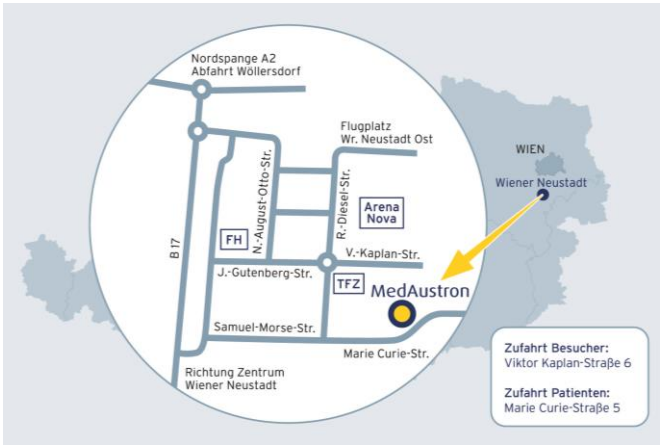
COMMISSIONING OF THE DOSE DELIVERY SYSTEM AT MEDAUSTRON

WORKSHOP ON INNOVATIVE DELIVERY SYSTEMS IN PARTICLE THERAPY

Gregor Kowarik, Torino, 24.2.2017

MEDAUSTRON



Located in the city of Wiener Neustadt

About 50km south of Vienna

County of Lower Austria

THE MEDAUSTRON FACILITY

KEY PARAMETERS

- **Accelerator:** Synchrotron; based on PIMMS design and engineering documentation and experience from CNAO
- **Ion species:** protons, carbon ions
- **Energy**
  - Clinical energies: p: 60-250 MeV; C6+: 120-400 MeV/u
    → **3-38 (p)/27 (C) cm penetration depth in water**
  - IR1 (non-clinical research): clinical energies + up to 800 MeV protons
- **Intensity**
  - Per spill: >1 * 10^{10} (p) / 4 * 10^{8} (C)
  - 4 different intensity levels
  - 0.1s (non-clinical) – 10s extraction time
- **Field/beam size**
  - Scanning field : 20x20 cm^2 (IR1-3), 12x20 cm^2 (IR4)
  - 4 nominal beam sizes: 4, 6, 8, 10 mm FWHM [in vacuum]
  - **Beam delivery total position tolerances:** < 0.5 mm

MEDAUSTRON PARTICLE THERAPY ACCELERATOR ("MAPTA")

Ion Sources

Linear Accelerator

Synchrotron

Beam Distribution

Beam Outlet for Nonclinical
Research & Engineering Applications

Accelerator Control System (Main Control Room)

Power Supplies/Device Control Units (2.OG)

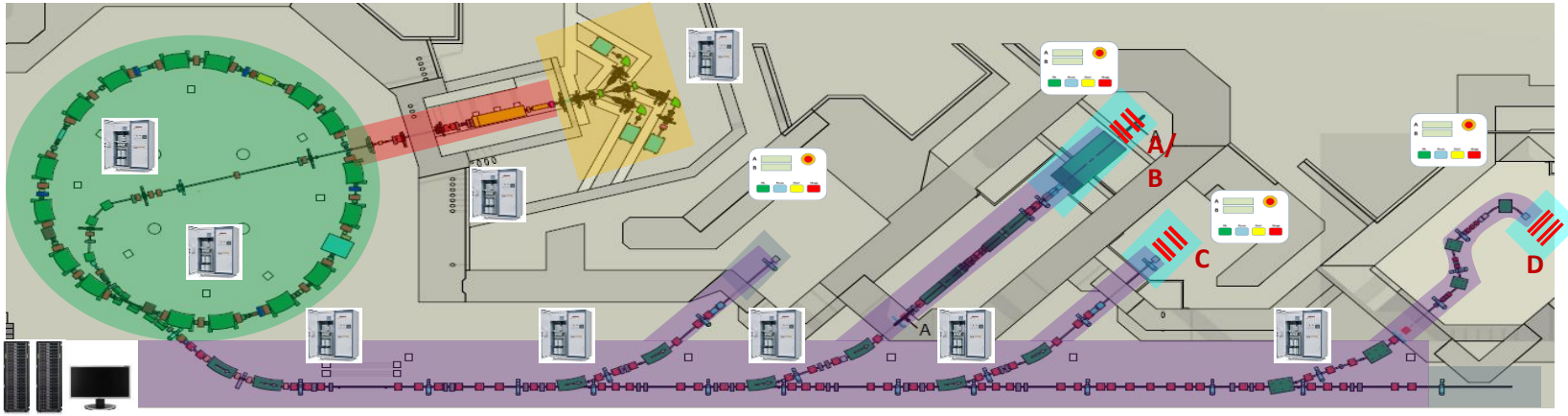
Dose Delivery System

A/B — Clinical Beamlines IR2:
horizontal 1 (A) and vertical (B)

C — Clinical Beamline IR3: horizontal 2 (C)

