

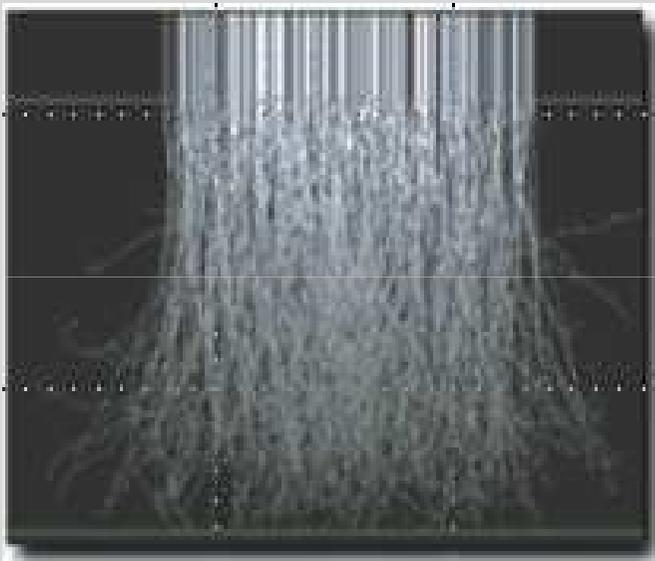


Special techniques overview : IORT

School on Medical Physics for Radiation Therapy
International Center for Theoretical Physics ,
Trieste 31 March 2017

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What is Intraoperative Electron Beam Radiation Therapy (IOERT)?



Intraoperative Electron Beam Radiation Therapy is the application of radiation directly to the residual tumor or tumor bed during cancer surgery

History

IORT is NOT a new approach to cancer management. As the result of pioneering work by Dr. Abe in Kyoto, Japan, IORT using linear accelerators has been used in the U.S.A., Europe and Japan for the treatment of malignancies in the abdomen (sarcomas, rectum, gynecologic and retroperitoneal tumors)

- *1909: Beck treated a patient with colon cancer using low-energy X-rays*
- *Early 1970, Dr. Abe in University of Kyoto, Japan*
- *1978, IORT pioneered in the U.S.A.:*
 - *Howard University/N.C.I., Washington, D.C.*
 - *Massachusetts General Hospital*



IOERT Advantages and Benefits

- *The treatment is performed at the time of surgery, when the target area (the tumor bed) is exposed and the applicator can be placed directly over the target*
- *Organs at risk may be retracted and shielded as necessary*
- *Residual tumor and tumor bed can be irradiated without irradiating sensitive skin.*

Patients with advanced disease can safely receive a higher dose of radiation, Substantially increases the effective dose of radiation to the tumor bed

IOERT Advantages and Benefits

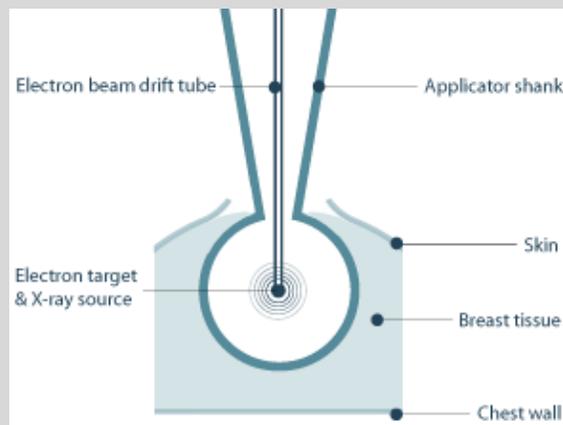
- *More rapid return to better quality of life by often eliminating of pre/post operative external beam radiation treatments*
- *Convenience and cost effectiveness*
- *Breadth of IOERT Clinical Applications (Locally advanced and recurrent rectal, Locally advanced and recurrent GYN, Pancreatic, Gastric, Bladder, Soft tissue, bone and retroperitoneal sarcomas, Head and Neck, Hepatobiliary, Esophageal, Central Nervous System Tumors, Breast, Prostate)*

IORT Low kV DEVICE₁



INTRABEAM™

- INTRABEAM™ Radiotherapy System (IORT) (Zeiss Surgical, Oberkochen Germany) has a miniature X-ray source at the end of a long 10-cm probe, 3.2 mm in diameter. At its end, the accelerated electrons strike a gold target resulting in a nearly isotropic X-ray distribution around the tip
- The miniature X-ray source delivers up to 50kV of energy to the target tissue, and the steep dose fall-off ensures that most of the dose stays in the target tissue. The decrease in radiation protects surrounding healthy tissue and minimises shielding requirements.
- Because the X-ray are of low energy, no special wall, floor or ceiling shielding is required and the treatment can be carried out in conventional ORs, which normally have adequate shielding for intraoperative diagnostic radiology.
- A typical dose rate is 2Gy/min at 1 cm from the center of target



<http://www.targit-research.org/clinics/intrabeam/mode-of-action/>

Intraoperative Irradiation, Techniques and Results, Humana Press

COMMISSIONING

IOP PUBLISHING

PHYSICS IN MEDICINE AND BIOLOGY

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NOTE

Dosimetry measurements with an intra-operative x-ray device

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Online at stacks.iop.org/PMB/55/N359

Abstract

The INTRABEAM 50 kV x-ray device can be used for intra-operative breast irradiation. Spherical applicators are added to the source providing a radially symmetric radiation dose. Dosimetric data for calculation of dose were measured for this unit and a superficial unit with a similar quality, as defined by half value layer (HVL). Chamber calibration and chamber correction factors, k_{ch} , were determined based on HVL to the IPEMB code of practice and addendum. Depth doses were measured using an ionization chamber and GafChromic EBT film. HVL was as 0.85–1.30 mm Al across the range of applicator sizes. Values of k_{ch} were found to be similar for the two units and all INTRABEAM sizes. Therefore, calibration of ionization chambers, radiochromic or other relative dosimeters could be performed on the superficial unit with the advantage of higher dose rates and lower dependence on small errors in detector positioning. Depth dose measurements performed using the ionization chamber agreed with chamber values, published and manufacturer data, giving a simple and robust method for commissioning and regular quality assurance.

1. Introduction

1.1. The INTRABEAM system

Partial breast irradiation after surgery is a topic of extensive current investigation of cancer. Several randomized trials are underway (Offersen *et al* 2009), c

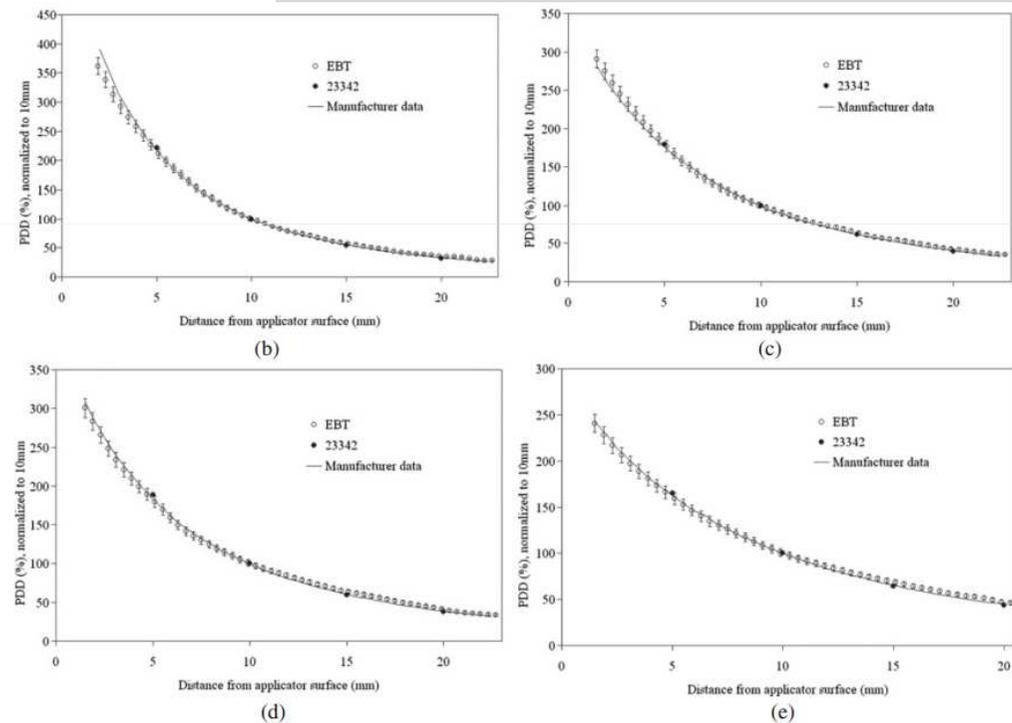


Figure 5. PDD curves for (a) Therapax 3, and INTRABEAM unit with (b) 1.5 cm, (c) 3.0 cm, (d) 3.5 cm and (e) 5.0 cm diameter applicators. Data are normalized to the point of clinical dose prescription: at the surface for the Therapax 3; and 10 mm from the applicator surface for the INTRABEAM unit. Error bars show estimated uncertainties in measurement, at the 1σ level.

IORT Low kV DEVICE₂

Low KV-IORT

AXXENT Xoft

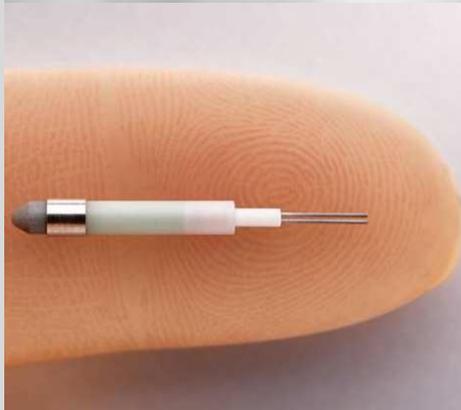


The Xoft S700 Axxent system is an **electronic brachiterapy** device that operates at energy between 20 and 50 kV.

The Axxent[®] Electronic Brachytherapy System[®] utilizes a proprietary miniaturized X-ray source to apply radiation directly to a tumor bed within the body.

The Axxent X-ray Source delivers high-dose rate, low energy radiation treatment without the use of radioactive isotopes.

It's a flexible device.



A microminiature X-ray tube is located inside a flexible, disposable sheath that permits water cooling of X-ray tube.

Source is designed for single patient use of 10 fractions.

The manufacturer quotes a nominal dose rate of 0,6 Gy/min at 3 cm in water.

Commissioning

Med. Phys. 37(10), October 2010

Surface applicator calibration and commissioning of an electronic brachytherapy system for nonmelanoma skin cancer treatment^{a)}

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(Received 26 April 2010; revised 10 August 2010; accepted for publication 11 August 2010; published 29 September 2010)

Purpose: The Xofig Axxent[®] x-ray source has been used for treating nonmelanoma skin cancer since the surface applicators became clinically available in 2009. The authors report comprehensive calibration procedures for the electronic brachytherapy (eBx) system with the surface applicators.

Methods: The Xofig miniature tube (model S700) generates 50 kVp low-energy x rays. The new surface applicators are available in four sizes of 10, 20, 35, and 50 mm in diameter. The authors' tests include measurements of dose rate, air-gap factor, output stability, depth dose verification, beam flatness and symmetry, and treatment planning with patient specific cutout factors. The TG-61 in-air method was used as a guideline for acquiring nominal dose-rate output at the skin surface. A soft x-ray parallel-plate chamber (PTW T34013) and electrometer was used for the output commissioning. GafChromic[®] EBT films were used for testing the properties of the treatment fields with the skin applicators. Solid water slabs were used to verify the depth dose and cutout factors. Patients with basal cell or squamous cell carcinoma were treated with eBx using a calibrated Xofig system with the low-energy x-ray source and the skin applicators.

Results: The average nominal dose-rate output at the skin surface for the 35 mm applicator is 1.35 Gy/min with $\pm 5\%$ variation for 16 sources. The dose-rate output and stability (within $\pm 5\%$ variation) were also measured for the remaining three applicators. For the same source, the output variation is within 2%. The effective source-surface distance was calculated based on the air-gap measurements for four applicator sizes. The field flatness and symmetry are well within 5%. Percentage depth dose in water was provided by factory measurements and can be verified using solid water slabs. Treatment duration was calculated based on the nominal dose rate, the prescription fraction size, the depth dose percentage, and the cutout factor. The output factor needs to be measured for each case with varying shapes of cutouts.

Conclusions: Together with TG-61, the authors' methodology provides comprehensive calibration procedures for medical physicists for using the Xofig eBx system and skin applicators for nonmelanoma skin cancer treatments. © 2010 American Association of Physicists in Medicine.

[DOI: 10.1118/1.3489379]

Key words: nonmelanoma skin cancer, basal cell carcinoma, squamous cell carcinoma, electronic brachytherapy, surface applicator

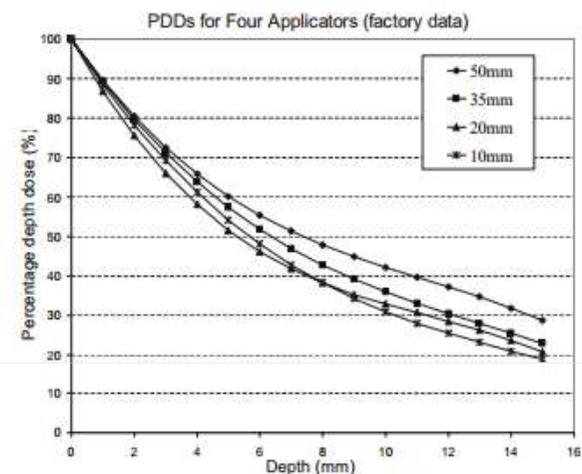


FIG. 10. Factory data of PDDs for four applicator cones. Diamonds, squares, rectangles, and stars represent the PDD curves for 50, 35, 20, and 10 mm cones.

Brief comment on Low kV QA

Daily and Pre-Treatment Checks:

For Intrabeam:

- mechanical checks on the probe straightness,
- verification of the symmetry of the dose in a plane orthogonal to the probe axis
- calibration of both internal and external radiation monitor

For Axxent system self-checks similar to brachithrapy system

Monthly Checks:

Only for Axxent system Output of the X-ray device is checked by means of an on-board well chamber; this also serves to check source positional accuracy and timer accuracy and linearity.

