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Case Study – Autoclave Batch Failure Prediction

Summary

Autoclave (also known as steam sterilizer) is a critical process equipment in medical and pharmaceutical industries used for sterilization. Most modern autoclave systems are equipped with sensors and controlled by automation systems(PLC/SCADA). These systems are operated on batch basis by human operators. The process parameters (vacuum, pressure, temperature etc.) of such systems have to be controlled tightly to meet the stringent quality control requirements. The process parameter control is not guaranteed due to the combination of multiple system connections, and human operations involved. This results in multiple issues during sterilization and validation cycles ultimately resulting in batch failures that cost time and money.

Vadict has developed a unique solution for such steam sterilization systems - to predict in real-time if the new batch will pass/fail. Vadict has developed algorithms that uses existing automation system data on process parameters(viz. pressure, temperature, time) to predict the failure of upcoming batch with >90% accuracy.

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1 Current state of Autoclave Systems

1.1 Autoclave System overview

Autoclaves uses high-temperature saturated steam for disinfection and sterilization. In autoclaves, items are exposed to steam at certain pressure and temperature for specified time. Sterilization process consists of multiple stages – chamber depressurization, heating, etc. Generally, autoclave operations are computer-controlled and pre-defined parameter values are set for automatic sterilization. Autoclaves are equipped with multiple sensors for process monitoring and control. Sensor value are continuously recorded in the data loggers.

Schematic diagram of an autoclave is shown in Figure 2.1. Variations of pressure and temperature are presented in Figure 2.2 for a sterilization cycle. First, a vacuum is created within sterilizer to achieve uniform pressure and temperature. After multiple pressurization and evacuation stages, required sterilization pressure and temperature (typical 121.1 °C) are achieved, which are then maintained for specified time based on the load (porous/non-porous) and application.

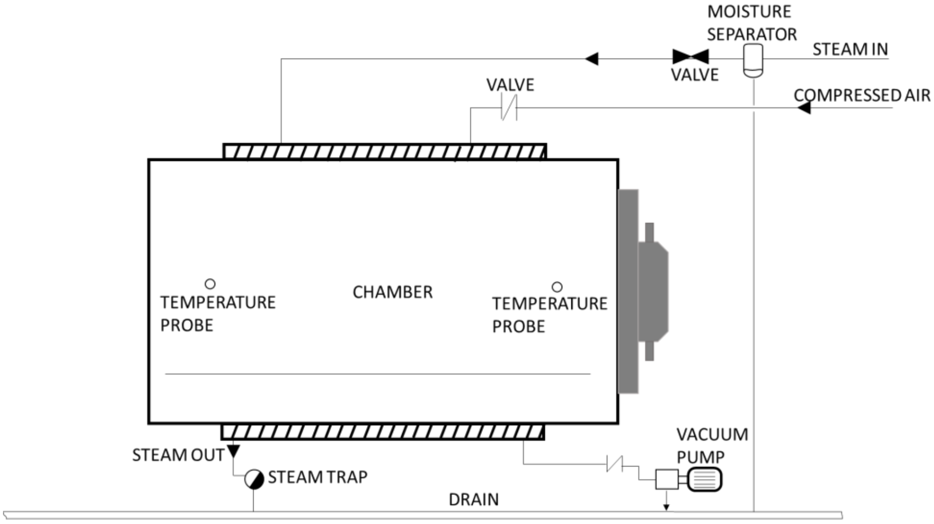

Figure 1.1 Schematic diagram of autoclave.

