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Research Article

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Comparison of Different Contact Material on ECG Signal

Nik Tehrani

International Technological University, San Jose, California

Abstract This test is designed to characterize and compare the signal quality of traditional wet (gel) electrode contact material vs. the dry (stainless steel) electrode contact material used in the device after post processing of collected raw data from each electrode type. Two types of contact electrode materials were used: 1) Electrode Pair A- Hydrogel Electrodes: MEDI-TRACE(R) 500 ECG ELECTRODE (K945479), and 2) Electrode Pair B- Stainless Steel Electrodes: 136 SS of final device.After frontend filtering and baseline removal, both pairs (A&B) are qualitatively similar. This is mainly due to the fact that SS tends to have more differential baseline movement caused by higher contact resistance to the skin. Results show that after signal processing (including bandpass filtering and additional baseline removal), two simultaneously captured ECG signals, the first one using HG electrodes, and the second using SS electrodes, are equivalent in terms of SNR and correlation. Although both this device (K172654) and predicate (K150869) use as dry electrodes and are equivalent, this report provides additional comparison of wet (gel) electrode with dry (stainless steel).

Keywords Signal quality wet (gel) vs. dry (stainless steel) electrodes, ECG signals, HG electrodes.

Introduction

The purpose of this test conducted by DynoSense Corp. was to characterize and compare the *signal quality* of traditional wet (gel) electrode contact material vs. the dry (stainless steel) electrode contact material used in the device after *post processing* of collected raw data from each electrode type.

Test Setup and Data Collection

- ✓ Two different types of contact electrode materials were used;
  - **Electrode Pair A**- Hydrogel Electrodes: MEDI-TRACE(R) 500 ECG ELECTRODE (K945479)
  - **Electrode Pair B**- Stainless Steel Electrodes: 136 SS of final device
- ✓ Data collection was carried out for both contact types simultaneously using identical device hardware version of the final product (hardware: 01051-02, 01051-03, Firmware: 0.3.51 Software: 2.0.21)
- ✓ Each electrode pair A and B were placed at same location next to each other during simultaneous capture.
- ✓ The device was connected to a PC with a Bluetooth dongle to capture and store the data.
- ✓ Each capture data is then post processed in exact technique used in final device (see below).

Capture and Post Processing Description

For each electrode type, the ECG signal is captured through same integrated analog frontend circuit (IC) of the device that consists of three instrumentation amplifiers to reduce large direct current (DC) changes and wideband noise. The signal is digitized with a 24-bit analog-to-digital conversion (ADC) at a sampling rate of 500 Hz and stored as *raw signal*. This *raw data* is bandpass filtered in the range of 0.05Hz-100Hz followed by additional baseline removal algorithm.

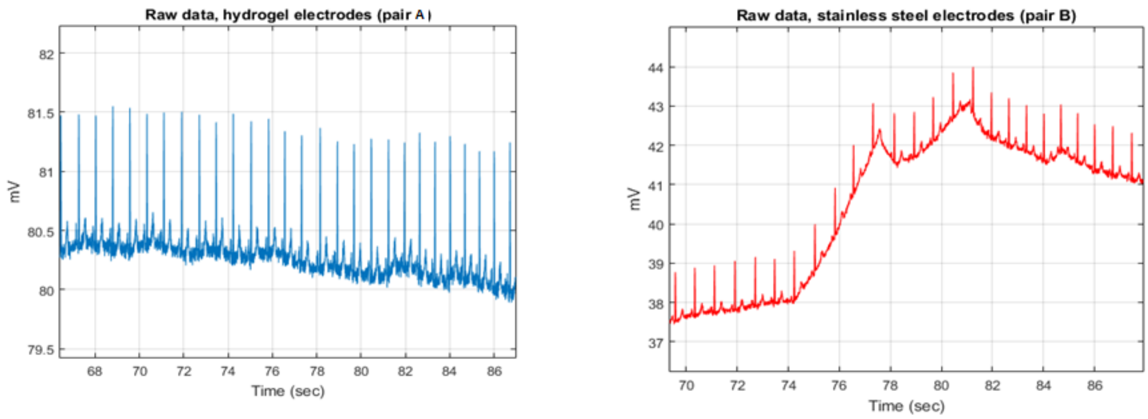

Figure 1: Example of captured raw signal for each electrode pair A and B.

