PHOTONICS
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SIT
Sordina IORT Technologies

LIAC HWL

mobile IOeRT accelerator

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"IntraOperative Radiation Therapy (IORT) in its broadest sense refers to the delivery of irradiation at the time of an operation.
IORT evolved as an attempt to achieve higher effective doses of irradiation while dose-limiting structures are surgically displaced."

"IntraOperative irradiation (IORT) refers to delivery of a single dose of irradiation to a surgically exposed tumor or tumor bed while the normal tissues are protected from the irradiation either by retracting the mobilized tissue or by shielding the anatomically fixed tissues. IORT has traditionally been performed by using an electron beam as the source of irradiation."

[Intraoperative Irradiation. Techniques and Results, Calvo F.A., Gunderson L.L. et al., Current Clinical Oncology, Second Edition, 2011.]

LIAC HWL:

Time zero between surgery and radiation

> 3.2 cm treated inside 90% isodose

Flexible and easy to use in multiple operating rooms

< 600 Kg

IntraOperative electron Radiation Therapy (IOeRT) is the most effective implementation of IORT technique and has been included in the ESTRO, ASTRO, NCCN and DEGRO Guidelines.

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NO NEED OF SHIELDING

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NO LONGER MOVING THE PATIENT:

the system allows to perform the treatment immediately after surgery avoiding to move the patient from the operating table.

LIGHT WEIGHT OF MOBILE UNIT:

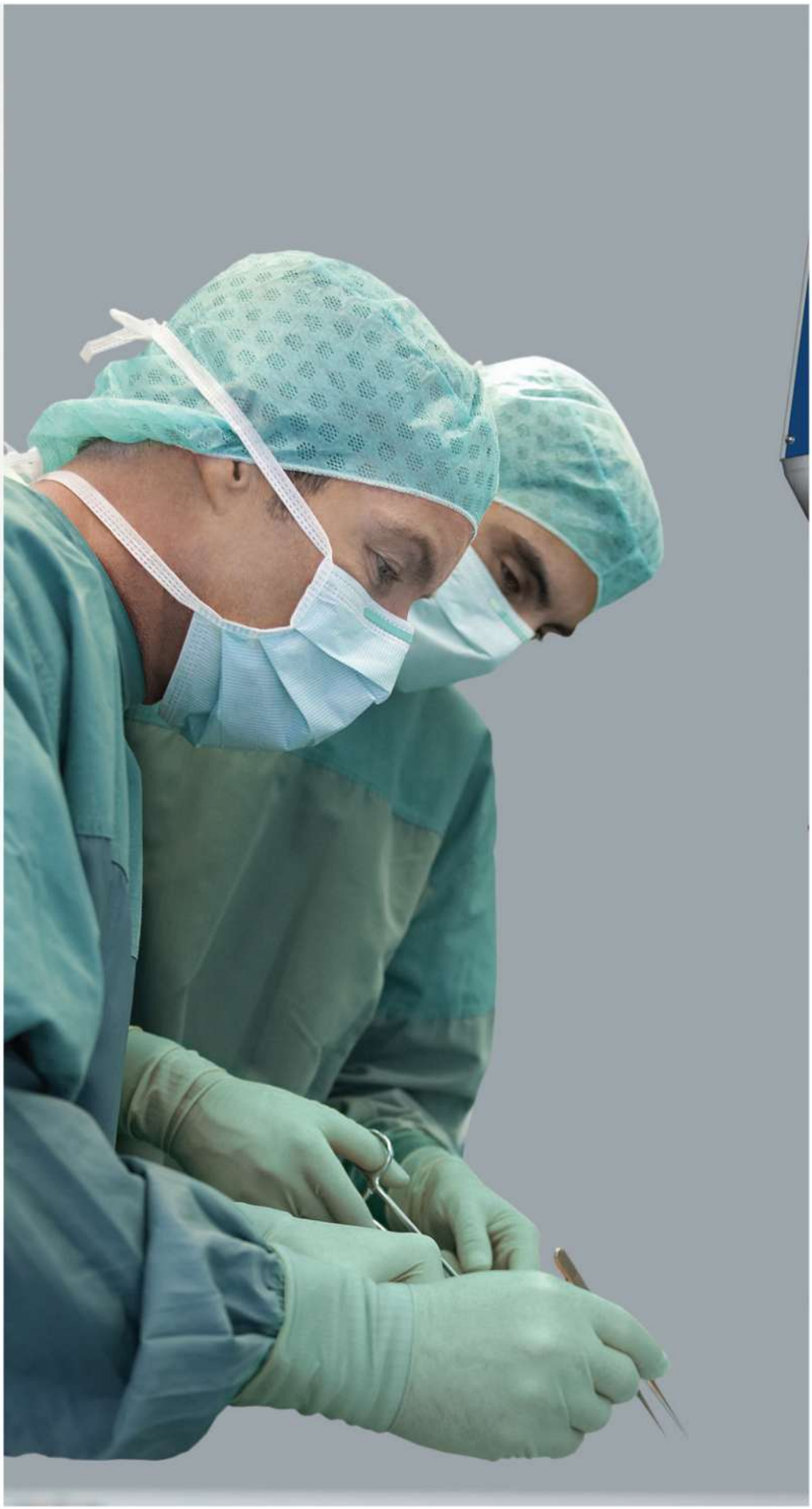
the impact in the operating room is minimal, and no structural changes are necessary. LIAC HWL weight is 570 kg.

