SEBRA®

operation manual

108731-IE

Model 2600
OMNI™ Sealer
Power Source

VANTE INC
IGNITING INNOVATION

Vante® SEBRA®
Model 2600
OMNI™ Sealer Power Source
- Operation Manual -

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CONSUMER INFORMATION

Proprietary rights

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Disclaimer

This manual is intended as a guide to provide the operator with necessary instructions on the proper use and maintenance of certain Vante products. This manual should be used in conjunction with instruction and training supplied by qualified Vante personnel.

Any failure to follow the instructions as described could result in impaired product function, injury to the operator or others, or void applicable product warranties. Vante accepts no responsibility for liability resulting from improper use or maintenance of its products.

Utilization of Vante products may require the operator to handle and dispose of blood-contaminated material. An operator must fully understand and implement all regulations governing the safe handling of blood products and waste, including the policies and procedures of their facility.

Handling and use of any blood products collected using Vante equipment are subject to the decisions of the attending physician or other qualified medical personnel. Vante makes no warranty with respect to such blood products.

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Chapter 1

Introduction

PRELIMINARY INFORMATION

Document scope

This manual is a guide for the operation, care and maintenance of the Vante® SEBRA® Model 2600 OMNI™ Sealer (hereinafter referred to as "the Power Source").

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.

Proprietary information

The Power Source is protected by U.S. Patent Number 5349166.

SYMBOLS

Symbols found in this document

The terms *Note*, *Caution* and *Warning* are used in this manual with the following symbols to notify the operator of important and/or critical information.

Note: provides useful information regarding a procedure or operating technique when using Vante material.

Caution: *advises the operator against initiating an action or creating a situation that could result in damage to equipment, or impair the quality of the blood products; personal injury is unlikely.*

Warning: advises the operator against initiating an action or creating a situation that could result in serious personal injury to the donor, the operator, or the blood product recipient.

Symbols found on the device

The following symbols may be found on the device or device packaging.

Shock hazard

Caution
Consult accompanying documents)

Protective earth (ground)
Identifies any terminal intended for connection to an external conductor, for protection against electrical shock in case of a fault.

Caution, Hot Surface

Power ON

Power OFF

Fuse

Electrical and electronic equipment waste (applies to EU only)
Dispose of the device using a separate collection method (according to EU and local regulation for waste electrical and electronic equipment).

Serial number

Catalog number

Manufacturer

Authorized representative in the European Community

DEVICE SPECIFICATIONS

Physical specifications

The approximate dimensions and weight of the Model 2600 device are as follows:

Table 1-1, Physical Specifications

Parameter	Specification
Power source dimensions	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 specifications

The electrical specifications for operating the Model 2600 device are as follows:

Table1-2, Electrical Specifications

Parameter	Specification
Power input	100-120/220VAC, 50-60 Hz
Current draw	6.3 A/4A INTERMITTENT
RF power output	150 watts minimum into matched 50Ω load, at initial power -up
Primary frequency	40.68±0.02 MHz

Environmental conditions

The following environmental conditions should be respected pertaining to operation and storage of the Model 2600 device:

Table 1-3, Environmental Conditions

Condition	Value
Installation category	I
Pollution degree	2
Ambient operating temperature	4°-38°C
Operating humidity level	90 percent maximum relative humidity, non-condensing

Warning: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Chapter 2

Product description

PRODUCT OVERVIEW

The Vante® SEBRA® Model 2600 OMNI™ Sealer is a compact, portable device that employs radio frequency (RF) to make uniform, quality seals on a variety of tubing sizes without power adjustment by the user. The Power Source consists of the Model 2600 Power Source ("the Power Source") and the Model 1105, a hand-held, manually-activated sealing head or the Model 2605, a bench-top automatic 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 2-1, OMNI™ Sealer with Hand-Held and Bench-Top Sealing Heads

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 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.*

Application

The Model 2600 Power Source is an instrument for making seals on tubing made of RF reactive thermoplastic materials typically used in blood banks, blood processing facilities and transfusion centers. Tubing utilized in the collection and handling of blood and blood products is typically made from thermoplastic vinyl, namely polyvinylchloride, or PVC, and it is this application for which this product is specifically intended.

