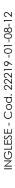


Dandy Stander

Use and Maintenance Handbook





Medifab Ltd

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ORMESA thanks you for the confidence placed in choosing our **DONDOLINO** standing frame.

DONDOLINO is a standing frame where the attention to its functionality unites with the respect of ergonomic and safety principles.

ORMESA then suggests you to read this handbook very careful to fully understand its contents. It will help you in becoming familiar with **DONDOLINO** soon and more efficaciously, and you will also find many practical advices to use it safely and in the best possible way and to keep it perfectly efficient.

Following our advice we'll help you in reaching the rehabilitation aim this aid has been designed for.

If, after reading it, you still have questions, contact your retailer, who will be happy to help you, or call ORMESA directly at +39 0742 22927, send a fax to +39 0742 22637 or send an e-mail to: info@ormesa.com

Luigi Menichini Managing Director



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↑ WARNINGS

- CAREFULLY READ AND UNDERSTAND THE INSTRUCTIONS IN THIS MANUAL BEFORE USING THE DEVICE BECAUSE THEY HAVE BEEN WRITTEN WITH THE USER'S SAFETY IN MIND and they will help the carer use the product safely and keep it in good working order. The Use and Maintenance Manual is an integral part of the product and must be carefully preserved for future reference.
- THE MANUAL IS INTENDED FOR TECHNICALLY QUALIFIED RETAILERS AND FOR USERS AND THEIR ASSISTANTS; it provides instructions for using the product correctly and must be supplemented by adequate knowledge of the rehabilitation program for which it has been prescribed.
- The manual reflects the technical state of the product at the time it was sold.
 ORMESA RESERVES THE RIGHT TO MAKE ANY CHANGES TO THE PRODUCT
 OR MANUAL suggested by experience, technical considerations or regulatory developments without any obligation to update its previous production and relevant manuals.
- DONDOLINO must be prescribed by a MEDICAL SPECIALIST who will also supervise its use.
- The effective use of DONDOLINO requires training by SPECIALIZED PERSON-NEL such as ORTHOPAEDIC TECHNICIANS, THERAPISTS OR DOCTORS.
- ATTENTION!: ADJUST DONDOLINO to the CORRECT POSITION for its use (see. § «HOW TO ADJUST DONDOLINO» pag. 14)
- <u>ATTENTION!</u>: after making any type of adjustment MAKE SURE that ALL ADJJUSTABLE PARTS ARE LOCKED, in order to avoid any possible danger to the User.
- DONDOLINO must only be used by persons whose bodily measurements and weight conform to the specifications in the paragraph "TECHNICAL CHARACTERIS-TICS" on page 8
- DONDOLINO must be used with the assistance and constant presence of qualified personnel or a family member.
- Make sure that all adjustable parts have been locked before each use.
- To make **adjustments while the product is in use**, follow the instructions in section "HOW TO ADJUST DONDOLONO" on pages 14 and following of the manual.
- <u>ATTENTION!</u>: THE PRODUCT IS NOT FIREPROOF, so keep DONDOLINO far from flames, cigarettes or fires.
- Clean DONDOLINO following the instructions shown in the "MAINTENANCE" section (see page 22).
- DONDOLINO IS ONLY DESIGNED FOR INDOOR USE

DONDOLINO IS A MECHANICAL MEDICAL DEVICE:



Perform REGULAR MAINTENANCE and CLEAN-ING following the instructions shown in the "Maintenance" chapter on page 22-23 and HAVE THE DEVICE INSPECTED AT THE INTERVALS INDICATED to VERIFY that it is WORKING PROPERLY and in GOOD CONDITION, otherwise warranty will fail and € marking will lapse



PRODUCT REPAIRS other than the regular maintenance shown on page 22-23 of the manual must be ONLY MADE by a SPECIALIZED SERVICE CENTER in the maintenance of mechanical aids for disables, otherwise warranty and € marking will be voided



Any CHANGES in the product and the REPLACE-MENT WITHOUT ORIGINAL PARTS OR COM-PONENTS ARE NOT AUTHORIZED. REFER ONLY TO ORMESA, otherwise warranty and € marking will be voided



In case of DOUBT about the SAFETY of the product or DAMAGE to parts or components, you are urged to IMMEDIATELY DISCONTINUE USE and CONTACT a SPECIALIZED SERVICE CENTER in the maintenance of mechanical aids for disables, or directly ORMESA.



