MEDICAL PACKAGING

→ **Impulse & vacuum**

→ **Rotary sealers**

→ **Heat sealer**

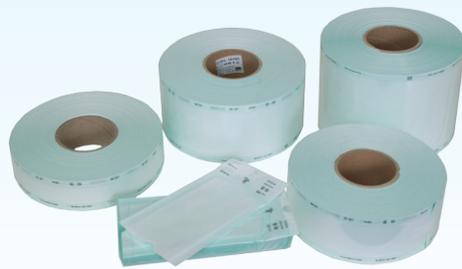→ **Packaging standards**

→ **Measuring devices**

AE> AUDION

Packaging machines

STERILE PACKAGING IN THE MEDICAL INDUSTRY

Healthcare is one of the most important fundamentals in our life; mankind is spending lots of money on a healthy lifestyle, health insurances and new developments, simply because good health is unaffordable.

Audion supplies several validatable sealers for the medical industry/healthcare. The machines have a strong price-quality ratio and are easy to work with. All machines are built according to the latest directives and create high quality seals. The different options and functions make Audion medical sealers suitable for a variety of medical packaging purposes.

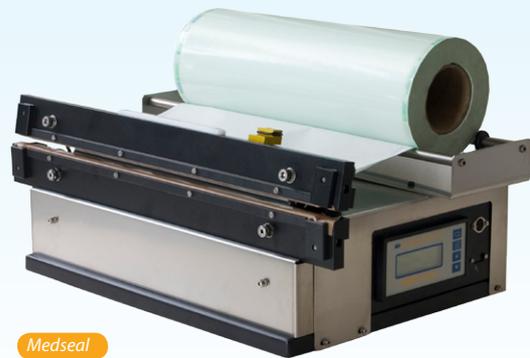In addition to the packaging machines, we can also supply equipment to support the validation process.

IMPULSE SEALERS & VACUUM PACKAGING

MEDSEAL and POWERSEALERS

Sealers for medical device & disposable manufacturers, for industries where precision and safety are of great importance.

MEDSEAL

Impulse sealing machines suitable for sealing sterilisation pouches (PE, PP/Paper, Paper/Paper).

Medical sterilisation pouches

Medseal

MEDSEAL

Model	460 MSIK	611 MSIK	460 MSIDK	611 MSIDK	460 MSIDVK	611 MSIDVK
Dimensions (LxWxH)	560 x 360 x 230 mm	710 x 360 x 230 mm	560 x 360 x 230 mm	710 x 360 x 230 mm	560 x 360 x 230 mm	710 x 360 x 230 mm
Power supply	230V-1Ph-50/60 Hz	230V-1Ph-50/60 Hz	230V-1Ph-50/60 Hz	230V-1Ph-50/60 Hz	230V-1Ph-50/60 Hz	230V-1Ph-50/60 Hz
Consumption	1700 W	2100 W	2100 W	2500 W	2100 W	2500 W
Seal length	460 mm	610 mm	460 mm	610 mm	460 mm	610 mm
Seal width	8 mm	8 mm	8 mm	8 mm	8 mm	8 mm
Weight	33 kg	40 kg	33 kg	40 kg	33 kg	40 kg
Single magnet closing	●	●	●	●	●	●
Possibility to heat only 1 seal bar	-	-	●	●	●	●
Bi-active seal bars	●	●	●	●	●	●
Electr. seal & cool time control	●	●	-	-	-	-
Digital seal temp/time control	-	-	●	●	●	●
Alarm function tolerance (+/- 5°C)	-	-	●	●	●	●
4 lines LCD	-	-	●	●	●	●
RS 232	-	-	-	-	●	●
Calibration report					option	option
ATM			option	option	option	option
Data software					option	option

Model	460 MSIK	611 MSIK	460 MSIDK	611 MSIDK	460 MSIDVK	611 MSIDVK
Directives			2004/108/EC + 2006/42/EC + 2006/95/EC			
Machine Standards	EN-IEC 60204-1 + EN-ISO 13857 + EN-ISO 12100		EN-IEC 61000-3.2 + EN-IEC 61000-3.3 + EN-IEC 60204-1 + EN-55014-1/a1 + EN-55014-2/a2 + EN-ISO 13857 + EN-ISO 12100			
Validation Standard (MSIDVK only)					EN-ISO 11607-2	

