



English

RITA® UniBlate™ Electrosurgical Device

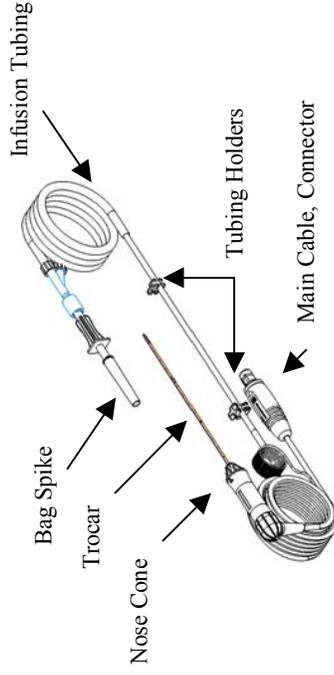
CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. Read all instructions carefully before use.

INDICATIONS FOR USE:

To be used in conjunction with the RITA 1500X RF Generator and IntelliFlow Infusion pump for the ablation of soft tissue.

DESCRIPTION:

UniBlate consists of an insulated primary trocar with two infusion holes and a temperature sensor positioned at the distal end. The UniBlate is designed to fit in a CT gantry, is available in 10cm, 15cm & 25cm lengths and has an integrated main cable and tubing set.



WARNINGS:

- The distal 4 mm of the device is NOT Radio opaque and will not appear under CT imaging.
- If the Tubing Set becomes occluded, improper or unpredictable lesion size may result.
- Do not attach anything (i.e., clamps, etc.) to the device. This may damage the insulation, which could contribute to patient injury.
- Patients with peripheral vascular deficiency are at increased risk of thermal injury from Dispersive electrodes.
- Patients with frail skin are at increased risk of skin damage from the adhesive on the Dispersive pads.

PRECAUTIONS:

- Do not bend or kink the trocar. This may cause damage and result in a non-functional device
- If the device is being used in a laparoscopic procedure, care must be taken to avoid a gas embolism.
- If the device is being used in a laparoscopic procedure, activation of the device when not in contact with target tissue may cause capacitive coupling.
- Having RF power on at the same time as infusion using a method different from these instructions may alter the path of the electrical energy away from target tissues.

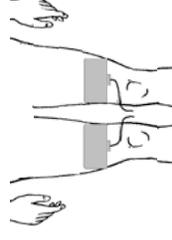
EQUIPMENT LIST:

- RITA Model 1500X Generator with software version v8.50 or higher.
- RITA Dispersive electrodes PN 700-102254 or
- RITA ThermoPad PN 700-102649 with adaptor cable PN 700-102648
- IntelliFlow Pump PN 700-102941
- Sterile 0.9% normal injectable saline solution (at least 250 cc bag required)

INSTRUCTIONS FOR USE:

The following is the recommended procedure for operating the UniBlate device.

1. Review and become familiar with the operation of the 1500X RF Generator and the IntelliFlow Pump. Refer to the instructions for use accompanying each product.
2. Inspect all devices and packaging for damage prior to use. Do not use any devices that are damaged or if the sterile barrier is breached. Do not use IntelliFlow Pump or RF Generator if either of them have been dropped or damaged.
3. Apply the Dispersive Electrodes according to the device's instructions. Place ThermoPads on a well-vascularized, muscular site¹ at least 25 cm from the ablation site. Electrode gel should not be used.



Avoid placement in areas where liquid may pool, under thermal blankets, and in areas where heat may be retained, e.g., under blankets or positioning bags. If a patient warming device is used, turn it off prior to the ablation. If leg/circulation compressors are used, use calf-length devices.

4. Connect the Dispersive Electrodes to the RF Generator. Ensure that any other dispersive electrodes used (for example, ECG electrodes or those used with an

¹ S. Nahum Goldberg, Luigi Solbiati, Elkan F. Halpern, G. Scott Gazelle. "Variables Affecting Proper System Grounding for Radiofrequency Ablation in an Animal Model." JVIR. 11:1069-1075, September 2000

electrosurgical cutting device) are NOT placed between the ablation location and the Dispersive Electrodes. (For example, when ablating in the liver, do not place the other electrodes on the buttocks. Instead, consider placing the other electrodes on the back of the arm).

5. Using sterile technique, open the UniBlate packaging tray and carefully remove the device.
6. Inspect the UniBlate's pre-attached tubing set prior to use. Do not use the device if the tubing set has any evidence of damage (e.g. kinks, cracks, etc.).
7. Connect the UniBlate's integrated Main Cable to the RF Generator's Device plug. Verify that pins of the connector and plug are not bent before continuing.

Note: The cable connectors are keyed to match the mating connector of the generator. Therefore, attaching the Cable to the RF Generator requires minimal force. If force is required, you may be incorrectly connecting the cable to the Generator damaging the pins in the process.

NOTE: For pump and generator operation and use of the entire system refer to the IntelliFlow Pump Instructions for use and the 1500X User's Guide.

