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Original Article

# A Study on the Usefulness of Development of a Steam Sterilizer Equipped with an Electronic Bowie-Dick Test System

Young Ok Bae*, Jun Soo Hwang†, Sung Il Kim‡, Joon Ha Lee*,§

*Department of Biomedical Engineering, Yeungnam University Graduate School, †MeDent Professional Co., Ltd., ‡Joeun Medical Co., §Department of Biochemistry and Molecular Biology, Yeungnam University College of Medicine, Daegu, Korea

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Corresponding author
Joon Ha Lee
(jhrhee@ynu.ac.kr)
Tel: 82-53-620-4534
Fax: 82-53-629-1344

To verify the usefulness of a steam sterilizer equipped with an electronic Bowie-Dick test system, this study was carried out using two methods, utilizing both a steam sterilizer and an electronic Bowie-Dick tester. The first method is to confirm the error detection of the chemical Bowie-Dick test pack and the electronic Bowie-Dick tester in a malfunctioning sterilizer environment. For this purpose, the Bowie-Dick test program for the steam sterilizer was used to test three types of test packs commonly used in hospitals and the electronic Bowie-Dick tester by changing the set values of temperature, time, and vacuum frequency. The second is an experiment to check the sterilizer's normal operation with the electronic Bowie-Dick tester and the usefulness of grasping the cause of the malfunction. The results showed that the sterilization temperature was the same as that of the test pack at a temperature 1~6˚C lower than the reference temperature of 134˚C. In the test with the sterilization exposure time as a variable, there was a normal discoloration at a time difference of 30~90 s. In the experiment using the number of vacuum cycles, the test was correct by performing the normal discoloration only at the normal condition of 3 times. The test results of 30 hospitals were 100 failure tests by a total of 291 Bowie-Dick tests. Of these, the failure factors related to an internal temperature that the chemical test packs could not detect were the greatest, and the four factors related to temperature, including the internal temperature, were found to be 71.18% of total malfunctions. In addition, the Bowie-Dick tester was provided within 30 min after the start of the Bowie-Dick test to confirm the performance of the sterilizer and the detailed cause. A steam sterilizer equipped with an electronic Bowie-Dick test system is used to manage individual sterilizers. In the current steam sterilizer with many temperature-related errors, it is possible to check the malfunction of the temperature difference that the test pack cannot detect, and the cause of error for the sterilizer is immediately detected after the test. The steam sterilizer equipped with the electronic Bowie-Dick test system assists with infection control with accurate sterilizer performance assurance.

Keywords: Bowie-Dick test, Steam sterilizer, Electronic Bowie-Dick test system

## Introduction

Sterilization is the process or the action of completely destroying all microorganisms, including viruses.[1] Sterilization is one of the fundamental infection management methods to decrease or prevent the danger of infection,[2] and among those methods, steam sterilization, which annihilates organisms by pressurized saturated moist heat,

is used in the destruction of all types of microorganisms.[3-5]

Before operating the steam sterilizer, to check whether its performance is normal, the Bowie–Dick test is used. This test detects the success or failure of air removal,[6] which is a central factor in the sterilization effectiveness of the steam sterilizer, whether or not there are mechanical effects, and whether the supplied steam's noncondensable gas exists.[7]

The Bowie–Dick tests that are currently being performed in hospitals rely on discoloration of a dispensed chemical test pack, but because the results are checked visually by an operator, controversy exists due to the proficiency of the operator or the possibility of the introduction of subjective opinions. In addition, because, even when one checks for mechanical defects, discoloration of the test pack is seen, it is impossible to check accurately the performance of the steam sterilizer. Moreover, it is difficult to judge the exact cause of the machine's malfunctioning only from test pack discoloration.

