Robotic UltraSound Image Guided Radiation Therapy System (RUSIGRTS)

Biomedical Systems Engineering
Masters Capstone Project EN.645.805.31_SP15

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by

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Intro & Need

- The background need is excellent visualization and targeting of the tumor (during planning and delivery) for effective external beam radiotherapy (EBRT) treatment.

- System need / purpose: precise & repeatable placement of the ultrasound probe to enable the imaging / targeting for EBRT.
Needs Analysis

~Needs elicited from the system stakeholders:

- Radiation Oncologists
- Medical Physicists
- Ultrasound Technicians
- Medical Sonographers
- Medical Robotics SMEs
Observation

~On-site & in-situ participation

Immersion into the operating environment aids understanding of the user needs!
## Needs Statements

<table>
<thead>
<tr>
<th>Number</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>N.1</td>
<td>User Need - Cooperative control of the ultrasound probe.</td>
<td>The system should cooperatively control the ultrasound probe position.</td>
</tr>
<tr>
<td>N.2</td>
<td>User Need - The system should securely fasten to the Clarity® ultrasound probe.</td>
<td>The system should securely fasten to the Clarity® ultrasound probe.</td>
</tr>
<tr>
<td>N.3</td>
<td>User Need - Data interface to Clarity®</td>
<td>The system should provide for data interface to existing Clarity® system.</td>
</tr>
<tr>
<td>N.4</td>
<td>User Need - Record probe position &amp; force</td>
<td>The system should enable a skilled professional clinician to quickly &amp; accurately record the position and related force characteristics of the US probe at the time that the Clarity systems registers the suitable US image (on SIM day).</td>
</tr>
<tr>
<td>N.5</td>
<td>User Need - Enable a less-skilled ultrasound tech to find ultrasound image.</td>
<td>The system should enable a less-skilled ultrasound tech to quickly find and maintain a suitable ultrasound image (on DEL day).</td>
</tr>
<tr>
<td>N.6</td>
<td>User Need - Allow the operator to work unobstructed</td>
<td>The system should allow the operator to work relatively unobstructed in the workspace and without occlusion.</td>
</tr>
<tr>
<td>N.7</td>
<td>User Need - Easily stored</td>
<td>The system should be easily stored and/or mobile.</td>
</tr>
<tr>
<td>N.8</td>
<td>User Need - Interoperate in the radiotherapy environment</td>
<td>The system should be designed to reliably integrate/interoperate in the existing radiotherapy environment.</td>
</tr>
<tr>
<td>N.9</td>
<td>User Need - Medical aesthetics - no mapped RQMT !</td>
<td>The system should have medical grade aesthetics.</td>
</tr>
<tr>
<td>N.10</td>
<td>User Need - System cost</td>
<td>The desired max cost for the system is around $100k.</td>
</tr>
<tr>
<td>N.11</td>
<td>User Need - System safety</td>
<td>The system should be safe to the user and the patient.</td>
</tr>
<tr>
<td>N.12</td>
<td>User Need - System security</td>
<td>The system should be secure.</td>
</tr>
</tbody>
</table>
CONOPS – cont’d

~Scenarios (or Use Cases)

- **Planned:**
  - SIM day
  - DEL day
  - Routine Maintenance
  - Development

- **Unplanned:**
  - Power Loss
  - Loss of Communications (from Clarity®)

