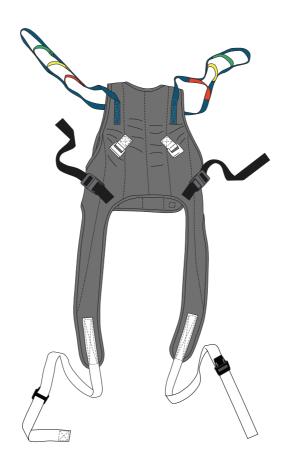
Loop Walking Slings



 $\mathsf{EN}\cdot\mathsf{ZH}\cdot\mathsf{DE}$

使用说明书·Bedienungsanleitung



Contents

ΕN

Foreword2	Apply the Loop Walking Jacket9
Customer Support2	,,,
Definitions in this IFU2	
Intended Use3	In Chair/Wheelchair (13 steps)11
Patient/Resident Assessment3	Remove the Loop Walking Jacket/Sling12
Expected Service Life3	
Pre-sale Information	Cleaning and Disinfection12
Safety Instructions4	Cleaning Instruction (4 steps)12
Safety Practises4	
Serious incident4	Disinfection12
Parts Designation5	Care and Preventive Maintenance
Preparations6	
Before First Use (6 steps)6	
Before Every Use (5 steps)6	
Select Sling Size7	Service and Maintenance13
Sling model MAA5000M7	Troubleshooting13
Sling model TEM7	
Sling Selection8	Label on the Sling15
Allowed Combinations8	
Safe Working Load (SWL)8	
Loop Attachment & Detachment9	
Attach the Loops (5 Steps)9	
Detach the Loops (2 steps)9	

WARNING

To avoid injury, always read this Instructions for Use and accompanied documents before using the product. Mandatory to read the Instructions for Use.

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Foreword

Thank you for purchasing Arjo equipment. Please read this *Instructions For Use (IFU)* thoroughly! Arjo will not be held responsible for any accidents, incidents or lack of performance that occur as a result of any unauthorized modification to its products.

Customer Support

If you require further information, please contact your local Arjo representative. The contact information is located at the end of this IFU.

Definitions in this IFU

Means: Safety warning. Failure to understand and obey this warning may result in injury WARNING to you or to others.

CAUTION Means: Failure to follow these instructions may cause damage to all or parts of the system or equipment.

NOTE Means: This is important information for the correct use of this system or equipment.

2

Intended Use

The Active sling and Loop walking sling (TEM series) are products intended for assisted transfer and rehabilitation of patients/residents with limited ability to move.

The Active sling and Loop walking sling (TEM series) should be used together with Arjo lift devices in accordance with the Allowed Combinations.

The Active sling and Loop walking sling (TEM series) shall only be used by appropriately trained caregivers with adequate knowledge of the care environment, its common practices and procedures and in accordance with this Instructions for use (IFU)

The Active sling and Loop walking sling (TEM series) are intended to be used in hospital environments, nursing homes, other health care facilities and home care.

The Active sling and Loop walking sling (TEM series) should only be used for the purpose specified in this Instructions for Use. Any other use is prohibited.

Patient/Resident Assessment

We recommend that facilities establish regular assessment routines. Caregivers should assess each patient/resident according to the following criteria prior to use:

- · Patient/resident sits in wheelchair
- Is able to partially bear weight on at least on leg
- · Has some trunk stability
- Dependent on caregiver in most situations

- Physically demanding for caregiver
- Stimulation of remaining abilities is very important Safe Working Load (SWL) for Active sling and Loop walking sling:
- MAA5000: 190 kg (418 lbs)
- TEM: 200 kg (440 lbs)

The right type and size of slings should be used after proper assessment of each patient/resident's size, condition and the type of lifting situation.

If the patient/resident does not meet these criteria an alternative equipment/system shall be used.

Expected Service Life

The expected service life of Active sling and Loop walking sling is the maximum period of useful life. The expected life of the slings is dependent on the actual use conditions. Therefore, before use, always make sure that the slings do not show any signs of fraying, tearing or other damage and that there is no damage (i.e. cracking, bending, breaking). If any such damage is observed, do not use the slings. If you have any doubts about sling safety, as precaution and to ensure safety, do not use the slings.

