEVICE HAS TO BE INSTALLED BY A SKILLED AND TRAINED PERSON.**

**BOOKLET ONE (1/2)**

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Dear Customer,

Thank you for choosing FERROX training stairs.

Our training stairs are specifically designed and manufactured for their application in the rehabilitation and physiotherapy sector in either a private or a hospital context. It is a functional and practical device for both the therapist and the patient.

This manual contains the instructions for safe and appropriate use for the people concerned.

Please read this manual carefully, study the instructions and keep it ready to hand to allow those using and maintaining the device, to consult the document at any time.

The personnel using this device must be properly trained to make proper use of it.

The manual is considered an integral part of the device and therefore **MUST** be taken along/handed on, in the event of relocation or handing over of the device.

FERROX S.r.l.

## 1. SAFETY INSTRUCTIONS AND WARNINGS



**Warning:** This manual contains important safety information that everyone involved with the use of the device **MUST** observe.

**Every person** in charge of installing or using the FERROX training stairs **MUST** read and study this manual carefully and follow all its instructions.

In accordance with the instructions outlined above, the manual must be kept ready to hand to allow those using and maintaining the device, to consult the document at any time.

For the guidelines to be applied correctly, this manual must always be available to users and those responsible for maintenance. It is advisable to print a few extra copies of the manual in case of loss or damage of the original.

Before installing or using for the first time:

1. Read these instructions **carefully** in order to avoid incorrect use or any form of damage.
2. Clean and disinfect the device.
3. Test the training stairs without the patient on them, to verify their functionality and **to identify any potential damage incurred during shipping.**

It is also recommended to check the functionality of the equipment **before** each use, checking the integrity of all its components.

	<b>The use of the training stairs must be in accordance with what is described in this manual.</b>
	<b>Any other use is inappropriate and firmly advised against by Ferrox LLP</b>

### SAFETY SYMBOLS TO KNOW AND TO OBSERVE




**Attention!** General risk to people and the environment

## 2. LOCATION AND INTENDED USE

The Ferrox training stairs are therapy and rehabilitation products. They can be used in a hospital or private context for treatment of healthy subjects as preventive measures or for rehabilitation for better functionality of the lower limbs.

The product can be reused several times, based on the specifications reported in Chapters 11 and 12 "Cleaning and Disinfection" and "Maintenance".

### 2.1 THE PATIENTS FOR WHOM THIS DEVICE IS INTENDED / NOT INTENDED

	<ul style="list-style-type: none"><li>• This medical device is intended only for patients with lower limb disability;</li><li>• Patients falling into one of the following categories cannot be treated with this medical device:<ul style="list-style-type: none"><li>a. People with significant loss of vision;</li><li>b. People suffering from vertigo or other balance disorders;</li><li>c. People who do not have fully functioning arms/hands to well support them on handrails.</li><li>d. People who do not have sufficient physical strength to ascend or descend the stairs safely.</li></ul></li><li>• The training stairs must be used on their own and not with other walking aids (eg. canes / crutches). They should only be used for their intended use, any other use is forbidden and dangerous.</li></ul>
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## 3. PEOPLE INVOLVED





In this manual :

**OPERATORS** are individuals or legal entities that allocate the training stairs, suggest or authorize its use, or use it themselves. Operators can be importers, distributors, representatives, dealers, buyers, medical doctors and end users. **The operators are responsible** to inform and train the user about the correct application and operation of the parallel bars.




**USERS** are individuals that have been trained and authorized for the installation, the use and the maintenance of the FERROX equipment. Users/operators **must** also be able to recognize and avoid potential dangers for patients.





**PATIENTS** are individuals with motoric and physical impairments in the lower limbs, where the training stairs serve as a therapeutic and /or rehabilitation tool in the opinion of the physiotherapist, doctor or therapist.