ORMESA warrants the DONDOLINO stander for 2 years. In case of problems, contact the retailer where you purchased it. . Always ask for original spare parts, otherwise the guarantee will decline

ORMESA will not be liable for damage in the following cases:

- use by an unsuitable person;
- incorrect assembly of parts or accessories;
- unauthorized modifications or service:
- use of other than original replacement parts and parts subject to wear (upholstery, wheels, etc);
- improper use (such as, transporting objects or loads larger or heavier than those shown in the instruction manual):
- damage caused by incorrect use and lack of regular maintenance, as shown in the instruction manual;
- exceptional events;
- failure to follow the instructions in this manual.

THE GUARANTEE DOES NOT COVER WEAR PARTS, which are subject to wear and tear, such as the upholsteries and the wheels.



HOW TO STORE AND TRANSPORT THE MEDICAL DEVICE

THE DEVICE MUST BE STORED AND PACKED using the Ormesa original packaging materials, unless the guarantee will be voided

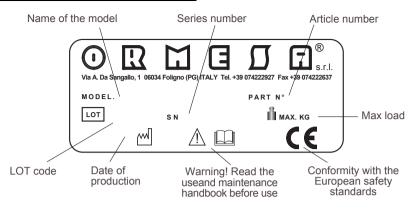
Once unpacked, THE TRANSPORT OF THE DEVICE must be done by ANCHORING ADEQUATELY it to the vehicle

When travelling by plane, or in the car, DO NOT SUBJECT THE FOLDED FRAME TO LOADS THAT, especially with road bumps, COULD DAMAGE ITS STRUCTURE

THE DEVICE MUST BE PARKED / STORED IN CLOSED AND DRY PLACES

The operating environment has no particular influence on the device unless it is used incorrectly, such as by leaving it parked for a long time in direct sunlight or exposed to bad weather such as rain, or in marine environments, where the salt air could corrode the paint and sliding parts. In this case, we recommend carefully cleaning and drying the frame following the instructions shown in the "Maintenance, Cleaning and Disinfection" chapter on pages 22-23 AND THE WARNINGS \triangle ON PAGE 23

LABELS AND PLATES



THE C€ MARKING CERTIFIES THAT DYNAMICO WALKING AID IS IN CONFORMITY WITH THE SAFETY STANDARDS FIXED BY THE EUROPEAN COMMUNITY, AND PARTICULARLY WITH THE 93/42/EEC AND SUBSEQUENT MODIFICATION AND SUPPLEMENTS.



SOME EXAMPLES OF WHAT SHOULDN'T BE DONE WHILE USING DONDOLINO

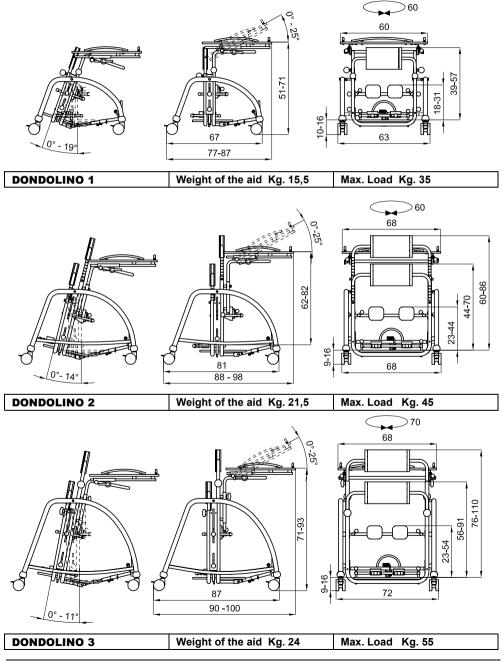
- DONDOLINO has to be used by those children whose bodily size and weight are just like the ones we specify: it has to be prescribed by a specialized doctor according to the laws, standards and rules in force
- Never put the aid on a slope
- Never lift the standing frame in order to move it while the User is using it
- Don't put anything too hot on the tray because the wood or covering could be hardly
- damaged
- In order to adjust the parts while the user is using it scrupulously follow the paragraph § "HOW TO ADJUST DONDOLINO" on page 14 of the Use and Maintenance Handbook
- DONDOLINO has not been designed for the outdoor use unless it is on flat paved ground, well sheltered from bad weather
- Never use the product if there are damaged or missing parts
- Always ask for original spare parts, on the contrary the guarantee decays and ORMESA will be no more responsible for the product