The expected service life Active sling and Loop walking sling:

Service time: 2 years
Shelf time: 5 years

Pre-sale Information

General	
Intended use, the intended user group and the intended environment; including any contraindications	See "Intended Use" on page 3
Expected lifetime of the product	See "Intended Use" on page 3
Maximum user mass	See "Sling Selection" on page 8
Sizing	See "Select Sling Size" on page 7
Compatible products	See "Allowed Combinations" on page 8
Name and address of the manufacturer	See back page

NOTE

Any organization that purchases hoists and body-support units shall make sure, that the combination(s) are safe either by requiring compatibility documentation for the combination(s) from the manufacturer(s) or by performing compatibility testing themselves hereby transferring the responsibility for a safe combination to the organization.

Safety Instructions

WARNING

To avoid injury, make sure that the resident is not left unattended at any time.

WARNING

To avoid falling, make sure that the user weight is lower than the safe working load for all products or accessories being used.

WARNING

To avoid injury, always assess the resident prior to use.

WARNING

To avoid injury, never let the resident smoke when using the sling. The sling can catch on fire.

WARNING

To avoid injury, only store the equipment for a short period of time. If stored longer than stated in the *IFU*, it can cause weakness and breakage in the material.

WARNING

To avoid injury, keep the equipment away from sun/UV-light. Exposure to sun/UV-light can weaken the material.

Safety Practises

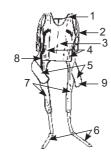
At any time, if the resident becomes agitated, stop transferring/transporting and safely lower the resident.

Serious incident

If a serious incident occurs in relation to this medical device, affecting the user, or the patient then the user or patient should report the serious incident to the medical device manufacturer or the distributor. In the European Union, the user should also report the serious incident to the Competent Authority in the member state where they are located.

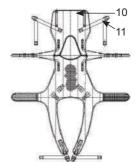
ΕN

Parts Designation



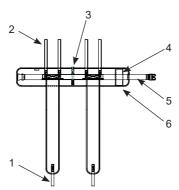
Loop walking jacket, folded

- 1. Colour coded neck biding for size reference
- 2. Attachment strap (with coloured loops)
- 3. Front of the jacket
- 4. Belt fixation strap (for the support belt)
- 5. Support belt (hook and loop)
- 6. Leg straps (white) and buckles



Loop walking jacket, unfolded

- 7. Leg sections
- 8. Chest straps (black with buckles)
- 9. Sling label (located on the front side of the waist belt)
- 10. Front of the jacket
- 11. Back straps (white with buckles)



Loop walking sling (TEM), unfolded

- 1. Leg straps
- 2. Chest strap
- 3. Colour coded back strap

- 4. Product label
- 5. Belt fixation strap (for the support belt)
- 6. Support Belt

Preparations

Before First Use (6 steps)

- 1. Check all parts of the sling, see section "Parts Designation" on page 5. If any part is missing or damaged - Do NOT use the sling.
- 2. Read this *IFU* thoroughly.
- 3. Check that the sling is clean.
- 4. Choose a designated area where the IFU should be kept and easily accessible at all times.
- **EN** 5. Make sure to have a rescue plan ready in case of a resident emergency.
 - 6. For questions, contact your local Arjo representative for support.

NOTE

Arjo recommends the name of the resident is written on the sling care label to avoid cross contamination between residents.

Before Every Use (5 steps)

1. Resident assessment must always determine the methods used in everyday care, see "Intended Use" on page 3.

WARNING

To avoid the resident from falling, make sure to select the correct sling size according to the IFU.

2. Check the allowed combinations against the sling and lift, see "Allowed Combinations" on page 8.

WARNING

To avoid injury, always make sure to inspect the equipment prior to use.

- 3. Check all parts of the sling, see "Parts Designation" on page 5. If any part is missing or damaged - Do NOT use the sling. Check for:
 - fraying
 - loose stitching
 - tears
 - fabric holes
 - soiled fabric
 - damaged buckles
 - unreadable or damaged label

WARNING

To prevent cross-contamination, always follow the disinfection instructions in this IFU.

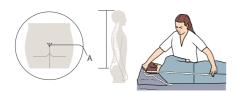
- 4. Check that the sling is clean. If the sling is not clean see "Cleaning and Disinfection" on page 12.
- 5. Before using the sling, read the lift *IFU* for transfer, transport and bathing.

Select Sling Size

How to measure, to select the correct sling size, differs depending on the sling model.