COMPONENT IDENTIFICATION

The Model 2600 Power Source, when coupled with the various sealing heads, becomes a system. Figure 2-2, Model 2600 OMNI™ Sealer Components shows the component parts of the sealing system with a Hand-Held Sealing Head and a Bench-Top Sealing Head. Table 2-1, "Power Source Component Functions," on page 2-5indicates the function of each component.

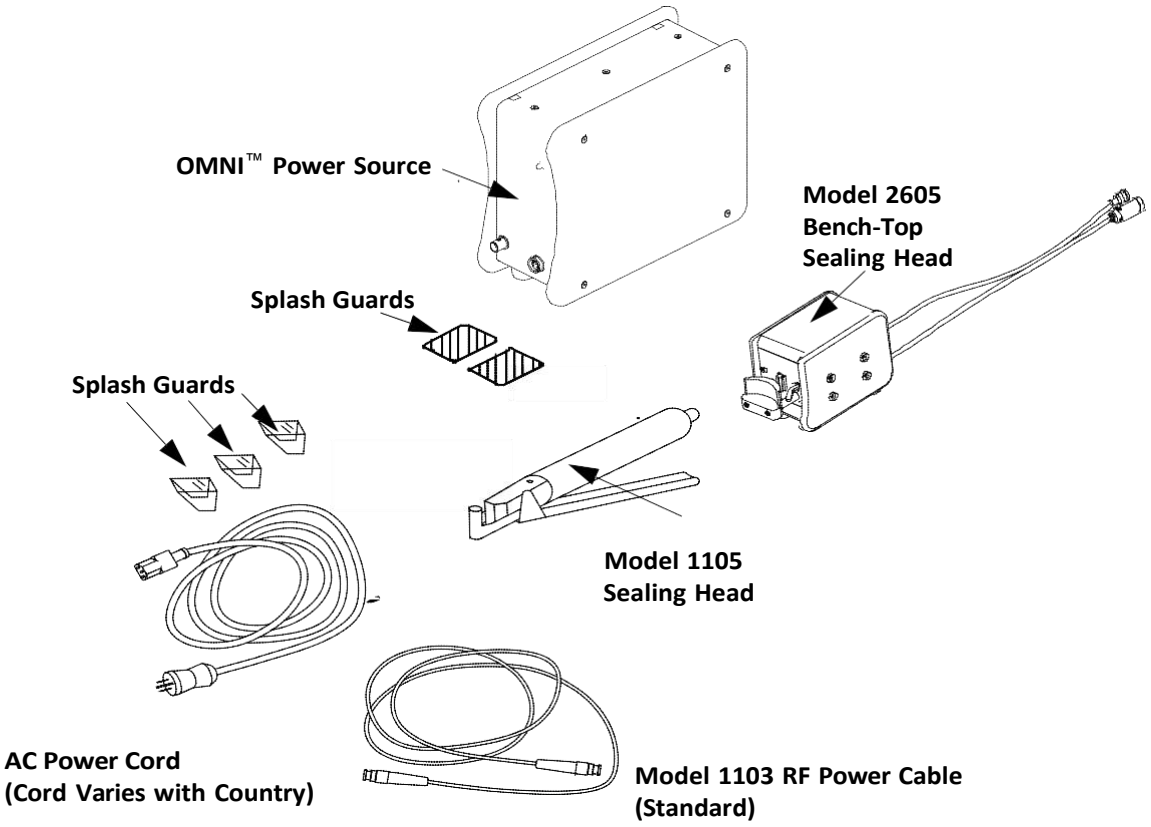

Figure 2-2, Model 2600 OMNI™ Sealer Components

Table 2-1, Power Source Component Functions

Component	Function
Model 2600 OMNI™ 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 1105 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 2605 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 1105 the sealing head jaws must remain closed until one second 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 1105 Sealing Head to the Power Source at the RF power output connector located on the front of the unit.
Model 2605 Cables	Connects the Model 2605 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.

Figure 2-3, OMNI™ Power Source Power Interface Panel, shows the power interface panel on the back of the OMNI™ Power Source. Figure 2-4, Serial Plate

Label for OMNI™ Power Source, depicts the serial plate. Each unit's serial plate (located on the rear of the unit) indicates the model number and serial number of the unit. Refer to the serial number when contacting Vante® Customer Care Center.

