Dependability Design of a Tracking Fluoroscope System for Orthopedic Diagnostics

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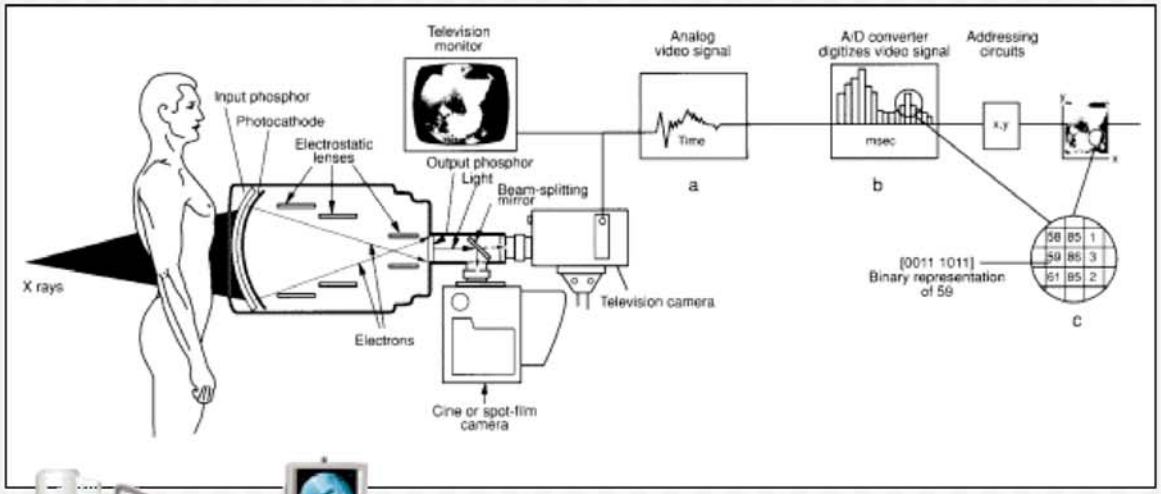
Tracking Fluoroscopy

- Background
  - Fluoroscopy in orthopedic applications
  - Fluoroscopy applied to biomechanics modeling and analysis
  - Examples of current practices
- Needed improvements
- The TFS Concept
- Dependability Issues and Approaches
- Summary

Conventional Fluoroscopy



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“Static” C-bar

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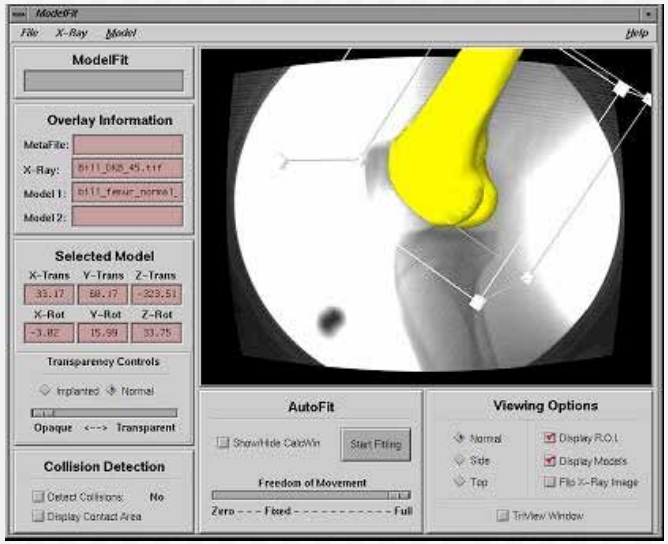
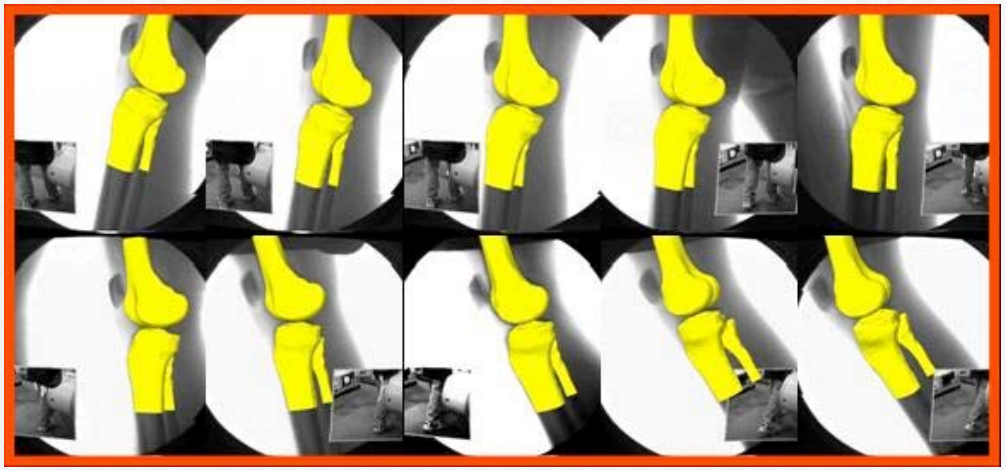
Fluoroscopy applied to biomechanics & surgical follow up

- Integrate 2D x-ray, CT scans,CAD, dynamics models…predict in vivo forces and motion details.





