

A close-up of a medical monitor screen showing vital signs in red digital text: SYS. 141, DIA. 84, MAP 10.9, and a heart rate of 71. The screen is part of a larger medical device with a white frame.

Case Study

Background

Medical devices, once accepted, have long product lives. Customers want and expect the medical device manufacturer to provide repair and refurbishment (refurb) services that maximize the device's useful life in a cost effective way.

Problem Statement

Repair and refurbishment of long-lived products requires different processes, systems and equipment for the original manufacturing processes. The responsibility to support customer needs typically falls to the OEM field service organizations and few medical device manufacturers are so equipped to manage repair and refurbishment effectively.

Medical Device Repair and Refurbishment

Medical Center of Excellence

NEO Tech has been working with numerous major global medical OEM's for more than 20 years providing a wide breadth of service solutions. NEO Tech offers Medical OEMs Engineering services, PCBA, microelectronics assembly, box assembly, electromechanical assembly and aftermarket repair & refurbishment services.

NEO Tech's Otay Mesa site in Tijuana Mexico is one of NEO Tech's medical Center of Excellence (COE) locations. The company has a dedicated repair facility within the COE. The main purpose of the COE is a concentration of expertise by subject matter, providing medical OEMs a service location that fully understands the quality, reliability and regulatory needs of the medical industry. Tijuana and the northern Baja region are particularly well suited for supporting the medical industry. There is a high concentration of Medical OEMs and many mission critical suppliers in the local area with deep experience building products for the medical industry, creating very effective medical ecosystems.

Repair and Refurbishment

NEOTech builds PCBAs, sub-assemblies and finished medical devices (FMDs) for medical device manufacturers. Many of these devices are integrated into hospital systems such as medication management and operating theatre systems increasing the difficulty of upgrading to a newer version of the device. The useful life of devices supporting these hospital systems can be extended with repair and refurbishment services.

Many manufacturers use their field service organizations to repair devices. This is a satisfactory solution for emergency and for simpler, stand-alone devices. But field service is too limited for systems or devices that are integrated into specialized systems. The solution often is a service depot that specializes in device repair and refurbishment; preferably co-located with the device manufacturing site. Fault diagnosis and analysis done in the depot can be used by sustaining engineering to design device improvements in the existing device as well as product managers with "next-gen" device requirements.



"We manufactured the original parts so it was a natural extension to perform repairs and eventually refurb. So we had intimate product knowledge as well as a single-piece flow manufacturing process that made it easier to absorb surges in returns that differentiated NEO Tech," said David Busch, NEO Tech's Vice President of Medical.

The dawning of a new service began, and NEO Tech worked to repair, refurbish/reclaim and refresh a broad range of medical devices. The service provides the customer with cost savings as well as significant time savings and accuracy benefits. It also addresses the customer's need for product continuity. Many of these systems are mechanical in nature so, eventually, components wear out and fail requiring replacement.

In the case of medication management products the cabinets and drawers are very precise and critical to the overall system function.

It was difficult for the medical facilities to go without them while they waited for replacements. The medical facilities asked NEO Tech's customer for "used" drawers and cubbies to quickly replace the worn/damaged units. The customer asked

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NEO Tech to propose how to fulfill this new requirement, which the company successfully did. NEO Tech saw the customer's need and stepped up immediately to help them, installing a like-for-like repair service that satisfied the need to minimize system downtime.

Improved Efficiency

If new products are the primary focus, a close second is repair and refurb. The COE recently was expanded to become a state-of-the-art facility for repair and refurb, based on industry – and customer – demand and need. This is beneficial to customers because it provides improved efficiency resulting in significant cost savings for OEM's bottom lines. Typically, material is 40-50 percent of a medical device's cost; reusing material costs via repair/refurbishment both saves these costs and also has the added benefit of reducing the waste stream if the same products are disposed.

Flexibly Managing High-Mix products

NEO Tech's COE is unique because it produces a high-mix of products, hence a wide variety of products are sent back to the center to be repaired or refurbished. The facility must be flexible enough to meet various needs – more than a thousand different SKUs come through the center. Therefore, skillful planning, resource allocation and skilled operators are a must.

The facility is set up in cells, as opposed to lines, and there are four of them dedicated to the repair and refurbishment of medical products. These cells can be reconfigured depending on the product that comes through, enabling NEO Tech to fix different types of products, materials and more. Setting up processes in a dedicated unit saves money because they are done in one central location. Tijuana is the most logical choice for this because it offers a lower cost structure and better quality products, as well as reduces medical contamination and scrap. Almost all of the returned material is custom and specialized and can be reinserted into useable medical devices.

Decontamination / Sterilization

Decontamination of inbound products is sometimes needed and can be performed either by customers or NEO Tech. In the case of medication management products NEO Tech receives medical cabinets, cubbies and drawers to repair or refurbish. Before they are sent to the COE, NEO Tech ensures that each has been thoroughly inspected to remove any spilled or wayward drugs before shipping them across the border. They are sterilized if necessary. NEO Tech then goes through the diagnostics of each product individually to determine if it is repairable or if it is scrap. If it is repairable, it is further determined if the fix is cosmetic or mechanical, and sent to the appropriate area to be worked on.

Sterilization of finished products can be performed again by customers or NEO Tech. Scrap can be dispositioned per environmental and safety standards with certifications back to the customer.

Traceability

NEO Tech offers either same-for-same or like-for-like repair services for the major components of a medical device such as PCBA diagnostics and repair, sub-assembly functional test and repair, and finished medical device (FMD) functional test and repair. Diagnostic services can be performed by customers or at NEO Tech. NEO Tech provides traceability and genealogy of repairs that support same-for-same repairs via its custom MES – Clarity.

A difference between general purpose electronics and medical programs is that with medical, companies must validate processes, eg. Maintain a detailed log of what has been

removed, replaced, etc. The regulatory aspect is key and medical COE's must be able to handle a high number of SKUs, which means they carry enough spare parts to repair efficiently. NEO Tech's COE is able to meet all of these exacting requirements in-house. Being able supply refurb alongside new provides the OEM added flexibility for spikes in demand.

Cost Savings and Benefits

In addition to meeting the stringent regulatory approvals, NEO Tech's services provide financial benefits by taking the cost off of the OEM which improves their bottom line, and simplifies OEMs' sales/field service departments by subcontracting the repair/refurb and enable them to focus on sales versus supply chain and operations. It also has environmental advantages (reuse vs. scrap). Product marketing advantages can be



achieved also where in cost critical emerging markets they can sell a refurbished system at a lower price point than a new system expanding the potential markets served.

As part of NEO Tech's refurb and reclaim service, the company can diagnose sub-assemblies and FMDs, and either refurb or scrap/reclaim sub-assemblies or FMDs based on customers' guidelines or perform refurb and reclaim on customer diagnosed units.

Product Refresh

An additional part of the NEO Tech aftermarket service offering – product refresh – is for when replacement parts are no longer available for a device to be repaired or refurbished. NEO Tech's product design engineering group can provide redesign services, upgrading obsolete components, or adding needed new product features. This is particularly valuable for older devices whose components have gone or are going end-of-life (EOL) and for which there is long-range demand.

Conclusion

Repairing, refurbing and/or refreshing products can be seen as a distraction by some medical device companies whose focus is on bringing new technology to market. Busch explained, "Innovation is the company differentiator and majority income source. Repairing and refurbishing 'old products' is not seen as a differentiator and not what most people want to work on even though it is highly critical to the end user, makes the product more sustainable and is a competitive marketing advantage." NEO Tech is happy to lend its experience and skill to provide cost and accuracy benefits to its medical device customers.

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