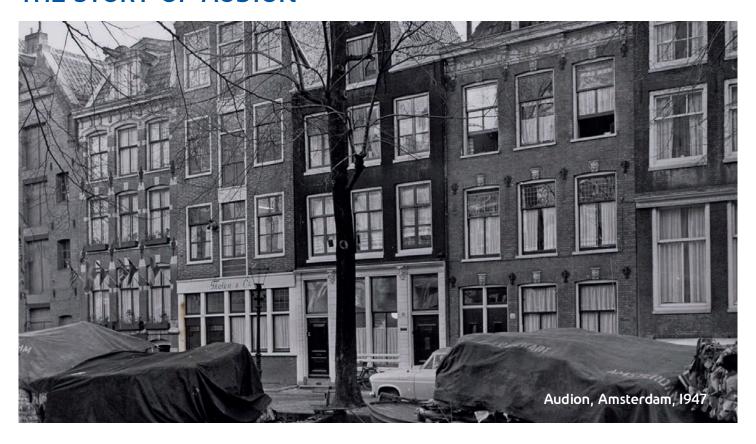


#### THE STORY OF AUDION



Audion Elektro B.V. was established in 1947 in Amsterdam. In the fifties the company started to focus on manufacturing sealing machines besides the trading business. In the past decades Audion has grown to become a leading name in the packaging industry. Today, with a worldwide dealer network, Audion is represented in more than 65 countries throughout the world.

#### **QUALITY**

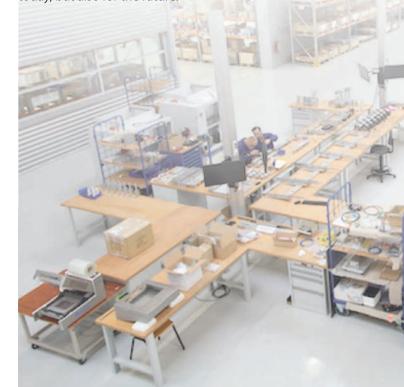
Audion packaging machines are characterised by outstanding quality. By keeping control over the development and production of the machines in the Netherlands , Audion has managed to stay flexible and customer oriented. The service Audion provides is regarded as a decisive advantage by our customers. Short delivery times of machines, parts and accessories and innovative solutions to diverse packaging problems are important qualities that distinguish Audion in the industry.

With Audion, you have a large choice of packaging machines that meet your production requirements. The experience and expertise accumulated over the years, in finding solutions for customers, is unique. The extensive machine range on our website shows that there's a solution for every packaging problem. As well as producing standard machines, we are happy to provide bespoke models if required.

Today, our machines are sold in over 100 countries which makes us one of the key suppliers for the global packaging industry. We pack everything - from medical devices, medicine and chemical raw material to industrial goods.

We do this with dedication and in a unique approach. We design and develop the machines ourselves, which gives us the opportunity to provide the best tools for our customers. The characteristic and appealing design consists of a smooth finish and round corners. This ensures less waste, optimal hygiene and efficiency in the processing and packaging of goods.

Our internal R&D enables us to stay on top of trends and latest innovations in the market. We not only provide you with the best products in the industry but we also take care of the service and maintenance which makes us a full service provider. Every market, from industrial to retail, standard or custom made, we develop a solution for your packaging challenges. Not only for today, but also for the future.



### **SPARE PARTS & SERVICE**





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# **UK** Derby Audion Elektro Ltd.



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### SPEEDPACK HYBRID MED/PHARMA

# Maximum productivity and safety for precise medical or pharmaceutical packaging.

Packaging medical instruments, medicines, test material for laboratories or other medically related products requires extra care on hygiene and safety.

Speedpack Hybrid Medical has a user-friendly software with up to 50 recipe templates. It is designed and tailored to meet the strict packaging requirements of the medical and pharmaceutical industry.

Speedpack Hybrid offers a highly flexible packaging solution. The integrated "bag-creator assembly" can work from both layflat tubing or from pre-opened bags on roll. On the user-friendly touchscreen bag and seal settings can be easily adjusted, such as desired bag length (material saving!) or validation settings.

