TIPCO

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INSTRUCTION MANUAL

Man.Tip. EN Rev.6 09/2025

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Pro Medicare®

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NOTE: The Illustrations in the following Instruction Manual may differ from reality; however, the methods of use and operation remain valid at all times. All technical data in this manual are approximate and do not constitute specifications.

INTRODUCTION

Dear User, thank you for choosing highly performing Pro Medicare medical device.
TIPCO is the indoor frame for positioning systems, it is the combination of technology and experience in the development of Positioning Systems for users with limited ability.
As manufacturer, Pro Medicare declares that the medical device complies with Regulation (EU) 2017/745. Pro Medicare's Quality Management System is certified according to UNI EN ISO 9001 and UNI EN ISO 13485 standards. This manual, drawn up on the basis of the requirements of Regulation (EU) 2017/745 on medical devices, is an indispensable tool for learning how to use the Device safely.
This manual contains all instructions for a correct and safe use of the indoor frame combined with the positioning system. To this end, it is important to read the information about how to use it carefully, with the express invitation to follow the prescribed indications.
As a manufacturer, Pro Medicare refers to the *Professional User* as the suitably qualified person (authorised dealer, orthopaedic technician, occupational therapist, healthcare professional, etc.), and to the *End User* (*or lay person*) as the person who is intended to use the Device (caregivers, family members, etc.).

The first commissioning, subsequent adjustments and Special Maintenance must exclusively be performed by the Professional User.

The Technical features of the device are reported in the *Annex A "Technical Features".*
After consulting this manual, for further information, please contact the Technical Sales Department at the number **+39 0831 777840**, Monday to Friday from 9 a.m. to 1 p.m. and from 2.30 p.m. to 6.30 p.m.
In case of emergencies outside the working hours, please send an email to **sales@promedicare.it**.
We will call you back as soon as possible.
In order to ensure appropriate After-Sale Monitoring of Devices placed on the market and put into service, or in the event of an incident during the use, please refer to the instructions stated in the relevant chapter.

USE

The *TIPCO* indoor frame for positioning systems has been designed and manufactured in compliance with the safety standards of Regulation (EU) 2017/745.
TIPCO indoor frame for positioning systems in combination with the paediatric positioning system is intended to be used indoor and only by children and adolescent users with the assistance of caregivers.
The first commissioning, subsequent adjustments and Special Maintenance must exclusively be performed by the Professional User. If a custom-made Positioning solution is fitted and adjusted as prescribed, it may not be used for other users.
The CE Declaration of Conformity refers exclusively to the Medical Device prepared and provided by the manufacturer, "as-is", when the Device is unchanged with respect to the standard configuration. The Professional User has the responsibility to guarantee the effectiveness and efficiency of the Device specially manufactured for the specific user.
Pro Medicare is constantly dedicated to innovate its own Devices; This can entail changes in form or technique on the devices and/or related accessories. Therefore, hypothetical complaints on values, images and schemes defined in the this manual, will not be accepted. Furthermore, for the complete list of the optional parts and/or accessories, please refer to the latest order form in force.

1. INSTRUCTIONS OF USE

1.1 Packaging and Transport

The original packaging contains the following components:
- *TIPCO* indoor frame with the push handle detached
- labeling and Instruction Manual.

Upon delivery, please check for the integrity of the package and immediately note any damages or anomalies on the shipping document. Then open up the packaging and check that the various parts do not show dents, drippings, deformations or tears. Otherwise note the anomalies found on the shipping document.
After performing these checks and if the product has not to be put into immediate use, we recommend to repack and store it in a dry place.
The above operation will be carried out by the Professional User who has to perform the assembling procedures of the TIPCO indoor frame for positioning system with the relevant Positioning System.

1.2 Monitoring and adjustments for the first Commissioning and/or subsequent adjustments

The first combination of the TIPCO indoor frame and the relevant positioning system must exclusively be performed by the Professional User, who is responsible of the combination and/or configuration.

1) Handlebar insertion

Connect the handle (pic. 1) only by inserting the tubes into the guides on the base and tighten all with the knobs provided.

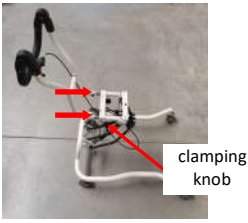
Check for correct tightening.

