

Executive Summary

Background

The University of Minnesota (UM) hosted the fall Industry Advisory Board (IAB) meeting of the Minimally Invasive Medical Technologies Center (MIMTeC), November, 18 - 19, 2008. The purpose of the meeting was to present a status of the Center's research, evaluate and determine direction of current research projects, receive feedback from the IAB on research and administrative issues, and provide an opportunity for two potential member companies to learn about the Center.

Center Developments

- Two new manuscripts and one new invention disclosure since spring meeting; more of each in process
- Dr. Bala Haridas is leaving MIMTeC for industry; Carlo Montemagno, PhD, Dean of the University of Cincinnati (UC) College of Engineering to be UC PI and Interim Co-Director
- IAB members chose to mentor research projects to increase interaction with students and better guide projects

Projects Presented, IAB Decisions & IAB Mentor(s)

UC Project	Project Title	PI	Decision	Mentor(s)
UC_07_01	Ultrasound temperature mapping for design verification of thermal devices	Doug Mast	Terminated; Reasonable time to conclude; likely 12/31	N/A
UC_07_02	Image based deformation analysis of soft tissues – Internal Organs	Bala Haridas to Doug Mast(new)	Ongoing; Approved but Needs 3D component to go to Yr. 3	P&G
UC_07_03	In vitro photoelastic model of arterial aneurysms with wall stress sensing capability	Bala Haridas	Concluded 8/31/08; IP may soon evolve from this for cardio area	N/A
UC_08_02	Human Device Interface in Catheter Based Interventions	Mary Beth Privitera	Commenced 9/1/08; Ongoing; Approved	Bos.Sci.
UMN Project	Project Title	PI	Decision	Mentor(s)
UMN_07_01	Neurophysiology of the Lower Urinary Tract	Gerald Timm	Ongoing; Approved	P&G/MDT
UMN_07_02	Design of MRI Compatible Instrumentation for Guided Interventions	Arthur Erdman	Ongoing; to be concluded due to potential conflicts & lack of 3D	MDT/ Bos.Sci.
UMN_07_03	Battery-Less Wireless Sensors for MIS and Other Biomedical Applications	Rajesh Rajamani	Ongoing; Approved; Needs intensive IP & literature search	EES/Cordis
UMN_08_01	New Tactile MEMS Sensors for Endoscopic End-Effectors	Rajesh Rajamani	Ongoing; Approved	EES/Cordis
UMN_08_03	Surface EMG Based 3D MAI Technique for Noninvasively Diagnosing Female Pelvic Floor Disorders	Gerald Timm	Proposed; Not Approved; too close to IAB R&D efforts & lack of 3D	N/A

Action Items and Responsible Person(s)

- Action 1: Finalize Conclusion of UC_07_01 (Dr. Mast & Dr. Hamlen)
- Action 2: Create a Bylaw to Address Project Termination (Mr. Ken Rosen)
- Action 3: Create an RFP for the Nanocopoeia Project (Dr. Hoerr, Mr. Chuck Doarn & Mr. Rosen)
- Action 4: Patent & Literature Search to Determine IP Space for UMN_07_03 (Dr. Rajamani)
- Action 5: IP Establishment/Licensing for Dr. Rajamani's Sensor Technology (Mr. Rosen)
- Action 6: Recruit Additional Member Companies (Mr. Rosen, Mr. Doarn & Mr. Ken Merdan)
- Action 7: Explore Adding an Additional Academic Institution (Mr. Rosen)
- Action 8: Facilitate the Establishment of IAB/Student Relationships (Mr. Rosen & Mr. Doarn)
- Action 9: Facilitate IAB Member Development of RFPs for Future Research (Mr. Rosen & Mr. Doarn)
- Action 10: Establish 6 Month Progress Format for Roadmaps & Presentations (Ken Rosen & Mr. Doarn)
- Action 11: Increase Presentation Length for Future Meetings (Mr. Rosen & Mr. Doarn)
- Action 12: Posters at Future Meetings to be Set-Up in Meeting Room (Mr. Rosen & Mr. Doarn)
- Action 13: Posters to be Submitted Prior to Meetings (Mr. Rosen & Mr. Doarn)
- Action 14: Design an Executive Summary Format for New Project Proposals (Mr. Rosen & Mr. Doarn)
- Action 15: Add an Administrative Issues Session Evening Prior to Meetings (Mr. Rosen & Mr. Doarn)
- Action 16: Include IAB Members, PIs and Students in Meeting Agendas (Mr. Rosen & Mr. Doarn)

Next Meeting: Monday - Wednesday, May 4-6, 2009 at the University of Cincinnati with a business meeting on the evening of May 4th.



Fall Industrial Advisory Board Meeting & Seminar Summary University of Minnesota November 18-19, 2008

The University of Minnesota hosted the fall meeting of the Minimally Invasive Medical Technologies Center (MIMTeC) Industrial Advisory Board (IAB) and seminar, November, 18-19, 2008. The Agenda is in Appendix A. The meeting was attended by representatives of both academic sites (UM and UC), industry (IAB members and guests) and NSF. A complete list of attendees is in Appendix B.

The meeting served as a venue for the presentation of the center's status, the presentation of research activities, evaluation and decisions on several ongoing IAB-funded research projects and one proposed new project, and an opportunity for two potential member companies to learn about the center. In addition, the meeting included a poster session, a presentation by NSF representatives on the I/U CRC program, a tour of the University of Minnesota's new Medical Devices Center's facilities, and feedback from the IAB to the MIMTeC center's researchers and administrators.

Opening Comments

Dr. Arthur Erdman opened the meeting by welcoming all of the attendees, and welcoming comments were also made by Dr. Mos Kaveh, the Dean for Research and Planning at the University of Minnesota's Institute of Technology. Each of the meeting's attendees introduced themselves.

