



Vante®

**INSTRUCTION
MANUAL**

MODEL 4600

RF Tube Sealer Power Source

This page intentionally left blank.

Vante[®]

3480 E. Britannia Dr., Suite 120
Tucson, AZ 85706 USA

Telephone (520) 881-6555
Fax (520) 323-9055
Toll Free (877) 565-5557

Part No. 46000810-01 Rev. D

This page intentionally left blank

Preliminary Information

Document Scope

This manual is intended as a guide for the operation, care and maintenance of the Vante Model 4600 RF Tube Sealer Power Source (hereinafter referred to as “the Power Source”). The information contained herein is based upon technical data that has been validated by Vante and is believed to be appropriate for the intended use of the product.

Intended Audience

This manual is intended for use by personnel having technical skills and a thorough understanding of the procedures for using radio frequency (RF) power to seal, form and/or weld RF reactive thermoplastic materials who understand that this product is to be used at their own discretion and risk.

Application

The Model 4600 RF Power Source is a part of a system and cannot be used independently. When used in conjunction with Model 4605 & 4105 sealings heads it is the Power Source used to make seals on tubing made of RF-reactive thermoplastic materials typically used in biopharmaceutical manufacturing. Tubing utilized in the manufacture of biopharmaceuticals is typically made from thermoplastic vinyl, namely polyvinylchloride (PVC) and ethyl vinyl acetate (EVA), this device has been tested and it is intended to be used with PVC tubing only.

Exclusions and Limits of Liability

Vante makes no warranties, expressed or implied, and assumes no liability in connection with any use of this information. If the Power Source or its related procedures are used for purposes other than those stipulated herein, validation of the specific application should be obtained, otherwise Vante assumes no liability or obligation nor guarantees product performance. Personnel using the Power Source do so at their own discretion and risk.

Vante shall have no liability for consequential, incidental, or exemplary damages of any description in connection with the products.

Proprietary Information

All rights are reserved. Copying of the protected designs associated with the Model 4600 Power Source is strictly prohibited without the prior written consent of Vante.

User Alerts

Throughout this document WARNINGS, CAUTIONS and NOTES are employed to notify the user of important and/or critical information.

WARNING: A Warning indicates a condition or procedure that could result in improper tube sealing or possible injury to the user. A Warning is enclosed with a bold-line box.

CAUTION: A Caution indicates a condition or procedure that could result in damage to the unit. A Caution is enclosed with a single-line box.

NOTE: A Note indicates important and/or useful information.

Safety Symbols

 Caution, risk of electric shock

 Caution

 Protective Earth (P.E.)

 Caution, Hot Surface

 Fuse

| On

○ Off

 WEEE – Indicates electronic equipment requiring proper recycling (EU only)

Regulatory Compliance Information

The Model 4600 RF Tube Sealer meets following directives:

- Electromagnetic Compatibility Directive – 89/336/EEC
- Low Voltage Directive – 73/23/EEC (as amended by 93/66/EEC)

Conformity Assessment Body: TUV SUD America.

For inquiries related to the CE marking of this product, please contact Vante at 3480 E. Britannia Dr., Suite 120 Tucson, Arizona 85706 U.S.A. +1-520-881-6555, +1-520-323-9055 (fax).

This page intentionally left blank

Table of Contents

Preliminary Information.....	v
Document Scope	v
Intended Audience	v
Application.....	v
Exclusions and Limits of Liability.....	v
Proprietary Information	vi
User Alerts	vi
Safety Symbols	vi
Regulatory Compliance Information	vii
Table of Contents	ix
Table of Figures	x
Table of Tables	xi
1. Power Source Description.....	1
1.1 Product Overview	1
1.2 Theory of Operation.....	1
1.3 Component Identification	2
1.4 Operating Environment.....	5
1.5 Tubing Specifications	5
1.6 Seal Cycle	6
1.7 Specifications.....	6
2. Power Source Operation	7
2.1 Setup	7
2.2 Sealing Procedure with Model 4105 Hand Held Sealing Head.....	8
2.3 Sealing Procedure with Model 4605 Bench Top Sealing Head.....	11
2.4 Seal Spacing.....	14
3. Maintenance.....	15
3.1 Cleaning Power Source Case	15
3.2 Troubleshooting	16
4. Failure Isolation	17
4.1 Failure Isolation	17
4.2 Fuse Replacement	17
4.3 Repair.....	18
5. Radio Frequency System Safety Considerations	21
5.1 General Information.....	21
5.2 RF Effects On Human Tissue	21
5.3 RF Effects On Pacemakers	21
5.4 Electrical Safety	21
5.5 RF Effects On Electronic Equipment	21
5.6 RF Effects in Potentially Explosive Atmospheres.....	21

Table of Figures

Figure 1.1 RF Tube Sealer with Hand Held and Bench Top Sealing Heads.....	1
Figure 1.2 Model 4600 RF Tube Sealer Components	2
Figure 1.3 RF Power Source Power Interface Panel.....	4
Figure 1.4 Serial Plate and Fuse/Rating Labels for Power Source	4
Figure 2.1 RF Power Cable Attachment (For Use with a Model 4105)	7
Figure 2.2 Model 4605 Bench Top Sealing Head Cable Attachment.....	8
Figure 2.3 Correct Technique for Holding the Sealing Head	8
Figure 2.4 Incorrect Technique for Holding the Sealing Head.....	9
Figure 2.5 Maintaining Compression During the Entire Sealing Process	9
Figure 2.6 Releasing the Sealing Head Lever at Seal Completion	10
Figure 2.7 Correct Sealing Method.....	11
Figure 2.8 Incorrect Sealing Method	12
Figure 2.9 Repeating the Seal Process	13
Figure 2.10 Multiple Seal Spacing.....	14
Figure 4.1 Releasing Fuse Holder Latch.....	18

Table of Tables

Table 1.1 Tube Sealer Component Functions.....	3
Table 1.2 Tubing Specifications	5
Table 3.1 Troubleshooting Guide	16

1. Power Source Description

1.1 Product Overview

The Vante Model 4600 RF Tube Sealer is a compact, portable device which employs radio frequency (RF) to make uniform, quality seals on a variety of tubing sizes without power adjustment by the user. The System consists of the Model 4600 Power Source (“the Power Source”) and can be teamed with either the Model 4105 hand-held, manually-activated sealing head or the Model 4605 bench-top segmenting sealing head (“the Sealing Head”) which creates a seal that is formed by the sealing head jaws in such a way as to make segment separation easy and uniform.



