Cognionics

March 10th, 2015

Advancements in Dry Electrode Technology for Medical Devices

Yu M. Chi -- Cognionics, Inc.

About Cognionics

UCSD spin-off from Prof. Gert Cauwenberghs' research

Founded in 2010

Started operations in summer 2011

Funded by NASA, Navy, NIH, IEM, TATRC and DARPA grants, early prototype sales and consulting services

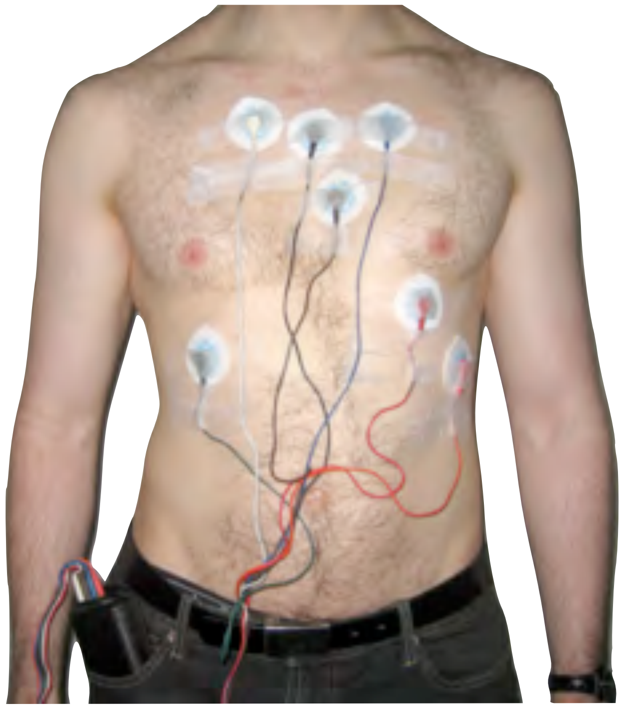
Currently 15 employees on payroll

3000 sq. ft. R&D office in San Diego

First commercial licensing deal signed in 2012

First commercial products on the market in 2013

Motivation



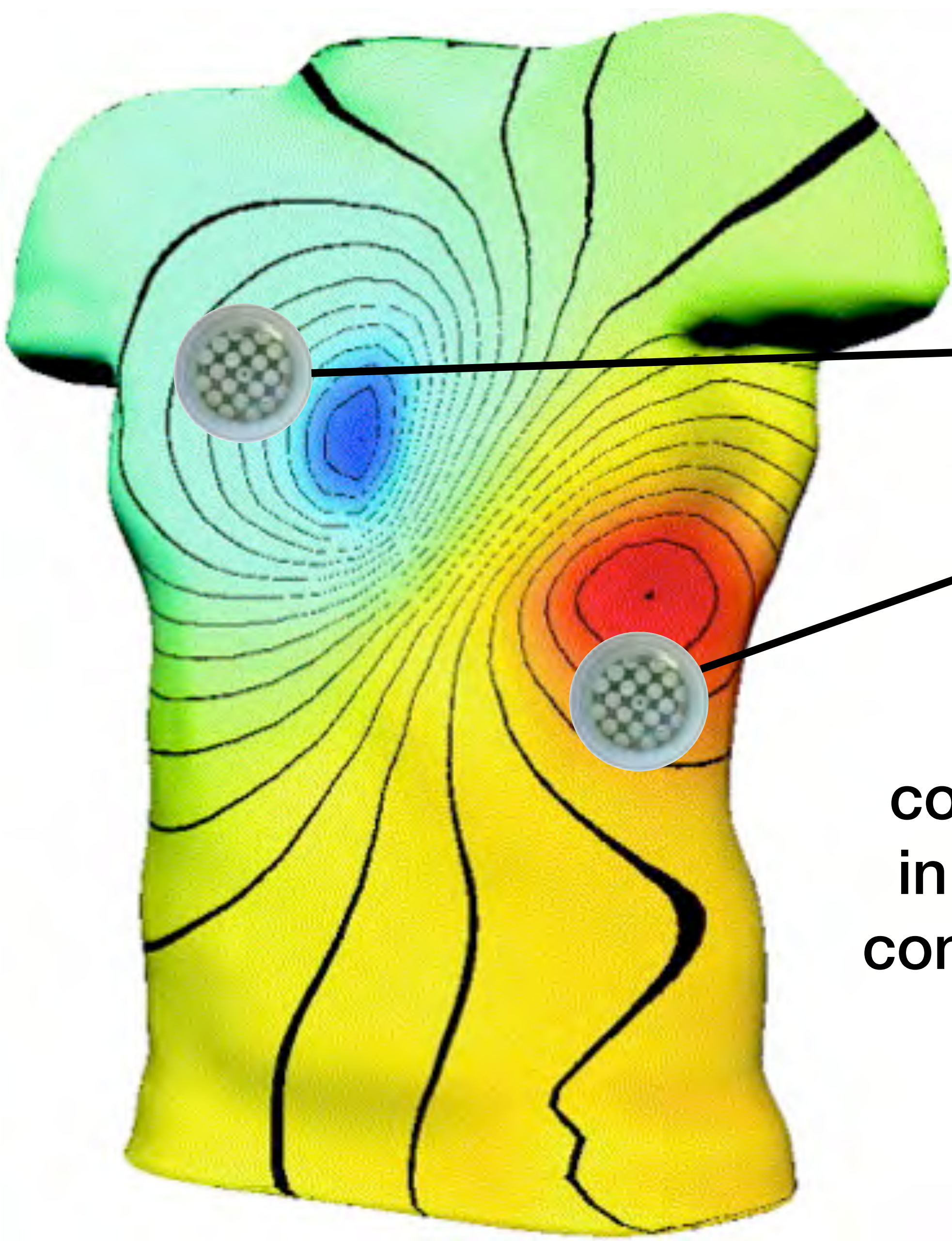
ECG/EEG:

- Simple to build
- Inexpensive to use
- Non-invasive for the subject
- Widely used in clinical and research settings
- Diagnostically useful information

Today's ECG/EEG sensors, however:

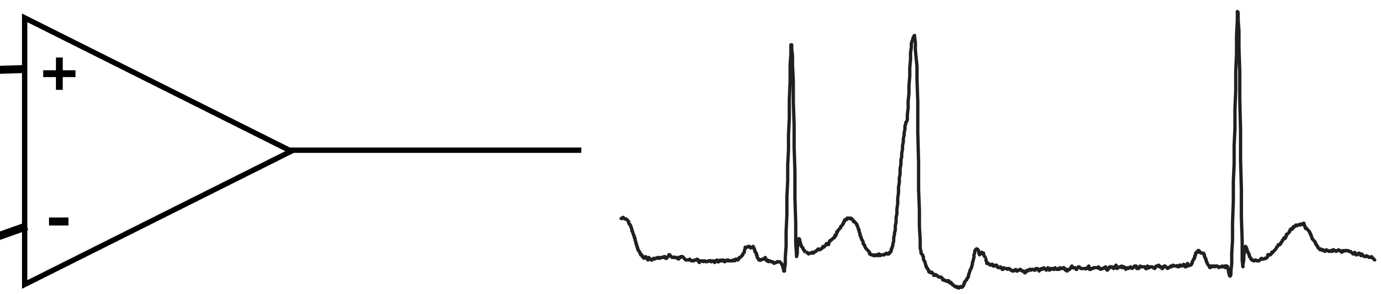
- Require adhesives and skin-irritating gels
- Number one patient complaint against mobile ECG/EEG devices
- Need for new, patient-friendly, sensor technologies
- Large usability barrier outside of laboratory environments

Origin of Biopotential Signals



Differential Amplifier measures a **voltage**

Output Signal



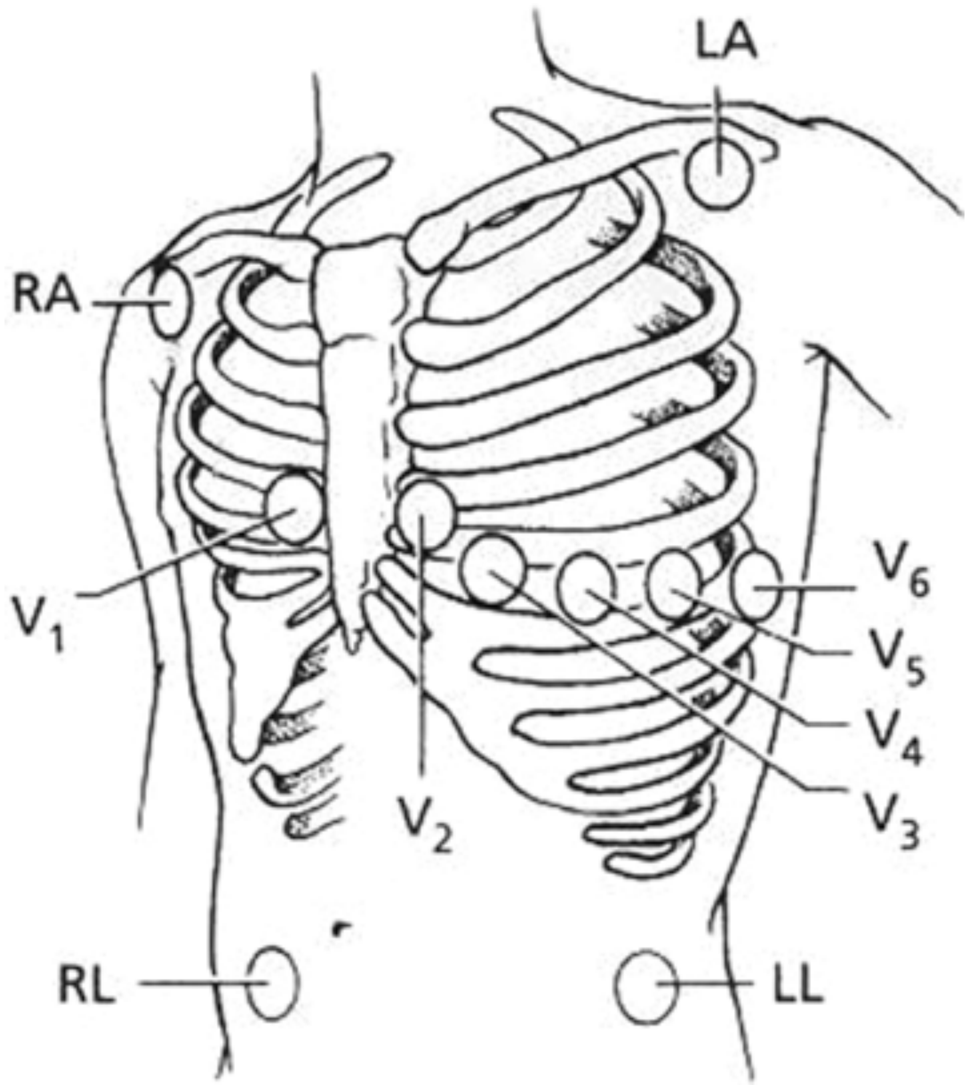
Sensors on the skin couple ionic conduction in the body to electrical conduction in an amplifier

Physiological activity generates electrical fields inside the body which are propagated via ionic currents

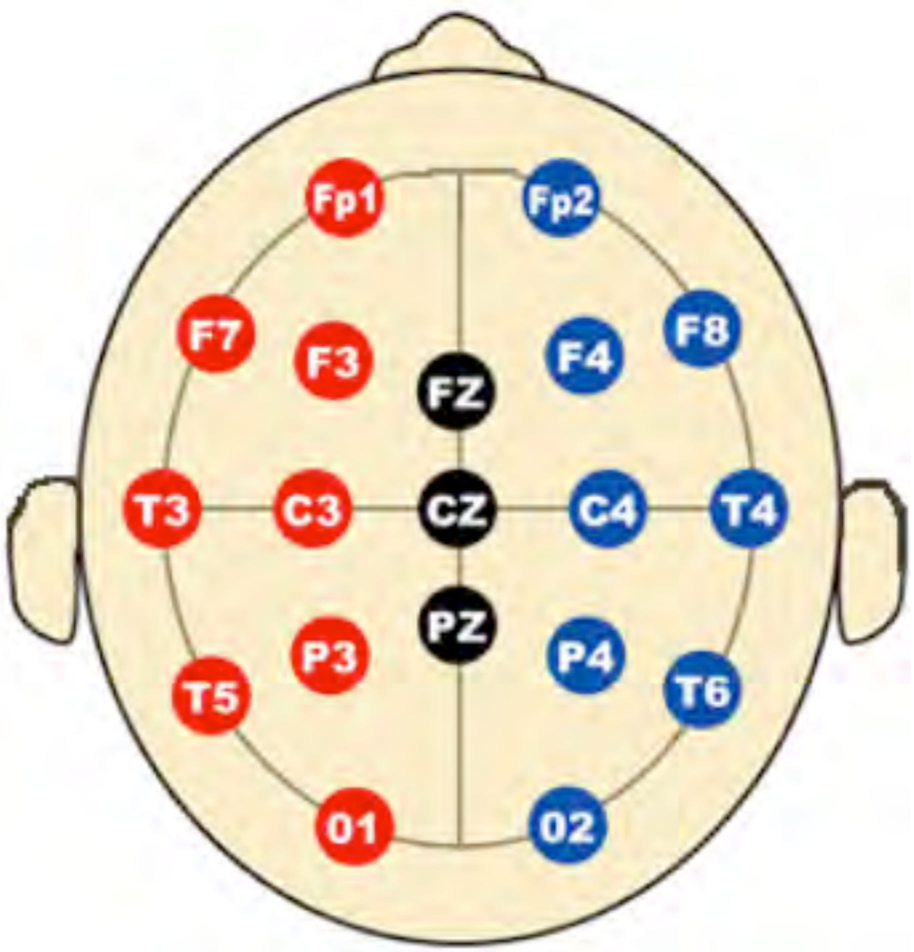
All biopotential signals require **at least 2 points of contact** and location of sensors is important

Placement of Sensors

Placement of sensors is critical to obtaining desired signal and rejecting noise



12 lead ECG



10-20 EEG

Challenges in Building a Low Noise System

Small signal with many potential sources of noise

Electronic Noise

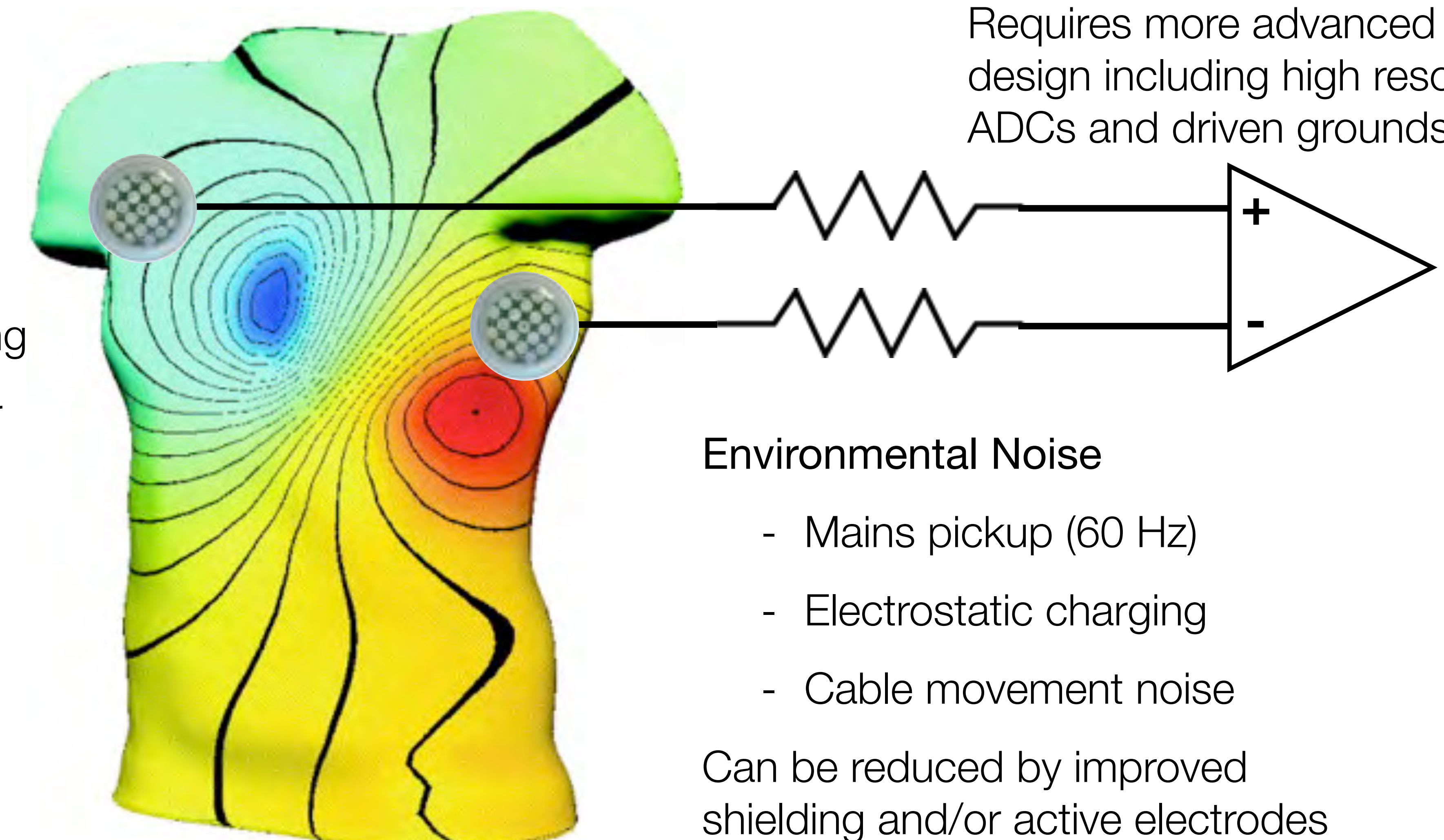
- Amplifier thermal noise
- Common-mode noise
- Quantization noise

Requires more advanced circuit design including high resolution ADCs and driven grounds

Sensor Noise

- Vibrations
- Skin potentials
- Electrochemical artifacts (improper metals)
- Poor contact
- Triboelectric charging

