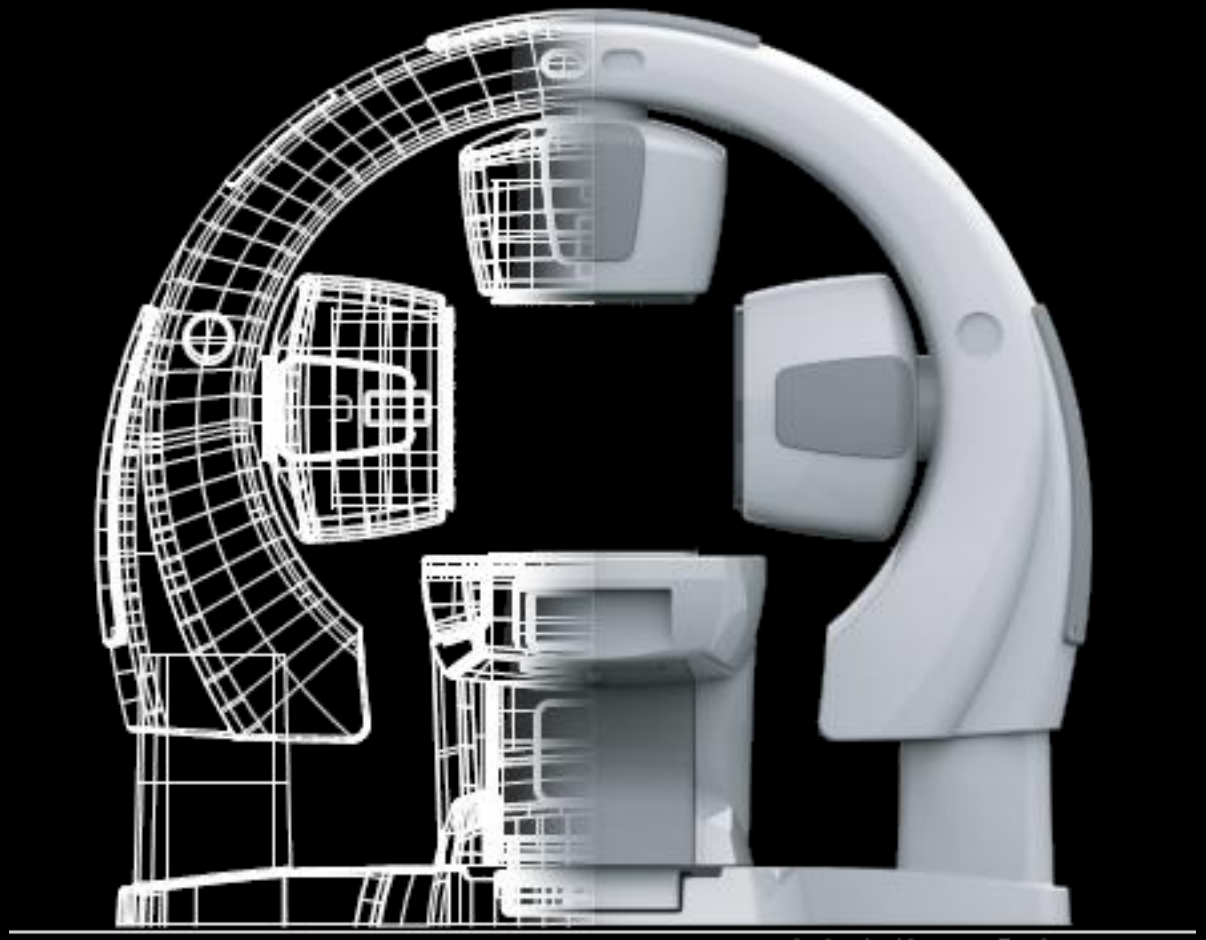
ALBA® 4D

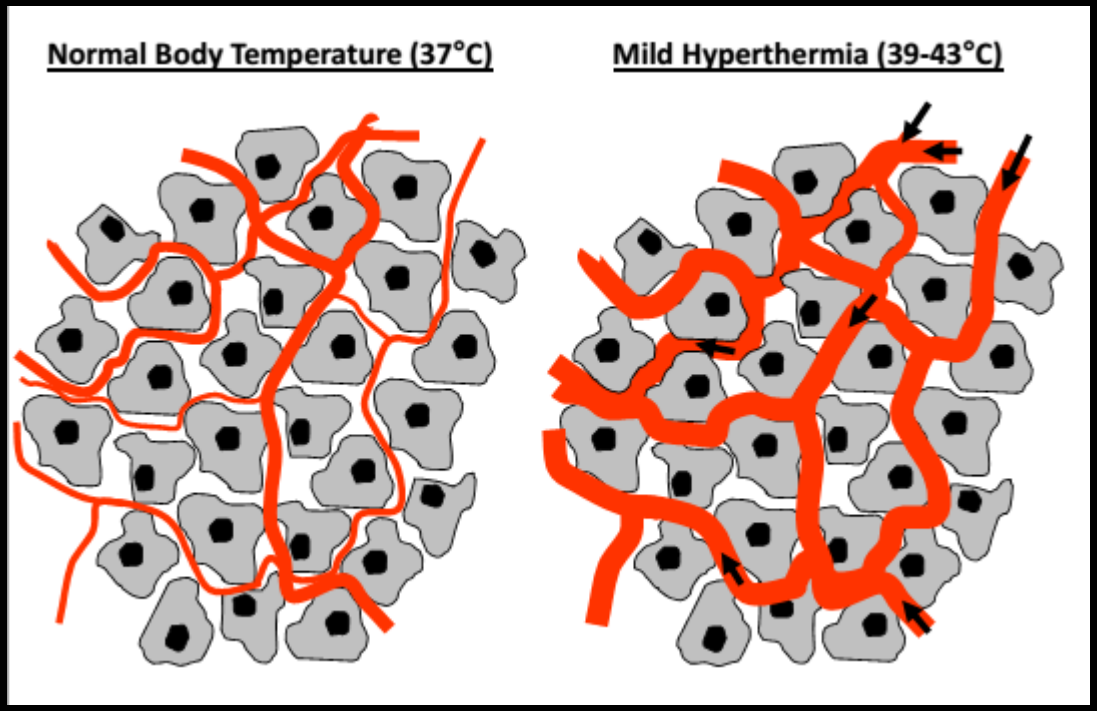
DEEP HYPERTHERMIA SYSTEM



HYPERTHERMIA

- Inducing a **controlled** temperature rise in solid tumors
- Goal temperature **41-43°C for 1 hr**
- **Always combined with RT and/or CT**
- 1x/2x a week

HYPERTHERMIA AND CHEMOTHERAPY



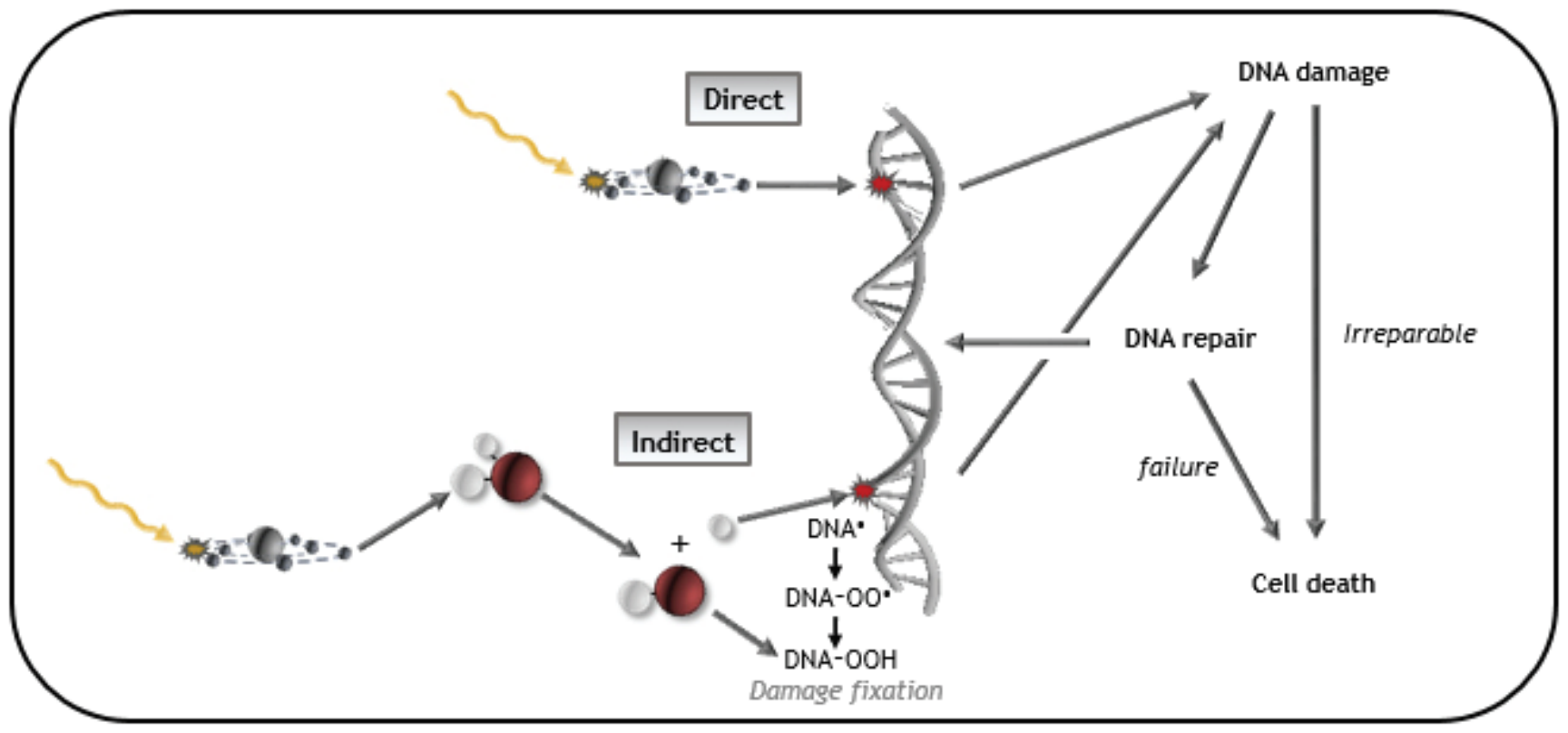
HEAT

→ Increase of blood flow;

→ Increase in permeability of cells membrane;

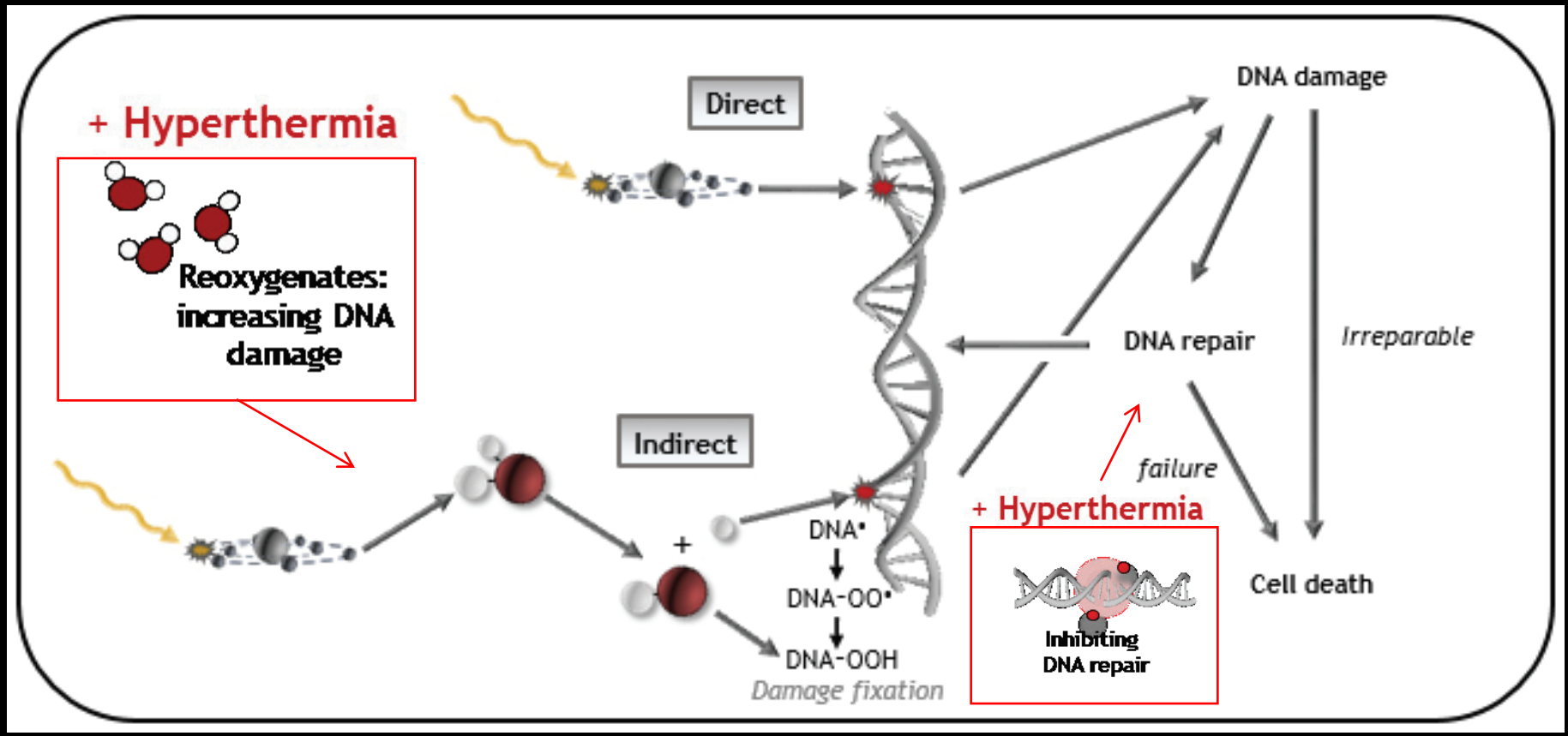
⇒ Increase of intratumoral drug uptake

HT + RT RATIONALE



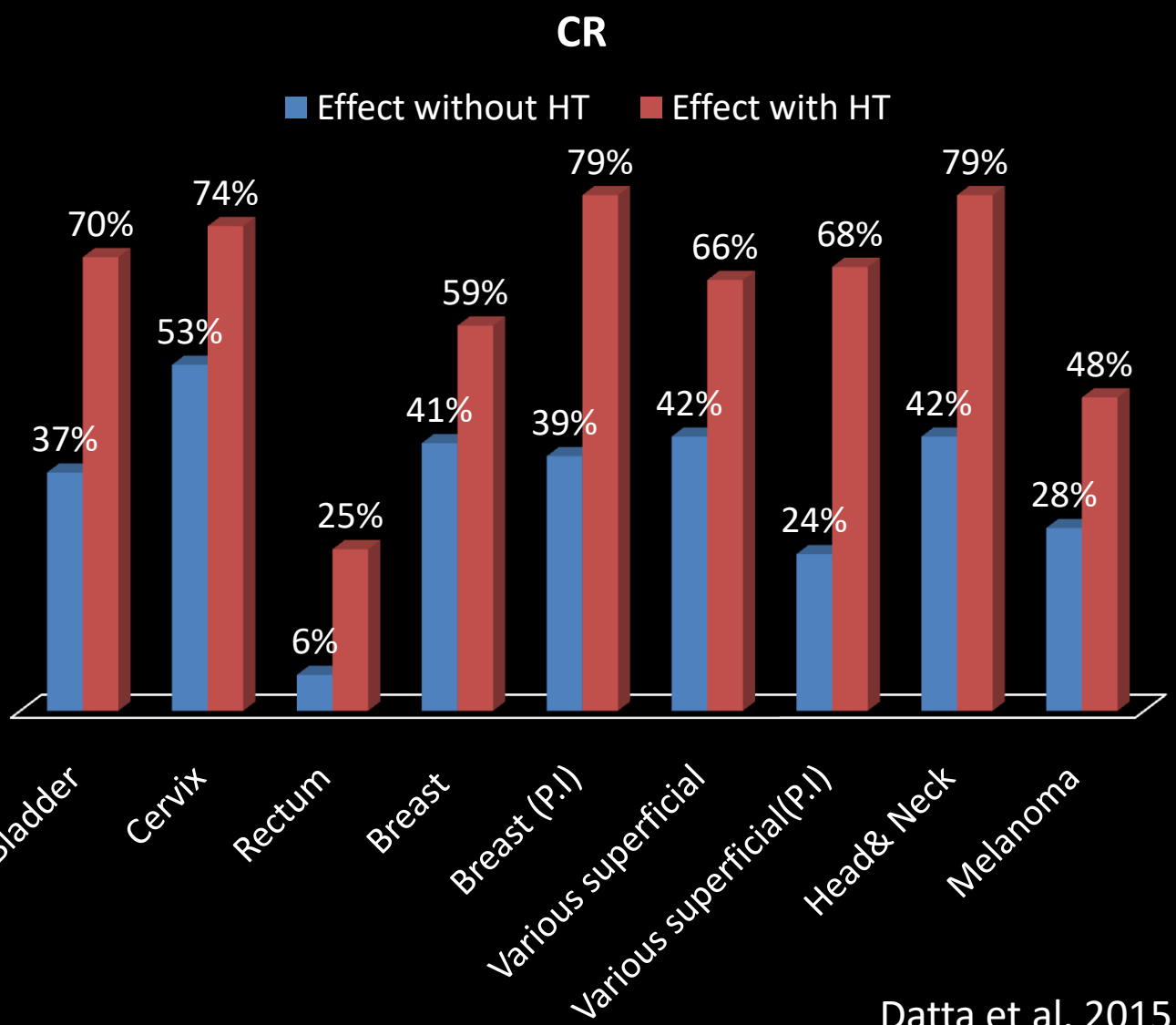
A. Oei et al., Radiation Oncology , 2015

