腫瘍温熱療法の技術革新：21世紀のがん治療に挑む

ハイパーサーミアのパラダイム転換

オンコサーミア
Oncothermia

Prof. Dr. Andras SZASZ
サース・アンドラーシュ

Head of Biotechnics Department,
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Thermotherapy is the oldest medical therapy

温熱治療はもっとも古い医療行為

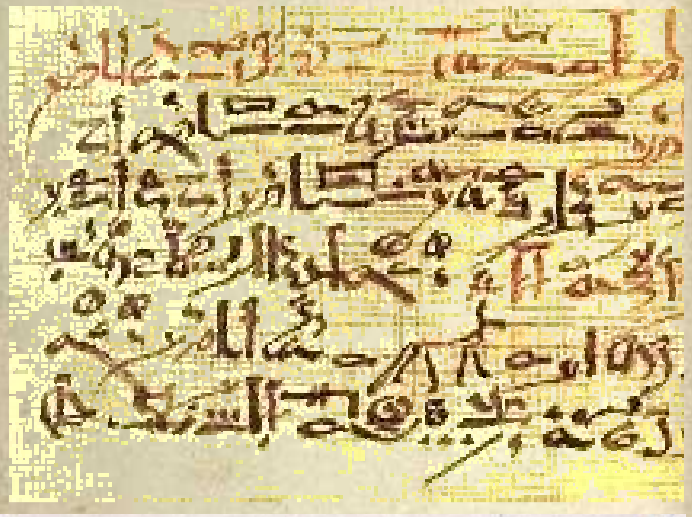
医学の父ヒッポクラテス

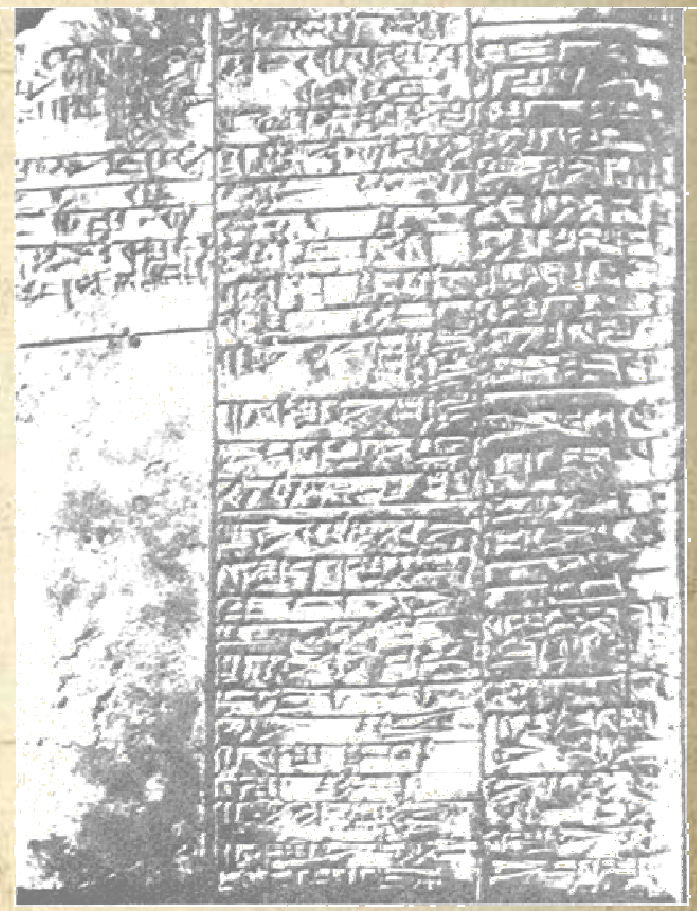
「熱を利用できない疾病は治癒不能」

温泉、お茶、アロマ、赤外線、サウナ、岩盤浴などは、みな素朴な信念にもとづいている。科**学的**裏付けに乏しい呪術から科**学に裏付けられた温熱**治療へ。
オンコサ**ーミアは科学的**裏付けのある**温熱治療の**手法である。

Arab medicine as early as 3000 years.

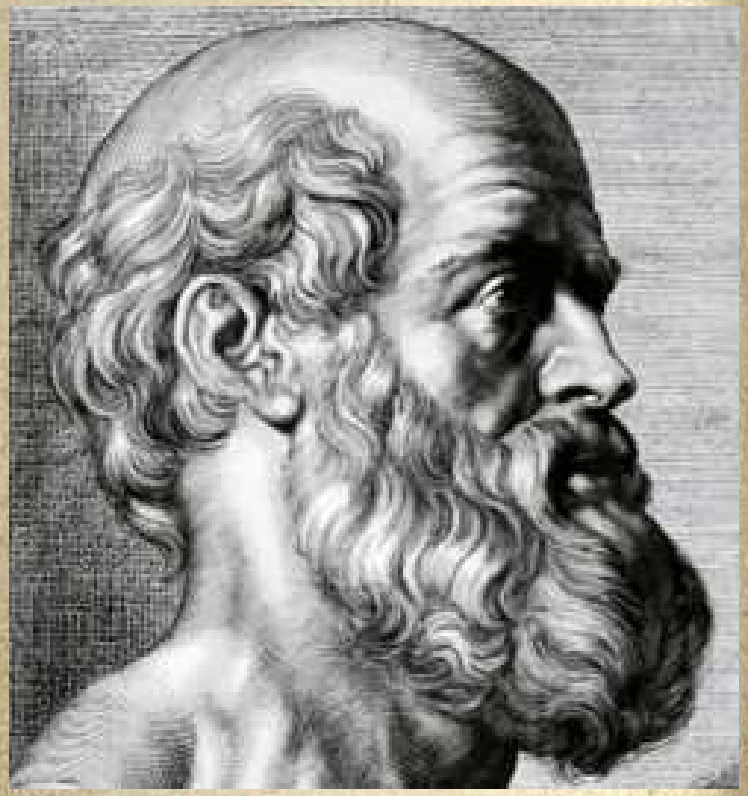
(Edwin Smith Surgical *Papyrus*)





THE OLDEST MEDICAL DIAGNOSIS
Clay tablet with pharmaceutical inscription from Nippur, late 3rd millennium B.C. (University Museum, University of Pennsylvania, Philadelphia)

Start of MEDICINE - Hippocrates



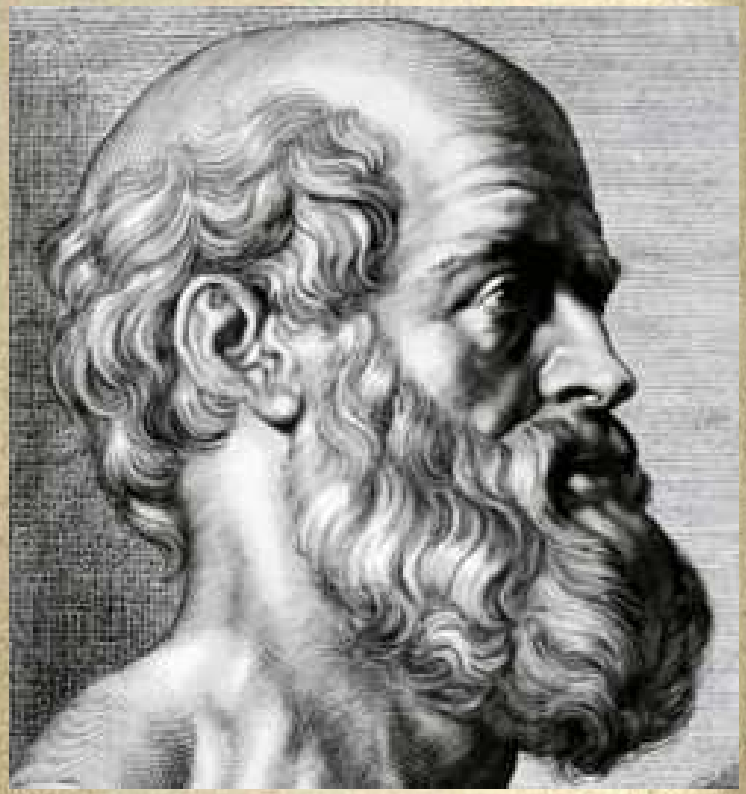
He described first
hyperthermia in oncology

a

b

Hyperthermia was the very first
treatment in oncology

Start of MEDICINE - Hippocrates



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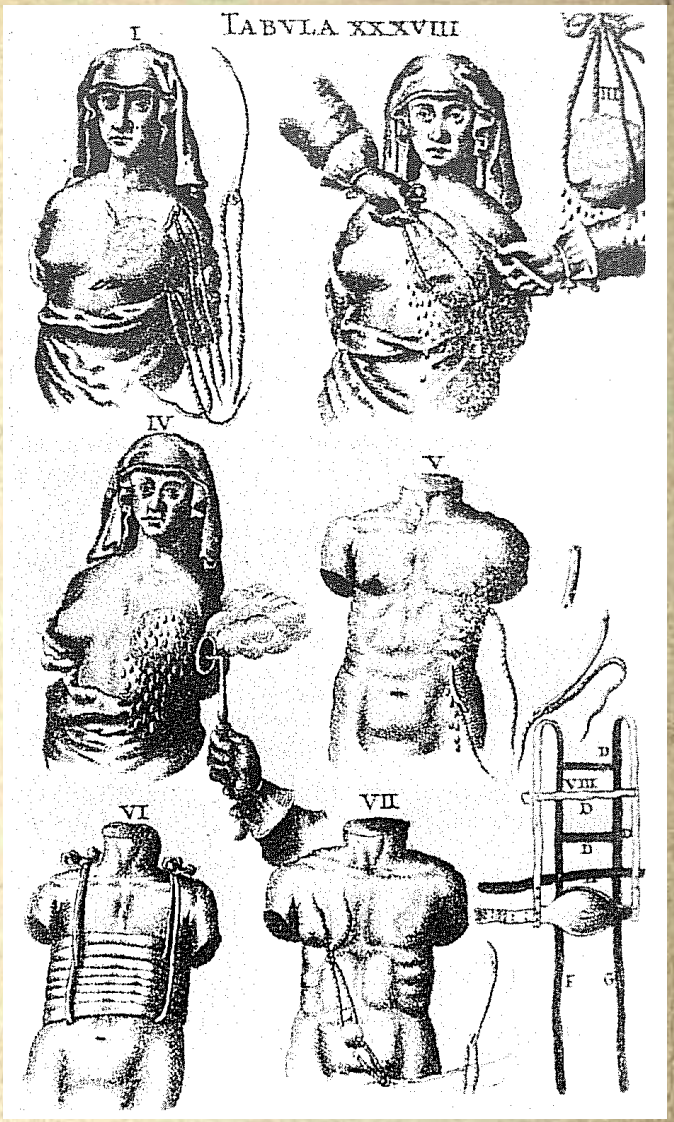
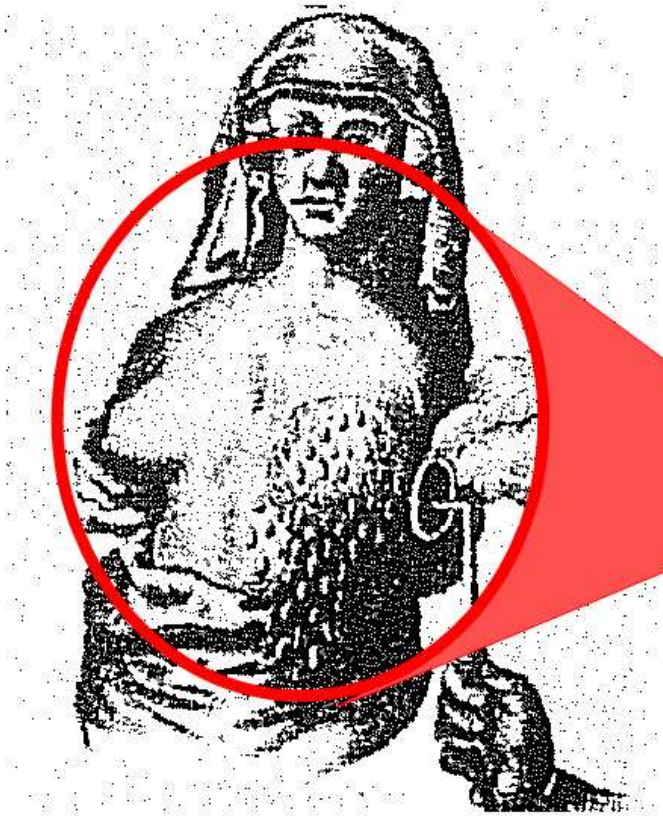
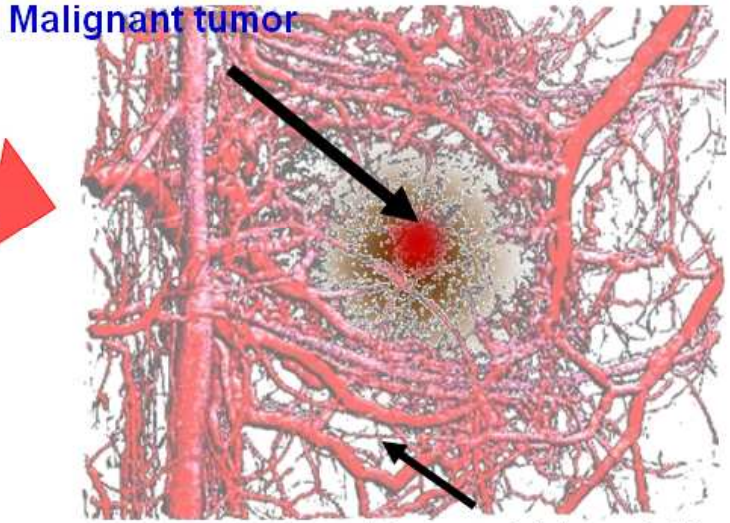


... and in the Middle Ages

Radiation by red-hot iron
（焼きごてによる治療）

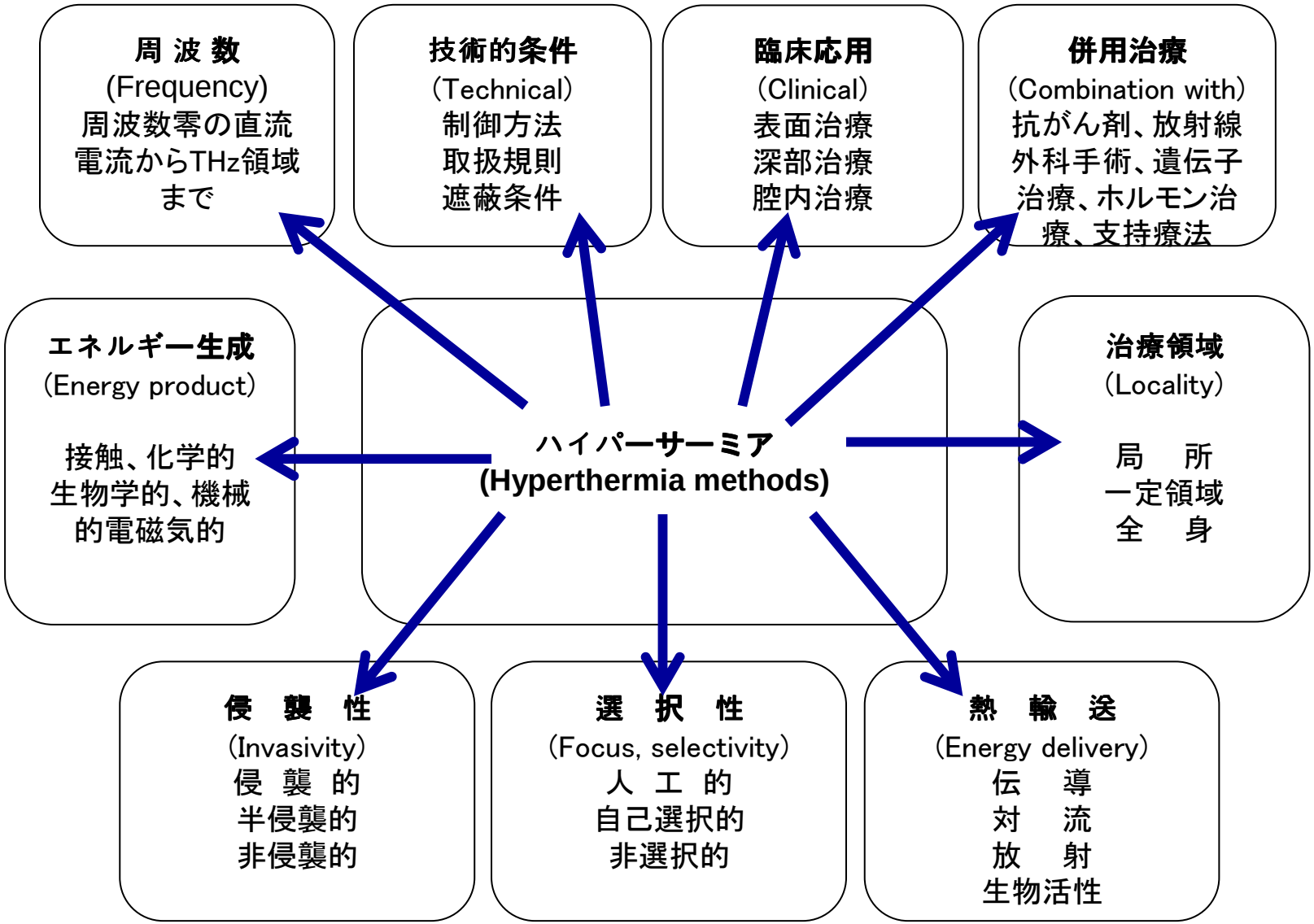




Local heating （局所加熱）→
intensifies the metabolism,
without extra supply →
burning out (焼灼する)

No deep heating was available

現代の加熱（過熱）療法
Hyperthermia（ハイパーサーミア）とは何か



Why has been thermo-therapy under-evaluated in Medicine?
その後の医学の歴史で、何故に温熱療法は過小評価されつづけてきたのだろうか

ヒッポクラテスの信念
No direct burn – “Nil nocere!”
“Do not harm!”

But, how is it possible? (しかし、それは如何にして可能か)

お湯と焼きごて以外の温熱手段を求めて

解決すべき課題は何か

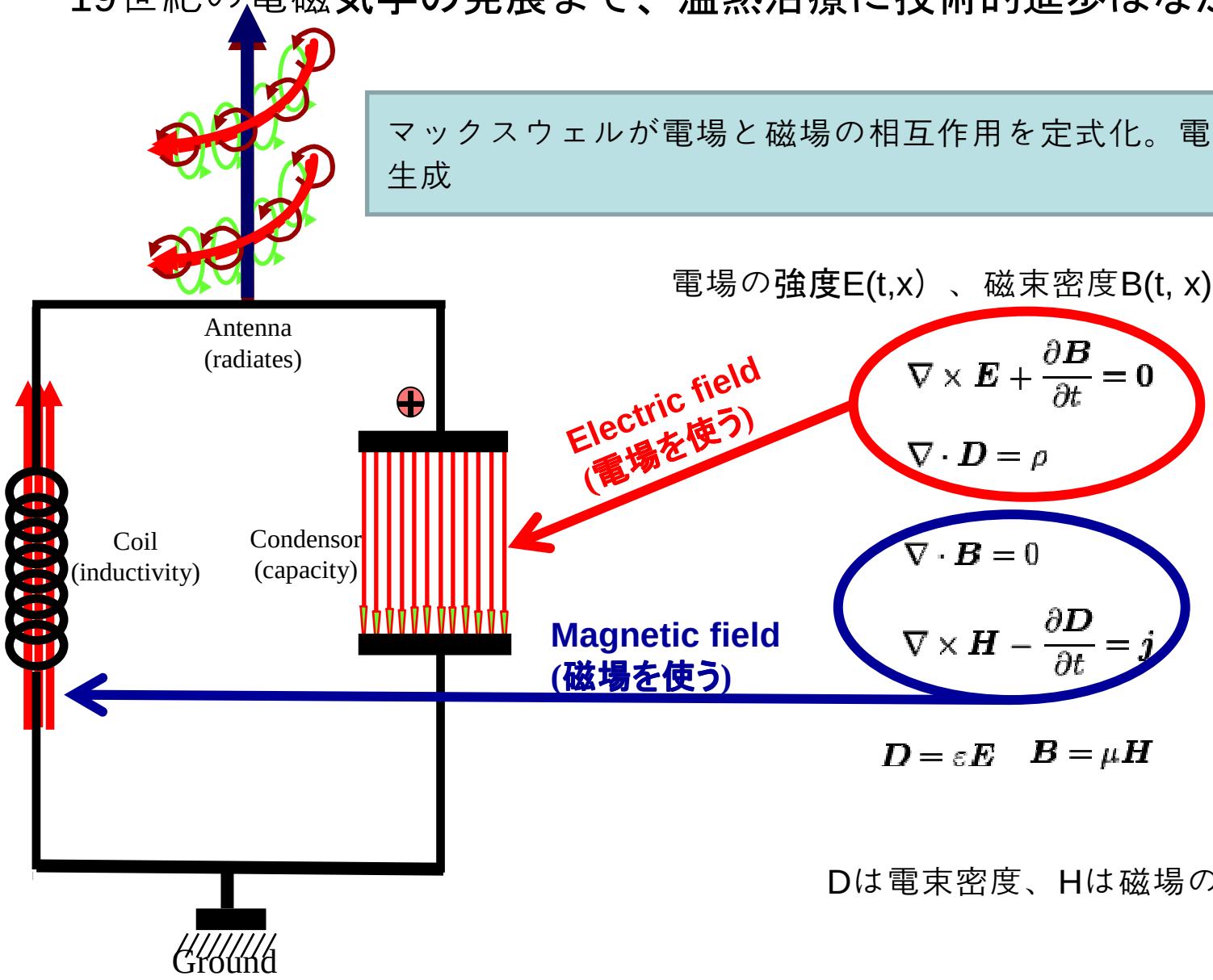
- deep-heating （深部をいかに熱することができるのか）？
- ？）かのるきでルーロトンコにうよのどは熱（ gnitaeh fo lortnoc　control of heating （熱はどのようにコントロールできるのか）？

- controversial results （何が治療効果を妨げているのか）

We have to wait for development of science, i.e. Electromagnetism in 19th century

19世紀の電磁気学の発展まで、温熱治療に技術的進歩はなかった

マックスウェルが電場と磁場の相互作用を定式化。電磁気学の生成



電場の強度E(t,x）、磁束密度B(t, x) とする時

$$\nabla \times \boldsymbol{E} + \frac{\partial \boldsymbol{B}}{\partial t} = \boldsymbol{0}$$

$$\nabla \cdot \boldsymbol{D} = \rho$$

$$\nabla \cdot \boldsymbol{B} = 0$$

$$\nabla \times \boldsymbol{H} - \frac{\partial \boldsymbol{D}}{\partial t} = \boldsymbol{j}$$

$$\boldsymbol{D} = \varepsilon \boldsymbol{E} \quad \boldsymbol{B} = \mu \boldsymbol{H}$$

Dは電束密度、Hは磁場の強度

We have to wait for development of science, i.e. Electromagnetism in 19th century

