



# User's Manual

# Xplore

For Xplore Small, Xplore Medium, Xplore Large

# **User's Manual for Xplore**

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Disclaimer: Minor differences between images and real product can occur in the user manual.

#### 1. Introduction

Congratulations on choosing the Xplore. Everyone has the right to movement. We at Made for Movement are dedicated to give the possibility of movement to persons with limited ability to move on their own. Xplore provides children, young people and adult's who have limited standing and walking abilities, with the opportunity to engage and be active. This User's Manual provides an introduction on how to use Xplore.

#### 2. Who can use the Xplore?

#### Intended use

The Xplore is an assistive device for standing and walking intended for children, adolescents and adults with significantly reduced or no ability for independent standing or walking. The Xplore is intended to be used by the person it is individually adapted to, to allow standing and walking in everyday activities.

The Xplore comes in 3 sizes and is suitable for people who are between 70 and 180 cm tall and who weigh a maximum of 80 kg. It is an individual device and will be fitted to each user individually.

#### Indications

The users of the Xplore have considerable to fully pronounced damage to the neuro-muscular system and movement-related functions of the body (muscle strength, muscle tone, endurance, coordination, function of voluntary movements, movement patterns) with impairment of activities as a result of brain disease (e.g. cerebral palsy, syndromes, trauma), damage to the spinal cord (e.g. paraplegic syndromes due to e.g. spinal trauma, spina bifida) or neuromuscular diseases (e.g. muscular dystrophies).

The users height is between 70 and 180 cm, and body weight is under 80kg.

#### Contraindications

- Bone fractures in lower limbs and/or torso (legs, pelvic, spine)
- Open skin lesions in areas of the body in contact with parts of the product

#### **Precautions for use**

No studies have reported negative effects or side effects from using Xplore.

Risk analysis shows that users with one or more of the following conditions should consult their doctor or therapist before starting to use the product to evaluate if benefits of use outweigh possible risks of injury or negative side effects:

- Major deformities (spine and lower limbs)
- Severe or fixed contractures in the lower limbs (Hip and knee flexion contractures >40°, pes equinus >25°)
- Osteoporosis with previous or suspected spontaneous fractures of the lower extremities
- Joint instability in the lower limbs (hips, knees, and ankles)
- Circulatory disorders
- Respiratory disorders
- Cardiac disorders
- Epilepsy with uncontrollable grand mal fits
- Severe spasticity interfering with positioning and movement in the product
- Pain while in standing weight-bearing position or when moving lower limbs

#### **Training and Assistive Persons**

Before the product is used, the supervisor must have received training (in accordance with Appendix 1) from an Made for Movement representative to monitor use and provide the user with any necessary assistance. The representative is usually a Made for Movement employee or a distributor / doctor / therapist who is appropriately trained and officially approved to work with the product.

The training includes a demonstration of all key features, transfer, attachment, safety, use and troubleshooting as described in Appendix 1. In addition, the instructions for use must be read, understood, used and retained for future reference.

Important: The settings of the product must not be changed in any other way than described in these operating instructions. Furthermore, the product may only be adjusted by an Made for Movement representative who have been trained in the adjustment of the product.

#### 3. Pre-Check

| What is a pre-check?                  | Pre-check is a check performed to discover wear on important parts.   |
|---------------------------------------|---|
| Types of pre-check:                   | <b>Daily</b> : The most important parts are checked daily before use.<br><b>Monthly</b> : Other wear parts are checked for wear once a month. |
| Why to perform:                       | To discover wear and replace worn parts before eventual part breakage.  |
| Who to perform:                       | Trained caretakers. Only trained caretakers are allowed to check + operate the product.   |
| What to perform:                      | The test-steps are described below.   |
| What to do if error<br>is discovered: | Contact your Made for Movement representative to agree on actions/repairs.  |

#### **Daily Pre-check:**

Daily, before use, the following <u>shall</u> be checked by the caretaker:

- 1. Belts Check that all belts are intact and without visible damages and that all seems are intact.
- 2. Buckles Check that the buckles are intact, and locks well.

#### Monthly Pre-check:

Once a month the following is to be checked by the caretaker:

- 1. Belts Check that all belts are intact and without visible damages and that all seems are intact.
- 2. Buckles Check that the buckles are intact, and locks well.
- 3. **Chest + Hip support** Hold on to both chest supports, and then try to push, pull and rotate the supports in all directions. Repeat on the hip supports. Check that all parts sit tight.
- 4. **Chassis** Apply the brake, lift up the front of the product by holding on to and raising the 2 front wheels. Try to push, pull and rotate the front axle in all directions while holding in the wheels. Check that all parts sit tight.
- 5. Feet divider Check that the divider is intact and is tight.
- 6. Wheels Check that the rear wheels can't move sideways on the axle more than 3mm.



Contact your Made for Movement representative if errors are discovered to agree on actions/ repairs. Don't use the product before this is settled.



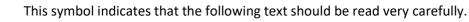
For more tips on how to execute the pre-checks, scan the QR code and examine the Pre-check instructions given.

### 4. Warnings 🔔

- 1. The Xplore shall only be used under supervision by a trained, responsible person.
- 2. The Xplore is an assistive personal device, and must under no circumstance be used by persons who the product is not fitted to.
- 3. The Xplore shall not be given any adjustments, not explained in this user's manual, by any others than Made for Movement, its representatives, or doctors/therapists who have received training to adjust the Xplore.
- 4. The Xplore shall only be used with shoes which fits the product (not sandals)
- 5. The Xplore with large wheels can be used both indoors and outdoors. Make sure that the surface is smooth and flat in order to prevent the user from tipping over or otherwise sustaining injuries. Using the product elsewhere is at your own risk.
- 6. The Xplore should not be used in a moist environment (shower, washing area, outdoors in rain etc)
- 7. The Xplore must be stored in a way which prevents people from using the Xplore as a toy or from influencing the settings of the product.
- 8. The Xplore must be stored in a dry room
- 9. During transport, the Xplore must be properly secured in order to prevent the product from becoming damaged or causing injury to anyone in the vehicle.
- 10. The Xplore shall only be lifted in the frame, none of the other parts.
- 11. The Xplore shall be adjusted when necessary to ensure that the Xplore fits the user in regard to user growth and user functionality. The adjustments must be performed by Made for Movement, it's representatives or people that have received training to do the adjustments.
- 12. The Tray does not provide any additional safety always keep the chest strap secured when the user is in the Xplore.
- 13. The belts and guide straps may lead to strangulation or other damages. Make sure to keep the product under constant supervision while in use and store it in a way that prevents unauthorized persons admittance to the product.
- 14. The Xplore has some parts that can cause a hand-injury if not operated correctly. These parts are labelled with the squeeze hazard sticker. There is a risk that fingers could become squeezed between the brackets on the column during handling and use. Be careful and pay attention to where the user places his/her hands, and where you, in your role as supervisor, hold onto the column.
- 15. Never use the product, with or without user, if the ambient temperature is exceeding the maximal temperature 40°C. Check the surface temperature of the Xplore before use. The temperature of the Xplore could be affected by radiators and direct sunlight, etc.
- 16. Make sure there always is a piece of clothing between the skin of the user and where the product comes in contact with the user. This will minimize the risk for wounds caused by gnaw and possible allergic reactions. All materials at the Xplore which are in contact with the user are tested for allergy.
- 17. The Xplore must be adjusted, used and set up as described in this user manual.
- 18. Do not over tight the guide strap to the leg supports if this is used. This may lead to damages at the user's knees and legs.
- 19. No modification of this equipment is allowed. Modifications may lead to dangerous situations and product breakdown.
- 20. Do not fit other accessories to the product. This will lead to non-compliance of the certification
- 21. If any abnormalities are discovered during the daily pre-check (chapter **Feil! Fant ikke** referansekilden.), the Xplore <u>must</u> be put in order before use.

