POLITECNICO DI MILANO

Corso di Laurea in Ingegneria dell'Automazione

SET UP AND VALIDATION OF AN ASSEMBLING SYSTEM OF IMPLANTABLE DEVICES FOR HYDROCEPHALUS TREATMENT

Relatore: Prof. Ferrarini Luca

Tesi di laurea di

Michelino Taurasi Matr. 740084

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First of all, I would like to thank all my colleagues Johnson&Johnson for giving me the opportunity to do my internship in their company and for their confidence in me. They made me feel a part of their team and I learned a lot during these months.

I would like to thank my advisor professor, for answering to my questions and for his guidance during the early stages of this work and of my internship in general.

ABSTRACT

The work of this thesis has been conducted during my internship (November 2010-July 2011) at the Department of Manufacture Engineering at Medos SA & Codman Sàrl Johnson & Johnson Company in Le Locle (Switzerland).

The purpose of my internship and, consequently, of this work is the set up, the optimization and the validation of a Semi-Automatic System for the assembling of implantable devices (Hakim Valves) for the hydrocephalus treatment.

Hydrocephalus can be defined as an excessive intracranial accumulation of cerebrospinal fluid (CSF) where the pressure of the CSF increases in order to maintain the balance between secretion and resorption rates.

At this time, the standard treatment for hydrocephalus is surgery. There is no long term medical treatment. The most common treatment with all forms of hydrocephalus is shunting. A shunt helps to drain the excess fluid and relieve the pressure in the brain.

The Semi-automatic System, object of this work, is studied to perform the complete Hakim valve subassembly range, starting from Precision valves to the Programmable one. The project, based on the current assembly line (manual), has been developed thanks to the competences and skills in the micromechanical field of watch sector and the deep knowledge of the medical aspects.

My goal as an intern was to carry out the various steps and associated activities needed to introduce the System in production. To this aim I had to define the initialization and production steps, the setting up of all the parameters, all the tolerances and the operations that the system has to perform. I also had the duty to write the tests for validating the manufacturing process in line with what is required by the medical sector.

This new Assembling System belongs to the constantly improving philosophy that makes, as surgeons say, “Hakim Valves work like Swiss watches”. Consequentially, all the settings fulfill the precision standards used in the Swiss watches micro-mechanical sector. Moreover this project has required the acquisition of the necessary prerequisites knowledge about rules and strategies applied in the medical implantable device sector in order to produce reliable and effective devices.

The assembling system has consisted in assembling different components together, testing their ability to resist a certain level of applied force. This work includes hardware and software programming along with statistic studies, mechanical settings, and mathematical proof based on empirical arguments.

Keywords: Hydrocephalus, Hakim Valve, Press Fit, Push Out Test, Validation.

ESTRATTO

Il lavoro di questa Tesi è stato condotto durante il tirocinio (Novembre 2010-Luglio 2011) svolto presso il Dipartimento di ingegneria della prozuzione della Medos SA & Codman Sàrl Johnson & Johnson Company in Le Locle (Svizzera).

Il mio tirocinio e, di conseguenza, questo progetto di tesi, hanno avuto come finalità la configurazione, l'ottimizzazione e la validazione del Sistema Semi-Automatico per l'Assemblaggio di Dispositivi Medici Impiantabili (Valvole Hakim) per il trattamento dell'Idrocefalo.

Il termine Idrocefalo si riferisce alla condizione in cui un accumulo eccessivo di liquido cerebro-spinale a livello intracranico innesca una ipertensione intracranica dovuta all'esigenza di bilanciare i livelli di secrezione e riassorbimento.
Attualmente, il trattamento standard per l'idrocefalea è rappresentato dalla chirurgia. Di fatto non esiste una soluzione permanente. Il trattamento più comune in tutte le forme di idrocefalea è rappresentato dall'impianto chirurgico di derivazione chiamato shunt. Lo shunt drena e rincanala il liquido in eccesso ad altre cavità del corpo come quella addominale o cardiaca.

Il sistema semi-automatico oggetto di questo lavoro di tesi è studiato per l'assemblaggio della gamma completa delle Valvole Hakim, a partire dalle valvole di Precisione fino alle Valvole Programmabili attivamente. Questo progetto, basato sull'attuale linea di assemblaggio (manuale), è stato sviluppato grazie alle competenze e al talento acquisiti nel settore della micromeccanica, dell'orologeria e alle intense conoscenze in campo medico.

Il mio obiettivo, all'interno del progetto, è definire le diverse operazioni del sistema durante la procedura di inizializzazione e produzione; la messa a punto e la configurazione di tutti i parametri e di tutte le azioni che il sistema deve eseguire, oltre alla scrittura dei vari tests richiesta per la validazione in campo medico. Tutto questo allo scopo di introdurre il sistema alla produzione. Ciascuno dei parametri selezionati deve essere accompagnato da una chiara motivazione dei presupposti e dimostrazione della scelta.
Il sistema di assemblaggio semi-automatico è ispirato alla filosofia di miglioramento continuo che permette, come dicono i chirurghi, alle "Valvole

Hakim di funzionare come degli orologi svizzeri". Di conseguenza, questo progetto ha richiesto l'acquisizione della conoscenza di tutti prerequisiti necessari relativi alle regole e alle strategie applicate al settore dei dispositivi medici impiantabili allo scopo di realizzare prodotti affidabili ed efficaci, nel rispetto degli alti standard di precisione del settore micro-meccanico dell'orologeria svizzera.

Il sistema di assemblaggio consiste, quindi, nell'assemblaggio di vari componenti verificandone, allo stesso tempo, la capacità di resistenza a determinati livelli di forza applicata. Questo lavoro ha comportato la necessità di programmazione di software e hardware nonché studi statistici, settaggi meccanici e verifiche matematiche basate su evidenze empiriche.

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INTRODUCTION

Miniaturization and integration of mechanical, sensing and control functions within confined spaces are important trends in designing new products in many industries. For products like implantable medical devices, the miniaturization is not only a trend, but it is considered a must, since the spaces are limited by the natural human shapes.

During my internship (October 2010 – July 2011) at the Department of Manufacture Engineering at Medos SA & Codman Sàrl Johnson & Johnson Company in Le Locle (Switzerland), I have been working on a micro assembly project that is the object of this work. The main part of my work has been the set up, the optimization and the validation of a Semi-Automatic System for the assembling of implantable devices (Hakim Valves) for the hydrocephalus treatment.

Hydrocephalus can be defined as an excessive intracranial accumulation of cerebrospinal fluid (CSF) where the pressure of the CSF increases in order to maintain the balance between secretion and resorption rates (Association, 1983). Under normal conditions there is a delicate balance between the rate at which CSF is produced and the rate at which it is absorbed. Hydrocephalus occurs when this balance is disrupted and the rate of absorption is less than the rate of production.
At this time, the standard treatment for hydrocephalus is surgery. There is no long term medical treatment. The most common treatment with all forms of hydrocephalus is shunting. A shunt is a flexible tube placed into the ventricular system that diverts the flow of CSF into another region of the body where it can be absorbed, such as the peritoneal (abdominal) cavity or the right atrium of the heart.

The current production of the Hakim Valve is a procedure of micro manufacture, although with the requirement of smaller size of the assembling components, the manual assembly starts to become unfeasible. As a result, micro assembly is becoming a sector of strategic importance in high labor cost areas due to the specific needs of automated assembly processes. The automated assembling of

miniaturized products requires radical rethinking and restructuring of the current technologies and manufacture engineering approaches in high-precision assembly.

The Hakim Valves production is concerned with the assembly of small parts into a Base Plate with high accuracy. Typical part dimension ranges of a few millimeters with part features often in the micrometer range. The typical positional accuracy required in Hakim Valve assembly is in the range of 0.001-0.005 mm.

Due to the size of the parts and different physical phenomena associated with micro assembly, the set up and the optimization of the all the Semi-Automatic Assembling System working parameters has been an extremely difficult and complex process with low yield where conventional positioning, handling and joining techniques have been often rendered inapplicable.

Some of the specific issues related to the precision assembly of the Hakim Valve include:

- Requirements for high-accuracy assembly of micro components;
- Stringent regulatory requirements and constraints for the validation procedures;
- Specific emphasis on time to volume as a critical system performance indicator;
- Cost-effective manufacture of large volumes of customized assembled products;
- The need for extremely reliable assembled products.

The Semi-Automatic Assembly Machine is studied to perform the complete Hakim valve subassembly range, starting from Precision valves to the Programmable ones. The project, based on the current, manual, assembly line, has been developed thanks to the competences and skills in the micromechanical field of watch sector and the deep knowledge of the medical aspects.

Previously to my arrival, the machinery was sitting at the engineering laboratory without software debugging and any kind of setting had been performed (the machine was just switching on).

Process automation has been a key requirement in micro assembly for the new components design of the Hakim Valve due to the small part size and the associated difficulties with manual manipulation and processing. Recent technology developments in high-precision micro actuation enabled the development of the new Semi-Automatic Assembling System with positioning accuracy of up to 0.001mm.

My goal consisted in the definition of the initialization and production steps, the setting up of all the parameters, all the tolerances and the operations that the system has to perform together with all the validations required by the medical sector in order to put the system in production. Each and every parameter chosen has to have a clear explanation of the reason why it has been selected.

The Semi-Automatic Assembling System, object of this work, belongs to the constantly improving philosophy that makes as surgeons say, "Hakim Valves work like Swiss watches". Consequentially, this project has required the acquisition of the necessary knowledge prerequisites about the rules and the strategies applied in the medical implantable devices sector in order to produce reliable and effective devices, as well as the precision standards used in the Swiss watches micro-mechanical sector

The assembling system has consisted in assembling different components together, testing their ability to resist a certain level of applied force. This work includes hardware and software programming along with statistic studies, mechanical settings, and mathematical proof based on empirical arguments.

Medos Codman (Johnson & Johnson Company)

Codman & Shurtleff Inc founded in 1857, with its headquarters in Rayhnam, Massachusetts (USA). Originally it provided instruments for medical, surgical, dental and veterinary use. In 1911, the company began a long and important partnership with Dr Harvey Cushing. He is the first surgeon to specialize in brain surgery. He is, indeed, considered to be «the father of neurosurgery». In 1964, Codman & Shurtleff Inc joins Johnson & Johnson and by means of an impressive product range, specializes in the treatment of nervous system disorders.

Medos Sàrl, Le Locle founded in 1983 is, in turn, the result of a close collaboration between Dr Hakim, a Colombian neurosurgeon, and Mr. Desaules, an engineer from Le Locle, who developed a revolutionary programmable valve for the treatment of hydrocephalus.

In 1991, Johnson & Johnson acquires Medos SA, and this allows the completion of the Codman product line in the field of neurosurgery.

With the creation of Codman Sàrl, Neuchâtel, in 1999, all Johnson & Johnson activities in the fields of neurosurgery and the treatment of hydrocephalus are successfully grouped.

2

PRELIMINARIES

2.1 Hydrocephalus

2.1.1 What is the hydrocephalus?

Hydrocephalus is a term derived from two Greek words: “hydro” meaning water and “kephale” meaning head. The first use of “hydrocephalus” term in recorded history was around the 433-377 BC by Hippocrates, although its today meaning differs from its original one.
Hydrocephalus is a condition in which an excessive amount of cerebrospinal fluid (hereafter CSF), accumulates within the cavities of the brain known as ventricles. This excessive amount of CSF can result from a blockage in the brain’s ventricular system which prevents the normal flow of the CSF, or as the result of a problem with CSF absorption as explained in Zemack, 2003.

2.1.2 Definition and types

Hydrocephalus can be defined as an excessive intracranial accumulation of cerebrospinal fluid (CSF) where the pressure of the CSF increases in order to maintain the balance between secretion and resorption rates. The CSF is produced within the cavities of the brain that are called ventricles, which could be practically considered as chambers filled with fluid. There are four in all: the two lateral ventricles, the third ventricle and the fourth ventricle. The ventricles are interconnected by narrow passageways. Our bodies produce approximately a pint (500 ml) of CSF daily, continuously replacing CSF as it is absorbed. Under normal conditions there is a delicate balance between the rate at which CSF is produced and the rate at which it is absorbed. Hydrocephalus occurs when this balance is disrupted and the rate of absorption is less than the rate of production.

Although there are many factors that can disrupt this balance, the most common is a blockage, or obstruction, somewhere along the circulatory pathway of CSF. The obstruction may develop from a variety of causes, such Cerebrospinal fluid (CSF) circulatory pathway. Because CSF is produced continuously, when its flow is blocked it will begin to accumulate upstream from the site of the obstruction, much like a river swells behind a dam. Eventually, as the amount of fluid accumulates, it causes the ventricles to enlarge and pressure to increase inside the head. This condition is known as hydrocephalus.
Obstruction of the CSF pathway often occurs within the ventricles. Although it can occur anywhere in the ventricular system, the site of blockage usually lies either within the narrow passageways connecting the ventricles or where the CSF exits, the fourth ventricle into the subarachnoid space. For example, because of its long, narrow structure, the aqueduct of Sylvius is especially vulnerable to becoming narrowed or obstructed so that it blocks the flow of CSF. Likewise, when the small openings of the fourth ventricle fail to develop, or develop improperly, they also may obstruct the flow of CSF. Hydrocephalus of this kind is called "noncommunicating" or obstructive hydrocephalus because the ventricles no longer provide free passage of CSF through them into the subarachnoid space.
Another type of hydrocephalus is Communicating or Extraventricular Obstructive Hydrocephalus. It usually results from a thickening of the arachnoid around the base of the brain, which blocks the flow of CSF from the spinal to the cortical subarachnoid spaces. CSF flows unrestricted through the ventricles, but a blockage between the spine and the fluid around the outside of the brain prevents the free flow of CSF through the subarachnoid space as shown in Delia R Nickolaus, 2004.

2.1.3 Causes

Hydrocephalus that is congenital (present at birth) is thought to be caused by a complex interaction of environmental and perhaps genetic factors. (a.g. Aqueductal stenosis, spina bifida, etc.) Some people with the Syndrome of Hydrocephalus in Young and Middle-Aged Adults (SHYMA) are classified as having decompensated congenital hydrocephalus. That is, the hydrocephalus may have been present at birth, and perhaps even treated in early childhood, but remained largely compensated and asymptomatic for many years. Congenital hydrocephalus can be diagnosed by assessing head circumference. If the head circumference is significantly larger than normal, according to standard charts and references, it is reasonable to suspect that hydrocephalus has been present since early life, even though it may not have been symptomatic in infancy. Acquired hydrocephalus arises after birth, and results from intraventricular haemorrhage, meningitis, head trauma, encephalitis, tumors or cysts. Sometimes

doctors are unable to pinpoint the cause of hydrocephalus. In this case, the hydrocephalus is deemed to be idiopathic, meaning of unknown cause. Whether genetic factors play any role in SHYMA, still remains obscure, although inherited forms of hydrocephalus are virtually unknown. The causes of SHYMA are similar to the causes of hydrocephalus at all ages, including processes that obstruct the ventricles, such as cysts or tumors, and processes that impair the flow of spinal fluid through the subarachnoid space, such as meningitis, encephalitis, concussion, head injury, or certain strokes and brain haemorrhages. Hydrocephalus does not always occur immediately after one of these predisposing conditions has occurred. In many instances, years or decades may pass before the symptoms of SHYMA become evident (Association, 1983).

2.1.4 Diagnosis

In infants and toddlers, the bones of the skull are not yet closed and hydrocephalus may be obvious. The child's head will enlarge, and the fontanel (soft spot) may be tense and/or bulging. The skin may appear thin and shiny, and the veins of the scalp may appear full or engorged. Symptoms may include vomiting, poor feeding, listlessness, irritability, constant downward gaze of the aeyes, and at times, seizures.

In older children and adults, the bones of the skull have closed. These patients have symptoms of increased intracranial pressure due to ventricular enlargement (from the extra CSF) which causes compression of the brain tissue. Symptoms may include, but are not limited to, headache, nausea, vomiting, visual disturbances, poor coordination, personality changes, lack of concentration, and lethargy. The signs and symptoms of increasing intracranial pressure are likely to change over time, as the cranial sutures (the joints between the bones of the skull) begin to close in the infant and toddler and are fully closed in the school age child.

Signs and symptoms of increased intracranial pressure are useful in the initial diagnosis of hydrocephalus and also when there is a shunt malfunction or infection as will be discussed later. Zemack, 2003 shows that in adults with normal pressure hydrocephalus, the symptoms are usually connected to difficulties in walking, mild dementia, and urinary incontinence (Zemack, 2003).

2.1.5 Shunting Treatment

In many cases, prompt treatment can reverse many of the symptoms of hydrocephalus, restoring much cognitive and physical functioning. If left untreated, however, symptoms can become quite disabling, leading to severe cognitive and physical decline. It appears that the length of time between onset of symptoms and diagnosis is a factor in the success of treatment. Another, as yet unmeasurable, factor that affects the outcome of treatment is the extent of reversible versus irreversible brain injury caused by hydrocephalus. Treatment is most successful when little irreversible injury has occurred. Transient improvement of symptoms after lumbar puncture or spinal fluid drainage by lumbar catheter is one way to demonstrate that some of the brain injury is still reversible.

At this time, the standard treatment for hydrocephalus is surgery. There is no long term medical treatment. The most common treatment with all forms of hydrocephalus is shunting. A shunt is a flexible tube placed into the ventricular system that diverts the flow of CSF into another region of the body where it can be absorbed, such as the peritoneal (abdominal) cavity or the right atrium of the heart. The shunt tube is about one-eighth inch in diameter and is made of a soft and pliable plastic that is well tolerated by our body tissues. Shunt systems come in a variety of models but have similar functional components. Catheters (tubing) and a flow-control mechanism (one-way valve) are components common to all shunts. The valve in the shunt maintains the CSF at normal pressure within the ventricles. The surgical placement of a shunt, which is performed by a neurosurgeon, is a relatively short procedure. The patient is brought to the operating room and is placed under general anesthesia. A small region of the scalp may be clipped or shaved, and, for a ventriculoperitoneal shunt, the entire area from the scalp to the abdomen is scrubbed with an antiseptic solution. Sterile drapes are placed over the patient. Incisions are made in the head and abdominal areas. The shunt tube is passed beneath the skin, in the fatty tissue that lies just below the skin. A small hole is made in the skull, and the membranes between the skull and brain are opened. The ventricular end of the shunt is gently passed through the brain int o the ventricle. The abdominal (peritoneal) end is passed into the abdominal cavity through a small opening in the lining (peritoneum) of the abdomen. This is where the CSF will ultimately be absorbed. The incisions are then closed. When the procedure is completed, sterile bandages may be applied to the incisions and the patient is taken to the recovery room where the anesthesia is allowed to wear off (Association, 2006).

Success of shunting

In some studies of patients with SHYMA, shunting has had extremely high rates of success, reversing marked decline and returning patients' lives to "normal".

However, due to the lack of data collected on this specific population, statistics are hard to come by.
Before the introduction of the CSF shunts, surgical treatment of patients with hydrocephalus was in many cases not feasible and patients in need of chronic care where admitted to the sanatorium. The invention of the valved shunts was a breakthrough in the treatment of the hydrocephalus even though the rate of complications was high. In the immediate years following their introduction. Within a few decades, the long-term rate of mortality was reduced from approximately 50% to 10%. The use of shunts for CSF drainage increased rapidly in the following years and continues to increase constantly.

2.2 The Hakim implantable Valve

2.2.1 Basic principle

A valve is a mechanical device that regulates pressure (i.e., a differential pressure valve). A valve typically functions as follows:

- When the difference between the inlet pressure and the outlet pressure exceeds the opening threshold, the valve opens (Figure 1).
- The pressure difference across the valve when it opens is called the "opening pressure"; the pressure difference when the valve closes is called the "closing pressure."
- The "operating pressure" is the pressure difference across the valve at a specific flow rate, as tested and specified by the manufacturer.

The Codman Hakim Valves are implantable devices that provide constant intraventricular pressure and drainage of CSF for the management of hydrocephalus. The components of the shunt system includes two catheters and a one-way Hakim valve.

The catheter placed in the ventricle of the brain is called the proximal catheter because it is closest to the ventricles. The catheter placed in either the peritoneal cavity (abdomen) or, occasionally, in the right atrium of the heart, is called the "distal catheter" because it is the catheter farthest way from the ventricles. Both catheters are attached to the one-way Hakim valve used to regulate the amount, direction, and pressure of CSF flow out of the ventricles.

There are several different kinds CSF valves. Each valve is designed to operate at a different pressure/flow range or performance level. The surgeon's choice of valve is based on an evaluation of the type of hydrocephalus and the individual needs of the patient.

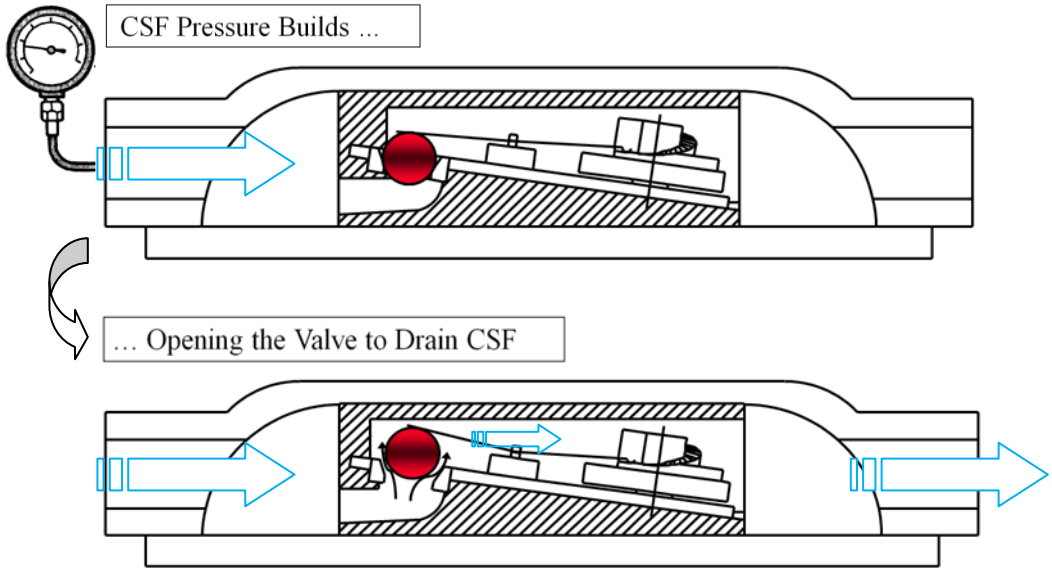

Figure 1 - Hakim Valve basic principle

2.2.2 Fluid dynamics

The human brain is immersed in the so-called cerebrospinal fluid (CSF), which protects the brain from mechanical stress (e.g. concussion), helps support its weight through buoyancy and also serves for the nutrient supply of the brain. In case of Hydrocephalus, the normal situations of production and reabsorption of this fluid are not balanced. The implantation of a passive pressure-control valve and of a catheter system (called "shunt") drains excess fluid into another body compartment (usually the stomach cavity). The pressure difference across the valve when it opens is called the "opening pressure of the Valve" (OPV).
The differencial pressure is calculated as:

$$\Delta P = ICP - OPV + HP - IAP \text{ (Figure 2)}$$

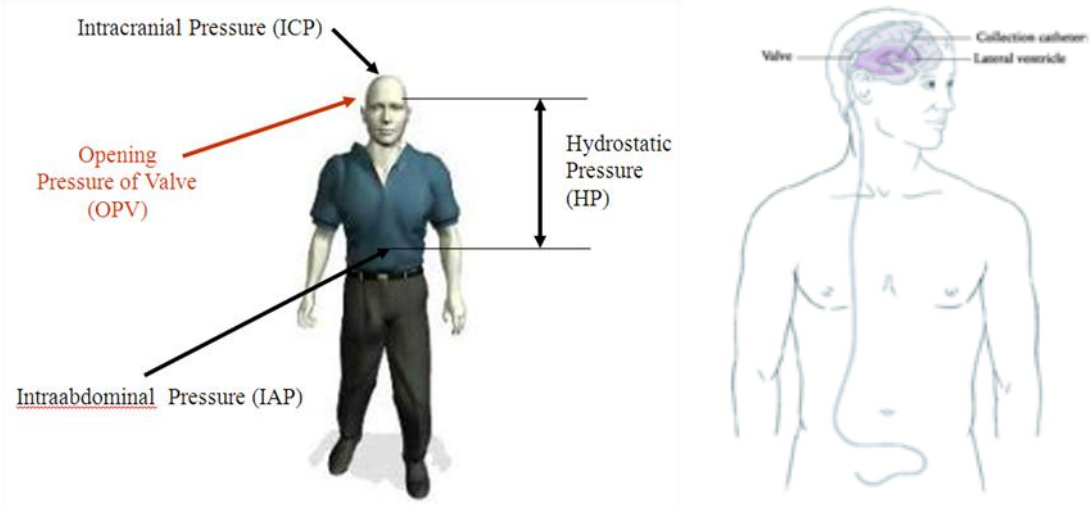

Figure 2 - Fluid dynamics with Hakim Valve

2.2.3 Different types of valve

Programmable

(HAKIM®, 2009)The Codman Hakim Programmable Valve (CHPV) is adjusted non-invasively by the use of a coded magnetic field transmitted by an external adjustment tool. By choosing one of 18 settings, the CHPV pressure can be adjusted between 30 mm H2O - 200 mm H2O in increments of 10 mm H2O (Figure 3).

Figure 3 - zoom Hakim Programmable Valve

Precsion

The Hakim Precision Fixed Valves have a pressure range of 10, 40, 70, 100, and 130 mmH²0 that must be set prior to implant. This setting cannot be changed non-invasively (Figure 4 - zoom Hakim Precision Valve).

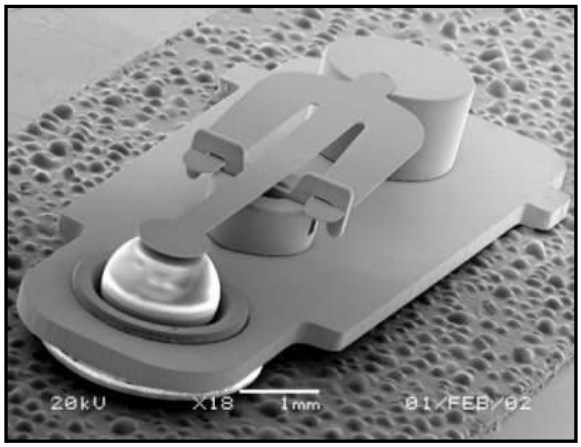

Figure 4 - zoom Hakim Precision Valve

2.2.4 The programmable valve

Major components

The Hakim Programmable Valve includes a valve mechanism that incorporates a flat 316L stainless steel spring in which the calibration is accomplished by a combination between a pillar and a micro-adjustable telescoping fulcrum. The valve chassis is made of titanium. The ball and the cone are manufactured from synthetic ruby. The intraventricular pressure is maintained at a constant level by the ball and cone valve seat design.

The base plate contains a pivot, spring pillar and spring fulcrum. The pivot is a stationary component that is assembled to the base plate. The stepper motor is connected to the pivot. The stepper motor can rotate and thus allowing for the flat spring to move and change the pressure settings as dictated by an external programmer. The spring pillar is a stationary component assembled to the base plate that holds the fulcrum. The fulcrum holds the flat spring in place and allows the valve to be programmed (Figure 5).

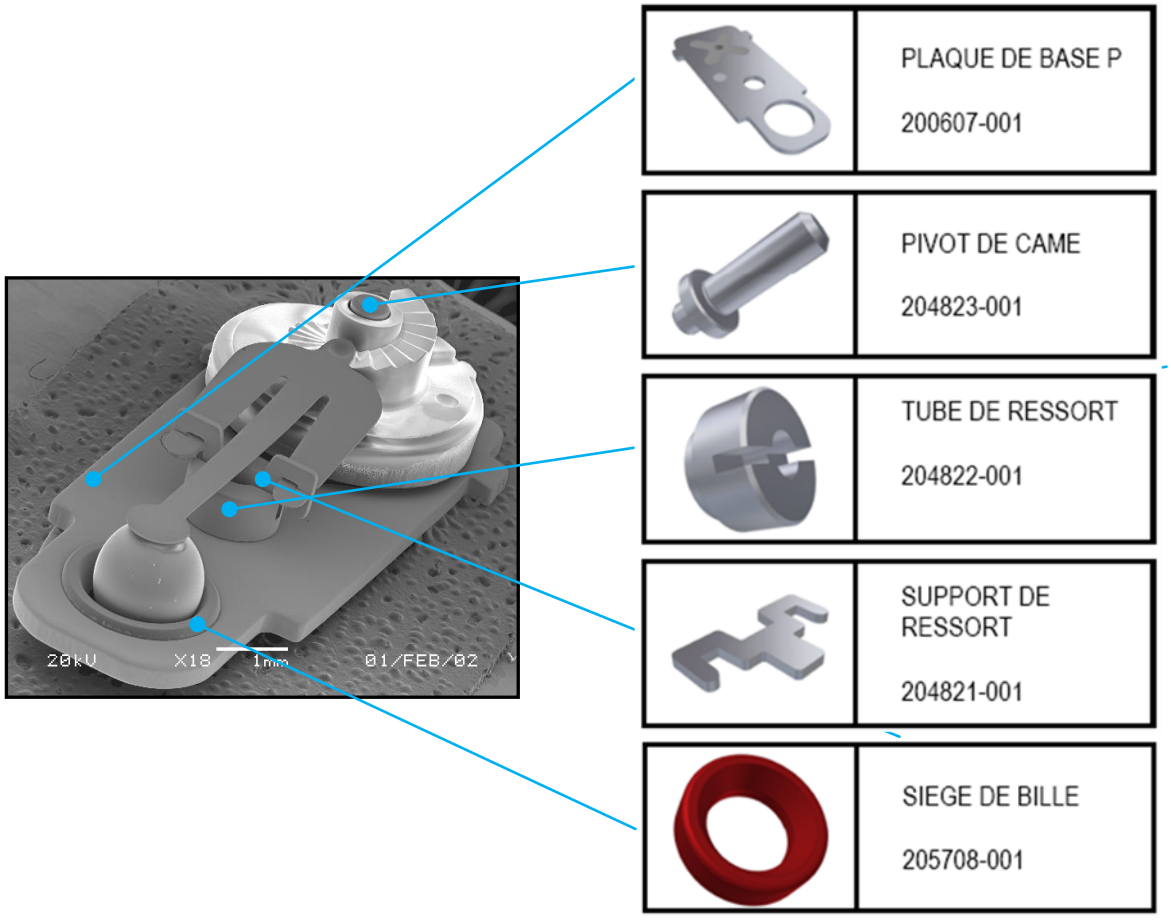

Figure 5 – Programmable Hakim Valve's major components

The assembling principle and interference definition

The Hakim valve is basically assembled by press fitting the components on the Base Plate. A press fit, also known as an interference fit or friction fit, is a fastening between two parts which is achieved by friction after the parts are pushed together, rather than by any other means of fastening. For metal parts in particular, the friction that holds the parts together is often greatly increased by compression of one part against the other, which relies on the tensile and compressive strengths of the materials the parts are made from. The Hakim valve assembling is a typical example of interference fits press fitting the shafts into their housings.

(Wikipedia)The interference fit is achieved by shaping the two mating parts so that one or the other (or both) slightly deviate in size from the nominal dimension. The word "interference" refers to the fact that one part slightly interferes with the space that the other is taking up. For example: a shaft may be ground slightly oversize, and the hole in the bearing (through which it goes to pass with an interference fit) may be ground slightly undersized. When the shaft is pressed into its housing, the two parts interfere with each others occupation of space; the result is that they elastically deform slightly, each being compressed, and the interface between them is one of extremely high friction—so high that even large amounts of torque cannot turn one of them relative to the other; they are locked together and they turn in unison.

Open Pressure Valve regulation

The pressure setting of the spring in the inlet valve unit is noninvasively adjusted by the use of an external programmer (Figure 7), which activates the stepper motor within the valve housing. The programmer (Figure 6) transmits a codified magnetic signal to the motor allowing eighteen pressure settings, ranging from 30 mm to 200 mm H2O (294 to 1960 Pa) in 10 mm (98 Pa) increments. These are operating pressures of the valve unit and have been determined with a flow rate of 15–25 mL H2O per hour. (HAKIM®, 2009)

Figure 6 - Pressure regulator programmer

Figure 7 - Hakim programmable valve adjustment

The valve is classified by its working pressure with a specified flow rate and not by the opening and closing pressures. The pressure that a valve sustains with a given flow is the parameter that reflects the working pressure of the valve once it is implanted. Before shipment, each valve is calibrated with special equipment.

The spring in the ball and the spring mechanism of the valve sits atop a rotating spiral cam which contains a stepper motor (Figure 8). The application of a specific magnetic field to the stepper motor will cause the cam to turn slightly, increasing or decreasing the tension on the spring and on the ball, thus changing the opening pressure of the valve.

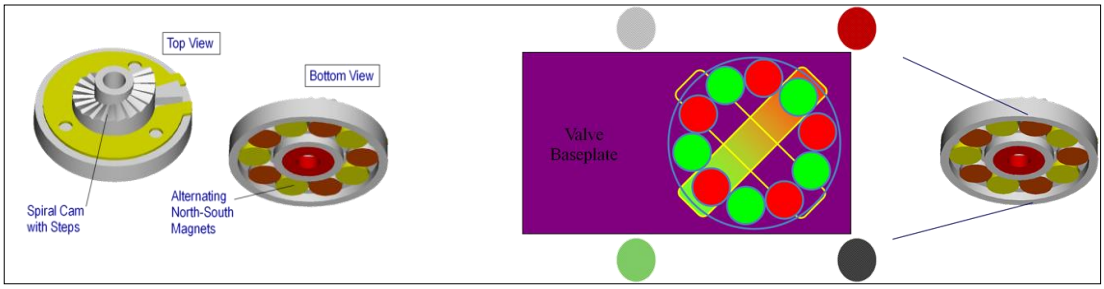

Figure 8 - Hakim Programmable Valve stepper motor - magnets disposition

Valve Configurations

Many different configurations and valve housing types allow customization for different needs and patient types without affecting performance (Figure 9).

Codma Hakim In-line and Right Angle Valves include a programmable valve with a low profile and flat bottom, and an in-line or right angle integral reservoir with or without Siphonguard.

Codman Hakim Standard Valves include a programmable valve, a pumping chamber, and an outlet valve available with a prechamber, without a prechamber, or with a Rickham reservoir.

Codman Hakim Micro Valves include a programmable valve with or without an integral Rickham reservoir.

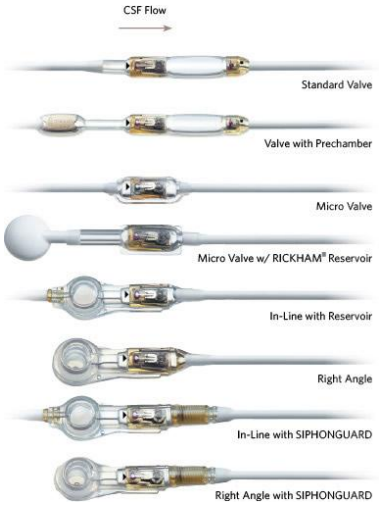

Figure 9 - Hakim valve configurations

Siphonguard Device: CSF flows through the inlet valve and enters the Siphonguard Device, where it flows into two internal passages. Under normal conditions, the majority of CSF flows through a central ruby ball and cone valve, and exits directly out of the distal port of the Siphonguard Device. The remaining CSF travels through a spiral passage that surrounds the central passage, and joins the fluid passing through the central passage, distal to the ball and cone valve. A sudden increase in CSF flow will close the ball and cone valve and the entire volume of CSF will be forced through the longer spiral passage, effectively slowing the rate at which CSF is shunted from the brain. Once the flow rate entering the Siphonguard Device decreases, the ruby ball separates from the valve seat, opening the central passage. As long as CSF continues to be shunted from the ventricles, flow through the spiral passage of the Siphonguard Device never stops, regardless of the patient's position (HAKIM®, 2009)

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2.2.5 Precision valve

The main difference between the programmable and precision valve base plate construction is that the precision valve base plate (Figure 10) has a stop pin instead of the pivot. The stop pin holds the flat spring in place and does not allow the pressure to be changed noninvasively. Thus the precision valve has the same settings during all its useful life.

