Surgical Robotics -- „Technical VI"

Summer School 2013

Gernot Kronreif

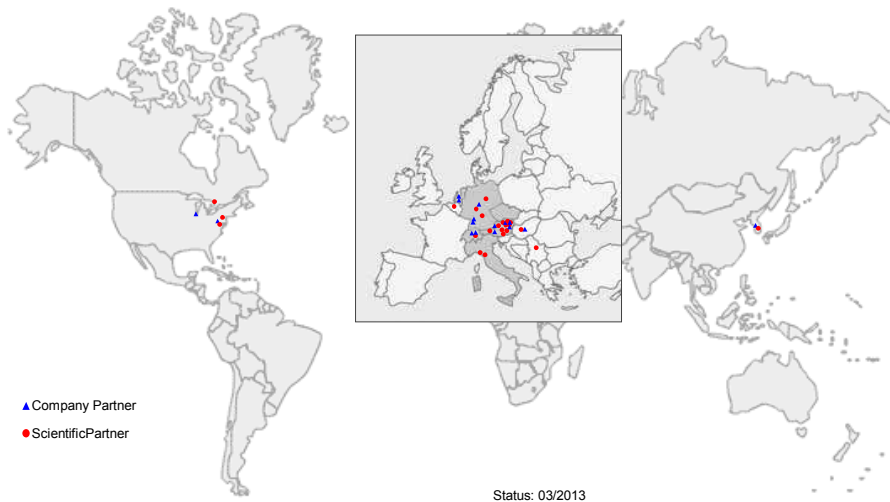Montpellier, 2013-09-09

Introduction

ACMIT – Center Vision

- … be a **leading European institution for innovative medical technology** in selected areas of "Integrated Systems for Minimally Invasive Procedures"

- … **develop and establish new technology** approaches for "Minimally Invasive Procedures" and modern therapies, to create a basis for cost reduction in medicine by using innovative technologies and to make surgery safer and more efficient

- … establish a research and innovation center for **collaborative research between science and industry** at the highest international level

---

ACMIT – Fact Sheet

+ **Multidisciplinary team of 25+ researchers**
  - MechEng, EEng, SWEng
  - Physics, Chemistry
  - Biomedical Engineering

+ **Key data:**
  - 1st funding period (2010-2014): overall budget of 18MEUR
  - 2nd funding period (2014-2017): overall budget 13MEUR
  - International network:
    25 industry partners
    27 research partners (technical + clinical)
  - Match funding
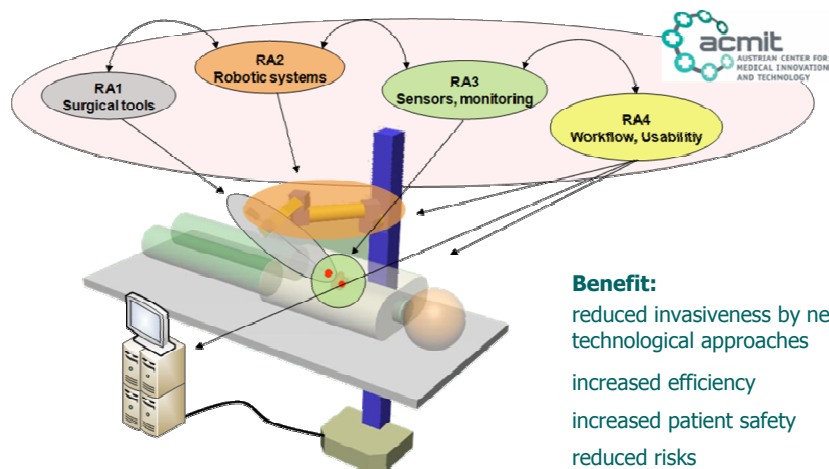
International Network of Partners

