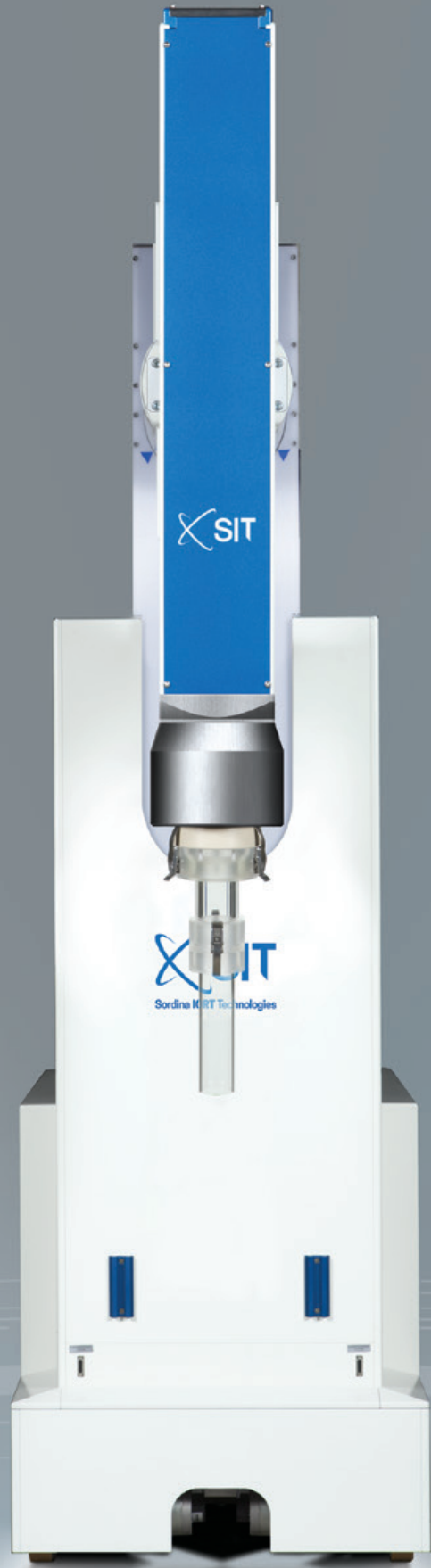




Sordina IORT Technologies

# LIAC<sub>HWL</sub>

mobile IOeRT accelerator



*"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

Easily usable in multiple operating rooms

**< 600** Kg

IntraOperative electron Radiation Therapy (IOeRT), which uses high energy electrons, is the most effective implementation of IORT.

# NO NEED OF SHIELDING

Only **100** seconds  
for **10<sup>e</sup>RT** treatment



## NO LONGER MOVING THE PATIENT:

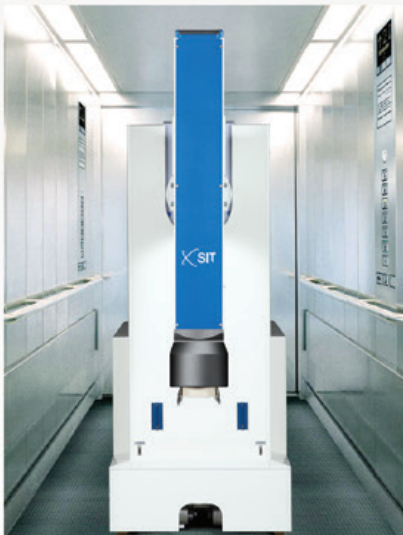
the system follows the treatment, thus avoids the need of moving patients from the surgical table.

## 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.

## TRANSPORT INTO STRETCHER ELEVATOR:

the dimensions are such that LIAC HWL can be easily transported to the operating room through the use of any stretcher elevator.



## FUNCTIONALITY IN MULTIPLE OPERATING ROOMS:

the system can be quickly moved via the dedicated remote control and utilized in any operating room, thus maximizing its employment.





X-SIT

### HARD-DOCKING PROCEDURE:

- fast and easy procedure that can be performed by expert teams in less than five minutes;
- safe and executable in any clinical configuration, thanks to the LIAC HWL architecture and the wide range of accompanying applicators;
- a reliable system that provides an accurate and repeatable beam collimation on the target.

X-SIT  
Sordire IORT Technologies SpA

### 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 (shift on the plane) permit to easily reach any district.

# FLEXIBLE & EASY TO USE

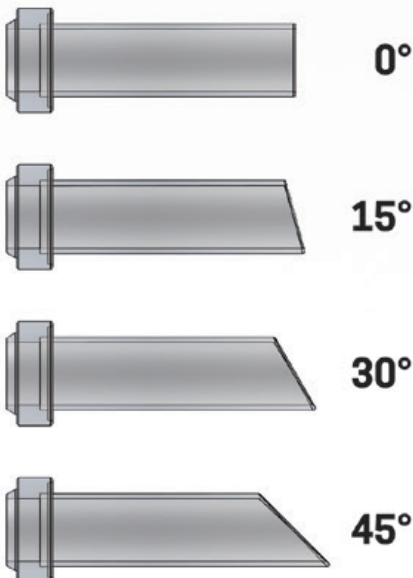
LIAC HWL is able to treat any clinical volume in the IOeRT environment.

