

"An unobtrusive and automated system for tracking surgical instruments"

--A collaboration between UCSD Hospitals, Surgery, Engineering, and private industry

THE PROBLEM – NEED IS SUBSTANTIAL

Increasing complexity of surgical instruments is prompting action

- The rising number of surgical procedures is creating an urgent demand for technologically advanced processes.
 - Less than 3% of hospitals have a system to track at the instrument level.
 - Count discrepancy in 1:8 of surgical trays with an average of 20 minutes to resolve results in significant revenue loss.
- Operating rooms are the main revenue generating space for hospitals.
 - Hospitals are seeking state-of-the-art technology that will support effective management of operating rooms to maximize performance and efficiency.
- Need for minimizing human errors rooms is pushing the uptake of innovative and advanced operating room solutions.
- Clinical Automation: Health reform is driving the need for hospitals to capture, store, aggregate, and retrieve clinical information via electronic mediums.

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Also...FDA Mandated...

"By September 24, 2020, all hospitals in the United States will be required to label each piece of equipment used in surgical operations and in long-term *in vivo* implantation"¹

- Unique Device Identifier (UDI) Rule
 - Amendment to section 502 of Federal Food, Drug, & Cosmetic Act of 1938, specifically to section 226 of the FDA Amendment Act of 2007 and to section 614 of the FDA Safety & Innovation Act of 2012²
 - 1. Gustafson, K. "Practical Limitations on Quantum Dot-Based Spectral Barcoding." Undergraduate Senior Design Project Report. Dept. of NanoEngineering, UC San Diego. La Jolla. June 9, 2015.
 - Center for Devices and Radiological Health. Unique Device Identifier System: Frequently Asked Questions, Vol. 1: Guidance for Industry and Food and Drug Administration Staff. U.S. Dept. of Health & Human Services: Center for Biologics Evaluation & Research, 2014; 1-14.

WHY TRACK INSTRUMENTS

COST SAVINGS

- Fewer purchases due to lost or missing instruments.
- Reduced labor times for tray assembly.
- Quicker processing times allow smaller instrument inventories.
- Reduced time needed to train instrument processing personnel.

IMPROVED EFFICIENCY

- Reduction of delays in surgical procedures.
- Reduction of missing instruments.
- More effective preventative maintenance.
- Fewer instruments out for repair.
- Improved inventory tracking.

IMPROVED SAFETY

- Identification of unprocessed instruments.
- Identification of instruments in recall.
- More effective replacement and repair of instruments.
- Decrease use of X-Ray.
- Patient care time

Two main hospital surgical throughput targets

Surgical tray preparation
 Automated counting of OR instruments

Instrument counting and tray prep currently rely on manual labor



INSTRUMENT TRAY PREPARATION IS COMPLEX AND COSTLY





•A market analysis indicates that surgical tray preparation in hospitals is a key area of focus for saving costs.

•The instruments in each tray differ according to each surgeon's preferences and according to procedure; assembled by low skilled personnel.

•Difficult to avoid mistakes as trays are complex

<u>COUNTING O.R. INSTRUMENTS AND SHARPS IS TIME</u> <u>CONSUMING WITH ERRORS, AND POSES INJURY RISK</u>



al & health presentation

Lost or miscounted instruments result in liability and lost OR time and revenue







OSHA injury data indicate that the OR is the site of frequent injuries due to sharps.

Kohn et. al. (2000) indicate that about 71% of the preventable adverse events occur in the operating room.

SOLUTIONS EXIST BUT THERE ARE SIGINIFICANT GAPS

Inadequate Solutions

- Not Cost Effective (\$1.00/instrument)
- Limited Efficacy (Difficult to scan/apply)
- Marker Difficult to Apply (Manually)
- Inefficient (Read only one at a time)
- Not User Friendly (obtrusive, affects feel of surgical instruments)



UCSD SOLUTION ADDRESSES EXISTING GAPS

- Invisible to the eye
- Automates Tray Assembly
- Eliminates Human Error
- Reduces Tray Assembly Time over 50%
- Marker is unobtrusive to the instrument user
- Cost effective: \$0.01 per marker