- 22. The chest and hip strap shall always be secured when the user is in the Xplore. The chest+hip straps can have looser fitting when walking in the Xplore, but cannot be taken of as this is for safety.
- 23. The The Xplore shall never be used close to flames or open fire, as the belts and paddings are not fireproof.
- 24. Do not push at the Xplore's seat, column or headrest with the user in the product. Use the escort handle.
- 25. Always use the Xplore in a well lit room, so all labels can be easily viewed.
- 26. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- 27. The use of synthetic clothes can cause an unharmful static shock in the product.
- 28. Contraindications should always be clarified before using the product for the first time.
- 29. Only persons who have received training in the use of the Xplore shall operate the product with the user. Please see Appendix 1 for details about the content of the training.
- 30. During use, some adjustment screws could loosen over time due to moving parts, adjustment parts or product torsion. Tighten any loose screws before use.
- 31. Always perform the Pre-Check before use to ensure safe use.

#### Symbols in this user manual:



This symbol indicates that the following text may provide you with some good tips.



This symbol indicates potential squeeze hazard

#### 5. Technical description

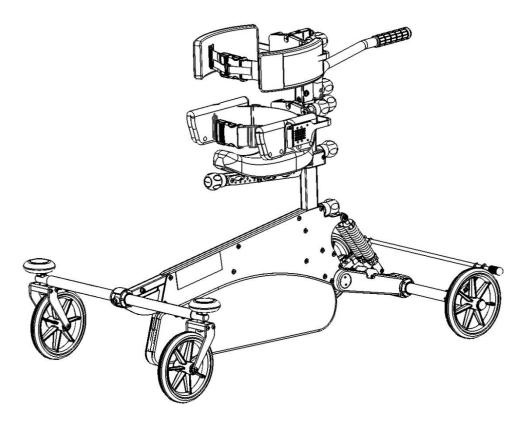


Figure 1: Xplore

Xplore is delivered in the following sizes:

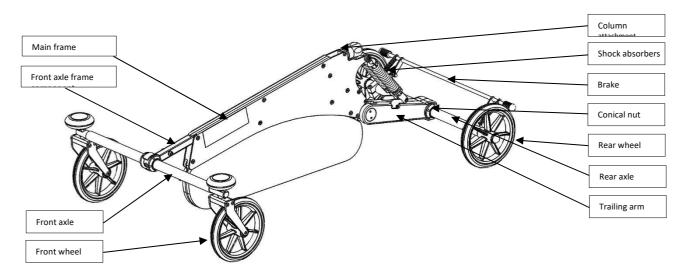
| Xplore Small  | Recommended user height 70-120 cm  |
|---------------|------------------------------------|
| Xplore Medium | Recommended user height 110-150 cm |
| Xplore Large  | Recommended user height 140-180 cm |

The Xplore is an individually adapted aid. Before the product is delivered, the height and width of the user must be measured. These measurements should be sent to Made for Movement who will be able to roughly adjust the product prior to delivery. A representative from Made for Movement or another qualified person will make the final adjustments in relation to the user and make sure that he/she receives an optimally adjusted product.

#### Serial number:

Each Xplore has its own unique serial number. The number is located under the frame.

#### 5.1 Chassis:



#### Figure 2: Xplore chassis

The chassis is shaped like an H. The front and rear axles are connected to the main frame. When a user stands or walks in the Xplore, he/she will have one leg on each side of the main frame, between the front and rear axles. The main frame between the user's legs will prevent the user from crossing their legs while using the Xplore.

The chassis has four wheels with a diameter of 185 mm (Small has 100 mm wheels in order to facilitate use by small users). The rear wheels are fixed and cannot turn. The rear wheels have a brake that can be activated. The front wheels can freely rotate through 360°. The rear wheels are mounted on the rear axle which has a fixed width. The front wheels are connected to the front axle which has a fixed width.

The front axle is equipped with horizontal wheels. These act as wall guards if the user collides with furniture or walls, etc.

If the product is to be transported, the rear axle can be dismantled from the main frame. Loosen the conical nuts and remove the axle from the main frame. A special tool for the conical nuts is supplied with the product. Please see the picture on the next page.



Figure 3: Xplore tool for the rear axle

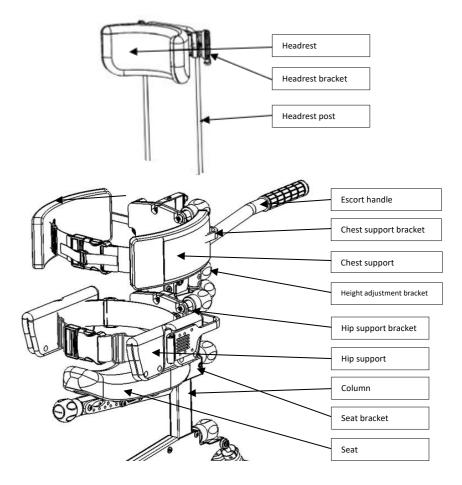
Please read Chapter 10. This chapter explains how to disassemble and assemble the Xplore for transport.

The Xplore's rear axle is supplied in one width. The rear axle is connected by a trailing arm which is sprung by using one or two shock absorbers. The shock absorbers can be supplied with two different types of spring rigidity.

The front axle is connected by a front axle frame component that is attached to the main frame.

The main frame is the connection point for all the other parts and will absorb load generated by the user.

The column with attachments for the seat, hip, chest and head supports is placed vertically in the main frame. The height of the column is adjustable.



#### 5.2 Column, seat, hip support, chest support and headrest:

Figure 4: Xplore column with headrest and companion handle mounted

The column is attached to the highest point of the chassis. The column extends down into the chassis and is held in place by a clamp with a fastening screw in front of the shock absorbers in the chassis. The lower height of the column is adjusted here.

The seat is attached to a seat bracket which in turn is attached to the column. The seat can be removed from the bracket. The height of the seat is adjustable.

The hip support is attached to a hip support bracket. The height and width of the hip support are adjustable. There are two belts attached to the hip support to secure the user's hips in the product. The lower belt goes backwards and the upper one goes forwards. This is to improve the user's hip movement when moving.

The upper adjustment of the column is carried out by using the height adjustment bracket on the column. A companion handle can also be mounted on this bracket by using a separate additional bracket. The height of the companion bracket is adjusted by adjusting the lower height of the column.

The chest support is attached to the column with a chest support bracket. The width of the chest support is adjustable. A chest belt is mounted on the chest support to secure the user's torso in

the product.

The chest support bracket attaches to the headrest post which is attached by using two small knobs.

The height of the headrest can be adjusted by either adjusting the height of the headrest posts in the chest support bracket, or by adjusting the headrest bracket vertically by loosening the screws that fasten it to the headrest bracket. The headrest bracket has a universal design which could enable any customised belts or other headrests to be attached to this bracket.