Annual Checks:

For Intrabeam:

- distance dose curve should be measured for every voltage and current settings and compared with those taken at the time of the commissioning using the water phantom.
- For Axxent system a more extensive set of tests is performed: source position accuracy and timer accuracy, the marker catheters are checked for their overall condition

Electron beam characteristics

- Rapid rise to 100%
- Region of uniform dose (proximal 90% to distal 90%)
- Rapid dose fall-off
- High surface dose
- Clinically useful range up to 5-6 cm depth

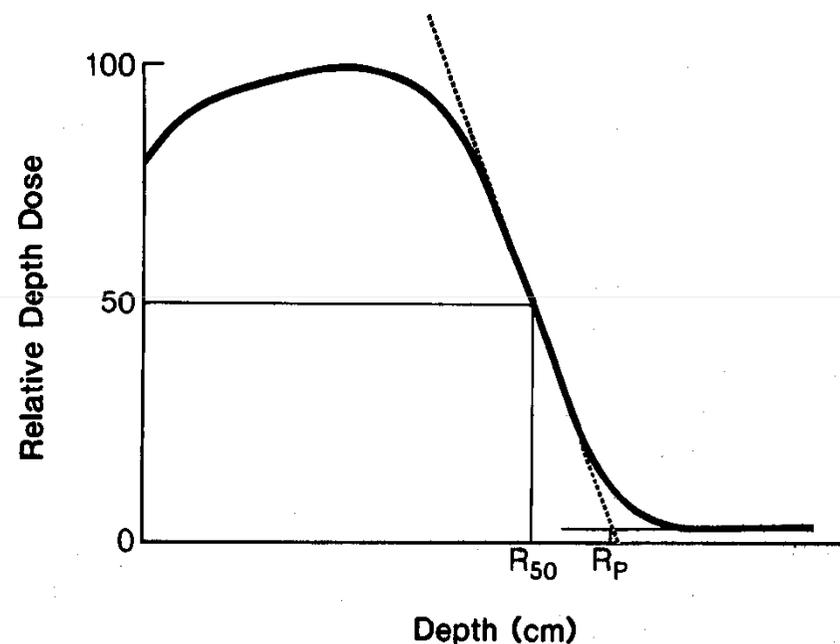


Figure 14.3. Depth dose curve illustrating the definition of R_p and R_{50} .

With conventional LINAC



IOERT with Conventional Equipment Using

- Patient Transportation
- Remove malignancy in operating room
- Temporarily close or cover the surgical wound
- Move the patient with all monitoring and anesthesia equipment– Out of Operating Room– Into radiation oncology treatment bunker
- Reopen surgical wound
- Treat with electron radiation from conventional accelerator
- Return to operating room
- Complete the surgery and close surgical wound

With dedicated linear Accelerators₁

MOBETRON



IOERT dedicated, selfshielded, mobile, electron linear accelerator available when needed in a standard operating room, **SOFT DOCKING system**
Dose per pulse = conventional linac

4 energy (4, 6, 9, 12 MeV)
90% isodose cm (1.1, 1.9, 2.9, 3.5)
SSD=50 cm
45 applicators (3 sets with 0°, 15°, 30° bevel angle)



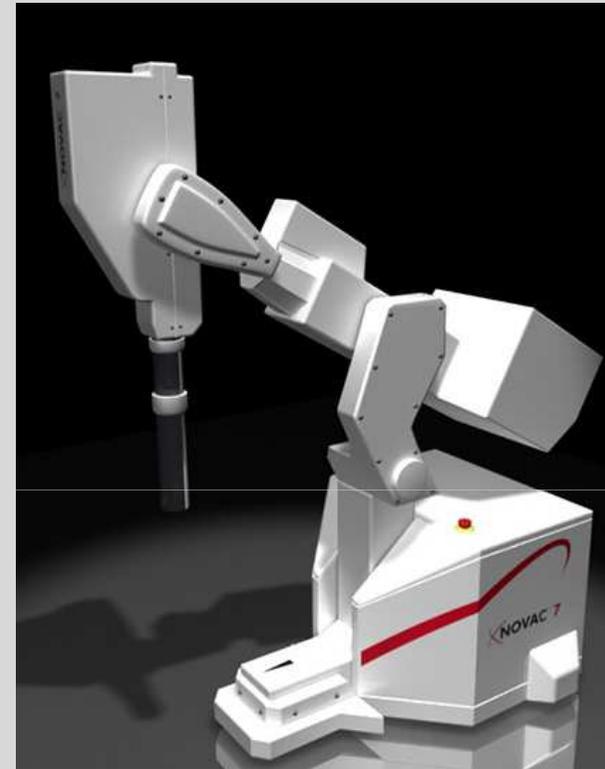
With mobile Linear Accelerators₂

LIAC



HARD docking system

NOVAC



SSD=80 cm

Model	LIAC 10 MeV	LIAC 12 MeV
Nominal Energy	4 - 6 - 8 - 10	6 - 8 - 10 - 12
Beam current	1.5 mA	1.5 mA
Frequency of emission	1 - 60 Hz (variabile)	1 - 60 Hz (variabile)
Scattering foil	75 micron brass	850 micron aluminum
Dose rate	2-30 Gy/min	3-40 Gy/min
Field Diameter	3,4,5,6,7,8,10 & 12 opz	3,4,5,6,7,8,10 & 12 opz
X-ray contamination	< 0.5 %	< 0.5 %
Power dissipation	2 kW	2 kW

Table 2. Liac® system characteristics

Model	Old Novac7 (Hitesys)	New Novac7 (NRT)
Nominal Energy	3 - 5 - 7 - 9 MeV	4 - 6 - 8 - 10 MeV
Beam current	1.5 mA	1.5 mA
Frequency of emission	5 Hz	9 Hz
Scattering foil	No	No
Dose rate	9 > e < 21 Gy/min	>6 e < 39 Gy/min
Field Diameter	4,5,6,7,8,10	3,4,5,6,7,8,10
X-ray contamination	< 0.2 %	< 0.2 %
Power dissipation	<1kW	<1kW

Table 1. Novac system evolution

– High dose per pulse (up to 12 cGy/p @ zmax)

<http://cdn.intechopen.com/pdfs/34246.pdf>

Docking

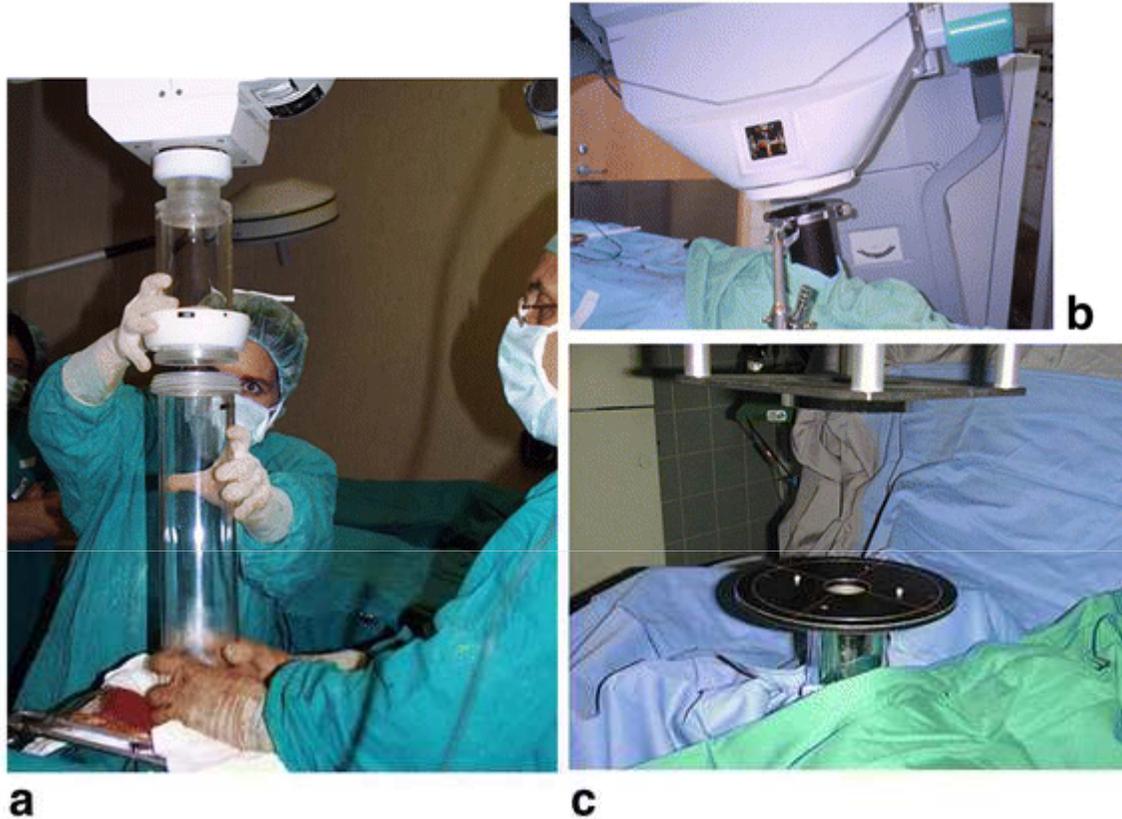


Fig. 2

Hard and soft docking technique in electron IORT. **a** Hard docking: the applicator is attached to a receptor on the accelerator head by a sterile person while a second sterile person holds the applicator in place. (shown for a Liac accelerator). **b** Soft docking: the applicator is attached to the couch with a table stand. There is no mechanical connection between applicator and accelerator. (shown for a Mobetron accelerator). **c** The alignment of accelerator and applicator is adjusted with a laser alignment system. (Shown for a Siemens Mevatron ME accelerator)

Properties of IORT Electron Cones

Shapes

- Circular
- Rectangular

Ends

- 0° 15° 30° bevel
- Material able to be sterilized
- Able to shield surrounding material from scattered electrons

Typical materials

Lucite, stainless steel, chrome-plated brass

Able to view irradiated volume

Direct visual viewing, Mirror reflector, Camera

Treatment Delivery

- Visual verification of treatment field
- Target volume in field of view
- Critical structures avoided
- Treatment field free of blood
- All personnel evacuated from room
- Deliver radiation as rapidly as possible
- High dose rate option useful (e.g. 600-1000 MU/min)
- visual monitoring of patient
- Blood pressure and pulse and breathing

Intraoperative radiation therapy using mobile electron linear accelerators: Report of AAPM Radiation Therapy Committee Task Group No. 72

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Radiation protection

The manufactures usually provide diagrams of stray radiation which can also be found in **publications**.

References:

Mobetron (Daves, Mills MD. Shielding assessment of a mobile electron accelerator for intraoperative radiotherapy. J. Appl Clin Med Phys. 2010; 11:3151)

LIAC (Ciocca M, Pedroli G, Orecchia R, Guido A, Cattani F, Cambria R, Veronesi U, Radiation survey around a Liac mobile electron linear accelerator for intraoperative radiation therapy. J Appl Clin Med Phys. 2001; 2: 165-73)

Novac7 (Andreoli S, Moretti R, Catalano M...Internal report to Ospedale di Bergamo on stray radiation of Novac7, Bergamo 2006)

Pay attention on the workload!!!!

JOURNAL OF APPLIED CLINICAL MEDICAL PHYSICS, VOLUME 10, NUMBER 4, FALL 2009

Dose consumption for quality assurance and maintenance with a dedicated IORT accelerator

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Radiation protection MOBETRON

TABLE II. Allowable monitor units per week for walls.

Lead (mm)	Concrete (mm)	Noncontrolled Distance to occupied area (meters)				
		1	2	3	4	5
0	0	600	2400	5400	9500	15000
5	25	800	3100	7100	13000	19600
10	50	1000	4200	9300	17000	26000
15	75	1400	5500	12000	22000	34000
20	100	1800	7200	16000	29000	45000
25	125	2400	9600	22000	38000	59000

1000 MU/min

Controlled

Lead (mm)	Concrete (mm)	Distance to occupied area (meters)				
		1	2	3	4	5
0	0	29 700	120 000	270 000	480 000	740 000
5	25	39 000	160 000	350 000	630 000	980 000
10	50	52 000	210 000	470 000	830 000	1 300 000
15	75	69 000	270 000	620 000	1 100 000	1 700 000
20	100	91 000	360 000	810 000	1 400 000	2 300 000
25	125	120 000	480 000	1 100 000	1 900 000	2 980 000

