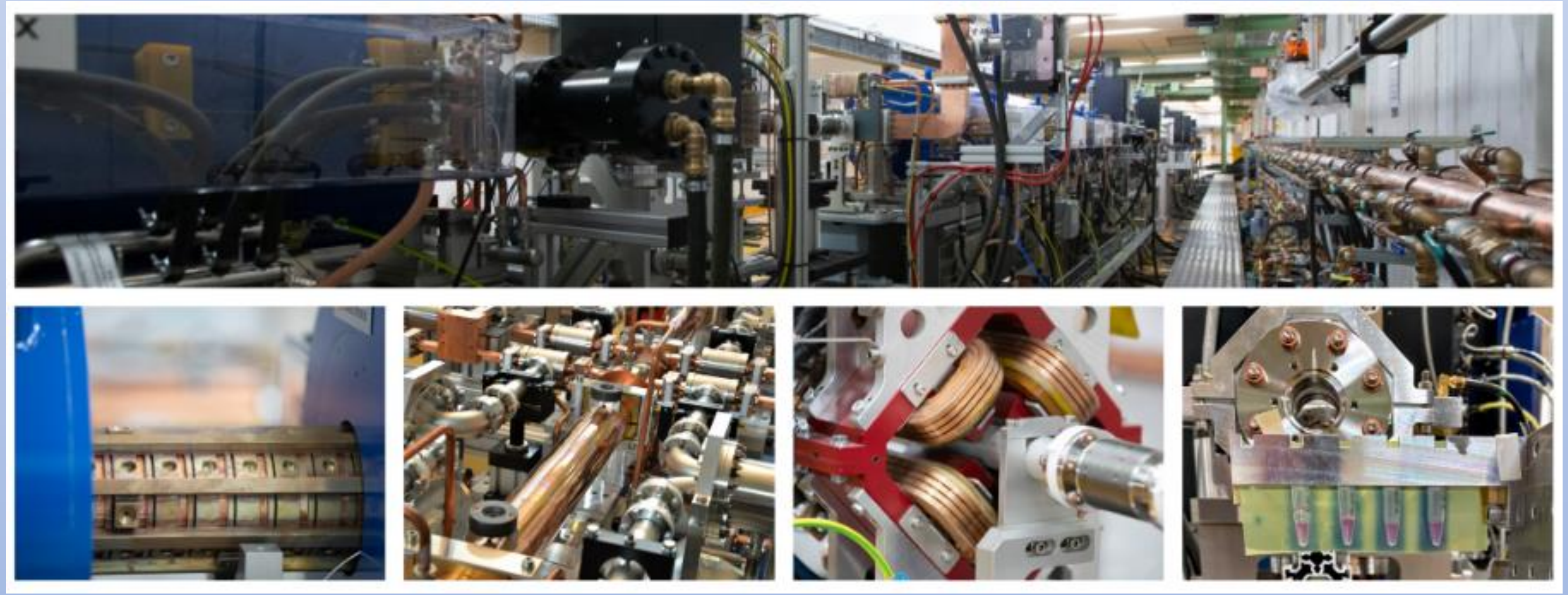
VHEE 2025

15–17 set 2025 - STFC, Daresbury Laboratory



Very High Energy Electrons: Clinical Perspective and Constraints for a Medical Device VHEE Flash

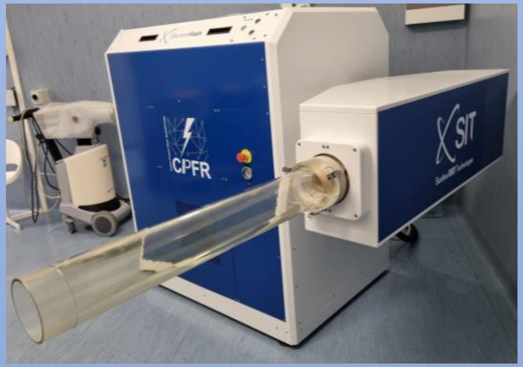
Giuseppe Felici, SIT S.p.A.

Sordina IORT Technologies

Scientific Awareness
- What are the questions?
- Identifying the challenges

Technological Development
- The most useful tools for the research;
- The right devices for clinical translation

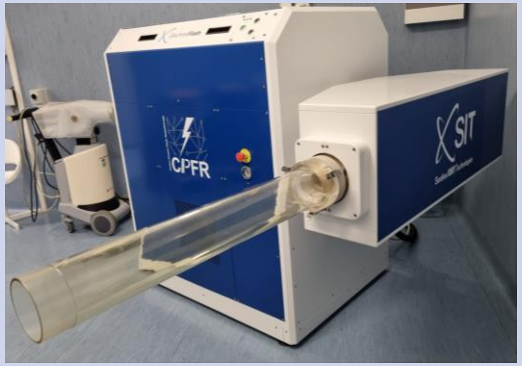
Let's find the best solutions without overshooting !



VHEE

LINAC

The pursuit of the VHEE Flash Medical Device represents the culmination of an extensive and intricate research and development trajectory.