- Emergency Stop (E-Stop)
Functional Concept

~Context Diagram (MS Visio)
Func Concept – cont’d

~Context Diagram (Vitech CORE)
Func Concept – cont’d

~ Top-Level Functional Diagram
One Lower-Level Functional Diagram – “Direct Force & Motion”
<table>
<thead>
<tr>
<th>Function</th>
<th>Function</th>
<th>based on [RQMT(s)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>FUNC.1</td>
<td>Direct Force &amp; Motion</td>
<td>N/A</td>
</tr>
<tr>
<td>FUNC.1.1</td>
<td>Calculate the Threat Boundary</td>
<td>RQMT.9 Collaborative Operation, RQMT.11 Avoid Radiation Therapy (RT) Beam, RQMT.24 Motion Envelope, RQMT.50 Guidance to Location, RQMT.55 Probe Move Duration, RQMT.66 Calculate Motion Envelope, RQMT.67 Calculate Threat Boundary, RQMT.70 Monitor Movement to Thresholds</td>
</tr>
<tr>
<td>FUNC.1.2</td>
<td>Calculate the Motion Envelope</td>
<td>RQMT.9 Collaborative Operation, RQMT.11 Avoid Radiation Therapy (RT) Beam, RQMT.24 Motion Envelope, RQMT.50 Guidance to Location, RQMT.55 Probe Move Duration, RQMT.66 Calculate Motion Envelope</td>
</tr>
<tr>
<td>FUNC.1.3</td>
<td>Compute Real-Time Margin of Probe to Threat Boundary</td>
<td>RQMT.9 Collaborative Operation, RQMT.11 Avoid Radiation Therapy (RT) Beam, RQMT.24 Motion Envelope, RQMT.50 Guidance to Location, RQMT.55 Probe Move Duration, RQMT.66 Calculate Motion Envelope, RQMT.68 Compute Threat Margin, RQMT.70 Monitor Movement to Thresholds</td>
</tr>
<tr>
<td>FUNC.1.4</td>
<td>Compute Velocity of Probe (Real-Time)</td>
<td>RQMT.50 Guidance to Location, RQMT.55 Probe Move Duration, RQMT.69 Compute Probe Velocity</td>
</tr>
</tbody>
</table>
Physical Concept

~ Top-Level System Physical Diagram
Phys Concept – cont’d

~One Subsystem Physical Diagram – Robot SS (Level 1)
Phys Concept – cont’d

~Subsystem Physical Diagram (cont’d) – Robot Arm (Level 2)
Phys Concept – cont’d

~Top-Level N2 Diagram
## Components to Functions Traceability – CORE Excerpt

<table>
<thead>
<tr>
<th>Number</th>
<th>Element</th>
<th>Description</th>
<th>type</th>
<th>performs</th>
</tr>
</thead>
<tbody>
<tr>
<td>SYS.1</td>
<td>Robot Subsystem</td>
<td>The Robot Subsystem primarily responsible for motion and force production.</td>
<td>Subsystem</td>
<td>N/A</td>
</tr>
<tr>
<td>SYS.1.1</td>
<td>Manipulator /</td>
<td>The robotic manipulator (i.e. robotic arm) moves the end effector from place to place. Robotic arms can be outfitted with many types of end effectors, which are suited to a particular application. In this case the end effector is an assembly of a precision force sensor and probe attachment. The manipulator has built-in position and force sensors that send data to the controller and to the control software.</td>
<td>Assembly</td>
<td>FUNC.8.1 Distribute WeightFUNC.8.2 Repel Moisture &amp; DustFUNC.8.3 Emit NoiseFUNC.8.4 Emit VibrationFUNC.9.1 Enable Access to HardwareFUNC.9.3 Exchange Hardware PartsFUNC.9.4 Perform Internal Diagnostics</td>
</tr>
<tr>
<td>SYS.1.1.1</td>
<td>Housing</td>
<td>The housing proved a level of aesthetics and encloses the robot arm sub-assemblies to repel dust, must and protect foreign objects from entering the drive mechanism.</td>
<td>HW Element</td>
<td>FUNC.3.1 Interface to the User via HWFUNC.3.4 Receive the User Input ForcesFUNC.8.1 Distribute Weight</td>
</tr>
<tr>
<td>SYS.1.1.2</td>
<td>Frame</td>
<td>The frame of the robot is the provides primary structural support.</td>
<td>Subassembly</td>
<td>FUNC.1.8 Generate the Output Forces</td>
</tr>
<tr>
<td>SYS.1.1.3</td>
<td>Drive Train</td>
<td>The robotic arm drive train consists of electrical servo motors using pulley and belt mechanism to displace the various arm links in a coordinated manner to ultimately move the end effector.</td>
<td>Subassembly</td>
<td>FUNC.1.8 Generate the Output Forces</td>
</tr>
</tbody>
</table>
Trade Study

