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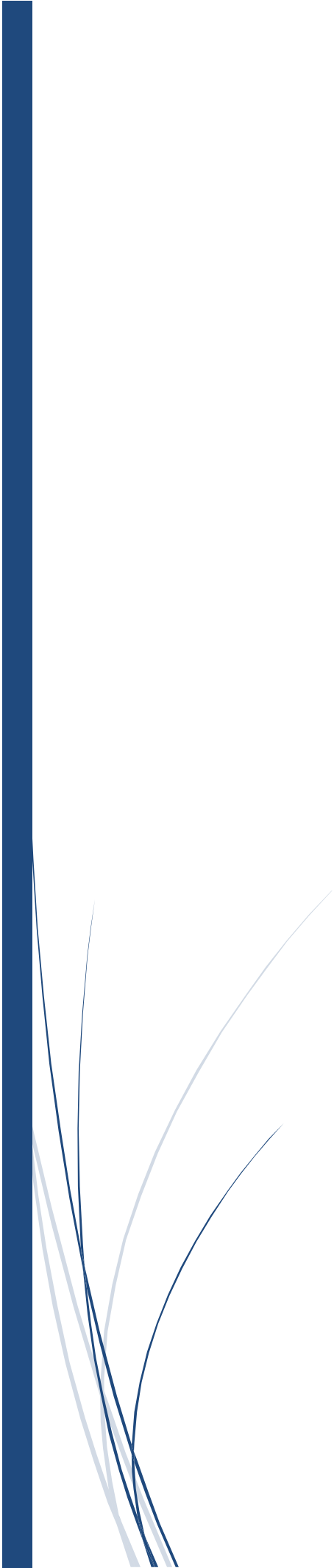
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From the Mainframe to the Flesh:

Pedagogical Approaches to Conceptualizing Human Experience in Bio-Modeling

Jamal Burns
OXFORD UNIVERSITY

Department of Education, University of Oxford
Assignment Cover Sheet

Candidate Number	Jamal Burns
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To one of my closest friends, Omar. Allowing me to use you as a springboard for ideas and general advice enabled me to give birth to this work. I remain in awe of your intelligence and am lucky to have been graced by someone with a mind like yours. I appreciate your friendship every day.

To my scholarship and departmental cohort, you make me feel warm. Academia is a dark, scary, and oftentimes cold place. Yet, with you all in my corner, I felt a cascade of warmth and energy. You all have undeniably blessed the souls you have touched and will continue to do so.

To those disenfranchised by the medical industrial complex, I dedicate this project to your pain, and I acknowledge the veracity and reality of your struggle.

Finally, I dedicate this project to idealism and hope.

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Abstract:

The design of medical instrumentation is a vital aspect of Biomedical Engineering (BME) programs. Yet, no full-length study analyzing the consequence of pedagogical methods on a medical device's final design has been conducted. Being that these technologies are created with a specific end-use in mind, an examination of instructional design is essential for ascertaining how the user has come to be understood by those drafting solutions on their behalf. As such, this thesis examines the ways that biomedical engineering programs conceptualize user experience through design instruction. It navigates essentialist questions like *who is a user* and evolves to investigate the theoretical crux of medical device making to ask *why* decisions are made and *what* apparatuses might inform these choices. Through this process, it discerns a lack of critical pedagogy in BME design curricula, and thus argues that biomedical engineering programs must take seriously the ideas of race, gender, and other social categories in the teaching of medical device design.

This work begins by reflecting on the socio-historical relevance of medical devices. In doing so, it outlines health, education, and illness as value-laden, multi-dimensional notions that are often singularized. This piece contends that such singularization limits the reach and effectiveness of design instruction, reifying the belief that science is distinct from social meaning. It then reflects on the use of technology in the development of medical devices. Here, it offers a generational description of mechanical Computer Aided-Design (CAD)—a band of software used to transform 2D sketches into 3D digital models. Finally, through a series of semi-structured interviews with six recent graduates of two top ranked BME programs, this work develops the concept of *exclusion as enactment* to describe the catastrophic impacts exclusion can have for those underrepresented in currently utilized instructional frameworks.

Table of Contents

Prologue: From Lecture to Hospital

When crafting this thesis, my advisor and I had several conversations regarding its theoretical and pluralistic nature. These conversations were filled with metaphors, analogies, and mental fragments. We expressed the need to ensure this work's interpretable accessibility while avoiding reductionist and rudimentary analysis. We mulled over the juxtaposition between theory and reality and were stimulated by the matrices developed from their conceptual intersections. These conversations were the result of, and resulted in, the many questions this thesis attempts to answer. The purpose of this prologue is to transform these conversations from intangible strings of thought into physical artifact. In doing so, this prologue seeks to provide a vignette for which this thesis can be grounded. It serves a soft introduction into this work.

The topic of biomedical engineering instruction is rich and diverse. Despite such richness, it has largely been under-explored. To my knowledge, this thesis is the first study of its kind to examine medical device design instruction with reference to ideas of culture and physiologic difference. In doing so, it deploys a theory I call *exclusion as enactment*. That said, this prologue has little interest in expanding those arguments, as they will be enumerated throughout the piece. It does, however, want to provide a small story which I would likely use to describe the impact of this work if I were invited to give a lecture. The idea of conceiving this work as a "lecture hall" came from one of the many sessions I had with my advisor. In the sense that invited lecturers must engage a variety of attendees—from those who consider themselves experts to complete novices—this thesis must do the same:

> We've all likely been marketed a device for our health, anything from the exorbitantly priced Apple watch to Covid-antigen tests. These devices are pushed with fervor under the belief that they will improve our lives. Now, what if I told you that was not always the case?
>
> We can turn to an article published in Harvard Health to exemplify this point. "Does your health monitor have device bias?" (Shmerling, 2021). The article describes the ways that certain medical devices are less effective among individuals with particular socio-demographic characteristics – for example, users who have darker skin, or lack mobility, or are of a gender minority. The article presents these issues, yet it does little to question why devices are designed this way or what considerations go into a final product. These unanswered questions are where this work both starts and ends. By examining how medical device designers are taught, we are better able to understand how such biases manifest and obscure the claims of care these devices report.

While the above is a theoretical scenario, the article is real and reflects the contrasting nature of medical device usage. Having this knowledge as the precursor to entry for this analysis will make its theoretical elements less jarring. At its core, the question of this thesis might reduce to: how do biomedical engineering students learn to design devices? As will be evident throughout this work, such a question—while deceptively simple—is quite complex.

Chapter 1 – Introduction: Medicine(s) Plural

1.1 Background:

This thesis must begin by stating what some might perceive as plainly obvious: medical devices are an omnipresent fixture of our reality. Though a simple truth, articulating this fact opens a plethora of possibilities for the succeeding analysis. In essence, this work is a centrifuge, separating the apparently concise construct of medical technology into its component parts—pedagogy, design, history, and social influence.[1] Through discerning the processes that bring medical technology from abstraction into material reality, this analysis examines the biases that belie notions of health and wellness often attributed to such devices. By opening discussion toward the more affective, immaterial influence of instruction, enriched meaning is given to not only medical device bias, but the way the "user" comes to be understood in the context of medical device design. More than a patient, a "user" is a doctor, a manufacturer, a financer. As this thesis evolves, it locates the user as a variously described entity, flexible and changing. This understanding of user-variability meets with and challenges understandings of what it means to be pedagogically holistic.

While there has been increased interest in medical device bias over the past few years, studies have used effectiveness as the primary marker in determining bias. In these scenarios, devices are critiqued for their variable efficacy between race, gender, and other social categories (Kadambi, 2021; Moran-Thomas, 2020; Shmerling, 2021). Absent these conversations is a consideration of bias outside of device mechanics. Particularly, the desire to understand the methods used in creating medical technology has been noticeably nonexistent. It is not enough to merely identify bias and suggest that devices be developed differently, which literature on device efficacy has primarily evinced (Baker & Hawn, 2021; Kadambi, 2021). This line of reasoning is reductive and relegates issues in device design to the technical. Instead, to capture the breadth of device design bias more adequately and to better be able to address the effects of this bias, an analysis of the pedagogical frameworks which inform device design is essential.

The underpinning ideals of design pedagogy—to design well, reflect on social issues, and generate knowledge—are particularly useful skills in the context of biomedical engineering (Ejsing-Duun & Skovbjerg, 2018). Despite the analytical depth a cross-sectional understanding of design pedagogy and technological efficacy can provide biomedical engineering, analyses on

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[1] This is not an exhaustive list.

design pedagogy in engineering exclusively center industrial or mechanical engineering, leaving biomedical untouched (Davies, 2013). That said, this work can extend the relevance of exhaustively explored aspects of design, like user interface, and place them in the context of underdiscussed variables like cultural inclusion (Ejsing-Dunn, 2018; Hanna et al., 2020). For example, Ejsing-Dunn and Skovebjerg (2018) describe elements of design in relation to instruction and inquiry noting "that inquiry is valuable not only when teaching design, but when engaging in design" (Ejsing-Dunn and Skovebjerg, 2018, p. 446). This theme of engagement is particularly interesting in the context of biomedical engineering, where designs often become pseudo-ligaments—invasive, imbedded, and worn. Indeed, the way that medical technology interfaces with its users is distinct and is critically examined throughout this work.

With this in mind, prior to delving into the nuance of these concepts, the task of this introduction is to describe the onus of this research project. It reflects the rationale for the selected research sites, articulates the theoretical contours of the analysis, and centralizes my primary research questions.

1.2 Science as Political Neutrality: An Explanation of Research Site(s)

There is a conflict characteristic of BME curricula: a desire to assert science as value-free, yet a need to attend to the value-centered interests of varying stakeholders (Bahm, 1971; Fearis & Craft, 2016; Jones & Zucker, 2000; Risman, 2001).[2] This conflict will be further explored in chapters two and four, but its articulation in this introduction is necessary context. Such a conflict points to the ways that knowledge in the discipline has been reported through the lens of objectivity but has been implemented through an inherent subjectivity. These elements of subjectivity contribute to medical device bias and mesh with systems of power prior to technology ever being thought of (Baker & Hawn, 2020; Fawzy et al, 2022; Hanna et al, 2020; Kadambi, 2021). With the understanding of education as an informative space, these values are no better examined than in the context of BME instruction (Brooks, 2018). From extending understandings of medical device bias to notating student interpretation of instructional experience, the implications of this research for pedagogy and engineering design are manifold.

That said, past literature on medical devices, with few exceptions, have been relatively distinct from conversations of the social effects of developed technology (Braun, 2014; Kadambi, 2021;

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[2] By no means is this piece suggesting that the conception of science as value-neutral is an exclusively American construct. Instead, it highlights and specifies American for contextual purposes only.

Fawzy et al., 2022). In respect to device design, manufacturability and usability have largely truncated conversations of social impact (Eubanks, 2010; Fearis and Craft, 2016). This thesis argues that a separatist logic divides science from social meaning, and the effects of this separation uniquely protrude in the American context (Benjamin, 2020; PEW Research, 2015). This holds especially true with reference to BME design, where a device's social influence is reduced to its clinical effectiveness. In other words, if a device works— and works well—it is categorically assigned positive social value, with little regard to how its use might contribute to the reification of specific social projects (Benjamin, 2020; Braun, 2014; Hanna et al., 2020).

While there have been earnest attempts to advocate for more equitable approaches to product development in adjacent fields like electrical and computer engineering, biomedical engineering has lagged in this regard (Benjamin, 2020; Buolamwini and Gebru, 2018; Hanna et al, 2020; Klein, & D'Ignazio, 2020). Following heightened awareness during the Covid-19 pandemic, some academics have begun to engage more thoughtfully with the idea of race in the creation of medical devices; however, other social factors—ability, size, etc.—remain unplumbed (Kadambi, 2021). This thesis seeks to seize on this newfound interest in the thinking of race in design and expand this reach into considerations of other social factors. While positively directed, these recent studies maintain an overreliance on the aspect of technological inefficacy, and thereby fail to adequately address the harden realities of structural and institutional oppression that are often embedded into technology. The study of device efficacy without the pretext of systemic power renders research short sighted. Faults in device design reflect faults in our social fabric. Ignoring this fact reduces social characteristics to biological or deterministic phenomena, reconstituted through a series of quasi-scientific processes (Hanna et al., 2020; Ifekwunigwe, 2018).

Citing Zuberi (2000), Hanna et al. (2020) exemplifies this point within the context of "deracializing" data projects:

> "The problem does not end with the collection of racial data; it only begins. The problem accelerates when we attempt to analyze these data statistically... The racialization of data is an artifact of both the struggles to preserve and to destroy racial stratification. Before the data can be deracialized, we must deracialize the social circumstances that have created racial stratification." (Zuberi, 2000 as citied in Hanna et al., 2020).

As this work advocates for a move away from bias and towards fairness, it must identify fairness as necessarily fluctuating and reliant on a social pulse. Further, it must understand the mutual

constitutions of social characteristics on one another—the way class informs race, race informs gender, and so on and so forth:

> "The concept of fairness, in addition to being situational, evolving, and contested from a number of philosophical and legal traditions, can only be understood in reference to the different social groups that constitute the organization of society." (Hanna et al., 2020, p. 1)

Since the understanding of bias as contextual is critical to addressing its effects on devices, this work focuses on the country context most familiar to the researcher. Aside from familiarity, the historical malleability of social society in the United States provides a fruitful analysis for assessing the value-centric nature of device design. With these goals as setting, this study focuses on the instructional design of medical technology in the United States and selects two Biomedical Engineering programs ranked within the top-25 as its research sites.[3]

1.3 Theory

1.3 Exclusion as Enactment

Theory is a cornerstone of this analysis. As such, this thesis develops and extends Annemarie Mol's concept of "doing medicine" to define exclusion as enactment. Exclusion as enactment can be understood as an examination of exclusion as a decision-making process, and it allows us to reflect on how the choice to exclude can generate tangible impacts in the real world.

Annemarie Mol, an ardent proponent of the tenants of actor network theory (ANT), and her work *The Body Multiple: Ontology in Medical Practice (2002)* are integral to this analysis.[4] In *The Body Multiple,* Mol makes the argument that despite diseases having an agreed upon ontology, phenomenological variation proves their multiplicity (Mol, 2002). That is, although on a biomolecular level diseases are the same, the way they manifest and interact with individuals is decidedly different. This means that diseases and medicine writ-large are "multiple" in nature (Broom, 2005; Jensen & Winthereik, 2005; Mol, 2002). Jensen and Winthereik (2005) articulate the philosophical underpinnings of Mol's argument, including the ancillary subpoint most

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[3] While rankings are inherently problematic, they serve as a good heuristic for this piece, as lower-ranked/emerging programs tend to borrow aspects of curriculum from high-ranked programs. Hence these two sites allow us to examine micro-practices that likely have relevance on a macro scale. (For more see: Borden & Bottrill, 1994). Rankings are based on US News and World Report's 2022 edition.

