

# VALIDATION GUIDE

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Useful guide for Packworld USA Impulse Heat Sealers



*Perfect Seals ... Every Time*

**Packworld** USA  
With  **T.O.S.S. Technology**  
The Optimum Sealing System

## ACKNOWLEDGEMENTS

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This booklet was prepared by Packworld USA as an aid in the Validation process used in producing and assuring perfectly repeatable heat sealing cycles and more reliable packaging.

The contributions of the institutions and the individuals involved are appreciated and gratefully acknowledged. Mr. Ron Pilchik, principal of the Techmark Group, was a key contributor. His book, “Validating Medical Packaging”, cited in this guide, is an important reference in the validation of medical packaging design and process.

### **DISCLAIMER**

This documentation is for reference only and is not intended to replace good engineering practice and design necessary to apply equipment to a given process. The user is responsible for any and all consequences of the design and application of the equipment. In no manner is Packworld USA liable for any situation by use of this document.

For More Information Contact **Packworld USA**

Phone 610-746-2765 Fax 610-759-1766

Email: [info@packworldusa.com](mailto:info@packworldusa.com)

539 South Main Street Nazareth, PA 18064

[www.packworldusa.com](http://www.packworldusa.com)

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# Packworld USA Impulse Heat Sealer Validation Guide for Medical Packaging

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This guide will be useful to the user of Packworld USA Impulse Heat Sealers when employed in joining polymeric materials, primarily pouches and trays.

In the Impulse Heat Sealing mode, the heating cycle is synchronized with the rhythm of the machine. The optimum sealing process begins with a pre-heated sealing element that engages the work-piece at an accurately pre-set temperature and jaw pressure. This promotes the co-mingling of the sealing surfaces. It is then followed by a controlled cooling cycle, while still under jaw pressure, allowing the material to reformulate and regain its strength and appearance.

This technique assures a perfect seal, each and every time.

## What Is A Perfect Seal?

“Each manufacturer must ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration and damage during the customary conditions of processing, storage, handling, and distribution”

*- FDA Quality System Regulation 820.160*

This requirement is universal to medical packaging and is the basis for package process validation and verification.

**A perfect seal** is one that does not allow microorganisms to enter (no channel leaks or other seal defects that can allow entry) and remains so during the rigors of processing (especially sterilization), storage, handling and distribution. (Seal integrity)

**A perfect seal** must be strong enough to withstand the rigors of handling and transportation and yet provide for convenient opening at the point of use. (Seal strength)

**A perfect seal** must be continuous without any visual defects. Visual inspections should be augmented with physical tests to assure uniformity and continuity.

*Please refer to the following websites to gather details on currently available test methods: [www.ASTM.org](http://www.ASTM.org) and/or [www.FDA.gov](http://www.FDA.gov).*

*Searching for medical device test methods within either website will provide the necessary information concerning appropriate tests and test methods.*

The properties of seal strength and seal integrity must be evaluated independently and concurrently. It is only by assuring a perfect seal, every time that the sterility is not compromised.

## Impulse Heat Sealing

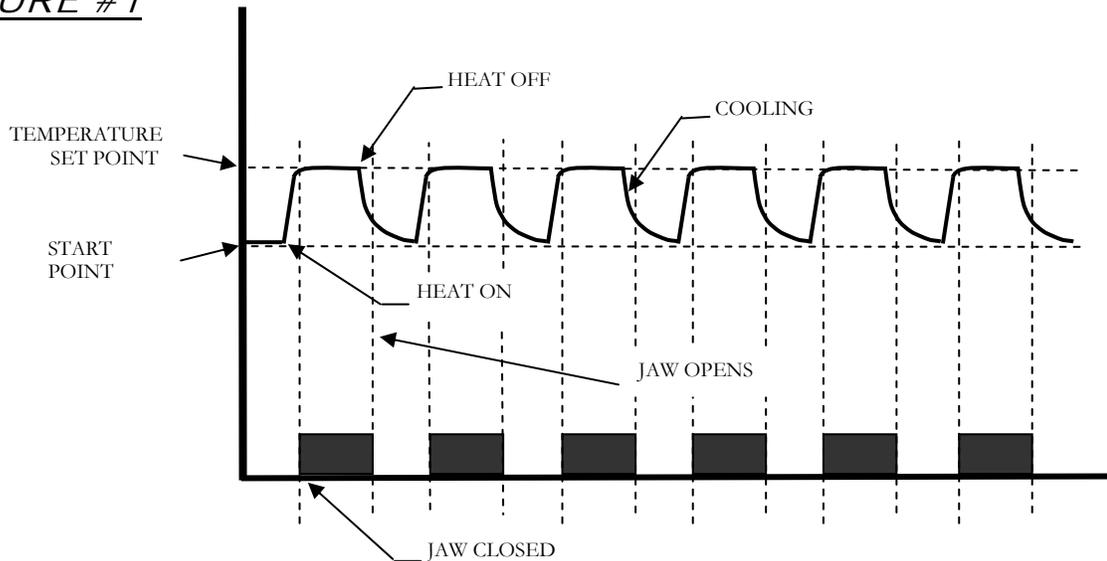
Impulse Heat Sealing is a methodology for assuring perfect seals. As stated above, the system heats the sealing materials under jaw pressure and maintains that pressure while the seal cools. There is no opportunity for the softened materials to shift or wrinkle outside of the jaws and provides for the seal completion under controlled pressure. **The actual sealing occurs when the materials cool together.**