Solved with better sensor materials and harnesses

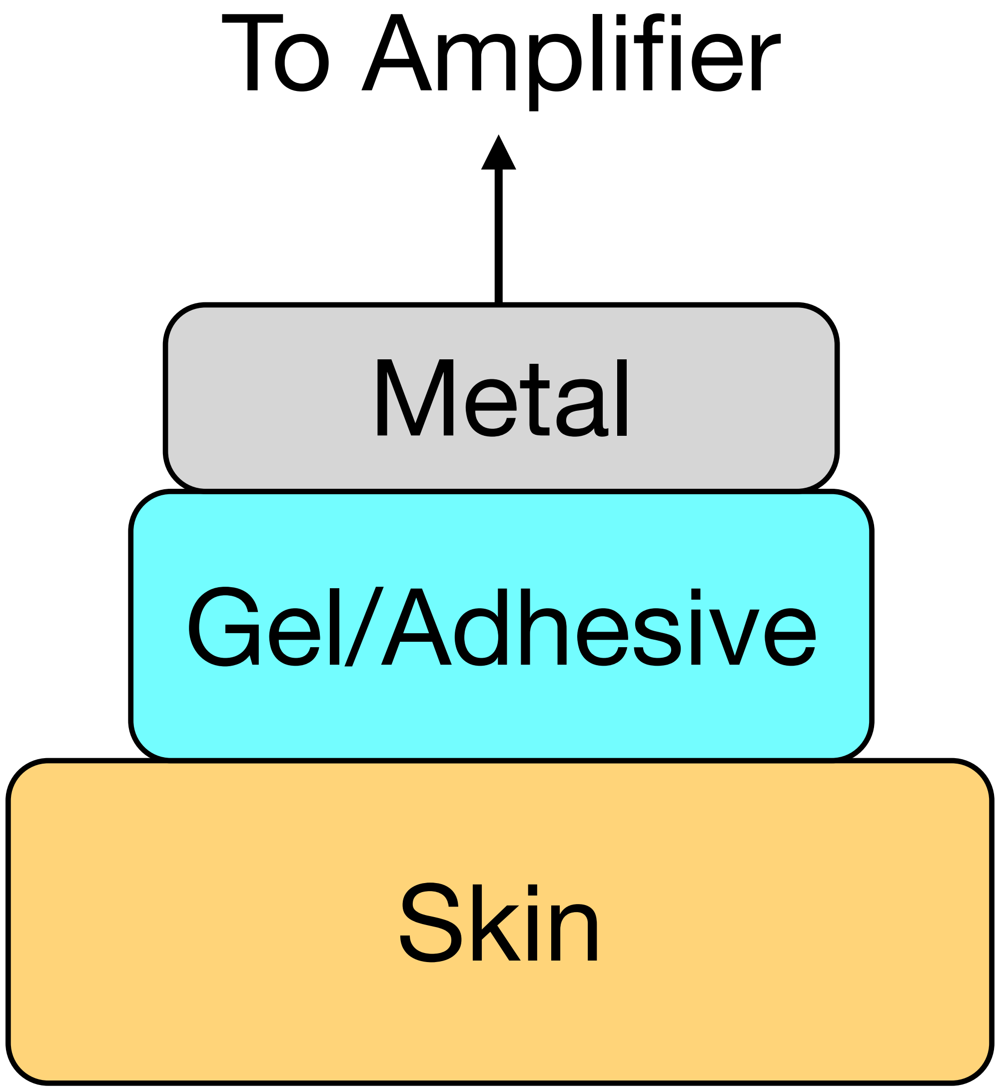


Environmental Noise

- Mains pickup (60 Hz)
- Electrostatic charging
- Cable movement noise

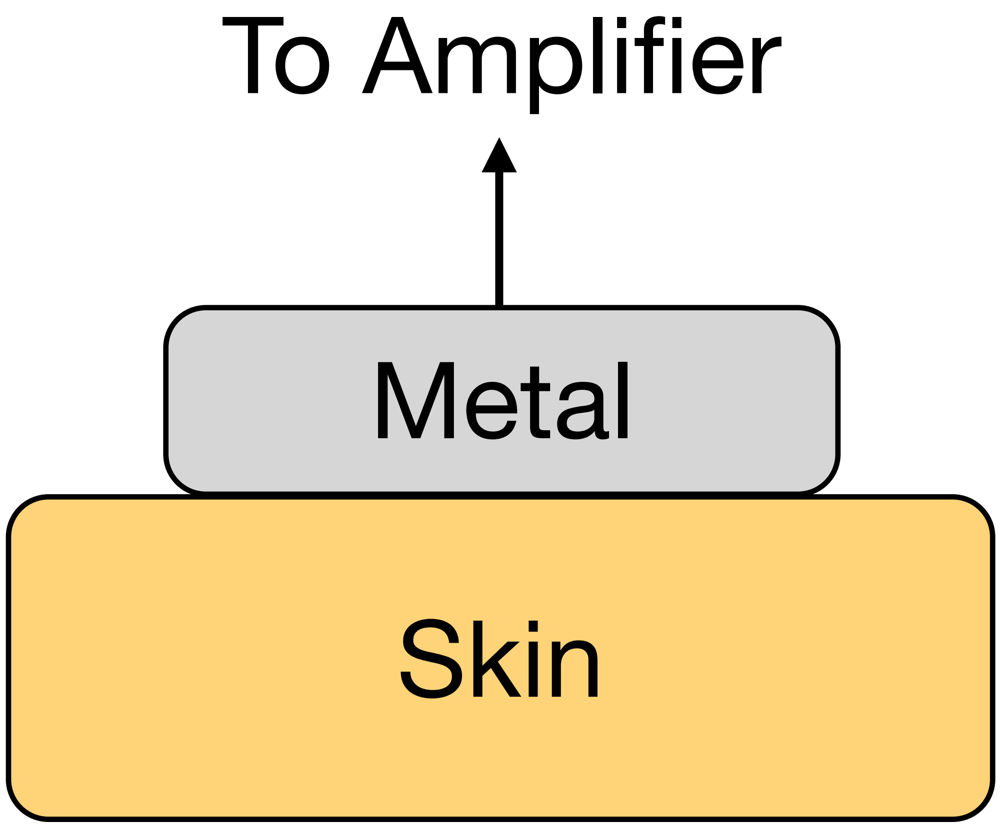
Can be reduced by improved shielding and/or active electrodes

Wet Electrodes



- Gel lowers contact impedance, buffers against movement
- Low impedance contacts makes electronics design straightforward
- Wet sensors are self contained and adhere to the skin by themselves
- No need for harnessing, just wires to an electronics box is OK

Dry Electrodes



- No adhesive!
- More comfortable, potentially long-lasting
- Loss of contact leads to unacceptable artifacts in signal
- Higher impedance contacts are prone to noise pick up
- Depends on harness/system to make contact to the body

Design Challenges:

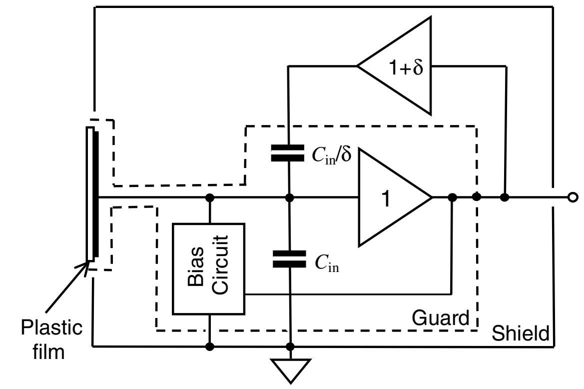
- Building a comfortable and secure harnessing system
- Contacting through hair (esp. EEG)
- Implementing low-noise acquisition electronics
- Optimizing the interface between skin and metal without conductive media

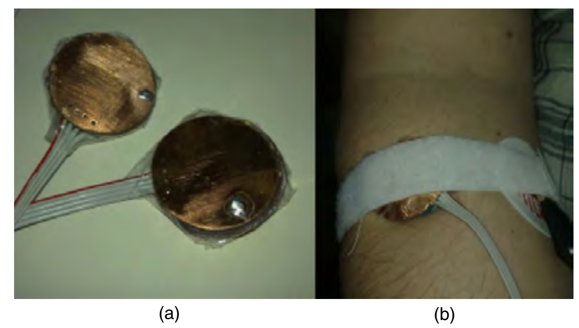
Types of Dry Electrodes

Dry Metal Contact

- Lots of examples in the market and research literature
- Can be very simple, bare metal works
- Gel-less contact with skin
- Performance also depends on quality of harnessing system

Capacitive





Spinelli et al. 2010

- Active buffering for impedance transformation at electrode source
- Can work OK through high resistivity materials (e.g., cotton) but not true insulators (e.g., synthetics)
- Movement artifacts are a huge issue in practice

Wet-Dry Hybrid

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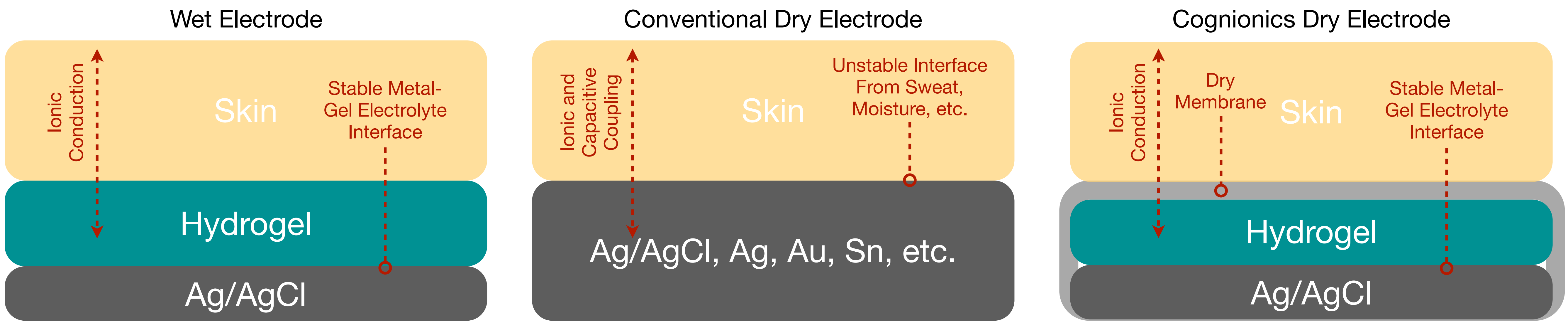
- Novel design that combines the best properties of wet and dry electrodes
- Dry contact surface with the skin
- Inner gel layer provides ionic conduction
- Stable gel to Ag/AgCl interface

Drypad Electrode Overview

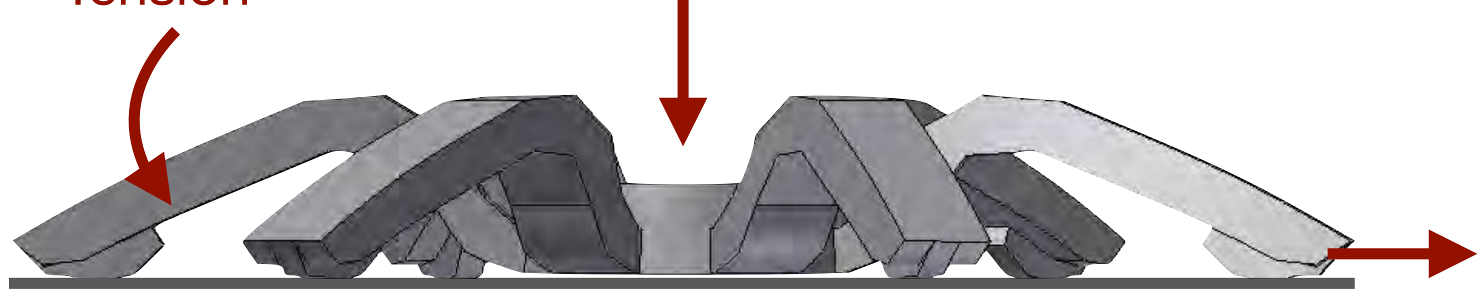


Wet electrodes work well due to stable electro-chemical interface provided by Ag/AgCl and conductive gel. Efficiently converts ionic conduction inside the body to electrical conduction.

Normal dry electrodes have an unstable electrochemical interface due to absence of gel and the use of non-ideal metals. Manifests as high contact impedances, drift and noise.

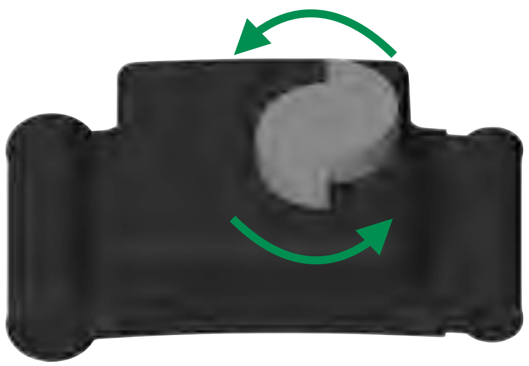
Cognionics electrode provides a dry surface via a membrane. Ionic conduction still occurs across membrane into inner gel layer. The electrical characteristics are similar to standard wet electrodes including low impedances and noise.

Flexible Electrode - Through Hair



High Density Headset Design

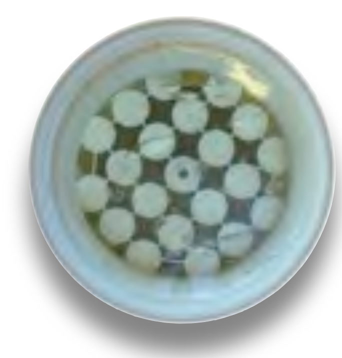
Precision Tension Adjustment



Wireless DAQ Electronics

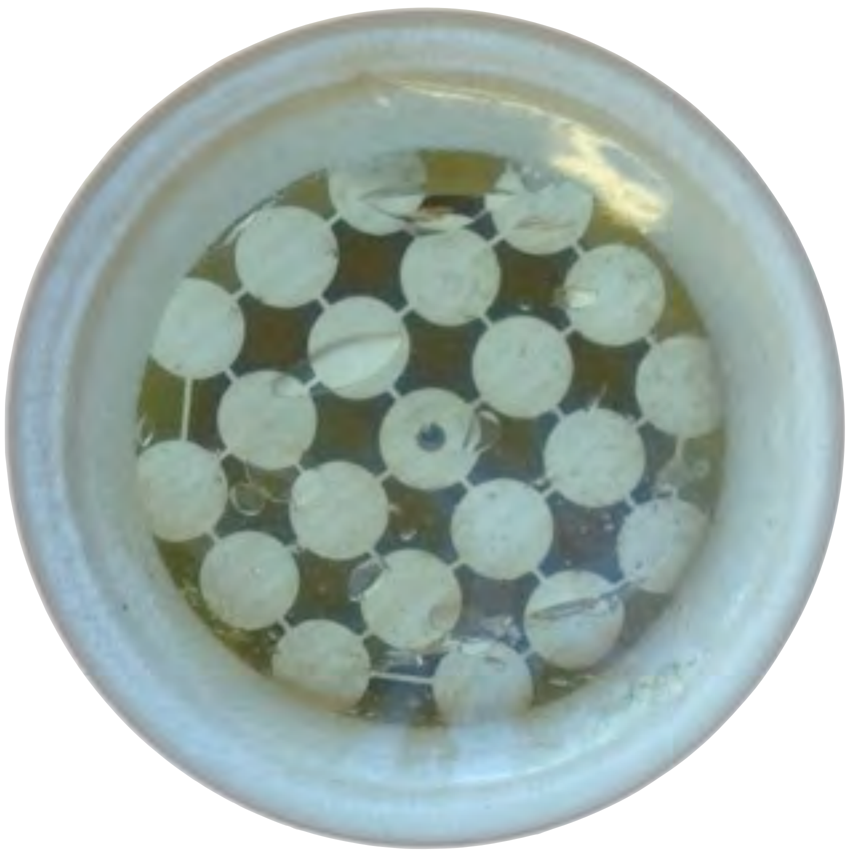
Flexible Dry Sensor

Pad Dry Sensor



But what is a ***Complete*** Dry Sensor System?

