An Equipment Behavioral Study in Fluidic Production Processes using Data for an Optimized Predictive Maintenance: Application to Pneumatic Valves in Biopharmaceutical Industry

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Predictive maintenance of production equipment is gaining increasing interest in the biopharmaceutical industry in the context of Industry 4.0, where reliability is essential to ensure product quality, equipment availability, and compliance with strict standards. Pneumatic membrane valves, critical for regulating fluid and gas flows in production systems, are of particular importance. The membrane, a primary wear component, is subject to mechanical stresses that can lead to deformations or ruptures. These can disrupt production and compromise product quality. Prognostic Health Management (PHM) is a promising approach to monitoring equipment condition. By leveraging representative data, it offers the possibility of modelling the evolution of equipment condition and anticipating potential failures. This predictive strategy, based on lifecycle phases and trends, facilitates targeted maintenance interventions before major failures occur. This article investigates PHM integration for pneumatic valve membrane maintenance in the biopharmaceutical sector. It proposes a method to identify experimental data, define lifecycle criteria, analyse these criteria, compare them with planned maintenance practices, and evaluate signal drifts to characterise the membrane state for future predictive maintenance development.

Keywords: *Predictive Maintenance, Mechanical Engineering, Fluidic Systems, Machine Learning, Modelisation, Biopharmaceutical Industry*

1. INTRODUCTION AND INDUSTRIAL CONTEXT

With the aim of ensuring the reliability of equipment and anticipating its failures, this article provides a reflection on the need to go beyond traditional planned maintenance methods. It presents a new framework based on an industrial problem submitted by a biopharmaceutical manufacturer partner. In section 2, we introduce the subject through a review of the state of the art regarding maintenance practices targeting industrial equipment, particularly pneumatic valve membranes. In section 3, we describe the system under study, using data from the experimental platform, which allows the modeling of the behaviour of the valve membranes. Afterwards, in section 4, we present the results obtained and propose indicators for the lifespan and degradation of the equipment, based on the collected data. Next, in section 5, we conduct a physical comparison between a new membrane and the degraded membrane in our study. Finally, in section 6, we conclude this paper and suggest some perspectives for this work.

With the emergence of Industry 4.0 technologies, pneumatic membrane valves can no longer be considered as enhanced valves, but as equipment that behaves like IoT (Internet of Things). This in turn offers the ability to assess functional conditions using a range of collected data.

The contributions of this study are as follows:

1. The characterisation of the life cycles and the detection of defects in the behaviour of an equipment item (applied to pneumatic valve membranes) during its lapping, maturity, and ageing phases.
2. The proposal and analysis of criteria for predicting the operational state of this equipment through the measurement of signals captured during the system performance. This proposal aims to introduce a predictive maintenance method.
3. The application of failure criteria in the biopharmaceutical environment, with particular reference to the quality constraints inherent to this industry.

There are significant challenges facing the biop–harmaceutical industry when it comes to optimising equipment maintenance, especially with regard to the transition from planned to predictive strategies. Current planned maintenance plans, widely adopted in the sector, are based on predefined schedules for the replacement of critical components. These include wear parts, based on the manufacturer's recommendations. However, this approach often leads to premature

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replacements, where still-functional components are discarded, resulting in a waste of consumables. Fur–thermore, planned maintenance fails to address residual defects, requiring remedial interventions that disrupt production and compromise product quality. This also increases costs due to unplanned downtime and quality problems.

Biopharmaceutical production is characterised by stringent requirements, as it operates in sterile and aseptic environments to guarantee product safety and compliance with regulatory standards. Fluidic production processes involve the precise regulation of liquid and gas flows. This is often carried out under difficult conditions, such as steam cleaning or exposure to acidic/alkaline agents. These processes demand equipment that is both inert to the product and resilient to cleaning protocols, so as to prevent contamination and maintain production integrity.

The advent of Industry 4.0 and the IoT offers promising avenues for optimisation. These technologies enable real-time monitoring and data-driven decision-making, thereby facilitating the transition to predictive maintenance. However, this transition requires an effective collection and processing of operational data to monitor the equipment condition and predict failures accurately. Without these data, the industry struggles to implement "just-in-time" maintenance strategies that align interventions with actual equipment conditions, resulting in reduced waste and improved reliability.

In this context, the equipment selected for this study is the pneumatic membrane valve, a critical component in fluidic production systems. This valve, widely used in biopharmaceutical settings, provides flow regulation while maintaining sterility. Its membrane, however, is prone to wear, deformation or rupture, which poses risks to production continuity and product quality.

1.1 State of the art

IoT-driven predictive maintenance

IoT-driven predictive maintenance has emerged as an area of interest in the biopharmaceutical industry [1-3], although its adoption remains limited compared to other sectors such as the automotive industry [4-5], the energy industry [6-8], or more broadly, the manufacturing industry [9-12]. By enabling the collection of real-time or near-real-time data, the Internet of Things offers un–precedented opportunities to effectively monitor equip–ment and anticipate failures. In several cases, techno–logies based on machine learning algorithms have de–monstrated their effectiveness in providing rapid and accurate failure diagnosis [13-14]. However, in the biopharmaceutical context, stringent regulatory require–ments, particularly in terms of quality standards, com–plicate the integration of these tools into real-world processes. These constraints necessitate specific solu–tions to ensure compliance with maintenance processes while fully leveraging the potential of IoT-derived data [15-16]. Despite these challenges, IoT applications in this sector reveal significant potential for innovation, particularly in terms of optimising processes and reducing costs associated with unexpected interruptions.

Prognostics and Health Management (Figure 1) pro–vides a structured methodological framework to antici–pate failures, extend equipment lifespan, and optimise maintenance. There are numerous examples in the sci–entific literature that describe the development of pre–dictive maintenance plans in the manufacturing indus–try, based on the general principles of this method [17-18].

As illustrated in Figure 1, the paradigm is based on a set of key steps: data acquisition, data refinement, ano–maly detection, diagnostics, and estimation of the remaining lifespan of target equipment. These app–roaches can be based on physical models, data-driven methods, or a combination of both. The implementation of PHM in the context of fluidic equipment demon–strates efficacy in the prevention of failures, the reduction of operating costs, and the minimisation of unplanned downtime. In critical environments such as the biopharmaceutical industry, where operational continuity is essential, the integration of PHM facilitates the alignment of operational needs with stringent regulatory requirements. This methodology is also highly flexible, which allows its application to a variety of equipment and scenarios, particularly those involving complex fluidic processes. A widespread adoption of this framework could transform industrial practices by combining performance, reliability, and compliance.

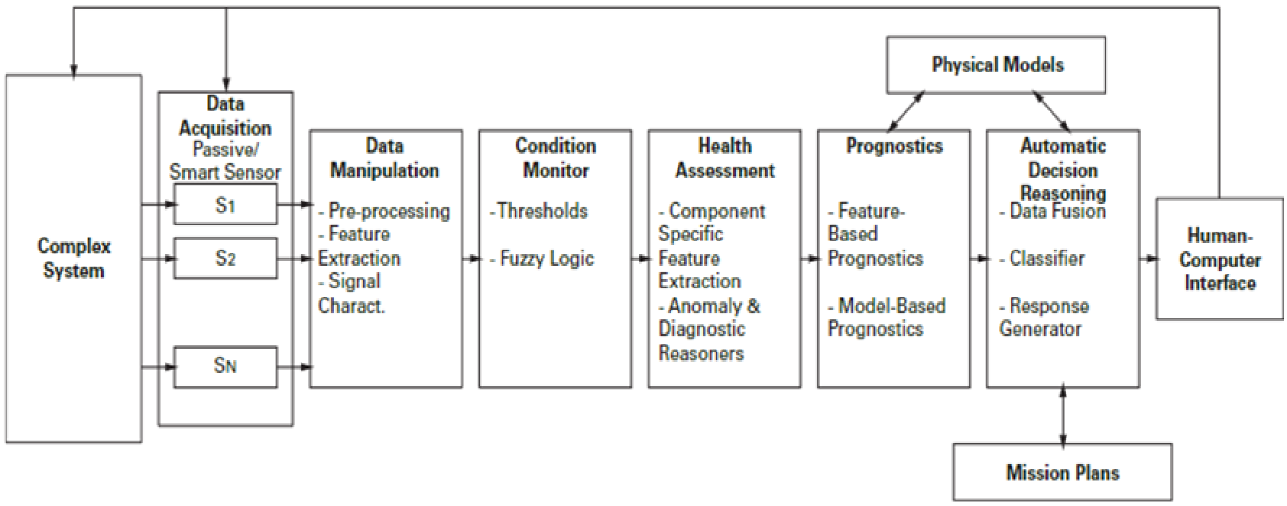

Figure 1. Illustration of the stages of PHM according to [19].

Pneumatic membrane valves present specific challenges related to membrane degradation. Their failures, undetectable by traditional methods, can lead to unplanned downtime and compromise product quality. Thanks to advances in IoT, these valves can now be equipped with intelligent positioning systems capable of collecting data representative of their operational state. Being independent of the control system, these data provide insight into phenomena such as progressive membrane degradation, thereby allowing the prediction and planning of maintenance interventions. The next section focuses on the studies carried out on this valve.