#### 4. GENERAL SAFETY INSTRUCTIONS FOR THE SAFETY OF WORKERS, PATIENTS AND USERS


	<ul style="list-style-type: none"> <li>• <b>Importers, distribution agencies, resellers and representatives must train their partners (buyers or not) in the correct use of the device.</b></li> </ul>
	<ul style="list-style-type: none"> <li>• Before first use, each user must be instructed and trained on the contents of the manual, which must always be provided by the operators;</li> <li>• The operator / user must always be aware of where this manual is kept;</li> <li>• Only authorized personnel having received adequate training should be allowed to operate or maintain the device;</li> <li>• <b>NEVER</b> allow the device to be used by unauthorized personnel;</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>ALWAYS</b> use the training stairs in a safe condition for operators, patients and others who are allowed to be present ;</li> <li>• Always prevent children from playing or staying near the training stairs;</li> <li>• To avoid injury, the authorized personnel responsible for the area where the training stairs are used, must prevent any unauthorized person to perform any movement or mechanical adjustment of the handrails;</li> </ul>
	<ul style="list-style-type: none"> <li>• The device is only to be used for their intended use, any other use is forbidden and dangerous.</li> <li>• <b>NEVER</b> use the equipment if it is not in perfect condition;</li> <li>• Follow the maintenance of the equipment according to the instructions contained in this manual to prevent damage over time due to wear or neglect;</li> <li>• Check that the patient is able to manage the height of the steps.</li> </ul>

## 5. SAFETY MEASURES


	<p><b>5.1 BEFORE EACH USE</b></p> <ul style="list-style-type: none"><li>• Never adjust the handrails with the patient on the training stairs. The patient could lose his balance and fall.</li><li>• Be very careful when changing the height or width (when feature is provided). Hold the handrail with one hand and with the other hold the switch or blocking lever. Hold the handrail with both hands at the centre and turn it. Never hold the rail on the sliding support tubes! Tighten the clamp handle by bringing it into the downward facing position!</li><li>• ALWAYS adjust the height of the handrails so that they are about ten centimeters above belly height of the patient.</li><li>• Observe the maximum height adjustment of the handrails ;</li><li>• <b>BEFORE</b> allowing the patient onto the device, <b>ALWAYS</b> check that the handrails have been properly secured and locked and that each lever is tightened to ensure that there won't be any movement of any parts of the device.</li><li>• <b>BEFORE</b> allowing the patient onto the device, let the patient know that the steps on the other side of the device are higher or lower (depending on the side of access) ;</li><li>• <b>BEFORE</b> allowing the patient onto the device, <b>ALWAYS</b> check that the walking platform is dry ;</li><li>• <b>NEVER</b> allow patients or operators to wear loose or long clothing or to carry on them other incompatible objects that could render the use of the device dangerous.</li></ul>
	<p><b>5.2 DURING EACH USE</b></p> <ul style="list-style-type: none"><li>• <b>NEVER</b> allow the patient to move if the handrails are not properly secured;</li><li>• <b>NEVER</b> leave the patient unattended at the training stairs;</li><li>• <b>NEVER</b> leave the patient unattended in the training room;</li><li>• <b>NEVER</b> allow yourself to be distracted whilst the device is being used. Stop using the device immediately in case of abnormal movements of the handrail or any deformation thereof.</li></ul>
	<p><b>5.3 UNPERMITTED CHANGES</b></p> <ul style="list-style-type: none"><li>• <b>NEVER</b> remove, damage or modify any of the safety devices;</li><li>• <b>NEVER</b> remove, damage or modify the identification label or any other important information necessary for the repair of the equipment and its accessories;</li><li>• <b>NEVER</b> modify the equipment. Any kind of unauthorized manipulation of the device may impair its proper functioning;</li></ul>

	<ul style="list-style-type: none"> <li>• This device cannot be sterilized</li> </ul>
	<ul style="list-style-type: none"> <li>• For cleaning instructions of the training stairs, refer to p.13</li> </ul>
	<ul style="list-style-type: none"> <li>• This unit requires special maintenance, see p.14</li> </ul>
	<ul style="list-style-type: none"> <li>• The use of Ferrox rehabilitation training stairs requires no technological skills or particular experience, but only a good ability to use the equipment.</li> </ul>