1000 MU/min

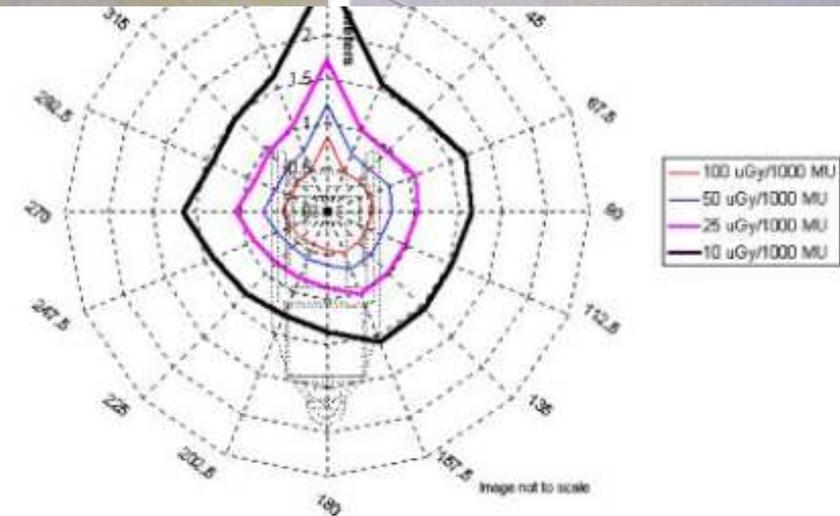
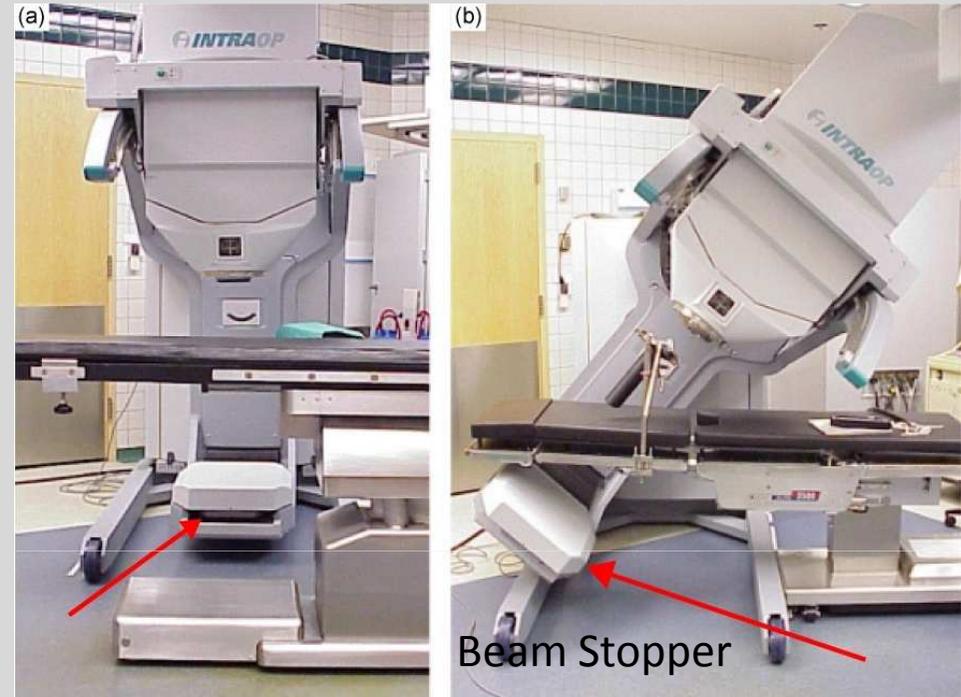
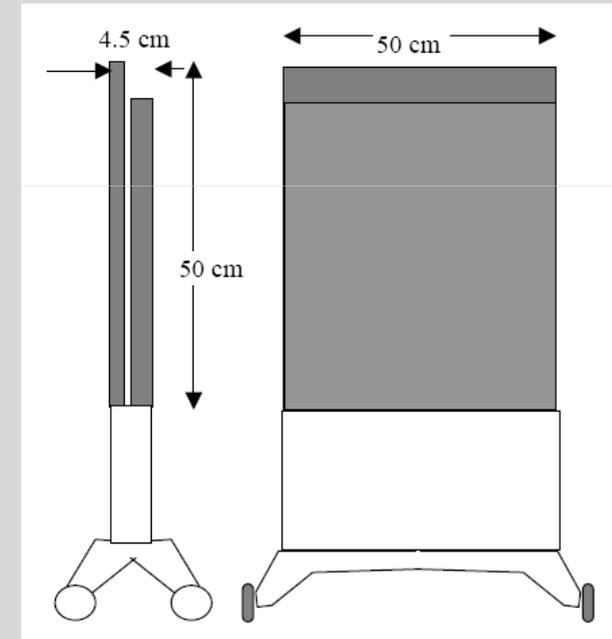
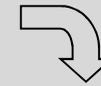
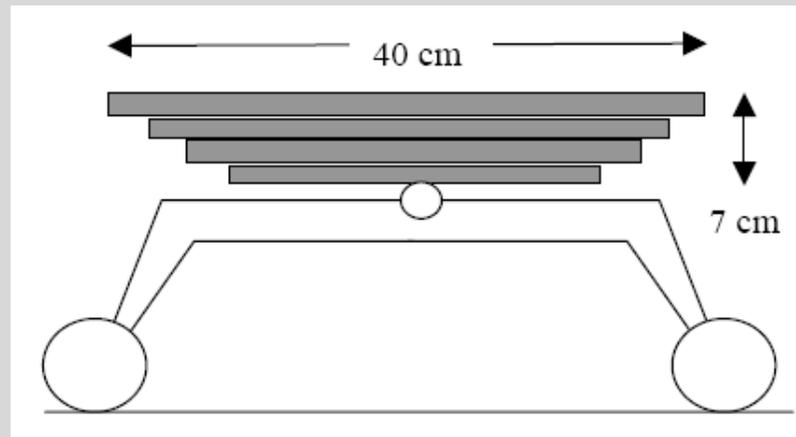
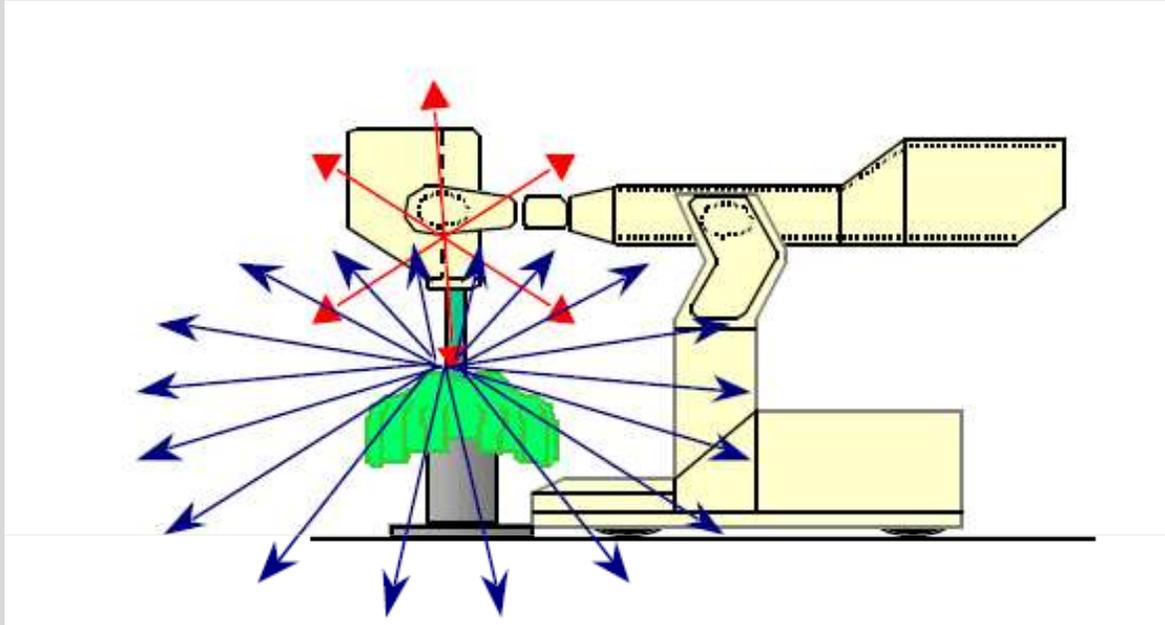


FIG. 5. Exposure curves in the X plane.

Radiation protection NOVAC



Reference dosimetry

For dedicated accelerators, characterized by a high dose/pulse, it is impossible to follow all the recommendations of the protocols (IAEA TRS 398, AAPM TG 51)

Ionization chambers cannot be employed and no published dosimetry protocol can be used.”

In AAPM guidelines for the measurement of the absorbed dose to water in reference conditions the use of the absolute dosimetric system of Fricke is recommended. A good solution is represented also by Alanine dosimetry. Fricke (ferrous sulfate) or alanine/EPR dosimetry

IAEA TRS-398

- $D_{w,Q} = k_{t,p} * k_{pol} * k_{sat} * M_Q * N_{D,w,Q0} * K_{Q,Q0}$

Conventional Dose-per-pulse:
the TVA method BUT


$$k_s = a_0 + a_1 \left(\frac{M_1}{M_2} \right) + a_2 \left(\frac{M_1}{M_2} \right)^2$$

This works for only 0.1-0.6 cGy/pulse

Due to the high density of electric charge produced in the chamber's volume per radiation pulse, the correction factor for ion recombination can be largely overestimated (up to 20%, **Piermattei, PMB, 45, 2000**) if the correction methods recommended by the international protocols are used (**TVA**)

With ionization chamber?

- “Di Martino” Method “Ion recombination correction for very high dose-per-pulse high-energy electron beams”; Med. Phys. 32 (7), 2204-2210 (2005)



In this work the dependence of k_s on the dose-per-pulse value is derived, based on the general equation that describes the ion recombination in the **Boag theory**.

A new equation for k_s , **depending on known or measurable quantities**, is presented.

The new equation is experimentally tested by comparing D_w measured with p-p IC to that measured using dose-per-pulse independent dosimeters, such as radiochromic films and Fricke dosimeters.

Charge collection efficiency in ionization chambers exposed to electron beams with high dose per pulse

R.F. Laitano¹, A.S. Guerra¹, M. Pimpinella¹, C. Caporali¹ and A. Petracchi²

Ion recombination models

Starting point:

More accurate models of the charge collection process, incorporating the free-electron component, developed by Boag et al. (PMB, 1996) [based on the results by Hochhäuser et al. (JPD, 1994) and Balk et al. (PMB, 1996)].

✦ Hüxley et al. (1974), Hochhäuser et al. (JPD, 1994)

Balk et al. (PMB, 1998)

$$\tau = a(1 - e^{-bE}) + c(1 - e^{-dE})$$

✦ Hochhäuser et al. (1994)

$$W = a + b \left[(1 - e^{-cE}) - \frac{d}{n} \left(1 + \frac{ce^{-nE} - ne^{-cE}}{n - c} \right) \right]$$

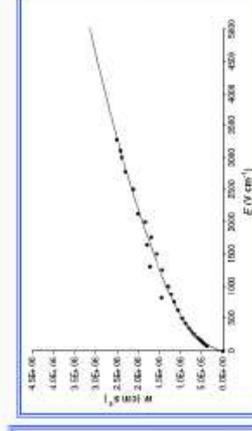
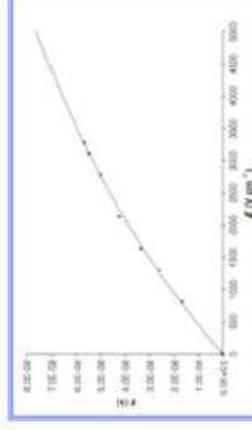
$$f''' = \lambda + \frac{1}{u} \ln \left[1 + \frac{e^{\lambda(1-\lambda)u} - 1}{\lambda} \right]$$

MODEL III

$$\lambda = 1 - \sqrt{(1-p)} - p = \frac{\omega\tau}{d} \left(1 - e^{-\frac{d}{\omega\tau}} \right)$$

$$u = \frac{\mu d^2 \tau}{V}$$

p ≡ free-electron fraction

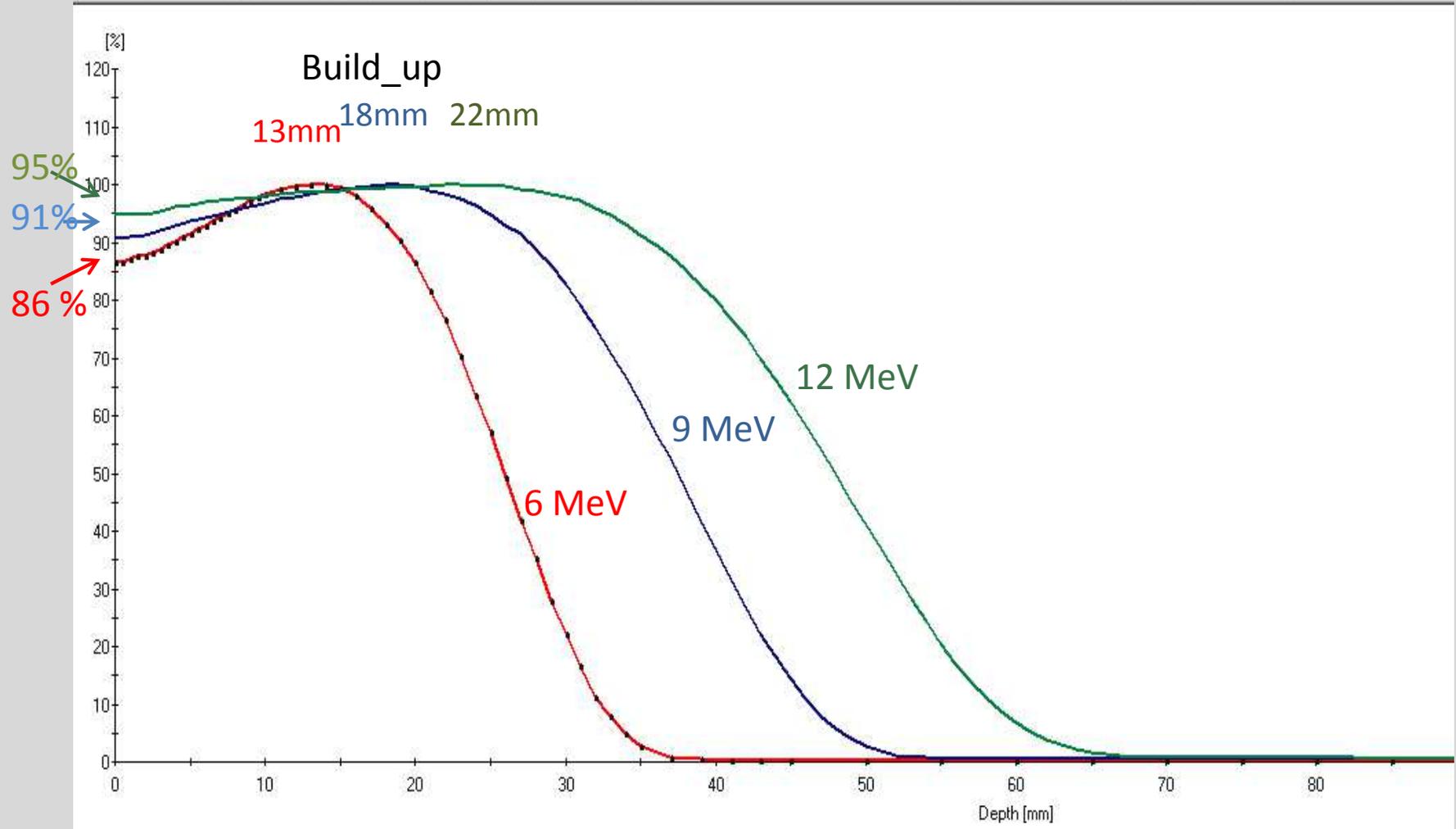


Commissioning

Measurements	Comment
Beam profiles (depth dose and cross plane profiles)	Measurements are done for each applicator and beam energy and should extend to region outside the treatment area
Applicator factors	Applicators factors are relative to a 10 cm circular cone, and the measurements are done at d_{max} for each applicator and beam energy
Air gap factors	The air gap factor is the ratio of dose with an air gap to the dose without one at d_{max} . Air gap factors are measured at the appropriate depths of d_{max} for each combination of applicator and beam energy
TG51 output calibration/ IAEA TRS 398	Output calibration is done at the TG-51 reference depth d_{ref} using the 10 cm circular applicator. From these measurements the dose/UM at d_{max} is determined
Leakage Profiles	Measurements are done for a limited sample of applicators and beam energy (including the highest beam energy) and should be made lateral to the applicator walls at various depths

Central axis percentage depth dose for a 10 cm circular applicator- MOBETRON

Visible	Type	Modality	Energy [MV/MeV]	Field [cm x cm]	Depth [mm]	OffAxis [mm]	Wedge/App.	Groupname	Comment	Accelerator	Block	Gantry [°]	Collimator [°]	Inplane Offset [mm]	Crossplane Offset [mm]
<input checked="" type="checkbox"/>	PDD	Electrons	6,00	10,0 x 10,0	---	0,00	A_10			MOBETRON	None	0,0	0,0	0,0	0,0
<input checked="" type="checkbox"/>	PDD	Electrons	9,00	10,0 x 10,0	---	0,00	A_10			MOBETRON	None	0,0	0,0	0,0	0,0
<input checked="" type="checkbox"/>	PDD	Electrons	12,00	10,0 x 10,0	---	0,00	A_10			MOBETRON	None	0,0	0,0	0,0	0,0

