INTELLICOSTING


# APPLYING FORENSIC COST ANALYSIS METHODS TO MEDICAL DEVICES

*Exploring cost teardowns of a consumer-grade pulse oximeter and electrocardiogram, based on the physics of the manufacturing and assembly processes.*

Forensic cost analysis methods have already gained traction in the automotive industry, which has long recognized the value of determining an accurate cost of components and assemblies based on realistic labor and materials costs, as well as the physics of manufacturing processes. What you might not know is that the lessons learned from automotive costing easily transfer to medical products, devices and equipment.

Unlike traditional cost analysis methods, which rely on historical cost data and estimates about manufacturing inputs, the forensic cost analysis approach is based primarily on the physics of all the manufacturing and assembly processes needed to produce a finished device. For example, we would derive the cost of molding a plastic housing component given its polymer, projected area, wall thickness and other attributes. Due to its high level of detail, we can base our analysis on specific molding machines that produce the parts at a specific cycle time.

Forensic costing repeats this process for every single mechanical and electronic component in a device's bill of materials. The models also add in the full range of traditional fixed and variable cost factors including capital equipment amortization, maintenance, taxes, insurance, research and development (R&D) and sales costs.

To illustrate what forensic cost analysis looks like for high-volume, mass produced medical devices, here are two teardowns of a pulse oximeter and TCL5007 electrocardiogram (ECG).

## PULSE OXIMETER COST ANALYSIS

Widely used through the COVID-19 pandemic, pulse oximeters employ light beams to estimate blood oxygen saturation and pulse rate without the need to draw blood samples. The following cost study focuses on an off-the-shelf, consumer-grade device from Walgreens. We performed a detailed cost analysis of every single component that makes up the device — right down to the labels. For the pulse oximeter, our analysis broadly fell into two device categories: the mechanical components and the electronics.


**Mechanical components.** For our mechanical analysis, we started by removing, weighing and photographing each component that makes up the device, capturing information on material type, dimensions, country of manufacture and quantity using proprietary costing software. This software allows our estimators to apply forensic costing models that identify the manufacturing and assembly operations for each component in the device. These models also provide us with a detailed understanding of the costs associated with a wide variety of manufacturing processes including machining, stamping, injection molding, heat treatment and plating.

Next, we accounted for the capital expenses, number of operators, scrap rates, raw material usage, raw material price, indirect labor, number out at each operation, burden, selling, general and administrative (SG&A) expenses and profit associated with the various mechanical components. In general, we can optionally adjust our models for labor rates, country of manufacture by operation, capital, SG&A and profit.

**Electronic components.** Our analysis of the pulse oximeter's electronic components also began with device disassembly, during which we noted manufacturing processes and design for manufacturability (DFM) concerns. We also took many photographs to document the teardown process. From there, we categorized all the electronic components by individual boards and circuits and applied cost models to each component by function — passive, discrete, active, application-specific integrated circuits (ASIC) and custom components.

Our electronics analysis often includes advanced methods to understand costs and, in many cases, we will apply forensic delayering, X-rays and microscopic photography to discover die area and manufacturer information. We also examine circuit board substrate materials to determine manufacturing process and material costs — including coatings, potting and flex material — and we assess design requirements like software, hardware design, mechanical design, test, validation and systems. For the pulse oximeter's electronics, we accounted for manufacturing factors such as capital requirements, labor, burden, SG&A and profit using machine cost models that analyze cycle times and line layout.

After compiling the mechanical and electronics findings into our final report, we found that the pulse oximeter's total manufacturing cost is just over $11 — not bad for a device that retails for as much as $40. Because this project is just a demonstration and not a customer project, we made a few assumptions about product volumes, location of manufacturing and assembly, labor rate and other cost factors. We based these assumptions on our experience analyzing other high-volume electronic devices.

## ECG COST ANALYSIS

This second example demonstrates how we can apply forensic cost analysis methods to a consumer-grade TCL5007 ECG, which detects the heart's electrical activity to record heart rate and rhythm. A commonly used medical instrument, ECGs play a role in most medical offices. Again, we took a forensic approach to cost analysis, breaking down and investigating each individual mechanical and electronic subcomponent within the product.

**Mechanical components.** First, we disassembled the finished ECG product and photographed and weighed each mechanical component.

Our proprietary software — which considers material type, quantity of components, country of manufacture and physical dimensions — enabled us to gain key insights into the costs of many manufacturing processes. After receiving these inputs, the models accounted for capital, number of operators, scrap rates, raw material usage, raw material price, indirect labor, number out at each operation, burden, SG&A and profit.

**Electronic components.** Like the mechanical components, we removed all the ECG's electronic pieces and photographed and weighed them, providing additional notes on DFM concerns and manufacturing processes. Next, we categorized the components by individual boards, circuits and mechanical assemblies. Afterwards, we evaluated and applied our cost models to the components by function of passive, discrete, active, ASIC and custom components.

In addition, we applied forensic physical delayering techniques to further extract die area and manufacturing information. To determine the manufacturing processes and material costs for coatings, potting and flex material, we examined each circuit board substrate material and considered design requirements like software, hardware design, mechanical design, testing, validation and systems. As with the mechanical costing, we investigated the manufacturing factors associated with capital requirements, labor, burden and SG&A using machine models to analyze cycle times and line layout.

After this comprehensive analysis of the TCL5007 ECG, we determined that the total cost to manufacture each unit is in the $50 to $60 range. The price for this device at a popular consumer-grade retailer is roughly $240.

## THE ADVANTAGES OF FORENSIC COST ANALYSIS

By establishing the cost baseline of a product, forensic cost analysis provides manufacturers with a roadmap to further reduce costs. As demonstrated by the pulse oximeter and ECG examples, this method creates a helpful reference point that lays out all material, manufacturing and assembly costs that manufacturers can then target to unlock savings. Can the wall thickness of a mechanical component be reduced, for example? Does the device require such a high number of fasteners? These are examples of some of the questions manufacturers can ask once they understand a product's true cost.

Beyond medical and automotive applications, the applications and benefits associated with forensic cost analysis span a wide range of industries like energy systems, electronics, military, aerospace and consumer products.

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