25 April | 11

Detecting Childhood and Adolescent Obesity in the United States: A Strategic Analysis for F-Indicator 10

By Anna Wiinberg

Anna Wiinberg
Mgmt 458-002H
Professor Linowes
Honors Capstone
25 April, 2011

Detecting Childhood and Adolescent Obesity in the United States:
A Strategic Analysis for F-Indicator 10

EXECUTIVE SUMMARY

Childhood and adolescent obesity is becoming an increasing health concern in many countries, including the United States. In Sweden, about one in four children are overweight and two to six percent of them are obese, according to the Swedish Research Portal.[1] In the United States, an estimated 17 percent of children and adolescents are obese, estimates the Centers for Disease Control (CDC).[2] Overweight children and adolescents face an increased risk of developing the following diseases: "hypertension, respiratory ailments, orthopedic problems, depression and type 2 diabetes as a youth."[3] Patients with abdominal obesity, which results in an "apple shaped" body type have even more increased risks. The high number of generally obese children and adolescents, in addition to the increased health risks for general and abdominal obesity, calls for an accurate, simple way of measuring body fatness.

The most common method used to measure general obesity in children and adolescents today is Body Mass Index (BMI). BMI is calculated and then compared to national percentiles to determine whether a patient is overweight. The problem with BMI is that it pays no respect to body composition. With this health concern in mind, Innovator Skåne AB, a Swedish company, is developing F-Indicator 10 and F-Index, a medical device and medical index, respectively, that diagnose abdominal obesity and measures abdominal body fatness. Abdominal fatness is associated with more increased risks than general obesity, making it especially dangerous, according to the Harvard School of Public Health.[4] Innovator Skåne AB wishes to launch this product in the United States.

In order to reach the market in the United States, I recommend Innovator Skåne AB to execute three recommendations. The first recommendation is to continue to seek patents, generate medical evidence and perfect the F-Indicator 10 prototype. This step is essential for any new medical device in the United States and is a critical action for ISAB. The second recommendation is to complete the United States' Food and Drug Administration (FDA) regulatory process. Completing this process will ensure that F-Indicator 10 is launched legally, keeping the safety of patients in mind. The final recommendation is to contract with a medical device corporation in the United States, rather than creating a start-up for F-Indicator 10.

---

[1] Energimyndigheten et al., "Hur drabbas barn av fetma?" Forskning.se, http://www.forskning.se/.
[2] Centers for Disease Control, "Obesity and Overweight for Professionals," Centers for Disease Control and Prevention, http://www.cdc.gov/.
[3] Ibid.
[4] "Abdominal Obesity: Definition and Measurement," Obesity Program, Harvard School of Public Health, http://www.hsph.harvard.edu/obesity-program/resources/abdominal-obesity/index.html#intro.

BACKGROUND

Company Overview

All company and product information, unless otherwise noted, was obtained through an interview with Stig Wiinberg, CTO of Innovator Skåne AB.

Innovator Skåne AB (ISAB) generates, promotes and develops new innovations in the Swedish region of Skåne. ISAB was established in early 2009 by Skåne Regional Council and owns ISAB entirely. The company is currently located at a leading hospital in the region, namely the University Hospital of Lund. ISAB's inventions are focused on promoting new innovations primarily in healthcare, though they do receive all types of ideas. ISAB writes that its vision is to build an innovation-rich region and a successful company that continues to grow and prosper.[5]

ISAB's business model is rather straightforward. Outside inventors suggest new ideas to ISAB that are developed if the product meets two criteria. The idea must have a "proof of concept," or does it work, and "proof of business," is there business potential? If the idea meets these criteria, then ISAB assists to develop the idea into a commercial product. ISAB aids in everything from obtaining product licenses to creating a start-up company for a new invention.[6] ISAB generates profit via selling product licenses, product royalties, and offering consulting services to Skåne Regional Council. ISAB then reinvests its profit to further develop the business.[7]

As the sole owner of ISAB, Skåne Regional Council provides ISAB with all of its funding (see appendix I for ISAB balance sheet). Though ISAB is a small daughter company with only seven employees and five board members, Skåne Regional Council employs 33,000 people (see appendix II for list of ISAB employees). VINNOVA, Sweden's national innovation agency, initially gave Skåne Regional Council 2,5 million Swedish kronor, or approximately $400,000 to start ISAB, according to

[5] Innovator Skåne AB, "Om Innovator Skåne," http://www.innovatorskane.com/.
[6] Innovator Skåne AB, "Om Innovator Skåne."
[7] Innovator Skåne AB, "Affärsplan Innovator Skåne AB," Om Innovator, http://www.innovatorskane.com/.

the Skåne Regional Council.[8] At the end of last year, the region allocated an additional 4,5 million Swedish kronor, or approximately $705, 000, to Region Skåne and ISAB to be spent over the next two years.[9]

Since 90 percent of Skåne Regional Council's budget and most of its personnel work in healthcare, innovations for ISAB tend to be health related. Moreover, ISAB's life science inventions have shown to be more interesting and have more development potential. Currently, ISAB is working with 25 ideas of which 23 are life science products. Five of these have been licensed to other companies.[10]

Product Overview

The proposed strategy focuses on one of ISAB's developing inventions called F-Indicator 10 and its F-Index, which was invented by Carl-Erik Flodmark, MD, PhD. Flodmark specializes in child and adolescent health at Skåne's University Hospital. The device is a preventive care tool that measures abdominal fat height. The intent is to use the device to measure abdominal obesity in children and adolescents; although, it can be used for adults. The Mayo Clinic defines childhood and adolescent obesity as "a serious medical condition that affects children and adolescents."[11] It occurs when the child or adolescent is well above his or her normal weight for his or her age or height" (see appendix III for pediatric subgroup and age ranges). [12] F-Indicator 10 offers a completely new, simple and accurate method for abdominal body fat monitoring. It also provides technological support for new and existing research in the field.

