

MODEL 3120

200 Watt RF Generator

Vante®

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

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

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Preliminary Information

Document Scope

This manual is intended as a guide for the setup, adjustment and operation of the Model 3120 RF Generator (hereinafter referred to as "the RF Generator". The information contained herein is based upon technical data that have been verified by Vante® and is believed to be adequate for the intended use of the product.

Intended Audience

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

Application

The Model 3120 RF Generator produces radio frequency (RF) to be used by a sealing head (such as the Model 3806 mid-size Tube Sealer) for making seals on tubing made of RF-reactive thermoplastic materials such as polyurethane, polyvinylchloride (PVC), Ethylene vinyl acetate (EVA), certain types of nylons and certain coextrusions. Tubing may be filled with liquid; however, the outside of the tubing must be clean and dry. Sealing is not recommended for flammable liquids or hazardous materials.



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



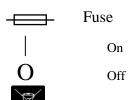
Caution, risk of electric shock



Caution (refer to accompanying documents)



Protective Earth (P.E.)



WEEE – Indicates electronic equipment requiring proper recycling (EU 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. Vante® assumes no liability or obligation nor guarantees product performance.

Proprietary Information

All rights are reserved. Copying of the protected designs associated with the Model 3120 is strictly prohibited without the prior written consent of Vante®.

References

1. *Medical Device Quality Systems Manual*, 1st edition, CDRH December 1996, U. S. Department of Health and Human Services.

CE Mark Information

For inquires 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).

Table of Contents

Prelim	inary Iı	nformation	V
	Intend Applie User A Safety Exclus Propri Refere CE M Table	ment Scope led Audience cation	V vi vi vi vi
1.	Descri	iption The RF Forming/Welding System	
	1.2 1.3 1.4	Theory of Operation User Safety Controller Interface	1 2
	1.5 1.6	Specifications	
2.	System	n Setup	7
	2.1 2.2	Installation	
3.	Maint	enance and Repair	9
	3.1 3.2	System Maintenance	
4.	Radio	Frequency System Safety Considerations	11
	4.1 4.2 4.3 4.4 4.5 4.6	Introduction	11 11 11

Table of Figures

Table 1.1 Control Port Pin Out	.3
Figure 1.1 Model 3120 RF Generator Front View	.4
Figure 1.2 Model 3120 RF Generator Rear View	.4
Figure 1.3 Serial Plate	.5
Figure 1.4 Fuse Labels	5

1. Description

1.1 The RF Forming/Welding System

- 1.1.1 The Model 3120 RF Generator is the foundation of a system used to perform sealing, forming and/or welding operations of RF reactive thermoplastic materials. It must be interfaced to various other components in order to create a system that performs the required operation. Paragraphs 1.1.2 through 1.1.5 describe, to a great extent, the possible ways in which a system is designed and assembled.
- 1.1.2 The unit may, or may not, be controlled by an external programmable logic controller which can be provided by Vante®, or the customer may provide his own control. An interface cable may be required, with the generator end being a 15 pin male D sub-miniature connector. A control board may be utilized within the sealing/forming/welding head in some applications, in which case an interface cable may not be required. The controller is activated either manually by a foot switch, which Vante® can provide, or by other means.
- 1.1.3 A matching network, provided by Vante®, is required and may be integrated into the forming or welding head.
- 1.1.4 The head itself may be designed and manufactured by Vante®, or the customer may design and manufacture his own in close association with Vante® 's engineering department so that it interfaces properly, both mechanically and electrically, with the matching network.
- 1.1.5 All necessary components (controller, coaxial cable, interface cable, foot switch, matching network, forming/welding head, control board, etc.), when supplied by Vante®, are provided at additional cost.

1.2 Theory of Operation

- 1.2.1 The physical properties of RF-reactive thermoplastic materials cause them 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 weld will be permanent.
- 1.2.2 The RF Generator is the instrument that produces, when actuated, a controlled amount of RF energy. The Sealer mechanically compresses the tubing across its diameter during the sealing and forming process. When the energy is removed and the tubing is allowed to cool under compression, a permanent seal is produced.

1.2.3 The RF Generator produces variable RF power at a minimum of 150 watts, the frequency of which is controlled by a solid-state oscillator/amplifier operating at 40.68 mHz. The RF power level, dwell time, and clamp time can be adjusted by the operator, allowing various tubing sizes and materials to be accommodated.