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

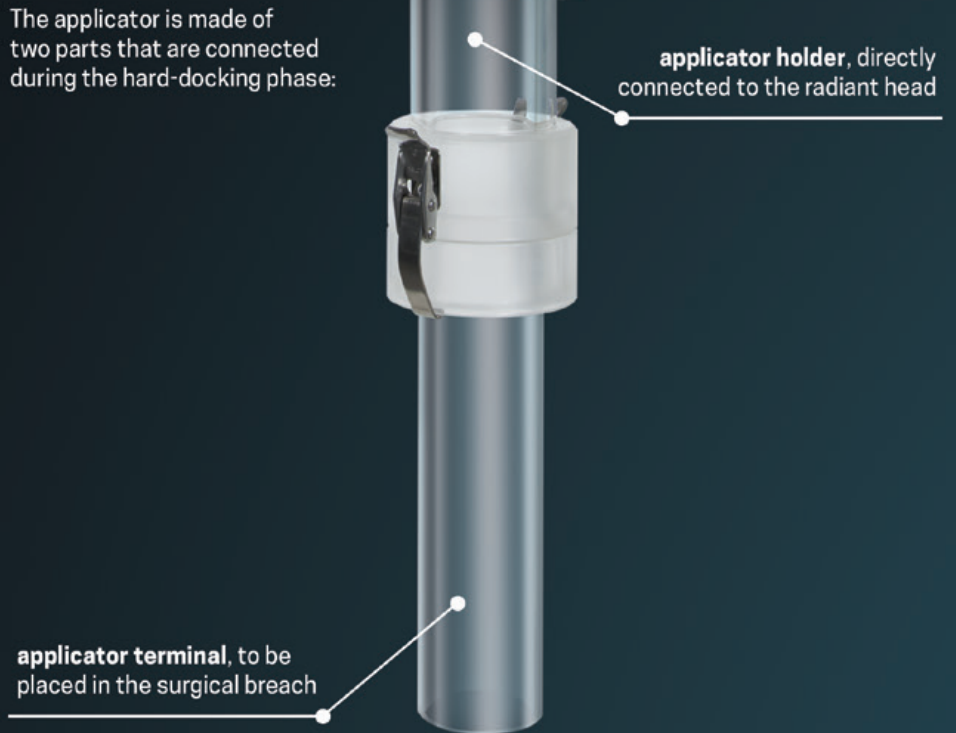
The 100% PMMA (polymethylmethacrylate) applicator allows:

- implementation of the safest and fastest hard-docking technique;
- 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;
- increase of the surface dose by more than 90%, thus avoiding the need of any bolus.

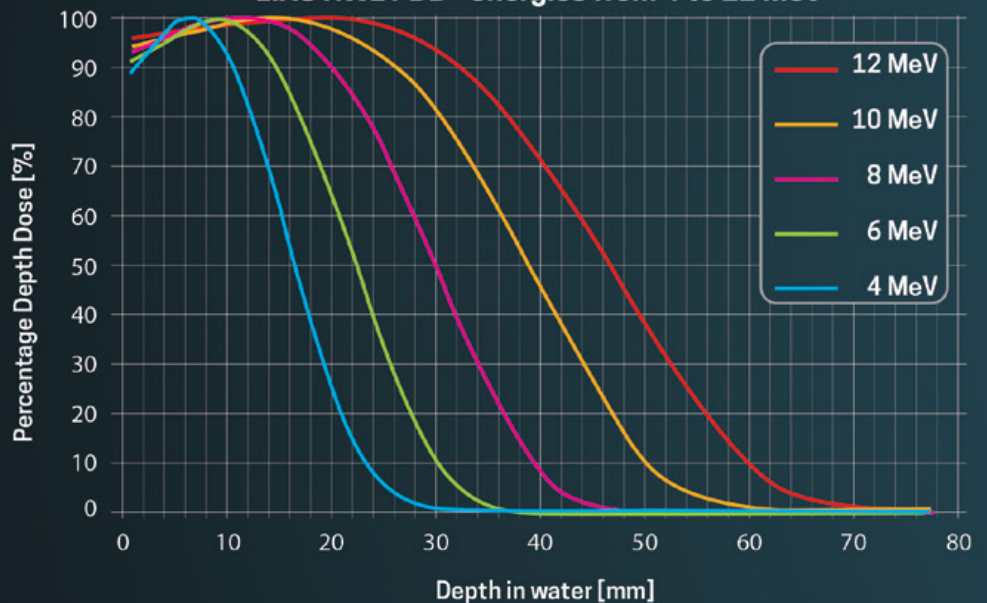
Applicators are available in diameters from 3 to 12 cm, and bevel angles of 0°, 15°, 30° and 45°.



The applicator is made of two parts that are connected during the hard-docking phase:



LIAC HWL PDD - energies from 4 to 12 MeV

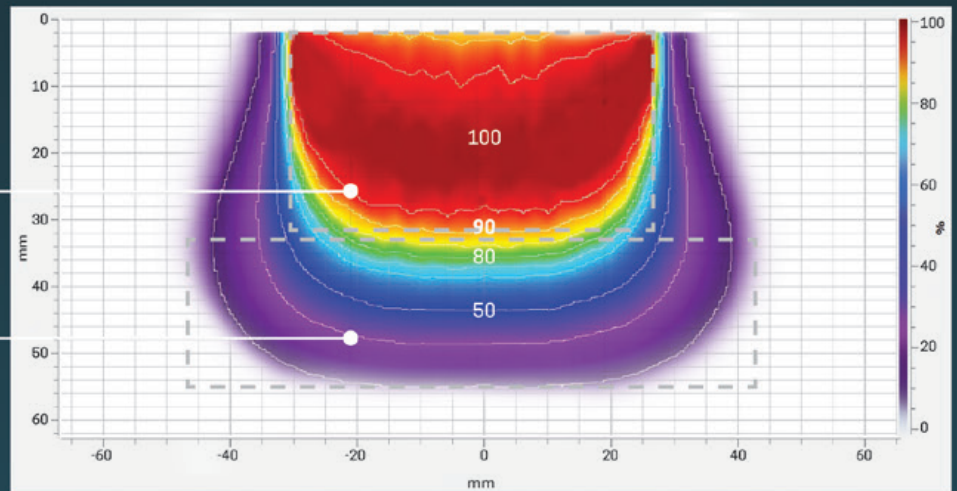


The appropriate energy and applicator selection allow to treat the target with a thickness of up to 3.8 cm inside the 80% isodose (up to 3.2 cm inside the 90% isodose).

