



ASSISTIVE PRODUCT SPECIFICATION FOR PROCUREMENT

Personal wireless remote microphone
systems

Objective:

The objective of this specification is to help organizations in procuring good quality personal wireless remote microphone systems that are durable and which assist individuals with hearing loss overcome the negative effects of talker distance, ambient noise, and reverberation.

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	Personal Wireless Remote Microphone Systems
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	<p>22 18 24 <i>Radio frequency transmission systems</i> Devices for receiving or transmitting high-frequency modulated electromagnetic waves. Included are, e.g. systems, transmitters and receivers for local one-way communication.</p> <p>A part of the following category: 22 18 <i>Assistive products that record, play and display audio and visual information</i> Devices that record or deliver information in audio or visual formats and products that combine any of those functions. Included are, e.g. audio and video equipment, televisions, sound transmission systems, products that process audio or visual information to enhance its quality and usefulness, such as filtering noises or converting analog to digital information.</p>
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 personal wireless remote microphone system consists of a microphone transmitter and receiver(s), designed to improve the signal-to-noise ratio (SNR) for individuals with hearing difficulties to overcome the negative effects of talker distance, ambient noise, and reverberation.
Purpose of 1.4	Refers to general characteristics of the assistive product that describes its appearance and components.
1.4 General features	A system consists of a wireless transmitting microphone and personal receiver(s) worn by the listener. Systems that operate on FM must comply with regional allocations of frequency bands. Systems that operate on DM should be within the 2.4 GHz ISM band or Bluetooth.
Purpose of 1.5	Refers to product models that are included in the specific APS.
1.5 Inclusion	<ul style="list-style-type: none"> • Robust radio transmitter with either built-in or external microphone that transmit either by digital modulation (DM) or frequency modulation (FM). • Rechargeable battery-operated radio transmitter. • Receivers that allow for direct audio input (DAI) or induction loop (T-coil) applications for compatible hearing aids and cochlear implants.
Purpose of 1.6	Refers to product models that are excluded in the specific APS.
1.6 Exclusion	<ul style="list-style-type: none"> • Hard wired microphone/receiver systems • AM, short wave radio and infrared based systems
Purpose of 1.7	Important, searchable words that relate to the specific assistive product.

1.7 Keywords	Personal wireless system, digital modulation (DM), frequency modulation (FM), signal-to-noise ratio (SNR), ambient noise, reverberation, talker distance
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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 personal wireless remote microphone systems.

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	FM transmitter	Children and adults with compatible hearing aids and cochlear implants.	FM radio transmission	Internal or external microphone that allows placement near the talker's mouth.
2	FM direct audio input (DAI) receiver	Children and adults with compatible hearing aids and cochlear implants	Compatible with the FM transmitter frequency	Universal designed application or design integrated receivers for specific hearing aids and cochlear implants.
3	FM induction (T-coil) receiver	Children and adults with compatible hearing aids and cochlear implants	Compatible with the FM transmitter frequency	Loop design to be worn around the neck of the user with breakaway capabilities to prevent injury.
4	DM transmitter	Children and adults with compatible hearing aids and cochlear implants	Transmission using 2.5 GHz or Bluetooth	Internal or external microphone that allows placement near the talker's mouth.
5	DM DAI receiver	Children and adults with compatible hearing aids and cochlear implants	Compatible with the DM transmitter	Universal designed application or design integrated receivers for specific hearing aids and cochlear implants.

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6	DM induction (T-coil) receiver	Children and adults with compatible hearing aids and cochlear implants	Compatible with the DM transmitter	Loop design to be worn around the neck of the user with breakaway capabilities to prevent injury.
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		The system should be light in weight so that they are wearable and user-friendly. They should be robust enough to be appropriate for use by individuals of all ages.		
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		<p>Current product standards for wireless communication technologies for potential hazardous effects associated with electromagnetic (non-ionizing) radiation interaction with human tissue.</p> <p>IEC 62209-2 Ed. 1.0: Human exposure to radio frequency fields from hand-held and body-mounted wireless communications devices – Human models, instrumentation and procedures – Part 2: Procedure to determine the specific absorption rate (SAR) for wireless communication devices used in close proximity to the human body (frequency range of 30 MHz to 6 GHz)</p> <p>Electromagnetic compatibility (EMC) and electrical safety assessments are mandatory for all electronic equipment including medical devices; IEC 60601-1: Medical electrical equipment – General requirements for basic safety and essential performance.</p> <p>Only FM transmitters that provide regionally authorized FM frequency bands for personal FM transmitters should be considered.</p> <p>DM transmitters should be based on 2.5 GHz (ISM band: Industry, Science and Medical) and be in compliance with current standards; EN 300 328: Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques.</p>		
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).		