Purpose:

To identify the most balanced (aka “best”) technical solution among a set of proposed viable solutions. These viable solutions are judged by their satisfaction of a series of measures (i.e. the requirements).
The Trade Study Approach

1. Determine Objectives
2. Establish Objectives
3. Establish Alternatives
4. Establish Criteria
5. Assign Criteria Scales, Weights or Utility Functions
6. Evaluate alternatives against each criterion
7. Apply Weights to Values
8. Score Alternatives
9. Perform Sensitivity Analysis
10. Results Sufficient to Select?
   - Yes: Select Alternative and Capture Trade Study Results
   - No: revisit alternatives and criteria
One detailed trade study (Robot Arm selection) using Analytical Hierarchy Process (AHP) to develop the criteria weighting.

[weighting ≡ relative ranking of importance]

Why AHP? AHP provides a logical framework to determine the benefits of each alternative...

Pairwise comparison with Robotics SME’s for the Selection Criteria:

<table>
<thead>
<tr>
<th></th>
<th>Arm weight</th>
<th>Arm Reach</th>
<th>Arm Repeatability</th>
<th>Arm DOF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm Weight</td>
<td>1</td>
<td>1/7</td>
<td>1/5</td>
<td>1/7</td>
</tr>
<tr>
<td>Arm Reach</td>
<td>7</td>
<td>1</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Arm Repeatability</td>
<td>5</td>
<td>1/7</td>
<td>1</td>
<td>1/7</td>
</tr>
<tr>
<td>Arm DOF</td>
<td>7</td>
<td>1/3</td>
<td>7</td>
<td>1</td>
</tr>
</tbody>
</table>

To illustrate, this cell indicates that DOF has very strong importance (7) relative to repeatability.
Analytical Hierarchy Process (AHP) - results

<table>
<thead>
<tr>
<th>difference of eigenvalues</th>
<th>e1</th>
<th>e2</th>
<th>result</th>
</tr>
</thead>
<tbody>
<tr>
<td>e1</td>
<td>0.034095</td>
<td>0.041515</td>
<td>-0.00742</td>
</tr>
<tr>
<td>e2</td>
<td>0.537902</td>
<td>0.545006</td>
<td>-0.0071</td>
</tr>
<tr>
<td>result</td>
<td>0.083939</td>
<td>0.094815</td>
<td>-0.01088</td>
</tr>
<tr>
<td>result</td>
<td>0.344064</td>
<td>0.318665</td>
<td>0.025399</td>
</tr>
</tbody>
</table>

Iterate matrix squaring and eigenvalue differencing until no difference in 4 decimal places…

The result is the ranking of order of importance of the selection criteria.

<table>
<thead>
<tr>
<th>e3 (Weighting)</th>
<th>Criteria</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.040743</td>
<td>Arm Weight (first row)</td>
<td>Least important</td>
</tr>
<tr>
<td>0.544602</td>
<td>Arm Reach (2nd row)</td>
<td>Most important</td>
</tr>
<tr>
<td>0.093657</td>
<td>Arm Repeatability (3rd row)</td>
<td>Third important</td>
</tr>
<tr>
<td>0.320998</td>
<td>Arm DOF (4th row)</td>
<td>Second important</td>
</tr>
</tbody>
</table>
Trade Study – cont’d

~Utility Functions - raw score for each criterion is translated to a utility score & normalized on scale of [0, 1]. (note: the utility scale used must be the same for each criterion)
## Trade Study – cont’d

### Raw Scores Including Cost
(pulled from product specification sheets available on the internet)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>UR5 (by Universal Robotics)</th>
<th>LBR Med / LBR5 iiwa (by Kuka)</th>
<th>MIRO Kinemedic (by DLR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>arm weight</td>
<td>18.4 kg</td>
<td>23.9 kg</td>
<td>9.80 kg</td>
</tr>
<tr>
<td>reach</td>
<td>850 mm</td>
<td>800 mm</td>
<td>1100 mm</td>
</tr>
<tr>
<td>repeatability</td>
<td>0.10mm</td>
<td>0.10mm</td>
<td>0.20mm</td>
</tr>
<tr>
<td>DOF (degrees of freedom)</td>
<td>6.0</td>
<td>7.0</td>
<td>7.0</td>
</tr>
<tr>
<td>Cost*</td>
<td>$15k</td>
<td>$75k</td>
<td>$75k* (est.)</td>
</tr>
</tbody>
</table>