# POWERFUL & SAFE

PLANNING TARGET VOLUME

HEALTHY TISSUE



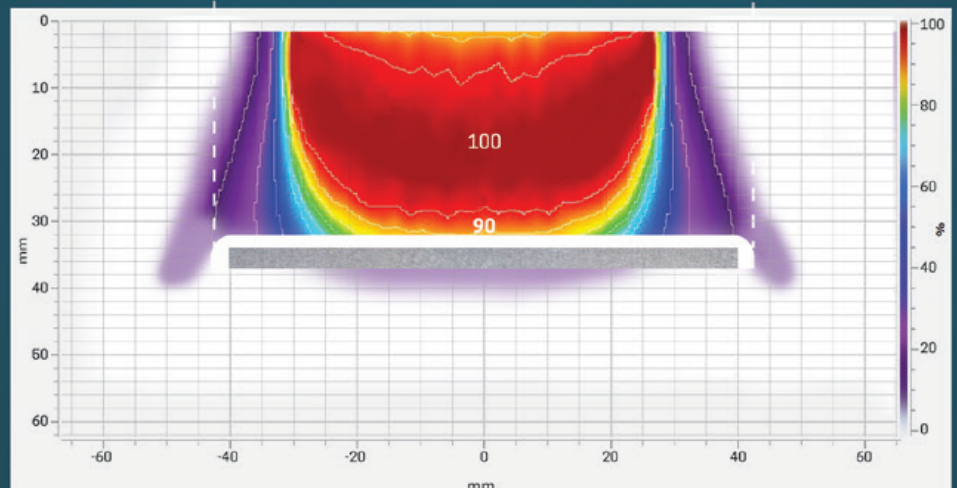
Isodose curve, applicator  $\varnothing$  6 cm, 12 MeV,  $0^\circ$  bevel angle.

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; 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, thus ensuring their protection.



Isodose curve modified by RP disc  $\varnothing$  8 cm, applicator  $\varnothing$  6 cm, 12 MeV,  $0^\circ$  bevel angle.

One of the limits to the easy and cheap implementation of an IOeRT program is represented by radiation protection. LIAC HWL has been specifically designed in order to minimize stray radiation: HWL stands for High WorkLoad, that is the number of patients per year that can be treated without going beyond the radiation protection admitted threshold.

# IMPROVED RAD PERFORMANCE

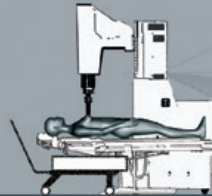
THE MINIMUM POSSIBLE AMOUNT OF STRAY RADIATION, FOR THE HIGHEST POSSIBLE WORKLOAD.

**Any thickness and material under radioprotection standards requirements.**

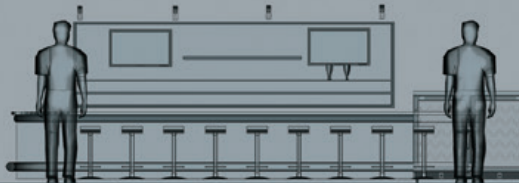
Upstairs



Patient Plane



Downstairs



**The high workload is always possible with any floor thanks to the modular beam absorber.**

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.

NO ADDITIONAL BARRIER, NOR MOBILE NEITHER FIXED, ARE NEEDED INSIDE THE OPERATING ROOM.



