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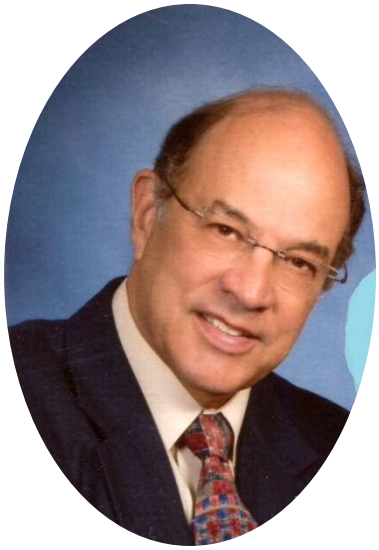
Radiation Therapy Software providing a True Dose Verification for Patients



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CEOCFO: ***Mr. Renner, what is the idea behind Math Resolutions?***
Mr. Renner: The idea is a product. I am basically a mathematician, but I also have expertise in radiation therapy. Currently, my product line is software for use in radiation therapy.

CEOCFO: ***What are some of the challenges in radiation therapy that software can address?***
Mr. Renner: Twenty six years ago, I was marketing a treatment planning system; however, I eventually sold that to Elekta in 1997. Treatment planning became too big of a project for one person to do - I am only one person, although I do have two employees currently - so I had to look for a smaller niche, just be on one specific need, so my present product is a quality assurance product. The idea that I am doing different than what other people have been doing for the last 16 years is creating a feedback loop where we will measure the radiation coming out of the machine as it is delivered for a treatment, and we will go backwards from the measured radiation field and calculate the dose the patient gets, and that record can then be compared to the intention. We create a feedback loop by measuring what comes out of the machine, tells the customer whether the patient is in fact getting the correct dose. The problem with radiation therapy is you cannot see radiation, you cannot smell it, you cannot touch it. The patient is in a room, there are three feet thick concrete walls when you treat them, so you are totally relying on calculations for a patient to get the correct radiation dose. It is not like if you administer medicine to someone a nurse can visually see the little syringe and how much she put in there - we do not have that kind of feedback in radiation therapy; it is all mathematical calculations. It has become so complicated, so complex, that it is imperative that there be various ways of insuring that someone has not pushed the wrong button on the calculator or computer and that the patient is in fact going to be getting the intended radiation dose.

CEOCFO: ***Are the radiation doses often wrong?***
Mr. Renner: There have been accidents. I know about 10 years ago the New York Times ran a series of articles on accidents in radiation therapy. I am sure everybody in every center is aware of some misapplication that can occur and has occurred - people, of course, want to hide their mistake if at all possible. If anyone could do an actual national survey and find out how often accident do occur - they do occur, and people have been injured or killed by accidents in radiation therapy, so it does happen.

CEOCFO: ***Are ways of measuring other than what you have developed? Are there checks and balances in place in some format?***
Mr. Renner: Yes - I am really a very small player in the QA market. In 16 years we have about 150 customers and there is probably 4000 to 6000 in radiation centers out there worldwide. That is one of the problems of being a small company - we do not have a lot of money for marketing. The standard way that people are doing it, is for example, a patient gets treated by seven radiation fields around the patient. They will have a device on the table and project one of those fields onto this device, which will just measure the intensity over the area of the device, and they will compare that to what they expect the radiation field to look like. You would check it field by field. That is a very popular way of doing it. The second

way of doing it is you would actually recalculate the plan to a plastic phantom - the same size as a patient's body, but it might be just a circulator or rectangular shape - you would recalculate the dose to that device, you would treat the device, and then you would make measurements within the device - of course you cannot do it inside a patient. The assumption is if you recalculate to some phantom and you successfully measure the right dose in the phantom, you make the assumption that you are giving the correct dose the patient. That is an assumption because it is possible - I had at least one case where the software flagged an error where there was something wrong with the calculation to the patient, but when the patient was pulled out and then they calculated it to a phantom, the phantom calculation was correct. The reason my software flagged a 15% error for one patient - and everyone before and after it is okay, and the physicist is trying to figure out what the problem was, so the first thing he did was he recalculated for a phantom, made a measurement, and that came back on the money. So now he is scratching his head, and said, "My software is still saying it is a 15% error," and did some research, and figured out that a wrong specific thing went wrong with the calculation to the patient that did not go wrong when they calculated it to the phantom. It is a tricky business. Everyone has to be careful. You have to be aware of what your assumptions are when you do these things.

