ESTABLISHMENT OF CHECKLIST OF DESIGN FOR SAFETY (DfS), LIFE-CYCLE ANALYSIS (LCA) AND DESIGN FOR MANUFACTURING (DFM) FOR IVD MEDICAL DEVICE BASED ON IEC 60601

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A project is submitted as partial fulfillment the requirement for the award of Master Degree of Mechanical Engineering

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JUNE 2021

"I hereby declare that I have read this thesis and in my opinion this report in terms of content and quality requirement fulfill the purpose for awarding Master Degree of Mechanical Engineering "

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DEDICATION

To my beloved family:

Azman Bin Abdullah

Norrasidah Binti Hassan

Abdullah Bin Montel

ACKNOWLEDGEMENT

"In the name Of Allah, the Beneficient, the Merciful"

First and foremost, Alhamdulillah all praise be to Allah, the Almighty for giving me His grace and mercy to complete this study.

I would like to acknowledge and extend my heartfelt gratitude to my supervisor Prof Madya Dr Nik Hisyamudin Bin Muhd Nor for willing accept me as his master student. His excellent supervision, invaluable guidance, advice, trust, help, support, determination, time, encouragement, assistance, understanding and patience from the initial to the final stage for this project are really appreciated.

Secondly, I would like to pay my heartfelt thanks to the prestigious institute, Universiti Tun Hussein Onn Malaysia (UTHM). I am also greatly indebted to Faculty of Mechanical and Manufacturing Engineering (FKMP) and Centre for Graduates Studies (CGS) of UTHM for providing good facilities and inspiring environment for me to complete this study comfortably.

In addition, thank you to my beloved families who are always give me support (mentally and physically), encourage and understand me during my study. Moreover my sincere thanks go to all friends who shared love and experiences with me and I will never forget for what they have done.

Thank you.

ABSTRACT

By 2030, medical industries is projected to grow exponentially, progressive to more sustainable policies and better performance towards achieving healthcare Sustainable Development Goals (SDGs). Designing the uprising star of In-Vitro Diagnostic (IVD) device casing is choose as a case study in this research because the current discovery of non-invasive jaundice meter in Malaysia are still in lab scale form with wooding casing thus made it not user friendly and not safe to be used. Therefore, this research purpose a comprehensive checklist for designing new medical device casing by considering Design for Safety (DfS) extracted from the famous international standards on safety MS IEC 60601 and Life-Cycle Assessment (LCA) principles for environmental impact with real side-by-side industrial manufacturing requirement for injection molding process applied on a case study of jaundice meter casing. The checklist have help to minimize modification period thus comply to safety standards (MS IEC 60601). As a result, DfS-LCA-DFM comprehensive checklist helps to decrease trouble for designers to read on long pages of regulatory book to comply to safety standards, doing forensic of redesigning due to not suitable design for manufacturing and saving cost of raw material during early design stage.

ABSTRAK

Menjelang 2030, industri perubatan dijangka berkembang dengan pesat, progresif kepada dasar yang lebih mampan dan prestasi yang lebih baik ke arah mencapai matlamat Pembangunan Mampan (SDGs) penjagaan kesihatan. Merekabentuk sebuah sarung peranti IVD yang kian popular telah dipilih sebagai kajian kes dalam penyelidikan ini kerana penemuan peranti *non-invasive jaundice meter* di Malaysia masih dalam bentuk skala makmal dengan bekas kayu sehingga menjadikannya tidak mesra pengguna dan tidak selamat digunakan . Oleh itu, tujuan penyelidikan ini adalah mewujudkan senarai semak yang lebih komprehensif untuk merekabentuk sarung alat perubatan baru dengan mempertimbangkan *Design for Safety (DfS)* yang diekstrak daripada piawaian antarabangsa yang terkenal mengenai keselamatan MS IEC 60601 dan *Life-Cycle Assessment* (LCA) untuk mengesan kesan alam sekitar dengan pengalaman pembuatan di industri bagi proses pengacuan suntikan yang digunakan untuk kajian kes sarung meter sakit kuning. Senarai semak ini membantu mengurangkan masa pengubahsuaian dengan mematuhi piawaian keselamatan (MS IEC 60601). Tuntasnya, senarai semak DfS-LCA-DFM yang komprehensif membantu mengurangkan masalah bagi pereka untuk membaca halaman panjang buku pengawalseliaan untuk mematuhi standard keselamatan, melakukan forensik reka bentuk semula kerana reka bentuk yang tidak sesuai untuk pembuatan dan menjimatkan kos bahan mentah semasa awal peringkat reka bentuk.

