



ELEKTROTOM HiTT® 106

Radiofrequency Thermoablation

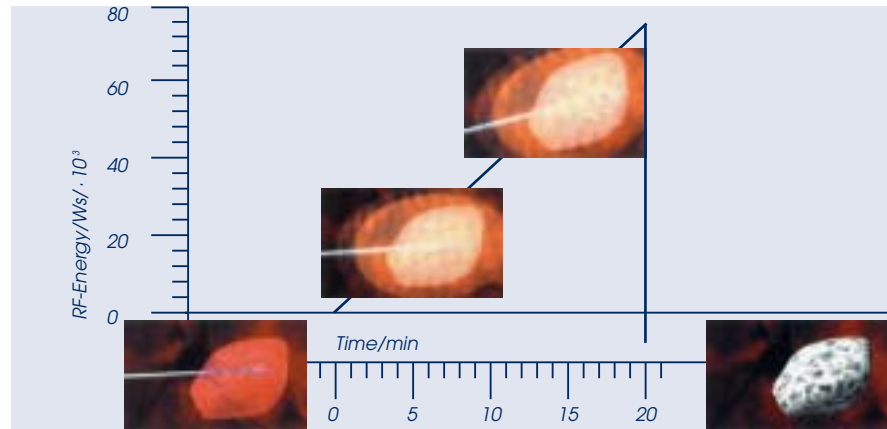
New hope for patients with inoperable tumors

Worldwide some 2 million people contract cancer of the liver every year. Unfortunately only around 30% of patients are suitable for surgical therapy. This has led to the development of new therapeutic strategies for the large collective of inoperable liver tumor patients. Among the most successful methods have been those involving energy application such as radiofrequency thermoablation (RFA).

Dedicated research and development in the medical field has made valuable contributions to improving treatment options for liver tumor patients. One noteworthy example of this is Highfrequency-induced thermotherapy, or HiTT for short. This form of treatment meets many patient and physician needs: a minimally invasive, effective yet organ sparing and low-risk method for the treatment of inoperable tumors, especially of the liver.

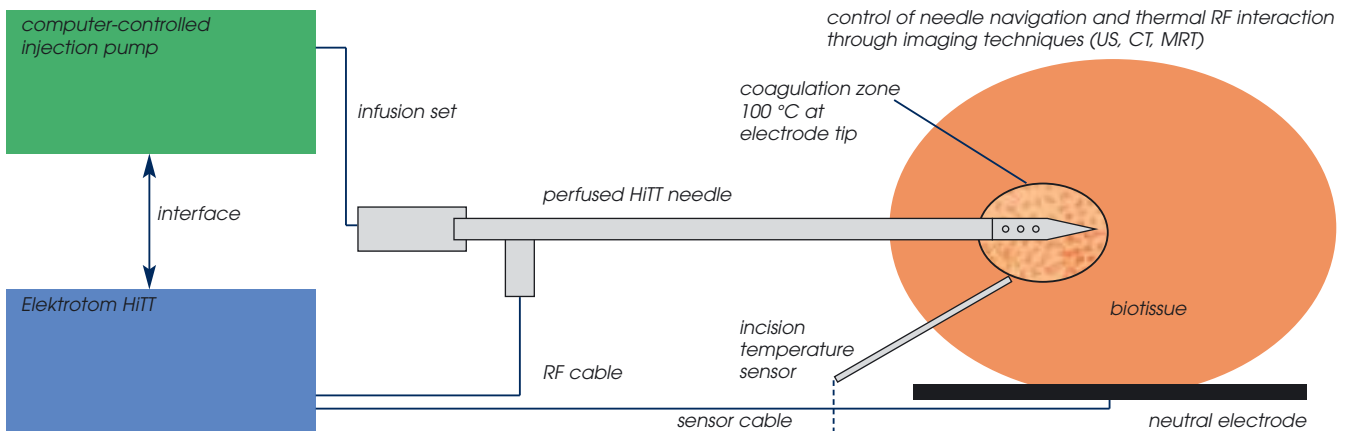
Heat plus saline – a patented success formula

The HiTT system provides a form of minimally invasive therapy that makes use of a hollow saline-perfused needle electrode with an insulated shaft.



