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BOARD # 20: Work in Progress: A Formal Medical Device Teardown as a Biomedical Engineering Learning Experience

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Work in Progress: A Formal Medical Device Teardown as a Biomedical Engineering Learning Experience

Abstract

This manuscript describes a course project that guides each biomedical engineering (BME) student through the scripted teardown of an inexpensive medical device: a fingerclip pulse oximeter. Supporting objectives are to increase a student's experience with the physical resources required to complete such a task, coupled with an improved awareness of the documentation needed to properly archive the process. The project addresses medical device user manuals, product priority dates, accuracy assessment, clinical device studies, regulation, component design, and manufacturing. Students also address ethical implications of teardowns, including the dissemination of the resulting device information. Pre/post-project surveys help to assess student self-perceptions of learning, and summative learning assessments based on topical rubrics are underway. To date, the month-long project has been utilized with 48 students enrolled in three offerings of a three-credit, senior-level, one-semester *BME 575 – Clinical Systems Engineering* course at Kansas State University as a means to introduce students to medical device development issues that they may not otherwise consider prior to employment.

I. Introduction and Educational Research Goal

Reverse engineering is a process whereby a person deconstructs a device to better understand how it operates, including features that enable its capabilities [1–4]. Motivations for such an endeavor include the desire to repair a device, a plan to update the device functionality, or an aspiration to identify the design elements that are publicly disclosed given their presence in a marketed physical product. Deconstruction of physical hardware and its documentation are often referred to as a "teardown" – a process that is legal and encouraged in industry, though the subsequent use of the lessons learned is limited [5]. While teardowns play a prominent role in the medical device industry, including as a means to keep tabs on competitors' products, the use of formal teardowns in biomedical engineering (BME) education is limited and has not been well documented in the literature. To be clear, the process of taking devices apart is not unusual or unexpected in a hands-on BME curriculum. However, carefully scripted, formal teardowns that involve device regulation research, performance assessments, careful deconstruction, physical component measurements, and the creation of quality images and documentation that are, e.g., defendable in court are not traditionally emphasized in BME education and are not typical elements of an "unboxing" exercise undertaken by an undergraduate BME student.

The following sections and appendices address the elements of a scripted teardown experience utilized in a three-credit, senior-level, single-semester *BME 575 – Clinical Systems Engineering* course at Kansas State University. This month-long project has been offered as part of three consecutive course offerings and has engaged 48 undergraduate students to date. At this point in their curricula, most of the BME students in this course have already learned fundamental concepts related to biomedical instrumentation, embedded software, printed circuit board layout/population, 3D printing, and basic medical product design. The research question affiliated with this work is the following: "Does a carefully scripted teardown exercise involving a simple medical device teach upper-level BME students the basic skills they need to prepare an evidence-quality report?"

II. Project Elements

A. Learning Objectives

Student learning objectives that support the higher-level research question can be framed in terms of student capabilities post-project. Upon completion of this teardown project, each student should be able to do the following: 1. **Operate** fingerclip (clothespin-style) pulse oximeters. 2. **Describe** the functional features of a fingerclip pulse oximeter. 3. **Distinguish** transmittance- versus reflectance-mode pulse oximeter sensors. 4. **Research** FDA approval and testing information affiliated with a medical device. 5. **State** the role of a predicate device in the FDA regulation and approval process. 6. **Seek** clinical performance information for consumer pulse oximeters. 7. **Evaluate** the relative performance of an inexpensive fingerclip pulse oximeter in comparison with a more expensive reference device. 8. **Operate** and **acquire** calibrated measurements with a Dino-Lite USB measuring microscope. 9. **Conduct** a methodical teardown of a medical monitoring device. 10. **Maintain** careful records (data and images) during a device unboxing and teardown process. 11. Methodically **conduct** a teardown and **record** information in such a manner that fully traceable results will be defendable in court. 12. **Clean** and **inspect** device surfaces. 13. **Identify** health hazards related to the use of isopropyl alcohol. 14. **State** ethical issues germane to device teardowns and hardware/software reverse engineering. 15. **Summarize** teardown results in an easy-to-follow format.

B. Methods

Teardown exercise components are addressed in the following sections. The target device is a Contec CMS50NA fingerclip pulse oximeter, and the reference device against which each Contec unit is compared is a Masimo MightySat® fingerclip pulse oximeter.