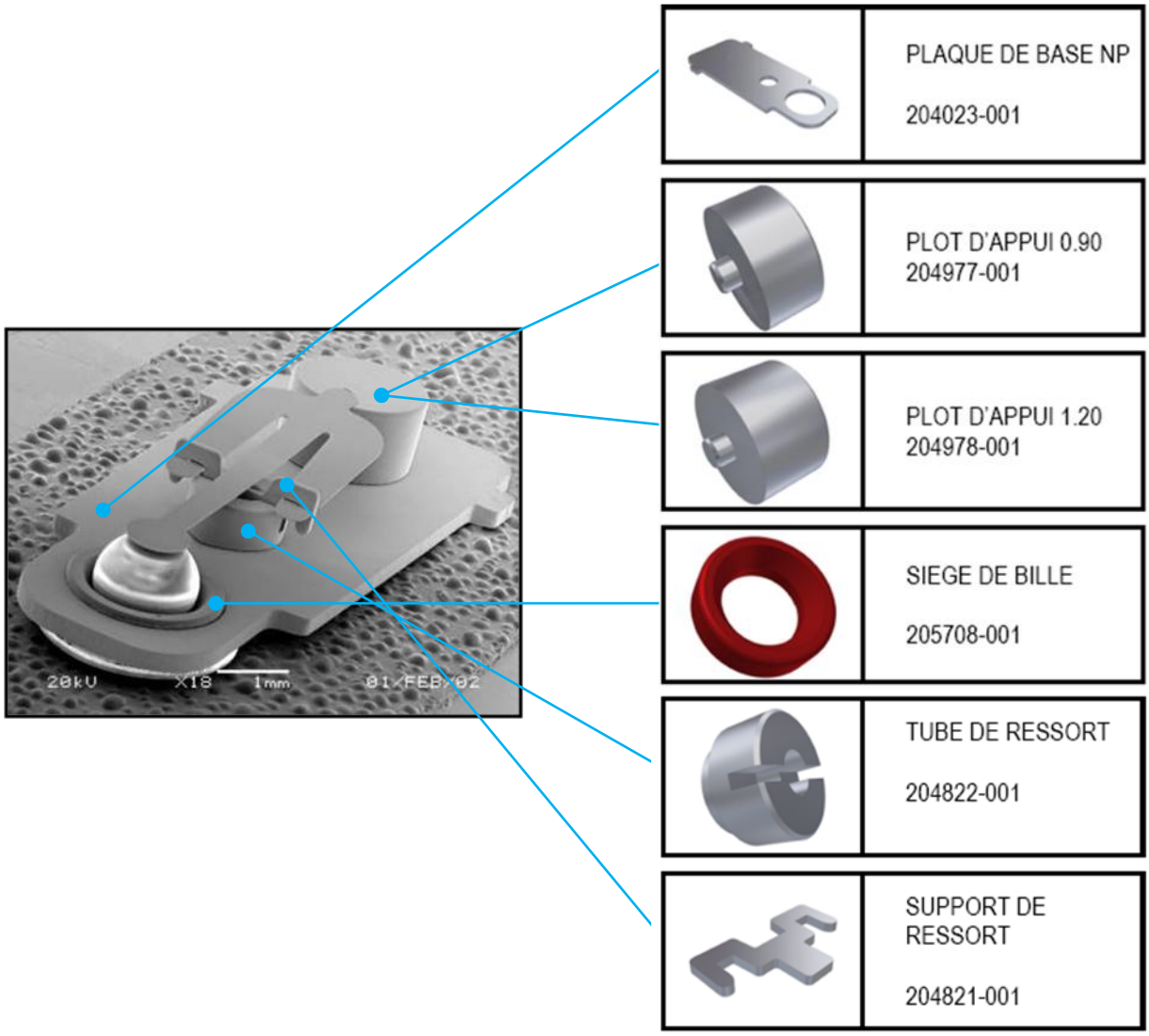


Figure 10 - Precision Hakim Valve's major components

3

PREVIOUS WORK

3.1 Introduction to the assembly system

3.1.1 Why an automatic system?

To stay competitive, Johnson&Johnson (JnJ) companies must have a flexible and agile manufacturing capability. Manufacturing is a competitive advantage for JnJ, but that calls for awareness of the manufacturing process within the company. As competition keep increasing, lead times are shrinking and manufacturing processes are becoming more elaborate. Moreover the medical sector requires the highest reliability for each product coming out from production lines.

According to the product development strategy, in Codman Medos it has been decided to follow on the improvement of the final product shortening, at the same time, the lead-time for the production. Since the assembly is a highly cost-intensive process, the engineering department focused on designing a special equipment to reduce the Work In Process time (hereafter WIP) during the earlier assembling steps of the Hakim Valve. Thus they started to work on designing a new equipment with the aim of increasing the quality of the final product using less time and less human resources. This project is the Semi-Automatic Assembly Machine and it appears like in (Figure 11).

The Semi-Automatic Assembly Machine, is studied to perform the complete Hakim valve subassembly range, starting from Precision valves to the Programmable one. The project, based on the current assembly line (manual), has been developed thanks to the competences and skills in the micromechanical field of watch sector on a deep knowledge of the medical aspects. The assembly machine has been integrated in the production line avoiding any further modification in the assembly cycle.

The system requires only one operator to load and unload components and to control the assembly process.

The vital importance of the valve implementation and the strict tolerance parameter has requested a continuous attention to precision in order to avoid any unexpected problems.

Figure 11 - Hakim Valve Semi-Automatic Assembly Machine

3.1.2 Presentation of the system

High level process flow chart

The semi-automated station is a single-station manned cell consisting of one worker tending the machine. The high level process flow chart (Figure 12) summarizes the operations realized by the cell.

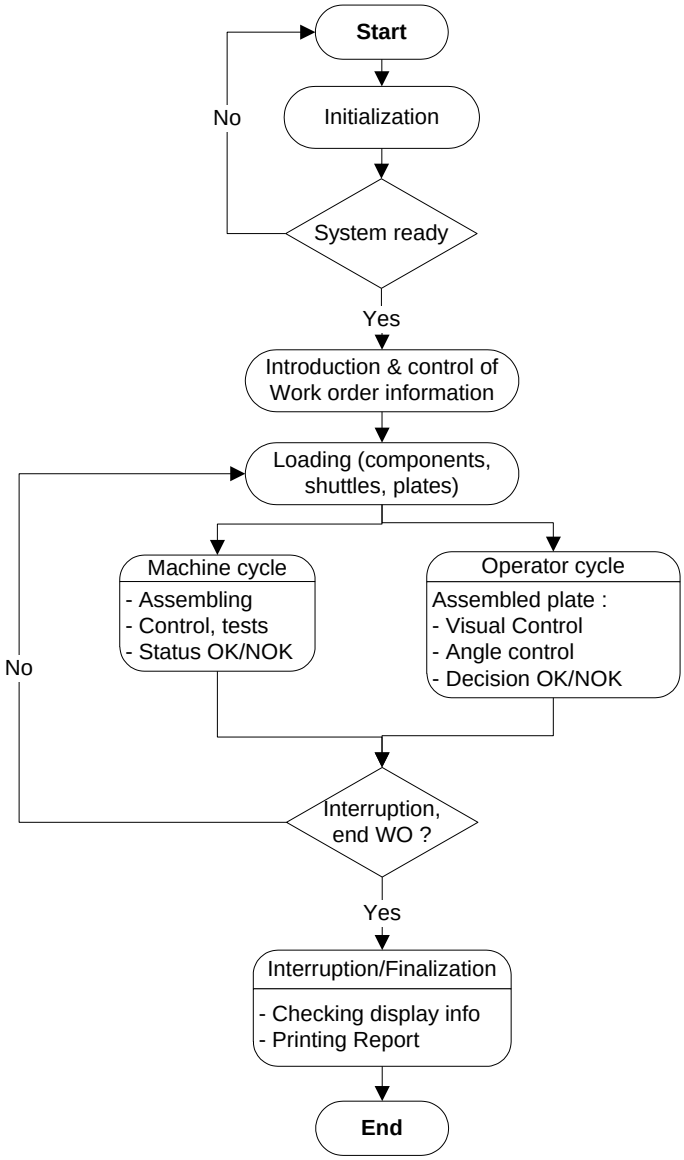


Figure 12 – High level system process flow chart

- The operator initialize the system and if it ends without any error he follows up using the software to give the instructions about the work order to be executed with the system
- The operator follows the instruction coming from the software and he load on a fixture called shuttle all the components which have to be assembled except the base plate.
- The operator puts the shuttle in the machine in the shutte axe
- The operator puts the base plates in the fixtures of the base plate axe and start the cycle
- The system starts to assemble the components using the machine components, actuators and sensors (more details will be explained in the following chapters).

Goal

The aim of the new equipment is to assemble the components coming from external providers in the three different configurations (Figure 13), (Figure 14) and (Figure 15)

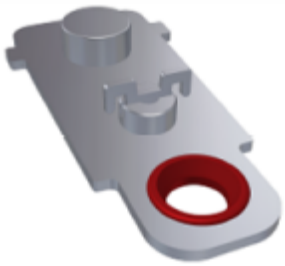


Figure 13- Precision sub-assembling Valve with 0.90mm Stop Pin

Figure 14 - Precision sub-assembling Valve with 1.20mm Stop Pin

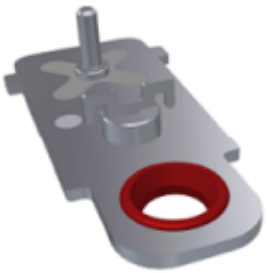


Figure 15 -Programmable sub-assembling Valve

In Chapter 2, the composition of each of the above configurations has been fully explained.

Beside the valve sub-assembling objective, there is also the push out control (holding test) for some of the components press fitted on the base plate. More details will be showed in the following chapters.

The manual process

The assembly process is a manual procedure which consists of serially connected stations where operators are located. The operators handle tools, components of various materials, and technologies, which are properly configured in ways that end with the assembling of the different Hakim valves configurations. More specifically, the assembly manual system is an assembling process of integrated equipment and human resources. Its function is to perform more processing and assembling operations on the base plate and on the set of the other parts. In the manually operated station the operator controls the handling tools, loads and unloads the assembling parts, manages and monitors the work cycle either continuously or for most of the cycle time. The operator may also be required to use a variety of work tools, such as tweezers, wrenches, or portable powered tools etc., to perform additional processes in the cell.

As it is clear from the Figure 16, the manual process is full of Work In Progress (WIP) time, thus the complete valve assembling time strongly depends from the how long do the WIP times last. Moreover the drilling operations required are performed outside the clean room and consequently other cleaning operations are required in order to fulfill the production standard requirements.

Flow chart of the manual process

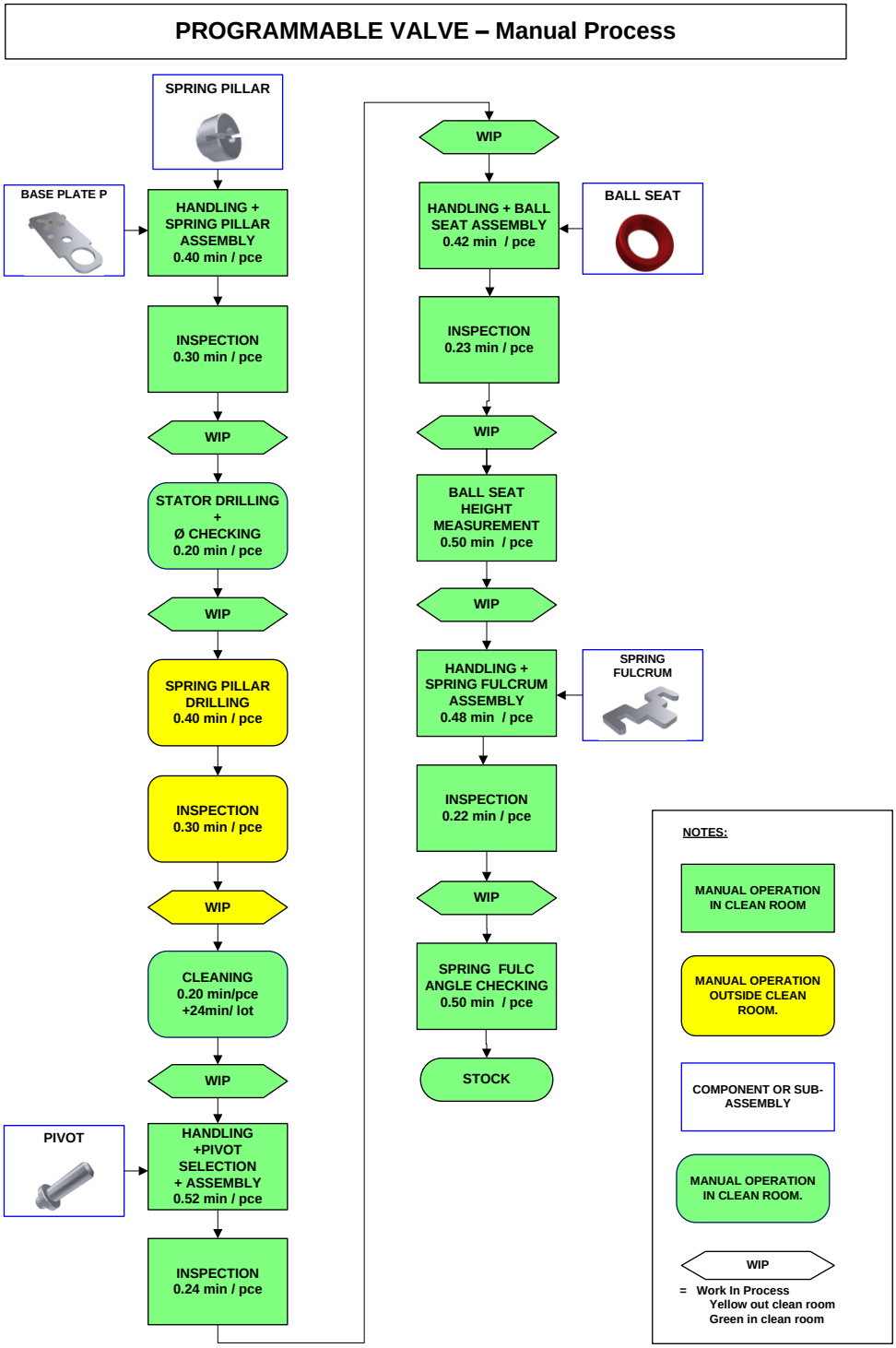


Figure 16 – Flow chart of the manual assembly process of the programmable valve

The Semi-Automated Process

The semi-automated station is the single-station manned cell consisting of one worker tending one machine. The machine is controlled by a software, leaving the operator free to perform additional tasks after the launch of each cycle, such as loading the components on the shuttle, loading and unloading the shuttle from the machine and controlling changeovers. The operator's attention is required at the end of every work cycle, when he has to perform a visual inspection to confirm that all required parts are assembled in the correct order, according to the software istructions.

There is a basic advantage connected with the automation of the process: avoiding all the WIP time needed between the diferrent operations of the manual assembly process (Figure 16). More precisely, each substep of the assembly is performed using the components previously loaded on the shuttle. Moreover, the operator disposes of two shuttles: one loaded with all the components available and the other occupied by the system in order to provide the components required during the assembling process.

The amount of time needed by the operator to load the components on the shuttle and visually control the assembling of the last valve is practically equal to the amount of time spent by the system for the realization of an assembling cycle. When the cycle is completed and the system opens the protection magnetic door, the operator is allowed to change the shuttle loading the one with all the components. At this step the system is stopped during 45 seconds because more than exchanging the shuttle, the operator has also to put out the complete valve from position 2, put the not-compite valve from posion 1 to position 2 and add new Base Plate to position 1 (Figure 17).

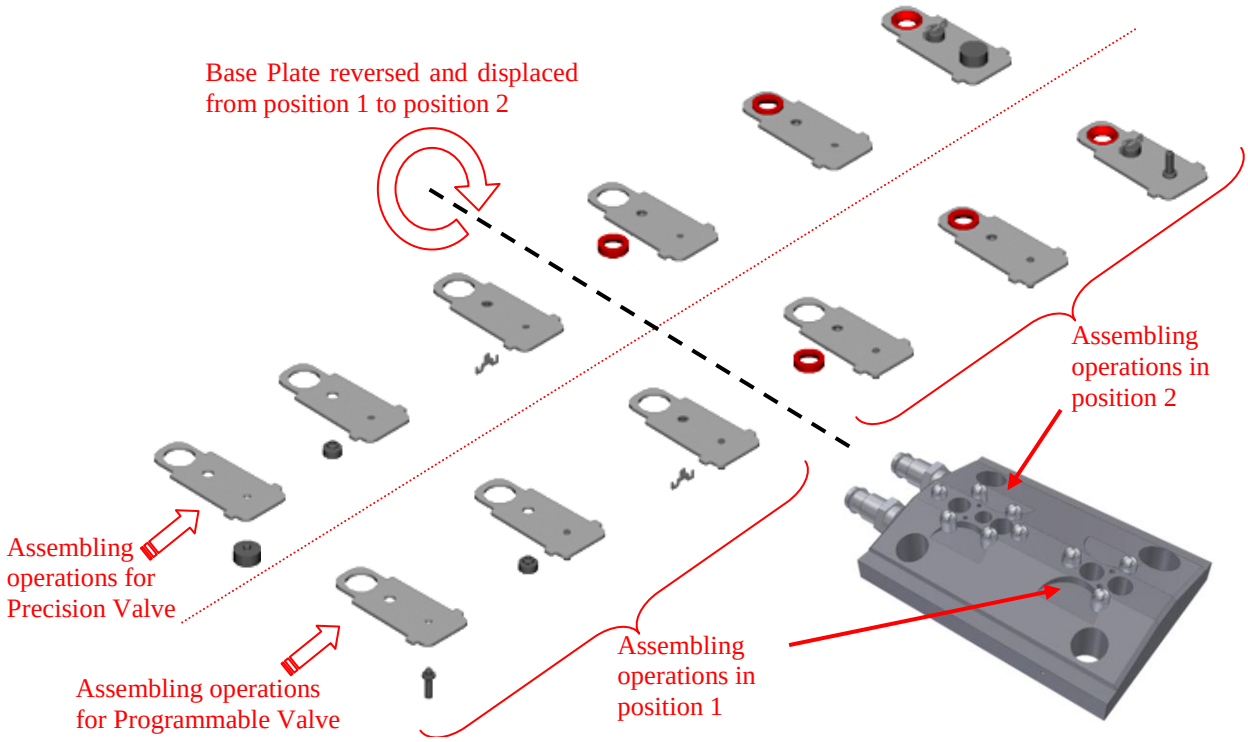


Figure 17 - Assembling operation on the P and NP valve in position 1 and 2 of the Base Plate fixture

Flow chart of the Semi-Automated Process

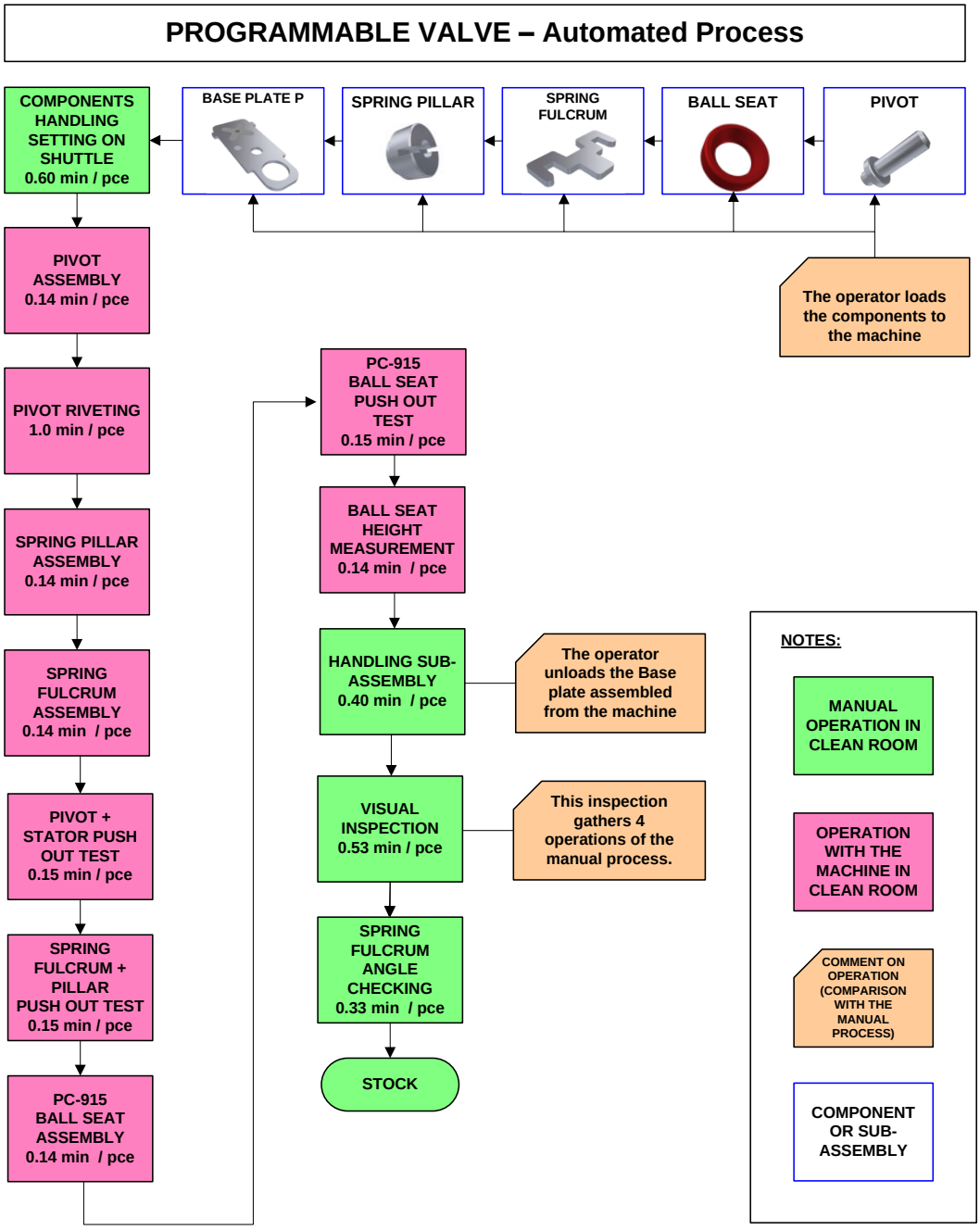


Figure 18 - Flow chart of the automated assembly process of the programmable valve

3.1.3 State of the art

Work in Progress and Planning

The system has been produced by Baldelli Automation whose core business consists in designing and manufacturing of special machineries for the medical, watch and automotive sectors. The knowledge acquired in these particular fields allows Baldelli team to provide specific solutions to handle the strictest tolerances and assembling micro components. The experience matured over the years results in a deep understanding, on behalf of the company, of the process in object, from the design to the production of the system itself.
At my arrival in Medos the machinery had just been delivered without software debugging and no kind of setting had been performed. In other words, the machine was just switching on, but it was not even possible end successfully the initialization procedure.
My goal consisted in the definition of the initialization and production steps, the setting up of all the parameters, all the tolerances and the operations that the system has to perform together with all the validations required by the medical sector in order to put the system in production. Each and every parameter chosen has to have a clear explanation of the reason why it has been chosen.
At my arrival the system was located in the engineering laboratory which has been fully equipped for the system purposes. After 5 months it was moved in the clean room where the final production test and validation procedures were performed.
A detailed planning (Figure 19) of all the operations to be performed and optimized was agreed between the various department. Such planning allowed me to operate and successfully resolve many issues that occured during the setup. I worked efficiently on the different areas, from the mechanic settings to the software debugging, thanks to the experience and the professionalism of the employees of all the different departments.

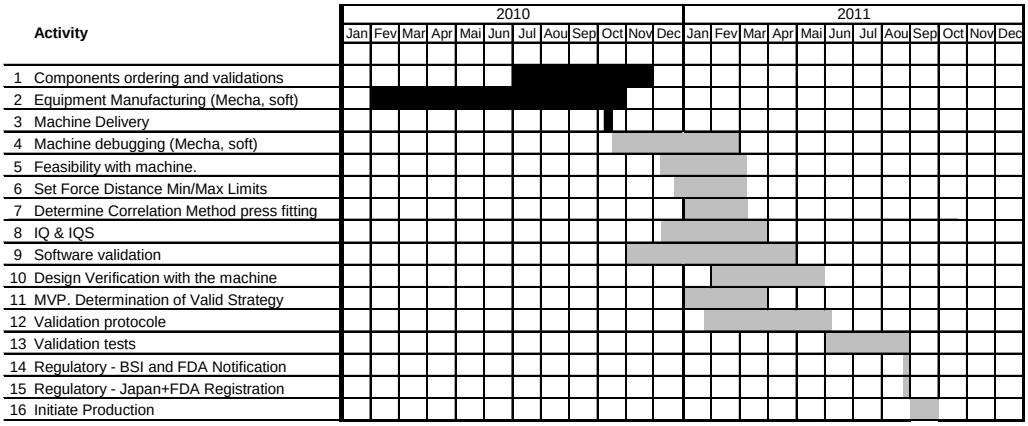


Figure 19 - project planning

3.1.4 Investment economical motives

		Valve P				Valve NP
Simulation N°		**Sim 1**	**Sim 2**	**Sim 3**	**Sim 4**	**0.9;1.2**
Valves per year		**28'500**	**35'000**	**50'000**	**100'000**	**11'500**
ACTUAL Total operator time per valve		**07.16 min**	**07.16 min**	**07.16 min**	**07.16 min**	**06.21 min**
NEW Total global operator time per valve		**03.87 min**	**03.87 min**	**03.87 min**	**03.87 min**	**03.87 min**
Saving per valve		**03.30 min**	**03.30 min**	**03.30 min**	**03.30 min**	**02.35 min**
Total machine time per valve		**02.48 min**	**02.48 min**	**02.48 min**	**02.48 min**	**02.12 min**
Max. mach capacity in 1 shift per day, 1 operat. per shift		**23'897 valves P (and NP)**				
Max. mach capacity in 1 shift per day, 2 operat. per shift		**47'793 valves P (and NP)**				
Max. mach capacity in 2 shifts per day, 1 operat. per shift		**47'793 valves P (and NP)**				
Max. mach capacity in 2 shifts per day, 2 operat. per shift		**95'586 valves P (and NP)**				
Hours productive per day per operator (Input)		**7.0 hours**				
Nb of days productive per year (Input)		**220 days**				
Nb of productive hours per oper. per year (Calculated)		1'540 hours				
Nb of productive hours perc oper. per year in 2 shifts (Calc)		3'080 hours				
Direct cost production (CHF/heure) (Input)		**42**				
ACTUAL operator time per year		**3'402 hours**	**4'178 hours**	**5'968 hours**	**11'936 hours**	**1'191 hours**
	At 14 hours per day	243 days	298 days	426 days	853 days	85 days
NEW operator time per year		**1'837 hours**	**2'256 hours**	**3'222 hours**	**6'444 hours**	**741 hours**
	At 14 hours per day	131 days	161 days	230 days	460 days	53 days
Operator time saved per year		**1'565 hours**	**1'922 hours**	**2'746 hours**	**5'492 hours**	**449 hours**
	At 14 hours per day	112 days	137 days	196 days	392 days	32 days
Nb of operators saved		**1.02**	**1.25**	**1.78**	**3.57**	**0.29**
Simulation 1	**Quantity of valves P and NP**	**40'000 valves P and NP**				
ACTUAL operator time per year		3'402 hours				1'191 hours
ACTUAL total operator time per year		**4'592 hours**				
ACTUAL time per valve ponderated per P and NP		**06.89 min**				
ACTUAL cost per valve ponderated per P and NP		**4.82 CHF**				
NEW operator time per year		1'837 hours				741 hours
NEW total operator time per year		**2'578 hours**				
NEW time per valve ponderated per P and NP		**03.87 min**				
NEW cost per valve ponderated per P and NP		**2.71 CHF**				
	Operator time saved	1'565 hours				449 hours
Operator time saved per year		**2'015 hours**				
Nb of operator saved		1.3				
Saving per year		**85 KFCH**				
Simulation 2	**Quantity of valves P and NP**	**46'500 valves P and NP**				
NEW operator time per year			2'256 hours			741 hours
NEW total operator time per year		**2'997 hours**				
	Operator time saved		1'922 hours			449 hours
Operator time saved per year		**2'372 hours**				
Nb of operator saved		1.5				
Saving per year		**100 KFCH**				
Simulation 3	Quantity of valves P and NP	61'500 valves P and NP				
NEW operator time per year				3'222 hours		741 hours
NEW total operator time per year		**3'963 hours**				
	Operator time saved			2'746 hours		449 hours
Operator time saved per year		**3'195 hours**				
Nb of operator saved		2.1				
Saving per year		**134 KFCH**				
Simulation 4	**Quantity of valves P and NP**	**111'500 valves P and NP**				
NEW operator time per year					6'444 hours	741 hours
NEW total operator time per year		**7'186 hours**				
	Operator time saved				5'492 hours	449 hours
Operator time saved per year		**5'941 hours**				
Nb of operator saved		3.9				
Saving per year		**250 KFCH**				

Figure 20 – Simulations of the investment economical motives

3.2 Adaptation and new design of the assembly components

3.2.1 Pivot

To allow the riveting of the pivot, the press fitting side has to be bigger than the current configuration and also the flange is in contact with the base plate

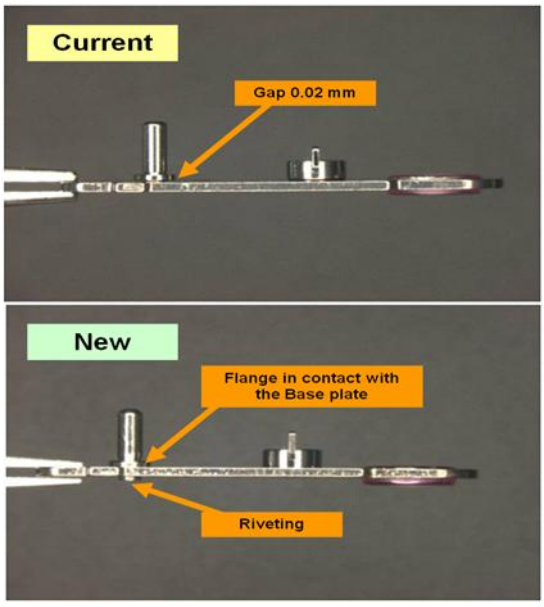


Figure 21 - current and new pivot design comparison

3.2.2 Valve casing

The valve casing is provided with a new slot to allow the extremity of the new pivot to be placed.

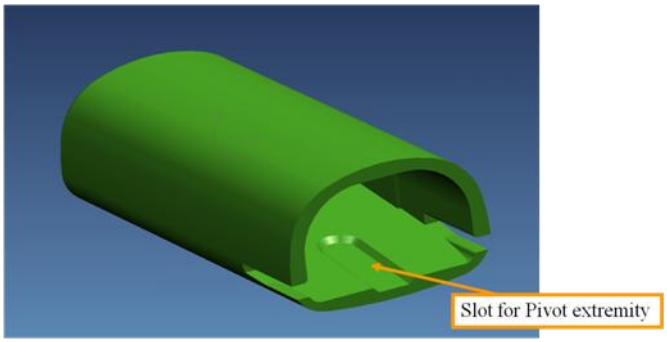


Figure 22 - New valve casing with the new pivot slot

3.2.3 Spring Pillar

The current design has the following issues:

- Internal hole deformed
- Need to be redrilled
- Operation made outside the clean room

The new design has the goal of removing the hole drilling and also preventing the inner hole from getting deformed.

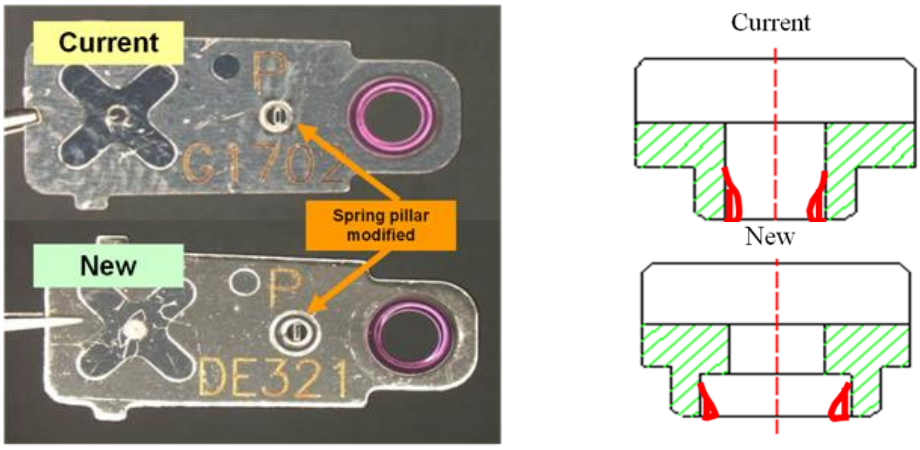


Figure 23 - current and new spring pillar design comparison

3.2.4 Spring Fulcrum

The current design has the following issues:

- Wings deformed during calibration (<1%)
- Flambement

The new design has the goal of increasing the spring fulcrum rigidity for the wings (deflection) and for the foot (flambement)

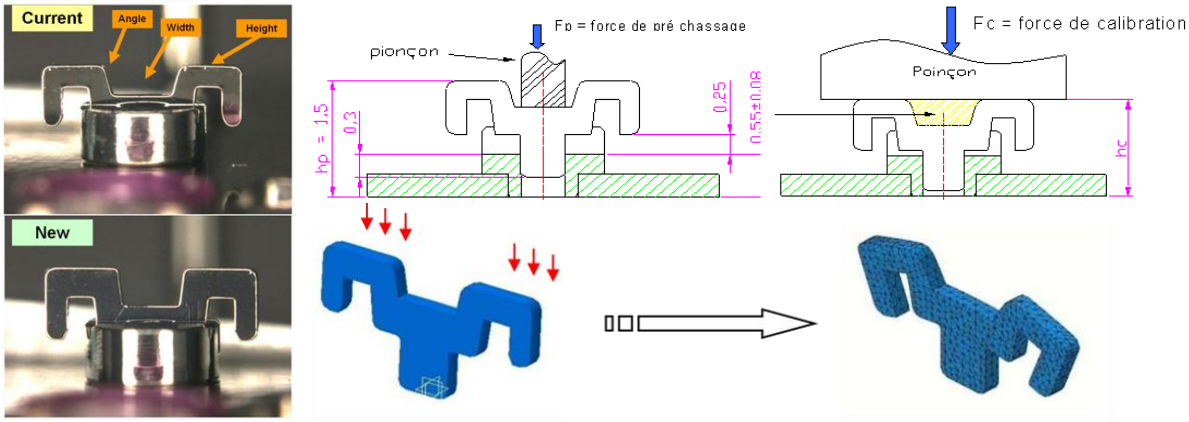


Figure 24 - current and new spring fulcrum design comparison

4

SYSTEM DESCRIPTION

4.1 The Shuttle

The shuttle is a special fixture tool designed to allow the placement of each component that will be assembled, except the base plate (Figure 27). This tool has been realized conforming to very strict precision tolerance ranges and is handled by an operator. Once the tool is in the machine, it will be displaced by one of the linear motors.

After being successfully recognized by the system, the cycle starts: a pneumatic axe blocks the shuttle against 3 ball-shape reference and the numeric controlled linear axe moves and place the shuttle in a position that allows the press to push the right shuttle tool. Each shuttle tool is provided with a component that is pressed by the press and press fitted in the base plate. At the end of each component press fitting the press gets down to its home position dragging along the shuttle tool in its home position by a special claw purpose-built (i.e. designed and constructed to serve this particular purpose). Then the linear axe moves the shuttle to the next component position and waits the press to come up (as described earlier) to complete the press fitting procedure.
The software recognizes at each cycle if the shuttle has been downloaded and uploaded again in the system. This check helps lessen the chance of a human mistake, such as the case where the operator forgets to load the charged shuttle instead of the one used for the last cycle.
Each shuttle tool can only move up and down and they are blocked in their homing position by a spring pushing a steel-ball, thus these tools cannot move during the shuttle displacements in order to avoid any collision with the other axes or fixed tools.

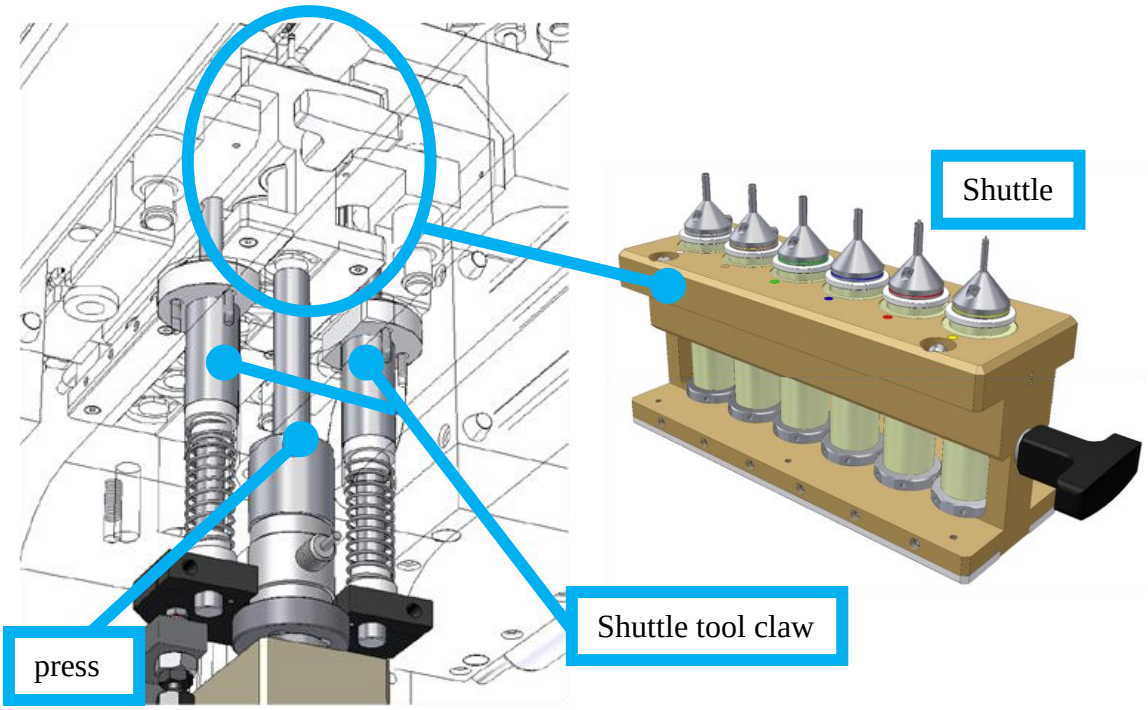


Figure 25 – the shuttle fixture and its location in the system during the assembling process: the press pushes the shuttles tool during the press fittings operations and the shuttle tool claw retires the tool when the press fitting is completed in order to avoid any conflict with the other axes during the shuttle displacements

4.1.1 The control tool and component tool dimensions

The shuttle is equipped with six tools, each one of them designed for a specific operation. Basically five of them (N,P,R,S,T,) (Figure 26) are fixtures shaped to allow the placement of a particular component, while one of them (U) (Figure 26) is made to perform the holding test after the press fitting. For each tool, a nominal measure per dimension was chosen (Table 1) and a certain tolerance margin per dimension was established, in order to calculate all the other parameters (complete calculation will be analyzed in the next chapters). The measuring process was standardized in collaboration with the mechanical shop, while the maintenance process, the force applied to tight the screws and other settings were standardized and explained in a dedicated procedure.