▲ Company Partner
● ScientificPartner

Status: 03/2013

Overview of Research Areas

"from user to treatment" in minimal invasive surgery

RA1
Surgical tools

RA2
Robotic systems

RA3
Sensors, monitoring

RA4
Workflow, Usabilitiy

Benefit:

reduced invasiveness by new technological approaches

increased efficiency

increased patient safety

reduced risks

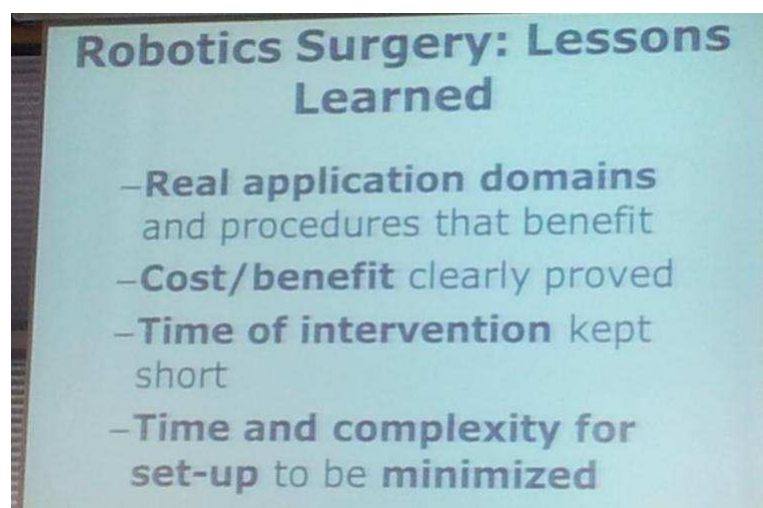# Surgical Robotics – Company's viewpoint

„Drivers" for Medical Robots

+ **„Error-free Surgery"**
  – Design and system in order to make interventions easier/safer
  – Integration of imaging and computer-assistance

+ **Enabling new intervention techniques**
  – „Superhuman" abilities (precision, access)
  – New IGT-applications by means of robots

+ **New aspects for clinical research**
  – Reproducibility, consistency, data acquisition

+ **Robots for education and training**
  – Mentoring
  – Integration of simulation and robotics

+ **… and others …**

Inhibitors for Medical Robots

- Cost effectiveness **not yet proved**
  - increase OR cost
  - technical team in the OR
  - training of the surgical team
  - setup and skin-to-skin times longer than conventional procedure
- Clinical added value **not yet clear:** *"it is difficult to prove their effectiveness since there are no established methods to relate conventional (non robotic) techniques that would serve as benchmarks …"*
- Compatibility with the environment of the OR (cluttered, other electrical devices…): **yet too bulky**
- **Safety**
  - the robot shares its working space with surgical staff and patient
  - "trail & error" or "doing again" motions are not allowed
  - sterilizability constraints

ERF, 03/2013, Lyon

Robotics Surgery: Lessons Learned

- Real application domains and procedures that benefit
- Cost/benefit clearly proved
- Time of intervention kept short
- Time and complexity for set-up to be minimized

Form MedTech-Pharma, 05/2013, Munich

Erkenntnis aus den ersten Jahren der „Medizinrobotik":

-Chirurgen sind neuen Techniken gegenüber aufgeschlossen!

-Industrielle Ansätze nicht übertragbar!

-Nach der Euphorie der Anfangszeit folgt die Ernüchterung!

→Neue Konzepte müssen einfach und effizient sein!

What makes a robot successful?

+ **Successful setup depends on four criteria:**
  – Device must provide quantifiable, functional benefits to the patient.
  – Device should improve the efficiency of therapists' current practice.
  – Device should be affordable for clinics yet profitable for manufacturers.
  – Device should not increase the cost of health care.

COST ‹ PRICE ‹ BENEFIT

What kind of push?

+ **Technology push?**
  - Worked with daVinci -- but always successful?
  - Requires certain amount of luck

+ **Medical push?**
  - Is technology enabler for a new (and better) treatment?
  - Needs evidence! (=time, money)

+ **Market push?**
  - Extremely intricate!
  - Is there any market? Opening a market is expensive!

## How to proof the benefit of a robot?

+ **Demonstration of clinical benefit**
  - Demonstration in clinical evaluation $\leftrightarrow$ robot is product
  - Can modularity help?