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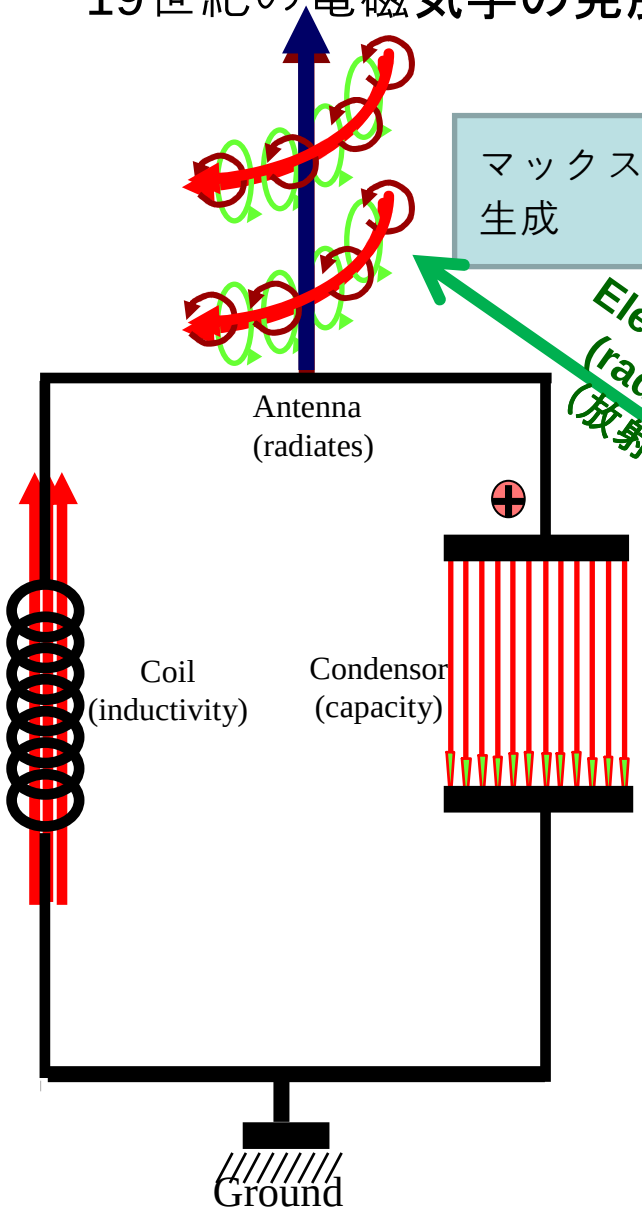

マックスウェルが電場と磁場の相互作用を定式化。電磁気学の生成

Electro-magnetic (radiative) field (放射熱を使う)

電場の強度E(t,x）、磁束密度B(t, x) とする時

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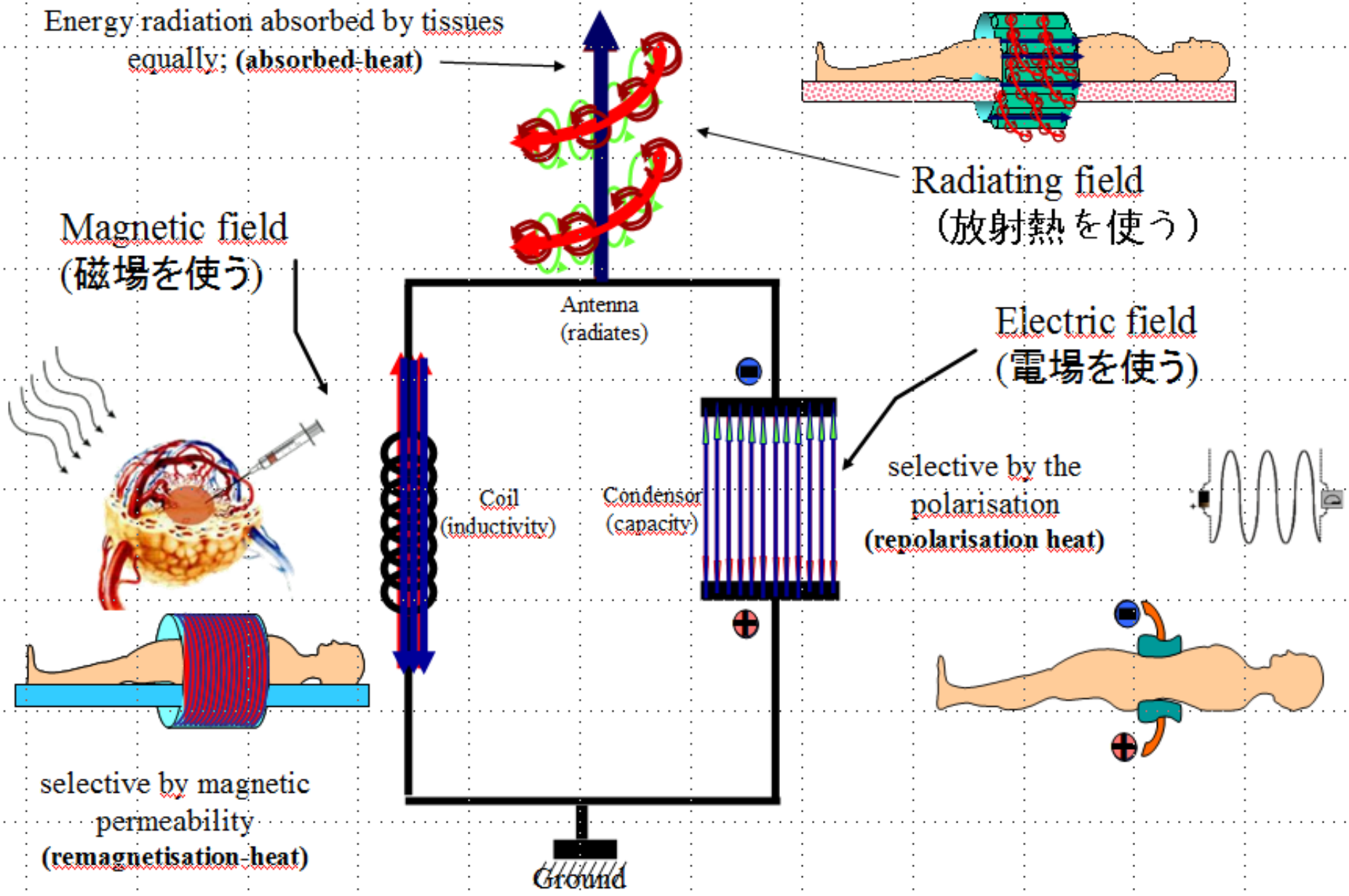
$$\boldsymbol{D} = \varepsilon \boldsymbol{E} \quad \boldsymbol{B} = \mu \boldsymbol{H}$$

Material in the fields

Dは電束密度、Hは磁場の強度

Electromagnetic heating（電磁気加熱の方法）



Contemporary Equipments of Hyperthermia in oncology

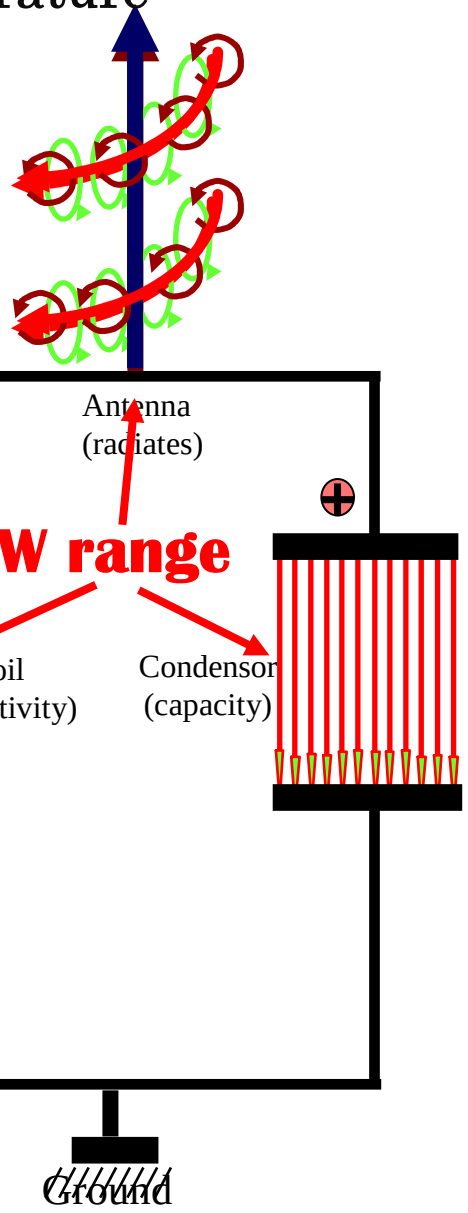
現在市販されているハイパーサーミア機器

Race for Power and Temperature

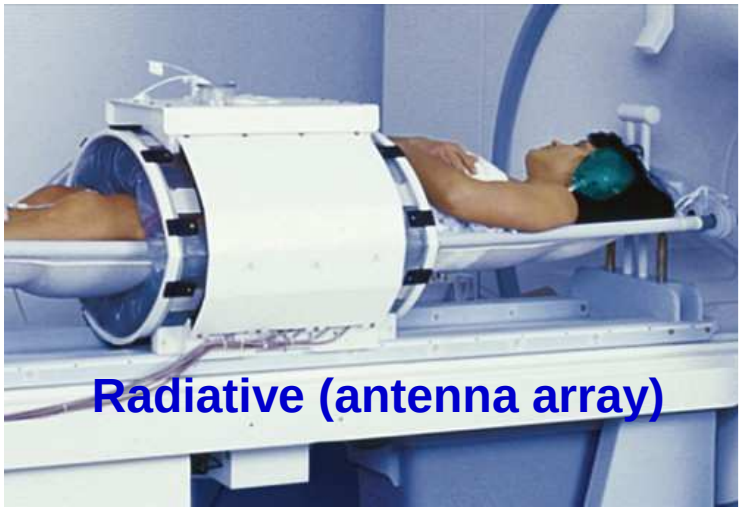
（出力と温度の競い合い）

Competition for 42℃

体内に42℃の温度を発生させるために、互いに競争



Up to 1,600 W energy!



Up to 1,800 W energy!

Up to 10,000 W energy!

Fatal Defect of Traditional Hyperthermia
（伝統的ハイパーサーミアの欠陥）

1500Wの出力の電気ポットを使えば、0.5ｌの水は3分間で沸騰する。現代のハイパーサーミア機器は60分前後の時間を使って、組織温度を6℃上昇させて、腫瘍組織を42℃に加熱する。ちょっと考えてみても、ハイパーサーミア機器には本質的な問題がある。

- 表面冷却によるエネルギーロスが大きい
- 腫瘍組織の選択性（集束性）がなければ、エネルギー効率は低い
- 集束性に欠ければ、腫瘍組織も健康組織も加熱してしまう

Contradicting Results (矛盾する臨床結果)

Articles

Comparison of radiotherapy alone with radiotherapy plus hyperthermia in locally advanced pelvic tumours: a prospective, randomised, multicentre trial

*Jacoba van der Zee, Dionisio González González, Gerard C van Rhoon, Jan D P van Dijk, Wim L J van Putten, Augustinus A M Hart, for the Dutch Deep Hyperthermia Group**

Lancet 2000; **355:** 1119–25

Miracle method?

Int.J.Rad.Oncol.Biol.Phys.61:145-153,2005

Int. J. Radiation Oncology Biol. Phys., Vol. 61, No. 1, pp. 145–153, 200
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0360-3016/05/$–see front matter

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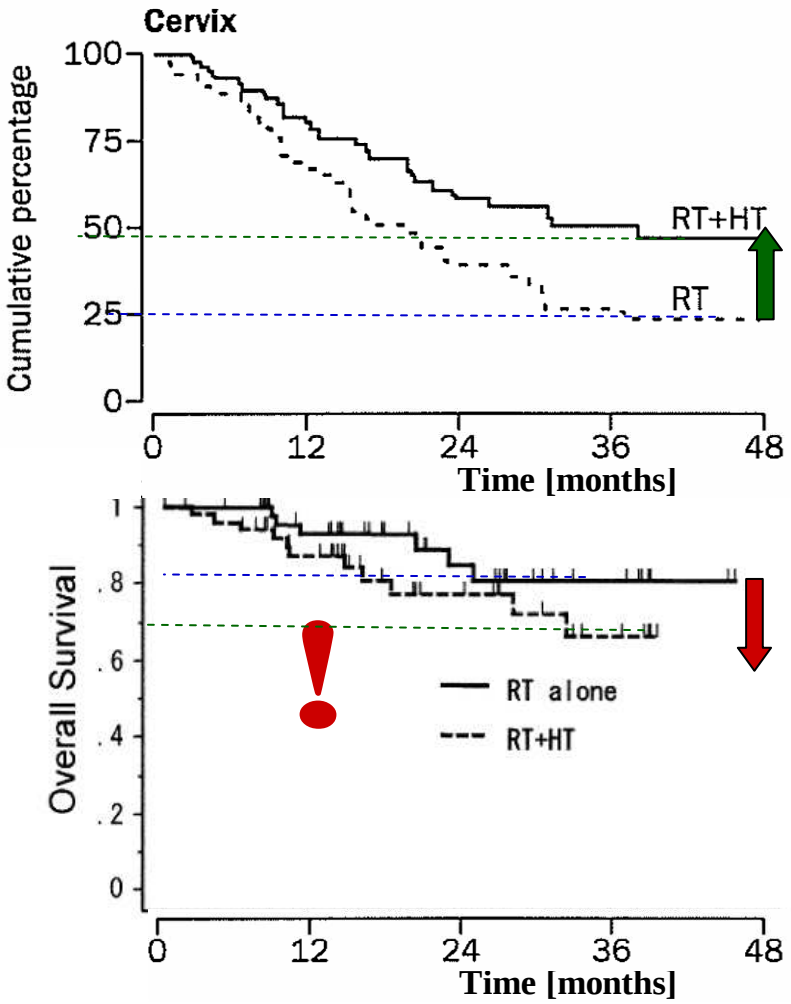
doi:10.1016/j.ijrobp.2004.04.057

CLINICAL INVESTIGATION **Cervix**

REGIONAL HYPERTHERMIA COMBINED WITH RADIOTHERAPY FOR UTERINE CERVICAL CANCERS: A MULTI-INSTITUTIONAL PROSPECTIVE RANDOMIZED TRIAL OF THE INTERNATIONAL ATOMIC ENERGY AGENCY

ARUMUGAM VASANTHAN, M.D.,* MICHIHIDE MITSUMORI, M.D.,† JEONG HO PARK, M.D.,‡ ZENG ZHI-FAN, M.D.,§ ZHONG YU-BIN, M.D.,‖ PRASKOVYA OLIYNYCHENKO, M.D.,¶ HIDEO TATSUZAKI, M.D.,** YOSHIAKI TANAKA, M.D.,†† AND MASAHIRO HIRAOKA, M.D.†



What the critical defect of contemporary hyperthermia is?

Int. J. Hyperthermia, June 2006; 22(4): 353–363

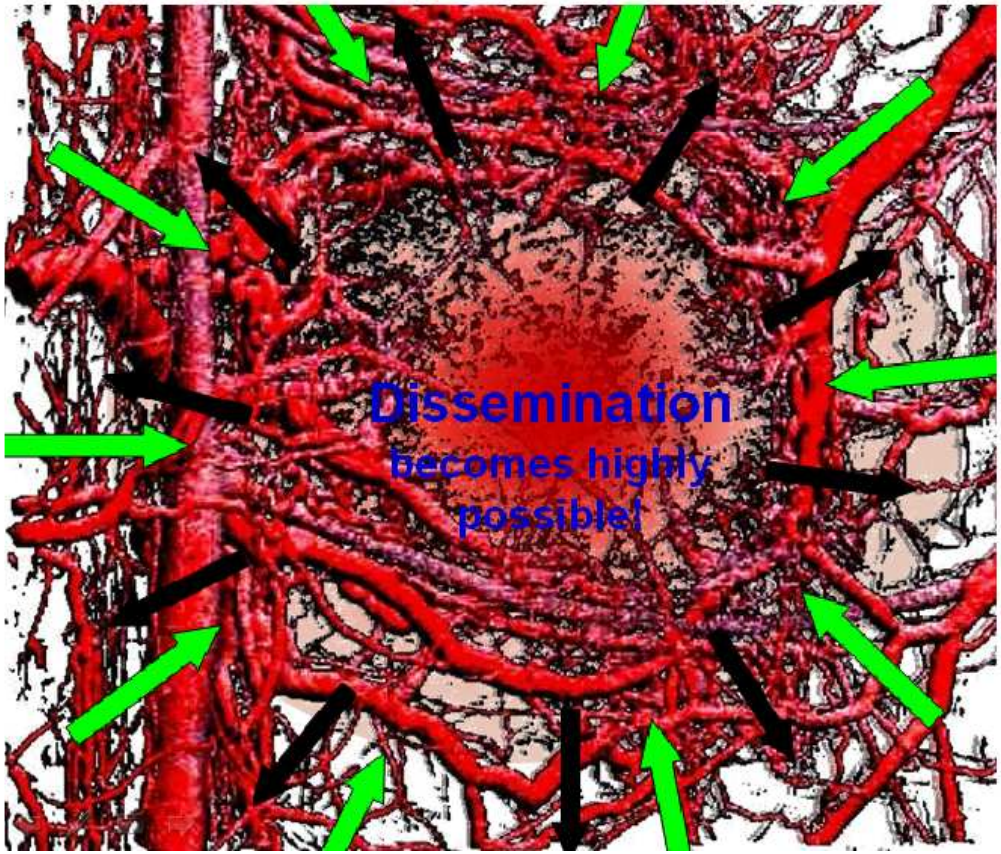
Taylor & Francis

Temperature data analysis for 22 patients with advanced cervical carcinoma treated in Rotterdam using radiotherapy, hyperthermia and chemotherapy: A reference point is needed

D. FATEHI[1], J. VAN DER ZEE[1], E. VAN DER WAL[1], W. N. VAN WIERINGEN[2,*], & G. C. VAN RHOON[1]

腫瘍温度を基準点にしたのでは臨床結果の再生（再試験）できない。温度を唯一の基準とする伝統的ハイパーサーミアは本質的な欠陥を抱えている

Extra nutrients (glucose, etc.) supply the tumor!



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Radiative antennas

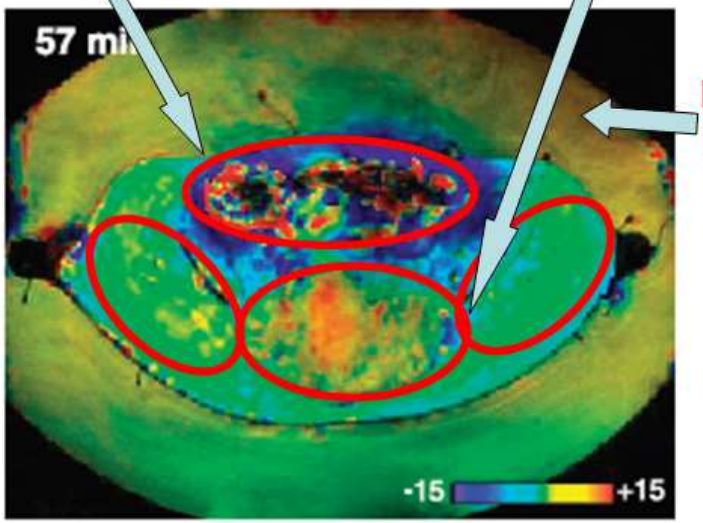
Gellermann J et al. Cancer Res 2005;65:5872-5880

Selectivity < 1°C

Unwanted hot spots

Desired heated area (naturally spread)

Power=1300 W



Bolus is heated

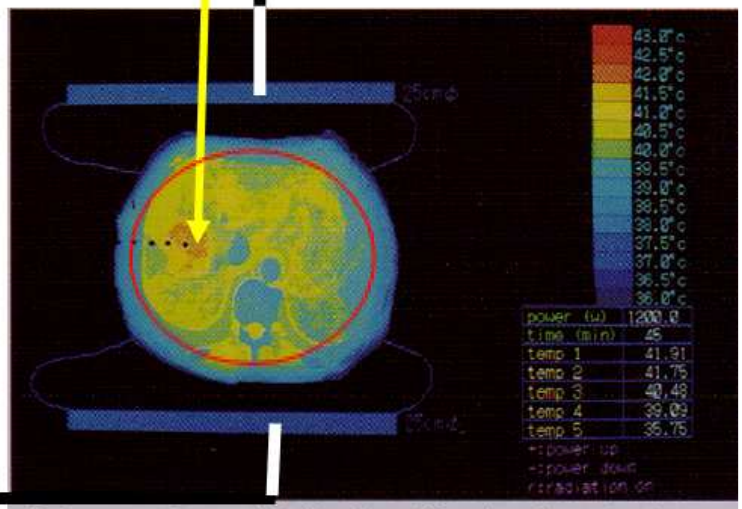
Capacitive antenna

From brochure of Thermotron

Selectivity < 1°C

41.9 °C **1200 W**

RF



▲Temperature distribution 45 min after start of heat

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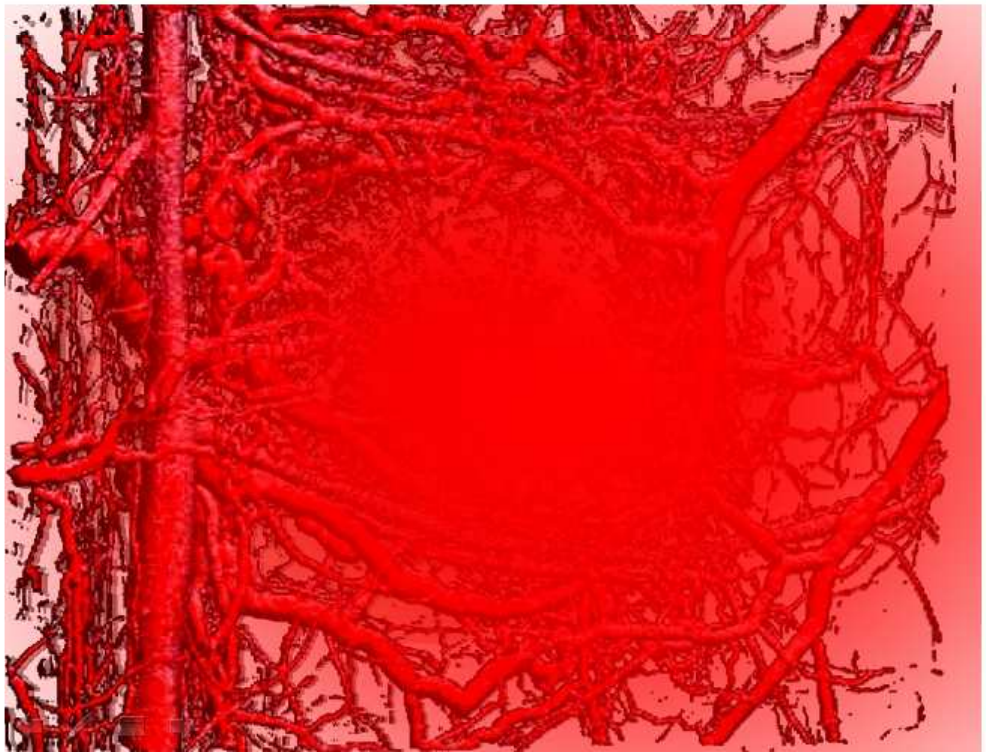
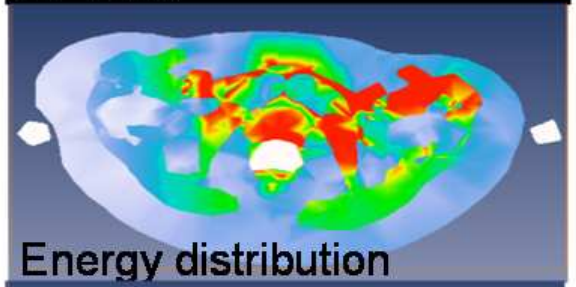
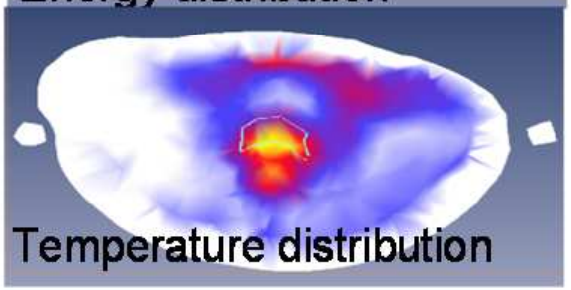
エネルギーと温度の混同