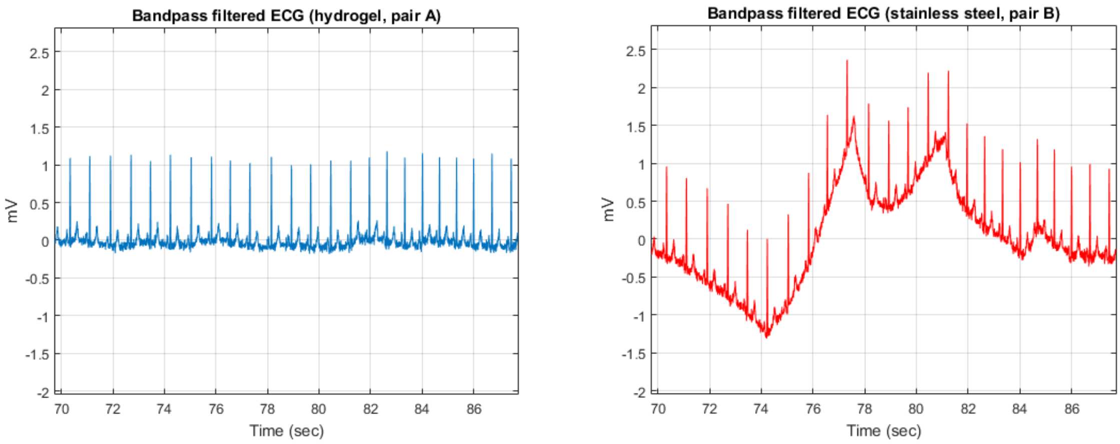

Figure 2: Example after bandpass filtered of each electrode pair A and B.

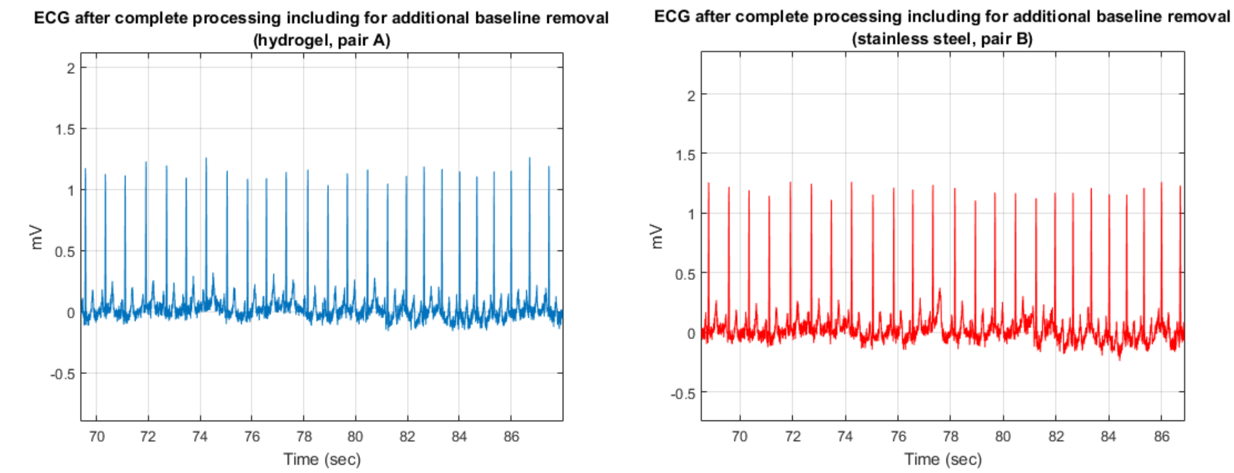

Figure 3: Example after complete processing for additional baseline removal for each electrode pair A and B.

As shown in Figure 3, after frontend filtering and baseline removal, both pairs (A&B) are qualitatively similar. This is mainly due to the fact that SS tends to have more differential baseline movement caused by higher contact resistance to the skin, as shown in Figure 1.

Population Study Description

Twenty one volunteers participated in the study with matching the U.S.demographic distributionprovided in table 1 below [1-2].

Table 1: Demographic

Number of subjects		21
Age		
	19-25	2
	26-54	11
	55+	8
Sex		
	Male	11
	Female	10
Ethnicity		
	White	14
	Non-white (African American, Hispanic, Asian, mixed Race, etc.)	7

Simultaneous ECG measurements were captured using SS and Standard Gel electrode from all twenty one (21) subjects.

Signal Quality Analysis

To study if the signal quality of dry SS electrode (Pair B) is comparable to the standard wet electrodes (Pair A), the SNR and correlation between these two electrodes are compared for the collected population.

