

RS01X – BERRY GLOBAL HEALTHCARE'S SINGLE-DOSE DPI GOES DIGITAL WITH AMIKO'S RESPIRO

In this article, Mauro Citterio, Director, R&D and Industrialisation; and Marco Franza, Sales & Business Development Director – Global Inhalation & Medical Devices, both of Berry Global Healthcare; and Martijn Grinovero, Chief Commercial Officer and Co-Founder of Amiko, discuss Berry Global Healthcare and Amiko's partnership to develop the RS01X connected single-dose dry powder inhaler, based on Berry Global Healthcare's commercialised RS01 inhaler and Amiko's Respiro digital health platform.

DIGITAL HEALTH – BENEFITS AND CHALLENGES

Digital health is fast becoming a well established concept in the drug delivery industry. The benefits to all stakeholders in the industry is a well-discussed topic, frequently the subject of conference talks and industry articles. For patients, digital technology can improve their quality of care with apps associated with their device to track usage, provide reminders and potentially offer guidance in correct usage of their device, which is an especially pertinent benefit in the respiratory sector, where patients' difficulties mastering their devices is notorious. For the healthcare provider (HCP), digital technology can give them insights into how their patients' medication regimens are proceeding using data direct from their drug delivery device. This increased level of insight not only has the benefit of being real-time, allowing HCPs to pre-empt potential crises, but also of being remote, not requiring a patient to make a journey into the clinic. For pharmaceutical companies, there's the significant benefit of digital devices allowing them to collect data on the performance of their medications, as well as saving them money from increased patient adherence.

However, alongside these myriad benefits, there are novel challenges for the drug delivery industry when it comes to

developing and deploying digital technology in medical devices. These challenges are varied, including the additional costs and expertise required for developing connected technology, regulatory challenges from both the usual regulators, such as the EU EMA and US FDA, and data protection regulations, such as the EU GDPR. There is also the potential for friction between technology companies moving into the healthcare space, coming from a world that gave us the mantra "move fast and break things", and established pharmaceutical and medical device companies investigating digital technologies, who often have more cautious and risk-averse approaches.



Martijn Grinovero
Chief Commercial Officer
and Co-Founder
E: martijn.grinovero@amiko.io

Amiko SRL
Piazzale Aquileia 6
20144 Milan
Italy

www.amiko.io



Mauro Citterio
Director, R&D and Industrialisation
E: mauro.citterio@plastiape.com



Marco Franza
Sales & Business Development Director
Global Inhalation & Medical Devices
T: +39 039 95 298 227
E: marco.franza@plastiape.com

Berry Global Healthcare
Plastiape SpA
via I° Maggio, 8
23875 Osnago
Italy

rpc-bramlage.com/healthcare



Figure 1: The RS01X connected and intelligent single-dose DPI.

Therefore, on this frontier of drug delivery device development, a successful partnership between a digital technology company and established drug delivery device manufacturer is hugely valuable. Such a partnership has come to fruition between Berry Global Healthcare, developer of the internationally successful RS01 dry powder inhaler (DPI), and Amiko, the digital technology company behind Respiro, a digital medicine solution for respiratory devices built on proprietary sensing technology, data science and elegant digital user experience design. Together, Berry Global Healthcare and Amiko have combined their expertise to produce the RS01X, a connected, intelligent single-dose DPI (Figure 1).

BERRY & AMIKO – A PARTNERSHIP FOR SUCCESS

The partnership between Berry Global Healthcare and Amiko marks a significant milestone in Berry Global Healthcare's stated commitment to bring innovation to the healthcare market that advances and improves the quality of patient care. With Amiko, Berry Global Healthcare has found a technology partner that shares its dedication to the cause of advancing respiratory care with technology. Both companies bring a key element of the RS01X DPI to the table.

Berry Global Healthcare provides the expertise of a well-established player in the respiratory drug delivery device industry. The RS01's intuitive patient-centric design provides ease of use and short administration time. It is also a most versatile device to work with, being designed to function with a wide variety of powders and capsules, as well as being available with different airflows to maximise the scope of its application.

With its excellent reputation, broad applicability, and established and proven place in the market the RS01 was a natural fit for adaptation to digital technology.

Amiko brings its proprietary digital respiratory technology: Respiro, a proven digital health product specifically designed for the respiratory market. Respiro combines connected sensors built into an inhaler with artificial intelligence (AI), data science and digital experience design to help deliver better patient outcomes. Along with Amiko's sensing technology, Respiro features a patient-facing app providing personalised guidance and feedback to patients to assist them in managing their condition, and a provider portal for HCPs, giving them data, insights into the progress of their patients' conditions and treatments, and predictive analytics to further enhance the quality of care they can provide.

Through their partnership, Berry Global Healthcare and Amiko have combined their expertise and products to bring the RS01 DPI into the world of digital healthcare, as the RS01X, made smart by Respiro. Commenting on this achievement, Vincent Clauzel, Managing Director, Berry Global Healthcare – Care Unit, said "The introduction of the RS01X is a significant milestone for Berry Global

"Through their partnership, Berry Global Healthcare and Amiko have combined their expertise and products to bring the RS01 DPI into the world of digital healthcare, as the RS01X, made smart by Respiro."

