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Product development of CT scanner and other medical devices post Covid pandemic

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Abstract : The COVID-19 pandemic has had a severe impact on medical device manufacturing, with disruptions at both the device and component level due to lockdowns and social distancing measures. While the post pandemic effects on medical device development is well understood, there is a need for a comprehensive review of the impact on medical device design and manufacturing and to address emerging trends due to component shortages. This paper aims to provide an assessment of the effects of increased demand for medical devices and propose a new model addressing the impact of just-in-time (JIT) manufacturing practices, rapid design change and validation strategies being undertaken, the transformation of the medical device repair and service industry, FDA and regulatory changes, provide a view on future trends in both R&D and manufacturing of medical devices.

Index Terms **- FDA, Medical Device, Part shortage, Healthcare, CT scanner.**

I. INTRODUCTION

The objective of this paper is to examine the supply chain challenges that arose in the aftermath of the COVID-19 pandemic in 2020, with a specific focus on their implications for electronic parts and their impact on medical device manufacturers. As many countries implemented shutdowns and social distancing measures, it resulted in the closure of manufacturing plants across the globe. This caused unprecedented part shortages within electronics industry and quickly spread to medical device manufacturing. The Economic Bulletin of 2021 by the European Central Bank pointed out that in the latter part of 2020, global production experienced strains due to imbalances between the supply and demand of specific goods, which impede global economic recovery (Economic bulletin,2021). Since the medical device industry also relied heavily on complex electronic components, reduced manufacturing and fewer medical devices lead to several health crisis. Manufacturers faced challenges in producing a wide range of medical devices, including diagnostic equipment as well as life-saving devices such as ventilators and defibrillators. An original equipment manufacturer (OEM) that manufactures medical devices would normally consider lead time, bill of materials (BOM) cost, and inventory requirements when planning production. This approach is effective for build-to-order manufacturing and stable product life cycles. However, it becomes inadequate when product demand surged, and parts sourcing is hindered by disruptions in the supply chain. Such disruptions combined with continued material shortage and increased operating cost, will negatively impacting overall profit margins. For medical device manufacturers to succeed and continue to innovate, they need to effectively manage supply chain risks and enhance product availability. This paper highlights the importance of having resilient and responsive supply chain, regulatory challenges, and methods to address design validation, during times of crisis.

II. LITERATURE SURVEY: MEDICAL DEVICE TRENDS

In response to the global impact of the Covid-19 pandemic, many countries made significant investments to enhance public access to healthcare infrastructure. Additionally, private health organizations, hospitals, and NGO's (non-government organizations) proactively stocked up on critical care devices, such as defibrillators, diagnostic and monitoring devices, ventilators, and other patient monitoring devices. During the pandemic, ensuring the availability of medical equipment was paramount to deliver essential patient care. The need for COVID-19 testing led to increased demand for testing and diagnostic devices, including PCR machines, rapid antigen tests, and other testing kits. Testing has been a critical tool in identifying cases, contact tracing, and controlling the spread of the virus, driving increased demand for testing and diagnostic devices. For example, the use of CT scan increased during the COVID-19 pandemic and attributable to the respiratory related emergency department (ED) visits (Timothy M. Loftus, 2022). With lockdowns and social distancing measures in place, there was an increased demand for home healthcare devices such as home oxygen therapy equipment, remote monitoring devices, and other medical devices that allow patients to receive care at home, reducing the need for hospital visits.

With companies grappling to meet demand surge, FDA played a crucial role by issuing emergency authorizations and collaborating with manufacturers to expedite product approvals. For instance, the FDA authorized the use of Ventilator Splitters during the COVID-19 pandemic, enabling the delivery of treatments to multiple patients using a single ventilator (FDA Letter to Health Care Providers, 2020). Such measures helped companies prioritize their validation efforts and ensure that their product

performance met essential patient safety requirements, thereby reducing delays in bringing products to market, including therapy, diagnostic imaging, and patient monitoring systems. The FDA's Guidance released in April 2020 (FDA guidance 2020) provided detailed proposals to expand the use of existing products available in hospitals, such as expanding the use of imaging systems previously categorized as fixed installation to now be considered for use in a mobile clinical environment. This illustrates the severity of the healthcare crisis and the transformative impact it had on the medical device manufacturing industry due to unprecedented regulatory changes.