Early Device Research. Each student first seeks Contec CMS50NA information online, including FDA 510(k) records, manufacturer information, and clinical performance reviews.

Initial Unboxing. Each student acquires pictures of their packaged Contec CMS50NA unit and then removes the exterior wrapping. They take pictures of the packaging (including model/serial numbers and any use-by dates), the front pages of any user documentation (including copyright dates), and the device itself. They then record the device meta data: serial number, model number, manufacture date, etc. Refer to *Appendices A.1* and *A.2* for representative images.

Device Accuracy Assessment. Each student performs a CMS50NA accuracy assessment, using a Masimo MightySat® fingerclip pulse oximeter as a reference. They acquire at least 25 time-aligned measurement pairs (e.g., index and middle fingers) using the two devices. The student captures images of (a) the devices while worn, with active displays, and (b) a wider view of the testing area. Using Microsoft Excel, the student determines absolute and relative pulse rates and SpO2 errors for all the data pairs. They then calculate various statistical parameters, including an RMS value for absolute error for the overall data set, consistent with the ISO 80601standard for pulse oximeter performance assessment [6]. Refer to *Appendix A.3* for representative images.

Training – DinoLite Measuring Microscope. Each student steps through Dino-Lite tutorial videos that teach the user how to make a calibrated distance measurement with a Dino-Lite USB microscope. *Appendix A.4* lists these Dino-Lite tutorials and provides representative images.

Device Deconstruction (Physical Teardown). Each student methodically deconstructs the device, taking pictures with the camera and/or microscope along the way. During this process, they (a) identify and measure external/internal device features, especially as related to optoelectronic signal components and light-management features, and (b) identify materials and electronic components. Refer to *Appendix A.5* for representative images.

Ethical Implications. Each student consults the literature to identify several articles that address ethical implications of hardware teardowns. They are to avoid searches focused on "reverse engineering" *per se*, as those articles usually address the ramifications of *software* deconstruction. A student should address the messaging in these papers related to ownership of hardware design ideas and their release, considering patents and intellectual property.

Project Report. Each student submits a Microsoft Word file with a title page, a table of contents, a section-by-section record of these activities, and references.

III. Project Assessment

Learning assessments in support of the primary educational research question will incorporate two instruments: (1) a pre/post-project survey – see *Appendix B* – that addresses students' self-perceptions of familiarity with regard to the project learning objectives, and (2) an assessment rubric – see *Appendix C* – that allows the instructor to (a) assign credit for individual project facets and (b) quantitatively assess the formal student learning objectives. With regard to each pre/post-project survey, learning is generally assumed to correlate with the post-minus-pre-project values provided by the students. (Note that the open-ended, bulleted items at the end of the survey are only incorporated in the post-project survey.) Additionally, to better assess the post-project survey responses in terms of pre-project responses, an ANCOVA (analysis of covariance) approach will be employed that utilizes those pre-project responses as comparative baselines. Results from the project assessment rubric will provide supplemental summative data to reinforce lessons learned from the ANCOVA analyses.

IV. Conclusion

This work-in-progress manuscript presents the learning objectives, student tasks, and assessment procedures affiliated with a senior-level, medical device teardown exercise assigned to students enrolled in *BME 575 – Clinical Systems Engineering* offered at Kansas State University. Student learning and performance assessments are ongoing and will be presented in a future paper. Minor modifications to this learning experience are also underway in response to both performance assessments and student feedback offered via pre/post-project surveys.

Acknowledgements

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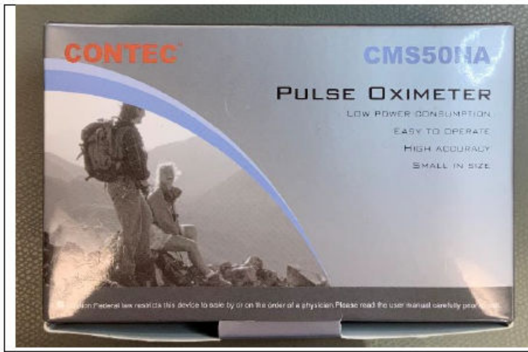
the BME students who provided representative images for this manuscript: Nicholas Edwards, John Baybutt, Elizabeth Goetz, Nic Jones, Emily Hertel, Reed Podoll, and Nicole Wagoner (in no particular order as related to Students A→G noted in the appendices). This work is exempt from human subject review under IRB exemption category §46.104(d), which relates to research conducted in established or commonly accepted educational settings [7].

