

공 고 규 격 서

[Commodity Description]

품 명	영상유도의료용고주파열상발생기		
	Radio-Frequency Lesion Generator		
수 량	1 set	KFDA 분류번호(등급)	A35040.01(3)

A. Features

1. G4 Radiofrequency generator independently and automatically controls up to four electrodes at once, in monopolar or bipolar mode, with thermal RF or pulsed RF (DOSE PRF) output. Multiple independent supplies and patent-pending multi-ouptut technology.
The G4 RF incorporates the most modern and advanced electronic design, making it more functional, reliable, and safe. Radiofrequency Products for Neurosurgery and Pain Therapy.
2. 4 RF Outputs : Thermal and Pulsed RF treatment on 1, 2, 3, 4 Electrodes, Independent.
3. Bipolar RF Coagulation Mode – 1 or 2 pairs of electrodes
4. 12-inch Full Color touch screen : 12" display with large-format numerals, visible form a distance
Intraoperative electrode testing.
5. The Impedance, Stimulator, RF Output, Timer, and Temperature controls are located logically from left-to-right on the front panel with large color-coded digital displays.
6. Personal Settings Presets : Load stored procedure settings, doctor and patient information. Patient and doctor presets, electronic record keeping, Save up to 20 users setting data.
7. Settings for Electrode Setup, Stimulation, Thermal RF, and Pulsed RF
8. Doctor Information
9. User Interface : Graphing Interface or One Touch Interface
10. Doctor Presets : Store hundreds of procedure settings for multiple doctors.
11. Patient Database : Store patient names, IDs, DOBs, and notes. Recall on repeat appointments.
12. Impedance Graphing – Real-time graphing
13. Push-button adjustment of the automatic set temperature during RF lesioning
14. Automatic stagger start : Simultaneous or stagger start of RF electrodes
15. Automatic or manual stagger start to identify problem placements
16. Simultaneous start for speed
17. Automatic Stimulation : Choose slow or instant-on ramp rate & Stimulation control with knob or screen.
18. Three control options : automatic, knob, or touch screen.
19. Ramp speed : individual auto ramp speeds for sensory and motor testing
20. Stimulation log : true log of sensory and motor testing levels
21. Two Interfaces for Customized Needs : your choice of a 2 interface, and large color-coded displays
22. One Touch interface :
Simple, digital, Very large displays, Simplified touch screen controls, Useful in a busy practice.
23. Graphing interface :

Advanced, graphical, Graph temperature and voltage, Knob or touch screen control,
Useful for advanced treatments

24. Pulsed RF E-dose control : The Pulsed RF mode (Auto E=dose pulsed RF) treatment of neuropathic pain while virtually eliminating the possibility of neuritis.
25. E-dose pulse RF - Automatic control of pulse settings to optimize nerve exposure to the electric field.
26. Automatic temperature control - automatically adjusts power to maintain selected tissue temperature.
27. Stagger Start : Electrodes turn on sequentially, spaced in time by this value.
28. Standard Mode : Control Temperature and Time for each electrode.
29. Individual Electrode Selection :
Thermal RF output consists of an RF waveform, and is delivered to all selected electrodes.
30. Continuous display of the wattes, volts, and milliamps when lesioning.
31. Stereotactic Brain Neurosurgery : CRW / Leksell stereotaxic System Compatible.
32. Self-Test : Output Test Plug plugs into the output jack and simulates a test load to check RF heating and temperature controls.
33. Print or export procedure record. Or save on G4 for later export. Settings, patient information, and procedural data can be digitally captured, charted, compiled, and printed by using Real-Time software which links the RF Generator.

