

Outsourcing the product development of ACUTE device

By

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TECHNICAL REQUIREMENTS

1. Preamble:

Proof of Concept of ACUTE – Anacusis Curing Technology, a portable, non-invasive hearing aid based on a unique, patent filed bone conduction method is developed in association with KSCSTE – Trivandrum & TrEST Research Park, Trivandrum. This is at its primitive form with assembly of some of the parts, handmade. This has to be translated to a commercial level product. Any Intellectual property emerging through this association shall also remain sole IP of client not the vendor.

2. Design Requirements:

The existing Proof of Concept needs to be translated to a working prototype and then to a commercial product. In the Proof of Concept, part of hard disks as well as hand crafted parts are used, mainly based on trial-and-error method. While transforming to prototype, proper engineering design process and applicable standards needs to be followed.

It is suggested to have a main module (waist held device) plus a head band, connected through wire. The main module will have a microphone, amplifier, rechargeable battery as well as a Bluetooth module whereas the head band will have the electrical to mechanical transducer (custom-made magnet and coil assembly). The UI and software applications are not mandatory, hence excluded from the RFQ; however, the associated firmware shall be developed and is included in the RFQ.

3. Scope of Work

The scope of work is to develop a portable, low cost, non-invasive ready for production hearing aid based on a bone conduction method.

Activities Includes-

- a. R&D and System Architecture Design
- b. Industrial Design
- c. Mechanical Design
- d. Electronics Design
- e. Firmware development
- f. Prototype builds.
- g. Testing validation
- h. Trials and iterations if any.

4. Applicable Standards

- ISO13485: Medical Devices, Quality Management System)
- ISO 60601-1 (Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance)
- ISO 14971 (Medical Devices, Application of risk management)
- ISO17664 (Sterilization of medical devices)
- IEC 60188-9 (Hearing Aids: Methods of measurements of characteristics of hearing aids with bone vibrator output)
- Latest ANSI standard.

Eligibility Criteria

1. The outsourcing company shall be located in Kerala State. It shall have an R & D wing for product development in same state.
2. The outsourcing company shall be into existence for minimum 5 years as on January 2023. It shall have product development experience not less than 5 patented medical products.
3. The product already developed by the outsourcing company shall be available in market or ready for industrialization (Shall submit proofs to claim the condition 2&3)
4. The outsourcing company shall have design expertise in Electronics, Industrial design, mechanical and firmware at one place. To keep up the IP confidentiality, the vendor shall not outsource part work further to third party companies without prior agreement from Principal Investigator or Patent Owner.
5. The outsourcing company shall have inhouse assembly, integration and basic testing facilities.
6. The company shall deliver the committed number of products in packaged box and with product catalogue/brochure
7. The Company has to do the complete product delivery in 18months.
8. The Outsourcing company shall be DSIR R&D recognized.
9. The Outsourcing company shall be ISO 9001 certified.
10. The Sales turn over for the year 2021-22 shall be above INR 1.0 Crores, with minimum 25 employees.
11. The outsourcing company shall provide a detailed technical proposal covering the technical approach planned.
12. The selection of outsourcing company shall be based on the evidences they submit for each criteria and technical evaluation based on the proposal they submit.