2) Orbital handlebar adjustment

- Push the side handlebar buttons (pic. 2)
- Adjust the Handlebar direction as desired
- Release the side handlebar buttons
- Make sure the two side buttons have been released.

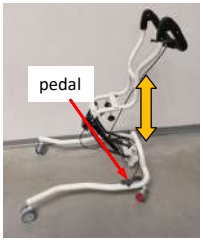
3) Height adjustment (pic. 3)

Press the pedal with foot at the posterior wheels, hold the handle and lift the positioning system mounting interface.



pic. 1: *Handlebar insertion*

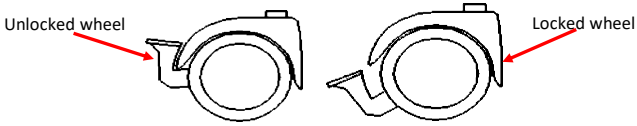
pic. 2: *Handlebar adjustment*



pic. 3: *Height adjustment*

4) Checking the brake (pic. 4)

Apply and release the brake on the two posterior wheels and check that the device is properly locked.



pic. 4: *Brake application*

5) Tilt in Space

The tilting is performed by activating the gas spring which is controlled by the lever located on the push handle. The tilt of the seat is continuously adjustable by using the operating lever. When the lever is released, the spring will lock the seat in the position reached.
In case of adjustment with the end user, the handle must be gripped firmly with both hands. Then the spring can be activated and the seat tilted. Do this very slowly, gradually and carefully.

During the adjustments always ensure the anti-tip system is correctly activated and that the user is well placed in the seat using the pelvic belt. Also make sure that the forearms are positioned on the relative upper limb supports in order to avoid the risk of entrapment.

pic. 5: *Tilt in Space*

1.3 Combination with the positioning system

After these checks the indoor frame is ready to be combined with the relevant positioning system. The professional user must check, by inspection, that the combination is performed safely.

The first combination of the TIPCO indoor frame and the relevant positioning system must exclusively be performed by the Professional User.

1.4 How to use it

The frame combined with the relevant positioning system, after the Professional User has performed the commissioning, is ready to be used. Daily operations such as the transfer from and to the system, must normally be performed by parents or caregiver.
Following there are all modes of use. Before to start any operation the professional user needs to educate the parent or caregiver about use. It will require to practise all daily operations and manoeuvre the *TIPCO* frame in areas where it should be used. It is good to develop one's own methods for safe use, adapted to the needs.

During daily use, components and/or accessories may become loose and affect adjustments. Check periodically that they have not changed. Never make any adjustments or changes without the intervention of the professional user.

a) Use of the TIPCO Components

Please, follow the instructions reported in section 1.2 page 5.

b) Use of the combined positioning sistem components

Please, refer to the relevant positioning system instruction manual.

c) End-user transfer from/to the System

Before performing these operations, it is important to discuss with the end user about the most natural and regular operations that needs to be done. This will help to make it easier for the user and it will reduce possible dangers.

Transfer from the System

√ Ensure the brakes are on, and the frame is locked from movements
√ Put the seat into a horizontal position by operating the tilting lever
√ Loosen any fixing harness
√ Disengage any thoracic supports and hip guides

Now the user is ready to be transferred. Please pay particolar attention to this operation.

Transfer to the System

√ Engage the brakes and make sure the frame is locked
√ Put the seat into a horizontal position by operating the tilting lever
√ Lift and transfer the user to the system by paying particular attention to this operation
√ Engage any thoracic supports and hip guides
√ Fasten any fixing components
√ Make sure that the user is in his normal seating position.

While the positioning operation is ongoing, ensure that no part of the body is trapped.

d) Trasport of the System

- Disassemble the Positioning System from the TIPCO Frame and make it compact for transportation in a vehicle

To transport the system it is necessary to disassemble the positioning system from the TIPCO frame as shown in the instructions reported in the combination section of the relevant manual.

Pay particular attention to these operations; do not lift the backrest by the thoracic supports and the seat by the armrests: they can become loose and change the configuration of the System. Lift only the components that cannot be detached. Be careful when folding the System as to not trap any moving part. Finally, upon reassembly, check that all configuration and settings have not been altered. If changes are noted, please contact the Professional User.

