ASSISTIVE PRODUCT SPECIFICATION FOR PROCUREMENT

Crutches

Objective:

The objective of this specification is to help organizations in procuring good quality crutches that are durable and which assist the individuals with mobility impairments in walking and standing

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	Crutches (elbow, axilla, forearm crutches)
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 03 06 *Elbow crutches* Hand-held devices providing support and balance when walking, comprising elbow support, shaft, handgrip and tip(s) 12 03 09 *Forearm crutches* Hand-held devices providing support and balance when walking, comprising horizontal support for the forearm, hand grip, shaft and one tip 12 03 12 *Axillary crutches* Hand-held devices providing support and balance when walking, comprising axilla support, shaft, handgrip and tip(s)
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 cane with underarm or forearm support that ends in a single shaft and ferrule tip. Elbow, axilla and gutter crutches all have a single shaft that which ends with a non-slip tip (ferrule). Crutches are used singularly or as a pair to enable the person to partial or non-weight bear on an affected lower limb(s) or with calipers.
Purpose of 1.4	Refers to general characteristics of the assistive product that describes its appearance and components.
1.4 General features	Straight or offset handle with ergonomically shaped hand grip. Telescopic height adjustable shaft ending in a single tip. Tip fitted with a single ferrule. Variety of ferrules available for different models and terrains. • Elbow crutches are aluminum with a closed or semi-circle cuff around the forearm, an ergonomically molded handle and the shaft is telescopic adjustable for height. • Axilla crutches can be wooden or aluminum, have a plastic covered handle and a cushioned horizontal bar which fits under the axilla. Leg and arm sections adjust independently for optimum sizing. • Forearm crutches have a molded plastic, padded forearm gutter with adjustable Velcro straps and a molded plastic handle, attached to a single telescopic height adjustable aluminum shaft with a single rubber ferrule tip.
Purpose of 1.5	Refers to product models that are included in the specific APS.
1.5 Inclusion	Wooden or metal elbow, axilla and forearm crutches
Purpose of 1.6	Refers to product models that are excluded in the specific APS.
1.6 Exclusion	iWALK
Purpose of 1.7	Important, searchable words that relate to the specific assistive product.

1.7 Keywords	Activity, in/out door mobility including unpaved roads and rural terrain, 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 crutches.

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	Elbow crutch	Generally for longer term use, non-weight bearing or partial weight bearing single lower limb, functional upper limbs	Adjustable for height. Height is the full length of elbow crutch. Max weight 100kg for pediatric sizes and 180kg for adult sizes Maximum weight of crutch 0.6-1kg depending on crutch size Models: • Height between forearm and cuff adjustable in addition to shaft. • Shaft height adjustability only. • Forearm cuff, handle and shaft continuous • Forearm cuff closed or semi-circle Sizes: Tall adult Adult Teenager	Made of durable lightweight metal (e.g. aluminum). The shaft (usually aluminum) should be in two parts, telescopic in nature, and height adjusting mechanisms should be made of stainless steel (high strength, low deformation, high abrasion resistance). Closed or semi-circle cuff around the forearm. Height between forearm cuff and handle can be adjustable (optional) Handgrip: usually made of durable plastic or rubber with pistol type handgrips. Ergonomically molded handle. Handle should be covered with a durable material (e.g. Nylon 6/6) which has good abrasion and hydrocarbon resistance. Shaft: height adjustable (via clip or push button- the pin should be made of stainless steel (high strength, low deformation and high abrasion resistance) Tips: non-slip, and replaceable/ interchangeable, usually made of durable rubber. Variety of types available for different environmental contexts. The ferrules should adhere to ISO standards and should fit the shaft of the crutch procured.