+ **Is demonstration of clinical benefit sufficient?**
  - Interfaces to existing setup
  - Economic constraints
    - New technology resulting in higher cost?
    - Is it possible to have any additional cost refunded?
  - Human factors
    - Impact of new technology to existing structures and processes
    - Usability, Intuitiveness
    - Valorisation of the user
    - "Patient push" – can easily turn into wrong direction

P. Finlay, CEO Medimaton

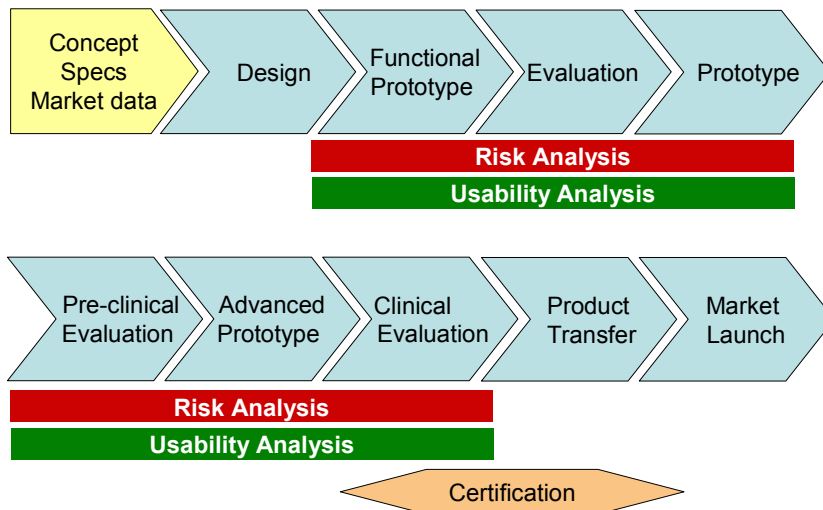## R. Kikinis, BWH-Harvard
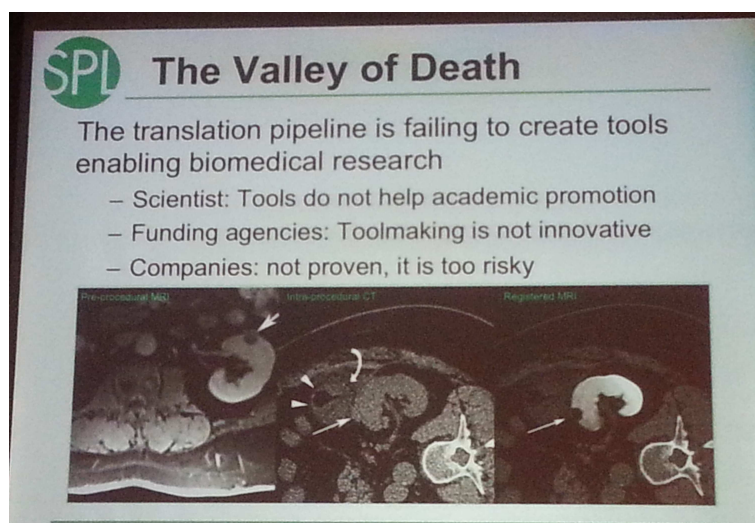
Open questions from company viewpoint

+ **How to prove medical outcome mid-/long-term?**
+ **Economic outcome**
+ **Usability vs versatility**
    – Single use systems?
    – Universal systems?
+ **Instrumentation**
    – Life-cycle?
    – Meeting clinical requirements
+ **Integration**
    – Integration into existing environment
    – Integration into existing work-flow

Development phases and documentation

The LOOOOOONG way to a product

Concept Specs Market data → Design → Functional Prototype → Evaluation → Prototype

Risk Analysis

Usability Analysis

Pre-clinical Evaluation → Advanced Prototype → Clinical Evaluation → Product Transfer → Market Launch

Risk Analysis

Usability Analysis

Certification

V&V-Tests and Reports

+ **Validation/Verification of the design and the development process …**
    – has to be performed
    – has to be documented (including measures, if applicable)
    – might include a clinical V&V (depending on national legislation)
    – **needs to be completed before market launch**

Source: ISO 13485, chapter 7.3.6

Checklist V&V-Test Reports

+ **Formal Aspects**
  - Purpose
  - Author
  - Date, Time
  - Relevant Standards
  - Traceability
  - Confirmation

+ **Content**
  - Test configuration
  - Method, Material
  - Expected result
  - IO/NIO criteria
  - Observed result
  - Measures (i.a., traceable)
  - Discussion

Safety

Industrial versus Medical Robots

Industrial Robots

- Isolated from the workers (appropriate training to interact with them) by preventing machine workspace from human intrusion