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2.4 Certificate of conformity	<p>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).</p> <p>If the product does not conform with applicable national or international regulations and standards, the supplier should provide a certificate that the product comply with the requirements in this call for tender and is safe and effective for use by the typical user.</p> <p>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.</p> <p>The certificate of conformity should be supplied in the official language or in English (other languages could be specified too).</p>
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	Size and weight are not fixed but the personal wireless remote microphone's transmitter and receiver(s) dimensions and weight should be indicated and in a range such that the wearer's comfort is assured.
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)	<p>Information on how to select, assemble, and adapt the personal wireless remote microphone system should be provided.</p> <p>Instructions on how to maintain, service, repair and refurbish the personal wireless remote microphone system should be provided.</p> <p>The technical information should be provided in the official language(s) of the tendering jurisdiction and/or in English.</p>
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.

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2.7 Instructions for use	<p>A user manual with instructions for use of the personal wireless remote microphone system should be provided by the supplier. Instructions on how to safely and effectively use the product, and how to maintain and clean it should be included. The user manual is intended for the user and/or caregiver.</p> <p>The user manual should be supported by simple diagram/picture material, and the contents written at an appropriate reader comprehension level</p> <p>Maintenance and care advice should include information appropriate to the local community, such as dehumidification strategies (WHO, 2017).</p> <p>The user manual should be provided in print format (WHO, 2017) and preferably also be available online.</p> <p>The user manual should be provided in the language(s) spoken by the intended wearer group (WHO, 2017).</p>
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	Personal wireless remote microphone systems should be able to function in ambient temperatures from +45 to -20 degrees Celsius and relative humidity ranging from 0% to 80% (WHO, 2004).
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	<p>Provided normal heedful use, the supplier should, during the warranty period and without extra expenses, repair parts which break during product delivery. This warranty comprises all spare parts and labour, except for normal wear and tear of the product.</p> <p>The warranty period should be specified. The warranty should be a minimum of 1 year. The same should apply for any couplings, spare parts and/or accessories.</p> <p>The supplier should cover all transport and travel expenses when repairing the transmitters and receivers.</p> <p>Following a reasonable written complaint, the supplier should repair or replace the product within 30 working days.</p>
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 device wearers, the personal wireless remote microphone system should be designed for a lifetime of at least 5 years.
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.

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2.11 Packaging, labelling, and state of assembly	Each transmitter and receiver should be permanently marked with the name of the manufacturer or distributor, the model name, serial number and year of manufacture. The packaging should withstand handling during transport (2017). The personal wireless remote microphone system 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 equipment. 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	In the tender, the supplier should provide the following information about the system: <ul style="list-style-type: none"> • Battery life for typical user. • Cautionary statements regarding product safety (e.g., storage out of reach of small children and animals; proper handling/disposal of rechargeable batteries).

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/repared 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 personal wireless remote microphone system will be transported and who should pay for the transportation should be provided.
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 50 personal wireless remote microphone systems 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.

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3.3 Accessories and spare parts	<p>The supplier should offer the following accessories:</p> <ul style="list-style-type: none"> • Transmitter and receiver(s) storage container for the end-user. <p>The supplier should offer the following spare parts:</p> <ul style="list-style-type: none"> • Transmitters • External microphones • Batteries • Receivers • Audio shoes for universal receivers <p>All parts that the transmitter and receiver consist of, and which may be replaced at some stage, should be offered as spare parts. 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.</p> <p>Spare parts should be made available for a period of at least 5 years after the last order of a hearing aid. The price of the spare parts should be offered per part and not per set or pair.</p>
Purpose of 3.4	Provides information regarding required maintenance services the supplier will provide, including the timeframe and frequency.
3.4 Maintenance	Servicing of units still under warranty should be available.
Purpose of 3.5	Provides information regarding required repairment services the supplier will provide, including the timeframe and frequency.
3.5 Repair	Not applicable in this call for tender.
Purpose of 3.6	Provides information regarding required refurbishment services the supplier will provide, including the timeframe and frequency.
3.6 Refurbishing	Not applicable in this call for tender.
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	Not applicable in this call for tender.
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	User guides and user videos should be available via the internet on the manufacture's website.
Purpose of 3.9	Provides information regarding other supply and service requirements.
3.9 Other supply and service requirements	Not applicable in this call for tender.