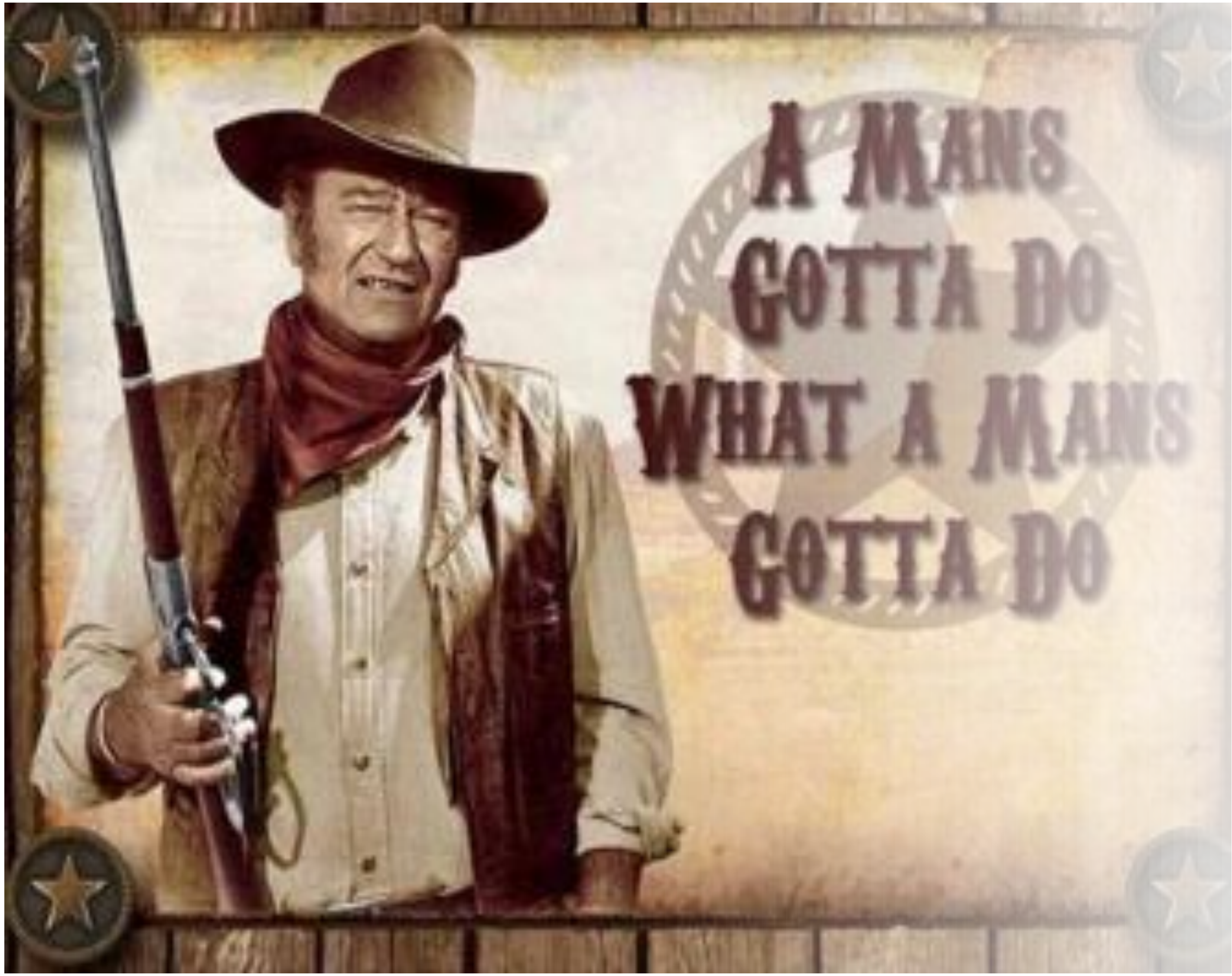
Radiobiology, basic investigation	First clinical application IOeRT and dermatologic cases	Deep seated tumours – VHEE (Very High Energy Electrons)
ElectronFlash	Chc Flash Prime	VHEE FLASH
	 	VHEE LINAC

ElectronFlash

- Adjustable mean dose rate between 0.005 – 1300 Gy/s with reference field Ø10 cm;
- Instantaneous dose rate higher than 10^6 Gy/s with reference field Ø10 cm;
- Mean dose rate up to 10.000 Gy/s with small applicator (IDR up to 10^7 Gy/s);
- Allows to modify different temporal beam structure's parameters:
  - ➢ Dose per pulse;
  - ➢ Pulse duration (0.2 – 4 µs);
  - ➢ Pulse repetition frequency (PRF: 1 -500 Hz);
- Beam monitoring:
  - ➢ Delivered dose (for each pulse and integral);
  - ➢ Beam energy;
- Optimized Human Machine interface;
- Compliant with IEC 60601-2-1.

International patent deposited in 2019, obtained in 2021

GOBIERNO DE ESPAÑA
MINISTERIO DE CIENCIA E INNOVACIÓN
Ciemat
Centro de Investigaciones Energéticas, Medioambientales y Tecnológicas



Moving to clinic ...

What a Company (SME) should do?

SIT
Sordina IORT Technologies

- Moving to clinic …

A COMPANY SHOULD DO…

A MEDICAL DEVICE

Medical Device Certification Pathway

Concept & Design
- Collection of clinical and safety requirements
- Definition of Design Inputs (ISO 13485, ISO 14971)

Prototyping & Pre-Validation
- Proof-of-concept and feasibility testing
- Initial risk analysis and bench testing

Technical Validation
- Based on VHEE-specific standard — under development
- Future dedicated standard for Very High Energy Electrons
- Electrical, mechanical, and software safety (IEC 62304, ISO 14971)

Clinical Validation
- Clinical Evaluation Report (CER) — MDR Art. 61
- Clinical studies according to ISO 14155

Certification & CE Marking
- Technical documentation review by Notified Body
- ISO 13485 quality system audit

Post-Market Surveillance
- Post-Market Clinical Follow-up (PMCF)
- Vigilance and continuous improvement

CHC FLASH Prime: World's first Flash Medical Device

- It can work both in Flash (300 Gy/s , 2 Gy/p) and Conventional Mode
- 10 and 6 MeV, both in Flash & Conv
- Dimension and weight fully compatible with any Operating Room
- Only 700 kg, just 50 kg heavier respect to HWL!
- Fast and safe commissioning thanks to a dedicated Monte Carlo based proprietary software
- Integrated with Imaging and Planning System, with a new Monte Carlo dose engine;
    - 3D US imaging integrated;
    - It can work both with US and CT-like images;
    - image guided docking
    - Treatment validation after docking
- Optimal Radiation Protection Performance
- Fully mobile system usable in multiple OR.