投入されたエネルギーは腫瘍組織のみならず、周辺組織を加熱する



No artificial control could be done





J.Van der Zee: Mumbai, 2005

加熱におけるエネルギー分布と温度分布は同じにならない

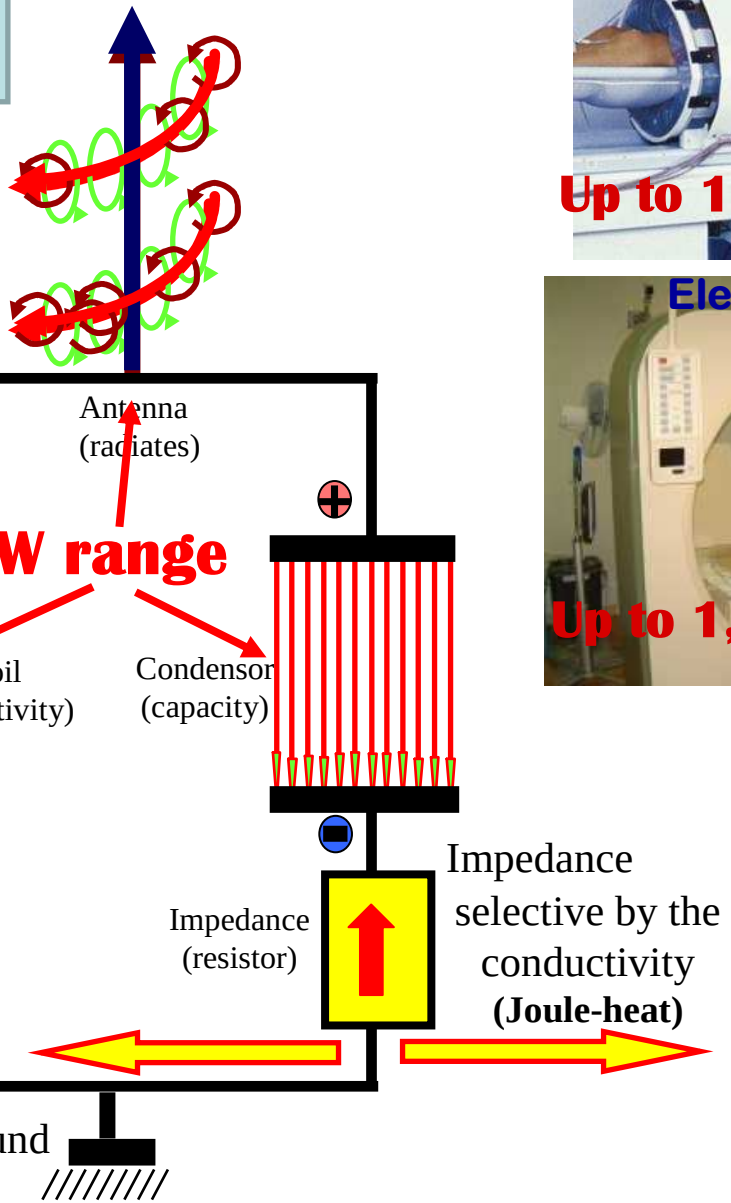
↓

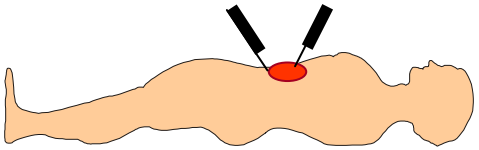
温度信仰は治療目的を喪失する

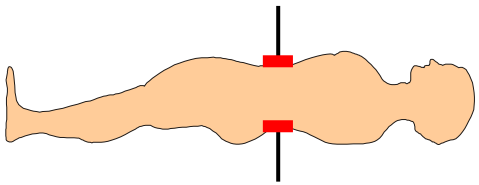
達成温度を目標にし、出力を上げるハイパーサーミアは、基本目標が間違っている

どうすれば腫瘍を叩くことができるのか。**温度と出力への信仰から**解き放たれることが大切。

パラダイムの**転換**







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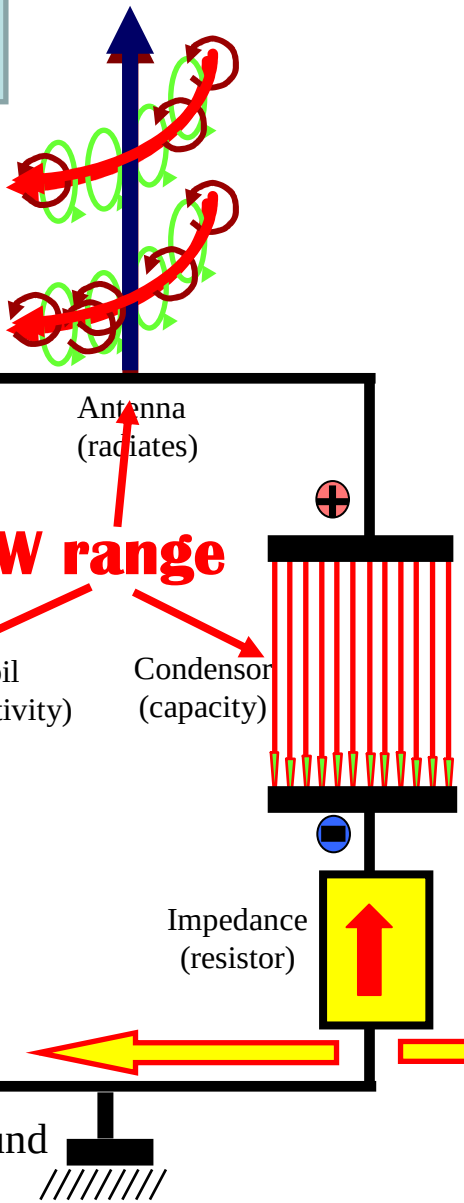

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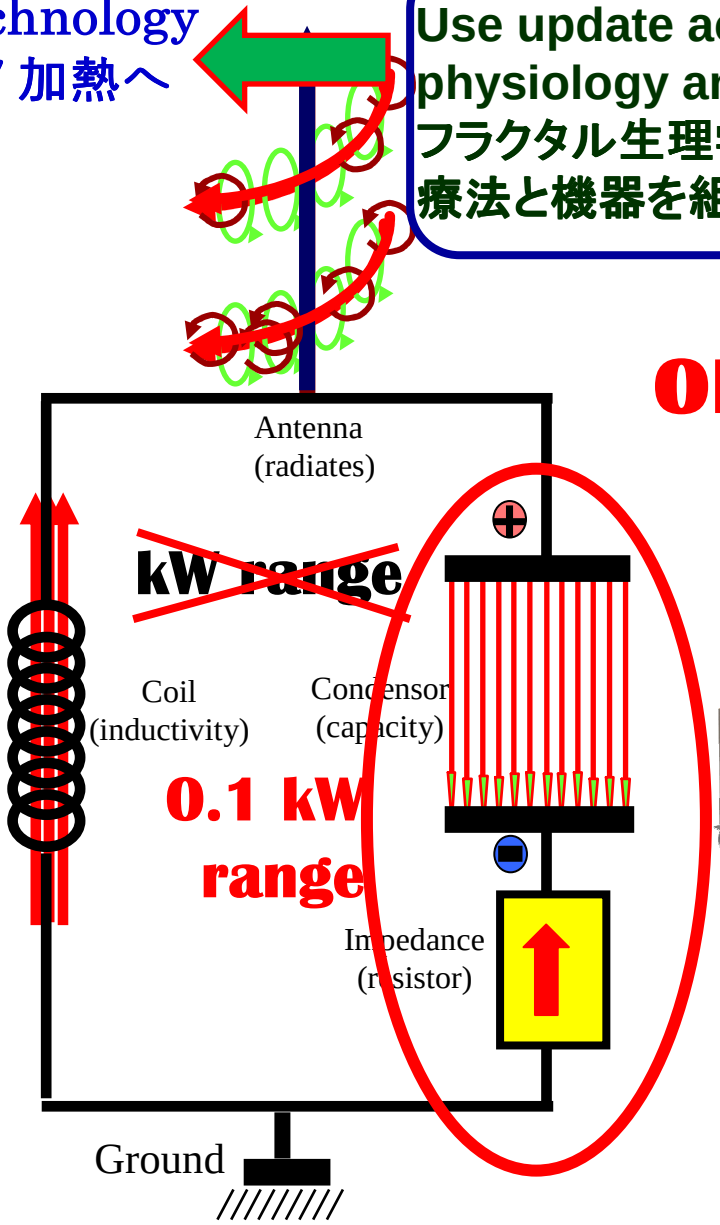
Direction of nano-technology
マクロ加熱からナノ加熱へ

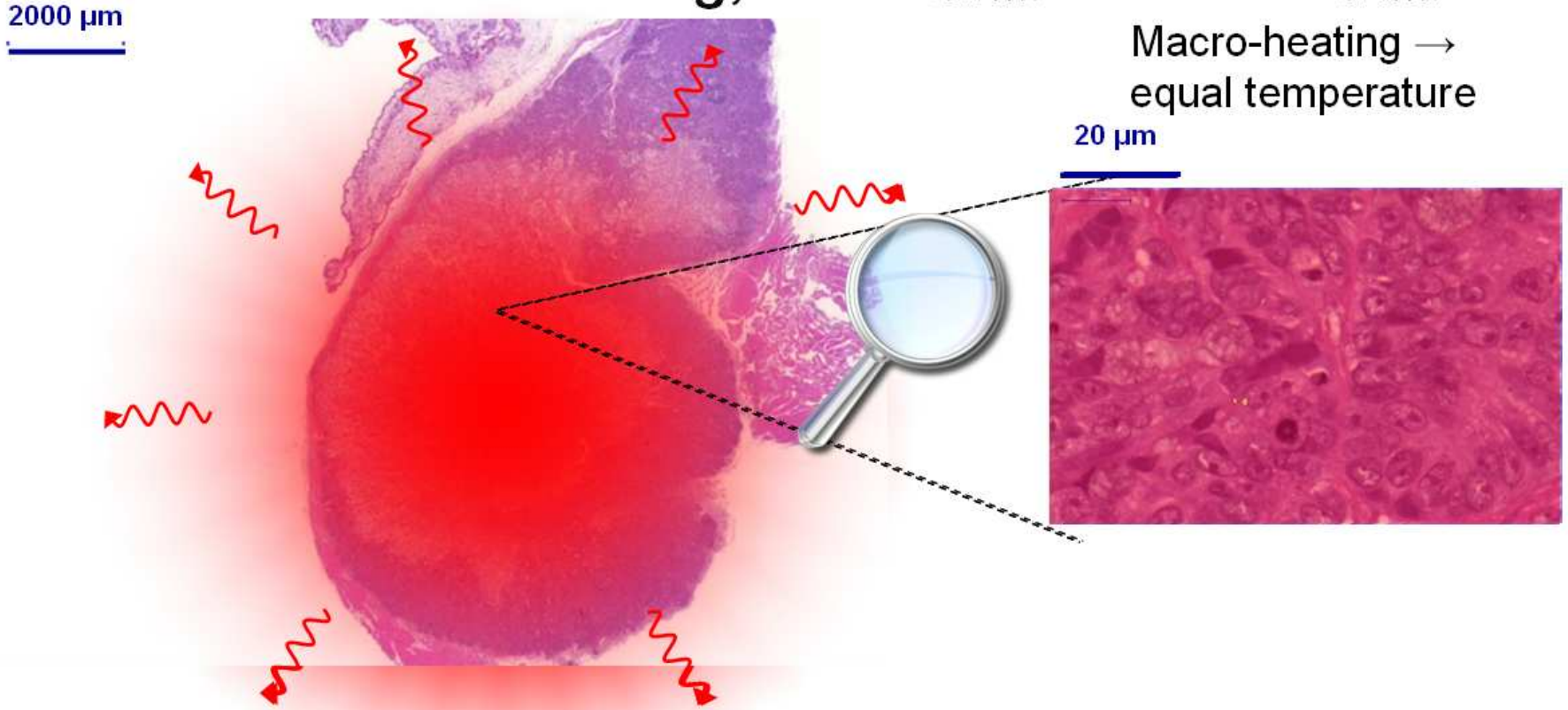
Use update achievements of fractal physiology and bioelectromagnetics!
フラクタル生理学と生体電磁気学 をベースに治療法と機器を組み立てる



oncothermia

Up to 100-700 W energy!
(0.5 W/cm²)
(high efficacy without high power)

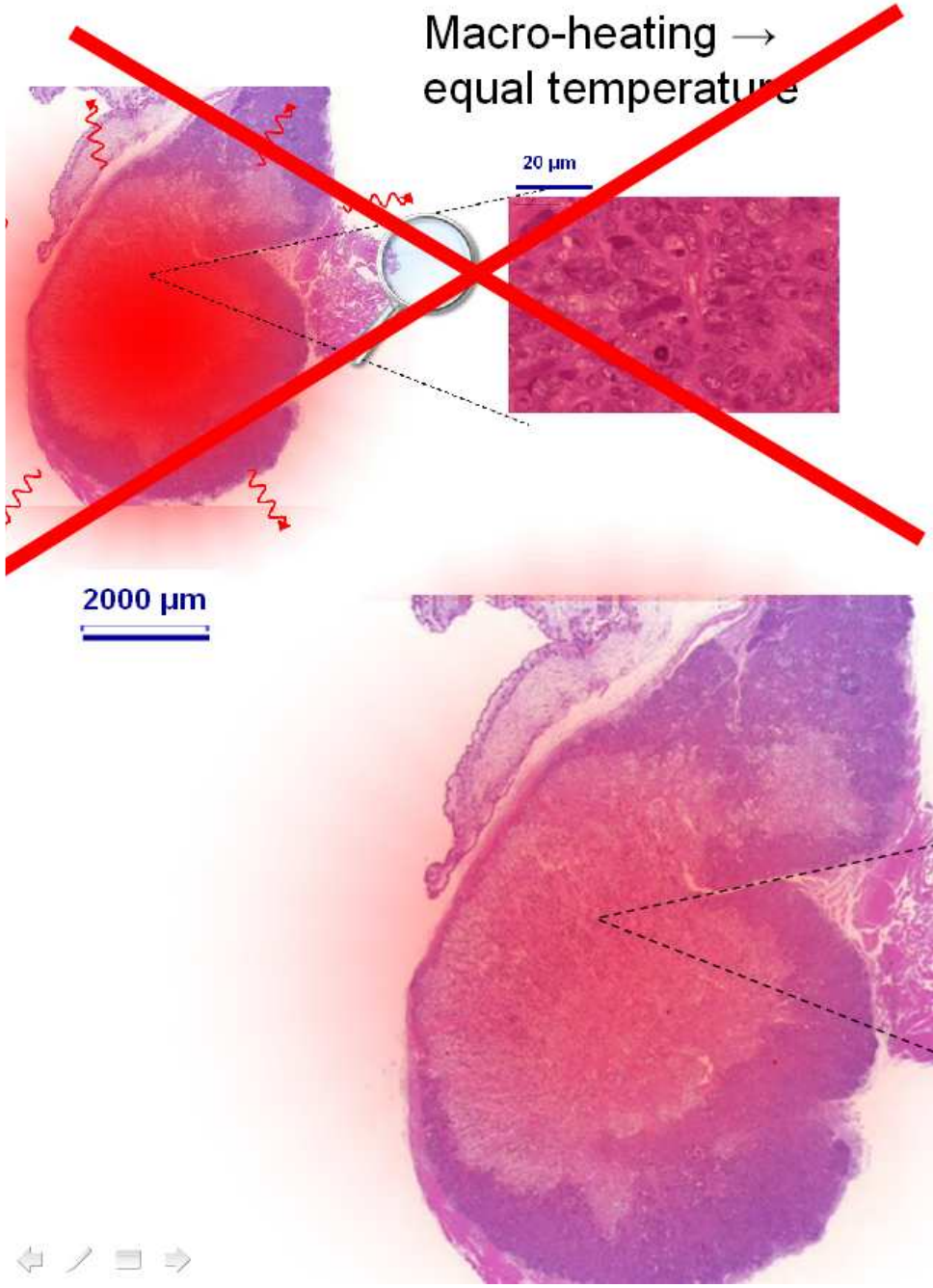
Oncothermia → nano-heating, マクロ加熱からミクロ加熱へ



High average temperature no inside heat-flow

平均温度が高くでも、内部への熱流入は限定的

Oncothermia → nano-heating, マクロ加熱からミクロ加熱へ



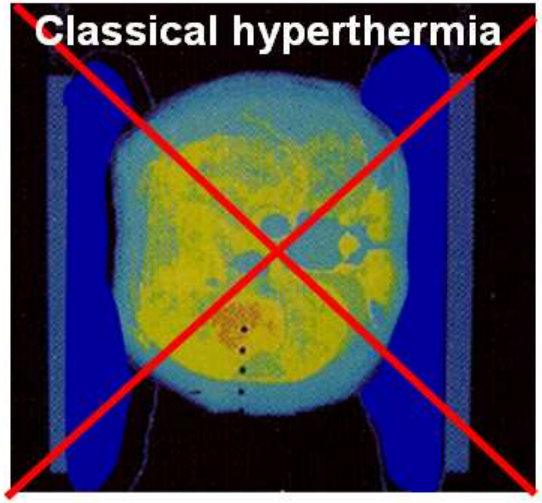
細胞ごとのナノ加熱を行うオンコサー

Nano-heating →
temperature differences

20 µm

Low average temperature,
intensive inside heat-flow

How to find the malignant cells? （ナノ加熱）



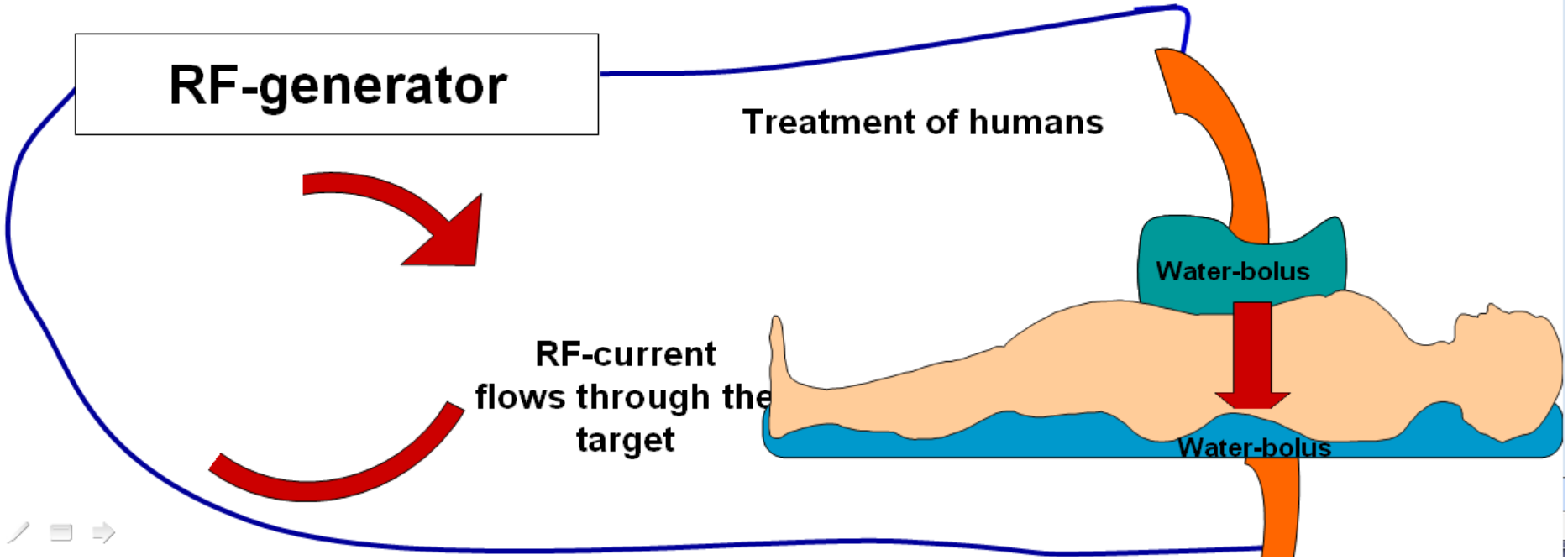
Oncothermia idea

Oncothermia paradigm

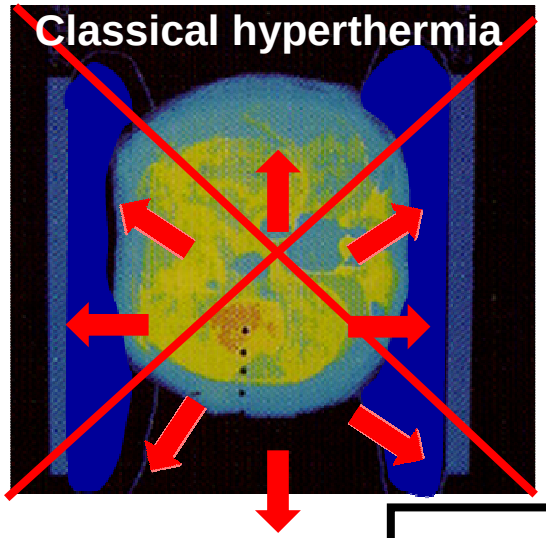
We do the same change of paradigm in hyperthermia as was made in light-technology

Energy is carried by 13.56 MHz RF-current, (AM-modulated)

The body is a part of the electric circuit



How to find the malignant cells? （ナノ加熱）



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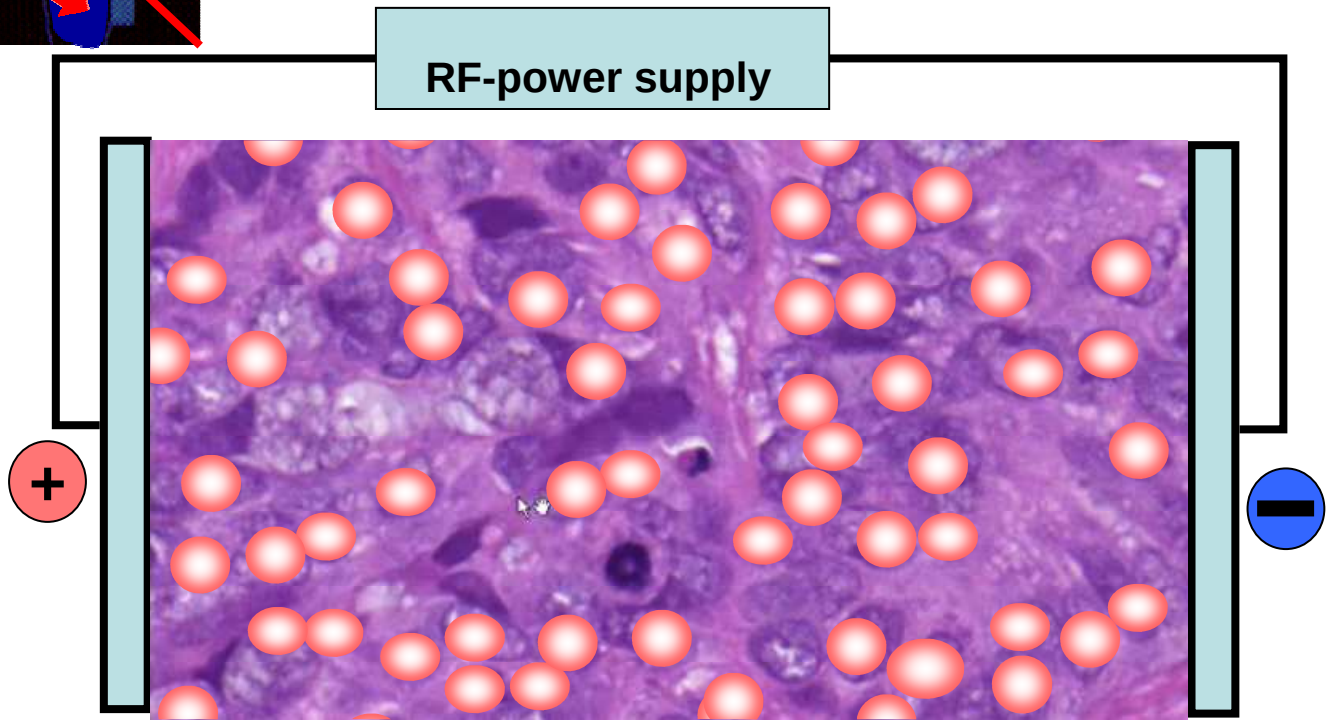

