AMICA
Apparatus for MICrowave and radiofrequency Ablation

THE NEW GENERATION OF INTERSTITIAL PROBES FOR MICROWAVE AND RADIOFREQUENCY THERMOABLATION
AMICA GEN

AMICA GEN is a programmable microwave (MW, 2450 MHz) and radiofrequency (RF, 450 kHz) generator, the only available generator capable of providing the two most widespread thermoablation technologies in the same hardware.

AMICA is the only system in the world that combines the two main thermal ablation technologies, radiofrequency (RFA) and microwave (MWA), in the same hardware.

INTRODUCTION TO THERMAL ABLATION

The ablation of a biological tissue consists in destroying it with a physical or chemical agent capable of killing its cells. In particular, thermal ablation is the coagulation necrosis induced in a mass of tissue by the effect of local overheating: cell death is practically instantaneous at temperatures of 60°C or more.

Ablation is currently used in clinical practice for destroying pathological tissues (for example, tumors or hypertrophic masses) in cases in which surgical resection is not practicable or contraindicated: hence the prevalence of interstitial or intracavitary ablation applicators, which are minimally invasive.

The pathological tissues most frequently subjected to ablation are solid tumors. The incidence of cancer increases with the age of individuals whilst the capacity to withstand surgical operations decreases.

The increase in the average age of the population thus causes an ever-increasing demand for local and regional treatments less invasive than traditional surgery.

In addition, compared to surgical resection, an interstitial ablation operation has shorter times and lower costs and risks before, during and after the operation, above all due to the significant reduction in invasiveness and the trauma suffered by the patient, the consequent reduction in the complication rate and side effects and the shortening of the post-operative course.

References - please look at page 10 & 11

Manufactured by: HS HOSPITAL SERVICE S.P.A.
FUNDAMENTAL REQUIREMENTS OF A THERMAL ABLATION SYSTEM

At present, heating from electromagnetic energy sources satisfies the most diverse needs better than any other ablation system (cryoablation, percutaneous ethanol injection (PEI), irreversible electroporation, “TACE” transarterial chemoembolization, “HIFU” high-intensity focused ultrasound, etc.):

Control of necrosis pattern
- Predictability of the therapeutic outcome (shape and size of the ablated volume) under assigned operating conditions (type of target tissue, type and dose of energy administered, method and duration of energy output)
- Minimum and maximum coagulation performance (shapability of thermal lesion)
- Confinement (sphericity, preservation of tissues around the target, lack of interference with implanted medical devices and prostheses)

Heating speed
- Short duration of treatment
- Low sensitivity to heat sinking effects due to blood circulation or bile ducts

Safety
- Minimal invasiveness, low intra- and post-operative complication rate, EMC compatibility and electrical safety, availability of alarms and hardware and software protective devices

Ease of use
- Short learning curve, full compatibility with the principal imaging techniques, easy access to the tumor, real-time control of the progress of treatment

Accessible costs
- It is therefore no surprise that the ablation techniques most commonly used today are radiofrequency thermal ablation (RFA) and microwave thermal ablation (MWA)

RADIOFREQUENCY THERMAL ABLATION (RFA)
- Radiofrequency (RF) consists of alternating electric currents at radio frequencies (typically around 450 kHz) that heat the tissues through the Joule effect and ionic agitation (the heat produced is directly proportional to the current density)
- RF applicators are thin interstitial electrodes (between 14G and 20G), capable of penetrating into the lesion to be subjected to ablation, where they inject RF currents of a suitably adjustable intensity. The electrical circuit is closed by special dispersion plates applied to the patient’s skin
- RF currents only heat the tissue near the exposed tip of the electrode: propagation of the heat takes place more slowly by thermal conduction
- RF technology is a reliable and economical method of generating, controlling and supplying energy to the tissues safely and effectively with low complication rates
- RF ablation is now widely used in the treatment of hepatocellular carcinoma (HCC) with a diameter of up to 3 cm and, to a lesser degree, lung cancer, osteoid osteoma and bone metastases; less systematically, there are reports in the literature of RF treatments on kidney, prostate and breast tumors.

