Design and Comparative Analysis of Quality Management Systems in Aseptic Process for Smart HACCP in Food and Beverage Industry

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Abstract: - Traditionally, food and drink have been used as a means of survival. In recent years, as technology has advanced and our quality of life has improved, we have begun to seek out better food - not just for the sake of the food itself, but to consume wisely, considering not only the ingredients but also the manufacturing process. Companies that used to simply produce and deliver products now need to provide services such as quality, promptness, and information, especially when it comes to quality control and safety, and quality management, which are directly related to the lives and safety of consumers. Many companies are introducing quality management systems to provide quality that meets the needs of customers and the market. With the development of information technology, quality inspection methods are becoming more diverse and sophisticated. However, the risk of defects occurring in the process still exists. In this paper, when a process fails due to an unknown cause, the analog/digital data of that process is selected and compared with normal cases. At that time, the analog/digital data of that process is selected and compared with normal and abnormal cases. Then, multiple regression analysis is used to describe the process of finding the failure point.

Key-Words: - HACCP, Smart HACCP, Aseptic, Food and beverage, Analysis, Simulation

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1 Introduction

Providing quality and reliability has become a major challenge for companies that supply food and beverages. Given that potential quality defects can occur in any process that produces a product for direct human consumption, it is essential to establish a system of control and management throughout the process, [1]. This is where Hazard Analysis and Critical Control Points (HACCP), a food safety management system, comes in. It aims to prevent biological, chemical, and physical hazards specifically related to food and beverage production processes by using more quantitative indicators and upper and lower limits for quality inspection targets than traditional quality control activities, [2].

With the recent development of information technology, it is possible to perform advanced food safety management through automation and improvement activities by incorporating IT technology into the existing HACCP system. The system can provide various services depending on which IT technology it is integrated with, such as identifying trends in all products and processes through data collection and analysis activities and providing users with quality-level predictions, [3].

The beverage production plant in the background of the study was the first beverage production line to undergo overall pre-verification for Smart HACCP certification in Korea after the establishment of Smart Factory. The aseptic failure of the washing water used to clean packaging materials such as containers and caps for beverages occurred, and some items produced in the PET bottle line were found to be out of standard. Therefore, production/quality managers in the factory conducted additional inspections of the aseptic process but were unable to identify the cause.

Select the line where the aseptic failure phenomenon occurred and the data of the aseptic water treatment process, and perform pre-processing to convert them into time series data. The data obtained in the above process is divided and analyzed using time series decomposition (production instruction information during the problem period, aseptic water flow statistics, heat exchanger discharge temperature statistics, etc.

Time series decomposition is divided into trend, seasonal, and residual data with time series characteristics. The de-composition model can be broadly divided into additive and multiplicative factor decomposition, [4]. Additionally, since the residuals of the time series decomposition follow a normal distribution, it is possible to detect anomalies by determining whether the current data exceeds a certain sigma of the period data, [5]. Therefore, regression analysis is performed by collecting time periods with residuals of 30 seconds or more. Through multiple regression analysis, we identified a list of tags that affect the sterility failure point, and identified precursor symptoms for selected tags, [6].

Describe the current aseptic process and its function, and identify possible causes. Analog data such as temperature, pressure, and flow rate of facilities, digital signals of pumps and valves, and production instruction data by period from MES (Manufacturing Execution System) are collected, and simulations are performed based on the data of normal and abnormal cases. After preprocessing the data into a time series, multiple regression analysis was used to suggest solutions to the problem.

The structure of this paper is as follows. First, in Section 2, I describe the food and beverage industry, Smart HACCP, and the sterilization process. Second, I briefly describe the process and environment where the problem occurred, compare the situation pre-symptoms and post-symptoms the aseptic failure, and my hypothesis. Section 4 describes the analysis based on time series data and the process of finding the cause. Finally, Section 5 concludes with a discussion of the result, implications, and future work of this thesis.

2 Related Work

2.1 Food and Beverage Industry

The food and beverage industry is one of the largest industries in the global economy and is constantly evolving. It is made up of many different sectors, including agriculture, processing, distribution, and retail. It is also driven by a variety of trends, including changing consumer preferences, technological innovation, and globalization. It creates a lot of jobs and contributes a lot to national economies. It has also been an important activity in nourishing humanity and spreading culture.

The food and beverage industry is changing rapidly. Consumers' dietary habits and overall lifestyles have changed compared to the past, and new food products are constantly being developed to meet their needs. It is expected to continue to grow in the future. As the population grows, technology improves, and the middle class expands, the demand for food and beverages of varying quality will increase, [7].