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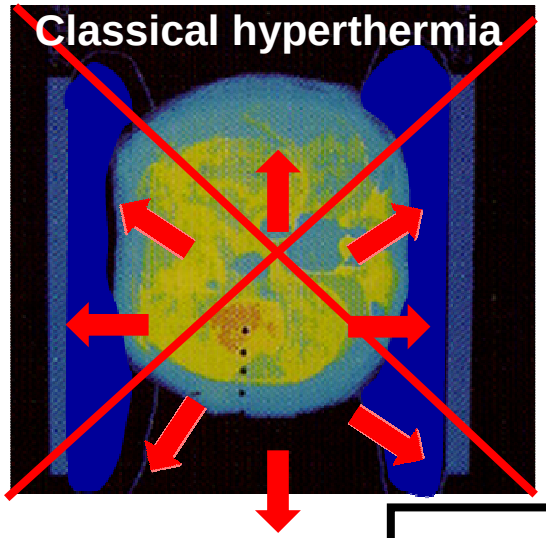

Oncothermia idea

Oncothermia paradigm

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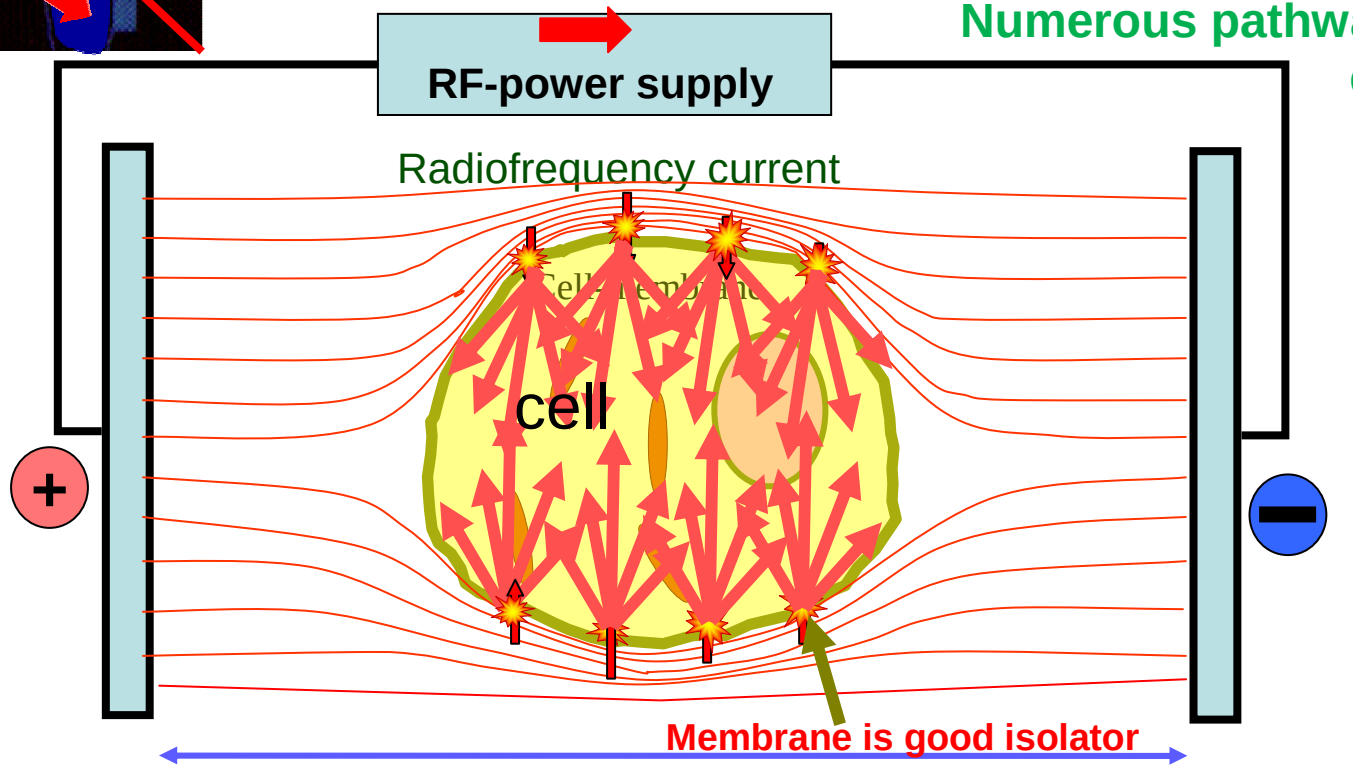
Energy is carried by 13.56 MHz RF-current, (AM-modulated)

Numerous pathways are excited



[max. 500 V/m = 5 V/cm ≈ 5 mV/cell]

How to find the malignant cells? （ナノ加熱）

Serious consequences:
On membrane:
- ✓Inducing apoptotic signal
- ✓Forming membrane-HSP
- ✓Higher transparency
- ✓Higher motility of domains
- ✓Rebinding E-cadherin
- ✓Damages on membrane

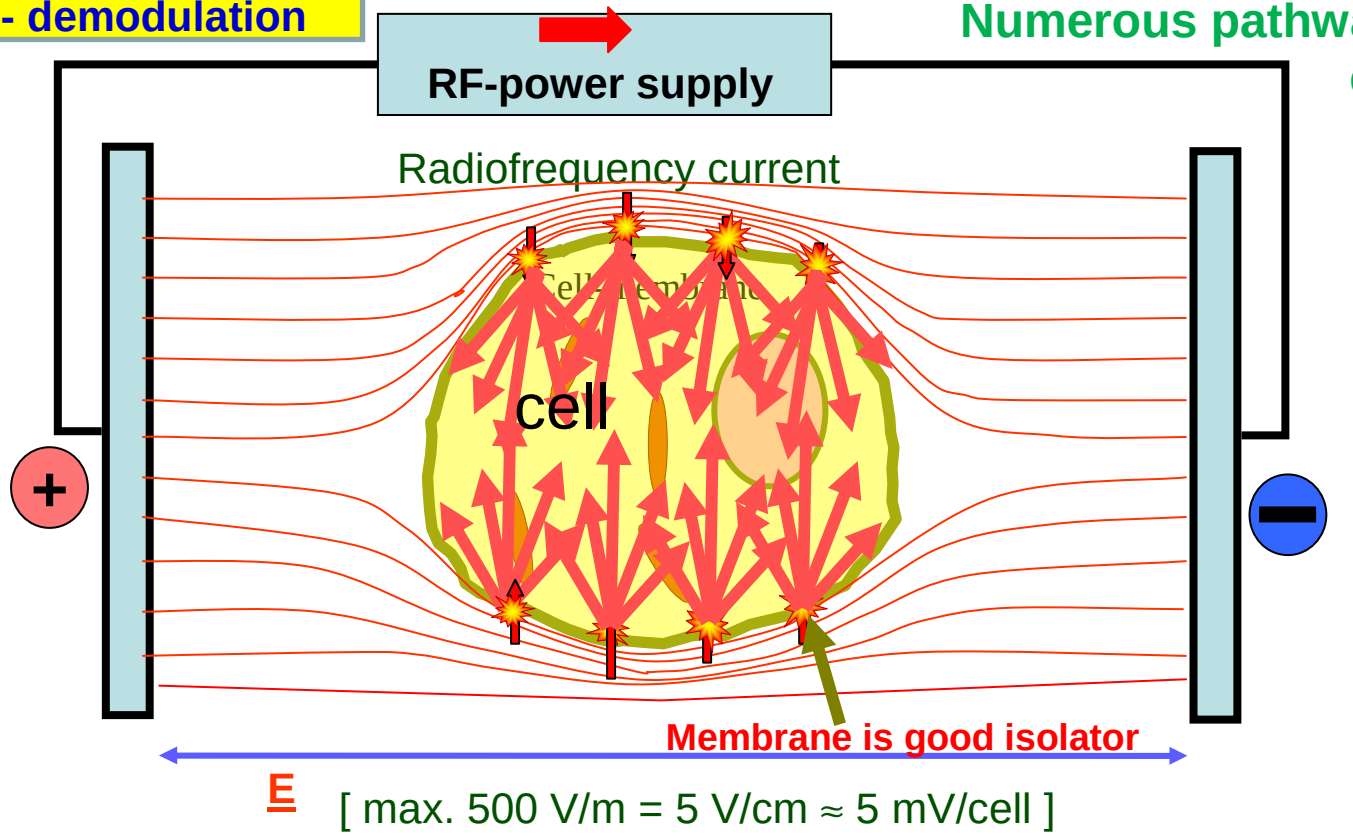
Rectification- demodulation

Serious consequences:
In cytoplasm:
- ✓Dilution of the cytoplasm
- ✓Higher pressure developed
- ✓Activated apoptotic pathways
- ✓Activated death receptors

Suppressed proliferation

ONCOTHERMIA
Naturally solves the control by
- Selection of cells
- Destroying of cells

Numerous pathways are excited



Oncothermia のナノ加熱を支持する原理

How is it arranged?

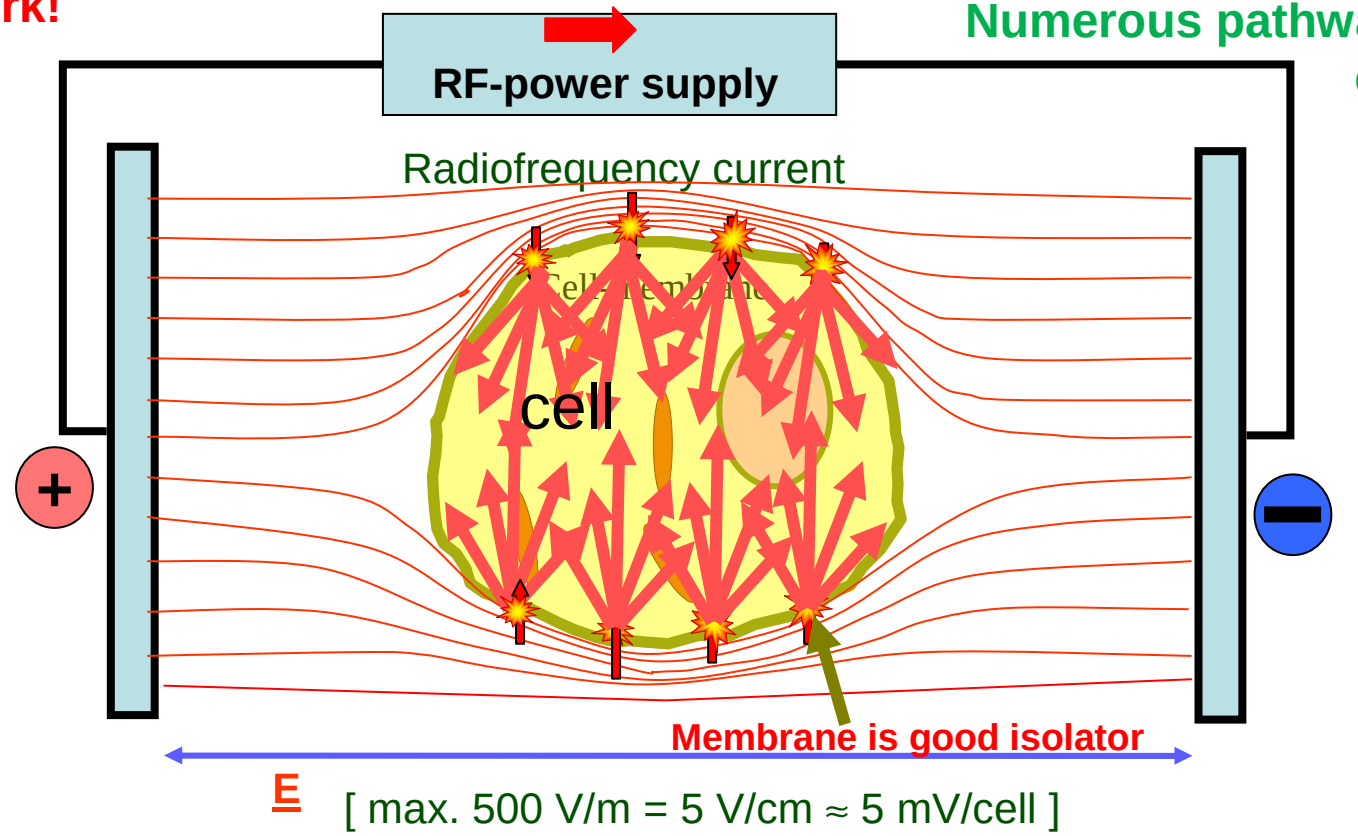
1. Selection by metabolic differences 代謝の差異を利用 **(Otto Warburg)**

2. Selection by dielectric differences 誘電率の差異を利用 **(Albert Szentgyorgyi)**

3. Selection by collectivity differences 細胞結合の差異を利用 **(fractal physiology)**

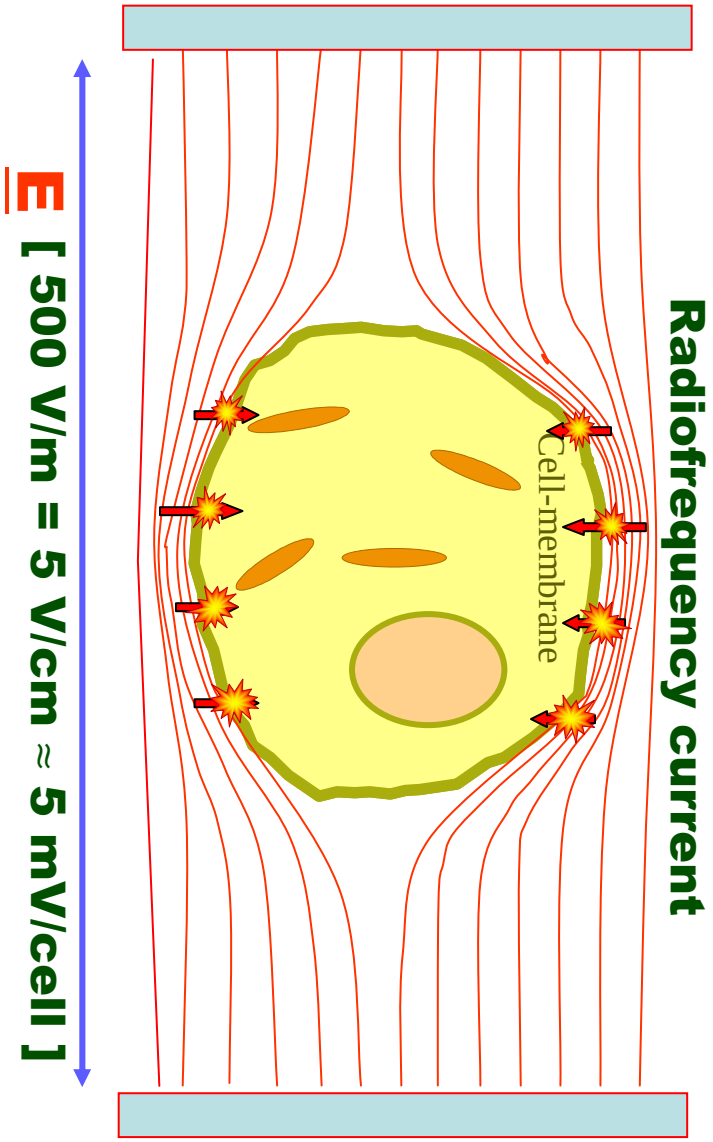
When the absorbed energy is too much, the nano-heating does not work!

Numerous pathways are excited

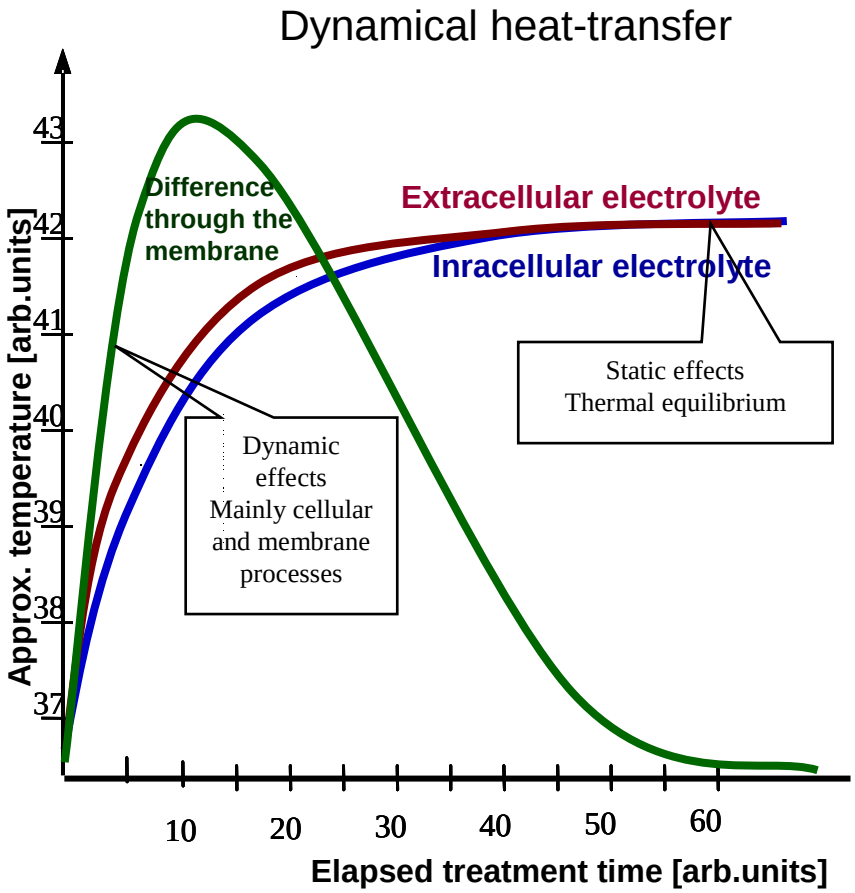


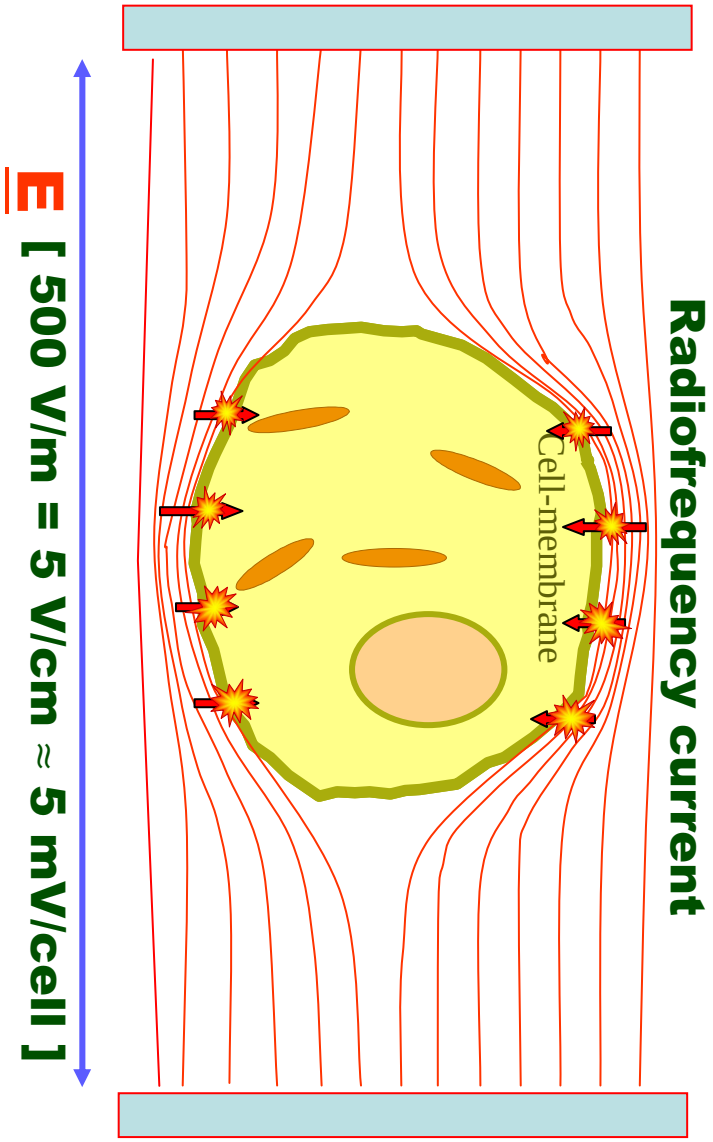
Selectivity on nano-scale

細胞膜の内と外の電解質の差異



Membrane damage leads mainly to apoptosis





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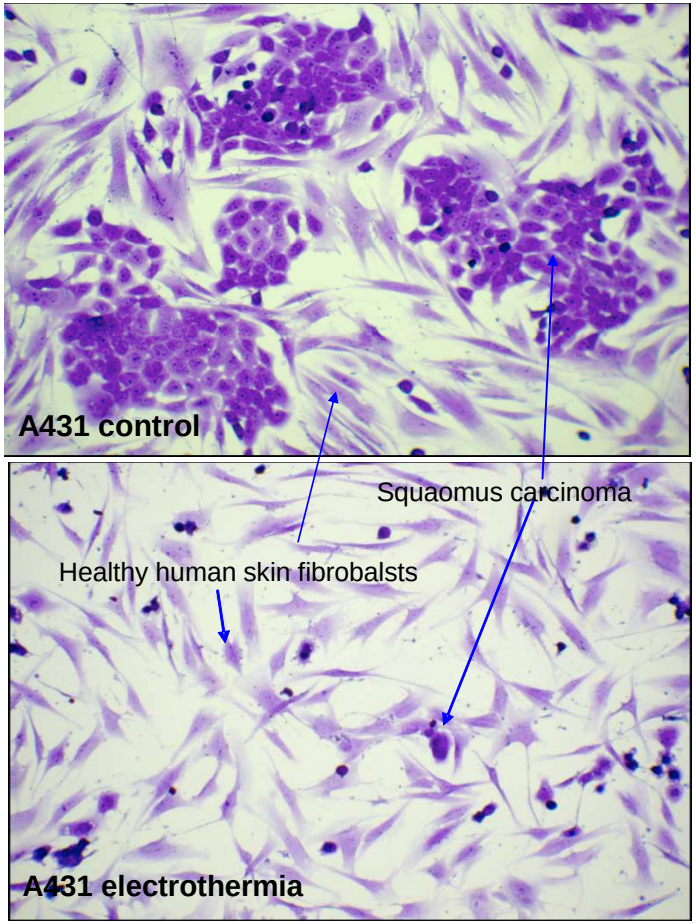
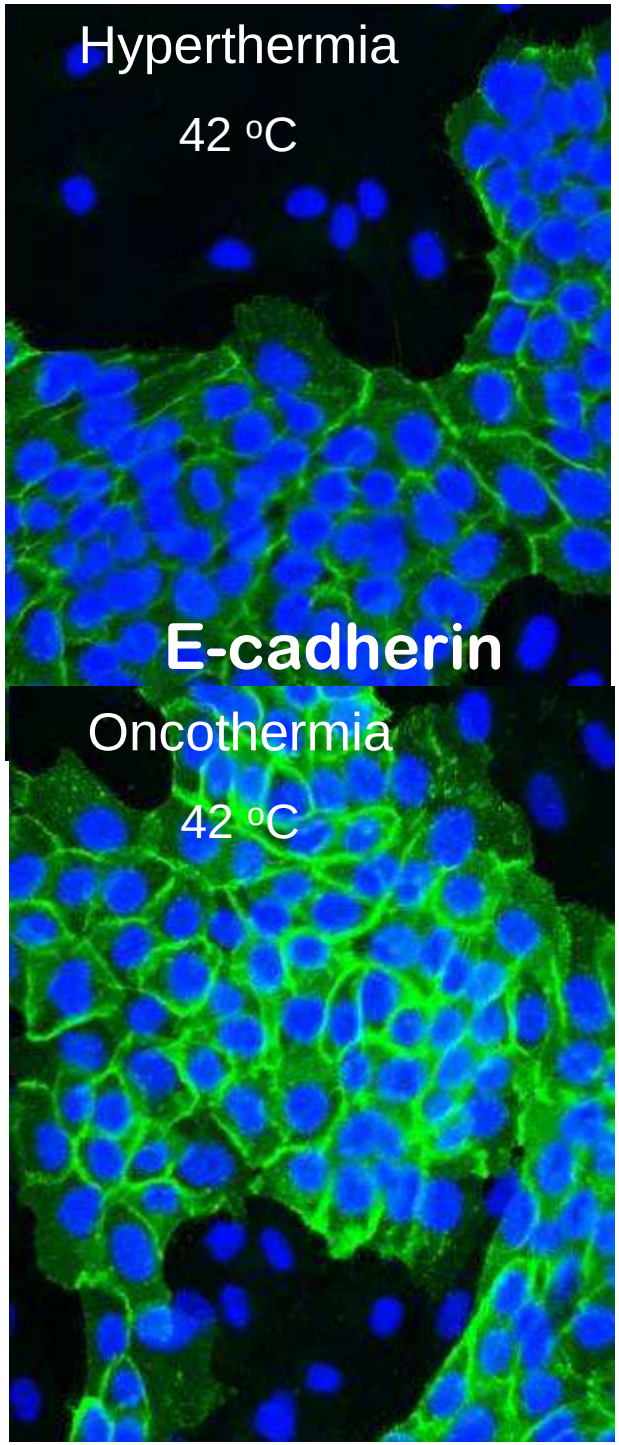


