FALCON 2.0

USER MANUAL
EVACUATION CHAIR



EnSafe.One®
A world open to all

This is a medical device.
Follow the instructions for use or label.

TABLE OF CONTENTS

Thank you for choosing ENSAFE.ONE products.

1. PURPOSE OF THE INSTRUCTION MANUAL

The purpose of this instruction is to provide all the information necessary for the correct and safe use of the product.
Before using, please read the manual carefully and follow the instructions given inside.
The manual includes:
• description and construction of the evacuation chair,
• the scope of its use ,
• the method of preparation for use,
• principles of safe use,
• information on technical inspections, maintenance and cleaning,
• warranty conditions, warranty card and maintenance record.
If you have any questions, please contact the seller or the manufacturer.

TABLE OF CONTENTS

1. Purpose of the instruction manual 2
2. Definitions 3
3. Warnings about the device 4
4. Explanation of symbols 5
5. Label 5
6. Purpose and scope of use of the evacuation chair FALCON 2.0 5
7. Technical specification 7
8. How to use the FALCON 2.0 evacuation chair 8
9. Unfolding the chair and seating the evacuee 9
10. Downward evacuation 9
11. Folding 10
12. Montage 10
13. Application of falcon 2.0 Evacuation chair 11
14. Cleaning and storage 11
15. Technical inspections 12
16. Failure 13
17. Lifespan and disposal of the product 13
18. Warranty 13



2. DEFINITIONS

Operator – a person who has acquired knowledge and competence in operating the product during training with an Authorized Trainer. With the acquired skills is able to use the product in a safe manner. Is a person authorized to use the product during evacuation or in case of need for transportation.

User – a person using the device in emergency situations, during evacuation exercises or as part of medical transport. This could be a person with special needs, requiring assistance in evacuating a building, a patient being moved to another location, or a person needing safe transport for medical reasons.

Person with special needs – a person who, due to his health or other limitations, is unable to move independently and requires support during evacuation or transportation.

Administrator – a person appointed by the customer who oversees the technical condition, the timing of technical inspections and the cleanliness of the products.

Authorized trainer – a person authorized by the Manufacturer to conduct training on the use of the product. He or she has the technical knowledge and practical experience that enable him or her to reliably and comprehensively provide information on the product.

Authorized service – entity designated by the Manufacturer to perform activities related to service, maintenance and repair of the product.

Technician – a person authorized by the Manufacturer with expertise in service, maintenance and repair of the product.

Medical device (according to Regulation EU 2017/745) – means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Incident (according to Regulation EU 2017/745) – means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect.

Serious incident (according to Regulation EU 2017/745)– means any incident that directly or indirectly led, might have led or might lead to any of the following:
(a) the death of a patient, user or other person,
(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
(c) a serious public health threat.

Serious public health threat (according to Regulation EU 2017/745) – means an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time.

3. WARNINGS ABOUT THE DEVICE

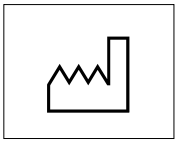
• Use the product according to its intended use;
• Only properly trained persons, registered in the list of persons authorized to carry out evacuation, are allowed to operate the product;
• Operator qualification is granted for a specific product, not for similar products;
• Before use:
- read the contents of this Operating Manual,
- inspect the technical condition of the product in accordance with the manufacturer's recommendations;
• If any damage or technical defects are found, immediately secure the product from further use and contact the Manufacturer;
• Never exceed the maximum load (max. 260 kg).
• The chair should be unfolded on a flat surface, to make it easier block the rear brakes beforehand;
• Getting on and off the evacuation chair should be done on a stable, flat surface, with the rear brakes locked;
• The operator is obligated to:
- properly secure the evacuee in accordance with the Manual, to avoid the risk of jamming body parts (Operator and/or User),
- provide constant supervision of the person in the chair,
- avoid sudden movements, as this may cause injury (to the User and/or Operator),
- hold the chair at all times while going down or descending the stairs,
- locking the brakes before seating the person in the chair.

• When evacuating a person weighing more than 120 kg, it is recommended to ensure the presence of an additional person for assistance, in order to minimize the risk of losing control of the device;
• The product may become hot when exposed to sunlight - take caution when coming into contact with its surface;
• During procedures involving a transported person, the Operator should use appropriate personal protective equipment (i.e., gloves, mask) to minimize the risk of contact with secretions;
• It is forbidden to use direct sources of heat or open flame near the product;
• Ensure that the product is used in an environment free of excessive moisture, dust and dirt that can lead to component failure or corrosion;
• Store the product in accordance with the manufacturer's recommendations;
• Technical inspections must be carried out in accordance with the schedule and rules set out in the Warranty Card attached to this Operating Manual;
• In the event of a medical incident involving the device, immediately notify the Manufacturer via www.ensafe.one or registered letter.