Table 1 – Nominal quotes and tolerances of shuttle tool drawings

Tool	SHUTTLE 1 and 2				
	H1	tolerance		H2	tolerance
Control (U)	100.260	± 0.010		99.510	± 0.020
Ball Seat (T)	99.580	± 0.015		H1 + 0.198	± 0.002
Pivot (S)	99.510	± 0.020		H1 - 1.570	± 0.030
Stop Pin (R)	99.530	± 0.020		H1 - 0.850	± 0.010
Spring Fulcrum (P)	99.440	± 0.020	H2	H1 - 0.600	± 0.010
			H3	H1 - 0.300	± 0.025
Spring Pillar (N)	99.500	± 0.020		H1 - 0.400	± 0.010

The shuttle is recognized by the system in base of the combination of the 3 screws on its backside (Figure 26). It is important to know the status of each shuttle, since it should not be possible to assemble any valve if the current shuttle has not been successfully initialized yet (see paragraph Setting up of the initialization parameters). Due to the combination of the three screws, the possible number of shuttle available for the assembling system cannot overcome the 8.
Once loaded in the system, the shuttle is fastened by a pneumatic system and it's centered pushing the three steel balls on the surface of the shuttle (Figure 26) against three cones used as a unique reference inside the system itself.

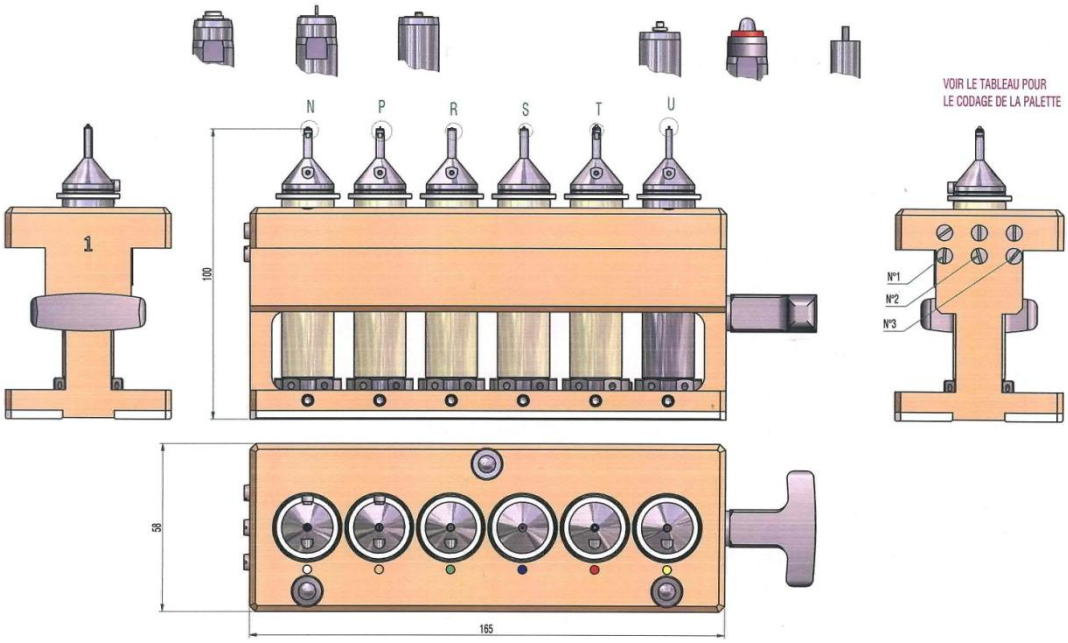


Figure 26 - Shuttle tool design

4.1.2 Components placement

Figure 27 shows the design and the picture about every components and the way they have to be loaded on the specific shuttle tool. For each shuttle tool, a unique-loading-way fixture was shaped in order to load components by avoiding any kind of mistake or confusion. Moreover the shape of each component placement was modified to avoid that the vacuum flow could dislocate the components. It was one of the most mechanically demanding issue: the difficulty lies in providing enough space to locate the components while at the same time avoiding the vacuum depression to dislocate the component during the shuttle tool displacement. The shuttle tool for the pivot component was the most challenging to fix because there was a complete empty chamber in the inner part of the tool itself that was causing the total leak of the pivot component.

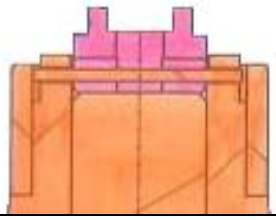
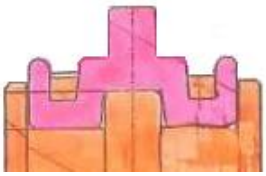
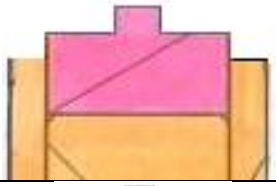
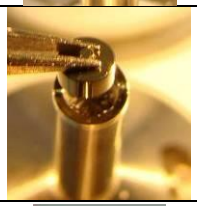
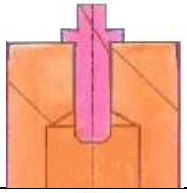
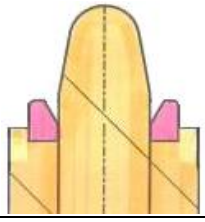
Component	Design	Tool placement	Picture
TUBE DE RESSORT			
SUPPORT DE RESSORT			
PLOT D'APPUI			
PIVOT			
SIEGE DE BILLE			

Figure 27 – zoom on the shuttle tools fixtures and components placement

4.2 The Base Plates axe

The base plates fixture is located just above the shuttle tools (Figure 28) and its displacement is parallel to the shuttle. The moovement is provided, as well as for the shuttle, by a numeric controlled linear axe. As shown in Figure 28 and Figure 17 - Assembling operation on the P and NP valve in position 1 and 2 of the Base Plate fixture, there are two positions available to locate the base plates: at each cycle the base plate from the position 2 (two) is completely assembled and tested, and then taken out from the system; at the same time the base plate from the position 1 (one) has completed the press fitting of the first three components (depending by the tipe of valve) and can be turned and placed in the position 2 (that is now available). In the position 1 (now available) it is placed a new base plate without any component assembled.
The base plates fixture is also provided by a vacuum aspiration that has the double aim of detecting the presence/absence of the base plates while also holding them during the displacement of the axis and the tools.

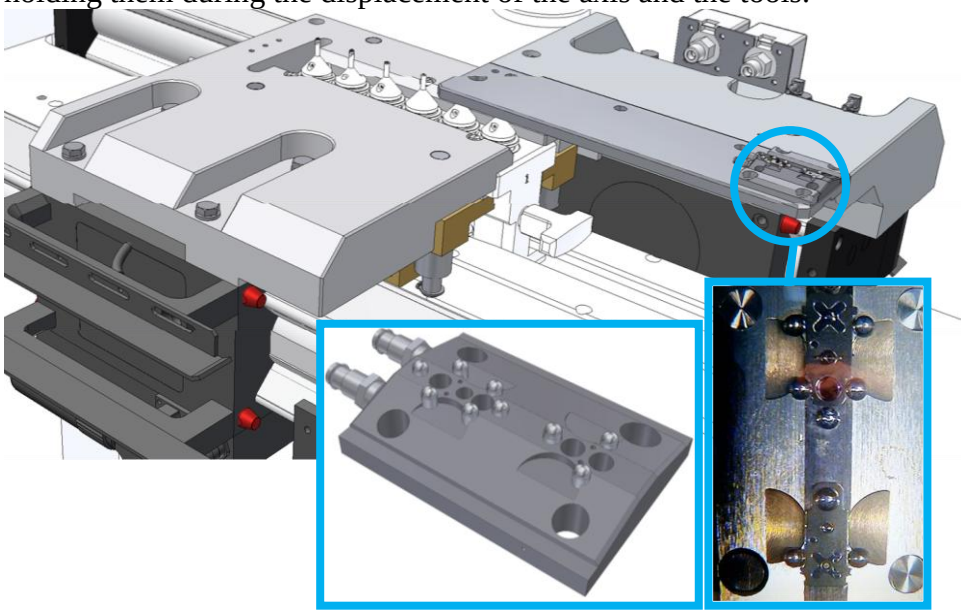


Figure 28 - the base plates axe and zoom on the base plates fixtures

4.3 Upper tools

During the assembling process the base plate has to be hold from the other side, avoid any kind of movement. For this reason the system has been equipped with 4 upper tools (also called blank holders) and a riveting tool, all pneumatically actuated. Each upper tool has a special shape designed according to both the component shape and its position on the base plate fixture. One of

the blank holder is used to perform all the press fittings in the position 1 of the base plate fixture. This tool is provided with a pin which is pushed by a spring used to center the hole of the base plate before the component press fitting starts. The home position of each blank holder is detected by a dedicated sensor. Only the Promess Press (paragraph 4.7) could move when these sensors are not activated and, as a consequence, the blank holders are not in the home position. (Figure 47)

4.4 The riventing tool

The riveting tool is the 5th upper tool and has the aim of deforming the extremity of the pivot and assure its holding after the press fitting procedure. This tool has required various settings due to its complexity and the crucial importance of its operations. As shown in the Figure 29, the deformation of the extremity of the pivot is made by pushing the pivot, already press fitted in its base plate hausing, against a special tool designed for the purpose. Reached 100N (settled after considering the distruction force for the pivot and damages on the base plate) registered by the Promess Press force sensor, the pivot goes down and the blank holder springs make sure that the pivot is not in contact with the riveting deforming tool. At this point the riveting tool actuated by a continuous current (CC) servo motors turns for a certain number of degrees and the pivot is pushed again with 100N. These operations are repeated for a number of times needed to assure the holding of the pivot during the valve useful life.

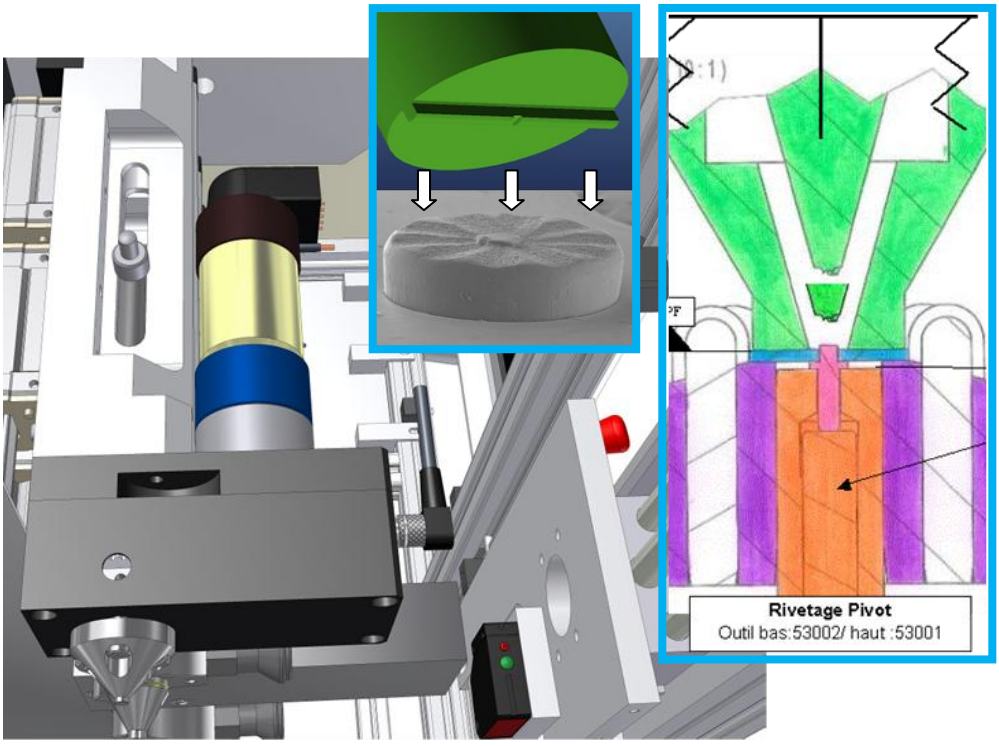


Figure 29 - The riveting tool and a pivot deformation zoom

4.5 Actuators and Sensors

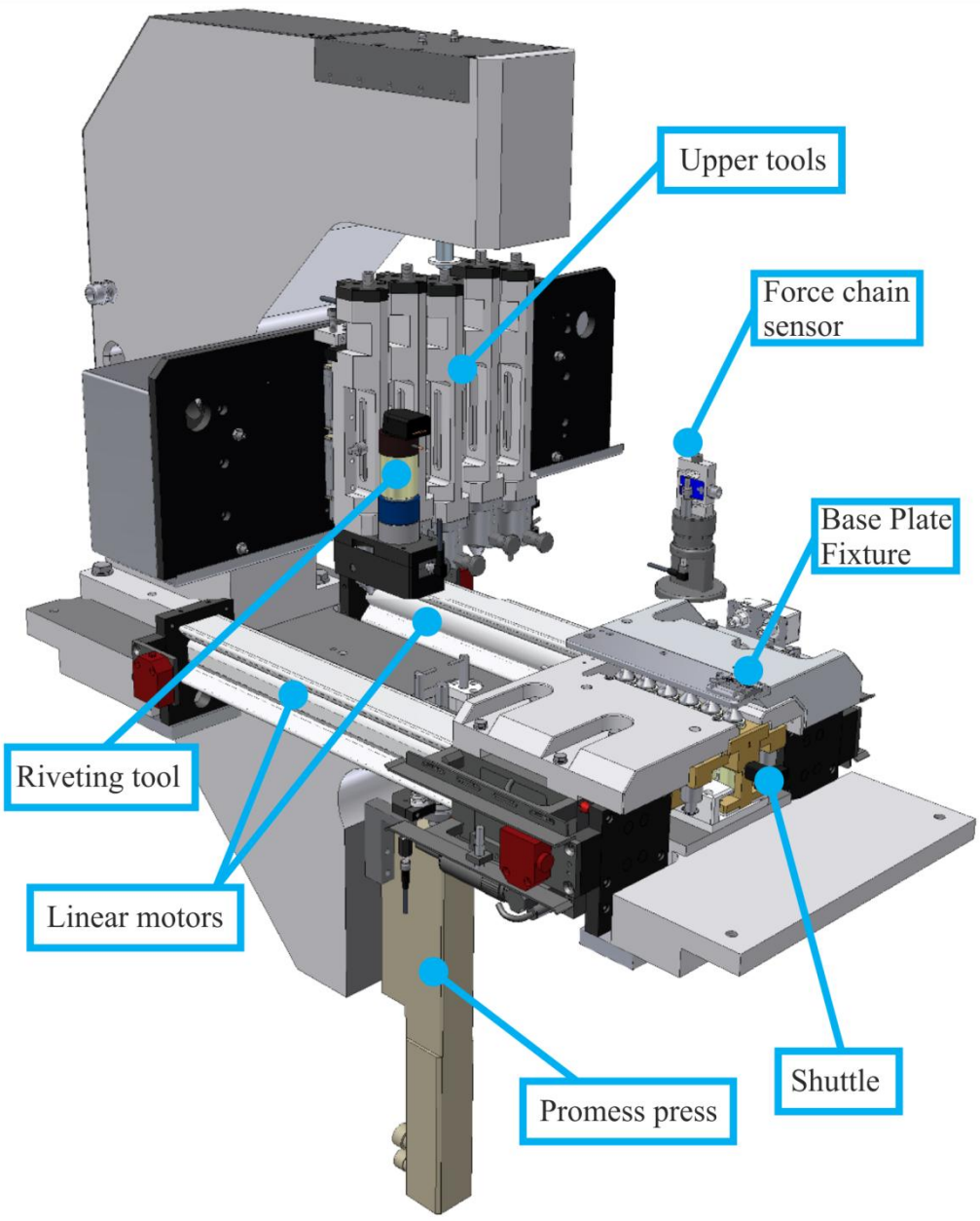


Figure 30 – the system main actuators and sensors

4.6 Linear motors

One could describe a linear motor as a rotary motor that has been unwrapped. The motor coils make up the forcer. Depending on the kind of design of the motor, one or two rows of magnets comprise the magnet track. In a rotary motor, the rotor spins while the stator is fixed. In a linear motor, either the forcer or the magnet track can be the moving component, which will be then integrated with an appropriate linear bearing. By suppling electrical current to the forcer, the resulting magnetic field interacts with the magnet track and drives the linear motor carriage forth and back.
Due to the direct drive nature of linear motors, there are no-mechanical components to add backlash, torsional windup, or other positioning errors to the system. Sub-micron resolution and repeatability are commonplace. Moreover, since the motor is directly coupled to the load, there are fewer components subject to failure. This property adds long term value to the atuator.
Application needs typically dictate what type of linear motor is the most suitable. Iron core linear motors use one row of magnets and a forcer with windings that are wrapped around iron poles. The nature of these windings provides a very efficient magnetic path in the motor: it produces the highest forces within the linear motor family. On the other hand, in ironless motors, windings are wrapped flatly and ride in a balanced, ushaped magnet track. Consequentially, ironless motors are ideal where smooth motion and a higher degree of accuracy are required, and for applications involving extremely high accelerations.

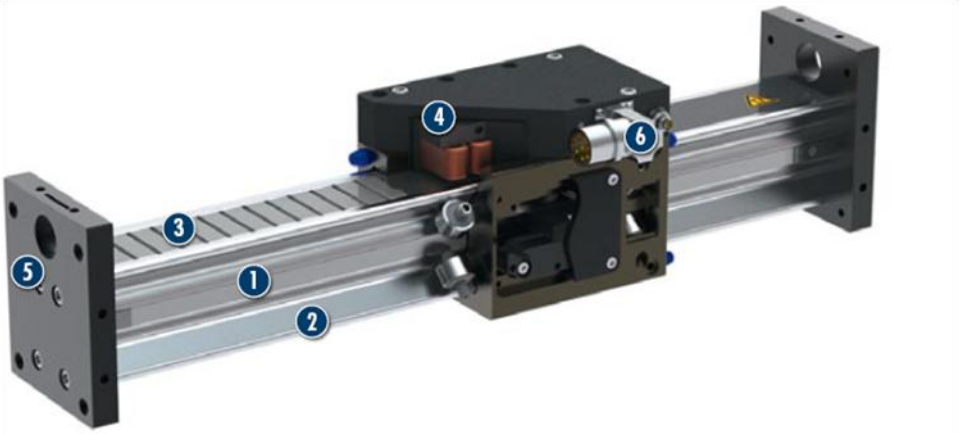
In the Semi-Sutomatic Sssembly System the higher degree of accurancy required during the short and smooth motions along with a lower force have led to choose as the main displacing actuators linear motors

The system is provided with three linear motors for the following axes motion:

- Shuttle axe
- Plate axe
- Upper tool axe

All of them having the following characteristics (Figure 31):

- 3-phase, electronically commutated AC synchronous linear motor.
- Primary part 3-phase copper coil body, secondary part iron mount with permanent magnets and dirt cover.



1 **Elongated X-shaped aluminum press-drawn section**
with high planar moments of inertia for maximum moment and shearing force load

2 **High precision, hardened and ground steel guide rails**
for optimum guidance properties and speeds

3 **Integrated secondary parts**
with high power magnets

4 **Compact primary part slide**
with mounting surfaces, rollers adjusted without play and integrated measuring system

5 **End plates**
for mounting sensors and shock absorbers

6 **Motor plug**

Technical data

Designation		MLD 100N
Max. driving force (*)	[N]	250
Rated force (**)	[N]	88
Max. speed	[m/s]	4
Max. acceleration	[m/s²]	40
Max. useful load (horizontal)	[kg]	15
Max. stroke	[mm]	2800
Repeat accuracy (***)	[mm]	0.01
Measuring system resolution (controller-dependent)	[µm]	0.5
Max. current	(A_{eff})	8.1
Max. continuous current at standstill	(A_{eff})	2.1
Max. ambient temperature	[°C]	40
Max. surface temperature	[°C]	70
Weight of guided slide inc. motor	[kg]	3.0
Weight of end plates	[kg]	0.75
Profile / 100mm stroke	[kg]	0.62

Figure 31 – Characteristics of the three linear motors

Stroke measuring system

The high degree accurancy is also provided by the optical incremental stroke measuring system.
This system works on the principle of optical scanning of the scale by the measuring head (Figure 32). Measured values can be output both as analog signals and as rectangular signals with interpolation. Resolutions of up to 0,05µm and position variations error of ± 2 µm

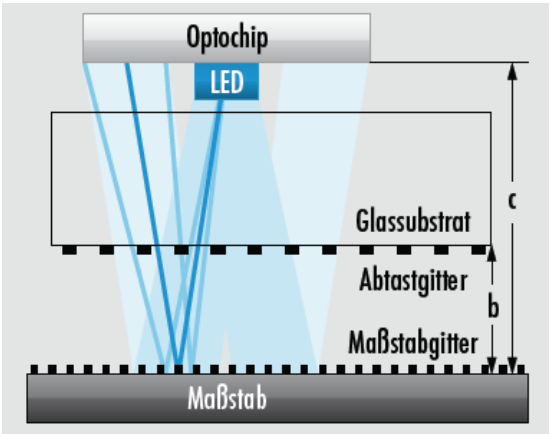


Figure 32 – linear motor stroke measuring system

can be achieved with no additional electronics. The scanning unit is used where lengths need to be determined with maximum precision and resolution with no mechanical reaction on the measuring instrument.

4.7 The Promess Press

After getting all the axis in the right position with high accurancy, the press fitting procedure starts. This procedure has been committed to the Promess Press that is located above the shuttle axe and able to push up the shuttle tools (Figure 33).

The assembly press is based on a spindle, installed in a solid steel housing, with high-precision press ram guidance. The actuating systems consist of three main components: a robust mechanical components with AC servo motor, a ball gear drive, and an integrated force transducer. More specifically, the ball gear drive is responsible for converting rotational movements into linear movements, while the integrated force trasducer directly measures both the joining forces and makes sure to be within the control curves.

The actuation is performed by an AC servo motor. The rotational movement of the servo motor is transferred to the ball or the roller gear drive and to the press ram, where it is converted to linear movement. With the spindle drive, the assembly press is able to apply the full force on both directions: the push and the pull one. The sequence of movements can be easily specified using the included control and monitoring software (Figure 36). The envelope and window functions make full monitoring and documentation of the assembly process possible.

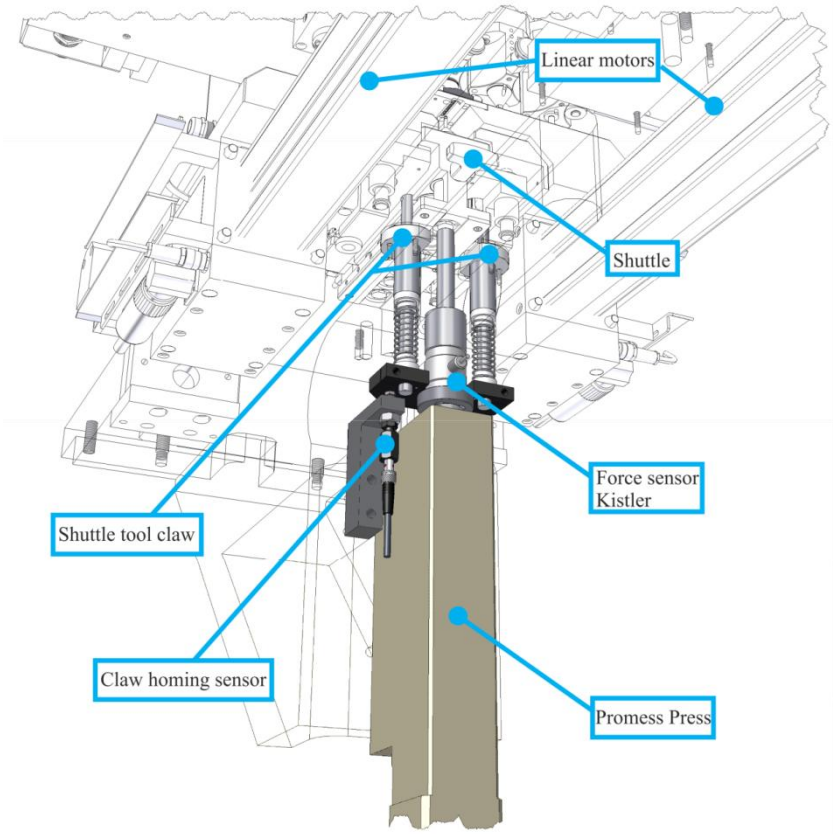


Figure 33 - Composition and disposition of the Promess press in the system

MAIN FUNCTIONS	
Nominal load	1 kN
Stroke	100 mm
Nominal speed	400 mm/s
Acceleration	5000 mm/s²
Dwell time of nominal load	at least 4 s
Weight	9,46 kg
Max. tool weight	0,5 kg *
INTEGR. PIEZO ELECTR. FORCE TRANSDUCER	
Transducer accuracy (dismantled)	0,5 %
System accuracy	< 1%
Smallest measuring step	0,28 N
Amplifier / W*H*D	Alu. die-cast hous. / 115*64*34.5 mm
Output signal	+/- 10 VDC
Protection class	IP 54
DISTANCE MEASURING	
Resolution	0,061 µm
Repeatability of positioning	< 0,01 mm**

Figure 34 - Characteristics of the Promess Press

4.7.1 Promess Press Position Sensor

The position and the force of the press are critical to the valve assembly process. Thus the choice of the Resolver as the position sensor has been the only viable one. Resolvers are considered superior to many other kinds of absolute position sensor because of their ruggedness, and ability to provide a very high degree of angular accuracy under severe conditions. Since the Resolver is a proportional device, it is also less subject to input signal anomalies. In other words a voltage or frequency variance will change both the sine and the cosine outputs equally. Resolvers also represent a cost-effective answer to the system control needs. Moreover, resolvers are substantially smaller than other trasducer approaches and consequencially it has been easier to integrate it in the press.

4.7.2 Promess Press software-hardware connection and functionalities

The promess press is located in the system as shown in the Figure 33. By the Profibus standard it is connected to its driver (Figure 36). The force sensor signal is amplified by a double channel amplifier: 40N channel used in case of test to have accurancy for weak forces and 400N channel in case of press fitting operations. The choice of the amplifier channel is managed by the system software, while all the other operations performed by the Promess Press are directly managed by the Promess dedicated sofware (Figure 36). With this software it is possibile to control the press operations using as variable under control the position or the force. There are a set of functions available in the software and it is possible to create different programs that use a set of consecutives functions which allow to performe the required operations. The software is user-friendly and it is possible to draw the curves force-distance for each moovement of the press (Figure 35 – force-distance Promess Press curve). Moreover it is possibile to record all the curves and the informations in an Access Database. This will

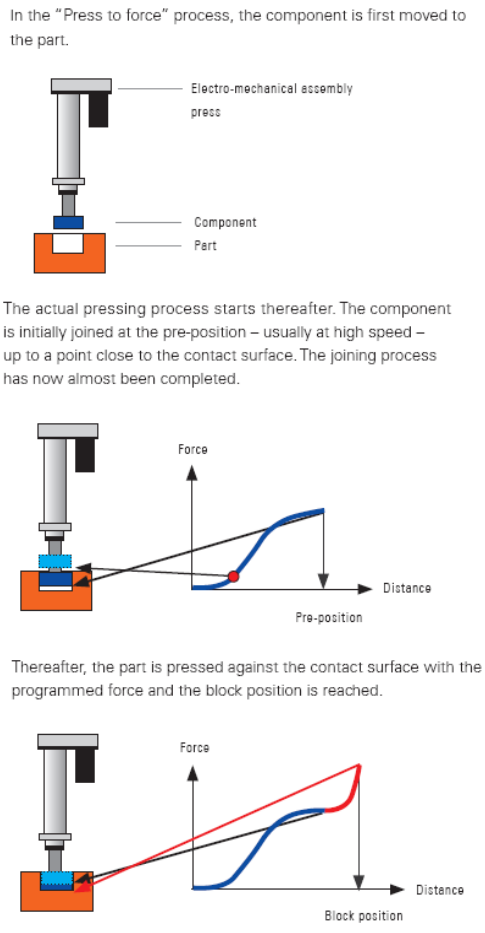


Figure 35 – force-distance Promess Press curve

allow to have the opportunity to analyze the data afterwords. In the database it is actually tough to find the data related to a certain set of performed operations and even harder is to treat the data once found.
Nevertheless the opportunity to record data and analyze them has been an irreplaceable tool during the parameters setting up. Understanding the conduct of the press under determined conditions has allowed supervising it changing parameters. This has been proved to be a successful way to solve problems concerning many issues.

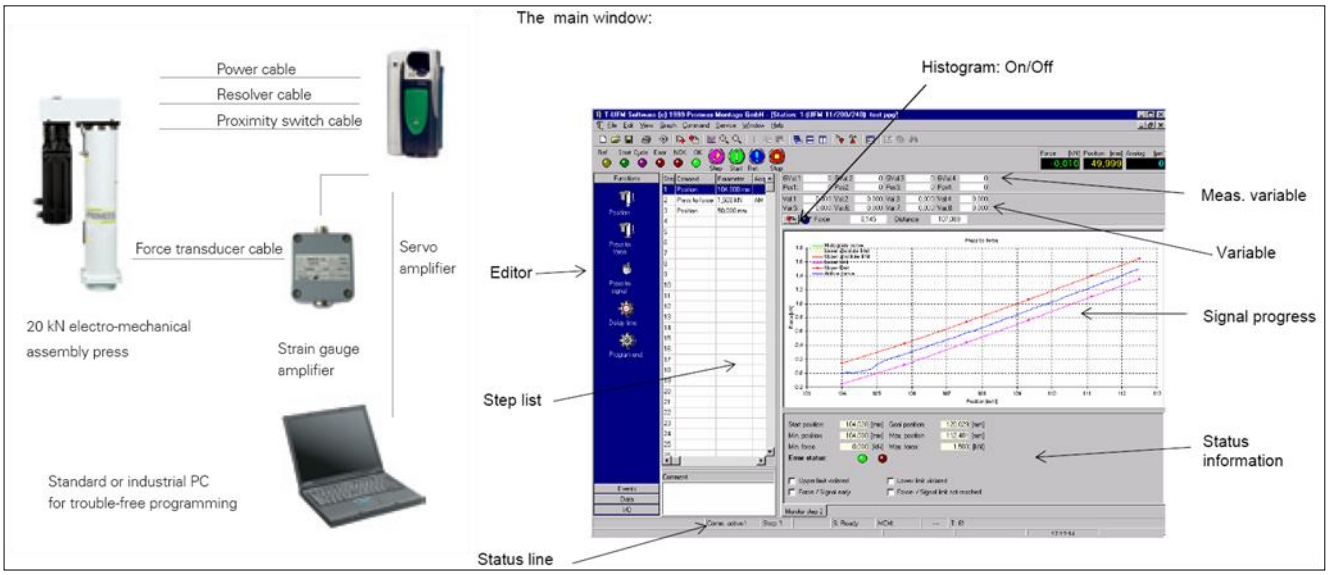


Figure 36 - Promess Press system connection and main screen software

4.8 Computer System description

The global process and the actuators drivers are managed by a dedicated main software. This software has been developed by a combinated use of the automation program "Twin Cat" and the visualization system “Movicon”, both of them installed on an industrial computer, the "PC Beckhoff". The software, which is delivered with the Promess axe, is also integrated in the main software and installed on the PC Beckoff. It is used as Human Machine Interface (HMI) and driver of the Promess press. The servo-controlled axis are managed during the process by a Numerical Command (NC) which will also receive data from the Promess Press and checks if the force and the displacement are correct with predefined parameters reference set. Different levels of functionality are available based on the type of access. Only the User is allowed to assemble

valves for human use, while all the other access levels can only make setting and tests.

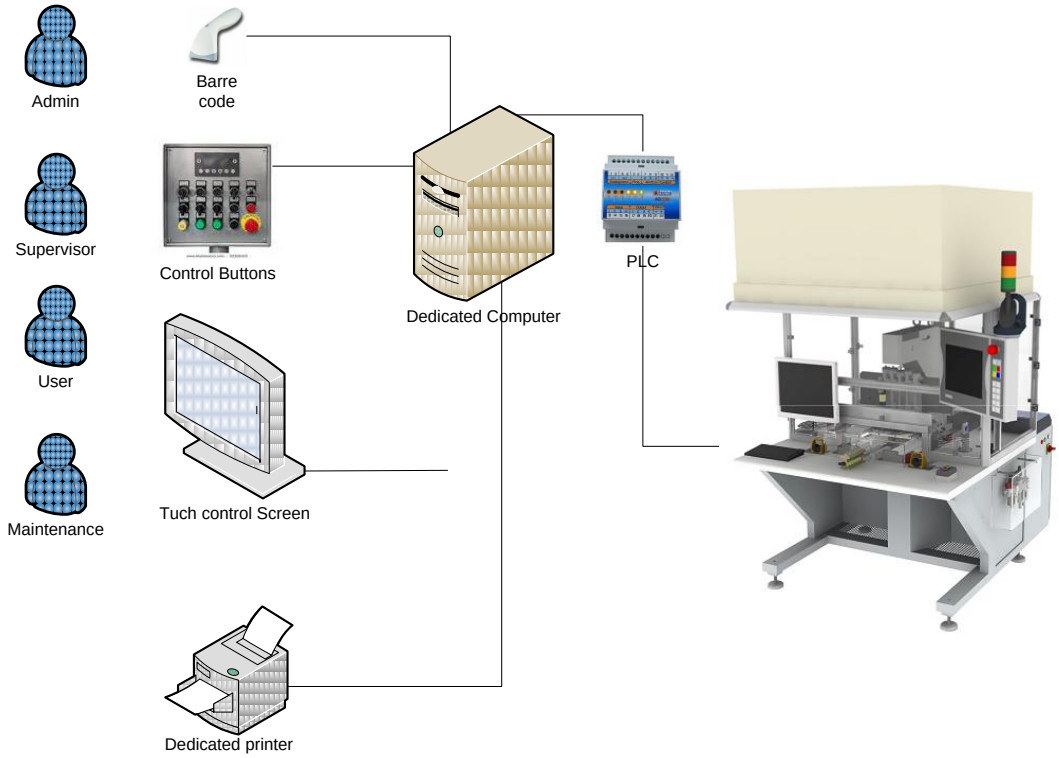


Figure 37 - Computer system scheme

4.9 The meaning of critical and not critical parameters

After the validation of the software by the Quality Department, the parameters which will influence directly the output of the system cannot be changed anymore, until a new validation of the software is performed (see validation chapter).

The parameters that are needed to set some of the options but that do not really have substancial influence on the system output are called as “not critical” parameters, and can be changed by the maintenance or the administrator.

5

WORK PERFORMED

5.1 Setting up of the initialization parameters

5.1.1 The goal of the initialization procedure

The system software does not allow the operator to start any assembling procedure before all the initialization steps are performed. These steps are crucial to the system to verify that every and each part of the system is working properly. It is important to avoid any kind of failure in the valves assembled. Performing the initialization consists in testing that the position of each tool is within certain tolerance ranges and that the force and the position sensors work within a certain margin of error.