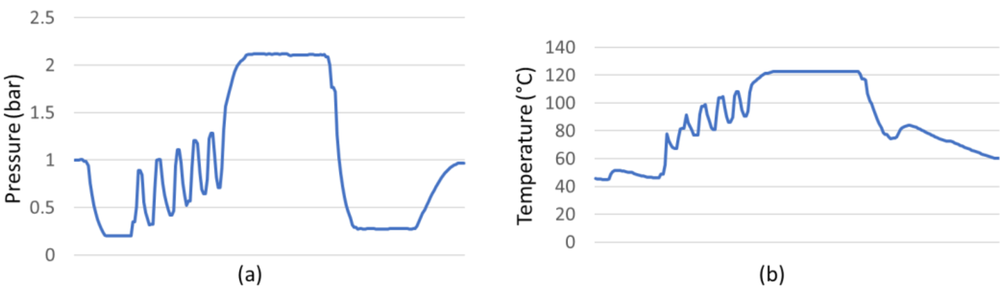

Figure 1.2 (a) Pressure and (b) temperature variation for one sterilization cycle.

1.2 Functional Monitoring

Different tests are performed to ensure proper functioning of sterilization process. Leak-rate and Bowie-dick tests are the common tests that are routinely performed to validate successful sterilization processes.

1.2.1 Bowie-dick test

Successful Bowie-dick test validates proper air removal within sterilizer. Test sheets with chemical sterilization indicators are placed inside the sterilizer. After the test process, sheets' appearance indicates whether desired vacuum was achieved or not. If equipment fails Bowie-dick test, vacuum creation process or steam generation need to be checked.

1.2.2 Vacuum leak test (VLT)

During VLT, pressure variation over a certain period is measured in the depressurized chamber. In case the pressure exceeds predefined limit (typically 0.013 bar for 10 min duration), test is called failed. High leak indicates maintenance requirement.

1.3 Problems faced with current generation of Autoclave systems

The biggest and most common problem faced is the batch failure of product being sterilized. This results in immense financial and time-to-market losses. The batch failure can be attributed to multiple different causes:

- Improper loading and packaging
- Improper procedure (human error)
- Equipment malfunctioning (e.g., faulty vacuum pump)
- Sensor malfunction
- Poor steam quality
- Leakage in gasket or jacket
- Lack of routine maintenance

2 Vadict's State-of-the-art Autoclave Batch Failure Prediction System

With the latest advances in IoT, smart sensing, data science, and cloud computing – it is possible to rethink the problems faced for Autoclave systems operations especially when there is high costs and time-to-market involved. Vadict digitizes , automates and interconnects all company assets; co-relates with informational data(ERP, EMS, etc.) and contextual data (FOREX, weather, etc.); enriches the data with intelligent algorithms; and augments this information with our deep-industry expertise to create business solutions.

Vadict has developed a unique solution that can predict the failure of batches(with >90% accuracy) in near real-time allowing our customers to prevent losses, while ensuring unnecessary maintenance is not required.

2.1 System architecture

Figure 3.1 presents end-to-end system architecture for IIoT-enabled autoclave process monitoring for failure prediction. Data collected by the autoclave automation system (PLC/SCADA) is integrated with Vadict IoT Platform via an IoT gateway placed at customer site. The IoT gateway leverages multiple security mechanisms to securely acquire data and then transmit data. This data is then processed by the unique algorithms to arrive at predictions in near real-time. The derived predictions are made available to end-users as alert notifications and also available on dashboards accessible over mobile/web.

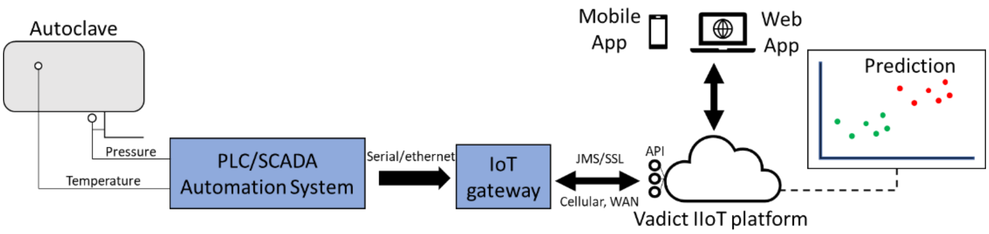

Figure 2.1 High level end-to-end system design.

