UPGRADING RESPIRATORY CARE WITH AI-POWERED SENSORS AND TRUE ADHERENCE DATA

In this article, Martijn Grinovero, Co-Founder and Chief Commercial Officer of Amiko Digital Health, and Fabian Schütte, Business Development Manager at Sanner GmbH, describe the potential of artificial intelligence-powered sensors used in combination with standard inhalers to upgrade respiratory therapy, and introduce Respiro®, an innovative digital health platform solution for respiratory care.

Digitisation has opened entirely new ways of interacting in all areas of our lives. Even in the pharmaceutical and healthcare sector, which has a tendency to be rather conservative, we are witnessing drastic changes. Digitisation makes improvements possible across a multitude of therapeutic areas. Conventional therapy can now be upgraded significantly with connected devices. Take respiratory health for example. With more than 300 million people affected by asthma globally, and 100 million suffering from COPD, treatment costs amount to over €80 billion (£70 billion) in the US[1] and Europe[2] each. Most of these costs result from complications and hospitalisations, most of which could be prevented through more adequate treatment.[3]

CONNECTED THERAPY HELPS PATIENTS AND HEALTHCARE PROFESSIONALS ALIKE

Developing new forms of treatment is challenging enough, and there are very sophisticated methods already available. However, it is not sufficient. To achieve more adequate treatment of asthma and COPD, we need to realise that no matter how sophisticated a method is, most patients struggle to follow their treatment plans, to administer their medication correctly and to support their treatment in

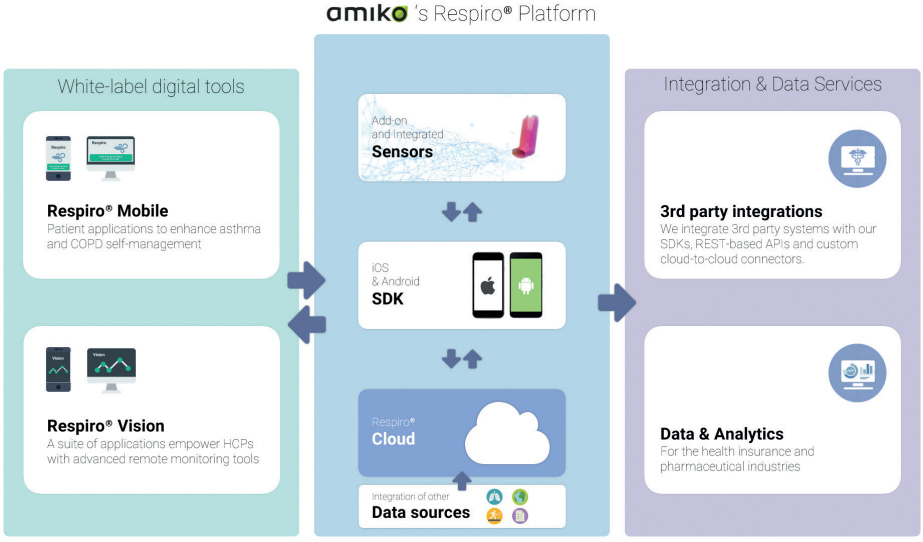

Figure 1: An overview of Amiko's Respiro platform.

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everyday life. On the other hand, physicians often lack the tools and the information to understand their patients' state of health, whether they are following their treatment plan and – most importantly – whether they are taking their medication in the correct way. This hinders them in finding the best therapy for each individual patient. This scenario suggests that rather than simply offering incrementally better medicines, we need new ways of delivering and upgrading respiratory care and activating patient self-management.[4]

Connected therapy has the potential to tackle the most important needs in respiratory care. First, it is about engaging patients and facilitating the process of self-management, for instance with technologies that track and guide optimum medication use. Connected therapy is designed to improve the patient experience with functionalities that are aligned to patients' needs, such as reducing the burden of disease management, and to facilitate greater self-care and self-activation. Second, it is about making sure that healthcare professionals receive the right information they need to make timely, evidence-based decisions. This can be facilitated by tools that provide real-time data on medication usage and patient health. Based on advanced real-time data, treatment can be personalised to optimise individual treatments and maximise health outcomes.[5] Furthermore, the possibility of real-time adjustments enables the shift from reactive to preventive and predictive medicine. This will ultimately lead to better clinical and economic outcomes.