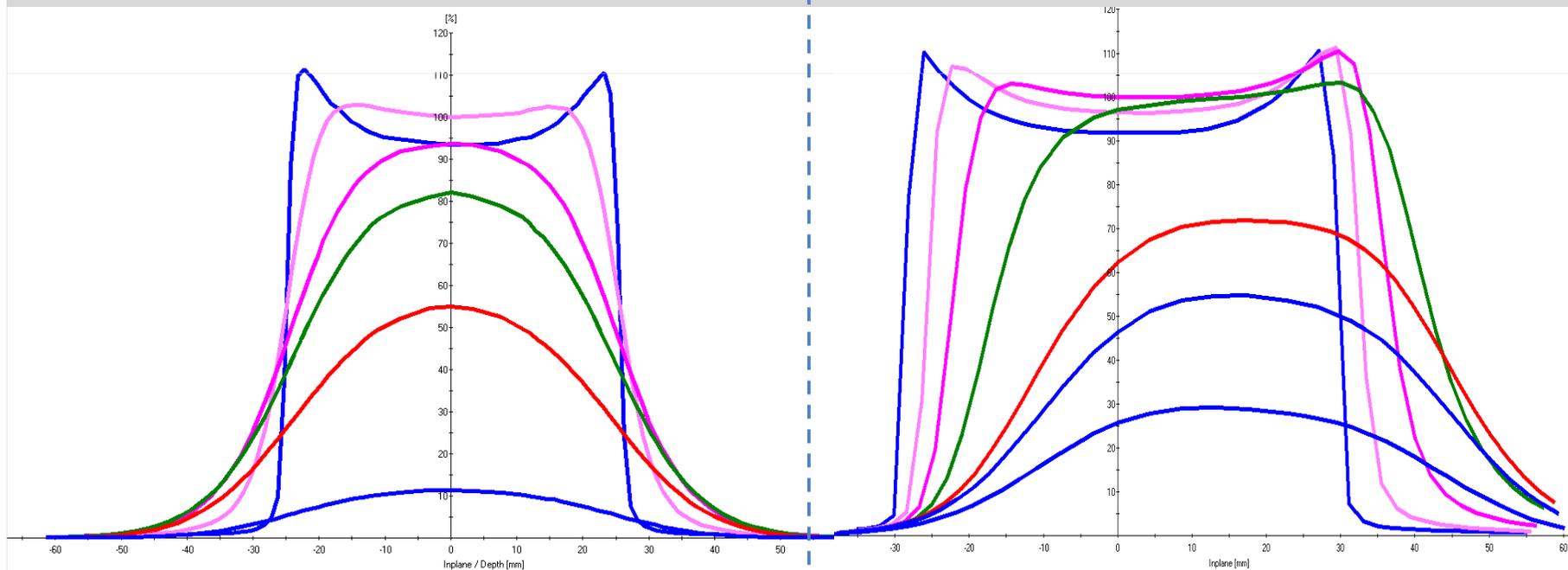


Beam profile at dmax and at different depth- MOBETRON

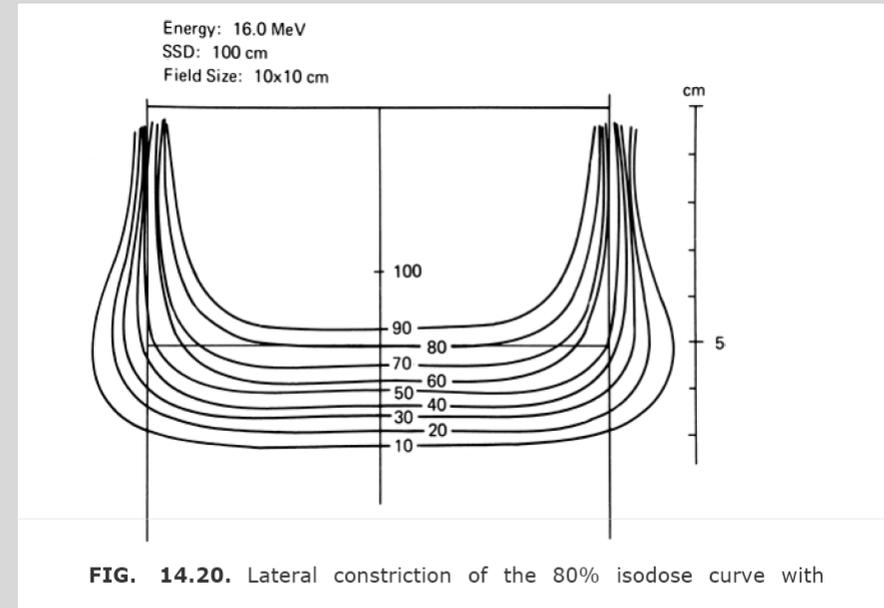
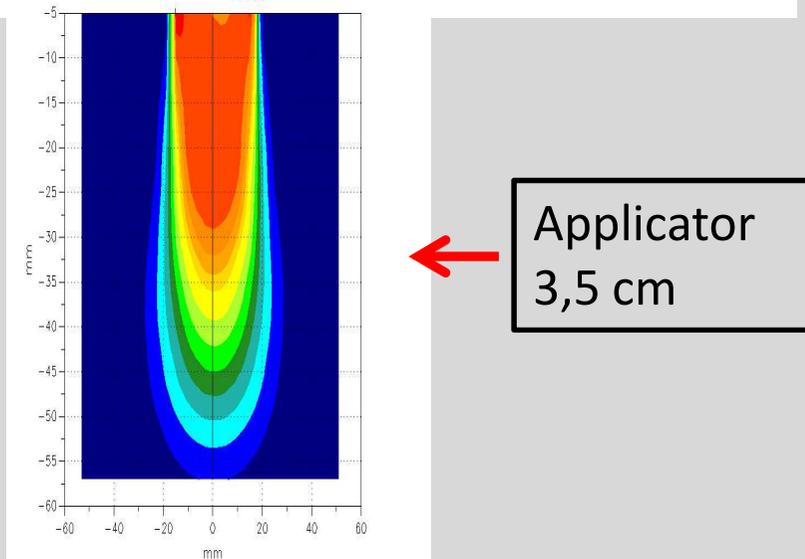
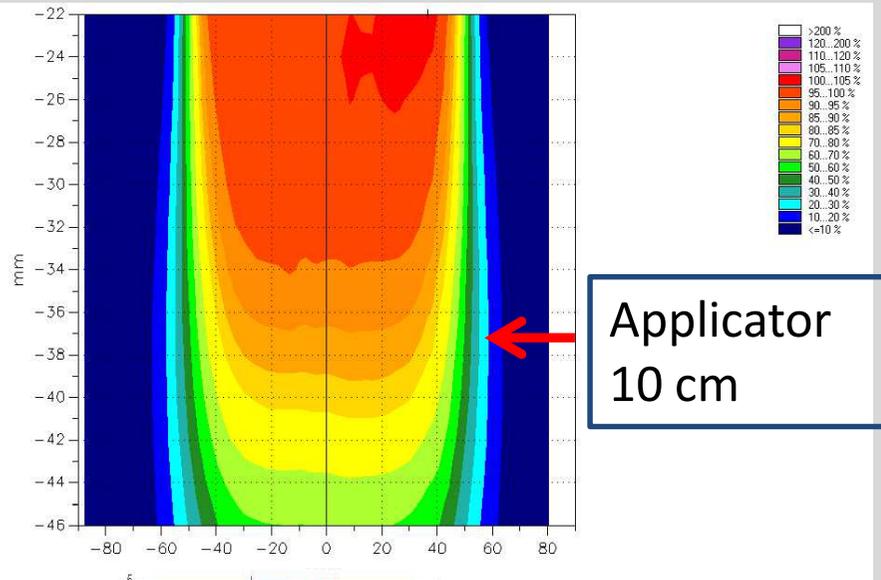
12 MeV, applicator diameter = 5 cm

FLAT

BEVEL 30°



Typical isodose distribution measured from MOBETRON 12 MeV

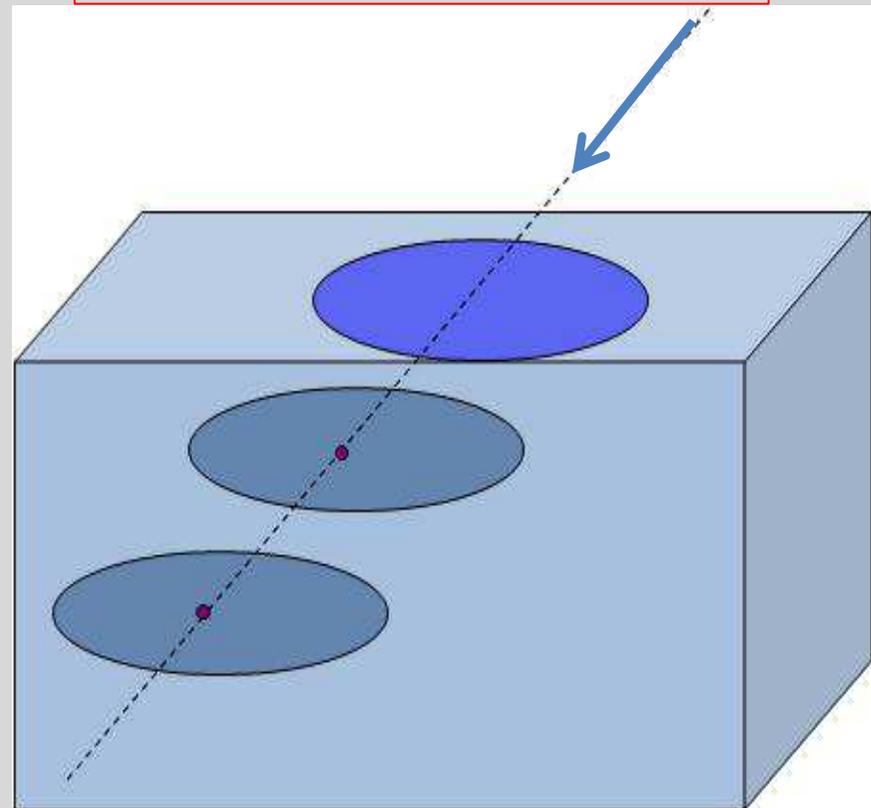


Leakage beams profile that extend beyond the applicator walls are needed to estimate the dose to normal tissue close to the applicator

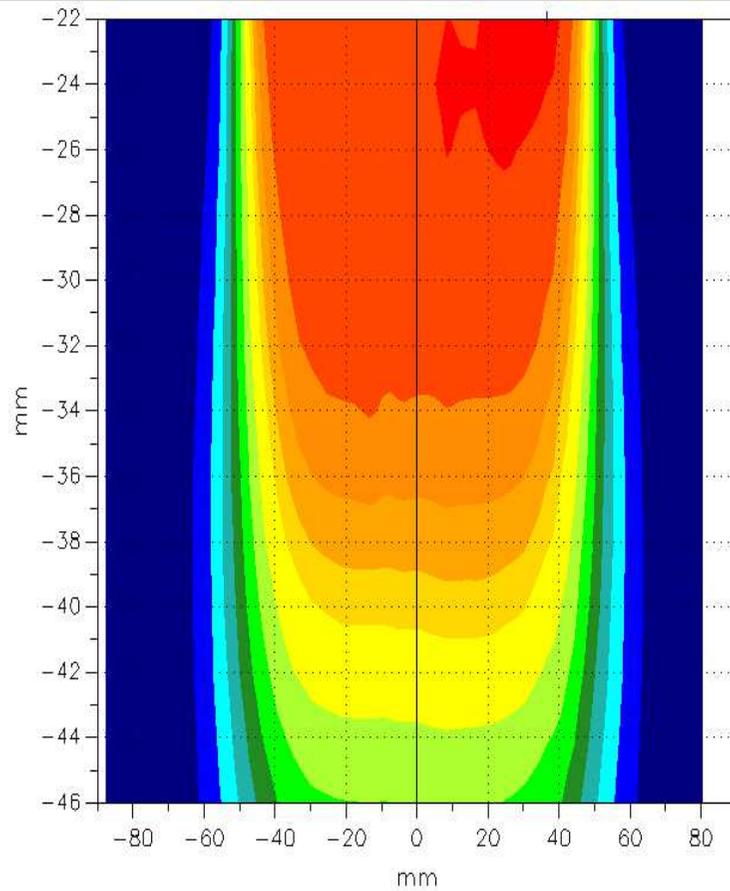
Dosimetry in non-reference condition



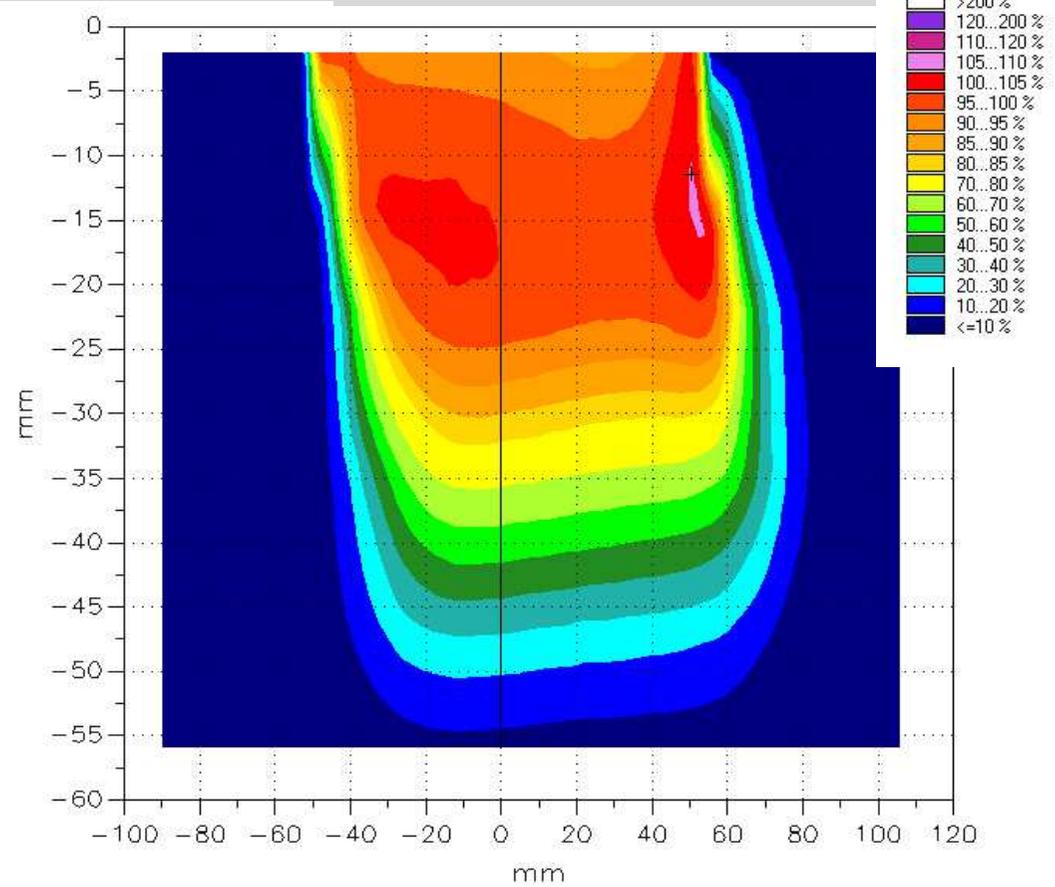
- ✓ High dose rate
- ✓ Beveled applicators