The success of RFA depends not only on the duration of heat application but also on the electrical conductivity of the target tissue, and it is to ensure good conductivity that saline perfusion is used. In this way tumor cells can be completely devitalized through RF energy at temperatures above 50 °C.

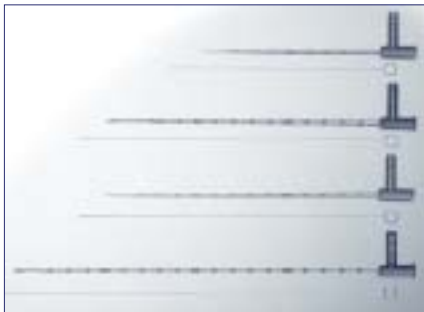
HiTT is both simple and superior Radiofrequency-induced Thermotherapy (HiTT)



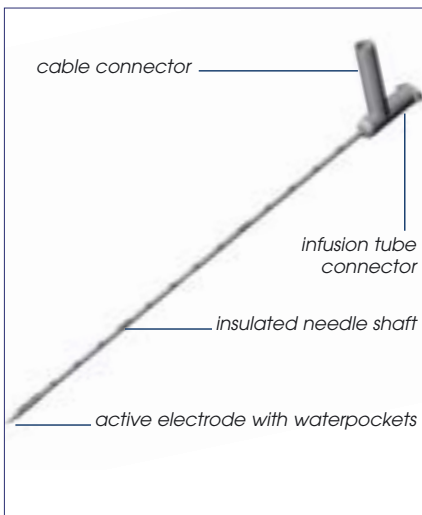
Developed and clinically evaluated in cooperation with German university clinics, HiTT is internationally certified as a "saline-enhanced" RFA method. Gastroenterologists, radiologists, liver surgeons and oncologists around the world rely on this demonstrably effective palliative treatment option. Application of saline prevents heat-induced tissue dehydration and stabilizes electrical conductivity and the progression of temperature at the needle electrode.

Easy to use – from needle insertion to operating the ELEKTROTOM HiTT®106 system

HiTT is as flexible as are the requirements placed on it. It provides the physician with a variety of shaft lengths and diameters as well as active needle electrodes of different lengths. The choice of instruments will depend on the medical indication in question and/or the imaging technique used.



Special surface finish, thermostable insulation, electrically conductive tip, microbores and waterpockets – all these features facilitate navigation and improve visibility no matter what imaging technique is used



The hollow needle electrode with a shaft diameter of 1.2, 1.6 or 2.0 mm is powered with alternating current at max. 1.2 A and 375 kHz. The active electrode tip is perfused with an outward flow of physiological saline solution at a rate of approx. 1 to 2 ml/min (20 to 40 drops/min).

HiTT needles have the following specific advantages:

- straight design similar to that of a biopsy needle
- special design of the active electrode tip
- no elastically bending or additional shifting electrodes

These features make needle navigation extremely easy. They minimize the risk of misplacement, and eliminate any difficulties in withdrawing the needle from the target area immediately after thermoablation.

Elektrotom HiTT®106 as a superior concept

In redesigning the mobile device system Integra put a special focus on maximizing operating ease and safety. Its automatic mode permits the physician to give all his attention to the patient. All application modes are available, whether temperature controlled, monopolar or bipolar.



Elektrotom HiTT 106 device system: computer-controlled radiofrequency generator, automatically controlled injection pump, cart and accessories. The system's automatic mode enables the physician to give all his attention to the patient.