[4] In *Actor-Network Theory: Sensitive Terms and Enduring Tensions (2010)* Mol rebukes the description of ANT as a theory, implying that it is reductionist to the power of ANT as a framework. I define Mol as an Actor Network Theorist for the sake of clarity, as her analytic approach is in-line with the academic conventions of ANT.

pertinent to this thesis.

> "…Mol argues that the object order is a precarious accomplishment which should be studied rather than assumed. An object (a disease for instance) is not a singular entity but a texture of partially coherent and partially coordinated enactments. In Mol's account, the ontology of an object is thus decentered to a multitude of practices. Objects do not exist in and of themselves but only through multiple situated practices." (Jensen & Winthereik, 2005, p. 266).

Somerville (1999) provides further insight into the notions of ANT for which Mol builds her analysis, with a particular focus on the presuppositional distinctions of object-subject inherent to modern organizational theory:

> "According to Kant, human thought has an irresistible impulse to unify and give systematic arrangement to all human experiences and cognitions. The "unity of apperception", which Kant also calls the "I think", is the ultimate condition of all experience and experience is always experience for a subject." (Somerville, 1999, p. 2).

The anti-Kantian framework in which Mol situated her work is pivotal to understanding her assertion that objects are multiple. For Mol, like Latour, the "ontological zones" birthed from a modern episteme are limited in their bifurcated categorization of the human and non-human, rendering the other as agentless—an acted upon rather than an actor in and of itself (Latour 1993 as cited in Somerville, 1999). As Jensen and Winthereik (2005) note, Mol challenges the standard Kantian claim that objects are separable from their various enactments. Mol's counterpoint is articulated in what she calls "being done".

> "It depends on everything and everyone that is active while it is being practiced. This disease is being done." (Mol, 2002, p. 32).

> "Because as long as the practicalities of doing disease are part of the story, it is a story about practices. A praxiography. The ''disease'' that ethnographers talk about is never alone" (Mol, 2002, p. 31).

While this work by no means unrelentingly accepts ANT as truth, it does find utility in Mol's conception of "being done" and the construction of "being " relevant to ANT. When we conceive of exclusion as a process which informs and creates our current social reality, we are better able to consider questions relevant to the decisions made in pedagogical frameworks. We can ask both *why* cultural and physiologic difference is excluded from design instruction and *how* such exclusions lead to inadequate care or contribute to institutional oppression. Treating exclusion as enactment as the preface of bias and device design allows us to examine the exclusion of social

factors in instructional contexts without acquiescing into a biologically essentialist argument. This is especially useful considering section 1.2 has established the fact that social characteristics are seldom rooted in true biologic difference. While these categories might be biologically non-existent, their social existence hold great influence (Hanna et al., 2020; Ifekwunigwe et al., 2017).

> "As we refuse essentialism, resisting the mantra-like categories of social life—race, ethnicity, class, gender—as coherent, in the body, "real," consistent, or homogeneous, we also take very seriously that these categories become real inside institutional life, yielding dire political and economic consequences. Even if resisted, they become foundational to social identities" (Weis & Fine, 2004, p. xv)

This theory, then, seeks to describe how the exclusion of specific frameworks in the pedagogical conception of medical technology and device design contribute to bias and limit the function of developed devices.

Mol's description of "being done" allows us to consider this once more:

> "Thus, an ethnographer/praxiographer out to investigate diseases never isolates these from the practices in which they are, what one may call, enacted. She stubbornly takes notice of the techniques that make things visible, audible, tangible, knowable" (Mol, 2002, p. 33).

The description of the practices by which something comes to be known must include choices of exclusion. The notation of these decisions, calls, or "enactments" forge a basis for how things come to be understood. To give a more concrete example, we can understand exclusion as enactment by examining the way spirometry was integrated into physical education curricula in the mid-nineteenth century. In *Breathing Race into the Machine: The Surprising Career of the Spirometer from Plantation to Genetics* Braun (2014) describes early adoption of spirometry into collegiate physical education programs. More specifically, she describes how the lung measuring device was implemented through ideological aims, supporting the "hierarchical ordering of white bodies" (Braun, 2014, p.56).

> "Hitchcock collected data on age, weight, height, girths of the chest, arm, and forearm, and strength on every college student. In the second year, he added lung capacity measurements assessed with the spirometer. In Hitchcock's hand, lung capacity became a key anthropometric variable in U.S. physical education, centered on the function and capacity of a vital organ system" (Braun, 2014, p.61). [5]

> "In such a context, lung capacity measurements, enmeshed in a discourse of vigor and fitness, would emerge as a tool for measuring, monitoring, and disciplining the physical

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[5] In the above quotation, Hitchcock refers to Edward Hitchcock, the first long-term professor of physical education and hygiene in the United States, a program established at Amherst College in 1861[5].

power of young American bodies, ensuring their future as leaders in a new world order." (Braun, 2014, p.59).

Braun's work is mentioned here in a precursory fashion, as further analysis will be had in chapter two. That said, Braun, in ways both implicit and explicit, points to the way physical education pedagogy informed the use and evolution of the spirometer. This insight is particularly useful, as it realizes what has here been described as hypothetical. That is, Braun's work shows how the exclusion of specific racial subjects informed real-time use of the spirometer, and how such use, while apparently objective, promoted highly political social aims. Moreover, her work suggests that the design of medical technology, in part, is influenced by instruction. Of course, Braun's work does not center design pedagogy or engineering instruction specifically, but it at the very least encapsulates the idea that design and instruction can be bidirectional informants of one another—iteratively and recursively shaping product output. In the context of spirometry and physical education, the desire to quantitively capture measurements of physical wellbeing further propagate the falsehoods of scientific neutrality expressed earlier in this introduction:

> "Guiding individual physical training plans and serving the lofty goal of measuring "the typical man"—of a decidedly Anglo-Saxon variety—anthropometry would be crucial to conferring scientific legitimacy on the field of physical education."

Braun's argument also relays these social systems as volatile, indefinite, and contextual. She proffers the standardization of man, claiming that such an effort simplifies, rather than complicates, interpretations of health. Such a process inherently inscribes a frame of normalcy onto the body, and this idea of normal excludes certain members of society.

With the frame of exclusion as enactment more firmly harnessed, this analysis can describe the ways that instruction and exclusion create realities of bias for medical devices. The remainder of this work develops what has been gestated in this introduction. It describes the ways in which medical devices and the curricula that inform their creation have value, permeate meaning and enact social influence.

1.4 Research aims and Questions

As mentioned above, the saliency of medical technology, paired with the understanding of science and engineering as value-neutral, has severely limited the scope of research that describes the socio-material impacts of medical devices. This, alongside the absence of literature which describes device design instruction in biomedical engineering, highlight the necessity and

originality of this thesis. In addressing this gap in the literature, I ask the following questions:

> 1: How can our current conceptions of medical device bias be expanded upon?
> 2: What values are imbued in medical device design curricula?
> 3: What defines a "user" in the context of medical device design and how is that user conceptualized?
> 4: What role does exclusion play in the crafting of medical devices?

1.5 Organization of Thesis

This thesis is organized into five chapters. chapter one serves as an introduction to the piece, it describes the rationale behind selecting research sites and comments on the theory which governs this analysis. Chapter two is a literature review; it describes the influence of economics in the instructional design process, presents models of design popularly used in BME programs, comments on the genealogy of mechanical CAD, introduces medical technologies with their distinct social histories, and investigates the role of social characteristics in device development. Chapter three is the methodology of this study. It reflects on the design of the research with particular attention to the role of researcher positionality, ethics, and rigor. In chapter four, research findings from interviews are reported and are considered within the context of the study. Lastly, chapter five concludes the thesis with a summary of the main findings and implications for further research.

Chapter 2 – Literature Review

"We cannot wonder, then, at the welcome given to these machines…The struggle for existence leads to strange devices." –Machine-Made Diagnoses in The British Medical Journal, 1895

2.1 Introduction:

The aim of this section is to synthesize available research on the academic discourses which constitute this thesis. That is, this section examines design modeling techniques, medical device bias, computer-aided design, and value-laden science in effort to adequately describe the mechanisms which inform contemporary practices in biomedical engineering pedagogy. While on the surface simple, this is a daunting task considering that such a synthesis requires the co-analysis of concepts which have not been priorly studied together. In attempting to distill a coherent narrative, this analysis will deploy the theoretical frames articulated in the introduction, further cementing the ways in which exclusionary enactments produce realities within medical technology. What is revealed in this section is a linearizing conceptualization of medical device design, reducing instruction to the quantifiably measurable, economically favorably, and plainly scientific while sacrificing discussions regarding the socio-cultural impacts of medical devices.

2.2 BME and Design Models

A significant portion of this thesis will focus on the effects, impacts, and outputs of Biomedical Engineering, and thus it must succinctly describe what biomedical engineering entails. Placing a definition on the practice will aid in orientating its influences and describing the varying relevance of pedagogical techniques which accompany it.

Most would agree that biomedical engineering is "an integrating medium for two dynamic professions – medicine and engineering" (Enderle & Bronzino, 2011). This intertwining of mediums grants ample opportunity for the interaction between medical professionals and engineers:

> "Since biomedical engineering involves applying the concepts, knowledges, and approaches of virtually all engineering disciplines (e.g., electrical, mechanical, and chemical engineering) to solve specific health care-related problems, the opportunities for interaction between engineers and health care professionals are many and varied." (Enderle & Bronzino, 2011, p. 17).

This definition, and the understanding of the interactivity of the field, provides base for a discussion on pedagogy. Before describing pedagogical technique, however, a description of the

basic curriculum structure of BME programs should be had. Undergraduate biomedical engineering pathways emphasize the strength of core sciences – chemistry, biology, mathematics, and physics—in their curriculum. Other aspects of the curriculum are focused on exposing students to the subspecialties within BME that might lead to careers or advanced degree offerings. These subspecialities include but are not limited to bioinstrumentation, biomaterials, biomechanics, clinical engineering, and tissue engineering (Enderle & Bronzino, 2011; Saltzman, 2009). This emphasis on the hard sciences is integral to biomedical engineering, and for good reason: engineers must possess a requisite amount of scientific knowledge to craft solutions to the ever-vexing problems endemic to health sciences (Enderle & Bronzino, 2011). That said, the problems endemic to health are not exclusively expressed through the rigidity of science, and this centralization on the scientific impedes—not accelerates—advancement.

In introducing the topic of medical technology, BME textbooks pronounce economic benefit first (Enderle & Bronzino, 2011; Saltzman, 2009). For example, in *Biomedical Engineering: Bridging Medicine and Technology* Saltzman (2009) begins discussion on medical devices by reflecting on industry growth:

> "The medical device industry… is one of the largest and rapidly growing sectors of the US economy." (Saltzman, 2009, p. 389).

This is more than mere rhetorical technique. It is in these texts where we find the first entanglement of biomedical engineering with disciplines external to science, in this case, economics. The arrangement of economic motivations as a necessary antecedent for the development of instruments is a fulcrum of biomedical engineering praxis. Such reflections can be understood by the prevalence of market motivations in the models used to teach design

Ogrodnik (2012) describes two dominant models of instructional design, one presented by Pahl & Beitz (1988) and the other developed by Pugh (1991). Ogrodnik describes each as "linear processes" in the way that they "fundamentally assume that the process starts at one end and moves (roughly) in a straight line to the final outcome." (Ogrodnik, 2012, p. 30). The Pahl and Beitz model focuses primarily on five phases: clarification, conceptual design, embodiment, detailed design, and final documentation:

> "The first phase can be considered a clarification phase. That is, this phase enables the designer (or design team) to make themselves fully aware of the need and the environment in which the need operates. It also gives the designer time to talk to the end-

users (et al.). All of this is necessary in order to develop a full specification before going on to the conceptual design phase. This phase enables the designer to develop initial ideas from which to select a single design to go through to the embodiment phase, where a final prototype is developed. Once accepted, the prototype can go through to design for manufacture (detailed design) and final documentation." (Ogrodnik, 2012, p. 31).

The rigidity of the process "suggests there is little space for alterations, changes of mind, and changes of demands." (Ogrodnik, 2012, p. 30) To meet the shortcomings of the Pahl and Beitz model, Pugh (1991) developed the concept of total design. Total design serves as a framework for assessing the "central core of activities" inherent to the design process (Childs et al., 2001, p. 1). It is considered to be a more rigorous approach as it reflects "the systematic activity necessary from the identification of a market need to the commercialization of the product to satisfy the market need" (Childs et al., 2001, p. 1). As such, the total design framework starts with the market (through market needs assessments) and ends with the market (through development of a solution for a proposed need). The entire process includes seven steps: Market needs assessment, conceptual design, detailed design, manufacturing, and product development/ market need solution.

Childs et al. (2001) note criticism of these design models in instructional domains, citing that some find them to be "too serialistic as opposed to holistic" (Childs et al., 2001, p. 5). When the purpose of technological development becomes rooted in a device's microeconomic potential, it ensures the obsolesce of other critical variables within design. Even with such critiques, these models hold importance in the instructional practices used in teaching design today (Childs et al., 2001; Orgodnik, 2012).

Despite the ways these models create a diagrammatic simplification of the design process, the techniques of design and the development of medical devices have a winding history— converging and diverging along the way. In fact, the inherent linearity of these models, underscored by the economic enunciations of medical device design, are aligned not only with instructional practice, but with the histories of the technologies which make medical device design possible. The remainder of this chapter focuses on these histories and their social manifestation to describe the dangers of approaching device design through the framework of economic and scientific insularity.

2.3 Computer Aided Design (CAD)

Enderle & Bronzino (2011) remark that "technology has struck medicine like a thunderbolt." If we are to take this analogy, then Computer Aided Design (CAD)—the software used to make 3D mock-ups of medical devices—has arguably left the most indelible mark on the practice. In the case of bioinstrumentation and medical device making, BME programs tend to require courses in the study of CAD. These courses enable students with the ability to fully realize the potential of the software, with particular emphasis on creating sketches, modifying drawings, defining parameters and constraints, assembly modeling, and advanced modeling (Androwis). A semantic understanding of these operations is not necessary for this analysis but outlining the breadth of themes covered in CAD courses can act as a useful mental reference. This section describes the technical advancements which grant CAD the function of medical device making.

In 1958, General Motors (GM) instituted an innominate research program to better understand impediments to the industrial design process (Carlson, 2017; Krull, 1994; Tornincasa & Monaco, 2010). Among the products of this research endeavor was Design Automated by a Computer (DAC-1), developed in 1961. DAC-1 was produced via a perceived need to expedite the drafting and computer-image translation process:

> "From these discussions, it became apparent that the time-consuming problems were in the areas of drafting and the translation of drawings into models, templates, production tools, and fixtures." (Krull, 1994, p.41).

DAC-1 was an amalgam of nine distinct technologies that were used in conjunction to develop a complete computer-based design environment (Krull, 1994). This set of technologies would launch the first-generation of Computer-Aided Design (CAD), defined by a technology's use of a one-dimensional modeling primitive and two-dimensional modeling space (Tornincasa & Monaco, 2010). A review of the generational developments within CAD, adopted from the work of Tornincasa and Monaco (2010), has been summarized in table 1.