Before the steam sterilization operation, by means of the Bowie–Dick test that checks the performance of the steam sterilizer, it is useful to have an infection system that provides and saves a result as an individual, objective, and unmodifiable numerical figure. Thus, the goal of this research is to check the utility of the development of a steam sterilizer equipped with an electronic Bowie–Dick test system. To do this, through tests that used an electronic Bowie–Dick tester, at the start of the Bowie–Dick test, the temperature and pressure values were checked. From the graph waveform drawn from the measured values, it was confirmed that the concrete cause of malfunction can be determined.

## Materials and Methods

The materials used in this experiment are the electronic Bowie–Dick tester, ebro electronic Bowie & Dick tester (EBI 15, ebro, Germany), and the software Winlog.med, which checks the utility of the electronic Bowie–Dick test system installed in the steam sterilizer, a steam sterilizer (a VSSR-G12W, SAKURA, JAPAN, which was installed in the Yeongnam Hospital Central Supply Room), and a Bowie–Dick test pack. Each test pack was manufactured based on EN ISO 11140-4, 11140-5 regulations, and the three test packs used the most were test packs A, B, and C. The conditions set by the manufacturers of the test packs for total discoloration were an exposure time of 3 min and 30 s and

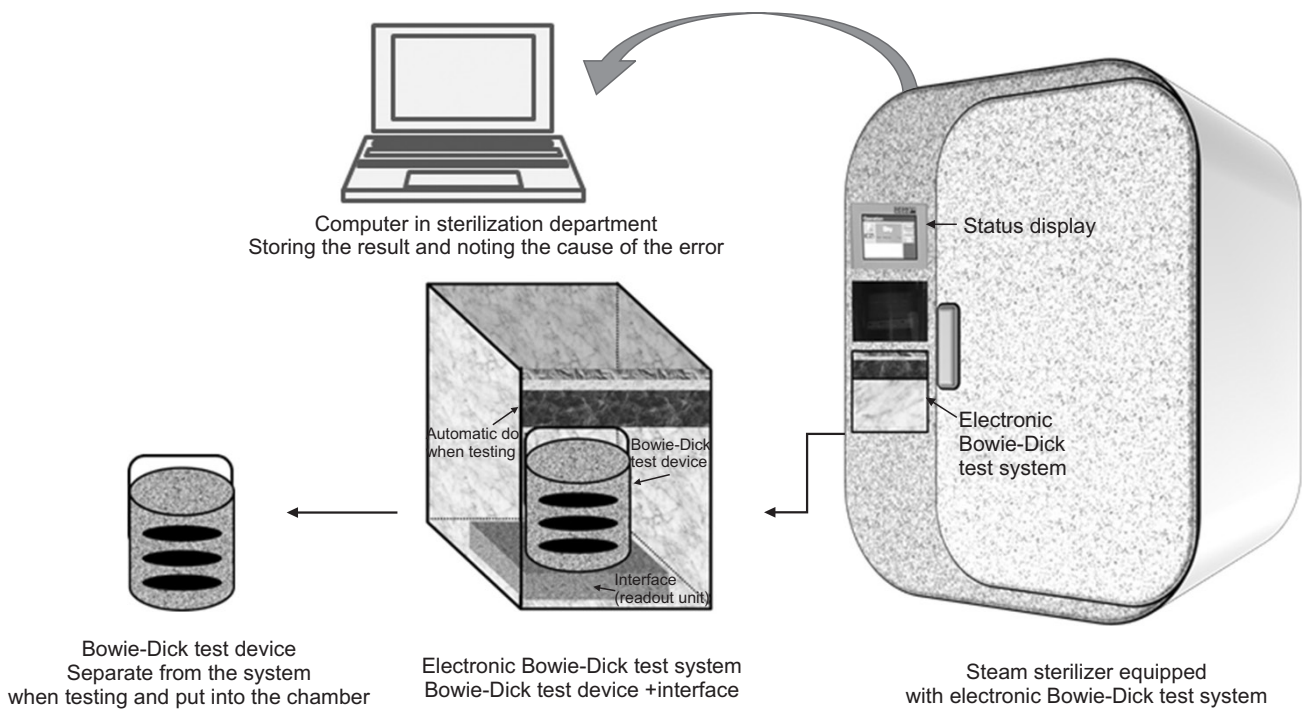



**Fig. 1.** Steam sterilizer equipped with electronic Bowie–Dick test system.

a sterilization temperature of 134°C for test packs A and B, and an exposure time of 3 min and 30 s and a sterilization temperature of 132°C for test pack C.