HT + RT RATIONALE



A. Oei et al., Radiation Oncology , 2015

HYPERTHERMIA - RANDOMIZED STUDIES



X 2

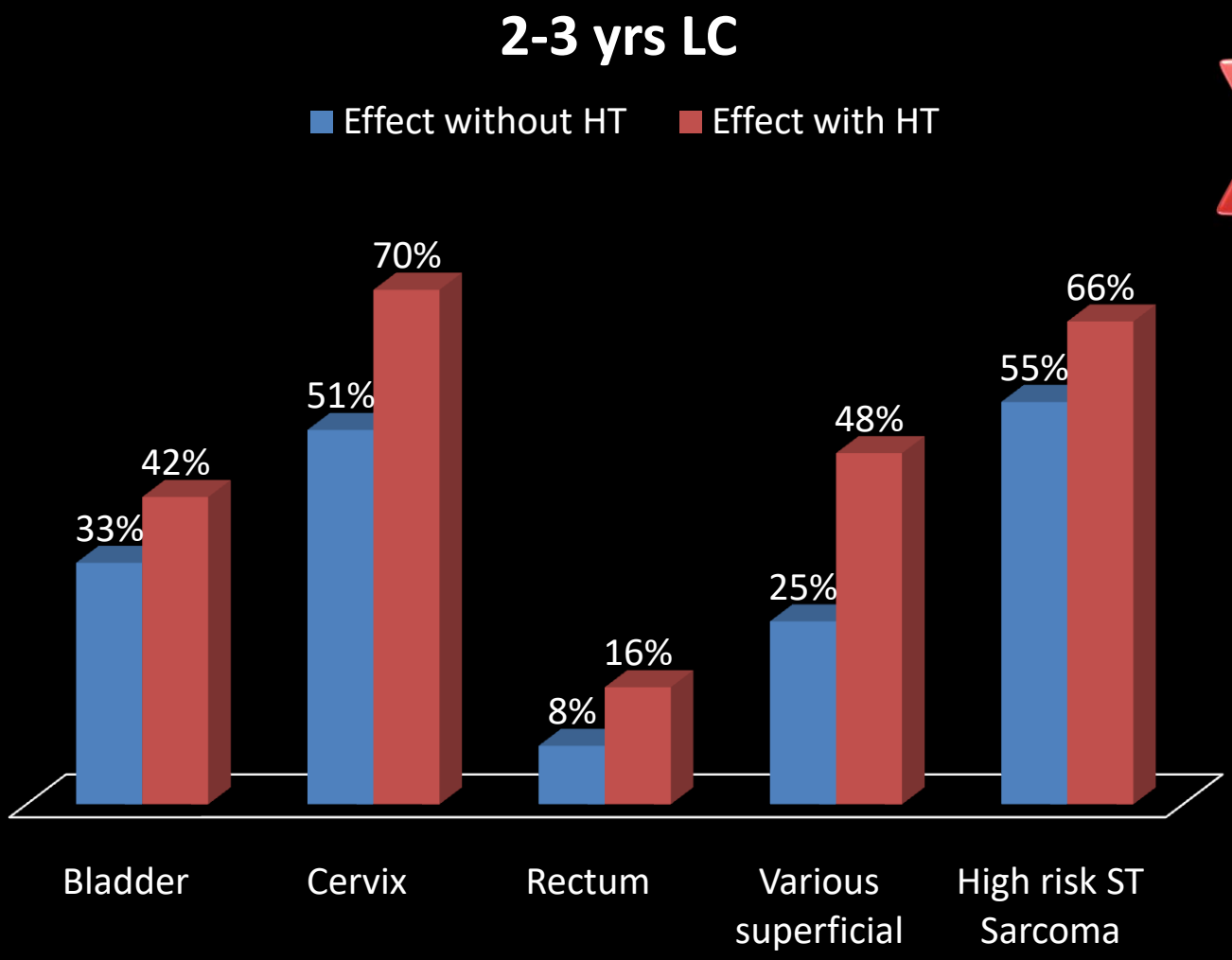
- "Medline" search

  Hyperthermia NOT fever AND cancer AND clinical trials

- 38 clinical trials
- 1987-2014

Datta et al. 2015, Cancer Treatment Reviews

HYPERTHERMIA - RANDOMIZED STUDIES



X 1.5

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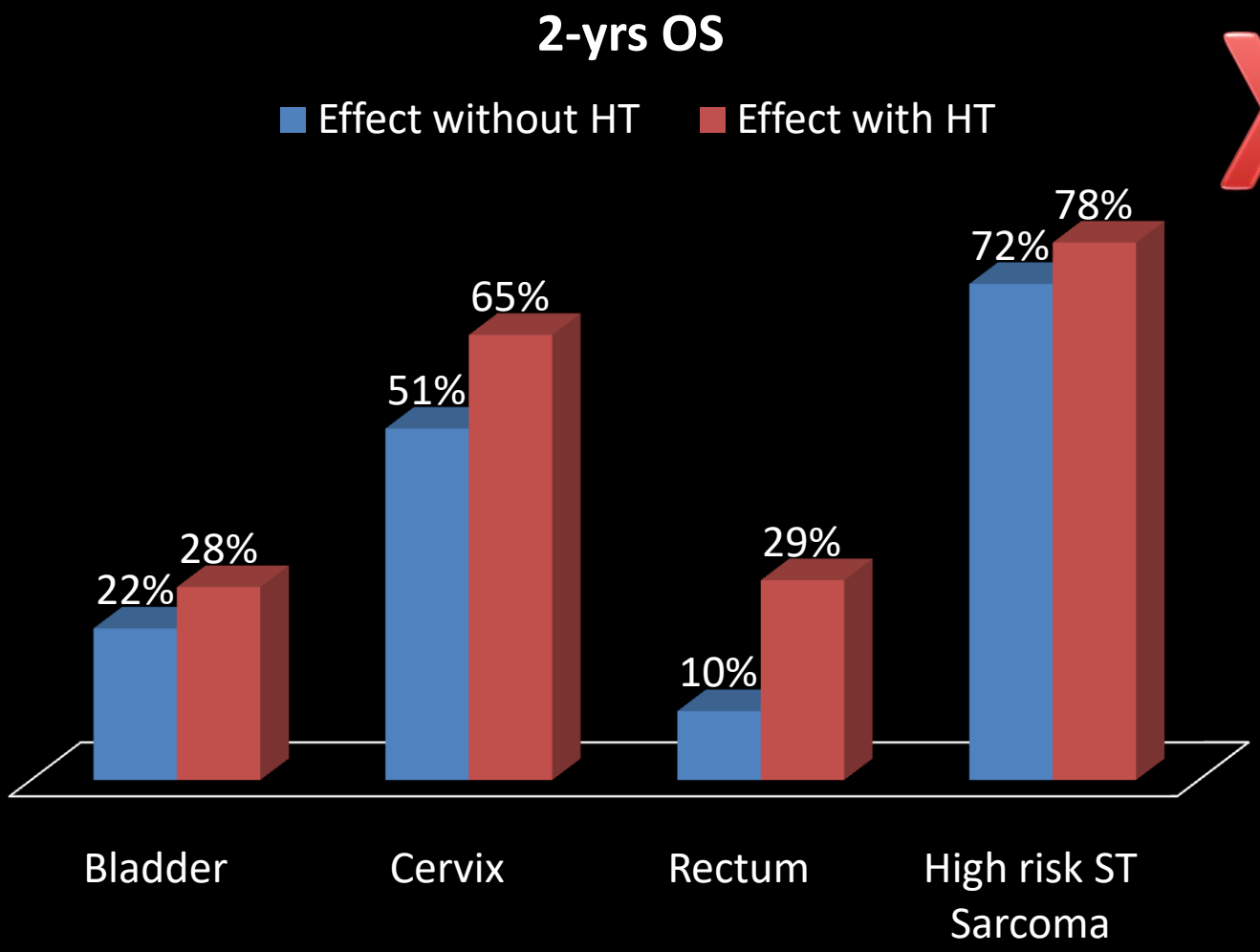
HYPERTHERMIA - RANDOMIZED STUDIES



X 1.5

- "Medline" search

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STANDARD CANCER TREATMENT

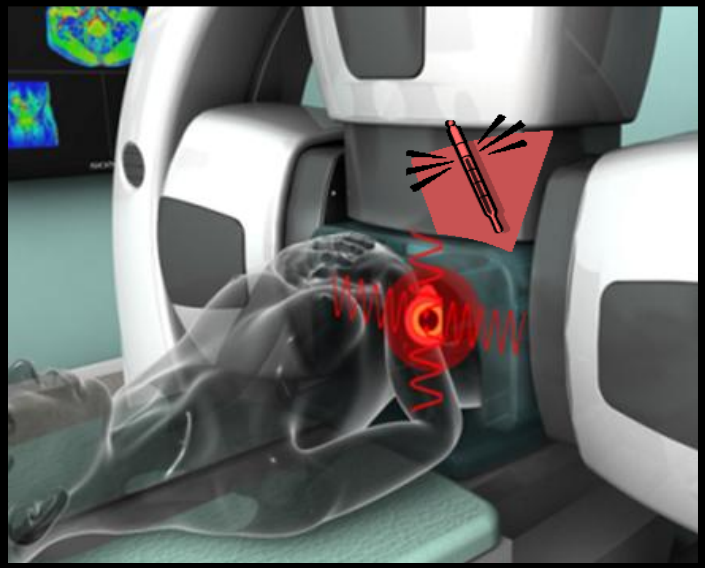
TUMOR		SND TREATMENT	PRIMARY OBJECTIVE	RESULTS
	Stage I/II	S+Adjuvant RT/CT	CR	Very good
PRIMARY	Stage III/IV	(Neo-adjuvant CT+) S+Adjuvant RT/CT	Surgery/ Conservative Surgery CR	May be improved
LOCO-REGIONAL RECURRENT		S/RT/Re-RT/CT	LC OS QoF	May be improved
METASTATIC	Oligometastatic	Curative RT/CT	OS Qof	May be improved
	Diffuse	RT/CT	Palliation	May be improved

Hyperthermia

- ↑↑ Radiotherapy effect
- ↑↑ Chemotherapy effect
- Without increasing normal tissue acute or late toxicity

ALBA 4D DEEP HYPERTHERMIA SYSTEM — MULTICHANNEL PHASED ARRAY SYSTEM

- 70 MHz
- Loco-regional HT
- Focal area ~ 12 cm
- Target temperature: 41-43 °C



CLINICAL INDICATIONS

Cervix and uterus

Rectum

Bladder

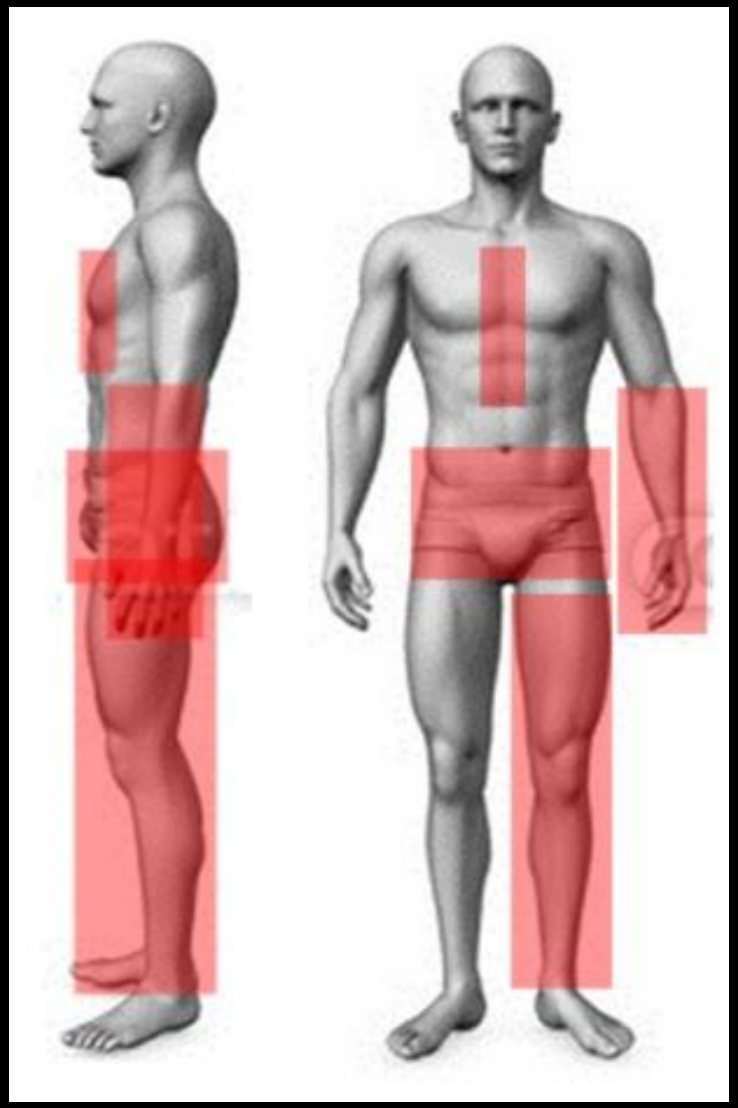
Prostate

Esophagus

Soft tissue sarcoma

Deep seated melanoma

Pancreas



FROM RESEARCH TO MARKET

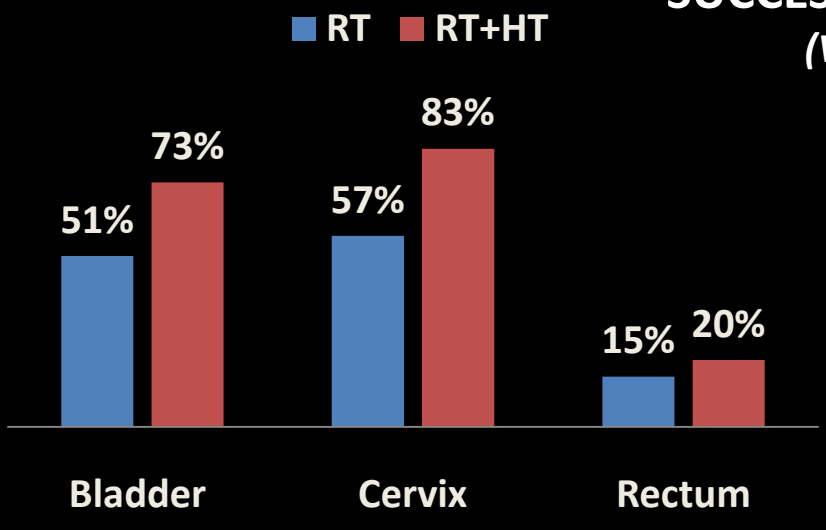
AMC-4
(1980 – 2003)

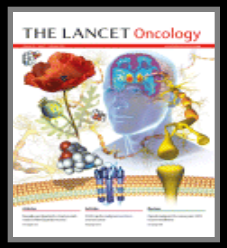
AMC-8
(2003 – 2013)

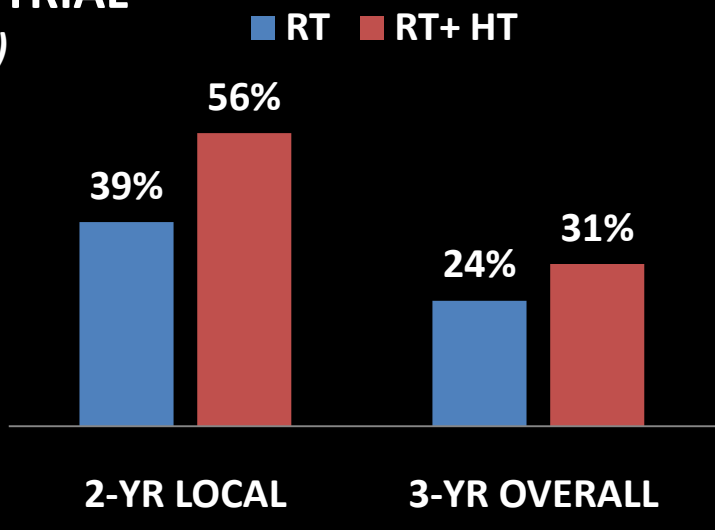
CLINICALLY PROVEN

SUCCESFUL PHASE III TRIAL

(Van der Zee, 2000)

