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Product Design Brief

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1. Document Brief

(Mumby, 2023) The company has identified an opportunity to extend its chemical alcohol detector system, used in breathalysers, to detect organic materials linked to virus infections. Following successful laboratory trials and patent registrations, the company aims to rapidly develop and launch a new 'Virus Detect' product. However, existing breathalysers cannot be used as a foundation, necessitating a completely new design. The company has prototyped electronic and mechanical systems and will collaborate with a London-based firm for the physical design. The manufacturing strategy will involve outsourcing electronic and mechanical components, while final assembly, testing, packing, and shipping will be conducted at the Welshpool factory. The CEO and Finance Director are seeking alternative suppliers to potentially reduce manufacturing costs.

2. Synopsis

In the authors previous Assignment (Monks, et al. 2023), the Chemical Detector System (CDS) was presented as an advanced home health hub designed for comprehensive health management for parents and children. With its state-of-the-art chemical detection technology, the CDS swiftly identifies and addresses infectious disorders, including those associated with the COVID-19 pandemic, by analysing breath samples for viral particles and biomarkers. Alongside this capability, the system offers additional features such as vital sign recording, medication reminders, symptom tracking, and personalized recommendations. By embracing this holistic approach, parents are empowered to vigilantly monitor their children's health in a thorough and efficient manner.

The home health hub from the Chemical Detector System holds a transformative potential to uplift family and children's well-being. Its design, grounded in sophisticated technology, offers an intuitive and comprehensive health management solution, aiming to elevate the health status of both individuals and families. With a solid foundation of precision, dependability, efficacy, and ease of use, the product is dedicated to fostering a society that is healthier and more robust.

3. New Market Potential

(Monks, et al. 2023) The CDS home health hub offers a unique opportunity to enter not only the health management market but also the indoor air quality monitoring market. With indoor air pollution becoming a global concern and the COVID-19 pandemic emphasising the importance of healthy indoor spaces (Saini et al., 2021), the CDS home health hub presents a compelling solution for homeowners, property managers, and businesses.

Leveraging cutting-edge chemical detection technology, the CDS effectively identifies and tracks various indoor pollutants such as volatile organic compounds, carbon monoxide, and other harmful gases (Buszewski et al., 2013). This technology provides real-time data, enabling users to proactively enhance air quality and limit exposure to damaging pollutants (Benammar et al., 2018). Key attributes of the CDS system include alerts for when pollutant concentrations surpass safe limits, customized suggestions to improve air quality, and a feature to monitor pollutant trends over time.

According to GIA (2023), the indoor air quality monitoring sector is expected to grow at a 9.6% compound annual rate from 2022 to 2030, hitting an approximate value of \$8.3 billion by 2030. This trend is largely fuelled by increased consciousness about health hazards related to indoor air pollution, the push for environmentally friendly construction, and the post-pandemic demand for healthier indoor settings (Sun et al., 2019). The CDS home health hub, with its novel approach to indoor air quality monitoring and integration of existing health management features, is strategically poised to exploit this growing market opportunity, providing a holistic health and wellness solution to its desired clientele.

4. Design Brief

The Design Brief section outlines the essential considerations, requirements, and specifications for the development of the Chemical Detector System home health hub. This guide covers various aspects, from aesthetics and branding to safety and performance, ensuring a successful product launch that meets user expectations and market demands. By addressing each heading in the design brief, we aim to create a reliable, effective, and user-friendly product that promotes health and well-being in indoor environments (Campbell-Bones, 2022).

Aesthetics

Definition: Aesthetics refers to the visual appeal, design, and overall appearance of the product.

Brief:

- Visually attractive design
- Consistent with branding elements
- Appealing colour scheme and materials
- Modern and sleek appearance

Key Features: Modern design, user-friendly interface, user-changeable colour scheme that matches home interiors.

Key Engineering Features: Ergonomically designed buttons or touch screen, LED indicators, clear and easy-to-read display.

Recommendations: Incorporate user preferences and feedback during the design process to ensure the product's visual appeal aligns with customer expectations.

Standards and Regulations: ISO 9241-210:2019: Ergonomics of human-system interaction - Part 210: Human-centred design for interactive systems (covers user-centred design, which can include aesthetics) (anon, 2019a).

Cross Referencing: Branding, Ergonomics, Materials, Size, Weight

Branding

Definition: Branding pertains to the product's identity, including its name, logo, and other design elements that convey its value proposition and connect with customers.