References

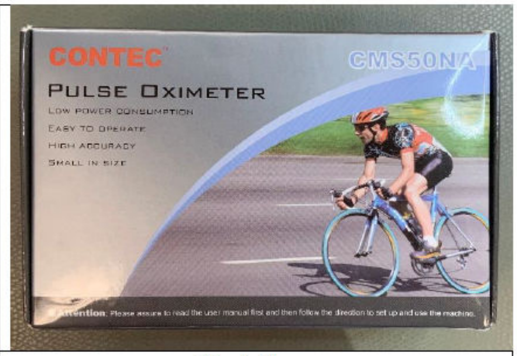
1. Giuntoli, David. Competitive Technology Teardown – A Springboard to Meaningful Innovation, Medical Product Design, November 17, 2022, https://www.mindflowdesign.com/insights/5-step-product-teardown-process/
2. What are Product Teardowns?, gHb Intellect, https://ghbintellect.com/what-are-product-teardowns/.
3. Medical Device Tear-down: Seven Tips, https://blog.spcollege.edu/engineering-manufacturing-building-arts-educational-information/medical-device-tear-down-seven-tips/
4. Dempsey, Paul. "Reviews consumer technology; The Teardown right to repair," *Engineering & Technology*, vol. 17, no. 3, pp. 68-69, April 2022, doi: 10.1049/et.2022.0324.
5. Gallagher, Keith, Cem Caner and Jenifer Deignan, "The Law and Reverse Engineering," 2012 19th Working Conference on Reverse Engineering, Kingston, ON, Canada, 2012, pp. 3-4, doi: 10.1109/WCRE.2012.66.
6. ISO 80601-2-61:2017. Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment, https://www.iso.org/standard/67963.html.
7. Exemptions (2018 Requirements). Subpart A. Basic HHS Policy for Protection of Human Research Subjects. §46.104 Exempt research. U.S. Department of Health and Human Sciences, https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html.

Appendix A – Representative Images

A.1. Target Device: Contec CMS50NA Fingerclip Pulse Oximeter



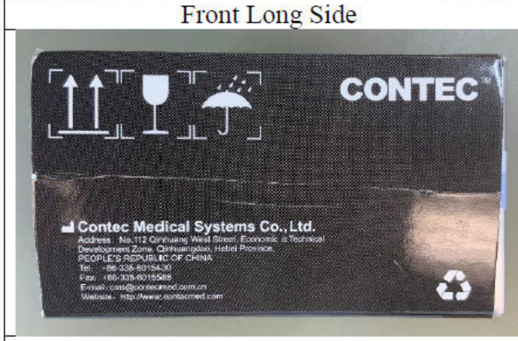
Front Face



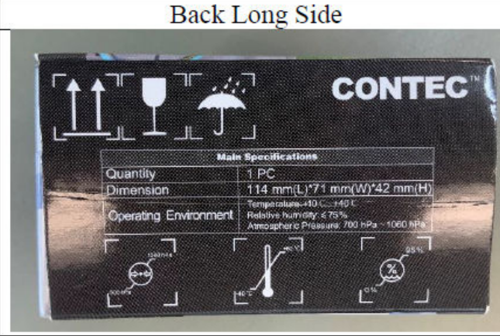
Back Face

Front Long Side

Back Long Side



Short Side (left of front face)



Short Side (right of front face)

Figure 1. Contec CMS50NA packaging and contents images acquired by Student A.