5.1.2 Initialization steps

The initialization procedure has to be performed by the operator every morning once the system is switched on. The software will not allow to start any work order before a complete initialization with at least one shuttle has been successfully completed.
After pushing the “Init” button the software guides the operator to execute the required actions to complete the procedure. The chart (Figure 38) shows the main steps of the initializations:

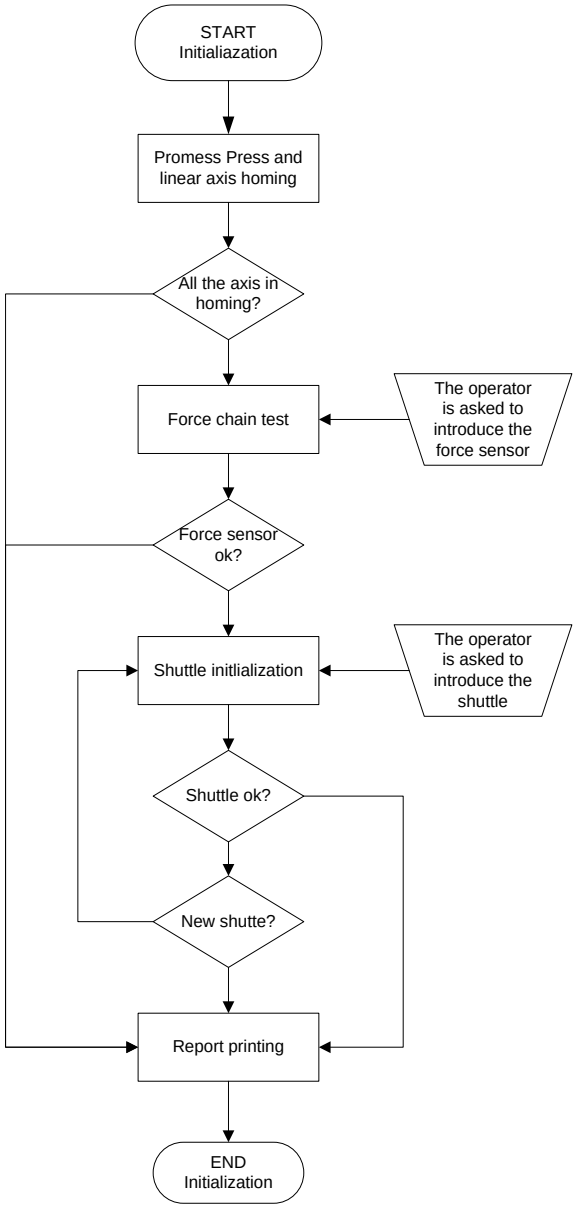


Figure 38 - main initialization steps

5.1.3 Initialization print report for daily production

A report is printed after each initialization also in case it does not end successfully. As shown in the following flow chart (Figure 38Figure 41), for each step the below information is printed out:

- Promess press and linear axes homing (Figure 39)

```
01: Initialisation générale
       Début du cycle: 20-05-2011/07:26:28
       Fin du cycle:   20-05-2011/07:49:42

  Axe linéaire presse-flanc: Bon
  Axe linéaire composant:    Bon
  Axe linéaire plaque:       Bon
  Initialisation Promess:    Bon
```

```
02: Codeur axe promess:              Bon
       Valeur=36608   Tol.Min.=35201   Tol.Max.=38000
```

Figure 39 - initialization report: Promess Press and linear axis homing

- Force chain test (Figure 40)

```
03: Capteur de force + ampli:       Bon
  Range  40N, Kistler, Vérification, Ecart, Tol.Min., Tol. Max., Résultats
      0        0.02       -0.05      0.07   -0.62      0.62      Bon
      9       10.49       10.41      0.08   -0.63      0.63      Bon
     18       18.61       18.60      0.01   -0.65      0.65      Bon
     27       26.41       26.25      0.16   -0.69      0.69      Bon
     34       34.41       34.25      0.16   -0.75      0.75      Bon

  Range 400N, Kistler, Vérification, Ecart, Tol.Min., Tol. Max., Résultats
      0        0.13       -0.01      0.14   -0.63      0.63      Bon
     90       88.97       88.71      0.26   -1.18      1.18      Bon
    180      178.47      179.12     -0.65   -2.10      2.10      Bon
    270      268.02      268.67     -0.65   -3.04      3.04      Bon
    360      359.25      359.89     -0.64   -4.02      4.02      Bon
```

Figure 40 - initialization report: force chain test

- Shuttle initialization

```
05: Navette 2                          Bon
       Test presse-flancs              Bon
   P1=18.056 *H1= 100.254 P1+H1= 118.310 Tol.Min.= 118.289 Tol.Max.= 118.359 Bon
   P2=18.024 *H1= 100.254 P2+H1= 118.278 Tol.Min.= 118.244 Tol.Max.= 118.314 Bon
   P3=18.025 *H1= 100.254 P3+H1= 118.279 Tol.Min.= 118.243 Tol.Max.= 118.313 Bon
   P4=18.764 *H2=  99.521 P4+H2= 118.285 Tol.Min.= 118.220 Tol.Max.= 118.330 Bon
   P5=18.041 *H1= 100.254 P5+H1= 118.295 Tol.Min.= 118.247 Tol.Max.= 118.317 Bon
   P6=18.031 *H1= 100.254 P6+H1= 118.285 Tol.Min.= 118.244 Tol.Max.= 118.314 Bon
      Tige= 0.739    Tige Min= 0.683    Tige Max= 0.783 Bon

       Mise en pression outillage   Bon
   53002= Bon
   52001= Bon
   51001= Bon
   57001= Bon
   54001= Bon
   56001= Bon

       Test outils bas              Bon
   P10=18.794  Tol.Min.=18.774  Tol.Max.=18.904   Bon
   P11=18.756  Tol.Min.=18.724  Tol.Max.=18.854   Bon
   P06=18.031  Tol.Min.=17.968  Tol.Max.=18.098   Bon
   P12=18.762  Tol.Min.=18.717  Tol.Max.=18.847   Bon
   P13=18.815  Tol.Min.=18.789  Tol.Max.=18.919   Bon
   P14=18.868  Tol.Min.=18.839  Tol.Max.=18.969   Bon
   P15=18.525  Tol.Min.=18.477  Tol.Max.=18.607   Bon
   P16=18.782  Tol.Min.=18.737  Tol.Max.=18.867   Bon
```

Figure 41 - initalization shuttle report

In the following paragraphs value facing and tolerances will be analyzed.

5.1.4 System initialization settings

5.1.4..1 Tolerance settings of the force chain test

During the initialization procedure the operator is asked to load the external force chain sensor (Figure 42) instead of a specific blank holder. After that the software performs a test which aims to check if the force detected by the Promess Press force sensor matches with the one detected on the external force sensor within a certain tolerance. The chain of forces tested are shown in the (Figure 40) and the tolerance range considered is based on all the errors occurring on the sensors and on the profibus communication.

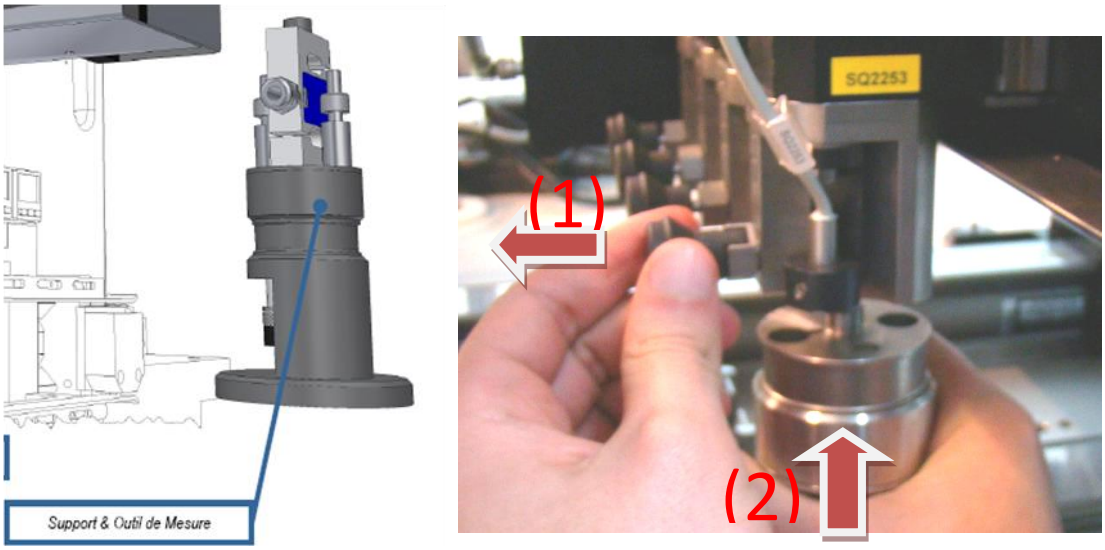


Figure 42 - Force captor: loading operation during the initialization procedure

As far as the external force sensor is concerned, we distinguish the following characteristics:

Force captor (Transducer)

- Type : AST KAP-S/500N/0.05
- Rated load : 500N
- Accuracy class : 0.05%
- Sensibility 2mV/V

Profibus-Interface (amplifier)

- AST Profibus-Interface DI 301DP
- Power Supply : 9 to 36V
- Connectivity for Strain gauge (DMS)

Cable

- Connecting table RS232 for setup DI301 DP
- XKC267, 5m

Connecting table Profibus (5pin cable connector, 5 pol. And D_SUB 9 pol.)

Caclculations:

Table 2 - Calculation kaptor error

-

							± Error for [N]		
	Type of error	**Applicable regarding the outpout range**	**From datasheets**	**±**	**unit**	**Error per N [1/N]**	**0**	**200**	**400**
Force captor KAP-S/500N/0.05	Sensibility	Yes	2 ± 0.005 mV/V	0.005	mV/V	0.0001	0.0001	0.02	0.04
	Linearity	Yes	Error ≤ 0.05 %S (S=Sensibility) Error ≤ 0.1mV/V	0.001	mV/V	0.00002	0.00002	0.004	0.008
	Hysteresis	No (only for pressure / traction)	Error ≤ 0.05 %S Error ≤ 0.1mV/V	0.001	mV/V	0.00002	0.00002	0.004	0.008
	Temperature	Yes	On zero/10k ≤ 0.05 %S On output/10k ≤ 0.05 %S Error ± 5°K = 0.05+0.05=0.1%S	0.002	mV/V	0.00004	0.00004	0.008	0.016
	Creep (30min) Glissement	Yes	Error ≤ 0.05 %S Error ≤ 0.1mV/V	0.001	mV/V	0.00002	0.00002	0.004	0.008
			Total Error Force captor	0.009	mV/V	**0.00018**	**0.00018**	**0.036**	**0.072**
Profibus-Interface DI 301DP	Strain gauge bridge	Yes	Error = 0.01%S for S=2mV/V Error = 0.02mV	0.0002	mV/V	0.000004	4.00E-06	8.00E-04	0.002
	Linearity	Yes	Error = 0.0015%S for S=2mV/V Error = 0.003mV	0.00003	mV/V	6.00E-07	6.00E-07	1.00E-08	2.00E-08
	Noise resolution	Yes	14 up to 19 bits at 2mV/V 24 bits A/D converter 500N force captor full range (500 / 2^24)*2^19 = 0.005N/V	0.005	N/V	0.0001	0.0001	0.02	0.04
	Input sensibility for 1 LSB	Yes	5nV for S=2mV/V	5.00E-09	V	0	1.00E-10	2.00E-12	4.00E-12
	Zero drift	Yes	20nV/K for S=2mV/V and 10°K	2.00E-07	V	0	4.00E-09	2.00E-11	3.00E-11
			Total Error Profibus	0.00023	mV/V	**0.0001**	**0.0001**	**0.021**	**0.042**
						Total Error ± [N]	**0.00028**	**0.0003**	**0.057**	**0.11**

As far as the Promess Press force sensor (Kistler), we distinguish the following characteristics:

Charge amplifier

- Kistler 5039A331Y0389
- Drift =<+/-0.05 pC/s
- Transition Reset/Operate Error= the bigger of (=<+/-1pC) ou (0<+/-1 mV)
- Output Error= +/- 1% of the instant output
- Error zero (reset) Error= <+/-10 mV

Press force sensor

- Kistler 9333
- Serial Number 1443188
- Calibration range : 0 to 0.5 / 5 / 50 KN
- Sensibility of the range 0 to 0.5 KN : about –4 pC/N
- According to the calibration certificate –3.940 pC/N

For the range 0 to 60°C :

- Linearity =+/-1.0% FSO (Full Scale Output)
  According to the calibration certificate <=0.1 % FSO
- Hysteresis <=1.0 % FSO

Amplificator

- Kistler 5039A331Y0389
- N° série 1479196
- Configurer range 1 : de 0 à 400N et range 2 de 0 à 40N

Calculations:

Table 3 - Calculation Kistler error

				± Error for [N]							
				Range 0-40N				Range 0-400N			
	Type of error	Applicable regarding the outpout range	From datasheets	0	10	36	40	0	180	200	400
Kistler Press force sensor Type 9333 Range : 0-0.5kN	Sensibility	N/A	0-05KN -3.940pC / N	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Linearity	Yes	Error = +/- 0.1 %FSO As Calibration certificate Then with a range of 500N on the total force chain the error is +/-0.5N	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
	Hysteresis	NO	Error=<1% FSO								
	Drift (Dérive)	Yes	Drift =<+/-0.05 pC/s If after Reset there is a measure during 5 secondes then drift max= +/-5x0.05 = +/-0.25 pC Sensor sensibility= -4 pC/N Then error max= 0.25pC / 4pC/N = +/-0.0625 N	0.0625	0.0625	0.0625	0.0625	0.0625	0.0625	0.0625	0.0625
Charge amplifier 5039A range 1 :0 to 400 N range 2 : range 1 :0 to 40 N	Transition Reset/Operate	Yes (if mV took account)	Error= the bigger of (=<+/-1pC) ou (0<+/-1 mV) Error due to pC: taking account sensibility (sensor sensibility= -4 pC/N) = 1pC / 4 pC/N = +/-0.25 N Error due to mV: taking account the amplifier factor (10V corresponds to 40N)= 0.004N (10V corresponds to 400N)= 0.04N	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
	Output error	Yes	Error= +/- 1% of the instant output applicable for the range 200N	0	0.1	0.36	0.4	0	1.8	2	4
	Error zero (reset)	Yes	Error= <+/-10 mV Error max due to mV: taking account the amplifier factor (10V corresponds to FCO)	0	0.01	0.03	0.04	0	0.3	0.1	0.4
Sampler		Yes	Error= +/- 1 digit Then with a samplig on 12 bits (resolution= 40N/4096=0.0098N) 400N/4096=0.098N	0.01	0.01	0.01	0.01	0.1	0.1	0.1	0.1
	TOTAL ERROR		Total Error ± [N]	0.56	0.57	0.67	0.69	0.57	1.91	2.08	4.06

The final values introduced as critical parameters in the system are listed in Table 4

Table 4 - Final parameters for the chain force check

		Elements Error ± [N]		Tolerance range [N]		Error ± [N]
		Verif chain	kistler			
0-40N	**0**	0.0003	0.56	-0.56	0.56	**0.56**
	9	0.0026	0.57	8.43	9.57	**0.57**
	10	0.0028	0.57	9.43	10.57	**0.57**
	18	0.0051	0.59	17.40	18.60	**0.60**
	20	0.0057	0.60	19.40	20.60	**0.60**
	27	0.0077	0.62	26.37	27.63	**0.63**
	30	0.0085	0.64	29.35	30.65	**0.65**
	36	0.0102	0.67	35.32	36.68	**0.68**
	40	0.0114	0.69	39.30	40.70	**0.70**
0-400N	**0**	0.0003	0.57	-0.57	0.57	**0.57**
	90	0.0256	1.07	88.90	91.10	**1.10**
	100	0.0280	1.17	98.80	101.20	**1.20**
	180	0.0511	1.91	178.04	181.96	**1.96**
	200	0.0570	2.08	197.86	202.14	**2.14**
	270	0.0767	2.77	267.16	272.84	**2.84**
	300	0.0850	3.07	296.85	303.15	**3.15**
	360	0.1022	3.66	356.24	363.76	**3.76**
	400	0.1100	4.06	395.83	404.17	**4.17**

5.1.5 Shuttle initialization settings

5.1.5..1 Tolerance setting for the upper tools position

The “test presse-flancs” shown in the printing initialization report (Figure 41) regards the position registered by the Promess Press when the shuttle control tool gets in contact with each blank holder with a weak force contact. The software follows up only if the position registered is within the tolerance defined, otherwise it stops the initialization procedure and asks if another shuttle is available.

The determination of the position and the tolerances for each blank holder and for each lower tool is critical. In facts it is important in order to avoid the possibility of collision between the axes during

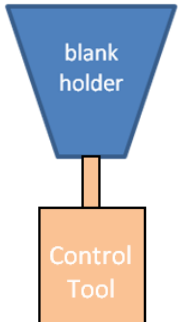


Figure 43 Control tool in contact with the blank holder

the assembling procedure and any kind of damage on the components.
The temperature effect was quite underestimated during the previous phases of the project, so it was necessary to execute a detailed study on the actual behavior of the system. This study was also intented to estimate the expected behavior of the system once it would have been located in the clean room for the production.

Temperature effect

The system performed several initialization procedures in order to measure the position of the blank holders. This showed that the variability of that position strongly depends from the temperature level.

The setting of the machine is made in the engineering laboratory where the range of temperatures fluctuate from 23.6°C (in the morning when the system is off) to 28.9°C (after the system was on for a whole day)

The temperature range in the clean room where the system will be located for the production is 19-24°C.

Distance: blank holders - Base plate fixture

Since the temperature affects all positions, to avoid any conflict between the blank holder and the base plate fixture, a distance test was performed. This test was made possible through installation of a measurement device (palpeur) between the blank holder and the base plate fixture as showed in the Figure 44

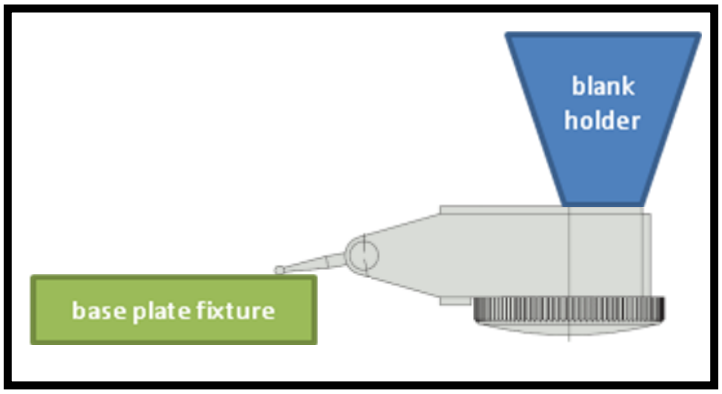


Figure 44 - measurement of the blank holder-base plate fixture distance

Results of the test:

Applying data included in the range (23-29°C) the test shows a linear relationship between the temperature changes and the displacement reaction (Figure 45). In other words, as the temperature increases, the distance between blank holder and the base plate fixture increases as well, and in a linear trend.

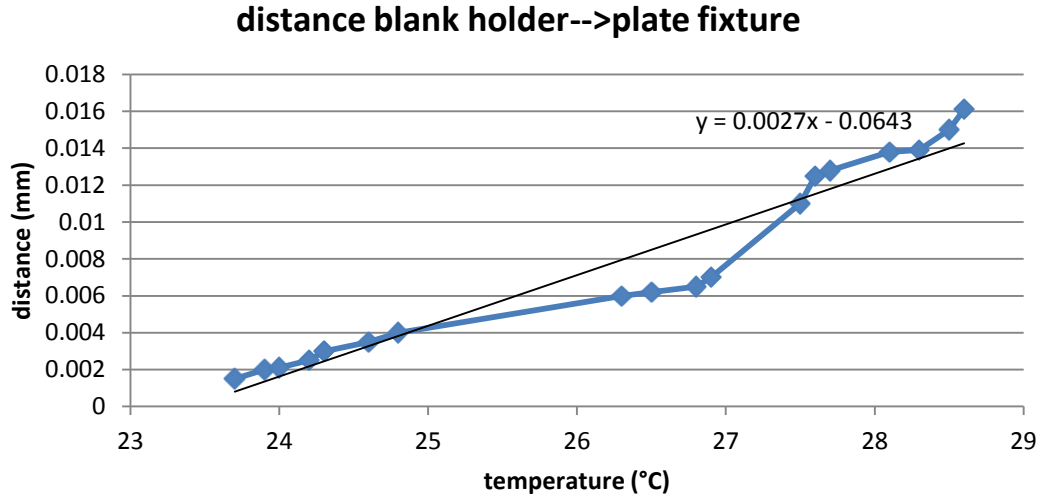


Figure 45 - Displacement graph for the blank holder - base plate fixture distance

Extrapolation of the expected behavior in the clean room

By applying the linear trend extracted from the test described above, It has been possible to obtain the temperature-displacement extrapolation of data for temperatures ranged from 19 to 24°C. Results are shown in Figure 46.

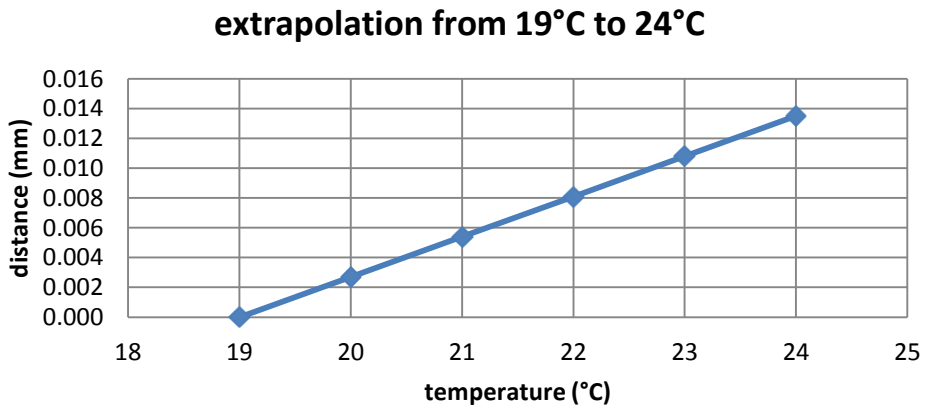


Figure 46 – Extrapolation of blank holder-base plate fixture distance for temperature 19-24°C

As the last graph (Figure 46) clearly shows, the total displacement of the blank holder for temperatures ranged from 19 to 24° is about 0.014mm. According to these results, the displacement expected at a temperature of 25°C would be 0.0162mm.

Blank Holder manual regulation

The blank holder can be regulated mechanically with a fine thread screw as shown in the Figure 47. This operation allows to provide a certain distance between the base plate and the blank holder. Distance is needed because the base plate has to be kept free to allow the components coming from the lower side to match up with the corresponding holes. The distance also avoids to scratch which would result if the base plate was pressed against its placing fixture. During the press fitting the Pess pushes the components along with the base plate while the upper tools hold, avoiding displacements.

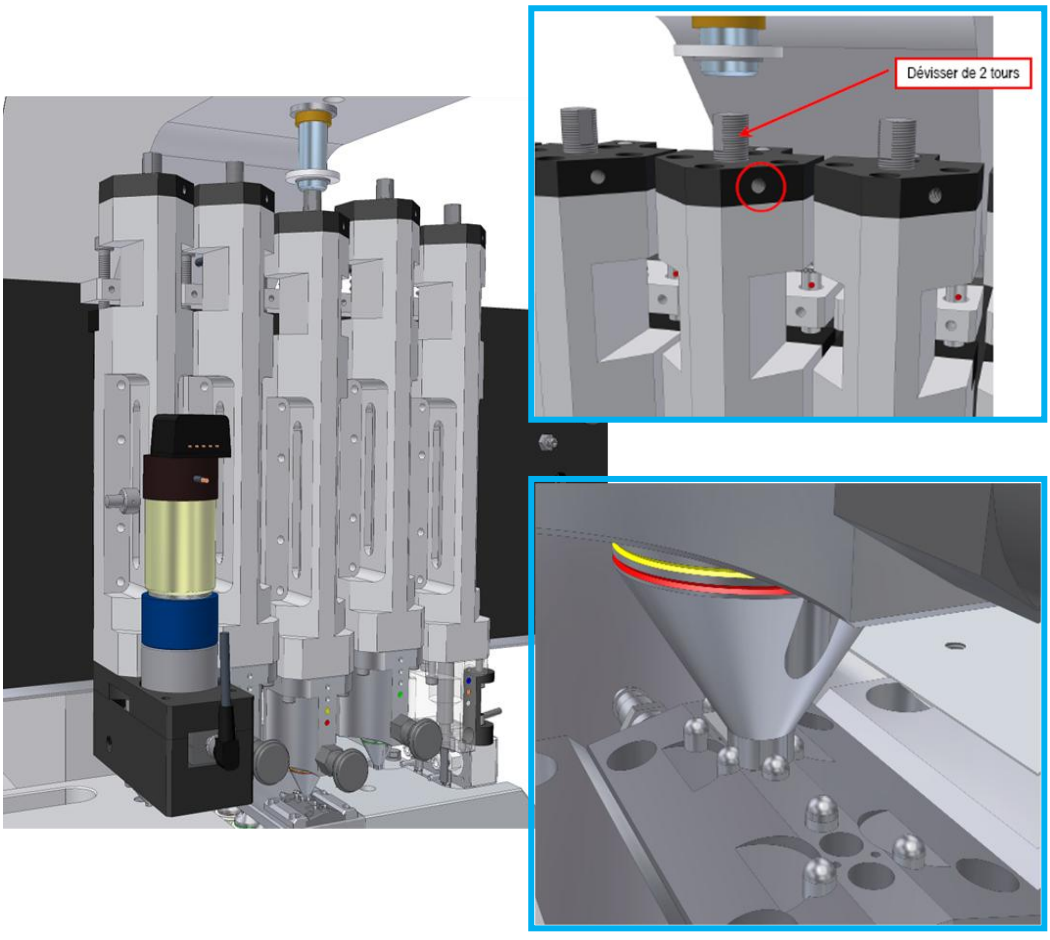


Figure 47
Left: Set of blank holder tools
Right-up: Zoom on the fine thread regulation screw
Right-down: Zoom on blank holder during the press fitting operation

The procedure for the regulation of the blank holders has been performed by Baldelli at a temperature set at 25°C with one of the base plate regulation listed in the Table 5:

Table 5 – blank holder regulation plate thickness

normal base plate max dimension:			0.320		
base plate regulation (mm)					
	min	max		diff min	diff max
Without angles	0.346	0.353		0.026	0.033
With 2 angles	0.347	0.356		0.027	0.036
With 3 angles	0.348	0.397		0.028	0.077

Considering the maximum thickness (0.320mm) and the minimum thickness of the base plate used to perform the regulation of the blank holders (without angels), the resulting displacement of the blank holder at different temperatures is as shown in Figure 48.

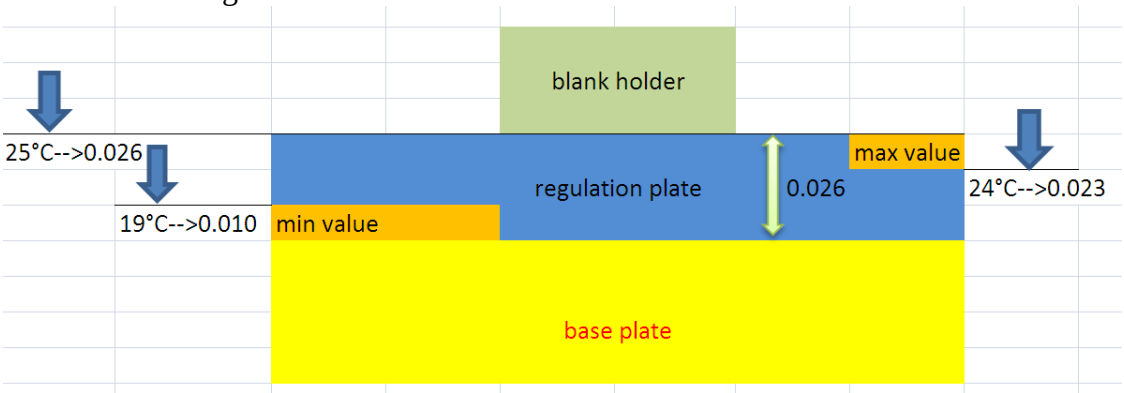


Figure 48 - displacement of the blank holder at different temperatures

Worst-case distance blank holder-base plate fixture

The distance between the blank holder and the base plate at 19°C based on the different regulation plate used during the regulation procedure is shown in Table 6

Table 6 - distance between blank holder and base plate fixture based on the different regulation plates

base plate regulation	
Without angles	0.010mm
With 2 angles	0.011mm
With 3 angles	0.012mm

All the cases show that there is no conflict with the base plate and there is a tolerance of around 0.010mm for each case, which is considered enough.

Determination of the Blank Holders tolerances

Table 7 reportes a list of the positions of the extremity of the Promess Press. The positions are individualized trough the set of initializations (see initialization report) performed on different days and at different time of each day, recording the temperatures of each test.

Table 7 - position of the extremity of the Promess Press taken from the set of initialization

	Shuttle 1 (mm)						Shuttle 2 (mm)					
T (°C)	P1	P2	P3	P4	P5	P6	P1	P2	P3	P4	P5	P6
23.6	18.078	18.032	18.033	18.776	18.038	18.033	18.064	18.016	18.018	18.781	18.023	18.018
23.9	18.086	18.039	18.040	18.783	18.046	18.040	18.072	18.025	18.026	18.790	18.031	18.026
24.1	18.086	18.039	18.040	18.783	18.044	18.039	18.072	18.024	18.026	18.790	18.031	18.026
24.7	18.085	18.039	18.040	18.783	18.045	18.040	18.072	18.025	18.027	18.791	18.033	18.026
25.2	18.089	18.041	18.044	18.786	18.049	18.043	18.076	18.027	18.030	18.794	18.035	18.030
25.3	18.088	18.042	18.044	18.786	18.049	18.044	18.075	18.027	18.030	18.794	18.036	18.030
25.4	18.091	18.043	18.045	18.788	18.051	18.045	18.076	18.029	18.031	18.795	18.036	18.031
25.6	18.093	18.045	18.047	18.788	18.053	18.046	18.079	18.030	18.033	18.796	18.038	18.033
25.9	18.094	18.046	18.049	18.789	18.055	18.048	18.081	18.032	18.035	18.798	18.039	18.035
26.2	18.096	18.047	18.049	18.791	18.056	18.049	18.081	18.033	18.036	18.800	18.040	18.036
26.3	18.098	18.049	18.053	18.793	18.058	18.052	18.084	18.036	18.039	18.802	18.043	18.039
26.9	18.101	18.054	18.056	18.798	18.062	18.055	18.087	18.039	18.041	18.806	18.046	18.041
27.0	18.102	18.054	18.057	18.798	18.062	18.056	18.088	18.039	18.042	18.807	18.048	18.042
27.2	18.104	18.057	18.059	18.800	18.064	18.058	18.090	18.041	18.043	18.808	18.049	18.043
27.3	18.105	18.057	18.060	18.801	18.066	18.059	18.091	18.041	18.044	18.809	18.050	18.045

P1-P2-P3-P5-P6 are the 5 blank holders contact with the H1 of the shuttle control tool, while P4 measurement is the contact with the H2 of the shuttle control tool (Figure 49).

The shuttle control tool measurement provided by the mechanical shop are:
H1 (shuttle 1) = 100.258mm
H1 (shuttle 2) = 100.258mm
H2 (shuttle 1) = 100.258mm
H2 (shuttle 2) = 100.258mm

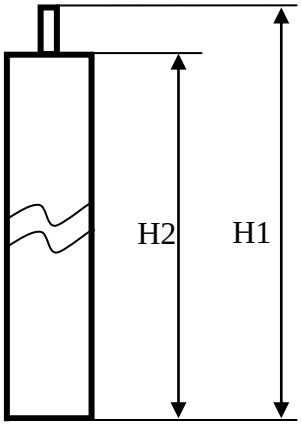


Figure 49 - control shuttle tool H1 and H2

Extrapolation of the behavior expected in the clean room for P1

By plotting the data on the distance-temperature relationship for each blank holder (Figure 50) it is easly noticeable the linear behavior. According to this result, I was able to extrapolate data regarding the expected behavior in the clean room (temperature ranged in the interval 19-24°C), taking into consideration the dimension of the shuttle control tool (Figure 51).

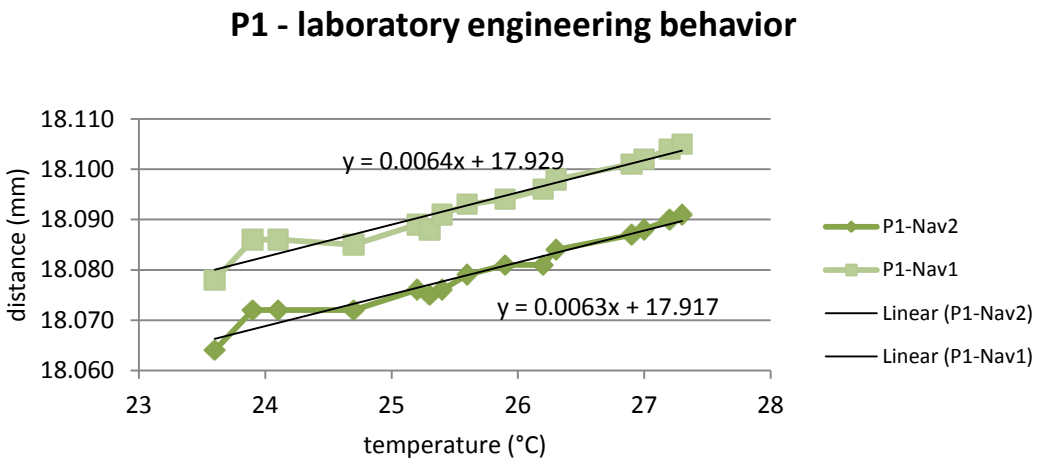


Figure 50 - P1 plotted data

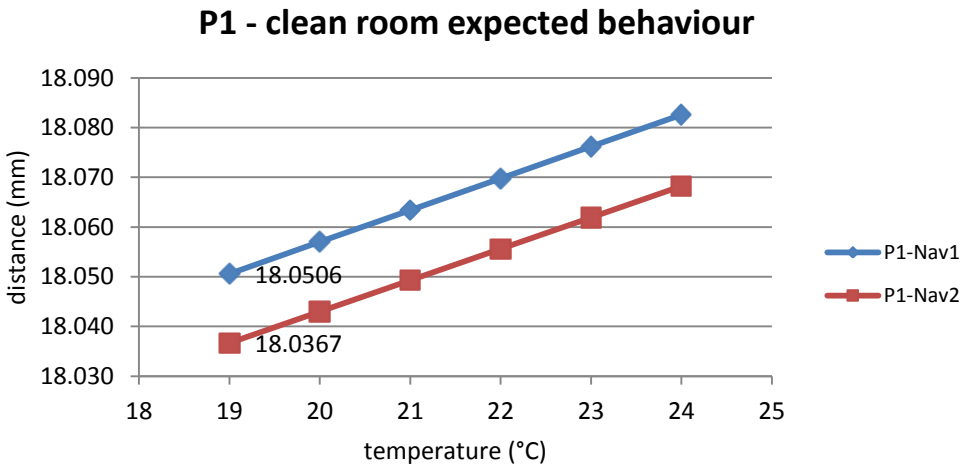


Figure 51 - expected P1 values in the clean room

Calculation of the lower tolerance limit for P1

In order to calculate the Promess Press position minimum, in case P1, each extrapolated point at 19°C has to be translated to the position obtained if the control tool (H1) was at its maximum nominal dimension (100.270mm – Table 1). The lowest Promess press position is chosen as the minimum between the 2 shuttles:

- Shuttle 1 = 18.039mm
- Shuttle 2 = 18.039mm

The lowest tolerance limit of the blank holder is obtained considering the lowest Promess Press position when the control tool (H1) is at its minimum dimension (100.250mm – Table 1):

- Shuttle 1 = 118.289mm
- Shuttle 2 = 118.289mm

Finally, the lowest tolerances is set as the minimum between the 2 shuttles. In this case it is:

- Min P1 = 118.289mm

Calculation of the upper tolerance limit for P1

The control tool maximum position value is calculated adding up 0.070mm to the minimum position value:

- Max P1 = 118.359mm

Tolerance limits for P2, P3, P5, P6

The tolerances limits for P2, P3, P5 and P6 are calculated following the same procedure showed for P1 and using the data of the table…:

- Min P1 = 118.289mm - Max P1 = 118.359mm
- Min P2 = 118.244mm - Max P2 = 118.314mm
- Min P3 = 118.243mm - Max P3 = 118.313mm
- Min P5 = 118.247mm - Max P5 = 118.317mm
- Min P6 = 118.244mm - Max P6 = 118.314mm

Tolerance limits for P4

P4 represents the only exception because instead of the H1 dimension, the H2 dimension of the shuttle control tool has been considered (Figure 52). Moreover, the tolerance applied is larger because P4 is only used by the system to measure the difference H2-H1 and to check if this difference is included within the design tolerances (Table 1):

- Min P4 = 118.220mm - Max P4 = 118.290mm

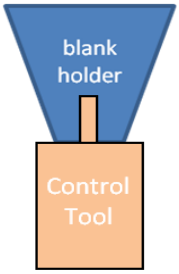


Figure 52 - P4: representation

5.1.5..2 Tolerance setting for the shuttle tools position

The "test outil bas" shown in the printing initialization report (Figure 41) is about the position registered by the Promess Press when the shuttle tools get in contact with their relative blank holders with a small force contact. The software follows up only if the position registered is within the tolerance defined, otherwise it stops the initialization procedure and asks if another shuttle is available.

The determination of the position and the tolerances for each shuttle tool is critically important in order to obtain well settled assembled valves and to avoid any kind of damage on the components.
The temperature effect was quite underestimate during the previous phases of the project, so it has been necessary to execute a detailed study about the behavior of the system and the estimation of the expected behavior once the system will be located in the clean room for the production

Determination of the shuttle tools tolerances

By using the same set of initialization (Table 7) performed for the setting of the blank holder tolerances, the values of the position of the extremity of the Promess Press in case of all the shuttle tools have been extracted. These position values are listed in Table 8

Table 8 - lower tool position values extracted from the previous set of initializations

Shuttle 2 (mm)							
T (°C)	P10	P11	P12	P13	P14	P15	P16
23.6	18.824	18.775	18.768	18.838	18.889	18.529	18.788
23.9	18.833	18.783	18.775	18.847	18.897	18.535	18.795
24.1	18.831	18.783	18.775	18.847	18.897	18.535	18.795
24.7	18.832	18.783	18.777	18.847	18.897	18.537	18.795
25.2	18.836	18.786	18.779	18.850	18.901	18.540	18.799
25.3	18.836	18.786	18.779	18.851	18.901	18.538	18.798
25.4	18.837	18.787	18.780	18.851	18.902	18.540	18.800
25.6	18.839	18.788	18.782	18.853	18.904	18.542	18.802
25.9	18.841	18.790	18.784	18.856	18.905	18.544	18.804
26.2	18.842	18.791	18.785	18.857	18.907	18.544	18.804
26.3	18.845	18.793	18.788	18.860	18.909	18.547	18.808
26.9	18.848	18.796	18.789	18.862	18.913	18.550	18.810
27	18.848	18.797	18.790	18.864	18.913	18.552	18.811
27.2	18.850	18.800	18.792	18.865	18.915	18.553	18.813
27.3	18.851	18.800	18.793	18.866	18.916	18.554	18.814

At this step of the process, the position of the upper tools have already been checked and it is confirmed that they are placed correctly. The acceptance tolerance for the shuttle tools can be bigger because it is used only to detect any potential dimensional problem regarding the tools or whether some component has been loaded on the shuttle tools by mistake.

The tolerance for the upper tools was set at 0.070mm. Also considering the design tolerance for each shuttle tool, it was decided keep a tolerance value equal to 0.130mm for the shuttle tools position, centered on the everage of the values in the Table 7.

