Medical, Health & Wearables

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Disclaimer: The material contained herein is biased towards Flexible Hybrid Integration approaches as a consequence of the NextFlex contribution. It is recognized that many rigid and semi-rigid approached are also widely used and should be part of the HIR.

Heterogenous Integration for Healthcare

- Imaging Modalities (much follows other sections of HIR)
  - CT, X-ray, MRI, Ultrasound and Terahertz
- Human Health Monitoring Sensors
  - Vital sign monitors, disease state, fatigue, hydration, wound care
  - Longer term devices that sense, assess and respond
- Implantable devices
  - Neural implants
  - Pacemakers
- Diagnostic systems
  - With both on- and in-body possibilities
  - Compact & stand alone
- Other related applications
  - Neonatal
  - Smart wound care
  - Smart PPE
  - other

The COVID-19 pandemic has created a significant need and drive for wearable monitoring devices that will support both clinical, home and personal care.

Emerging Medical Device Technology

HIR Chapter 4: Medical, Health and Wearable

- *Focus is on emerging wearable medical device technology.*






- Imaging Modalities
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  - Pacemakers
- ✓ Diagnostic systems
  - With both on- and in-body possibilities
  - Compact & stand alone
- Others


Application Space: Focus on Wearable Devices

- Wearables based on COTS components (2016 and before)
  - Pulse, heart-rate, temperature (basic non-medical grade vitals)

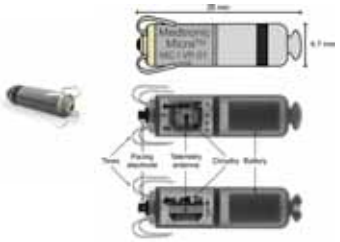
- Applications
- Clinical
  - Patient monitoring, diagnosis and therapy
- Occupational
  - Factory or harsh conditions
- Extreme Performance
  - Military, Public Safety/Homeland Security, Professional Athletics)
  - Mentally & physical demanding settings
- Wellness/Fitness
  - General personal use -- information only

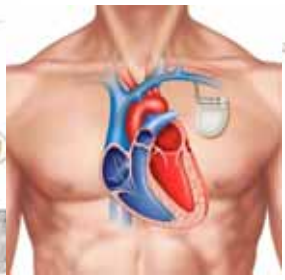
- Wearables based on non-COTS (2017 and after)
  - Form Factor
    - Conformability
    - Stretch-ability
    - Transparency
    - Semi-Breathability
  - Basic medical grade vitals
  - Physiological: ECG, EEG, SpO_2, BP, RR, temperature and more
  - Motion, strain and pressure sensors
  - Integrated multi-sensor systems
  - Fluid and biomarker analysis (using micro fluidic systems)
    - Sweat sampling (absorption and wicking)
    - Interstitial fluid and blood (micro needles)

Miniaturization

Implantable cardiac monitors

Implantable Pacemakers



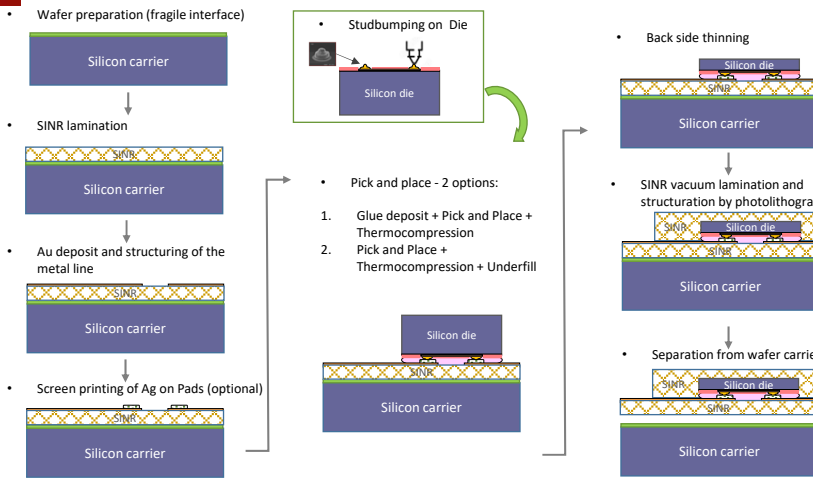


Medtronic
Engineering the extraordinary

Scott Savage, Medtronic

leti
CEA tech

ChipInFlex - Wafer level integration - Encapsulation in a hermetic silicon box



Applications: Implantable devices

- Heart Stimulation
- Cochlear implants
- Brain stimulation
- Brain activity sensing
- Vagus nerve stimulation
- Retinal implants
- Contraceptif implant
- Connected custom prostheses
- Bladder Stimulation