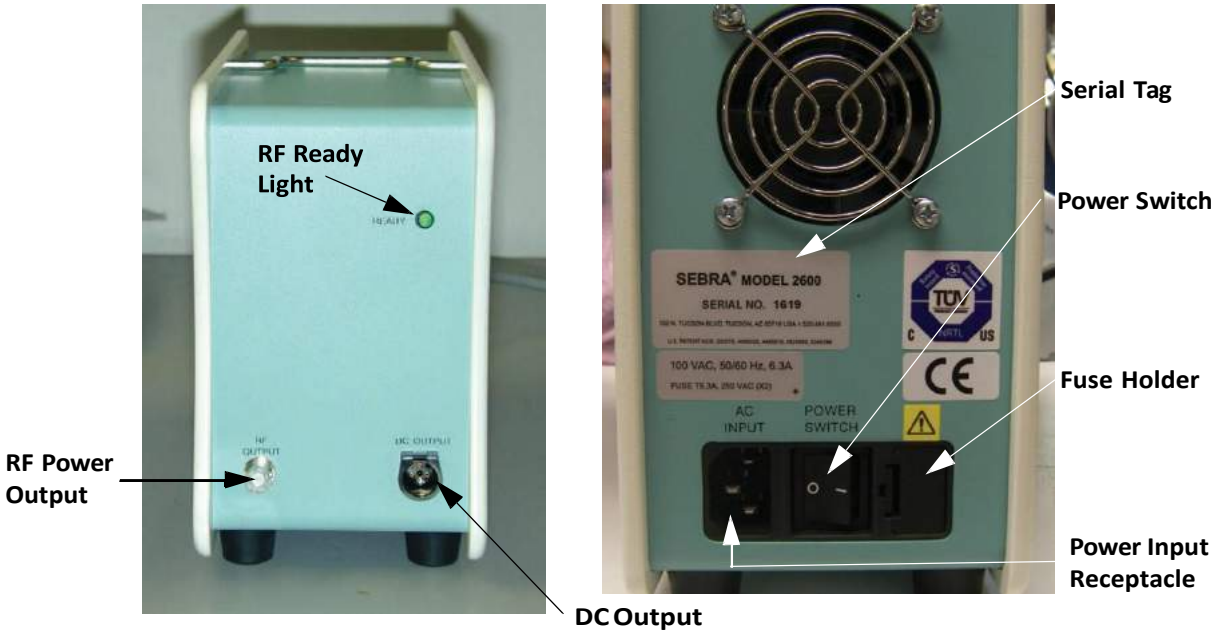

Figure 2-3, OMNI™ Power Source Power Interface Panel

Figure 2-4, Serial Plate Label for OMNI™ Power Source

Caution: *Unit equipped with dual fuses. Disconnect power cord before replacing fuses.*

OPERATING ENVIRONMENT

The OMNI™ Power Source will perform effectively when used in a typical blood bank, blood processing facility or transfusion center environment. Variations in 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 OMNI™ 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.

SEALING APPLICATIONS

The use of the Bench-Top or Hand-Held Sealing Head with the OMNI™ Power Source will determine which size tubing can be sealed. Table 2-2 describes the appropriate applications for each Sealing Head.

Table 2-2, Sealing Applications

Sealing Head	Recommended Tubing	Applications/Bag Sets
Model 2605 Bench-Top Sealing Head	Standard blood bag tubing; IV sets, transfer sets.	Segmenting.
Model 1105 Hand-Held Sealing Head	All tubing sizes.	Segmenting, component processing, apheresis units, cell wash tubing, leuko-reduction, stem cell and progenitor cell processing, manufacturing cryo-precipitate.

PVC TUBING SIZE CATEGORIES

Note: For more information regarding the types of PVC material that can be sealed, contact Vante® Customer Care Center.

Table 2-3 shows typical recommended size categories and corresponding dimension ranges of PVC tubing that can be sealed with the Power Source.

Table 2-3, PVC Tubing Size Categories

Tubing Size Category	Outside Diameter Range	Wall Thickness Range	Examples
Small	0.080-0.147 inch 2.0-3.7 mm	0.020-0.030 inch 0.5-0.8 mm	Anti-coagulant and saline drip lines
Medium	0.148-0.179 inch 3.8-4.5 mm	0.020-0.035 inch 0.5-0.89 mm	Blood bag tubing
Large	0.180-0.260 inch 4.6-6.6 mm	0.030-0.040 inch 0.8-1.02 mm	Apheresis, dialysis and cell wash sets

Note: Table 2-3 illustrates typical tubing sizes found in the blood banking 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. Contact your Vante representative for further information.