# IO PROTECTION

<0.2  $\mu\text{Sv}/\text{Gy}$  @ 3 m DISTANCE  
IN PATIENT PLANE

7 cm drywall



**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).

**IOeRT treatment**



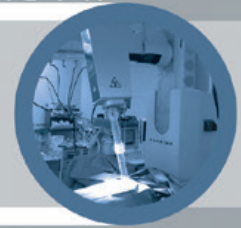
Surgical removal of the tumor



Target preparation surgery



Hard-Docking procedure



IOeRT irradiation

**IOeRT SINGLE DOSE**  
For a selected class of patients



**HYPOFRACTIONATED EXTERNAL RT CYCLE**  
For a selected class of patients



**EXTERNAL STANDARD RT CYCLE**



**IOeRT BOOST + HYPOFRACTIONATED EXTERNAL RT CYCLE**



**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.

# 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).

# BREAST APPLICATION

## IOeRT as BOOST

| STUDY  | TREATMENT   | NUMBER OF TREATED PATIENTS | LOCAL CONTROL  |
|--|---|----------------------------|--|
| Sequential Intervention Study  | <b>IOeRT BOOST (9 Gy at 90% isodose)</b><br>+ external standard RT of 51-56.1 Gy (1.7 Gy per fraction)    | 190                        | <b>100%</b><br>4.3 years follow up (1)<br><b>98.4%</b><br>10 years follow up (2) |
|  | external standard RT of 51-56.1 Gy (1.7 Gy per fraction)<br>+ external BOOST of 12 Gy                     | 188                        | 95.7%<br>6.9 years follow up (1)<br>92.8%<br>10 years follow up (2)              |
| ISORT Pooled Analysis  | <b>IOeRT BOOST (10 Gy at 90% isodose)</b><br>+ external standard RT of 50-54 Gy (1.7-2 Gy per fraction)   | 1109                       | <b>99.2%</b><br>6 years follow up (3)  |
| Case Series Results of a Locally Advanced Breast Cancer (LABC) Post Induction Chemotherapy | <b>IOeRT BOOST (9 Gy at 90% isodose)</b><br>+ external standard RT of 51-57 Gy (1.7-1.8 Gy per fraction)  | 83                         | <b>98.5%</b><br>5 years follow up (4)  |
|  | external standard RT of 51-57 Gy (1.7-1.8 Gy per fraction)<br>+ external BOOST (12 Gy, 2 Gy per fraction) | 26                         | 88.1%<br>5.7 years follow up (4)   |
| Triple-negative Breast Cancer Experience *   | <b>IOeRT BOOST (9.6 Gy median Dmax)</b><br>+ external standard RT (median total dose of 54 Gy)            | 71                         | <b>93%</b><br>8.1 years of follow up (5)   |
| Updated 10-year results of unselected cohort of patients: Clinical Stages I through III    | <b>IOeRT BOOST (10 Gy at 90% isodose)</b><br>+ external standard RT of 54 Gy (1.6-2 Gy per fraction)      | 770                        | <b>97.2%</b><br>10.1 years of follow up (6)                                      |

1. The Salzburg concept of intraoperative radiotherapy for breast cancer: Results and considerations, Reitsamer R. et al., Int. J. Cancer, Vol.118, pp. 2882-2887, 2006
2. Intraoperative (IOERT) versus external electron boost in breast conserving-operated breast cancer patients. 10-year results of a matched-pair analysis [Abstract]. Fastner G, Reitsamer R, Kopp M, Menzel C, Glueck S, Merz F, et al., Strahlenther Onkol 2011;187:73-4.
3. IORT with electrons as boost strategy during breast conserving therapy in limited stage breast cancer: Long term results of an ISORT pooled analysis, Fastner G., Sedlmayer F., Ciabattini A., Orecchia R., Valentini V. et al., Radiotherapy and Oncology, Vol. 108, Issue 2, pp. 279-286, 2013.

## IOeRT as SINGLE DOSE

| TREATMENT  | PATIENTS SELECTION CRITERIA           | NUMBER OF TREATED PATIENTS | LOCAL CONTROL                            |
|--|---------------------------------------|----------------------------|--|
| <b>21 Gy prescribed at 90% of isodose</b>                      | SUITABLE PATIENTS<br>ASTRO guidelines | 294                        | <b>98.5%</b><br>5.8 years follow up (8)  |
| <b>21 Gy prescribed at Dmax</b><br>(18.9 Gy at 90% of isodose) | SUITABLE PATIENTS<br>ASTRO guidelines | 226                        | <b>99.6%</b><br>46 months follow up (9)  |
| <b>21 Gy prescribed at 90% of isodose</b>                      | SUITABLE PATIENTS<br>ASTRO guidelines | 758                        | <b>98.8%</b><br>5.2 years follow up (10) |

### ASTRO GUIDELINES UPDATE: broader selection criteria

In September 2016, ASTRO published the Update of the Accelerated Partial breast Irradiation (APBI) Consensus Statement in order to provide a guidance on use of IORT for Partial Breast Irradiation (PBI) in early stage breast cancer [7].

On the basis of the published evidence and the mature results obtained thanks to the 5.8 years follow-up of the ELIOT trial, it has been recognized the efficacy of performing the IORT with electrons.

In details, the ASTRO society stated the following recommendations:

- IORT with electrons (IOeRT) can be used in the clinical practice outside of a clinical trial for the suitable group of patient;
- IORT with low energy x-rays can never be used outside of a clinical trial.

4. IOERT as anticipated tumor bed boost during breast-conserving surgery after neoadjuvant chemotherapy in locally advanced breast cancer-Results of a case series after 5-year follow-up, Fastner G. et al., Int. J. Cancer, Vol. 136, pp. 1193-1201, 2015. DOI: 10.1002/ijc.29064
5. Survival and local control rates of triple-negative breast cancer patients treated with boost-IOERT during breast-conserving surgery, Fastner G. et al., Strahlenther Onkol., Vol.192, n.1, pp:1-7, 2016
6. Intraoperative Tumor Bed Boost with Electrons in Breast Cancer of Clinical Stages I Through III: Updated 10-Year Results. Kaiser J, Kronberger C, Moder A, Kopp P, Wallner M, Reitsamer R, Fischer T, Fussl C, Zehentmayr F, Sedlmayer F, Fastner G. Int J Radiat Oncol Biol Phys 2018;102(1):92-101. doi: 10.1016/j.ijrobp.2018.05.028.
7. Accelerated Partial Breast Irradiation: Executive Summary for the Update of an ASTRO Evidence-Based Consensus Statement, Correa C, Harris, E.E. et al., PRO, 2016 (DOI: 10.1016/j.prr.2016.09.007).
8. How Do the ASTRO Consensus Statement Guidelines for the Application of Accelerated Partial Breast Irradiation Fit Intraoperative Radiotherapy? A Retrospective Analysis of Patients Treated at the European Institute of Oncology, Leonardi M. C., Maisonneuve P, Mastropasqua G., Morra A., Lazzari R., Rotmensz N., Sangalli C., Luini A., Veronesi U., and Orecchia R., Int. J. Radiation Oncol. Biol. Phys., Vol. 83, No. 3, pp. 806-813, 2012.
9. Accelerated Partial Breast Irradiation using only intraoperative electron radiation therapy in the early stage breast cancer, Maluta S. et al., Int J Rad Onc, pp.1-8, 2012.
10. Breast cancer electron intraoperative radiotherapy: assessment of preoperative selection factors from a retrospective analysis of 758 patients and review of literature, Takenen S. et al., Breast Cancer Res Treat, 165(2):261-271, 2017