Impulse Heat Sealing provides:

- Precise timing of both heating and cooling
- Precise sealing temperature control
- Accelerated temperature ramp up
- Rapid cooling
- Retention of the work piece during cooling
- Pressure control
- Contoured heating contact surface
- Temperature gradient across the heating element.

The Time/Temperature process is depicted as follows in a 6-cycle display:

FIGURE #1



Precise Time/Temperature controls are essential in the creation of consistent and repeatable seals. This can be achieved by the use of high response Temperature Controllers and Heatseal Bands that are certified to have consistent and repeatable performance characteristics.

# Calibration Certification of Temperature Controllers and Heatseal Bands

All Packworld Impulse Heat Sealers employ state of the art controllers that are calibrated and certified to an NIST traceable standard at the Packworld facility.

Packworld installed temperature controllers are designed to operate with high precision when used in concert with Alloy-20C Heatseal Band material. All controllers are 100% inspected and receive calibration certification before being released into production. Controllers are certified by heating a band to a set of predetermined temperatures in the range of 100° to 250°C. The temperature is measured at each data point utilizing NIST traceable instruments and recorded. The inspection procedure confirms that the Controller is accurately measuring the temperature of the Heatseal Band throughout its functional temperature range. The test results for each controller are then logged and maintained by Controller Model and Serial Number.

All Alloy 20C Heatseal Band material is certified by the source to conform chemically and physically to the Alloy 20C specification. In addition, each lot is tested for its performance characteristics.

Proper use of Alloy-20 Heatseal Bands depends upon an understanding of the nature of the bands. The simplest form of Alloy-20 Heatseal Band is the Taper Band. This band is essentially flat but the edges of the band have been tapered down to about one-third of the nominal thickness. The tapering process removes the otherwise sharp corner at the edge of the band. This minimizes the thinning of the plastic film along the edge of the seal that would otherwise weaken the film and cause "zipper" failures at the edge of the seal.

This is beneficial because a generous amount of heat and force is delivered in the area closer to the center of the seal area and both heat and force are moderated at the edges thereby minimizing the thinning effect at the edge of the seal and preserving the strength and integrity of the package.

**It is recommended that controllers be sent back to the factory annually for calibration certification.**

Calibration of temperature is accomplished in **4 Steps** by following the **Temperature Validation Guide** (Appendix – Temperature Validation)

Verifying time of the RES heat seal controllers – **Timer Accuracy Publication** (Appendix – Timer Accuracy)

## Maintenance of Packworld Impulse Heat Sealers

All Packworld Impulse Heat sealers require very little maintenance. See maintenance instructions in the owner's manual and ***Frequently Asked Questions*** (Appendix PWFAQ).

The controller is virtually maintenance-free. Besides keeping the faceplate clean and all electrical connections tight, the controller needs no maintenance. A yearly calibration service is available for customers who wish to maintain records of sealing operations for purposes of validation.

## Operator Training

It is essential that all personnel assigned to the equipment be trained in the principles, operations, set-ups, maintenance and evaluation of outputs to assure that a full understanding of the process exists in all involved staff. In so doing, the likelihood of issues will be minimized, or fully eliminated. This training must be undertaken utilizing controlled training techniques and successful completion of the training is documented and filed in an appropriate manner.