Center Status

The MIMTeC Center's status was presented by Dr. Erdman. This included an overview of the I/UCRC model, governance and operations, and key developments since the center's last meeting, which was held on May 5 - 6, 2008 at the University of Cincinnati.

Key developments included a new invention disclosure, two new manuscripts and a change of leadership at the University of Cincinnati. The manuscripts resulted from IAB-funded research performed by Drs. Doug Mast and Raj Rajamani, and the invention resulted from Dr. Rajamani's research.

New Manuscripts & Invention

Dr. Mast's manuscript, "Ultrasonic monitoring of *in vitro* radiofrequency ablation by echo decorrelation imaging," was approved by the IAB to be published, and Dr. Rajamani's manuscript, "Novel MEMS Stiffness Sensor for In-Vivo Tissue Characterization Measurements" was delayed for 90 days by the IAB, as MIMTeC member companies Medtronic, Procter & Gamble and Ethicon Endosurgery are interested in the intellectual property evolving from this research, "Micro-Sensors for In Vivo Measurement of Tissue Stiffness."

In addition to noting these key research outcomes, Dr. Erdman mentioned that additional manuscripts will soon evolve from both the MRI and lower urinary tract research, and he

suggested that these be submitted to the IAB at the same time to make the review process more efficient.

Dr. Bala Haridas mentioned that there may soon be an invention disclosure evolving from project (UC_07_03) entitled: “In Vitro Photoelastic Model of Arterial Aneurysms with Wall Stress Sensing Capability.” This IP can be used for a tool to measure stress in the cardio area.

Request for Future Research Direction from IAB

Dr. Erdman, Dr. Haridas and Alex Schwarzkopf requested that the IAB become more proactive in recommending to the center project ideas for future research, so that the center can better focus upon the needs of member companies.

Request for IAB Direction on Additional MIMTeC Academic Partners

Alex Schwarzkopf, a consultant to the NSF, who started and led for many years the Industry/University Cooperative Research Center (I/U CRC) program, mentioned that MIMTeC could become stronger if it were to add a third academic institution and requested that the IAB suggest institutions with which it has strong existing relationships, and who may be interested in joining this consortium. The University of Texas Southwestern Medical Center was cited as a possible partner.

Access to New Medical Devices Center Facilities at University of Minnesota

Dr. Erdman informed the IAB of MIMTeC’s access to the facilities at the new Medical Devices Center at the University of Minnesota, enhancing the capabilities for MIMTeC research.

Change in University of Cincinnati Leadership

Dr. Haridas had directly contacted individual IAB members during the past couple of months to inform them that he is returning to industry, and vacating his position as the Center Co-Director and PI. He stated that his goal is for this transition to be “seamless” for the IAB and that he has a transition plan in-place.

Dr. Haridas’ MIMTeC Co-Director and UC PI roles will be assumed by Dr. Carlo Montemagno, the Dean of the University of Cincinnati’s College of Engineering. Dr. Montemagno who was unable to attend the meeting had a short video presented in which he expressed his strong support for MIMTeC, including his commitment of his institution to continue to support MIMTeC in every way possible. Mr. Doarn will assume the UC Co-PI role for MIMTeC as well as continue his current role as the administrative director at UC.

NSF Representatives’ Presentation to IAB (Alex Schwarzkopf)

Re-emphasis on Addition of Third Academic Institution

Alex Schwarzkopf again stressed the need for MIMTeC to add a third academic institution to its consortium, to give the center a stronger base and make it better able to grow into the future.

Primary Advantage of Access to Students

Alex stressed to the IAB and the potential member companies the primary benefit of an I/U CRC is “access to students,” and that centers use this as a “recruiting tool,” because it allows companies to get to know these students to a much greater extent than what they can learn through the normal job interview process. As a result, Alex suggests that companies’ HR functions help to fund MIMTeC membership.

Other I/UCRC Opportunities

Alex noted that many I/U CRC members, which tend to be Fortune 500 companies, are members of more than one center. He also mentioned that while the I/U CRC membership agreement “is not perfect,” it has “worked for 30 years and we’re not fooling with it.” Alex mentioned two new centers in the healthcare sector – one in the processing of pharmaceuticals and the other in healthcare transformation.

Glenn Larsen, the IIP Program Director for the NSF, noted other research opportunities available to MIMTeC, such as TIE, GOALI and IRE grants. Glenn noted that any IP resulting from international research would need to be transferred to the United States.

He also mentioned that a Fundamental Research Supplement would again be available for MIMTeC to apply for this fiscal year, and that the NSF will match up to \$75,000 of industry funding that is invested in the research, bringing the potential funding for a two-year project from the existing \$150,000 to \$300,000.

Presentation & Feedback of Ongoing Projects

Researchers from UC and UM presented the ongoing projects that had been approved by the IAB at the May, 2008 meeting. The proposal titles and PIs are highlighted in Table 1. The reviews were conducted by the MIMTeC Evaluator, Dr. David Meyer. Each IAB member reviewed the research projects and completed the Level of Interest Feedback Evaluation (LIFE) Forms. The completed LIFE forms appear in Appendix C.

The objective of the project presentations was to update the IAB on the status and progress of the projects since the May 08, give the IAB the opportunity to provide feedback to the researchers and to make decisions on whether each project should continue or change course.

One of these projects (UC_07_03), entitled “In Vitro Photoelastic Model of Arterial Aneurysms with Wall Stress Sensing Capability,” was completed at the end of August, so its presentation was of its final conclusions and outcomes.

In response to IAB feedback and resulting NSF recommendations from I/U CRC Program Director Dr. Rathindra DasGupta at the spring meeting, project presentations were limited to 5 minutes in length, Q&A to 10 minutes and 5 minutes were given to LIFE Form discussions. The resulting length per project was 20 to 25 minutes.

