AmDTx Manual for Patients

Contents

1. Background and product overview

AmDTx is a Class I SaMD (unregulated in most markets) mobile health platform, clinically validated to reduce symptoms of depression, anxiety, and stress, compared to placebo control, across a wide spectrum of mental illness severity in both adolescents and adults [1-8]. Patients extract clinical benefit via a range of psychotherapeutic options, and are able to improve their ability to self-assess their mental wellbeing by comparing personal inputs with objective measures obtained via computer vision and deep neural networks (a form of AI). Health data captured through the platform are securely delivered to clinicians via their institution's electronic health records infrastructure.

AmDTx has generated installs to the range of 100,000 worldwide and has a 4.9-, 4.9-, 5.0- and 5.0-star rating in Apple's Canadian, US, Switzerland, and Singaporean App Stores, respectively. AmDTx is available for free to you via your healthcare provider.

AmDTx provides you with a range of psychotherapeutic options. A large focus has been placed on medical-grade mindfulness meditation practices that are administered through several features accessible from the home screen (Figure 1).

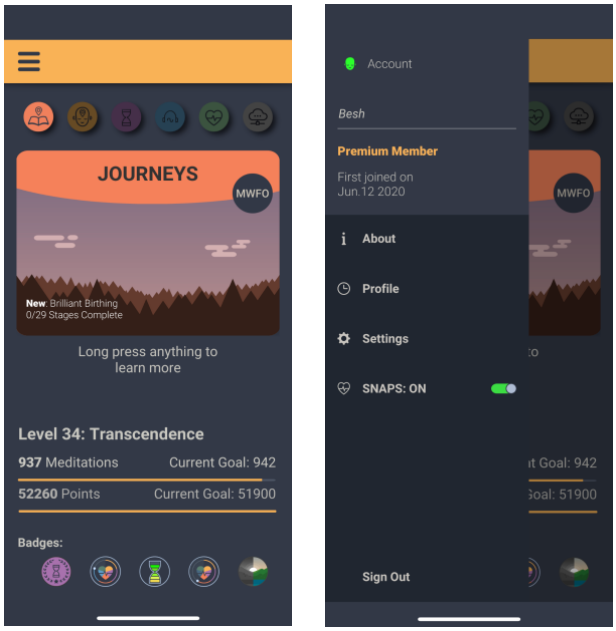

Figure 1 | AmDTx. Home screen (also called the "main menu"). At the top, you can select how to proceed. Shown here, the "Journey" option is selected. "My Insights" and other features are shown in Figure 2. While on the Home screen, you can press and hold on any item to receive a brief description of what that feature does. The three lines (or "burger" icon) at the top left open a sidebar (shown within the image on the right). The sidebar is where you can access the Settings, obtain more information about AmDTx, and view your Profile details, such as use statistics and the Badges you have earned as you engage meaningfully with AmDTx.

Unique to AmDTx as a mobile health platform is the inclusion of benchmarked digital biomarkers comprised of i) a fully objective quantification of stress through the mobile device camera, ii) a self-assessment of stress, iii) an implicit calculation of mood, and iv) free-form journaling. These elements of AmDTx are described in detail in Section 2.

AmDTx can be used to complete meditation sessions, or other forms of digitally delivered psychotherapy, via a variety of training features (Figure 2).

