Study on rectification of issues faced by ultrasonic welding of medical “e-stethoscope” by adhesive bonding technique

S C Bhopi1, V B R Miriyala2, S V Parab3, A S Haldankar4 and S P Pandey5

1,2Department of Mechanical Engineering, Fr. Conceicao Rodrigues College of Engineering, Fr. Agnel Ashram, Bandstand, Bandra (W), Mumbai – 400050, India, Affiliated to Univ. of Mumbai.
3,4,5Ayu Devices Pvt Ltd, M-09, CSRE 3rd Floor, SINE Incubator, IIT Bombay, Powai, Mumbai-400076, India.

E-mail: siddeshbhopi1994@gmail.com

Abstract: Ultrasonic welding is used as an effective method for the welding of thin films in medical plastics for pills to the packing of medical devices. It provides the device with high adherence to sustain in the working environment. Despite being one of the most acceptable methods to fuse the materials in the medical field, it’s few limitations can cause a great impact on the quality of the product. The paper deals with the problem faced by a company named “Ayu Devices Pvt Ltd.” which manufactures Electronic Stethoscopes. The device case was welded using the ultrasonic welding process, but because of the frequency conveyed on different electronic components, it led to the rejection of the devices in the quality check-up. Since the rejection rate raised to an approximation of 45% at the quality check-up, there was a need to find an alternate method in a similar device case. The adhesive bonding technique using cyanoacrylate is adopted for further manufacturing of the device. A fair comparison is made based on the bond strength delivered and the rejection percentage due to electronic components failure by both the methods.

1. INTRODUCTION

A stethoscope is a device used by medical practitioners for listening to the heart rhythm and lungs' sound of the patient. An Electronic Stethoscope is a modern age stethoscope that is designed and developed for sound amplification, recording of the heart and lung sounds in the form of audio and phonocardiogram. An Electronic stethoscope acquires input signal, either acoustic or electric, from the diaphragm (acoustic diaphragm or piezo-electric diaphragm)[1]. The input signal is converted into a digital pulse that is transferred through a combination of filters and amplifiers in such a manner that the output signal is free from the noise and can be amplified to the desired value to hear the crisp sound of heart and lung[1]. Figure 1 depicts the flowchart of various phases (viz. Data Acquisition, Pre-processing, and Signal processing) through which sound signal travels for reduction of input noise and enhance the desired output. This output is used for better diagnostics.

The recent development in machine learning and artificial intelligence has influenced the further development of E-stethoscope. An AI algorithm analyses the phonocardiogram detects the faint murmur in the heart and generates the report regarding the same. This has helped majorly in rural areas where heart specialist doctors are not readily available.
The primary health care doctor or nurse checks the patient using an E-stethoscope, and if the report shows any abnormalities then the patient is advised to visit the specialist doctor for further diagnostics.

2. LITERATURE REVIEW

According to “Matter | Britannica.com”, all the bodies in nature oscillate in various amplitudes and frequencies depending upon its interaction with the surroundings as well as with internal molecules[2]. When a body vibrates with the influence of the surrounding or any other vibrating body then it is known to be forced vibration. When a body vibrates with its molecules in unison without the influence of an external body, it is known as free vibration[2]. This free vibration is also termed as self-vibration or the natural frequency of the body.

When the body is in forced vibration, the frequency of the external body matches the self-vibrating frequency of the body, the amplitude of the vibration reaches its relative maximum. This frequency at which a drastic variation is observed in the characteristics of the body is known as the resonance frequency[3]. Depending upon the source of external frequency and characteristics of the body there is a change in the type of resonance, i.e. if the body is under mechanical oscillation then the resonance is known as mechanical resonance as stated by J. W. Park[4] or if the body is suspended in an electromagnetic field then it is termed as electromagnetic resonance.

According to E. Sancaktar, Ultrasonic welding is a sub-division of Friction welding[5]. Small projections or a surface extrusion are present on either side of two fusing bodies which generates friction. The bodies are vibrated at a frequency above the audible frequency i.e. above 20 kHz (kilohertz) along with pressure applied from the top. I. F. Villegas states that the vibration and pressure result in the generation of heat at the intersection of the two bodies[6]. For welding, the generated heat must produce temperature above the melting temperature of either body for the fusion to initiate[6]. Thus, the pressure, frequency and time for which the process is carried are calculated for better results.