細胞膜の内と外の温度勾配が悪性細胞の破壊メカニズムを起動させる

Co-culture with normal human skin fibroblasts as a model of a squamous carcinoma

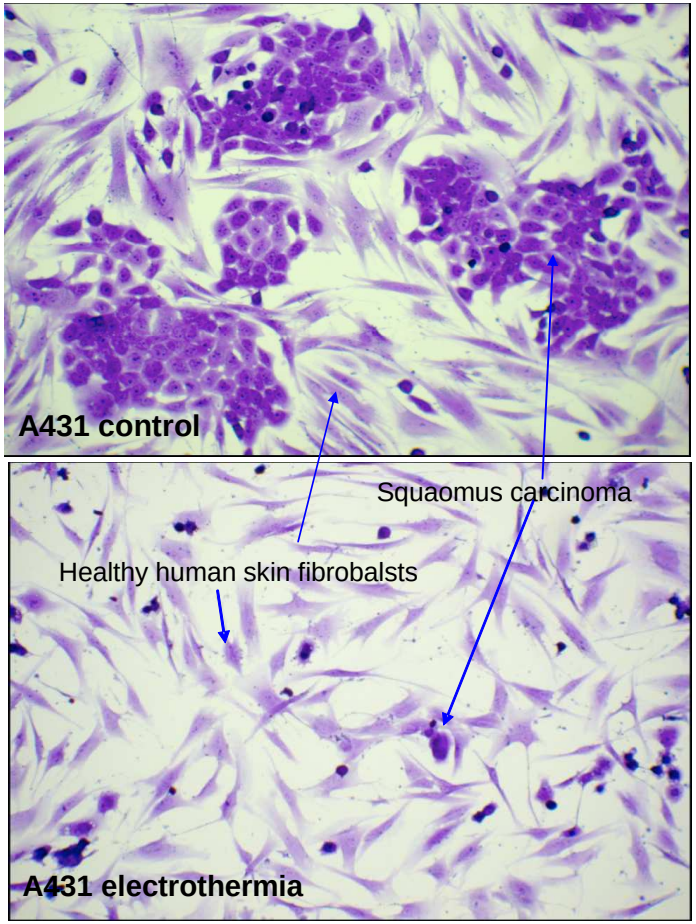
Dr.Brunner G, Munster Univ., Hornheide Germany



Selectivity on nano-scale

細胞膜の内と外の電解質の差異

Eカドヘリンで見た比較



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Squamous carcinoma (A431) growing with normal human skin fibroblasts cells (100.000/ml) were exposed to electrothermia, incubated for 24 h at 37°C

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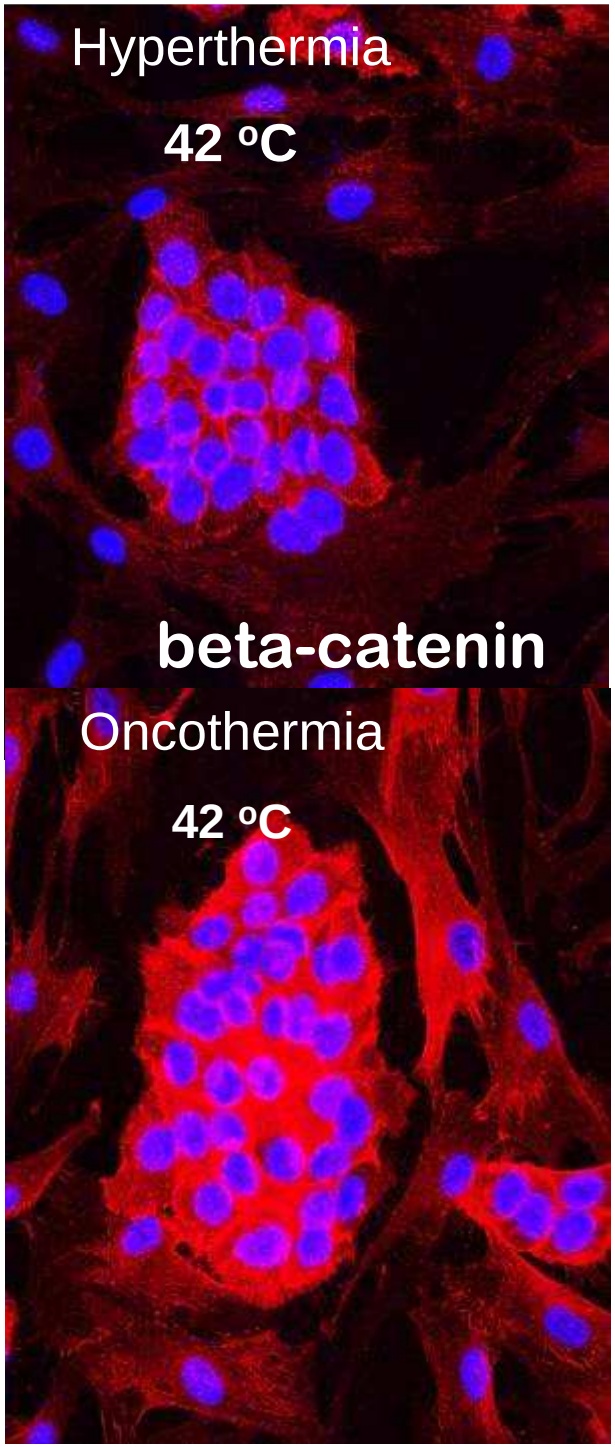
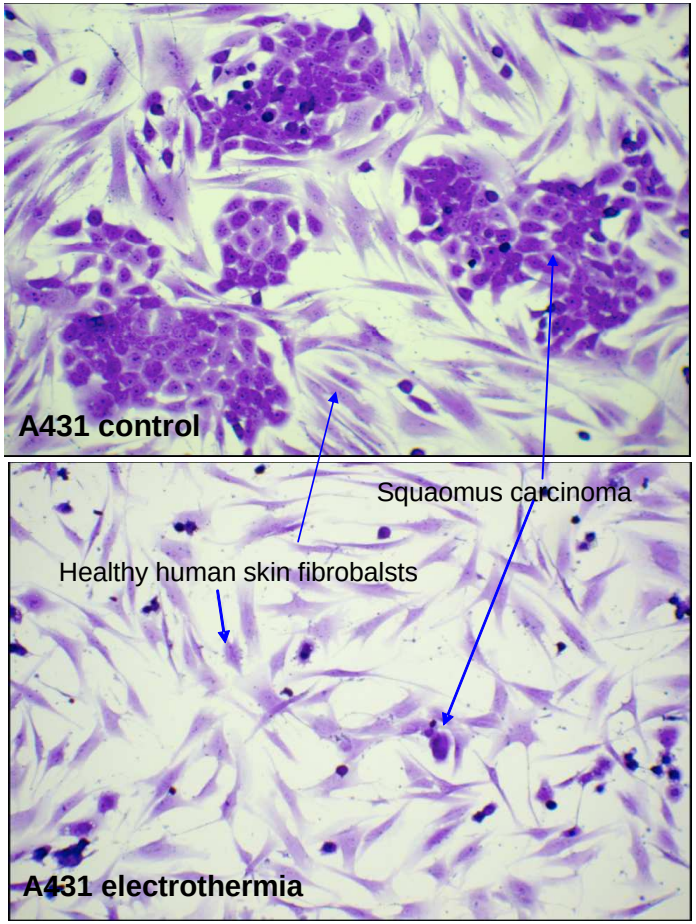


Selectivity on nano-scale

細胞膜の内と外の電解質の差異

B-カテニンで見た比較



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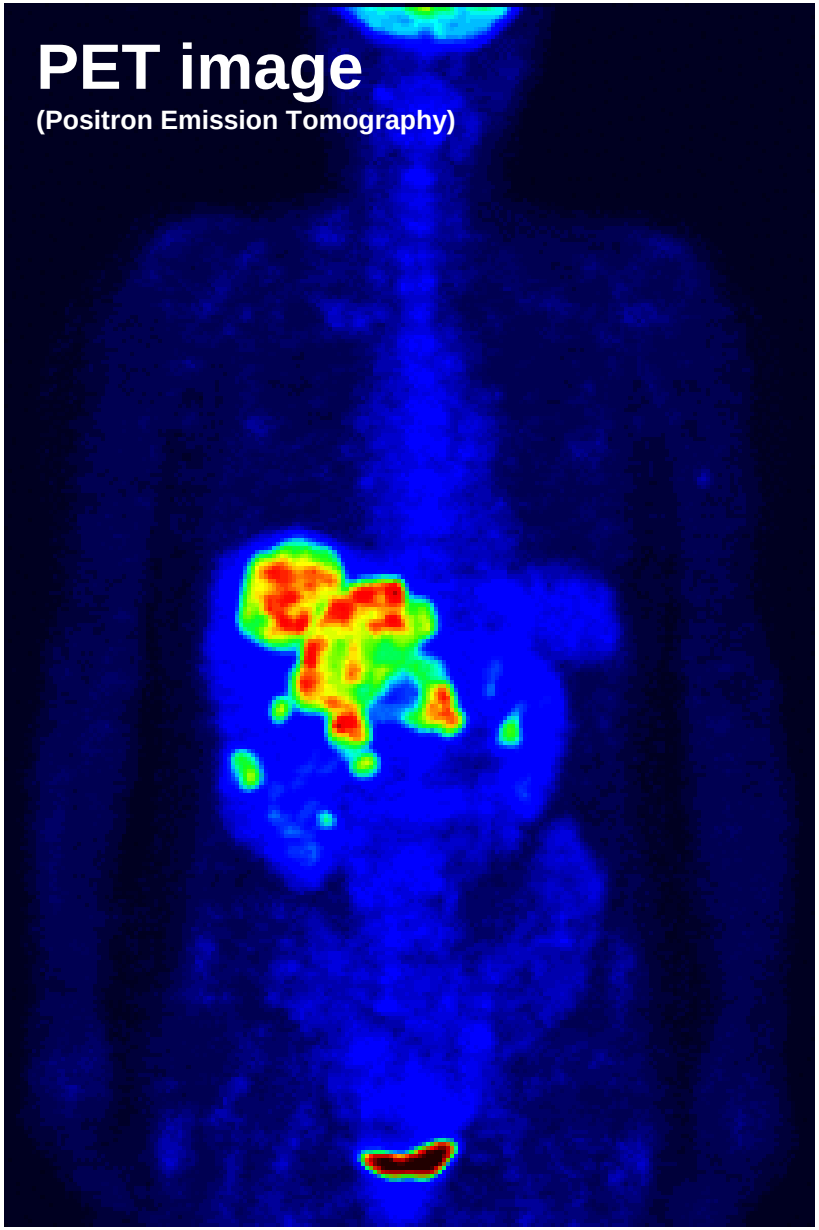
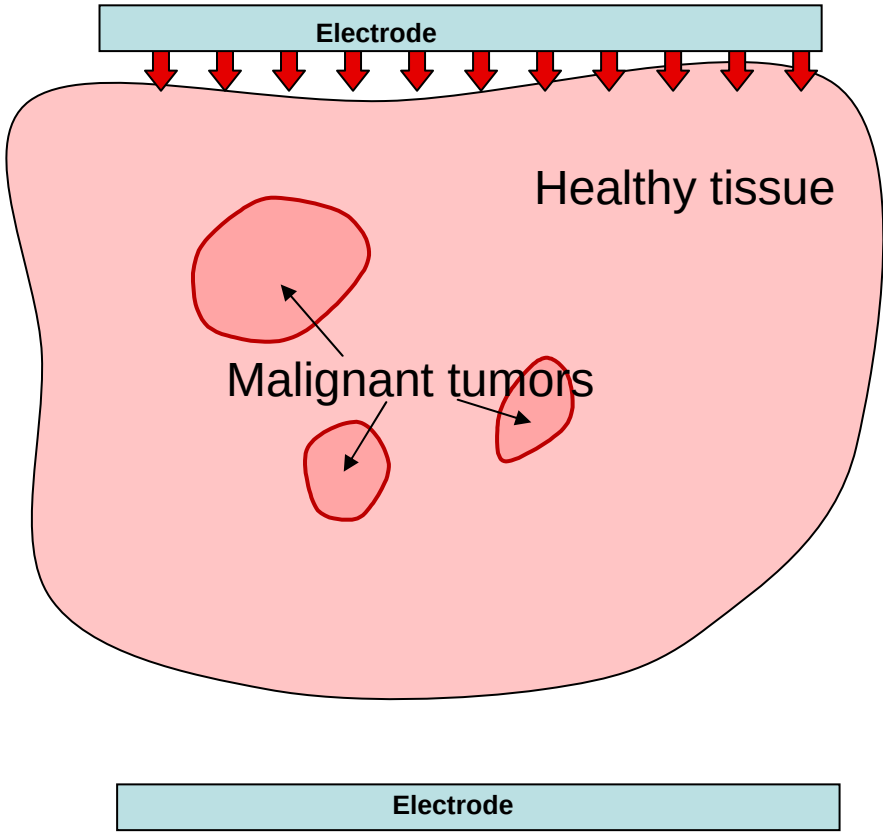
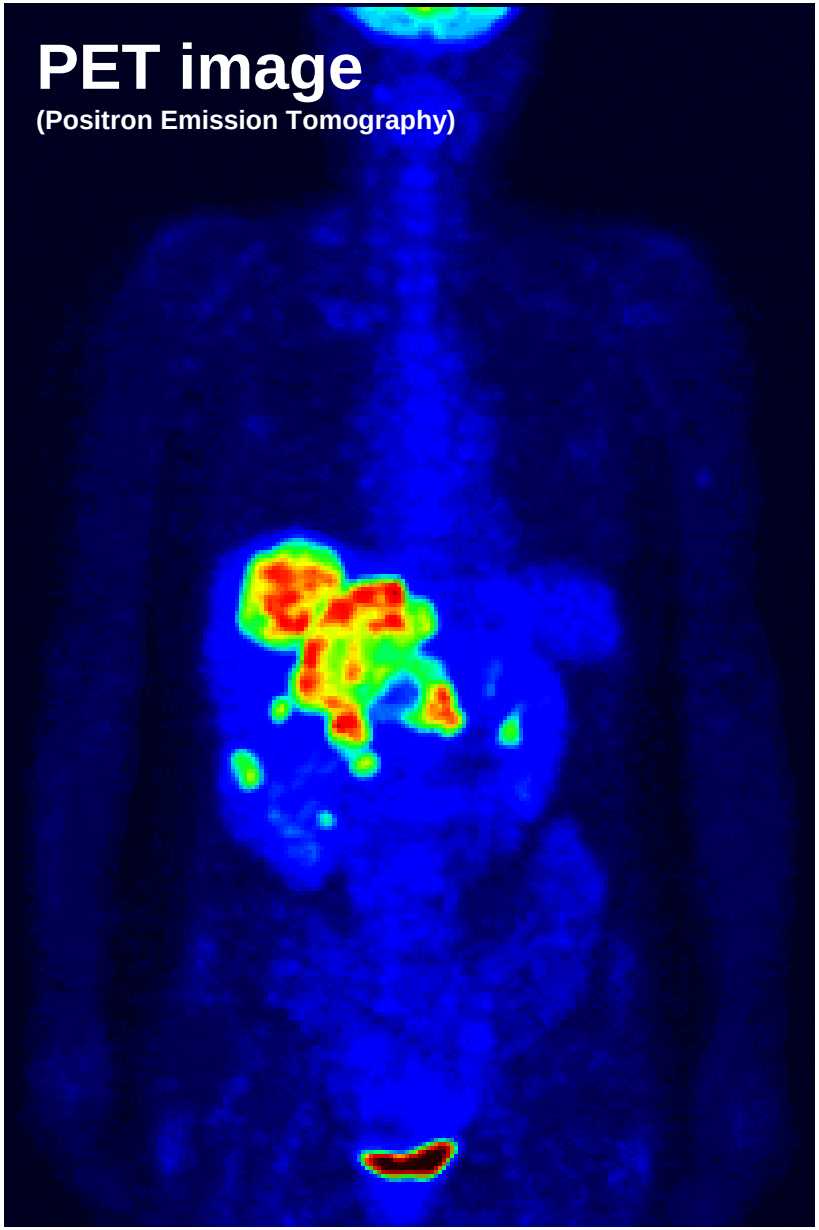


Selectivity in macro-scale
選択的加熱のマクロ図解





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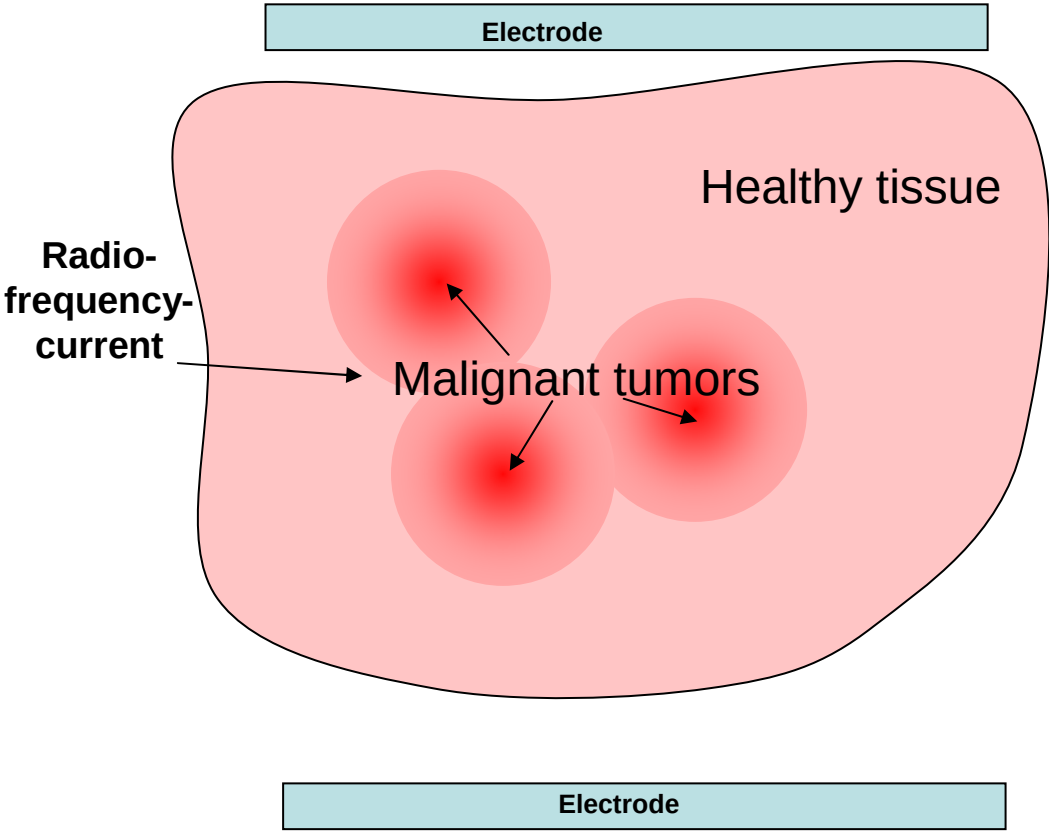
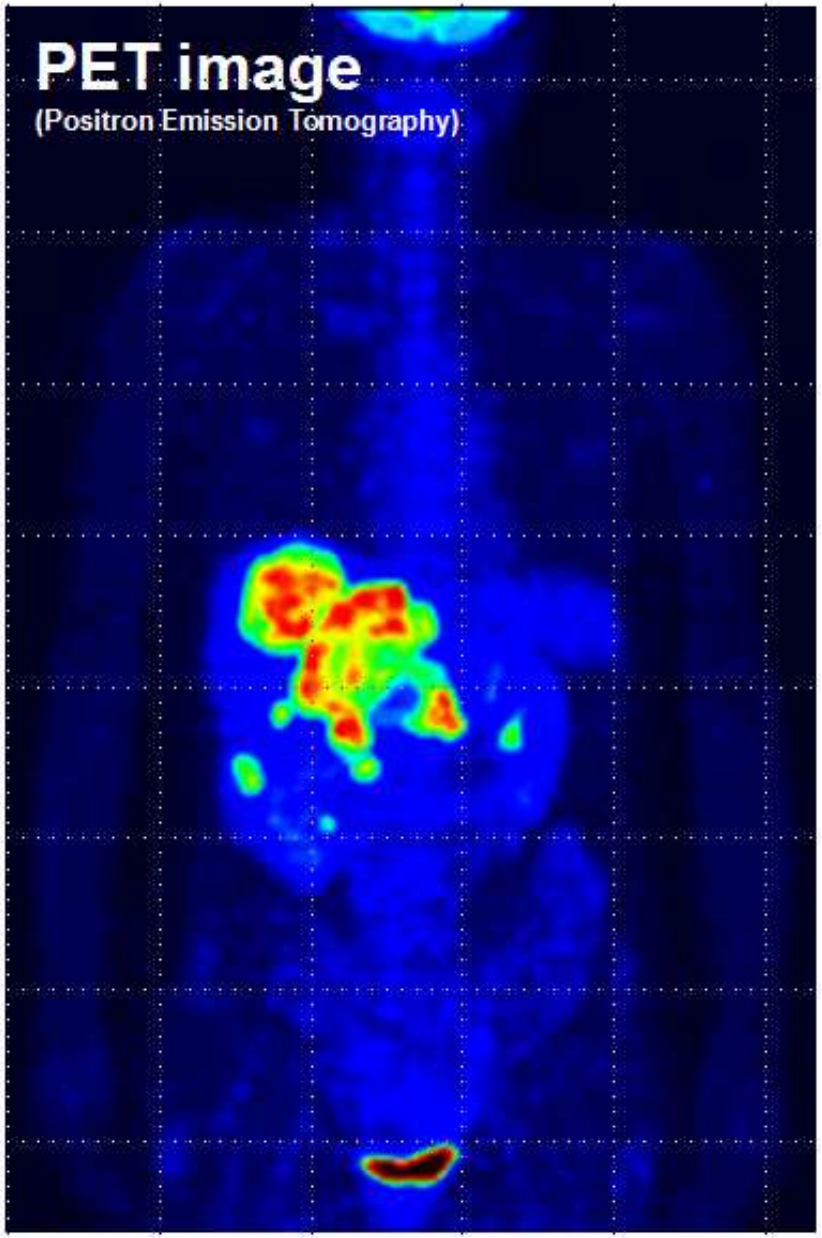


