



INSTRUCTION MANUAL

MODEL 4605

Bench-Top Segmenting Head

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Preliminary Information

Document Scope

This manual is intended as a guide for the operation, care and maintenance of the Model 4605 Bench-Top Segmenting Head. 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 products, procedures, and safety requirements for the collection, processing and handling of biopharmaceutical products.

Application

The Model 4605 Bench-Top Segmenting Head is part of a system and cannot be used independently. When used in conjunction with the Model 4600 RF Power Source, it is the instrument 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) or ethylene 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 Sealing Head 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 Sealing Head do so at their own discretion and risk.

Proprietary Information

All rights are reserved. Copying of the protected designs associated with the Model 4605 Sealing Head 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



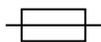
Caution, risk of electric shock



Caution



Protective Earth (P.E.)



Fuse



On



Off



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

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1. Sealing Head Description

1.1 Product Overview

The Vante Model 4605 Bench-Top Segmenting Head (“the Sealing Head”) is part of a system which employs radio frequency (RF) to make uniform, quality seals on tubing used in biopharmaceutical manufacturing. A Vante Model 4600 RF Power Source provides RF power to the Sealing Head and controls RF power and sealing time. The manually-activated Sealing Head forms a seal with its jaws in such a way as to make segment separation easy and uniform.

The Sealing Head is equipped with a splash guard for operator protection from inadvertent contact with media in the unlikely event of tubing rupture.

1.2 Theory of Operation

The physical properties of PVC 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 weldable 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 Sealing Head receives a controlled amount of RF energy from the Power Source 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.

1.3 Component Identification

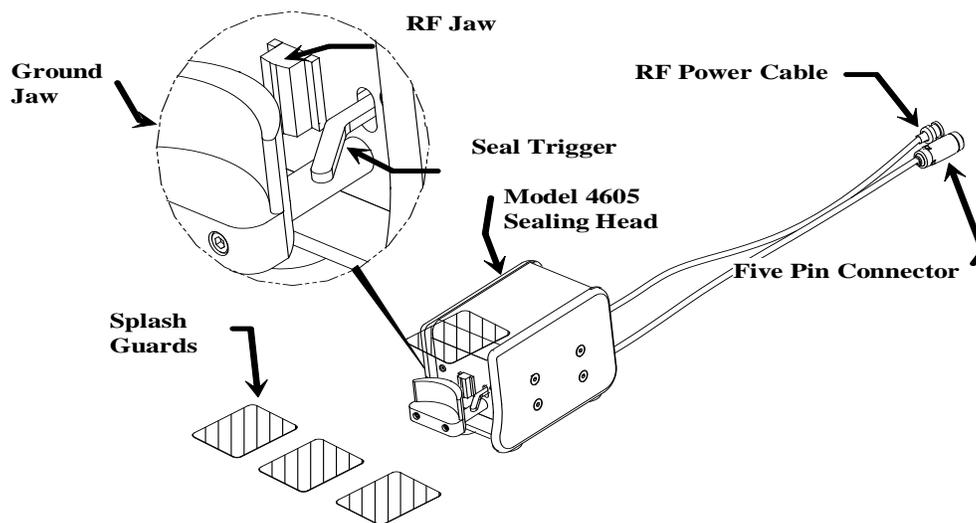


Figure 1.1 Model 4605 Segmenting Head

Table 1.1 indicates the function of each component included with the Sealing Head.

Component	Function
Ground Jaw	Compresses tubing while RF is applied to form seal.
RF Jaw	Delivers RF energy to tubing to form seal.
Splash Guard	Protects the operator from accidental exposure to media in the unlikely event of a tubing rupture.
Seal Trigger	A micro switch that activates the sealing head jaws.
RF Power Cable	Provides RF power connection to the Model 4600 Power Source.
Seven Pin Connector	Provides control voltage connection to the Model 4600.

Table 1.1 Sealing Head Component Functions

1.4 Environment

The Sealing Head will perform effectively when used in a typical biopharmaceutical manufacturing environment. Variations in media and environmental conditions of the facility and/or the level of contamination and/or moisture on the RF ground 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.

Mechanical

Dimensions:	7 in. L x 4 in. W x 4.2 in. H 17.8 cm L x 10.2 cm W x 10.7 cm H
Operating weight	5.3 lb 2.4 kg
Shipping weight:	8 lb 3.6 kg

2. Sealing Head 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.

NOTE: If possible, retain shipping containers and packing materials for future use.