## Qualification of Packworld Impulse Heat Sealers

Qualification of the equipment to produce “perfect seals” is a formal process that is well documented in industry guidance documents (*ISO 11607*). There are three levels of qualification that need to be evaluated.

### Installation Qualification

Installation Qualification (IQ) is defined as the establishment of the fact that all key elements of the installation adhere to the manufacturer's recommendations.

Each Packworld owner's manual details the appropriate method of installation, the defined environment for placement of the equipment and the required services.

Packworld must be contacted if these recommendations cannot be implemented as defined. Any modified recommendations must then be adhered to. These modifications must be in written form and added to the IQ documentation.

The IQ is best accomplished with the establishment and completion of a checklist signed by the installer and countersigned by an overseer.

## Operational Qualification

Operational Qualification (OQ) answers questions about the equipment operating properly.

Examples of proper operation include the heating elements reaching and maintaining temperature set points, accuracy of timing sequences, and alarms, if installed, reacting properly to out-of-range measurements or unsafe conditions.

While it is desirable to make individual empirical measurements of critical parameters to assure operational integrity, the alternative of evaluating seal quality is a valid means of assurance. Employing output analysis, the evaluation of seals produced at a pre-determined set of operating conditions, is efficient and economical and provides, in many instances, more valuable data than empirical measurements.

## Process Qualification - (See Appendix One)

Process qualification (PQ) is defined as the means to determine the process parameter settings that will produce perfect seals. This is often referred to as a Process Capability Study. This study establishes the process limits, for the particular package under test.

The suggested test protocol found in **Appendix One** can be employed to develop the process limits.

In the protocol, initial set points are utilized and bracketed on either side by an amount that will still produce perfect seals. The initial set points are usually those suggested by the pouch supplier and are derived from set points employed at their location to seal the sides and top of a similar pouch.

The ranges are expanded or contracted based on test results until acceptable limits are reached. This is referred to as the *process window*. After the process window is established, sealing is accomplished by setting the equipment up at the midpoint of the window. Confidence that perfect seals can be produced any where within the established range is assured. This range of settings allows for any unanticipated drift within the equipment, environment, or irregularities in the packaging materials.

## Process Validation

Process validation is considered to be a total process that includes written protocols, evidence that the equipment as installed meets design criteria and specifications (IQ), use of calibrated instrumentation to collect data, and evidence that the equipment can deliver the desired outcomes with predetermined tolerances under established operating

conditions (OQ) and is reproducible as demonstrated by replicate runs and process challenges (PQ).

*-Abstracted from ISO 11607-2000*

Validation is formally defined as: “establishing documented evidence which provides a high degree of assurance that a specific process i.e. sealing, will consistently produce a product, i.e. a seal, meeting its predetermined specifications and quality attributes”.

*-from: “Validating Medical Packaging, Ronald Pilchik, CRC Press*

The validation system employs IQ, OQ and PQ as described above and combines these with process trials at preset operating settings. Replicates are undertaken and data collected and analyzed to determine the consistency between trial runs and conformance to predetermined specifications and attributes, primarily seal strength and seal integrity.

After satisfactory completion of the trials, data is compiled and incorporated with the IQ, OQ, PQ, calibration data, maintenance records and personnel training records into a permanent file.

This completed file represents the information that supports the assertion that the package sealing process is reproducible over replicate runs and that there is a high degree of assurance that the process will continue to perform so over extended time.

Packworld further recommends the employment of continuing “verification” activities; that is, setting up the equipment and testing seals at the onset of every production lot to comply with predetermined standards. Further, it is always good practice to evaluate seals periodically during the course of operation.

Packworld trusts that this guide will simplify the validation process in support of its line of Impulse Heat Sealers.

# Process Qualification for the Packworld USA Impulse Sealer

## 1.0 Objective

This protocol was developed to verify and document that a Packworld Impulse Sealer can consistently produce an acceptable seal.

## 2.0 Background

The impulse sealer has been designed to produce seals for sterilization pouches, for medical packaging applications. It is compatible with a wide range of heat sealable pouch materials. With impulse sealing, the heating cycle is synchronized with the rhythm of the machine.

The optimum sealing process begins with a heated sealing element that engages the work-piece at an accurately set temperature and jaw pressure. This promotes the comingling of the sealing surfaces.

It is then followed by a controlled cooling cycle, under jaw pressure while the material regains its strength and appearance during reformation.