#### 5.3 Correction system thigh and ankle

A correction system can be mounted on the Xplore for users who require correction of their legs to align their position and enable them to walk. Cuffs are attached around to the lower part of the user's thighs and/or ankles. Guide straps/elastics are attached to these and passed through the U-tube on the column and/or through the rollers at the front axle.

For details on how to use this, please refer to Chapter 12.4

#### 6. Adjusting the Xplore to users

When an Xplore model is ordered for a new user, the measurements of the user should be taken so that the correct product size can be selected for the user before delivery. Such measurements are usually taken by a physiotherapist/occupational therapist. Made for Movement's measurement form can be used for this purpose.

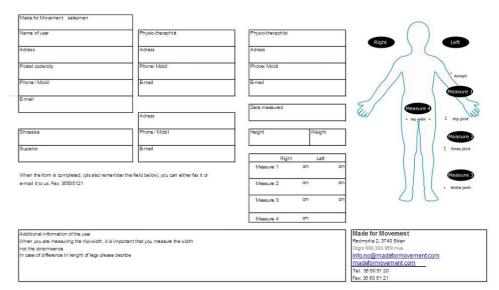


Figure 5: Xplore Using the measurement form

#### 6.1 Checking the Xplore's measurements before delivery:

The chassis is selected on the basis of the height and weight of the user. The widths of the hips and chest are assessed against the standard adjustment interval to see if the user could use the standard components. The user's weight and walking pattern are assessed against the shock absorber's standard springs, or to see if any other spring options need to be selected.

The functions and quality of the Xplore are checked before it is delivered for final customisation.

#### 6.2 Adjusting the Xplore for a user

The Xplore will be adjusted by a representative from Made For Movement, or another qualified person. Adjustments will be carried out at school, at home or at a place deemed to be most appropriate by the purchaser of the product.

#### Rough adjustments:

Place the chassis on a flat surface.

**Hip bar height** – Posision the hip bar at the height of the trochanter. Tip: measure length from the sole of the foot to trochanter while the user is lying down. Please refer to the picture below to see where the trochanter is located on the body.

Hip bar width – Position the hips bars 1-2 cm wider than the user's hip width

Seat height – Position the seat bracke just below the hip bar bracket on the column

**Chest support height** – Position the highest point of the chest support in line with the distance between the user's armpit and sole of the foot.

**Chest suport width** – Position the chest support 1-2 cm wider than the user's chest width.

Make sure that the roughly adjusted supports and belts are securely fastened. Transfer the user to the seat and secure the hip and chest support. Remember to always support the user on the seat while belts are secured so that the user does not fall out of the product. The user is now secured in the product and the fine tuning can be carried out.

#### Fine tuning:

**Seat** - Lower the seat to the position were the use get the right amount of weight bearing and contact with the ground to move forward in an appropriate pattern. Hold on to both the front handle of the seat and the rear fastening knob when adjusting the height and exert upward resistance during adjustment to avoid the user from dropping downwards. During this stage the user is also secured by supporting him/her beneath the arms.

**Hip support** - Adjust the height of the hip bar so the hip belt is position above the hip flexor and do not prevent the user from bending the hip joint.

**Hip bar width** - The width of the hip bar can be adjusted wider in order to provide greater freedom of movement.

**Hip belt length** - can be loosened or tightened. This to position the user either more forward or backward in the device.

**Chest support** - Adjust the chest support height in according to the user's need for support on the upper body. The higher up the chest support is the more support. Lower chest support gives less support and more freedom of movement. It is important that the user is not given more freedom of movement than he/she can handle safely.

The chest support should **ALWAYS** be in use. It is a safety feature preventing the user from falling out of the device.

**Chest support width** - The chest support bar can be adjusted wider in order to provide greater freedom of movement.

**Chest belt** - can be loosened or tightened in length both in the front and at the back. This to adjust the persons position forward or backward in the device.

**Chest and hip support interplay** - By adjusting the lengths of the chest and hip belts, the user's alignment in the device can be adjusted.

Accessories – can be used when more corrected positioning of the user in the device is needed.
 Headrest - Adjust height-wise in order to accommodate the desired level of the headrest.
 Please refer to Chapter 12.1 Headrest for details.

**Correction system thigh and ankel** - see Chapter 12.4 for details on how to configure this.

#### **Optimal positioning in the Xplore**

**Seen from the front** - The user is perpendicular to the ground, as far as is practically feasible.

**Seen from the side** - The user is perpendicular to the ground, or tilted slightly forwards (1-3 degrees).

**Testing -** The user is now positioned in the Xplore. The strength of the shock absorber can be adjusted to enable mobility forward. Amount of weight bearing on the feet will depend on how much the user is supported by the seat and height of the column.

**important:** The Xplore shall only be adjusted by a Made for Movement representative or another qualified person who has been trained by Made for Movement.

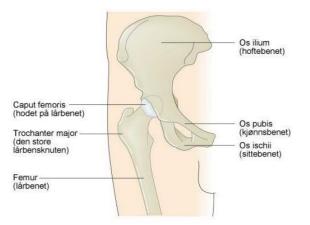


Figure 6: Illustration showing where the trochanter is located on the user's femur.

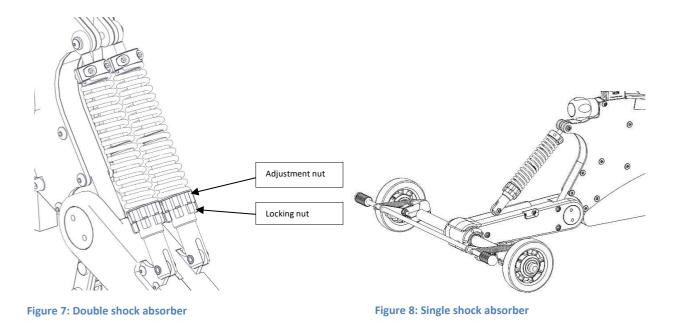
#### 7. How to adjust the Xplore parts

#### 7.1 Shock absorbers

**Variants**: The Xplore Small is supplied with one shock absorber and the Medium and Large models have two shock absorbers.

**Shock absorber stiffness:** the correct level of the shock absorber is adjusted by a Made for Movement representative when the first adjustments are made. If the desired shock absorber stiffness changes at a later date, this can be adjusted as follows: loosen the locking nut by hand (3) by turning it two to three times. If you want to increase the stiffness, turn the adjustment nut in a clockwise direction. Turning it anticlockwise will reduce the stiffness. Adjust the second shock absorber equally. Tighten the locking nut (3) against the adjustment nut after the shock absorber has been adjusted.

**Special adjustments:** for users with special needs, the springs can be replaced in order to adjust the suspension over and above the standard settings. MFM has 2 different spring strengths that are available for special adjustments. These may be required if the user's weight and/or movement patterns maximise the displacement of the springs so that the bottom part of the frame touches the floor. Initially an attempt could be made to tighten the spring(s), but if this does not produce satisfactory results then switching to stronger springs can be tried.



#### 7.2 Adjusting the height of the column

The Xplore comes in 3 sizes covering the size ranges defined in Chapter 5. In order to adapt the device to the user you should select the model that fits the user's height.

Adapting the device to suit the user is carried out by adjusting the height of the column, seat, hip and chest supports.