Chc FLASH Prime: designed to comply with IEC Standards (present and future ones)

- **Temporal beam structure (pulse duration, PRF):**
  - Irradiation parameters to be set (…). MU is not enough!
  - HMI
- **Monitoring challenge**

- **TPS:**
  - Beyond DVH: adding DRVH & IDRVH, # pulses, irradiation time…
  - Mandatory interface with Treatment Unit (IORT)

- **Radiation protection monitoring**


IEC

IEC 60601-2-1

Edition 3.0 2009-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV

And now, VHEE Flash Medical Device!

SIT works in the Italian VHEE network, together with La Sapienza. The project has been initially funded in the framework of Italian PNRR, https://www.healitalia.com/home-page .
The project has officially started on 1st December 2022.

Status of SAFEST @ Sapienza

L. Giuliano, E. Chiadroni, M. Coppola, A. Curcio, C. Di Carlo, S. Farina, G. Franciosini, M. Magi, A. Mostacci, M. Migliorati, V. Patera, R. Remetti, A. Sarti, L. Palumbo ***Sapienza University of Rome***

L. Ficcadenti, E. Lalli ***INFN – Rome***

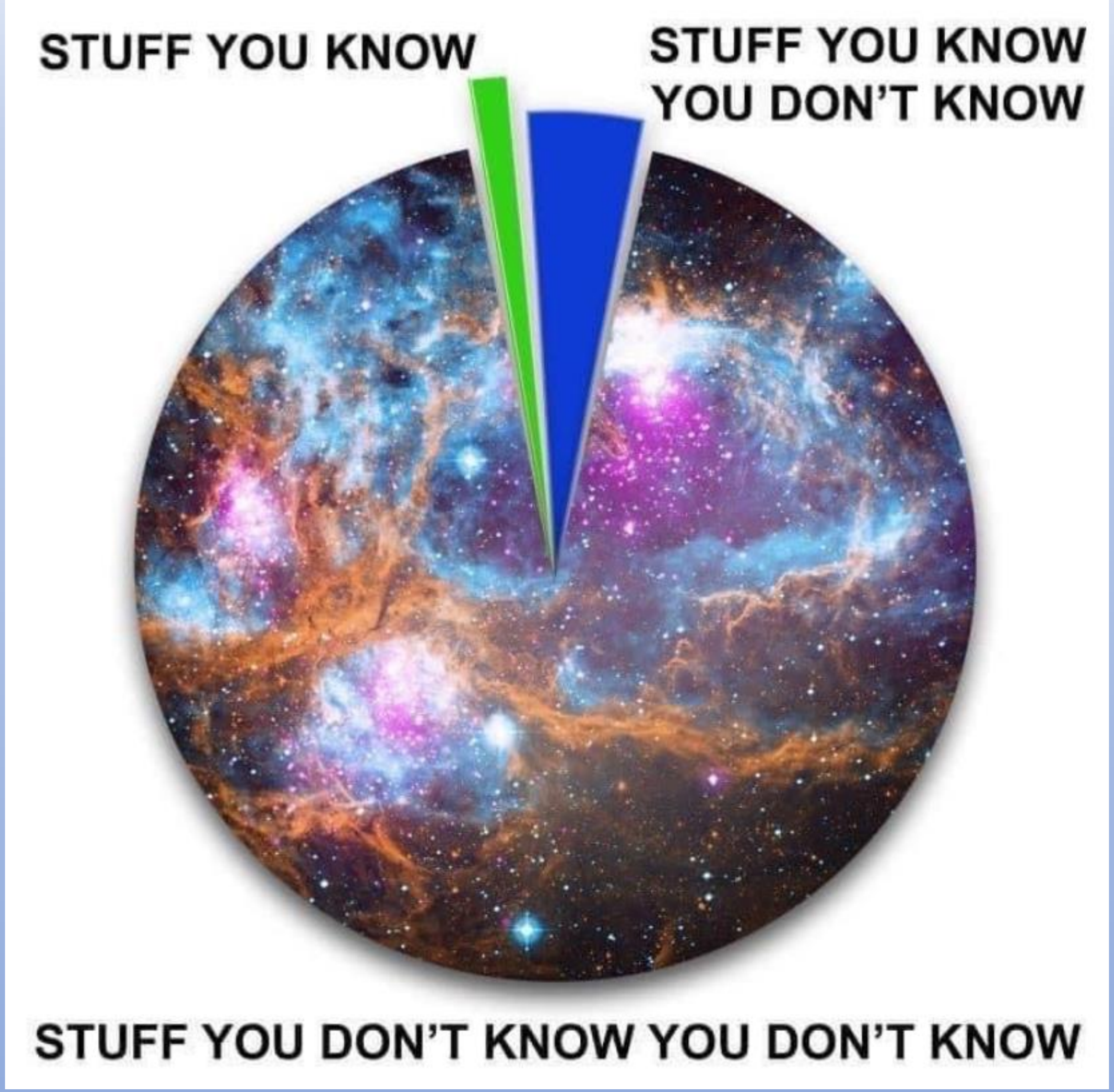
D. Alesini, F. Cardelli, R. Di Raddo, L. Faillace, G. Franzini, A. Gallo, L. Piesanti, S. Pioli,