1.2. Valve failure detection

Due to its critical role in flow management, the valve is a central part of the equipment in any manufacturing process involving fluids. It can be configured in various forms [20]. Industrial valves typically consist of a valve body and an actuator that allows their opening and closing. They may be manual or automatic (controlled by a PLC (Programmable Logic Controller)), and the actuator can be equipped with a spring and/or a piston. The control can be electric or pneumatic. A variant used in fluidic processes incorporates a membrane between the actuator and the valve seat, making detection of failures difficult due to their invisibility. In the era of Industry 4.0 principles, where maintenance practices are undergoing a transition toward so-called predictive methods, a question arises as to the applicability of these practices to membrane-equipped valves. Accordingly, the following section will present a review, in chronological order, of several noteworthy studies that could support the predictive maintenance of industrial valves.

Thus, the first study by [21] describes the use of a Recurrent Neural Network (RNN) for fault detection in pneumatic control valves without membranes. The experiment involved analysing the displacement of the valve positioner and comparing the 4-20mA signal collected from a fault-free valve with induced fault signals. The authors observed variations in the electrical signals that could be correlated with drift states, consistent with visual classifications established by experts. To this end, a neural network was employed to process the signals and classify them based on features and known failure types. The second study [22] proposed a model-based prognostic approach to characterise failures in pneumatic valves without membranes within a liquid hydrogen transfer system. The research consisted of modelling physical parameters and time-series data, including air injected into the pneumatic actuator, valve positions, and opening and closing times. Both the physical parameters of a healthy valve and those of a degraded valve were presented. The experiment was based on real and simulated data to determine the Remaining Useful Life (RUL).

Two studies addressing the detection and diagnosis of pneumatic actuator failures were also identified. For instance, the authors of [23] proposed an Adaptive Neuro-Fuzzy Inference System (ANFIS) model for the detection and diagnosis of failures in a pneumatic actuator valve without a membrane in the cement industry. In this study, they focused on the pneumatic actuator. Nineteen actuator-related failures were charac–terised. Their model was based on generated training data, 75% of which was used for training and 25% for testing. The data considered five characteristics: poten–tiometer movement, pump input and output power, inlet pressure, outlet water temperature, and differential pre–ssure transmitter output, creating a labelled output indicating the presence (and type, if any) of an error or its absence. Concerning the study conducted by [24], an edge detection approach was used to identify failures in the pneumatic actuator of a valve without a membrane. To this end, photos of the system were collected, a region of interest was identified in each photo, and the borders of this region were extracted. Then, the positional changes of the elements in the region of interest were calculated. If an abnormal spatial position change was detected, a fault was recorded.

Furthermore, it was reported in [25] that various machine learning algorithms were compared to predict failures in Pressure Regulated Shutoff Valves (PRSOV). These pneumatic control valves are notably found in aircraft fuel supply circuits. The authors simulated failures such as leaks, spring malfunctions, and friction to generate training data. They then trained and compared six algorithms (SVM, kNN, NB, CART, MLR, MLP) to diagnose the faults.

In 2021, two studies were published addressing similar problems. The study conducted by [26] proposed a failure diagnosis methodology for pneumatic valves without membranes. This approach was based on the use of Fault Detection and Diagnosis (FDD) techniques and decision trees. For this experiment, they used a test platform called 'AUTHOMATHIKA', equipped with a pneumatic actuator, a control valve, and a positioner. The authors developed a methodology to leverage sensor data to characterise failures. Based on the obtained failure patterns, a decision tree classification was performed to diagnose faults. Another study by [27] detected 14 of the 19 faults associated with simulated pneumatic valves without membranes using the "DAMADICS" benchmark, with detection performed through the CVA-SMD (Canonical Variate Analysis on Square of the Mahalanobis Distance) method. Various failure categories were addressed, including those in the valves themselves, as well as in the servomotor and positioner. Furthermore, other more general failures were studied, one of which involved faults due to fatigue in the internal membranes of the servomotor. The authors tested the CVA-SMD method for fault detection and compared it with more common statistical methods such as PCA-T^2 (Principal Component Analysis) and SVA (Surrogate Variable Analysis). The results of this study showed that the CVA-SMD method exhibited the lowest False Alarm Rate and the highest False Discovery Rate among the statistical methods.

Finally, a paper by [28] examined the application of a DGM (1,1) (Dynamic Grey Model type 1,1) system for predictive maintenance of pneumatic valves without membranes. The focus of this study was on the equipment employed in the oil industry. This approach was used to target redundancies in signals measured from pneumatic actuators to model failures, enabling their prediction in the future.

The scientific literature contains numerous studies conducted in this field and on this equipment, which primarily address failures related to the pneumatic actuators of valves. Consequently, no studies have been identified in the literature that specifically target the degradation of membranes in pneumatic valves, which are commonly found in liquid process industries, particularly in the biopharmaceutical sector.

Despite recent advances in predictive maintenance for industrial valves, current studies have significant limitations, particularly in addressing membrane-based systems. The majority of existing research concentrates on pneumatic actuators or valves without membranes, and often relies on simulated data or narrowly focused industrial scenarios. These approaches overlook the specific wear mechanisms and degradation patterns associated with valve membranes, especially in fluidic environments where membrane integrity is critical. This lack of consideration for membrane wear represents a significant gap in the scientific literature. In an attempt to fill this gap, our study introduces a novel methodology designed to detect and model membrane degradation using advanced data processing techniques, providing more reliable wear indicators that can be applied in real-world conditions.

2. DESCRIPTION OF THE SYSTEM STUDIED

2.1 Pneumatic membrane valve

The pneumatic membrane valve is used in fluidic production processes. It is specifically employed in the biomedicine industry due to its compatibility with sterile and aseptic production environments. In addition to its role as a fluid blocker, the valve membrane is designed to be inert with respect to the product circulating in the production lines, thereby ensuring the non-contamination of the processed product. It must also withstand cleaning of the production lines using steam or other agents, whether acidic or alkaline. They are generally composed of rubber and/or plastic materials and can rupture, deform, and have a significant impact on the production process by reducing equipment availability and introducing a risk of product contamination.

Biopharmaceutical production equipment fitted with pneumatic membrane valves is also difficult to access, as it is generally located in controlled atmosphere environments specific to industries producing biomedicines. The most common maintenance plan currently used by our industrial partner, and more broadly in the biopharmaceutical industry, is the planned maintenance plan [29]. The membranes of pneumatic valves, which are the major wear parts of this equipment, are replaced based on a usage duration criterion derived from manufacturer recommendations, integrated into a planned maintenance plan. While this approach allows wear parts to be monitored over time, it does not guarantee the absence of equipment failures. In our use case, premature membrane wear due to non-compliant assembly and sudden failures are poorly addressed by planned maintenance. Furthermore, replaced membranes are often removed prematurely as they remain viable, raising the issue of consumable waste.

As the membranes cannot be seen without prior disassembly of the entire equipment, it is important to have state indicators to enable "just-in-time" maintenance and to establish relevant timeframes for predicting maintenance interventions.

The pneumatic membrane valve (Figure 2) consists of a valve body through which the fluid flows, a pneumatic actuator enabling the opening and closing of the valve, and a membrane that connects the valve seat to the actuator. The actuator, once supplied with compressed air, exerts a vertical force on the membrane, allowing fluid circulation through the valve seat.

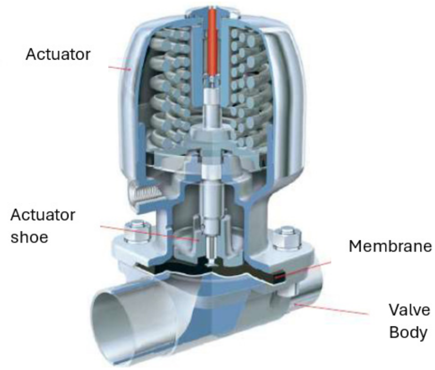

Figure 2. GEMÜ Biostar 650 pneumatic membrane valve

Generally, the equipment can be made of various materials (plastic or metal), depending on the fluid that will flow through the valve and the product non-contamination requirements specific to the production process. The valve body also serves as support for the actuator and the membrane.

The pneumatic actuator is a component that enables the opening and closing of the valve. Compressed air is injected into the actuator’s chamber, thereby exerting pressure on an internal spring. This in turn allows vertical movement of the membrane and the passage of the fluid through the valve body. The valve closes when the supply of compressed air to the actuator chamber is interrupted, causing the internal spring to relax and the membrane to return to its initial position. This principle is illustrated in Figure 3.

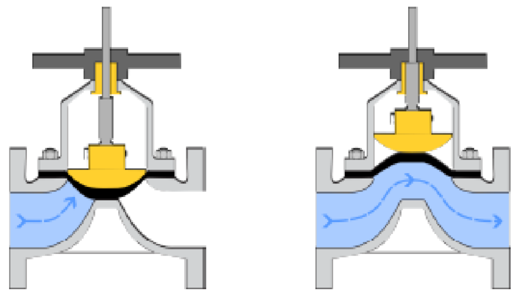

Figure 3. Principle of a membrane valve derived from [30]

The membrane is attached to the actuator by screws and is subjected to the compressed air injected into the actuator, making a vertical movement to allow or prevent fluid flow. Our study focuses specifically on EPDM/PTFE (Ethylene Propylene Diene Monomer / Polytetrafluoroethylene) membranes (Figure 4), which are commonly found in the fluidic processes of our industrial partner. However, they can be made from different materials depending on the process constraints.