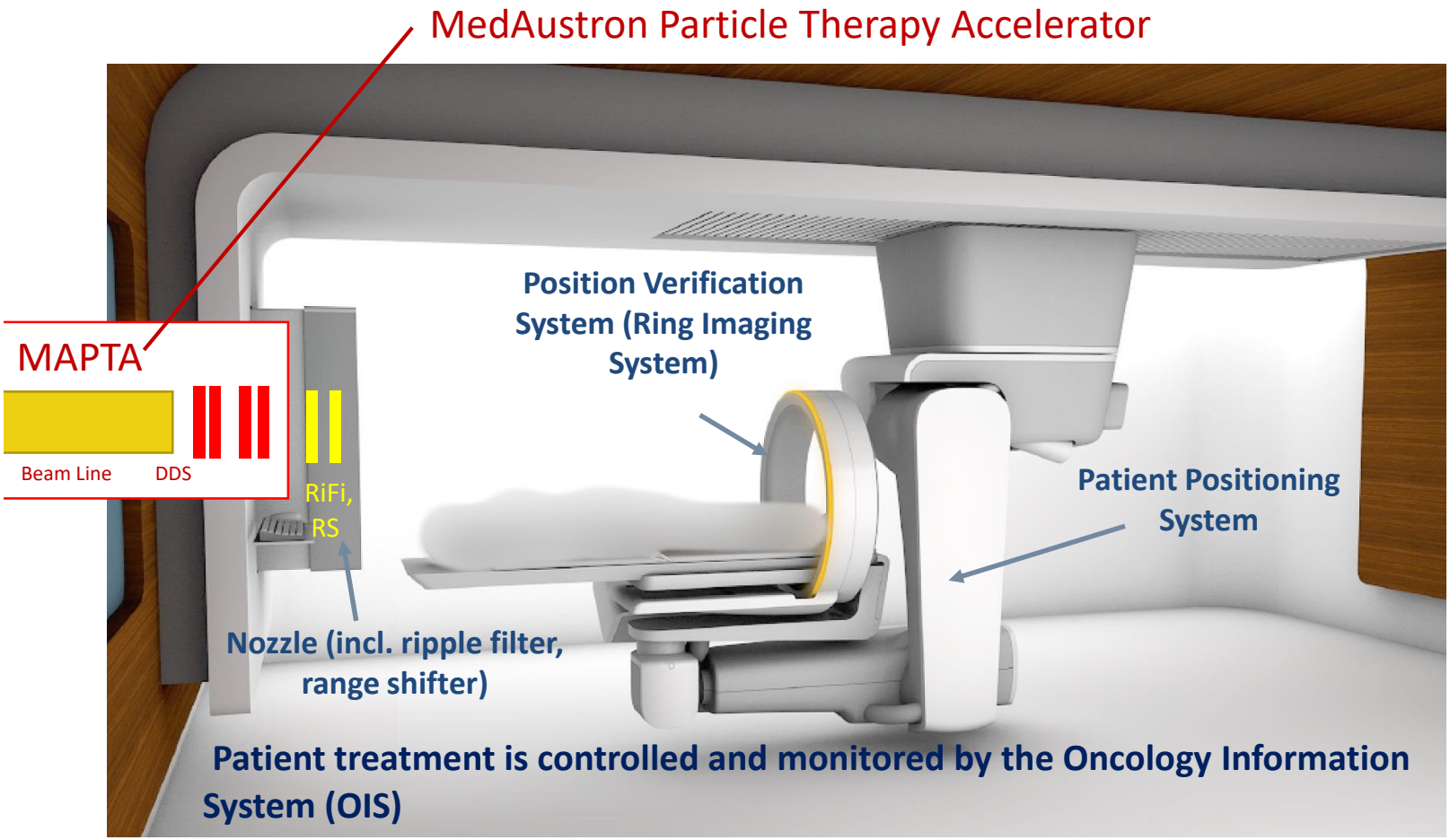
D — Clinical Beamline IR4: Gantry Beamline (D)

MAPTA Treatment Control Panel
(Local Control Rooms 1 to 4)

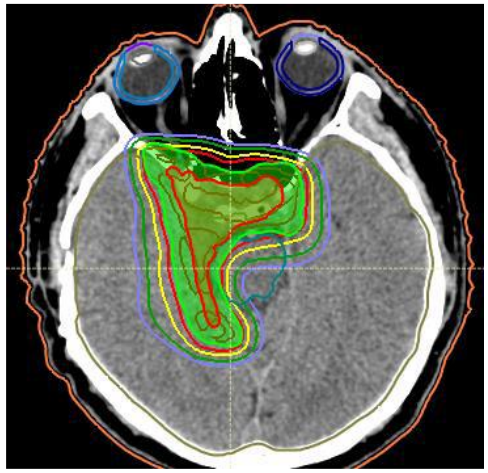


CE according to the Medical Device Directive (MDD)

MEDAUSTRON PARTICLE THERAPY SYSTEM („MAPTS“)



