

PROJECT ANGELO

Statement of Positioning, Intended Use, Transparency Notes, Verification, Risks, Warnings, and Documentation Limits

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OSHOWA Certification: UID IT000017

Important Notice

ANGELO is an Open Source hardware project intended for experimental, educational, and social inclusion purposes. It is **NOT** a medical device, not a hearing aid, and is not intended for the diagnosis, prevention, or treatment of hearing-related medical conditions. For any need related to hearing health, users are advised to consult only qualified medical specialists and healthcare professionals.

ANGELO is an open hardware platform. Anyone who downloads, studies, replicates, or modifies these files does so for personal, social, educational, or maker research purposes and under their own responsibility.

The project is carried out on a voluntary basis, without industrial structure, without clinical purpose, and without any formally established association supporting regulatory or documentation development. Available time and resources are primarily dedicated to responding to real social needs, sharing open knowledge, and progressively improving the technical documentation.

Nature of the Project

ANGELO is an open hardware platform for the experimental amplification and equalization of environmental and voice-related audio signals in non-clinical contexts. The project originates as an open hardware initiative focused on personal research, technical experimentation, educational activities, maker culture, and social inclusion.

The project is intended to be studied, assembled, replicated, adapted, and improved as an example of open source audio electronics. Its documentation is made available so that makers, fablabs, schools, technicians, independent researchers, volunteers, and local communities may understand its architecture, assess its limitations, replicate it responsibly, and, if they wish, contribute to its evolution.

Declared Intended Use

ANGELO is intended for experimental, educational, demonstrative, community, and relational uses in non-clinical settings. It may be used as a study project, an audio electronics experimentation platform, an educational object in STEM activities, a maker project, or support for social inclusion and community participation initiatives.

ANGELO is not intended for clinical or healthcare use. It is not intended to compensate for hearing loss or other pathological conditions. It is not intended for diagnosis, treatment, prevention, monitoring, or cure of medical conditions. It does not replace devices prescribed by physicians, audiologists, hearing care professionals, or other healthcare practitioners. Any use different from what is declared here is under the full responsibility of the user, builder, or any downstream distributor.

Target Groups and Project Classification

The main intended audiences of the ANGELO project are makers, fablabs, schools, universities, informal volunteer groups, educators, independent researchers, people interested in open source audio electronics, and local communities engaged in social inclusion practices.

The project may indirectly benefit people involved in social, relational, or community activities in which environmental listening and sound experimentation are part of the experience, while it remains clear that the project is neither conceived nor distributed as a clinical or healthcare solution.

ANGELO is classified as Open Source Hardware, an open audio hardware platform, an experimental and educational project, and a non-clinical social inclusion project.

Declared Regulatory Positioning

ANGELO is released as an Open Source hardware project for experimental, educational, and social purposes, with an explicitly non-medical positioning. The author and volunteer contributors do not present it as a medical device, hearing aid, certified healthcare aid, or product intended for diagnostic or therapeutic purposes.

As of the date of this document, ANGELO is not offered as a medical device under applicable regulations, is not accompanied by medical conformity declarations, and is not presented as a product approved by healthcare regulatory bodies.

Any references to electroacoustic measurement methods or technical practices commonly used in other contexts are employed solely as engineering benchmarks to better understand circuit behavior, improve technical transparency, and support replicability. Such references do not imply medical classification and do not constitute evidence of healthcare regulatory compliance.

Anyone who assembles, distributes, adapts, or repositions ANGELO for purposes different from those declared in this document assumes full technical, legal, and regulatory responsibility for that choice.

Project Development Status

ANGELO is an open source hardware project with working prototypes, public technical documentation, experience of use in social contexts, and dissemination, educational, and maker-community activities. The project may be described as a replicable experimental system with intermediate maturity, suitable for study, replication, non-clinical testing, demonstrations, and collaborative improvement.

It is not declared as an industrial medical product, nor as a device certified for healthcare use. The documentation is continuously improved in a manner compatible with the voluntary nature of the project and the resources available. Some aspects of validation, systematic testing, and documentation standardization remain under development.

License and Open Philosophy

ANGELO is released under the Creative Commons Attribution-ShareAlike 4.0 International license (CC BY-SA 4.0). The documentation, files, and materials made available are intended to promote study, transparency, access to knowledge, and collaborative improvement.

ANGELO is an open hardware platform. Anyone downloading these files does so for personal or social research purposes. The use, replication, modification, or distribution of the materials made available must comply with the terms of the license and with the regulations applicable in the user's jurisdiction.

