



ALBA4D

precision hyperthermia

MULTIBEAM RF GUIDED DEEP HYPERTHERMIA

CERVICAL CANCER

VAGINAL CANCER

VULVA CANCER

OVARIAN CANCER

RECTAL CANCER

BLADDER CANCER NMI AND MI

SOFT TISSUE SARCOMA

PROSTATE CANCER

OESOPHAGEAL CANCER

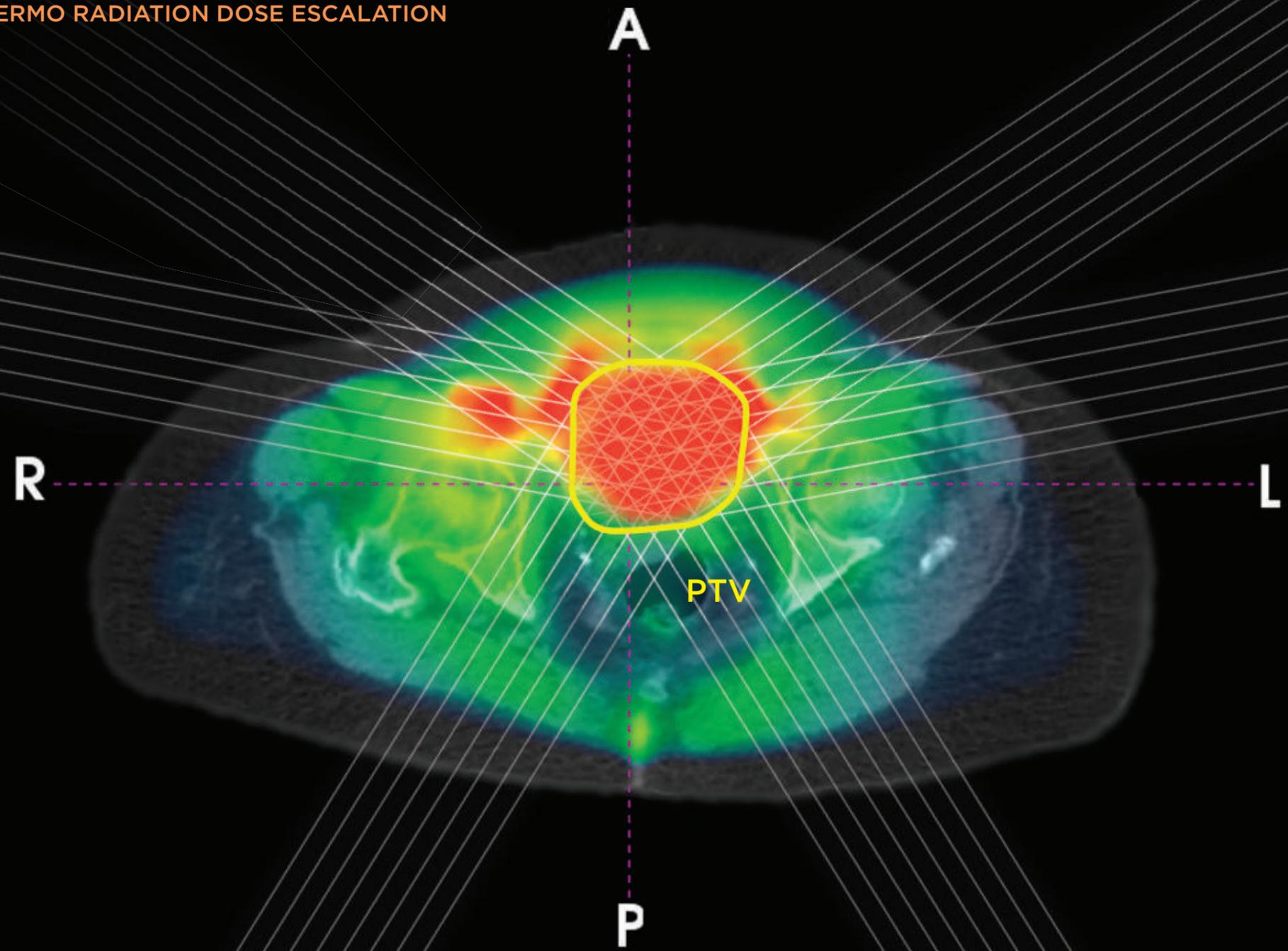
PANCREATIC CANCER

PAEDIATRIC TUMORS

PERITONEAL CARCINOMATOSIS



THERMO RADIATION DOSE ESCALATION



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HYPERTHERMIA RADIO-BIOLOGICAL RATIONALE

Hyperthermia (HT), heating tumors in the range 41-43°C, is a powerful radio and chemosensitizer. The effectiveness of HT as well as its safety, in combination with radiotherapy and chemotherapy, has already been proven in phase III clinical trials [1,2] particularly in patients with very large or very advanced stages of cancer and recurrent tumors. HT enhances the effect of radiotherapy on the tumor, without additional toxicity for healthy tissues, thanks to of three synergistic mechanisms:



1. INHIBITION OF DNA REPAIR:

HT enhances the effectiveness of radiotherapy by inhibiting repair of DNA damage. [3,4,6,7]



2. REOXYGENATION

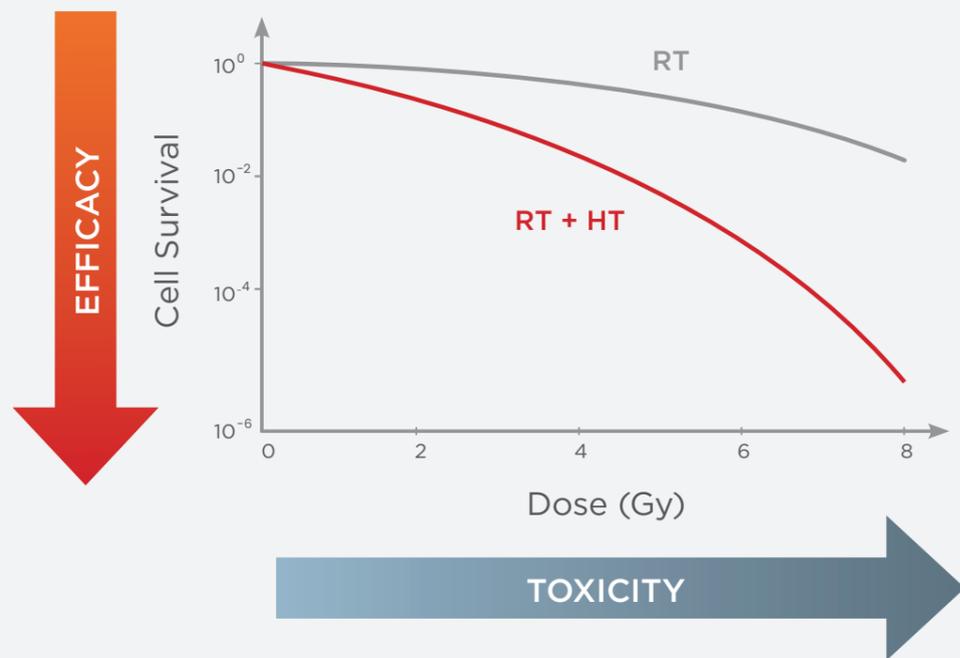
HT increases tissue perfusion resulting in reoxygenation, thereby reducing hypoxia and increasing radiosensitivity. With regards to chemotherapy, hyperthermia targets its action within the heated tumor region without affecting systemic toxicity. It has also been shown that local hyperthermia has the capability of inducing systemic anti-tumor immune responses. [3,4,5]



3. DIRECT CELL KILLING:

HT selectively kills radioresistant hypoxic tumor cells. [3]

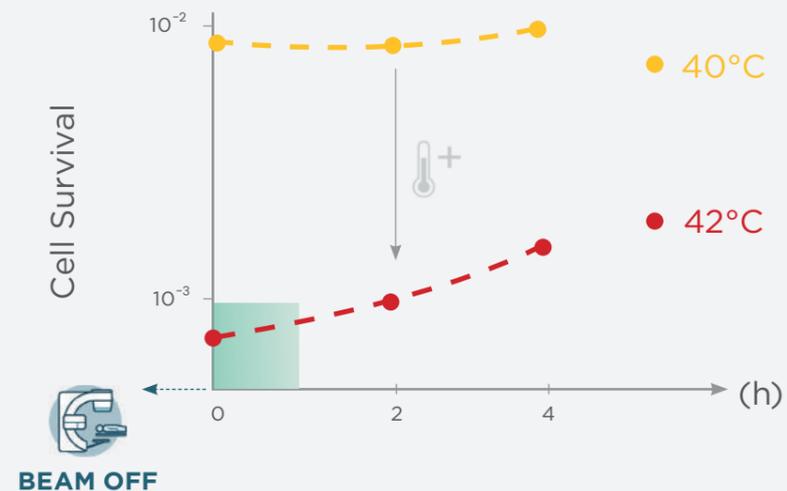
HYPERTHERMIA AS A CLINICAL DOSE-FRACTIONATION OPTIMIZER



LQ - MODEL TEMPERATURE DEPENDENT α & β

Clinical data show a significant hyperthermia-induced reduction of the α/β ratio, a.o. for recurrent breast cancer, head and neck cancer, and cervical cancer. [4,8,9] This can be used to effectively optimize clinical dose-fractionation schedules. The hyperthermic enhancement of the α and β parameters can vary per tumor type and is strongly temperature-dependent.

THERMORADIOTHERAPY DOSE ESCALATION INCREASES WITH: HIGH TEMPERATURE & SHORT TIME INTERVAL



TIME INTERVAL: from RT beam off to HT > 41°C

BOOST UP TO 10/20 Gy OR MORE WITH NO ADDITIONAL TOXICITY

HIGHER THERMO-DOSE

Higher temperature for reoxygenation and more direct cell killing for an effective thermodose escalation.

SHORT TIME INTERVAL

Achievable as the units allow for a short preparation time and ultrafast and precise Hyperthermia treatment delivery.

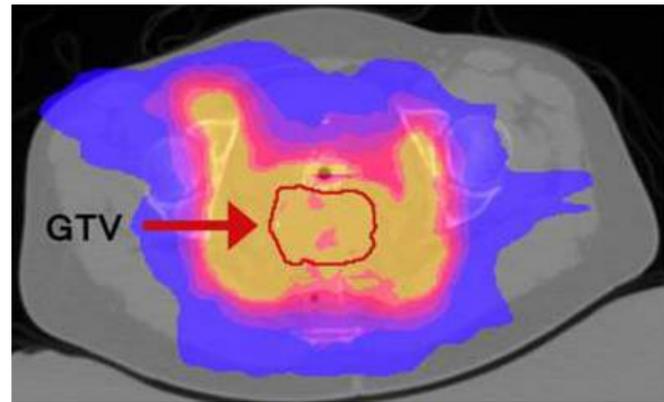
THERMORADIATION ERA

IMRT, IGRT, SBRT, Protons and Carbon Ion are achieving their maximum potential.

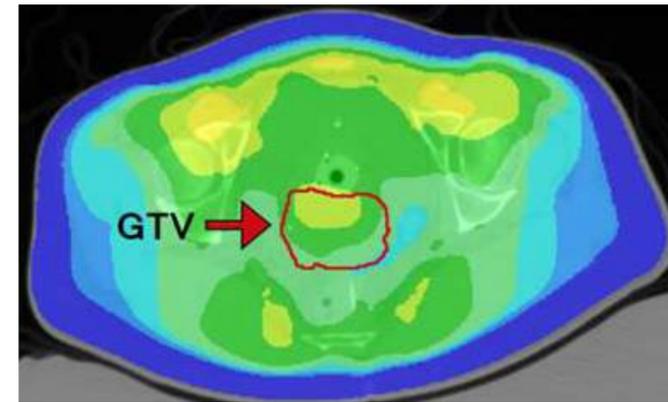
Fast thermoradiation represents a new gateway in the field of oncology to solve the remaining radiation dose limitations due to exposure of organs at risk.

Precision Hyperthermia delivered on GTV/PTV with short RT-HT interval time and high thermal dose biologically modifies the tumor environment obtaining high equivalent radiation dose unattainable with only radiotherapy, even using precision. [9,10,11]