SELECTED PROJECT MILESTONES



Oct 2012: Building finished, moving in

Dec 2012: Sources installed and operational

Dec 2013: Injector Installed and operational

Mar 2014: Synchrotron installed

Apr 2014: First Turn in Synchrotron

Jul 2014: First Acceleration

Oct 2014: First Extraction and beam in irradiation room

Dec 2014: QMS Certificate EN ISO 13485:2012

Dec 2015: First complete integration - "One Plan Runs Through"

April 2016: First beam in IR1 (non clinical research)

June 2016: "Anlagenbuch" (electrical safety) - OeNorm E8001 (8007, 60601, 62353, etc)

June 2016: MAPTA "System Freeze" – starting system level tests and medical commissioning

Dec 2016: CE label received for horizontal fixed beamlines

Starting clinical operation in one room - First patient

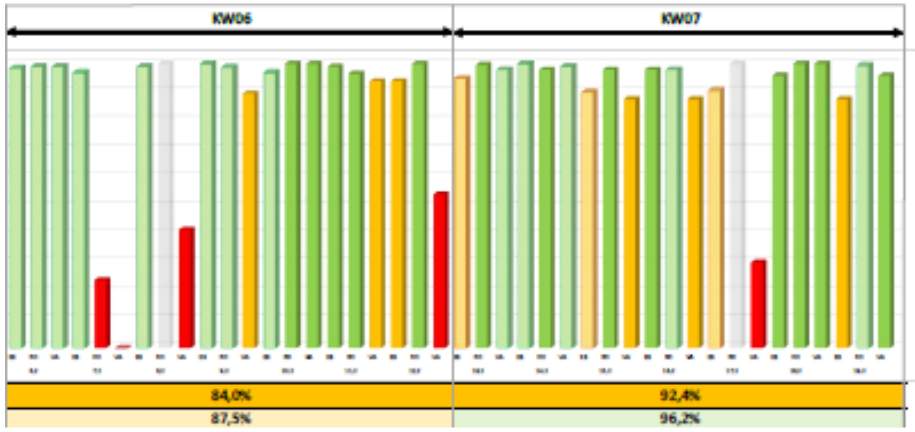
TIMELINE

	2016	2017	2018	2019	2020	2021
Modalities	p H	p H+V	p H+V C H+V	p H+V+Gantry* C H+V	p H+V+Gantry C H+V	p H+V+Gantry C H+V
						
Rooms	1	2	2	3	3	3
Med. Shifts	1	1	1	2	2	2

* Gantry cardinal angles in Q3/2019

PATIENT NUMBERS AND UPTIME

- Therapy Accelerator Uptime
  - Continuously >80% (weekly average) since 15 weeks
  - >95% last week
- Currently approx. 3-7 patients per day
- Indications: meningioma, prostate, extremities
- Planned soon: Pediatrics (after stabilisation of uptime)
- Patient in-room time <1h
- QA time:
  - Machine QA <50 minutes
  - Handover at 6am
  - MP QA approx. 3-4h



NON-CLINICAL RESEARCH

- **Areas of research**
  - Applied and translational Radiobiology
  - Radiation physics
  - Medical radiation physics and Oncotechnology
- **Linked to**
  - Vienna University of Technology
  - Medical University Vienna
- **Same configuration as in the treatment rooms but additional features for physics experiments**

REGULATORY FRAMEWORK

MAPTA:

- MDD: ClassIIb medical device
- Certification in accordance to Annex II MDD
  - Quality management system according to ISO 13485
  - Product design assessment (Technical documentation)
- Conformity declaration

Zertifiziertes QM-System mdc ISO 13485

CE 0815

Declaration of Conformity by Manufacturer/Notified Body + Tests, Control, Examinations by Notified Body

MAPTS:

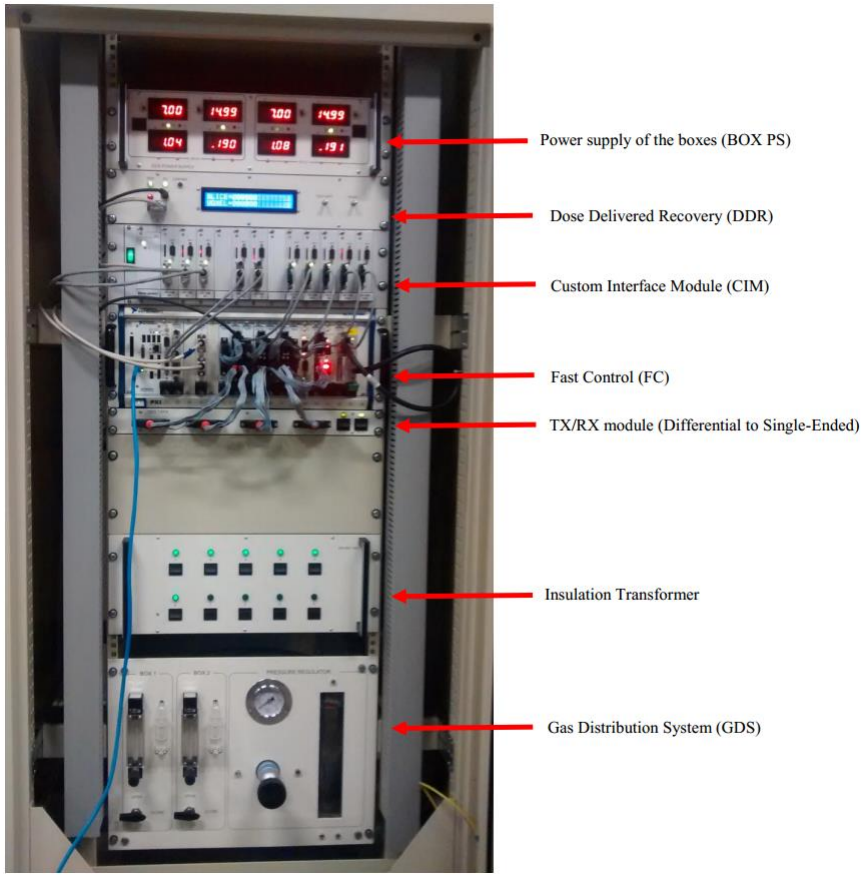
- System declaration (MAPTS)

Facility – national regulations:

- Environmental impact assessment procedure
- Electrical safety
- Radiation protection
- Authorisation as a clinic

DOSE DELIVERY SYSTEM

- CE certified medical product manufactured by CNAO
- Same system as in use at CNAO (with minor differences)
- 20x20 cm2 field size (12x20 cm2 for the Gantry)
- 2 Integral ionisation chambers
- 2 Strip ionisation chambers per axis (MedAustron)
- Operating gas: Nitrogen
- Active position feedback loop
- Interlocks: position, size, intensity



TECHNICAL COMMISSIONING

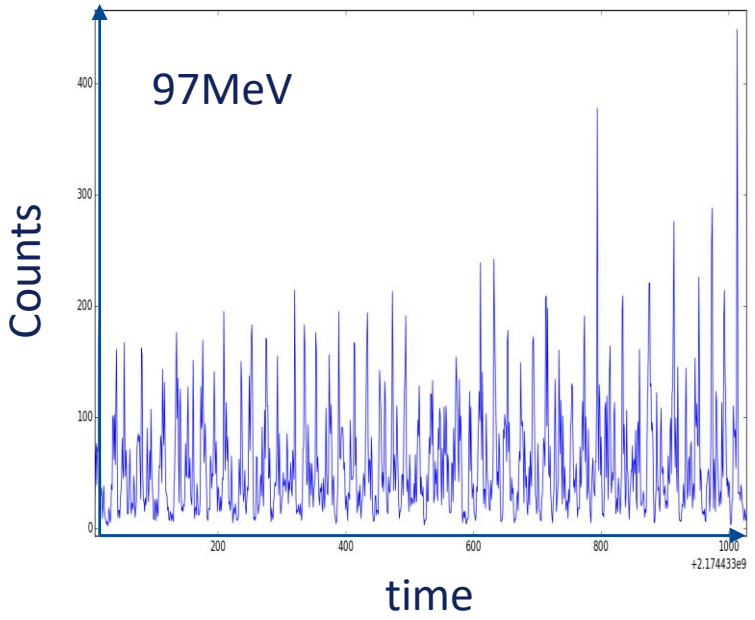
- Performance tests at the CNAO facility
- Installation & system integration at MedAustron
- Basic performance/integration tests with beam
- Development of calibration tools and procedures
- Development of analysis tools
- Technical characterisation; bugfixing
- Compliance analysis to the IEC60601-2-64 and determination of configuration settings
- Support of treatment record analysis (Medical Physics)