2.2 Smart HACCP

Smart HACCP is a food safety management system that uses IT technologies such as big data and the Internet of Things (IoT) to collect and analyze data at all stages of food production, processing, distribution, and sales. It improves the efficiency and convenience of food production companies' existing HACCP operations while automating the production process to efficiently manage cross-contamination of pathogenic microorganisms, which previously relied on manual work, to improve the competitiveness of the food industry. In addition, by preventing human error and data falsification in advance, it can provide consumers with high confidence in food safety, [8].

2.3 Aseptic Process

In factories that produce food and beverages, quality control throughout the production process is essential. Due to the nature of these products, they are directly consumed by consumers and therefore have a direct impact on their safety and health. Therefore, quality control (QC) procedures must be in place to ensure that not only the raw materials, but also the packaging materials meet predetermined quality standards for purity, stability, and other quality attributes. QC is essential to ensure product safety and quality and can help reduce consumer complaints. There are different aspects of QC to consider depending on the product you are producing, and it is a continuous improvement activity, [9].

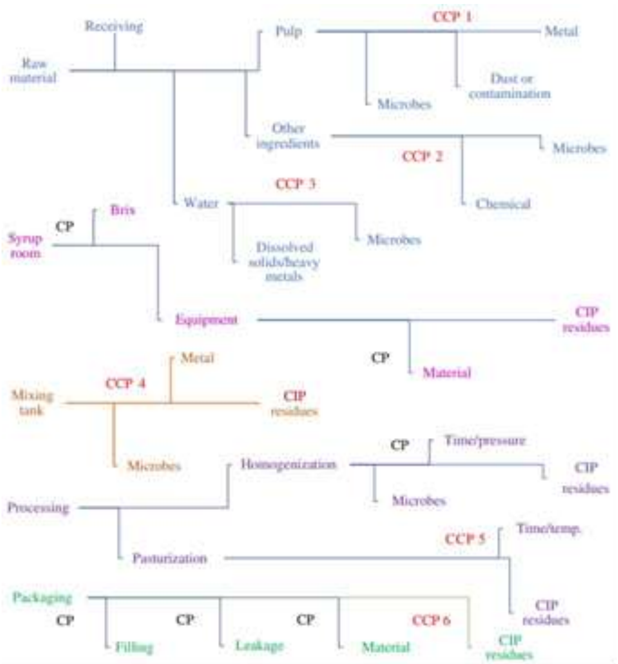

Fig. 1: Flowchart of General Fruit Juice Processing. Describing (QUALITY CONTROL IN BEVERAGE PRODUCTION: AN OVERVIEW, January 2019).

As shown in Figure 1, describes the different critical control points for a flowchart of general fruit juice processing.

Aseptic processing is a preservation technique that uses heat or chemicals to kill harmful microorganisms and sterilize products to prevent recontamination. The goal is to eliminate or inactivate microorganisms from both the contents and the packaging, achieving a commercially sterile state. Typical techniques include thermal treatment with hot steam or hot water, chemical treatment with hydrogen peroxide, and irradiation. Aseptic processes require strict process control and monitoring to ensure that sterility is maintained throughout the entire production process. After sterilization or aseptic processing, the aim is to monitor and control critical control points (CCPs) to prevent recontamination and ensure a proper aseptic environment for equipment and products. As shown in Figure 1, control points (CPs) and CCPs are designated and managed for each process. Although it is a complex and costly task, it can be a useful tool for companies that want to produce safe and high-quality products. It is an important technology in modern food processing and packaging, mainly used in the production of beverages (juices, dairy products, etc.), liquid foods, and products that require maintaining product integrity and stability, [10].

3 QMS for SMART HACCP

3.1 System Architecture

Figure 2 shows a simplified flow chart of the beverage production plant that is the subject of the paper. First, the water stored in the buffer tank (T401A) is transferred to the heat exchanger. High-temperature steam is provided by the boiler. The water flowing into the water pipes in the heat exchanger comes into contact with the hot steam indirectly (by spraying the surface of the water pipes with hot steam). The water is then heated until the water temperature reaches the aseptic processing standard. Water that has been sterilized by heat treatment is sterile if it meets the criteria. If the temperature of the water does not reach the standard, sterility is not guaranteed. The phenomenon of de-sterilization can assume several causes. Firstly, insufficient heat treatment of the steam due to the unintended introduction of additional water. Secondly, insufficient heat treatment due to steam at a lower than standard temperature. And the possibility of an unknown causative agent entering due to a faulty process interlock.

