Breas Medical AB Improves Quality and Traceability in Production

with WF2111 – Fingerprint Reader for LabVIEW

Abstract

This application note describes how medical companies such as Breas Medical AB, has become more efficient in their production environment, and at the same time, increase quality and traceability by using the WireFlow WF2111 USB Fingerprint reader for LabVIEW. The WF2111 has helped operators at Breas ease and fasten their daily electronic signatures. Test stations have become more compact and traditionally keyboards, has in some cases become obsolete. Additional impacts are shortened test times, increased productivity and more secure electrical authorization of test records.

Problem

Breas Medical AB develops and produces high end homecare ventilation and sleep therapy products [1]. This implies that the production facility must comply with a number of federal regulations from the Food and Drug Administration (FDA). One important issue in all these regulations is the Part 11 that covers areas such as electronic signatures during assembly and tests. It is essential that each produced medical device has a unique Device History Record (DHR) in which all important events for each unit is saved in order to have full traceability on all devices and its components. This DHR needs to include which operator assembled the unit and at which time. The DHR needs also to include all test results and which operator performed and confirmed the different test results through the production flow.

Figure 1. Vivo 50. Life wupporting ventilator from Breas Medical AB.

Traditionally electronic signatures are carried out using a Single Sign On (SSO) together with an operator password. Breas Medical produces well over 50 000 units including spare parts each year. Each produced unit has a number of different assembly and test points, starting from board tests to final packing and shipping. Each event needs to be stored and traced in the DHR. This means that each year hundred thousands of electronic records needs to be signed by operators at Breas. Even if each login with traditional SSO and password only takes about 5 seconds for an operator, it gives an astonishing ~140 hours each year on just electronic authentications.

Breas constantly work with improvements of the automated test stations in order to shorten the test times, improve quality and make it easier for operators to run the automated tests for the high-end products.

Solution

Breas Medical uses today both TestStand and LabVIEW from National Instruments in the production environment in order to test and validate each product according to regulation and requirements. A number of test station controlled by Breas operators runs in parallel in order to test all types of ventilator units.

WireFlow has helped Breas incorporate the WF2111 USB Fingerprint reader in the existing production environment at their site in Mölnlycke outside Göteborg. The WF2111 is specifically made for LabVIEW and TestStand applications. The CMOS sensor delivers superior image quality with 256 gray scale values in every single programmable pixel. The unit is shipped with complete examples and LabVIEW™ VI's for capturing images and state-of-the-art biometric algorithms for enrolment and identification [2].

he implementation of the fingerprint sensor was done as a complementary to the existing SSO and password. Each operator could in the new implementation enroll a unique fingerprint in just a second and assign the operators existing SSO and password with the enrolled fingerprint. Once the enrolment is done and information is stored in the database file, the fast algorithm of the USB device then finds the matching fingerprint in a fraction of a second and signs the DHR. The database file is encrypted and common for all test stations at Breas. Therefore, the operator only need to assign a single fingerprint at one station which will then work for all stations at the production site.

Figure 4 shows an operator at Breas electronically confirms that the unit is assembled according to instructions using the WF2111 fingerprint sensor. At this point the LabVIEW program creates the unique DHR which includes information about the scanned components including operator identification. Unit is then transferred to another test station for system tests in which the WF2111 is once again used to sign the test results.

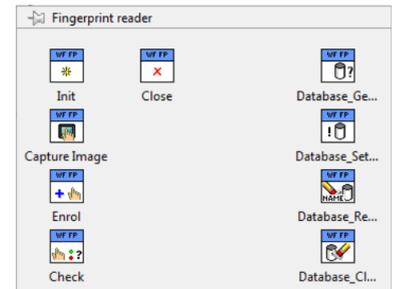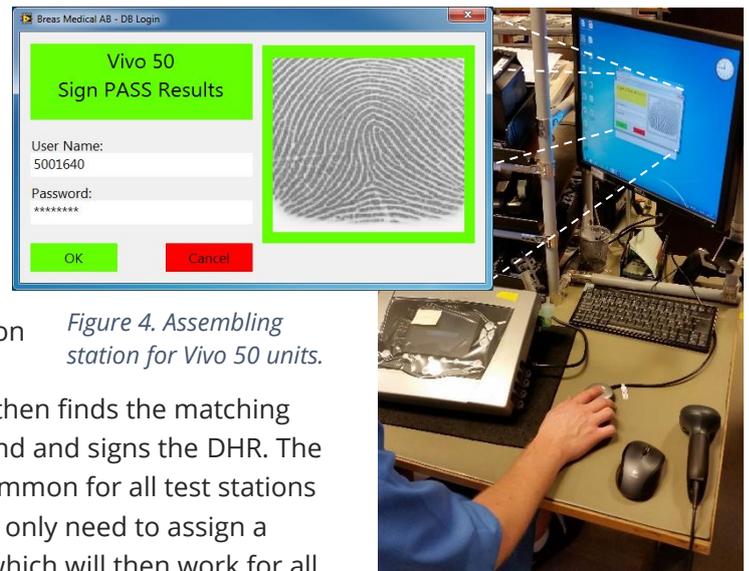*Figure 2. WF 2111 USB Fringerprint Reader for LabVIEW*

Figure 3. LabVIEW driver for the WF 2111.

Figure 4. Assembling station for Vivo 50 units.

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