### Utility Scores for the Alternatives
(are the corresponding value in the Utility Functions)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>UR5 (by Universal Robotics)</th>
<th>LBR Med / LBR5 iiwa (by Kuka)</th>
<th>MIRO Kinemedic (by DLR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>arm weight</td>
<td>0.45</td>
<td>0.10</td>
<td>1.0</td>
</tr>
<tr>
<td>reach</td>
<td>0.77</td>
<td>0.72</td>
<td>1.0</td>
</tr>
<tr>
<td>repeatability</td>
<td>1.0</td>
<td>1.0</td>
<td>0.70</td>
</tr>
<tr>
<td>DOF (degrees of freedom)</td>
<td>0.80</td>
<td>1.0</td>
<td>1.0</td>
</tr>
</tbody>
</table>
~**Weighted Utility Scores** (calculated by multiplying the alternative’s Utility Value of the alternative for that criteria times the weighting of that criteria)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Weighting</th>
<th>Utility Score for UR5 (by Universal Robotics)</th>
<th>Utility Score for LBR Med / LBR5 iiwa (by Kuka)</th>
<th>Utility Score for MIRO Kinemenedic (by DLR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>arm weight</td>
<td>0.040743</td>
<td>0.02</td>
<td>0.00</td>
<td>0.04</td>
</tr>
<tr>
<td>reach</td>
<td>0.544602</td>
<td>0.42</td>
<td>0.39</td>
<td>0.54</td>
</tr>
<tr>
<td>repeatability</td>
<td>0.093657</td>
<td>0.09</td>
<td>0.09</td>
<td>0.07</td>
</tr>
<tr>
<td>DOF (degrees of freedom)</td>
<td>0.320998</td>
<td>0.26</td>
<td>0.32</td>
<td>0.32</td>
</tr>
</tbody>
</table>

Note: the “Arm Weight” Utility score for the **LBR Med** robotic arm rounded down to 0.0, based on two significant figures.
~Combined Scores of the Alternatives~ (...calculated by summing the weighted utility scores. Does NOT include cost.)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Weighting</th>
<th>UR5 (by Universal Robotics)</th>
<th>LBR Med / LWR 3 (by Kuka)</th>
<th>MIRO Kinemedic (by DLR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>arm weight</td>
<td>0.040743</td>
<td>0.018</td>
<td>0.004</td>
<td>0.041</td>
</tr>
<tr>
<td>reach</td>
<td>0.544602</td>
<td>0.417</td>
<td>0.392</td>
<td>0.545</td>
</tr>
<tr>
<td>repeatability</td>
<td>0.093657</td>
<td>0.09</td>
<td>0.09</td>
<td>0.07</td>
</tr>
<tr>
<td>DOF (degrees of freedom)</td>
<td>0.320998</td>
<td>0.26</td>
<td>0.32</td>
<td>0.32</td>
</tr>
<tr>
<td>cost ($1k)</td>
<td></td>
<td>0.79</td>
<td>0.81</td>
<td>0.97</td>
</tr>
<tr>
<td></td>
<td></td>
<td>28</td>
<td>75</td>
<td>75(est)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.028</td>
<td>0.011</td>
<td>0.013</td>
</tr>
</tbody>
</table>

~Cost-Effective Selection Function~ ...calculated by dividing the Combined Score by the Cost (in $1,000).
## Sensitivity Analysis — Change Arm Weight Selection Criteria Weighting