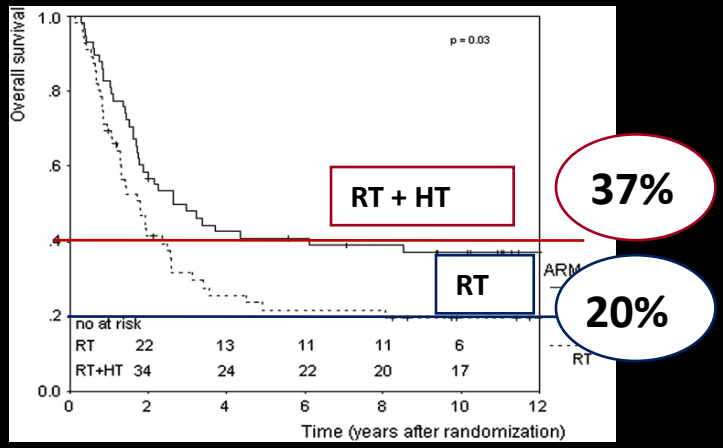






12 YEARS FOLLOW UP

OVERALL SURVIVAL

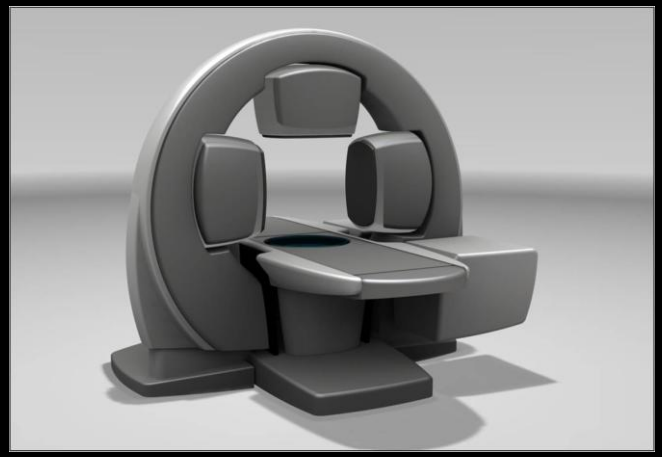


FRANCKENA ET AL
IJROBP 2008

PRODUCT DEVELOPMENT

2017

2012



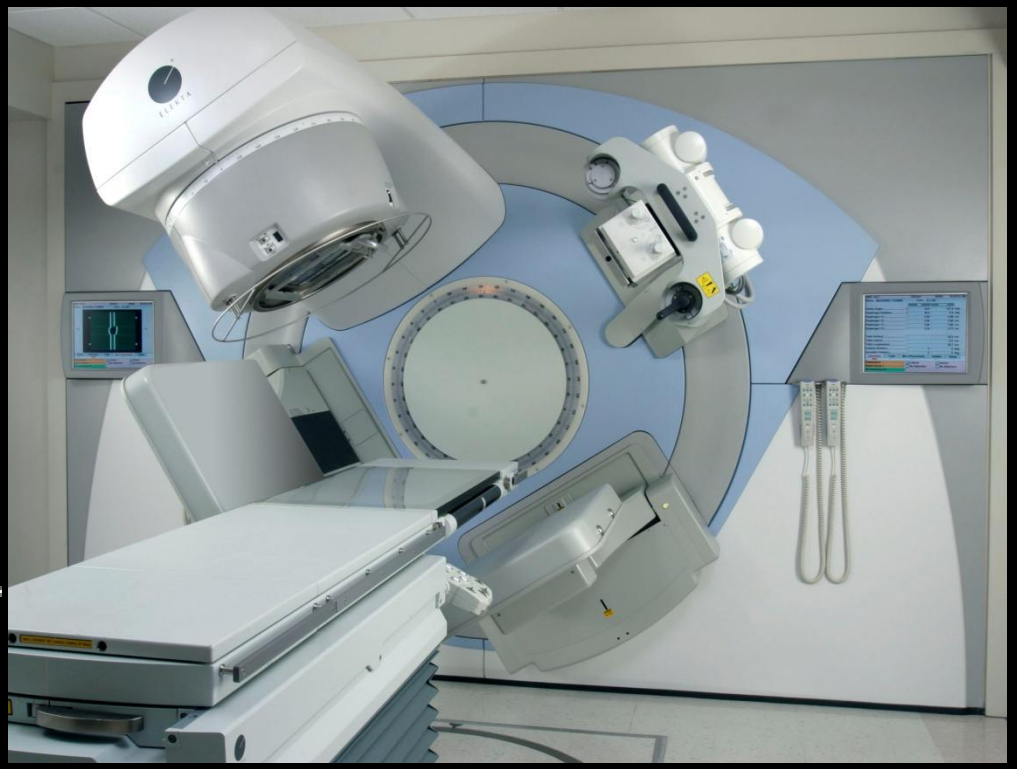
ALBA 4D
DEEP HYPERTHERMIA SYSTEM

PRODUCT DEVELOPMENT

PHILOSOPHY

CE

ESHO



DESCRIPTION & COMPARISON

MECHANICS

RF

COOLING SYSTEM

THERMOMETRY

DESCRIPTION & COMPARISON

MECHANICS

THERMOMETRY

RF

COOLING SYSTEM

MECHANICS

BED MOVEMENT

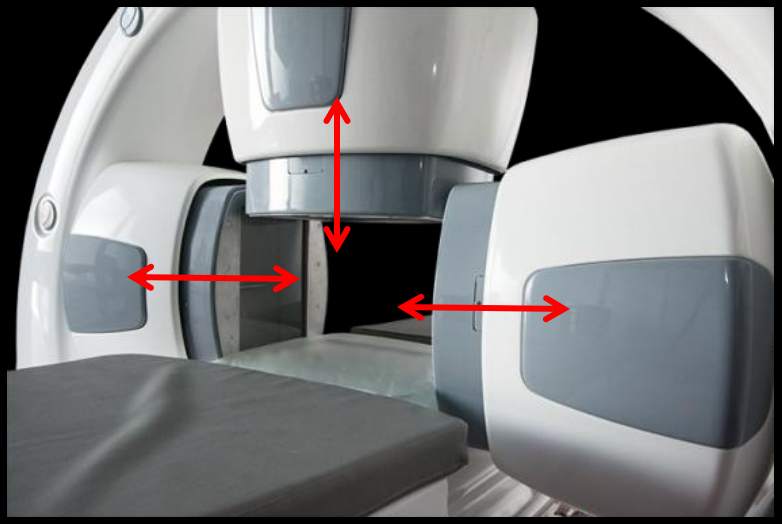
Manual positioning of the bed

- easy and comfortable patient preparation
- fast emergency removal

MECHANICS

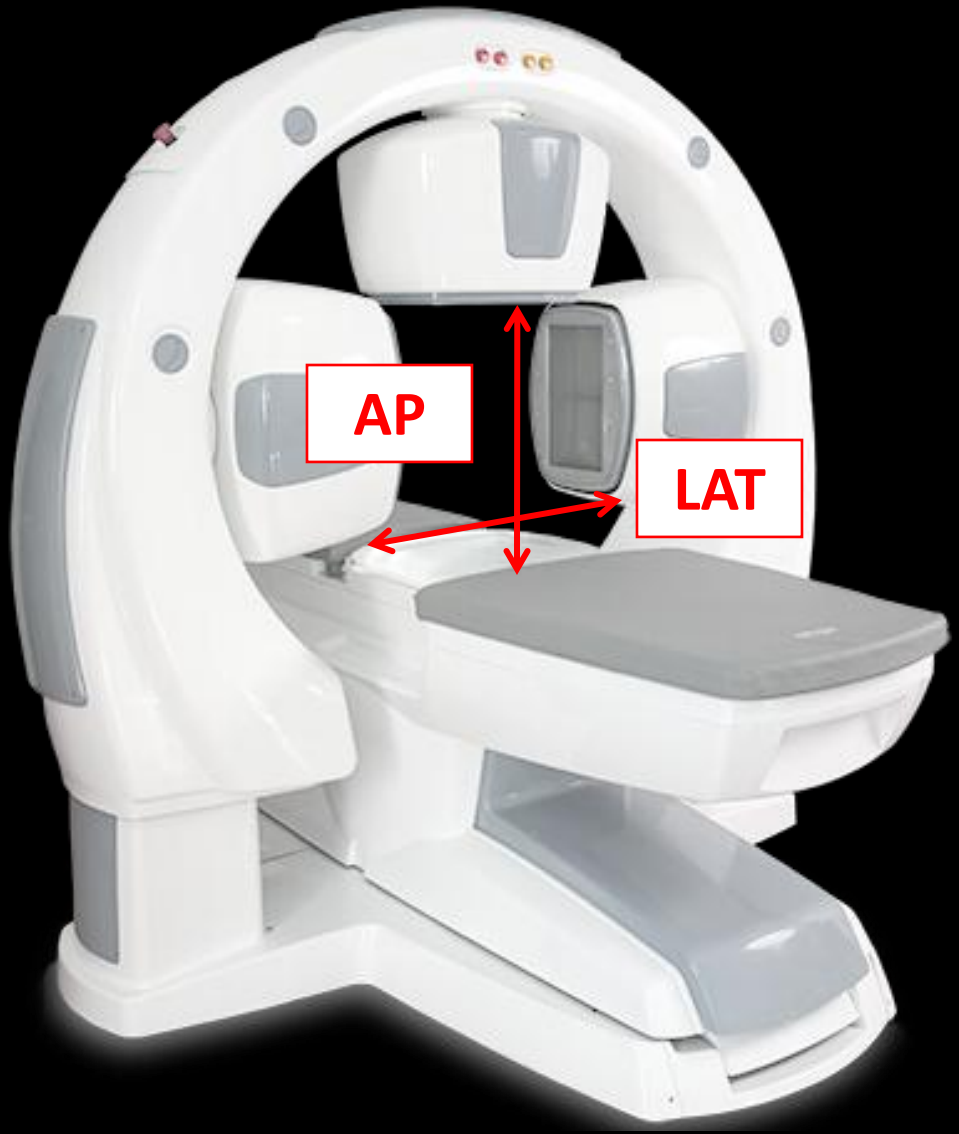
GANTRY MOVEMENT

ANTENNAS MOVEMENT



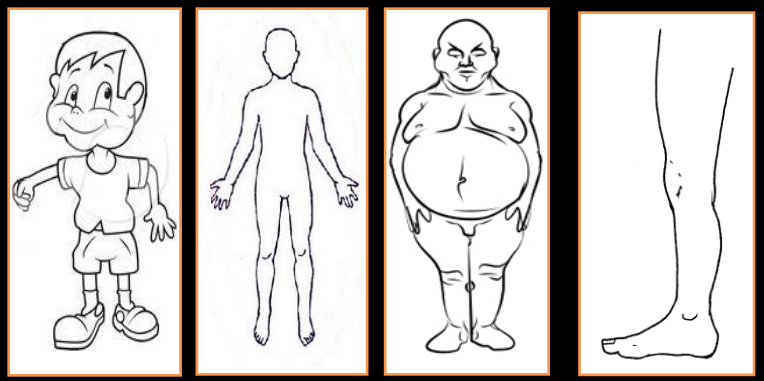
Automatic record of gantry and antennas position

MECHANICS



- AP : 33- 73 cm
- LAT: 46-60 cm

ADAPTATION TO DIFEFENT SIZE



MECHANICS

Crs = (Peso totale x fattore di sicurezza) – peso totale

MECHANICS

Crs = (Peso totale x fattore di sicurezza) – peso totale

ALBA 4D
DEEP HYPERTHERMIA SYSTEM

MECHANICS

INTEGRATED POSITIONING LASERS

DESCRIPTION & COMPARISON

MECHANICS

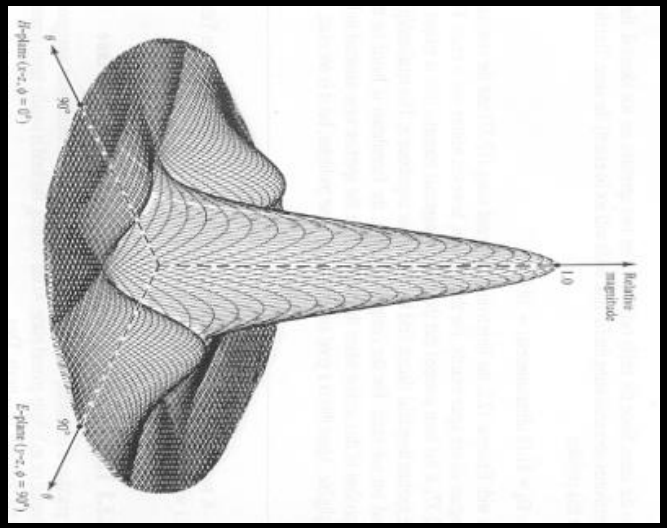
THERMOMETRY

RF CONTROL

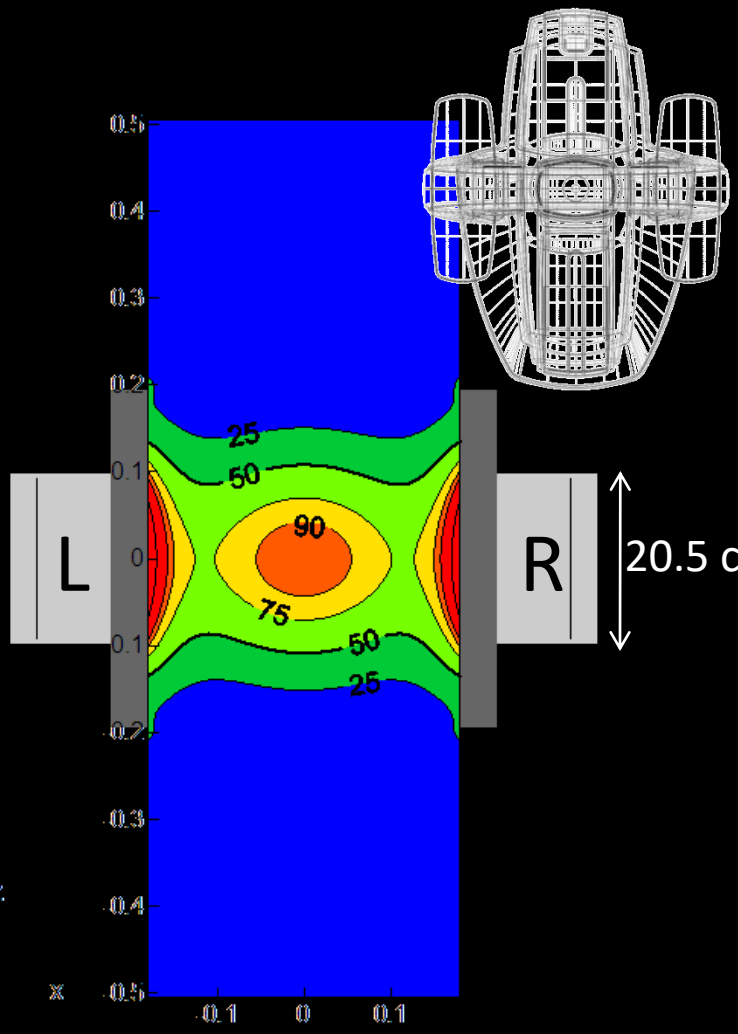
COOLING SYSTEM

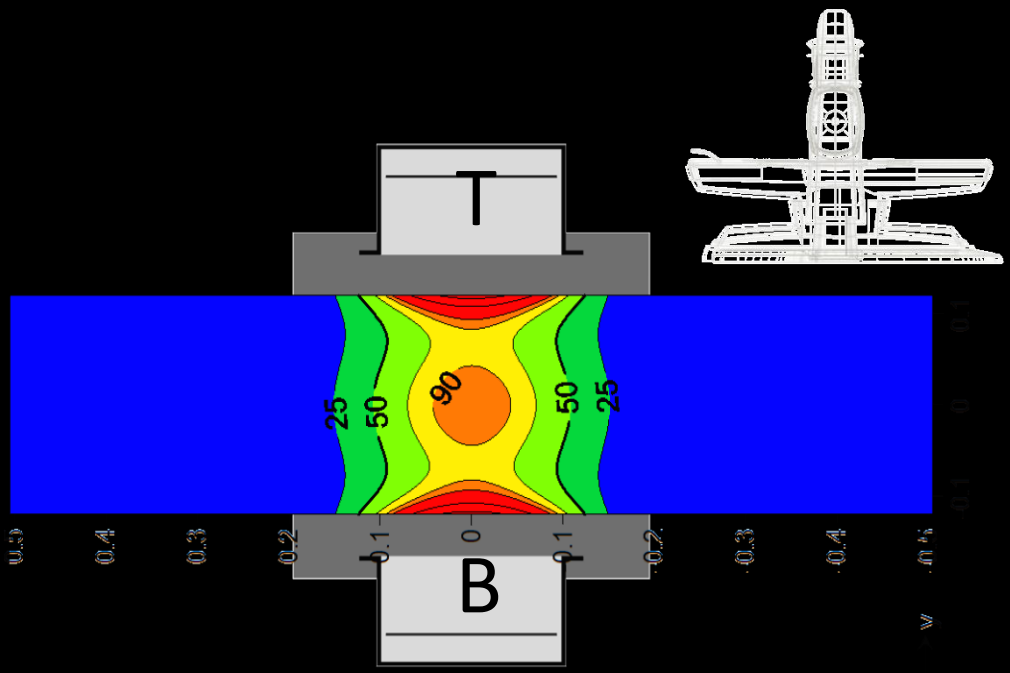
ANTENNAS

- 70 MHz
- Waveguide applicator



SIMULATED SAR DISTRIBUTION



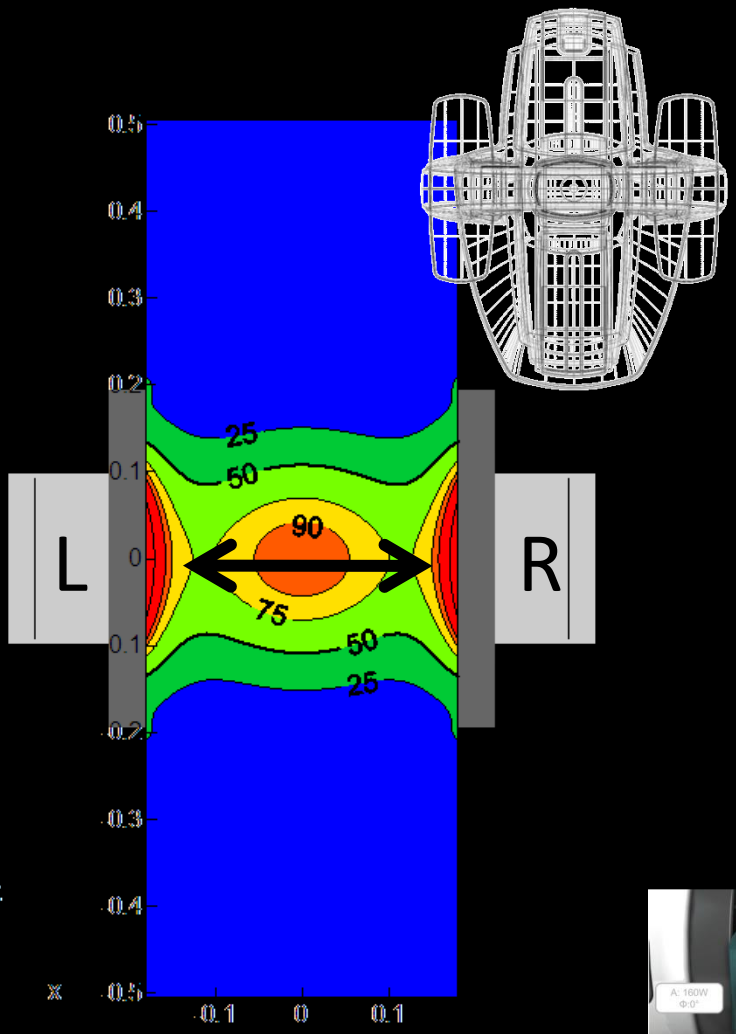


Focal area ~ 12.5 cm

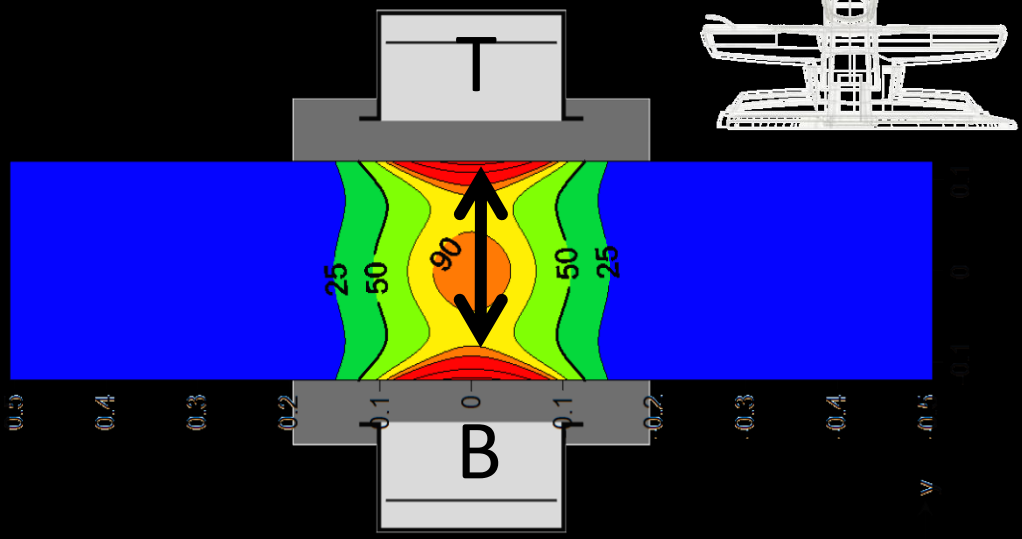
P = intensity

ϕ= position

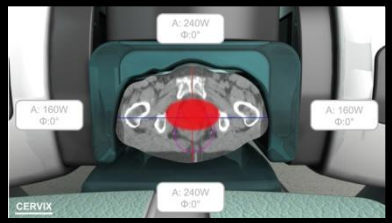
FOCUS STEERING



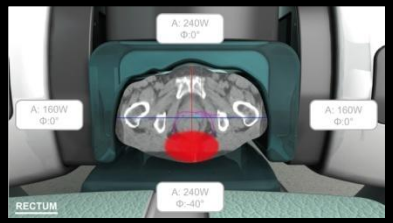
$\Delta\phi=10° \longrightarrow \Delta s= 1cm$



