Óbuda University

PhD Thesis

Design of processes supporting the development of medical devices

by

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Declaration of Authorship

I, József Klespitz, declare that this thesis titled, 'Design of processes supporting the development of medical devices' and the work presented in it are my own. I confirm that:

• This work was done while in candidature for a research degree at this University.

• Where I have consulted the published work of others, this is always clearly attributed.

• Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work.

• I have acknowledged all main sources of help.

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PhD Candidate

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Date

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Abstract

Hemodialysis machines are responsible for removing metabolic waste products from the human blood when the body cannot excrete them on its own. With their help it is possible not only to improve the life quality of patients with kidney malfunction, but in certain cases this is the only way to keep someone alive.

The software component in these machines has significantly improved with the accessibility of powerful computing devices. Not only the expectations of experts has changed (more accurate device, improved patient safety, cost efficient operation), but also the international regulations have been modified. Altogether, these facts raise a challenge for development teams. In this thesis I am analyzing two aspects of the aforementioned problems.

During treatment, the blood of the patient is extracted and filtered extracorporeally. The purification is done by using special dialysis fluids where at the end, excess fluid is removed. This means that the fluid transfers have to be supervised to keep the patient fluid balance. Soft computing methods were developed and compared with conventional control methods in the first thesis group. This approach is novel for the industry and analyzes have proved it to be effective. The developed controllers are comparable with the existing solution with the advantage of possible incorporation of additional expert knowledge. The controllers were developed to be not only suitable for testing and analyzes, but they can be easily integrated into existing machines.

The quality of a newly developed machine is highly depending on the applied development process. Different supporting tools are used to decrease documentation related burden, eliminate redundancies and to reduce human workload. The tools in the development toolchain are called application lifecycle management system and they can be homogeneous or heterogeneous depending on the number and connectivity of software providers. The second thesis group discusses how enhanced traceability and consistency can be achieved when using these systems. The idea of augmented lifecycle space was created as a software independent solution to find missing artifacts in software development. Furthermore, it makes possible for stakeholders to select and prioritize the deficiencies.

Absztrakt

A szükségtelen anyagcsere termékeket hemodialízis készülék segítségével lehet eltávolítani az emberi vérből. Segítségükkel a veseelégtelenségben szenvedőknek nem csak az életminőségét lehet így javítani, hanem bizonyos esetekben ez az egyetlen mód az életben tartásukra.

Ezen gépek szoftver komponense jelentősen fejlődött a nagy teljesítményű eszközök terjedésének köszönhetően. Nem csak a szakértő felhasználók elvárásai (úgymint pontosabb eszköz, magasabb betegbiztonság, költséghatékony működtetés) emelkedtek, hanem a nemzetközi szabályozások is változtak. Mindezek együtt kihívás elé állítják a fejlesztő csapatokat. Jelen disszertációban a korábban említett problémák két aspektusát vizsgálom.

Kezelés közben a beteg vérét kinyerik és a testen kívül megszűrik. A megtisztítást speciális dialízis folyadék segítségével végzik, ahol is a felesleges folyadékmennyiséget eltávolítják. Ezért a beteg folyadékegyensúlyának megtartása érdekében a folyadék áramlásokat felügyelni kell. Az első téziscsoport a lágy számítási módszerek fejlesztését és hagyományos módszerekkel való összehasonlítását tartalmazza. Az így fejlesztett szabályozók összehasonlíthatóak a meglévő megoldásokkal, miközben megvan az az előnyük, hogy szakértői tudással bővíthetők. A szabályozókat nem csak tesztelési és analitikai célokra lehet használni, hanem könnyen integrálhatóak meglévő gépekbe.

Egy újonnan kifejlesztett gép minősége nagyban függ az alkalmazott fejlesztési folyamatoktól. Különböző támogató eszközök alkalmazhatóak a dokumentációs terhek csökkentésére, illetve az emberi terhelés csökkentésére. A fejlesztési eszközláncban található eszközöket együtt applikációs életciklus menedzsment rendszernek hívják, ami lehet homogén vagy heterogén a benne található szoftverek számától és összekötöttségétől függően. A második téziscsoport azt tárgyalja hogyan lehet a nyomon követhetőséget és konzisztenciát növelni ezen rendszerekben. A kiterjesztett életciklus tér, mint egy szoftver független megoldás, a hiányzó fejlesztési artifaktok megtalálására érdekében lett kifejlesztve. Mi több, segítségével a döntéshozók a hiányosságokat válogathatják és fontossági sorrend szerint rendezhetik.

1. Introduction

1.1. Research focus

This doctoral thesis is related to hemodialysis machines, their operation and their development. Hemodialysis machines are used to replace or support the kidney functionality during malfunction which process is known as blood purification. Renal replacement therapies are required in case of kidney malfunction which can be grouped as acute and chronic kidney failure. It is also used to improve quality of life until the kidney of the patient could be transplanted. The need for such machines is well demonstrated by showing that chronic kidney disease is the 9th leading death cause in the United States [1].

Chronic kidney disease is built up over a longer period of time while the glomerular filtration ratio (blood purification capability of kidney) is gradually decreasing. After a certain threshold, the kidney cannot remove enough metabolic waste products and it begins to accumulate in the body. The accumulation of these waste materials results unpleasant symptoms (fatigue, drowsiness, itching, joint pain) in the beginning, but it could achieve life threatening conditions as well [2].

This makes it inevitable to remove the waste products by blood purification. In case of chronic kidney disease these treatments have to be repeated multiple times a week where each treatment lasts for 4-6 hours. The treatments get more frequent with the weakening performance of kidney. In the end kidney transplantation is inevitable and also this is the only permanent cure for chronic kidney disease [3]. The chronic kidney disease is spreading, estimated to affect more than 10% of adults in the United States, elder people over 70 years are especially threatened [4].

On the other hand, acute kidney injury is the rapid loss of kidney functionality. It is caused by a trauma with a variety of backgrounds [5]. According to Susan et al. [6] every one in five adults and one in three children experiences acute kidney injury in hospital care. Critically ill patients are especially threatened and their mortality is significantly affected by the presence or absence of renal replacement therapy [5].

Acute kidney injury typically lasts for hours or days. If the injury does not recover (at least partially) within 3 weeks then it is considered chronic kidney disease. The chance of recovery depends on the cause and the severity, for further information see Bellomo et al. [5]. It is crucial to use renal replacement therapies upon indication [7] to improve outcome, to decrease excess hospital costs and to enhance the chance of kidney function recovery [8]. In case of acute kidney injury a so called continuous renal replacement therapy is used. Here, the blood purification is continuous and it can lasts over 72 hours as the patient’s condition requires.

By looking at statistics, the hospitalization need and the morbidity is slightly decreasing in the United States, while the overall occurrence of chronic kidney disease is stagnating thanks to the healthcare system and prevention [9]. Detailed demographics can be found at [10]. Although most metrics are available only regarding the United States, still further estimation can be done. The increasing occurrence of kidney failure is expected in both developed and developing countries as diabetes and high blood pressure, the two important pandemics, are the leading causes of kidney failure [1] [11]. Due to these facts together with the limited possibility of kidney transplantation (which is the one and only final cure in end stage renal disease) it is clear that these patients has to be taken care of. Altogether, this raise the need for modern and economic hemodialysis machines to prolong the life and to improve the living conditions of patients.

As it was shown above, the blood purification treatment is different in case of the two diseases. Although, the facility need is different, yet the phenomena behind each therapy is similar [12]. The blood of the patient is removed via a cannula and it is flowing through a tubing system extracorporeally. Hereby, the blood is running through a capillary system (filter), where capillaries are made from semipermeable membrane. The waste materials are removed via this membrane with various methods [13].

When there is a counter flow of dialysis fluid on the other side of semi-permeable membrane and waste material is removed via diffusion then the therapy is called hemodialysis. When there is no dialysis fluid on the other side of the semi-permeable membrane and the pressure difference forces part of the blood through the membrane creating the so called ultrafiltrate then it is called hemofiltration. When there is also a counter flow of dialysis fluid and the pressure difference also secretes ultrafiltrate then the therapy is called hemodiafiltration. Each therapy type has its own indication. When ultrafiltration is created then it is necessary to replace the removed fluid volume. This is solved by administering dialysis fluid to the blood of the patient. In each cases, the purified blood is flowing through an air trap to remove air bubbles from the blood before introduced back into the body.

Acute hemodialysis machines are usually mobile (to let them move between intensive care units), the necessary fluids are stored in different bags and also the waste products are collected in separate bags. On the other hand, the chronic machines (where the mobility is not an issue) are connected to a small dedicated water plant and the machine creates itself the dialysis fluids and transfer waste materials to the sewers.

Although the principles of hemodialysis is simple and it has not changed significantly over its century old history, still it is not self-evident to launch a new device on the market. First of all it is a medical device thus it is capable to harm (and even kill) someone. Therefore, it is a safety-critical application where the related standards and directives has to be fulfilled and the manufacturer has to guarantee the safe operation. Tremendous amount of documentation and proper processes are needed to develop successfully a machine while continuously considering and avoiding possible risks and hazards. The documentation burden and process control is supported by various software tools. To ease this job many tools can be found on the market even with some solutions dedicated to the medical device domain. The communication and information share between these applications is a crucial point, where further improvements are still needed.

The dissertation is organized around two problems. First, it will be discussed how the patient fluid balance can be kept by controlling the fluid pumps in the system. Hereby, soft-computing methods are analyzed as a novel application field together with other control methods mostly unknown for the industry.

However, it is not satisfactory to only insert a suitable controller in the machine software, but it has to meet every requirement while complying the specified development processes. The second part will discuss this topic: Namely, how a software development can be supported by different tools and how the transparency and quality of development could be improved with little to no human interaction. Thus, the application of a novel method is demonstrated which is capable to find deficiencies and it also provides a workflow automatically in order to get rid of these problems.

2. Control of hemodialysis machines

2.1. Technical background

In hemodialysis machines peristaltic pumps are responsible for fluid transportation including blood of the patient [12]. They are transporting liquids by repeatedly compressing an elastic tube(segment) without getting in contact of the transferred fluid. Peristaltic pumps can be operated with disposable tubing which is practical as the treated blood gets in contact only with the sanitized kit. This way infection and contamination can be avoided. Furthermore, the tubing of treatment kit can be created from biocompatible materials. This way the chance of (blood) coagulation can be reduced together with the chance of filter clogging without even using anticoagulation materials. Finally, peristaltic pumps are gentle to the transported fluid. This is especially important in case of blood, as the breakdown of corpuscles (formed elements) should be avoided. From medical point of view the only drawback of peristaltic pumps is their inaccuracy.

Hemodialysis machines typically operate with two roller peristaltic pumps (at least for the main pumps). The operation of such a pump can be characterized as the following: At the beginning of the sequence the first roller closes the tubing inlet. Afterwards, the roller moves forward and pushes the pump segment to the manifold. This way it pushes the fluid inside the tube forward and generates a pressure wave. Before reaching the outlet the other roller closes the tube inlet, this way it prevents the black-flow. After the first roller leaves the outlet, the other roller's task will be to generate the next pressure wave. This sequences repeats over time and this creates a continuous flow in the tubing. More details can be read about peristaltic pumps at [KJ2].

During treatment the blood is partially re-exchanged with dialysate fluid, but excess body fluid can also be removed. However, the balance between total amount of given and removed fluids has to be the same as specified by the doctor (typically a negative amount of fluid to support the lacking secretion of body). This prescription is defined as net fluid removal and it is defined as flow rate [ml/h] which might change throughout the treatment. The actual removal can be bigger or equal to zero in spite of the above. If the kidney of patient is capable to remove satisfactory amount of water and only the clearance has to be supported then this amount is zero. If the kidney cannot remove enough water or other indication exists then the actual value is defined by doctors according to current needs.

This is one of the most crucial aspects of these machines as removing excess fluid is necessary to improve health of patient. On the other hand, removing too much fluid can lead to dehydration which might increase to a life threatening level. (Not to mention that it is guaranteed that it further burdens the already bad general condition of the patient.) Furthermore, in certain machines peristaltic pumps are also used for transporting drugs. Heparin might be administered for prevention of anticoagulation or calcium replacement might be necessary when it is removed with citrate complex, again for anticoagulation purposes. The precise transfer is even more crucial in such cases as overdosing, hypocalcaemia or hypercalcaemia may occur. Altogether, this raise the need for regulation and supervision of fluid transport.

In case of acute hemodialysis machines, the different liquids (such as the dialysate, or effluent fluids) are collected and treated in different bags. This is necessary to keep the machine mobile, to let it move between different premises (operating rooms, intensive care units, etc.). This way no external water supply is necessary. The fluids (dialysate and substitution fluids) are removed from these bags, while the effluent fluid is collected similarly. This way, the fluid transports can be measured with weighting scales. With the comparison of measured and desired fluid volumes it is possible to calculate delivery errors. (The idea can be utilized for chronic hemodialysis machines as well, but it is more difficult to measure the transferred volume in the absence of fluid bags and separate weighting scales.)

The inaccuracy of peristaltic pumps is the main reason of feed-back control [14]. The elasticity of tube segment may result approximately ± 10% in total transferred volume due to deviation of production [15]. Furthermore, the transferred volume is depending on pressure ratio which might further worsen the fluid balance. The accumulation over the long therapy time (up to and over 72 hours) could further increase these effects. The fatigue of tubing material has to be also mentioned. The continuous repeated squeezing of the material will make it stiffer over time. Thus, it will be unable to reshape completely to its original form which also means that the inner volume (thus the transfer volume) gets decreased. Finally, pressure ratios may alter the volume of elastic tube segment. By increasing the pressure ratio it is capable to force more fluid into the tube segment, "blowing it up like a balloon". This means increased transfer volume. On the other hand, decreased pressure ratio hinders the filling of the tube segment in a way that during relaxation it is not filled to its full capacity. Naturally, this decreases the transfer volume. From these two phenomenon the negative pressure ratio is the more relevant, as such pressure levels can be practically reached. The other (positive) case is less common, but it has to be still kept in mind. Either way, both of these phenomenon develops out of normal operating range. Therefore, the controller has to be prepared for these cases, but the expectations are different compared to normal operation mode (i.e. less control reserve).

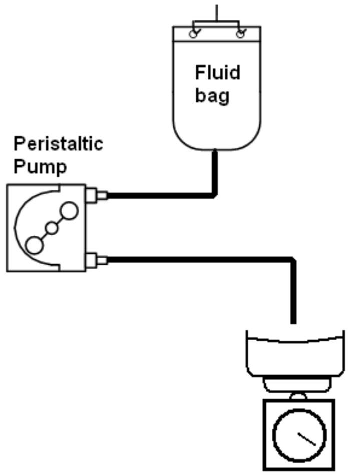
Many complex approaches can be found in the literature about controlling hemodialysis machines. Most of these (e.g. [16, 17, 18, 19]) are estimating techniques where a set of physiological parameters (e.g. arterial blood pressure, heart rate, blood density, etc.) are selected and used to override therapy parameters. This seems to be promising, but at the moment manufacturers do not take the risk of letting the intervention decided by the machine. Machine calculations are only used for decision support and the final decision is made by the expert. This way the aforementioned systems remain promising but they are not available on the market. (Still, it is an interesting thought to have self-setting machines which are tuning treatment parameters to the actual need of the patient. This could be as exciting step as a completely autonomous car in traffic.)

It has to be mentioned that patient fluid balance control is not the only place where feedback control is necessary. The different pressure ratios shall be kept between certain boundaries mostly to prolong the life of the filter and ease the operation of peristaltic pumps. Furthermore, the temperature of the blood has to be maintained as it is cooling extracorporeally. This can be also used to improve patient comfort as the temperature of re-introduced blood affects the temperature sensation of patient.

This part of thesis targets to demonstrate the use of non-conventional control methods for regulating patient fluid balance via peristaltic pumps. First soft computing methods and their performance will be presented. Afterwards, the design of a classical PI controller will be shown by using tensor product transformation. Each of the designed controllers should be suitable for real-life application with possibility of integration into an existing machine.

2.2. Model of controlled system

One pump and its related tubing with fluid bag was separated as a subsystem as Figure 1 presents. The pumps could be analyzed altogether as a single multi-input multi-output (MIMO) system. However, this idea was neglected, as the testing (and generally the verification and validation procedure) would be more demanding. Furthermore, the correlations between the pumps can be neglected as a good approximation without risking the compliance of performance requirements. Thus, the more simple single-input single-output (SISO) approach was supported. In this case the controller of subsystems eliminates errors of the corresponding pump and in summary this will result the accurate transportation from systemic point of view.



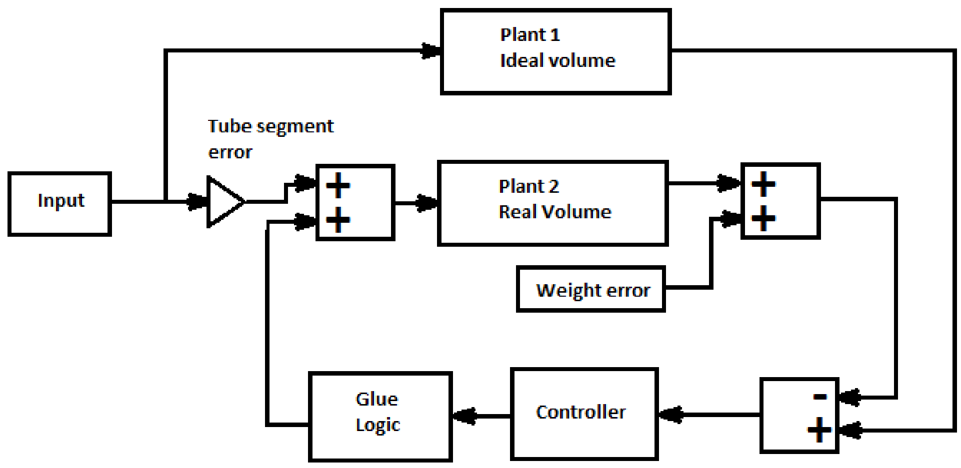
1. Figure Analyzed subsystem

The separated subsystem consists a peristaltic pump responsible for the fluid transport, a bag responsible for granting or collecting the fluid and a weighting scale responsible for measuring transferred fluid weight. This subsystem was identified with specific regards to insecurity in fluid transport volume, quantitation error of weighting scale and the insecurity of rotation of pump head [KJ1]. Although, multiple advanced identification model were used (namely ARX, ARMAX and Box-Jenkins), still the single state-space model was the most accurate model which resulted the following transfer function:

$$H(s) = K_{pump}/s \qquad (1)$$

By identifying the K_{pump} amplification, the root mean square error was measured 0.13% as percentage of full scale (or 1.3 grams). This could be caused by the simplicity of subsystem and the time invariant property of the selected subsystem.

The final model of the analyzed system can be seen on Figure 2. Here, two main branches can be distinguished. Each branches contain the identified transfer function. The first branch is responsible for the ideal transfer volume, also this is the reference signal. Therefore, the transfer function is unchanged in the first branch. The second branch is responsible for the real transfer volume which includes the possible errors and distortions. It starts with a gain responsible for slope errors. Here, the tube related errors can be introduced (fatigue, pressure dependency, tube inaccuracies and rotation dependency). This is followed by the transfer function. After that, constant can be added to the system, responsible for the different weight measure errors. Simulation of single weight error and residual error can be executed with its help.



2. Figure Model of the controlled system

The output of the model is equal with this second branch. The difference of the estimated transfer volume (first branch) and real transfer volume (second branch) is the error signal. This error signal is provided for the controller which creates the feedback signal. This signal is fed back via a glue logic to the second branch to compensate its inaccuracy. The glue logic (and the positive feedback) is similar to a practical implementation to make the integration of the analyzed controllers possible.

This model has the benefit of the generic controller which can be replaced with any selected controller. Initially, a PID controller was inserted and for the other measurement the results of this controller meant the benchmark. The integral term is necessary as the residual error means fluid imbalance in the body of the patient which cannot be tolerated. The derivative term is only necessary to reduce the settling time to reach tight control.

The following properties of the controllers were analyzed:

- settling time
- overshoot
- accuracy
- robustness

Each of these have a physiological meaning and relevance. Let them see in order: settling time shall be minimized as the error of a pump means fluid imbalance in the body. It is important to minimize the time with fluid imbalance, but it can be tolerated most of the time as the human body is robust from this perspective. However, it is vital to minimize this time when the effluent pump is transferring drugs as the effect of deviation can be more destructive in such cases. The overshoot means unnecessary burden for the patient, thus it needs to be avoided at all if possible. The accuracy is a long term goal which reduce the time and amount of fluid imbalance. Finally, robustness is necessary to handle uncertainty in the system such as the volume of elastic tube segment, the fatigue of this tube and delivery fluctuation caused by pressure.

2.3. Fuzzy controllers

In the following chapters the designed controllers are presented together with the achieved results. The reference is always the PID controller as one of the motivation of this research is to prove for industrial developers that the performance of soft computing methods can be equal or even better in safety-critical environment. The aforementioned reference PID controller [KJ1] was designed for a 61° phase margin [20]. Later on this is used always as a base for comparison. Moreover, some selected controllers were tested in a real hemodialysis machine too. Thus, the results of comparison got verified as well.

2.3.1. Design of the controllers

First of all, a simple fuzzy controller was created. Mamdani-type fuzzy controller was chosen for the implementation as they are closer to the human thinking and the task was basically capturing the system related expert knowledge [21]. The computational efficiency was not a target in the initial phase as the aim of the research was to show the usability of fuzzy logic in the given environment [22]. Moreover, the used tool (Matlab) has a dedicated command for transforming Mamdani-type systems to Sugeno-type system. This way, if the controller proves to be effective then it is still possible to utilize the efficiency of Sugeno-type systems later during the implementation.

Originally, a simple fuzzy controller was designed with a single input as the base of research. At that time, there were no requirements about the strictness of control and intervention. Thus a fine resolution was applied on the single input signal of the system which was the transfer volume error. The error signal was covered by 19 membership functions weighted from 1% to 50% with the following pattern: 1%-2%-5%-10%-20%-etc. Intermediate regions were covered by triangular-shaped membership functions characterized by:

$$f(x) = \begin{cases} 0, \; if \;\; x \leq a \\ \frac{x-a}{b-a}, \; if \;\; a \leq \; x \leq b \\ \frac{c-x}{c-b}, \; if \;\; b \leq x \leq c \\ 0, \; if \;\; c \leq x \end{cases} \qquad (1)$$

where a and c characterize the region where the f function is non-zero and it is assumed that $a \neq b$ and $b \neq c$. The values of a and c are selected for each membership function in a manner that their overlapping sequence intersects only the adjacent membership functions. Furthermore, the defined regions by a and c are increasing continuously proportionally with the error signal. To guarantee the symmetry let $= \frac{a+c}{2}$. The centers of 19 membership functions are belonging to error 0, ±1, ±2, ±5, ±10, ±20, ±50, ±100, ±200 grams of delivery error. None of the membership functions cover transfer volume errors over ±500 grams. These values were based on initial consideration and worst case scenario calculations. Later, these assumptions got rejected in spite of the first results.