Needed Improvements

- Natural movements, e.g., walking, climbing steps, etc.
- Hips, ankles, and knees imaging…with simple set ups
- Loaded and unloaded conditions
- Faster frame rates
- Reduced radiation exposure

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Tracking Fluoroscope Concept

- Mobile platform with omni-directional propulsion to “track” human subject.
- Platform-mounted vertical and horizontal translational servos to track skeletal joint movement wrt body.
- **Extensive embedded real-time computing.**
- Tetherless and self-powered.
- Speeds: walking to jogging.
- Evaluate hips, knees, and ankles.

{Patent Pending}

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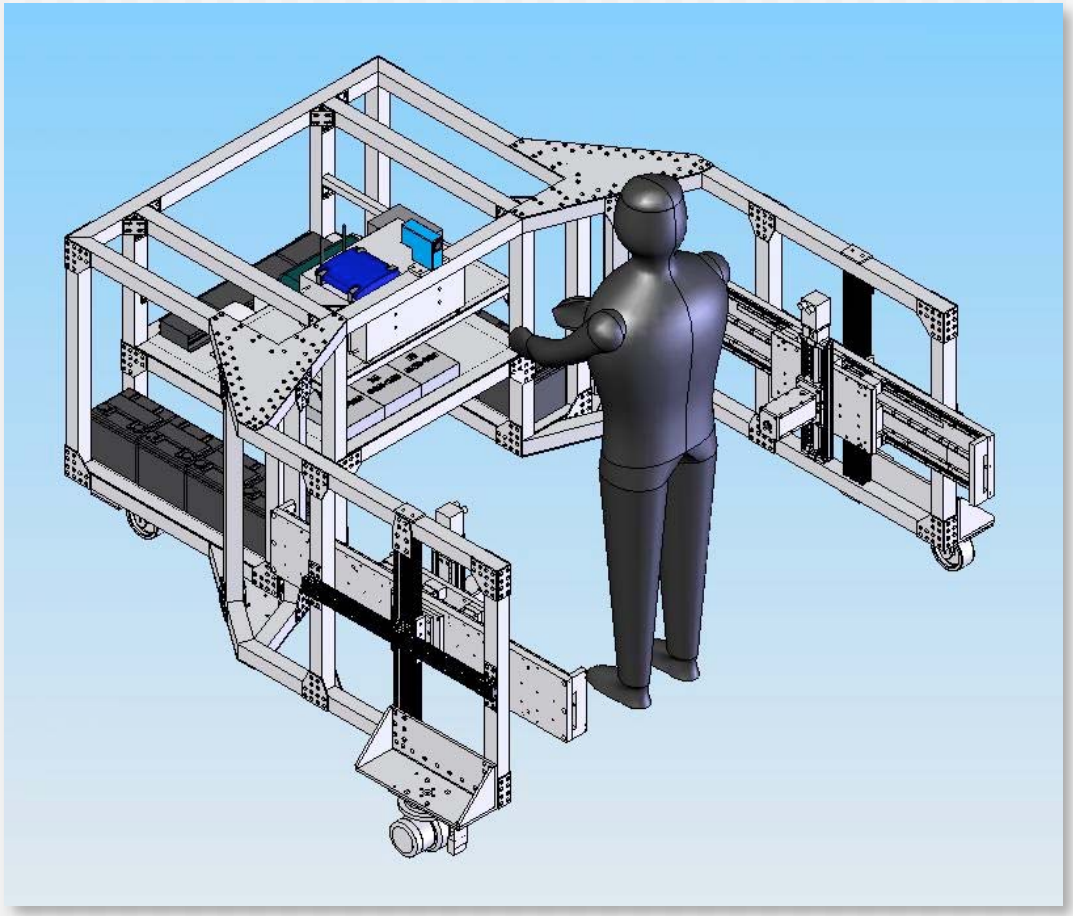
UT-CMR TFS Prototype