HiTT for monopolar or bipolar radiofrequency thermoablation

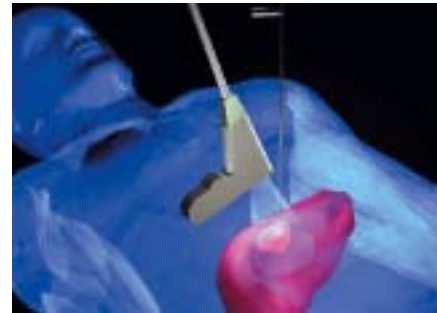
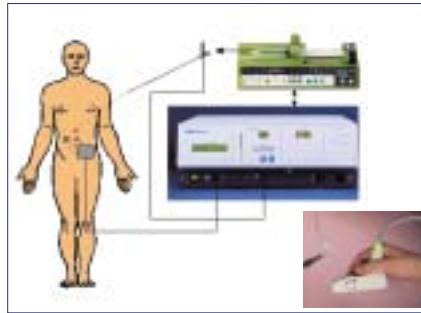
Which application technique of radiofrequency ablation (RFA) is ideal in a given case depends on various factors:

- proximity of the tumor location to heat-sensitive tissues
- size and geometry of the desired tumor necrosis zone
- active and passive elements of the RF circuit

The Elektrotom HiTT 106 device system gives the physician the choice of using RFA in monopolar or bipolar technique.

Bipolar thermoablation provides substantial advantages in terms of operating safety in the case of difficult tumor locations close to heat-sensitive tissues or of insufficient image control. It makes the neutral electrode dispensable: only used if the surgeon wants to retain the option of combining the bipolar and monopolar techniques in one therapeutic session.

Short current paths between the needle tips, which measure no more than 30 mm apart, focus the RF energy turnover entirely on the tumor area.



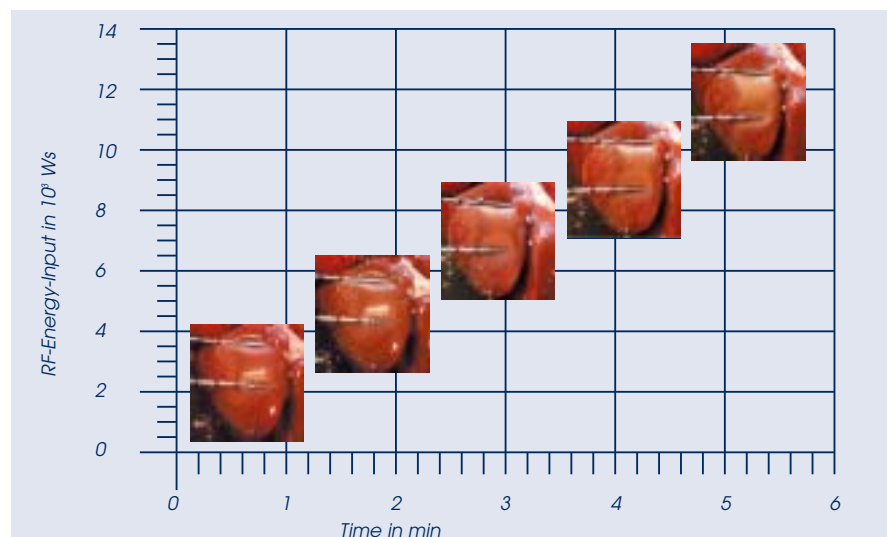
Monopolar RF application

A large-area neutral electrode of low thermal capacity is used for an electric pole on the patient's body. After local or general anesthesia the thermally active needle electrode is inserted.



Bipolar RFA application

This is done by parallel insertion of two active needle electrodes or insertion of a special bipolar needle electrode into the target area. This technique does not require the use of a neutral electrode.