Figure 1.1 RF Tube Sealer with Hand Held and Bench Top Sealing Heads

1.2 Theory of Operation

The physical properties of PVC and EVA plastic tubing (and other RF-reactive thermoplastic materials) cause it to dielectrically heat at a molecular level in the presence of RF energy. This energy causes the plastic to soften due to the friction of the vibrating molecules. In this softened condition, the plastic becomes sealable because the molecules are free to intermingle under the application of external forces, such as compression. If allowed to cool while the forces are applied, the material will be permanently reshaped.

The Power Source is an instrument that, when actuated, generates a controlled amount of RF energy at the sealing head while mechanically compressing the tubing across its diameter during the dielectric sealing and forming process. When the energy is removed and the tubing is allowed to cool under compression, a permanent seal is produced.

The Power Source produces a minimum of 150 Watts of RF power, the frequency of which is controlled by a solid-state oscillator/amplifier operating at 40.68 MHz. The RF energy level and seal time are controlled by means of a proprietary solid-state circuit

design, allowing various tubing sizes to be automatically accommodated. *The Power Source requires no manual power or timing adjustment by the user.*

1.3 Component Identification

The Model 4600 Power Source, when coupled with the various sealing heads, becomes a system. Figure 1.2 shows the component parts of the sealing system with a Hand Held Sealing Head and a Bench Top Sealing Head. Table 1.1 indicates the function of each component.