Healthcare globally, as well as for innovation in respiratory devices. We are very excited to have established a successful and very close partnership with Amiko to achieve this." From Amiko's perspective, the company is thrilled to have in Berry Global Healthcare a partner with vision, ambition and market experience, and excited about the RS01X and Respiro becoming available to patients and care providers at scale.

RS01X – CONNECTED & INTELLIGENT DPI

The RS01X tracks a patient's inhaler use via inbuilt sensors, and connects to Amiko's Respiro app using Bluetooth wireless technology. The data captured by

"The RS01X automatically captures, stores and encrypts objective inhaler-use data, covering various metrics of user-generated inhalations, such as inhalation flow rate and duration, to power its predictive analytics and personalised user advice."

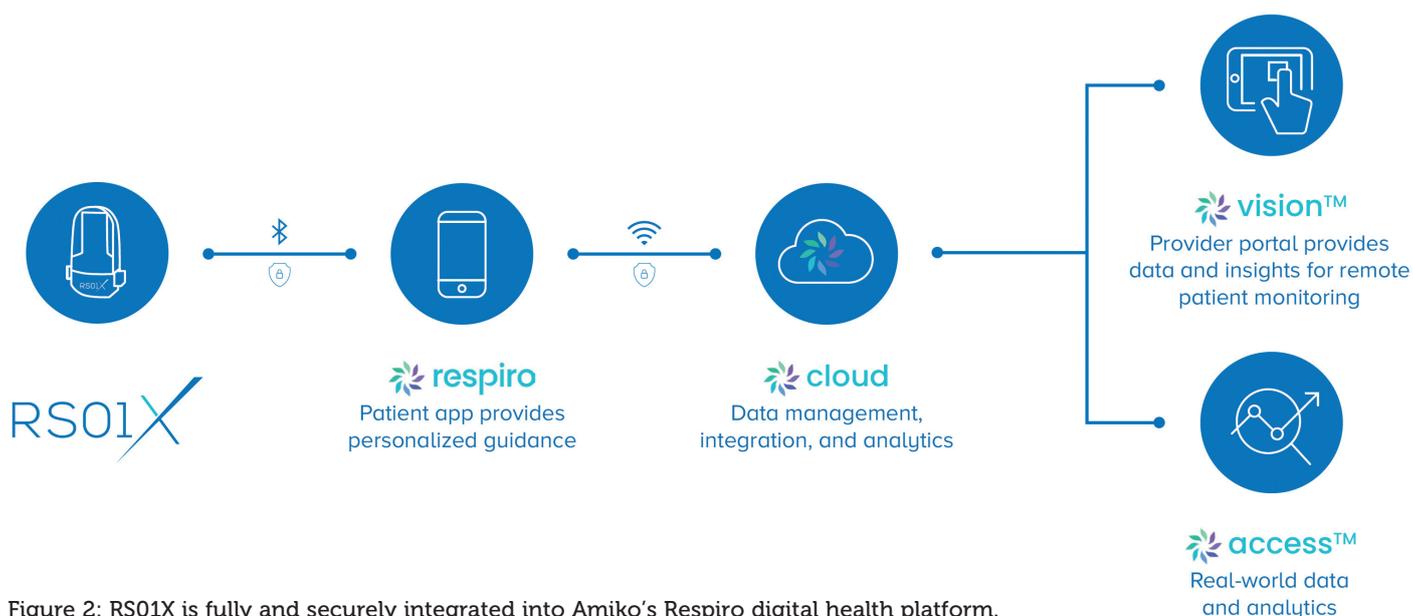


Figure 2: RS01X is fully and securely integrated into Amiko's Respiro digital health platform.

the RS01X's sensors enables the companion app to provide patients with personalised feedback on their care.

The Respiro companion app can provide guidance and feedback on proper usage technique to a patient for their inhaler, as well as adherence-improving tools, such as personalised feedback and reminders for when they are due to take their medication. Such tools improve the overall quality of patient care because, with proper technique, patients are able to get the full efficacy of their treatment, which leads to better health results. In turn, better results lead patients to adhere to their prescribed medication regimen more reliably, resulting in improved long-term treatment results.

The Respiro app is powered by AI to better assist patients and enable them to self-manage their conditions more effectively. This has been demonstrated with Respiro in clinical studies and over 30 commercial programmes; the percentage of patients showing proper medication adherence and correct inhalation technique improved remarkably amongst patient populations using Respiro-powered inhalers.

The RS01X automatically captures, stores and encrypts objective inhaler-use data, covering various metrics of user-generated inhalations, such as inhalation flow rate and duration, to power its predictive analytics and personalised user advice. The inhaler's sensors monitor the patient's inhalation without requiring a mechanic or pneumatic connection to the inhaler air flow path.

