

**Testing of the EBI 16 – Bowie & Dick PCD
with the corresponding software
with respect to the requirements of EN/ISO 11140-4:
“Class 2 indicators as an alternative to the Bowie and Dick – Type Test
for the detection of steam penetration”**


Manufactured by: Xylem Analytics Germany GmbH, ebro Dr.-Karl-Slevogt-Str. 1; 82362 Weilheim

The purpose of the study was to compare the EBI 16 – Bowie & Dick PCD with the corresponding software with respect to its ability to recognize insufficient steam penetration in a steam sterilizer under the conditions described in the table. Tests have been performed in a sterilizer according to EN 285.

The physical parameters of temperature and pressure within the chamber of the sterilizer have been recorded with **EBI 16** data loggers. The results of the data evaluation of the logger data with the software **Winlog.validation 3.61** have been compared to the results of temperature measurements in a Bowie-Dick standard test pack. The similar function of the Bowie&Dick evaluation module in other versions of this or other software products has to be declared separately by the manufacturer.

Test condition	Cycles performed		
	B.1 Air removal by sub-atmospheric pulsing	B.2 Air removal by transatmospheric pulsing	B.3 Air removal by superatmospheric pulsing
“Pass” cycle	√	√	√
“Fail” cycle modified air removal	√	√	x
“Fail” cycle induced leak	√	x	x
“Fail” cycle air injektion	√	x	√
√ = test required x = test not required (see EN/ISO 11140-4)			

Based on the examinations - reported and documented under Project-No. 15616 - SMP declares that all required tests shown in the table have successfully been carried out and the required pass or fail results were achieved.

<p>Tübingen, Nov. 07, 2016</p> 	<p>The laboratory of SMP GmbH is accredited as testing laboratory by DAkkS according to DIN EN ISO / IEC 17025:2005 and guidelines 93/42/EEC and 90/385/EEC. The accreditation is valid for the methods described in certificate D-PL-17769-01-01. The accreditation for examinations according to EN/ISO 11140-4 was requested.</p>
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