Open consultation on Metrology for Radiation Protection

Support for technological trends: EURAMET's Work Programme on 'Metrology for Industry (Call 2023)'

Existing radiation protection issues at the novel FLASH units from the point of view of users

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On behalf of the working group from the ESTRO physics workshop on *Physical aspects of FLASH*

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UHDR RT

Conventional RT

Mean dose-rate
~ 4 Gy/min

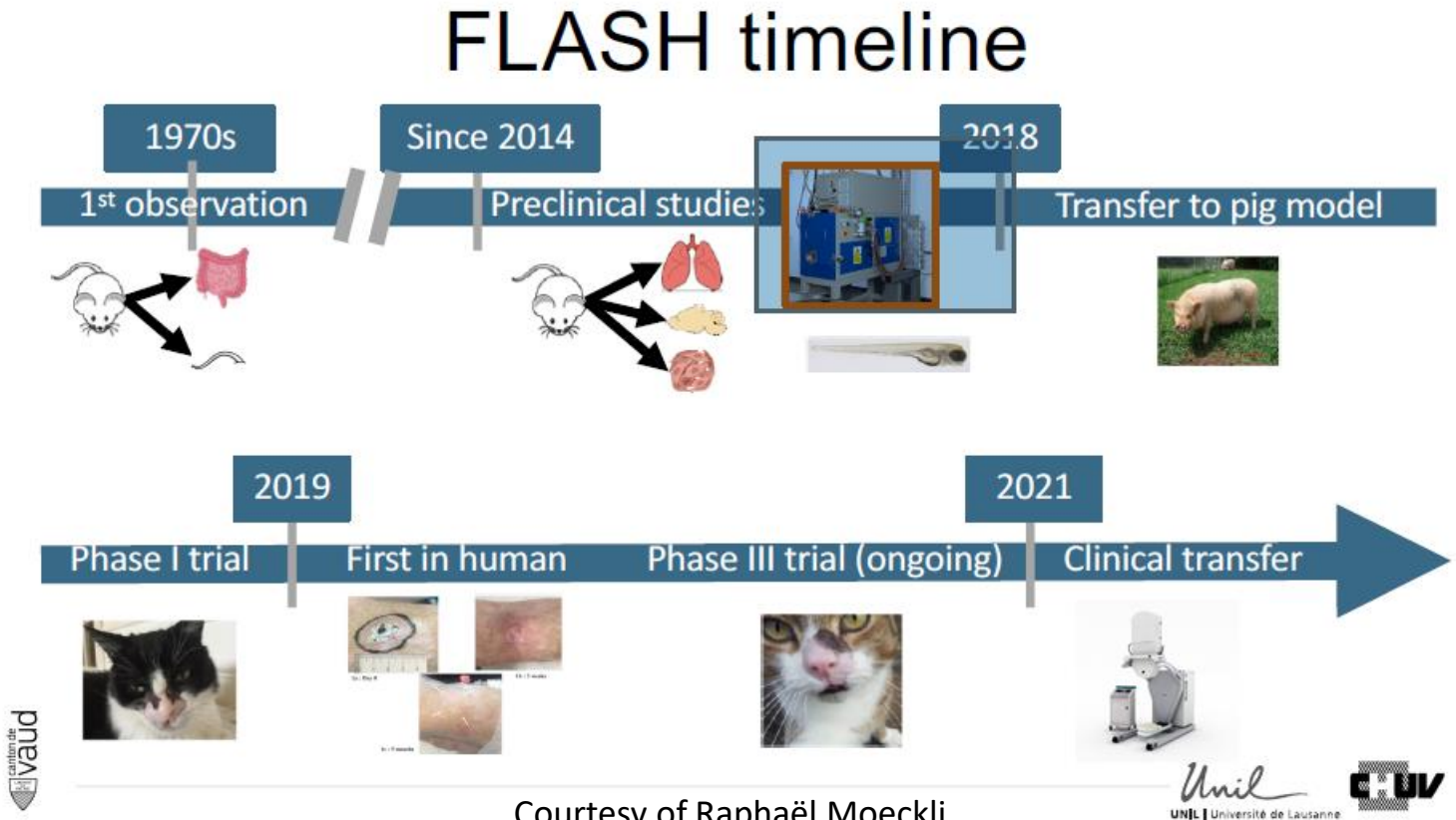
Treatment time
~ minutes

UHDR RT

Mean dose-rate
~100 Gy/s

Treatment time
< 1 s

- **Increase in differential response between normal tissue and tumors**
- **Short treatment times (<1s)**
  Motion management
  i.e. remove intra-fraction motion
  Patient comfort



Courtesy of Raphaël Moeckli

- FAST -01, 1° clinical trial completed, FLASH proton RT, Cincinnati Children's Hospital
- IMPULSE trial, phase I , skin M+ from melanoma, CHUV