The final values are the following

- Min P10 = 18.774mm - Max P10 = 18.904mm
- Min P11 = 18.724mm - Max P11 = 18.854mm
- Min P12 = 18.717mm - Max P12 = 18.847mm
- Min P13 = 18.789mm - Max P13 = 18.919mm
- Min P14 = 18.839mm - Max P14 = 18.969mm
- Min P15 = 18.477mm - Max P15 = 18.607mm
- Min P16 = 18.737mm - Max P16 = 18.867mm
- Min P6 = 17.968mm - Max P6 = 18.098mm

5.2 Press Fitting Control

5.2.1 How is the press fitting controlled?

As explained in paragraph 4.7, the Promess Press is equipped with a resolver to control the position and with a force sensor to control the force applied at the extremity of the press. By the Promess press software it is possible to trace a force-distance curve. In real time, the same software checks whether the force-distance curve lays inside certain curves that are called limit curves (Figure 53). These last curves are settled up in order to avoid any kind of damage in case of contact with other axes, when the components are not in the right position or to detect the absence of any component.

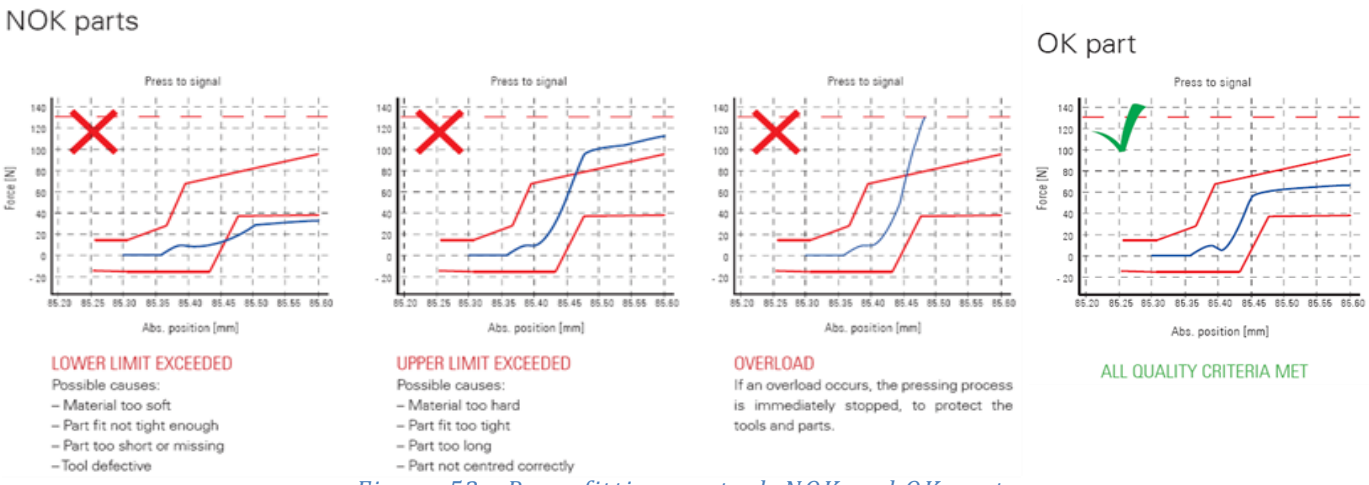


Figure 53 - Press fitting control: NOK and OK parts

5.2.2 Press fitting force

In (Figure 54) there is and example of the Promess Press software screen: On the left there is a part of the program used for assembling the programmable base plate. The line highlighted in blue corresponds to the active function.
On the right there is the drawn curve corresponding to the executed function highlighted in blue. This active function is “Presser sur bloc” that corresponds to a press fitting and then the graph shows the curve of this press fitting (ball seat). The segments on red are the 2 limit curves: the upper limit curve and lower limit curve.

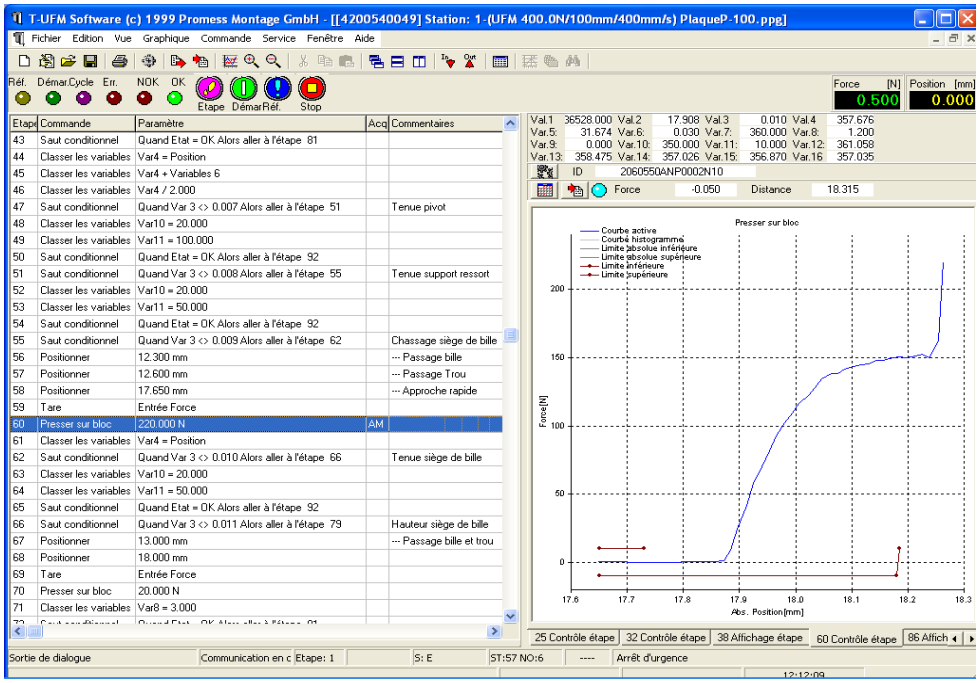


Figure 54 - Promess press example press fitting screen

One of the functions available in the Promess Press software is called “Press to force”. This is the function used in almost all the press fitting steps where the variable under control is the force. Only the Sping Fulcrum is press fitted using the function “Positon”. In Figure 55 is shown in detail all the parameters of these functions.

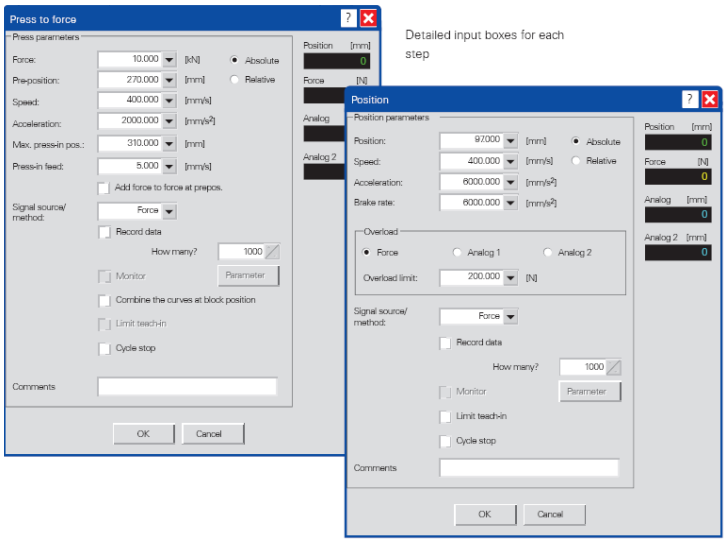


Figure 55 - "presser sur block" function details

For each component it has been chosen the set of parameters of the function and showed in details in the following paragraphs.

5.2.3 Ball seat press fitting step parameters

Maximum force supported by the Ball seat and the Base plate before destruction

The force maximal allowed by the machine is 400 N.
For the Ball seat by experience, force max is above 400 N.
For the Base plate there is no mark on the Base plate due to the shuttle tooling at the end of the press fitting below 300N. Then the roughness must be low (Ra max= 0.1 micron) and checked frequently (after 500 press fittings).

Press fitting displacement parameters

Table 9- Ball Seat "presser sur bloc" function parameters

Parameter	Value	Unit
Force range	400	N
Ft	220	N
Pinter	17,700	mm
Sinter	4	mm/s
Ainter	1000	mm/s^2
Pt	19,000	mm
St	0.200	mm/s
At	N/A	mm/s^2

5.2.4 Stop Pin press fitting step parameters

Maximum force supported by the Stop pin before destruction

The force maximal allowed by the machine is 400 N.
By experience, for the Stop pin, force max is above 400N.

Press fitting displacement parameters

Table 10 - Stop Pin "presser sur bloc" function parameters

Parameter	Stop pin 1.20	Stop pin 0.90	Unit
Force range	400	400	N
Ft	300	300	N
Pinter	17.600	18.000	mm
Sinter	4	4	mm/s
Ainter	1000	1000	mm/s^2
Pt	18.500	18.800	mm
St	0.200	0.200	mm/s
At	N/A	N/A	mm/s^2

5.2.5 Spring pillar press fitting step parameters

Maximum force supported by the Stop pin before destruction

The force maximal allowed by the machine is 400 N.
By experience, for the Stop pin, force max is above 400N.

Position displacement

Position displacement for the tool pin protection (displacement to a determined position with the instruction “Positionner” with a overloading force that avoids to damage the pin of lower tooling in case of wrong position of the spring pillar on the shuttle tool)

Table 11 - Spring Pillar preposition function parameters

Parameter	Value	Unit
Ft-overload	15	N
Final position	17,900	mm
Speed	0,2	mm/s
Acceleration	1000	mm/s^2
Deceleration	1000	mm/s^2

Press fitting displacement parameters

Table 12 - Spring Pillar "presser sur bloc" function parameters

Parameter	Value	Unit
Force range	400	N
Ft	300	N
Pinter	17,956	mm
Sinter	2	mm/s
Ainter	1000	mm/s^2
Pt	19,000	mm
St	0,2	mm/s
At	N/A	mm/s^2

5.2.6 Spring fulcrum press fitting step parameters

Maximum force supported by the spring fulcrum before destruction

The force maximal allowed by the machine is 400 N.
The maximum force supported by the Spring fulcrum is 60N. Above there is a risk of shearing.

Press fitting displacement parameters

The Promess instruction is not “Presser sur bloc” (displacement until force Ft) but a displacement to a determined position with the instruction “Positionner”

Table 13 - Spring Fulcrum "presser sur bloc" function parameters

Parameter	Value	Unit
Force range	400	N
Position	Variable 2	mm
Speed	0,05	mm/s
Acceleration	1000	mm/s^2
Deceleration	1000	mm/s^2

Variable 2= P14 – Hs + Fs
With:

- P14= Position 14 acquired during the initialization
- Hs= “Hauteur de Chassage Support. This parameters is adjustable from the menu “Production Options-Non critical parameters”

- Fs= depth of the slot of the tooling shuttle. This slot keeps the spring fulcrum in place during the press fitting. This parameters is adjustable from the menu “Production Options”

5.3 Method for the setting of the limit curves

Figure 56 below illustrates in orange a typical curve of Ball seat press-fitting.

- Vertical axis is the force in N.
- Horizontal axis corresponds to the position of the servo-controlled axis..
- The position is given in mm referring to the “homing” position of the axis set during the initialization.
- Lower limit is set to reduce the axis displacement in case of component missing.
- Upper limit is set to stop the displacement in case of obstacle met by the axis.Upper and lower limits are to be determined for each component assembling.

Step A. Determination of point P4 to P8

P4 to P8 are shown as example in Figure 56. The principle of this determination is the following:
Measure the height of 10 components and assemble them.
Extract the curves in Excel and analyze them.
Extrapolate the segment P2-P3 (to P4). The intersection of this straight with the positions axis is P4(extrapolated). This point corresponds to the position of the axis when the component is completely assembled and there is no force applied.
The components height and the shuttle tool height determine the point P4(calculated).
Calculate the Offset= P4(extrapolated)- P4(calculated). This Offset will be used below to compensate the position of points P5(calculated), P6(calculated), P7(calculated), P8(calculated),
Points P5(calculated), P6(calculated) are calculated using:

- Max and Min of the shuttle tool height
- Max and Min of the components height

Points P5 and P6= P5(calculated) and P6(calculated) - Offset
Points P7 and P8 are got translating P5 and P6 of the press fitting distance determined from the component design.

Step B. Determination of the Upper Limit U1-U2.

The Upper Limit U1-U2 is shown as example in Figure 56
This limit is set to protect the machine tools in case of collision with an obstacle.
The position of U1 is defined from the starting of the axis displacement.
The position of U2 is defined from P7.
The force value of U1-U2 is set between 5 and 20N depending the level of the press fitting force. It takes account the noise of the chain of force plus a margin.

Step C. Determination of the Lower Limit L1-L2-L3.

The Lower Limit L1-L2-L3 is shown as example in Figure 56
This limit is set to limit the displacement if there is no component on the shuttle tool. That is also to detect a force sensor defect.
The position of L1 is defined from the starting of the axis displacement.
The position of L2 is defined from P4.
The force value of L1-L2 is set around -5N because there is no reason for the sensor to have a lower value. It takes account of the noise of the chain of force minus a margin.
The position and the force of L3 are set to ensure to detect the absence of component.

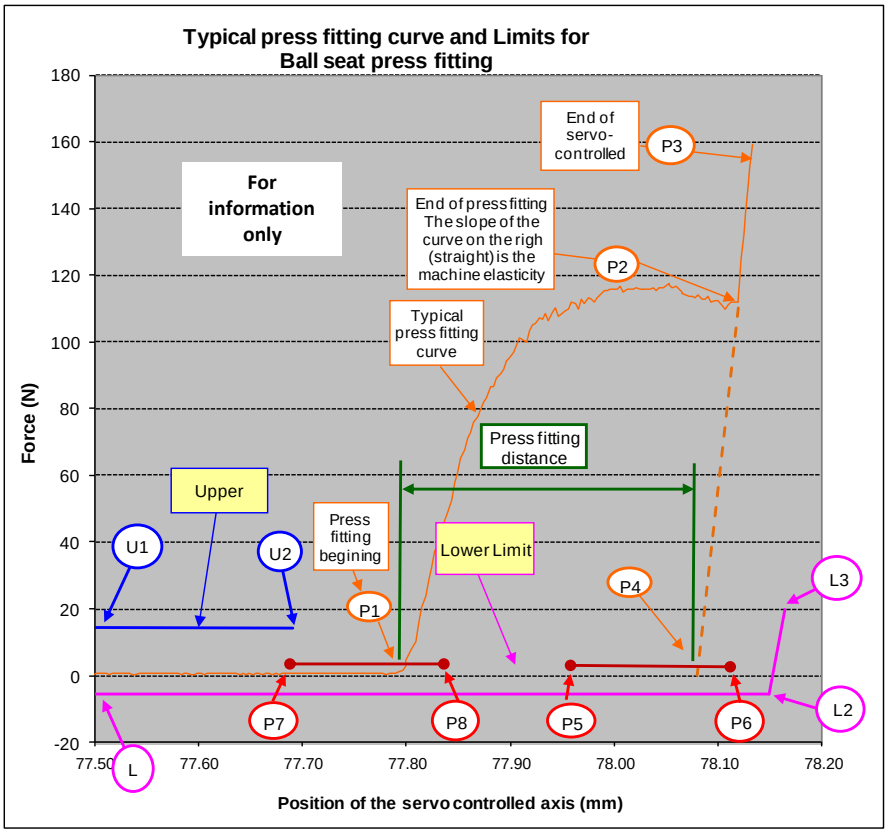


Figure 56 - Press fitting curve example and limit points indication

5.3.1 Ball seat press fitting limit curves settings

Determination of point P4

This point corresponds to the position of the axis when the component is completely assembled and there is no force applied, as shown in the Figure 56 and explained in the step B of Paragraph 3.2 of this document.

The values of P4(calculated) and P4(extrapolated) allow to calculate the values of the offset as explained below.

P4 (calculated):

10 base plates and 10 ball seats have been measured and 5 of them have been assembled using the shuttle 1 and the other 5 using shuttle 2.
Before and after the assembling procedure it has performed an initialization procedure in order to measure the height of the assembling tool (P15- The definition of this point is explained in paragraph 5.1.5..2) and check if it doesn't change (not more than ±0.001mm) between the beginning and the end.

Table 14 - Ball Seat P4 calculations

Navette	Initialization data			Ball Seat height	Base Plait height	Total height	P4 (calculated)
	index	before test	after test				
1	P15	18.523	18.523	0.614	0.301	18.222	**18.233**
				0.614	0.305	18.218	
				0.612	0.303	18.220	
				0.609	0.301	18.222	
				0.609	0.301	18.222	
2 T	P15	18.545	18.546	0.615	0.301	18.244	
				0.609	0.302	18.243	
				0.611	0.302	18.243	
				0.612	0.298	18.247	
				0.618	0.299	18.246	

Total Height=InitializationBeforeTest-BasePlateHeight.

P4(calculated)=average of all the values of the total height column.

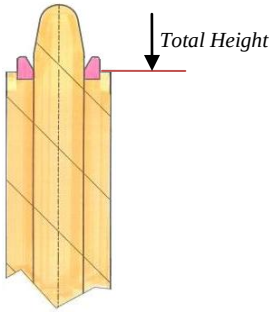


Figure 57 - Ball Seat total height

P4 (extrapolated):

During the assembling procedure the data force-position have been registered and plotted. These slopes have been used to extrapolate the segment P2-P3 to P4 (Figure 56):

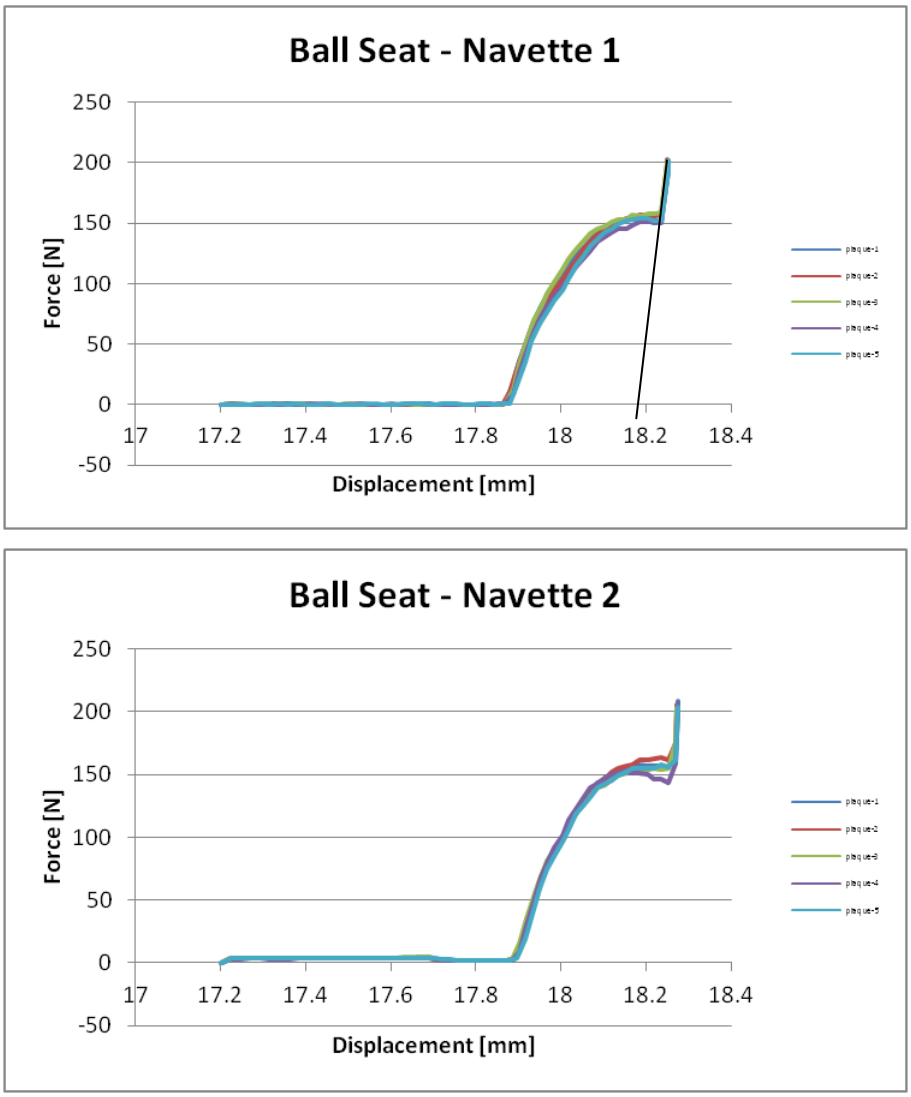


Figure 58 - Ball Seat P4 extrapolated for the shuttle 1and 2

Table 15 - calculations for Ball Seat P4 extrapolated

Navette	plaque-1		plaque-2		plaque-3		plaque-4		plaque-5		P4(extr)
	mm	N	mm	N	mm	N	mm	N	mm	N	
1	18.175141	0	18.1778086	0	18.16391	0	18.1733986	0	18.1709512	0	**18.209**
2	18.2455646	0	18.2384982	0	18.25034	0	18.2470673	0	18.248959	0	

P4(extrapolated)=average of all the extrapolated point at 0N

Offset

The offset is the difference P4(extrapolated)-P4(calculated)

Table 16 - Ball Seat offset calculation

P4(extrapolated)	P4 (calculated)	Offset
18.209	**18.233**	**-0.024**

Determination of point P5, P6, P7, P8.

These points are calculated using:

- Max and Min of the shuttle tool height
- Max and Min of the components height
- Press fitting distance
- Offset

Table 17 - Ball Seat P5, P6, P7 and P8 calculations

Lower Tool tolerances			Components		Offset	P5	P6
index	min	max	Base Plate				
			min	max			
P15	18.477	18.607	0.300	0.320	-0.024	**18.181**	**18.331**

Press fitting Lower Tool			Press Fitting Component		Press fitting distance		P7	P8
tool	min	max	Ball Seat					
			min	max	min	max		
redH2	0.198	0.202	0.595	0.625	0.393	0.497	**17.754**	**17.938**

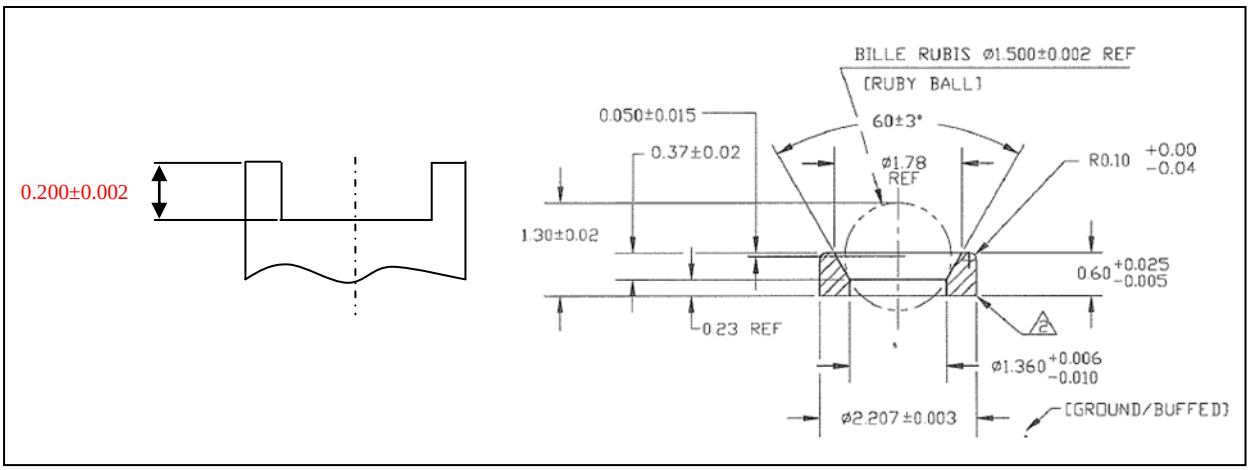


Figure 59 - Ball Seat design

Min(press fitting distance)=min(press fitting lower tool)-max(ball seat)
Max(press fitting distance)=max(press fitting lower tool)-min(ball seat)

Calculation of the point P5

- P5= min(lower tool tolerances)-max(Base Plate)-Offset

Calculation of the point P6

- P6= max(lower tool tolerancies)-min(Base Plate)-Offset

Calculation of the point P7

- P7= P5-max(press fitting distance)

Calculation of the point P8

- P8= P6-min(press fitting distance)

Determination of the limits

Table 18 - Ball seat limits: Upper and Lower limits points

UPPER LIMIT	Position	Force (N)
U1	17.650	10
U2	17.730	10
U3	N/A	N/A
LOWER LIMIT		
L1	17.650	-10
L2	18.180	-10
L3	18.185	10

- U1 and L1 is the value of the Press position before starting the press fitting step
- U2 is the value of P7 calculated above minus a margin of 0.024mm
- L2 is the value of P6 calculated above minus a margin of 0.001mm
- L3 is equal to L2+0.005mmm

5.3.2 Stop Pin press fitting limit curves settings

All the missing calculations and explanations of this paragraph are the same of paragraph 5.2.3.

Determination of point P4

P4 (calculated) - stop pin 0.90

Table 19 - Stop Pin 0.90 P4 calculations

Navette	Initialization data				Stop Pin height	Base Plait height	Total height	P4 (calculated)
	index	before test	After test	H2				
1	P12	18.777	18.777	0.849	0.895	0.308	18.423	**18.423**
					0.895	0.310	18.421	
					0.901	0.307	18.418	
					0.893	0.309	18.424	
					0.893	0.304	18.429	
2	P12	18.783	18.782	0.842	0.896	0.304	18.425	
					0.895	0.310	18.420	
					0.897	0.310	18.418	
					0.890	0.307	18.428	
					0.894	0.303	18.428	

P4 (calculated) - stop pin 1.20:

Table 20 - Stop Pin 1.29 P4 calculations

Navette	Initialization data				Stop Pin height	Base Plait height	Total height	P4 (calculated)
	index	before test	After test	H2				
1	P12	18.778	18.778	0.849	1.200	0.307	18.120	**18.115**
					1.201	0.305	18.121	
					1.210	0.312	18.105	
					1.211	0.307	18.109	
					1.210	0.306	18.111	
2	P12	18.783	18.782	0.842	1.201	0.305	18.119	
					1.202	0.305	18.118	
					1.211	0.305	18.109	
					1.204	0.306	18.115	
					1.201	0.305	18.119	

total height=InitializationBeforeTest+H2-StopPinHeight-BasePlateHeight

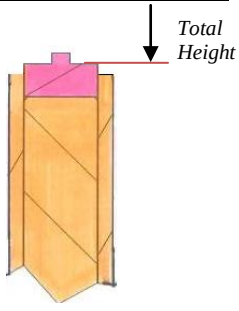


Figure 60 - Stop Pin total height

P4 (extrapolated) - stop pin 0.90:

Table 21 - calculations for Stop Pin 0.90 P4 extrapolated

Navette	plaque-1		plaque-2		plaque-3		plaque-4		plaque-5		P4(extr)
	mm	N	mm	N	mm	N	mm	N	mm	N	
1	18.1340905	0	18.1322418	0	18.13257	0	18.1366849	0	18.1405834	0	**18.128**
2	18.1149485	0	18.1219175	0	18.1222881	0	18.1222881	0	18.124707	0	

P4 (extrapolated) - stop pin 1.20:

Table 22 - calculations for Stop Pin 1.20 P4 extrapolated

Navette	plaque-1		plaque-2		plaque-3		plaque-4		plaque-5		P4(extr)
	mm	N	mm	N	mm	N	mm	N	mm	N	
1	18.4315519	0	18.4320145	0	18.4359075	0	18.4366801	0	18.4354395	0	**18.445**
2	18.4483917	0	18.4563085	0	18.461653	0	18.4564431	0	18.4589748	0	

Offset - stop pin 0.90:

Table 23 - Stop Pin 0.90 offset calculation

P4(extrapolated)	P4 (calculated)	Offset
18.445	**18.423**	**0.022**

Offset - stop pin 1.20:

Table 24 - Stop Pin 1.20 offset calculation

P4(extrapolated)	P4 (calculated)	Offset
18.128	**18.115**	**0.014**

Determination of point P5, P6, P7, P8 - stop pin 0.90:

Table 25 - Stop Pin 0.90 P5, P6, P7 and P8 calculations

Lower Tool tolerances			Components				Offset	P5	P6
index	min	max	Base Plate		Stop Pin 0.90				
			min	max	min	max			
P12	18.717	18.847	0.300	0.320	0.880	0.920	0.022	18.315	18.485

Press fitting Lower Tool			Press Fitting Component		Press fitting distance		P7	P8
tool	min	max	Stop Pin 0.90					
			min	max	min	max		
greenH2	0.840	0.860	0.280	0.320	0.280	0.320	17.995	18.205

Determination of point P5, P6, P7, P8 - stop pin 1.20:

Table 26 - Stop Pin 1.20 P5, P6, P7 and P8 calculations

Lower Tool tolerances			Components				Offset	P5	P6
index	min	max	Base Plate		Stop Pin 1.20				
			min	max	min	max			
P12	18.717	18.847	0.300	0.320	1.180	1.220	0.014	18.023	18.193

Press fitting Lower Tool			Press Fitting Component		Press fitting distance		P7	P8
tool	min	max	Stop Pin 1.20					
			min	max	min	max		
greenH2	0.840	0.860	0.280	0.320	0.280	0.320	17.703	17.913

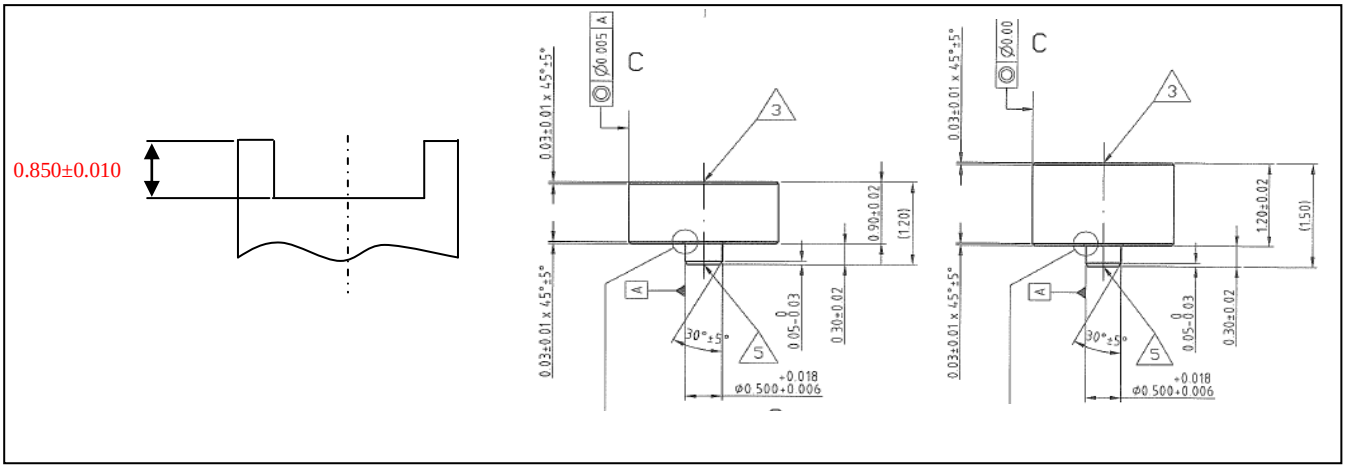


Figure 61- Stop Pin 0.90 and 1.20 designs

Calculation of the point P5

- P5= min(lower tool tolerances)+max(H2)-max(BasePlate)-max(StopPin)-Offset

Calculation of the point P6

- P6= max(lower tool tolerances)+min(H2)-min(BasePlate)-min(StopPin)-Offset

Determination of the limits

Table 27 -Stop Pin 1.20 limits: Upper and Lower limits points

Stop pin 1.20		
UPPER LIMIT	**Position**	**Force (N)**
U1	17.200	30
U2	17.695	30
U3	N/A	N/A
LOWER LIMIT		
L1	17.200	-10
L2	18.217	-10
L3	18.223	30

- U1 and L1 is the value of the Press position before starting the press fitting step
- U2 is the value of P7 calculated above minus a margin of 0.008mm
- L2 is the value of P6 calculated above plus a margin of 0.024mm
- L3 is equal to L2+0.005mmm

Table 28 - Stop Pin 0.90 limits: Upper and Lower limits points

Stop pin 0.90		
UPPER LIMIT	**Position**	**Force (N)**
U1	17.200	30
U2	17.995	30
U3	N/A	N/A
LOWER LIMIT		
L1	17.200	-10
L2	18.517	-10
L3	18.523	20

- U1 and L1 is the value of the Press position before starting the press fitting step
- U2 is the value of P7 calculated above
- L2 is the value of P6 calculated above plus a margin of 0.032mm
- L3 is equal to L2+0.005mmm

5.3.3 Spring Pillar press fitting limit curves settings

All the missing calculations and explanations of this paragraph are the same of paragraph 5.2.3.

Determination of point P4

P4 (calculated)

Table 29 - Spring Pillar P4 calculations

Navette	Initialization data				Spring pillar height	Base Plait height	Total height	P4 (calculated)
	Index	before test	after test	H2				
1	P13	18.847	18.848	0.404	0.607	0.307	18.337	**18.334**
					0.609	0.305	18.337	
					0.608	0.306	18.337	
					0.609	0.307	18.335	
					0.608	0.307	18.336	
2	P13	18.847	18.847	0.400	0.609	0.309	18.329	
					0.608	0.308	18.331	
					0.609	0.305	18.333	
					0.610	0.308	18.329	
					0.606	0.308	18.333	

Total height=InitializationBeforeTest+H2-SpringPillarHeight- BasePlateHeight

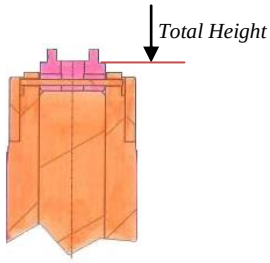


Figure 62 - Spring Pillar total height

P4 (extrapolated)

Table 30 - calculations for Spring Pillar P4 extrapolated

Navette	plaque-1		plaque-2		plaque-3		plaque-4		plaque-5		P4(extr)
	mm	N	mm	N	mm	N	mm	N	Mm	N	
1	18.3433799	0	18.3453113	0	18.3466569	0	18.3482879	0	18.3494703	0	**18.340**
2	18.3280038	0	18.330	0	18.33306	0	18.33686	0	18.34282	0	

Offset

Table 31 - Spring Pillar offset calculation

P4(extrapolated)	P4 (calculated)	Offset
18.340	**18.334**	**0.007**

Determination of point P5, P6, P7, P8:

Table 32 - Spring Pillar P5, P6, P7 and P8 calculations

er Tool tolerances			Components				Offset	P5	P6
index	min	max	Base Plate		Spring Pillar				
			min	max	min	max			
P13	18.789	18.919	0.300	0.320	0.600	0.620	0.007	18.252	18.402

Press fitting Lower Tool			Press Fitting Component		Press fitting distance		P7	P8
tool	min	max	Spring Pillar					
			min	max	min	max		
whiteH2	0.390	0.410	0.280	0.320	0.280	0.320	17.957	18.127

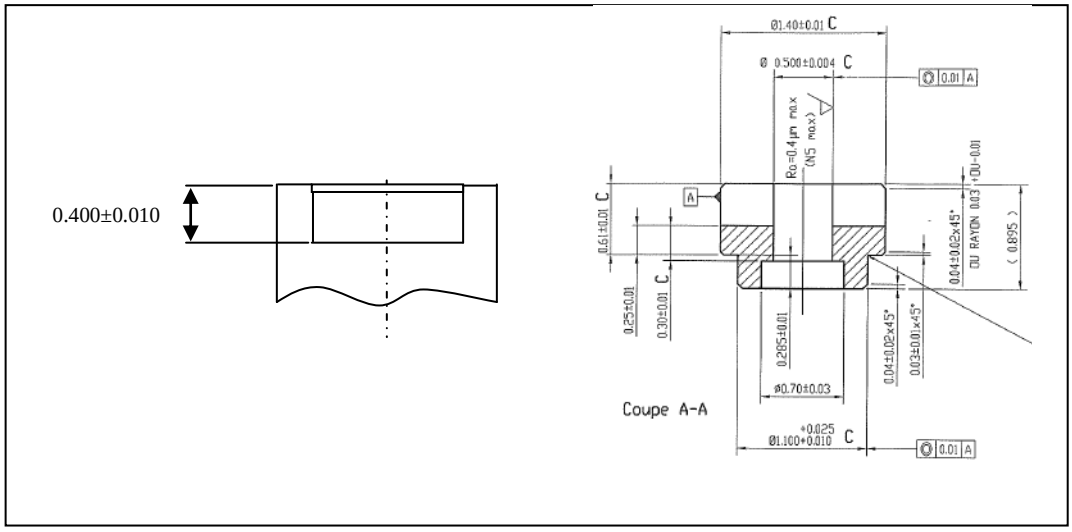


Figure 63 - Spring Pillar design

Calculation of the point P5

- P5= min(lower tool tolerances)+max(H2)-max(BasePlate)-max(SpringPillar)-Offset

Calculation of the point P6

- P6= max(lower tool tolerances)+min(H2)-min(BasePlate)-min(SpringPillar)-Offset

Determination of the limits

Table 33 - Spring Pillar limits: Upper and Lower limits points

UPPER LIMIT	Position	Force (N)
U1	17.900	30
U2	17.956	30
U3	N/A	N/A
LOWER LIMIT		
L1	17.900	-10
L2	18.425	-10
L3	18.430	30

- U1 and L1 is the value of the Press position before starting the press fitting step
- U2 is the value of P7 calculated above minus a margin of 0.001mm
- L2 is the value of P6 calculated above plus a margin of 0.023mm
- L3 is equal to L2+0.005mmm

5.3.4 Spring Pillar press fitting limit curves settings

All the missing calculations and explanations of this Paragraph are the same of Paragraph 5.2.3.