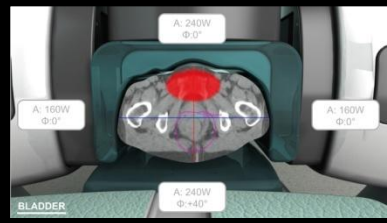
CERVIX



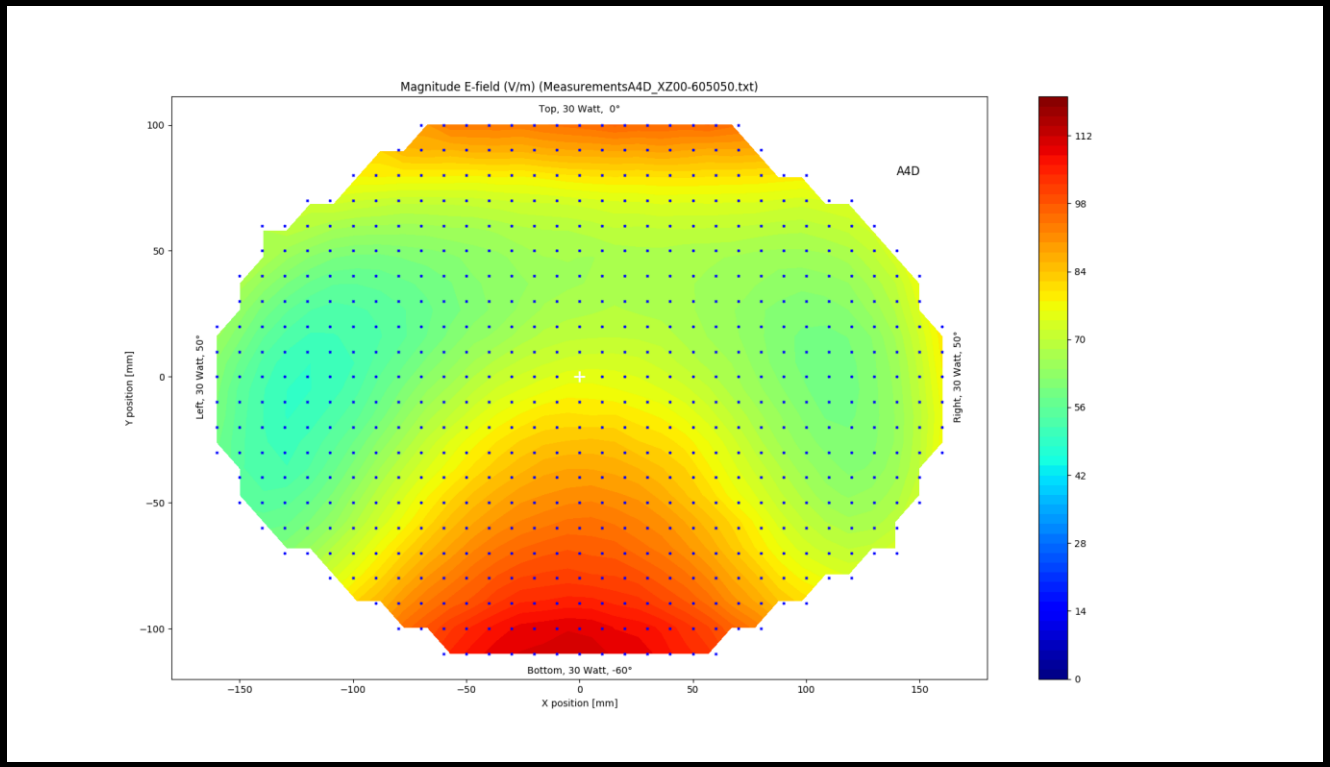
RECTUM



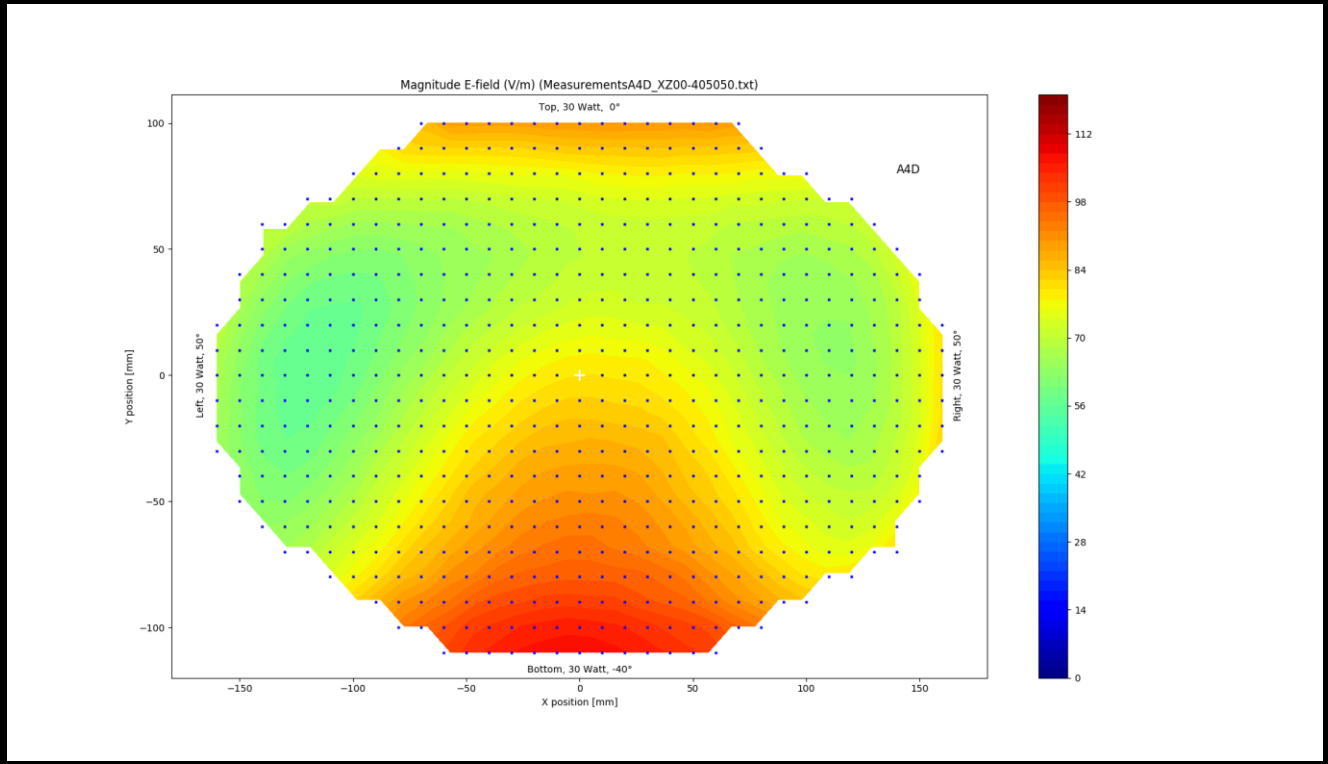
BLADDER



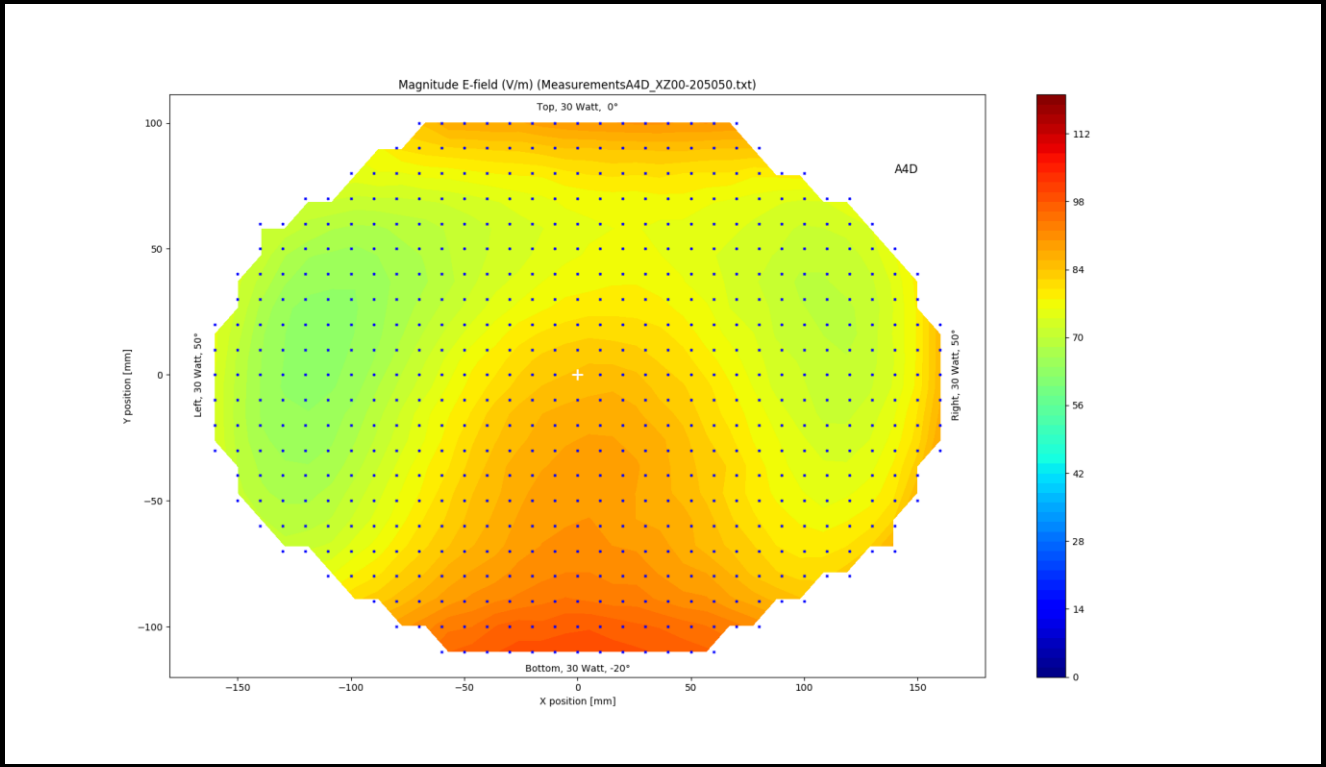
FOCUS STEERING



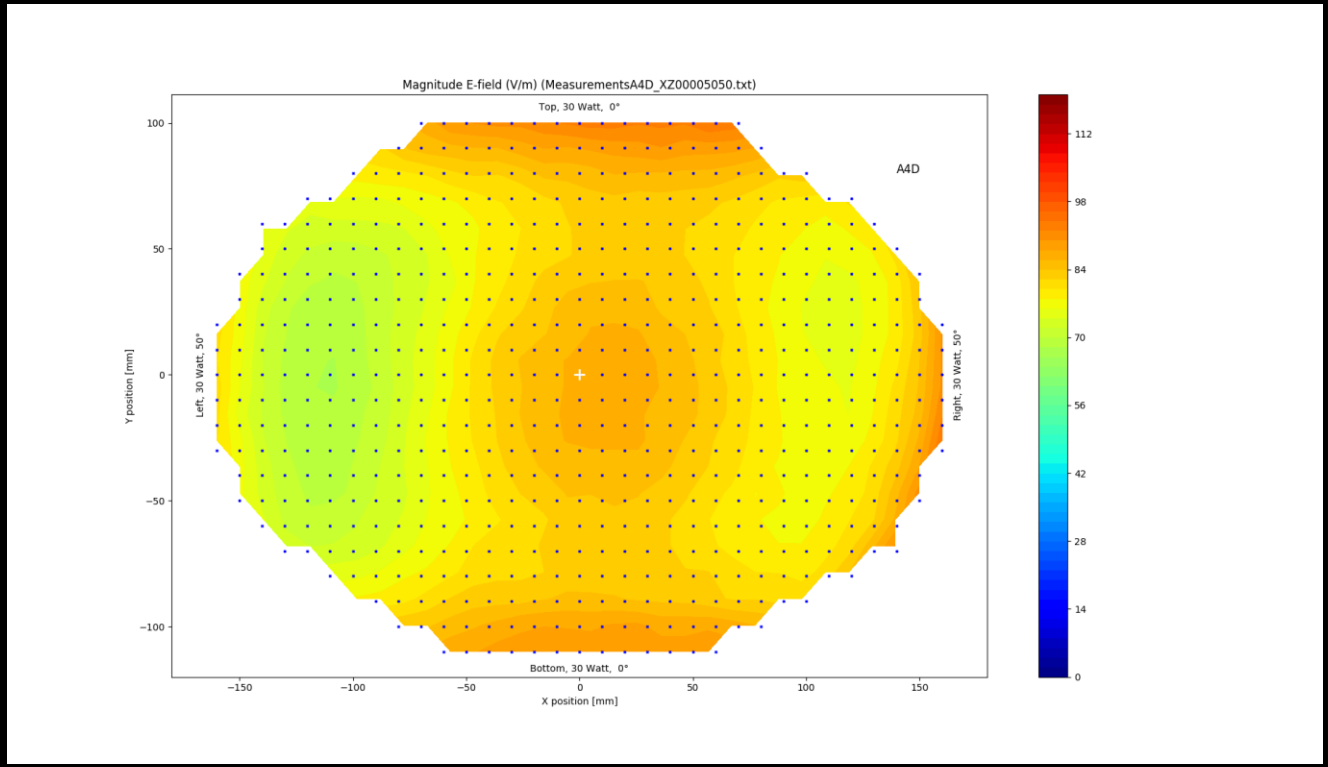
FOCUS STEERING



FOCUS STEERING

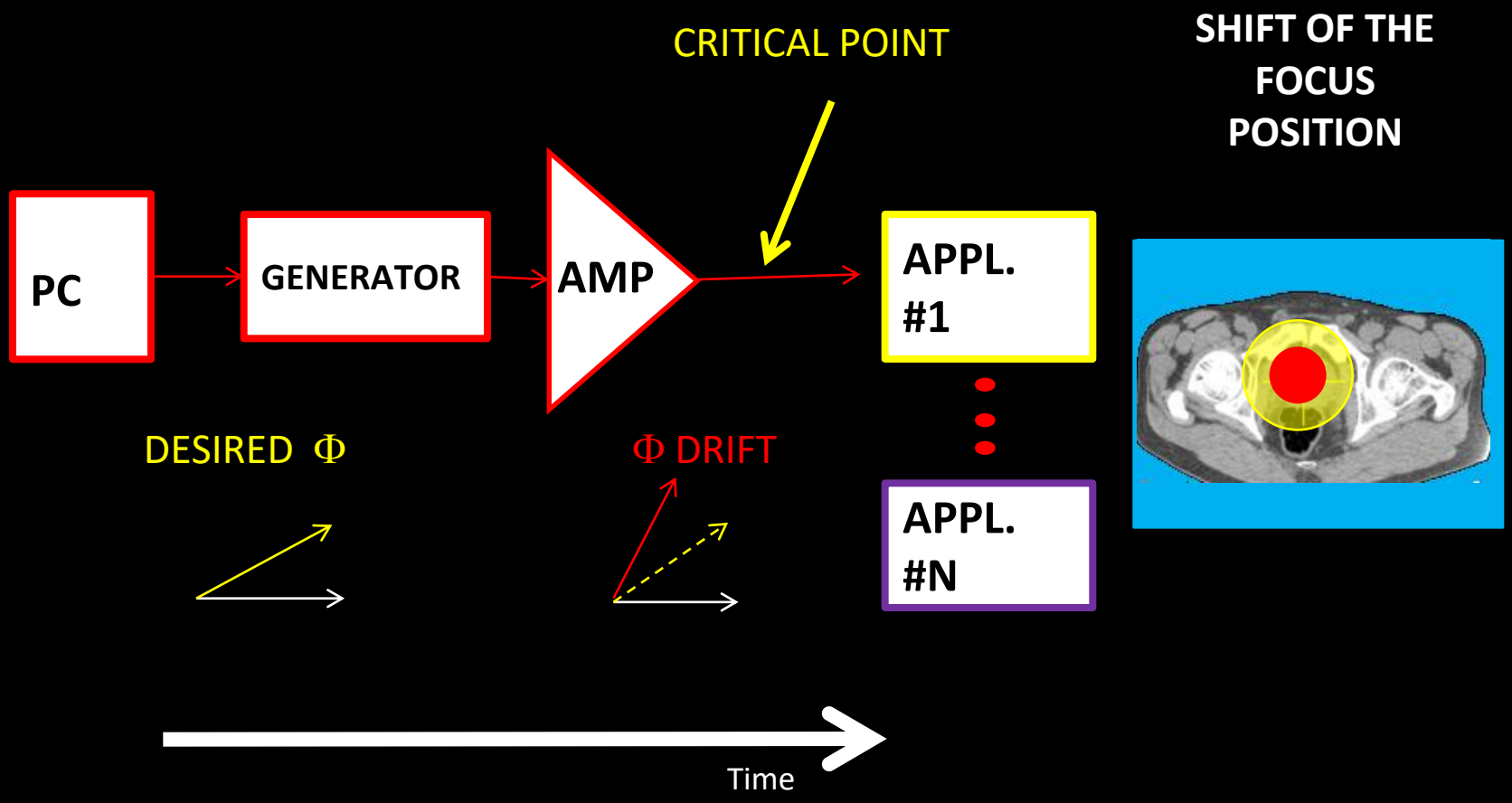


FOCUS STEERING



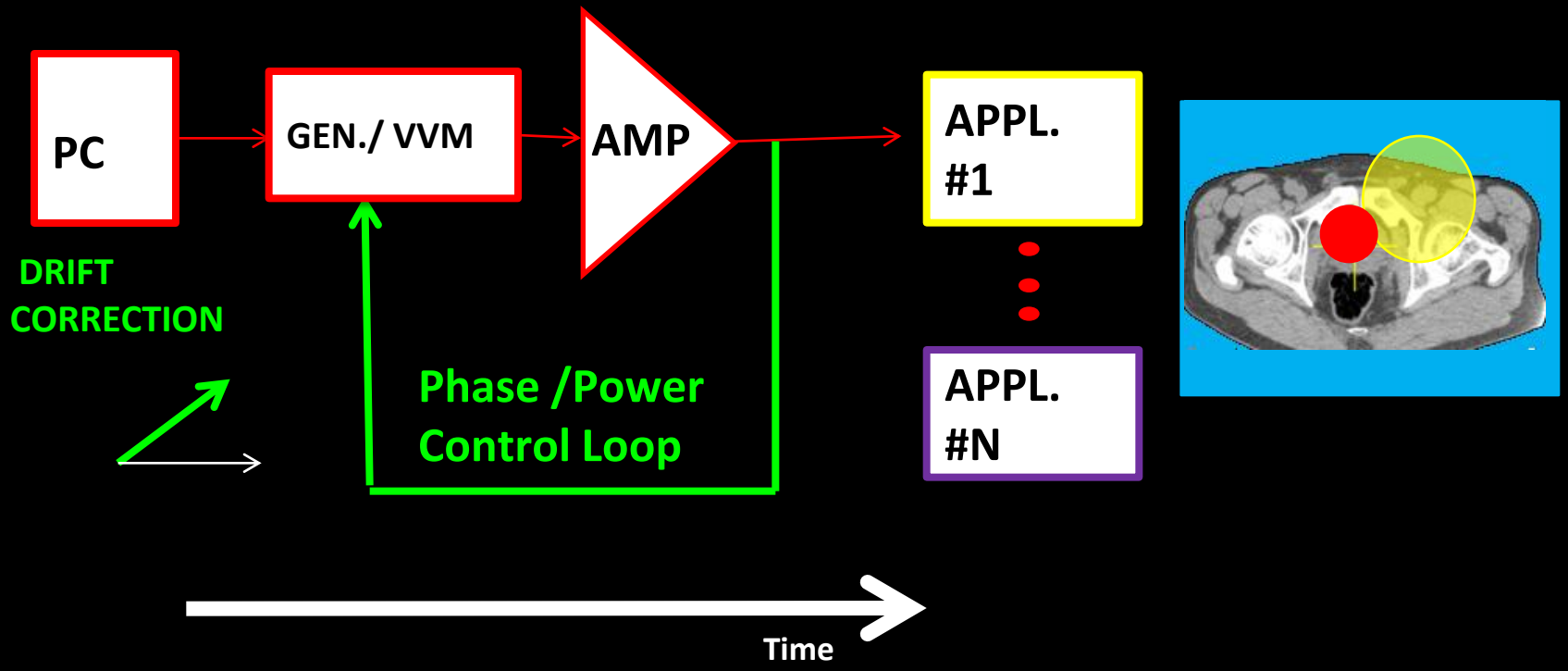
MAJOR REQUIREMENTS
PHASED ARRAY SYSTEM FOR DEEP HT

PHASED ARRAY INTRINSIC ISSUES → **SUB-OPTIMAL TARGET HEATING**

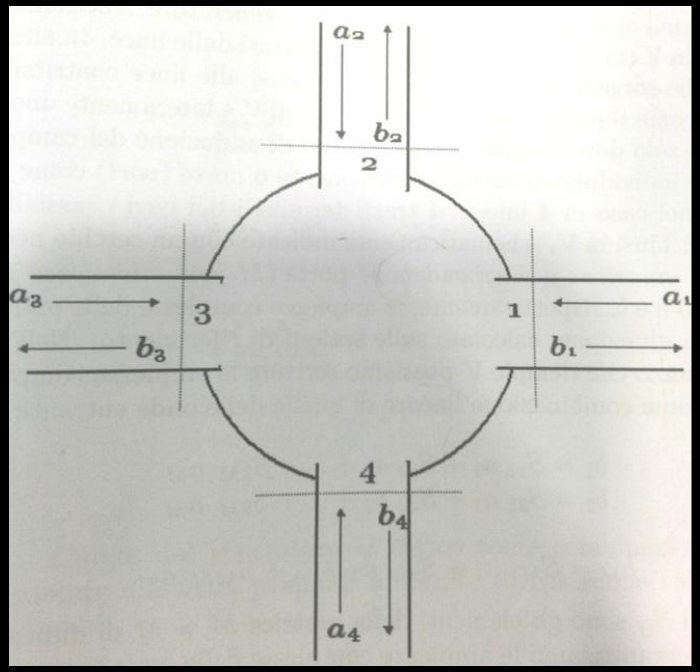


MAJOR REQUIREMENTS
PHASED ARRAY SYSTEM FOR DEEP HT

FEEDBACK SYSTEM → **OPTIMAL TARGET HEATING**



IMPEDANCE MISMATCHING



a_i= forward power of i-esimo ch

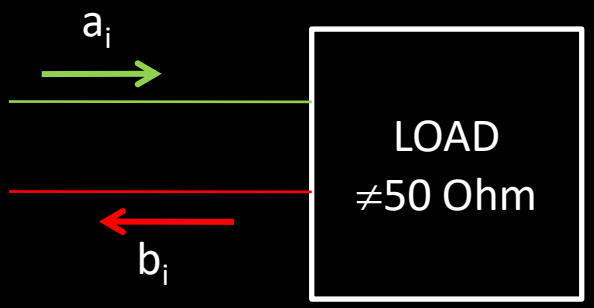
b_i= reflected power of i-esimo ch

$$\underline{\mathbf{b}} = \underline{\underline{\mathbf{S}}} \cdot \underline{\mathbf{a}}$$