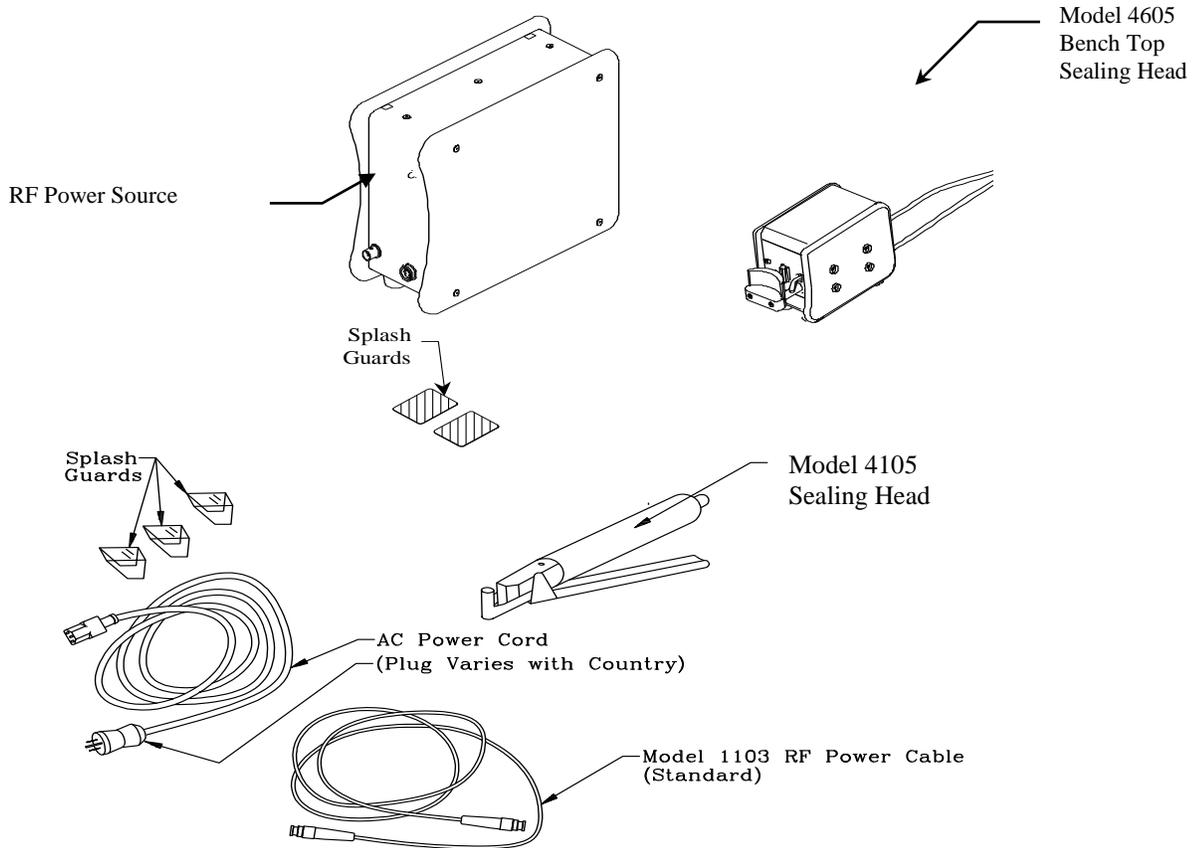


Figure 1.2 Model 4600 RF Tube Sealer Components

Component	Function
Model 4600 RF Power Source	Provides RF power to the sealing head. Automatically controls RF power and sealing time.
RF Ready Light	LED located on the front of the unit labeled "READY". Illuminates when RF power is ready.
Model 4105 Hand Held Sealing Head	Hand-held, manually-activated unit consisting of the RF jaw/tube assembly, ground jaw and lever. Compresses tubing between the RF and ground jaws while Power Source applies RF energy.
Model 4605 Bench Top Sealing Head	Bench-top, automatically activated unit consisting of the RF jaw, ground jaw and seal trigger and RF power cables. It automatically performs the sealing operation when the seal trigger is activated.
Sealing Indicator Light	Light on sealing head which indicates duration of RF power. For the Model 4105 the sealing head jaws <i>must</i> remain closed until two seconds after indicator light turns completely off.
AC Power Cord	Detachable AC power cord. Plug end varies with country in which Power Source is used to provide AC power connection to the country-specific AC Power Source.
Model 1103 RF Power Cable	Connects the Model 4105 Sealing Head to the Power Source at the RF power output connector located on the front of the unit.
Model 4605 Cables	Connects the Model 4605 Sealing Head to the Power Source with an RF connector and a DC connector.
Power Input Receptacle and Fuse Holder	Located on the rear of the Power Source. Connects the Power Source to detachable AC power cord and houses the user-replaceable fuse.
AC Power Switch	Turns AC power "on" or "off". Rocker-type switch located on the rear of the Power Source, labeled "Power Switch". Illuminates to indicate that the power supply is connected to AC power.
RF Power Output	Female BNC connector providing RF power to the sealing head.
Serial Plate	Indicates the model number, the serial number, the fuse information and the required power input of the Power Source. Located on the back of the unit.

Table 1.1 Tube Sealer Component Functions

Shown in Figure 1.3 is the power interface panel located on the back of the Power Source. Figure 1.4 depicts the serial plate and fuse/rating label which specifies the power input requirements for the Power Source. Each unit's serial plate (located on the rear of the unit) indicates the model and serial number of the unit. Refer to the serial number when contacting Vante™ or one of its authorized service centers.

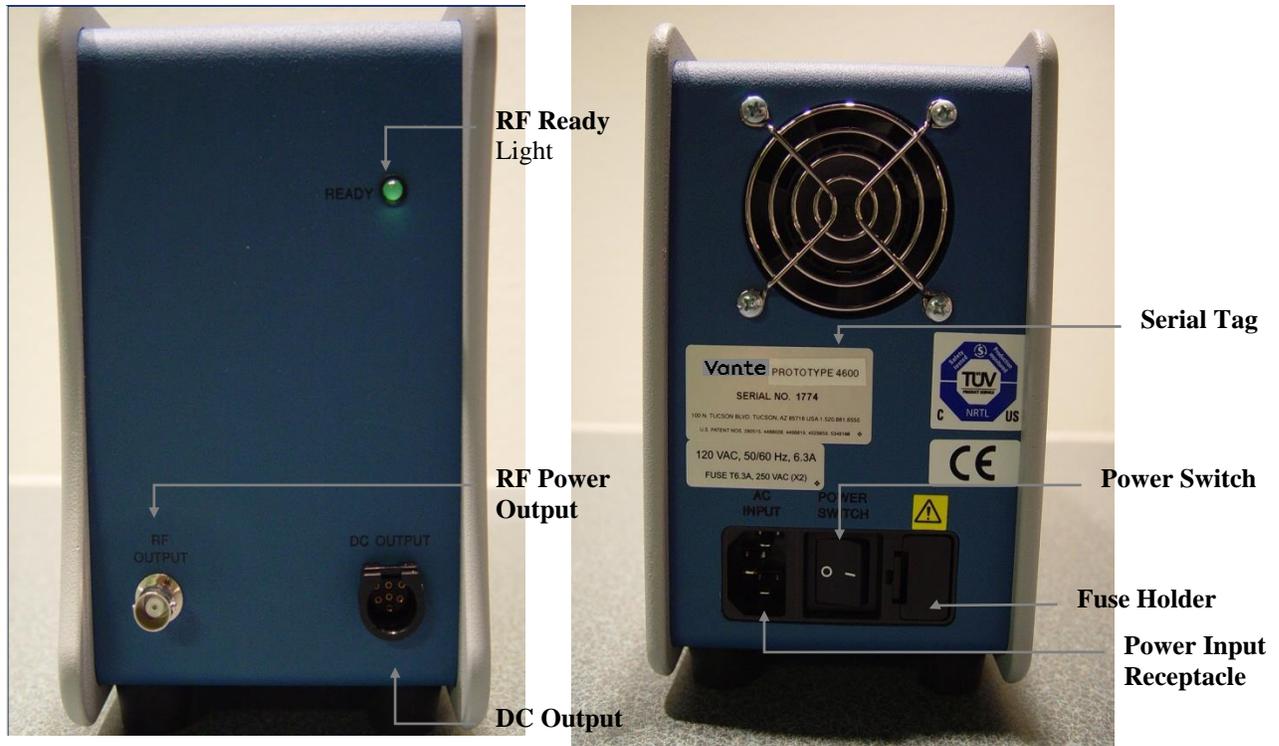


Figure 1.3 RF Power Source Power Interface Panel

Vante®

MODEL 4600 SERIAL NO. XXXX

100 N. TUCSON BLVD. TUCSON, AZ 85716 USA 1.520.881.6555

120 VAC, 50/60 Hz, 6.3A FUSE T6.3A, 250 VAC (X2)	230 VAC, 50/60 Hz, 4A FUSE T4A, 250 VAC (X2)
100 VAC, 50/60 Hz, 6.3A FUSE T6.3A, 250 VAC (X2)	

Figure 1.4 Serial Plate and Fuse/Rating Labels for Power Source

CAUTION: Unit is equipped with dual fuses. Disconnect power cord before replacing fuses.