1.3 User Safety

- 1.3.1 The Sealer is intended for use by personnel trained by their organization for using RF equipment to seal or weld plastic tubing or parts in a controlled environment.
- 1.3.2 Vante® RF Sealers meet or exceed appropriate electrical safety standards and pose no electrical shock hazard when used with properly fused and grounded outlets. Reference, "Radio Frequency System Safety Considerations" section included at the end of this manual.

WARNING: Sealing is not recommended for tubing containing flammable liquids or hazardous materials.

1.3.3 The Model 3120 Generator has a thermal protection circuit which will cause the unit to shut down if internal temperatures exceed 55°C. After a short period of time (when internal temperatures are below 55°C) the generator will reset and operation can resume.

1.4 Controller Interface

1.4.1 When required, the control port is located on the front of the Generator and is a 15 pin female D sub-miniature connector. Refer to Table 1.1 for pinout connections.

1.4.2 The following chart lists the control port pinouts.

PIN	CONNECTION
1-6	NO CONNECTION
7	RF ENERGIZED SIGNAL (+12 VDC WHEN RF POWER IS ON)
8	RF COMMAND (GROUNDING CAUSES RF TO TURN ON)
9	GROUND
10	NO CONNECTION
11	CONSTANT +24 VDC SUPPLY
12	GROUND
13-15	NO CONNECTION

Table 1.1 Control Port Pin Out

1.5 Specifications

1.5.1 Mechanical:

Size (H x L x W) 4 in x 17 in x 12 in (10 cm x 43 cm x 30.5 cm)

Operating Weight 27 lbs (12.3 kg)

Shipping Weight 30.5 lbs (13.8 kg)

1.5.2 Electrical:

Power Input 100-230 VAC 6.3A 50/60 Hz

RF Power Output Variable

200 W minimum, at maximum output setting

Main AC Power Fuses 2 x 250 VAC, 5 x 20 mm T6.3A

Booster/Driver Fuses PCBA Board, F1, F2, F3

3 x 250 VAC 2 AG/3A

NOT USER REPLACEABLE

1.5.3 Operating temperature and humidity (generator only):

8 - 38°C @ 90% maximum relative humidity, non-condensing

1.6 Component Identification

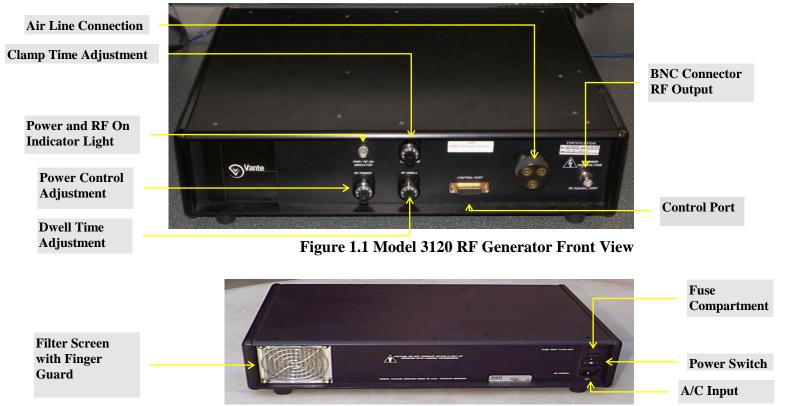


Figure 1.2 Model 3120 RF Generator Rear View

- 1.6.1 Figure 1.3 depicts the serial plate which specifies the power input requirements for the model. Each unit's serial plate indicates the model number and serial number of the unit.
- 1.6.2 Refer to the serial number when contacting Vante® or one of its authorized service centers.

Vante

MODEL 3120 SERIAL NO. XXXX

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

Figure 1.3 Serial Plate

100-230 VAC, 50/60 Hz, 6.3A

FUSE 6.3A, 250 VAC (X2)

Figure 1.4 Fuse Label

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2. System Setup

2.1 Installation

- 2.1.1 Remove the RF Generator and all other Vante® components from their respective shipping cartons and visually inspect them for obvious damage. Contact Vante® if any damage is found.
- 2.1.2 Check to see that the power cord plug matches the power receptacle for the country in which the system is being used. If it does not, contact Vante®.