HEADING TOWARDS TRUE ADHERENCE

Respiratory medicine is at the forefront of the digital healthcare wave. Several connected drug delivery solutions are already approved and marketed, including both add-on and embedded designs for inhalers. Some of these solutions have demonstrated the ability to increase adherence to asthma and COPD medication in clinical studies. This is a promising first step, since the success of any medication depends on the individual patient's adherence to the dosing regimen, and at least 50% of all patients do not take their daily medicine as prescribed. However, the delivery of respiratory medications is mainly achieved by inhalers, which require several, often complex, steps for administration.[6] Each device has specific instructions on how it must be used, including pre-actuation steps (for instance removing the protective cap or pushing a lever) to ensure successful actuation and reliable drug delivery.[7]

Figure 2: Making inhalers smart with Respiro Sense (a), either as add-on device (b) or integrated solution (c).

> "Currently available inhaler solutions only capture adherence information, and do not assess the way in which patients use their devices."

Most patients make drug delivery technique errors leading to significantly decreased levels of medication efficacy, even if they take the right dosage. These technique errors compromise both drug delivery and the overall treatment effectiveness, increasing the risk of severe exacerbations and hospitalisation for patients with asthma or COPD. Hence, a solution is required that combines the measurement of both adherence and technique, in other words, a solution that provides a measurement of true adherence, reflecting the actual inhaler use. Yet currently available inhaler solutions only capture adherence information, and do not assess the way in which patients use their devices.[4]

RESPIRO – LEVERAGING THE POWER OF TRUE ADHERENCE DATA

Appropriate monitoring is crucial to find out whether patients adhere to the prescribed regimen and whether they use the correct drug delivery technique. True adherence can only be achieved by monitoring both factors: correct dosing and correct inhaler technique. Detailed information about true adherence in both research and real-life settings is essential for a better understanding of the use and the effectiveness of an inhaled drug therapy. This information is also important for the development and assessment of personalised interventions promoting adherence and correct inhaler technique. With Respiro, the digital health company Amiko has developed such a solution, which we will introduce in detail in the following paragraphs.

Amiko was founded in 2015 and develops solutions to enable the transition from conventional to connected therapies. The company's first commercial product is Respiro® (Figure 1), a complete, CE certified digital platform that uses proprietary sensor technology to collect true adherence data from respiratory medication use, offering both tools and analytics to maximise the value of this data, so that actionable insights can be derived for patients, healthcare providers, pharmaceutical producers and payers. Amiko's Respiro platform received the first prize at the prestigious IBM Watson AI XPRIZE's annual Milestone Awards (2017). All sensor devices and software tools are developed under Amiko's ISO 13485:2016 quality management system and are designed to meet current and future security and privacy requirements, including the 2018 EU General Data Protection Regulation (GDPR) and the US Health Insurance Portability and Accountability Act (HIPPA), of 1996.

The Core: Sensor Technology

At the core of the platform is the patented Respiro Sense technology, which powers Amiko's sensor solutions for respiratory medications. The technology is suited for both add-on and integrated smart inhalers, where low power consumption and cost-efficiency are key factors (Figure 2).