Table 1. Current Funded MIMTeC Projects

LIFE Form Number	MIMTeC Project Number	Project Titles	Principal Investigator
UC_07_01	MIMTeC_UC07_01	Ultrasonic Temperature Mapping for Design Verification of Thermal Devices	T. Douglas Mast, PhD
UC_07_02	MIMTeC_UC07_02	Image-Based Deformation Analysis of Soft Tissues – Internal Organs	Bala Haridas, PhD
UC_07_03	MIMTeC_UC07_03	In Vitro Photoelastic Model of Arterial Aneurysms with Wall Stress Sensing Capability	Bala Haridas, PhD
UC_08_02	MIMTeC_UC08_02	Human Device Interface in Catheter Based Interventions	Mary Beth Privitera, M. Des.
UM_07_01	MIMTeC_UM07_01	Neurophysiology of the Lower Urinary Tract	Gerald Timm, PhD
UM_07_02	MIMTeC_UM07_02	Design of MRI Compatible Instrumentation for Image Guided Interventions	Arthur Erdman, PhD
UM_07_03	MIMTeC_UM07_03	Battery-Less Wireless Sensing for MIS and other Biomedical Applications	Rajesh Rajamani, PhD
UM_07_04	MIMTeC_UM07_04	New Tactile MEMS Sensors for Endoscopic End-Effectors	Rajesh Rajamani, PhD

Feedback on Existing Projects

The IAB decided to terminate, as soon as possible, the project entitled “Ultrasonic Temperature Mapping for Design Verification of Thermal Devices,” due to a lack of the temperature range precision necessary for such research to be relevant to IAB members. The IAB will work with the project’s PI, Dr. Mast, to determine how best to conclude this project, as soon as possible, while causing minimal disruption to the students performing the research. A suggested timeframe for this was the end of December, 2008.

The IAB also decided to allow the project (UM_07_02) entitled “Design of MRI Compatible Instrumentation for Image Guided Intervention,” to conclude in June. This project was too close to some of the internal R&D efforts at IAB companies for them to feel comfortable providing needed direction to the research in the presence of competing companies. In addition, there was a lack of a 3-D component to this research, which limited its value to IAB members. The IAB met with the project’s research team to discuss how best to finalize the project.

IAB Chair Dr. Cushing Hamlen noted that project (UC_07_02), entitled “Image-Based Deformation Analysis of Soft Tissues – Internal Organs” needs to progress to 3D, or it will go on probation. The project’s PI is working with GE to determine whether this is possible.

The IAB stated that the remaining 4 projects “looked good.” LIFE form feedback on each of the existing projects can be found in Appendix C.

Presentation & Feedback on Proposed Project

One proposed new project (UM_08_03), as shown in Table 2, was presented, entitled “Surface EMG Based 3D Muscle Activity Imaging (MAI) Technique for Noninvasively Diagnosing Female Pelvic Floor Disorders.” The IAB decided not to fund this project because it conflicted

with Nanocopoeia's desire to have its own project and because the project, as presented, is too focused. The IAB requested that it be reformulated to better demonstrate the utility of its approach, so that it can be applicable to a number of areas and a range of issues.

Table 2. Proposed New MIMTeC Project

LIFE Form Number	MIMTeC Project Number	Project Title	Principal Investigator
UM_08_03	MIMTeC_UM_08_03	Surface EMG Based 3D Muscle Activity Imaging (MAI) Technique for Noninvasively Diagnosing Female Pelvic Floor Disorders	Gerald Timm, PhD

Final Project Status

The IAB's decisions have resulted in the project status shown in Table 3.

Table 3. MIMTeC Project Tracking Sheet for IAB-Sponsored Projects

Cincinnati Project Number	Project Title	PI	Year Approved	07 Funding	08 Funding	Status	Comment
MIMTeC_UC_07_01	Ultrasound temperature mapping for design verification of thermal devices	Doug Mast, PhD	2007	\$ 62,500	\$ 62,500	Funded Years 1 & 2; Terminated at Fall, 2008 Meeting	Put on probation for 6 mos at May 08 IAB meeting Terminated
MIMTeC_UC_07_02	Image based deformation analysis of soft tissues – Internal Organs	Doug Mast, PhD	2007	\$ 62,500	\$ 62,500	Funded Years 1 & 2	Funded for Y2 - May 08 IAB approval; Doug Mast took over PI role from Bala
MIMTeC_UC_07_03	In vitro photoelastic model of arterial aneurysms with wall stress sensing capability	Bala Haridas, PhD	2007	\$ 62,500	\$ 62,500	Funded Years 1 & 2	Funding extended through summer 08 to wrap up. Completed
MIMTeC_UC_08_02	Human Device Interface in Catheter Based Interventions	Mary Beth Privitera, M.Des.	2008	N/A	Remainder of UC_07_03	Funded Year 2	Approved at May 08 IAB. Funding will start after MIMTeC_UC07_03 is complete in late summer of 08
Minnesota Project Number	Project Title	PI	Year Approved	07 Funding	08 Funding	Status	Comment
MIMTeC_UMN_07_01	Neurophysiology of the Lower Urinary Tract	Gerald Timm, PhD	2007	\$ 62,500	\$ 62,500	Funded Years 1 & 2	Funded for Y2 - May 08 IAB approval
MIMTeC_UMN_07_02	Design of MRI Compatible Instrumentation for Guided Interventions	Arthur Erdman, PhD	2007	\$ 62,500	\$ 62,500	Funded Years 1 & 2	Funded for Y2 - May 08 IAB approval
MIMTeC_UMN_07_03	Battery-Less Wireless Sensors for MIS and Other Biomedical Applications	Rajesh Rajamani, PhD	2007	\$ 62,500	\$ 62,500	Funded Years 1 & 2	Funded for Y2 - May 08 IAB approval
MIMTeC_UMN_08_01	New Tactile MEMS Sensors for Endoscopic End-Effectors	Rajesh Rajamani, PhD	2007	\$ 62,500	\$ 62,500	Funded Years 1 & 2	Year 1 Funding from TATRC; Year 2 by IAB