See the Instruction Manual for the Model 4600 Power Source for proper setup.

2.2 Tubing Specifications

Shown in Table 1.2 are tubing sizes validated by Vante.

Sealing Head Model	Description	Tubing Type	Outside Diameter	Wall Thickness
4605	Bench-top Segmenting Head	PVC	0.080 – 0.18 inch (2.0 – 4.6 mm)	0.020 – 0.037 inch (0.5 - .94 mm)
		EVA	N/A	N/A

Table 1.2 Tubing Specifications

*Although the 4605 may make good seals on tubing that falls outside this range, duty cycle and heat build up may be affected. Call Vante customer service for more information.

2.3 Sealing Procedure

WARNING: Wear disposable protective gloves while working with media or potentially hazardous fluids.

For sealing and segmenting tubing, place the Sealing Head in a convenient location, allowing clear access to the jaws and routing the cable so that it does not interfere with other activities.

Lay the tubing through the slot of the 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 2.1.

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. After the seal is formed, the sealing jaw will retract to its original position.

WARNING: Do NOT pull the tubing or bag through the sealing region. Under *no* circumstances should the tubing be pulled at the instant of sealing. An opening in the tubing could 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.

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.

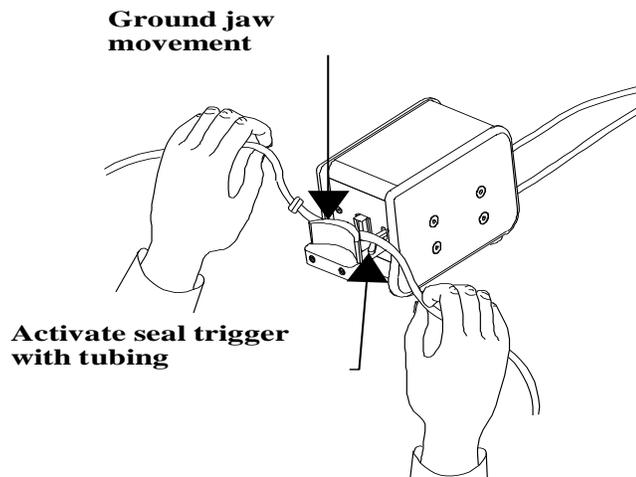


Figure 2.1 Correct Technique for Holding the Tubing

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 and will not allow for good contact, resulting in poor or ruptured seals.



Figure 2.2 Incorrect Technique for Holding the Tubing

NOTE: When the Sealing Head is operated, a minor arc discharge may occur between the sealing jaws.

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: 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.

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

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 2.3). Activate the seal trigger to either the right or left, but for best results, move the completed seals to the left (while facing the jaws) to avoid their interfering with the seal trigger.

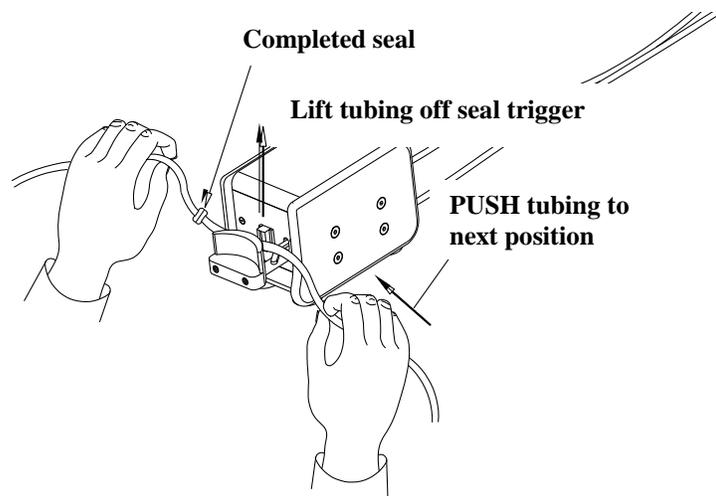


Figure 2.3 Repeating the Seal Process

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 while the sealing jaws are clamped. This action 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 due to contamination of the sealing region.

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.

2.4 Seal Spacing

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.

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

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 2.4.