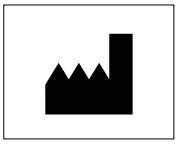
⚠ WARNING!

• DO NOT EXCEED THE MAXIMUM LOAD (MAX. 260KG)!
• NEVER LEAVE THE USER UNATTENDED!
• ONLY PROPERLY TRAINED AND COMPETENT OPERATORS SHOULD OPERATE THE PRODUCT

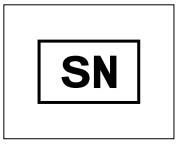
4. EXPLANATION OF SYMBOLS



MANUFACTURE DATE



MANUFACTURER NAME



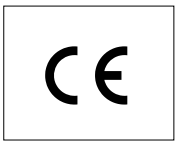
PRODUCT SERIAL NUMBER



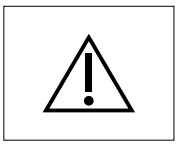
MEDICAL DEVICE



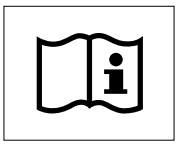
PERMISSIBLE USER WEIGHT



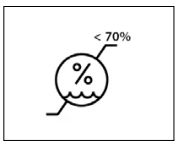
CONFORMITY ASSESSMENT



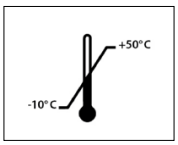
WARNINGS



PRODUCT INSTRUCTIONS FOR USE



AIR HUMIDITY

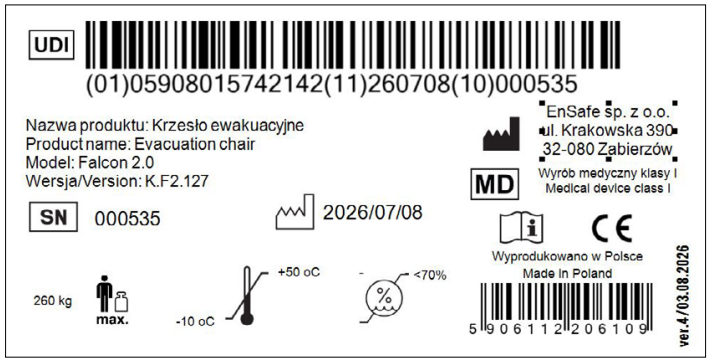


STORAGE TEMPERATURE

5. LABEL

Label – contains the required information identifying and describing the medical device, including:

- name of the Manufacturer,
- model of the product,
- manufacturing date,
- serial number,
- maximum permissible load (user weight),
- CE conformity marking,
- marking classifying the product as a medical device,
- UDI identification code,
- a pictogram indicating the need to read the Instructions for Use before using the device.



The label is located on the back support, left leg on the inside. **It must never be removed or covered.**

6. PURPOSE AND SCOPE OF USE OF THE EVACUATION CHAIR FALCON 2.0

The FALCON 2.0 evacuation chair is a Class I medical device designed for the evacuation and/or transport of people with special needs. It allows one person to safely, efficiently, and comfortably move the user both down stairs and on flat surfaces; transport upstairs is only possible with the assistance of at least two operators. It is used in emergency situations when rapid evacuation from a building is necessary, especially when there is no access to elevators.

People with special needs include: people with physical disabilities (permanent or temporary) or intellectual disabilities (people who cannot make decisions independently and remain under the supervision of a caregiver), seniors, pregnant women, persons with temporary injuries (e.g., broken legs), overweight persons who cannot move independently (the weight of a person with special needs cannot exceed 260 kg).

Contraindications:

The person operating the evacuation chair (Operator) may not perform this function if:

- has not undergone the required training in the use of the product;
- has physical limitations that may prevent safe use (e.g., problems with balance, motor coordination, musculoskeletal disorders);
- does not have sufficient physical strength to maneuver the device, especially on stairs;
- has medical conditions that may affect the operator's ability to operate the device safely (e.g., epilepsy, vestibular disorders), or has an implanted pacemaker;
- is not dressed appropriately: lack of stable footwear with flat soles; clothing that is too loose, flowy, or ill-fitting, which may increase the risk of snagging on parts of the device (moving mechanisms); clothing that restricts the operator's movements or limits their ability to maneuver the product;
- unable to cope with high stress or time pressure;
- under the influence of alcohol, intoxicants, or drugs that affect consciousness, reflexes, or motor coordination.