RADIATION DOSE



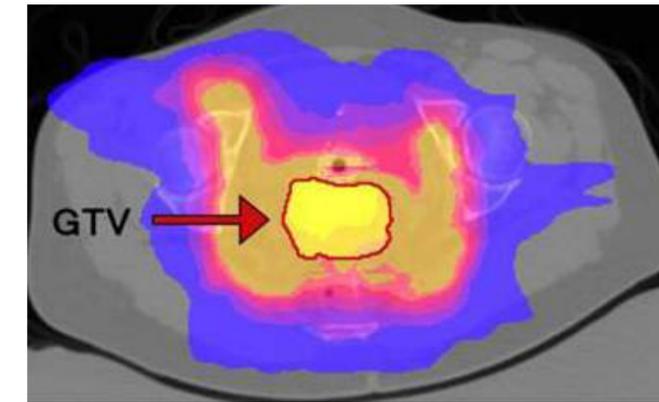
HYPERTHERMIA TEMPERATURE



TEMPERATURE

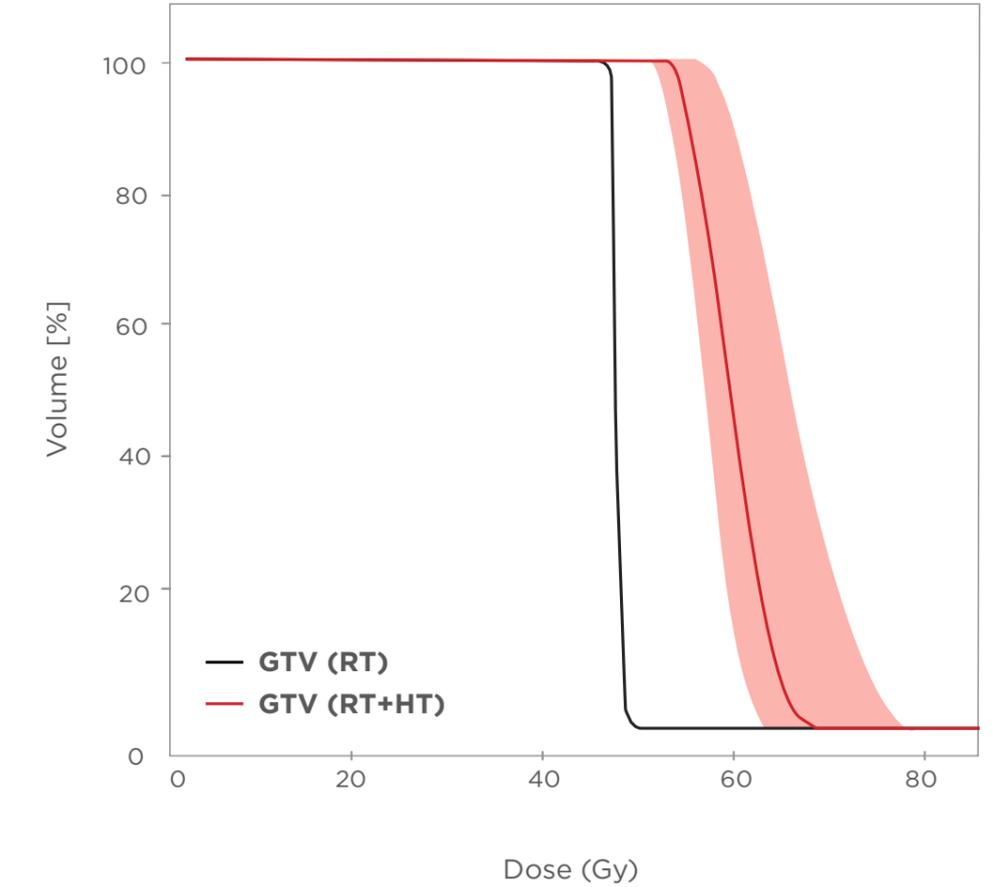
- <37°C • 40°C
- 37°C • 41°C
- 38°C • 42°C
- 39°C

EQUIVALENT RADIATION DOSE



ISODOSE

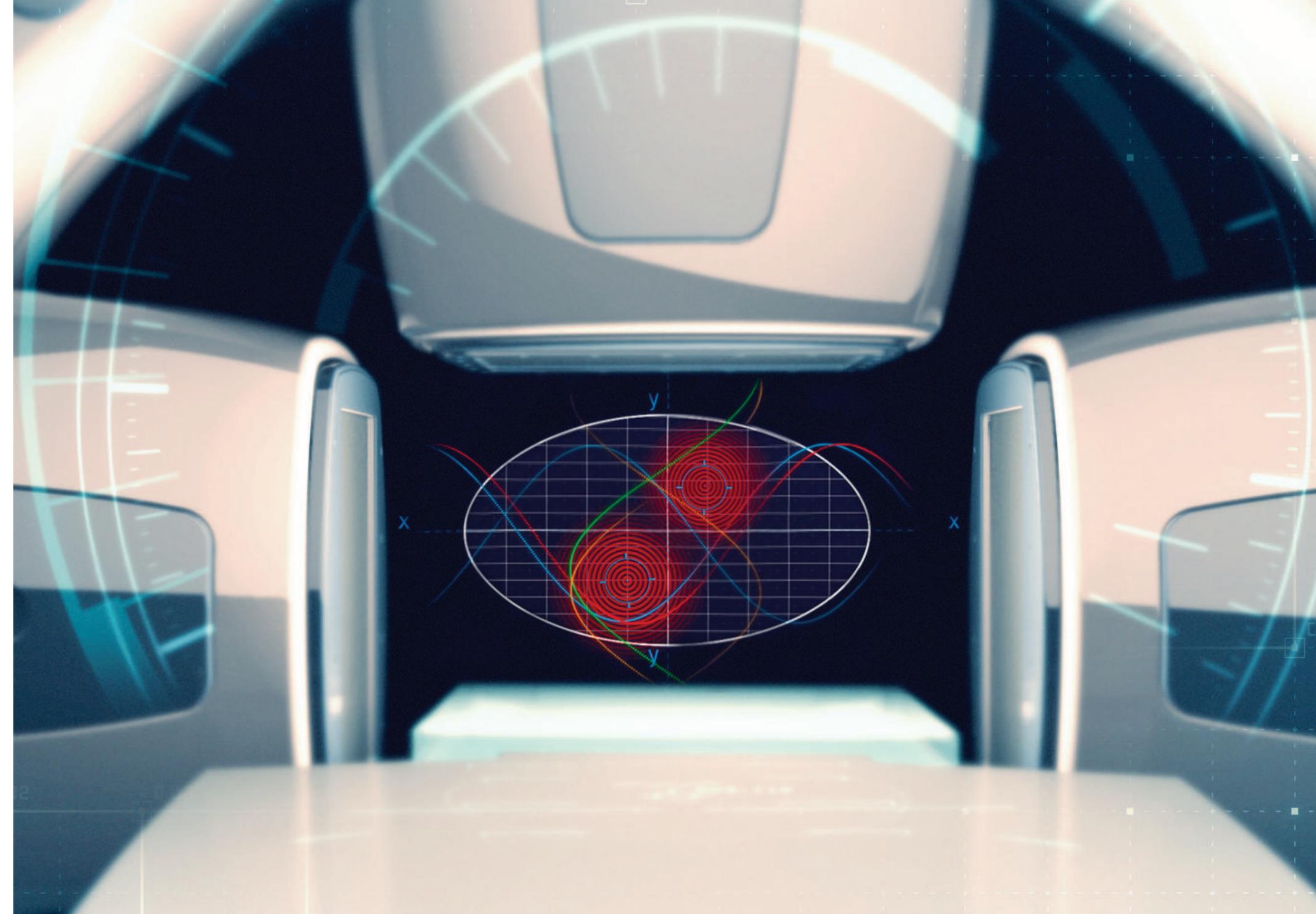
- 23 Gy (50%) • 41.4 Gy (90%) • 49.2 Gy (107%)
- 32.2 Gy (70%) • 43.7 Gy (95%) • 52.9 Gy (115%)
- 36.8 Gy (80%) • 45.1 Gy (98%) • 57.5 Gy (125%)





ULTRAFAST ELECTRONIC PHASE TARGET COLLIMATOR

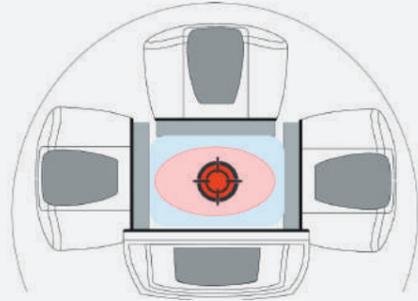
The ALBA 4D system has a RADAR-based technology unit consisting of a multi-beam phased array of 4 waveguide antennas working at 70 MHz radiating 4 beams independently modulated in phase and amplitude to focus the energy onto the target at any depth and location in the pelvis, abdomen and extremities.



ALBA 4D KEY FEATURES FOR AN EFFECTIVE THERMODOSE ESCALATION

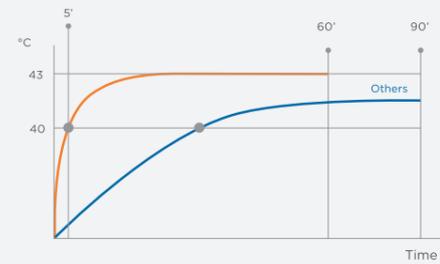
PRECISION

Multibeam iso-phase collimation at target cross section for precise delivery and focal spatial stability.



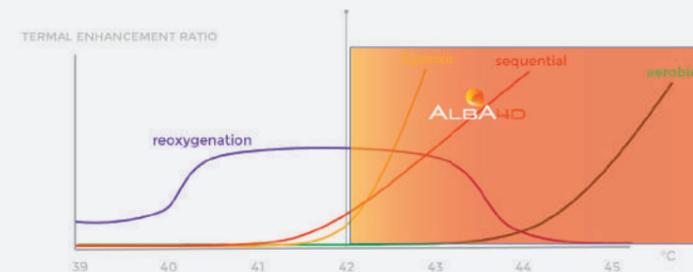
VELOCITY

Ultrafast RF-guided tracking system to generate high density focus at planned target coordinates for a sharp effective temperature $>41^{\circ}\text{C}$ rise and short time interval from RT Beam OFF to HT $> 41^{\circ}\text{C}$.



HIGH TEMPERATURE

41°C - 43°C temperature boost delivered in the superior focal volumes available for an effective THERMODOSE ESCALATION.



ALBA4D





15.000 PHASE/AMPLITUDE MEASUREMENTS PER SECOND



15.000 MEASUREMENTS PER SECOND RF GUIDED HYPERTHERMIA

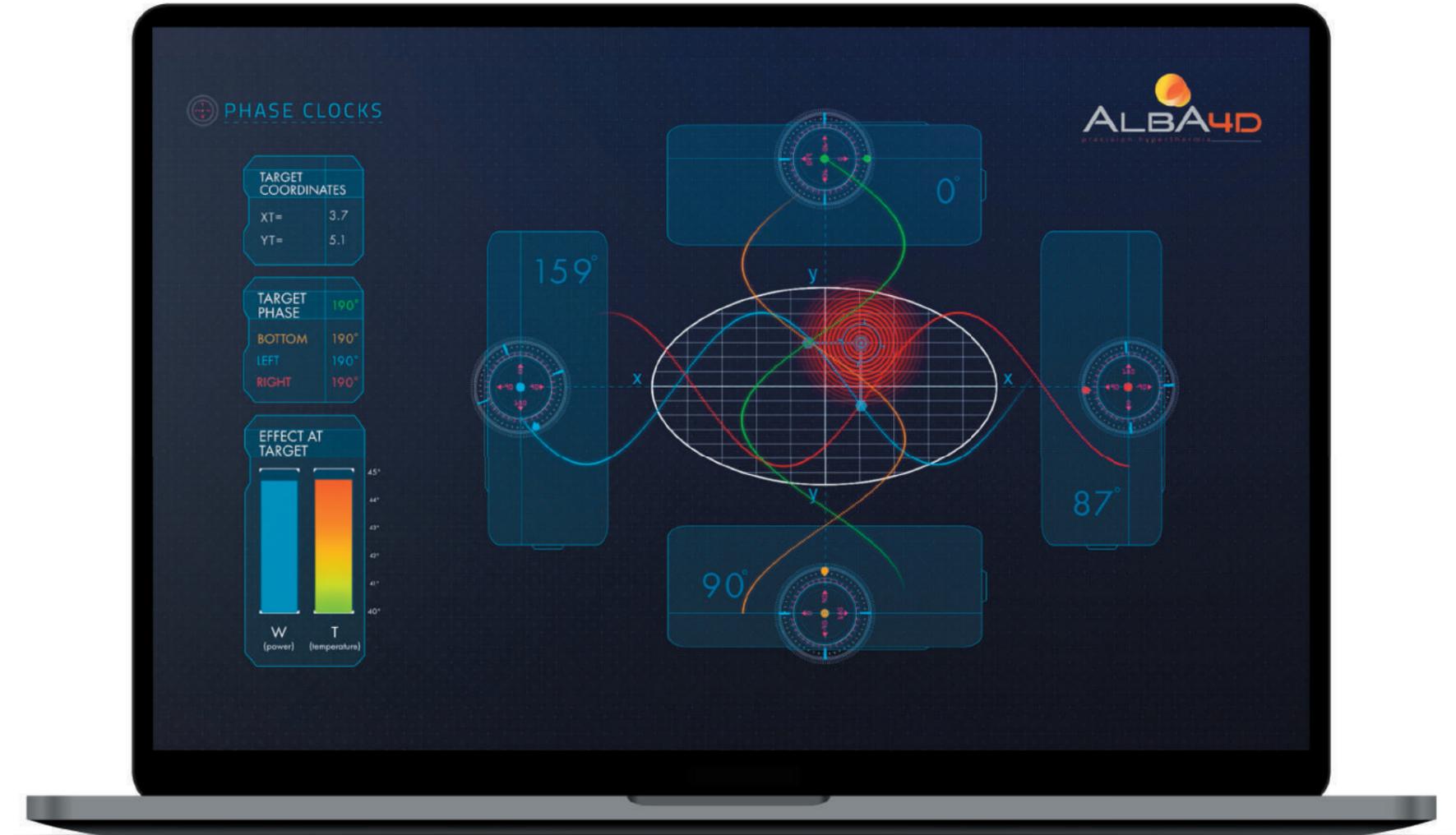
ALBA 4D is equipped with state of the art radar technology based on a multi-channel digital RF generator (DDS) with embedded ultra fast detectors (DET) to measure and track amplitude and phase of the forward and reflected RF power signals.

