Saint Francis Regional Cancer Center Radiation Oncology Department 94 Woodland Street Hartford, CT 06105 Tel 860-714-4568 Fax 860-714-8019 Date: Sept. 12, 2007 To: Monica Orendi Mail Contol 140786 Fax#610 337-5269 06-00854-03 From: B. Ellen W. Icox 03001246 # Of pages including cover page _____ Message: Dear Ms Orenda Attached-confirmation of Si 90 seuce receipt. and training record for George Paulonnis. Please advise if everything received is satisfactory? Sincerely Ellen Wilcox is satisfactory

Joseph Colasanto, M.D. Bruce Kaplan, M.D. Richard Shumway, M.D. Eric van Rooy, M.D.

140786 NMSS/RGN1 MATERIALS-002

4350 International Boulevard Norcross, GA 30093 (770) 717-0904



healthcare for everyone

Date: 9/6/07

To: Dr. Ellen Wilcox

From: Chris Sherman

Subject: Confirmation of Receipt of Radioactive Sources

This letter is being sent to you as confirmation of receipt, by Best Vascular, of an active sources and transfer devices from Saint Francis Regional Cancer Center.

Transfer Device: 89347 with active source train: ZA709 was received on 3/11/05

Regards,

Chris Sherman Lead, Radiation and Systems (770) 717-0904 ext. 3120 OVD51-D

SFH CANCER CTR-RAD ONC

003/013

KETA

Active Transfer Device within White Lead-Lined Storage Container

ORDER # (REF):TDA-2040

Jacketed Radiation Source Train (JRST) Active Length: 40mm Description: SICW.2.H 40 : series of 16 Model SICW.2 sealed sources jacketed in a stainless steel coil (0.47 mm OD) with non-radioactive radiopaque marker welded to each end. Radionuclide: Sr-90 Total Activity: 2.09 GBg Assay Date: 12Jun02

ansfer Device Serial #: 89 Effective Date	347 From: 09Nov04	Radiation Source Train Serial #: ZA709 To: 09May05		
	Maximum Balloon Diameter (mm)	Reference Vessel Diameter (mm)	Dose @ 2mm (Gray)	Dwell Time (Sees) or (Mins, Sees)
Vith Visting	≥ 2.5 to < 3.5	≥ 2.7 to ≤ 3.35	18.4	190 3, 10
itent	\geq 3.5 to \leq 4.0	> 3.35 to ≤ 4.0	- 23.0	238 3, 58

Use the following treatment chart ONLY after the required six month Leak Test is completed.

Effective	Date From: 10May05		To: 09Nov05	
	Maximum Balloon Diameter (num)	Reference Vessel Diameter (mm)	Dose @ 2mm (Gray)	Dwell Time (Secs) or (Mins, Secs)
With Frieting	≥ 2.5 to < 3.5	≥ 2.7 to ≤ 3.35	18.4	193 3, 13
Stent	\geq 3.5 to \leq 4.0	> 3.35 to ≤ 4.0	23.0	241 4, 01

NOTE: If the ratio of the maximum balloon diameter to reference vessel diameter is between 1/1 and 1/1.2, dose can be prescribed according to balloon diameter. Dose can also be administered by visual assessment of reference vessel diameter.

Radiation Output: 0.1030 Gy-s-'± 20% in H2O at 2 mm from the center line of the Radiation Source Train. Date: 12Jun02

Result traceable to the National Institute of Standards and Technology. Uniformity verified +/- 10% along the middle portion of the Radiation Source Train.

Sealed Radioactive Source:

AEA Technology, QSA GmbH, Model SICW.2 Radionuclide: Sr-90 Activity: 0.131 GBq/Source

The contained activity per source is the product of the measured source train absorbed dose rate in Gy/sec, at 2mm from the source center line in water and the conversion factor 34.2mCi/seed (1.27GBq/seed) per Gy/sec. The contained activity in the source train is equal to the contained activity per source times the number of sources in the train.

