

Project Note

GMP-conforming test system for new breast pump

Zühlke developed a new test system based on a manual test station for the final testing of a breast pump. Testing runs automatically and handles two pumps concurrently, for greater throughput and greater depth of testing.

Task

Medela is a company that develops and produces medicinal suction devices and nursing aids. The company was increasing its production output for its new Swing breast pump and needed a new system for automatically testing and labelling two completely assembled devices at a time. The specified cycle time was about 40 seconds per testing procedure. Zühlke created the entire test system, from tender specifications to final qualification procedure, in accordance with GMP standards.

Implementation

Based on the user requirements defined jointly with the customer, Zühlke devised a detailed solution. The major challenge was to integrate a laser labelling system and to devise an automated coupling of the vacuum output for the test specimen. To minimize development risks, the team clarified both of these points in detail in the design phase. The test run was controlled by a software created in LabVIEW. A graphical user interface provides the user with simple guidance through the individual test steps to ensure quick orientation. An intelligent set of valves is used to control the numerous pneumatic elements and is connected with the control PC over an Ethernet interface. The labelling laser marks the serial numbers on the pumps that have passed the test. Independent safety elements prevent any danger to the user from moving mechanical parts or escaping laser radiation. Zühlke erected the completely assembled plant at the customer's and conducted qualification procedures according to GMP standards (IQ, OQ, PQ) with the customer before the plant was put into practical operation.



Technical Data

LabVIEW
ProE
Orcad

Customer benefits

- Drawing on its years of experience, Zühlke can offer GMP-conforming development, qualification and documentation of test systems for use in medical environments.
- With their broad expertise in LabVIEW, experts developed software architecture with a much faster test cycle than specified.
- Zühlke assumed project responsibility and, as system supplier, created the entire test system in its own workshops and laboratories.

Zühlke Engineering AG
Wiesenstrasse 10a
8952 Schlieren (Zurich)
Switzerland
Phone +41 44 733 6611
Fax +41 44 733 6612
info@zuehlke.com
www.zuehlke.com