Harness/ Mechanics

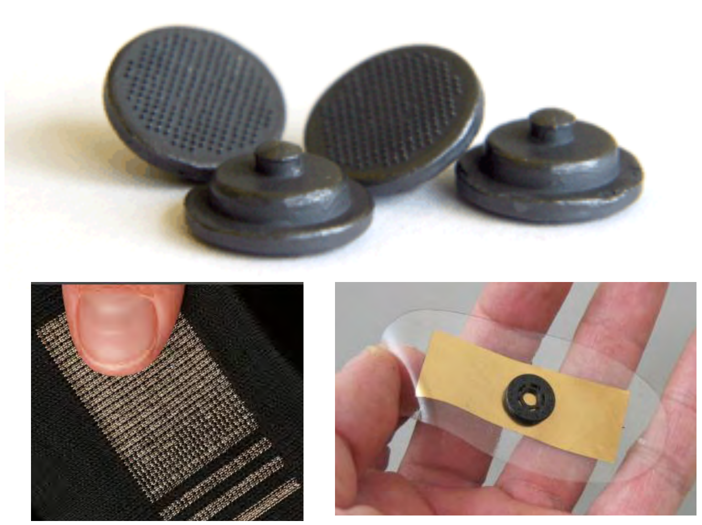


The 'Sensor'

Electronics

Current Dry ECG Options

Standalone Sensors



- Many designs out there ranging from metal plates to textiles and polymers
- Minimal real benefit compared to inexpensive hydrogel electrodes, still requires tape and adhesives
- More advanced versions include built-in amplifiers which can reduce some but not all types of noise

Event Monitors

- One lead event monitors well known, some are adding mobile capabilities (e.g., phone integrated)
- More advanced systems can emulate 12-lead recordings
- Lack of continuous recording limits utility but may be useful as a replacement for wet electrodes in short in-clinic readings

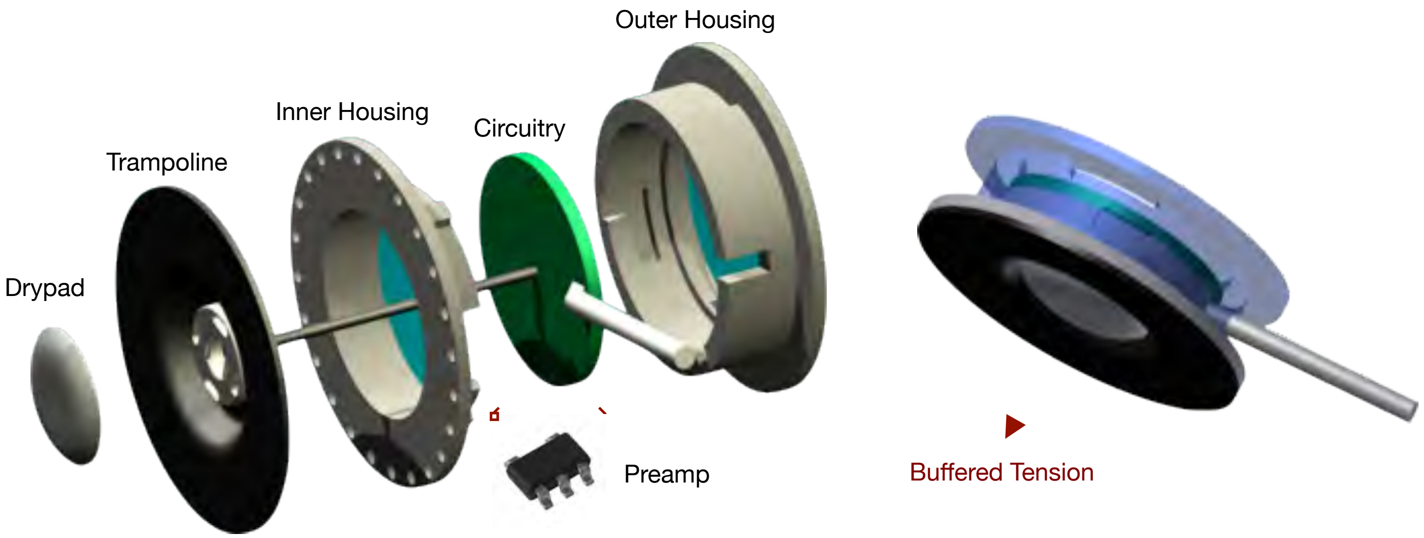
Complete Systems

- Dry electrodes are well suited, in theory, for long-term ambulatory monitoring
- Many different designs including belts, shirts, vests etc.
- Artifacts are a huge issue: comfortable harness results in excessive movement and tight harnesses are uncomfortable

However, achieving low noise diagnostic recording is hard – especially for ambulatory use
Need to correctly design a complete system, not just individual components

Cognionics Dry ECG System

- Evaluation 3-lead mobile ECG belt
- Operates in both dry contact and non-contact mode - difference in tightness
- Onboard high-resolution data acquisition (24-bits, DC-100 Hz, 500 samples/sec)
- Dry contact version can be worn over long periods without discomfort



- Mechanical assembly for each Drypad sensor
- 'Trampoline' provides regulated tension holding sensor on body
- Guards against movement artifacts and sensor contact loss

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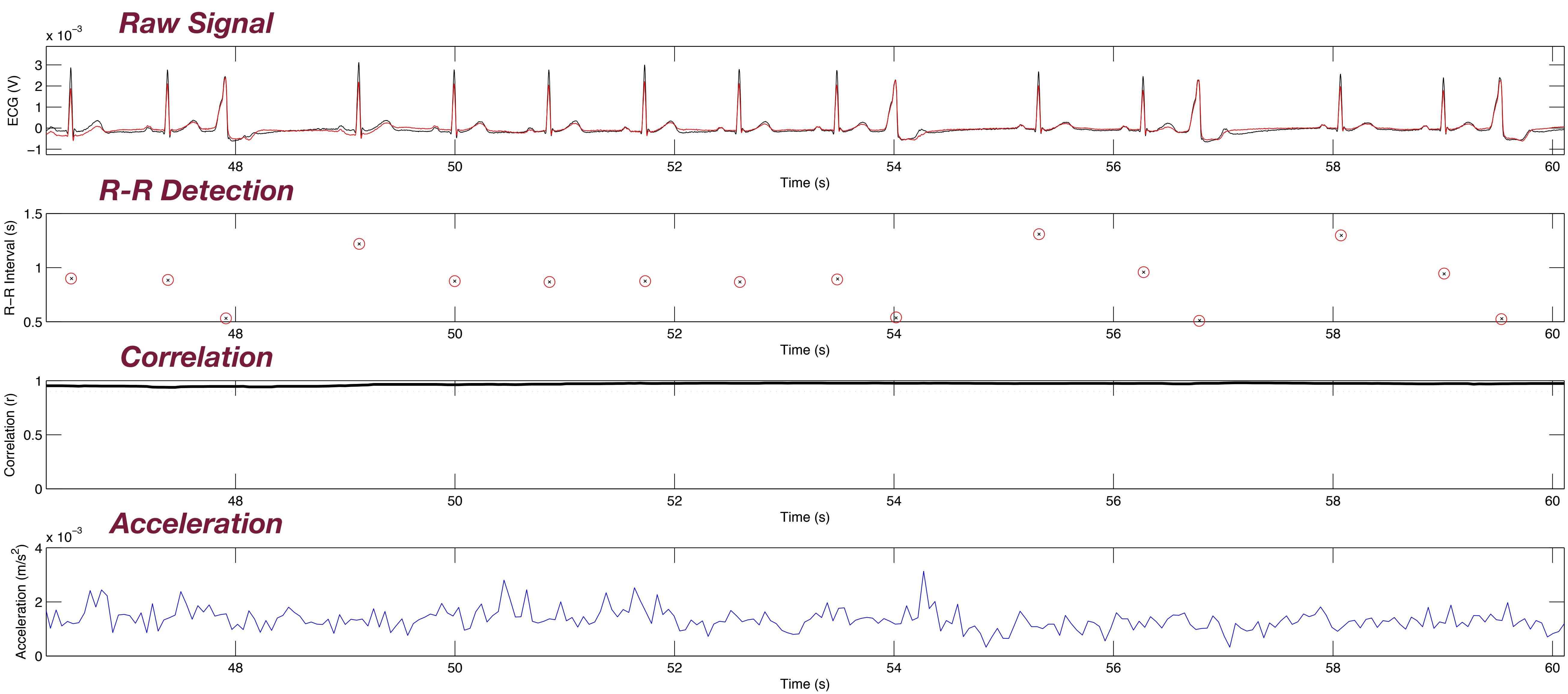
Dry ECG System Evaluation

Current 10 Subject Study:
Two pairs of sensors - Wet/Dry
Simultaneous signal acquisition with accelerometer data



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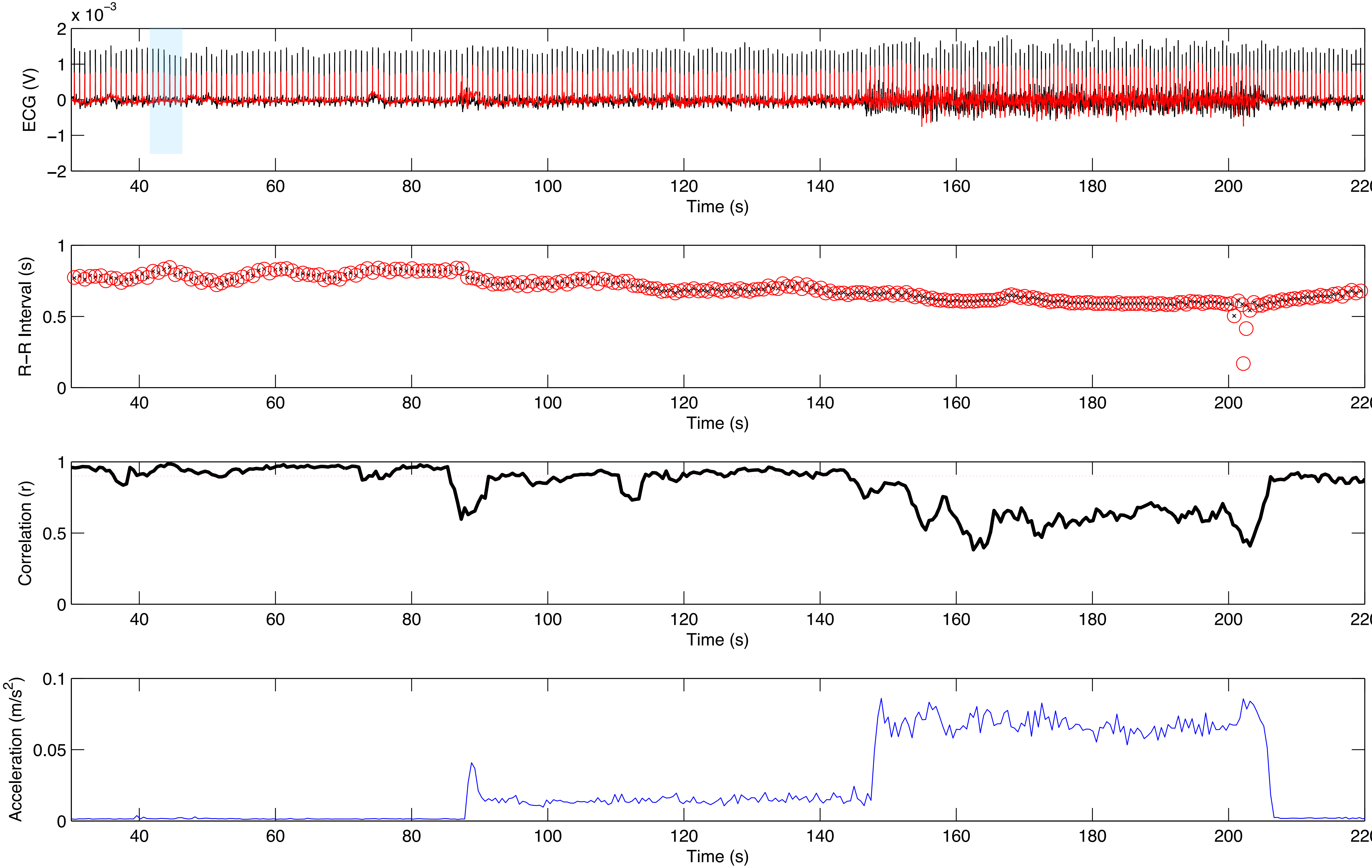
Sample Evaluation Data



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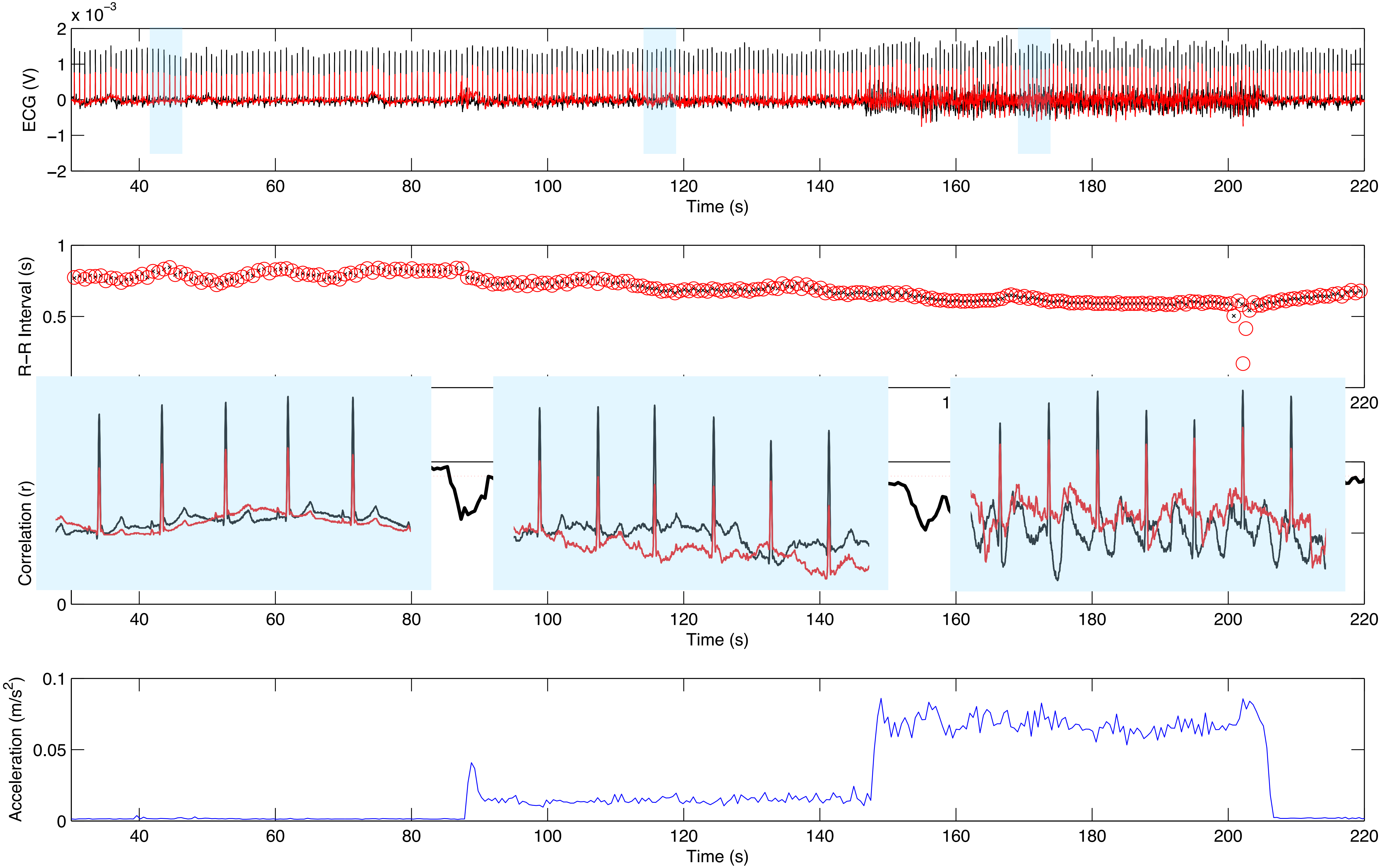

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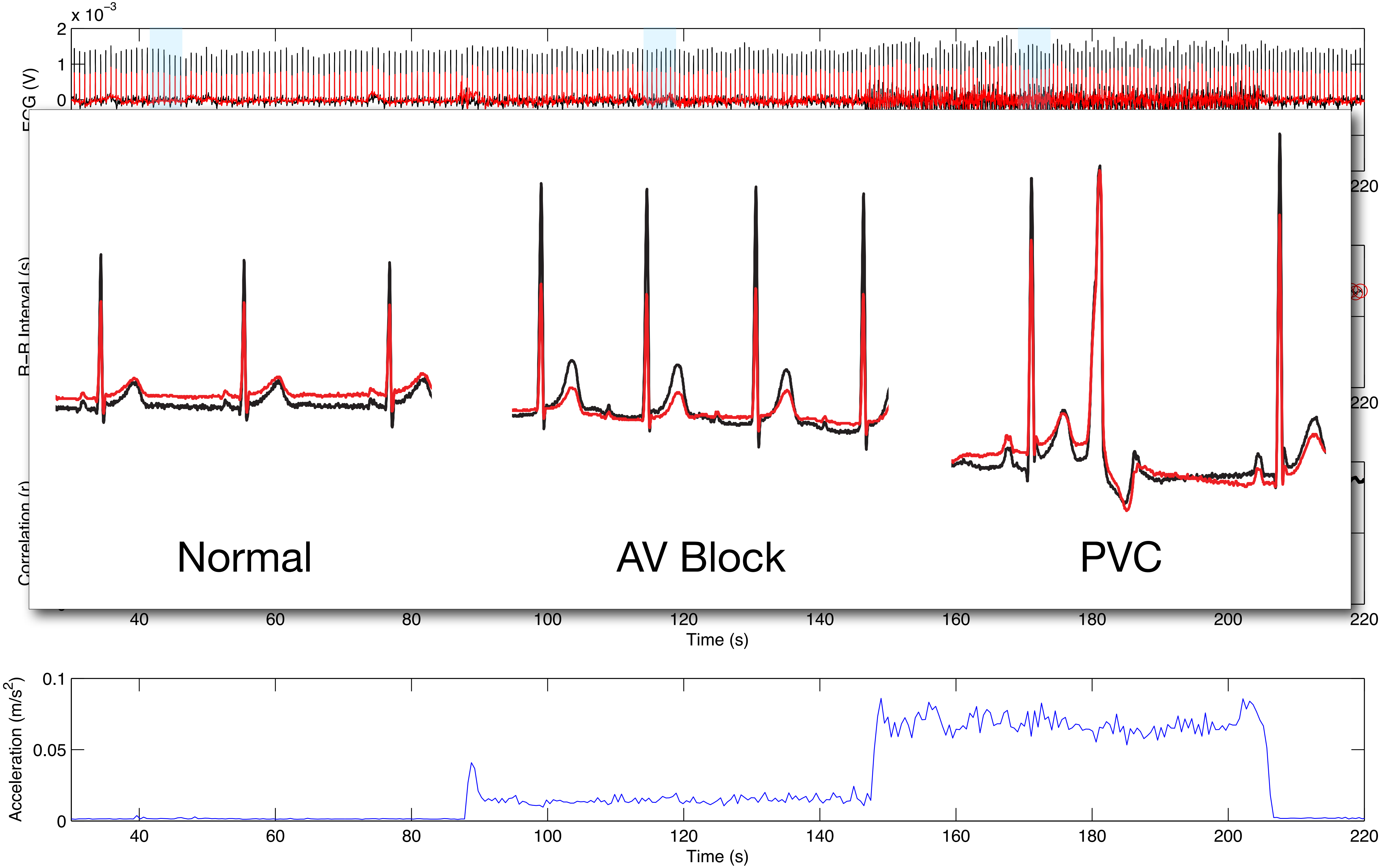
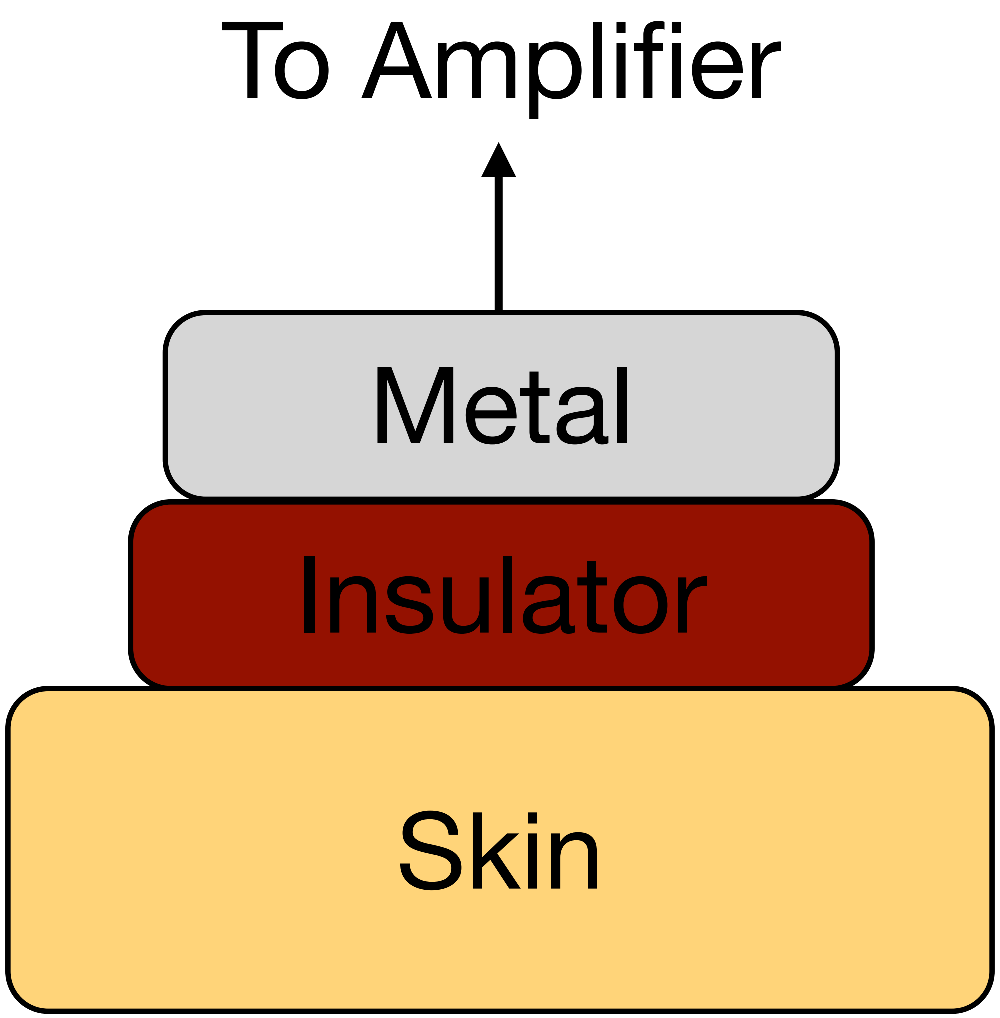


