

**Product Specification Document**

<b>Project Name:</b>	Wearable AAC
<b>Date:</b>	13 /03/2025
<b>Release Number:</b>	6
<b>Brief:</b>	The Wearable Augmentative and Alternative Communication (AAC) is a device designed to help individuals with speech and communication impairments to express themselves. <u>The design consists of the Google Glass equipped with eye-tracking technology, projecting a keyboard onto the lens of the glasses. The users select keys via gaze, with input converted to speech for hands-free communication. The 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 75 percent of cases, this condition impacts the ability to speak, leading to speech difficulties or even the loss of speech. [1.1, 1.2]</u>

**Commented [BL1]:** Shifting from possessive "our" design to "the" in order to make the phrase more objective.

**Commented [TS2]:** Reduced references for description of cerebral palsy and speech loss

No.	Aspect	Objective	Specification	Test Method
1	Functionality and Performance	<u>Speech Output Accuracy</u>	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 to compare the model's predicted outputs against the true labels. Using the data from the table, calculate the accuracy rate [2.1, Appendix I].
2		<u>Volume Control</u>	To ensure clear communication in both quiet and loud environments, the speech output should have adjustable volume controls, allowing users to set the volume between 30 to 80 dB [2.2].	Conduct a volume test following BS EN ISO 3746:2010 <u>Section 5</u> . Use a sound level meter (SLM) 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. [2.3, 2.4]
3		<u>Vocabulary Breadth</u>	The device should support daily spoken communication, allowing for a range of 7000 to 18 000 words [2.5].	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		<u>Speech Output Speed</u>	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) [2.6].	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 and compare it to the aimed range. [2.7]

**Commented [BL4]:** The specific section that is followed for the test has been added: *Section 5 - Measurement Procedure*.

**Commented [BL3]:** Reference has been changed from a website to more credible article with the relevant section that explain where the target value was taken from.

**Commented [BL5]:** The reference now includes the chapter and page number where the daily spoken word range was sourced.

5		<u>Real-time Response</u>	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. [2.8, 2.9]	Run 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 [2.9].
6		<u>Eye Gaze Text Input &amp; Selection</u>	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° [2.10].	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	<u>Weight</u>	The device's weight should fall within the range of current wearable devices on the market, ranging from 30 grams to 250 grams or not exceed the range of products of its same type by 10%. [Appendix II]	Measure the final product's weight using a digital scale and check against the range specified.
8		<u>Frame Size</u>	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 [3.1].	Measure the width using a tape measure with a resolution of 0.5mm.
9	Usability, Interface, and Ergonomics	<u>Ease of Use/Accessibility</u>	The device should be intuitive and easy to operate for users with CP in the 3-5 level on the Gross Motor Function Classification System (GMFCS), after a period of trial and calibration. [The satisfaction level should be at least 70%. [4.1]	Test the device using the BS EN ISO 9241-171:2008 Part 9 guidelines. Enrol at least three CP patients (n≥3) from various levels of GMFCS and gather their feedback on their experience. [4.2]
10		<u>Comfortable Design</u>	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 BS EN ISO 9241-210: 2019 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 for qualitatively evaluating the comfort of the components [4.3,4.4]
11		<u>Multimodal Interaction</u>	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 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. [4.5]
12		<u>Visual Feedback</u>	A visual indicator will be used to provide a 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		<u>Wireless Data Transmission</u>	The device should employ wireless technology to transmit data from the eye gaze input 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 [4.6]

**Commented [BL6]:** Included the weight range of current wearable devices directly, instead of strictly referencing the appendix to check the table.

**Commented [TS7]:** Added resolution for tape measure

**Commented [TS10]:**  
Section added: Part 9: Requirements for non-keyboard input devices

**Commented [BL8]:** Added a clear target audience for our test to be properly conducted.

**Commented [BL9]:** The pass/fail criteria for intuitive and easy has been added for more precision to conduct the test.