F-Indicator 10 measures the amount of fat via abdominal height using the breastbone as a reference point. This gives an F-index, a new indicator for tracking abdominal obesity. Studies have

[8] Region Skåne, "Mer pengar att satsa på innovationer," Region Skåne, http://www.skane.se/templates/page.aspx?id=322808.
[9] Region Skåne, "Mer pengar."
[10] Ibid.
[11] Mayo Clinic, "Childhood," Mayo Clinic, http://www.mayoclinic.com/health/childhood-obesity/DS00698.
[12] Ibid.

shown that although obesity is linked to a number of health risks, the placement of fat around the abdomen increases those risks. *The Tufts University News Letter* included an article in 2008, which cited a number of studies showing that abdominal obesity increases the risks for death, heart disease, cancer and dementia.[13] Likewise, abdominal fatness has shown to be a more accurate indicator of cardiovascular risk than general obesity, according to a 2007 study by Smith and Haslem in *Current Research and Medical Opinion.*[14]

F-Indicator 10 measures abdominal fat height by using a safe, low-intensity green laser. The measurements of the height of the breastbone and height of the abdomen are taken from an overhead-measuring device that shines the laser onto the patient's abdomen while the patient is lying down (see appendix IV for product image). The F-Index is calculated by dividing the height of the abdomen by the height of the breastbone. F-Indicator-10 is mobile and digital, allowing physicians to use the device in many rooms and save measurements digitally on a laptop. A result of one, or very close to one, means that the patient has a normal weight. Above one indicates that the person is overweight, and below one indicates that they are underweight. Currently, the device has an estimated price of circa $3100 - $4700 and has a current production cost of $300 to $500, depending on the quantity produced. The price estimates were determined by a research study in which international customers attending a conference on childhood obesity were asked to state how much they would be willing to pay for F-Indicator 10.

The new F-index is envisioned to replace Body Mass Index (BMI), a commonly used indicator for detecting obesity. Currently, obesity is screened in children using Body Mass Index, which is obtained from weight and height measurements, writes the CDC (see appendix V for BMI

[13] Anonymous. "Gut-Check Time: Why Belly Fat Poses Extra Risks," *Tufts University Health & Nutrition Letter* 26, no. 5 (2008): 6, http://search.proquest.com/docview/196365795?accountid=8285 (accessed March 18, 2011).

[14] Jr, Sidney C. Smith and David Haslam, "Abdominal Obesity, Waist Circumference and Cardiometabolic Risk: Awareness among Primary Care Physicians, the General Population and Patients at Risk - the Shape of the Nations Survey*," *Current Medical Research and Opinion* 23, no. 1 (2007): 29, http://search.proquest.com.

formula).[15] The child's BMI is then compared to BMI percentiles of other children.[16] If the child has a BMI above the 85th percentile, then he or she is considered to be at risk for obesity.[17] However, BMI is limited in that it can only be used to screen for obesity – not diagnose it. The CDC notes that though BMI is a useful screening tool as it *correlates* with body fatness, it is not a diagnostic tool because it does not *measure* body fatness per se.[18] F-Index is a better index than BMI because F-index actually measures body fatness, thereby surpassing some of the limitations of BMI. BMI is also size and age dependent – F-Index is not. F-Index is easier to understand in that a patient can see with their eyes their F-index and track their own development. F-Index also surpasses a number of other obesity measures that are later explained in the market analysis section.

The invention is still in its early stages of development. So far, ISAB has a patent in Sweden and is seeking one in the United States. ISAB is still in the process of obtaining its PCT license, which is necessary to seek patents in other countries. The PCT process usually takes at least 30 months. Therefore, the product would likely be launched in the United States in a minimum of five years.

WHY THE UNITED STATES?

In the United States, Childhood and adolescent obesity rates are notoriously high, creating a need for a tool to accurately diagnose and assess this population. The United States has the highest obesity rate in the world for adults, with approximately 30 percent of the population being overweight or obese, indicates 2005 OECD data.[19] Though there are fewer worldwide statistics available for childhood and adolescent obesity, the United States ranks as one of the highest in this category too, according to data from the British Government Office for Science (see appendix VI for

[15] Centers for Disease Control, "Obesity and Overweight for Professionals."
[16] Ibid.
[17] Ibid.
[18] Ibid.
[19] "Obesity statistics," Countries Compared, OECD Health Data 2005, Nationmaster n.d., http://www.nationmaster.com/graph/hea_obe-health-obesity.

graph).[20] The following industry analysis section explains the current industry and market conditions in the United States.

INDUSTRY ANALYSIS

Market Structure

As a monitoring instrument used by healthcare professionals, F-Indicator 10 is a medical device that adheres to the medical device industry, specifically the medical supplies and equipment manufacturing segment. In the United States, this industry segment is compromised of "about 11,000 companies with combined revenue of $75 billion," according to Hoovers, Inc.[21] At first glance, the shear size and earning potential in the industry make it highly attractive; however, this industry also comes with a number of challenges.

Market Trends

Screening for childhood obesity is becoming an essential component of preventive health care, as childhood obesity is a significant health risk in the United States. The high and growing rate of childhood obesity creates a demand for adequate screening devices. An estimated 17 percent of American children and adolescents from age two to 19 are obese, indicates the 2007-2008 National Health and Nutrition Examination Survey (see appendix VII for obesity map and VIII for growth chart).[22] Compared with as early as 1963-1970, this number has increased by over four times, as there were only four to five percent of children and adolescents considered obese, according to the U.S. Department of Health and Human Services.[23] By 1988-1994, this number rose to 11 percent and has continued to rise to 17 percent.[24]

---

[20] "Obesity: in statistics," BBC NEWS Health, n.d., http://news.bbc.co.uk/2/hi/health/7151813.stm.
[21] Hoover's, Inc, "Medical Equipment & Supplies - Industry Overview" Hoover's, http://subscriber.hoovers.com/.
[22] Centers for Disease Control, "Obesity and Overweight for Professionals."
[23] U.S. Department of Health and Human Services, "Childhood Obesity," aspe.hhs.gov, http://aspe.hhs.gov/health/reports/child_obesity/.
[24] Ibid.

Opportunities

There are many consequences and co morbidities of childhood obesity that present a large health and economic incentive to screen for it. The CDC offers a comprehensive list of consequences that include increased risks for psychosocial disorders, cardiovascular disease, asthma, hepatic steatosis (fatty liver), sleep apnea and type-2 diabetes.[25] The CDC also cites a 2003 study, which showed that in 1998, annual costs for obesity and overweight patients in the United States was $78.5 billion nationally or approx $100 billion in 2011 dollars with inflation considerations.[26] To break it down, another 2003 study showed that the median cost of treating a patient with just type-2 diabetes fell between $1700-$2100 per patient annually.[27] In other words, the health and economic stakes for preventing obesity are high, presenting a market opportunity for the medical device industry to provide screening instruments that can diagnose and prevent childhood obesity.

