We hereby approve the thesis/dissertation of

_________________________  Jacob Levi

candidate for the _______Master of Science_______ degree*.

(signed)  _______________  Edward M. Caner  ________________________

(chair of the committee)

_________________________  Bruce E. Terry

_________________________  Robert W. Brown

_________________________  David P. Rohler

_________________________  Steven Izen

(date)  ____________  11/18/2011

*We also certify that written approval has been obtained for any proprietary material contained therein.
# Table of Contents

List of Tables 6

List of Figures 7

Acknowledgements 9

Abstract 11

1 Value Proposition 13

1.1 Need 13

1.1.1 Growing Problem 13

1.1.2 Lack of Specific Directions 14

1.1.3 Great Deal of Dose Variation 14

1.1.4 No Standards or Common Metric 15

1.1.5 Cancer 17

1.1.6 Lawsuits 19

1.1.7 Why Does Overdosing Happen? 20

1.2 Approach 23

1.2.1 PI’s Process 23

1.3 Benefits to Costs 28

1.4 Competition 30

1.4.1 CT Scanner Vendors 30

1.4.2 QA Measurement Providers 35

1.4.3 Medic Vision 36

2 VRIO Analysis 37

2.1 Resources 37

2.2 Capabilities 37

2.3 Valuable 38

2.4 Rare 38

2.5 Imitable 38

2.6 Organized to Exploit 38

2.7 VRIO Analysis Conclusion 39
3 SWOT Analysis

3.1 Strengths

3.2 Weaknesses

3.3 Opportunities

3.4 Threats

3.5 SO Strategies

3.6 WO Strategies

3.7 ST Strategies

3.8 WT Strategies

3.9 SWOT Table

4 Porter’s Five Forces Analysis

4.1 The Threat of the Entry of New Competitors

4.2 The Threat of Substitute Products or Services

4.3 The Bargaining Power of Customers

4.4 The Bargaining Power of Suppliers

4.5 The Intensity of Competitive Rivalry

4.6 The Analysis

5 Blue Ocean Strategy

6 Business Model Canvas

6.1 Customer Segments (CS)

6.2 Value Proposition (VP)

6.3 Channels (CH)

6.4 Customer Relationship (CR)

6.5 Revenue Streams (R$)

   6.5.1 Early Revenue Stream

   6.5.2 Sustainable Revenue Streams

   6.5.3 Future Revenue Streams

6.6 Key Resources (KR)

6.7 Key Activities (KA)

6.8 Key Partnerships (KP)

6.9 Cost Structure (CS)
List of Tables

Table 1: SWOT Analysis 44
Table 2: suggested diameters and contrast level 65
List of Figures

Figure 1: Variability in radiation dosing according to patient size. 15
Figure 2: Total CT Procedure Volume, Hospital and Non-Hospital Sites, 1995-2010 17
Figure 3: Projected number of future cancers that could be related to CT scan use in the United States in 2007 according to cancer type. 18
Figure 4: Estimated percentage radiation attributable risks of death from typical CT scans of (a) the head and (b) the abdomen. 18
Figure 5: A visual of the right dose, for a specific patient for a specific application. 22
Figure 6: Possible designs for PI's calibration phantom 24
Figure 7: Calibration graph for two scanners (no two scanners are alike) 25
Figure 8: Expenditure for cancer care divided by site of cancer 28
Figure 9: Lost productivity due to cancer deaths 29
Figure 10: DoseWise tools 32
Figure 11: How does iDose⁴ work? 33
Figure 12: VRIO Analysis 39
Figure 13: Blue Ocean Strategy framework 49
Figure 14: Five years forecast 61
Figure 15: CT scanner 64
Figure 16: Phantom 65
Figure 17: Contrast performance curve resulting from a single protocol measurement 67
Figure 18: Illustration of a detectability mapping. Pins are numbered 1-9 from largest to smallest. Mapping from smallest detected pins to ExLCD contrast measured. 68
Figure 19: Block diagram for ExLCD method of generating the performance curve. 69
Figure 20: The calibration graph 70
Figure 21: Comparison between a single protocol contrast performance curve with ExLCD contrast performance curve. 71
Figure 22: Data flow for optimal protocol selection example 73
Acknowledgements

I would like to acknowledge my mentors: Ed Caner and Bruce Terry for making this journey interesting, for constantly challenging me and for helping me beyond the scope of this degree.

Specifically, I would like to thank Bruce for the long hours he helped me with this thesis and for sharing his vast knowledge and experience in business and life.
I’d also like to thank Ed for giving me a new perspective on science and for all the interesting lessons and discussions.

I’d like to thank David, Tom and Steven from Plexar Imaging for all their help and support.
Specifically, I would like to thank David for the long hours, constant help and good advice.
I’d also like to thank Tom for answering all my scientific questions.

I’d like to thank my wife and children for their support and for the long hours of staring at my back without complaining. Without their help I couldn’t do it.

I’d like to thank my parents for their support. Without them, none of this was possible.

Thanks for reading.
Enjoy.
Plexar Imaging
Entrepreneurship in the CT Industry

Abstract by
JACOB LEVI

Radiation exposure in medical imaging has become a major concern all around the world. Specifically, CT scanners carry the highest risk of a high dose of radiation, delivering hundreds of times more radiation than that of a single X-ray image.

Studies have shown a direct relation between CT scans, the chance of getting cancer, and mortality rates. The contradicting problem is that lowering the radiation dose causes inferior image quality, which may result in rescan or a misdiagnosis.

Plexar Imaging, a startup situated in Cleveland, has found an innovative way to reduce unnecessary exposure to radiation in CT scans, by quantifying the lowest dose that will produce acceptable image quality, as determined by the radiologists in a hospital system.

The product of a CT scan is a set of images. The requirement is that the radiologist can make the right diagnosis from those images. With a universal metric based on image quality and a method to calibrate any CT scanner to that metric, PI has developed a way to make sure the desired IQ will be achieved while using only the least amount of radiation that is necessary.

The use of IQ as the measurement unit will help standardize the radiation dosage in CT scans, and will provide, for the first time, a common scale technologists and radiologist can use to communicate with each other.
Plexar Imaging

Radiation exposure has become a major concern all around the world. Cell phones, microwaves, medical imaging, etc., are all being tested to reveal the dangers they carry. There is a consensus regarding the harmful effects of one kind of radiation: ionizing radiation has enough energy to rip electrons from an atom; it can augment the structure of a DNA molecule when going through live tissue and cause cancer as well as other things like skin burns and hair loss. In medical centers, many people are exposed to ionizing radiation, X-rays, by X-ray machines and computer tomography (CT) scanners, the two imaging technologies most commonly used worldwide. CT scanners carry the highest risk of a high dose of radiation, delivering hundreds of times more radiation than that of a single X-ray image.¹

Studies have shown a direct relation between CT scans, the chance of getting cancer, and mortality rates.² In recent research it was estimated that 36,000 people will get cancer every year due to a CT scan that they have had in the past.³ This alone explains why there is a big effort to reduce radiation doses in CT scans. The contradicting problem is that lowering the radiation dose causes inferior image quality (IQ) or reduced contrast, which may result in rescan or a misdiagnosis.

