

Dry Electrode Harness System for Wireless Self Acquisition of Resting 12-lead ECGs to Android Smart Phones

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Why would NASA want a dry-electrode harness for 12-lead ECG?



- 1) Reduce lead wire “spaghetti” (like that shown at lower left)
- 2) Eliminate ECG electrode disposables
- 3) Eliminate adhesives (irritating and uncomfortable)
- 4) Reduce don/doff time and overall time for 12-lead ECGs
- 5) Prevent the common clinical problem of reversed lead wire placements
- 6) Make 12-lead ECGs more “mobile”
- 7) Allow non-physician crewmembers to easily “self-collect” 12-lead ECGs



Recent work at NASA-JSC:

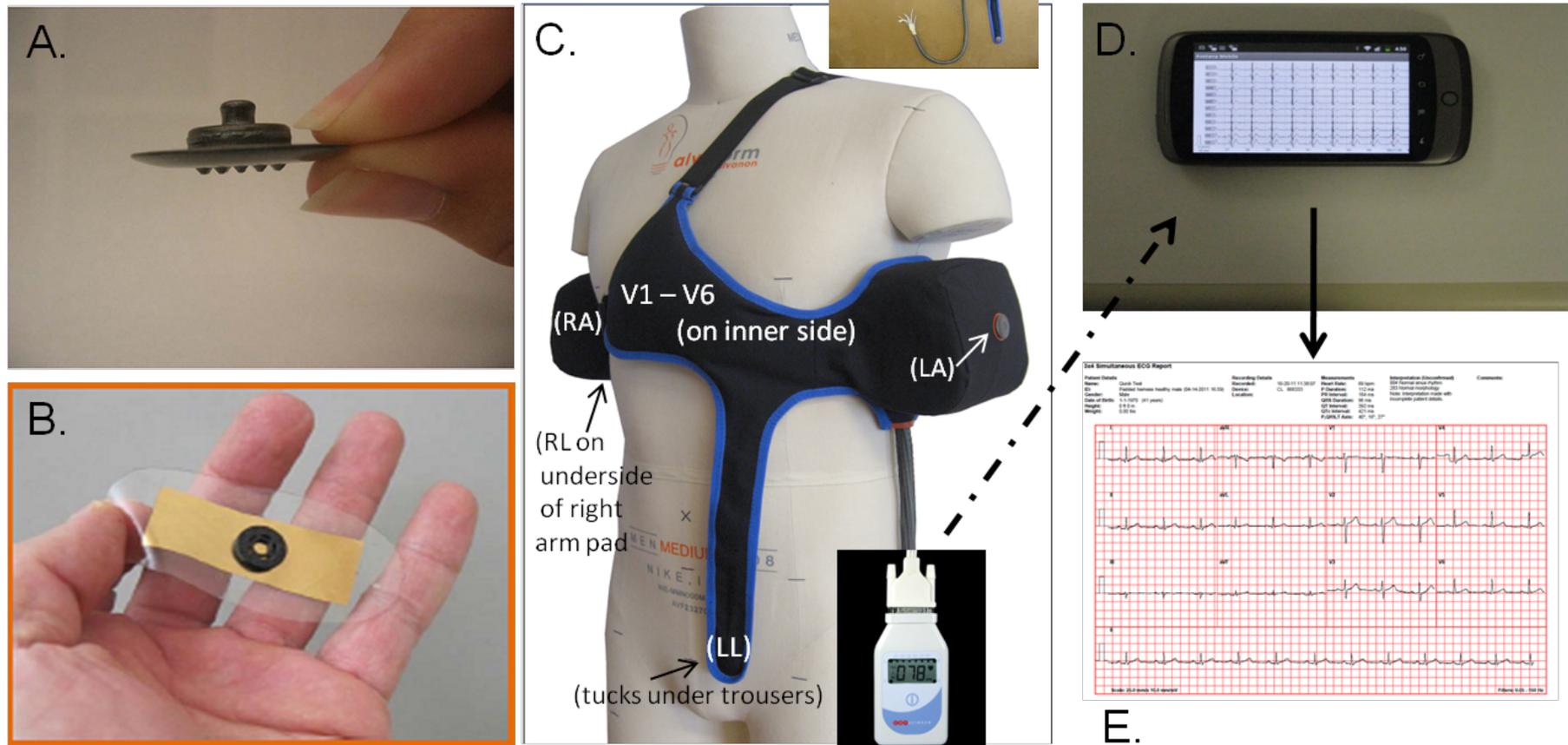


Figure:

- A.** Orbital's Research Inc.'s dry electrode as an individual sensor (already FDA cleared)
- B.** NanoSonic's dry electrode as an individual sensor (not yet FDA cleared)
- C.** Orbital's electrodes in our 12-lead ECG harness, with wireless ECG transmission (dotted arrow) via Bluetooth
- D.** Receiving Android smart phone
- E.** Printout of 12-lead ECG obtained from harness as received by phone.

Abbreviations: RA, RL, LA, LL: right arm, right leg, left arm and left leg electrodes, respectively

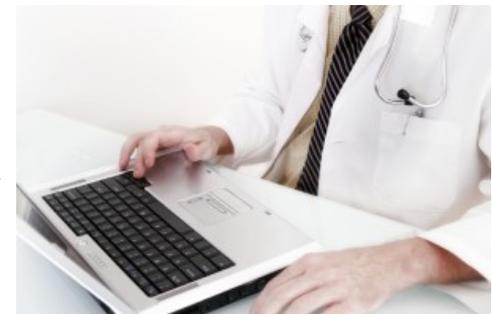
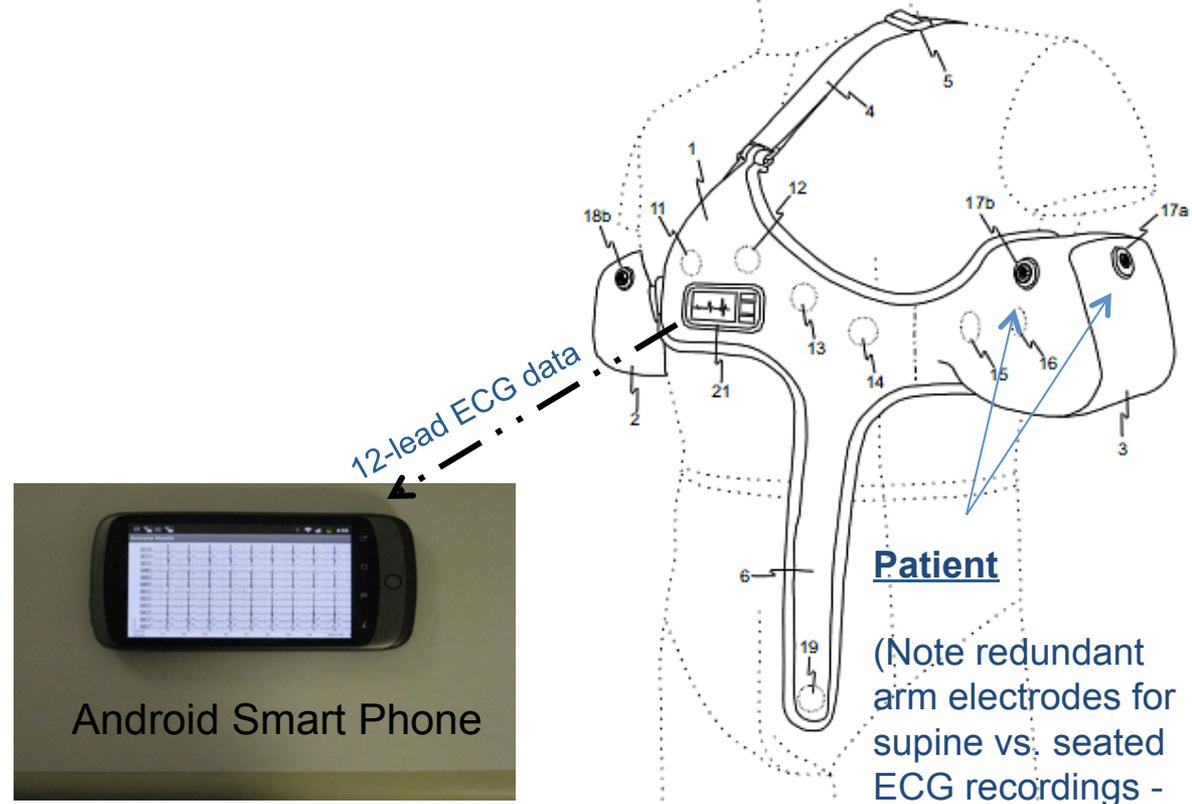
We ultimately envision embedded wireless 12-lead ECG electronics