Isodose distribution , MOBETRON 12 MeV



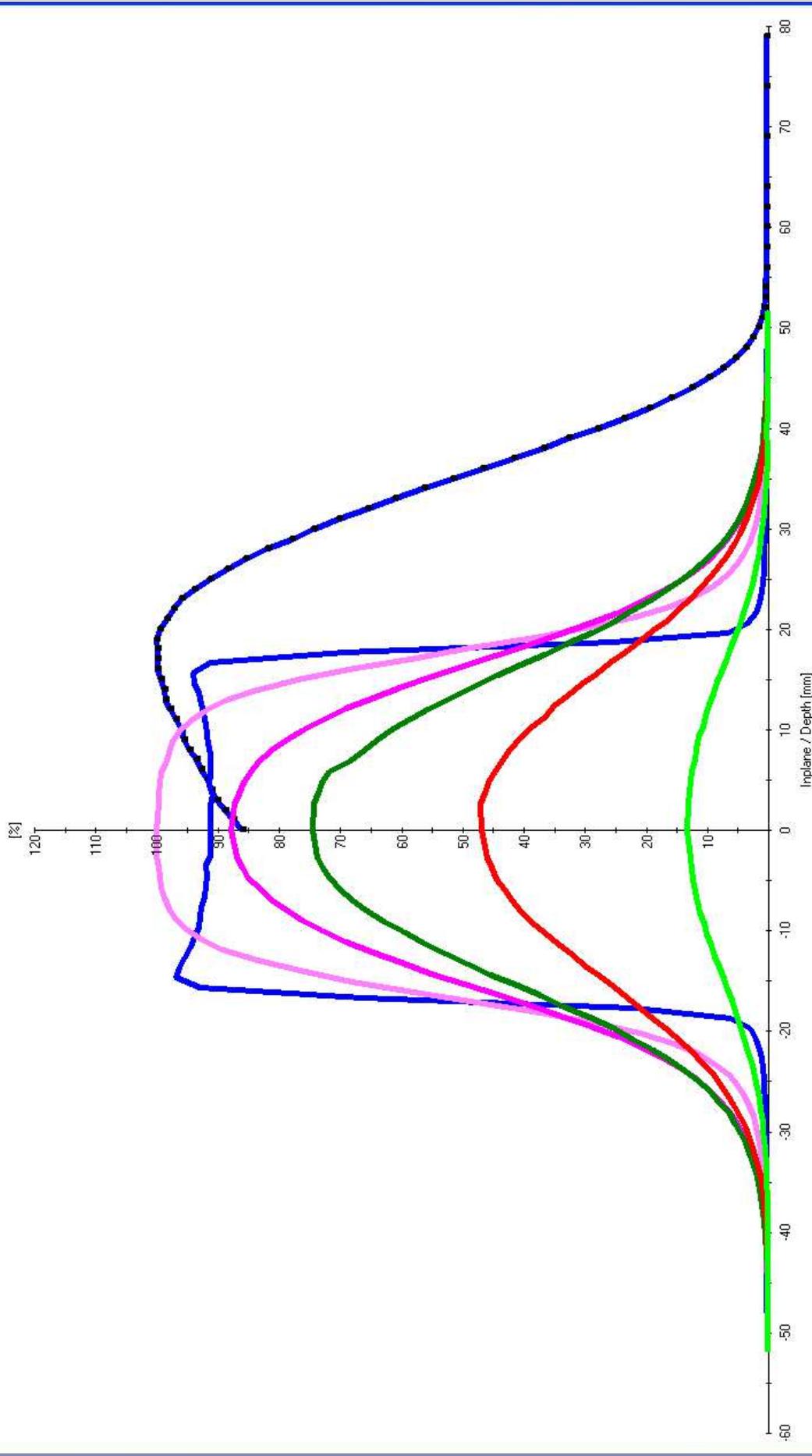
Flat applicator



30° beveled applicator

Open Close Save Analyze Process Profiles PDDs All Scans Isodoses 3D Color Wash Discrete Continuous Zoom 1:1 Size Contents

Visible	Type	Modality	Energy [MV/MeV]	Field [cm x cm]	Depth [mm]	OffAxis [mm]	Wedge/App.	Groupname	ommel	Accelerator	Block	Gantry [°]	Collimator [°]	Inplane Offset [mm]	Crossplane Offset [mm]	reas-Ang [°]	SSD [cm]	Correction
<input checked="" type="checkbox"/>	PDD	Electrons	9.00	3.5 x 3.5	---	0.00	A_3.5			MOBETRON	None	0.0	0.0	0.0	0.0	0.0*	50.0	Processed
<input checked="" type="checkbox"/>	Inplane Profile	Electrons	9.00	3.5 x 3.5	5.00	0.00	A_3.5			MOBETRON	None	0.0	0.0	0.0	0.0	0.0*	50.0	Raw Data
<input checked="" type="checkbox"/>	Inplane Profile	Electrons	9.00	3.5 x 3.5	18.00	0.00	A_3.5			MOBETRON	None	0.0	0.0	0.0	0.0	0.0*	50.0	Raw Data
<input checked="" type="checkbox"/>	Inplane Profile	Electrons	9.00	3.5 x 3.5	27.00	0.00	A_3.5			MOBETRON	None	0.0	0.0	0.0	0.0	0.0*	50.0	Raw Data
<input checked="" type="checkbox"/>	Inplane Profile	Electrons	9.00	3.5 x 3.5	31.00	0.00	A_3.5			MOBETRON	None	0.0	0.0	0.0	0.0	0.0*	50.0	Raw Data
<input checked="" type="checkbox"/>	Inplane Profile	Electrons	9.00	3.5 x 3.5	37.00	0.00	A_3.5			MOBETRON	None	0.0	0.0	0.0	0.0	0.0*	50.0	Raw Data
<input checked="" type="checkbox"/>	Inplane Profile	Electrons	9.00	3.5 x 3.5	45.00	0.00	A_3.5			MOBETRON	None	0.0	0.0	0.0	0.0	0.0*	50.0	Raw Data



PTW-DataAnalyze

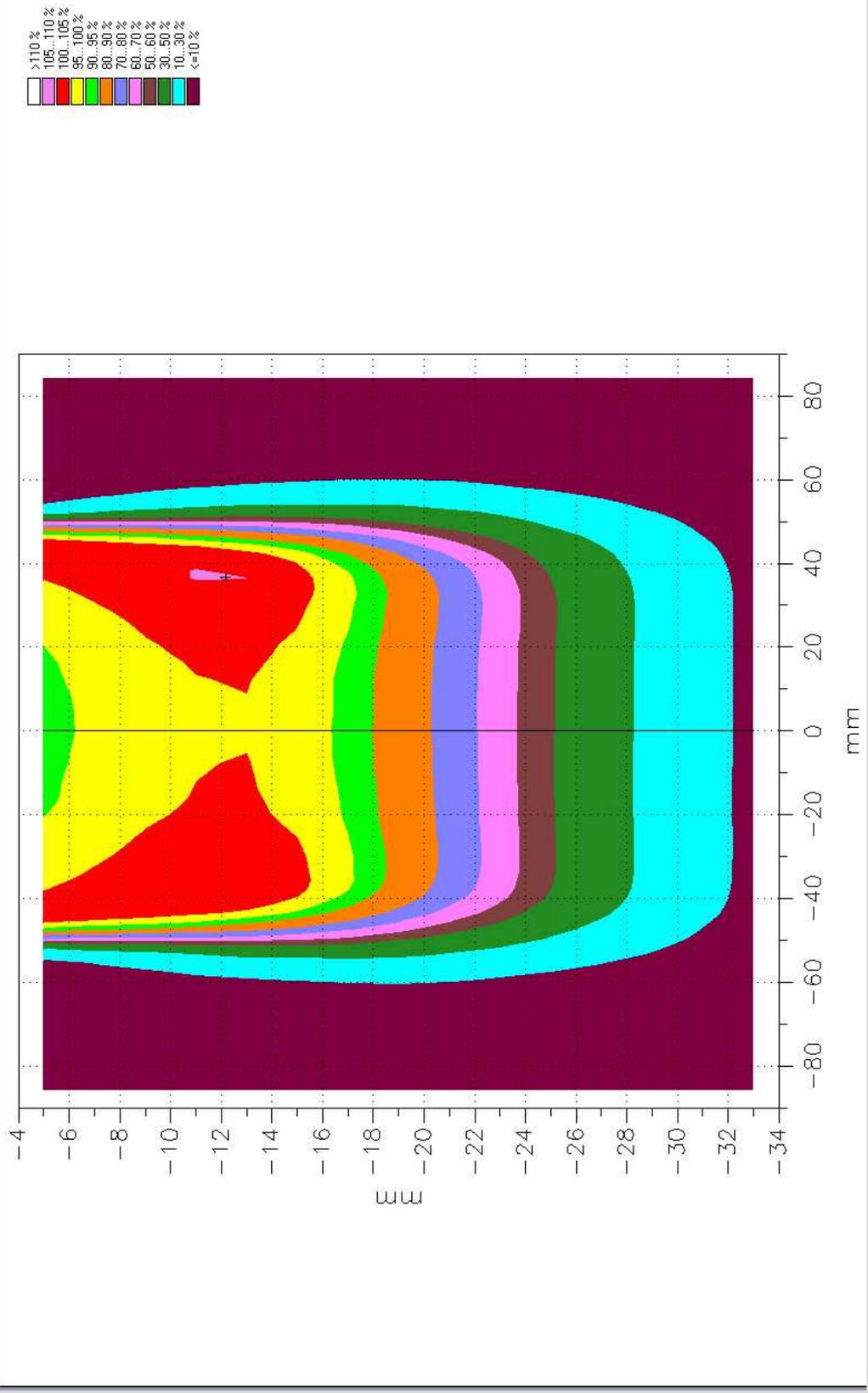
File Edit View Graphics Tools Window

Open Close Save Analyze Process

Profiles PDDs All Scans Isodoses 3D Color Wash Discrete Continuous Zoom 1:1 Size Contents

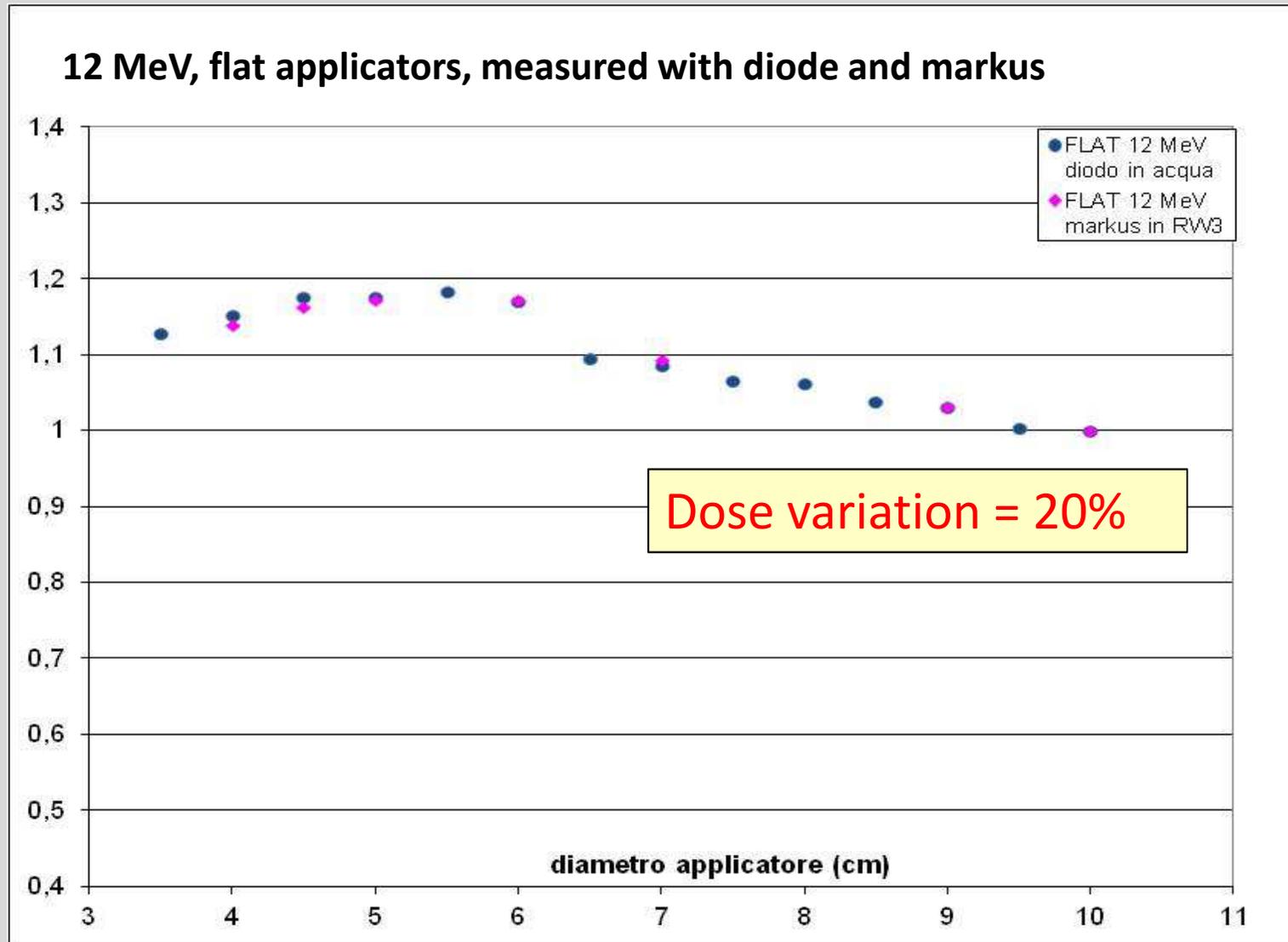
Type Modality Energy [MV/MeV] Field [cm x cm] Depth [mm] DOffAxis [mm] Wedge/App. Groupname Comment Accelerator Block Gantry Collimator Inplane Offset [mm] Crossplane Offset [mm] es.Angle [°] SSD [cm] Correction

Matrix Electrons 6.00 10.0 x 10.0 0.00 A_10 400BETRON None 0.0 0.0 0.0 0.0 50.0 Raw Data