Brief:

- Strong brand identity
- Clear value proposition
- Cohesive design elements across packaging and product
- Consistency with company's overall brand strategy

Key Features: Clear and consistent branding, easy-to-recognise logo, company colours and fonts.

Key Engineering Features: Branding on the exterior of the device, packaging, and user manuals.

Recommendations: Conduct market research to identify effective branding strategies that resonate with the target audience and differentiate the product from competitors.

Standards and Regulations: No specific ISO standards or regulations apply to branding. However, branding should follow industry best practices and consider target audiences (parents and children).

Cross Referencing: Aesthetics, Company Constraints, Environment, Market Constraints, Packaging

Company Constraints

Definition: Company constraints include internal factors such as budget, resources, and company policies that may impact the product development process.

Brief:

- Limited budget for development and marketing
- Availability of skilled personnel and resources
- Existing company policies and guidelines
- Time and resource allocation among other ongoing projects

Key Features: Budget limitations, resource availability, company values and vision.

Key Engineering Features: Design within budget, use of available resources, adherence to company vision in product design.

Recommendations: Perform an in-depth analysis of the company's resources, capabilities, and limitations to determine the feasibility of the project and to identify potential areas for improvement.

Standards and Regulations: ISO 9001:2015: Quality management systems - Requirements (relevant to company-wide quality management) (Anon, 2015a).

Cross Referencing: Finance, Intellectual Property, Legal, Logistics, Manufacturing Facilities, Processes

Customer

Definition: Customer refers to the target market and user base for the product, including their needs, preferences, and expectations.

Brief:

- Parents of young children
- Health-conscious individuals
- Seeking reliable and accurate health monitoring solutions
- Prioritise user-friendly and convenient devices

Key Features: User-friendly interface, ease of use, clear instructions, accessibility for all users.

Key Engineering Features: Intuitive user interface, easy installation, user guides and support.

Recommendations: Integrate user personas and user journey maps into the design process to better understand customer needs, preferences, and pain points.

Standards and Regulations: ISO/IEC Guide 14:2018: Purchase information on goods and services intended for consumers (covers customer-related information) (Anon, 2018a).

Cross Referencing: Aesthetics, Ergonomics, Performance, Quality, Safety, Social & Cultural

Circular Economy

Definition: Circular Economy is an economic model that promotes sustainability, waste reduction, and resource efficiency through the design, production, and end-of-life management of products.

Brief:

- Minimise waste during production and packaging
- Use of recyclable or biodegradable materials
- Design for easy disassembly and recycling
- Encourage repair, refurbishment, and reuse

Key Features: Recyclable materials, modular design for easy replacement and repair, energy-efficient operation.

Key Engineering Features: Selection of eco-friendly materials, designing for disassembly and recycling, energy-efficient electronics.

Recommendations: Explore potential partnerships with recycling or refurbishing facilities to minimise waste and maximise resource utilisation throughout the product life cycle.

Standards and Regulations: ISO 14021:2016: Environmental labels and declarations - Self-declared environmental claims (relevant to circular economy product claims) (anon, 2016a).

Cross Referencing: Environment, Materials, Packaging, Product Life Span, Standards & Specifications

Documentation

Definition: Documentation includes all necessary paperwork, manuals, and guides related to the product, ensuring compliance, and providing information for users and stakeholders.

Brief:

- User manual with clear instructions and illustrations
- Compliance and certification documents
- Maintenance and troubleshooting guide
- Materials and component specifications

Key Features: Clear and concise user manuals, quick start guides, safety information, maintenance instructions.

Key Engineering Features: Well-organised documentation, easily accessible resources, comprehensive technical specifications.

Recommendations: create a centralised documentation repository to ensure easy access and version control for all project-related documents.

Standards and Regulations: ISO/IEC/IEEE 26511:2018: Systems and software engineering - Requirements for managers of information for users of systems, software, and services (covers documentation requirements) (anon, 2018b).

Cross Referencing: Intellectual Property, Legal, Maintenance & Repair, Standards & Specifications

Environment

Definition: Environment refers to the ecological impact of the product throughout its lifecycle, from production to disposal.

Brief:

- Energy-efficient manufacturing processes
- Use of eco-friendly materials
- Minimised packaging waste
- End-of-life recycling and disposal options

Key Features: Energy efficiency, low environmental impact, sustainable materials, and packaging.

