

Technical Assessment and Clinical Perspectives

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Disclosures

Răzvan lordache is an employee of GE Healthcare

🍈 Senographe Pristi

Outline

Product Presentation Technical Assessment Quality Control



1 Product Presentation





Your challenges at the heart of our mission

PATIENTS • Ease patients' anxiety when they enter the room • Healthy women should receive a screening exam at the lowest possible dose • Making the examination as comfortable as possible

TECHNOLOGISTS • Patient discomfort can affect positioning • A new design to avoid physical strain

 RADIOLOGISTS & CLINICIANS

 • Superior diagnostic accuracy⁽¹⁾

 • Versatility (2D/3D, screening & diagnosis capabilities)

 • Efficient 3D reading experience







COMFORT FOR PATIENTS

Rethinking patient positioning^{2/3}

All parts in contact with the patient have been redesigned. The gentle, rounded corners reduce likelihood of discomfort when coming in contact with patient.

Thin Bucky (5 cm) for comfort especially for:

Large abdomen
Wheelchair access
Sensitive breasts









COMFORT FOR PATIENTS

Easing anxiety on the way to diagnosis

ô Senographe Pi

Low dose technology Cancer is enough to worry about. Worrying about radiation exposure should never get in the way

Senographe Pristina's integrated 3D mammography delivers superior diagnostic accuracy at the same low dose as 2D FFDM – the lowest patient dose of all FDA approved systems^(1,5)

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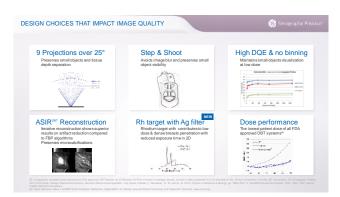
CONFIDENCE FOR TECHNOLOGISTS



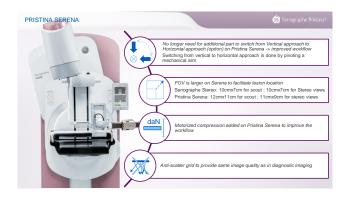






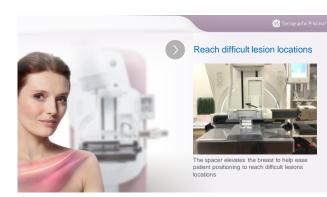










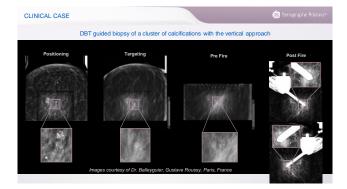




The sample imaging unit is intended to provide digital x-ray images of the biopsy excised tissues while the patient is still under compression.



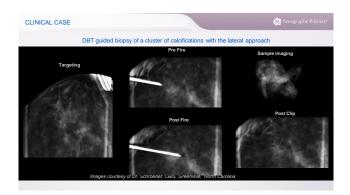
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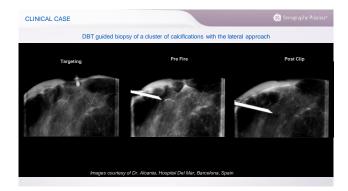


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2 Technical Assessment

IMAGE CHAIN EVOLUTION ON PRISTINA



X-RAY GENERATION Dual track : Mo or Rh Filtration : Mo or Ag Gantry-integrated generator

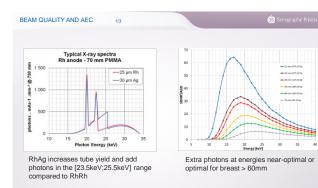
DETECTOR & GRID High ratio grid (R11) 100µm Csl + aSi detector air cooled

뻀 Senographe F

IMAGE ACQUISITION

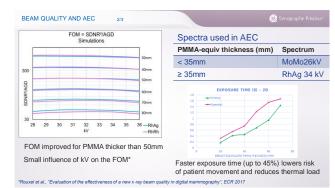
AEC in 2D/3D: DOSE (2D only), STD, STD+, implant mode (2D only) Updated AEC mode in CESM Only 2 beam qualities used in AEC in 2D/3D 3D sweep: 9 projections over 25 degrees

sweep: 9 projections over 25 degrees









BEAM QUALITY AND AEC 3/3

Senographe Pris

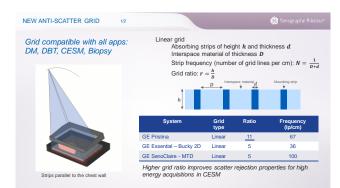
Replacing Rh by Ag improves FOM on thicker breasts

Because of small influence of kV on FOM, we can use a constant kV irrespective of the breast thickness