Front View of the CMS50NA

Lateral View

Bottom View

Opening View

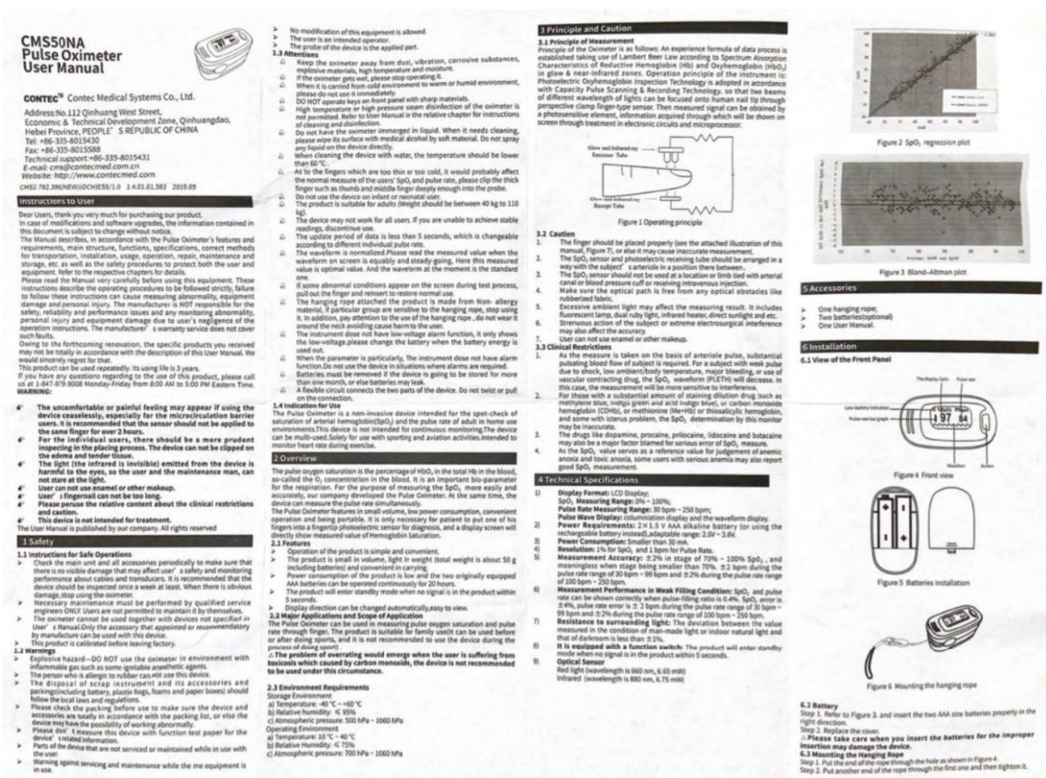


Figure 2. Contec CMS50NA device and manual images acquired by Student A.

A.2. Reference Device: Masimo MightySat® Fingerclip Pulse Oximeter

Figure 3. MightySat® images acquired by Student G.

A.3. CMS50NA Accuracy Assessment and Work Area Images

Figure 4. Measurement comparison images acquired by Student C (left) and Student D (right).

Figure 5. Work area image acquired by Student G.

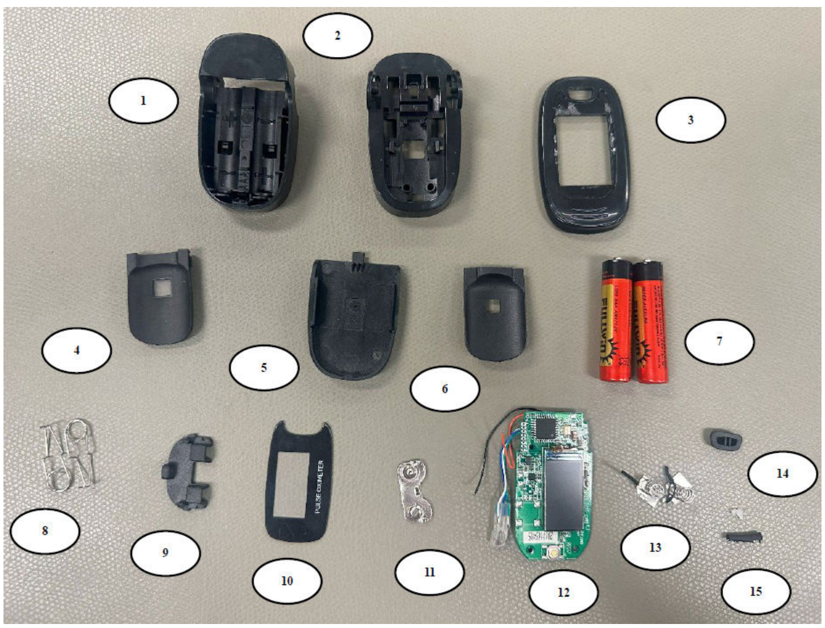
A.4. Dino-Lite USB Microscope Tutorials and Example Images

Dino-Lite USB Microscope Tutorial URLs:

- How to: Use the Auto Calibration target (CS-40 / CS-41) (0:49), https://www.youtube.com/watch?v=mivZvOLtEBA
- About Working Distance - Dino-Lite Digital Microscopes (2:22), https://www.youtube.com/watch?v=uPI2o5TY_JY&t=10s
- DinoCapture 2.0 Software Tutorial - Part 1: Basic Features (7:39), https://www.youtube.com/watch?v=4UOWvpDWJos
- DinoCapture 2.0 Software Tutorial - Part 2: Measurement (5:32), https://www.youtube.com/watch?v=C-hfl-Vkq3Q
- DinoCapture 2.0 Software Tutorial - Part 3: Advanced Features (3:48), https://www.youtube.com/watch?v=O5R3eciFx3s
- How to use DinoCapture 2.0 for Dino-Lite on Windows (29:41), https://www.youtube.com/watch?v=Kybb6y4VfxQ

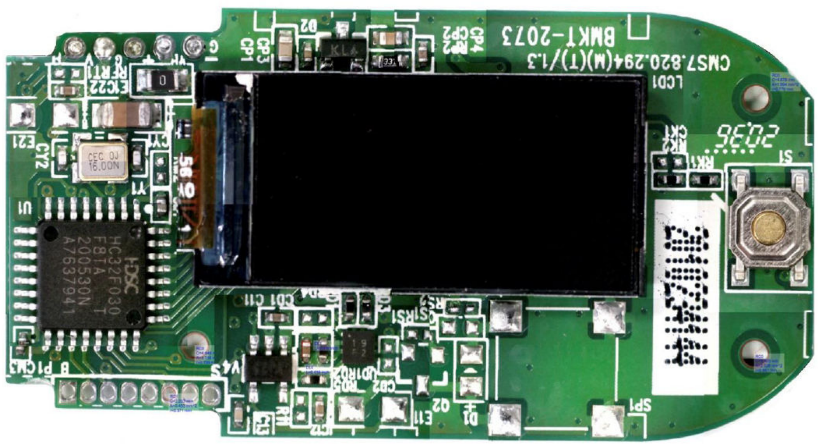
Figure 6. Earring (upper) and dime (lower) images acquired by Student F.

A.5. Device Deconstruction Images

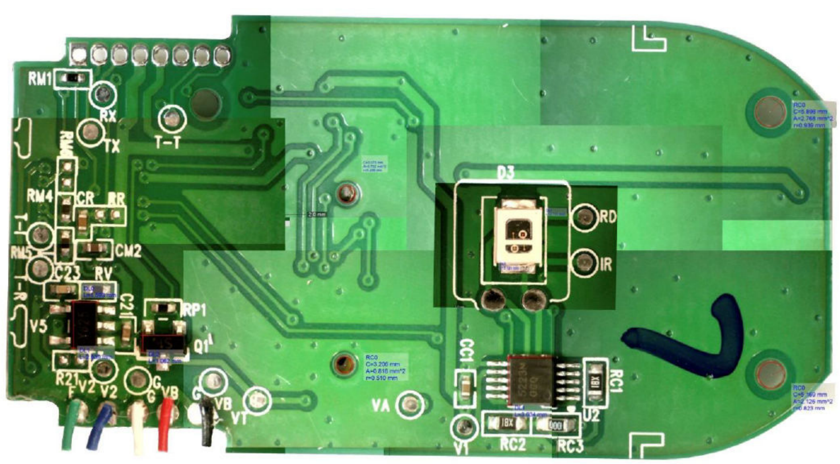


1	Device Bottom Base	9	Pull-up Plastic Tab
2	Device Middle Base	10	Plastic Screen Cover
3	Device Top Base	11	Battery Contact Plate
4	LED Cover 1	12	PCB and Display Screen
5	Battery Cover	13	Springs
6	LED Cover 2	14	User Button
7	AAA 1.5V Batteries	15	Adhesives and Wire Protector
8	Clip Coils		

Figure 7. Device deconstruction work area (upper) and Contec CMS50NA component (lower) images acquired by Student B.

