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Product Specification Document

Project Name:	Wearable AAC
Date:	28 /11/2024
Release Number:	5
Brief:	The wearable Augmentative and Alternative Communication (AAC) is a device designed to help individuals with speech and communication impairments to express themselves. Our design consists of AR glasses equipped with eye-tracking technology alongside speakers to project speech output. Our device is user-centered for individuals whose speech has been affected by cerebral palsy (CP). CP is a neurological condition that affects the brain's ability to control muscles movement and coordination. As a result, in about 1/3 to 2/3 of cases, this condition impacts the ability to speak, leading to speech difficulties or even the loss of speech. [1] [2] [3]

No.	Aspect	Objective	Specification	Test Method
1	**Functionality and Performance**	Speech Output Accuracy	The device should have the ability to correctly translate the user's input into intended speech with an accuracy rate from 80% and above.	Use a confusion matrix [4] to compare the model's predicted outputs against the true labels. Using the data from the table, calculate the accuracy rate [Appendix I].
2		Volume Control	The speech output should have adjustable volume controls, allowing users to set the volume between 30-80 dB [5]. This range ensures clear communication in both quiet and loud environments.	Conduct a volume test following ISO 3746:2010 Section 5 [6]. Use a sound level meter (SLM) [7] placed 1 meter from the device's speaker in a quiet environment. Measure the sound level at the lowest and highest volume settings to ensure proper volume range.
3		Vocabulary Breadth	The device should support daily spoken communication, allowing for a range of 7000 to 18 000 words [8].	Use online Speech-to-Text software to input speech into the device throughout the day and transcribe it. Check the word count of the transcribed text to ensure it falls within the specified range.
4		Speech Output Speed	The device should match the speed of current AAC devices that use word prediction and abbreviation, achieving a response rate of 2-5 words per minute (WPM) [9].	Record the user speaking through the device for 5 minutes using an online voice recorder. Upload the recording into a text-to-

				speech software, then count the total number of words spoken. Calculate the WPM [10] and compare it to the aimed range.
5		Real-time Response	The device is capable of accurately processing and responding to the user's input—whether through gestures or text—with a latency not exceeding 400ms [11].	Run a latency testing software on the device to monitor the system's real-time latency and compare the measured latency with the target value set by ITU-T G.114 [12].
6		Eye Gaze Text Input & Selection	The device should track eye movement to enable users to input text and select options, facilitating efficient communication without manual interaction, with an accuracy ranging from 1° to 2° [13].	Ask the user to gaze at a series of targets on the screen. The eye-tracker system will then compare the user's gaze position to the target locations, to calculate the deviation angle.
7	**Size and Weight**	Weight	The device's weight should fall within the range of current wearable devices on the market [Appendix II] or not exceed the range of products of its same type by 10%.	Measure the final product's weight using a digital scale and check against the range specified [Appendix II].
8		Frame Size	The frame should have an adjustable width to fit an adult head securely, ranging from 13.5 cm to 15.5 cm for women and 14.5 cm to 16.5 cm for men [14].	Measure the width using a tape measure.
9	**Usability, Interface, and Ergonomics**	Ease of Use/Accessibility	The device should be intuitive and easy to operate for users with CP. Patients should be able to use the device after a period of trial and calibration.	Test the device using the [15] guidelines. Enrol at least three AAC users (n≥3) and gather their feedback on their experience.
10		Comfortable Design	The design should integrate into the user's daily routine and be comfortable to wear for extended periods of time. The device should not make patients feel isolated or stigmatized for wearing it.	Test the device against the ISO 9241-210: 2019 [16] guidelines by surveying users on their feedback on their interaction with the design in daily settings. Perform a comfort test specified by ASTM F 1154 Standard Practices [17] for qualitatively evaluating the comfort of components
11		Multimodal Interaction	The device must be able to recognize and respond to various types of input (voice, touch, or gesture) and give clear, understandable feedback to the user. This should allow the user to alert caretakers through other forms of input in case of emergencies	Test the device against BS EN ISO 9241-303:2011 Section 5 [18] guidelines by evaluating the system's response to various input modalities. Trigger each input defined within the system and assess whether the output is accurate.
12		Visual Feedback	LED lights are used to provide a visual signal to others when the AAC user is speaking.	The device should be worn by the user and check if the device alerts others when the user types a letter/word. The test should be run multiple times with different letters and words.
13		Wireless Data Transmission	The device should employ wireless technology to transmit data from the sensors to the voice generation unit.	Conduct tests to ensure the device comply with regulations and standards outlined in BS EN ISO/TS 7344:2024 – Section 6/7 [19]