The electronic components used on the PCB (Printed Circuit Board) of a device are affected due to vibration loading over a period, stated by A. M. Veprik[7]. During ultrasonic welding, the PCB also undergoes the vibration stress which results in alteration of the characteristics of the components. If the natural frequency of the components lies between the welding frequencies, then it may also cause the cracking of the components, which is mentioned in the “Capacitors Q&A NE Handbook series 2013”[8]. The problem of resonance in electronic components is majorly observed in capacitors and transducers. The electromechanical resonance caused in the capacitors has a high tendency for crack initiation in capacitors. Flexing of the board under vibrational stress causes an inverse piezoelectric
effect on the capacitors[9][10]. The floating of the components is also a cause of failure of the device while ultrasonic welding[11]. The improper support structures may lead to alteration to solder strength.

Figure 2 shows an Electronic stethoscope (AyuSynk) with all the components(Microphone, PCB, Speaker, etc.) installed before case fusion.

![Figure 2. Components in the device(AyuSynk- E-stethoscope with Bluetooth)](image)

3. PROBLEM DEFINITION AND QUALITY TEST BEFORE AND AFTER ULTRASONIC WELDING

Ayu Devices Pvt. Ltd manufactures an Electronic Stethoscope. The company manufactures two versions of Electronic Stethoscope viz. one without Bluetooth and one with Bluetooth. The external case for enclosing the circuitry is made of ABS(Acrylonitrile-Butadiene-Styrene) polymer considering its medically compatible properties and the endurance strength for heavy loading. The whole unit was made in two cavities and they were fused using the ultrasonic welding method. The parameters used for welding are stated in Table 1. The bond strength of ultrasonic welding for ABS material is 29.3 MPa (Derived after prototype testing)

| SR. NO. | POINTS       | VALUES     |
|---------|--------------|------------|
| 1       | Air Pressure | 40psi      |
| 2       | Weld time    | 0.2sec     |
| 3       | Hold time    | 1sec       |
| 4       | Amplitude    | 80%        |
| 5       | Trigger      | 520        |
| 6       | Booster      | Gold       |
| 7       | Horn         | Titanium   |
| 8       | Level Plate  | NO         |

After every phase of the production cycle, the devices go through a quality check-up in a semi-automatic manner. As the production quantity increased, it was observed that the rejection of devices was prominent post ultrasonic welding. The problem arises mainly in the transducers and Bluetooth units. Figure 3 shows the test setup for a speaker which is done in a closed enclosure with a sound frequency range of 80 Hz to 680Hz (working frequency range of the selected speaker). The Bluetooth connectivity is checked manually based on connectivity between the device and the mobile phone. The major concern was developed when the rejection rate raised to 45 percent post ultrasonic welding.
The speaker is accepted when the peak amplitude crosses the benchmark of 0.75Vp (peak voltage) as per the quality criteria defined by the company. Any output below the amplitude of 0.75Vp was rejected. Figure 4 is the output graph of the speaker of device code S63, here figure 4a denotes the speaker output before ultrasonic welding and figure 4b denotes the output of speaker post-ultrasonic welding. 45 percent of the speakers and Bluetooth units aggregate were rejected post ultrasonic as per the data of the last quarterly report in the year 2019. This statistical data put a huge setback to the production unit.

For replacing the rejected components post welding, the case was needed to be broken to retrieve the working components. This process consumed a lot of workforces, time and money. This led to the need to find the alternative for fusing the two cavities of the case.

3.1. Constraints for proposing an alternative approach.
3.1.1 The abundance of case cavities.
Initially, when the mold was designed and manufactured, a high quantity of enclosure case was manufactured. Only a small quantity was used to manufacture and sell the devices. The wastage of the remaining quantity was to be avoided. This created a major hindrance in changing of the device enclosure. Around 75-80 percent of the cases were left unturned.