Note: Only selected projects are listed, resulting in gaps in project numbers (UC_08_01 was not selected)

Presentation of New Fundamental Research Supplement Project

Dr. Erdman presented a Fundamental Research Supplement awarded to MIMTeC earlier this year, and commenced this fall, entitled “Merging 3D Anatomical and Surgical Tool Virtual Representations.” The purpose of presenting this NSF-funded project was to make the IAB aware of this research, which could be valuable to member companies’ ability to enhance their internal R&D efforts. Dr. Cush Hamlen asked about how companies could get the same computing power that the University of Minnesota has through its super computer center, and Dr. Erdman replied that companies could gain access to this. Dr. Hamlen also inquired about the amount of power used for this type of development, and Dr. Erdman responded that it includes 12 parallel processors.

Feedback on Meeting from IAB

During the course of the meeting, the IAB provided feedback to MIMTeC staff on a variety of both project-specific and administrative issues. These are listed as follows:

- **Request for Bylaws to Address Project Termination**

IAB Chair Dr. Cushing Hamlen suggested that a bylaw be established to handle project terminations in a way that minimizes disruptions for researchers while finishing in a reasonable amount of time for industry members to apply their resources toward more relevant research. This understanding will also help PIs avoid putting their students at risk.

- **Concern About IP Issues with UM_07_03**

A representative of an IAB member expressed concern about potential IP conflicts with the energy harvesting aspect of the battery-less/wireless sensor technology developed in UM_07_03. The IAB requested that Dr. Rajamani perform an intensive IP and literature search in this area, including newspaper articles, to avoid potential IP infringement lawsuits, as the IP space in this area is crowded, and lawsuits can be very costly. Dr. Hamlen noted that if the space in this area is too crowded, then it may not be worth the risk. Dr. Rajamani expressed his confidence that the IP in the areas of knee-generated power harvesting and inductive coupling is sufficiently unique. Dr. Erdman mentioned that he would have the University of Minnesota’s Office of Technology Commercialization assist Dr. Rajamani in this effort.

- **Project Mentoring/Student Access**

The IAB requested that it have more direct interaction with students and be able to provide more direction to individual projects. So it was decided that IAB members mentor individual projects. This would enhance the value of student access to member companies while also maximizing the quality of MIMTeC research and keeping it relevant to IAB needs. As a result, IAB members chose the projects they would like to mentor, and these relationships are shown in Table 4.

Table 4. IAB Project Mentorship

Project, PI	Sponsor Mentor
UC_07-01, D. Mast	EES/Cordis
UC_07-02, D. Mast	P&G
UC_08-02, M. Privitera	Boston Scientific
UM_07-01, G. Timm	P&G, Medtronic
UM_07-02, A Erdman	Medtronic, Boston Scientific
UM_07-03, R. Rajamani	ESS/Cordis
UM_08-01, R. Rajamani	ESS/Cordis

- RFPs**

The IAB wants to start implementing the RFP process. This is an especially relevant time to do this as most of the new project proposals will be presented at the upcoming spring meeting. However, the IAB decided that the timeframe for RFP submissions can be kept open throughout the year. Nanocopoeia's request for a new project will get top priority at the spring meeting, and Dr. Bob Hoerr is working on this request, and wants to explore possibilities at each university site. Nanocopoeia won't need IAB approval for this project because it's been established that incoming companies can get a project of their choosing. It was suggested that this new project be funded, initially, from funds remaining from the terminated UC_07_01 project.
- Difficulty for IAB to Distinguish What's Happened in Last 6 Months**

The IAB would like to have more specific information on what each project has accomplished since the previous meeting. Dr. Ryo Minoguchi of Procter & Gamble recommended that the project roadmaps have to two columns – one for key objectives and the other for what has been achieved since the last meeting.

This would be in addition to the changes have been made in how MIMTeC projects are presented, including the one page Road Maps, which are submitted two prior to the semi-annual meetings,
- Presentation Length**

The presentation limit of 5 minutes was not enough time for the IAB to fully-absorb the content; one member mentioned that the presentations would end just as he was starting to fully capture the essence of what was being presented. While the IAB understands that the 5 minute limit was instituted due to presentations being too long at the spring meeting, they requested that it be lengthened – perhaps to 10 minutes.
- Poster Session Scheduling & Submission Prior to Meetings**

One IAB member suggested that the poster sessions at meetings occur prior to the project presentations, because it provides the IAB with a better, more in-depth understanding of the research. This would help the IAB to fully appreciate the work

that's been done and make members more effective at evaluating the projects during LIFE Form sessions.

Feedback on the Meeting from the NSF

NSF representatives Dr. Schwarzkopf and Mr. Larsen, and MIMTeC Evaluator Dr. Meyer, provided feedback to MIMTeC staff on the following issues:

- **I/U CRC Program Director Wants All Centers to Have More Members**
Alex Schwarzkopf and David Meyer stressed MIMTeC's need to recruit additional member companies for sustainability. David mentioned that this is a major objective of the I/UCRC Program Director, Rathindra DasGupta, and Alex repeatedly noted that MIMTeC has a minimum amount of industry members and funding, as SBIR memberships don't apply to these minimum standards. Mr. Ken Merdan of Boston Scientific mentioned that he could help in recruiting St. Jude Medical to join the center, as he knows Mr. Steve Hackett, who attended the meeting on behalf of that company.
- **More Effectively Show What's Been Accomplished Since the Last Meeting**
By focusing upon and effectively conveying the value of outcomes, IAB members may be more likely to renew projects.
- **Use More Effective Approach to Pitch New Projects**
Alex suggests that the center researchers submit a one page executive summary for new projects.
- **In the Future, Include IAB Members, PIs and Students in Meeting Agendas**
Dr. Meyer recommended that all of these participants' names be included on the agendas.