2.2 Data Processing

Historical data of all the processes (sterilization, bowie-dick, VLT, etc., about 10000 batches) were used in this study. Pressure and temperature data were captured at 30 s interval. Figure 4.1 shows distribution of failed VLT. It can be observed that the frequency of failure has reduced, therefore, dataset was split into two parts for further analysis.

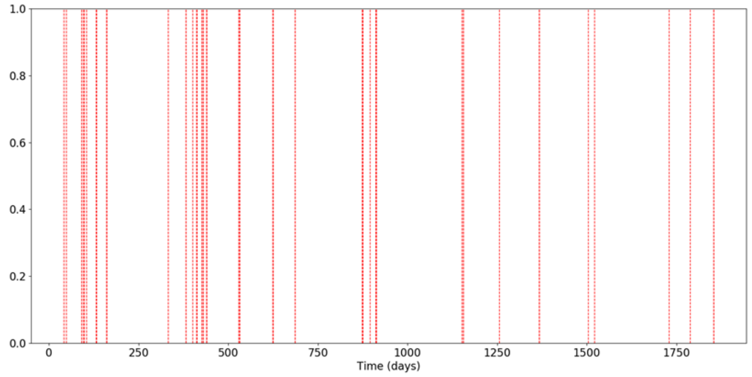

Figure 2.2 Distribution of VLT fail events (vertical dashed lines).

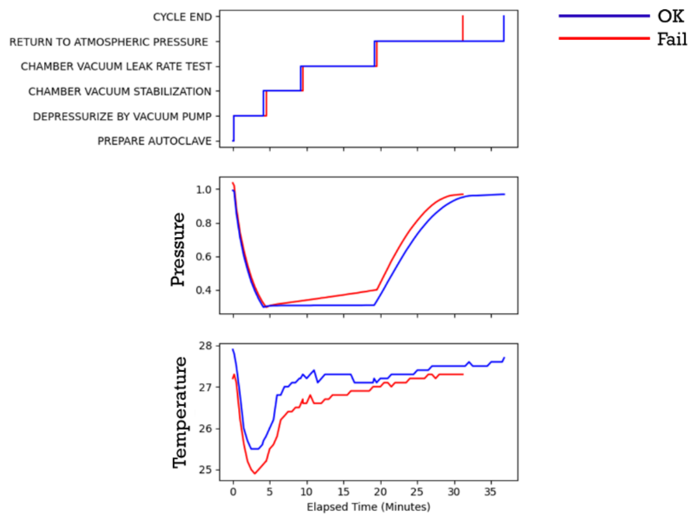

Figure 2.3 Pressure and temperature variation for passed and failed VLT cycles.

2.3 Model development

After data screening, filtering, and visualization, different numerical and categorical features were derived from the available dataset. During model building, dataset was split into 70 and 30% for training and validation, respectively. Key information of machine learning model is provided in the table below.

Table 1 Machine learning model information.

Train/validation set	70/30
Sampling	Oversampling techniques
Model algorithm	Neural Networks
Model type	Classification
Input	Numerical + categorical features

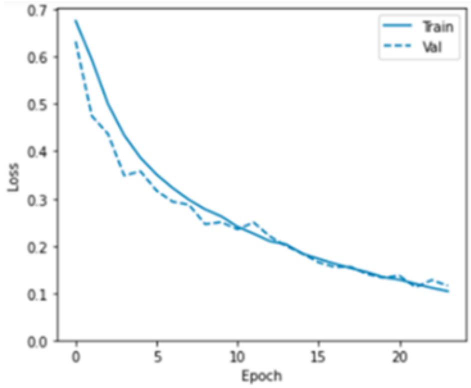

Figure 2.4 Evolution of loss value with iterations.

2.4 Results

Different ML models were developed. The best model predicts the failed batches with 80% accuracy (true positives), and passing batches with 90.63% accuracy (true negatives).
These results are expected to improve as the system gathers more data and the algorithms are tuned to look for specific failure scenarios.