# MULTI-CANCER APPLICATION

| DISTRICT          | INDICATION<br>Stage / Locally advanced          | INSTITUTION<br>reference          | RESULTS                            |
|-------------------|---|-----------------------------------|------------------------------------|
| PANCREAS          | Unresectable                                    | MGH (1)                           | 2 y 16% OS (survivors > 5 y)       |
|                   | Bordeline                                       | MCR (2)                           | 84% LC; 3 y 40% vs 0% OS           |
|                   | Resectable                                      | HGUGM (3)                         | 5 y 58% LC                         |
|                   | Unresectable or<br>borderline-resectable        | MGH (4)                           | 35.1 months of median OS           |
| ESOPHAGO-GASTRIC  | Resectable                                      | HGUGM (5)                         | 5 y 85% LC                         |
|                   | Stage II and III                                | Meta-analysis HCMU (6)            | IORT improved LC                   |
| GASTRIC           | Resectable                                      | Systematic review (7)             | St III IOeRT promoted OS           |
| RECTAL            | cT2-4 N+  | HGUGM (8)                         | 5 y 96% LC                         |
|                   | Primary and recurrent                           | Systematic review (9)             | IOeRT improved LC and OS           |
|                   | Unresectable T4                                 | MCR and CHE (10)                  | 5 y 19.3% LR, DFS 55%, OS 56%      |
|                   | Recurrent                                       | MCR and CHE (11)                  | 5 y 45.3% local re-recurrence rate |
|                   | pT4N0/T1-4N+                                    | Multivariate analysis (12)        | 5 y 89.7% LC and 69.0% DFS         |
| PROSTATE          | Metastatic D1 and D2                            | Saitama Cancer C (13)             | 5-10 y 75/52% OS                   |
| RENAL             | Recurrent/Primary resectable                    | US-Europe<br>Pooled-analysis (14) | 5y 37% (p) vs 55% (r) OS           |
| PEDIATRIC         | Ewing/Rhabdomyosarcoma                          | Pooled-European (15)              | 5-10 y 74% - 68% OS                |
|                   | Neuroblastoma + sarcoma<br>incomplete resection | Heidelberg Univ (16)              | 1/18 local recurrences             |
|                   | primary extremity soft-tissue                   | Multicentric Pooled Analysis (17) | 10 y 85% LC, 76% DFS, 81% OS       |
| SARCOMAS          | Retroperitoneal                                 | Heidelberg Univ (18)              | 5 y 72% LC                         |
|                   | Retroperitoneal                                 | MCR (19)                          | 5 y 89% LC                         |
|                   | Retroperitoneal                                 | Boston Univ (20)                  | 5 y 54% OS for liposarcoma         |
|                   | Resectable retroperitoneal                      | Univ Freiburg (21)                | 5 y 89.5% survival rate            |
|                   | Extremity soft tissue                           | Pooled-European (22)              | 5 y 82% LC                         |
|                   | Osteosarcomas                                   | Pooled-European (23)              | 10 y 82% LC, 73% OS                |
| OLIGO-RECURRENCES | Gynaecologic, rectal                            | HGUGM (24)                        | 5 y 53% LC, 46% OS                 |
|                   | STS, head and neck<br>uterine, colorectal       | Univ of Navarre (25)              | 5 y 31% LRC, 57% DMFS,<br>31% OS   |

(1) Cancer. 2013; 119:4196-204  
 (2) J Gastrointest Oncol. 2013;4:352-60  
 (3) Pancreatol. 2013;13:576-82  
 (4) American Journal of Clinical Oncology 2016  
 (5) Ann Surg Oncol. 2013;20:1962-9  
 (6) Minerva Med. 2017;108(1):74-83  
 (7) Mol Clin Oncol. 2015; 3:185-189  
 (8) Radiother Oncol. 2014;112:52-8  
 (9) Surg Oncol. 2013;22:22-35  
 (10) J Gastrointest Oncol. 2016; 7(6):903-916  
 (11) Eur J Surg Oncol. 2017 Jan;43(1):107-117

(12) Am J Clin Oncol. 2015 Feb;38(1):11-6.  
 (13) Int J Clin Oncol. 2016  
 (14) Int J Radiat Oncol Biol Phys. 2014;88:618-23  
 (15) Int J Radiat Oncol Biol Phys. 2015;92:1069-76  
 (16) Int J Radiat Oncol Biol Phys. 2006;64:235-41  
 (17) Int J Radiat Oncol Biol Phys. 2014;90(1):172-80  
 (18) BMC Cancer. 2014;14:617  
 (19) J Surg Oncol. 2014;109:798-803  
 (20) Int J Clin Oncol 2017; 1-6  
 (21) Radiation Oncology 2017; 12:29  
 (22) Strahlenther Onkol. 2014;190:891-8

# NCCN GUIDELINES UPDATE: IOeRT PRACTICE CONSOLIDATION

## REMARKS / IOERT effects

IOERT (applicator  $\leq$  8cm), Charlson comorbidity index  $\leq$  3 and chemotherapy improve OS

Median survival: 23 m R0 vs 10 m R2/unresectable  
98% local control with IOeRT boost

IOERT with neoadjuvant CT and CRT improve survival.  
No toxicity incremented by IOeRT

IOeRT significant improvement of LC

Favourable effect of IOERT in pts with stage II and III

Any stage IOeRT promoted local control

Prognostic index for risk-adapted treatment.