There are currently a number of ways to screen for obesity. Wells and Fewtrell explain these various techniques in their article, "Measuring Body Composition" in the *Archives of Disease in Childhood*. They cite the following measures: BMI, skin fold pinching, waist circumference, and bioelectric impedance analysis (BIA) (see appendix IX for a more detailed explanation). [28]

Each of these methods has limitations. Though BMI is a useful screening tool as it correlates with body fatness, the CDC notes that it is not a diagnostic tool because it does not measure body fatness per se.[29] Fat can also be measured via skin fold pinching; however, this method has proven

[25] Centers for Disease Control, "Obesity and Overweight for Professionals: Childhood," Centers for Disease Control and Prevention, http://www.cdc.gov/.
[26] Centers for Disease Control, "Obesity and Overweight for Professionals: Economic Consequences," Centers for Disease Control and Prevention, http://www.cdc.gov/.
[27] M. Brandhal et al.,"The direct medical cost of type 2 diabetes," *Diabetes Care* 8 (2003): 2300-4, http://www.ncbi.nlm.nih.gov/pubmed/12882852.
[28] J C K Wells and M S Fewtrell, "Measuring Body Composition," *Archives of Disease in Childhood 91,* no. 8 (2006): 612-617, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2082845/?tool=pmcentrez
[29] Ibid.

to be less accurate and less precise when measuring obese children, writes Wells and Fewtrell in the *Archives of Disease in Childhood.*[30] Likewise, waist circumference is used to measure central fatness. In adults, a waist to hip ratio is compared to waist circumference to get a better understanding of body fat composition and can also be performed on children.[31] This is very similar to how F-Indicator 10 and F-Index function. The key difference is that F-Indicator 10 and F-Index use the breastbone as a reference, which in turn creates an easy index that can help track weight changes. Finally, Bioelectric impedance is limited in that it makes assumptions about body shape and is age dependent.[32] The limitations of these methods create an opportunity for a product that is limitation-free. In this way, F-Indicator and F-index are fulfilling a need for advancement in body fat monitoring technology.

Threats

This is a highly competitive industry given that there are about 11,000 companies that produce medical devices. Despite the thousands of companies in the industry, it is very concentrated. The 50 largest companies in the industry generate 75 percent of the revenue, according to Hoovers.[33] There are also a few "big players" that offer vast product portfolios. Some of these leading companies include GE Healthcare, Siemens Healthcare and Philips Healthcare.[34]

These large firms produce a range of medical devices that span the healthcare industry. Out of the three companies mentioned, GE Healthcare is the only one that has a product competitor of F-Indicator 10, namely a body composition analyzer called "Lunar InBody."[35] However, there are also a number of companies that are committed to body weight and composition monitoring for

[30] J C K Wells and M S Fewtrell, "Measuring Body Composition."
[31] Ibid.
[32] Ibid.
[33] Hoover's Inc., "Medical Equipment and Supplies."
[34] Ibid.
[35] GE Healthcare, "Lunar InBody - Body Composition," GE Healthcare, https://www2.gehealthcare.com/

professional and home use. These include but are not limited to: Tanita Corporation, Omron, Detecto, A&D Medical, Medweigh, Seca, HealthOMeter and Siltec. Though many of these companies' products are used to weigh and measure patients, few have products that specifically measure body fatness. Tanita Corporation, Omron, Medweigh and HealthOMeter all make body fat analyzing scales in addition to more simple scales.

The apparent leader in this niche is Tanita Corporation, a Japanese-based company that manufactures precision scales and balances.[36] Tanita Corporation is F-Indicator 10's greatest threat in that it specializes in body fat composition analyzers that measure body fatness using bioelectric impedance (BIA). Tanita has products for both professional and consumer use, has a market share of 50 percent in Japan and a significant presence in the United States.[37] Most of its home use products cost under $100 whereas its professional products cost between $1000 and $2000.[38] Tanita is trying to develop a presence in the childhood obesity market and recently issued a body composition analyzer in February that is specifically designed for measuring body fatness in children, is for home use and is FDA approved.[39]

In addition to a highly competitive landscape, companies also face dense regulations. F-Indicator 10 would need to be approved by the Food and Drug Administration (FDA) in order to be sold in the United States, according to the FDA website.[40] The FDA has three classes of regulations for medical devices depending on the product. F-Indicator 10 would most likely be class II, which includes undergoing special controls and general controls (see appendix X). ISAB would need to

[36] Tanita Corporation, "About Us," Tanita Montioring Your Health, http://www.tanita.com/en/.
[37] Ibid.
[38] Ibid.
[39] Ibid.
[40] U.S. Department of Health and Human Services, "Guidance Documents (Medical Devices and Radiation-Emitting Products) > Premarket Assessment of Pediatric Medical Devices," U.S. Food and Drug Administration, http://www.fda.gov.

follow the procedures for pediatric medical devices; however, since it also uses a laser, it would need to adhere to rules on radiation.[41]

INTERNAL ANALYSIS

Strengths

ISAB has several strengths that include its skilled employees, valuable product portfolio and government funding. Though a small task force, ISAB's team has the experience, skills and capabilities that has allowed the company to develop quickly and produce deliverables. ISAB has a product portfolio with many promising ventures that will ensure the company's continued growth. Given that ISAB is owned and fully supported by the Regional Council of Skåne, it has the advantage of having a constant income. This constant funding facilitates ISAB's day-to-day operations, as well as providing investment money for some of its projects.

F-Indicator 10 also has several strengths that were noted in the product overview. These include its simple F-index that is not age, weight or height dependent, its digital and mobile qualities and its ability diagnose abdominal abesity and measure abdominal fat.

Weaknesses

ISAB's youthfulness and small size make it vulnerable to competition. Since it has only been around since early 2009, it has not yet had the time to fully experience the learning curve that comes with starting any new business or government entity. In addition, its small size leaves it somewhat disadvantaged, as it does not have much capital, organization slack or financial leeway for emergency situations. Larger companies tend to have a better survival rate because they are more difficult to acquire, have organization slack and more "cushion for turnaround," according to

[41] Ibid.

Wheelen and Hunger in *Strategic Management and Business Policy.*[42] Nonetheless, ISAB expects to have more financial leeway in about five years, when some of its inventions will be on the market and it begins to collect royalties for them.

F-Indicator 10's weakness is similar to ISAB. It is still early in the development process, though it has undergone risk assessment in Sweden and can be used on patients in the clinic in which it is undergoing studies. There is still data collection occurring that will assess its medical benefits. Results from these studies will eventually be published in a medical journal, which will help with its publicity and credibility. Likewise, it still needs a patent and FDA approval in the United States – two essentials in bringing a medical device such as F-Indicator 10 to market.

ACCOMPLISHMENTS TO DATE

Though ISAB has only been in existence since early 2009, it has achieved several noteworthy accomplishments. ISAB has been able to develop a strong product portfolio comprised of 25 inventions, all in different stages of development. ISAB has secured contracts with five companies, with one invention for each company. Furthermore, it recently received its first royalty of 11,000 Swedish kronor, which is about $1750. ISAB has had several accomplishments with F-Indicator 10. It has been able to secure a Swedish patent, applied for a PCT license and is working to receive a patent in the United States. It is undergoing beta testing with one prototype while developing a second prototype. ISAB is scheduled to conduct research with both prototypes in the fall. The data from this research will serve as medical evidence for the F-Index. ISAB has performed pricing research for F-Indicator 10 where it asked customers at an international conference how much they would be willing to pay for the product. This data was then used to establish a market price estimate.