Cooling the seal between the jaws prevents shifting of the incomplete seal by retaining pressure until the seal is set.

## 3.0 Procedure

3.1.1 Turn the impulse sealer on and allow it to achieve start up conditions.

3.1.2 Set aside 90 pouches for seal studies.

3.1.3 Separate the pouches into three groups of thirty.

3.1.4 Label 30 “low”

3.1.5 Label 30 “nominal”

3.1.6 Label 30 “high”

3.1.7 Seal each of the groups of 30 pouches employing a table similar to the table below. The specific parameters will depend upon the material(s) being sealed. Example: Poly/Tyvek might be as shown below:

<i>Group</i>	<i>Low</i>	<i>Nominal</i>	<i>High</i>
<i>Seal Temperature (ST)</i>	115°C	120°C	130°C
<i>Sealing Time</i>	1.5s	2s	3s
<i>Cooling Temperature</i>	80% of ST	70% of ST	60% of ST

Note: Sealing parameters are based on empirical data obtained from the pouch fabricator and modified as required by preliminary seal studies to determine low, nominal and high ranges. The above table utilizes parameters as examples. It is not suggested that these are the “only” or “usual” starting points.

*The objective of this activity is to establish a wide “sealing window” so that acceptable sealing will still be accomplished if random variations occur in the materials or process. If the results obtained at the limits in the proposed matrix are not acceptable, adjust the parameters until successful seals are produced.*

*The range of adjustment is critical to successful sealing during routine operations. There is no need to establish “failure” settings, only to define as wide a range of settings that will produce acceptable seals.*

*Record these ranges as the “sealing window”.*

3.2 Visually inspect all seals for damage, appearance defects and channels.

Note: ASTM has suggested a test method: ASTM F1886 to be employed to perform this inspection.

3.3 Perform a seal strength test on the sealed pouches from each group. ASTM burst test F1140 is recommended. Record the burst values.

## 4.0 Acceptance Criteria

4.1 All seals must visually pass for damage, appearance defects and channels.

4.2 All pouches must burst on the side seals (those produced by the pouch fabricator) rather than the end seal (produced by the impulse sealer). Record the burst values of each pouch.

4.3 All three groups of sealed pouches must produce acceptable seals.

Note: An acceptable seal is defined as one that will remain intact during the usual conditions of sterilization, transportation, distribution and storage. The way to determine this value is to perform package design validation. Information on the means for performing package design validation is available.

## 5.0 Final Report

At the completion of the study, a final report will be written including all of the data collected. A statement of the acceptability or unacceptability will be included. All recorded burst values should be tabulated and a calculation of Standard Deviation (S.D.) should be performed. It is recommended that burst values have an S.D. that shows a consistency of values within a set of 30 pouches and of values between sets. The acceptable S.D. is developed on a case-by-case basis and is representative of the consistency of the process and the needs of the package.

All deviations will be documented in the final report. These deviations will be evaluated to determine the overall adequacy of the study or if repetition is warranted.

# Temperature Calibration for a Packworld USA machine (A-1)

## Required instruments:

An NIST Traceable Thermocouple Thermometer and a Thermocouple.

## A Suggested Unit:

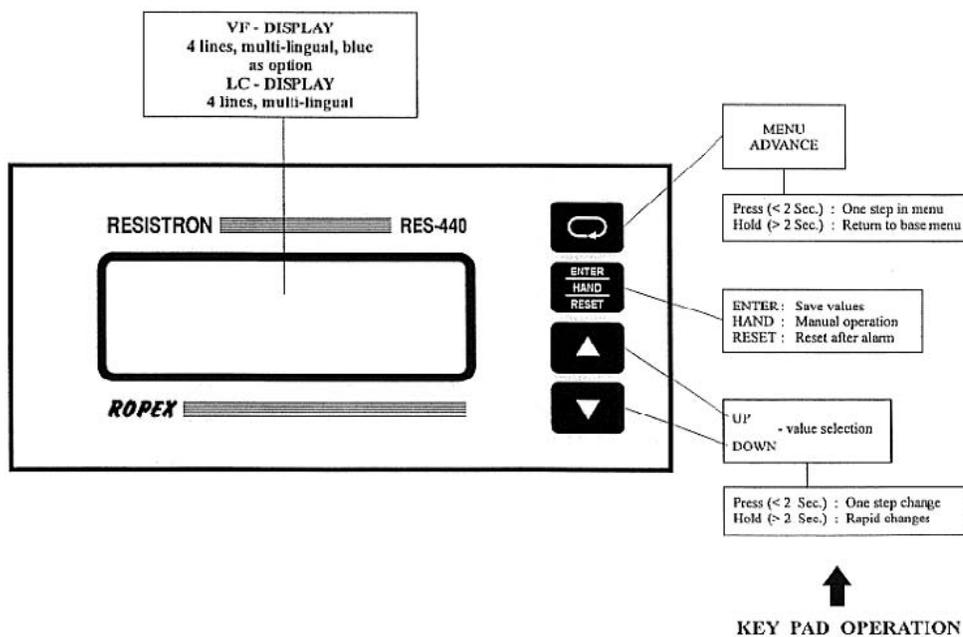
Omega Series 870 Thermocouple Thermometer Model# 871A