Table 1: CAD systems through a multi-generational period

Generation	Key features	Dimensions of Modeling primitives	Dimensions of Modeling Space
First-Generation: Drafting	"Object represented by the projection of its edges on a 2D Plane" (Tornincasa & Monaco, 2010, p.4)	One-dimensional	Two-Dimensional
Second-Generation: Wireframing	"Object represented by the projection of its edges in a 3D plane" (Tornincasa & Monaco, 2010, p.4)	One-dimensional	Three-Dimensional
Third-Generation: Boundary Representation	"Object represented by its boundary surfaces" (Tornincasa & Monaco, 2010, p. 5); Guarantees that surfaces form a complete partition of space.	Two-Dimensional	Three-Dimensional
Fourth-Generation: Constructive Solid Geometry	"Object is represented by the occupied 3D-Space" (Tornincasa & Monaco, 2010, p. 5)	Three-Dimensional	Three-Dimensional
Fifth-Generation: Parametric Features based system	"Object is represented by its features" (Tornincasa & Monaco, 2010, p. 6). System builds a "history tree" storing prior iterations of designs for future use.	Two Dimensional or Three-Dimensional	Three-Dimensional

The successors of DAC-1 would not only enhance the dimensional capacity of the technology but would also transition it from an industry-exclusive tool to one accessible to the public. The push into the public domain began in 1975 when United Computing produced Unigraphics, a first of its kind 2D modeling and drafting system, for public use. Though it was not until 1983 when United Computing and competitor Autodesk released their respective PC-Run CAD programs, Unigraphics II and AutoCAD, did the potential commercial uses for CAD unveil themselves.[6] With rapidly advancing systems and more readily deployed software engineering techniques, the mid-range market would be developed with the release of Solidworks 3D CAD for windows in 1995.

Though the economic barrier of CAD was at least partially eliminated, there remained a technical barrier for most potential users. As such, the genealogy of computer-design technique following the emergence of the mid-range market split into two practices: direct modeling and parametric modeling, each eventually succeeded by the strength of hybrid modeling. In their taxonomic definition of parametric modeling, Jassen and Stouffs (2015) describe the technique as "a collection of modelling operations that are linked into a network that can be topologically sorted, that is, the order of execution of the modeling operations can be defined prior to execution." (Jassen and Stouffs, 2015, p.158). In layman's terms, parametric models have been described as a recipe of sorts-- where each constraint and relationship is optimized in the design, and the system catalogs every step into a features based history tree, resulting in each new step being dependent on the prior.[7] Under this general definition, Jassen and Stouffs (2015) describe four subsections of parametric modeling: object, dataflow, associative, and procedural. The "distinguishing factor for these modelling methods is how they support iteration" (Jassen and Stouffs, 201, p. 162). These delineations have been summarized in table 2.

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[6] . Despite touting their public accessibility, the sticker-price for these technologies were exorbitant for most customers, with AutoCAD and Unigraphics II entering the market at several thousand $USD.

[7] You can think of this process like baking a cake, where the amount of flour you add to the mixture influences the number of eggs, and so and so forth. No one factors can be considered without the context of the prior.

Table 2: A description of CAD Modeling Systems

Modeling Type	Iteration Type	Key features	Examples
Object Modeling	Does not Support	No iteration occurs	Trimble SketchUp
Associative Modeling	Single-Operation	Applies the same operation simultaneously over multiple different entities	Entity-Relationship Model, Binary Relations
Dataflow Modeling	Implicit Multi-Operation	Additional parameters assigned multiple input values, with an operation iterating over multiple entities	Cyclo-Dynamic Data Flow, Boolean Parametric Data Flow
Procedural Modeling	Explicit Multi-Operation	Currently modeled via the use of data sinks or recursion, explicit-multi operation iteration directly delineates the iterative process through use of nodes with specialized semantics which influence the control flow	Data storage/ Archival devices

While a powerful tool, parametric modeling requires a greater deal of technical knowledge than its counterpart, direct modeling.

> "By this technology designers can perform quick and immediate models editing without knowing anything about their modeling history but simply translating and rotating faces, edges and nodes." (Tornincasa & Monaco, 2010, p.7).

The simplicity of the direct modeling technique rests in the fact that a designer does not need to know the constraints of the prior model to change it. This, coupled with the fact that the practice is incredibly similar to older 2D drafting techniques, makes it easier for designers to apply their creations with new technology. Also referred to as "history-free" design, the strength of direct modeling nestles its primary weakness: without needing prior knowledge of the design, the system can "alienate" designs from their original intent. As Ushakov (2006) captures:

"practically any editing operation unrecognizably changes the original model, 'alienating' it from the design intent. A table is no more a table; a bearing is no more a bearing, etc." (Ushakov as cited in Tornincasa & Monaco, 2010).

Though models which focus singularly on parametric or direct techniques are still available, they've been largely supplanted by hybrid models which infuse both practices. The shift toward hybridism is a result of the desire to deploy the strength of the parametric model with the ease of direct modeling:

"The actual trend in CAD software development is to integrate direct editing tools in traditional history-based software to preserve the control and automation of parametric technology gaining the flexibility and direct interaction of direct modelers" (Tornincasa & Monaco, 2010, p. 8).

Biomedical engineering programs primarily deploy hybrid-based systems, with Solidworks and Autodesk Fusion being two prominent options. These technological developments are described here because of their pedagogical and professional relevance. The design process may start with a sketch on paper but CAD—quite literally—dimensionalizes it. For designs ever to be manufactured, they must be digitally rendered. These renderings allow for 3D-printing, high-concept prototyping, and use tests—each a requisite of medical device making prior to final production (Ogrodnik, 2012).

With the plurality of technique and the relative accessibility of the technology, designers of all types, including those who draft medical technologies, can find utility in design aided computer technology. By way of skills categorization, the developments within CAD show that individuals with varying skillsets can use the technologies available dependent on their level of comfort. Thus, the question of who a user might be is considerably less relevant in the context of CAD. Those who can think of a design can and do have the potential to be CAD users. However, the effects of eventual designs, especially in the context of medical devices, begs the question: Who does a medical device designer think of as a user?

2.4 VOC and The Making of the Costumer

In searching for a potential "user" of medical device technology the equally ambiguous term "customer" proves to be a useful starting place. The application of the word customer to describe users of medical technology is socially encoded, and this section elucidates the very real influence of the term on the medical device industry. Moreover, its use allows us to gesture at the implications of a capitalist thought on engineering design.

The first comprehensive study of customer engagement in engineering settings utilized the market term Voice of the Customer (VOC). Griffin and Hauser (1993) describe VOC as the first step in a larger process known as Quality Function Deployment (Figure 2). Quality Function Development (QFD) "promises decreased product-development costs, decreased product-development time, and improved customer satisfaction" and thus has had manifold relevance in engineering settings (Griffin & Hauser, 1993, p. 22). More specifically, VOC serves as the process by which user needs are identified, structured, and prioritized (Figure 3). Griffin and Hauser argue for the concretization of this framework in engineering since engineers "require greater detail on customer needs than is provided by the typical marketing study." (Griffin & Hauser, 1993, p. 2).

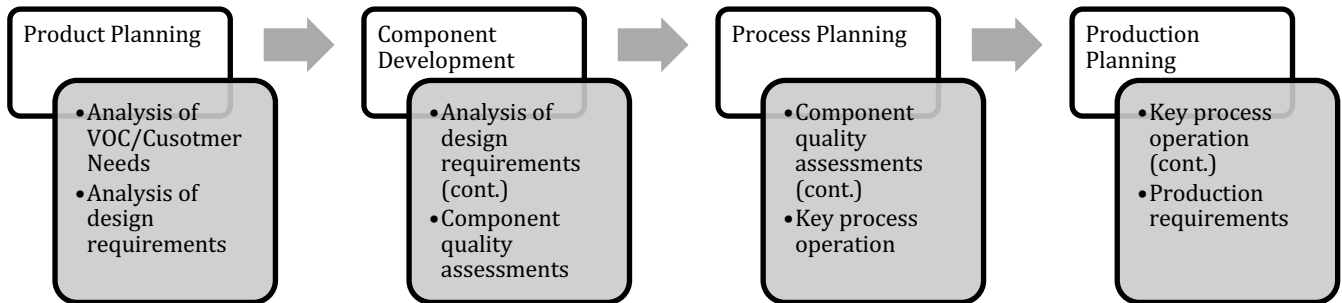| Product Planning		Component Development		Process Planning		Production Planning
•Analysis of VOC/Cusotmer Needs •Analysis of design requirements	→	•Analysis of design requirements (cont.) •Component quality assessments	→	•Component quality assessments (cont.) •Key process operation	→	•Key process operation (cont.) •Production requirements

Figure 2: QFD Process Adopted from Jahan et al. (2016)

VOC must be understood in terms of its industry relevance. It's deployment centers the desire to accelerate and maximize the profit-based outputs of technological innovations. Even the term innovation holds a specific connotation in the context of engineering development:

> "We consider innovation in the capitalist model: invention leading to measurable business success as opposed to interesting but unprofitable creativity" (Fearis and Craft, 2016, p. 1131).

This analysis does not describe, at length, the nuances of VOC. Instead, it takes the considerations laid forth by Griffin and Hauser (1993) and describes their influence on the professional methods of medical device making. That said, once we place the desire for profit and technological innovation at the forefront of VOC, we are allowed to consider an analysis of VOC as an analysis of "specific tradeoffs in engineering design" (Griffin & Hauser, 1993, p. 2). Tradeoffs are an aspect of medical device formation that follow the logic of exclusion as enactment (Mol, 2002). Innately, tradeoffs are a matter of included and excluded choices, and

while they are inevitable in the process of product development, examining the decision-making processes behind these exclusions can uncover implicit interests. What might constitute a tradeoff is variable dependent on the device; security interests might be of concern for wearable devices, whereas biomechanical mimicry might be of interest for implantable heart devices (Altawy & Youssef, 2016; Rodriguez-Villegas et al., 2018). Regardless of the type of tradeoff made, the VOC process provides a basis for which these exclusions can be built.

Identifying needs

- Methods for identifying needs include hosting focus groups or conducting customer one-on-ones. While this task is primarily qualitative, analysis of the data tends to be quantative.

Structuring Needs

- Methods for structuring needs include customer sorting and clustering, this allows a researcher to develop a co-occurence matrix to sufficently create a structured hiearchy of needs.

Prioritzing Needs

- The least methods based tier of the AOC process, prioritzing needs considers the integration of structured needs into a product's final design basedon its costs, manufacturability, and need-type (attitude, perference, or utility).
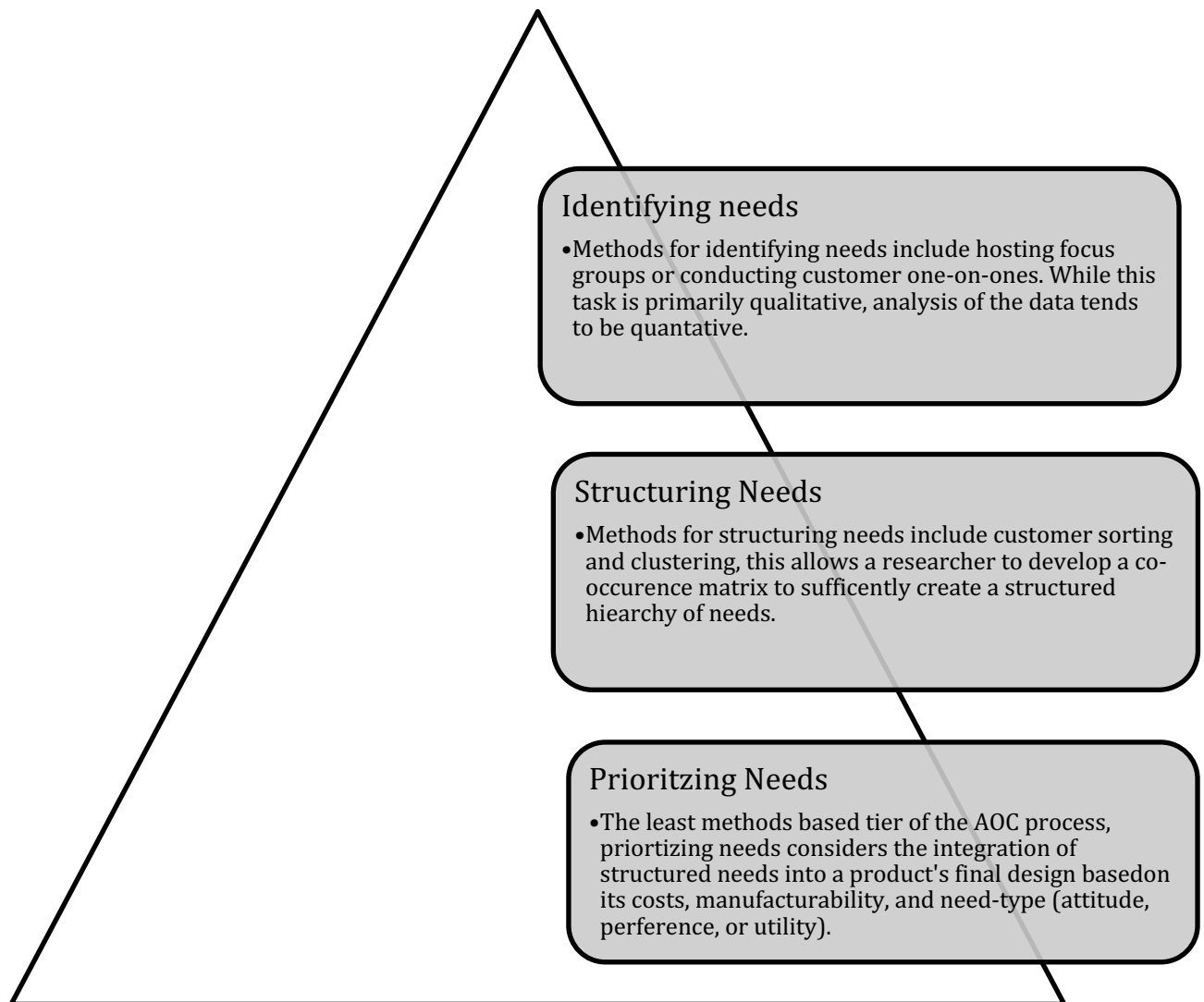
Figure 3: Voice of Customer Process

The process of VOC is reminiscent of a utilitarian ideology, as it inherently fails to capture the needs of a minority in the pursuit of an aggregate picture of the customer; that said, this phenomenon will be further discussed in chapter four (Scarre, 1996). Despite this fact, the

relevance of the technique and its emphasis on ascertaining customer interest through economic and quasi-mathematical means has found much welcome in engineering design.