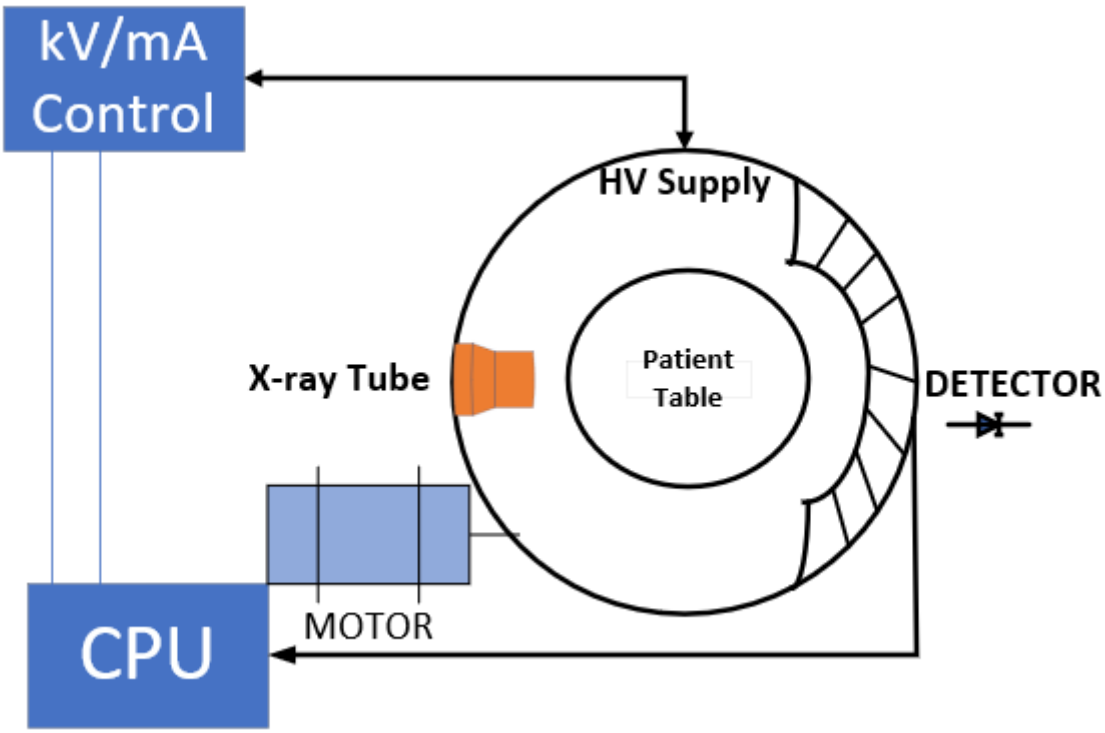

Figure 1: CT System architecture

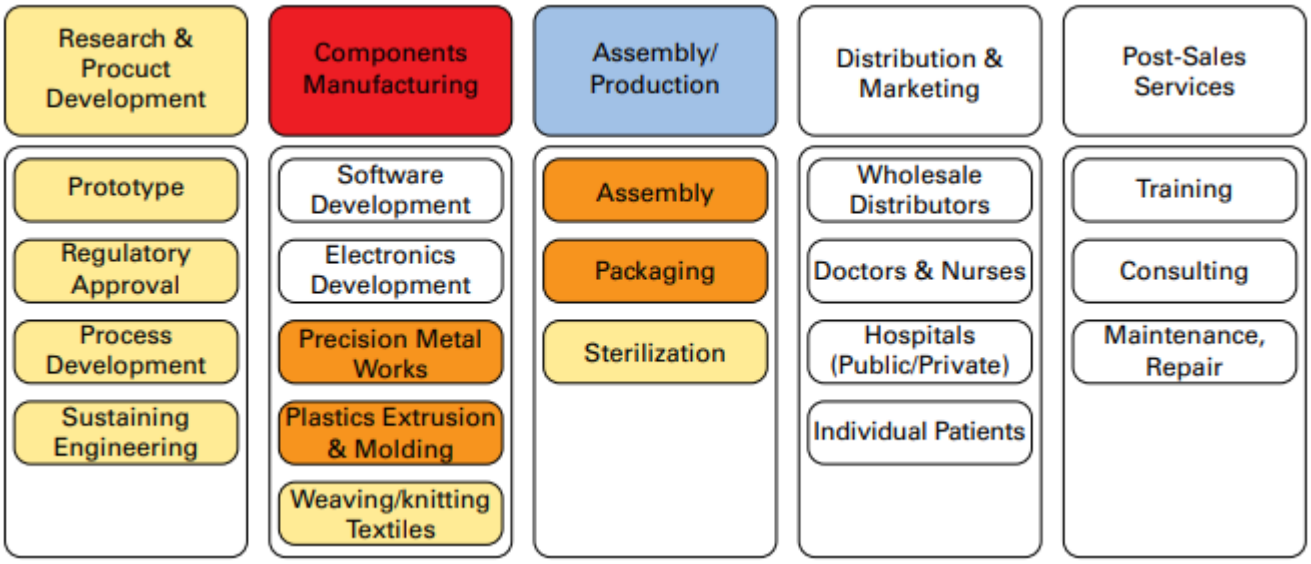

Figure 2: CT device manufacturing (Gereffi's (2016).

III. JUST IN TIME MANUFACTURING AND ITS IMPLICATIONS

The implementation of Just-in-Time (JIT) manufacturing practices can enhance supply chain efficiency and reduce inventory costs. JIT is a versatile tool that can be applied to both domestic manufacturing operations and operations spanning multiple geographical locations. In the medical device manufacturing industry, JIT principles are commonly followed to source parts from various locations both domestically and internationally, to build assemblies that meet the regulatory requirements of different nations. JIT supply chain management is also prevalent in other industries, such as wood and non-metallic mineral products, where approximately 30% of companies report participation in JIT supply chains (Frank Pisch,2020). Medical device manufacturers often rely on multiple contract manufacturers to produce various parts such as printed circuit boards, passive components like resistors, capacitors, and inductors, digital components like FPGAs, microcontrollers, and processors, cable assemblies, sensors, transducers, and more. Depending on the customer locations, similar assemblies may be sourced from different vendors. For instance, products intended for sale in India may be procured locally and assembled within the country. This approach helps in reducing inventory costs as manufacturers do not need to maintain excessive inventories.