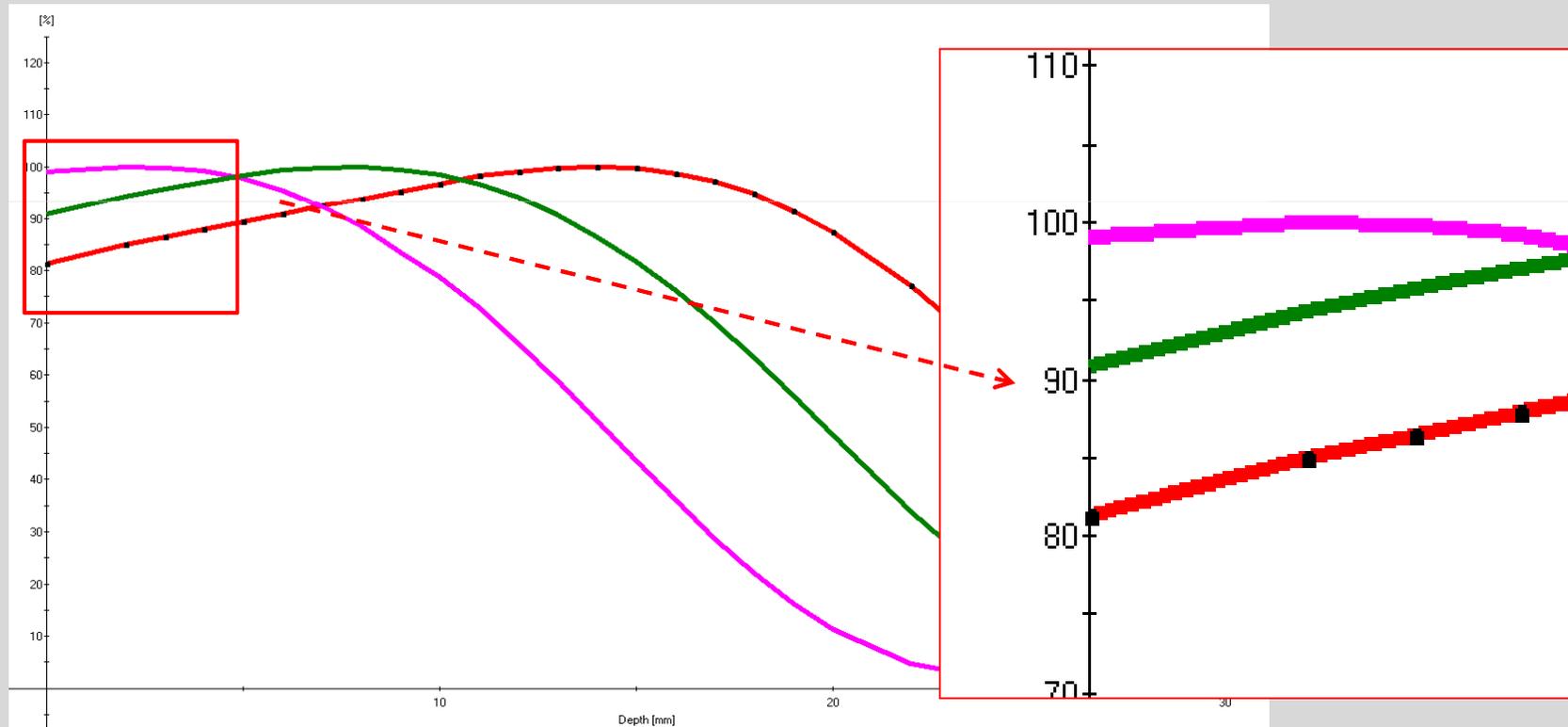


Applicator factors

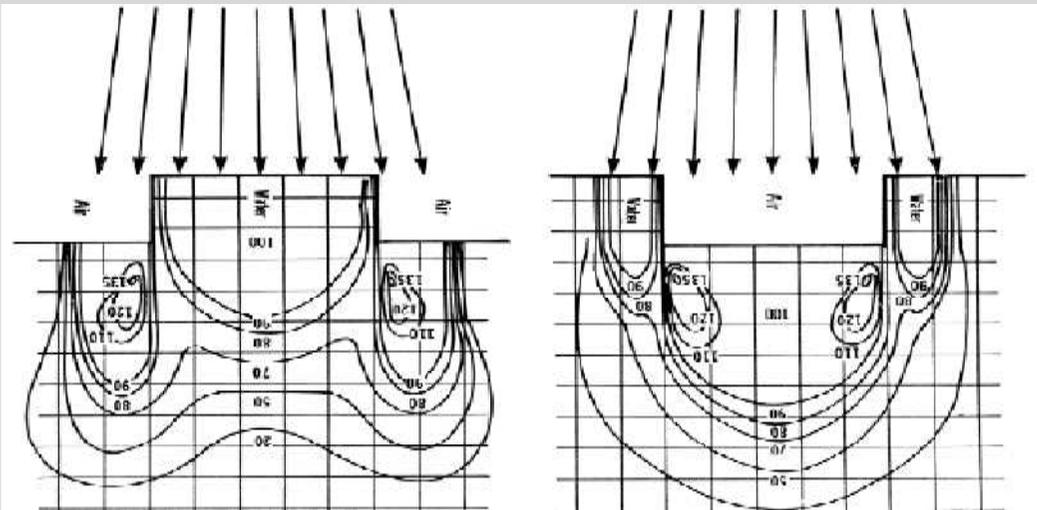
(# energy * # applicators= 132 combinations)



BOLUS



AIR GAP

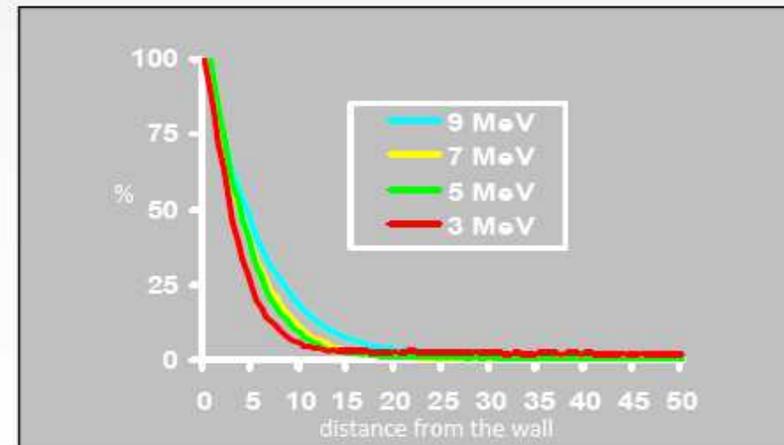
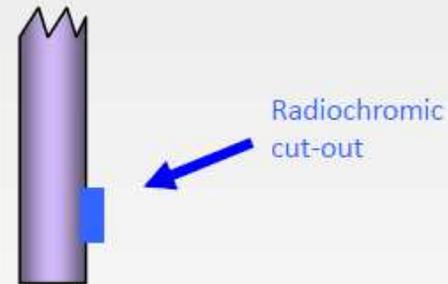


$$OF_{\text{gap}} = OF_{50} \left[\frac{50}{50 + \text{gap}} \right]^2$$

Dimensione applicatore (cm)	Gap aria (cm)	OF	Energia (MeV)		
			6	9	12
10	0,5	misurato	0,991	0,981	0,989
		formula	0,980	0,980	0,980
	1	misurato	0,975	0,971	0,976
		formula	0,961	0,961	0,961
5	0,5	misurato	0,972	/	0,986
		formula	0,980	/	0,980
	1	misurato	0,958	/	0,972
		formula	0,961	/	0,961

Radiation leakage

- ✧ It is recommended to estimate the % of the radiation scattered through the applicator's walls, as a function of the beam energy and of the distance from the walls and from the base of the applicator
- ✧ Solid phantom plus radiochromic films or TLD



Quality Assurance recommendations

TABLE IV. Summary of the quality assurance recommendations for mobile electron accelerators used for IORT.

Parameter	Tolerance	Action level
Day of use		
Output constancy	3%	Recommended
Energy constancy	Range of energy ratios corresponding to 2-mm shift in depth dose	Recommended
Door interlocks	Functional	Recommended
Mechanical motions	Functional	Recommended
Docking system	Functional	Recommended
Monthly		
Output constancy	2%	Recommended
Energy constancy	Range of energy ratios corresponding to 2-mm shift in depth dose	Recommended
Flatness and symmetry constancy	3%	Recommended
Docking system	Functional	Recommended
Emergency off	Functional	Recommended
Annually		
Output calibration for reference conditions	2%	Required
Percent depth dose for standard applicator	2 mm in depth over the range of clinical interest	Required
Percent depth dose for selected applicators	2 mm in depth over the range of clinical interest	Recommended
Flatness and symmetry for standard applicator	2%	Required
Flatness and symmetry for selected applicators	3%	Recommended
Applicator output factors	2-3 %	Recommended
Monitor chamber linearity	1%	Recommended
Output, PDD, and profile constancy over the range of machine orientations	As above	Recommended
Inspection of all devices normally kept sterile	Functional	Recommended

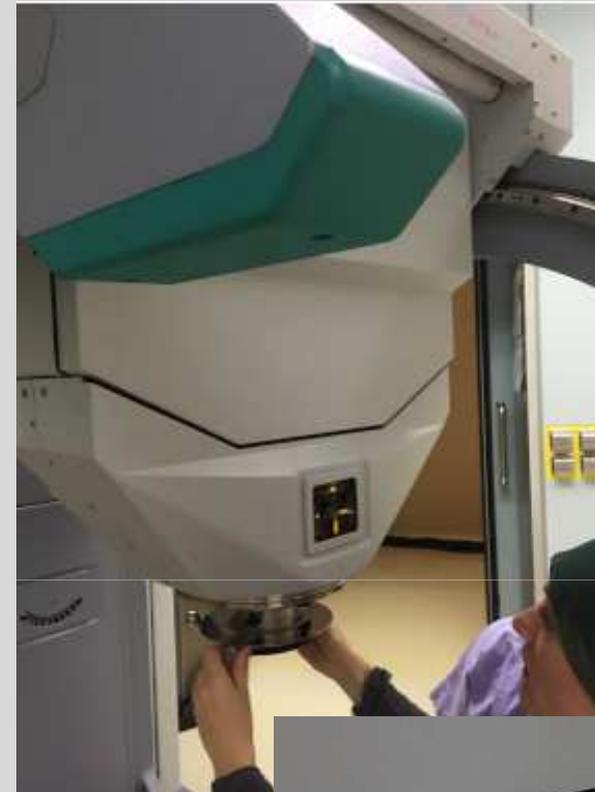
TRIESTE EXPERIENCE in breast IOERT



In 2012, the Department of Radiotherapy of the “*Ospedali Riuniti di Trieste*” has acquired a dedicated accelerator, the Mobetron for an intraoperative radiation therapy (IORT), and the clinical activity has started at the end of June 2012

More than 90 patients have been treated for breast cancer.

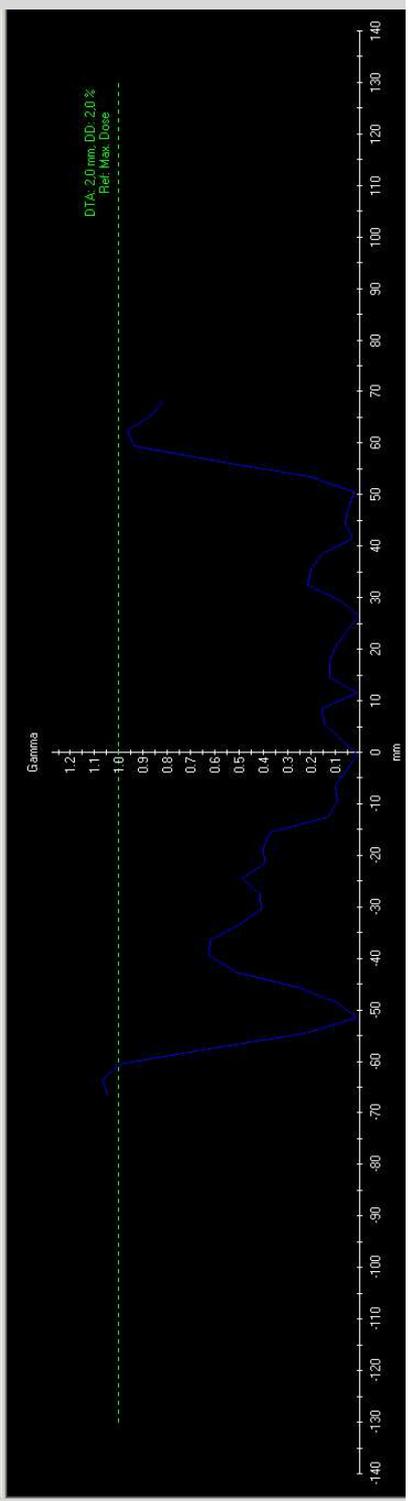
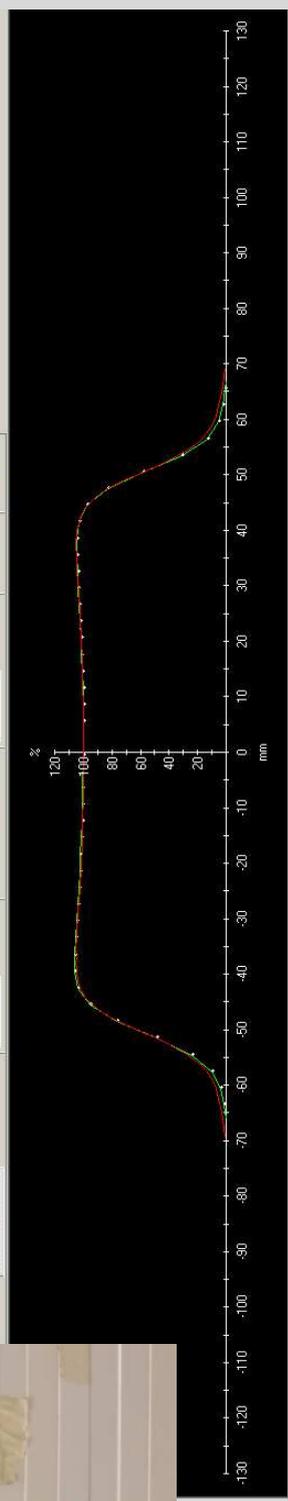
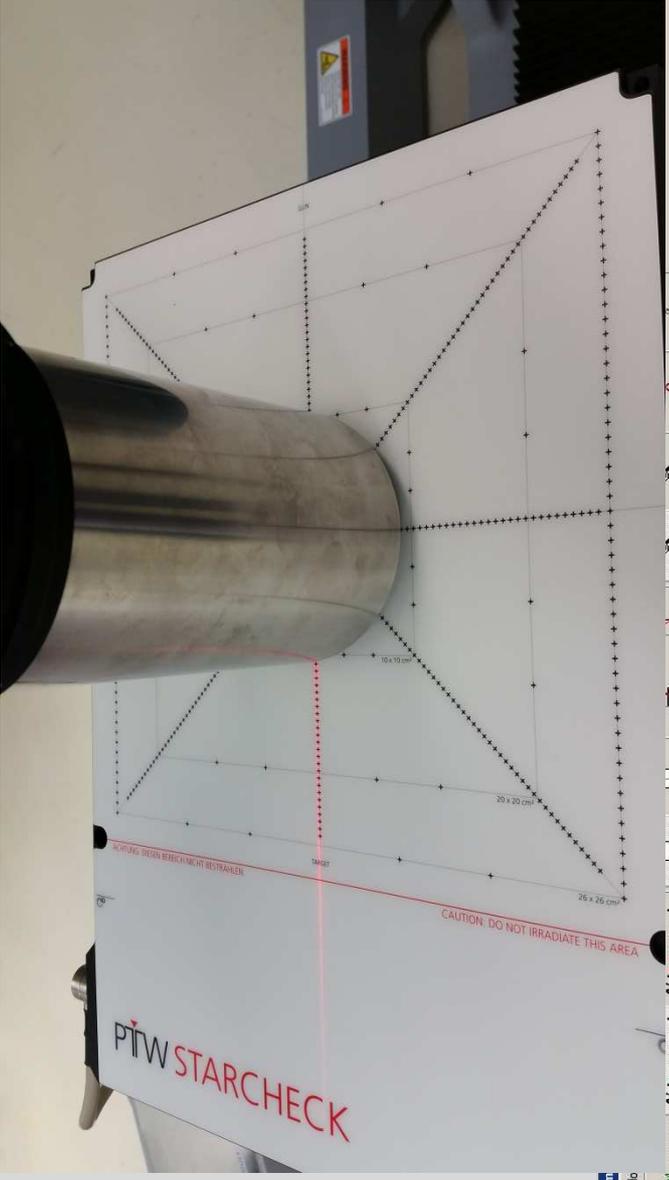
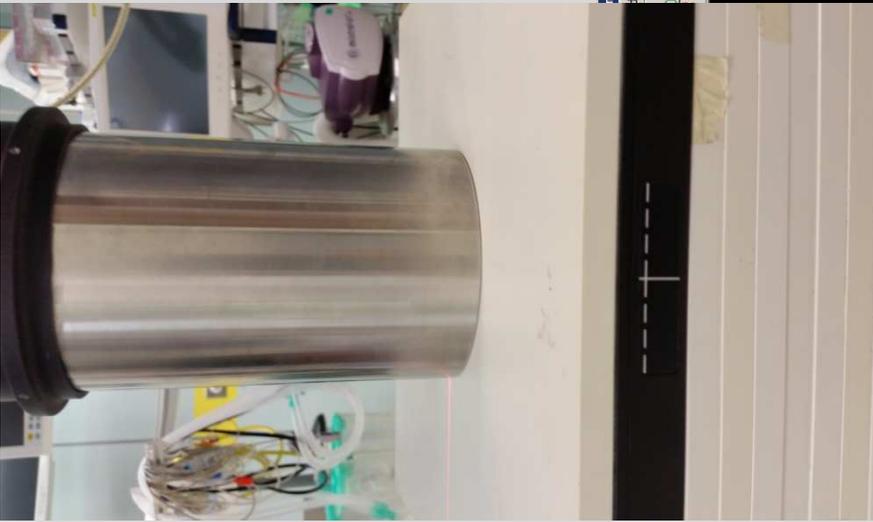
Daily QA