Radiation overdose is often conceived as something from which one immediately gets sick. While that does happen occasionally when the overdose is very high, it is not the only case of concern. Any dose above the minimum dose needed is considered an overdose.
Plexar Imaging (PI), a startup situated in Cleveland, has found an innovative way to reduce unnecessary exposure to radiation in CT scans, by quantifying the lowest dose that will produce acceptable image quality, as determined by the radiologists in a hospital system.

The product of a CT scan is a set of images. The requirement is that the radiologist can make the right diagnosis from those images. With a universal metric based on image quality and a method to calibrate any CT scanner to that metric, PI has developed a way to make sure the desired IQ will be achieved while using only the least amount of radiation that is necessary.

The use of IQ as the measurement unit will help standardize the radiation dosage in CT scans, and will provide, for the first time, a common scale technologists and radiologist can use to communicate with each other.
1 Value Proposition

In the following section, PI's value proposition\(^4\) will be analyzed according to Curtis R. Carlson’s approach. The questions answered are: Is there a need for a product that will lower radiation doses? What is PI's approach? Are there any benefits to costs from using PI's product? Are there any competitors and what do they offer?

1.1 Need

1.1.1 Growing Problem

The need to reduce radiation levels and the damage of high radiation dose has been widely addressed in the public media lately. Walt Bogdanich from the New York Times wrote a series of articles called “Radiation Boom\(^5\). The series contains tens of articles all addressing this urgent matter. ABC news\(^6\), NPR\(^7\) and many others, covered lawsuit cases, new published papers, etc. A congressional hearing regarding radiation overdose was held. In California preventive radiation overdose legislation was recently passed.\(^8\) Senator Padilla, who authored the California Senate bill, said: “This bill will provide physicians the information they need to track dosage levels, identify errors and prevent patients from receiving overdoses of radiation”.

Radiation overdosing is an urgent and important subject, particularly with CT machines. Several studies published recently show a direct relation between CT scans and cancer and death.\(^9\,10\,11\)
1.1.2 Lack of Specific Directions

No matter how sophisticated the scanner being used, the fact is, the technologist running the scan has some freedom to generally set the radiation dose\(^1\), for example, when adjusting to patient size. The technologist will then use the auto exposure function of the scanner. The auto exposure can slightly change the general dose chosen by the technologist. Each dose reduction technique that is currently on the market, with the exception of PI's extended low contrast detectability (ExLCD), does not prescribe to the technologist precisely how to set the scanner. It is left to the technologist’s expertise to set some parameters to the best of his knowledge.

1.1.3 Great Deal of Dose Variation

It is hard to imagine that something this important and dangerous can be set to unnecessarily high doses so easily. The lack of specific instructions to the technologist, leads to a big dosage variation. On one day a patient can get a certain dose and the next week he can get a higher dose for exactly the same procedure, done by the same technologist, often due to changes in the patient’s water density. This variation often grows larger if a different technologist runs the scan. Figure 1 shows a hypothetical illustration of the variation for a given procedure and two different scanners\(^2\): The X-axis shows the water equivalent diameter of patient size and the Y-axis shows the dose. For example, a patient sized 300mm has a variation between 13 to

\(^1\) This will be covered in more detail in section 1.1.3 on page 8.
\(^2\) This is generated data to illustrate the problem and not real world data.
26 CTDI\textsubscript{vol}, which is a 2X variance. Should a patient get twice the dose of that of another patient of the same size? The obvious answer is: he shouldn't!

![Graph showing variability in radiation dosing according to patient size.](image)

Figure 1: Variability in radiation dosing according to patient size.\textsuperscript{12}

1.1.4 No Standards or Common Metric

Although preventing excessive dosage is a highly desired goal, it is not the most important achievement of ExLCD. Imagine trying to answer the following question: what is the distance between New York and Chicago? Now imagine there is no definition of distance. One answer might be: about
two tanks of gas. Is that a good answer? What type of car are you driving? A semitrailer? A racecar? Or maybe a highly efficient hybrid car? It is very hard to answer the question without a proper scale to use.

Surprisingly, this situation is not too far from what happens in the CT world today. If a doctor wants to order a CT scan, he has no way of telling the technologist what image quality he needs to make a diagnosis, simply because there is no standard scale for IQ. Furthermore, if a scan were done today on one CT scanner and the doctor were satisfied with the IQ, there is no way to tell the technologist how to achieve the same IQ on another scanner, i.e. what settings to use.

There isn't an acceptable universal scale. Dose is not a good metric because every CT scanner has its own sensitivity; the dose being set by the electric current running through the X-ray tube. Unfortunately, different tubes will produce different radiation given the same current, because of different filters, age of tube, etc. This is where ExLCD changes the playing field. By providing a measured scale based on IQ, a standard can be set. A radiologist can say: "for this diagnosis I need this value of IQ", and the ExLCD system will deliver this image quality while ensuring that the patient does not receive unnecessary radiation. This is truly a breakthrough.
1.1.5 Cancer

Two independent studies in recent years estimated that 1 of 2000 people who undergo a CT scan will eventually develop cancer from that scan\textsuperscript{13,14}. This can be extrapolated to the entire population of the US. Using 80 million as the number of CT scans done annually in the US (Fig. 2), this estimates that 40,000 new CT related cancers in the future.

![Figure 2: Total CT Procedure Volume, Hospital and Non-Hospital Sites](image)

The risk of developing a CT related cancer was estimated\textsuperscript{15}; Figure 3 shows the estimated number of cancers which will be developed due to a CT scan done in 2007. The data is divided by cancerous organ\textsuperscript{16}.

Another study\textsuperscript{17} calculated the risk of dying due to a CT scan. The younger a person is, the more his cells are multiplying, thus a genetic mutation caused by radiation has a higher probability of becoming a cancerous tissue. Therefore, the younger the patient is, the higher is his or her risk of dying in the future due to a CT scan. The risk also changes according to the organ that is being scanned. For example, an abdominal scan holds a higher
risk than a head scan because of the difference in the dosage used and relative sensitivity to radiation (Fig. 4).¹⁸

Figure 3: Projected number of future cancers that could be related to CT scan use in the United States in 2007 according to cancer type.¹⁹

Figure 4: Estimated percentage radiation attributable risks of death from typical CT scans of (a) the head and (b) the abdomen.²⁰
1.1.6 Lawsuits

There are now multi-million dollar lawsuits regarding CT radiation overdoses in the US.\textsuperscript{21,22} It was reported that at least 400 people across the country have been injured\textsuperscript{23}. The FDA is issuing new regulations that will help to reduce the overdose incidents\textsuperscript{24}. But the question is, “are new regulations enough?” Probably not. A system is needed that will make sure an overdose can’t happen.

Each of the patients in Image 1 had a Brain Perfusion Scan. Although very rare, about 260 injuries out of the 400 happened in Mt. Sinai Hospital in San Diego, CA, on one malfunctioning scanner. This scanner gave patients up to 10 times the required dose in a period of 18 months before someone

\textbf{Image 1: CT overdose outcomes}
noticed the problem.

The fact is that these overdoses can happen is due to lack of an effective control system; one that will make sure only the necessary dose will be used. This is exactly what the recent California legislation is trying to achieve (for more details see Section 1.1.1).