Heterogeneous Integration Workshop | Jean-Charles Souriau| May 31 2022 | 6

e-Textiles for Medical Applications

Applications:
- movement monitoring/feedback
- stimulation
- treatment (e.g. light)
- active support
- wearables as interface for implantable devices

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Medical Grade Wearables

Next generation ECG patch

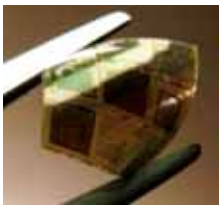
3D substrate
Ultrathin chips
Integrated battery
Wireless IR communication
Non traditional substrate (stretch flex)
Multi-Sensor integration
Non-traditional substrates
Compliance with established production flow
Disposable Features (module, degradeable portions)
Wireless RF communication & power
Multi-sensor/multi-domain
Edge pre-processing
Secure uplink
Multi-Domain (MEMS/electronics)
Super-flex/stretch non-traditional substrate
Fine line (10/10)
Component embedding including authentication

Erik Jung, Fraunhofer IZM

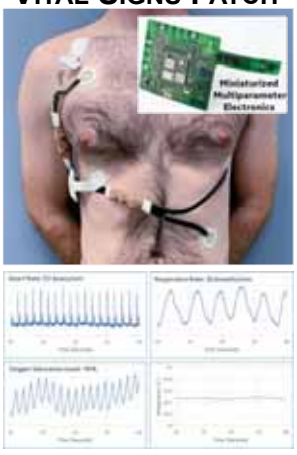
Fraunhofer IZM

MEDICAL HIR OBJECTIVES

- Physiological: ECG, EEG, SpO_2, BP, RR, temperature and more
- Motion, strain and pressure sensors
- Fluid level and fluid bio-marker sensors
- Smart bandages
- Smart PPE
- Integrated multi-sensor systems
- Communications
  - Device integrated antennas (Bluetooth)
  - Advanced printed antennas solutions for multi sensor on-body applications
- Energy Management
  - Batteries, inductive charging to harvested energy
  - Compact, safe, high energy density batteries



VITAL SIGNS PATCH

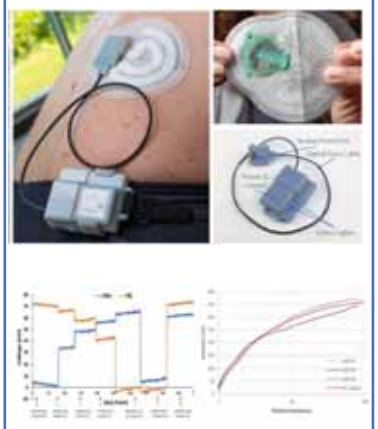


-Continuous wireless vital signs sensing for up to 1 week (Clinical grade)
3-Lead ECG, Respiration, Reflective PPG, Core Body / Skin Temperature, Accelerometer
- End-to-end prototype manufacturing & supply chain development
Disposable devices
- Algorithms
Android UI, Decision Making, CNIBP

INTERSTITIAL FLUID PATCH

-On-demand wireless minimally invasive measurement of metabolites, proteins and hormone concentrations
Lactate, cytokines, catecholamines. Patch actuation
-End-to-end prototype manufacturing & supply chain development
Reusable electronics unit & disposable sensors
- Algorithms
Android UI

SWEAT HYDRATION PATCH



- Continuous wireless hydration sensing during moderate/intense exercise for up to 24 hours
Electrolytes (Na, K), Sweat rate
-End-to-end prototype manufacturing & supply chain development
Reusable electronics unit & disposable sensors
- Algorithms
Android UI

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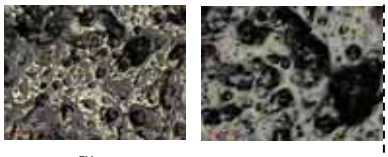
Materials