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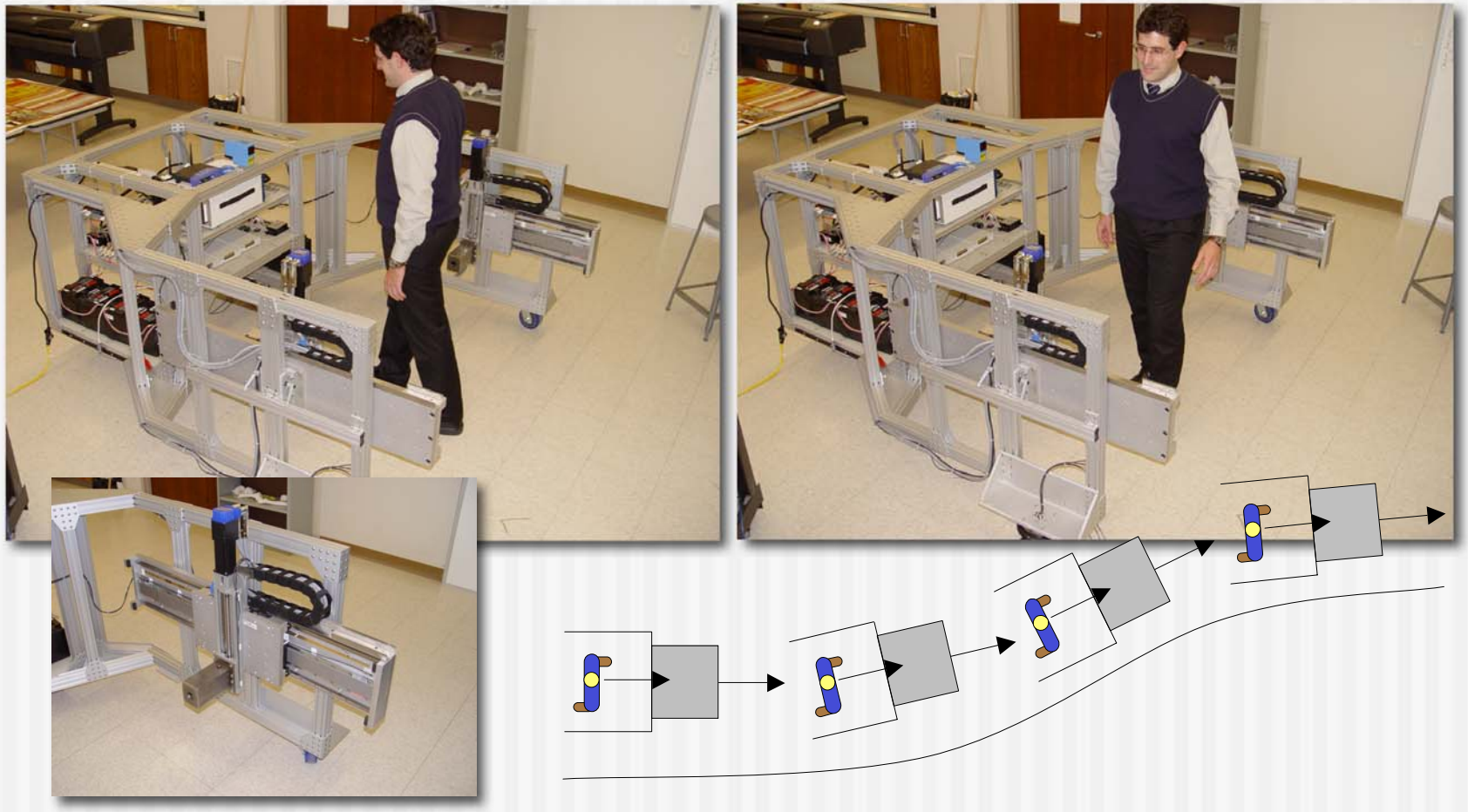
UT-CMR TFS Prototype