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Weighting</th>
<th>UR5 (by Universal Robotics)</th>
<th>LBR Med / LBR5 iiwa (by Kuka)</th>
<th>MIRO Kinemedic (by DLR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>arm weight</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>reach</td>
<td>0.544602</td>
<td>0.42</td>
<td>0.39</td>
<td>0.56</td>
</tr>
<tr>
<td>repeatability</td>
<td>0.093657</td>
<td>0.09</td>
<td>0.01</td>
<td>0.07</td>
</tr>
<tr>
<td>DOF (degrees of freedom)</td>
<td>0.320998</td>
<td>0.26</td>
<td>0.32</td>
<td>0.32</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.77</td>
<td>0.81</td>
<td>0.93</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.027</td>
<td>0.011</td>
<td>0.012</td>
</tr>
</tbody>
</table>

This row is recalcd “Operational Utility”

This row is recalcd Cost-Effective Selection Function

## Sensitivity Analysis — Change Arm Reach Selection Criteria Weighting

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Weighting</th>
<th>UR5 (by Universal Robotics)</th>
<th>LBR Med / LBR5 iiwa (by Kuka)</th>
<th>MIRO Kinemedic (by DLR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>arm weight</td>
<td>0.040743</td>
<td>0.018</td>
<td>0.004</td>
<td>0.041</td>
</tr>
<tr>
<td>reach</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>repeatability</td>
<td>0.093657</td>
<td>0.09</td>
<td>0.09</td>
<td>0.07</td>
</tr>
<tr>
<td>DOF (degrees of freedom)</td>
<td>0.320998</td>
<td>0.26</td>
<td>0.32</td>
<td>0.32</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.37</td>
<td>0.42</td>
<td>0.43</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.013</td>
<td>0.006</td>
<td>0.006</td>
</tr>
</tbody>
</table>

This row is recalcd “Operational Utility”

This row is recalcd Cost-Effective Selection Function
## Sensitivity Analysis — Change Arm Repeatability Selection Criteria Weighting

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Weighting</th>
<th>UR5 (by Universal Robotics)</th>
<th>LBR Med / LBR5 iIwa (by Kuka)</th>
<th>MIRO Kinemedic (by DLR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>arm weight</td>
<td>0.040743</td>
<td>0.018</td>
<td>0.004</td>
<td>0.041</td>
</tr>
<tr>
<td>reach</td>
<td>0.544602</td>
<td>0.42</td>
<td>0.39</td>
<td>0.56</td>
</tr>
<tr>
<td>repeatability</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>DOF (degrees of freedom)</td>
<td>0.320998</td>
<td>0.26</td>
<td>0.32</td>
<td>0.32</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.69</td>
<td>0.72</td>
<td>0.91</td>
</tr>
</tbody>
</table>

This row is recal'd "Operational Utility"

## Sensitivity Analysis — Change Arm DOF Selection Criteria Weighting

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Weighting</th>
<th>UR5 (by Universal Robotics)</th>
<th>LBR Med / LBR5 iIwa (by Kuka)</th>
<th>MIRO Kinemedic (by DLR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>arm weight</td>
<td>0.040743</td>
<td>0.018</td>
<td>0.004</td>
<td>0.041</td>
</tr>
<tr>
<td>reach</td>
<td>0.544602</td>
<td>0.42</td>
<td>0.39</td>
<td>0.56</td>
</tr>
<tr>
<td>repeatability</td>
<td>0.093657</td>
<td>0.09</td>
<td>0.01</td>
<td>0.07</td>
</tr>
<tr>
<td>DOF (degrees of freedom)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

This row is recal'd "Operational Utility"

This row is recal'd Cost-Effective Selection Function
~Selection with Rationale

- **Recommendation:**
  Based on the analysis in this Trade Study Report, the selected best alternative for the RUSIGRTS robotic arm technical subsystem is the DLR Miro Kinemedic. This was the most balanced solution for Operational Utility and cost-effectiveness.

- **Rationale:**
  Regarding criteria profile, the Operational Utility score of 0.97 was atop the list in all selection criteria except cost-effectiveness of 0.013 (ranked 2nd).

- **Sensitivity synopsis:** the trade study results are not sensitive because the highest operational utility alternative selection is not affected with slight variations in the method of combined score calculation.

Sensitivity Analysis results also ranked the Miro Kinemedic as first in all selection criteria rankings and 2nd in cost-effectiveness.

