ASSISTIVE PRODUCT SPECIFICATION FOR PROCUREMENT

Walking Frames

Objective:

The objective of this specification is to help organizations in procuring good quality walking frames that are durable and which assist individuals to move with more stability.

World Health Organization

1. Product description

The purpose of this section is to provide specific key details relevant to the assistive product so that it is easily identifiable.	
Purpose of 1.1	Name of product as per WHO priority APL and/or commonly used names.
1.1 Name of product	Walking frames
Purpose of 1.2	As per ISO 9999 classification and terminology document (refer https://www.iso.org/standard/60547.html).
1.2 ISO 9999 code	12 06 03 *Walking frames* Frames which a person lifts to move, that enable maintenance of stability and balance and support of body weight while walking or standing; with hand grips, without forearm support and with either four tips or two tips and two castors Included are, e.g. rigid or articulated walking frames, assistive products for walking with two castors in combination with two rubber stick buffers/tips.
Purpose of 1.3	Describes the product type in clear, simple, easily understood language and the intended use in addressing functional needs.
1.3 Description and intended use	A device that improves balance and relieve weight bearing either fully or partially on a lower extremity.
Purpose of 1.4	Refers to general characteristics of the assistive product that describes its appearance and components.
1.4 General features	Frame with handgrips on top without forearm support, that has four height adjustable shafts ending in either four tips or two tips and two castors. There are a variety of tips and castors available for different models and terrains.
Purpose of 1.5	Refers to product models that are included in the specific APS.
1.5 Inclusion	• Foldable walking frames • Rigid or articulated walking frames • Walking frames with 4 tips • Walking frames with 2 castors in combination with 2 rubber stick buffers/tips
Purpose of 1.6	Refers to product models that are excluded in the specific APS.
1.6 Exclusion	• Rollators • Reciprocal walking frames
Purpose of 1.7	Important, searchable words that relate to the specific assistive product.
1.7 Keywords	Activity, in/outdoor mobility, mobility products, mobility devices, participation, rehabilitation

2. Product requirements

The purpose of this section is to provide details of all applicable requirements relative to the specific assistive product. A requirement is mandatory and typically describes what a product should be able to do, how it should appear (product and packaging) etc. Only supply and service requirements considered applicable in procurement of walking frames.

2.1 Functional requirements

Purpose of 2.1	A functional requirement refers to technical details and other specific functionality that define what a product variation is supposed to accomplish. Per product variation, the requirement should describe the typical user, specific characteristics of the product (in addition to the general features above) as well as

		the requirements for standard configuration of the product. It is important to focus on performance requirements rather than form factors. It is important to have a clear and specific description of the typical users including e.g. health condition, functional limitation or demographics (range of age, body weight, height, etc). If applicable, specific context of use (e.g. indoor/outdoor, in noisy environment, etc) should be specified in the product variations.		
Item	**Product variations**	**Typical user**	**Specific characteristics**	**Requirements for standard configuration**
1	Rigid or articulated walking frames	Individuals with partial or non-weight bearing in one lower limb or frail individuals struggling with balance or endurance. The person should be able to ambulate with minimal additional support and have the ability to grip, lift and place the frame in front of them in order to use it correctly. Fair grip strength and upper limb mobility required. Acceptable level of cognition required to ambulate independently and operate the walking frame effectively. Non-foldable types are often used in hospital or fixed facility settings.	4 tips	Handgrip and non-slip replaceable rubber tips or ferrules. (The handgrip is the part of the walking frame/walker with is normally held by the hand when the frame is in use.)
2	Foldable walking frames	Individuals with partial or non-weight bearing in one lower limb or frail individuals struggling with balance or endurance (especially those needing to traverse uneven terrain on a daily basis). The person should be able to ambulate with minimal additional support and have the ability to grip, lift and place the frame in front of them in order to use it correctly. Fair grip strength and upper limb mobility required. Acceptable level of cognition required to ambulate independently and operate the walking frame effectively. Foldable designs are best suited to clients who will use public or private transport, or whose houses have limited space for storage.	4 tips	Frame must fold into a flat position with legs together. When in the extended position, the frame must be secure to prevent collapse while walking. Folding/unfolding of the walker must be smooth and easy to operate.

3	Walking frames with 2 castors in combination with 2 rubber stick buffers/tips	Individuals with partial or non-weight bearing in one lower limb or frail individuals struggling with balance or endurance. The person should be able to ambulate with minimal additional support and have the ability to grip, lift and place the frame in front of them in order to use it correctly. Fair grip strength and upper limb mobility required. Acceptable level of cognition required to ambulate independently and operate the walking frame effectively.	2 castors and 2 tips	Castors could enable propulsion in all directions or simply forwards and backwards. Castors can be fitted in different sizes and thicknesses depending on the environmental needs of the user- the potential to do this depends on the design and configuration of the product.
Purpose of 2.2	Brief and clear description of general product performance requirements and overall qualities (e.g. stability, strength, durability, waterproof, etc).			