14	**Environmental**	Humidity	The device should operate reliably at standard indoor humidity levels, ranging from 30% to 60% [20], without any reduction in performance or damage to its components.	Test the device's functions and components integrity with a humidifier in a sealed chamber for the range specified, following the BS EN IEC 60068-3-4:2023 – damp heat test standards [21].
15		Temperature	The device should function effectively within typical indoor and outdoor temperature levels in the UK, ranging from -5 to 35 °C. [22]	Test the device functions for 8 hours within the specified temperature range, following the BS EN 60068-2-2:1993 dry heat testing guidelines [23].
16		Lighting	The device must function effectively in normal indoor and outdoor lighting conditions, ranging from 100 to 1000 lux [24].	Test the device in a controlled lighting environment within the specified range to ensure its performance is not impacted by lighting conditions. Use a lux meter to measure the light intensity [25].
17		Dust Protection	The device should have a minimum IP54 rating (or higher) for protection against dust.	Test the device according to BS EN IEC 60529: 1989 [26], using the IP5X test for dust protection, which involves exposure to dust for 8 hours in a controlled dust chamber.
18		Water Protection	The device should have a minimum IP54 rating (or higher) for protection against water splashes.	Test the device according to BS EN IEC 60529: 1989 [26], using the IPX4 test method for water protection, which involves exposure to splashing water from any direction for 5 minutes.
19		Vibration Resistance	The device should be able to withstand light vibrations that may occur during regular use, ranging from 10Hz to 55Hz.	Test the device according to BS EN IEC 60068-2-6 [27]. Expose the device to continuous vibrations ranging from 10Hz to 55Hz for 2 hours to simulate everyday movement.
20	**Portability**	Compact Design/Ease of Storage	The device should feature a foldable design that allows it to collapse into a compact form. Detachable components should be included to further reduce their size, making it easier to store in pockets, bags, or cases.	The design should follow the guidelines specified in BS EN ISO 21856:2022 Section 15 [28] for folding and locking mechanisms for assistive devices. Have a user store the folded and the detached form of the glasses and check if it fits in everyday storage spaces.
21		Wearability	The device should be designed to be worn by users without the need of external support, such as mounts, a screen or a tablet. It should be self-contained, without requiring a plug-in power supply, to avoid any cables that would hinder mobility.	Have users wear the device for 2-4 hours during normal activities, then survey them on comfort and fit. Use their feedback to assess wearability
22	**Safety & Secur**	Heat Safety	The surface temperature of the device must be limited to 41 $°C$ according to BS EN ISO 21856:2022 Section 10 [28]. Ensure that no part of the device exceeds a temperature that	Use the infrared thermometer to measure the surface/components temperature and compare with the safety standards defined by BS EN IEC 62368-1 [29].

			could cause harm or discomfort to the user due to overheating.	
23		Electrical Safety	The electronic components used in the product should be safe to prevent electrical shocks. The components used must be UKCA/CE [30] rated. All the components and wires should be encapsulated to prevent electric danger from direct contacts.	Perform a series of electrical test including leakage measurement tests, earthbound testing and visual inspection in accordance with BS EN 60601-1-11:2015 [31].
24		Safe Surface	The design should feature smooth surfaces, round corners, no sharp edges, and no protruding parts.	Ensure the product comply with BS EN ISO 21856:2022 Section 19 [32]. Test with hands where necessary.
25		Electromagnetic Compatibility	The device should not emit excessive electromagnetic interference (EMI) that could affect other devices or receive interferences that could affect its performance during wireless transmission.	Test against the BS EN IEC 60601-1-2 standards to measure electromagnetic emissions and immunity [33].
26		Material Safety	Materials used should be hypoallergenic and non-toxic to prevent skin irritation or health risk.	Perform a Biocompatibility test in accordance with BS EN ISO 10993-1 standard for biological evaluation of medical devices [34] [35].
27		Battery Safety	The device should comply with safety requirements for sealed secondary lithium batteries used in portable applications.	Test according to BS EN IEC 62133 (Part 1:2012 and Part 2:2017) by performing a series of electrical, thermal, mechanical, and chemical abuse test [36].
28	**Life, Reliability and Maintenance**	Expected Product Lifespan	The product should have an expected lifespan of 2 years with 4-8 hours of daily use. The device should be resistant to wear and tear during the period.	The device should be tested by performing the Taber abrasion test specified by the BS EN ISO 9352:2012 [37] standard with the electronics components undergoing reliability test method.
29		Drop and Impact Resistance	The device should be able to withstand accidental drops from typical heights encountered in daily use (approximately 1 meter or 3 feet), without sustaining any major physical damage and losing functionality.	Drop testing according to the BS EN 60601-1-11:2015 Section 1 [31]. Drop the device 6 times from 1 meter onto a hard surface. Verify the device remains fully functional without significant damage.
30		Battery Life	The device should feature a long-lasting, rechargeable battery that ensures reliable performance over time with a minimum of 300 charge cycles [38].	Test the battery's lifespan by conducting a cycle life test based on BS EN 61960-3:2017 [39].
31		Software updates	The device should be reprogrammable considering new version of software to improve recognition accuracy.	Use modular testing to ensure the newer version does not corrupt the old functions and improve the performance.