A handshake simplifies eventual integration with counters, robotics or other automatic infeed devices. Everything to create the perfect medical package.

Speedpack Hybrid Medical comes up to cleanroom class 8.

#### Medical product solutions

- Validatable sealing system (IQ/OQ scripts)
- Impulse sealbars (8 mm seal) for sealing sterilisable packaging material (Tyvek, medical peelable paper laminate)
- Chevron seal
- Special knife for thicker film materials
- Stainless steel cover

- · Clean air inlet and air exhaust
- · Printer or labeler
- Easy product load film grippers
- Stainless steel funnel
- Air extruding
- Cleanroom version
- High Speed version





# SPEEDPACK HYBRID MED/PHARMA HIGH SPEED



For ultimate speed in bag making and bag filling, the High Speed version of Speedpack offers a great solution.

This powerful packaging machine is constructed with two heads: the first head integrating film rollers and offering space for mounting a (label) printer; the back head in which the bag making assembly is integrated. This solution enables you to produce shorter bags at high speed, even when a coding on the bag is desired!

Bottom seal and top seal of the bag are made independently from each other (when the top seal is made on the first bag, the bottom seal is already made at the next bag), facilitating a great capacity!

This high speed version is perfectly suitable when small bags are required, for packaging in medical and pharma industry in medical film.

# PRACTICE CASE 400 SPKHI / 400 SPKRI + 400 SPKR HS

# Medical/ pharma market, 8 mm impulse seal, Tyvek lay flat tubing

Average output for small bags, using lay flat Tyvek tubing, 8 mm impulse seal, label printer, batch production (every bag the same label), special seal requirements: straight and good looking seal, validation of sealing.

#### **400 SPKHI**

Speedpack Hybrid (standard), Impulse seal approx. 7 bags/ minute\*

#### **400 SPKRI + 400 SPKR HS**

Speedpack Hybrid High Speed Impulse seal approx. 15 bags/ minute\*

\* depending on validation requirements and filling time; output can be higher when less cooling time is acceptable for end user

# Medical/ pharma market, 8 mm impulse seal, HDPE lay flat film

Average output for small HDPE bags, using HDPE lay flat tubing, 8 mm impulse seal, label printer, batch production, seal validation with highest requirement on both seal quality and on the seal appearance.

#### **400 SPKHI**

Speedpack Hybrid (standard), Impulse seal approx. 5 bags/ minute\*

#### **400 SPKRI + 400 SPKR HS**

Speedpack Hybrid High Speed Impulse seal approx.

10 bags/ minute\*

\* depending on validation requirements and filling time; output can be higher when less cooling time is acceptable for end user









# SPEEDPACK TABLETOP

A smart industrial bagger that excels in flexibility and productivity.

This tabletop all-electric automatic poly bagger efficiently bags and seals your products at high speed from pre-opened bags on roll.

Just simply choose your ideal bag size, plug in the Speedpack Tabletop and start packing your products! No compressed air is needed.

Speedpack Tabletop 300 features an industrial quality and user-friendly touchscreen interface with the capacity to store up to 50 jobs. The integrated load shelf can be adjusted to various angles, ensuring optimal setup for bulky products.



# POWER SEALER PLUS PSR PLUS 520/720/1020/1320

# VACUUM POWER SEALER PLUS VAC PSR PLUS 520/720/1020/1320

This validatable tabletop impulse sealer, standard equipped with the user-friendly Audion Touch Techware, is suitable for sealing flexible films. Up to 50 seal parameter recipes can be stored so that the operator always has the ideal pre-set settings available for each product/package. Due to the heavy-duty construction and the high performance seal bars, thick and/or special films are sealed effortlessly with a reliable 8mm seal.

• PSR PLUS models are without vacuum system.



- VAC PSR PLUS models are with an integrated vacuum system.
- Vacuum system allows vacuuming and / or gas flushing of your package.





# VAC PSR PLUS IP65 I020 MOTORIZED SUPPORT AND PRINTER

Validatable Vacuum Power Sealer Plus 1020 IP65 for pharmaceutical applications, packaging tablets and powders.