ESTRO Physics Workshop 2021 on Physics Aspects of FLASH RT

- 32 participants from Europe and US
- 5 vendors (IBA, Varian, SIT, IntraOp, RaySearch)

White paper focusing on harmonization of terminology in FLASH RT

Proposals for radiobiological experiments allowing safe implementation

Recommendations for the clinical implementation of ultra-high dose rate radiotherapy: a focus on patient's safety and radiation protection

Minimum and optimal requirements for a safe clinical implementation of ultra-high dose rate radiotherapy: a focus on patient's safety and radiation protection

Aim of the paper:

- harmonization and standardization of all aspects of clinical implementation related to patient's safety and radiation protection → to help medical physicists to clinically implement UHDR-RT

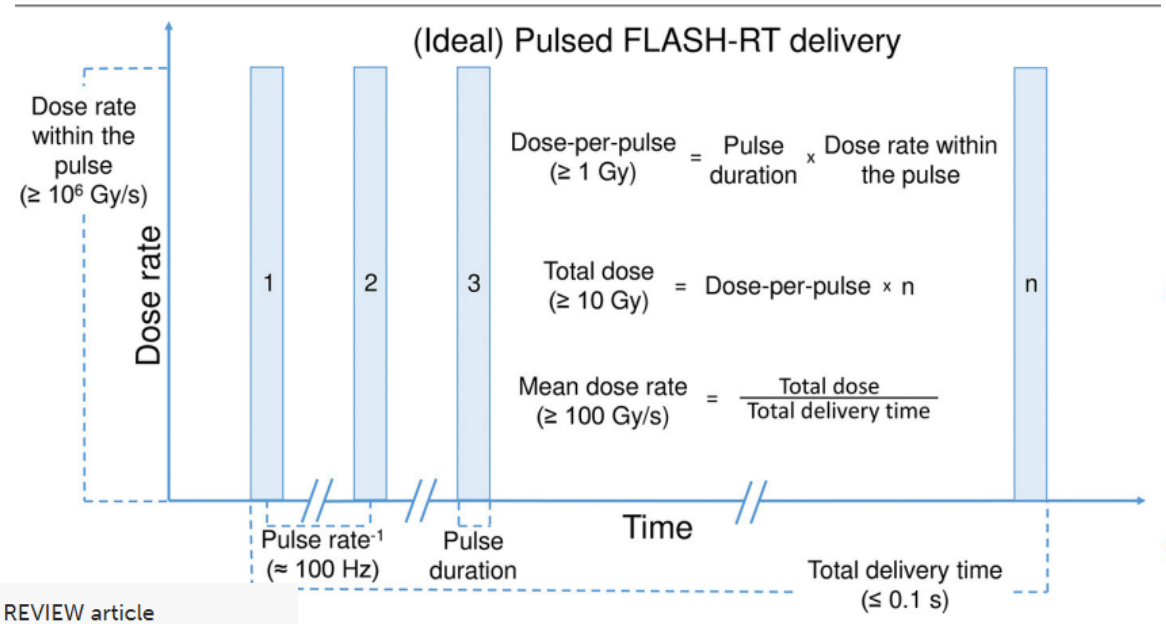
- This document can be the basis of a process to steer proactively the establishment of new regulations that covers the UHDR-RT mode