- Subsequent start-up of the TIPCO Frame and recombination of the Positioning System with the Frame

At the end of the trip, bring out the positioning system and the TIPCO frame and proceed with commissioning as described in section 1.2 on page 5 of this manual. Finally, it is necessary to combine the positioning system on the TIPCO frame as described in combination section of the relevant manual.

After having performed these operations make sure that the TIPCO Frame combined with the Positioning System is stable, easy to move and that all components work in harmony. If you hear noise, vibrations or if there are any changes to the normal conditions of use, please contact the Professional User; He will check the safety conditions, the suitability for use and the effectiveness of the Device.

1.5 Recommendations for Use

In order to guarantee safe use and a long lasting performance of the Frame for Positioning System, please find below advices for the user:

√ Carefully follow the instructions reported in this manual
√ Follow the recommendations provided by the Professional User
√ Keep the Device away from heat sources
√ Carry out thorough cleaning and pay close attention to the standard maintenance.

2. GENERAL WARNINGS

All announcements reported in this section describe the conditions and situations that may cause danger to the user or to third parties. Please read carefully before using and putting in service the System. To ensure the correct use of the Device, some operations, such as the first commissioning and adjustments, must only be performed by authorized people - *the Professional User* - Some daily operations can obviously be performed by the *End User* (*or lay person*). Therefore, there will be specific warnings for those concerned. In particular, the term *Professional User* describes the suitably qualified person (authorised dealer, orthopaedic technician, occupational therapist, healthcare professional, etc.), while, the term *End User* describes the person who is intended to use the Device (caregivers, family members, etc.).

2.1 Warnings for the Professional User

For further information, please contact the Technical Sales Department at the following number:

+39 0831 777840

- Max. Load: See Annex A *"Technical Features"*
- Preliminary Operations for correct Commissioning: (to be performed in accordance with the instructions provided in *sect. 1.2*)
  - ∗ After having performed these operations make sure that the *TIPCO* Frame combined with the Positioning System is stable, easy to move and that all components work in harmony
  - ∗ Check for noise, vibration, or changes to the normal conditions of use to ensure safety conditions and the suitability for use.
- Adjustments: (to be performed in accordance with the instructions provided in *sect. 1.2*)
  - These operations must be performed by authorized people
  - After having performed these adjustments, be aware of any noise, vibrations or any changes to the normal conditions of use
  - Unauthorized modifications or the use of parts not supplied or approved by the manufacturer may affect the safe and operational integrity of the system and be cause of danger.
- Combination with the positioning system: (please, perform this operation as by following the instructions described in combination section of the relevant manual).

2.2 Warnings for the End User

Before using the Device ensure the Professional User explains the procedures for correct commissioning and standard maintenance For further information, please contact the Professional User.

- Maximum Load: See Annex A *"Technical Features"*
- **Environmental Conditions:**

a. The *TIPCO* frame is designed to be used on hard indoor floor surfaces;
- Do not use the TIPCO frame outdoors or on uneven ground. This may cause damage to the wheels, axles and sealing screws of the base
- Be careful when using the device on wet or smooth surfaces.

b. Contact with water and excessive moisture can cause components of the structure to oxidise and start to show signs of decay, so:
- Do not use the wheelchair in the shower, pool or environment in contact with water. Some components may be damaged and cause malfunctions.
- Avoid extreme humid places (for example: do not bring the wheelchair into a steamy bathroom after a shower)
- Avoid contact with seawater
- If the device comes in contact with water or dirt, please carry out an immediate and thorough clearing.

c. Severe environmental conditions may affect the features of the materials used, the functionality and performance of the structure, so:
- Avoid the exposure to extreme temperatures
- Avoid prolonged exposure to sunlight. Some parts may overheat.

- **Components and options:**

***Footrests*:** The footrests are the lower part of the frame and closer to the floor, so avoid to pass over obstacles that may collide with them causing damages. Also:
- Make sure user's feet do not "hang" over or become trapped between the footplates
- Do not place any weight on the footrest to prevent the frame tipping forwards
- Do not stand or lean the *TIPCO* frame on the footrest; they may detach from the footrest tubes or break
- Make sure, after each adjustment, that the footrest does't touch the front wheels.