The two end regions were covered individually with unique membership functions. Transfer volume errors below -500 grams were covered by a z-shaped membership function characterized by:

$$f(x) = \begin{cases} 1, \ if\ x \le a \\ 1 - 2\left(\frac{x-a}{b-a}\right)^2, \ if\ a \le x \le \frac{a+b}{2} \\ 2\left(\frac{x-b}{b-a}\right)^2, \ if\ \frac{a+b}{2} \le x \le b \\ 0. \ if\ x \ge b \end{cases} \qquad (2)$$

where a is the limit of maximal (considered) transfer error based on acquired knowledge and a-priori information. b is reasonably close value to guarantee the steepness of the transition.

Transfer volume errors above 500 grams were covered by an inverse z-shaped function characterized by:

$$f(x) = \begin{cases} 0, \ if\ x \le a \\ 2\left(\frac{x-a}{b-a}\right)^2, \ if\ a \le x \le \frac{a+b}{2} \\ 1 - 2\left(\frac{x-b}{b-a}\right)^2, if\ \frac{a+b}{2} \le x \le b \\ 1. \ if\ x \ge b \end{cases} \qquad (3)$$

where b is the limit of maximal (considered) transfer error based on acquired knowledge and a-priori information. a is reasonably close value to guarantee the steepness of the transition.

The error signal is normalized by the used tool (Matlab), and T-norm is used to calculate the result of membership functions:

$$T\left(\mu_A(x),\ \mu_B(x)\right) = \mu_A(x) * \mu_B(x) \qquad (4)$$

where μ_A and μ_B are the affected membership functions and * means the minimum of $\mu_A(x)$ and $\mu_B(x)$.

The initial result were unsatisfactory with this setup. First of all, this controller was unable to remove the residual error from the system. On the long run this cannot be tolerated, its elimination is mandatory. Furthermore, it is a vital aspect for the controller to find the exact operating point for the elastic tube segment. This kind of adaptivity is necessary, to set the reserve accordingly. This means that the control range (coming from directives) is defined in the range of real transfer volume. The better we can set this volume, the more reserve the system have. Thus, the error can be removed faster.

These needs have two additional reasons as well. First of all, the tube will age throughout the therapy and this decreased elasticity will result in less transfer volume, the operating point will be shifted. The adaptivity is important to follow this, and keep the control range as wide as possible. The other phenomena explains the need for the wide control range: both the increment and decrement of the systemic pressure can affect the transfer volume significantly. Moreover, this pressure might change suddenly (compared to the velocity of system) thus introducing error into the transfer. The wider range we have the better we can compensate this and other disturbing effects in order of the improved patient service.

To solve these problems two other fuzzy controllers were created one with integrating property and another one which is capable to adapt.

At first the problem of residual error was targeted. Just like in case of the PID controller an integral term is necessary to solve this. The usage of the integral of error signal was unsuccessful due to instabilities. This way the solutions were combined and the number of inputs of fuzzy controller was increased. At first, the introduction of a derivative term seems to be useful as well in order to have an estimator. Unfortunately, this is impractical as the error is based in weight calculation where the resolution of weight measurement is 1 gram. This is in the range of real errors and it is impossible distinguish them. Therefore, the introduction of a derivative term only decreases the performance due to the wrong predictions [23].

It was clear from the results of original fuzzy controller that the number of membership functions can be highly reduced and the considered range of the error signal can be decreased. These can be done due to the facts, that most of the reactions for various membership functions/certain regions could not been distinguished and with a proper controller during normal operation not even the ±100 range was exceeded. (Otherwise, in certain scenarios error over this threshold can be reached, but these are special situation where reaction for maximal error is suitable to handle these cases as well.)

In spite of the above mentioned facts the error signal was covered by seven membership functions during fuzzyfication. The intermediate five functions were triangle shaped membership functions as described in Eq. (1). These were distributed equidistantly between the selected extremities (±50 gram), in a manner that membership function might intersect only their adjacent membership functions. The only exception is the central function responsible for minimal to no error. This one was a tighter function centered on 0. This function was referred later as “MinErr”, while the other ones were generated from the big/small and positive/negative word pairs. The terminal membership functions were changed to trapezoidal membership functions characterized as:

$$f(x) = \begin{cases} 0, & if (x < 0)\ or\ (x > d) \\ \frac{x-a}{b-a}, & if\ a \le x \le b \\ 1, & if\ b \le x \le c \\ \frac{d-x}{d-c}, & if\ c \le x \le d \end{cases} \quad (5)$$

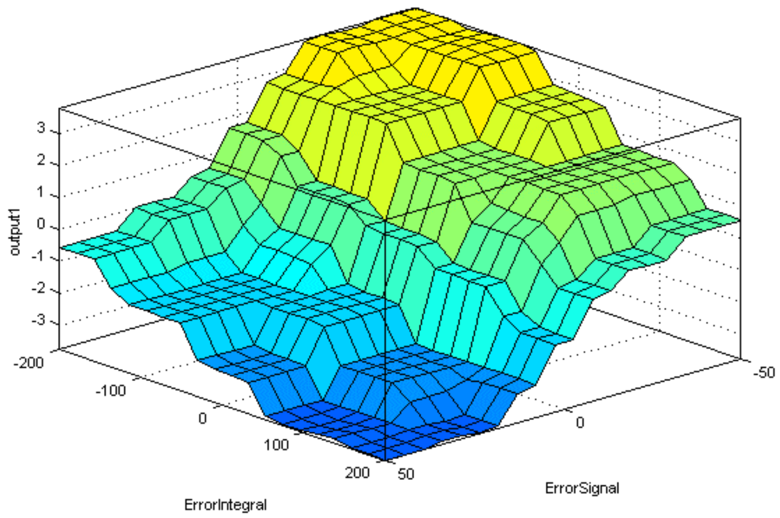
where c was selected as -50 grams for the negative extreme as the maximum error to consider (based on experiences with previous fuzzy controller), and b was selected as -200 grams as them maximum possible error to be tolerated (above this safety measures are required according to directives) a and d are selected to be somewhat lower than b and c respectively in a way to provide the necessary slope. Similarly, on the positive extreme the b was selected as 50 grams and c was selected as 200 grams just like in case of the negative extreme. a and d was selected in the same manner as well.

The other input, the integral of error signal was covered with five membership functions. Due to the high quantitation error it was known that the range should be increased compared to the error signal and the small values did not need finer coverage. The intermediate membership functions are triangle shaped as described in Eq. (1) and they covered the full range equidistantly. Names used during fuzzyfication are referring to these as “Minimal”, “Positive” and “Negative”. The other two membership functions are trapezoid membership functions as described in Eq. (5). The trapezoid membership functions outreach the thresholds by ±200 g (determined empirically) and the integral of error signal is also saturated at ±200 g. Saturation was necessary as the system would be otherwise capable to accumulate significant amount of error which is not desired, as it might cause high overshoot and significantly longer transient time (this is the so called windup phenomenon). Anti-windup systems are commonly used in PID controllers and it is highly advised to use one in this very situation. This will prevent the unnecessary increase of the integral of error if the control signal is in saturation. In order do this the output and the saturated value of the output are compared. A switch is operated with the result of this comparison. If the output is not saturated, then the error signal is pronounced on the output of the switch, otherwise a zero value is integrated over time. This is the so called anti-windup logic [24] [25].

The selected method of inference in this controller was the max-min method, and the method of defuzzyfication is the classical center-of-gravity (COG). The input signals were normalized automatically by the development environment (Matlab) [26].

The output is covered with 9 membership functions for defuzzyfication. The seven of intermediate one were triangle shaped membership functions as described in Eq. (1). The extremities were covered by trapezoid functions just as in previous cases, their characteristics are as in Eq. (5). The covered range means here ±10% control; the trapezoid membership functions outreach this thresholds. Similarly, the control signal is saturated at ±10%. In the middle of the range three tight triangular-shaped functions can be found. The central one means minimal control, together with the two others next to it. These three functions are responsible for the fine control of the system near the operating point. The other triangular membership functions cover significantly larger intervals and they cover equidistantly the remaining control range. Together with the trapezoid membership functions these are the ones responsible for error removal. As an additional safety measure, the glue logic also had a secondary limitation for the control signal, maximizing it in ±10% of actual flow rate.

Altogether, 35 rules are defined for this controller. The goal was to keep the error signal dominant: if the integral of error can stimulate the effect of the error signal their presages agree, but obstruct, if their presage is different. This can be seen from the surface map presented on (Fig. 4.).



3. Figure Surface map of the fuzzy controller

Rules consisted similar expressions as in the following examples:

If ErrorSignal is BigNegative and ErrorIntegral is Negative, then ControlSignal is BigPositive.
If ErrorSignal is BigNegative and ErrorIntegral is Positive, then ControlSignal is MiddlePositive.
If ErrorSignal is SmallNegative and ErrorIntegral is Minimal, then ControlSignal is MiddlePositive.
If ErrorSignal is Minimal and ErrorIntegral is Negative, then ControlSignal is SmallPositive.
If ErrorSignal is Minimal and ErrorIntegral is Minimal, then ControlSignal is Minimal.

2.3.2. Iterative Learning Control for fuzzy controllers

When designing the adaptive fuzzy controller it was attempted to create a control signal with the use of integral of error combined with iterative learning control [27, 28, 29, 30]. Iterative learning control can be applied effectively when the systems fulfills criteria originally stated by Arimoto [31]:

1. Every trial ends in a fixed time of duration T>0
2. A desired output $y_d(t)$ is given a priori over that time with duration $t \in [0, T]$.
3. Repetition of the initial setting is satisfied, that is, the initial state $x_k(0)$ of the objective system can be set the same at the beginning of each trial: $x_k(0) = x_0$ for k = 1, 2, …(5)

4. Invariance of system dynamics is ensured throughout these repeated trials.
5. Every output $\Delta y_k = (y_k(t) - y_d(t))$ can be utilized in construction of the next input $u_{k+1}(t)$.
6. The system dynamics are invertible, that is, for a given desired output $y_d(t)$ with a piecewise continuous derivative, there is a unique input $u^d(t)$ that excites the system and yields the output $y_d(t)$.

These criteria are only fulfilled with some minor assumptions. T in Crit. 1. cannot be forecasted generally in our case as it is depending on the set flow rate. Moreover, this flow rate may vary over a wide range where at low flow rate this time increases significantly. Furthermore, this time will depend on the accessible control range. If the system is not capable to find the operating point correctly then the slope error will reduce control reserve which increase the mentioned time. Still, for a given transfer volume this time can be calculated assuming that the operating point is set correctly.

As the system is slow compared to the controller Crit. 2. is always fulfilled. Initial state is varying over time due to the fatigue and changing pressure conditions, but in the short term the system parameters can be considered fix (good assumption) and during normal operation pressure is highly invariant. Therefore, $x_k(0)$ can be considered fix according to Crit. 3. These facts also confirm the assumption of system invariance as prescribed in Crit. 4.

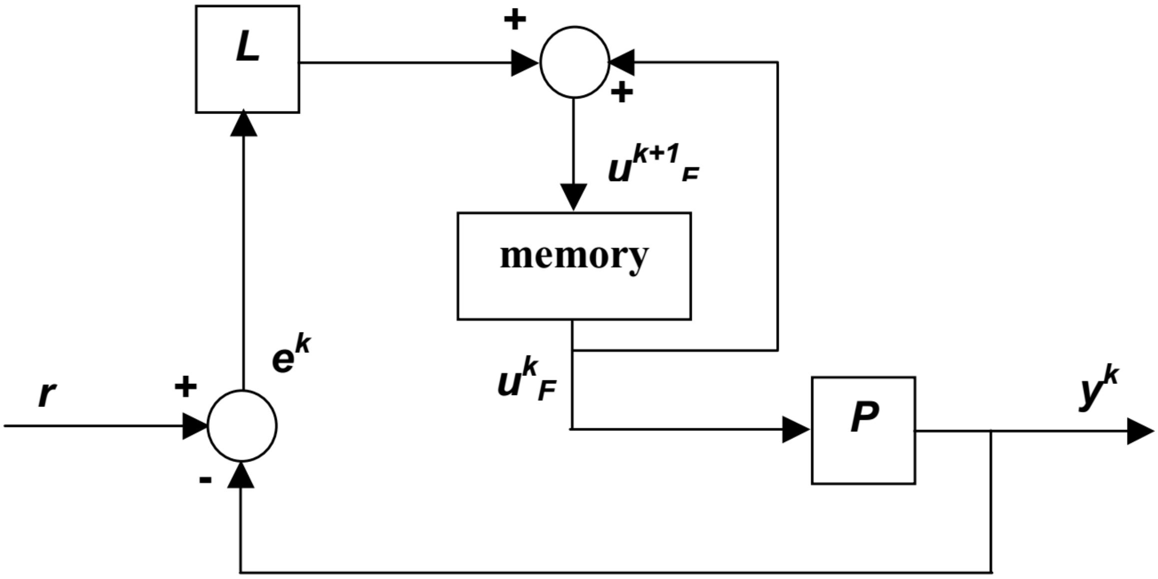
The single output signal contains implicit information regarding the operating point (change) thus it can be used (and it is used) in calculation of the next input which confirms Crit. 5. The system description is simple as described in (1) and according to this transfer function it can be easily proved that the system dynamics are invertible.

According to these facts, it can be stated that the analyzed system can be effectively controlled by using iterative learning control techniques.

In this design the iterative learning control method will be used to refine the operating point in each step. To realize it the first (and simplest) realization of ILC has been used [32]. Here, u_k^F is the control signal. This way the controller needs to establish $e_k(t)$ in a manner that it is only the modification of the control signal and it will only affect the system during the next iteration as u_{k+1}^F. With other words the output signal can be calculated as [33]:

$$u_{k+1}(p) = u_k(p) + K_d[e_k(p+1) - e_k(p)] \qquad (6),$$

where u(p) is the output signal in iteration k, Kd is a scalar designed for the controller and e_k is the p^{th} input sample in iteration k. The original model used for construction of ILC can be seen on Fig. 4.

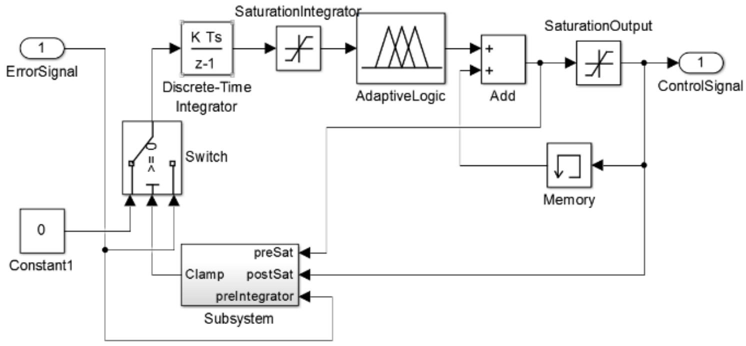


4. Figure Original model of iterative learning control [34]

In spite of the facts above, the following structure was created for the implementation of the adaptive fuzzy controller: The error signal is clamped depending whether the control signal is in saturation or not. This clamped error signal is then integrated. The result of integration provides the input for the fuzzy inference system described later. However, this integral signal is also saturated as an additional redundancy (whenever the system reaches safety threshold not only an external safety measure is executed, but also the integral signal is saturated). This approach has double benefits. First of all, the residual error can be compensated. Furthermore, the single input makes the design simpler, this way it is easier to keep the system under control (not to mention that debugging/fine tuning can be executed more quickly with less effort).

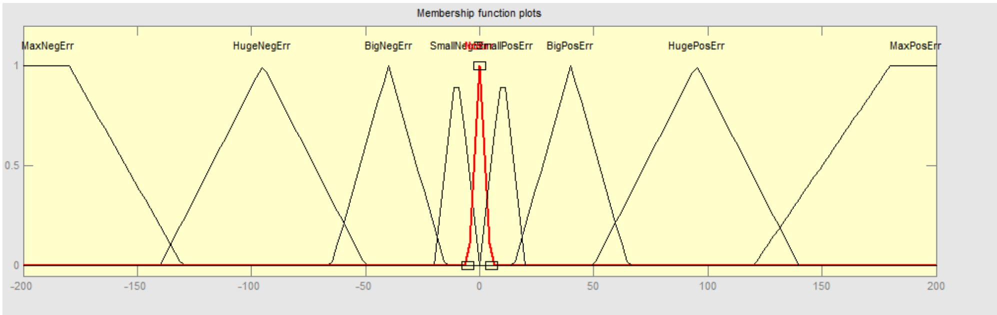
As it was discussed previously, the so called windup effect may appear with the introduction of saturation. That is the reason why the clamping circuit had to be set up as it is controlled by the pre- and post-saturation control signals.

The ILC is realized after the fuzzy inference system. Here, the output signal is summed with the previous (saturated) control signal, resulting in the new control signal. After saturation this will affect the transfer volume of the pump and it will be also connected to a memory block to be stored for the next iteration to be used. The basic concept behind these is that fuzzy control is able to find the flow error in rough steps and with fine steps it is able to hold the flow close to the new operation point. The schematic of adaptive fuzzy controller can be seen in Fig. 5.



5. Figure Internal structure of adaptive fuzzy controller

The only input (error integral) was covered by 9 membership functions in this case. Two of them are trapezoid membership functions on the two extremes, characterized as in Eq. (5); the acceptable error range is ±200 g·s (the error integral is saturated in order to stay in the range). The other five membership functions are triangle-shaped membership functions as described in Eq. (1). The width of the membership functions has increased to the extremes, the small errors were covered with tighter membership functions, than the big errors. For defuzzyfication the output is covered very similarly (9 membership function in total, trapezoid functions on extremities, triangle-shaped functions otherwise); here the maximum output signal is equivalent to 1%. The membership functions for the input of adaptive fuzzy logic can be seen in Fig. 6 as an example.



6. Figure Membership functions covering the input of controller

When defining the rule base, a quasi linear compliance was expected. The presage and size of the output signal was directly related to the presage and size of the integral of error signal. This relationship is reflected by the nomenclatures used for naming membership functions. This way it is possible to create an appropriate logic with 9 rules. Some selected rules can be read below for illustration:

If ErrorIntegral is BigNegative, then OutputSignal is BigDecrementing.
If ErrorIntegral is SmallPositive, then OutputSignal is SmallIncreasing.
If ErrorIntegral is Minimal, then OutputSignal is Minimal.

2.3.3. Performance of fuzzy controllers

Let's see how these controllers perform according to measures presented previously. The measured flows were selected in order to fit to the values applied in the real system. The PID controller is used as reference for the following reasons: It was already implemented and it proved to be effective. Furthermore, PID controller is commonly used and it is widely known in the industry. These preconceptions had to be overcome for better spread of application of soft computing controllers.

First of all, settling time, overshot and accuracy have been examined. The selected flows were 100, 300, 500, 1000 and 1500 ml/h as collected in Table I. These cover the most relevant values over the operating range.

When examining the settling time, the system was burdened with 5 ml volume error, while a perfect tube segment was assumed (0% slope error). The 5 ml amount is a typical error in practice. The error was considered compensated (and time measurement was stopped) if the error of the system was between ±1 g and the output signal of the controller is in the ±1% environment of the steady-state output [8]. (The ±1% range for control signal in steady-state was the result of other system requirements.) The results are summarized in Table I.

Settling time [s]	100 ml/h	300 ml/h	500 ml/h	1000 ml/h	1500 ml/h
PID	265	267	242	239	239
Fuzzy	656	658	659	660	660
IntegroFuzzy	1309	1247	1240	1306	1275
AdaptiveFuzzy	396	264	238	225	221

Table I. Settling Time

The integro-fuzzy logic has increased settling time compared both to the PID controller and the original fuzzy controller. Hence, it can be said that this controller is not suitable for control, further tuning is necessary to achieve an acceptable result. On the other hand the adaptive fuzzy controller has almost the same settling time as the PID controller. Over 300 ml/h is slightly faster, but at 100 ml/h it is slower. The results are acceptable, but faster settling would be recommended under 100 ml/h.

In order to examine the overshoot of the system, a worst case event was set: the pump segment was able to transfer 10% less fluid and at the beginning the system had 20 ml more transferred volume, than expected (-10% slope error, 20 ml offset error). The peak of the (first) overshoot was measured compared to zero error value. The measured overshoots are summarized in Table II.

Overshoot [g]	100ml/h	300 ml/h	500 ml/h	1000 ml/h	1500 ml/h
PID	9	9	9	10	11
Fuzzy	1	0	0	-7	-10
IntegroFuzzy	0	-2	-2	-10	-10
AdaptiveFuzzy	2	2	2	2	2

Table II. Overshoot

One advantage of the fuzzy controllers may be the small overshoot. The original fuzzy logic and the integro-fuzzy controller have minimal overshoot under 1000 ml/h, but over it they have as high overshoot as the PID controller has. The adaptive fuzzy controller has minimal overshoot independently of the flow.

The accuracy of the controllers was measured with the conditions used for measuring overshoot, but the measured quantity was calculated on a 200 seconds wide window after the steady-state was reached. The results of measurements are collected together in Table III.

Accuracy [g*s]	100 ml/h	300 ml/h	500 ml/h	1000 ml/h	1500 ml/h
PID	0	0	1	0	1
Fuzzy	494	-42	-718	-5721	-8504
IntegroFuzzy	-662	-1823	-2322	-8214	-8573
AdaptiveFuzzy	135	48	16	-51	-84

Table III. Accuracy

The PID controller had no residual error and in steady state the volume of error slightly differed from 0. On the other hand the fuzzy controllers had residual error, which is clear from Table III. The size of the residual error depends on the flow and in the case of the original controller and the integro-fuzzy controller it is significant at almost any flow. (It has to be stated that the expectation would be the opposite. Still, the integro-fuzzy controller was unable for fine control and the small – 1 gram – errors were accumulated during the measurement. These are the causes for the difference.) The adaptive fuzzy controller has significantly smaller error in the steady state. If it is considered that these results were measured during 200 s, then it can be asserted, that the error of adaptive controller is sufficiently low. Furthermore, some trend can be seen in the case of adaptive logic, as if the integral of error was decreasing with the increase of flow. With simulations on the extremes (50 and 3000 ml/h) it was proved, that the error is sufficiently low even in this range (278 and -141 g*s respectively).