POWERSEALERS: IST MED & MAGVAC MED

Powersealers are heavy duty machines, suitable for large volumes as well as delicate products. Powersealers are available as standard sealer (IST MED) and with vacuum possibility (MAG-VAC MED). A support stand and different tables are optional to adjust the machine to the required working position

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Advantages

- Suitable for use in validated processes.
- Compact and heavy duty design
- Strong price-quality ratio
- User friendly digital panel
- MAGVAC can be used for vacuum packaging and modified atmosphere packaging (MAP)
- Bi-active sealing bars suitable for laminates and thick pouches
- Pneumatically closed sealing bars (no overheating of electro magnets)
- The Magvac and IST can be placed in horizontal and vertical sealing position in combination with a support
- Built according to the latest directives

IST MED

MAGVAC MED + support + worktable
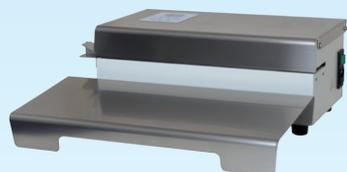
IST MED & MAGVAC MED

Model	520 IST MED	720 IST MED	1020 IST MED	520 MVMED	720 MVMED	1020 MVMED
Dimensions(LxWxH)	590x232x487 mm	790x232x487 mm	1110x232x487 mm	590x232x487 mm	790x232x487 mm	1110x232x487 mm
Power supply	230V-1Ph-50/60 Hz	230V-1Ph-50/60 Hz	230V-1Ph-50/60 Hz	230V-1Ph-50/60 Hz	230V-1Ph-50/60 Hz	230V-1Ph-50/60 Hz
Consumption	2500 W	3000 W	2600 W	2500 W	3000 W	2600 W
Seal length	520 mm	720 mm	1020 mm	520 mm	720 mm	1020 mm
Seal width	8 mm	8 mm	8 mm	8 mm	8 mm	8 mm
Film thickness	40-400 micron	40-400 micron	40-400 micron	40-400 micron	40-400 micron	40-400 micron
Gas flush option	-	-	-	●	●	●
Venturi pump	-	-	-	11,3 m^3/h	11,3 m^3/h	11,3 m^3/h
Air pressure	> 6 bar	> 6 bar	> 6 bar	>6 bar	> 6 bar	> 6 bar
Bi-active seal bars	●	●	●	●	●	●
Bag stretch unit	-	-	option	-	-	option
Validatable seal time/ seal temperature/ seal pressure	●	●	●	●	●	●
Digital seal temp/time control	●	●	●	●	●	●
Alarm function tolerance (+/- 5°C)	●	●	●	●	●	●
4 lines LCD	●	●	●	●	●	●
RS 232	●	●	●	●	●	●
Calibration report	option	option	option	option	option	option
ATM	option	option	option	option	option	option
Data software	option	option	option	option	option	option
BS PSR (Bag suport)	option	option	option	option	option	option
OT PSR (work table)	option	option	option	option	option	option
SP PSR (support stand)	option	option	option	option	option	option

Model	520 IST MED	720 IST MED	1020 IST MED	520 MVMED	720 MVMED	1020 MVMED
IP value	IP 20					
Directives	2006/42/EC + 2004/108/EC					
Machine Standards	EN 983+A1/ EN 1037 + A1/ EN-IEC 60204-1/EN-ISO 13850/ EN-ISO 12100					
Validation Standard	EN-ISO 11607-2					

MEDICAL ROTARY SEALERS

Contimed D662 MD, D665 MD, D665 MP, D666 MPCV, D770 MPCV & D775 MPCV

Advanced medical rotary sealers for sealing and coding medical sterilisation pouches.

Contimed D662 MD

Basic medical rotary sealer, perfect model when needing a high quality compact sealer for a modest budget.

Contimed D665 MD

Medical rotary sealer for medium to large production quantities for closing different types of non transparent sterilisation bags.

Contimed D665 MP

Medical rotary sealer with built-in matrix printer to print: date, operator name, serial number and codes on the pouches.

Contimed D666 MPCV

Advanced medical rotary sealer for validated processes through constant monitoring of all seal parameters and alarm/block functions when a parameter is out of range.