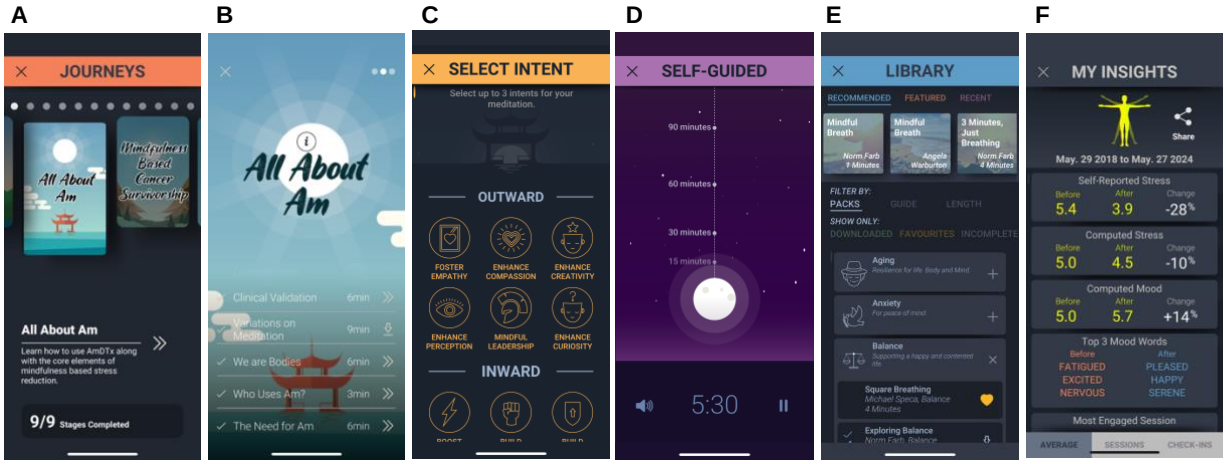

Figure 2 | Various means through which you can develop a personalised resilience practice. (**A**) Journey selection screen from which you can find step-by-step courses, including the course "All About Am" that serves as an introduction both to AmDTx and to meditation. (**B**) List of meditations and training sessions from the corresponding Journey. (**C**) The first page of the "My Moment" screen where you can tap on words and symbols that represent your personal aims for practicing, after which Am's algorithm will identify content specifically suited for your immediate desires. (**D**) A simple timer, animated by a moon setting into the sea. This feature is used to allow you to keep track of practices that you complete on your own (i.e., "Self-Guided"). (**E**) Am's full Library where you can directly access training content. The Library has several search filters to help you find what you like. You can also favourite content to easily locate practices that have resonated particularly well with you. (**F**) The "My Insights" page where you can view how each individual practice within AmDTx impacted you personally. You can also view the average impact that sessions have had on you (as shown in the image), as well as your wellbeing metrics captured during standalone "Check-Ins".

2. Digital biomarkers and other measurements

Objective Quantification of Stress. You can obtain a prediction of your level of stress via a 30 second "selfie" video captured with the front-facing device camera (Figure 3). Since the human heartbeat is partly controlled by the autonomic nervous system, and the autonomic nervous system is primarily what mediates the human stress response, heart rate data can be used to quantify stress. This is accomplished within AmDTx by determining your heart rate and heart rate variability through an algorithm developed by Mobio Interactive in collaboration with the University of Waterloo [9-11]. Meanwhile, the actual measure of stress is computed by a neural network that has 86% accuracy [12] in predicting the stress "quadrant" you are experiences at that moment in time. The quadrants are "none", "low", "medium", and "high". All recordings are completed within AmDTx, and no external devices are required. AmDTx will specifically request your permission prior to completing any recordings. Importantly, no video or image

data are stored or transmitted to the cloud. Instead, AmDTx does the required math in real time so that your privacy is protected.