Capacitive Electrodes

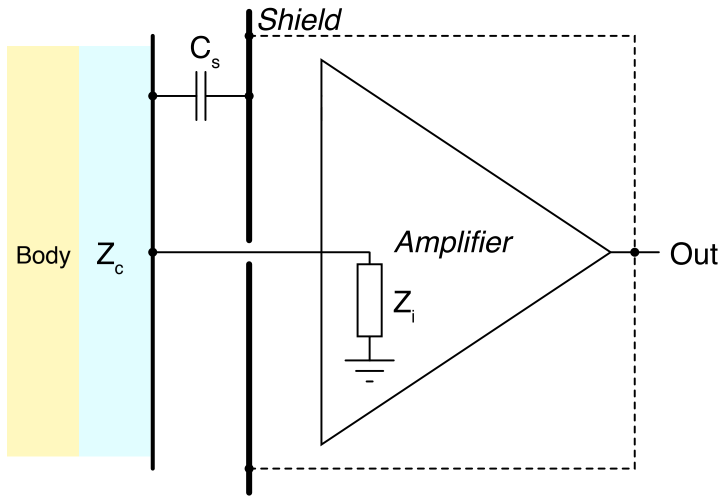


- No direct skin contact!
- Like dry electrode but even higher contact impedance
- Enables novel form-factors and use cases

Design Challenges:

- Optimizing input circuitry
- Controlling motion artifacts
- Minimizing noise pickup

Challenges in Non-contact Sensing



Biopotentials are at low frequencies: 0.05 - 100Hz (few kHz for EMG)

Standard wet adhesive electrodes offer a low impedance (5k to 100k)

Zc << Zi

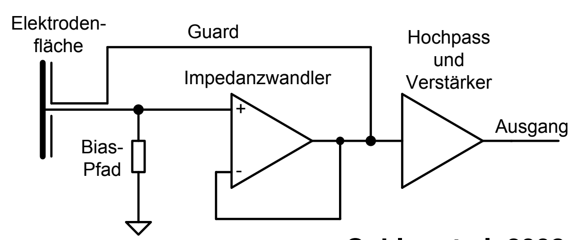
Non-contact sensors couple via extremely high impedances: 1 to 50pF same order of magnitude as an amplifier's input impedance. No reliable DC path.

Zc ~ Zi

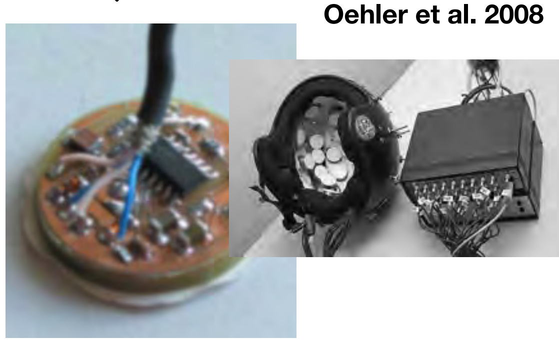
Gain, CMRR, noise and interference rejection are all significantly compromised

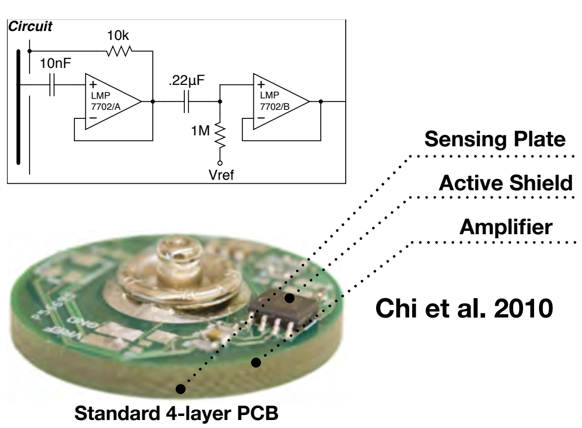
Review of Sensor Implementations

Active field with numerous papers and dissertations on the topic:



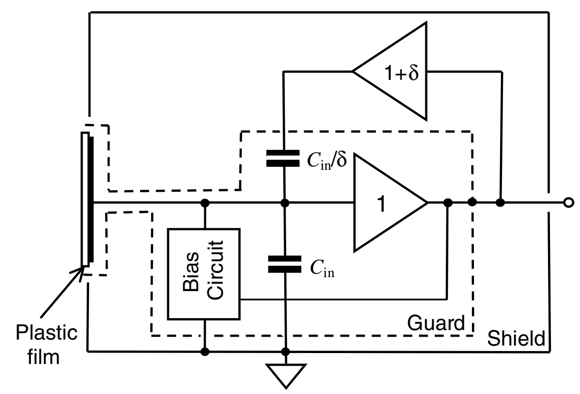
Oehler et al. 2008

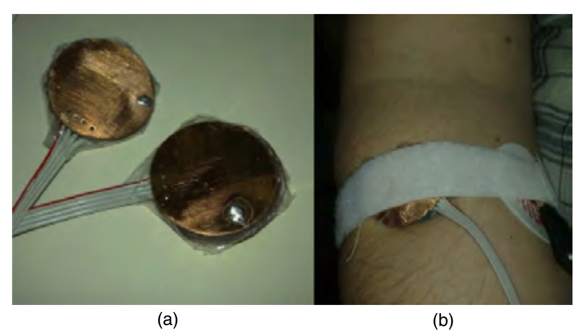




Chi et al. 2010

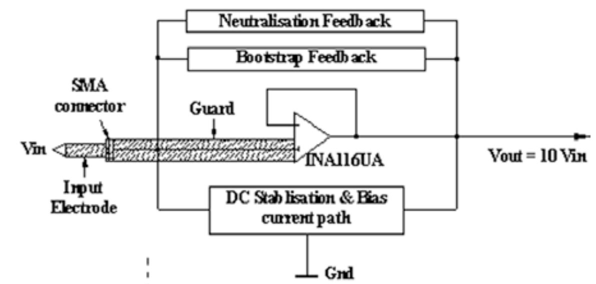
Many designs are fairly 'conventional'

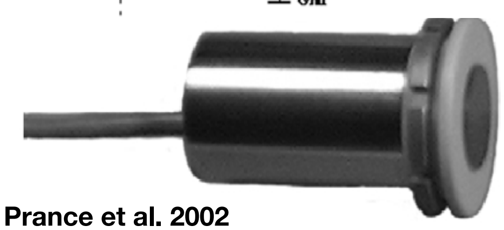




Spinelli et al. 2010

Some designs use clever tricks - here a insulated wire wrapped around the input pin of the opamp implements a >1T biasing resistor

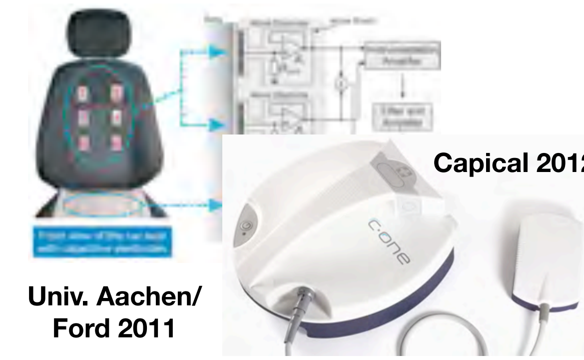




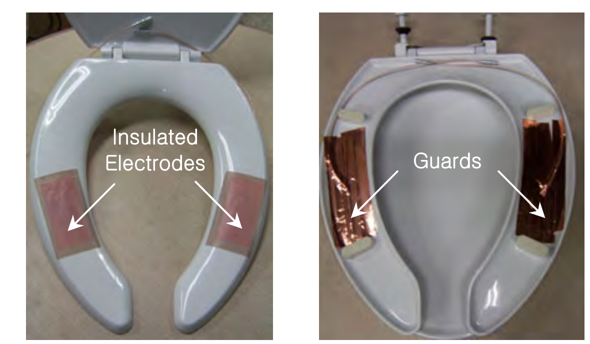
Prance et al. 2002

Quasar, Inc.

Other designs use sophisticated circuit designs



Univ. Aachen/ Ford 2011



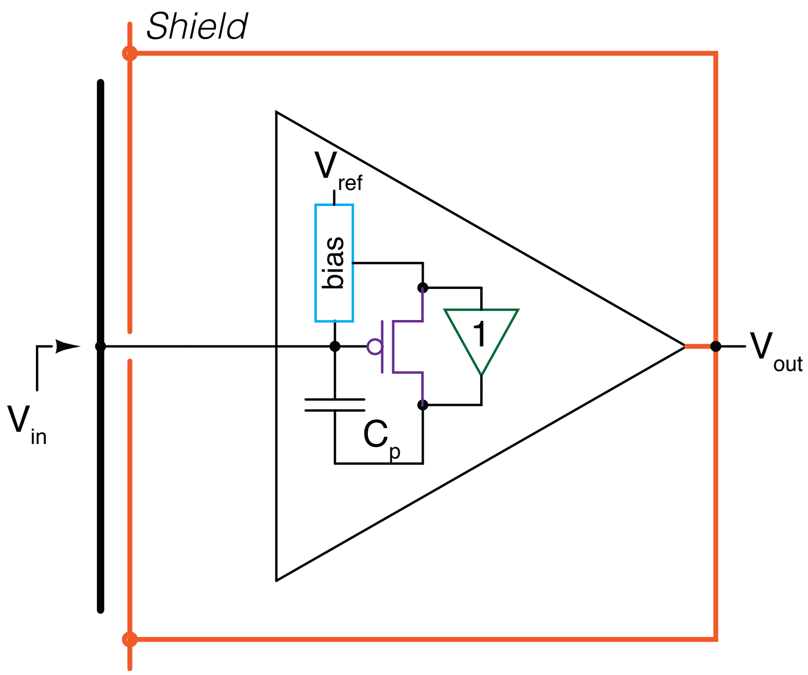
Kim et al. 2004

A few imaginative applications can be found - for example a toilet mounted ECG

Artifacts are a major issue in practice when sensors are deployed

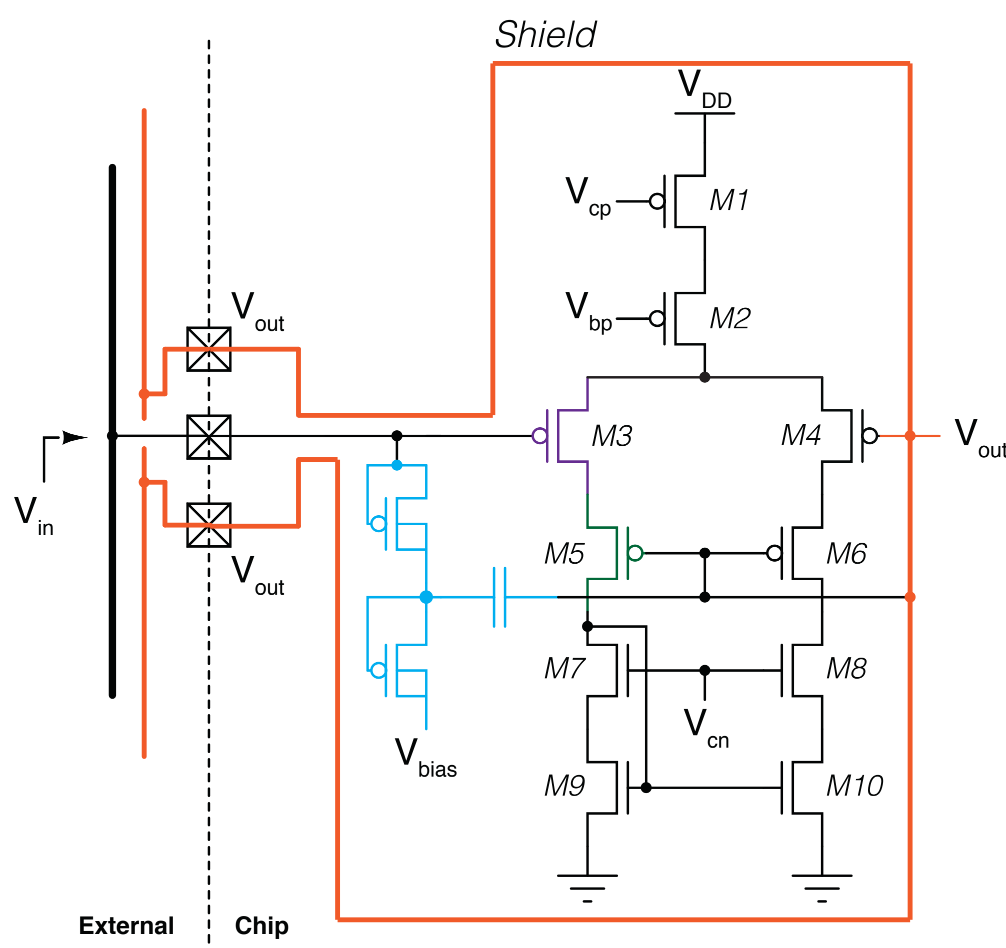
An Integrated Solution

Sensor Concept



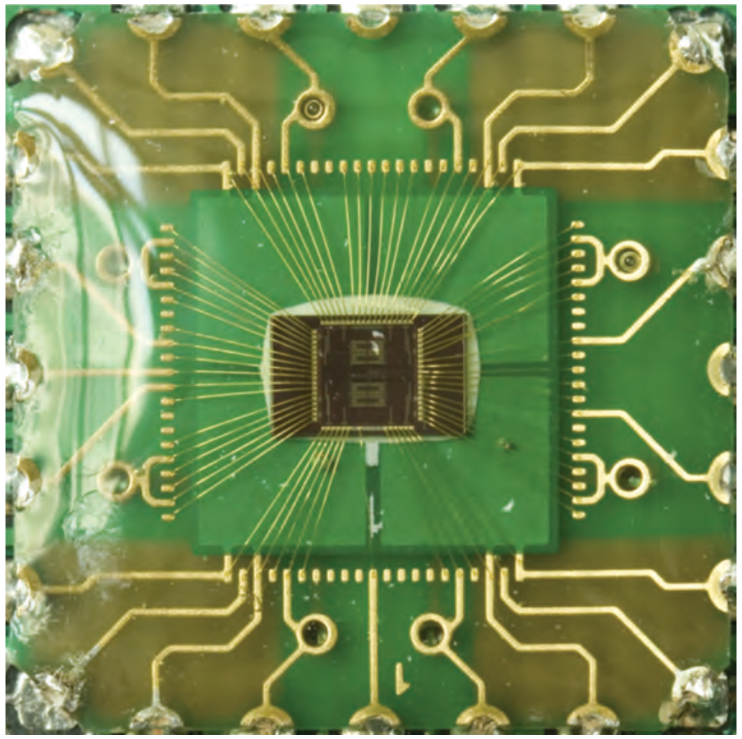
Extend active shielding structures and key bias structures to within the amplifier package itself

Circuit Implementation



Unity gain OTA (no component matching needed) with modifications to further reduce parasitic input capacitances