B. Specifications

1. ELECTRICAL SUPPLY
 - 1) Mains AC Voltage Selection : 100 Vac, 120 Vac, 220 Vac, 240 Vac
 - 2) Frequency : 50/60 Hz
2. ENVIRONMENT OPERATING RANGE
 - 1) Temperature : 15 °C to 40 °C
 - 2) Humidity : 15 – 80% non-condensing relative humidity
 - 3) Atmospheric Pressure : 500 – 1060 hPa
3. IMPEDANCE MONITOR
 - 1) Range : 0 – 3000 ohms digital
 - 2) Resolution : 1 ohm between 0 – 999 ohms, 100 ohms between 1000 – 3000 ohms
 - 3) Accuracy : ± 20 ohms between 30 and 100 ohms $\pm 20\%$ between 100 and 3000 ohms
4. STIMULATOR OUTPUT
 - 1) Rate : 2, 5, 50, 75, 100, 150, 180, 200 Hz
 - 2) Duration / Width : 0.1, 0.5, 1, 2, 3 milliseconds
 - 3) Voltage-regulated Mode : 0 – 5 volts
 - 4) Current-regulated Mode : 0 –10 mA
5. THERMAL & PULSED RF OUTPUT
 - 1) Timing :
 - (1) Selectable : 0:05 – 30:00 minutes (min:sec)
 - (2) Resolution : 1 second
 - (3) Accuracy : $\pm 1\%$
 - 2) Watts :
 - (1) Range : 0 to 50 watts average (into 100 Ω load)

- (2) Resolution : 1 watt (Thermal RF output only)
- (3) Accuracy : $\pm 20\%$ of full scale (Thermal RF output only)
- (4) Frequency : 480 kHz

6. Volts :

- 1) Range :
 - (1) Thermal RF: 0 to 105 Volts RMS
 - (2) Pulsed RF: to 100 Volts peak
- 2) Resolution :
 - (1) Thermal RF: 1 Volt RMS
 - (2) Pulsed RF: 1 Volt Peak
- 3) Accuracy : $\pm 10\%$ of full scale

7. Current :

- 1) Range : 0 to 700 mA RMS over 60 seconds
- 2) Resolution :
 - (1) Thermal RF : 1 mA RMS
 - (2) Pulsed RF : 1 mA Peak
- 3) Accuracy : $\pm 10\%$ of full scale

8. PULSED RF SETTINGS :

- 1) Repetition Rate ("Pulse Rate") : 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 PPS (Hz)
- 2) Duration ("Pulse Width") : 2 – 50 milliseconds
- 3) AUTO Thermal RF (480 kHz carrier frequency)
 - (1) Auto Temp : Off, 37–95°C
 - (2) Auto Timer : 5 sec – 30 min
 - (3) Auto Stepped : Start, Step, Final Temps and Times
 - (4) Power : 0–50 Watts

9. AUTO Pulsed RF (480 kHz carrier frequency)

- 1) Auto Temperature : Off, 37–95°C
- 2) Auto Timer : 5 sec – 30 min
- 3) Voltage : 0-100 Volts Peak
- 4) Rates : 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Hz
- 5) Widths/Durations : 2, 3, ... , 30 msec
- 6) E-dose: Control Voltage or Pulse Width

10. TEMPERATURE MONITOR

- 1) Range : 0 °C to 110 °C
- 2) Resolution : 1 °C
- 3) Accuracy : ± 3 °C between 40 °C and 90 °C
 ± 4 °C between 10 °C and 40 °C & between 90 °C and 110 °C

11. GENERAL

- 1) Size : W 36.2 cm x H 24.1 cm x D 30.9 cm
- 2) Weight : 22 lbs (10 kg)

3. Consist of :

1) G4 Radiofrequency Generator, Fully Automated, 4 RF outputs	1 ea
2) RF Thermocouple Electrode, 5cm	1 ea
3) RF Thermocouple Electrode, 10cm	6 ea
4) RF Cannula, 5cm, 10p/bx	1 Box
5) RF Cannula, 10cm, 10p/bx	1 Box
6) EZ-FIX Compressor, Cushion	1 ea
7) ARC Support W Slide Right/Left,, Spar	1 ea
8) Disp. Ground Pad, 50p/bx	1 Box
9) Storage Cart	1 ea
10) Operating Manual (영/한), Service Manual	1 ea

D. Remark

1. 검수 후 **3年 무상보증 보증**
2. 공급자는 사용자 측에서 요구한 장소에 납품 및 설치 완료시키고, 설치에 따른 부대비용은 공급자 부담으로 하며, 사용자가 원활하게 사용할 수 있도록 시험 운영 및 교육 시행을 완료하여야 한다.
3. 공급자는 사용자 요청시 원내 동종 운영 장비 재배치에 따른 이전설치를 지원한다.
4. 공고 규격서의 명칭과 기능은 본 입찰에서 요구되는 심사 기준(성능, 구성품)을 표기한 것.