In the case of biomedical engineering, Eubanks et al. (2010) describe a method of VOC directly developed for medical devices. Adopted from Battelle's Health and Life Science's Medical Device Solutions group, the process is described as a "standardized, scalable approach to performing VOC as part of medical device design." (Eubanks et al., 2010, p. 1). The process outlined centers seven points: Develop VOC objective statement, review existing data, develop customer profile matrix, develop interview logistics plan, create the interview guide, conduct the interview, and derive requirements. This method, while more neatly enumerated, is not greatly distinct from prior works on VOC in engineering. Though two aspects of Eubanks' analysis do prove to be fruitful for this work. The first, despite being just a footnote, moves us one step closer to answering the evasive question— *who is a user*:

> "Note that the use of the term "customer" in this paper refers to the end-user (doctor, nurse, patient, etc.) that will be affected by the product or service eventually developed from this effort" (Eubanks et al., 2010, p. 1).

In reflecting on a lecture in Biomedical Engineering at Johns Hopkins University, Fearis and Craft (2016) describe an exercise where they ask their students the same deceptively simple question this section has attempted to tackle: "Who is the customer for a new medical device?" (Fearis and Craft, 2016, p. 1131). After a flurry of responses, Fearis and Craft highlight the interjection "umm" as an answer which accurately underscores the question's hidden complexity. After which, they suggest that, instead of customers, individuals be termed stakeholders:

> "More accurately they should be termed stakeholders, for each has an opinion and stake in what is needed and what "good" looks like from their unique perspective" (Fearis and Craft, 1131).

They describe patients, sponsors, nurses, and purchasing departments as example stakeholders. Fearis and Craft end their work by emphasizing the importance of "placing a deep understanding of all stakeholders" (Fearis and Craft, 2016, p. 1133). That said, the use of the VOC process to numerate customer or stakeholder needs brings forth several questions: what do we make of the user who is not able to articulate their needs or desires? How are stakeholders prioritized and what stakeholders—if any—are marginalized through this process? Is it enough to simply understand a stakeholder? How do we actionize on such understanding?

These questions point to the second utile notion drawn from Eubanks (2010). That is, they suggest that a benefit of the VOC process is the way it "provides a validated, traceable history of the customer". This emphasis on a traceable history conceives of both the user and the device as non-stagnant entities. This understanding of the fluid person and technology might be hard to discern amidst the atomistic, linear design models described in the first section of this chapter but placing the conversation of the traceable figure within the context of bias and instruction can be useful in revealing these notions.

2.5 Medical Device Bias

In *Achieving Fairness in Medical Devices,* Kadambi (2021) argues that bias in medical devices takes on three forms: Physical bias, computational bias, and interpretation bias. He delineates these categories by characterizing the way biases manifest in real-time:

> "A medical device can exhibit physical bias, where physical principles are biased against certain demographics. Once data are collected, computational bias, which pertains to the distribution, processing, and computation of data that are used to operate a device, must be considered. Subsequent implementation in clinical settings can lead to interpretation bias, where clinical staff or other users may interpret device outputs differently based on demographics." (Kadambi, 2021, p. 30).

Kadambi furthers his analysis by describing the ways these biases are reflected in particular devices and practices—focusing respectively on pulse oximetry, dataset diversity, and spirometry. Distinguishing between these biases is useful in parsing the various ways medical devices interact with user-subjects. In reference to physical bias, Kadambi critiques the pulse oximeter and optical bio-sensory technology writ-large. These devices use light sensors to produce readings on blood-oxygen levels; however, these readings are often misinterpreted on darker skinned individuals (Fawzy et al., 2022; Kadambi, 2021; Sjoding et al., 2020).[8] Kadambi references Sjoding et al. (2020), who noted that "Black patients had nearly three times the frequency of occult hypoxemia that was not detected by pulse oximetry as White patients" (Sjoding et al., 2020, p. 2478). These results were reinforced by Fawzy et al. (2022) where they describe the latent effects of inadequate pulse oximeter readings. Specifically, Fawzy et al. (2022) describe how faulty occult hypoxemia readings resulted in delayed covid-19 therapy for

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[8] Kadambi's choice of using pulse oximetry to describe physical bias is poignant, as there is greater traction on the topic following the Covid-19 pandemic. A review of publications on the ProQuest and Oxford SOLO Library databases shows that, of publications with keywords "Pulse Oximeter Bias," 39.5% and 28.2%, respectively, were published after the start of the pandemic.

darker-skinned persons:

> "The results of this cohort study suggest that racial and ethnic biases in pulse oximetry accuracy were associated with greater occult hypoxemia in Asian, Black, and non-Black Hispanic patients with COVID-19, which was associated with significantly delayed or unrecognized eligibility for COVID-19 therapies among Black and Hispanic patients." (Fawzy Et al., 2022, p. 730).

Moving to computational bias, Kadambi describes the lack of gender diversity in chest x-ray imaging databases. He notes that this imbalance "worsens the quality of diagnosis for female patients," and reflects on Larrazabal et al. (2020) to highlight that increasing "gender representation to 50% female boosts diagnostic performance not only for females but also for males" (Kadambi, 2021, p. 30). Lastly, in reviewing interpretation bias, he mentions the spirometer, a device which measures lung function. Kadambi critiques the deployment of race-correction values. Also referred to as ethnic-adjustment factors, race-correction values are used to account for a patients race when measuring lung capacity.

> "In the United States (US), spirometers use either correction factors of 10% to 15% for individuals labelled 'black' and 4% to 6% for people labelled 'Asian', or population-specific standards, usually those derived from the third US-based National Health and Nutrition Examination Survey for 'Caucasians', African Americans and Hispanic." (Braun, 2015, p. 99).

These values treat race as a biological truth rather than a social factor. Often in the case of spirometry, these "correction" values are applied under the belief that non-white people have naturally lower lung capacities (Braun, 2014; Kouri et al., 2021; Vyas et al., 2020). Their application hinders proper diagnosis of illness and can even limit access to social services like supplementary disability income (Texeira, 1999; Braun 2014). That said, this bias does not mean that medical professionals—and Biomedical engineers—should disengage with race.

> "To be clear, we do not believe that physicians should ignore race. Doing so would blind us to the ways in which race and racism structure our society. However, when clinicians insert race into their tools, they risk interpreting racial disparities as immutable facts rather than as injustices that require intervention." (Vyas et al., 2020, p. 880).

In all, Kadambi's framework of bias, while useful in conceptualizing the insufficiencies in device implementation, generally disregards the *process* of making devices. More than this, Kadambi's tri-tiered model of bias only addresses the influence of other technologies in the context of computational bias. This isolates the way medical technology interacts with other technology, which is particularly damaging considering the hyper-interactive nature of hospitals,

clinics, and other venues where medical technology is likely to be deployed (Enderle & Bronzino, 2011; Mol, 2002). In addition, Kadambi's proposed solution to medical device bias leaves much to be desired. His proposal centers "fairness" in that he suggests that corporations and academic research outputs adopt self-evaluation criteria in their development and discussion of medical devices:

> A "fairness" statement for the evaluation of studies of medical devices could use the three categories of bias as a rubric: physical bias, computational bias, and interpretation bias. A medical-device study does not need to be perfectly unbiased to be reported." (Kadambi, 2021. p.31).

Despite offering this evaluative framework, Kadambi does not describe precisely how such evaluation will occur. As he notes, "a medical-device study does not need to be perfectly unbiased to be reported," yet he does not describe how much bias is *too* much, which poses difficulty in using fairness—which inherently presents a sense of subjectivity—as a measurement for bias. Beyond the issue of measurability, by singularly using his developed criteria of physical, computational, and interpretation bias, there is a potential for other biases to go undetected. It is this concept of still proliferated yet undetected bias which leads this analysis to conceptualize a fourth form of bias: Instructional design bias, which is implicit bias that manifests through design instruction. In fact, it is in the interpretative bias of spirometry where this work identifies yet another connective tendon between medical device design and pedagogy in the form of instructional device bias.

2.6 Codifying Curriculum: Spirometry and Anthropometry

Braun (2014) describes the development of spirometry as "enmeshed in an industrial capitalist system that emerged concurrently with enthusiasm for precision instruments, measurement, and statistical analysis" (Braun, 2014, p. xv). Though apparently objective and systematized, "the outcome of spirometric measurement was historically contingent" (Braun, 2014, p. xx). The idea that spirometric outcomes were contingent on historical mechanisms is essential for this section of the chapter. This notion underscores the malleability of medical technology and the potential exportation of a device's uses and purposes. Figure one briefly describes the history of spirometry. This timeline is a useful reference, as this thesis is primarily interested in the way that certain historical values informed use of the spirometer in instructional contexts. ted in the way that certain historical values informed use of the spirometer in instructional contexts. For the sake of clarity and brevity, this section will focus on the adoption of spirometry and anthropometry in early physical education programs, reflected as point two in the timeline.

1. Development of the Spirometer by John Hutchinson (Braun, 2013; Barun, 2014; Braun, 2015; Kouri et al., 2021).

• 1840; United Kingdom

2. Spiromery and anthropometry are adopted into early Physical Education Programs in the US (Barun, 2021).

• 1860; United States

3. Wide-Scale adoption of spirometry for pre-opertive throacic surgery assessments (Barun, 2014; Kouri et al., 2021).

• 1920; United States

4. Development of the FEV_1 /Forced Vital Capacity Value, a value used to predict ventillatory limitations during exhalation (Kouri et al., 2021).

1947-1956; United States & France

5. Research interst in spirometry for prognosis of cardiorespitory issues (Kouri et al., 2021).
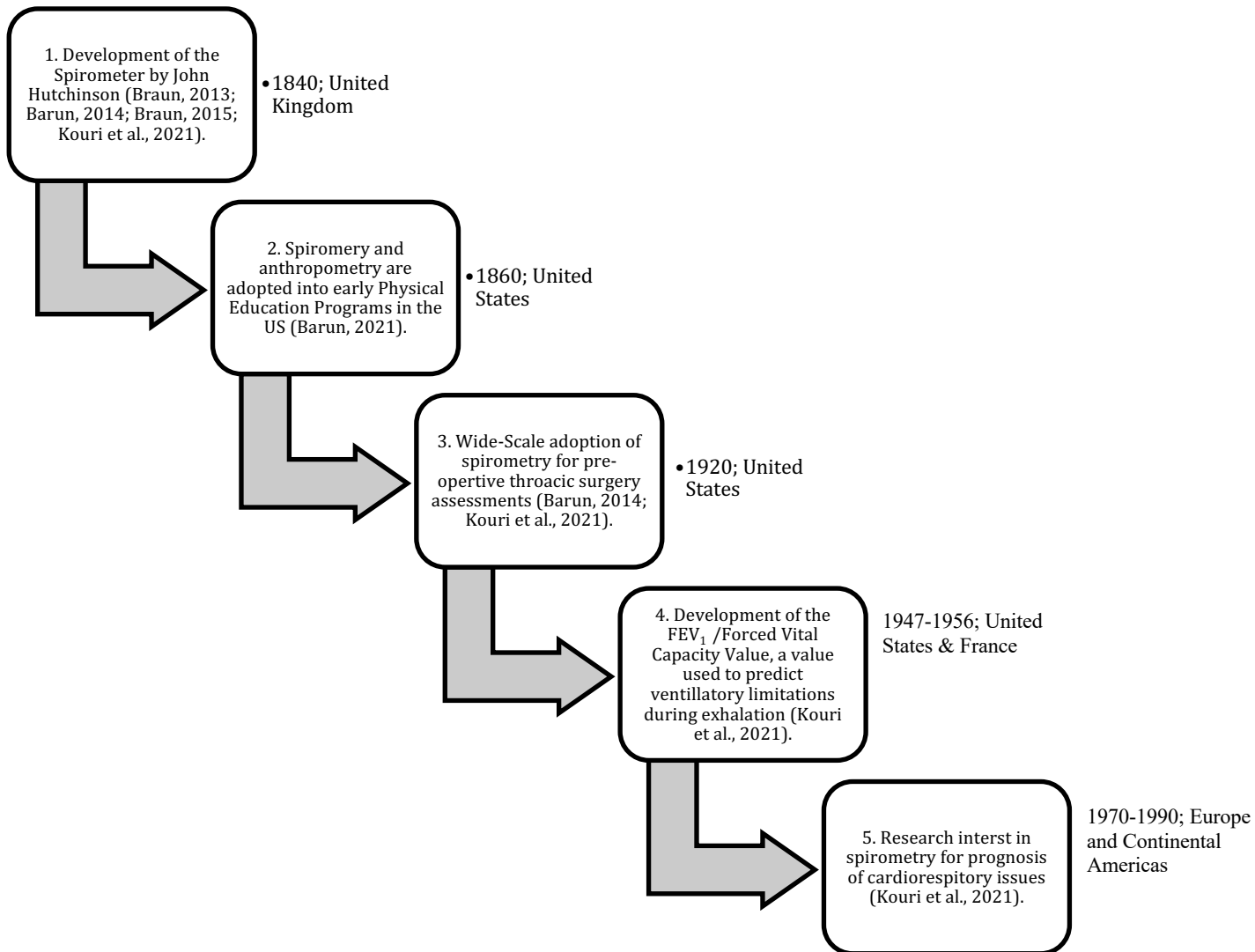
1970-1990; Europe and Continental Americas

Figure 1: A brief timeline of the spirometer

In referencing the adoption of spirometry, anthropometry, and experimental physiology in physical education, Braun engages the influence of instruction on the implementation, design, and use of the spirometer. Braun begins by describing the establishment of the first collegiate physical education program in the United States, officially chartered by the Board of Trustees at Amherst College in 1860. Reflecting on the rationale for the establishment of this program, Braun describes the transformation of fitness from a matter of chance into a moral question of drive and piety.

> "Taming the unruly "animal spirits" and "vices" of this motley student population required a plan to inculcate balance, self-reliance, and patience, rooted in notions of republican fitness for self-government and later Anglo-Saxon superiority." (Braun, 2014, p. 58).

Be it a means to an end, or an end in and of itself, physical culturalists found the wanning physical prowess of the collegiate populace an ideal site to attempt to standardize their ideals of health and wellbeing. Amherst College president Williams Stearns (1854-1876), a reformed minister and preacher, considered the maintenance of the body as a key route to actualize one's relationship with God and strengthen their spirit. Stearns took particular interest in the prospect of physical education, stating that, "No one thing…has demanded more of my anxious attention" (Stearns, 1858 as cited in Braun, 2014). In attempting to ascertain a state of "conclusive whiteness" (Roediger, 1991 as cited in Braun, 2014) these early physical education programs found health and its quantification to be key. Thus, directors of physical education departments methodically cataloged the anthropometric data of their exclusively white male student bodies.

As reflected in Stearns comments, the values of a nineteenth century—reeling the anxieties of a vacillating white racial identity—were imbedded in the development of pedagogy, and this influenced the use and role of technology.

> "Sustained for more than fifty years by cultural enthusiasm for technological innovation, faith in quantification, and an anxiety-ridden quest for fitness, physical educators had tirelessly measured lung capacity on thousands of students."