1.1.7 Why Does Overdosing Happen?

1.1.7.1 Protocols

A CT scanner is a complex machine with many settings. To make things easier for the technologist, protocols were developed. Each imaging center typically has a "General Protocol" established for each diagnostic task. The General Protocol can be printed on a sheet and put in a notebook next to the scanner. Usually changes to the General Protocol come from the chief technologist or the clinical physicist. They are often set up with assistance from the vendor's application specialists. The General Protocol includes both scan and reconstruction parameters. The Specific Protocol includes specific parameters for the patient and contains more scan settings.
1.1.7.2 The Technologist’s Role

Some of the parameters, both in the General Protocol and in the Specific Protocol affect the dose. While some of the parameters are dictated by the protocols, others are left for the technologist to choose from within a range according to his experience. For example, the patient size can cause the technologist to change the scan parameters, resulting in a higher or lower dose.

From here on, it will be said that the technologist can choose the radiation dose according to his experience. One should remember that it is more complicated than this.

The CT technologist uses his experience to determine the general amount of radiation needed for a scan, and that in itself is kind of a guessing game that can result in an overdose.

With ExLCD, the radiologists who read the CT scans, determine the IQ suitable and then, ExLCD “tells” the technologists how to set up the scanner, thus eliminating the estimation of some parameters in the scan.
1.1.7.3 Why Doses Tend to Be High

There is a narrow range of optimum dosage determined by patient's physique and the organ being scanned. A higher dose will produce good IQ, but unnecessary high dose to the patient. A lower dose will result in poor image quality that might lead to a misdiagnosis or the need for a rescan (Fig. 5). Since a rescan costs the hospital money and, more importantly, is more dangerous than an overdose, (because it at least doubles the patient’s exposure), technologists will have tendency to err on the high side.

**Figure 5:** A visual of the right dose, for a specific patient for a specific application.
1.2 Approach

There is a big effort by the Original Equipment Manufacturers (OEMs) of CT scanners and other companies to reduce radiation dosing. Huge improvements have been achieved in recent years and radiation levels have been reduced tremendously. However, there is still one problem left unattended: the bottom line is, the technologist sets the final radiation dose according to his estimation. One can surely say that the technologist is given too much of a range to choose from.

On a scanner running some kind of dose reduction technique, like “iterative reconstruction”, the technologist can choose a lower dose, but the question is: will he? And, if so, what is the right dose? Each patient requires a different dose; can the technologist estimate the lowest dose correctly every time, for each patient on every scanner? This is the situation today, and this is where PI will make the biggest difference. PI, for the first time, will suggest the right dose, on a specific scanner, for a specific patient according to the measured image quality the doctor requires to be able to produce the correct diagnosis.

1.2.1 PI’s Process

PI's process is divided into two steps: (1) Calibration: ExLCD software processes multiple scans of the ExLCD phantom to map the scanner settings to IQ. And (2) Protocol selection: ExLCD software uses the pre-scan and the scanner calibration to determine the best protocol settings which will deliver the right dose.

---

**iii** More on this in the competition section.

**iv** Iterative reconstruction will be discussed in section 1.4.1.1 on page 14.
1.2.1.1 Calibration

The ExLCD phantom is a specially designed object with known X-ray attenuation (Fig. 6). On the scanner that is to be calibrated, a number of CT scans are taken of the phantom over a wide range of operating parameters. The phantom is designed so that it is possible to map operating parameters to detectability index over the entire operating range of the scanner (Fig. 7). The standard, off-the-shelf phantoms that are currently available are not sufficient to measure the image quality to PI's new standards. Current phantoms can only show low contrasts, usually 0.3%, 0.5% and 1% contrast from the background. PI's new ExLCD requires many more contrast points, so a calibration graph can be generated over a much broader contrast range for the scanner.

![Possible designs for PI's calibration phantom](image)

**Figure 6: Possible designs for PI's calibration phantom**

After a CT scanner has been calibrated with the phantom, it is possible to discuss relative dose levels for scans with comparable measured image quality, even across scanners.
Since every CT scanner runs many different protocols, a calibration graph will be made for each one of the protocols. This comprehensive scan takes about one hour.

1.2.1.2 ExLCD Clinical Software

When scientists come up with a new protocol for a CT scan, they publish a range of dose settings for the protocol on the scanner they are working with. Up until PI's invention, this gave the CT technologist only a general range of the dose to use. Since every CT scanner has different attributes and different capabilities, this data is not accurate enough. Furthermore, even the same exact model of CT scanner will need different settings according to, for example, the age of the X-ray tube.

PI's innovative ExLCD considers the end result, which is measured image quality (IQ). After the radiologist agrees on a desired IQ for a specific protocol, for example: head scan, the calibration graph

Figure 7: Calibration graph for two scanners (no two scanners are alike)
can tell the technologist how much dose is needed to obtain that IQ.

In other words, using the data from the calibration process, the ExLCD clinical software can translate the protocol's published data to any CT scanner that has been calibrated.

This approach standardizes the radiation dose given on all CT scanners connected to the ExLCD network.
1.2.1.2.1 Patient-Sensitive

The standardization of the radiation dose is only half of the equation. The second part of the equation is the patient's physique. A child requires a much lower dose than a fully-grown adult. PI's approach uses the pre-scan done before every CT scan. This pre-scan uses a very low dose and is designed to help the technologist adjust the scan. PI uses the data generated in the pre-scan to evaluate patient's physique. The patient’s water-equivalent diameter is then calculated. Every vendor has its own way of calculating the patient’s attenuation to X-ray radiation. In his paper, Menke compares five acceptable ways of calculating this\textsuperscript{26}. Menke’s conclusion is that water-equivalent diameter is the most accurate method. With this method, the protocol data and the scanner calibration data, the ExLCD clinical software can find the ideal dose for the specific patient in the specific application (Fig. 5). ExLCD will then tell the technologist how to set some of the scan parameters.
1.3 Benefits to Costs

As mentioned before, at least 400 patients sustained visual injuries in a CT scan. Although the compensation in this kind of a lawsuit can reach millions of dollars, it is usually not the case.

Another higher cost, although indirect and long term, is the cost of dealing with the CT related cancer patients. About 40,000 people will develop cancer every year due to a CT scan they had in the past. The total expenditure for cancer care in 2006 was $104.1 billion\(^{27}\) (Fig. 8). The lost productivity due to cancer deaths was $134.8 billion\(^{28}\) (Fig. 9). Therefore, the total cost of cancer is $238.9 billion per year. Dividing the total cost by the number of people that have cancer, 11,714,000\(^{29}\) yields a little more than $20,000 per patient annually. Multiplying the cost of a cancer patient by the number of people who get cancer from CT scans in one year comes to $600 million per year, an astounding sum.

![Figure 8: Expenditure for cancer care divided by site of cancer.](image)
To be fair, not all CT related cancers happen due to overdose. The higher the dose is, the higher the chance for developing cancer, and one can get cancer even with a low dose scan. It is said that a 2500 rem dose will induce cancer, but 25 rem will induce cancer in 1% of the cases (CT scans use up to 2 rem). This is called the linear effect\textsuperscript{30}. Unfortunately it will be extremely difficult to prove in court. Nevertheless, the potential cost for the scanner owner and the actual current cost for taxpayers is enormous.

As of now, PI will charge $5 per scan, with a minimum number of scans. At that price it would be cost effective for Medicare to support the use of ExLCD, due to the short and long term effects of overdosing.