Key Engineering Features: Power management systems, use of recyclable materials, minimising waste in production.

Recommendations: Conduct an environmental impact assessment to identify potential risks and mitigate any negative consequences associated with the product.

Standards and Regulations: ISO 14001:2015: Environmental management systems - Requirements with guidance for use (relevant for environmental aspects of the product) (anon, 2015b).

Cross Referencing: Circular Economy, Materials, Packaging, Product Life Span, Standards & Specifications

Ergonomics

Definition: Ergonomics deals with the product's usability, comfort, and ease of use for the intended customer base.

Brief:

- User-friendly interface and controls
- Comfortable and intuitive design
- Easy to set up and operate
- Accommodates users of different ages and backgrounds

Key Features: Comfortable user experience, easy access to buttons and controls, intuitive design.

Key Engineering Features: Ergonomic shape and size, easily accessible ports and buttons, clear display.

Recommendations: User testing and ergonomic evaluations to optimise the product's design for comfort, ease of use, and accessibility.

Standards and Regulations: ISO 9241: Ergonomics of human-system interaction (series of standards covering various aspects of ergonomics) (anon, 2019a).

Cross Referencing: Aesthetics, Customer, Safety, Size, Weight

Finance

Definition: Finance encompasses the financial aspects of product development, including budgeting, pricing, and cost management.

Brief:

- Establish a realistic budget for product development
- Determine competitive pricing strategy
- Monitor and control development and production costs
- Evaluate return on investment and profitability

Key Features: Cost-effective design, competitive pricing, financial feasibility.

Key Engineering Features: Optimised component selection, minimising production costs, ensuring the project stays within budget.

Recommendations: Conduct regular financial tracking and reporting to monitor project costs, identify potential budget overruns, and ensure efficient allocation of resources.

Standards and Regulations: No specific ISO standards or regulations apply to finance.

Cross Referencing: Company Constraints, Installation, Logistics, Market Constraints, Product Cost

Installation

Definition: Installation refers to the process of setting up and integrating the product into the user's home or intended environment.

Brief:

- Easy and quick installation process
- Minimal tools and expertise required
- Clear and concise installation instructions
- Compatibility with various home environments

Key Features: Easy installation process, clear instructions, minimal tools required.

Key Engineering Features: Simple device setup, user-friendly installation guides, modular design for easy assembly.

Recommendations: Develop a comprehensive installation guide, tutorial videos, and other support materials to assist users in setting up the product.

Standards and Regulations: No specific ISO standards or regulations apply to installation. Regulations may vary depending on the country and industry.

Cross Referencing: Customer, Documentation, Ergonomics, Finance, Maintenance & Repair

Intellectual Property

Definition: Intellectual Property (IP) includes the patents, trademarks, copyrights, and trade secrets related to the product and its components.

Brief:

- Identify and protect patents for innovative technology
- Register trademarks for branding elements
- Maintain confidentiality of trade secrets
- Ensure compliance with IP laws and regulations

Key Features: Unique design elements, patented technology, protection of proprietary information.

Key Engineering Features: Developing and protecting innovative technology, filing for patents, maintaining trade secrets.

Recommendations: Conduct a patent search and consult with an IP attorney to identify and protect any novel aspects of the product.

Standards and Regulations: No specific ISO standards or regulations apply to intellectual property. National and international IP laws and regulations apply.

Cross Referencing: Company Constraints, Documentation, Legal

Legal

Definition: Legal pertains to the various laws, regulations, and standards that govern the development, manufacturing, and marketing of the product.

Brief:

- Adherence to safety and health regulations
- Compliance with international trade laws
- Respect of intellectual property rights
- Proper handling of customer data and privacy

Key Features: Compliance with laws and regulations, ethical practices, user privacy protection.

Key Engineering Features: Adhering to safety standards, ensuring data protection, maintaining user confidentiality.

Recommendations: Seek legal counsel to ensure compliance with all applicable laws and regulations governing the product's design, manufacturing, and distribution.

Standards and Regulations: No specific ISO standards or regulations apply to legal. National and international laws and regulations apply.

Cross Referencing: Company Constraints, Intellectual Property, Standards & Specifications

Life in Service

Definition: Life in Service refers to the period during which the product is expected to function effectively and meet user expectations.

Brief:

- Durable and high-quality materials
- Consistent and reliable performance
- Long-lasting sensors and components
- Support for software updates and improvements

Key Features: Durability, reliability, low maintenance requirements.