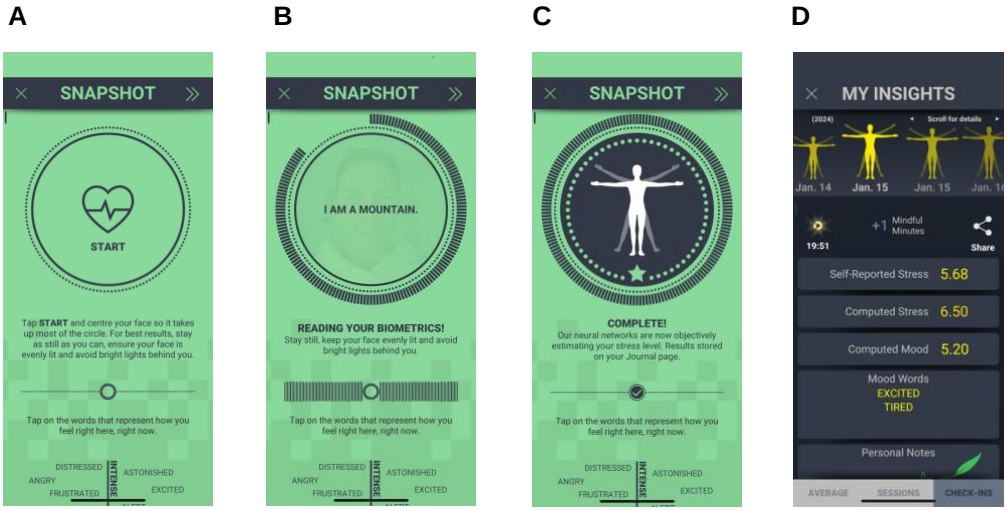

Figure 3 | Objective Assessment of Stress via a Selfie Video. (**A**) Initial screen provides you with simple instructions on how to use the feature. (**B**) While you are completing the 30 second selfie video, a riddle is overlaid, and an animation of the heart rate signal processing plays below the video. (**C**) Upon completion, you are informed that the results are being calculated and when ready can be accessed on within My Insights. Mobio Interactive has intentionally separated the reporting of results from the capture of those results so that you can focus on your practice without distraction. You can then continue with the rest of the "Snapshot" assessment (i.e., moodboard, stress-slider and free journaling). (**D**) On the My Insights page, you can view how your practice has affected you personally. Shown are the results from a Snapshot assessment prior to a Self-Guided Session. The objective quantification of stress is called "Computed Stress".

Self-Assessment of Stress. Stress is independently measured via a "stress-slider" tool (Figure 4), which is an example of an "ecological momentary assessment" (EMA). To use this tool, simply move the indicator on the slider to anywhere along the scale from "none" (0) to "extreme" (10). Alternatively, you can select any of the "stress faces" positioned above the slider. This stress slider measure has been demonstrated to correlate significantly with psychological surveys of wellbeing [1].

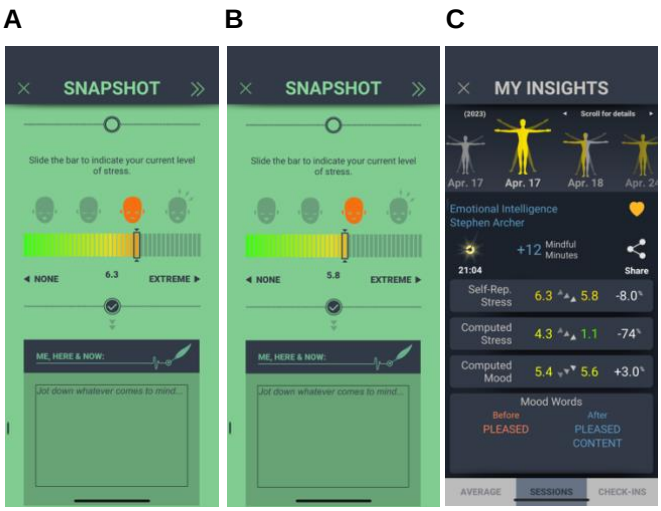

Figure 4 | Self-Assessment of Stress via a Stress-Slider. (**A**) Example of the stress-slider completed if you were to assess your stress to be "6.3" of the way between "none" (0) and "extreme" (10) before completing a session. (**B**) Example of the stress-slider completed if you were to assess your stress as "5.8" after completing a session. (**C**) On the AmDTx My insights page, you can view your responses for that individual session and compare your assessment with the objective results from the selfie video ("Computed Stress").

Self-Assessment of Overall Mood. Your overall mood can be measured via a custom "circumplex" or "moodboard", which is another example of an ecological momentary assessment. All you need to do is tap on the words that represent how you feel in the moment. The axes of the moodboard span from "mild" to "intense" and from "unpleasant" to "pleasant". A total of 32 words are available, arranged in four quadrants (Table 1). To convey meaning and make the tool more engaging, the moodboard is animated by an object that morphs in both shape and colour to your unique selection of words. Results of the implicit mood calculation are reported back to you on the My Insights page under the heading "Computed Mood" (Figure 5). The implicit measure of mood has been demonstrated to correlate significantly with psychological surveys of wellbeing [1].

Table 1 | Moodboard "mood words".

Quadrant 1 (top right)	Quadrant 2 (bottom right)	Quadrant 3 (bottom left)	Quadrant 4 (top left)
Astonished	Serene	Miserable	Distressed
Excited	Content	Sad	Angry
Alert	Calm	Depressed	Frustrated
Delighted	At ease	Droopy	Afraid
Amused	Satisfied	Gloomy	Nervous
Glad	Relaxed	Board	Alarmed
Happy	Sleepy	Fatigued	Tense
Pleased	Quite	Tired	Annoyed