Figure 4 - Membrane de vanne pneumatique de la marque GEMÜ

These valves can also be equipped with an electrical position indicator (Figure 5) screwed onto the actuator. The main function of this device is to inform the PLC managing the valves about its open or closed state by sending back information based on a potentiometric value representative of its position.

Figure 5 - GEMÜ electrical position indicator

2.2 Failure modes

The primary failure mode identified for these mem–branes is the deformation of the PTFE layer.

PTFE is a synthetic fluorinated polymer known for its chemical resistance and low friction coefficient [31]. However, one of its main weaknesses is its low mec–hanical strength [32]. Compared to other industrial plastics, it is more prone to deformation or flattening under high mechanical loads or prolonged stress, particularly at low temperatures.

The valve membrane under study comprises a PTFE component, which is mobile and in direct contact with the products. It is subjected to mechanical stress each time the valve is actuated. Due to the properties of the plastic material, the opening-closing movement causes progressive deformation in the stress zones of the membrane. This deformation can create a retention area in the fluidic system that may be difficult to reach during production line cleaning processes, potentially paving the way for product contamination. Such deformation may also prevent the membrane from properly fulfilling its sealing role in the line.

In extreme cases, the deformation can lead to sudden rupture in this part of the membrane. This type of rup–ture would result in a significant product leakage thr–ough the actuator drain ports.

While the occurrence of membrane deformation is inevitable due to the material properties and operating conditions, it should be noted that the phenomenon can be exacerbated by non-conform mounting of the mem–brane to the actuator (e.g., non-compliant tightening).

3. TEST BENCH EXPERIMENTATION

The experiment described here consists of reproducing the control of a pneumatic membrane valve as it would be used in the production process, with the imple–mentation of a system enabling the monitoring of some data related to the stress exerted on the membrane.

The equipment and operational expertise used to conduct this experiment were provided by our industrial partner. All the equipment employed is identical to that found on the production lines.

3.1 Materials

To collect data representative of membrane degradation under experimental conditions, we established a test bench (Figure 6). This was designed to simulate the conditions encountered in the fluidic production process of our industrial partner. This test was equipped with a pneumatic membrane valve, a pump, and an automated control and monitoring system. The size (ND) of the pneumatic membrane valve used for the experiment was selected based on a representativeness criterion, as it is the most commonly used size at our industrial partner's facilities. Finally, the valve under study was assembled and prepared by an expert from the company in question, ensuring compliant mounting.

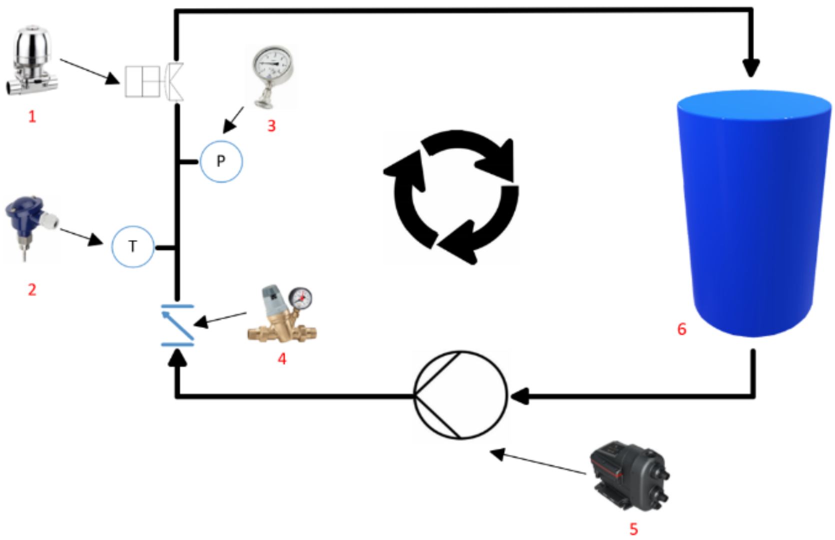

Figure 6. Schema of the test bench

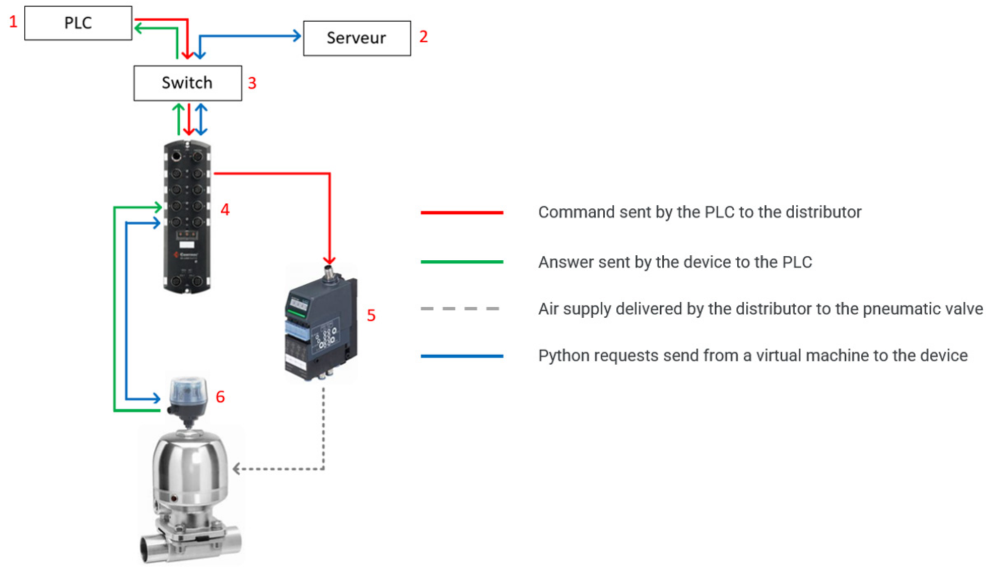

Figure 7. IO-Link architecture for test bench control + Python data collection system

The test bench consists of a closed loop filled with purified water, comprising:

- A pneumatic membrane valve (1)
- A temperature sensor (2)
- A pressure gauge (3)
- A pressure reducer (4) to ensure stable pressure in the circuit upstream of the valve
- A pump equipped with a leak detector for potential leaks in the supplied circuit (5)
- A collection tank (6)

3.2 Test bench control

An IO-Link automation architecture (Figure 7) was implemented to control the bench and collect relevant data for transfer into a Data Lake-type database, created for this purpose. IO-Link is a point-to-point commu–nication protocol used in industrial automation. This system consists, at least, of a programmable logic con–troller (PLC) and a "master" module to which sensors and actuators, referred to as "slaves," are directly connected. Several scientific publications describe test platforms using IO-Link [33-34].

In our case study, one advantage of IO-Link is the ability to communicate with the "slave" equipment without involving the PLC and without affecting the flow of control frames addressed by the PLC to the equipment.

The test bench architecture contains the following components :

- A PLC (1)
- A server hosting a database (2)
- An unmanaged switch (3)
- An IO-Link master (4)
- A pneumatic valve island for valve control via the actuator (5)
- A 30mm stroke electrical position indicator (6)

The acquisition script, written in Python, was used to communicate with the electrical position indicator via the IO-Link master, without involving the PLC. Such data is referred to as "acyclic." They are not specifically required by the PLC to control the equipment, but are employed by the equipment for its own operation. For the purposes of our study, we have retrieved poten–tiometric values that allow the valve to indicate whether it is open or closed, according to its switching diagram (Figure 8).

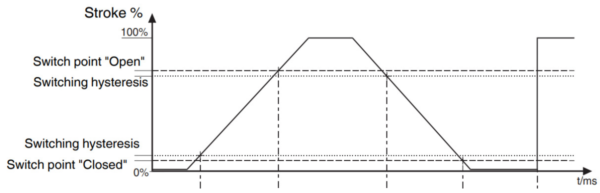

Figure 8 - Switching diagram from the equipment manufac–turer's instructions

3.3 Methods

The data used for our case study are derived from the electrical position indicator of the valve (Figure 5). They were continuously collected using a data collector Python script.

- **Conduct of the experiment**

An EPDM/PTFE membrane was installed in a compliant manner on the pneumatic actuator of the ND25 valve by a technical expert employed by our industrial partner. This precautionary measure was necessary to avoid the failures associated with non-conform mounting, as described in the "Failure Mode" section.

- **Test bench control conditions**

The liquid circulating in the loop was purified water. The physical parameters of the circuit are as follows:

- ≈ 2 bars of pressure in the manifold
- Liquid at ≈ 25°C

These parameters are representative of physical conditions found in biopharmaceutical production lines. The experiment was conducted on a continuous basis for twelve months. Opening/closing cycles, each lasting a total of one hour and twenty minutes, were performed and controlled by a programmable logic controller

(PLC). The valve opening lasted five minutes, followed by a closure period of one hour and fifteen minutes. This allowed 20 cycles per day, simulating accelerated process conditions.