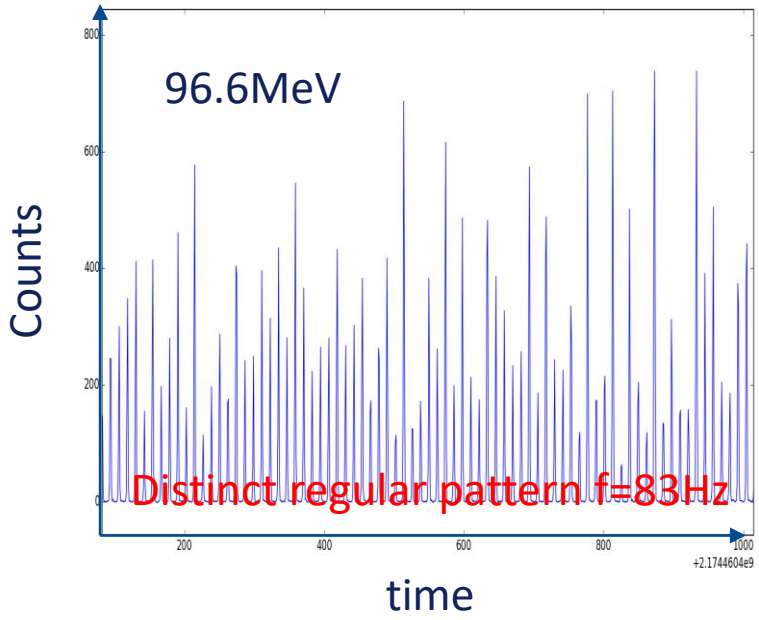
TECHNICAL CHARACTERISATION

- Charge collection efficiency
- Linearity of the monitors (intensity)
- Dynamics of the scanning
- Interlock behaviour
  - Positions
  - Spotsize
  - Intensities
- Environmental conditions: acoustic noise, EMC, etc.
- Compatibility: X-rays, vibrations, etc.
- Dosimetric analysis: 2D, 3D

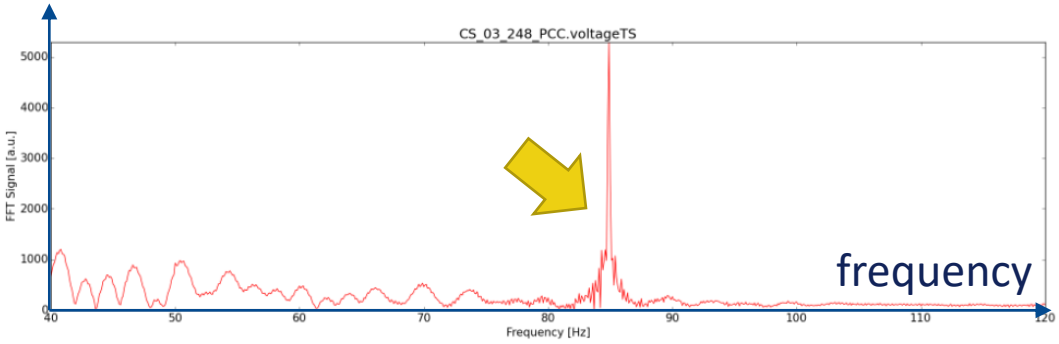
INTERLOCKS REVEALING AN ISSUE WITH PCO RIPPLE