#### Equipped with the following extras:

- Constructed in IP 65 version ceremic blasted
- Motorized support
- 2 Bayonet nozzles in AIS 316, 20 mm wide
- Hepa filters
- · Label printer
- Gas pressure switch
- External exhaust on pump, valves and cylinders
- Frame IP54
- · Motorized bag support

**SPECIAL ENGINEERING PROJECT** 

#### POWER SEALER: PACKAGING IN CLEANROOMS

#### Our vision

Audion Packaging Machines has been the trusted supplier of packaging solutions to suppliers and leading companies active in pharmaceutical, medical and chemical markets for many years. The life science industry continues to grow unabated. At the same time, we see that the demand is increasing. Companies and suppliers must continue to innovate and design at the highest level in order to maintain their competitive edge. Packaging is extremely important, especially for high-quality healthcare products, medicine raw material and medical devices.

#### Powersealer in cleanroom conditions

A clean room is a clean working environment that is designed to reduce or eliminate contamination of the product, production process or research taking place in that environment. The atmosphere in a (ISO 5) cleanroom must contain 10,000 times fewer particles larger than 0.5 µm than normal atmosphere. That's from 35 million parts per cubic metre to about 3,500. Audion Packaging Machines has developed a vacuum POWER SEALER PLUS IP65 720 version, specifically designed for use in cleanroom environments. A number of important adjustments have been made for this purpose. These adjustments were made after intensive cooperation with contamination experts from various companies. This has resulted in a range of sealers and vacuum sealers that fully meet all the requirements of an ISO 5 cleanroom environment.



#### Calibration and validation

Especially in the pharmaceutical and medical world, there is a high demand for process validation. Each package must meet specific requirements. Especially in the medical/pharma sector it is important to use sealers that can be calibrated, which makes validation of sealing processes possible. Validation of sealing processes ensures that guarantees can be given for the continuous quality of the seal. This concerns parameters such as sealing pressure, sealing time and temperature. The Power Sealer can be supplied with a calibration certificate and all relevant validation scripts.

#### **Innovation**

Like many of our customers active in the life science industry, we also continue to innovate, in terms of quality, operating comfort and convenience, but also in terms of connectivity and local/remote data analysis.

#### Power Sealer USPs:

- · Proven quality in cleanroom environments
- Different seal bar lengths
   Sizes: 520 mm, 720 mm, 1020 mm, 1320 mm
- Validated sealing process possible
- Calibration possible
- Easy to operate with Audion Touch Techware
- All models in stainless steel
- · Vacuum by means of clean Venturi pump
- Multiple compressed air extraction options
- Extensive customisation possible
- IP65 (dust and water resistant)
- Compatible with EN 868-5 and DIN 58993
- Fully complies with ISO 11607-2 and ISO/TS 16775

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

#### Power Sealer PLUS XL

Validatable stainless steel impulse sealer for sealing extra large bags (2000 or 2500 mm sealing bars) (PE/ aluminium laminate/ anti static film). Sealing and cooling times are independently adjustable depending on the quality of plastic used. The PSR PLUS XL is standard equipped with a top and bottom sealing bar (bi-active). The PSR PLUS XL needs a connection to a compressed air circuit and is operated by means of a foot switch, leaving both hands available for guiding the bag.

Our customers use this machine for packaging medicine powder in bulk.

This machine is also available with an integrated vacuum and gas flush functionality (VAC PSR PLUS XL).



# **AUDIONVAC**Validatable Vacuum Chambers

Complies to ISO 11607-2 validation requirements for sealing. Critical process parameters to be controlled and monitored:

- Vacuum / gas level
- · Seal temperature
- Seal time
- Seal pressure
- Automatic stop of cycle if one of the critical parameters has exceeded alarm limit.
- · Critical process parameters can be calibrated.
- Seal data can be logged and exported to PC via USB stick.
- Equipped with accurate Audion Temperature Controller (ATC).
- Equipped with user friendly touchscreen interface.
- Access level controllable by login passwords for different user levels.
- · Bi-active seal bars
- · Seal width 8mm.