It is through the process of surveying and recording anthropometric data where Braun highlights how the *exclusion* of individuals from data collection created very real notions of what it meant to be a "man" and how the standardization of this already flawed concept created historical and social riptides that remain relevant today.[9] In reference to the spirometer, using the framework

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[9] In the introduction of her work, readers uncover the inspiration behind Braun's book. In it, she describes a 1999 Asbestos lawsuit. The lawsuit centered Black workers who, upon being exposed to Asbestos and subsequently

Kadambi (2021) provides, this data-collection might be said to have taken the form of a primordial computational bias, since "computational" datasets were not yet possible. Though not entirely a misnomer, none of the outlined descriptions of medical device bias Kadambi puts forth can adequately describe the spirometer. Hence, understanding it in terms of instructional design bias grants the ability to examine the ways that social standardization, codified by curriculum design, became integrated into the device.

For example, Braun details the way that physical education programs gained legitimacy through the proliferation of academic materials:

> "To bring coherence to this vast enterprise, physical educators published manuals with precise instructions for taking measurement, illustrations of instruments, and sample anthropometric cards to facilitate examinations on masses of students."

While these programs purported to use objective metrics, the idea of objectivity was necessarily marred. Hitchcock commented on the "ulterior object" of his work, which centered the desire to methodize the—white—body into a singularity.

> "The ulterior object, however, was to help ascertain what are the data or constants of the typical man, and especially the college man. I have conceived no theory on the subject and have instituted but very few generalizations; but my desire has been to carefully compile and put on record as many of these observations as possible for comparison and verification of statistical work in this same direction by many other persons in America and Europe." (Hitchcock as cited in Braun 2014).

On a technological level, Braun describes portability as a central concern since the spirometer's inception. Initial versions of the spirometer were "large and unwieldy" (Braun, 2014, p. 14). It was a combination of research outputs and the emerging scientific identity of physical education which motivated desire to manufacture the spirometer on a wider scale. In doing so, varying solutions emerged to solve "the problems of portability and cost" (Braun, 2014, p. 15).

> "Their tireless collection of data solidified the importance of anthropometry to an increasingly scientifically rooted physical education. The broad scope of anthropometric measurement also gave a major impetus to the manufacture of equipment, which included spirometers." (Braun, 2014, p. 73)

> "By the early twentieth century, mechanics had developed extensive technological expertise for modifying, manufacturing, and marketing the spirometer, providing the infrastructure for its uptake in domains other than anthropometry, most significantly that of clinical medicine." (Braun, 2014, p.)

The need for portable, cheap devices in wholesale adoption of spirometry in physical education

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having reduced lung capacities, were denied access to disability services because medical professional applied race-correction values which assumed that Black people naturally had reduced lung capacities.

programs is worthy of note. Institutions like Harvard, which was the first school to follow Amherst's footsteps, participated in the manufacturing of these devices. It cannot be understated how the design of the spirometer was fundamentally altered by physical education curriculum. The measurement of lung capacity became all but a cornerstone element of curricula, and the need to manufacture these devices en masse spurred the creation of these manufacturing companies that worked to develop portable, cost-friendly products. In fact, Harvard's manufacturing of these devices was partly inspired by their development of "strength tests," which measured a person's "physical power, working capacity, and efficiency" (Braun, p. 70). These tests, among other attributes, "turned to lung capacity measurements as a marker of physical fitness".

> "To meet the demand for spirometers… most colleges and universities… founded new manufacturing and supply companies, among them the Harvard Instrument Company, Cornell Outfitting Company, the Narragansett Machine Company, Tiemann Brothers, A. G. Spaulding & Company, and the National Spirometer Company." (Braun, 2014, p. 81).

The use of the spirometer, and the standardizing practices of capturing race, interprets the non-white subject as scientifically inarticulable— incapable of being rendered on the same spatial platform as their white counterparts. Detailing this narrative has two-fold benefit. The first is that it highlights how value-imbued technology can problematically shape educational practice. The second is to provide one well-enumerated example of how a lack of historical context can recycle elements of oppression.[10] It is the marriage of these two points which is most relevant for this thesis: the lack of attention given to elements of social history in design instruction maintain medical harm and bias. There is no better exemplification of this notion than the fact that spirometers in the twenty-first century are created, manufactured, and distributed with race-adjustment settings. It shows an inherent lack of historical awareness from each stage of the development process—from drafting to market. If this thesis has yet to convince its readers of the importance of interrogating design curricula, let this be the moment which removes the veil of scientific myopia from the practice of device design.

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[10] I focus on spirometry for brevity. Other value imbued technology has been discussed earlier in this chapter. These include x-ray databases with imbalanced gender datasets or skin-tone based variability in pulse oximetric readings. There is a laundry list of other technology which fall under this umbrella. A few more include blood-pressure monitors, which are often coded with the same race correction values as spirometric devices, and lower-limb replacements which often exclude considerations of postural flexibility in the hip and knee, which are necessary for prayer among those of the Islamic tradition. For more: Fawzy et al., 2020; Kadambi, 2020; Sharifudin et al., 2015; Texeira, 1999

2.7 Conclusion

In the epigraph for this chapter, I highlight a quote from the Vol 1. No. 1775 of the British Medical Journal. The quote describes the "struggle for existence" as an impetus behind the development of "strange devices". Existence can be read in two ways; the first describes the fact that medical devices are developed with the purpose of extending life, the second describes role of medical devices in rationalizing said life. The qualifiers "strange" and "welcome" describe a device's initial foreignness and the embrace—or lack thereof—of its potential use.

The quote highlights what this literature review has established: medical devices are value-laden social projects with subjective meaning. From early medical devices, which the quote uses as theoretical base, to the technological enhancements available through CAD, this fact has remained. Further, this section has described how instruction and curriculum have informed the design of medical devices through time, and it ponders the nature of a "user," which will be furthered in chapter four. In all, this literature review has sufficiently weaved a cohesive narrative between the development of medical devices, instructional curriculum, pedagogy, and technology.

Chapter 3 – Methodology

3.1 Introduction

The first two chapters of this work have introduced the issue of medical device design bias and have organized the piecemeal elements of history, instruction, and technology which inform current understandings of the phenomenon. The aim of this section is to describe the methodology deployed in this work, with particular interest given to researcher philosophy, research rigor, and research design. I begin with a rejection of a potential post-humanist critique of this analysis by describing the possibility of realizing research participants as coherent, conscious beings without need to ignore the relevance of non-human agents. I follow with a comment on research design—qualitative interviews—with description of the coding techniques used to analyze data. To round out the section, I discuss the relative rigor of my research practice with reference to its theoretical justification, replicability, and interpretive support.

3.2 pre-Posthumanism

Through use of Mol's framework of "being done" and the idea of exclusion as a form of enactment, there might be an urge to categorize this work under a broad, sweeping posthumanism umbrella. I do engage, at least partly, with post-humanist thought, and ignoring the err of posthumanism in this work would be unjust. For instance, I have commented dutifully on the *effects* of medical devices and curriculum materials on each other and society at large. Some could argue that I am providing these non-human actors with agency. This assertion is not one which I desire to protest; for all intents and purposes, these are agents, at least in this narrative. That said, the simple acknowledgment of the agency of non-human actors cannot be the sole impetus for posthumanist categorization— for one, it ignores posthumanism as a method and secondly, and perhaps more acutely, it inaccurately terms any acknowledgement of non-human agency as equivalent to that of human agency.

Kipnis (2015) posits viewing manifestos—and more accurately, the effects of those manifestos—as actors themselves, distinct and separate from the authors who pen them:

> "And are these texts, by Latour or Lukács or Marx, human or nonhuman agents? Clearly it would be wrong to suggest that the effects of the texts are simply the responsibility of the authors themselves." (Kipnis, 2015, p.47)

Kipnis is keen on not absolving the author entirely. In this sense, he treats the texts as non-human agents whose meaning is contingent upon the interrelatedness of human agents—that is, associated agency of these texts is derived from the author(s) and the reader(s). Kipnis' analogy proves poignant for this work, as medical devices are akin to literature in the way that authors are akin to designers. Allow us to take the interpretative bias of the spirometer once more, though the spirometer has a set function— like literature, it is the way such results are interpreted that have social impact (Braun, 2015; Kadambi, 2021; Kipnis,2015). The acknowledgement of the social effect or agency of non-human actors does not, however, require an acquiescence into posthumanist theory or method. In fact, it is Kipnis' primary thesis which reigns true for this analysis:

> "I suggest granting agency to everything (which is to acknowledge that anything and everything could affect us) but differentiating types of agency."

In the Latourian, posthumanist categorization of agency, the differentiation of human/non-human is non-existent. These are webbed non-hierarchical categories, each enacting a non-quantifiable yet equal impact on one another. This line of thought has proved ill-fitting for this analysis. For example, in student interviews, participants appeared to value their curriculum as an agent and implicitly denoted its agency in a hierarchical fashion: Instructional materials had more agency than students because of the legitimacy granted to those materials by professors. As such, this piece recognizes agency, particularly non-human agency, as meditated through a power that is quintessentially rational.

Herein lies the second failure of a posthumanist generalization: this thesis is expressly political. The aim of this work is to recognize the limitations of instruction, the way those limitations inform bias, and to engender change in a measurable capacity. ANT and post-humanism have been critiqued for their lack of attention to social issues (Gregory, 2014; Kipnis, 2015; Martin, 2014). Writers like Deleuze and Guattari (1983) suggest the inability to render human agents as "present, conscious, or coherent" (Mazzei, 2013, p. 734). While philosophically intriguing, these critiques obfuscate power dynamics through a pseudo-determinist lens. This has brash implications for this thesis. For example, this makes the "traceable" history of the customer described in the last chapter impossible and disallows discussions of how structural power influence decision making. Further, what this decoupling of the human consciousness gives way to is a deontological position which blurs the lines of "reality… subjectivity... and

representation" (Mazzei, 2013, p. 735).

> "When these disciplines ontologise themselves, treat themselves as complete, a form of epistemological closure occurs with a consequence of a theodicy of technique, of pure application. … Their social and epistemological retractions are advanced by them as the limits of the world. Such a path is deontological in form. The discipline becomes an obligation without having to be consequential." (Gordon as cited in Clifford, 2017).

Rather than favoring a purely reductive framework that isolates human rationality, I engage with non-human actors without need to surrender to post-humanist methodologies that might overtheorize the results of this work. Perhaps, then, this thesis can be considered a "pre" posthumanist critique. It recognizes the coherency, legitimacy, and rationality of human agency without forgoing the influence of non-human actors. That said, it distinguishes between human/non-human actors by describing agency as meditated through power—rationally derived. Thus, in terms of the exclusion-as-enactment element pronounced earlier in this piece, exclusion represents a series of choices made by rational (human) actors that can shape elements of power given to non-rational (non-human) actors, and thereby influence the experiences of other actors, human or non-human. For example, the choice to exclude darker skinned individuals in pulse-oximeter prototyping creates faulty devices. These faulty devices later impact who receives treatment for occult hypoxemia. Lack of treatment can result in the further degradation of health for diseases not adequately detected. [11]

All said, this theoretical basis best allows us to consider the narratives of student's as intelligible and meaningful. Engaging with student interviews as reflections of instruction strengthens the potential for this analysis to produce genuine change—both in the ways that participants envision design and in the ways that curricula can approach the design process.

3.3 Research Design

This study uses in-depth individual (IDI) semi-structured interviews and data-source triangulation as its research design. Data source triangulation "involves the collection of data from different types of people, including individuals, groups, families, and communities, to gain multiple perspectives and validation of data." (Carter et al., 2014, p. 545). With its focus on students at varying levels of their academic careers—some at the master's level, others at the undergraduate level—this methodology allows the researcher to consider the continuities and

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[11]This process is not always as linearly derived as this example.

contrasts between these subgroups to grant greater nuance to the research questions established at the onset of this piece. By using IDI semi-structured interview and data source triangulation, this study was able to present information on the ways in which Biomedical Engineering students are taught device design.

3.4 Interview and Thematic Analysis

I was drawn to the qualitative for its articulation of meaning and knowledge formation (Braun & Clarke, 2006; Evans, 2018; Galletta, 2013). More specifically, semi-structured interviews were a valuable method of investigation because they allow researchers to "explore subjective viewpoints and gather in-depth accounts of people's experiences" (Evans, 2018, p. 1). In determining who to interview, a purposeful criterion sampling method was deployed. Purposeful criterion sampling ensures the "identification and selection of information-rich cases related to the phenomenon of interest." (Palinkas et al, 2013, p. 553). As this research is interested in hearing BME student experience of design instruction, the sampling framework "to identify and select all cases that meet some predetermined criterion of importance' was all but inevitable (Palinkas et al, 2013, p. 555). The criteria I put forth were the following:

1. A student who completed their undergraduate degree in BME within 36 months of the start of the interview OR a student currently enrolled in a master's program for BME/ Device design
AND meets all the following:
2. A student who attended University X or Y
3. A student who has had prior experience with CAD
4. A student who has had prior experience with medical device design

Participants were recruited through a process which included academic departmental outreach, social media outreach, near-peer recommendation, and word of mouth (For outreach materials see Appendix A). This filtering process allowed for the most relevant, up-to-date narratives of student experience to be captured. Once participants were identified, I hosted six, thirty-minute interviews with recent graduates and currently enrolled students of biomedical engineering programs from two highly ranked universities (Table 3). This study limited its scope to two universities with similar student populations and rankings for the sake of analytical refinement. This allowed the researcher to analyze student data without getting engulfed by the minutia and noise characteristic of studies whose site selection might be more fluid.

Table 3: Profile of participants [12]

Number	Name	Gender	University	Enrollment Status
1	Ashur	Male	University X	Graduate Student; Graduated 2022
2	Royce	Male	University X	Undergraduate Student; Graduated 2021
3	Nasser	Male	University Y	Undergraduate Student; Graduated 2021
4	Antonia	Female	University X	Graduate Student; to graduate in 2023
5	Alexandria	Female	University X	Undergraduate Student; Graduated 2021
6	Xavia	Female	University Y	Undergraduate Student; Graduated 2019

Each interview followed the same format, which began with an introduction describing the details, goals, and aims of the project, followed by questions which covered three broad themes: the utility of CAD, curricular emphasis on stakeholder analysis, and the consideration of cultural and physiologic difference in the development of medical devices. The interviews ended with concluding remarks and an opportunity for students to add information they felt was relevant but

[12] Pseudonyms generated from the random name generator: behindthename.com

not adequately covered. An interview schedule with more detailed information can be found in Appendix D.

3.5 Data Collection and Analysis

All interviews took place over Microsoft Teams. Following the conclusion of each interview the interviews were transcribed. The coding of each interview, however, had not begun until all interviews were completed. For thematic analysis, this work utilizes both research-driven (latent) and data-driven (semantic) coding techniques. Latent codes allow for the data to be presented through the theoretical and conceptual frameworks of this thesis, while semantic codes allow us to consider the direct explications of experience as described by students (Braun & Clarke, 2013; Damayanthi, 2019). The combination of these techniques allows for a more quality result, as it considers both that which falls into theory and that which exists outside of it.