TECHNICAL SPECIFICATIONS

- DONDOLINO is available in three sizes (see page 8)
- **FRAME** varnished with non-toxic epoxy-powder paint and with chromium-plated and adjustable parts. It is adjustable in tilt
- TABLE in multilayer wood. It is adjustable in height, tilt and depth. It can be removed
- KNEE-PADS adjustable in height, width, depth and in a rotatory movement
- **HEELRESTS** adjustable in depth and width
- MULTILAYER WOOD BASE adjustable in height
- PELVIC SUPPORT adjustable in its circumference thanks to Velcro straps, in height, back and forward
- CHEST SUPPORT (just for size 2 and 3) adjustable in its circumference thanks to Velcro straps and in height
- Unpierceable **WHEELS**, diam. 75 mm, with brakes. Thanks to the wheels the aid can be moved from one room to another with the User

The numbers divided by the dash specify a minimum and a maximum adjustment

Measures in cm



WHAT DONDOLINO IS AND WHAT IT IS FOR

DONDOLINO IS A STANDING FRAME DESIGNED AND MANUFACTURED TO HELP CHILDREN FROM 1 TO 10 YEARS OLD TO ACHIEVE AND MAINTAIN AN UPRIGHT POSITION.

DONDOLINO HAS BEEN DESIGNED AND MANUFACTURED:

- for training and achieving an independent upright position
- to maintain a vertical position with a two-foot load, as an alternative to an independent position that would otherwise be impossible

It is important to remember that:

- the upright position is the ideal antigravity posture for human beings. It represents the conquest of a two-legged bearing that thus frees the upper limbs and hands from acting as support and protection
- what we mean by posture is the body's constant relation with its environment, achieved by maintaining a balance between the elastic forces of the protagonist and antagonist muscles, and between the body's inner forces and the forces exerted on it by the outside environment
- posture is maintained by integrating visual, vestibular and somatic-sensory proprioceptor information DONDOLINO is an aid that allows this information to be integrated and facilitates this process

MORE SPECIFICALLY AN APPROPRIATE USE OF DONDOLINO CAN FACILITATE:

- gaining experience with a posture that can act as an alternative to the one that has been "forced" or "partially forced" on the child by his pathology, as well as enabling proper placement of the joints so that controlled and modulated variations can be introduced. The aim of all this is to prevent from deformity
- Training the antigravity musculature
- **controlling and straightening the head.** Conditions that are facilitated by the reduced antigravity involvement of the trunk: this is achieved thanks to the table which is considered as an adjustable chest support (the table can be removed once adequate control of the trunk has been attained)
- Experiencing visually guided manual activity. Thanks to this it is possible to integrate the visual information drawn from the objects with the information coming from the child's own body when it is in the correct posture
- Therefore this involves the possibility of grasping, catching and exploring, initially on an
- overall level and then selectively, and handling through simple or complex constructive activities,
- using objects
- This is also facilitated by the fact that the upper limbs have been relieved of their protective and support functions

IN ADDITION, THE UPRIGHT POSTURE ALSO ENABLES THE FOLLOWING:

- A **IMPROVED RESPIRATORY CAPACITY** through increased ventilation and a decrease in obstructive phenomena
- **B IMPROVED PERISTALSIS**
- **C IMPROVED CIRCULATION**

Above all it is important to emphasize that **DONDOLINO** Is an **AID THAT CAN ENHANCE THE CHILD'S CAPACITY TO ADAPT TO HIS SURROUNDINGS**, or in other words, to interact positively with the world around him.

This will ultimately lead to MORE PERSONAL AUTONOMY, so that the child can establish good relations with himself, with the others and with his physical environment: his skill at "getting in touch with".



HOW DONDOLINO WORKS

It works very simply and safely.

DONDOLINO is a standing frame composed of a lateral frame that **is graduated so that its** height can be easily adjusted.

When the child is standing he is supported by wide straps across the pelvis and trunk that can be adjusted from the front to the back (to follow knee-hip flexion) as well as in its circumference

Two front knee pads and two heel rests fix the position of the lower limbs. The physiatrist and/or therapist must continuously monitor the child's position on the DONDOLINO.