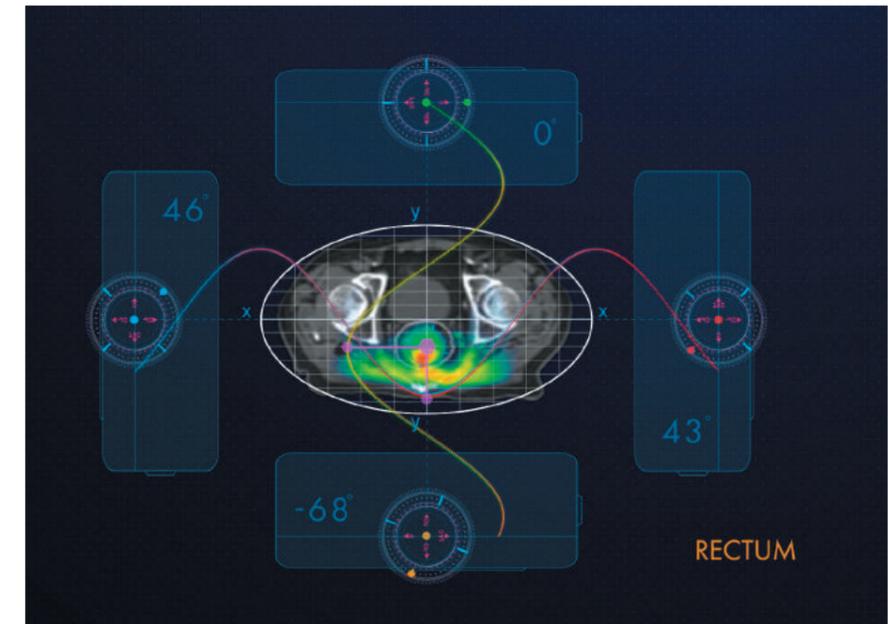
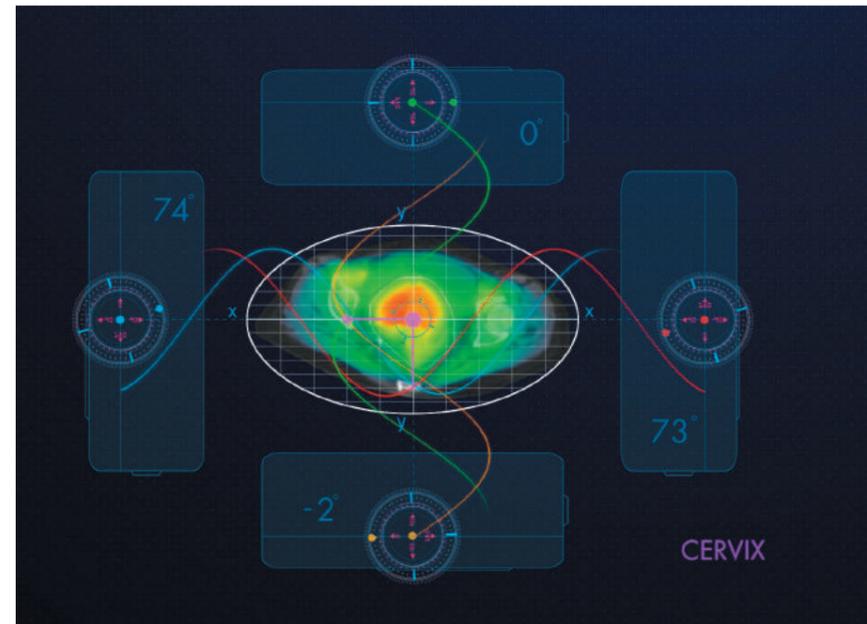
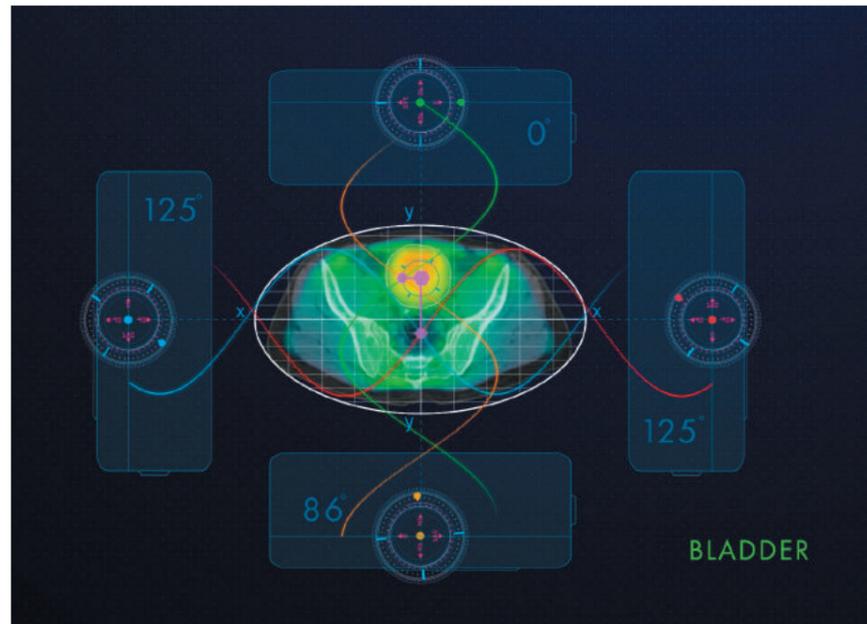
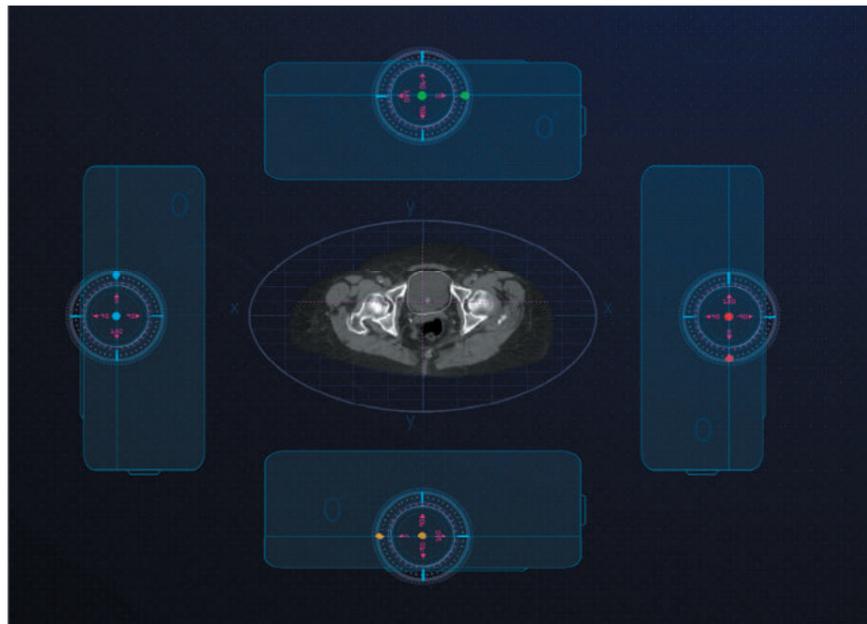
ALBA 4D RF fast feedback control allows a high power density and precise RF guided focus positioned on target coordinates for the entire duration of the treatment.

ALBA 4D unique RF engine does not need any real time Magnetic Resonance imaging to track the focal zone.

MULTI-BEAMFORMING WITH 4 RF E-FIELDS IN ISOPHASE AT GTV/PTV COORDINATES

The ALBA4D RF beams, independently and digitally modulated in amplitude and phase, allow the automatic electronic collimation of the 4 RF beams in iso-phase at target cross section coordinates obtaining a max power deposition on target and sparing all other healthy tissues including subcutaneous fat layers. [12]





- **AUTO FOCUSING AT GTV/PTV**

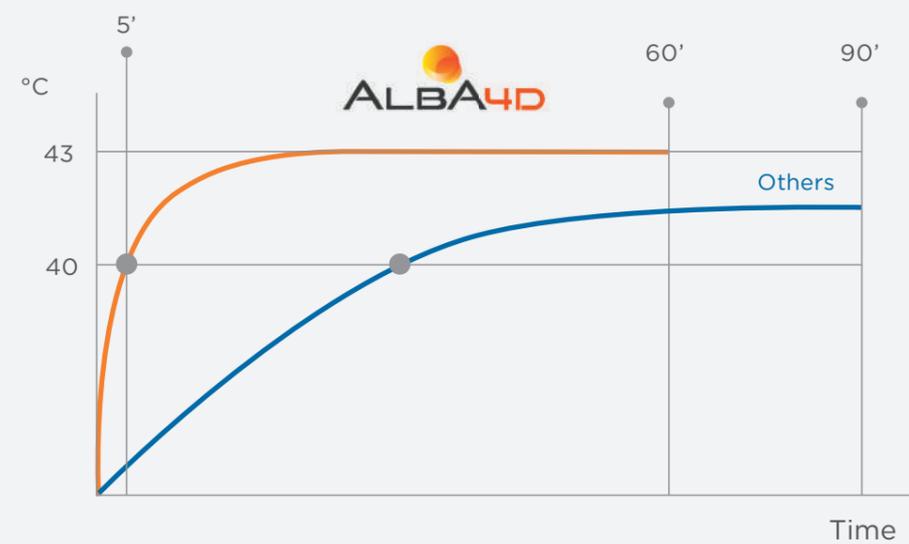
Multibeam collimation at GTV/PTV coordinates planned via RT TPS CT/MRI patient specific image measurements.

- **FAST TARGET HEATING**

Fast temperature rise up to 41°C in less than 5-10 minutes.

- **HOT SPOT SUPPRESSION**

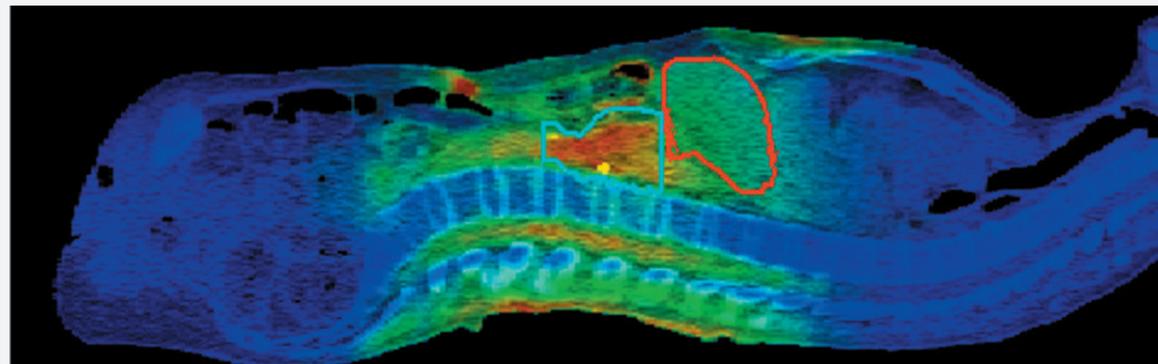
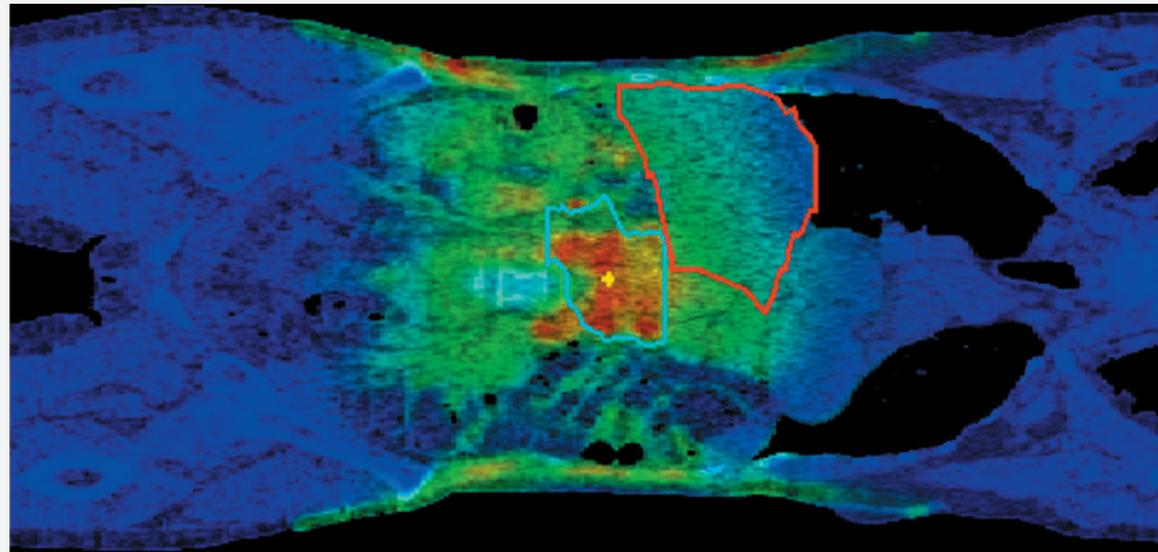
Therapeutic temperatures achieved within the target seated at any depth while avoiding overheating of the subcutaneous fat layer.



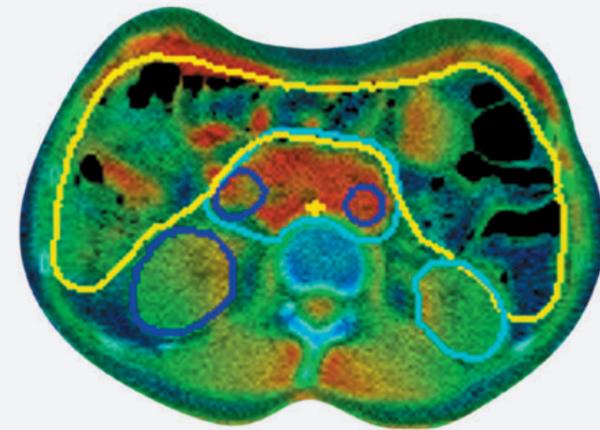
FAST HIGH THERMAL DOSE SAFELY DELIVERED AT THE TARGET

EFFECTIVE LOCOREGIONAL DEEP HYPERTHERMIA [12,13,14]

Hyperthermia modulated in amplitude and phase focuses the energy precisely on the target and obtains a high dose escalation for a better clinical outcome both with hypo and hyper RT fractionations.

