E4B Innovation Executive Summary

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Innovation title: US4All
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One Line Pitch: We aim to improve disease diagnosis in remote settings through user-friendly ultrasound imaging.

Project Summary: Ultrasound (US) has the potential to revolutionize diagnostic medicine, especially in emergent, rural, and global health settings. In the ER, deadly health crises can be immediately identified, without the need for expensive and time-consuming imaging exams that unnecessarily expose patients to radiation and require precious minutes before their treatment. In rural and global health settings, patients can have access to this rapid diagnostic ability at their nearest clinic, as the technology is portable and cost-effective. So what's stopping ultrasound from taking over the world? A huge barrier is the difficulty associated with both acquiring US images - orienting and maneuvering the probes to capture the underlying anatomical and physiological state - and interpreting the results, requiring detailed training. But what if point-of-care ultrasound (POCUS) devices could automatically determine if you are correctly looking at the target region or organ? We propose to create a software that gives any user, regardless of the level of training they have had with POCUS devices, the confidence that their images are accurate, reducing the barrier to the widespread adoption of POCUS technology. Our software will accomplish this by guiding the user as they maneuver the device, to inform them if they are indeed imaging their intended target. Furthermore, the software will provide basic interpretation of the results, which can be confirmed by a radiologist in-house or via a telehealth option if needed in rural settings. As a result, patients worldwide will receive faster, cheaper, more accurate results, where previously they may have had no realistic options.

Management: Two members of the management team (Alex Alvarez and Mahi Assefa) are MD students with burgeoning experience in the use and application of US imaging in clinical settings. Additionally, both have experience working in global/rural health settings with topics related to health disparities. Alex and the third member, Katie Sosnowski, are working toward their Ph.D. in Biomedical Engineering. Alex works in an US physics and imaging lab, and Katie has experience with point-of-care devices and machine learning (ML) algorithms that can be applied in remote settings. The team is also seeking talent in a few areas, especially in the application of ML in signal/image acquisition and multimodal image fusion (especially US and MRI). We are also seeking members of a Business Advisory Board who have experience marketing products.

End-user Problem: Rapid, accurate diagnosis of disease in remote settings (i.e., rural and global settings) is often difficult due to limited tools for diagnosis. Often, medical providers in this setting must refer patients to tertiary care centers in larger cities far away to make an appropriate diagnosis with complex, expensive imaging modalities (i.e., CT, MRI, PET, etc.) or lab work. This impedes beginning an appropriate course of treatment for the patients' ailments and requires significant transportation and financial barriers to such care. Due to its low cost and portability, POCUS has the ability to increase diagnostic precision in these remote settings. However, detailed training is required—specifically, a 23-day US rotation involving 150 US scans for ER physicians[1] or around 2 years of training for US technicians[2]. This barrier to care runs deep in most medical professions as physicians, nurses, EMTs, phlebotomists, and techs lack the skills and confidence to use these powerful devices, thus limiting their application.

Target Market: According to Prescient & Strategic Intelligence Market Research, in 2017, the global

[1] https://www.sciencedirect.com/science/article/pii/S0736467905002362
[2] https://www.allalliedhealthschools.com/medical-imaging/ultrasound-technician-certification/

POCUS device market generated $1.9 billion in revenue[3]. While this represents a large market, we believe that there is a much larger market of end-users who have not yet started using these devices due to lack of training. In 2010 in the US, there were 68,135 physicians providing medical care in rural areas in the US; additionally, there were 11,942 physician assistants, 444,688 RNs, and 38,984 EMTs/paramedics in such settings[4]. This number is just a small slice of the total number of low-, mid-, and high-level providers in remote settings globally. As such, we would first like to capture this market of end-users by addressing lowest-hanging fruit in this market - emergent and urgent diagnosis for end-users in remote settings (i.e., emergency medical services, community-based clinics, federally qualified rural health centers, etc. making significant life-or-death decisions) and the US manufacturers that serve their communities. After capturing this market, we can envision expanding our device to the larger group of providers in remote settings for all kinds of diagnoses. Additionally, an improved training device could revolutionize medical education in large urban and academic centers, expanding the eventual potential market even further.

