

# VALIDATABLE MEDICAL HEAT SEALER

## MODELS TS-4V AND TS-4V-ISJ



**Testing Machines, Inc.** is proud to introduce the **TS-4V Medical Heat Sealer with validatable operation to meet ISO 11607-2**. This standard covers packaging for terminally sterilized medical devices with Part 2 specifying validation requirements for forming, sealing and assembly processes. This sealer comes in two models: **TS-4V Standard** and **TS-4V-ISJ** with Interchangeable Seal Jaws. The **TS-4V** is a precision heat sealer designed to produce accurate heat seals for peel strength measurement & testing of flexible packaging films, film foil laminates, non-woven materials and other substrates. The **TS-4V** also provides the capabilities of process validation.

The **TS-4V** produces accurate and consistent seals utilizing a precision load cell system which measures and displays the total force applied to the film sample. An integrated *Digital Electronic Controller* displays the sealing force. Load tare functionality and dual selectable timer activation set points are also standard.

The **TS-4V** process validation capabilities include Upper Temperature Validation Port, Lower Temperature Validation Port, Seal Dwell Timing Validation Port and Seal Cylinder Pressure Validation Port & Digital Pressure Gauge. These ports allow for meeting ISO and other standards that require the heat sealing process to be validated. External, certified and calibrated, instruments can be connected to the **TS-4V** to carry out the process validation.



*(above) Validation ports on the right side of the unit provide the critical data outputs required to maintain the validation process.*



### TS-4V Heat Sealer Standard Features

- Digitally Controlled Temperature
- Digitally Controlled Seal Dwell Time
- Digital Seal Pressure Output Display
- Independent Upper and Lower Sealing Temperatures
- Switch Selectable Dual Pressure Set Points for Timer Initiation
- (1) Upper Temperature Validation Port
- (1) Lower Temperature Validation Port
- (1) Seal Cylinder Pressure Validation Port w/ Digital Pressure Gauge
- (1) Seal Dwell Timing Validation Port
- Footswitch Operation
- Safety Guards and Switches for Safe Operation
- Maintenance Hardware Kit
- ASTM F2029 Standard Practices for Making Heatseals for the Determination of Heatsealability of Flexible Webs as Measured by Seal Strength
- Meets ISO 11607-2 Packaging for sterilized medical devices with validation.

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### COMPONENTS AND OPTIONS

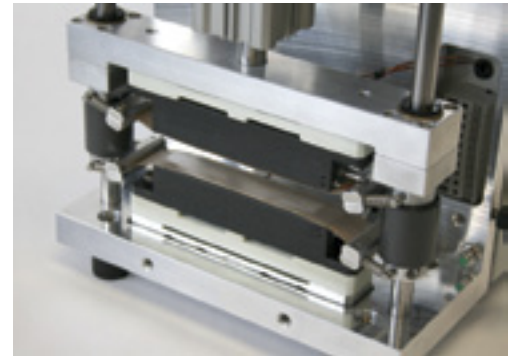
- **TS-4V Standard Model: Uses a 1-Piece Fixed Seal Design**
- **TS-4V-ISJ Model: Uses a Quick-Change Seal Jaw Insert Design**
- **Precision Seal Jaws and Seal Jaws Inserts with Desired Seal Pattern**
  - 1.0" [25.4mm] to 4.0" [101.6mm] Length of Seal
  - 0.25" [6.35mm] – 1.0" [25.4mm] Width of Seal
  - Flat, Vertical, Horizontal, Standard and Custom Geometry Forms Available
  - Standard and Special Coatings Available
  - Seal Jaws and Seal Jaw Inserts: *SOLD SEPARATELY*

### OPTIONAL ITEMS

- **Shelf Style Film Sample Tray**
  - Stationary 1 Piece Design
- **Manual Sliding Film Sample Tray**
  - Precision Bearing Guided Slide Table Design
  - Magnetic Film Sample Hold Down
  - Repeatable Film Sample Presentation
- **Digital Thermometer for Temperature Validation**
  - Calibration Documentation
  - Type "J" M-M Interconnect Cable
- **Digital Timer for Timing Validation**
  - Calibration Documentation
  - Interconnect Cable
- **Digital Pressure Gauge for Seal Cylinder Pressure Validation**
  - Calibration Documentation
  - Interconnect Line and Fitting
- **Lower Seal Temperature Control ON/OFF functionality**
- **Anti-Stick Mechanism**

The TS-4 Anti-Stick Mechanism provides an Anti-Stick sealing surface to the upper and lower seal surfaces. For use with Polyethylene materials, certain coated materials, or any other sealing applications where material sticking is an issue.

  - PTFE Coated Fiberglass Woven Cloth, .005" [.127mm] Thickness
  - Upper and Lower Seal Jaw Face Cover Straps
  - Spring Loaded Self-Tensioning Strap Mechanism
  - Easy Strap Replacement
- **Accessory Seal Jaws and Seal Jaw Inserts**
  - 1.0" [25.4mm] to 4.0" [101.6mm] Length of Seal
  - 0.25" [6.35mm] – 1.0" [25.4mm] Width of Seal
  - Flat, Vertical, Horizontal, Standard and Custom Geometry Forms Available
  - Standard and Special Coatings Available



(above) Optional Anti-Stick PTFE Fiberglass cloth saves time and eliminates film sticking to sealing jaws.



(above) All aspects of the process are controllable on the front panel using digital inputs and displays.

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### TECHNICAL SPECIFICATIONS

#### Sealing Temperature

Range Ambient - 205 °C [400 °F]  
Resolution 0.1 Degrees

#### Sealing Pressure

Range Minimum 9 kg [20 lb]  
Range Maximum 72.5 kg [160 lb]  
Resolution 0.1

#### Seal Dwell Time

Range Minimum 100ms  
Range Maximum 99s  
Resolution 10ms

#### Load Cell

Capacity 136 kg [300 lb]  
Accuracy 0.09 kg [0.2 lb]  
Repeatability 0.09 kg [0.2 lb]  
Calibration 5-Point Accredited Calibration

#### Seal Jaw Options

Length 25.4mm [1.0"] - 101.6mm [4.0"]  
Width 6.35mm [0.25"] - 25.4mm [1.0"]  
Seal Surface Flat, Vertical, Horizontal, Standard or Custom Geometry Forms Available

#### Machine Requirements

Power 110V to 240VAC 50/60Hz  
Air (clean, dry) 621KPa-827KPa [90PSI - 120PSI]  
689kPa [100PSI] Recommended

#### Physical Specifications

W x D x H 25.4 cm x 30.4 cm x 54.6 cm [10" x 12" x 21.5"]  
Weight 20.4 kg [45 lbs.] Approximate

#### Standards

ASTM ASTM F2029 Standard Practices for Making Heatseals for the Determination of Heatsealability of Flexible Webs as Measured by Seal Strength  
ISO ISO 11607-2 Packaging for sterilized medical devices with validation.

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