The evacuation chair should not be used for people:

- who are unable to independently and actively maintain an upright position (e.g., with muscular flaccidity, loss of postural tension),
- who have sudden, uncontrolled muscle tensions,
- with violent tics or seizures,
- whose body weight exceeds the allowable load of the device, as specified in the technical specifications.



In case of any doubts regarding the use of the device for a specific user, consult the user themselves, their caregiver (if present), or the person responsible for medical care—e.g., a paramedic, physician, or qualified personnel.



It is prohibited to use the product in a manner which is not in accordance with its intended purpose.

The product may be used in accordance with these Instructions for Use **only by properly trained and competent operators** as an aid to ensure safe evacuation and/or transportation of persons with special needs. The owner, manager of the building or person actually in charge of the building must provide the necessary evacuation procedures, trained personnel and periodic technical inspections of equipment involved in evacuation, including the FALCON 2.0 Evacuation Chair (inspections should be carried out by an Authorized Service designated by the Manufacturer) and maintenance activities of the evacuation chairs. This will guarantee the safe evacuation of all Users from the facility in a situation of danger to life or health before the arrival of emergency services.

7. TECHNICAL PARAMETERS



Folded chair



TECHNICAL PARAMETERS		
Manufacturer:	EnSafe sp. z o.o.	
Address:	Krakowska Street 390, 32-080 Zabierzów	
Product type:	Evacuation chair	
Model:	FALCON 2.0	
Product class:	I	
Maximum permissible weight of the User:	260 kg	
Total weight of the product (without accessories):	17,2 kg (without accesories)	
Dimensions when folded [H x W x D]:	117 x 63 x 38 cm	
Dimensions when unfolded [H x W x D]:	159 x 63 x 100 cm	
Width of the seat with the frame:	41,5 cm	
Backrest width:	41,5 cm	
Storage and use temperature:	-10°C	+50°C
Air humidity for storage and use:	< 70%	
Telescopic retractable handle (3 extension positions)	1 pc	
Retractable front handles	2 pcs	
Construction:	steel and aluminium powder-coated	
Seat and headrest material:	Polyester	
Safety belt with an aviation buckle	2 pcs	
Additonal leg safety belt:	1 pc	

8. HOW TO USE THE FALCON 2.0 EVACUATION CHAIR



The FALCON 2.0 evacuation chair may only be used by authorized individuals, i.e., Operators.

Before use, the operator is required to inspect the technical condition of the evacuation chair - in particular, check:
1. whether the frame is free of damage and cracks,
2. whether the wheels are properly attached,
3. whether there is no looseness in the bolted connections (bolts and nuts),
4. wear and tear of running belts,
5. whether the fabrics have no abrasions/splits.

The operator should be dressed in a manner that ensures complete freedom of movement. Flat-soled footwear that fits well, does not cause discomfort, and is difficult to accidentally slip off is required (flip-flops, among other things, are not permitted). Clothing should be ergonomic and must not restrict freedom of movement when operating the product. It is unacceptable to wear loose, flowing items of clothing that could get caught or tangled in moving parts of the device.

Before placing the User in the chair, assess whether additional operators are needed to ensure safety and efficient evacuation. It is recommended to involve a person to provide support if the weight of the evacuated person exceeds 120 kg. If you have any doubts about the suitability of the product for a particular user, consult the user themselves, their caregiver (if present), or medical personnel, such as a paramedic, nurse, or doctor. The user should be able to maintain a stable, upright position with proper support for the thighs and back, should have their seat belts properly fastened, and must not lean to the sides.



The operator must never leave the user unsupervised in the chair.



The operator must never let go of the chair when descending/sliding down stairs. The operator must avoid sudden movements with the chair, as this may cause injury to the user.

9. UNFOLDING THE CHAIR AND SEATING THE EVACUEE

Unfolding, folding, getting in and out of the chair should be done on a stable, flat ground, with the rear wheels locked.



01 Place the folded chair vertically on the rear wheels.



02 Unfold the chair by holding the seat and the telescopic handle



03 Pull the red strap located at the backrest level towards you and extend the telescopic handle upwards, ensuring it locks into the desired position.