Omega “Cement-On” “K” Type Thermocouple Model# CO1-K

Throughout this document you will be instructed to make settings changes on the TOSS RES Temperature Controller. Before getting started it is important to familiarize yourself with navigating the temperature controller.

The TOSS RES Temperature Controller has been designed to make navigation simple and easy. Pressing and releasing the “Menu Advance” key allows the user to navigate the various menus found on the RES controller. The “Up” and “Down” arrows are used to change the settings while the “Enter” key is used to accept and store the user’s desired settings.

**Figure #1**



Packworld USA heat sealing machines come equipped with the heat seal band configuration required for each customer’s specific application. To validate the temperature of a Packworld USA heat sealer, the following steps should be followed:

## **STEP #1 – Machine Start-Up**

- a) Plug machine into appropriate outlet (i.e. 115V/20amp or 220V/20amp). b) Connect air supply to “Air In” port located on the back of the machine. (This is for pneumatically operated machines only) c) Make sure circuit breaker found on the back of the machine is ON. (This is for pneumatically operated machines only) d) Make sure the “E Stop” is released (in the out position). (This is for pneumatically operated machines only) e) Turn on machine.

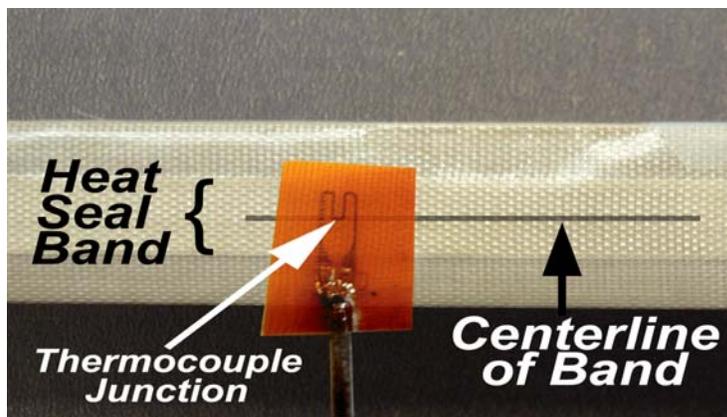
**The TOSS RES Heatseal Controller opening screen will look similar to the following:**

**Picture #1**



- f) Position the thermocouple so that its electrical junction rests directly over the centerline of the heatseal band. Adhere the thermocouple to this point with thin mil Kapton tape. (See Picture #2)

**Picture #2**



- g) Turn on the NIST Traceable Thermocouple Thermometer, read and record the ambient temperature displayed on the reader.

- h) Compare the ambient temperature reading to the “Act” (actual) temperature displayed on the TOSS RES controller. (“Act” temperature can be found in the upper right hand corner of the display – see Picture #1)
- i) If ambient temperature matches the “Act” temperature proceed to Step #2.
- j) If ambient temperature is different than “Act”, an auto-calibration must be performed at ambient temperature.
- k) To perform auto-calibration at ambient temperature, press and release the “Menu Advance” key found on the RES controller until you reach the “Settings 107 AUTOCAL” screen. (See – Picture #3)

Picture #3



- l) Using the “Up” and/or “Down” arrows keys on the controller, change the “AUTOCAL to” temperature until it matches your ambient temperature reading as displayed on your thermocouple thermometer, then press the “Enter” key to run the ambient temperature auto-calibration function.
- m) Immediately following the end of the “AUTOCAL” function, the RES controller screen will flash a “Setting 108 – Start AUTOCOMP?” command. Press the “Enter” key to perform this operation. **Note: The “AUTOCOMP” command is only displayed for a couple of seconds at the end of the “AUTOCAL” function. The “Enter” key MUST be pressed during that time to successfully execute the “AUTOCOMP”.** (See – Picture #4)

Picture #4



- n) Once complete, the RES controller will return to the main menu screen. The “Act” temperature will stabilize and should then match the ambient reading displayed on the NIST Traceable Temperature Reader. **Note: “Act” temperature may fluctuate +/- 1° from ambient. This is caused by small energy pulses being delivered to the heat seal band which enables the controller to read the heat seal bands actual temperature.**

o) Connect the foot pedal plug to the appropriate outlet found on the back of the machine.