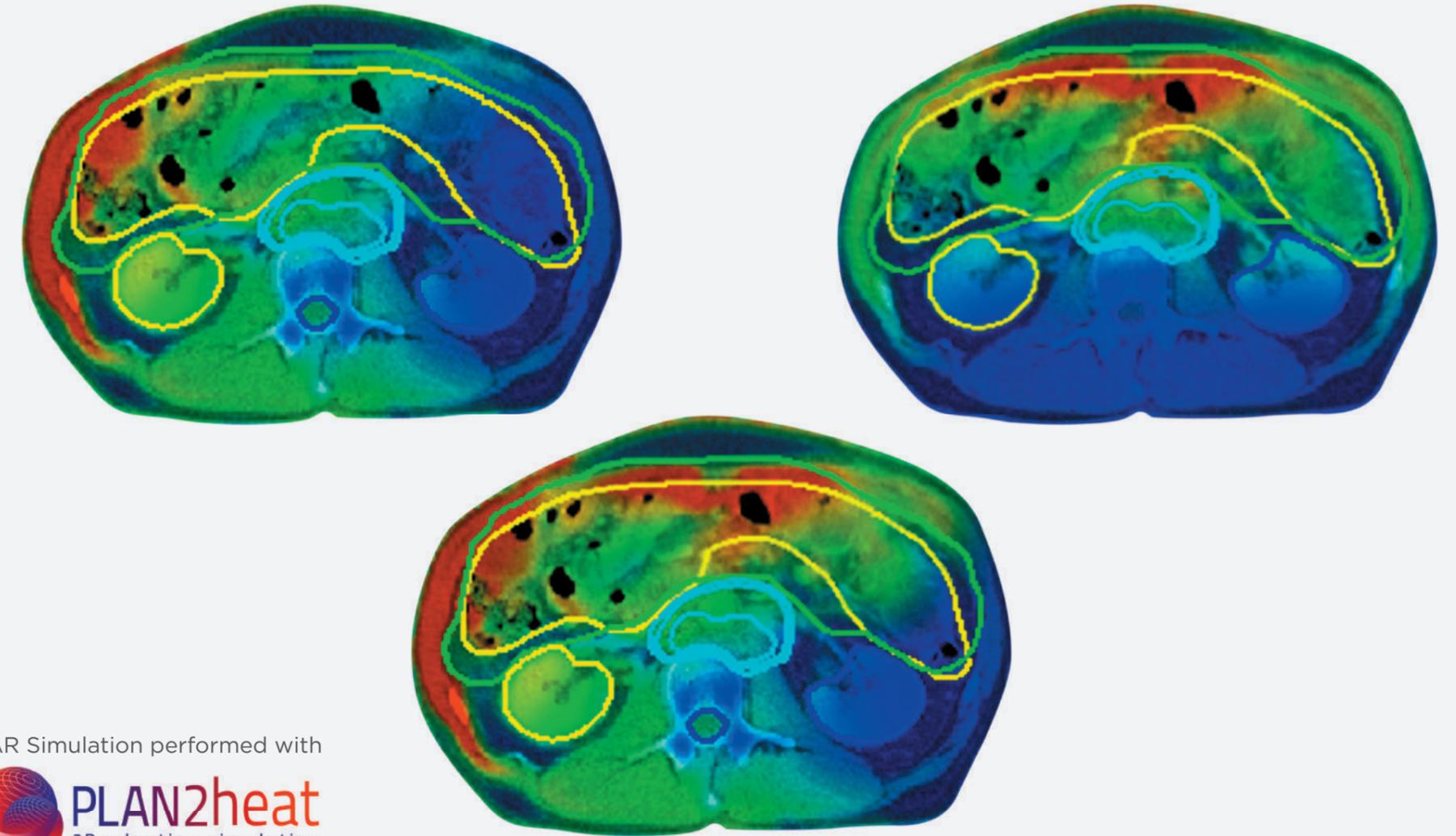


SUPERIOR FOCAL ZONE FOR
LOCOREGIONAL DEEP SEATED TARGET



4D HYPERTHERMIA

Controlled real time focus movement to comply with the target shape and motion through an automatic switching between distinct predefined phase and amplitude settings.



SAR Simulation performed with



System conformable to the patient's specific geometries



PATIENT SPECIFIC ADAPTIVE GANTRY AND ADVANCED POSITIONING SOLUTION

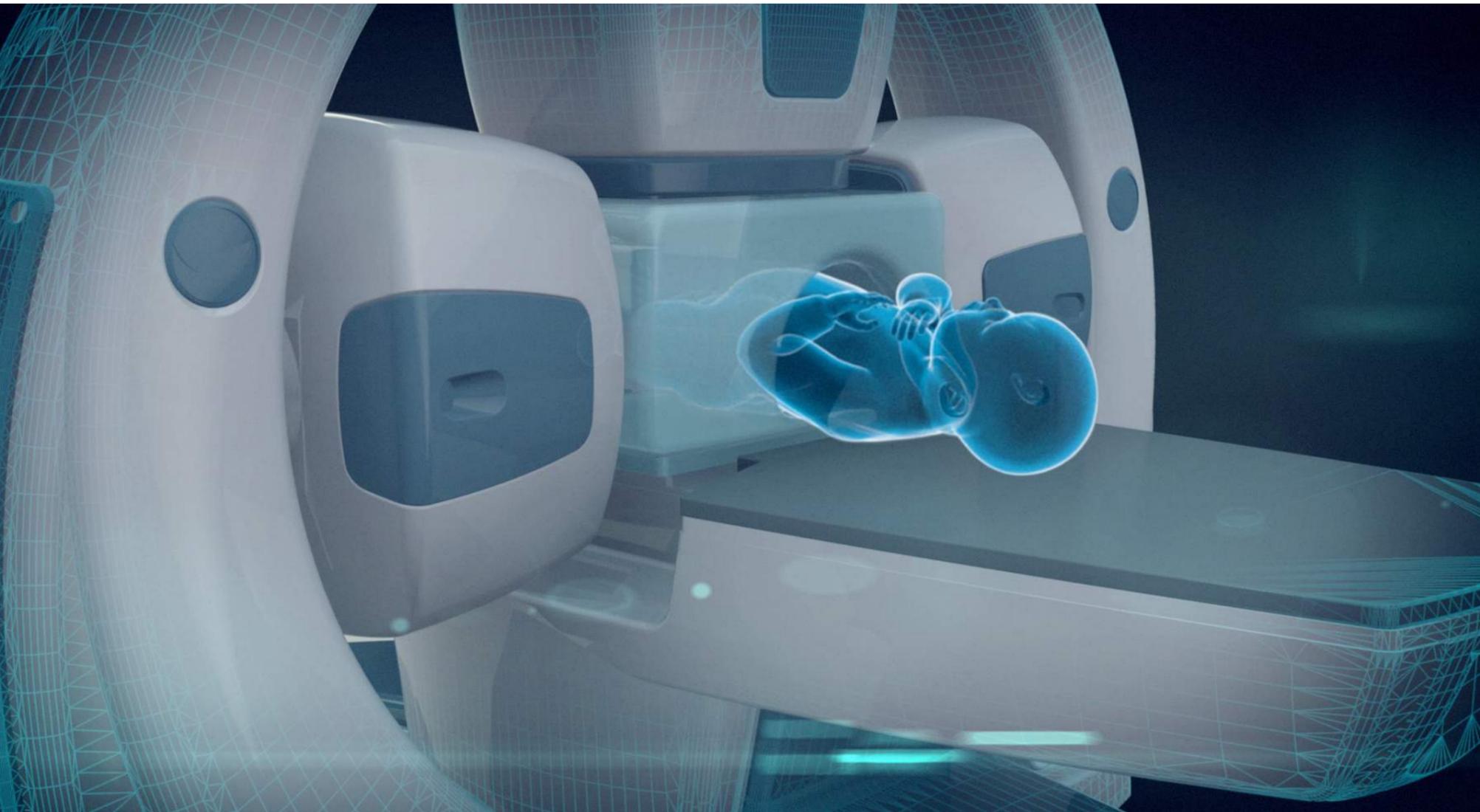
The motorized controlled movement of the gantry and of the waveguide antennas towards the patient allows ALBA 4D to adapt its mechanical configuration to different patient sizes and anatomies, thus enhancing treatment efficiency and patient comfort.

Embedded laser pointing system for optimal cranio-caudal, dorso-ventral and lateral patient positioning. This allows for both reproducibility of the antennas/patient positioning throughout all the treatments, as well as collimation of the antennas/patient configuration with ALBA easyPLAN and PLAN2heat simulation software.



SAME GANTRY-ARRAY FOR DIFFERENT PATIENT GEOMETRY

The robotized gantry as a whole moves vertically to align the ALBA 4D iso-center to the patient's dorso-ventral center. The gantry holds 3 out of the 4 70-MHz waveguide antennas and their motion mechanisms which robotically move them forward and backward, to and from the patient, to adapt to different patient sizes.

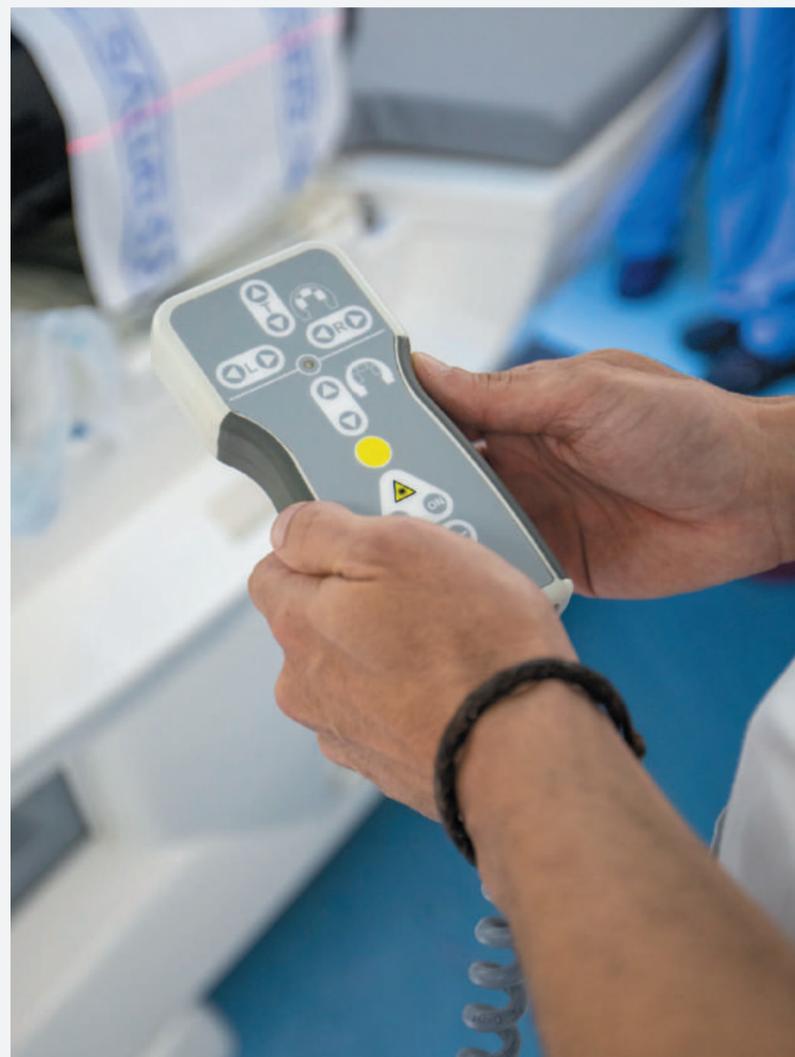




Automatic record and display of all mechanical parameters related to individual patient specific position:

- Gantry position
- Antenna position
- Water bolus volume

Two keyboards positioned on the two sides of the ALBA 4D system allow simple control of the whole gantry movement including antennas.