Action Items/Next Steps for MIMTeC and Task Owner(s)

- Action 1: Finalize Conclusion of UC_07_01 (Dr. Mast & Dr. Hamlen)**
Dr. Mast will work with IAB Chair Dr. Hamlen to determine how best to conclude UC_07_01 as soon as possible.
- Action 2: Create a Bylaw to Address Project Termination (Mr. Rosen)**
MIMTeC staff will work with IAB members to draft a bylaw to address this issue.
- Action 3: Create an RFP for the Nanocopoeia Project (Dr. Hoerr, Chuck Doarn & Ken Rosen)**
MIMTeC staff will work with Dr. Hoerr to develop an RFP for the Nanocopoeia project, which can use funding from the terminated UC_07_01 project.
- Action 4: Patent & Literature Search to Determine IP Space for UM_07_03 (Dr. Rajamani)**

Dr. Rajamani will perform an intensive IP and literature search in this area, including newspaper articles, and report his findings to the IAB.

Action 5: IP Establishment/Licensing for Dr. Rajamani’s Sensor Technology (Mr. Rosen)

The University of Minnesota will continue to work on the establishment and licensing of Dr. Rajamani’s invention, “Micro-Sensors for In Vivo Measurement of Tissue Stiffness.”

Action 6: Recruit Additional Member Companies (Mr. Rosen, Mr. Doarn & Mr. Merdan)

Both universities will become more proactive in recruiting new IAB members. Ken Merdan will assist in the recruitment of St. Jude Medical through his relationship with Steve Hackett.

Action 7: Explore Adding an Additional Academic Institution (Mr. Rosen)

MIMTeC staff will work with IAB members to identify potential academic institution partners and explore with these institutions the possibility of joining MIMTeC as a third academic site.

Action 8: Facilitate the Establishment of IAB/Student Relationships (Mr. Rosen & Mr. Doarn)

MIMTeC staff will work with IAB members and students to coordinate the establishment of mentoring relationships, by providing all of these participants with contact information and arranging initial meetings.

Action 9: Facilitate IAB Member Development of RFPs for Future Research (Mr. Rosen & Mr. Doarn)

MIMTeC staff will re-submit to IAB members the RFP forms that have been developed for this purpose and facilitate discussions between IAB members and researchers to develop project concepts.

Action 10: Establish 6 Month Progress Format for Roadmaps & Presentations (Mr. Rosen & Mr. Doarn)

MIMTeC staff will change how roadmaps are designed and projects are presented, to make it easier for the IAB to determine what’s been accomplished in each project since the previous meeting. The project roadmaps could have the format recommended by Dr. Minoguchi: two columns – one for key objectives and the other for what has been achieved since the last meeting.

Action 11: Increase Presentation Length for Future Meetings (Mr. Rosen & Mr. Doarn)

The MIMTeC staff and IAB have agreed that an optimal presentation length for future meetings is 10 minutes, with 10 minutes for Q&A and 5 minutes for LIFE Forms.

Action 12: Posters at Future Meetings to be Set-Up in Meeting Room (Mr. Rosen & Mr. Doarn)

Posters at future meetings will be set-up in the meeting room, with an introductory session occurring in mid-morning of the first day following the opening introductions and NSF/Center presentations. The project presentations can then begin following the introductory poster session prior to lunch.

Action 13: Posters to be Submitted Prior to Meetings (Mr. Rosen & Mr. Doarn)

Posters will be included with project roadmaps in the pre-meeting email to IAB members two weeks prior to meetings.

Action 14: Design an Executive Summary Format for New Project Proposals (Mr. Rosen & Mr. Doarn)

MIMTeC staff will design a one page executive summary format for new project proposals to be submitted with the pre-presentation roadmaps two weeks prior to future meetings.

Action 15: Add an Administrative Issues Session Evening Prior to Meetings (Mr. Rosen & Mr. Doarn)

It was recommended that MIMTeC's administrative issues be discussed in a session the evening before the first day of future meetings, to utilize the time people have after arriving for the meetings and to free-up time to focus more upon research during the day-and-a-half sessions that follow.

Action 16: Include IAB Members, PIs and Students in Meeting Agendas (Mr. Rosen & Mr. Doarn)

All of these participants' names should be included on future meeting agendas; the researchers' names can be attached to the projects they're presenting and the IAB names can be listed at the beginning of the document.

Next MIMTeC Meeting

The next IAB meeting is tentatively scheduled for Monday - Wednesday, May 4 - 6, 2009, at the University of Cincinnati. There will be a business meeting on the evening of May 4th. Additional information about this meeting will be made available in April of 2009.



