MODERNISATION OF TESTING MODULES AND PROCEDURES IN AN AUTOMATED ASSEMBLY LINE

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Abstract: This dissertation discusses the issue of modernisation of testing modules and procedures in an automated assembly line adapted to manufacture medical pressure transducers in Aesculap Chifa company. The manufactured transducer is used for invasive measurement of patient's physiological pressure, and, therefore, must not pose any threat either to patient's health or life. This is the reason why the operation of the assembly line has been identified, testing modules and procedures have been evaluated and the construction modifications have been suggested. During the research, the influence of suggested construction modifications, enhanced with procedure changes, has been verified.The suggested adjustments have enabled, as required, to improve the operation of automated assembly line adapted to manufacture medical pressure transducers.

Key words: Modernisation, Assembly Line, Medical Pressure Transducer

1. INTRODUCTION

Nowadays, "modern semiconductor sensors, the so-called silicon pressure sensors" (Tietze and Schenk, 2009) are used to measure the pressure. They can be divided into two main groups: piezoresistive sensors and capacitive sensors.

Piezoresistive pressure sensors register membrane deflection triggered by pressure. A tensometric bridge is placed on the membrane. Depending on the accuracy needed, piezoresistors can be arranged in a quarter-bridge, half-bridge or full-bridge circuit (full-bridge circuit guarantees highest accuracy). The pressure applied to the membrane strains and presses the piezoresistors. Then, in accordance with the piezoelectric effect, they change their resistance (piezoresistors deflected in the same direction are located at the opposite legs of the bridge).

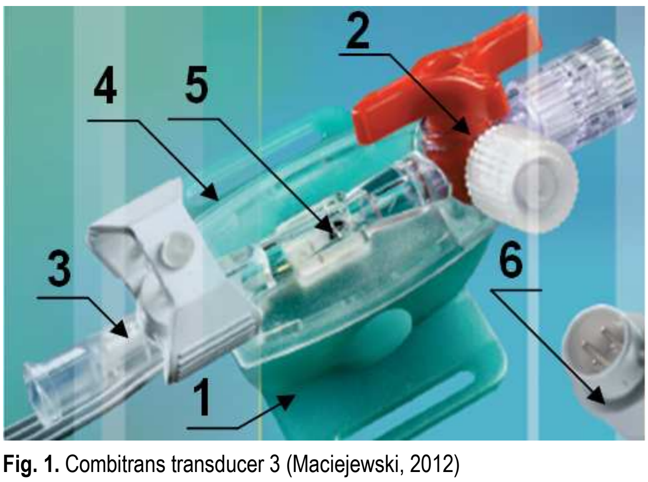

Fig. 1. Combitrans transducer 3 (Maciejewski, 2012)

Piezoresistors fitted in the silicon base which constitutes the membrane are used for the measurements where a great sensor sensitivity is necessary. Sensors produced in such a way are cheaper than those manufactured by means of the "evaporation of the constantan or platinum and iridium layer" technique (Tietze and Schenk, 2009). They are also above ten times more sensitive but they have a higher temperature coefficient.

Combitrans 3 transducer illustrated in Fig. 1 is made up of a lower housing (1), a stopcock (2), a flush device (3), but most of all of a piezoelectric pressure sensor (MPX2300DT1)-(5) fitted in the upper housing (4). The way of combining the elements complies with the ISO 594/1-1986 (E) norm. We differentiate between two types of Lauer-Lock (LL) connection fittings: male and female ones. Sensor pins are soldered to the cable with a plug (6) at its end.

MPX2300DT1 series pressure sensor produced by Motorola company is a miniature integrated circuit plated with a thermoplastic polymer material – a white polysulfone used for medical purposes. A non-toxic, non-allergic, dielectric silicon gel covers the piezoresistive element. Thanks to the gel's distinctive characteristics the separating membrane which is generated does not attenuate stress. It also prevents the piezoresistor and its elements from corrosion in the Ringer's solution chemical environment. Furthermore, the characteristics of silicon guarantee such a level of electrical insulation that both the operation and the lifespan of the sensor are not threatened even in the event of a patient's defibrillation. The sensor has been also equipped with a temperature compensating circuit.