- **Verification of membrane conditions**

Disassembling and reassembling the valve causes disturbances in the recorded potentiometric readings; therefore, we decided to schedule only one disassembly to verify the condition of the membrane. We prog–rammed this dismantling once 3,500 cycles had been reached. This horizon was chosen on the basis of our industrial partner's current maintenance practices. It is worth noting that in an industrial context, this horizon may vary depending on the equipment and its position on the production line.

- **Signal characterisation**

In the following section, we will discuss the raw signal as well as the methods employed to process it. We followed the steps shown in Figure 9.

The raw signal collected in this study consists of potentiometric values returned by the position indicator upon valve closure. Specifically, it includes all values recorded once the position indicator exceeds a prede–fined threshold, automatically established by the system, enabling it to signal to the PLC that the valve is closed.

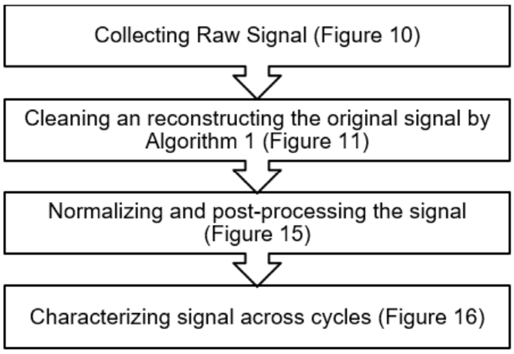

Figure 9 – steps followed to characterise the collection signal

The signal comprises a set of "settling" profiles of the membrane against the valve seat once the closed state is reached, cycle after cycle of valve opening and closing. Figure 10 shows the signal for a set of 7 open/close cycles, highlighting the emergence of a drift.

The studied signal covered the entire lifecycle of a membrane, from its installation on the actuator to its replacement, after reaching a condition deemed con–cerning the PTFE component in contact with the pro–duct. The signal was submitted to post-processing to highlight the main phases of the membrane's lifecycle, namely, lapping, maturity, and ageing, in accordance with the Weibull distribution.

This law consists of a probability distribution used to model the reliability and lifespan of materials and systems. Introduced by Waloddi Weibull [35] in 1951, this distribution is particularly useful for analysing the probability of survival and failure of systems. It is defined by three parameters: location (γ), scale (η), and shape (β). The shape parameter determines the distribution of failure rates. If $\beta < 1$, the failure rate is relatively high, but decreasing, which corresponds to the elimination of early defects and the lapping period. If $\beta = 1$, the maturity phase is characterised by a low and constant failure rate, with components having proven their resilience to early defects. If $\beta > 1$, the ageing phase is marked by an increasing failure rate over time, as components experience wear. This flexibility allows the Weibull distribution to model the lifespan of various components, such as electronic components [36-37], mechanical systems [38], or pneumatic valves [39].

During the lapping phase, membranes are generally robust and experience few failures. The maturity phase is characterised by stable performance and maximum reliability. In contrast, during the ageing phase, failures become more frequent due to material degradation. How–ever, in addition to the normal changes associated with lifecycle phases, sensors can detect signals indicating abnormal disturbances. These disturbances may result from external factors such as pressure variations, temperature fluctuations, impurities in the fluid passing through the valve, or mechanical malfunctions.

By characterising the signals from sensors installed on the valves, it is possible to accurately determine a memb–rane's life-cycle phase and predict its future behaviour. The analysis of potentiometric data, which measures variations in resistance or voltage in response to operating conditions, enables the identification of distinct signatures associated with each phase of the lifecycle: lapping, maturity, and ageing. During the lapping phase, potentiometric values typically show significant variations. As the membrane reaches the maturity phase, these values remain relatively constant but may begin to show signs of fatigue through slight fluctuations. Finally, during the ageing phase, poten–tiometric values display more pronounced variations, indi–cating an increased risk of failure onset. By monitoring these potentiometric variations, it is possible to define precise transition thresholds between life cycle phases. For instance, a specific potentiometric level may indicate the membrane's transition from lapping to maturity or from maturity to ageing. This approach could be integrated into a predictive maintenance strategy, thereby minimising downtime and costs associated with unexpected failures.

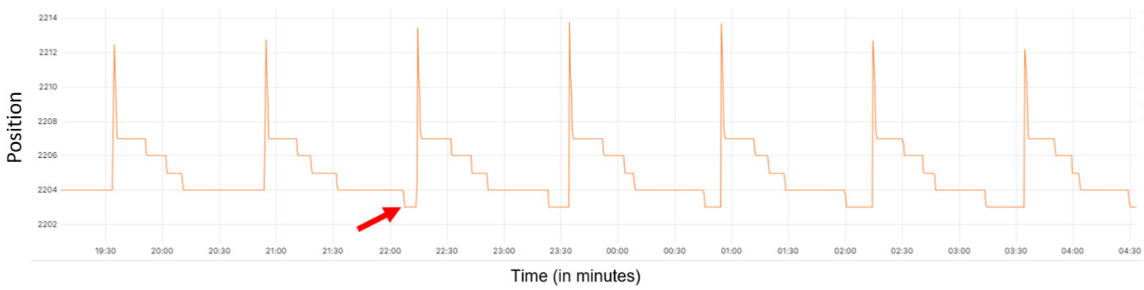

Figure 10. Potentiometric signal obtained by the position indicator for 7 cycles with drift

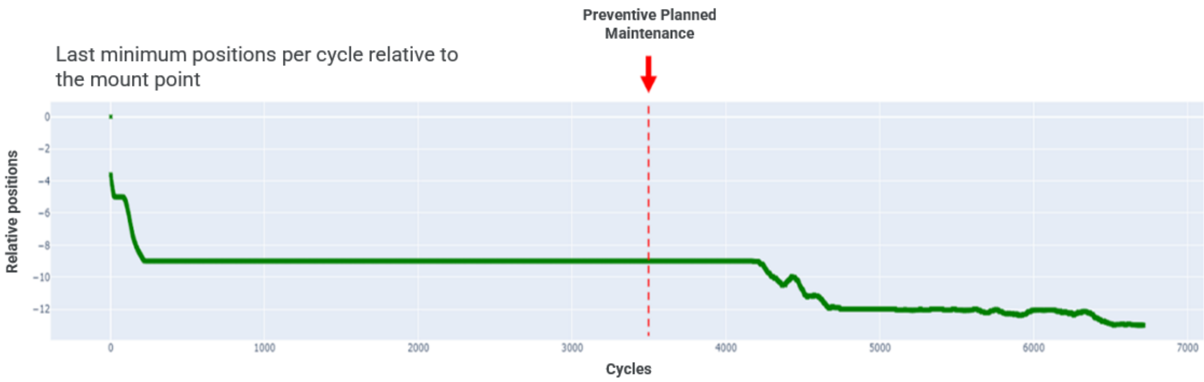

Figure 11. Raw signal reconstructed with minimum values

```
LOAD DATASET_PATH INTO df

ADD COLUMN cycle = ROUND(df["Valve cycles user"])
DROP COLUMNS ["Timestamp", "Valve cycles user"] FROM df
GROUP BY "cycle" INTO df_cycles:
    CALCULATE ["mean", "min", "std", "median"]

COMPUTE df_cycles["centered_closed_pos"] =
    df_cycles["Pos. Ferme Last"]["min"] - initial_closed_pos

SET WINDOW_SIZE = 5

COMPUTE df_cycles["moving_average"] =
    MOVING_AVERAGE(df_cycles["centered_closed_pos"], WINDOW_SIZE)
```

Figure 12. Algorithm 1, pseudo-code used for signal reconstruction and the establishment of moving averages

- **Signal post-processing**

As shown in Figure 10, the studied profiles extracted from the raw signal are characterised by a succession of more or less prolonged plateaus. We observed that changes in the profile were mainly due to the appearance of additional plateaus and/or the modulation of existing plateaus in the raw signal.

- **Cleaning of the original raw signal**

We initially cleaned and reconstructed the original signal using Algorithm 1 (Figure 12). The purpose of this procedure is to display only a moving average of the minimum position values in the profiles, per cycle, centered relative to the reference value obtained when a new membrane is mounted on the actuator (Figure 11). Indeed, the raw signal is not directly usable due to its inherent noise and fluctuations resulting from opera–tional variations. These fluctuations obscure the under–lying degradation trends of the membrane, making its interpretation difficult and unreliable. Therefore, in ac–cordance with PHM principles, it is essential to perform a signal cleaning.

The variables "Timestamp", "Valve cycles user", and "Pos. Ferme Last" are the indices collected directly from the GEMÜ electronic position indicators. For more clari–ty, we have decided not to modify their names in the code.

In our case, the moving averages are obtained using the formula (1):

$$moving\_average_i = \frac{1}{W}\sum_{j=1}^{i+W-1} centered\_closed\_pos_j \quad (1)$$

In our case, the moving averages with the following parameters :

→ x: current index in the time series

→W: smoothing window (size of the moving average)

→ : the summation index that iterates over the W points starting from .