EASY TRANSPORTATION:

LIAC HWL can be easily moved from one operating room to another and from one floor to another with any stretcher elevator.

EXTRAORDINARY STABILITY:

The latest technological developments were applied to LIAC HWL to offer the user a superior stability up to a level never seen before.



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HARD-DOCKING PROCEDURE:

- fast and easy procedure that can be performed in less than 5 minutes;
- thanks to LIAC HWL architectural structure any anatomical region can be easily reached;
- repeatable beam collimation on the target is guaranteed by the wide range of applicators.

5 DEGREES OF FREEDOM:

3 independent degrees of freedom of the radiant head (elevation, roll angle and pitch) and 2 degrees of freedom of the Mobile Unit (backwards/forwards, left/right).

FLEXIBLE & EASY TO USE

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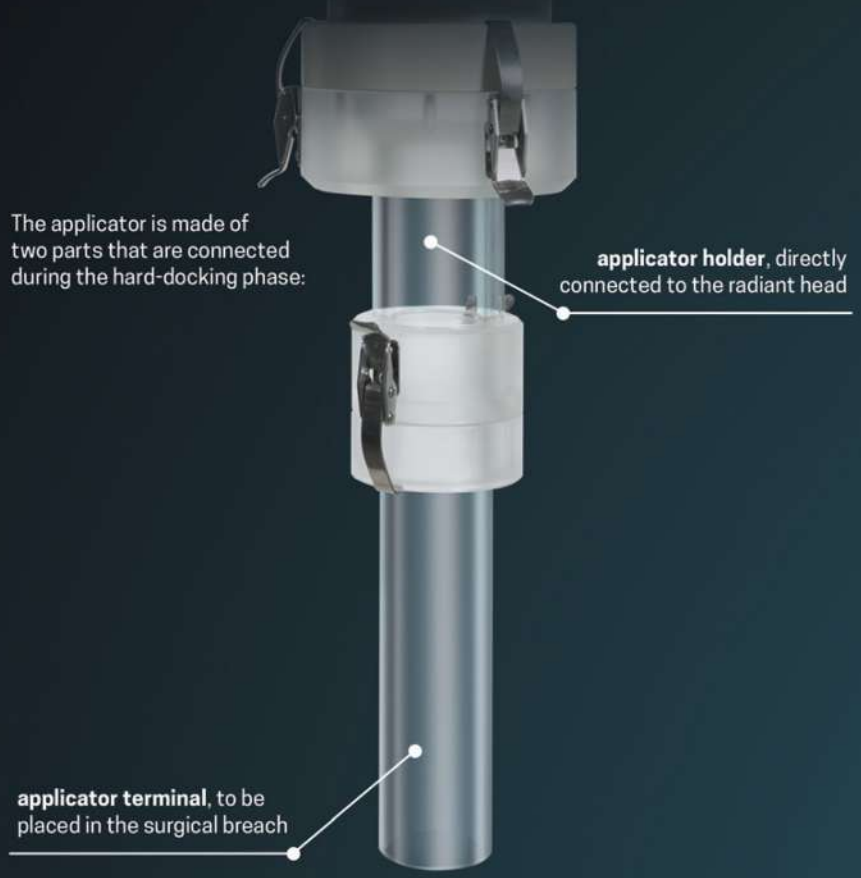
LIAC HWL is able to treat any clinical volume in the IOeRT environment.

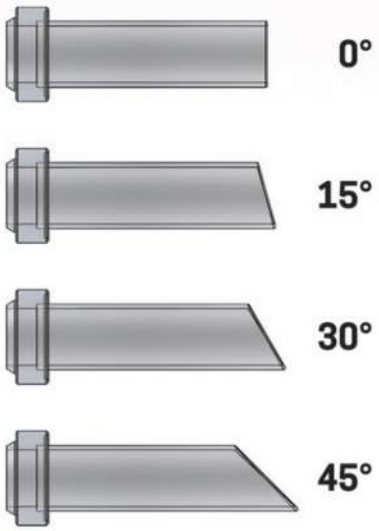
By selecting the correct applicator/energy combination, it is possible to treat any neoplastic disease effectively and safely.