CEOCFO: ***Are you selling directly to the end user, and might you partner with other companies that are supplying other parts of the system or other products in the same arena? How do you reach customers?***
Mr. Renner: In the United States we have tried two different times to have a partner, and the partners in both cases were not effective in selling. Right now, I do not even have any distributors in the United States, and we have very few sales in the United States. In Europe, we were able to get a couple of distributors - one in France, one in Italy and one in the UK – and they have been very successful for us in selling our software. We are also starting to have some success in South Korea. We just put three systems in South Korea, a couple in China, and we have a very good distributor in Japan. So we have gotten some sales there. We are still a very small company, so we do not have a huge budget. It is very difficult to support software all the way around the world like that. Right now, one of my employees is in South Korea. He has been there two weeks. He was in China two weeks before that. He has been out there on the road now for a month. And we had a minor disaster in the last center in South Korea - we shipped a computer a month ago to the site – and their IT department loaded some anti-virus software that broke the system. The distributor then reloaded the operating system and they loaded the wrong driver for one of the cards we are using, and we just spent now five days trying to figure out why all of the sudden we cannot calculate on his computer as we were initially not told a thing. We finally figured out that the wrong driver for this calculation card had been loaded.

CEOCFO: ***Are people in the radiology community looking for a better method or is it more realizing the value when it is presented to them?***
Mr. Renner: I think it is a little bit of both. When you present it to them, they realize the value, but they are also looking for something that is easy and does not have to spend time. One advantage of my system is the physicist does not have to go into the clinic after hours to set equipment up on a couch and run through the treatment plan. I am using the imaging device that is currently on the machine so that the technicians who treat the patient can take the data during the day. The downside of that is that I am using this imaging device in a way it was not designed to be used. I have virtually no support from manufacturers of the imaging device, so we are always trying to figure out how to work around the system to get the information that we need, and that has been a real trial for us. That also means the data flow is not very smooth from the imaging device to our software. So the larger companies who are competing with us for the last year have now come out with software that is more automated that does not quite do the same thing but they are getting close to doing what we are doing.

CEOCFO: ***Do people that you are selling to know your personal history and is that a reason they may give a second look at your product?***
Mr. Renner: Some people are aware of the work I have done in the past - I have about 22 papers I have published over the last 40 years that I have been in this business. Some people are aware of the work I have done in the past and some people are not. Those who are aware of that do generally give me a second closer look than those who do not.

CEOCFO: ***You had a recent FDA clearance - what have you added to the mix?***
Mr. Renner: The last FDA clearance, I had been using what is called a pencil beam algorithm to calculate the dose, and that algorithm is not the state of the art algorithm, not quite as accurate in the thorax in your lungs. I have always known it would take me probably a year to code up the current state of the art algorithm, and that is why I did it and it did indeed take me an entire year to do. I also knew it would be difficult and a lot of work to get the thing running fast. We are still not as able to run this algorithm as fast as the algorithm runs on some of the other treatment systems. Again, it is a limitation of being one person and there is only so much I can do. We have never grown the company to the point where we could actually hire a team of people. I am looking at retiring, so my biggest problem now is who do I hand this company over to.

We have been approaching our competitors to see if we can find someone who is interested in taking on this product, and so far we have only received lukewarm response. We have had two people take a good look at it, maybe three companies, but no one has made a solid offer.

CEOCFO: ***Put it together for our readers. Why pay attention to Dosimetry Check?***
Mr. Renner: I think it is important because we actually demonstrate the dose to the patient that they are actually receiving. That is one more step than the competition is doing. This gives you a slightly higher degree of assurance that a mistake has not been made somewhere.

CEOCFO: ***Do you think that the accountability that is supposedly going to be required in healthcare might encourage more people to pay attention?***
Mr. Renner: I think it will. The reason why we have sales in Europe is the government has made a suggestion that they want some kind of verification and measurement actually made during treatment that the dose is correct, and we do that because we can measure these radiation fields while the patient is being treated. In the U.S., there is not a requirement like that so because of the increasing requirement in Europe we get more sales. If the U.S. ever decides to make that kind of requirement, then you are going to need software and a system like I have. The other thing I have noticed is that the medical physicists in Europe have more time to deal with projects, whereas the physicists here are pretty much stretched to the limit. I have gotten in a situation where someone calls me up with a problem, and they ask me to look at it, but then I get, “Well, I will not be back until next Wednesday,” because they are covering two different hospitals. As long as everything goes okay, they can get through each day, but as soon as anything happens that is a problem, they do not have the bandwidth to deal with it. They have to run over to the other hospital. I have noticed that medical physicists in the United States are under more pressure than they are in Europe as far as the number of facilities and patients that they are having to cover.