I interacted with the data through use of Braun and Clarke's (2006) six-stage process for thematic review: familiarization, initialization, theme aggregation, theme review, theme definition, and final write-up. To successfully deploy all stages, I engaged with my data in an iterative manner—cycling through reading transcripts prior to coding and coding multiple times to ensure accuracy and coherency. When coding, I started solely with semantic coding. Following, I used latent coding for each of my research questions, so that I could adequately pinpoint where participant experience aligned with theory.

3.6 Rigor

In outlining how to assess research rigor, Oliver (2011) emphasizes three points: theoretical justification, replicability, and interpretative support. Not only has this piece described its own theoretical approach—exclusion as enactment—in analyzing how instructional methods could reify medical device bias, but it has also extended the theoretical works of other writers (Bahm; Braun; Kadambi). The level of theoretical engagement in this piece proves its relevance and significance. In terms of replicability, the research design, sampling methods, recruitment strategies, data-handling strategies, and philosophical positions of this work are clearly articulated. This sufficiently allows for other researchers to recreate the settings of this research. Finally, interpretative support refers to the notion that "the 'data' of a qualitative study should support the interpretations made by the research team" (Oliver, 2011, p. 360). The next chapter

of this analysis will confirm attainment of interpretative support, as results indicate a clear lack of instructional emphasis on physiological and cultural difference and an overreliance on economic stakeholders which in turn create a value-interested system capable of reproducing medical device bias.

3.7 Ethics

This research project has received approval by the Central University Research Ethics Committee at the University of Oxford (Appendix A). Beyond internal ethics approval, safeguards were put in place to ensure the minimization of risk for participants of this study. To ensure transparency and to offer the opportunity for questioning, prior to the start of interviews, participants were provided with an informed consent form (Appendix B) and participant information sheet (Appendix C). Further, during data analysis, participants and their institutional affiliations were replaced with pseudonyms. Finally, data storage and deletion protocols were in-line with policies put forth by the University of Oxford.

3.8 Limitations

This research, while rigorous and well-conceptualized, was not exempt to limitations. Giving the time constraints of a master's thesis, a limited number of students were able to be interviewed. Beyond time constraints, the exposure of this research might have been limited based on recruitment strategy, particularly the lack of foresight given to the tactic of academic departmental outreach. This is largely because the academic calendars of the UK and US are misaligned, so communication between departments were fickle and slow. For the sake of future research, greater time-sensitivity should be given to the tactic of recruiting students via academic departmental outreach and a larger sample size of participants accrued.

Chapter 4 – Results and Discussion

4.1 Introduction:

In drafting this thesis, I wrestled with what Galletta (2012) would call a sense of conceptual restlessness:

> "You may experience a sense of conceptual restlessness as ideas press for consideration. Leading up to this point, your analysis has involved a repeated close reading of the data and locating instances that relate to your research question in some way — complicating your question, offering new meaning, raising additional questions... As this process unfolded, a new phase began, that of drawing thematic codes together into categories when they share common dimensions." (Galletta, 2012)

This section articulates the converges, divergences, intersections, and "common dimensions" of interview data to sufficiently put forth a thematic analysis true to the experiences described by research participants. The themes rendered in this work can be segmented into three general categories:

1. Describing the Design Process
2. Describing the Utility of CAD
3. Evaluating curriculum and instruction

The themes eventuated from this process can be summarily described by the theory and literature which foregrounded this chapter. Given the style of this thesis—particularly its discursive and theoretical nature—the collapsing of discussion and results feels appropriate, as reporting the results of this study necessarily entails a discussion of meaning and context. As such, this chapter will begin by expanding upon thematic categories and describe their relevance to the literature and theory.

4.2 The Design Process:

The design process encompasses the entirety of medical device creation and is the primary impetus behind this work. It comes as no surprise, then, that the design process protruded in conversations with participants. Three sub-themes constitute this broader thematic category:

1. A consideration of the design process as iterative— starting with a needs assessment and ending with product development.
2. Understanding the users as a variable identity
3. The instructional emphasis on low-fidelity modeling

These subcategories allow us to answer three of the four research questions that were articulated in section 1.4.

> What values are imbued in medical device design curricula?
> What defines a "user" in the context of medical device design and how is that user conceptualized?
> What role does exclusion play in the crafting of medical devices?

4.2.1 Iteration

As illustrated by the models of Pugh (1990) and Pahl & Beitz (1984), needs assessments initialize the design process. Participants described needs assessments as iterative and fundamental. Beyond identifying their significance, participants also noted how the process' inherent iteration included a series of trade-offs between designers and customers. These necessary omissions were usually spoken of in a positive light— prefaced by the idea that trade-offs result in more efficient and functional devices. In the event these trade-offs were not discussed with positive connotation, participants highlighted how specific omissions were a result of inability (fiscal, physical, scientific) or lack of foresight.

> I guess the first step is defining user needs. That is kind of how we learn, right? Talking to the client, asking all the questions in your mind, trying to establish what exactly the problem is and clarify it and understand it.
>
> (Alexandria)

> When designing a new thing I think the most important thing is to think about what the purpose… is and what the user needs.
>
> (Royce)

> So, I think the first thing that I was always taught in my formal education was to ask why… Trying to figure out what that angle is, as opposed to just giving the consumer the thing that they ask for.
>
> (Ashur)

Students found that needs assessments allowed for inquiry-driven analysis. This level of inquiry provided students the opportunity to explore their intellectual curiosity and brainstorm solutions. While considerations of feasibility were critical later in the process, students typically regarded brainstorming as an unrestrictive space.

> To begin with, we tried to first understand what the problem is, and kind of just have a really open, exploratory iterative process to understand what problem we are designing for anyways?
>
> (Xavia)

So, we used to do a divergent-convergent process for coming up with ideas. So first just put everything on the board, anything, no idea is too far out there. Just put everything on there and then narrow some down and then diverge again and think of more things based on what you've narrowed down.

(Alexandria)

In line with this exploratory approach, graduate students from University X described the use of a mood board technique. This technique clarified the vision behind designing and was meant to discern the social, spatial, and functional capacity of devices.

So, in that initial class, we actually did a couple of different projects which were smaller. These weren't like client focused projects. They were more of like our professor was like hey, here is something I want you to think about, start designing it, give me a mood board for what these devices should evoke and stuff like that.

(Ashur)

Before we even touch the paper, we make these things … mood boards. The idea is to be able to understand where your device is being used, who is going to use it, what is the environment it's being used in.

(Antonia)

While these inquiry-driven explorations are aligned with positive valuations of the design process (Ejsing-Dunn, 2018), exclusions still occurred and were based on stakeholder analyses. Through this process, stakeholder prioritization was not neatly delineated. That said, the financer/sponsor and user/customer were the stakeholders often given the most priority. For example, Royce describes his program's implementation of the VOC process described in chapter two:

So, with the program that I was in, one of the classes I was able to take was to help find those stakeholder needs and it's usually call like VOX (voice of customer, voice of business, voice of whoever) and typically, business has all the money, so even if a doctor thinks something would be good, if it's too expensive, then of course you can't.

(Royce)

Ashur emphasized the need to consider the doctor and the patient:

So, typically, the two main stakeholders we focused on were the patient and the person [installing] the device.

(Ashur)

While there were variable interpretations of which stakeholders earned the right to be prioritized, students commented that prioritization was an embedded aspect of their program instruction. Four key factors emerge as being the primary drivers in considering which stakeholder to prioritize: device financeability, device manufacturability, device safety, and device utility.

4.2.2 User Variability

Students generally had reservations with defining a user. As Fearis and Craft (2016) noted, the user exists as a multifaceted, amorphous identity. Participant hesitation to place precise frames around user identity reflects this point well. Though characteristically indefinable, in this analysis, doctors and patients were the subgroups most frequently regarded as "users" of medical technology. Students were clear to distinguish between moments where doctors might be considered a user over a patient and vice-versa. A doctor was considered a user if the device required implantation, surgery, or generally interfaced with their professional responsibilities (e.g., A suturing device). Patients were considered the user if the device was straight-to-market or had little need for doctor interference (e.g., An inhaler). These categories were treated as the rule of thumb but were not fundamentally mutually exclusively. In some instances, both doctors and patients were described as users. In the case of a pacemaker, for example, where a patient must live with the device on the day-to-day, but it is inoperable without doctor installation and monitoring. Ultimately useful for this analysis, was the overwhelming belief that a user was context dependent.

In the context of instruction, the user was demarcated through case studies. These case studies were often described as remarkably undetailed, providing little information outside of a general problem statement. This level of exclusion, like stakeholder analyses, left the conception of the user up to the student-designer. Antonia describes an example case study given to her prior to being tasked with developing a pediatric pulse oximeter. Let alone enough to describe the user, Antonia laments that the problem statement was insufficient for gauging the issue at hand:

> We're given a problem statement, usually if we're lucky. Otherwise, they don't even give up that. But they gave us a problem statement which was 'parents often struggle with using an oximeter or any devices that are handheld on kids because kids are fidgety. They don't like being things being clamped.'
>
> And that's it. That's the problem statement.
>
> (Antonia)

The relative scarcity of user constraints within instruction prompted students to question the utility of these approaches, which will be described in greater detail in section 4.4. For example, Nasser critiqued the lack of societal awareness present in his program and described societal factors as peripheral, but never center to, the work of he and his course mates undertook:

> They were trying to make a bigger deal of like DEI stuff and so we had one problem set with one question that was like 'you should take an implicit bias test' that's as close as we ever got to society in like any engineering classes.
>
> (Nasser)

The lack of social consideration, coupled with incomplete information, means that students are often left to their own devices when it comes to discerning information regarding the user. In other words, students are burdened by the task of crafting their own user based on the knowledge they have of a specific medical device or ailment. In determining values for data constraints (e.g., average height), students spoke of using decades-old manuals or online demographic databases to ascertain relevant, "standard" anthropometric information. Online databases were generally regarded as demographically representative, but barriers to accessing these data—for instance, the need for a subscription—minimized their use. Royce comments on this phenomenon and the frequency in which he resorted to Google searches to gather information:

> Yeah, there's like an official website for that, but you have to pay to get access to that data. So, some of it was just given to us. Other things, I just googled it… hand size is something that's pretty easy to measure. So, you know somebody out there would probably just say on a form be like "hey, average hand sizes are whatever.
>
> (Royce)

The reductive framework of ease which Royce applies to the cataloging of hand size inspired the creation of the epilogue which follows this piece. To synopsize that epilogue and this section more broadly: the inability of BME programs to provide representative anthropometric data maligns efforts to create equitable medical devices. Anthropometric data collection in the US has been, as Braun (2014) described, rooted in institutional and systematic power, and this is well reflected in something as mundane as a Google search.

4.2.3 Low Fidelity Modeling

With the patient described and stakeholder analyses produced, discussions of prototyping were had. Students noted that low-fidelity modeling occurred prior to the development of more advanced technological solutions. This granted students kinesthetic benefit, allowing them to hold devices, manipulate their ergonomics, and reference their dimensions to other objects.

> Then you start prototyping it and in some of the cases it's super low fidelity, like putting together cardboard boxes or like cutting out stuff, making things with clay to kind of get a sense or have something to hold in your hand.
>
> (Alexandra)

> I think another good way to get feedback is a prototype. You can just use rulers and pencils and put all of that thing together with tape and ask people to use it and see what's the first way they grab it and stuff like that.
>
> (Antonia)

The goals of some design projects were to create low tech products. In these cases, project goals were centered around reducing costs of already available devices. In one case, Nasser describes an effort to build a hemoglobin sensor with smartphone technology to reduce the costs of other light sensory technology.

> So, in undergrad, I worked on one big BME project, which was a hemoglobin sensor... and there's a device that does something similar that's on the market in the US for like a couple 1000 dollars. So, we were like that's super expensive, could you replicate it with a smartphone?
>
> (Nasser)

4.2.4 Centralized Thematic Interpretation

Data regarding the design process proved generative for this analysis. Such data show that the values of prioritization, brainstorming, and kinesthetic interaction are central to approaches of design. The epilogue birthed from this section further supplements these findings and suggests that the values of data simplification and scientific neutrality are more insidious, yet equally prevalent, features of instruction. Further, this section has highlighted that "users" are defined in non-stagnant ways and are conceptualized through the aims and functions of a device. That is, exactly who a user might be is largely rooted in how one uses a device and what that device does. Lastly, the design process compels us to consider the ways in which exclusion manifests through instruction. That is, it describes the codification of exclusion through a series of trade-offs, stakeholder analyses, and ill-detailed case studies.

4.3 The Utility of CAD

CAD acts as a nucleus of medical device design today, as its use moulds abstract ideas into physical shape. Therefore, discussing student perceptions of the strengths and limitations of CAD is useful not only in understanding the more technical aspects of device design, but in processing the way that the technology has altered how students interact with objects in their professional, academic, and everyday lives. This section also addresses a necessary aspect of the more general question of how biomedical engineering students learn device design.

4.3.1 Benefits of CAD

As Tornincasa and Monaco (2010) highlighted, mechanical CAD's generational advancements have accelerated its technical potential. While a plethora of CAD models exist, students noted Solidworks and Autodesk – both with hybrid capabilities—as the programs of choice at their institutions. In assessing the positives of CAD, participants echoed the value of its multi-dimensional modeling function (Tornincasa and Monaco, 2010). Since CAD is primarily used after initial sketch phases, students described the transition from 2D sketch to 3D model as transformative. By this I mean, students commented on the ways that CAD provided insight that could not be conceived through 2D sketches, which they later reflected on and implemented. Participants also described how CAD allowed even the most amateur 2D-sketch artists to bring their ideas to life.

> In fact… a couple times when I've been working on CAD, it's given me something a lot better than what I had originally thought of… just, like, experimenting around, I think it gives you more ideas in a way.
>
> (Alexandria)

> So, for me, I'm very bad at drawing like I'm horrible at drawing. I cannot draw straight lines. So having a 3D software to help me, you know, put what's in my brain, onto a screen that can draw straight lines and make things in the right dimensions. It's super helpful.
>
> (Royce)

Students also altered their perceptions of everyday life. They noted that the software allowed them to reduce objects in the physical world to their component parts.

> It's like when I learned what different ingredients did, I started appreciating food more… I feel like 3D modeling means that now I look at a lot of the world and I'm mentally breaking it up into pieces. Like, I'll look at the table and be like, "OK, that's like a flat plane of a top and four individual legs"
>
> (Nasser)

4.3.2 Limitations of CAD

Students did describe certain limitations of CAD, and most of these complaints were in the domain of advanced modeling. The most prevalent concern was that CAD did not model biological systems well, so its use was insufficient in cases that involved solutions rooted in immunology, drug-transport systems, or pharmaceuticals.

I think that the fluid simulations on CAD extremely are designed for the Automotive World and there's not much for the medical device world, even though medical device and building parts is what CAD is used for a lot.

(Antonia)

A lot of BME projects don't necessarily lie in the mechanical engineering of medical devices. And it's more like fluids or like soft tissue. So, it sometimes felt piecemeal. Like we were trying to learn all these skills, but we didn't necessarily like bring them all together.