As Frank Pisch highlighted in his study on just-in-time supply chains and global production, suppliers that adopt JIT practices may prioritize their own profits, sometimes at the expense of downstream buyers (Frank Pisch,2020). However, implementing a model of vertical integration and multi-plant firms with incentives for individual organizations can enhance overall supply chain efficiency. This approach encourages collaboration and alignment of goals among different entities in the supply chain, leading to improved performance and outcomes. While just in time (JIT) supply chain management was preferred by medical device manufacturers, the shortage of components since 2020 put pressure on their operations and companies struggled to keep up with demand. Companies needed to quickly identify alternate components that are suitable for their application and undergo design validation to comply with FDA requirements.

IV. PROPOSED MODEL: USING RAPID DESIGN METHODOLOGIES AND COMPONENT VALIDATION

One critical aspect in production development is finding Bill of Materials (BOM) alternates in the shortest possible time. This was not easy during Covid induced chip shortages, since medical devices use several critical microprocessors and FPGA, which are not easy to redesign without detailed validation, documentation, and approval process which can take several months. Once acceptable parts are identified and tested for functional requirements, the supply chain needs to swiftly procure new inventory and implement changes through contract manufacturers. The ability to rapidly identify alternative components directly impacts the ability of companies to continue shipping medical devices to hospitals and EMS customers, requiring them to innovate and bring products to market more efficiently. This entails investing in product redesign, leveraging technological advancements, and staying updated with changing regulatory requirements. Efficient BOM alternate identification can contribute to improving overall product performance, patient safety, and navigating the dynamic landscape of the medical device industry.