Appendix A

MIMTeC Fall Meeting Agenda University of Minnesota 2nd Floor Radisson University Hotel - Minneapolis

Tuesday, November 18, 2008

MIMTeC Industrial Advisory Business Meeting – Session 1 Hubert H. Humphrey Room

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|---------------|--|
| 7:30 – 8:00 | Registration & Continental Breakfast |
| 8:00 – 8:15 | Welcome (<i>Review of Schedule</i>)
Art Erdman, Ph.D. (Director)
Balakrishna Haridas, Ph.D. (Co-Director) |
| 8:15 – 8:30 | Roundtable Introductions of Participants |
| 8:30 – 8:45 | Opening Remarks
Mos Kaveh, Ph.D.
Dean for Research & Planning at the University of Minnesota's Institute of Technology |
| 8:45 – 9:00 | IAB Administrative Issues, Including By Laws Overview
Cushing Hamlen, Ph.D.
IAB Chair |
| 9:00 – 9:30 | State of the Center Review
Art Erdman, Ph.D.
MIMTeC Director |
| 9:30 – 10:00 | NSF Update
Alex Schwarzkopf, Consultant to, Founder & Former Program Director of NSF I/UCRC Program
Glenn Larsen, Program Director for the Division of Industrial Innovation and Partnerships (IIP), NSF |
| 10:00 – 10:15 | Break |
| 10:15 – 12:15 | Presentations & Feedback of Current IAB-Funded Research Projects
5 Minute Presentations, 10 Minute Q&A and 5 Minutes for LIFE Forms |
| 12:15 – 12:45 | Lunch (Box Lunches) |

- 12:45 – 1:45 Presentations & Feedback of Current IAB-Funded Research Projects
5 Minute Presentations, 10 Minute Q&A and 5 Minutes for LIFE Forms
- 1:45 – 2:45 Concurrent Session #1: IAB Closed Door Session (to discuss ongoing projects)
- 1:45-2:15 Attendees other than IAB-Tour of the Medical Devices Center (Shepherd Labs)
- 2:15-2:45 Concurrent Session #2: Q&A MIMTeC & Potential New Members (to present various aspects of MIMTeC center and membership)
- 2:45 – 3:00 Break
- 3:00 – 3:45 IAB Closed-Door Session with Potential New Members (after which potential members leave).
- 3:45 - 4:30 IAB Closed Door Session (to discuss remaining project and administrative issues and for sponsor survey feedback to MIMTeC NSF Evaluator, David Meyer)
- 4:30-5:00 Tour of the Medical Devices Center (Shepherd Labs)
- 5:00 – 6:30 Break
- 6:30 – 8:30 Dinner – Poster Sessions (Members and Researchers only)
Nolte Room

Wednesday, November 19, 2008

**MIMTeC Industrial Advisory Business Meeting – Session 11
Regents Room**

- 7:30 – 8:00 Continental Breakfast
- 8:00 – 8:10 Welcome
Art Erdman, Ph.D.
- 8:10 – 9:15 Discussion of Proposed New Projects (and LIFE Forms for each)
David Meyer, Ph.D.
Evaluator Moderated
- 9:15 – 10:15 Closed Door IAB Members Only (for discussion of proposed projects & unresolved administrative issues)
Moderator - IAB Chair Moderate



- 10:15 – 10:30 Break
- 10:30 – 11:30 Feedback to Center from IAB
- 11:30 – 12:30 Administrative Items, Website/Reporting Presentations, Closing Comments
- 12:30 Adjourn

**Appendix B
Participants List**

2008 MIMTeC Fall Meeting IAB Attendees

IAB Member Organization	Attendee	E-mail	Phone
Medtronic	Cushing Hamlen Principal Scientist Medtronic Corporate Science and Technology	cushing.hamlen@medtronic.com	(763) 505-4559
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Ethicon EndoSurgery	Michael Clem, DVM, MS Director, Worldwide R&D	mclem@eesus.jnj.com	(513) 337 3337
	Foster Stulen	fstulen@its.jnj.com	(513) 337-3112
Procter & Gamble	Gary Gross Senior Scientist. P&G Pharmaceuticals	gross.gj@pg.com	(513) 622-3010
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	Ken Merdan R&D Director, Applied Technologies	ken.merdan@bsci.com	(763) 255-0434
Nanocopoeia	Bob Hoerr Chief Executive Officer	bobhoerr@comcast.net	(651) 209-1184

Greatbatch and Cordis were not in attendance. Cordis was represented by Ethicon Endo-Surgery (both are Johnson and Johnson companies)



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2008 MIMTeC Fall Meeting Potential Member, NSF & University Attendees

Potential Member Organization	Attendee	Email
St. Jude Medical	Steve Hackett	SHackett@sjm.com
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Appendix C
LIFE Form Reviews of Existing & Proposed Projects

LIFE Form Review

Minimally Invasive Medical Technologies (University of Minnesota) - November 17th, 2008

Level of Interest

Title VIII w/ CNIA

- (UC_07_01) Ultrasonic Temperature Mapping for Design Verificati ... 0 2 1 2 2**
- (UC_07_02) Image-Based Deformation Analysis of Soft Tissues â€ ... 1 1 2 2 1**
- (UC_07_03) In Vitro Photoelastic Model of Arterial Aneurysms wi ... 0 0 2 2 3**
- (UC_08_02) Human Device Interface in Catheter Based Interv ... 2 4 0 0 1**
- (UM 08-04) Surface EMG based 3D Muscle Activity Imaging (MAI) T ... 0 0 0 0 0**
- (UM 08-3) Merging 3D Anatomical and Surgical Tool Virtual Repre ... 0 0 0 0 0**
- (UM_07_01) Neurophysiology of the Lower Urinary Tract 1 4 0 0 2**
- (UM_07_02) Design of MRI Compatible Instrumentation for Image G ... 1 2 4 0 0**
- (UM_07_03) Battery-Less Wireless Sensing for MIS and other Biom ... 3 1 2 0 1**
- (UM_07_04) New Tactile MEMS Sensors for Endoscopic End-Effectors 3 2 0 1 1**

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LIFE Form Review

Minimally Invasive Medical Technologies (University of Minnesota) - November 17th, 2008

Project: (UC_07_01) Ultrasonic Temperature Mapping for Design Verification of Thermal Devices

Project PI: T. Douglas Mast, PhD (UC)

Level of Interest

Very Interested - 0

Interested - 2

Interested with Change - 1

Not Interested - 2

Abstain - 2

Interested

- would be interested in better resolution at the lower end temperature range for a testing application.