SEAL CYCLE

The Sealer "seal cycle" (or duty cycle) is defined as the time period, in seconds, between consecutive, repetitive seals. The seal cycle is approximately one (1) second or up to 1,400 seals per hour on standard blood bag tubing. The maximum seal cycle and hourly rate will vary with different types and sizes of tubing. Operating the Sealer as fast as it allows is acceptable, however, if continuously sealing at the maximum rate, 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.

Chapter 3

Power source operation

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SETUP

1. Remove the components from their protective shipping containers and visually inspect them for obvious damage. Contact Vante® Customer Care Center if any damage is found.

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

2. Connect the AC power cord to the power input receptacle located on the rear of the Power Source. Refer to the serial 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 serial 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 Vante Customer Care Center.

3. 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 off position and connect the AC power cord to the AC power receptacle.
4. 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 3-1, RF Power Cable Attachment (For Use with a Model 1105)).

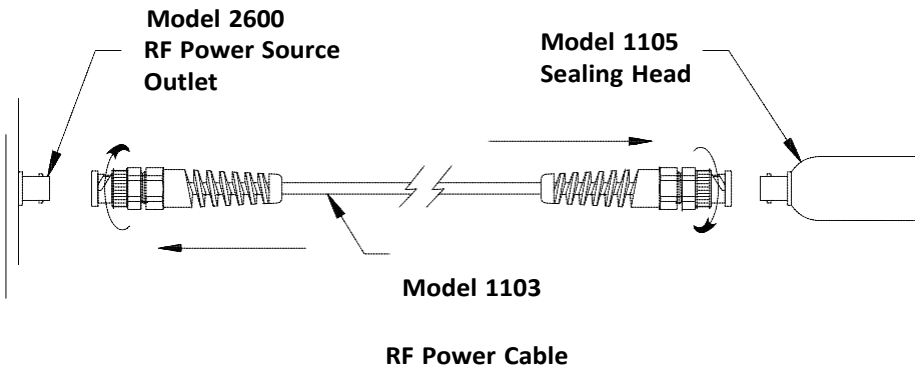

Figure 3-1, RF Power Cable Attachment (For Use with a Model 1105)

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!*

5. 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 3-2, Model 2605 Bench-Top Sealing Head Cable Attachment.

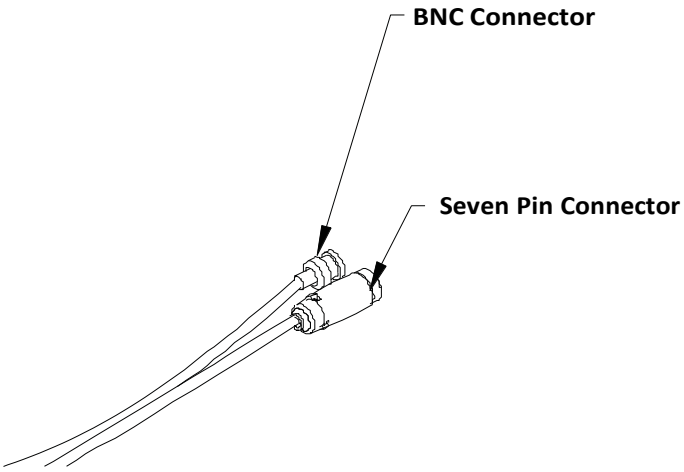

Figure 3-2, Model 2605 Bench-Top Sealing Head Cable Attachment

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!*

6. 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.
7. Turn on the unit by pushing the rocker type power switch on the rear of the Power Source to the "|" (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.

SEALING PROCEDURE WITH MODEL 1105 HAND-HELD SEALING HEAD

1. 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 3-3, Correct Technique for Holding the Sealing Head. 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.

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 blood or plasma 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.