Fabricated Chip

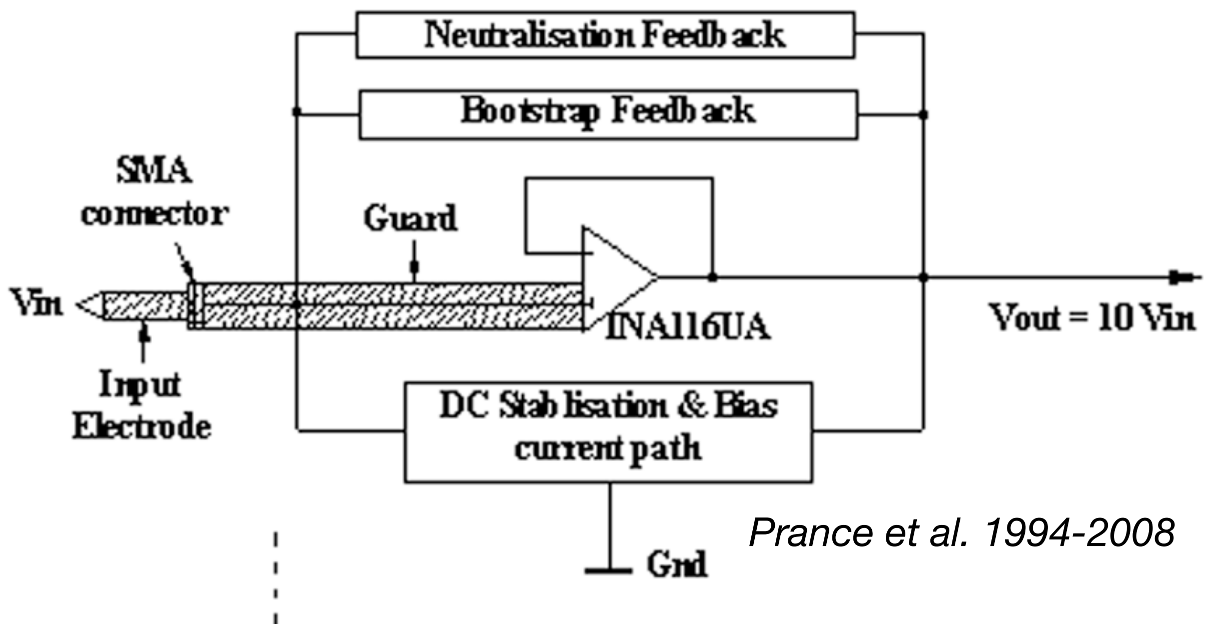


Chip mounted on special packaging to form complete active shield

Y. M. Chi, C. Maier, G. Cauwenberghs, IEEE JetCAS 2012

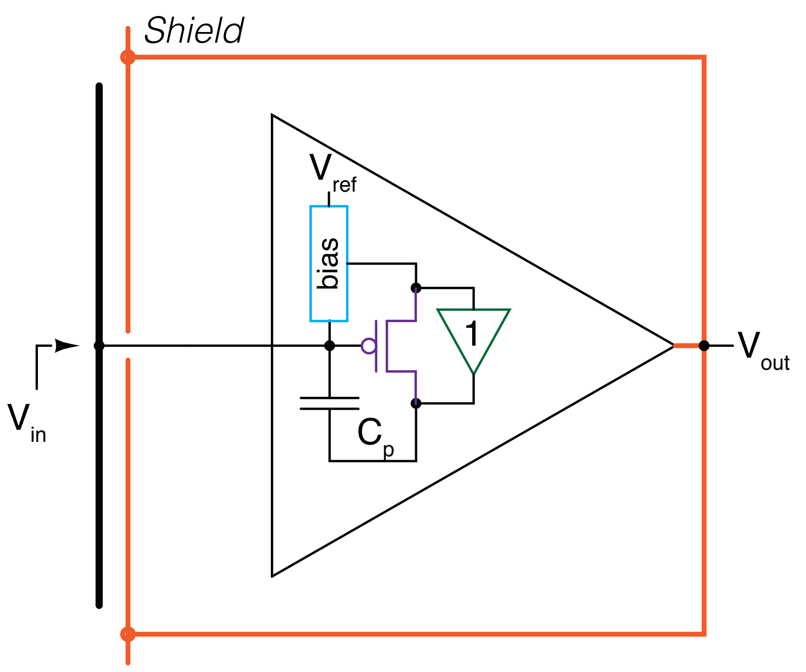
Complexity/Power/Cost Compared

Discrete Sensor Design



Prance et al. 1994-2008

Integrated Sensor Design



Previous designs have required **manually tuned** input neutralization and complex input biasing schemes

Custom design allows for full bootstrapping on the input node and does **not need any adjustments**

Neutralization requires multiple amplifiers per sensor and consume **too much power for mobile use (400μW-15mW)**

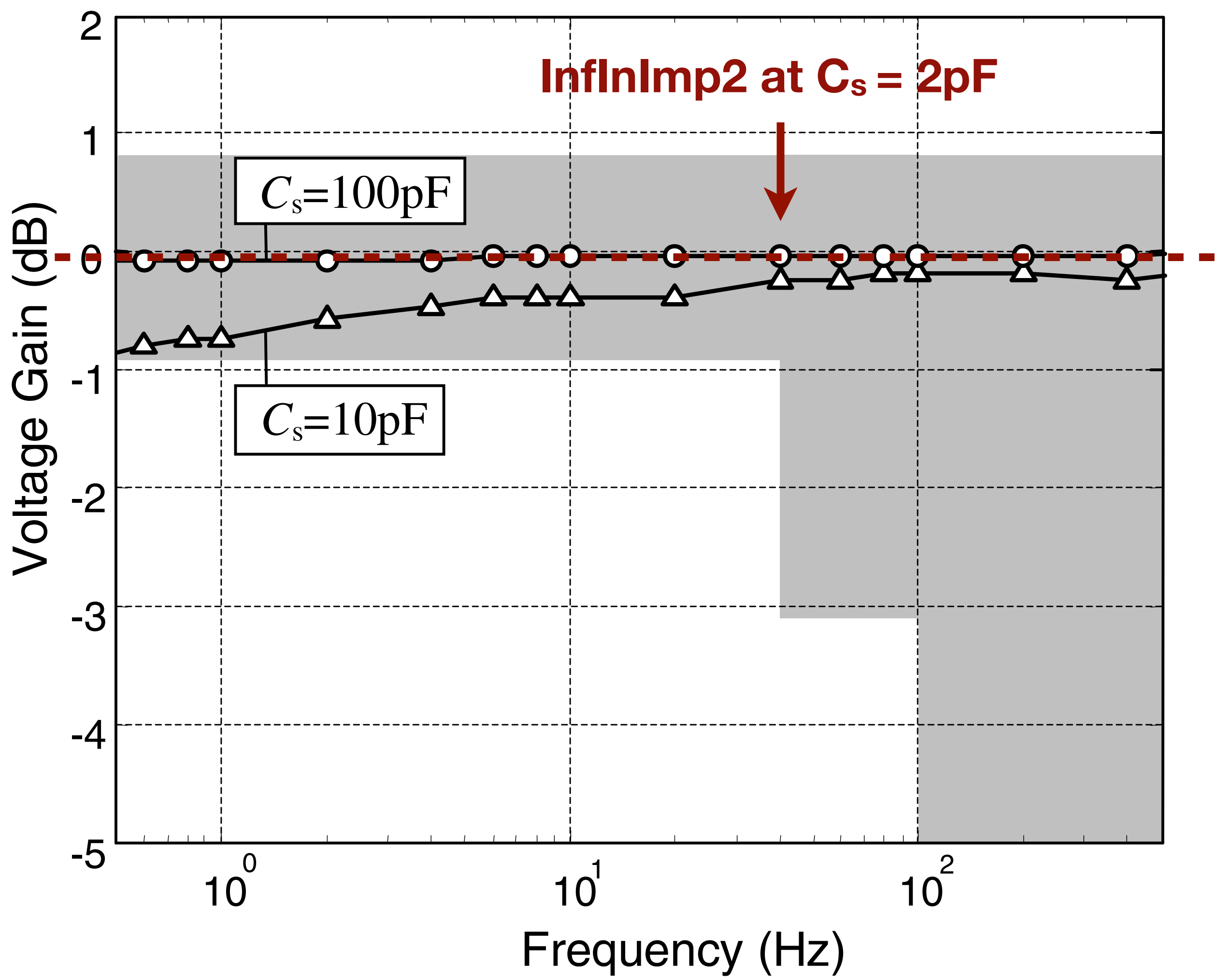
Micropower design only consumes enough power for ECG/EEG. Current prototype operates off a 3V supply at 1.5μA/sensor

Expensive electrometer amplifiers (TI INA116) are $7-10/unit

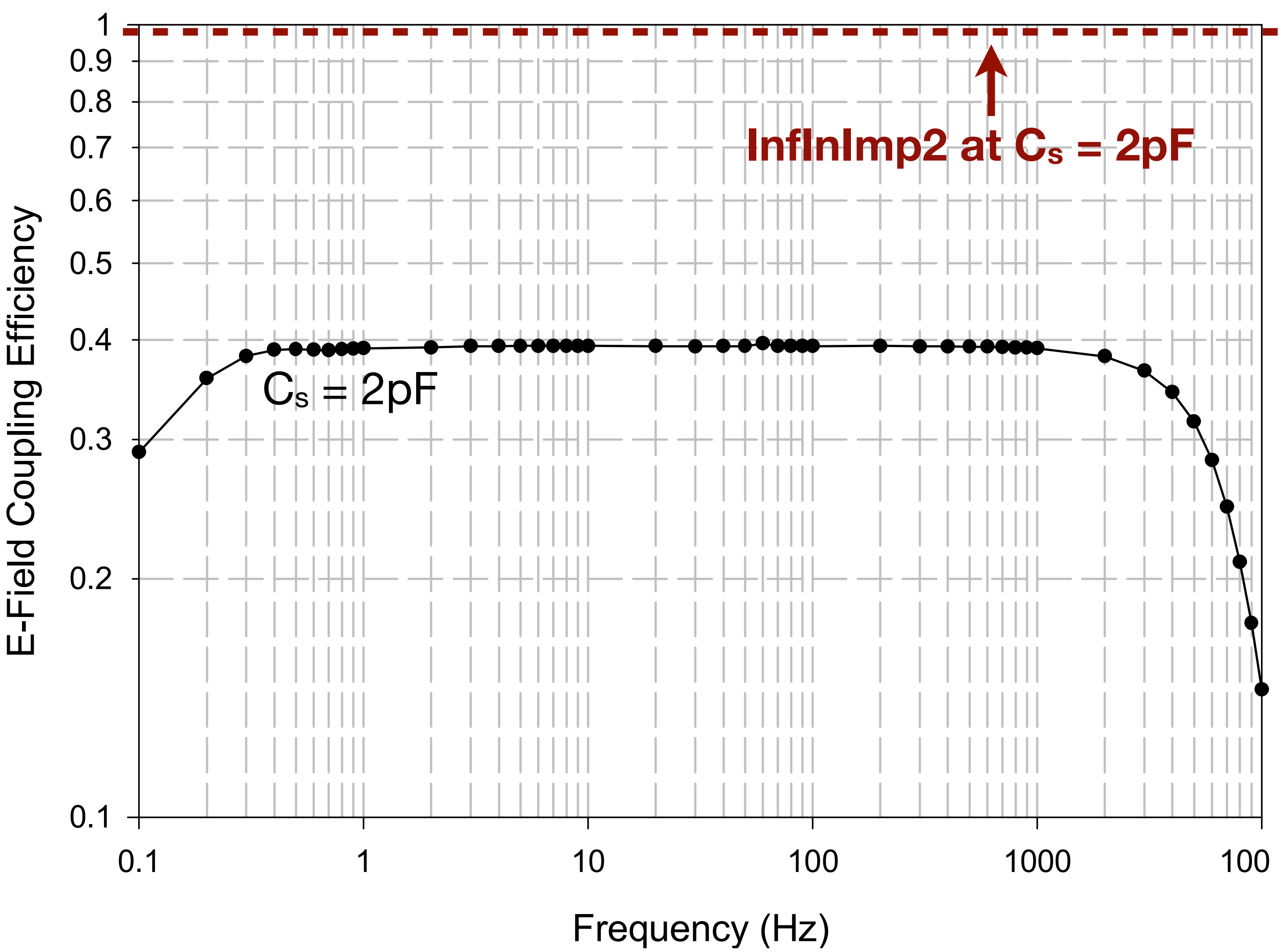
Low cost 0.5μM CMOS process is used to fabricate the chip

Frequency Response Compared

Typical results previously reported in the literature:



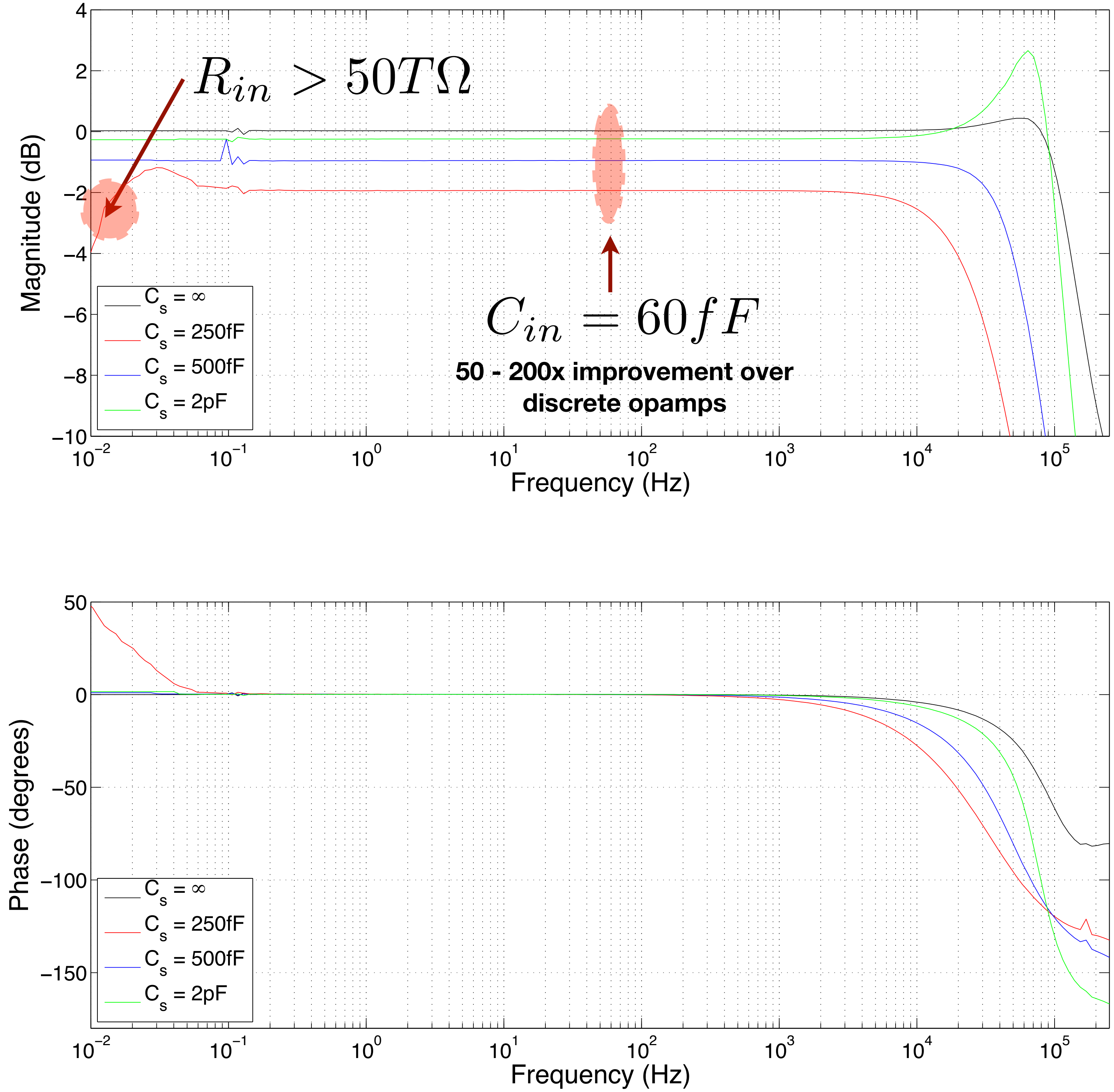
Manually tuned neutralization network with TLC2274 opamp - Spinelli et al. 2010



INA116 (gold standard) ultra-high impedance instrumentation amplifier - Krupka et. al. 2001

InfInImp2 - first integrated ultra-high input impedance that achieves femtofarad input capacitance *without* any manual calibration of adjustment