(Xavia)

Then biology is weird. I feel like there's just so many things that are counterintuitive like drugs for instance, where there's no visual analog for that. And so, I think it [CAD] definitely hasn't helped in that area.

(Nasser)

Other students also described time as a central issue with CAD. This manifested in one of two ways: the time it took to design a device or the time it took to learn how to use the software. As opposed to the inability to indicate biosystems, these limitations were often qualified as surmountable with experience.

In terms of drawbacks with 3D modeling, I would say it is something that takes longer. You know, if you're good at drawing, it's really easy to just take a pen and pencil and just scribble out… But it's very good for like detailed work.

(Royce)

Do like you can learn it obviously, but I think it's like sort of hard and sort of scary. There's like a steep learning curve when you're first learning it. But I also know… people had had plenty of years of experience with CAD beforehand and it was like second nature to them.

4.3.3 Centralized Thematic Interpretation

The benefits and limitations of CAD were expressed through two themes: technical and sociocultural. In the technical regard, expressions of positivity included the ability to render devices in 3D, highlight previously unseen issues, and easily apply manipulations and edits. Drawbacks centered the lack of biofluid/systems modeling, which reduces the scope of technologies that could be developed. Regarding the sociocultural, positive elements of CAD included envisioning physical assemblages of the word and garnering appreciation for the construction of mundane material. Limitations centered the associated learning curve and the way experience acts as a barrier to entry.

4.4 Evaluating Curriculum and Instruction

With its emphasis on device bias and instruction, this thesis investigated student interpretation and evaluation of their curriculum and instruction. The findings of these data were condensed into three subthemes:

1. An inherent lack of attention given to cultural/physiologic difference in biomedical engineering programs.
2. A desire by students to supplement their scientific, technical education with more humanistic extracurricular activities.
3. Moral questions on data aggregation

This section allows us to consider the only remaining research question—How can our current conceptions of medical device bias be expanded upon? – and expand upon the questions of value imbuing and the role of exclusion.

4.4.1 Lack of Cultural/Physiologic Difference

Again, this thesis does not claim a biological essentialism in terms of considering cultural or physiologic difference. It remains steadfast in the belief that these demographic characteristics are socially constructed (Ifekwunigwe et al., 2017). Yet, as has been explicated quite thoroughly, the social relevance of these factors has limited device efficacy and further disenfranchised communities (Braun, 2014; Fawzy et al., 2022; FDA, 2015; Kadambi 2021; Sjoding et al., 2020). Understanding how students approach these sensitive topics, then, is an important element in considering how biases and tools of marginalization are perpetuated. That said, each participant in the study described a lack of attention given to cultural or physiologic difference during their instruction. The effects of this blind spot were multiple in nature. For some students, it had live-time impact on the efficacy of their devices. For others, it made the curriculum feel incomplete.

> I genuinely think that there is an extreme, extreme lack of cultural understanding.
>
> (Antonia)

> Yeah. I wouldn't say they [Cultural variations] were ever formally conceptualized. There was probably some discussion about it… but I cannot think of a scenario where that was formally discussed.
>
> (Ashur)

Alexandria provides an illustrative example of a project where she was tasked with developing a pulse oximeter. The device she developed, through the instructions given to her, failed to work on her skin, which was darker in complexion in comparison to her classmates'. As a result, she

described studies of pulse oximetry bias in the limitations section of her analysis and was dismayed by her professor's apparent lack of knowledge on the topic:

> In fact, for one of my classes, we had to build a pulse oximeter… and then demonstrate its working functionality to our professors, and mine would not work properly… part of my analysis of that device is… that same research of skin tone affecting the readings. And my professors were like "ohh yeah, that is a very interesting point." And I was like "There's no way, you haven't heard of this before?'"
>
> (Alexandria)

I wish not to gloss over Alexandria's narrative. Her story nestles so many of the reasons behind this analysis. Taking her anecdote with generosity, the professors had a lack of knowledge regarding these studies. At its least generous, her professors had a lack of care. Regardless of whether care or knowledge was deficient, the biases embedded into pulse oximetry were inherited by instructors and then passed on to designers to be integrated into a final product.

While less potent, other students described feeling that holistically considerations of people interacting with devices were relegated to the point of unimportance:

> And one thing that I honestly wish we had more of was just like actually talking about people because we spent a lot of time very, very honed-in on the scientific applications of things… but the people entering that or an example of how to use this with a patient was a minor footnote at the end of a very long lecture.
>
> (Nasser)

While several of the studies mentioned throughout this analysis focus on race, interview participants were made clear that physiologic variation could encompass several non-exhaustive categories like age, ability, weight, or skin-tone (see Appendix D). In these scenarios, students described how implicit biases manifested in other ways:

> I don't think I thought about… the question ability… so I think that the de facto, imagined user.. was probably able bodied and… Yeah, that's an implicit sort of bias that I wasn't even like surfacing in my mind.
>
> (Xavia)

When discussed, student's felt that these considerations should be implemented in the curriculum.

> I think we should think about patient backgrounds when we [design]. I think that's a very good point. And I actually I'm so inspired to make a suggestion to my professors right now.
>
> (Antonia)

> I think that a lot of the design that we were being taught or that was like showcased were very high tech … like how can we create a soft robotic heart that mimics the mechanical motions of a human heart and whatnot, but… I've later come to felt feel like there's so many, like, not as technically complex, but very critical design sorts of needs that exist.
>
> (Xavia)

4.4.2 Curricular Supplementation

Given this lack of consideration of these important sociocultural factors, certain students sought to supplement their academic experience with extra and co-curricular activities. Their engagement with these activities helped expand their conceptions of medicine and engineering— often prompting them to scrutinize the methods and practices of BME and incorporate the traditionally underrepresented.

Students described the feeling of unlocking new knowledge, and the ways such knowledge shifted their perspectives of engineering.

> My sophomore year, I started taking sociology classes … for the first time we were just like, this is the background about how this thing developed… , these are the societal implications of this concept. And I was like, 'societal implications. We never talked about those and engineering.'
>
> (Nasser)

> I didn't know how to orient myself to questions [of my thesis]. And so I ended up reading a lot of medical anthropology in order to find some language to talk about how we take seriously differences in medical device design based on culture
>
> (Xavia)

The thesis project Xavia mentions above was her senior project, which focused on creating an engineering solution that mitigated barriers to healthcare accessibility for LGBT Thai people in Thailand. The device she eventually developed was a dilator to be used by trans women following gender-affirming vaginoplasty. With a dual major in gender studies and Biomedical Engineering, Xavia expressed a palpable discomfort with the notion of outlining "standard" measurements for her device. She describes this tension through the context of western voyeurism and orientalism:

> So, I feel like it was really weird to put down a number as like what the dimensions of this dilator should be… it feels very like hard coding this ideal of what you these dimensions should be for this organ… there's a lot of baggage that comes to that with that… it made me really uncomfortable sometimes because there's so much sexually violent colonial baggage about Asian people's genitalia, as perceived by the West."

These deeply ethical considerations were not limited to standardization, but also to data collection:

> Because we were working with patients in India, but most of the patients in like the general [are of data collection] are Caucasian. ,So it was just like we know for a fact that the people that we are testing this on and the people that would actually be using this look very different
>
> (Nasser)

More than moral quandaries, these social informants compelled engineers to consider barriers which might exist to accessing their devices, with many stressing a desire to deploy technologies in lower-resourced economic regions at little to no costs:

> In the future, I want to focus on medical devices that can be used in lower resource settings and lower resource hospitals.
>
> (Alexandria)

> I guess in my senior design project.. that project never got to the point of being commercialized or being sold or anything. But I was very adamant in my mind that it, if it ever did get to that point, I wouldn't want to like charge for it. I wouldn't want to make a profit off of it.
>
> (Xavia)

4.4.3 Centralized Thematic Interpretation

The vapidity of social factors in BME programs clarifies and expands conceptions of medical device bias. Participant stories show how this deficit understanding of social factors not only exist within the texts outlined by this piece, but also in the classroom assignments administered to students. Some pupils turned to more humanistic and social-scientific disciplines to better garner socio-historical knowledge. These ventures reinvigorated them and spiked their intellectual stimulation, but also presented them with moral dilemma. Students positively waivered on their approaches to device design and amplified the influence given to social factors.

Conclusion:

Each section of this chapter explicitly addresses one or more of the thesis' research questions. In doing so, it describes the ways in which the three primary themes, and their various subthemes, elucidate key elements of biomedical engineering praxis.

This chapter began with an analysis of student interpretation of the design process. This section described the importance of inquiry-driven brainstorming and low-fidelity modeling for idea generation. In moving from the ideas stage to more granular details, this chapter highlighted the value of stakeholder analysis, described the ways the users were identified and conceptualized through device function, and commented on the iterative nature of device design.

It then followed with a conversation on CAD—the band of software which enable the creation of these devices—with specific notation of its advantages and disadvantages. By and large, students favorably commented on CAD. Students noted that it allowed them to animate ideas and invited those with self-described subpar 2D drawing skills into the fold of engineering. When CAD was limiting, it had much to do with duration of time it took to learn its features and its inability to mimic biologic systems.

The final section commented on student desire to pursue extra/co-curricular activities to supplement their BME instruction. Overwhelmingly, students regarded their biomedical engineering education as uncritical of cultural or physiologic difference. At times, students inherited this sense of non-criticality. When they were aware of such differences, they found intellectual satiation outside of their course—usually in humanistic or social scientific disciplines. The methods of inquiry borrowed from non-engineering disciplines also allowed them to expand upon questions of agency/structure. These pontifications resulted in moral dilemmas regarding data-aggregation, western voyeurism, and device cost.

Chapter 5 – Conclusion

5.1 Summary of Study

This thesis has reported on a research study with current and recent graduates of Biomedical Engineering programs at one of two top-ranked universities in the United States. It began with an earnest question: How do biomedical engineering students learn about design? This query, while superficially simple, was later divided into four research questions for which this work built its central analysis:

> 1: How can our current conceptions of medical device bias be expanded upon?
> 2: What values are imbued in medical device design curricula?
> 3: What defines a "user" in the context of medical device design and how is that user conceptualized?
> 4: What role does exclusion play in the crafting of medical devices?

The themes generated from this research reveal a lack of critical pedagogy within BME design instruction. That is, instructional approaches tend to isolate the technical or economic aspects of medical device making while forgoing the social realities in which those devices are created. This study has surmised that this underemphasis on the socio-historical reifies medical device bias – creating a harmful cycle of marginalization. The exclusion of these more humanistic approaches act in deleterious ways which juxtapose the stated goals and functions of medical device making.

While these results are bleak, this study also suggests that engineering practices are not immovably steadfast. Students appeared to be receptive of the idea of their program's implementing enhanced focus on social characteristics in approaching design frameworks, even going so far as to note that they would bring suggestions to their instructional coordinators. At the very least, participants noted that the interview repositioned their thoughts in approaching design and believe they will adopt more care and criticality in future opportunities for product development.

5.2 Implications for further research

This research could be greatly expanded on two fronts: perspective building and observational knowledge assessment. Since this study has focused on the nature of student experience, future research could incorporate the opinions of other relevant parties—instructors, manufactures,

doctors, etc. This will allow greater insight and perspective building, further confirming or challenging the findings of this study.

Future research could also add more interactive, observational approaches to their methodologies. For example, if the participants were student designers, students could model their design process in real-time. Participants could be asked to render devices on CAD, 3D print them, and outline their thought process; researchers could then observe these actions. Additional observational analysis could illuminate the results of this study and reveal aspects of the design process that are more subliminal or idiosyncratic.

As mentioned in section 4.2.1, I was inspired to write this epilogue following a passing comment made by Royce, one of my research participants. Allow me to reposition that comment here for context:

> Yeah, there's like an official website for that, but you have to pay to get access to that data. So, some of it was just given to us. Other things, I just googled it… hand size is something that's pretty easy to measure. So, you know somebody out there would probably just say on a form be like "hey, average hand sizes are whatever.

Royce's laissez-faire attitude toward the cataloging of hand sizes struck me. The simplicity he attributes to the measuring of anthropometric data does not grant credence to the power systems which have historically informed the practice of anthropometry (Braun, 2014). Following the conclusion of our interview, I googled "Average hand size". What I located indicates several flaws with conceiving anthropometric data aggregation as simplistic. More than this though, my findings reflected a general lack of pedagogic intentionality in the consideration of *where* anthropometric data come from. Royce is not to blame for his desire to acquire this information, but his program's lack of description regarding user constraints, and its failure to provide him with demographically representative anthropometric data, contribute to the erroneous assumptions of data simplicity and scientific neutrality. That is, if program's implicitly trust public information to be accurate, they welcome a barrage of misinformation. Below I describe the information I uncovered through this simple exercise.

The first non-ad link which appeared after typing in the declarative statement "Average Hand Size*"* was from *healthline,* a magazine "dedicated to making health and wellness information accessible, understandable, and actionable" (Healthline, 2022). The linked article read: *What's the Average Hand Size for Men, Women, and Children?* The information from the children category of the article was derived from a US Department of Health, Education, and Welfare (HEW) survey. As a trained US historian turned educational researcher, this source jutted out to me, namely because HEW has not existed for forty-three years. Upon further investigation, the information presented in the article came from a 1973 report *Selected Body Measurements of Children 6-11 Years.* The data derived from this report were collected between 1963 and 1965. This means that the first set of readily available information for the hand-size of children is nearly six-decades old. To encapsulate that more critically: the data collection period for this study occurred prior to the legal cessation of race-based segregation in the United States. Figure 2 shows an example questionnaire which uses the outdated and hyper-racialized term "Negro" to

describe those who identify as Black. Further, the methods of data collection, unsurprisingly, fail to describe attempts of obtaining racial plurality. Figure 3 indicates the counties of study under review—as geographically expansive as this cross-section is, virtually all these counties were white-majority at the time of collection.

Figure 3: Questionnaire for Health Examination Survey. Source: US Department of Health, Education, and Welfare (1973). Selected Body Measurements of Children 6-11 Years.

Figure 2: Number of sample children and number and percent examined, by strand number and location: Health Examination Survey, 1963-65 Source: US Department of Health, Education, and Welfare (1971) "Sample Design and Estimation Procedures Fora National Health Examination Survey of Children".

Whether or not Royce used the data from this healthline article for his project is quite irrelevant. The issue here is the fact that, rather than providing resources for pupils to access more up-to-date and demographically representative data, his institution sanctioned the use of Google, which in at least one case provided racially exclusive, archaic information. This practice reflects the assumption that all data is good data. That data is void of social meaning. That as long as one creates an efficacious device, then where they get their data from should not matter. All of these assumptions have been ferociously challenged in this work. The nature of this epilogue, and Royce's brief comment, capture the essence of this thesis well. It indicates that medical device instruction is distant from where it needs to be. The hope is that this thesis puts it one step, and sixty-years, forward.

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Appendix A

A.1 CUREC Approval

Dear Jamal,

Your application for 'From the Mainframe to the Flesh: Pedagogical Approaches to Conceptualizing Patient Experience through the use of 3D-Imaging Software' has been considered on behalf of the DREC in accordance with the procedures laid down by the University for ethical approval of all research involving human participants.

