



General view of testing automation



Testing station for penetration depth adjustment torque



Testing station for force needed to pull off and put on the cap

technik GmbH simultaneously constructed assembly line and testing automation.

The machine which is important for process verification and validation tests all user-relevant functions and additionally checks if all values meet the demands of the requirements specification, such as clamping force and cycle torque. A dummy drum was specially designed for the purpose of determining the insertion force of the drum. This dummy represents the characteristics of the drum and provides system-relevant data. The documentation of the measured values occurs per batch and is stored inside a data file.

With the complete realization of the customer's idea „lancet system with a drum“ in high-volume production, WILDEN could once again prove its market position as bearer of know-how for the entire value-added chain as well as development partner and system supplier. „The longtime experience and technical competence of WILDEN AG in combination with the trust of Roche Diagnostics in our work facilitated the bypassing of in-between steps like prototype tools and thus a tight schedule of two and a half years could be realized,“ comments Angela Schubert, director of the area „Development International“ at WILDEN AG.

WILDEN produces the new Accu-Chek Multiclix lancet device in its production plant for Medical Plastic Systems in Pfreimd, Germany. Assembly takes place in the Czech subsidiary in Horšovský Týn. For this, WILDEN's special-purpose machinery engineers designed and built a complex modular assembly line. „It combines and integrates fully-automated and manual assembly units and passes them into the qualified and validated testing automation,“ explains Manfred Baumann, director of the Technical CompetenceCenter at WILDEN in Wackersdorf/Germany. This machine forms another example of the high competence level of WILDEN AG in terms of fully-integrated production concepts.

As a system supplier, WILDEN also supported Roche Diagnostics with the documentation for the CE-certification and realized the qualification according to „Good Manufacturing Practice“ (GMP).

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Award winning medical product: The innovative Accu-Chek Multiclix Lancing System

Roche Diagnostics entrusted WILDEN AG, as a long-term partner and system supplier, with the development of an innovative lancet system for people with diabetes. The technical realization of the visionary „lancing system with a drum“ is a further example of the extensive service spectrum of WILDEN AG: From the customer's concept to the highly automated high-volume production of a CE-certified medical product.

For people with diabetes, self-testing their blood glucose is a vital daily practice. In many cases they have to sample their blood several times a day in order to determine their blood glucose. This is the only way to adjust therapy, diet and exercise to maintain good control of diabetes. Experience has underlined that the best method to perform less painful glucose self-testing is through the use of a skin-pricking device in combination with a blood glucose monitoring system.

Roche Diagnostics is the world market leader in the field of diabetes monitoring. These experts in diagnostics are dedicated to improving the handling and comfort of daily finger pricking, referred to as lancing. For the realization of their newest vision, the Accu-Chek Multiclix lancet system, an innovative lancet device with a built-in lancet drum, the company sought a partner with the appropriate know-how in medical technology. „This is why we entrusted our long-term system supplier and partner WILDEN AG with the development and production of this innovative lancing

WILDEN realized tight schedule:

Within a two-and-a-half year period, a customer's concept was executed into a product ready for sale.

The testing and assembly automation built at WILDEN AG represents the high competence level of WILDEN Werkzeug- und Automatisierungstechnik GmbH in terms of fully integrated production concepts.



Development Team „Lancet Device“ WILDEN AG



First conceptual design



Realization of the first design

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World novelty!

Changing - with just one turn: Roche Diagnostics introduces a new lancing system to the market:

Accu-Chek Multiclix

Roche Diagnostics entrusts its long-term partner WILDEN AG with the complete value-added chain for the new lancing device for people with diabetes.

- Product development
- Design and construction of molds as well as assembly and testing automation
- Injection molding of the 17 plastic components
- Assembly of the 17 plastic components and 3 purchased parts
- Support for the documentation for the CE-certification



Component design
using CAD



Design of Assembly
Automation



Components of the
ACCU-CHEK® Multiclix

system," explains Dirk Bandau, Head of Lancing Systems at Roche Diagnostics.