Frequency Response



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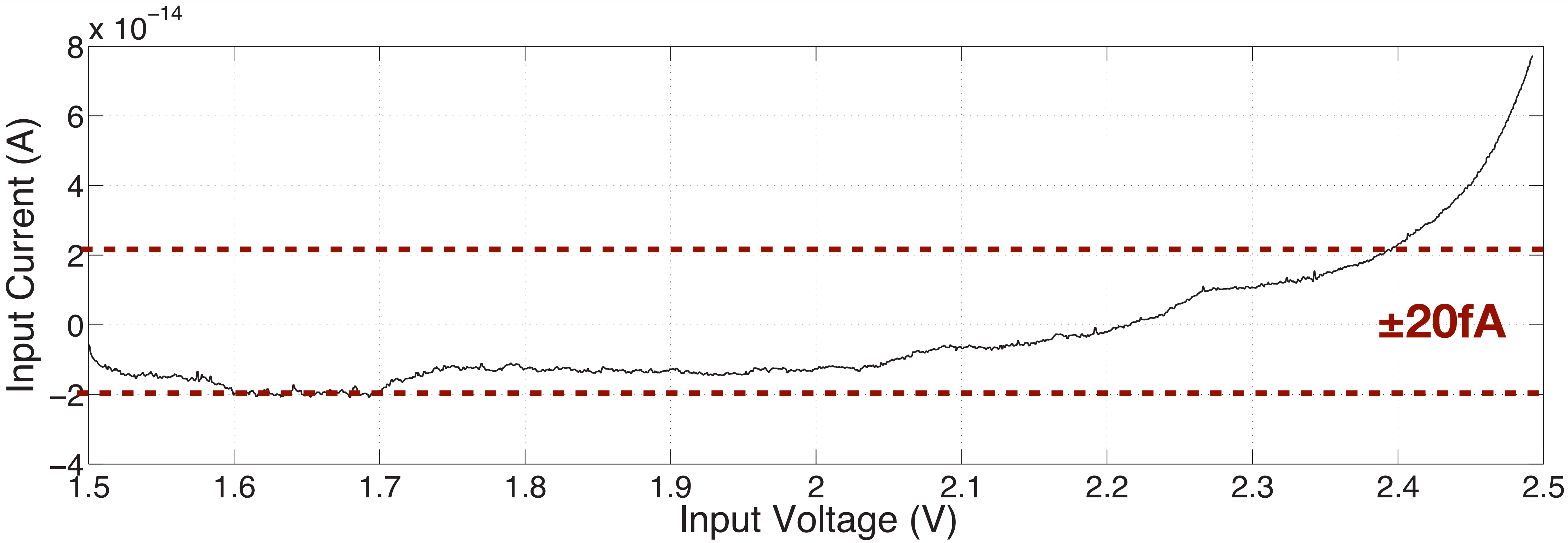
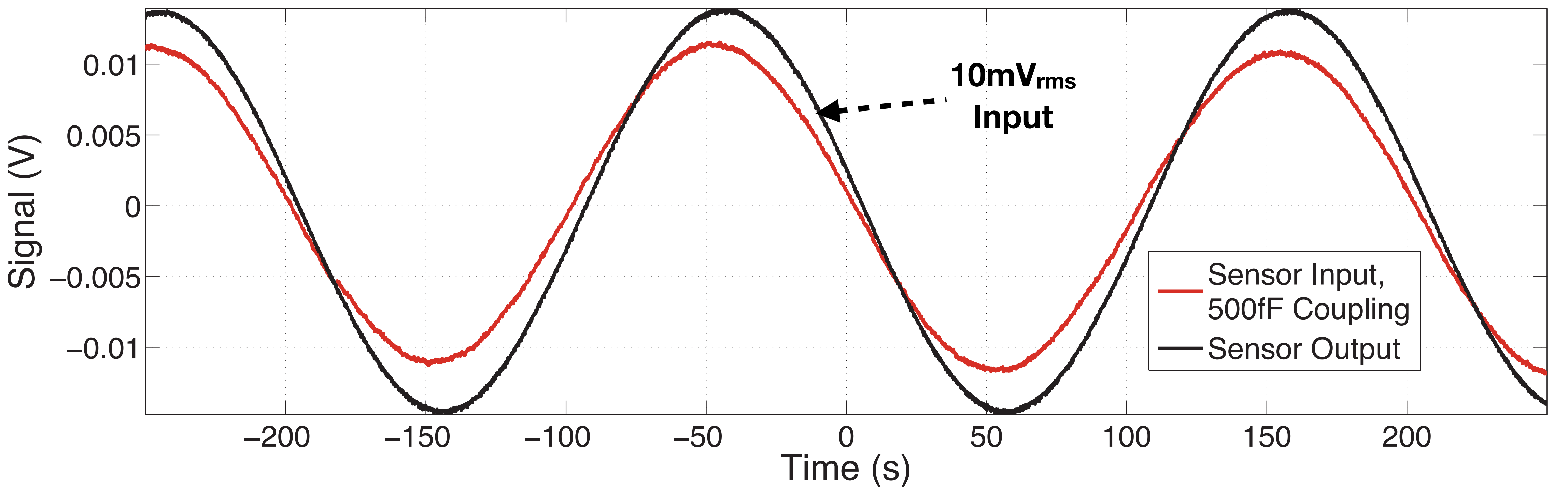
Input Bias Current

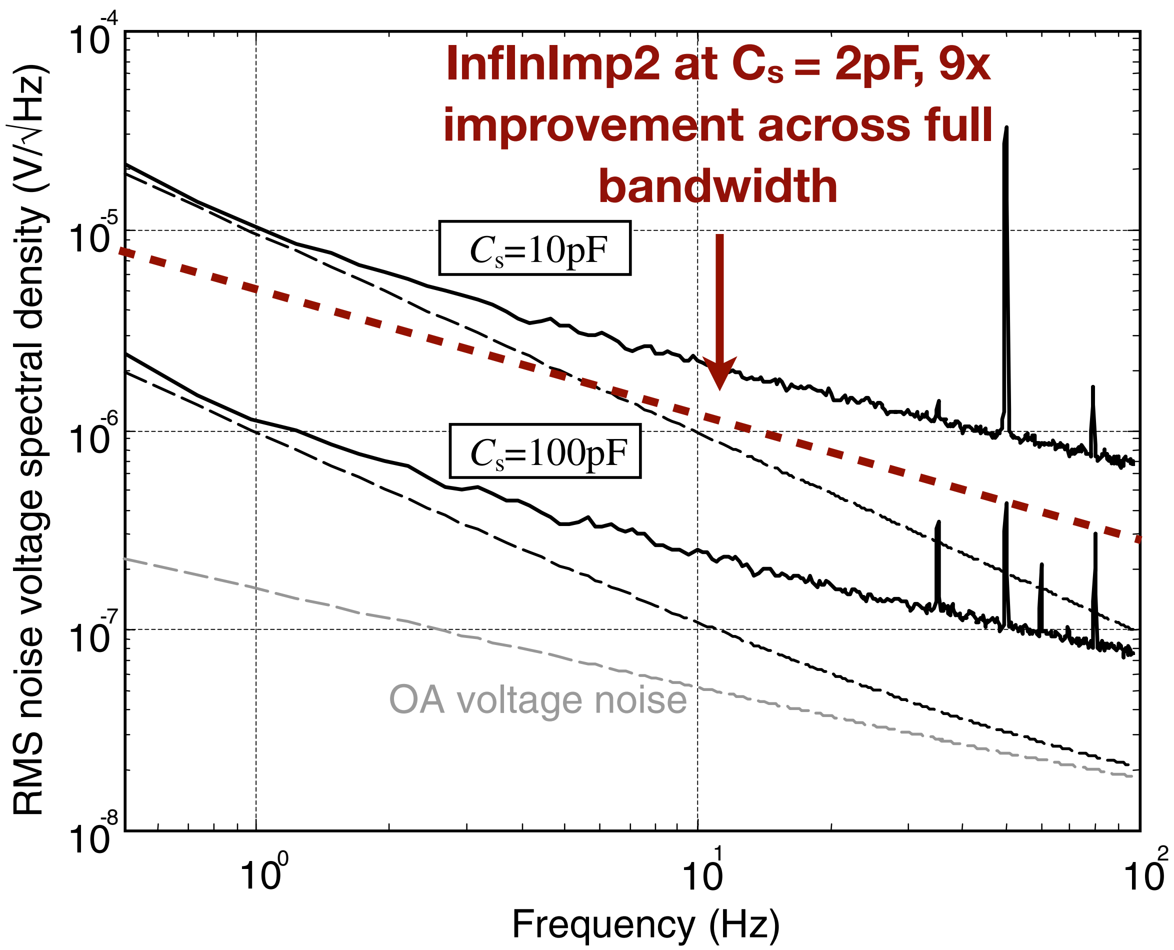




Y. M. Chi, C. Maier, G. Cauwenberghs, IEEE JetCAS 2012

Noise Compared

Typical results previously reported in the literature:



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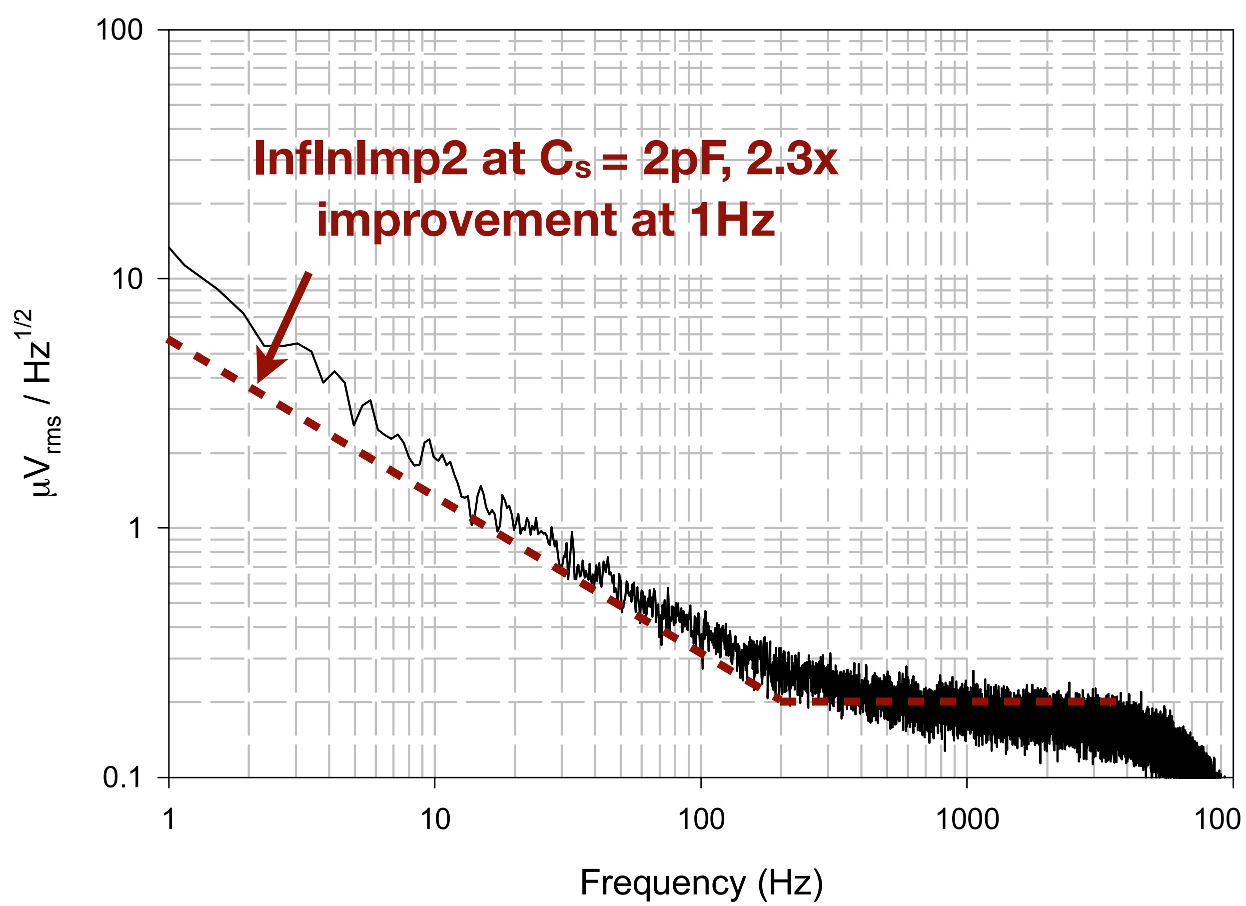

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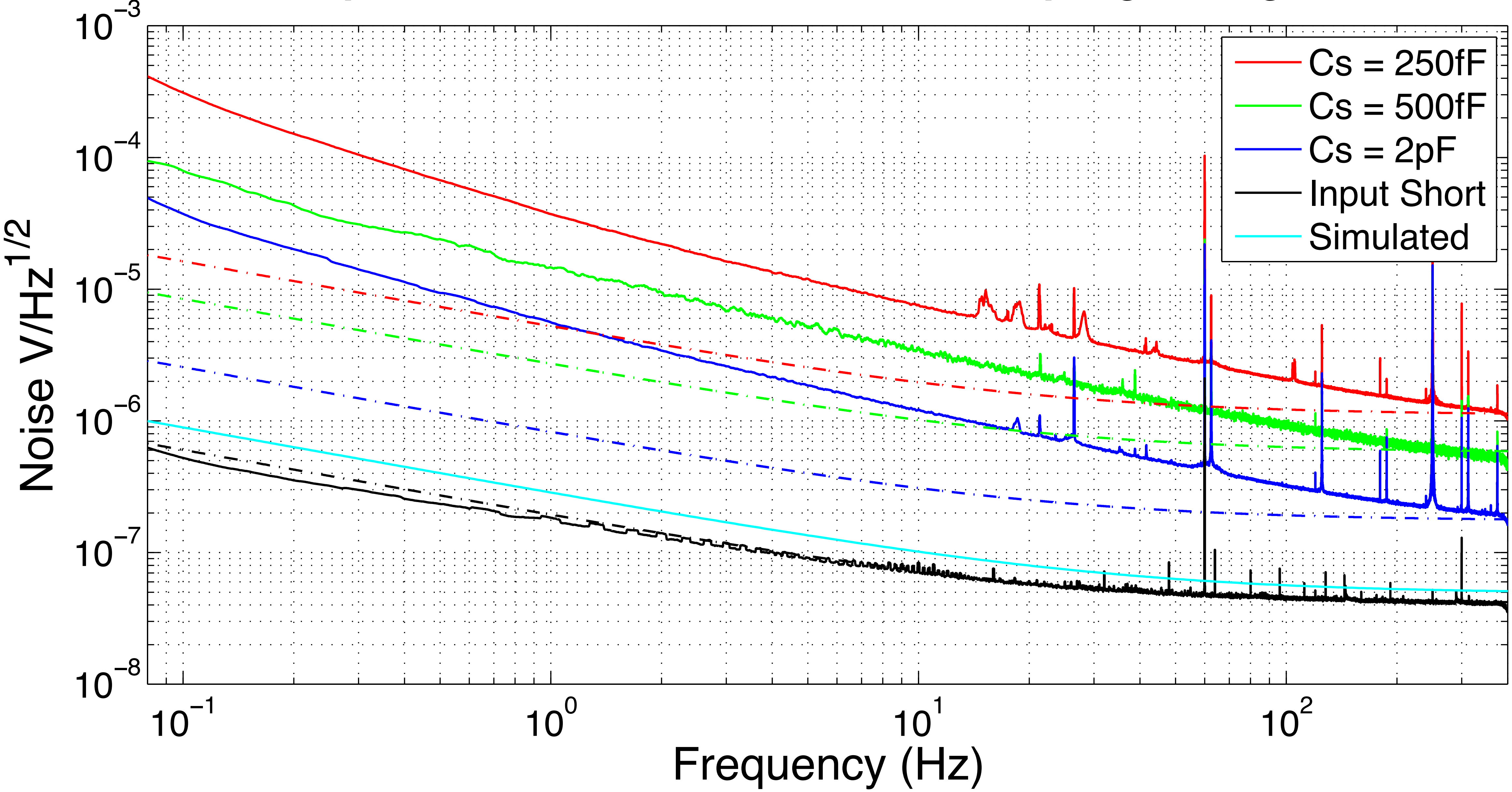
Measured Noise Spectra

Input Referred Noise at Different Coupling Strengths

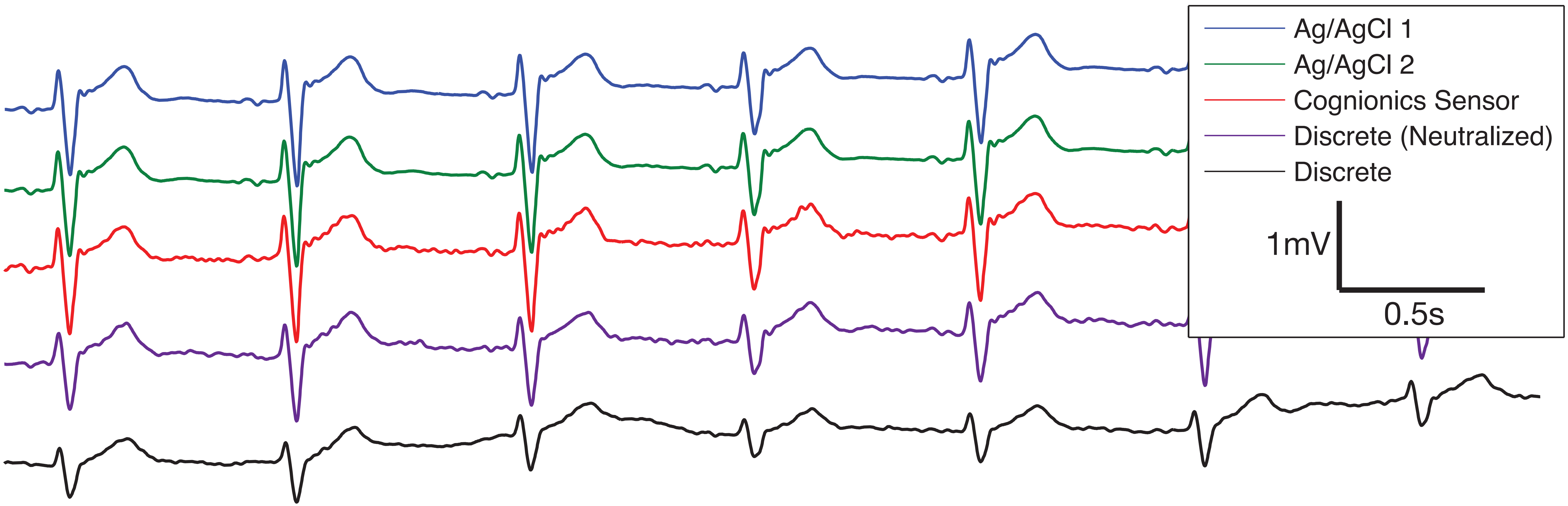


Intrinsic input capacitance is approximately 6pF based on the noise gain model
Low frequency noise behavior still dominated by current noise effects (~50aA/Hz$^{1/2}$)

Y. M. Chi, C. Maier, G. Cauwenberghs, IEEE JetCAS 2012

ECG Signal Validation on Actual Subject

Simultaneous ECG recording using different sensors (0.05Hz to 35Hz BW)



All 5 sensors were placed on the forearm referenced against a common chest electrode - should observe same signal since the arm is at an equipotential with respect to ECG

2 reference Ag/AgCl electrodes as control

Three capacitive sensors: discrete (neutralized), discrete and integrated all placed through a thick cotton sweater (Impedance ~ 1G || 30pF)