MICROWAVE THERMAL ABLATION (MWA)
- Microwaves are electromagnetic radiation with a frequency of between 300 MHz and 300 GHz that induces atomic and molecular dipole rotation, creating a kind of friction that converts part of the energy of the field applied into heat (dielectric heating)
- This form of heating is particularly efficient in materials with high water content, like most biological tissues
- A microwave applicator may deposit radiant energy inside the human body in a localized and controlled way, irrespective of the electrical properties of the tissue and without any need for dispersion plates

References - please look at page 10 & 11

Manufactured by: HS HOSPITAL SERVICE S.P.A.
AMICA GEN AGN-H-1.2

Product
- Automatic identification of the type of applicator (RF or MW), the model (gauge, length and exposure) and automatic selection of the corresponding type of energy to be supplied
- Automatic identification of the energy output mode (AUTO, MAN, TEMP) and auto setting of the default parameters
- Automatic control peristaltic pump built into the generator for internal cooling of both types of applicator
- Essential and user-friendly graphic interface: LCD touch screen and rotary knob for browsing through the setup menus
- Possibility of adjusting the power output (MW and RF) during both the setup and the treatment phases
- Storage of data and settings from the latest ablation session

Technical Characteristics
- Microwave (2450 MHz /190 W) and radiofrequency (450 kHz /200 W on 50 Ω load) dual generator
- Two different MW energy delivery modes: MAN (continuous power delivery) and PULSED (intermittent power delivery [40])
- Three radiofrequency energy output modes: AUTO (power regulated automatically according to impedance), MAN (preset power output) and TEMP (power regulated automatically according to the temperature set)
- Equipped with an automatic procedure for cauterizing the applicator entry path at the end of treatment (track ablation)
- Built-in AMICA-PUMP peristaltic pump
- LCD touch screen and rotary knob
- Connectivity: AMICA GEN is interfaceable with a PC or other external devices by specific serial communication port (RS 232)
- Service output (30 VDC /100 mA) for powering external devices
- Maximum portability and compactness: the lightest (12 kg) and smallest (45x38x13 cm) thermal ablation device in the world

Safety Characteristics
- Self-diagnosis of applied parts status and of MW and RF amplifiers
- Automatic shut-off of energy output in case of an alarm or error
- Acoustic and visual warning of the alarm state, of the correct connection and functioning of the applied parts
- Constant monitoring of the energy output: continuous measurement of direct and reflected MW power; continuous measurement of power, current and RF impedance
- Calculation of net MW and RF energy deposited in the tissues
- Local or remote control of energy output (MW and RF)
- Direct energy output emergency stop button

AMICA GEN AGN-H-1.2 is a programmable solid-state generator that can output, control and release radiofrequency power (RF, at 450 kHz) and microwave power (MW, at 2450 MHz).

References - please look at page 10 & 11
Manufactured by: HS HOSPITAL SERVICE S.P.A.
**BENEFITS OF LOCO-REGIONAL TREATMENTS**

- minimally invasive, precise, simple to use, safe and inexpensive [1], [15]
- may be performed via the percutaneous or laparoscopic route or even in an intraoperative setting
- compatible with the principal imaging techniques (US, CT, MRI) [2], [7]
- may be performed under general anaesthesia or deep sedation. Sometimes a local anaesthetic and mild sedation are sufficient
- well tolerated by patients and widely applicable [3]
- short sessions and rapid post-operative course
- immediate therapeutic effect
- low complication rate [4]
- may be performed in the operating theatre, but also in the CT room or an outpatient department [5]
- reduction of costs for healthcare facilities

**BENEFITS OF RFA**

- regular and repeatable ablation volume [16]
- proven efficacy in the treatment of hepatocellular carcinoma (HCC) with a diameter of up to 3 cm [6]
- real-time display of the development of the coagulation zone

**BENEFITS OF MWA**

- repeatability, uniformity and homogeneity of the ablation volume (no skipping) [8], [9], [14]
- larger ablation volume [10], [11], [21]
- accurate real-time display of the development of the coagulation zone
- rapid heating of the tissue subjected to treatment (much less sensitive to heat sinking) [8]
- possibility of treating a vast range of tissues (fatty, spongy and irregular tissues, bone tissues and muscle fibres) such as: liver, lung, kidneys, bone, breast, etc. [10], [11], [12]
- possibility of treating patients with implanted metal devices (pacemaker, prosthesis, clip, stent, etc.)