Progression of coagulation for bipolar thermoablation after insertion of the two HiTT needles

HiTT brings the patient into focus

Image control has become a measure of progress in modern medicine. HiTT is compatible with all current imaging techniques (sonography, CT, MRT). This means that the percutaneous or intraoperative placement of needles, as well as their thermal effects, can be controlled with standard equipment. Image quality may vary, depending on the technique being used. The choice of an imaging technique will depend on the indication in terms of:



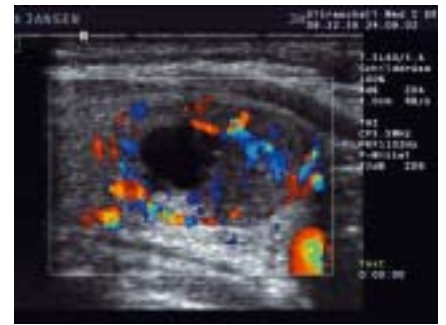
- form of therapy
- type of anesthesia
- the physician's experience with interventions under image control



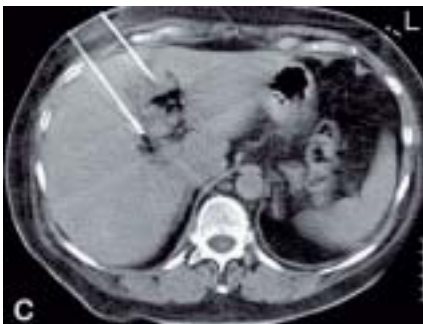
Successful treatment of a small metastasis from colon cancer. Contrast-enhanced CT scan obtained 10 days after RF ablation.



Bipolar HiTT thermoablation of a paravertebral metastasis of a renal tumor.



Color duplex sonography of an adrenal adenoma following HiTT thermoablation.



Bipolar application with two needle electrodes.



CT-Scan four months after treatment.



Successful treatment of a single HCC 3 months. Transverse contrast-enhanced MR imaging obtained 3 months after treatment.

Technical data

The device system consists of the following components: RF generator, injection pump, equipment cart and accessories.

RF GENERATOR

Voltage supply	100-120/220-240 V AC ±10%; 50/60 Hz
Power consumption max. RF-power output max.	1.5 A (120 V) / 0.75 A (230 V) 60 W/250 Ohms, impedance-controlled
RF nominal frequency Adjustable parameters:	375 kHz power output, activation time max. temperature when operated with temperature sensor, program memory with 4 memory locations
Display of current parameters:	impedance energy input in watt seconds, operating temperature when using temperature sensor, saline volume flow, alphanumeric information and safety codes
Dimensions Weight	L x W x H = 405 x 395 x 145 mm 10.2 kg

INJECTION PUMP

Power consumption Feed rate	23 VA 0.1 – 200 ml/h for 50 ml syringe, automatically controlled by RF generator via RS 232-data interface
Dimensions Weight	L x W x H = 330 x 120 x 155 mm 2.2 kg

EQUIPMENT CART

Integrated coupler sockets Dimensions Weight	 L x W x H = 445 x 550 x 854 mm 32 kg
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 1275 conforms to 93/42/EEC