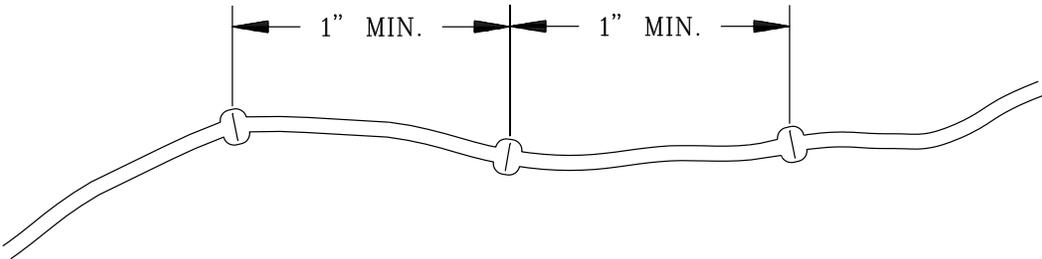


Figure 2.4 Multiple Seal Spacing

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

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3. Cleaning the Sealing Head

Other than periodic cleaning, the Sealing Head is designed to be maintenance free and to withstand substantial wear and tear. However, damage may occur as a result of dropping any of the major components, i.e., the Sealing Head or the Power Source. If any component is dropped, examine for obvious damage and confirm functionality before using. Contact Vante if the Sealing Head fails to operate properly.

WARNING: To obtain satisfactory seals at all times, be sure the sealing region and all adjacent areas are always kept clean and dry.

CAUTION: 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.

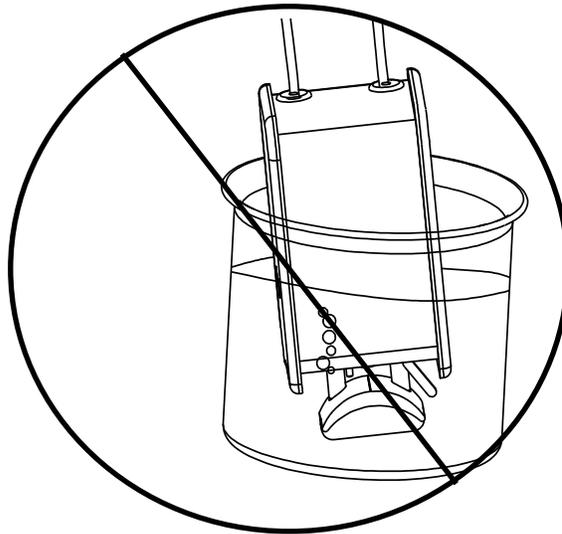


Figure 3.1 Incorrect Cleaning Technique

3.1 Topical Cleaning of the Sealing Region

WARNING: Always wear disposable protective gloves while working with media or potentially hazardous fluids.

NOTE: Units returned to Vante for repair are subject to biohazard charges if any Sealing Head component is contaminated. See below for the recommended cleaning procedure.

WARNING: Topical cleaning of the Sealing Head is performed in this section using denatured or isopropyl alcohol. The user should follow the alcohol manufacturer's recommendations for usage and be sure that the product material safety data sheet is carefully understood and observed.

NOTE: The illustrations in this section show the splash guard removed for clarity. However, to perform a topical cleaning, it is not necessary to remove the splash guard.

Disconnect the Sealing Head from the Power Source by removing the RF power cable and five-pin connector from the Power Source.

WARNING: Failure to separate the Sealing Head from the Power Source prior to cleaning may result in an RF burn to the operator during the cleaning process.

Clean the open sealing region, including the RF jaw, with alcohol (denatured or isopropyl) applied to one end of a cotton swab, as shown in Figure 3.2. *Be sure the RF power cable is disconnected from the RF Power Source!*

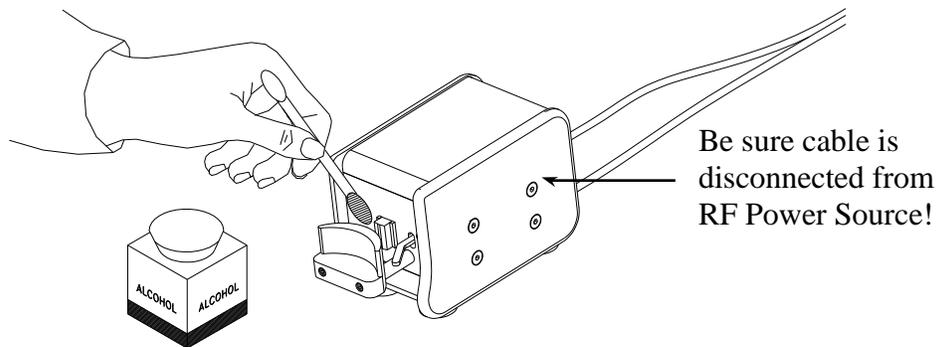


Figure 3.2 Cleaning the Sealing Region

CAUTION: Clean the RF jaw, ground jaw and adjacent areas with alcohol only!