**The Packworld USA Impulse Heat Sealing machine is now ready to begin Temperature Validation.**

**STEP #2 – Temperature Validation**

a) Leaving the thermocouple in place, press and release the “Menu Advance” key once to arrive at the “Setting 101” screen (Sealing Temp). Using the “Up/Down” arrows, set the sealing temperature to 150°C and press “Enter” to save. (see – Picture #5)

**Picture #5**



b) Press and release the “Menu Advance” key until you arrive at “Setting 104” screen (Sealing Time). Using the “Up/Down” arrows, set the sealing time to 10 Seconds and press “Enter” to save. (see – Picture #6)

**Picture #6**



c) Press and release the “Menu Advance” key until you arrive at the “Setting 105” screen (Cooling Temp). Using the “Up/Down” arrows, set the cooling temperature to 50°C and press “Enter” to save. (see – Picture #7)

**Picture #7**



d) Press and release the “Menu Advance” key until you arrive back at the opening screen. (see – Picture #1)

- e) Leaving the thermocouple in place begin a sealing cycle by pressing down on the foot pedal.
- f) Allow the NIST Traceable Thermocouple Thermometer to settle (approximately 8 to 10 seconds) and observe its temperature reading. If the NIST reader is showing a temperature of 150°C (+/- 1°C) then proceed to Step #4.
- g) If the NIST reader shows a temperature other than the 150°C set point (+/- 1°C), a system calibration must be performed. Proceed to Step #3.

**STEP #3 – Calibrating the System**

- a) While at the open screen, press the “Menu Advance” key down and hold for three seconds until the “Configuration 201” screen (Language) appears. (see – Picture #8)

**Picture #8**



- b) Press and release the “Menu Advance” key until you arrive at the “Configuration 203” screen (Temperature coefficient). Using the “Up/Down” arrows, set the Temperature coefficient to “variable” and press “Enter” to save. (see – Picture #9)

**Picture #9**



- c) Press and release the “Menu Advance” key once to arrive at the “Configuration 204” screen (Temperature coefficient). (see – Picture #10)

**Picture #10**



- d) Adjusting the “ppm” setting in this screen allows you to calibrate the system to the NIST Traceable Thermocouple Thermometer. A 10 point reduction to the “ppm”

setting will reduce the controlled temperature by approximately 1°- 2°C degrees. Conversely, a 10 point increase to the “ppm” setting will increase the controlled temperature by approximately 1°- 2°C degrees. Based on your temperature reading at the 150°C set point, change the “ppm” setting accordingly. Press the “Down” arrow key to reduce the ppm setting followed by the “Enter” key to save the setting or press the “Up” arrow key to increase the “ppm” setting followed by the “Enter” key to save the setting.

e) Press and release the “Menu Advance” key until you arrive back at the opening screen. (see – Picture #1)

f) Leaving the thermocouple in place, begin a sealing cycle by pressing down on the foot pedal.

g) Once again, allow the NIST Traceable Thermocouple Thermometer to settle (approximately 8 to 10 seconds) and observe its temperature reading. If the NIST reader is showing a temperature of 150°C (+/- 1°C) then proceed to Step #4. If the NIST reader still shows a temperature other than the 150°C set point (+/- 1°C), continue to make adjustments to the “ppm” per the above procedures until the NIST temperature reading equals the 150°C set point.

Once this calibration is complete it is now time to continue validating the heat seal temperature at various temperature points ranging from 100°C to 200°C.