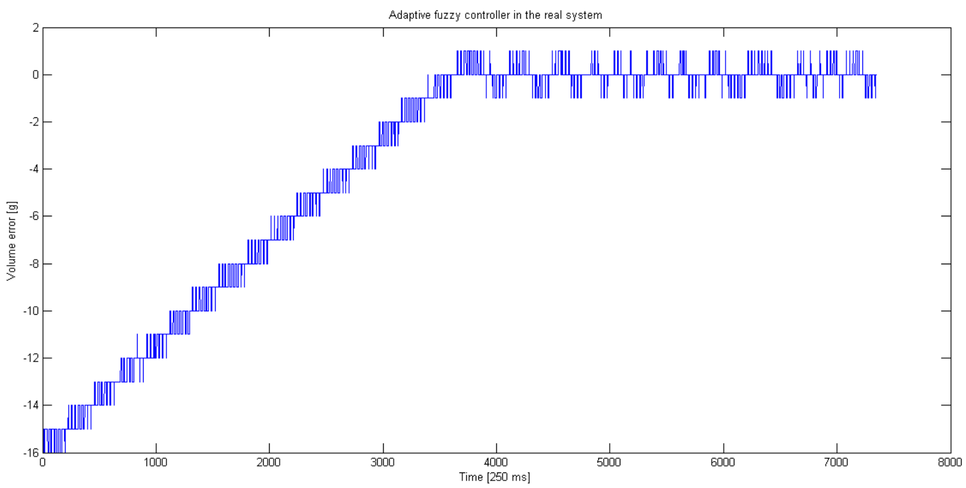
The quantitative measurement for robustness did not happen as it is hard to create quantitative requirements. However, the system stability was checked using errors out of the tolerance range [KJ3]. The swinging of the fluid bag was simulated by adding sinusoid signal on the output of the plant. The amplitude of the sine wave was chosen 10 ml, its frequency was set to 0.25 Hz. A considerably bad tube segment was simulated with a 30% slope error and with 100 ml offset error. The controllers' performance was acceptable in every case. Furthermore, the threshold for instability has not been reached.

At can be stated that, the integro-fuzzy controller showed significantly worse results, than the PID controller or the adaptive fuzzy logic. However, it has been shown that it is possible to control the system with the help of the integral of error.

The adaptive controller is almost as fast as the PID controller, and at higher flows it is even faster. It has minimal overshoot and the residual error is acceptable. As a result it can be said, that the adaptive fuzzy logic could substitute successfully the PID controller. Furthermore, its adaptivity represents a huge benefit for embedded systems.

2.3.4. Evaluation in real environment

The designed controllers were not only tested, but the promising ones were also implemented in the real system. The PID controller was already tested. From the newly introduced controllers the adaptive fuzzy controller was implemented on a machine. The result of the measurement for this controller (at 500 ml/h fluid flow) is shown on Fig. 7.



7. Figure Result on target machine with adaptive fuzzy controller

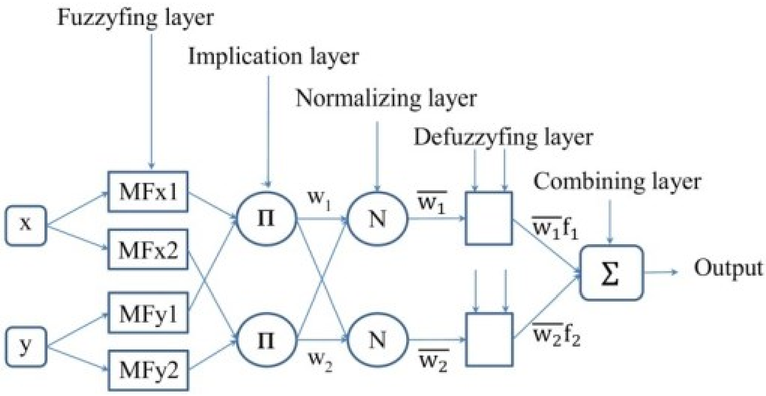
It can be seen, that the real system is significantly slower, but according to [KJ1] this could be expected. The controller was able to compensate the 20 g error introduced, while the slope error was about 10%. Moreover, in the steady state, the system almost always had error, but it never left the ±1 g range. From the picture it can be seen that the resolution of the weighting scale can be measured to the error signal. This makes difficult to find the operating point exactly. This way, it can be expected for the error to appear regularly which confirms the applicability of iterative learning control.

In spite of simulation results and real machine test it can be stated that either the classical PID controller or the adaptive fuzzy control is advised for implementation in a market product. The adaptive fuzzy controller has the advantage of not having any overshoot while the settling time is not increased. Furthermore, the adaptive fuzzy controller is capable to follow the changes of the operating point (changes of transfer volume of elastic tube segment). On the other hand, the PID controller is less demanding in term of computational capacity. Furthermore, the testing and tuning of the PID controller needs less skill and a-priori knowledge compared to the fuzzy controller. Altogether, it was demonstrated that in industrial environment the soft computing method can be as effective as the classical controller and it is only the choice of the company whether to utilize the benefits of the fuzzy controller or to stick the common solution.

2.4. Adaptive Neuro-Fuzzy Inference Systems

The amount of residual error raises the needs for other improved soft computing controllers. Instead of complicating/redesigning the existing fuzzy controllers the applicability of adaptive neuro-fuzzy inference systems (ANFIS) was analyzed [35].

ANFIS systems use a layered structure as shown on Fig. 8. The task is to define the suitable membership functions for fuzzyfication and defuzzyfication (for the “if” and “then” parts) and to teach the rules for the decision making subsystem (in this case the parameters for the neurons) through training [36]. In order to check their efficiency and reliability two different ANFIS controllers were created.



8. Figure Internal structure of ANFIS [37]

In the first case a simple solution was applied; the controller contains an ANFIS system having the error signal as input, while its output is the control signal. In this solution 9 membership functions were used for the fuzzyfication and defuzzyfication (classical ANFIS - cANFIS). The distribution of membership functions followed the pattern used in the previous controllers: Trapezoid membership function are responsible for the extremities and they reach up to ±200 grams where there is a safety threshold. The other membership functionS are triangle-shaped membership functions. Near zero the membership function is selected narrower and wider membership functions are used for bigger errors. Only adjacent membership function may intersect with each other.

2.4.1. Training sets

The training data contained a large recording. In this, the behavior of the PID controller was taken as a sample, and it was mimicked as it has most of the beneficial properties (except the presence of overshoot). Measurements were taken with the PID controller at flows of 100, 300, 500, 750, 1000 and 1500 ml/h [38]. At each flow the input and the output of the PID controller was recorded for:

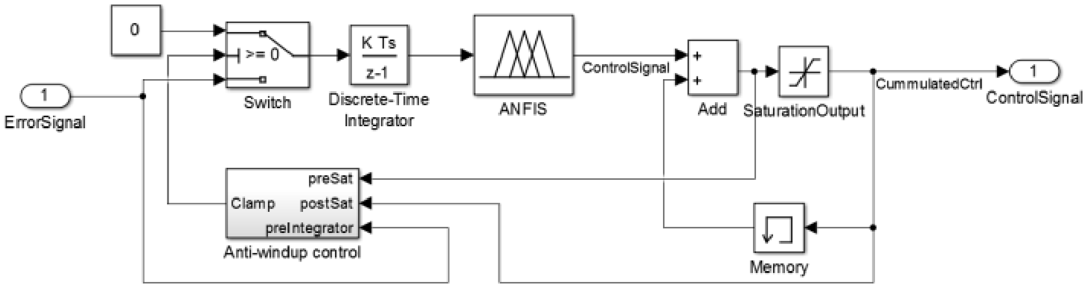
- no offset and no slope error,
- ±5g of offset error,
- ±1, ±3, ±5 and ±7% of slope error,
- ±10% of slope error and ±20g of offset error.

The records were concatenated, but some structures were cut off from them. At higher errors, it has appeared as if large control signal was necessary. In these cases, the rising part of the signal was cut off (e.g. in the case of 10% of slope error and -20g of offset error the first 15-20 measurements were cut off, as this rising part was unnecessary and from the first part of the measurement were kept where the control signal did not changed namely, the compensation was executed). Overshoots were also cut off. This has resulted artificial signals with optimal behavior: The error signal is correlated to the control signal, without any overshoot.

As a result, the training data contained the expected behavior for high, middle and low flows and also for high, medium and low errors in various combinations. This training together with the above mentioned fuzzyfication and defuzzyfication functions has resulted a classical ANFIS controller which has replaced the controller of the system (as shown on Fig.2.).

2.4.2. Controller design

The other designed controller followed the structure of the adaptive fuzzy system from [KJ3]. However, in this case the fuzzy logic is replaced with an ANFIS. This resulted in the modified ANFIS (mANFIS) structure. The input (error signal) is integrated through an anti-windup system, and this is connected to the ANFIS. On the output of the ANFIS iterative learning control method is applied [39, 40, 41]; the saturated output value (control signal) is fed back through a memory unit (Fig. 9.).



9. Figure Modified ANFIS structure with ILC

The simplest description of an ILC can be described with the following equation [34]:

$$u_{p+1} = u_p + K{*}e_p \qquad (7),$$

where u_p is the input to the system during the pth repetition, e_p is the control signal on pth repetition and K is a design parameter representing operations on e_p. To implement it, a simple feedback loop was created, where the final saturated control signal is fed back through a memory unit. This means, that the K parameter is one and the output of the controller (e_p) will affect the final control signal.

The ILC was introduced to eliminate the residual error, which was experienced in case of the classical ANFIS situation (cANFIS). Furthermore, a yet unmentioned problem occurred as well: In one hand the controller has to eliminate the inaccuracy of the tube segment caused by the production, while on the other hand the tube segment will fatigu over time. However, this fatigue will change very slowly (approx. 1-2% per day). As a result, the ILC was introduced to make the controller capable to follow this slow change [42].

The idea behind this concept was to combine the adaptivity reached through iterative learning control and the optimal control behavior reached by training sets. In this case 7 membership functions were used for fuzzyfication and defuzzyfication. The extremities were covered by trapezoid membership functions as characterized in Eq. (5) and the intermediate ones were triangle-shaped membership functions as described in Eq. (1). Near zero the membership functions were tighter, and only adjacent membership function were let to intersect each other [43].

Training data was manually generated in this case. The target values of the control signal were extracted from the measurements done with the PID controller (when there was only slope error). The output was defined to reach this limit in 10-20 steps (more steps in case of high flows, less steps in case of low flows). The goal was to avoid the remaining overshoot and achieve better result compared to the already mentioned PID controller.

2.4.3. Evaluation of controller performance

Results are presented mostly through the defined metrics just like above. The four controllers (PID as reference, adaptive fuzzy system as best solution from previous comparison, classical ANFIS, and modified ANFIS) were compared through the given properties and only the one with the best performance was realized in practice in a real hemodialysis machine.

The examined properties were settling time, overshoot, accuracy and robustness measured at flows of 100, 300, 500, 1000 and 1500 ml/h just like in the previous comparisons.

In order to examine the settling time 5 ml offset error was applied simulating a static 5 ml of volume error. 0% slope error is applied, which assumes an ideal tube segment. The error was considered compensated, when the error signal first reached value 0 and did not leave its ±1 ml environment. (The ±1 ml tolerance is due to the quantitation error.) The results are shown in Table IV.

Settling time [s]	100 ml/h	300 ml/h	500 ml/h	1000 ml/h	1500 ml/h
PID	888	296	184	92	65
AdaptiveFuzzy	888	296	178	92	61
cANFIS	888	296	177	96	68
mANFIS	889	296	178	92	61

Table IV. Settling time results

Regarding the settling time, relevant difference could be found compared to [KJ1] [KJ3]. This is due to the changed saturation rules, which are in the new model stricter. Furthermore, the flow dependence is closer to the real behavior of the system, which verifies the changes.

The controllers have minimal differences compared to each other. The PID controller is slower at 500 ml/h and the cANFIS is slower at 1500 ml/h than the others, but the difference is insignificant. The settling time at the lowest (100 ml/h) flow increases drastically for every controller hence, it would be advisable to further decrease it if possible.

A worst case event was set to examine the overshoot of the controllers; the tube segment was able to transfer 90% of the expected volume (-10% slope error) and the system was also weighted with 20 ml volume error (20 ml offset error). The measured overshoots are presented in Table V.

Overshoot [g]	100 ml/h	300 ml/h	500 ml/h	1000 ml/h	1500 ml/h
PID	1	2	3	6	9
AdaptiveFuzzy	1	1	1	2	2
cANFIS	1	1	1	2	2
mANFIS	1	1	1	1	1

Table V. Overshoot results

At higher flows the PID controller had overshoot. The adaptive fuzzy system and the ANFIS controllers had only minimal overshoot, the least in case of the cANFIS (here it is basically equal with the quantitation error which was desired).

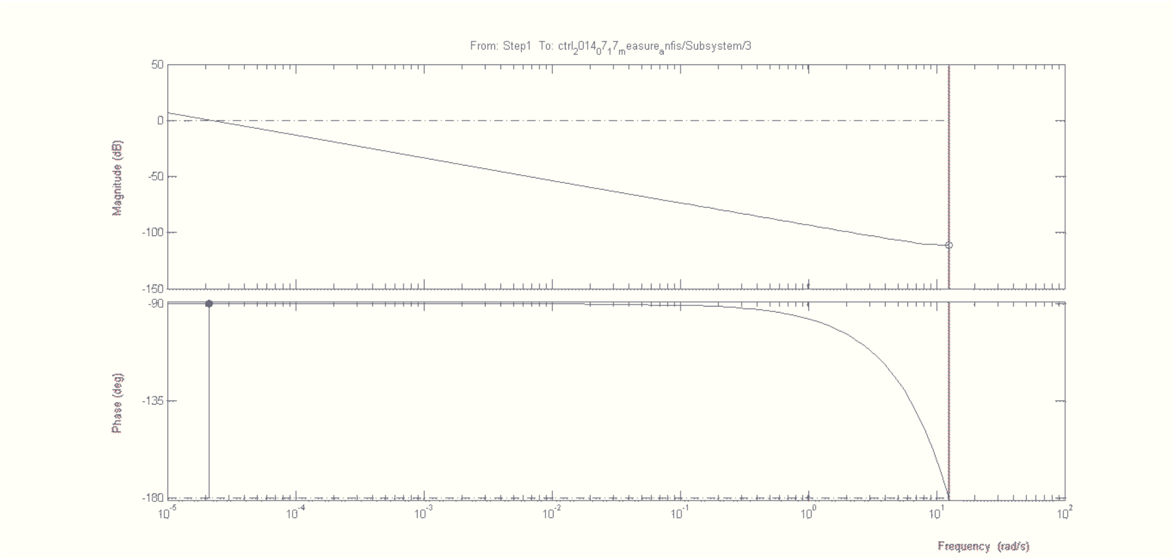
From accuracy point of view, the same settings were used as in the case of overshoot investigation (-10% slope error, 20 ml offset error). The quantitative measurement included a 200 s long integration of the error signal in steady-state. Results can be seen in Table VI.

Accuracy [g * s]	100 ml/h	300 ml/h	500 ml/h	1000 ml/h	1500 ml/h
PID	-1	-1	1	0	1
AdaptiveFuzzy	-3	0	-3	-5	-4
cANFIS	-102	-100	-122	-213	-304
mANFIS	0	2	-1	-2	-2

Table VI. Accuracy measurement results

The task of the controller was not only to compensate the errors (tube segment error, volume errors, etc.), but to remove residual error in order to reach a strict control. The PID controller had virtually no residual error. The adaptive fuzzy system and the mANFIS had only minimal residual error that can be tolerated. The cANFIS had relevant residual error; hence, it is clear that at higher flows it was not able to keep the error at zero levels.

Finally, from robustness point of view the controllers were checked using the same methods as in the previous experiments. At first a sine wave was applied as weight error, which simulated periodic disturbances (e.g. shaking of the weighing scale). The amplitude was 10 ml with the frequency of 0.25 Hz. Secondly, an extreme disturbance out of range error was applied and a tube segment with -20% delivery error and 100 ml of volume error. The controllers kept their stability with acceptable performance. The stability of the system is analyzed in Fig. 10. The phase margin was 90°, while the gain margin was 112 dB, confirming the stability of the system.



10. Figure Bode-diagram of modified ANFIS structure

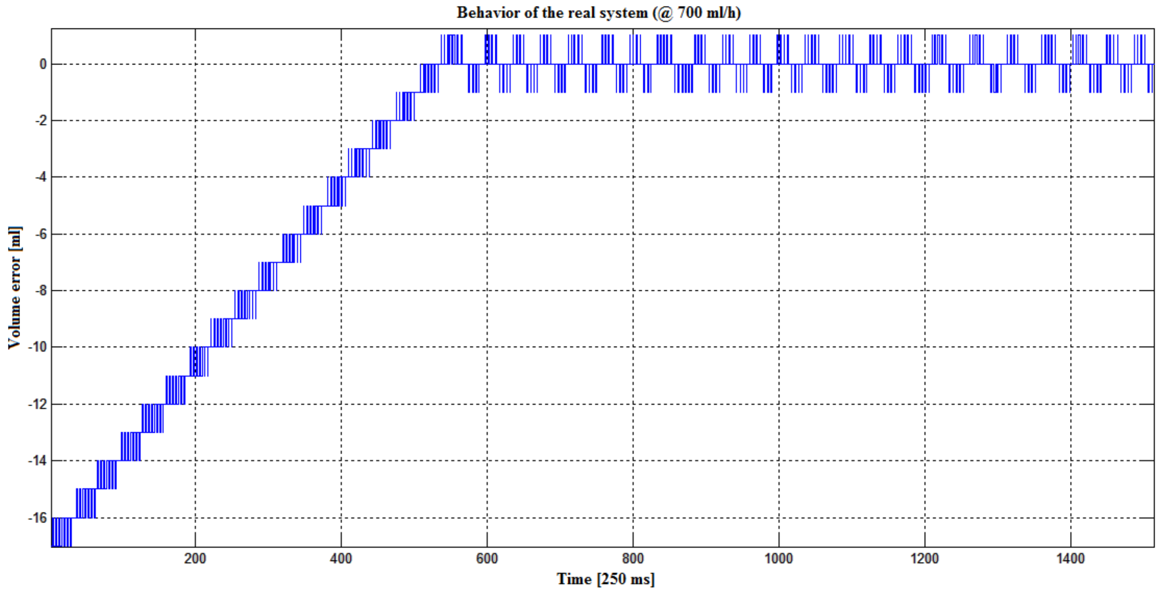
One relevant property of the controller is also how they can adapt to their environment. To check this property, a common tube segment was defined. In reality the tube segment has an error, meaning that this error should be compensated and use it as an operating point. The designed PID controller is not adaptive; hence, automatic adjustment is required in real time [43] [41]. It can compensate the errors, but it is unable to adapt to newer working points. On the other hand, the other three controllers (adaptive fuzzy system, cANFIS and mANFIS) were capable to adapt.

The PID controller is computationally the least expensive, the other ones require more resources for their operation. The adaptive fuzzy system needs empirical experiences with the pump, as these experiences are built in the fuzzy logic. The ANFIS controllers need training data for teaching and their structure has to be defined.

From the examined controllers above the best choice proved to be the mANFIS controller. It eliminates residual error; also it has no overshoot and has the same settling time as the others. Furthermore, the teaching (creating a training data set) makes it easier to modify and reuse compared to the adaptive fuzzy system.

2.4.4. Evaluation on real machine

Thus, the mANFIS controller was realized and tested on a real hemodialysis system where the result are shown on Fig. 11.



11. Figure Results with modified ANFIS controller on target machine

The real system was weighed with 20 g of weight error, the tube segment had unknown delivery error. It took 127 s for the controller to compensate the errors and reach the steady-state. It is slightly slower than during the simulation, but this was expected similarly to previous measurements. In steady-state the volume error fluctuates between ±1 ml due to the high quantitation error. The result for three selected controllers can be seen on Table VII. where the measurements were executed on a real hemodialysis machine.

@ 1000 ml/h	Settling time [s]	Overshoot [g]	Accuracy [g*s]
PID	618	4	12
AdaptiveFuzzy	875	2	43
mANFIS	772	1	37

Table VII. Measurements on the real system

The settling time is reasonable if the higher amount of error is considered. The differences between the results are caused not only by the differences between the controllers, but by the differences between the tube segments as well. As every measurement ("treatment") requires new tubing, it could happen, that one tube segment has for example +5% of error, while the other one has -7% error.

It can be concluded, that in terms of settling time and accuracy, the PID controller is the most beneficial, and also this is the least demanding in terms of computational capacity. The fuzzy and the ANFIS controller has the benefit that they have only a minimal overshoot (basically equal with the quantitation error of weight measurement). Here, the modified ANFIS has lower settling time and better accuracy which predetermines that it is the better soft computing controller from all of the designed controllers.

However, before the application of modified ANFIS controller it is recommended to execute some improvements. First of all, the number of neurons and their relationships should be optimized for better computational efficiency. Secondly, a training data set should be created based on the expectation: It works to mimic the PID controller, but better result could be achieved by using expert knowledge, idealizing the control itself. Finally, it would be beneficial to provide some simple way for fine tuning the controllers (e.g. direct setting of sinapse parameters ω_{kn}). This is recommended as the creation of training data is slow and not straightforward for users with less knowledge in soft computing methods.

Altogether, it can be stated that the classical PID controller can be used in this control problem. However, it has some properties which either need to be neglected or should be fixed with additional "expert systems" (e.g. handling transfer volume changes caused by pressure ratio changes). The control problem can be solved with soft computing methods too, where the use of fuzzy controller complemented with iterative learning control circuit and an ANFIS system has been proved. These controllers already contain expert knowledge and their performance is satisfactory even when compared to the PID controller. On the other hand, they require more computational capacity which might limit their application in such embedded systems. Still, it is mostly up to the decision of stakeholders which solution to use. Probably this research helps the spreading of soft computation methods in (safety-critical) industrial applications.

On the long run (apart from optimizing the fuzzy control) it would beneficial to analyze the control possibilities considering a systematic approach. Namely, in case of drug administration it is the target to minimize the error and provide as accurate transfer rate as possible. Otherwise, the target is to keep the fluid balance of the patient. It is a satisfactory solution to control each pump individually and this way the resulting fluid balance will be correct. However, in certain situation this is not an optimal solution as the temporary flow rate changes (e.g. compensation of some error) might result unnecessarily high fluid balance change.