The following Figure 3 is the heat exchanger and boiling process. The water in the heat exchanger is in direct contact with the hot steam in the boiler and indirectly by the hot steam in the boiler, transferring the heat from the steam to the water. transfer heat from the steam to the water. The water receives the hot steam and steam causes its temperature to rise and the steam to cool. If the temperature of the steam is not low enough to heat the water, it will not be heated to the required temperature, and sterilization cannot be guaranteed.

The threshold for the heat exchanger discharge temperature is 139 ◦C to 141 ◦C. If the discharge temperature rises above the threshold, additional water is added, and if the temperature falls below the threshold, water is stopped. The water buffer tank should not simply check the amount of water entering and leaving the discharge temperature but should be blocked by a pre-modeled process interlock.

The following Figure 4 is After passing through the aseptic treatment process, the water is rapidly cooled to use the aseptically treated water in subsequent processes. The cooled water used in the process is reintroduced into the heat exchanger for sterilization again, which must also be controlled by a process interlock. If there is an abnormal inflow outside of the process interlock, this can cause a drop in the discharge temperature.

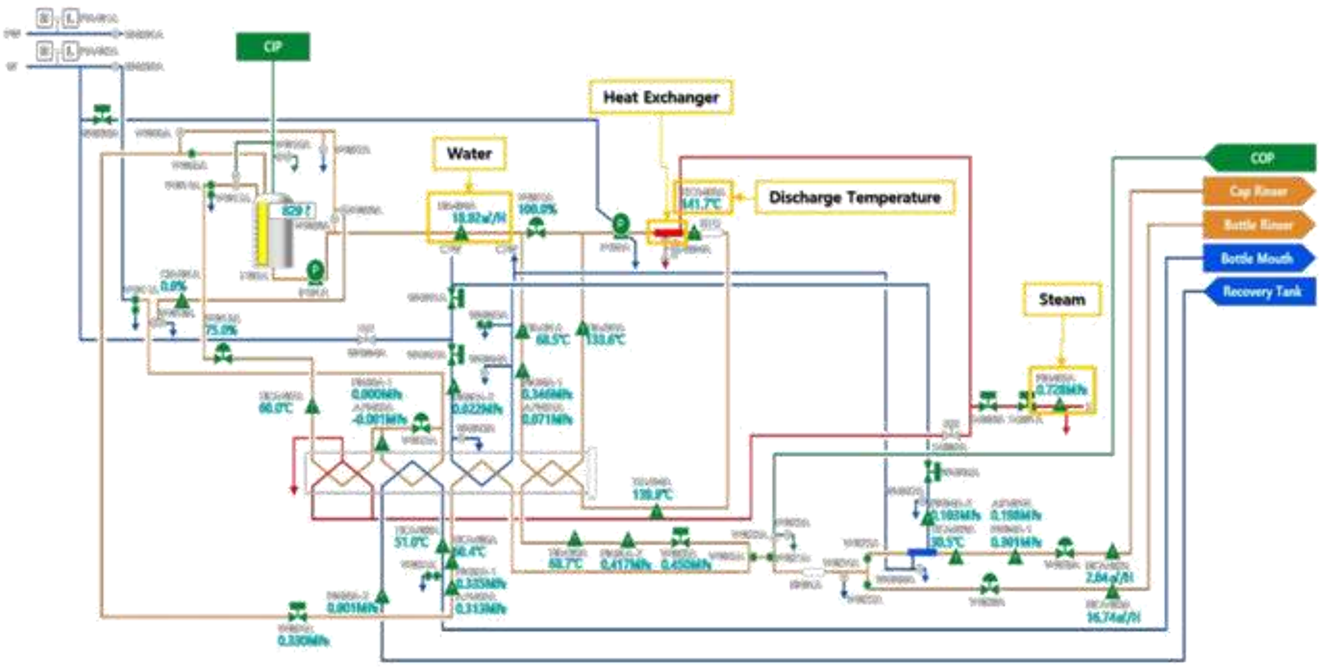

Fig. 2: Aseptic Process for Smart HACCP

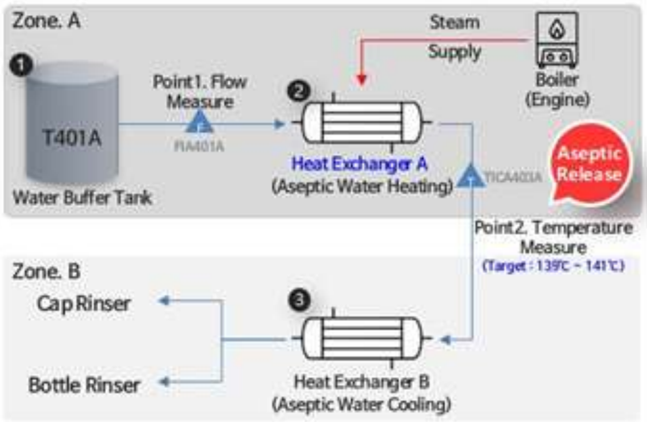

Fig. 3: Aseptic Process and the Potential for Failure(Pre-symptoms).

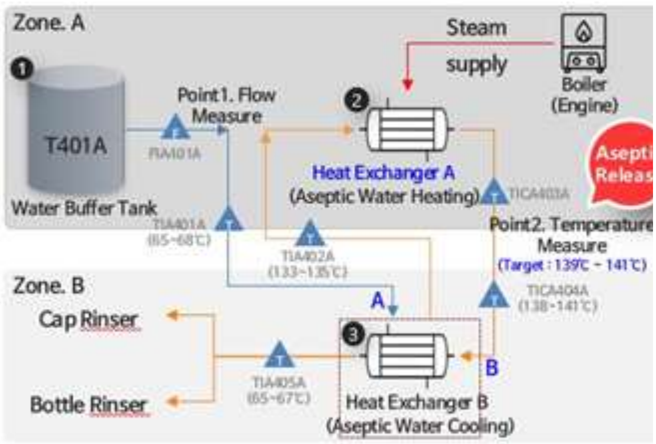

Fig. 4: Aseptic Process and the Potential for Failure(Post-symptoms).

(When the water is in Zone.A passes Point.2, if the temperature is below the threshold, the process in Zone. B is stopped by a pre-interlock. Therefore, the case in Figure 4 case is excluded from the above requirements.)