[42] Thomas L. Wheelen, and J. David Hunger, *Strategic Management and Business Policy, Concepts*, Eleventh ed., (Upper Saddle River, NJ: Pearson/Prentice Hall, 2008), 209.

PROBLEMS OUTSTANDING

ISAB is still unclear about its strategy for F-Indicator 10. First, it needs to decide whether to create a start-up around ISAB or whether to sell the licenses to a larger corporation such as Philips Healthcare. Second, it needs to decide which markets to focus on. It is currently considering Sweden, the United States and China. Third, it needs to complete all patent and regulatory processes.

ISAB has asked me to propose a strategy for how to reach the United States' market. ISAB would like to enter the United States' market, despite the competitive landscape, because of the market demand and currently available product's limitations. The high numbers of obese children and adolescents, in addition to the large amount of money spent on treating those patients each year, create a market opportunity for F-Indicator 10. Moreover, ISAB understands that if they can manage to tap the American market, it may be easier to venture into smaller markets.

One challenge that the company faces in meeting development steps for F-Indicator 10 is that it is a small start-up with limited capital. This means that the measures taken to reach the United States will have to be somewhat modest. For example, while larger medical device companies may pay tens of thousands of dollars to buy a medical conference exhibition space for marketing purposes, ISAB does not have the financial means. Therefore, the following recommendations keep these limitations in mind.

RECOMMENDATIONS

As F-Indicator 10 is a product in its early stages, it still has a few years of development before it can be launched. With that said, there are three critical recommendations that ISAB should follow in order for F-indicator 10 to successfully reach the United States market. I recommend the following:

1. Continue to seek patents, generate medical evidence and perfect prototype
2. Complete United States regulatory measures
3. Contract with a medical device corporation in the United States

These recommendations are explained in the action plan.

ACTION PLAN

1. Continue to seek patents, generate medical evidence and perfect F-Indicator 10 prototype

This is a crucial step if ISAB is to have any chance of bringing F-Indicator 10 to fruition. Without a patent in the United States, F-Indicator 10 has no protection against intellectual theft. Patents protect a company against competitor copycats for a number of years, depending on how long the company is able to secure the patent. F-Indicator 10 will most likely have a patent of 20 years, with about 15 remaining after having gone through the FDA approval process, believes CTO Stig Wiinberg. Medical evidence is also crucial for positioning F-Indicator 10 as a credible, results-oriented medical device that diagnoses abdominal obesity and measures abdominal fatness. This medical evidence will eventually be published in a medical journal, which will help it gain publicity and act as a credible selling point. Finally, ISAB needs to perfect the prototype in order to be able to market it. These measures are currently underway and are expected to take about 30 months – the time it normally takes to obtain a patent. This measure would not require any additional costs, as it has already been budgeted for by ISAB.

2. Complete United States regulatory measures

As explained in the industry analysis, the medical device industry in the United States offers many regulatory challenges. First, the FDA must approve F-Indicator 10 before it can be marketed. In order to do so, ISAB should follow the FDA guidelines listed on the FDA website for pre-market

approval (PMA) or 510(k) process procedures, depending upon how the FDA classifies the device.[43] These guidelines detail all of the necessary steps that any company must follow before it can legally sell its medical device on the United States market.[44]

As a part of the FDA approval process, ISAB will have to set up clinical testing, similar to the clinical risk analysis, beta testing and data collection being performed in Sweden. This testing would need to occur at a clinic in the United States, which means that ISAB will need to contact an American clinic. In order to increase the chance of being accepted to perform research at a clinic, ISAB should contact several clinics. In particular, ISAB should partner with clinics that have wards geared towards bariatric treatment and research.

Some clinics and hospitals that have special units dedicated to childhood and adolescent obesity research include: The Mayo Clinic, University of Southern California Childhood Obesity Research Clinic (CORC) and the Children's Hospital of Pennsylvania (CHOP), among many others across the United States. The Children's Hospital of Pennsylvania would be especially relevant as it recently received a grant of $10 million from The Foundation for a Healthy America in March 2011, notes George Bochanski from the CHOP.[45] Bochanski goes on to say that the grant will fund childhood obesity prevention by supporting "childhood obesity research, clinical care, and outreach efforts."[46] In this way, the CHOP would make strategic sense, as F-Indicator 10 aligns with The Foundation for a Healthy America's mission for the grant.

3. Contract with a medical device corporation present in the United States

ISAB was faced with the decision of whether to create a start-up around F-Indicator 10, or whether to contract with a medical device corporation, sell the product licenses and collect

[43] U.S. Department of Health and Human Services, "Guidance Documents."
[44] Ibid.
[45] George Bochanski, "CHOP Awarded Grant for Childhood Obesity Prevention," The Children's Hospital of Philadelphia, http://www.chop.edu/news/chop-awarded-grant-for-childhood-obesity-prevention.html.
[46] Bochanski, "CHOP Awarded Grant for Childhood Obesity Prevention."

royalties. Considering the medical device industry conditions, ISAB's financial standing and start-up risk, ISAB should contract with a medical device corporation and collect royalties instead of building its own start-up for the product.

As illustrated in the industry analysis section, the medical device industry is concentrated and competitive. These two conditions would make it difficult for a vulnerable start-up to enter the market. What is more, ISAB is itself a small start-up with limited financial capabilities. It does not currently have the capital necessary to launch a start-up in the United States. Besides this factor, there is also a relatively low survival rate involved in starting a new business. The Small Business Association documents that in the United States, 70 percent of new businesses survive at least the first two years and only 50 percent survive at least the first five years, according to data from 2000.[47] Given the recession that the United States has faced for the past few years, conditions for new businesses are still tough. In 2008, there was a 10 percent turnover rate for entry and 10 percent turnover for exit.[48]

Prospective Contractors

ISAB should sell its product licenses to a company that does not currently have any products that would directly compete with F-Indicator 10. ISAB voiced the concern that companies with competing products sometimes will buy up an invention only to prevent it from competing with its current products. Possible fits include Medtronic, Philips Healthcare and Siemens Healthcare, as these corporations do not produce body fat analyzers or similar body fat monitors.[49] Below is a brief overview of prospective F-Indicator 10 contractors.

[47] Small Business Association, "Office of Advocacy - Frequently Asked Questions," sba.gov, http://www.sba.gov/advocacy/7495.
[48] Ibid.
[49] "Facts & Figures - Philips," n.d., http://www.healthcare.philips.com/us_en/about/Company/factsandfigures.wpd.