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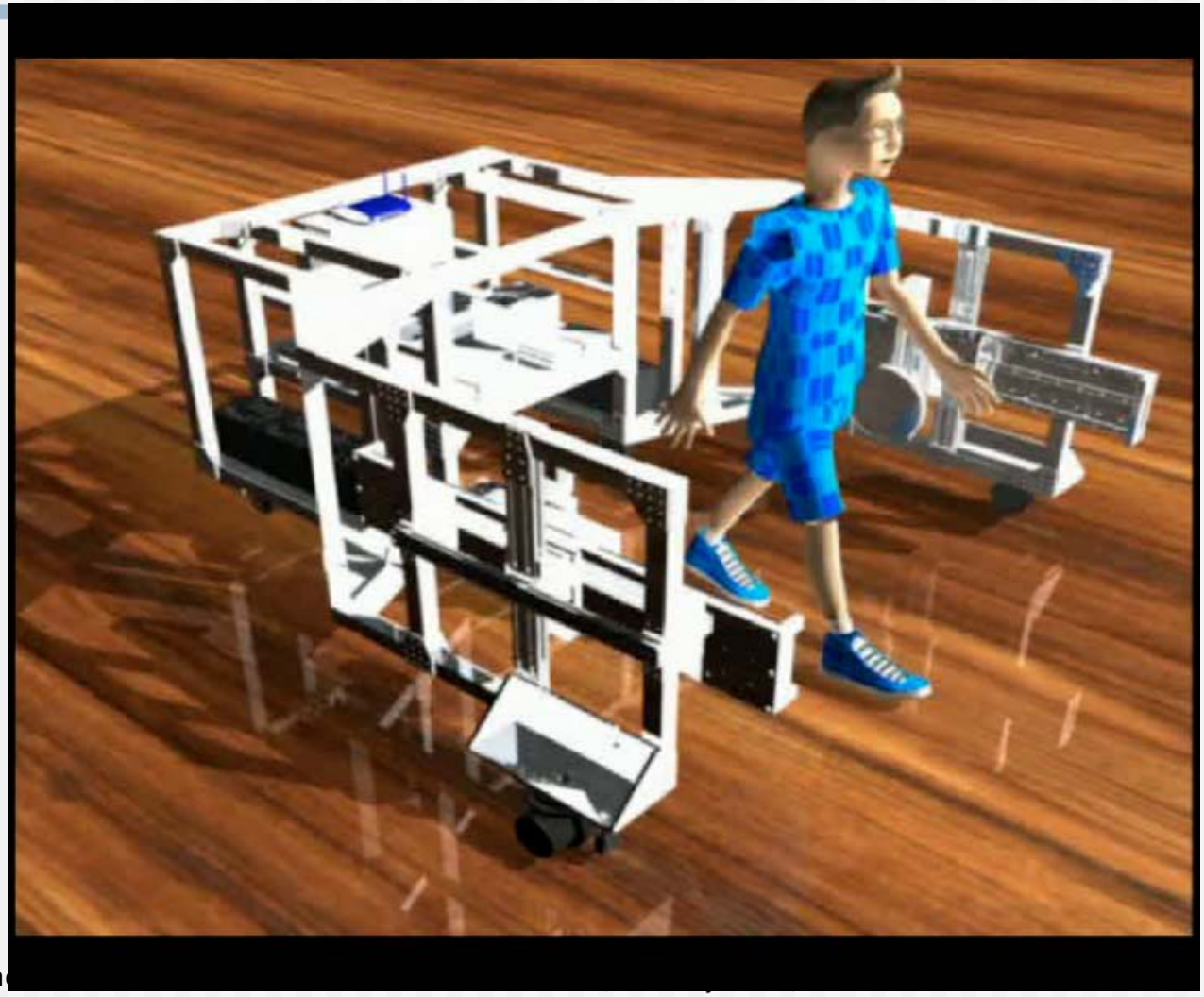
TFS Animation



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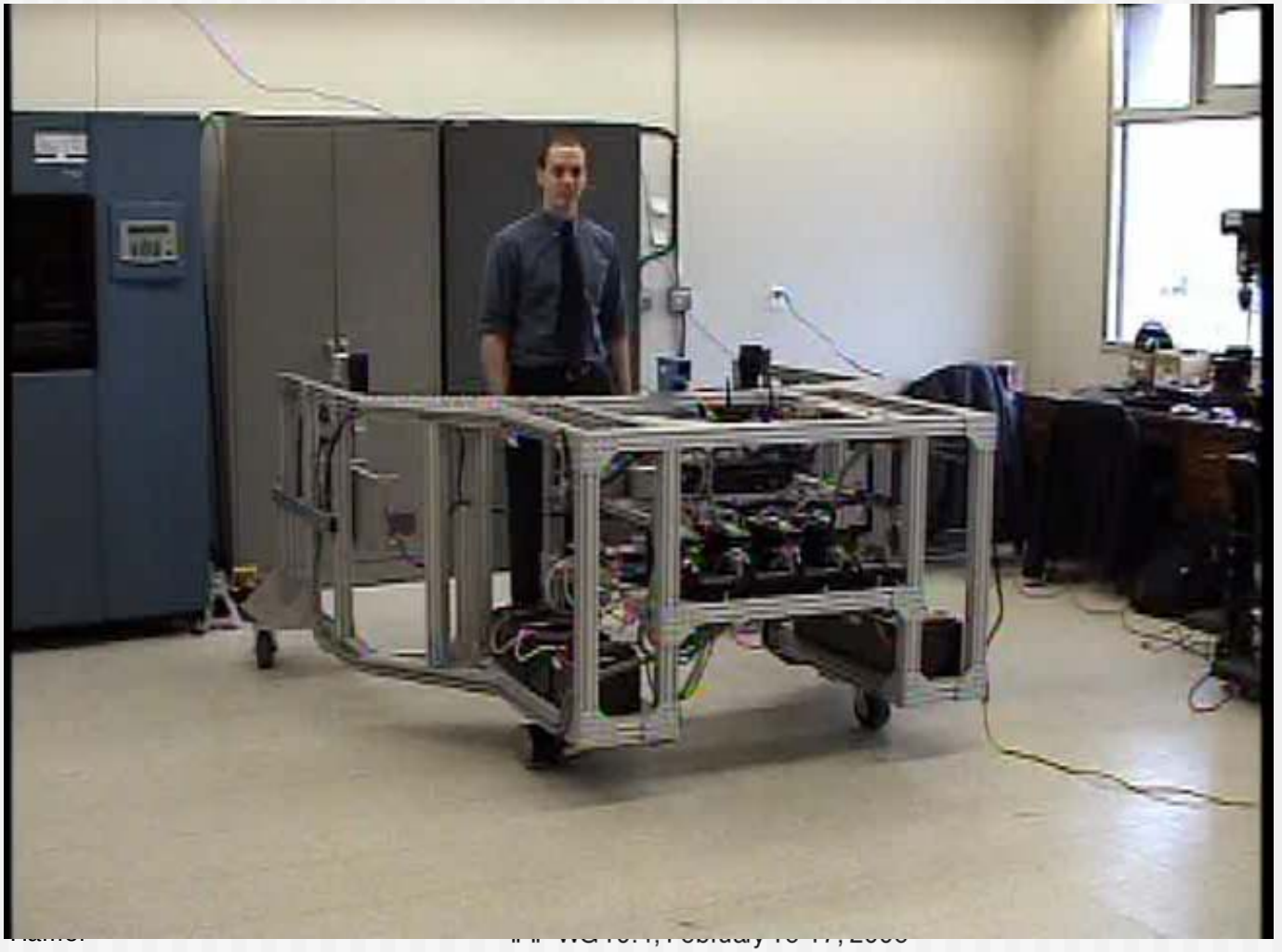
TFS Prototype Operation