2.2 General design requirements	Should be height adjustable. The walking frame should be easy to operate, parts being replaceable, strong/durable. Made of durable lightweight metal, usually extruded anodized aluminum. Height adjustable mechanisms should be made of stainless steel. The pin should be made of stainless steel, at least 6mm in diameter and electroplated to prevent corrosion (high strength, low deformation and high abrasion resistance). **Handgrip**: usually made of durable plastic or rubber or foam. Hand grips should be resistant to perspiration and scuffing and which does not stain the hands. The palm section of the hand grip may not include any pronounced lump. **Tips**: non-slip, and replaceable, usually made of durable rubber. Durable rubber shoes should be fitted to each leg. The shoes should be fitted so that they cannot be removed by pulling and twisting. Shoe diameter: 44 mm where it makes contact with the floor. Shoe may taper to approximately 30 mm. The hole in the shoe should be at least 35 mm deep. The floor contact of the shoe should be concave with an anti-slip tread. The end of the tube onto which the shoe is fitted should be plugged. **Shaft**: height adjustable (via clip or push button). Holes should not become enlarged with repeated use or adjustments. Foot pieces and cuff to slide freely over the full extensibility and can easily be disassembled; clearance between sliding parts not to exceed 1mm. **Optimal features**: some are foldable. Some have castors **Frame**: durable, lightweight materials (e.g. extruded, anodized aluminum), upper tube being at least 25.4 x 1.62mm and the lower tube being at least 21.6 x 1.4mm, of quality at least equal to that of type E1B of BS1474. If tubes are anodized aluminum the quality should at least be that of 6063T6, and tubes at least 1,5 mm thick Alternatively, steel tubing can be used of a quality that is at least equal to a grade 45. Foot pieces and cuff to slide freely over the full extensibility and can easily be disassembled; clearance between sliding parts not to exceed 1mm. Frame may be riveted or bolted together. Where components are joined, plastic spacers, fitting snugly to the tube, should ensure a rigid assembly. Nuts should have nylon locking inserts. Bolts may not protrude beyond the nuts. Rivets should have a washer on the clinched side to prevent them pulling loose. There should be no sharp points. **Legs**: Height adjustable via clip or push button. The pin should be made of stainless steel, at least 6mm in diameter and electroplated to prevent corrosion (high strength, low deformation and high abrasion resistance). The two front legs should be splayed forward, width at the base of the front end: +/- 450 mm (minimum). The two back legs should be splayed backward, width at the base of the rear end: +/- 600 mm. Height adjustment on all four legs by means of two spring-loaded pins and matching holes. Spring loaded pins should be at least 8 mm in diameter. Holes must not be countersunk. Pins should protrude at least 2 mm beyond the outside of the outer tube. Height adjustable legs should have an anti-rattle bush at the top of the inner tube. **Handgrip**: usually made of durable plastic or rubber (e.g. injection-molded polypropylene of grade 2340PC).

	Load: The walking frames should withstand a load of minimum 100 kg. Quality of metal is critical for durability, especially with regards to holes for height adjustments. Holes should not become enlarged with repeated use or adjustments.
Purpose of 2.3	Details of existing or in-progress national or international standards should be provided here, whether freely or commercially available.
2.3 Standards	All documentation should be in official language of the country or in English (other languages could also be specified). The test laboratories should be accredited for the methods of the appropriate standard(s) at the time of the testing. A sum of the results from the test laboratories that states the fulfillment of the requirements should always be provided. The sum should be dated and signed and delivered together with the offer. Requirements for testing should include: Quality, durability and strength of materials used for shaft, feet, adjustment pins and ferrules, castors and wheels Typical test progression follows the sequence of stability test, static load test, fatigue test Walking frames should comply with and be tested according to relevant national or international standards. Tests (static loading test is a bare minimum) should be carried out by accredited test laboratories. The deformation of testing items should meet the requirement of standard limited range. Post-market product validation through standardized testing and inspection standards is critical in ensuring uniform quality, and the reliance on document review without post-market product testing should be discouraged. *Current product standards for walking frames:* ISO 11199-1:1999. Walking aids manipulated using both arms ISO 24415-1 Tips for assistive products for walking - Requirements and test methods - Part 1: Friction of tips ISO24415-2: 2011: Tips for assistive products for walking- requirements and test methods- Part 2: durability of tips of crutches (excludes tips manufactured for special purposes such as ice and snow) CNS 15191 (2010)/BS 5181 (1975)/ CPSA 0073 (1996): static loading and junction strength test for wooden walking sticks. CNS 15192 (2010): adjustable metal walking sticks EN 1985 Walking aids - General requirements and test methods or equivalent.
Purpose of 2.4	A certificate of conformity confirms that a product conforms to applicable national and/or international regulations. If a certificate is required for the specific assistive product, this information should be requested, e.g., CE (Europe), COC (Japan), GCC (USA).