CAUTION: Do not connect the power cord to AC mains at this time.

2.1.3 Verify that all connections are correct before proceeding.

2.2 Adjustment and Operation

WARNING:	Do NOT place fingers or any other objects near or between the
	electrodes in the forming/welding head when the generator RF
	power is on. Severe burns or damage to the electrodes can occur!

- 2.2.1 Verify the AC power switch is in the "off" position and connect the AC power cord to any nominal ac voltage in the 100 230 Vac range.
- 2.2.2 Turn the RF Generator on by toggling the rocker switch located on the back of the unit. The power-on light will illuminate green, indicating that power is on. The power-on light will be amber when RF energy is being produced. The fan in the back of the Generator will begin to operate. The Generator requires no warm-up period due to transistorized electronics design.

NOTE: Vante® may recommend initial control settings for start-up purposes only; however, the user is responsible for determining the proper control settings for particular applications.

2.2.3 Set the control settings and air pressure to the appropriate level for the desired application. RF dwell time should be no longer than necessary to make a good seal or weld.

CAUTION: Excessive RF dwell time may cause permanent damage to the Generator.

WARNING: Sealing is not recommended for tubing filled with flammable or other hazardous materials.

- 2.2.4 Be sure that the materials to be sealed, formed or welded are clean and dry. Perform the operation and evaluate the result.
- 2.2.5 Adjust the power, dwell time and/or air supply settings, if applicable, as needed to obtain the desired seal/form/weld quality. Only slight adjustments to the recommended setting should be required.
- 2.2.6 Once the desired result is obtained, continue to perform the sealing, forming or welding operation as needed.

NOTE: The RF Generator is equipped with a thermal protection circuit which will cause the unit to shut down if unusually high levels of usage occur or tuning is mismatched. In such case, the power-on light on the front of the panel will remain illuminated, the fan will continue to run, but there will be no RF power output. Wait several minutes for the unit to cool and proceed with sealing/forming/welding operations at a rate that will not cause generator shutdown. If problem persists, contact VanteTM for other possible solutions.

3. Maintenance and Repair

3.1 System Maintenance

3.1.1 The only maintenance required for the model 3120 RF Generator is keeping the fan intake filter and air exhaust ports free of accumulated dust to ensure proper airflow.

WARNING: Turn off the Generator and disconnect the sealer by removing all connectors prior to cleaning. Failure to do so may result in an RF burn to the operator during the cleaning process.

3.2 Repair

- 3.2.1 The replacement of a fuse, located in the AC input receptacle on the back of the unit, is a rare occurrence. If the unit is plugged into an AC power source and the AC power-on light is not illuminated when the rocker switch is in the on position, then one of the fuses *may* need replacement.
- 3.2.2 To access the fuse compartment the AC cord must be unplugged. Release the fuse holder slide latch by inserting the end of a flat blade screwdriver into the detent and sliding the fuse holder out until the fuses are exposed (Figure 1.2).
- 3.2.3 Examine the fuses and replace as required. If the fuses are not blown, check again to be sure all other connections are correct. *Be sure to replace fuses with one of the specified rating!* If fuses continue to blow, contact Vante®.
- 3.2.4 For all other questions and/or problems, call Vante® directly at 520-881-6555 or 877-565-5557.

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

Vante® Model 3120

4. Radio Frequency System Safety Considerations

4.1 Introduction

4.1.1 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.

4.2 RF Effects On Human Tissue

4.2.1 Vante® RF instruments are in compliance with (IEEE) C95.1-1991, standards for safe exposure levels to RF energy. However, misuse or direct contact between tissue and RF electrode(s) can result in severe RF burns.

4.3 RF Effects On Pacemakers

4.3.1 There is no evidence that Vante® RF instruments interfere with the function of modern cardiac pacemakers. However, as a precaution, Vante® recommends that RF sealers not be operated in a continuous, rhythmic duty cycle within an eight-foot radius of an individual wearing a pacemaker.

4.4 Electrical Safety

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

4.5 RF Effects On Electronic Equipment

4.5.1 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.

4.6 RF Effects In Potentially Explosive Atmospheres

4.6.1 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.