In fact **DONDOLINO** is used by handicapped children during their developmental period. Since they grow up quickly and they can also change in terms of their pathological picture, this entails constant assessment and adjustment.

ATTENTION: Before starting to position the child, brake the wheels of DONDOLINO!

When starting it is advisable to have an adult stand behind the child and hold his sides firmly if the child has an adequate control of the trunk. Otherwise, the child should be supported by his armpits.

The therapist should temporarily position the lower limbs first, followed by the pelvis and the chest. At this point, always attempting to get the child cooperate as actively as possible and explaining him what is being done and why, the position of the feet in the heel rests and knee pads must be controlled.

following any flexion that may be present. Subsequently, the pelvis must be controlled through the pelvic support and then, the trunk must be controlled using the chest support.

It is important to pay special attention to "dosing" the right amount of chest and pelvic support. There must be an adeguate support to assure a minimum amount of stability.

Avoid any excessive support since it could give the child a heavy feeling of "confinement". At the same time, however, the support must not be too "light" since this could cause a reaction of "fear of falling" or instability.

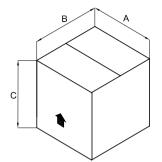
If the child is able to communicate, it is important to listen to his feelings and impressions so that the amount of restraint can be "modulated" as correctly as possible.

Always bear in mind that **DONDOLINO** is a standing frame that must allow the child to carry out several activities and that it was not designed to keep him still and immobilized. This is the main objective that must be taken as a guideline in using this aid, which should work as a tool "to do things in a correct and favourable position".

Naturally the correct posture will be different from one child to another according to their age, motor picture and overall picture.

INITIAL PREPARATION

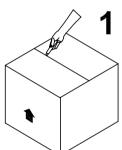
INFORMATION ABOUT THE PACKING

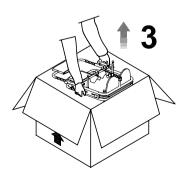


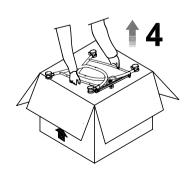
STANDING FRAME	A cm	B cm	C cm	VOLUME m³	WEIGHT kg
DONDOLINO 1	70	66	70	0.323	21
DONDOLINO 2	80	80	84	0.537	28
DONDOLINO 3	80	85	93	0.632	31

HOW TO TAKE DONDOLINO OUT OF THE CARTON



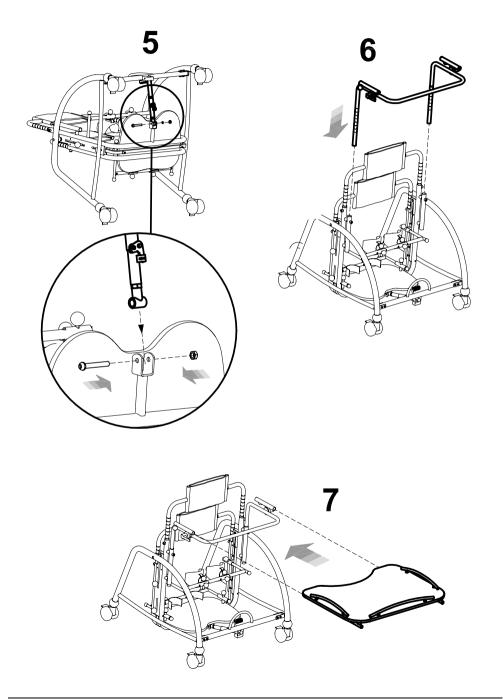






HOW TO ASSEMBLE DONDOLINO 2

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HOW TO ADJUST DONDOLINO

WHILE ADJUSTING THE STANDING FRAME IT IS IMPORTANT TO FOLLOW THREE PHASES AND IT MUST BE ADJUSTED UNDER THE DIRECT CONTROL OF THE DOCTOR WHO PRESCRIBES IT

1ST. PHASE: YOU HAVE TO CONSIDER:

- 1.the height of the child from under his chest to the ground is needed to fix the chest support;
- **2.the height from the knee-cap to the ground** is needed to fix the knee-pads of the standing frame:

You can measure while the child is standing or while he is laying.