IntelliFlow Pump set up

8. Obtain a minimum of 250 cc bag of sterile 0.9% normal injectable saline solution.
9. Remove cap on Tubing Set spike and insert spike in the saline bag.
10. Hang the saline bag on the IV pole mounted on the IntelliFlow Pump.
11. Gravity purge the system of all air bubbles by allowing fluid to free flow through system to the black tubing holder.
12. Load the tubing set on the Occlusion Bed of the IntelliFlow Pump with the black tubing holder towards the device and the white towards the saline bag as shown per the diagram below.



PRECAUTION: Ensure that the tubing follows only one groove in the occlusion bed or latching the pump will pinch the tubing.

13. Latch the occlusion bed.
14. Connect IntelliFlow Pump to the RF Generator per the pump's instructions for use.

Generator set up

15. Turn on the generator. The generator will run a self test. Press the RF ON/OFF button and the generator will be in the Purge mode.

16. Verify that the Device's temperature sensor is functioning by holding the trocar tip between your sterile, gloved finger and thumb. The temperature reading on the RF Generator (temp 5) should increase. If it does not, check connections and try again.

17. Prime the tubing set while in Purge mode by pressing the "A" button once to begin the purge of air. Once the air is purged and a continuous flow of saline leaves the tip of the trocar, press the "B" button once to stop the purge process.

18. Press the CONTROL MODE button once. Generator's display should read "UniBlate".

19. If using an introducer system, ensure that the **insulated** introducer is from RITA Medical Systems, Inc. Refer to the introducer system instructions for use for introducer placement instructions.

Device Size	Hard Introducer	Soft Introducer
10 cm	NA	NA
15 cm	6 cm, PN 700-102330	10 cm, PN 700-102636
25cm	6 cm, PN 700-102330 11 cm, PN 700-102331	10 cm, PN 700-102636 13 cm, PN 700-102637

20. Adjust the device for the desired exposed electrode length (1cm to 2.5cm) by rotating the nose cone of the device. See Table 1. Area shows ablation zone.

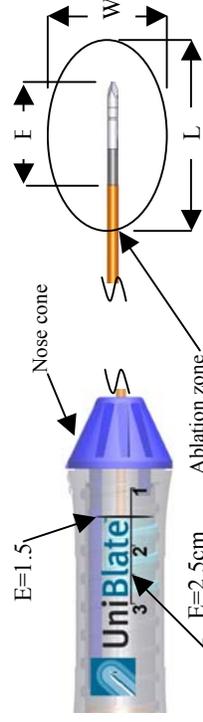


Table 1, Liver Ablation Settings with Infusion

(W)	(L)	(T)	(E)
1.0	1.0	1.5	1.00
	1.5	1.5	1.50
	2.0	2.5	2.00
1.5	2.5	3.5	2.00
	3.0	4.0	2.50
	1.5	4.5	1.00
2	2.0	4.0	1.50
	2.5	5.5	2.00
	3.0	5.0	2.50
2.5	2.0	7.5	1.50
	2.5	9.0	2.00
	3.0	9.0	2.50
2.5	3.0	15.0	2.50

L=Target ablation length, W=Target ablation width, T=time, E=Exposed Electrode Length

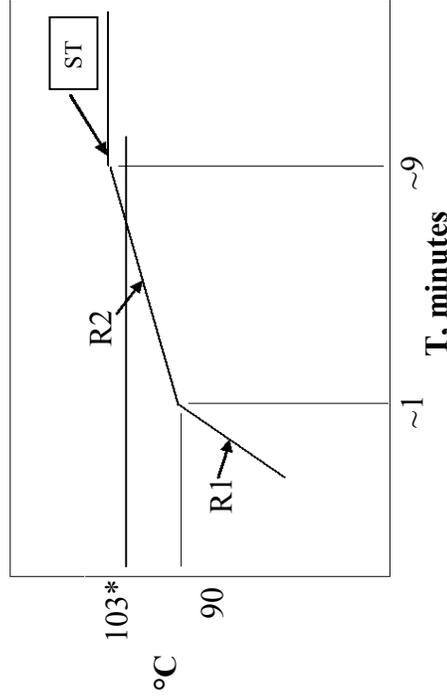


Figure 1, UniBlate Default Algorithm

R1 = Ramp 1 = 1.3°C/second

R2 = Ramp 2= 1°C/37 seconds

ST = Set Temperature

* = Default Set Temperature

- Using imaging guidance (e.g., ultrasound, CT) place the Device into the target tissue. The tip of the trocar should be placed at the distal edge of the lesion. Using the 1-cm markings on the Trocar can assist in placement of the device.

Note: The ablation will grow beyond the trocar tip according to Figure 2.