Polymer marker

Marker exposed to Optical reader

NANO-OPTICAL ENGINEERING SOLUTION FOR INSTRUMENT TRAY PREP



NANO-OPTICAL ENGINEERING SOLUTION FOR OPERATING ROOM INSTRUMENT

COUNTING

Faster Tray Assembly: Reduced by 50% --> Fully Automated --> Assures Tray Accuracy --> Eliminates Human Error



KEY core technologies:

 (1) <u>Instrument label – Nanoengineering</u>, chemical engineering -durable
 -unobtrusive

(2) <u>Coding Algorithm - Nanoengineering</u>
 -robust
 -able to uniquely identify tens of thousands of instruments

(3) <u>Optical reading System – Opto-electrical engineering</u>
 - fast
 - good resolution

Nano Based Label



Schematic diagram showing the general configuration of an instrument tracking system.

nQDs of various colors as a mixture within a polymer matrix. Each nQD emits a discrete, bright color of narrow wavelength band.

Coding

- A spectral barcode is a photocurable polymer ink, embedded with quantum dots (QDs), that exhibits unique fluorescent properties
- By varying the QD ratio, we create inks with unique fluorescence spectra
- Each ink is applied to only one surgical instrument





Basic Space-Wavelength Encoding principles



THE UPPER SERIES OF DRAWINGS ILLUSTRATE HOW A SPATIAL PATTERN CAN BE CONVERTED TO A FOURIER PATTERN THAT IS NOT AFFECTED BY **OBJECT MOVEMENT.** THE MIDDLE DRAWINGS SHOWS HOW DIFFERENT COLORS CREATE A DISTINCT SPECTRUM. THE BOTTOM DRAWINGS SHOW WHAT HAPPENS WHEN DIFFERENT COLORS ARE MIXED, THEIR AMPLITUDE IS VARIED, AND A DISTINCT SPATIAL PATTERN IS APPLIED. THE RESULT IS A FOURIER TRANSFORM, DIFFERENT SPECTRA, AND DIFFERENT AMPLITUDES. ALL THREE FEATURES EXPAND THE NUMBER OF

DURABILITY: Fluorescent Signal Maintained After 100 Autoclave Cycles

Control Instrument



Instrument 1 100 autoclave cycles



Instrument 2 100 autoclave cycles



Note: 2.5x Magnification and 800 ms exposure

Courtesy: Helmi Lwin, MD – UCSD Surgery

• UCSD Fellow in Surgery – collaborator with UCSD engineering team

Peak Pixel Intensity vs Exposure Time After 100 Autoclave Cycles



Size of labeled area on instruments relative to control did not differ after autoclaving



*p = 0.55

Repeated estimates (3 per each of two instruments; n = 6 each for pre and post autoclaved) of labeled area. (both parametric and nonparametric) t-test – **no significant difference between area estimates before and after**

Results using our initial formulation polymer show that label is durable and that detection of label occurred after 100 autoclave cycles

Optical acquisition system parameters that can be optimized

- 1. Camera sensitivity
- 2. Optical clarity
- 3. Breadth and depth of field
- 4. Magnification

Prototype system developed at UCSD engineering

Prototype lightproof surgical tray enclosure and acquisition system

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Prototype Acquisition System – Labeled Instruments

Suture needles and sutures labeled unobtrusively



Prototype system identified marked instruments and missing items

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Primary Competing Technologies

- Radio frequency identification (RFID)
- Laser Engraving

Competing technologies tend to be less robust, more difficult to implement, and more expensive to maintain than spectral barcoding.

In some cases the feel of the instrument, especially small, delicate instruments, is compromised

COMPETITOR MATRIX

CAPABILITIES	NanoMed	Haldor	Censitrac	Microsystems	Surgidat	Key surgical	
	Polymer Marker	RFID	BarCode				
Automated Tray Scan	 Image: A second s						
Invisible Marking	1						
Cost Effective	1						
Marks All Instrument types and sutures	1						
Tray Marking	1		\checkmark	1	\checkmark	√	
Instrument Maintenance	1	 Image: A second s	 Image: A second s	1	\checkmark	 Image: A second s	
Manual Tray Assembly	1	1	1	1	\checkmark	1	

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Company formed by personnel from UCSD Engineering, UCSD Health, and private interests – *NanoMed Tracking*

NanoMed will enter the market through its development partner: - Successfully complete product integration within an UCSD hospital