Description: Sr-90 wire in scaled single stainless steel capsule. Length: 2.5mm

Diameter: 0.38mm ISO 2919 classification : C53X1,2,3 11

" Where X1, X2 and X3 represent respective special "impact", "step" and "crush" tests simulated for circumstances that could reasonably be expected to exist outside the Beta-Cath™ 3.5F System during off-normal accident situations.

ISO Leak Test: ISO 9978, Notes, immersion into ultrasonic cleaning water with detergent solution at 70°C for at least 30 mins. <185 Bq Result: Date: 12Apr02

Novoste Leak Test:

HzO passed over the Radiation Source Train and then analyzed for radioactive content using liquid scintillation counting. Result: <185 Bq Date: 09Nov04

*Do not use or ship the device unless a leak test has been performed within the previous six months. Follow the radiation safety and handling instructions in the User's Manual. Test the device for leakage at intervals not to exceed 6 months. Use a leak test method capable of detecting 185 Bq (0.005 uCl) of Sr/Y-90. Immediately withdraw a leaking device from use and store it for disposal and/or return to Novoste. File a report of any leaking device with the authority and notify Novoste. Retain leak test records.

Certified by Novoste (Corporation:
50.00	
Clame Doube	11-9-04
Manufacturing	Date
adult	11 alar
C-FIJAULX	11/0/04
Quality Assurance	'Date

Noveste" Beta-Cath, β-Cath, β-Rail and Beta-Cath System design logo are trademarks of Novoste Corporation

NON-STERILE

E)YA

		Sondor's Coord
1	Express Runbar Control Control	4a Emmas Packana Service
	Data 3/9/05 Sender's FedEx Account Number	FedEx Priority Overnight FedEx Standard Overnight FedEx Tender motion FedEx Tender motion
	Sender's Ellen Grein Phone (860) 7144568	FedEx 20 ay FedEx Express Saver
	company Saint Francis Hospital + Med. Ch.	Feds Enviropenternat enables Ministran Cher penns (new
	Address 94 Woodland Steel	FodEx 1Day Freight FedEx 2Day Freight FodEx 2Day Freight FodEx 2Day Freight FodEx 3Day Freight The Instinues day**
	city Hartland sur (TTO DELDE	5 Packaging
2	Your Internal Billing Reference OPTIONAL	Fordisk Fordisk Fall* Fordisk Large Fall stand Pale Fordisk Large Fall stand Pale Fordisk St
3	To Recipient's Craif Reed Phone (770) 717-6086	Spectel Handling Include FodEx address in Section 1 Austalable ONLY for Austalable ON
	Company NOVOSTE CORP/ RADIATION FAC	No No Yes nor miss the backled. Yes Dry Ice Dry Ice Dry Ice, & UN Ises r kg Dargeman seatch Brakking Dry ice Carrison To Backgrantson Carros Aircreft Only
	We current deliver to P.O. ZIP codes. Dept. Poor Subjection Address	Payment Bill dec Ester (vells: Acct Na. or Grads Card Na. balance. Sendler Acct Na. is Section K Recipient Third Perty Credit Card Cast/Check
	To request a pockage be hard at a specific Foots location, prize Foots address hare. City NORCROSS State GA ZIP 30093-3017	Total Packages Total Weight Total Declared Valuet
	Try online shipping at fedex.com	Four liability is limited to \$100 unless you declare a higher value. See beck for details. FeelEx Use Only B Sign to Authorize Delivery Without a Signature
	ond in our curriert Sinkte Guida, including terms that limit our fability. Qurestions? Visit our Web site at fedex.com or call 1.800.66FedEx 1.800.463.3339. 02887571	By signing you sucharize us to deliver this shipment without obtaining a signifular and agree to indexacily and hold us harmlass from any resulting claims. 24 Stif-New Data 11/03 -Part / 15/02/901994-2008 Falls-7/11/TED IN U.S.A
	· · · · · · · · · · · · · · · · · · ·	

.