Higher frequency of intensity interlocks



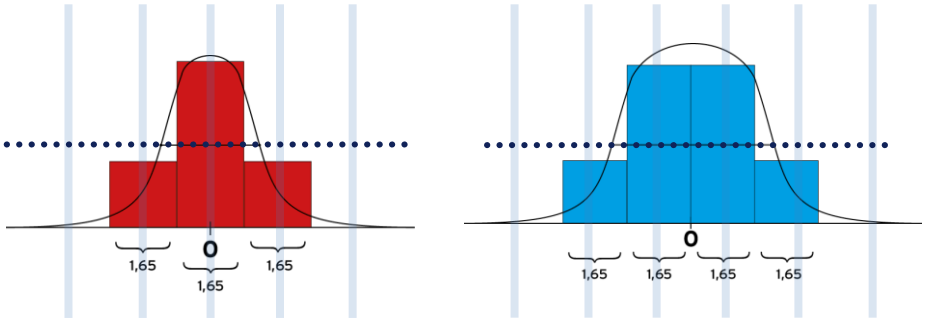


Ripple on the power converters of main ring quads was found to be present



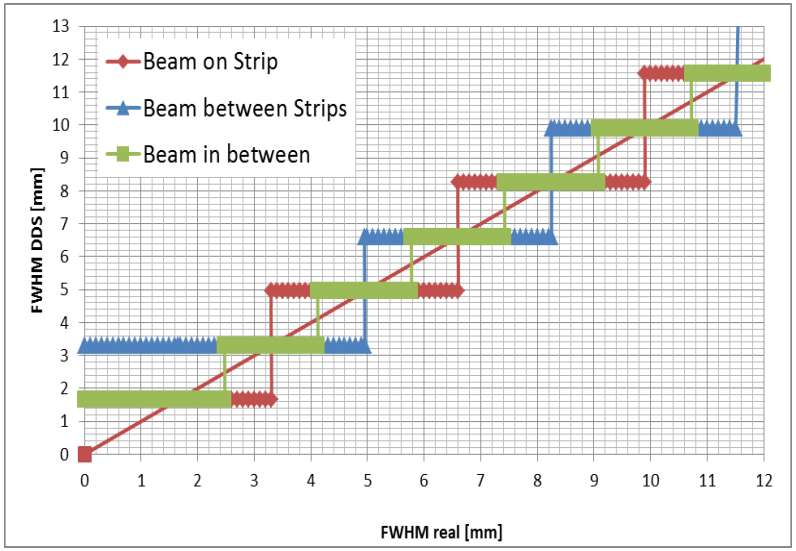
SPOTSIZE INTERLOCK

Methodology is based on counting number of strips → strong position dependency



Beam on Strip

Beam between Strips

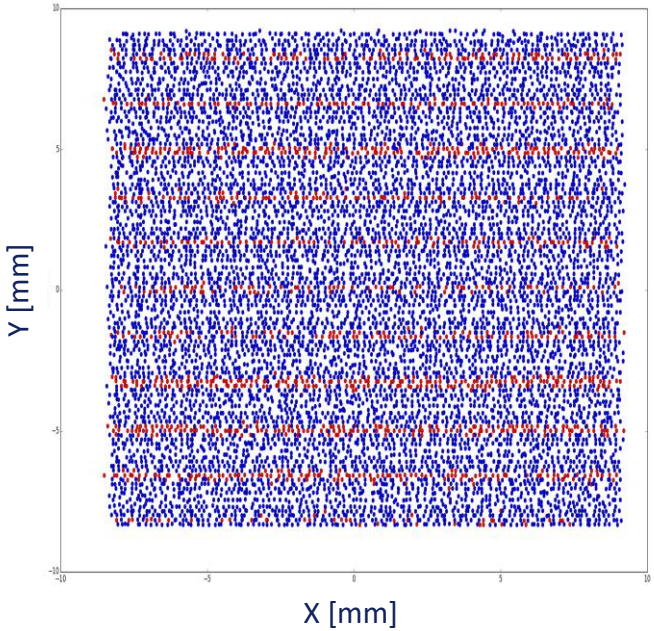


The DDS does not provide diagnostic information regarding the measured spotsize → empirical study was performed to benchmark a simulation in order to characterisze the behaviour

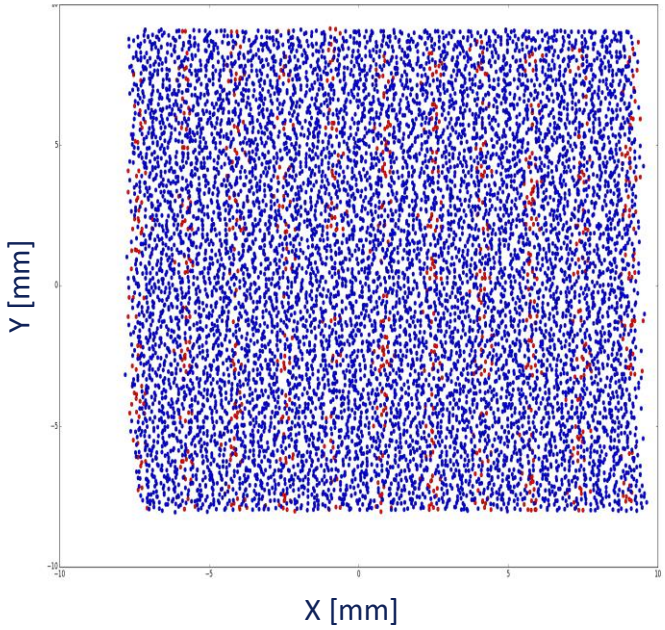
SPOTSIZE INTERLOCK

Position-dependent FWHM result of the same beam leads to position-dependent interlock trigger

Horizontal strip chamber
Distribution of interlocks (red)