- **Stipulation:**
  As previously mentioned, the Miro Kinemedic price was based on similarity to a known system (the LBR Med ~$75,000) and an actual price greater than the estimate used would decrease the Miro's cost-effectiveness.
The planned informal trade studies include:
• End effector force sensor selection
• Uninterruptable Power Supply (UPS) selection
• Mobile (trolley system) vs stationary
• Processing hardware selection
• Database software selection

Lastly, any effect on our technical risk? We’ll see…
Summary of all risks

<table>
<thead>
<tr>
<th>Risk ID</th>
<th>Category</th>
<th>Risk Title</th>
<th>Initial</th>
<th>Final</th>
<th>Objective</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Likelihood</td>
<td>Consequence</td>
<td>Likelihood</td>
</tr>
<tr>
<td>001</td>
<td>Technical / Program</td>
<td>Available SMEs</td>
<td>3</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>002</td>
<td>Technical</td>
<td>Probe Placement Precision</td>
<td>3</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>003</td>
<td>Technical</td>
<td>Limited Resources</td>
<td>3</td>
<td>3</td>
<td>2</td>
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<td>004</td>
<td>Cost</td>
<td>System cost</td>
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<td>005</td>
<td>SM4</td>
<td>Complex SE Project Chosen</td>
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<td>007</td>
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<td>008</td>
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<td>009</td>
<td>Operation</td>
<td>Work Process Integration</td>
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<td>Opportunity: Injury Reduction</td>
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<tr>
<td>011</td>
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<td>High Probe Force</td>
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<td>4</td>
<td>1</td>
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<tr>
<td>012</td>
<td>Technical</td>
<td>Obstruction of Probe Markers</td>
<td>4</td>
<td>5</td>
<td>1</td>
</tr>
</tbody>
</table>
# Risk Mgmt – cont’d

## Detail on One Technical Risk

### RISK SUMMARY WORKSHEET

**Risk Title:** 002 – Probe Location Precision  
**Risk Owner:** E. Walker  
**Date:** 4/5/15

### Description of Risk

If the US probe location and position produced by the system is not precise enough then the US image will not be of sufficient quality to register in Clarity®.

### Consequence if Risk is Realized

Poor ultrasound image quality in Clarity would hamper the operator's ability to locate and recognize the target anatomy inside the patient's body. Any automatic segmentation performed by the system would also be disrupted thereby reducing confidence in the radiation dosage delivery.

### Risk Reduction Plan

<table>
<thead>
<tr>
<th>Action/Event</th>
<th>Date</th>
<th>Success Criteria</th>
<th>Risk Level if Successful</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Scheduled</td>
<td>Actual</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>9/16/14</td>
<td>9/26/14</td>
<td>1. User needs elicted and refined per JHU SE practices. Completion of RAR.</td>
<td>L 3 C 4</td>
</tr>
<tr>
<td>2.</td>
<td>10/17/14</td>
<td>2/19/15</td>
<td>2. Completion of FAR</td>
<td>3 4</td>
</tr>
<tr>
<td>3.</td>
<td>3/14/15</td>
<td>2/24/15</td>
<td>3. Completion of TSR</td>
<td>2 4</td>
</tr>
<tr>
<td>4.</td>
<td>4/1/15</td>
<td>3/26/15</td>
<td>4. Completion of CDR</td>
<td>2 4</td>
</tr>
<tr>
<td>5.</td>
<td>4/11/15</td>
<td>4/5/15</td>
<td>5. Completion of A-Spec</td>
<td>1 4</td>
</tr>
</tbody>
</table>

Defining subsystems and their requirements will ultimately lead to component specs that may fulfill the system requirement definition.
Risk Mgmt – cont’d

- Detail on One Technical Risk – (continued)

Risk Waterfall Chart

Legend:
- Planned
- Actual

Key:
- SM4 = Project Start
- RAR = Requirements Analysis Report
- FAR = Functional Analysis Report
- TS = Trade Study
- CDR = Conceptual Design Report
- A-SP = System Spec
### Risk Summary Worksheet

