I. PROBLEM
Understanding and Defining

a) What problem(s) are you solving?

b) Who is this a problem for? For example, is it a problem for a business, an intermediary, or a consumer?

c) What is the desired outcome of using your product?

d) Is the problem you’re solving in a low-resource market actually a problem in the U.S.?
II. USERS

Segmenting and Understanding Their Needs

a) Who are the target users? Who are all the customers?

b) Are there different segments of users who might take advantage of a solution? How do they differ from each other?

c) How does each user or stakeholder address the problem?

Example

ReMotion Knee user evaluation: The ReMotion Knee’s target user in India and other low-income countries tends to be young and active. This type of amputee has lost a limb due to traumatic injury and is often eager to be fit with a prosthesis to return to “normal” life.

In the US, however, low-income patients tend to be older and inactive. Their amputations resulted from disease and other poor health causes. If a designer were starting with these user needs to develop prostheses, he or she would likely design two different knees.

TOOL-TO-USE

Customer Value Chain Analysis

A visually mapping tool that indicates how customers or stakeholders are related to each other and what they value. The mapping of the customers enables designers to fully consider the range of user needs and requirements, as well as a structure to make tradeoffs during product development.
SECTION II: Market
Use this section to evaluate the U.S. market and the viability of market entry.

III. PRODUCT OFFERING
Defining Requirements and Expectations

a) Will the product need to have different features or functionality for entry into the higher income market? How much will that cost?
b) What additional requirements or support will be needed for market entry?
c) Are there expected norms of the product’s features, presentation, and support in your second market?
d) Will one product address the needs of all market segments or user groups?

Example

With Cellscope, a smartphone-compatible otoscope, the original intent was to provide health care diagnosis for populations that might not otherwise have access to ear, nose, and throat specialty care. In the U.S., according to ENT specialists, the Cellscope Otoscope is largely aimed at parents of children with frequent health problems, a different target user and use scenario.
SECTION II: Market
Use this section to evaluate the U.S. market and the viability of market entry.

IV. MARKET SIZE
Understanding the Opportunity for Impact

a) What is the size of the market? How is it segmented?
b) If you have different segments, will you need different market entry strategies?
c) Will your product meet the needs of all segments?
d) What portion of the market will you need to capture to have your intended impact?

TOOL-TO-USE

Market Sizing and Demand Forecasting

Market sizing aims to calculate the total number of users who could benefit from a product as well as the portion of those users who would actually be able and willing to purchase such a product. Standard approaches include “top-down” or estimating need based on macro factors (e.g., the number of premature babies born in the US), and “bottom-up” or estimating need based on the smallest unit of measure available (e.g., the number of hospitals in the US with neonatal intensive care units). There are myriad ways to approach these calculations—the U.S. Small Business Association provides some general guidance useful to those inexperienced in the area.

Effective tools distinguish between the overall need for a product and the actual demand for a product based on infrastructure and ability to pay. The Bill and Melinda Gates Foundation’s Demand Forecasting Tool is a comprehensive document that walks through these exercises in detail using vaccines, prevention diagnostics, and other medical products.
SECTION II: Market

Use this section to evaluate the U.S. market and the viability of market entry.

V. SALES & MARKETING

Reaching Users and Markets

a) What are the existing purchasing paths for similar products?
b) How do purchasing decision makers learn about new products?
c) What kind of sales force is required to generate product sales?
d) Do medical professionals need to see documented research or clinical trials?
e) How important is brand reputation in the category?

TOOL-TO-USE

Customer Segmentation Tool

This table from USAID’s Center for Accelerating Innovation and Impact prompts the entrepreneur to look at each customer group or segment, and consider their motivations in using the product, as well as how to best reach them.
SECTION II: Market

Use this section to evaluate the U.S. market and the viability of market entry.

VI. COMPETITION

Anticipating a Reaction

a) What and who is your competition?
b) How have those competitors changed over time?
c) Can you differentiate your product from competitive products in any area besides price?
d) How well-resourced are your competitors?
e) How important is the U.S. market to your competitors?