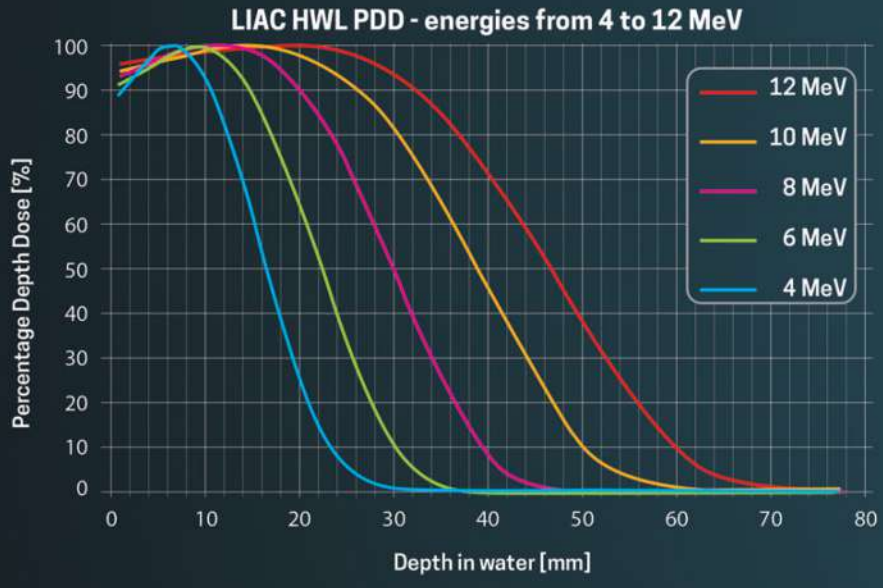
The 100% PMMA (polymethylmethacrylate) applicator allows:

- implementation of the safest and fastest docking technique: the hard-docking;
- direct visualization of the surgical breach, thanks to the transparency of the material and the length of the terminal applicator;
- full compatibility with x-rays imaging;
- the minimum x-ray production;
- the maximum surface dose.



Applicators are available in diameters from 3 to 12 cm, and bevel angles of 0°, 15°, 30° and 45°.





The appropriate energy and applicator selection allow to treat the target with a thickness of up to 3.8 cm inside the 80% isodose (up to 3.2 cm inside the 90% isodose).

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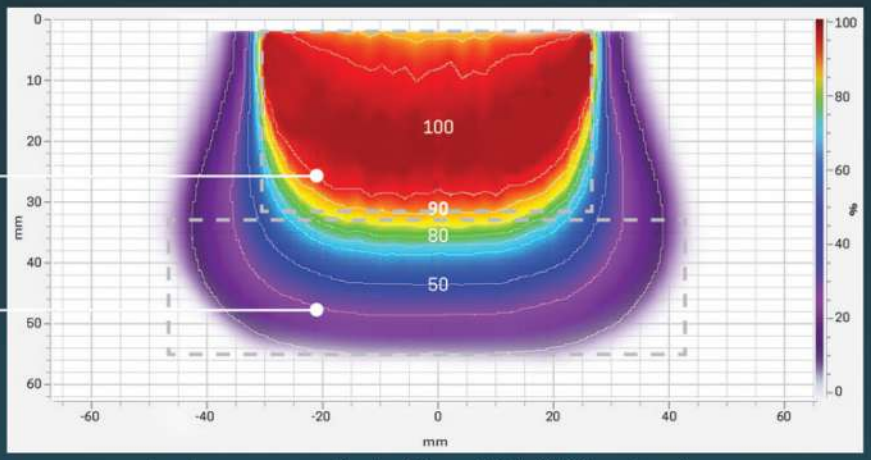
POWERFUL & SAFE

PLANNING TARGET VOLUME

HEALTHY TISSUE



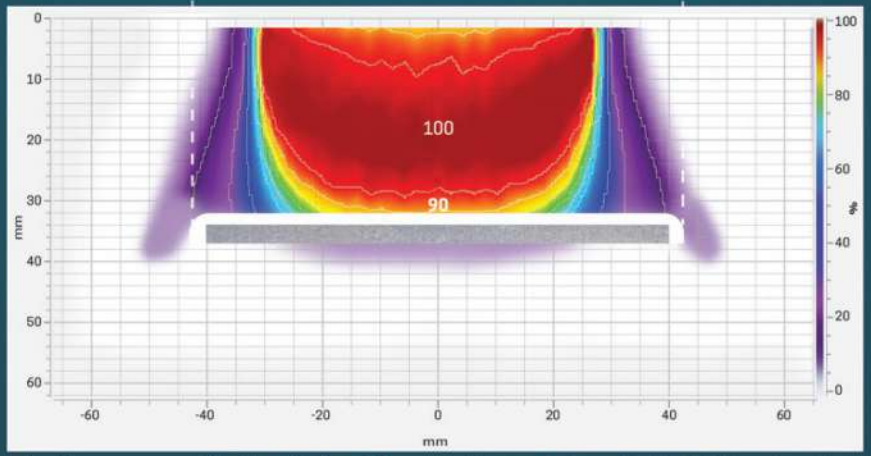
Isodose curve, applicator Ø 6 cm, 12 MeV, 0° bevel angle.

