I'd like to introduce to you, Gene Cardarelli from Rhode Island Hospital. He's assistant professor at the Brown University School of Medicine, received his PhD in medical physics at UMass. And I'd like to mention one thing as we move into these talks. We're going to let our three speakers finish their work as we eat lunch and then right after that we'll save - we'd like to save all questions for a panel discussion after. Thank you.

DR. CARDARELLI: Thank you Randy. Just wanted to thank Xoft for inviting me to speak today. This is exciting technology. We've been selected as one of the three sites to be involved in the first 40-patient trial. And I would like to acknowledge my colleagues that assisted me in the commissioning, Jessica Hiatt, assistant physicist, Zhen Zheng, who happens to be sitting over there on the left and one of our residents, Jaros Hepel. So today, I'm going to talk about some clinical implementations, acceptance testing, real quickly, mostly concentrate on the commissioning tests that we perform, some treatment planning verifications, applicator tests and some phantom measurements that I hope you find entertaining. This is the balloon, some quick pictures of what you were just seeing. And these are the source specifications in a table format that you would need to be able to put into your system. We have a PLATO planning system at our institution, so most of the data that I have is for a PLATO system, but BrachyVision, there's also instructions on how to input the required data for your planning system as well. So these are the long list of acceptance tests that we performed. I won't go through every single one of them, but they are outlined pretty clearly in the Xoft documentation when you receive your unit. In particular, the applicator setup and confirmed dwell positions and power failure tests and one very important test is called the pull back test, which the unit - the source itself is pulled back mechanically, and you need to verify that it pulls back the amount that you want it to pull back. So I'm going to mostly concentrate on the commissioning tests. We perform control of functionality, beam stability, output stability, well chamber constancy, timer accuracy, source transit time, positional accuracy, safety characteristics. And we did all of this in a couple of days, so it really didn't take that much time. That was not a true statement. That was supposed to be a joke. Okay. This is the Axxent controller. The controller arm, which is mechanically put into position, is here. The electrometer is placed right on the other side of this unit, which you can't see, and that's connected to the well chamber, which you'll be measuring the source output for each treatment. So for setup and delivery, you need to enter the patient data and import the dwell time file, which is created on a spreadsheet outside of the system. And you have to perform a source calibration prior to treatment. Source is placed in the well chamber and the output for that particular time is then adjusted for the dwell times that you generate. So each - when you generate your plan from PLATO, the dwell times are put into a spreadsheet, the spreadsheet then goes into the system, and then the adjusted calibration output adjusts the times for that particular treatment; a little different than iridium 192. Then you perform your treatment delivery and then it generates a treatment log file. In the treatment log file is mA/kV parameters that you can pull off and graph, which we'll show in a minute. Of course, you have to make sure that the status indicator lights are working and your emergency offs are functioning, as you would in any type radiation delivery device. So for beam stability, we were able to graph the kVp and mA values. I stole this slide from one of our other presenters in previous talks. Essentially, there is this white line, which isn't labeled, is the ramp up of the x-ray source, like any other x-ray source, to get up to the operating voltage and current. We're also able to plot the beam current and graph the startup dose; this assists us in making sure we're giving the right output to our patients. The next is a measurement of the output stability. This is a spreadsheet that we made, basically on the same plan. A number of different trials with the same source, just a straightforward, simple stability test with an average and standard deviation calculation, so very, very, the stability is very stable. Next, we wanted to make sure our well chamber was functioning properly, so we have, or we're lucky enough to still have some cesium in our department, so we have a 4.0 mg cesium source and we decay that and we do the same test for our iridium source, as well, to make sure that the well chamber is working properly. Next, we check the timer accuracy. We take measurements in the same position and graph the time - graph the output - the total charge versus time, create a graph and you want to make sure it's a straight line, that's our goal. So I'm not telling any of you in here about any ground-breaking physics; this is just implementation process and what you need to do for this control, just like you would - for this system, just like you would for another brachytherapy system or any other output device. Also, for those who remember cobalt, we have a timer end effect because of the ramp-up and there is a number of different ways to calculate that. We use an interpellation with linear regression and a value, which we got was 2.5 seconds, comes out pretty close to some of the other published investigators as well. The line is a correlation coefficient of one, so that's what our criteria is. We would perform - probably perform these number of tests on each source. The time adjustment, which is calculated in the spreadsheet, takes into account these factors. The 1.06 factor has been a published measured Monte Carlo factor for the balloon, due to the barium in the surface of the balloon. So when you are doing your calibration values, you want to make sure you take out the 1.06 if you're not using the balloon. The air-kerma strength is SK and the - this is compared to an iodine source from NBS and that's what the R*C is on the ends of SK. So one of the most - more important tests that we thought we needed to do was make sure that the source was going to the place where we think it's going to go. And the first test is to do a relative source position test to make sure that when the source moves an increment, it moves the amount of increment that