When faced with a shortage of alternative components, medical device manufacturers may have to make strategic decisions regarding complex integrated circuit (IC) selection. A new model is proposed to expedite product development and address part shortage issues.

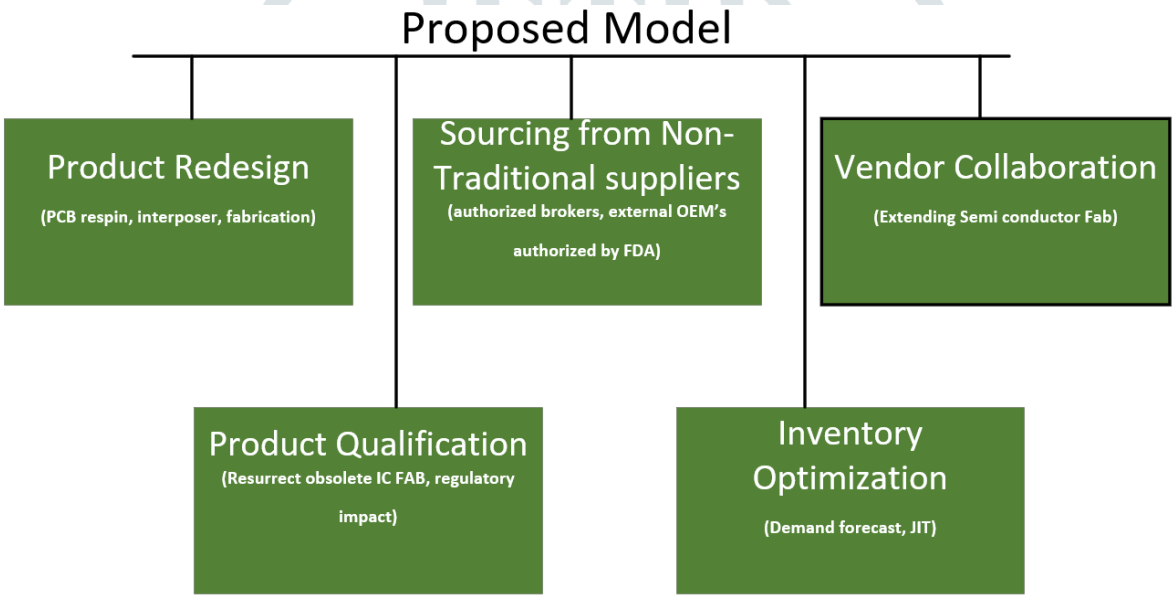

Figure 3: Proposed Product development Model.

Redesign: Manufacturers may opt to redesign their product to accommodate available ICs with similar functionalities or specifications. This could involve making modifications to the device's design, software, or functionality to ensure compatibility with the available ICs. For instance, interposer PCB design can be used to facilitate the use of alternate packages when the desired component with the right footprint is unavailable. Although the interposer design is not new, this PCB fabrication method helped address ongoing challenges with component shortages in the medical device industry.

Sourcing from Non-Traditional Suppliers: In some cases, manufacturers may need to explore non-traditional suppliers or markets to find available ICs. This could involve searching for ICs from different regions or countries or considering suppliers that were not previously part of their usual supply chain. When sourcing parts from non-traditional suppliers, it's important to ensure the quality and authenticity of the components, as counterfeit or substandard parts can pose risks to the performance and reliability of the final product. Thoroughly vetting the non-traditional suppliers, verifying their credentials, and testing for compliance with relevant standards and specifications are essential steps in the sourcing process.

Vendor Collaboration: Manufacturers may collaborate with their IC vendors to find suitable alternatives. This could involve working closely with the IC vendors to identify potential substitutes or exploring options for custom fabrication or modification of existing ICs to meet their specific requirements.

