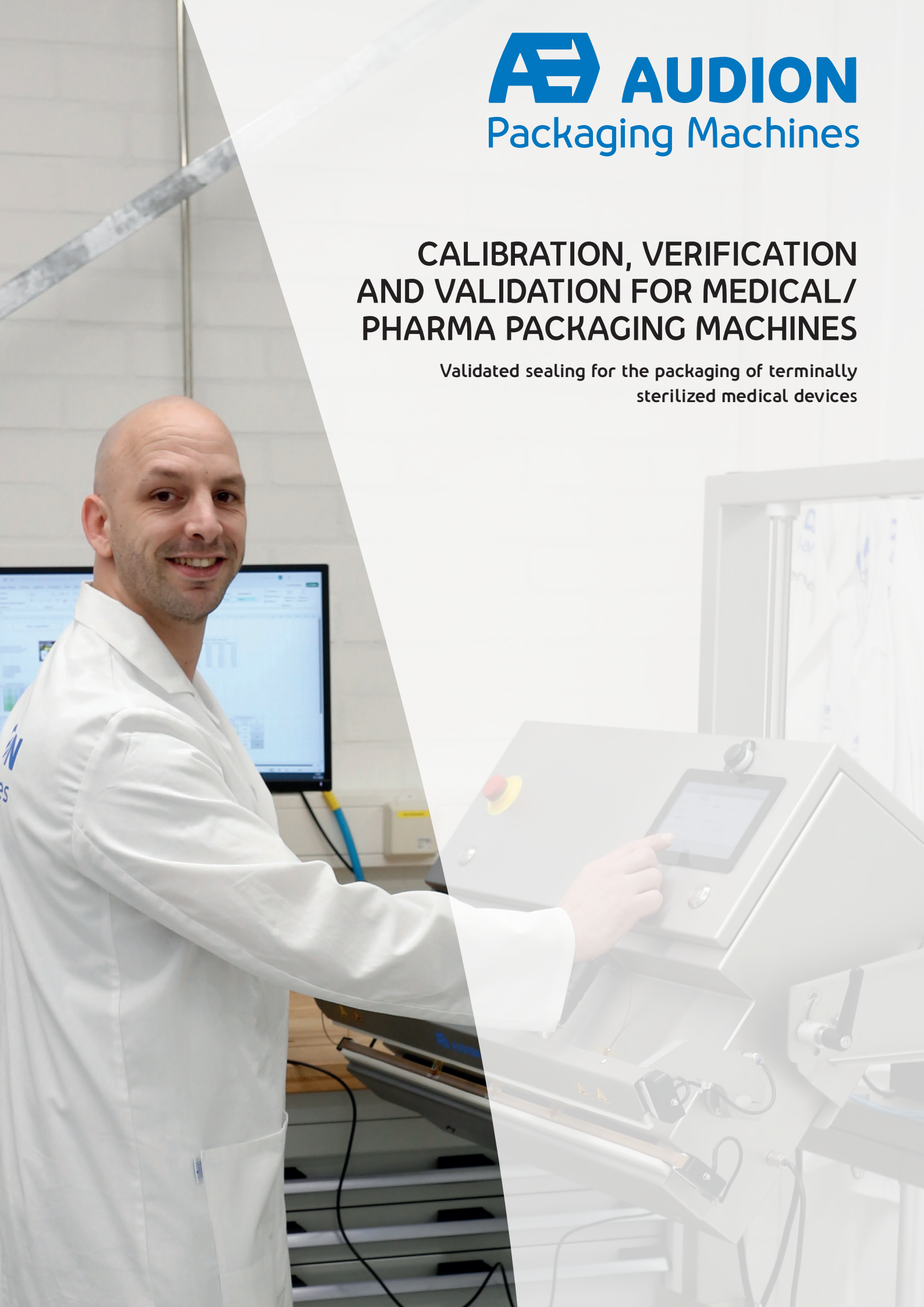
AUDION
Packaging Machines

CALIBRATION, VERIFICATION AND VALIDATION FOR MEDICAL/ PHARMA PACKAGING MACHINES

Validated sealing for the packaging of terminally sterilized medical devices



“Our service engineer will visit your factory with calibrated measuring instruments and test kits, and issue a certificate accompanied by all relevant documents.”