3.1.2 Time for research and development in the PCB and its components.
The PCB which was prior designed did not have Bluetooth integrated. An external Bluetooth unit is put together due to the need for up-gradation. This resulted in the inclusion of a floating connection in
the components. To remove the redundancy of the floating components, a new PCB was needed to be
designed with a constraint of the same dimensions as it will be integrated with the same enclosure
case. This created a setback as the space required for the previous components was more and
integrating all the functions in the same PCB was next to impossible with the current skillsets of the
PCB designer. This causes the rise to a search for new components that can be readily available in the
market. Thereafter the testing and debugging of the PCB circuit is a tedious job that requires
maximum time. After the designing of a new PCB, the quality and performance testing are
painstaking job.

3.1.3. Effect on the production flow cycle and the overall costing.
Due to a high rejection rate, the time and workforce required for retrieving the working components
from the defective device are high which causes the delay in the overall production cycle. Also, it
affects the monthly target and results in a delay of shipment of orders. This whole process is carried
out manually, therefore the overall cost for the manufacturing of each device is raised drastically.

4. VARIOUS COMMERCIALLY AVAILABLE PROCEDURES FOR WELDING OF ABS
PLASTIC SURFACES

4.1. Laser welding.
In this type of welding, a high-intensity laser beam is focused with the help of mirrors or lens on the
area where the welding process is desired[12], as shown in figure 5. The laser beam generates heat at
the intersection. This results in the fusion of the cavities. Figure 5. Laser welding process [12]

The temperature created is much high, which when not controlled may cause damage to the
circuitry[13]. The cost of welding is much high due to the high consumption of energy and
maintaining a controlled environment.

4.2. Hot gas welding.
In hot gas welding, a hot stream of air is passed through the surfaces of two mating bodies and a filler
material is used for sealing of the two bodies[14].

4.3. Hot plate welding.
The parts are aligned using fixtures, later a heated plate is inserted at the intersection of two mating
bodies[15]. The parts are heated till melting points, the heated plate is then removed, and the two
cavities are pressed to an extent that the two bodies fuse. This method delivers a bond that is
airtight[16]. Figure 6 shows the process flow of Hot plate welding.
The main drawback of this method is the hot plate is in direct contact with the internal components.

4.4. Mechanical fastening.
Mechanical fasteners, shown in figure 7, contain screws, nuts, and bolts for holding the two bodies properly. It requires special arrangements or holes on one part for screwing it to the other part[16]. It is the cheapest method for attaching two cavities. But the major reason for the rejection of this method relies on the constraint that the case cannot be modified according to the requirement.

4.5. Adhesive bonding.
In this method, the surface for fusion is cleaned and a bonding agent is applied on the surface. The body is subjected to pressure for ensuring proper adhesion. Depending upon the material to be bonded[15], the adherent material is selected. The bond strength depends upon coverage of the surface area, the pressure applied and the tendency of the adherent to hold the body material.

5. METHOD ADAPTED
After thorough research of the methods available in the market, adhesive bonding was selected because of better bond strength, readily available and cost-efficient. For ABS material, mainly 3 types
of adhesives used namely cross-linked polymer adhesives, Epoxy resin bonding adhesive and polymerization adhesives[18]. The proposed and accepted adhesive was a polymerization adhesive named cyanoacrylate due to its adequate bond strength and cost-efficiency. Figure 8 shows a product named “Hi-Bond” which contains Cyanoacrylate adhesive. The proposed bond strength of the cyanoacrylate is 10-20 MPa[18] according to DIN EN 1465 which proves to serve its purpose.

![Hi-Bond (CyanoacrylateAdhesive)](Ayu Devices Pvt Ltd, IIT Bombay, Powai, Mumbai)

6. EXPERIMENT FOR COMPARISON OF THE BOND STRENGTH

6.1. Theoretical calculation.
For better bond strength, the device must withstand the impact after minor accidents.
For impact force, we can calculate the total energy which will be required to withstand the accident.

Total Energy = Potential Energy + Kinetic Energy

Therefore,
T.E = mgh + ½ mv²
Where m = mass of device = 79gm = 79 * 10⁻³ kg
g = gravitational pull = 9.81m/s²
h = height, the height is assumed to be 5.6 feet (the average height of man in India) = 1.70688m

Therefore,
Potential Energy = 79 * 10⁻³ * 9.81 * 1.70688 = 1.32282 joules
Assuming the same amount of kinetic energy is imparted on the device.