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LIST OF ABBREVIATION AND SYMBOLS

%	:	percentage
ASTM	:	American Society for Testing Materials
JIS	:	Japan Industrial Standard
EQS	:	Environment Quality Standards
OSHA	:	Occupational Safety and Health Administration
MS	:	Malaysia Standards
IEC	:	International Electrotechnical Commission
NKEA	:	National Key Economic Area
GHTF	:	Global Harmonization Task Force
R&D	:	Research And Development
SDGs	:	Sustainable Development Goals
EPPs	:	Entry Point Projects
RM	:	Ringgit Malaysia
IVD	:	In vitro diagnostic
NPSA	:	National Patient Safety Agency
QFD	:	Quality Function Deployment
FDA	:	Food and Drug Administration
ISO	:	International Organization for Standardization

CHAPTER 1

INTRODUCTION

1.1 Background of Study

By 2030, the international community should have moved towards a more sustainable approach to environmental protection, poverty eradication and health promotion across life. In the Sustainable Development Goals (SDGs), the new global agenda prioritizes equity and human rights based approaches with emphasis on health and universal coverage. The increase in new pharmaceuticals, the rapidly changing health technology markets and a lack of market encouragement for older drugs are putting increasing pressure on the ability of health systems to provide full and affordable access to health care. The increased regulatory burden, the lack of regulatory capacity in many countries and the increase in the number of defective and counterfeit products on all markets impedes efforts to ensure health products quality, efficiency and safety. At the same time, medical research and development (R&D) innovation has led to new products that can bring about sustainable public health improvements and greater access (World Health Organization, 2017). The Global Harmonization Task Force (GHTF) has facilitated a convergence of medical device health, performance and efficiency standards and regulatory practices. The GHTF also promotes technological innovation and simplifies international trade. The main means by which their objectives are achieved is through the publication and dissemination of harmonized guidance documents for specific regulatory activities (Ramakrishna *et al.,* 2015).

By 2030 onwards, the leading players in the medical device industry will be those who play an active role in providing value by engaging with clients, patients and consumers (end users). This will entail a change by diagnosis and cure to prevention through integrated' smart' services and solutions that minimize care costs and improve

performance. Innovation will have a significant impact, contributing to prevention and, if appropriate, highly effective, minimally invasive treatment options that reduce hospital time. (Stirling *et al.,* 2018)

Globally, the medical device industry is set to grow rapidly, with global annual sales estimates increasing by more than 5 percent per year and reaching nearly US$ 800 billion by 2030. Such estimates reflect increasing demand for innovative new devices (such as wearables) and services (such as health data), as lifestyle diseases are becoming more prevalent, and economic development is unlocking the huge potential in emerging markets as shown in Figure 1.1–especially China and India.(Stirling *et al.,* 2018).

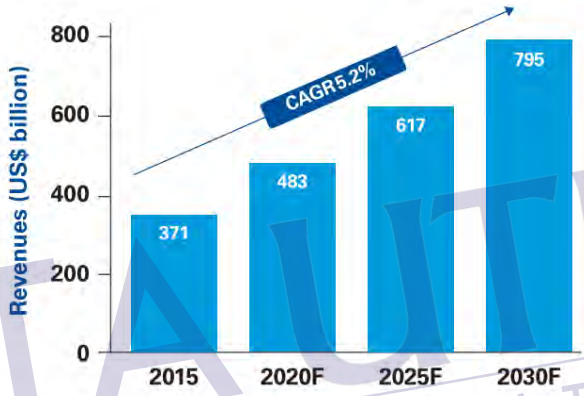

Figure 1.1: Global Medical Device Sales Forecast to 2010 (Stirling *et al.,* 2018).