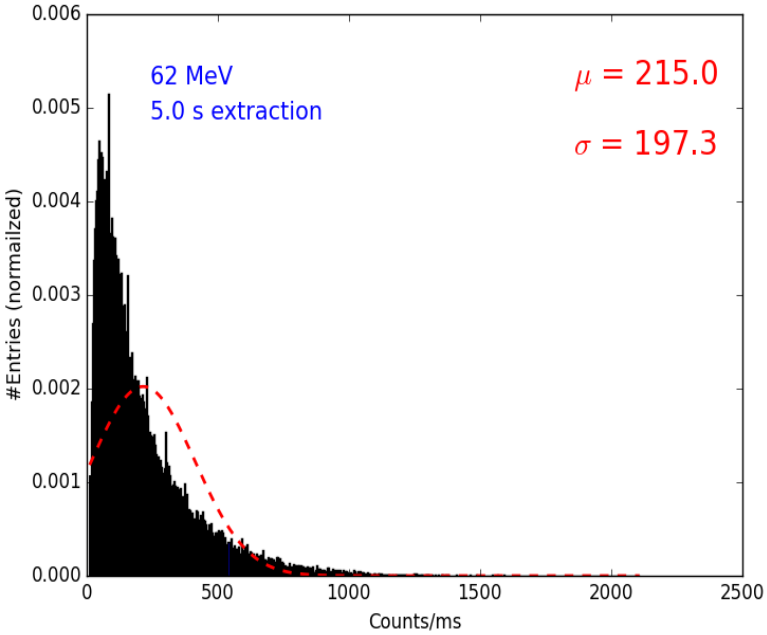


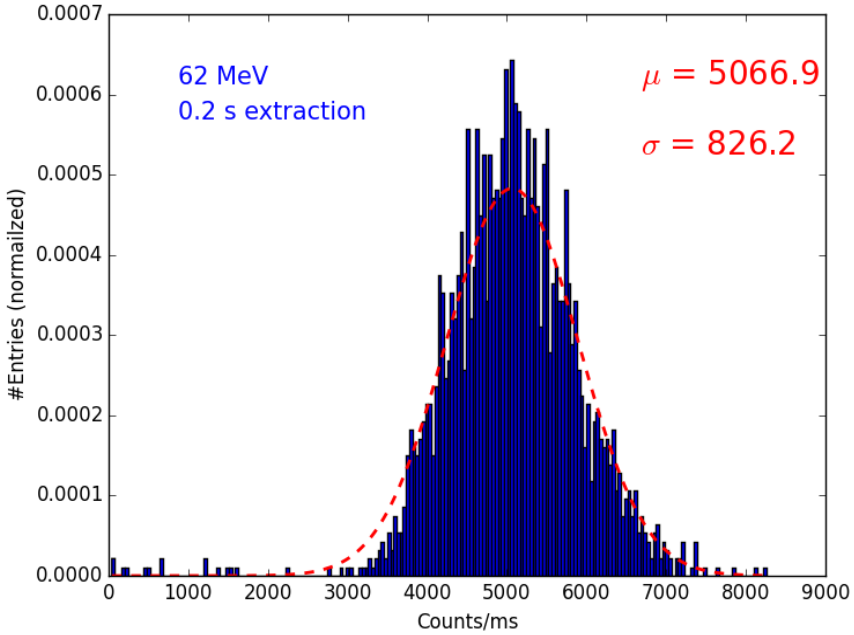
Vertical strip chamber
Distribution of interlocks (red)

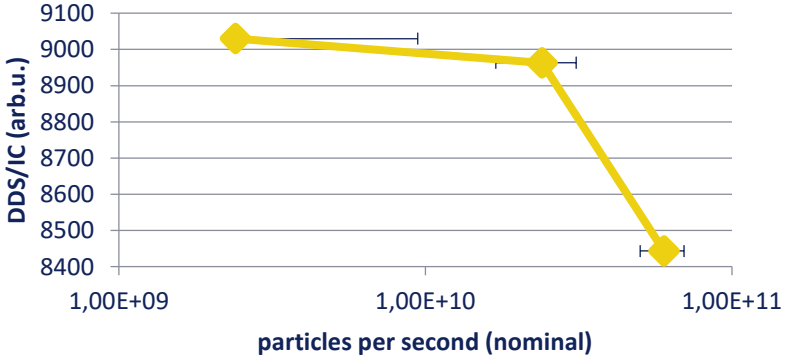


FWHM Upper Threshold = 110%

MONITOR LINEARITY (INTENSITY)

