TECHNICAL SPECIFICATIONS OF RADIO FREQUENCY ABLATION SYSTEM-PAIN PROCEDURES/HIGH FREQUENCY ABLATION UNIT

| S. No. | De | escription of Specifications: R. F. Machine | |
|----------|--|---|--|
| 1. | The Equipment should be useful for standard RF ablation & Cooled RF ablation | | |
| 2. | Indications: Cervical | pain, Thoracic pain, facet pain, Lumber Spine pain, Sacro-iliac Joint | |
| | | ip Joint pain, Knee pain, Trigeminal neuralgia. | |
| 3. | RF generator must support Bipolar RF for Biacuplasty procedure | | |
| 4. | | have separate quad cool pump assembly to treat cooled RF related | |
| 5. | muscle / nerve origin ch | | |
| <u> </u> | RF must have water cooled probe. The equipment should have following features in a single unit | | |
| 0. | a) Standard RF | a have following features in a single unit | |
| | b) Pulsed mode | | |
| | c) Cooled RF | | |
| | d) Bipolar Mode | | |
| | | | |
| 7. | | e customizable treatment profiles for quick access. | |
| 8. | | profiles can be added and deleted as per user convenience. | |
| | The system should be able to record clinical logs for the past therapies. Minimum 120 procedure logs should be supported. | | |
| 9. | , | port individual probe control before and during treatment. Start and | |
| | | ual probe with respect to temperature and time. | |
| 10. | The system should auto ramp time. | matically extend procedure time if Set Temp does not reach allotted | |
| 11. | | display Ramp Time, time at Set Temp, and total procedure time in | |
| | graph form. | | |
| 12. | The system should have demo mode for Cooled, Standard, Bipolar, Transdiscal, Pulsed and | | |
| 13. | Stimulation mode for users to review. | | |
| 14. | The system should be able to test pump unit, upgrade software and enable live output. The system should display warning with numeric code and actionable error message. | | |
| 15. | Screen Display | | |
| | The equipment should have LCD color touchscreen. | | |
| | Should display grap | phical interface in Real-time, display impendence, temperature, time | |
| | and voltage indepe | | |
| | | ould have the feature of independent Probe control for better | |
| 16. | performance & save | e procedural time. Standard Temperature & Time duration: | |
| 10. | RF energy For Standard RF | Temperature display 80-degree C and time 90seconds | |
| | For Bipolar RF | Temperature display 60 degree C and time 50 seconds Temperature display 40-degree C and time 15 minute | |
| | For pulse RF | Temperature display 42-degree C and time 90 seconds | |
| | For Cooled RF | Temperature display 60-degree C and time 2:30 minutes | |
| 17. | On insertion of RF Ca | ble , the equipment should recognize the | |
| | Standard RF probes | | |
| | Bipolar probes for a | | |
| | Cooled RF Should h operation. | ave automatic mode to recognize various cables for minimal manual | |
| | operation | | |

| 18. | Impedance measurement, Stimulation, RF output: | | |
|-----|---|----------------|--|
| | The impedance measurement should be in the range of 1- 3000 ohms | | |
| | • Impedance can be measured in before and during lesion in "Lesion mode", befor | | |
| | "stimulation mode" and during cooled RF in Auto temperature mode. | | |
| | Stimulation voltage mode: 0.00-10 V, 0.01 V increment | | |
| | Current mode: 0.00-10 mA, 0.01 mA increment. | | |
| | • Stimulation rate: 1-Shot, 2, 5, 10, 20, 50, 75, 100, 150, 180 and 200 Hz | | |
| | Stimulation pulse duration: 0.1, 0.2, 0.5 and 1.0 MS | | |
| | RF energy: 460 KH | | |
| | Maximum Power: 80W | | |
| 19. | Software Shutdown Limits During RF Delivery or Stimulation (Safety feat | ures): | |
| | • Measured Impedance: $< 25 \Omega$ or $> 3,000 \Omega$ | , | |
| | Measured Temperature: < 15°C, > 100°C | | |
| 20. | Scope of Supply: | | |
| | a) R. F. Machine (Advanced Cooled Upgradable Generator) | 1no | |
| | b) Connecter cable for Trans-discal Biacuplasty procedure | 1no | |
| | c) 4 Channel Standard RF | 1no | |
| | d) 4 Channel Cooled RF | 1no | |
| | e) Peristaltic Quad Pump to perform multi–Cooled RF. This needs to be operated | 1no | |
| | in conjunction to the RF generator. | | |
| 21. | The equipment is to be supplied with consumables: | | |
| | RF split grounding Pad | 100 no | |
| | Standard RF flexible probe 100mm length, Reusable | 1no | |
| | Standard RF flexible probe 145mm length, Reusable | 1no | |
| | Standard RF flexible probe 55 mm length, Reusable | 1No | |
| | Standard RF Cannula supporting 100mm length, 5 mm active tip for Trigeminal | 20 no | |
| | Neuralgia | | |
| | Standard RF Cannula supporting 100mm length, 10 mm active tip | 20 no | |
| | Standard RF Cannula supporting 100mm length, 5 mm active tip | 20 no | |
| | Standard RF Cannula supporting 145 mm length, 5 mm active tip | 20 no | |
| | Standard RF Cannula supporting 145 mm length,10 mm active tip | 10no | |
| | Knee Procedure Cooled RF kit - 75mm probe length, with 4mm active tip | 20no | |
| | Lumbar Facet Procedure Cooled RF kit – 100 mm probe length, with 4mm | 20110 20 no | |
| | active tip | 20110 | |
| | • Sacro Iliac & Hip Joint Cooled RF kit - 150 mm probe length, with 4mm | 20 no | |
| | active tip | 20 | |
| | • Shoulder Joint procedure Cooled RF kit - mm75 probe length, with 2mm | 20 no | |
| | active tip | | |
| | | | |
| | • Cooled Disc Biacuplasty kit for Disc procedure TDK2-17-150-6 MM Active tip | 20 no | |
| 22. | Others: | | |
| | • Model should be latest. Older machines/model & refurbished machines will | ll not be | |
| | considered. | | |
| | Comprehensive warranty for 5 years for the complete system. | | |
| | • Quote Comprehensive maintenance contract [CAMC] for complete system for a | additional | |
| | 5 years after expiry of warranty of 5 years. | | |
| | Breakdown complaint must be attended within 24 hours. | | |
| | • All steps to be taken to maintain 95% uptake time of the equipment failing whic | h penalty | |
| | clause would be imposed and warranty will extend 3 times of the downtime. | | |
| | • Confirmation of availability of recommended spares for the maintenance. | | |
| | • The system should have BIS/CDSCO/US FDA/European CE certification. | | |

| Parent company should provide undertaking of suppling the consumables for 10 years |
|---|
| from the date of Installation of machine.Parent Company/OEM should provide technical training support to the user department. |
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| During initial period & after training, the company should provide authorized person to assist the staff of dept. in using the machine for the RF procedures/ cases as & when required. |
| • Service engineer available with each & every authorize distributor end. |