- Possibility to enter in the workspace (for maintenance purpose or learning procedures) without stopping the machine:
  - Disconnecting of the protection devices
 - Activating the "manual mode" with limited speed

Medical Robots

- Medical robots cooperate with the human (surgeon and staff) and interact the patient

- Harsh constraints and specifications in the design itself, especially for active medical devices

- Influence of human factor and clinical constraints specific to mechanical devices for medical purpose
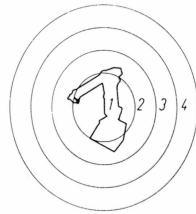

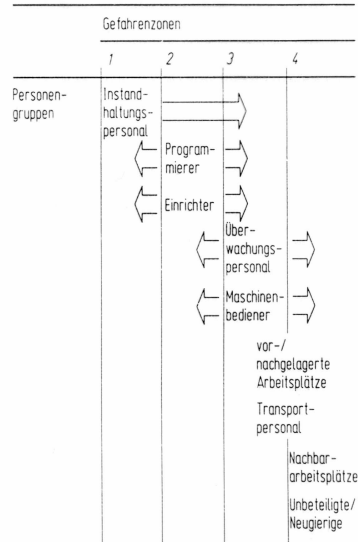## Industrial Robots: Risk potential

+ **Risks due to automatic operation**
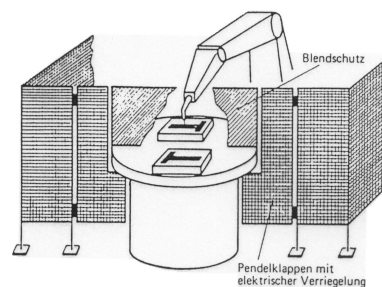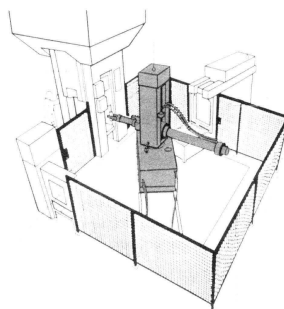
+ **Risks due to robot/cell setup, programming, testing**
+ **Risks due during recovery after breakdown of robot/cell**
+ **Risks due to robot maintenance and/or repair**

Industrial Robots: Users at risk

Industrial Robots: Hazards

+ **Typical risks for programmers, tool setter, etc**
    – Clamping/shearing at kinematic structure
    – Clamping/shearing between robot and periphery
    – Movement with high speed
    – Un-determined trajectories
    – Risky movement due to wrong/incomplete input
    – Risky movement due to wrong sequence
    – Risks due to un-synchronized movement in linked processes (wrong or unexpected input signals)

➔ **Similar operation conditions as for surgical robots ➔ risk reduction measurements from EN775 also suitable for surgical robots**

Industrial Robots: Safety measures for programming

+ **Avoiding potential clamping/shearing areas**
    – cover, appropriate mechanical design
+ **Define safety areas for persons working inside the safety fence**
+ **Limitation of robot's working area according to the task requirements**
    – mechanical stoppers, software limits
+ **Movement of the robot only when particular button pressed**
+ **Emergency-Stop at Teach-Box**
+ **Reduced robot speed during programming mode**
    – Operation with high speed only during activation of a dedicated confirmation button (dead-man switch)

Safety: Human Factor

- Work done on human being:
    – Change in working conditions with each patient (characteristics of soft tissues, position of the patient on the operating table, size of the body and accessibility of the organs,…)
    – Task and execution specific to a patient: no "trial/error" nor "doing again" movements
- Robot directly in contact with the patient and staff:
    – Necessity of preoperative studies to plan the intervention
    – Modification of planning during the operation itself, according to the surgeon diagnostic, possible complications or patient organism behavior
- Surgeon is not "robotic specialists":
    – Dedicated user-friendly HMI: task-oriented, allowing an easy manipulation of the system
    – Robot transparency: avoiding singularities, mechanical joint limits, reconfiguration procedures,…

Safety: Clinical Issues

- Every component of the system in contact with the sterile field must be sterilized (generally, the robot is covered by a sterile sleeve while the tool is separately sterilized by an autoclave procedure);