	Now	Emerging	Future
Enables	Basic applications, performance and process specific requirements to enable early technology demonstrations.	Establish supplier base for functional material sets, in-situ characterization tools, establish databases that enable technology adoption.	Product and application specific materials, sources, process and integration requirements that enable technology adoption/manufacturing.
Substrates	20% elongation, <10% deformation over 1000 cycles,	Flex/stretch for extreme environments, >5yr lifetime, low loss (such as <0.0003 at >10GHz with high permeability, low magnetic loss.) Substrates that are in-vivo, soft tissue compatible	30-50% elongation, <10% deformation over 1000 cycles, biodegradable substrates for sustainability
Active	Temperature, humidity, pressure transductive inks, force and haptic sensing media	Long use life transductive ink for T, humidity, pressure, shock, strain, chemical sensing, tunable magnetic/varactors, in-vivo micro-stress/strain	Printed actives for battery/energy storage, conformal energy harvesting, high resolution transducer array for artificial skin
Passive/Conductor	Improve conductivity <4X bulk metal, low T cure <130C, high T solderable >230C, stretch 20%	…plus: printed alternative to Cu, bidirectional elongation w/ 10% resistivity change at 1000 cycles, printable at <10um,	…plus: flexible battery electrodes, improved conductivity <2X bulk metal, stress absorbing conductor for via/interconnect
Passive/Insulator	Substrate & process compatible dielectrics, encapsulants and selective permeable membranes for low cure (<130C). High T>230C stable, stretchable >20% elongation w/ <10% deformation @ 1000 cycles.	Biocompatibility, >L band compatibility, >5yr use lifetime in natural environment, high dielectric constant.	<0.0003 loss at 10GHz, use at 260C; 30-50% elongation w/ <10% deformation @1000 cycles, super-hydrophobic, biodegradable, in-vivo and microfluidic compatible, flexible NIR plastic & waveguide materials

Highly Stretchable Metal Gel: Isothermal Fatigue Cycling

DC Test Coupon and Experimental Setup

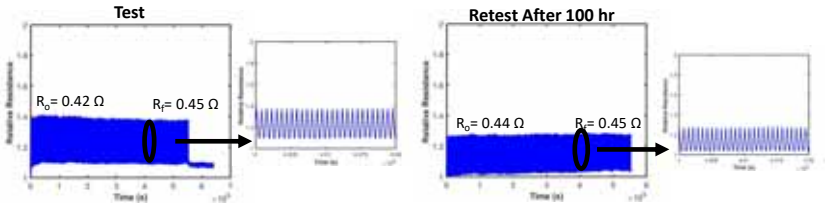
Microstructure of Metal Gel



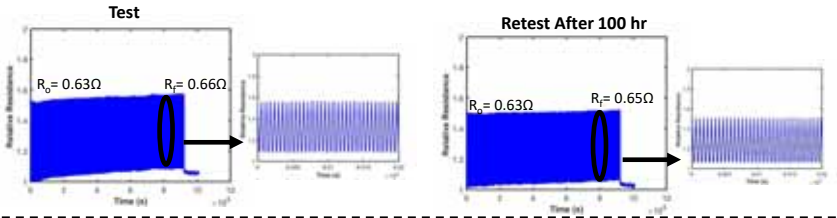
Liquid Wire™ Metal Gel consists of eutectic Ga-In-Sn liquid metal alloy with oxide and proprietary additives.

Strain amplitude= 30%
Extension rate= 5, 10, 20 and 30 mm/s for 8000 cycles per trial at four extension rates

Liquid Wire™ Made to Move

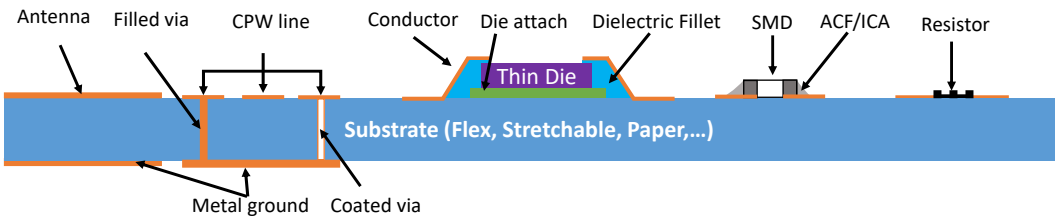


Strain amplitude= 50%
Extension rate= 5, 10, 20 and 30 mm/s for 8000 cycles per trial at four extension rates



- During cyclic loading at strain amplitude of 30% the sample shows **fatigue free behavior up to 16000 (8000+8000) cycles.**
- **In follow-on testing, the sensors are reliable at even 100% strain amplitude for 30,000 cycles.**

FHE KEY DESIGN ASPECTS



Substrate
- Flexible, stretchable
- Light weight
- Low cost
- Sustainable
- Compatible with different inks

Conductors
- Well defined and uniform structures
- Excellent adhesion
- Low temperature processing
- Highly conductive
- Reliable

Assembly
- Low temperature components attachment materials
- Interaction between the ink and substrate
- Rigid-to-Flex consideration

ELEMENTS FOR WEARABLE FHE

- Circuitization
  - Die < 100 I/O & pitch > 200 µm
  - Flexible and stretchable substrates
    - Single-layer to multi-layer
  - Printed vs plated conductors
- Non-printed components
  - Flexible interposers
  - Thin die (flip-chip) bonding
    - 50 µm to 10 µm wafers
    - Need unpackaged die
- Device Assembly
  - Methods (PnP) for 50 to 10 µm thick die
  - Embedded passive & active components
  - Panel to Roll
- Encapsulation
  - For single to multiple die
  - Flexible/Conformable

