The MedAustron Experience
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MedAustron in Austria

Wiener Neustadt

MedAustron Center

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MedAustron in Austria

OWNERSHIP STRUCTURE

Federal State of Lower Austria

100 %
Holding structure

EBG MedAustron GmbH
**MedAustron in Austria**

**OWNERSHIP STRUCTURE**

Our main task is the operation of the facility as an outpatient clinic.

Treatment of up to 1000 patients/year in full operation from Austria and foreign countries.

We focus on the further development of this treatment method and the technology behind.

Our facility is used for basic and translational research.

»EBG« stands for construction and operating company.
From concept to clinical operation

From first initiatives to first patient treatment - almost 30 years of history

- **1989 – 1994**: Reorientation towards an ion therapy center -> **MedAustron**
- **1989**: „AUSTRON“ feasibility study (research facility for neutron spallation source)
- **1995**: Company foundation
- **2005**: Signing of basic agreement on realisation: Rep. of Austria, Fed. State of Lower Austria, City of Wr. Neustadt
- **2007**: Completion of building
- **2012**: First patient treatment
- **2016**:
From concept to clinical operation

1989 – 1994

Reorientation towards an ion therapy center
-> MedAustron

1995

„AUSTRON“ feasibility study (research facility for neutron spallation)

1996 – 2000

Proton-Ion Medical Machine Study
(CERN, MedAustron, TERA Foundation)

1998

„MedAustron“ feasibility study

1999 – 2004

„MedAustron“ design study

2005

Company foundation

04/2007

Signing of basic agreement on realisation:
Rep. of Austria,
Fed. State of Lower Austria,
City of Wr. Neustadt
From concept to clinical operation
- High technology branch

- Company foundation
- Cooperation with CNAO and INFN (Know-how on accelerator technology)
- First beam at Injector Test Stand at CERN
- Completion of building
- Designing, tendering and manufacturing of accelerator components
- Cooperation with CERN (Know-how on accelerator technology)

Dates:
- 04/2007
- 11/2007
- 07/2008
- 2008 - 2012
- 08/2012
Accelerator development
– Collaboration Agreements

• Nov. 2007: Collaboration agreement with CERN in the fields of hadron therapy and clinical and non-clinical research with particle beams in particular for the construction of MedAustron in Wiener Neustadt.

• July 2008: Cooperation agreement with CNAO and INFN on an exchange of technical information and know-how on accelerator technology aiming to re-work the CNAO accelerator design.

• August 2008: Partnership agreement with CERN on work related to the design, manufacturing follow up and construction of the MedAustron accelerator facility.

   -> starting point for accelerator development
Accelerator development
– MedAustron @ CERN

• Scope:
  • (Re)design of the accelerator
  • (Re)design and manufacturing of all accelerator components (220 manufacturers from 23 countries)

• Team @ CERN:
  • Up to 50 persons
  • Joined team:
    • Technical experts from CERN
    • Employees of MedAustron

• Duration: 2008 – 2013
Accelerator development – MedAustron @ CERN

Conventional Magnets and Vacuum chambers:
• New EM design
• New Mechanical design

Special Magnets (electrostatic and magnetic septa):
• New EM design
• New Mechanical design

Power Converters and Synchrotron RF:
• New designs

Control System:
• New In-house development
Accelerator development – MedAustron @ CERN

Injector Test Stand:
• From ion source to RFQ
• Measurement bench for beam qualification
• First beam in March 2012
• Dismantled and shipped to MedAustron in Autumn 2012
Product Development of the THERAPY Accelerator

**Status @ End 2012:**
- Accelerator components available/manufacturing process
- Proof of principle for the Injector
- Start of accelerator installation in Austria ahead of us

**How to come to a product to be used/allowed to be used for patient treatment?**

**Missing:**
- Certification strategy
- Patient safety systems
- Beam application aspect and strategy how to integrate the accelerator into the higher-level treatment system
Product Development
-Certification Strategy

- Statement of Austrian Ministry of Health:
  
  The Therapy Accelerator of the Particle Therapy Center MedAustron is to be classified as a medical product and is to be handled in accordance with the Medical Product Law and the European Medical Device Directive 93/42/EWG.

