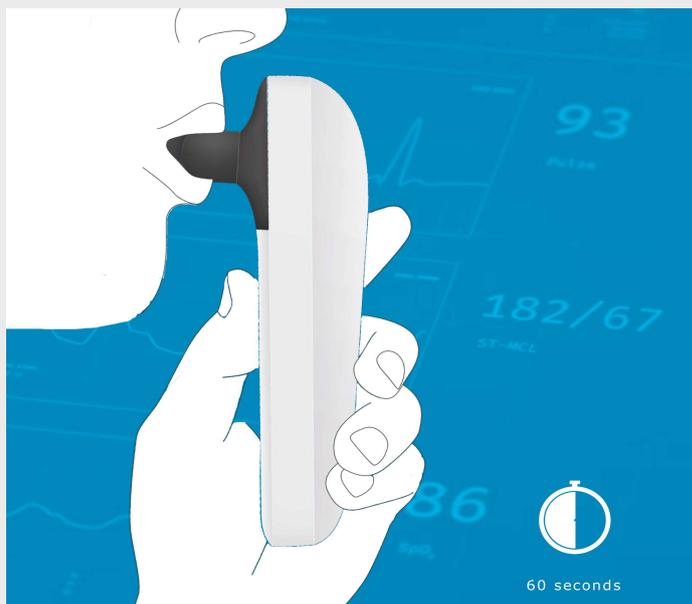


The first check-engine light for people

FROM HAVING A DREAM TO MAKING A DIFFERENCE





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Few products can make a bigger difference to the lives – and *quality of life* – of people than medical devices.

But however promising an idea and passionate a vision a medtech startup has, in this regulated and challenging industry there is no easy way to getting that life-changing product to the patients.

Or maybe there is. **iO life science** is dedicated to being one.

small startup – big vision

Baltimore-based medtech startup Multisensor Diagnostics (MDx) has ambitious dreams and visions. MDx aims to simplify healthcare for high-need patients and empower them through personalized, home-based care. Their patent-pending, handheld technology enabling rapid health assessment of individuals is envisioned to deliver just that and become the first marketed ‘check-engine light for humans’.

When placed in the mouth by a patient like an inhaler, MDx’ flagship device, the MouthLab, can provide eight different health indicators in less than a minute through analysis of breath, saliva and mucous membrane. And the concept holds huge potential for incorporating further parameters and even biomolecular analyses in the future. Measurement of blood glucose levels for diabetics as well as detection of kidney failure and even oral, lung and breast cancers are expected capabilities for future product generations.

from reactive to proactive health interventions

The use application is also something that MDx hopes to expand with time. Their long-term vision is to contribute to a change in the very *culture* of healthcare monitoring; the paradigm shift to *preventive medicine*. Allowing – and encouraging – not only chronically ill patients but even the healthy population to observe their health to this degree in a proactive and approachable way is a natural next aim for MDx. This could potentially improve general welfare significantly through more extensive prevention and early diagnosis of serious disease.

With a widespread adoption of the MouthLab device and its successive generations, many hospitalizations and surgeries can be avoided, and the success rate of treatments increased.

This vision resonates very well with that of **iO life science**. The founder of iO, Rajan Patel, has dedicated his entire professional career to advancement of medical technology. After more than 30 years in the medical device industry, **iO life science** as a consultancy is the embodiment of Mr. Patel’s personal belief in a strictly patient-centric, leading-edge approach to design of healthcare technology.



a perfect match

In 2017, with a small team consisting of just the two founders, MDx was on the lookout for external R&D expertise. After more than three years' intense development of the MouthLab, Sathya Elumalai and Gene Fridman had a functional lab bench prototype ready, but needed assistance to get to the next stage. Their hand-built mockup was effective, but unattractive and fragile, and therefore neither well-suited for product demos for potential users and customers, nor for investor presentations.

One of MDx' business advisors introduced the startup to **iO life science**. This turned out to be the beginning of a close collaboration centered around the common passion to make a difference by improving patient care.

For MDx, the first encounter with **iO life science**, an initial Discovery Workshop for which the cross-functional **iO** team flew into Baltimore, marked a change in the way of seeing external collaborations - and their core product. *"After two days of intense project discussion and requirements gathering process, we realized we found a strategic partner more than a device developer", says Mr. Elumalai, who is the CEO of MDx. "The scope of the project dramatically changed once we realized the potential of iO's team in not only changing the look of the device but the efficiency and user experience"*.

good design goes well beyond aesthetics

iO life science is often met with a client request to transform a medical technology into a nice-looking product. *"However", says founder, Mr. Patel, "the secret behind a successful device is a more holistic and integrated approach including focus not only on effectiveness and aesthetics, but also on optimal use flow and user experience, maintainability, service, education material, and many other aspects. This is how we go about it at iO"*.

From believing their main need was a facelift of the existing MouthLab prototype, through the encounter with **iO** MDx recognized the value of a more extensive and deeper approach. The initial teamwork between **iO** and MDx revealed to the startup that a full redesign and restructuring of internal components would be extremely beneficial and even enable additional, high-value functionality and a better user experience to be designed into their device.

faster iterations, cheaper learnings

Conducting design changes at this early stage is usually relatively straightforward and inexpensive, and this is why **iO** are generally eager to be involved from early-stage development.

"At this point there is a great inherent potential to shape both the product architecture and the hardware and software user interfaces to facilitate the optimal user and patient experience for a medical device", says Operations Lead and Systems Engineer at iO life science, Barney Gerrard.

This is a discipline that **iO** has practiced through years of working with medtech startups, uncompromising in their user-centered and integrated design approach.



Many of iO's previous clients have done exactly like MDx; utilized iO's broad product development capabilities and agility to take a concept or immature technology quickly from the lab bench to a demonstration device and into the hands of potential users and investors. The partnership with iO has led to a solid foundation for further refinement of the product concept, reducing risk of late, expensive design modifications.

a winning, virtual alliance

On a practical level, the collaborative work between the MDx and iO teams was executed based on weekly WebEx meetings. *"The efficiency of using this method to work remotely was only just realized after we started our collaboration with iO"*, says Dr. Fridman, CTO, explaining how the interdisciplinary work was facilitated after the initial workshop.

The efficiency meant that even the additional functionality to be designed into the MouthLab demo device did not postpone the project, and the joint efforts enabled MDx to meet a very tight deadline to pitch for a major partnership and funding opportunity – and convincingly secure this.

During the first year of the collaboration between iO and MDx, the startup has won several competitions and awards for their product under development, amongst them *Bridging the Gap Award, Tech10, New Space People's Choice Award* and *M2D2 Boston*. The attention and publicity created via pitching and presenting throughout the U.S. has eventually enabled MDx to find commercial partners and fund the next product iteration which will result in a marketable version of the MouthLab device.

together towards the end-goal

Mr. Elumalai and Dr. Fridman have also chosen iO to be the development partner managing and executing this next project phase. The iO team will be responsible for updating the mechanical and electronic design, development of firmware, software and the graphical user interface of dedicated web and mobile phone applications. All of these design components will be implemented in, or integrated with, maturing prototypes for technical testing and user testing throughout the development. The iO team will furthermore manage the documentation of the process necessary for obtaining FDA approval to market the device and accessories.

MDx are excited to have iO on board once again. Mr. Elumalai is not in any doubt about how much the encounter with iO has meant for MDx and their flagship product, which is maturing and getting closer to making its way – and a difference – to chronic patients around the world. *"I would recommend iO and founder Rajan Patel to anyone in the industry looking for a reliable developer who can buy into the vision of your company and translate that vision into reality"*, he concludes.