Heart stents

### **GENERAL INFORMATION**

A vacuum chamber machine removes the air out of a bag by using a vacuum pump. Once the air has been removed the bag is sealed. The Audionvac models start with a small tabletop model and progress through various sizes to a very large double chamber unit. The cabinet of every model is made of stainless steel, while the chamber is either constructed of stainless steel (VMS machines) or aluminum (VM machines). Each model has a unique combination of different types of lids and chambers.

# SHRINK PACKAGING H 22 SA

This Audionpack seal/shrink combination is equipped with an automatic outfeed conveyor which speeds up production. The Audionpack is ideal for moderate production quantities (max. 200 – 500 packs per hour). The machine operates with a shrink hood instead of a tunnel. The hood is closed by an electronic hold-down magnet during the film sealing and heat-shrink wrapping operations. Almost any product can be shrink wrapped in this clever machine. AUDIONPACK shrink wrap machines have an accurate temperature control – a better seal quality and longer wire lifetime than most other similar machines in this market segment.





# CS-MATIC 100

This new automatic shrink sealer works with a continuous side sealer and a longitudinal intermittent sealing system that has at least 3 indisputable advantages:

- Unlimited length of product that can be packed
- · Significant increase in production capacity
- · Less waste film, resulting in lower costs



## TE-MATIC 18

TE-Matic shrink tunnel which can be used in combination with L-Sealers and EL-Matic machines.

The main features of the TE-MATIC tunnel are:

- Adjustable shrink tunnel temperature
- · Adjustable conveyor speed
- Tunnel air flow regulation by flaps
- Tunnel conveyor with silicone coated rotating rollers
- Control panel with back lighted LCD
- · Automatic cool down function for end of shift
- · Reduced power consumption
- · Rollers can be fixed for PE
- 6 working programs





# **TUBE SEALER**

Compact table top impulse sealer equipped with bi-active sealing bars; a moving thermo controlled impulse seal bar and a fixed heat seal bar (code seal prepared).

- Compact model
- Front loading machine
- Different tube length possible (for each different cap size a new tube holder is necessary)
- Preparation of code is integrated in the machine (for 4 or 6 tubes, different heat seal bar). Max. 10 characters possible per tube
- 9 storage programs
- Automatic adjustment of sealing pressure
- Electronic control of seal and cool time
- Option to add characters for code seal (max. 10 characters)



### **ROTARY MEDICAL SEALERS**



### CONTIMED D660 V

The D660V is a medical rotary sealer where temperature, pressure and speed can be validated according to ISO 11607-2. The various parameters can be exported to a PC or laptop via a USB stick. The sealer is suitable for sealing PE, PP, PA/PE, Tyvek® pouches and other laminate materials. The seals are made according to EN 868-5 and DIN 58953-7-2010.

#### CONTIMED D662 MV

Rotary medical sealer with complete control of all sealing parameters. Conforms to the validation requirements of ISO 11607-2 and its guidance ISO/TS 16775.

The process parameters can be recorded on a USB memory stick. The sealer can handle polypropylene/paper and laminated materials. The seals are made according to the requirements, and conforms to the sealing requirements of EN 868-5 and DIN 58953-7.



# CONTIMED D666 MPCV

The D 666 MPCV is our advanced medical rotary sealer for sealing and coding medical sterilization pouches. This sealer is developed to seal pouches and conforms to the sealing requirements of EN 868-5 and DIN 58953-7. Using a multi-line seal, seal pressure and an in-feed speed of 10m/min., this machine can be used for closing paper/polypropylene and medical pouches.

The built-in matrix printer can be used to print: date, operator name, batch number and codes, directly on the pouches. The D 666 MPCV can be used for validatable processes through constant monitoring of all seal parameters.

# CONTIMED D775 MPCV

Advanced medical rotary sealer for sealing and coding medical sterilization pouches. The machine is suitable for packing sterilized products and conforms to the sealing requirements of EN 868-5 and DIN 58953-7.

It represents the ultimate evolution of Audion production in the medical field, with adjustable speed, a 15 mm seam seal, wide color touch screen and data memory on board. Data from the whole sealing process can be shared ensuring full validation to the relevant standards. It has a built-in printer with 2 lines of print.