→ : the signal values to be smoothed.

As shown in Figure 11, this initial reconstruction reveals a visualisation of a first signal phase up to 219 cycles. This phase is characterised by a high signal value that steadily decreases, which can thus be likened to a lapping period.

The second phase, which extends from 220 to 4,212 cycles, is characterised by a constant signal, which may represent the maturity phase of the membrane.

Finally, the third phase begins at 4,213 cycles, mar–ked by a signal decrease compared to the previous pha–se. It is in this third phase that the onset of rupture can be anticipated, making it the ageing phase.

To illustrate, the figure shows the preventive main–tenance horizon applied by our industrial partner, esti–mated at 3,500 cycles.

We initially cleaned and reconstructed the original signal using Algorithm 1 (Figure 12). The purpose of this procedure is to display only a moving average of the minimum position values in the profiles, per cycle, centered relative to the reference value obtained when a new membrane is mounted on the actuator (Figure 11).

After processing the original signal with Algorithm 1 to isolate the moving average of the minimum posi–tion values per cycle, our focus turned to the inter–mediate plateaus within the signal profiles. The Iden–

tification of irregularities in the plateaus could reveal early degradation trends that may not be observable in the raw signal.

- **Processing of the original raw signal**

There are several examples in the scientific literature that address signal processing for industrial equipment. For instance, there are cases involving rotating mach–inery [40] and electrical equipment [41-42], where sig–nals are analysed using Fourier transforms and Wavelet Analysis. [43], furthermore, they propose a post-pro–cessing method for audio signals using a Support Vector Machine (SVM) and a filtering window to extract patterns of interest. Actually, there are various generic approaches that must be adapted depending on the signal to be processed. Given that we are dealing with a specific, regular, and time-series signal, we chose to process our signal using a polynomial fitting algorithm (using Python's PolyFit library). This was performed to capture events related to the modulation of intermediate plateaus in the profiles to be analysed (Figure 10).

We developed an algorithm that first retrieves for each profile:

- The number of plateaus detected per profile.
- Their temporal amplitude, with 1 point on the y-axis corresponding to ½ second.

All these characteristics are then compiled into histograms, from which we extract, using Algorithm 2 (Figure 14), the values of a linear regression and a second-degree polynomial regression (Figure 13) based on the least squares method.

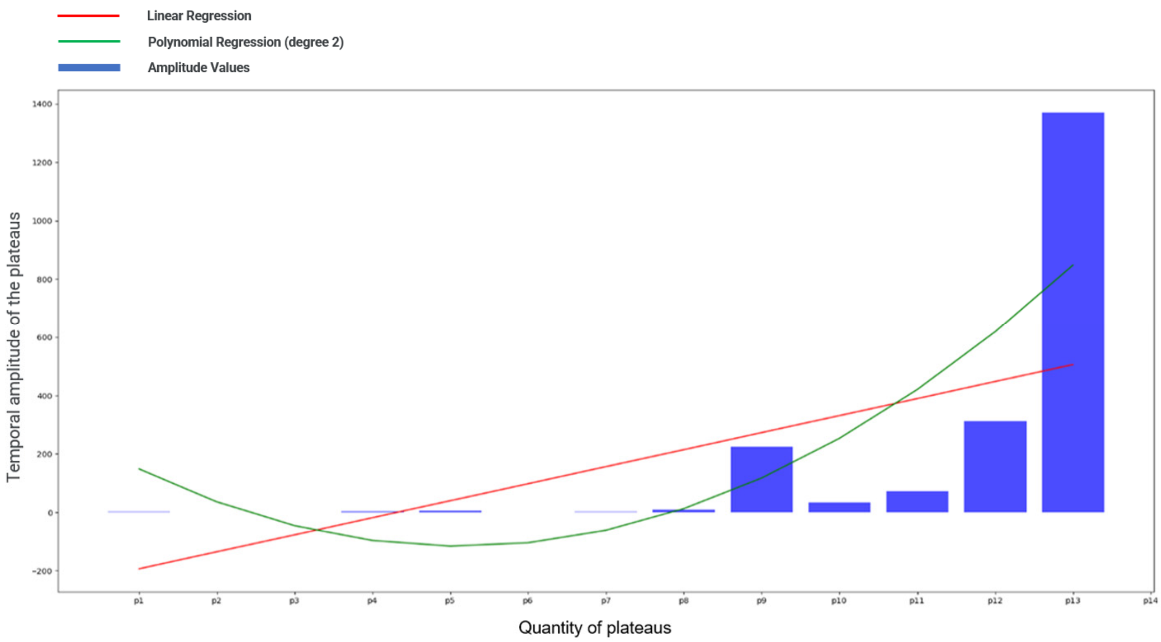

Figure 13. Extraction of characteristic values from cycles via PolyFit

```
LOAD DATASET_PATH INTO df
SELECT ['Timestamp', 'Pos. Ferme Last', 'Valve cycles user'] FROM df
GROUP BY "Valve cycles user" INTO df_groups

FOR cycle, group IN df_groups:
    INIT cycle_data = { 'Cycle': cycle, 'Nombre de paliers': 0 }
    palier_changes = (group['Pos. Ferme Last'] != group['Pos. Ferme
Last'].shift(1)).cumsum()
    FOR palier, palier_indices IN group.groupby(palier_changes).groups:
        cycle_data["Longueur_palier_" + palier] = MAX(palier_indices) -
MIN(palier_indices)
        cycle_data['Nombre de paliers'] += 1
    APPEND cycle_data TO result_list
df = CREATE DataFrame FROM result_list

FOR cycle IN RANGE(MIN(df['Cycle']), MAX(df['Cycle'])):
    IF ALL p_columns EXIST IN df.columns:
        values = GET_VALUES(df, cycle, p_columns)
        indices = FIND_NON_NAN(values)
        IF LENGTH(indices) >= 2:
            linear_coef = POLYFIT(indices, values, DEGREE=1)
            poly_coef = POLYFIT(indices, values, DEGREE=2)
            APPEND cycle, linear_coef, poly_coef TO cycles_list
```

Figure 14. Algorithm 2, the pseudo-code used for extracting characteristic values of cycles

The following 4 values allow the characterisation and revelation of marked differential values depending on the signal evolutions in the different profiles studied. They are obtained by using the formulas (2),(3), (4), (5):

Linear regression:

$$y = ax + b \tag{2}$$

With the following parameters:
→ y : Values of the temporal amplitudes of the steps
→ x : Index of the last detected level
→ a : regression coefficient
→ b : ordinate at the origin

Linear Regression + Least Squares:

$$S(a,b) = \sum_{i=1}^{n}\left(y_i - \left(ax_i + b\right)\right)^2 \tag{3}$$

With the following parameters:
→ $S(a,b)$: cost funciton
→ n: number of observations
→ x_i, y_i: data point values (input/output)
→ a, b: coefficients to be optimised to minimise the error

Quadratic (polynomial) regression:

$$y = ax^2 + bx + c \tag{4}$$

With the following parameters:
→ y: Values of the temporal amplitudes of the steps
→ x: Index of the last detected level
→ a: coefficient of x^2
→ b: coefficient of x
→ c: constant (ordinate of the origin)

Quadratic (polynomial) regression + Least squares:

$$S(a,b,c) = \sum_{i=1}^{n}\left(y_i - \left(ax_i^2 + bx + c\right)\right)^2 \tag{5}$$

With the following parameters:
→ $S(a,b,c)$: cost funciton
→ n: number of observations
→ x_i, y_i: data point values (input/output)
→ a, b, c: coefficients of the polynomial to be adjusted

Our research focuses on the second-degree poly–nomial values because they highlight the modulation of the intermediate plateaus that appear in the profiles. After extraction and normalisation, the following post-processed signal emerged (Figure 15).

As previously indicated, the figure shows the mem–brane replacement horizon currently in effect at our industrial partner, corresponding to the date of planned preventive maintenance. Contrary to the observations presented in Figure 11, a significantly less stable signal is evident, revealing isolated drift events that correspond to time periods during which maintenance activities causing signal losses were performed. These maintenance acti-svities include server updates, equipment replacements, and disassembly for membrane inspection.

- **Transformation and extraction of life phase patterns**

To enhance our investigation of the raw signal, we applied a transformation technique to verify the presence of characteristic lifecycle patterns within the data. This transformation was essential to complement our study, as it allowed us to systematically search for and uncover as many explicit patterns as possible that might reflect the membrane's behaviour over time. The scientific literature has documented many methods that focus on repro–cessing signals to highlight abnormal sequences, so we selected an approach consistent with these established practices. The aim of this approach was to detect potential anomalies or trends that may not be immediately apparent in the original signal. This step ensured a thorough ana–lysis, providing a deeper understanding of the membrane's performance and condition.

[44] The study proposed a classification of errors in an electrical signal using PCA (Principal Component Analysis). This linear method transforms original varia–bles into new orthogonal variables (principal compo–nents) that maximise variance. This technique is used for data compression and noise reduction.