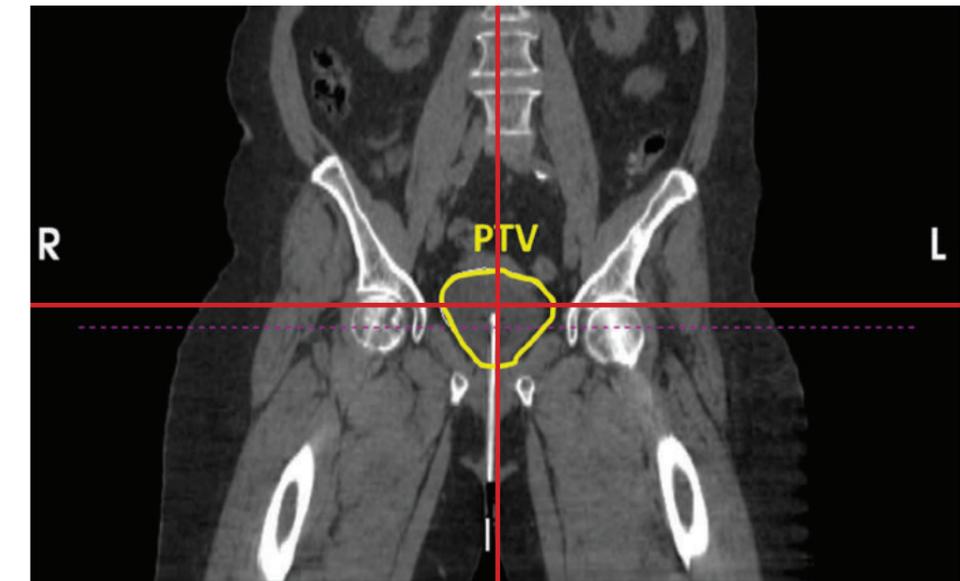
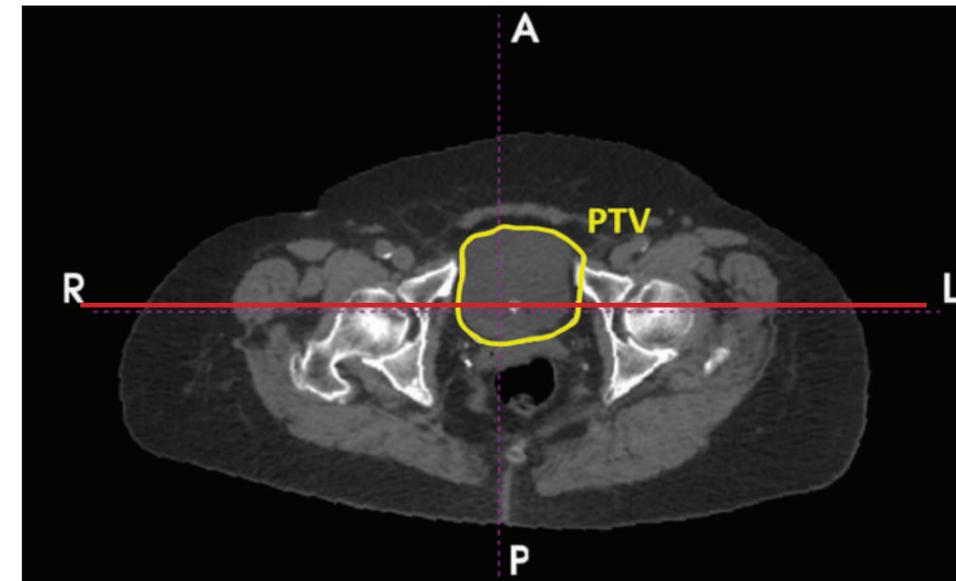
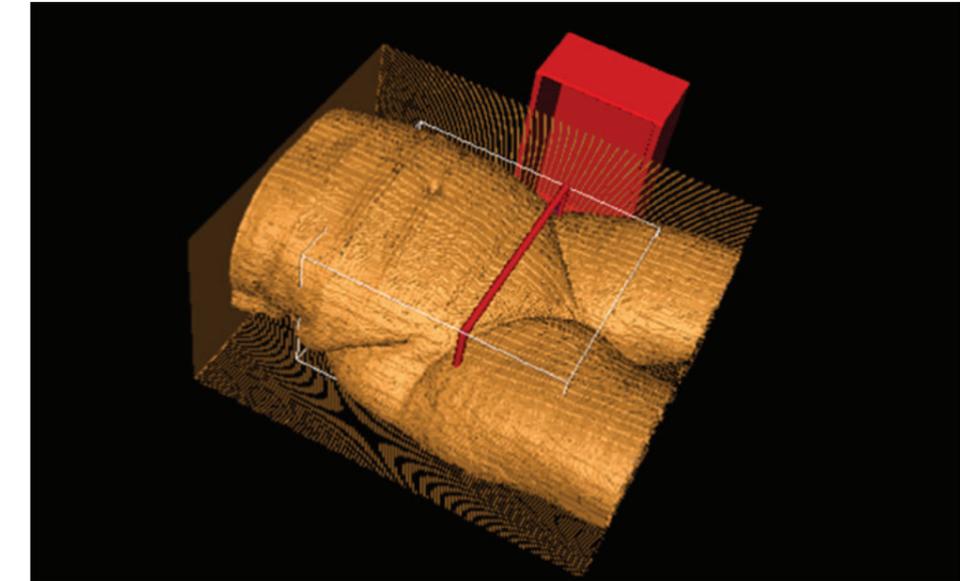
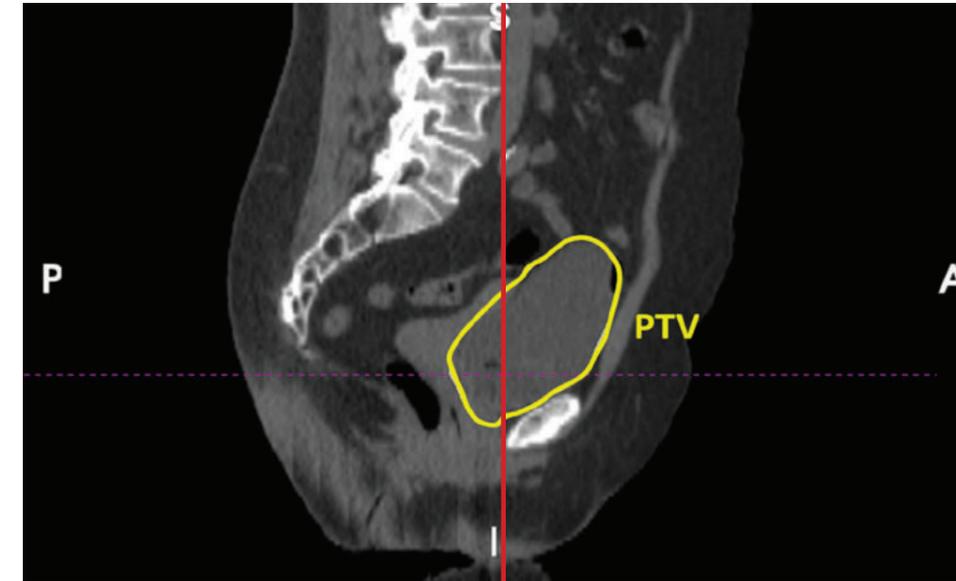


**EMBEDDED LASER FOR
PRECISE SYSTEM AND
PATIENT POSITIONING**

Three alignment lasers are provided for accurate patient positioning: one cross ceiling mounted laser for lateral and cranio-caudal patient positioning, and 2 lasers embedded in the left and right antenna covers for dorso-ventral patient positioning.



ALBA 4D laser positioning system allows the operator to align the center of the patient to the center of the ALBA 4D antenna gantry, passing through the center of the tumor.



Fast and safe streamlined patient and system positioning procedure.

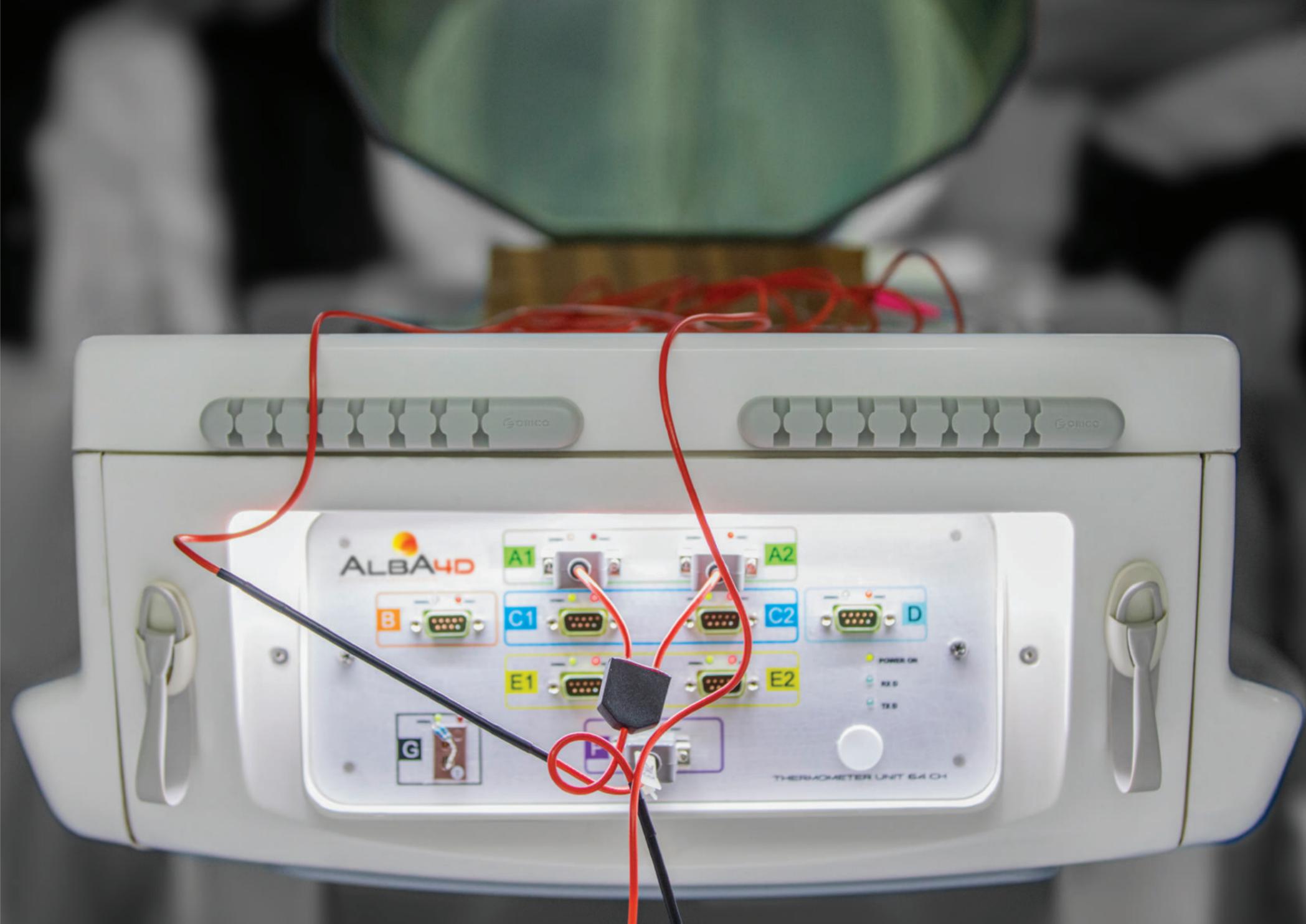




64-CHANNEL DIGITAL THERMOMETER FOR REAL TIME *IN-VIVO* DOSIMETRY

ALBA 4D is equipped with a real-time dosimetry system for temperature measurement consisting of 64 - sensors allowing simultaneous detection of the temperature in 64 spatial points.

The sensors are grouped into multi-tip probes to be placed in the natural body cavities to extensively monitor the temperature throughout the treatment both in the target volume and in healthy tissue.





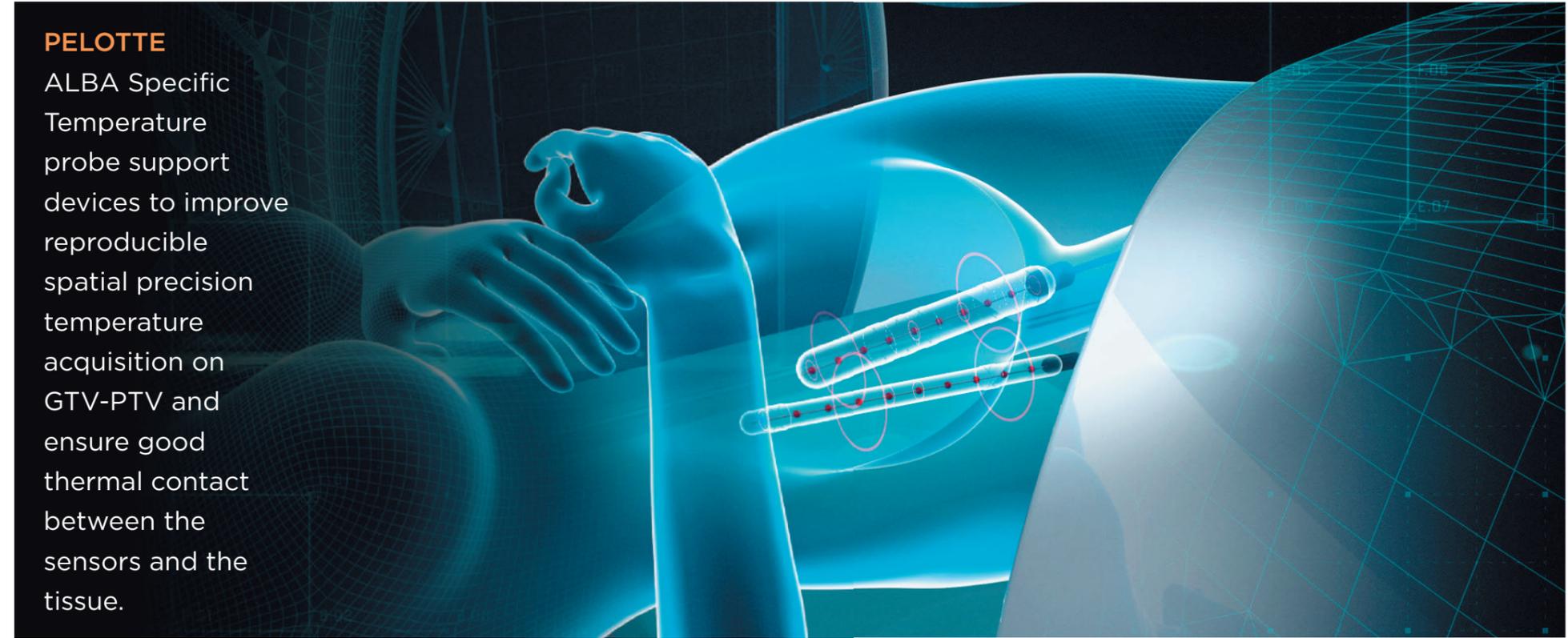
64-CH THERMOMETRIC SYSTEM

64-channel digital thermometer for a fast detection of temperature sensors in 64 spatial points at an excellent accuracy of $\pm 0.2^\circ$.

- Extensive *in-vivo* dosimetry and display of the measured temperatures at their real location for an effective and top-quality treatment delivery.
- Automatic/Semi-automatic temperature sensor assignment with respect to the GTV/PTV for a reliable GTV-PTV temperature dosimetry.

PELOTTE

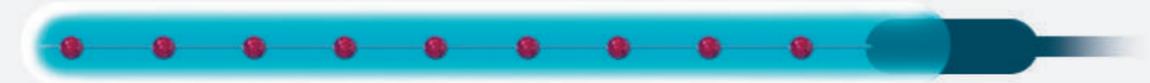
ALBA Specific Temperature probe support devices to improve reproducible spatial precision temperature acquisition on GTV-PTV and ensure good thermal contact between the sensors and the tissue.