- The principal core process is safe operation of the product (the product is produced only once and will be continuously further developed).

- Medical device classifications: -> class IIb medical device
CE: PATHS OF CONFORMITY ASSESSMENT

Medical Device Directive 93/42/EEC

Technical File
- product description
- essential requirements
- standards applied
- risk analysis
- clinical data
- instruct. for use / label

Classification (annex IX): I, IIa, IIb, III

Classification (annex IX):
- I
- IIa
- IIb
- III

Design Phase

INTERNAL DESIGN CONTROL
(annex VII)

EC TYPE-EXAMINATION
(annex III)

EXTERNAL EXAMINATION OF
PRODUCT DESIGN
(annex II,4)

EXTERNAL EXAMINATION OF
PRODUCT DESIGN
(annex II,4)

Production Phase

INTERNAL PRODUCTION CONTROL
(annex VII)

EXAMINATION OF EVERY PRODUCT
(annex IV)

EXAMINATION OF EVERY PRODUCT
(annex IV)

PRODUCTION QUALITY ASSURANCE
(annex V)

PRODUCTION QUALITY ASSURANCE
(annex V)

PRODUCT QUALITY ASSURANCE
(annex VI)

PRODUCT QUALITY ASSURANCE
(annex VI)

Declaration of Conformity by Manufacturer

DECLARATION OF CONFORMITY

Declaration of Conformity by Manufacturer

DECLARATION OF CONFORMITY

+ Tests, Control, Examinations by Notified Body

Declaration of Conformity by Notified Body
CE: PATHS FOR LIGHT ION BEAM MEDICAL EQUIPMENT

Medical Device Directive 93/42/EEC

Technical File
- product description
- essential requirements
- standards applied
- risk analysis
- clinical data
- instruct. for use / label

Classification (annex IX): IIb

EXTERNAL DESIGN CONTROL (annex VII)

EXTERNAL PRODUCTION CONTROL (annex VII)

EXAMINATION OF EVERY PRODUCT (annex IV)

EXAMINATION OF PRODUCT DESIGN (annex II,4)

QUALITY SYSTEM (annex II,3)

EC TYPE-EXAMINATION (annex III)

QMS acc. EN ISO 13485 since end of 2014

Declaration of Conformity by Manufacturer / Notified Body + Tests, Control, Examinations by Notified Body
Product Development - Certification/Patient Safety Systems

Goal: Certified accelerator (CE acc. to MDD)
-> fulfillment of applicable standards:
  • IEC 60601 series
  • IEC 60601-2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment

Missing:
  • Certification strategy
  • Patient safety systems
  • Beam application aspects; integrate into the higher-level treatment system (workflow)

-> Introduction of the so-called Medical Front-End
Product Development
- Patient Safety Systems
- Beam application and higher level treatment system integration

THERAPY ACCELERATOR:

“Medical Front End” – in accordance with standards related to medical devices
- Components/Systems relevant for safety related to Intended Use (patient safety)
- Components/Systems relevant for overall treatment workflow
  - Dose Delivery System
  - Independent Termination System
  - Energy Verification System
  - Treatment Control Panel
  - Etc...

“main” Accelerator – in accordance with industrial standards

Risk Management, Standards, Functional Safety
CE (MDD): THERAPY ACCELERATOR SYSTEM OVERVIEW

- 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
- Clinical Beamlines IR2: horizontal 1 (A) and vertical (B)
- Clinical Beamline IR3: horizontal 2 (C)
- Clinical Beamline IR4: Gantry Beamline (D)
- MAPTA Treatment Control Panel (Local Control Rooms 1 to 4)
Installation and commissioning @ MedAustron