![Figure 9: Lost productivity due to cancer deaths](image-url)
1.4 Competition

Due to the importance of radiation overdose and the growing need for a solution, there are a number of competitors. The competitors can be divided into three groups: CT scanner vendors like Philips and Siemens; Quality Assurance (QA) measurement providers like ImageAnalysis, IrisQA, and ImpactScan; and newly published protocols that are constantly trying to lower radiation dose. There is at least one more company that does not necessarily fall into one of the three groups, Medic Vision (MV). MV can significantly reduce dose in CT scans on every type of CT scanner through iterative reconstruction.

1.4.1 CT Scanner Vendors

CT vendors have been seriously addressing the overdose problem in the past years. Although all major vendors have some kind of dose reduction scheme, like the use of filters, beam shapers, etc., only two of the newest technologies will be presented as typical.
1.4.1.1 Philips DoseWise and iDose®

iDose® is the newest member of Philips DoseWise® (DW) tools. DW tools include filters, detectors, collimators, and Automatic Current Selection (ACS), which changes tube current according to patient size, and dose modulation tools such as Z-axis Dose Modulation (Z-DOM) and Dynamic Dose Modulation (D-DOM) to automatically adjust dose delivered to the patient, according to individual physiology and optimizing dose by anatomic region.31

"The iDose iterative reconstruction technique uses advanced reconstruction algorithms to enable equivalent diagnostic image quality at a fraction of the dose, overcoming the inherent challenges of low-dose scanning, such as noisy images and image artifacts."32
According to Philips’ iDose⁴ is an innovative Statistical Iterative Reconstruction technique in which iterations are performed both in the projection and image domain, using sophisticated system and noise models in the domain that is best suited for the correction of the relevant noise/artifact characteristics while keeping structure intact.”³³
iDose⁴ has many advantages. The most interesting one, says Philips, is the ability to use up to 80% less radiation dose than "regular" CT scanners or improving resolution by 68%. It is important to understand that right now a hospital has no way of knowing that using iDose⁴ really saves 80% of the radiation. In fact, it is probably much less than 80% if compared to scans done by an experienced technologist. More important than that, is the fact that iDose⁴ does not find the minimum dose that will produce the needed measured image quality. The technologist still controls the dose. Furthermore, iDose⁴ is incorporated in newer Philips scanners, and does not give a solution for existing scanners.
1.4.1.2 Siemens Image Calibration Device (IDC)

In its patent (US 2009/0127451 Al), Siemens mentions the use of a phantom as a calibration method. Siemens claims that this is not an accurate way to determine the required dose for a patient, mainly because the difference between patients. For example, a patient who weighs more will need a higher dose, but how can one determine how much more. Siemens also claims that producing a calibration graph with the phantom will not provide data on the dose in future scans. PI has solved this problem by using the pre-scan done before every CT scan to calculate patient’s water-equivalent diameter. PI uses a multi-contrast phantom to calibrate over the whole operating range of the scanner and it uses a measureable IQ. This allows PI to calculate the needed dose more accurately. Siemens offers the use of an image calibration device (ICD). This device will be shaped like a mattress and the patient will be lying on it during the scan. The required ICD, in one scan, can be a filter and in another contain radioactive materials. This means that several ICDs are needed for each scanner. According to the needs of the specific scan, the proper ICD will be chosen. When the ICD is scanned at the same time with the region-of-interest (ROI), the combined image of the patient and the ICD may be used to calibrate the dose in real time. The major drawback of this method is that every scanner will
require several ICDs. Instead of one phantom per facility and a calibration every few months, an ICD will have to be chosen for every scan.

1.4.2 QA Measurement Providers

QA measurement providers like ImageAnalysis, IrisQA and ImpactScan are providing hospitals with tools to manage its CT scanners and assure they work properly. For example, IrisQA uses a phantom to provide tracking of several important parameters like pixel size, linearity, slice thickness, noise, uniformity and much more. Tracking these parameters is very important for the early detection of irregularities; and will allow timely maintenance of the CT scanner. However, this will not help the technologist set up the scanner to use the minimal dose needed for a scan because it monitors the proper function of the scanner but does not actively affect each scan. Also, it will not help comparisons of dose between two scanners.
1.4.3 Medic Vision

Medic Vision\(^{34}\) (MV), an independent Israeli software firm, has an iterative reconstruction technique that much like iDose\(^4\) can reduce the radiation dose significantly. The big advantage of MV over iDose\(^4\) is that MV's solution can work with any scanner. Still, the problem remains, the technologist needs to choose the right dose from too wide of a range. MV could become an interesting strategic partner of PI. The combination of improving any make of scanner so it can scan at the lowest dose possible today and the technology that will find that lowest dose could become the winner in this market, particularly for the legacy machines.
2 VRIO Analysis

VRIO analysis, originally developed by Barney and Hesterly, is used to evaluate how a business compares to the competition and how it performs.

2.1 Resources

PI doesn't have many resources at its disposal beyond its brainpower and its professional network. PI’s main asset is a patent application that was filed on July 17, 2009, but has not yet been issued.

PI also collaborates with several hospitals: Cincinnati Children's Hospital, Massachusetts General (MGH), Cleveland Clinic Foundation (CCF), University Hospitals (UH), UCLA, and MetroHealth (MH). PI can use the hospital's CT scanners to test ExLCD in a clinical environment. At MGH, a cadaver study on image quality and dose can both use PI’s tools and help PI with the development and efficacy of the ExLCD.

2.2 Capabilities

One of PI's strongest capabilities is that of the team of founding innovators: Tom Toth was a key scientist and engineer at GE Healthcare for over 20 years, with focus on CT physics and CT dose reduction; David Rohler has been the president of Plexar Associates, Inc. for the past 24 years, specializing in product and algorithm development for the medical and industrial imaging communities; and Steven Izen has been a professor of mathematics at Case Western Reserve University for 28 years, and is a well-published CT mathematics expert.
2.3 Valuable

PI's invention is very valuable. It directly addresses the dire need for controlling and lowering radiation dosing. Not only that, but it does so in an innovative way. PI's innovation helps CT technologists find the right dose for each patient for each application on any existing CT scanner. It can translate dose from every scanner or protocol to any other scanner, and it does all that in a cost effective way.

2.4 Rare

Innovations designed for lowering radiation dose are starting to be more common. So are new protocols that use a lower amount of radiation. However, the ability to find the lowest dose that will produce a desired measured image quality and the ability to translate doses from one scanner to another is rare, and is at the heart of the ExLCD method.

2.5 Imitable

PI's innovation is not easily imitable even without a patent. The ExLCD software is running a complicated mathematical calculation; furthermore, it likely will be protected by a utility patent, which is now pending.

2.6 Organized to Exploit

Is PI ready to exploit its resources and its position? The answer is no. It needs more capital and some more time to get proof of concept and a working system; only then PI will be organized to exploit its resources.
2.7 VRIO Analysis Conclusion

According to the VRIO framework, if a company is valuable, rare, difficult to imitate, but it is not organized to exploit, its performance is above normal, but it has only a temporary competitive advantage (Fig. 12). The temporary competitive advantage is due to the fact that competitors might catch up by the time the company will be ready to exploit, for example: sell a good-enough product.

