

REPORT

EHEDG 02 sterilisability test
retractable holder EXtract 830M for
pH-probes and biomass sensors
Test no. 552/12.07.2016

Exner Process Equipment GmbH
D-76275 Ettlingen

The report covers 11 pages with 4 figures, 2 tables and 1 appendix.

The test results apply only to the subject equipment.
The tests have been carried out according to the test requirements by
trained personnel.



Prof. Dr.-Ing. Fritz Jacob
Director



Weihenstephan,
October 12th 2016



Deutsche
Akkreditierungsstelle
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Accreditation according DIN EN ISO/IEC 17025:2005 for: „microbiological tests
for cleanable equipment used in the food production”

The present report is done in cooperation with Dr.-Ing. Jürgen Hofmann.

Weihenstephan, October 12th 2016



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Summary

Exner Process Equipment GmbH, Industriestr. 6A, D-76275 Ettlingen, Germany, commissioned the Research Centre Weihenstephan for Brewing and Food Quality, Technische Universität München in Weihenstephan, Germany, to perform the EHEDG Sterilisability Test Method [1] to test the steam sterilisability of the food contact surface of a manual retractable holder. For this, a retractable holder type EXtract 830M for assembly in a GEA Tuchenhausen Varinline ball housing with a pipe diameter of 2.0" was provided as an example for this retractable holder series. Two series of tests were performed, one with a pH probe type EASYFERM Plus VP 225 the other with an optical biomass sensor type EXcell 230.

The test results show that the product contact surface of the retractable holder type EXtract 830M is in-line steam sterilisable according EHEDG requirements. There are no cold spots in the equipment. The tests were done for three times with each sensor. The received results are comparable to each other.

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1. Purpose

Exner Process Equipment GmbH, Industriestr. 6A, D-76275 Ettlingen, Germany, commissioned the Research Centre Weihenstephan for Brewing and Food Quality, Technische Universität München in Weihenstephan, Germany, to perform the EHEDG Sterilisability Test Method [1] to test the steam sterilisability of the food contact surface of a manual retractable holder. For this, a retractable holder type EXtract 830M for assembly in a GEA Tuchenhausen Varinline ball housing with a pipe diameter of 2.0" was provided as an example for this retractable holder series. Two series of tests were performed, one with a pH probe type EASYFERM Plus VP 225 the other with an optical biomass sensor type EXcell 230.

2. Description of the test object

Name and Type of test object	manual retractable holder EXtract 830M with pH-probe EASYFERM Plus VP 225 and optical biomass sensor EXcell 230
Model code	--
Process mounting	Varinline® ball housing
Materials of construction	Housing: stainless steel 1.4404 / AISI 316L Cylinder: stainless steel 1.4404 / AISI 316L Insertion rod: stainless steel 1.4404 / AISI 316L
Surface treatment	Housing: product contact surface without damages, $R_a \leq 0,8 \mu\text{m}$ Cylinder: product contact surface without damages, $R_a \leq 0,8 \mu\text{m}$ Insertion rod: product contact surface without damages, $R_a \leq 0,8 \mu\text{m}$ Sealing: smooth surface without any damages
Seal type	O-Ring: Insertion rod/Process connection, Insertion rod/Cylinder, Sensor/Insertion rod, Housing/Insertion rod
Seal material	EPDM

A photo of the retractable holder with the pH-probe is shown in Figure 1. Further detailed information on the test object is given in Appendix A.