A manufactured transducer is connected to patient circuits and, hence, it must not be either life- or health-threatening. The elements of the machine which are not separated from it during the production have to be made of the materials which do not react with its component parts.

AB08024 machine (Fig. 2) was designed with a view to automated assembly and Combitrans 3 testing. It is made up of three, properly robotised, production units (Żurek et al., 2011). The role of the first one is to link the upper housing to the stopcock and the flush device. The second one is supposed to solder the pressure sensor with the cable and to assess the quality of the connection formed. Production units 1 and 2 which work together with the main transport unit fit the sensor into the upper housing. The assembly of the lower housing and the transducer testing is done by the third production unit.

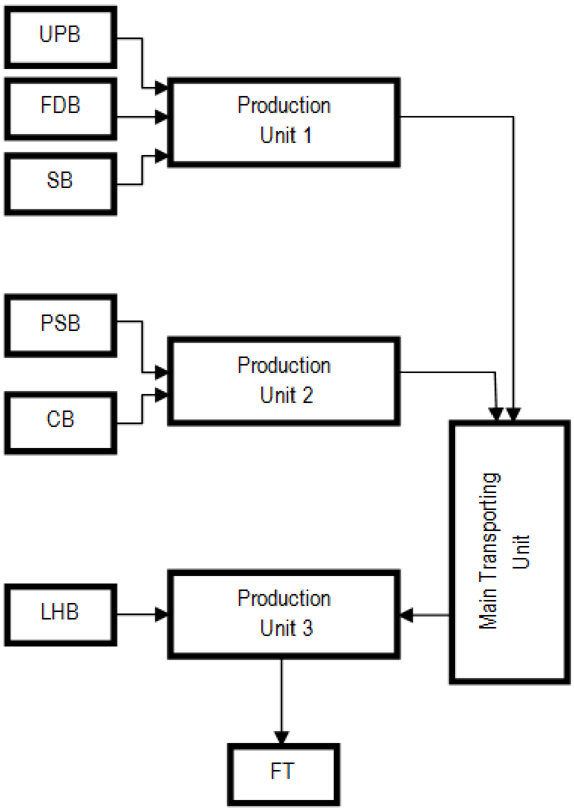

Fig. 2. Flow chart of the AB08024 machine: UPB – upper housing batcher, FDB – flush device batcher, SB – stopcock batcher, PSB – pressure sensor batcher, CB – cable batcher, LHB – lower housing batcher, FT – finished transducer (Maciejewski, 2012)

Automated line to produce the AB08024 machine is equipped with two testing modules. The first one makes it possible to control the quality of the connection between the sensor and the cable to which it has been soldered. The second one measures the quality of the assembly of component parts and the features of the transducer (tightness, flush device flow rate). Based on the procedures agreed upon in the company, a sensor soldered to the cable (or a transducer) is rejected or accepted and delivered to further assembly.

The first module is an electrical tester pulled by a pneumatic actuator to the cable plug. The quality of the cable plug-electrical tester socket connection has a bearing on the voltage values which can be read on pins 2 and 3 of the sensor. Due to problems with access to electrical connection as many as 50 component parts out of the 100 properly assembled ones were classified as faulty.

The testing module 2 consists of the electrical tester, transducer's sealing mandrel, the engine which makes it possible to change the position of the stopcock and the station pumping the air into the transducer. Sealing mandrel and electrical tester change their positions using the pneumatic actuators.

Acceptance or rejection of a transducer being assembled is governed by a multistage testing procedure for module 2 (Fig. 3).

