TAM UX REPORT

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SUMMARY

The tracheal acoustic monitor (TAM) is a new medical device that monitors patients' breathing via a microphone placed over the trachea. This report outlines user experience goals and concerns, based on observations by the TAM team during a 2024 pilot study of the device's use in 100 endoscopy procedures at Lucile Packard Children's Hospital. It first describes the background of the device, including its motivation as an alternative to popular yet flawed monitors currently in use. Then, it gives an overview of the hospital operating room environment, describing the types of users who may interact with the device and what their roles are in the context of a medical procedure. It outlines five essential user needs– sterility, reliability, versatility, clarity and security– that should inform future TAM designs. In particular, this section highlights the need for the microphone "head" of the device to have clear and consistent contact with the patients' neck and the importance of creating a user interface that is as simple and streamlined as possible. In addition to these five essential needs, the subsequent section notes several other user interface issues– adhesion, single vs multi-use components, cost per use, integration with existing technologies, user education and customizability– that merit consideration while designing future iterations of the device. Lastly, the report includes two sketches of potential future device designs, describing how each improves upon the current design.

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BACKGROUND

The TAM

The tracheal acoustic monitor (TAM) is a new medical device that monitors patient breathing via a microphone over the trachea. It is based on a precordial stethoscope, a specialized stethoscope placed at the throat, that was popular among anesthesiologists in the mid to late 20th century but has fallen in use over the last few decades due to the rise of other breath monitors such as end-tidal CO2 (etCO2) and pulse oximetry (SpO2). While simultaneous etCO2 and SpO2 monitoring is currently considered medical standard, these monitors nonetheless leave gaps in the coverage and thus gaps in patient care. etCO2 detects the volume of carbon dioxide exhaled by a patient; however, this method works best when patients are intubated in a closed circuit, and can be inconsistent patients who cannot be intubated (such as those undergoing gastrointestinal procedures) and who must use more loosely-fitting masks and cannulas. SpO2 detects the level of oxygenation in the blood; however, a patients' oxygen levels can take up to a few minutes to drop after they stop breathing. Although practitioners also visually monitor patients to detect signs of breathing, attempts to breathe do not necessarily mean the patient is actually able to inhale; some patients may make "breathing-like" chest and mouth movements while experiencing an obstruction elsewhere in the respiratory tract. Hypoxic (low-oxygen) events during and after procedures can have serious consequences: one study found that occurrence of any hypoxemia within the first three postoperative days was associated with an increased risk of mortality in the year following a procedure; in severe cases, hypoxemia can lead to deterioration and permanent damage or organ function or death. Moreover, hypoxic events add to healthcare costs for both patients and providers: unplanned intubations and other complications from hypoxemia can lead to longer hospital stays and increased resource usage. Unfortunately, these events are common during procedures: an internal review of EGD cases at Lucile Packard Children's Hospital (LPCH) found that about 25% of patients experienced hypoxemia.

The TAM seeks to provide better information about the presence and quality of breaths than current methods by directly monitoring airflow through the trachea in a non-invasive manner. Currently, the device consists of a "head" placed on the patients' throat which contains two MEMS microphones: one facing in to capture breath sounds in the trachea and one facing out to capture noise from the operating room. In future, the outer microphone will be used to cancel environmental noise from the inner microphone, leading to a cleaner signal. The device "head" is held in place by a tracheotomy tie. It connects via a wire to an audio interface, which feeds into a computer running the open-source audio software Audacity which displays a spectrogram showing the patients' breathing. Eventually, the device will be wireless and connect to the computer via Bluetooth.

