SteamSpy

Sales Presentation

REV02-2017

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SteamSpy

Instruction

How to use this presentation?

- The following sales presentation is a training document. It is not a legally binding document for customers.
- Content can be flexibly selected depending on the presentation purpose.
- The presentation shall not be handed out to third parties – neither in paper nor in electronic form. It is intellectual property of MMM Group.

SteamSpy

Sales Support Presentation EN

Contents

- The mission of a Bowie & Dick test
- Bowie & Dick tests today
- “SteamSpy” solution
- Challenges for SteamSpy
- Frequently asked questions (Q&A)

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For Selectomat PL

The mission

When the CSSD staff start working, the MMM steam sterilizer shall be ready for production

-- within a short time

-- without much effort for the personnel

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Current solution:

Old MMM sterilizers

1. Start a vacuum test program (20 min)
2. Run an empty cycle (30 min)
3. **Insert BD test** and start the program (35 min)
4. Evaluate the test:
   - → with paper (3 min)
   - → electronically (8 min)
5. After approx. 90 min, personnel starts the real production.

New MMM sterilizers

(automatic warmup):

1. A vacuum test is started
2. An empty cycle is run
3. **Insert BD test** and start the program (35 min)
4. Evaluate the test:
   - → with paper (3 min)
   - → electronically (8 min)
5. After approx. 45 min, personnel starts the real production.

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The new solution targets to:

→ increase sterilization safety

→ be more economical than current solutions

→ be more enviromentally friendly

→ be „ready“ for sterilization without time delay

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Bowie & Dick Test according EN 285

The original test package is ...

- difficult to get (!)
- almost impossible to use!

Conditioning on a laundry rack

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Alternative Bowie & Dick Test

- **Alternative Bowie&Dick-Test Systems** are standardized by **ISO 11140-4**
- They must provide the same efficiency as the “original”:
- Check of all three potential error sources:
  - Leakage
  - A vacuum switch point which is deferred (too high)
  - Non condensable gas contained in the steam supply (simulated by air injection)
- Tests carried out with three different types of processes :
  - Pulsing vacuum method
  - Pulsing overpressure method
  - Transatmospheric method

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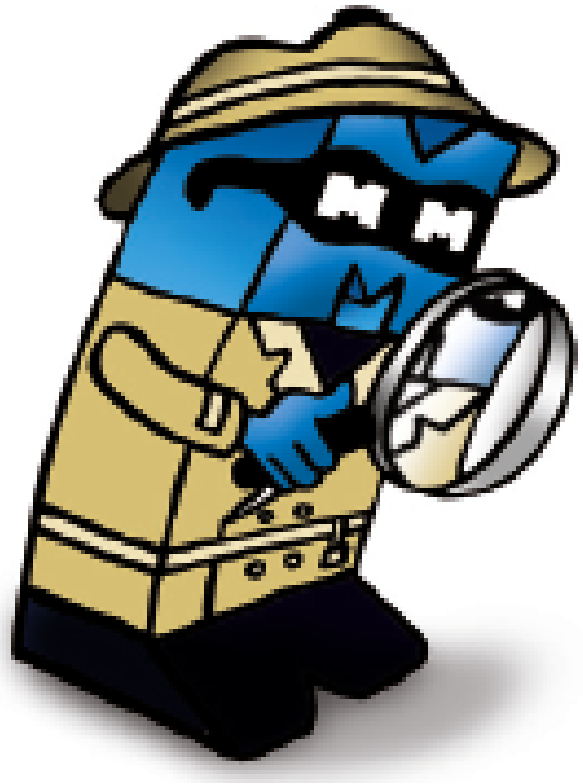

The MMM Solution
„SteamSpy“
conforming to standards

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Integrated Automatic B&D test

- MMM patented **integrated B&D** test for level of process safety and documentation
- Without manual handling
- Automatic documentation
- Can be integrated into the automatic warm up-sequence in the morning (vacuum-test, heating, B&D-program)
- Produces no chemical or paper waste
- No use of conventional B&D test necessary

Daily Bowie-Dick Test
and routine control in one.