![VRIO Analysis Table]

Figure 12: VRIO Analysis
3 SWOT Analysis

SWOT analysis helps one find business strategies. After listing PI's strengths, weaknesses, opportunities and threats, several strategies can be developed. There are four categories: Using strengths to exploit opportunities (SO), using strengths to deal with threats (ST), using opportunities to overcome weaknesses, and last, dealing with weaknesses and threats (WT).

3.1 Strengths

PI has many strengths. Its biggest strengths are (1) ExLCD can work with any CT scanner; (2) it can translate doses from one scanner to another; (3), it can find the lowest dose possible to get a desired image quality and by that optimize the procedure; and (4) it provides a standard for dose in CT scans. The calibration process can be done when the scanner is not being used, at night, for example. Another advantage is that one phantom can be used to calibrate many scanners.

3.2 Weaknesses

ExLCD is not a product yet. PI only has achieved a simulated proof of concept. This is not enough; a physical proof of concept must be obtained. To do that, a prototype phantom must be fabricated and tested on several scanners. To achieve that PI must raise more capital and obtain a proof of concept as quickly as possible.
3.3 Opportunities

The biggest opportunity is that this is a relatively new market. This is not a new market in the truest sense, little effort was spent on trying to lower dose up until recently; previously the technologies that were used were static. A technologist applied a filter or other kind of radiation control, but it was still a guessing game. Only recently is dose control becoming a real-time technology with a controlled process.

Not only is this a relatively new market, but there is a big international need for this new technology.

Another opportunity PI has is landing more grants. After receiving the prestigious GLIDE A grant, PI should be able to get additional grants more easily, for example, the Innovation Fund of the Lorain County Community College Foundation which gives up to $100K to Northeast Ohio startups.

3.4 Threats

The biggest threats for PI are the scanner vendors. Huge companies like Siemens and Philips have enormous resources; working channels of distribution; and they are putting a lot of effort into solving the overdose problem.

Another threat is from companies like Medic Vision that can lower dose on every scanner.

It is however, important to remember that these are threats only in cases that a potential buyer has enough money to buy only a partial solution. In fact, the competitors’ products are complementary to PI’s ExLCD and the best solution would be to buy both, yet the best value would be PI.
3.5 SO Strategies

SO strategies use strengths to help exploit opportunities.

PI already landed the prestigious GLIDE A initial $25K grant. Once a company gets one grant, it tends to be slightly easier to get more grants. PI should use this and the fact that they have a product that supersedes some of the competitive products, to land more grants and raise more capital.

PI should also use its strengths to place itself as a strong competitor in this industry. PI should promote the idea that radiation dose should not be guessed and that measured standardization is required and entirely possible. This can be achieved by publishing papers on the subject. Once the issue is understood, that the problem is not only lowering dose, but also choosing the right dose based on real measurable data and not hunches of technologists. PI could then provide the solution.

3.6 WO Strategies

WO strategies use opportunities to deal with weaknesses.

PI should raise capital. With the money it should develop a prototype phantom to be used in preliminary tests to help get a proof of concept. That will help in getting even more money. A product could then be developed.

PI can use the clinical studies done by its collaborators, such as the cadaver study in MGH, to obtain proof of concept more quickly.
3.7 **ST Strategies**

ST strategies use strengths to eliminate threats.

PI should emphasize the fact that only ExLCD can actually find the lowest dose required. For each existing scanner, PI can help get the best results with the lowest dose possible. None of the other companies out there can say that. Solutions like Philips iDose⁴ are embedded only in new Philips scanners and can't work with existing scanners like ExLCD can. This should be used to convince existing scanner owners to use ExLCD before they buy a new scanner.

Siemens ICD can't correlate between two scanners. To use it, each scanner will need several ICDs, which drives up the cost. On the other hand, PI ExLCD can translate doses from one scanner to any other scanner. Its calibration process uses one phantom and can be done when the scanner is not being used for medical purposes. This means that one phantom can be used for multiple scanners. These facts can help convince respective buyers to go with ExLCD and not a new OEM CT. Since competitors have superior access to channels of distribution, a good strategy might be using word of mouth in the research community such as the recent MGH presentation and the upcoming presentation at RSNA.

3.8 **WT Strategies**

WT strategies are about establishing a defensive plan to prevent the company's weaknesses from making it highly susceptible to outside threats.

PI's patent is its defensive plan. The patent will exclude the competition, giving PI the time it needs to obtain the proof of concept, manufacture and market the ExLCD product.
### 3.9 SWOT Table

<table>
<thead>
<tr>
<th><strong>Strengths - S</strong></th>
<th><strong>Weaknesses - W</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Highly knowledgeable and experienced team.</td>
<td>1. Not a product yet</td>
</tr>
<tr>
<td>2. ExLCD works with any CT scanner.</td>
<td>2. Need more money to develop product</td>
</tr>
<tr>
<td>3. Can find the lowest dose possible.</td>
<td>3. No physical proof of concept.</td>
</tr>
<tr>
<td>4. Can translate doses from one CT scanner to another.</td>
<td></td>
</tr>
<tr>
<td>5. Offline calibration process.</td>
<td></td>
</tr>
<tr>
<td>6. Calibration process uses one phantom that can calibrate many scanners.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Opportunities-O</strong></th>
<th><strong>SO strategies</strong></th>
<th><strong>WO strategies</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Big international need for lowering radiation dose.</td>
<td><strong>S1-4/O2:</strong> Use all of the strengths and benefits of ExLCD to land more grants.</td>
<td><strong>W1-4/O2:</strong> All PI weaknesses are solvable with more money. PI should raise capital, land more grants and address those issues. The fastest way to get revenue is providing the scan history diagnosis (Step 1).</td>
</tr>
<tr>
<td>2. Grants / raise capital</td>
<td><strong>S1-4/O1,3:</strong> Use all of the strengths and benefits of ExLCD to meet the need and to be established as a new competitor in this market.</td>
<td></td>
</tr>
<tr>
<td>3. Relatively new market</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Threats - T</strong></th>
<th><strong>ST strategies</strong></th>
<th><strong>WT strategies</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Philips iDose⁴.</td>
<td><strong>S1/T1:</strong> Philips iDose⁴ is embedded in new Philips scanners and can't work with existing scanners like ExLCD can. This should be used to convince existing scanner owners to use ExLCD before they are buying a new scanner.</td>
<td><strong>W1,3/T1-3:</strong> PI's IP will protect it and provide the necessary time to deal with its weaknesses.</td>
</tr>
<tr>
<td>2. Siemens ICD.</td>
<td><strong>S2,4/T2:</strong> Siemens ICD can't correlate between two scanners. To use it each scanner will need several ICD's which drives the cost up. Since these two issues are PI's strengths, they can be used to lower the threat from Siemens.</td>
<td></td>
</tr>
<tr>
<td>3. Competitors have superior access to channels of distribution</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4 Porter’s Five Forces Analysis

Porter's Five Forces Analysis\textsuperscript{37} is a framework for business strategy development and industry analysis. The Five Forces analysis helps to determine the competitive intensity of a specific market and therefore its attractiveness.

4.1 The Threat of the Entry of New Competitors

There is always a threat of new competitors entering the market. That said, in this specific market, although attractive, one needs certain skills to be able to start a company. High-level mathematics and knowledge of imaging techniques makes this market suitable only for trained professionals. This is why it is safe to assume that new companies may be formed, but not too many of them.