I. Validated sealing for the packaging of terminally sterilized medical devices

In both the healthcare and pharmaceutical markets, maintaining sterility and preventing infection are crucial to providing the right care. Whether in an operating room or any other setting, the caregiver must be confident that a device will not cause additional complications. A so-called Sterile Barrier System ensures that a sterilized device is packaged in such a way that it provides an acceptable microbial barrier and allows for aseptic presentation until the point of use. In many parts of the world, medical packaging is regulated as stringently as if it were medical instruments.

Audion Packaging Machines provides companies active in the Medical/Pharma market not only with validatable sealers but also with calibration and validation services to ensure that your packaging always complies with the strict requirements of ISO 11607-2:2019. Our services are essential because traceability, reproducibility and the availability of documentation are central to the standard and depend on regular verification, calibration and validation. Audion offers its customers all the necessary calibration and validation services as well as tools for regular verification by the customers themselves.

A medical device is aseptically presented at the point of use

Audion Validation Services

Audion distinguishes 3 separate services for the calibration and validation of our packaging machines:

- Audion Factory Calibration
- IQ/OQ Check (Installation- / Operational Qualification)
- Seal Integrity Tests

Sterile barrier system

Calibration only certifies the preciseness of the sealing parameters of the packaging machine and is therefore only the first step towards a seal that is compliant with ISO 11607-2:2019 . The subsequent IQ/OQ Check ensures that the packaging machine and the material together provide the required result: the right, consistent seal. The documents Audion provides after completing both stages will be a significant part of your validation process. We also offer our Seal Integrity Tests separately as an additional service. Our service engineer will visit your factory with calibrated measuring instruments and test kits, and issues a certificate accompanied by all relevant documents. Each service is discussed in more detail, followed by an overview of the tools and accessories that our customers can use to regularly verify their seal parameters and - quality.

Validated sealing process

2. Audion Factory Calibration

Audion provides a range of calibration services for our extensive range of validatable sealers that are being used in the Medical and Pharma markets as well as certain high-tech industries. Our offering includes impulse sealers, rotary heat sealers, Speedpack Hybrid and validatable vacuum chambers. Regular user verification and the recommended yearly re-calibration ensure that validatable sealers keep delivering the required seal quality.