I am pleased to inform you that, based on the information provided to DREC, the proposed research has been judged as meeting appropriate ethical standards, and accordingly, approval has been granted. I would like to inform you that you will be required to update us on any amendments to your study should you need to change your research methods and may need to complete a data protection impact assessment if you use online platforms to conduct and record interviews. There is an application for this, and it is kept separate from the ethics committee. Please see the link below for more information.
https://researchsupport.admin.ox.ac.uk/policy/data/checklist

Please continue to follow all current guidance issued by CUREC during the pandemic, notably COVID-19: CUREC guidance on research involving human participants, https://researchsupport.admin.ox.ac.uk/governance/ethics/coronavirus

If needed, please follow the guidance on online data collection and research methods issued by the University,
(1) https://researchsupport.admin.ox.ac.uk/covid-19/data#collapse2299911
(2) https://infosec.web.ox.ac.uk/article/guidelines-for-using-zoom

If relevant, please also check the CUREC website for their best practice research guides, https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/bpg

Yours sincerely,

Pinar

Dr Pinar Kolancali
Postdoctoral Researcher
Departmental Research Ethics Committee Member
15 Norham Gardens, Oxford OX2 6PY

A.2 Recruitment Templates

A.2.1 Student Recruitment Email Template

Hello [Insert Institution Name] students!

My name is Jamal Burns and I'm a current master's student at the University of Oxford. I'm studying education and technology. More specifically, my research project seeks to investigate the ways in which the user is conceptualized in the design process for medical instrumentation. It will specifically focus on the pedagogical methods used in Biomedical Engineering (BME) programs as they relate to the use of 3D-Imaging Software (e.g., CAD) in the development of medical instruments.

As part of my research, I humbly request your time in my study.

What would that look like?

We are looking for volunteers (18 years of age or older) to participate in a research study which consists of an interview and an optional case-study where the participant will design a medical device. The interview will focus on the human design methodologies present in program instruction, and how you conceive of the user when curating medical devices.

Why am I asking you?

Currently, no full length studying examining pedagogical and instructional influences on conceptualizing user-experience in 3D-device design exists. As such, your insights will be valuable in filling this gap in the literature.

Thank you for your time and excited for future connections,

Jamal Burns | Jamal.burns@wolfson.ox.ac.uk

A.2.2 Professor Recruitment Email Template:

Hello [Insert Professor's Name]

My name is Jamal Burns and I'm a current master's student at the University of Oxford. I'm studying education and technology. More specifically, my research project seeks to investigate the ways in which the user is conceptualized in the design process for medical instrumentation. It will specifically focus on the pedagogical methods used in Biomedical Engineering (BME) programs as they relate to the use of 3D-Imaging Software (e.g., CAD) in the development of medical instruments.

As part of my research, I humbly request your time in my study.

What would that look like?

I would love the opportunity to interview you (or other relevant faculty at your institution) on your approaches to conceptualizing user experience when you teach students medical device design.

In addition to your time, I would love if you could administer some promotional material to your students, as I am looking to interview both professors and students for my project. While I would appreciate both your insight and your student's, if you are only able to complete one of these two requests, that would still be of great benefit.

Thank you for your time and excited for future connections,
Jamal Burns | Jamal.burns@wolfson.ox.ac.uk

Jamal Burns
Jamal.burns@wolfson.ox.ac.uk
Research Title: From the Mainframe to the Flesh: Pedagogical Approaches to Conceptualizing Patient Experience through the use of 3D-Imaging Software

A.2.3 Poster for Student Outreach:

OXFORD UNIVERSITY RESARCH STUDY

WHAT IS IT?

This research project will focus on the pedagogical methods used in Biomedical Engineering (BME) programs as they relate to the use of 3D-Imaging Software (e.g., CAD) in the development of medical instruments.

HOW LONG WILL IT TAKE?

The interview will take no more than half-an-hour. In the event that you are asked (and are willing) to produce a 3D rendering of a medical instrument, then such rendering must be returned within two weeks of the date which it was assigned.

WHY IS THIS BEING RESEARCHED?

No full length studying examining pedagogical and instructional influences on conceptualizing user-experience in 3D-device design exists.

Jamal Burns

Jamal.burns@wolfson.ox.ac.uk

Research Title: From the Mainframe to the Flesh: Pedagogical Approaches to Conceptualizing Patient Experience through the use of 3D-Imaging Software

Consent Forms

Jamal Burns, Msc Education (Digital and Social Change)
Department of Education
University of Oxford, 15 Norham Gardens, Oxford OX2 6PY, United Kingdom
University tel: +44 1865 274024
University email: Jamal.burns@wolfson.ox.ac.uk

Consent to take part in Thesis on Pedagogical Approaches to Medical Device Design:

Central University Research Ethics Committee (CUREC) approval reference: [CIA-22HT-061]

Purpose of Study: I am researching how pedagogical model's conceptualize user experience in the design of medical instrumentation. Specifically, I am investigating how devices rendered using 3D-imaging software consider various aspects of a potential user.

	Please initial each box if you agree with the statement
I confirm that I have read and understand the Participant information sheet for the above research. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I understand that my participation is voluntary and that I am free to withdraw at any point until 01/Aug/22, without giving any reason.	
I understand who will have access to personal data provided, how the data will be stored and what will happen to the data at the end of the project.	

I understand that I may be identifiable from research outputs, including the resulting dissertation. Though, anonymity can be ensured upon request.

I consent to being audio and video recorded.

I understand how audio and video recordings will be used in research outputs.

Use of quotations: Please indicate your preference (select *one* option):
    a) I do not wish to be quoted. **or**
    b) I agree to the use of quotations in research outputs if I am not identifiable.

I give permission for you to contact me again to clarify information.

I understand how to raise a concern or make a complaint.

I consent to the use of my name in any final research outputs.

I agree to take part.

_____   dd / mm / yyyy   _____
Name of participant   Date   Signature

_____   dd / mm / yyyy
_____
Name of person taking consent   Date   Signature

Participant Information Sheet

Jamal Burns, Msc Education (Digital and Social Change)
Department of Education
University of Oxford, 15 Norham Gardens, Oxford OX2 6PY, United Kingdom
University tel: +44 1865 274024
University email: Jamal.burns@wolfson.ox.ac.uk

From the Mainframe to the Flesh: Pedagogical Approaches to Conceptualizing Patient Experience

PARTICIPANT INFORMATION SHEET

Central University Research Ethics Committee Approval Reference: [CIA-22HT-061]

1. **Introductory paragraph**

   You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please contact the research lead if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

2. **Why is this research being conducted?**

   This research project seeks to investigate the ways in which the user is conceptualized in the design process for medical instrumentation. It will specifically focus on the pedagogical methods used in Biomedical Engineering (BME) programs as they relate to the use of 3D-modeling Software (e.g., CAD) in the development of medical instruments.

   As of yet, no full length studying examining pedagogical and instructional influences on conceptualizing user-experience in 3D-device design exists. As such, your insights will be valuable in filling this gap in the literature.

3. **Why have I been invited to take part?**

   We are looking for volunteers (18 years of age or older) to participate in a research study. These individuals must be affiliated with a BME program in the US (either as a recent alumni, student, or professor).

4. **Do I have to take part?**

   No. It is up to you to decide whether or not you participate. You can withdraw yourself from the study, without giving a reason, by advising me of this decision. The deadline by which you can withdraw any information you have contributed to the research is 01/Aug/2022. Any data collected prior to your point of withdrawal will be deleted and will not be used for analysis.

5. What will happen to me if I take part in the research?

Where:
All interviews and surveys will be collected virtually. Interviews will be conducted through Microsoft Teams. With your consent, these conversations will be recorded for accuracy and assurance purposes. Audio and visual recordings, along with transcripts of our conversation(s) will be uploaded and stored on Microsoft One Drive.

How:
You will fill out a consent form, which allows the researchers to use your interview for final analysis. If you wish, you can ensure anonymity through your informed consent form. Otherwise, anonymity is not guaranteed; however, the research seeks to identify generalizable trends and is thus less interested in specific individual feedback

How long will this take:

The interview will take no more than half-an-hour. In the event that you are asked (and are willing) to produce a 3D rendering of a medical instrument, then such rendering must be returned within two weeks of the date which it was assigned.

For your convivence and advanced transparency, in section 6 of this document, I have included a non-exhaustive list of interview questions.

What you will need to do:

You will be asked to complete an interview, and if it is deemed mutually feasible by the researcher and participant, you will be asked to produce a 3D rendering of a medical device.

With your consent, I would like to audio and video record you so I can have an accurate record of our conversation. These recordings are only used for transcription purposes. After your interview and (should you choose) your device rendering, your involvement with the research is done.

Again, if you wish, you may withdraw yourself from the study at any point until 01/Aug/2022.

6. **Interview Questions:**

   This is a **non-exhaustive** list of questions you might be asked in an interview. Again, the goal of the interview is to elucidate the ways in which BME programs seek to conceptualize patient/user experience in their instruction of medical device design.

    Example Questions:

A. Walk me through your typical design process. What do you think about first? What questions do you ask? What is your general approach?
B. What factors, if any, do you consider most relevant when you design?
C. How has 3D-imaging software enhanced your understanding of design? How has it limited said understanding?

          1 If elaboration is needed, "Has CAD/3D-Imaging allowed you to conceive of designs you would not priorly have been able to? Inversely, has it limited your imaginative scope?

D. As you understand them, what influences shape the drafting/ design process for medical devices?

E. Independent the way you were taught to design, do you prioritize certain stakeholders in your process? If so, *how* do they ensure this prioritization?

          1 Follow up question for those in the Biomed device industry: Do you find that your corporate entity and its interests align with your prioritization, or do you find that their interests diverge? How do you reconcile this difference?

F. How did your program describe various stakeholder interests (manufacturers, patients, corporations, doctors) when educating on the design process? Did your institution prioritize one stakeholder over the other? If so, do you agree with this prioritization?

G. To your knowledge, did instructions regarding the design of devices consider a patient's culture and how their culture might influence their interpretation of their body, or were devices developed with a singular anatomic understanding of the body?

7. **What are the possible disadvantages and risks in taking part?**

No physical, emotional, or psychological risks are associated with your participation in this study. Should this change, you are at full discretion to leave the study or inform the researchers so that the study can be modified to accommodate your needs.

8. **Are there any benefits in taking part?**

While there are no immediate benefits for those people participating in the project, it is hoped that this research will lead to the creation of more human-cantered pedagogical frameworks in BME programs. That said, no direct personal benefits will occur due to your participation in this research.

9. **What information will be collected and why is the collection of this information relevant for achieving the research objectives?**

Only personal data necessary for research (e.g., participant age) will be recorded in accordance with UK GDPR and the Data Protection Act. No personal details will need to be shared with parties outside of the University of Oxford. Further, most data from which analysis is derived will be generalized. A participant may be identified from their interview, though steps are in place to ensure that this occurs at a minimum. (An example where a participant might be identified is a professor who describes, at length, their various institutional affiliations or teaching appointments, thus limiting their ability to remain anonymous).

All interview transcripts and audio data will be recorded virtually on Microsoft Teams, the university's only approved virtual interview technology. Files will then be uploaded securely to Microsoft Nexus365's One Drive for Business. Data will be removed three years [15/Aug/2025] following the completion of the study.

The findings from the research will be written up in a dissertation. That said, I would like your permission to use direct quotations. A copy of my dissertation will be deposited both in print and online in the [Oxford University Research Archive](#) where its access will be restricted to members of Oxford University.

10. Data Protection

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the study. The University will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest. Further information about your rights with respect to your personal data is available at https://compliance.admin.ox.ac.uk/individual-rights.

11. Who has reviewed this study?

This study has received ethics approval from a subcommittee of the University of Oxford Central University Research Ethics Committee. Ethics reference: [CIA-22HT-061].

12. Who do I contact if I have a concern about the research or I wish to complain?

If you have a concern about any aspect of this study, please contact Jamal Burns (jamal.burns@wolfson.ox.ac.uk) or Rebecca Eynon (rebecca.eynon@oii.ox.ac.uk) and we will do our best to answer your query. *We* will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible:

Chair, Education Ethics Committee;
Email: student.curec@education.ox.ac.uk Address: University of Oxford, 15 Norham Gardens, Oxford OX2 6PY, United Kingdom

13. Further Information and Contact Details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

Jamal Burns
Department of Education
University of Oxford, 15 Norham Gardens, Oxford OX2 6PY, United
Kingdom University tel: +44 1865 274024
University email: Jamal.burns@wolfson.ox.ac.uk

Appendix D

Interview Schedule

Part 1 Introduction:

"Hello,

Thank you again for agreeing to participate in this interview. Before we begin, I would like to reiterate the goals of my project and your role within it. This research project seeks to investigate the ways in which the user is conceptualized in the design process for medical instrumentation. It will specifically focus on the pedagogical methods used in Biomedical Engineering (BME) programs as they relate to the use of 3D Modeling Software (e.g. Mechanical CAD) in the development of medical instruments. In investigating this topic, I am interested in the intersection between design pedagogy, history, and culturally relevant engineering. Your insight as a recent alum is invaluable here, and again, I thank you for your time.

With that, do you have any questions before we begin?"

Part 2: Questions

1. Walk me through your typical design process. What do you think about first? What questions do you ask? What is your general approach?

2. What factors, if any, do you consider most relevant when you design?

3. How has 3D-modeling software enhanced your understanding of design? How has it limited said understanding?
      If elaboration is needed, "Has CAD/3D-Imaging allowed you to conceive of designs you would not priorly have been able to? Inversely, has it limited your imaginative scope?

4. As you understand them, what influences shape the drafting/ design process for medical devices?

5. Independent the way you were taught to design, do you prioritize certain stakeholders in your process? If so, *how* do they ensure this prioritization?

6. How did your program describe various stakeholder interests (manufacturers, patients, corporations, doctors) when educating on the design process? Did your institution prioritize one stakeholder over the other? If so, do you agree with this prioritization?

7. Do you feel that the medical device industry/ BME programs do an adequate job at conceptualizing and considering user needs? Can they do more, and if so, can you point to any specific area where these enhancements can be made?

8. In your experience, when taught the design process, were certain stakeholders marginalized or forgotten?
>   Potential Follow-up: Do you feel that the division of stakeholder interests in your program was just? Should certain stakeholders hold more priority (more so than others)?

9 . To your knowledge, did your program consider physiological variation when instructing on device design? (Physiological variation defined as skin-tone, weight, age, ability)
>   If additional context is required, describe the [Pulse Oximeter study](#).

10. To your knowledge, did instructions regarding the design of devices consider a user's culture and how their culture might influence their interpretation of their body, or were devices developed with a singular anatomic understanding of the body?

11. Can you comment on the pedagogical aims of your program in reference to the design process for medical devices?
>   If elaboration is needed, "In terms of instruction, what values do you think your institution emphasized when it came to teaching about design."

Part 3: Conclusion

"Before we close, do you have any further questions or comments that you feel were not encapsulated in this interview?"