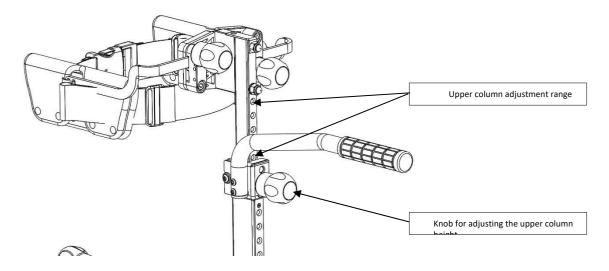


Figure 9: Xplore Upper column

The height of the upper column is adjusted by loosening the column height knob, sliding the column to the desired height and tightening the knob firmly again.

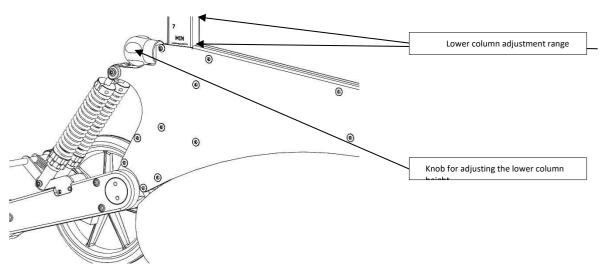


Figure 10: Xplore Lower column

The height of the lower column is adjusted by loosening the column height knob, sliding the column to the desired height and tightening the knob firmly again. Please make sure that the column does not go further down than the bottom of the chassis.

**Important:** please ensure that the column is lowered at least 100 mm into the frame. Less than 100 mm will cause the column to become unstable.



**Important:** The Xplore should only be adjusted by a Made for Movement representative or another qualified person who has been trained by Made For Movement.



**Important:** when using the cuffs and guide straps/elastic bands, and after adjusting the column, please ensure that the guide straps/bands roll freely over the rollers. If not, adjust the height of the U-bar.



**Important:** the Small model is supplied with two lower column components. The shortest Small column component is used for the smallest Small users, and the longest column component is used for the tallest Small users. As the child grows, there may be a need to switch from the shortest to the longest lower pillar component. Please contact your Made for Movement representative to plan this when applicable.

#### 7.3 Adjusting the height of the chest support, hip bar and seat

The Xplore's chest support, hip bar and seat employ the same principles as those used for height adjustment. By loosening the knob which holds them in place, they can be adjusted to the desired height and then tightened again. Check that the brackets on which the knobs are mounted are securely attached to the column.

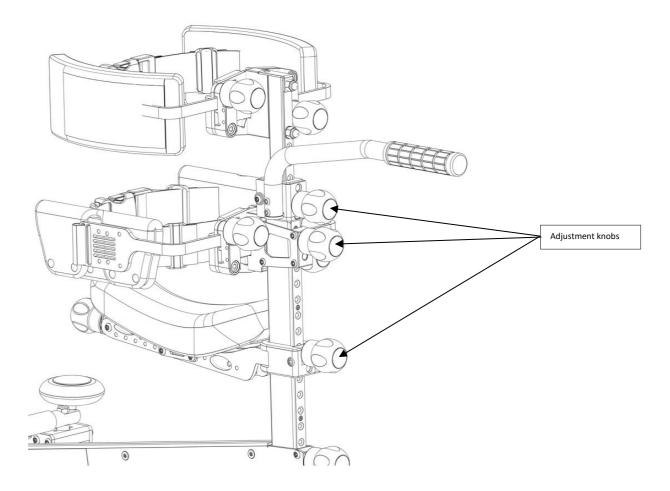
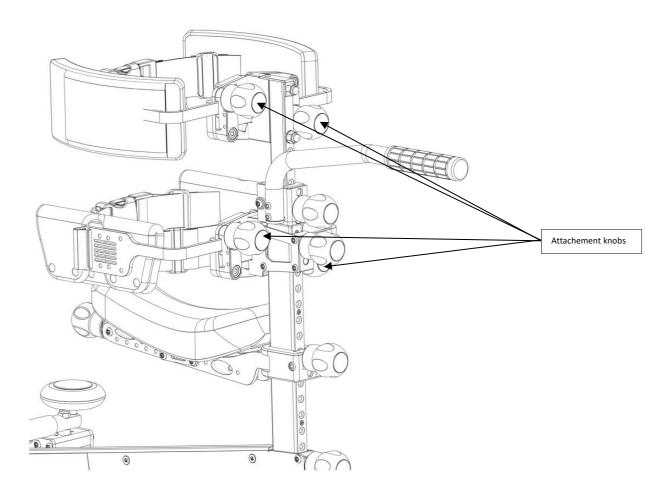


Figure 11: Height adjustment of the Xplore's chest support, hip bar and seat

#### 7.4 Adjusting the width of the chest support and hip bar

The Xplore's chest support and hip bar employ the same principles as those used for width adjustment. By loosening the knobs that secure the arms of the chest support and hip bar, the arms can be pushed outwards or inwards to the desired width. Tighten the knobs again. Please check to ensure that the arms have been fastened securely.



#### Figure 12: Adjustment of Xplore's chest support and hip bar

#### 8. Using the Xplore

#### 8.1. Duration of use

Duration of use of the Xplore will depend on the user's physical and mental health. The user's healthcare professionals are responsible for assessing this.

#### 8.2. Training

The following assumes that the Xplore has been adapted to suit the user by a Made for Movement representative or another qualified person. The people assisting the user in the Xplore **MUST** have received the necessary training in the use of the product and have read and understood the contents of this manual. Appendix 1 should be used to ensure that all safe use aspects have been covered during the training. The information below explains how to get a user in and out of the Xplore.

#### 8.3. Shoes

The Xplore must be used while wearing shoes. You should also check that the shoes fit well when using the Xplore. Do not use sandals.

#### 8.4. Preparations before use

Place the Xplore on a flat surface and apply the brake by pressing the brake lever down (push the lever up to release the brake). Ensure that all the buckles are open before transferring the user to the Xplore. Check that the seat is at the correct height. Check that all the supports and seat are properly tightened.

#### 8.5. How to get the user into the Xplore

There are 3 main ways of getting the user into the Xplore: some assistance/lifting, by transferring the user or by using a sling/harness. Common to all these methods is that the user is transferred to the seat of the Xplore. For the smallest and lightest users, it is usually easiest to lift the user to the seat. Heavier users can be assisted from standing over to the seat if their functional abilities allow such.. For heavier users, it may be appropriate to use a personal lifter or hoist in order to ensure safe and comfortable transfer for both the user and the assistant..

#### 8.6. Securing users in the Xplore

When the user has been transferred to the seat, secure the chest and hip belts immediately to secure the user. Fasten the chest belt first using the locking clips until you hear a click. Control that it is locked securely. Fasten the hip belt in the same way. The user will now be safely positioned in the Xplore.

Please note that the seat must always be in place in order to ensure safe use. If the seat is removed the user could slide down and out of the product.

Please also note that an assistant should be constantly checking to ensure that the user is sitting securely on the seat until the belts have been fastened.

The user should ALWAYS wear the hip and chest belt while in the Xplore. If it is discovered that user's movement pattern is being impaired by the belts, these could be slightly loosened and, if necessary, lowered slightly. This will give the user better freedom of movement, while at the same time preventing the user from falling out of the product.