Therefore, the total energy required to withstand the minor accidents becomes,
T.E = 2 * Potential energy = 2 * 1.32282
T.E = 2.64564 joules

Taking the factor of safety as 3 for better results.
Therefore,
Final Energy imparted = T.E * Factor of safety
= 2.64564 * 3
= 7.93692 joules

6.2. Experimental check-up.
1. The surface is prepared using isopropanol solution.
2. 0.4 mL of cyanoacrylate is spread evenly covering the entire surface area of the intersecting faces.
3. For even bonding, the device is kept under a manual press machine, shown in figure 9, along
with the single cavity that was used in ultrasonic welding for better support and to avoid damage to projected components (viz. button, potentiometer wheel) and slight pressure is applied.

![Manual Press machine](image)

**Figure 9.** Manual Press machine

(Ayu Devices Pvt Ltd, IIT Bombay, Powai, Mumbai)

4. The device is kept for curing for about 2-3 hours.
5. Every 10 devices in the batch of 200 devices are tested by manual impact testing.

If 8 out of 10 devices withstand the impact test, then the batch is accepted for further quality testing.

7. RESULTS AND DISCUSSION.

Conversion of Joules to Pascal,
From the definition of Joule and Pascal[19], we can deduce that
1 joule of energy = 1 Pascal of pressure exerted (assuming unit area)
Therefore, theoretically, the minimum energy required to withstand the impact load (7.93692 joules) is far less than the minimum bond strength of cyanoacrylate for ABS material (10 MPa).
An increase in power backup by approximately 13 percent was observed in the battery discharge test.

7.1. Result of acoustic testing.
The acoustic testing is done of the frequency range of 80 Hz to 680 Hz. The acoustic test for the speaker with device code A10A124 is shown in figure 10. Figure 10a shows a graph of the speaker amplitude output in volts vs input frequency before adhesive bonding and figure 10b shows a graph of the speaker amplitude output post-adhesive bonding.
7.2. Result of manual testing.
A manual test was carried on 5 devices each with Ultrasonic Welding and Adhesive bonding and the number of tests passed by components is displayed in table 2 and table 3 respectively.

7.2.1. Ultrasonic Welding results.

| Tests                              | Pre-Ultrasonic Welding | Post-Ultrasonic Welding |
|------------------------------------|-------------------------|-------------------------|
| Impact                             | 5/5                     | 5/5                     |
| Led                                | 5/5                     | 4/5                     |
| Volume Control wheel               | 5/5                     | 5/5                     |
| Acoustic (with device kept on full volume) | 5/5                     | 3/5                     |
| Charging Socket                    | 5/5                     | 4/5                     |
| Battery Backup                     | 5/5                     | 4/5                     |
| Bluetooth unit                     | 5/5                     | 3/5                     |

7.2.2. Adhesive Bonding results.

| Tests                              | Pre-Adhesive Bonding    | Post-Adhesive Bonding    |
|------------------------------------|-------------------------|-------------------------|
| Impact                             | 5/5                     | 5/5                     |
| Led                                | 5/5                     | 5/5                     |
| Volume Control wheel               | 5/5                     | 5/5                     |
| Acoustic (with device kept on full volume) | 5/5                     | 4/5                     |
| Charging Socket                    | 5/5                     | 5/5                     |
| Battery Backup                     | 5/5                     | 5/5                     |
| Bluetooth unit                     | 5/5                     | 5/5                     |

Figure 10. (a) Graph of speaker output before Adhesive bonding. (b) Graph of speaker output after Adhesive bonding (Device code A10A124).

(Ayu Devices Pvt Ltd, IIT Bombay, Powai, Mumbai)
8. CONCLUSION

After an overall study from the research and the experimental data, we can conclude that
1. The bond strength of the adhesive bonding is approximately one-third of ultrasonic welding. But the strength delivered by the adhesive is more than adequate.
2. The components were not affected after bonding with cyanoacrylate as no vibrational loading was imparted.
3. The rejection percent was decreased drastically after the adaptation of the adhesive bonding technique.
4. The ultrasonic welding was conducted at a specialized facility, whereas adhesive bonding is carried out in-house due to which the time constraints became easier to follow.

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