Malaysia have introduce National Key Economic Area (NKEA) which highlighted 12 economic sector towards becoming high income country. The areas are:

1. Oil, Gas and Energy
2. Palm Oil
3. Financial Services
4. Tourism
5. Business Services
6. Electronics and Electrical
7. Wholesale and Retail
8. Education
9. Health
10. Information and Communication Technology

11. Agriculture
12. Greater Kuala Lumpur

Medical devices industry covers a wide range of industries from fostering rubber and clothing, textiles, chemicals, computers and engineering a. The Government has listed medical devices as one of the high-potential growth sectors under the Eleventh Malaysia Project (RMK-11). The industry has also been identified as one of the growth areas under the Healthcare NKEA under which eight Entry Point Projects (EPPs) have been announced and targeted to contribute RM17.1 billion in revenue and RM11.4 billion in GNI, and to generate 86,000 jobs by 2020. There are about more than 200 suppliers of medical devices, mostly the surgical gloves producing small and medium-sized enterprises (SMEs). However, higher value-added and technologically advanced products such as cardiac pacemakers, stents, implantable orthopedic devices, electro-medical, therapeutic and monitoring devices are also included in the industry (Ministry of International Trade and Industry 2016). Figure 1.2 showed that the projection is expected to grow for investors and exports for the medical device industry up to 2020. Therefore, there's no question that the medical device industry is rising quite increasingly in Malaysia.

	2006-2010	2011-2015	2016-2020	2006-2020	2006-2020
	(RM billion)				Average Annual Growth (%)
Investments	4.1	6.2	9.1	19.4	9.2
Investments per year	0.8	1.2	1.8	1.3	n.a[1]
Exports (end period)	9.0	13.9	18.4	18.4	8.6

Note: [1] Not applicable
Source: Ministry of International Trade and Industry

Figure 1.2: Projections for The Medical Device Industry
(Ministry of International Trade and Industry, 2016)

Medical devices used for in vitro diagnosis (IVD) are research sets and instrumentation used to evaluate patient subjects and aid with clinical diagnosis or health management decisions. As shown in Figure 1.3, IVD will remain the number one product sector in 2022 with revenue of $70.8 billion-more than 13 percent of the

total revenues of the market. Cardiology takes second place, with annual sales increasing from $42.1 billion in 2015 to $62.3 billion in 2022. Neurology is projected to be the fastest growing development sector between 2015 and 2022, with a CAGR of 7.6 percent (Levorlino & Uhqugart, 2016).

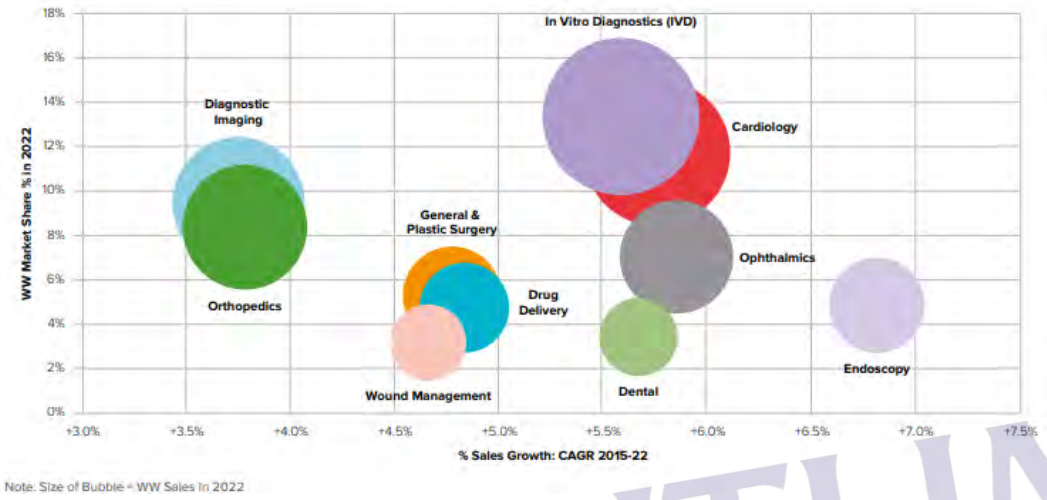

Figure 1.3: Analysis on Top 10 Device Areas in 2020
(Levorlino & Uhqugart, 2016)

The high demand on IVD device market have made the niche area been explored more by researcher. This research will tap on one off high-end IVD device which is jaundice meter.