Determination of the press fitting position

In this case the variable under control is the position instead of the force.
The press fitting step is completed when the Press Promess reaches a certain position. This position is calculated as explained below:

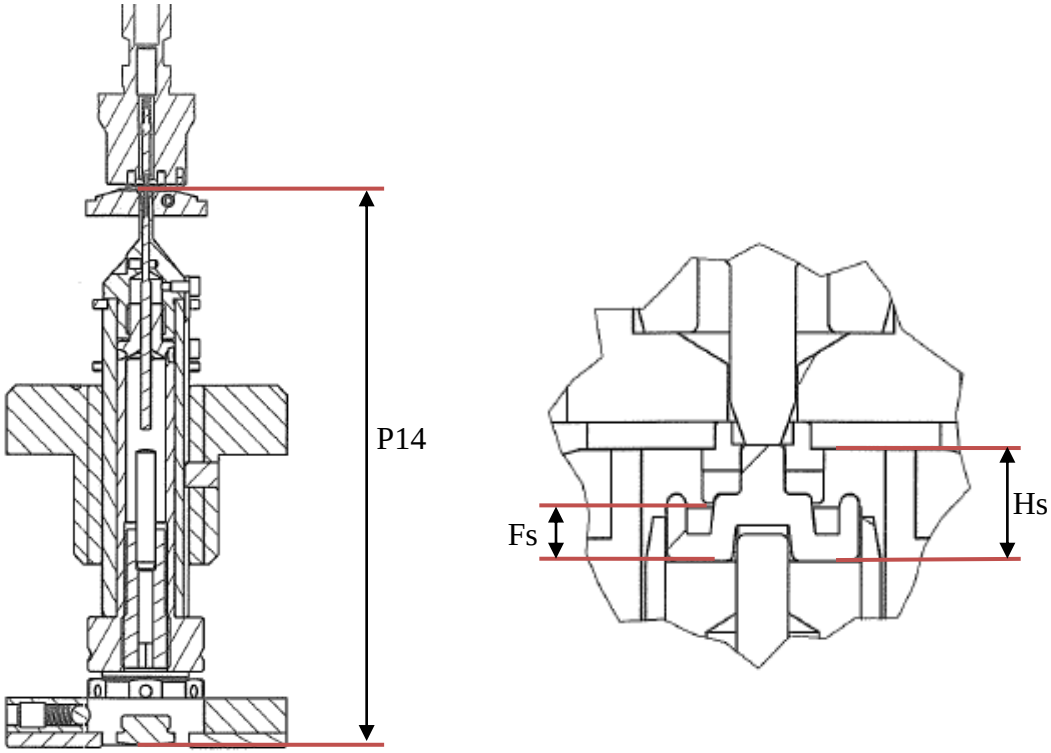


Figure 64 - Spring fulcrum shuttle tool: initialization reference. Fs (critical parameter) and Hs (not critical parameter)

- P14 = Height of the assembling tool (51001-grey tool) measured during the initialization procedure
- Hs = Value “Hauteur de chassage support de ressort” in the menu “Option de production – Parametres Standard”

- Fs = Value “Profondeur fente outil support de ressort” in the menu “Option de production – Parametres Critiques”

- Position equation: P14 – (Hs – Fs)

Press fitting tool tolerances

Table 34 - Spring fulcrum shuttle tool range of tolerance

Lower Tool tolerances		
index	**min**	**max**
P14	18.839	18.969

Determination of the limits

Table 35 - Spring Fulcrum limits: Upper and Lower limits points

UPPER LIMIT		
U1	17.500	20
U2	17.650	20
U3	N/A	N/A
LOWER LIMIT		
L1	17.500	-10
L2	17.950	-10
L3	N/A	N/A

- U1 and L1 is the value of the Press position before starting the press fitting step
- U2 is the value of min(lower tool tolerances) minus a margin of the press fitting distance of 1.189mm
- L2 is the value of max(lower tool tolerances) minus a margin of 1.019mm

5.3.5 Pivot press fitting limit curves settings

All the missing calculations and explanations of this paragraph are the same of paragraph 5.2.3.

Determination of point P4

P4 (calculated)

Table 36 - Pivot P4 calculations

Navette	Initialization data			pivot height	Base Plait height	Total height	P4 (calculated)
	Index	before test	after test				
1	P10	18.841	18.841	0.215	0.312	18.314	18.304
				0.218	0.307	18.314	
				0.217	0.307	18.316	
2	P10	18.817	18.816	0.215	0.310	18.292	
				0.216	0.308	18.293	
				0.215	0.309	18.293	

Total Height=InitializationBeforeTest-PivotHeight-BasePlateHeight

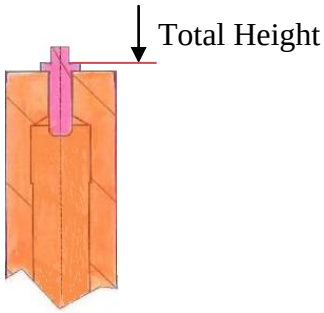


Figure 65 - Pivot total height

P4 (extrapolated)

Figure 66 - calculations for Pivot P4 extrapolated

Navette	plaque-1		plaque-2		plaque-3		P4(extr)
	mm	N	mm	N	mm	N	
1	18.3195759	0	18.3199642	0	18.3195145	0	18.307
2	18.2951798	0	18.2946544	0	18.2936905	0	

Offset

Table 37 - Pivot offset calculation

P4(extrapolated)	P4 (calculated)	Offset
18.307	18.304	0.003

Determination of point P5, P6, P7, P8:

Table 38 - Pivot P5, P6, P7 and P8 calculations

Lower Tool tolerances			Components				Offset	P5	P6
index	min	max	Base Plate		Pivot				
			min	max	min	max			
P10	18.774	18.904	0.300	0.320	0.210	0.230	0.003	18.221	18.391

Press Fitting Component		Press fitting distance		P7	P8
Spring Pillar					
min	max	min	max		
0.410	0.430	0.410	0.430	17.791	17.981

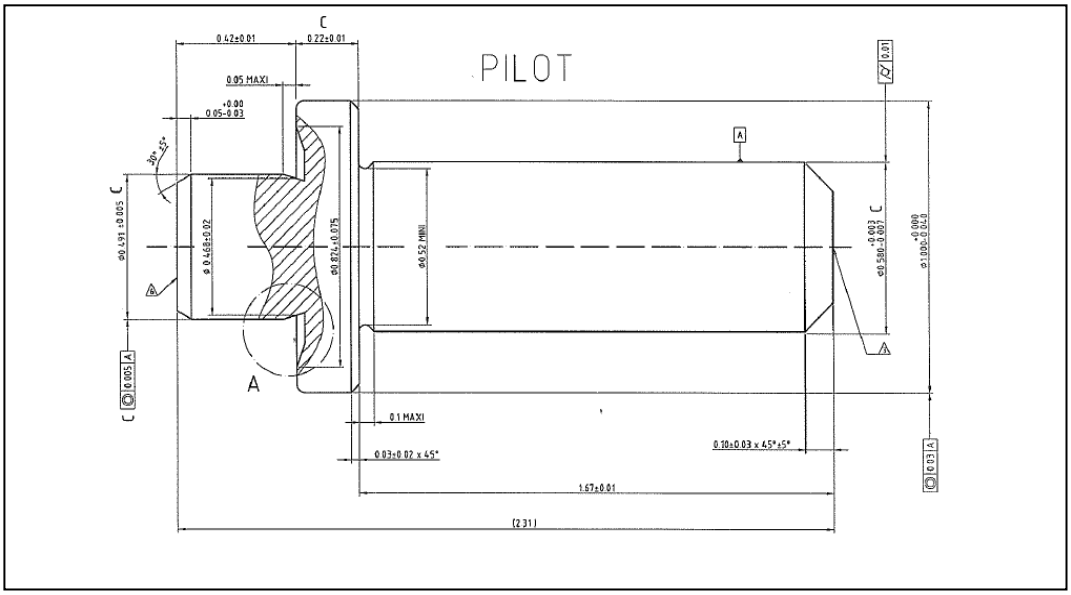


Figure 67 - Pivot design

Calculation of the point P5

- P5= min(lower tool tolerances-max(BasePlate)-max(Pivot)-Offset

Calculation of the point P6

- P6= max(lower tool tolerances)-min(BasePlate)-min(Pivot)-Offset

Determination of the limits

Table 39 - Pivot limits: Upper and Lower limits points

UPPER LIMIT	Position	Force (N)
U1	17.200	30
U2	17.791	30
U3	N/A	N/A
LOWER LIMIT		
L1	17.200	-10
L2	18.436	-10
L3	18.441	30

- U1 and L1 is the value of the Press position before starting the press fitting step
- U2 is the value of P7 calculated above
- L2 is the value of P6 calculated above plus a margin of 0.045mm
- L3 is equal to L2+0.005mmm

5.3.6 Riveting limit curves settings

All the missing calculations and explanations of this paragraph are the same of paragraph 5.2.3.

Determination of point P5, P6, P7, P8:

Table 40 - Riveting P5, P6, P7 and P8 calculations

Lower Tool tolerances			Components				P5	P6
index	min	max	Base Plate		Pivot			
			min	max	min	max		
P11	18.724	18.854	0.300	0.320	0.210	0.230	18.174	18.344

Press Fitting Component		Press fitting distance		P7	P8
Spring Pillar					
min	max	min	max		
0.410	0.430	0.410	0.430	17.744	17.934

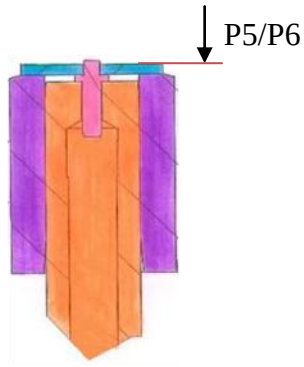


Figure 68 - Riveting P5 or P6

Calculation of the point P5 base plate side

- P5= min(lower tool tolerances-max(BasePlate)-max(Pivot)

Calculation of the point P6 base plate side

- P6= max(lower tool tolerances)-min(BasePlate)-min(Pivot)

Calculation of the point P7

- P7= P5-max(press fitting distance)

Calculation of the point P8

- P8= P6-min(press fitting distance)

Determination of the limits

Figure 69 - Riveting limits: Upper and Lower limits points

UPPER LIMIT		
U1	18.350	70
U2	18.450	70
U3	N/A	N/A
LOWER LIMIT		
L1	18.350	-10
L2	18.645	-10
L3	18.650	30

- U1 and L1 is the value of the Press position before starting pushing the riveting upper tool (P6+0.006mm)
- U2 is the value of P6 calculated above plus a margin of 0.106mm
- L2 is the value of U2 calculated above plus a margin of 0.195mm
- L3 is equal to L2+0.005mmm

5.4 Press fitting behavior evaluation

5.4.1 What is this evaluation about?

The press fitting procedure has to be performed successfully within all the components measuring range. Thus, there is a need to evaluate the behavior of each component with different dimensions after having been assembled by the system using the press fitting steps and the control limits shown in the previous chapter. More importantthan the force is checking if assemblage has any visual problem.

5.4.2 Press fitting components preparation

All the parts are measured before assembling.
To measure these parts use:

- Pin gages, applicable for minimum circles of inner diameters. See Figure 70
- Werth machine, applicable for average circles of inner diameters. See Figure 70
- Micro-comparator Cary-Monocote, applicable for average circles of outer diameters.

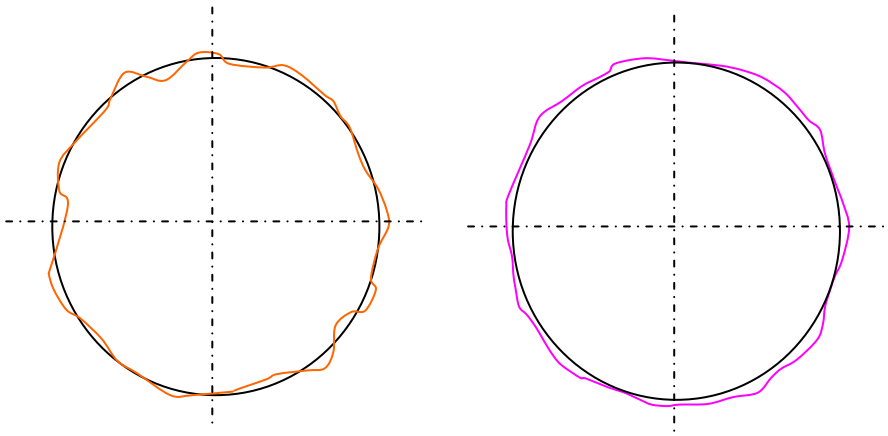


Figure 70 - Inner and outer diameter measurement

For the same inner diameter measurement there could be an offset between:

- average circle
- minimum circle

Due to the form defect (if the circle is not rounded). Special care of the form defect is taken into consideration during these measurements.

The inner diameters of the following components are measured with pin gages with resolution each micron and tolerance +/-0.4 micron:

- Base plate hole for Pivot
- Base plate hole for Ball seat

Measurement tolerance is estimated to +/-1.0 micron.

The inner diameters of the following components are measured with Werth machine (measurement with camera) with resolution each micron:

- Base plate hole for Spring pillar
- Base plate hole for Pivot
- Base plate hole for Stop pin
- Spring pillar

For these Ø it has been taken 3 measurements and select the parts with range below or equal to 2 microns. The others are rejected.
The measurement tolerance is estimated to +/-1.5 microns.

The outer diameters of the following components are measured with Micro-comparator Cary-Monocote with resolution each 0.5 micron. Measurement tolerance is estimated to +/- 1.0 micron:

- Ball seat
- Spring pillar
- Stop pin
- Pivot

Then interference or gap in assembling of 2 components is affected of a certain tolerance. This tolerance depends of the measurement means used. For the following combinations of measurement means we have the corresponding tolerances:

- Pin gages + Micro-comparator Cary-Monocote
  $= +/-(1^2+1^2)^{1/2} = +/- 1.4$ micron
- Werth machine + Micro-comparator Cary-Monocote
  $= +/- (1.5^2+1^2)^{1/2} = + /- 1.8$ micron

5.4.3 Removing test results in the different interference cases

This disassembling operation is independent from the push out test performed by the automated assembly system (see following chapters).

Remember that the word "interference" refers to the fact that one part slightly interferes with the space that the other is taking up. When the shaft is pressed into its housing, the two parts interfere with each other's occupation of space. The result is that they elastically slightly deform, each being compressed, and the interface between them is one of extremely high friction (see paragraph 4.2)

The removing test is made on the Lloyd machine of the Quality Control Department. This is a measurement machine, equipped with special tools and fixtures designed for the Hakim valve components, and it is used to register the force and the displacement with accurate high precision during the disassembling operation. The output of this test is the real push out force for the different cases of interference.
Obviously the goal of this last test is to submit the components press fitted to a certain range force until the component moves.

There is a clear difference between this test and the one performed by the automated system: the first test has the aim of verifying the exact force of disassembling for each component in base of the interference; the test performed by the semi-automatic system has the aim of checking if the component is not dislodged after applying the minimal force that it's expected to hold.

In the next paragraphs it has been reported only the case on minimum interference because if the capability condition is respected in this case, it will be consequently respected in the case of maximum interference

5.4.4 Ball Seat removing test

Case of minimum interference

Table 41 - Ball Seat interference minimum

	Ø Base plate	**Ø Ballseat**	**Interference**	**Fmax IN**	**Fmax OUT**
Unit	mm	mm	mm	N	N
BSAG1-1	2.196	2.200	0.004	51.88	35.7
BSAG1-2	2.196	2.200	0.004	45.88	33.1
BSAG2-1	2.196	2.200	0.004	60.21	37.8
BSAG2-2	2.196	2.200	0.004	38.77	22.8
BSAG2-3	2.196	2.200	0.004	38.77	25.5
BSAG2-4	2.196	2.200	0.004	37.55	25.2

This evaluation is made considering the minimal interference 0.004 mm.
The number of points used to test this case is 6. Although it is a small number of points to calculate statistics it can be considered as a trend.
The distribution for push-out force is normal.
Capability (P_{pk}) for push-out force regarding 5 N = 1.32. Then the capability condition (Capability >1) is respected.
The capability (P_{pk}) for push-out force regarding 10 N = 1.01.

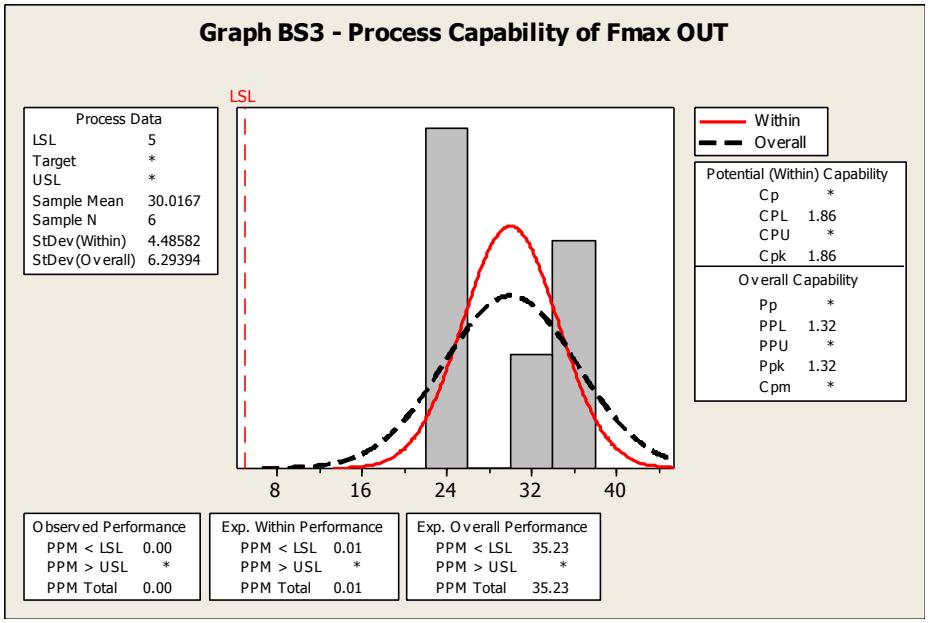


Figure 71 - Ball Seat Capability test

5.4.5 Stop Pin removing test

Case of minimum interference

Table 42 - Stop Pin interference minimum

	Ø Base plate	Ø Stop pin	Interference	F_{max}(N) Press Fit	F_{max}(N) Push-out
Unit	mm	mm	mm	N	N
STAE1	0.494	0.498	0.004	99.66	52.8
STAE1	0.494	0.498	0.004	107.77	56.1
STAE1	0.494	0.498	0.004	98.32	65.1
STAE1	0.494	0.498	0.004	106.21	63.4
STAE1	0.494	0.498	0.004	102.99	64.1
STAE1	0.494	0.498	0.004	102.21	54.7
STAE1	0.494	0.498	0.004	99.99	69.5

This evaluation is made considering the interference 0.004 mm. A 0.003 mm minimal interference was not possible because there was not Base plates available. The Base plates is needed to allow this kind of interference. It means that the component designs consider a new minimal interference of 0.004

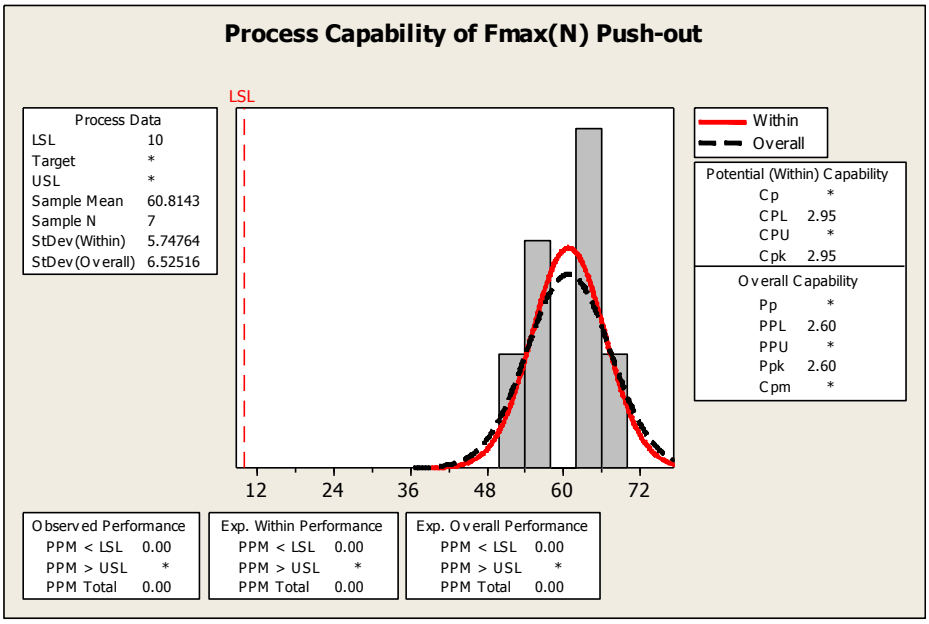


Figure 72 - Stop Pin capability test

The distribution for the push out force is normal.
Capability (Ppk) for push-out force regarding 10 N= 2.60 that is very good. Then the capability condition (Capability >1) is respected.
Note that for the Stop pin there is no specification concerning the push our force. Then the capability is mentioned only for information and there is no need to analyze the maximum interference case.

5.4.6 Spring pillar removing test

Case of minimum interference

Table 43 - Spring Pillar minimum interference

	Ø Base plate	Ø Spring pillar	Interference	F_{max}(N) Press Fit	F_{max}(N) Push-out
Unit	mm	mm	mm	N	N
SPAB1-1	1.095	1.105	0.010	86.5	41.5
SPAB1-2	1.095	1.105	0.010	91.4	38.2
SPAB1-3	1.095	1.105	0.010	112.7	47.6
SPAB1-4	1.095	1.105	0.010	82.2	41.3
SPAB1-5	1.095	1.105	0.010	87.0	43.0
SPAB1-6	1.095	1.105	0.010	83.2	40.5
SPAB1-7	1.095	1.105	0.010	85.5	41.0
SPAB1-8	1.095	1.105	0.010	91.6	42.1
SPAB1-9	1.095	1.105	0.010	97.3	44.5
SPAB1-10	1.095	1.105	0.010	91.3	41.4
SPAG-2			0.010	59.1	34.1
SPAG-4			0.010	89.4	46.9
SPAG-5			0.010	96.6	54.2
SPAG-6			0.010	65.8	42.1
SPAG-7			0.010	100.3	51.7
SPAG-8			0.010	61.0	38.1
SPAG-9			0.010	91.2	47.3
SPAG-10			0.010	84.6	49.8

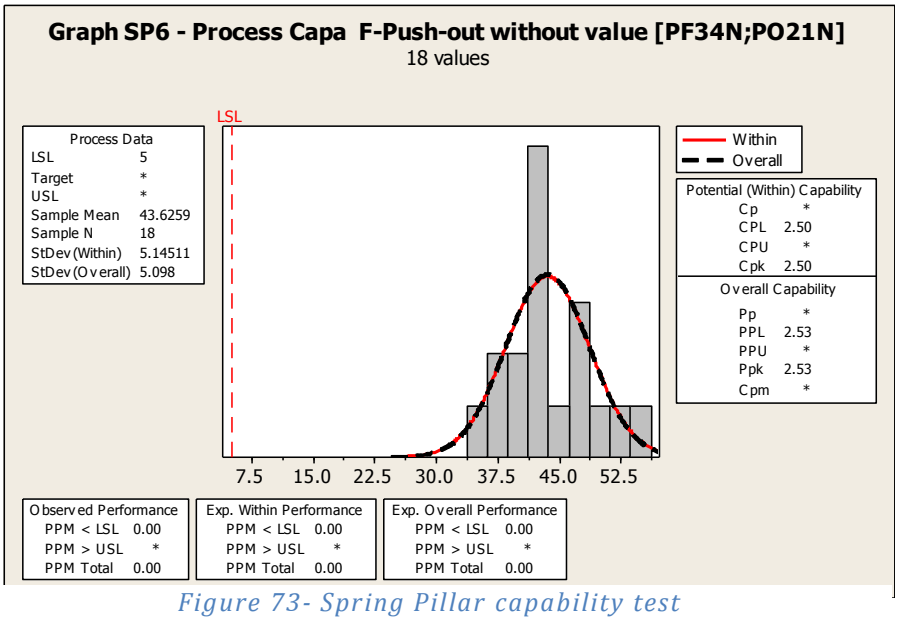


Figure 73- Spring Pillar capability test

This evaluation is made considering the minimal interference 0.010 mm.
The length 0.30 +/-0.01 according with the Spring Pillar design.
The distribution for push-out forces is normal
Capability (Ppk) for push-out force regarding 5 N = 2.53 that is very good
Then the capability condition (Capability >1) is respected.
Capability (Ppk) for push-out force regarding 10 N = 2.17.

5.4.7 Spring fulcrum removing test

Various tests have been performed with the same lot of Spring pillar but with different lot of Spring fulcrums to simulate the different interference ranges between Spring fulcrum and Spring pillar.

Spring fulcrum press fitting method

The Spring fulcrums are press fitted on the machine at the position in Figure 74

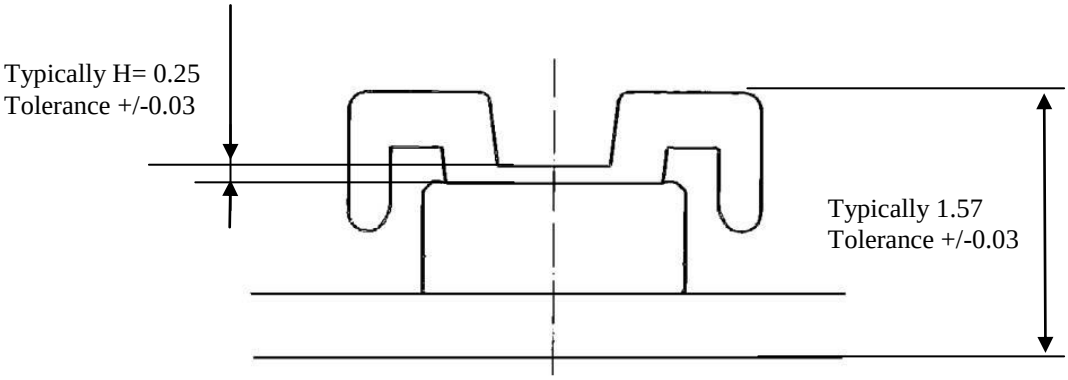


Figure 74 - Spring Fulcrum press fitting position

Global results:

All the distributions are normal.
The best result is for the nominal interference case with Capability (Ppk)=1.40.

The worst case is represented in case of the minimal interference with Capability (Ppk)=0.67. This results from the push out force control on the semi-automatic system inactivated.
In the others cases of interference the Capability is close to the requirement of 1.
Note that the validated process will be with the push out force control activated on the machine and set to guaranty 5N. At this condition and as there is a margin of 1 N between the minimal push out force control with the machine (minimum requirement=5N) and the minimal push out force after calibration (minimum requirement=4N), there is no risk to accept a part with a push out force after calibration below 4N.

5.4.8 Pivot removing test

Case of minimum interference

Table 44 - Pivot minimum interference

	Gap between Pivot and base plate	**F_{max}(N) Push-out**
Unit	mm	N
PIAL-1	0.012	57.2
PIAL-2	0.012	56.4
PIAL-3	0.012	58.5
PIAL-4	0.012	54.5
PIAL-5	0.012	58.6
PIAL-6	0.012	60.8
PIAL-7	0.012	58.8
PIAL-8	0.012	56.0
PIAL-9	0.012	67.2
PIAL-10	0.012	57.3
PIAL-11	0.012	54.0
PIAL-12	0.012	63.6

The distribution for push-out force is normal. ¨
The Capability (P_{pk}) for push-out force regarding 10 N = 4.19 that is very good.
Then the capability condition (Capability >1) is respected.

5.5 Push out force for the holding test evalutation

5.5.1 Why this evaluation?

This evalutation concerns all the components press fitted by the Automated Assembling System and its main goal is to simulate the mechanical behavior of the valve by estimating the acceleration exerted on its components. The evaluation will allow to set the minimal push out forces (holding test) in order to assure that the components will not dislodge during the valve useful life. It is also been performed a test with the application of the force estimated. The aim of this last test is to establish the parameters for scrapping the valves which won't support the applied force.

5.5.2 Valve configuration and estimation strategy

For programmable and non-programmable valves, the estimation is made analysing the mechanical behavior of an implanted valve in static conditions and in dynamic conditions (i.e. during a shock). Follwing the consideration extracted from the experiments on the human decelerations edvenements, it has been calcutad for each component assembled, the minimum foce that it has to hold during the valve useful life.

The 2 designs included in Figure 75 together with the compents mass listed in the Table 45 have been used for all the calculations in the following paragraphs.

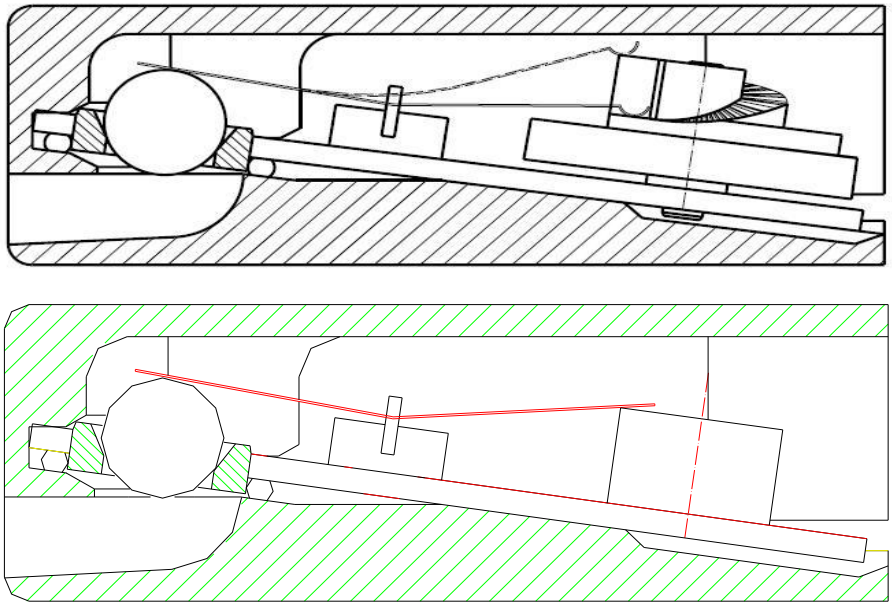


Figure 75 - Programmable and Precision valve design

Table 45 - components mass

Part	Mass (kg)
Spring	1.6E-06
Ball seat	5.3E-06
Ball	6.3E-06
Spring pillar	7.4E-06
Spring fulcrum	1.3E-06
Pivot	2.7E-06
Stop pin 1.20	1.7E-06
Motor	3.2E-05

5.5.3 Human body acceleration

Aircraft and motor vehicle crashes will continue to occur in spite of all human efforts to prevent them. However, serious injury and death are not inevitable consequences of these crashes. It has been estimated that approximately 85 percent of all aircraft crashes are potentially survivable without serious injury for the occupants of these aircraft. This estimate is based upon the determination that 85 percent of all crashes met two basic criteria. First, the forces involved in the crash were within the limits of human tolerance without serious injury to abrupt acceleration. Second, the structure within the occupant's immediate environment remained substantially intact, providing a livable volume throughout the crash sequence. In other words, contrary to popular belief, most aircraft crashes are not "smoking holes" (Shanahan, 2004).

Injury in a crash is the result of human response to force application to the body and it is important to understand which are the limits of human tolerance without serious injury to abrupt acceleration in order to evaluate which is the limit force by which the valve components can be dislodged

A quantitative stress analysis of the human body to limits of voluntary tolerance of crash type impacts and decelerations have been performed in the last years. These dynamic stress analyses, including 76 human experiments with rocket-sleds (test platform that slides along a set of rails) decelerated from aircraft crash velocities and more than 200 experiments with human volunteers on swings, catapults and other decelerating devices, provided criteria for aircraft and ground vehicle safety design and human body acceleration limits.

Acceleration is defined as the rate of change in velocity of a mass and is frequently stated in units of feet per second per second or feet/second2 (meters/second2. It is related to force by the familiar equation,

F = ma, where F = force, m = mass, and a = acceleration.

Acceleration may be described in units of G which is the ratio of a particular acceleration (a) to the acceleration of gravity at sea level (g = 32.2 ft/sec2 or 9.8 m/sec2) or G = a/g. As a result, crash forces can be thought of in terms of multiples of the weight of the objects being accelerated.

Figure 76 is the curve, the Eiband Curve, for accelerations in the +Gz axis, analogous to the direction of forces experienced in an ejection seat or a vertical crash of a helicopter. It is a plot of uniform acceleration of the vehicle as demonstrated in the lower right-hand corner, versus the duration of the acceleration for pulses up to approximately 150 milliseconds. As the legend on the graphs notes, these exposures were all survivable with essentially idealized seat and restraint systems. The graph illustrates that individuals voluntarily tolerate accelerations up to approximately 18 G without injury, and spinal injury does not occur below accelerations of approximately 20-25 G.

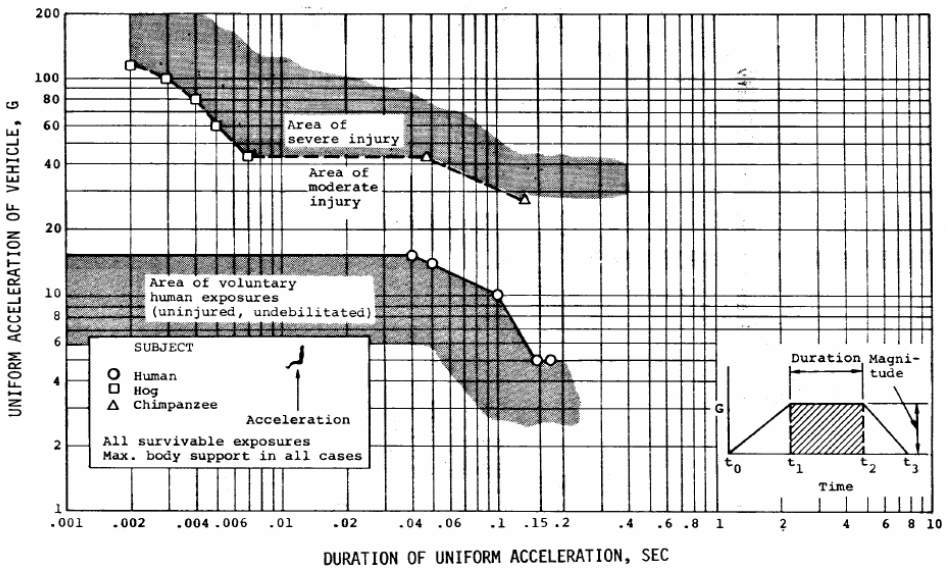


Figure 76 - Eiband Curve for accelerations in the +Gz axis

Figure 77 depicts the analogous curve for the –Gx direction, such as would be experienced in a head-on collision. Note that the tolerance in this axis is over 40 G.

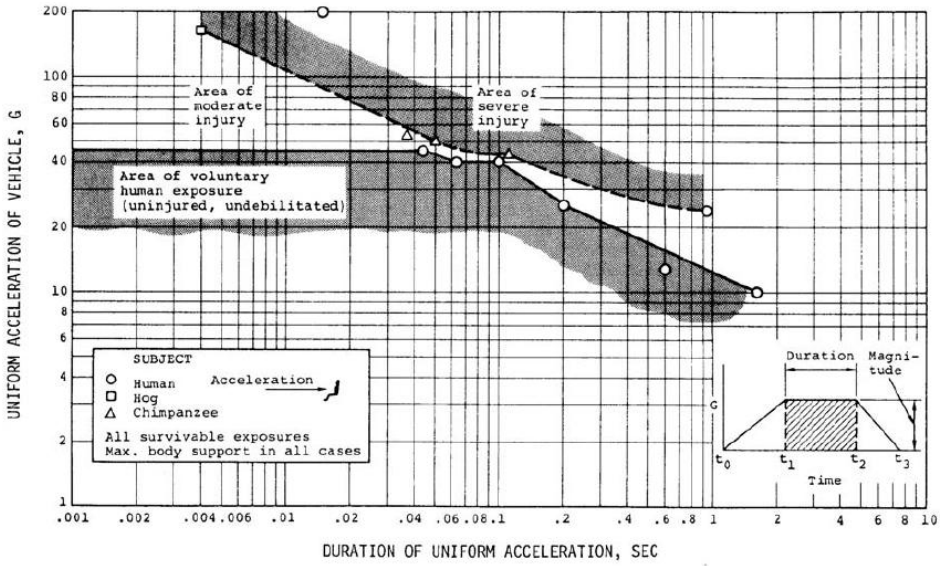


Figure 77 - Eiband Curve for accelerations in the -Gz axis

Similar curves are available for the other axes. A summary of estimates of human tolerance acceleration used as comparison in the next paragraphs is listed in (Table 46).

Table 46 - Examples of acceleration supported by the human body

Body	**Acceleration [m/s^2]**	**Acceleration ["g"]**	**Remark**
Human body	400 to 460	40 to 46	Acceleration max supported by the body, without injuries
Human body	1'800	180	Acceleration max supported by the body, with injuries

5.5.4 Acceleration during a shock

5.5.4..1 Ball Seat component

Determination of F_{Total}

The total force supported by the Ball seat is the sum of the static force and the dynamic force occurring for example during a shock.