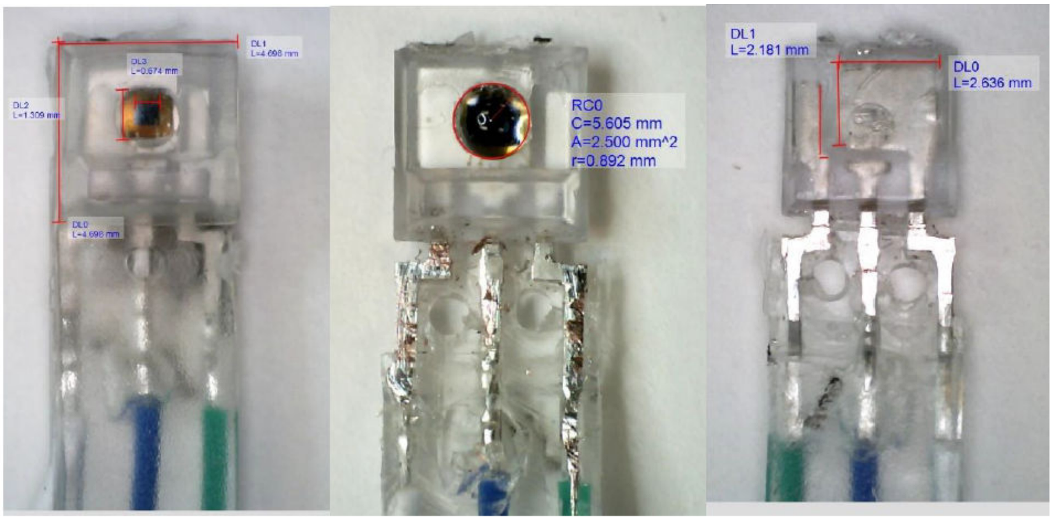


Top Face of the PCB



Bottom Face of the PCB

Figure 8. Work area (upper), PCB top (middle), and PCB bottom (lower) images acquired by Student A.



A) Spectral Sensor B) Sensor cleared of any protecting film C) Sensor Electronic Design

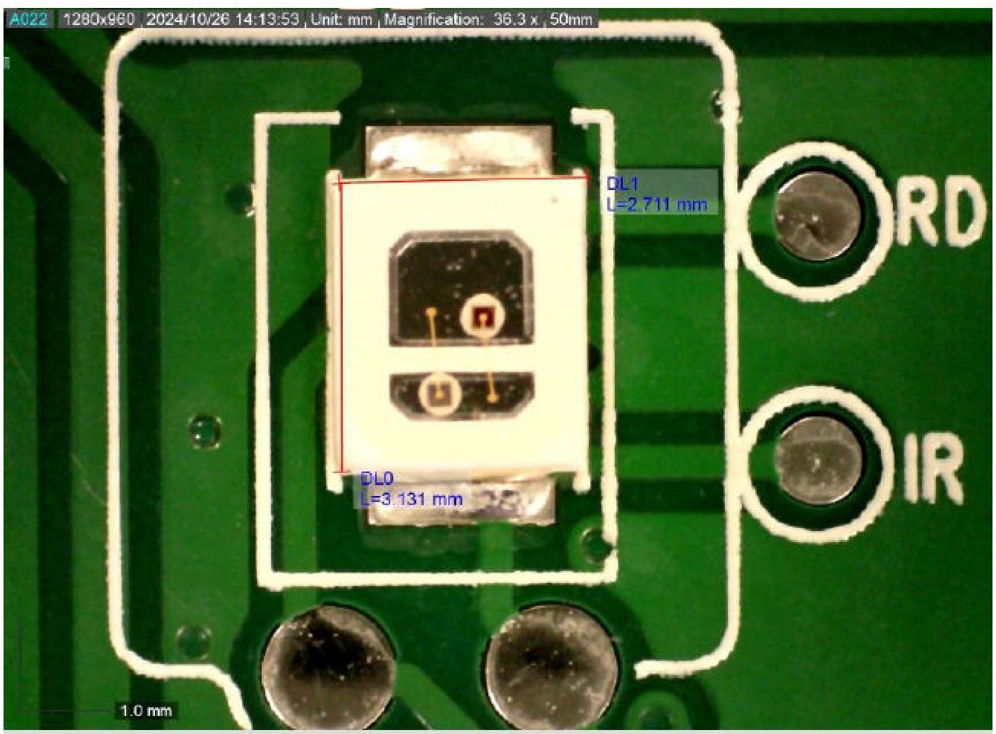


Figure 9. Photodiode detector (upper) and red/IR LED (lower) images acquired by Student A.