The operation of the automated assembly line has manifested that there are difficulties tightening the Combitrans 3 transducer during the filling, stability and tightness tests. Plastic deformations of the element responsible for closing the tip of the flush device were reported. Similarly to module 1, the quality of the cable plug-electrical tester socket connection made it impossible for the machine to operate properly. Lower voltage values visible on pins 2 and 3 decreased the value of the actual pressure in the transducer. As a result, transducers were classified as faulty (around 23% of production volume). Those transducers which were accepted during the filling test were rejected during the tightness test. In the end, every manufactured transducer was rejected, despite the product assembly sequence being correct (Bourne et al., 2011; Martinez et al., 2009; Suszyński et al., 2009).

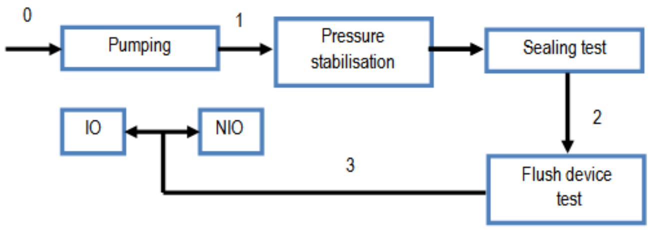

Fig. 3. Flow chart of testing procedure for module 2; 0 – placing the transducer; pulling the station pumping the air, sealing mandrel, electrical tester; solenoid valve opening; 1 – closing the stopcock; solenoid valve closing; 2 – pulling the sealing mandrel back; 3 – lower housing assembly; opening the stopcock; rejection (NIO) or acceptance of the transducer (IO) (Maciejewski, 2012)

The aim of the modern automated assembly line is that out of 100 properly manufactured transducers only one sensor-cable link (module 1) and 5 finished transducers (module 2) could be classified as faulty.

2. THE ASSESMENT OF TESTING MODULES AND PROCEDURES

The advantage of the construction of testing module 1 is that it is possible within a short period of time to get electrical connection between the plug pins and the electrical tester socket, whereas the quality of this connection constitutes its drawback. It stems from the differences in the conductivity of materials used to produce the transducer. Nickel, which forms the upper layer of the pins has a low value of electrical conductivity – 14.3×10^6 S/m, silver, material used to produce the tester socket – 61.39x10^6 S/m, whereas copper – 58.0x10^6 S/m (Collective work, Industrial Metrology Laboratory, 2002).

Quality control of the connection being soldered is exercised by measuring voltage values on individual pins. If these values exceed tolerance range, the sensor with the cable will be classified as faulty. Tab. 1 presents the required voltage values (amplified sound) when the sensor is supplied with alternating voltage of the value of 6 V.

Tab. 1. Testing procedure parameters – module 1 (Maciejewski, 2012)

Pin no.	Voltage value [V]	Voltage value tolerance [V]
2	2.98	+/- 0.02
3	2.98	+/- 0.02

The control procedure of solder quality is properly exercised if it leads to a good electrical connection between the cable pins and the electrical tester socket. Otherwise, suitable component parts are classified as faulty and rejected automatically.

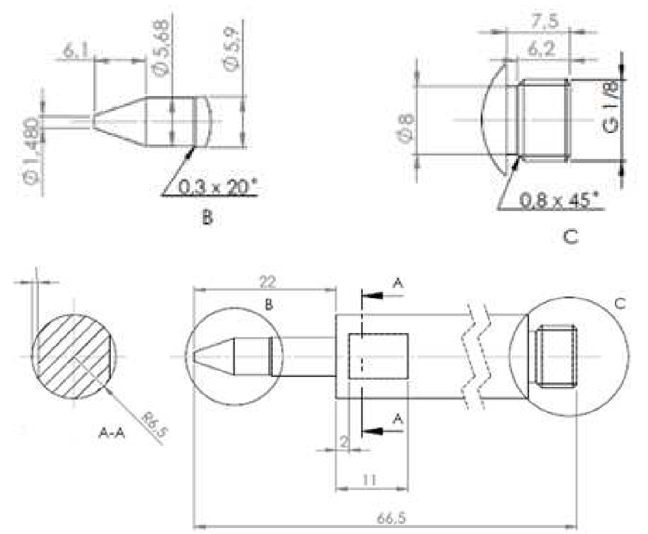

Fig. 4. Sealing mandrel construction 1 (Maciejewski, 2012)