Selecting a higher kV value

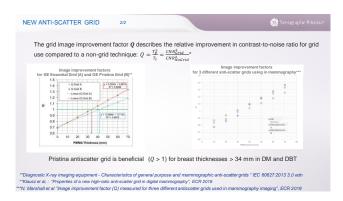
- reduces the exposure time and risk of patient movement
- improves patient comfort
- reduces the thermal load to the tube, allowing higher patient throughput

The factor of merit being only based on x-ray physics, the same operating point is used whatever the mode of operation (2D, DBT, biopsy, etc)









3 Quality Control

QUALITY CONTROL ON PRISTINA

🍈 Senographe Pr

There is a QC manual for Senographe Pristina (2D)

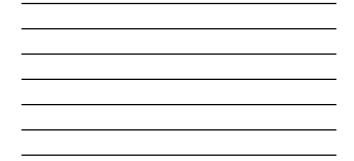
There is a QC manual with additional specific tests for each application:

- o Senographe Pristina 3D
- SenoBright HD (CESM feature of Senographe Pristina)
- Pristina Serena (stereotactic biopsy feature of Senographe Pristina)
- o Pristina Serena 3D (3D stereo biopsy feature of Senographe Pristina)



QUALITY CO	ONTROL ON	PRISTINA		á	Senographe Pristina ¹
	QC manual Pristina	QC manual Pristina 3D	QC manual SenoBright HD	QC manual Serena	QC manual Serena 3D
Pristina (2D)*	Х				
Pristina 3D*	Х	Х			
SenoBright HD	Х		х		
Serena	Х			Х	
Serena 3D	Х			X&	X&

*ACR Digital Mammography QC can be used instead of the GE QC for Pristina (2D) and Pristina $_{\rm 3D}$



HYSICIST TESTING	ON PRISTINA (2D)	🎲 Sent	
Minimum Frequency	Test	2D	
Annually / MEE	Acquisition station monitor cleaning	х	
Annually / MEE	Image uniformity and bad pixels Test*	х	
Annually / MEE	IQST test*	х	
Annually / MEE	ACR phantom score	х	
Annually / MEE	AOP and SNR check*	х	
Annually / MEE	Artifact Evaluation; Flat Field Uniformity	х	
Annually / MEE	Collimation Assessment	х	
MEE	Compression paddles chest wall edge alignment	х	
Annually / MEE	Sub-system MTF Measurement	х	
Annually / MEE	Breast Entrance Exposure, AGD, and Reproducibility	х	
Annually / MEE / troubleshoot	Test for flexible paddle deflection in compression	х	
MEE / troubleshoot	kVp Accuracy and Reproducibility	х	60
Annually / MEE	Beam Quality Assessment (HVL)	х	Automated lasts
Annually / MEE	Radiation Output	х	ated
Annually / MEE	Mammographic Unit Assembly Evaluation	х	m qi

SICIST TESTING	STING ON PRISTINA 3D			
Minimum Frequency	Test	2D	3D	
Annually / MEE	Acquisition station monitor cleaning	Х		
Annually / MEE	Image uniformity and bad pixels Test*	х	х	
Annually / MEE	IQST test*	х		
Annually / MEE	ACR phantom score	х	х	
Annually / MEE	AOP and SNR check*	х	х	
Annually / MEE	Artifact Evaluation; Flat Field Uniformity	х		
Annually / MEE	Collimation Assessment	х		
MEE	Compression paddles chest wall edge alignment	х		
Annually / MEE	Sub-system MTF Measurement	х		
Annually / MEE	Breast Entrance Exposure, AGD, and Reproducibility	х	х	
Annually / MEE / troubleshoot	Test for flexible paddle deflection in compression	х		
MEE / troubleshoot	kVp Accuracy and Reproducibility	х		
Annually / MEE	Beam Quality Assessment (HVL)	х		"Automated tests
Annually / MEE	Radiation Output	х		ated
Annually / MEE	Mammographic Unit Assembly Evaluation	х		(tom
Annually / MEE	Volume Coverage		х	"AL



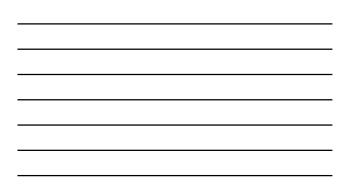


TECHNOLOGIST TESTING ON PRISTINA (2D)

Minimum Frequency	Test	2D
Daily	Acquisition station monitor cleaning	x
Weekly	Viewbox and viewing conditions test	x
Weekly	Image uniformity and bad pixels test*	x
Weekly	IQST test*	x
Weekly	ACR phantom score	x
Monthly	AOP and SNR check*	x
Monthly	Visual checklist	x
Monthly	Acquisition station monitor check	x
Quarterly	Repeat analysis check	x
Semi-annually	Compression force test	х
		*Automated tests