B. Spataro, A. Vannozzi ***INFN-LNF***

G. Cuttone, G.S. Mauro, G. Sorbello, G. Torrisi ***INFN-LNS***

A. Bilancia, G. Felici, M. Di Francesco, V. Galasso, J. Pensavalle ***S.I.T. Sordina IORT Technologies S.p.A.***

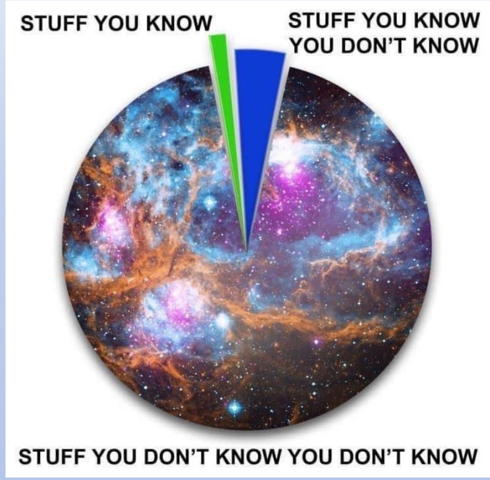
VHEE Flash Medical Device 2023



Is this the situation ?

Sordina IORT Technologies

VHEE Flash Med. Dev.



Stuff we know	Stuff we don't know	Stuff we don't know we don't know
LINAC	Dose delivery system	?
TPS	Dose monitoring system	
Dose monitoring system	Standards	
Radiation Protection		

Sordina IORT Technologies

frontiers | Frontiers in Physics

TYPE Original Research
PUBLISHED 17 December 2024
DOI 10.3389/fphy.2024.1511830

OPEN ACCESS

EDITED BY
Jiaru Shi,
Tsinghua University, China

REVIEWED BY
Kiki Theodorou,
University of Thessaly, Greece
Lanchun Lu,
The Ohio State University, United States

*CORRESPONDENCE
J. H. Pensavalle,
jakeharold.pensavalle@gmail.com
G. Felici,
giuseppefelici1971@gmail.com

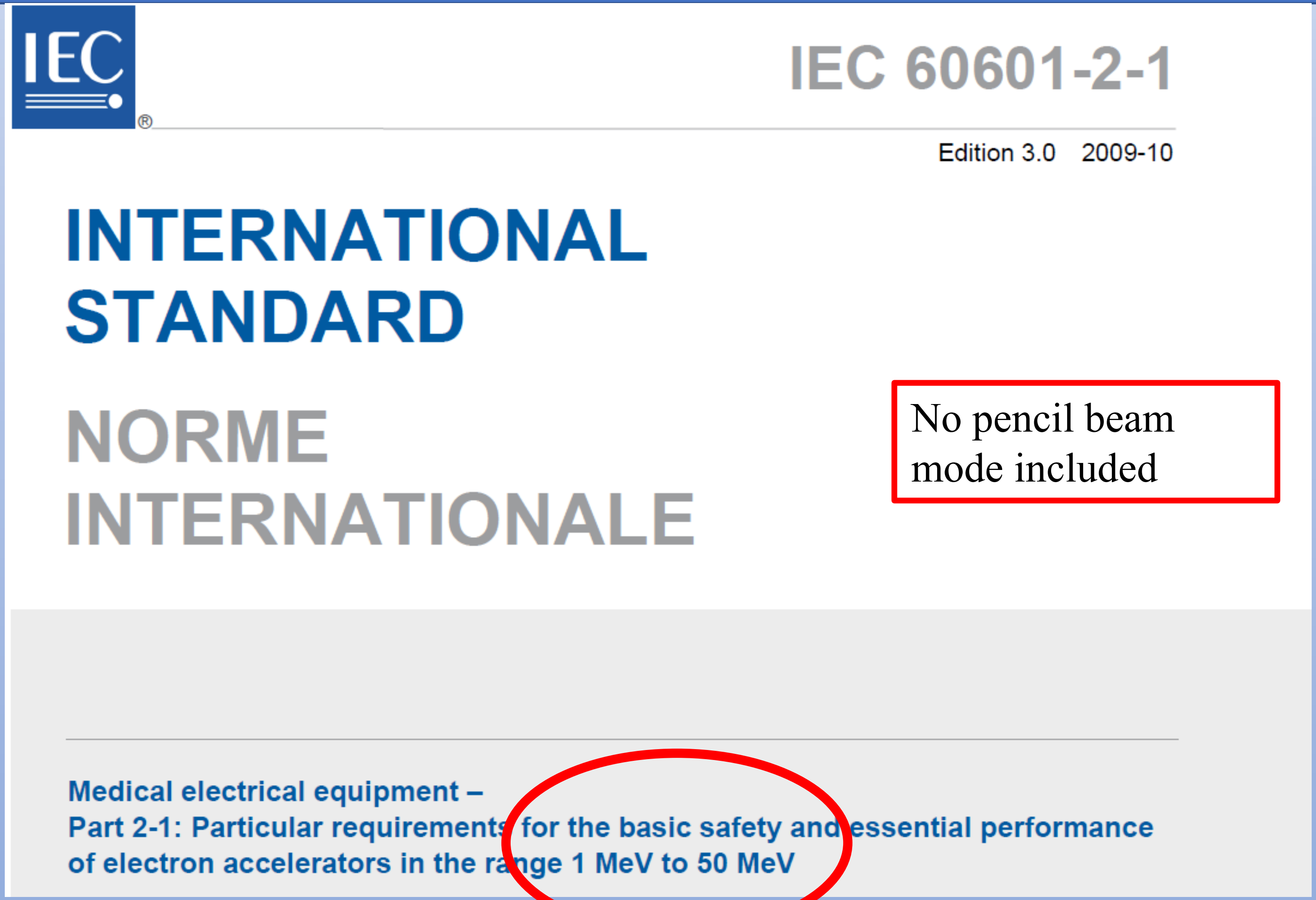
RECEIVED 15 October 2024
ACCEPTED 02 December 2024
PUBLISHED 17 December 2024