Sling model MAA5000M

- Measure from the patient's coccyx/seat (A) to top of the head,
- 2. Measure the patient's waist circumference,





3. Follow the sizing chart below to pick the correct size.

		Top of head to coccyx			
	cm (in)	65-74 (25.5-29)	75-83 (29.5-32.5)	84-89 (33-35)	90-94 (35.5-37)
ence	65-79 (25.5-32)	S	М	L	XL
Waist	80-105 (31.5-41.5)	S	М	L	XL
circu	106-129 (41.5-51)	L	L	L	XL

Sling model TEM

1. Measure the patient's waist circumference,



2. Follow the sizing chart below to pick the correct size.

cm (in)	Waist circumference		
0111 (111)	60-89 (23.5-35) 88-107 (34.5-42) 108-125 (42.5-49)		
	S	M	L

Basic components for proper sling fit:

- · Patient waist size
- · Patient thighs size.

Waist Size

After selecting a size of the sling, apply the sling around the patient making sure the sling "centre stripe" is centred on the spine.

If the patient's body touches or falls outside the edge ribbing of the sling, change to a larger sling. This will prevent skin abrasions and tears as well as minimize the possibility of a patient falling or rolling out of the side of an undersized sling.

Thighs Size

After properly fitting the waist, place the leg straps around the sides of the hips and legs, then under the thighs and up between the legs.

If the sling has been applied correctly, the patient's thighs should only be in contact with the padded portion of the leg strap.

If however, the narrow ribbing (extension strapping) of the leg portion is exposed to the skin, skin abrasions and tears may appear. Therefore, a modified sling with longer padded leg section may be indicated.

Extended padded leg sections are rarely required. They are more commonly required for residents/patients with overly large thighs.

Sling Selection

The resident's physical disabilities, weight distribution and general physique needs to be taken into consideration when selecting a sling.

Article number	Safe Working Load	Product Description	Size
MAA5000	190kg (418 lbs)	Loop walking jacket	S, M, L, XL
TEM	200 kg (440 lbs)	Loop walking sling	S, M, L

Allowed Combinations

WARNING

To avoid injury, always follow the allowed combinations listed in this *IFU*. No other combinations are allowed.

Safe Working Load (SWL)

- Only use the sling with the lifts and spreader bars listed below.
- Always follow the lowest SWL of the total system. E.g. the Maxi Move lift/spreader bar has a SWL of 125 kg (275 lbs) and the Loop walking jacket has a SWL of 190 kg (418 lbs). This means that the Maxi Move lift/spreader bar has the lowest SWL. The resident is not allowed to weigh more than the lowest SWL.

	Lift	Maxi M	Maxi Move		Maxi Sky 440	Maxi Sky 600	Maxi Sky 2	Voyager	V5/ Voyager
	SWL	125 kg (275 lbs)		227 kg (500 lbs)	200 kg (440 lbs)	272 kg (600 lbs)	272 kg (600 lbs)	190 kg (418 lbs)	200 kg (440 lbs)
	Spreader Bar	2 point Small	2 point MediumS	2 point loop walking jacket	Fix	2 point Medium	2 point spreader bar medium	Carry Bar	2 point spreader bar
Sling	SWL	Size	Size	Size	Size	Size	Size	Size	Size
MAA5000	190 kg (418 lbs)	S, M	S, M, L, XL	S, M, L, XL	S, M, L, XL	S, M, L, XL		-	-
TEM	200 kg (440 lbs)	-	-	-	S, M, L	S, M, L	S, M, L	S, M	S, M, L

8

Loop Attachment & Detachment

2 point spreader bar:

First attach the shoulder loops, then attach the leg loops.

Attach the Loops (5 Steps)

WARNING

Use the same loop length and loop colour on the straps for both shoulders.

- Place the loop over the spring loaded latch (A). (See Fig. 1)
- 2. Pull the loop down to force the latch to open.
- 3. Make sure that the spring loaded latch closes completely with the loop inside. (See Fig. 1)
- 4. Make sure that the latch is moving freely.
- 5. Make sure loops and straps are not twisted.

NOTE

 The loops lengths on the straps are used to adjust the resident's position and comfort.

Detach the Loops (2 steps)

Make sure that the weight of the resident is taken up by the receiving surface before removing the loop.

Method 1

- 1. Press the spring loaded latch open.
- 2. Remove the loop.

Method 2

- Pull one side of the loop over the hook and spring loaded latch. (See Fig. 2)
- 2. Pull down the loop. (See Fig. 3)

Apply the Loop Walking Jacket

In Chair/Wheelchair (22 steps)

For transfer/transport refer to respective lift *IFU*.