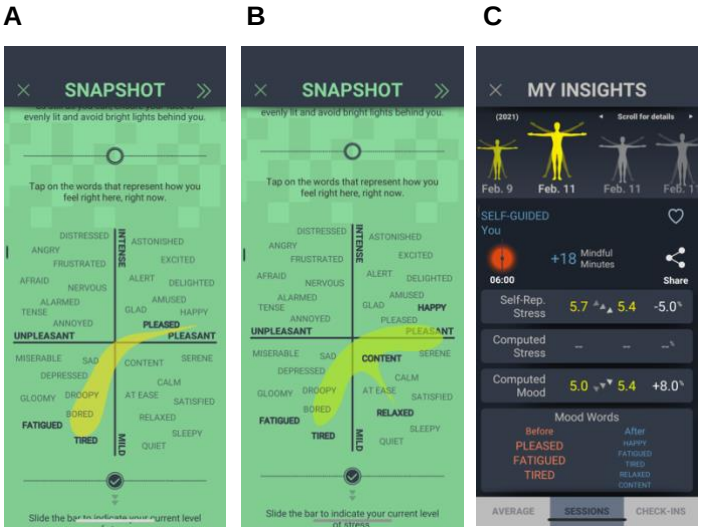

Figure 5 | The moodboard feature in AmDTx. (**A**) Example of the moodboard when selecting words "pleased", "fatigued" and "tired" before a session. (**B**) Example when selecting "happy", "pleasant", "content", "relaxed", "fatigued" and "tired" after a session. (**C**) The My Insights page showing your mood results (and other data) for this session.

It is also possible to input your intention (i.e., motivation) and current mood to rapidly find sessions that are appropriate for you in the moment. This feature is called “My Moment” within AmDTx (Figure 6). There are a total of 24 intentions, divided into two categories: “inward” and “outward” according to general focus of the guided session (Table 2).

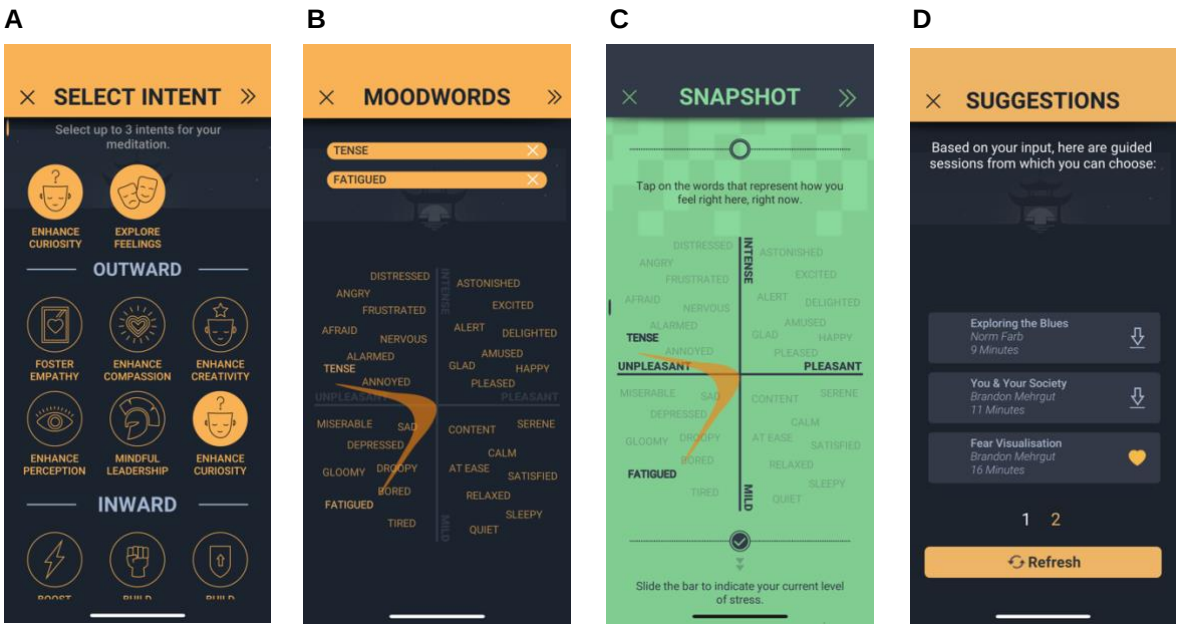

Figure 6 | The “My Moment” feature. (**A**) The screen where you input your intention behind completing a session at this moment in time. (**B**) Here you provide the second layer of input needed for AmDTx to search its library for content that will resonate with you in the moment. You can enter up to 3 mood words during this step. (**C**) You can then complete the usual Snapshot feature (note that the moodboard will be pre-filled with your selections from the previous screen). (**D**) With the input you provide, AmDTx provides suggested sessions to fit your current intention and mood.