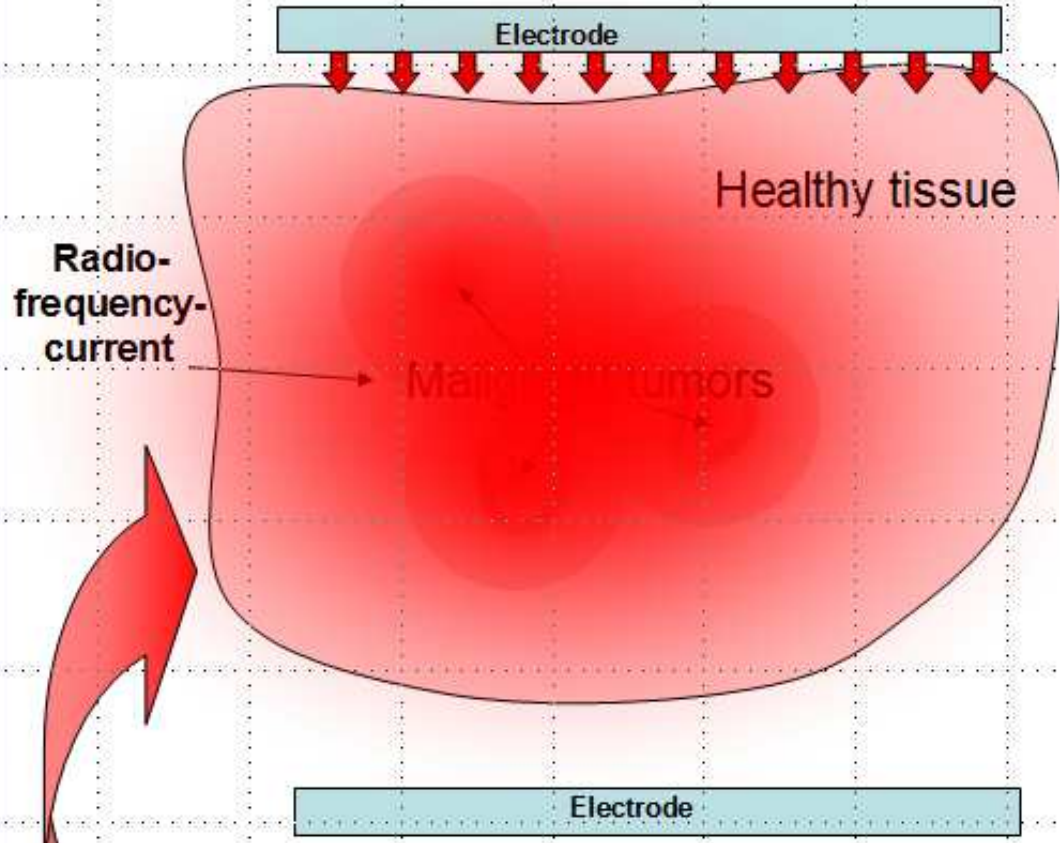
加熱の選択性：オンコサーミア

Focus is automatic. It follows any changes.



Oncothermia selects and kills the malignant cell on natural way!

Selectivity in macro-scale
選択的加熱のマクロ図解



加熱の選択性：オンコサーミア

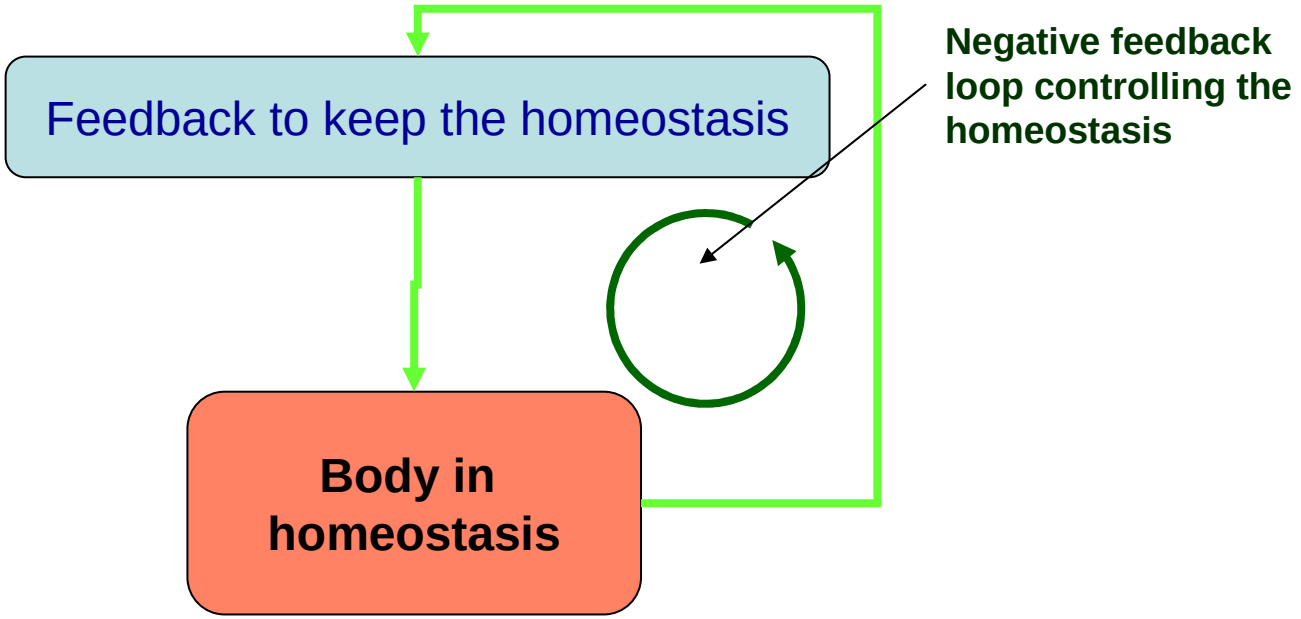
Focus is automatic. It follows any changes.

When the absorbed energy is too much, the local selection does not work!

吸収エネルギーが大きすぎれば、選択性は機能しない

Oncothermia for health-care of our ages

オンコサーミアは疾病治療、
ヘルスケアの有力な方法



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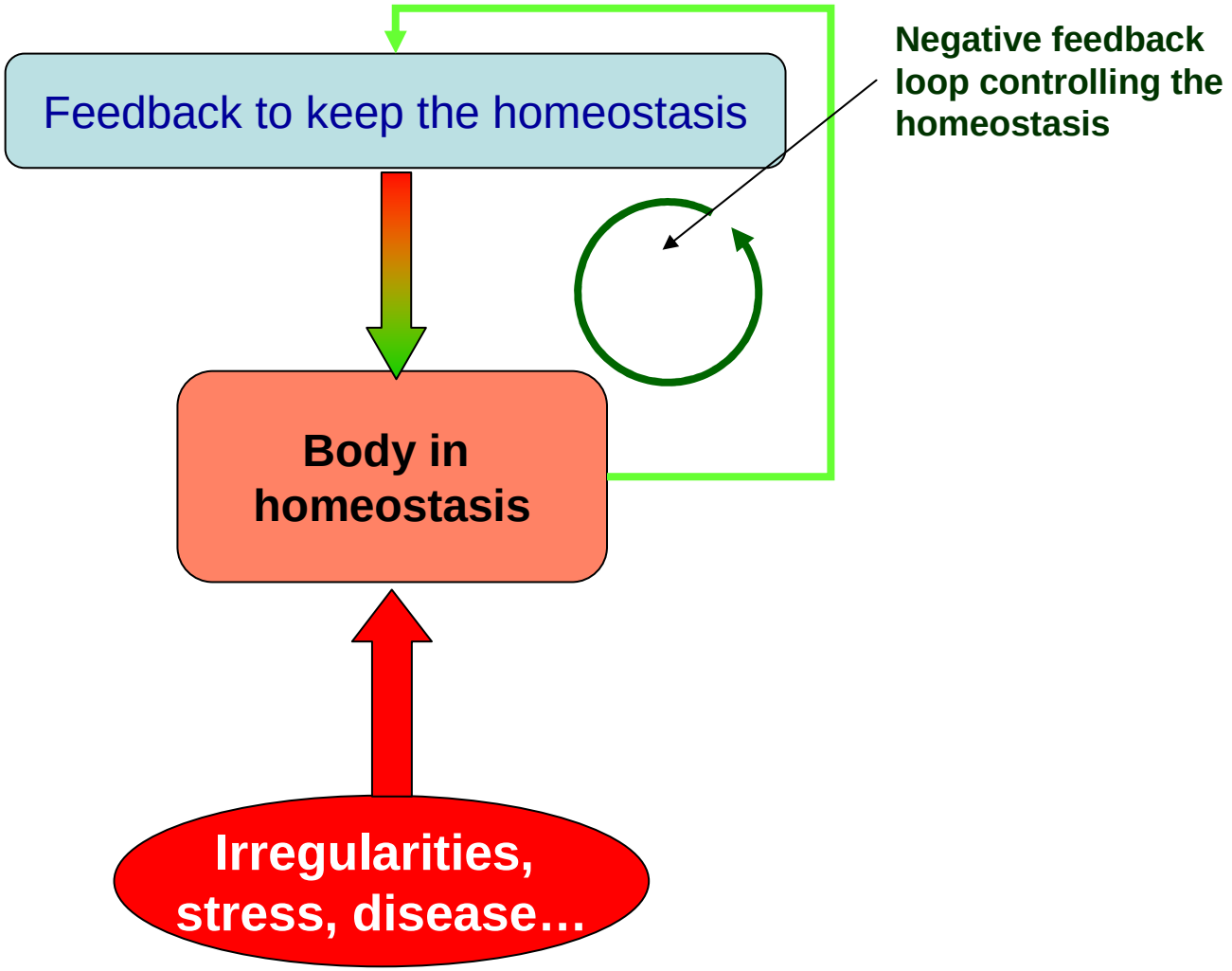

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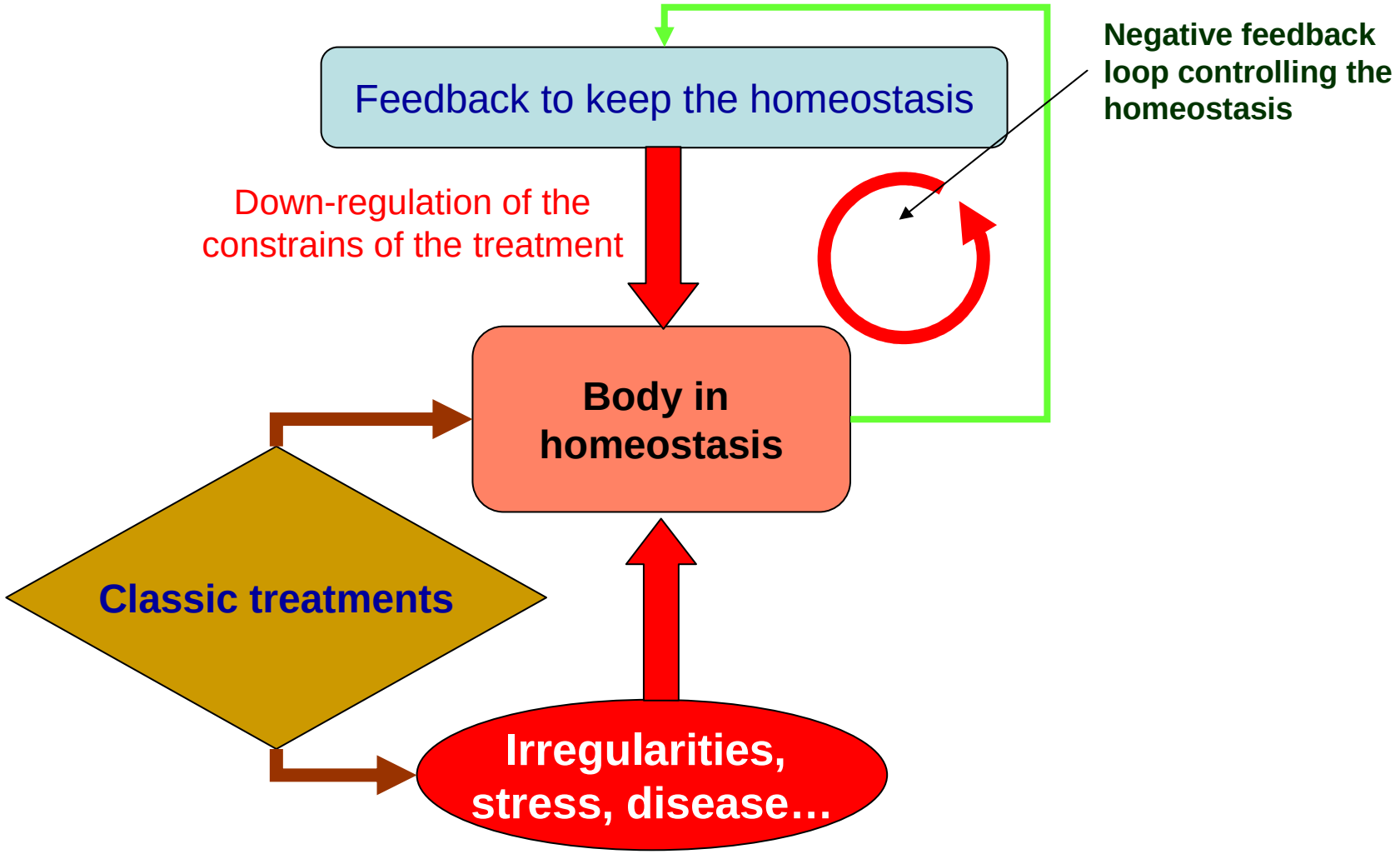

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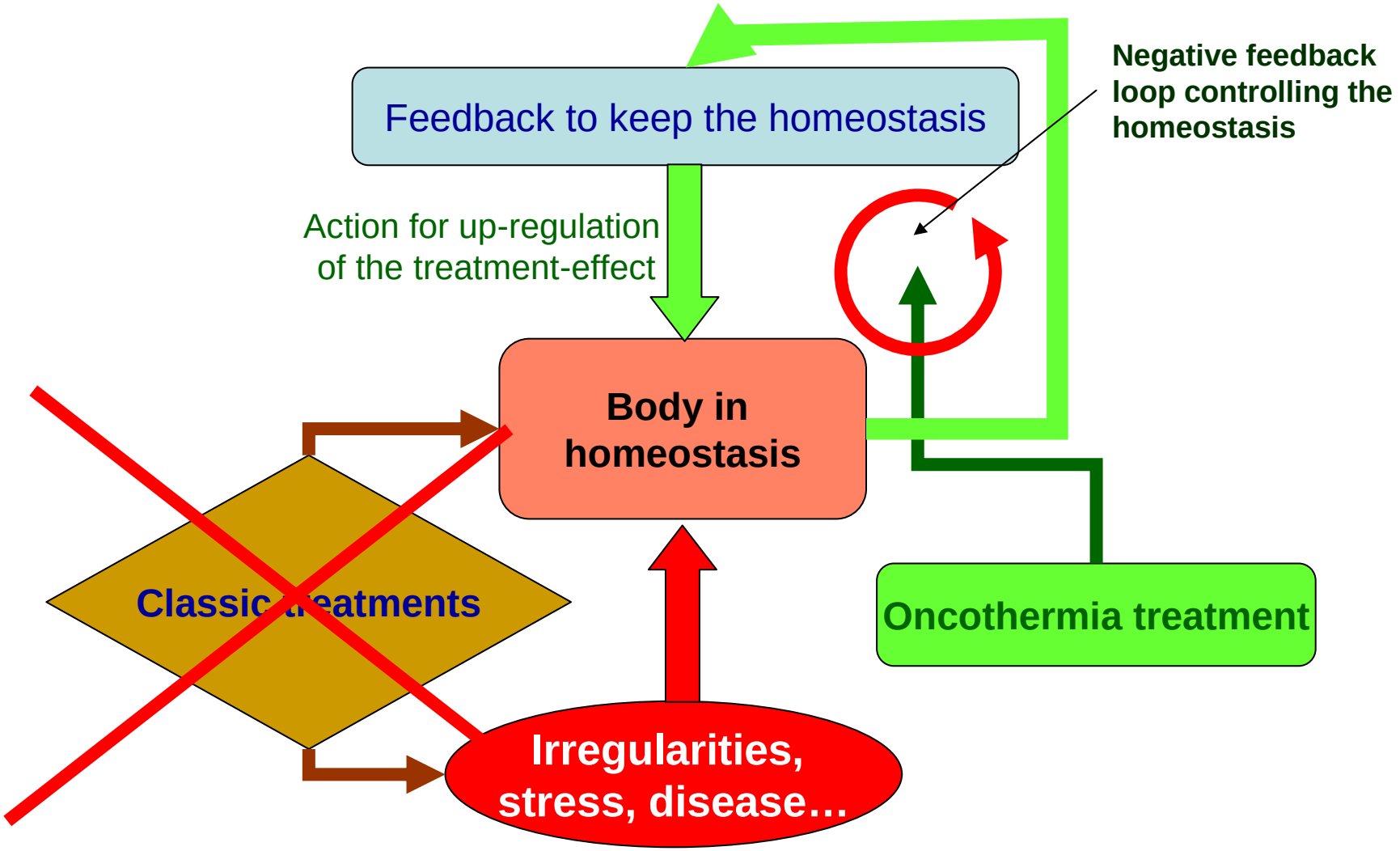
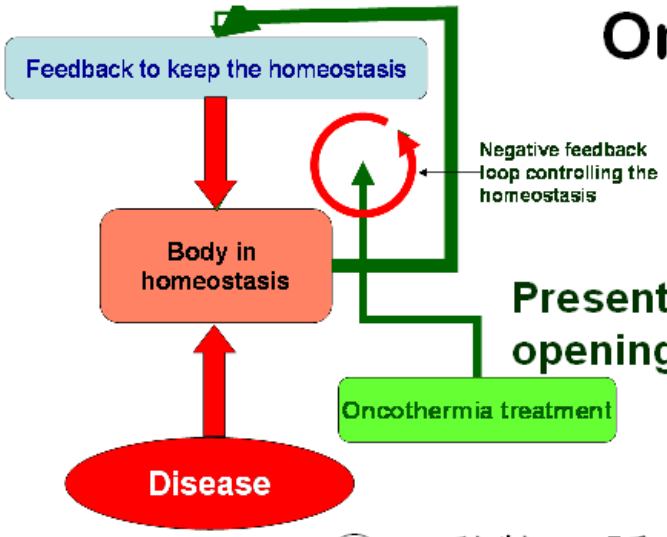




Oncothermia for health-care of our ages

オンコサーミアは疾病治療、
ヘルスケアの有力な方法

Present application is human oncology. However the future is opening the wide range applications, like application in fields of

① 動物の腫瘍治療に利用 (veterinary use)

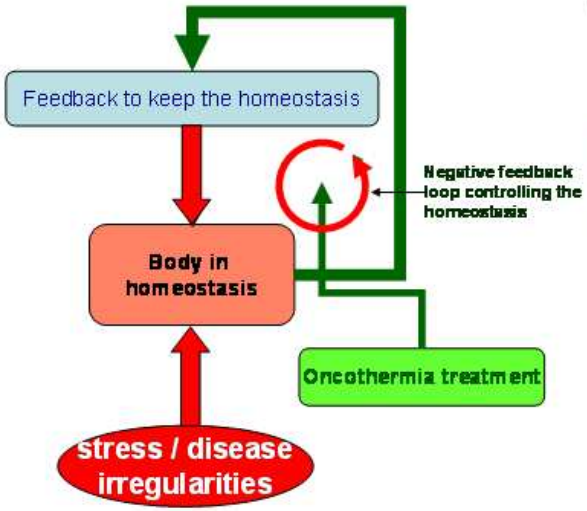
② 人間や動物の物理治療に利用 (physiotherapy)
生体の深部を温めることができるので、筋肉や腱の治療に有効

③ スポーツ競技に利用 (sport-medicine)
各種競技のウォームアップ手段。競技に入る15分ほど前から競技に使う筋肉や腱を温める。ウォームアップの現代化。

④ 美容に利用 (cosmetic use)
セルライト除去などの脂肪燃焼に利用できる。

⑤ ●●●

We are pioneering the new paradigm of the medicine and healthcare:
break the dominance of pharma-products!