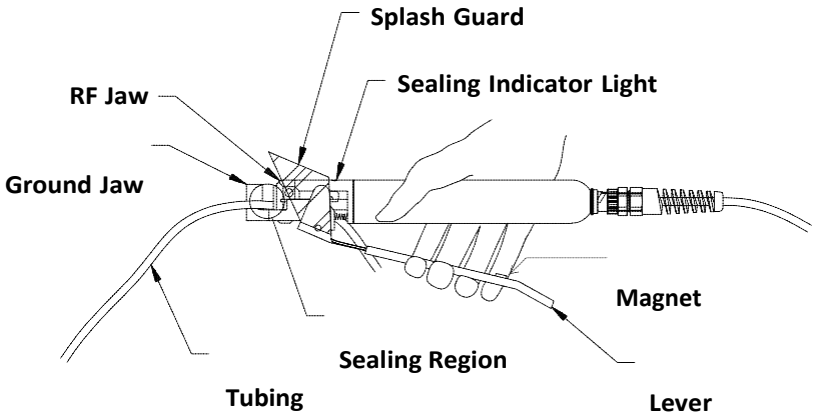

Figure 3-3, Correct Technique for Holding the Sealing Head

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

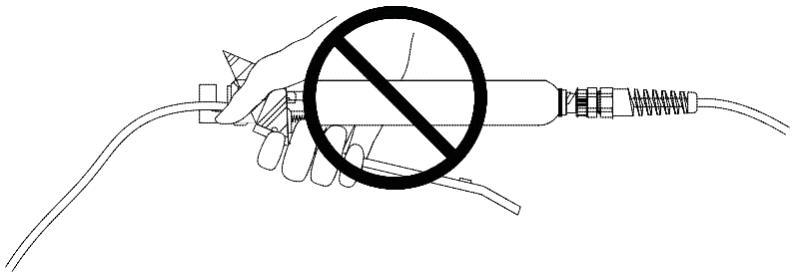

Figure 3-4, Incorrect Technique for Holding the Sealing Head

2. To make a seal, squeeze the lever until it touches the sealing head body, and hold it there (see Figure 3-5, Maintaining Compression During the Entire Sealing Process). This compresses the tubing and activates the sealing energy, visually indicated by the illumination of the sealing indicator light. *Continue to squeeze the lever until one second after the sealing indicator light completely extinguishes.* Holding the lever closed will not cause overheating or burn-through of the tubing.

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.

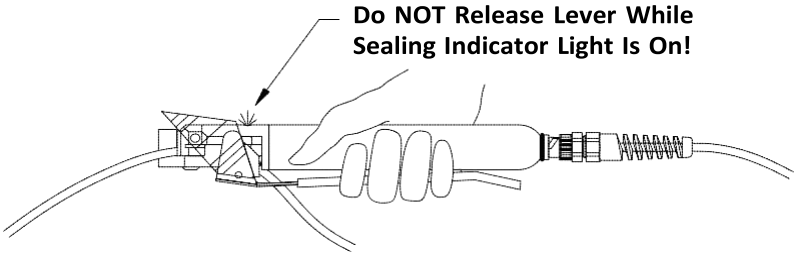

Figure 3-5, Maintaining Compression During the Entire Sealing Process

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.*

3. The seal is typically completed in one second, as indicated one second after light on the sealing head goes out. After that, the lever may be released. Another seal cannot be made until the moveable lever has been fully opened. See Figure 3-6, Releasing the Sealing Head Lever at Seal

Completion. For more information refer to the Operation Manual for the Model 1105 Sealing Head.

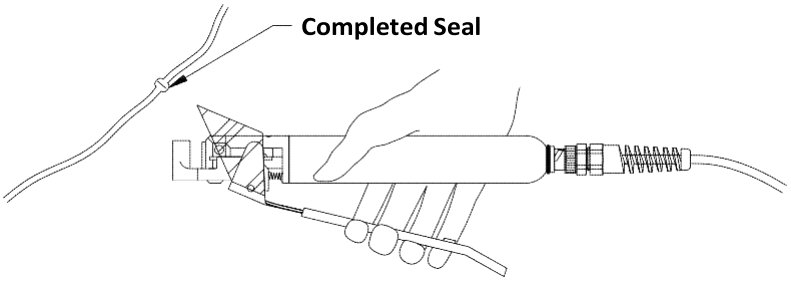

Figure 3-6, Releasing the Sealing Head Lever at Seal Completion

Note: Large cell wash tubing seals may require additional compression of the lever after the indicator light goes out to ensure formation of the best seal. Typically, this will result in a seal time of 1½ seconds.