Another method, which is nonlinear , employs t-SNE to capture interdependencies within an EEG (Electroen–cephalography) signal, as described by [45]. The principle of SNE (Distributed Stochastic Neighbor Em–bedding) involves the reduction of signal data points' dimensionality to visualise complex data in 2D or 3D while preserving the local structure of the points as much as possible.

A third transformation method that is frequently encountered in literature, involves the employment of deep learning methods and AutoEncoders. [46] This technique is applied to study acoustic variations in the biodiversity of temperate and tropical environments. Its objective is to amplify periodic signals and reduce biases. This method relies on neural networks to encode data into a lower-dimensional latent space.

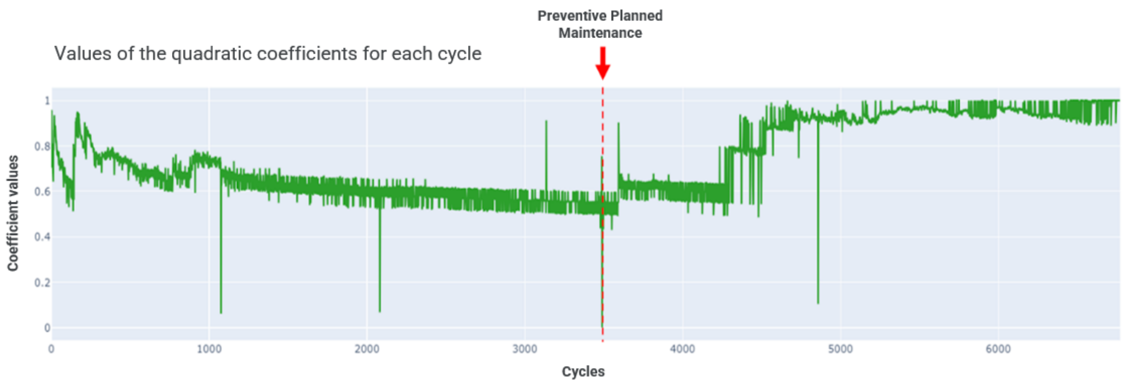

Figure 15. Normalised and post-processed signal

In our application case, and given the nature of the data, we decided to use a t-SNE method on the set of descriptive statistics values extracted by Algorithm 1. Our objective was to verify the presence of patterns not visible in the signals obtained thus far.

t-SNE consists of a dimensionality reduction method proposed by [47] for the purpose of visualising multidimensional data in 2D or 3D. Consequently, the axes of a t-SNE plot do not have physical or measurable significance. The resulting coordinates do not corres–pond to specific units, but rather reflect the local structure of the data [48]. t-SNE preserves neigh–borhood relationships, in other words, points similar in the original space will remain close in the reduced space, though the distances between points have no absolute value. The presence of observed groupings or clusters indicates similar relationships; however, exact distances between points are not preserved. The primary objective of t-SNE is to reveal data structures rather than to maintain precise distances or scales.

This method involves the application of a nonlinear transformation to the input data to project it into a lower-dimensional space. Then, a calculation of the probability of similarity in the original space is perfor–med on the input data. This is followed by projecting the values into a low-dimensional space, defining a similarity distribution in that space, and finally mini–mising the cost function using the Kullback-Leibler divergence via gradient descent.

The method described here, along with the related equations, is derived from an article by [47]. The results of the signals decomposed by t-SNE, which are consi–dered the most relevant, are illustrated by Figure 16. This figure combines four distinct signals, which are labeled as follows:

a) Mean values, representing the average behaviour of the signals per cycle;

b) Minimal values, indicating the lower bounds of signal variation per cycle;

c) Standard deviation, reflecting the variability of the signals within each cycle;

d) Median values, providing a robust measure of central tendency per cycle.

These statistical measures offer a comprehensive view of the signal characteristics across the analysed cycles.

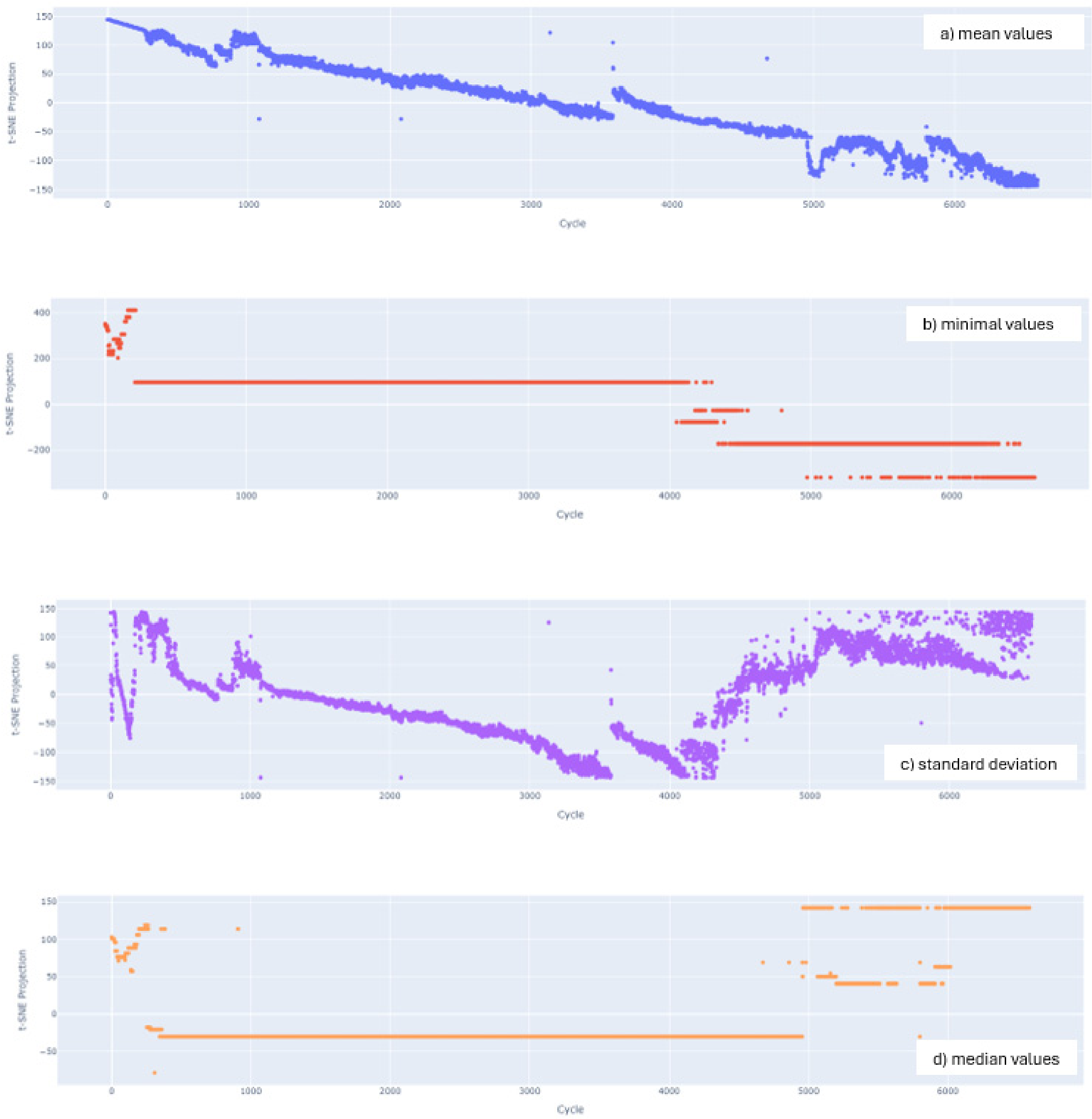

Figure 16. t-SNE decomposition of signal statistics per cycle, based on the method by Maaten & Hinton (2008)

The results of this decomposition can subsequently constitute a working basis for signal processing inten–ded to detect the different phases of the equipment's life.

4. EXPERIMENTAL RESULTS ANALYSIS

The following analysis focuses on the data presented in Figures 11 and 15. Our decision the reason for choosing these results is that :

- In the first case (Figure 11), the values are derived directly from the original raw signal.
- In the second case (Figure 15), the values result from post-processing aimed at highlighting the internal modulations of plateaus for each cycle.

Figure 16 provides a complementary role, serving to consolidate the initial findings presented in Figures 11 and 15. They offer a broader perspective on the signal’s statistical behaviour, which can be leveraged in future research. As the focus of our study was a phenomenon of progressive drift, we established a comparison between a stable signal and a more variable, noisy signal. This enabled the verification of whether both signals follow consistent trends. It is important to note that the first relates to the drift of the raw signal cycle by cycle, while the second focuses on the number, distribution, and amplitude of the plateaus composing each cycle’s signal.

As explained in the "Signal Characterisation" sec–tion, we organised the signal analysis around the physical characteristics related to material degradation, namely lapping, maturity, and old age.

4.1 Lapping

In our study, the lapping of the equipment begins at the first cycle and extends to an interval ranging from cycle 219 to cycle 277. We base this assertion on the characteristics of the two signals:

- Raw signal : The reconstructed raw signal shows a continuous decline from cycle 1 to cycle 219. The potentiometry will have lost 9 points compared to the first cycle before stabilising.
- Post-processed signal : The post-processed signal exhibits a certain amplitude in normalised values of 0.44 points, before stabilising at approximately 0.71 points from cycle 277 onward.