- a) **OUTPUT CONSTANCY**
- b) **ENERGY CONSTANCY**
- c) **LASER DOCKING SYSTEM FUNCTIONALITY**
- d) **MOVIMENTS FUNCIONALITY**

Periodic QA





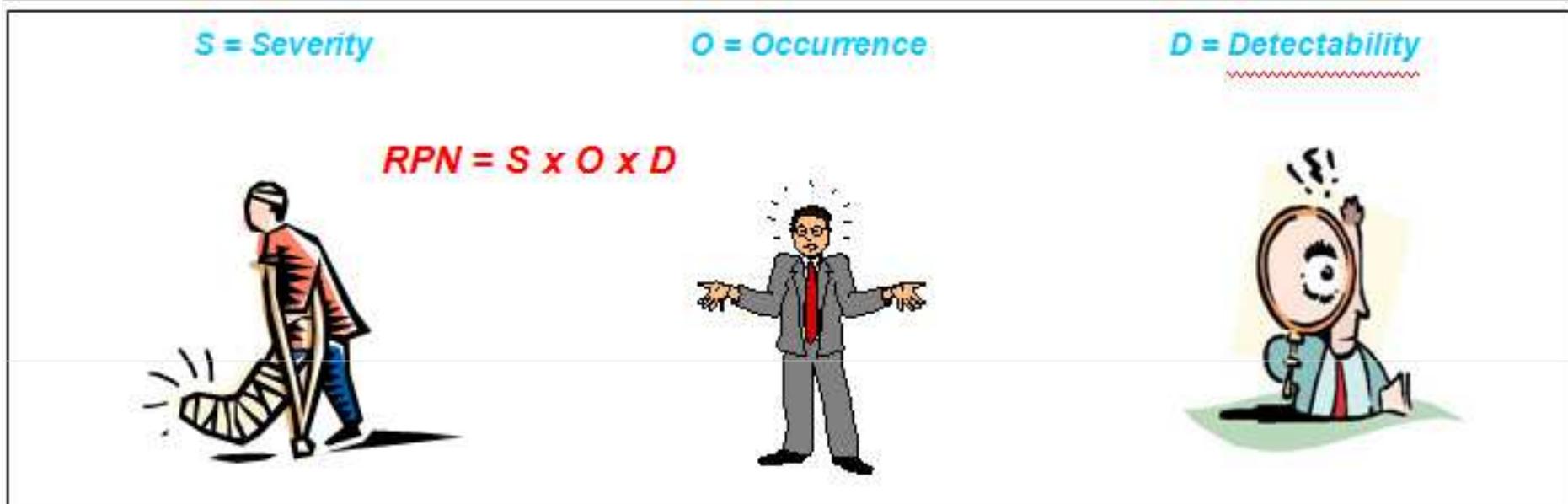
FMECA: Methodological steps

Failure Mode and Effects Analysis (FMEA) and Failure Modes, Effects and Criticality Analysis (FMECA) are methodologies designed to **identify potential failure modes** for a product or process, **to assess the risk associated with those failure modes**, **to rank the issues in terms of importance** and to identify and carry out corrective actions to address the most serious concerns.

- **Step 1 define analysis object** (breast IOERT)
- **Step 2 establish working group** (Radiation Oncologist, Medical Physicist, Surgeon, Anesthesiologist, Radiotherapy Technicians, nurse)
- **Step 3 describe the process** (flow chart of IOERT)
- **Step 4 analysis** (identify the criticisms, sources of risk potential failure mode (FM), evaluate risk priority number (RPN))
- **Step 5 corrective actions**

FMECA

(Failure Mode and Effects Criticality Analysis)



The risk analysis was completed by asking the members of the team to evaluate the **Risk priority number (RPN)** of each FM, obtained by multiplying the estimated frequency of occurrence (O) by the detectability (D) of the FM and the expected severity of the damage to the patient (S), using a 5-point scale (from 1 to 5) for each parameter; thus the lowest score is 1 and the highest score is 125. The smaller the RPN, the lower is the risk; the larger the RPN, the higher is the risk.

FMECA High risk processes

PROCESS STEP	PROFESSIONAL FIGURES	PROCEDURE	FAILURE MODE	FAILURE EFFECTS	FAILURE CAUSES	INITIAL RISK RANKING				CORRECTIVE ACTIONS	REVISED RISK RANKING			
14	Radiation Oncologist -Surgeon	Definition of the CTV	Wrong definition of the CTV	Underdose of the CTV and/or unintended normal tissues irradiation	Inadequate evaluation of the CTV	4	4	4	64	Evaluation of the tumour dimensions on preoperative medical imaging; accurate intraoperative definition of the CTV	4	2	2	16
18	Physicist	Preparation of gafchromic film and placement on the perspex bolus	1) Inadequate placement	Wrong measure of the delivered dose	Erroneous observation of the "In vivo dosimetry" Procedure	4	3	5	60	Careful observation of the "In vivo dosimetry" Procedure	4	2	4	32
			2) Wrong calibration, use, conservation of the gafchromic film											
19	Radiation Oncologist -Surgeon	Applicator placement	Absent or incomplete adherence of the applicator to the tumour bed	Non-homogeneous irradiation	Air gap presence, blood accumulation, very sloping tumour bed	4	4	4	64	Accurate visual control, correct placement of the patient on the operating table	4	3	3	36
20	Radiation Oncologist -Surgeon	Alignment of the protective plate	Misalignment of the protective plate	Unintended normal tissues irradiation below the tumour bed	Low accuracy in the alignment	5	4	4	80	Selection of a plate much larger than the applicator size	5	3	4	60

severity

occurrence

detectability

IOERT in vivo dosimetry

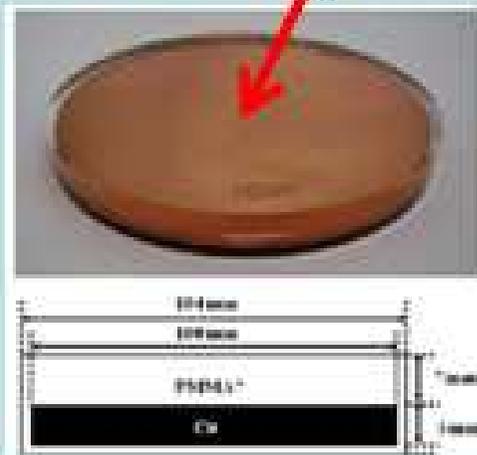
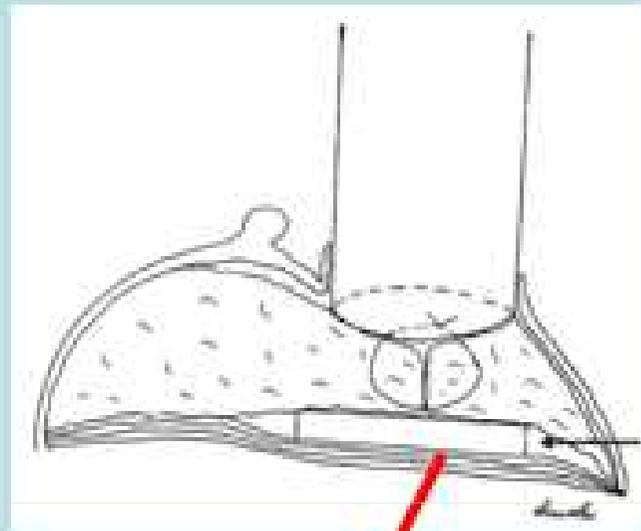
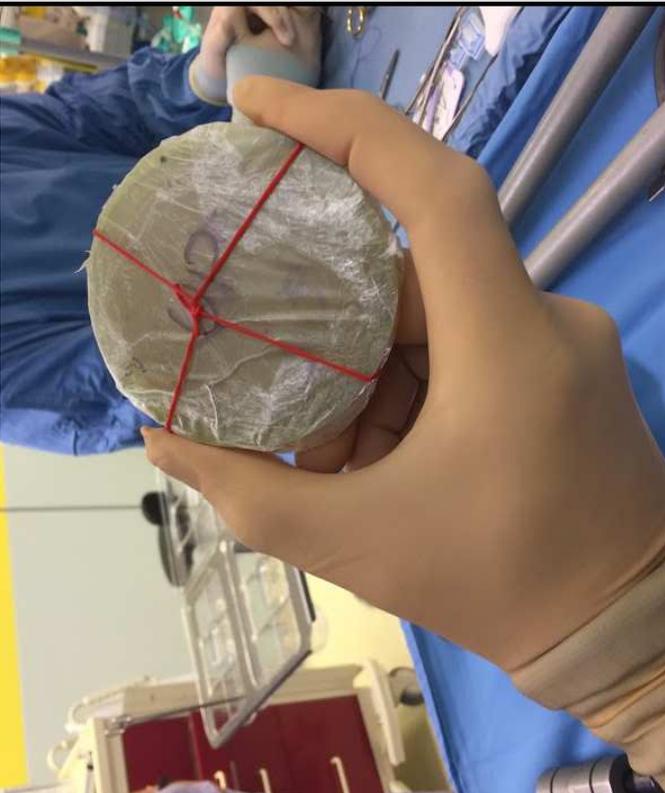


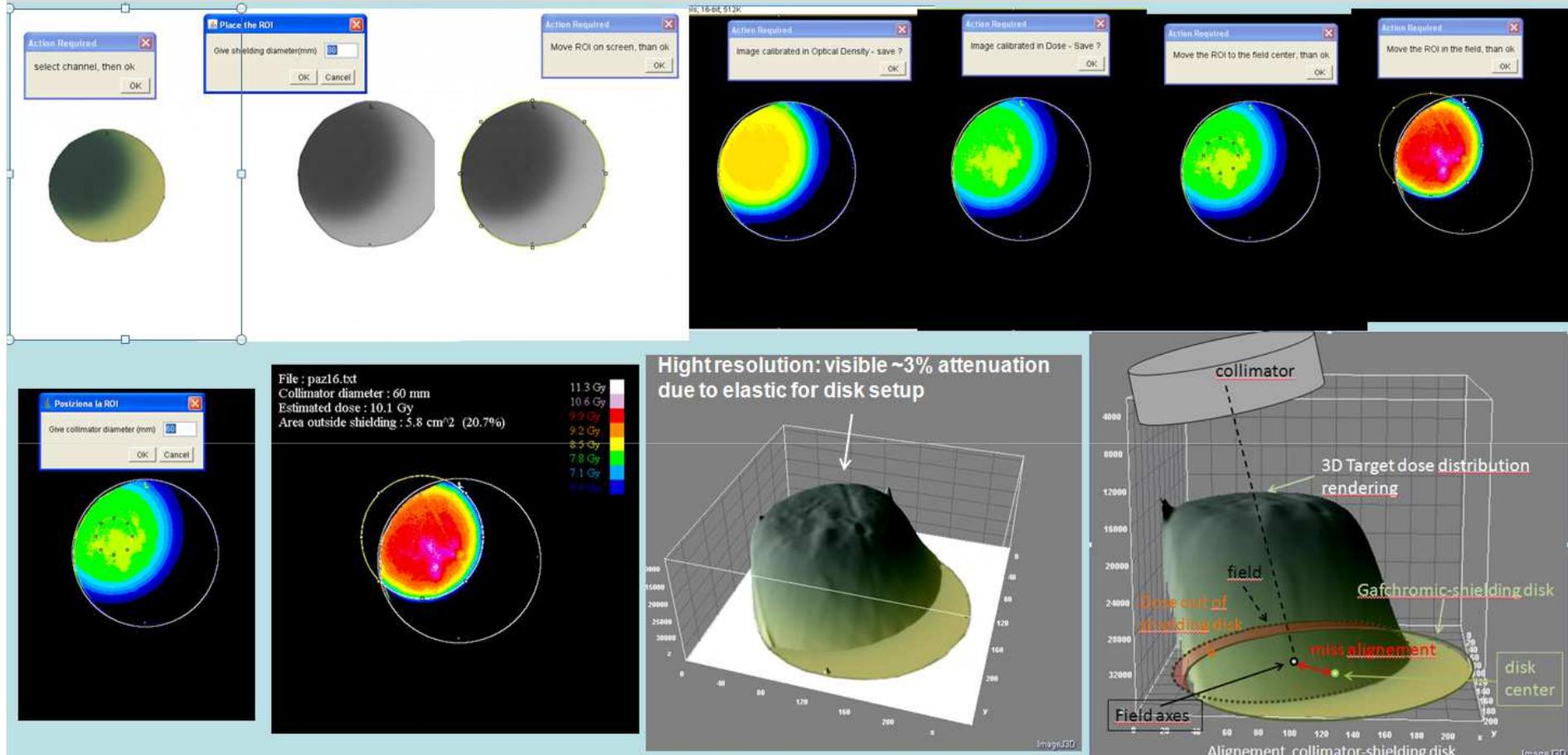
Fig.1 Reference to World J Surg (2009) 33:2587–2592



Fig.2 Picture of the shielding placement and gafchromic films at the two side of the shield after treatment



EBT3 gafchromic film analysis



JOURNAL OF APPLIED CLINICAL MEDICAL PHYSICS, VOLUME 16, NUMBER 1, 2015

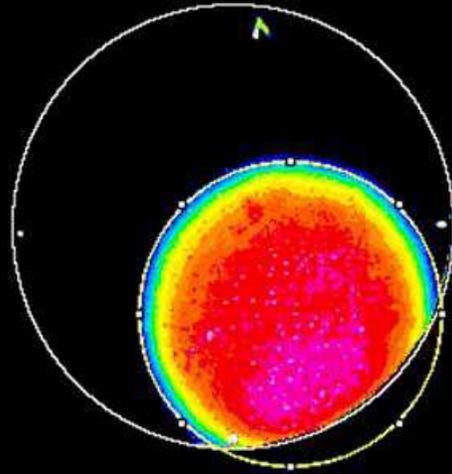
***In vivo* dosimetry and shielding disk alignment verification by EBT3 GAFCHROMIC film in breast IOERT treatment**

Mara Severgnini,^{1*} Mario de Denaro,¹ Marina Bortul,² Cristiana Vidali,³
Aulo Beorchia³

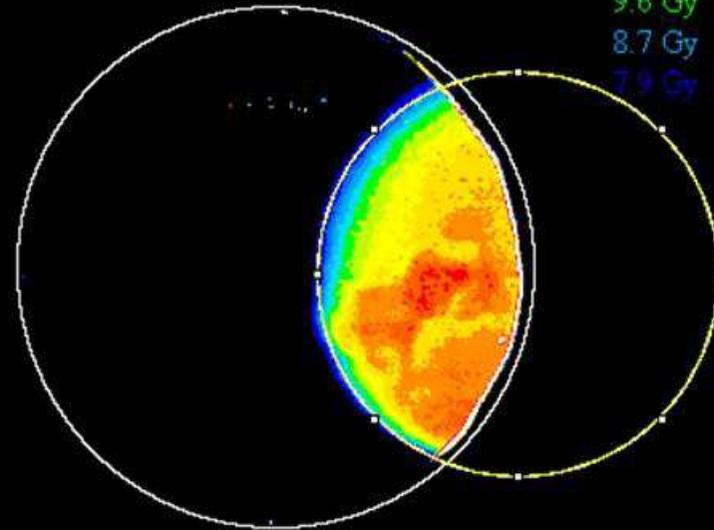
*Department of Medical Physics;*¹ *Department of Surgery;*² *Department of Radiation Oncology;*³ *A.O.U. Ospedali Riuniti, Trieste, Italy*
mar.severgnini@aots.sanita.fvg.it