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A "dependable" TFS would be reliable & safe

- Should be reliable…high availability.
- Should be rad technician/MD friendly and intuitive.
- Should be "friendly" to subjects of all ages and conditions
- Should be ultra-safe to subjects being diagnosed:
  - Potential collisions,
  - Radiation exposure.
- Should be self-protective:
  - Potential collisions with environment.

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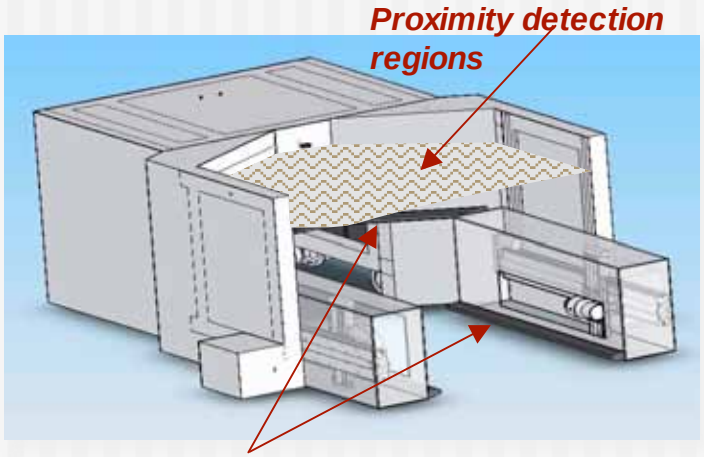
Safety vulnerabilities…motion control

- TFS operating environment is a dynamic robot/human environment
- Concerns
  - Electronic/software faults
  - Sensor (perception) malfunctions
  - Unexpected subject/patient behavior
  - Operator errors
- Consequences
  - Improper radiation exposure…operating license
  - Potential collisions with subject…injury
    - Mobile platform - subject tracking
    - X-ray, image intensifier modules - joint tracking
  - Potential collisions between TFS and environment…damage/repairs

Safety Approaches…patient interaction

- Active
  - Operational limit checking
    - Vehicle velocity and acceleration
    - Wheel drive motor current limits
  - Patient physical contact
    - "Touch grounding" of TFS body.
    - "Bumper" switches at critical locations
  - Suitable redundancy
    - Control/computer architecture
    - Independent sensor channels
  - Suitable hardware interrupts…Dedicated E stops
- Passive
  - Slip clutches in drive train
  - "Cow-catchers"
  - Grab rails



Safety approaches…patient radiation exposure

- Absolute control of location of radiation 3D volume.
- Active Controls…
  - Independent definition of LOS…visible laser designator
  - Real-time tracking error monitoring
  - Spurious x-ray monitoring
  - Suitable redundancy
    - Control/computer architecture
    - Independent sensor channels

At this point, R&D regulated by US Food and Drug Administration and State authorities.