32	**Cost**	Competitive pricing	The device's purchase and installation costs should remain competitive with similar products in the high-tech AAC market that do not include tablets. The total price, including all associated costs, should be around £631.80 [Appendix III].	Add up all the costs associated with the purchase of materials, installation and shipping and any other costs incurred and compare it with the target value.
33		Low maintenance cost	All components of the device should be replaceable, readily available in the region, and cost-effective to replace when necessary.	Dissemble and reassemble all the components and check that the device is fully functional. Ensure that all the components are readily available in the UK.
34	**Legal and Regulatory**	Compatibility with Existing Intellectual Properties	The device should be compatible with the existing IPs and conform to the UK intellectual properties guidelines [40].	Ensure there are no conflicts with the existing IPs through database search throughout the development phase. Or, when necessary, state where they are used.
35		Product Liability and Warranty	The device should provide complete transparency, clearly explaining its functionality. The warranty period should be 1 year, covering defects in material and manufacturing, repairs and replacement, but excluding accidental damage.	Ensure that the product liability and warranty follow the Consumer Rights Act 2015 [41].
36		Labeling Requirement	All required labeling, including regulatory marks, safety warnings, manufacturer details, and usage instructions, should be clearly visible on the device itself.	Test if the labelling complies with the ISO 15223-1:2021 standards [42].
37		Data Protection and Privacy	The user should have full control over their data. Collection and storage of data must be done with the permission of the user and should be immediately discarded after processing the information.	Ensure the use and processing of patient data follows the Data Protection Act 2018 [43].
38		AI Safety	Should AI models be used for decoding and speech output, patient data and privacy should be protected during the model training and after its implementation. Efforts should also be made to minimize inappropriate outputs.	Ensure the AI model usage and training procedure adhere to the 5 core principles in the white paper “AI regulation: a pro-innovation approach” and refer to the EU AI Act for more detailed and specific edge cases [44] [45].

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Appendix

Appendix I: Accuracy formula

$$Accuracy = \frac{TP + TN}{TP + TN + FP + FN}$$

Appendix II: Reference table for weights of the existing products

DEVICE	BRAND and MODEL	WEIGHT /grams	Average weight /grams
AR Glasses [I]	Xreal Air 2 Pro	72	76
	Rokid Max	75	
	Virtue Pro	77	
	X real Air 2 Ultra	80	
Headphones	Bose QuietComfort ultra [II]	250	220
	Sony WHCH720NW_CE7 [III]	190	
Fitness trackers and smart watches	Fitbit charge 6 [IV]	30	36.97
	Apple series 10(titanium) [V]	41.7	
	COROS pace 3 (nylon band)[VI]	39	

Fig 1: Table with the weight of similar wearable devices in grams

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Appendix III: Reference table for prices of the existing products

DEVICE	DESCRIPTION	PRICES (from) £
Magic Eye Fx Pro	Software that takes various form of input such as eye gaze ,sound, switches and more. device that allows a fun interactive way to learn communication skills [I]	850
Hey_ speech box	Device that can transcribe text to speech. The text is sent to the device through a compatible software. The device will work within 10m [II][III]	570
Getting started with communicators bundle	Introductory communication aid. It is an easy to use speech device. It includes a single message, sequential communicators, and a two message device with 3 levels allowing the user to learn to communicate [IV]	570
Go Talk Express 32	Device that allows storing messages. It has a capacity of 1600s allowing user to communicate [V]	619
Grid 3 from smartbox	Software package that lets users to communicate and control other devices like computers. It allows access through eye gaze, switch technology and touch and pointing devices[VI]	550
Average		631.8
DEVICES THAT USES TABLETS		
Nova Chat 8	Software on an 8" android tablet with carrying handles. The device has a capacitive touchscreen is accessible by touch or stylus [VII]	3185 (excl.tax)
Eye on Elite from EyeTech	Device that uses eye tracking technology with a tablet allowing communication just using their eyes [VIII]	7450
Grid Pad 13	Device with a tablet that allows many access options including eye gaze camera [IX]	8495
Average		6376.7(around10xdevices that doesn't use tablets)

Fig 2: Table with prices of current high tech AACs (including AACs with tablets and AACs without tablets)

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