1.4 Operating Environment

The Power Source will perform effectively when used in a typical biopharmaceutical manufacturing environment. Variations in tubing type and size, processing media, actual environmental conditions of the facility and/or the level of contamination and/or moisture on the ground and RF jaws and/or tubing exterior may affect actual performance. Users are advised that when temperature and humidity conditions seem less than what might be considered comfortable for humans, it is best to slow the rate of repetitive sealing, to be certain the sealing head and tubing are clean and dry, and to frequently check the quality of seal being produced.

The Power Source and Sealing Head should be stored between 10.0° and 122° F (-12 to 50°C). To ensure optimal performance, it is recommended that the Sealer be acclimated to the ambient environmental operating temperature for approximately one hour prior to use.

1.5 Tubing Specifications

Table 1.2 illustrates typical tubing sizes found in the biopharmaceutical industry. The table also represents those tubing sizes validated at Vante. It is not intended to absolutely define operating performance characteristics. Allowances are made for dimensions and tolerances that fall outside of these typical tubing sizes. Users may verify sealer function and performance on tubing sizes not included here.

Sealing Head Model	Description	Tubing Size	Outside Diameter	Wall Thickness
4105	Hand-held Sealing Head	Small	0.080-0.147 inch (2.0-3.7 mm)	0.020-0.030 inch (0.5-0.8 mm)
		Medium	0.148-0.179 inch (3.8-4.5 mm)	0.020-0.035 inch (0.5-0.89 mm)
		Large	0.180-0.260 inch (4.6-6.6 mm)	0.030-0.040 inch (0.8-1.0 mm)
4605	Bench-top Segmenting Head	Small	0.080 – 0.18 inch (2.0 – 4.6 mm)	0.020 – 0.037 inch (0.5 - .94 mm)

Table 1.2 Tubing Specifications

1.6 Seal Cycle

The Sealer “seal cycle” (or duty cycle) is defined as the time period, in seconds, *between* consecutive, repetitive seals. The maximum seal cycle and hourly rate will vary with different types and sizes of tubing, processing media and environmental conditions of the facility. Operating the Sealer as fast as it allows is acceptable, however, if continuously sealing, the Sealer may automatically shut down to avoid overheating. The green “seal ready” light will remain illuminated but seals cannot be made. If this occurs, leave the power on so the fan will continue to run. Allow five minutes for cooling, ensure the green seal ready light is on, and resume sealing.

1.7 Specifications

Mechanical

Dimensions

Power Source: 10.5 L x 4.4 W x 7.1 H in.
(26.7 x 11.1 x 18.1 cm)

Operating weight

Power Source with cord: 9.6 lb (4.4 kg)
Hand Held Sealing head: 0.6 lb (0.3 kg)
Bench Top Sealing head: 5 lbs (2.3 kg)

Electrical

Power input 100-120/230 VAC, 50/60 Hz

Current draw 6.3A /4A INTERMITTENT

Mains AC power fuse 250VAC, 5x20mm T6.3A/T4A INTERMITTENT

RF power output 150 watts min into matched 50Ω load, at power-up

Primary frequency 40.68±0.02 MHz

Environmental Conditions

Installation Category I

Pollution Degree 2

4°-38°C at 90 percent maximum relative humidity, non-condensing.

Altitude tested up to 2000 m.

2. Power Source Operation

2.1 Setup

Remove the components from their protective shipping containers and visually inspect them for obvious damage. Contact an authorized Vante service center if any damage is found. If possible, retain shipping containers and packing materials for future use.

Connect the AC power cord to the power input receptacle located on the rear of the Power Source. Refer to the voltage/fuse plate located on the back of the unit to determine the appropriate AC power input. The Power Source must be 100, 120 or 230 VAC, 50/60 Hz as indicated on the rating plate.

NOTE: Check to see that the power cord plug matches the power receptacle for the country in which the Power Source is being used. If it does not, contact an authorized Vante service center.

Place the Power Source on a desk or lab counter for convenient use and route the AC power cord to prevent interference with other equipment or activities. Verify the AC power switch is in the "O" (off) position and connect the AC power cord to the AC power receptacle.

When using the Power Source with a Hand Held Sealing Head, attach one end of the RF power cable to the Power Source and the other end to the sealing head. Connect the cable by pushing the connectors together and rotating clockwise until locked (see Figure 2.1).

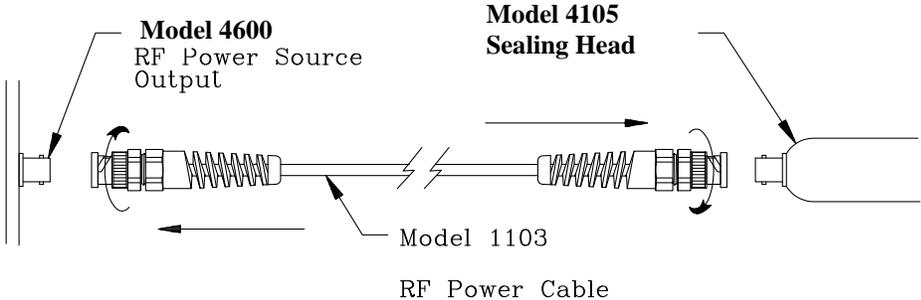


Figure 2.1 RF Power Cable Attachment (For Use with a Model 4105)

CAUTION: Do NOT attempt to use any other length or type of RF power cable. Unauthorized substitution of the RF power cable may result in malfunction of the Power Source and will void the warranty!

When using the Bench Top Sealing Head, connect the BNC connector end of the Bench Top Sealing Head to the RF output on the back of the Power Source. Rotate the

connector clockwise to lock it in place. Plug the seven-pin connector into the DC output. See Figure 2.2.