Standard requirements for clinical very high energy electron and ultra high dose rate medical devices

J. H. Pensavalle[1]*, F. Di Martino[1,2,3], A. Cavalieri[4], M. Celentano[1,3], A. De Gregorio[5,6], M. Di Francesco[7], G. Franciosini[6,8], L. Galluzzo[7], L. Masturzo[1,3], G. Milluzzo[9], P. Montay-Gruel[10,11], F. Paiar[2,4,12], M. Pantaleoni[13], V. Patera[6,8], S. Pioli[14], P. Poortmans[15,16], F. Romano[9,17], A. Sarti[6,8], A. Subiel[18,19], A. Vannozzi[14] and G. Felici[7]*

Standards

No IEC Standard today …


IEC 60601-2-1

Edition 3.0 2009-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

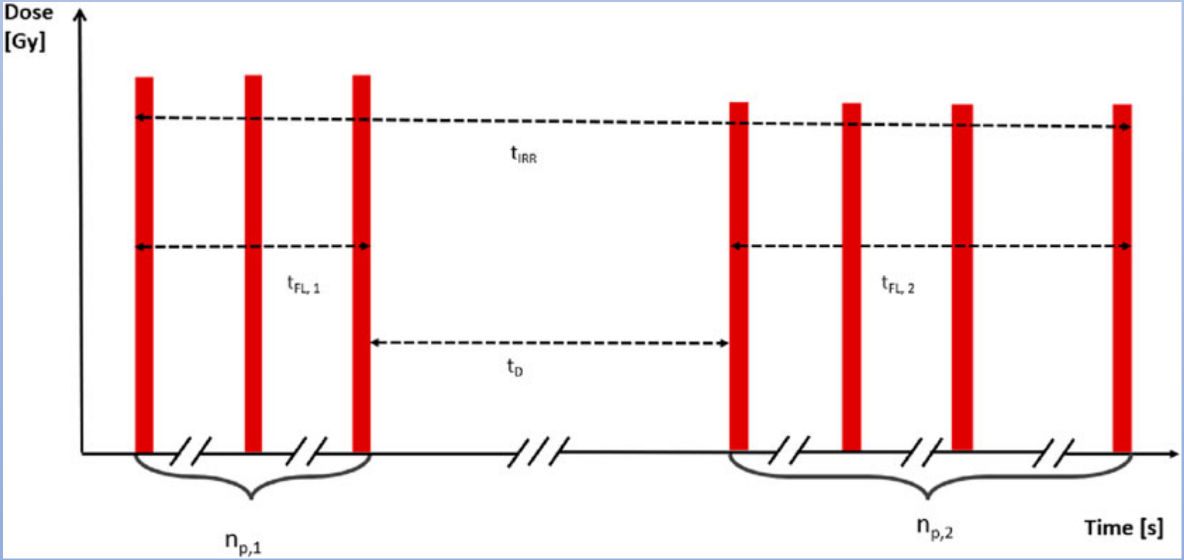
Medical electrical equipment –
Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV

No pencil beam mode included

SIT
Sordina IORT Technologies

Basic safety and essential performance

-Basic safety and essential performance boils down to identifying and controlling the fundamental variables.




IEC 60601-2-1
Edition 3.0 2009-10
INTERNATIONAL STANDARD
NORME INTERNATIONALE
Medical electrical equipment –
Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV

Basic safety and essential performance – physical observables	
Conventional	VHEE UHDR
Ionizing Radiation (X, e, p, …)	TIME (Total Irradiation time, time of pulse, etc.)T, t_p
Beam Energy E	Rates (what rates? Average? Instantaneous?)D/t
Beam Fluence φ	Dose (Total, per fraction, per pulse) D_T, D_F, D_p
Dose (Total, per fraction) D_T, D_F	Beamlet Position and Divergence X, Θ

Monitoring System (according to International Electrotechnical Committee)

Is this an autonomous vehicle (AV)?

SIT
Sordina IORT Technologies

Monitoring System (according to International Electrotechnical Committee)

Is this an autonomous vehicle (AV)?