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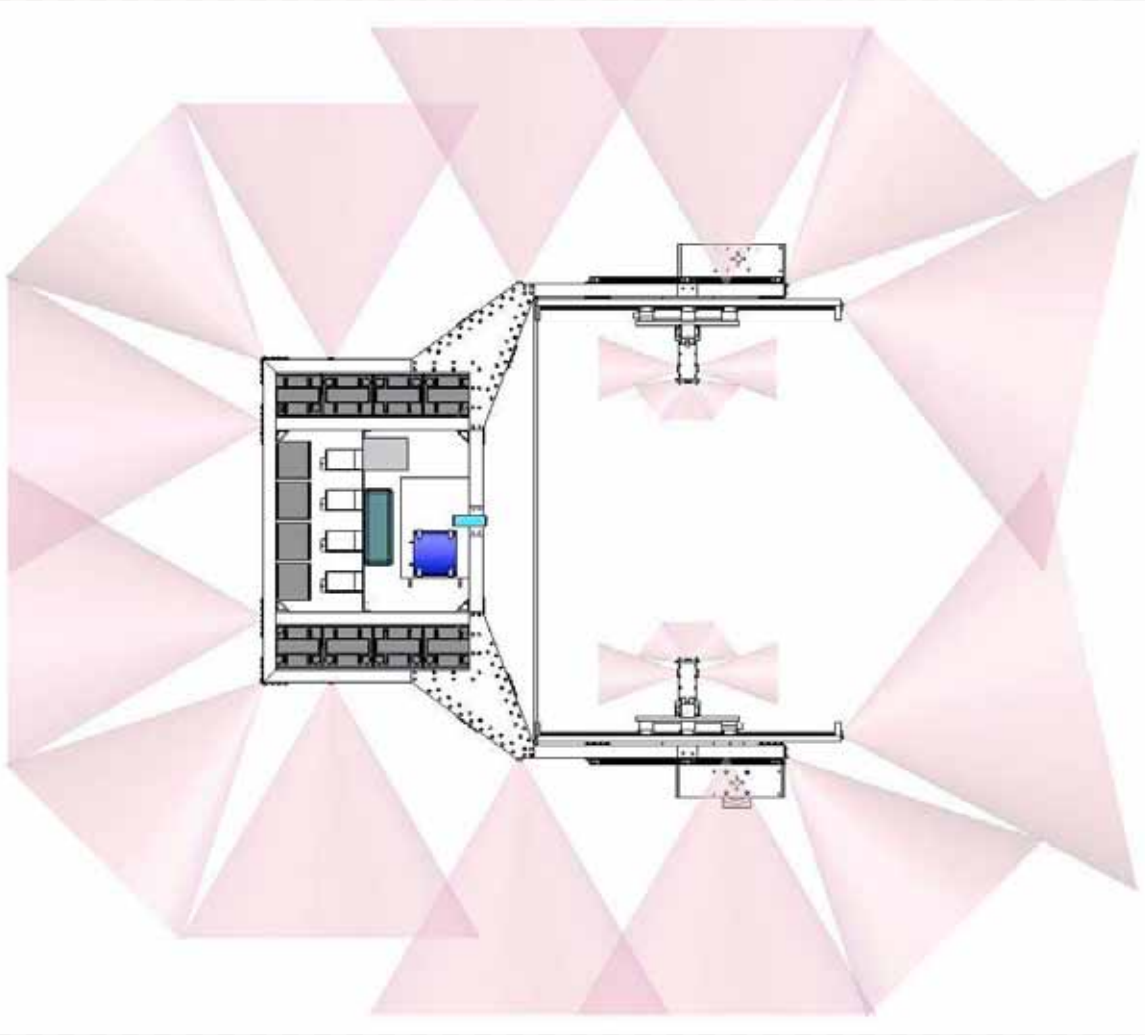
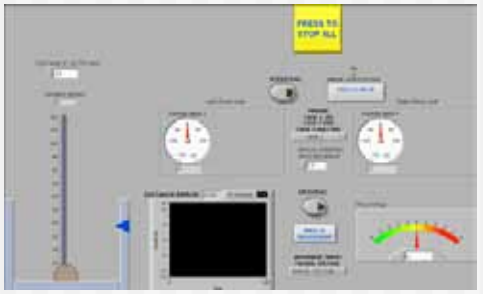
Safety…collisions with environment



Dependability concerns…design perspective

- TFS Domain [h/w & s/w]:
  - Human proximity:
    - Close (0.2–2.2 m/s), 400 kg: O (secs)-O(0.1 secs)
    - Dynamic situation
  - Communications, control, and drive systems fault tolerance…cost effectiveness.
  - Dependable [accuracy & response time] human-machine interfaces…set up integrity; emergency stops
- *Safety within development cycle.*