No toxicity increment by IOeRT

IOeRT and Preop CRT improve OS

IOeRT advantage in pts with R1 and R2 resection

No increase of acute and long-term complications

In D2 IOERT significantly cancer-specific survival

Survival affected by nodal involvement,  
sarcomatoid features and IOERT dose

R1 and recurrent influence outcome

6 clinical significant late toxicity

IOeRT boost increased LC with low toxicity rates

Preoperative IMRT for external RT escalation

89% vs 46% S+RT vs S alone ( $p=0.003$ )

IOeRT and adjuvant EBRT improved survival for liposarcoma

Pts  $\geq$  55 years and R2 resection are adverse for survival

In-field LC promoted by IOeRT dose  $\geq$ 12.5 Gy

R1 adverse for local control

EBRT + IOeRT compensate adverse factors fragmentation

Gross macroscopic resection is significant for LRC  
and radiation dose for survival

(23) Radiother Oncol. 2016

(24) Ann Surg Oncol. 2015 Suppl 3:1247-55

(25) Radiother Oncol 2015;116(2):316-22

Additional references:

- Pancreas: Semin Radiat Oncol. 2014;  
24:126-31

- Extremity recurrent sarcomas: Sarcoma.  
2015;:91:3565

Since 2016 NCCN (National Comprehensive Cancer Network) has recommended IOeRT in the treatment of:

- soft tissue sarcoma of extremity/trunk/head-neck and retroperitoneal/intra-abdominal sarcoma;
- rectal cancer resectable for very close or positive margins, especially for T4 or recurrent cancers;
- colon cancer locally unresectable, especially for T4 or recurrent cancers;
- pancreatic adenocarcinoma unresectable or locally recurrent cancer;
- cervical cancer recurrent disease;
- endometrial cancer recurrent disease;
- uterine sarcoma for radiologically isolated vaginal/pelvic recurrence;
- bladder cancer (stage IV A) for patients with complete response to chemotherapy or chemoradiotherapy;
- malignant pleural mesothelioma (stage I-III) medically operable for patients with residual disease.

MGH = Massachusetts General Hospital

HCMU = Hospital of China Medical University

MCR = Mayo Clinic Rochester

CHE = Catharina Hospital Eindhoven

LC = Local Control

LRC = Local Regional Control

OS = Overall Survival

DMFS = Disease Metastasis Free Survival

m = months

y = years

pts = patients

(p) = primary locally advanced disease

(r) = recurrent disease

St = stage

IMRT = Intensity Modulated RadioTherapy

IOeRT = IntraOperative electron RadioTherapy

R0 = complete remission

R1 = microscopic residual tumor

R2 = macroscopic residual tumor

C = Centre

S = Surgery

CT = Chemotherapy

CRT = Chemoradiotherapy

RT = Radiation Therapy

EBRT = External Beam Radiation Therapy

SR = Survival Rate

STS = Soft Tissue Sarcoma

D1 = cancer spread to the lymph nodes only

D2 = cancer spread to the distant lymph nodes and/or to bones or internal organs

HGUGM = Hospital General Universitario Gregorio Marañón

ct2-4 N+ = clinical stage transmural or metastatic nodes

pT4N0/T1-4N+ = locally advanced stage involving other organs/structures or metastatic pelvic nodes

## 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.

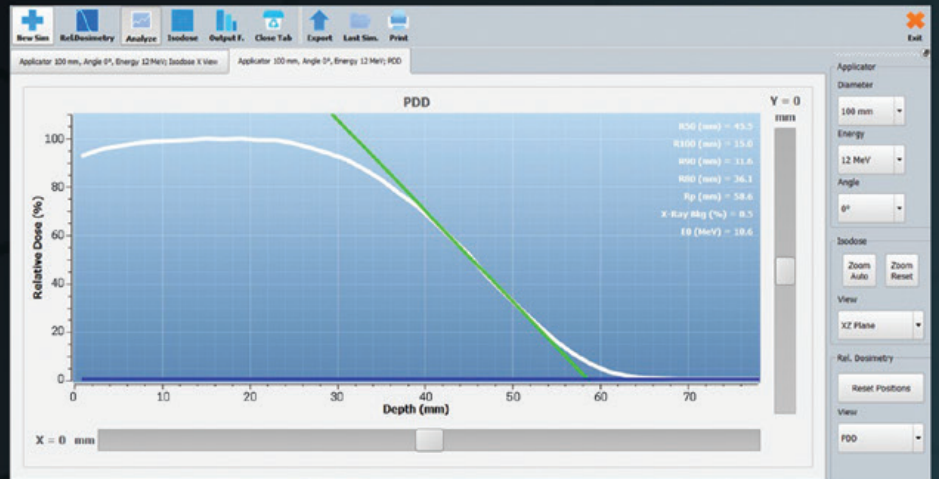
It is sufficient to connect the mobile unit and the control unit by a dedicated cable.