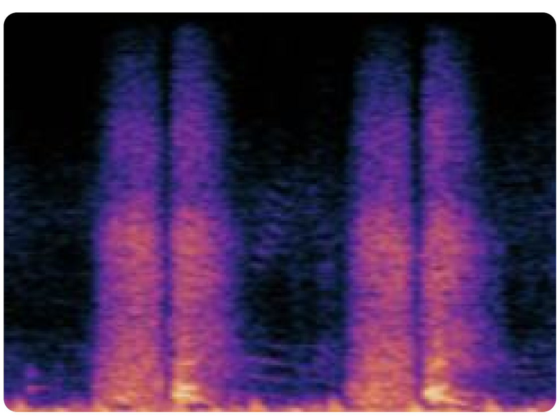
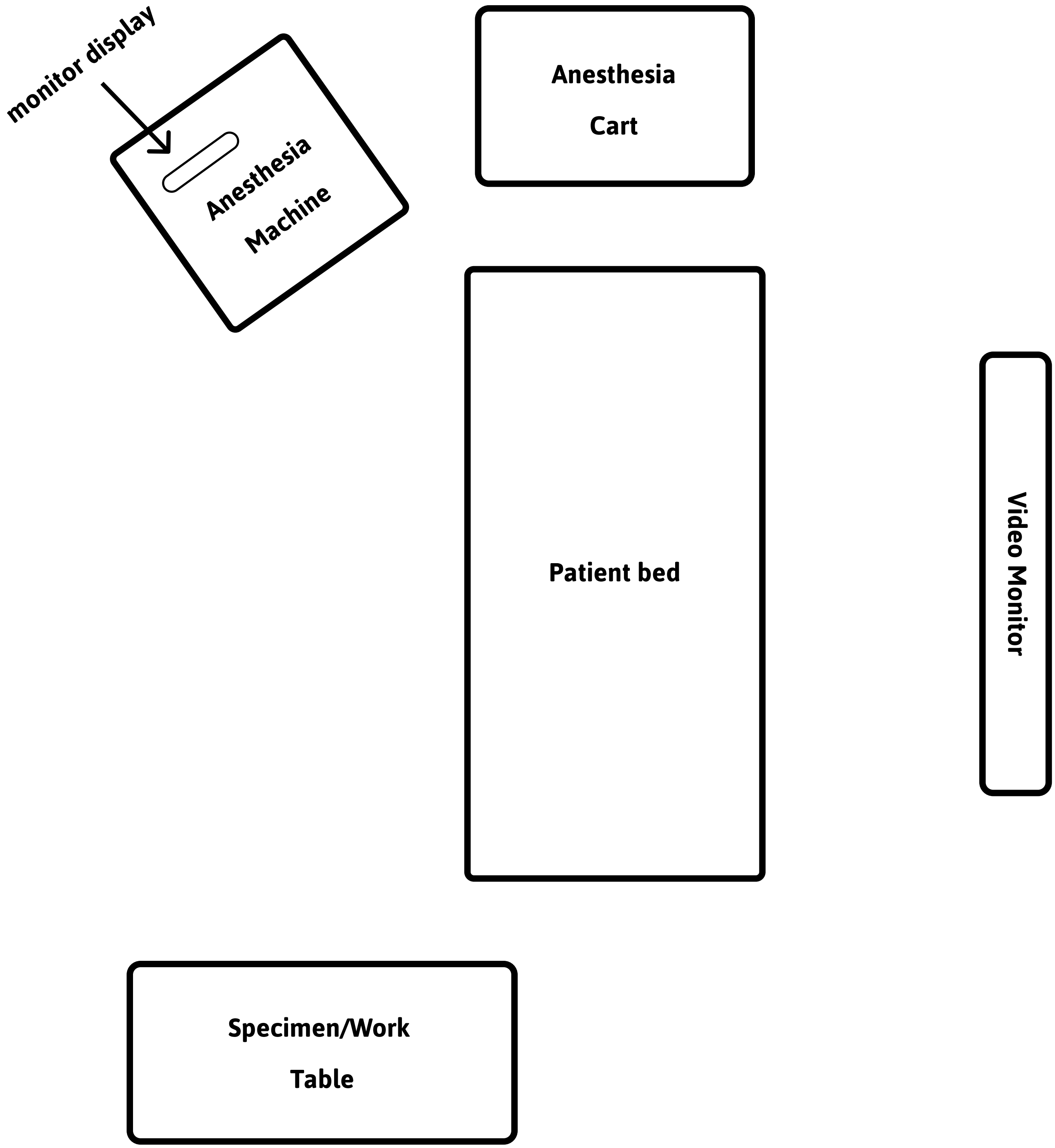


Figure 1: Breaths on TAM spectrogram display

Figure 2: The TAM device on a patients' neck

The OR

While there is a wide variety of potential applications for the TAM, including at outpatient clinics and in home care, the team is currently focusing on use of the TAM in hospital procedures where patients are anesthetized. Thus, we are concentrating primarily on its use in the operating room (OR) and secondarily on its use in the post-anesthesia care unit (PACU). A typical procedure room in LPCH is laid out like this:



Generally, the following people are on the OR team:

Anesthesiologist

The anesthesiologist is primarily responsible for the overall safety and comfort of the patient. In addition to administering anesthesia, the anesthesiologist monitors patient vitals, intervening when necessary.