The HS AMICA hybrid system, which combines the RF and MW technologies in a single generator, allows the operator to choose the most suitable technology according to:

- the morphological and histological characteristics of the tumor to be treated
- the type of tissue to be treated
- the presence of structures beside the tumor (e.g. vessels, colon, etc.)
- the expected cost-benefit ratio

<table>
<thead>
<tr>
<th>Item no.</th>
<th>Specification</th>
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<tbody>
<tr>
<td>AGN-3.2</td>
<td>2450MHz/190W programmable solid-state MW generator, with built-in peristaltic pump</td>
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<tr>
<td>AGN-H-1.2</td>
<td>Programmable RF (450kHz/200W @ 50 Ohm) and MW (2450MHz/190W) generator, with built-in peristaltic pump</td>
</tr>
<tr>
<td>AGN-R-1.1</td>
<td>Programmable RF generator (450kHz/200W@50Ohm) with built-in peristaltic pump</td>
</tr>
</tbody>
</table>

**References - please look at page 10 & 11**
AMICA PROBE MW

AMICA PROBE is a single-use interstitial applicator for percutaneous or intraoperative use for the microwave thermal ablation of soft tissues.

AMICA PROBE MW • PERFORMANCE
► Ablation up to a transverse diameter of 5.7 cm in 15 minutes at 100W\textsuperscript{1} [23], [34]
► More spherical ablation up to 4.5 cm transversal diameter\textsuperscript{3}
► Full control of the necrotic area, maximum repeatability and safety of treatment due to the combined action of the patented mini-choke\textsuperscript{2} (which eliminates the effects of retrograde heating) device and the cooling inside the applicator [22], [23], [24]
► Size and sphericity index adjustable by varying the duration and power of ablation [34]
► Clinical efficacy and safety of use demonstrated on a wide range of tissues [21], [26], [27], [28], [29], [30], [31], [32], [35]
► Better ratio between available gauge and sphericity index than all other microwave applicators on the market

AMICA PROBE MW • TECHNICAL CHARACTERISTICS
► Medical grade stainless steel cannula with depth markers. A large white band extending between 3 cm and 4 cm from the tip improves control during the track ablation by pointing out the proximity of the antenna to the skin
► Pyramidal metal tip to facilitate tissue penetration
► Excellent visibility under US and CT guidance
► Integrated memory chip for identifying the applicator and recording the factory settings
► Internal temperature sensor for measuring the temperature of the applicator probe
► Built-in or separable hydraulic line and coaxial power cable (identified by the suffix -DC)
► Multiple use per patient
► Possibility of using multiple applicators at the same time [10]
► No dispersion plates applied to the patient

The disposable kit that comes with the device comprises:
- Polyethylene removable guard assembled above the probe of the applicator
- Insertion depth indicator
- Disposable scalpel for preliminary cutting of the patient’s skin
- Operating drape with hole at the centre
- Applicator with sponge for disinfecting the patient’s skin
- Cable holder/fixator

References - please look at page 10 & 11
Manufactured by: HS HOSPITAL SERVICE S.P.A.
### COAGULATIVE PERFORMANCE OF AMICA PROBE IN EX-VIVO BOVINE LIVER