Safety, radiation protection and regulation

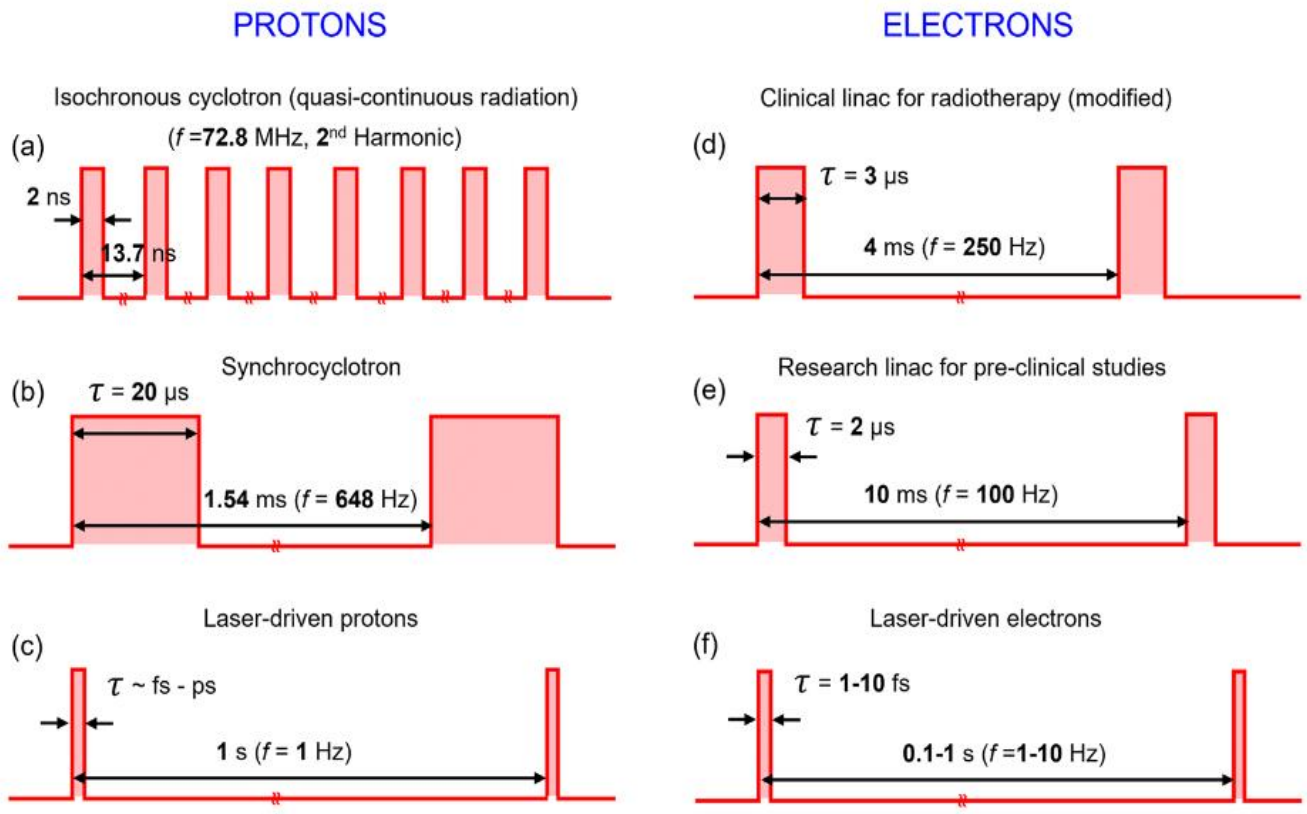
- Which parameters of the beam are really necessary to describe the UHDR beam?
- Which parameters are reasonable for a radiation protection point of view ?
- Implementation of UHDR-RT within the frame of current regulations (IEC 60601, ..)
- Rethink which are the relevant parameters → define new threshold values for the new parameters

→ suggest to change and adapt regulations for UHDR-RT

Which parameters of the beam are really necessary to describe the UHDR beam?