Contimed D770 MPCV

Full validatable medical rotary sealer for sealing and coding medical sterilisation pouches.

Contimed D775 MPCV

Audion's most advanced validatable touch screen medical rotary sealer with built-in matrix printer to print: date, operator name, serial number and codes on the pouches.

Model	D662 MD	D665 MD	D665 MP	D666 MPCV	D770 MPCV	D775 MPCV
Dimensions	430 x 230 x 182 mm	554 x 270 x 222 mm	554 x 270 x 222 mm	554 x 270 x 222 mm	621 x 300 x 330 mm	621x300x330mm
Weight	12,5 kg	16	18 kg	18,5 kg	26 kg	26 kg
Seal speed	6 m/min	10 m/min	10 m/min	10 m/min	10 m/min	Adjustable sealing speed 3-13 m/min
Seal width	12,5 mm multi-line	15 mm multi-line	15 mm multi-line	15 mm multi-line	15 mm multi-line	15 mm multi-line
Temperature range	10-195 ^{o}C	max. 200 ^{o}C	max. 200 ^{o}C	max. 200 ^{o}C	max. 200 ^{o}C	max. 200 ^{o}C
Temperature controller accuracy	+/-5 ^{o}C	+/- 1 %	+/- 1 %	+/- 1 %	+/- 1 %	+/- 1 %
Automatic in-feed block when temp changes > +/- 5 ^{o}C	-	●	●	●	●	●
Automatic in-feed block when speed changes > +5 % or -9 %	-	-	-	●	●	●
Automatic in-feed block when pressure changes > +25N or -15N	-	-	-	●	●	●
Alarm on temperature	●	●	●	●	●	●
Alarm on pressure and spreed	-	-	-	●	●	●
Internal matrix printer	-	-	● 9 dots	● 9 dots	● 18 dots, 2 lines	● 18 dots, 2 lines
Printed symbols according to the EN980 standard	-	-	-	●	●	●
LC display for parameter settings/programming	●	● 2 lines	● 2 lines	● 4 lines	● 4 lines	● touch screen
Stainless steel top cover plate (epoxy coated base)	●	●	●	●	●	●
Self adjusting pressure wheel adapts to different pouch thicknesses	●	●	●	●	●	●
Production date, different expiry periods, operator names, batch numbers, different counter functions programmable	-	-	●	●	●	●
Batch counter	-	●	●	●	●	●
External LAN connection Traceability	-	-	-	-	●	●
Internal clock, calendar function	-	-	●	●	●	●
Safety thermostat	●	●	●	●	●	●
Consumption	500 W	550 W	600 W	600 W	650 W	600W
Power	230V-1 ph-50/60 Hz	230V-1 ph-50/60 Hz	230V-1 ph-50/60 Hz	230V-1 ph-50/60 Hz	230V-1 ph-50/60 Hz	230V-1 ph-50/60 Hz
Options	D662 MD	D665 MD	D665 MP	D666 MPCV	D770 MPCV	D775 MPCV
Stainless steel support table	● (standard)	●	●	●	●	●
Stainless steel slip roller conveyor	●	●	●	●	●	●
Label printer (can also print bar codes)					●	
Thermo transfer printer (can be connected separately)						●

* All Audion rotary sealers are suitable for sealing laminated paper, laminated aluminium and tyvek pouches. Fully transparent pouches can not be sealed on these sealers.

HEAT SEALER

300 MHS - dental sealer

Compact table top medical heat sealer for sterile and hermetic packaging of medical tools without the risk of burning the packaging material. The 12 mm flat seal is ready in just 4 seconds, when the machine gives a light and acoustic signal.
The machine can accommodate a large selection of roll widths. The integrated work table gives extra comfort while working. The fixed filmreelholder makes it possible to use different roll sizes at the same time. The cut-off device enables the operator to create the required length of package. The heated top seal bar has a fixed temperature and gives a solid seal. All these futures make this heat sealer an excellent choice for a variety of services in the healthcare sector; from dental to veterinary practices.