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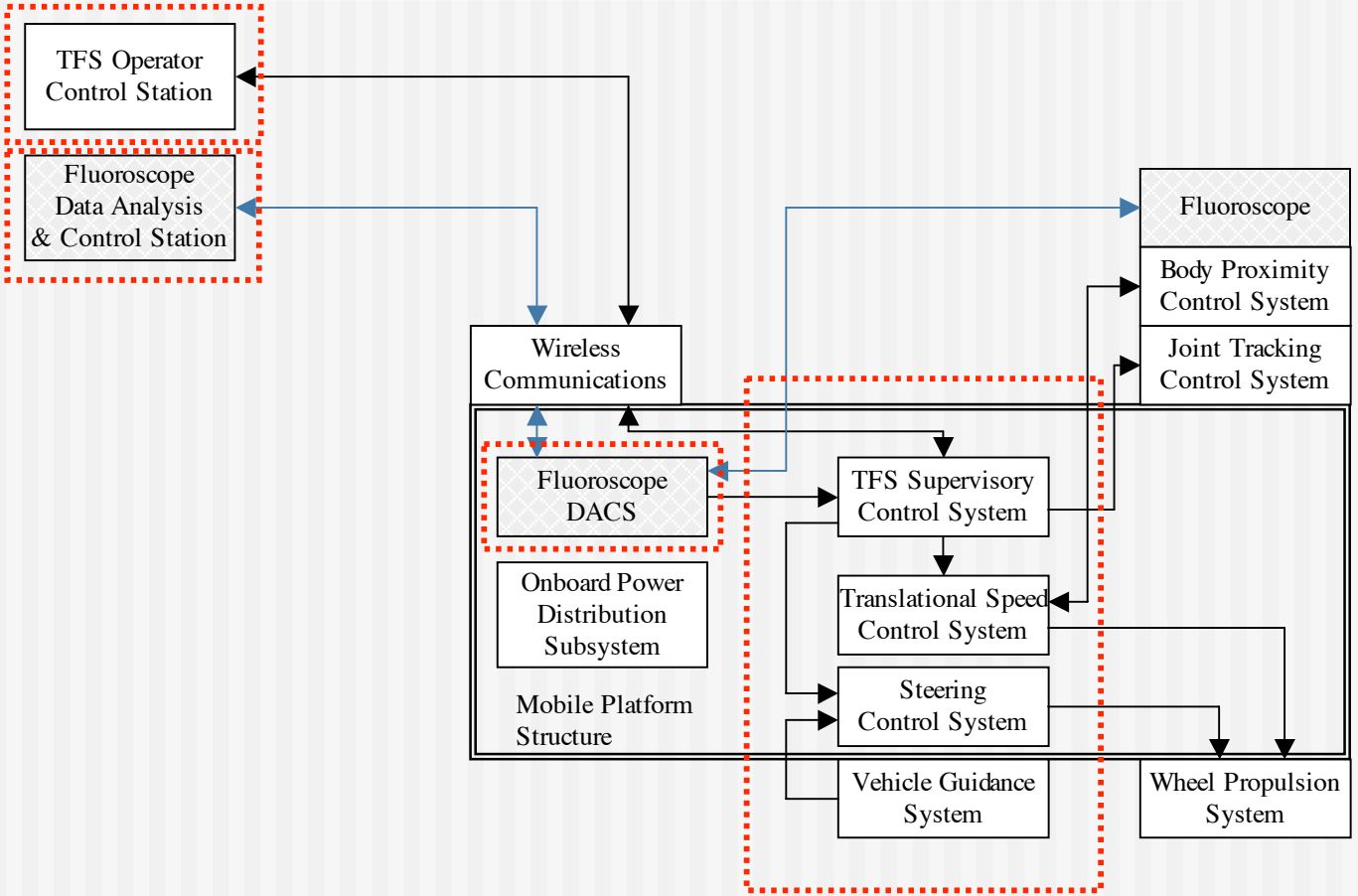
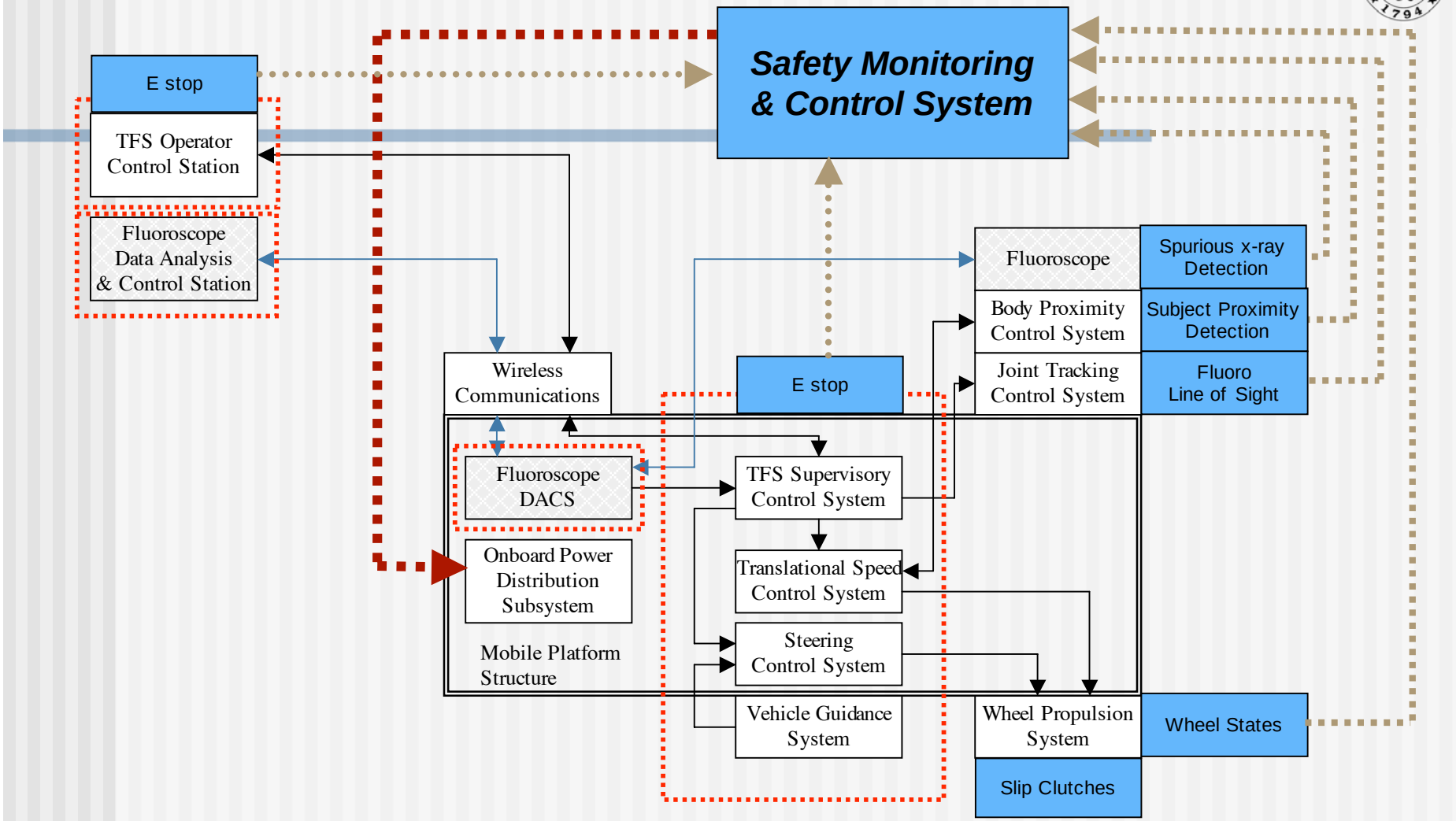
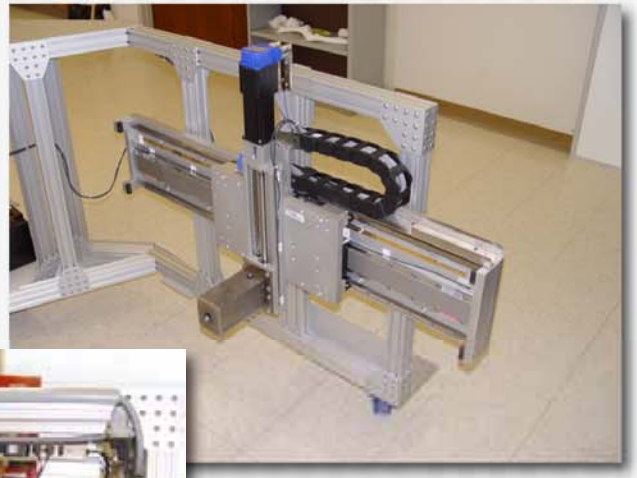
TFS functional architecture