SIT
Sordina IORT Technologies

Radiation Protection – Safety and usability

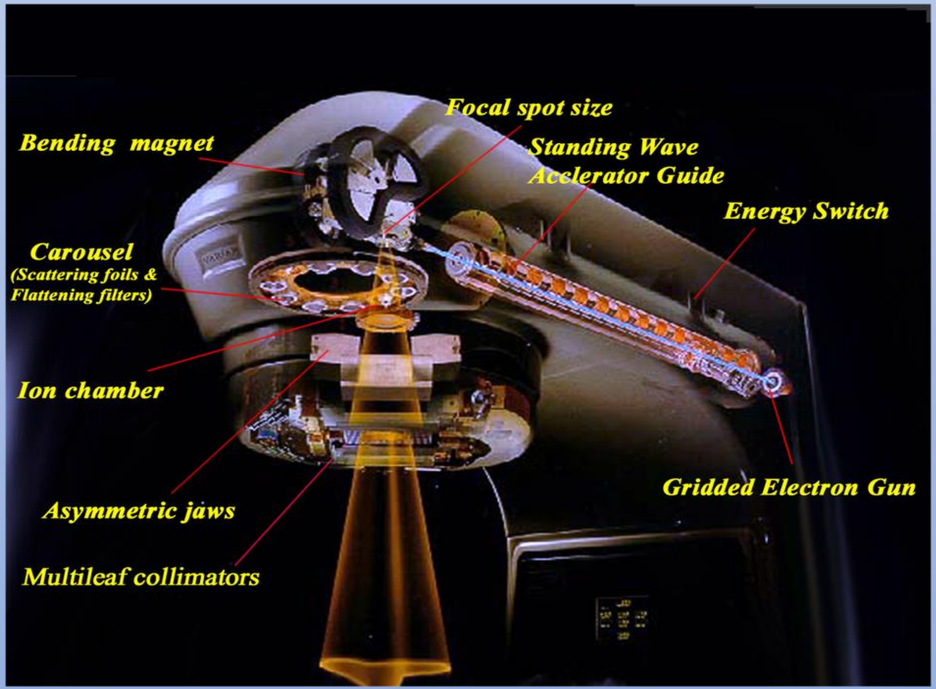
BEWARE!
Radiation protection could become a show stopper

Sordina IORT Technologies

Where does stray radiation come from?

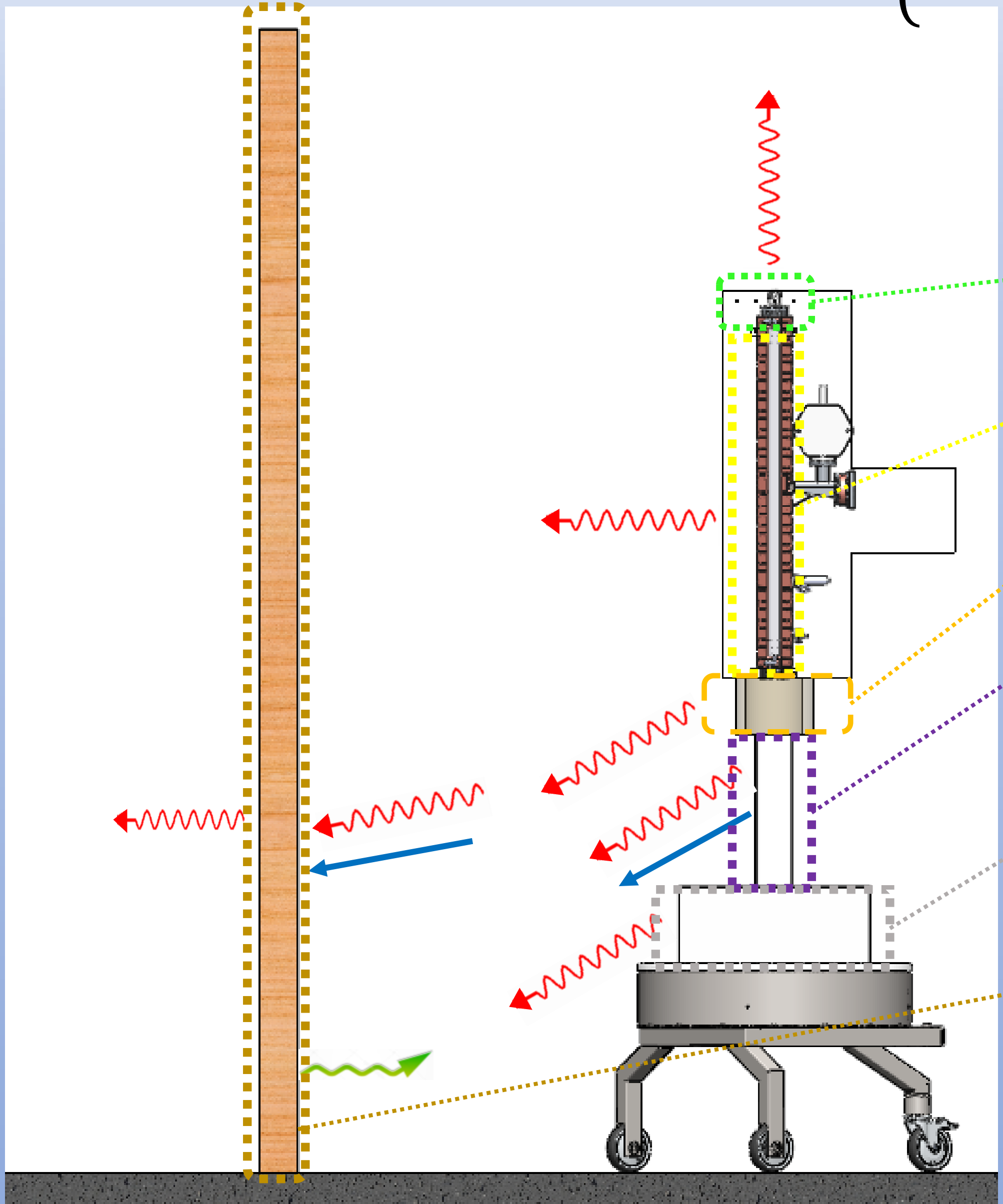
The stray radiation produced by a medical linac, according to NCRP 151, can be identified as

1. direct beam;
2. leakage radiation (**LR**);
3. scattered radiation from the patient (**PSR**);
4. scattered radiation from the walls (**WSR**);
5. secondary radiations (including photo neutrons and neutron capture gamma rays) produced in the accelerator head or in scattering throughout the room.