UC San Diego Health

Leverage UCSD results to expand through out the 11 hospital UC Healthcare system



Focus on California, with 355 hospitals, the most hospitals after Texas, 383



NanoMed only needs 280 hospitals to capture 5% of the 5600 US hospitals to be the market leader

Grow market presence through major Medical Distributors

Target Medical Device manufacturers who are required to track Class I, II & III devices

Partner with major healthcare companies who want to broaden their offering:

- HP / Becton Dickenson / Covidien

Market Opportunities

TODAYS MARKET	 \$1.1B US Market / \$2B Global Market 5600 Hospitals in the US Less than 3% of hospitals track individual surgical instruments Fragmented Market / No dominant Player
NanoMed CORE COMPETENCIES	 Surgical Instrument Tracking Solution Inventory Management Software Solution Manage Instrument Inventory Instrument Maintenance & Repair Instrument Usage
ANCILLARY MARKETS	 ✓ Aerospace: Track Airplane Components ✓ Government/Military: Track Weapons ✓ Construction: Track Materials & Tools ✓ Automotive: Car Components

Market Profile



KEY MILESTONES – WHERE ARE WE NOW

QUANTOM DOT/POLYMER MARKER	Beta complete and validated. Developed over 6 years a Polymer formulation blended with Quantum Dots that emits a unique fluorescent spectral signature when exposed to a source of light.Quantum Dot code validation and optimization.Successful Reliability Testing: Autoclaving & Sterilization.
OPTICAL READER	Beta complete and validated. Successfully read the Qdot/Polymer Marker through the use of a amplifier-digitizer configured to filter the spectral signature and digitized the signal into a readable format.
NEXT STEPS	 Qdot Polymer: Optimize formulation for volume production Optical Reader: Design & develop hospital ready unit from proof of concept. Polymer Applicator: Design & develop desk top unit from existing HP printer technology Software: - Modify platform from existing software provider for initial product launch - Develop proprietary software platform



• Software: Develop NanoMed Proprietary Platform

Optical Reader – 12 months



OPTICAL READER

2 MONTHS

2 MONTHS

Phase I – Color Space Trade Study & Concept Review power spectral distribution of markers Perform bi-sphere excitation vs. emission fluorescence measurements Calculate power budget Review suitable detection technologies Transform spectral code into suitable color space Calculate just detectable color difference map Color space tolerance analysis First order algorithmic vision design

Phase II- Project Planning

Any additional design/engineering trades System Architecture/Specification Document Preliminary component/materials selections Identify high-risk design activities and mitigation plans Provide preliminary schedule information Provide preliminary component cost information Coordinate any proof-of-concept experiments Preliminary Design Review 2 (PDR2) – include manufacturing

OPTICAL READER

Phase III – Engineering Proof of concept (demonstrator) OTS parts **Rev 01X Engineering** Vendor selection **3 MONTHS** Preliminary Design Review 3 (PDR3) - include manufacturing Provide engineering confidence testing plan (ECT) Rev 01X documentation control Order prototype hardware **Phase IV – Prototype** Assembly Engineering Confidence Testing (ECT) **3 MONTH** Critical Design Review 1 (CDR1) - include manufacturing Engineering Change Orders (ECOs) Provide DVT Plan including any regulatory - include manufacturing Rev 02X documentation control Order Pilot Production Parts - include manufacturing

OPTICAL READER

Phase V – Pre Production Support manufacturing operation Support quality and first article inspections in manufacturing Design Verification Testing (DVT) Critical Design Review 2 (CDR2) - include manufacturing Engineering Change44 Orders (ECOs) Rev 03X documentation control



CSA Group Overview

Optical Reader - Technology Partner

- Headquartered in Seattle founded in 1919
- Employees: 1800
- Product Development
- Optical Design Engineering
- Opto-Mechanical Engineering
- Systems Engineering
- Mechanical & Electrical Engineering
- Firmware & Software
- Industrial Design

- Optics Sole Focus
- 100+ years of Optics experience
- Quantum Dot experience





🕹 ModiCaro

Printer / Applicator – 12 mths





PRINTER / APPLICATOR

Phase I - Feasibility Feasibility testing using hardware test beds System Architecture Labeling Ink Imaging / Reading System Project Planning

Phase II – Detail Design

ME Detail Design Print Head Carriage Maintenance Module Ink Delivery System X-Y-Z Motion Stages Instrument tray design Mechanical structure