Signal-to-Noise (SNR) Comparison

Signal (QRS template) definition: The ECG signal (noise free) is defined by a "QRS template" derived from the median (average) of individual QRS of the processed ECG (Figure 4, shown as a solid blue color).
Noise definition: The "noise" is defined by the difference between the QRS template and each individual QRS in entire ECG signal (Figure 4, defined as Noise = (A – B))
Signal-to-noise definition: The SNR is the ratio of the power of the signal (QRS template) to power of the noise.

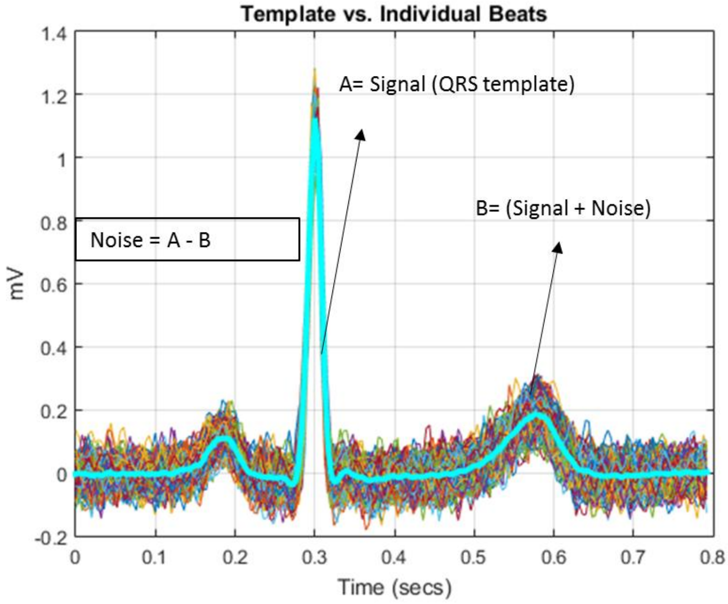

Figure 4: The clean signal is defined by the median template beat. The noise is defined by the difference between individual beats and the template

Table 2 (and Figure 5), below, shows computed SNR for each subject for *Pair A* and *Pair B*and the differences (Pair A-Pair B). We also computed the mean and standard deviation across all population.

Table 2: SNR rations and mean calculations for hydrogel and stainless steel for all 21 records (see Figure 5)

Subjects	Pair A Hydrogel electrodes SNR	Pair B Stainless Steel SNR	Pair A- Pair B Difference
S1	23.1	23.6	-0.5
S2	2.9	3.3	-0.5
S3	9.8	6.56	3.3
S4	6	6.9	-0.9
S5	11.8	10.8	1.0
S6	2.6	1.3	1.3
S7	6.4	3.3	3.1
S8	4.6	6.9	-2.4
S9	16.3	12.9	3.4
S10	25.4	26	-0.6
S11	22.8	21.1	1.7
S12	15.1	13.8	1.2
S13	13.9	9.2	4.6
S14	7	6.5	0.5
S15	2.2	2.2	0.0
S16	9.6	6.4	3.2
S17	3.3	3.6	-0.3
S18	15.2	12.8	2.4
S19	9.5	6.6	2.9
S20	9.4	7.7	1.7
S21	5.4	5.1	0.3
Mean	10.6	9.4	1.2
Std	7	6.9	1.8

Endpoints and success criteria for SNR result

Confidence interval for the true mean difference was computed to define the accuracy of the estimate and establish acceptable limits for the mean differences (true mean difference).

Confidence interval for the true mean difference is calculated as below:

$$\bar{d} \pm t * \frac{Sd}{\sqrt{n}}$$

- $\bar{d}$ is the mean vector of differences between hydrogel and stainless steel measures.
- Sd is the standard deviation of the differences
- $\frac{Sd}{\sqrt{n}}$is the standard error of the mean difference

Summary Analysis for Difference	n	$\bar{d}$ Mean difference	Sd standard deviation of the differences	$\frac{Sd}{\sqrt{n}}$ standard error of the mean difference mean
	21	1.2	1.8	0.393

With the acceptable assumption of 95% confidence and on (n – 1) degrees of freedom, confidence interval for the true mean difference is therefore:

$$\text{Confidence Interval} = \ \bar{d} \pm 2.086 * \frac{Sd}{\sqrt{n}} == \ [0.381, 2.019]$$

This confirms that with 95% level of confidence, we can be sure the mean difference in SNR between Pair A and B is lower than difference across population of each Pair A or B and lies somewhere between just 0.381 and 2.019 and summarized below.

				95% Confidence Interval	
Difference	Degree of freedom (df)	t	Mean difference	lower	upper
	20	2.086	1.2	0.381	2.019

Note that the SNR degradation in range of 0.381 to 2.019is smaller compared to the standard deviation of the measures of either Pair A (std: 7) or Pair B (std: 6.9), proving that difference between contact materials has no meaningful SNR impact when compared against across all populations.