In parallel: work on Medical Front-End system, QMS, certification process

- Start of accelerator installation: 08/2012 - 01/2013
- Completion of building

- Start of synchrotron commissioning: 03/2014

- First proton beam in treatment room: 11/2014

- Fully established treatment system workflow: 12/2015

- Successful CE certification, Start of patient treatments: 08/2016 - 12/2016

- Start of research program

In parallel: work on Medical Front-End system, QMS, certification process
OUR FACILITY

Irradiation Rooms
Three rooms for patient treatment

Research
Separate irradiation room only for scientific use

Ion Sources
and linear accelerator

Synchrotron
Circular accelerator
LINEAR ACCELERATOR
RFQ and IH-tank, acceleration up to 7 MeV
SYNCHROTRON
Acceleration up 400 MeV/u for carbon ions
TRANSFER LINES

Guiding the particles to the irradiation rooms
PROTON GANTRY

Offering beam irradiation angles of larger 180 degrees
PRESENT STATUS

• Presently 25 patients/day (from 8am – 6pm)
• 2 rooms in operation with protons only
TREATED INDICATIONS

Meningeoma 44%

ENT Tumors 16%

Chordoma & Chondrosarcoma of the Skull Base 11%

Pediatric Tumors 10%

Re-Irradiation 11%

Gastrointestinal (upper) 1%

Prostate 3%

Sarcoma 4%

December 2016 – May 2018
Mainly „established“ indications, suitable for horizontal beam line
Status and Outlook

- Commissioning of further modalities (beam lines, ion species) in parallel to clinical operation.
- Full operation by end of 2021.

- Start of pediatric patient treatments: 12/2016
- Vertical beamline for patient treatments: 07/2017
- Carbon ions for research: 06/2018
- Patient treatments with carbon ions: 05/2019
- 2nd room for patient treatments: 02/2020
- 2nd room with carbon ions, horizontal beam line: 12/2020
- Patient treatments with Gantry: 12/2021
Further development of the Therapy Accelerator

Status:

Beside a well running machine...

- Accelerator performance can not be fully exploited due to safety constraints (dose limits in case of failure scenarios) -> limit the beam intensity

- Switching times between beam lines to be optimised
Further development of the Therapy Accelerator

Further development program (under elaboration):

**Improve treatment (beam on) time:**
Performance increase projects:
- **Scope:** Exploit full accelerator potential (intensity)
  - Change of extraction method (Betatron core to RF KO)
  - B-field regulation
  - Multi Energy Extraction

**Improve switching times:**
- **Scope:** Parallelization of workflow steps
  - B-field regulation

**Enabling new treatment modalities:**
- **Scope:** Gating, etc...
Lessons learned

**MedAustron situation:** „research“ accelerator

**Missing:** Medical product (Therapy Accelerator) considering beam application, safety aspects, etc...

**Key lessons learned:**

- Do proper product development from the beginning of such a complex project (following established industrial/medical standards).

- Take requirements from different origins into account from the beginning:
  
  - User requirements (e.g.: beam application)
  
  - Regulatory requirements (e.g.: patient safety)

  - Reliability requirements (→ optimize uptime, reduce system complexity to minimum required, keep it as simple as possible)
Lessons learned

Key lessons learned:

• Maintainability requirements -> reduction of preventive maintenance times

• Usability/operability requirements -> allow for fast and efficient monitoring and debugging

-> optimize every component w.r.t. the above requirements

-> key drivers for **successful and efficient operation!**
THOUGHTS ON A NEXT GENERATION FACILITY

Goals:
- Cheaper
- Smaller footprint
- Higher performance (faster beam application)

Benchmark: Presently existing one-room proton therapy systems.

There needs to be a market for next generation ion facilities.
THOUGHTS ON A NEXT GENERATION FACILITY

Thinking about ideas and technologies for a next generation ion facility, clinical beam applicability needs to be considered from the beginning.

Design a next generation facility from a user perspective (reliable, fitting the clinical requirements) and market needs.

-> Requires close the co-operation of research centers, treatment facilities and industry.

-> MedAustron can and wants to contribute with our experience and knowledge!
THANK YOU for your attention!

www.medaustron.at