Let's use IORT as easy reference (hydrogen atom)…

$$\begin{cases} SR = PSR + LR + WSR \\ LR = L_X^{B} + L_X^{AG} + L_X^{PBLD} + L_X^{AP} + L_{e-}^{AP} \end{cases}$$



LEAKAGE RADIATION

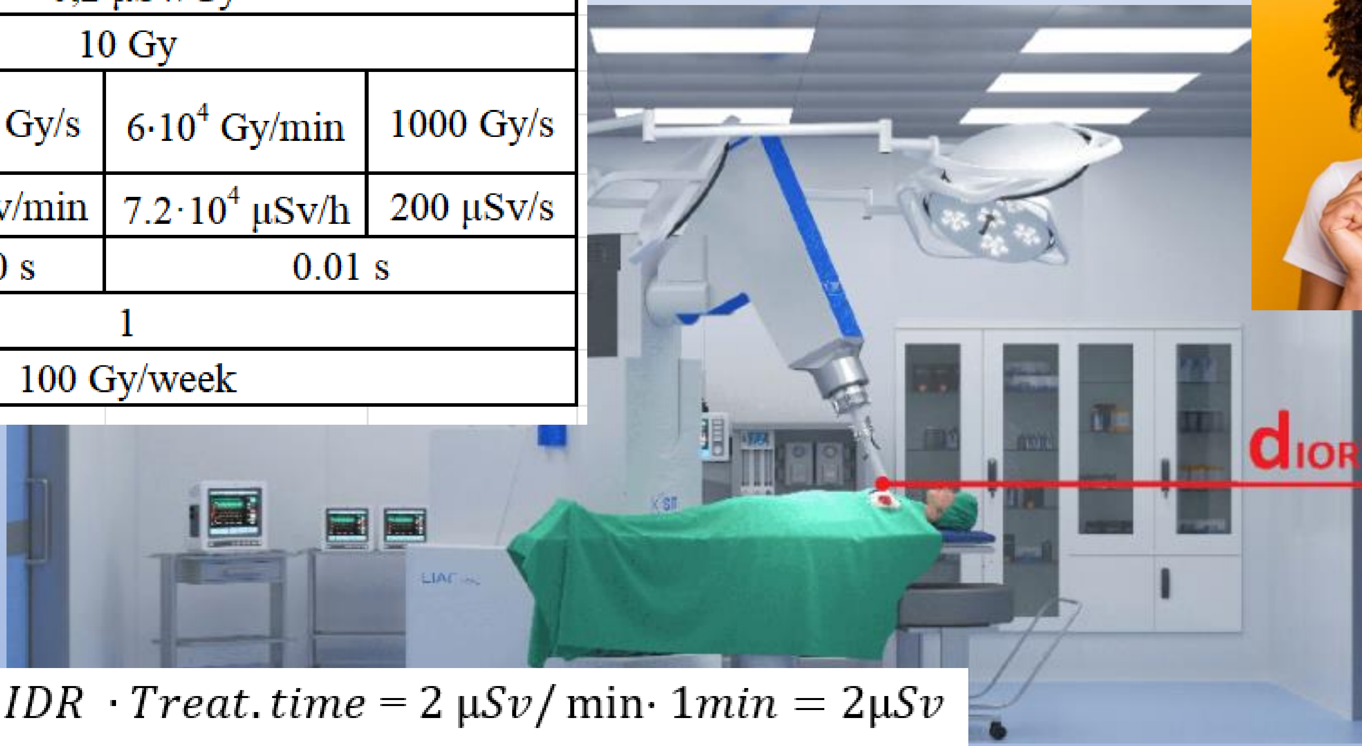
1. $L^{B}{}_{X}$ Backward radiation (180°)
2. $L^{AG}{}_{X}$ Accelerating waveguide (0° – 360°)
3. $L^{BLD}{}_{X}$ Primary BLD (0° - 90°)
4. $L^{AP}{}_{X}$, $L^{AP}{}_{e}$ Applicator (0° - 90°)

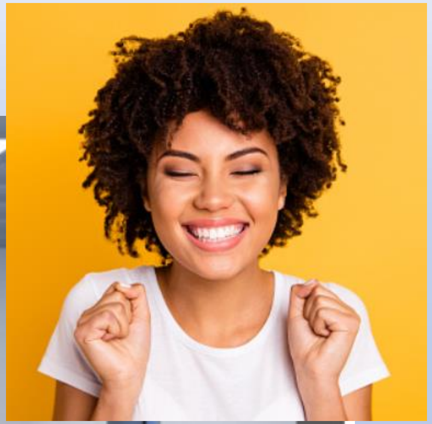
PATIENT SCATTERED RADIATION

WALL SCATTERED RADIATION

IOeRT RP according to TADR ICRP & NRCP

	CONVENTIONAL		FLASH	
Stray Rad @ 3 m	<0,2 μSv/Gy			
Total Dose	10 Gy			
Average Dose Rate $\dot{D}_0$	10 Gy/min	0.17 Gy/s	$6 \cdot 10^4$ Gy/min	1000 Gy/s
Stray Rad IDR	120 μSv/h	2 μSv/min	$7.2 \cdot 10^4$ μSv/h	200 μSv/s
Treatment Time	1 min	60 s	0.01 s	
# MAX Patient/Hour	1			
MAX weekly W	100 Gy/week			