Ordering data

	ELEKTROTOM HiTT 106, 220-240 V
EK-033-00-04	ELEKTROTOM HiTT 106, 220-240 V, without accessories
EZ-420-01-04	Infusion syringe pump to take a 50 ml plastic syringe, 220-240 V
EZ-420-02-04	Connection cable for data interface RS 232
EZ-069-20-04	Trolley for ELEKTROTOM HiTT 106, without mains cord
	ELEKTROTOM HiTT 106, 100 V
EK-033-00-59	ELEKTROTOM HiTT 106, 100 V, without accessories
EZ-430-00-01	Infusion syringe pump, for low voltage supply
EZ-420-02-04	Connection cable for data interface RS 232
EZ-000-33-04	Cable for low voltage supply of infusion syringe pump EZ-430-00-01
EZ-069-20-01	Trolley for ELEKTROTOM HiTT 106, international version with integrated main sockets, 100-240 V, without mains cord
	ELEKTROTOM HiTT 106, 115-127 V
EK-033-00-66	ELEKTROTOM HiTT 106, 115-127 V, without accessories
EZ-430-00-01	Infusion syringe pump, for low voltage supply
EZ-420-02-04	Connection cable for data interface RS 232
EZ-000-33-04	Cable for low voltage supply of infusion syringe pump EZ-430-00-01
EZ-069-20-01	Trolley for ELEKTROTOM HiTT 106, international version with integrated main sockets, 100-240 V, without mains cord
	Cables
EZ-000-05-04	Earth-bonding cable IEC 601, 0,35 m
EZ-000-35-04	Earth-bonding cable IEC 601, 5 m
EZ-000-41-04	Mains connecting cable with plug 'Europe' IEC 601, 4 m
EZ-000-42-04	Mains connecting cable with plug 'Italy' IEC 601, 4 m
EZ-000-43-04	Mains connection cable with plug 'Switzerland' IEC 601, 4 m
EZ-000-44-04	Mains connecting cable with plug 'Canada', 'Japan' IEC 601, 4 m
EZ-000-45-04	Mains connecting cable with plug 'UK' 13A IEC 601, 4 m
EZ-000-46-04	Mains connecting cable with plug Hospital Grade for USA, 4 m
	Option: footswitch
EZ-835-00-04	Foot switch, double pedal, explosion proof, cable 3.5 m, for ELEKTROTOM HiTT 106
	Accessories
EZ-280-01-04	Connection cable for HiTT needle electrode, sterilizable, 4.5 m
EZ-294-00-04	Neutral electrode cable with two clips for HiTT long time application
EZ-344-10-04	Disposable neutral electrode, laterally split, conductive area 169 cm ² , 10 x 5 pieces
EZ-348-00-04	Bipolar adapter for HiTT
EZ-420-03-04	Insertion temperature sensor type K, Ø x shaft length: 0.6 x 280 mm, with cable, sterilizable
EZ-420-05-04	Y-piece for introducing the temperature sensor into the HiTT needle and connecting the infusion line, 5 pieces
EZ-420-06-04	Tube with luer-lock connector, 25 pieces
EZ-420-07-04	50 ml plastic syringe, 20 pieces
EZ-835-00-04	Foot switch, double pedal, explosion proof, cable 3.5 m, for ELEKTROTOM HiTT 106
	Standard applicator
EZ-700-10-04	HiTT needle electrode, Ø x shaft length x electrode length: 1.2 x 100 x 10 mm
EZ-703-15-04	HiTT needle electrode, Ø x shaft length x electrode length: 2.0 x 150 x 15 mm
EZ-703-20-04	HiTT needle electrode, Ø x shaft length x electrode length: 2.0 x 150 x 20 mm
EZ-704-15-04	HiTT needle electrode, Ø x shaft length x electrode length: 2.0 x 200 x 15 mm
EZ-704-20-04	HiTT needle electrode, Ø x shaft length x electrode length: 2.0 x 200 x 20 mm
EZ-708-15-04	HiTT needle electrode, Ø x shaft length x electrode length: 1.6 x 150 x 15 mm
EZ-708-20-04	HiTT needle electrode, Ø x shaft length x electrode length: 1.6 x 150 x 20 mm
EZ-709-15-04	HiTT needle electrode, Ø x shaft length x electrode length: 1.6 x 200 x 15 mm
EZ-709-20-04	HiTT needle electrode, Ø x shaft length x electrode length: 1.6 x 200 x 20 mm
	MRI applicators
EZ-706-15-04	HiTT needle electrode, Ø x shaft length x electrode length: 1.7 x 200 x 15 mm, MRI-compatible
EZ-707-15-04	HiTT needle electrode, Ø x shaft length x electrode length: 1.7 x 150 x 15 mm, MRI-compatible
EZ-707-20-04	HiTT needle electrode, Ø x shaft length x electrode length: 1.7 x 150 x 20 mm, MRI-compatible



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