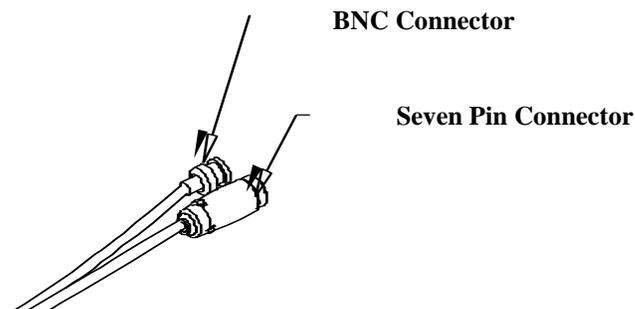


Figure 2.2 Model 4605 Bench Top Sealing Head Cable Attachment

CAUTION: Do NOT attempt to use any other length or type of RF power cable. Unauthorized substitution of the RF power cable may result in malfunction of the Power Source and will void the warranty!

Place the Bench Top Sealing Head in a convenient location, allowing clear access to the head and routing the cable so that it does not interfere with other activities. Turn on the unit by pushing the rocker-type power switch on the rear of the Power Source to the "I" (on) position. The RF ready light *on the front of the Power Source* will illuminate immediately, indicating that the Power Source is ready for use.

2.2 Sealing Procedure with Model 4105 Hand Held Sealing Head

For sealing and segmenting tubing, hold the sealing head in the palm of either hand with the fingers on the moveable lever so that the splash guard and sealing indicator light face the operator, as shown in Figure 2.3. In this position, the tubing can be easily placed into the space ("sealing region") between the RF and ground jaws, sealed, and *pushed* through the region to the next sealing position by the operator's free hand.

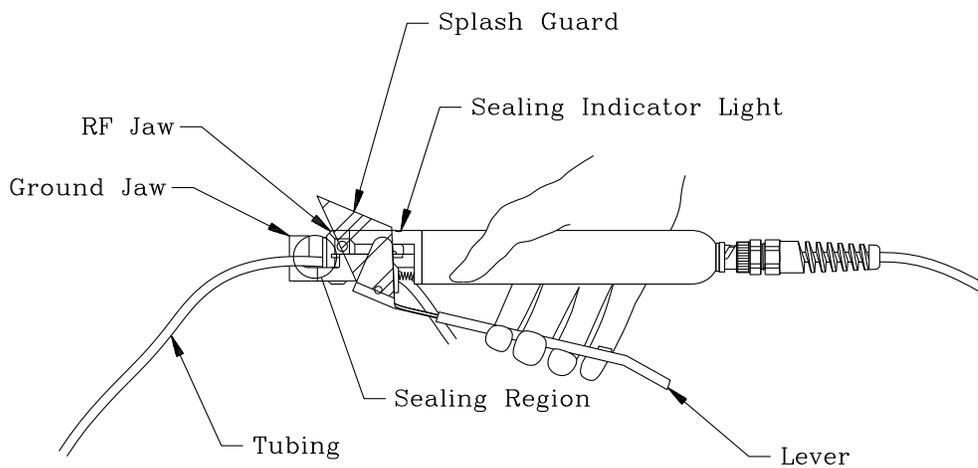


Figure 2.3 Correct Technique for Holding the Sealing Head

CAUTION: The sealing region *must* open facing upward so the operator may ensure that the tubing is fully seated between the RF jaw and ground jaw and clearly observe the sealing indicator lamp on the sealing head.

WARNING: Do NOT pull the tubing through the sealing region. Under *no* circumstances should the tubing be pulled at the instant of sealing. This may cause an opening in the tubing, which will subject the media to non-sterile conditions and the user to potentially hazardous fluids. In addition, the sealing head may become damaged by arcing caused by contamination of the sealing region.

WARNING: Do not place fingers in close proximity to the sealing region while sealing. Radio frequency burns may occur.

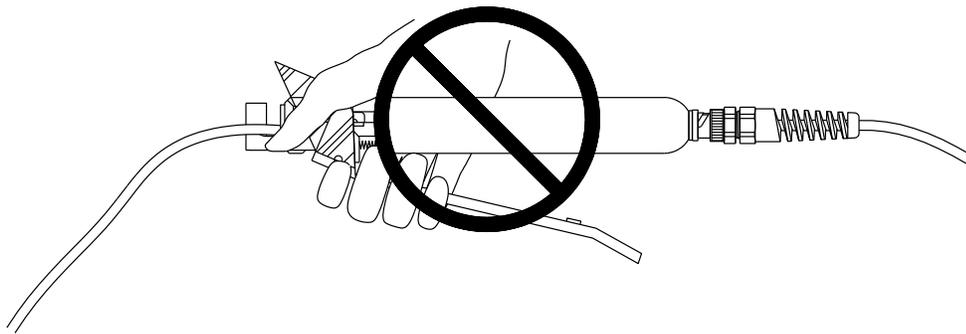


Figure 2.4 Incorrect Technique for Holding the Sealing Head

To make a seal, squeeze the lever until it touches the sealing head body, and hold it there (see Figure 2.5). This compresses the tubing and activates the sealing energy, visually indicated by the illumination of the sealing indicator light. *Continue to squeeze the lever for two seconds after the sealing indicator light completely extinguishes.* Holding the lever closed will *not* cause overheating or burn-through of the tubing.

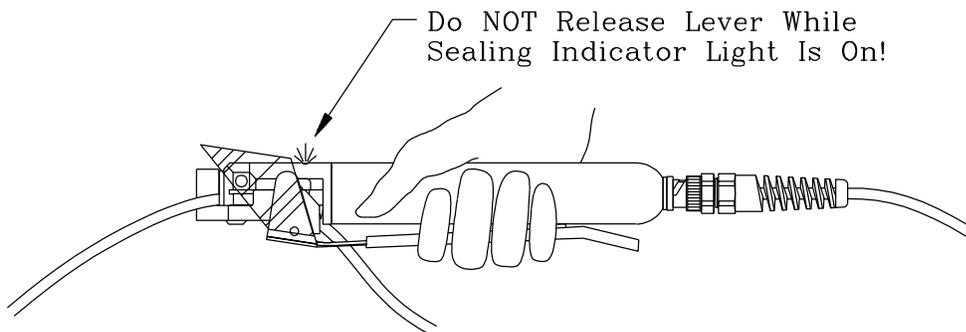


Figure 2.5 Maintaining Compression During the Entire Sealing Process

WARNING: Dimming of the indicator light will occur, but do not release the lever until *after* the indicator light is completely off! Premature lever release will cause incomplete sealing and/or ruptured tubing. Holding the lever closed will *not* cause overheating or burn-through of the tubing.