#### **STEP #4 – Temperature Validation**

a) Leaving the thermocouple in place, press and release the “Menu Advance” key until you return to the opening screen.

b) Press and release the “Menu Advance” key once to arrive at the “Setting 101” screen (Sealing Temp). Using the “Up/Down” arrows, set the sealing temperature to 100°C and press “Enter” to save.

c) Press and release the “Menu Advance” key until you arrive back at the opening screen. **Note: Leave Sealing Time set to 10 seconds and Cooling Temperature set to 50°C.** Activate the foot pedal to cycle the machine. Read and record NIST Traceable temperature.

d) Press and release the “Menu Advance” key once to arrive at the “Setting 101” screen (Sealing Temp). Using the “Up/Down” arrows, set the sealing temperature to 150°C and press “Enter” to save.

e) Press and release the “Menu Advance” key until you arrive back at the opening screen. Activate the foot pedal to cycle the machine. Read and record NIST Traceable temperature.

f) Continue following Step #4 as you work your way thru testing at temperatures up to 200°C.

## Verifying timer accuracy of RES Heat Seal Controllers used in PackworldUSA Ltd. Heat sealers (A-2)

### **Objectives**

Verify the accuracy of the timing function of Ropex 400 Series Heat Seal Temperature Controllers used in Packworld USA Ltd. heat sealing machines.

### **Scope**

This procedure applies to the RES Heat Seal Temperature Controllers that have timing functions. As of 10/06, this includes the RES-440 and RES-445 Model Controllers

### **Device & Materials required**

Laurel Electronics, Inc. Timer – Model# L6000FR

Cable with a DIN-8 Plug for connection to DIN-8 receptacle on the rear of the heat sealing machine. A suitable cable, p/n 172-0008 is available from Mouser Electronics. ([See Attached](#))

Connect the DIN-8 cable to the timer so that the opening of a contact on pins 1 and 4 of the cable triggers the timer. The timer should stop timing when the contact closes. Make sure that all of the unused wires of the cable are separately insulated and terminated.

### **Procedure**

1. Connect the heat sealer to electrical and air sources and turn the power to the machine on.
2. Connect the Timer to an electrical source to power up timer.
3. Plug the DIN-8 plug coming from the timer into the DIN-8 receptacle on the back of the heat sealer.
4. Hold the scroll key down on the machine's RES temperature controller for several seconds until you reach the "Configuration" menu.
5. Advance through the menu by pressing and releasing the scroll key until you reach "Configuration 202 – Factory Settings:"

6. Press the Up/Down arrows to set “Save Custom Settings” and press Enter twice to save.
7. Advance through the menu until you reach “Configuration 210 – Cool Mode”.
8. Press the Up/Down arrows to set Cool Mode to “Time”.
9. Advance through the menu until you reach “Configuration 211 – Sealing Time Starts”.
10. Press the Up/Down arrows to set “Sealing Time Starts at Start Heating” and press Enter.
11. Advance to “Configuration 212 – Relay K1:” and Press the Up/Down arrows to set “Switches with Start Signal” and press Enter.
12. Advance to “Configuration 217 – Temperature Diagnosis:” and Press the Up/Down arrows to set “Off” and press Enter.
13. Advance to “Configuration 222 – Output 1:” and Press the Up/Down arrows to set “Switches with Start Signal” and press Enter.
14. Advance all the way through “Configuration” screens back to the main screen.
15. Press and release the scroll key to arrive at “Setting 104 – Sealing Time” and press the Up/Down arrows to set sealing time to 0.5 seconds and press Enter.
16. Press and release the scroll key to arrive at “Setting 105 – Cooling Time” and press the Up/Down arrows to set sealing time to 0.0 seconds and press Enter.
17. Step on the foot pedal to activate a cycle.
18. Record value found on NIST calibrated stopwatch.
19. Repeat steps 15, 16, 17, & 18 at time setting of 2 Seconds, 5 Seconds, and 10 Seconds. (Other time settings can be tested if one desires)
20. Once Time testing is concluded be sure to recall custom setting by holding the scroll key down for several seconds to return to the “Configuration” menu.
21. Advance through the menu by pressing and releasing the scroll key until you reach “Configuration 202 – Factory Settings:”

22. Press the Up/Down arrows to set “Recall Custom Settings” and press Enter twice to save.
23. Advance all the way through “Configuration” screens back to the main screen.