ISO Calibration Certificate

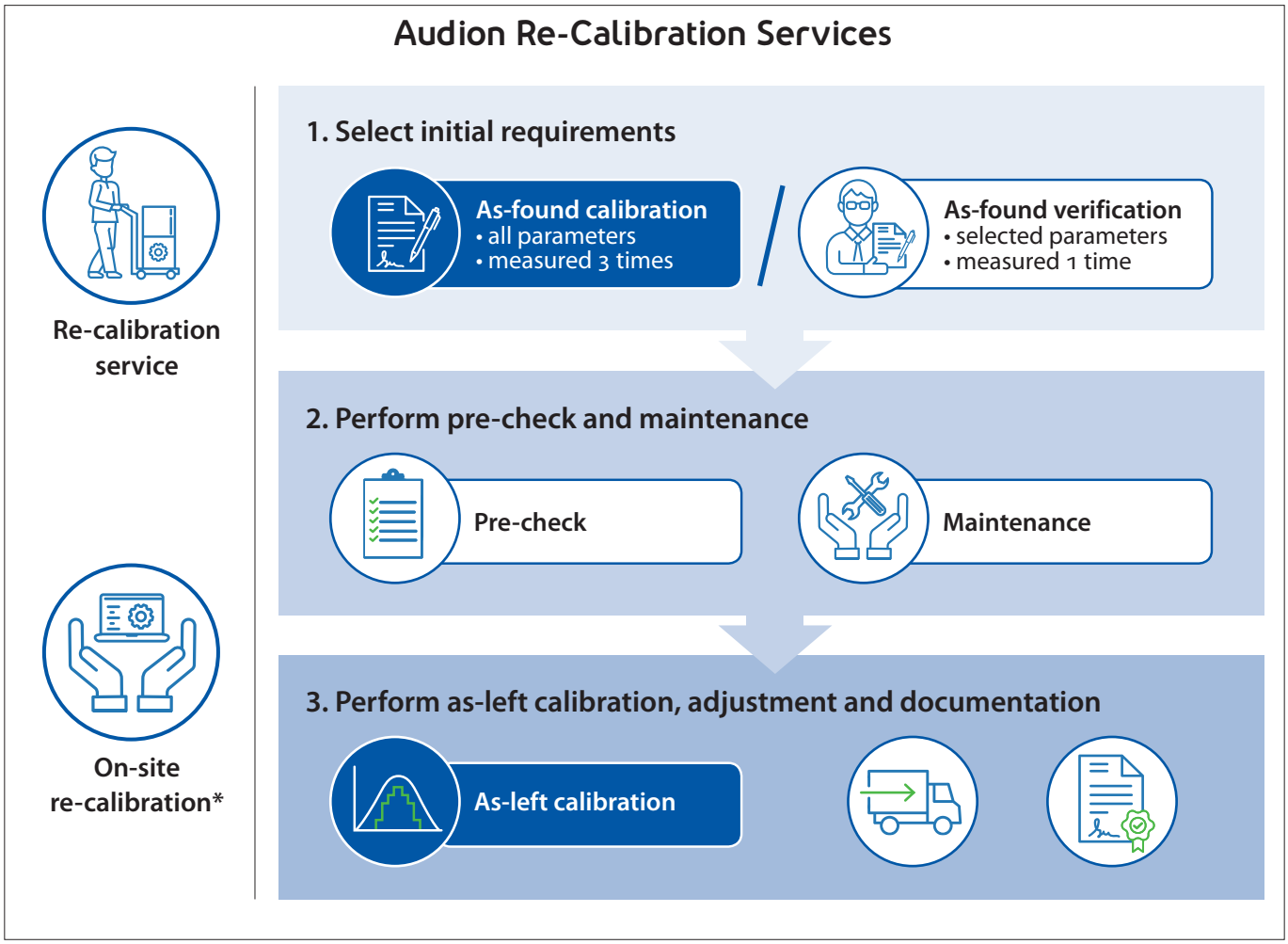
The three parameters that determine the quality, and therefore consistency of the seal are temperature, time/speed and pressure/force. In the case of a vacuum chamber, vacuum pressure is added as the fourth parameter. During calibration, our service engineers calibrate and, if needed, adjust the parameters and provide you with the calibration certificate.

All calibration procedures and instruments are checked and documented in accordance with the requirements set out by ISO 9001. Additionally, the used reference standards are calibrated under ISO 17025 accreditation and therefore traceable to (inter)national standards.

Calibrating temperature on a rotary sealer

Re-calibration Services

Audion's re-calibration services confirm the preciseness of the critical process parameters after a year and is often the final step to 'clear' your annual production. The subsequent pre-check, maintenance and as-left calibration ensure that your validatable sealer is again ready for use in daily production. Of course, our Service Team will provide you with all necessary documentation. We recommend that re-calibration is performed on a yearly basis for packaging machines that are used to seal devices that are subject to strict requirements.



** Only available for select packaging machines and in certain regions. Contact your Audion representative or dealer*

As-found calibration

As-found calibration is simply a must for demanding markets. Their quality control processes, industry standards, certification or even regulation requires a regular re-calibration of their packaging equipment. During the as-found calibration, all applicable parameters - temperature, time, force and, in the case of a vacuum chamber, vacuum pressure - are measured three times.

As-found verification

But for most of our customers, the attractively priced 'As-found verification' option is a worthwhile check that allows them to verify if their production run has been packaged as required. Our specialist performs single checks of the essential temperature and force parameters as well as an initial inspection to ensure that the device is functioning properly. It is less thorough than the as-found calibration but, in practice, covers the ground necessary to be able to clear production. This is especially the case when combined with regular user verification.

Loadcell calibration for seal force

Calibration procedures are clearly specified in the working instructions

Collected data will be carefully analysed and documented

Pre-check and maintenance

Maintenance is performed based on an extensive inspection during which our engineers check:

- Test wear-sensitive parts
- Test seal regulation on operation and set parameters
- Internal and external visual inspection of the machine
- Ensure correct functioning of electrical and pneumatic components
- Review application settings

As-left calibration

The as-left calibration is performed by Audion's Service engineers to the standard of the original factory calibration. When necessary, we adjust parameters to ensure that your seal temperature, force, duration, and possibly vacuum falls within the predetermined values. The calibration results are documented in accordance with the ISO 9001 standard.