Safety Monitoring & Control System
E stop
TFS Operator Control Station
Fluoroscope Data Analysis & Control Station
Wireless Communications
E stop
Fluoroscope
Spurious x-ray Detection
Body Proximity Control System
Subject Proximity Detection
Joint Tracking Control System
Fluoro Line of Sight
Fluoroscope DACS
TFS Supervisory Control System
Onboard Power Distribution Subsystem
Translational Speed Control System
Steering Control System
Mobile Platform Structure
Vehicle Guidance System
Wheel Propulsion System
Wheel States
Slip Clutches

Current Status



- **Installing fluoro components**
- Joint tracking subsystem test and evaluation.
- Enhance subject tracking
- Refine software…*studying FDA standards and expectations*
- Move to local hospital

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Summary

- Tracking fluoroscopy will enhance orthopedic research and clinical practice.
- TFS is a “robot” operating in close proximity to human subjects.
  - Prototype has demonstrated subject tracking.
  - Performance envelope includes dynamic motion and collision hazards.
- Medical users expect high availability and absolute patient safety.
- TFS will involve complex embedded computer control and data acquisition architecture.
- Potential hardware/software faults represent very serious human dangers.
- Primary dependability assurance…multi-layered approach
  - Design verification
  - Active controls
  - Layers of redundancy
  - Passive assists/protection where possible
- Levels of validation/verification required being studied.