The IOeRT technique ensures reduction of dose exposure of the healthy tissue during the irradiation.

In breast cancer treatment, the use of a radioprotection disc **(Italian Patent no. 1392099)** temporarily inserted between the target and the chest wall fully protects the healthy tissue underneath.

The disc is a medical device made of steel and PTFE (polytetrafluoroethylene), biocompatible and sterilizable materials; it is available in the following diameters: 4, 5, 6, 7, 8, 9, 10 and 11 cm.

The disc has 4 holes placed along the crown, which allow adhesion to underlying tissues ensuring their protection.



Isodose curve modified by RP disc Ø 8 cm, applicator Ø 6 cm, 12 MeV, 0° bevel angle.

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LIAC HWL CAN BE INSTALLED IN ANY STANDARD OPERATING ROOM

The use of LIAC HWL is bound to the implementation of a radioprotection plan by a Radiation Protection Officer.
The compilation of a radioprotection preliminary plan is strictly connected to the smooth and successful LIAC HWL installation and clinical use.
Preparing an accurate radiation protection plan is very easy! Only the following installation site data are requested:
- Architectural structure
- Electrical plant
- Radioprotection safety plants
- Required workload
- Surrounding rooms use and occupancy.

IMPR

THE MINIMUM POSSIBLE AMOUNT OF STRAY RADIATION, FOR THE HIGHEST POSSIBLE WORKLOAD.

LIAC HWL HAS BEEN SPECIFICALLY DESIGNED IN ORDER TO MINIMIZE STRAY RADIATION.

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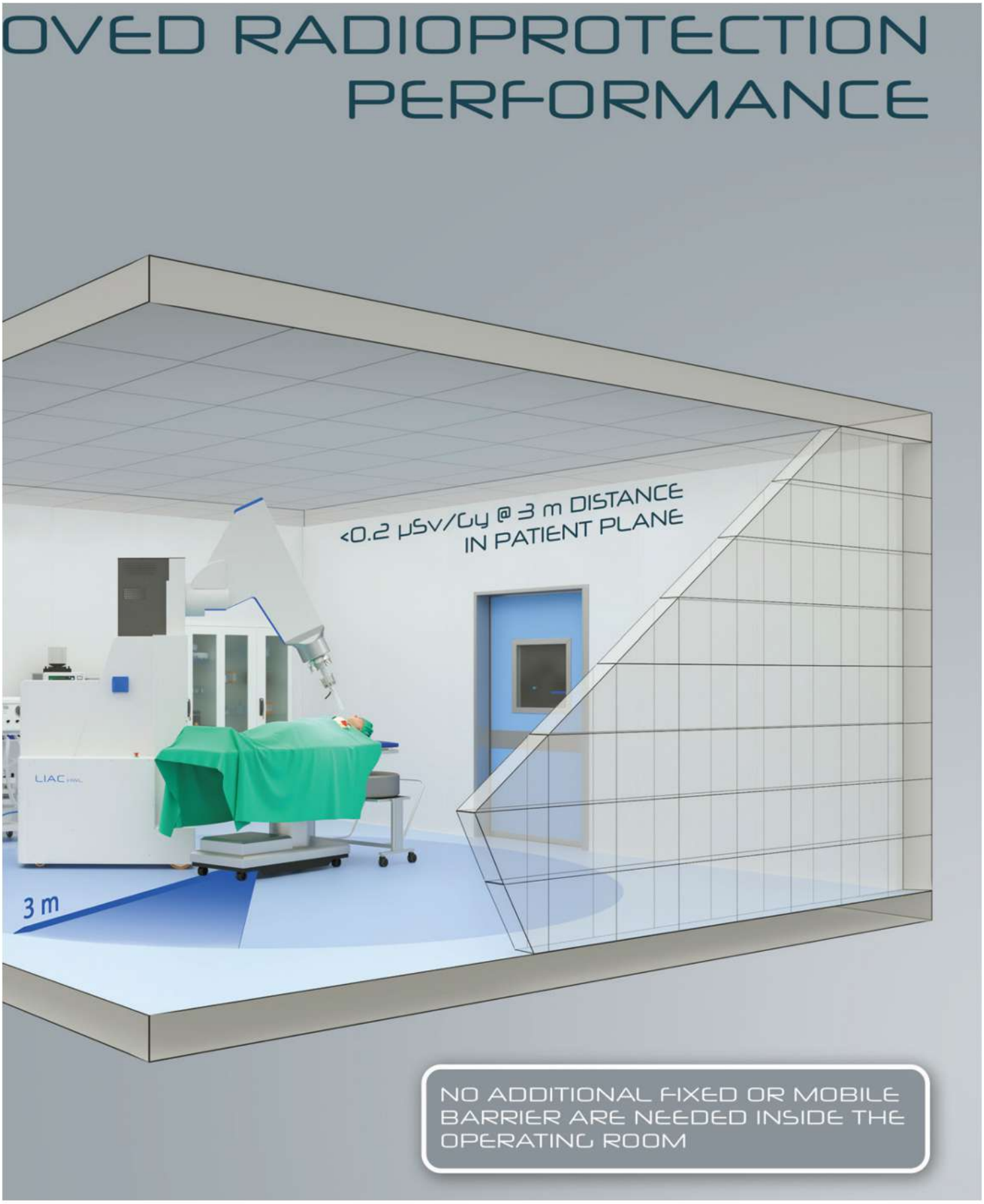
OVED RADIOPROTECTION PERFORMANCE