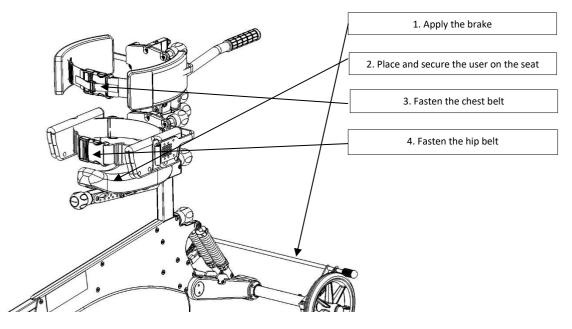


Figure 13: Xplore User Protection order

#### 8.7. How to get the user out of the Xplore

Move the Xplore close to the area to which the user will be transferred.

There are 3 main ways of getting the user out of the Xplore: some assistance/lifting, by transferring the user or by using a sling/harness. Common to all methods is that the user is transferred from the Xplore by lifting or being transferred from the seat to a chair, wheelchair or bed, etc. For the smallest and lightest users, it is usually easiest to lift them from the seat. Heavier users can be assisted from the seat into standing if their functional abilities allow such.. For heavier users, it may be appropriate to use a personal lifter or hoist in order to ensure safe and comfortable transfer for both the user and the assistant. When using a sling/harness this must be attached to the user and the lifter before loosening chest and hip belts on the Xplore in order to ensure safe transfer.

Always ensure that the user is secured by the assistant at all stages of the transfer when belts on the Xplore are released.

#### 9. Who can perform the initial adjustments and follow-up adjustments

#### 9.1. Initial adjustment

- The Xplore is a personal aid and can only be used by the person for whom the product has been adapted.
- The Xplore should only be adjusted by a Made for Movement representative or another qualified person who has been trained by Made For Movement.

#### 9.2. Follow-up adjustments

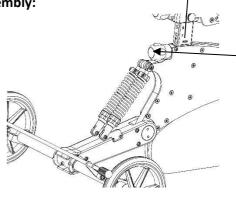
- The Xplore needs to be adjusted to accommodate growth when required.
- The Xplore can only be follow-up adjusted by a Made for Movement representative or another qualified person who has been trained by Made For Movement.

#### 10. Transport

The Xplore can be dismantled for packing or transportation without changing the settings.

When dismantling/assembling the rear axle and the column, you will need the following tools: a special spanner for the rear axle.

#### **Disassembly:**



#### **Dismantling the column:**

Loosen the tightening knob in front of the shock absorbers. Lift the column out of the frame.

Tip: to put the column back in the same position, count the number of holes on the column between the chassis and the upper column adjustment bracket.

Figure 14: Xplore knob for loosening the column



#### Dismantling the rear axle:

Loosen the conical nuts and pull the rear axle backwards.

Figure 15: Xplore tools for loosening conical nuts on the rear axle.

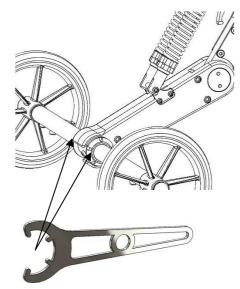
# Assembly:

#### Assembling the column:

Loosen the tightening knob in front of the shock absorbers. Lift the column back into the frame.

Count the number of holes on the column for correct placement. Tighten the tightening knob and check to ensure that the column has been securely assembled.

Figure 16: Xplore Assembling the column



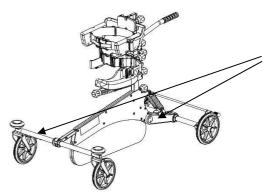
#### Assembling the rear axle:

Push the rear axle into the trailing arm opening. Tighten the conical nuts on both sides of the trailing arm using the special tool.

Check to ensure that the rear axle has been securely fastened.

Figure 17: Xplore Using the tool to tighten the conical nuts.

#### Carrying the product:



#### Carrying points:

Carry the product by holding the front axle and the trailing arm that holds the rear axle.

Figure 18: Xplore carrying points.

#### **11.** Technical information

#### 11.1. Labelling



Figure 19: Xplore Small metal sign



Figure 20: Xplore Medium metal sign



Figure 21: Xplore Large metal sign

| Xplore                                    | Small                 | Medium                  | Large                 |
|---|-----------------------|-------------------------|-----------------------|
| Max. product height:                      | 94 cm                 | 110 cm                  | 140 cm                |
| Max. product length:                      | 103 cm                | 114 cm                  | 127 cm                |
| Max. product width:                       | 55 cm                 | 70 cm                   | 80 cm                 |
| Product weight:                           | 12.9 kg               | 16.7 kg                 | 19 kg                 |
| Wheels:                                   | 100 x 22 mm           | 185 x 28 mm             | 185 x 28 mm           |
| Max. user weight:                         | 30 kg                 | 50 kg                   | 80 kg                 |
| Recommended height of user:               | 70*-120 cm            | 110-150 cm              | 140-180 cm            |
| Hip width:                                | 16-26 cm              | 20-32 cm                | 28-45 cm              |
| Upper column adjustment:                  | 0-25 cm               | 0-25 cm                 | 0-32 cm               |
| Lower column adjustment:                  | 0-9 cm                | 0-12.5 cm               | 0-16.5 cm             |
| Min. seat height:                         | 31 cm (27 cm*)        | 43 cm                   | 45 cm                 |
| Max. seat height:                         | 50 cm                 | 70 cm                   | 88 cm                 |
| Turning radius:                           | 100 cm                | 120 cm                  | 130 cm                |
| Area of usage: indoors                    | Yes                   | Yes                     | Yes                   |
| Area of usage: outdoors in dry weather    | Yes**                 | Yes                     | Yes                   |
| Min. product height ***                   | 52 cm u.hs            | 72cm u.hs 82cm          | 97cm u.hs 107cm       |
|   | 62 cm m.hs            | m.hs                    | m.hs                  |
| Seat width                                | 7 cm                  | max. 13.5cm             | max. 13.5cm           |
|   |                       | min.7cm                 | min.7cm               |
| Seat depth                                | 22 cm (padded seat)   | 30 cm (saddle)          | 30 cm (saddle)        |
| Chest support adjustment interval         | 42 cm                 | 40 cm                   | 38 cm                 |
| Chest support height measured             | Min: 45c cm   Max:    | Min: 65cm               | Min: 95 cm   Max:     |
| from the ground                           | 87 cm                 | Max: 105 cm             | 133 cm                |
| Weight with accessories****               | 15.9 kg               | 20.4 kg                 | 22.4 kg               |
| Standard weight                           | 12 kg                 | 16.5 kg                 | 18.5 kg               |
| Delivery size<br>(dimensions and weight): |                       |                         |                       |
| Column****                                | 47x47x16.5 cm   5 kg  | 59x47x16.5cm  <br>5.9kg | 84x47x30cm  <br>7.2kg |
| Chassis                                   | 93x25x5.5 cm   4.3 kg | 103x33x5.5cm            | 116x33x5.5cm          |
|   |                       | 5.3kg                   | 5.8kg                 |
| Rear axle                                 | 50x15x10 cm   1.7 kg  | 70x20x23cm              | 77x20x23cm            |
|   |                       | 2.6kg                   | 3.2kg                 |
| Front axle                                | 57x20x9 cm   1.9 kg   | 70x26x8cm               | 77x26x8cm             |
|   |                       | 3kg                     | 3.1kg                 |
| Profile measurements:                     |                       |                         |                       |
| Troffic measurements.                     |                       |                         |                       |