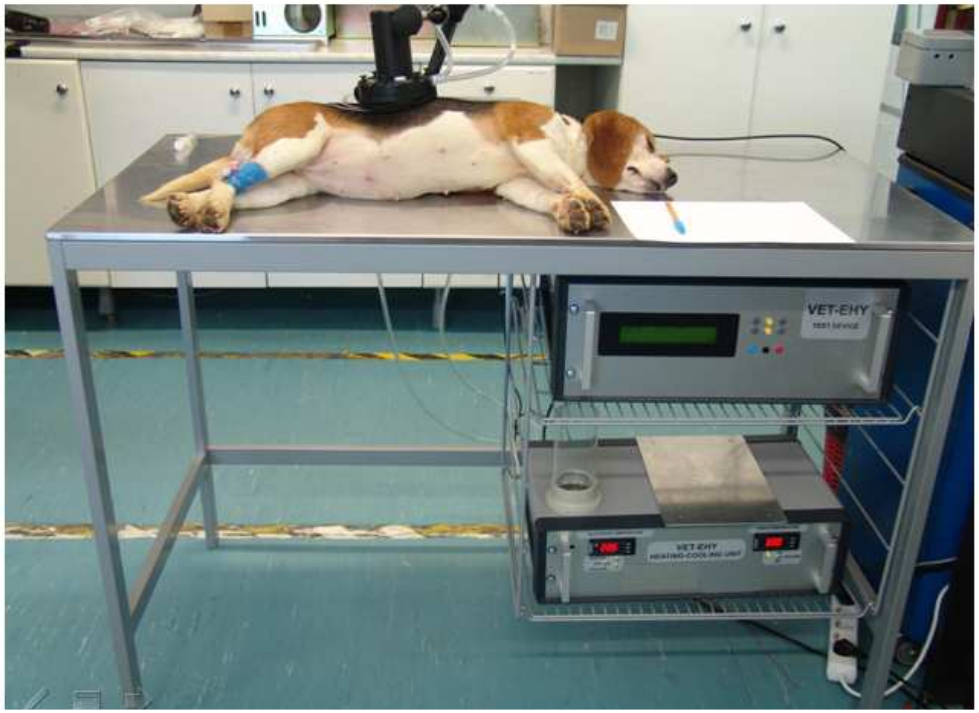
Oncothermia for health-care of our ages

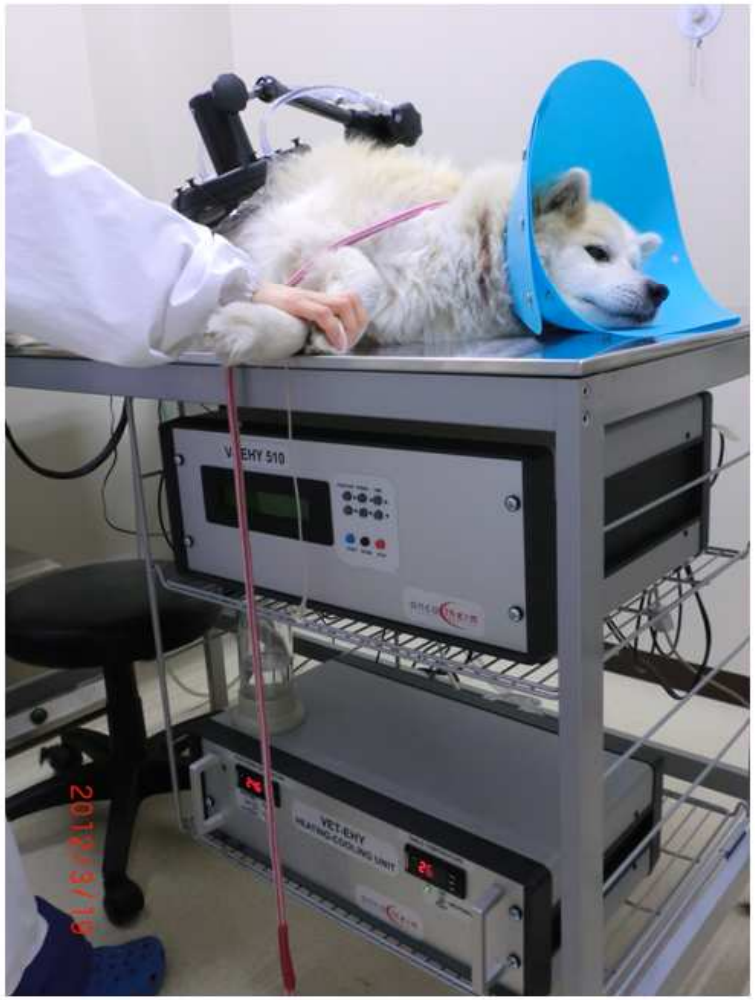
生活の質を高めるオンコサーミア

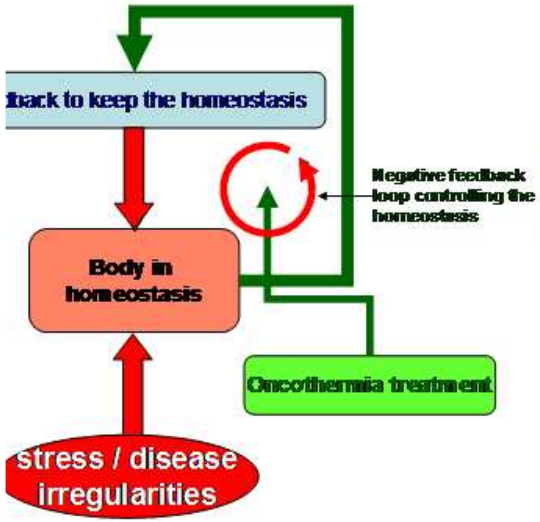
Oncothermia is a new paradigm of medicine, could be applied in various fields of curative and palliative care

動物の腫瘍治療への応用

オンコサーミアの腫瘍治療はほとんどすべての腫瘍にたいして、どの進行段階でも補助的治療として利用できる







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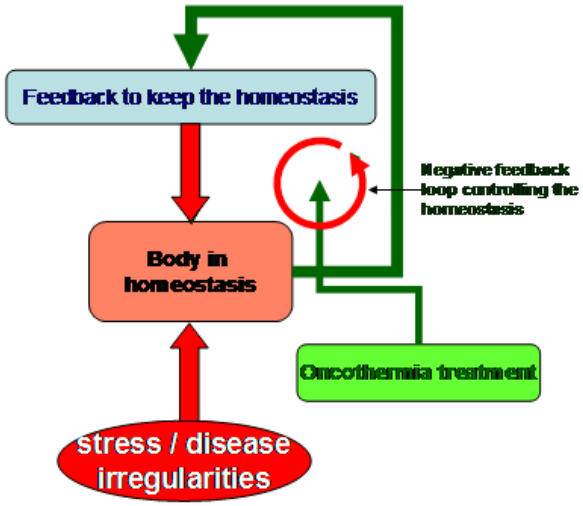
Oncothermia is a new paradigm of medicine, could be applied in various fields of curative and palliative care

オンコサーミアは喘息やアレルギーにも有効

コサーミアの腫瘍治療はほとんどすべての腫瘍
ハして、どの進行段階でも補助的治療として利

動物の腫瘍治療用の応用



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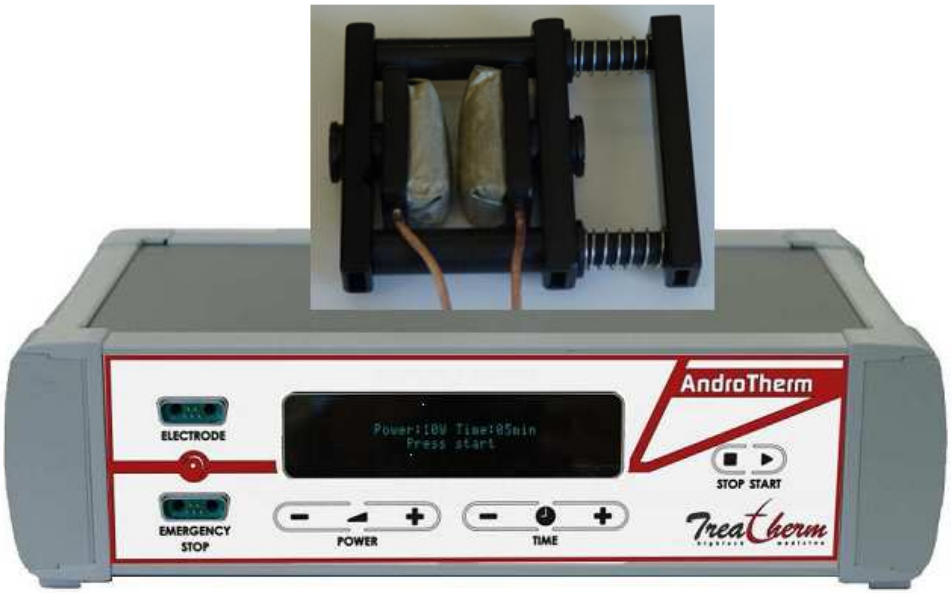
男性生殖器治療にも利用

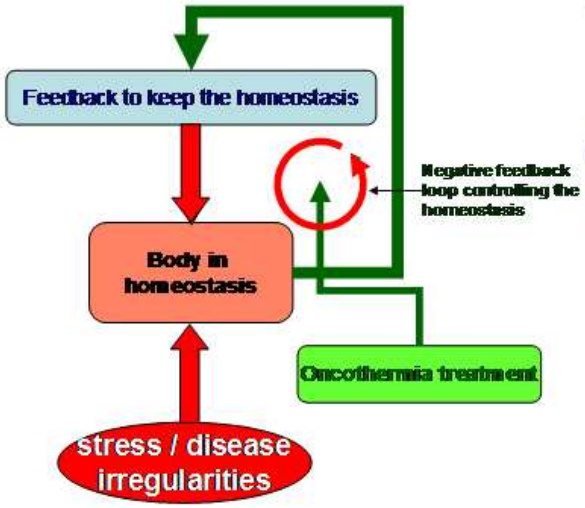


Oncothermia for health-care of our ages

生活の質を高めるオンコサーミア

Oncothermia is a new paradigm of medicine, could be applied in various fields of curative and palliative care

深部を温めるブースター（物療機器）



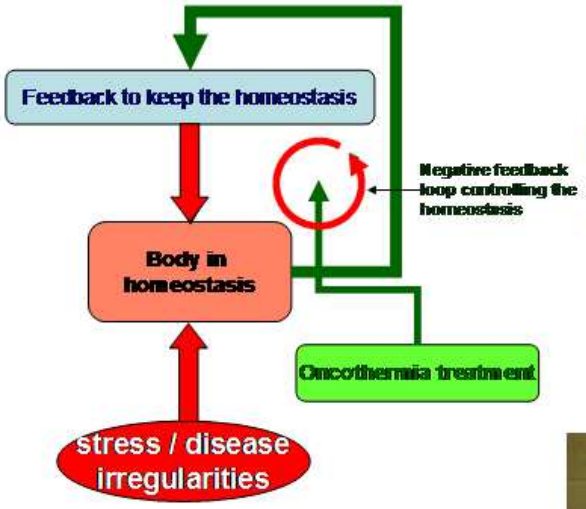
オンコサーミアの腫瘍治療はほとんどすべての腫瘍にたいして、どの進行段階でも補助的治療として利用の応用

動物の腫瘍治療

オンコサーミアは喘息やアレルギーにも有効

男性生殖器治療にも利用

It locally increases the blood-flow a
effective. It is a kind of personalize



Oncothermia for health-care of our ages

生活の質を高めるオンコサーミア

Oncothermia is a new paradigm of medicine, could be applied in various fields of curative and palliative care

電極パットの形状を変えることで
体のあらゆる部分に応用できる

オンコサーミアの腫瘍治療はほとんどすべての腫瘍にたいして、どの進行段階でも補助的治療として利

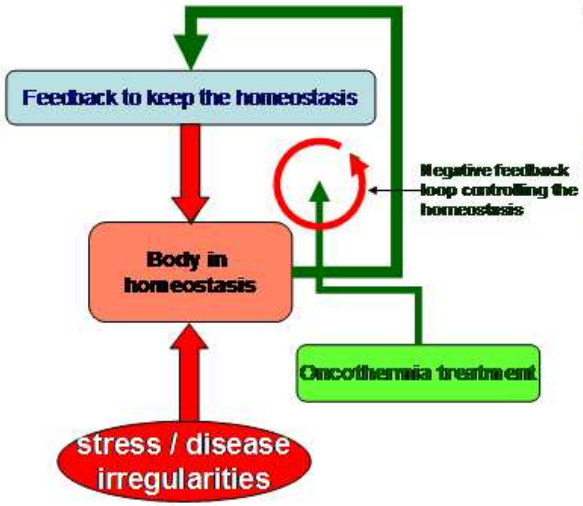
動物の腫瘍治療用の応用

オンコサーミアは喘息やアレルギーにも有効

男性生殖器治療にも利用

深部を温めるブースター（物療機器）

Its effect together with the heating, the increased blood-flow provides a TENS (Transcutane Electric Nerve Stimulation) with pain-killing facility.



Oncothermia for health-care of our ages

生活の質を高めるオンコサーミア

Oncothermia is a new paradigm of medicine, could be applied in various fields of curative and palliative care

オンコターム社の主力製品

オンコサーミアの腫瘍治療はほとんどすべての腫瘍にたいして、どの進行段階でも補助的治療として利用できる

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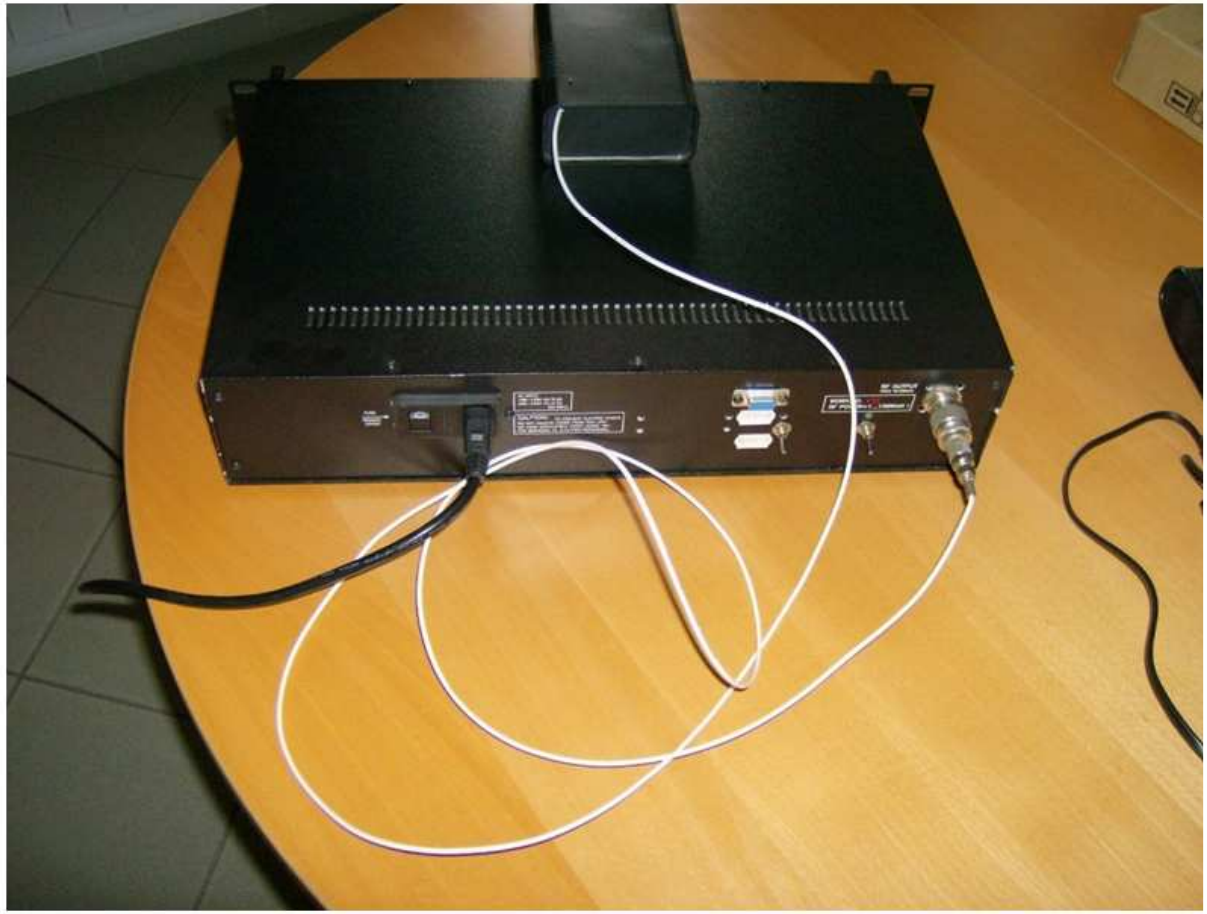

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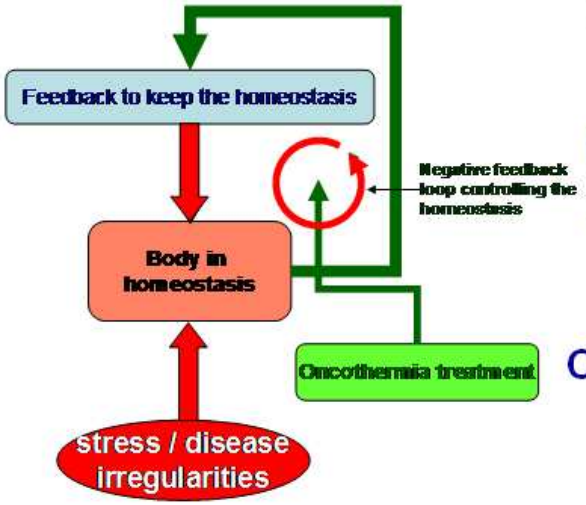

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電極パットの形状を変えることで
体のあらゆる部分に応用できる

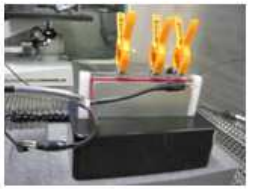
オンコターム社の主力製品

Compact human oncology

Multilocal human oncology

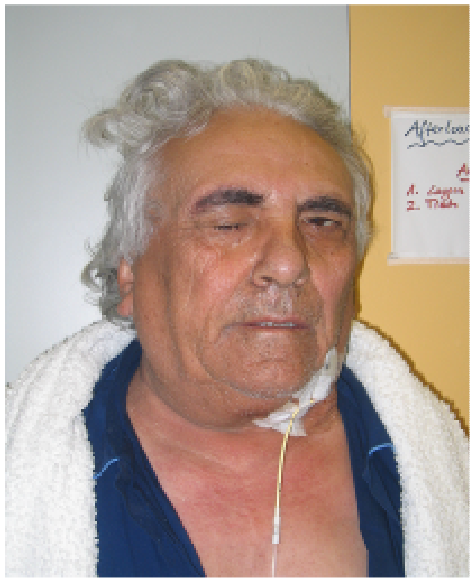
Transurethral (intraluminar)

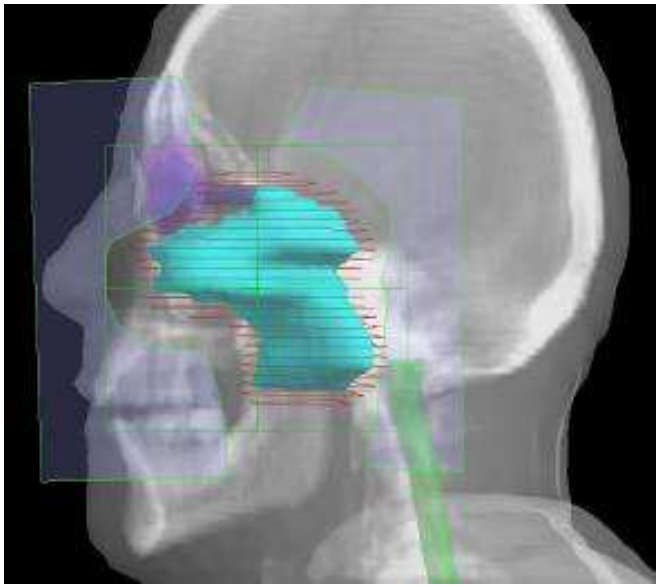
Research units

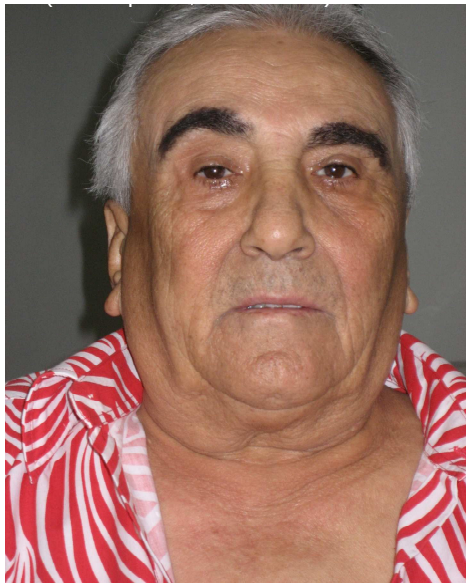


-オンコサーミアは安全なハイパーサーミア

Investigator: Prof.Dr.H. Renner,**Department:** Klinikum Nord, Nürnberg, Germany, **Patient:** REN1. 67 y, male. **Diagnosis:** Sinus sphenoidalis, inoperable. **Histology:** Squamous epithelium carcinoma. **Development:** Complete right opthalmoplegy
Therapy: Radiotherapy, 54 Gy, fractional, Oncothermia: 6 sessions, after radiotherapy. **Result:** complete remove of eye-block







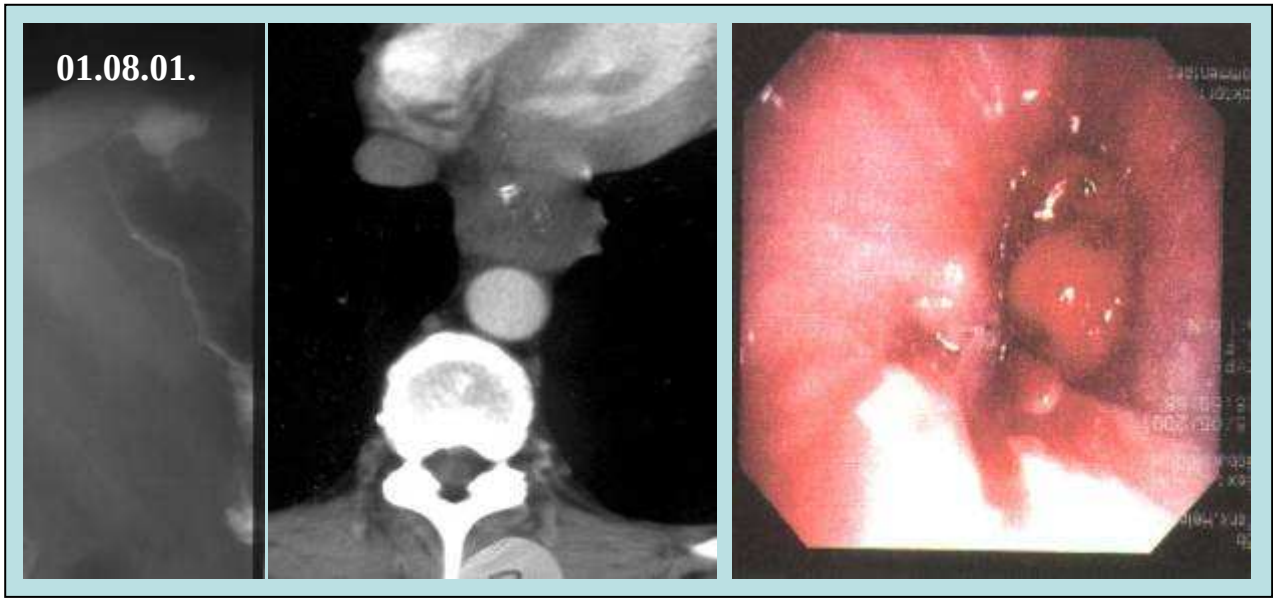
Investigator: Prof.Dr. A. Herzog, **Institute:** Fachklinik Dr.Herzog, Nidda**,** (Bad Salzhausen), Germany; **Diagnosis:** Non-Hodgkin lymphoma, **Patient:** 38 y, female, **Stage:** WHO IV**Treatment:** Oncothermia + Bendamustin, **Results:** Complete Remission, (CR)

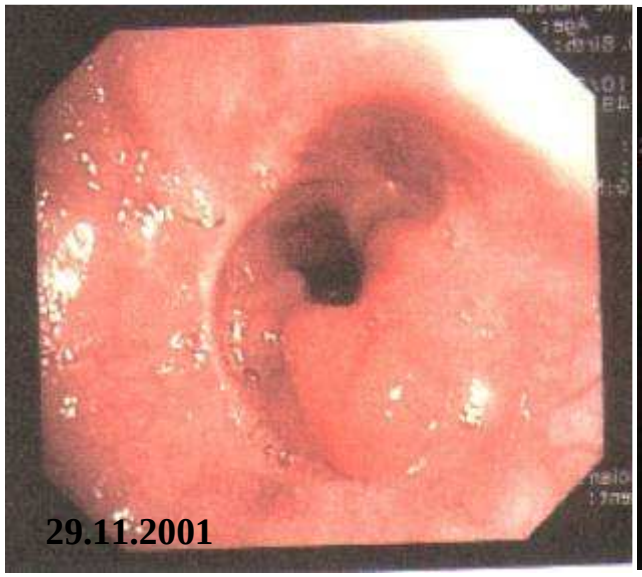
Esophagus carcinoma （食道がんの事例）

Investigator: Prof.D.Gronemeyer & Dr.H.Sahinbas
Department: Department of Radiology and Microtherapy, University of Witten-Herdecke, Bochum, Germany