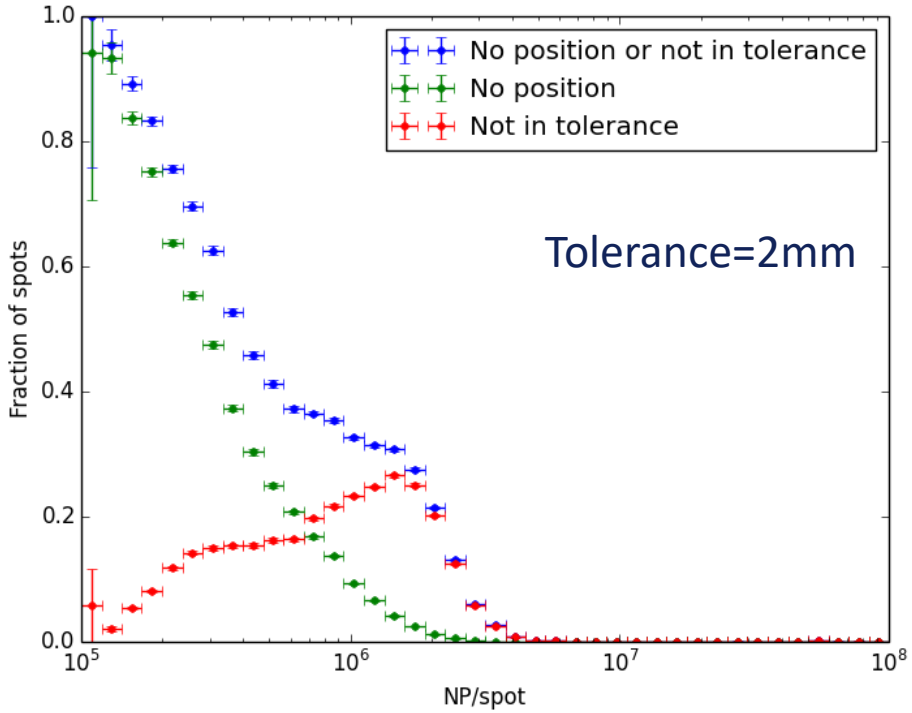






TREATMENT RECORD ANALYSIS

Deviations of spot positions



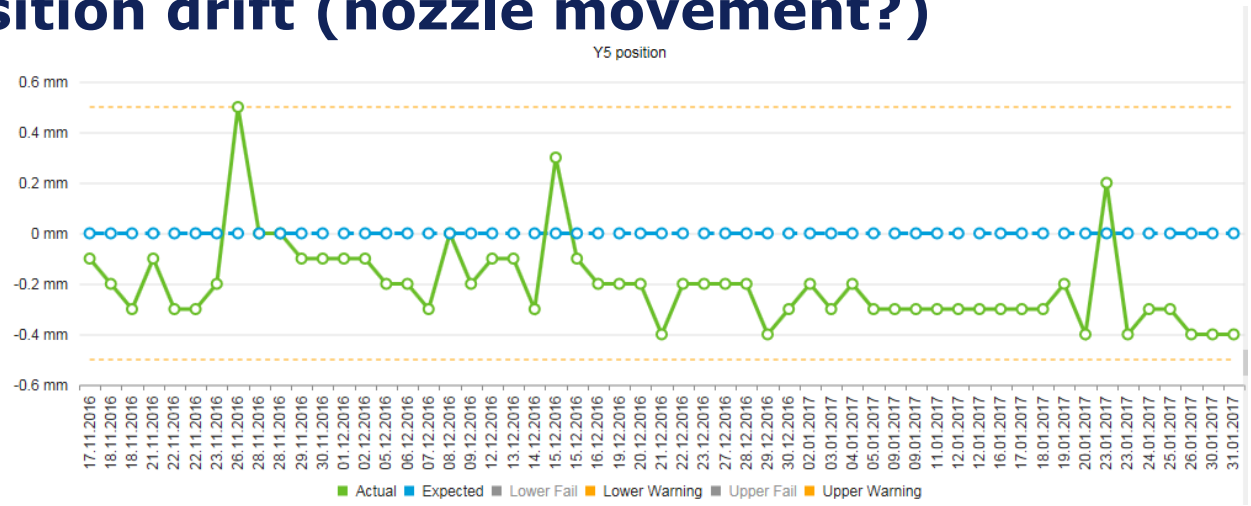
According to DDS 60601-2-64 compliancy analysis: For deg20%: ~2.7E6 NP/spot for spot measurement needed.

- 1M NP/spot still:
  - ~10% spots w/o position
  - ~25% spots out of tolerance
- 4M NP/spot :
  - Nearly all spots with position and within tolerance

Medical Physics is performing studies of the dosimetric impact of the reported deviations

MONITORING DRIFT BEHAVIOUR

- **Position drift (nozzle movement?)**



- **Dosimetric drift**

Date	Purpose	Energy [MeV]	z_ref [mm]	Dose [Gy]	Diff. Dose to Baseline 19.08.2016 [%]
2/13/2017	Yearly QA	252.7	20.0	0.157	0.2%
2/13/2017	Yearly QA	248.8	20.0	0.158	0.3%
2/13/2017	Yearly QA	240.8	20.0	0.161	0.1%
2/13/2017	Yearly QA	232.6	20.0	0.163	-0.2%
2/13/2017	Yearly QA	224.2	20.0	0.166	-0.7%
2/13/2017	Yearly QA	215.7	20.0	0.170	-0.8%
2/13/2017	Yearly QA	207.0	20.0	0.175	-0.9%
2/13/2017	Yearly QA	198.0	20.0	0.180	-1.0%
2/13/2017	Yearly QA	188.7	20.0	0.186	-1.0%
2/13/2017	Yearly QA	179.2	20.0	0.191	-1.2%
2/13/2017	Yearly QA	169.3	20.0	0.199	-1.3%
2/13/2017	Yearly QA	159.0	20.0	0.208	-0.7%
2/13/2017	Yearly QA	148.2	20.0	0.219	-0.4%
2/13/2017	Yearly QA	136.8	20.0	0.234	0.0%
2/13/2017	Yearly QA	124.7	20.0	0.253	0.3%
2/13/2017	Yearly QA	111.6	20.0	0.280	0.0%
2/13/2017	Yearly QA	97.4	20.0	0.305	-0.5%
2/13/2017	Yearly QA	97.4	14.0	0.319	-0.4%
2/13/2017	Yearly QA	81.3	14.0	0.365	-1.0%
2/13/2017	Yearly QA	72.4	14.0	0.417	-0.8%
2/13/2017	Yearly QA	62.4	14.0	0.514	-0.4%

COMPATIBILITY ISSUES AND LIMITATIONS / OUTLOOK

- Compliance to IEC 60601-2-64
- Different accelerator as compared to CNAO, but
- Intensity limitations:
  - currently limited to 20% of nominal number of particles per spill
  - Interlock latency and chamber performance at high intensities
  - Position regulation -> position interlock latency
- For Risk Analysis and analysis of compliance to standards, a detailed understanding of the exact behaviour is needed, beyond the level of available documentation
- Organisational inefficiencies

MedAustron