			Pediatric 4-10yr	
2	Axilla crutch	Generally for shorter term use, non- or partial-weight bearing one lower limb or bilateral swing-through gait required, also beneficial when a client lacks sufficient upper limb/scapular strength for safe use of elbow crutches	Adjustable for height. Materials used: Wooden Plastic Metal Sizes: Tall adult Adult Pediatric 4-10yr Maximum weight of crutch 1.6 – 2.0kg depending crutch size and materials used	Made of wood or aluminum. For wooden axilla crutches, high strength laminated timber is required. High density rubber horizontal bar, cushioned, fitting under the axilla Handgrip: high density rubber/ plastic covered handle, pistol grip or rounded. Leg and arm sections adjust independently for optimum sizing-both floor to handgrip height and the distance between the handgrip and the axilla pad is adjustable. Tips: non-slip, and replaceable/ interchangeable, usually made of durable rubber, meets ISO standards. Available in small, medium or large sizes
3	Forearm crutch	Short term use, non-weight bearing or partial weight bearing single lower limb, also has an affected forearm(s) or grip strength necessitating a different model of crutch	Adjustable for height. Telescopic handle rotates through 360 degrees. Height from handle to ground is 960 – 1130 mm Max body weight: 100kg Weight around 1kg	Made of durable lightweight metal (e.g. extruded anodised aluminum); upper tube- 25.4 x 1.62 mm (6063T6); lower tube -21.6 x 1.4 mm (6063T6). Bidder shall supply document/certificate from supplier along with samples for testing, to certify type of aluminum alloy and strength used. The aluminum shaft should be in two parts, telescopic in nature. Molded plastic and vinyl padded forearm with hook and loop velcro Handle: Adjustable, ergonomically designed, firmly connected to the main frame, immovable, injection-moulded grey plasticised PVC Height & forearm adjustable height via stainless steel pin locking mechanism- single or double spring-loaded pins (spring clips) on each foot piece. Foot pieces shall slide freely over the full extensibility. Maximum clearance between sliding parts shall be 1 mm.

				Spring clips: Double pin type, at least 6 mm in diameter, electroplated to prevent corrosion Optional: Adjustable telescopic handle rotates through 360 degrees and locks to suit individual forearm length. Non-Slip Crutch Rubbers, Grey injection moulded, plasticised PVC; non-marking, non-slip with steel or plastic insert, removable and replaceable.
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	Easy to operate, replaceable parts, strong/durable. Minimum length handle to floor: 57cm (to fit a person of 110cm tall), and maximum length: 104cm (to fit a person of 200cm tall)- Crutches suitable for adults as well as children and persons of shorter stature, delivered to the local community.			
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 the dominant local language for the country procuring and English (other languages could be specified too). **Current product standards for crutches:** The handle and shaft should be made of durable lightweight metal, usually aluminum (quality of metal critical for durability- especially with regards to holes for height adjustment- these should not become enlarged with repeated use or adjustments) Shaft: height adjustable (via clip or push button) usually of anodized aluminum. Spring clips: Double pin type, at least 6 mm in diameter, electroplated to prevent corrosion (the pin should be made of stainless steel (high strength, low deformation and high abrasion. resistance) Handgrip: usually made of durable plastic or rubber with different shaped handgrips. Ergonomically designed, firmly connected to the main frame, immovable, injection-moulded grey polypropylene, grade 2340PC Grip compound: Shore 20A hardness thermo plastic Ergonomically molded handle. The stability of handle on shaft is critical for safety and durability, and should not come loose with wear and tear. Handles should be covered with a durable material such as Nylon 6/6 which has good abrasion and hydrocarbon resistance Cuff: injection moulded polypropylene, grade 2340P, hinged to allow 90º movement in the vertical plane with no movement in the horizontal plane Tips: non-slip, and replaceable/ interchangeable, usually made of durable rubber. Variety of types available for different environmental contexts. The ferrules should adhere to ISO standards, should fit the shaft of the crutch(es) procured and distribution should preferably be decentralized to improve access to replacements at minimal cost to end user. Must meet ISO 24415-1:2009 and 24415-2: 2011 Tips for assistive products for walking- requirements and test methods Part 1: friction of tips and part 2: durability of tips. Injection-moulded, plasticised PVC, non-marking, non-slip with steel or plastic insert, removable and replaceable **Material standards for tubing:** Aluminum tubing shall be of quality at least equal to that of Type E1B of BS 1474. This is usually extruded anodised aluminum, and the upper tube 25.4 x1.62 (6063T6); lower tube - 21.6 x 1.4 mm (6063T6). Aluminum shafts can also be covered with a phosphate coating and two layers if baking enamel that comply with national or international standards. Alternatively, they can be chromium plated. Steel tubing shall be of a grade of 45 Class D2T2 of SABS 647. The tubes shall be finished with a zinc chromate primer and two coats or baking enamel that complies with local or international standards. Chromium plated and galvanized steel can also be utilized, if it complies with local or international standards. *A Vernier caliper can be used to measure thickness of aluminum tube walls. If product feedback indicates poor durability, then specify thicker tubing for the next round of tendering.*