#### 11.2. Specifications and dimensions on the Xplore

| Lower column component  | 5x2 cm   | 5x2 cm            | 5x2 cm                    |
|---|--|-------------------|---------------------------|
| Upper column component  | 2.5x1.5 cm   | 2.5x1.5 cm        | 2.5x1.5 cm                |
| Front axle frame component  | 2x2 cm   | 2x2 cm            | 2x2 cm                    |
| Materials that come into contact with the user over time (applied parts):   | Material:  | Fabric thickness: | Padding<br>thicknes<br>s: |
| Chest padding   | Neoprene/Polyester   | 0.65 cm           | 0.65 cm                   |
| Seat padding  | Neoprene/Polyester   | 0.65 cm           | 2.5 cm                    |
| Lower leg padding   | Neoprene/Polyester   | 1 cm              | 1 cm                      |
| Leg divider   | Polycotton/Polyethyl<br>ene                                  | 0.06 cm           | 0.9 cm                    |
| Back padding  | Polyethylene   |                   | 1 cm                      |
| Materials that can come into<br>contact with the assistant and<br>user<br>over a shorter period of time<br>(accessible parts) | Material:  | Fabric thickness: |                           |
| Nylon band  | Nylon  | 0.1 cm            |                           |
| Aluminium   | AA6082-T6, EN-<br>AW5754, AA6061                             | N/A               |                           |
| Stainless steel   | AISI304/1.4301,  | N/A               |                           |
| Steel   | Domex 600, S355,<br>SS2384 spring steel                      | N/A               |                           |
| Plastic   | POM,<br>Polycarbonate,<br>Polypropylene,<br>Nylon,<br>Acetal | N/A               |                           |

\* For the smallest users, the seat padding is attached directly to the frame to enable the use of the Xplore as early as possible. The seat post is removed and stored during this period. As the user grows, the seat padding is moved back to the seat post that is re-attached to the seat bracket on the column.

\*\* The Xplore Small has smaller wheels than Medium and Large. These are not suitable for attempting edges or walking on slopes or uneven surfaces such as gravel. Outdoor use of the Xplore Small should take place on flat and even surfaces without any obstacles. When using the Xplore Small outdoors, the user should be kept under continuous supervision.

Abbreviations: u.hs = without headrest. m.hs = with headrest

\*\*\*\* With the following accessories: companion handle, support handle with fastening, paddings, headrest, one-way bearing, directional lock.

The Small model it is supplied with two lower column components with different lengths. The shortest of these should be replaced with the longest one as the child grows.

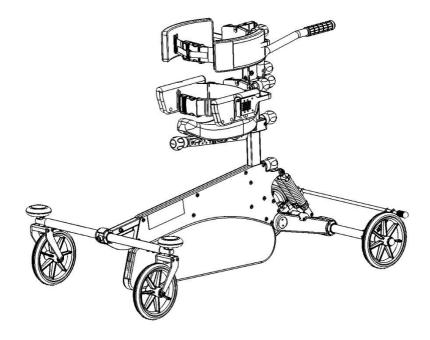


Figure 22: Xplore complete

#### *12.* Extra equipment

#### 12.1. Headrest

The height-adjustable headrest can be mounted on the chest support bracket. The height is adjusted by loosening the knobs which hold the headrest bar and then adjusting the height and tightening the knobs again in order to fix the headrest in the desired position.

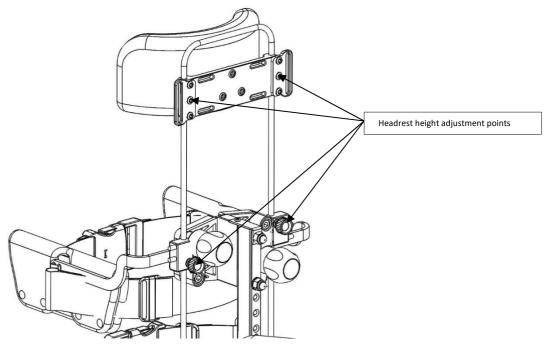


Figure 23: Xplore headrest

#### 12.2. Side handles

Side handles can be mounted on the hip bar if the user needs something to hold on to while walking.

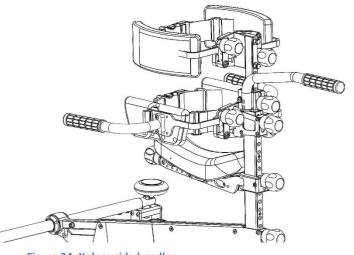


Figure 24: Xplore side handles

#### 12.3. Escort handle

The upper column adjustment bracket can be expanded to hold the bracket used for attaching the escort handle. Screw the escort handle into the column by tightening the knob on the mounting bracket. The height of the escort handle can be adjusted by adjusting the height of the lower column adjustment.

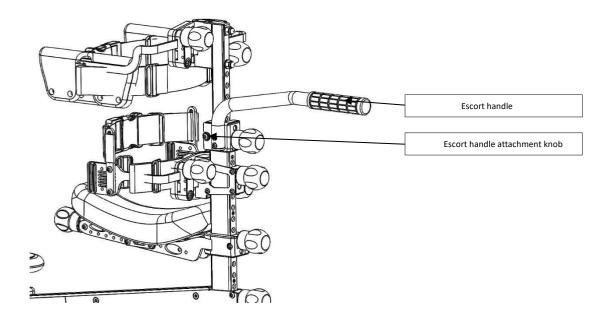


Figure 255: Xplore escort handle

#### 12.4. Correction system for thighs and ankles

For users who require correction of their legs to align their position to enable them to walk, a correction system with cuffs can be used. Cuffs with ring fasteners, are attached around the user's thighs- and/or ankles. They are tightened and fastened with Velcro bands. Make sure that these are not over-tightened since this would be uncomfortable and could restrict blood flow to the legs.

Spreader rollers are mounted on the front axle and a U-tube behind the column. Guide straps or elastic bands with carabiner hooks are threaded through the spreader rollers and U-tube rollers and attached to the cuffs. The guide straps/bands are adjusted by a Made for Movement representative to correct standing position and achieve alignment and still allowing the user to move freely forward.

The guide straps/bands have a number of functions:

- To stretch the user's legs
- To correct the user's walking pattern
- To place the user's legs in alignment with the upper body

Guide straps or elastic bands - or a combination of these - can be used. This is assessed on the basis of the user's needs.

Elastic bands are more flexible compared to guide straps. They are typically used to correct walking pattern and increase the stretch over the knees. The flexibility in the bands allow more freedom of movement

Guide straps are not flexible, but may be appropriate to use in situations where more forces is required to correct and inappropriate gait pattern. There will be less flexibility when the user walks with guide straps.

If the correction system is not needed anymore, simply remove them and the straps/bands. The spreader rollers and U-tube can remain on the product as they do not interfere with its use, and they will be ready for the next time they are needed.

Setting up the correction system requires knowledge and experience and should only be done by a Made for Movement representative or another qualified person trained by Made For Movement.

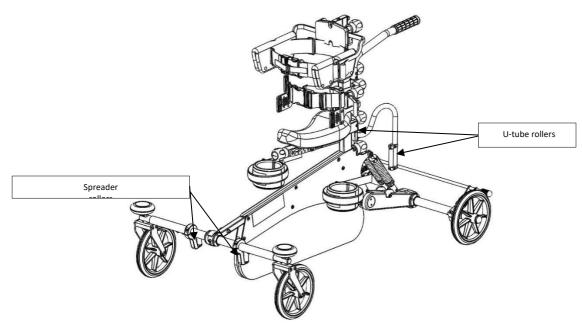


Figure 266: Xplore spreader rollers and U-tube









Figure 277: Details of Xplore spreader rollers and U-tube

#### 12.5. Chest padding

Chest padding can be attached to the belt below the arms of the user to provide pressure relief.