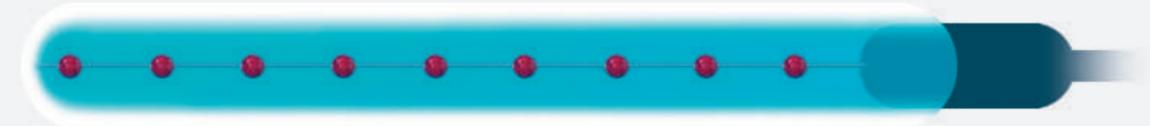
RECTAL PELOTTE



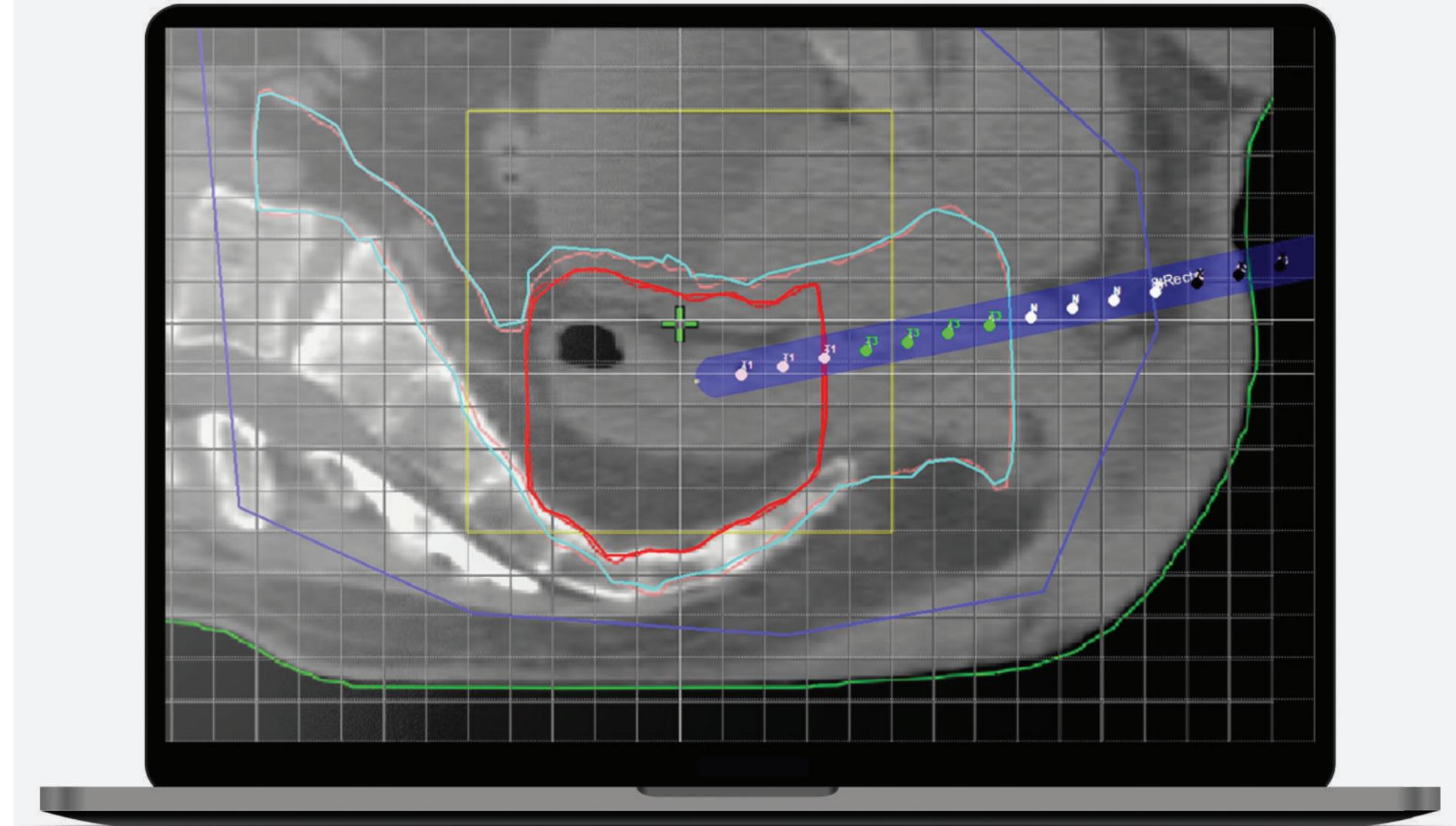
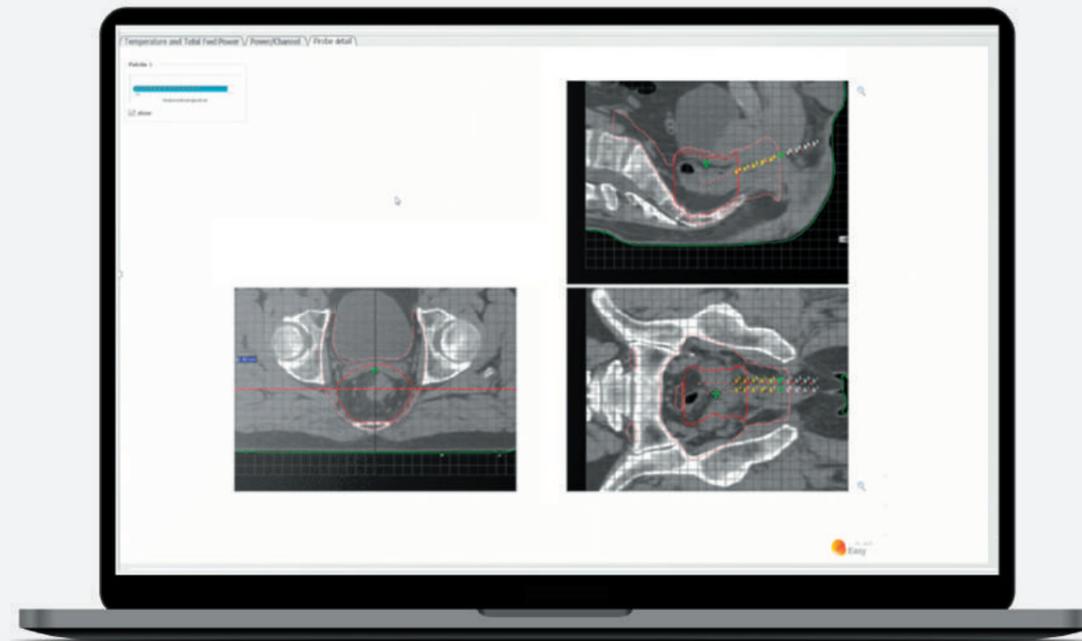
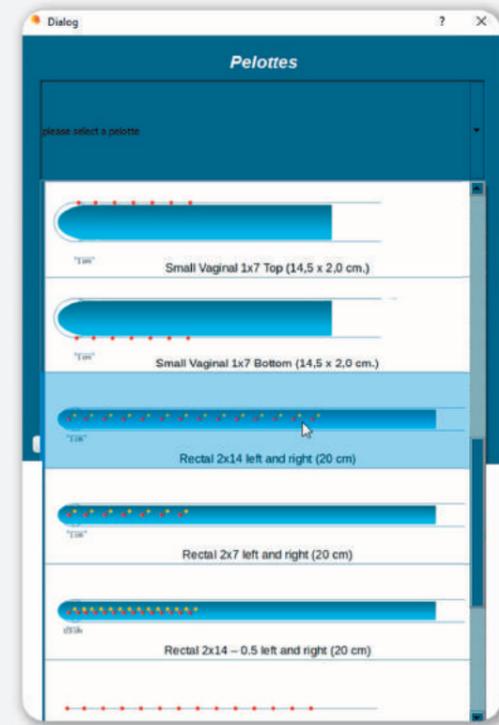
SMALL VAGINAL PELOTTE



LARGE VAGINAL PELOTTE



- **SENSOR SUPPORT DEVICES:** Optimal sensor support device selection according to specific patient anatomy and GTV/PTV geometry.
- **CT/MRI IMAGE GUIDED HT:** advanced solution to pelotte/temperature sensor positioning at defined target coordinates.
- **REAL-TIME TEMPERATURE MAP VISUALIZATION:** temperature data displayed on patient GTV-PTV and normal tissue at known coordinates.





ERGONOMIC SYSTEM DESIGNED FOR PATIENT COMFORT AND SAFETY

ALBA adaptive multibeam phased array deep hyperthermia platform is specifically designed to ensure integrated patient-centered care in the utmost safety whilst ensuring maximum patient comfort.



DEDICATED PATIENT TOOL

- Stable patient couch to guarantee high precision positioning and reproducibility between treatments.
- Fast patient couch extraction with thermometric system integrated into the couch for a safe and easy user experience.
- Especially designed ALBA mattresses for optimal patient comfort and CT/MRI image acquisition that exactly reproduces the patient position during treatment for high quality dosimetry.





PATIENT COMFORT AND ENTERTAINMENT

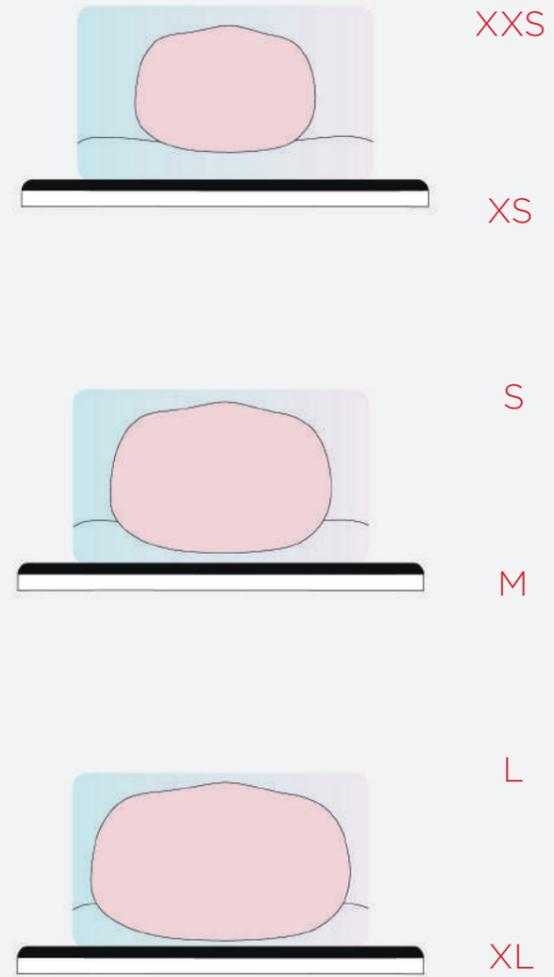
ALBA 4D is the only system equipped with an integrated patient ventilation system consisting of 8 ventilators which can be adjusted in intensity and direction for patient comfort. In addition, the patient can watch a movie or listen to music during the treatment with a tablet or a mobile phone.

- Integrated ventilators with adjustable intensity.
- Easy to use multimedia device support.



DIFFERENT SIZED TOP WATER BOLUSES

- Two independent bottom and top patient adaptive water boluses filled with circulating thermo-regulated deionized water (10-25°C) are interposed between the patient and the RF antenna array.
- No water pressure over the patient thanks to the different patient specific sized boluses (from XXS to XL) and the patient specific geometry adaptive gantry.
- Optimal adaptation of the RF antenna positions for a maximum power deposition in the target region.
- Effective high comfort cooling of the patient's superficial tissue during treatment.

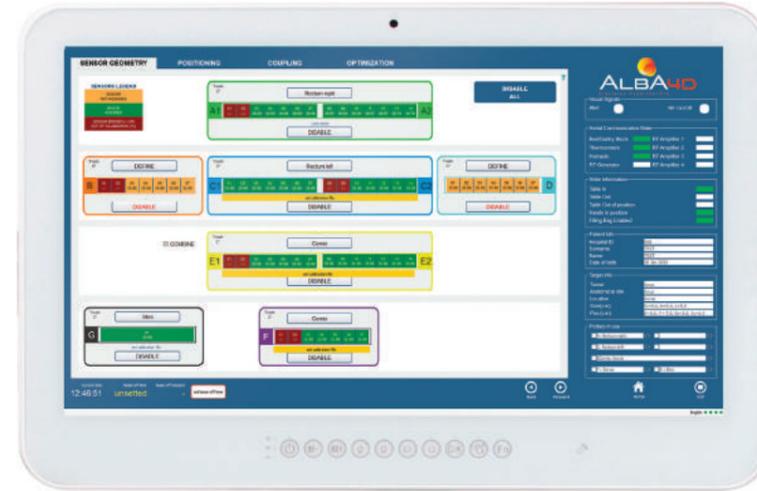


ALBA 4D DEDICATED TREATMENT SOFTWARE CONSISTS OF A STREAMLINED 6 STEP GUIDED USER INTERFACE (GUI) TO EASE TREATMENT WORKFLOW AND ENHANCE TREATMENT QUALITY

User-friendly software interface to expedite the radiation therapist's workflow in advanced oncology departments.