Also would be interested in proof of concept in a more scarred tissue.

1. Useful for R & D of new instruments during research phase.
2. Continued improvement in temperature measurement precision at the severe and ablation time ranges desired.
3. Testing in-vitro in larger number of animals desired.

Interested with Change

- Concerned that application in diseased tissue not included. Time domain information should be stated.

Team must understand or propose potential procedural applications....

Interested in understanding accuracy at cryogenic temperatures.

Not Interested

- The group has done an excellent job of meeting the requirements previously requested by the IAB. This technology does not pertain to our current business.

Abstain

- no longer pursuing developments requiring tissue temperature measurement.

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LIFE Form Review

**Minimally Invasive Medical Technologies (University of Minnesota) -
November 17th, 2008**

**Project: (UC_07_02) Image-Based Deformation Analysis of Soft Tissues – Internal
Organs**

Project PI: Bala Haridas, PhD (UC)

Level of Interest

Very Interested - 1

Interested - 1

Interested with Change - 2

Not Interested - 2

Abstain - 1

Very Interested

- This work has progressed very well. Moving towards a 3D measurement system is very key for our interests. While the intent is to deliver Ashok/'s thesis with the software, it would be most helpful if the software package included online documentation (help file, recommended settings, etc).

Interested

- Like to see a resolution goal set for 3d. Like to see a validation plan for in vivo.

If this has good resolution would be valuable for in-vivo tissue deformations with diseased tissue. I think 3d is essential.

Interested with Change

- Must have 3d data to understand deformation entirely. Why not use CT instead?

- 1. 3D more useful than 2D measurements. Lack of availability to 3D gray scale data is a critical impediment working in GE will be important to resolve this.

- 2. More in-vivo testing for multiple applications for imaging would be good to better understand if the technique is narrow in scope or could be much more broad.

Not Interested

- not in current development scope

- potential research tool, but not clinically applicable to areas of interest to our business

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LIFE Form Review

**Minimally Invasive Medical Technologies (University of Minnesota) -
November 17th, 2008**

**Project: (UC_07_03) In Vitro Photoelastic Model of Arterial Aneurysms with Wall Stress
Sensing Capability**

Project PI: Bala Haridas, PhD (UC)

Level of Interest

Very Interested - 0

Interested - 0

Interested with Change - 2

Not Interested - 2

Abstain - 3

Interested with Change

- See little value as presented. A key change should be made to make this useful if this is to continue. Device seal against vessel wall governs the pressure in a sac. For examination of device efficacy the simulated sac needs to have properties closer to an actual diseased vessel.

Possibly interested

- Ensure adequate documentation of construction processs and material design of the phantom... Demonstrate data of support constructs and phantom geometries.

Not Interested

- not sufficiently representative of clinical application.
- Three dimensional analysis of stress fields is desired over 2D.

Would need to correlate how the measured change in stress on the model related to in vivo stress changes.

IP submission not recommended.

Abstain

- Good progress since last meeting.

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LIFE Form Review

**Minimally Invasive Medical Technologies (University of Minnesota) -
November 17th, 2008**

Project: (UC_08_02) Human Device Interface in Catheter Based Interventions

Project PI: Mary Beth Privitera, M. Des. (UC)

Level of Interest

Very Interested – 2

Interested - 4

Interested with Change - 0

Not Interested - 0

Abstain - 1

Very Interested

- very relevant to future device design considerations and human factors validation.
- Capture other extremely relevant information important to the success of the outcome. This would include things like QCA data, device data (pressure, orientation. This system captures mistakes and inefficiencies. Would this lead to qualifications testing for physicians?

Interested

- like the /"compact/" multichannel interface and ability to view / compare multiple procedures simultaneously. Would look forward to seeing the system / technique applied in surgical procedures relevant to our business.

Researchers should also consider application in flexible endoscopy - colonoscopy, ERCP – with fluoro imaging for scope positioning.

Our past work in ethnographic research has shown the data to be applicable to many steps in device development.

- The plan for this work looks well thought out.

We would recommend the group consider the use of 3D motion capture on some non-patient cases to provide correlations of fine motor skills to end-effector changes that could then be later used to relate to actual patient procedures. This would eliminate concerns on sterile environments and patient care concerns, but provide a data set that could be used for building a fundamental hand model as it relates to catheter based procedures.

- 3D motion capture critical for clinical usefulness will be useful for physical education on capture tool usage

Abstain

- Nice start to project. Inability to capture 3D seems like it could be limiting.



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LIFE Form Review

**Minimally Invasive Medical Technologies (University of Minnesota) -
November 17th, 2008**

**Project: (UM 08-04) Surface EMG based 3D Muscle Activity Imaging (MAI) Technique
for Noninvasively Diagnosing Female Pel**

Project PI: Zhang, Timm, Erdman (UM)

Level of Interest

Very Interested - 0

Interested - 0

Interested with Change - 0

Not Interested - 0

Abstain - 0



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LIFE Form Review

**Minimally Invasive Medical Technologies (University of Minnesota) -
November 17th, 2008**

Project: (UM 08-3) Merging 3D Anatomical and Surgical Tool Virtual Representations

Project PI: A. Erdman, C. Doarn (UM)

Level of Interest

Very Interested - 0

Interested - 0

Interested with Change - 0

Not Interested - 0

Abstain - 0



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LIFE Form Review

**Minimally Invasive Medical Technologies (University of Minnesota) -
November 17th, 2008**

Project: (UM_07_01) Neurophysiology of the Lower Urinary Tract

Project PI: Gerald Timm, PhD (UM)

Level of Interest

Very Interested - 1

Interested - 4

Interested with Change - 0

Not Interested - 0

Abstain - 2

Very Interested

- The group should keep in mind that despite the challenges with the material property database, this type of model is valuable in that it would allow investigators to look at the effect of tissue properties on conditions such as incontinence. In other words, the model could be used to conduct a virtual Design of Experiment (DOE) evaluation. The goal shouldn't necessarily be to quantitatively match tissue properties, but to get realistic estimates for use in the model. This study will also benefit from other MIMTeC projects that are targeting measurement of soft-tissues through non-invasive measurements.