Measured Correlation

Table - Sensor Correlation Comparison

Electrode Pair	*r*	*b*
Ag/AgCl - Ag/AgCl	0.992	0.999
Ag/AgCl - Integrated	0.953	0.996
Ag/AgCl - Discrete (calibrated)	0.918	0.865
Ag/AgCl - Discrete	0.715	0.541

r **- Pearson's correlation coefficient (insensitive to pure scaling errors), measures noise and distortion**
b **- linear regression coefficient, measures gain error due to electrode-input impedance division**

Low input capacitance integrated front-end significantly more accurate than previous discrete implementations

Y. M. Chi, C. Maier, G. Cauwenberghs, IEEE JetCAS 2012

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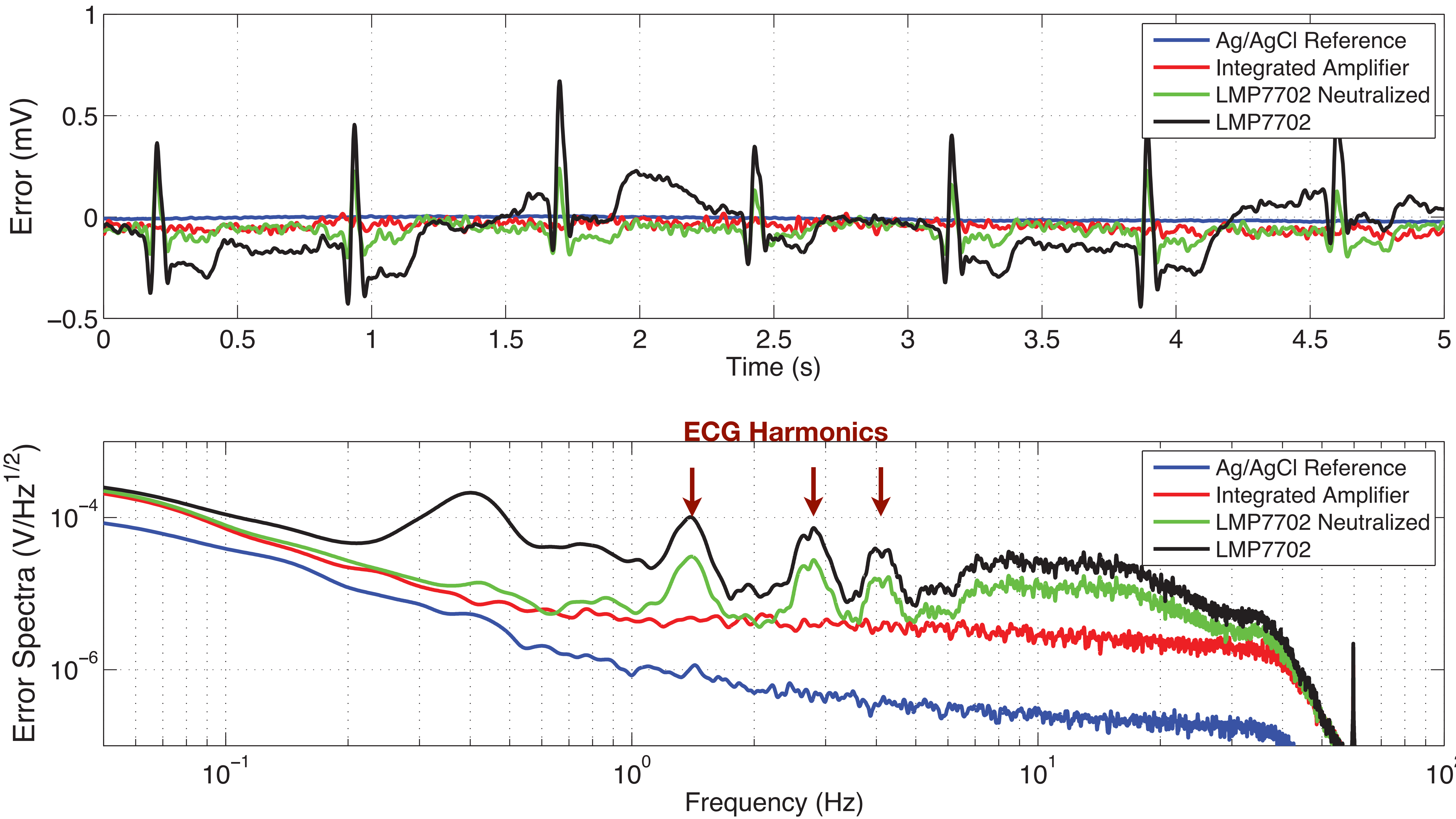
Residual Sensor Error

Difference Between Two Electrodes Should be Zero (CMRR = ∞)

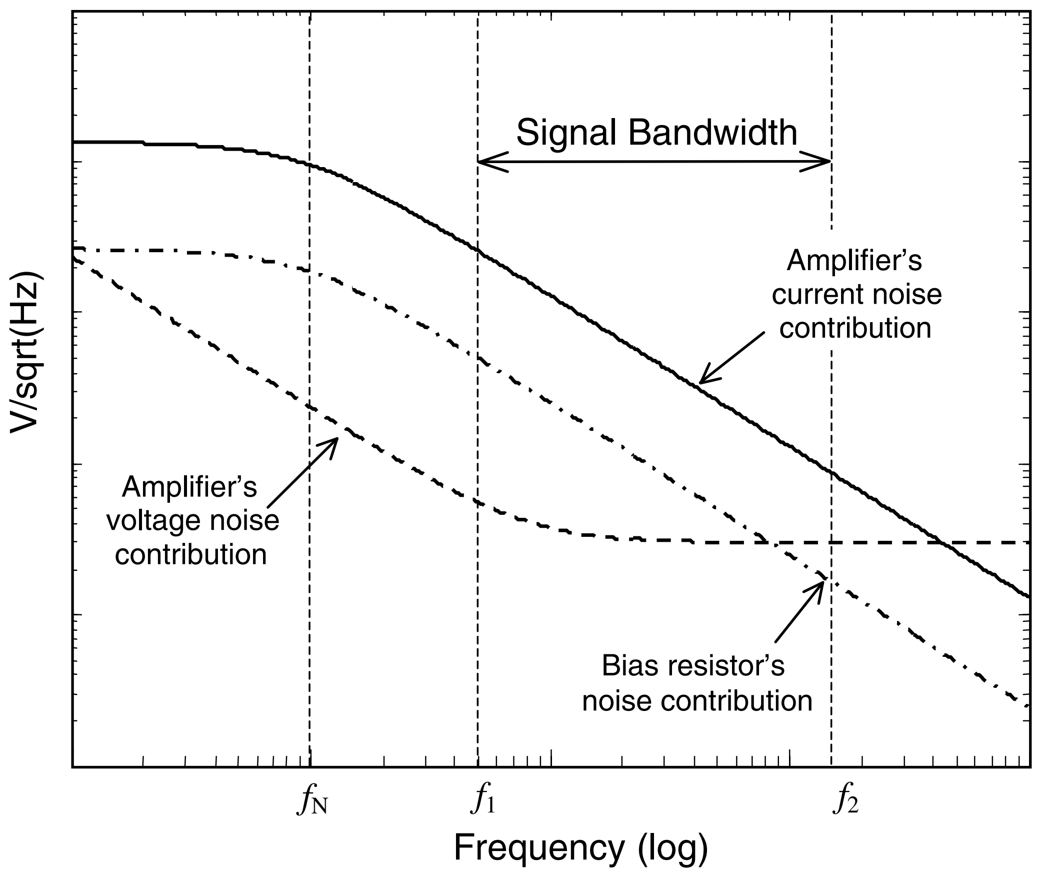


Y. M. Chi, C. Maier, G. Cauwenberghs, IEEE JetCAS 2012

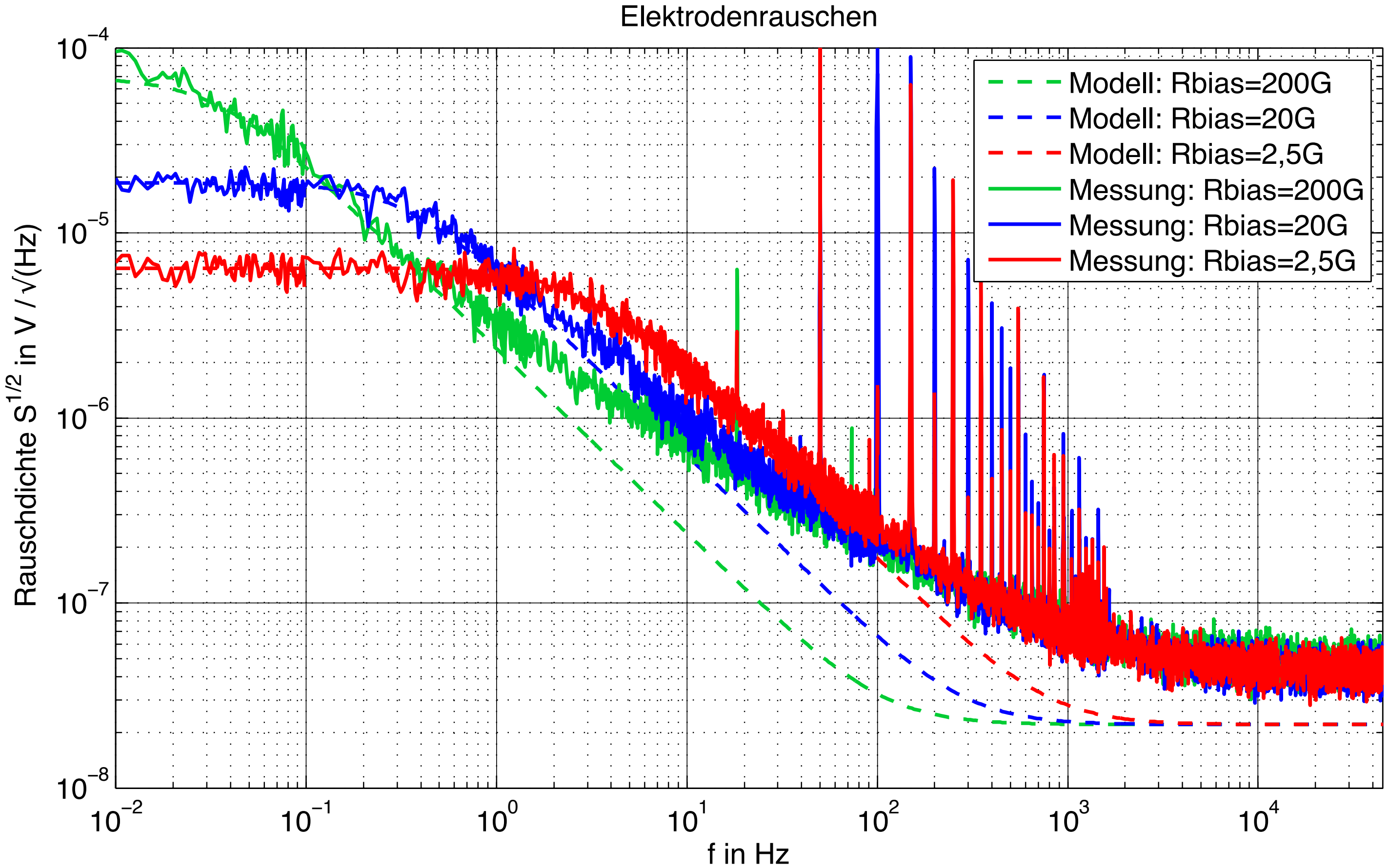
Previous Attempts at Noise Modeling

Noise limits based on coupling to purely capacitive source:

$$v_n^2 = [v_{na}^2(1 + \frac{C_{in,0}}{C_s})^2 + \frac{i_n^2}{\omega^2 C_s^2}]\Delta f$$



Spinelli et al. 2010



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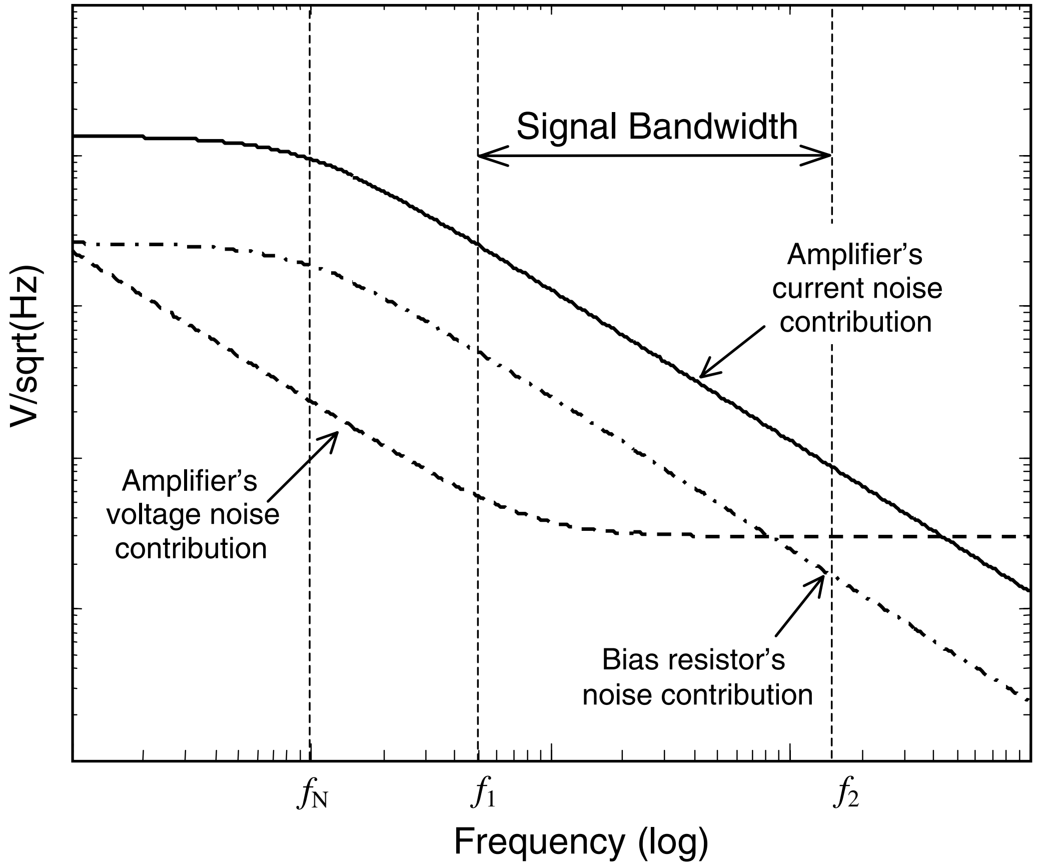
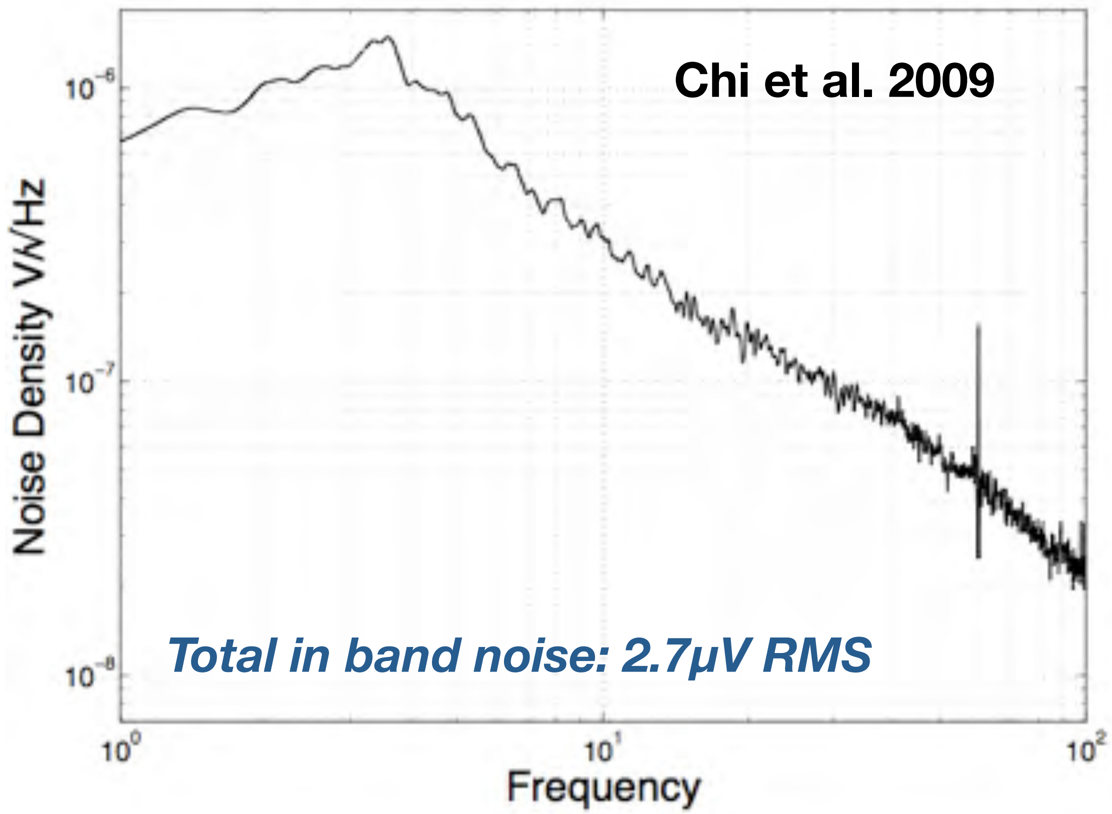


Spinelli et al. 2010



Previous understanding in literature has always used the model of an ideal capacitive source for noise modeling - assumption that noise can be reduced with improved circuit design and components (e.g., lower current noise).