1.2 Problem Statement

The innovator greatest challenges in millennial era is to generate ideas and innovate products in repeatable and scalable fashion. Rapid growing in medical device industries have targeted several billions of sales by 2022. One of world's top demand device is IVD have stolen the attention of many researchers to tap on it. Due to high demand from customers, IDV medical devices are one of the upsurge stars in product development. Recorded by the National Patient Safety Agency (NPSA), from April 2006 to March 2007, 24,207 patient safety accidents were recorded concerning medical devices. The documentation discovered by (B.D. *et al.,* 2014) noticed inconsistency in each stage method including inadequate marking, unclear protocol, lack of unit-wide standardization and other reasons.

Previous researcher mainly focus on the sustainability of the casing through environmental impact by using specific method rather than implementing more on safety and standardization. Thus, this research will merge elements of safety, environment and manufacturing requirement to fulfil IEC 60601 . In this case, DFS-DFM-LCA checklist is created to develop a more comprehensive design guide for IVD medical device casing for direct manufacturing.

1.3 Objective

The objective of this research are :

1. To design a jaundice meter casing
2. To develop DFS-DFM-LCA comprehensive IVD medical device design checklist
3. To produce mouldable and safe design of jaundice meter casing
4. To comply DfS with MS IEC 60601

1.4 Scope

1. Identify the criteria for DfS, DFM and LCA method in the embodiment.
2. Establishing the relation between DfS,DFM and LCA method through checklist.
3. Limitation case study is on casing design of jaundice meter.
4. Focus specifically to inline MS IEC 60601.

1.5 Significant of Study

The significant of this research is it will contribute in new assessment method to promote safe, effective and usable design. This research will significantly help designers choosing method in embodiment phase thus improve their product and create more sustainable medical device in the future.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

This chapter will discuss about previous literatures on the research on different method used for various cases. "Medical device" is generally any tool, device, implement, system, appliance, implant, in vitro reagent or calibrator, software, material intended by the manufacturer to be used, alone or in combination, for one or more particular purposes of diagnosis, prevention, tracking, treatment or disease relief, injury compensation; (Medical Devices Bureau Ministry of Health Malaysia, 2013).

2.2 The Overview of Medical Device

According to the World Health Organization,' Medical Device' means any device, tool, implement, computer, equipment, implant, reagent for in vitro use, software, material or other similar or related element intended by the manufacturer to be used, alone or in combination, for human use, for one or more specific medical purposes of the manufacturer.:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,

- disinfection of medical devices
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means (World Health Organization, 2014; Medical Devices Bureau Ministry of Health Malaysia, 2010).

Reported by the United Kingdom Department of Health, in an article entitled "An Organization with a Memory," and records repeated cases happening not only in the medical sector but also in industry and research. In this particular aspect, however, patient safety is generally not assured (Department of Health London, 2000). Reported by the National Patient Safety Agency (NPSA), 24,207 patient safety incidents have been reported involving medical devices among April 2006 to March 2007, which is equivalent to 3% of the total reported incident over the period (Patient Safety Observatory, 2007). From these reported incidents in 2008, 303 incidents were classified as occurring in fatal or serious patient injury. (National Patient Safety Agency, 2010) Reports indicate that such an incident has a classic system failure which can therefore be prevented from occurring (Panel, 2007; Toft, 2001).

Record found deficiencies at each point, including inadequate marking, ambiguous procedures, lack of unit standardization and other causes (B.D. *et al.,* 2014). Over the course of the year, further analyzes have found that design of medical devices was one of the issues. For example, incorrect link, recognition problem and lack of user feedback contributed to an incident involving patient safety. The recognition of the user's role in identifying user error by workers and vendor has helped to improve purchase decisions, scopes and pick well-designed products. Therefore, NPSA suggested that safe design principles and standards be demonstrated for a more standardized system that needs to be considered into practice to consider user specifications, sense of use and future use environment (Martin *et al.,* 2008). Table 2.1 indicates the classification of the accident as specified by NPSA in 2008 according to their classes. The data collected have also shown that medical device accident causes are in the top five reported incident causes, though medical device safety is often overlooked (A. N. *et al.,* 2009).