The properties of the steam sterilizer equipped with an electronic Bowie-Dick test system can be seen in Fig. 1. This system is made of a BD test device for testing experimental performance and of an interface that loads data after the experiment. The Bowie-Dick test device is separate from the steam sterilizer. During the performance test, a test is performed inside the chamber where the microorganism is placed, and the temperature and pressure inside the sterilizer and of the sterilizer materials are measured.

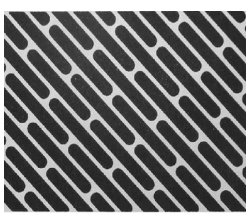
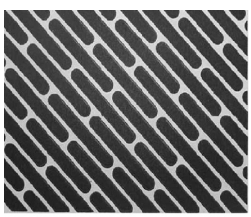
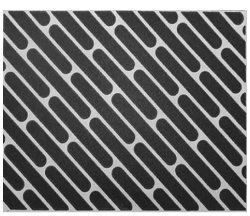
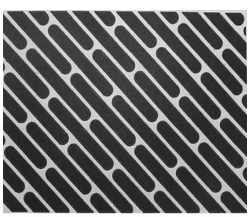
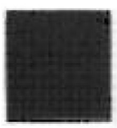
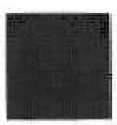
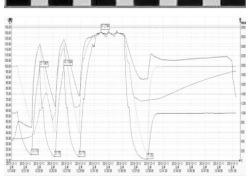
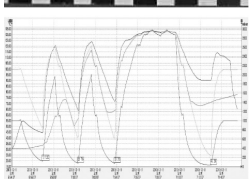
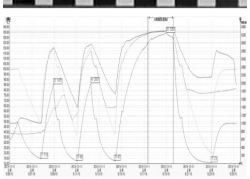
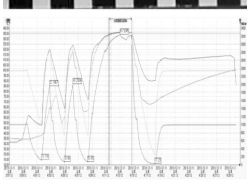
It is designed so that, after an experiment, it can be read only through the interface installed in the steam sterilizer so that there is individual sterilization management, and the preciseness can be verified by short cycles of the separated test device so that a credible performance result can be obtained.

The experiment is carried out through two methods. The first one compares the chemical Bowie-Dick test pack with EBI 15 error detection during malfunctioning of the steam sterilizer. The second uses the EBI 15 to check the utility of determining the reasons for the malfunctioning of the steam sterilizer.

In the first experiment to check the discoloration of the Bowie-Dick test pack during malfunctioning of the steam sterilizer, the temperature, time, and vacuum frequency of the sterilization BD program (VSSR-G12, which has a normal Bowie-Dick operating temperature of 134°C, exposure time of 3 min and 30 s, and vacuum frequency of three times) were changed, and experiments were performed with the three types of Bowie-Dick test packs commonly used in hospitals and an EBI 15.

In an environment where the steam sterilizer malfunctioned, experiments were carried out for 4 min at each temperature of 125°C, 126°C, 127°C, 128°C, 129°C, and 130°C, and for 3 min at each temperature of 129°C, 131°C, and 132°C. Experiments were carried out at 134°C with the time variable of the steam sterilizer selected at 1 min, 2 min, 3 min, and 4 min. Then, experiments were carried out for 4 min at 134°C with the vacuum frequency inside the

**Table 1.** Sterilization temperature and exposure time satisfying normal discoloration.

| Pack | 128°C | 131°C | 134°C | 134°C |
|---|---|---|---|---|
| | 4 min | 3 min | 2 min | 3 min |
| A |  |  |  |  |
| B |  |  |  |  |
| C |  |  |  |  |
| Winlog |  |  |  |  |
| Result |  |  |  |  |

steam sterilizer set to once, twice, and three times. Since each experimental result supported other experimental results, experiments were not repeated.