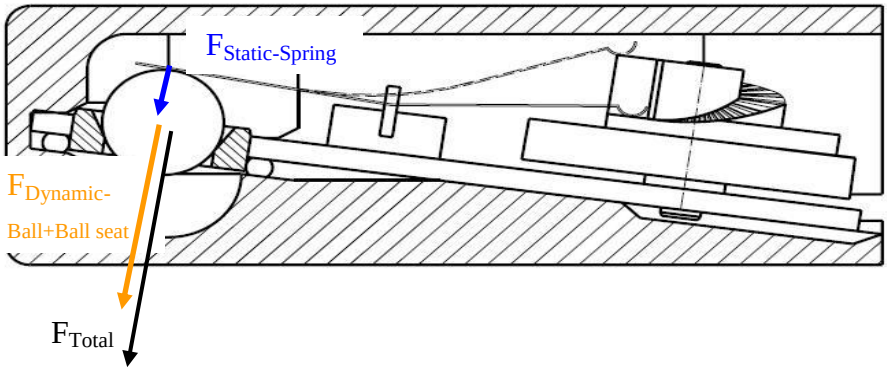


Figure 78 - Ball seat force vectors

F_{Static}

In static the force on the Ball is produced by the Spring reaction against the Ball. This force is transmitted against the Ball seat.
For Motor in position 200 (Figure 6) the force of the Ball against the Spring is:

F_{Static}= 0.3 gf (gram x force).

$F_{Dynamic}$ during a shock

Hypothesis

The 3 components, namely the Ball seat, the Ball and the Spring are assumed rigid together. It's admitted $F_{Dynamic}$ equal to the force on the 3 components during the shock and this force is applied on the gravity center of the Ball seat.
In reality the Spring is elastic but it's considered the less favourable condition for the calculations.

Calculation of the required acceleration during the shock for dislodging Ball seat resisting to 5N

$F_{Dynamic}$ = Mass of the 3 components x A

$$F_{Dynamic} = (MassBallSeat + MassBall + MassSpring) \times A$$

With A = Acceleration

Mass of the 3 components=1.3E-05 kg

$$F_{Total} = F_{Static} + F_{Dynamic} \Rightarrow 5N = 3E^{-3}N + (1.3E^{-5}\ kg \times A\ m/s^2$$

$$A = \frac{(5 - 3E^{-3})\ N}{(1.3E^{-5})\ kg} \Rightarrow 384'500\ m/s^2 = 38'450\ \text{“g”}$$

With $F_{Total} = F_{TotalMax}$ = 5N

And “g” = earth gravitation

Final parameter

The calculations made above for $F_{TotalMax}$ = 5N, give an acceleration in a range largely above what a Ball seat can realistically be exposed to (Table 46).

Then **$F_{TotalMax}$ = 5N** can be acceptable as limit before to remove the Ball seat.

5.5.4..2 Sping Pillar component

Determination of F_{Total}

The total force supported by the Spring pillar is the sum of the static force and the dynamic force occurring for example during a shock.

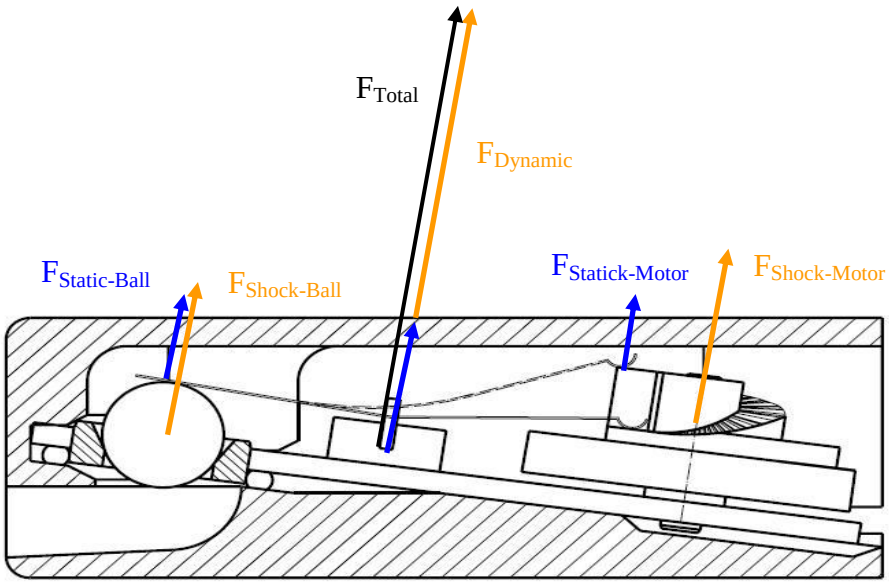


Figure 79 - Spring pillar and Sprign fulcrum force vectors

F_{Static}

In static mode, the force on the Spring pillar is produced by the Spring reaction against the Motor, the Ball, and transmitted by the Spring fulcrum to the Spring pillar.
For Motor in position 200 (Figure 6) the force of the Ball against the Spring is 0.3 gf (gram x force). As the distance Spring pillar-ball get closer to the distance Spring pillar-Point of contact with Motor, then the force produced by the Motor against the Spring is also 0.3 gf.
Then $\mathbf{F_{Static}}$ **=** 2 x 0.3 gf = 0.6 gf = $\mathbf{6E^{-3}}$ **N**

$F_{Dynamic}$ during a shock

Hypothesis 1:

The 5 components, namely the Spring pillar, the Spring Fulcrum, the Spring, the Motor, and the Ball are assumed rigid together. Moreover we admit $F_{Dynamic}$ equal to the force on the 5 components during the shock and this force is applied on the gravity center of the Spring pilar.
This model is far the reality and unfavorable for our evaluation (calculated acceleration below the reality).

Hypothesis 2:

The 3 components Spring pillar, Spring Fulcrum and Spring are rigid together. A part (10%) of the force produces on Motor and Ball during the shock is transmitted on the Spring fulcrum by the Spring that is consider here with a certain elasticity. This force is transmitted integrally from the Spring fulcrum to the Spring pillar.
The force resultant is applied on the gravity center of the Spring pillar.

Calculation of the required acceleration during a shock for dislodging Spring pillar resisting to 5N

For hypothesis 1:

$F_{Dynamic}$ = Mass of the 5 components x A
With A = Acceleration
Total Total Mass (kg) Hypo 1 = 4.9E-05

$$F_{Total} = F_{Static} + F_{Dynamic} \Rightarrow 5N = 6E^{-3}N + 4.9E^{-5}kg \times Am/s^2$$

$$A = \frac{(5 - 6E^{-3})N}{4.9E^{-5}kg} \Rightarrow 102'000 \text{ m/s}^2 = \mathbf{10'200\ "g"}$$

With $F_{Total} = F_{TotalMax} = 5N$
And "g" = earth gravitation

For hypothesis 2:

Total Total Mass (kg) Hypo 2 = 1.0E-05

$$F_{Dynamic} = \left(MassSpring + MassFulcrum + MassPillar\right) + 0.1 \times \left(MassMotor + MassBall\right) \times A$$

With A = Acceleration

$$F_{Total} = F_{Static} + F_{Dynamic} \Rightarrow 5N = 6E^{-3}N + \left(.0E^{-5} + 0.1 \times 3.8E^{-5}\ kg \times Am/s^2\right.$$

$$A = \frac{\left(6E^{-3}\ N\right)}{\left(1.0E^{-5} + 0.1 \times 3.8E^{-5}\ kg\right)} \Rightarrow 362'000\text{m/s}^2 = \mathbf{36'200\ "g"}$$

With $F_{Total} = F_{TotalMax} = 5N$
And "g" = earth gravitation

Final parameter

The calculations made above for $F_{TotalMax} = 5N$, give in the 2 hypotheses an acceleration in a range largely above what a Spring pillar can realistically be exposed to (Table 46).

Then $\mathbf{F_{TotalMax} = 5N}$ can be acceptable as limit before to remove the Spring pillar.

5.5.4..3 Sping Fulcrum component

Determination of F_{Total}

The total force supported by the Spring fulcrum is given by the sum of the static force and the dynamic force occurring for example during a shock (Figure 79).

F_{Static}

In static mode, the force on the Spring fulcrum is produced by the Spring reaction against the Motor and the Ball.
For Motor in position 200 the force of the Ball against the Spring is 0.3 gf (gram x force). As the distance Spring pillar-ball is close the distance Spring pillar-Point of contact with Motor, then the force produced by the Motor against the Spring is also 0.3 gf.
Then $F_{Static} = 2 \times 0.3\ gf = 0.6\ gf = 6E^{-3}\ N$

Definition of $F_{Dynamic}$ during a shock

Hypothesis 1:

The 4 components Spring Fulcrum, Spring, Motor, Ball are assumed rigid together. Moreover we admit $F_{Dynamic}$ equal to the force on the 4 components during the shock and this force is applied on the gravity center of Spring fulcrum.
This model is far the reality and unfavorable for our evaluation (calculated acceleration below the reality).
If we get in the calculation a very high acceleration, we can assume that in reality the case is not probable and we have a force level against the Spring fulcrum largely below 4N.

Hypothesis 2:

Spring Fulcrum and Spring are rigid together. A part (10%) of the force produces on Motor and Ball during the shock is transmitted on the Spring fulcrum by the Spring that is consider here with a certain elasticity.
The force resultant is applied on the gravity center of Spring fulcrum

Calculation of the required acceleration during a shock for dislodging Spring fulcrum resisting to 4N

For hypothesis 1:

Total Total Mass (kg) Hypo 2=4.2E-05
$F_{Dynamic}$ = Mass of the 4 components x A
With A = Acceleration

$$F_{Total} = F_{Static} + F_{Dynamic} \Rightarrow 4N = 6E^{-3}N + 4.2E^{-5}kg \times Am/s^2$$

$$A = \frac{(4 - 6E^{-3})N}{4.2E^{-5}kg} \Rightarrow 95'100 \text{ m/s}^2 = 9'500 \text{ “g”}$$

With $F_{Total} = F_{TotalMax}$ = 4N applicable after calibration
And “g” = earth gravitation

With $F_{Total} = F_{TotalMax}$ = 5N applicable before calibration
the Acceleration A = 11’875 “g”.

For hypothesis 2:

Total Total Mass (kg) Hypo 2=2.9E-06

$$F_{Dynamic} = \left[MassSpring + MassFulcrum \right] + 0.1 \times \left(MassMotor + MassBall \right) \times A$$

With A = Acceleration

$$F_{Total} = F_{Static} + F_{Dynamic} \Rightarrow 4N = 6E^{-3}N + \left(2.9E^{-6} + 0.1 \times 3.8E^{-5} \right) kg \times Am/s^2$$

$$A = \frac{\left(4 - 6E^{-3} \right) N}{\left(2.9E^{-6} + 0.1 \times 3.8E^{-5} \right) kg} \Rightarrow 596'000 \text{ m/s}^2 = 59'600 \text{ “g”}$$

With $F_{Total} = F_{TotalMax}$ = 4N applicable after calibration
And “g” = earth gravitation

With $F_{Total} = F_{TotalMax}$ = 5N applicable before calibration
the Acceleration A = 74’500 “g”.

Final parameter

The calculations made above for $F_{TotalMax}$ = 4N and 5N, give in the 2 hypotheses an acceleration in a range largely above what a Spring fulcrum can realistically be exposed to.

Then **$F_{TotalMax}$ = 4N** can be acceptable as limit before to remove the Spring fulcrum after calibration. Before calibration **$F_{TotalMax}$ = 5N** can be acceptable (Table 46).

5.5.4..4 Pivot component

Determination of F_{Total}

The total force supported by the Pivot is the sum of the static force and the dynamic force occurring for example during a shock.

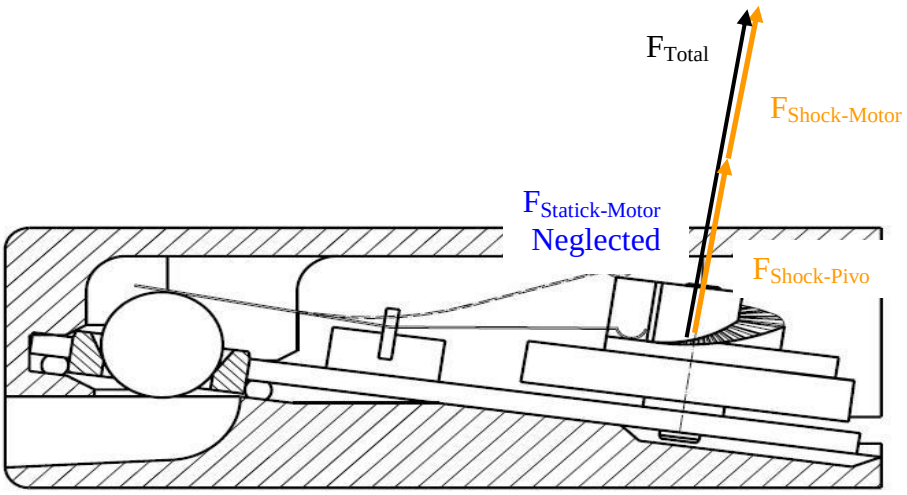


Figure 80 - Pivot force vectors

F_{Static}

In static the force on the Pivot is produced by the Spring reaction against the Motor. This force is in opposition to $F_{Dynamic}$ and will be neglected in the following analysis.
Then F_{Static} = 0 N

Definition of $F_{Dynamic}$ during a shock

Hypothesis

The Pivot, Motor components are assumed rigid together. We admit $F_{Dynamic}$ equal to the force on the 2 components during the shock and this force is applied on the gravity center of Pivot.

$F_{Dynamic}$ = Mass of the 2 components x A
With A = Acceleration
Mass of the 2 components=3.5E-05

Calculation of the required acceleration during a shock for dislodging Pivot resisting to 10N

$$F_{Dynamic} = (MassPivot + MassMotor) \times A$$

$$F_{Total} = F_{Static} + F_{Dynamic} \Rightarrow 10N = 0N + (.5E^{-5}\ kg) \times Am/s^2$$

$$A = \frac{10N}{(.5E^{-5}\ kg)} \Rightarrow 286'000\ m/s^2 = 28'600\ \text{“g”}$$

With $F_{Total} = F_{TotalMax} = 10N$
And “g” = earth gravitation

Final Parameter

The calculations made above for $F_{TotalMax} = 10N$, give an acceleration in a range largely above what a Pivot can realistically be exposed to.

Then **$F_{TotalMax}$ = 10N** can be acceptable as limit before to remove the Pivot.

5.5.5 Determination of the discriminating system parameters for the holding test.

In the previouses paragraphs it has been established which force has to be applied in order to test if the component will hold in its press fitted position during the useful life valve. Now it is necessary to assure that the system will be able to determine after each test if the valve can be accepted or not. This evaluation is made considering the position of the component before and after applying the force that has to be hold.
The step followed for this evaluation are the following:

- Lower control tooling comes in contact with the component with high speed and a force of 2N.
  Position P0 is recorded.
- Lower control tooling gets down of 0.010 mm from P0 and comes in contact with the component with lower speed a force of 2N.
  Position P1 is recorded.

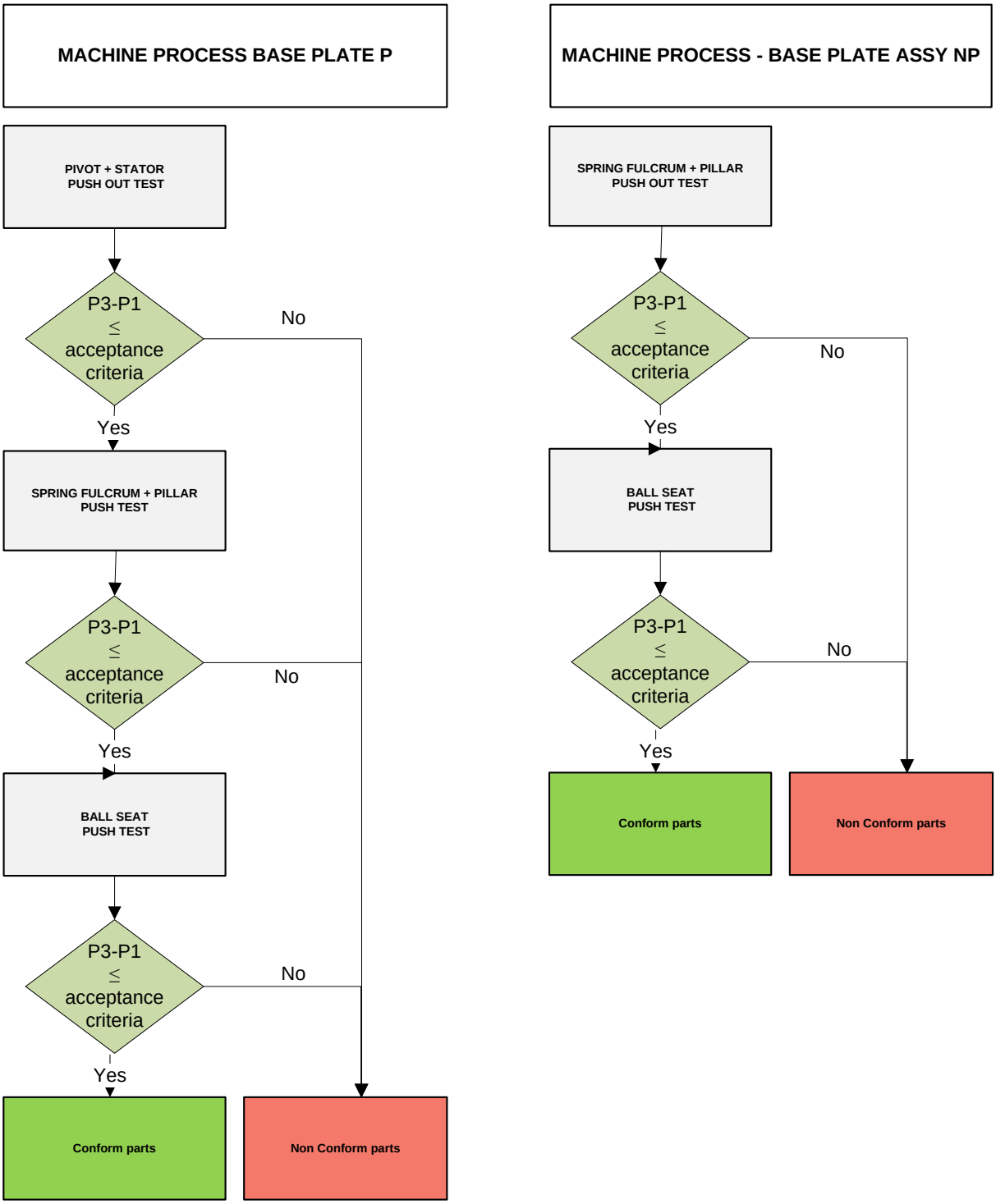


Figure 81 - Flow char of the holding test in for the P and NP valve types

- Lower control tooling gets down of 0.010 mm to position $P_{Before\ Contact}$ and get up to be in contact with a force of 5N.
  Position P2 is recorded.
- Lower control tooling gets down of 0.010 mm to position $P_{Before\ Contact}$ and comes in contact with the component with a force of 2N.
  Position P3 is recorded.
- If P3-P1≤ Max (P3-P1) it can be concluded that the Ball seat has not moved during the control and the assembling is accepted by the machine.
- If P3-P1> Max (P3-P1) the assembling is rejected.

These steps are repeated for 30 valves per each shuttle. The aim is to calculate the Max(P3-P1) (Table 47) and introduce it in the system as a discrimination parameter which will be used to determine if the valve can be accepted or not.
Max (P3-P1) has to be defined for each of the 3 components for which the holding test is performed (ball seat,spring fulcrum,pivot) (Figure 81).

5.5.5..1 Ball seat push out parameter

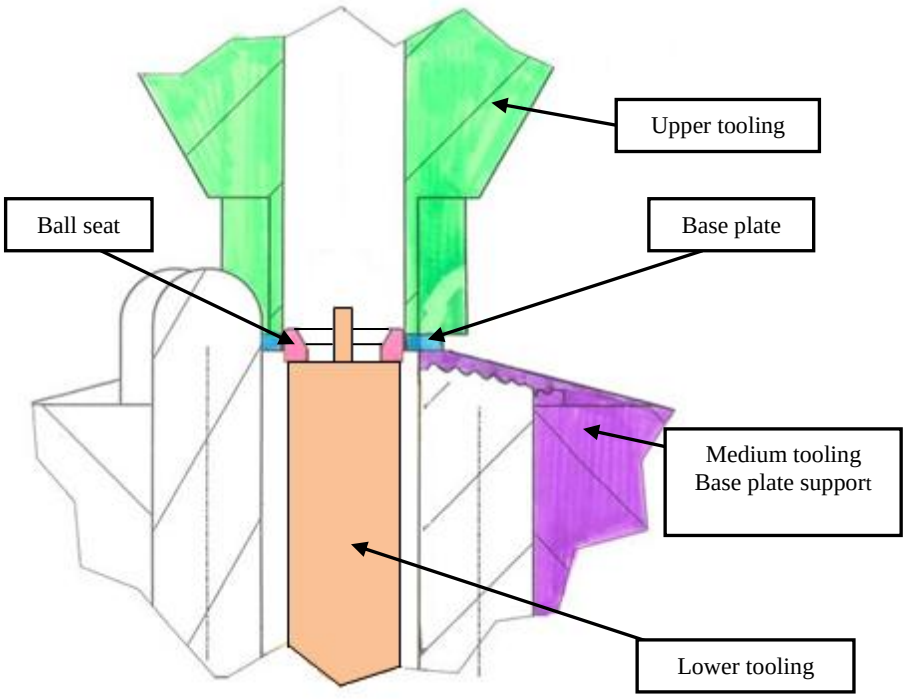


Figure 82 - Ball seat holding test tools

The ball seat holding test is the only one that uses the base (H2) of the shuttle control tool (Figure 49) instead of the extremity.
The Table 47 shows an exemple of the results for all the 30 Ball Seat tests performed with shuttle 2:

Table 47- example of pushing out (holding) test

Base plate reference	Shuttle	P0	P1	P2	P3	P3-P1
1	n2	17.981	17.978	17.981	17.978	0.000
2	n2	17.988	17.987	17.99	17.987	0.000
3	n2	17.973	17.971	17.975	17.972	0.001
4	n2	17.99	17.99	17.993	17.99	0.000
5	n2	17.96	17.958	17.962	17.958	0.000
6	n2	17.976	17.975	17.98	17.975	0.000
7	n2	17.969	17.966	17.969	17.966	0.000
8	n2	17.968	17.967	17.972	17.969	0.002
9	n2	17.968	17.966	17.969	17.966	0.000
10	n2	17.978	17.977	17.98	17.977	0.000
11	n2	17.966	17.963	17.966	17.963	0.000
12	n2	17.982	17.979	17.982	17.98	0.001
13	n2	17.966	17.964	17.968	17.965	0.001
14	n2	17.979	17.977	17.981	17.978	0.001
15	n2	17.973	17.971	17.973	17.973	0.002
16	n2	17.988	17.986	17.989	17.986	0.000
17	n2	17.98	17.977	17.981	17.977	0.000
18	n2	17.993	17.992	17.996	17.992	0.000
19	n2	17.986	17.985	17.988	17.985	0.000
20	n2	17.99	17.99	17.993	17.99	0.000
21	n2	17.966	17.964	17.967	17.964	0.000
22	n2	17.973	17.971	17.973	17.971	0.000
23	n2	17.965	17.963	17.966	17.962	-0.001
24	n2	17.966	17.964	17.97	17.965	0.001
25	n2	17.98	17.977	17.98	17.978	0.001
26	n2	17.96	17.957	17.961	17.957	0.000
27	n2	17.974	17.971	17.974	17.971	0.000
28	n2	17.959	17.957	17.96	17.957	0.000
29	n2	17.978	17.976	17.979	17.976	0.000
30	n2	17.955	17.952	17.956	17.953	0.001
Average						**0.0003**
SD						**0.0007**
Aver+4xSD						**0.0030**
Min						**-0.001**
Max						**0.002**

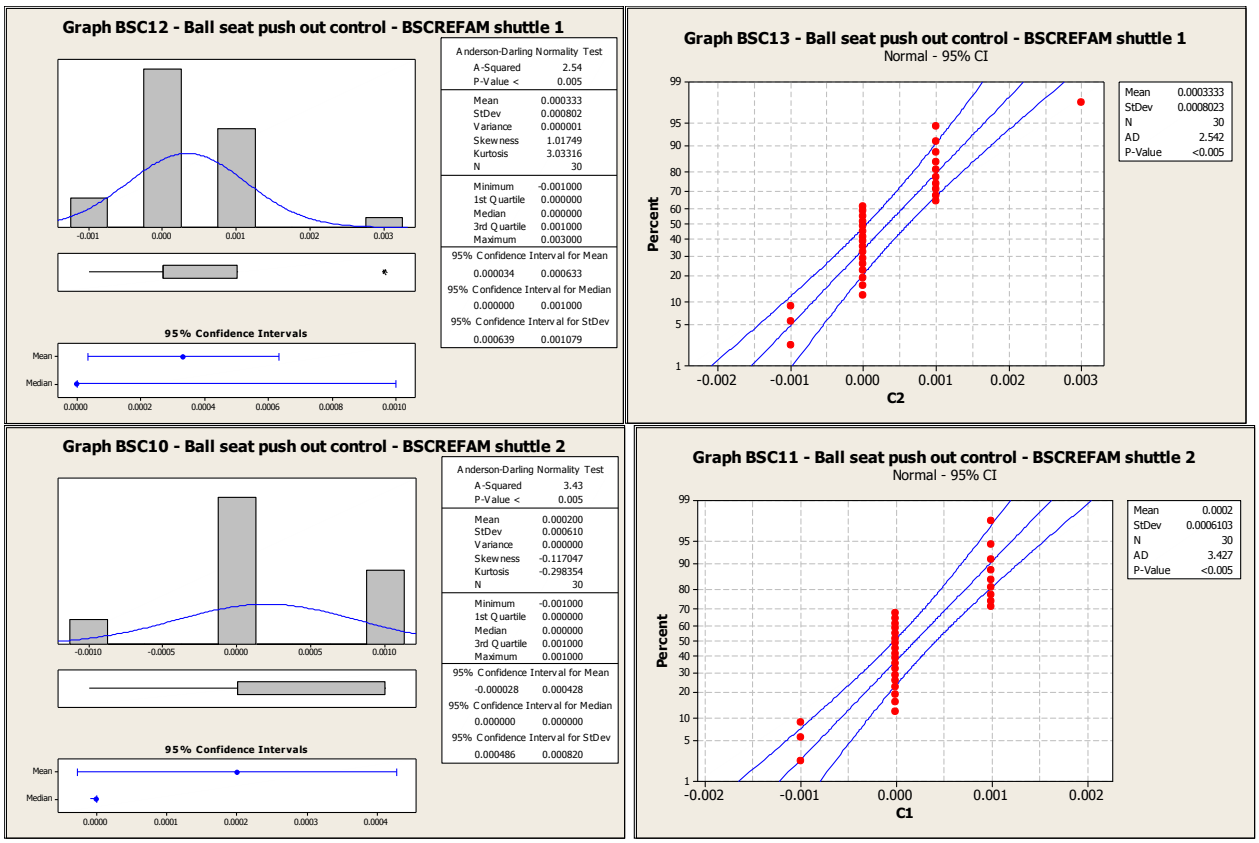


Figure 83- distribution of the Ball Seat holding test results

Results:

Table 48 - Final results of the Ball Seat holding test

	Shuttle 1	Shuttle 2
Unit	mm	mm
Average (P3-P1)	0.0003	0.0002
Stand Dev	0.0008	0.0006
Average (P3-P1)-4x Stand Dev	0.0035	0.0026

The 2 distributions are not declared normal by Minitab. That is due to the low resolution of the measurement system. In the 2 cases the excursion is -0.001 to +0.001 mm (excepted the one special case with shuttle 1). Nevertheless the data spread looks like a normal distribution. See graphs (Figure 82). For the 2 shuttles the results are very close.
Calculating the Average (P3-P1)-4xStand Dev, the limit is equal to 0.0035 and 0.0026 mm. Adding a margin of 0.0015 mm it can be admitted a maximum for P3-P1 equal to 0.005 mm.

5.5.5..2 Spring pillar and spring fulcrum push out parameter

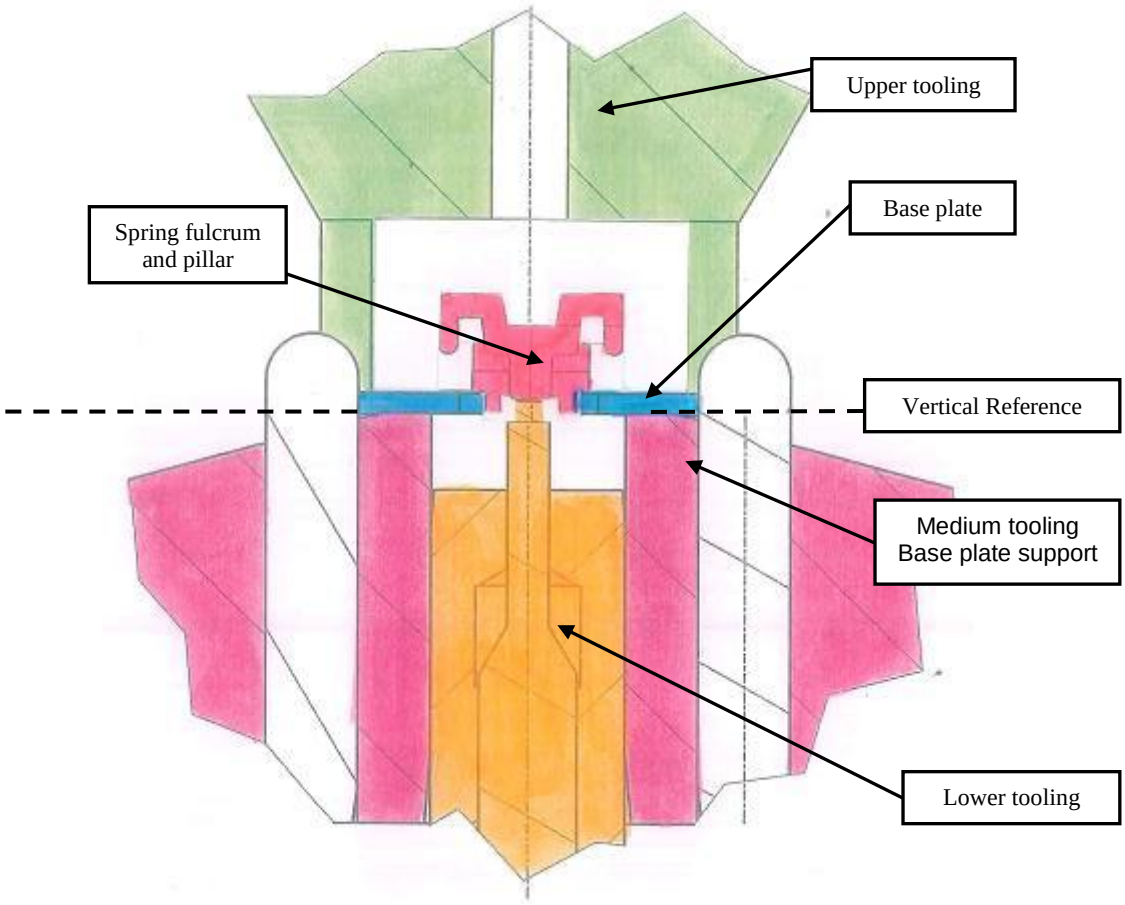


Figure 84 - Spring pillar and spring fulcrum holding test tools

The adjustment between Base plate and Spring pillar, or between Spring fulcrum and Spring pillar is chosen hard in order to have no displacement of the Spring fulcrum or the Spring pillar when the force of 5N is applied.
To confirm the absence of any displacement, a visual check, after the push out test, is performed to show that there is no gap between the Spring pillar and the Base plate. In complement the high of the Spring fulcrum is measured vs the Base plate.

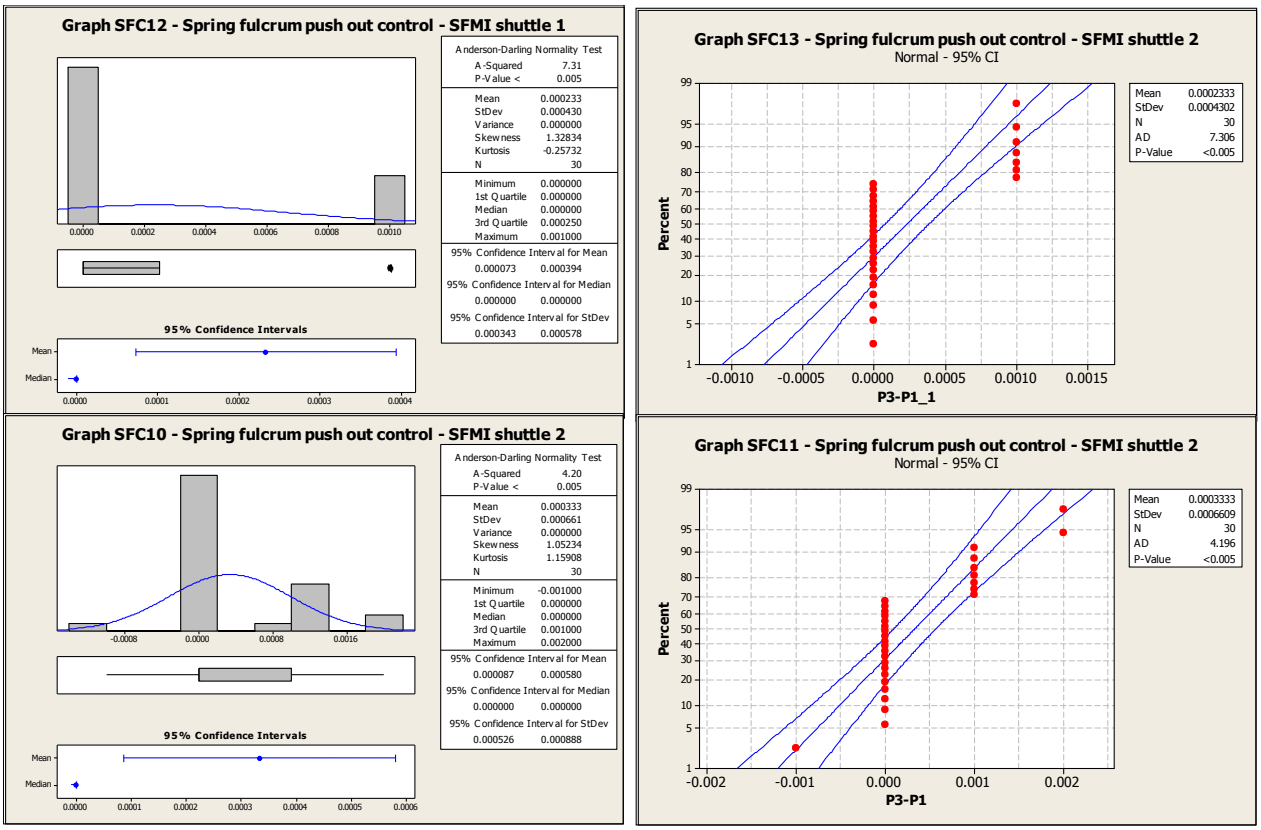


Figure 85 - distribution of the Spring Fulcrum holding test results

Results:

Table 49 - Final results of the Spring Fulcrum holding test

	Shuttle 1	**Shuttle 2**
Unit	mm	mm
Average (P3-P1)	0.0002	0.0003
Stand Dev	0.0004	0.0007
Average (P3-P1)-4x Stand Dev	0.0020	0.0030

The 2 distributions are not declared normal by Minitab. That is due to the low resolution of the measurement system. In the 2 cases the excursion is -0.001 to +0.002 and 0.0 to +0.001 mm. Nevertheless the data spread looks like a normal distribution. See graphs (Figure 83). The values are generally bigger for Shuttle 2.
Calculating the Average (P3-P1)-4xStand Dev, the limit is equal to 0.002 and 0.003 mm. Adding a margin of 0.0020 mm we can admit a Max for (P3-P1) equal to 0.005 mm.