Product Qualification: If suitable alternate integrated circuits (ICs) are not available, manufacturers may need to initiate the qualification process for new ICs that offer similar functionalities as the originally planned components. This may require resurrecting obsolete fabrication techniques, conducting thorough validation tests, and ensuring compliance with regulatory requirements to ensure the performance, safety, and efficacy of the newly manufactured components. This process may involve extensive efforts to evaluate the equivalency of the new ICs, validate their performance, and ensure they meet regulatory standards to maintain product quality and reliability.

Inventory Optimization: Medical device manufacturers need to optimize their inventory management practices, including closely monitoring inventory levels, streamline processes, implementing demand forecasting, and adopting just-in-time (JIT) inventory strategies to minimize reliance on unavailable ICs and reduce the risk of shortages.

It is important to note that these examples are contingent upon the specific circumstances and regulatory requirements of each medical device manufacturer. Proper due diligence, including consultation with experts and compliance with regulatory guidelines, should be followed to ensure the safety and efficacy of medical devices in the market.

Validation of medical device components is a crucial process aimed at ensuring the safety, effectiveness, and compliance with specifications of components used in medical devices. When incorporating alternate components into existing products, a systematic approach encompassing design, manufacturing, and testing is necessary. Therefore, medical device component validation can leverage advanced testing techniques, and methodologies to ensure the functionality, reliability, and safety of the substituted components. Examples of new component validation techniques include:

Simulation and Modeling: Using advanced simulation and modeling techniques to assess the performance and compatibility of alternate device's circuitry. This may involve computer-aided design (CAD) simulations, finite element analysis (FEA), and other modeling tools to simulate the behavior of the device under different operating conditions.

Testing and Characterization: Conducting rigorous testing and characterization of alternate parts to evaluate their electrical, thermal, mechanical, and reliability properties. This may involve accelerated life testing (ALT), environmental testing, stress testing, and other specialized tests to ensure that the alternate parts meet the required specifications and performance standards.

Validation and Verification: Implementing robust validation and verification processes to ensure that the alternate parts function as intended in the specific medical device application. This may involve conducting functional testing, performance testing, and safety testing to verify the compatibility of the alternate parts with the device's intended use and regulatory requirements.

Real-time Monitoring and Control: Utilizing real-time monitoring and control systems to continuously monitor the performance of alternate parts in the field and ensure that they meet the expected performance levels. This may involve implementing sensor-based monitoring, data analytics, and remote monitoring to detect any deviations in performance and take corrective actions in a timely manner.

Regulatory testing and standards: To validate medical device components, adherence to regulatory testing and standards is essential. In the United States, medical devices must undergo FDA approval, while in the European Union, the European Medicines Agency regulates the process. For electronic components used in medical devices, compliance with IEC60601-1 requirements, which serve as design guidelines for both FDA and EU, is crucial.

V. RESULTS AND DISCUSSION

4.1 Results of proposed model.

According to the GEP Global Supply Chain Indicator, the volatility index has decreased significantly from a peak value of approximately 7.0 in December 2022 to the lowest value of 0.48 in March 2023 (GEP, 2020). A higher index value typically indicates increased transportation costs, stockpiling, item shortages, and backlogs resulting from supply chain constraints. A recent study published (McKinsey 2022) discusses the evolving landscape of components, with automotive suppliers adapting their portfolios. The study predicts that from 2021 to 2030, less than half of the components will remain unchanged, while most electronic parts are expected to present growth opportunities. In response, component manufacturers are anticipated to reimagine their process capabilities, diversify their product mix, shift away from capital-intensive plants, and optimize individual plants to generate higher return on investments (ROI).

With advancements in electronic component availability and the emergence of new materials through technological innovation, medical device manufacturers must proactively adapt to new manufacturing processes, consider material substitutions, expand distribution channels, and diversify operations. It is crucial to maintain adequate inventory levels and normalize backlogs to mitigate supply chain challenges and enable swift recovery from unexpected shifts in product demand or supply shortages. Strategic planning and agile operational management are essential to ensure uninterrupted supply chain operations and swift recovery from potential disruptions in the dynamic medical device industry.