Current emphases:

1) Preparing harnesses for demonstration in space (have not yet flown)

2) Lowering the cost of the embedded electronics from ~\$2,000 (approximate cost now if one uses COTS) to ~\$200? If we can do this, the system might be inexpensively employed in the third world and other underserved areas that have cell phone service (e.g., paired with remote analyses)

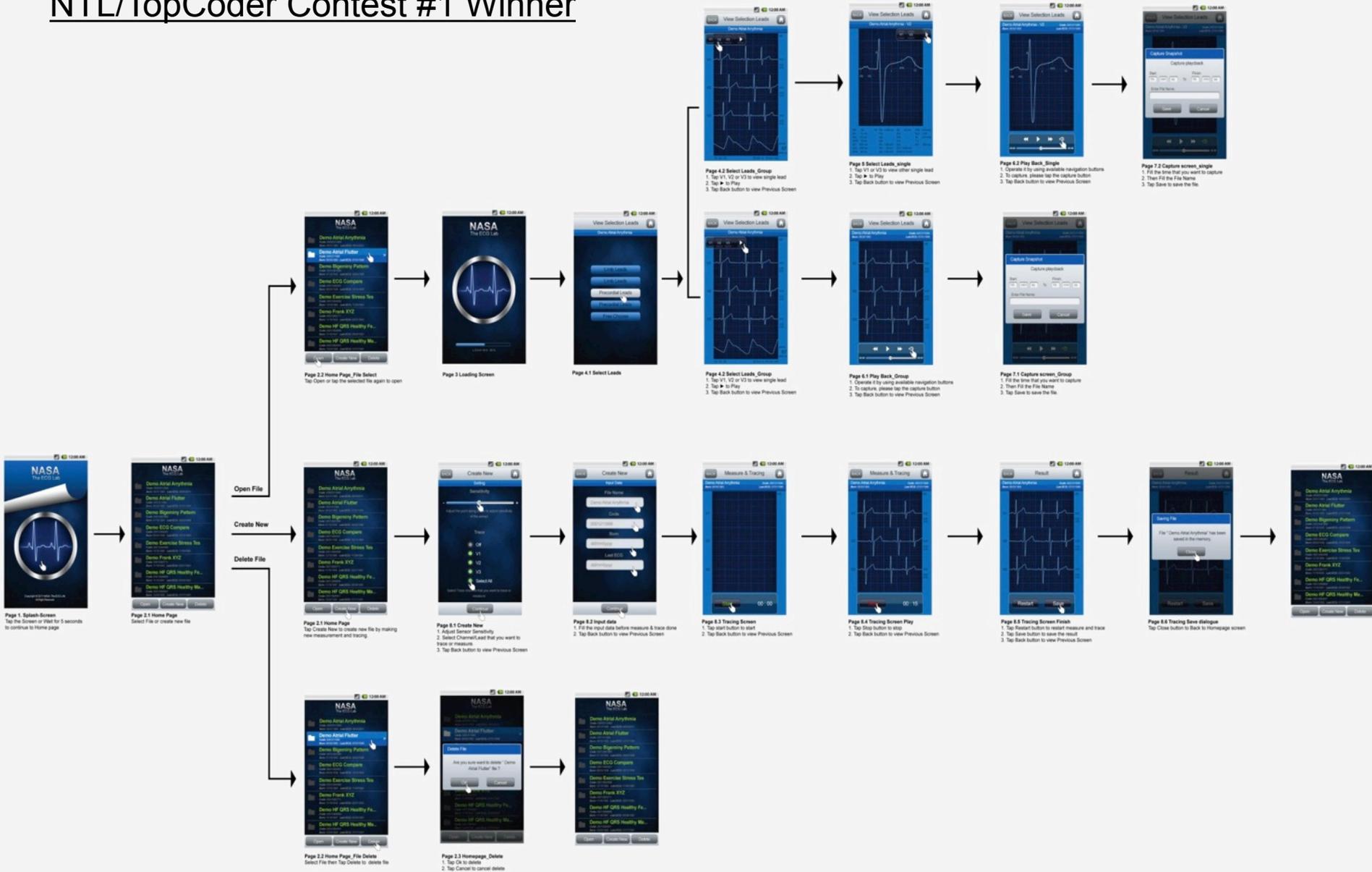
3) Building and hopefully making available to anyone an inexpensive or “free” Android GUI for full 12-lead ECG. The **NASA Tournament Lab** (NTL) and **TopCoder** are currently helping us build GUI-related functionalities via sponsorship of crowd-sourced java programming contests