Fig. 4 presents a conical element with the flare angle of α = 40°, responsible for tightening the transducer during the test. The manufacturer of the assembly line did not take into account the flare angle of the cone for the male LauerLock connection fitting of the approximate value of 3.44°. As a result, the connection between the flush device and the cone was not on its surface but around the mandrel's periphery. This resulted in undesirable plastic stress (Connolly, 2009).

The transducer is filled with air to a required pressure value by means of an EVT307-5DO-01F-Q solenoid valve, which works in the open-loop mode. When the transducer is not being filled with air, voltage is supplied to the coil. Current flow increases the temperature of the solenoid valve, the elements to which it is connected and the air in the solenoid valve. The values of the temperature of the elements of module 2 were 46°C, 27°C, 21°C for the solenoid vale, the station filling the transducer with air and the sealing mandrel, respectively.

In the circuit in question the air warmed by the solenoid valve is pumped into the transducer, where it cools down. The relationship between the temperature, pressure, and ideal gas volume is perfectly explained in the Clapeyron equation.

Having assumed that the individual gas content does not change and having transformed the Clapeyron equation we got (1) and (2):

$$\frac{p}{T} = \frac{mR}{V} = const \tag{1}$$

$$\frac{p_1}{T_1} = \frac{p_2}{T_2} = const \tag{2}$$

Equation (2) means that the relationship between pressure and the temperature of the air before and after pumping is constant. Hence, the air cooling down in Combitrans 3 transducer has an influence on its tightness test result.

Testing procedure for module 2 was presented on the flow chart (Fig. 2). It includes: filling test, pressure stability test, tightness test and flush device test. Parameters for separate tests were given in Tab. 2.

It should be noticed that the testing time plays a vital role, influencing the average production cycle time. Particular attention should be paid to the pressure stabilisation time, which needs to be prolonged due to the pumped air being of higher temperature than the transducer's one. This increased labour consumption makes new solutions necessary to be found for economical reasons (Chen et al., 2012; Żurek at al., 2010, 2012).

Tab. 2. Testing procedure parameters – module 2 (Maciejewski, 2012)

Stage no.		
1	Filling time [ms]	800
	PA3027 sensor max/min pressure after filling [mmHg]	330.00
		260.00
	MPX2300DT1 sensor pressure tolerance in comparison to PA3027 sensor pressure [mmHg]	12.00
		12.00
2	Stabilisation time [ms]	1.200
	MPX2300DT1 sensor max/min pressure difference, with reference to the previous stage [mmHg]	25.00
		-10.00
3	Sealing test time [ms]	1.000
	MPX2300DT1 sensor max/min pressure difference, with reference to the previous stage [mmHg]	0.25
		-2.50
4	Flush device testing time [ms]	800
	MPX2300DT1 sensor max/min pressure difference, with reference to the previous stage [mmHg]	140.00
		90.00
Testing procedure duration time [ms]		3.800

In the case of the sealing test, time, as well as minimum and maximum values of the transducer's pressure difference at the end of the sealing test and stabilisation can be modified. The pressure values should be observed during the production process, in order for the difference tolerance to be changed. Similarly to the previous tests, the flush device test consists in measuring the pressure value at the end of the test and comparing it with the value from the previous examination.

3. PROPOSALS FOR CONSTRUCTION CHANGES IN THE ASSEMBLY LINE

A proper material for the cable plug pins was needed to create an electrical connection of good electrical conductivity. The pins were nickel-plated copper rods before the tests. As copper has autopassivating properties, it was proposed to make silver-plated pins which would guarantee the lack of electric tension falls where the plug is connected to the socket.

