Designing Hardware, Journey from Novice to Not-Bad

Ace Medlock, Kendrick Shaw, Eric Herman

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ADS1290 breakout

Figure 2: 2012 board

- through-hole with 1 64pin QFP
- 2011-11-26 begin design
- 2012-01-23 boards arrive
- 2012-03-04 reading data

https://github.com/OpenElectronicsLab/ads1298-breakout
Figure 3: OpenHardwareExG in the case

- 3 boards stacked, but testing of base-board hard
- example usage:
  http://openelectronicslab.github.io/eeg-mouse/
  https://github.com/OpenElectronicsLab/OpenHardwareExG
Figure 4: OpenHardwareExG Shield

- designed testing, cheaper and easier for others
- made some errors and three different revs
- example usage: quantified self

https://github.com/OpenElectronicsLab/OpenHardwareExG_Shield
Current Project: Holter Monitor

- asked for advice from Humatem and received some great guidance
- special purpose
- goal of FDA or EC certification
  - EC medical device regulation is currently changing (2020) and we don’t really know the process yet
  - Need to design for safety from the start: Plan to do a ground-up redesign with eye on certification once we’re happy with the prototype

https://github.com/OpenElectronicsLab/OpenHardwareHolterMonitor
Many excellent FOSS tools to support hardware hackers

- for both hardware and firmware
- Arduino-type boards and tools lower the barrier to entry
KiCAD eeschema

Figure 5: kicad-eeschema-screenshot.png
Figure 6: kicad-pcbnew-screenshot.png
Populated PCB

Figure 7: populated-holtermonitor_small.jpg
Arduino build environment

```c
uint64_t chipid;

void setup() {
    Serial.begin(115200);
}

void loop() {
    chipid=ESP.getEfuseMac(); //The chip ID is essentially its MAC address (length: 6 bytes).
    Serial.printf("ESP32 Chip ID = %04X",(uint16_t)(chipid>>32)); //print High 2 bytes
    Serial.printf("%08X\n",(uint32_t)chipid); //print Low 4 bytes.
    delay(3000);
}
```

Done uploading.

Wrote 3072 bytes (128 compressed) at 0x000008000 in 0.0 seconds (effective 1543.7 kbit/s).
Hash of data verified.

Leaving...
Hard resetting via RTS pin...

Figure 8: arduino-build-screenshot.png
Figure 9: openscad-screenshot.png
Learning surface mount soldering

Figure 10: rev0: through-hole except the chip
Learning surface mount soldering

- “Pin sweep” method of soldering ICs
- I learned it by watching YouTube!
Learning surface mount soldering

Figure 11: 0603 surface mount resistor
Solder paste

Figure 12: solder paste
Solder paste

Figure 13: surface mount components soldered with solder paste
Solder paste

Figure 14: Solder paste under the microscope
Solder paste

Figure 15: solder paste joint: OK
Solder paste

Figure 16: solder paste joint: cold solder
Soldering using a dissection scope

Figure 17: using a microscope for soldering
Hand-soldering surface mount

Figure 18: hand solder 01
Hand-soldering surface mount

Figure 19: hand solder 02
Hand-soldering surface mount

Figure 20: hand solder 03
Hand-soldering surface mount

Figure 21: hand solder 04
Hand-soldering surface mount

Figure 22: hand solder 05
Hand-soldering surface mount

Figure 23: hand solder 06
Hand-soldering surface mount

Figure 24: hand solder 07
Hand-soldering surface mount

Figure 25: hand solder 08
Hand-soldering surface mount

Figure 26: hand solder 09
Hand-soldering surface mount

► The job of a solder joint is to conduct electricity, not to look pretty

Figure 27: ugly, but works
Hand-soldering surface mount

Figure 28: hand-soldered 0201 capacitor
Fixing misteaks
Fixing mistakes

Pads:
D
G
S

Feet:
G
S
D

Oops
Fixing mistakes

- You will make mistakes. You will be able to fix them.

Figure 29: rotated Q10
Fixing mistakes

Figure 30: flipped Q1-Q2
Fixing mistakes

Figure 31: cut traces
Fixing mistakes

Figure 32: green wire into the chip
Safety is important, and often fairly simple

Figure 33: goggles
What could go wrong?

- User error
- Spills
- Power surges
- Hacking
- Drops/falls
- etc.
How serious is it

Figure 34: Paper cut vs nuclear explosion
How likely is it

Examples:

- **Very likely:**
  - user forgets to turn device off overnight
  - device dropped from 1 meter above ground
- **Very unlikely:**
  - user starves while using device because they forgot to eat
  - device dropped out of airplane
Risk

\[ \text{Risk} = \text{Severity of harm} \times \text{Probability of harm} \]

(e.g. ISO 14971)
Acceptable risk

Acceptable risk varies by circumstance

Figure 35: free climber

¹Image by Heinz Hummel from Pixabay, Pixabay license
Mitigation

Decrease the risk of the event

▶ example: remove internet connectivity from a device to make it less likely to be hacked

Decrease the severity of the event

▶ example: add a disconnection alarm to a ventilator so it fails loudly rather than quietly if it is accidentally disconnected from the patient
Example: Risk of electrical shock

- Small currents can be dangerous when crossing the heart
- Current rather than voltage
  - Pacemaker voltages (~2 volts)
  - Minimum fibrillation currents
    - 10s of milliamps through skin
    - 10s of microamps at the heart
  - Resistances can be very low in a medical context
    - central lines, surgery, etc.
- Probability may be low, but severity can be high
Risk of shock between electrodes
Risk of shock between device and ground

Figure 37: Device-ground shock risk
Risk of shock between devices

Figure 38: Interdevice shock risk
Example Mitigation: Isolation

- Batteries (Safety Extra Low Voltage, or SELV)
  - e.g.: unplugged laptop
- Creepage and clearance
- Power isolation
- Data isolation
## Leakage current standards

<table>
<thead>
<tr>
<th>Leakage Current</th>
<th>Body</th>
<th>Body Floating</th>
<th>Cardiac Floating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Earth</td>
<td>500 μA</td>
<td>500 μA</td>
<td>500 μA</td>
</tr>
<tr>
<td>Enclosure</td>
<td>100 μA</td>
<td>100 μA</td>
<td>100 μA</td>
</tr>
<tr>
<td>Patient</td>
<td>100 μA</td>
<td>100 μA</td>
<td>10 μA</td>
</tr>
</tbody>
</table>

- Note that these are very low currents
- Can only be 2-5 times larger even if component fails
Designing for failures

- Safe if any one component fails
- 2 means of patient protection
  - Two layers of basic isolation vs. reinforced isolation
- Current limiting resistors on patient connections
Take home message

- a little thought about safety goes a long way
- great tools and resources to support you
- don’t be too intimidated
  - try
  - repeat
  - you’ll improve as you go
- happy hardware hacking!
References and Contacts

▶ Tools
  ▶ https://www.arduino.cc/
  ▶ https://kicad-pcb.org/
  ▶ https://www.openscad.org/

▶ Books
  ▶ The Art of Electronics, Horowitz and Hill
  ▶ Medical Instrumentation Application and Design, Webster

▶ SMD Soldering technique videos
  ▶ https://www.youtube.com/watch?v=eg2hxpy–gg
  ▶ https://www.youtube.com/watch?v=JKqgU2Hw3mY

▶ Contact
  ▶ https://github.com/OpenElectronicsLab
  ▶ eric.herman@gmail.com
  ▶ ace.medlock@gmail.com
  ▶ kms15@case.edu