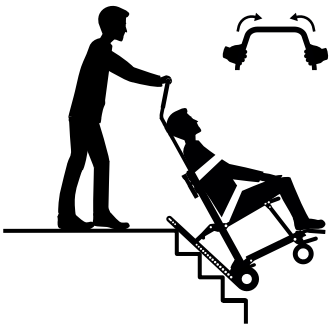


04 Sit the user down, fasten the safety belts, unfold the rear handles, and release the rear wheel brakes.

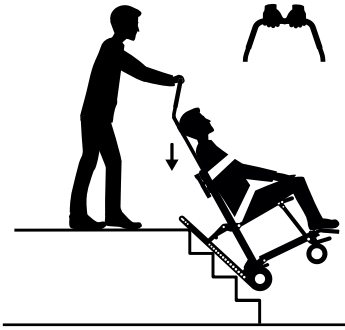
10. DOWNWARD EVACUATION



01 Ensure that the transported person has all safety belts fastened. Fold the operating handles. Tilt the chair into the descent position while holding the telescopic handle on the sides.



02 Change your hand position by gripping the chair from the top of the telescopic handle.



03 Press the chair firmly against the stairs and begin the descent. As you approach the last steps, you can prepare to shift the chair into a vertical position.

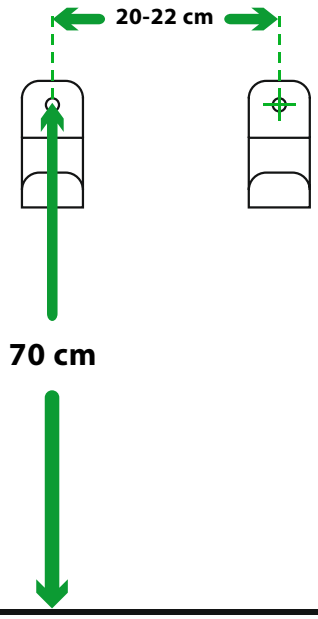


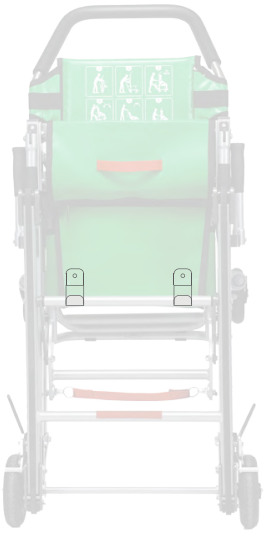
04 Unfold the handles designed for operating the chair, then proceed on a flat surface to the designated evacuation assembly point.

11. FOLDING

1. Lock the brake on the rear wheels.
2. Lower the telescopic handle to its minimum height while simultaneously pulling the red strap located at the back of the seat.
3. Fold the rear handles.
4. Fold the armrest (if applicable).
5. Pull the red strap located between the rails, then tilt the chair forward to fold it.
6. Finally, secure the chair in its folded position using the safety straps.

12. MONTAGE







*

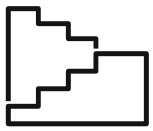
01 Unpack the package and check that it is complete.
Prepare the installation site by checking that there are no technical installations (gas, water, sewage, electrical, etc.). Install the brackets at a height of 70 cm from the floor. Drill holes and install wall plugs, then hang the hooks. For walls other than concrete, select the appropriate type of wall plugs.

The manufacturer is not liable for damage to the building or chair resulting from installation by unauthorized persons or outside the manufacturer's authorized service.

02 Hang the chair on the attached bracketss, making sure that it is stably hung.

03 Optional (additional equipment): use a protective cover and attach an evacuation chair sign.

13. APPLICATION OF FALCON 2.0 EVACUATION CHAIR



Standard staircases



Do not use on narrow or twisting staircases (winder, spiral)