4.2 The Threat of Substitute Products or Services

For a person with the right knowledge in this field, it may be possible to come up with a solution similar to PI's, given enough time. This is why PI's patent must provide the barrier to competition. PI's patent clearly presents the use of measured image quality as the standard for radiation dosage, giving CT as an example. It presents the calibration method and the way ExLCD correlates between different scanners. It covers PI’s method of determining the patient’s body water equivalence, which is an important component of PI’s process. A study by Jan Menke, MD, showed that this is the most accurate way to evaluate the dose needed\textsuperscript{38}. It looks the patent is well written and covers the most important aspects of PI invention. Furthermore, it does that in a broad way. Therefore, it will be hard to imitate PI's solution; so the threat of a substitute product or service is low.
4.3 The Bargaining Power of Customers

Since PI is currently the only one with the unique solution that can find the right dose and that can correlate between scanners, customers will not have much bargaining power; especially if the use of PI's invention became mandatory by the FDA or insurance companies. However, hospitals today can choose a different solution that will lower dose and forfeit these two advantages. In that case they will have a partial solution. This argument can give customers some bargaining power.

4.4 The Bargaining Power of Suppliers

Since this business is more of a service and not selling products, the bargaining power of suppliers is irrelevant.

4.5 The Intensity of Competitive Rivalry

It looks like there is a high intensity of competitive rivalry. This is a market that sells thousands of scanners per year, both new and used, not millions. According to the latest IMV report\textsuperscript{39}, There are almost 13,000 CT scanners in the US and almost 55,000 worldwide. The average replacement age of a CT scanner in the last years is 8 years. This is why the competition for making a sale is high. PI has managed to place itself in a unique position. It can make any scanner better. It is a vital addition to any existing scanner. In that sense, PI has a competitive edge.
4.6 The Analysis

When examining the whole dose control market, PI appears to be right in the heights of the attractiveness range. On one hand, there are not many new competitors entering the field every year and this market does not rely on suppliers. On the other hand, there is a threat of substitute products or services and customers have some bargaining power. The intensity of competitive rivalry looks medium to high.

When looking at PI's specific market, the picture looks a little different: because of the unique solution, the customers have only limited bargaining power. There is no sign of a substitute product or service that can do exactly what PI's solution can. Therefore, the intensity of competitive rivalry is low for PI. PI has managed to put itself in a Blue Ocean in this market (covered in the next section).
5 Blue Ocean Strategy

Blue Ocean Strategy\(^4\) (BOS) in a nutshell suggests that instead of competing with all the competitors on the same market in a cut throat competition, hence: Red Ocean, one should find a way to steer into a Blue Ocean where there is no competition at all. Or in the words of Guy Kawasaki: "niche thyself".\(^1\)

To reach to the Blue Ocean, the BOS framework suggests four possibilities: (1) eliminate some of the factors that the industry takes for granted; (2) reduce some factors below the industry standards; (3) raise some factors above the industry standard; (4) create new factors that the industry has never offered (Fig. 13).

PI has eliminated the direct dose reduction approach that everybody else in the industry is working on. It created two new capabilities never before offered in the industry: finding the lowest radiation dose for a specific scanner that will produce a desired IQ; and correlating between several different scanners. PI has raised the importance of measured IQ as the benchmark for the quality of CT scans, and found an innovative way for finding the dose that will produce the desired IQ.
Figure 13: Blue Ocean Strategy framework

By doing the above, PI has found its Blue Ocean. Instead of competing with everyone else in this market about the uncertainty of how low can you go, dose-wise, PI takes every machine, with its capabilities and produces the best results possible. PI has created a new market with no known competitors.
6 Business Model Canvas

The Business Model Canvas helps in the development of new business plans.

6.1 Customer Segments (CS)

PI's customers are CT scanner facilities, usually hospitals. There will be two types of customers: customers who will buy the calibration software and hardware and customers who will prefer to get the calibration part as a service. Both types of customers will pay the annual license fee for the ExLCD clinical software. Other possible customers are hospitals that will want PI to only run the assessment on their scanners. The assessment will provide valuable data to the hospital. This option will be discussed in Section 9: Plan B.

6.2 Value Proposition (VP)

PI's value proposition was discussed in depth in Section 1.

6.3 Channels (CH)

There will be few channels PI will use to deliver value to its customers: sales, technicians, web and published papers. Both the salesmen and the technicians can be either PI’s employees or contractors. The salesmen can do most of their job from PI’s HQ. Technicians or contractors can go to hospitals and the selling of calibration packages or services will be done only by PI direct sales.

A help-desk might be needed to provide immediate assistance to customers. In the beginning, the help-desk service can be done by the technicians in Cleveland, but as PI will grow, this service will have to be separate.
6.4 Customer Relationship (CR)

PI will have to provide personal assistance to its customers. From the first steps of demonstrating the need, through the process of calibrating and installing ExLCD, to the help-desk service, customers will want a person to talk to. This can be done by the sales force and by the technicians. Most of that communication can be done over the phone or on the Web out of Cleveland.

6.5 Revenue Streams (RS)

Three types of revenue streams will be suggested: an early revenue stream, sustainable revenue stream and future revenue streams.

6.5.1 Early Revenue Stream

The earliest revenue stream is providing dose variation assessment to hospitals. The assessment will provide the hospital the scan history graph, which will determine if there is unnecessary dose variations or faulty equipment. This can be done without a phantom and without the ExLCD. This early revenue stream will help PI get the necessary capital to manufacture the phantom and obtain physical proof of concept.

6.5.2 Sustainable Revenue Streams

The sustainable revenue stream will be from charging $5 per scan while using the ExLCD.
6.5.3 Future Revenue Streams

In the future there might be two additional revenue streams: (1) connecting a hospital to PI’s image quality database. This database will contain the image quality preferences of many other hospitals, and will give a hospital the ability to see how it’s doing compared to other hospitals. The data will be anonymous; (2) providing the hospital with a Q/A system.

6.6 Key Resources (KR)

PI will have to have enough phantoms and ExLCD systems to meet the market demand. It will need some sales people that can do most of their work from PI HQ; and technicians that will meet with customers; first to demonstrate ExLCD and then to actually install one if the sale was successful. These sales people and technicians can be PI's employees or contractors.

PI will need a help-desk. In the beginning this can be done by the technicians.

6.7 Key Activities (KA)

PI will have several key activities: (1) sales. The sales force will sell assessments, calibrations, ExLCD and in the future the use of the IQ DB and Q/A system; (2) calibration, installation and maintenance, as well as educating the customers about how to use the product will be done by technicians; (3) helpdesk; (4) consulting.
6.8 Key Partnerships (KP)

PI has already created some valuable partnerships, some are strategic and some are with potential customers. One important strategic relationship is with BioEnterprise (BioE). BioE helps PI with business guidance, business plan development, introductions and connections.

The Science and Technology Entrepreneurship Program (STEP) at Case Western Reserve University also is helping PI with the creation of its business plan. Cincinnati Children's Hospital, Massachusetts General Hospital, Cleveland Clinic Foundation, University Hospitals, UCLA, and MetroHealth, are used as clinical sites for CT scanner calibration, historical clinical data analysis and assessment of efficacy of ExLCD and might also be potential customers in the future.