According to these facts it would be interesting to analyze the resulting flow of the system and set the control signals considering this so called net fluid removal. This can be already solved by multiple input single output (MISO) controllers. However, it would be even more beneficial when the cross relationships of the pumps would be explored and by using this information a multiple input multiple output (MIMO) controller could mean the optimal solution of this problem.

2.5. LMI-based feedback regulator

As it was implicitly mentioned in the previous chapters, the classical PID controllers are favored in industrial application [44]. The reasons behind this are that PID controllers are easy to tune, easy to implement and easy to understand (thus easy to debug). Moreover, the controller design is executed by personnel with little knowledge about the optimal tuning of PID controllers. Therefore, the aim was not only to demonstrate the industrial applicability of soft computing methods, but to provide a systematic design method for conservative companies. Consequently, in this part a non-conventional design method is presented which can be used in safety-critical applications. The details of Linear Matrix Inequality (LMI) based feedback regulator design is presented via Tensor Product (TP) transformation.

In order to do this, the first step is to characterize the behavior of the system. According to previous results this could be written in the following form for an ideal case:

$$v_{ideal}(t + Ts) = v_{ideal}(t) + K_{u0nom} , \quad (8)$$

where u_{0nom} is the nominal flow and v is the transferred fluid volume, K parameter defines the transfer and T_s is the sampling period (250 ms).

This has to be modified according to the following when different error sources are considered:

$$v_{real}(t + T_s) = v_{real}(t) + K\, u_{0real}\, (1 + u), \quad (9)$$

where $u_{0real} = u_{0nom} + u_{0error}$ and u is limited by the system requirements. (Here, u_{0real} is the real flow, u_{0nom} is the nominal flow and u_{0error} is the error of flow.)
The pressure dependence is neglected at first, as it is more practical to correct it with a feed-forward control, while for the other parts a feedback control was designed.

The K parameter can be considered time invariant for the controller design as its changes are negligible because detectable changes can be measured over days (multiple hours). The system itself is much quicker compared to these changes in normal operation.

The structure of the model is based on the one already presented one in the previous chapters with the improvements introduced for the fuzzy controller design. Here, the model comprises two branches, both with the same plant. The first branch realizes an ideal behavior, where the ideal transfer volume is calculated. In the second branch the real transfer volume is created by introducing the offset and slope errors. The schematic of the applied model is the same as on Fig. 2.

The possible errors include slope error, which simulates the volume error of the tube segment. With constant error the deviation of production can be simulated, while a slow dynamic change can be introduced to mimic the fatigue. A static offset error can simulate accumulated volume error in the system. The dynamic offset error can simulate unexpected environmental effects, such as the partial block of tubing, movement of weighting scale or other disturbances.

The error signal is created by subtracting the real transferred volume from the real transferred volume. Then, the control signal is created and fed back to the system. It is important to note that the control signal is limited in the one hand due to the hardware issues that prohibit the use of arbitrary control signal. On the other hand – and this is a stricter limit – there are system requirements, based on given standards that strongly limit the magnitude of the control signal. This saturation is embedded in the model.

2.5.1. Controller design

The following error system can be concerned to design a controller [45, 46, 47] by creating $\Delta v = v_{real} - v_{ideal}$:

$$\Delta v(t + T_s) = \Delta v(t) + K\, u_{0nom}\, u + K\, u_{0error}, \qquad (10)$$

where the goal of the control is to reach zero state. In the formula T_s means the sample time, Δv is the change of transferred mass, u_{0nom} is the nominal flow, u means the current flow rate, u_{0error} is the error of flow and K is the parameter of the system (as above).

The main idea is to design a PI controller, as the proportional component is capable to eliminate the error of the tube segment (slope error), while the integrator is responsible to eliminate the other error components, especially the small ones by accumulation. Discrete controller has to be designed, as the controller is applied in a real machine.

The control input of the PI controller can be determined as follows:

$$u = -\begin{bmatrix} F_1 & F_2 \end{bmatrix} \begin{bmatrix} \Delta v(+z) \\ \sum\big(\Delta v(+z)\big) T_S \end{bmatrix} \qquad (11)$$

where z is the measurement error and the integrator eliminates the effect $K\, u_{0error}$ of (3), *F1* and *F2* are the controller's parts.

Equation (3) expanded with the integral of Δv results:

$$\begin{bmatrix} \Delta v(t+T_S) \\ \sum_0^{t+T_S} \Delta v T_S \end{bmatrix} = \begin{bmatrix} 1 & 0 \\ T_S & 1 \end{bmatrix} \begin{bmatrix} \Delta v(t) \\ \sum_0^{t} \Delta v T_S \end{bmatrix} + \begin{bmatrix} \mathrm{K} u_{0real} \\ 0 \end{bmatrix} u + \begin{bmatrix} K u_{0error} \\ 0 \end{bmatrix} \quad (12)$$

The goal is to create complete state feedback to reach zero state control. The target is to prove that control design based on Linear Matrix Inequalities (LMI) techniques is effective in safety-critical systems. First, Tensor Product (TP) model transformation is applied according to [49, 50, 51].

The Linear Parameter Varying (LPV) model can be written as (using the accustomed notation):

$$\boldsymbol{x}(t+T_S) = \boldsymbol{A}(p(t))\boldsymbol{x}(t) + \boldsymbol{B}(p(t))\boldsymbol{u}(t),\ t \in \Omega \quad (13)$$

where $\boldsymbol{x}(t) \in \mathbb{R}^{n}$, $\boldsymbol{u} \in \mathbb{R}^{j}$, $\boldsymbol{A} \in \mathbb{R}^{n\times n}$, $\boldsymbol{B} \in \mathbb{R}^{n\times j}$ (n=2, j =1 here) and the state variables are:

$$\boldsymbol{x}(t) = [\Delta v(t) \quad \textstyle\sum_0^t \Delta v(i) T_S]^T \quad (14)$$

the control signal is $\boldsymbol{u}(t)$

the scheduling parameter is represented by $p = u_{0real} \in \mathbb{R}$,

the $\boldsymbol{S} \in \mathbb{R}^{n\times n+j}$ parameter depending state matrices are:

$$\boldsymbol{S}(p) = [\boldsymbol{A}(p(t)) \quad \boldsymbol{B}(p(t))] = \begin{bmatrix} 1 & 0 & K u_{0real} \\ T_S & 1 & 0 \end{bmatrix} \quad (15)$$

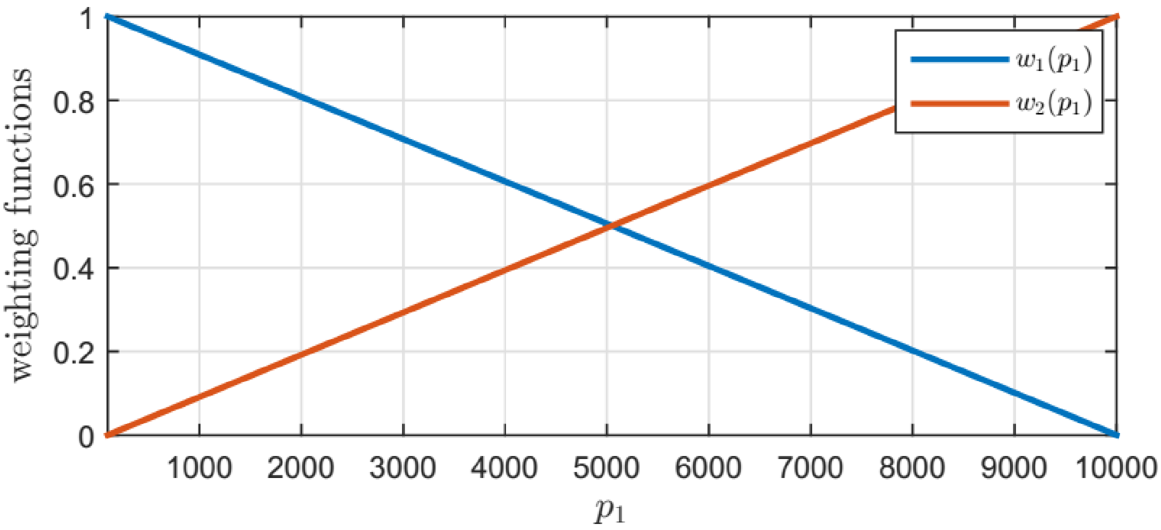
The TP model resulted by the execution of the transformation [48]:

$$\boldsymbol{x}(t+T_S) = \boldsymbol{S}(p) \begin{bmatrix} \boldsymbol{x}(t) \\ u(t) \end{bmatrix} \quad (16)$$

where $\boldsymbol{S}(p)$ is given in a convex tensor product form:

$$\boldsymbol{S}(p) = S\, x_1 \boldsymbol{w}(p) = \textstyle\sum_{j=1}^{2} w_j(p) \boldsymbol{S}_j\ ,\ \boldsymbol{w} \in \mathbb{R}^{j} \quad (17)$$

The resulting $\boldsymbol{w}$ weighting functions are shown on Fig 12. weight.



12. Figure Weighting functions

The control input was sought for full state feedback control in addition to quadratic stability of system (15) in spite of [50, 52, 53].

In order to numerically solve the above mentioned LMI problem, the YALMIP toolbox [52] and MOSEK solver [53] were used for optimization. Further details of calculation can be found in [KJ6].

During implementation, anti-windup feedback was applied to the system, as saturation occurs.

2.5.2. Evaluation of the controller

The quality of the designed controller was examined by the following properties:

- settling time
- overshoot
- accuracy

The settling time was examined by assuming ideal tube segment (no slope error) and measuring how much time does it need to compensate 5 ml error. The idea behind this is that there are some cases when the system may accumulate volume error. A good example is if the weighting scale is got stuck temporarily for a brief time (e.g. it is pushed against a bed).

This compensation time was measured over the regular flow range of the system (100-1500 ml/h). Also the minimal compensation time was calculated. The average settling time was 1.67 times more than the minimal compensation time ($\sigma = \pm 0.1$). These values are acceptable, as during the calculation of minimal compensation time some issues were intentionally neglected (e.g. system delay, inertia of the pump, etc.). Furthermore, the slower system means that the machine is gentler to the patient, due to the smoother compensation and the less impulse-like compensations. Altogether, this seems to be an optimal comprise between compensation time and patient needs.

The investigation of the settling time and the overshoot used the same assembly. Here a worst case situation was examined, namely the tube segment had the biggest acceptable error (-10% slope error, less volume transfer), while high, namely 20 ml, offset error was introduced (according to the normal behavior this means a rarely occurring high error during standard operation). The settling time was measured according to the following method: from the start of error injection the time was measured until the error signal does not leave the ±3 grams range.

Overshoot cannot be measured below 1000 ml/h, the maximal overshoot was measured at 1500 ml/h with the value of 3 ml. The overshoot of the system was minimal; hence, it can be neglected. Although this parameter may be seemingly less relevant, it still has a greater importance. The overshoot gives information about the patient burden of the control. The overshoot is a temporary volume error, which is not inherent. This error is introduced by the controller and it burdens the patient by administering or removing too much fluid to/from her/his body. As a result, the 3 ml overshoot is an irrelevant amount compared to the blood volume of a human (which is approx. 5 liters).

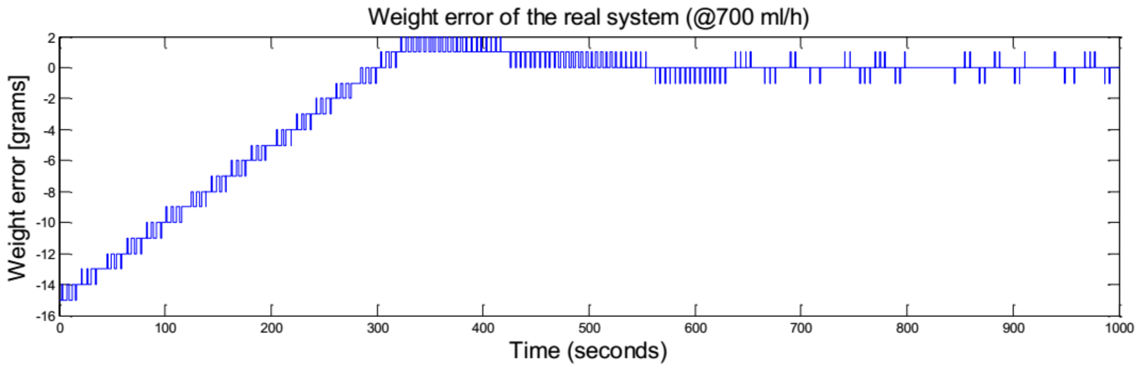
The settling time is in correlation with the patient fluid balance. It is inevitable to keep the patient fluid balance (sum of removed and administered volumes), otherwise the patient could get dehydrated or she/he could have too many water in her/his body. To ensure the patient's fluid balance, the long term volume error should tend to zero. To examine this, the integral of the error signal was calculated for a 200 s wide window. The average of sum of error was 2 ml ($\sigma = \pm$ 1 ml). This amount can be neglected compared to the fluid blood volume, also it proves, that there is no error accumulation in the system.

2.5.3. Verification in real environment

The designed controller was embedded to the real system with automatic code generation.

The previous measures were examined with the real system as well, by preserving the examination conditions. The average settling time was 1.92 times of the minimal compensation time ($\sigma = \pm 0.32$). This amount is significantly higher compared to those obtained by simulations. The most important reason for this is that during simulation ideal tube segment (with perfect transfer) was assumed. However, in the reality this is unfeasible and the tube segment has a transfer error as well. As the system has to compensate the slope error and the volume error, this phenomena explains the difference. The overshoot was similarly zero at low flow rates, while it appears at high (over 1000 ml/h) and the maximal value of overshoot is 3 ml. The average of sum of error in steady-state was 5 ml ($\sigma = \pm$ 2 ml), which is a small increase, but it can be still neglected.

The error signal of a measurement on the real machine is presented on Fig. 13. The quantitation error presents that the weighting scale is capable to measure the weight as an integer. This situation explains the reason why the derivative of the error signal could not be used for controller design; although it would have been beneficial.



13. Figure Result of PI controller on the target machine

Further research will focus on the optimization of the anti-windup system, according to [54], [55]. The pressure dependence is neglected at the moment, but it could be compensated with a feed-forward control. This should be also integrated in the system.

2.6. Conclusions

During the research I have successfully designed fuzzy controllers, ANFIS controllers and a PI controller engineered via TP transformation. Each of these controllers were compared with a reference PID controller. The following conclusions can be made: The PID controller can be effectively used for controller the fluid transportation, but it is not capable to adapt to the changing environment (fatigue, pressure change, etc.). Moreover, it does not incorporate any additional expert information regarding the system. The adaptive fuzzy controller has no overshoot, while it has similar performance compared to the PID controller. It includes some expert knowledge. However, its resource requirement is higher, which could be improved by using Sugeno-type fuzzy logic. The modified ANFIS controller again has similar performance, without overshoot. In terms of computational capacity, this is the most demanding option. However, it has the potential to outperform both of the previously mentioned controllers with an improved training set. The designed PI controller shows the importance of tuning and also it shows a technique which could be effectively used in practice.

As a conclusion, I would advise the industrial users to use PI or PID controller with proper tuning method instead of the ones used generally. If the resource is not so limiting then I would suggest using fuzzy controllers, as it contains the knowledge commonly accumulated in companies which could mean competitive advantage against other manufacturers. Finally, if the resource need does not mean any problem and there are available people with related knowledge then I suggest to use ANFIS controller. With proper training set this could mean an optimal solution with adaptivity together with the embedded expert knowledge. Furthermore, the ANFIS controller is the one which could be extended most easily to an advance MIMO control system.

Thesis Group 1

Thesis group 1: Non-conventional control methods of hemodialysis machines

Thesis 1
I have designed and compared multiple controllers for the transfer volume control of hemodialysis machines. These controllers were compared with a classical PID controller in terms of settling time, overshoot and accuracy. In case of fuzzy controllers a Mamdani-type inference system using integral of error signal completed with anti-windup system and iterative learning control circuit proved to be effective. Regarding ANFIS method, an ANFIS system completed with iterative learning control circuit proved to be effective. Finally, an LMI-based feedback regulator development was demonstrated via TP-transformation for those developments where there is no customary design method for PID controllers and it is intended to stick to this classical control method.

Thesis 1.1
I have created and demonstrated that using a fuzzy inference system where the error signal and the integral of the integral of error signal were used to create the control signal. Furthermore, I have created an adaptive fuzzy controller with the help of iterative learning control method. This latter adaptive fuzzy controller is comparable to the reference PID controller in terms of accuracy and settling time. Moreover, it has no overshoot and it is capable to adapt the changes of the tube segment such as fatigue. The applicability was verified with testing the controller on a target machine which confirmed the results of simulation.

Thesis 1.2
I have created two ANFIS based controllers and demonstrated their usability considering practical implementation. One of them was a classical ANFIS system, while the other was completed with an anti-windup system and an iterative learning control circuit. This latter modified ANFIS system is comparable to the reference PID controller in terms of accuracy and settling time. Moreover, it has no overshoot and it is capable to adapt the changes of the tube segment such as fatigue. The applicability was verified with testing the controller on a target machine which confirmed the results of simulation.

Thesis 1.3
As PID controller is still commonly used in industrial application it is vital to provide design methods to find optimal control. In this part I have demonstrated how an LMI-based feedback regulator can be designed with the help of tensor product transformation. The design controller had satisfactory results both in terms of accuracy, settling time and overshoot when implemented on a hemodialysis. It proved to be applicable as a systemic design method which can be utilized in other safety-critical applications as well.

Relevant own publications pertaining to this thesis group:

[KJ1], [KJ2], [KJ3], [KJ4], [KJ5], [KJ6],

3. Application lifecycle management system improvements

3.1. Basics of application lifecycle management systems

So far the development of a single system component was presented. However, it is not enough to integrate every components into the system, but also it has to be ensured that the machine is safe for every intended application. Safety-critical systems have so high risk of causing harm that this risk must always be reduced to a level “as low as reasonably practicable” (ALARP) required by ethics, regulatory regimes, and standards (IEC 61508). Therefore, the manufacturer is responsible for guarantying the safety for customers where the manufacturer promises the guarantee via statements and external certification bodies and authorities are responsible for its inspection. (With other words: the safety compliance is certified by independent organizations.) A very good summary can be read about different roles in [56].

However, safety is not obvious in software development. With the growing complexity of software it is getting harder to test it exhaustively to explore every malfunction. This way only a majority of problems will be revealed and the possible occurrence of errors cannot be specified exactly only statistically. Therefore, not the software itself is the main target of inspections but the development process instead. (In spite of the above mentioned facts, it is very interesting that the probability of occurrence of software failure is 100% by definition.)

Furthermore, it seems to be logical to use highly qualified developers in order to achieve high quality software. Interestingly, the practice shows otherwise. It is more important to have a well-established workflow, which contains steps not only for developing but for controlling as well. According to studies [6, 57, 58] it is more effective to have a well-designed and executed process than committed people.

The reason behind this might be found in the human nature which is error prone especially in repetitive and/or boring tasks. Therefore, these processes consists not only steps for the execution but also for monitoring. With continuous reviewing and analysis the mistakes can be discovered and corrected. Furthermore, the software engineers get feedback about their job and about commonly committed mistakes. Altogether, this is the only practical way to achieve the goal: software with satisfying quality for the consumer. However, it is subject of debate which software development approach is better [59, 60, 61, 62].

This does not mean that skilled developers are unwanted anymore, but it means that the human factor shall be reduced as much as possible. Due to these reasons various measures can be done. A typical example is the coding/modelling guideline. This simple prescription creates a base for common work which results better overall understanding (readability) and reduce the chance of integration problems. Furthermore, it often contains defensive techniques to avoid frequent programming mistakes (e.g. in “if 10 = = i” statement always checks equality, while “if i = = 10” can be mistaken with “if i = 1” assignment check). Moreover, processes usually require the mutual analysis of each other’s work products (reviews), and also there shall be a guide which defines how the certain development steps are following each other (called development process) which prevents aberrations.

Meanwhile, stakeholders and organizations have realized that certain measures are more effective at certain fields. This has resulted that upon agreement a set of selected recommendations have been collected and are enforced on every manufacturer of the respective field. These regulations and recommendation can be found as the appropriate standards and directives. Each safety critical field have its own main standard (e.g. ISO 26262 for automotive, DO-178C for avionics, EN 50126 for railway and ISO 13485 for medical domain). Moreover, it is satisfactory to use some selected standards, but every related (specific) standard and directive has to be applied.

For the special case of medical software development, the standard IEC 62304 Medical device software - Software life cycle processes, was released in 2006, and is under review to be harmonized with ISO/IEC 12207:2008 (Systems and software engineering -- Software life cycle processes).

MDevSPICE® [63] [64], released in 2014, facilitates the assessment and improvement of software development processes for medical devices based on ISO/IEC 15504-5, and enables the processes in the new release of IEC 62304 to be comparable with those of ISO 12207:2008. The above points give just a glimpse of the changes heavily affecting software developers in the medical devices domain.

Instead of containing actual recommendations of techniques, tools and methods for software development, IEC 62304 encourages the use of the more general IEC 61508-3:2010 Functional Safety of Electrical/Electronic/ Programmable Electronic Safety-related Systems – Part 3: Software requirements, as a source for good software methods, techniques and tools.

The above mentioned standards should be completed with the ISO 14971 safety standard together with ISO 13485 quality standard. Furthermore, the regional or country specific regulations have to be complied, again just as an example the Medical Device Directive for the EU or the regulations of Food and Drug Administration (FDA) in case of the United States.

The examples above illustrates well the struggle when every relevant prescription has to be selected and considered. The required processes mean significant documentation burden and practically compliance is impossible without the use of supporting tools. These tools support various fields of development: requirement management, change management, version handling, architecture modeling, test documentation, project management, etc. Altogether, they are called application lifecycle management (ALM) tools or ALM system. (There are also product lifecycle management systems which are highly similar with slightly different scope.) In this research only a part of the above mentioned tools are considered, namely the ones which are directly involved in the software development process. This way requirements management, test management and issue management are covered together with workflow control, but for example project- and quality management are omitted for the above mentioned reasons. Fig. 14 [65] shows well the general concept by connecting requirement-, test- and change management artifacts and placing it in the context of the global development process and management.