Being powered by Respiro, the RS01X is seamlessly integrated into Amiko's digital health platform (Figure 2). RS01X and the Respiro app incorporate the latest industry-standard security and privacy protections.

However, if a patient is willing to share their data with their HCP they can gain access to a wealth of further advantages in the form of collaborative decision making and data-driven treatment adjustments. Data from the RS01X can be shared either in person using the Respiro PDF reports, or digitally, and in real-time, using the Respiro digital health platform.

All of this technology has not changed the familiar design of the RS01. The RS01X is just as easy to use, familiar and functional as the original. This includes the RS01's internal medication delivery geometry, ensuring that the medication delivery of the RS01 and RS01X is completely equivalent. In addition to the familiarity and versatility of the RS01 base, the RS01X includes a built-in battery so that no additional charging is required for the duration of its usage.

CONCLUSION

The RS01X combines Berry Global Healthcare's 50 years of experience in inhaler design, development and manufacturing with Amiko's expertise in developing hardware enabled, AI-powered digital health technology. The RS01X builds upon the globally recognised RS01 design

without sacrificing any of the original device's simplicity, usability or versatility to provide a device that offers advantages to all stakeholders, and advances inhalation technology into the digital age.

ABOUT THE COMPANIES

Berry Global is a worldwide supplier of a broad range of innovative non-woven, rigid, and flexible products used every day in both consumer and industrial end-markets. Berry is a Fortune 500 company with operations that span 290 locations across six continents. Berry Global Healthcare's mission is to have a positive impact on disease management and the environment. Berry Global Healthcare offers a wide number of specialisations in drug administration, including oral, nasal, pulmonary and ophthalmic, as well as an extensive range of pharmaceutical packaging.

Amiko is an AI and advanced data analytics company that provides Respiro, a digital medicine platform that combines connected inhaler sensors, apps, and data analytics to enable enhanced respiratory care. Respiro is a certified medical device and has been used in clinical studies and over

"All of this technology has not changed the familiar design of the RS01. The RS01X is just as easy to use, familiar and functional as the original. This includes the RS01's internal medication delivery geometry, ensuring that the medication delivery of the RS01 and RS01X is completely equivalent."

30 commercial programmes across Europe. Amiko, which is ISO 13485:2016 certified, serves patients, healthcare providers and pharmaceutical companies.

ABOUT THE AUTHORS

Mauro Citterio is a Member of the Board of Plastiapè SpA (a Berry Global company), where he leads R&D and industrialisation activities. Since joining the company in 1998, Mr Citterio has had various responsibilities, including technical and economical evaluation of new business opportunities, costing and pricing, development of new design concepts, project management, equipment industrialisation and maintenance. He founded the company's core team dedicated to regulatory compliance for medical devices. He is named as inventor or co-inventor on multiple international patents and has been an invited lecturer at various international conferences. Mr Citterio holds an MSc in Management, Economics and Industrial Engineering.

Marco Franza is Sales & Business Development Director – Global Inhalation & Medical Devices, at Berry Global Healthcare. He was previously Director, Sales, Marketing and Key Accounts at Plastiapè, until it was acquired by Berry in 2019. Mr Franza has extensive experience in the commercial side of the drug delivery industry, having held roles related to sales, business development and marketing. His roles have had a particular focus on inhalation devices, which are both a key growth factor for the company and a passionate personal interest.

Martijn Grinovero is the Chief Commercial Officer and Co-Founder of Amiko. He is responsible for leading Amiko's commercial go-to-market teams, including sales, marketing, commercial relationships and business growth. Mr Grinovero has an MSc in Strategic Management from the Rotterdam School of Management (Netherlands).

2021

EDITORIAL CALENDAR

Publication Month	Issue Topic	Materials Deadline
January	Skin Drug Delivery: Dermal, Transdermal & Microneedles	Dec 31, 2020
February	Prefilled Syringes & Injection Devices	Jan 14, 2021
March	Ophthalmic Drug Delivery	Feb 4, 2021
March /April	Drug Delivery & Environmental Sustainability	Feb 18, 2021
April	Pulmonary & Nasal Drug Delivery	Mar 4, 2021
May	Delivering Injectables: Devices & Formulations	Apr 1, 2021
June	Connecting Drug Delivery	May 6, 2021
July	Novel Oral Delivery Systems	Jun 3, 2021
August	Industrialising Drug Delivery	Jul 1, 2021
September	Wearable Injectors	Aug 5, 2021
September /October	Drug Delivery & Environmental Sustainability	Aug 19, 2021
October	Prefilled Syringes & Injection Devices	Sep 9, 2021
November	Pulmonary & Nasal Drug Delivery	Oct 7, 2021
December	Connecting Drug Delivery	Nov 5, 2021

Join 30,000 biopharma professionals who read ONdrugDelivery Online and/or in Print.
Subscribe Online Today!

RS01X

Made smart with  respiro



Connected and intelligent single-dose dry powder inhaler

RS01X™ tracks inhaler use and connects to the Respiro® app to provide personalized guidance to improve adherence and inhaler technique.



amiko

Berry

| healthcare