Key Engineering Features: Selecting high-quality components, designing for longevity, and ensuring ease of maintenance.

Recommendations: Develop a comprehensive after-sales support strategy, including warranty policies, troubleshooting guides, and customer service channels.

Standards and Regulations: No specific ISO standards or regulations apply to life in service.

Cross Referencing: Maintenance & Repair, Product Life Span, Quality, Reliability

Logistics

Definition: Logistics involves the planning, coordination, and execution of processes related to the transportation, storage, and delivery of the product.

Brief:

- Efficient supply chain management
- Timely delivery of raw materials and components
- Optimised inventory and storage solutions
- Effective transportation and distribution network

Key Features: Efficient supply chain management, streamlined shipping and distribution processes.

Key Engineering Features: Selecting reliable suppliers, optimising transportation routes, and reducing lead times.

Recommendations: Explore alternative shipping methods and carriers to optimise delivery times and minimise transportation costs.

Standards and Regulations: ISO 28000:2007: Specification for security management systems for the supply chain (relevant to logistics security) (anon, 2007).

Cross Referencing: Company Constraints, Finance, Shipping, Time Scale

Materials

Definition: Materials refer to the raw materials, components, and substances used in the production and construction of the product.

Brief:

- Selection of high-quality and durable materials
- Compliance with safety and environmental regulations
- Cost-effective sourcing and procurement
- Lightweight and attractive materials for aesthetics and portability

Key Features: High-quality, durable, and eco-friendly materials, cost-effective choices.

Key Engineering Features: Material selection based on performance requirements, environmental impact, and cost.

Recommendations: Investigate new materials or material technologies that could improve the product's performance, durability, or sustainability.

Standards and Regulations: ISO 13485:2016: Medical devices - Quality management systems - Requirements for regulatory purposes (covers material considerations for medical devices) (anon, 2016b). ISO 14044:2006: Environmental management - Life cycle assessment - Requirements and guidelines (covers material life cycle considerations) (anon, 2006).

Cross Referencing: Aesthetics, Circular Economy, Environment, Product Cost, Weight

Manufacturing Facilities

Definition: Manufacturing facilities are the physical locations where the product is produced, assembled, and packaged.

Brief:

- Adequate production capacity and resources
- Compliance with safety and environmental standards
- Efficient and cost-effective manufacturing processes
- Flexibility to scale production as needed

Key Features: Efficient production, quality control, adherence to safety standards.

Key Engineering Features: Optimising manufacturing processes, ensuring proper equipment maintenance, and training employees.

Recommendations: Conduct facility audits to ensure compliance with relevant industry standards and best practice, as well as assessing production capacity and efficiency.

Standards and Regulations: ISO 13485:2016: Medical devices - Quality management systems - Requirements for regulatory purposes (covers manufacturing facility requirements for medical devices) (anon, 2016b). ISO 45001:2018: Occupational health and safety management systems - Requirements with guidance for use (relevant to manufacturing facility safety) (anon, 2018c).

Cross Referencing: Company Constraints, Environment, Processes, Product Cost, Time Scale

Market Constraints

Definition: Market constraints include external factors such as competition, market demand, and consumer preferences that may impact the product's success.

Brief:

- Competitive landscape analysis
- Understanding of target market preferences
- Awareness of industry trends and innovations
- Adaptability to changing market conditions

Key Features: Understanding market demands, analysing competition, identifying target customer segments.

Key Engineering Features: Designing the product to meet market needs, considering price sensitivity, and staying competitive.

Recommendations: Conduct ongoing market analysis to identify emerging trends, opportunities, and threats that could impact the product's success.

Standards and Regulations: No specific ISO standards or regulations apply to market constraints. Market constraints are typically dictated by regional, national, or industry-specific regulations.

Cross Referencing: Branding, Company Constraints, Customer, Finance, Politics

Maintenance & Repair

Definition: Maintenance & Repair encompasses the necessary upkeep, troubleshooting, and repair services required to ensure the product's ongoing performance and reliability.

Brief:

- User-friendly maintenance instructions
- Accessible customer support and service network
- Availability of spare parts and components
- Modular design for easy repair and component replacement

Key Features: Easy maintenance, availability of replacement parts, clear repair instructions.

Key Engineering Features: Modular design for easy repair, ensuring the availability of spare parts, and providing maintenance guides.