Remote physician (or automated)

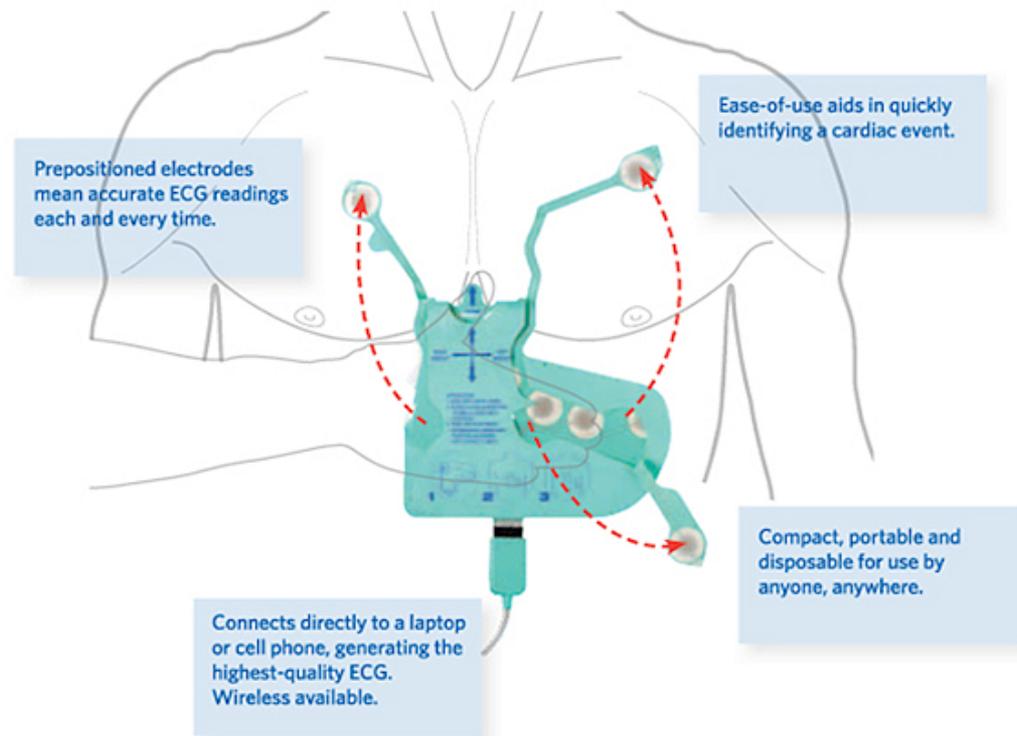
Flowchart of ECG Lab operation

NTL/TopCoder Contest #1 Winner



A disposable alternative for 12-lead ECG self-administration:

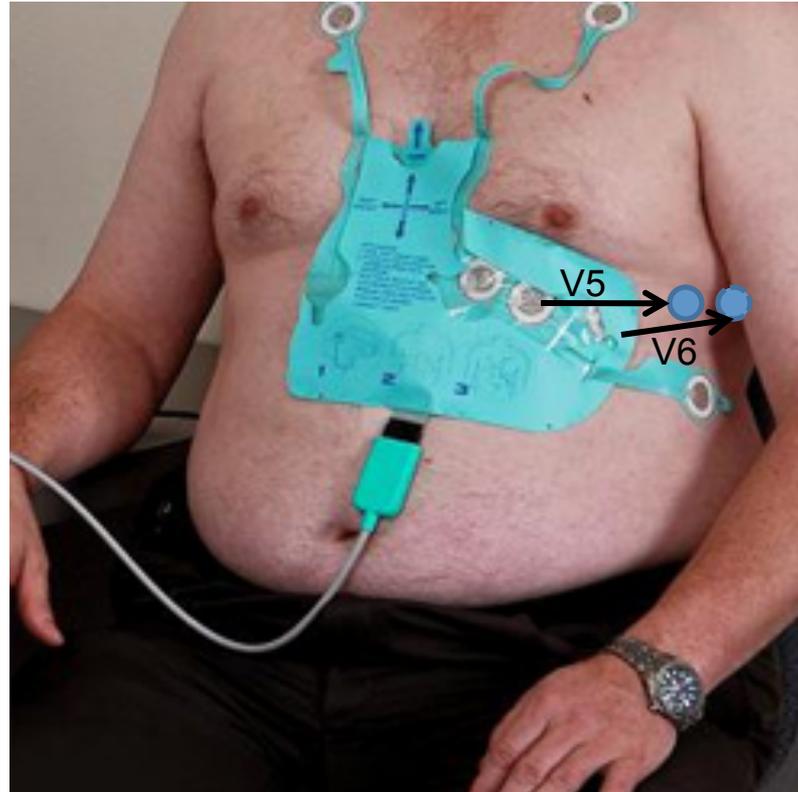
The ***ECG Glove*** from NYC-based “INeedMD, Inc” (recently FDA cleared)



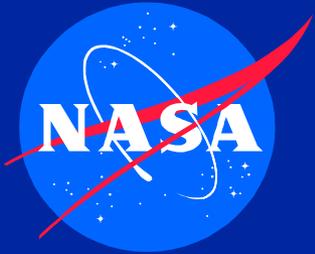
- Uses standard adhesives (not dry electrodes) like any other single-use disposable
- Expense an issue (~\$20 per glove “retail” single use), but advantages are high portability, sterility, rapid don/doff

My own experience with this disposable “glove” is that *if it is properly sized*, it works well for resting 12-lead ECG, but it’s not yet ready for ambulatory 12-lead ECG

What is meant by “properly sized”?



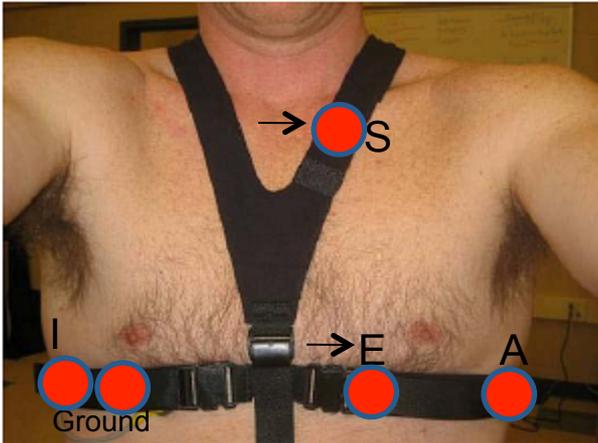
Clearly one size does not “fit all” ...
(And the same thing applies to all harnesses, shirts, etc)





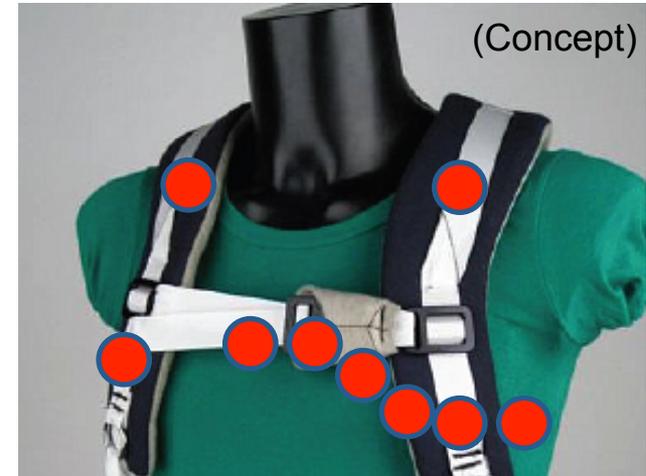
BACK-UP SLIDES FOLLOW

Two other “concept harnesses” we’re working on for continuous ambulatory “12-lead” ECG