Misalignment examples

File : paz14finale.txt
Collimator diameter : 55 mm
Estimated dose : 10.5 Gy
Area outside shielding : 2.1 cm² (8.9%)

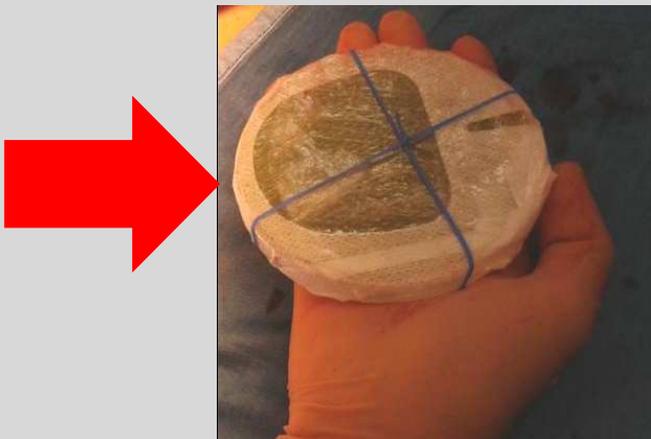
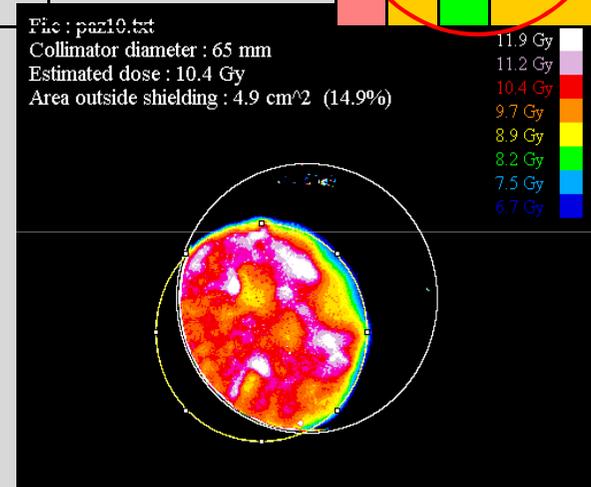
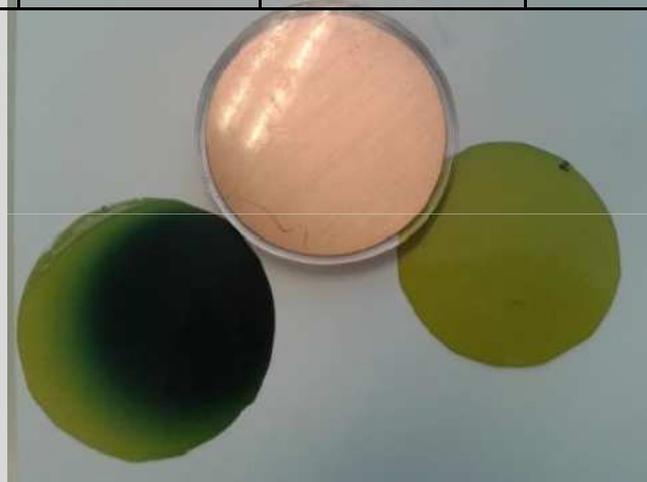


70 mm
6 Gy
g : 21.2 cm² (55.3%)



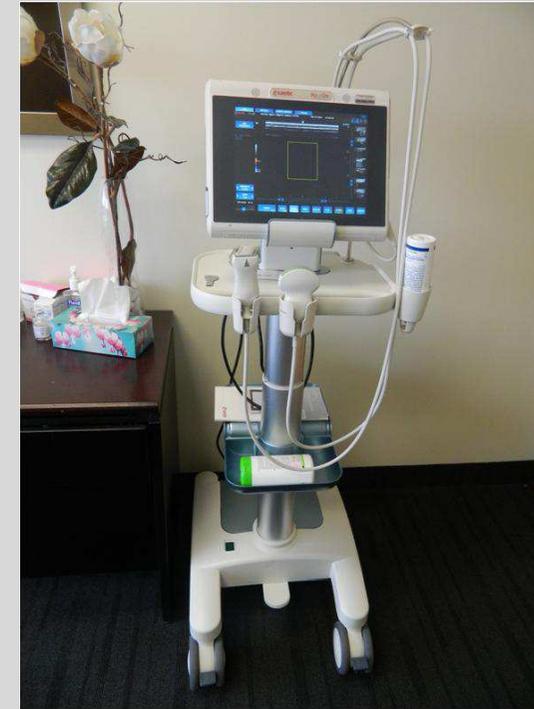
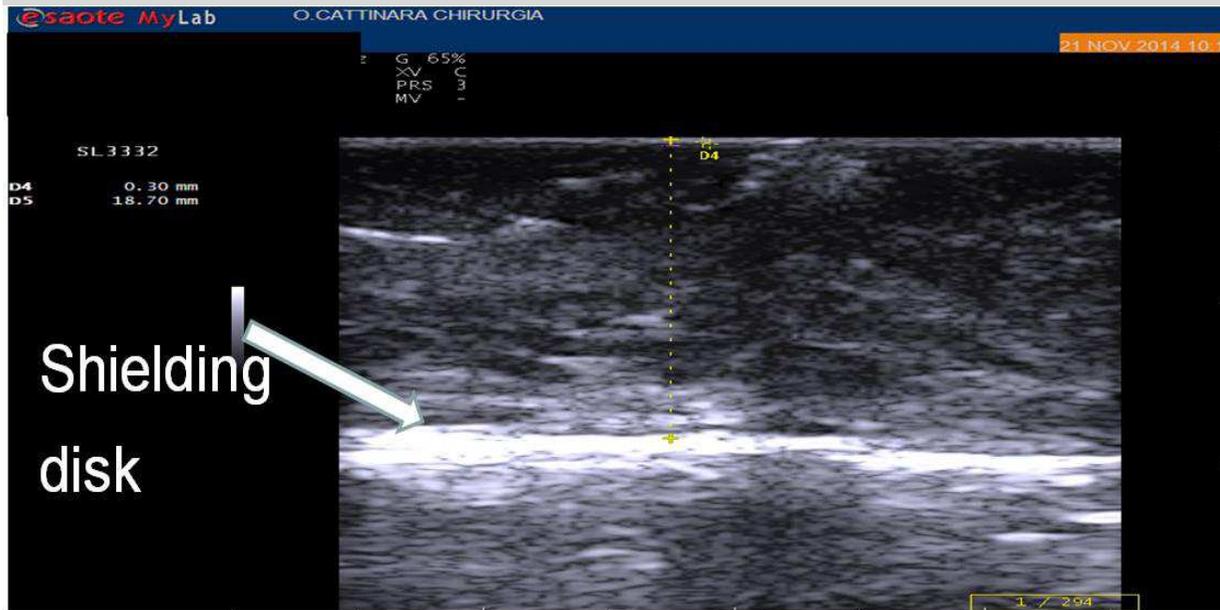
Most critical step

PROCESS STEP	PROFESSIONAL FIGURES	PROCEDURE	FAILURE MODE	FAILURE EFFECTS	FAILURE CAUSES	INITIAL RISK RANKING
20	Radiation Oncologist - Surgeon	Alignment of the protective plate	Misalignment of the protective plate	Unintended normal tissues irradiation below the tumour bed	Low accuracy in the alignment	5 4 4 80

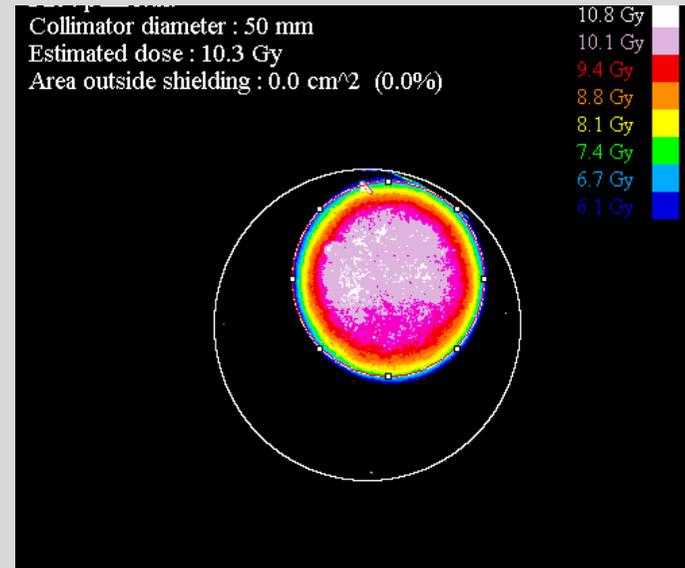


INITIAL RISK RANKING				CORRECTIVE ACTIONS	REVISED RISK RANKING			
5	4	4	80	Selection of a plate much larger than the applicator size and new setup	5	3	4	60

Ultrasound introduction



INITIAL RISK RANKING				CORRECTIVE ACTIONS	REVISED RISK RANKING			
5	3	4	60	Selection of a plate much larger than the applicator size and new setup ULTRASOUND	5	3	2	30





Immediate
Feedback!

Thick measurement: comparison between needle and ultrasound

Negligible average difference of 0,1 mm (range 0,1-1,2)

patient	data	method	point1 mm	point2 mm	point3 mm	point4 mm	point5 mm	average mm	STD	ultrasound vs needle mm
44	21/11/14	needle	14,0	13,0	9,0	10,0	14,0	12,0	2,3	0,2
		ultrasound	11,8	10,3	n.a.	n.a.	14,5	12,2	2,1	
45	05/12/14	needle	11,0	13,0	18,0	17,0	n.a.	14,8	3,3	-0,3
		ultrasound	10,3	14,0	16,9	16,6	n.a.	14,4	3,1	
46	19/12/14	needle	7,0	11,0	6,0	10,0	13,0	9,4	2,9	-0,4
		ultrasound	8,8	9,3	9,0	8,9	n.a.	9,0	0,2	
47	09/01/15	needle	10,0	13,0	11,0	8,0	8,0	10,0	2,1	0,4
		ultrasound	9,4	12,0	12,8	8,1	9,5	10,4	2,0	
48	16/01/15	needle	11,0	14,0	12,0	10,5	11,0	11,7	1,4	0,3
		ultrasound	10,4	15,0	11,5	11,5	11,8	12,0	1,7	
49	23/01/15	needle	15,0	9,0	12,0	9,0	13,0	11,6	2,6	0,0
		ultrasound	11,5	10,8	13,4	7,9	14,6	11,6	2,6	
50	29/01/15	needle	5,0	5,0	6,0	6,0	6,0	5,6	0,5	0,2
		ultrasound	5,0	5,9	6,4	5,3	6,4	5,8	0,6	
51	29/02/15	needle	5,0	9,0	6,0	9,0	4,0	6,6	2,3	0,5
		ultrasound	5,6	8,7	5,7	10,1	5,2	7,1	2,2	
52	05/03/15	needle	15,0	14,0	11,0	14,0	12,0	13,2	1,6	-0,8
		ultrasound	13,4	14,0	10,9	13,5	10,3	12,4	1,7	
53	19/03/15	needle	15,0	14,0	20,0	15,0	18,0	16,4	2,5	-0,5
		ultrasound	16,6	14,3	18,4	13,9	16,2	15,9	1,8	
54	23/04/15	needle	10,9	12,0	11,2	10,0	13,0	11,4	1,1	-0,4
		ultrasound	10,0	12,0	12,0	9,0	12,0	11,0	1,4	
55	30/05/15	needle	11,0	6,0	13,0	15,0	9,0	10,8	3,5	-1,2
		ultrasound	10,0	5,2	13,5	10,7	8,4	9,6	3,1	
56	07/05/15	needle	8,0	10,0	9,0	9,0	9,0	9,0	0,7	0,2
		ultrasound	7,6	9,1	10,6	9,1	9,5	9,2	1,1	
57	14/05/15	needle	7,0	8,0	5,0	5,0	5,0	6,0	1,4	0,3
		ultrasound	7,1	7,5	6,4	4,7	6,1	6,3	1,1	
58	28/05/15	needle	10,0	10,0	14,0	10,0	11,0	11,0	1,7	-0,4
		ultrasound	10,9	9,0	14,5	9,0	9,5	10,6	2,3	
59	11/06/15	needle	13,0	9,0	9,0	15,0	8,0	10,8	3,0	-0,6
		ultrasound	11,3	8,3	8,3	14,6	8,5	10,2	2,8	
60	18/06/15	needle	5,5	5,5	9,0	4,0	n.a.	6,0	2,1	0,9
		ultrasound	6,1	5,8	8,7	6,8	n.a.	6,9	1,3	
61	08/10/15	needle	16,0	9,0	16,0	11,0	15,6	13,5	3,3	-0,1
		ultrasound	16,0	8,7	15,5	12,0	14,7	13,4	3,0	
62	15/10/15	needle	10,0	10,0	9,0	5,0	9,0	8,6	2,1	-0,1
		ultrasound	9,9	9,8	10,3	4,1	8,4	8,5	2,5	
63	29/10/15	needle	9,0	11,0	7,0	7,0	15,0	9,8	3,3	0,1
		ultrasound	9,7	11,8	6,6	7,4	14,1	9,9	3,1	

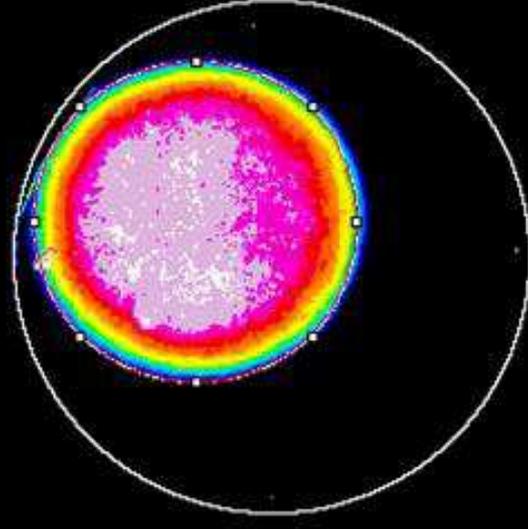
- The EBT3 in vivo dosimetry confirmed that the ultrasound application reduced the misalignment in terms of electrons field area outside the shielding disk from 5.6cm^2 to 2.6cm^2
- The percentage of patients in which the shield is perfectly aligned (field totally inside the shield) after sonography introduction improved from 23% to 68%

3 time more probable to have perfect alignment between collimator and disk

Collimator diameter : 50 mm

Estimated dose : 10.3 Gy

Area outside shielding : 0.0 cm² (0.0%)



- Intraoperative Sonography showed to be accurate in the evaluation of target depth
- After US addition very good results in term of dose delivered and shielding alignment have been obtained
- Significant reduction of undesirable dose

Reduction of disk misalignment score from high risk to medium risk!

Therefore, patients treated after IOUS guidance had less acute toxicity from radiation therapy (35% vs. 52%).

Thank you for your attention!