Packing medical instruments

Specifications

Seal width:	12 mm flat
Seal length:	300 mm
Heating:	Single heated, fixed temperature
Knife:	Manual operated
Indicator:	2 colour led (red is error, green is ok)
Film reel holder:	Fixed /suitable for a large selection of film
Standards:	EN-ISO 12100, EN-IEC 60204-1,EN-1037+A1
Directives:	2006/95/EC, 2004-108-EC
Values:	IP 20, class 1
Power:	230V-1phase-50 Hz

MHS 300

STANDARDS IN THE MEDICAL PACKAGING INDUSTRY

Over the last years, different standards have been developed in this sector to ensure that the best available techniques are used on a high level when our health is involved.

The EN 868 is the most well-known standard when it comes to sterile packaging. All packaging materials and systems must comply with the restrictions given in Part 1. Part 2-10 relates to the requirements and test procedures for different packaging materials. These tests can be used to show that all requirements have been fulfilled.

The ISO 11607 standard; "Packaging for end-sterilized medical products" has already been used for several years at international level. The ISO committee decided in 2002 to combine both EN 868 - 1 and ISO 11607 in one new revision; this lead to the joint revision ISO 11607 part 1 and 2. Part 1 is about the requirements and test procedures for packaging materials, part 2 about the validation requirements of packaging processes.

According to this standard, all packaging processes must be able to be validated. Validation requires reproducible processes. As it comes to the sealing of pouches, the Audion sealers are very easy to validate; they operate automatic and can therefore produce the same seal time after time. The parameter controllers on these validatable sealers constantly monitor all critical parameters and block the machine when they are out of the acceptable bandwidth.

To guarantee the accordance with the machine specifications, our calibration service can be used; the sealer parameters are measured in an official laboratory. We supply an accredited calibration certificate to prove the accuracy of the sealer.

MEASURING DEVICES

APT-100

The APT 100 is a device for measuring tensile strength of seals made on medical bags. The APT 100 is designed to perform peel tests following the ASTM F88-00 as well as the EN868-5. The machine clamps a specimen and pulls the seal apart, measuring the tensile strength with load cell. The machine collects the data 100 times per second and displays the maximum seal strength.

By transferring the data to a PC, the complete test result will be presented in table and colored graphic chart. Besides the seal strength, the seal width can also be measured according to your own seal strength definition. The result can be printed out as peel test report for one of your validation processes.

To guarantee the accordance with the machine specifications, our calibration service can be used for the APT-100 We supply an accredited calibration certificate to prove the accuracy of the device.

Technical features & specifications

- Maximum measuring force: 100,0N
- Measuring unit: N, Kgf, Lbf
- Sampling rate: 100 data/sec.
- Increments: 0,1N
- Measuring accuracy: +/- 0,4% or full scale
- Data transfer interface: USB cable
- Operator/Administrator registration
- Measuring setting memory: 5
- Test data storage: 120
- Specimen thickness: 30 - 200 micron (per clamping layer)
- Power supply: AC 100 – 240V, 1 phase, 50/60 Hz.
- Power consumption: 9 W
- Machine size (WxDxH): 370 x270 x 200mm
- Machine weight: Approx. 8kg

Measuring settings & Judgment criteria

- Peel origin (starting position): 10 mm or 25 mm
- Peel speed: 200 mm/min. or 300 mm/min.
- Test end detection: Auto or manual
- Max. seal strength upper limit: 0,1 – 100,0N
- Max. seal strength lower limit: 0,0 – 99,9N
- Effective seal width: 6,0 mm
- Qualified seal width: 0 - 10,0 mm

APT-100

Peel test report

15mm wide sample cutter set

This is a special twin blade cutter for easily cutting out 15mm wide specimen for peel test. The blades are fixed on the sides of an anodized aluminum block. The sharp blades are covered by the plastic protection plate which prevents damaging the blades as well as injuring your fingers. To use the cutter, simply press the blades against the sealed material on the cutting mat.

Specifications

- Cutter
- 140 xx 228 mm cutting mat
- 10 spare blades
- Blade replacing tool

ATM

In order to facilitate your validation process, we developed the ATM. With this sophisticated device, you can measure the temperature between the sealing wires and calibrate the machine in accordance with the measured values. Accordingly to validation processes, the seal temperature needs to be calibrated after changing a sealing wire in the machine. With the Audion ATM device this will now be a very easy operation to do.

Specifications

- Digital display
- Standard calibration certificate included
- Hard carry case

ATM with carry case