REVIEW article
Front. Oncol., 17 January 2020
Sec. Radiation Oncology
https://doi.org/10.3389/fonc.2019.01563



F. Romano, Med Phys 2022

Which parameters trigger the FLASH effect ?

- Average dose rate > 40 Gy/s
- Duration of the entire irradiation
- Dose-per-pulse
- Instantaneous dose rate
- Pulse duration and frequency

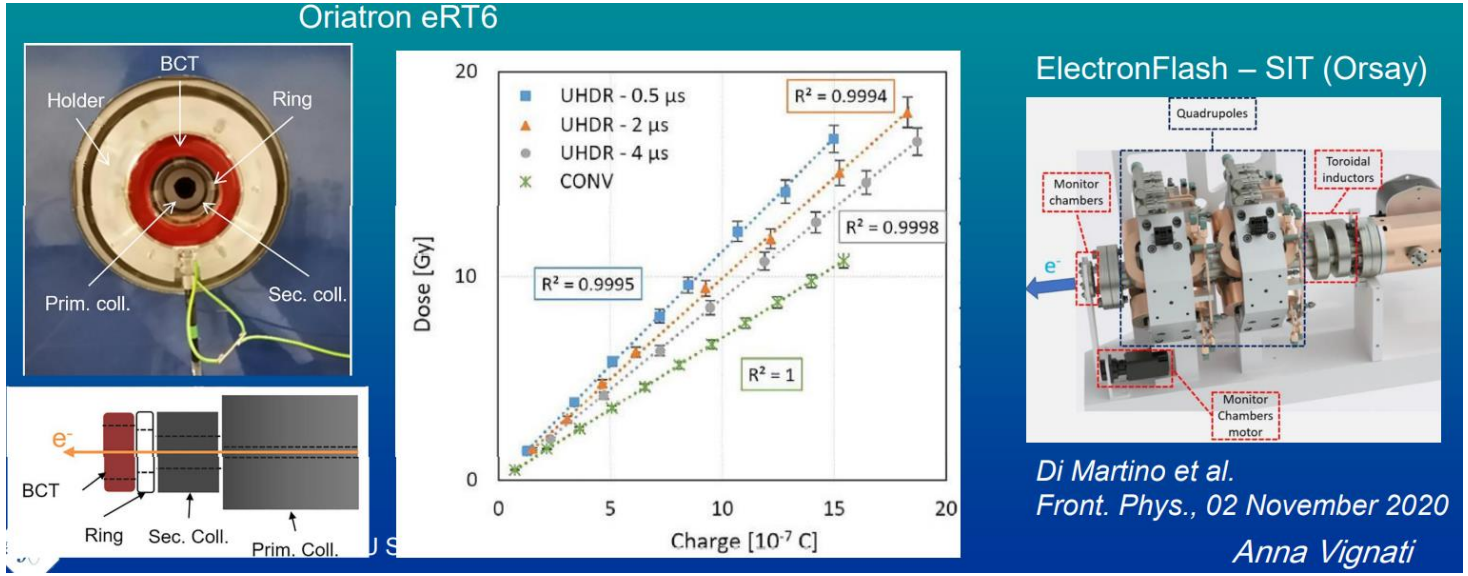
Safety: Beam monitoring

One crucial problem emerging from using UHDR irradiations for clinical transfer is ***the need for new beam monitoring devices.***
This need comes from the heavy saturation [i.e, non linearity] that conventional transmission chambers usually used in clinical practice experience in UHDR modes.
[Oesterle et al. J of Applied Clinical Medical Physics – Oct 2021]

- ✓ introduction of correction factors
- ✓ optimization of existing technologies
- ✓ investigation of novel radiation detection methods