These partnerships will help PI become a successful business. Once PI becomes a sustainable business these partnerships may fade; others will be long-term customers.

If PI decide to use a third party company to run its sales force and/or its technician force, these third party companies will be PI most important partners.

Another key partner is the phantom manufacturer; in fact there could be some joint development

in case a central database for IQ will be used, there may be more contractors involved.

PI should consider MV as a future strategic partner. This partnership might have the power to rule the CT market, since these two companies combined, provide a complete solution for any scanner out there.
6.9 Cost Structure (CS)

PI has a value-driven cost structure. That means that PI is more concentrated on delivering value to its customers than minimizing costs, like, for example, Wal-Mart or easyJet.

PI’s fixed costs will be mainly comprised of salaries, rents (if any), storage, R&D, administration and the company’s facilities.

The variable costs would be the technician force and the phantom manufacture.

Some of these functions, both in fixed and variable costs, might be done by contractors.

More details will be presented in assumptions.
7 Innovation Type

It is hard to decide what kind of innovation ExLCD is. On one hand it can correlate doses from one CT scanner to another and it can find the lowest dose that will produce a certain image quality. No other device out there can do that. From this perspective, it looks like this is a breakthrough innovation.

On the other hand, the real capability of the scanner to perform scans in lower dose doesn't change.

From this perspective, ExLCD is an incremental innovation.

Another thing to consider is the invention of the measured image quality scale. It is hard to imagine that in this high-tech field, there isn’t a scale professionals can use to communicate with each other. A radiologist can’t tell the technologist what he needs in order to make the right diagnosis. This suggests that ExLCD is a breakthrough.

After considering the impact of ExLCD, it looks like it’s a breakthrough innovation; one that enhances safety, lowers radiation dose, correlates between different scanners and provide professionals a scale they can work with.
8 ODI

Outcome Driven Innovation\textsuperscript{44} (ODI) helps an entrepreneur tailor an innovation to a specific customer need or needs. At first the jobs to be done will be stated and then customer's outcome expectations will be listed.

8.1 Job Map

PI's job to be done (JTBD) is:

Optimize CT scan protocols, for use and standardization in any CT scanner and operating mode, e.g. reduce the range given to the technologist in some parameters.

8.2 Universal Job Map

8.2.1 Define

Customer’s outcome expectations are:

1. Minimize the amount of radiation given to a patient in a CT scan.
2. Minimize the likelihood of dose irregularity that exists in different CT scans.
3. Minimize the amount of radiation overdoses in CT scans.
4. Minimize hospital liability in CT scans.
5. Increase radiation related safety on a CT scan.
6. Minimize the guessing game of choosing the right dose in a CT scan.
7. Minimize the amount of rescans due to low image quality.
8. Increase the likelihood of hospital-wide CT scan precision.
9. Minimize the time it takes to set up a scan.
8.2.2 Locate

The assessment (Step 1) that will be performed on a hospital's CT scanners will locate faulty equipment and protocols that are constantly giving a higher dose to patients.

8.2.3 Prepare

The hospital's CT scanners will be calibrated to prepare them for the use with the ExLCD system.

8.2.4 Confirm

The hospital's requirements for IQ will be confirmed by using the Plexar Imaging Protocol Builder (Step 3).

8.2.5 Monitor

In the future a Q/A system (Step 4) might be provided to monitor the hospitals CT scanners.

8.2.6 Modify

The IQ standards could be modified by the PI IQ DB (Step 5).

Additional improvements to the ExLCD system will be made.
9 PI's Approach and Revenue Streams
Getting to Plan B

In “Getting to Plan B” the authors say that no business plan stays the same as originally concepted. Saras D. Sarasvathy calls this “effectuation”: changing your plan as needed as you go along. A business starts with a business plan called plan A. A dashboard is created to measure how well plan A is doing and alternatives to plan A are thought. According to the results from the dashboard the entrepreneur changes his plan A as needed to finally finish with a sustainable business working on plan B.

PI is in a position known to almost every startup: it needs capital. Capital is needed to build a working phantom, and get data from real CT scanners to obtain a proof of concept. Once these are out of the way, PI can start selling its product and service. One solution is to raise capital, but that means giving away a chunk of the company. Grants take time and might not be enough. One option PI has, is to start giving an auditing service (Plan "B"). This auditing service requires neither the phantom nor the ExLCD software. The hospital will get a graph like the one in Fig. 1. This graph will be produced showing every scanner in the hospital at every protocol. From that graph the hospital will know the extent of its dose variability, and if it has a rogue scanner or if there is a technologist that is constantly giving a higher dose. This Plan "B" can help PI to make some revenue and open channels of communication with the right people in the hospitals. The criteria used to evaluate whether Plan "B" is working, or the dashboard, is how many audits are being done. There is a leap of faith in this plan, which is: will the hospitals want to know? Once the hospital knows it has a problem, it is obligated to fix it.
Another issue to consider is: is it a good idea to show the hospital the problem without offering a solution? What might happen is that the hospital will go for an available solution like Medic Vision. This is not a deal breaker since no one else has PI’s solution.

PI's Plan "A", and its main business, is providing the calibration or selling the calibration package and installing and licensing the ExLCD software. A price scheme should be offered to hospitals according to the number of CT scanners in the hospital. The dashboard will record sales statistics and will reveal if the price scheme needs changes or not.

In the future, after enough data will be collected from hospitals, PI could provide hospitals access to the PI's IQ database. This will allow hospitals to share each other's IQ preferences and will help with global standardization. This will be plan "C".

Plan "D" might be a Q/A system.
11 Five Year Forecast

Figure 14: Five year forecast
12 Why Will They Succeed?

Plexar Imaging will succeed because it has a unique solution to a dire problem. PI's solution finds the lowest dosage possible to obtain a desired measured image quality. Furthermore, it can translate doses from any CT scanner or protocol to any other CT scanner.

All of the OEMs have a solution that will produce a good image quality with lower dosage, but none of the competitors suggests the right dose to the technologist, ending up with the technologist estimating the right dose. In that sense, PI created a Blue Ocean for itself.

Using PI's solution will lower radiation dosage by finding the lowest dose possible for a specific scan on a specific scanner, consequently enhancing safety and reducing hospital liability.

Using PI's solution will provide radiologists and technologists a scale they can use to communicate with each other. Furthermore, it will make it much easier to translate protocols from one site to another and from one type of scanner to another. This new measurable scale will, for the first time, allow the creation of a standard in CT scan dosage, which will help to protect people from the risk of overdose.

In the long run millions of dollars will be saved for the health care industry.
13 ExLCD Technology

The following section will cover the technology behind ExLCD. After explaining the basics of CT scanners, the building blocks of ExLCD will be covered. The last part of this section will show how all the components of ExLCD work together.

13.1 CT Basics

A CT scanner uses X-rays to generate its images. In regular X-ray imaging, the object of interest, usually a patient, is located between an X-ray tube and a film. When the tube emits X-rays the film darkens according to the amount of photons that hit it. To produce an image, some of the photons must pass through the body and some must be absorbed. Another way of looking at this is by saying that the body attenuates the X-ray.