Recommendations: Offer a repair service, replacement parts, or maintenance kits to prolong the product's life and ensure continued customer satisfaction.

Standards and Regulations: ISO 13485:2016: Medical devices - Quality management systems - Requirements for regulatory purposes (covers maintenance and repair requirements for medical devices) (anon, 2016b). ISO 55000:2014: Asset management - Overview, principles, and terminology (relevant to maintenance and repair) (anon, 2014).

Cross Referencing: Customer, Documentation, Installation, Life in Service, Product Life Span

Packaging

Definition: Packaging refers to the materials, design, and presentation used to protect and transport the product.

Brief:

- Protective and durable packaging materials
- Attractive and informative package design
- Minimised waste and use of eco-friendly materials
- Compliance with shipping and handling requirements

Key Features: Eco-friendly materials, compact design, clear branding, and product information.

Key Engineering Features: Designing packaging to protect the product during shipping, minimising waste, and providing clear instructions.

Recommendations: Use eco-friendly, recyclable, or biodegradable materials for packaging to minimise environmental impact and appeal to environmentally conscious consumers.

Standards and Regulations: ISO 18602:2013: Packaging and the environment - Optimisation of the packaging system (covers environmental considerations in packaging) (anon, 2013). ISO 11607-1:2019: Packaging for terminally sterilised medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (anon, 2019b).

Cross Referencing: Branding, Circular Economy, Environment, Shipping, Weight

Performance

Definition: Performance encompasses the product's functionality, accuracy, and effectiveness in meeting user needs and expectations.

Brief:

- Accurate and reliable chemical detection
- Real-time air quality monitoring and data analysis
- Personalised recommendations for users
- Consistent performance over time

Key Features: Accurate chemical detection, real-time data monitoring, personalised recommendations.

Key Engineering Features: High-quality sensors, efficient data processing, robust algorithms for analysis and recommendations.

Recommendations: Set clear performance benchmarks and goals to facilitate objective evaluation and comparison against competing products.

Standards and Regulations: ISO 80369: Small-bore connectors for liquids and gases in healthcare applications (series of standards covering performance aspects of connectors used in medical devices (anon, 2018c).

Cross Referencing: Customer, Quality, Reliability, Safety, Testing

Politics

Definition: Politics refers to the political environment, including government policies, regulations, and trade agreements, that may impact the product's development, production, and marketing.

Brief:

- Compliance with national and international regulations
- Understanding of political factors affecting market entry
- Adaptation to trade policies and agreements
- Awareness of potential political risks and opportunities

Key Features: Understanding political influences, regulatory requirements, and potential policy changes.

Key Engineering Features: Designing the product to comply with current and potential future regulations, monitoring political landscape for potential changes.

Recommendations: Monitor any changes in political climate or regulations that could potentially affect the product's development, manufacturing, or distribution.

Standards and Regulations: No specific ISO standards or regulations apply to politics.

Cross Referencing: Company Constraints, Legal, Market Constraints, Standards & Specifications

Processes

Definition: Processes involve the various methods, techniques, and procedures used throughout the product development, manufacturing, and distribution stages.

Brief:

- Streamlined research and development processes
- Efficient manufacturing and assembly techniques
- Quality control and assurance procedures
- Effective distribution and logistics planning

Key Features: Streamlined manufacturing processes, efficient quality control, and waste reduction.

Key Engineering Features: Optimising production processes, implementing quality control checks, and minimising waste generation.

Recommendations: Conduct a thorough cost analysis to identify potential cost-saving opportunities in design, materials, manufacturing, or logistics.

Standards and Regulations: ISO 9001:2015: Quality management systems - Requirements (relevant to process management) (anon, 2015c).

Cross Referencing: Company Constraints, Finance, Manufacturing Facilities, Logistics, Time Scale, Prototyping

Prototyping

Definition: Prototyping is the creation of functional or conceptual models of the product for evaluation, testing, and refinement purposes.

Brief:

- Rapid and cost-effective prototyping methods
- Iterative design and refinement process
- Validation of product functionality and aesthetics
- Incorporation of user feedback and testing results

Key Features: Iterative design, functional prototypes, testing and refining the design.

Key Engineering Features: Creating prototypes to test functionality, ergonomics, and aesthetics, refining the design based on feedback and testing results.

Recommendations: Incorporate rapid prototyping techniques, such as 3D printing or CNC machining, to accelerate the design iteration process and identify potential issues early on.