### **VALIDATION AND SUPPORT SERVICES**



#### **SEAL INTEGRITY TEST**

Would you like to know the integrity of your seal? Call our service department for SIT (seal integrity test) services.

Our experienced service engineer will visit your factory with calibrated measuring devices and test kits. Seal samples will be made with your sealer and material, and the following tests will be carried out.

- Seal check according to ISO 11607-2 (to check intact seal for a specified seal width)
- Dye penetration test according to ASTM F1929 (to check no channels or open seals)
- Peel test according to EN 868-5 Annex D (to check tensile strength of seal)

When the results are qualifying the requirements, a certificate will be issued accompanied by relevant documents.



#### **CALIBRATION SERVICES**

Would you like your sealing process to be validated conforming ISO 11607-2? Then your sealer must be calibrated.

Audion provides calibration services for our validatable sealers. The critical process parameters (seal temperature, seal force, seal time/speed, etc.) are measured with traceable measuring devices and a calibration certificate will be issued.

New sealers, as well as sealers already in use can be calibrated. For re-calibration, the sealers are requested to be returned to Audion. We first check the status of the sealer. If necessary, parts will be replaced, and/or the parameters will be fine-tuned. The sealer will then be calibrated.

If the sealer cannot be returned to Audion, call our service department to make an appointment for on-site calibration.

#### STANDARDS AND CERTIFICATES

Our equipment has been installed in various pharma/medical environments:

- GMP
- Cleanrooms
- MDR
- ISO 11607-2 & ISO/TS 16775
- EN 868-5 & DIN 58993

#### **VALIDATION SERVICES**

#### IQ/OQ SCRIPTS

Would you like your sealing process to be validated conforming ISO 11607-2? Or do you want to be sure that the sealer you are buying conforms the ISO requirements? Call our service department to make an appointment for IQ/OQ Scripts.

Our experienced service engineer will visit your factory with validation protocols, calibrated measuring devices and test kits.

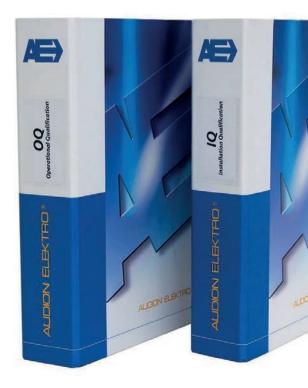
#### **Contents of IQ check:**

- · Check critical alarms and functions.
- Operation training for your operation staffs.
   Operation training certificates will be issued.
- Maintenance training for your service staffs.
   Maintenance training certificate will be issued.

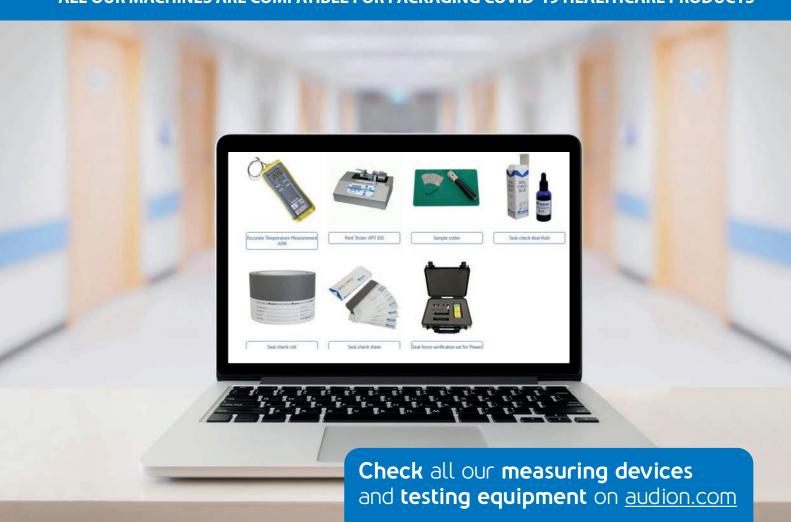
#### **Contents of IQ check:**

- · Verification of appropriate sealing parameters.
- Make seal samples at target parameters as well as at the worst-case conditions.
- Carry out seal integrity tests:
  - Seal check according to ISO 11607-2 (to check intact seal for a specified seal width)
  - Dye penetration test according to ASTM F1929 (to check no channels or open seals)
  - Peel test according to EN 868-5 Annex D (to check tensile strength of seal)