Constructional changes proposed in the second testing module refer to the mandrel that seals the transducer. A new version of the sealing mandrel (Fig. 5) was designed, on the basis of ISO 594/1-1986 (E) and the original mandrel structure (Fig. 4).

The modernised structure 2 (Fig. 5) has one of its parts shortened, with a diameter of less than 5 mm, which, together with a proper curvature added, allowed for greater stiffness and facilitated the mandrel production (smaller deflection of the rod treated). The conical surface was designed according to ISO 594/1-1986 (E).

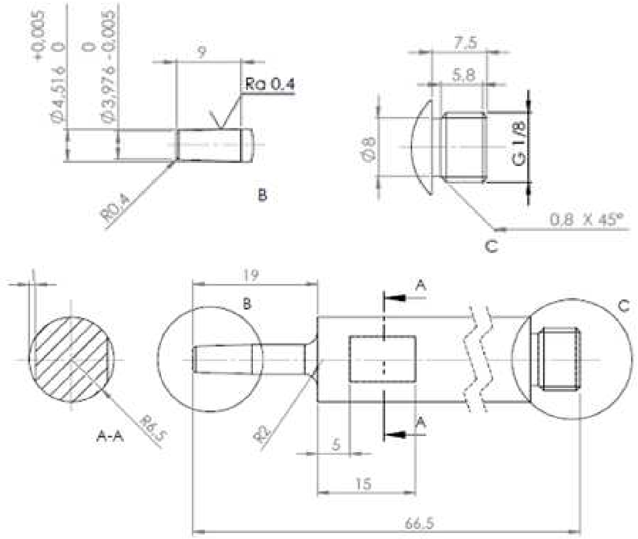

Fig. 5. Sealing mandrel construction 2 (Maciejewski, 2012)

4. VERIFICATION TESTS

Checking whether the first testing module operates properly consisted in the visual control of the rejected soldered connections. The quality of the accepted components' connections was inspected when the second testing module's functioning was being verified (the automatic machine accepted 525 connections of the sensor and the cable).

The automated assembly line rejected 7 connections of soldered component parts out of 525 transducers manufactured, while the visual control proved a bad solder quality in 6 cases and no faults were found in one case.

The quotient of the number of suitable components' connections and the number of good transducers was less than 1 per mil, which proves that the modernisation proposed and conducted on the testing module 1 one was correct.

Pressure transducers' user properties were verified by means of manually operated stationary testers. Air flow volume was measured using the MPS 5 device, and the sealing test was conducted by means of the MPS40 device by JW FROEHLICH company. The flush rate of the flush device was not tested when a given transducer proved not to be tight.

As it has already been stated, 525 Combitrans 3 transducers produced by the modernised automated machine underwent the verification tests. The testing procedure parameters were changed in their production process. Tab. 3 includes the chosen parameters and the results of the 0, 1 and 12 verification tests.

Testing procedure parameters of the 0 verification test are consistent with the ones proposed by the manufacturer of the automated machine. The results of this test reflect the influence of the changes proposed on the automated machine's operation. As it has already been stated, 100% of suitable transducers were wrongly qualified. This value decreased to 60.61% after the testing modules' modernisation. This proves that there is a need for procedural changes that would allow for balancing the assembly line (Corominas et al., 2011; Martinez ate al., 2009).

The results of the 1 and 12 verification tests are consistent with the requirements established at the beginning. Respectively, 4.08% and 2.50% of the transducers are wrongly qualified. The testing time of the 12 examination is more than 3 times shorter than the 1 test's time.