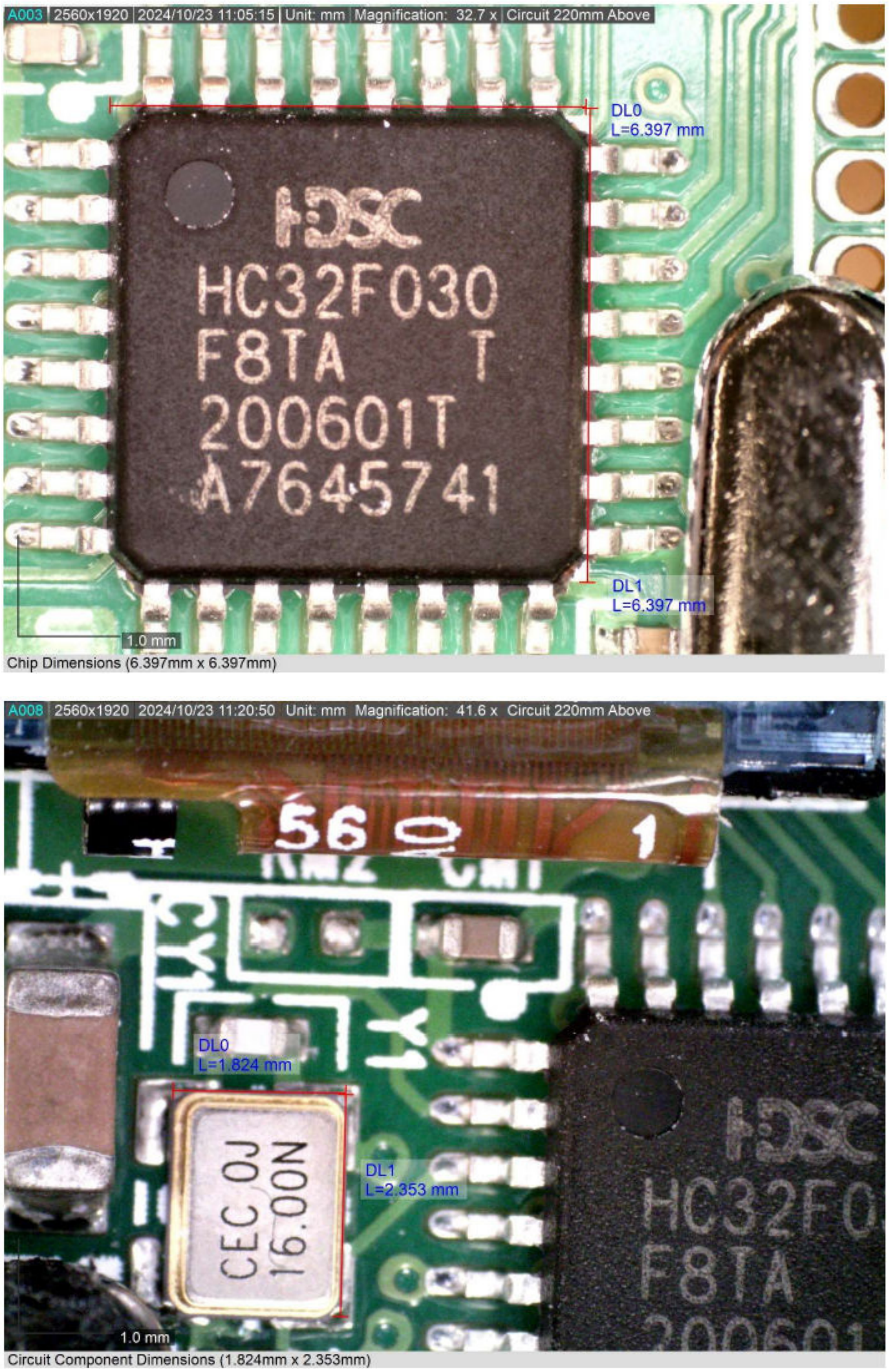


Figure 10. Microcontroller (upper) and crystal oscillator (lower) images acquired by Student E.

Appendix B – Pre/Post-Project Survey

Post-Project Survey: BME 575 Project

Dr. Warren, DUE 3084, December 6, 2024

Name: ______________________________

The two goals of this short survey are (1) to gauge the level of post-project understanding with regard to the subjects addressed in the Fall 2024 BME 575 teardown project and (2) to gather feedback from students with regard to the highlights of the effort as well as potential improvements that could be made in subsequent offerings. This information will be used to help assess the project in terms of its viability as a learning tool.