Table 2 | Intentions.

Outward	Inward		
Foster empathy	Boost energy	Find Balance	Self-actualise
Enhance compassion	Build Discipline	Hone focus	Reduce anxiety
Enhance creativity	Build resilience	Increase endurance	Refresh
Enhance perception	Explore feelings	Injury recovery	Relax
Mindful leadership	Facilitate sleep	Know myself	Mind-body connection
Enhance curiosity	Feel good	Manage pain	Time to myself

3. Commitment and engagement data

AmDTx will automatically keep track of your "meaningful engagement" with the platform. Meaningful engagement is defined as activity within AmDTx that corresponds to psychotherapy training via Journeys, Library, My Moment, or Self-Guided features, as well as time spent in self-reflection and/or self-assessment via the My Insights and Snapshot features.

Depending on the healthcare provider through which you obtained access to AmDTx, special reminders to engage may also be pre-programmed and received to your mobile device using push notifications. These playful nudges are intended to help you benefit from AmDTx and are a private and personalised way for you to receive additional coaching.

Also again depending on the particular healthcare provider that has made AmDTx available to you, daily engagement data may be shared with your physician, and your physician may choose to use these data in assessing your best treatment options. If you are taking part in a research trial, then the study team will also be able to review your meaningful engagement data on a near real time basis.

Engagement data are recorded to determine what forms of content are most impactful for you personally. That is the ultimate power of this platform: The ability to understand what matters most to you, and get that material to you in the most convenient and effective way possible.

Points (Table 3) and badges (Figure 7) are provided to support your engagement.

Table 3 | Calculation of points within AmDTx.

Form of Engagement	Points Earned	Form of Engagement	Points Earned
Guided, or Self-Guided Session	2 per minute	Face scan (selfie video)	5
Self-Assessment (Snapshot)	2 per minute	Invite a friend	20
Self-Reflection (My Insights)	2 per minute	Contact us	10
Snapshot element (Stress slider, Moodboard, Intend board)	1 each	Rate the app	50

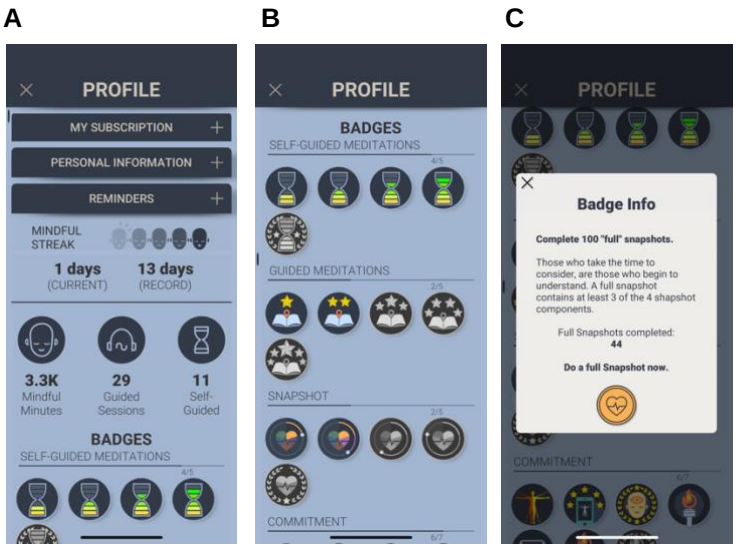

Figure 7 | Badges. To reinforce meaningful engagement, you are rewarded with various badges to mark your progress. (**A**) Locate your list of Badges on the Profile page. (**B**) Badges are organised in groups according to various types of goals. (**C**) When you tap on a Badge, a popup opens to provide a description of how that badge can be earned along with a one-tap button to access that individual feature. Badges thus double as a simple navigation tool.

4. Your confidentiality

All data are collected in a de-identified fashion. If you are taking part in a study, then only a unique participant ID# is stored, as it is required to link AmDTx data with data that researchers may be obtaining from you. If that is the case, then the key to the ID# file is kept in a separate encrypted file with the researchers (not with Mobio Interactive). All data collected by AmDTx are stored in one of Mobio Interactive's secured servers, and always in the legal jurisdiction where you are located. Mobio Interactive is not able to identify you, even if you are taking part in a research study. All data collection through AmDTx is done so in accordance with HIPAA, PHIPA, GDPR, as well as any additional local regulations that may apply. No audio or video from the phone is ever transferred or stored. Any data that could identify you (e.g., your account email) are encrypted ("hashed"), while simultaneously converting the information into unique tokens that are used as self-destructing anonymous identifiers. For more information, we welcome to you access the Mobio Interactive Privacy Policy.

