

Project Note

Final Test System for New Breast Pump

Our customer provides nursing aids an breast pumps. Therefore an easy-to-operate testing system has to be developed. Zühlke did the validation and documentation in accordance with GMP guidelines.

Task

Medela AG develops and produces medical suction equipment and nursing aids. For its new generation of breast pumps, the company wanted to devise an easier to operate test system for conducting the final tests on the most important parameters of the main functions during production. Zühlke’s task was to develop, validate and document the entire test system in accordance with Good Manufacturing Practices.

Implementation

In an initial step, Zühlke drew up all GMP-conforming documents and had them approved in collaboration with the customers. After a brief design phase, the team completed the entire mechanical and electrical systems and the software. A special construction fixes the breast pump in place while also establishing a contact between it and the test system.

The sensors for the vacuum, electrical and voltage measurements as well as the entire electronic system for power feed and the digitalisation of measured values are integrated in a separate aluminium housing. A US Bund Ethernet interface connects the test system with a standard PC. Zühlke developed the test program in Lab-VIEW. A graphic user interface guides the user through the entire test procedure. Just two buttons are required for controlling the tests. All test data is deposited in the central data management system of Medela AG. Along with the actual test procedure, the program also features additional functions like user management and calibration routines.



Customer benefits

- Development, validation and documentation of the test system in full compliance with GMP were assured by the years of experience Zühlke has amassed in the medical equipment sector.
- The LabVIEW experts from Zühlke implemented a software architecture that allows the test system to be upgraded to a fully automated system trouble-free.
- Zühlke assumed overall responsibility for the project and created the final 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