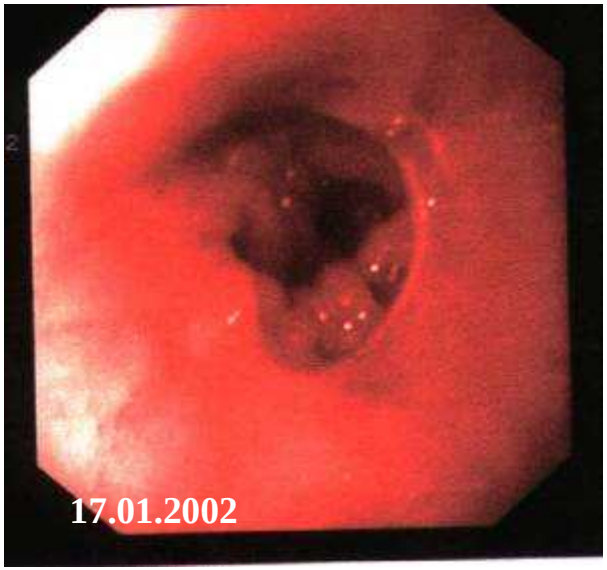
Patient: M, 46 y, male
Diagnosis: 4/00, Esophagus-Ca.
Therapies:
- **Surgery:** 4/00
- **Chemotherapy:** Multiple CxT
- **Radiotherapy:** (50 Gy) from 01.08.01,
- **Recidiv:** Anastomiosenrecidiv / Multiple bougienage and Anastomose, Full block of food-passage in Esophagus,
- **Oncothermia:** monotherapy from 27.09.01 –23.11.01

Result: Complete remission (CR) Free-food passage
Follow-up: Censored





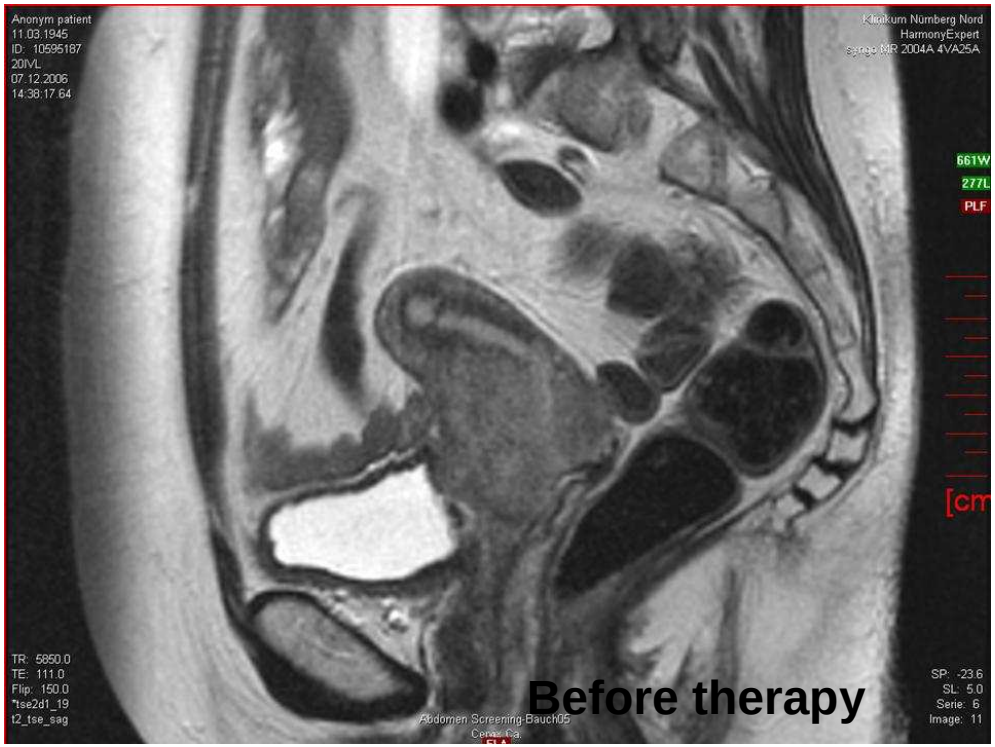
after 6x oncothermia



after 12x oncothermia

Cervix carcinoma （子宮がんの事例）

Investigator: Prof. H. Renner
Department: Klinikum Nord, Nürnberg, Germany
Patient H.K, 61 y, female; Cervix carcinoma; cT4 cN0 M0 G3
Histology: Squamous cell carcinoma;
Therapy: 12/06-01/07 bimodality therapy, Radiotherapy: 50.4 Gy; (5x1.8 Gy/weeks); oncothermia: 6 sessions.
Control: 3 months later hysterectomy (Wertheim).
Result: pathologically complete remission ypT0ypN0

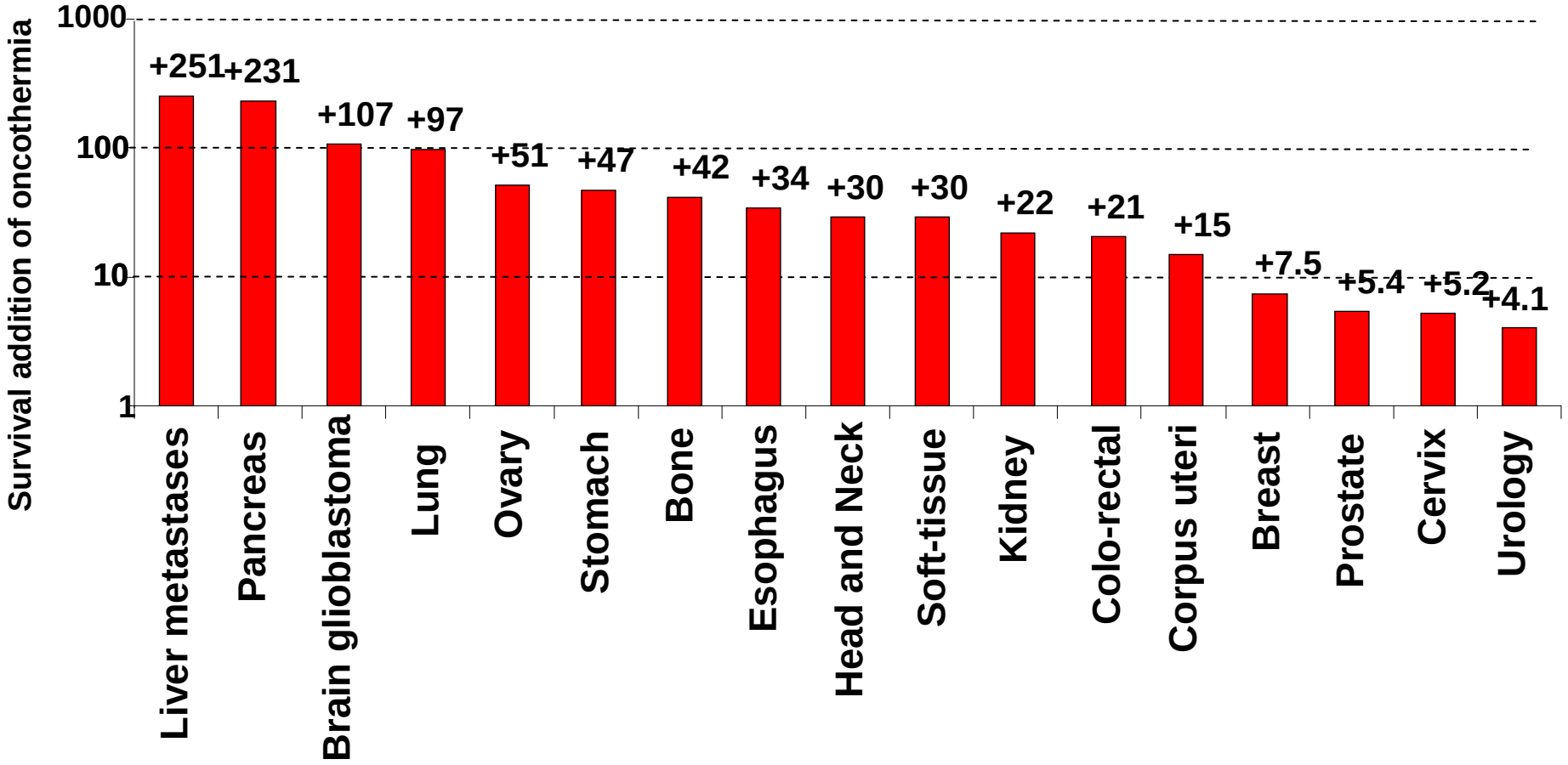


Before therapy

After therapy (CR)

Oncothermia results （国際データベースとの比較）

Additional 1st year survival ratio to NCI (USA) database by oncothermia (%)



Oncothermia adds survival benefits for all the investigated tumor localizations

Clinical studies

No	Study	n	1st year survival (%)	Median overall survival (m)	Responsnding patients/ ratio (%)	Median overall survival of respondin g patients (m)	Median overall survival of non-respondin g patients (m)	OER	Place
1	Bone-metastases 1	11			90.9				Reinkenheide, Bremerhaven
2	Bone-metastases 2	6		40.1					HttMed Clinic
3	Breast cancers	103	97.1	52.1	45	274.8	10.9	25.2	HttMed Clinic
4	Colorectal cancer (rectosigmoid junction)	12			34.1				Peterfy Hospital
5	Colorectal cancer (rectum)	92			57.1				Peterfy Hospital
6	Colorectal cancer (rectum)	114			44.2	109.8	23.2	4.7	Peterfy Hospital
7	Esophagus study 1	12	41.7	28.49	35	29.4	8.5	3.5	HttMed Clinic
8	Esophagus study 2	7		6.8					Nurnberg Nord, Clinic
9	Glioma efficacy study 1.	27	86.2	23.6	43	66.2	18.2	3.6	HttMed Clinic
10	Glioma efficacy study 2.	140	71.7						Witten-Herdecke University
11	Glioma efficacy study 3.	45		15					Nurnberg Nord, Clinic
12	Glioma efficacy study 4.	19	68.0	21.8	59	32.6	12.4	2.6	St.Georg Clinic
13	Glioma efficacy study 5.	36	60.0						BioMed Clinic
14	Glioma efficacy study 6.	179							BioMed Clinic
15	Glioma efficacy study 7.	12		10	25				St.Giuseppe Hospital
16	Glioma toxicity study	24							Regensburg University,
17	Head and neck	64	92.2	26.1					HttMed Clinic
18	Kidney cancer	39	84.6	35.9	48	78.4	33.7	2.3	HttMed Clinic
19	Liver metastases from vaious origine 1	25		20.5					HttMed Clinic
20	Liver metastases from vaious origine 2	28							Reinkenheide, Bremerhaven
21	Liver metastasis form colorectal origine 1	80	86.0	24.1					BioMed Clinic
22	Liver metastasis form colorectal origine 2	15			80				Siloah Clinic
23	Liver metastasis form colorectal origine 3	30		22					Spedali Civili Brescia
24	Liver metastasis form rectal origine	29							Semmelweis University
25	Lung cancers (Adeno + small-cell)	67			47.7				Yonsei University
26	Metastatic brain study	15	90.0	46.2	73	48.2	16.1	3.0	HttMed Clinic
27	Non-small cell lung cancer meta-analysis.	311	67.0		21	53.4	18.1	3.0	St.Borbala Hospital
28	Osteo-sarcoma	62							St.Georg Clinic
29	Pancreas tumors 1/a	73	52.1	9.93	58	25.5	8.4	3.0	Peterfy Hopital
30	Pancreas tumors 1/b	26	46.2	11.6					HttMed Clinic
31	Pancreas tumors 2	30	31.0		41	34.4	5.6	6.1	St.Georg Clinic
32	Pancreas tumors 3.	42	52.4	12.3					VeraMed Clinic (Meshede)
33	Pancreas tumors 4.	13	40.0	11.9					Nurnberg Nord, Clinic
34	Pelvic gynecological cancers (cervix)	38	86.8	27.6	25	63.5	20.9	3.0	Peterfy Hospital
35	Pelvic gynecological cancers (ovary)	27	100.0	37.8	67	132.7	19.4	6.8	Peterfy Hospital
36	Pelvic gynecological cancers (uterus)	9	100.0	61.5	62	68.5	32.0	2.1	Peterfy Hospital
37	Prostate cancer	18	88.9	38.8	72	53.4	7.6	7.0	HttMed Clinic
38	Rectum carcinoma	7			71				Nurnberg Nord, Clinic
39	Rectum carcinoma	65							Semmelweis University
40	Soft tissue sarcoma	16	100.0	35.9	31	115.3	31.3	3.7	Peterfy Hospital
41	Somach study	68	58.9	14.4					HttMed Clinic
42	Urinary bladder cancer	18	85.0	36.5	73	42.0	22.6	1.9	Peterfy Hospital

Clinical studies

Local oncothermia:

42 studies - 2054 patients in 4 countries, 14 different clinics

All data are published, at least at conferences, including ASCO

Oncothermia is applied presently in 24 countries

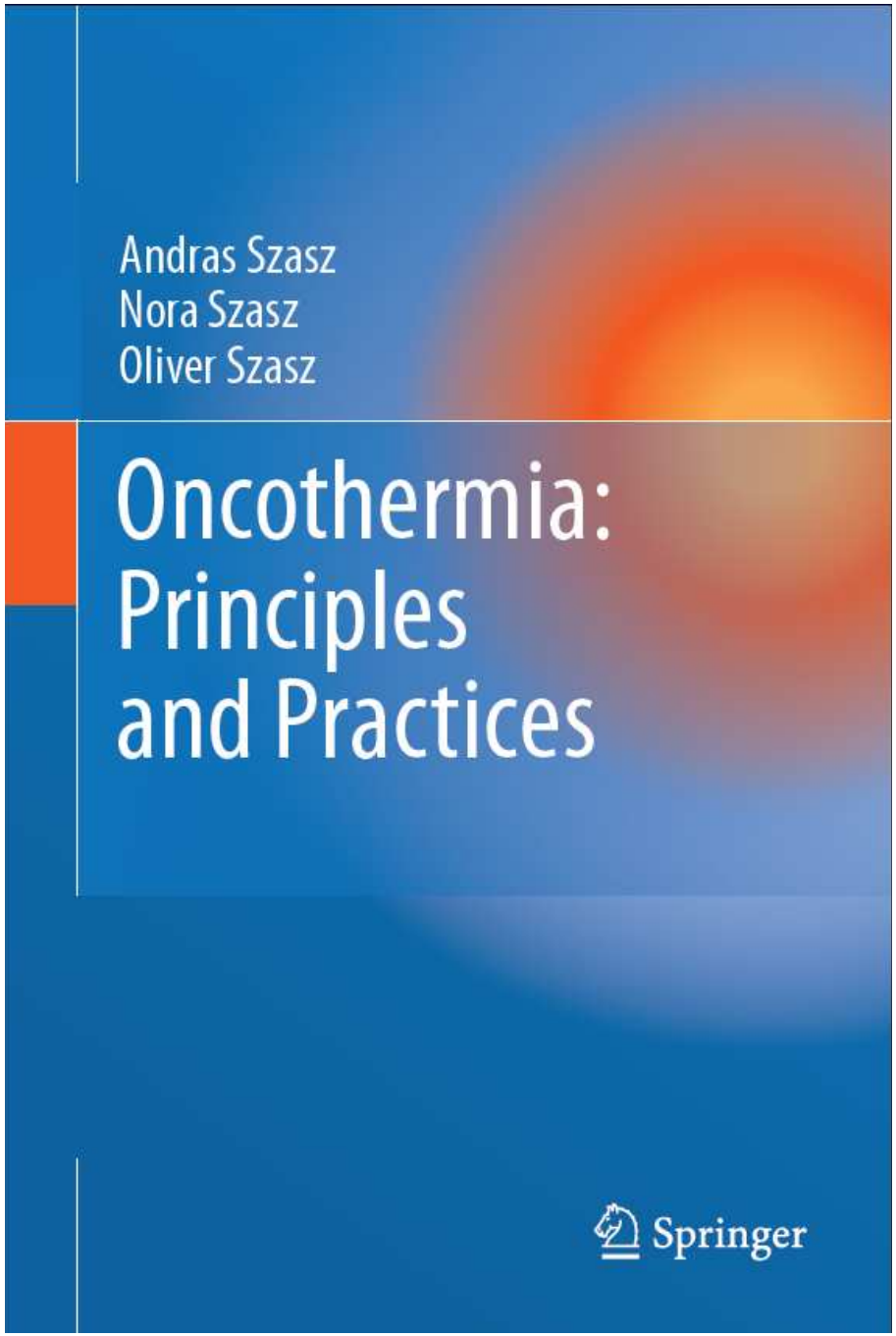
~300 installations

~ 100.000
oncothermia treatments are provided yearly worldwide

Clinical studies

More data in book (570 pages)

& Oncothermia Journal



Clinical studies

More data in book (570 pages)

& Oncothermia Journal

& Conferences, & symposia

HYPERTHERMIA

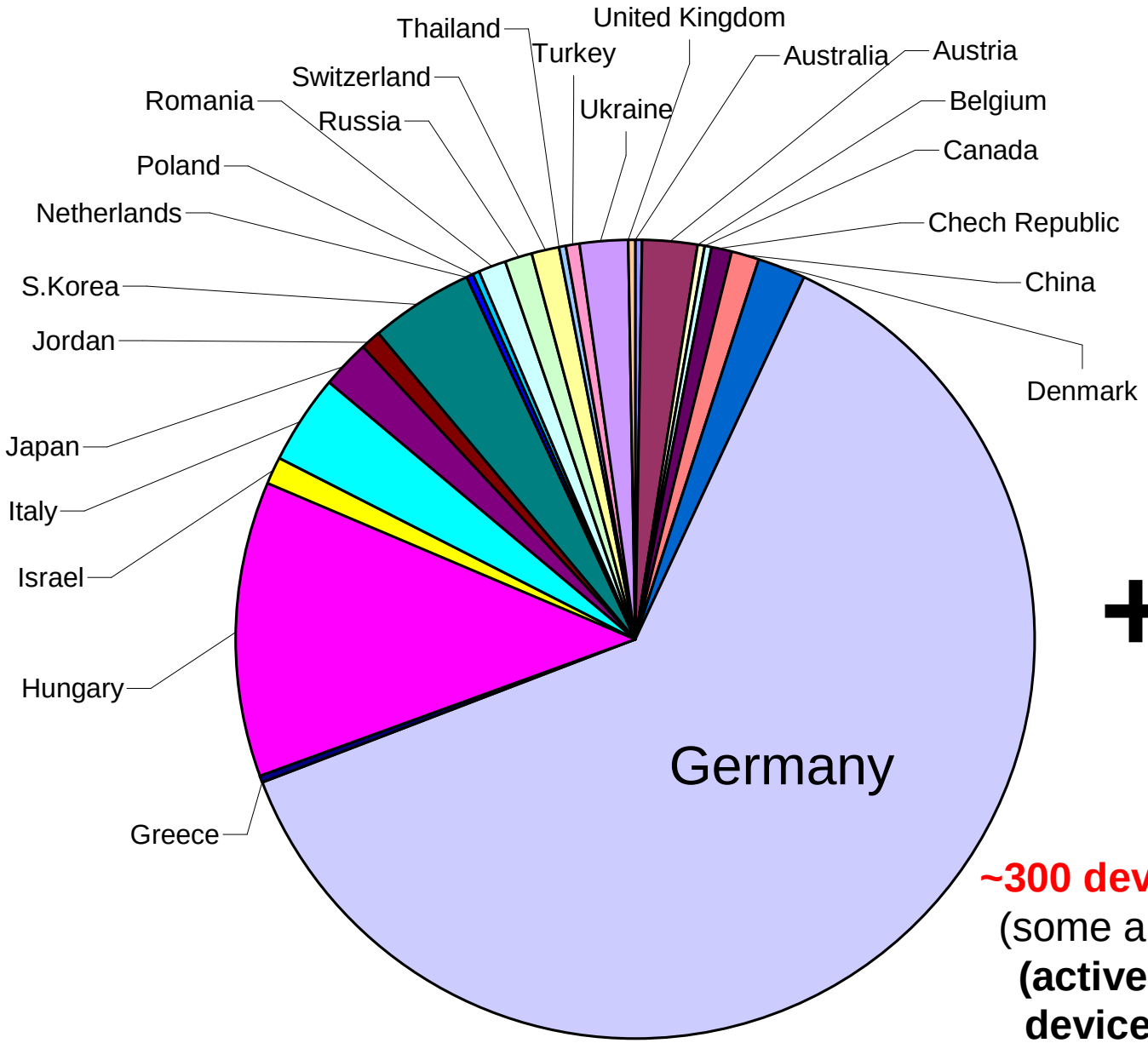
How to break-through?

XXXI. Conference of the International Clinical Hyperthermia Society (ICHS)
Jointly with 2nd International Oncothermia Symposium
October, 2012, Budapest, Hungary

XXXI.
Conference of the
International Clinical
Hyperthermia Society
(ICHS)
In: Budapest, Hungary
On: October 12th-14th 2012

国際臨床ハイパーサーミア学会

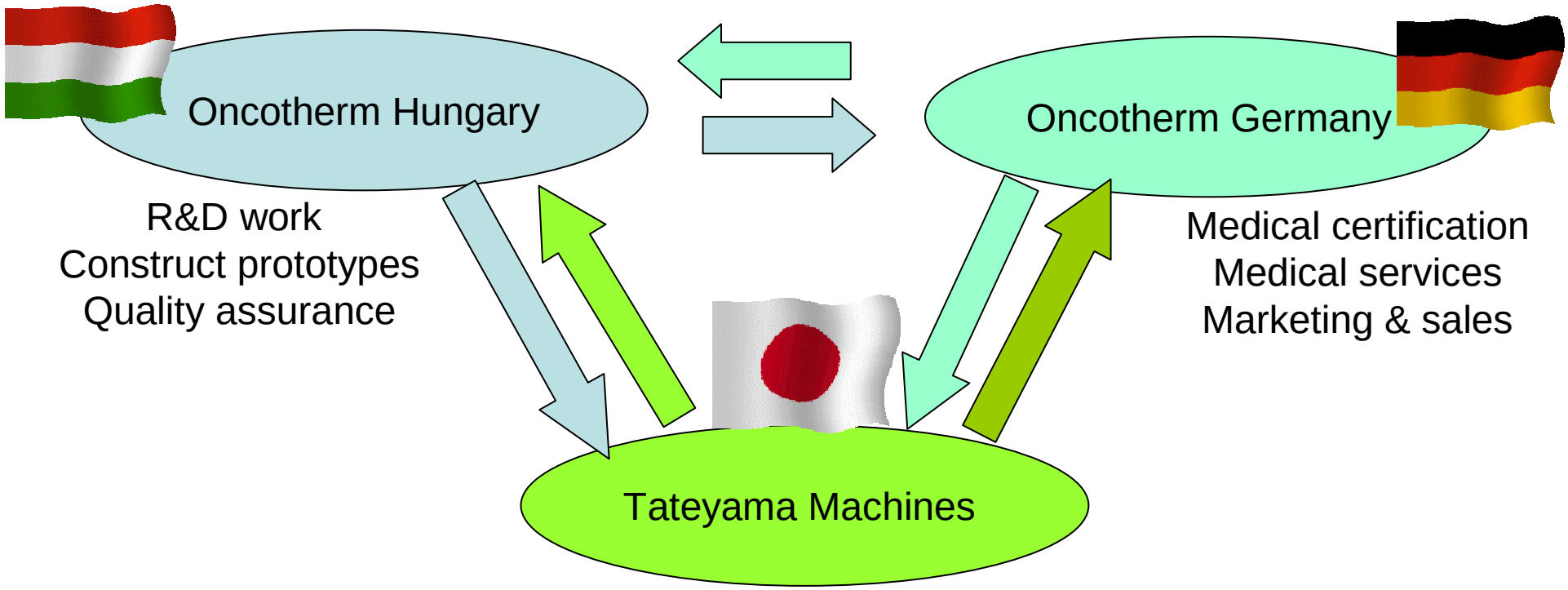
Oncotherm presence in the World



+ Brazil and South Africa are contracted

~300 devices in 24 countries
(some are out of our control)
(actively controlled ~220 devices in 19 countries)

Oncotherm organization



✓ **Hungarian R&D**

✓ **German medical knowledge**

Japanese electronics & technology

ハンガリー、日本、ドイツの拠点をネットワークに
最適な事業提携を実現