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Steam Spy: Integrated Automatic B&D test

- advantages of an *integrated,* non-chemical alternative Bowie&Dick-test:
- no “double” documentation; result of the B&D-test is stated on the batch documentation
- the result is available immediately after the end of the process
- the automatic warm up-sequence in the morning (vacuum-test, heating) can be extended by the Bowie&Dick-test-program, so at the end of the sequence the sterilizer is completely ready for production
- testing the compliance with ISO-11140-4 only with the “real” cycle

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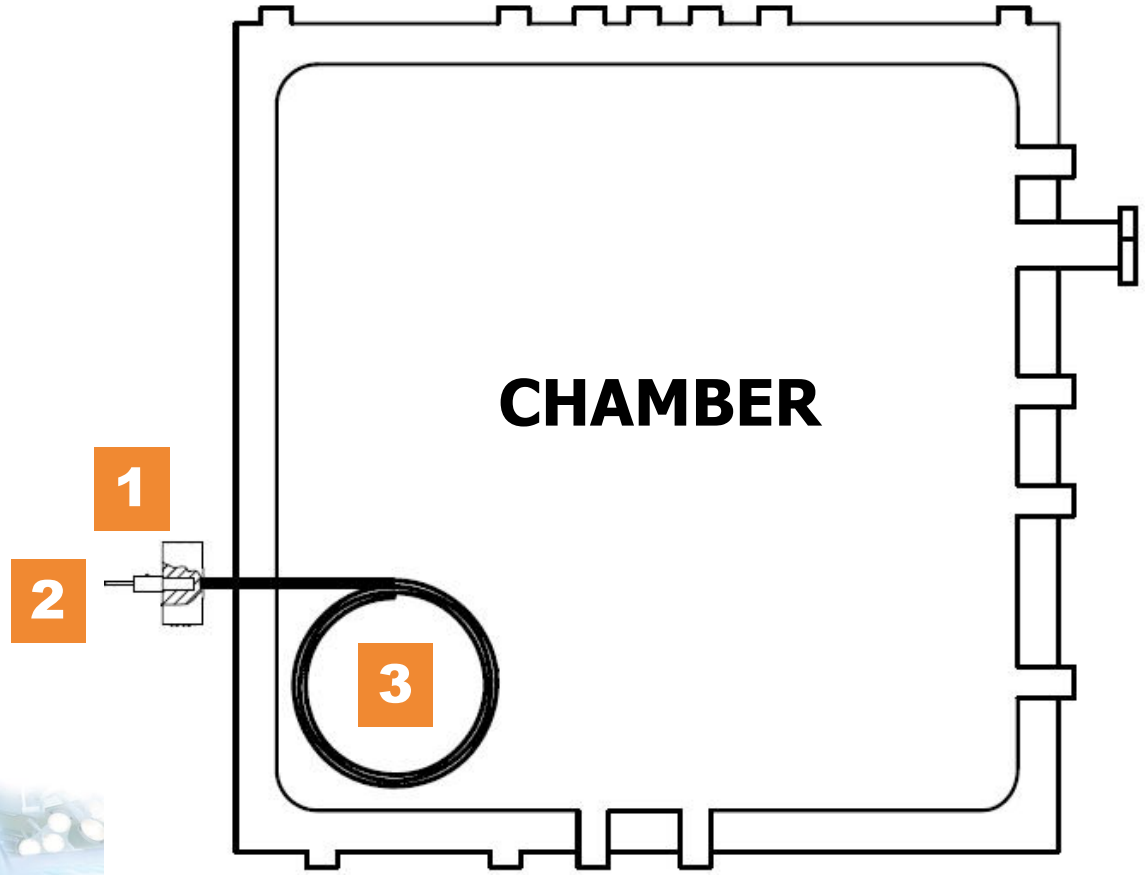
Steam Spy: Integrated Automatic B&D test

1 process challenge device, defines the amount of steam that penetrates through the tube

2 Pt100-temperature sensor; analysis of the temperature course gives the result *pass* or *fail*

3 tube, simulates the difficulty of steam penetration for porous load



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SteamSpy can also be used as additional batch control system:

- Most systems that are available are compliant to EN 867-5
- SteamSpy tests according to EN 867-5 are completed

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Advantages of an *integrated*, non-chemical alternative Bowie&Dick test:

- No double documentation, result of the B&D test is printed on the batch protocol.
- The result is available without delay at the end of the process
- The B&D test program can be added to the automatic warmup program. The sterilizer is ready for production at the end of the “Automatic warmup” procedure.
- Tests according to ISO-11140-4 are carried out with effectively running program

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Challange & Solution

When the CSSD staff starts working,
the MMM steam sterilizer shall be ready
for production

➡ **within a short time**

✓ **without much effort for the personnel**

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Old MMM sterilizers

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New MMM sterilizers (automatic warmup):

1. A vacuum test is started
2. An empty cycle is run
3. **Insert BD test** and start the program (35 min)
4. Evaluate the test:
   - → with paper (3 min)
   - → electronically (8 min)
5. After approx. 45 min, personnel starts the real production.