Standards and Regulations: No specific ISO standards or regulations apply to prototyping.

Cross Referencing: Aesthetics, Ergonomics, Materials, Testing, Weight

Product Cost

Definition: Product Cost refers to the total expenses incurred in the development, production, and distribution of the product, including material, labour, and overhead costs.

Brief:

- Cost-effective material sourcing and procurement
- Efficient manufacturing processes to minimise costs
- Optimal product pricing strategy
- Balancing cost with quality and performance

Key Features: Cost-effective design, competitive pricing, maximising profit margins.

Key Engineering Features: Selecting cost-effective components, minimising production costs, optimising supply chain management.

Recommendations: Conduct a thorough cost analysis to identify potential cost-saving opportunities in design, materials, manufacturing, or logistics.

Standards and Regulations: No specific ISO standards or regulations apply to product cost.

Cross Referencing: Finance, Materials, Manufacturing Facilities, Processes, Weight

Product Life Span

Definition: Product Life Span is the expected duration of the product's functionality and usefulness, from its production to its eventual disposal or replacement.

Brief:

- Durable and long-lasting components
- Regular maintenance and updates to extend life
- Support for recycling and responsible disposal
- Balancing product life with technological advancements

Key Features: Durability, reliability, expected lifespan of the product.

Key Engineering Features: Selecting high-quality materials and components, designing for longevity, and ensuring ease of maintenance and repair.

Recommendations: Set a target product lifespan and identifying strategies to extend the product's life, such as modular or upgradeable components.

Standards and Regulations: No specific ISO standards or regulations apply to product life span.

Cross Referencing: Circular Economy, Environment, Life in Service, Maintenance & Repair, Material, Quality

Quality

Definition: Quality refers to the product's overall excellence, dependability, and ability to meet or exceed user expectations.

Brief:

- High-quality materials and components
- Rigorous quality control and assurance measures
- Compliance with industry standards and specifications
- Commitment to continuous improvement and user satisfaction

Key Features: High-quality components, accurate performance, meeting, or exceeding industry standards.

Key Engineering Features: Rigorous quality control, compliance with industry standards and regulations, continuous improvement.

Recommendations: Implement a robust quality management system, including quality control checks, audits, and continuous improvement initiatives.

Standards and Regulations: ISO 9001:2015: Quality management systems - Requirements (relevant to product quality) (anon, 2015c).

Cross Referencing: Customer, Life in Service, Performance, Reliability, Standards & Specifications

Quantity

Definition: Quantity refers to the number of units produced and distributed, based on market demand, production capacity, and other factors.

Brief:

- Accurate demand forecasting and inventory management
- Scalable production capacity to meet demand fluctuations
- Balancing economies of scale with customisation options
- Optimising batch sizes for cost efficiency

Key Features: Scalable production, meeting market demands, efficient inventory management.

Key Engineering Features: Optimising manufacturing processes to produce desired quantities, managing inventory levels, and ensuring timely delivery to customers.

Recommendations: Analyse market demand and forecasting production requirements to optimise inventory management and reduce the risk of stockouts or excess inventory.

Standards and Regulations: No specific ISO standards or regulations apply to quantity.

Cross Referencing: Finance, Logistics, Manufacturing Facilities, Market Constraints, Time Scale

Reliability

Definition: Reliability is the product's ability to consistently perform its intended functions without failure over its life in service.

Brief:

- Robust and durable design
- Rigorous testing and validation procedures
- Redundant and fail-safe features
- Availability of maintenance and repair services

Key Features: Consistent performance, durability, and longevity.

Key Engineering Features: Selecting reliable components, designing for robustness, and implementing quality control measures.

Recommendations: Conduct reliability testing under various conditions to ensure consistent performance throughout the product's life.

Standards and Regulations: No specific ISO standards or regulations apply to reliability.

Cross Referencing: Customer, Life in Service, Performance, Quality, Safety

Safety

Definition: Safety encompasses the product's ability to minimise risks and hazards for users and the environment, while complying with relevant regulations and standards.

Brief:

- Compliance with safety regulations and standards
- Use of non-toxic and safe materials
- Clear and concise safety instructions and warnings
- Incorporation of safety features and fail-safes

Key Features: Compliance with safety standards, built-in safety features, and rigorous testing.

Key Engineering Features: Integrating safety features (e.g., automatic shut-off mechanisms, temperature sensors, alarms), ensuring adherence to relevant safety standards (e.g., IEC 60601 for medical devices).