$$\underline{\underline{\mathbf{S}}} = \begin{pmatrix} S_{11} & \cdots & S_{1N} \\ \vdots & \ddots & \vdots \\ S_{N1} & \cdots & S_{NN} \end{pmatrix}$$

S_{ii} :the lower the better

IMPEDANCE MISMATCHING



a_i = forward power of i-esimo ch

b_i = reflected power of i-esimo ch

THE MORE THE LOAD ≠ 50 OHM
THE MORE REFLECTED POWER (b_i) IS HIGH ⇨ **INSTABILITIES IN THE LINE** ⇨ **NOT RELIABLE MEASUREMENTS FROM BI-DIRECTIONAL COUPLERS**

ALBA 4D
DEEP HYPERTHERMIA SYSTEM

MECHANICS

RF CONTROL

THERMOMETRY

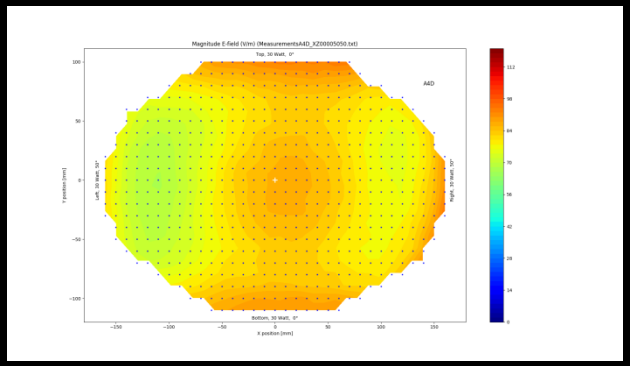
COOLING SYSTEM

WATER BOLUS

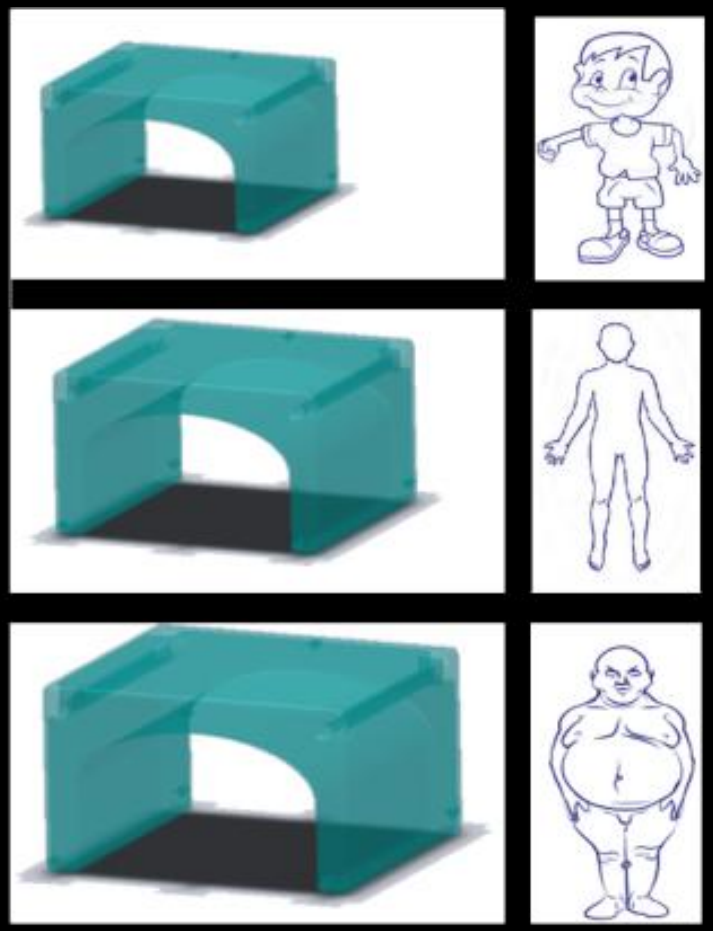
“C “ shaped top water bolus

Rectangular bottom bolus

- OPTIMAL ADAPTATION
- INDEPENDENTLY THERMO-REGULATED
- AUTOMATIC RECORD OF WATER VOLUME



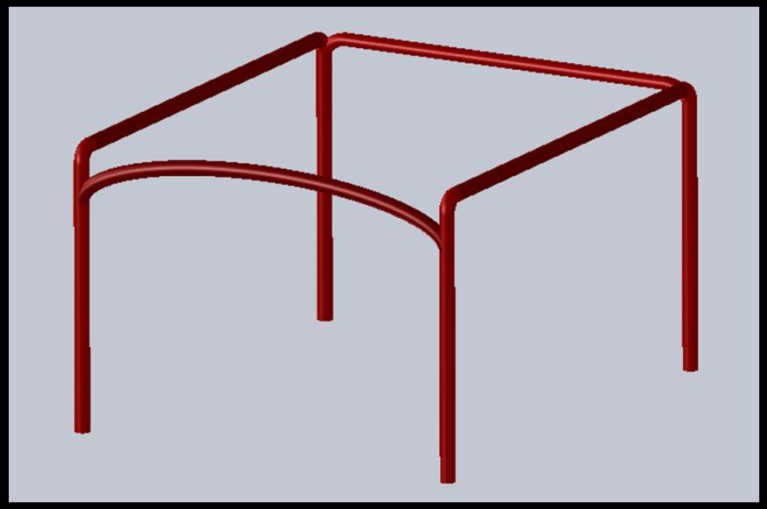
WATER BOLUS

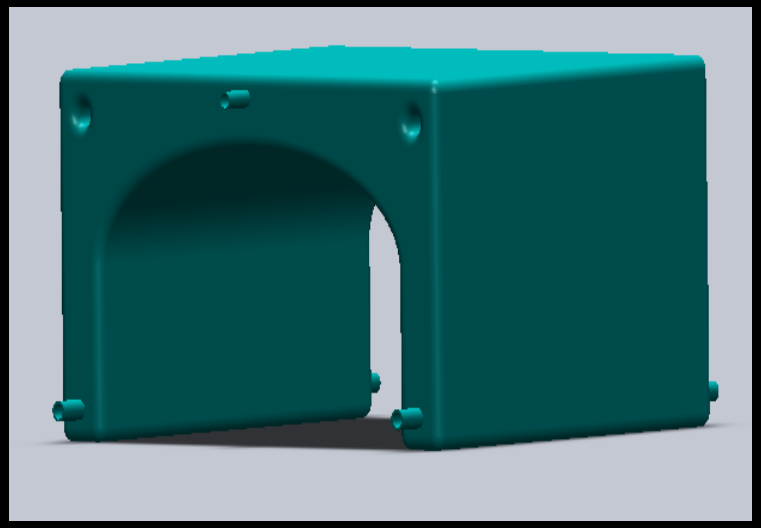


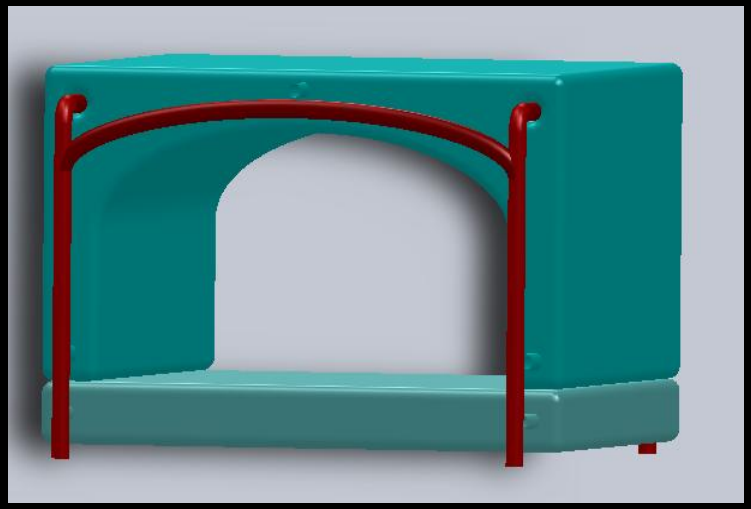
DIFFERENT TOP BOLUS
ACCORDING TO PATIENT SIZE