## Seal Pressure Calibration Procedures (A-3)

1. Remove the plug from the “air pressure” calibration port found on the back of the machine.
2. Connect an NIST calibrated Air Pressure Gauge to the “air pressure” calibration port.
3. Plug machine into appropriate outlet (i.e. 115V/20amp or 220V/20amp).
4. Connect air supply to “Air In” port located on the back of the machine.
5. Make sure circuit breaker found on the back of the machine is ON.
6. Make sure the “E Stop” is released (in the out position).
7. Turn on machine.
8. Increase the machines sealing pressure gauge to 20, 40, 60, 80, & 95 psi and at each value, read and record the pressure reading as indicated on the NIST calibrated air pressure gauge.
9. Turn machine off.
10. Remove air supply from machine.
11. Remove NIST air pressure gauge from calibration port and replace the plug.

### Acceptance

The performance of the gauge on the machine is deemed acceptable if the gauge values are within the following tolerances:

- For 0 – 100 psi Dial gauges, tolerance is  $\pm 3$  psi
- For 0 – 100 psi Digital gauges, tolerance is  $\pm 2$  psi

## RES CONTROLLER TEMPERATURE ALARM ACTIVATION (A-4)

### **Low Temperature Alarm Test:**

Hold the scroll key down for several seconds until you reach the “Configuration” menu.

Advance through the menu by pressing and releasing the scroll key until you reach “Configuration 202 – Factory Settings:”

Press the Up/Down arrows to set “Save Custom Settings” and press Enter twice to save.

Advance through the menu until you reach “Configuration 211 – Sealing Time Starts”.

Press the Up/Down arrows to set “Sealing Time Starts at Start Heating” and press Enter.

Advance to “Configuration 217 – Temperature Diagnosis:” and Press the Up/Down arrows to set “On” and press Enter.

Advance to “Configuration 218 – Time Delay for Temperature Diagnosis:” and Press the Up/Down arrows to set “0.0” and press Enter.

Advance all the way through “Configuration” screens back to the main screen.

Press and release the scroll key to arrive at “Setting 101 – Sealing Temp.” and press the Up/Down arrows to set sealing temperature to 240°C and press Enter.

Advance to “Setting 104 – Sealing Time” and press the Up/Down arrows to set sealing time to 0.1 seconds and press Enter.

Advance all the way through “Settings” screens back to the main screen.

Step on the foot pedal to activate a cycle.

The maximum temperature attained in 0.1 seconds will be less than the set point therefore activating the Low Temperature Alarm. The RES Alarm light will illuminate and the controller will read:

### **ALARM**

**Error: Seal Wire Error Code: 309 “Sealing Temperature to Low”**

Press and release the Enter key to reset machine.

Hold the scroll key down for several seconds to return to the “Configuration” menu.

Advance through the menu by pressing and releasing the scroll key until you reach “Configuration 202 – Factory Settings:”

Press the Up/Down arrows to set “Recall Custom Settings” and press Enter twice to save.

Advance all the way through “Configuration” screens back to the main screen.

### **High Temperature Alarm Test:**

#### **Materials needed:**

2” Strip of Alloy 20 Heatseal Band 10mm x .10mm  
20 gage wire – 12” long with Insulated Alligator clips on both ends  
1 mil Kapton tape

Testing for the High Temperature Alarm is a little more complicated. The resistance of the band will be greater at higher temperatures; therefore, we must simulate “High Temperature” by introducing additional resistance when the temperature of the heatseal band has already reached the set point.

The first step is to effectively shorten the heatseal band by using a thin Alloy 20 shunt that is taped perpendicular to the heatseal band using Kapton tape at a point about 3” past the copper heat-sink on either end of the heatseal band. Using the 20 gage wire with insulated alligator clips attached to both ends, connect one clip to the shunt and the other clip to one of the contact screws found on the nearest jaw end block.

With the shunt and alligator clips in place run the **AUTOCAL**. This will reduce the initial resistance that will be measured by the controller.

With the shunt and alligator clips in place, set the sealing temperature of the controller to about 100°C with 5.0 seconds heating time, and activate the machine.

When the temperature reaches 100°C, remove the alligator clip from the contact screw on the jaw end block. (Before the sealing cycle times out)

Removing the clip will simulate “High Temperature” by introducing additional resistance to the circuit. The RES Alarm light will illuminate and the controller will read:

### **ALARM**

**Error: Seal Wire Error Code: 308 “Sealing Temperature to High”**

**Packworld USA**  
**539 South Main Street**  
**Nazareth, PA 18064**  
**610-746-2765**  
**610-759-1766**  
**[www.packworldusa.com](http://www.packworldusa.com)**  
**email: [info@packworldusa.com](mailto:info@packworldusa.com)**