PRINTER / APPLICATOR





PRINTER / APPLICATOR

Phase IV – Assembly & EVT TEST

Assembly of all mechanical, fluidic and electrical components

Debug/Test

Sub-system optimization Print accuracy confirmation Image quality testing Debug of firmware/software

Phase V – Manufacturing Planning & Refinement EE/Controls Design EE Schematic





Novo Engineering Overview

Printer - Technology Partner

- Location: San Diego and Minneapolis
- Employees: 80
- Markets: Medical & BioTech
- Medical ISO 13485 & ISO 9001
- FDA Class I, II & III
- Product Development
- Prototype Manufacturing
- Systems Engineering
- Mechanical & Electrical Engineering
- Firmware & Software

Printer Market Focused

- 50 years of Printer experience
- Piezo & Thermal Ink Jet Experts
- Hewlett Packard background
- Medical & Printer experience





MadiCare

Ink Formulation – 9 mths





INK FORMULATION – 9 mths

Phase I - Quantum Dot Selection

Cyan PL:490-500 nm Qys>80% FWHM: <35 nm Green PL:525-535 nm Qys>80% FWHM: <35 nm Yellow PL:560-570 nm, Qys>80% FWHM: <35 nm Orange PL:585-595 nm, Qys>80% FWHM: <35 nm Orange Red PL:615-520 nm, Qys>80% FWHM: <35 nm Red PL:630-640 nm, Qys>80% FWHM: <35 nm

Phase II – Formulation of Inks or Dispersions

QDs Ink:

– The QDs could be dissolved in different solvent with different polarities and viscosities.

- The QD ink suit for printing process.

QDs Polymer dispersions:

– There are several steps for the dispersion:

ligand exchange; mixing; evaporation of the solvent; coating for optics

QDs Optics Modulation



INK FORMULATION

Phase III - Prototype Evaluate Adhesion Viscosity Clarity

Phase IV - Production





NN Labs Overview

Ink Formulation - Technology Partner

- Location: Arkansas & China
- Employees: 250
- Ink Development
- Quantum Dot Manufacturing
- QD Displays
- QD Lighting
- QD Coating
- QD Screen Printing
- QD Optics Detectors

- QDot World Leader
- Lab Scale to Production
- Low Cost Manufacturing
- Broad Product Line



ModiCaro

NanoMed Tracking – Collaboration Between UCSD Surgery and Engineering

John Clark - CEO

- John has 30 years of experience developing and commercializing medical device technologies.
- Founder and CEO of Global Cancer Technology and American Radiosurgery.
- Launched 10 medical device start-up companies and Founder of Edmonds Medical Systems, Clinical Diagnostic Products, Andros
 Medical & Laser Centers.

Marc Potvin - President & COO

- 25 years in operations, sales & marketing, engineering, supply chain and strategy roles throughout the US and globally. 15 years experience in the medical device market space.
- Founded Agility Management in 2008, a Human Capital company sold in 2015.
- Served as a Board member of Connect/SDSI, a business incubator for start-ups.

Tom Hamelin - VP Hospital Operations - UCSD

- 30 years of Hospital Administration experience. Senior Director UCSD Perioperative Services and Radiology
- Former Director at UMMC, ST Vincent Hospital and Boston Medical Center.
- Former Vice-President at Awarepoint. Holds a BS, BSN, MSN, MBA and Doctorate of Nursing Practice (DNP)

The UCSD Engineering Team

- Sadik Esener PhD, Applied Physics and Electrical Engineering, UCSD. Internationally known expert in photonics, opto-electronics. Director of OSHU's Institute for Early Cancer Detection Research. Part of 12 startup companies and co-founder Genoptix, Nanogen, OriMedix, Devacell, and Ziva.
- Wolf Wrasidlo- PhD, Organic Chemistry from San Diego State University & University of Erlangen. Highly experienced polymer and organic chemist. Founder of Brunswick Biotechnetics and Neuropore.
- Milan Makale PhD, Radiation Biology at the University of Alberta and MSEE in Biomedical Engineering at GWU. Faculty member at UC San Diego Moores Cancer Center. Specializes in medical devices and imaging. Co-founded Engineered Medical Devices Inc., Lemma Pharmaceuticals.





Marc Potvin - President

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