WATER BOLUS

WATER BOLUS







WATER BOLUS

DESCRIPTION & COMPARISON

MECHANICS

RF CONTROL

COOLING SYSTEM

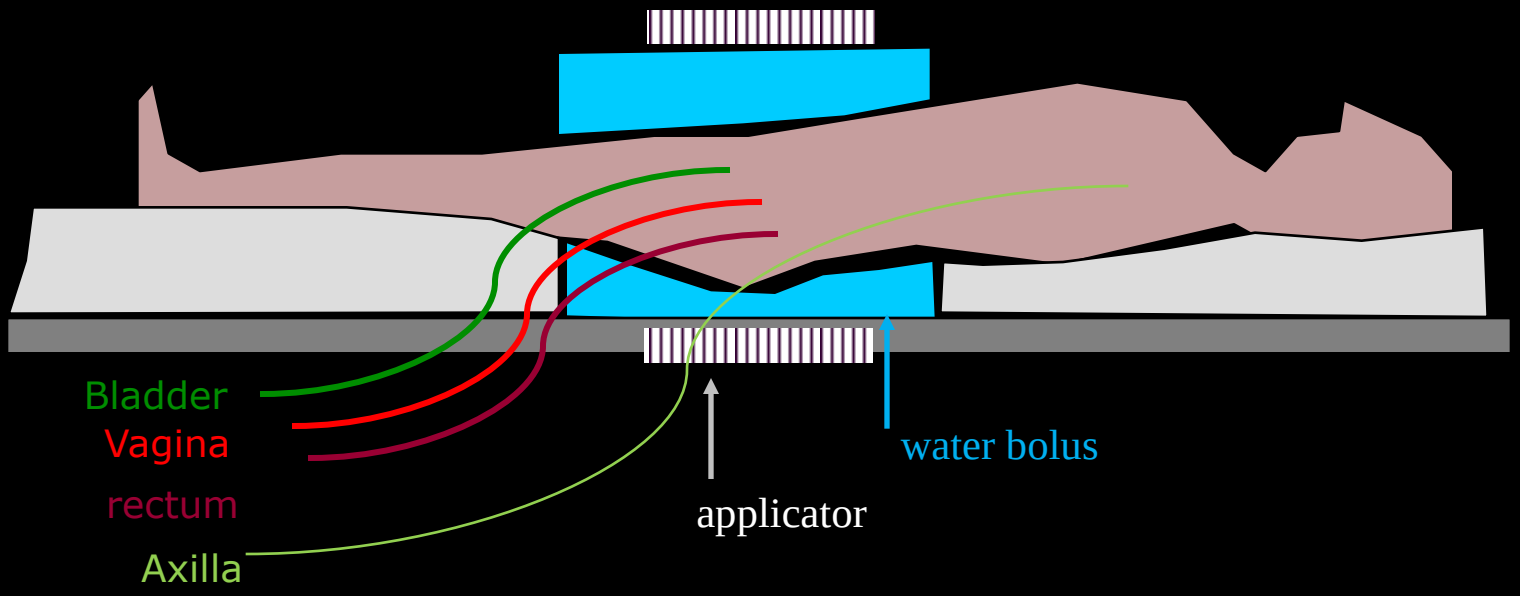
THERMOMETRY

ALBA 4D
DEEP HYPERTHERMIA SYSTEM

ESHO

Invasive thermometry is the the ONLY ESHO approved measuring system

REAL TIME DOSIMETRY



64 SENSORS

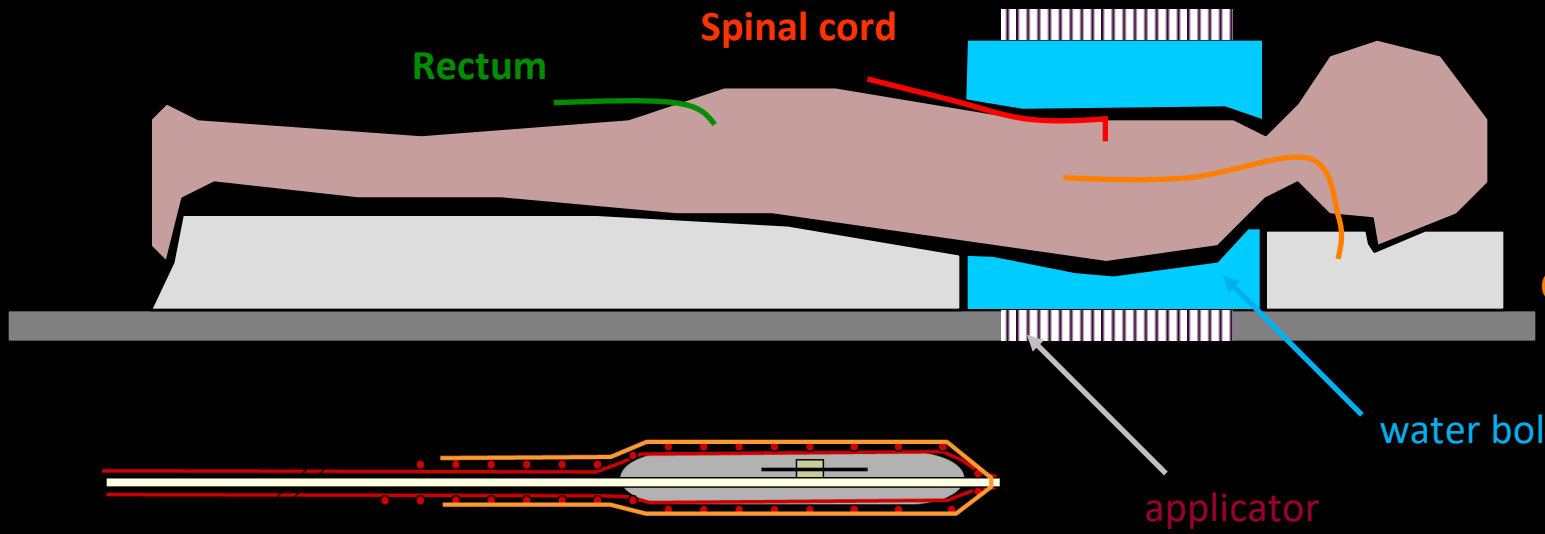
POSITIONED IN NATURAL CAVITIES

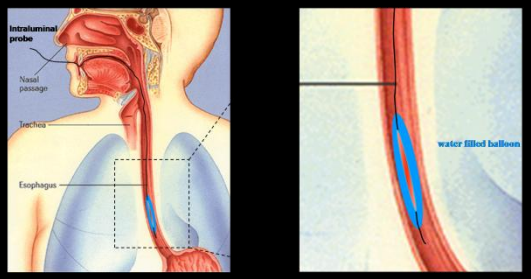
ALBA 4D
DEEP HYPERTHERMIA SYSTEM

ESHO

Invasive thermometry is the the ONLY ESHO approved measuring system

REAL TIME DOSIMETRY

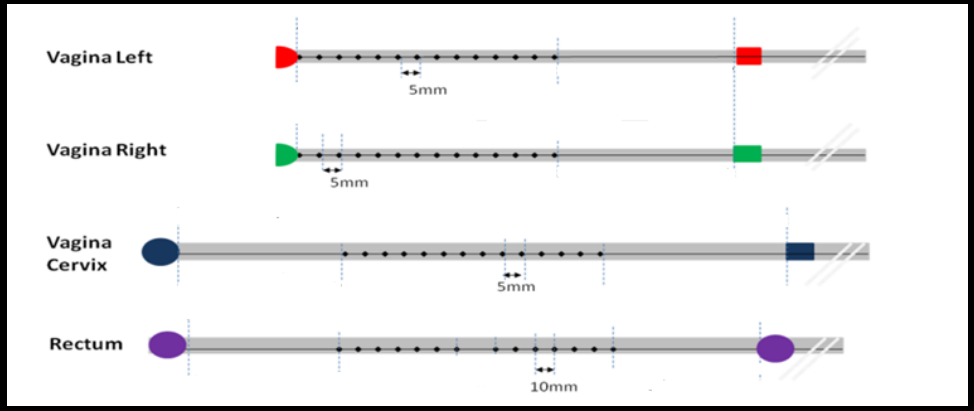


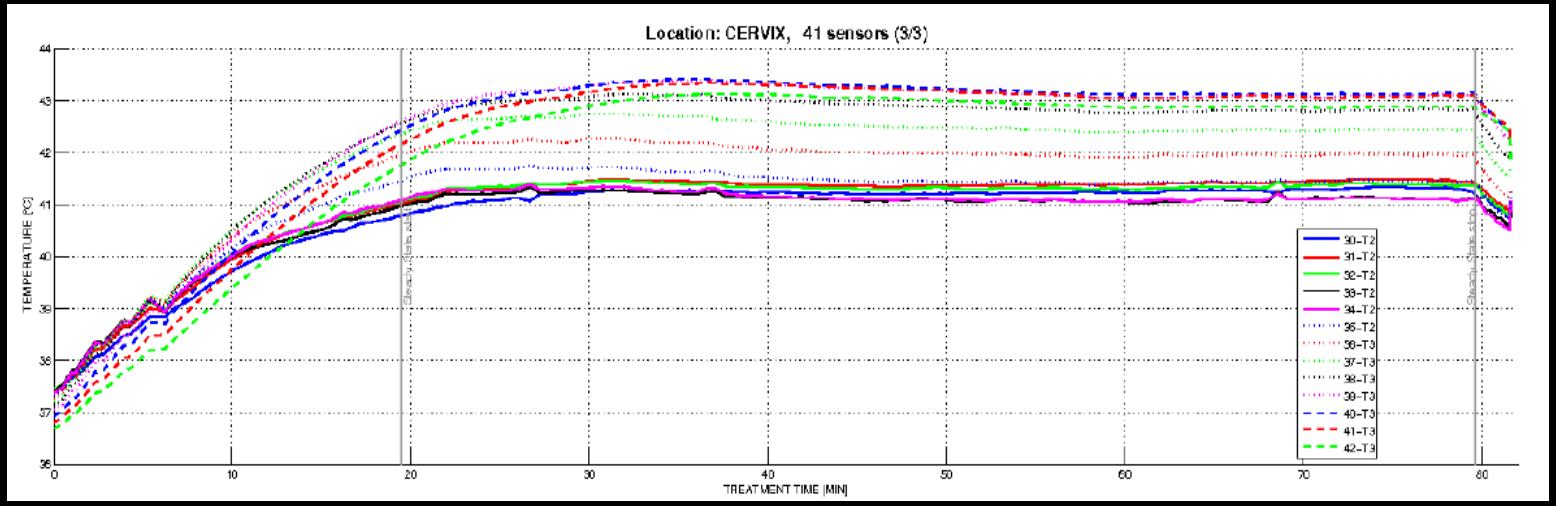


64 SENSORS

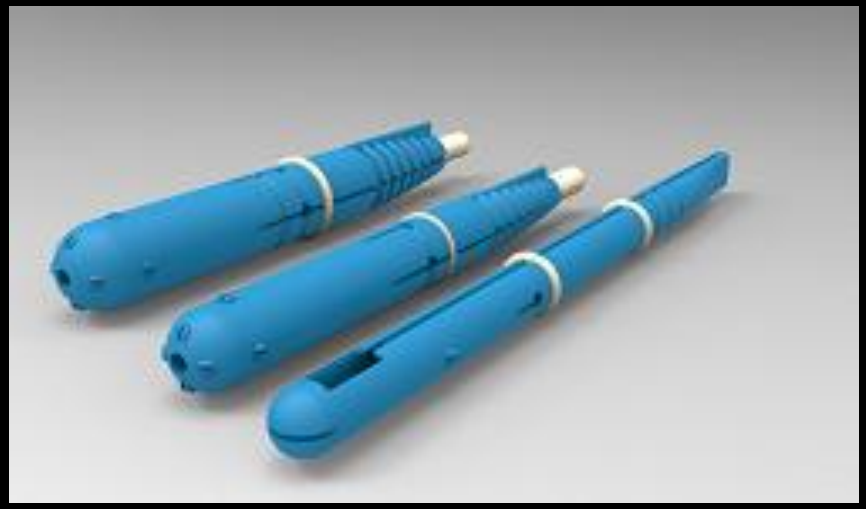
POSITIONED IN NATURAL CAVITIES

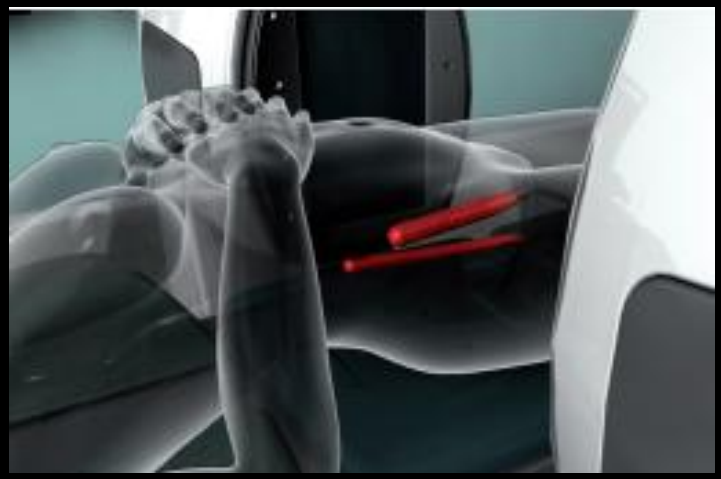
MULTI-TIPS TEMPERATURE PROBES

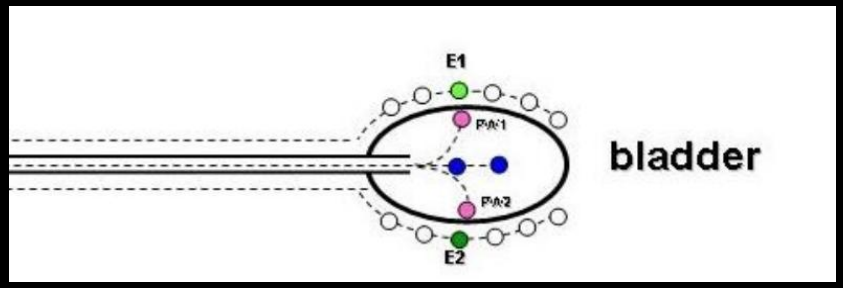


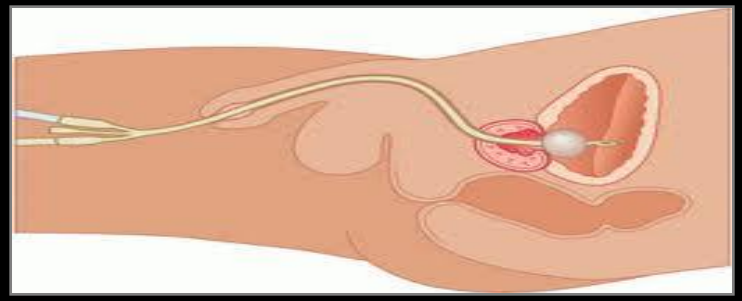


SPECIAL SUPPORT DEVICES









PATIENT COMFORT

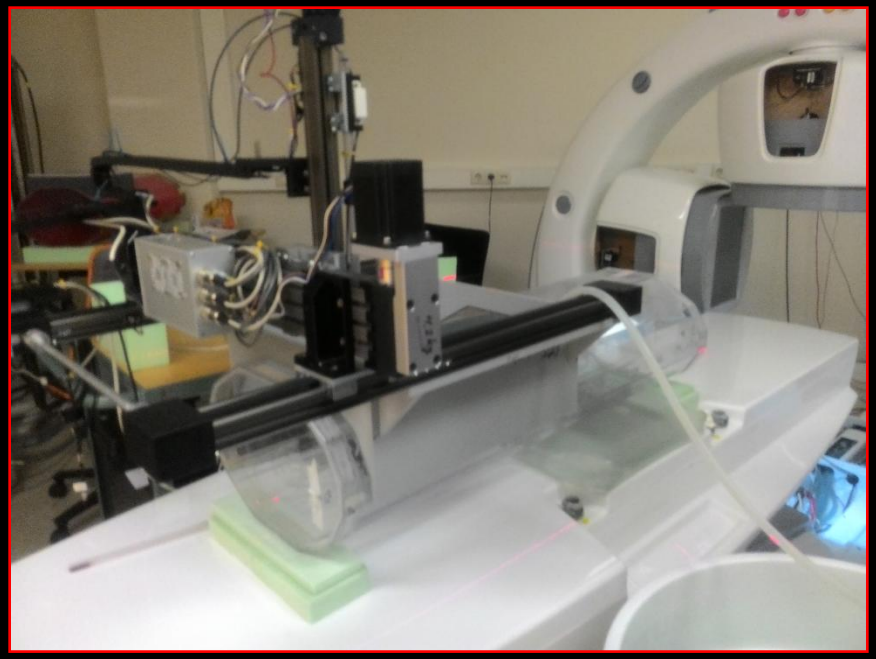
IPAD

4 FANS WITH
ADJUSTABLE INTENSITY

Q.A

RADIOTHERAPY

HYPERTHERMIA



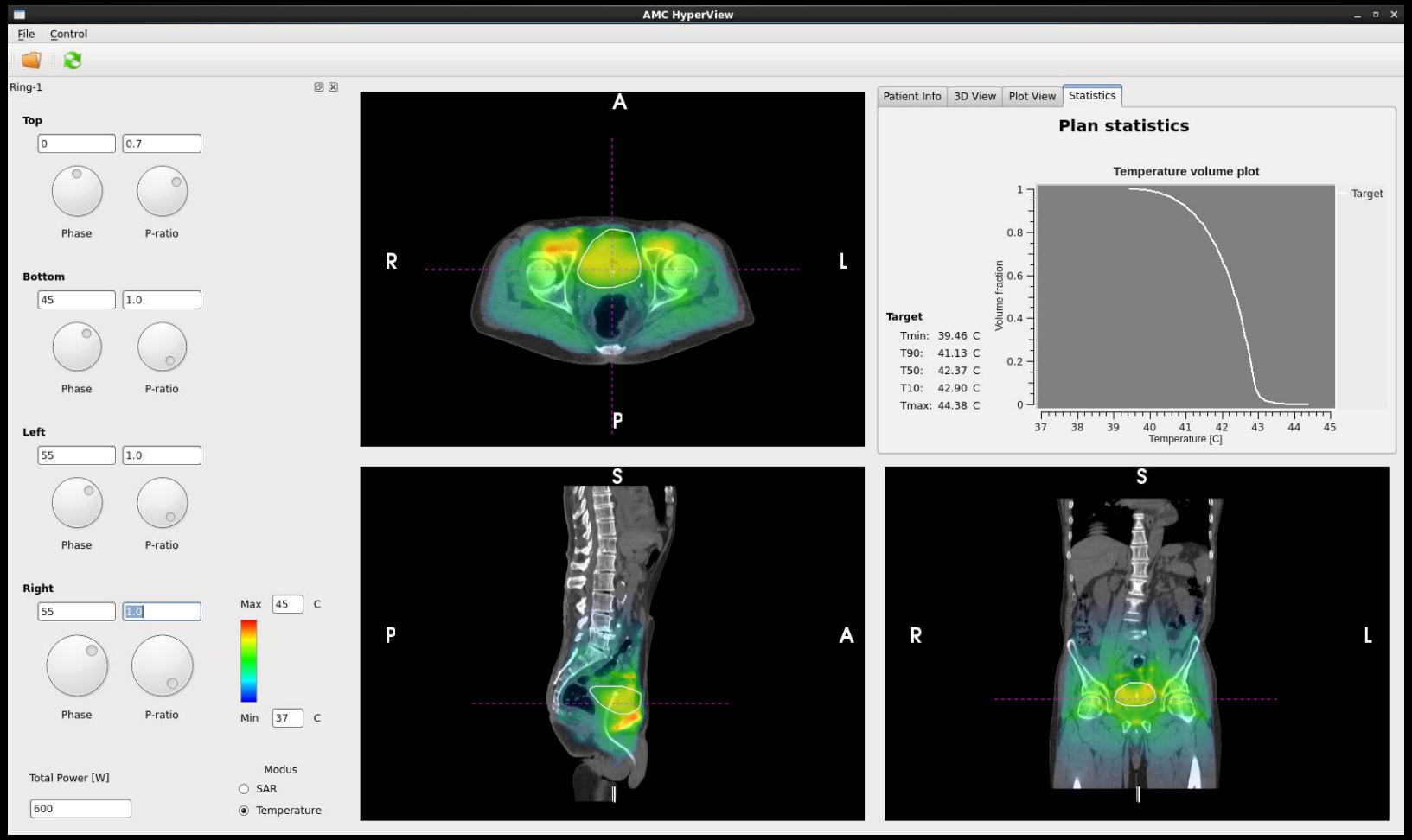
ALBA 4D
DEEP HYPERTHERMIA SYSTEM

chi CE c'è

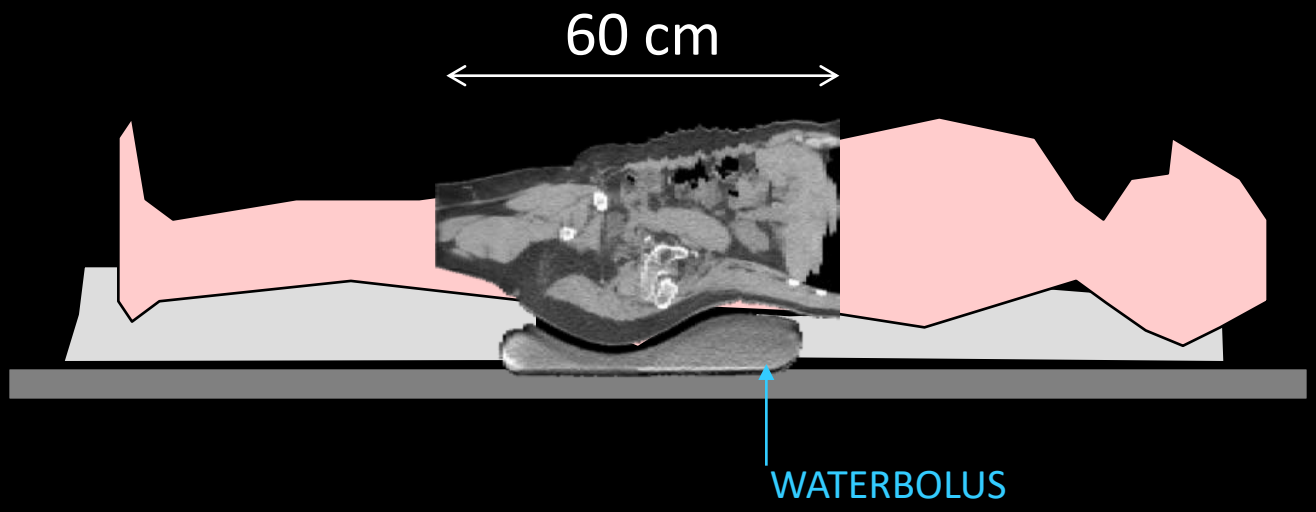
- Requisiti Essenziali
- Gestione del rischio
- Descrizione del prodotto
- Ciclo di sviluppo, disegno ed implementazione
- Valutazione clinica (pubblicazioni)