you tell it to. And Xoft supplies a nice phantom with graduations in it that reflect back on GafChromic film, so you can measure the distance between movements. And you see the source a little darker there and there and there, you can measure the position differences. But that doesn't really tell us where it is relative to the imaging that you're doing. So we have to come up with a different test for the imaging. So for our iridium source, we take an x-ray film, and then we just do a treatment on the x-ray film, and we do an autoradiograph, like you would normally. But because of the dose rate of this source and the low energy, the sensitivity of the film that we use is much higher then we needed to. So we had to come up with a dual way of measuring it. We take an x-ray on V-film, and then we take another x-ray on GafChromic film and we fuse the images and we come up with an image that looks like this. You can see the dummy source here and we can measure the distance from each - from this position up to the center. And these are the points for the registration, so that you can determine the first position, dwell position, which is what you need for your planning. So when you take an image, or a CT, and you find the dummy position, then the source is overlaying on that, and now we're sure that the source is going to the right dwell position. This is the GafChromic film, what it looks like, and this is only for one-second exposure by the way. And this is what happens when you expose it to XV film, you - it saturates the film, so that's one of the challenges we had initially. Next, we looked into some safety characteristics. Indicator lights, interlocks, power failure checks, treatment data recovery and surveys. And probably each institution needs to do their own survey with the patient in the place. This is not a person, this is a - this was taken from one of the presentations by Xoft. This is a goat, so this circle there is the center of where the source would be. So you'd want to center it where your applicator is not at the udders. But the most important thing about this slide is the range of exposures. All of our measurements were within those ranges and obviously are very sensitive to distance. And you probably want to make them in multiple planes as well. And I'm sure your radiation regulatory people will want to know what those exposure rates are. We do use a portable shield at the controller; mostly because we have personnel that are concerned about exposures, but the rates at the controls are pretty low, so. Next, I'm going to go into some treatment planning verification. And see how I'm doing for time here. So the first thing you need to do is, enter your TG-43 source parameters into your planning system. Verify the dose within the pending calculations, that's what we do, you don't have to do that, that's what we did. Compare film to - film to plan for one source and then for a multi-source plan. Create a phantom with applicator in place, image the phantom, calculate the isodose distributions, measure the point doses with TLDs, or some other type of detectors, and hopefully your physician will give you more than a long weekend to do all these measurements. So here are some of the - everyone's familiar with these, hopefully everyone's familiar with the TG-43 formula, so I won't go into all of that. I'm sure Bruce will be glad to go into that for you, if you like. So here are the TG-43 parameters for the Xoft source, the air-kerma strength is 110,000. The dose rate constant is .709, and these are the values that you'd enter into your planning system. This is the radial dose function data for PLATO and BrachyVision. There will be a test afterwards for this table, everyone will get one, so. The most important thing is that, for PLATO, you can't measure in half cm values and you have to interpellate the zero, so, whereas, BrachyVision you can use 0.5 cm for the first 2.0 cm. Now the next table, I purposely put it in there so that you couldn't read it, but in PLATO, you have to put these numbers in by hand. Unless you have somebody that's really good in UNIX, you can have them put it in for you and then you can just verify the numbers. And this is our independent dose calculation spreadsheet that we have, which Dr. Zheng developed. It was very helpful; it takes the same dose - dose dwell times and positions and calculates the total dose. And you can see the difference; we were within 1%, 1.2%. So it's same data, different calculation, outside of the planning system. The next one is our phantom measurement, and I have to thank my resident for doing the molds. He asked me what was a good model for breasts and I really didn't know, so. There's always room for JELL-O, so he made a mold out of JELL-O, and we put a balloon in there and CT'd it and treated it and did an end-to-end test. So we imaged the phantom, and the - actually, the CT numbers came out pretty close to water, so, we were happy about that. And ran a plan, calculated isodose distributions, and I think this is out of order here, but here are some of the - and then we measured point doses on the outside of the phantom. And we did it from different types of plans, single dwells, multi dwells, some skin optimized plans and we were within 3.5%. And these are for optical stimulated luminescent [15:05], which are somewhat new for this energy range, so we were pretty happy with these results. We had one that was an outlay that we're going to repeat. But these measurements, literally, were taken a couple of weeks ago, so we're pretty happy about those. Next we - the ultimate question, we wanted to compare to the MammoSite distribution. And this is a MammoSite that we did a few years ago, and then we just used, substituted the Xoft source, so the big question is, we want you to figure out which one is the Xoft source and which one is the iridium source? So, that'll keep you all at bay for a while. But the source on your right, since the Xoft source is less anisotropy on the top and more on the back, this would be the Xoft source, and this is calculated exactly the same as this one. And we also, finally, we did some applicator tests. We test the balloon symmetry prior to installation into a patient and also the ability of the source to bend and we got about 15 degrees. And it's not really the balloon applicator that's the problem on bending, it's the source itself that can't be bent more than 15 degrees. So with that, I just want to thank you. I think I made my time limit. Thank you.