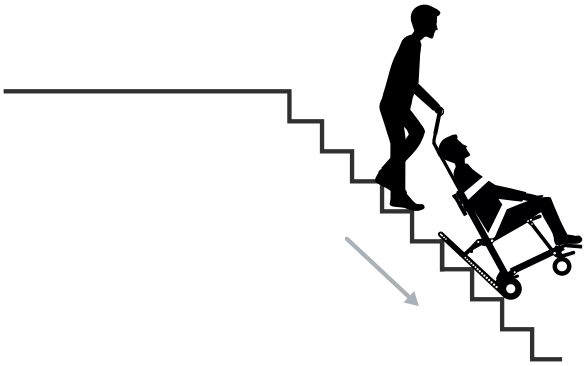


20° - 40°

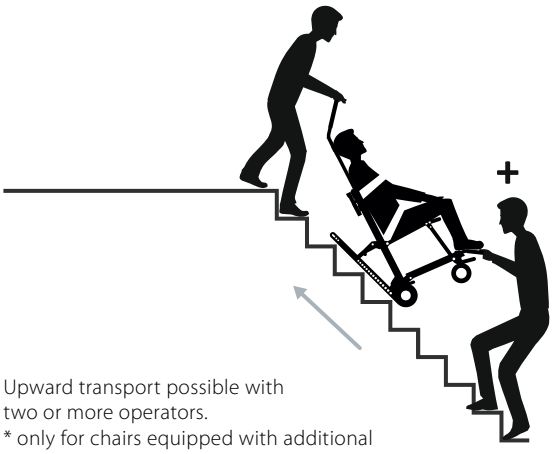
Optimum angle of stairs



Maximum load of the chair is 260 kg



Can be transported down stairs with just one operator



Upward transport possible with two or more operators.
* only for chairs equipped with additional accessories: rear transport handle and footrest with handle

After extending the lower handles, ensure that they lock into the positioning latches.

14. CLEANING AND STORAGE

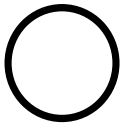
Clean exposed metal parts using a damp cloth/sponge with commonly available cleaning agents designed for cleaning this type of surface, then wipe dry. Do not use high-pressure water, as it may penetrate joints and remove lubricants, increasing the risk of corrosion. Failure to follow this recommendation may affect the service life of the product.
The surface should be disinfected using commercially available surface disinfectants.

Due to the danger associated with the risk of contact with the secretions of the transported person, the Operator or Administrator must always wear appropriate personal protective equipment, such as gloves, mask, etc. during all checking and cleaning procedures.

Textiles should be dry cleaned. Do not wash. Do not iron. Do not bleach or chlorinate. Do not tumble dry.



Do not tumble dry



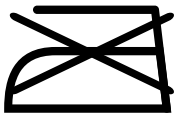
Dry cleaning



Do not wash



Do not bleach or chlorinate



Do not iron



Do not use direct heat or flame sources.

The product should be cleaned after each use. Allow the product to dry completely before storing. Store the product in a dry, clean, ventilated place at a temperature between -10°C and +50°C and relative humidity maintained at <70%.

15. TECHNICAL INSPECTIONS

The product should undergo annual technical inspections to verify its efficiency and compliance with the safety requirements specified by the Manufacturer at the time of placing the product on the market. Inspections may only be performed by an Authorized Service Center designated by the Manufacturer, which has qualified technical personnel. In the absence of a current annual inspection (in accordance with the provisions of the Warranty Card), the product must be immediately secured against further use and stored until servicing is performed. If the inspection is not performed, the product should be withdrawn from use, disposed of in accordance with applicable regulations, or reported to the Manufacturer for further action.



EnSafe sp. z o.o. shall not be liable for the use of a product that has not undergone the mandatory technical inspection allowing for further operation.

The maintenance activities listed below may be performed by a trained operator:

- Manual assessment of nuts and bolts: stability, no movement of components, no twisting, no looseness in connections;
- Wheel lock check: the lock is functioning properly, the wheels are locked;
- Technical condition of the chair – visual assessment: no cracks, breaks, signs of corrosion, for textile elements (seat, headrest, belts): no abrasions, damage;
- Belts in skids: visual assessment – no cracks, excessive abrasions.

The inspection should be carried out each time before use or at least once a year (if stored correctly).



If you notice any technical defects in the chair or its individual components, immediately stop using the product and contact the Manufacturer.

If the above recommendations are not followed, **the product should be disposed of and this fact reported to the manufacturer, or withdrawn from use**.

16. FAILURE

In the event of a product failure, secure it and mark it appropriately to prevent its use. Then report the fact to the seller and/or Manufacturer, who will arrange for a visit by an Authorized Service Technician.

Contact details can be found at **www.ensafe.one**

17. LIFESPAN AND DISPOSAL OF THE PRODUCT

The used product should be recycled in accordance with national regulations.

18. WARRANTY

Details regarding the warranty can be found on the enclosed warranty card.

Manufacturer:
EnSafe sp. z o.o.
ul. Krakowska 390
32-080 Zabierzów, Poland

Brand name of the product: **Evacuation chair Falcon 2.0**
Country of origin: Poland

Product Information:

Class I medical device, in accordance with Rule 1, Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of t he 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

Contact with the Manufacturer: biuro@ensafe.one

MD CE

Release Date: 22.01.2025
Instructions updated: 29.10.2026
Version No: FALCON 2.0 WER. 02