CAUTION: Never squeeze the lever when non RF-reactive materials are in the sealing region or if the Power Source is not connected and turned on. Damage to the lever and poor Power Source operation may result.

The seal is typically completed in one second. The lever should be held closed for two seconds after the sealing head light completely extinguishes. At that time, the lever may be released. *Another seal cannot be made until the moveable lever has been fully opened.* See Figure 2.6. For more information refer to the Instruction Manual for the Model 4105 Sealing Head.

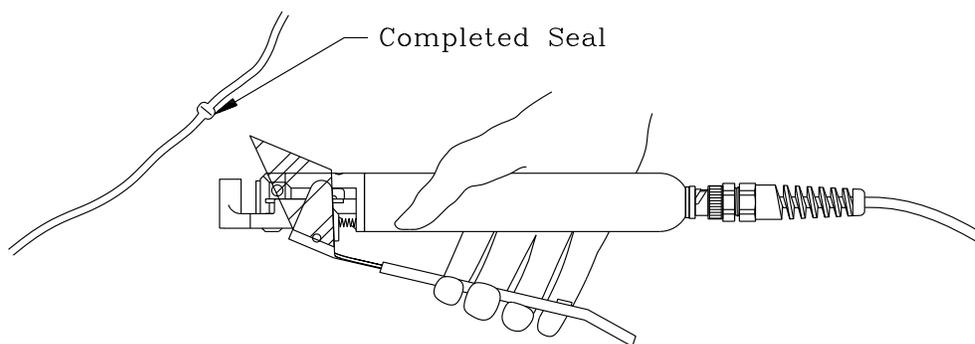


Figure 2.6 Releasing the Sealing Head Lever at Seal Completion

NOTE: The Power Source is equipped with a thermal protection switch to prevent the equipment from becoming damaged. If thermal cutout is reached, the power source will not work for several minutes until the temperature of the equipment lowers.

WARNING: The Power Source is designed for rapid sealing applications; however, extreme heavy duty use may result in thermal build up in the jaw area which can cause poor seal quality or tubing ruptures. If you should experience these problems, reduce the rate of sealing, as necessary, or allow for periods of rest for the Sealing Head.

WARNING: If you observe arcing while making a seal, follow the instructions in the Troubleshooting Guide section under “Arcing or Bad Seals.” Although a seal made when you experience arcing may look acceptable, it may be inadequate. Take precautions as if this is an inadequate seal.

WARNING: Under *no* circumstances should the tubing be separated by pulling it at the instant of sealing. This may cause an opening in the tubing, which will subject the media to non-sterile conditions and the user to potentially hazardous fluids. In addition, the sealing head may become damaged by arcing caused by contamination of the sealing region.

2.3 Sealing Procedure with Model 4605 Bench Top Sealing Head

NOTE: For clarity, the splash guard is not shown in some of the figures in this manual; however, it should always be in place during the sealing process.

To make a seal, lay the tubing between the jaws (“sealing region”), allowing the weight of the tubing to press against the seal trigger (a slight additional manual force may be required), as shown in Figure 2.7. When the trigger is activated, the RF sealing jaw will compress the tubing against the ground jaw and RF power will be applied for approximately one second. The front plate of the Sealing Head will glow during RF application. After the seal is formed, the sealing jaw will retract to its original position.

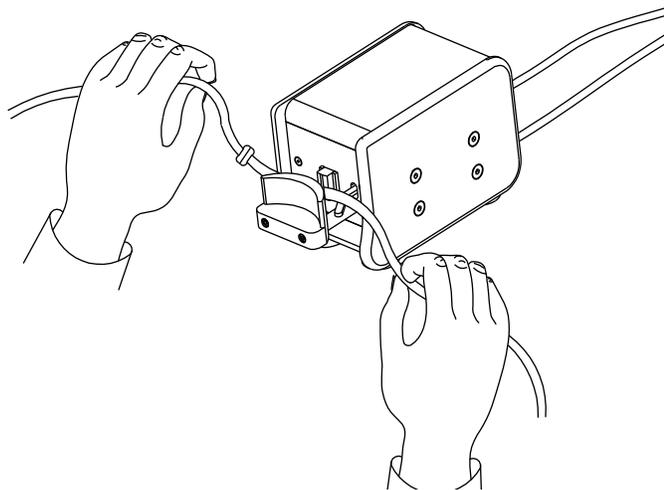


Figure 2.7 Correct Sealing Method

WARNING: Always operate the Sealing Head with the splash guard in place. Do NOT pull the tubing through the sealing region. Under *no* circumstances should the tubing be pulled at the instant of sealing. This may cause an opening in the tubing, which will subject the media to non-sterile conditions and the user to potentially hazardous fluids. In addition, the Sealing Head may become damaged by arcing caused by contamination of the sealing region.

WARNING: Do not place fingers in close proximity to the sealing region while sealing. Doing so will subject the operator to a radio frequency burn hazard.



Figure 2.8 Incorrect Sealing Method

The seal is completed in approximately one second, as indicated when the sealing jaw retracts. Another seal cannot be made until the sealing jaw fully retracts and the seal trigger has been completely released.