### REQUIREMENTS FOR THE SAFE PLACEMENT OF THE DEVICE

	<ul style="list-style-type: none"> <li>• The training stairs are NOT designed to be used outdoors.</li> <li>• The device must not be placed near heat sources such as radiators or stoves using flame or near open flames. It is not classified as fireproof class IM 1.</li> <li>• Check that lifting and lowering movements for adjustment of the device do not interfere with chairs, tables or other furniture parts.</li> <li>• The person installing the device must ensure optimal access to and use of the system. The person installing the device should also be responsible to clean and adjust the device.</li> </ul>
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### TERMS OF USE

	<p><b>CLOTHING AND HYGIENE</b></p> <ul style="list-style-type: none"> <li>• <u><i>It is mandatory for the user and the patient to use of disposable gloves and shoes with clean rubber soles and disposable overshoes</i></u></li> <li>• It is mandatory to disinfect the handrails daily with specific products (alcoholic solutions).</li> </ul>
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## 6. IDENTIFICATION LABEL

### 6.1 LABEL -- Explanation

A copy of the identification label shown below, with the corresponding technical information, has been attached to the device. It is used to identify the product and its specifications if technical problems occurred or spare parts were needed.

The label must **NEVER** be removed, damaged or covered.

#### IDENTIFICATION LABEL



<i>Symbols</i>	<i>Description</i>	
	CE Mark	
	Manufactured	
	Catalogue Number	
	Serial Number	
	Fabrication Date	
	Manufactured	
	Unique Device Identification	
	Read the manual	
	Max. charge	

Graphical Symbols for use in Labeling Medical Devices **BS EN 980**

## 7. PRODUCT DESCRIPTION

### 7.1 LA STRUCTURE

The supporting structure is made of tubular steel, of a square, rectangular or round cross-section, which is electro-welded. Handrails are painted with polyester paint, the rest is painted with epoxy-polyester. Pivots and sliding parts are galvanized. All cut-off points are covered with plastic caps. When present, the non-slip rubber at the base of the floor is 100% synthetic.

**Maximum permissible load for handrails: 140 kg (70 kg for each side).**

### 7.2 COVERING

Imitation leather, **SKAI** Original, Class IM1

### 7.3 THE MECHANICAL COMPONENTS FOR HEIGHT ADJUSTMENT

The adjustment of the height of the handrail is achieved by one of the levers via a pressure mechanism.

### 7.4 DIMENSIONS OF THE FULLY INSTALLED TRAINING STAIRS

	STRAIGHT OF RECTANGLE "BROOKLYN"		REDUCED "PONTICELLO"			
<b>MODEL</b>	<b>260355</b>			<b>260357</b>		
<b>DIMENSIONS IN CM</b>	STRAIGHT 310 X 60 <b>ANGLE</b> 167X199	-	-	182X60	-	-
<b>ADJUSTABLE HEIGHT IN CM</b>	70Δ97		70Δ97			-
<b>WEIGHT</b>	120 KG			90 KG		

### 7.5 PRODUCT LIFE

**This product, if used properly, has a product life of 10 years. This period is ensured by proper maintenance and daily cleaning.**

## **8. INSTALLATION AND ASSEMBLY**

### **8.1 STATE OF RECEIPT**

The training stairs are delivered in two or more boxes. Estimating an average weight of 25 kg per package, the training stairs must be manually moved by at least two people.

### **8.2 ASSEMBLY**



The device is equipped with a manual for installation and set up ; follow the instructions for correct installation and use.

### **8.3 PACKAGING**

The packaging material has to be disposed off in accordance with the effective, local regulations on waste management.

## **9. INSTALLATION ENVIRONMENT**

The FERROX training stairs are not for outdoor use.

Ambient conditions of the environment in which the device should be used:

- \*Temperature min 10°C max 40°C
- \*Humidity min 30% max 75%
- \*Pressure min 700hPa, max 1060 hPa

## 10. CONTROLS

### 10.1 MECHANICAL COMPONENTS FOR ADJUSTING THE HEIGHT OF THE HANDRAILS

Setting the height and width of the handrails (only for some models with base) is achieved by clamping handles (retaining levers) provided with an interlocking mechanism.