Figure 288: Xplore chest padding

#### 12.6. Front wheel directional lock

A directional lock can be mounted on the front wheels, allowing the wheels to be locked in a forward position. By unlocking the wheels, these can rotate freely through 360 degrees.

#### 12.7. One-way rear wheel

The rear wheels can be supplied with a one-way function, so that the Xplore can only move forwards. Any backward movement will cause the rear wheels to lock. This may be relevant for users who find it difficult to move forwards.

### 12.8. Support handle

The support handle is useful for users who need to an extra support point for hands/arms.. The support handle comes in two different sizes: 310 mm width (standard) and 410 mm width (wide).

If necessary, the length of the support handle can be cut to fit the user concerned.

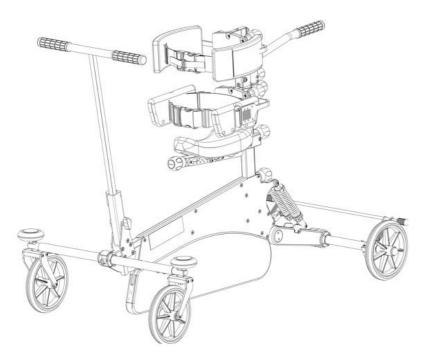


Figure 29: Xplore support handle

# 13. Tests and approvals for

The Xplore and its accessories are CE marked in accordance with the following regulation and standards:

EU 2017/745 Medical Device Regulation (MDR) FOR-2021-05-09-1476 Forskrift om medisinsk utstyr NS-EN 12182 :2012 SS-EN 12182 :2012 DIN EN ISO 11199-3 :2005 §4.3 NS-EN ISO 14971 :2019 NS-EN ISO 13485 :2016

Declaration of conformity is available upon request.

This user's manual is delivered together with the product. The user's manual can also be downloaded from our web-site: www.madeformovement.com

# 14. Waste handling

All the parts of the Xplore can be recycled. The product should be delivered to an approved waste management facility. Straps, elastic bands, padding and clips can be treated as normal household waste.

# 15. Cleaning and maintenance

### a. Cleaning

The Xplore should be cleaned with a damp cloth and mild soapy water. Do not use solvents, high pressure washers or other strong cleaning methods. The same applies to the straps and padding. If the Xplore is used outdoors, sand and dirt must be brushed off properly after use.

The Xplore is resistant to disinfectants and can be disinfected if necessary with commercially available disinfectants or those listed on the Norwegian Medicines Agency's VAH/RKI list.

The cuffs can be machine-washed, max. 40°C. Avoid using a tumble dryer.

Use mild soap!



### b. Adjustment for user growth and function change

Due to the user's growth and user's potential change in function, the product needs to be adjusted by Made for Movement, its representatives or a doctor/therapist/technician that have been trained on how to execute this. Up to 3 adjustments can be necessary each year.

Remote guidance on simpler adjustments:

For simpler child growth adjustments, remote guidance of caretakers by MFM representatives is possible. The caretakers must have received training on how to do the adjustments when receiving the product, and they can be guided over video-telephony to enable safe adjustments. This method is always agreed upon between the parties when delivering the product, so the caretaker is confident in executing the adjustment. The MFM representative shall always approve the adjustment over video-telephony so it can be visually checked that the adjustments are performed correctly.

| Inspection                  |  |
|-----------------------------|--|
| Daily Pre-Check:            | Perform the <u>daily</u> Pre-Check as described in chapter 3 before use.   |
| Monthly Pre-Check:          | Perform the monthly Pre-Check as described in chapter 3 once a month.  |
| Findings from<br>Pre-Check: | If there are findings from the Pre-Check, a repair must be ordered. The product shall not be used again before it's repaired, unless otherwise agreed with the representative that it is ok to use the product until it has been repaired. |
|                             |  |
| Maintenance                 |  |
| Washing:                    | Keep the product clean. If necessary, disinfect the product.   |
| Repairs:                    | Repairs and replacement of worn parts are performed by a Made for Movement representative. Order repairs from your local Made for Movement contact person.   |

# c. Technical inspection and maintenance

⚠

Important: If pre-checks and repairs are not being executed, and repairs documented, then the product certification is broken, and Made for Movement is no longer liable for any unwanted events, incidents or injuries that occur. That responsibility is upon the customer in the unlikely event that the pre-checks and eventual repairs are not performed. The two years warranty will also not be valid if the pre-checks and repairs are not executed.

### Maintenance information:

Made for Movement develops and produces unique standing, activity and walking aids for disabled persons. These products are designed with moving parts to enable smooth operation, and easy and safe use. Some of the moving parts and key components will get worn down during use, and will need to be replaced when worn out. Daily and monthly pre-check are executed to make sure the unit is safe to use over time, and that wear is discovered and repaired.

Typical wear parts are listed below. Other parts can also get worn out due to the users use and/or movement pattern, and these will also need to be replaced if worn out. A repair must be ordered if wear is identified, and the product shall not be used again until the product is repaired. The exception is if the MFM representative assesses the case and defines that the product can be used until the repair, and this is clearly agreed upon by the user/caretaker and the MFM representative.

Examples of worn parts that are not covered during the warranty period are: wheels, padding, straps, belts, guide straps, seat upholstery and brakes.

Examples of parts that could become worn during the course of 2-5 years\*. On the chassis: forks, shock absorbers, wall guards, spreader rollers, column attachments, side plates. On the column: padding on the back plate, forearm supports, hip bars, headrest bar, headrest cushion. Accessories with padding, moving parts or parts exposed to heavy wear and tear may also become worn and should therefore be replaced.

\* Normally most of these parts will last for many years, however MFM enable walking in the Xplore for users with a-typical movement, weight-bearing, strength and/or walking pattern, and the pace of parts being worn down is highly individual due to the users use.

Remember that cleaning and maintenance needs to be performed for the warranty to be valid.

Labels are very seldomly worn out, but for somewhat special cause they are worn out and difficult to read, these shall be replaced by Made for Movement.



Do not execute maintenance when the product is in use or the user is in the product.

# 16. Reuse

The Xplore can be reused by a new user when the period of use ends. If the Xplore is to be reused, the product must be returned to Made for Movement or its representative. A reuse service will be carried out involving disinfection and the replacement of worn parts.

If the product is older than its expected life span of 5 years, any parts that could affect safe usage will be assessed and replaced if necessary.

The following conditions apply to reuse:

- Product repairs and maintenance have been carried out by Made for Movement.
- The Xplore has been used and treated in accordance with this manual.

# 17. Warranty

Made for Movement provides the product with a 2-year warranty. This warranty does not cover accessories supplied by companies other than Made for Movement. Normal parts subject to wear and tear are not covered by the warranty (read more about this in Chapter 15).

Expected lifetime for the product is 5 years.

The following criteria must be met in order for the warranty to be valid:

- Repairs executed by Made for Movement, its representative or trained partner.
- The pre-check and the maintenance (chapter 3+15) has been executed, and maintenance can be documented.
- Repairs which are covered by the warranty, must be approved in advance by Made for Movement Group AS. Warranty claims should be sent Made for Movement within reasonable time (2 months at most). Claims put forward after this might lose the right to claim warranty.
- The product has not been rebuilt or repaired by other than Made for Movement Group AS or it's representative or trained partner.
- The product has been kept clean.
- The product has been treated normally and in compromise with this user's manual.