To make another seal, lift the tubing up to release the trigger and push the tubing to the next seal position (see Figure 2.9). Activate the seal trigger with the tubing to repeat the process. The completed seals may be moved to either the right or left, but for best results, move the completed seals to the left (while facing the head shell) to avoid their interfering with the seal trigger. For more information, refer to the instruction manual for the Model 4605 Sealing Head.

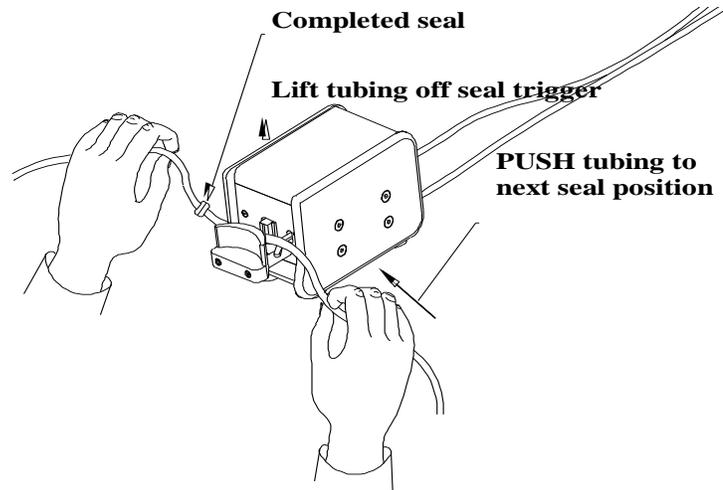


Figure 2.9 Repeating the Seal Process

WARNING: Be sure to *push* the tubing through the sealing region to the next position. Under *no* circumstances should the tubing be separated by pulling it at the instant of sealing. An opening in the tubing may occur, which will subject the media to non-sterile conditions and the user to potentially hazardous fluids. In addition, the Sealing Head may become damaged by arcing caused by contamination of the sealing region.

Seal spacing must be in accordance with the guidelines specified in Section 2.4.

WARNING: Multiple seals spaced less than the recommended distance may cause a rupture of a sealed tubing segment.

NOTE: The Power Source is equipped with a thermal protection switch to prevent the equipment from becoming damaged. If thermal cutout is reached, the power source will not work for several minutes until the temperature of equipment lowers.

WARNING: If you observe arcing while making a seal, follow the instructions in the Troubleshooting Guide section under “Arcing or Bad Seals.” Although a seal made when you experience arcing may look acceptable, it may be inadequate. Take precautions as if this is an inadequate seal.

WARNING: The Power Source is designed for rapid sealing applications; however, extreme heavy duty use may result in thermal build up in the jaw area which can cause poor seal quality or tubing ruptures. If you should experience these problems, reduce the rate of sealing, as necessary, or allow for periods of rest for the Sealing Head.

2.4 Seal Spacing

The Sealer is designed to allow repetitive seals to be made on a length of tubing filled with media. However, several factors control how closely the seals may be spaced.

Seals which progress along an open-ended length of tubing may be spaced as desired, but ½ inch (1 cm) is the recommended minimum.

Seals which progress along a **close-ended** length of tubing, as in a segmenting process, must be spaced *no less* than the bag manufacturer's recommendation, to avoid rupture of the tubing due to pressure build-up.

Multiple seals in close proximity are not required, nor are they recommended when using the Power Source. If multiple seals must be used, they should be spaced at least one inch (2.5 cm) apart, as shown in Figure 2.10.

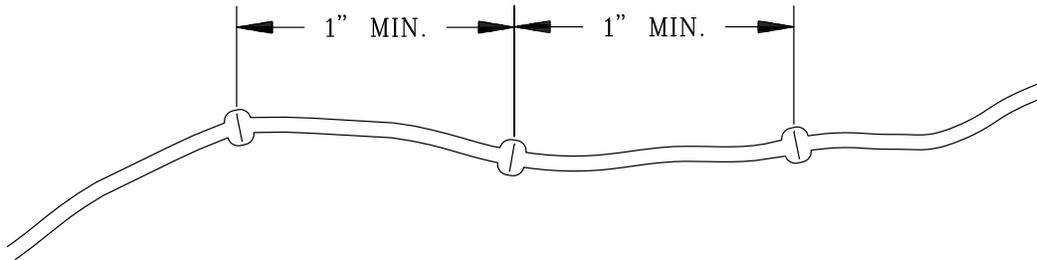


Figure 2.10 Multiple Seal Spacing

WARNING: Never attempt to make segmentation seals closer than recommended without validating for seal integrity.

3. Maintenance

Other than periodic cleaning, or when moisture, media, or other contaminants are visible, the sealing head and Power Source are designed to be maintenance free and to withstand substantial wear and tear. Damage may occur as a result of dropping either the Sealing Head or the Power Source.

Because the Power Source is capable of detecting RF arcing which may be due to moisture or other contaminants in the sealing region, the Power Source performance will be reduced if the sealing region becomes contaminated or wet with fluids. To obtain satisfactory seals at all times, ensure the sealing region and all adjacent areas are always kept clean and dry.

Do NOT, under any circumstances, submerge the sealing head in any kind of liquid. This will damage the RF jaw/tube assembly and void the warranty.

3.1 Cleaning Power Source Case

Ensure that the AC power switch located on the rear of the Power Source is in the "O" (off) position. Disconnect the AC power cord from the AC outlet. Disconnect the RF power cable and AC power cord from the Power Source.

Apply a cleaning solution made from a mild detergent (or household cleaner such as Formula 409) and water to a clean soft towel. Wipe the Power Source case with the *damp* towel until clean. Ensure the Power Source is completely dry before placing back into service.

Periodically vacuum the fan area to remove dust or other build-up.