Proceduralist

The proceduralist focuses on the specific procedure or surgery that the patient is receiving, concentrating on one part of the patient (i.e., just the knee in an ACL reconstruction or just the GI tract in an EGD).

Student Physicians

Fellows, residents and medical students shadow the attending anesthesiologist or proceduralist, sometimes conducting procedures or administering anesthesia depending on their level of training and experience.

Nurses

Nurses execute and assist with a wide variety of tasks, including assessing the patient before procedures, transporting and adjusting the patient, ensuring patient information and charting is correct and monitoring the patient during and after their procedure.

Anesthesia Tech

Anesthesia technicians clean, test and reset anesthesia equipment before each procedure.

Surgical Tech

Surgical technicians clean and reset the operating room before each procedure, maintaining sterility and ensuring sufficient amounts of accessible supplies.

A typical procedure entails the following workflow:

Anesthesia techs, surgical techs and nurses prepare room for procedure

Patient check-in

Patient arrives at hospital front desk and completes medical forms.

↓

Preop

Patient provides medical background to and is examined by a nurse. Proceduralist and anesthesiologist consult with the patient. Sometimes, patients are given preoperative sedatives.

↓

OR Transition

Patient is transported to the OR in a bed by a nurse and the anesthesiologist. Monitors are applied, and the patient is induced by the anesthesiologist.

↓

Procedure

The proceduralist works while nurses assist. The anesthesiologist monitors patient vitals, administering additional anesthetics and performing physical interventions (such as opening the airway) as necessary

↓

Postop

The patient is transported by the nurses and anesthesiologist to the post-anesthesia care unit (PACU), where they are monitored by nursing staff. When they are awake, the proceduralist consults with the patient.

The Study

The TAM team conducted a study of the effectiveness of the first-generation prototype device over a two month period in summer 2024. The monitor was used in over 100 pediatric GI endoscopy procedures at Lucile Packard Children's Hospital, with the primary goal of describing the sensitivity of the TAM relative to etCO2 for detecting airflow. Additionally, the team hoped to determine if there is a difference in the rate of hypoxemic events when anesthesiologists can view the TAM waveform. The design needs and considerations in the following sections stem from observations made by the team in the OR as well as conversations with anesthesiologists and nurses over the course of the study.

DESIGN NEEDS

Based on the observations of myself and the research team in the OR, all future device iterations should optimize for the following five essential user experience needs:

Sterility

Reliability

Versatility

Clarity

Security

Sterility

Sanitation is a major concern in the OR, and all equipment must be designed and used to minimize risk of healthcare-associated infections. Any items that come in direct contact with the patients, such as gas lines, breathing masks, cannulas, blankets, and gowns are replaced between procedures. All surfaces are wiped down. Future TAM designs should be easily cleanable or replaceable, feature non-porous surfaces and avoid ridges and crevices so as to minimize contamination risks.

Reliability

The TAM is intended to be used for early detection of adverse health events; thus, it must be extremely reliable. The device must maintain a consistent and constant signal, with a clear and interpretable flow of information. One of the major issues the research team encountered in this pilot study was the device shifting off of the center of the throat during procedures. Patients often move while being induced, frequently in powerful, jerky movements. Moreover, the medical care team moves patients during procedures, changing positions or placing equipment such as a bite block. The TAM must be able to both resist slipping and be sensitive enough to pick up signals despite disturbance. Future models should also be resistant to bending, pressure, and fluids and be compact enough to be easily stored within the OR or anesthesia tech rooms.

Versatility

The TAM is intended for use in a wide range of patients. Thus, it must attach comfortably to patients with different neck sizes; moreover, it must stay in place while the patient is in a variety of positions. One important feature of most OR equipment is that it is modular: large equipment is on wheels and can be moved around the room, small equipment is carryable and cables and lines can be attached and re-attached as needed. Accordingly, the TAM should be able to easily connect and disconnect from other equipment. In particular, the transition between OR and PACU monitoring should be as seamless as possible.

Clarity

In order for the TAM's output to be helpful, it must be clear. The OR is fast-moving and filled with potential distractions. In addition to visually observing the patient, anesthesiologists and nurses already have to manage distractions. In addition to visually observing the patient, anesthesiologists and nurses already have to manage three to four monitor screens surrounding them and a plethora of lines attached to the patient, as well as carts containing equipment and medications. Thus, future TAM designs should take care to be as simple as possible, utilizing well-contrasted colors and readable fonts with large waveforms/spectrograms and text. Practitioners should be able to glance at the monitor for a few seconds and get meaningful information from it. Furthermore, care should be taken to reduce alarm fatigue (i.e. only display auditory or visual signals when truly necessary) and clerical or charting tasks associated with the monitor.