In the second experiment, to confirm the utility of error detection of the steam sterilizer equipped with an electronic Bowie–Dick test system during malfunctioning, an EBI 15 was used, and from October 1, 2013 to November 28, 2017, experiments were carried out in 30 hospitals to check the normal performance and to determine the causes of errors in sterilization.

## Results

After completion of the Bowie–Dick program in the sterilizer, we determined whether chemically the Bowie–Dick test pack's change was uniform, which is an important factor in judging its performance.

Table 1 shows the results of experiments using sterilization temperature and exposure time. For the A, B, and C test packs, at a sterilizer exposure time of 4 min starting from an average sterilizer time of 128°C, and at a sterilizer exposure of 3 min starting from 131°C, the color wholly showed a uniform normal discoloration. The Winlog.med program graphs in Table 1 and Table 2 show the EBI's measured temperature and pressure per second. The green and blue lines indicate the temperature inside and outside the specimen, and it was confirmed that the environment inside the chamber changed according to the change in the conditions of the sterilizer.

As shown in Fig. 2(a), in experiments using the sterilization temperature as the variable, nothing depended on the sterilization temperature, so the result that "assessment was impossible" was produced. As shown in Fig. 2(b) in the Winlog.med program, how operations of the sterilizer changed depending on changes in the Bowie-Dick test conditions was shown by detailed measurements.

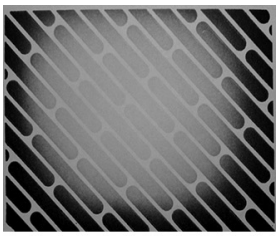
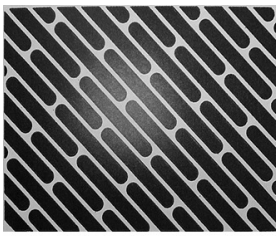
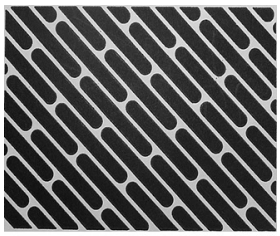
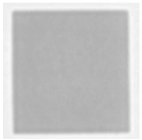
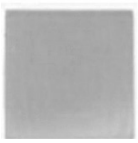
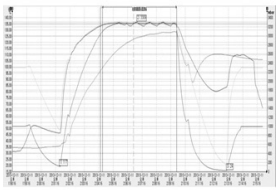
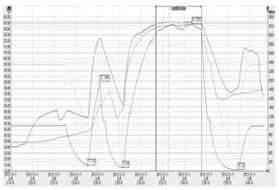
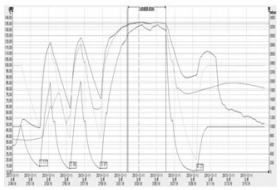
Table 1 shows that, at the average temperature of 134°C, using the sterilization exposure time as the variable, for a sterilization exposure time of 2 min for the A and B test packs, and for a sterilization exposure time of 3 min for the C pack, uniform discoloration was seen. The measured temperature and pressure values from the Winlog.med program are seen in the graphs, and looking at the sterilization time and results, it's possible to confirm that sterilization worked based on the selected time range.

Regarding discoloration based on vacuum frequency, at a sterilization temperature of 134°C, and a sterilization exposure time of 4 min, as seen in Table 2, the A, B, and C test packs showed failure when the vacuum frequency was once or twice, because a discoloration that was not normal was seen. Success was achieved when the vacuum frequency was three times and a normal discoloration was seen. The vacuuming process is a factor that influences the pressure and temperature, and this is seen in the left part of the Winlog.med program's graph, where a peak was numerically confirmed. Bowie–Dick test failure factors according to malfunctions in the vacuum frequency were confirmed, as seen in the results in the lowest part of Table 2.