**(Continuous Mode)**

<table>
<thead>
<tr>
<th>SIZE (Length x Diameter)</th>
<th>POWER(^7)</th>
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<tbody>
<tr>
<td></td>
<td>20W</td>
</tr>
<tr>
<td></td>
<td>3 MIN</td>
</tr>
<tr>
<td>20W</td>
<td>24 x 16</td>
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<tr>
<td>40W</td>
<td>27 x 20</td>
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<tr>
<td>60W</td>
<td>31 x 27</td>
</tr>
<tr>
<td>80W</td>
<td>38 x 33</td>
</tr>
<tr>
<td>100W</td>
<td>10 MIN</td>
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<tr>
<td></td>
<td>27 x 20</td>
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<tr>
<td></td>
<td>31 x 27</td>
</tr>
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<td></td>
<td>38 x 33</td>
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### COAGULATIVE PERFORMANCE OF AMICA PROBE IN EX-VIVO LIVER

**(Pulsed Mode)**

<table>
<thead>
<tr>
<th>POWER(^7)</th>
<th>TIME(^8)</th>
<th>SIZE (Length x Diameter)</th>
<th>SPHERICIT INDEX (D/L)</th>
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</thead>
<tbody>
<tr>
<td>20W</td>
<td>10 MIN</td>
<td>22x22</td>
<td>1.00</td>
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<tr>
<td>40W</td>
<td>5 MIN</td>
<td>29x25</td>
<td>0.86</td>
</tr>
<tr>
<td>70W</td>
<td>10 MIN</td>
<td>36x33</td>
<td>0.92</td>
</tr>
<tr>
<td>100W(^9)</td>
<td>10 MIN</td>
<td>42x36</td>
<td>0.86</td>
</tr>
<tr>
<td>120W(^9)</td>
<td>10 MIN</td>
<td>51x41</td>
<td>0.80</td>
</tr>
<tr>
<td>140W(^9)</td>
<td>10 MIN</td>
<td>53x46</td>
<td>0.87</td>
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### AMICA Disposable Microwave Ablation Probes

<table>
<thead>
<tr>
<th>Item no.</th>
<th>Model</th>
<th>Description</th>
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<tbody>
<tr>
<td>APK11150T19V5(^4)</td>
<td>11Gx150mm</td>
<td>Gauge 11G, length 150mm</td>
</tr>
<tr>
<td>APK14150T19V5(^4)</td>
<td>14Gx150mm</td>
<td>Gauge 14G, length 150mm</td>
</tr>
<tr>
<td>APK14200T19V5(^4)</td>
<td>14Gx200mm</td>
<td>Gauge 14G, length 200mm</td>
</tr>
<tr>
<td>APK14270T19V5(^4)</td>
<td>14Gx270mm</td>
<td>Gauge 14G, length 270mm</td>
</tr>
<tr>
<td>APK16150T19V5(^4)</td>
<td>16Gx150mm</td>
<td>Gauge 16G, length 150mm</td>
</tr>
<tr>
<td>APK16200T19V5(^4)</td>
<td>16Gx200mm</td>
<td>Gauge 16G, length 200mm</td>
</tr>
<tr>
<td>APK16270T19V5(^4)</td>
<td>16Gx270mm</td>
<td>Gauge 16G, length 270mm</td>
</tr>
</tbody>
</table>

Available versions:
gauge: 11G, 14G, 16G
shaft length: 150, 200, 270 mm
built-in or detachable cables
high power version (100W)

References - please look at page 10 & 11

Manufactured by: HS HOSPITAL SERVICE S.P.A.
RF AMICA PROBE RF is a single-use interstitial electrode for percutaneous or intraoperative use for the radiofrequency thermal ablation of soft tissues.

**AMICA PROBE RF • PERFORMANCE**
- Coagulation up to a transverse diameter of 3.5 cm in 12 minutes at 200W in AUTO output mode
- Maximum coagulation performance obtained through automatic control of the power output (AUTO mode) and internal cooling that prevents carbonization of the tissues around the exposed tip

**AMICA PROBE RF • TECHNICAL CHARACTERISTICS**
- Power available at the RF AMICA-PROBE radiofrequency electrode: up to 200W with an impedance of 50 Ω measured between the electrode and the dispersion plates
- Excellent visibility under US and CT guidance
- Trocar pyramidal tip to facilitate tissue penetration without skin incision
- Integrated memory chip for identifying the applicator and recording the factory settings
- Internally cooled straight monopolar electrode
- Temperature sensor beside the tip of the electrode for measuring cooling efficiency
- Medical grade stainless steel cannula with depth markers
- Built-in hydraulic line and power cable
- Multiple use per patient