Table 2.1: Classification of incident that is reported in 2008 by NPSA (Thomas *et al.,* 2009)

	Number in group in incident report	Number remaining in initial group after reclassification	Percent remaining in initial group after reclassification, %	Number in group reallocated by investigators
Access admission, transfer and discharge	362	312	86	1032
Clinical assessment	266	217	82	499
Consent, communication, confidentiality	232	172	74	549
Documentation	247	227	92	552
Implementation of care	412	336	82	1047
Infection control	174	161	93	257
Infrastructure, staff	814	714	88	1289
Medical/equipment	647	586	91	1003
Medication	1145	1096	91	1450
Patient acc ident	330	273	83	286
Treatment procedure	786	366	43	576
Other	200	57	23	365
Total	5615	4517	80	8905

Reported by the grades of the European Pressure Sore Advisory Panel that 119 cases of sore pressure are linked to medical devices. In 87 cases of pressure sore, sometimes associated with medical devices on admission, it was recommended that treatment management and daily monitoring should be carried out (A. N. *et al.,* 2008; Antony N. *et al.,* 2009). There is no accurate or safe number of patient safety to be considered safe but a low reporting rate can be interpreted as safe and a high reporting rate can be described as unsafe representing a culture of greater openness (Quarterly Data Summary Publications Guidance Notes on National Reporting and Learning System, 2016).

For its consumption, Malaysia currently imports about 95 per cent of the medical device. The medical devices industry is a highly diversified industry, producing a wide range of products and equipment from medical gloves, implantable devices, orthopedic devices and dialysis devices to diagnostic imaging equipment and

minimally invasive surgical equipment and other devices that can be used for medical, surgical, dental, optical and general health purposes (Medical Devices Bureau Ministry, 2013)

The medical device is primarily defined by the Malaysian Medical Device Authority as any device, tool, implement, system, appliance, implant, calibrator or in vitro reagent, material or software developed by the manufacturer to be used alone or in combination for different purposes for humans (European Commission & Health, 2010). Generally clarified by the U.S. government's 2016 Top Market Report, a medical device is described as any piece of equipment or tool used to treat or diagnose disease and requires direct patient contact. US medical device companies are have highly respected ranks due to their innovations and high-tech product. In recent years, the investment in medical device research and development have ben doubled than previous years (Report, 2016).

The medical device universe, largely encompasses specifically emitting special technological innovation, which includes hundreds of different technologies and thousands types of products. Six major technology themes were identified and elaborated as highly likely to prefigure medical device innovation over the next decade: (1) electronics technology; (2) detection, diagnosis, and monitoring technologies; (3) decentralized care technologies; (4) minimally invasive technologies; (5) synthetic organs, tissues, and combination device / biological and device / drug technologies; and (6) demographically oriented technologies (Herman & Devey, 2007).

More than billions patients across the globe depend on medical device and its technologies. Most of them are used in diagnosis, prevention and disease treatment. Medical technologies such as wheelchairs, contact lenses and pregnancy test are frequently used by humans (Cunningham et al., 2015).

2.2.1 Design guide for Medical Device

For centuries research have search into ways to design medical device and have came out with various guidelines or tips on how to design a good medical device.

2.2.1.1 User-Centered Design Approach

User-Centered approach are the most common approach that been used in designing medical device aside from data driven design due to organized and more reliable in designing process (De Troyer & Leune, 1998). It also adds to customer satisfaction when using the product because it fits the needs of user.

2.1.1.1.1 Medical Devices and User-Centered Design

Due to high demand in this field, the emphasis on designing medical devices has increased in previous years. Most designers have focused more on design, human error, usability and patient safety in their conceptual design in relation to a user-device design implementation. A number of projects have been organized with the intention of improving this dimension. The role of medical device in patient safety events was investigated by the National Patient Safety Agency in the United Kingdom in 2007. Looking at all reported deaths and major injuries, the cause of the incident is mainly the design of the medical device that is not safe to use (Martin *et al.,* 2012).