Recommendations: Incorporate additional safety features or redundancies to further minimise the risk of accidents or malfunctions

Standards and Regulations: IEC 61508: Functional safety of electrical/electronic/programmable electronic safety-related systems (relevant to safety considerations) (anon, 2010). IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (anon, 2021). IEC 61010-1: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements (relevant for laboratory-related aspects of the product) (anon, 2020).

Cross Referencing: Customer, Environment, Ergonomics, Legal, Reliability

Size

Definition: Size refers to the product's dimensions, footprint, and overall scale, impacting its functionality, aesthetics, and user experience.

Brief:

- Compact and portable design
- Optimised dimensions for user comfort and convenience
- Balance between size and performance capabilities
- Adaptability to different environments and user preferences

Key Features: Compact design, portability, easy storage.

Key Engineering Features: Optimising size for functionality and user-friendliness, considering the size in relation to manufacturing and shipping costs.

Recommendations: Explore ways to miniaturise internal components or optimise the device's layout to reduce its overall size without compromising functionality.

Standards and Regulations: No specific ISO standards or regulations apply to size. However, size should be considered for the user experience, ease of installation, and overall ergonomics.

Cross Referencing: Aesthetics, Ergonomics, Materials, Weight

Shelf Life and Storage

Definition: Shelf Life and Storage pertain to the product's ability to maintain its quality and functionality while in storage or during transportation, as well as its overall lifespan when not in use.

Brief:

- Defined shelf life for optimal performance
- Appropriate storage conditions and guidelines
- Protective packaging to prevent damage or degradation
- Clear expiration date and disposal instructions

Key Features: Proper storage conditions, maximising shelf life, maintaining optimal performance.

Key Engineering Features: Designing the product for long-term storage, providing clear storage guidelines, ensuring regular maintenance and battery replacement.

Recommendations: Provide clear storage guidelines and best practices on product packaging and documentation to help users maintain the device's performance and longevity.

Standards and Regulations: ISO 13485:2016: Medical devices - Quality management systems - Requirements for regulatory purposes (covers storage and shelf-life requirements for medical devices (anon, 2016d)).

Cross Referencing: Environment, Logistics, Packaging, Shipping, Standards & Specifications

Shipping

Definition: Shipping refers to the transportation and delivery of the product to distributors, retailers, and end users.

Brief:

- Efficient and reliable shipping methods
- Compliance with international shipping regulations
- Minimised shipping costs and environmental impact
- Tracking and monitoring of shipments

Key Features: Secure packaging, efficient shipping methods, compliance with international shipping regulations.

Key Engineering Features: Selecting appropriate packaging materials, planning transportation routes, and adhering to shipping regulations (e.g., Dangerous Goods Regulations for chemical sensors).

Recommendations: Explore options for expedited shipping or local distribution centres to improve delivery times and enhance customer satisfaction.

Standards and Regulations: ISO 28000:2007: Specification for security management systems for the supply chain (anon, 2007).

Cross Referencing: Logistics, Packaging, Shelf Life and Storage, Weight

Social & Cultural

Definition: Social & Cultural factors include the cultural norms, values, and social dynamics that may influence the product's design, marketing, and adoption.

Brief:

- Cultural sensitivity and inclusivity in design
- Adherence to ethical and social responsibility standards
- Localisation of marketing and branding efforts
- Understanding of target market demographics and preferences

Key Features: Cultural sensitivity, promoting a culture of proactive health management, user-friendly interface.

Key Engineering Features: Designing an interface that accommodates users of different backgrounds, emphasising benefits and value propositions that resonate with the target market.

Recommendations: Conduct cultural sensitivity assessments and adapting marketing messages to resonate with diverse audiences and promote product acceptance across different regions.

Standards and Regulations: No specific ISO standards or regulations apply to social and cultural aspects. However, it is essential to consider cultural sensitivities, diversity, and user needs when designing the product.

Cross Referencing: Aesthetics, Branding, Customer, Market Constraints, Politics

Standards & Specifications

Definition: Standards & Specifications are the technical and regulatory requirements that the product must meet to ensure its quality, safety, and compliance.

Brief:

- Compliance with industry and regulatory standards
- Clear and detailed product specifications
- Adherence to best practices and guidelines
- Regular updates to meet evolving requirements

Key Features: Compliance with industry standards and regulations, ensuring product safety and effectiveness.