Minimum Frequency	Test	2D	
Daily	Acquisition station monitor cleaning	х	
Weekly	Viewbox and viewing conditions test	х	
Weekly	Image uniformity and bad pixels test*	х	х
Weekly	IQST test*	х	
Weekly	ACR phantom score	х	х
Monthly	AOP and SNR check*	х	х
Monthly	Visual Checklist	Х	
Monthly	Acquisition station monitor check	х	
Quarterly	Repeat analysis check	х	
Semi-annually	Compression force test	х	

YSICIST FESTING	STING ON SENOBRIGHT HD 68 Senographe Pr		
Minimum Frequency	Test	2D	CESM
Annually / MEE	Acquisition station monitor cleaning	х	
Annually / MEE	Image uniformity and bad pixels Test*	х	х
Annually / MEE	IQST test*	х	
Annually / MEE	ACR phantom score	х	
Annually / MEE	AOP and SNR check*	х	х
Annually / MEE	Artifact Evaluation; Flat Field Uniformity	х	х
Annually / MEE	Collimation Assessment	х	
MEE	Compression paddles chest wall edge alignment	х	
Annually / MEE	Sub-system MTF Measurement	х	
Annually / MEE	Breast Entrance Exposure, AGD, and Reproducibility	х	х
Annually / MEE / troubleshoot	Test for flexible paddle deflection in compression	х	
MEE / troubleshoot	kVp Accuracy and Reproducibility	х	
Annually / MEE	Beam Quality Assessment (HVL)	х	х
Annually / MEE	Radiation Output	х	
Annually / MEE	Mammographic Unit Assembly Evaluation	х	





TECHNOLOGIST TESTING ON SENOBRIGHT HD

CESM	2D	Test	Minimum Frequency
	х	Acquisition station monitor cleaning	Daily
	x	Viewbox and viewing conditions test	Weekly
х	x	Image uniformity and bad pixels test*	Weekly
	x	IQST test*	Weekly
	х	ACR phantom score	Weekly
х	х	AOP and SNR check*	Monthly
	х	Visual Checklist	Monthly
	х	Acquisition station monitor check	Monthly
	х	Repeat analysis check	Quarterly
	x	Compression force test	Semi-annually
utomated tes	*Auto		

YSICIST TESTING	ON SERENA	- 🎲 Ser		
Minimum Frequency	Test	2D	Serena	
Annually / MEE	Acquisition station monitor cleaning	Х		
Annually / MEE	Image uniformity and bad pixels Test*	х	х	
Annually / MEE	IQST test*	х		
Annually / MEE	ACR phantom score	х	х	
Annually / MEE	AOP and SNR check*	х	х	
Annually / MEE	Artifact Evaluation; Flat Field Uniformity	х		
Annually / MEE	Collimation Assessment	х		
MEE	Compression paddles chest wall edge alignment	х		
Annually / MEE	Sub-system MTF Measurement	х		
Annually / MEE	Breast Entrance Exposure, AGD, and Reproducibility	х	х	
Annually / MEE / troubleshoot	Test for flexible paddle deflection in compression	х		
MEE / troubleshoot	kVp Accuracy and Reproducibility	х		Automated tests
Annually / MEE	Beam Quality Assessment (HVL)	х		held
Annually / MEE	Radiation Output	х		ntam
Annually / MEE	Mammographic Unit Assembly Evaluation	х		"AL

Minimum Fr	requency	Test	2D	Serena
Annually	/ MEE	Localization accuracy		х
Annually	/ MEE	Needle holder accuracy check		х
Annually / MEE approach clini		Localization accuracy for horizontal approach option		x
Annually	/ MEE	Stereotactic breast biopsy unit Assembly evaluation		x





CHNOLOGIST TESTING ON SERENA		🎲 Ser	🎡 Senographe Pr	
Minimum Frequency	Test	2D	Serena	
Daily	Acquisition station monitor cleaning	х		
Weekly	Viewbox and viewing conditions test	х		
Weekly	Image uniformity and bad pixels test*	х	х	
Weekly	IQST test*	х		
Weekly	ACR phantom score	х	х	
Monthly	AOP and SNR check*	х	х	
Monthly	Visual Checklist	х		
Monthly	Acquisition station monitor check	х		
Quarterly	Repeat analysis check	х		
Semi-annually	Compression force test	х		
Each day biopsy are performed	Localization accuracy		х	
When new device programmed	Accuracy check before using new puncture tool		х	
Each day biopsy are performed	Needle holder accuracy check		х	
Monthly if horizontal approach used	Localization accuracy for horizontal approach option		x	
		*Autr	omated tes	