Medtronic. Medtronic is a global medical technologies company that has a wide range of products that "diagnose, prevent and monitor chronic conditions," explains Medtronic.[50] It was founded in 1949 and had annual revenue of $15.8 billion in 2010.[51] Medtronic has two distinct groups: the Cardiac and Vascular Group and the Restorative Therapies Group.[52] Medtronic's strategy is to partner with medical professionals worldwide to develop medical technologies. This strategy would make it a viable option for ISAB in that it is open to collaborating with other companies.

Philips Healthcare. Philips Healthcare is similar is a subgroup of Philips Group.[53] In 2009, Philips Healthcare contributed to one-fourth of Philips' sales, bringing in $11 billion annual sales in 2009.[54] Its specialties include: anesthesiology, cardiology, mother and child care, oncology, orthopedic, surgery and women's healthcare.[55] Philips engages in partnerships with companies and new inventors. The contact person for finding out more about how to engage in a partnership or contract with Philips Healthcare is Mr. Steve Metz (see appendix XI for his email address).

Siemens Healthcare. Siemens Healthcare is a subdivision of Siemens Group, which had annual revenue of about $109 billion in 2010.[56] Siemens Healthcare focuses on Hospital IT, Imaging IT and Diagnostics IT.[57] Siemens does not necessarily buy up another product but rather chooses to partner with existing firms. In fact, Siemens encourages partnerships from around the world, as it

[50] "Medtronic Newsroom - The world leader in medical technology," Medtronic at a Glance," n.d., http://wwwp.medtronic.com/Newsroom/MedtronicAtAGlance.do?lang=en_US.
[51] Ibid.
[52] Ibid.
[53] "Facts & Figures," Philips Healthcare, n.d. http://www.healthcare.philips.com/us_en/about/Company/factsandfigures.wpd.
[54] Ibid.
[55] "Products and Solutions," Philips Healthcare, n.d. http://www.healthcare.philips.com/.
[56] "About Us," Siemens Global Website, Siemens Healthcare, n.d., http://www.siemens.com/about/en/.
[57] Ibid.

notes on its website.[58] Previous Siemens' partnerships have included clinicians, research groups and individual scientists.[59]

In order to partner with Siemens, ISAB would need to submit a proposal via Siemens' website. The proposal must include the following: "an executive summary, published or publicly available intellectual property information, three main value drivers of your proposal, contact data" and a list of Siemens employees that ISAB has already contacted.[60]

Other Considerations

In order for ISAB to be able to contract with a large corporation, it will need to prepare a comprehensive proposal, similar to the one that Siemens is requesting, which it can show to prospective contractors. The proposal would serve as an informative selling tool. It would include sections such as an executive summary, company overview, product overview, any medical evidence, intellectual property information, a valuation of the product, why the corporation should sell F-Indicator 10 and ISAB contact information. ISAB will overall be able to use this document to market its concept.

Once ISAB has established a product proposal, ISAB should try to sift through its social network to establish what types of contacts it may have available at prospective contractors. The last proposal requirement that Siemens details shows that in many large corporations, it is vital to "know someone." These corporations filter through lots of proposals everyday and so having a personal contact in the company that can vouch for ISAB would be extremely valuable.

---

[58] "Partnering," n.d., Siemens Global Website, Siemens Healthcare, http://www.medical.siemens.com/webapp/wcs/stores/servlet/CategoryDisplay~q_catalogId~e_-1~a_categoryId~e_1005653~a_catTree~e_100005,1005653~a_langId~e_-1~a_storeId~e_10001.htm.

[59] Ibid.

[60] "Submit Your Idea," Philips Healthcare, n.d., http://www.medical.siemens.com/.

ESTIMATED COSTS AND BENEFITS

Costs

1. Continue to seek patents, generate medical evidence and perfect prototype

No additional costs will be incurred as ISAB has already budgeted for this step.

2. Complete United States regulatory measures

The FDA charges the following fees for small businesses (gross revenue of less than or equal or $100 million in gross receipts or sales)[61]:

- $2175 to review a 501(k)/PMA application
- $2179 for establishment registration fee
- Other costs include the time ISAB personnel spend filing the FDA application, which is included in their salaries.

Clinical studies:

ISAB has discovered that with several of its prototypes, physicians are often eager to have their name associated with a new breakthrough study and are often willing to *pay* ISAB to be a leader in the study. Since F-Indicator offers an entirely new index for measuring abdominal obesity, it is considered a medical breakthrough. For example, ISAB was asked to attend an international conference in Stockholm on Childhood Obesity as a special guest. ISAB was able to set up a promotional exhibit for free because the conference organizers found the invention to be so significant.

If the physician is not willing to pay ISAB, then ISAB would have to pay the following expenses:

- $300-$500 per prototype used in the study

[61] U.S. Department of Health and Human Services, "Premarket Notification [510(k)] Review Fees," U.S. Food and Drug Administration, http://www.fda.gov/.

- Other direct material costs would be low as the data is gathered digitally on a computer
- Direct labor costs would be high as average family physician salaries are circa $120,000 to $160,000 per year, according to Payscale[62]
- Flights to and from the United States for ISAB personnel to set up the studies $600-$1000 roundtrip per person (depending on when the flight is booked and what seats are chosen)

Because of these costs, ISAB is hoping to be able to find a research center willing to help cover much of the costs. With its recent win of $10 million in grant funding, the Children's Hospital of Philadelphia could be a promising option.

3. Contract with a medical device corporation

The only costs incurred in this recommendation would be the time spent setting up meetings with corporate representatives, travelling expenses and any legal fees associated with signing contracts.

- Time spent setting up and attending meetings with corporate representatives is budgeted into ISAB's employee salaries
- Travelling expenses are highly dependent upon what company is chosen and where the offices are located
- Legal fees would most likely be minimal as Skåne Regional Council has lawyers on hand

Benefits

The benefits of taking these three measures will outweigh its costs with the expected product royalties that will come once F-Indicator 10 is launched in the United States. The benefit of the first two measures, namely seeking patents and completing the FDA regulatory process, is that ISAB will be able to legally sell F-Indicator 10 in the United States. These two steps are critical if ISAB wants to enter the United States market.

[62] Payscale, Inc. "Doctor of Medicine (MD) Degree - Doctor of Medicine Salary" http://www.payscale.com/research/US/Degree=Doctor_of_Medicine_(MD)/Salary.

The major benefit of the third recommendation, namely licensing F-Indicator 10 to a large corporation, is that ISAB will be able to enter the United States' saturated medical device industry. The large corporation will have the resources and experience necessary to successfully tap into this market. In addition, ISAB will not have to incur costs associated with producing and promoting F-Indicator 10 in areas such as production and marketing.