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AN EASY

STRAY RADIATION IS MEASURED IN THREE DIFFERENT AREAS WITH RESPECT TO THE OPERATING ROOM WHERE LIAC HWL IS INSTALLED

LIAC HWL is provided with a specific barrier to be placed under the operating table, the beam absorber.
Beam absorber proper positioning is guaranteed by the shield positioning device (SPS) that provides the correct position of the beam absorber respect to the LIAC HWL Mobile Unit.
A specific interlock prevents the irradiation in case of beam absorber mispositioning.

TVL (cm)

Angle	Lead	Concrete
180°	3,0	18

Stray radiation

E [MeV]	SR at 1 m [µSv/Gy]
90°	0.07

Typical Scenario:
- Weekly workload 100 Gy/week
- Distance 1 m
- 20 cm concrete ceiling implies an attenuation greater tha 10;

Stray Radiation downstairs SR_D, in the ***HOT SPOT***, it is Calculed as
SR_D < 100 Gy/w • 0.07 µSv/Gy • 0.1 = 0.7 µSv/w <<20 µSv/w

TVL (cm)

Angle	Lead	Concrete	Drywall
90°	1,3	12	30

Stray radiation

Drywall thickness [cm]	E [MeV]	SR at 3m [µSv/Gy]
5	6	0.16
	12	0.20
6	6	0.15
	12	0.18
7	6	0.13
	12	0.17

Typical Scenario:
- Weekly workload 100 Gy/week
- Distance 3 m
- Floor 7 cm drywall;

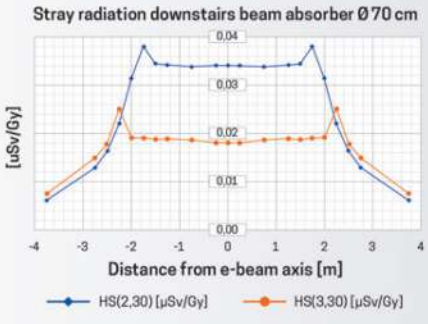
Stray Radiation downstairs SR_D, in the ***HOT SPOT***, it is Calculed as
SR_D <100 Gy/w • 0.17 µSv/Gy = 17 µSv/Gy = 17 µSv/w <<20 µSv/w

TVL (cm)

Angle	Lead	Concrete	Drywall
90°	1,3	12	30

Typical Scenario:
- Weekly workload 100 Gy/week
- Distance 3 m
- Floor 20 cm concrete;

Stray Radiation downstairs SR_D, in the ***HOT SPOT***, it is Calculed as
SR_D < 100 Gy/w • 0.05 µSv/Gy = 5 µSv/w <<20 µSv/w