The LIAC HWL installation only requires availability of:

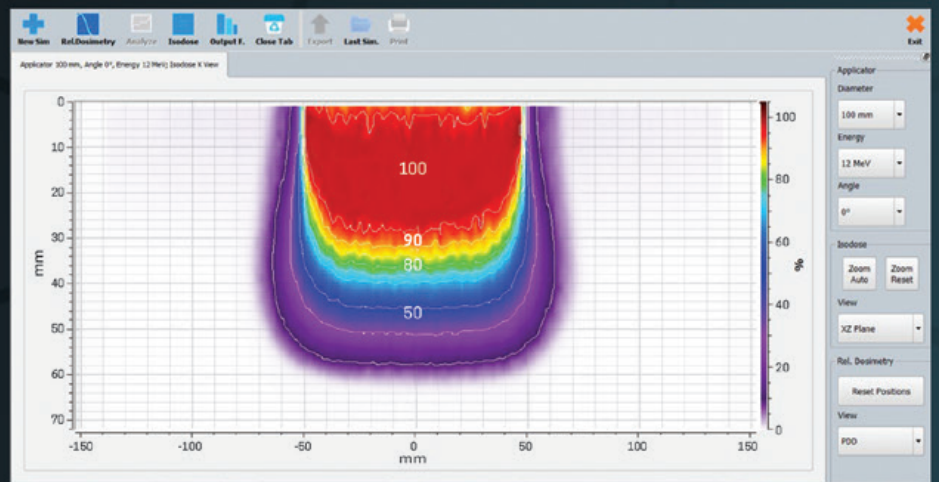
- socket (230 mono-phase + ground [V] 50/60 [Hz]);
- acoustic and optical signaling system, where required.

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

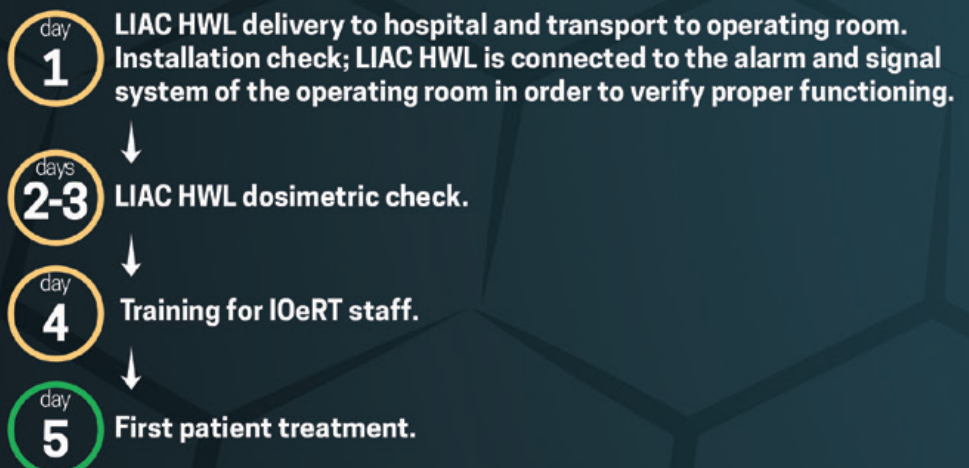
Thanks to the experience honed over the years, SIT is able to run an ad hoc preliminary protoxicimetric studies based upon the hospital's operational needs and the selected operating room.



PDD analysis, applicator  $\varnothing$  10 cm, 12 MeV energy,  $0^\circ$  bevel angle.



Isodose curve, applicator  $\varnothing$  10 cm, 12 MeV energy,  $0^\circ$  bevel angle.





# FAST COMMISSIONING AND PLUG & PLAY INSTALLATION



## INSTALLATION SITES

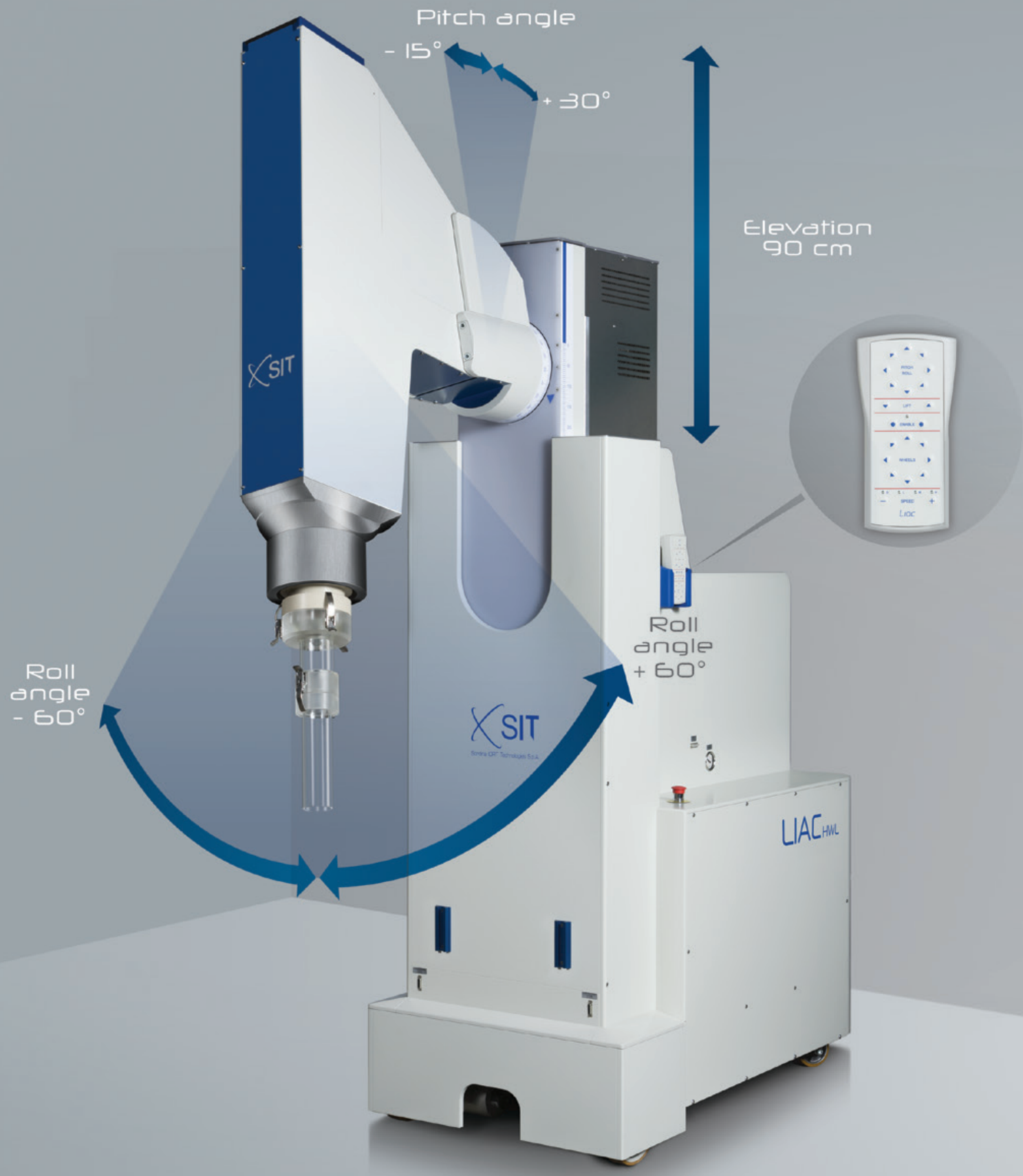
- Italy
- Austria
- Belgium
- Chile
- Costa Rica
- Cuba
- Ecuador
- Georgia
- Germany
- Greece
- Iran
- Kazakhstan
- Kuwait
- Mexico
- Poland
- Russia
- Saudi Arabia
- Spain
- Switzerland
- Thailand
- Turkey
- USA - Florida
- USA - Illinois
- USA - Oklahoma
- USA - Pennsylvania
- Venezuela