2ND. PHASE: INITIAL ADJUSTMENT WITHOUT THE CHILD AND CONSIDERING THE MEASURES THAT YOU MUST MEASURE BEFORE

3RD, PHASE: SUBSEQUENT ADJUSTMENT WITH THE CHILD

Check:

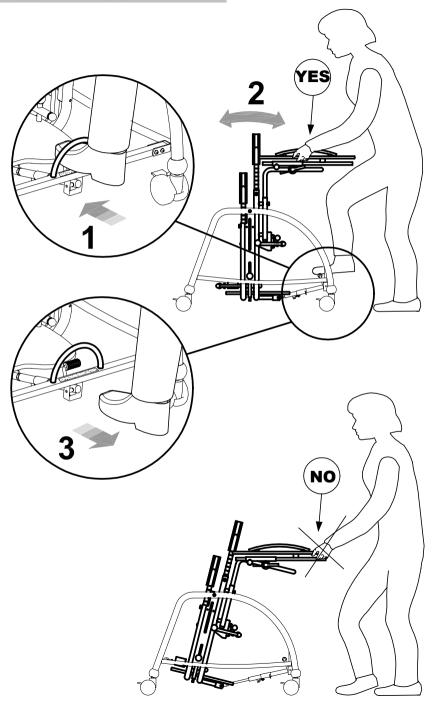
- 1.that the back strap, once it is closed, is in the middle of the bottom. The height of the arm supports depends on the position of the back support of the pelvis;
- 2.the position of the knee-pads;
- 3.the position of the heel rests in width and depth;
- **4.the position of the table.** It must be fixed controlling the height of the User from under his elbow to the ground (minimum height). Shouldn't it be possible to make this control, you can measure the distance from the bended elbow to his feet while the User is laving.
- 5.the vertical alignment of the chest and pelvis
- 6.the flexion of the limbs: the vertical position is determined by the front and back
 - adjustment of the pelvis support, of the knee-pads and of the heel rests.

WARNINGS: ALL THE ADJUSTABLE PARTS MUST HAVE BEEN WELL LOCKED!!! Always check that all the adjustments have been correctly fixed in order to avoid any possible danger to the User.

WARNINGS:

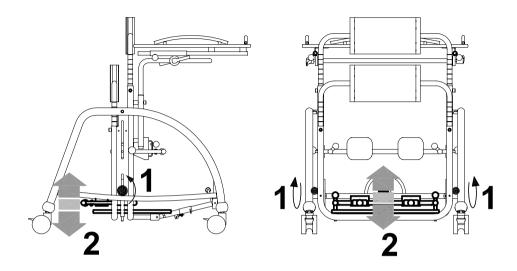
THE ADJUSTMENTS MUST BE ALWAYS CONTROLLED BY THE DOCTOR WHO PRE-SCRIBES THE AID AND BY THE THERAPIST WHENEVER THEY THINK IT IS NEEDED. THIS IS IMPORTANT TO OPTIMIZE THE VERTICAL POSITION BECAUSE THE RIGHT USE OF THE STANDING FRAME CONDITIONS THE FLEXION OF THE USER AND IT REDUCES HIS RIGIDITY

ADJUSTMENT of the FRAME in TILT

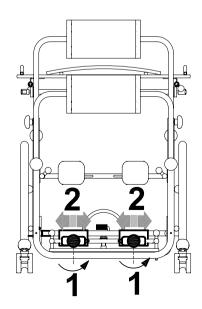


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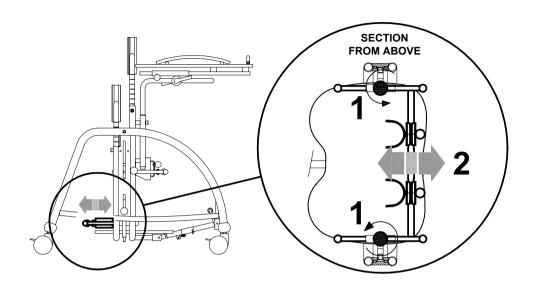
ADJUSTMENT of the FOOTREST in HEIGHT