F-Indicator 10's expected patent lifespan, with the development process subtracted out, is 15 years, which gives ISAB a long time period to collect royalties. It is too early to predict the exact percentage of royalties that ISAB can enjoy because it will depend on its ability to conjecture medical evidence, choose a price, and value the product. It will also vary based on ISAB's ability to negotiate and secure a contract with a large medical device corporation. However, ISAB expects the product to produce sufficient royalties to at least cover cost of development, if not much more.

APPENDICES

Appendix I - ISAB Employees

1. Ronnie Halvardsson, *CEO*
2. Stig Wiinberg, *CTO*
3. Jonas Jönsson, *Business Developer*
4. Kristin Alnemo, *on maternity leave*
5. Jenny Bengtsson, *Business Developer*
6. Thomas Persson, *Development Engineer*
7. Erik Johansson, *Development Engineer*

Appendix II - ISAB Balance Sheet December 31st 2010

Everything listed in SEK.

	Starting Balance	Starting Total	Period	Ending Total
ASSETS				
Fixed Assets				
Material Fixed Assets				
Inventories and tools	87,067.93	87,067.93	16,394.50	103,462.43
Accumulated depreciation of inventories and tools	(5,310.00)	(5,310.00)	(19,513.00)	(24,823.00)
Computers			16,668.75	16,668.75
Accumulated depreciation of computers			(122.00)	(122.00)
Total Material Fixed Assets	81,757.93	81,757.93	13,428.25	95,186.18
Financial Fixed Assets				
Other Long term Claims	1,200,000.00	1,200,000.00	0.00	1,200,000.00
Total Fixed Assets	**1,281,757.93**	**1,281,757.93**	**12,428.25**	**1,295,186.18**
Current Assets				
Short Term Claims				
Accounts receivable			463,750.00	463,750.00
Taxes and fees	871,315.00	871,315.00	84,429.00	171,744.00
VAT Receivable	384,738.00	384,738.00	(61,209.00)	323,529.00
Other current assets	24,000.00	24,000.00	(24,000.00)	

Misc. prepaid expenses and accruedincome			14,248.00	14,248.00
Total Short Term Claims	496,053.00	496,053.00	477,218.00	973,271.00
Cash and Bank				
Checking account	334,730.34	334,730.34	1,324,639.50	1,659,369.84
Bank (other accounts)	100,298.15	100,298.15	(100,298.15)	
Total Cash and Bank	435,053.00	496,053.00	1,224,341.35	1,659,369.84
Total Current Assets	**931,081.49**	**931,081.49**	**1,701,559.35**	**2,632,640.84**
Total Assets	**2,212,839.42**	**2,212,839.42**	**1,714,987.60**	**3,927,827.02**
EQUITY, PROVISIONS AND LIABILITIES				
Equity				
Share capital	(100,000.00)	(100,000.00)		(100,000.00)
Balanced profit or loss	1,444,028.25	1,444,028.25	3,051,622.33	4,495,650.58
Year End Results	(6,400,000.00)	(6,400,000.00)	(5,000,000.00)	(11,400,000.00)
Total Equity	(2,004,349.42)	(2,004,349.42)	(184,111.49)	(2,188,460.91)
Short Term Liabilities				
Payables 1			(1,096,758.84)	(1,096,758.84)
Payables 2	(10,359.00)	(10,359.00)	(229,891.00)	(240,250.00)
Staff Tax	(17,418.00)	(17,418.00)	(16,186.00)	(33,604.00)
Statutory social fee and special wage tax	(216.00)	(216.00)	(22,527.20)	(2,743.20)
Other accrued costs and prepaid revenues	(164,472.00)	(164,472.00)	(165,178.00)	(31,650.00)
Total Short Term Liabilities	(208,490.00)	(208,490.00)	(1,530,876.11)	(1,739,366.11)
Total Equity, Provisions and Liabilities	**(2,212,839.42)**	**(2,212,839.42)**	**(1,714,987.60)**	**(3,927,827.02)**
CALCULATED RESULTS	0.00	0.00	0.00	0.00

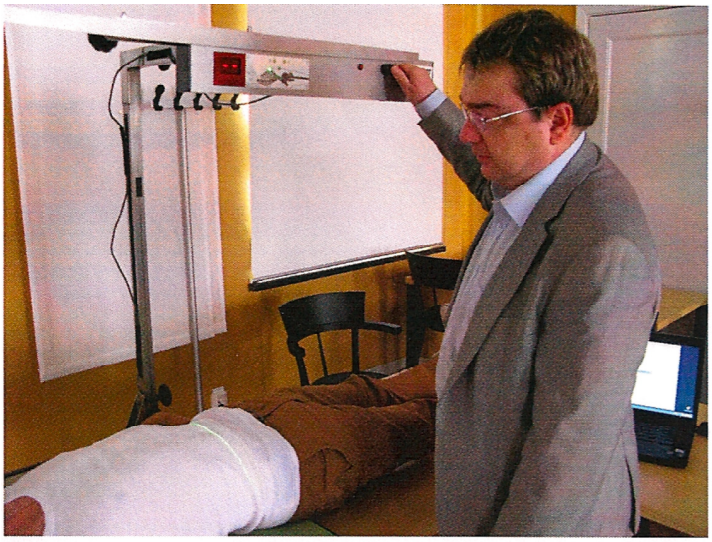
Appendix III – FDA Pediatric Subgroups and Age Ranges: [63]

Newborn (neonate) – from birth to 1 month of age

[63] U.S. Department of Health and Human Services, "Guidance Documents."

Infant – greater than 1 month to 2 years of age
Child – greater than 2 to 12 years of age
Adolescent – greater than 12 to 21 years of age