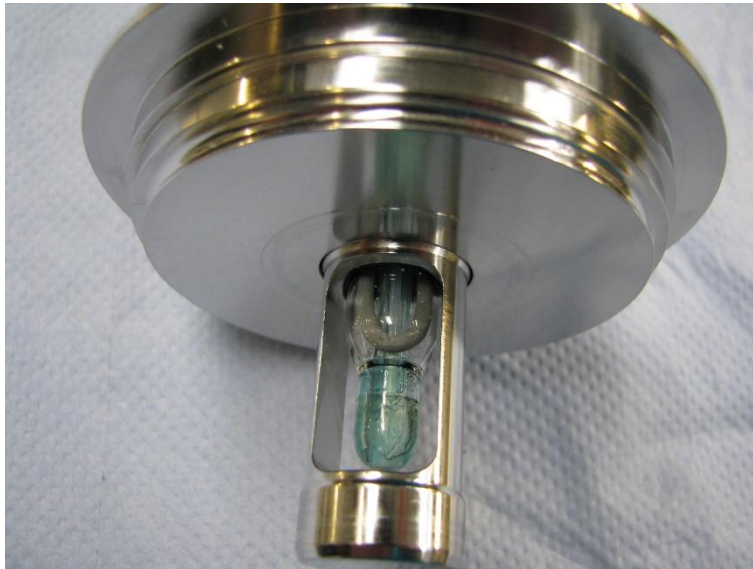


Fig. 1: Retractable holder, type EXtract 830M with pH-probe EASYFERM Plus VP 225

A photo of the retractable holder with the biomass sensor is shown in Figure 2. Further detailed information on the test object is given in Appendix A.



Fig. 2: Retractable holder, type EXtract 830M with biomass sensor EXcell 230

3. Time schedule

The test object arrived at the Research Centre Weihenstephan for Brewing and Food Quality, Technische Universität München in Weihenstephan, Germany in July 2016 and was registered under test numbers 552.1 and 552.2/12.07.2016. The investigation was carried out from July 13th until October 10th 2016.

4. Method and material

With this test the steam sterilisability of food processing equipment can be investigated. Before conducting the test program, the equipment should have passed the in-place cleanability test. All applied elastomeric components were checked against the test strain for antimicrobial properties. Prior to testing, the test object was dismantled, thoroughly cleaned and degreased by hand, steam-sterilized in-line or autoclaved at 121°C for 30 minutes.

Trypticase soy broth (TSB) is pumped through the test circuit to provide a medium for any indicator micro-organism surviving in the test equipment after the sterilization test procedure.

The dismantled test equipment is soiled with the spore solution of *Bacillus subtilis* on all relevant areas in a concentration of approx. 10^7 per cm³. After drying in a clean bench the test object was reassembled and built in a test rig [Fig. 2] for the Sterilisability test.

The sterilization takes 30 minutes at 121°C. After this the two valves for the steam circulation were closed and the valves of the tryptic soy broth were opened. Subsequent the tryptic soy broth is circulated for 5 days at ambient temperature (20 – 25 °C). If the broth remains clear after 5 days the equipment is classified as in-line steam sterilisable. If the TSB becomes turbid a sample is taken and examined for the presence of *Bacillus subtilis*.

The test should be passed three times, by comparable results.

Note

Although the test strain in TSB at 25 °C growing rapidly (turbidity within 24 h), a much longer incubation time (5 days) was chosen. So that the microorganisms are given sufficient time to grow through cracks, crevices and pores, thus contaminating the inside. The applied contamination corresponds to a worst case scenario.

If the sterilization test carried out earlier, the bacteria tightness test can be followed without disassembly. As long as the TSB is clear and sterile, the outer side can be contaminated.