WARNING

Do not cross the shoulder straps.

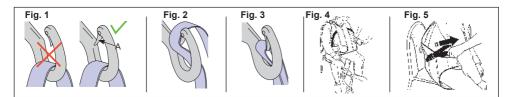
- 1. Place the lift nearby.
- 2. Apply the brakes on the wheelchair.
- Place the Loop walking jacket over the resident's head.
- Position the back of the jacket as far down as possible behind the resident's back. The front of the jacket has two loops positioned at waist level for reference.
- 5. Place the leg flaps underneath the resident's legs.

WARNING

To avoid injury when using a loop walking jacket, make sure the belt is pulled through the belt fixation strap.

- Place the support belt around the resident's back and pull it through the belt fixation strap on the front of the *Loop walking jacket*. Make sure the support belt is not twisted. (See Fig. 4)
- Fasten the support belt securely by pressing the hook and loop together. The support belt should be tight but comfortable for the resident.
- 8. Connect the chest straps (coloured black) with the black straps on the back of the *Loop walking jacket*. (See Fig. 5)
- Pull the loose ends to adjust the chest straps. The straps should be tight but comfortable for the resident.

Continue with the steps on the next page.



WARNING

To avoid injury when using a loop walking jacket, make sure to connect the straps correctly (white to white and black to black).

If a white strap is connected to a black strap, the seam can break, casing the resident to fall out.

10. Connect the leg straps (coloured white) with the buckles on the back of the Loop walking jacket. Do NOT cross the leg straps. (See Fig. 6)

WARNING

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To avoid jamming patients genitals make sure not to attach the leg straps at the belt buckle.

- 11. Pull the loose ends to adjust the leg straps. The straps should be tight but comfortable for the resident.
- 12. Make sure that the:
 - straps are not twisted,
 - · straps are not caught by the wheelchairs castors,
 - · sling attachment points at shoulders and legs are clear of the body and have enough reach to attach to the spreader bar,
 - · leg sections of the sling is long enough to reach around the patients mid thigh to support well and that the sling is not twisted underneath the legs.
 - · patients upper body is inside the coloured edging of the sling,
 - patients head is well supported by the sling (if head support sling used).

WARNING

To avoid injury to the resident, pay close attention when lowering or adjusting the spreader bar.

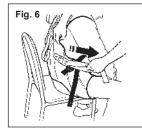
13. Position the lift/spreader bar in front/above of the resident's head. (See Fig. 7)

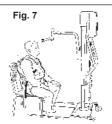
- 14. Apply the lift brakes and adjust the spreader bar if necessary. Pay attention to the resident's head and spreader bar.
- 15. Attach the loops to the lift/spreader bar. Make sure the same coloured loops are used on both sides. (See Fig. 8)
- 16. Slightly lift the resident up to create some tension. See the lift IFU

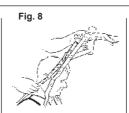
WARNING

To avoid the resident from falling, make sure that the sling attachments are attached securely before and during the lifting process.

- 17. Make sure the sling is attached correctly and the resident is comfortably in the sling. If an adjustment is needed, lower the resident and make sure that the weight of the resident is taken up by the receiving surface before removing the loop.
- 18. Ask the resident to stand during the lifting exercise.
- 19. Continue lifting. See the lift IFU.
- 20. Once the resident is standing it may be necessary to slacken the white leg straps for better leg movement.
- 21. Press on the buckle to release the leg strap enough to reposition. (See Fig. 9)
- 22. If using a floor lift and the resident is standing, supported and comfortable, help the resident to rotate 180°, away from the lift.









Apply the Loop Walking Sling

In Chair/Wheelchair (13 steps)

For transfer/transport refer to respective lift IFU.

WARNING

To avoid injury to the resident, pay close attention when lowering or adjusting the spreader bar.