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Device Integration, Packaging and Assembly

	Now	Emerging	Future
Enables	Thinned die and compliant assembly methods. Stretchable and conformal substrates. Flexible low dielectric and low loss RF materials.	Clothing/textile substrates for wearable applications. Printed features for RF and hi-speed function. Flexible interposed for fine-pitch die attach	Embedded components and integrated passives. Encapsulation for harsh environments. From sheets to roll based device assembly.
Circuitization	Low I/O (<100) and pitch (>200µm) for controllers, memory, communication w/ compliant chip attach	Flexible substrates w/ stretchable circuitry, RF materials, textile substrates	Multi-layer flex circuits w/ internal power/ground, vias and embedded function. Printed conductors, transmission lines, dielectrics, vias RCL, sensors and 3D features
Non-printed components	Thin die flip-chip bonding Stress/defect free die thinning & dicing for <50µm wafers	Flexible interposer for fine-pitch, <50 µm thick die. Reliable interconnect/assembly of <50µm die. Thinning/dicing of <10 µm wafer. Non-contact methods	Interposers for <10µm die, stretchable interposers w/ embedded components. Assembly of <10µm die, integration of power sources and passives. Embedded passive components
Device assembly	Pick/place of <50µm die w/o interposers	Assembly of FHE interposers with fine-pitch for <50µm die. From sheets to roll based assembly	Assembly of <10µm die with, w/o interposer, non-contact methods, embedding passive/active in high density flex, roll-based assembly
Encapsulation	Single-die, sheet/batch process Flexible & conformable	Multi-mode & higher I/O count Sustainability/recyclability	High-volume/low cost R2R Harsh environment applications

ROADMAP NEEDS

- Unpackaged thin die
- Compliant interconnect and attach methods
- Stretchable & conformable substrates (films & textiles)
- Flexible low Dk/Df
- Printed passives and RF
- Metal-like printed conductors
  - Thermal, laser, photonic based metal oxide reduction/particle-flake sintering
  - Use of (localized) reducing gas (hydrogen/nitrogen) processes
- Embedded components
- Encapsulation for range of environments
  - On-body, in-body, high/low temperatures humidity
- Scalable manufacturing
  - Panels to rolls

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Application Roadmap: Wearable

	Now	Emerging	Future
Electro Physiological	Clinical grade wearables (ECG,EMG, Temperature, Respiration, BP, O_2)	Disposable clinical grade wearable. Low-cost, low-profile sensors (such as facial sensors for CO_2-based RR or clothing/shoe embedded sensors)	Low-cost multi-sensor systems w/ energy harvesting and integration with AI
Motion, Strain & Posture	Wearables for rehab (physical therapy) assistance	Low profile pseudo skin sensors integrated w/ prosthetics	Low-cost, low-profile wearable sensors and exoskeletons for bone and muscle degeneration
Worker Safety & Productivity	Environment aware PPE (electrical, temperature, collision, hazards)	Extreme environment sensing and feedback (toxic gases, confined spaces, dehydration, etc.); for worker's mental fatigue and stress prediction and prevention	Low-cost wearables for real time musculoskeletal injury, nerve fatigue prediction algorithms based on work-load
Fluid Biomarkers Smart Bandages	Continuous & non-invasive electrolyte sensing	Non-invasive wound monitoring and healing; sensors for non-invasive metabolite (lactate, glucose) sensing	Non-invasive drug metabolites sensing and optimum drug delivery; non-invasive innate biomarker sensing (from stress, cancer to infectious diseases,…)
Other		Wearable accessories, such as flexible displays, for augmented reality	Wearable medical imaging devices; Smart low cost optical, auditory and haptic prosthetics for medical

ROADMAP NEEDS

TWG welcomes input, collaboration and contributions from other technologists including those in the medical device industry.

Chapter revisions include:

- Reorganization into sections: current/future technology, product/packaging requirement, and challenges.
- Identification of technology drivers based on current and evolving unmet medical needs
- Implantable medical devices including pacemaker, defibrillator, neurostimulator, and cardiac, glucose and GI monitors.
- Regulatory requirements and compliance challenges
- Medical device and (human) tissue interactions, and device safety
- Broad impacts of COVID-19
- Miniaturization in interconnect, assembly, materials and systems integration
- Sections on power, battery, wireless communication and OS integration

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Thank You!

- Reviewers of this chapter
- Wilfred Bair & Jason Marsh (formerly at NextFlex)
- Scott Miller (NextFlex)
- Grace O'Malley (iNEMI)
- Benson Chan (Binghamton University)
- Department of Defense (Manufacturing USA)
- AFRL
- NextFlex Community

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