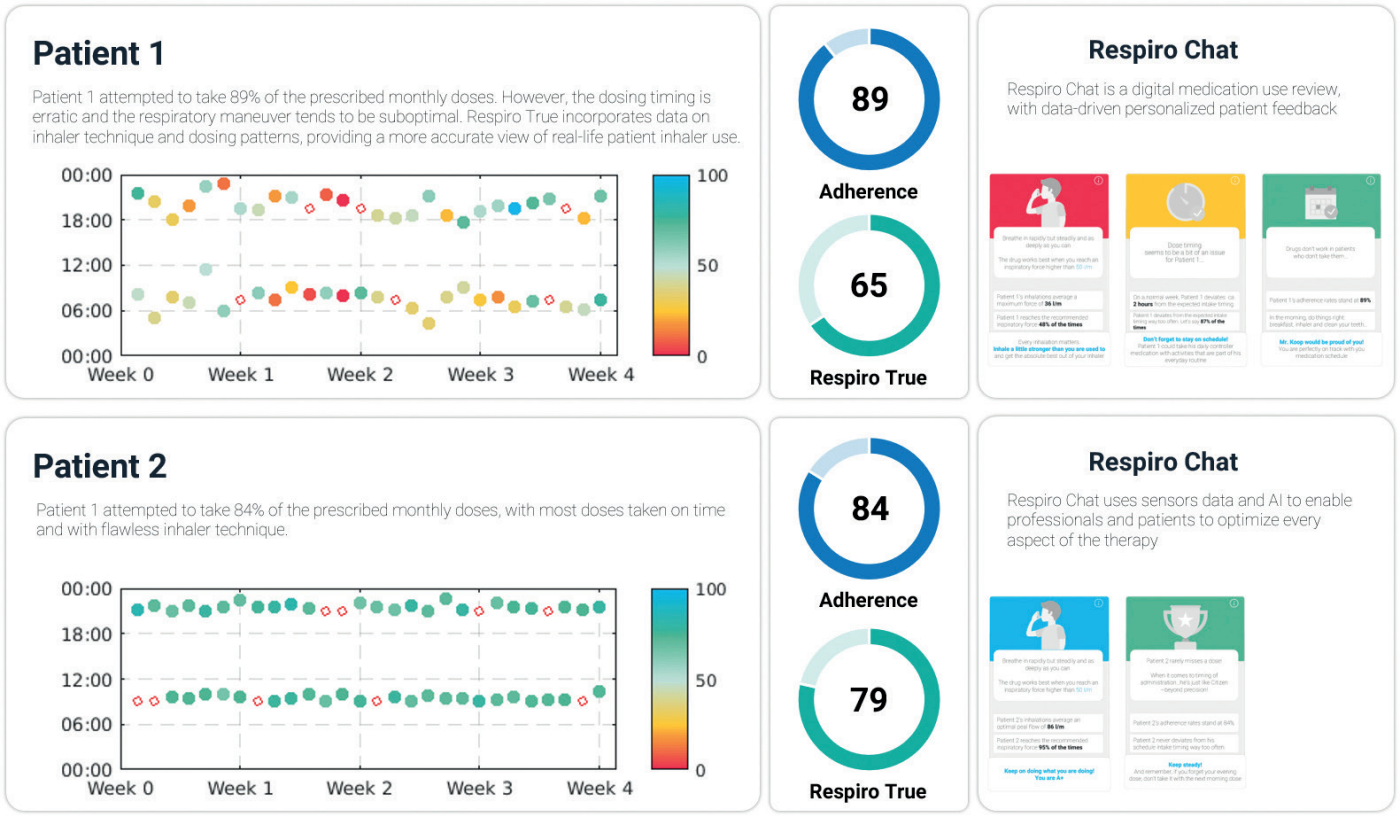

Figure 3: Respiro True is a novel adherence metric that expands the traditional measurement of adherence with data on inhaler technique and dosing patterns.

The sensors automatically track data on the entire respiratory manoeuvre, including data on inhaler technique to record when, and how well, patients use their inhalers and to help monitor lung health. Most importantly, patients do not need to change their accustomed therapy, but are supported in optimising how they use their inhalers: the same steps are used to inhale the prescribed dose, the delivery path is not interrupted, and they receive the same handling and delivery performance.

The Respiro sensors run real-time machine learning algorithms, which demonstrate the advantages of using artificial intelligence (AI) with end devices, integrated within a medical product. The collected data is processed, stored and encrypted independently on the sensor device. This approach is beneficial in terms of functionality, security, cost and power consumption. The device can offer active guidance to patients while they are using their inhaler. It can issue smart dose reminders and improve the quality of the inhalation technique. Further, the device can apply advanced cryptographic techniques without significantly impacting the power drain of the overall system, while ensuring an optimal degree of cybersecurity and data privacy. The costs associated with data persistence and storage are minimised. Finally, battery life is extended with fast and affordable over-the-air data transfer. In a nutshell, the Respiro Sense technology delivers a solution that fulfils the requirements of optimal power consumption and low sensor production cost, with the flexibility to seamlessly add new features to deliver ever more reliable and detailed results.