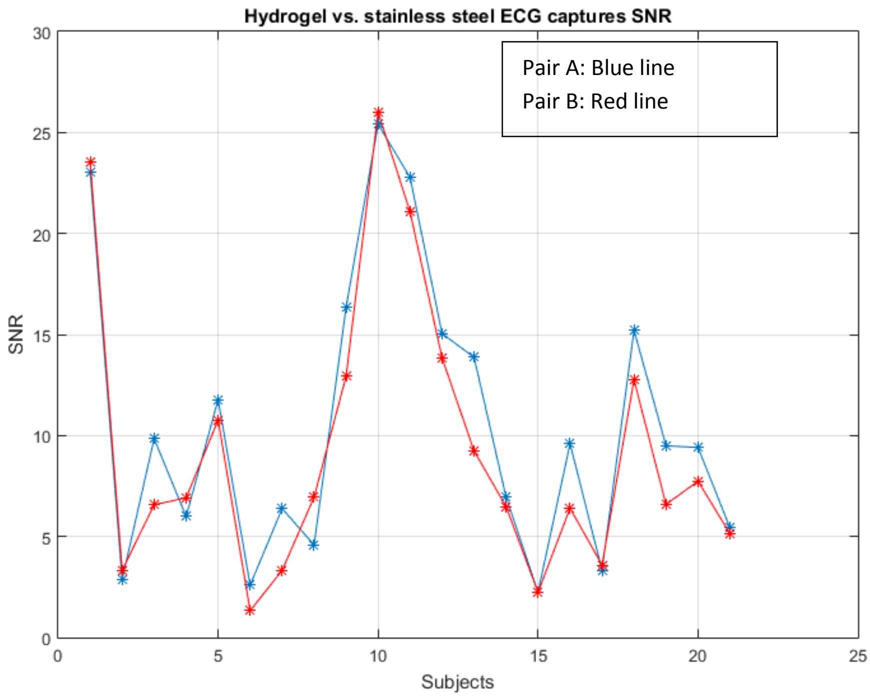

Figure 3: Linear SNR

Correlation Coefficient Comparison

We assess the similarity of HG electrodes and SS electrodes ECG captures by computing the Pearson correlation coefficient between both Pair A and Pair B:

Pearson correlation coefficient Equation

$$r = \frac{\sum_{i=1}^{N}(x_i - \bar{x})(y_i - \bar{y})}{\sqrt{\sum_{i=1}^{N}(x_i - \bar{x})^2}\sqrt{\sum_{i=1}^{N}(y_i - \bar{y})^2}},$$

- N is the sample size
- x_i, y_i are the single samples indexed with i
- $\bar{x} = \frac{1}{N}\sum_{i=1}^{N} x_i$, (the sample mean); and analogously for$\bar{y}$.

For each subject an interval of 60 secs for a data sampling rate of 500Hz is used to calculate correlation coefficients which corresponds to 30000 data points (N=Sample size in Pearson correlation coefficient formula). The correlation coefficient was computed using Pearson correlation coefficient for each subject using both electrodes. The results are listed in Table 3:

Table 3: Correlation between ECG records from wet get (Pair A) and stainless steel (Pair B) for all 21ECG records

Subject	Correlation
S1	0.972
S2	0.884
S3	0.938
S4	0.951
S5	0.959
S6	0.788
S7	0.897
S8	0.922
S9	0.963
S10	0.975
S11	0.978
S12	0.969
S13	0.952
S14	0.893
S15	0.864
S16	0.925
S17	0.897
S18	0.948
S19	0.9298
S20	0.9405
S21	0.9254
Mean correlation	0.927
Std of the correlation	0.045

Signals of both pair of electrodes show mean correlation of 0.927confirming a strong correlation between both types of ECG electrodes (correlation above 0.7 is reported as threshold of strong correlation) [1].[1] Additionally the subject having the highest noise (S6) resulted in a correlation of 0.788, which still meets the acceptance criteria.

Conclusions

Results show that after signal processing (including bandpass filtering and additional baseline removal), two simultaneously captured ECG signals, the first one using HG electrodes, and the second using SS electrodes, are equivalent in terms of SNR and correlation.

Although both this device (K172654) and predicate (K150869) use as dry electrodes and thus are equivalent, this report provides additional comparison of wet (gel) electrode with dry (stainless steel) to further show use of dry electrode does not adversely affect performance of captured ECG waveform.

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