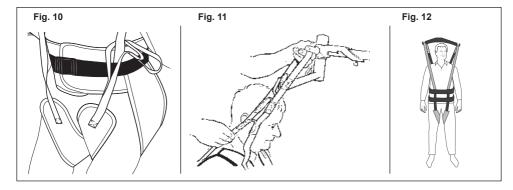
- Position the lift/spreader bar in front/above of the resident's head.
- Place white fabric of the Loop walking sling next to the patient. Labels and outside straps are on the outside.
- Lean patient forward in the chair and make sure the patient is supported.
- 4. Place the sling around user's chest area, clip belt and snug tightly with belt strap.
- Two legs sections will extend down each side. Slide panels under left and right leg.
- Thread right chest strap through right leg strap.
 Thread left chest strap through left leg strap (See Fig. 10).
- Arms will always be between chest straps and back straps.
- Adjust the sling loops higher or lower in either the front or the back to tilt the body in either direction to correct posture.
- Always use the same colour loop on the rear shoulder straps for both sides (See Fig. 11). Use the same colour loop on the chest straps for both sides.
- 10. Make sure that:
 - the sling is not caught on any obstructions (e.g. wheelchair brake or handle),
 - the sling sections between the legs are providing snug support. If not, reinstall the sling

- threading the chest straps through a lower loop (grey or black),
- the sling attachment points at shoulders and legs is clear of the body and have enough reach to attach to the spreader bar,
- the leg sections of the sling is long enough to reach around the patients mid thigh to support well and that the sling is not twisted underneath the legs,
- the patients upper body is inside the coloured edging of the sling,
- the patients head is well supported by the sling (if head support sling used).

WARNING

To avoid the resident from falling, make sure that the sling attachments are attached securely before and during the lifting process.

- 11. Slightly lift the resident up to create some tension.
- 12. Make sure the sling is attached correctly and the resident is comfortably in the sling. If an adjustment is needed, lower the resident and make sure that the weight of the resident is taken up by the receiving surface before removing the loop.
- 13. Ask the resident to stand during the lifting exercise. (See Fig. 12).



Remove the Loop Walking Jacket/Sling

In Chair/Wheelchair (12 steps)

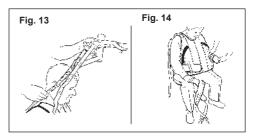
- 1. Apply the brakes on the wheelchair.
- Position the resident, with his/her back against the chair/wheelchair.
- 3. If using a floor lift, open the chassis legs if needed.

WARNING

To avoid injury to the resident, pay close attention when lowering or adjusting the spreader bar.

- 4. Lower the resident into the chair/wheelchair. See lift *IFU*.
- Make sure that the resident's lower back is positioned all the way in against the chair/ wheelchair.
- 6. Detach the sling loops from the lift. (See Fig. 13)
- 7. Move the lift away from the resident. Pay attention to the resident's head and the spreader bar.

- 8. Unbuckle the white leg straps.
- 9. Unbuckle the black chest straps.
- 10. Pull the hook and loop patches apart to open the support belt.
- 11. Pull out and remove the support belt from the loops. (See Fig. 14)
- 12. Take off the *Loop walking jacket or Loop walking sling*.



Cleaning and Disinfection

WARNING

To prevent cross-contamination, always follow the disinfection instructions in this *IFU*.

WARNING

To avoid material damage and injury, clean and disinfect according to this *IFU*:

- · No other chemicals are allowed.
- · Never clean with chlorine.
- Chlorine will deteriorate the surface of the material.

WARNING

To avoid injury, always remove the sling before disinfecting the lift.

The *Loop walking jacket* sling should be cleaned when they are soiled or stained and between residents

Cleaning Instruction (4 steps)

- 1. Detach the sling from the lift.
- 2. Close all buckles and hook and loop attachment on the slings and belts prior to washing.

3. Machine wash the *Loop walking jacket (MAA5000)* at 70°C (158°F).

Machine wash the *Loop walking sling (TEM)* at 80°C (176°F).

In order to obtain sufficient level of disinfection, please wash according to local hygiene legislation.

- 4. Do NOT
 - wash with other items that have rough surfaces or sharp objects
 - tumble dry (Loop walking sling (TEM))
 - use any mechanical pressure, pressing or rolling during the washing and drying process
 - · use bleach
 - · use gas sterilization
 - · use autoclave
 - dry clean
 - steam
 - drv clean

Cleaning Chemicals

For all slings use common commercial detergent without optical brightener.

No other chemicals are allowed e.g. chlorine, softener, iodine based disinfectants, bromine and ozone.

Disinfection

The only allowed disinfection is disinfection by washing.

EN

Care and Preventive Maintenance

WARNING

To avoid injury to both resident and caregiver, never modify the equipment or use incompatible parts.