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 hemolysis, 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 Chapter 4, Table 4-1, "Troubleshooting Guide," on page 4-3 under "Arcing or Bad Seals." Although a seal made when you experience arcing may look acceptable, it may be inadequate for centrifugation. 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 blood or plasma 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.

SEALING PROCEDURE WITH MODEL 2605 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.

1. 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 3-7, Correct Sealing Method. 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.

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 blood or plasma 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.

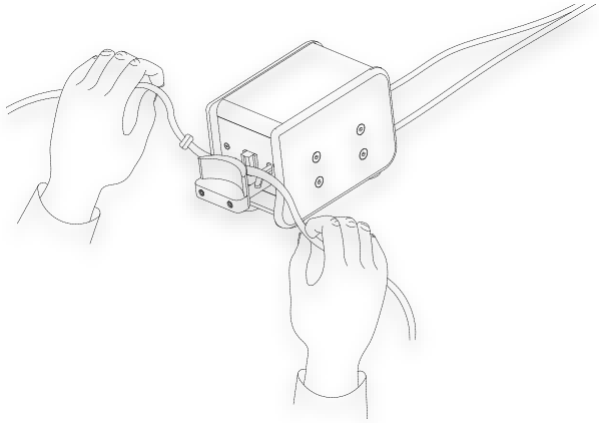

Figure 3-7, Correct Sealing Method

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 3-8, Incorrect Sealing Method

2. 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.
3. To make another seal, lift the tubing up to release the trigger and push the tubing to the next seal position (see Figure 3-9, Repeating the Seal Process). 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 operation manual for the Model 2605 Sealing Head.

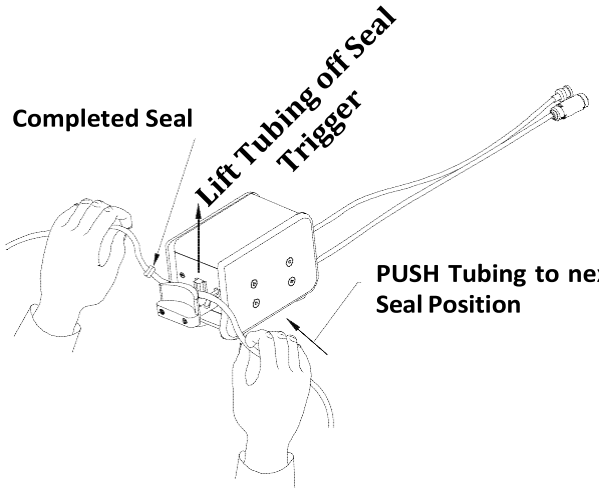

Figure 3-9, Repeating the Seal Process

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 blood or plasma 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 Seal spacing on page 3-10.

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 for centrifugation. 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 hemolysis, 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.

SEAL SPACING

Note: The Sealer is designed to allow repetitive seals to be made on a length of tubing filled with blood or blood products. However, several factors control how closely the seals may be spaced. For standard blood bag tubing, follow the instructions provided by the bag manufacturer.

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

Seals that progress along a **close-ended** length of tubing, as in a segmenting process, must be spaced no less than the blood 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 3-10, Multiple Seal Spacing.

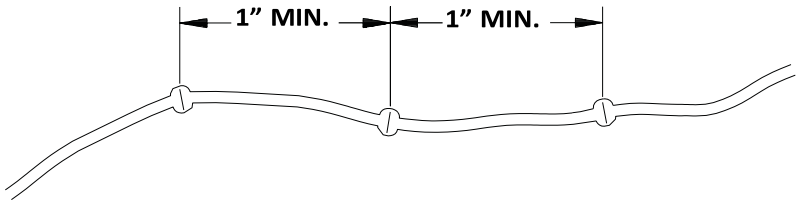

Figure 3-10, Multiple Seal Spacing

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

Chapter 4

Maintenance

P/N VT-108731-IE, Manual revision: B

CLEANING OMNI™ POWER SOURCE CASE

Caution: *Because the OMNI™ 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.*

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.*

Note: Other than periodic cleaning, or when moisture, blood, or other contaminants are visible, 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.

1. 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.
2. Apply a cleaning solution made from a mild detergent or household cleaner (such as Formula 409®) and water (NO BLEACH) 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.