Armrest: The armrests cannot support the weight of the *TIPCO* frame. if used for lifting the frame, they may become damaged and can break.

- **Use:**

- **Maximum Load:** See "Technical Features" reported on the Annex A
- If you hear noise, vibrations or any abnormality after a few days of use, please contact the professional user
- Be careful when moving the wheelchair over uneven ground or obstacles, which if in contact with wheels, they can cause the wheelchair to tilt
- To reduce the risk of a tipping, do not hang bags, backpacks or any other weight on the system
- Max accepted gradient: 5°
- When the device is stationary, make sure that the posterior wheels are locked
- If the device is in its most tilted and reclined position, the caregiver must avoid slopes and/or sudden movements that may cause instability hazards
- If the device is in its most tilted and reclined position, the caregiver must avoid that the end user with unbalanced positions and/or sudden movements may cause instability hazards
- The device cannot be used with the stairlift
- During height adjustment pay attention to the footrests, they may hit obstacles
- Do not place any weight on the push handlebar to avoid tipping backwards
- The correct use of the device does not allow weights of any kind (bags, backpacks, etc.) to be placed on it. This would cause serious problems to the stability and structural resistance of the device with serious consequences for the user
- Pay attention to any obstacles or drops that could cause the tipping of the device
- All operations perfomed on the device, such as, seat adjustments, adjustments, movements and transfers of the user, must be done with care to avoid dangers to the user and the end user
- In the event that an accident causes a loss of performance, do not use the system and consult the professional user
- In the case of a sudden deterioration in performance, do not use the system and consult the professional user
- Never perform any adjustment or change without the intervention of the professional user
- In case of malfunctions resulting from other causes, including poor maintenance of the wheelchair, the professional user should be consulted
- Frequently check all the connection of the positioning system on the *TIPCO* frame and verify for a safe and fully functional operations.

3. NEGATIVE ADVERSE EFFECTS

Generally the sole use of the *TIPCO* frame should not cause any adver effects such as allergies, skin irritations or redness, as there is not direct contact. Otherwise, please contact both the Doctor and the Professional User immediately. To read more information about the positioning system, please, refer to the relevant instruction manual.

4. RESTRICTIONS OF USE

The Frame for Positioning System has been designed and manufactured to provide the end user the correct positioning support within the normal activities of social relations, school or leisure time. Any other use may compromise the safety of the Device.

Mandatory Requirements

- Do not drill or crush the gas spring
- Do not drive the *TIPCO* frame with the positioning system fully tilted on steep slopes
- When the system is not tilted, make sure the user is not too forward to exclude the possibility of tipping forward
- When the user in on board, avoid lifting the *TIPCO* frame by the legrests or any posture accessories. If it is necessary, lift the *TIPCO* frame by the sides of the structure, making sure the seat doesn't move during this operation
- Get help from additional people when you have to lift the *TIPCO* frame over obstacles or down stairs
- All replacement parts or adjustments not authorized by the manufacturer are strictly forbidden
- For safety, never leave the user alone in the *TIPCO* frame, especially in the case of children
- Apply the brakes whenever *TIPCO* frame-user is stationary

- Please, pay particular attention when moving on rough or uneven terrain which can damage the system
- The *TIPCO* frame is not suitable for users affected by high tone and/or movement disorders
- Smoking and/or open flames are prohibited.

For further restrictions, please also refer to the instruction manual of the positioning system.

5. STANDARD MAINTENANCE

In order to guarantee a good functioning and long lasting performances in safe conditions it is necessary to check regularly and make periodically maintenance. This operation must be performed by the end user. The regular maintenance consists of two parts: cleaning and mechanical parts checking.

- *Cleaning* -

The metal and plastic parts can be cleaned with a damp cloth with cold water without addition of detergent, taking care to go over everything with a dry cloth.

- *Mechanical Parts Checking* -

The following operations have to be performed:

- Daily general check to ensure that screws, nuts and knobs are not loosen, that there are no signs of wear and tear on metal parts, that the seat is firmly attached to the *TIPCO* frame and that any accessories are firmly mounted to the structure
- Monthly check for wheels wear
- Monthly monitoring of parking brakes efficiency
- Monthly inspection the tension of the cable for the proper operation of the gas spring
- Monthly check the screws and their tightening mechanism.