Before and After Every Use

Visually check all exposed parts

The caregiver shall inspect the sling before and after every use. The complete sling should be checked for all deviations listed below. If any of these deviations are visible, replace the sling immediately.

- Fraying
- · Loose stitching
- · Tears
- Holes
- Discolouration or stains from bleaching
- Sling soiled or stained
- Unreadable or damaged label

When Soiled, Stained and Between Residents

Clean/Disinfect

The caregiver should make sure that the sling is cleaned according to "Cleaning and Disinfection" on page 12, when it is soiled or stained and between residents. If the soil or stains are still visible, replace the sling immediately.

Storage

When not in use, the slings should be stored away from direct sunlight where they are not subject to unnecessary stain, stress or pressure, or to excessive heat or humidity. The slings should be kept away from contact with sharp edges, corrosives or other possible things that could cause damage on the sling.

Service and Maintenance

It is recommended that qualified personnel inspect the condition of the sling twice a year (every 6 month), according to ISO 10535.

Troubleshooting

Problem	Action
The resident is not positioned correctly in the sling.	Make sure the loops are attached at the right length. Make sure the straps are not twisted. Make sure the resident is positioned on the inside of the sling. The outside has a label for reference. Make sure the resident is centred in the sling.
The resident feels discomfort in the leg area when seated in the sling.	Make sure that there are no creases on the leg flaps of the sling. Make sure the leg flaps are attached at the right length.
It is difficult to use the sling in combination with the lift.	Use the sling only in accordance with the combinations described in section "Allowed Combinations" on page 8.
The resident feels discomfort in the waist area.	Adjust the support strap, tighten or loosen.
The sling is sliding up under the resident's arms.	 Tighten the support strap for a more comfortable fit. Make sure the sling size is correct. If the problem consists change to a smaller size.
The resident feels discomfort while using the sling.	Adjust the support strap for a more comfortable fit.

Technical Specifications

General	
Safe working load (SWL) = Maximum total load	See "Allowed Combinations" on page 8
Service life - Recommended period of service	2 years* * Refer to "Expected Service Life" on page 3
Shelf life - Maximum storage period of new unpacked product	5 years
Model and Type	See "Sling Selection" on page 8

EN

Operating, Transport and Storage Environment			
	0°C to +40°C (+32°F to +104°F) Operating and Storage -25°C to +60°C (-13°F to +140°F) Transport		
	Max 15–70% at +20°C (68°F) Operating and Storage Max 10–95% at +20°C (68°F) Transport		

End of Life Disposal	
Package	The bag consists of soft plastic, recyclable to local legislations.
Sling	Slings including stiffeners/stabilizers, padding material, any other textiles or polymers or plastic materials etc. should be sorted as combustible waste.

Parts and Accessories	
Measuring tape	MTA1000

Label on the Sling

Care	and Washing Symbols
770	Machine wash 70°C (158°F)
×	No bleaching allowed
	No tumble drying allowed
×	No Ironing allowed
X	No dry cleaning allowed
Time Time	Machine Wash 80°C (176°F)
\odot	Tumble drying allowed

REF XXXXXXX-X	Article number with -X refers to the sling size.
REF XXXXXXX	If the article number is stated without the size letter at the end, it means the sling is a One Size.
Fibre Conten	t
Fibre Conten	t Polyester
	-

Article Number

Turrible dryllig allowed		
Certificates/Markings		
C€	CE marking indicating conformity with European Community harmonised legislation	
MD	Indicates the product is a Medical Device according to EU Medical Device Regulation 2017/745	
UDI	Unique device identifier	
Symbol for Loop		
1.1		

Use a loop spreader bar.

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Misc. Symbols		
n ₅	Safe Working Load (SWL)	
ŕ	Resident's name symbol	
(ir)	Single patient multiple use	
	Record symbol	
[]i	Read the IFU before use	
REF	Article number	
~~	Manufacturing date and year	
<u>l</u>	Manufacturer name and address	
~	Read the <i>IFU</i> before use Article number Manufacturing date and year	

UK Symbol explanation

This section is only applicable to United Kingdom (UK) market when UK marking is applied to the Arjo medical device labelling.



UK marking indicating conformity with UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended)

UK Responsible Person & UK Importer:

Arjo (UK) Ltd, ArjoHuntleigh House, Houghton Regis. LU5 5XF

Is the appointed UK Responsible Person as defined in UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended).

For Northern Ireland (NI) CE marking will still apply until further amendment to applicable regulations.