Appendix IV - Image of F-Indicator 10



Appendix V - BMI Formulas

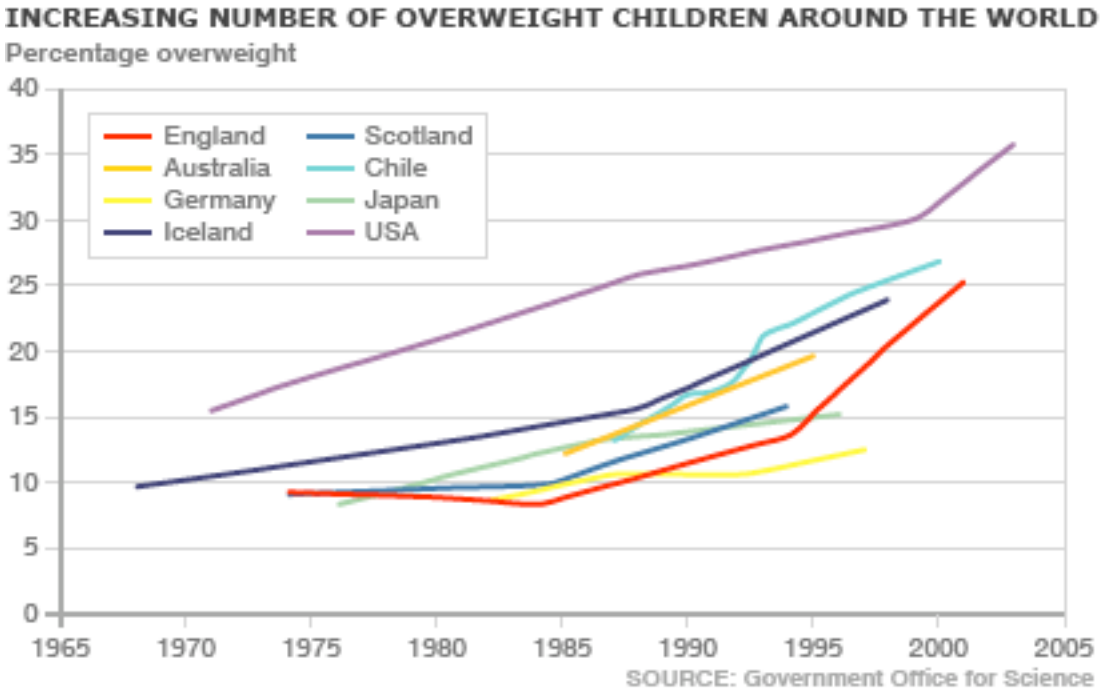
Metric Formula: weight (kg) / [height (m)]^2

Imperial Formula: weight (lb) / [height (in)]^2 x 703

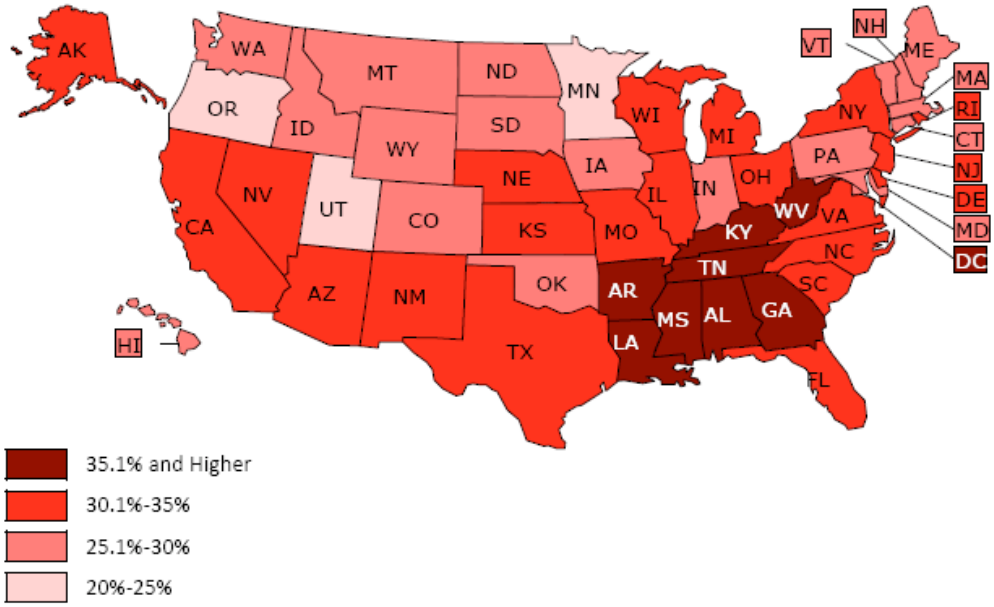
Source: "Assessing Your Weight," Centers for Disease Control[64]

[64] Centers for Disease Control, "Healthy Weight: Assessing Your Weight," Centers for Disease Control and Prevention, http://www.cdc.gov/.

Appendix VI – Percentage Overweight Around the World[65]



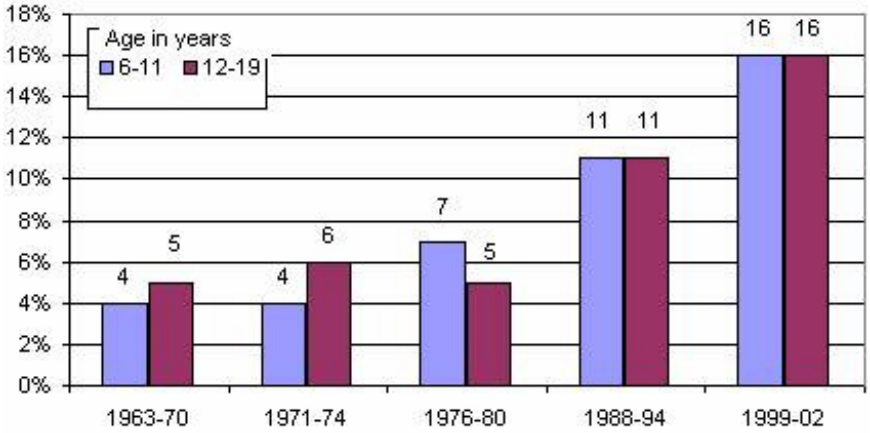
Appendix VII - Percentage of Children Who Are Overweight or Obese



Obesity in this map is defined using BMI percentiles.
Source: The National Surveys of Children's Health 2007 Data[66]

[65] "Obesity: in statistics," BBC NEWS Health, n.d., http://news.bbc.co.uk/2/hi/health/7151813.stm.
[66] National Conference of State Legislatures, "Childhood Obesity Trends - State Rates," NCSL, http://www.ncsl.org/?tabid=13877.

Appendix VIII - Prevalence of overweight among children and adolescents ages 6-19 years



NOTE: Excludes pregnant women starting with 1971-74. Pregnancy status not available for 1963-65 and 1966-70. Data for 1963-65 are for children 6-11 years of age; data for 1966-70 are for adolescents 12-17 years of age, not 12-19 years.