After cleaning the contaminated areas of the sealing region, immediately dry with the dry end of the cotton swab (Figure 3.3).

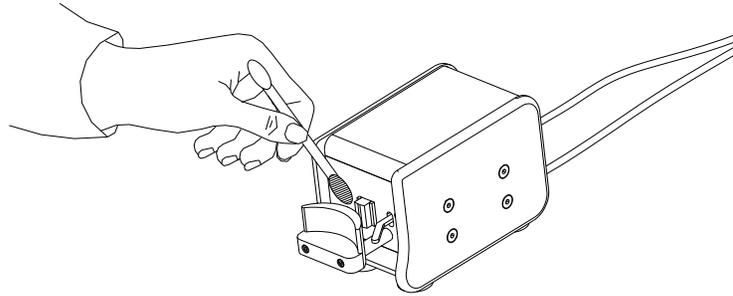


Figure 3.3 Drying the Sealing Region

If the splash guard was removed for topical cleaning, be sure to follow the cleaning procedure in Section 3.2 before reinstalling a new splash guard.

If the above procedure does not result in satisfactory performance, contact Vante.

Properly dispose of all used cleaning materials.

3.2 Splash Guard Replacement

NOTE: The Sealing Head assembly comes with a clear plastic splash guard to provide operator protection in the event of a tubing rupture during sealing. It is made with a self-adhesive coating for easy attachment. Extra splash guards are provided with each shipment and are available for purchase from Vante.

WARNING: To avoid coming in contact with any media or potentially hazardous fluids, always wear disposable protective gloves while handling and cleaning the Sealing Head components.

Disconnect the Sealing Head from the Power Source by removing the RF power cable and seven pin connector from the Power Source.

WARNING: Failure to separate the Sealing Head from the Power Source prior to removing or attaching the splash guard may result in an RF burn.

Remove the existing splash guard from the Sealing Head and properly dispose of it.

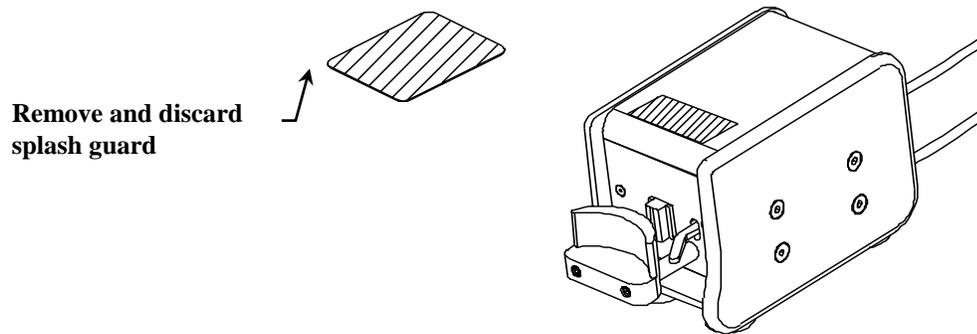


Figure 3.4 Removing Splash Guard from Sealing Head

Remove the adhesive residue from the surface with a commercially available solvent cleaner such as De-Solv-It®, Goo-Gone® or WD-40®, applied to a cotton swab (see Figure 3.5).

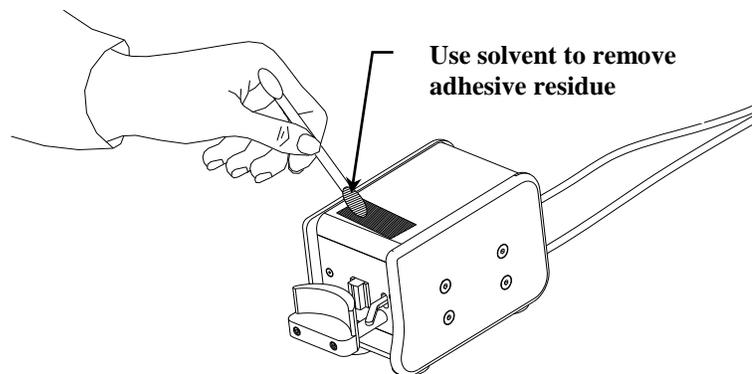


Figure 3.5 Removing Adhesive Residue

Dry the Sealing Head completely.