14. Figure Content of an Application Lifecycle Management System

3.2. Heterogeneous and homogeneous ALM systems

The tools are selected by the manufacturer and they have to fit into the company processes. Most commonly plan driven software development is applied in such developments; although this is not required by standards and directives [66]. Therefore, ALM systems on the market target mostly companies with plan-driven software development method [67] [68], but these systems use different approaches by accentuating different components. Companies should be careful when choosing or replacing ALM systems. Some of the most important factors to be considers are listed below without the need for completeness. During the evaluation of different setups it should be checked:

- What is the actual cost of the tool (licenses, education/training, maintenance, need for a server, cost of migration)?
- What costs can be saved (additional automation, reduced human effort, difference compared to the previous system)?
- What can be saved by improved usability and maintenance (mostly work hours, but morale may change as well)?
- What indirect benefits can be achieved (direct connection with existing tools, better transparency, easier audition)?
- What can be ground for refusal (security risks, global strategy, exclusive suppliers)?

Some of these factors are hard to measure if it is possible at all, but on the long run it is worthy to evaluate precisely as it can be a key factor in the future [KJ7].

Depending on the choice, few to many different tool suppliers might be chosen. Every stored item in the ALM system, which is related to the software development process one way or another, is called artifact. The aim of the development is to generate every artifact and their connection correctly, besides shipping a working software of course. Depending on the number suppliers and the connectivity of selected tools heterogeneous and homogeneous ALM systems can be distinguished.

ALM system is homogeneous in case of a single (or few) suppliers with great interconnectivity. Here, the overall visibility of artifacts is good, and the relationship between artifacts can be easily created and maintained. Most of major players [69] have tools or program suites to satisfy most of the needs (e.g. IBM Rational Family, HP Quality Center or Polarion ALM just to mention a few).

However, software development and the market of ALM solution is a quickly evolving and fast changing field with many competitors. This way, it can be risky to rely on a single manufacturer especially when considering that maintenance should be provided sometimes over decades. On the other hand, it also happens to tailor ALM system together from different tools due to historical reasons, special needs or owned knowledge [KJ7] [KJ8]. In such cases, the transparency is reduced, the connection of artifacts in different tools needs to be created (typically manually) and the users have to switch between the different interfaces.

Altogether, this raise the need to connect the components of a heterogeneous ALM system in a unified manner to get rid of disadvantages and exploit the benefits. In this part of thesis I demonstrate a novel and general (software independent) approach through an example which is capable to significantly improve the usefulness of heterogeneous ALM systems and even homogeneous ALM systems can benefit from it. However, it must be highlighted that the research itself can be considered as a feasibility study. Therefore, each of the size of the database, the complexity of analysis and the number and type of used tools could be increased one by one. Under the present circumstances the presented systems are suitable for the initial conclusions and additional experiments, but before actual utilization they should be definitely expanded.

Connectivity inside of heterogeneous ALM systems is not the main topic of this thesis, but it is important to discuss in order to understand better the motivations. It is straightforward that it is necessary to make available every necessary item for the corresponding people and only for them. With other words, repository with suitable access right setting is inevitable together with proper version control.

The number of used tools in a single development shows that the idea of single repository is not working. In case of this approach, the conception is to keep every item or its copy at a single location where each of the tools can access to it. Only the number of artifacts already makes it difficult to setup and handle such a repository, not to mention other problems. The parallel usage and conflict handling can be cumbersome even for single files with few concurrent users and the hardship can be imagined if this problem is scaled up to company level. Furthermore, a single repository is more vulnerable to data breach, as in this case all information can be directly accessed after am intrusion. These problems and other (nowadays) self-evident features (e.g. chat-like commenting possibility) make this approach impractical at least for substantial developments.

Another approach is the point-to-point integration where the different tools are connected via scripts or simple middleware. This practice still can be observed, especially, when few tools needs to be connected to the otherwise compact system. However, this solution is very expensive. Not only the scripts and middleware has to be written one-by-one, but also when a tool has a major upgrade its interfaces have to be revised. The price of regular modification is still high independently whether the connections are maintained by third party or they are supervised by internal personnel. In some cases this technique is inevitable, but generally it is advised to keep the number of its application low.

A next level of integration is the (Enterprise) Service Bus. The participants are still able to get in interaction with each other, but this is done via an intervening level instead of direct connection. This middleware is capable to communicate in every direction with the other tools and it is responsible to hide the difference of interfaces during communication. The benefit of this solution is that only a single entity has to be maintained. However, the solution is still rigid. For example it could be problematic to handle different versions of a single tool with different interfaces. (In case of legacy and maintenance problems this might easily occur.)

The state-of-the-art solution is performed by the Open Services for Lifecycle Collaboration (OSLC). OSLC uses web services to integrate the different tools. It does not create an intervening layer between the tools, but it defines standardized interfaces for the different use-cases (requirement management, change management, etc.) considering the specialties for each of these domains. All the major player with relevant market share have joined to this initiation which way it means a reliable solution for integration. The interfaces (so called adaptors) are maintained by the vendors, so the maintenance cost is reduced from the side of the users. Furthermore, it makes possible to connect artifacts via URIs without copying objects which is significant saving both in data storage and power resources. Clearly, it was created to serve the connection and interaction based development environment of our decade. Moreover, it is fulfilling the four criteria of linked data by Tim Berner Lee [70].

It is advised to use OSLC for integration to utilize the ideas later discussed in this part of thesis. If I might use this metaphor: it is always better to speak a common language then using a translator continuously. Furthermore, some traceability related problems (discussed later) can be easily solved with the direct connectivity. Even more, with the general availability it is possible to create dedicated interfaces for user groups where the commonly used functionalities can be reached from a single windows without switching there-and-back of different applications. This highly improve the user experience and slightly reduce the workload.

Naturally, there are mixed solutions on the market. It is worthy to mention Kovair Bus which is working as a service bus, but it is supporting and using OSLC protocol on its interfaces. The most important benefit of this solution is that they can hide custom (non-OSLC compliant) interfaces and omit the need of writing separate OSLC adaptors. However, it has the same disadvantage as a completely homogeneous ALM system. Namely, the development is relying on a single vendor.

3.3. Traceability and Consistency

Traceability is connection between different artifacts. With its help it is possible to follow and inspect each development phase beginning with the original requirement through the implementation until the final validation of the finished software. This way it is not only possible to know about the reason of presence of each line of code, but also it is possible to check which processes were applied during the development. The latter is more important, because the quality of code is guaranteed by processes instead of people and tools. Either way, traceability represents some kind of connection between different artifacts which is most commonly parent-child relationship.

One of the important question of software development is to guarantee the traceability throughout the development. Traceability can be realized in various ways. It is enough to use unique identifiers and refer to it at other occurrences, but it is also possible to use direct links (e.g. URIs). This latter has the benefit to reach quicker the linked artifact which is helpful in many situations.

Bidirectional traceability is a key notion of all process assessment and improvement models. [71] reports about an extensive literature review which classifies the models involving software traceability requirements according to the scope of the model, that is:

- Generic software development and traceability including CMMI and ISO/IEC 15504 evolving into the ISO/IEC 330xx (Information technology -- Process assessment) series of standards (SPICE).
- Safety-critical software development and traceability including DO-178C (Software Considerations in Airborne Systems and Equipment Certification) and Automotive SPICE.
- Domain specific software traceability requirements which, in the case of medical devices for example, include the already mentioned IEC 62304 (Medical Device Software – Software Life Cycle Processes), MDD 93/42/EEC (European Council. Council directive concerning medical devices), Amendment (2007/47/EC), US FDA Center for Devices and Radiological Health Guidance, ISO 14971:2007. (Medical

Devices – Application of Risk Management to Medical Devices), IEC/TR 80002–1:2009 (Medical Device Software Part 1: Guidance on the Application of ISO 14971 to Medical Device Software), and ISO 13485:2003 (Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes)

It ought to remember about the fact that the medical domain typically follows the automotive domain [72], so it is rewarding to follow it to be prepared for possible changes.

It is important to highlight that traceability is fully recognized as a key issue by the agile community as well [73] [74].

Unfortunately, complete and consistent traceability as well as the actual assessment of the satisfaction of the crucial traceability requirements is practically impossible to achieve with the heterogeneous variety of application lifecycle management (ALM) tools that companies are using [75]. Following a manual approach, which is the only existing choice, traceability assessors can only rely on sampling which has ultimate weaknesses detailed later in this paper.

It is evident that there are software development artifacts that can only be created by humans (customer expectations, sales, market research, etc.). Yet, there are other artifacts which can hardly be managed manually including for example the documentation of low level test results or results of automated testing (e.g. static and/or dynamic code analysis). Similarly, the number of relationships, including traceability links, between the different artifacts becomes prohibitive even in the simplest practical cases, so the handling and maintenance requires automated support.

It is a fact that 50-60% of software defects are related to requirements development [76]. Here, the rate of leakage (inherited defect which is detected only at a later stage) is 53% in the requirements phase and 68% in the design phase [71]. It is trivial that this problem raises the need for the improvement of current tools used to manage software development, especially requirements management.

Despite these facts, a significant proportion of people in charge of software development see traceability as a mandatory burden or as a useful but cumbersome duty [77, 78, 79]. The need for traceability is undeniable, but the full compliance is difficult to enforce in everyday practice [80]. An example of the need is a developer exploring the code for possible effects of code modification. But a new employee also needs the traceability feature to get familiar with the code and the system it models. Furthermore, valuable indicator numbers can be presented with its help for the (upper) management. Finally, assessors have to rely on the traceability system to ascertain about the capabilities of the processes [81].

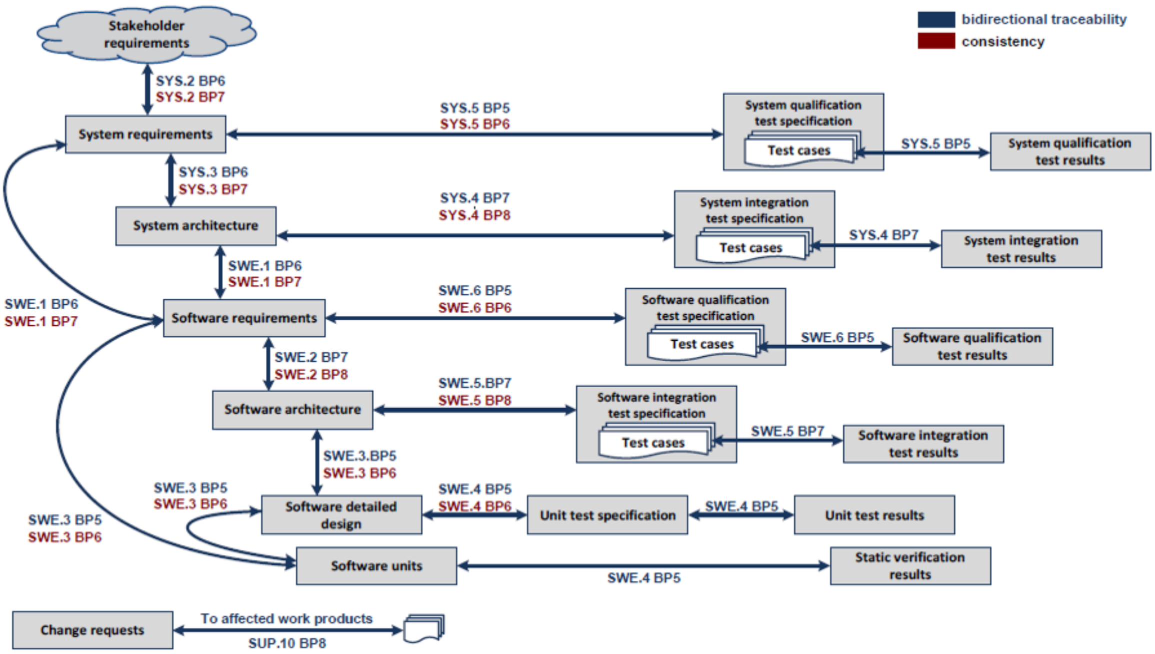
The aforementioned problems coincide with our experiences [KJ10]. Although, senior management is most of the time aware of the importance of traceability, developers are naturally prone to neglecting it. Paradoxically, developers are the ones who first suffer from the deficiency of traceability (e.g. code fragments to redesign for satisfying requirement changes are difficult to find) and their productivity is definitely increased in case of a well-designed traceability environment.

Therefore, to solve this contradiction traceability should be ubiquitous as it was explained by Gotel at al. [82] and it is one of the best summary. In their perception traceability shall be:

- „Purposed. Traceability is fit-for-purpose and supports stakeholder needs (i.e., traceability is requirements-driven)."
- "Cost-effective. The return from using traceability is adequate in relation to the outlay of establishing it."
- "Configurable. Traceability is established as specified, moment-to-moment, and accommodates changing stakeholder needs. "
- "Trusted. All stakeholders have full confidence in the traceability, as it is created and maintained in the face of inconsistency, omissions and change; all stakeholders can and do depend upon the traceability provided."
- "Scalable. Varying types of artifact can be traced, at variable levels of granularity and in quantity, as the traceability extends through-life and across organizational and business boundaries."
- "Portable. Traceability is exchanged, merged and reused across projects, organizations, domains, product lines and supporting tools."
- "Valued. Traceability is a strategic priority and valued by all; every stakeholder has a role to play and actively discharges his or her responsibilities."
- "Ubiquitous. Traceability is always there, without ever having to think about getting it there, as it is built into the engineering process; traceability has effectively "disappeared without a trace."

It is the aim of this thesis to show a method to get closer to the above mentioned ubiquitous bidirectional traceability.

The latest version of AutomotiveSPICE requires consistency beside traceability Fig.15. This seems to be an uprising trend, because it seems to be self-evident not to have contradiction between the different work products. However, achieving this goal is absolutely not self-evident. In case of huge databases (e.g. in case of requirements) it is likely to find items which at least partially contradicts. The situation is even more crucial in case of many product (software) variants or in case of frequent modifications. The reason behind this is that there is basically no one who oversees everything which makes possible to get such mistakes undetected, especially in case of simple numeric refinement. Unfortunately, the literature regarding consistency is less extensive compared to traceability problems.



15. Figure Traceability and consistency relationships in Automotive SPICE v3.0

A missing traceability link does not necessarily means possible malfunctions. (Although, it indicates inappropriate processes.) On the other hand, inconsistency will likely cause unwanted operations due to its nature. Furthermore, the absence of any relationship can be easily detected, while the quality and quantity of existing links are more difficult to evaluate (to have exactly as much relationship as required, all pointing to the right direction). The situation is the same in case of consistency: The involved items cannot be simple processed (numerically), but their content shall be also considered. This and the qualitative traceability analysis both raise the need for sophisticated approaches to be able to handle them.

3.4. Augmented Lifecycle Space

ALM environments can and mostly do provide extensive support for creating traceability links and overviewing existing links. There is however a fundamental difference between creating, overviewing links and proving that no links are missing which is the exact duty of the assessor and fully justifies the ultimate need for Automated Traceability Assessment.

The difference is a special case of the logical difference in mathematics between the proof of the existence of an object satisfying given properties and the proof of the non-existence of such an object. The existence (∃) can be proven by showing an instance, while the proof of non-existence is equivalent to showing that the property is not satisfied by any object (∀), which can obviously be much more difficult.

Regarding the task of traceability assessors, the currently only possible manual approach they have to be content with is sampling which has ultimate weaknesses in addition to the logical difficulty of proving non-existence described before:

- Traceability is basically restricted to the closed ALM system. Representational State Transfer (REST) APIs are mostly available for providing internal data. However, there is need for a standardized open form of exchange made possible by the emerging OSLC (Open Services for Lifecycle Collaboration) approach to be discussed.
- Useful traceability reports including the traceability matrix can be generated. However, the manual processing of these reports, due to their size, is only possible with very small examples whose complexity is exceeded by the simplest industrial applications. The reports only contain already existing artifacts while missing artifacts can only be discovered by manual inspection. The reports are static while requirements and identified defects, for example, are very dynamically changing artifacts, and may even originate from outside the ALM system.
- Assessors and users may be easily confused by the complexity of the set of widgets, such as buttons, text fields, tabs, interfaces, and links which are provided to access and edit all properties of resources at any time.
- Assessors and users need to reach destinations such as web pages and views by clicking many links and tabs whose understanding is not essential for the assessment.

In summary, the logical and technical challenges themselves, together with the people and process challenges, fully justify the need for the automation of the assessment and improvement of the completeness and consistency of traceability [83].

In spite of the facts above it is highly recommended to take preventive steps and to improve the existing ALM system. The idea of Augmented Lifecycle Space (ALS) was create by Biro et al. [KJ10] for this reason, namely, to improve existing ALM system without using additional software tools. The main target of ALS is to find missing relationships, artifacts and inconsistencies in the analyzed system and to provide workflows in order to correct the found problems.

The benefits of ALS are most clear in heterogeneous ALM systems, but even homogeneous systems can utilize it. At first, the generic approach will be presented which have to be tailored to the ALM system where it is used. Afterwards, it will be highlighted which participants and how can benefit from the usage of ALS approach.

The Augmented Lifecycle Space approach suggests to utilize the following steps in order to achieve its goals [KJ10]:

“1. Categorize all existing artifacts of the homogenous or heterogeneous tool environment according to the elements of the chosen model containing traceability requirements (e.g. requirement, architecture element, test case, etc.).

2. Analyze the existing relationships (links) and the artifacts in the system and identify those which are missing but should exist according to the traceability requirements of the model.

3. If one of the two artifacts necessary for a required relationship is missing, automatically augment the system with the corresponding artifact whose links will be initially missing of course.
4. Analyze the relationships (links) of the augmented system. If a relationship (link) required by the model is missing, then automatically generate the task of the workflow for bridging the relationship gap.
5. Execute the relationship gap bridging workflow generated in the previous step involving manual intervention if necessary."

As it is clear from the enumeration above, the steps were created to be generic to make it possible to use in any environment. As it was stated previously, this also means that the mentioned steps have to be tailored to the target ALM system and to the existing development processes. The aim of these experiments is to provide an answer for the question raised in [KJ10]: "How to technically access artifacts and their relationship in a homogeneous or a heterogeneous tool environment".

The beneficiaries of application of ALS consists both people from manufacturers and assessors as well. The task of an assessor is to explore any deficiencies related to development processes. This can only be done by using work products and lifecycle management artifacts which highly limits their possibilities and the completeness of the analysis. Such problem is proving the non-existence where traceability links are good shows a good example to the previously mentioned facts. It is more or less straightforward to check traceability links which are necessary (i.e. check them). On the other hand, proving that a traceability link is not necessary is more problematic. The job of assessors cover each cases, but nowadays the limited scope and access makes it impossible to complete their jobs perfectly. With proper categorization and analysis it is possible to check not only the existence and correctness of traceability links but also it is possible to analyze the correctness of non-existence as well.

This is not the only way how ALS approach helps the job of assessors. Nowadays, assessors are relying on samples provided by the company. When speaking about ten thousands of artifacts it is clear that it is impossible to check everything over a few day (maximum a fortnight). Furthermore, it is possible to trick from the side of the company by showing prepared, spotless examples. By using ALS it is possible (for the company) to analyze the whole system and the assessor can check the final result which consists a global overview. This is a win-win situation: the assessor can execute a more complete analyses with less effort, while the company can prepare for the assessment and the deficiencies can be corrected before the visit. This clearly reduces the efforts for an assessment from both side. (Not to mention that the chance of cheating is also reduced.)

In addition to the above, companies have even more benefits from using the idea of ALS. First of all, the navigation will be better thanks to the complete traceability. Secondly, the automatic workflow generation not only disencumber group leaders and lower management, but it also improves overall software quality by quick error correction. The permanent consistence reduces the chances of errors and this way it is reducing development cost. Furthermore, it can be useful for (upper) management as well by providing key performance indicators and guaranteeing continuously proceeding development without relapses. This way the investment into such supervisor system is noticeably rewarding for the companies especially with extensive developments.

3.5. Demonstration of Augmented Lifecycle Space approach

3.5.1. Application practice

The general idea was presented in previous the chapter. However, the implementation raises many technical difficulties which has to be overcome. In this chapter a demonstration project will be presented to show the practical implementation and use of ALS approach. The project was executed in spite of technical action research method [84] for validation.

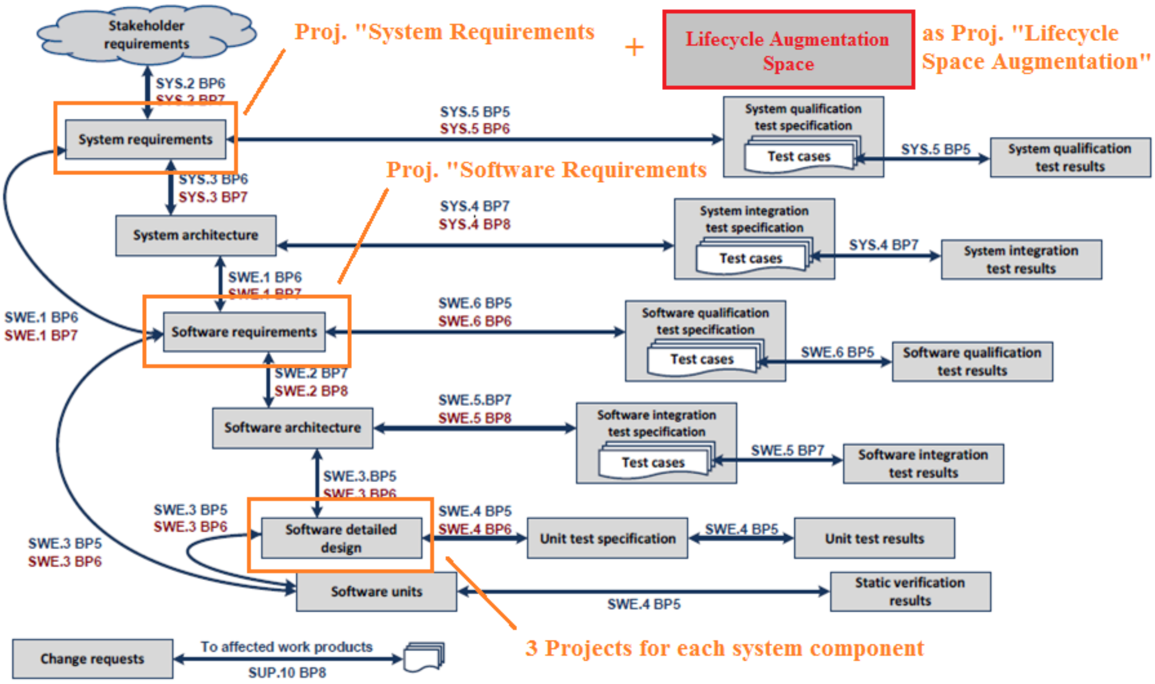
So far general ideas and solutions were presented. Still, it is important to highlight that these researches was created for the medical domain, specifically for the development of hemodialysis machines. This does not affect the general applicability, but still it could be a valuable information for the possible future users. The often referred AutomotiveSPICE contains traceability and consistency related requirements which are expected to be incorporated in the medical domain as well.