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New MMM sterilizers with automatic B&D test (automatic warmup):

1. A vacuum test is started
2. An cycle with empty chamber is run
3. **B&D test** is started
4. Electronic test evaluation (autom / man.): (1 min)

After approx. 1 min, the sterilizer is ready for real production. ✓

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„...increase sterilization safety“

Extract: Expertise of SMP – Tübingen:

Project-Nr.: 1621041009

Comparison of the SteamSpy System from MMM Münchener Medizin Mechanik GmbH with the requirements of the EN/ISO 11140-4 Standard: “Class 2 indicators as an alternative to the Bowie and Dick – Type Test for the detection of steam penetration”

In summary, it can be said that, unlike conventional Bowie-Dick-Type Test packs, **SteamSpy** not only recognizes faults reliably, but also shows if the Bowie-Dick Cycle has been run in accordance with all pertinent norms and in specification.

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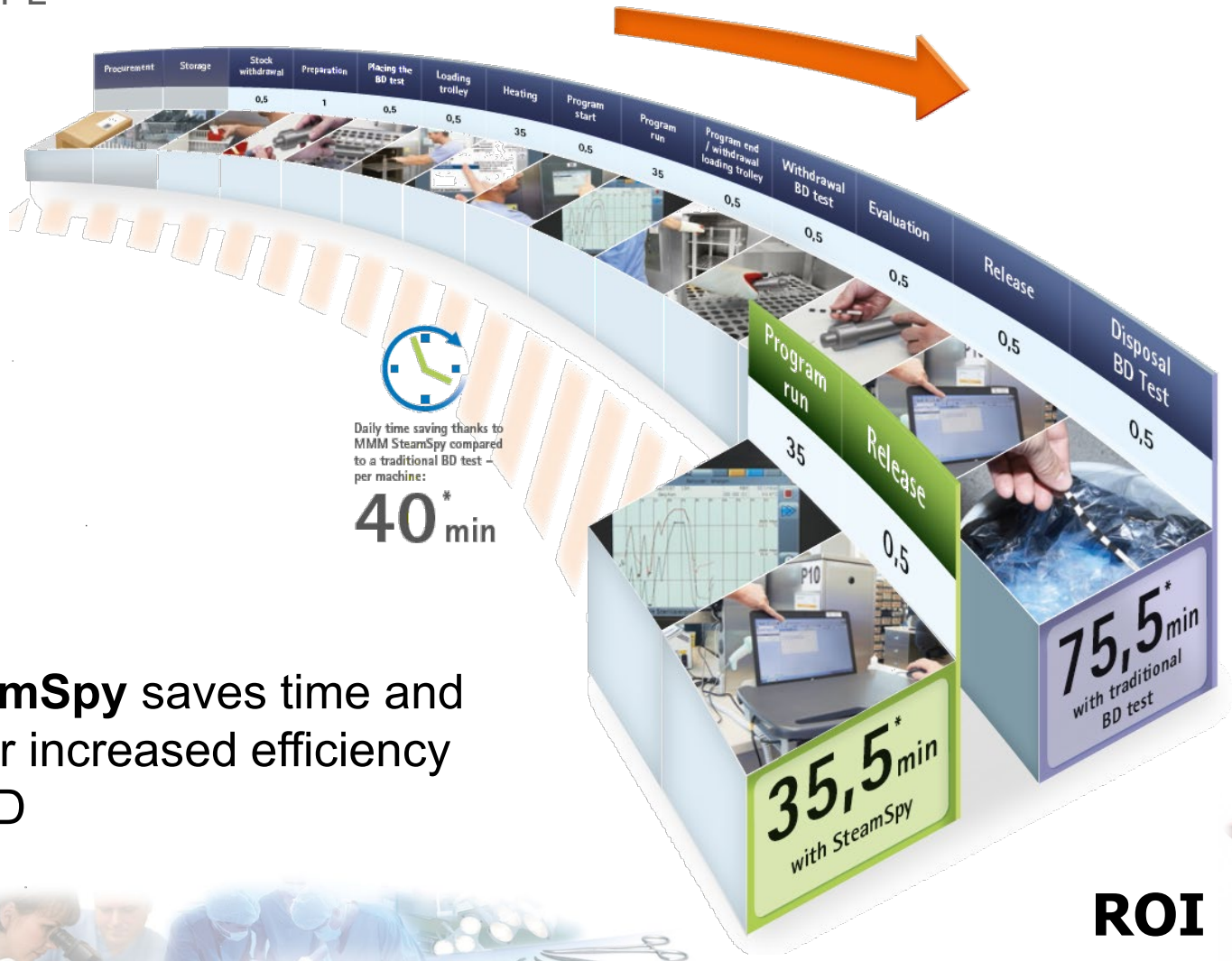