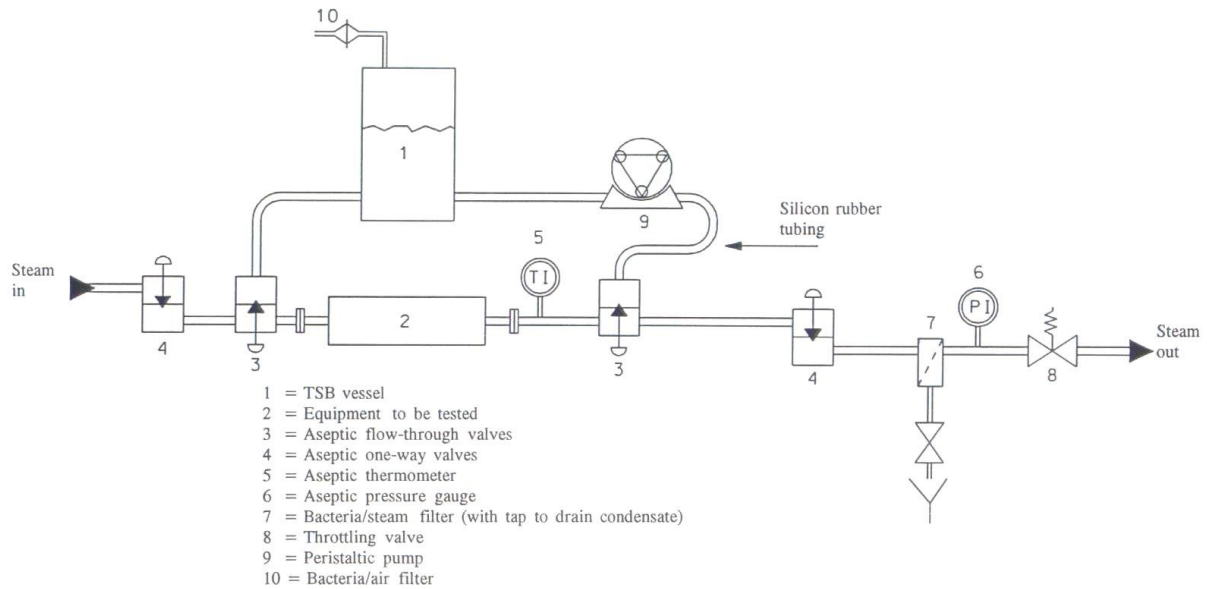


Fig. 3: Testrig for steam sterilisation method

4.1. Specific testing conditions

Standardized testing conditions were applied. The test was done according the published EHEDG procedure, Document 5 [1]. Broth was pumped for 15 minutes per hour using a timer.

The retractable holder type Extract 830M was mounted in a Varinline® ball housing for sterilization. Steam was blown first through the ball housing and afterwards through the ports of the retractable holder. Temperature control was performed through a throttle valve.

For incubation after the sterilization a bottle containing one liter of sterile TS broth was connected via silicone hoses to the retractable holder and was pumped using a hose pump.

5. Result

The in-line steam sterilisability test was conducted three times on the test object with both sensors. The individual results of the tests are comparable with each other.

Material testing: The applied EPDM O-rings of the sensor are steam sterilisable and showed no antimicrobial properties.

The test results are shown in table 1 and 2 with the turbidity of the broth.

Table 1: Survey of the test results of pH probe EASYFERM Plus VP 225

	test 1	test 2	test 3
reference sample (TSB with spores)	turbid	turbid	turbid
blind sample (TSB with spores)	clear	clear	clear
EXtract830M with pH-probe EASYFERM Plus VP 225	clear = sterile	clear = sterile	clear = sterile

Table2: Survey of the test results of biomass sensor EXcell230

	test 1	test 2	test 3
reference sample (TSB with spores)	turbid	turbid	turbid
blind sample (TSB with spores)	clear	clear	clear
EXtract830M with biomass sensor EXcell230	clear = sterile	clear = sterile	clear = sterile

6. Conclusion

The test result demonstrates that the food contact surface of the retractable holder EXtract 830M with mounted pH-probe EASYFERM Plus VP 225 or biomass sensor EXcell 230 is in-line steam sterilisable and sterilisable according EHEDG. There are no cold spots in the equipment.

The test equipment is categorized as in-line steam sterilisable.

7. Records

Original data sheets, protocols and the final report will be filed in the archives of the Research Centre Weihenstephan for Brewing and Food Quality, Technische Universität München in Weihenstephan, Germany for 10 years after completion of the study.