Remove the paper backing from adhesive on the new splash guard.

Align and attach the new splash guard. See Figure 3.6.

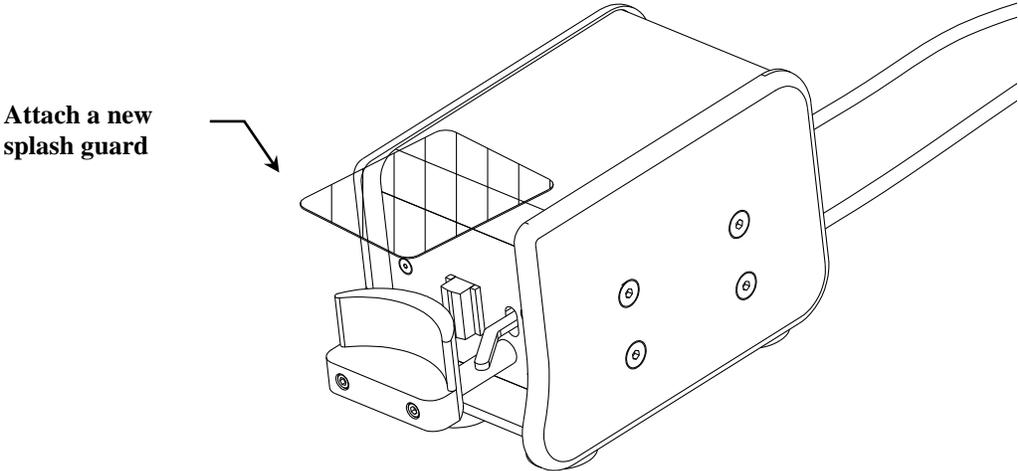


Figure 3.6 Attachment of New Splash Guard

3.3 Cleaning Sealing Head Case

Disconnect the Sealing Head from the Power Source.

Apply a cleaning solution made from a mild detergent (or household cleaner such as Formula 409®) and water to a soft wiping tissue. Wipe the Power Source and/or Segmenting Head case with the *damp* tissue until clean. Make sure the surfaces are completely dry before putting back into service.

CAUTION: Do not apply fluids directly to the Sealing Head case and do not over-saturate 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 or Segmenting Head in any liquid.* Use only alcohol to clean the sealing region and adjacent areas.

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4. Repair

4.1 Troubleshooting

Problem	Cause	Action
Sealing Head “Arcs” (“Arcing” is indicated by a flash of blue light at the time of sealing.)	Tubing or sealing region is moist or contaminated.	Ensure the outside of the tubing, the sealing region and adjacent areas are free of moisture and any other contaminants.
	Jaws bent out of position or not properly aligned.	Call Vante.
Bad seals or intermittent seals occur.	Sealing Head/Power Source combination may not give optimum performance.	Check to see if another Sealing Head connected to the Power Source gives better results.
	Improper tubing material is being sealed.	Ensure proper tubing type and size (usually PVC) is being used.
RF jaw fails to move or chatters when triggered.	Sealing Head cables not properly connected to Power Source.	See Instruction Manual for Power Source.
	Sealing region is contaminated.	Ensure the sealing region and adjacent areas are free of any contaminants.

4.2 Returning a Unit for Repair

The Sealing Head is designed to be maintenance free, except for cleaning. Do not attempt any field repair. Questions regarding repairs should be directed to an authorized Vante repair center.

To return the Sealing Head to Vante for repair, call the Customer Service Department for an RMA (Return Material Authorization) number. Clean the Sealing Head of any media or potentially hazardous fluid. 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.

WARNING: Failure to properly package the components for shipping may increase any repair costs.

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.

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5. Radio Frequency System Safety Considerations

5.1 Introduction

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.

NOTE: Vante recommends strict adherence to the procedures specified in the instrument Instruction Manual. Misuse or modification of an instrument may result in unsafe or hazardous situations.