On-site calibration option

We offer re-calibration services for Audion sealers both in our own Calibration facilities as well as, for a selection of our packaging machines, on-site calibration.
Our representative will inform you of your options during machine selection or when re-calibration is to be completed.

3. Importance of user verification

Calibration is an essential step towards compliance with the ISO 11607-2:2019 standard but is, by itself, not enough. All parameters were within the predetermined tolerances at the time of calibration, but these may deviate in the future due to a variety of reasons. That is why it is important to regularly verify the operational parameters, to be scheduled on a weekly or monthly basis along with regular maintenance work.

Verification instruments

Audion offers a wide range of instruments that enable customers to perform regular verification of their seal parameters. Regular verification helps you find incorrect performance of your sealer in an early stage.
Available verification instruments are:

Article codes	Type	Parameter to verify	Applicable machines
ATM	Temperature meter with flat K-probe 	Seal temperature	Power Sealer (VAL PSR / PSR PLUS) Medseal (MSIDV) Contimed Vacuum chamber (VAL VMS) Speedpack Hybrid (SPKH)
AFMR	Force gauge 	Seal force	Power Sealer (VAL PSR / PSR PLUS) Medseal (MSIDV)
ASPM	Differential pressure meter 	Seal pressure	Vacuum chamber (VAL VMS)
AVLM	Vacuum meter 	Vacuum pressure	Vacuum chamber (VAL VMS)

“Operational Qualification is completed with the purpose of determining the right parameter setting and tolerances, as well as ensuring that the closure is consistent and meets up with the acceptance criteria.”

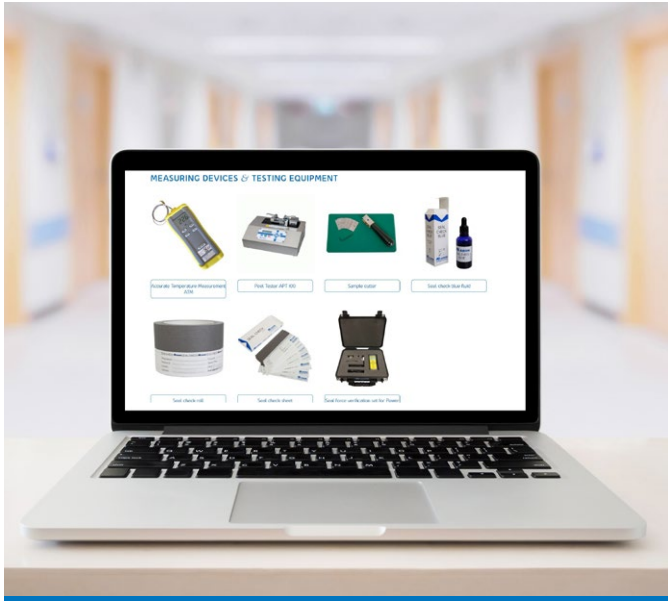
4. IQ/OQ Check

Besides calibration services, we offer Installation and Operational Qualification checks at the customer's location:

- **Installation Qualification verifies that your packaging machine has been installed and configured according to our specifications and installation checklist.**
- **Operational Qualification is completed with the purpose of determining the right parameter setting and tolerances, as well as ensuring that the closure is consistent and meets up with the acceptance criteria.**

IQ Check

Installation Qualification is, in practice, a check to determine if our packaging machine can perform, as expected, in your real-world operating environment. Our service engineer tests each packaging machine for correct installation and functionality, takes note of all specifications and critical process parameters and checks whether all necessary documents are present. As part of the Installation Qualification, our service engineer will train your staff for the operation and maintenance of the packaging machine. A training certificate will be issued for each staff member.