In a CT scanner the film is replaced with a banana shaped detector. Both the X-ray tube and the detector can rotate around the patient, who is lying on a table (Fig. 14).

While rotating around the patient, hundreds of projections are being taken from different angles. A computer uses these projections to generate a 3D image of the area that was scanned.
13.2 ExLCD Components

An overview of the ExLCD core technology contains two major processes: (1) Calibration: ExLCD software processes multiple scans of the ExLCD phantom to map the scanner settings to IQ; and, (2) Protocol selection: ExLCD software uses the pre-scan and the scanner calibration to determine the best protocol settings which will deliver the right dose.

13.2.1 The Scanner Calibration

The calibration provides the mapping between image quality (contrast index) to flux index and vice versa, since the graph is monotonic. The correlation is obtained by scanning a phantom (Fig. 19).
13.2.1.1 The Phantom

Plexar Imaging’s phantom is a cylindrical shaped object, with at least two different diameters, containing sets of pins with different diameters and different contrasts (Fig. 15). Table 2 shows a set of suggested diameters and contrasts.

Since the characteristics of the phantom are well known, it is possible to use the generated images to calibrate the CT scanner.

![Phantom Image]

**Figure 16: Phantom**

<table>
<thead>
<tr>
<th>Contrast Set #</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
<th>15</th>
<th>16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contrast Levels (HU)</td>
<td>1.0</td>
<td>2.4</td>
<td>5.8</td>
<td>14.1</td>
<td>34.0</td>
<td>82.1</td>
<td>198.2</td>
<td>478.5</td>
<td>1155.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Used with 20 cm Diameter</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Used with 40 cm Diameter</td>
<td>❌</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 2: suggested diameters and contrast levels**
13.2.1.2 Contrast Index

Contrast index (M) encapsulates two measures: (1) contrast (c) and (2) object size (p). Bigger objects are easier to image and higher contrast objects are easier to image.

\[ M = \frac{M_0}{c \cdot p} \]

(1)

\( M_0 \) is an arbitrary constant for bringing the measure, M, into a convenient numerical range.

Practically, in a CT scanner, M will be measured using a phantom where \( c \) is the pin’s contrast measured in Hounsfield units (HU) where one HU corresponds to 0.1% of water attenuation and \( p \) is the pin size in millimeters (mm).

13.2.1.3 Flux Index

Flux index encapsulates four measures: (1) the current supplied to the X-ray tube, measured in milliamps (mA); (2) the image slice thickness in mm; (3) the scan time measured in seconds; (4) the object’s diameter measured in cm. The flux index formula is presented in equation (2):

\[ FluxIndex = mA \cdot sliceThick \cdot scanTime \cdot \frac{e^{-objDiam*attWater}}{e^{-refDiam*attWater}} \]

(2)
13.2.1.4 The Calibration Process

In order to obtain the relationship between contrast index to flux index, the phantom is scanned using different protocols (settings). This relationship is governed by two types of noise: quantum and electronic. The quantum part can be obtained by using only one protocol. One protocol generates one data point on the graph. Then, a slope of ½ is used to generate the entire graph (Fig. 16). The slope of ½ is calculated by considering the quantum nature of the X-ray beam, but completely disregarding the equipment’s electronic noise. The electronic noise can’t be calculated since it’s different for every scanner.

![Contrast performance curve resulting from a single protocol measurement](image)

Figure 17: *Contrast performance curve resulting from a single protocol measurement*

With ExLBD, the phantom is scanned multiple times using different scanner settings. This effectively covers the whole
operating range of the CT scanner. Each of the generated images is then evaluated by the ExLCD algorithm. Each image contains three sets of contrasts levels and the algorithm determines which is the smallest pin detectable (Fig. 17). For each contrast level the corresponding contrast index is calculated, generating a data point on the calibration graph. This process is called detectability mapping.

Figure 18: Illustration of a detectability mapping. Pins are numbered 1-9 from largest to smallest. Mapping from smallest detected pins to ExLCD contrast measured.

The entire detectability process is illustrated in Fig 18. The statistical method uses the Rose criterion to calculate detectability index for each pin in an image (equation 3);

\[ \nu = \frac{C \cdot p \sqrt{\pi}}{\sigma 2S} \]  

(3)

where C is the measured object contrast, p is the pin diameter, S is the image pixel size and \( \sigma \) is the measured standard deviation of the background noise.
The Rose criterion determines that objects that scores a
detectability index greater than four is considered detectable.
Plexar Imaging found that using five as a threshold better
correlates to human observations in this case.

Figure 19: Block diagram for ExLCD method of generating the
performance curve.
Once the detectability process is finished the calibration graph can be plotted by using the least squares method. This graph contains the quantum noise and the electronic noise and it covers the whole operating range of the scanner (Fig. 19).

**Figure 20: The calibration graph**

This graph contains both quantum and electronic noise. Figure 21 shows the difference between the two.
13.2.2 Protocol Recommendation

Radiologists will decide what the required contrast index for each protocol is. This can be done within a hospital or by an authority that will standardize CT scans.

When a patient is about to undergo a CT scan, the type of scan (head, chest, abdomen, etc.), will determine the contrast index needed. From the scout image, the patient’s water equivalent diameter will be calculated. Using the calibration graph of the scanner, the flux index will be obtained. With that data the mAs can be calculated, which can be used to provide the technologist with the right settings for the scanner (Fig. 21). These settings will provide the requested contrast index with the minimal dose possible.
13.2.2.1 Patient Water Equivalent Diameter

In order to obtain a good image, a part of the X-ray must be absorbed by the body. If none of the X-ray passes through, or all of the X-ray passes through the image will contain no details. This can be considered as attenuation. It is obvious that bigger patients will absorb more X-ray radiation, meaning they have greater attenuation. To find the minimal dose needed in CT imaging, this attenuation must be found. Using the body measurements is not enough since people have different densities. One way to evaluate this attenuation is by using the patient water equivalent diameter. With this method a denser spot will have a greater water equivalent diameter. Summing the different water equivalent diameters along a line which is the body’s diameter, will yield the patients water equivalent diameter (Eq. 4):

\[ D_{\text{weq}} = 2 \times \sqrt{\sum_{x,y} \frac{I(x,y)}{\pi}} \]  \hspace{1cm} (4)

where \( I(x,y) \) is obtained from the scout image\(^v\) (Eq. 5)

\[ I(x,y) = (\text{image}(x,y)/100 + 1) \times \text{PixelArea} \]  \hspace{1cm} (5)

The problem is, there is no image to calculate this diameter from, before the scan. PI estimates this diameter from the pre-scan. Comparing PI’s estimate to the calculation above (after the scan is done) shows good correlation.

\(^v\) A scout image is a short, low dose image taken before every CT scan to help the technologist position the patient and adjust the scanner.
Figure 22: Data flow for optimal protocol selection example
Bibliography


3 Imaging, Plexar. *ExLCD-A Solution for CT Dose based on Image Quality, GLIDE presentation*. Cleveland, Feb 8, 2011.


12 Imaging, Plexar. *ExLCD-A Solution for CT Dose based on Image Quality, GLIDE presentation*. Cleveland, Feb 8, 2011.


16 Ibid.


18 Ibid.


28 Ibid.


32 Philippe Coulon, PhD. *Patient radiation dose optimization in CT.* 2010.