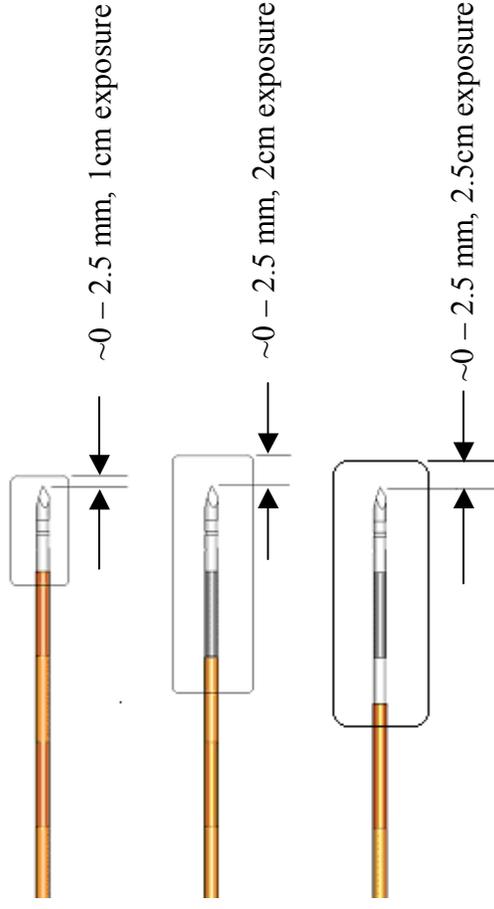


Figure 2, Ablation Growth

- Verify position of the device with imaging (e.g., ultrasound, CT).
- Adjust the RF time using the up/down arrows according to Table 1 based on the desired length and width of the ablation taking into account margins. Default RF time is 15 minutes, but default time and electrode exposure may not provide the desired ablation size. This adjustment of RF time prior to starting RF will set the default RF time for the next ablations. RF time adjustments during a procedure will not adjust the default.
- RF set temperature defaults to 103°C. Modifying the set temperature will offset the endpoint of the first ramp shown in Figure 1 by the number of degrees different from the default setting, e.g. a 100°C set point will drop the endpoint of the first ramp from 88°C to 87°C.
- Depress the foot pedal or the RF ON/OFF button on the Generator. RF power will begin to increase until target temperature is reached. Power is defaulted to 30 Watts.
- The RF power will turn off after target temperature has been maintained for the time the user has set in step 23.
- Confirm that the 30 second cool down temperature is 60°C or greater. If not then turn on RF power for an additional 5 minutes

28. If desired, Track Ablate using 20 - 50 W can be performed during removal of the trocar (generator defaults to 20 W).
29. Turning RF ON and OFF. If the user turns off the RF during the procedure, and then subsequently turns the RF back on, the generator will use Ramp 1 (1.3°C per second) to reach whatever setpoint the generator had been stopped at during the Ramp 2 (88°C to 101°C), and then will resume Ramp 1 to reach the target temp of 101°C. The timer will not re-start until the new setpoint temp has been reached.

Prior to additional ablation:

- Verify the continuous flow of fluid from the trocar tip between each ablation.
- Gently remove any accumulated tissue from the device with wet gauze.
- If device is removed prior to cool down, Set Temp and RF time may be reset by pressing the Mode button placing the generator into infusion mode and back to UniBlate Mode.

TROUBLE SHOOTING GUIDE

Temperatures are not rising:

- If temperature has not risen for 2 minutes, and power is stable or declining, retract the trocar ½ cm.

Infusion holes are occluded:

- If a hole or holes are occluded, turn off the RF energy and check that the fluid tubing has not become kinked, pinched or clamped.
- If a hole becomes fully occluded with tissue, gently wipe the device with sterile gauze or soak the device tip in hydrogen peroxide.
- The nominal pump infusion rate will be 0.20 ml/minute. If an impedance event occurs (an impedance rise over 400 ohms), the pump rate will be increased to 0.30 ml/minute and then again to 0.40 ml/minute. The infusion rate will not exceed 0.40 ml/minute, and over time will be reduced to 0.20 ml/minute if there are no subsequent impede-out events. The display will show, “INFUSING, POWER ON IN 11 seconds” when event occurs. If the infusion rate remains at 0.40 ml/minute, the generator will add 3 minutes to the Set Time and turn off when the RF time counts down to zero and display, “ABLATION DONE.”
- If “UNKNOWN DEVICE” is displayed, ensure the software is v8.50 or higher.
- If “NO DEV” is shown on the LED, the device is not plugged in.

- Refer to the 1500X User Manual for additional trouble shooting information

SPECIFICATION

- Generator power output curves can be found in The Model 1500X Generator User Guide and Service Manual P/N 160-102929, Figures 1 through 4.
- The UniBlate device is MR Compatible for MR systems operating at 1.5 Tesla or lower.

RETURNS

- Defective devices may be returned to RITA Medical Systems, Inc.
- RITA Medical System’s Customer Service should be contacted for all returns.

REF	Catalog Number
	Use By
	Sterilized Using Ethylene Oxide
	Attention, consult accompanying documents
	Do Not Reuse
	Lot Number
	Latex Free
	

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