8. References

1. A method for the assessment of in-line sterilisability of food processing equipment, EHEDG-Doc. 5, 2nd edition, 2004.

Appendix A

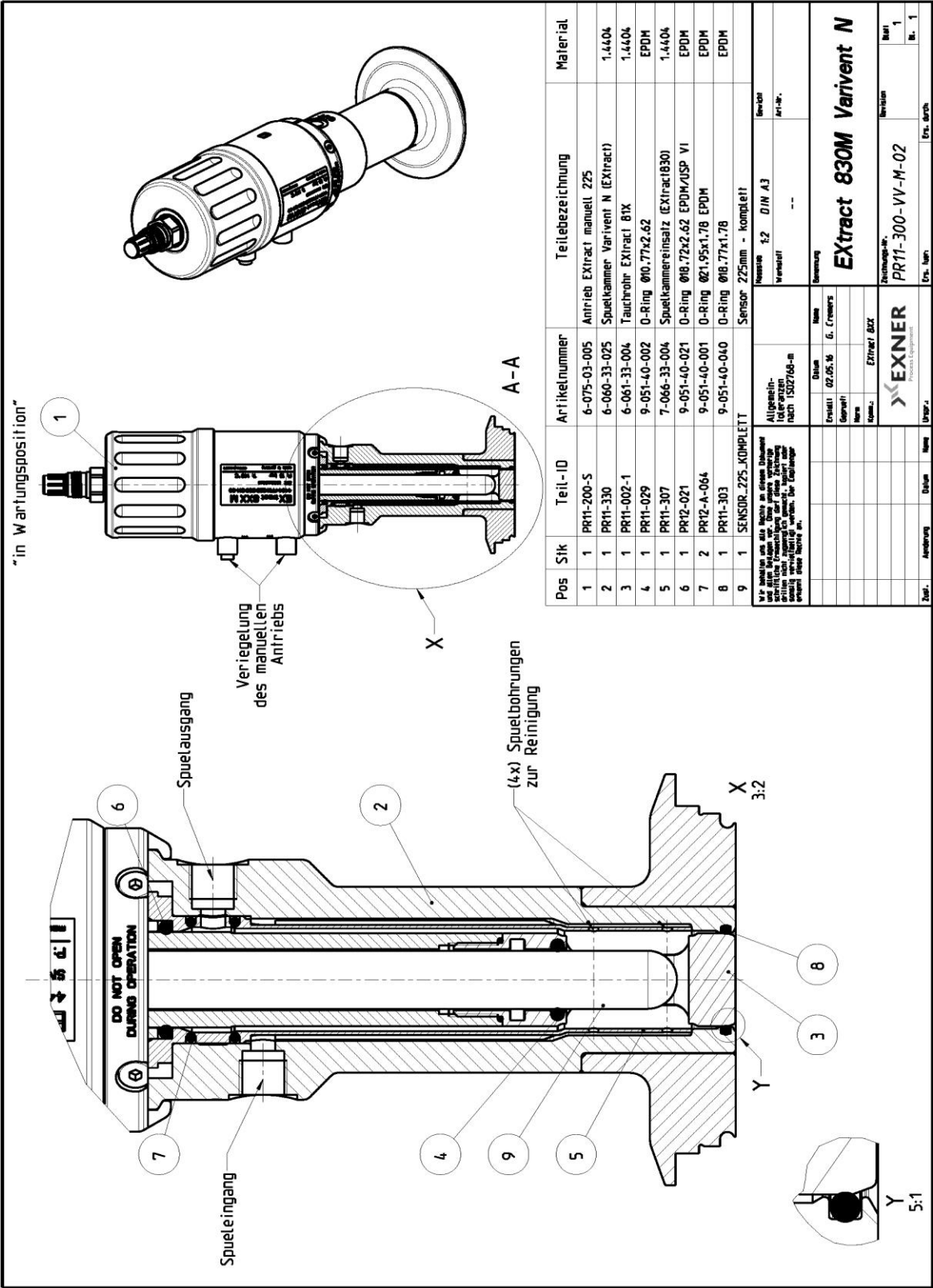


Fig. 2: Drawing and sectional view of the retractable holder EXtract 830M