ASSISTIVE PRODUCT SPECIFICATION FOR PROCUREMENT

Speech Generating Devices

Objective:

The objective of this specification is to help organizations in procuring good quality speech generating devices that are durable and which assist the individuals with impairment or difficulty in communication.

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	Speech Generating Devices
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	22 21 09 *Dialogue units* Electronic devices that enable direct communication Included are, e.g. portable and non-portable digital electronic displays, paper, recorded and synthetic speech output equipment.
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	An electronic device whose central purpose is to generate speech. Enables the user to generate speech output to convey a message to another person.
Purpose of 1.4	Refers to general characteristics of the assistive product that describes its appearance and components.
1.4 General features	A hardware includes several electronic components for storing and using digitized speech (i.e., recordings and retrievals of voice messages for use) and/or synthesized speech (i.e., speech that is generated synthetically by the device through activation of letters/words/symbols to access the words and sentences). It usually has a hard and protective casing (usually metal or plastic), varies in size and weight. It usually contains the following components: speaker (for voice output) and microphone (for digital voice recording); camera (for digital capture of images for use in the device); power switch; battery power light; source of power / stored power; screen (e.g. with LED backlight) for the user to see the letters/pictures selected for the message generated, prior to its being spoken; screen for the communication partner to see the letters/pictures selected for the message generated; volume control; LED light indicators (e.g. color, solid/blinking), a touch panel; ports (e.g. for USB, for switch) The following features are usually included in general: settings for programming (e.g, to set privacy controls, language, security questions, number of pictures on a grid); memory for storage of messages for later retrieval of a history feature for message retrieval; methods to delete, clear, wipe messages from the history or memory; user control to switch off automatic storage of messages. May have a range of additional features that enable access to other computer systems (e.g., for computer access, environmental control, access to the Internet and social media).
Purpose of 1.5	Refers to product models that are included in the specific APS.
1.5 Inclusion	Augmentative and Alternative Communication; AAC Voice output communication aid, VOCA
Purpose of 1.6	Refers to product models that are excluded in the specific APS.

1.6 Exclusion	Non-electronic devices
Purpose of 1.7	Important, searchable words that relate to the specific assistive product.
1.7 Keywords	Augmentative and Alternative Communication; AAC; Speech Generating Device, speech output, voice output communication aid, VOCA, communication aid, communication device

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 speech generating devices.

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	Speech generating device	Person with complex communication needs, including speaking	A device designed primarily for the purposes of being a communication aid that permits speech generation (voice output).	Can be mounted securely on a wheelchair tray or other mounting system to protect the device during use and to enable the user access.

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	Device is made of materials that are safe for children and adults to touch and hold. Durable and portable. Technique to increase the rate of communication, such as coding and prediction. Speech recognition (for hoarseness), which converts the voice information of the other party into text presentation.
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	Comply with national and international standards for production in the country it is produced. All documentation should be in English for translation to the language of the country in which the product is made available.
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 conform with 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). If the product does not conform with applicable national or international regulations and standards, the supplier should provide a certificate that the product complies with the requirements in this call for tender and is safe and effective for use by the typical user. 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 supplied in English and main local language.
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 about the overall dimension and weight of the device 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 about the device and its accessories should be provided. Information of maintenance, clean, and repair should be included. should specify how to use the item. Information for intended use should be provided. Information should be provided in print or electronic format. All information should be provided in English and in the main local language.
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 with instructions for use of the device should be provided by the supplier. It should provide instructions on how to safely and effectively use the product, and how to maintain and clean it. It is intended use for the user and/or care-giver. The user manual may be provided in print or electronic format. The user manual should be provided in English and in the main local language.
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 device should be designed to be used in wet and/or dry environments. They should also withstand ambient temperatures from -30 to +50 degrees Celsius and relative humidity ranging from 15% to 100%. Information about usage outside should be provided (e.g. glare on screens and visibility in sun or shade).
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	The warranty period should be in keeping with the Consumer Law of the country, after delivery of the devices. The same should apply for spare parts and accessories. The supplier should cover all transport and travel expenses when repairing the devices. Following a written complaint, the supplier should repair or replace the product within the period outlined by the Consumer Law of the country.
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 Speech Generating Device should be designed for a lifetime of at least 1 -5 years. 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	Each device should be delivered in a package with a label clearly stating details of the product. All necessary parts should be included in the package. The package should withstand handling during transport. The device 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 tools. 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	Maximum load information should be provided if secondary service agreements are provided through other companies. Suppliers should give public notice of obsolescence of device. A means for the user to provide feedback to the supplier should be provided.

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 device will be transported must be provided and who should pay for the transportation.
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 rollators and receiving delivery of them must not exceed 30 calendar 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	Accessories that enhance instrument control, such as switches, joysticks, cursors, etc. should be provided. The supplier should offer the above accessories at least 5 years after the last order of the devices.
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 maintenance 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 refurbishing jobs are done on the same route; hotel bills; 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 workshop on assembling, fitting and maintaining the devices.
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 payment per hour, including definitions of when a job starts and finishes; travel expenses, from – to, fee per km, rules when several training sessions are done on the same route; hotel bills; 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 3.9	Provides information regarding other supply and service requirements.
3.9 Other supply and service requirements	Information about payment per hour, including definitions of when a job starts and finishes; travel expenses, from – to, fee per km, rules when several supply or service jobs are done on the same route; hotel bills; 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.)