MMM SteamSpy saves time and money – for increased efficiency in the CSSD

ROI

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SteamSpy works completely without chemical indicators. Is it a real BD test?

SteamSpy works on a purely physical basis by measuring the temperature as a detector. The evaluation of the temperature value and the way it rises, produces the automatic evaluation of whether the test was passed or failed.

The performance requirements for an alternative BD test are standardized by ISO 11140-4.

All tests defined by this standard – particularly the identification of leakages, air injections and remaining air – are carried out and approved by an independent test laboratory.

This makes SteamSpy a fully-fledged, alternative Bowie-Dick test compliant to ISO 11140-4 and may replace products that work on the basis of chemical indicators.

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SteamSpy evaluates a temperature measurement. Is it able to discriminated hot air and steam?

It is common knowledge, that systems working on the basis of temperature measurement are not able to discriminate between hot air and water, if certain conditions are given. Particularly if a temperature probe is placed at the end of thin tubes. Incoming steam quickly heats up the steam from outside and the temperature probe reaches a temperature even if the steam did not stream through the tube.

When SteamSpy was constructed, we took this problem into account. The actual test body with the temperature probe is placed outside of the sterilizer chamber, which means that a temperature rise is induced by steam which penetrates the tube..

Fail tests according to ISO 11140-4 (identification of leakages, air injection and remaining air) are based on the fact that air is produced at the detector and must be identified. Each alternative Bowie-Dick test system according to ISO 11140-4 – be it chemical or physical – is able to discriminate between hot air and steam.

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Is it possible to test the function of SteamSpy as an alternative Bowie&Dick-Test?

A full testing of an alternative Bowie&Dick test system would mean, that a FAIL-test against all three sources of error (leakage, air injection and remaining air) must be carried out on site. However, it would be very difficult and time-consuming to induce a reproducible leakage or air injection corresponding to the errors defined in ISO 11140-4. Taking the justifiable effort into account, this could only be done for testing the remaining air, where the vacuum switch points are shifted until the „standardízed“ error is induced.

The MMM steam sterilizer *Selectomat PL* with integrated SteamSpy is equipped with this test program. It can be activated for test purposes any time. If the error message „integrated B&D test failed“ is produced when running this test program, you may assume that SteamSpy is working correctly.

Do you know any other Bowie-Dick test (be it chemical or physical) which can be testes in such a simple and smart way)?

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Which performance requirements are covered by the batch control system SteamSpy?

Relating to air removel, SteamSpy is a challenging test which is suitable for monitoring steam penetration of simple hollow bodies as well as of solid or porous packaged goods during each cycle. The test requirements of the sterilization process are identical to those of the challenge device according to DIN EN 867-5.

How do you test the suitability of SteamSpy as batch control system?

The suitability as batch control system must be verified as a function of the load at each process validation.

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How do you test the function of SteamSpy as batch control system?

A defined error status, where the batch control system shows an error, can be produced by artifically rising the vacuum switch points. Thus, more remaining air stays inside the chamber and the load.

The MMM steam sterilizer *Selectomat PL* with integrated SteamSpy is equipped with this test program. It can be activated for test purposes any time.
The switch points of this test program are configured in such a way that a process challenge device according to DIN EN 867-5 must produce an error.
If the error message „integrated B&D test failed“ is produced when running this test program, you may assume that SteamSpy is working correctly.

This is it.....

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...for your attention

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