Transparency Regarding Documentation and Organizational Limits

The project documentation is shared in good faith and is progressively improved in a manner consistent with the voluntary, open, and non-profit nature of the initiative. In the absence of a formally funded association or industrial structure, some sections remain intentionally essential, while still being considered sufficient to provide transparency, replicability, and general understanding of the project.

The project's operational priority is to respond to real social needs, support the sharing of technical knowledge, and maintain accessibility to an open hardware initiative. For this reason, part of the technical and procedural documentation is consolidated progressively over time.

Critical Design Notes

For correct replication of the ANGELO project, particular attention should be paid to keeping all project files aligned to the same revision. BOM, schematic, PCB, manuals, and technical notes should always refer to the same project revision.

During assembly, the orientation and polarity of components must be carefully checked, especially for integrated circuits, transistors, LEDs, electrolytic capacitors, and power connectors. Errors in orientation or polarity may cause malfunction, overheating, or permanent damage.

Only the power supply method specified for the documented revision should be used. Inappropriate power sources, incorrect connections, or reversed polarity may compromise circuit operation.

It is recommended not to use the device while it is charging, both to avoid unwanted noise and to reduce non-optimal operating conditions.

Performance and perceived sound level may vary depending on the headphones or earphones used. It is therefore recommended to always start from minimum volume and increase gradually only if necessary.

Proximity between microphone and headphones may generate acoustic feedback. Configurations that favor this phenomenon should be avoided.

If certain components are unavailable, they should only be replaced with technically verified equivalents. Uncontrolled substitutions may alter the behavior, reliability, and performance of the project.

Where 3D-printed enclosures or additional mechanical parts are used, tolerances, correct connector fit, and the absence of cable pinching or abnormal mechanical stress on wires and components should be verified.

Bill of Materials and Replicability

The project bill of materials includes, where available, component reference, quantity, manufacturer, manufacturer part number, supplier, and supplier part number. Accessory parts or equivalent alternatives may be indicated separately when commercial availability changes over time.

The open hardware nature of the project allows reasoned component substitution, provided that technical compatibility is maintained and the possible influence of substitutions on overall performance is understood.

Essential Assembly Guide

ANGELO is an open hardware platform developed in a volunteer context for experimental, educational, and social purposes. This assembly description is intended to facilitate basic replication of the project, while not constituting an exhaustive industrial assembly manual.

The absence of a formally funded production or association structure means that part of the documentation is maintained progressively. However, the shared files are considered sufficient to allow makers, technicians, fablabs, and competent users to understand and replicate the project in a reasonable manner.

At minimum, replication requires the PCB of the correct revision, the BOM matching the same revision, the listed electronic components, the basic tools required for assembly where applicable, any mechanical parts

or enclosure, a power source compatible with the documented revision, compatible headphones or earphones, and any microphones included in the configuration.

The recommended general procedure is to first verify that all files belong to the same revision, check the availability of the BOM components, assemble the components respecting polarity, orientation, and connector placement, visually inspect solder joints and the absence of short circuits, connect the compatible power supply, perform a first power-on without prolonged use, verify power-on, volume control, audio output, and the correct operation of any microphones, place the circuit in the enclosure if applicable without pinching cables or components, and finally repeat a functional check.

When in doubt, it is recommended to begin with low-volume tests. Unverified substitute components should not be used. If the device shows abnormal noise, smell, overheating, instability, or unexpected behavior, testing must be stopped immediately.

This guide is intentionally essential and should be read together with the schematic, bill of materials, user manual, critical design notes, and risk assessment.

Verification of Correct Function

To consider a build of the ANGELO project correctly assembled, it is recommended to verify at least correct power on and power off behavior, coherent behavior of any indicator light included in the revision, proper operation of the volume control, presence of audio output signal, operation of the internal microphone if present, operation of the external microphone if present, and absence of unusual smell, overheating, or abnormal electrical behavior.

From an electrical standpoint, it is recommended to verify the absence of obvious short circuits, correct power supply behavior, current consumption compatible with expected circuit operation, and correct connection of the main connectors.

From an audio standpoint, it is recommended to verify signal transmission, coherent response to volume variation, absence of abnormal distortion at low level, and predictable behavior under saturation or feedback conditions.

At some stages of development, the project has been subject to theoretical analyses, simulations, and non-clinical experimental checks in support of engineering understanding of the system. Such checks do not constitute healthcare certification or medical conformity declarations.

Summary Risk Assessment

ANGELO is an experimental open hardware project. The main reasonably foreseeable risks concern excessive sound level, acoustic feedback, incorrect assembly, improper power supply, use while charging, unverified component substitution, improper interpretation of the project as a healthcare device, use by vulnerable persons without adequate support, deterioration of cables, connectors, or battery, and hygiene issues in case of shared use.