Ideal characteristics of a beam monitoring system

- High temporal resolution
  - ideally: intra-pulse monitoring
  - reaction time: inter-pulse
- High spatial resolution
- Beam transparency
- Large response dynamic range
- Large sensitive area
- Radiation hardness
- (Beam energy)



Beam current transformers are not able to provide information about the beam spatial distribution (flatness and symmetry) as requested by international standards to ensure the patient safety during delivery.
[F. Romano et al. Med Phys. 2022;1–21]

Safety

IEC standard 60601 1-2-1 for medical devices used in RT

✓ Many of the recommendations apply for both conventional and UHDR irradiations such as:

- monitoring of the absorbed dose
- presence of independent and redundant dose monitoring systems

✓ Some recommendations such as the online displays of spot positions are not appropriate for a sub-second, almost instantaneous delivery of UHDR RT

✓ Dose rate considerations should be integrated in this recommendations.

A sudden drop of the dose rate (as caused by a delivery interruption, for example) may cause a loss of the FLASH effect with a potentially serious clinical consequences, unless mitigated in the course of the treatment.

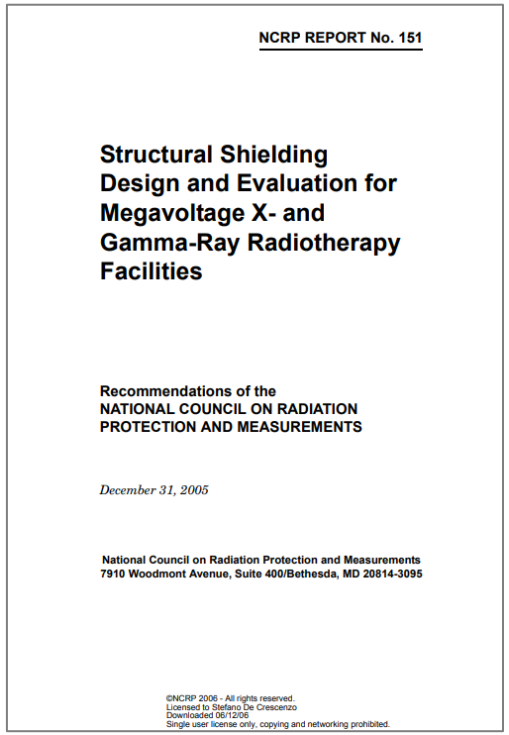
Need of new guidelines

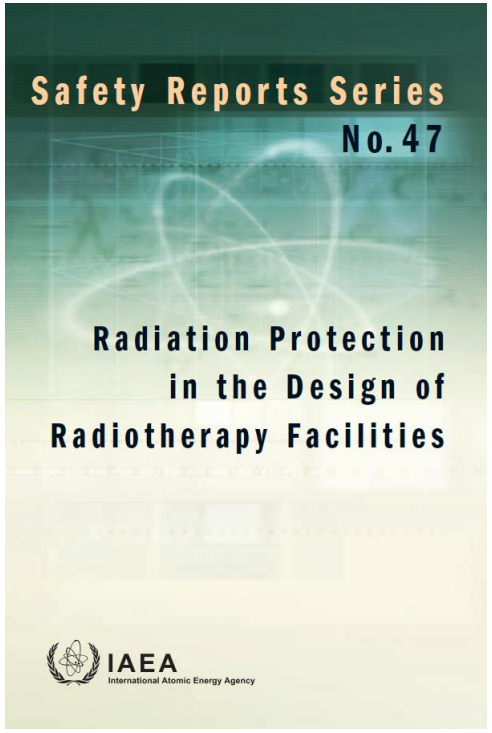
- Is symmetry and flatness useful during 100 ms?
- How would the monitoring be performed?
- How to control the temporal structure of the beam
- How to avoid overdosage (D_{pulse} > 10 %D_{tot})?
- How to compensate for underdosage (missing pulse)?
- Would IEC be ready to change the rules?