5. References

1. Walsh, K. M., Saab, B. J., & Farb, N. A. (2019). Effects of a Mindfulness Meditation App on Subjective Well-Being: Active Randomized Controlled Trial and Experience Sampling Study. *JMIR Ment Health*, *6*(1), e10844. https://doi.org/10.2196/10844

2. Bergerot, C., Bergerot, P., Molina, L., Lee, D., Philip, E., & Bultz, B. (2022). *Psycho-Oncology and the Relevance of a Biopsychosocial Screening Program*. *36*, 552–556.

3. Bergerot, C. D., Malhotra, J., Bergerot, P. G., Philip, E. J., Govindarajan, A., Salgia, S., Hsu, J., Matos Neto, J. N., Molina, L. N. M., Vasconcellos, V. F. de, Muddasani, R., Chawla, N. S., Castro, D. V., Chehrazi-Raffle, A., Saab, B., Carlson, L. E., & Pal, S. K. (2022). Prospective assessment of a smartphone-app based mindfulness program for patients with metastatic renal cell carcinoma (mRCC). *Journal of Clinical Oncology*, *40*(6_suppl), 324–324. https://doi.org/10.1200/JCO.2022.40.6_suppl.324

4. Bergerot, C. D., Philip, E. J., Bergerot, P. G., Siddiq, N., Tinianov, S., & Lustberg, M. (2022). Fear of Cancer Recurrence or Progression: What Is It and What Can We Do About It? *American Society of Clinical Oncology Educational Book*, *42*, 18–27. https://doi.org/10.1200/EDBK_100031

5. Hood, P., Ramachandran, M., & Devitt, R. (2022). Growing pains: Lessons learned from a failed mobile mindfulness clinical trial for patients with complex care needs. *Contemporary Clinical Trials Communications*, *26*, 100858. https://doi.org/10.1016/j.conctc.2021.100858

6. Patel, A., Calahong, B., Dhawan, M., Leynes, L. P., Daros, A., Saab, B., Quilty, L. (2023, June 20). Effects of a Mindfulness App for Outpatients Waitlisted for Psychological Interventions [Poster presentation]. 2023 Society for Digital Mental Health Annual Meeting, Virtual meeting

7. Subnis, U. B., Farb, N. A., Piedalue, K.-A. L., Speca, M., Lupichuk, S., Tang, P. A., Faris, P., Thoburn, M., Saab, B. J., & Carlson, L. E. (2020). A Smartphone App–Based Mindfulness Intervention for Cancer Survivors: Protocol for a Randomized Controlled Trial. *JMIR Research Protocols*, *9*(5), e15178. https://doi.org/10.2196/15178

8. Garrett, B.M., Tao, G., Taverner, T., Cordingley, E., & Sun, C. (2020) Patients perception of virtual reality therapy in the management of chronic cancer pain. *Heliyon*. 6(e03916). https://doi.org/10.1016/j.heliyon.2020.e03916

9. Chwyl et al. (2016). A Bayesian Multi-Scale Framework for Photoplethysmogram Imaging Waveform Processing. *Journal of Computational Vision and Imaging Systems, 2*(1). https://doi.org/10.15353/vsnl.v2i1.114

10. Chwyl et al. (2016). Time-Frequency Domain Analysis via Pulselets for Non-Contact Heart Rate Estimation from Remotely Acquired Photoplethysmograms. *Computer and Robot Vision, 13th Edition,* 201-207. http://doi.ieeecomputersociety.org/10.1109/CRV.2016.45

11. Chwyl et al. (2016). SAPPHIRE: Stochastically Acquired Photoplethysmogram for Heart Rate Inference in Realistic Environments. *IEEE International Conference on Image Processing (ICIP),* 1230-1234. https://doi.org/10.1109/ICIP.2016.7532554

12. Al-Jebrni, A. H., Chwyl, B., Wang, X. Y., Wong, A., Saab, B. J. (2020) AI-Enabled Remote and Objective Quantification of Stress at Scale. *Biomedical Signal Processing and Control*. 59(05/2020: 101929) https://doi.org/10.1016/j.bspc.2020.101929