4.2 Maturity

The maturity of the studied equipment manifests as a signal that is more stable than that of the lapping phase, continuing until an interval ranging from cycle 219 to cycle 4,268. Characteristics of maturity include :

- Raw signal : Strict stability of the reconstructed raw signal from cycle 219 to cycle 4,212. The poten–tiometry displayed in this range is also -9 points relative to the value at cycle 1.
- Post-processed signal : Stable and slightly down–ward curves in the post-processed signal. By cycle 4,268, the normalised coefficient value drops to approximately 0.59, representing a loss of about 0.12 since the start of the maturity phase.

4.3 Old age

The old age phase, in contrast, begins relatively abruptly. This stage is manifested through a differential modulation between the two signals:

- Raw signal : Beyond 4,219 cycles, it appears as a continuous decline in the reconstructed raw signal until cycle 4,743. At this point, 3 additional points will have been lost, with the potentiometry stabi–lising at -12 points relative to cycle 1. This stability persists until cycle 5,103, after which the poten–tiometry drifts slowly with a slightly negative trend until the end of the test at 6,715 cycles.
- Post-processed signal : Beyond 4,268 cycles, the normalised post-processed signal reverses its curve compared to the raw signal. Until cycle 5,139, the post-processed signal rises from approximately 0.55 to about 0.90. Beyond this point, the signal stabilises and begins a slightly positive drift. This final drift phase is also punctuated by acute events (single-cycle peaks) that bring the normalised signal to 1.

Generally speaking, the discrepancies observed bet–ween the raw signal and the post-processed signal can be explained by the fact that the former represents only the minimum positions, whereas the latter involves a finer analysis of the complete signal. Beyond this discrepancy, we can establish that variations in the post-processed signal are correlated with those in the raw signal.

4.4 Materialised Failure

As already mentioned in the "Failure Mode" section, valve membranes are susceptible to two types of failure:

- Progressive deformation leading to a breach in the sealing system and the creation of retention zones.
- Rupture of the PTFE layer.

Our case study showed that an internal leak in the system occurred at cycle 5,172. It was detected by the booster and physically confirmed by a slight beading in the tank. This implies that, with a system pressure of 2 bars, the membrane has deformed sufficiently that it can no longer provide internal sealing.

Since the leak did not present any danger to the installation or the experiment itself, we decided to continue the test to determine the maximum signal drift, which stabilised at 1 on a normalised scale. This maximum drift was observed in the post-processed signal, maintaining a value of 1 from cycle 6,667 to cycle 6,715, marking the end of the experiment.

Figure 17 shows this leakage within a stable zone of the old age phase, directly preceding a new phase of drift with a negative trend.

Figure 18 reveals that the leakage is this time located in a zone of instability in the ageing phase. To link the observed signal drifts with the physical characteristics of the membrane, we conducted an elasticity test on the equipment. This test consists of comparing between the elasticity of the used membrane with that of a new membrane.

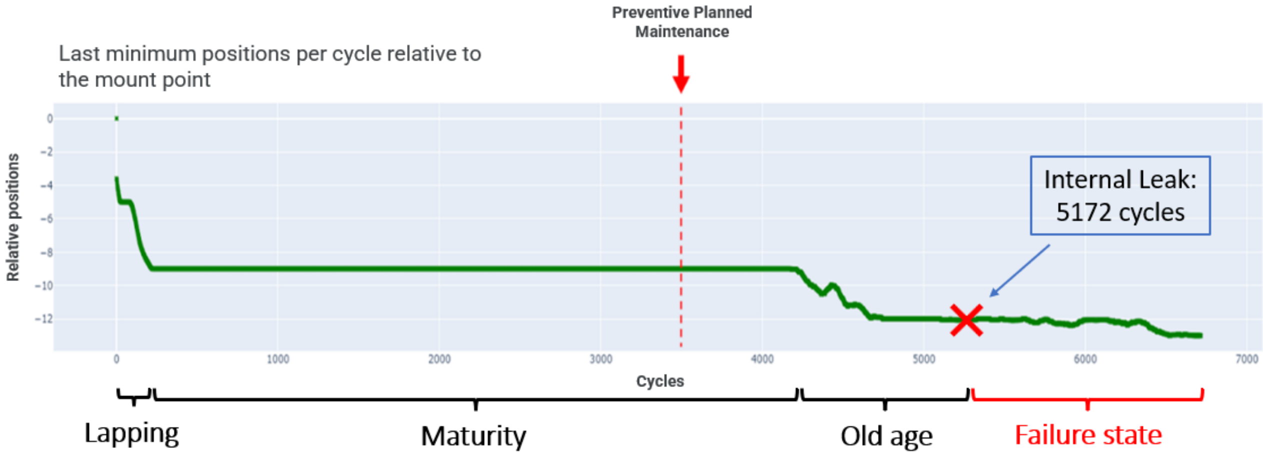

Figure 17. Raw reconstructed signal annotated with the fault indicated

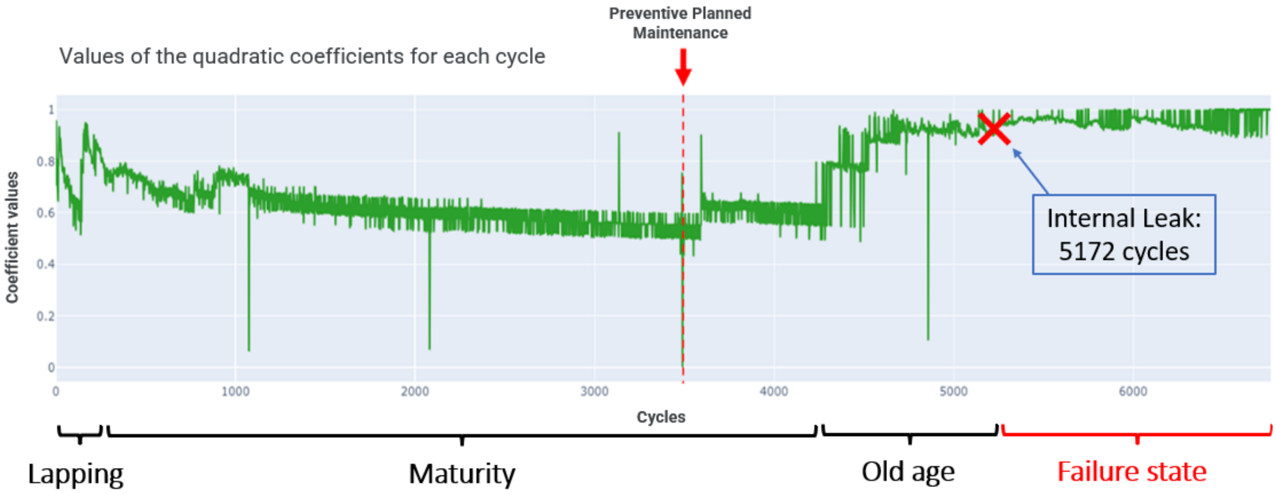

Figure 18. Normalised post-processed and annotated signal with indicated failure state

Figure 18 reveals that the leakage is this time located in a zone of instability in the ageing phase. To link the observed signal drifts with the physical characteristics of the membrane, we conducted an elasticity test on the equ–ipment. This test consists of comparing between the elas–ticity of the used membrane with that of a new membrane.

5. DISCUSSION OF PHYSICAL CHARACTERI–SATION OF MEMBRANE DEGRADATION

To estimate this elasticity drift, a university test plat–form (Figure 19) was used to compress the membranes and measure the force (N) required to achieve a specific stroke.

Each membrane underwent 200 compression cycles. The test parameters are as follows :

• 2 samples:

◦ A new reference membrane

◦ The degraded membrane from our study, of the same reference

• Type of stress: Compression

• Displacement: 2 mm

• Compression speed: 50 mm/min

The results are presented in Figure 20. The trace of the new membrane is shown in blue; the trace of the worn membrane is shown in orange.

This reveals that the new membrane requires more force than the worn membrane to achieve the target displacements. The curves of the new membrane (in blue) exhibit higher force values, expressed in N, for the same displacement level.

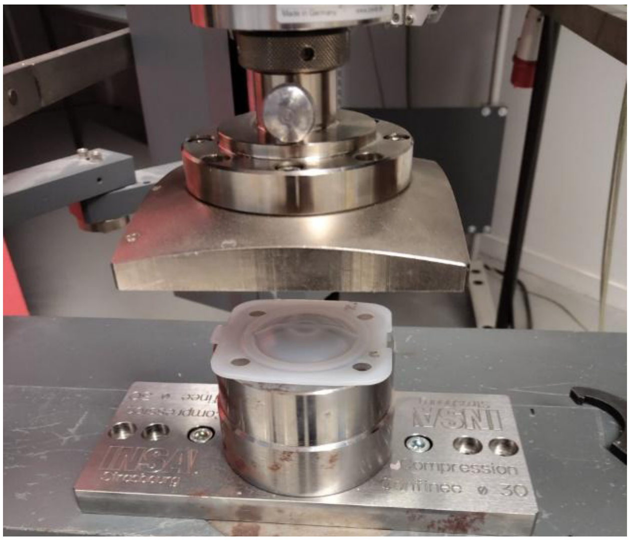

Figure 19. Testing Platform, University Press

- Interpretation: The new membrane displays signi–ficant rigidity, indicating that it effectively resists compression.