- Documenti di progettazione (disegni meccanici, schemi elettrici, data sheet componenti critici)
- Prove di compatibilità elettromagnetica
- Schede materiali a contatto con il paziente e prove biocompatibilità
- Progetto di etichettatura
- Depliant e Manuali
- Dichiarazione di conformità

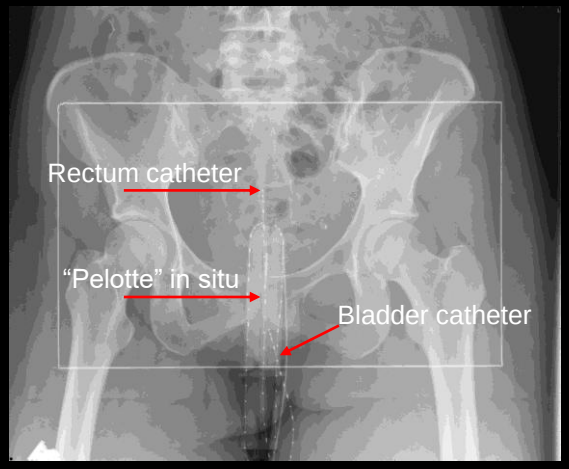
ALBA 4D
DEEP HYPERTHERMIA SYSTEM

HYPERTHERMIA TREATMENT PLANNING SYSTEM



PATIENT SPECIFIC IMAGING (CT SCAN) IN TREATMENT POSITION





CT SCAN / X RAY
WITH THERMOMETRIC PROBES
INSERTED

TARGET DELINEATION (BLADDER)

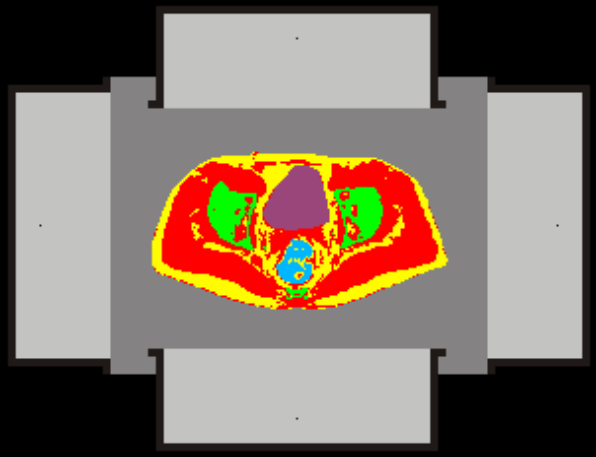
transversal

sagittal

coronal

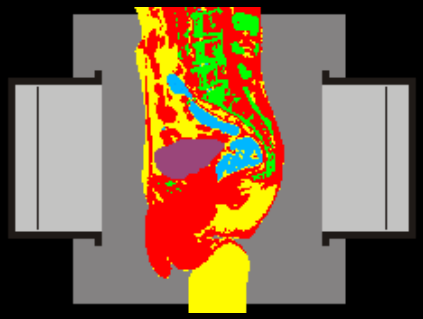
PATIENT POSITIONING

TISSUE SEGMENTATION

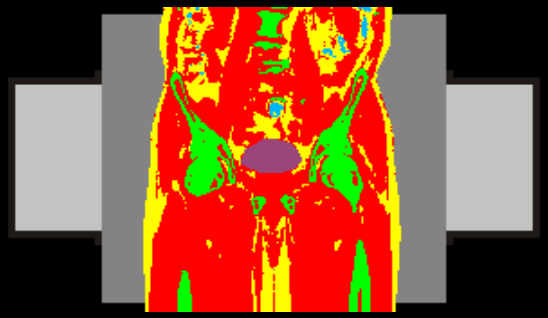


- muscle
- fat
- bone
- air
- target

Transversal

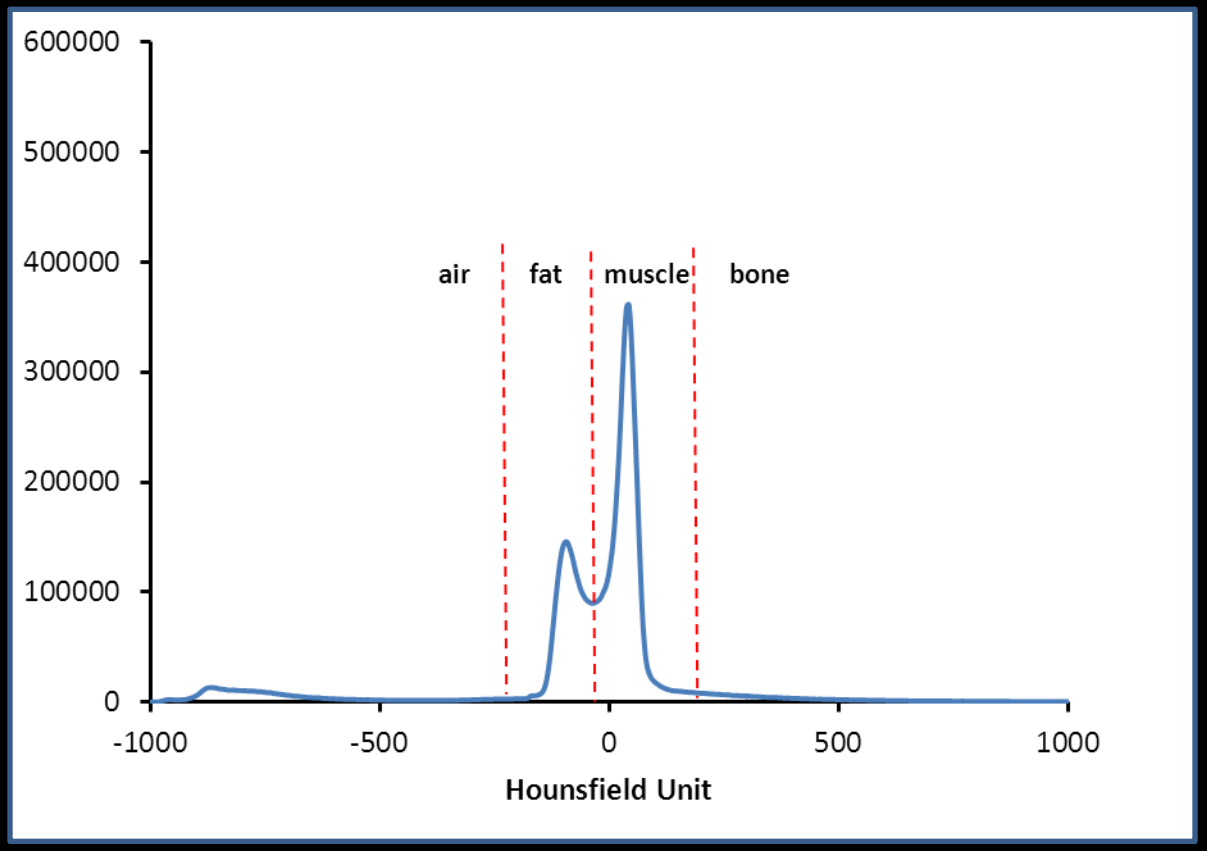


Sagittal

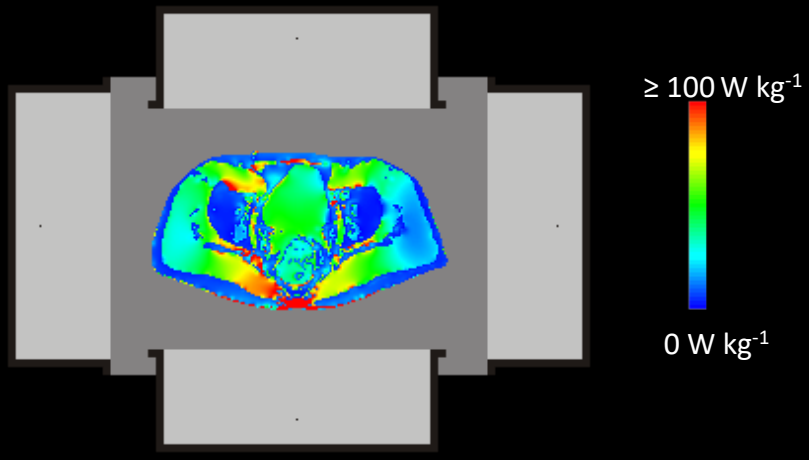


Coronal

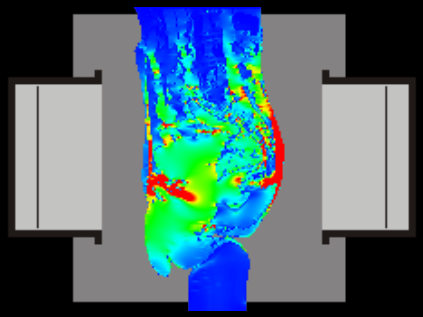
SEGMENTATION BASED ON CT HOUNSFIELD UNITS



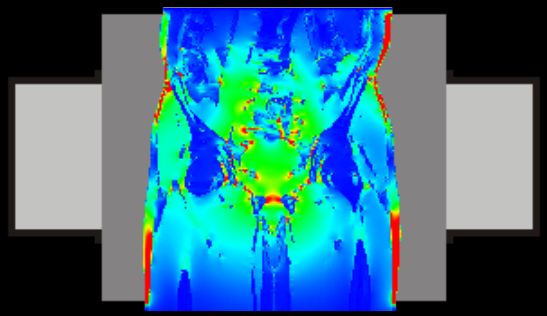
SAR SIMULATION(W/Kg)



Transversal



Sagittal

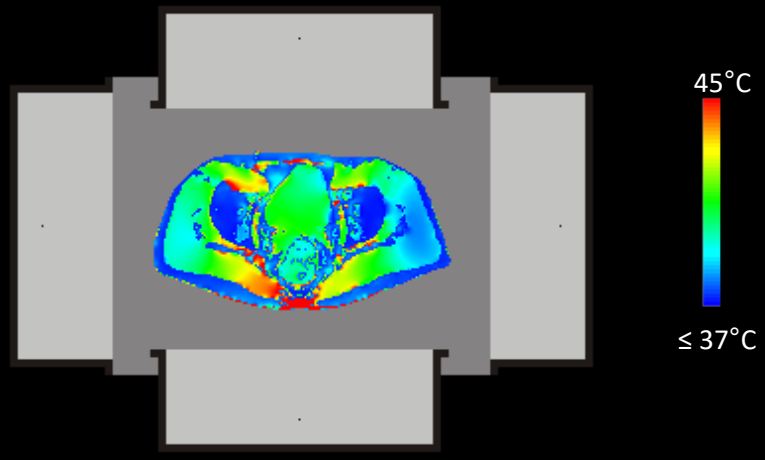


Coronal

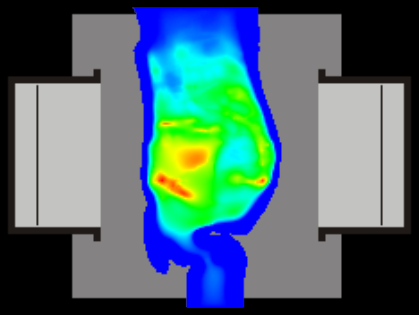
Penne's Bioheat equation

$$\rho_t c_t \frac{\partial T}{\partial t} = \nabla(k_t \nabla T) + c_b w_b (T - T_b) + Q$$

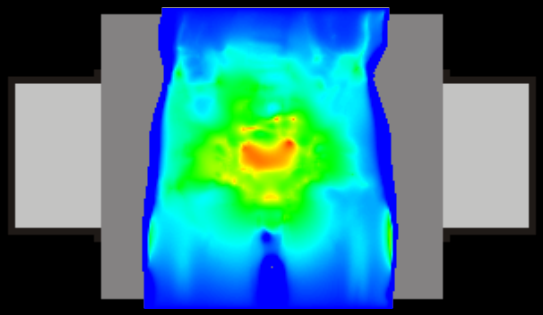
TEMPERATURE SIMULATION(C °)