“Modified EASI” style of dry electrode harness wherein one can “derive” the 12-lead ECG from only 5 electrodes (gets the electrodes “off the arms”)

- Already built by Orbital Research Inc as part of a NASA SBIR, but requires custom hardware
- Would also require a license from Philips to commercialize (due to use of the EASI technique)
- Some cardiologists cry “foul” on EASI 12-leads



An ambulatory style of dry electrode harness that will look more like this “concept” (i.e., with backpack-style straps employing full Mason-Likar 12-lead ECG)

- In initial prototyping phase right now
- If it works well, it will be immediately compatible with several manufacturers’ COTS ECG hardware that is already FDA cleared

Some alternative embodiments...12-lead ECG “shirts” (e.g., for ambulatory ECG too?)



Nanosonics' **"EKGear"** 12-lead ECG shirt with "metal rubber" dry electrodes on underside and overlying tight vest that must also be fit over the shirt for the electrodes to properly abut and sense



SmarTex's **"WEALTHY"** garment, a 12-lead ECG leotard-shirt with embedded "textile" electrodes developed under EU funding. The version I evaluated in circa 2006-7 still required the user to place an adhesive substance on top of the conductive textile

ISSUES:

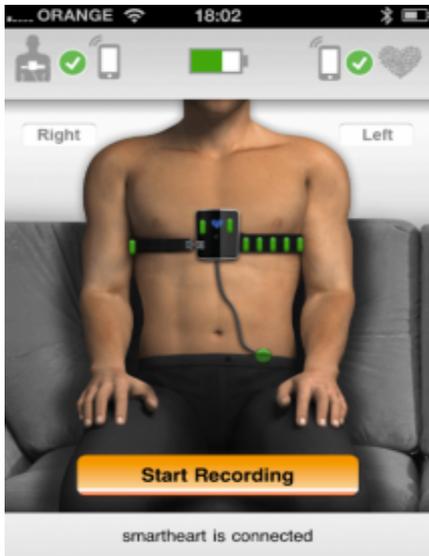
- Discomfort still an issue for these, especially with prolonged wear
- Donning and doffing still too time-consuming and cumbersome for use in space
- Electrode placement locations difficult to make "clinically standard" (foiled by "tenting", etc. constraints)
- Insufficient shielding of internal lead wires has been a problem → unacceptable signals during ambulation

Is a "tight shirt" really the ideal form factor for 12-lead ECG? (Possibly eventually, but not yet!)

Some alternative embodiments for resting 12-lead ECG (all from Israel).



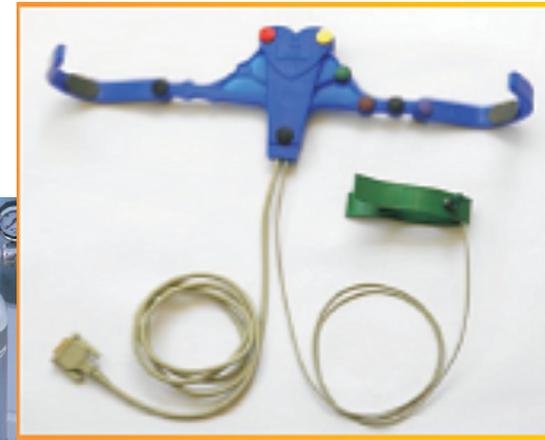
SHL's "CardioSenC" harness for 12-lead ECG; has an embedded earlier generation cell phone for slow transmission of snapshot ECGs only. One squeezes the RA and LA electrodes into one's armpits.



SHL's newer "SmartHeart" version (left), to be released in fall 2012, **details TBD.**



Tapuz Medical's rubberized "Apron" for resting 12-lead ECG; patient "stretches" arm-loop electrodes backward



Commwell Medical's "Glove" for resting 12-lead ECG (Israeli designed, Illinois based)