**Probe models already available:**
gauge: 17G & 18G  
shaft length: 100, 150, 200, 270 mm  
exposed tip length: 5, 10, 15, 20, 25, 30, 35 mm
### GENERAL USE [6] [36]
(Liver - Lung Uterine Fibroid Bone Metastasis Kidney, Etc)

<table>
<thead>
<tr>
<th>Item no.</th>
<th>Specification</th>
<th>Item no.</th>
<th>Specification</th>
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<tbody>
<tr>
<td>RFH1700E05V1</td>
<td>17G x 100 mm, 5 mm exposed tip</td>
<td>RFH17150E30V1</td>
<td>17G x 150 mm, 30 mm exposed tip</td>
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<tr>
<td>RFH17100E07V1</td>
<td>17G x 100 mm, 7 mm exposed tip</td>
<td>RFH17150E35V1</td>
<td>17G x 150 mm, 35 mm exposed tip</td>
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<tr>
<td>RFH17100E10V1</td>
<td>17G x 100 mm, 10 mm exposed tip</td>
<td>RFH17200E10V1</td>
<td>17G x 200 mm, 10 mm exposed tip</td>
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<td>RFH17100E20V1</td>
<td>17G x 100 mm, 20 mm exposed tip</td>
<td>RFH17200E20V1</td>
<td>17G x 200 mm, 20 mm exposed tip</td>
</tr>
<tr>
<td>RFH17100E30V1</td>
<td>17G x 100 mm, 30 mm exposed tip</td>
<td>RFH17200E35V1</td>
<td>17G x 200 mm, 35 mm exposed tip</td>
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<tr>
<td>RFH17100E40V1</td>
<td>17G x 100 mm, 40 mm exposed tip</td>
<td>RFH17200E40V1</td>
<td>17G x 200 mm, 40 mm exposed tip</td>
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<tr>
<td>RFH17100E50V1</td>
<td>17G x 100 mm, 50 mm exposed tip</td>
<td>RFH17200E50V1</td>
<td>17G x 200 mm, 50 mm exposed tip</td>
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<tr>
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<td>17G x 150 mm, 10 mm exposed tip</td>
<td>RFH17200E15V1</td>
<td>17G x 200 mm, 15 mm exposed tip</td>
</tr>
<tr>
<td>RFH17150E20V1</td>
<td>17G x 150 mm, 20 mm exposed tip</td>
<td>RFH17200E25V1</td>
<td>17G x 200 mm, 25 mm exposed tip</td>
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<tr>
<td>RFH17150E30V1</td>
<td>17G x 150 mm, 30 mm exposed tip</td>
<td>RFH17200E35V1</td>
<td>17G x 200 mm, 35 mm exposed tip</td>
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<tr>
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<td>RFH17200E40V1</td>
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<tr>
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<td>17G x 150 mm, 50 mm exposed tip</td>
<td>RFH17200E50V1</td>
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#### THYROID GLAND [37] [38]

<table>
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<th>Specification</th>
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<tbody>
<tr>
<td>RFH18070E05V1-T</td>
<td>18G x 70 mm, 5 mm exposed tip</td>
</tr>
<tr>
<td>RFH18070E07V1-T</td>
<td>18G x 70 mm, 7 mm exposed tip</td>
</tr>
<tr>
<td>RFH18070E10V1-T</td>
<td>18G x 70 mm, 10 mm exposed tip</td>
</tr>
<tr>
<td>RFH18070E15V1-T</td>
<td>18G x 70 mm, 15 mm exposed tip</td>
</tr>
<tr>
<td>RFH18100E05V1-T</td>
<td>18G x 100 mm, 5 mm exposed tip</td>
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<tr>
<td>RFH18100E07V1-T</td>
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<tr>
<td>RFH18100E10V1-T</td>
<td>18G x 100 mm, 10 mm exposed tip</td>
</tr>
<tr>
<td>RFH18100E15V1-T</td>
<td>18G x 100 mm, 15 mm exposed tip</td>
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#### OSTEOID OSTEOMA [20]