3.2 Compare Symptoms

The following Figure 5 shows a simulation of the data when the sterilization process is running normally. The blue line is the heat exchanger discharge temperature, and the orange line is the buffer tank that supplies water. In this normal case, the discharge temperature and water flow rate do not change. (However, there is a point where the flow rate briefly decreases. This is due to a different process issue that briefly changed the water flow rate, but is not related to that issue).

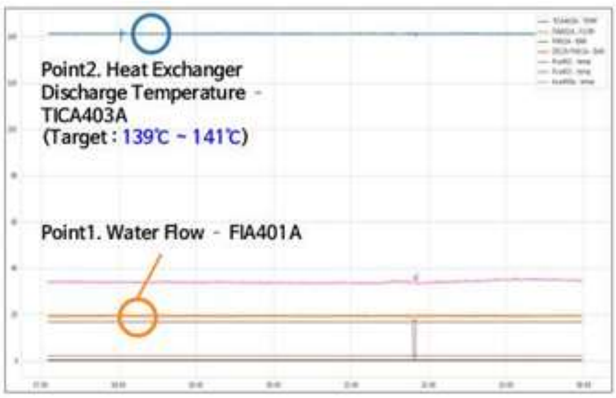

Fig. 5: Simulation Result (Normal Case)

A sterility failure occurs when the temperature of the sterile water in the heat exchanger is abnormally low. If the temperature is abnormally low, the water will not be sterile. I name the pre-symptoms and post-symptoms, depending on when they occur. In particular, the causes of the pre-symptoms, which will be discussed in this paper, can be deduced as follows. The hot steam from the engine room boiler. Or, water entering the heat exchanger from the buffer tank.

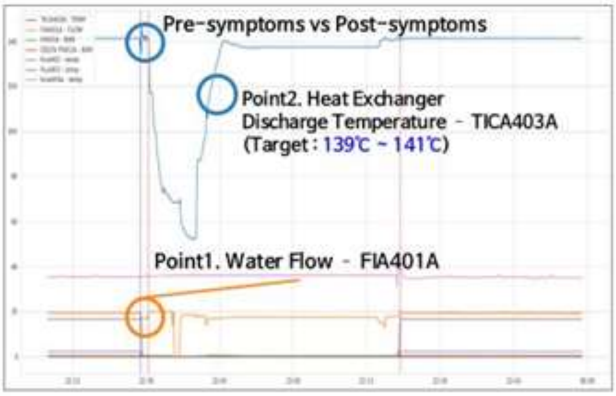

Fig. 6: Simulation Result (Abnormal Case)

Figure 6 shows a simulation of the data at the time of suspected pre-symptoms and post-symptoms. The sequence of data changes is as follows.
1st, drop in heat exchanger discharge temperature (Blue line).
2nd, decrease in water flow rate(Orange line).
3rd, after some time, the water flow rate switches to a maximum(Orange line).
4th, after another time, a sharp drop in the heat exchanger discharge temperature(Blue line).
The heat exchanger discharge temperature, which is a criterion for sterilization, has not reached the threshold and sterilization has occurred.