As public awareness about healthcare increases and nations invests more in public health management, hospitals worldwide are recognizing the importance of ensuring the availability of diagnostic and treatment devices. This is expected to drive an increase in demand for medical devices. Just-in-time (JIT) inventory practices, which aim to minimize inventory levels, may prove to be more expensive for hospitals compared to periodic ordering and frequent inventory stock-up. Research conducted in the field of behavioral economics has examined different inventory policies in the context of the COVID-19 pandemic and has found that regular order and reorder policies are economically viable and can minimize wastage. As a result, it is anticipated that supply chains will continue to face challenges, as medical original equipment manufacturers (OEMs) invest in and enhance their supply chain processes. Despite efforts to expand electronic component manufacturing and establish new plants globally, it may take years before the industry can witness a surplus of parts. During this time, medical device manufacturers may need to phase out outdated devices, accelerate the adoption of new technologies, and their growth prospects will depend heavily on the availability of diverse parts in the market. This situation could lead to equity issues, where companies with greater purchasing power are more likely to navigate the crisis successfully, while startups and smaller companies may continue to struggle.

4.2 Conclusion.

The shortage of electronic parts has had a significant impact on the medical device industry, leading to a national health crisis. While the industry is gradually recovering from supply chain issues, returning to the pre-pandemic supply chain environment, it will likely take a considerable amount of time for majority of manufacturers to get back to normal operations. he availability of

electronic parts plays a crucial role in the development of advanced medical devices that often rely on sophisticated integrated circuits. Insufficient availability of these components can disrupt innovation and result in a shortage of patient care and therapeutic devices, as witnessed during the COVID-19 pandemic. Companies that can make significant investments in product redesign and implementing supply chain mitigation strategies are more likely to succeed in this challenging environment. However, there are various challenges, such as technological limitations and geopolitical pressures, that may hinder global trade and the movement of electronic components across nations. As highlighted in this research paper, the adoption of new design validation methodologies, along with a favorable regulatory environment, can potentially provide a boost to medical original equipment manufacturers (OEMs), including the repair and service industry. These measures can help overcome obstacles and facilitate the availability of electronic parts, enabling medical OEMs to continue their operations smoothly and contribute to the development of innovative medical devices.

VI. ACKNOWLEDGMENT

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REFERENCES

[1]European central bank in Economic bulletin, pp. 52, Issue 8, 2021. [Online]. Available: https://www.ecb.europa.eu/pub/pdf/ecbu/eb202108.e n.pdf.
[2] FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices In accordance with Section 710 of the Food and Drug Administration Reauthorization Act of 2017 (FDARA).
[3] Frank Pisch, “Covid-19 and the future of international supply chains”, Centerpiece, pp 3-4, Summer 2020. [online] Available: https://cep.lse.ac .uk/pubs/download/cp584.pdf.
[4] Global eProcure, GEP, 2020 Accessed [online]. Available: https://www.ge p.com/knowledge-bank/global-supply-chain-volatility-index.
[5] Using Ventilator Splitters During the COVID-19 Pandemic - Letter to Health Care Providers, 2020. [online]. Available: https://www.fda.gov/medical-devices/letters-health-care-providers/using-ventilator-splitters-during-covid-19-pandemic-letter-health-care-providers.
[6] Guidance for Industry and Food Drug Administration Staff, pp. 09, April 2020, [online]. Available: https://www.federalregister.gov/d/2023-05094.
[7] McKinsey insights., “Amid disruption, automotive suppliers must reimagine their footprints”, April 2022. https://www.mckinsey.co m/industries/automotive-and-assembly/our-insights/amid-disruption-automotive-suppliers-must-reimagine-their-footprints#/
[8] Timothy M. Loftus, et al., “Impact of the COVID pandemic on emergency department CT utilization: where do we go from here?” American Society of Emergency Radiology pp. 882, Springer, 2022.
[9]FDA, Computer tomography, 2023, [online] Available:https://www.fda.gov/radiation-emitting-products/medical-x-ray imaging/computed-tomography-ct.
[10] Gereffi, Gary. (2016). Global Value Chains and Upgrading: Export Promotion in FTZs. World FZO Bulletin. 2-11.