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. Vacuum the fan area to remove dust or other build-up from the area.

TROUBLESHOOTING

Table 4-1, Troubleshooting Guide, offers diagnosis and actions for many commonly reported problems. For any problems or failures not listed, please contact the Vante® Customer Care Center.

Table 4-1, Troubleshooting Guide

Problem	Diagnosis	Action
Not sealing.	No power to Power Source.	Ensure all connections are correct (refer to Chapter 3. Ensure the AC power switch is in the "|" (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 Vante Customer Care Center if using a Bench-Top Sealing Head.
	Problem with Sealing Head.	See Sealing Head Operation Manual.
	Blown Fuses.	Ensure the fuse(s) is (are) not blown. See Chapter 5 if the fuse requires replacement.
	Component failure.	Contact Vante Customer Care Center.
Arcing or bad seals.	Contaminated sealing area.	Clean sealing jaws (see Sealing Head Operation 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 prior to releasing the Hand-Held sealing head lever.
	Misuse of sealing head.	Ensure the sealing head is being used properly (see Sealing Head Operation Manual). Ensure tubing for blood and blood products (usually PVC) is being used. 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 Operation Manual). If not aligned, contact Vante Customer Care Center.

Chapter 5

Failure isolation

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FAILURE ISOLATION

Caution: *To avoid problems with the OMNI™ 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 Vante® Customer Care Center for evaluation and repair.

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 "**|**" (on) position, then the fuse *may* need replacement.

1. Turn the AC power switch to the "**O**" (off) position and disconnect the AC power cord from the AC outlet and Power Source.
2. Release the fuse holder slide latch by inserting the end of a flat blade screwdriver into the detent as shown in Figure 5-1, Releasing Fuse Holder Latch. Pull the fuse holder slide out until it stops and the fuse is exposed.

Figure 5-1, Releasing Fuse Holder Latch

3. 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!*

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

CUSTOMER SERVICE

Services

Clinical training

The local Vante representative will provide staff training upon delivery of the equipment and should be contacted to organize further instruction if needed.

Repair service

Vante maintains a worldwide network of company-trained service representatives responsible for responding to technical needs concerning equipment. If service beyond the routine maintenance and cleaning described in this manual is required, the local Vante representative should be contacted to provide specific instruction.

Product return guidelines

If, for any reason, merchandise must be returned to the company, the customer should contact the local Vante representative to arrange for repairs or returns using procedures to ensure proper handling and subsequent analysis. No returns will be accepted without advanced authorization.

Warning: Vante products must be properly cleaned and packaged prior to their return. It remains an important responsibility of the customer to reduce potential health hazards by being aware of the risks involved in the shipping, handling and testing of this material. Units returned to Vante for repair are subject to biohazard charges if any component is contaminated with blood or blood products.

Chapter 6

Radio frequency system safety considerations

GENERAL INFORMATION

Vante manufactures a variety of instruments that incorporate the use of radio frequency (RF) for sealing, welding, or forming thermoplastics. Typical uses include the sealing of blood bag and apheresis tubing, and plastic welding or forming manufacturing 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 Interna- tional Telecommunications Union (ITU) for industrial, scientific, and medical (ISM) use. The following is an advisory regarding RF instrument use and associated safety considerations.

RF effects on human tissue

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

RF effects on pacemakers

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

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.

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.

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.

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

Chapter 7

Reference information

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APPENDIX A: EMC STANDARD REQUIREMENTS

Caution: *The Model 2600 device must be operated in an environment in accordance with the guidance given in IEC 61326 Standard, Electrical equipment for measurement, control and laboratory use – EMC requirements.*

Operation precautions

Mobile radio frequency (RF) communication equipment not approved by Vante and portable communication equipment can affect the system. Any accessories and cables not approved by Vante used in conjunction with the device may increase hazards and influence compatibility with EMC requirements. Therefore, non-approved accessories and cables must not be used.

In addition, the Model 2600 device and accessories must not be placed directly adjacent to, or on top of other equipment, unless specifically approved by Vante.

Electromagnetic immunity

Note: The Model 2600 device is intended for use in the electromagnetic environment specified below. The customer or operator of the Model 2600 device should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 2	The Model 2600 system must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The Model 2600 system is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

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