Experiments on the utility of detecting malfunctioning sources of the steam sterilizer with an equipped electronic


**Fig. 2.** (a) Unevaluated result value and (b) measurement data of the Winlog.med program.

**Table 2.** Discoloration and Winlog.med program data according to the number of vacuum cycles.

| Pack | Vacuum (number of times) | | |
|---|---|---|---|
| | 1 | 2 | 3 |
| A |  |  |  |
| B |  |  |  |
| C |  |  |  |
| Winlog |  |  |  |
| Result |  |  |  |

Bowie-Dick test system took place from October 1, 2013 to November 28, 2017. In 30 hospitals, the EBI 15 was used, and the Bowie-Dick test was performed 291 times. The normal performance of the sterilizer was checked 191 times. Performance abnormalities were checked 100 times. As confirmed in Table 3, through experiments to confirm the performance of hospital sterilizers, the failure factors confirmed by the Bowie-Dick test were the outer temperature of the EBI 15 instrument not reaching the sterilization temperature, the inner temperature of the specimen, differences in the EBI instrument's inner and outer temperature sensors, the range of sterilization, the sterilization exposure time, the maximum equilibration time, and the remaining air. Among those, four were related to temperature. The case that occurred the most was the incongruity that the inside of the specimen did not reach the sterilization temperature.

## Discussion

In steam sterilization operations, the most important thing is that through the passage of steam, an accurate sterilization temperature is arrived at for the sterilization operation materials, and that it is maintained for as long as the sterilization exposure time.

The results from this experiment show lack of confidence in the guarantee of normal sterilization performance by the chemical Bowie-Dick test pack that is currently used frequently.

The test pack showed successful discoloration even under the Bowie-Dick test failure conditions of sterilization time and sterilization exposure time.

In experiments that used the EBI 15, the most important factor was that the hospital sterilizers could not detect the interior temperature of the chemical test packs. Including

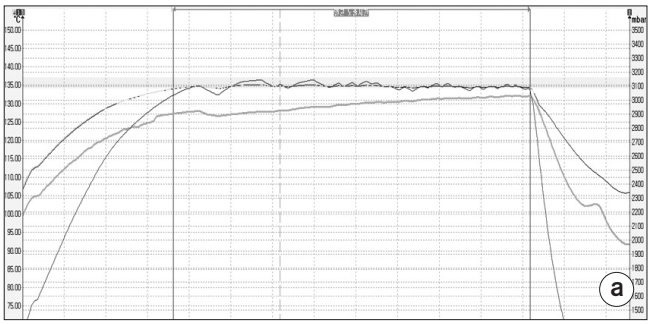
**Table 3.** Cause of failure according to the experiments using the electronic Bowie–Dick tester EBI 15.