Table 1. Boiler operating environment(Normal).

Type	Property	Value	Unit
Aseptic Water Inlet	Temperature	132.6	C
Aseptic Water Inlet	Pressure	3.71095	kgf/cm2g
Aseptic Water Inlet	Mass Flow	16190	kg/h
Aseptic Water Outlet	Temperature	140.4	C
Aseptic Water Outlet	Pressure	3.51095	kgf/cm2g
Aseptic Water Outlet	Mass Flow	16190	kg/h
Steam Inlet	Temperature	173.089	C

Table 2. Boiler operating environment(Abnormal).

Type	Property	Value	Unit
Aseptic Water Inlet	Temperature	132.6	C
Aseptic Water Inlet	Pressure	3.71095	kgf/cm2g
Aseptic Water Inlet	Mass Flow	20000	kg/h
Aseptic Water Outlet	Temperature	138.918	C
Aseptic Water Outlet	Pressure	3.51095	kgf/cm2g
Aseptic Water Outlet	Mass Flow	20000	kg/h
Steam Inlet	Temperature	173.089	C

Table 1 shows the boiler operation data when the aseptic process is performed normally, and Table 2 shows the boiler operation data when the aseptic failure occurs. In the normal case, the aseptic water flow rate is 16190kg/h and the discharge temperature is about 140 ◦C. The boiler operation data for the aseptic failure case shows that the aseptic water flow rate exceeds 20000 kg/h and the discharge temperature is lower than the baseline at about 138.9 ◦C. Although the temperature is low, it should be considered that the flow rate is already significantly higher than normal. This is because it would be unreasonable to assume that the aseptic failure was caused by the temperature of the steam provided by the boiler.

4 Experiment

4.1 Simulation Environment

The following Table 3 lists the environments in which you will perform simulations and analyses.

Table 3. Software Tools : Simulator, Language, DBMS.

Item	Option
Simulator	DWSIM
Language	Python 3.9 (64-bit)
DBMS	SQL Server 2016 Standard

The simulator uses DWSIM. DWSIM is available on multiple operating systems including Windows, Linux, and MacOS. In particular, it is an open-source CAPE-OPEN simulator, which is widely used for process simulation in thermodynamics and chemistry, making it accessible to beginners.

Python is a free-to-use language, simple, extensible, and portable. It is also a popular language for data analytics.

According to the specifications in Table 4, the server operating system of the factory where the data for this paper is collected is Windows Server 2016, and the DBMS is MS SQL Server 2016, Standard. For this research, it is not necessary to distinguish the DBMS specifically, [11].

Table 4. View Basic Information: PC 1.

Item	Option
CPU	Intel(R) Core(TM) i7-10510U CPU 1.80GHz 2.30 GHz
RAM	32.0GB
Disk	1.50TB(SSD 500GB)
OS	Windows 10 Enterprise

Two PCs are used as shown in the specifications in Table 4 and Table 5. They were used for programming and simulation respectively. In Table IV, the two machines have similar specifications except for the graphics card.

The following Table 6 information about the servers from which the data was loaded. The specifications of the server are also listed in this paper because they were used to extract the data needed in the preliminary work of the analysis.

Table 5. View Basic Information: PC 2.

Item	Option
CPU	Intel(R) Core(TM) i7-9750H CPU 2.60GHz 2.60GHz
RAM	32.0GB
Disk	1.0TB(SSD)
GPU	NVIDIA GEFORCE GTX 1660 TI
OS	Windows 11 Pro

Table 6. View Basic Information: DB Server.

Item	Option
CPU	Intel(R)Xeon(R) Gold 6152 CPU @3.20GHz 2.10 GHz
RAM	192.0GB
Disk	3.0TB)
GPU	NVIDIA GEFORCE GTX 1660 TI
OS	Windows Server 2016

4.2 Comparative Analysis

In this paper, I used Python but omitted the source code.

Simulations were performed to determine if the heat ex-changer discharge temperature, which is the baseline information that affects aseptic failure, varies within the baseline.