To read more checking, please, refer to the relevant positioning system instruction manual.

6. ADAPTATIONS WITH STRUCTURAL CHANGES AND/OR SPECIAL MAINTENANCE

Special maintenance should be performed when one or more structural components deteriorate in such way to compromise the performance and safety of users. In this case do not use the Device and immediately contact the Professional User who shall promptly inform the manufacturer about the nature of the malfunction and/or the failures found in order to proceed with the necessary interventions.

The instructions below must be followed at all times:

- Check for the integrity of any knob, screw, nut and lever
- Structure mechanism failure, such as brackets and screws in general: they must be replaced with original parts provided by the manufacturer, restoring the original safety conditions
- Components breakages or tears such as plates, tubes and *TIPCO* frame linkage components: they must be replaced with original parts provided by the manufacturer
- For all structural components it is strictly forbidden to perform any repair and repair by welding, bolted or riveted joints
- We recommend a gradual adaptation of the system to any user's needs.

The non observance of the above clauses will automatically void the CE mark.

For special maintenance, the End User must refer to the Professional User who has to send the appropriate form *"Annex 1 - Warranty Replacement, Adaptations with structural changes and/or special maintenance"* to the manufacturer within 24 hours of the request for intervention. To read more about special maintenance, please, refer to the relevant positioning system instruction manual.

7. PERFORMANCE AND DURABILITY

Pro Medicare S.r.l. ensures that its own production of the *TIPCO* Indoor Frame for Positioning Systems has been designed and produced in compliance with the safety regulations as required by the relevant Regulation (EU) 2017/745.

The benefits provided by the above mentioned medical device, are therefore suitable and respond to the project's purpose, which is the mobility of users with severe disabilities, considering a more effective rehabilitation plan based on correct posture and stability. The realistic life span of the *TIPCO* Indoor Frame for Positioning System is 5 years. This value is purely indicative because, even if the duration expected in the design phase is much greater, it is significantly determined by the way the device is used (which may be how it has been used and if it has been used continuously compared to what was intended in the design phase), by the correct use and careful maintenance.

It is also reasonable to consider a slight reduction in performance over time due exclusively to:

- shocks and accidental events
- natural wear of the components.

Both performance and relative life span expectancy are however dependent by the periodic verification of the suitability, combination safety and the right System adjustments and have to be exclusively performed by the Professional User; regular reas-

sessment by the professional user should therefore be provided in order to check the suitability, safe and integrity of the system. If the Professional User deems it necessary, he can make adjustments to provide the right support and maintenance.
The reconditioning of the device is prohibited if not expressly authorized by the manufacturer.
To read more about performance and durability, please, refer to the relevant positioning system instruction manual.

8. WARRANTY

Pro Medicare S.r.l. warrants the devices functionality for a maximum period of 24 months, covering all manufacturing defects from the first commissioning and 12 months on components and covers replaced under special maintenance starting from the date of commissioning after refurbishment and 12 mounths for wear parts.
The warranty is valid if the device is used as indicated within this instruction manual.
The warranty is voided in the following cases:

- improper use and/or in case of force majeure
- improper and/or inappropriate use for users affected by high tone and/or movement disorders
- a failure arising from an unauthorized tampering or faulty maintenance by third party that compromises the correct functionality and safety of the products
- any modification made without the manufacturer's authorization
- accidental damages and wear of the essential components
- structural changes of the end user
- failure or damages during the transportation: the Professional User is pleased to refer to the general sales conditions
- stolen or loss.

For warranty replacement of components, the End User must refer to the Professional User who has to send the appropriate form "*Annex 1 - Warranty Replacement, Adaptations with structural changes and/or special maintenance"* to the manufacturer within 24 hours of the request of intervention. It is also essential for the manufacturer to receive a completed *Warranty Registration Form*.