<table>
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</tr>
<tr>
<td>RFH18100E07V1-T</td>
<td>18G x 100 mm, 7 mm exposed tip</td>
</tr>
<tr>
<td>RFH18100E10V1-T</td>
<td>18G x 100 mm, 10 mm exposed tip</td>
</tr>
<tr>
<td>RFH18100E15V1-T</td>
<td>18G x 100 mm, 15 mm exposed tip</td>
</tr>
</tbody>
</table>

#### LAPAROSCOPIC PROCEDURE [31]

<table>
<thead>
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<th>Item no.</th>
<th>Specification</th>
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<tbody>
<tr>
<td>RFH17250E30V1</td>
<td>17G x 250 mm, 30 mm exposed tip</td>
</tr>
<tr>
<td>RFH17270E20V1</td>
<td>17G x 270 mm, 20 mm exposed tip</td>
</tr>
<tr>
<td>RFH17270E25V1</td>
<td>17G x 270 mm, 25 mm exposed tip</td>
</tr>
<tr>
<td>RFH17270E30V1</td>
<td>17G x 270 mm, 30 mm exposed tip</td>
</tr>
<tr>
<td>RFH17270E35V1</td>
<td>17G x 270 mm, 35 mm exposed tip</td>
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### COAGULATION PERFORMANCE OF RF AMICA-PROBE ON BOVINE LIVER

<table>
<thead>
<tr>
<th>Ablation size (Length x Diameter)</th>
<th>Length of exposed tip (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automatic energy delivery mode 200W max, 10 minutes</td>
<td>10 mm</td>
</tr>
<tr>
<td></td>
<td>13 x 11</td>
</tr>
</tbody>
</table>

### AVAILABLE MODELS - RF AMICA-PROBE

References - please look at page 10 & 11
Manufactured by: HS HOSPITAL SERVICE S.P.A.
References:

1. From ex vivo tests on bovine liver at room temperature.
2. World patent of the Italian National Research Council (CNR), on an exclusive licence to HS
3. From ex vivo tests on bovine liver at room temperature in pulsed mod energy deliver y
4. For the high-power version with a short coaxial cable (1.5m), add the following suffix to the code: –S1.5
5. For the version with detachable cables, add the following suffix to the code: –DC
6. Size of necrosis obtained from the mean of three repetitions on adult bovine liver, initially at room temperature (~20°C): all sizes were obtained using a single applicator and single insertion. The in-vivo sizes of coagulation necrosis could vary (a diameter of -10% and a length of -20% are estimated) due to blood per fusion
7. Net power in the radiant part of the applicator
8. Continuous energy output
9. Only with 1.5 m coaxial cable (~S1.5)
10. Per formance chart applicable to 14G AMICA-PROBE models only, cooled using pre-refrigerated water (<10°C). Size of necrosis obtained from the mean of three repetitions in ex vivo bovine liver, initially at room temperature (~20°C): all sizes were obtained using a single applicator and single inser. The in vivo sizes of the coagulation necrosis could change (~10% in diameter and -20% in length) due to blood per fusion
11. Pulsed energy deliver y mode. Pulse width (TON): 4 sec; Latency (TOFF): 6 sec
12. Only achievable with AMICA-GEN units featuring a 190W microwave amplifier on board
13. Only achievable with AMICA-GEN units featuring a 190W microwave amplifier on board and with the detachable applicator model only (add the ~S1.5 suffix to the code)
14. From ex-vivo test on bovine liver at room temperature
15. For the version with straight handle, replace V1 with V2
16. Size of necrosis obtained from the mean of three repetitions on adult bovine liver, initially at room temperature (~20°C): all sizes were obtained using a single applicator and single insertion. The size of the in-vivo coagulation necrosis could vary due to blood per fusion.
17. Available AGN unit featuring a 190W microwave amplifier on board

References:

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