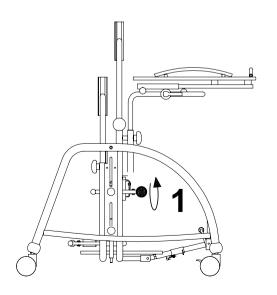
ADJUSTMENT of the HEELREST in WIDTH

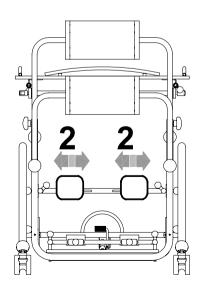


ADJUSTMENT of the HEELRESTS in DEPTH

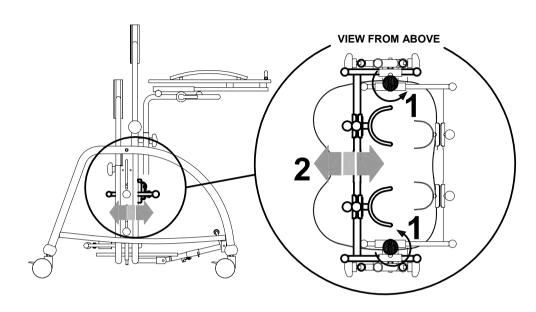


ADJUSTMENT of the KNEE-PADS in WIDTH

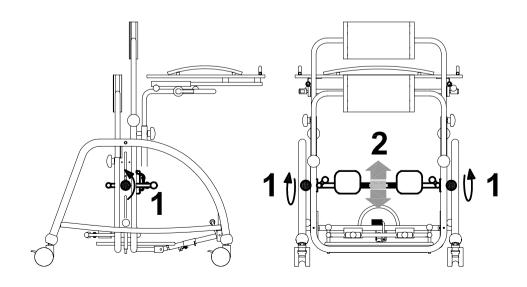




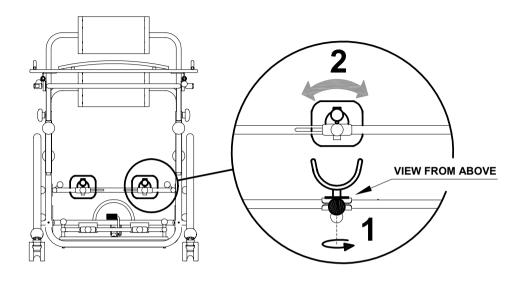
ADJUSTMENT of the KNEE-PADS in DEPTH



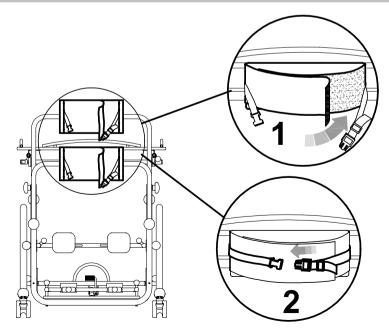
ADJUSTMENT of the KNEE-PADS in HEIGHT



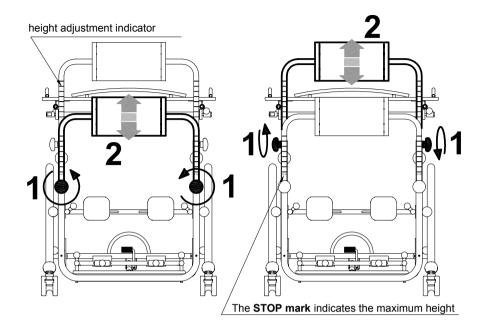
ADJUSTMENT of the KNEE-PADS in a ROTATORY WAY



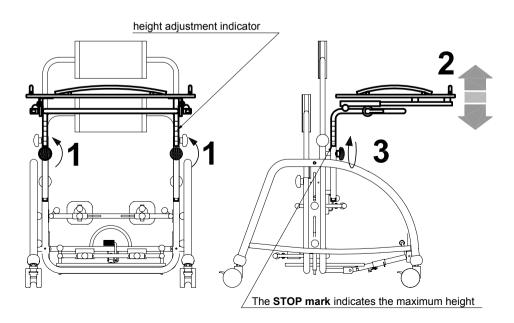
ADJUSTMENT of the CHEST and PELVIC SUPPORT in its CIRCUMFERENCE



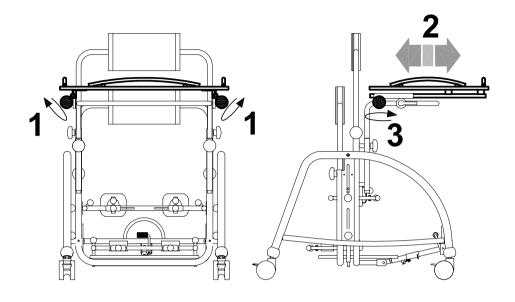
ADJUSTMENT of the CHEST and PELVIC SUPPORT in HEIGHT