Excessive volume, the use of highly sensitive headphones, or feedback conditions may cause discomfort or auditory fatigue. The recommended mitigation is to always start from minimum volume, increase gradually, and stop use in case of discomfort.

Proximity between microphone and headphones may generate whistling, sound peaks, and discomfort. In such cases, the relevant elements should be separated and the volume reduced.

Assembly errors, reversed polarity, defective soldering, or incorrect components may cause non-function, overheating, or damage to the circuit. Careful visual inspection, continuity checks, and comparison with the schematic and BOM are therefore recommended.

The use of incorrect batteries or power sources may cause malfunction or damage. Only a power source compatible with the documented revision should be used.

Use during charging may introduce noise or abnormal behavior and should be avoided.

The use of technically unverified equivalents may make system performance unpredictable. Substitutions should only be made after reasoned technical evaluation.

Improper interpretation of the project as a healthcare device may generate inappropriate expectations or non-coherent uses. For this reason, all project documents reiterate that ANGELO is not a medical device.

If the project is used by vulnerable persons or in contexts where autonomous management of volume or configuration may be difficult, supervision by an adult, caregiver, or operator is recommended.

Wear or damage affecting cables, connectors, or battery may cause interruptions, intermittent contact, or failure risk; periodic inspection and suspension of use in case of defects are therefore recommended.

In case of shared use of headphones or microphones, regular cleaning practices should be adopted.

Even with normal open-design precautions and prudent use, residual risk remains due to the experimental, replicable, and non-industrial nature of the project. End users are responsible for assessing the suitability of the device for their specific context of use.

Foreseeable Adverse Outcomes

Improper use, incorrect assembly, non-prudent volume adjustment, or the use of incompatible accessories may result in acoustic discomfort, unpleasant or distorted listening, sound feedback, interruption of operation, damage to the circuit or accessories, and a user experience not aligned with expectations.

In case of discomfort, abnormal noise, overheating, unusual smell, or unexpected behavior, use of the device must be stopped immediately.

Essential Use Warnings

Users are advised to always start with minimum volume and increase it gradually only if necessary. In case of discomfort, whistling, or abnormal sounds, use must be discontinued. The device must not be used while charging. Cables, connectors, battery, and accessories should be periodically checked. Damaged accessories must not be used. In case of shared use, headphones and microphones should be cleaned regularly. For any doubt concerning hearing health, only qualified healthcare professionals should be consulted.

Essential Maintenance

To keep the ANGELO project in reasonable operating condition, it is recommended to periodically inspect cables, jacks, connectors, and battery, verify the regular operation of the volume control, check for any mechanical loosening, regularly clean shared accessories, and suspend use in case of visible damage, overheating, or abnormal behavior.

Declared Open Issues

The project is open and continuously evolving. As of the current date, the following are declared as open issues: further standardization of assembly documentation, consolidation of community-replicable test procedures, expansion of verification data across different combinations of headphones and accessories, progressive alignment among hardware revisions, manuals, and dissemination materials, more systematic collection of real-world non-clinical usage feedback, improvement of documentation maintenance consistent with the project's voluntary nature, and possible future development of additional protection or control functions where compatible with the simplicity of the open design.

The project is developed without a dedicated industrial structure and without specific funding for advanced regulatory or editorial activities. The operational priority is to respond to social needs and make technical knowledge freely available, while improving documentation over time.

Documentation Continuity and Minimal Legacy Plan

As an open hardware project, ANGELO adopts a documentation continuity principle based on public sharing of available source files, maintenance of known project revisions, traceability of the main versions of BOM, schematic, and manuals, and the possibility for the community to replicate, archive, and improve the project even in the absence of centralized production.

The absence of a formally dedicated industrial or association structure makes this plan necessarily minimal, but consistent with the project's open hardware philosophy.

Conflict of Interest Statement

As of the date of this document, the ANGELO project is developed and shared within an open source and volunteer-based framework. Unless explicitly stated otherwise in specific documents or collaborations, no binding industrial sponsorship or conflict of interest is declared that would alter the project's open and non-clinical nature.

Conclusion

ANGELO is an open hardware platform developed for experimental, educational, and social inclusion purposes. The documentation made available is intended to promote transparency, replicability, technical understanding, and collaborative improvement, in keeping with the project's open, voluntary, and non-medical nature.

ANGELO is not a medical device, is not a hearing aid, and is not intended for the diagnosis, prevention, or treatment of hearing-related medical conditions. Anyone who downloads, assembles, uses, or modifies these files does so for personal or social research purposes and under their own responsibility.

For any need related to hearing health, users must consult only qualified medical specialists and healthcare professionals.