1. Patient Data Loading



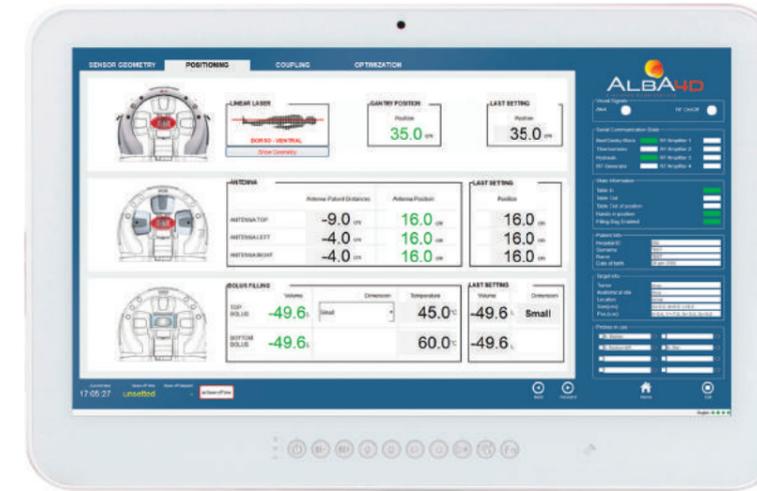
3. Temperature Tips Assignment



5. Coupling and Optimization



2. Preliminary System Checks



4. System and Patient Positioning Checks



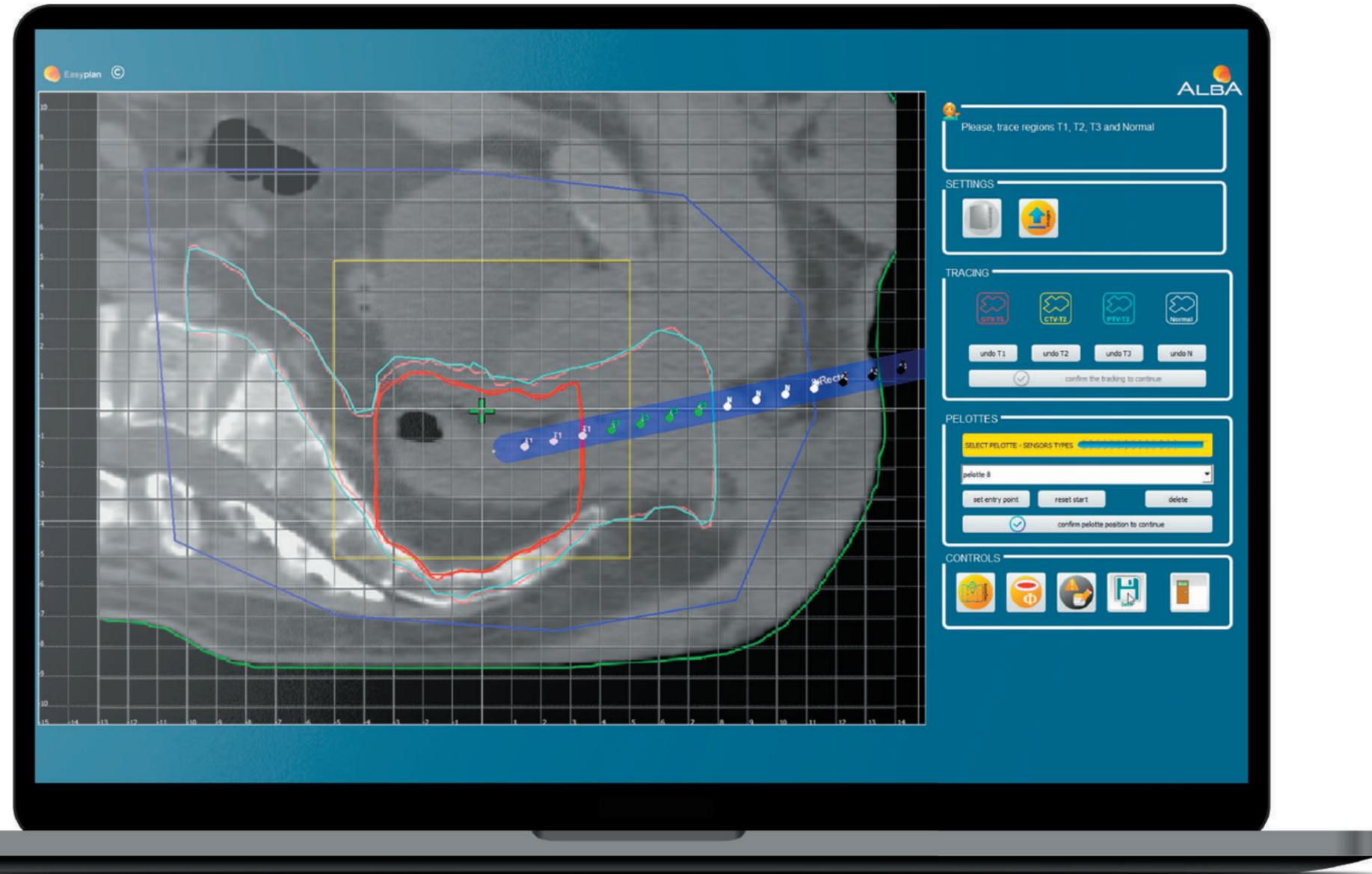
6. Treatment Delivery and Control Checks



ALBA SOFTWARE TO FACILITATE HT TREATMENT

Dedicated software to ease treatment workflow, assist the user in planning treatment and correct settings and enhance treatment quality.





Software developed to facilitate the workflow and the transfer of patient-specific data necessary for the treatment settings with ALBA 4D from the radiation-oncologist/physicist to the RT technicians.

ALBA easyPLAN:

- Involves an easy-to-use GUI for recording the following data taken from any TPS for radiotherapy: patient's radiological images, patient-specific anthropometric data (such as dimensions and subcutaneous fat thickness, dimensions and coordinates of the tumor target), longitudinal position of the target with respect to the radio opaque markers (necessary to align the target to the iso-center of the array);
- Provides suggestions as to the optimal treatment phase settings for the collimation of the 4 RF beams;
- Provides suggestions as to the positioning of the temperature probes and their classification based on their position with respect to the target.

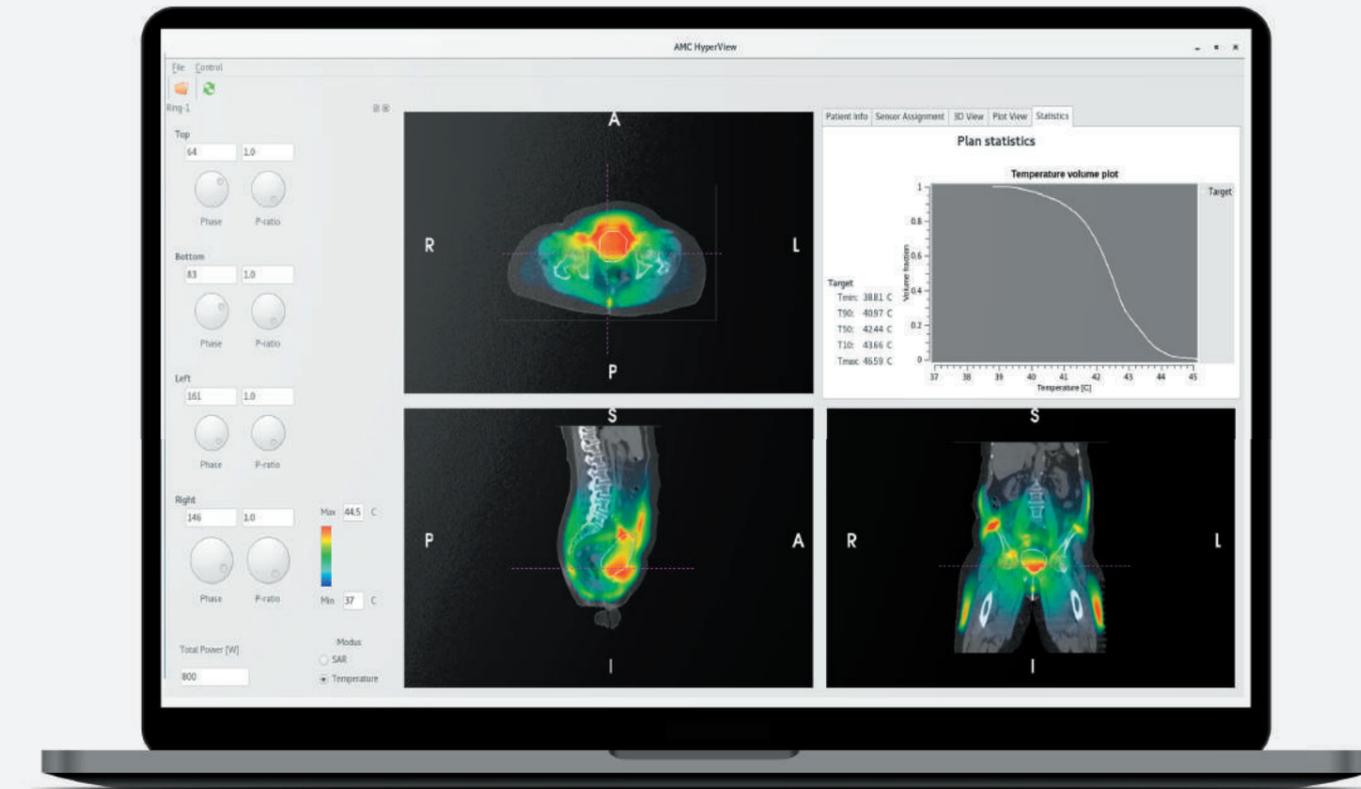
ALBA easyPLAN is not yet CE marked and therefore it is not yet a medical device. The purpose of the software is to speed-up and facilitate the flow of information from the physicist/radiotherapist to the hyperthermia operators.



Dedicated hyperthermia treatment planning software to support treatment strategies consisting of a streamlined user-friendly Guided User Interface (GUI). [15,16,17,18]

1. Patient model generation: import of patient specific DICOM images (CT/MRI); automatic Hounsfield unit-based segmentation and delineation of GTV/PTV, at risk organ contours or import from commercially available RT planning system; delineation and removal of any artifacts;
2. Automatic assignment of dielectric and thermal properties; assignment of thermal boundary conditions; definition of resolution for calculation and cubic grid generation.
3. Patient model-ALBA ON4000D registration: import of ALBA ON4000D array model; automatic antenna-patient gap filling with dielectric properties and thermal conditions of the water bolus.
4. Electromagnetic field distribution calculation. Calculation is performed by solving Maxwell's equations applying the FDTD method.
5. SAR and temperature distribution calculation and visualization; temperature is calculated from by solving the Pennes' bio heat equation. The user-friendly graphical user interface shows SAR and temperature distributions on the 3D image data sets (transverse, sagittal, coronal views). The user interface provides information about the amount of power absorbed in the tumor region and shows a temperature-volume histogram of the tumor target, with a summary of the predicted minimum and maximum temperature and of the indexed temperatures T10, T50, and T90.

*ALBA PLAN2heat - for research purposes only.



HTP can help with the following points:

- Adequate phase settings;
- Heating ability analysis;
- Hot spot suppression;
- Applicator selection;
- Evaluation of target coverage and heating depth.

High quality treatment guaranteed over time



QUALITY ASSURANCE

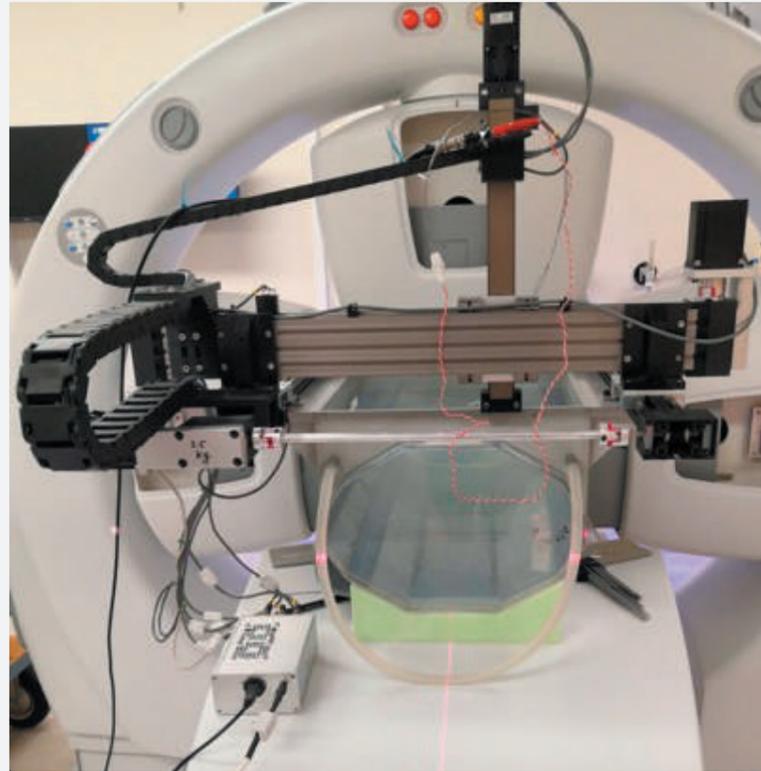
Dedicated tool in full compliance with the guidelines of the European Society of Hyperthermic Oncology (ESHO) guarantees high level, quality hyperthermia treatment over time. [12,19]



3D ANTENNA BEAM ELECTRIC FIELD MEASUREMENT

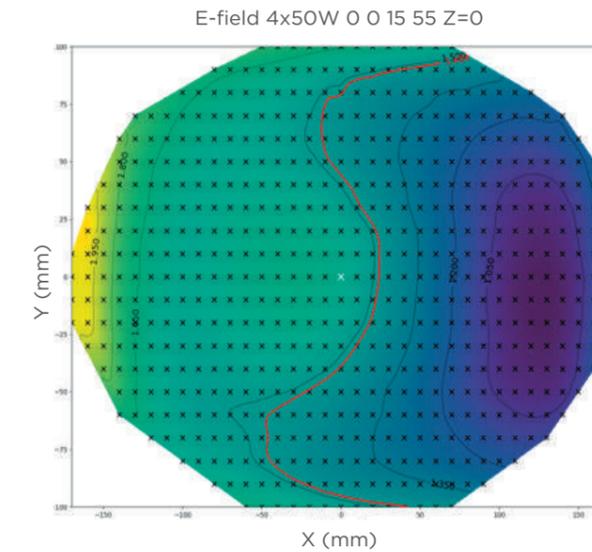
Specific QA tool designed to test and verify hyperthermia antenna array performance in a muscle equivalent phantom for 3D antenna multibeam assessment.

The quality assurance non-ionizing chamber consists of a muscle-equivalent, elliptical shaped liquid phantom, a 3-axis EM compatible motorized robot, a high sensitivity electric field probe, and a digital voltmeter. The dedicated software produces an automatic reconstruction and display of the measured 3D E-field distribution.

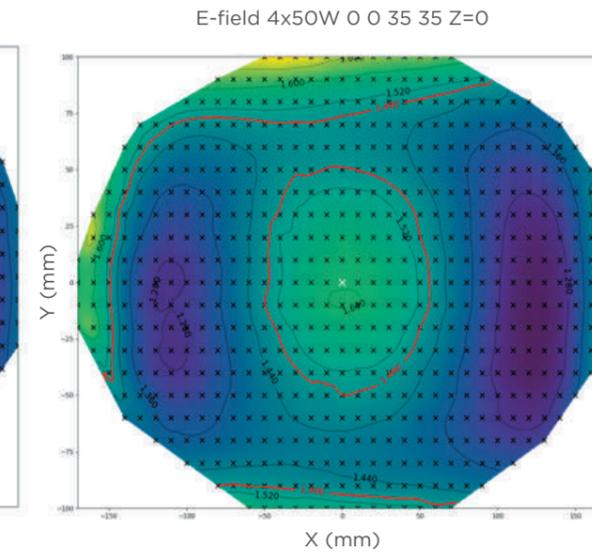


3D E-field measurement phantom is used for Hyperthermia device QA tests of:

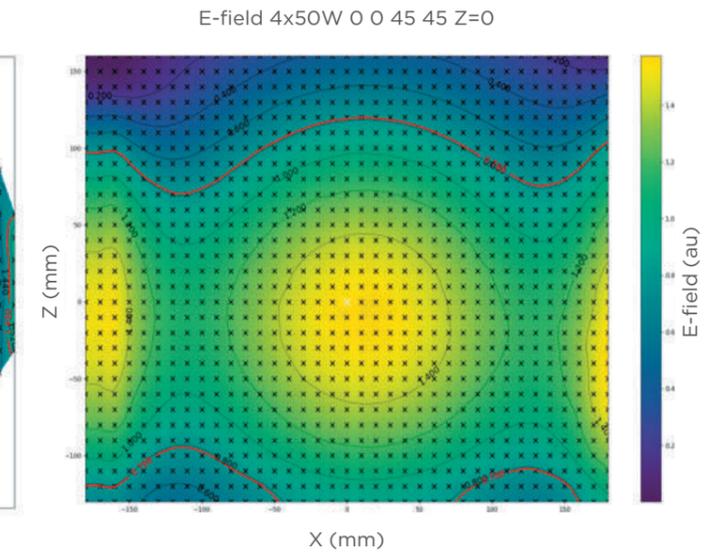
- Geometrical focus zone assessment (90% and 50% SAR levels);
- Focus steering capability;
- Qualitative verification of treatment planning simulation.