While benchtop measurements corroborate theory - actual noise for ECG/EEG on subjects is *always much higher than that predicted by the noise equations.*

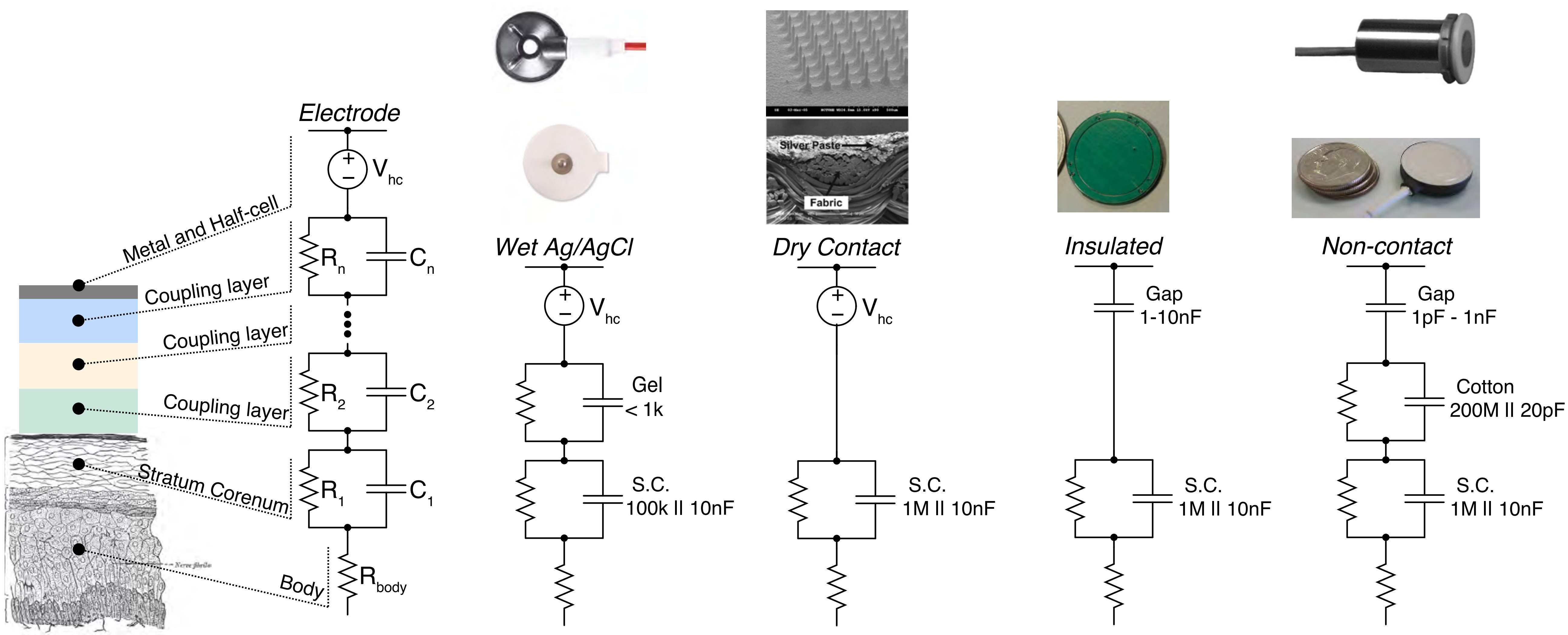
Cognionics

March 10th, 2015

Noise in 'Capacitive' Biopotential Electrodes

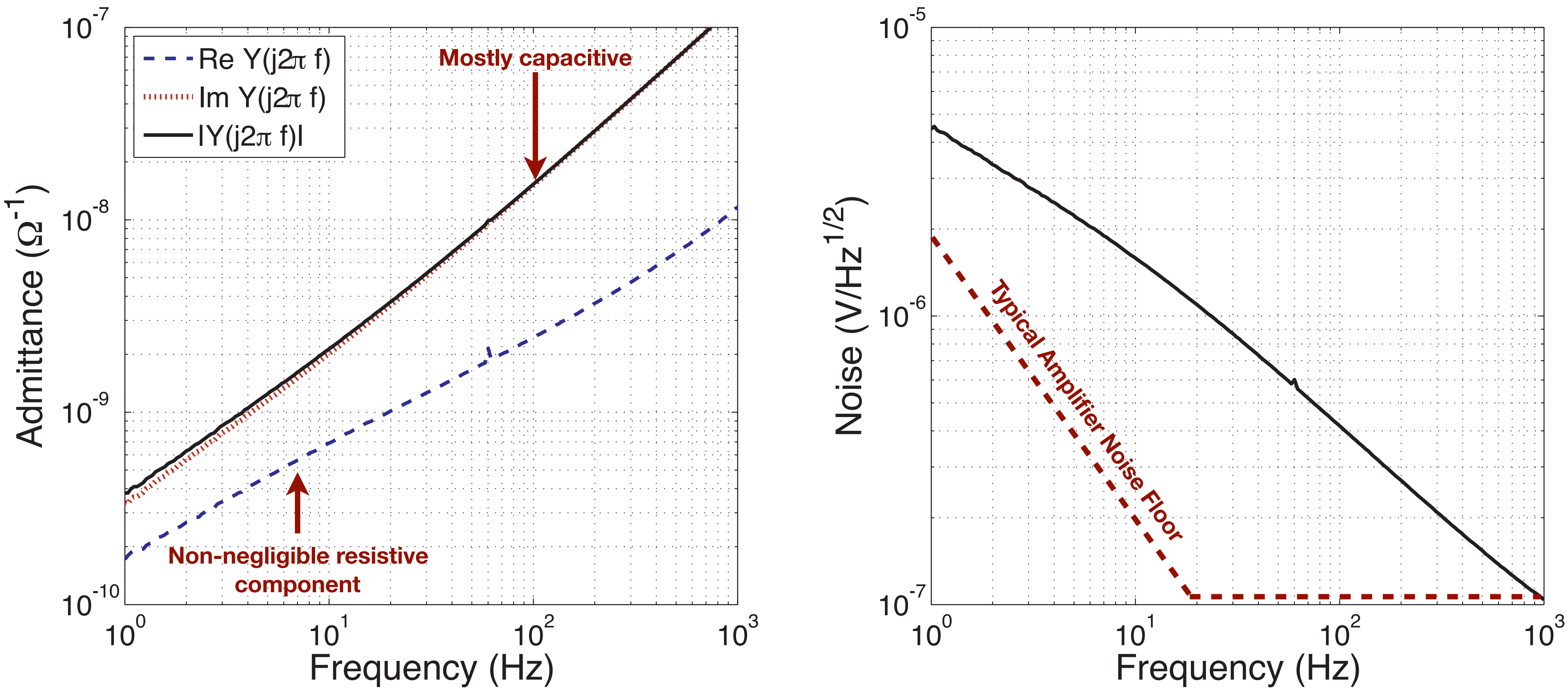
Noise equations work if the coupling is through a near ideal dielectric (e.g., air gap) - not practical for E*G applications

Must also consider the properties of the coupling medium between the sensor and body - cotton, hair, etc.



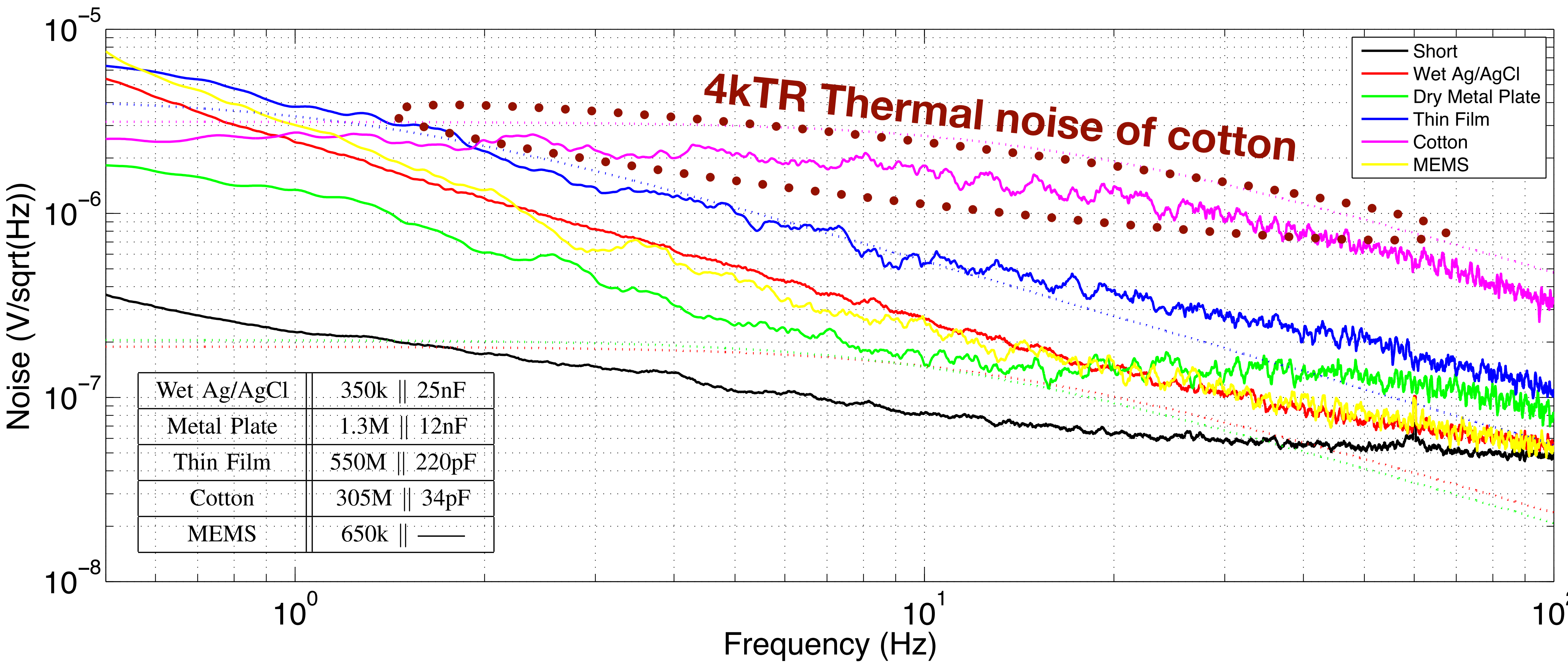
Electrical Properties of the Interface

Measured impedance of cotton fabric using a lock-in amplifier:



Signal coupling is not through an ideal capacitor!

Measured Interface Noise Spectra

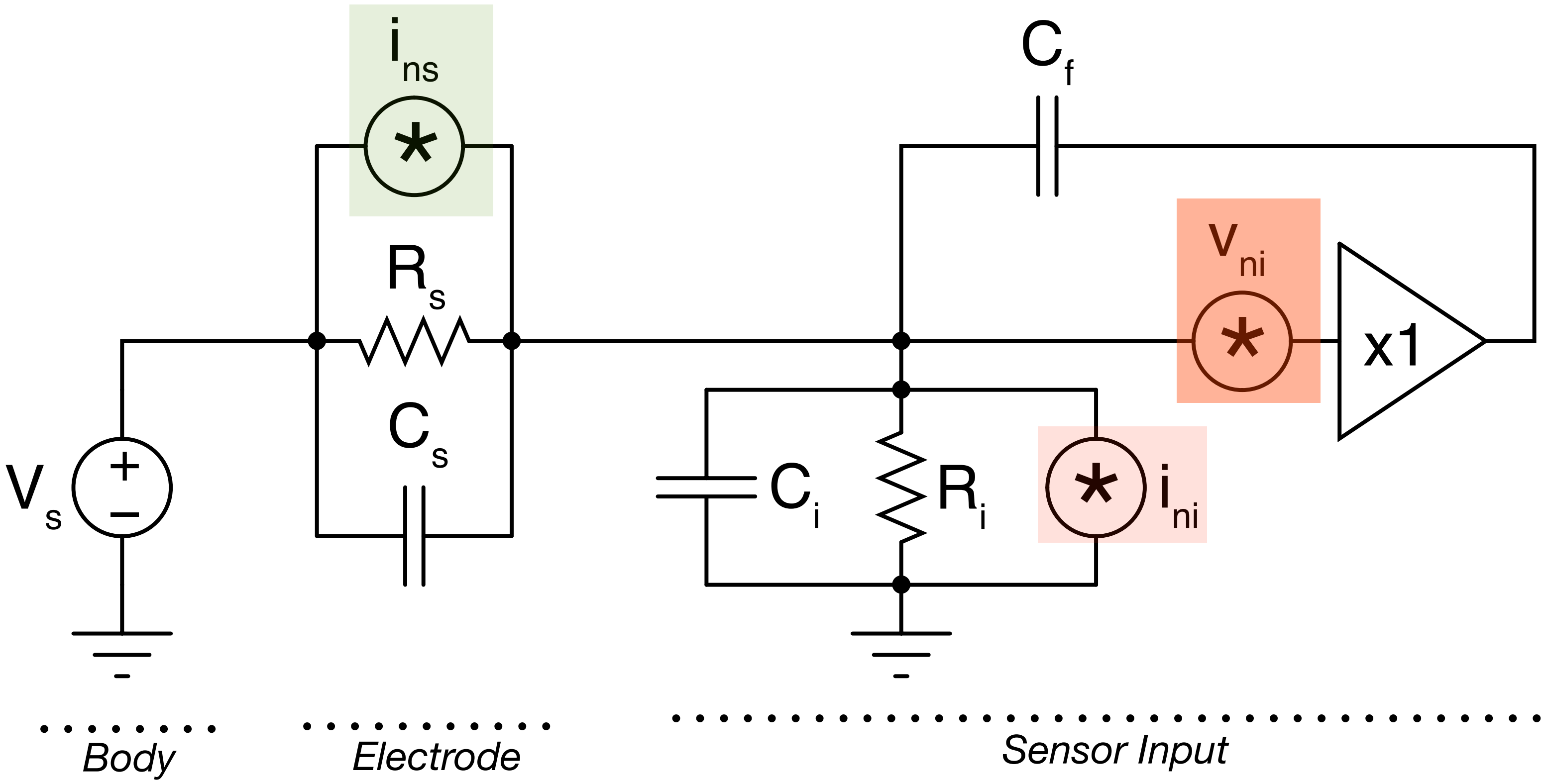


Coupling media may actually generate the largest amount of noise within the signal bandwidth:

Interface Noise - 3μV/Hz$^{1/2}$

Yu M. Chi, Tzyy-Ping Jung, Gert Cauwenberghs, IEEE Reviews in Biomedical Engineering, 2010

Noise with Real Electrode Interfaces



i_{ns} = 4kT/R_s
i_{ni} = 4kT/R_i (resistor) or 2kT/r_d (diode)
v_{ni} = amplifier input thermal noise

Total Output Noise:

$$v_{out,n}^2 = [\frac{4kT}{R_s}|Z_s\|Z_{in}|^2 + \frac{4kT}{R_i}|Z_s\|Z_i|^2 + v_{ni}^2|1 + sC_f(Z_s\|Z_i)|^2]\Delta f$$

Noise Figure:

$$F = 1 + \frac{R_s}{R_i} + \frac{v_{ni}^2 R_s}{4kT}(\frac{1}{|Z_s\|Z_i|^2} + \omega^2 C_f^2)$$

$$Z_i \to \infty$$

Infinite input impedance achieves optimal noise figure

$$F \to \infty, R_s \to \infty$$

Amplifier noise dominates for purely capacitive sources

More Realistic Values:

Z_s = 1G||20pF, Z_i = 1T||5pF, C_f = 5pF, V_{ni}= 90nV/Hz$^{1/2}$, f = 5Hz

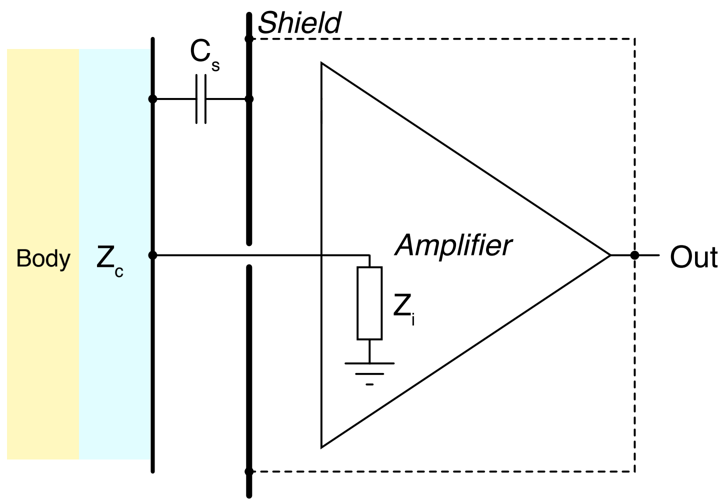
F = 0.002dB !!

Key Difficulty:

Some insulation (e.g., cotton) generate large amounts of thermal noise (1 TMΩ) yet do not have enough shunt capacitance (~20 pF) within ECG/EEG frequency bands. *Noise is not circuit limited!*

Yu M. Chi, Tzyy-Ping Jung, Gert Cauwenberghs, IEEE Reviews in Biomedical Engineering, 2010

Input Impedance and CMRR



Electrodes with input capacitance of 5pF, coupling with 20pF and 25pF to body:

$$CMRR \approx \frac{|Z_{in}|}{|Z_1 - Z_2|} \approx \frac{C_1 C_2}{C_{in}|C_1 - C_2|}$$

CMRR ~ 26dB!, Can add DRL for additional 40dB of CMRR (ok for wireless)

If input capacitance is 60fF, CMRR = 64dB (much better)

Assume 100mV 60Hz CM Interference, 1mV ECG Signal

CMRR = 26dB: SNR = -14dB

CMRR = 64dB: SNR = 24dB

CMRR = 104dB: SNR = 64dB (clinical grade)

CMRR, Interference Rejection drives input impedance need more than noise figure

Challenges and Future Directions

Building Novel Sensor Systems

- Less need to focus on low-noise input amplifiers for most applications
- Opportunity to design very low-power, highly integrated systems
- Possible to make very inexpensive, ubiquitous sensors
- And/or place sensors in places that are currently impractical
- Major need for complete and integrated systems

Finding the Right Applications

- Medical market is conservative and very cost-conscious
- Many conventional technologies (e.g., sticky electrodes) are cheap, perform well and more than ‘good-enough’
- Better to focus on new and underserved applications rather than trying to replace existing technology
- Need to tailor sensor/system design to specific application
- Don’t forget the appearance, mechanics and user experience!