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AND SAFE APPROACH TO RADIATION PROTECTION

UPSTAIRS

PATIENT LEVEL

DOWNSTAIRS

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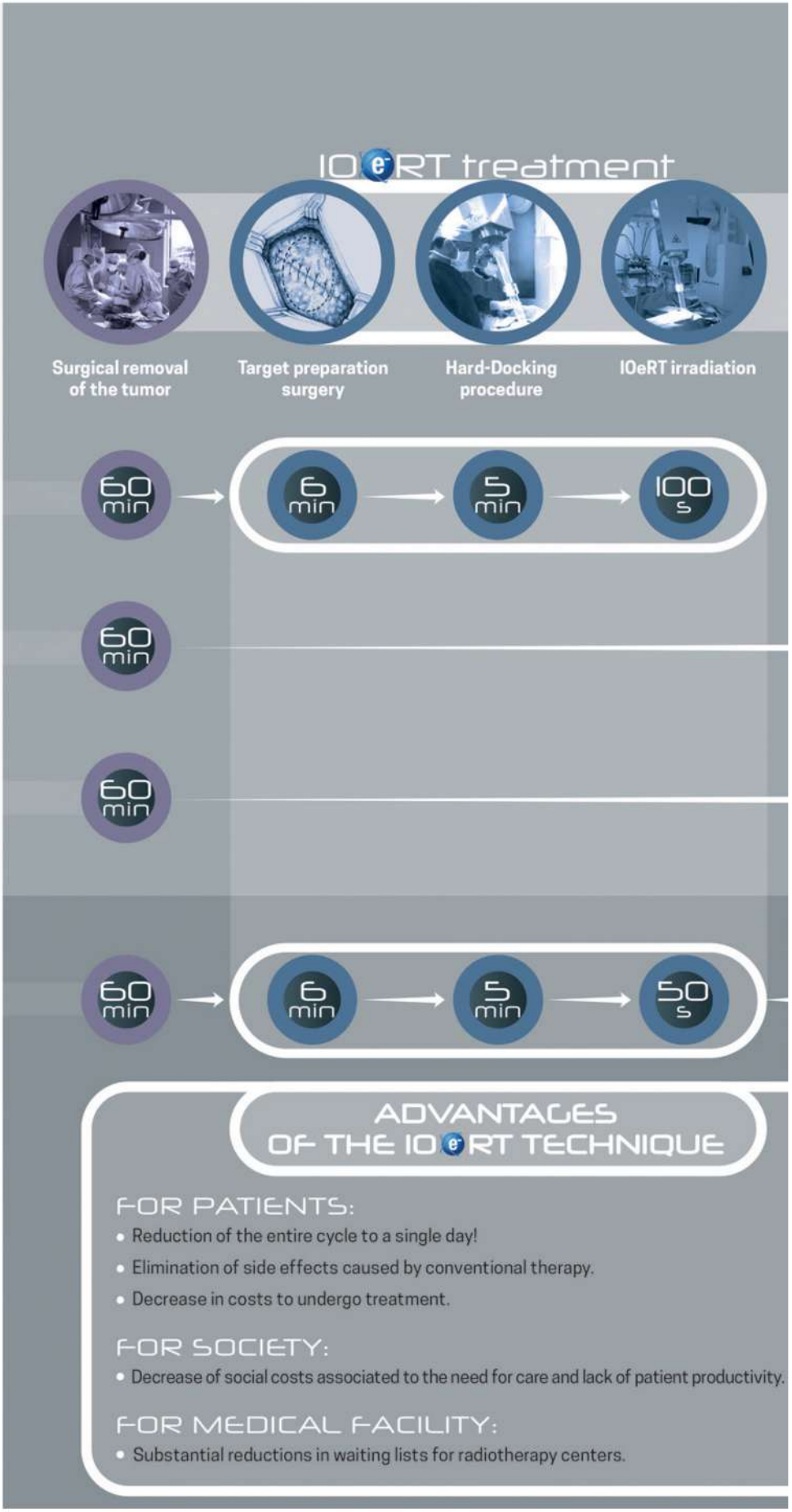
IOeRT CAN BE PERFORMED EITHER AS:

- SINGLE DOSE, a single treatment which replaces the entire external radiotherapy cycle.
  (ELIOT protocol for breast cancer)
- BOOST, followed by a reduced external radiotherapy cycle.
  (HIOB protocol for breast cancer).



ADVANTAGES OF THE IOeRT TECHNIQUE

FOR PATIENTS:

- Reduction of the entire cycle to a single day!
- Elimination of side effects caused by conventional therapy.
- Decrease in costs to undergo treatment.

FOR SOCIETY:

- Decrease of social costs associated to the need for care and lack of patient productivity.

FOR MEDICAL FACILITY:

- Substantial reductions in waiting lists for radiotherapy centers.

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EFFECTIVE & QUICK

Waiting time
between lumpectomy and radiation therapy

External radiation therapy treatment

ONLY 1 TREATMENT DELIVERED DURING SURGERY

7/9 weeks waiting time → 5/16 Fractions delivered in 2/3 weeks

7/9 weeks waiting time → 25/33 Fractions delivered in 5/7 weeks

7/9 weeks waiting time → 13/15 Fractions delivered in 2/3 weeks

THE BEST ACHIEVABLE LOCAL CONTROL, THANKS TO IOeRT BOOST DELIVERED AT TIME ZERO

FOR CLINICAL PRACTICE:

- Improvement of local control is a conditio sine qua non for disease free and overall survival.
- Reduction (in the case of boost) and elimination (in case of single dose) of the external radiotherapy cycle.
- Time zero between surgery and the delivery of radiotherapy, neoplastic cells growth from microscopic residual disease follows an exponential course immediately after surgery. Giving IOeRT this problem is solved.
- Precision, thanks to direct visualization of the target.
- Significant reduction of dose to healthy tissues, the direct access of irradiation to the target allows to displace and mechanically protect numerous dose-sensitive normal tissue uninvolved by cancer.
- Minimization of side effects, less toxicity, complete skin sparing and better cosmesis outcomes compared to external beam radiation therapy.
- Feasibility of the treatment as the only solution when external radiation therapy is critical or even not possible (treatments of recurrences, patients with a pacemaker or decreased mobility).
- IOeRT boost is particularly efficacious for the treatment of locally advanced cancers. IOeRT boost combined with external RT and chemotherapy allows to achieve excellent results of local control and overall survival (2016-2017 NCCN guidelines).