Transversal

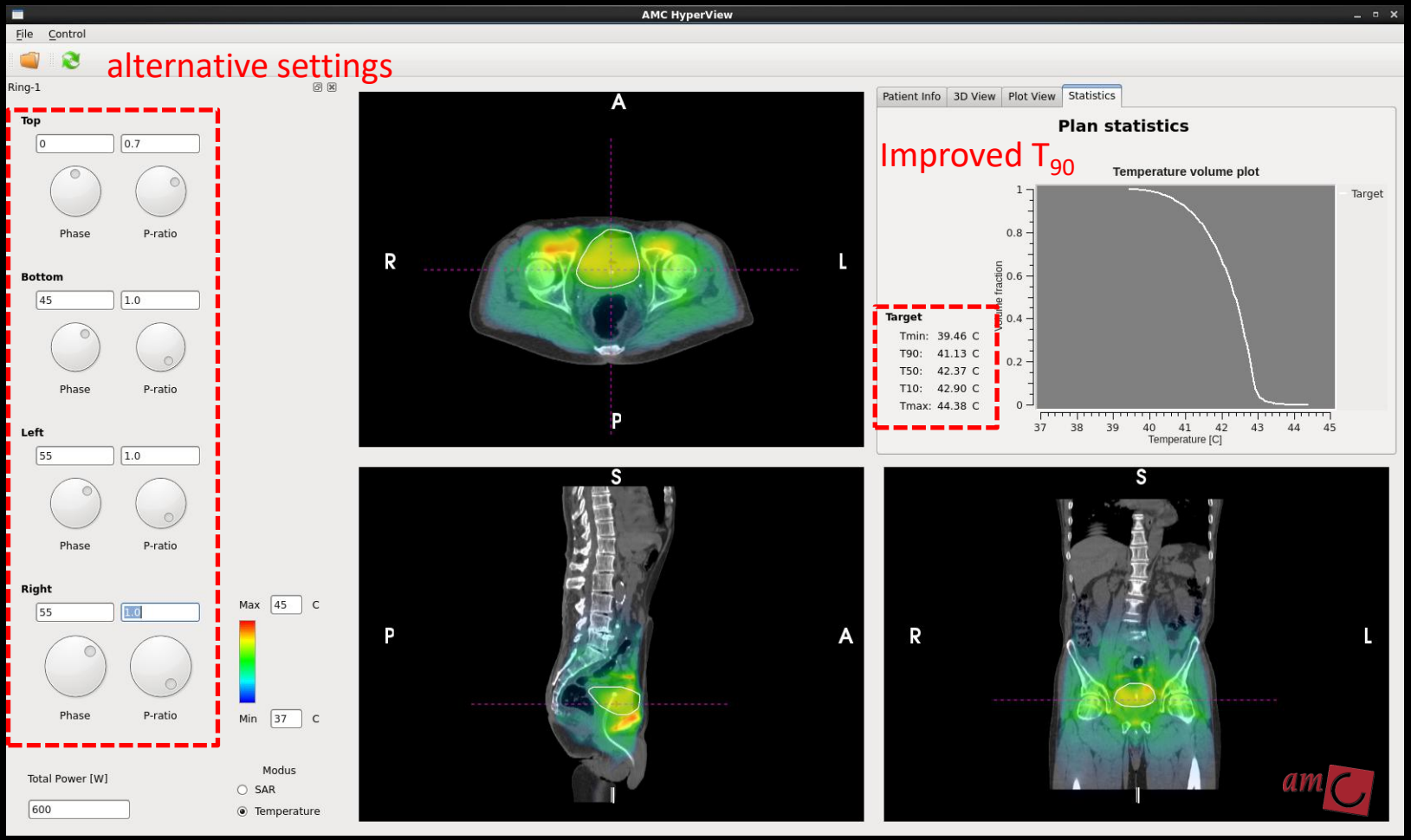


Sagittal

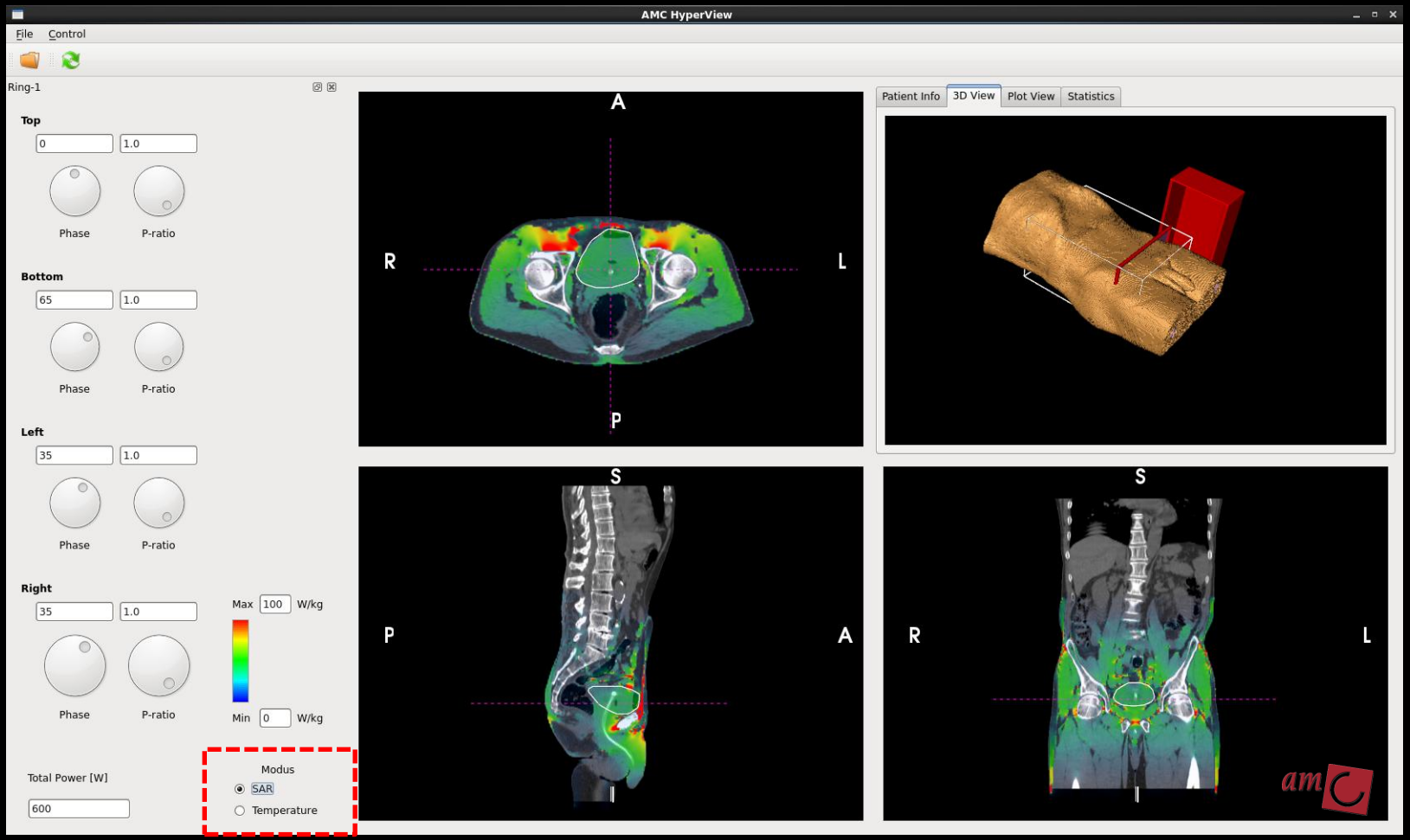


Coronal

Graphical user interface provides visualization and assistance during treatment



Graphical user interface provides visualization and assistance during treatment

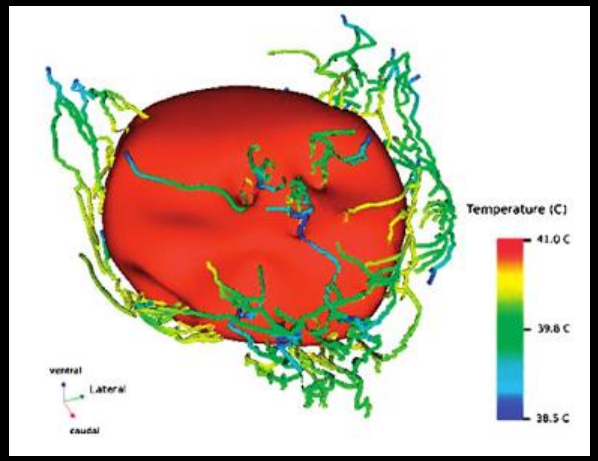


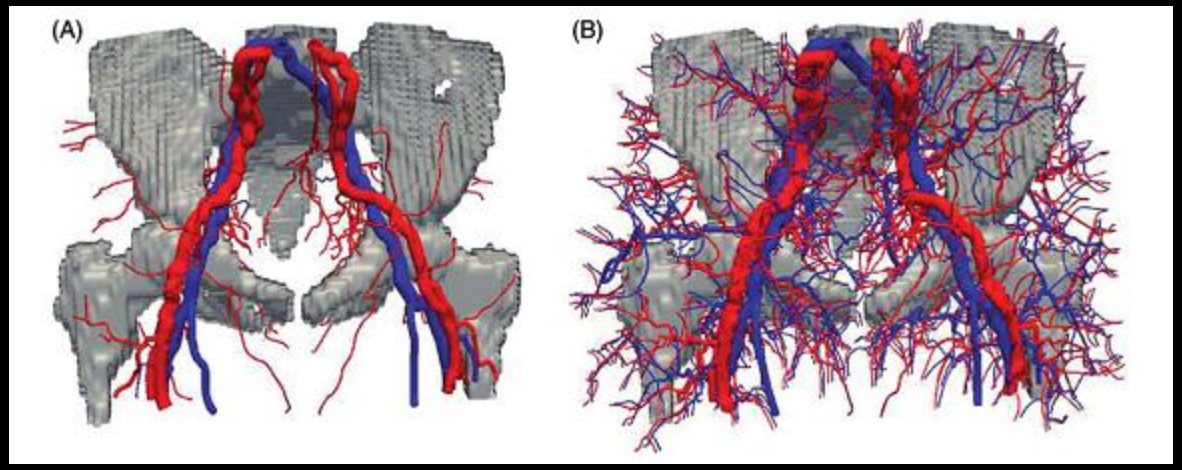
SAR/temperature visualization

MODELING **BIOHEAT TRANSFER**

Different methods available

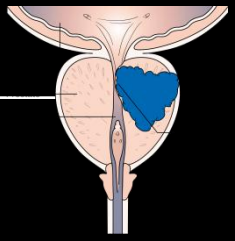
1. Continuum ⟶ Pennes bio heat equation
2. **Discrete vessels** ⟶ e.g. DIVA (Discrete vasculature)



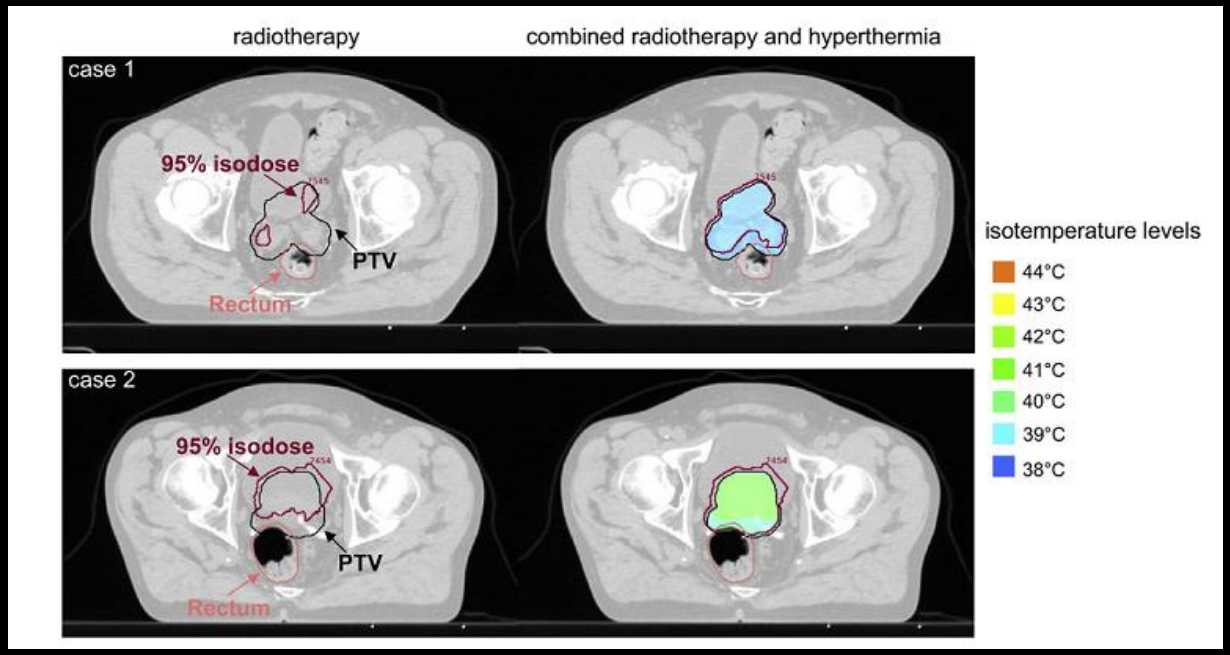


Kok et al, 2013

LA PROSTATE CANCER



15 prostate cancer patients treated with RT without HT.
The effect of adding HT to RT was evaluated using the AMC-4 regional HT device and assuming a 1-h time interval between RT and HT.



Conclusion:
adding HT is equivalent to a radiotherapy dose escalation of about 10 Gy,

76 Gy RT ALONE ⟶ 86 Gy RT+ HT

TREATMENT DATA

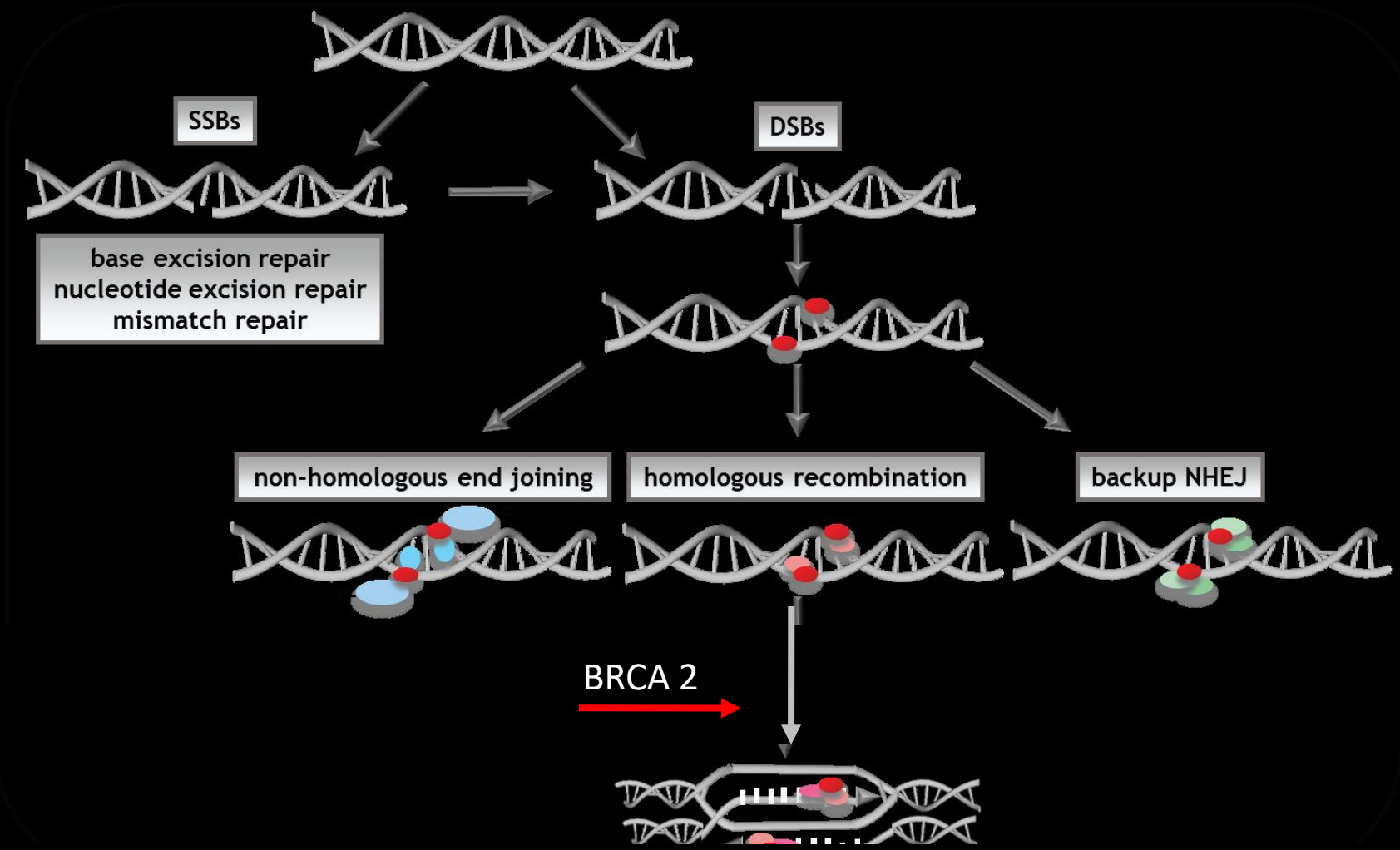
All data are recorded in a standardized way according to the guidelines

READY FOR MULTICENTRIC STUDY


HEALTHMYNE | QIDS
AURA

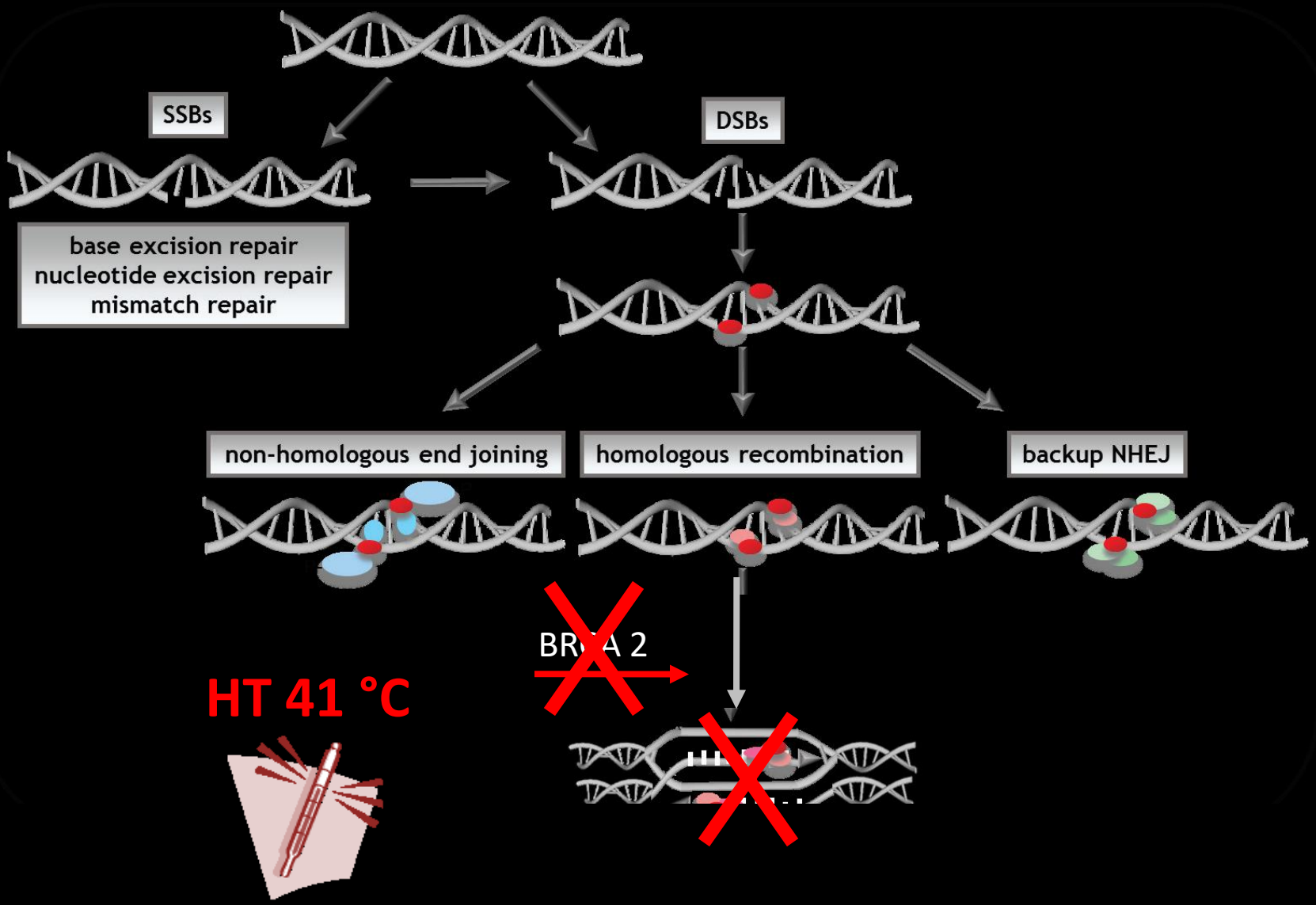
Thank you for your attention

HT INHIBITS DNA REPAIR



A. Oei et al., Radiation Oncology , 2015

HT INHIBITS DNA REPAIR



A. Oei et al., Radiation Oncology , 2015