Check all our **measuring devices** and **testing equipment** on audion.com

OQ Check

During the Operational Qualification, the service engineer tests and thoroughly documents all items in the test plan

<Determine sealing parameters and tolerances>

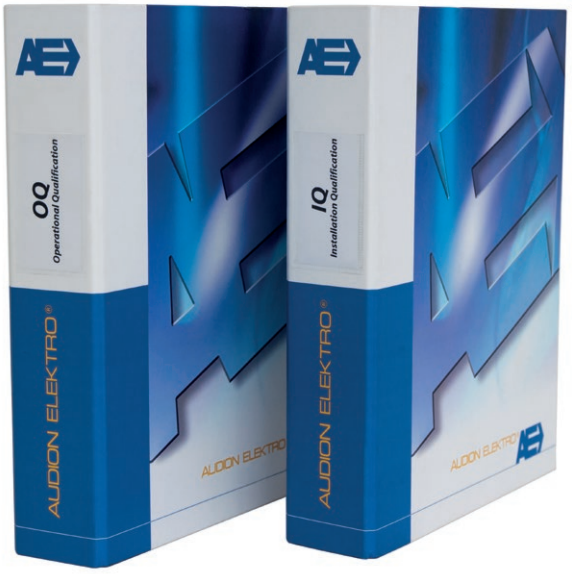
<Determine acceptable criteria>

<Worst case testing>

- Worst-case samples are made by setting all parameters on their upper and lower limits
- Integrity tests are performed on the worst-case samples.

Seal Integrity Test includes:

- **Seal check in accordance with EN ISO 11607-2**
- **Dye penetration test ASTM F 1929**
- **Peel test EN 868-5:2018 annex D**



IQ/OQ Documentation

Audion will provide you with all the necessary IQ and OQ documents for the validation of our packaging machines. These documents were developed in accordance with the checklists of ISO/TS 16775:2014, which is the guideline for the application of ISO 11607-1 and ISO 11607-2. The resulting documents are an essential component of your validation documentation and will be provided to you digitally.

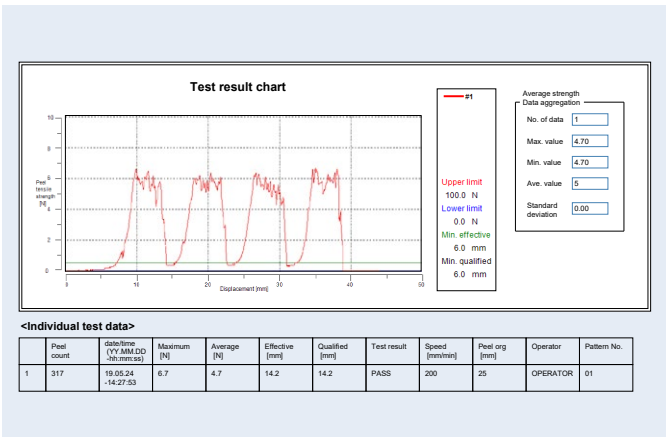
5.Seal Integrity Tests

Regular verification of your seal quality is an important part of quality control. Audion offers our Seal Integrity Test as a separate service to support your seal quality inspection. Our service engineer will visit your factory with test kits to complete the following tests:

Seal Check

The Seal check according to ISO 11607-2 makes sure that the seal is intact for a specified seal width.

Peel Test



	Peel count	date/time (YY.MM.DD -hh:mm:ss)	Maximum [N]	Average [N]	Effective [mm]	Qualified [mm]	Test result	Speed [mm/min]	Peel org [mm]	Operator	Pattern No.
1	317	19.05.24 -14:27:53	6.7	4.7	14.2	14.2	PASS	200	25	OPERATOR	01

APT 100 peel tester checks the tensile strength of the seal according to EN 868-5 Annex D.

Dye Penetration Test

Dye penetration test according to ASTM F1929 ensures that there are no channels that offer a contamination risk.

Seal integrity test tools

The following tools and accessories are also available through the Audion Dealer Network:

Article codes	Descriptions
APT 100	Peel tester 
ASC INK-B	Audion Seal Check Blue 50ml 
ASC SHEET	Audion Seal Check sheet 100pcs 175x75mm 
ASC ROLL	Audion Seal Check Roll 50m x 75mm 

Peel Test Service for regular seal quality verification

Customers that would appreciate verification at more regular intervals can make use of our Peel Test Service. The customer sends samples to the Audion Factory where we will perform Peel Tests and provide the customer with a (digital) test report.

Training Services

Audion can provide trainings for parameter verification and/or seal integrity test. Contact our Service department for an offer.

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We kindly invite you to contact us for exploring various packaging solutions tailored to your business!

AUDION
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audion.com

Call our advisors

NL +31 294 49 1717

DE +49 28 21 73300

UK +44 1332 404 330