Key Engineering Features: Adhering to relevant standards (e.g., ISO 13485 for medical devices), maintaining certifications and compliance documentation.

Recommendations: Stay up to date with evolving industry standards and regulations, and regularly revisiting the product's compliance to ensure ongoing adherence.

Standards and Regulations: ISO 13485:2016: Medical devices - Quality management systems - Requirements for regulatory purposes (covers overall quality management system requirements for medical devices) (anon, 2016d).

Cross Referencing: Documentation, Environment, Legal, Quality, Safety

Testing

Definition: Testing involves the systematic evaluation and validation of the product's functionality, performance, safety, and reliability through a series of controlled experiments and trials.

Brief:

- Comprehensive testing plan and procedures
- Evaluation of performance under various conditions
- Testing for safety, reliability, and durability
- Iterative design improvements based on testing results

Key Features: Rigorous testing for accuracy, reliability, and effectiveness, validation of performance.

Key Engineering Features: Conducting various testing methods (e.g., laboratory testing, field testing, user testing), refining the design based on testing results.

Recommendations: Incorporate feedback loops and iterative testing processes throughout the product development cycle to continuously refine and improve the product based on user feedback and test results.

Standards and Regulations: ISO 14971:2019: Medical devices - Application of risk management to medical devices (covers risk management and testing requirements for medical devices) (anon, 2019c).

Cross Referencing: Performance, Quality, Reliability, Safety, Prototyping

Time Scale

Definition: Time Scale refers to the schedule and milestones for the product's development, production, and distribution, including deadlines and key target dates.

Brief:

- Realistic and achievable timeline for development
- Incorporation of contingencies and buffer times
- Regular progress updates and assessments
- Coordination of production, logistics, and marketing efforts

Key Features: Clear project milestones, timelines, and deadlines, ensuring timely completion of the project.

Key Engineering Features: Planning and executing project tasks, identifying potential delays, adjusting the project plan as needed.

Recommendations: Implement project management best practices, such as Agile methodologies, to improve project timeline accuracy and responsiveness to changes.

Standards and Regulations: No specific ISO standards or regulations apply to the time scale. However, project management best practices should be used to ensure timely delivery of the product.

Cross Referencing: Company Constraints, Finance, Logistics, Manufacturing Facilities, Prototyping

Weight

Definition: Weight is the product's mass, impacting its portability, user experience, and shipping costs.

Brief:

- Lightweight design for portability and ease of use
- Balance between weight and durability
- Optimised materials and components for reduced weight
- Consideration of shipping and handling implications

Key Features: Lightweight design, easy portability, durability without compromising functionality.

Key Engineering Features: Balancing lightweight materials with structural integrity, optimising component placement to distribute weight evenly, considering weight in relation to manufacturing and shipping costs.

Recommendations: Explore lightweight materials or innovative manufacturing techniques that can help reduce the product's weight without sacrificing durability or functionality.

Standards and Regulations: No specific ISO standards or regulations apply to weight. However, weight should be considered for the user experience, ease of installation, and overall ergonomics.

Cross Referencing: Aesthetics, Ergonomics, Materials, Shipping, Size

5. Summary

The goal of the CDS home health hub design brief is to develop an all-encompassing health management system that tracks indoor air quality. To create a successful product, the brief takes into account factors like appearance, branding, ergonomics, safety, and performance. The CDS should be branded with an emphasis on dependability and innovation and have a contemporary, user-friendly design that appeals to a variety of user groups.

Safety and dependability are crucial, and the CDS complies with all applicable standards, recommendations, and laws. There will be built-in alerts as well as temperature sensors, automated shut-off mechanisms, and other features. Quality components, production techniques, and testing procedures all contribute to reliability.

Size, shelf life, storage, transportation, and weight are all addressed in the design brief to ensure the best portability, handling, and financial efficiency. To appeal to target customers and promote proactive health management, social and cultural aspects are also considered.

Meeting regulatory requirements requires adherence to standards and specifications, particularly those pertaining to medical equipment and chemical detection. The effectiveness and performance of the CDS will be rigorously tested, including in the lab, in the field, and with users.

The brief considers how long it takes to build a product, laying out deadlines and milestones for a timely launch. The primary objective of the CDS home health hub design brief is to create a dependable, efficient, and user-friendly product that provides a distinctive solution for monitoring indoor air quality while fostering health and well-being.

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