In the **PRO** version, a sliding spring switcher allows to adjust the height and rotation of the handrails.

### 10.2 ADJUSTMENT LEVER AND TIGHTENING

The height adjustment levers are a sensitive part of the equipment and should be handled carefully by the users.

Before each use and after each adjustment, the operator must ensure that:

- Handrails are set up according to the patient's body size and according to the therapy protocol for each patient;
- The levers set do not exceed the minimum / maximum dimensions granted by the structure;



**The use of training stairs must be only made after the correct locking of the described adjustment points.**

**If the handrails are unstable or unsafe despite these operations, contact Ferrox. It may be that the instructions for assembly were not carried out in the right sequence.**

**If the problem persists, contact FERROX.**

## 11. CLEANING AND DISINFECTION


Cleaning of the device is fundamental for the maintenance of proper hygienic conditions.

Given the number of patients passing through the training stairs, and given the fact that it is not possible to perform adequate cleaning between the patients, it is compulsory to wear disposable gloves, as well as shoes with a rubber sole, clean and protected with overshoes.

There will thus be no direct contact between the patient and the training stairs and the device could be cleaned daily :

- clean the floor and base with a damp cloth
- disinfect the handrail with an alcoholic solution

In case of accidental contamination with potentially infectious material (blood, pus) or if the patient has an infection, chemical disinfection will be necessary. To this end you are advised to only use products approved for clinical disinfection.

	<ul style="list-style-type: none"><li>• The surface of the walking platform must always remain dry, intact and flat. All damage must be repaired immediately to avoid that obstacles be created for the patient ;</li><li>• Use a damp cloth and classic detergents for cleaning ;</li><li>• <b>CAUTION</b> do not use other detergents which could cause abrasion or which might attack the surface of the parallel bars. Alcoholic solution is recommended by the paint manufacturer and should only be used to clean the metal parts.</li><li>• The surface around and below the training stairs must be kept clean and dry. Aggressive floor cleaning liquid detergents may corrode metal parts of the structure.</li><li>• Check all components of the training stairs frequently, including: sliding supports, locking levers and switches, in order to protect their integrity and to avoid malfunction.</li><li>• Perform maintenance according to this manual to avoid damage to persons or things caused by wear or lack of care. See p.14 for further information ;</li><li>• Contact your dealer or Ferrox LLP for further information</li></ul>
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## 12. MAINTENANCE

Maintenance must be performed only by qualified personnel familiar with the device.

Ferrox deems the following maintenance as necessary :


### **A) After each use, check visually :**

- for any gnashing and check the integrity of the blocking mechanisms on the handrails.
- the state of wear of the steps. This part must be replaced in case you would suspect a risk of accident.

### **B) Once a month check :**

- ↓ That the boards of the stairs are in good condition: these should not show any distortion, residues from previous use and loose or damaged pieces of the covering material. The panels must be perfectly even, without cracks or other deformations, safely fixed to the frame;
- ↓ **The support rods** : these must be secured to the frame, vertically in both directions;
- ↓ **The sleeves**: they must be intact, without fissures, the lever and the screw in perfect condition to perform the blocking function ;
- ↓ **Sliding supports**: the linear tube, vertical and circular in section, without obstacles or impediments to the sliding and rotation in the stem;
- ↓ **The handrail** without any deformation, perfectly in line.

C) Check periodically: at least every six months check the wear of screws and the adjustment mechanisms.

	<b>It is absolutely forbidden to make temporary repairs.</b>
	<b>For operational safety of the training stairs, only parts recommended and authorized by Ferrox must be installed.</b>

Components that are not conform to the descriptions must be replaced.

**For operational safety of the training stairs, only parts recommended and authorized by Ferrox must be installed.**

### 13. TERMS OF USE, TRANSPORT AND STORAGE

The FERROX training stairs should be transported, used and stored under the following temperature, humidity and pressure conditions:

**Ambient conditions:**

\* Temperature min +10°C max 40°C

\*Humidity min 30% max 75%

\*Pressure min 700hPa, max 1060 hPa

### 14. DISPOSAL OF COATED AND METAL PARTS



■ The device as well as its accessories have to be disposed off in accordance with the effective, local regulations on waste management.