- The curves of the worn membrane (in orange) show that the force required for the same displacement is lower than for the new membrane.
- Interpretation : The degradation of the membrane has led to a loss of rigidity and a change in its mec–hanical properties (material fatigue, loosening of internal components). A lower force requirement sug–gests deterioration of the worn membrane, potentially increasing the risks of leaks or failures.

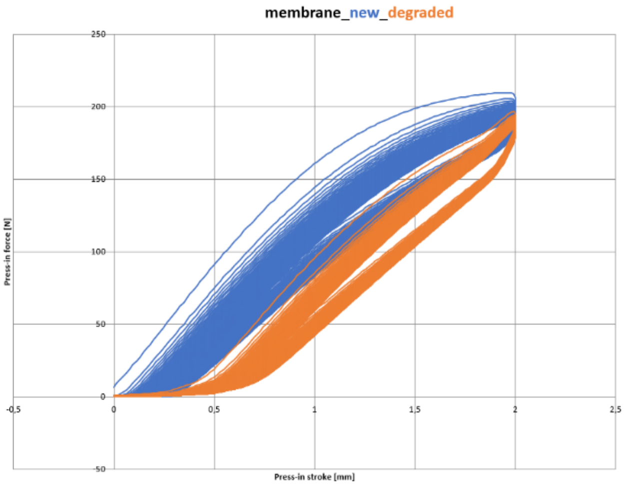

Figure 20. Results of comparative compression tests of the new membrane versus the used membrane

From the beginning of the test, the new membrane required a much higher force (approximately 6.47 N) to be compressed, whereas the worn membrane required only about 0.81 N. This demonstrates a significant vari–ation (less rigidity and more elasticity) after use.

Concerning the new membrane, the graph indicates that for subsequent runs and from the onset of comp–ression, the force decreases slightly but remains within a high range (around 6.43 N). This suggests a certain consistency in its resistance to compression. However, in the case of the worn membrane, the required force is low and remains stable at around 0.80 N, indicating that it has lost much of its ability to resist compression. This implies that the worn membrane is significantly more elastic than the new membrane.

This experiment highlights a tangible physical chan–ge in the characteristics of the studied material. How–ever, it does not address certain questions related to the stress exerted on the equipment. To further explore the results obtained, it would be a valuable addition to this article to conduct simulations to assess the theoretical fatigue of the equipment under conditions like those described in the "Test bench experimentation" section.

6. CONCLUSION

This article has presented a framework for evaluating the evolving state of industrial equipment, with the aim of transitioning from planned to predictive maintenance.

6.1 Main contribution

We identified relevant operational data, i.e., signals that indicate the status of health equipment, and leveraged Internet of Things (IoT) technologies to capture this data in real time. Several signal post-processing steps were then applied, including filtering and feature extraction, to derive pertinent information regarding the condition of the equipment. We also presented the potential application of the PHM (Prognostics and Health Management) framework to a wear component commonly found in biopharmaceutical production processes, namely the pneumatic valve membrane. The implementation of this framework requires the availability of representative data equipment under study, which can then be used to establish thresholds and more advanced data processing to determine a predictive maintenance horizon.

We propose in this article the following points :

- A method for recovering representative data of the state of an industrial equipment : membrane through potentiometric values.
- Equipment life criteria, based on an analysis of the signals obtained in this study.
- A comparison of extracted signals and resulting equ–ipment life criteria versus current planned main–tenance practices in a biopharmaceutical industry.

6.2 Main practical applications

The work developed in this article has already led to a number of practical applications. It is possible to make use of all the profiles presented in the 'Signal post-processing' and 'Transformation', and Extraction of life cycle models' sections. They can serve as a basis for the implementation of a data processing system using mac–hine learning techniques, capable of classifying the different life phases of the equipment identified in this study. This system can also be used to estimate the residual life from the processed signals, thus providing a basis for a predictive maintenance system. Further–more, the results of this work can enable the design of a decision support system, capable of helping main–tenance operators to optimise their interventions in industrial contexts subject to strict quality standards.

6.3 Limitations

It is important to note that, despite the valuable infor–mation provided by the data collected, certain limi–tations need to be recognised, principally with regard to the representativeness of the tests conducted. Indeed, the experimental conditions and the type of valve tested do not fully represent all configurations used in bio–pharmaceutical production environments. The Varia–bility of operating conditions, such as different types of fluid, variations in temperatures and pressures, and the specific features of each production facility, can influ–ence the behaviour of pneumatic valve membranes. Therefore, the results obtained from tests performed on a specific valve cannot be generalised to all valves present in various industrial processes, though they may be applicable to pneumatically controlled valves ope–rating under similar conditions.

Thus, the aim of future studies will be to propose a generic framework that can be applicable to different types of equipment in several fields of industry. Moreover, the study was conducted on the basis of a single experiment. It would be necessary to replicate this study to achieve statistical representativeness and ensure that the signals and membrane lifespan indicators are reproducible.

6.4 Perspectives

Our future work will focus on a method that enables us to establish a prognosis of failure occurrence based on the behavioral model proposed in this article. We will create a data processing system with machine learning techniques to enable the classification of life phases and the accuracy of residual life predictions, while refining the decision support system for broader industrial applications. We also aim to address the limitations identified in Section 6.3 by conducting extensive testing across diverse valve configurations and operating conditions, including varied fluid types, temperatures, and pressures, to obtain greater representativeness. Furthermore, we will replicate the experiments to achieve statistical validity, enabling the development of a generic framework that can be adapted to different equipment and industry sectors.

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NOMENCLATURE

i	current index in the time series
j	summation index that iterates over the W points starting from i
W	smoothing window (size of the moving average)
a	regression coefficient (1) of coefficient of x^2 (2)
b	ordinate at the origin
c	constant (ordinate at the origin)
x	Index of the least detected level
y	Values of the temporal amplitude of the steps
n	number of observations
$S(a,b)$	cost function (3)
$S(a,b,c)$	cost function (5)
(a,b,c)	coefficients of the polynomial to be adjusted
x_i, y_i	values of data points
x_i^2	Square of the value x at index i

Acronyms and abbreviations

PHM	Prognostic Health Management
IOT	Internet Of Things
PLC	Programmable Logic Controller
RNN	Recurrent Neural Network
RUL	Remaining Useful Life
ANFIS	Adaptive Neuro-Fuzzy Inference System
PRSOV	Pressure Regulated Shutoff Valves
SVM	Support Vector Machine
kNN	k-Nearest Neighbor
NB	Naive Bayes
CART	Classification and Regression Trees
MLR	Multiple Linear Regression
MLP	Multi-Layer Perceptron
CVA-	Canonical Variate Analysis on
SMD	Square of the Mahalanobis Distance
PCA	Principal Component Analysis
SVA	Surrogate Variable Analysis
DGM	Dynamic Grey Model
EPDM	Ethylene Propylene Diene Monomer
PTFE	Polytetrafluoroethylene
ND	Nominal Diameter
IO-Link	Input/Output Link
t-SNE	t-distributed Stochastic Neighbor Embedding
EEG	Electroencephalography

СТУДИЈА ПОНАШАЊА ОПРЕМЕ У ФЛУИДНИМ ПРОИЗВОДНИМ ПРОЦЕСИМА КОРИШЋЕЊЕМ ПОДАТАКА ЗА ОПТИМИЗОВАНО ПРЕДИКТИВНО ОДРЖАВАЊЕ: ПРИМЕНА НА ПНЕУМАТСКЕ ВЕНТИЛЕ У БИОФАРМАЦЕУТСКОЈ ИНДУСТРИЈИ

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Предикативно одржавање производне опреме добија све веће интересовање у биофармацеутској индустрији у контексту Индустрије 4.0, где је поузданост неопходна за осигурање квалитета производа, доступности опреме и усклађености са строгим стандардима. Пнеуматски мембрански вентили, кључни за регулисање протока флуида и гаса у производним системима, од посебног су значаја. Мембрана, примарна компонента која се хаба, подложна је механичким напрезањима која могу довести до деформација или пуцања. То може пореметити производњу и угрозити квалитет производа.

Прогностичко управљање здрављем (ПХМ) је обећавајући приступ праћењу стања опреме. Коришћењем репрезентативних података, нуди могућност моделирања еволуције стања опреме и предвиђања потенцијалних кварова. Ова предиктивна стратегија, заснована на фазама и трендовима животног циклуса, олакшава циљане интервенције одржавања пре него што дође до већих кварова.

Овај чланак истражује интеграцију ПХМ-а за одржавање мембрана пнеуматских вентила у биофармацеутском сектору. Предлаже метод за

идентификацију експерименталних података, дефинисање критеријума животног циклуса, анализу ових критеријума, њихово поређење са планираним праксама одржавања и процену померања сигнала како би се окарактерисало стање мембране за будући развој предиктивног одржавања.