5.5.5..3 Pivot push out parameter

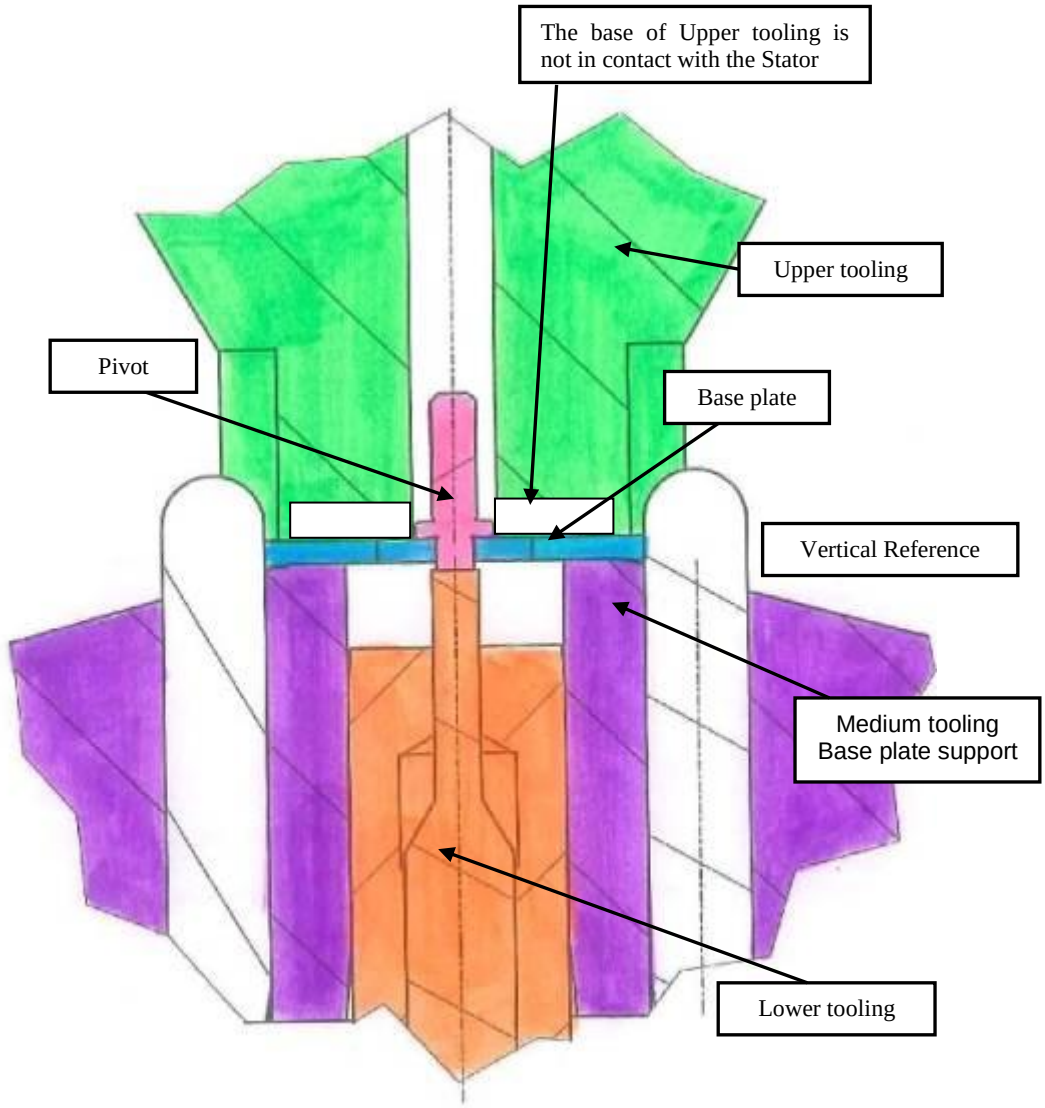


Figure 86 - Pivot holding test tools

The adjustment between Base plate and Pivot is chosen hard in order to have, after riveting, no displacement of the Pivot when the force of 10N is applied.
To confirm the absence of any displacement, a visual check, after the push out (holding) test, has shown that there was no gap between the Pivot flange and the Base plate (Figure 21).

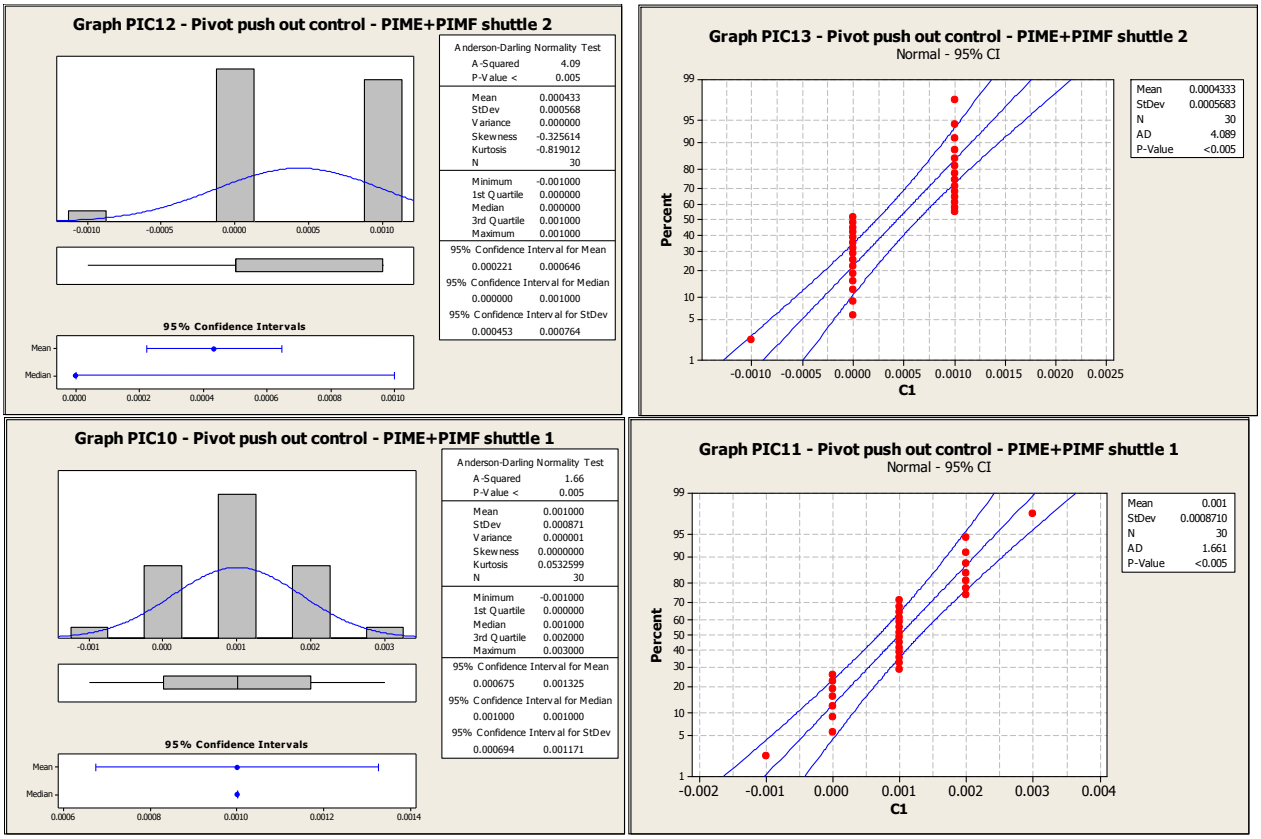


Figure 87 - distribution of the Pivot holding test results

Results:

Table 50 - Final results of the Pivot holding test

	Shuttle 1	**Shuttle 2**
Unit	mm	mm
Average (P3-P1)	0.0010	0.0004
Stand Dev	0.0009	0.0006
Average (P3-P1)-4x Stand Dev	0.0045	0.0027

The detailed results are in the 2 following pages.
The 2 distributions are not declared normal by Minitab. That is due to the low resolution. In the 2 cases the excursion is -0.001 to +0.003 and -0.001 to +0.001 mm. Nevertheless the data spread looks like a normal distribution. See Graphs PIC10 to 13.
The values are bigger for Shuttle 1.
Calculating the Average (P3-P1)-4xStand Dev, the limit is equal to 0.0045 and 0.0027 mm. Adding a margin of 0.0015 mm we can admit a
Max for (P3-P1) equal to 0.006 mm.

5.5.6 Zero Acceptance Number Sampling Plan C=0.

The semi-automatic system allows to introduce and to perform the assembling operations by lot of components. Although the first lots of sub-assembled valves will be inspected 100 percent by the holding test showed before, it has been requested to have the possibility to use the Zero Acceptance Number Sampling Plan C=0. This kind of sampling plan has been chosen as part of the standards Johnson&Johnson.

The Acceptance Sampling is a sampling inspection in which decisions are made to accept or not to accept (rejection) a sub-assembled lot of valves based on the results of a sample or samples selected from the lot. Sampling inspection is, in turn, defined as: the inspection of products using samples (as distinct from 100 percent inspection)

One of the important developments in the field of quality control is the use of sampling procedures wherein the amount of inspection or sample size depends upon the extent to which quality of product is satisfactorily controlled. Under these procedures, inspection results, obtained on samples from successive lots of product, are summarized to obtain a measure of the general level of quality and it is uniform from lot-to-lot. Whenever such summaries indicate a satisfactory state of control, reductions in the amount of inspection can be safely made.

In addition to having economic advantages, these plans are simple to use and administer. Originally developed for military products, these plans have found wide use in many industries where lot-by-lot attribute sampling exists, regardless of product, and especially where emphasis is being placed on zero-defects output.

There is no specific sampling plan or procedure that can be considered best suited for all applications. It is impractical to cite all the applications where these C=0 plans are used. Some of these are machined, formed, cast, powered metal, plastic and stamped parts. They have found application in receiving inspection, in-process inspection, and final inspection in many industries. Wherever lot-by lot sampling potential exists, regardless of product, the C=0 plans may be applicable.

In Johnson&Johnson it has been continually striving the 100 percent of good products. Assuming that in the automatic system the inspection capability is 100 percent efficient in detecting non-conformances, the only way to assure 100 percent good product is to 100 percent inspect everything. This is then the objective of sampling: the automatic system samples because in the same lot the components are similar ant it can be saved time. What it has been seeking, therefore, is sampling plan that economically provides with a reasonable amount of protection to ensure the 100 percent good quality.

A representative sample is necessary to assure reliable results. The way agreed with the system software programmer to obtain a representative sample is by

random sampling. Randomness was achieved when each sub-assembled valve in the lot has an equal chance of being selected for the sample.
In the critical parameters software screen it has been placed a table of numbers (Figure 88) corresponding to the C=0 table (Figure 89) for each holding test.

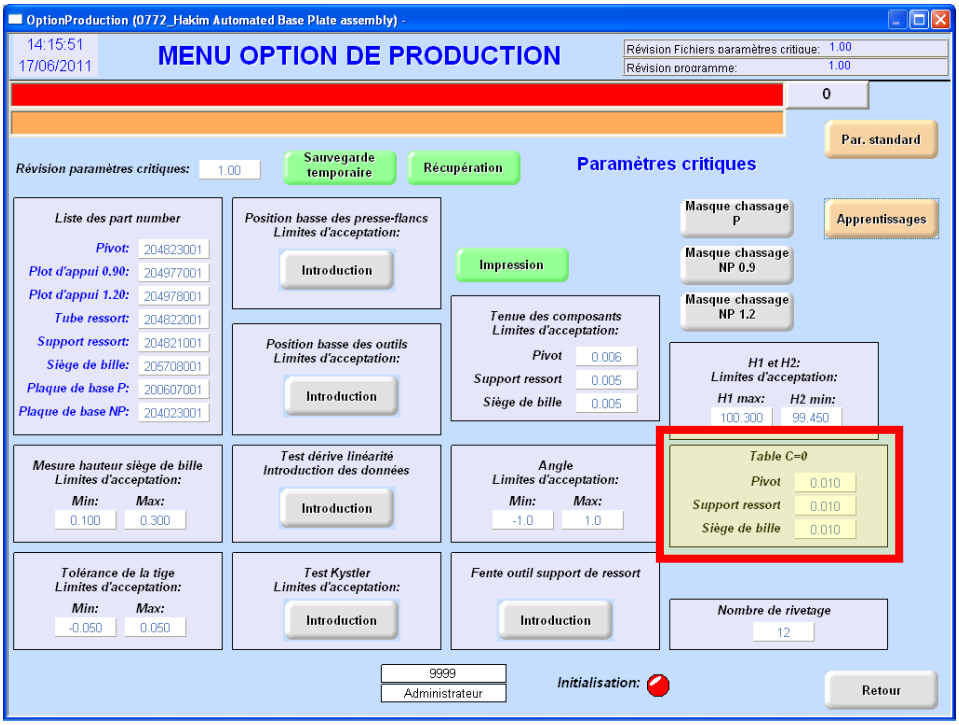


Figure 88 - Table C=0 critical parameters screen

C=0 SAMPLING PLANS
INDEX VALUES
(ASSOCIATED AQLS)

	.010	.015	.025	.040	.065	.10	.15	.25	.40	.65	1.0	1.5	2.5	4.0	6.5	10.0
LOT SIZE	SAMPLE SIZE															
2 to 8	*	*	*	*	*	*	*	*	*	*	*	*	5	3	2	2
9 to 15	*	*	*	*	*	*	*	*	*	*	13	8	5	3	2	2
16 to 25	*	*	*	*	*	*	*	*	*	20	13	8	5	3	3	2
26 to 50	*	*	*	*	*	*	*	*	32	20	13	8	5	5	5	3
51 to 90	*	*	*	*	*	*	80	50	32	20	13	8	7	6	5	4
91 to 150	*	*	*	*	*	125	80	50	32	20	13	12	11	7	6	5
151 to 280	*	*	*	*	200	125	80	50	32	20	20	19	13	10	7	6
281 to 500	*	*	*	315	200	125	80	50	48	47	29	21	16	11	9	7
501 to 1200	*	800	500	315	200	125	80	75	73	47	34	27	19	15	11	8
1201 to 3200	1250	800	500	315	200	125	120	116	73	53	42	35	23	18	13	9
3201 to 10,000	1250	800	500	315	200	192	189	116	86	68	50	38	29	22	15	9
10,001 to 35,000	1250	800	500	315	300	294	189	135	108	77	60	46	35	29	15	9
35,001 to 150,000	1250	800	500	490	476	294	218	170	123	96	74	56	40	29	15	9
150,001 to 500,000	1250	800	750	715	476	345	270	200	156	119	90	64	40	29	15	9
500,001 and over	1250	1200	1112	715	556	435	303	244	189	143	102	64	40	29	15	9

*Indicates entire lot must be inspected
NOTE: The Acceptance Number in all cases is ZERO.

Figure 89 - reference table C=0 and number to introduce in the system for having a certain quantity of samples

5.6 Ball Seat height measurement

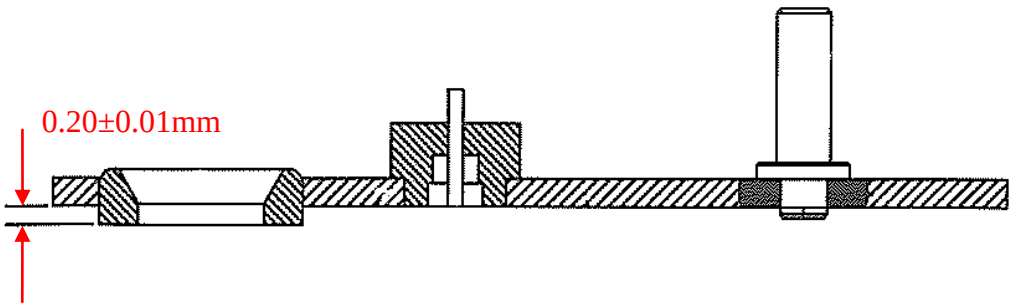


Figure 90 - Ball Seat height: range of tolerance

After the push out (holding) test of the Ball Seat component, the system has to check whether its position is within a certain tolerance or not. This check is made in 3 steps.

1. At first the position of the base plate without ball seat is measured (Figure 91). This operation requires putting out of the center the control shuttle tool because its diameter is smaller than the ball seat housing diameter. This operation can only be performed when the Promess Press axe is in its homing position and thanks to the high degree accurancy of the optical incremental stroke measuring system of the shuttle axe actuator, it is actually possible to displace the control shuttle tool of about 0.020mm
2. In second, the position of the ball seat previously press fitted on the Base plate is measured (Figure 82).
3. The difference between the 2 positions is the ball seat height

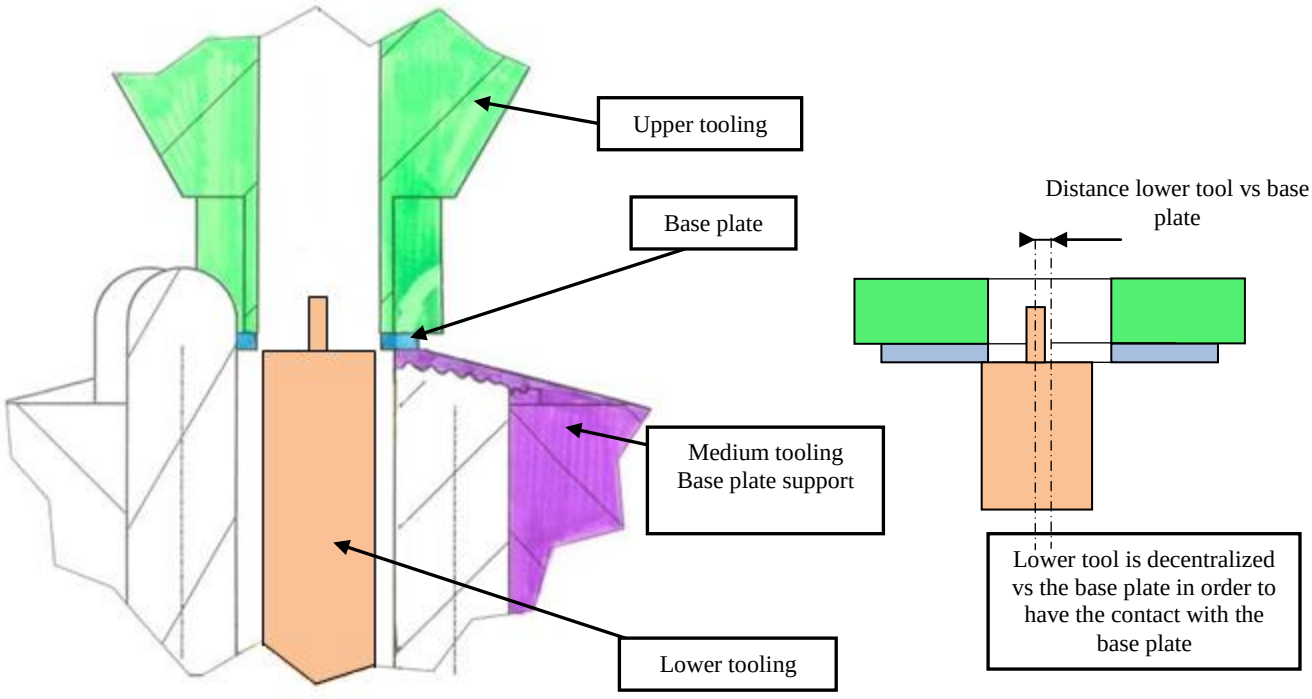


Figure 91 - Base plate position measurement: the control shuttle tool is decentralized to allow the contact with the Base Plate

5.7 Measurement repeatabiliy and reproducibility

For testing the two main characteristics of the measurement system: its repeatability and its reproducibility, a software section together with some tools have been developed

What is repeatability? When doing a measurement system analysis, it is needed to find out how accurately a measurer can repeat their measurement. The measure is usually a person, but in this case it is the machine itself doing the measurements. Basically it is needed to demonstrate that if it is measured, for examples, the height of the Ball Seat in two different days, the result is the same.

What is reproducibility? Reproducibility looks at how well a measurer can reproduce a measurement already performed by another measurer. Again, the measurer here is the system itself. Basically it is needed to demonstrate if, for examples, the height of the Ball Seat with two different shuttles, the result is the same.

The software allows performing similar steps of the push out test. It is possible to change parameters and register positions for the three tested components, as shown in Figure 92.

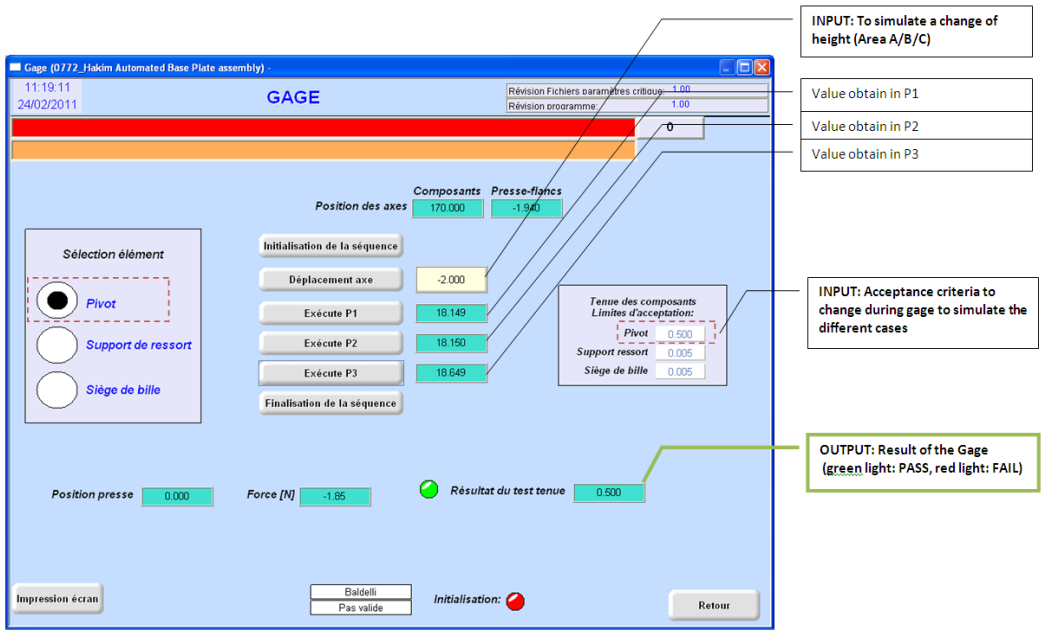


Figure 92 - gage screen

The push out test is simulated with a blank holder with two different heights:

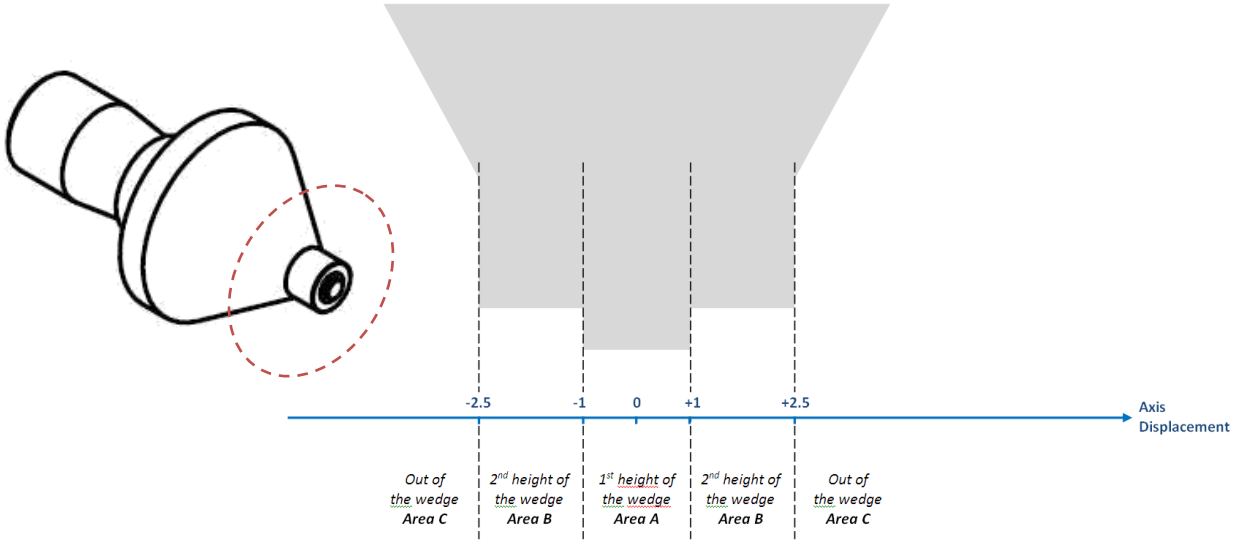


Figure 93 - Gage blank holder

In order to simulate the different cases detected by the system (Table 51), the following parameters are alternatively changed to verify that the machine is able to segregate good and bad sub-assemblies (only applicable for the gage, not applicable at production level):

- Acceptance criteria in the software: the operator can change the value of acceptance criteria.
- Axis displacement: the operator can position the Promess axis in the Area A, B or C.

Table 51 - Gage cases

Case#	Real Case	Simulated case	Position of the Promess axis in Step 1 =P1	Position of the Promess axis in Step 2=P2	Position of the Promess axis in Step 3=P3	P3-P1 (mm)	Value of the specification in the software	Expected result
Case 1	**assembly conform:** the component didn't move during push test	**P3-P1(=0) < acceptance criteria**	A	A	A	≈0	>0 mm	PASS
		P3-P1(=0) < acceptance criteria	B	B	B	≈0		
Case 2	**assembly conform:** the component softly move during push test	**P3-P1 < acceptance criteria**	A	A or B	B	≈0.5	>0.5mm	PASS
Case 3	**assembly conform:** the component move at extreme limit acceptable during push test	**P3-P1 = acceptance criteria**	A	A or B	B	≈0.5**	≈0.5**	PASS

6

SYSTEM PROCESS VALIDATION

6.1 What is the process validation?

In Johnson&Johnson the products manufacturing follows the regulations of the Food and Drug Administration (FDA). The FDA is an agency of the United States Department of Health and Human Services and requires that manufacturing processes have to be designed and controlled to assure that in-process materials and the finished products meet predetermined quality requirements and do so consistently and reliably.

(FDA, 2011)The FDA defines the Process Validation as the collection and the evaluation of data, from the process design stage through production, which establishes scientific evidence that a process is capable of consistently delivering quality product. Process validation involves a series of activities taking place over the lifecycle of the product and process and its activities are described in three stages.

Stage 1 – Process Design: The manufacturing process is defined during this stage based on knowledge gained through development and scale-up activities.

Stage 2 – Process Qualification: During this stage, the process design is evaluated to determine if the process is capable of reproducible manufacturing.

Stage 3 – Continued Process Verification: Ongoing assurance is gained during routine production that the process remains in a state of control.

These are the typical activities of each stage, but in practice, some activities might occur in multiple stages.

Before any batch from the process is commercially distributed for use by consumers, a manufacturer should have gained a high degree of assurance in the performance of the manufacturing process such that it will consistently produce medical products meeting those attributes relating to identity, strength, quality, purity, and potency. The assurance should be obtained from objective information and data from laboratory-, pilot, and/or commercial scale studies. Information and data should demonstrate that the commercial manufacturing process is capable of consistently producing acceptable quality products within commercial manufacturing conditions.

A successful validation program depends upon information and knowledge from product and process development. This knowledge and understanding is the basis for establishing an approach for the control of the manufacturing process that results in products with the desired quality attributes. Manufacturers should:

Understand the sources of variation

Detect the presence and degree of variation

Understand the impact of variation on the process and ultimately on product attributes

Control the variation in a manner commensurate with the risk it represents to the process and product

Each manufacturer should judge whether it has gained sufficient understanding to provide a high degree of assurance in its manufacturing process to justify commercial distribution of the product. Focusing exclusively on qualification efforts without also understanding the manufacturing process and associated variations may not lead to adequate assurance of quality. After establishing and confirming the process, manufacturers must maintain the process in a state of control over the life of the process, even as materials, equipment, production environment, personnel, and manufacturing procedures change.

Manufacturers should use ongoing programs to collect and analyze product and process data to evaluate the state of control of the process. These programs may identify process or product problems or opportunities for process improvements that can be evaluated and implemented through some of the activities described in Stages 1 and 2.

Manufacturers of legacy products can take advantage of the knowledge gained from the original process development and qualification work as well as manufacturing experience to continually improve their processes.

6.2 Process Validation steps performed during the set up of the system

(FDA, 2011)In all stages of the system lifecycle, it has been followed the standard procedure good project management and good archiving that capture scientific knowledge and made the process validation program more effective and efficient. An experienced practice has ensured uniform collection and assessment of information about the process and enhanced the accessibility of such information later in the product lifecycle

It has been used an integrated team approach to process validation that includes expertise from a variety of disciplines (e.g., process engineering, industrial pharmacy, statistics, manufacturing, quality, assurance, and etc).

Various studies have been initiated to discover, observe, correlate, or confirm information about the product and process. All studies have been planned and conducted according to sound scientific principles, appropriately documented, and approved in accordance with the established procedure appropriate for the stage of the project lifecycle.

6.2.1 Process Design

(FDA, 2011)The process design is the activity of defining manufacturing process that will be reflected in planned master production and control records. The goal of this stage is to design a process suitable for routine manufacturing that can consistently deliver a product that meets its quality attributes.

Process knowledge and understanding has been the basis for establishing an approach to process control for each of the system operation and for the system process overall. Strategies for process control have been designed to reduce input variation, adjust for input variation during manufacturing (and so reduce its impact on the output).

As it is clear from the “work performed” chapter, the maniacal attention to the control of each operation, from the initialization procedure to the holding test, is the result of the validation philosophy.

The focus on the process controls address variability to ensure quality of the product. Many tests have been performed in order to decide the equipment monitoring at significant processing points. Decisions also have been taken regarding the type and extent of process controls aided by the earlier risk assessments, then enhanced and improved as process experience gained.

6.2.2 Process Qualification

During the Process Qualification (PQ) stage of process validation, the process design is evaluated to determine if it is capable of reproducible manufacture. This stage has two elements: (1) design of the facility and qualification of the equipment and utilities and (2) process performance qualification (PPQ). Successful completion of Stage 2 is necessary before commercial distribution. It is essential that activities performed to assure proper facility design and commissioning precede PPQ. Here, the term qualification refers to activities undertaken to demonstrate that utilities and equipment are suitable for their intended use and perform properly. These activities necessarily precede manufacturing products at the commercial scale. (FDA, 2011)
Qualification of utilities and equipment included the following activities:

- Selecting utilities and equipment construction materials, operating principles and performance characteristics based on whether they are appropriate for their specific uses.

- Verifying that utility systems and equipment are built and installed in compliance with the design specifications (e.g., built as designed with proper materials, capacity, and functions, and properly connected and calibrated).

- Verifying that utility systems and equipment operate in accordance with the process requirements in all anticipated operating ranges. This should include challenging the equipment or system functions while under load comparable to that expected during routine production. It has also included the performance of interventions, stoppage, and start-up as is expected during routine production. Operating ranges are capable of being held as long as would be necessary during routine production.

Since the semi-automatic system performs also as a measurement system during the push out test and for the Ball Seat height measurement, a dedicate software and hardware development has been realized with the goal of demonstrating that the system is able to detect if the assembled valves are conform or not with the requirements.

6.2.2..1 Process Performance Qualification (PPQ)

As explained by FDA (2011) the PPQ is a written protocol that specifies the manufacturing conditions, controls, testing, and expected outcomes. It is essential for this stage of process validation since it discusses the following elements:

- The manufacturing conditions, including operating parameters, processing limits, and component (raw material) inputs.
- The data to be collected and when and how it will be evaluated.
- Tests to be performed (in-process, release, characterization) and acceptance criteria for each significant processing step.
- The sampling plan, including sampling points, number of samples, and the frequency of sampling for each unit operation and attribute. The number of samples should be adequate to provide sufficient statistical confidence of quality both within a batch and between batches. The confidence level selected can be based on risk analysis as it relates to the particular attribute under examination. Sampling during this stage should be more extensive than is typical during routine production.
- Criteria and process performance indicators that allow for a science- and risk-based decision about the ability of the process to consistently produce quality products. The criteria should include:
  - A description of the statistical methods to be used in analyzing all collected data (e.g., statistical metrics defining both intra-batch and inter-batch variability).
  - Provision for addressing deviations from expected conditions and handling of nonconforming data. Data should not be excluded from further consideration in terms of PPQ without a documented, science-based justification.[17]
- Design of facilities and the qualification of utilities and equipment, personnel training and qualification, and verification of material sources (components and container/closures), if not previously accomplished.
- Status of the validation of analytical methods used in measuring the process, in-process materials, and the product.
- Review and approval of the protocol by appropriate departments and the quality unit.

The PPQ combines the actual facility, utilities, equipment, and the trained personnel with the commercial manufacturing process, control procedures, and components to produce commercial batches. A successful PPQ has confirmed the process design and demonstrated that the commercial manufacturing process performs as expected. The PPQ had a higher level of sampling, additional testing, and greater scrutiny of process performance than the typical of routine production. The level of monitoring and testing had to be sufficient to confirm uniform product quality throughout the batch. The increased level of scrutiny, testing, and sampling has continually improved through the process verification stage as appropriate, to establish levels and frequency of routine sampling and monitoring for the Hakim Valve and its process.

6.2.3 Software validation

The decision to implement system functionality by using software has been made during the system design. Most of the software requirements have derived from the overall system regarding those aspects in the system that have to be implemented using a software. There are user needs and intended uses for a finished device, but users did not specify whether those requirements are to be met by hardware, software, or some combination of both. Therefore, software validation has been considered within the context of the overall design validation for the system. (FDA, 2002)
Documented requirements specification has been written and represents the user's needs and intended uses from which the product is developed. A primary goal of software validation is to then demonstrate that all completed software products comply with all documented software and system requirements. The correctness and completeness of both the system requirements and the software requirements have been addressed as part of the design validation process for the device. Software validation includes confirmation of conformance to all software specifications and confirmation that all software requirements are traceable to the system specifications. Confirmation is an important part of the overall design validation to ensure that all aspects of the medical device conform to user needs and intended uses.
While software shares many of the same engineering tasks as hardware, it has some very important differences. For example:

- The vast majority of software problems have been traceable to errors made during the design and development process. While the quality of a hardware product is highly dependent on design, development and manufacture, the quality of a software product is dependent primarily on design and development with a minimum concern for software manufacture. Software manufacturing consists of reproduction that can be easily verified. It is not difficult to manufacture thousands of program

copies that function exactly the same as the original; the difficulty has come in getting the original program to meet all specifications.

- One of the most significant features of software is branching, i.e., the ability to execute alternative series of commands, based on differing inputs. This feature is a major contributing factor for another characteristic of software – its complexity. Even short programs can be very complex and difficult to fully understand.
- Typically, testing alone cannot fully verify that software is complete and correct. In addition to testing, other verification techniques and a structured and documented development process have been combined to ensure a comprehensive validation approach.
- Unlike hardware, software is not a physical entity and does not wear out. However, as software is constantly updated and changed, such improvements have been sometimes countered by new defects introduced into the software during the change.
- Unlike some hardware failures, software failures have occurred without advanced warning. The software's branching that allows it to follow differing paths during execution, have hidden some latent defects until long after the software product has been introduced in production.
- Another related characteristic of the software has been the speed and ease with which it has been changed. This factor cause both software and non-software professionals to believe that software problems can be corrected easily. Combined with a lack of understanding of software, it leaded the manager to believe that tightly controlled engineering is not needed as much for software as it is for hardware. In fact, the opposite was true. Because of its complexity, the development process for software have been even more tightly controlled than for hardware, in order to prevent problems that cannot be easily detected later in the development process.
- The software development process have been well planned, controlled, and documented to detect and correct unexpected results from software changes, although seemingly insignificant changes in software code created unexpected and very significant problems elsewhere in the software program.

7

FUTURE DEVELOPMENTS

In the Semi-Automatic Assembling System there is a clear need for modular and highly customizable miniaturized production systems based on plug and produce assembly units with micro accuracy of operation. From an equipment point of view, the key emphasis should be in the future on developing new solutions for automatic handling of large volumes of the very small valve components, and the development of multi-process micro assembly modules using a smaller mechanical base and incorporating a wide variety of specialized product-specific processes, capable of meeting the increased demands on process capability, repeatability and traceability.

One multi-process module that could be developed in the future would have the aim of a total automation solution for the assembly process. In a nutshell, taking the small components from an available stock and loading them on the shuttle by a pick-and-place micro robot integrated in the system; the same robot would be able to take off the assembled valve and add a new one, as explained in the previous chapters.
Due to the predominant adhesive forces acting on the part surface in micro assembly, releasing the part by the robot gripper would be a more challenging task than the actual process. If the gravitational forces are dominant, the object will fall into place by itself once the gripper opens. Most of the micro grippers currently used in industry are scaled down versions of mainstream grippers for larger parts (e.g. grippers with pneumatic or motor driven fingers). There is anyway a large variety of micro gripper prototypes currently being developed using innovative technologies and principles. However, most of the developments are still within the research domain and very few have been implemented in a production environment.
Since the valve components have a specific position when loaded on the shuttle, feeders could be used instead of classic loaders. Feeders have the function of

presenting parts that were previously randomly oriented to an assembly station at the same position, with the correct orientation and the correct speed. One of the current trends in micro feeding is the use of distributed micro motion systems for the manipulation of micro parts. The approach is based on arrays of tiny actuators where each imparts a simple motion. Through the cooperation of some micro actuators, complex motion tasks can be realized, moving objects over relatively large distances and possibly in different directions and orientations. Moreover a feasible alternative to contact manipulation due to the reduced weight of the parts in micro assembly is the development of contactless grippers.
Despite the significant developments in micro manufacturing, joining of micro products is still relatively less developed as a technology domain. Micro joining techniques have initially been developed for silicon-based products. These have been combined with "scaling down" to micro level of traditional joining processes such as fastening, riveting, pressing, welding and gluing. Each process is constrained in terms of size, tolerance and applied force range which limits their applicability in the micro domain. While such traditional joining solutions are still widely applicable in micro assembly, there is an emerging set of micro assembly processes that are being developed specifically for micro-scale products.

Micro assembly has developed rapidly over the last few years and all the predictions are that it will remain a critical technology for high value products in a number of key sectors such as medical and pharmaceutical. The key challenge is to match the significant technological developments with a new generation of micro products that will firmly establish micro assembly as a core manufacturing process.

8

CONCLUSIONS

"In today's industries, the only alternative to manual assembly, at least for the most critical operations, is automatic assembly, which improves the output in terms of time, cost and quality assurance. If high production volumes of micro products have to be delivered in an efficient and reliable way, automatic assembly is the ultimate means to which efforts have to be aimed." (micromanu.com, 2008)

Based on this consideration, the Semi-Automatic system is totally fulfilling the company expectations. The cost advantage gained is not marginal; in fact, the 80% of the Hakim Valve production cost is attributable to the assembly process. This further confirms the need of cost-effective automated micro assembly solutions that can be deployed in industrial applications.

Thanks to the technologies today available and used by the Semi-Automated Assembling System, such as high precision positioning devices, precision tracking and control of applied forces, process monitoring and feedback, it has been relatively easy to adapt the new equipment in the "super-clean" production environments with high quality standards. The opportunity to test samples set depending on the lot dimensions will allow the deployment of reconfigurable ways for volume manufacture of products in close proximity to the patient needs. Different lots of valves have been already produced by the System. If they will successfully pass the validation tests, they will be implanted for the Hydrocephalus treatment.

During the next months, the System will be definitely validated and able to initiate the production of thousands of valves that will improve the life of many people in the world.

From the personal point of view, I think that this project made me finally experience “at first hand” some practical aspect of the engineering manufacture issues.

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