Security

The TAM operates in a sensitive medical environment. It is possible that the microphone will pick up protected health information (PHI) or other details of the procedure. Therefore, all data must be securely processed, transmitted and stored.

DESIGN CONSIDERATIONS

Adhesion

Most current OR monitors mix single and multi-use components. For example, the heart rate, etCO2 and SpO2 monitors all have single-use sensors that connect to the patient; however, those lines connect into the anesthesia machine and all processing is done on that computer. Single-use components come in sterile packaging and reduce risks of contamination between patients; even so, they generate significantly more waste and may be more expensive over time than multi-use monitors.

Single vs. Multi-use components

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Cost per use

Cost per use will also be an important element of future designs. Ideally, the cost per use will be on par with or less than current breath monitors in order to encourage hospitals to use the technology.

Integration with existing technologies

Currently, patient monitors are routed through the anesthesia machine, a large piece of operating room equipment that facilitates ventilation, monitoring and medication administration. While LPCH uses Phillips machines in their operating rooms, other popular brands include GE and Draeger. Monitor outputs are displayed on a screen and readings are automatically input into charting software. The TAM should be able to either integrate directly with these systems or operate smoothly alongside them for ease of use and to facilitate adoption among physicians.

User education

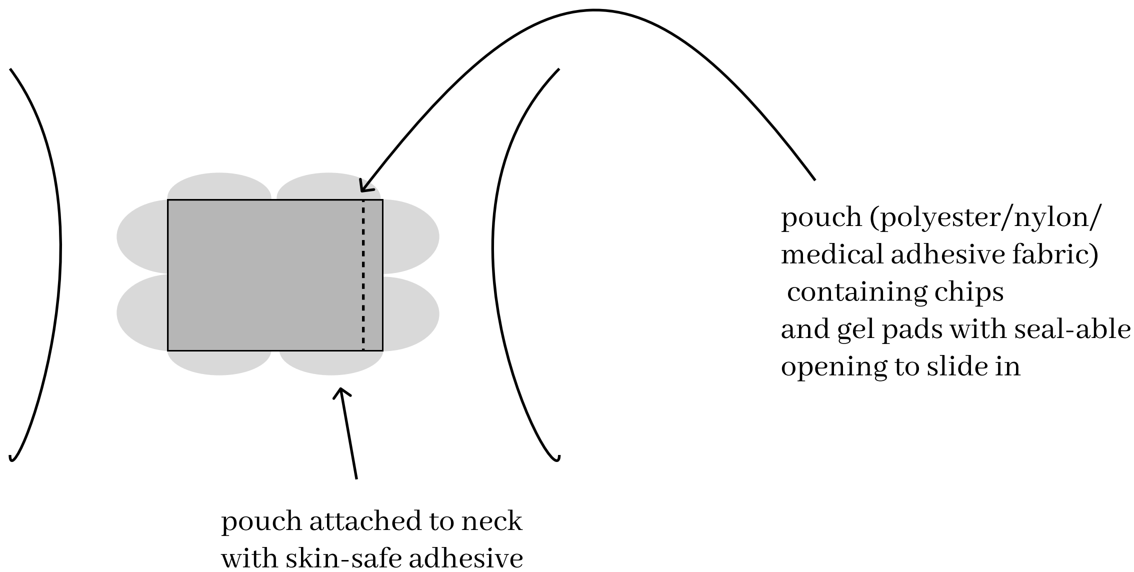
In our initial clinical tests we have had little to no user education. While the onboarding process should be smooth and relatively swift, it should include enough information for anesthesiologists and nurses to be able to identify a variety of breath sounds (for example, typical breathing, obstructed breath and speech/vocalization).

Customizability

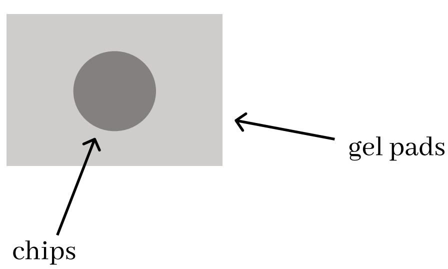
Different applications and practitioners may require different information from the device. In particular, future iterations should consider whether different users should be able to customize the level of information displayed on the TAM output, such as a basic, uniform waveform only setting and more advanced spectrogram settings, and the types of auditory cues and alarms delivered by the device.