WORLDWIDE SERVICE ENGINEERS  
NETWORK COORDINATED BY  
SIT HEADQUARTER.

| 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<br>≥ 90 %      model 12 MeV  |
| Beam Current                                       | ≤ 1.5 [mA]  |
| Field Dimensions                                   | Ø: 3, 4, 5, 6, 7, 8, 10 [cm]<br>(9, 12 [cm] on request)<br>Angles: 0°, 15°, 30°, 45°  |
| Flatness (maximum energy value)                    | ≤ 12 %      Ø 12 [cm]<br>≤ 7 %      Ø 10 [cm]<br>≤ 4 %      Ø 9 [cm]<br>≤ 3 %      Ø 8, 7, 6 [cm]<br>≤ 9 %      Ø 4, 5 [cm]<br>≤ 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<br>@ 3 m distance | < 0.2 µSv/Gy  |
| <b>MOBILE UNIT</b>                                 |   |
| Length   | 210 [cm]   83 [inch]  |
| Width  | 76 [cm]   30 [inch]   |
| Height (minimum value)                             | 180 [cm]   71 [inch]  |
| Weight   | 570 [kg]   1257 [lb]  |
| <b>CONTROL UNIT</b>                                |   |
| Length   | 80 [cm]   32 [inch]   |
| Width  | 60 [cm]   24 [inch]   |
| Height   | 120 [cm]   47 [inch]  |
| Weight   | 120 [kg]   265 [lb]   |
| <b>ELECTRICAL SPECIFICATIONS</b>                   |   |
| 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]  |
| <b>ACCESSORIES</b>                                 |   |
| Mobile radioprotection barrier                     | lateral barrier<br>beam absorber (horizontal)   |
| Suturable Radioprotection Disc                     | Ø: 4, 5, 6, 7, 8, 9, 10, 11 [cm]  |
| Software   | MU Calculation<br>Dose View   |



# TECHNICAL FEATURES



For more information about scientific  
and clinical evidences related to  
IOeRT technique:  
ISIORT web  
[www.isiort.org](http://www.isiort.org)

**SIT Patents:**

RADIATION DOSE CONTROL DEVICE FOR  
CONTROLLING AN ELECTRON  
BEAM PULSE DELIVERED DURING IORT

ABSORBER DEVICE

DEVICE FOR SHAPING AN ELECTRON  
BEAM OF A MACHINE FOR  
INTRAOPERATIVE  
RADIATION THERAPY

IORT MEDICAL ACCELERATOR WITH A  
PARTICLES BEAM ENERGY  
MEASURING DEVICE

SHIELDING DEVICE, IN PARTICULAR FROM  
RADIATION EMITTED  
BY AN ELECTRON ACCELERATOR

MACHINE FOR INTRAOPERATIVE  
RADIATION THERAPY

A IONIZING RADIATION BEAM DETECTOR

LIAC HWL

TREATMENT PLANNING SYSTEM  
(TPS) FOR IOeRT (PATENT PENDING)

**Registered Office**

Galleria del Pozzo Rosso, 13  
36100 Vicenza, Italy  
Phone +39.0444.233711  
Fax +39.0444.233790

**Operative Head Quarter  
& Main Factory Premises**

Via dell'Industria, 1/A  
04011 Aprilia (LT), Italy  
Phone +39.06.92062446  
Fax +39.06.9257970  
Fax +39.06.56561431

**S.I.T.**

**Sordina IORT Technologies S.p.A.**

V.A.T. Number 03782160240



[info@soiort.com](mailto:info@soiort.com)  
[www.soiort.com](http://www.soiort.com)

Management  
System  
ISO 9001:2015  
EN ISO 13485:2015



[www.tuv.com](http://www.tuv.com)  
ID 3105061319



Sordina IORT Technologies