USING DATA AND AI FOR BETTER TREATMENT OUTCOMES

The Respiro platform uses data and AI to assist healthcare professionals and empower respiratory patients to achieve better treatment outcomes. The data collected and processed by the sensors flows into the Respiro cloud, which is designed to evolve continuously with therapeutics, patient-reported, behavioural, physiological and environmental data (Figure 3). The system suggests the optimum therapy path and the right level of healthcare resources for each individual, thus reducing costs and increasing therapy effectiveness. It does so by identifying and quantifying adherence and inhaler technique, and by identifying the correct choice of inhaler device. It further enables accurate, remote, real-time case prioritisation for early prediction and prevention of disease exacerbations. Advanced insights on medication use and effectiveness are made available, too.

Interactive digital tools create a more personalised, connected care experience and simplify self-management, encouraging patients to engage in their own therapy. Amongst these digital tools is a patient diary to track different asthma and COPD medications, symptoms, triggers, peak flow measurements and flare-ups. Personalised support and data-driven feedback help improve adherence and inhaler technique, while patients receive medication reminders and have a channel for enhanced provider-patient communication available. Clients can choose to offer Amiko's Respiro end-to-end service as a white label solution or use the data services built on flexible representational state transfer (REST)-based application programming interfaces (APIs), Android and iOS software development kits (SDKs) and custom connectors for legacy system requirements (Figure 4).

A PARTNERSHIP FOR TRUE, SMART ADHERENCE

In January 2018, Amiko and the primary packaging and device specialist Sanner announced their development and

commercial partnership to expand Amiko's Respiro portfolio. Sanner was founded in 1894 and is an established partner to global pharmaceutical companies in the design, development, industrialisation and manufacturing of custom-made drug delivery and dosing systems for powders, solids and liquids. Sanner's portfolio and expertise ranges from primary packaging solutions to mixing devices, injection and application systems. For the respiratory care sector, Sanner develops and manufactures nicotine substitute inhalers, metered-dose inhaler (MDI) actuators with counters and dry-powder inhalers (DPIs). Moreover, Sanner is an industry partner for integrated and drop-in desiccant solutions, as well as consumable add-ons such as moisture-tight drug storage cartridges or mouthpieces with integrated filters. Besides increasing drug stability and ensuring the accurate performance of drug delivery devices, Sanner provides solutions that help improve medication adherence and compliance.

The two companies are working closely together to incorporate Amiko's Respiro Sense into custom add-on or integrated device solutions for respiratory device or drug producers who are looking for new connected solutions. As a start-up, Amiko offers a quick development process for the development of fully functioning, CE marked devices, which clients can use and test in low-volume strategic projects. As a fully integrated contract manufacturer, Sanner supports Amiko with its deep knowledge in all activities leading up to and including design, engineering and scale-up manufacturing. Bringing connectivity to respiratory care is the first step in marketing this novel technology. In the future, other respiratory delivery systems including nasal sprays and nebulisers, as well as injectables, applicator systems or pharmaceutical primary packaging for further therapeutic areas, will follow.

Figure 4: Respiro offers advanced inhaler sensors and data analytics.

ABOUT THE COMPANY

Amiko

Amiko develops advanced sensor technologies and digital health solutions to assist healthcare professionals and empower patients to achieve better outcomes. Founded in 2015, Amiko has headquarters in London, UK, and ISO 13485:2016 certified R&D laboratories in Milan, Italy. Amiko serves commercial, institutional and individual customers all over the world, and is growing to become a global provider of advanced medication sensor and data analytics technologies.

Sanner

Based in Bensheim, Germany, the Sanner Group was founded in 1894 and is now in its fourth generation as a family-owned enterprise. Sanner develops and produces high-quality plastic packaging and drug delivery systems for pharmaceutical, medical and healthcare customers. The group gained international recognition for its desiccant know-how and moisture protection solutions. With more than 500 employees, Sanner is present all over the world, amongst others in Germany, China, India and the US. The company produces over two billion plastic units each year for standard and customised packaging and drug delivery solutions.

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ABOUT THE AUTHORS

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Fabian Schütte is Business Development Manager at Sanner, responsible for the product segment Engineered Packaging Solutions, with a focus on customised primary packaging systems and devices. Before taking on this position at Sanner two and a half years ago, Mr Schütte worked in the segment of glass primary packaging systems and injection devices at Gerresheimer Bünde (Bünde, Germany).