**Commented [TS11]:** Changed LED lights to visual indicator since LED lights were a design choice

14	Environmental	<u>Humidity</u>	The device should operate reliably at standard indoor and outdoor humidity levels, ranging from 20% to 70%, without any reduction in performance or damage to its components. [5.1]	Test the device's functions and components integrity with a humidifier in a sealed chamber for the range specified, following the BS EN IEC 60068-3-4:202 Part 3-4: damp heat test standards [5.2].
15		<u>Temperature</u>	The device should function effectively within typical indoor and outdoor temperature levels in the UK, ranging from -15 to 35 degrees Celsius. [5.3]	Test the device functions for 8 hours within the specified temperature range, following the BS EN 60068-2-2:1993 Part 2-2 dry heat testing guidelines [5.4].
16		<u>Lighting</u>	The device must function effectively in normal indoor and outdoor lighting conditions, ranging from 100 to 1000 lux [5.5].	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 [5.6].
17		<u>Dust Protection</u>	The device should have a minimum IP54 rating (or higher) for protection against dust.	Test the device according to BS EN IEC 60529:1989+A1:1999+A2:2013, using the IP5X and IPX6 test for dust protection, which involves exposure to dust for 8 hours in a controlled dust chamber. [5.7]
18		<u>Water Protection</u>	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+A1:1999+A2:2013, using the IPX4 test method for water protection, which involves exposure to splashing water from any direction for 5 minutes. [5.7]
19		<u>Vibration Resistance</u>	The device should be able to withstand light vibrations that may occur during regular use, ranging from 10Hz to 55Hz. [5.8].	Test the device according to BS EN IEC 60068-2-6:2007. Expose the device to continuous vibrations ranging from 10Hz to 55Hz for 2 hours to simulate everyday movement. [5.8]
20	Portability	<u>Compact Design/Ease of Storage</u>	The device should feature a foldable design that allows it to collapse into a compact form, to fit into a standard eyeglass case, with the dimensions of 15x6x4 cm. 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 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 an eyeglass case with the specified dimensions. [6.1]
21		<u>Wearability</u>	The device should be designed to be worn by users without the need for 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 & Security	<u>Heat Safety</u>	The surface temperature of the device must be limited to 41 degrees Celsius, as specified in BS EN ISO 21856:2022 Section 10. Ensure that no part of the device exceeds a	Use the infrared thermometer to measure the surface/components temperature and compare with the safety

**Commented [BL12]:** Both indoor and outdoor cases have been considered, rather than just the indoor case.

**Commented [BL13]:** Reference has been changed to a more appropriate and reliable article.

**Commented [BL14]:** Reference has been changed from the MET office to a more credible and appropriate article.

**Commented [BL15]:** Reference has been changed to a more appropriate book that cover the functionality of lux meter, with the relevant chapter.

**Commented [TS16]:** Changed to a more recent amended version of the standard.

**Commented [BL17]:** Reference has been added to explain where the 10Hz to 55Hz comes from.

**Commented [BL18]:** A portability criterion has been added, considering technical values for how small the device should collapse.

			temperature that could cause harm or discomfort to the user due to overheating. [7.1]	standards defined by <a href="#">BS EN IEC 62368-1:2024+A11:2024</a> [7.2].
23		<u>Electrical Safety</u>	The electronic components used in the product should be safe to prevent electrical shocks. The components used must be UKCA/CE rated. All the components and wires should be encapsulated to prevent electric danger from direct contacts. [7.3]	Perform a series of electrical test including leakage measurement tests, earthbound testing and visual inspection in accordance with BS EN 60601-1-11:2015+A1:2021 [7.4].
24		<u>Safe Surface</u>	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. Test with hands where necessary. [7.5]
25		<u>Electromagnetic Compatibility</u>	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 [7.6].
26		<u>Material Safety</u>	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- <a href="#">Part 10</a> standards for biological evaluation of medical devices [7.7, 7.8].
27		<u>Battery Safety</u>	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 [7.9].
28	Life, Reliability and Maintenance	<u>Expected Product Lifespan</u>	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 standard with the electronics components undergoing reliability test method. [8.1]
29		<u>Drop and Impact Resistance</u>	The device should be able to withstand accidental drops from typical heights encountered in daily use, approximately 1 meter, without sustaining any major physical damage and losing functionality.	Drop testing according to the BS EN 60601-1-11:2015 Section 1. Drop the device 6 times from 1 meter onto a hard surface. Verify the device remains fully functional without significant damage. [8.2]
30		<u>Battery Life</u>	The device should feature a long-lasting, rechargeable battery that ensures reliable performance over time with a minimum of 300 charge cycles <a href="#">[8.3]</a> .	Test the battery's lifespan by conducting a cycle life test based on BS EN 61960-3:2017 Section 3 [8.4].
31		<u>Software updates</u>	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.

**Commented [BL19]:** Changed to a more recent amended version of the standard.

**Commented [TS20]:** Added missing section part 10 - tests for skin sensitization

**Commented [BL21]:** Reference has been changed to a more appropriate article.

32	Cost	<u>Competitive pricing</u>	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		<u>Low maintenance cost</u>	All components of the device should be replaceable, readily available in the region, and cost-effective to replace when necessary.	<u>Disassemble</u> 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	<u>Compatibility with Existing Intellectual Properties</u>	The device should be compatible with the existing IPs and conform to the UK intellectual properties guidelines [10.1].	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		<u>Product Liability and Warranty</u>	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 [10.2].
36		<u>Labeling Requirement</u>	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 BS EN ISO 15223-1:2021 Part 1 standards [10.3].
37		<u>Data Protection and Privacy</u>	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 [10.4].
38		<u>AI Safety</u>	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 [10.5, 10.6].

Commented [TS22]: Spelling error corrected

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**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 smart box	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 Eye Tech	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(around 10x devices 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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