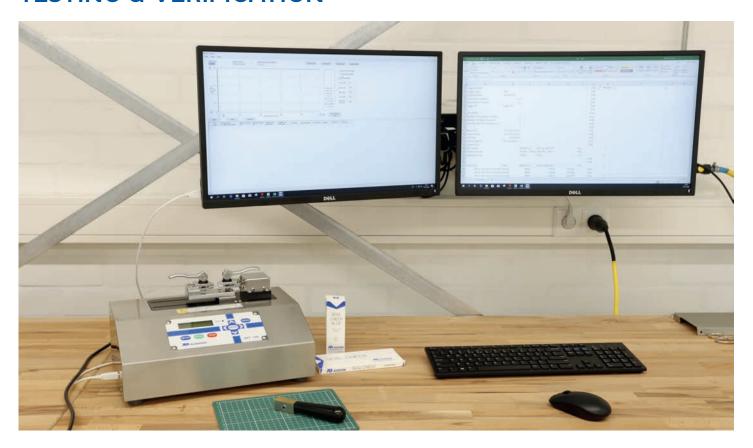
When all the checks and tests have qualified the requirements, certificate of IQ check and OQ check will be issued, accompanied by all relevant documents.



#### ALL OUR MACHINES ARE COMPATIBLE FOR PACKAGING COVID-19 HEALTHCARE PRODUCTS



# **TESTING & VERIFICATION**





# **PEELTESTER APT 100**

The APT 100 is a device for measuring tensile strength of seals made on medical bags.

The APT 100 is an instrument for measuring tensile strength of seals made on peelable bags, especially designed for testing (preformed) sterile barrier systems according to EN868-5 Annex D or ASTM F88.

The average strength is measured by discarding 10% on each side of the measuring curve. In case of a ribbed seal, the non-sealed areas including 10% on each side are excluded from the average calculation.

- Conforms to the requirements of EN868-5, Annex D.
- The test result is clearly presented on PC screen in colored graphic chart.
- Pass/fail judgment on average strength or maximum strength.
- Configurable judgment criteria.
- Also measures seal width according to your own definitions of seal strength.
- Peel test report with your own company logo.



A AUDION





# SEAL TEMPERATURE VERIFICATION INSTRUMENT

Accurate Temperature Measurement (ATM) in order to facilitate your validation process.

With this sophisticated device, you can measure the temperature between the sealing wires and calibrate the machine in accordance with the measured values. According to validation processes, the seal temperature needs to be calibated after changing a sealing wire in the machine.

With the Audion ATM device this will now be a very easy operation to do. The ATM can be used for our Medical Sealers and for the Validatable Power Sealers.

# SEAL FORCE VERIFICATION SET FOR POWER SEALER

To ensure the quality of your seal, we recommend to check the seal force regularly. Audion offers a complete seal force verification set, AFMR (Audion Force Measurement Ring) for your Power Sealer. Connect the Power Sealer's loadcell and the AFMR's ring type loadcell with the provided tools and apply force. The read-out value of the AFMR can be used for verification and/or calibration. Upon request, the AFMR can be calibrated with ISO 17025 accreditation.

#### Verification instruments for validatable vacuum chambers

 AVLM: Vacuum level verification instrument



• **ASPM:** Seal pressure verification instrument





# CALIBRATION



We have our own calibration room at our manufacturing and testing facility in Weesp, the Netherlands.

Providing calibration and machine services at our own facility. We not only offer the calibration package but utilizing your equipment time out of production we offer a full service and maintenance package on the units both prior to and post calibration. Audion now offer calibration on the critical process parameters (seal temperature, seal force, seal time/speed, etc.). We follow international standards using independently tested reference instruments.





**HEALTHCARE** 

MEDICAL

CHEMICAL

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