Should the product fail to work in a satisfactory manner, please contact Made for Movement or its representative by calling +47 35 50 51 20 or sending an e-mail to: info.no@madeformovement.com

Please inform Made for Movement if the product does not work properly or as expected. Do not use the product until it has been repaired.

# 18. Declaration of Conformity

Declaration of conformity is available as stand-alone document. See chapter 13 for approvals.

Producer: Made for Movement Group AS Rødmyrlia 2 3735 Skien Norway

Tel. +47 35 50 51 20 Fax +47 35 50 51 21 info.no@madeformovement.com www.madeformovement.com BRN: NO 991 237 615 VAT

# CE

# **Appendix 1 – Training for users and/or assistants**

### Training and assistants

Before starting to use the product, the user or its assistive person <u>must</u> receive training from a Made for Movement representative.

Only trained users/assistive persons are allowed to operate the product.

The training program consist of, at minimum, the below topics.

The user / assistive person has received training within the following topics:

| Completed:<br>Y/N: |
|--------------------|
|                    |
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Set N/A (Not Applicable) for topics that are not relevant in this case

# Training of others by superusers

A superuser can train other assistants/caretakers. A superuser have received training on how to use the product by a Made for Movement representative and is officially approved to work with the product. The superuser will train other assistants/caretakers in accordance with the user manual and use the Appendix 1 during training.

Assistants/caretakers that have received training by the superuser shall be noted below. This filled-in written document should be stored securely where the product is being used, and in compliance with GDPR, so that no personal information is publicly available. The document shall be available for Made for Movement upon request.

# <u>Please note that only persons that have received training are allowed to operate the product with the user.</u>

| The product serial no: |  |
|------------------------|--|
| User initials:         | (user is the person (anonymized) using the product)                        |
| Superuser (name):      | (superuser is responsible for the training of other assistants/caretakers) |

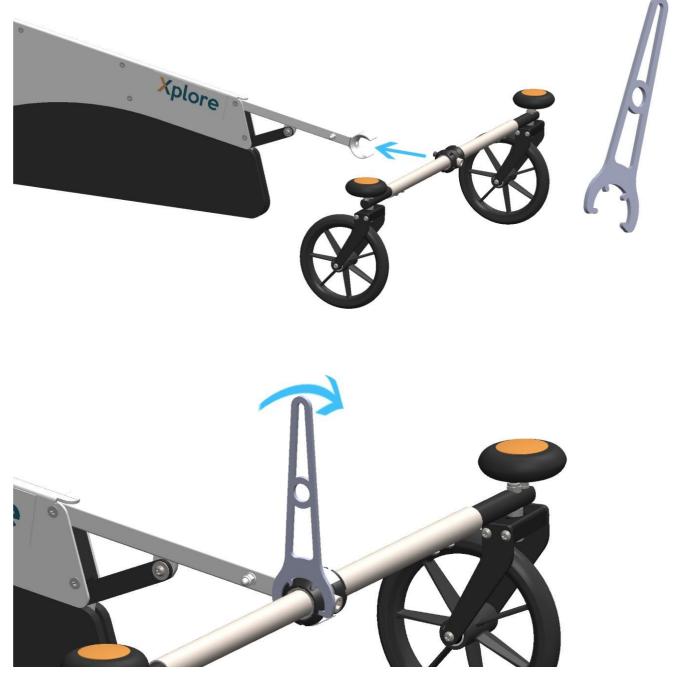
| Persons that have received training by the superuser: (BLOCK LETTERS) | Date training received: |
|---|-------------------------|
|   |                         |
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# **Appendix 2 - Assembly Guide**

The main parts of the Xplore are easily assembled manually by just using a special tool. The illustrations below show how.

### Step 1

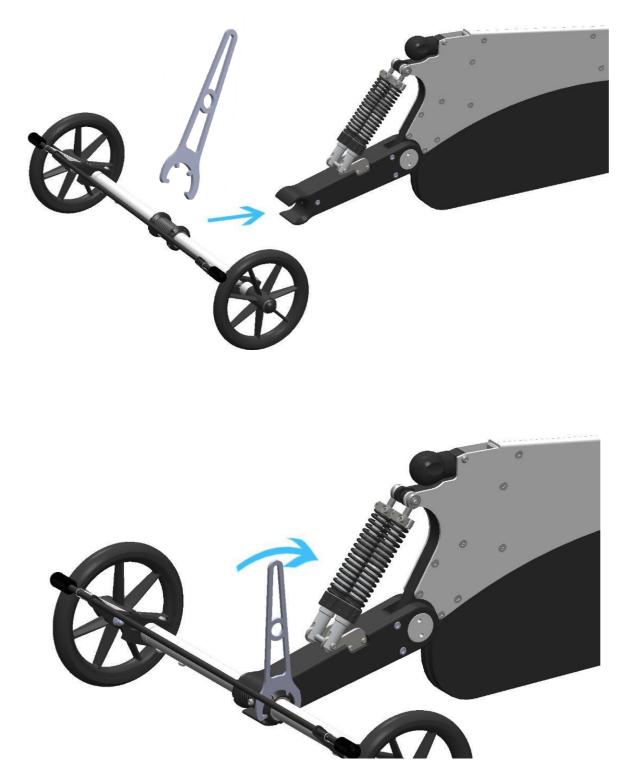
Attach the front axle to the frame using the special tool. Tighten both nuts well.





### Step

Attach the rear axle to the frame using the special tool. Tighten both nuts well.





### Step

The seat: push the seat into the seat bracket.

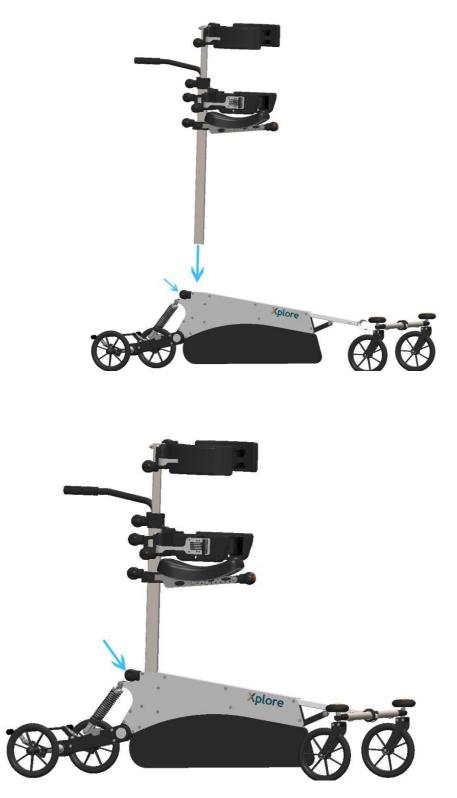
Companion handle: unscrew and remove the tightening handle (1.). Insert the companion handle into the bracket (2.) Replace and re-tighten the tightening handle.





Step

Loosen the column tightening handle which is attached to the chassis and push the column down into the chassis. Tighten the tightening handle in order to secure the column. Tighten well.





**Step** The product is ready to use



Appendix 2 - Rev 01/20 CTS 11.11.20