	Axilla and metal elbow supports shall be of steel or aluminum plate of acceptable quality. **Specific tests:** ISO 11334-1:2007 specifies requirements and test methods for elbow crutches fully equipped with handgrip and tip. The methods specify testing of separation, static load capacity, fatigue and resistance to low temperature embrittlement. ISO 11334-1:2007 also gives the requirements relating to safety, ergonomics, performance, and information to be supplied by the manufacturer, including marking and labelling. Basically: The handle and shaft should be subjected to a compressive maximum load test, with the crutch adjusted to maximum height and supported in the upright position. In axilla and elbow crutches, a minimum of 1.1kN is applied thorugh the handle. Thereafter in elbow crutches, 2000N±2% is applied through the shaft at the highest point of the upright crutch. In axilla crutches, 1.1kN is applied through the vertical at a central point on the axilla cushion. Upon testing, the maximum deflection shall not exceed 40mm, it shall not break or become deformed, the adjustments shall not slip and play at any point shall be considered unacceptable. Axilla support cushions in axilla crutches should be subjected to both compression and strength and fixing tests. Compression tests are achieved through fixing a 5kg cylinder to three points on the axilla cushion and measuring the maximum compression as an expression of the original thickness. Compression shall not exceed 65%. For strength and fixing test, the sides of the axilla cushion are gripped by two plates (75mm x 15mm x 1.6mm) and the crutch inverted. A 2.5kg weight is then suspended from the plates and the cover material shall show no sign of tearing, nor shall the cushion become attached at any point. The test is repeated at two other points on the cushion. Finally, elbow crutches should be subjected to a slip and marking test. The crutch is adjusted to maximum height and supported loosely in the upright position on a linoleum floor. Suspend a mass of 22kg from the handle and allow the crutch to lean forward 15 degrees from the vertical in the direction of the load. The crutch shall not slip and the floor shall not be marked.
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 and should be signed by an authorized person at the supplier. If crutches 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 crutch is safe and effective for use by the typical user, including detailed reports of tests performed, should also be provided. If a crutch 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. The certificate should specify the product, all applied standards, if any, and the name and contact information of the supplier and be provided with the tender. The certificate of conformity is a legal document and should be signed by an authorized person at the supplier. The certificate of conformity should be in the dominant national language of the country being supplied and in English (other languages could be specified too).
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

Elbow crutches: *(*rough guide)*

Size	Child, 4-7 yrs	Child, 6-10 yrs	Youth	
Overall Length (mm)	550-750	645-920	760-1090	905-12
Handle Height (mm)	380-530	465-690	560-815	685-94
Arm Pad to Hand Grip (mm)	170-220	180-230	200-275	220-29
Max User Weight (kg)	100kg			
Unit Weight (kg)	1kg	1kg	1.2kg	1.2kg

Axilla crutches * (*rough guide*)

Size	Youth	Adult
Overall Length (mm)	960-1160 aluminum	1145-1345 aluminum 1090-1290 timber
Handle Height (mm)	740-790 aluminum	795-845 aluminum 730-780 timber
Arm Pad to Hand Grip (mm)	220-370 aluminum	350-500 aluminum 360-510 timber
User Height (mm)	1370-1575mm aluminum	1565-1775mm aluminum 1520-1720 timber
Max User Weight (kg)	200kg for aluminum 100kg for timber	200kg for aluminum 100kg for timber
Unit Weight (kg)	1.6kg aluminum	2kg aluminum 1.8kg timber

Gutter crutches *(rough guide)

Size	Pediatric	
Handle to gutter (tip to tip)	450-325mm	380-22
Full length of vertical shaft	705mm	535mn
Full length telescopic inner pole	470mm	430mn
Proximal end telescopic inner pole to adjustment pin	30mm	30mm
Maximum adjusted height vertical shaft and t elescopic inner	1140-915mm	940-72
Mass	Shall not exceed 1kg	Shall n

Information about the overall width, height, length and weight of crutches must always be provided. If applicable, dimensions in operating and folded modes must be provided.

Minimum and maximum heights of the handles and width between handles must be provided.

