I would like to give you a little bit of a flavor of what we have observed during the clinical – the preclinical testing of this system. In a typical fashion in an outline slide here, which we'll basically discuss a little bit about system description, which was already mentioned by Kathy. Some testing methodology, what test did we perform, what are the results of those and what are our suggestions or, you know, summary or conclusions. Our institution is fortunate to be – to have one of our surgeons extremely interested in this technology – it's a breast surgeon. The radiation oncologist might be interested, the medical physicist has no choice, so we are, therefore, slated to be one of the sites for the clinical study. We were also fortunate to have the system on site for testing for about two weeks, and during that time for the first week we had a Xoft representative with us talking with us about the system, as you can see in this picture here. A little bit about system description, these are two hard-working physicists trying to look at this controller graphical user interface; instead they are looking at Tom who is taking picture of them. On this picture you can see the flexi-shield for radiation protection, the source tube and the applicator shot of the controller and a picture of the x-ray source with the high-voltage connections. A little bit about a system, the x-ray source. The x-ray source is inserted in this flexible catheter. Please note the codes. Flexible can have a lot of meanings, as we will discuss a little bit later on. The operating potential is 50 kV. It has an output of about 18 Gy per minutes at 1.0 cm in tissue. You'll see these specified as 1 Gy per minute at 3.0 cm in tissue because of its intended use and is water cooled, as Kathy mentioned before. A little bit more about the x-ray source – for as for the physicist, obviously this size extremely important, you know, what is the size of the anode from where the x-rays are originating? Another picture of the balloon, please note the radiation probe lumen is the thickest one and the other serve, the other two lumens serve the drainage and the inflation purposes. Now, once you get a system like this on site, how are you going to treat it, you know, do you want to treat it as a superficial unit? Do you want to treat it as an HDR unit? How are you going to deal with it? We, based on our discussion with Xoft and amongst ourself, we say we're going to follow a methodology as it's specified in this task group which many of us are familiar with it, with them. And it's basically applying to hide those rate brachytherapy. So, we use this report and then we also make use of the system log file examination. We use a set of standup measurements which, with the equipment which is either provided by Xoft or is available in any therapy clinic. So the task that we perform, we were looking at the graphical user interface functionality, beam stability, output stability, timer accuracy and effect, source transit time, positional accuracy of the source, some safety characteristics and some general design constraints that we observed during testing. If you haven't done so, please stop at booth 102 and you can see a live demo of the system. The controller allows you to enter the patient data, import the dwell-time file, perform source calibration, treatment delivery, treatment interruption recovery, and provide you with treatment log files. So as you can see, it's pretty much just the same way like any other HDR unit. In terms of beam parameters abilities, we were looking at the generator parameters first, kV and mA. Direct measurement is impractical unless you get access to the generator, so we make use of the system log files. We also look at the beam current from the log files. As you can see in this picture here, the system needs some time to ramp up. During the ramp up, you also can see that the system does not record the time; however, some radiation comes out. So, we call it the startup dose. We want to know what's the magnitude, what type of quality, beam quality do we have during that time and how to account for it in the treatment planning system. I also have to give a talk on Wednesday where I will present more detail on this issue, so if you want to, you can participate or you can look it up on line. So, returning to our parameter stabilities, we look at a single source over different days and these are the results. As you can see, everything is less than 1%. Different tube on the same day, okay – we also look at, you know, four tubes, that's how many we got – and then we check the output constancy versus time. Now if you remember the picture of the system, you probably could see – let me see if I can go back really fast. Maybe I don't have it in here, anyway, if you look at the system, there is on the side of the system there is a standup imaging electrometer and there is also a well chamber. So, every time you perform a procedure, the unit, or the source has to be calibrated. In this slide here, I'm showing you the output constancy versus time for a four-day single tube how it behaves. So once a calibration current is measured using the well chamber, a correction factor is applied and I'll show you to the next slide, but when you look at the corrected collection charge, the agreement between the older daily output is pretty good. So in here we are looking at output constancy of four sources. Please note that although on this source we have an 85.6 nanoamps, as measured by the well chamber on electrometer system, after Xoft does its internal correction and – you know, there were some papers on that or some talks on that, I don't have the details here – but you can see at the end, the corrected collection charge is pretty constant. Now to measure the end effect, Xoft has provided us with this phantom and the phantom has a PTW soft x-ray chamber inserted here or embedded in here with a TNMC electrometer. Then we did it in the classical way. We measured the charge collected during different exposure time including the startup time or during stable operation. At the end of it, these are the dwell times that we use, we came out with a, using the regression analysis, a two second timer accuracy on this system, which may be clinical significant and will have to be taken into account. Now another thing that we look at is the source transit time. So how long does it take the source to travel over the 7.5 cm distance, which is the maximum travel distance? If you compare that with the HDR sources, you can see that we have a system which is pretty similar to coat on coat, you know, with the HDR system available out there. However, if you look at the maximum source speed, it's only 0.83 cm per second, compare that to 2.5 cm per second so it takes a little bit longer for the system to get from one point to another. So if you have to treat 7.7 cm balloon in 0.5 cm steps, the source will be in transit for 8.4 seconds and that is a quite sizeable amount of time, however, we brought this to the attention of Xoft and they provide us with some information which shows that for the system, you know, for the intended use, you know, which is basically using into a balloon of certain diameters and the doses that are intended to deliver every time, you see an effect of about 1% or less. Obviously this will require a little bit more investigation by the clinical physicist. Then, like every other HDR system, we look at the source position accuracy. We found, using radiochromic film, we found a precision of about 1.0 mm. We look at the step-size accuracy and we found that a step-size accuracy is about better than half a millimeter. All sources that we got were manufactured to identical length. A better source position QA device will be extremely useful to have. Now remember I say the flexibility of the source catheter coat on coat? Obviously it's not even close to an HDR source wire, you know, which can navigate a 2.0 cm radius. This system, once you have a 15 degree flex on the catheter, the source either gets out of the nest or you get a fault. This has some clinical implications and especially for the surgeon involved which requires, you know, that the balloon be placed properly and it has to be sure that you ensure a straight approach to the balloon's x-ray source lumen. We also evaluate the safety characteristics of the system, emergency stop, but then sudden power failure, treatment stop button, treatment pause, treatment interruptions, radiation safety. We look at all this parameters and we found them, you know, functional. So what we would like to see improve, you know, for the next release? We'd like to see a better way to attach the system, the x-ray source catheter to the arm. The clip was found to be fragile, actually, in one of the sources it was, it broke. The source travel might be too limited to

7.5 cm. One of the catheter that George is going to talk about can go, can have a 7 cm length. A physics mode would be helpful for us to be able to do measurements or to evaluate the sources without having to go through the entire process. Oppression and temperature gauge, as part of the system, will be extremely helpful because the intended –remember you don't need a bunker to use this, you can put it anywhere. Well, you don't have pressure and temperature gauge just everywhere, so having it part of the system might be a good thing. Then during the testing we had an interlock failure, where there was possible to have x-ray generated with no water flow in the cooling tube, however we were not able to reproduce it. So, in summary, we found that the system has a stable output and source position accuracy of 1.0 mm or less. Timer and accuracy on linearity, adequate. Turn on, turn on dose needs to be quantified and documented. Source transit effects on delivered dose, about 1%. The safety interlocks were found to be functional. Patient exposure history was always recoverable during treatment interrupt. Source movement rate could be extended, or should be extended, and source attachment to the nest could be redesigned. And I would like to acknowledge these distinguished gentlemen who helped me during the testing process and with that I would like to pass it on to our friend, George, who's going to talk about treatment planning system. Thank you.