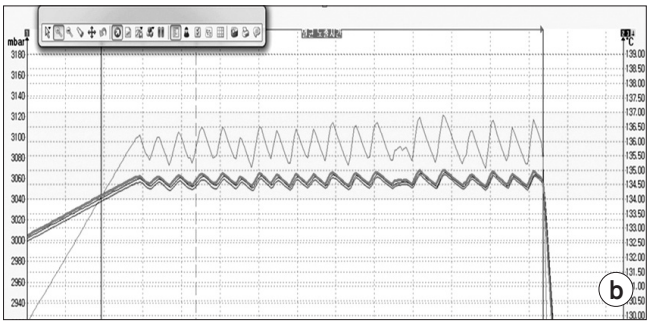
| Hospital | Experiment day | Number of tests | Failure Count | Fail factor | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Internal temp. | No temp. reached | Sensor temp. difference | Temp. range | Exposure time | Residual air | Equilibration time |
| 1 | 2013-10-31 to 11-08, 2013-12-13,16 Numbers 1 to 4, each once 2015-08-06 Numbers 1 to 4, each 3 times | 56 | 14 | 5 | 6 | 1 | 4 | 7 | | |
| 1-1 | 2013-10-02 to 12-04 Numbers 1 and 2, each 1 to 2 times | 104 | 2 | 2 | | 2 | | | | |
| 2 | 2015-08-12 | 8 | 5 | 2 | 2 | | 2 | 1 | | |
| 3 | 2014-08-12 | 5 | 5 | 5 | | 4 | 2 | 3 | 1 | 2 |
| 4 | 2014-03-04, 21 | 8 | 5 | 3 | | 1 | | 4 | | |
| 5 | 2014-01-27 | 4 | 1 | | | 1 | | | | |
| 6 | 2015-09-17, 2016-02-18 | 7 | 6 | 3 | | 2 | 2 | 2 | 1 | |
| 7 | 2014-04-09 | 2 | 2 | | 2 | | | | | |
| 8 | 2013-12-26 | 3 | 3 | | 2 | | | | 1 | |
| 9 | 2013-12-26 | 1 | 1 | | 1 | | | | | |
| 10 | 2015-01-07 | 3 | 2 | | | | 2 | | | 1 |
| 11 | 2014-07-22 | 2 | 2 | 1 | | | 1 | | 1 | |
| 12 | 2014-01-10, 28 | 7 | 3 | | | 1 | | | 3 | |
| 13 | 2014-07-15 | 2 | 0 | | 2 | | | | | |
| 14 | 2013-11-05 | 4 | 2 | 1 | | 2 | | | | |
| 15 | 2015-02-04 | 1 | 1 | | | | 1 | | 1 | 1 |
| 16 | 2014-07-06, 08 | 6 | 1 | | | | | | | 1 |
| 17 | 2015-01-19 | 3 | 1 | 1 | | 1 | 1 | | | |
| 18 | 2014-02-03 | 2 | 2 | | 2 | | | | | |
| 19 | 2014-07-04 to 08-20 | 21 | 13 | 3 | 9 | | 2 | 1 | 1 | |
| 20 | 2014-08-07 | 2 | 1 | 1 | | 1 | | 1 | 1 | 1 |
| 21 | 2015-07-24 | 2 | 0 | | | | | | | |
| 22 | 2015-08-06 | 4 | 3 | 1 | 1 | | 1 | | 2 | |
| 23 | 2014-07-10 | 1 | 0 | | | | | | | |
| 24 | 2014-09-16 | 5 | 3 | 1 | | 1 | 2 | | 1 | 1 |
| 25 | 2014-03-25, 2013-11-04 | 4 | 2 | 1 | | 1 | | | 1 | |
| 26 | 2014-07-28 | 3 | 3 | 3 | | | | 3 | | |
| 27 | 2014-06-11, 08-01, 2015-09-04 | 7 | 6 | 4 | 2 | 2 | 1 | 1 | 3 | |
| 28 | 2015-01-08 | 7 | 4 | 2 | 2 | 2 | | | 2 | |
| 29 | 2016-01-14, 2017-03-14 | 5 | 5 | 2 | 1 | 1 | 1 | | | |
| 30 | 2017-11-28 | 2 | 2 | 2 | | 1 | | | | |
| Total | 2013-10-01 to 2017-11-28 | 291 | 100 | 43 | 32 | 24 | 22 | 23 | 19 | 7 |

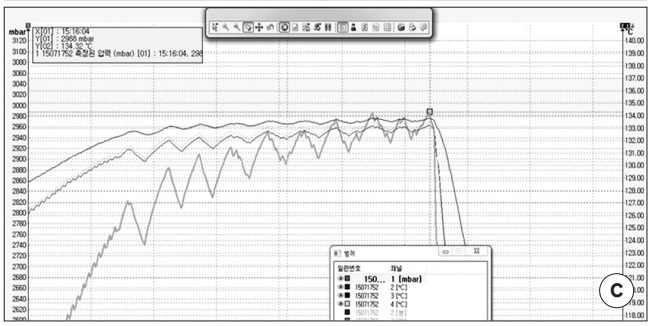
the interior temperature, the four factors related to the interior temperature comprised 71.18% of malfunctions.