There are three main types of data for analysis: log/digital data, facility operating history, and production history data. Analog data is temperature, pressure, flow, etc. collected by SCADA. Log data is temperature, pressure, flow, etc. collected by SCADA. Digital data includes things like pump and valve on/off data. Unavailable data includes history, production history, and equipment alarm data. Unplanned maintenance history (unplanned and unexpected equipment anomaly alarms) is a component of the smart factory system deployed in the factory. It is a component of the smart factory system built in the factory, utilizing data from MES and SCADA. Unlike the conventional method, which takes a long time to determine the corresponding tag by simply comparing normal data with sterilization failure-related data, it is possible to determine the corresponding tag by simply comparing sterilization failure data with sterilization failure-related data. Also, because visual judgment is unreliable Select tags related to sterilization by checking for outliers in the residue.

Figure 7 shows the resulting graphs for two cases of time series decomposition. After preprocessing, the time series is decomposed into the normal operating conditions of the aseptic process and the date of aseptic failure. Decompose the time series based on the normal operating conditions of the aseptic process and the date of aseptic failure, [12].

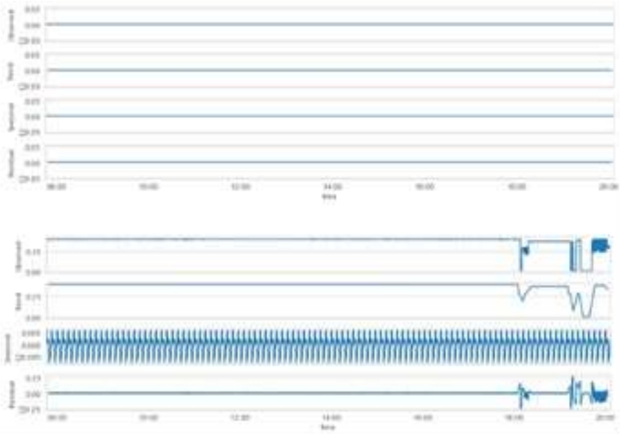

Fig. 7. Compare Time-series Decomposition Data Graphs (Compare normal and Abnormal cases).

5 Results

Simply comparing the normal data with the data related to sterilization failures to determine the corresponding tags is time-consuming, and visual judgment is unreliable. Therefore, we screen for tags related to sterilization failures by checking for outliers in the residuals (Checking the quantified data), [13]. We check when the residuals for each tag are outliers, which can be detected by logic that determines whether the current data exceeds a certain sigma of the historical data (Remember that after time series decomposition, residuals follow a normal distribution, [14]). The threshold can be set to 3 sigma or 6 sigma, which we set to 6 sigma in this paper.

	TAG	time		TAG	time
12	PRS1_D10163	2022-09-25 18:39	29	PRS2_D10107	2022-09-26 1:06
1	PRS1_D10107	2022-09-25 20:00	36	PRS2_D10128	2022-09-26 1:07
19	PRS1_D10801	2022-09-25 20:00	35	PRS2_D10127	2022-09-26 1:07
14	PRS1_D10403	2022-09-25 21:11	47	PRS2_D10801	2022-09-26 1:07
16	PRS1_D10406	2022-09-25 21:11	49	PRS2_D10804	2022-09-26 1:08
15	PRS1_D10405	2022-09-25 21:11	24	PRS2_D10101	2022-09-26 1:10
0	PRS1_D10102	2022-09-25 21:12	41	PRS2_D10146	2022-09-26 1:11
11	PRS1_D10162	2022-09-25 21:12	45	PRS2_D10403	2022-09-26 1:11
18	PRS1_D10421	2022-09-25 21:14	40	PRS2_D10145	2022-09-26 1:11
13	PRS1_D10164	2022-09-25 21:14	33	PRS2_D10123	2022-09-26 1:11
10	PRS1_D10144	2022-09-25 21:15	48	PRS2_D10802	2022-09-26 1:11
9	PRS1_D10143	2022-09-25 21:15	44	PRS2_D10402	2022-09-26 1:12
7	PRS1_D10141	2022-09-25 21:15	46	PRS2_D10404	2022-09-26 1:13
6	PRS1_D10127	2022-09-25 21:15	43	PRS2_D10401	2022-09-26 1:14
4	PRS1_D10125	2022-09-25 21:15	32	PRS2_D10122	2022-09-26 1:14
3	PRS1_D10123	2022-09-25 21:15	38	PRS2_D10142	2022-09-26 1:15
21	PRS1_D10803	2022-09-25 21:15	31	PRS2_D10121	2022-09-26 1:15
2	PRS1_D10121	2022-09-25 21:15	30	PRS2_D10108	2022-09-26 1:16
20	PRS1_D10802	2022-09-25 21:15	42	PRS2_D10147	2022-09-26 1:22
52	PRS5_D10801	2022-09-25 22:04	37	PRS2_D10141	2022-09-26 1:22
5	PRS1_D10126	2022-09-25 22:36	39	PRS2_D10144	2022-09-26 1:24
22	PRS1_D10804	2022-09-25 22:36	26	PRS2_D10103	2022-09-26 1:58
17	PRS1_D10407	2022-09-25 23:06	25	PRS2_D10102	2022-09-26 1:59
28	PRS2_D10106	2022-09-26 1:06	34	PRS2_D10124	2022-09-26 1:59
			27	PRS2_D10105	2022-09-26 2:03
			51	PRS5_D10125	2022-09-26 7:10