### 15. APPLIED STANDARDS

- The Company works with a Quality Management System according to ISO 9001:2015
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- EN 12182 Assistive products for persons with disability - General requirements and test methods

Ferrox medical treatment tables are classified as Class I medical devices in accordance with the provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017.

DECLARATION OF CONFORMITY  
SEE APPENDIX A 2/2



## 16. WARRANTY

- 1) The FERROX training stairs are covered by a three-year warranty for manufacturing defects, which is valid \*\*\* from the day indicated ON THE INVOICE OR THE RECEIPT.  
\*\*\* hospitals and rehabilitation centers, where heavy use is foreseeable, a one-year warranty applies.
- 2) The warranty does **NOT** cover consumable parts, such as: the coating of the steps, sliding tubes, handles and snap clamps.
- 3) The warranty does **NOT** cover any dysfunction or damage resulting from incorrect or wrong use, intentional misuse, or any use of the device other than for its intended purpose, or when operated by unqualified staff.
- 4) The warranty does **NOT** cover personal injury, material damage or other kinds of damage, resulting from the operation of the device by unauthorized and unqualified staff, wrong use or as a result of the device not being serviced.
- 5) The warranty does NOT cover damage caused to the sliding mechanism and handrail if one of the two sliding supports were not fully blocked or if the instructions for setting the handrails have not been followed as instructed.
- 5.1** The warranty does **NOT** cover cuts on the walking surface incurred through the use of sharp or pointed objects for unpacking.
- 6) The warranty does NOT cover any damage incurred on the coating of the steps that have been walked on with outdoor shoes, stiletto heels, etc.
- 7) **FERROX** supplies and delivers all parts required for repair, maintenance or exchange, free of charge. This service is on the account of the distributor / retailer. The faulty parts have to be returned to **FERROX** within 15 days from the receipt of the repair parts, otherwise they will be charged for.
- 8) In order to claim warranty, the invoice as well as the identification data provided in the manual (or the serial number indicated on the product) has to be posted to **FERROX**. This permits to identify the production date and hence the production batch/-series (see page 9).
- 9) The warranty is only valid for the first time buyer and it is **not** transferable.

**NOTE: The rapid and unpredictable evolution of individual companies does not guarantee the availability of spare parts in the long run. FERROX makes an effort to maintain adequate stocks to minimize any inconvenience caused by such cases.**

## 17. RESPONSIBILITIES

### DECLINE OF THE MANUFACTURER'S RESPONSIBILITY

**In view of what is written in the laws in force concerning 'work equipment', the manufacturer assumes no responsibility, directly or indirectly if:**

- the instructions in the provided manual are not observed;
- the device is operated by insufficiently informed or unqualified staff;
- the device has been statically or functionally modified;
- the device is used for an application other than that intended;

the patient's diagnosis is wrong.

**The obligations of the operator / user, reported in the directives regarding 'work equipment' coincide with what is required by the manufacturer, which reiterates that:**

- The equipment must be used only in conformity with its characteristics;
- It is necessary to assess the risks in relation to the work to be performed, and the characteristics of the working environment before operating the device;
- The equipment must be maintained and controlled in a systematic, accurate and consistent way.

**The people in charge of operating the device should:**

- Have been informed on the terms of use and predictable anomalies;
- Have been trained to use the equipment;
- Follow training programs and adapt their work to the instructions received;
- Take care of the equipment they have been entrusted;
- Do not modify equipment;
- Report immediately any defect or fault observed.

The careful observation of these guidelines by all concerned will ensure not only safe use but also the smooth operation and servicing over time.

## 18. MANUFACTURER'S ADDRESS

**For parts orders, reports of malfunctions, customer service, recommendations and inquiries please contact:**

**FERROX S.r.l.**

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ITALY

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