The difficulties of connecting different ALM tools is slightly out of the scope of this thesis. It means only a technical (but rather difficult) challenge, but it has no direct connection with the theory of ALS method. Therefore, a homogeneous system was used to execute analysis and experiments to be able to focus on the actual problem. As it was stated previously, it is recommended to use OSLC standard related solutions to connect different tools and create a more homogeneous environment, where Tasktop Sync or even Kovair Bus can be useful as an already implemented integration tool.

For the experiment, I have installed an ALM system purely by using JIRA. JIRA is a trending issue and project tracking software [85]. Although, it is rather young, still it is leading before some elder and more significant players (e.g. IBM or HP) according to Gartner [86]. This means that their vision regarding software development management is progressive, so they know what the actual challenges in the mentioned field are. Meanwhile, they do not only see the problems but they also provide an efficient way to solve it in a user friendly way.

From the scope of the research, another advantageous property of JIRA is that it was possible to mimic the other wanted functionalities as well (requirements management, test management) with some minor modification. This way it was easy to create traceability links (JIRA already supports their creation) and it was possible to access the different artifacts via a single API (JIRA Rest API). However, this is not a limitation but the purpose was to make the demonstration as simple and transparent as possible. The traceability and consistency checker and issue generator was written in C# language and it was executed via web access on the database.

The structure of the demonstration project can be seen on Figure 16. This refers to the already mentioned Automotive SPICE V-model [87], because the traceability and consistency relationships are clearly marked and thanks to the many practical applications it is well explained.



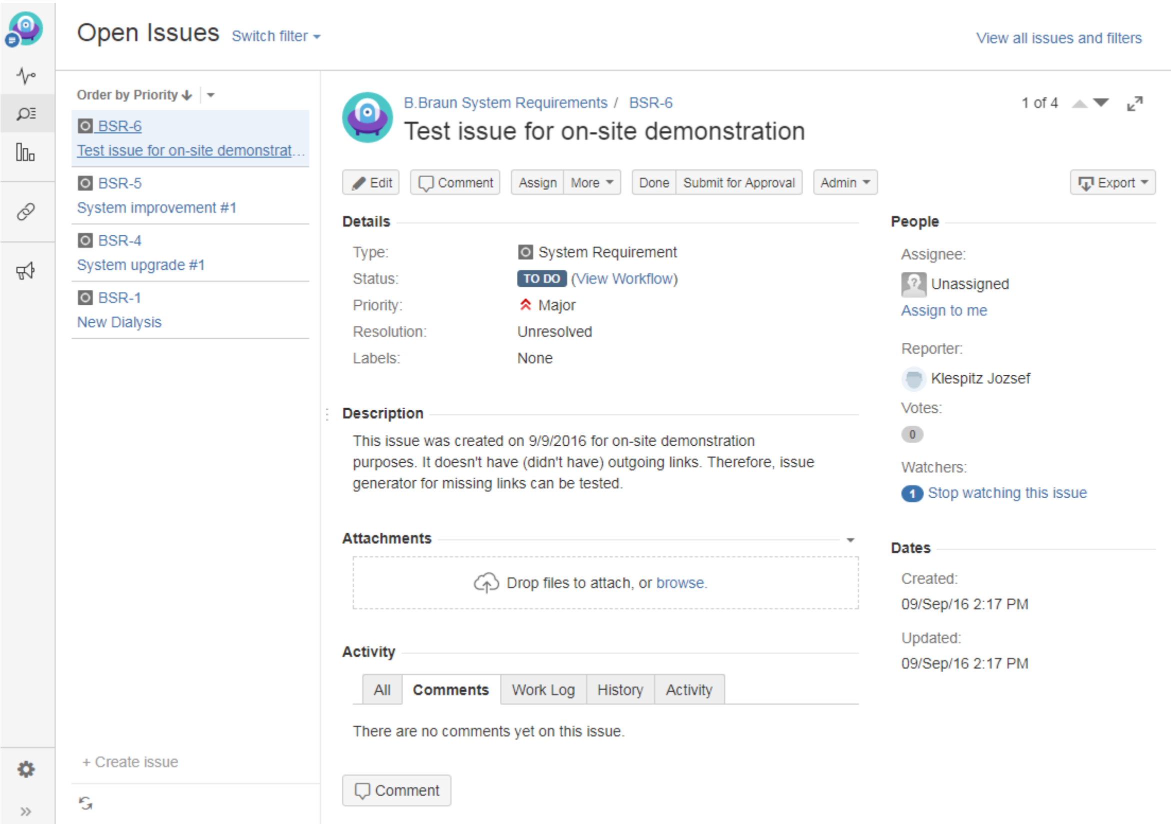
16. Figure Traceability and consistency relationships from Automotive SPICE featured in this research

Another candidate could have been the 'Traces' model of SoQrates Working Group [88]. This model was created especially for traceability and reusability. However, it is still in development and there is less support for the practical application. Nonetheless, it is worthy to keep this model in mind as their approach could help to create more complex analysis for traceability and consistency in the future.

3.5.2. Homogeneous test system

During the examination two JIRA projects were created for requirement management artifacts: one for system requirements, one for software requirements. In practice usually there are more detailed resolutions and finer granulation, but the relationships and their analysis are very similar. Parent-children or ascendant-dependant connection is expected with few (typically one) to many relationships. Meanwhile, semantic similarity persists due to the decomposition. Other conclusions are much more difficult to find or formulate. In case of the requirements the information is stored in project related issues.

The requirements themselves are stored in the description part of an issue (Fig. 17). The status of issue is used to store briefly the activity and life cycle of the requirement (approvals and acceptances). Hierarchy can be created with issue links, where the type is strictly related to the project. Furthermore, issue links are the ones which connects requirements, tests and implementation together. Each relationship has to have its very own kind to make relationships clear and readable. Also, requirements have a unique field called test coverage. The related verification and validation test results are summarized briefly in this field and it is handled programmatically (details below). The statements above are equally true for system- and software requirements as well.



17. Figure Example requirement „issue"

There are three projects responsible for the software detailed design. These projects refer to software components with different safety level. Direct relationship does not occur between these software components. Indirect relationships are defined at higher levels (e.g. interface definitions), but such relationships are neglected during analysis at the moment. Upon expert advisory, the investigation could be expanded.

Similarly as in case of requirements, issues are responsible for the implementation. A single issue is created to a software feature or component which can be reasonable separated from other parts. The description of features can be found in the description part of the issue. Also, issue links are responsible to connect issues with related requirements and test sets. The status is used to follow the lifecycle of the feature in the workflow. In these cases, the workflow is unique (it has to be) and it reflects the readiness of the component. The workflow (behind the issue) has to be set up according to the needs of the developers. This typically means that there are states for approval, implementation, code review, and unit testing.

Two other projects are responsible for system and software tests and they are tightly related to software and system requirements. Issues are created for each single test cases are expected in a manner that the description of an issue contains the detailed test description. Additional remarks can be included in the comments and there is a unique field as well. This latter contains a flag about positive and negative test cases. This is a rough simplification of equivalence class testing [89] yet it is still often forgotten (more details below). The status information is selected from a simplified workflow (just as in case of requirements). Acceptance, approval and progression can be recorded. Issue links are used to connect test cases to the requirements where a quick summary can be created from the number of linked tests and their actual statuses.

Unit test specifications (responsible for testing software detailed design) are omitted as they have no any additional benefit from the perspective of research, they just increase the number of projects and artifacts with no any unique nature. Furthermore, it is worthy to mention that it is practical to use at least partially automated test methods to check the software units due to their high number and fast changing nature.

There is an additional project which is only partially connected to the development process. This one is responsible for the lifecycle space augmentation. The workflow here is created in spite of possible defects what may occur. It basically covers the whole development process, where the possible entry points can be selected to eliminate the found deficiencies. There is no possibility to jump forward in the workflow, because the following items are affected for sure (just as in case of development). Here, the description is responsible to explain the found problem. Issue links are containing the links of related issues in other projects (in order to find them more quickly).

This project is handled separately from the development. It is used only for creating workflows to get rid of the discovered deficiencies. Therefore, it can be treated more lightly with minimal human effort. Moreover, the process (and tool) related requirements are not concerned because these artifacts are not used in any work products. The selected and approved workflows can be later migrated to the development process itself, or these issues can also be used (again after supervision) to programmatically affect the development workflow (e.g. force a workflow into a previously state as if it was not finished).

This system has many deficiencies: First of all, it is impossible to use it in practice. JIRA issues are not designed to work as a requirement management or test management tool. (Although, there can be found complementary programs/extensions among other third party applications.) Secondly, the structure is very rigid and it depends heavily on the workflows.

Developer teams need more flexibility in practice to be able to react on certain exceptional events (e.g. development process change or tool exchange). Finally, it is hard to fit for the needs. Unique fields can be created, but the management (of deviation from standard) can be extremely cumbersome later.

On the other hand, this structure has many beneficial features as well. There is only single tool: This way the user has to learn the usage of a single environment only. A common interface is available, so the user does not have to switch between multiple windows and views. Furthermore, the transparency and readability is great as we are speaking about a homogeneous system. It can be affected with a single programming interface (JIRA REST API). Most of all, the artifacts and the system is homogeneous, thus every item can be handled in the same manner, which makes processing quicker and easier.

Even with all these drawbacks it is still a powerful system to demonstrate the operation and usage of ALS method. By using it, it is possible to focus on the key problems instead of struggling with (important but negligible) technical issues. The previously shown steps regarding the application of ALS method could be implemented as the following:

3.5.3. ALS for homogeneous system

At first categorization is done by analyzing the project names. The project clearly defines the type of stored artifacts, so using a suitable naming convention makes identification easy. Otherwise, semantic analysis is necessary which not only makes the separation more difficult, but also the accuracy is expected to be worse.

The second step is the analysis of categorized items where examination is relied on the already mentioned Automotive-SPICE (see Fig. 15.). Let's consider traceability check and consistency analysis separately. In case of traceability it is important to point it out that relationship (traceability link) should exist only between adjacent levels. (For example a Software requirements should have traceability link to System architecture –as its parent-, it should have traceability links to Software architecture –children- and it should also have links to the related Software qualification test specifications.) This way the analysis should consider first the relationship and the type of relatives. Namely, it should be checked for every requirement that it have a linked parent (if applicable), it have links to its children (if applicable) and also a test specification should be linked. No other traceability link should be accepted. In case of test specification the analysis is simpler. The related requirement should be linked together with the test result (if they are stored separately).

Furthermore, the actual state of the requirements should be considered. The chronology might be disrupted even though the system requirements should precede the software requirements. It is quite common to change high level requirements even in safety critical developments due to changing circumstances and extrinsic expectations. Therefore, if two requirements are found with a valid traceability link, then their last modification date should be checked. In such case the parent requirement must be “older” (sooner modified) than the children. Otherwise, requirements get obsolete and even inconsistencies might occur.

Consistency is much harder to be inspected. From Fig. 15. it can be seen that consistency should be kept throughout the development and the only space where consistency check can be omitted is between test specifications and test results (consistency cannot even be interpreted in this case). There is no simple analytical method contrary to traceability. One possible method could be the semantic analysis of related items. A possible solution could be the use of Fuzzy markup language (FML) to categorize the expression in the different items [90]. The comparison of these items should provide information about possible inconsistencies.

The following step is the augmentation of system with the missing items. This step gives a reaction for traceability problems, and for inconsistencies. If a traceability link is missing it is not unequivocal if only trace link is missing or complete item. Therefore, to give a unified reaction for each cases, this case is always treated as if the link is missing together with the item.

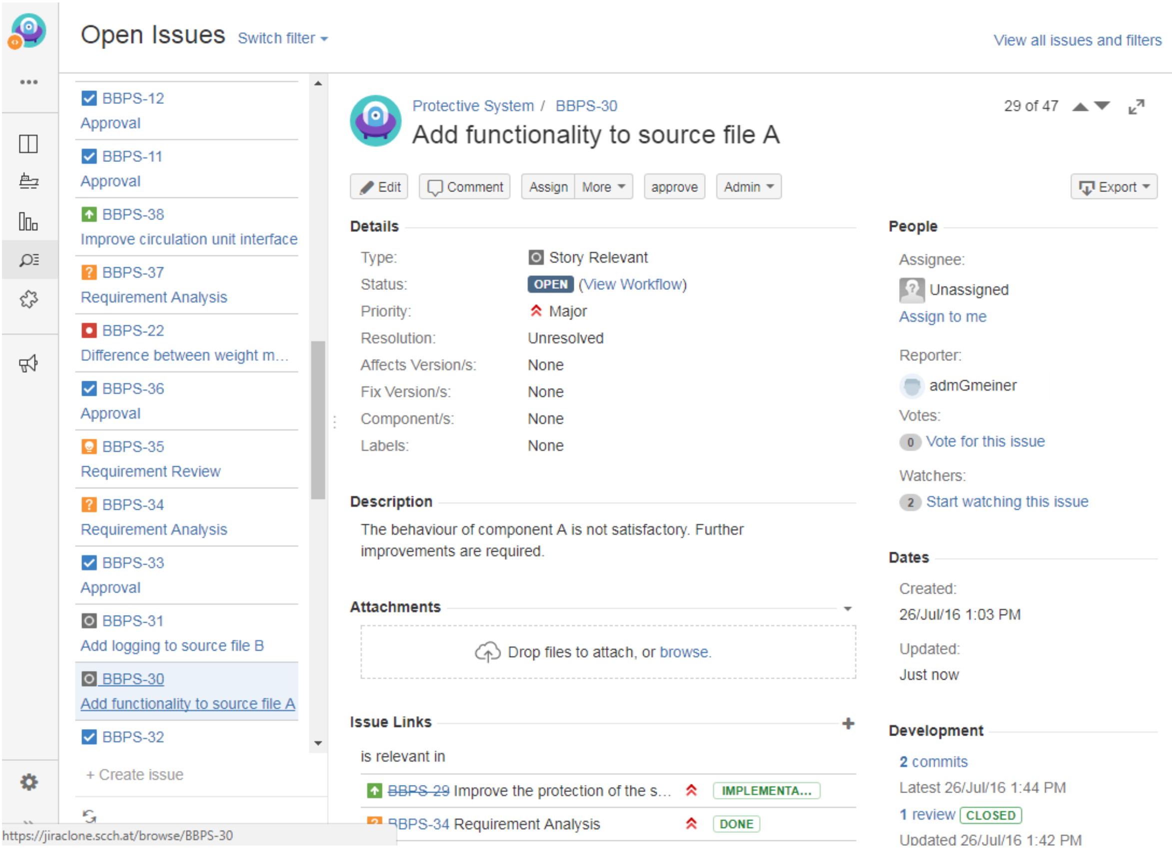
If the chronological order of requirements is broken then review should be prescribed and no augmentation artifact shall be created. Instead, everything can be continued normally if the change does not affect the children. Otherwise, all the dependents should be refreshed. The same methodology should be applied in case of tests. In this case it is self-evident that the test case (together with test results) is the children with later modification while the tested requirement is the parent artifact.

The final step means the execution of workflow. This step includes the creation of augmented artifacts if necessary. However, it is highly depending on the company and their applied practice. Generally, it can be stated that the (later) proposed general workflow of development can be used and this workflow should be redirected to the step where the error was introduced.

In practice the above mentioned steps cannot be separated exactly. Namely, two main steps can be distinguished: During the first step the analysis is executed, while in the second one the workflow designated to solve the problem is generated. These automatized phases can be separated into the particles which correspond to the presented phases of ALS method. The actual operation of the demonstration method is discussed below. First the process of checking is introduced followed by the workflow generation and the structure of generated workflows.

3.5.4. Analysis and detections

The first picture Fig.18 shows the structure of a JIRA issue. What is important from the displayed data is the identifier (generated from the project abbreviation and a constantly increasing unique identifier number), the description (containing every necessary information about the issue, including written metadata to be processed), the issue links (with clear reference to the project and item where they are showing) and the date of last modification. This latter cannot be found, but it is stored in the background.

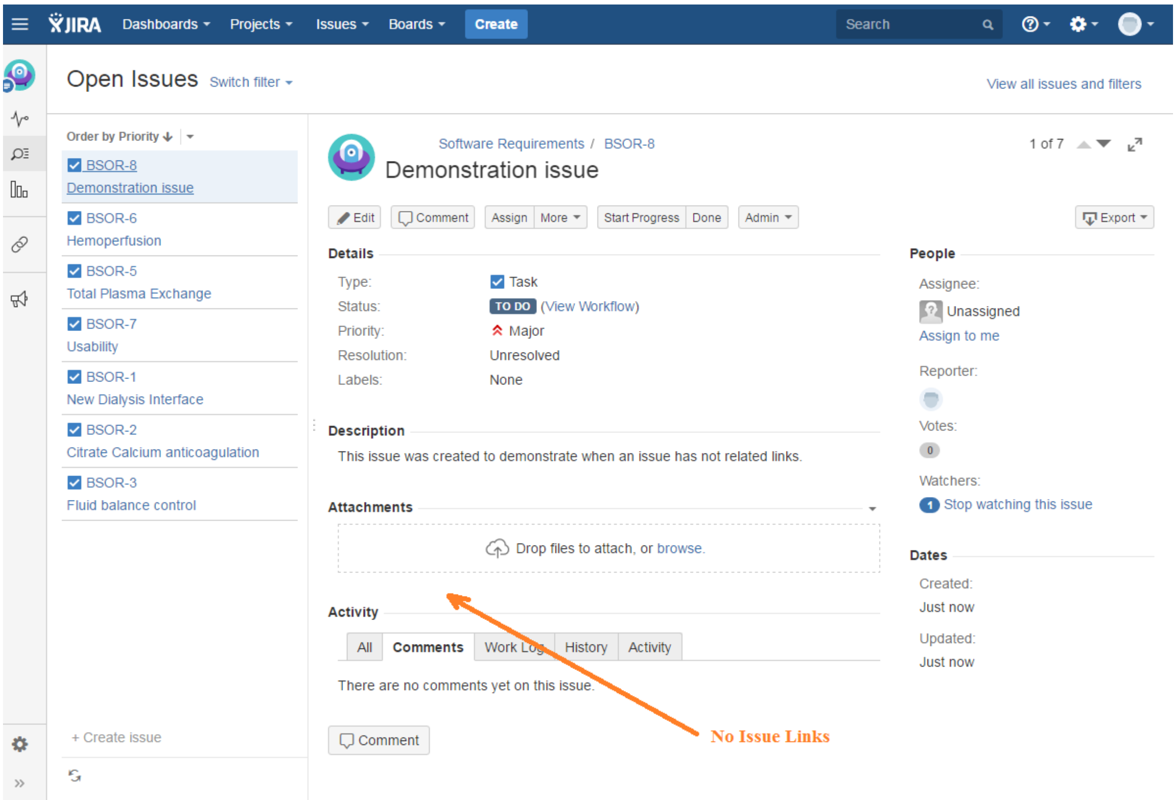


18. Figure Example „issue" with issue links

Initially, the scripts log in in order to get access to the database. After proper identification (which is actually an existing user but this should be replaced with a new identifier designated for this automation) all issue is queried within a single project. Data collection is continued by collecting every issue link associated to artifacts within the project. Every necessary information can be later accessed in the possession of these items.

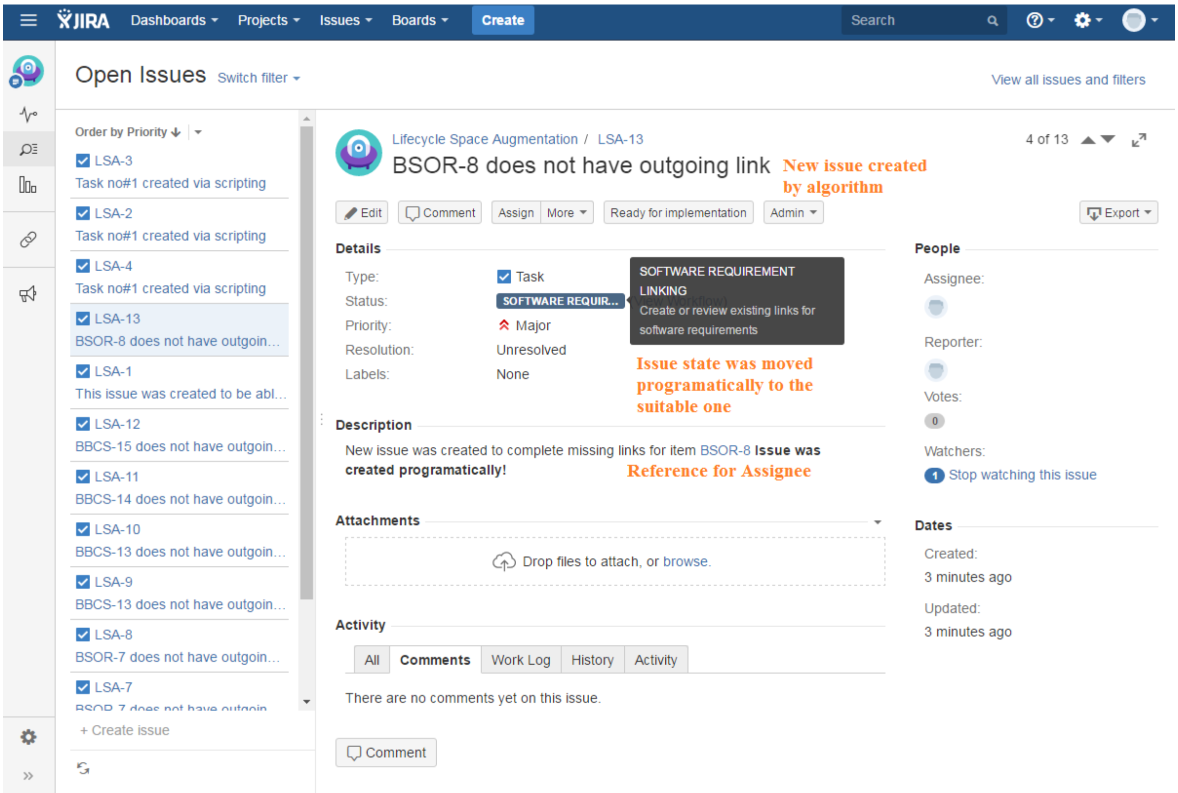
The issue links are checked against the expectation: Top level requirements (system requirements in this case) shall consist links to lower level requirements and to its own test cases. Bottom level requirements (implementation claims in this case) shall consist links to higher level requirements and to its own test cases. Requirements on the intermediate levels (software requirements in this case, but architectures would belong here otherwise) shall consists links to both higher and lower level requirements together with its own test cases. Here, the lower and higher level requirements means a direct level below or above the actual level. In spite of bilateral traceability it is forbidden to jump across multiple levels, a certain requirements shall appear at every level.