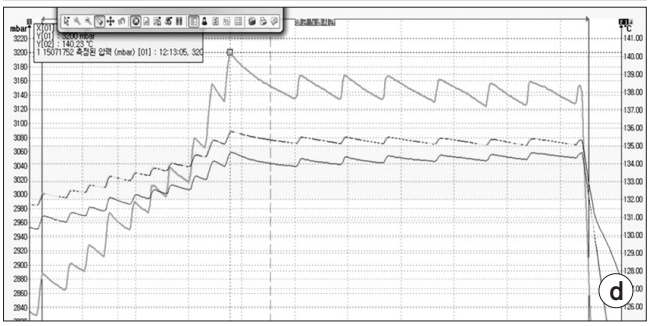
After the start of the Bowie–Dick test, within 30 min, through the produced result, the reason for malfunctioning was determined. A graph was formed with the measured temperature and pressure per second. If the result is analyzed, as shown in Fig. 3, not only, as in (a), (b), (c), and (d), can the problem factors be determined to be caused by the residual gas, an air pocket, condensation, emission, leaks, overheating, etc., but also, as shown in the numerical values in (e), it is possible to correct the machine following an accurate analysis.

For sterilization to manage infection, when the sterilizer is operating normally, sterilization can be achieved effec-



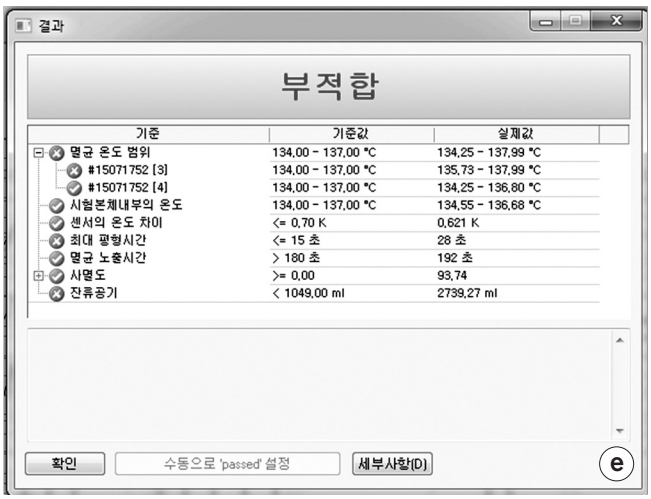




**Fig. 3.** Analysis of malfunctions based on (e) evaluation results provided by the program and characteristic graph waveforms of (a) air pocket, (b) wet steam, (c) leakage, and (d) overheated steam.

tively without economic, time, and manpower losses. Before steam sterilization operations, by carrying out experiments to check performance, such as checking steam infiltration, temperature adjustment, and time adjustment, resterilization operations after sterilization due to failed sterilizations can be decreased, and the saving of data and its use, which plays an important role in guaranteeing sterilization in infection management, has to be simple. The utility of a steam sterilizer equipped with an electronic Bowie-Dick test system that can automatically accurately manage every steam sterilization performance test value without work by the operator was confirmed.

## Conclusion

In this research on the usefulness of developing a steam sterilizer equipped with an electronic Bowie-Dick test system, the guaranteeing of the individual performance of the steam sterilizer, acquiring and saving of objective information data, and understanding errors during malfunctioning were checked. Through accurate sterilization measurement, regular validation is possible, and through the simplicity of data use and the sharing of online data, it is hoped that this work will establish a definitive sterilization detection system.

## Conflicts of Interest

The authors have nothing to disclose.

## Availability of Data and Materials

All relevant data are within the paper and its Supporting Information files.

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