9. POST-MARKET SURVEILLANCE AND POSSIBLE INCIDENTS

Pro Medicare S.r.l. ensures that their medical devices have been manufactured within the strict compliance, criteria and requirements established by the relevant applicable standards, guarantee functioning under the safety conditions prescribed by Regulation (EU) 2017/745.
The post-market surveillance system is set up and implemented in accordance with the quality management system adopted by Pro Medicare S.r.l. and is aimed to actively and systematically collect, record and analyse relevant data on the quality, performance and safety of its devices during their whole life, to establish the necessary conclusions and to determine, implement and monitor any preventive and corrective actions (art. 83 MDR).
These activities are also ensured through accurate market surveillance of the medical devices already present on the market, as also included in Art. 84 of the same Regulation (EU)2017/745.
To ensure Post-Market Surveillance, Pro Medicare S.r.l. shall implement all activities together with Professionals and Stakeholders to establish and keep updated a systematic procedure which is useful to collect and promptly analyze the experience gained on devices that have been placed on market, in order to identify any need for improvement or modification.
This surveillance activity also includes any incidents or serious incidents defined by the MDR as:

- "incident": 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 (art. 2(64) MDR)
- "*serious incident*": 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 (art. 2(65) MDR).

Serious incidents must be reported to the manufacturer and, through EUDAMED, to the competent authority.
Non-serious incidents, on the other hand, do not have to be reported to the competent authority; they must, however, be documented and taken into account in the manufacturer's quality management system and reported in accordance with the requirements of Art. 88 MDR.
It follows, therefore, that upon the occurrence of both serious incidents and possible non-serious incidents to end users and their companions or to professional users in connection with the use of the device **it is mandatory to send** to **Pro Medicare** a copy of a fully completed "*Annex 2 - Reporting of after-sale incidents*".
Pro Medicare S.r.l., as soon as it receives the aforementioned form, will provide the appropriate communications to the professional/end user, including the possible authorization to repair the damaged device or its replacement, also providing for the adoption of measures within its competence, appropriate to the nature and gravity of the incident detected.
In cases of particular urgency **it is mandatory** to contact the manufacturer at the following number **+39 0831 777840** sending to ***sales@promedicare.it*** the fully completed *Annex 2* as soon as possible.

10. DISPOSAL/RECYCLING

Please, follow the local disposal and recycling regulations.
Following there is the description of all materials used (It is recommended to proceed with a separation of the different components of Positioning System accessories):

- Aluminium: handlebar
- Steel: structure
- Plastic: handgrips, wheels, packaging
- Paper: cartoon or wrapping paper.

If the system is combined with a positioning system, please refer also to the relevant instruction for use.

11. LABELING

The label is placed on the lower part of the *TIPCO* frame and it is also sticked on the second page of this manual.
Product data are indicated on the label. In case of replacing parts orders and/or reports, the serial number of the product is duly requested. A facsimile of the label is shown below:

MD Medical Device
SN Serial Number
REF Catalog Number
CE Mark
Manufacturer
Manufacturing date
Recovery/Recyclable
Handle with care
UDI Unique Device Identifier
Consult Instruction for Use
Keep dry

Annex A - "Technical Features"

The *TIPCO* Indoor frame is composed by a steel tube supported by swivel castors to which have been hooked other steel parallelogram structures that support and maintain the positioning system connection system. All the four wheels are swivel castors to facilitate and provide shifts in tight spaces, such as home environment. Posterior wheels are also equipped with brakes to lock the *TIPCO* base everywhere. The trapezoidal tube has been designed to allow users to move freely also between narrow doors and spaces, following the stability requirements of the current legislation.
The height adjustment of the seat is performed by a system of parallelogram rods that is connected with the tube by means two plates. The adjustment in safe conditions is performed with or without the user seated in the system and can be operated by pushing down the gas spring pedal with foot.
The tilt in space of the *TIPCO* frame seat is possible. This is performed through a lever placed on the push handlebar to facilitate the caregiver operation.
The handlebar is easy to adjust only by pushing the button located on the side; the handlebar can be detached from the *TIPCO* frame to facilitate transfer and transport operations.
For further information, please contact the Technical Sales Department at the following number:

+39 0831 777840

TECHNICAL FEATURES

		Size 2	Size 3
TIPCO	Maximum seat to floor height (cm)	63	63
	Width overall dimensions (cm)	67	67
	Depth overall dimensions (cm)	80	88
	Tilt in space (°)	-5+30	-5+30
	TIPCO Load (kg)	50	50
	TIPCO Weight (kg)	13.6	14

For the combination with another Company Frame for positioning system, please refer to the relevant Instruction Manual.