Customer Validation: Our innovation has been validated from a variety of perspectives. Jeff Hersh, MD, PhD, CMO, GE Healthcare informed us that while software exists for helping users obtain high-quality images, there remains a problem with users not knowing if they are truly "looking at what they think they're looking at"[5]. Furthermore, Joshua Stilley, MD, EM Physician, MU Health told our group that "POCUS is great, but takes a lot of practice. The ability for the software to guide the user would be great for inexperienced providers"[6]. When asked if automated interpretation is useful for physicians even when they will ultimately make an overriding diagnosis, William Fay, MD responded: 'In the case of electrocardiography I think it's very useful…sometimes it catches things where I realize, 'Oh, I might not have noticed that!'…I haven't seen that as much in the ultrasound world…so I think what you have is a worthwhile approach." We also heard of the difficulties with the current educational platform from Deanna Dobson, an ultrasound technician in training: "We have been using…a simulator you plug into your cpu with software and it has pre-captured cases, it is kinda hard to use and takes some practice getting used to it"[7]. Therefore, we are confident that our educational/interpretation software will be quite useful for healthcare workers and allow for greater patient access to accurate diagnosis in settings where this may not currently be possible.

Technology Validation: Artificial intelligence has been widely applied in medical imaging for feature classification and automated diagnosis based on these features. While novel, extending the use of AI for coaching improved image acquisition will not require significant advances in the algorithms used. Additionally, as POCUS devices already exist on the market for safe diagnosis of disease, we envision that the application of our technology will be seamless.

Sales/Marketing Strategy: We plan to take a three-pronged approach to sales and marketing. The first mechanism will be to piggyback on the marketing that existing POCUS companies use. As our business model will be initially focused on licensing software to these companies, we will initially rely on existing strategies of marketing. The second prong of our approach will focus on advertising through medical societies (e.g., AMA, MSF, etc.) and scientific/society-based conferences (e.g., AMA EXPO, STFM). Finally, we will offer free POCUS training videos online as a mechanism for advertising our solution.

Business Model: Our initial business model will be focused on developing software that can be licensed and applied to all POCUS systems currently available. As technology with similar features made by Butterfly Network goes for $420/year,[8] we think customers would be willing to pay $100/year for an initial pilot version, and $400/year for the full version once it becomes available. Per

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[3] https://www.psmarketresearch.com/market-analysis/pocus-device-market

[4] https://www.ruralhealthinfo.org/assets/1275-5131/rural-urban-workforce-distribution-nchwa-2014.pdf

[5] Personal interview.

[6] Email correspondence.

[7] Text message correspondence.

[8] https://www.butterflynetwork.com/pro

a licensing deal, we will obtain a portion of that (we may suggest 70/30 where we obtain 70% of profits specifically attributed to our software).

Competitors/alternative solutions: Currently, the largest competitors are society-based training workshops that train medical providers in the use of US. Additionally, there are a few companies that have begun developing similar devices/software in specific settings. Caption Health ($60.9 million in funding,18 investors[9]) and EchoNous (active operating status, 17 registered patents, has FDA approval for KOSMOS platform[10]) have produced AI-based US acquisition software specifically targeted for cardiac imaging. Finally, the major medical imaging companies (GE, Philipps, Mindray, etc.) have active research and development and could be a big competitor in this market.

Competitive Advantage: Our competitive advantage lies in our team's combined and growing expertise in machine learning techniques, medical practice, ultrasound technology, and point-of-care devices.

Ethical Risk Assessment: A potential issue that this device could pose is its use as the only examination by a medical provider, or as the final authority where a radiologist is needed to identify false positives/negatives. We will limit this ethical risk by clearly stating the limitations of the software on its labeling and when the user first boots the system to use. Furthermore, we need to ensure a wide diversity of patient images are used as a training database, to prevent misdiagnoses due to insufficient inclusion of diverse patient samples images.

Risk Assessment:

Risk factor	**Risk mitigation strategy**
Users do not want to use new software	Talk with potential users to understand how their transition to our technology could be made seamless (i.e. what features can we make similar, how difficult is our pilot software to use, etc.)
Opposition from those invested in alternatives (i.e. ultrasound training programs, even the makers of other imaging modalities)	Partnership with some of these alternative providers will be key where possible. We can also subsidize software for existing training programs.
On the global/rural health front, POCUS devices aren't available yet in certain countries or regions and therefore we cannot target those end-users	Start by targeting companies serving regions that have POCUS devices available; if successful, these companies might have an interest in expanding with us to other regions
Companies do not understand how our solution differentiates itself and therefore do not see the value in partnering with us.	Talk with lots of people to understand the complications with current devices/software; create simulations demonstrating the difference between our software and available software

Use of Funds:

Source of funds	**Specific activity**	**Funds required**	**Deliverable**	**Delivery by**
?	Market technology to companies and users	$11,000	Convince companies to partner (obtain agreements)	August 2021
?	Hire personnel skilled in ultrasound, AI, programming	$90,000	Technology validation	August 2021
?	Purchase equipment for high-performance computing	$10,000	Technology validation	September 2020
Total initial funds		$101,000		

[9] https://www.crunchbase.com/organization/bay-labs-inc

[10] https://www.crunchbase.com/organization/echonous