The projects belonging to a certain level (containing a certain type of requirements) are stored in look-up tables (in this case with a single entry), while the test cases are stored in a similar way. The collected issues are tested against these groups. If there is no match then the expectation are not met and a new issue shall be generated to the ALS project. The creation of look-up table is permissible as in a typical development the number of groups at certain levels is limited and this structure is changing seldom. Furthermore, the creation and inspection of this structure can be automatized.



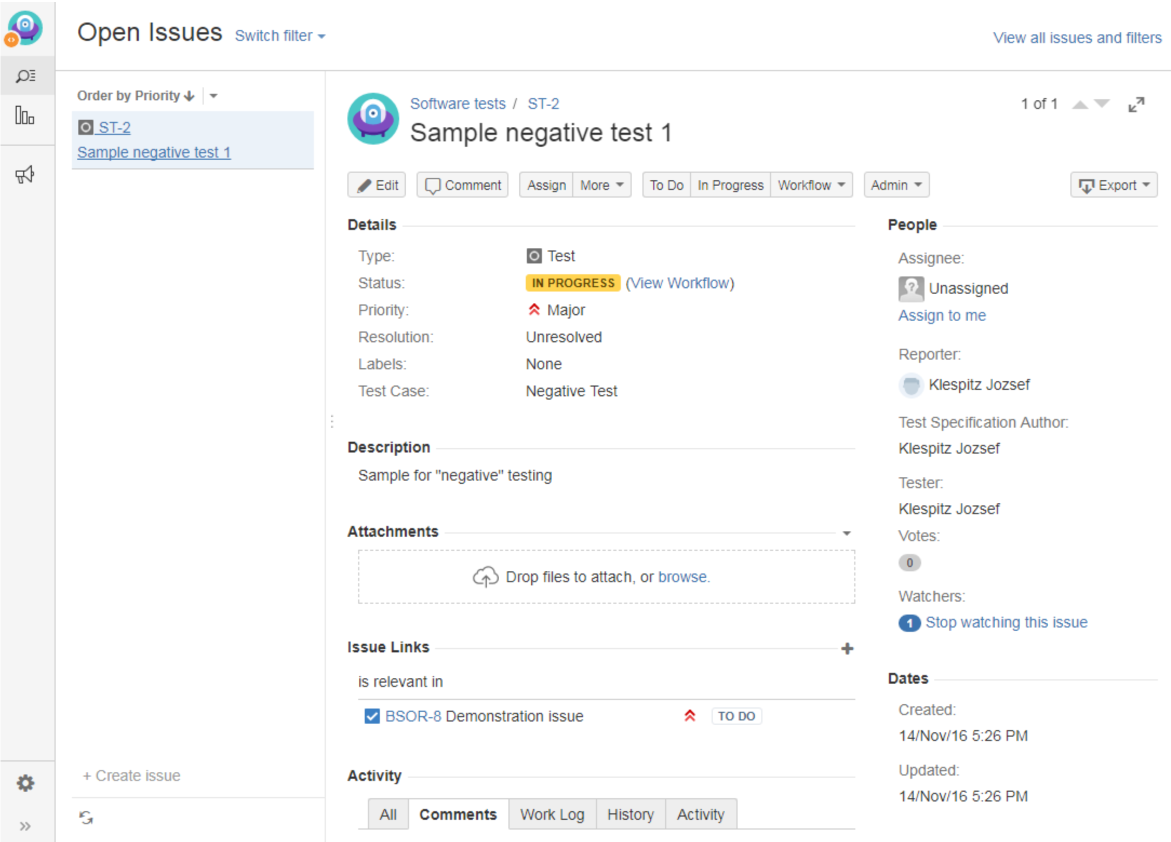
19. Figure Defected issue with missing links

On Fig.19 it can be seen that the issue links field is empty which means that this requirement has no any existing relationship although it should have both incoming and outgoing links as it is a software requirement (known from the identifier 'BSOR'). In response to this on Fig.20 can be seen that a new issue is created in the dedicated project (identifier 'LSA') to fix this issue. In the description there is a clear instruction what caused the generation of this issue with a direct (clickable) link to the origin. It would make sense to add an issue link instead of direct link with the benefit of seeing whether the issue was solved or not (when solved the identifier of issue link is marked with strikeout). However, it must be kept in mind that the project responsible for lifecycle space augmentation is not an existing work product and it is not in any kind of direct relation with the product under development in order to keep it independent and keep it out of scope of standards and directives (together with the involved additional workload). Therefore, it is wise not to create any visible linkage between these projects.



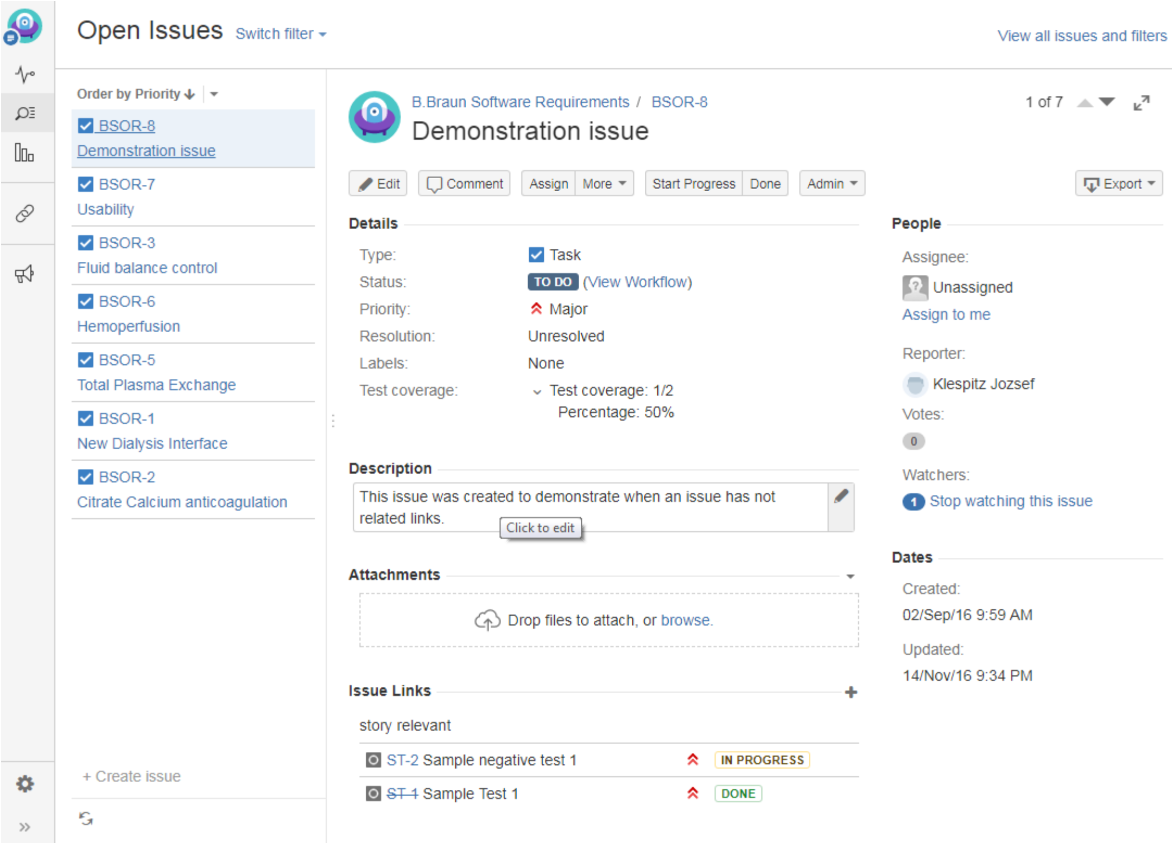
20. Figure Workflow generated automatically to fix missing linking

In case of analyzing the related tests the situation is a bit different. In spite of boundary value analysis [91] it is not enough to test only for valid values but whenever it is possible out of bound values shall be tested as well. It is an important step of assessment to check the existence of each scenario. (For the sake of simplicity inbound tests are called 'positive tests' while out of bound tests are called 'negative tests'.) Therefore, during this analysis it is considered whether a test case is negative or positive and each cases shall be covered at least once. Furthermore, an initiation is demonstrated in case of tests. The total number or related tests are numerated together with their actual state (passed or failed/not tested). From these date a minor indicator, the test coverage, can be calculated. The analysis calculates this as a percentage and it is added to the tested requirement in a unique field (or it is refreshed if exists already).



21. Figure Example test requirement for out-of-bound test case

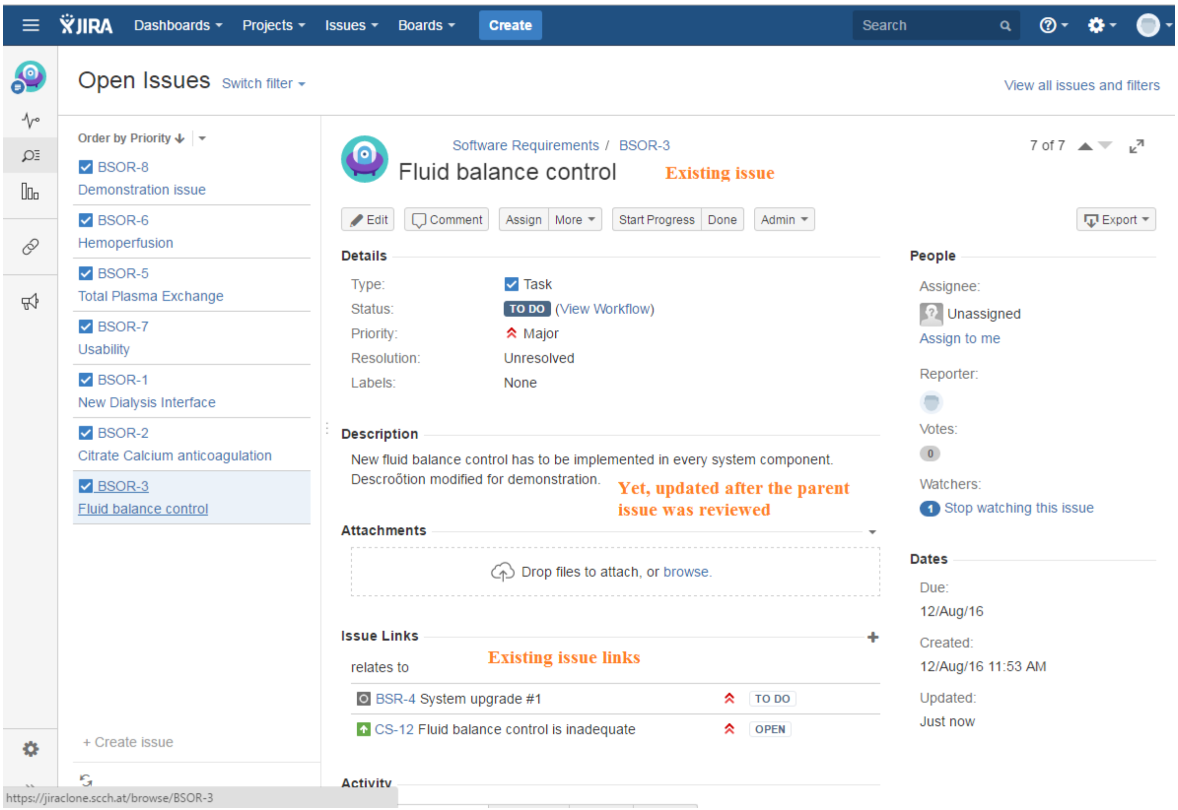
Fig. 21 shows an example for analyzing test cases. It should be highlighted that above in the description there is a custom field showing that it is a negative test case. Otherwise, it would be cumbersome if even possible figuring out whether a given case an inbound or out of bound test. Fig.22 shows the referred requirement. Here it can be seen that one test case is executed (marked as strikeout and status is 'Done'). This can be seen from above where the test coverage unique field is now automatically updated showing that one case is executed, meanwhile another one is pending.



22. Figure Parent requirement of previous test showing test coverage

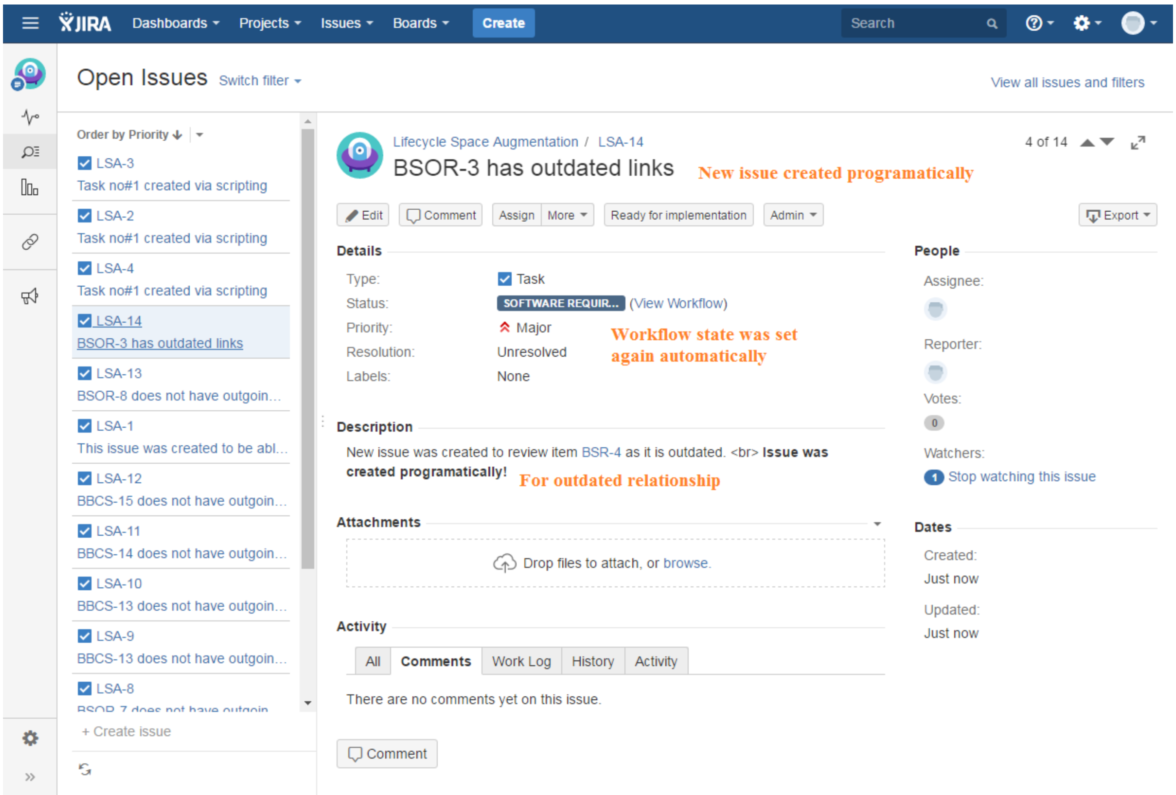
So far information already queried were used for analysis. In order to test obsolescence it is necessary to collect more data. The last modification data of the analyzed item is known and it can be used for comparison. However, the last modification data is unknown initially, they should be requested. Therefore, each issue link of the checked artifact is followed and last modification date is collected from the origin item. Afterwards, it is possible to check the chronological order between the requirements.

Incorrect chronological order shall be revised at least with an additional review to find out whether the modification affects related objects or not. It is important to highlight that this defect appears twice: It can be found when analyzing the parent-child and child-parent relationships. Therefore, it is worthy to check it only in one direction, preferable in the direction of dependency as this is the direction of error spreading as well. Moreover, it cannot be forgotten that these kind of analysis affects not only the requirements but tests as well because this latter objects could also get obsolete. The generated issue in the ALS project shall reflect the above mentioned aspects.



23. Figure Outdated issue

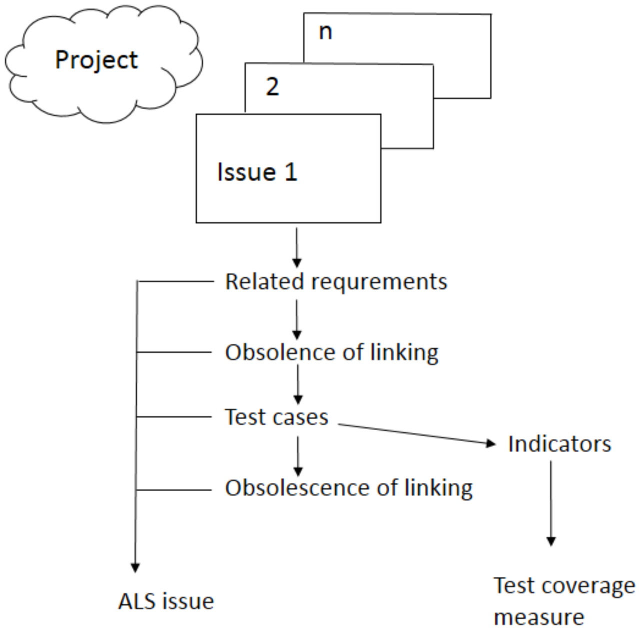
For this scenario Fig.23 is showing an example where the requirements meet every condition but it was refreshed later than its dependents. This fact cannot be seen from the displayed parameters, this kind of defects can only be found programmatically. In response to this an issue generated as shown on Fig.24. The solution is similar as it was shown in case of missing traceability links, but the workflow is set to review the found item instead of create a new issue link as it was prescribed in the previous scenario.



24. Figure Workflow generated for reviewing outdated item

At this point it should be decided whether a single workflow is used for each issue or multiple different workflows for each type of problems. This latter provides the possibility to evaluate each case in a unique manner and it also keeps the possibility of handling very similar cases separately. However, it is only seldom needed as the original development workflow is typically a homogeneous process with as few case handling which makes it possible to get rid of problems induced by the diversity.

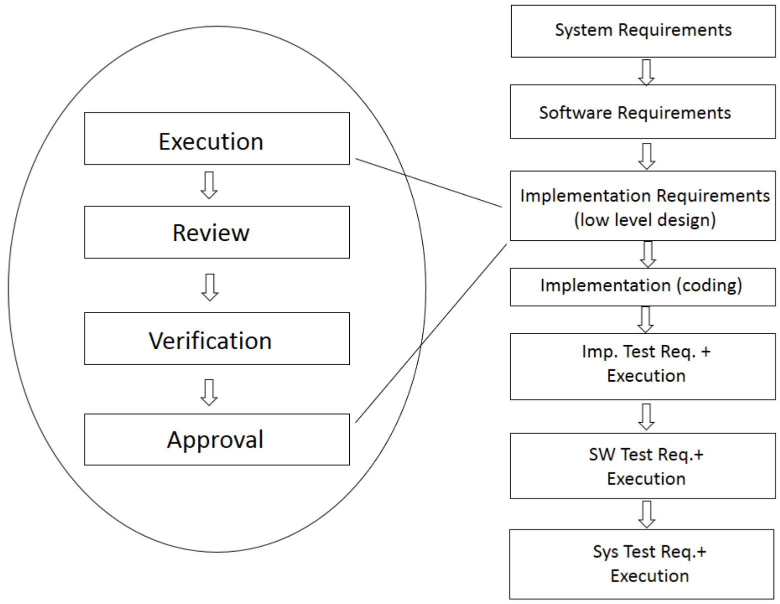
Due to these facts, the other choice was used for implementation. Namely, a single workflow is responsible to fix the found deficiencies. This approach has many benefits: First of all, the maintenance is much easier and less error prone as only a single item should be checked and fixed. Secondly, it can mimic the original workflow which is (in good case) tailored to the need of the company. Finally, the positioning through this workflow can be done programmatically which in certain cases reduce the human effort. The general structure of workflow is presented on Fig.25.



25. Figure Overview of featured problems

In practice, this means that the necessary correction steps are concatenated. This makes sense because a modification of an artifact in the workflow automatically involves the rework of every following (linked) artifact due to obsolescence. As it was mentioned above such a workflow should be tailored to the need of the company. Generally, it can be stated that each artifact consist the following four steps before the next item can be utilized: execution, review, verification, approval. (Where execution means the writing of requirements and test cases, implementing the requirement – i.e. coding– , or execution of test cases.)

The above mentioned four steps were repeated for each process step in the applied development process (e.g. the process model in Automotive SPICE, Fig.15) when creating the responsible test workflow. Together, this means at least seven times four different steps (40 steps total considering positive and negative testing) as shown on Fig.26. in a single workflow (assuming there is a single artifact at each level). This workflow is completed with additional direct transitions from review step(s) to closing state. The reason behind this concept is the case when the obsolescence analysis results a false positive finding and review shows that the artifact is still valid even so it is older than its parent. In such scenarios there is no need for further intervention and it is allowed to close the issue directly. Otherwise, a modification is executed on the system. This means that each following step in the development process should be executed (at least formally) again.



26. Figure Generic workflow scheme

The above presented workflow model is also stored in a look-up table. This look-up table is used by the issue generator. Depending on the finding the necessary position can be identified and the workflow is transited through the preceding steps automatically. This is permissible as this structure changes seldom and it can be even generated automatically from the database.

3.5.5. Industrial feedback on results

Altogether, the above mentioned steps demonstrated that the idea of Augmented Lifecycle Space approach is practicable in case of homogeneous ALM systems. After the demonstration was possible for a medium software development company to evaluate the results. They were requested to evaluate the existing scripts and results as it is recommended by technical action research method [92]. The company employed approximately 75 developers in the field of medical device development at the time of evaluation.

The most valuable feedback was from their side that the issue generation is not practical as high number of issues can be generated and it is really demanding to lead them through the workflow. Their proposal was to use existing ALM system and force the workflows of problematic artifacts to a state where intervention is necessary. In case of active development this is more beneficial as it is prohibiting spillover of the deficiencies. Furthermore, it also stops the original workflow which means that unnecessary steps are prohibited. In other words, the workflow steps are executed only once when everything is correct compared to the original situation when a certain step could have been executed in spite of the incorrect artifact and once again during correction. This modification should be surely considered, but it requires the access to a workflow used in development which is highly risky from the company side.