2.4 Certificate of conformity	A certificate that the product conforms to applicable national or international regulations and standards should be provided (for example, a declaration of conformity with the medical device directive or the medical device regulation of the European Union). The certificate of conformity is a legal document, should be signed by an authorized person at the supplier, and specify the name and contact information of the supplier and be provided with the tender. The certificate of conformity should be supplied in official language of the country being supplied or in English (other languages can also be specified). If the walking frames do not comply with or are not tested according to relevant national or international standards, the supplier should provide a certificate that the product comply with the requirements in this call for tender. Documents supporting that a walking frame is safe and effective for use by the typical user, including detailed reports of tests performed, should also be provided. If a walking frame does not comply with national or international standards, the supplier is liable for any damages and injuries caused by a product that is used according to its purpose by the typical user as stated above.
Purpose of 2.5	Lists the relevant scope of information required to identify the appropriate size and weight of the assistive product in its standard configuration (specific dimensions may be given if appropriate).
2.5 Size and weight	Information on the dimensions of the walking frame (minimum length and maximum length in cm), the weight of the walking frame, folding mode (folding, telescope) should be provided. Typically adjustable in adult sizes from approximately 81-92 cm, with children's, youth and tall sizes available. • Mass: less than 2 kg
Purpose of 2.6	Lists the relevant scope of information that should be provided to service providers (e.g. how to select, assemble, fit, adapt, follow up, maintain, repair, refurbish the assistive product). The desired language(s) in which the technical information should be provided should be stated.
2.6 Technical information (for service providers)	Information on how to assemble and adapt the walking frame should be provided. Instructions on how to maintain, service, repair and refurbish the walking frame should be provided. The technical information should be provided in the official language of the country being supplied or in English (other languages can also be specified).
Purpose of 2.7	Lists the scope of information, and its format, that should be provided to end-users to show how to safely use the assistive product.
2.7 Instructions for use	A user manual should accompany the walking frame in the appropriate language and format for the country by the supplier including electronic and/or print format. It should provide instructions on how to safely and effectively use the product, and how to maintain and clean it. It is intended for the user and/or caregiver. The user manual should be provided in the dominant language of the country being supplied, and if applicable, in English (other languages can also be specified). The objective should be to ensure safe use of the walking frame.
Purpose of 2.8	Refers to the various weather and other environmental conditions, e.g., temperatures, humidity, rain, snow, sunshine, that the assistive product should be able to withstand.

2.8 Environment of use	The walking frames should be capable to manage sand, mud, rocky terrain, rain, snow, ice, sleet- this will affect the materials used in the shaft, as well as the technical specifications, quality and type of ferrules, castors and wheels available for the product. The walking frames should be capable to withstand temperatures from +50 to -30 Celsius and relative humidity from 15 - 90%. A variety of ferrules, castors and wheels that fit the specific shafts procured should be made available, suitable to the specific environmental needs of each country.
Purpose of 2.9	Refers to the duration of the warranty period and the details of the warranty the manufacturer/supplier should provide within the specified period.
2.9 Warranty	Provided normal heedful use, the supplier should, during the warranty period and without extra expenses, repair parts which break for the products delivered. This comprises all spare parts and labour, except for normal wear and tear of the product. The warranty period should be at least 2 years after delivery of the walking frames. The same should apply for spare parts and accessories. In low resource and rural areas, 'normal use' may not match the manufacturers definition, due to environmental demands to be placed on the device daily. The supplier should cover all transport when repairing the walking frames under warranty and a replacement walking frame should be provided to the user whilst repairs are being done, at no additional cost to the user. Following a verbal or written complaint, the supplier should repair or replace the product within 30 working days.
Purpose of 2.10	Refers to the expected duration, in years, of the assistive product. Documents describing how this is ensured must be provided.
2.10 Lifespan	Given the purpose of use by typical users, the walking frame should be designed for a lifetime of at least 5 years. Care should be taken as in low resource and rural areas, 'normal use' may not match the manufacturers definition, due to environmental demands to be placed on the device daily. Documents describing how this is ensured should be provided.
Purpose of 2.11	Lists the scope of information required in packaging and labeling the assistive product. Explains the state of assembly the assistive product should be in when received by the end-user.
2.11 Packaging, labelling, and state of assembly	Walking frames can be delivered in bulk in boxes, with a label clearly stating details of the product. Individual plastic wrapping of each walking frame within a box is not necessary. The package should withstand handling during transport. The walking frame should be delivered fully assembled or assembled to such an extent that the remaining assembly can be carried out with the use of commonly available screwdrivers or wrenches.
Purpose of 2.12	Refers to additional product requirements, depending on the specific assistive product, e.g., material, corrosion-resistance, adjustability, foldability, etc.
2.12 Other product requirements	The supplier should provide the following information about walking frames: • Permitted cleaning methods • Whether it is a set cost per annum over 5 years or whether there are price adjustment negotiations required per annum • Whether they are willing to allow a few samples to be issued to representative end users to product test for 6 months to assess durability and appropriate design for the specific environments and end user requirements of that specific country's context

3. Supply and service requirements

From the information provided below, only those supply and service requirements considered applicable may be used in a procurement bid.