Transversal view
FOCUS ON THE LEFT



Transversal view
FOCUS IN THE MIDDLE

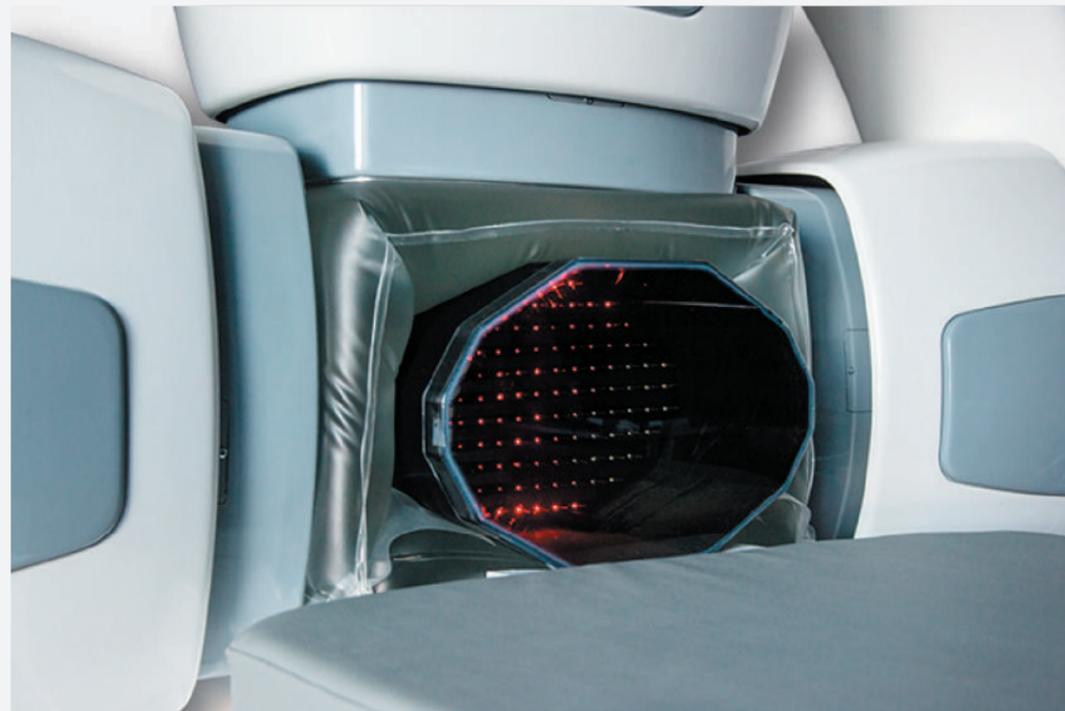


Coronal view
FOCUS IN THE MIDDLE

LED MATRIX PHANTOM FOR RAPID QUALITATIVE TESTS

A light-emitting diode (LED) matrix elliptical phantom, simulating a cross section of the human torso, designed to display the real-time focus steering resulting from the adjustment of the amplitude and phase of the array antennas. The phantom is filled with homogeneous saline solution with electrical properties equivalent to body muscle tissue at 70 MHz and has transparent ends for viewing the LEDs.

LED matrix consists of 137 LED dipole sensors positioned in an elliptically shaped Plexiglas structure with a square grid diode spacing of 2 cm. The light output from the LEDs is directly proportional to the local electric field strength generated by the RF ring array.



THERMOMETRIC CALIBRATION KIT

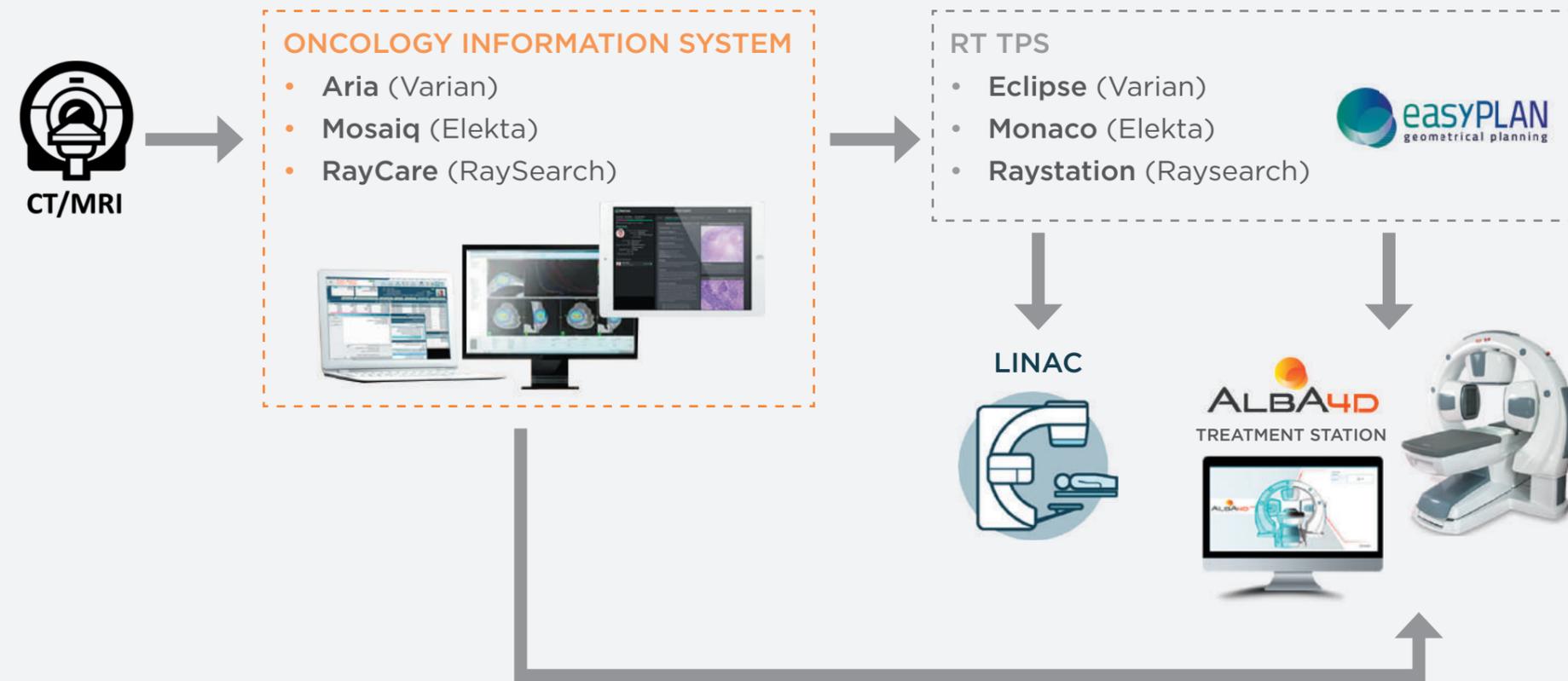
Quality assurance kit necessary for the accurate calibration procedure of the thermometric system (thermometer + temperature sensors) with an accuracy of $\pm 0.2^{\circ}\text{C}$ (in compliance with ESHO guidelines) , including thermostatic bath, calibrator and software tool.



Advanced calibration tool for highly accurate temperature monitoring.

DATA MANAGEMENT SYSTEM AND INTEGRATION INTO RT WORKFLOW

- Patient personal data are imported as DICOM Worklist and treatment reports can be saved in PDF thanks to the data management system.
- Software fully integrated with HIS/OIS/PACS system to improve the integration of hyperthermia into the oncological information system.



SITE PLANNING

A standard ALBA 4D treatment unit consists of an RF shielded treatment room, an operator console, a technical room and a changing room. A site planning guide is provided to help with the layout of the premises which will host ALBA 4D.

Our designers are available to optimize the space to guarantee safety rules for patients and operators and ensure compliance with the hyperthermia unit workflow within the RT department.





RESEARCH AND DEVELOPMENT

At Med-Logix we believe in continuous research and development performed with the precious support of clinical users in Hospitals and Academic Centers fighting every day to cure cancer patients. All of today's and tomorrow's projects aim to bring hyperthermia technology to the standards of modern radiotherapy in order to be used daily in the clinical environment giving its contribution to the world wide oncological community.



30 YEARS OF RESEARCH NOW AVAILABLE FOR ROUTINE CLINICAL USE

The ALBA 4D project is inspired by the AMC 4/8 systems developed by the hyperthermia team of the Academic Medical Center of Amsterdam. Since the early 80's the AMC Cancer Research Center has been one of the most active institutes in the use of hyperthermia with more than 3000 successfully treated patients.

ALBA 4D is the product of the union between the most modern and efficient technologies specifically designed for hyperthermia and vast clinical and technical experience gained over 30 years of research and clinical applications.



ORTHOTOPIC PRECLINICAL DEEP PHASED ARRAY HYPERTHERMIA SYSTEM

Preclinical research using a dedicated high resolution small animal hyperthermia device is essential to support translation of novel cancer therapies from lab to bedside and to optimize treatment schedules for radiotherapy and/or chemotherapy combined with hyperthermia. Translation of pre-clinical results into viable treatment protocols requires treatment techniques for laboratory animals similar to clinical treatments. The dedicated ALBA micro HT system has been recently developed for this purpose. This small animal heating device is composed of eight 1.66 GHz waveguides in a ring, to enable focused tumor heating that is comparable to human hyperthermia treatments. PLAN2Heat Treatment planning will be available to ensure adequate focusing on the target location.

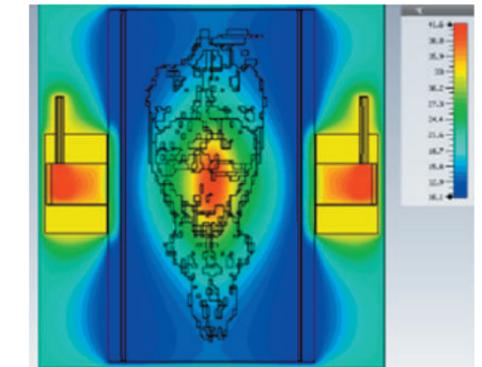
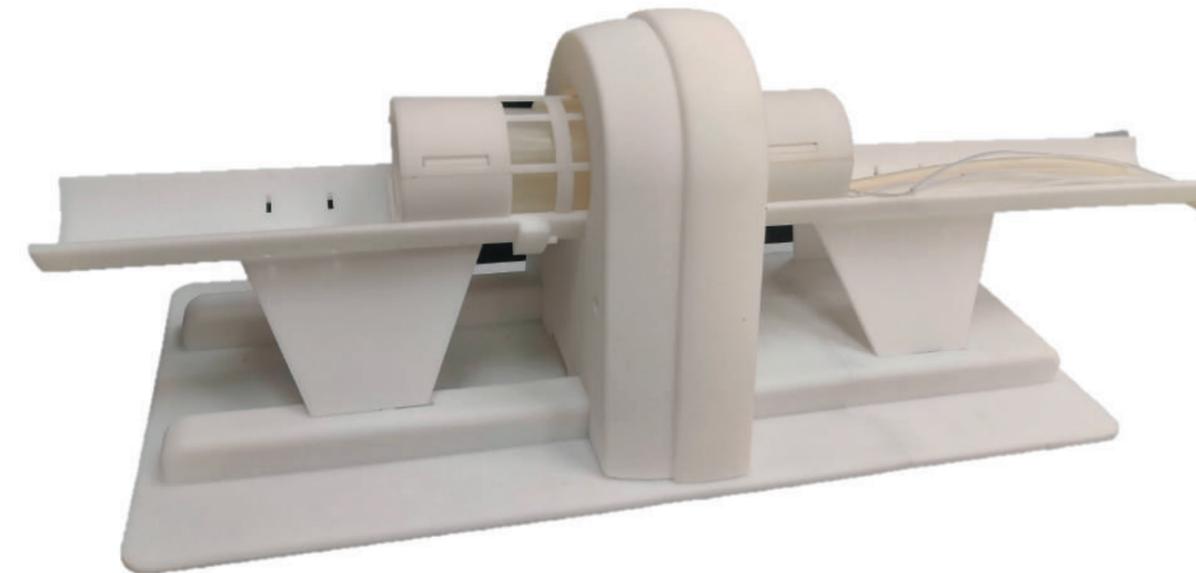


Figure 13-28: Liver temperatures on v= -2 mm plane

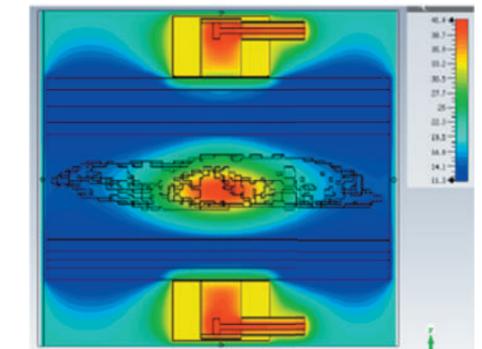


Figure 13-28: Liver temperatures on u= 0 mm plane

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