Interested

- No direct application for our company, but interested in the potential to obtain tissue characterization data for input to internal finite element models.
- Look at high speed load data for tissue properties.
- It might be better to study women with stress incontinence post birth versus athletes stress incontinence and compare these data with the cadaver data of women that had stress incontinence. I would think that older women would be open to being treated with implantable medical devices for stress incontinence and that women athletes are not likely to want this type of therapy.
- Need models of adjacent organs. Need some kind of empirical data to demonstrate the model. Models should also include muscle contraction, volume influence etc. Need to track evolution (documentation) of the model itself.

Abstain

- Appears to be generating novel data with broad applicability.

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LIFE Form Review

**Minimally Invasive Medical Technologies (University of Minnesota) -
November 17th, 2008**

**Project: (UM_07_02) Design of MRI Compatible Instrumentation for Image Guided
Interventions**

Project PI: Arthur Erdman, PhD (UM)

Level of Interest

Very Interested - 1

Interested - 2

Interested with Change - 4

Not Interested - 0

Abstain - 0

Very Interested

- Continued investigation into possible effects of other materials and coatings is of great interest, as well as different shapes and sizes.

Expansion beyond image distortion of great interest, such as temperature changes in particular.

Would like to have the project team share results to date with Medtronic employees, and get input from Medtronic employees on additional materials, sizes, and shapes to study.

Interested

- Perhaps look at other MR factors such as heating.

Look at geometry factors as well. ie. curved structures that cross the field at different angles.

- The group has greatly refocused their efforts to provide definitely data on the effect of material, shape and orientation to MRI compatibility. We commend them for this work.

We believe they are on the right track and think this is a good example of how the MIMTeC collaboration should work with b/w industry and academia.

Interested with Change

- Would be interested in seeing characterization of more complex implants, such as sensors, injection ports, indwelling catheters, gastric bands, hernia meshes with shape retention elements. Would appreciate evaluation of other facets of MR compatibility, such as heating and displacement. Could the lab do contract evaluations, under GLP, of proprietary materials to characterize for FDA submission?

- Not clear what specific progress has been made other than coating experiments and perhaps optimal coil selection.

Would have been nice to see a specific plan for the next period rather than general goals, i.e. specific material modifications versus the survey of materials not likely to be used in an implantable device.

- Interested in seeing characterization of a wider variety of materials and along more facets of MR compatibility - heating and motion - for stents and intravascular appliances. Also interested in methods to increase visibility of some materials to improve visibility in MR guided procedures.

- Recommend working with external MRI data sources for analysis of structures more suitable in size for medical devices. Expand the analysis to include theoretical modeling and agreement to empirical data...

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LIFE Form Review

**Minimally Invasive Medical Technologies (University of Minnesota) -
November 17th, 2008**

**Project: (UM_07_03) Battery-Less Wireless Sensing for MIS and other Biomedical
Applications**

Project PI: Rajesh Rajamani, PhD (UM)

Level of Interest

Very Interested - 3

Interested - 1

Interested with Change - 2

Not Interested - 0

Abstain - 1

Very Interested

- Potential application in pressure sensing within fluid filled gastric bands to correlate with continued efficacy in achieving weight loss - interested in ability to sense both pressure and injection port (containing sensor) orientation.

Potential R&D application for sensing tissue end effector pressure profiles without interference of wires.

Potential application in sister company efforts in orthopedics, etc.

- See a lot of value in this type of work. Coupling systems are less attractive than other battery less systems.

- Develop theoretical energy consumption models

Interested

- Progress has been well made on this project. We see applications for this sensor far beyond implantables. We have an interest in extending the transmission range beyond 5 cm and in reducing the size of the total sensor package.

Interested with Change

- Interested in potential application for extraluminal pressure sensing in AAA grafting. Comfortable waiting for increased maturity in other applications.

- There are companies that have wireless, battery-less capacitive pressure sensors and piezoresistive pressure sensors in FDA approved clinical trials (CardioMEMS, Savacor, etc). It is not clear how the sensor system proposed here is different than these. If there is no difference, it is not clear what value this work has to this consortium. There is interest in energy harvesting in-vivo, not in energy harvesting on the body or in orthopedic devices.

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LIFE Form Review

**Minimally Invasive Medical Technologies (University of Minnesota) -
November 17th, 2008**

Project: (UM_07_04) New Tactile MEMS Sensors for Endoscopic End-Effectors

Project PI: Rajesh Rajamani, PhD (UM)

Level of Interest

Very Interested - 3

Interested - 2

Interested with Change - 0

Not Interested - 1

Abstain - 1

Very Interested

- Not sure what the clinical applications would be for our business, but interested in staying involved for R&D purposes. Would like to understand mechanism for sharing patent costs with other interested IAB companies. Will commit to funding patent, pending approval of my company legal counsel and management.
- We recommend the group consider a feasibility study of use of the sensors for non-linear/dynamic properties after the in-vivo testing has been completed.
- This is excellent technology development and are very impressed with the progress made to date. Questions remain with respect to device durability. Would also be interesting to know the individual junctions performance that make up the total average signal from the device.

Interested

- Continued development of interest, in particular to measure Young's modulus properties, sheer force measurements, pressure and other mechanical properties as well.
- Check out material biostability.

Not Interested

- Don't immediately see application in our business.

Abstain

- Significant progress during most recent interval.