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 crutches should be provided. Instructions on how to maintain, service, repair and refurbish the crutches should be provided. The technical information should be provided in the dominant national language of the country being supplied and 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 short user manual should accompany the crutches in the appropriate language and format for the country. 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 person and/or care-giver. The objective should be to ensure safe use of the crutches. • Generally, for axilla and elbow crutches, to measure for the correct height, the elbow should be bent at 15-30 degrees when standing straight and holding the walking stick in one hand, while the handgrip should at the wrist level.
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 crutches 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 available for the product. The crutches should be capable to withstand temperatures from +50 to -30 degrees Celsius and relative humidity from 15 - 90%. A variety of ferrules 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 on 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 crutch(es). The same should apply for spare parts and accessories. When awarding a tender, end users should be enlisted to trial products for a period of minimum 6 months. Review of wear and tear on the different products in that environment should be done, prior to awarding the tender. The supplier should cover all transport when repairing the crutch(es) under warranty and a replacement crutches should be provided to the person whilst repairs are being done, at no additional cost to the person. Following a written complaint, the supplier should repair or replace the product within 10 working days and no more than 30 working days or other specified. There should be a stipulated turnaround time for items under warranty.
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 crutches 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	Package and transport should take place so that damage to the crutches, accessories and spare parts is avoided. However, this should not be at the expense of the environment and it is not necessary to wrap each crutch in plastic. A secure cardboard/wooden box with a bulk purchase is acceptable. Where possible, local manufacturers should be sought. The package should withstand handling during transport. The forearm crutches 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. If any special tool is required, it should be included with the delivery.
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	Not applicable in this tender.

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 crutches will be transported should be provided and who should pay for the transportation. Package and transport should take place so that damage to the crutches, accessories and spare parts are avoided. It is not necessary to wrap each crutch in plastic. A secure cardboard/wooden box with a bulk purchase is acceptable. Where possible, local manufacturers should be sought.
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 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 accessories and spares: All parts that the crutches consist 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 crutches 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 crutch. The price of the spare parts should be offered per part and not per set or pair. Spares specific to crutches: Ferrules: Ferrules provide traction and support when the crutch is used at an angle. A variety of ferrules exist for different terrains and user requirements. These includes ridged rubber stopper, robust ferrules and ice ferrules amongst others. Elbow crutch: Accessories: Neoprene hand protectors Cuff protectors Sherpa Ferrule: flexible neck and suction base. The flexible neck is designed to allow the smooth base of the ferrule to remain in full contact with the ground despite changes with the ground angle. Spares: Standard rubber ferrule Axilla crutch: Accessories: Slip-Knot Ferrule: The two-piece ferrule features a metal ball and socket joint that allows the ferrule's studded base to be in contact with the ground at all times. Sherpa Ferrule: flexible neck and suction base. The flexible neck is designed to allow the smooth base of the ferrule to remain in full contact with the ground despite changes with the ground angle. Spares: Crutch arm pads, standard Crutch 3/16 bolt set, including bolt, nut and washer 66 and 145mm- or dependent on model) Standard rubber ferrule
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.) There should be a loan set of crutches of the same type and size from the company whilst the original device is being repaired, if repairs are such that this is required.
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.) It is highly recommended in low resource settings, to ensure returns of crutches once recovery has occurred. Returned crutches can be refurbished by the base institution and reissued, provided no structural damage has occurred.
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 selecting, assembling, adapting, fitting and maintaining crutches should be provided to the service provider, so that service providers are able to teach the end-user how to use crutches safely and follow-up.
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 and maintaining the crutch(es) should be provided to the end-user. Minimum training for the person should include: how to walk with crutches (gait scheme depending on problem and weight bearing), how to sit, stand, going up and down stairs. Training should also include how to adjust crutches, as well as basic maintenance and repairs instructions (e.g. how to 'open up' the telescopic feature monthly and shake the dirt out, especially in sandy areas). General safety tips should be given to end-user such as: how to check that the adjustment buttons are fully protruding, after having adjusted the length, how to ensure the ferrule is secure and not worn, how to assess the handle and forearm cuff for stability on the shaft, and how to check the whole crutch before every use to ensure shaft is not bent or with cracks.
Purpose of 3.9	Provides information regarding other supply and service requirements.

3.9 Other supply and service requirements	In the tender, the supplier should provide the following information about the crutches: • Permitted cleaning methods • Operating instructions, including adjustability • Accessories and spare parts: compatibility, delivery time, cost, delivery points • Whether it is a set cost per annum over 5 years or whether there are price adjustment negotiations required per annum <u>Decommissioning</u> This should be done if there are any visible signs of damage to the shaft (such as bending or excessive corrosion) or a loose handle. Aluminum is recyclable, and a contract can be signed with local recycling companies to remove the decommissioned items.