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LIAC HWL COMMISSIONING

The LIAC HWL commissioning is performed in accordance with primary international protocols through the use of standard dosimetric instrumentation, as well as use of a proprietary software based on a Monte Carlo Simulation.

The use of such software allows to dramatically reduce (3 working days) the dosimetric characterization of the accelerator already during its acceptance test performed at the main factory.

The clinical dosimetry of the totality of combinations (4 energies x 9 diameters of the applicator x 4 bevel angles) is immediately available, thus allowing to overcome the need for execution of the whole experimental characterization.

The software results are generated starting from a simple set of experimental measurements and using a Monte Carlo library of simulated monochromatic beams across the whole spectral region.

Thanks to the user-friendly interface, these results are easy and quick to use. During the clinical phase, the display of real-time isodose curves guides the correct choice of applicator and energy.

PLUG & PLAY INSTALLATION

LIAC HWL is a plug & play device.

It is not necessary to conduct any upgrading in operating rooms.

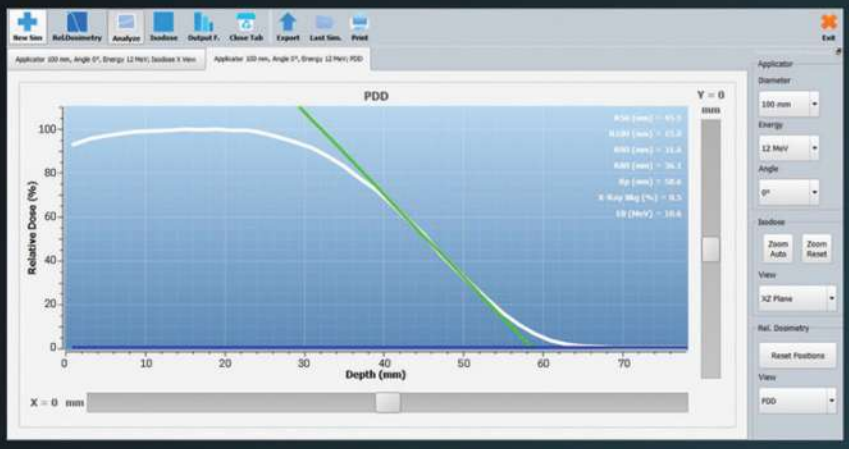
It is sufficient to connect the mobile unit and the control unit by a dedicated cable.

The LIAC HWL installation only requires availability of:
- socket (230 mono-phase + ground [V] 50/60 [Hz]);
- acoustic and optical signaling system, where required.

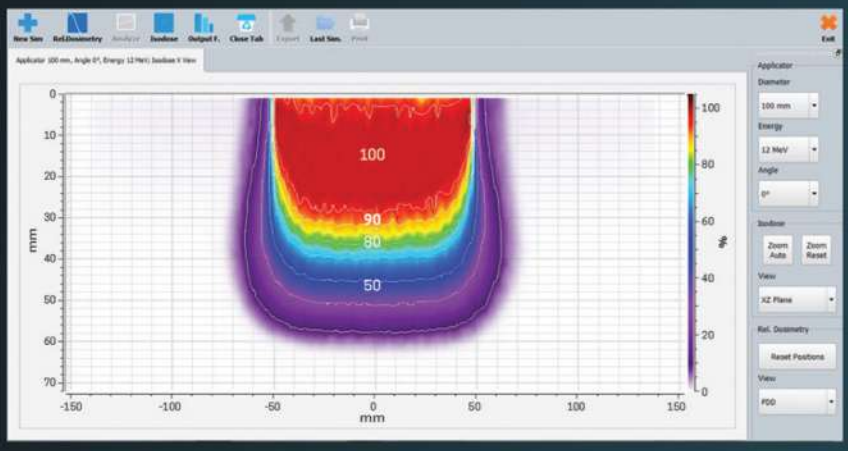
After just 5 days after delivery at its destination site, the system is ready for the first IOeRT treatment.

Thanks to the experience gained over the years, SIT is able to run an ad hoc preliminary proteximetric studies based upon the hospital's operational needs and the selected operating room.