- Environment is usually unstructured: operating rooms are cluttered with several other medical systems (radiology, anesthesia, surgery, etc.). The robot position with respect to the patient varies between two operations and even a single operation. Thus, its dimensions have to be reduced;

- The robot has to be easily and quickly transportable in and out of the operating room

- Required functionalities are defined according to each kind of clinical operations ➜ new medical robots have often been designed for specific operations;

Special Requirements for Medical Robots

In contact with human body

- **Specific functionalities**
- **Easily movable**
- **Optimal size**
- **Manually controllable**

- **Unstructured environment,**
- **No repetitive tasks,**
- **Sterilization of the components…**
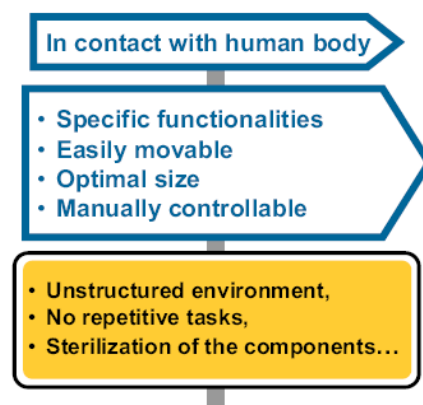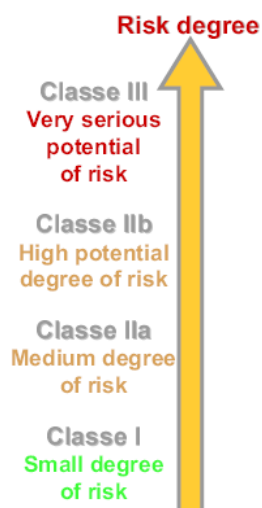
Safety Strategy

- Elementary rules for designing a "safe" surgical robot:
  - No uncontrolled motions
  - No excessive force on patient
  - Keep the surgical tool in a predefine workspace
  - Supervision by the surgeon of any motion

- To guarantee a high level of safety, a medical device such as a robot may be designed considering the main following principles:
  - The degree of redundancy in control and sensing
  - The possibility to design an intrinsically safe system (i.e. capacity to decrease the maximum level of risk by construction)
  - The tradeoff between reliability and safety. (… and cost)

- Reduction of functionality!
  - Decrease DOF, ROM, operation speed, etc
- → **Do what is NEEDED, rather than what COULD BE DONE**

Safety: Regulations and Standards

- In European Community: ISO 9000 norm has been modified to comply with the specific constraints of medical devices in the European directive 93/42/CEE.

- CE marking: the EN 46000 certification enacts the various criteria necessary to classify all the medical devices according to four classes.

- Device classification depends on:
  1. its life span use: from a few minutes (temporary) to several years (implantable)
  2. its invasiveness or non-invasiveness
  3. its surgical or non-surgical use
  4. its activeness or inactiveness
  5. the vital or non-vital body parts concerned by the device

Risk degree

Classe III
Very serious potential of risk

Classe IIb
High potential degree of risk

Classe IIa
Medium degree of risk

Classe I
Small degree of risk

Intended Use

+ **Based on EN ISO 14971 ("Medical devices — Application of risk management to medical devices")**
+ **Description should include:**
    – Description of the main function(s) of the system.
    – In what way(s) might the medical device be deliberately misused?
    – What is the role of the system for assisting the user?
    – Is there any direct physical interaction between user and robot?
    – To what mechanical forces will the robot be subjected?
    – Description of the users of the system. Does use of the robot require special training or special skills?
    – Is the user controlling the system? Is successful application of the robot critically dependent on human factors such as the user interface?
    – Information about the environment of use. Is the robot changing or influencing the environment?
    – Who is installing the system?
    – What are the requirements concerning maintenance and system calibration?

"Medical Devices Directive" (93/42/EEC)

+ **Article 3:**
    – The devices must meet the essential requirements … which apply to them, taking account of the intended purpose of the devices concerned.

    – Essential requirements regarding to:
        • Design
        • QA-Systems
        • Harmonized standards
        • General Essential Requirements

    Safety and Effectiveness

+ **Remark:**
Where a relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC … shall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex I to this Directive.