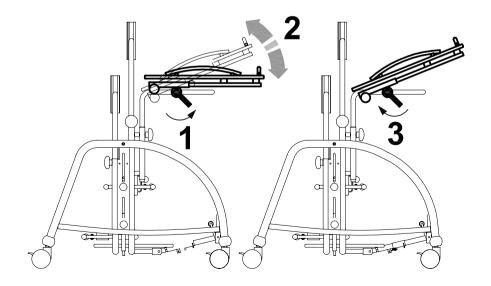
ADJUSTMENT of the TABLE in HEIGHT



ADJUSTMENT of the TABLE in DEPTH



ADJUSTMENT of the TABLE in TILT



MAINTENANCE, CLEANINGAND DISINFECTION OF DONDOLINO

REGULAR (OR PREVENTIVE) MAINTENANCE)

REGULAR MAINTENANCE MUST BE PERFORMED ONCE A MONTH. REGULAR MAINTENANCE IS REQUIRED TO KEEP THE PRODUCT WORKING PROPERLY AND SAFELY AND IS ESSENTIAL FOR KEEPING THE C€ MARK

THE MANUFACTURER IS NOT LIABLE FOR THE PERFORMANCE OF THE PRODUCT UNLESS REGULAR MAINTENANCE IS PERFORMED (ATTACHMENT 1, DIRECTIVE 93/42/EEC). THE MANUFACTURER ALSO RECOMMENDS THAT YOU HAVE THE <u>SUPPLIER PERFORM A COMPLETE REVIEW OF THE PRODUCT'S OPERATION AND SAFETY WITH THE FOLLOWING FREQUENCIES:</u>

- 1) within 3 months from purchase;
- 2) within six months from purchase;
- 3) once a year after the first year from purchase

Clean and disinfect the device and its accessories regularly, following the instructions provided below.

CLEANING AND DISINFECTIND THE VARNISHED AND CHROMIUM-PLATED FRAME

Clean and disinfect the varnished and chromium-plated parts of the aid with a soft cloth dipped in a household detergent and disinfectant, such as alcohol diluted in water.

DO NOT GREASE THE ADJUSTABLE PARTS.

CLEANING AND DISINFECTION OF THE COVERING (padded parts)

Clean the coverings with a soft cloth dipped in water with detergent and a neutral home disinfectant.

CLEANING THE WHEELS

Clean the wheels at least once a month by keeping them free from waste (threads, hair etc...) which can stick to them.

CLEANING THE TABLE

Clean the table with a damp sponge dipped in neutral soap diluted in water. After rinsing, dry well with a soft cloth.

CLEANING THE BASE

Use a soft cloth with water and a mild detergent.

After cleaning, dry thoroughly with a soft cloth.



If you notice any <u>INEFFICIENCY</u>, even partial, of the <u>BRAKES</u>, <u>immediately contact</u> <u>the reseller where you purchased the product</u>, who will determine whether they need to be repaired or replaced to avoid dangerous situations that could cause accidents.



Do NOT perform maintenance or replace parts or accessories when the user is sitting on the device



Intensifie all checks in marine environments, clean more often, anoint the parts exposed to salt corrosion (such as chrome, bolts and screws)



EXTRAORDINARY (OR CORRECTIVE) MAINTENANCE

EXTRAORDINARY MAINTENANCE MEANS ANYTHING DONE TO THE PRODUCT THAT IS NOT MENTIONED ABOVE.

WE RECOMMEND THAT THE USER, RETAILER AND HEALTH FACILITIES ENTRUST ALL EXTRAORDINARY OR CORRECTIVE MAINTENANCE TO THE MANUFACTURER OR OTHER FACTORY-AUTHORIZED SERVICE CENTRE.

ANY OTHER SOLUTION WILL RESULT IN THE USER AND THE THIRD-PARTY MAINTAINER FULLY RESPONSIBLE FOR THE RESULTS OF THEIR WORK AND THE MANUFACTURER WILL ONLY BE LIABLE FOR ORIGINAL DEFECTS OF MATERIALS OR WORKMANSHIP.



If the product is to be disposed of, it must be done according to the law in the country of destination

CUSTOMER SERVICE AND SPARE PARTS

Only contact the retailer where you purchased the product for service and replacement parts.