Furthermore, the accident involves developers who did not understand the device's meaning alone and did not predict a danger scenario. They also do not consider user-friendliness first prior to fabrication resulting in the device not reaching client satisfaction (Aljazzazi *et al.,* 2013; Amoore, 2014; Kaufman *et al.,* 2003). Ergonomic or widely known as human factor has made a significant contribution to the safety of medical devices, highlighting the contribution that will enhance healthcare safety is discipline, especially in design (Fennigkoh & Diego, 2009; Martin *et al.,* 2008; Moray, 2000; U.S. Department of Occupational Safety and Health Administration, 2000).

The medical error report published by the Institute of Medicine has significantly increased understanding of the extent, duration, nature and severity of the mistake. Motor vehicle accidents, breast cancer, or HIV, and medical negligence are among the top eight leading causes of death in the US. (Zhang *et al.,* 2003) Technologies such as Health Information Technology (HIT) have been developed to reduce the risk of serious injury to patients in hospital. (Horsky *et al.,* 2005) Thus it proves that the use of technology can save life itself.

A study is conducted in the field of shoulder surgery where "A brief inventory of tiredness of the shoulder health established by QFD technique" The use of QFD techniques is to establish an instrument for diagnosing the severity of symptoms on the neck and shoulder.(Liu, Lee, & Huang, 2009).Previous research made by Kianfar have used QFD methodology to Reliability-Centered Maintenance (RCM) to improve RCM capability in maintaining the functions of the plants. Their objective is mainly to preserve the function of plant with least resource.

Further productivity has been restored by applying these approach to the RCM (Kianfar & Kianfar, 2010). Self-management programs are increasingly dependent on the use of technology to promote the home care process. Other tools range from medical devices such as glucose monitoring to advanced computer-mediated telemedicine services offering interactive assistance, as well as access to the World Wide Web. Even if such devices are required to meet certain requirements, their usability is very little understood (Zhang *et al.,* 2003).

2.2.1.2 FDA Design Guide

Many of today's medical devices are truly incredible marvels of life-saving engineering. Nevertheless, most of them are very complicated and while they may be made up of very smart widgets, they need more than great engineering to reach the market. Partly because software (which does not lend itself to inspection in order to determine its quality) is such an integral part of many products, it was decided that a process of design was required to ensure quality products. This process is called "product controls" and must be applied throughout the design process and observed. Design controls are a series of well-defined standardized procedures to be followed in a design process to ensure that the resulting product is safe, reliable and in a competitive marketplace can be efficient. The method will be considered in four parts at this discussion:

1) The main phases of the process
2) The objectives of each phase in the design process
3) Key outside considerations
a) Regulatory requirements
b) Reimbursement

In a large organization the protocol can be very detailed and formal, or more comfortable and informal in a small company. With less product lines and market segments smaller companies can handle a less detailed process with required resources. Whether the company is large or small, the process complicated or simplified, clear steps need to be taken and reported to ensure that the outcome is a final product that complies with regulatory compliance requirements in a secure, efficient and competitive manner (Gilman *et al.,* 2009).

A useful diagram shown in Figure 2.1 has been released by the Food and Drug Administration Center for Devices and Radiological Health (FDA) that summarizes beautifully the steps they involve in a design-controlled cycle. The development process shown in the example is a traditional waterfall model. The design proceeds through a logical sequence of stages or phases. Requirements are basically developed, and a device is designed to meet those requirements. The design is then tested, transferred to creation and the device is built. Throughout practice, input paths between each step of the process and prior phases would be expected, reflecting the iterative nature of product development. This definition has, however, been omitted from the figure to make the impact of design controls more distinct on the design process.

The importance of the design input and the verification of design outputs. After reviewing the design input and determining that the design input specifications are acceptable, an iterative process of translating certain requirements into a system design begins. The first step is to turn the criteria into product specifications or high level specifications. Thus, those specifications are an output of design. Upon checking that the high-level specifications adhere to the requirements of design inputs, they become the design input for the next phase in the design process, and so on. This basic methodology is consistently used throughout the entire design process. Each design input is converted into a new design output; each output is verified as being in accordance with its input; and it then becomes the design input for another step in the design process, thus translating the design input requirements into a device design that meets those requirements.

The example is also illustrative of the value of design feedback. The design checks in the design process are carried out at strategic points. A review is conducted, for example, to ensure that the requirements for design inputs are appropriate before they are converted into design specifications. One is used to ensure the system design

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