CONVENTIONAL $R_h = H_{pt} = IDR \cdot Treat.time = 2\ \mu Sv/\min \cdot 1min = 2 \mu Sv$

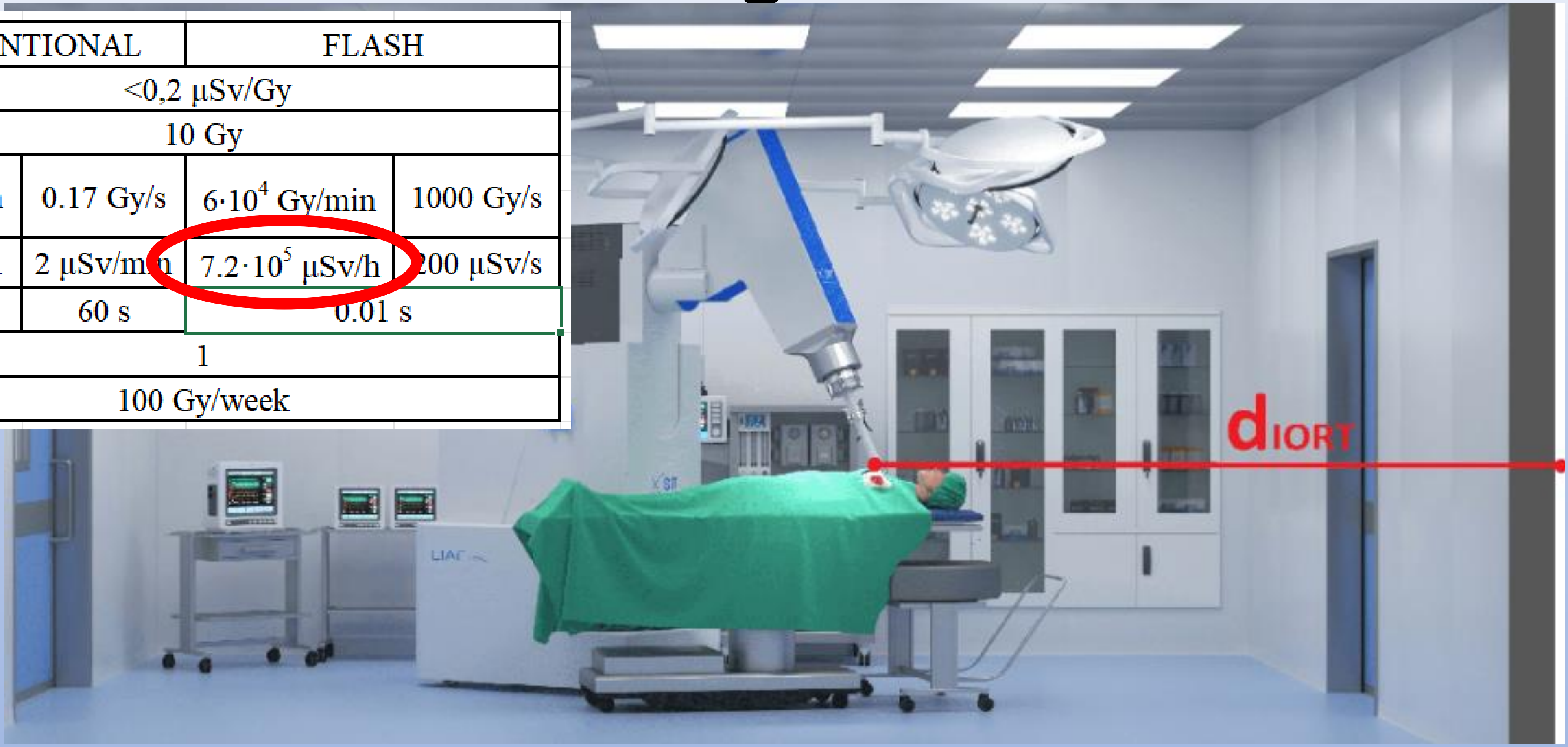
FLASH $R_h = H_{pt} = IDR \cdot Treat.time = 200\ \mu Sv/s \cdot 0.01s = 2 \mu Sv$

CONVENTIONAL $$R_w = \frac{IDR \cdot W \cdot U}{\dot{D}_0} = \frac{120 \frac{\mu Sv}{h} \cdot 100 \frac{Gy}{week}}{600\ Gy/h} = 20 \frac{\mu Sv}{week}$$

FLASH $$R_w = \frac{IDR \cdot W \cdot U}{\dot{D}_0} = \frac{7.2 \cdot 10^5 \frac{\mu Sv}{h} \cdot 100 \frac{Gy}{week}}{3.6 \cdot 10^6\ Gy/h} = 20 \frac{\mu Sv}{week}$$

IOeRT RP according to IDR

	CONVENTIONAL		FLASH	
Stray Rad @ 3 m	<0,2 µSv/Gy			
Total Dose	10 Gy			
Average Dose Rate $\dot{D}_0$	10 Gy/min	0.17 Gy/s	$6 \cdot 10^4$ Gy/min	1000 Gy/s
Stray Rad IDR	120 µSv/h	2 µSv/min	$7.2 \cdot 10^5$ µSv/h	200 µSv/s
Treatment Time	1 min	60 s	0.01 s	
# MAX Patient/Hour	1			
MAX weekly W	100 Gy/week			



In order to lower IDR below 10 µSv/h …
…around 5 TVL would be needed, more than 75 cm of concrete each wall, and more than 120 on the floor (plus the beam stopper) …

VHEE'25
15th – 17th September 2025

Thank you for your attention!

giuseppe.felici@soiort.com