The purpose of this section is to describe key supply and service requirements that are needed in order to ensure that the assistive product is received in due time, operational, being maintained/repaired and refurbished.	
Purpose of 3.1	Lists the scope of information to be requested on how the assistive product will be transported to the place of delivery.
3.1 Transportation	Information on how the walking frames will be transported should be provided and who should pay for the transportation. Package and transport should take place so that damage to the walking frames, accessories and spare parts is avoided.
Purpose of 3.2	Specifies the time between placing an order and receiving delivery of the assistive product (e.g. that it should not exceed 30 calendar days).
3.2 Delivery time	The time between placing an order of up to 100 walking frames and receiving delivery of them should not exceed 30 working days.
Purpose of 3.3	Refers to the specific details of the various accessories and spare parts available for the assistive product, including pricing and availability.
3.3 Accessories and spare parts	The supplier should offer the following spares: • Ferrules • Castors or wheels • Handgrips All parts that the walking frames consists of, and which may be replaced at some stage, should be offered as spare parts and available as close to the end user as possible to reduce travel costs and improve accessibility to end users and their families. The supplier should state which variations of walking frames the accessories and spare parts are meant for. When an accessory consists of one part, the same part should not be offered both as an accessory and a spare part, but only as an accessory. When an accessory consists of several parts that can be replaced, all replaceable parts should be offered as spare parts. Spare parts should be made available for a period of at least 5 years after the last order of a walking frames. The price of the spare parts should be offered per part and not per set or pair.
Purpose of 3.4	Provides information regarding required maintenance services the supplier will provide, including the timeframe and frequency.
3.4 Maintenance	Information about payment per hour, including definitions of when a job starts and finishes; travel expenses, from – to, fee per km, rules when several repair jobs are done on the same route; hotel bills; who should provide the spare parts; in cases the job is done by a sub-supplier, the invoice should be sent by the supplier with the contract. The prices should be according to the contract. (More information may be requested to be provided.)
Purpose of 3.5	Provides information regarding required repairment services the supplier will provide, including the timeframe and frequency.
3.5 Repair	Information about payment per hour, including definitions of when a job starts and finishes; travel expenses, from – to, fee per km, rules when several repair jobs are done on the same route; hotel bills; who should provide the spare parts; in cases the job is done by a sub-supplier, the invoice should be sent by the supplier with the contract. The prices should be according to the contract. (More information may be requested to be provided.)
Purpose of 3.6	Provides information regarding required refurbishment services the supplier will provide, including the timeframe and frequency.

3.6 Refurbishing	Information about payment per hour, including definitions of when a job starts and finishes; travel expenses, from – to, fee per km, rules when several repair jobs are done on the same route; hotel bills; who should provide the spare parts; in cases the job is done by a sub-supplier, the invoice should be sent by the supplier with the contract. The prices should be according to the contract. (More information may be requested to be provided.)
Purpose of 3.7	Specifies if training service providers is required by suppliers, and the key elements included in the training (e.g. selection, assembly, fit, maintenance and repair of the assistive product). Refers to detailed training contents or materials, if available and applicable.
3.7 Training of service providers	Information about assessing, selecting, assembling, adapting, fitting, maintaining, and repairing the walking frame should be provided to the service provider.
Purpose of 3.8	Specifies if training users is required by suppliers, and the key elements included in the training (e.g. training to users should include fit, use, maintenance and cleaning of the assistive product). Refers to detailed training contents or materials, if available and applicable.
3.8 Training of users	Information about adapting, using, storing, and maintaining the walking frame should be provided to the end-user.
Purpose of 3.9	Provides information regarding other supply and service requirements.
3.9 Other supply and service requirements	<u>Decommissioning</u> This should be done if there is any visible sign of damage to the frame (such as bending or excessive corrosion). Aluminum is recyclable, and a contract can be signed with local recycling companies to remove the decommissioned items. The manufacturer should indicate the average lifespan of the product in years, with normal use. However, care should be taken as in low- and middle-income countries, 'normal use' may not match the manufacturers definition, due to environmental demands to be placed on the device daily. Thus, it is critical that samples are issued to selected end users to trial in the field over a period of at least 6 months prior to awarding a tender, so that wear and tear in the contextual environment can be ascertained.