The advantages of the new concept, which has been a joint development of engineers from both Roche Diagnostics and WILDEN AG, quickly became apparent. In an initial market survey with diabetics conducted by Roche Diagnostics, size, design, handling and surface feel were rated especially positive.

The biggest innovation of the Accu-Chek Multiclix lancing system was achieved in the realization of the safety aspect. „When loading or extracting the lancet drum, the risk of injury is eliminated. Instead of the hitherto used single lancets, this lancing system has a lancet container with 6 integrated lancets within a drum housing," explains Richard Forster, product developer Medical Plastic Systems at WILDEN, who designed and optimized the drum up to the development release by Roche Diagnostics.

„The drum concept was designed to meet the daily needs of people with diabetes who has to check their blood glucose level up to four times a day - in some cases even more often," explains Peter Sachsenweger, product developer Medical Plastic Systems at WILDEN. Due to the six lancet drum, the patient no longer needs to take additional lancets with him. Furthermore, since the needle tips are surrounded with soft plastics, they remain sterile until they are used for the first time. Only when the user presses the release button of the Accu-Chek Multiclix the needle will penetrate this sterile cover and uncover the tip. Thus, blood sampling is performed using an unused lancet with a sterile needle which reduces the risk of infection.

Another big advantage of the Accu-Chek Multiclix involves psychological aspects of lancing. With other lancing systems, people with diabetes must remove the cap from the lancet, exposing the needle tip, which may heighten perceived pain. With the Accu-Chek Multiclix there are no caps to remove, so users don't have to see the needle anymore.

One of the most important aspects for a hygienic and comfortable blood sampling is the regular change of lancets. With the Accu-Chek Multiclix lancing system, this is easily performed!

The innovative lancet drum

- Contains six lancets for gentle blood sampling
- Hygienic handling:
- Easy change of a lancet without direct contact
- Easy disposal of used drums (domestic waste)

The innovative Accu-Chek Multiclix lancing system

- With eleven adjustable penetration depths
- Safe and accurate lancet movement
- Convenient display of lancet supply

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„The new concept by Roche Diagnostics also highlights safety with regard to the disposal of used lancets," Sachsenweger continues. „Single lancets with open needle tips - as with existing systems - now belong to the past."

Via a display on the device, the diabetic is always informed on how many unused lancets are still available. If the last available lancet is reached, the display indicates this with a corresponding color code. In order to change the drum, the user just has to pull off the cap of the lancet device. Afterwards, he can easily remove the used drum. Re-inserting a used drum is not possible. Additionally, the adjustable penetration depth simplifies an easy blood sampling even in case of slight skin thickenings or bad blood circulation.

In its final version, the Accu-Chek Multiclix consists of 17 plastic components and three springs. Both technically sophisticated system assemblies, lancet device and drum, were designed in close cooperation of Roche Diagnostics and WILDEN until the developed product was released for series production. After the WILDEN engineers received the design release for their system assemblies, they created prototypes of both the lancet device and drum.

By constructing the function models, the developer team at WILDEN acquired enough know-how to enter directly into designing and constructing the single series molds for the device. Soon thereafter, WILDEN conducted first tests close to reality using injection molded parts from their own production and the purchased metal parts. In addition to technical aspects in terms of molds and assembly, particular emphasis during the test runs was put on user-specific features. The whole spectrum of handling was tested. From changing the drum and adjusting the penetration depth via a tension-and-trigger process as well as changing the lancet up to display modes „Tension mode", „Drum state", and „Penetration depth".

The short development time also results from a consistent utilization of state-of-the-art technical engineering tools. Following the concept of Simultaneous Engineering, the technicians of WILDEN Werkzeug- und Automatisierungs-



Product ready for sale:
ACCU-CHEK® Multiclix



Smooth blood sampling



Removal of the
used drum