WARNING: Do not apply fluids directly to the Power Source case and do not oversaturate the cleaning solution applicator. The fluids may run into the electronic components and cause contamination of the electronics and subsequent unit malfunction. *Never immerse the Power Source in any liquid.*

3.2 Troubleshooting

The following chart offers diagnosis and actions for many commonly-reported problems. For any problems or failures not listed, please contact the Vante Customer Service Department.

Problem	Diagnosis	Action
Not sealing.	No power to Power Source.	Ensure all connections are correct (refer to Section 2.1). Ensure the AC power switch is in the "I" (on) position and the RF ready light is illuminated.
	RF cable malfunction.	Replace Model 1103 RF cable if using a Hand Held Sealing Head; contact an authorized Vante repair center if using a Bench Top Sealing Head.
	Problem with Sealing Head.	See Sealing Head Instruction Manual.
	Blown Fuses.	Ensure the fuse(s) is (are) not blown. See Section 4.2 if the fuse requires replacement.
	Component failure.	Contact an authorized Vante™ repair center.
Arcing or bad seals.	Contaminated sealing area.	Clean sealing jaws (see Sealing Head Instruction Manual).
	Moisture in the sealing area or on the tubing.	Ensure the outside of the tubing, the sealing region and adjacent areas are clean and dry.
	Premature release of hand held lever.	Ensure the sealing indicator light is extinguished for at least two seconds prior to releasing the Hand Held sealing head lever.
	Misuse of sealing head.	Ensure the sealing head is being used properly (see Sealing Head Instruction Manual). Ensure tubing is within the tubing specifications recommended within this Instruction Manual. Some other tubing materials may give poor seals or none at all.
	Sealing head jaws not aligned.	Ensure the sealing head jaws close evenly (see Sealing Head Instruction Manual). If not aligned, contact an authorized Vante™ repair center.

Table 3.1 Troubleshooting Guide

4. Failure Isolation

4.1 Failure Isolation

To avoid problems with the Power Source, keep the tubing exterior and sealing head clean and dry at all times.

If the system fails to operate properly, connect a different sealing head and RF power cable to the Power Source to isolate the failed component.

If the Power Source performs properly, then the sealing head is suspected. If the Power Source fails to function properly, then the Power Source *may* be the cause of malfunction. In any event, contact your nearest Vante™ authorized service representative or Vante™ for evaluation and repair.

4.2 Fuse Replacement

If the unit is plugged into an AC Power Source, and the RF Ready light is not illuminated when the switch is in the "I" (on) position, then the fuse *may* need replacement.

Turn the AC power switch to the "O" (off) position and disconnect the AC power cord from the AC outlet and Power Source.

Release the fuse holder slide latch by inserting the end of a flat blade screwdriver into the detent as shown in Figure 4.1. Pull the fuse holder slide out until it stops and the fuse is exposed.



Release latch with
screwdriver

Figure 4.1 Releasing Fuse Holder Latch

Examine the fuse(s) and replace, as required. If the fuse(s) is (are) not blown, check again to be sure all other connections are correct and place the fuse back into the fuse holder slide.

CAUTION: Replace the fuse with one of the specified rating only!

Push the fuse holder slide back into the power input receptacle until the latch engages. Plug the AC power cord into the input power receptacle and the AC outlet. Turn the AC power switch to the "I" (on) position. If the RF Ready light fails to illuminate, or if the fuse blows again, contact Vante.

4.3 Repair

Other than external cleaning and vacuuming the fan, the Power Source is designed to be maintenance free. Do not attempt a field repair of any kind. Questions regarding repairs should be directed to an authorized Vante service center.

To return the Power Source to Vante for repair, call for a Return Material Authorization (RMA) number with the unit serial numbers available.

To ship Power Source, use the original shipping containers and packing material if possible. Otherwise, wrap the components separately in plastic bubble wrap or other suitable packing material that will provide sufficient shock protection. Place them in a shipping carton large enough to contain the individually wrapped components, or place each one in its own shipping carton of suitable size.

<p>CAUTION: Failure to properly package the components for shipping may increase any repair costs.</p>

NOTE: Units returned to Vante for repair are subject to biohazard charges if any Sealer component is contaminated with media or other potentially biohazardous materials.

This page intentionally left blank

5. Radio Frequency System Safety Considerations

5.1 General Information

Vante manufactures a variety of instruments which incorporate the use of radio frequency (RF) for sealing, welding, or forming thermoplastics. Typical uses include biopharmaceutical tube sealing, thermoplastic welding and thermoplastic forming processes. When in operation, these RF instruments emit radio frequency energy to people, other instruments, and equipment located in close proximity. Current Vante RF instruments operate at a frequency authorized by the Federal Communications Commission (FCC) and the International Telecommunications Union (ITU) for industrial, scientific, and medical (ISM) use. The following is an advisory regarding RF instrument use and associated safety considerations.

5.2 RF Effects On Human Tissue

Misuse or direct contact between tissue and RF electrode(s) can result in severe RF burns.

5.3 RF Effects On Pacemakers

There is no evidence that Vante RF instruments interfere with the function of modern cardiac pacemakers.

5.4 Electrical Safety

Vante RF devices meet or exceed appropriate electrical safety standards, and pose no electrical shock hazard when used with properly fused and grounded outlets

5.5 RF Effects On Electronic Equipment

Vante instruments produce RF power, and during operation emit some RF energy from the electrodes. While most modern electronic equipment and instruments provide shielding from RF energy, improperly shielded electronic devices operating in close proximity to an RF instrument may be affected. If interference is suspected, appropriate electronic shielding, moving equipment further away from the RF instrument or operating from a different electrical circuit may be necessary.

5.6 RF Effects in Potentially Explosive Atmospheres

Do not operate Vante RF instruments in any area with a potentially **explosive** atmosphere. It is possible for the RF electrodes to arc, initiating an explosion or fire.