Tab. 3. 0, 1 and 12 verification tests' results (Maciejewski, 2012)

Stage no.	Procedure	Test 0	Test 1	Test 12
1	Filling time [ms]	800	800	800
	PA3027 sensor max/min pressure after filling [mmHg]	330.00	330.00	330.00
		260.00	260.00	260,00
	MPX2300DT1 sensor pressure tolerance in comparison to PA3027 sensor pressure [mmHg]	12.00	12.00	12.00
		12.00	12.00	12.00
2	Stabilisation time [ms]	1.200	4.000	1.200
	MPX2300DT1 sensor max/min pressure difference, with reference to the previous stage [mmHg]	25.00	25.00	25.00
		-10.00	-10.00	-10.00
3	Sealing test time [ms]	1.000	4.000	1.000
	MPX2300DT1 sensor max/min pressure difference, with reference to the previous stage [mmHg]	0.25	0.25	0.50
		-2.50	-2.50	-2.50
4	Flush device testing time [ms]	800	4.000	800
	MPX2300DT1 sensor max/min pressure difference, with reference to the previous stage [mmHg]	140.00	140.00	140.00
		90.00	90.00	90.00
Testing procedure duration time [ms]		3.800	12.800	3.800
Number of manufactured transducers		140	55	42
Number of accepted transducers (IO)		52	47	39
Manual control	Sealing test IO	52	47	39
	Flush rate test IO	52	47	39
	Total IO	52	47	39
Number of rejected transducers (NIO)		88	8	3
Manual control	Sealing test	80 IO 8 NIO	2 IO 6 NIO	1 IO 2 NIO
	Flush rate test IO	80	2	1
	Total IO	80	2	1
Number of suitable transducers produced		132	49	40

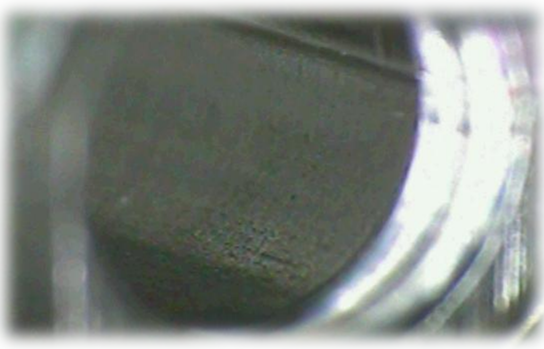

Fig. 6. Surface of a randomly chosen flush device (Maciejewski, 2012)

The visual control of the transducers produced referred to the inner surface of the flush device. The aim of the control was to check if the polymer structure could be damaged in any way. The control was led by means of the Heidenhain ND 1300 Quadra Chek device, compatible with the Lynx microscope. Visual assessment of randomly chosen transducers did not reveal any damages in the flush device's inner layer (Fig. 6), and the presence of the sealing mandrel's material was also not detected.

5. CONCLUSION

Functioning assessment of the automated assembly line to manufacture medical pressure transducers revealed a number of problems related to their assembly quality control. The reservations referred to the 1 and 2 testing modules' construction and the parameters of the testing procedure 2.

Bad quality of the electrical connection between the transducer examined and the electric tester had a negative influence on the testing procedure. Wrong Combitrans 3 sealing mandrel construction, in turn, caused the occurrence of plastic stresses during the production cycle.

Automated assembly line modernisation referred to the materials used to produce elements of the electrical connection between the pressure transducer and module of the automated machine. Silver was used as the material for cable pins. Due to this, only one good solder connection out of 525 was rejected.

The mandrels sealing the transducer (Fig. 4) during the tests were produced in the Division of Technology Machines of the Poznan University of Technology. The quality of shape and volume of the elements produced allowed for the automated machine's functioning assessment after its modernisation.

The duration of the testing procedure was taken into account while choosing the best parameters for it. The production costs increase together with the rise in average production time. While the testing procedure of the test 1 takes 12.8 s, it is only 4 s in the case of the test 12. What is crucial, is that all the transducers accepted by the automated machine fulfil the conditions of being allowed for use.

During the verification tests a slight wear of the sealing mandrel's conical surface was noticed, which was the result of the surface not being heat-treated. The mandrel's resistance to abrasive wear increased after the material's hardening and tempering, as well as controlling the shape and volume accuracy.

The testing modules and procedures modernisation proposed allowed for the fulfilment of requirements established for the functioning of the automated assembly line to manufacture medical pressure transducers.

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