FAST COMMISSIONING



PDD analysis, applicator Ø 10 cm, 12 MeV energy, 0° bevel angle.



Isodose curve, applicator Ø 10 cm, 12 MeV energy, 0° bevel angle.

Just 5 days after delivery at hospital, LIAC HWL is ready for the first IOeRT treatment.

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AND PLUG & PLAY INSTALLATION

day 1 LIAC HWL delivery to hospital and transport to operating room. Installation check; LIAC HWL is connected to the alarm and signal system of the operating room in order to verify proper functioning.

↓

days 2-3 LIAC HWL dosimetric check.

↓

day 4 Training for IOeRT staff.

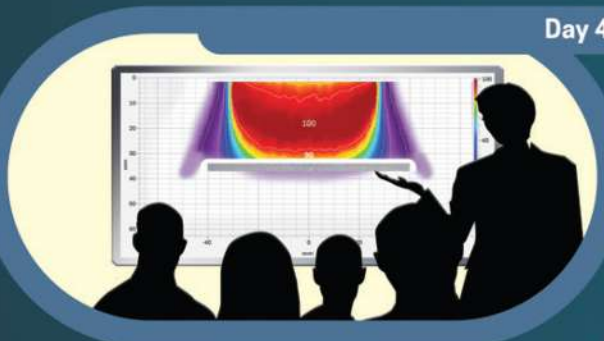
↓

day 5 First patient treatment.

Day 1

Day 2/3

Day 4



Day 5

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SIT has 2 operating sites in Italy: Administration and Legal Affairs, Purchase and Logistics, Marketing and Sales Department are located in Vicenza, whilst R&D, Manufacturing, Technical Department, Quality and Regulatory Affairs, and After Sales Service are located in Aprilia.

SIT has been able to build so far a wide and solid network of agents and distributors worldwide, which contribute actively and constantly to the promotion of high technology in the field of IOeRT all over the world.

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Belgium
Chile
Costa Rica
Cuba
Ecuador
Georgia
Germany
Greece
Iran
Israel
Kazakhstan
Kuwait
Mexico
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INSTALLATION SITES

WORLDWIDE SERVICE ENGINEERS NETWORK COORDINATED BY SIT HEADQUARTER.

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FEATURE	VALUE
Nominal Energies (model 12 MeV)	6, 8, 10, 12 [MeV]
Nominal Energies (model 10 MeV)	4, 6, 8, 10 [MeV]
Surface Dose	⩾ 88 % model 10 MeV ⩾ 90 % model 12 MeV
Beam Current	⩽ 1.5 [mA]
Field Dimensions	Ø: 3, 4, 5, 6, 7, 8, 10 [cm] (9, 12 [cm] on request) Angles: 0°, 15°, 30°, 45°
Flatness (maximum energy value)	⩽ 16 % Ø 12 [cm] ⩽ 7 % Ø 10 [cm] ⩽ 4 % Ø 9 [cm] ⩽ 3 % Ø 8, 7, 6 [cm] ⩽ 9 % Ø 4, 5 [cm] ⩽ 12 % Ø 3 [cm]
Symmetry (maximum energy value)	⩽ 3 %
Applicator length	40 [cm]
Source Surface Distance (SSD)	64.5 [cm]
Dose rate (applicator Ø 10 cm)	10 ÷ 30 [Gy/min]
E-gun pulse duration	⩽ 4 [μs]
Long term stability	⩽ 3 %
Short term stability	⩽ 1 %
Linearity	⩽ 1 %
PDD Bremsstrahlung tail	⩽ 0.4 %
Stray radiation in patient plane @ 3 m distance	< 0.2 μSv/Gy
MOBILE UNIT	
Length	210 [cm] | 83 [inch]
Width	76 [cm] | 30 [inch]
Height (minimum value)	180 [cm] | 71 [inch]
Weight	570 [kg] | 1257 [lb]
CONTROL UNIT	
Length	80 [cm] | 32 [inch]
Width	60 [cm] | 24 [inch]
Height	120 [cm] | 47 [inch]
Weight	120 [kg] | 265 [lb]
ELECTRICAL SPECIFICATIONS	
Temperature	18 ÷ 25 [°C] | 64.4 ÷ 77 [°F]
Relative humidity	30 ÷ 75 % (not condensing)
Voltage	230 mono-phase + ground [V]
Voltage variation	± 10 %
Frequency	50/60 [Hz]
Nominal capacity	2 [kVA]
Environment power dissipation	1.8 [kW]
ACCESSORIES	
Mobile radioprotection barrier	lateral barrier beam absorber (horizontal)
Suturable Radioprotection Disc	Ø: 4, 5, 6, 7, 8, 9, 10, 11 [cm]
Software	MU Calculation Dose View

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TECHNICAL FEATURES

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