**Risk Title:** 012 – Obstruction of Probe Markers  
**Risk Owner:** E. Walker  
**Date:** 2/23/14

<table>
<thead>
<tr>
<th>Description of Risk</th>
<th>Risk Type:</th>
</tr>
</thead>
<tbody>
<tr>
<td>If ultrasound probe markers are obstructed in line-of-sight to the optical tracking camera then probe pose awareness is lost.</td>
<td>Technical</td>
</tr>
<tr>
<td>If line-of-sight tracking is lost, the system loses it's pose awareness and it's capability to accurately place the ultrasound probe.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Consequence if Risk is Realized</th>
<th>Likelihood</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
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<td>2</td>
</tr>
<tr>
<td>5</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk Reduction Plan</th>
<th>Action/Event</th>
<th>Date</th>
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<th>Risk Level if Successful</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Include the function to establish the related function &amp; to recover from system errors</td>
<td>N/A N/A</td>
<td>1. Noted in FAR</td>
<td>L C</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>2. Choose the subsystem area of study &amp; perform trade study.</td>
<td>N/A N/A</td>
<td>2. Complete TSR</td>
<td>3 5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Implement the function via physical subsystem &amp; components.</td>
<td>N/A N/A</td>
<td>3. Complete CDR</td>
<td>2 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Quantify the performance</td>
<td>N/A N/A</td>
<td>4. Complete the A-Spec.</td>
<td>1 4</td>
<td></td>
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</table>
## System Specification

~Numbers of Req’ts & Percent Quantitative

<table>
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<th></th>
<th>Total</th>
<th>Quant</th>
<th>%</th>
<th>Qualitative</th>
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<td></td>
<td>Binary</td>
</tr>
<tr>
<td>RAR</td>
<td>79</td>
<td>40</td>
<td>51%</td>
<td>77</td>
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<tr>
<td>FAR</td>
<td>92</td>
<td>40</td>
<td>43%</td>
<td>90</td>
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<tr>
<td>Trade Study</td>
<td>93</td>
<td>41</td>
<td>44%</td>
<td>90</td>
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<tr>
<td>CDR</td>
<td>100</td>
<td>48</td>
<td>48%</td>
<td>90</td>
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<tr>
<td>System Spec</td>
<td>125</td>
<td>118</td>
<td>94%</td>
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</table>

- **Rqmt growth over the SE lifecycle:** 79 to 125 rqmts... ~58% increase.
### ~Key Performance Parameters (KPPs)

<table>
<thead>
<tr>
<th>rqmt #</th>
<th>requirement description</th>
</tr>
</thead>
<tbody>
<tr>
<td>RQMT.1</td>
<td>The system shall comply with US Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) - Code of Federal Regulations (CFR) Title 21.</td>
</tr>
<tr>
<td>RQMT.9</td>
<td>The system shall be capable of collaborative (stable, one-hand manual guidance side-by-side with a single user).</td>
</tr>
<tr>
<td>RQMT.12</td>
<td>The system shall have payload of at least 5 kg (~11 lbs).</td>
</tr>
<tr>
<td>RQMT.13</td>
<td>The system shall facilitate avoidance of the radiation therapy beam (during DEL day operations) by 2 cm ± 0.5 cm relative margin.</td>
</tr>
<tr>
<td>RQMT.27</td>
<td>The system shall operate on 110 VAC +/- 5%.</td>
</tr>
<tr>
<td>RQMT.30</td>
<td>The system shall have motion envelope / workspace volume &gt; 61 cm³ (2 ft³).</td>
</tr>
<tr>
<td>RQMT.32</td>
<td>The system shall be able to physically attach to &amp; sustain connection to the Clarity® compatible ultrasound probes for the full 12 hr duty cycle.</td>
</tr>
</tbody>
</table>
Summary

~Final Concept, and any Further Work

- System Maturity & Readiness for Deployment
- Specific Design Aspects (Notice to Designers)
- Medical Grade Aesthetics
Lessons Learned

- Manage Competing Stakeholder Expectations

- Communicate SE Principles

- Functional Overlaps vs. Modular Partitioning
  - (tight binding / loose coupling)

- Avoid “Analysis Paralysis” (and keep the pace)
  - “let the SE process design the system for you”
The End / Questions