Need to develop international standard for each UHDR beam modality

Radiation protection and regulations

- International guidelines and recommendations have been established for safety and radiation protection rules in conventional radiotherapy (e.g. EURATOM directive 2013/59, ICRP, NCRP, IEC,IAEA, etc)
- Each country has developed its own regulatory body based on these international guidelines and recommendations.





The thickness of the shielding is calculated based on:

- dose limits outside the shielding barriers

- kind of irradiation, its energy

- presence of leakage and patient scattered radiation

Shielding design

The thickness of the shielding barriers is calculated based on:

- dose limits outside the shielding barriers for occupational exposure or the public
- kind of irradiation, its energy
- presence of leakage and patient scattered radiation

Different countries use different ways of defining the dose limits by different countries considering:

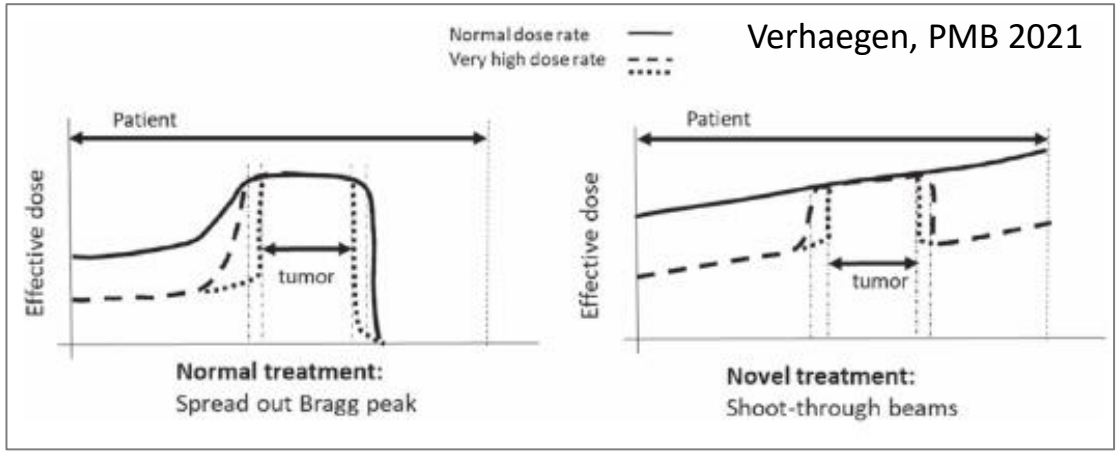
- instantaneous dose rate → problematic for UHDR
- dose in-any-hour
- the time-averaged dose rate (after accounting for occupancy and workload)

As the total (clinical) dose will not be that different from the current dose delivered in RT, and considering that the number of patients treated per hour will be less or equal to current practice → in many cases shielding will not require substantial modifications.

Shielding design in special cases

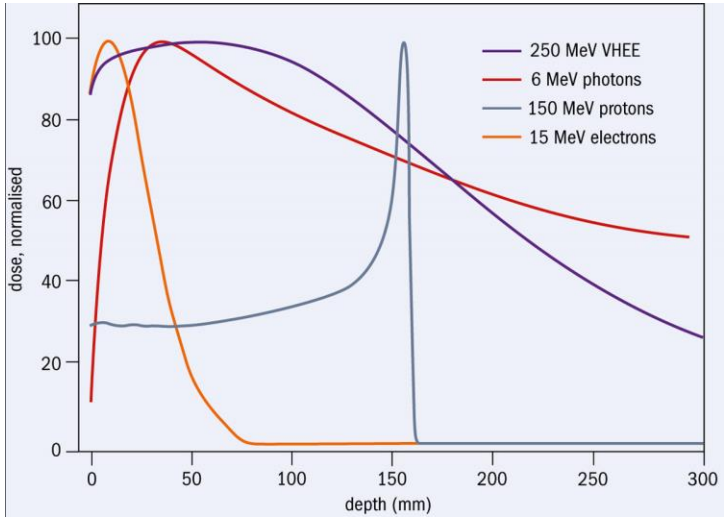
Reassessment of the shielding might be needed in special cases:

- for UHDR proton therapy in transmission mode (in contrast with the standard clinical mode of operation, where the beam stops in the patient)



- for VHEE beams due to the increased yield of neutron production with respect to HEE beams or for linear accelerator vaults converted from photon therapy into electron therapy

A survey of the photon and neutron radiation outside the barriers might be advisable ensuring that only detectors appropriate for pulsed irradiations are used (Caresana 2014)



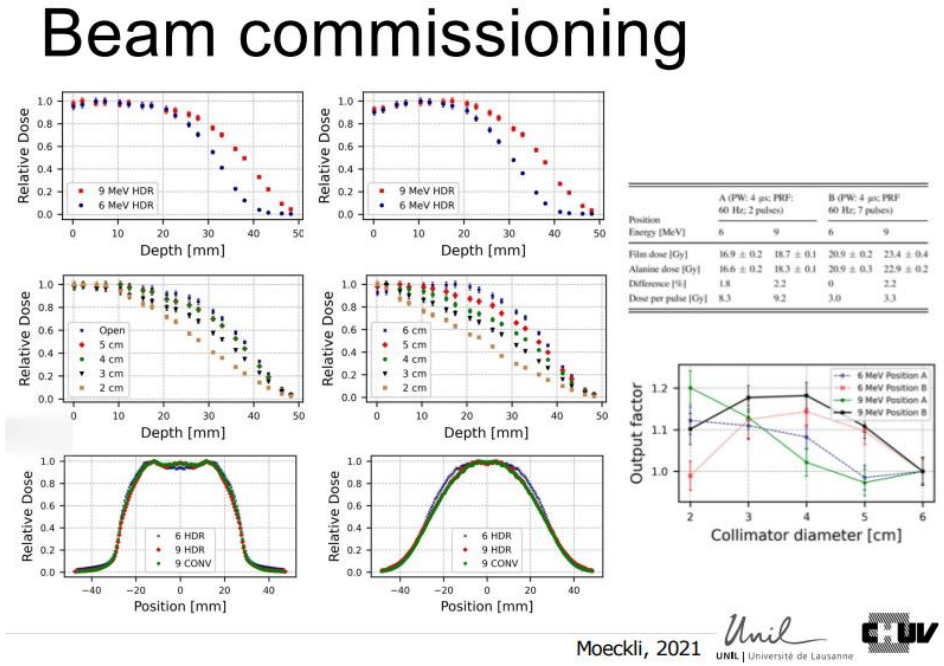
Commissioning /QA

Limitations from radiation protection to perform the measurements

Just to have an idea…..
to treat ~ 1’200 patient / year , the beam on time in UHDR is about 5 min!

The workload for commissioning and QA can change significantly with

respect to the clinical practice → ad-hoc procedures should be established



Clinical workload	Implementation of weekly workloads or dose-rate-in-any-hour concepts in national regulations (NCRP)
Physics workload Commissioning /QA procedures	- Limit amount of testing performed at UHDR (perform part of the tests in conventional dose rates) - UHDR testing should be performed only outside standard working hours (or in separate rooms)

Conclusions

- There is a urgent need to develop international standards for each UHDR beam modality to facilitate the clinical translation
- We recommend that national regulations should be adapted to UHDR, implementing guidelines based on weekly workload/integral dose (NCRP 151).
- For commissioning / QA procedures of UHDR machines that could change significantly the workload with respect to the clinical practice, ad-hoc procedures should be established.
- Harmonization in safety and radiation protection regulations between different countries would be desirable for the introduction of this new technology.
- Harmonisation between practice in different countries will pave the way for better reproducibility of the experiments, as well as harmonised protocols in the first human applications.

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Thanks for your kind attention !