DESIGN PROPOSAL 1

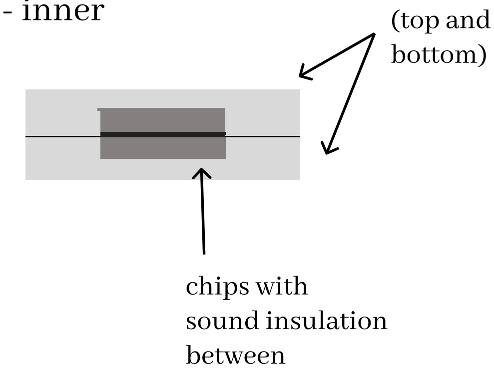
TOP - outer



TOP - inner



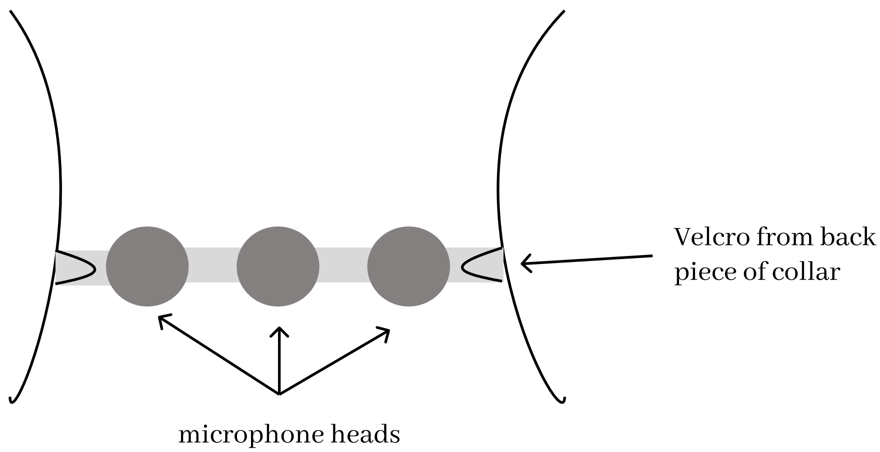
CROSS SECTION - inner



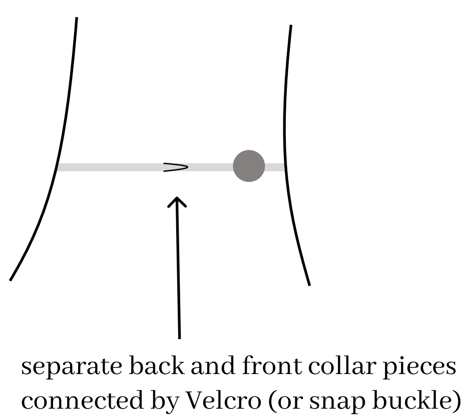
This proposed design consists of a microphone “head” comprised of two chips with sound insulating material in between, that are nested into two gel pads. The gel pads can then be slid into a fabric pouch which attaches to the patient neck via skin-safe adhesive. The microphone head and gel pads can be reused, while the fabric pouch can be changed between patients, maintaining sterility while reducing cost and setup time. Because of the gel pads and fabric casing, the device will fit flexibly around the neck on patients of different sizes while providing a strong signal, which can be sent via Bluetooth to a computer for processing and display.

DESIGN PROPOSAL 2

TOP



SIDE



This proposed design uses an array of three microphone heads instead of one; theoretically, if one microphone moved out of position or had poor contact with the patients' neck, the other two could compensate. However, this compensation would require either some "choice" algorithm, which would choose the signal from the microphone head with the best contact and placement to display to users, or a convolution algorithm combining the three inputs to create one super-output. Additionally, this design features a two-part neck strap, with one piece that can be laid on the patients' pillow before they lay down and another piece that can be draped over their neck.

USER QUOTES & SUGGESTIONS

- etCO2 was not showing output, but anesthesiologist commented that they could still see patient breathing on TAM
- Anesthesiologist specifically asked for iPad during control case
- "This contact is garbage" (in reference to poor contact due to loose neck strap)
- Patient breathing through mouth so etCO2 monitor did not work, but anesthesiologist commented they could still tell patient was breathing because of TAM
- "You're [technologically] in the 1960s, but you could get to the 2000s"
- Anesthesiologist asked for larger display of spectrogram on ipad (hard to read)
- Suggestion to place on side of throat to reduce sliding when patient lateral
- Suggestion that mic was not staying in place because wire weight was dragging it down
- The TAM is "very cool and actually saved" the anesthesiologist and his team "two cases ago"
- "Sweet!"

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