Source: US Department of Health and Human Services. [67]

Appendix IX - Methods for Measuring Childhood Obesity/Body Fatness

1. *Body Mass Index* - Body Mass Index is obtained from weight and height measurements, writes the Center for Disease Control (CDC).[68] The child's BMI is then compared to BMI percentiles of other children.[69] If the child has a BMI above the 85th percentile, then they are considered to be at risk for obesity.[70] The CDC notes that though BMI is a useful screening tool as it correlates with body fatness, it is not a diagnostic tool because it does not measure body fatness per se.[71]

2. *Skin fold Pinching* - Fat can be measured via skin fold pinching to measure skin fold thickness; however, this method has proven to be less accurate and less precise when measuring obese children, writes Wells and Fewtrell in the *Archives of Disease in Childhood.*[72] These skin fold measurements must be compared to a reference population to figure out whether a patient is becoming fatter or thinner.[73]

3. *Waist Circumference* - Waist circumference can be used to measure central fatness – the kind of fat that is most indicative of adverse consequences such as "lipid profile or insulin resistance than total fat."[74] In adults, a waist to hip ratio is compared to waist circumference to get a better understanding of body fat composition and can also be performed on children. Comparing body shape, or the waist-hip ratio, with waist circumference provides a more accurate reading of body

[67] U.S. Department of Health and Human Services, "Childhood Obesity," aspe.hhs.gov, http://aspe.hhs.gov/health/reports/child_obesity/.
[68] Centers for Disease Control, "Obesity and Overweight for Professionals."
[69] Ibid.
[70] Ibid.
[71] Ibid.
[72] J C K Wells and M S Fewtrell, "Measuring Body Composition."
[73] Ibid.
[74] Ibid.

composition.[75] This is very similar to how F-Indicator 10 and F-Index function, though the key difference is that F-Indicator 10 and F-Index use the breastbone as a reference, which in turn creates an easy index that can help track weight changes.

4. *Bioelectric Impedance* - Bioelectric impedance measures body impedance to an electric current. It is limited in that it makes assumptions about body shape and is age dependent.[76] This measurement is performed via body composition analyzers, or scales that send a current through the body, such as those produced by Tanita Corporation and explained in the industry analysis section.

Appendix X - Classes of FDA Medical Devices[77]

Class I – General controls e.g. elastic bandages, examination gloves[78]
Class II – General and special controls e.g. powered wheelchairs, infusion pumps[79]
Class III – Premarket approval required e.g. implantable pacemaker, endosseus implants[80]

Appendix XI – Contact information for Philips Healthcare employee Steve Metz

Email: steve.metz@philips.com

[75] Ibid.
[76] Ibid.
[77] U.S. Department of Health and Human Services, "General and Special Controls," U.S. Food and Drug Administration, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm.
[78] Ibid.
[79] Ibid.
[80] Ibid.

Works Cited

BBC. “Obesity: in statistics.” BBC NEWS Health. http://news.bbc.co.uk/2/hi/health/7151813.stm.

Bochanski, George. “CHOP Awarded Grant for Childhood Obesity Prevention.” The Children’s Hospital of Philadelphia. http://www.chop.edu/.

Brandhal, M. et al.“The direct medical cost of type 2 diabetes.” *Diabetes Care* 8 (2003): 2300-4. http://www.ncbi.nlm.nih.gov/pubmed/12882852.

Centers for Disease Control. “Obesity and Overweight for Professionals: Childhood.” Centers for Disease Control and Prevention, http://www.cdc.gov/.

Centers for Disease Control. “Obesity and Overweight for Professionals.” Centers for Disease Control and Prevention. http://www.cdc.gov/.

Centers for Disease Control. “Obesity and Overweight for Professionals: Economic Consequences.” Centers for Disease Control and Prevention. http://www.cdc.gov/.

Centers for Disease Control. “Healthy Weight: Assessing Your Weight.” Centers for Disease Control and Prevention. http://www.cdc.gov/.

Energimyndigheten et al.. “Hur drabbas barn av fetma?” Forskning.se. http://www.forskning.se/.

“Facts & Figures,” Philips Healthcare, n.d. http://www.healthcare.philips.com/us_en/about/Company/factsandfigures.wpd.

Harvard School of Public Health. “Abdominal Obesity: Definition and Measurement.” Obesity Program. http://www.hsph.harvard.edu/obesity-program/resources/abdominal-obesity/index.html#intro.

Hoover’s, Inc. “Medical Equipment & Supplies - Industry Overview.” Hoover’s. http://subscriber.hoovers.com/.

Innovator Skåne AB. “Affärsplan Innovator Skåne AB.” Om Innovator. http://www.innovatorskane.com/.

Innovator Skåne AB. “Om Innovator Skåne.” http://www.innovatorskane.com/.

GE Healthcare. “Lunar InBody - Body Composition.” GE Healthcare. https://www2.gehealthcare.com/.

Mayo Clinic. “Childhood.” Mayo Clinic. http://www.mayoclinic.com/.

Medtronic. “Medtronic Newsroom - The world leader in medical technology.” Medtronic at a Glance. http://wwwp.medtronic.com/Newsroom/MedtronicAtAGlance.do?lang=en_US.

National Conference of State Legislatures. “Childhood Obesity Trends - State Rates.” NCSL. http://www.ncsl.org/?tabid=13877.

Nationmaster. Obesity statistics.” Countries Compared. OECD Health Data 2005. http://www.nationmaster.com/graph/hea_obe-health-obesity.

Region Skåne. “Mer pengar att satsa på innovationer.” Region Skåne, http://www.skane.se/templates/page.aspx?id=322808.

Siemens Healthcare. “About Us.” Siemens Global Website. http://www.siemens.com/about/en/.

Siemens Healthcare. “Partnering.” Siemens Global Website. http://www.medical.siemens.com/.

Small Business Association. “Office of Advocacy - Frequently Asked Questions.” sba.gov. http://www.sba.gov/advocacy/7495.

Smith, Jr, Sidney C and David Haslam. "Abdominal Obesity, Waist Circumference and Cardiometabolic Risk: Awareness among Primary Care Physicians, the General Population and Patients at Risk - the Shape of the Nations Survey." *Current Medical Research and Opinion* 23, no. 1 (2007): 29, http://search.proquest.com.

Tanita Corporation. “About Us.” Tanita Montioring Your Health. http://www.tanita.com/en/.

Tufts University. "Gut-Check Time: Why Belly Fat Poses Extra Risks," *Tufts University Health & Nutrition Letter* 26, no. 5 (2008): 6. http://search.proquest.com/docview/196365795?accountid=8285 (accessed March 18, 2011).

U.S. Department of Health and Human Services. “Guidance Documents (Medical Devices and Radiation-Emitting Products) > Premarket Assessment of Pediatric Medical Devices.” U.S. Food and Drug Administration. http://www.fda.gov.

U.S. Department of Health and Human Services, “Premarket Notification [510(k)] Review Fees,” U.S. Food and Drug Administration, http://www.fda.gov/.

U.S. Department of Health and Human Services. “Childhood Obesity.” aspe.hhs.gov. http://aspe.hhs.gov/health/reports/child_obesity/.

U.S. Department of Health and Human Services. “General and Special Controls.” U.S. Food and Drug Administration. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm.

Wells, J C K and M S Fewtrell. “Measuring Body Composition.” *Archives of Disease in Childhood 91,* no. 8 (2006): 612-617, http://www.ncbi.nlm.nih.gov/.

Wheelen, Thomas L. and J. David Hunger, *Strategic Management and Business Policy, Concepts*, Eleventh ed., (Upper Saddle River, NJ: Pearson/Prentice Hall, 2008), 209.