Another important remark has mentioned the timing and scope of analysis. At the beginning of a development project it is irrelevant whether all items are analyzed or not. The repair of found problems does not risk the final development, but instead they increase the quality. On the other hand, near to release or in maintenance phase the amount of issues can be tremendously high with little effect on quality and safety. Not to mention the fact that considerable amount of defects are introduced in the maintenance/code reworking phase of development [93].

The suggestion was to consider a certain state of the lifecycle space (e.g. around baselines) and execute the analysis only for the newly created or modified artifacts. This assumes that the previously baselined lifecycle space is considered complete in speak of traceability and consistency. (A good example could be for such a situation being right after an assessment. Here, not only the company declares the compliance and completeness but also the assessors make it ascertain that these statements are valid.) This way previously abandoned problems are excluded which could case high burden in time and human effort to fix. Furthermore, fixing these problems typically have small if any effect on the final product.

This approach includes the actual (general) analysis as well. If there is no marked baseline the analysis is still equal to the aforementioned complete investigation. Otherwise, the script should not consider any artifact which originates before the specified baseline and it should be executed only on this restricted lifecycle space.

In spite of the technical action research method, another verification phase should be executed with (possibly) other companies on the new checker containing the recommended modifications.

3.5.6. Summary of the homogeneous case

This section has presented the augmented lifecycle space approach as a novel method for finding traceability gaps and inconsistencies for application lifecycle management systems. The applicability was presented in a homogeneous systems, namely in JIRA. A demo system was created where every project was responsible for a single process step from Automotive SPICE process model. The demonstration script was capable to find missing requirements, outdated relationships and missing test case while it was able to provide basic measures related to test coverage. In spite of technical action research method, the results were presented to a company for verification. They have suggested to use the development workflow directly to get rid of the problems instead of generating issues to repair. Furthermore, it would be beneficial to be able to limit the scope of examination to a reduced lifecycle space containing artifacts created/modified only after a specified baseline.

3.6. Demonstration for heterogeneous ALM system

Automotive SPICE has the following definition for traceability [87]: "The degree to which a relationship can be established between two or more products of the development process, especially products having a predecessor-successor or master-subordinate relationship to one another."

Interestingly, this definition has no provisions about the technique to establish the relationship. It means it is irrelevant whether it is a direct ('clickable') link to the target artifact or it is only a textual reference to the location. Obviously, the above mentioned two cases are not equivalent. In the previous chapter the JIRA system was homogenous, there was a possibility to open the referred item with a single click. Moreover, all of the hits were opened in the same environment, in the same window. This made the use of the system simple and efficient by requiring only a web browser from the user.

These benefits are lost whenever a heterogeneous ALM system is established and the number of problems are increasing with the increasing variety of tools. This chapter targets to prove the applicability of ALS approach in a heterogeneous environment.

3.6.1. Used tools and system setup

It is a rational decision to keep the new experiment as close as possible to the previous attempts, because the implementation for ALS approach was already created for JIRA (via REST API) and it can be reused. Furthermore, the reimplementation of existing solution will have no additional gain from the perspective of experiment. Due to these considerations, the workflow management, low level design (implementation) and test management was kept in JIRA as it was discussed above. On the other hand, the requirements were recreated in IBM Rational DOORS.

This is a dedicated program for requirement management which is especially popular among medium and large companies (approx. 76% of users [94]). Although, it is a time-honored system, yet its user base is still expanding [95]. Its modular structure and its efficient handling of large database makes it popular. Furthermore, it has a unique scripting language called DXL (DOORS eXtension Language). This scripting language makes it possible to use (almost) all of the program features programmatically.

In DOORS it is possible to create a folder tree in order to organize the different entities in it according to the rationale behind the structure. In this attempt it was unnecessary to create such a hierarchy due to the low number of modules. Instead, a formal module – the base component of DOORS – was created for every requirement level. Similarly, as it was modeled in JIRA, a single formal module was created for system and software requirements levels from Automotive SPICE, while three separate formal modules were created for software detailed design (again, according to ASPICE).

The internal structure of formal modules was kept very simple due to the experimental nature of research. This means that for each requirement group a single header object was created, which described the nature of artifacts found in the module. Below this header, at the very same level were introduced the requirements one by one.

Linking between the requirements were created with drag-and-drop method, supported by DOORS. This creates direct (clickable) link between two artifacts containing information about subordinate relationship (yellow arrow: outgoing link pointing to children, red arrow: incoming link pointing to parent objects). This is how traceability was realized between requirements. However, it is impossible to create external links this way, which means that test cases and test results should be traced otherwise. (This latter statement excludes some special cases: For example Matlab has an official extension which makes it possible to create such links between the implementation model blocks and DOORS requirements. However, the number of such option is highly limited and it is typically implementation related which means that it cannot be used for our intended purpose.)

The idea was to keep the solution simple and diverse compared to the existing ones. Therefore, a new column (attribute) was created for each formal module with content 'TestRequirement'. Here, the unique JIRA identifier should be inserted to create a textual traceability link between the requirement and its tests cases. This fulfills traceability according to its definition, but it is impossible to check directly the test coverage (as discussed later).

In the above described state, there is no direct relationship between artifacts stored in DOORS and JIRA. In spite of the aforementioned problems, it seems to be reasonable to connect them somehow, possibly with direct connection. OSLC is the most promising from the above mentioned connection methods. Two official (supported) solutions exists for this purpose. One is the OSLC adapter of Tasktop Sync and the other one is the Kovair Omnibus which are available for JIRA. This is reduced to Kovair Omnibus only when considering the requirement management domain [96].

During the research, Tasktop Sync was available for evaluation, but there was no access for Kovair Omnibus. The evaluation has shown that Tasktop Sync is not suitable directly to realize ALS method. Its main purpose is to keep databases synchronized. The synchronization is realized by creating a table of correspondence and mirroring items to databases where they are missing. In this situation the problem would be nothing different from the previous study, as every artifact would be available in JIRA and processing of information would be the same.

Tasktop Sync can also create direct links between artifacts without copying them. In this case the connection is realized via a URIs. In such case, the data is not copied, but it should be acquired via web call. Unfortunately, JIRA REST API does not support this type of information access. This way it seems to be impossible (at the moment) to utilize the benefits of Tasktop Sync in this research. If Kovair's Omnibus has an API where the artifacts can be accessed programmatically, then it can be used in heterogeneous environment to make it look like a homogeneous one. In this case the already implemented solution should be migrated to the platform of Kovair.

In spite of the above mentioned facts, a completely different case is when point-to-point integration is applied and the two tools are used parallel with custom integration. The disadvantages of this setup has been already discussed, still this is a relevant, life-like scenario worthy to examine. The realization of this point-to-point integration was analyzed in details and it is discussed below.

The structure of elements were already presented and so was the idea of ALS approach. The task was to (partially) re-implement it in an environment where direct data access is limited. Furthermore, mutual data sharing should be also solved without increasing significantly the amount of used resources.

As most of the artifacts are stored in JIRA it seems beneficial to use it as an “integration” platform and implement ALS method again in JIRA, especially because the generated workflows are created also there. (Not to mention that the existing scripts can be reused with minor modifications.)

3.6.2. Analysis in collaboration

The main question is how and what kind of information shall be sent between the systems. It is beneficial to execute as many analyzes as possible in DOORS, as the DXL language was designed specifically to support database transactions in it. (Although, there is no numerical evidence but this kind of data processing is likely much more economical in DOORS compared to JIRA.) Afterward, the results can be sent to JIRA and used there. For sending information a common data type was chosen, it was sent as a .CSV file. This file should be created on the machine where JIRA scripts are running to eliminate the need of sending or remote access. With a local DOORS access this should not mean any problem, especially because the scripts can be run basically anywhere thanks to the web based implementation of JIRA.

When following the ALS method the first step is to execute the analysis. It is easy to find items which are completely missing traceability links. DOORS does even have dedicated function for this analyzes as the pseudo code below demonstrates:

```
Filter f = hasLinks(linkFilterOutgoing, "AnalyzedModule")  // For system requirement
Filter f = hasLinks(linkFilterBoth, "AnalyzedModule")  // For software requirements
Filter f = hasLinks(linkFilterIncoming, "AnalyzedModule")  // For software detailed design
isEmpty(f)
```

If the filter ‘f’ results empty then the analyzed module has no artifact with no any linked requirements. When ‘f’ contains artifacts then the CSV shall be edited or created. When the CSV is empty it shall start with a time stamp to help the identification and to document the execution of analysis. Afterward, the module shall be identified first. In order to do this the name of the module shall be added followed by the DOORS link of the mentioned model. Now it is possible to enumerate every artifact with deficiency. Here, first an error code is inserted to make the identification of the problem easier later on. Finally, the identifier of the artifact should be added which shall be the unique DOORS identifier. In case of missing traceability link there is no other required information. The CSV file should look like the following:

```
43:18:09.19.04.2017.
SR, doors://62.715.124.61:8183/?=version=2&prodID=0&urn:trysys::1-000000000000-B-03102204
…
Missing link, 1, SR13
Missing link, 1, SR27
…
```

The situation is a bit different for finding missing test cases and test results. The linked test cases are stored in an attribute for each requirement. Therefore, this argument shall be checked for every requirement. If it is empty then test cases are missing or they are unlinked and if there is only a single test case linked then its pair (negative or positive counterpart) is missing. In each cases, the missing test link shall be created (together with the test cases if necessary).

Analysis of chronology is a bit more difficult. For this examination, the linked parent artifacts shall be collected for every single requirement. Afterward, the default 'Last Modified On' attributes shall be compared for requirements and its parents. Whenever, a parent is later modified than its dependent, a new issue shall be created to review the relationship and consistency of requirement content.

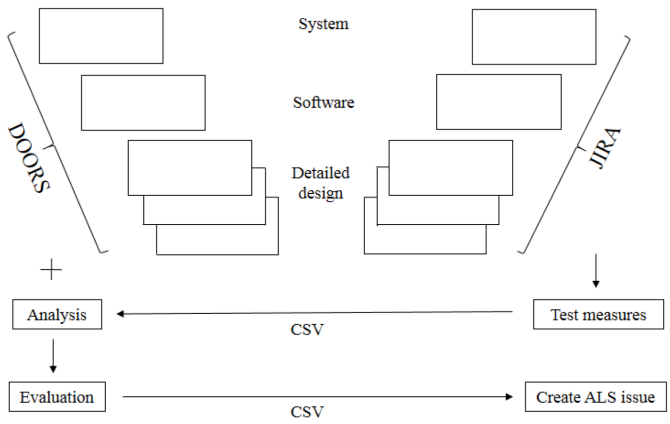
So far, decisions were made from information which is available inside of a single tool. However, there are cases when this information is not satisfactory, as in case of test coverage measurement. To be able to calculate test coverage, it is not enough anymore to know whether there are linked test case(s) or not, but their results are also important. Naturally, the information exchange can be realized in various ways.

First of all, the Tasktop Sync could be useful here if there is a correspondence setup between the JIRA issues and DOORS artifacts. To reduce the storage capacity need only the actually used information should be synchronized. This includes, the identifier of test case (which can be even directly linked after synchronization and there is no further need for the additional attribute), the state of the test case (not executed, failed, passed) and the alignment of test case (inbound or out-of-bound case). This solution would create an almost completely homogeneous environment, but instead of JIRA, now the DOORS would be providing this homogeneous system. This setup was rejected as it has little new outcome from my perspective.

Instead, the required information was packed to a CSV file for the analyzed project and this file was sent to DOORS. This latter program has extracted the stored information (namely, identifier, status of test, and alignment of test) and from these measures it is capable to calculate the measure which was lacking so far.

The existing solution needs human intervention to generate the CSV file from JIRA, to execute the analysis in DOORS and to create the new workflow according to ALS. During the experiment it was possible to do it this way as the number of modules and projects are limited. Nevertheless, it is possible to execute each steps programmatically, but it has no additional value to the experiment (at the moment). However, on the long run it is worthy to consider the possibility of automation to eliminate human intervention and to hide it in the every days.

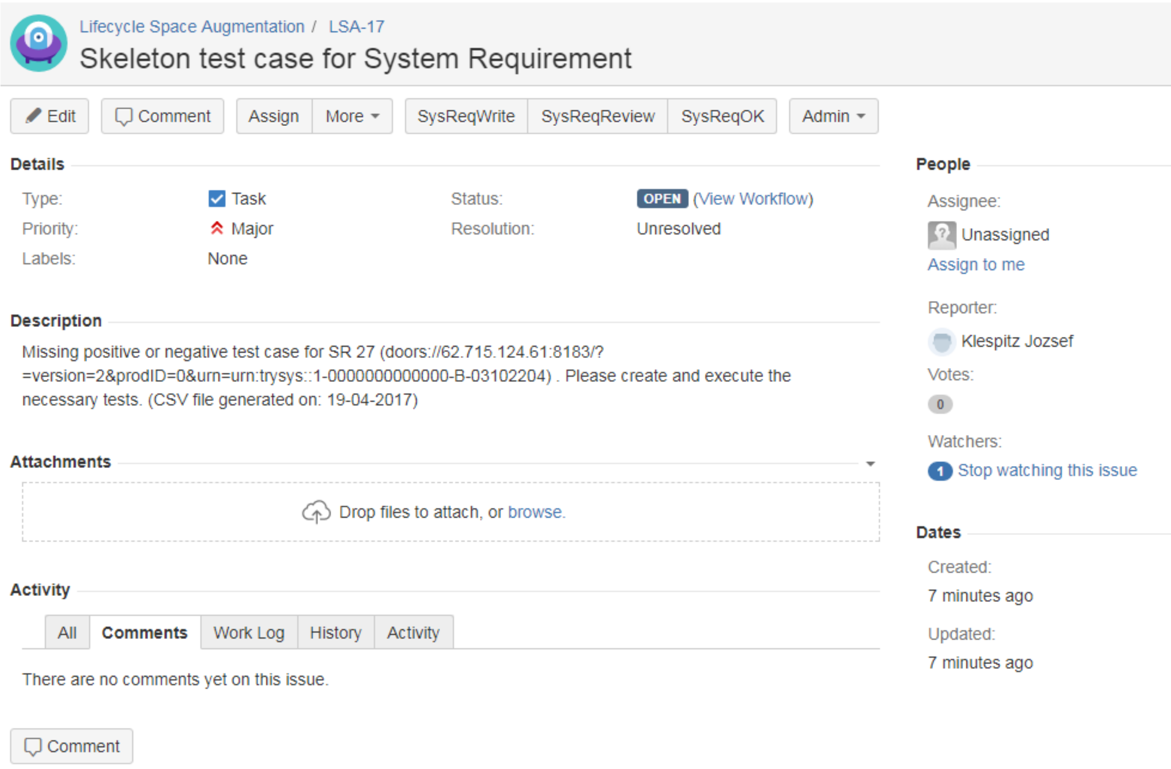
An overview of the above mentioned steps can be found on Fig.27. It summarize well the logical steps of execution. First the information is collected from JIRA database and the required test measures are inserted to a CSV file. This file is passed to DOORS where the information is extracted and it is processed with every other available information. Afterwards, the found problems are collected and the CSV file is overwritten. This is then sent back to be processed by JIRA, where the ALS related workflows are generated.



27. Figure Information flow in heterogeneous system analysis

3.6.3. Result and feedback for heterogeneous case

The generated workflows are the very same as in the previous experiment. There is no reason to change it and with no any exact target development. So far they are modeling completely well the possible needs. The result of a generated issue can be seen on Fig.28. It is clear from the picture that there is no direct link, the source of the problem cannot be accessed by clicking on the identifier. However, the mentioned identifier is unique so it can be located easily. To make the search even more effective the DOORS URL is added which opens the formal module where the problematic artifact can be found. There is also a timestamp to check whether the problem might still exist or it could have been solved.



28. Figure Generated workflow in heterogeneous system with reference to the place of finding

This solution has two ultimate weaknesses. First of all, it requires maintenance not only from JIRA, but also the DXL scripts has to be kept up-to-date. Furthermore, in case of huge databases the constant generation of CSV files (please note that every (!) test item should be added) has enormous resource need. This can be tolerated for this demonstration, but in practice it should be replaced with more effective methods. (A possible solution could be a framework which programmatically calls the DXL and JIRA scripts and this framework would be responsible to share the necessary information between the systems via function calls with proper parameters.)

In terms of technical action research method [84], the next step for this experiment should be the verification of conception with industrial partners. It has failed during the course of my PhD studies to effectively evaluate the idea with third-party. However, it is highly likely that the statements for the previous, homogeneous setup are valid here as well. Namely, it would be beneficial to modify an existing workflow and force users to follow every rule. Furthermore, it would be possibly welcomed here as well to start the evaluation from a certain baselined condition of the system. This way, only the modification should be checked so the resource need is highly reduced by finding problems only which were newly introduced to the system.

However, the question is always open: How can be the above mentioned solutions further improved? As Biro at al. [KJ10] has stated in their study finding traceability gaps is not self-evident. According to this aspect, the plain analysis of quantity and quality of relationships is not enough because the decomposition/integration of requirements are required for the correct statement. This means that the content of the requirements play huge role here which cannot be easily processed by computers. This raise the need for semantic analysis of requirements which still not guarantees that every traceability gap or inconsistency would be found. As an alternative solution, machine learning could be utilized to discover relationship between artifacts, but the existing literature is limited for this topic [97].

On the other hand, the application of formal methods is an already applied technique. Indeed, the application of formal methods is recommended by the Capability Maturity Model Integration (CMMI) above safety integrity level (SIL) 2 and it is highly recommended for the highest safety-level (SIL 4) systems. This means that the lack of application of formal methods must be discussed in details where this mentioned reason will be checked by third-party during assessment (typically certification bodies). This fact together with the challenges posed by the increasing complexity of software [98] shows the importance of formal methods, still it is not generally welcomed by everyone in the industry.

Although, the total test coverage and spotless decomposition can be guaranteed only by formal methods in software engineering [99], yet it is still not unconditionally applied [100]. The main reason behind this is among others that artifacts should be formulated more computer-likely and less like natural language and also might be often faced with computational problems. When the numbers for formal methods related studies are compared with ones discussing verification or testing [100] it can be realized that most probably companies still to the classical approach.

Still, it can be used in practice, but the application is not seamless as Mashkoor at al. [101] has already stated. According to their study, it is possible to use formal methods to decompose requirements while guaranteeing consistency and error free specifications, but it is hard to handle the abstractness compared to the product under validation. Also, the decomposition itself is not straightforward. However, completeness and complete mathematical description are still tempting properties which makes it worthy to use them in further studies.

These were the motivations among others to start the development of a tool which utilize the existing results and further improve them with the help of formal methods. One of the important features of this proposal is what we have learned from previous evaluation.

This process is called 'graceful integration' as the up-front effort need to process artifacts is reduced. The processing is less demanding as only newly created or modified items are considered as the existing part of the system is thought as complete and consistent. The system is called Requirements Traceability and Consistency checking Tool (RTCT) [KJ13]. The main aim is to provide a tool which can be integrated as a middleware practically into any systems, which can prove formally that the stored artifacts are mutually consistent and they satisfy the applied requirement traceability model.

3.6.4. Summary for heterogeneous case

The ALS approach cannot only be used in case of homogeneous systems, but it is applicable in heterogeneous case as well. Although, making the system more homogeneous with the help of (continuous) synchronization is more rewarding, but with simple information sharing methods the same result can be achieved. As this current example has shown it was possible to generate workflows to bridge traceability gaps and fix inconsistencies in a system which utilize DOORS to manage requirement and use JIRA to handle workflow and manage testing.

Furthermore, it has been pointed out that it would be beneficial to use formal methods for finding deficiencies and proving the completeness of system in terms of traceability and consistency. This is imagined, through the so called ‘graceful integration’ where the analysis is not started from the ground but from an existing state of the system.

Thesis group 2

Thesis group 2: Practical application of Augmented Lifecycle Space approach

Thesis 2
I have created custom application lifecycle management system in order to prove the applicability of Augmented Lifecycle Space approach. Result has shown that it can be used practically both in homogeneous and heterogeneous system and with modification it can be beneficiary for software development companies.

Thesis 2.1
I have proven the applicability of ALS method for homogeneous systems. The implemented solution is capable to find traceability missing traceability links, detect chronological inconsistencies and provide basic measures regarding test coverage. For the according type of found deficiencies the program generates a workflow automatically which should be followed in order to fix the problems.

Thesis 2.2
I have proven the applicability of ALS method for heterogeneous systems as well. The solution is capable to find traceability gaps, major inconsistencies and it also provides basic measures. The implemented solution also realizes a minimal point to point integration between the two system components to provide a platform form information sharing. Similarly, this solution also generates workflow to make possible the correction of found deficiencies.

Relevant own publications pertaining to this thesis group:

[KJ7], [KJ8], [KJ9], [KJ10], [KJ11], [KJ12], [KJ13], [KJ14],

4. Summary

It is undeniable that acute and chronic kidney disease is a serious problem. With treatment lives can be saved and/or the life quality of the patients can be significantly improved. This thesis discuss how fluid balance and drug administration can be solved in hemodialysis machine, used for blood purification in case of kidney injury.

In the first thesis group, controller designs were shown which are mostly unknown for the industry. Two fuzzy controllers, two ANFIS controllers were designed together with a PI controller where TP transformation was used for parameter tuning. These all were compared with a PID reference controller.

As a result it can be stated, that the soft computing methods can remove the overshoot while the PID and PI controllers are not capable to do this. Furthermore, the soft computing methods consist expert knowledge which could further improve their beneficial properties. Although, these are more resource demanding, but their other properties are comparable or superior compared to the PID controller.

The most effective controllers were implemented on a real machine which was used for verification. The results has shown similar results as in the simulations. This means that any of the promising controllers can be used in practice. It is only the choice of the companies to spread soft computing methods in safety-critical systems also.

It was also stated that it is not satisfactory to have a proper controller, but the used development processes has to fulfill the related standards and directives. This means a significant documentation burden which can be eased by using Application Lifecycle Management systems. In these systems a vital question is to have complete traceability and consistency.

It is not a straightforward question to find the related deficiencies. To support this the idea of Augmented Lifecycle Space was introduced which gives a general approach to find traceability gaps and inconsistencies.

I have implemented the ALS approach for a homogeneous and for a heterogeneous test environment. The idea proved to be useful and efficient for each cases. For both systems it was possible to find missing links, and missing test cases together with outdated artifacts. I was able to generate workflows automatically which consisted steps for fixing the explored problems. According to the feedbacks, these solutions should be further improved to make it possible to run the analysis only on changes since certain baselines. This idea could benefit much from machine learning and/or formal methods. These concepts should be evaluated in the future.

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