This project targeted specific learning objectives: tasks a student should be able to perform upon completion of the project. On a scale of 1 to 5, note your level of comfort/familiarity with the following items, which relate directly to the learning objectives for the project. Here, "1" means no comfort and "5" means high confidence.

Learning Objective	**Rating**
1. **Operate** finger-clip (clothespin-style) pulse oximeters.	
2. **Describe** the functional features of a finger-clip pulse oximeter.	
3. **Distinguish** transmittance- versus reflectance-mode pulse oximeter sensors.	
4. **Research** FDA approval and testing information affiliated with a medical device.	
5. **State** the role of a predicate device in the FDA regulation and approval process.	
6. **Seek** clinical performance information for consumer pulse oximeters.	
7. **Evaluate** the relative performance of an inexpensive finger-clip pulse oximeter in comparison with a more expensive reference device.	
8. **Operate** and **acquire** calibrated measurements with a Dino-Lite USB measuring microscope.	
9. **Conduct** a methodical teardown of a medical monitoring device.	
10. **Maintain** careful records (data and images) during a device unboxing and teardown process.	
11. Methodically **conduct** a teardown and **record** information in such a manner that fully traceable results will be defendable in court.	
12. **Clean** and **inspect** device surfaces.	
13. **Identify** health hazards related to the use of isopropyl alcohol.	
14. **State** ethical issues germane to device teardowns and hardware/software reverse engineering.	
15. **Summarize** teardown results in an easy-to-follow format.	

Please identify the following:

- The element of the project that you most appreciated.
- The element of the project that you least appreciated.
- The portion of the endeavor that took the most time.
- The portion of the endeavor that has the most perceived relevance to your upcoming professional work.
- Any elements of the project (e.g., hands-on or research-oriented) that you believe should be emphasized or even enlarged in scope.
- Any elements of the project that you believe should be de-emphasized.
- Other types of medical devices that would be appropriate targets for such an exercise.
- Other comments/feedback you wish to share.

Appendix C – Project Assessment Rubric

BME 575 Teardown Project Assessment Sheet, Fall 2024, Dr. Warren, DUE 3084

Student: XXXXXXXX   Total: ______ / 100

Tasks		**Subtotal:** xx/85
Early Device Research – Contec CMS50NA Fingerclip Pulse Ox		xx/15
• User manual	x/1	
• Functionality/feature listing	x/2	
• FDA 510(k) information (device class, predicate devices, etc.)	x/4	
• FDA testing information	x/2	
• Original device manufacturer	x/2	
• Performance reviews/studies (same family of Contec devices)	x/4	
Initial Unboxing		xx/5
• Pictures of packaging, user documentation, and the device	x/3	
• Device meta data (serial/model numbers, manuf date, …)	x/2	
Accuracy Assessment (Reference: MightySat unit)		xx/25
• 25 time-aligned meas pairs; devices worn on same hand	x/4	
• Images of individual paired measurements	x/4	
• Image(s) of the wider testing area	x/2	
• Calculations		
○ 25 pulse rate and SpO_2 values	x/3	
○ Absolute/relative errors	x/2	
○ min, max, and average ± stDev for absolute errors,	x/2	
○ min, max, and average ± stDev for mags of absolute errors,	x/2	
○ min, max, and average ± stDev for relative errors,	x/2	
○ min, max, and average ± stDev for mags of relative errors,	x/2	
○ an RMS value for absolute error for the overall data set.	x/2	
Training – DinoLite Measuring Microscope		xx/5
• Measurements on two interesting small items	x/5	
Device Deconstruction		xx/25
• Pictures of the intact device	x/2	
• Pictures of the wider work area	x/2	
• Pictures of the deconstructed device	x/7	
• Identification of …		
○ Internal/external device <u>features</u> (i.e., optoelectronic components, light-management features, …)	x/5	
○ Internal/external device <u>measurements</u> (i.e., optoelectronic components, light-management features, …)	x/5	
○ Materials	x/2	
○ Electronic components	x/2	
Ethical Implications		xx/10
• Articles (3 or 4)	x/4	
• Steer away from "reverse engineering"	x/2	
• Messages regarding ownership of ideas and their release (e.g., patent ownership and public release of teardown information)	x/4	
Project Mechanics		**Subtotal:** xx/15
• Word file submission	x/2	
• Proper report sections (title page, table of contents, section-by-section record of activities, and references)	x/5	
• Attribution for non-original material	x/3	
• Overall quality of work (readable; high-quality images;)	x/5	