Fig. 8: Data extracted by checking for outliers in the residuals(Tag).

Figure 8 is the Tag information selected through the previous task (Data selected by checking outliers in the residuals). However, as mentioned earlier, instantaneous changes in values caused by already-known causes are not meaningful for sterilization cause detection. To select only meaningful data, we separately select only data lasting more than 30 seconds.

	TAG	time	19	PRS2_D10101	2020-09-26 1:10
0	PRS1_D10142	2020-09-25 18:39	20	PRS2_D10146	2020-09-26 1:11
1	PRS1_D10806	2020-09-25 18:39	21	PRS2_D10403	2020-09-26 1:11
2	PRS1_D10163	2020-09-25 18:39	22	PRS2_D10145	2020-09-26 1:11
3	PRS1_D10403	2020-09-25 21:11	23	PRS2_D10123	2020-09-26 1:11
4	PRS1_D10405	2020-09-25 21:11	24	PRS2_D10802	2020-09-26 1:11
5	PRS1_D10406	2020-09-25 21:11	25	PRS2_D10402	2020-09-26 1:12
6	PRS1_D10162	2020-09-25 21:12	26	PRS2_D10404	2020-09-26 1:13
7	PRS1_D10421	2020-09-25 21:14	27	PRS2_D10401	2020-09-26 1:14
8	PRS1_D10164	2020-09-25 21:14	28	PRS2_D10122	2020-09-26 1:14
9	PRS5_D10801	2020-09-25 22:04	29	PRS2_D10142	2020-09-26 1:15
10	PRS1_D10126	2020-09-25 22:36	30	PRS2_D10121	2020-09-26 1:15
11	PRS1_D10804	2020-09-25 22:36	31	PRS2_D10108	2020-09-26 1:16
12	PRS1_D10407	2020-09-25 23:06	32	PRS2_D10147	2020-09-26 1:22
13	PRS2_D10107	2020-09-26 1:06	33	PRS2_D10141	2020-09-26 1:22
14	PRS2_D10106	2020-09-26 1:06	34	PRS2_D10144	2020-09-26 1:24
15	PRS2_D10128	2020-09-26 1:07	35	PRS2_D10103	2020-09-26 1:58
16	PRS2_D10127	2020-09-26 1:07	36	PRS2_D10102	2020-09-26 1:59
17	PRS2_D10801	2020-09-26 1:07	37	PRS2_D10124	2020-09-26 1:59
18	PRS2_D10804	2020-09-26 1:08	38	PRS2_D10105	2020-09-26 2:03

Fig. 9: Check for outliers in residuals for more than 30 consecutive seconds

Figure 9 is the result of extracting only continuous data over 30 seconds. After analyzing the time series data, we can select a list of tags related to sterilization failures. When all tags were analyzed, the following group of tag values Table 7 showed residual outliers around the time of sterilization failure.

Table 7. List of Abnormal Residuals.

PRS2_D10107	PRS2_D10106	PRS2_D10128	PRS2_D10127
PRS2_D10801	PRS2_D10804	PRS2_D10101	PRS2_D10146
PRS2_D10403	PRS2_D10145	PRS2_D10123	PRS2_D10802
PRS2_D10402	PRS2_D10404	PRS2_D10401	PRS2_D10122
PRS2_D10142	PRS2_D10121	PRS2_D10108	PRS2_D10147
PRS2_D10141	PRS2_D10144		

Select meaningful data from the residuals of time series data and perform a regression analysis to determine causality and influence. Perform simple regression analysis to verify the validity of the regression analysis. Furthermore, derive a list of tags that influence the sterilization failure Tag through multiple regression analysis. From this analysis, we identified the precursor symptoms for the selected Tags.