Harmonized Standards

```
                    ┌──────────────────┐
                    │   Standards for  │
                    │     products     │
                    └──────────────────┘
              ↙              ↓              ↘
    ┌──────────┐      ┌──────────┐      ┌──────────┐
    │  Design  │      │  Design  │      │ Software │
    └──────────┘      └──────────┘      └──────────┘
```

• EN 60601-1 (General, Design)   • EN 60601-1 (General, El. safety)   • EN 60601-1-4
• ISO 10555-x (Catheters)   • EN 60601-1-1(Systems)   • EN 62304
• ISO 10993-x (Biocomp.)   • EN 60601-1-2 (EMC)
• Etc ...   • ISO 14971
    • Etc ...

```
    ┌──────────┐      ┌──────────────────┐      ┌──────────┐
    │ Company  │ ←──  │   Standards for  │  ──→ │ Process  │
    └──────────┘      │   organisation   │      └──────────┘
                      └──────────────────┘
```

• EN 13485, etc..   • EN 60601-1-4
   • EN 62304
    • ISO 14971, etc..

Essential Requirements

+ **General Essential Requirements:**
    - … when used under the coordination and for the purposes intended, the device will not compromise the clinical condition or the safety of patients, or the safety and health of users …
    … acceptable risks when weighed against the benefits to the patient …
    - … solutions adapted by manufacturer … must conform to safety principles … apply the following principles in the following order:
        • eliminate or reduce risks as far as possible (inherently safe design),
        • take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,
        • inform users of the residual risks due to any shortcomings of the protection measures adopted.
    - … devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way …
    - … characteristics and performances … must not be adversely affected … during the lifetime of the device … when the device is subjected to the stresses which can occur during normal conditions of use
    - … not be adversely affected during transport and storage …
    - … undesirable side-effect must constitute an acceptable risk when weighed against the performances intended …

Risk Management
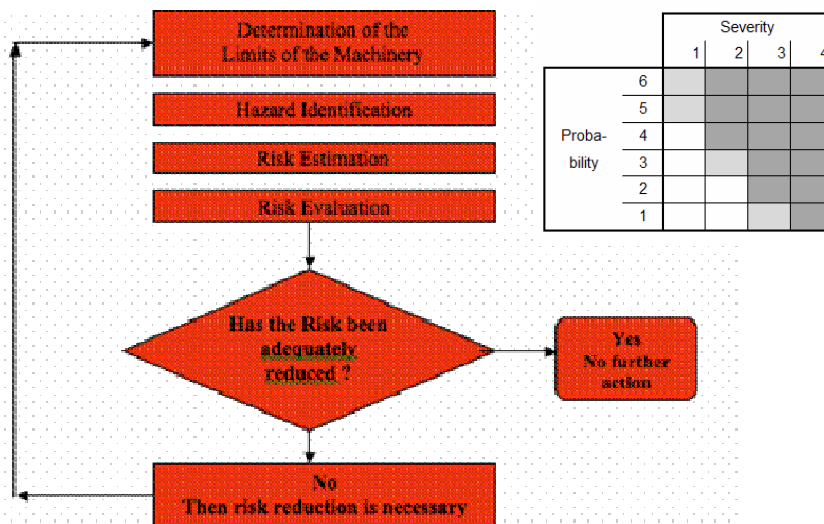
Remark: How to identify threads?

+ Standards
+ Existing RAs of similar products
+ Feedback from engineering and marketing team, users of similar products
+ Brainstorming in a RA team
+ Analysis of existing databases and reports
  (e.g.: http://www.fda.gov/cdrh/maude.html)
+ Annex A and D of ISO 14971

Risk Management

Failure Mode and Effects Analysis (FMEA) Worksheet

Page: | of

| System, Product, or Process: | | | | Owner: | | | | | Date: | | | | | |

		Background			Rating				Countermeasure				Results			
Description	Potential Failure Mode	Potential Effect of Failure	Root Causes	S E V	O C C	D E T	R P N	Owner	Due- / Done	Action	S E V	O C C	D E T	R P N		

Contact

Austrian Center for Medical Innovation and Technology
operated by Integrated Microsystems Austria GmbH

Dr. Gernot Kronreif (CSO)
Gernot.Kronreif@acmit.at

Viktor Kaplan-Straße 2 / Geb. A / 1.Stock
A - 2700 Wiener Neustadt
Tel. +43 2622 22859 – 20
Fax +43 2622 22859 – 55
www.acmit.at