TOOL-TO-USE

Porter’s Five Forces

This is a classic framework for considering all aspects that influence profitability in an industry, from the power of suppliers to the threat of new entrants. This video provides a good summary to guide your thinking around the five forces.
SECTION III: Structural

Use this section to assess the minimum requirements for product sales in the U.S.

VII. REGULATORY REQUIREMENTS

Meeting Federal Requirements

a) What certifications and registrations are required to sell product in the U.S. market?

b) How much do required registrations cost, and how long does the certification processes take?

c) How will registration costs affect the affordability of your product?

TOOL-TO-USE

Is Your Product Regulated?

The FDA provides a series of webpages that asks questions to help you classify your device. This is a good first step in understanding what regulatory requirements you will need to meet. While device classes vary by country they overlap more than they differ.

VIII. LIABILITY INSURANCE AND INTELLECTUAL PROPERTY

Managing Risk

a) What kind of liability insurance do you need in the U.S. market?

b) How does the cost compare to revenue and impact?

c) Will introducing your product provoke intellectual property litigation from competitors?

d) How will the costs of liability insurance and IP filings affect affordability of the product?

Example

The nonprofit Gradian Health found that liability insurance for its affordable Universal Anesthesia was relatively affordable compared to U.S. markets where costs were higher due to the greater likelihood of litigation.

TOOL-TO-USE

None. Talk to industry experts and do your research—many companies provide liability insurance. You will need legal expertise to perform the intellectual property analysis. Nonprofits can often access these resources on a pro-bono basis.
IX. DISTRIBUTION
Putting Products in People’s Hands

a) How are these products distributed in the U.S.? Directly or through 3rd party distributors?
b) Which distribution approach best reaches underserved populations?
c) How does a decision about your distribution model affect the affordability of the product?
d) What incentives must you provide to convince distributors to carry your product?
e) How important are existing relations between distributors and other manufacturers?

TOOL-TO-USE

Distributor Landscape Analysis
This is a modification of USAID’s Center of Accelerating Innovation and Impact’s Manufacturing Landscape Analysis: Using your customer value chain, focus in on how the product reaches your target buyers. Conduct due diligence to evaluate the companies and their offerings.
SECTION III: Structural
Use this section to assess the minimum requirements for product sales in the U.S.

X. HEALTH CARE SYSTEMS & REIMBURSEMENT
Paying for Your Product

a) Does the U.S. have a product reimbursement structure for this category?
b) If so, how will that affect your market entry?
c) Do you understand all stakeholders’ incentives as it relates to reimbursement and payment?
d) Are there nonprofits, government agencies, or investment organizations interested in seeing your product enter the U.S. market?

TOOL-TO-USE

Physician Fee Schedule Search
Practitioners evaluate your product on the reimbursability. Reimbursement codes, unfortunately, tend to be siloed by specialty and there is not an all-encompassing tool. This is one of the reasons why US medical device companies like Medtronic produce clear reimbursement guides for their products. As a starter reference, we recommend: Physician Fee Schedule Search from the U.S. Centers for Medicare and Medicaid Services (CMS).
TOOLS OVERVIEW

I. Sanford Biodesign Need Statement

See examples of need statements and their development on the website for the textbook Biodesign: The Process of Innovating Medical Technologies.

II. Customer Value Chain Analysis

A visually mapping tool that indicates how customers or stakeholders are related to each other and what they value. The mapping of the customers enables designers to fully consider the range of user needs and requirements, as well as a structure to make tradeoffs during product development.

III. Landscape Analysis

Landscape analysis is research and review of other products and concepts that fully or partially address the defined problem. By understand the landscape of solutions, designers can also understand the rationale and expectations of target users and stakeholders. In Biodesign this is also called “existing solutions.”

IV. Market Sizing and Demand Forecast

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X. Physician Fee Schedule Search

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