	TAG1	TAG2	rsquared_adj	fvalue	pvalue	coef -0	coef -1
90	PRS2_D10101	PRS2_D10402	0.807393	67608.274005	0.000000e+00	71.459548	155.744102
87	PRS2_D10101	PRS2_D10403	0.674697	33451.318613	0.000000e+00	87.913100	162.885221
89	PRS2_D10101	PRS2_D10802	0.633021	27820.959674	0.000000e+00	72.769752	199.140738
88	PRS2_D10101	PRS2_D10123	0.613899	25644.488311	0.000000e+00	72.855637	196.749428
93	PRS2_D10101	PRS2_D10122	0.485494	15219.594311	0.000000e+00	67.789728	179.223556
94	PRS2_D10101	PRS2_D10121	0.480565	14922.124635	0.000000e+00	57.819522	231.583712
91	PRS2_D10101	PRS2_D10404	0.379899	9881.645454	0.000000e+00	94.922636	0.625055
92	PRS2_D10101	PRS2_D10401	0.210561	4302.690307	0.000000e+00	122.822605	0.181893
95	PRS2_D10101	PRS2_D10108	0.166681	3226.925983	0.000000e+00	72.060630	3.552386
97	PRS2_D10101	PRS2_D10141	0.004235	69.597546	7.854954e-17	164.968201	-34.321135
98	PRS2_D10101	PRS2_D10144	0.002944	48.618543	3.229774e-12	142.064344	-0.031096
96	PRS2_D10101	PRS2_D10147	0.001892	31.567559	1.958044e-08	142.074762	-0.027616

Fig. 10: Results of Regression Analysis.

Figure 10 shows the results of a simple regression between one independent variable and one dependent variable.

1st, R Squared (rsquared adj) is the coefficient of determination, and the closer it is to 1, the higher the explanatory power of the regression model.

2nd, F value (fvalue) is the ratio of the square mean of the regression equation to the square mean of the residuals (A large ratio means that the regression is significant in explaining the relationship between the two variables.).

3rd, Probability of significance (P > |t|): higher than 0.05 is not suitable for use as a variable.

4th, coef (coefficient): Coefficient of the regression equation, independent variable = intercept + (dependent variable coef * dependent variable)

After checking the R-value and fvalue, the Tags that are judged to be causally related to TICA403 (heat exchanger discharge temperature PRS2 D10101) are shown in the following Table 8.

Table 8. Tag Results Causally Related to Sterilization Failure.

PRS2 _D10402	PRS2 _D10403	PRS2 D10802
PRS2 _D10123	PRS2 _D10122	

Table 8 shows the Tag values that were determined to be causally related to the heat exchanger discharge temperature deviating from the baseline, [15].

6 Conclusion

In this paper, we analyzed the phenomenon of aseptic failure in aseptic processing. It shows how to solve the problem in practice. Before the analysis, I defined some hypotheses.

1st, the temperature of the steam heating the water is lower than the reference. To identify any abnormalities in the boiler engine and heat exchanger, separate checks were carried out. However, they were operating in the normal range, so the simulation for verification was also conducted under normal conditions. Since the simulation was performed under normal conditions, we did not find a causal relationship between the temperature of the vapor and sterility.

2nd hypothesis is an unusual influx of water. The entry of water into the heat exchanger is specifically named a pre-symptom. The simulation results confirm that there is a correlation between the abnormal inflow of water into the heat exchanger and the discharge temperature.

3rd hypothesis is that the cooling treatment water is reintroduced into the heat exchanger. This is because if cold water flows back into the heat exchanger, the discharge temperature can be lowered. This is separately named the post-symptom. However, due to limitations in collecting relevant data, this hypothesis was not verified.

For further analysis of the cause of de-sterilization, we need SCADA Tag information, which is not yet defined. In addition, the design specifications for each heat exchanger should identify its type and performance and the cause of the discharge temperature variation.

It requires a deep understanding of the process, such as how to control the sterile water temperature. It is also a good idea to install an additional flow meter, as you will need to verify that the flow value is maintained at 20m3/h in case of sterilization failure. And, additional instrumentation for the boiler steam or heat exchanger is also required.

A faulty branching logic based on heat exchanger discharge temperature was identified and the discharge temperature measurement sensor was replaced. More data and further analysis will be conducted to ensure the aseptic reliability and stability of the process.

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Conflict of Interest

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