CONDITIONS FOR DURABILITY, REUSE AND REASSIGNMENT TO A NEW USER

Granted that Ormesa products should be selected, evaluated and ordered for the needs of an individual user, reuse is however possible with the respect the following conditions.

Based on the experience of other similar sold models, on technological progress, on the guarantees of the Quality Management System certificated in 1998 according to ISO 9001, there is adequate confidence that the average lifespan of the DONDOLINO is about 5 years, on condition that it is used according to the directions given in the user manual.

Only when the conditions for storage and transport of chapter HOW TO STORE AND TRANSPORT THE MEDICAL DEVICE" are followed, the periods in which the product is stored at the dealer should not be considered in that time period

Factors unrelated to the product such as the development of the user, its diseases, the use and the surrounding environment can make significantly lower the duration of life of the product; on the contrary, if the indications on the use and maintenance are properly observed, the reliability of the product can extend well beyond the lifetime average above.

Prior to recycling or reassignment an already used Ormesa product, it is required that:

- a doctor or therapist verifies that the aid is appropriate and adequate to meet the dimensional, functional and postural needs of the new user, and if all its components are suitable / appropriate for him. You should also consider that the C€-marking and the manufacturer's responsibility for safety requirements for the product remain only if the original product still has not changed and only original accessories or spare parts have been applied
- qualified technical personnel of a company specialized in the maintenance
 of technical aids for disabled people performs a detailed technical inspection to verify its condition and wear, the absence of any damage and failure
 of all components / adjustments, the presence of the user's manual, of the
 label with the date and serial number. A copy of the manual and maintenance may be always requested to the retailer that supplied the product or
 directly to Ormesa
- The product has been thoroughly cleaned and disinfected following the directions given in the "MAINTENANCE, CLEANING AND DISINFECTION" Chapter

We recommend you keep written records on all inspections performed on the product before any assignment to the new user.



In case of doubt about the safety of the product or damage to parts or components, you are urged to immediately discontinue use and contact a specialized service center in the maintenance of mechanical aids for disabile, or directly ORMESA



Via A. Da Sangallo, 1 Paciana 06034 FOLIGNO PG ITALY



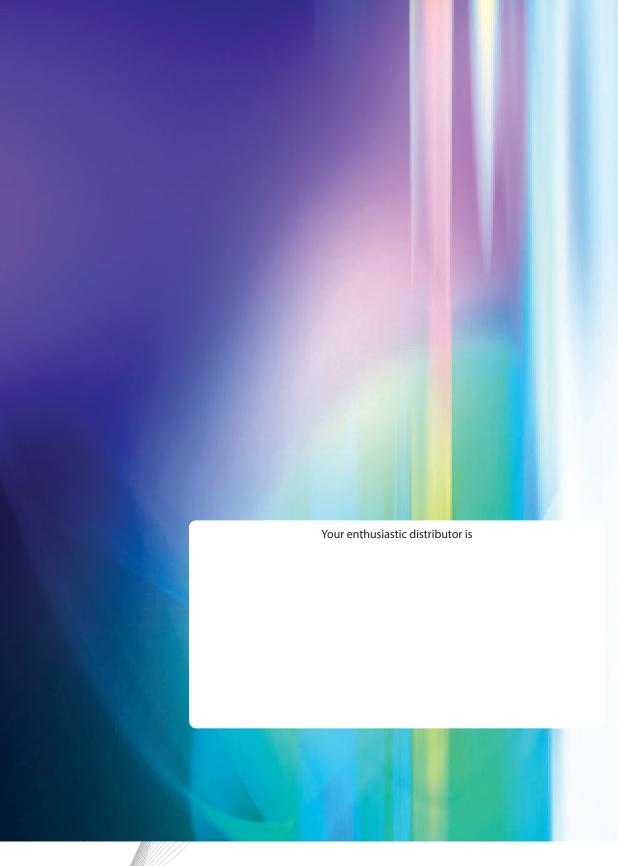
COMPANY WITH
MANAGEMENT SYSTEM
CERTIFIED BY
= ISO 9001 =
= OHSAS 18001 =



FDA REGISTERED - USA

Authorized Dealer	
\	

The technical Data and information given in this handbook are not binding. ORMESA reserves the right to carry out any necessary change without prior notice or replacements





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