國 004/013

SFH CANCER CTR-RAD ONC

09/12/2007 08:48 FAX 860 714 8019

•

ALLIEURICE RECEITED

Customer Site In	formation:		
Facility Name	New Dritain	General 1705	nital
Street Address	5 Hichland	L Ft	for the second s
City	New Brita	in	
State or Prov.	C7	Postal Code	06050
Country	us		
Phone		Fax	
Date Of Course			

For the purposes of the training records list below all those receiving BrachyVision Training (to any level) along with job function (e.g. Oncologist, Physicist etc.), signature and initials.

Name	Job Function	Signature	Initials
George PAULONIN is	Physicist	Am 1-l	A
Email address	Phone number	Fax number	
GPAIAXX @ YAHOO. COM	860 224-5520	86-2245714	

Name	Job Function	Signature	Initials
			· · .
Email address	Phone number	Fax number	
		•	

Name	Job Function	Signature	Initials
		•	
Email address	Phone number	Fax number	
•			

Name	Job Function	Signature	Initials
Email address	Phone number	Fax number	
· · ·			

Instructor Name: Signature: Initials: .

TSWI BrachyVision Training Agenda & Outline 121404 Printed on 07/01/2005

COMPANY CONFIDENTIAL Page 3 of 12

2006/013

Brander Vision 6.5 Thanking Chilling

Session 1 - Brachy Vision

System Overview Explain general aspects and structure of the BrachyVisid

Explain general aspects and structure of the Brachyvision software.	
Integration of BrachyVision within the Vision / Eclipse product line	_
System capabilities	┏
The basic Tasks	Ū
The basic workspaces	G-
Focus and scope windows	Ц
Tool bars and menus	5
Trainers Initials:	••••••••••••••••••••••••••••••••••••••
Creating a plan from plane films (e.g. Bronchus) Explain in detail all steps required to generate a simple plan from plane films.	
Selection Workspace Configuring Import Filters	
Importing and connecting Images	
Using a Vidar Scanner (for VXR16, leave for 90s after logging in)	
Using a flatbed film scanner	¥
Cropping an image	Ŕ
Scaling the image (to scale the pixels)	
Trainers Initials:	

Attendees Initials:

Creating a plan	9
Discuss possible reconstruction methods and their requirements along with the advantages and disadvantages of each.	9-
Inserting an imaging geometry including definition of all imaging parameters, particularly for the Reconstruction Jig if this is to be used.	I
Image Registration including a definition of the registration point	ſ
Demonstration of how to rotate an image if scanned in at an angle, including explanation that the image does not visibly rotate, just the orientation	ſ
Image processing	
Demonstration of how to insert an applicator including a discussion on the possible sources of reconstruction error i.e. patient movement, incorrect geometry parameters, incorrect registration point entry.	
Use of the zoom, pan and edit contour tool	
Use of measurement tools emphasising that measurements are at film size (magnified).	5
Using a digitiser	X
inserting the source positions (pen, applicator properties)	
inserting Reference points and lines stressing that Entry Workspace should only be used for anatomical reference points visible on the film and that geometric reference points should be entered in the Planning Workspace.	
Applicator entry from co-ordinates	9
Ising Template plans	\prec

τA.....

Attendees Initials:

.....

Trainers Initials:

<u>Planning Workspace</u> Set all dwell times function	Π.
Show dwell controller	
Show dwen controller	
Inserting Reference points and normalising to them.	
Inserting a reference line at a distance and optimising to it using a volume optimisation – magnification in the planning workspace is 1.0!!!	ſ
Use of the Shaper Tool	Ð
Normalising to reference points and basal dose points	5
Using dose measurement tools	B
Changing the Isodose values using Templates and individually plus 3D	Ŀ
Viewing 3D dose on Radiographs	G-
Changing the 2D and 3D matrix	Ŀ
Changing materials etc	
Viewing Plan Report including ways to reconfigure its output e.g. Hospital name or source co-ordinates.	
Exporting to VariSource / Gammamed	
Copying a plan	9
Trainers Initials:	

TSWI BrachyVision Training Agenda & Outline 121404 Printed on 07/01/2005

Attendees Initials:

Session 2 - BrachyVision

Allow further familiarisation with the features of BrachyVision listed above with the development of a plan for a Vaginal Cylinder application and a Cervix application.

Explain the possible techniques for planning a cylinder application and show how this can be achieved with BrachyVision. Include the following methods: Uniform loading, optimise to a line at the side of the applicator, optimise to a line a covering the end of the applicator as well as the side.

Explain the possible techniques for planning a cervix application and show how this can be achieved with BrachyVision. Include the following methods: Simulation of Manchester or other low dose rate techniques and optimisation techniques.

Dose Prescription

Explain how the Prescribed Percentage and Prescribed Dose per fractions are used to set the isodoses i.e. if the Prescribed Percentage is 80% and the Prescribed Dose per fraction is 600cGy, the 100% isodose will display 750cGy.

If either of these values are then changed the dose will re-scale accordingly.

Dose fractionation.

Explain how the number of fractions can be set in two places and how the effects of changing the fractionation in these places is as follows:

1) Plan properties – This will keep the dose per fraction the same. The display will show the overall dose for the two fractions however the dwell times will be for the individual fractions.

2) Plan Organiser – This will divide the dose per fraction by 2 therefore dividing the dwell times per fraction by 2. Again the system will display the isodoses for the entire plan but the dwell times will display the dwell times for each fraction.

Trainers Initials:

Attendees Initials:

4

P

M

M

۰.	<u>Session 3 - BrachyVision</u> Explain in detail how 3D CT based plans may be generated with BrachyVision using a prostate case as an example.
•	Selection Workspace Configuring DICOM Deamon and the DICOM Import Filters
	Importing and connecting Images
	Creating a 3D data set
	Trainers Initials:
	Attendees Initials:
	<u>Contouring Workspace</u> Creating 3D structures including use of the auto contouring tools, post processing tool, manual contouring tool, paint brush, eraser, splinesnake, livewire, contour editor, copying and pasting contours and interpolating contours.
	Using segmentation wizard and Boolean operators
	Generation of a PTV from a CTV through the use of the Margin tool
	Trainers Initials:
	Attendees Initials:

TSWI BrachyVision Training Agenda & Outline 121404 Printed on 07/01/2005

COMPANY CONFIDENTIAL Page 9 of 12

Planning Workspace	
Creating a plan	
Inserting an applicator from the 3D image data	
Using automatic catheter detection	ſ
Use of implant templates	₽ .
Inserting the source positions (pen, applicator properties) including the use of the 3D image data to assist with this process.	
Using automated source placement	5
Geometrical optimisation	Ŀ
Use of Shaper Tool followed by Normalisation	
Changing materials etc	B
3D Dose calculation and visualisation	B
DVHs including adding structures	E .
Trainers Initials:	

Attendees Initials:

TSWI BrachyVision Training Agenda & Outline 121404 Printed on 07/01/2005 ۰.

2 2

<u>Session 4 - BrachyVision</u> Explain miscellaneous features of BrachyVision not covered in the previous s	essions.
Starting a new plan from an existing plan - Film	
Starting a new plan from an existing plan – CT	-
Creating a plan with multiple films	R
Creating a 3D plan from a hardcopy CT film - Scaling Image	X
Generation and use of DRRs	Ð
Copying Registration points from one plan to another	
Matching two 3D data sets –using manual and least squares fit	
Copying and Pasting structures from one data set to another	E
Matching Film and CT	K
Summing Plans including dose visualisation and DVH for summed plans	8
Creation and use of Library Applicators	X
Planning for seeds implants	Ř
Creating template plans	
Planning from ultrasound	\mathbf{X}
Plan Evaluation workspace	ľ
Trainers Initials:	

P

9

P

P

I

P

Ð

Ø

M

Session 5 - BrachyVision

Explain all aspects of the system configuration including back-up and archive procedures.

Dose Unit configuration Source and Afterloader configuration Installing a new source wire Updating the source used in a plan Updating the treatment date Configuring Imaging Geometries Configuring Isodose Templates Configuring Structure Templates Configuring Applicator Templates User Configuration

 Attendees Initials:

TSWI BrachyVision Training Agenda & Outline 121404 Printed on 07/01/2005 COMPANY CONFIDENTIAL Page 12 of 12